Automated Hematology Analyzer MEK-7300K

OPERATOR'S MANUAL

Celltac ES

Automated Hematology Analyzer

MEK-7300K

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Automated Hematology Analyzer

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If you have any comments or suggestions
on this manual, please contact us at:
www.nihonkohden.com

0614-904173

In order to use this product safely and fully understand all its functions, make sure to read this manual before using the product.

Keep this manual near the instrument or in the reach of the operator and refer to it whenever the operation is unclear.

The contents of this manual are subject to change without notice.

Trademark

The mark printed on the SD card that is used in this instrument is a trademark. The company name and model name are trademarks and registered trademarks of each company.

CE

Contents

GENERAL HANDLING PRECAUTIONS

This device is intended for use only by qualified healthcare personnel.
Use only Nihon Kohden approved products with this device. Use of non-approved products or in a non-approved manner may affect the performance specifications of the device.

Please read these precautions thoroughly before attempting to operate the instrument.

1. **To safely and effectively use the instrument, its operation must be fully understood.**

2. **When installing or storing the instrument, take the following precautions:**
   (1) Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and dust, saline or sulfuric air.
   (2) Place the instrument on an even, level floor. Avoid vibration and mechanical shock, even during transport.
   (3) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.
   (4) The power line source to be applied to the instrument must correspond in frequency and voltage to product specifications, and have sufficient current capacity.
   (5) Choose a room where proper grounding is available.

3. **Before Operation**
   (1) Check that the instrument is in proper operating order.
   (2) Check that the instrument is grounded properly.
   (3) Check that all cords are connected properly.
   (4) Check that battery level is acceptable and battery condition is good when using battery-operated models.

4. **During Operation**
   (1) The instrument must receive continual, careful attention.
   (2) Turn power off when trouble is found on the instrument.

5. **To Shutdown After Use**
   (1) Turn power off with all switches and keys returned to their original positions.
   (2) Remove the cords gently; do not use force to remove them.
   (3) Clean the instrument together with all accessories for their next use.

6. **The instrument must receive expert, professional attention for maintenance and repairs. When the instrument is not functioning properly, it should be clearly marked to avoid operation while it is out of order.**

7. **The instrument must not be altered or modified in any way.**

8. **Maintenance and Inspection**
   (1) The instrument and parts must undergo regular maintenance inspection.
   (2) If stored for extended periods without being used, make sure prior to operation that the instrument is in proper operating condition.

WARRANTY POLICY

Nihon Kohden Corporation (NKC) shall warrant its products against all defects in materials and workmanship for one year from the date of delivery. However, consumable materials such as recording paper, ink, stylus and battery are excluded from the warranty.

NKC or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided these products are used as prescribed by the operating instructions given in the operator's and service manuals.

No other party is authorized to make any warranty or assume liability for NKC's products. NKC will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than NKC or its authorized agents without prior consent of NKC may be cause for voiding this warranty.

Defective products or parts must be returned to NKC or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Nihon Kohden approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

In the USA and Canada other warranty policies may apply.

RESPONSIBILITIES – PROFESSIONAL USERS

This instrument must be used by a professional user with a full knowledge of operating this instrument, only for the stated intended use and according to the instructions for use. Instructions in the operator's manual must be followed, especially the following points.

- Storage and stability of reagents
- Handling of reagents
- Instrument installation
- Connection of all tubes to inlets and outlets
- Connection of all tubes to reagents and waste container
- Checking the amount of reagents and waste fluid
- Calibration
- Quality control
- Maintaining and servicing

If deviating from the instructions, the professional user does it at the risk and liability of the laboratory and only after validation by the laboratory. Nihon Kohden has no responsibility over such deviations.

EMC RELATED CAUTION

This equipment and/or system complies with the International Standard EN 61326-2-6 for electromagnetic compatibility for electrical equipment and/or system for measurement, control and laboratory use. However, an electromagnetic environment that exceeds the limits or levels stipulated in the EN 61326-2-6, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1. Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone:
   Install the equipment and/or system at another location if it is interfered with by an emitter source such as an authorized radio station. Keep the emitter source such as cellular phone away from the equipment and/or system.

2. Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:
   Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.

3. Effect of direct or indirect electrostatic discharge:
   Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.

4. Electromagnetic interference with any radio wave receiver such as radio or television:
   If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative for additional suggestions.

This equipment complies with International Standard EN 55011: 2007 Group 1, Class B. Class B EQUIPMENT is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

The CE mark is a protected conformity mark of the European Community. Products with the CE mark comply with the requirements of the In vitro Diagnostic Medical Device Directive 98/79/EC.

NOTE about Waste Electrical and Electronic Equipment (WEEE) directive 2002/96/EC
For the member states of the European Union only:
The purpose of WEEE directive 2002/96/EC is, as a first priority, the prevention of waste electrical and electronic equipment (WEEE), and in addition, the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste.
Contact your Nihon Kohden representative for disposal.

Conventions Used in this Manual and Instrument

Warnings, Cautions and Notes

Warnings, cautions and notes are used in this manual to alert or signal the reader to specific information.

WARNING

A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.

CAUTION

A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

NOTE

A note provides specific information, in the form of recommendations, prerequirements, alternative methods or supplemental information.

Explanations of the Symbols in this Manual and Instrument

The following symbols found in this manual/instrument bear the respective descriptions as given.

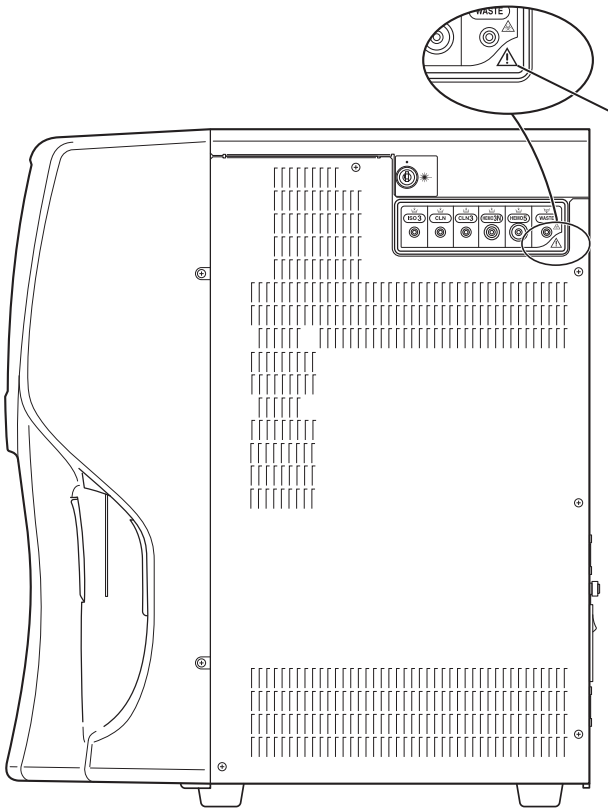
On panel

Symbol	Description	Symbol	Description
	AC power off (Disconnection from the mains)		Inlet
	AC power on (Connection to the mains)		Outlet
	Main power lamp		Biohazard
	“Off” only for part of the equipment		Serial port 1
	“On” only for part of the equipment		Serial port 2
	Auto print		Serial port 3
	Feed		Printer socket
	Print		USB socket
	Reset		Memory card socket (Read data from store)
	Clean		Alternating current
	Eject key (Tube holder open)		Equipotential terminal
	Count		Fuse (time lag)
	ISOTONAC•3 (diluent)		Date of manufacture
	CLEANAC (detergent)		Laser on
	HEMOLYNAC•3N (hemolysing reagent)		IN VITRO DIAGNOSTIC MEDICAL DEVICE
	HEMOLYNAC•5 (hemolysing reagent)		The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the In vitro Diagnostic Medical Device Directive 98/79/EC.
	WASTE		Products marked with this symbol comply with the European WEEE directive 2002/96/EC and require separate waste collection. For Nihon Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal.
	Attention, consult operator’s manual		

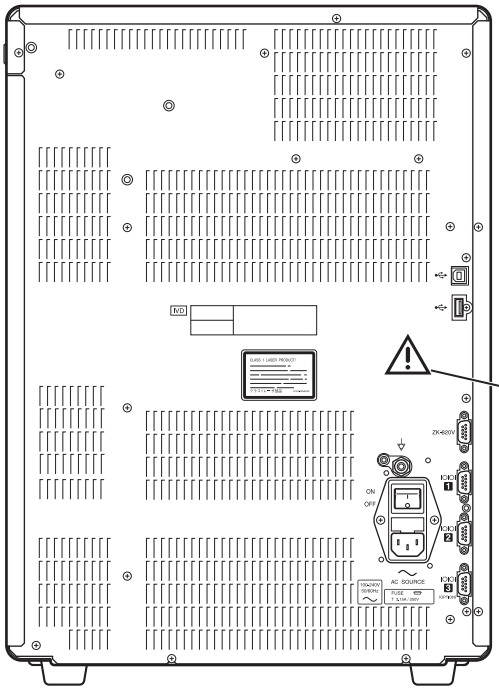
On screen and recorded data

Symbol	Description
?	When displayed beside NE, NE%, LY, LY%: Room temperature high When displayed beside NE, NE%, LY, LY%, MO, MO%, EO, EO%, BA, BA%: Optical count error When displayed beside NE, NE%, LY, LY%, MO, MO%: Room temperature low When displayed beside WBC or RBC measured value: Sample error When displayed beside HGB measured value: Dirty measurement baths
!	When displayed beside WBC measured value: Poor hemolyzation When displayed beside HGB measured value: HGB voltage adjustment error When displayed beside MCHC measured value: Abnormal MCHC
*	When displayed beside WBC measured value: Small nucleated cell When displayed beside NE, NE%, MO, MO%, BA, BA%: Immature granulocytes When displayed beside NE, NE%, EO, EO%: Ne-Eo interference When displayed beside NE, NE%, LY, LY%, MO, MO%, EO, EO%, BA, BA%: Blasts When displayed beside NE, NE%, EO, EO%: Left shift When displayed beside LY, LY%, MO, MO%: Atypical lymphocytes When displayed beside LY, LY%, MO, MO%: Ly-Mo interference When displayed beside HGB measured value: HGB circuit error/WBC measured value is OVER When displayed beside RBC and PLT measured values: PLT-RBC interference When displayed beside PLT: PLT low value (below 50,000/µL)
C	When displayed beside WBC or PLT measured value: Platelet coagulation
	Reagent level graph
	SD card is inserted
	Open the alarm window

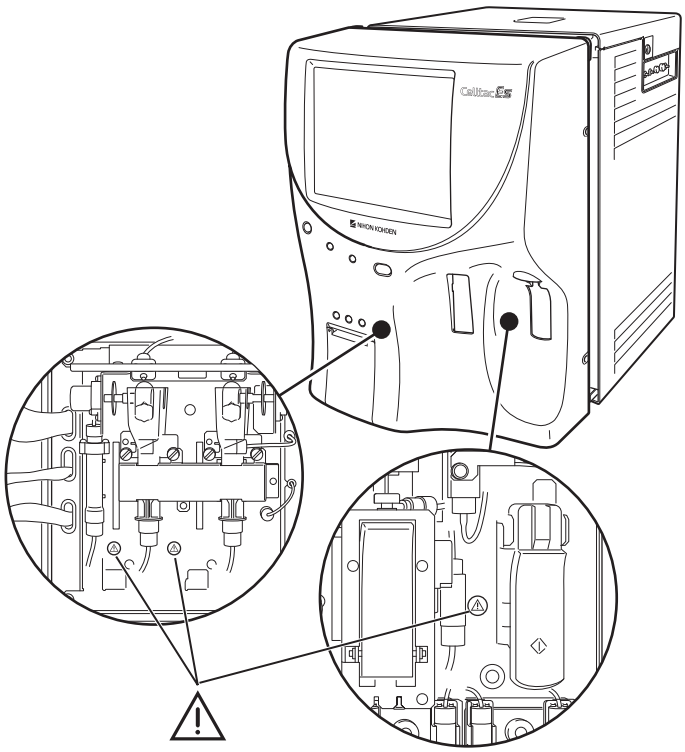
Caution Labels on the Analyzer



Refer to “Connecting Tubes” in Section 2.



Refer to warnings and cautions in “Connecting the Power Cord and Grounding the Analyzer” in Section 2.



NOTE

- Replace the filters periodically.
- When attaching the filter joint assembly, be careful not to bend or damage the filter packing at the bottom of the measurement bath.
- When there is a leakage, check that there is no scratch or damage to the circumference of the filter.

Text Conventions in this Manual

In this manual, procedural instructions are explained in logical groups, using numbered steps. Illustrations and drawings appear where they are useful to the explanation. Text conventions are as follows:

Screen Name

The screen name is printed in mixed-case, regular letters; for example, Ready screen.

Touch Screen Keys

The screen has some touch screen keys which are pressure-sensitive. Pressing one of these touch screen keys initiates the action specified by a screen label. Screen labels are shown in mixed-case, regular letters; for example, Quality control key.

Data Entry Field Names

Fields that accept data entered by the Operator have their names shown in regular, mixed-case font enclosed within carats < >.

Hard Keys (Keys on the Panels)

The keys on the panels are shown in regular, mixed-case font enclosed in brackets; for example, [Clean].

Screen Messages

Screen messages or other screen displays will appear in regular, mixed-case font enclosed in quotation marks, for example, “Priming”.

Information	Presentation	Examples
Screen name	Regular, Mixed-Case	Menu screen
Touch screen keys	Regular, Mixed-Case	Quality control
Field names	Regular, Mixed-Case, enclosed within carats < >	<Dilute mode>
Hard keys (Panel keys)	Regular, Mixed-Case, enclosed within brackets	[Clean]
Screen Message	Regular, Mixed-Case, enclosed within quotation marks	“Priming”

How to Use This Manual

Manual Organization

The major sections of the manual and their contents are as follows:

Section 1: General

This section provides an overall description of the system. It names the major system components and describes their uses or functions.

Section 2: Preparation

This section provides detailed instructions for system setup and configuration. It explains proper location, requirements, and steps for installation.

Section 3: Principles of Operation

This section explains the principles behind the system's operation. It describes what the system measures and how those measurements are made.

Section 4: Performance Characteristics and Specifications

This section contains useful details on the dimensions of the analyzer, proper operating environment, and performance specifications.

Section 5: Operating Instructions

This section explains the procedures for daily start-up and shutdown, sample collection and handling, and routine operation of the analyzer including use of stored data.

Section 6: Calibration Procedures

This section describes the calibration process. It discusses calibration materials, guidelines, and methods.

Section 7: Operational Precautions and Limitations

This section contains a summary of known factors that may adversely affect the proper operation of the analyzer or the quality of the output.

Section 8: Hazards

This section covers possible hazards arising from the operation of the analyzer, as well as decontamination and waste handling procedures.

Section 9: Service and Maintenance

This section discusses routine maintenance and cleaning on a daily, weekly, monthly, and as required basis. Also included are detailed instructions for removing and cleaning certain components to ensure proper system performance.

Section 10: Messages and Troubleshooting

This section contains a troubleshooting guide to help users identify probable causes of a system malfunction or of suspect data, and to suggest the proper corrective action.

Section 11: Quality Control

This section covers the proper mixing, handling, and running of control material, setting up QC files, and using the QC capabilities of the analyzer.

Appendices

Appendix A

This appendix lists the part numbers of components, accessories, controls, reagents, and consumables associated with the analyzer for user convenience when placing orders.

Appendix B

This appendix contains information on setup of the optional bar code reader.

Appendix C

This appendix contains specimen data reports.

Appendix D

This appendix contains the list of factory default settings.

Manual Construction

The physical construction of the manual supports its sectional organization.

Contents

The Contents at the beginning of this manual lists each section and its subsections.

Section Separators

A large separator tab marks the start of each section.

Safety

Throughout the manual, signal words appear where the nature of the information warrants special attention.

Operation, maintenance, and servicing of hematology systems may expose individuals to potential safety and health hazards. All work must be performed as described in the operator's manual or as directed by Nihon Kohden. For detailed safety information, refer to Section 8 "Hazards".

Warnings are inserted throughout this manual to alert personnel to potential hazards.

For detailed safety information, refer to Section 7 "Operational Precautions and Limitations" and Section 8 "Hazards" in this manual.

Section 1 General

Introduction

The MEK-7300K Automated Hematology Analyzer provides simultaneous 23 parameter and 2 research parameter measurement. It provides quick counting and all operations are performed automatically just by putting the sampling nozzle into a sample container with whole blood and pressing the [◇ Count] switch. The analyzer also has a cap pierce unit to measure samples in capped tubes in closed mode. Results and data are displayed on a color LCD screen and full reports can be printed on an optional printer.

The analyzer automatically cleans blood from the sampling nozzle, so it is safe and there is no risk of touching the blood. The analyzer has self-check, quality control and other programs for reliable data management system.

To achieve full performance, thoroughly read this operator's manual before operating the analyzer.

To use the analyzer safely and effectively and keep it in optimum condition, follow the operating and maintenance instructions in this manual.

NOTE

Use only Nihon Kohden parts and accessories to assure maximum performance from your instrument.

Measured Parameters

23 parameters and 2 research parameters can be measured on the MEK-7300K hematology analyzer.

WBC*[1]: White Blood Cell Count
NE%: Neutrophil Percent
LY%: Lymphocyte Percent
MO%: Monocyte Percent
EO%: Eosinophil Percent
BA%: Basophil Percent
NE: Neutrophil Count
LY: Lymphocyte Count
MO: Monocyte Count
EO: Eosinophil Count
BA: Basophil Count
RBC*[1]: Red Blood Cell Count
HGB*[1]: Hemoglobin Concentration
HCT*[1]: Hematocrit Percent

$$HCT = \frac{\text{Red blood cell volume}}{\text{Blood volume}} \times 100$$

MCV*[1]: Mean Corpuscular Volume

$$MCV = \frac{HCT\ (\%)}{RBC\ (\times 10^6/\mu L)} \times 10$$

MCH*[1]: Mean Corpuscular Hemoglobin

$$MCH = \frac{HGB\ (g/dL)}{RBC\ (\times 10^6/\mu L)} \times 10$$

MCHC*[1]: Mean Corpuscular Hemoglobin Concentration

$$MCHC = \frac{HGB\ (g/dL)}{HCT\ (\%)} \times 100$$

RDW-CV: Red Blood Cell Distribution Width in CV
RDW-SD: Red Blood Cell Distribution Width in SD
PLT*[1]: Platelet Count
PCT: Platelet Crit
MPV: Mean Platelet Volume
PDW: Platelet Distribution Width
IG%*[2]: Immature Granulocyte Percent
IG*[2]: Immature Granulocyte

*[1] CBC (complete blood count) parameters
*[2] Research parameters

Features

- **Simultaneous 23 parameter measurement**
  The analyzer simultaneously measures 23 parameters (CBC and WBC 5 part differential). WBC, RBC and PLT are measured by the electrical resistance detection method. WBC is differentiated into neutrophil, lymphocyte, monocyte, eosinophil and basophil by the light scatter technique - flow cytometry with laser.

- **Infection prevention**
  To help eliminate the risk of touching blood, you can perform measurement in closed mode without removing the cap of the sample tube.

- **Automatic sampling**
  Once the sample is aspirated through the sampling nozzle, all other operations are performed automatically. The sample is automatically diluted and measured. After measurement, the analyzer is cleaned and the waste fluid is automatically treated.

- **Automatic sampling nozzle cleaning**
  The analyzer automatically cleans remaining blood from the sampling nozzle. This also helps eliminate the risk of touching blood during measurement.

- **Automatic clog removal and recounting**
  After each counting, the analyzer removes blood protein and dust particles from around the aperture caps to prevent clogging. Even if a clog occurs, the analyzer automatically removes the clog and recounts the sample.

- **High accuracy and reproducibility**
  The analyzer reduces counting error by automatically diluting samples and wiping the sampling nozzle. The analyzer provides high accuracy and reproducibility with a low dilution ratio of 200:1 for WBC, 40,000:1 for RBC and 360 µL of diluted sample. Built-in circuits automatically compensate for cell miscount due to coincidence (simultaneous cell passage) and fluid temperature variation. The aperture is shielded from external noise and clogging is prevented.

- **Color LCD touch screen**
  The analyzer has a color TFT LCD with 800 × 600 pixel resolution which clearly displays the results and various messages. The touch screen allows easy and intuitive operation of the analyzer. You can enlarge the numerical data and scattergram by touching them. Screen messages prompt the operator through operation.

- **Pre-diluted blood counting**
  Pre-diluted blood (10 or 20 μL) can be measured. The sample needs to be diluted before measurement. 30 μL of venous blood can also be measured. This sample does not need to be diluted before measurement.

- **Automatic self-check**
  When the analyzer is turned on, the analyzer automatically starts priming and checks itself. If a problem is detected, the LCD displays an alarm message, e.g. BUBBLE, NO DILUENT or CLOG, so you can quickly identify and fix the problem.

- **Variety of quality control programs**
  A variety of quality control programs are provided to enable calibration for WBC, RBC, PLT, HGB and HCT, calculation of mean value and CV value, $\overline{X}$-R and L & J quality control programs, and normal range setting on the screen.

- **Data management**
  The analyzer can store measurement data of up to 400 samples and histograms of up to 50 samples. Stored measurement data can be printed, deleted or transferred to an external device.

- **Automatic priming and cleaning**
  The analyzer automatically primes the fluid path when the power is turned on and cleans the fluid path when the power is turned off.

- **Selectable 23 parameters or 8 (CBC) parameters measurement**
  Measuring parameters can be selected from 8 (CBC) parameters or 23 (CBC and WBC 5 part differential) parameters. Measuring only the 8 CBC parameters reduces reagent consumption.

- **Password protected access**
  Measurement conditions, such as calibration coefficient, normal range and quality control, are managed by the operator who has the password to access these setting screens. Miscalculation caused by inappropriate measurement condition settings can be avoided.

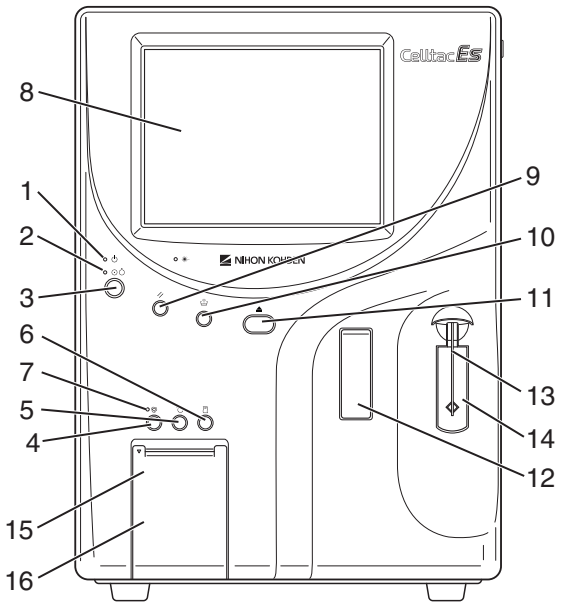
- **High dilution measurement**
  When the WBC measured result is high, the sample can be recounted by diluting the sample with higher ratio.

- **Reagent management**
  The amount of reagent and waste fluid can be monitored by the hematology analyzer and a message can be displayed to alert the operator that a reagent is nearly run out or the waste container is becoming full.

- **Data sending and receiving with USB**
  The measurement data and work list can be sent and received by connecting a personal computer to the USB connector (device) and using the QP-822V data management software.

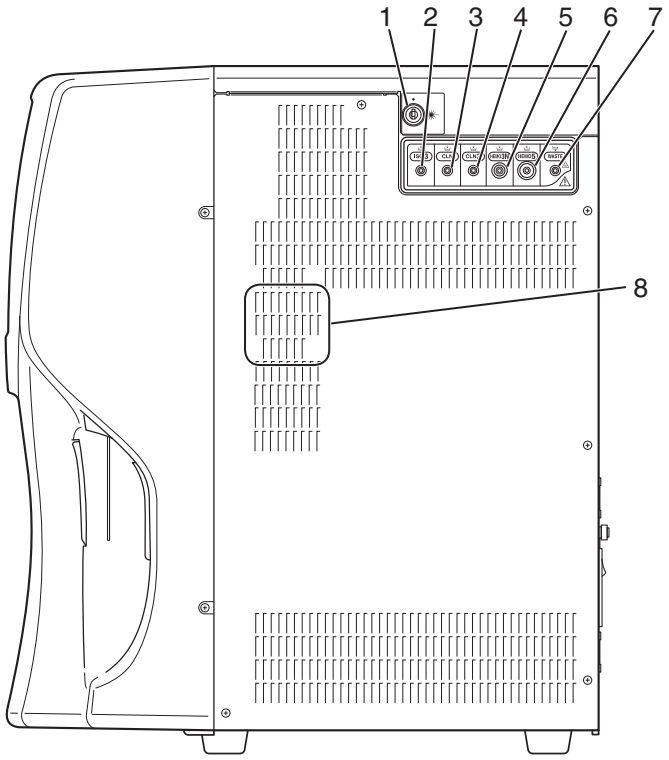
Panel Description

Front Panel



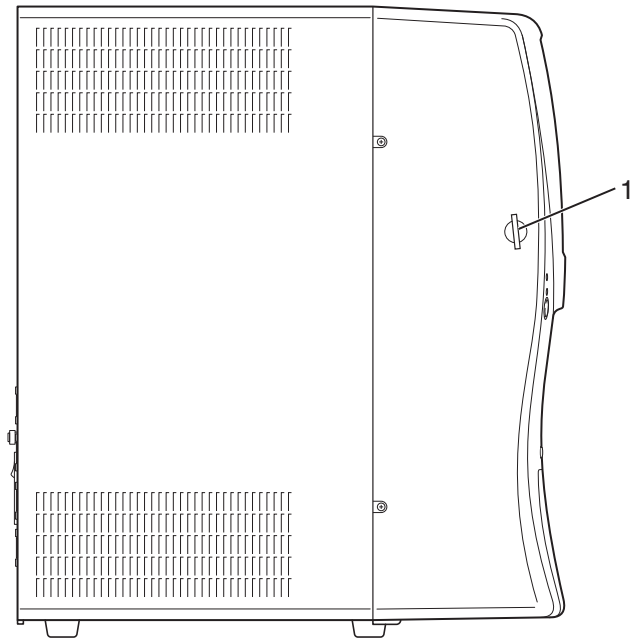
No.	Name	Description
1	Main power lamp	Lights when the [Main power] switch on the rear panel is turned on.
2	Power lamp	Lights when the [Main power] switch on the rear panel and [Power] key on the front panel are turned on.
3	Power key	Turns the analyzer power on or off when the [Main power] switch on the rear panel is turned on. When the power is turned on, priming and self-check are automatically performed and the Ready screen appears.
4	Auto print key	Switches the printing mode between automatic and manual for the printer.
5	Feed key	Feeds paper of the printer while held down.
6	Print key	Prints displayed data on the printer.
7	Auto print mode lamp	Lights when automatic printing mode is selected.
8	LCD display	Displays various messages, measured data and touch screen keys.
9	Reset key	Stops operation when pressed during operation. Returns to the Ready screen when pressed while changing settings. Use this key only when an error occurs.
10	Clean key	Cleans the fluid path, aperture and manometer with detergent. Automatically primes after cleaning the fluid path. Press this key when clogging occurs, the manometer becomes dirty or bubbles occur in the manometer.
11	Eject key	For closed mode only. Opens the tube holder to set the sample tube.
12	Tube holder	For closed mode only. Holds a sealed vacuum blood collecting tube. Press the [Eject] key to open. After measurement, the holder automatically opens.
13	Sampling nozzle	For open mode only. Aspirates the sample. Dispenses the diluent when in the pre-dilution blood mode.
14	Count switch	For open mode only. Aspirates the sample and starts counting.
15	Printer unit (WA-730VK)	Thermal array printer. Prints out measured data and sample ID no. (optional)
16	Printer door	For the recording paper of the WA-730VK printer unit. To open, pull the upper left corner (optional).

Right Side Panel



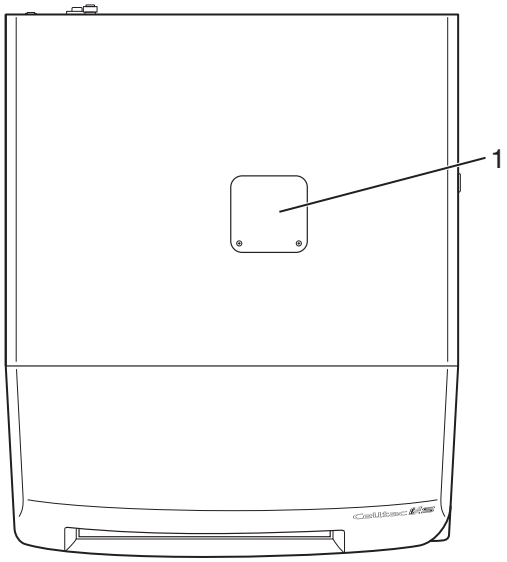
No.	Name	Description
1	Laser switch	Turns the laser on or off with the laser key for WBC 5 part differential measurement.
2	ISO3 Diluent inlet	Inlet for the ISOTONAC•3 diluent.
3	CLN Detergent inlet	Inlet for the CLEANAC detergent.
4	CLN3 Detergent inlet	Inlet for the CLEANAC•3 detergent.
5	HEMO3N Lysing reagent inlet	Inlet for the Hemolynac•3N lysing reagent.
6	HEMO5 Lysing reagent inlet	Inlet for the Hemolynac•5 lysing reagent.
7	WASTE Waste outlet	Outlet for waste such as used lyse, detergent and aspirated samples.
8	Vent hole for fan	Vent hole for the fan. **NOTE** Do not block the hole. It affects the measurement capability.

Left Side Panel



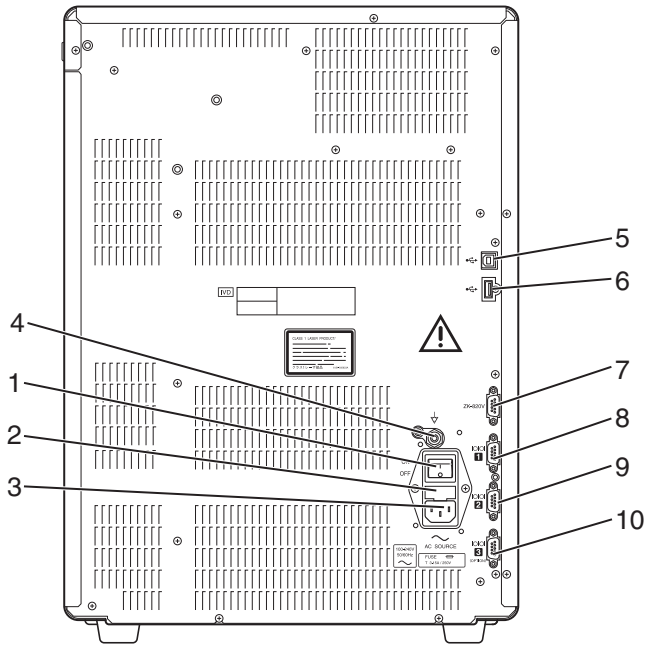
No.	Name	Description
1	SD card slot	Insert an SD memory card.

Top Panel



No.	Name	Description
1	Flow cell cover	For adjusting the flow cell position.

Rear Panel



No.	Name	Description
1	Main power switch	Supplies the power to the analyzer when it is turned on. Under normal conditions keep this switch turned on.
2	Fuse holder	Contains the time lag fuse. To replace the fuse, contact your Nihon Kohden representative.
3	Power socket	Connects the AC power cord to supply AC power to the analyzer.
4	Equipotential ground terminal	Connects the ground lead to the equipotential ground terminal on the wall for earth grounding.
5	USB socket (device)	Connects a personal computer to send and receive data.*
6	USB socket (host)	Connects a barcode reader (Keyence BL-N60UB or equivalent).
7	ZK-820V Bar code reader socket	Connects to an optional ZK-820V hand-held bar code reader and supplies power to the bar code reader when connected. Power supply voltage: 5 V DC (pin 9: 5 V, pin 5: GND) Rated current: 200 mA
8	Serial port 1	Connects to the optional WA-731V/461V card printer or PC.
9	Serial port 2	Connects to the optional WA-731V/461V card printer or PC.
10	Option port	Connects to the external instrument.

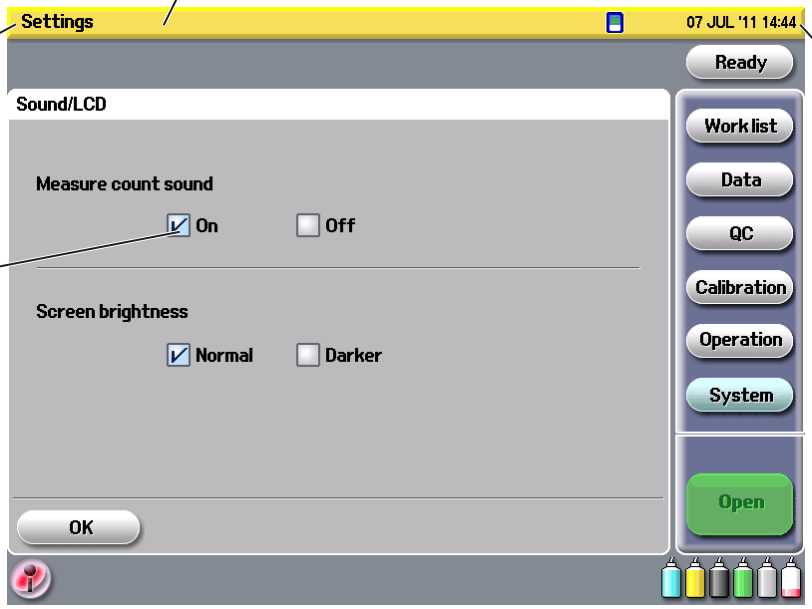
* To connect to a personal computer, the QP-822V data management software is required.

Basic Operations

Screen Information

Status bar
When the type of operator is “service”, the status bar is orange.
When the type of operator is “lab technician”, the status bar is blue.
When the type of operator is “other user”, the status bar is green.
For details, refer to “Assigning Users and Passwords” in Section 5.

Screen name



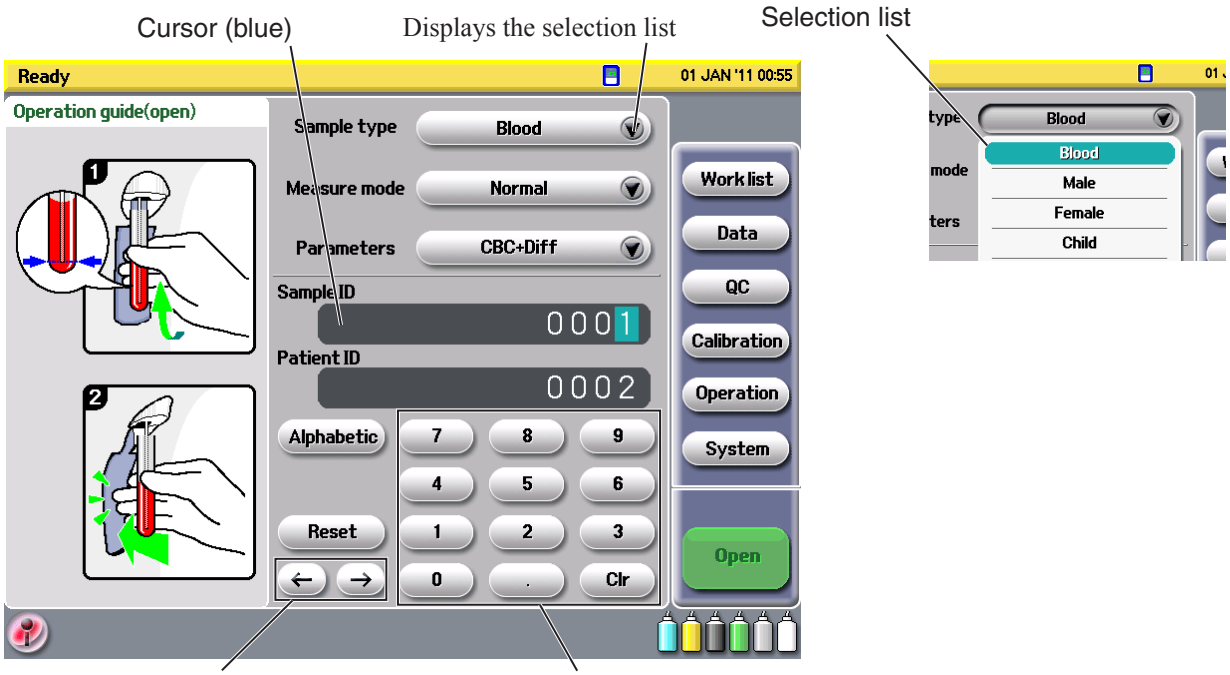
Check box

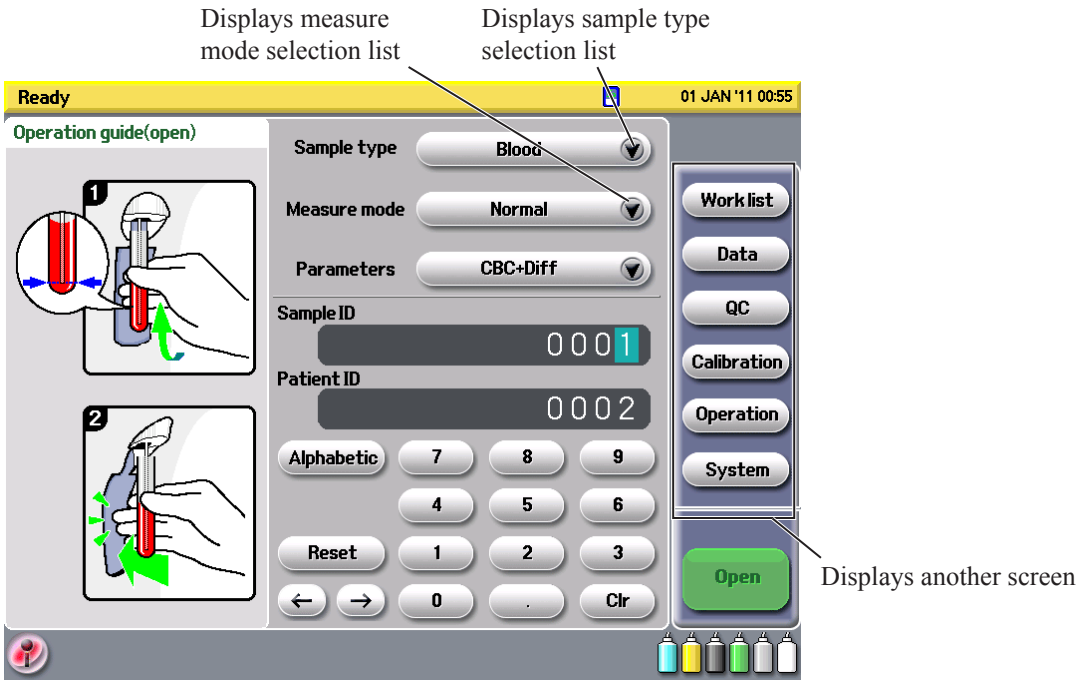
Date and time
For details, refer to “Setting Date and Time” in Section 5.

Using Touch Screen Keys

NOTE

Do not use a sharp object to press the touch screen. Use your finger.


Cursor (blue)
Displays the selection list
Selection list
Ready
01 JAN '11 00:55
Operation guide(open)
Sample type
Blood
Measure mode
Normal
Parameters
CBC+Diff
Sample ID
0001
Patient ID
0002
Alphabetic
Reset
Work list
Data
QC
Calibration
Operation
System
Open
Blood
Male
Female
Child
Use arrow keys to move cursor
Use the numeric keys to enter a value and press the Enter key to register the setting


Displays measure mode selection list
Displays sample type selection list
Ready
01 JAN '11 00:55
Operation guide(open)
Sample type
Blood
Measure mode
Normal
Parameters
CBC+Diff
Sample ID
0001
Patient ID
0002
Alphabetic
Reset
Work list
Data
QC
Calibration
Operation
System
Open
Displays another screen

Reagent System

Introduction

A reagent system which is specifically formulated for this analyzer provides optimal system performance. Use of reagents other than those specified in this manual is not recommended, as analyzer performance can be affected. Each analyzer is tested at the factory using the specified reagents, and all performance claims are generated using these reagents. For information on ordering reagents, refer to Appendix A “Parts and Accessories”.

CAUTION

If reagent has been frozen, it must not be used.

Reagents

Diluent

Diluent is for doing the following:

- Act as the diluent for the WBCs, RBCs, PLTs, and HGB.
- Maintain the cell volume of each RBC and PLT during the count and sizing portion of the measurement cycle.
- Provide a conductive medium for impedance counting and sizing of cells and platelets.
- Rinse the sampling nozzles and flow systems.

Lysing Reagent

The analyzer uses lysing reagent as hemolysing reagents:

- Rapidly lyse the RBC and minimize the resultant cell stroma.
- Alter the WBC membrane to allow the cytoplasm to slowly diffuse and shrink the membrane around the nucleus and any granules that may be present.
- Convert hemoglobin to a modified hemoglobin complex that is measurable at 540 nm (The quaternary ammonium lysate participates to form a chromogen for hemoglobin measurement.).

Detergent

The analyzer can use two types of detergents: CLEANAC and CLEANAC•3:

- Provide an optically clear solution that is used to obtain the zero reference during the HGB measurement cycle.
- Provide proper meniscus formation in both metering tubes and maintain it during each run cycle.
- Rinse both measurement baths and sub baths, both metering tubes, and the fluid path with minimal bubble formation.
- Remove protein buildup and provide detergent cleaning within the analyzer. It is used in scheduled and unscheduled maintenance.

Reagent Storage

Reagents must be stored at room temperature to ensure optimal performance. All reagents should be protected from direct sunlight, extreme heat, and freezing during storage. Temperatures lower than 0ºC (32ºF) can cause reagent layering that changes the tonicity and conductivity of the reagents. If any reagent has been frozen, it must be disposed of according to federal, state, and local regulations.

Each length of reagent inlet tubing is attached to a cap that minimizes evaporation and contamination during use. Ensure that all reagent caps are not damaged, and are securely attached to containers during use. Reagent quality can deteriorate with time. Therefore, use all reagents before the expiration date on the label.

Handling Reagent

When handling reagents, pay special attention to the following:

- Wear protective gloves when handling reagents.
- Never transfer the contents of a reagent container to an unmarked container or other reagent container.
- Thoroughly clean all spills. Remove any dried residue in and around the reagent inlet connectors located on the right side panel of the analyzer.
- Dispose of reagents and waste fluids according to federal, state, and local regulations.
- Always wash your hands after handling reagents.

Background Count

Always run a background count after installing a fresh container of reagent. Values reported must be within the following specifications:

- WBC $\leq$ 0.2 ($\times 10^3/\mu L$)
- RBC $\leq$ 0.05 ($\times 10^6/\mu L$)
- HGB $\leq$ 0.1 g/dL
- PLT $\leq$ 10 ($\times 10^3/\mu L$)

Controls and Calibrator

Controls and calibrator are reference materials used to test, set, and monitor analyzer performance. For information on ordering controls and calibrators, refer to Appendix A “Parts and Accessories”.

Controls

Day-to-day verification of system calibration is performed using controls. Running these stabilized reference products is recommended to test analyzer accuracy. The following controls are used in the analyzer system:

Control: tri-level whole blood quality control materials designed to monitor CBC and WBC values obtained on hematology systems.

Calibrator

Calibration of the directly-measured parameters can be performed using calibrator. Calibration is discussed in Section 6 “Calibration Procedures”.

Consumables

For information on ordering parts, accessories, reagents, controls, calibrators, and consumables, refer to Appendix A “Parts and Accessories”.

Section 2 Preparation

General

WARNING

Never use the analyzer in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

WARNING

Never use the analyzer in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

Environmental Requirements

WARNING

Install the analyzer outside the patient environment. If it is installed inside the patient environment, the patient or operator may receive electrical shock.

CAUTION

Use this analyzer under the following conditions.

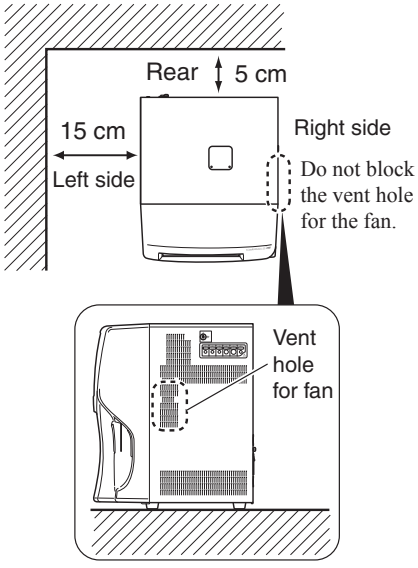
Temperature: 15 to 30°C (59 to 86°F)

Humidity: 30 to 85% (noncondensing)

Air pressure: 70 to 106 kPa

70 kPa air pressure equals 3,000 m above sea level. Do not use the analyzer at altitudes higher than 3,000 m above sea level.

- Operate the analyzer in a room with a temperature range of 15 to 30°C (59 to 86°F). Keep the temperature of diluent and lysing reagent within this temperature in order to obtain reliable data.
- No measurement can be done in dusty areas because the aperture for specimen aspiration is very fine and can get clogged. Therefore, install the analyzer in a dust-free area.
- Do not install the analyzer in direct sunlight.
- Do not place containers of reagent or fluid on the analyzer. To prevent electrical problems or electric shock, avoid spillage in or around the analyzer because the fluid is highly conductive.
- Select a stable, flat buffering stand to set the analyzer on.
- If possible, use an independent AC outlet only for this analyzer. The analyzer must not share an AC outlet with noise generating equipment such as a centrifuge, constant temperature bath (thermostat), refrigerator, air conditioner or ultrasonic cleaner.



- Make sure that there is more than 5 cm of space between the rear panel and the wall and 15 cm of space between the left panel and the wall for adequate ventilation.
- Do not block the vent hole for the fan.
- When there is any problem in the analyzer, turn off the main power immediately and disconnect the power cord from the AC outlet. Take the analyzer out of service and check for damage.

Initial Preparation

Inventory

Confirm that the analyzer shipment contains the following:

- Celltac Es hematology analyzer
- Standard accessories
- Reagents
- Controls and calibrator
- Operator's manual
- Printer (optional)
- ZK-820V Hand-held bar code reader (optional)

Standard Accessories

- Power cord
- Ground lead
- Fuse, 3.15 A time-lag
- Filter assy (4)
- Pump tube (N) assy
- Sampling nozzle
- Diluent tube, marked blue, 1.5 m
- Waste tube, marked red, 1.5 m
- Detergent tube for CLEANAC, marked green, 1.5 m
- Cleanac tube 8 for CLEANAC•3, marked white, 1.5 m
- 18 L container cap (3)
- 18 L tube assy 2
- 500 mL tube assy
- Hemolynac•3 cap
- Hemolynac•3 tube (570), marked yellow
- 18 L tube assy (waste)
- Hemolynac•5 cap
- Hemolynac•5 tube (570), marked black
- Waste container (601)
- Cleanac tube assy (8222) (2)
- Laser key

Visually inspect these items for damage. If there is any damage, contact your Nihon Kohden representative.

Unpacking

Remove the analyzer from the shipping container and visually inspect for damage. If there is any damage, contact your Nihon Kohden representative. Use two people when lifting or moving the analyzer.

CAUTION

Use two people and be careful when moving the analyzer. Otherwise, you may injure your back or be injured from dropping the analyzer.

Waste Disposal Requirements

WARNING

Potential Biohazard. Observe all biosafety and chemical hazard precautions for waste disposal. Operators are responsible for disposing of waste in accordance with local, state, and federal regulations.

CAUTION

Waste container must be stored at the same level or below the analyzer, never above.

CAUTION

The waste is under pressure. Be sure that the waste tube is securely placed in the waste container, flow of waste is unobstructed, and all analyzer components are located away from possible waste overflow.

Installation Flowchart

1. Place the analyzer in the appropriate place.
2. Connect external instruments such as printer, ZK-820V hand-held bar code reader and PC, if necessary.
3. Connect the power cord and if necessary, perform grounding. Do not turn on the power of any instrument at this stage.
4. Connect the diluent, detergent, lysing reagent and waste container to the analyzer.
5. Check that the pump tubes are not disconnected or damaged.
6. Turn on the power of the analyzer and connected external instruments.
7. Perform Strong cleaning on the Operation screen.
8. Check the settings on the Settings screen. Make sure that the date and time settings are correct. Refer to Section 5.
9. Calibrate the analyzer. Refer to Section 6.
10. Check the daily accuracy.

Connecting an External Instrument to the Analyzer

A personal computer, card printer (WA-460V/461V or equivalent) and external printer can be connected to the serial port and a ZK-820V hand-held bar code reader can be connected to the bar code reader socket on the rear panel.

Before connecting the external instrument to the analyzer, make sure that the power on the instruments is turned off.

For changing the printing and communication format, refer to "Changing Output Format" in Section 5.

CAUTION

When several medical instruments are used together, ground all instruments to the same one-point ground. Any potential difference between instruments may cause electrical shock to the operator.

When more than one electrical instrument is used, there may be electrical potential difference between the instruments. Potential difference between instruments may cause current to flow to the connected to the instruments, resulting in electrical shock (micro shock).

Always perform equipotential grounding when required.

CAUTION

Connect only the specified instrument to the analyzer and follow the specified procedure. Failure to follow this instruction may cause instrument malfunction.

CAUTION

In order to avoid any safety hazard, only connect personal computers which are approved by UL 60950.

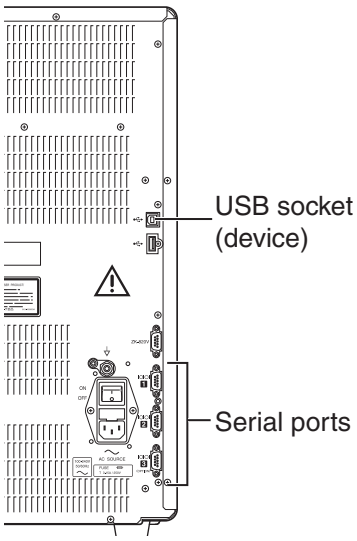
CAUTION

The analyzer should only be connected to an external instrument which complies with the CISPR 11 (Edition 4: 2003), Group 1 and Class B standard.

CAUTION

Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected from the AC socket. Otherwise, the operator may receive electrical shock or injury.

Connecting a PC



A locally purchased PC can be connected to the serial port or USB socket (device) on the rear panel.

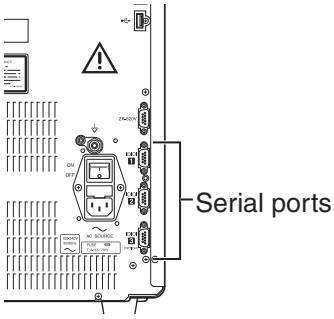
NOTE

- In order to avoid any safety hazard, only connect personal computers which are approved by UL 60950.
- Only use the 3-prong power cord for the PC.
- Set the correct connection settings.
- The PC can be connected to either the serial port or USB socket. When the PC is connected to the serial port, only the numeric data can be sent to the PC; the scattergram and histogram cannot be sent.
- To connect the PC to the USB socket (device), the optional QP-822V data management software is required. The measurement result can be sent to the PC after every measurement.

Disconnecting the USB Cable

Disconnect the USB cable from the PC to disconnect the USB communication. Connect the USB cable again to restart the communication. You cannot disconnect the communication by clicking the icon on the task bar of the PC.

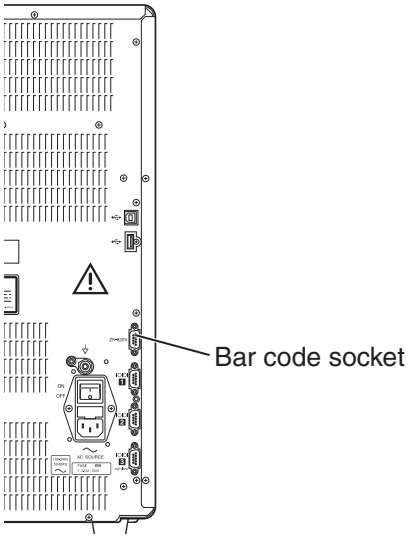
Connecting a Card Printer



The WA-460V/461V card printer can be connected to the serial port on the analyzer. On the WA-460V/461V card printer, only the numeric data is printed. Histograms cannot be printed.

Connect the card printer cable to the card printer and the serial port on the analyzer. For changing the printing and communication format, refer to “Changing Output Format” in Section 5.

Connecting a ZK-820V Hand-held Bar Code Reader (Option)



The optional ZK-820V hand-held bar code reader can be used for reading the bar code label (up to 13 characters) on the sample tube. For details about the hand-held bar code reader, refer to the bar code reader manual.

The bar code reader can read the following codes:

- Industrial 2 of 5
- ITF
- JAN/EAN/UPC
- CODABAR (NW-7)
- CODE 39
- CODE 93
- CODE 128

Before turning on the analyzer power by pressing the [Power] key on the front panel, connect the bar code reader cable to the bar code socket on the rear panel.

When the bar code reader is connected, the power is supplied through pin 9 of the bar code reader socket.

NOTE

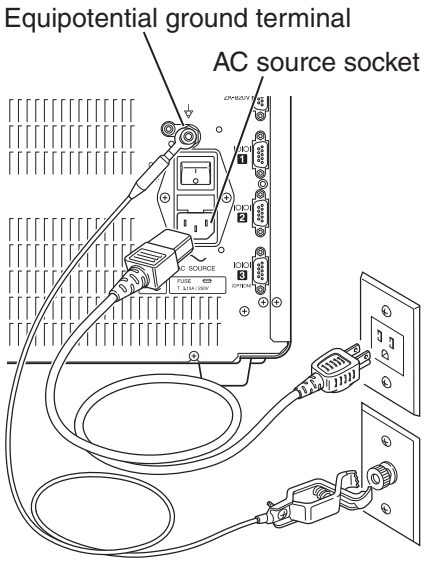
Do not connect instruments other than ZK-820V hand-held bar code reader to the bar code reader socket.

To set the various settings for the hand-held bar code reader, read the bar code attached to the bar code reader manual with the hand-held bar code reader within 15 seconds after turning the bar code reader power on. After changing the settings, turn the bar code reader power off.

You can also use the bar codes in “Bar Codes for Using the ZK-820V Hand-held Bar Code Reader” in Appendix B.

Connecting the Power Cord and Grounding the Analyzer

Connecting the Power Cord



CAUTION

Only use the provided power cord. Using other power cords may result in electrical shock or injury to the operator.

Connect the provided power cord to the AC SOURCE socket on the rear panel and plug the cord into a 3-prong AC outlet.

Equipotential Grounding

CAUTION

When several medical instruments are used together, ground all instruments to the same one-point ground. Any potential difference between instruments may cause electrical shock to the operator.

When more than one electrical instrument is used, there may be electrical potential difference between the instruments. The potential difference between the instruments may cause current to flow to the patient connected to the instruments, resulting in electrical shock (macro shock).

Always perform equipotential grounding when required. When equipotential grounding is required, connect the equipotential ground terminal on the rear panel of the analyzer to the equipotential ground terminal on the wall (equipotential grounding system) with the equipotential grounding lead (potential equalization conductor).

Connecting Tubes and Installing Reagents

In order for the analyzer to operate correctly, you must install all reagents and the waste tube before the power is turned ON.

Materials Required

- Powder-free gloves, lab coat, safety glasses
- ISOTONAC•3 diluent
- CLEANAC detergent
- CLEANAC•3 detergent
- Hemolynac•3N lysing reagent
- Hemolynac•5 lysing reagent
- Reagent inlet tubes and waste outlet tube
- Waste container (or appropriate drain)
- 2 L container
- Lint-free cloth

CAUTION

Only use Nihon Kohden recommended reagents and consumables. Otherwise the measurement result cannot be guaranteed and incorrect reagent concentration can cause equipment damage.

CAUTION

If reagent has been frozen, it must not be used.

Diluent (ISOTONAC•3)

NOTE

- If the diluent contacts the skin or eyes or is swallowed, wash immediately and thoroughly with water.
- Use the diluent at room temperature 15 to 30ºC (59 to 86ºF).
- When the temperature of the diluent decreases to less than 15ºC (59ºF), it may influence WBC differential parameters (NE, LY, MO, EO, BA) but not influence the WBC count.
- Do not put new diluent in old diluent bottles.

Detergent

CLEANAC•3

WARNING

Do not allow CLEANAC•3 detergent to come into contact with acid. Contact with acids can cause the release of poisonous chlorine gas.

WARNING

Do not swallow the CLEANAC•3 detergent. If swallowed, see a physician immediately.

CAUTION

If the CLEANAC•3 detergent contacts the skin, eyes or mouth, wash thoroughly and immediately with water and see a physician.

NOTE

Store the detergent at room temperature 15 to 30ºC (59 to 86ºF).

CLEANAC

WARNING

Do not swallow the CLEANAC detergent. If swallowed, see a physician immediately.

NOTE

Store the detergent at room temperature 15 to 30ºC (59 to 86ºF).

Lysing Reagent

Hemolynac•3N

CAUTION

Do not swallow the Hemolynac•3N lysing reagent. If swallowed, see a physician immediately.

CAUTION

Avoid reagent contact with the skin. If it contacts the skin or eyes, wash thoroughly with water and see a physician immediately.

CAUTION

If the Hemolynac•3N lysing reagent contacts the skin, eyes or mouth, wash thoroughly and immediately with water and see a physician.

Hemolynac•5

CAUTION

Do not swallow the Hemolynac•5 lysing reagent. If swallowed, see a physician immediately.

CAUTION

If the Hemolynac•5 lysing reagent contacts the skin, eyes or mouth, wash thoroughly and immediately with water and see a physician.

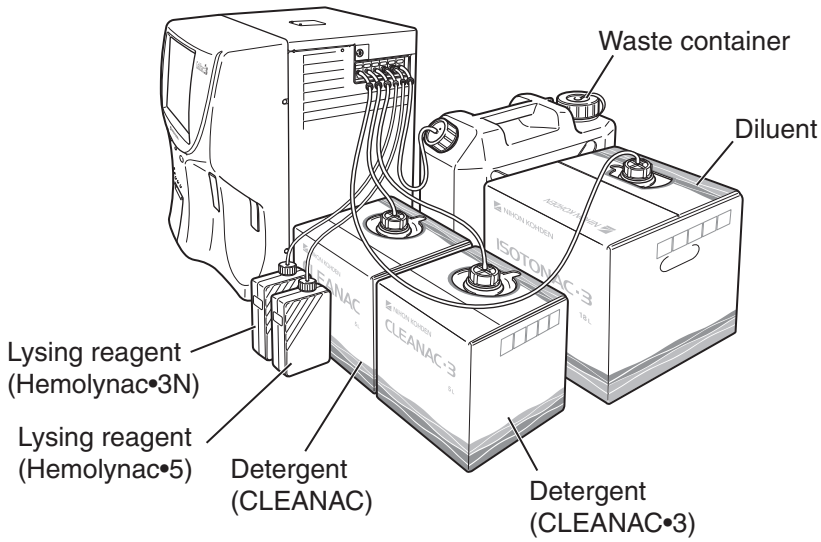
NOTE

- Use the reagent before the expiration date on the package or label and within the specified period after opening.
- Use only the specified cap for the hemolysing reagent. Otherwise the reagent concentration changes and it affects the measurement.
- Do not use the reagent outside of the designated laboratory.
- Completely seal the cap of the reagent when storing it.
- Read the instructions thoroughly to use the hemolysing reagent.
- Do not put new lysing reagent in old lysing reagent bottles.

Connecting Tubes

NOTE

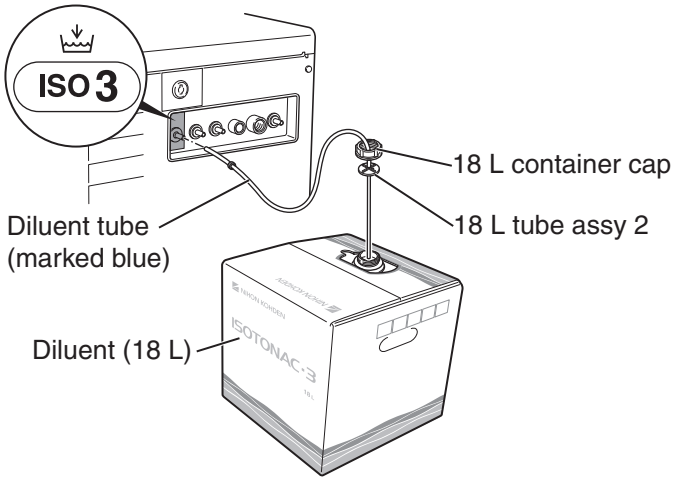
- When connecting tubes or replacing reagents, do not let dust or bacteria enter the port or bottle. The analyzer may get damaged.
- Do not squeeze or bend the tubes. The tube may get accidentally disconnected or the analyzer may get damaged.
- Install the diluent and detergent container at the same level.
- Install the reagents so they do not block the vent hole for the fan.
- If necessary, cut the diluent tube and reagent tube to an appropriate length (2.0 m or less) when the length of the tube does not fit. For the lysing reagent and detergent, use only the specified tubes.
- Follow the instructions on each package for handling the diluent and detergent.
- For handling the lysing reagent, refer to the manual of the reagent.
- After installing the reagents, do not block the vent hole on the bottle cap.



Diluent Tube

NOTE

Try to keep the diluent container at the same level as the analyzer.



1. Connect the diluent tube (marked blue) to the ISO3 inlet on the right side panel.
2. Pass the diluent tube through the 18 L container cap.
3. Connect the end of the diluent tube to the 18 L tube assy 2.
4. Put the 18 L tube assy 2 into the diluent container and tighten the 18 L container cap.

Detergent Tube

NOTE

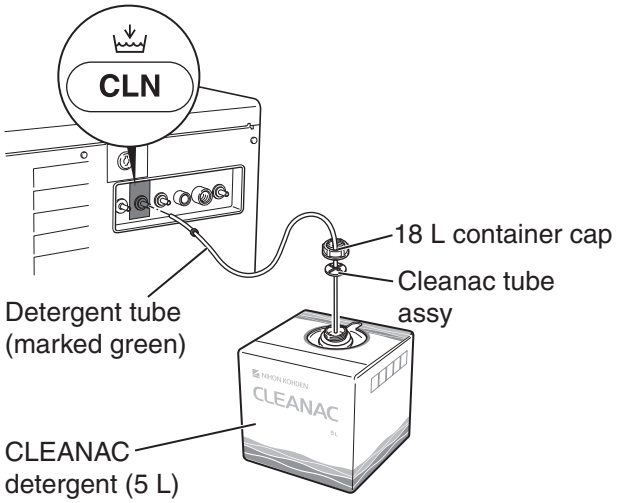
Only use the specified detergent tubes for the detergent.

For performing strong clean, use CLEANAC•3 detergent. For other purposes, use CLEANAC detergent.

CLEANAC Detergent

NOTE

Try to keep the CLEANAC detergent container at the same level as the analyzer.

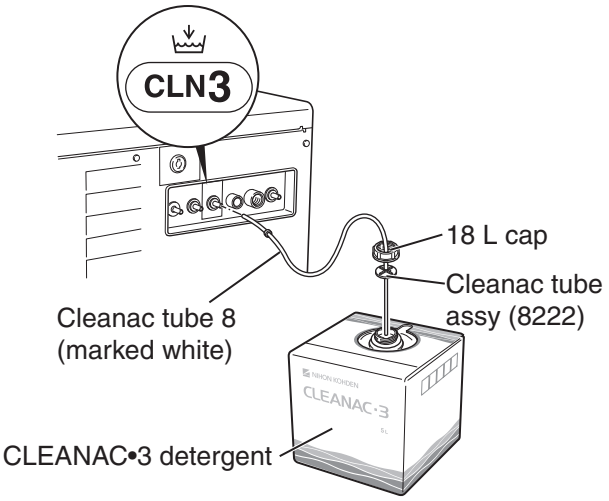


1. Connect the detergent tube (marked green) to the CLN inlet on the right side panel.
2. Pass the detergent tube through the 18 L container cap.
3. Connect the end of the detergent tube to the cleanac tube assy.
4. Put the cleanac tube assy into the CLEANAC container and tighten the 18 L container cap.

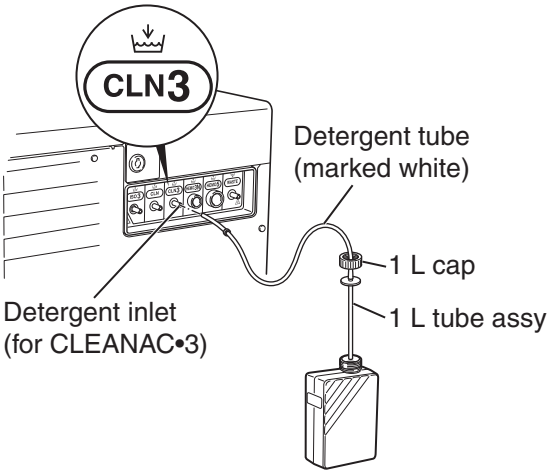
CLEANAC•3 Detergent

NOTE

Place the CLEANAC•3 detergent container at the same level as the analyzer.

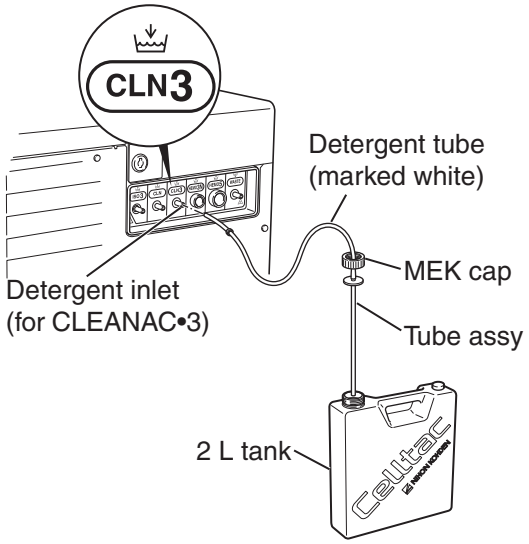


1. Connect the cleanac tube 8 (marked white) to the CLN3 inlet on the side panel.
2. Pass the cleanac tube 8 through the 18 L cap.
3. Connect the end of the cleanac tube 8 to the cleanac tube assy (8222).
4. Put the cleanac tube assy (8222) into the CLEANAC•3 container and tighten the 18 L cap.



When the CLEANAC•3 (1 L) is used

1. Connect the detergent tube (marked white) to the CLN3 inlet on the side panel.
2. Pass the end of the detergent tube into the 1 L cap and attach the 1 L tube assy.
3. Put the 1 L tube assy into the tank and tighten the cap.



When the YZ-0066 reagent bottle set is used

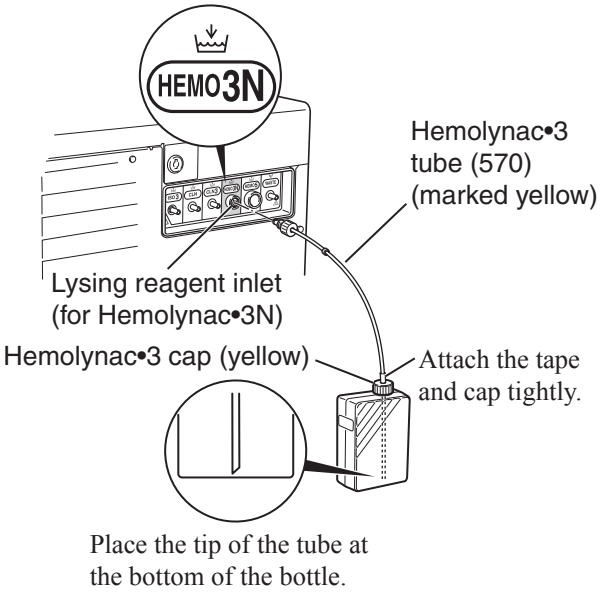
1. Pour the detergent (CLEANAC•3) into the 2 L tank.
2. Connect the detergent tube (marked white) to the CLN3 inlet on the right side panel.
3. Pass the end of the detergent tube into the MEK cap and attach the tube assy.
4. Put the tube assy into the tank and tighten the cap.

Lysing Reagent Tube

NOTE

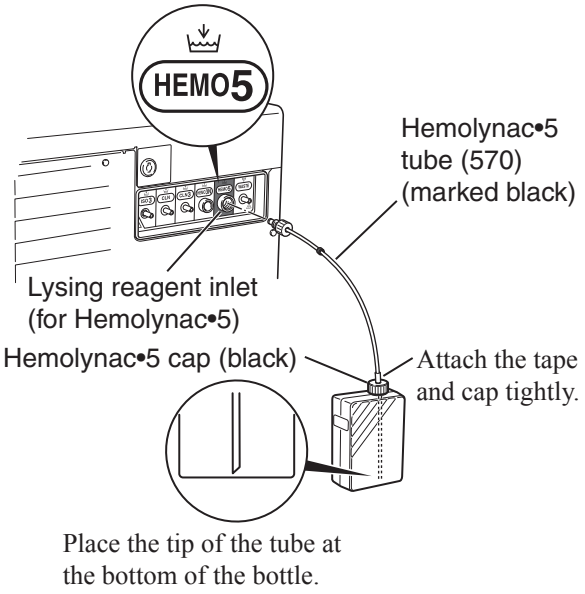
- Place the lysing reagent container at the same level as the analyzer.
- Only use the specified lysing reagent tubes for the lysing reagent.

Hemolynac•3N



1. Replace the lysing reagent cap with the Hemolynac•3 cap (yellow) and tighten the cap.
2. Connect the Hemolynac•3 tube (570) (marked yellow) to the HEMO3N inlet on the right side panel.
3. Put the other end of the tube into the lysing reagent container through the Hemolynac•3 cap (yellow). Attach the tape and cap tightly and place the tip of the tube at the bottom of the bottle.
4. When using the reagent tray, place the lysing reagent container on the upper shelf of the reagent tray.

Hemolynac•5

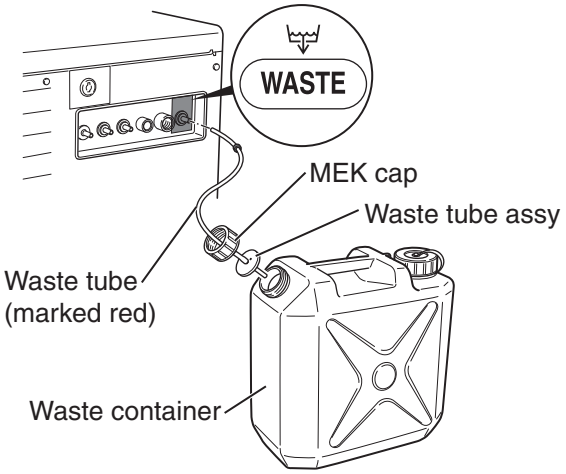


1. Replace the hemolysing reagent cap with the Hemolynac•5 cap (black) and tighten the cap.
2. Connect the Hemolynac•5 tube (570) (marked black) to the HEMO5 inlet on the side panel.
3. Put the other end of the tube into the hemolysing reagent container through the Hemolynac•5 cap (black). Attach the tape and cap tightly and place the tip of the tube at the bottom of the bottle.

Waste Fluid Tube

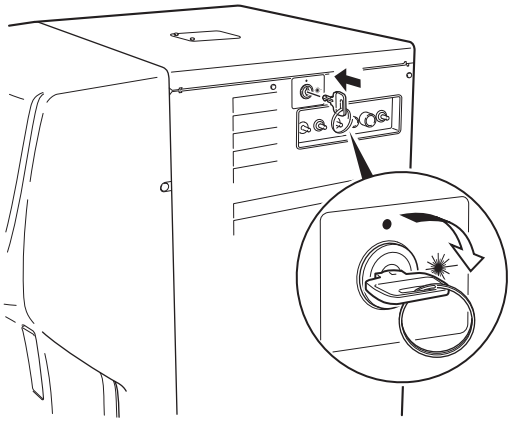
NOTE

Try to keep the waste container at the same level as the analyzer.



1. Connect the waste tube (marked red) to the waste outlet on the right side panel.
2. Pass the waste tube through the MEK cap.
3. Connect the waste tube to the waste tube assy.
4. Insert the waste tube assy into the waste container and tighten the MEK cap.

Turning the Laser Switch On

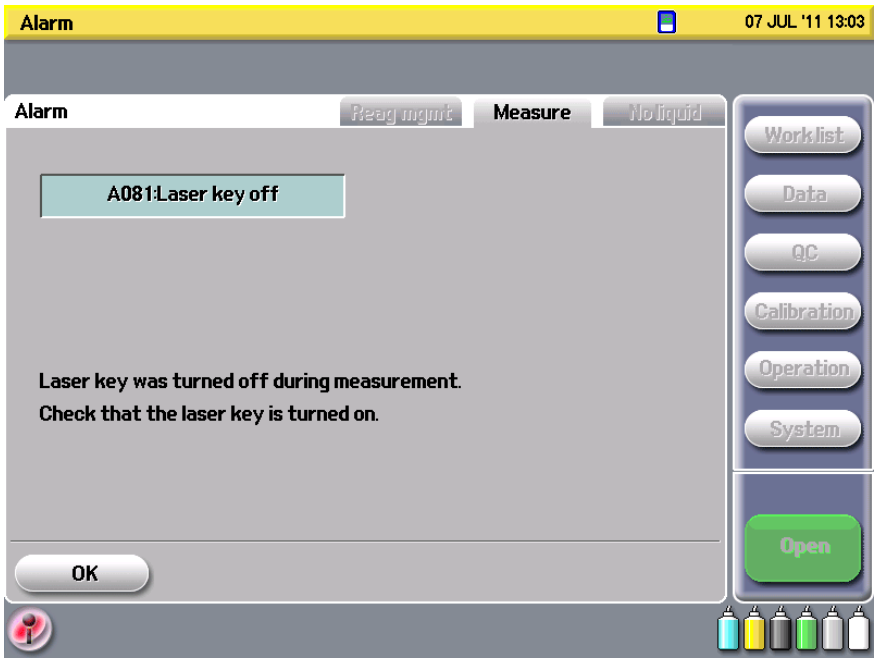


1. Insert the laser key into the laser switch hole on the right side panel.

2. Turn the laser switch to ON.

NOTE

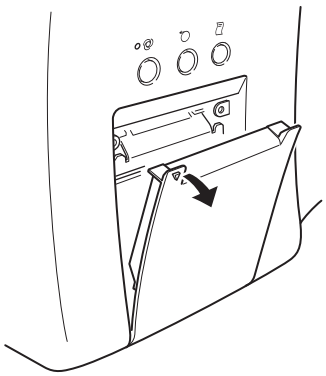
- When the measurement is performed with the laser switch turned off, CBC can be measured but an alarm is displayed and there is no WBC 5 part differential scattergram and data.
- Store the key in a safe place.



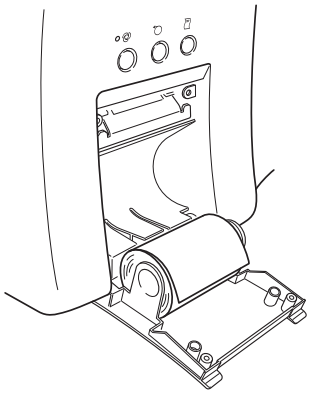
Loading Recording Paper in the WA-730V Printer Unit (Option)

NOTE

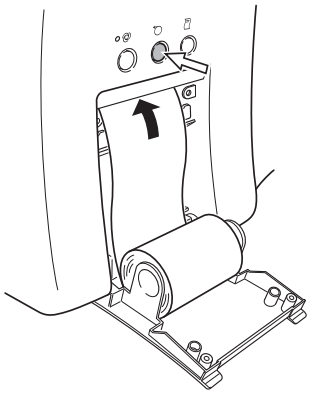
- The WA-730V printer unit is optional (built-in type).
- Only use the specified recording paper.



1. Open the printer door.

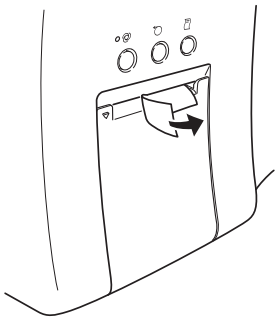


2. Set the recording paper in the paper tray in the direction as shown.



3. Insert the recording paper into the slot.

4. Press the [↺ Feed] key on the front panel until the recording paper comes out from the printer unit.



5. Put the paper through the opening of the door and close the door.

6. Cut the extra paper.

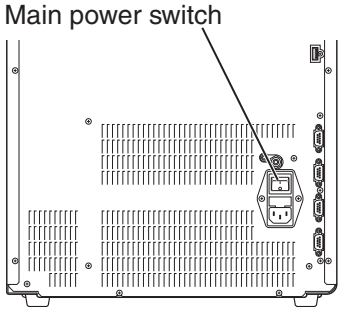
Turning Power On

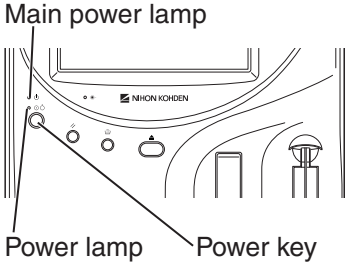
Check Before Turning Power On

Check the following items before turning on the power.

Item	Check
Accessories and consumables	Sufficient diluent, detergent and lysing reagent.
Connection and settings	Power cord is connected properly.
	Grounding lead is connected properly when equipotential grounding is required.
	Tubes are connected properly.
	Diluent, detergent and lysing reagent containers are connected and have no dust in them.
	Waste container is in place and empty.
	Enough recording paper in the optional printer.
	External instruments (e.g. PC and printer) are properly connected.
Appearance	No scratches, dirt or leakage (especially in the measurement baths, sub baths and pump tube).
	No key or switch is broken.
	No damage to the power cord.
	Waist container is not full.
	Analyzer is not wet.
Quality control	Run quality control by measuring a hematology control.
Use after long term storage	Aperture caps are clean.
	Pump tube and pinch valve tube are not broken and not disconnected.

Turning On the Power





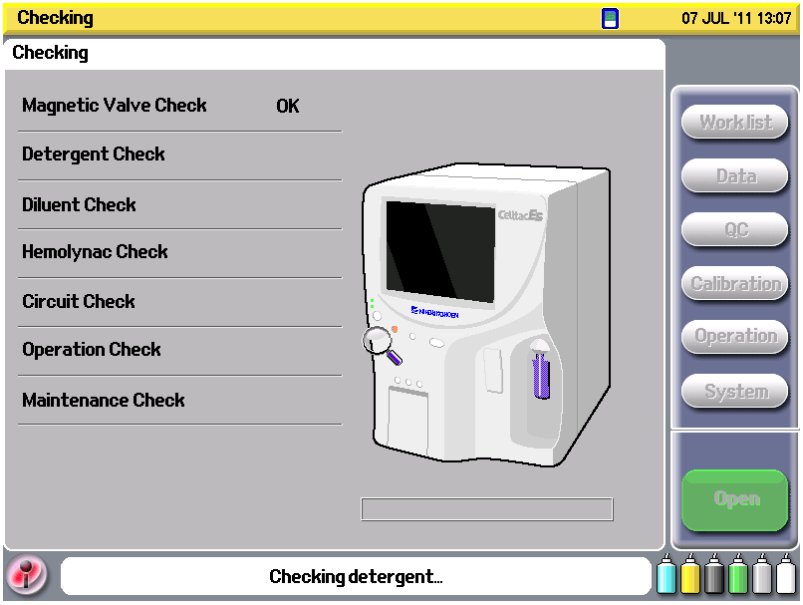
1. Confirm that the analyzer, printer (optional), and ZK-820V hand-held bar code reader (optional) power cords are connected to grounded power outlets.

2. Set the printer power switch ON.

3. Press the [Main power] switch on the rear panel to ON. The [Main power lamp] on the front panel lights.

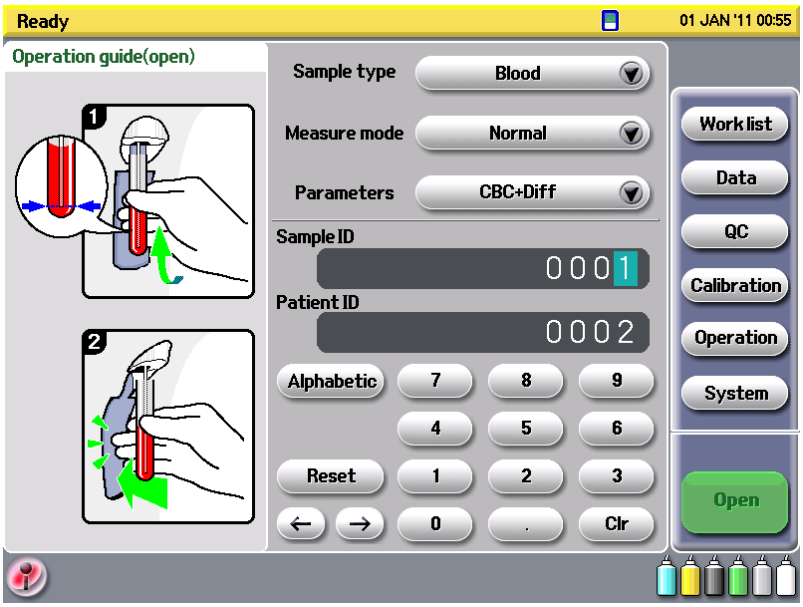
   Always leave the main power ON except for storage and transport of the analyzer.

4. Press the [Power] key on the front panel ON. The [Power lamp] lights and the screen illuminates within 15 to 30 seconds. Cleaning of the fluid path, priming and circuit self-check are automatically performed, and the "Checking detergent" message appears. When the laser switch on the right side panel is turned on, the laser lamp also lights.



If there is an error, “Fail” appears on the screen.

After priming operation is completed, the Ready screen appears.



NOTE

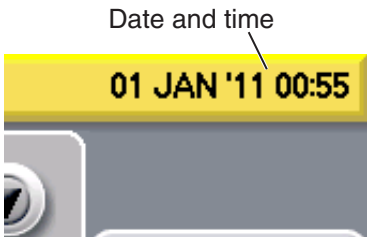
If an error message appears, refer to “Alarm Messages” in Section 10.

5. Perform strong cleaning by pressing the Operation key → Strong clean key.

6. After strong cleaning, press the OK key.

7. Press the Ready key to display the Ready screen.

Checking the Date and Time Settings



After turning the analyzer ON, date and time must be checked. To correct the date and time on the upper right corner of the screen, refer to “Setting Date and Time” in Section 5.

Cleaning the Analyzer

After installing the analyzer, turn the power on to refill reagents into the analyzer.

After installing the analyzer or long term storage, perform strong cleaning. Refer to “Using the Analyzer after Storage” in section 9.

Check After Turning On the Power

Check the following items after turning on the power to start operating safely and properly. If any problem is detected, take the proper countermeasure according to Section 10 “Messages and Troubleshooting”.

Item	Check
Turning on the power	There is no fire, smoke or smell.
	The analyzer is not too hot.
	There is no electric shock.
	The main power and power lamps light.
	No alarm message is displayed on the screen.
Basic operation	The messages are displayed properly.
	Keys and switches operate properly.
	The touch screen keys function properly.
	The lamps and LED indication are correct.
	The measured background noise values are proper.
	The measured hematology control values are proper.
	The printer works properly.
	The date and time are correct.
	No alarm message is displayed on the screen during operation.
After long term storage	Perform Strong cleaning on the Operation screen.

NOTE

At the start of the day, check that the date and time settings are correct.

Optical Adjustment

After installing the analyzer, perform optical adjustment to measure samples correctly. Refer to “Performing Optical Adjustment” in section 5.

Checking Daily Accuracy

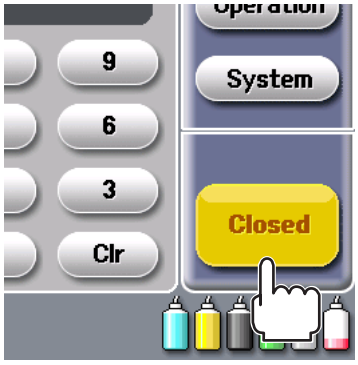
To assure measurement reliability, check the analyzer daily before measurement. For details on the measurement reliability, refer to Section 11 “Quality Control”.

- Count the diluent to measure background noise.
- Count the MEK-5D hematology control to check accuracy.

Measuring Background Noise

Count the diluent to measure background noise. When using the analyzer in closed mode, measure background noise in closed mode. When using the analyzer in open mode, measure background noise in open mode. Background noise increases in the following cases.

Problem	Countermeasure
Old diluent. Germs begin to breed in the diluent 60 days after opening.	Replace diluent.
Dust in the diluent container.	Replace diluent.
Extremely high or low diluent temperature (normal range is 15 to 30°C (59 to 86°F)).	Adjust diluent temperature to 15 to 30°C (59 to 86°F).
The sampling nozzle is clogged and bubbles occur in the sub bath.	Replace the sampling nozzle with a new one.

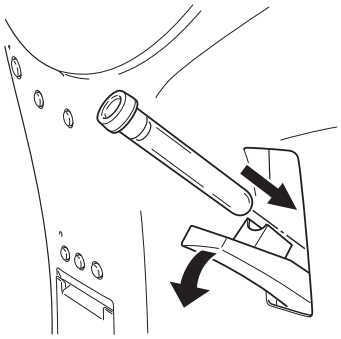


There are two ways to measure background noise. One is by pressing the [◇ Count] switch. The other is using the Background screen of the Other screen. When measured on the Background screen, “Fail” appears beside the parameter which is over the acceptable value on the result screen.

Measuring Background Noise in Closed Mode

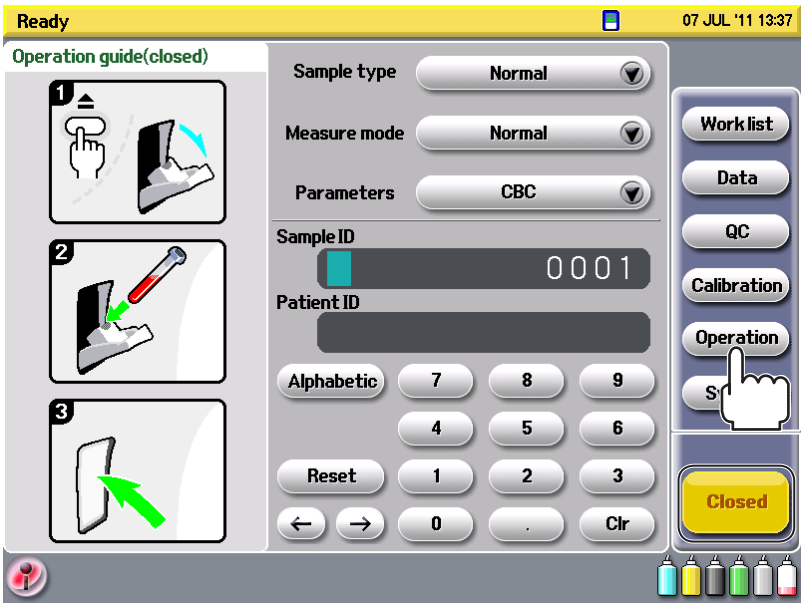
Measuring by Pressing the [◇ Count] Switch

1. Select “Closed” for sampling mode on the Ready screen.
2. Press the [⏏ Eject] key on the front panel. The tube holder opens.
3. Set an empty tube in the tube holder.
4. Close the tube holder. Diluent is measured. If the tube holder is closed without setting a tube, measurement is not performed.
5. The tube holder opens automatically after finishing diluent measurement and the result is displayed.

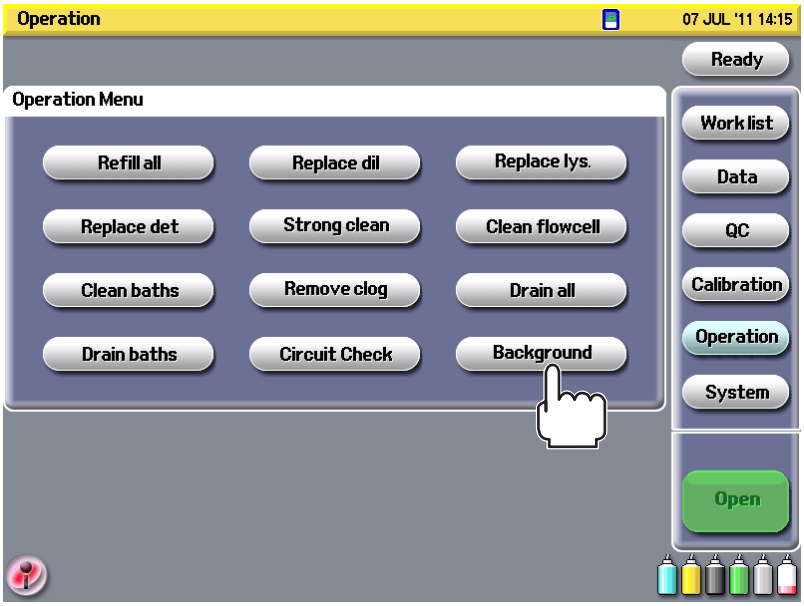


Measuring on the Background Screen

1. Check that “Closed” is selected for sampling mode and press the Operation key on the Ready screen.



2. Press the Background key on the Operation screen.



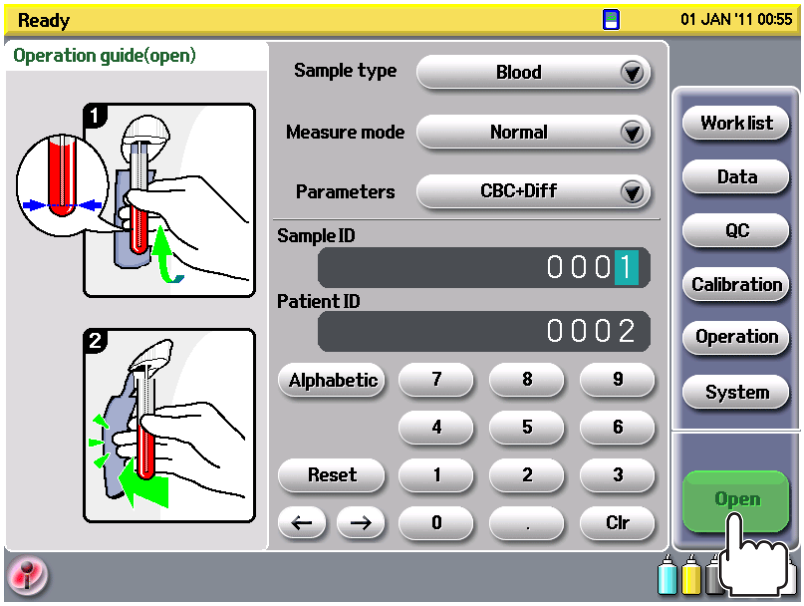
The “Measure background noise?” message appears on the screen.

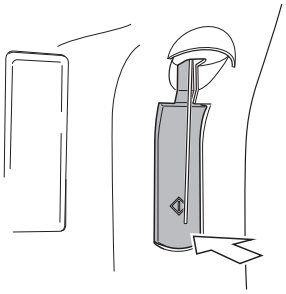
3. Press the Yes key to measure background noise. The result is displayed after the measurement is complete.

Measuring Background Noise in Open Mode

Measuring by Pressing the [◇ Count] Switch

1. Select “Open” for sampling mode on the Ready screen.

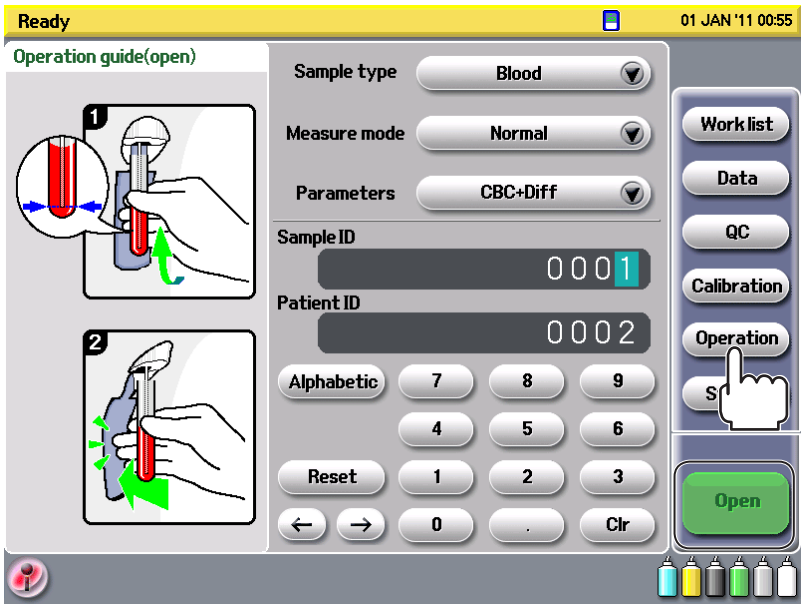




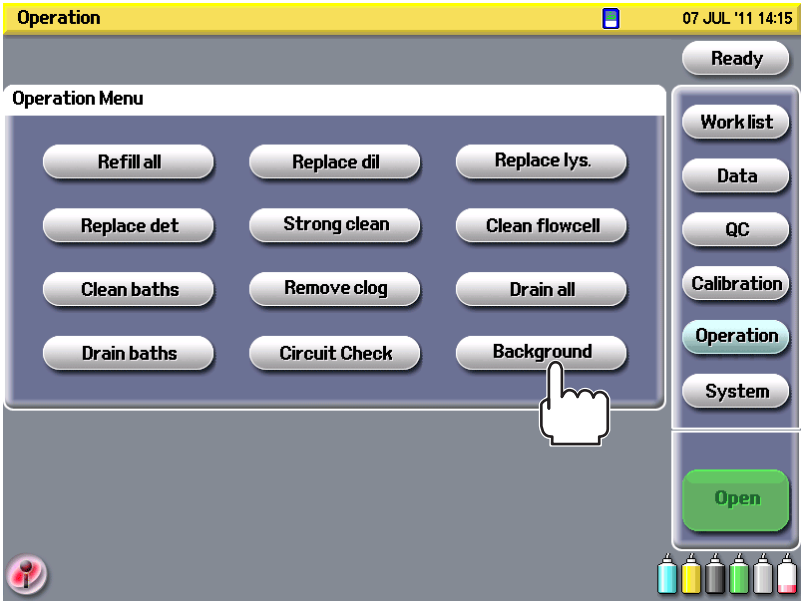
2. Press the [◇ Count] switch to count the diluent. There is no need to aspirate the diluent from the sampling nozzle. The result is displayed after the measurement is complete.

Measuring on the Background Screen

1. Check that “Open” is selected for sampling mode and press the Operation key on the Ready screen.



2. Press the Background key on the Operation screen.

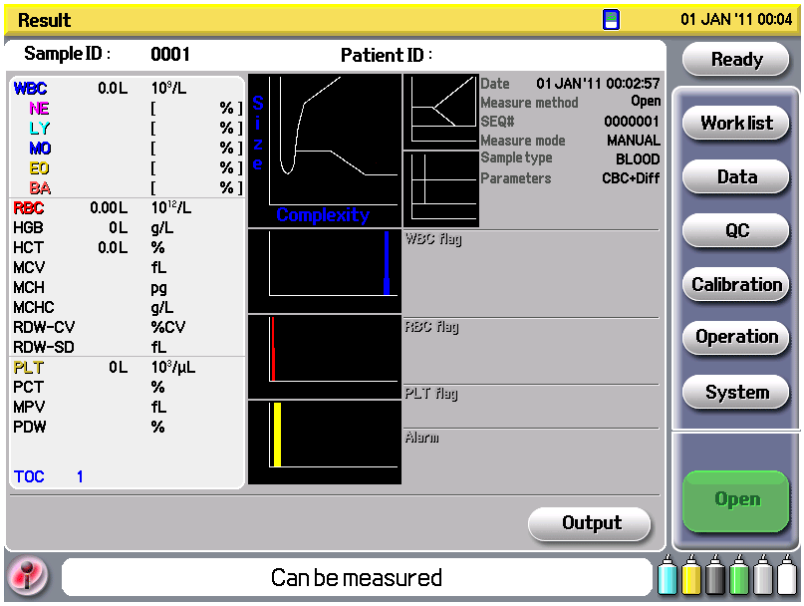


The "Measure background noise?" message appears on the screen.

3. Press the Yes key to measure background noise. The result is displayed after the measurement is complete.

Results

The result is displayed on the screen after measurement.



Make sure that the values are less than or equal to the following values.

WBC: 0.2 ($\times 10^3/\mu L$)
RBC: 0.05 ($\times 10^6/\mu L$)
HGB: 0.1 (g/dL)
PLT: 10 ($\times 10^3/\mu L$)

When measured on the Background screen, "Fail" appears beside any parameter which is over the acceptable value.

Disregard the other parameter values because noise does not affect them.

If the values are greater than the values listed above, check the following items, press the [Clean] key on the front panel to clean the fluid path, and recount the diluent.

- The diluent is clean.
- No bubbles in the diluent.
- The aperture caps are clean.
- The aperture caps are firmly attached.
- The measurement baths and sub baths are clean.

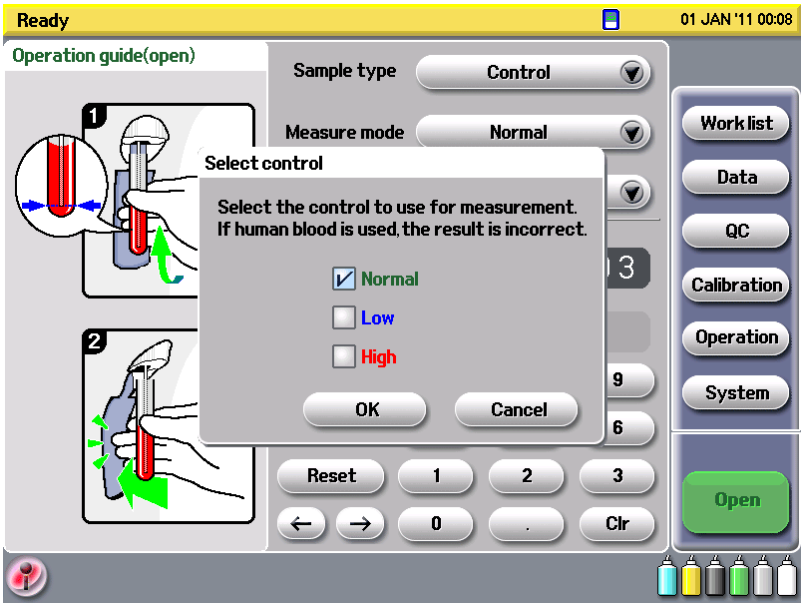
Measuring Hematology Control

To check the measurement accuracy of the analyzer, measure a hematology control.

NOTE

The hematology control is for controlling the accuracy of the analyzer. It is made from healthy human blood. Because living cells are used, handle and store the control correctly according to the explanation of the assay sheet.

1. On the Ready screen, set the measurement settings as follows.
   - Sample type: Control
     On the control select window, select the control to use and press the OK key. When the Cancel is pressed, the Sample mode returns to Normal.
   - Measure mode: Normal
   - Parameter: CBC + Diff



Set the control type as follows.

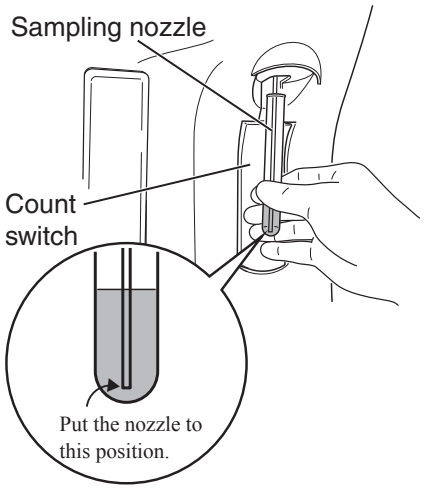
Hematology control	Setting
MEK-5DN	Normal
MEK-5DL	Low
MEK-5DH	High

2. Measure a hematology control.

NOTE

- Before measurement, make sure that the control setting matches the control.
- After measurement, the Sample type returns to Normal.

Open mode



i) Remove the cap of the hematology control and put the sampling nozzle into the control as shown in the illustration.

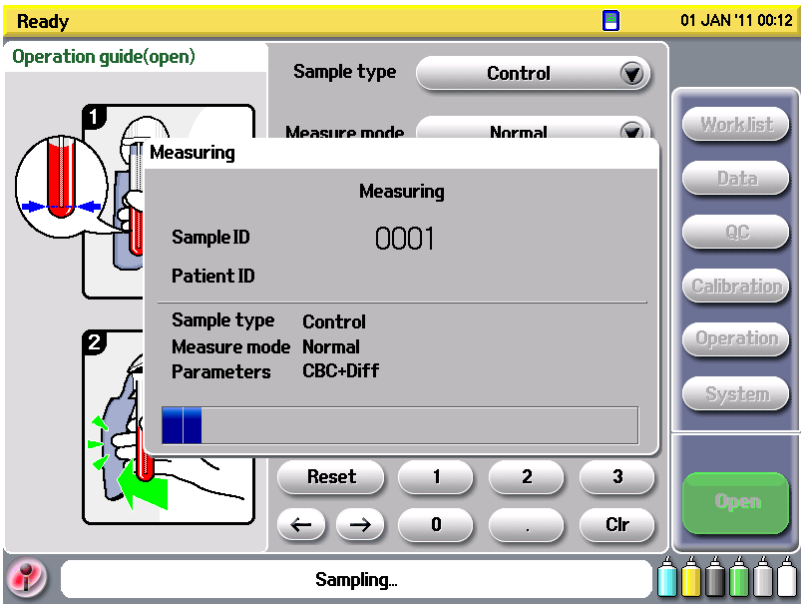
NOTE

Do not let the sampling nozzle touch the bottom of the hematology control. This may prevent aspiration of the control.

ii) Press the count switch to start measurement. When the switch is pressed, the sample is aspirated, diluted in the analyzer and measured. During measurement, the “Measuring” message is displayed.

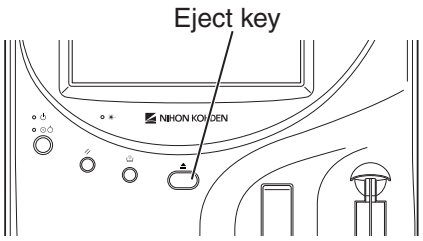
NOTE

Do not lower the sample while it is being aspirated.

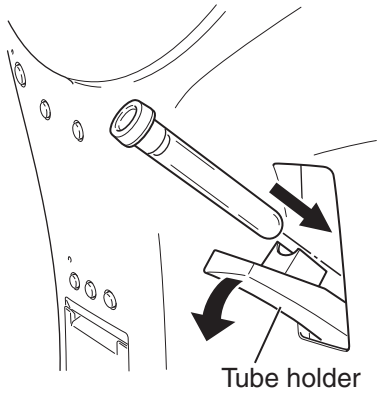


Closed mode

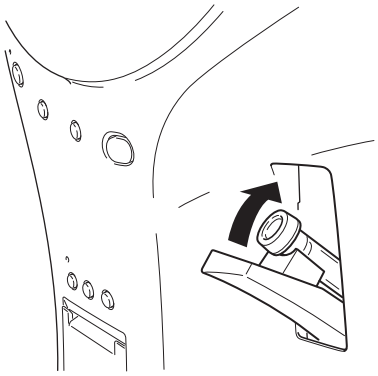
Set the hematology control to the tube holder.



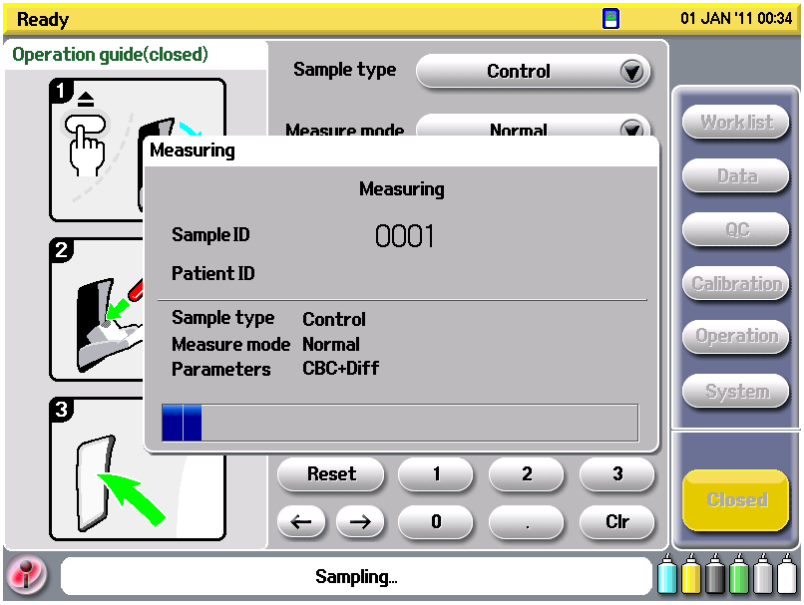
i) Press the eject [⏏] key to open the tube holder.



ii) Set the hematology control into the tube holder.



iii) Close the tube holder. The measurement automatically starts. During measurement, the “Measuring” message is displayed.



3. Check that the measurement value is within the range of the expected value on the assay sheet.

Preparing SD Card

Use a QM-001D or specified SD memory card for this analyzer.

NOTE

- Only use the specified SD card. Otherwise, data cannot be saved or the analyzer may get damaged.
- The operation of a mini or micro SD card with conversion adapter cannot be guaranteed.
- An SDHC or SDXC memory card cannot be used.

Safety Information about the SD Card

NOTE

For handling and safety information about SD card, refer to the SD card manual together with this manual.

Handling and Storage

- Keep the SD card slot clean. If dust gets into the slot, the SD card will not function.
- Do not handle the SD card while eating or drinking.
- Do not get the SD card wet.
- Do not give impact to the SD card by dropping or bending.
- Do not expose the SD card to direct sunlight or leave it in a high temperature place.

Environmental Conditions

- Storage environment
  Temperature: –20 to +65°C (–4 to +149°F)
  Humidity: less than 95% (noncondensing)
- Operating environment: same as the analyzer

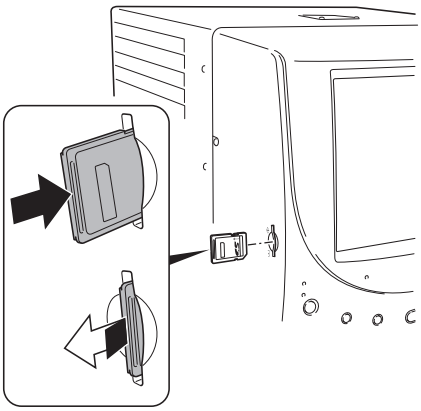
Data Processing

- Initialize the SD card on this hematology analyzer. An SD card that was initialized on other instruments cannot be used. Refer to “Formatting SD Card” in section 5.
- Do not use an unspecified instrument to save data to the SD card. The card may get damaged.
- Do not remove the SD card or turn off the power during data processing. The card may get damaged.

Inserting and Removing the SD Card

NOTE

- When inserting or removing a SD card, turn off the power of the hematology analyzer. The data in the card may get damaged or the hematology analyzer might not operate correctly.
- Do not bend the SD card or insert it at an angle.



Insert the SD card into the SD card slot so that the label on the SD card is toward front.

When removing the SD card, push the card once and remove it.

Section 3 Principles of Operation

Operation Theory

Electric Cell Counting

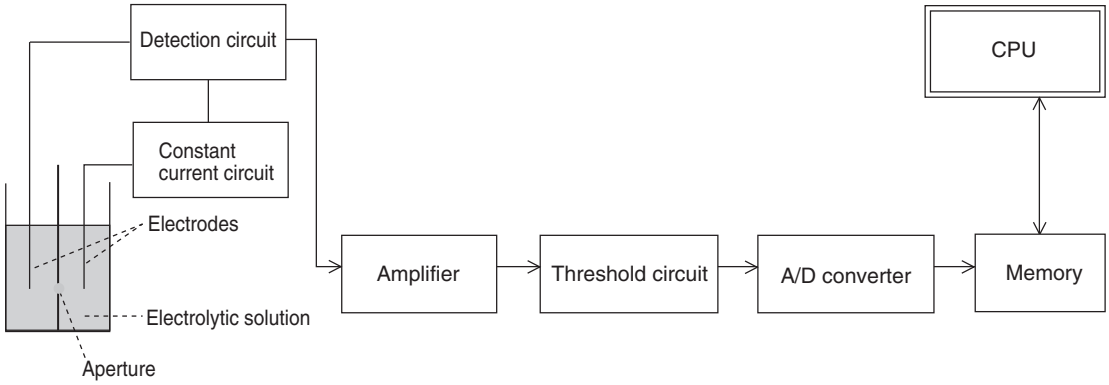
Counting Method

The hematology analyzer uses the volumetric impedance method of cell counting.

In this method, an electrolytic solution (diluent) containing suspended blood cells is aspirated through the aperture. Two electrodes, an internal electrode and an external electrode, are located close to the aperture and a constant current flows between them. When a blood cell passes through the aperture, the resistance between the electrodes momentarily increases and a very small voltage change occurs corresponding to the resistance. The voltage signal is amplified and is sent to the electronic circuit.

A threshold circuit eliminates signals caused by electrical noise, dust, debris and particles which are smaller or larger than blood cells.

To find the peak values, the signals are sent to the A/D converter. The acquired data is stored in memory for each individual peak value. The data is corrected by the CPU and displayed on the screen.



The number of signals for each size cell is stored in memory as a histogram. Counted cells of RBC and PLT can have overlap sizes so the CPU can discriminate the count for each type of cell. See the “Red Blood Cell and Platelet Counting” section.

Sometimes two or more cells pass through the aperture at the same time. This is called coincidence. When the sample solution is sufficiently diluted and mixed, this can be statistically predicted to a high degree of accuracy. The software contains a coincidence correction table to compensate for this.

Red Blood Cell and Platelet Counting

Data of the RBC and PLT pulses are stored in the memory as a histogram.

Normal blood shows a clear separation between the PLT volume range and RBC volume range (Fig. A) so an accurate PLT count is easily acquired. However, when abnormal blood such as microcytic blood is counted (Figs. B and C), the separation is unclear. In these cases, for accurate PLT counting, the CPU determines the PLT and RBC distribution pattern, and sets the upper threshold (PLT HI) to the lowest count.

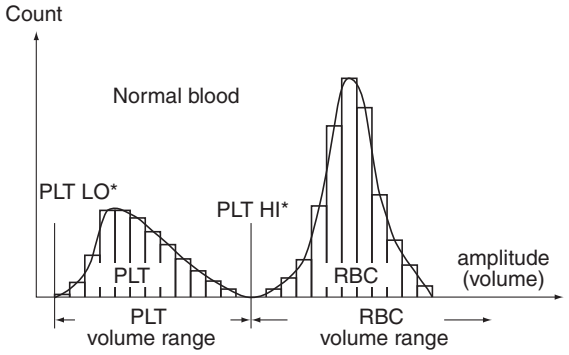


Fig. A

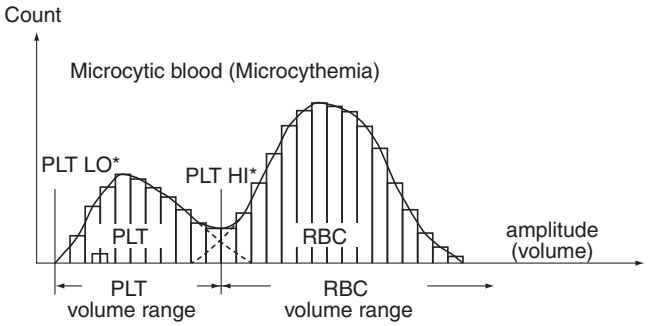


Fig. B

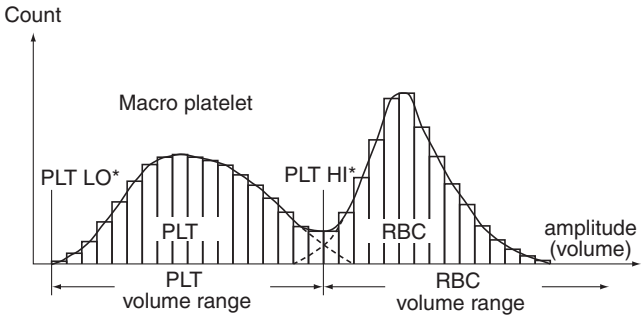


Fig. C

PLT LO*: Lower threshold
PLT HI*: Upper threshold

Principle of Hydraulic Operation

For accurate counting of the blood cells in a diluent solution, a constant volume of solution must be aspirated through the aperture. The manometer controls this volume by measuring diluent level by an optical sensor and aspirating the diluent by the rotary pump.

Aspiration and dispensing of the sample are performed alternately by an electromagnetic valve. The waste fluid is drained from the hematology analyzer by the rotary pump.

The priming of diluent and cleaning with detergent are also performed by the electromagnetic valves.

The CPU controls the electromagnetic valves, pump rotations and rotation direction. If an air bubble enters the manometer, the CPU generates an alarm sound and displays an error message on the screen.

Hemoglobin Measurement

Chemical Processing

A hemolysing reagent is added to the diluted blood sample to break the red blood cell membrane and release the hemoglobin.

Spectrophotometric Measurement Method

The hemoglobin is measured by spectrophotometry. This method measures the optical density of the sample solution. The optical density is proportional to the amount of hemoglobin in the sample solution.

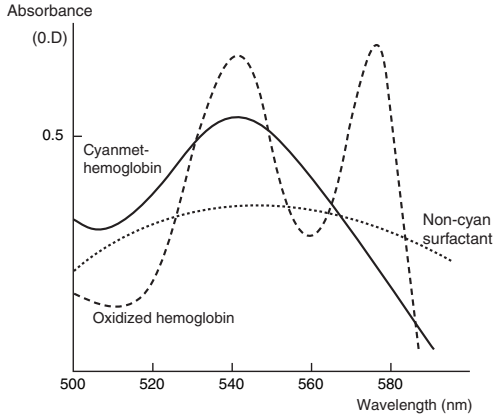
Spectrophotometric measurement is based on the principle that different materials absorb different amounts of different wavelengths of light. When light strikes a material, some of the light is absorbed by the material and some passes through. The amount of absorbed light at each frequency forms a unique optical "fingerprint" for that material.

In this hematology analyzer, hemoglobin is measured in the measurement baths. An LED shines one wavelength of light through the sample solution. A photodiode receives the light which is not absorbed by the solution. The amount of received light is converted to an electric signal which is amplified by the preamplifier. The amplified signal is sent to the A/D converter.

The amplified signals from the sample and diluent are required for measuring the hemoglobin concentration. The sample data is sent to the CPU. The CPU converts the ratio of these data to logarithmic data, multiplies it by the calibration coefficient and displays the result on the LCD.

After measurement, the sample and diluent are drained from the hematology analyzer. The sample is a highly concentrated protein solution. If the sample is left in the measurement baths for a long time, the measurement baths gradually become dirty. To prevent this problem, the measurement baths are automatically cleaned by dispensing the diluent after each measurement.

Hemoglobin absorption characteristics

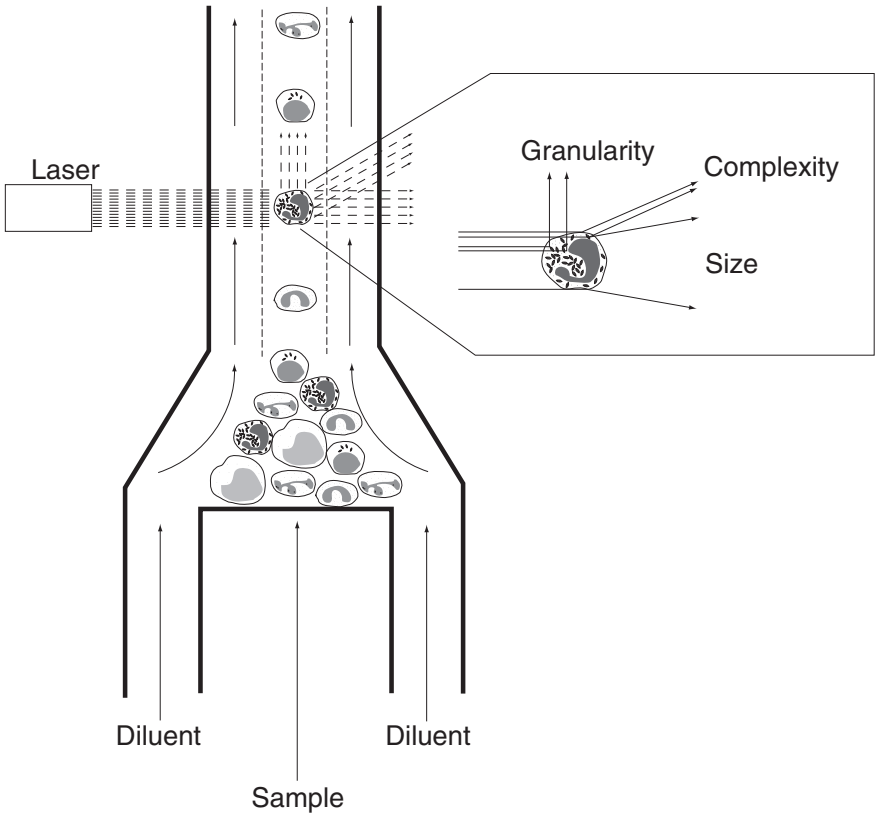


Principle of WBC Differential Operation

The hematology analyzer uses the light scatter technique to differentiate WBC into neutrophil, lymphocyte, monocyte, eosinophil and basophil counts.

The diluted blood sample is injected into the flow cell. Blood cells pass through the sensing zone in a single file. A laser beam through the sensing zone is scattered by the passing cells and the scattered light is detected. The angle and intensity of scattered light depend on the volume and characteristics of the cell. From this, WBC can be differentiated into 5 parts.

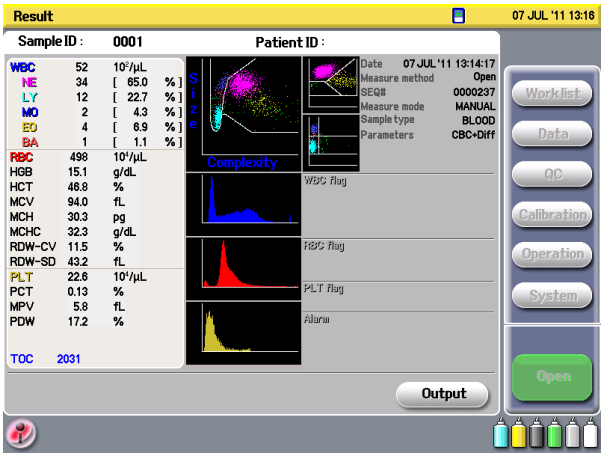
For details about the scattergrams, refer to “Measurement Results” later in this section.



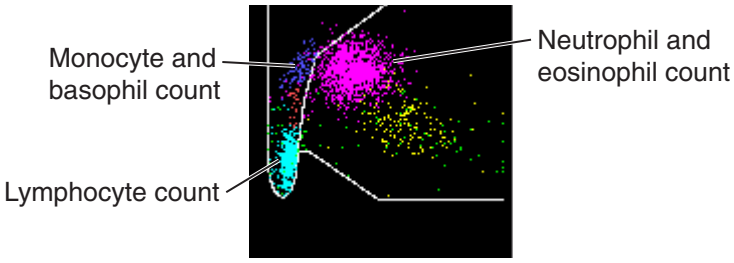
Measurement Results

WBC Scattergrams

There are 3 WBC scattergrams. You can compare 3 scattergrams at a time. You can also enlarge one scattergram to examine it.

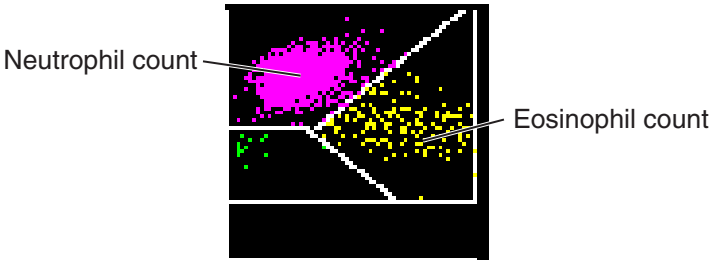


The main scattergram is divided into 3 areas.

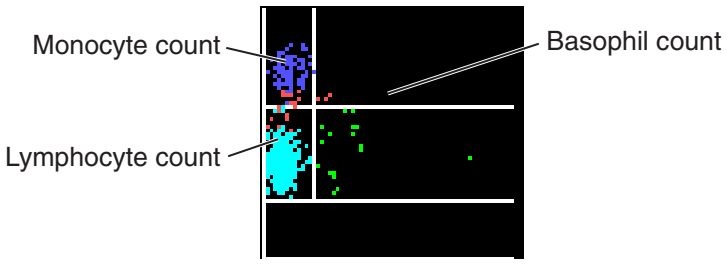


The lymphocyte count is acquired from the lymphocyte area.

The NE-EO scattergram is the neutrophil, eosinophil and ghost 2 area expanded with the granularity as the horizontal axis. The neutrophil count and eosinophil count can be acquired from this scattergram.

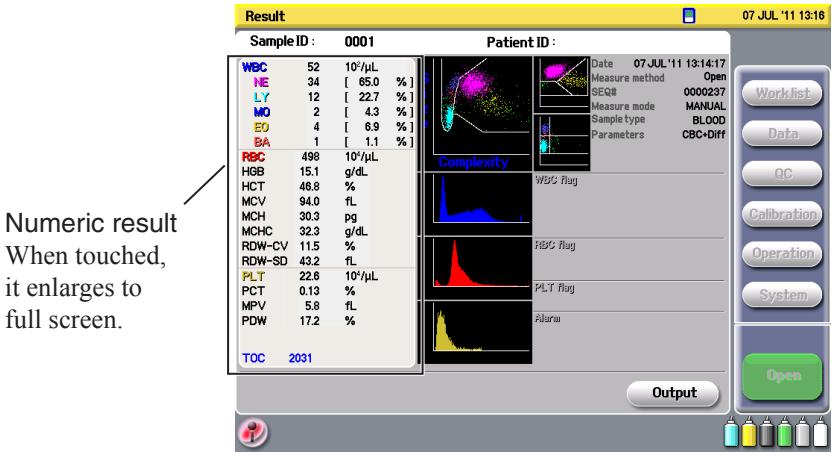


The MO-BA scattergram is the monocyte and basophil area expanded with the granularity as the horizontal axis. The monocyte count and basophil count can be acquired from this scattergram.



Histograms

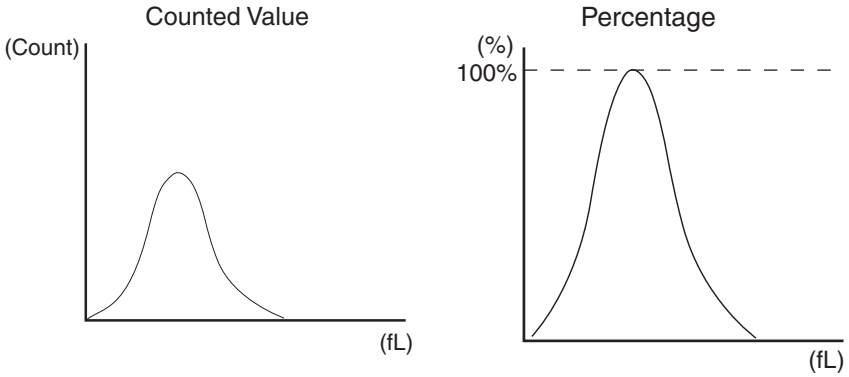
On the Result screen, you can view three histograms. You can examine the histograms when anisocytosis occurs or hemolyzation is poor.



Vertical Axis Type for the Histogram

Counted value (COUNTED): The vertical axis on the graph represents numerical count values.

Percentage (%): The vertical axis on the graph is fixed at 100% full scale regardless of the total counted value. Therefore, the trend of particle volume distribution can be easily judged even though the total counted value is not shown.



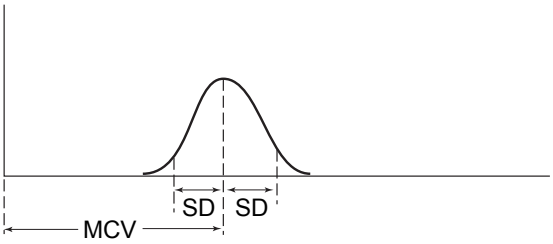
The horizontal axis represents the blood cell volume.
(fL = 1×10^{-15} L)

RBC (Red Blood Cell) Distribution Histogram

RDW (red blood cell distribution width) is automatically calculated from the RBC distribution histogram.

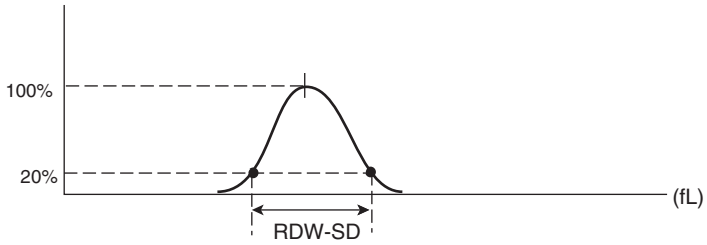
The RDW indicates the deviation ratio of the red blood cell volumes on the histogram.

$$\text{RDW-CV (\%)} = \frac{\text{Standard deviation of red blood cell volumes (SD)}}{\text{Mean cell volume (MCV)}}$$



RDW-SD (fL)

The RDW-SD is the distribution width of the 20% frequency level when the peak of the RBC particle size distribution width is 100%.



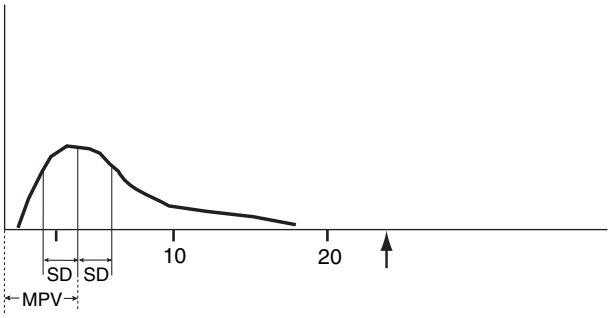
PLT (Platelet) Distribution Histogram

The following parameters are automatically calculated from the PLT distribution histogram.

- Platelet Crit (PCT)
  The PCT indicates the ratio of the platelet total volume on the histogram to the aspirated whole blood volume.

- Mean Platelet Volume (MPV)
  The MPV indicates the mean of the platelets volume on the histogram.

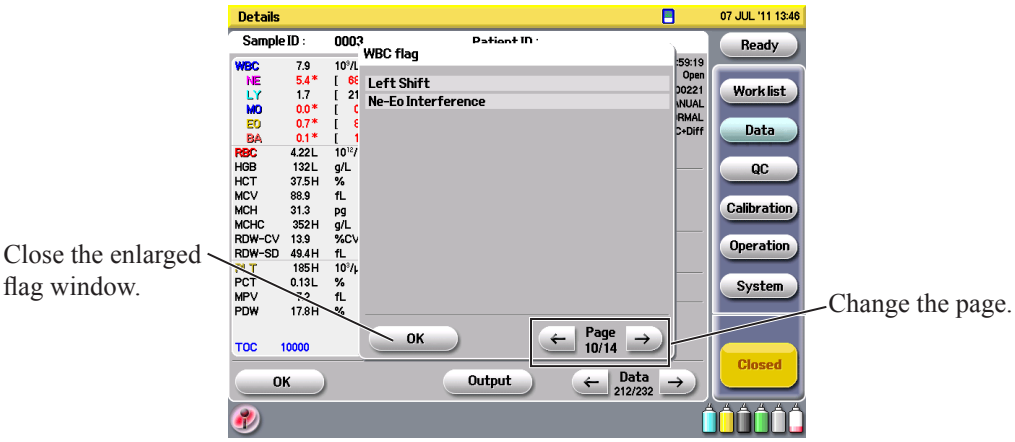
- Platelet Distribution Width (PDW)
  The PDW indicates the deviation ratio of the platelet volumes on the histogram.



Flags

Flags are displayed when the measurement result is above or below the threshold for each item. The following list is the factory default settings. You can change the threshold on the Flags screen of the Settings screen. Refer to “Flag Settings” in Section 5.

You can enlarge flags by pressing the flag on the Result screen.



Flag	Appears when
WBC	
• Leukocytosis	WBC is above 18 × 10^3/µL
• Leukopenia	WBC is below 2.5 × 10^3/µL
• Neutrophilia	NE is above 11 × 10^3/µL
• Neutropenia	NE is below 1.0 × 10^3/µL
• Lymphocytosis	LY is above 4.0 × 10^3/µL
• Lymphopenia	LY is below 0.8 × 10^3/µL
• Monocytosis	MO is above 1.0 × 10^3/µL
• Eosinophilia	EO is above 0.7 × 10^3/µL
• Basophilia	BA is above 0.2 × 10^3/µL
• Blasts	Presence of blasts is suspected
• Immature Gr	Presence of immature granulocytes is suspected
• Left Shift	Left shifted cells
• Atypical Ly	Presence of atypical lymphocytes is suspected
• Small Nucleated Cell	Presence of small nucleated cells is suspected
• Ly-Mo Interference	Overlap of population of lymphocytes and monocytes is suspected
• Ne-Eo Interference	Overlap of population of neutrophils and eosinophils is suspected

RBC

- Erythrocytosis RBC is above $6.5 \times 10^6/\mu L$
- Anemia HGB is below 10.0 g/dL
- Anisocytosis RDW-CV is above 20.0%
- Microcytosis MCV is below 70 fL
- Macrocytosis MCV is above 110 fL
- Hypochromia MCHC is below 29.0 g/dL
- Abnormal MCHC MCHC is below 28.0 g/dL or above 38.0 g/dL

PLT

- Thrombocytosis PLT is above $600 \times 10^3/\mu L$
- Thrombocytopenia PLT is below $60 \times 10^3/\mu L$
- PLT Clumps Presence of PLT clumps is suspected
- PLT-RBC Interference Overlap of population of PLT and RBC is suspected
- If "C" appears on the right side of the WBC or PLT data, the PLT may be coagulated.

If "*" appears on the right side of the measurement value, the measurement result might not be reliable. Check the sample with the manual differential counts.

Section 4 Performance Characteristics and Specifications

Specifications

Measured Parameters, Ranges and Reproducibility to Specimen

Specifications except WBC population were determined using hematology control blood (MEK-5DN), counted 10 times consecutively.

Measured Parameters	Measuring Range	Reproducibility to Specimen (CV: Coefficient of Variation)
WBC: White blood cell count	0 to 299 × 10^3/µL	within 2.0%CV
NE%: Neutrophil percent	0 to 99.9%	within 5.0%CV
LY%: Lymphocyte percent	0 to 99.9%	within 5.0%CV
MO%: Monocyte percent	0 to 99.9%	within 12.0%CV
EO%: Eosinophil percent	0 to 99.9%	within 20.0%CV
BA%: Basophil percent	0 to 99.9%	within CV30.0% (>2%) or average value ±1% (0 to 2%)
NE: Neutrophil count	0 to 299 × 10^3/µL	—
LY: Lymphocyte count	0 to 299 × 10^3/µL	
MO: Monocyte count	0 to 299 × 10^3/µL	
EO: Eosinophil count	0 to 299 × 10^3/µL	
BA: Basophil count	0 to 299 × 10^3/µL	
RBC: Red blood cell count	0 to 14.9 × 10^6/µL	within 1.5%CV
HGB: Hemoglobin concentration	0 to 29.9 g/dL	within 1.5%CV
HCT: Hematocrit	0 to 99.9%	—
MCV: Mean cell volume	20 to 199 fL	within 1.0%CV
MCH: Mean cell hemoglobin	10 to 50 pg	—
MCHC: Mean cell hemoglobin concentration	10 to 50 g/dL	
RDW-CV: Red blood cell distribution width	0 to 50%	
PLT: Platelet count	0 to 1490 × 10^3/µL	within 4.0%CV
PCT: Platelet crit	0 to 2.9%	—
MPV: Mean platelet volume	0 to 20.0 fL	
PDW: Platelet distribution width	0 to 50%	

Detection Method

Blood cell count: Electrical resistance detection
Hemoglobin: Surfactant method (colorimetric method)
Hematocrit: Histogram calculation
WBC population: Light scatter by laser
Platelet crit: Histogram calculation
RBC distribution width: Histogram calculation
Platelet distribution width: Histogram calculation

Standardization Analysis Method

WBC: ICSH1988 ICSH: The assignment of values to fresh blood used for calibrating automated blood cell counters. Clin Lab Haematol, 10:203-212, 1988

RBC: ICSH1988 ICSH: The assignment of values to fresh blood used for calibrating automated blood cell counters. Clin Lab Haematol, 10:203-212, 1988

HGB: NCCLS H15-A2 H15-A2: Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood Second Edition; Approved Standard (1994)

HCT: NCCLS H7-A2 H7-A2: Procedure for Determining Packed Cell Volume by the Microhematocrit Method Second Edition; Approved Standard (1993)

PLT: Brecher & Cronkite Method: Morphology and enumeration of human blood platelets, J Appl Physiol 3 365 (Dec) 1950; Brecher G, Cronkite EP

Dilution Ratio

- Venous blood

  Sample volume: 55 µL (for 23 parameters)/30 µL (for WBC, RBC, HGB, HCT, MCV, MCH, MCHC, and PLT)

  WBC/HGB: 200:1

  RBC/PLT: 40,000:1

- Pre-dilution blood

Sample volume:	10 µL	20 µL
WBC/HGB:	1200:1	600:1
RBC/PLT:	240,000:1	120,000:1

Counting Time

Open mode: 63 s/sample (from measurement start to data display)

Closed mode: 75 s/sample (from measurement start to data display)

Display

Display: 10.4 inch, LCD with backlight and touch screen keys

Resolution: 800 × 600 dots

Screen size: approx. 211.2 × 158.4 mm

Display contents: Numerical data, scattergrams, histograms, measuring conditions, alarm message and other messages, touch screen keys

Data Storage

Numerical data for all counted parameters for up to 400 samples and histograms and scattergrams for up to 50 samples

Environmental Conditions

Storage temperature: –20 to +60ºC (–4 to +140°F)

Operating temperature: 15 to 30ºC (59 to 86°F)

Storage humidity: 10 to 95%

Operating humidity: 30 to 85% (noncondensing)

Storage atmospheric pressure: 70 to 106 kPa

Operating atmospheric pressure: 70 to 106 kPa

Operating altitude: less than 3000 m

Power Requirements

Power requirements: 110 to 240 V ± 10% AC, 50/60 Hz
Power consumption: 250 VA

Dimensions and Weight

Dimensions: 382 W × 465 D × 532 H (mm)
Net weight: approx. 35 kg

Electromagnetic Compatibility

IEC 61326-1: 2005
IEC 61326-2-6: 2005
EN 61326-1: 2006
EN 61326-2-6: 2006

CISPR11: Edition 4: 2003, Group 1, Class B
EN 55011: 2007, Group 1, Class B

The power supply short interruption test is performed through a transformer which has at least three times the power capacity of the instrument.

Safety

Safety standards: IEC 61010-1 2nd Edition: 2001
EN 61010-1 2nd Edition: 2001
IEC 61010-2-081: 2001
IEC 61010-2-101: 2002
EN 61010-2-101: 2002

Laser: IEC 60825-1: 2007
EN 60825-1: 2007

Type of protection against electrical shock: CLASS I EQUIPMENT
Degree of protection against harmful ingress of water: IPX0 (non-protected)
Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE: EQUIPMENT not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE
Mode of operation: CONTINUOUS OPERATION
EQUIPMENT types (classification): Indoor stationary EQUIPMENT
Pollution Degree: 2 EQUIPMENT

Requirements for marking of IN VITRO DIAGNOSTIC instruments: EN1658: 1996

Bar Code Specifications

Bar Code Format

The following formats with or without check digits are acceptable:

- Industrial 2 of 5
- ITF
- JAN/EAN/UPC
- NW-7
- CODE 39
- CODE 93
- CODE 128

Bar Code Label Specifications

Refer to Appendix B for complete information on bar code label formats, check digits and specifications.

Transfer Format PC (V03-01)

Transfer Example to a PC

Common data block "_" in the Transferred Data in Characters column indicates a blank (0x20)

Transfer Items	Example	No. of Byte	Transferred Data in Characters	Transferred Data in Hexadecimal
<Start> Common data block				
Start of Text	0x02	1	STX	02
Hematology analyzer information				
Type	"MEK-7222"	11	M E K - 7 2 2 CR	4D 45 4B 2D 37 32 32 32 20 20 0D
Parameter no	"22"	6	2 2 CR	20 20 20 32 32 0D
Send data bytes	"01024"	6	0 1 0 2 4 CR	30 31 30 32 34 0D
Sampling mode	"MANUAL"	13	M A N U A L CR	4D 41 4E 55 41 4C 20 20 20 20 20 20 0D
Parameter	"CBC + Diff"	13	C B C + D i f f CR	43 42 43 20 2B 20 44 69 66 66 20 20 0D
Sample code	"01"	3	0 1 CR	30 31 0D
Sample label	"BLOOD"	17	B L O O D CR	42 4C 4F 4F 44 20 20 20 20 20 20 20 20 20 20 20 0D
Rack location	"MMM"	5	M M M CR	4D 4D 4D 20 0D
Seq#	"0000001"	11	0 0 0 0 0 0 1 CR	30 30 30 30 30 30 31 20 20 20 0D
Software version	"V01-01"	9	V 0 1 - 0 1 CR	56 30 31 2D 30 31 20 20 0D
Analysis program version	"V04-02"	9	V 0 4 - 0 2 CR	56 30 34 2D 30 32 20 20 0D
Format version	"V03-01"	9	V 0 3 - 0 1 CR	56 30 33 2D 30 31 20 20 0D
Total data bytes	"01536"	6	0 1 5 3 6 CR	30 32 35 33 36 0D
Data block pattern	"1"	6	1 CR	31 20 20 20 20 0D
Reserve data		4	SP × 3 Byte + CR × 1 Byte	20 × 3 Byte + 0D × 1 Byte
Measurement data				
Date	"20050101"	17	2 0 0 5 CR 0 1 CR 0 1 CR	32 30 30 35 0D 30 31 0D 30 31 0D 20 20 20 20 20 0D
Time	"153000"	9	1 5 CR 3 0 CR 0 0 CR	31 35 0D 33 30 0D 30 30 0D
ID	"ABCDEFGH:0001"	16	A B C D E F G H : 0 0 0 1 CR	41 42 43 44 45 46 47 48 3A 30 30 30 31 20 20 0D
WBC	"6.2"	7	6 . 2 CR	20 36 2E 32 20 20 0D
NE%	"70.6"	7	7 0 . 6 CR	37 30 2E 36 20 20 0D
LY%	"21.2"	7	2 1 . 2 CR	32 31 2E 32 20 20 0D
MO%	"2.5"	7	2 . 5 CR	20 32 2E 35 20 20 0D
EO%	"5.4H"	7	5 . 4 H CR	20 35 2E 34 48 20 0D
BA%	"0.3"	7	0 . 3 CR	20 30 2E 33 20 20 0D
NE	"4.4"	7	4 . 4 CR	20 34 2E 34 20 20 0D
LY	"1.3"	7	1 . 3 CR	20 31 2E 33 20 20 0D
MO	"0.2"	7	0 . 2 CR	20 30 2E 32 20 20 0D
EO	"0.2"	7	0 . 2 CR	20 30 2E 32 20 20 0D
BA	"0.0"	7	0 . 0 CR	20 30 2E 30 20 20 0D
RBC	"5.10"	7	5 . 1 0 CR	35 2E 31 30 20 20 0D
HGB	"14.4"	7	1 4 . 4 CR	31 34 2E 34 20 20 0D
HCT	"42.3"	7	4 2 . 3 CR	34 32 2E 33 20 20 0D
MCV	"86.2"	7	8 6 . 2 CR	38 36 2E 32 20 20 0D
MCH	"28.5"	7	2 8 . 5 CR	32 38 2E 35 20 20 0D
MCHC	"33.1"	7	3 3 . 1 CR	33 33 2E 31 20 20 0D
RDW-CV	"11.5"	7	1 1 . 5 CR	31 31 2E 35 20 20 0D
PLT	"280"	7	2 8 0 CR	20 32 38 30 20 20 0D
PCT	"0.15"	7	0 . 1 5 CR	30 2E 31 35 20 20 0D
MPV	"7.2"	7	7 . 2 CR	20 37 2E 32 20 20 0D
PDW	"18.5"	7	1 8 . 5 CR	31 38 2E 35 20 20 0D
Reserve data		210	SP × 209 Byte + CR × 1 Byte	20 × 209 Byte + 0D × 1 Byte
Flag data (with flag +, without flag (space))				(ex. 20 0D)
Leukocytosis	"+"	2	+ CR	2B 0D
Leukopenia	"+"	2	+ CR	2B 0D
Neutrophilia	"+"	2	+ CR	2B 0D
Neutropenia	"+"	2	+ CR	2B 0D
Lymphocytosis	"+"	2	+ CR	2B 0D
Lymphopenia	"+"	2	+ CR	2B 0D
Monocytosis	"+"	2	+ CR	2B 0D
Eosinophilia	"+"	2	+ CR	2B 0D
Basophilia	"+"	2	+ CR	2B 0D
Blasts	"+"	2	+ CR	2B 0D
Immature Granulocyte	"+"	2	+ CR	2B 0D
Left Shift	"+"	2	+ CR	2B 0D
Atypical lymphocytes	"+"	2	+ CR	2B 0D
Poor hemolyzation	"+"	2	+ CR	2B 0D
Small nucleated cell	"+"	2	+ CR	2B 0D
Ly-Mo interference	"+"	2	+ CR	2B 0D
Ne-Eo interference	"+"	2	+ CR	2B 0D
Reserve data		14	SP × 13 Byte + CR × 1 Byte	20 × 13 Byte + 0D × 1 Byte
Erythrocytosis	"+"	2	+ CR	2B 0D
Anemia	"+"	2	+ CR	2B 0D
Anisocytosis	"+"	2	+ CR	2B 0D
Microcytosis	"+"	2	+ CR	2B 0D
Macrocytosis	"+"	2	+ CR	2B 0D
Hypochromia	"+"	2	+ CR	2B 0D
Abnormal MCHC	"+"	2	+ CR	2B 0D
Reserve data		10	SP × 9 Byte + CR × 1 Byte	20 × 9 Byte + 0D × 1 Byte
Thrombocytosis	"+"	2	+ CR	2B 0D
Thrombocytopenia	"+"	2	+ CR	2B 0D
PLT Clumps	"+"	2	+ CR	2B 0D
PLT-RBC interference	"+"	2	+ CR	2B 0D
Reserve data		8	SP × 7 Byte + CR × 1 Byte	20 × 7 Byte + 0D × 1 Byte
Reserve data				
Reserve data		400	SP × 399 Byte + CR × 1 Byte	20 × 399 Byte + 0D × 1 Byte
<End> Common data block				
End of Text	0x03	1	ETX	03

Extended data block "_" in the Transferred Data in Characters column indicates a blank (0x20)

Transfer Items	Example	No. of Byte	Transferred Data in Characters	Transferred Data in Hexadecimal
<Start> Extended data block				
Start of Text	0x02	1	STX	02
Hematology analyzer information				
Identifier	"EXP"	4	E X P CR	45 58 50 0D
Send data bytes	"00512"	6	0 0 5 1 2 CR	30 30 35 31 32 0D
Type	"MEK-7222"	11	M E K - 7 2 2 2 CR	4D 45 4B 2D 37 32 32 32 20 20 0D
Unit no	"1"	3	1 CR	20 31 0D
Work list data				
Name	"DAVID"	27	D A V I D ... … CR	44 41 56 49 44 … … 20 20 20 20 … … 0D
Sex	"MALE"	7	M A L E CR	4D 41 4C 45 20 20 0D
Date of birth	"19800219"	11	1 9 8 0 CR 0 2 CR 1 9 CR	31 39 38 30 0D 30 32 0D 31 39 0D
Age	"22"	4	2 2 CR	20 32 32 0D
Department	"INTERNAL"	14	I N T E R N A L CR	49 4E 54 45 52 4E 41 4C 20 20 20 20 20 0D
Physician	"WATSON"	27	W A T S O N ... ... CR	57 57 41 54 53 4F … … 20 20 20 … … 0D
Operator name	""	9	CR	20 20 20 20 20 20 20 20 20 0D
Comments	"No problem."	129	N o p r o b l e m . ... CR	4E 4E 6F 20 70 72 6F 62 6C 65 6D … … 20 20 20 20 20 20 … … 0D
Normal range table no	"0"	2	0 CR	30 0D
Work list flag	"1"	2	1 CR	31 0D
Control mode flag	""	2	CR	20 0D
Reserve data for work list data		32	SP × 31 Byte + CR × 1 Byte	20 × 31 Byte + 0D × 1 Byte
Normal range setting data				
WBC-LOW	"4.0"	5	4 . 0 CR	20 34 2E 30 0D
WBC-HIGH	"9.0"	5	9 . 0 CR	20 39 2E 30 0D
NE%-LOW	"42.0"	5	4 2 . 0 CR	34 32 2E 30 0D
NE%-HIGH	"85.0"	5	8 5 . 0 CR	38 35 2E 30 0D
LY%-LOW	"11.0"	5	1 1 . 0 CR	31 31 2E 30 0D
LY%-HIGH	"49.0"	5	4 9 . 0 CR	34 39 2E 30 0D
MO%-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
MO%-HIGH	"9.0"	5	9 . 0 CR	20 39 2E 30 0D
EO%-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
EO%-HIGH	"3.0"	5	3 . 0 CR	20 33 2E 30 0D
BA%-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
BA%-HIGH	"2.0"	5	2 . 0 CR	20 32 2E 30 0D
NE-LOW	"1.7"	5	1 . 7 CR	20 31 2E 37 0D
NE-HIGH	"7.7"	5	7 . 7 CR	20 37 2E 37 0D
LY-LOW	"0.4"	5	0 . 4 CR	20 30 2E 34 0D
LY-HIGH	"4.4"	5	4 . 4 CR	20 34 2E 34 0D
MO-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
MO-HIGH	"0.8"	5	0 . 8 CR	20 30 2E 38 0D
EO-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
EO-HIGH	"0.3"	5	0 . 3 CR	20 30 2E 33 0D
BA-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
BA-HIGH	"0.2"	5	0 . 2 CR	20 30 2E 32 0D
RBC-LOW	"3.80"	5	3 . 8 0 CR	33 2E 38 30 0D
RBC-HIGH	"5.30"	5	5 . 3 0 CR	35 2E 33 30 0D
HGB-LOW	"11.0"	5	1 1 . 0 CR	31 31 2E 30 0D
HGB-HIGH	"17.0"	5	1 7 . 0 CR	31 37 2E 30 0D
HCT-LOW	"36.0"	5	3 6 . 0 CR	33 36 2E 30 0D
HCT-HIGH	"56.0"	5	5 6 . 0 CR	35 36 2E 30 0D
MCV-LOW	"80.0"	5	8 0 . 0 CR	38 30 2E 30 0D
MCV-HIGH	"100"	5	1 0 0 CR	20 31 30 30 0D
MCH-LOW	"28.0"	5	2 8 . 0 CR	32 38 2E 30 0D
MCH-HIGH	"36.0"	5	3 6 . 0 CR	33 36 2E 30 0D
MCHC-LOW	"31.0"	5	3 1 . 0 CR	33 31 2E 30 0D
MCHC-HIGH	"37.0"	5	3 7 . 0 CR	33 37 2E 30 0D
RDW-LOW	"11.5"	5	1 1 . 5 CR	31 31 2E 35 0D
RDW-HIGH	"16.5"	5	1 6 . 5 CR	31 36 2E 35 0D
PLT-LOW	"120"	5	1 2 0 CR	20 31 32 30 0D
PLT-HIGH	"380"	5	3 8 0 CR	20 33 38 30 0D
PCT-LOW	"0.10"	5	0 . 1 0 CR	30 2E 31 30 0D
PCT-HIGH	"1.00"	5	1 . 0 0 CR	31 2E 30 30 0D
MPV-LOW	"5.0"	5	5 . 0 CR	20 35 2E 30 0D
MPV-HIGH	"10.0"	5	1 0 . 0 CR	31 30 2E 30 0D
PDW-LOW	"12.0"	5	1 2 . 0 CR	31 32 2E 30 0D
PDW-HIGH	"18.0"	5	1 8 . 0 CR	31 38 2E 30 0D
<End> Extended data block				
End of Text	0x03	1	ETX	03

- "0x0D" is at the end of each item as separating character.
- Each item is entered by ASCII code. Only "Start of Text" and " End of Text" are entered by control code.
- Each item is initialized at space (0x20). Unused items are also initialized at space and have "0x0D" in the end.

Transfer Format PC (V05-01)

Transfer Example to a PC

Common data block "_" in the Transferred Data in Characters column indicates a blank (0x20)

Transfer Items	Example	No. of Byte	Transferred Data in Characters	Transferred Data in Hexadecimal
<Start> Common data block				
Start of Text	0x02	1	STX	02
Hematology analyzer information				
Type	"MEK-7300"	11	M E K - 7 3 0 0 CR	4D 45 4B 2D 37 33 30 30 20 20 0D
Parameter no	"23"	6	2 3 CR	20 20 20 32 32 0D
Send data bytes	"01024"	6	0 1 0 2 4 CR	30 31 30 32 34 0D
Sampling mode	"MANUAL"	13	M A N U A L CR	4D 41 4E 55 41 4C 20 20 20 20 20 20 0D
Parameter	"CBC + Diff"	13	C B C + D i f f CR	43 42 43 20 2B 20 44 69 66 66 20 20 0D
Sample code	"01"	3	0 1 CR	30 31 0D
Sample label	"BLOOD"	17	B L O O D CR	42 4C 4F 4F 44 20 20 20 20 20 20 20 20 20 20 20 0D
Rack location	"MMM"	5	M M M CR	4D 4D 4D 20 0D
Seq#	"0000001"	11	0 0 0 0 0 0 1 CR	30 30 30 30 30 30 31 20 20 20 0D
Software version	"V01-01"	9	V 0 1 - 0 1 CR	56 30 31 2D 30 31 20 20 0D
Analysis program version	"V04-02"	9	V 0 4 - 0 2 CR	56 30 34 2D 30 32 20 20 0D
Format version	"V05-01"	9	V 0 5 - 0 1 CR	56 30 35 2D 30 31 20 20 0D
Total data bytes	"02048"	6	0 2 0 4 8 CR	30 32 30 34 38 0D
Data block pattern	"2"	6	2 CR	32 20 20 20 20 0D
Reserve data		4	× 3 Byte + CR	20 × 3 Byte + 0D × 1 Byte
Measurement data				
Date	"20050101"	17	2 0 0 5 CR 0 1 CR 0 1 CR	32 30 30 35 0D 30 31 0D 30 31 0D 20 20 20 20 20 0D
Time	"153000"	9	1 5 CR 3 0 CR 0 0 CR	31 35 0D 33 30 0D 30 30 0D
ID	"ABCDEFGH:0001"	16	A B C D E F G H : 0 0 0 1 CR	41 42 43 44 45 46 47 48 3A 30 30 30 31 20 20 0D
WBC	"6.2"	7	6 . 2 CR	20 36 2E 32 20 20 0D
NE%	"70.6"	7	7 0 . 6 CR	37 30 2E 36 20 20 0D
LY%	"21.2"	7	2 1 . 2 CR	32 31 2E 32 20 20 0D
MO%	"2.5"	7	2 . 5 CR	20 32 2E 35 20 20 0D
EO%	"5.4H"	7	5 . 4 H CR	20 35 2E 34 48 20 0D
BA%	"0.3"	7	0 . 3 CR	20 30 2E 33 20 20 0D
NE	"4.4"	7	4 . 4 CR	20 34 2E 34 20 20 0D
LY	"1.3"	7	1 . 3 CR	20 31 2E 33 20 20 0D
MO	"0.2"	7	0 . 2 CR	20 30 2E 32 20 20 0D
EO	"0.2"	7	0 . 2 CR	20 30 2E 32 20 20 0D
BA	"0.0"	7	0 . 0 CR	20 30 2E 30 20 20 0D
RBC	"5.10"	7	5 . 1 0 CR	35 2E 31 30 20 20 0D
HGB	"14.4"	7	1 4 . 4 CR	31 34 2E 34 20 20 0D
HCT	"42.3"	7	4 2 . 3 CR	34 32 2E 33 20 20 0D
MCV	"86.2"	7	8 6 . 2 CR	38 36 2E 32 20 20 0D
MCH	"28.5"	7	2 8 . 5 CR	32 38 2E 35 20 20 0D
MCHC	"33.1"	7	3 3 . 1 CR	33 33 2E 31 20 20 0D
RDW-CV	"11.5"	7	1 1 . 5 CR	31 31 2E 35 20 20 0D
PLT	"280"	7	2 8 0 CR	20 32 38 30 20 20 0D
PCT	"0.15"	7	0 . 1 5 CR	30 2E 31 35 20 20 0D
MPV	"7.2"	7	7 . 2 CR	20 37 2E 32 20 20 0D
PDW	"18.5"	7	1 8 . 5 CR	31 38 2E 35 20 20 0D
Reserve data		210	SP × 209 Byte + CR	20 × 209 Byte + 0D × 1 Byte
Flag data (with flag +, without flag (space))				(ex. 20 0D)
Leukocytosis	"+"	2	+ CR	2B 0D
Leukopenia	"+"	2	+ CR	2B 0D
Neutrophilia	"+"	2	+ CR	2B 0D
Neutropenia	"+"	2	+ CR	2B 0D
Lymphocytosis	"+"	2	+ CR	2B 0D
Lymphopenia	"+"	2	+ CR	2B 0D
Monocytosis	"+"	2	+ CR	2B 0D
Eosinophilia	"+"	2	+ CR	2B 0D
Basophilia	"+"	2	+ CR	2B 0D
Blasts	"+"	2	+ CR	2B 0D
Immature Granulocyte	"+"	2	+ CR	2B 0D
Left Shift	"+"	2	+ CR	2B 0D
Atypical lymphocytes	"+"	2	+ CR	2B 0D
Poor hemolyzation	"+"	2	+ CR	2B 0D
Small nucleated cell	"+"	2	+ CR	2B 0D
Ly-Mo interference	"+"	2	+ CR	2B 0D
Ne-Eo interference	"+"	2	+ CR	2B 0D
Reserve data		14	SP × 13 Byte + CR	20 × 13 Byte + 0D × 1 Byte
Erythrocytosis	"+"	2	+ CR	2B 0D
Anemia	"+"	2	+ CR	2B 0D
Anisocytosis	"+"	2	+ CR	2B 0D
Microcytosis	"+"	2	+ CR	2B 0D
Macrocytosis	"+"	2	+ CR	2B 0D
Hypochromia	"+"	2	+ CR	2B 0D
Abnormal MCHC	"+"	2	+ CR	2B 0D
Reserve data		10	SP × 9 Byte + CR	20 × 9 Byte + 0D × 1 Byte
Thrombocytosis	"+"	2	+ CR	2B 0D
Thrombocytopenia	"+"	2	+ CR	2B 0D
PLT Clumps	"+"	2	+ CR	2B 0D
PLT-RBC interference	"+"	2	+ CR	2B 0D
Reserve data		8	SP × 7 Byte + CR	20 × 7 Byte + 0D × 1 Byte
Reserve data				
Reserve data		400	SP × 399 Byte + CR	20 × 399 Byte + 0D × 1 Byte
<End> Common data block				
End of Text	0x03	1	ETX	03

Extended data block "_" in the Transferred Data in Characters column indicates a blank (0x20)

Transfer Items	Example	No. of Byte	Transferred Data in Characters	Transferred Data in Hexadecimal
<Start> Extended data block				
Start of Text	0x02	1	STX	02
Hematology analyzer information				
Identifier	"EXI"	4	E X I CR	45 58 50 0D
Send data bytes	"00512"	6	0 0 5 1 2 CR	30 30 35 31 32 0D
Type	"MEK-7300"	11	M E K - 7 3 0 0 CR	4D 45 4B 2D 37 32 32 32 20 20 0D
Unit no	"0"	3	0 CR	20 31 0D
Work list data				
Name	"DAVID"	27	D A V I D ... … CR	44 41 56 49 44 … … 20 20 20 20 … … 0D
Sex	"MALE"	7	M A L E CR	4D 41 4C 45 20 20 0D
Date of birth	"19800219"	11	1 9 8 0 CR 0 2 CR 1 9 CR	31 39 38 30 0D 30 32 0D 31 39 0D
Age	"22"	4	2 2 CR	20 32 32 0D
Department	"INTERNAL"	14	I N T E R N A L CR	49 4E 54 45 52 4E 41 4C 20 20 20 20 20 0D
Physician	"WATSON"	27	W A T S O N ... ... CR	57 57 41 54 53 4F … … 20 20 20 … … 0D
Operator name	""	9	CR	20 20 20 20 20 20 20 20 20 0D
Comments	"No problem."	129	N o p r o b l e m . ... CR	4E 4E 6F 20 70 72 6F 62 6C 65 6D … … 20 20 20 20 20 20 … … 0D
Normal range table no	"0"	2	0 CR	30 0D
Work list flag	"1"	2	1 CR	31 0D
Control mode flag	""	2	CR	20 0D
Reserve data for work list data		32	SP × 31 Byte + CR × 1 Byte	20 × 31 Byte + 0D × 1 Byte
Normal range setting data				
WBC-LOW	"4.0"	5	4 . 0 CR	20 34 2E 30 0D
WBC-HIGH	"9.0"	5	9 . 0 CR	20 39 2E 30 0D
NE%-LOW	"42.0"	5	4 2 . 0 CR	34 32 2E 30 0D
NE%-HIGH	"85.0"	5	8 5 . 0 CR	38 35 2E 30 0D
LY%-LOW	"11.0"	5	1 1 . 0 CR	31 31 2E 30 0D
LY%-HIGH	"49.0"	5	4 9 . 0 CR	34 39 2E 30 0D
MO%-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
MO%-HIGH	"9.0"	5	9 . 0 CR	20 39 2E 30 0D
EO%-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
EO%-HIGH	"3.0"	5	3 . 0 CR	20 33 2E 30 0D
BA%-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
BA%-HIGH	"2.0"	5	2 . 0 CR	20 32 2E 30 0D
NE-LOW	"1.7"	5	1 . 7 CR	20 31 2E 37 0D
NE-HIGH	"7.7"	5	7 . 7 CR	20 37 2E 37 0D
LY-LOW	"0.4"	5	0 . 4 CR	20 30 2E 34 0D
LY-HIGH	"4.4"	5	4 . 4 CR	20 34 2E 34 0D
MO-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
MO-HIGH	"0.8"	5	0 . 8 CR	20 30 2E 38 0D
EO-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
EO-HIGH	"0.3"	5	0 . 3 CR	20 30 2E 33 0D
BA-LOW	"0.0"	5	0 . 0 CR	20 30 2E 30 0D
BA-HIGH	"0.2"	5	0 . 2 CR	20 30 2E 32 0D
RBC-LOW	"3.80"	5	3 . 8 0 CR	33 2E 38 30 0D
RBC-HIGH	"5.30"	5	5 . 3 0 CR	35 2E 33 30 0D
HGB-LOW	"11.0"	5	1 1 . 0 CR	31 31 2E 30 0D
HGB-HIGH	"17.0"	5	1 7 . 0 CR	31 37 2E 30 0D
HCT-LOW	"36.0"	5	3 6 . 0 CR	33 36 2E 30 0D
HCT-HIGH	"56.0"	5	5 6 . 0 CR	35 36 2E 30 0D
MCV-LOW	"80.0"	5	8 0 . 0 CR	38 30 2E 30 0D
MCV-HIGH	"100"	5	1 0 0 CR	20 31 30 30 0D
MCH-LOW	"28.0"	5	2 8 . 0 CR	32 38 2E 30 0D
MCH-HIGH	"36.0"	5	3 6 . 0 CR	33 36 2E 30 0D
MCHC-LOW	"31.0"	5	3 1 . 0 CR	33 31 2E 30 0D
MCHC-HIGH	"37.0"	5	3 7 . 0 CR	33 37 2E 30 0D
RDW-CV-LOW	"11.5"	5	1 1 . 5 CR	31 31 2E 35 0D
RDW-CV-HIGH	"16.5"	5	1 6 . 5 CR	31 36 2E 35 0D
PLT-LOW	"120"	5	1 2 0 CR	20 31 32 30 0D
PLT-HIGH	"380"	5	3 8 0 CR	20 33 38 30 0D
PCT-LOW	"0.10"	5	0 . 1 0 CR	30 2E 31 30 0D
PCT-HIGH	"1.00"	5	1 . 0 0 CR	31 2E 30 30 0D
MPV-LOW	"5.0"	5	5 . 0 CR	20 35 2E 30 0D
MPV-HIGH	"10.0"	5	1 0 . 0 CR	31 30 2E 30 0D
PDW-LOW	"12.0"	5	1 2 . 0 CR	31 32 2E 30 0D
PDW-HIGH	"18.0"	5	1 8 . 0 CR	31 38 2E 30 0D
<End> Extended data block				
End of Text	0x03	1	ETX	03

Extended data block 2

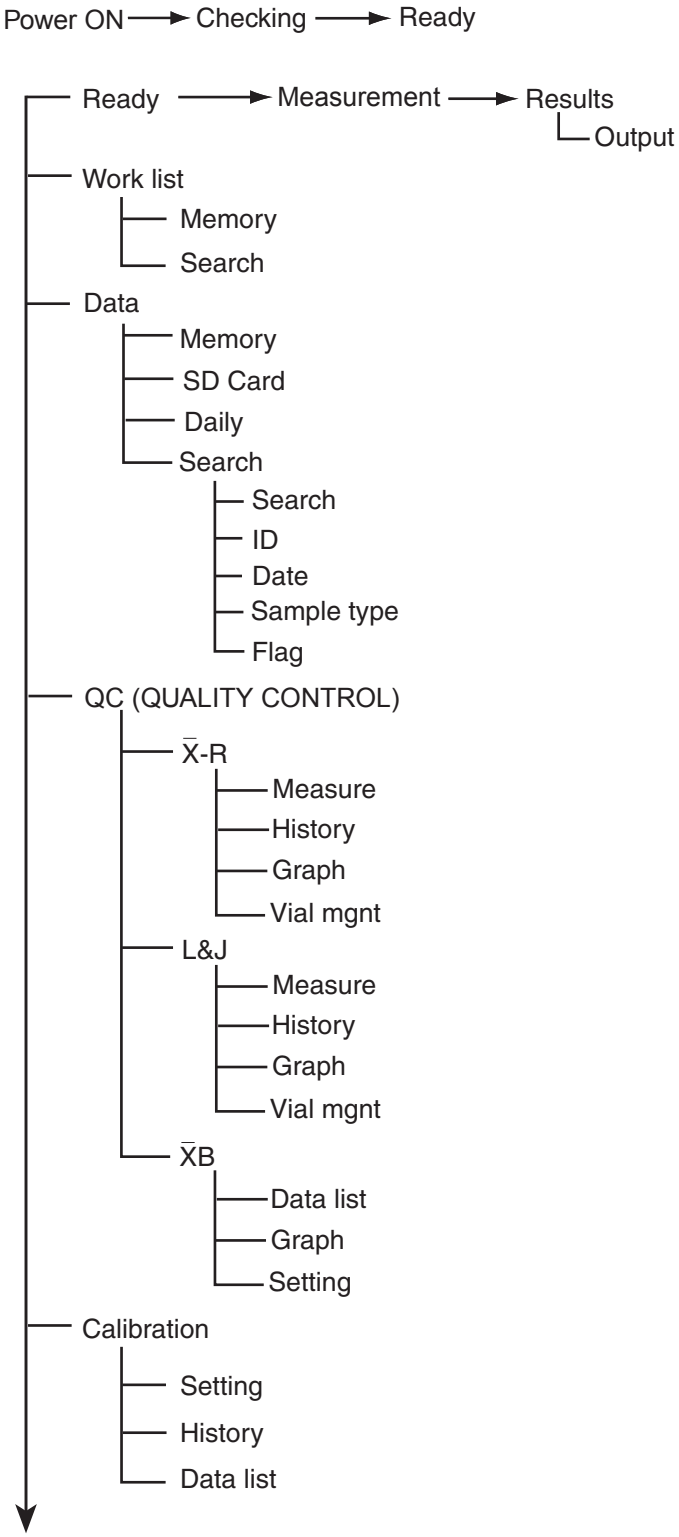
Transfer Items	Example	No. of Byte	Transferred Data in Characters	Transferred Data in Hexadecimal
MEK-7300 extended data				
<Start> Extended data block				
Start of Text	0x02	1	STX	02
Hematology analyzer information				
Identifier	“EX2”	4	E X 2 CR	45 58 32 0D
Send data bytes	“00512”	6	0 0 5 1 2 CR	30 30 35 31 32 0D
Type	“MEK-7300”	11	M E K - 7 3 0 0 CR	4D 45 4B 2D 37 33 30 30 20 20 0D
Serial no	“1234567”	8	1 2 3 4 5 6 7 CR	31 32 33 34 35 36 37 0D
Reserve data		49	× 48 Byte + CR × 1 Byte	20 × 48 Byte + 0D × 1 Byte
Measurement data				
Patient id	“12345”	17	1 2 3 4 5 CR	31 32 33 34 35 20 20 20 20 20 20 20 20 20 20 20 0D
Reserve data		48	× 47 Byte + CR × 1 Byte	20 × 47 Byte + 0D × 1 Byte
RDW-SD	40.3	7	4 0 . 3 CR	34 30 2E 33 20 20 0D
IG	0.2	7	0 . 2 CR	20 30 2E 32 20 20 0D
IG%	1.3	7	1 . 3 CR	20 31 2E 33 20 20 0D
Reserve data		56	× 55 Byte + CR × 1 Byte	20 × 55 Byte + 0D × 1 Byte
Normal range data				
RDW-SD-LOW	“39.0”	5	3 9 . 0 CR	33 39 2E 30 0D
RDW-SD-HIGH	“46.0”	5	4 6 . 0 CR	34 36 2E 30 0D
Reserve data 1	“”	5	CR	20 20 20 20 0D
Reserve data 2	“”	5	CR	20 20 20 20 0D
Reserve data 3	“”	5	CR	20 20 20 20 0D
Reserve data 4	“”	5	CR	20 20 20 20 0D
Reserve data		80	× 79 Byte + CR × 1 Byte	20 × 79 Byte + 0D × 1 Byte
Unit data				
WBC	“×10^2/uL”	12	× 1 0 ^ 2 / u L CR	78 31 30 5E 32 2F 75 4C 20 20 20 0D
RBC	“×10^4/uL”	12	× 1 0 ^ 4 / u L CR	78 31 30 5E 34 2F 75 4C 20 20 20 0D
HGB	“g/dL”	12	g / d L CR	67 2F 64 4C 20 20 20 20 20 20 20 0D
HCT	“L/L”	12	L / L CR	4C 2F 4C 20 20 20 20 20 20 20 20 0D
PLT	“×10^4/uL”	12	× 1 0 ^ 4 / u L CR	78 31 30 5E 34 2F 75 4C 20 20 20 0D
RDW-CV	“%CV”	12	% C V CR	25 43 56 20 20 20 20 20 20 20 20 0D
PDW	“%”	12	% CR	25 20 20 20 20 20 20 20 20 20 20 0D
Reserve data		96	× 95 Byte + CR × 1 Byte	20 × 95 Byte + 0D × 1 Byte
<End> Extended data block				
End of Text	0x03	1	ETX	03
		Total 512		

- “0x0D” is at the end of each item as separating character.
- Each item is entered by ASCII code. Only “Start of Text” and “ End of Text” are entered by control code.
- Each item is initialized at space (0x20). Unused items are also initialized at space and have “0x0D” in the end.
- For the communication, consult your Nihon Kohden representative.

Section 5 Operating Instructions

Screen Configuration

Flowchart of Screens

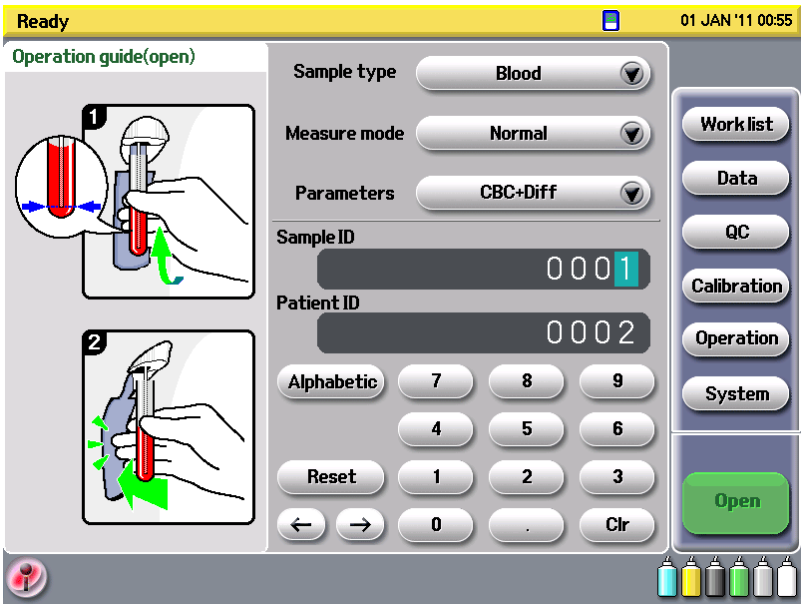


- Operations
  - Refill all
  - Replace dil
  - Replace lys.
  - Replace det
  - Strong clean
  - Clean flowcell
  - Clean baths
  - Remove clog
  - Drain all
  - Drain baths
  - Circuit Check
  - Background
- System
  - Users
  - User Maint.
  - Error log
  - Adj. Flowcell
  - Settings
    - Sample type
    - Normal range
    - Units
    - Operation
    - Flags
    - QC Settings
    - Reagent mgmt
    - Auto Clean
    - Date & time
    - Output
    - Formatting SD card
    - Sound/LCD
    - Initialize
  - Service (This screen is for service personnel when performing maintenance.)

Ready Screen

The Ready screen is displayed when the analyzer is powered on and after cleaning and priming.

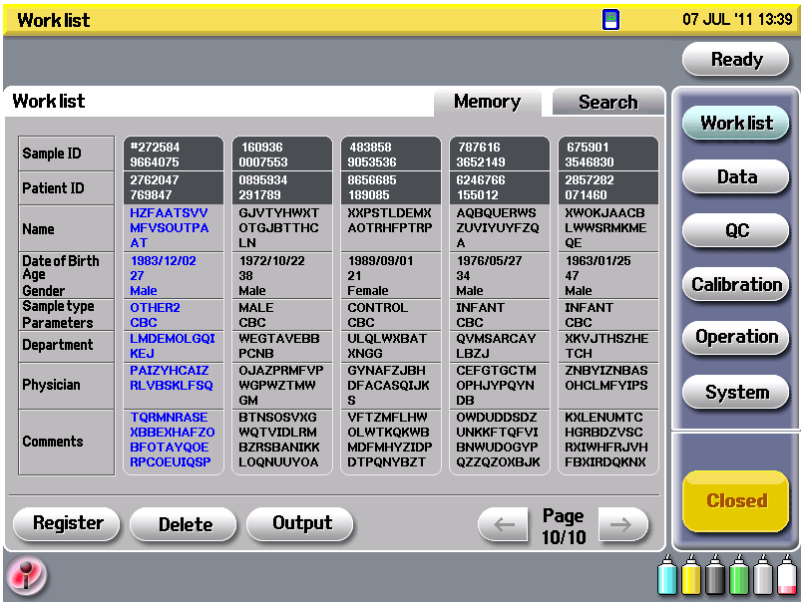
On the Ready screen, you can immediately start measurement after checking measuring accuracy and setting various necessary settings. You can set the sample ID and select open mode or closed mode.



Work List Screen

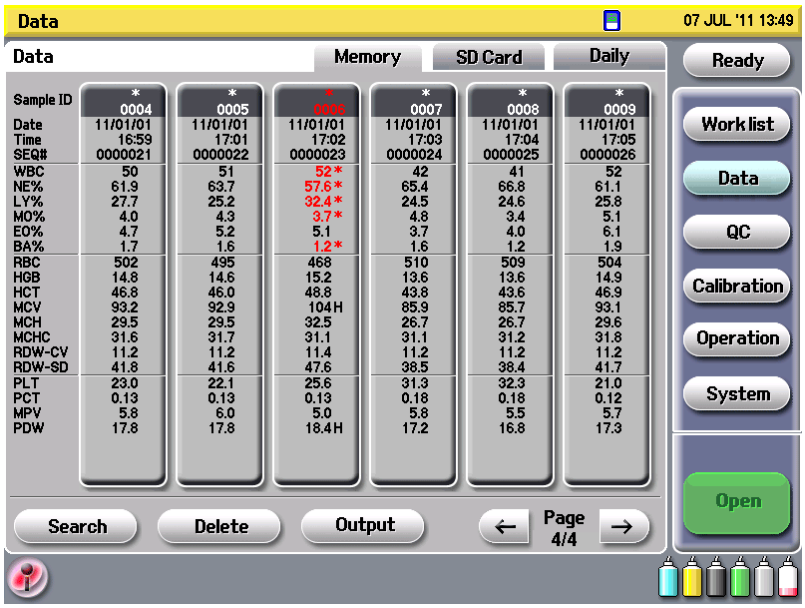
On this screen, you can manage work lists or start measurement from a work list.

By registering work list, the analyzer can set measurement parameters for each sample or attach patient information to the measurement data. Up to 50 work lists can be registered. Refer to “Using Work Lists” in this section.

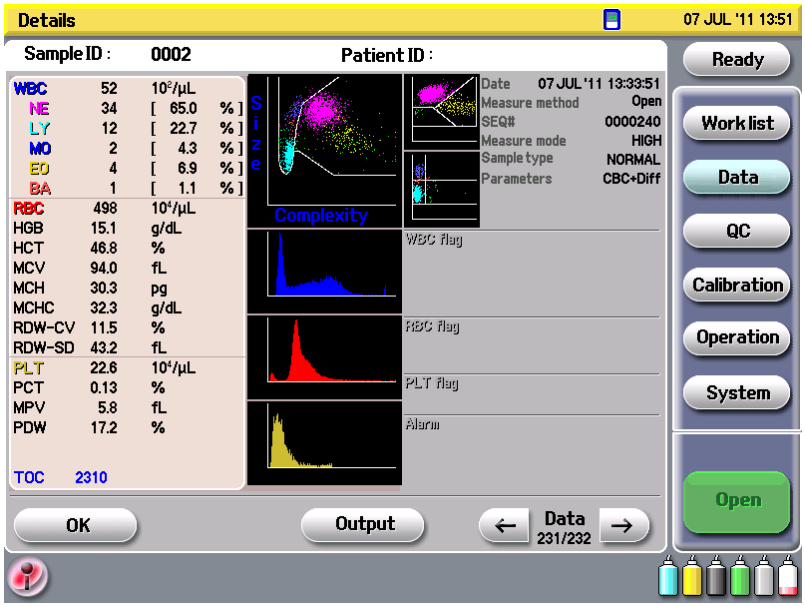


Data Screen

On the Data screen, you can display measured results. Histograms of a measured sample can be displayed by pressing the desired data and pressing the Detail key. You can delete, print or transfer data to a personal computer. Refer to “Handling Data” in this section.



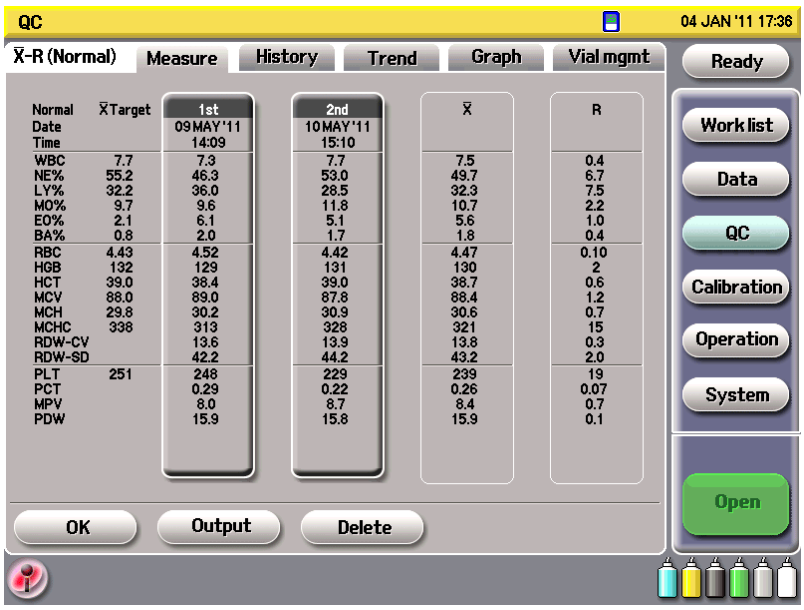
Data-List screen



Data-Details screen

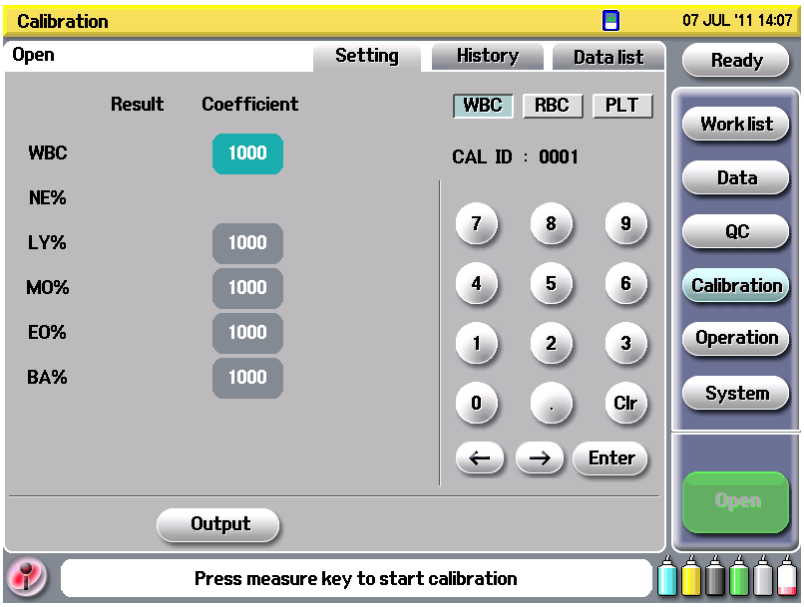
Quality Control Screen

Quality control refers to the precision, accuracy and reproducibility in the system. The analyzer provides four programs for quality control. Refer to Section 11 “Quality Control”.



Calibration Screen

The calibration coefficient is used in converting the data to the measured values to make the measured values as close as possible to the real values. Calibration can be performed in venous blood and pre-diluted blood individually. Refer to Section 6 “Calibration Procedure”.

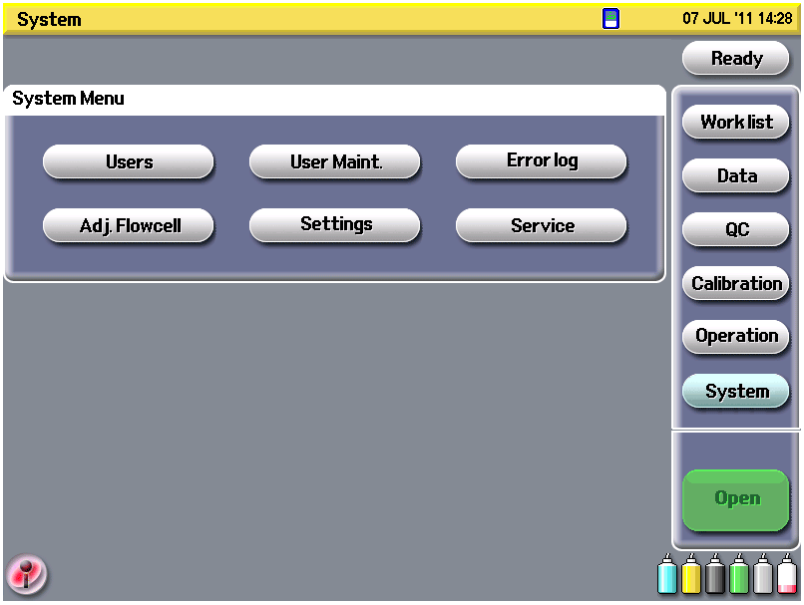


Operation Screen

On the Operation screen, you can prime, clean and drain the fluid path inside the analyzer.

System Screen

On the System screen, you can change various settings, such as normal range, sensitivity and threshold, date and time, and display format, etc. Refer to "Changing Settings" in this section.



Changing Settings

General

Before starting measurement, change any necessary settings, such as measurement mode, upper and lower limits, date and time.

You can also set a warning window to display when reagent or waste reaches the warning level.

System Screen

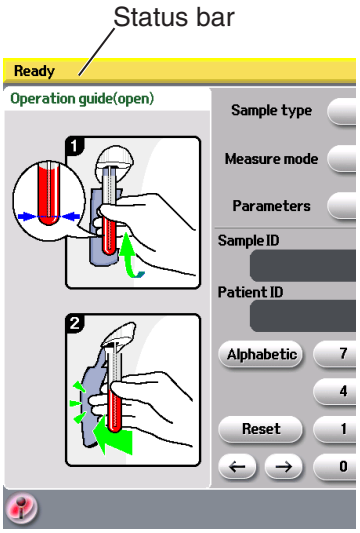
On the System screen, you can set the following items.

Item	Description
Users	Set the users and passwords for operating the analyzer.
User Maint.	• Clean or prime the analyzer before turning off the power for each maintenance procedure. • Display and reset the operating time, measurement count and use of periodic replacement parts.
Error log	Display the error log.
Adj. Flowcell	Adjust the flow cell and optical sensitivity (rough and fine).
Settings	Refer to “Settings Window” later in this section.
Service	Qualified service personnel can use this for maintenance or repair of the analyzer.

Assigning Users and Passwords

General

To prevent measuring with wrong measurement conditions, some screens and functions can only be entered or changed by a user with authority and a password. There are three levels of authority.



Service: For servicing the analyzer. Can enter any screen and change any settings. The status bar on the screen is yellow.

Lab technician: For changing settings. Can enter any screen and change any settings except for the Service screen. The status bar on the screen is blue.

Other user: Can only perform measurement and view data and settings. The status bar on the screen is green.

The following screens cannot be entered by an other user.

- Initialize
- Maintenance
- Service

On the Users screen, an Other User can select a user but only a Lab Technician or Service user can add or delete a user.

On the Users screen, the first three users are preset and cannot be changed. "Factory" is for engineers servicing the analyzer. "MEK-7300" is for changing settings for the first time after installing the analyzer. "USER" can only perform measurement and check measurement data. The passwords for "MEK-7300" and "USER" are:

MEK-7300: 7300
USER: 0000

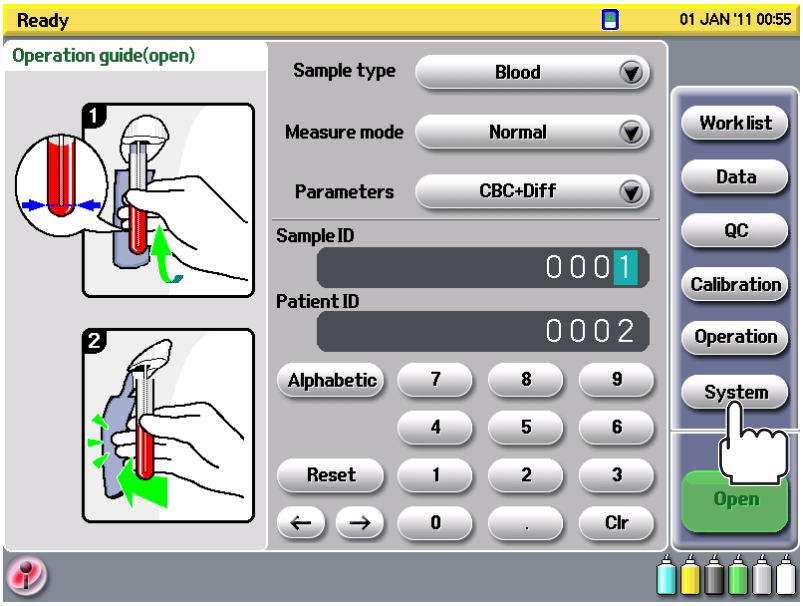
"Factory" is the default setting.

NOTE

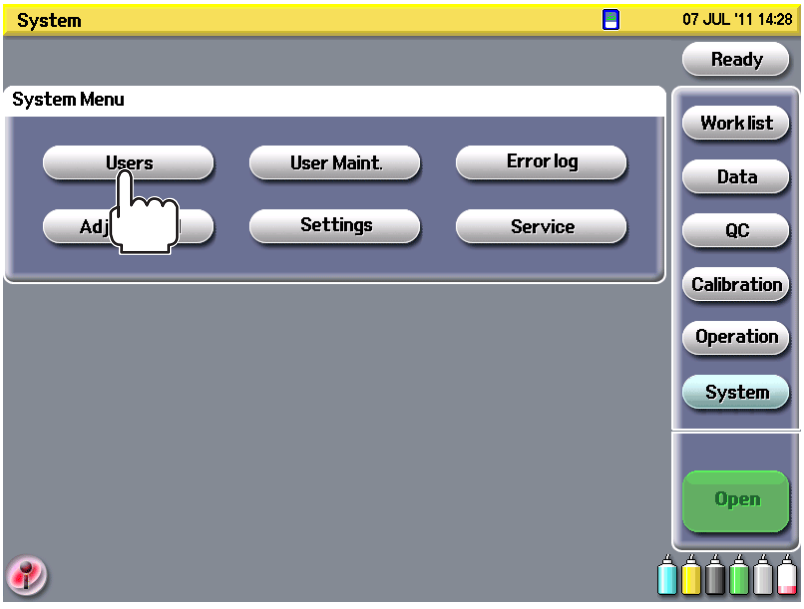
Set the Users settings according to your facility's conditions.

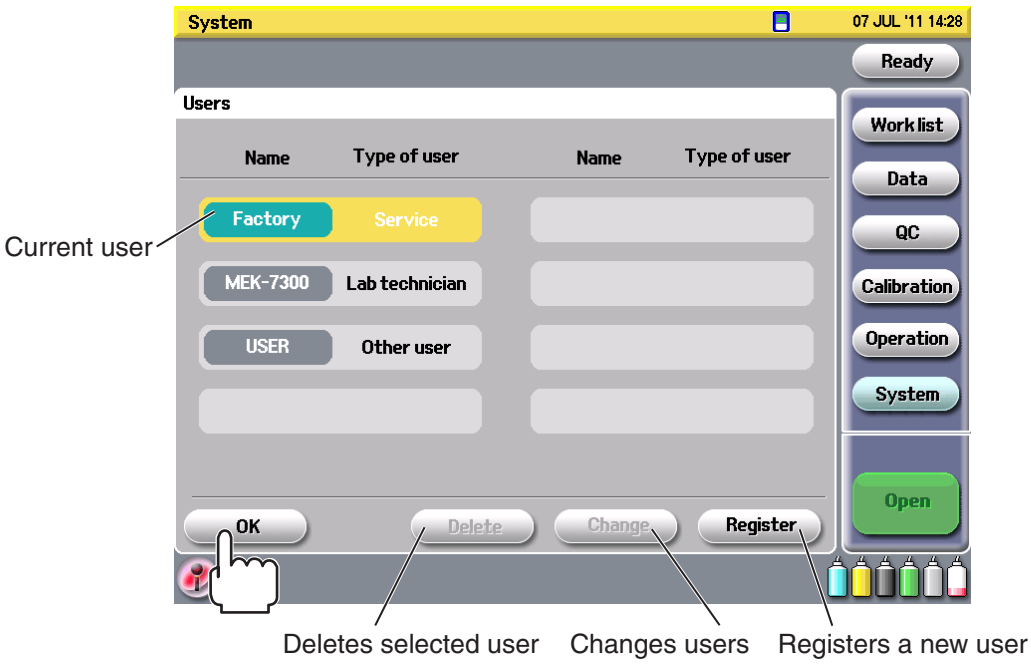
Displaying the Users Screen

1. Press the System key.



2. Press the Users key on the System screen. The Users screen is displayed.





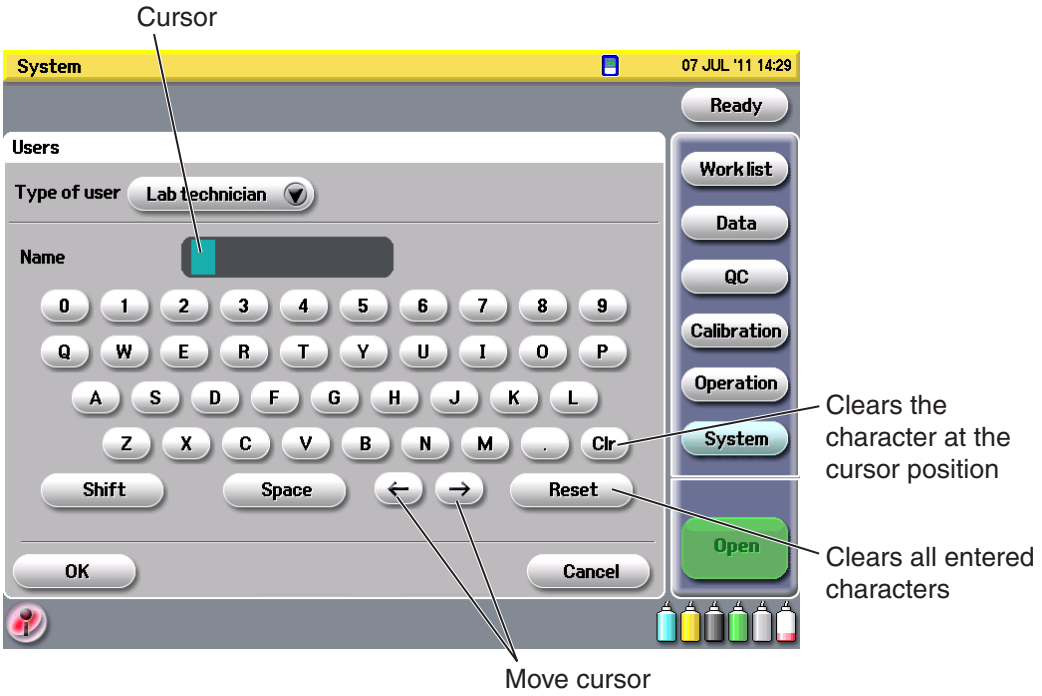
3. Press the OK key to return to the System screen.

Adding a User

A new user can only be added by either a Lab technician or Service user. Up to 8 users can be registered (including the factory default users).

1. Press the Register key on the Users screen.

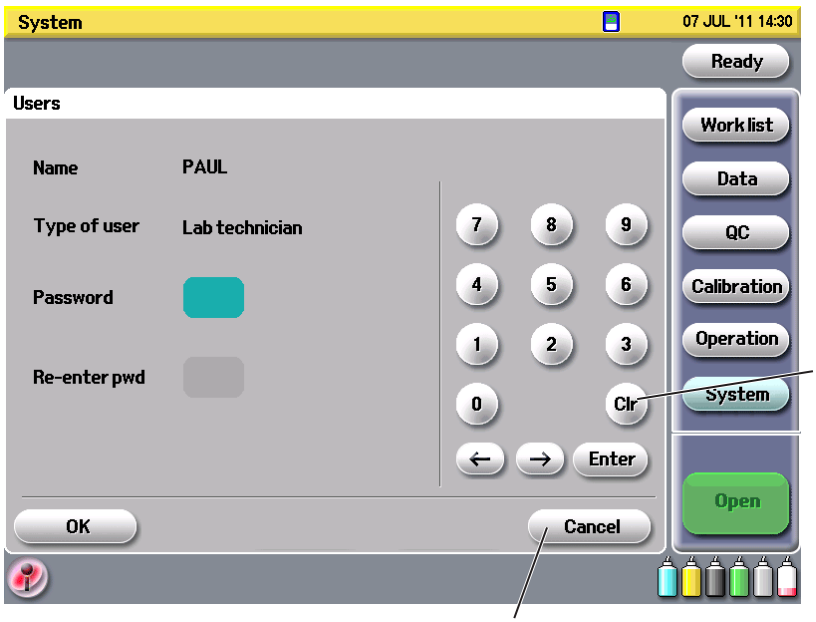
2. Use the displayed keyboard to enter the user name in the <Name> box (up to 8 alphanumerics).



3. Select “Other user” or “Lab technician” for the type of user from the selection list in the <Type of user> box.

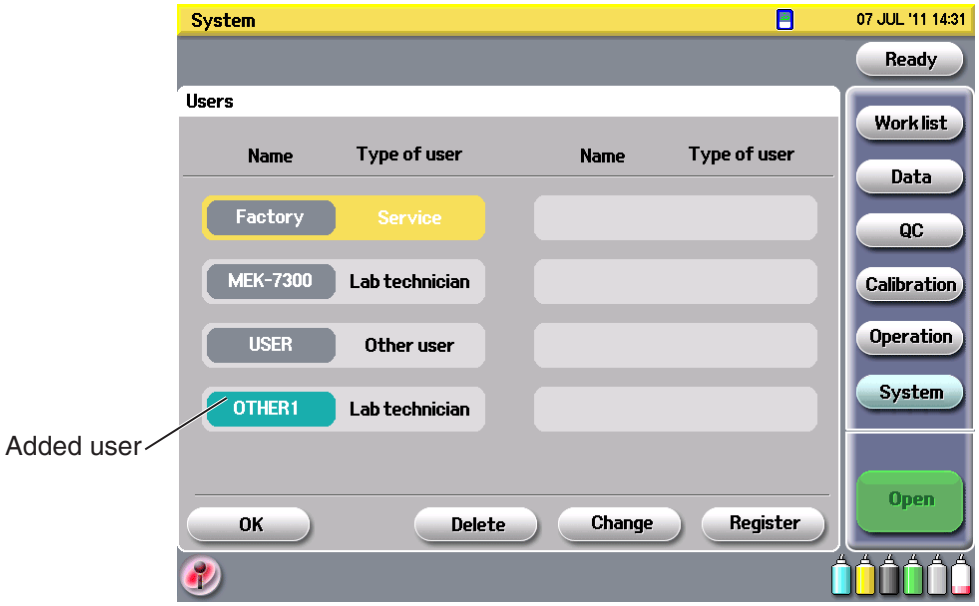
4. Press the OK key. The password entry screen opens.

5. Enter the 4-digit password using the displayed numeric keys. The entered password appears as “****” in the <Password> box.



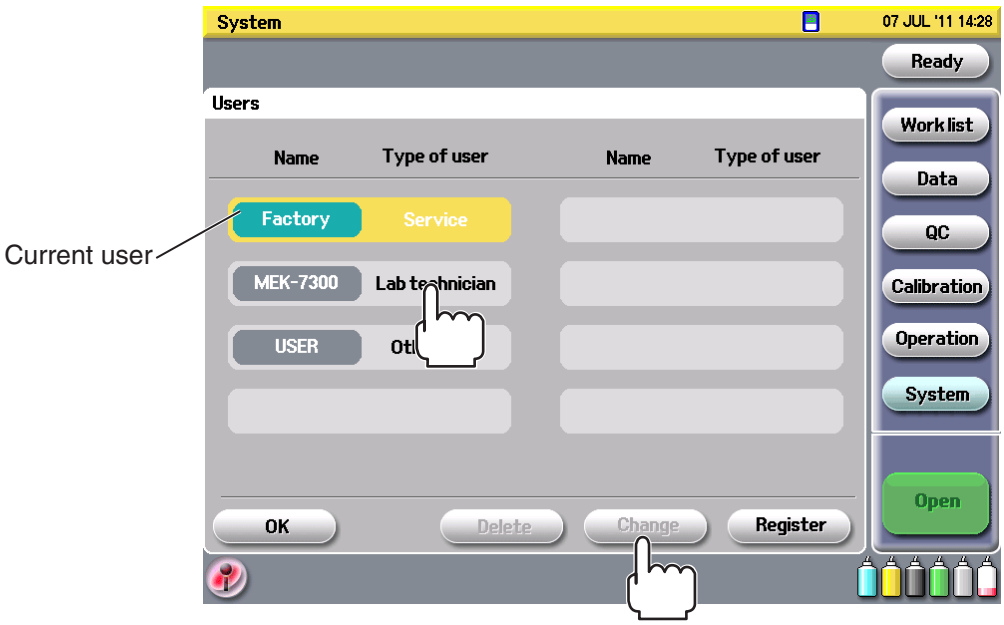
6. Press the Enter key. The cursor moves to the <Re-enter pwd> box.

7. Re-enter the password and press the Enter key to confirm the password. The screen returns to the Users screen and the new user is added to the user list.

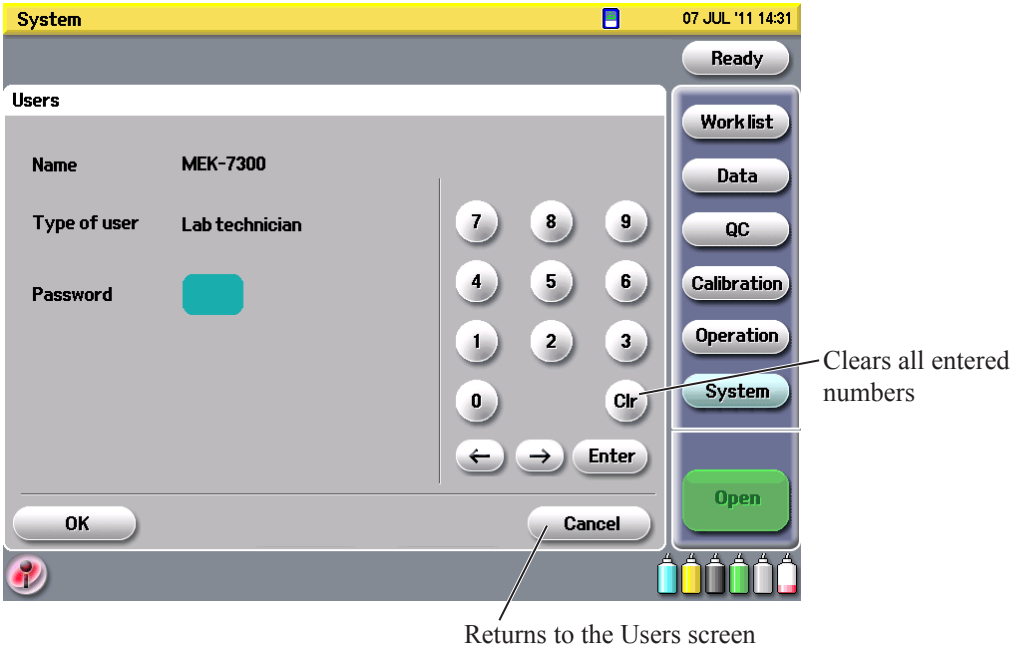


Changing a User

1. Select the desired user on the Users screen.



2. Press the Change key. The password window is displayed.



3. Enter the password for this user using the numeric keys on the window and press the Enter key. When the correct password is entered, the current user (indicated by the yellow labels) changes to the selected user.

   If an incorrect password is entered, the “Incorrect password” message appears. Enter the correct password.

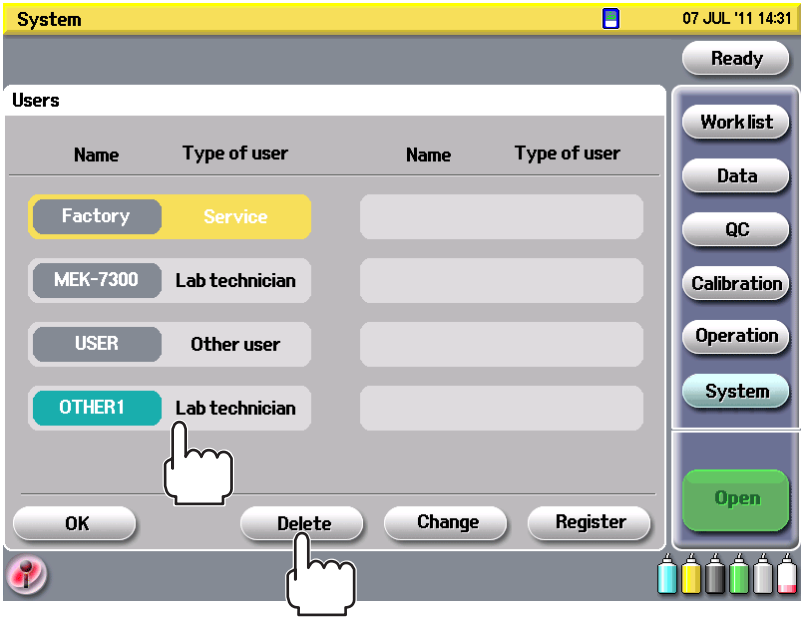
Deleting a User

Only a Lab technician or Service user can delete a user.

NOTE

Factory, MEK-7300 and USER are the default settings and cannot be deleted.

1. Select the user to be deleted on the Users screen.



2. Press the Delete key. The “Delete user?” message is displayed.

3. Press the Yes key to delete the selected user. The user is deleted and the screen returns to the Users screen.

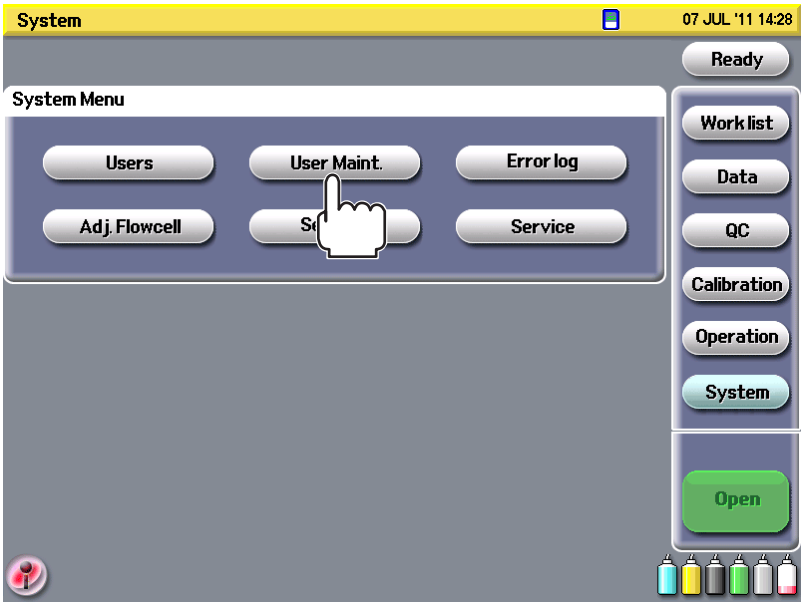
   Press the No key to not delete the selected user.

Doing Maintenance

On the User Maintenance window, you can clean or prime the analyzer before turning the power off. For details, refer to Section 9 “Service and Maintenance”. You can also display the measurement count and reset the use of periodic replaceable parts.

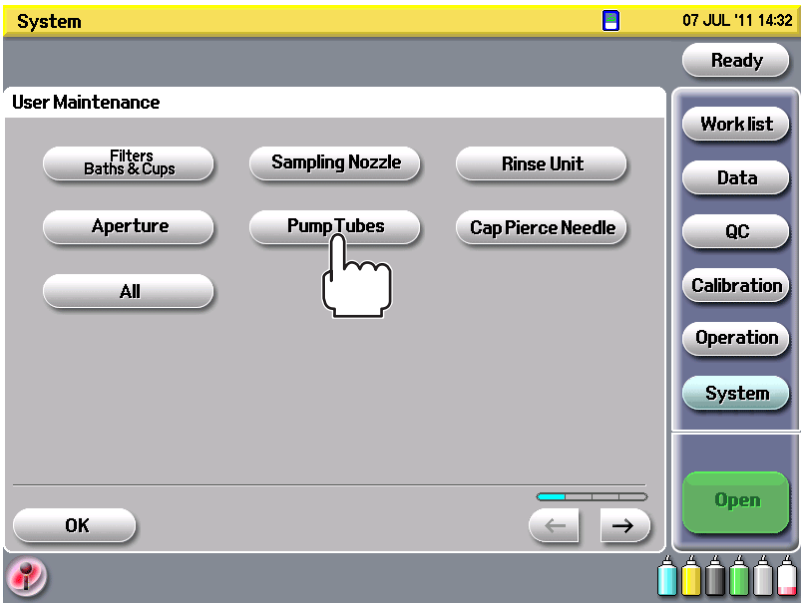
Cleaning and Priming the Analyzer

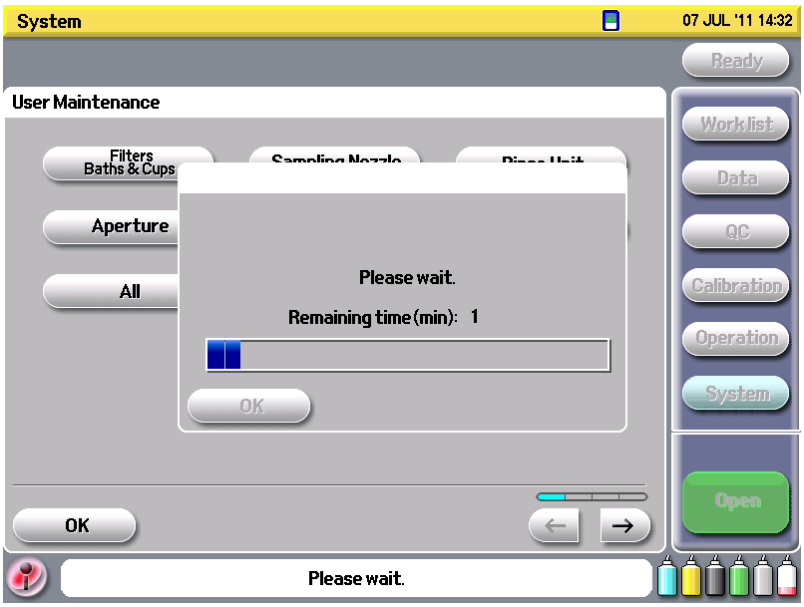
1. Press the User Maint. key on the System screen.



2. Press the desired key for maintenance. A confirmation message appears.

3. Press the Yes key. The analyzer is automatically cleaned and primed.



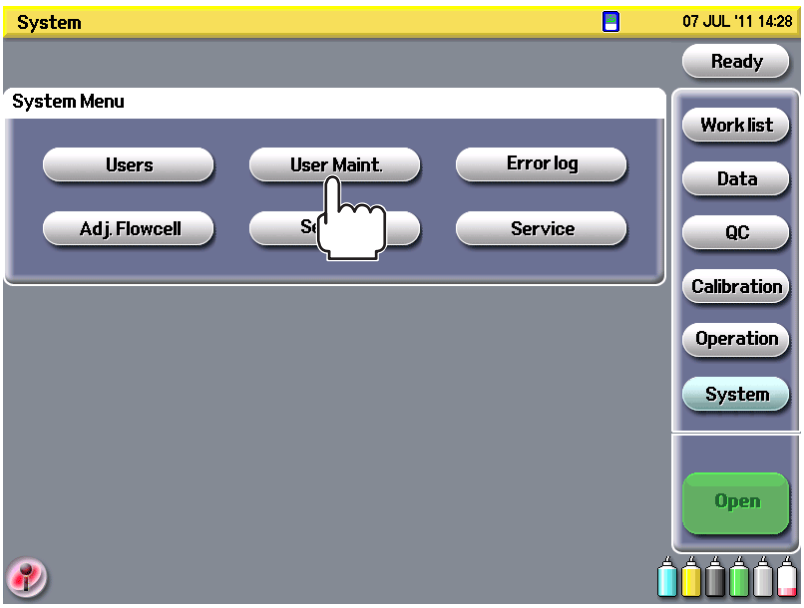


After cleaning and priming, press the OK key to return to the User Maintenance window.

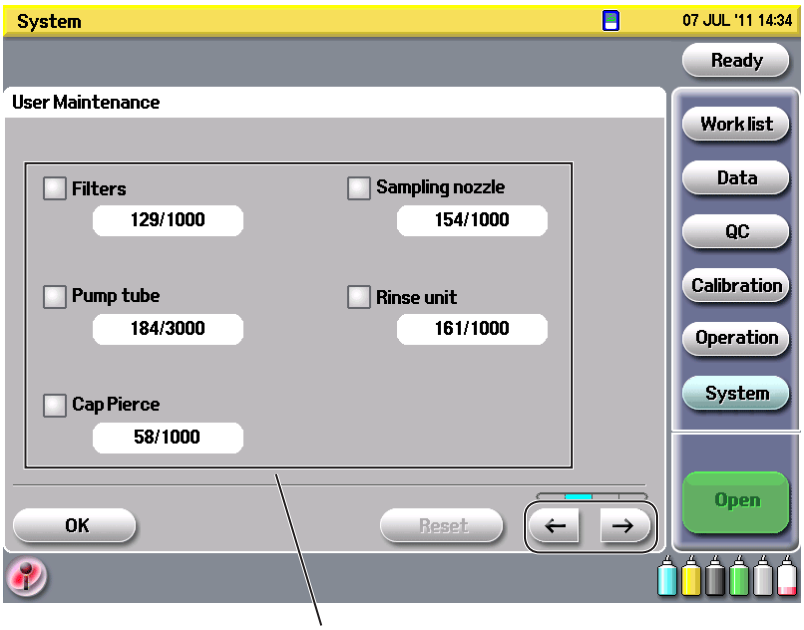
Displaying the Use of Periodic Replaceable Parts

The use of periodic replaceable parts can be displayed. Use the information for maintenance. When replacing the parts, reset the use of the parts. The message which indicates replacement disappears.

1. Press the User Maint. key on the System screen.



2. Press the arrow key to display the second page.



The time of use/The time to display message

3. Press the OK key to return to the System screen.

The Number of Times to Display Message

When the filter, pump tube, rinse unit, cap pierce and sampling nozzle are used more than the following number of times, a message to indicate replacement appears. When the message appears, check and replace the parts. After replacing the parts, reset the number of times of use.

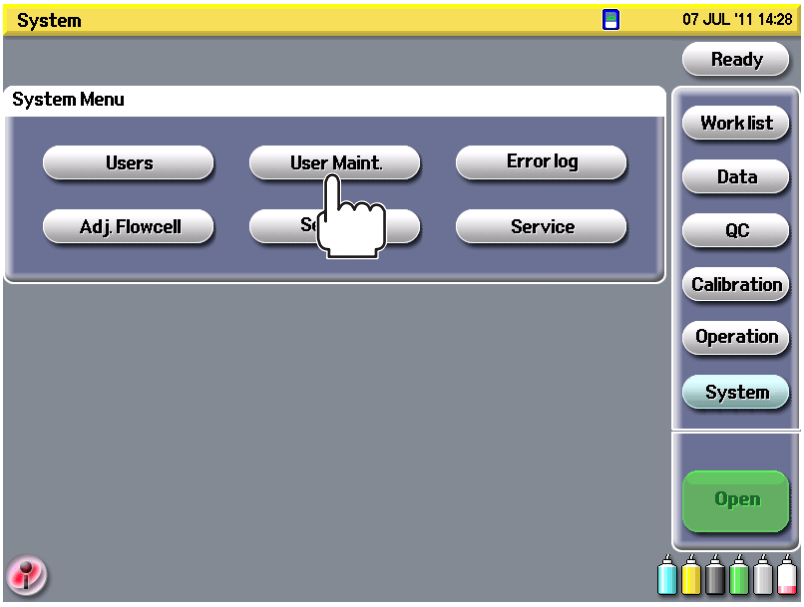
The times to display message

- Filters: 1000
- Pump tube: 3000
- Rinse unit: 1000
- Sampling nozzle: 1000
- Cap pierce: 1000

Resetting the Number of Times of Use

After replacing the parts, reset the number of times of use.

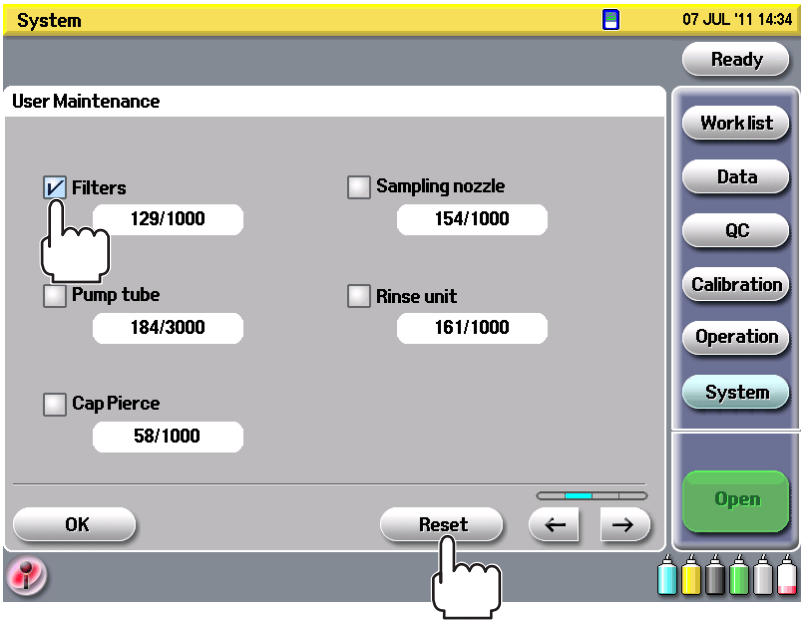
1. Press the User Maint. key on the System screen.



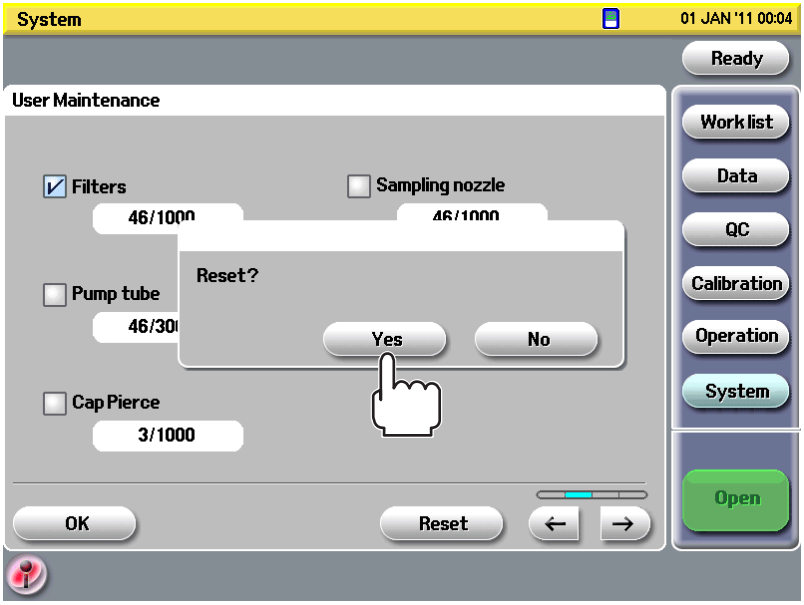
2. Press the arrow key to display the second page.

3. Press the desired parts to reset the times of use. The parts are checked.

4. Press the reset key. The confirmation window is displayed.



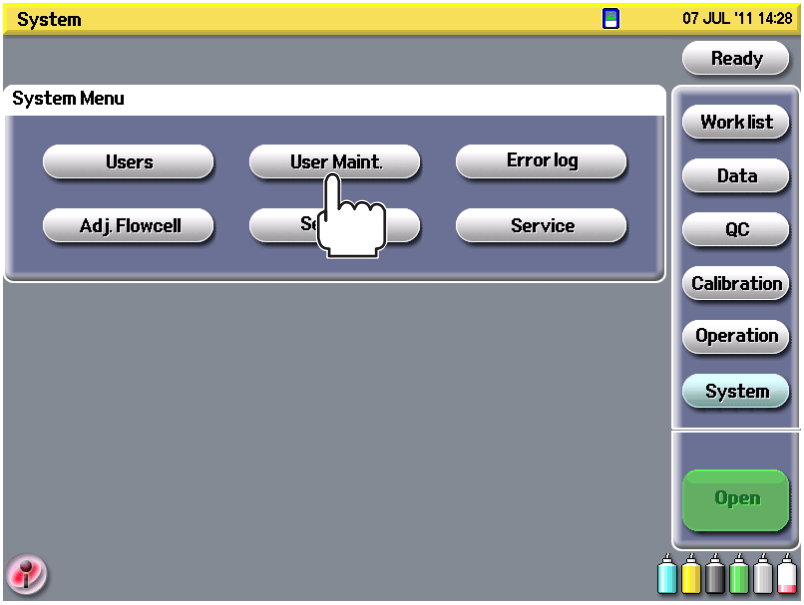
5. Press the Yes key. The number of times of use is reset to 0.



6. Press the OK key to return to the System screen.

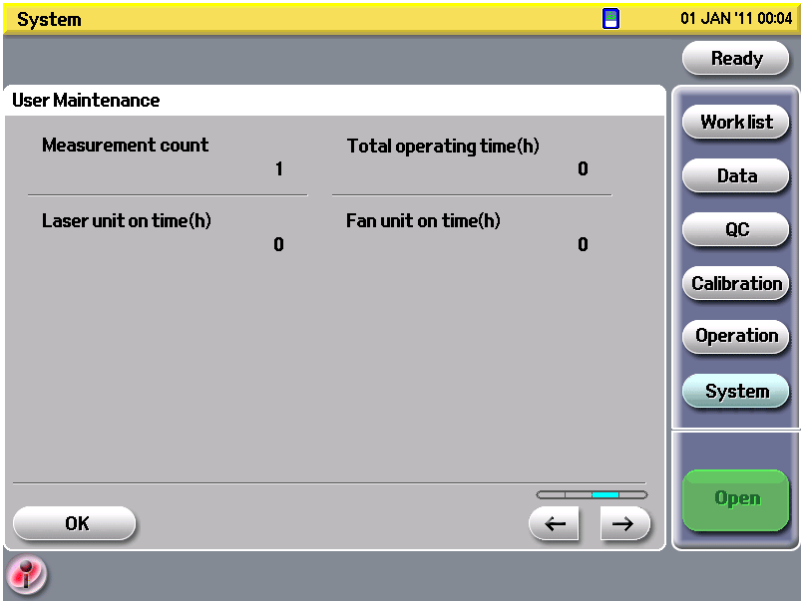
Checking the Operation History

1. Press the User Maint. key on the System screen.



2. Press the arrow key to display the third page.

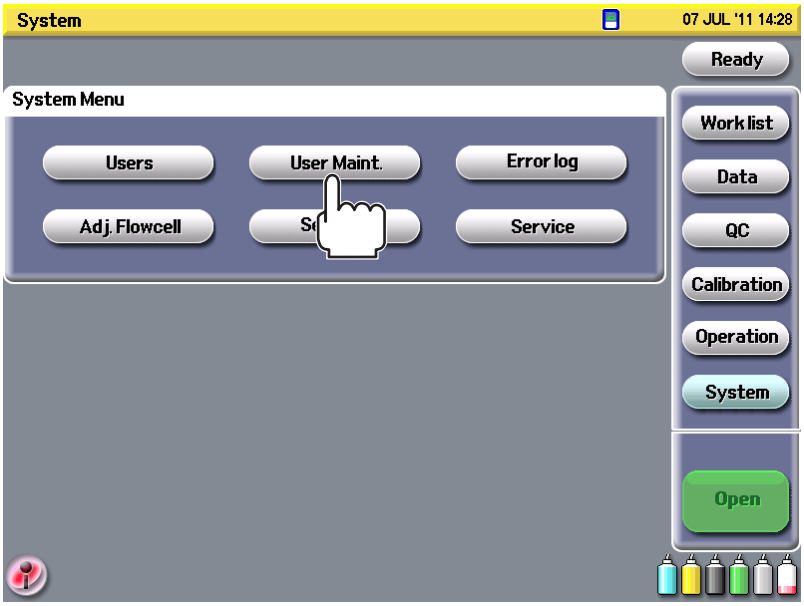
3. Check the Measurement count, Total operating time and Laser unit on time.



4. Press the OK key to return to the System screen.

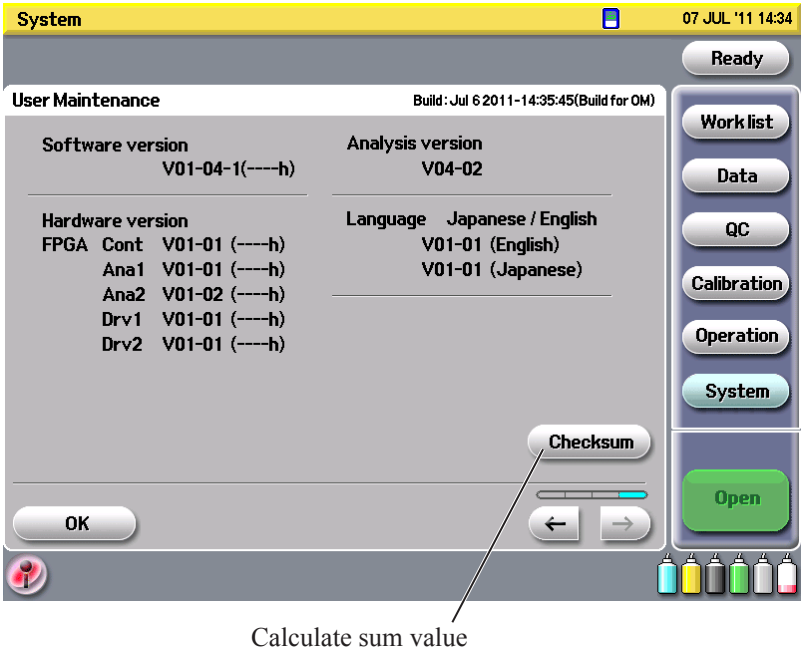
Checking the Software Information

1. Press the User Maint. key on the System screen.



2. Press the arrow key to display the fourth page.

3. Check the software information.



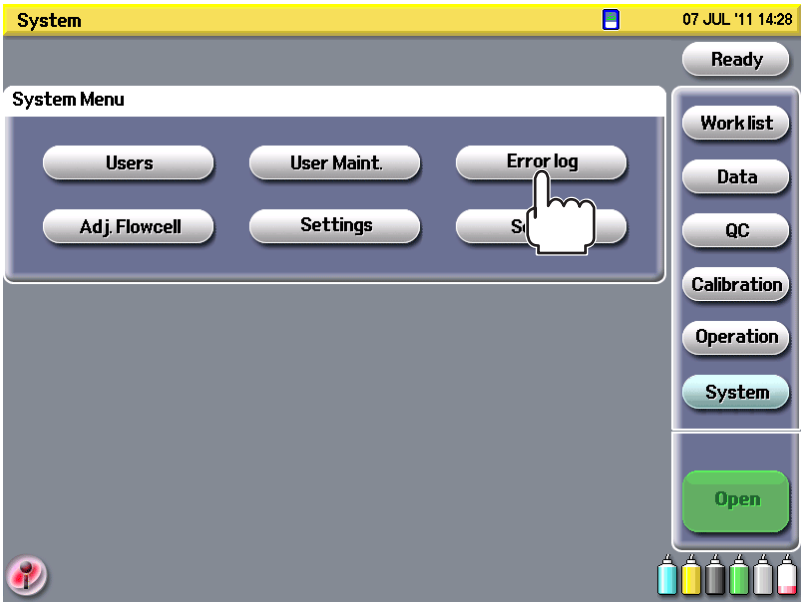
Calculate sum value

4. Press the OK key to return to the System screen.

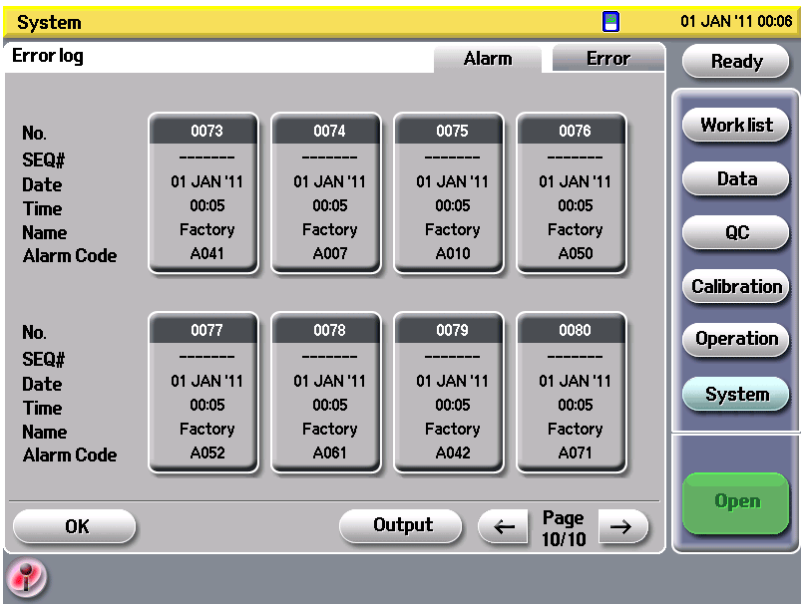
Checking the Error Log

The alarm and error history can be displayed on the Error log window. For details, refer to Section 10 “Messages and Troubleshooting”.

1. Press the Error log key on the System screen.

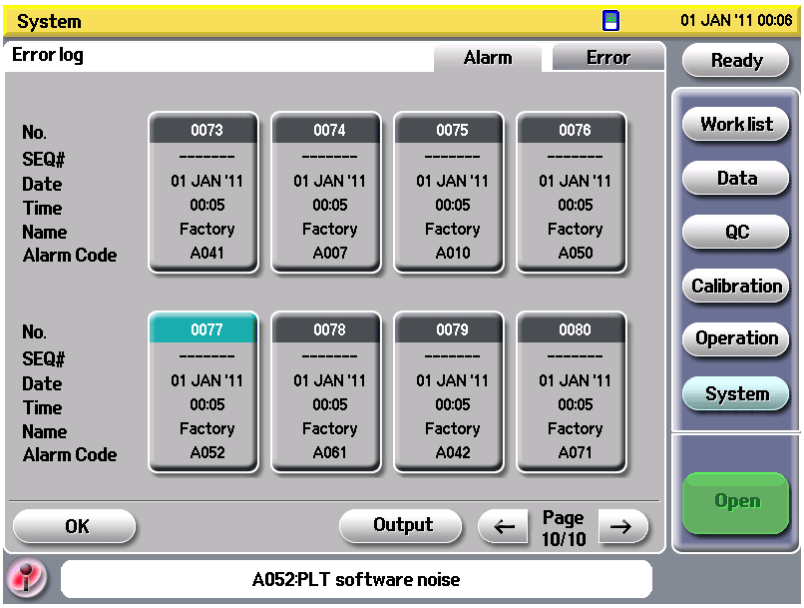


2. Press the Alarm or Error tab.



When <Output with "Output" key> setting on the SD Card setting is set to "On", you can capture the window and send it to the SD card by pressing the Output key.

3. Press the desired data to check. The error or alarm is displayed on the lower part of the screen.



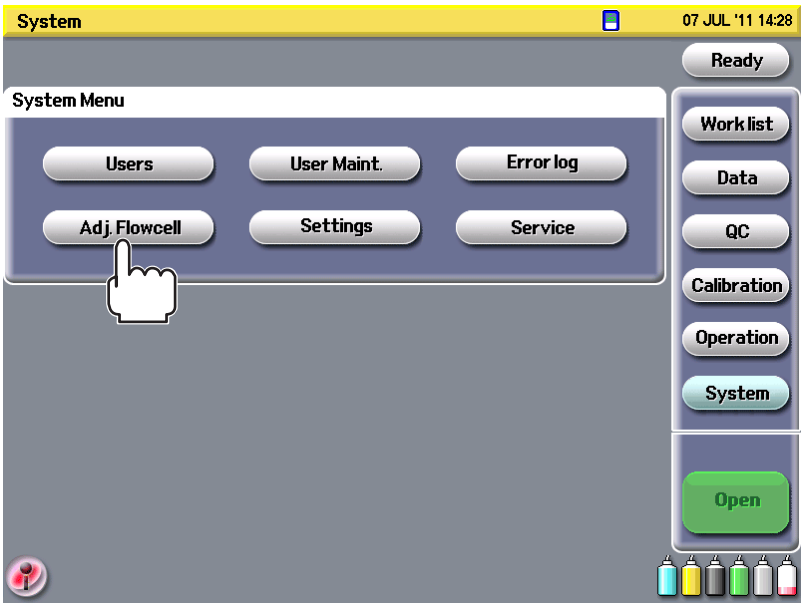
4. Touch the OK key to return to the System screen.

Performing an Optical Adjustment

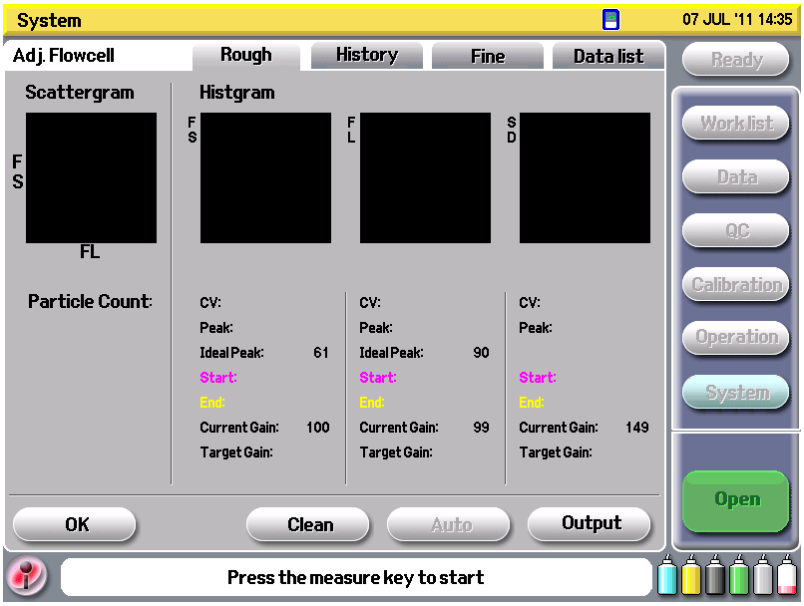
Measure particles and perform optical adjustment (rough and fine) on the Adjust flow cell window. For details, refer to "Checking the Particle Distribution Width" in Section 9.

Displaying the Adj. Flowcell Window

1. Press the Adj. Flowcell key to display the Adj. Flowcell window.



2. Press the desired tab to adjust.



3. Press the OK key to return to the System screen.

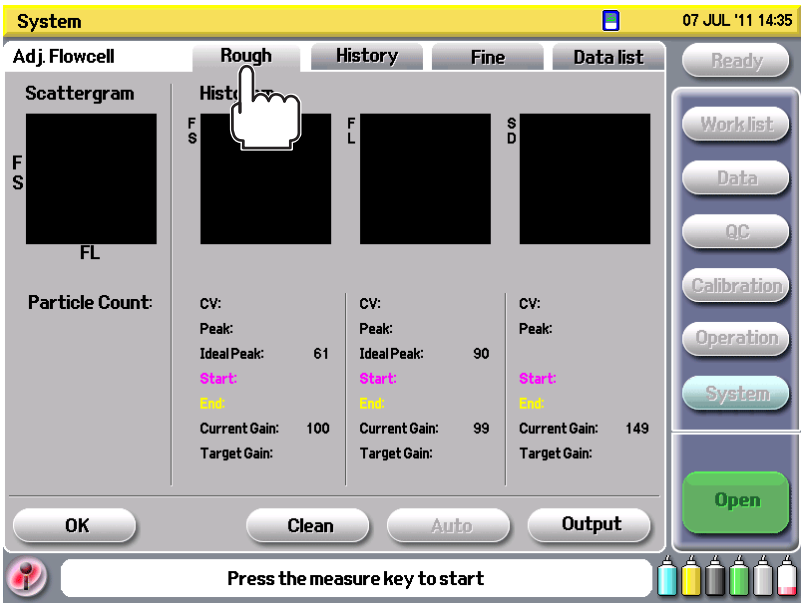
Doing Optical Adjustment

Adjust the sensitivity and threshold for WBC 5 part measurement by flow cytometry method. The adjustment enables the analyzer to measure human blood correctly. After adjusting roughly with YZ-0194 standard particle, adjust finely with MEK-CAL measurement data. Do the adjustment when installing the analyzer or when each white blood cell distribution in the scattergram of normal human blood (stored at room temperature within eight hours after collection) is outside the area.

Doing Optical Adjustment Roughly

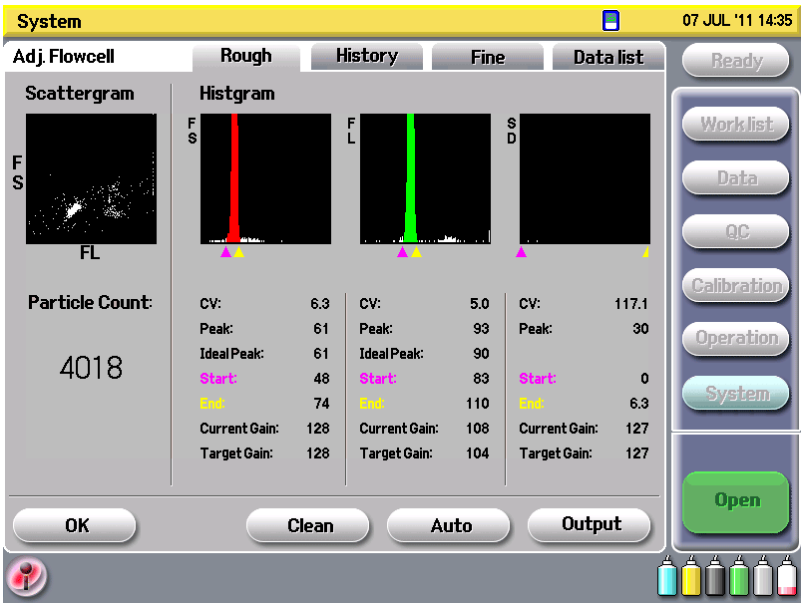
1. Press the Rough tab on the Adj. Flowcell window.

2. When the sampling mode is Closed, press the key and change the mode to Open.



3. Press the count switch to aspirate and count the YZ-0194 normal particles.

4. After measurement, the CV and peak of the FS and FL histogram are calculated and displayed. Check that the CV of FS and FL are 7.0% or less.



5. If the CV is more than 7.0%, press the Clean key to clean the flow cell. If the CV is still more than 7.0% after cleaning, adjust the flow cell position.

   If the CV of FS and FL is less than 7.0%, press the Auto key.

6. When another window is displayed after adjustment, the analyzer automatically performs cleaning.

When doing more detailed setting, do the fine optical adjustment.

Doing Fine Optical Adjustment with MEK-CAL

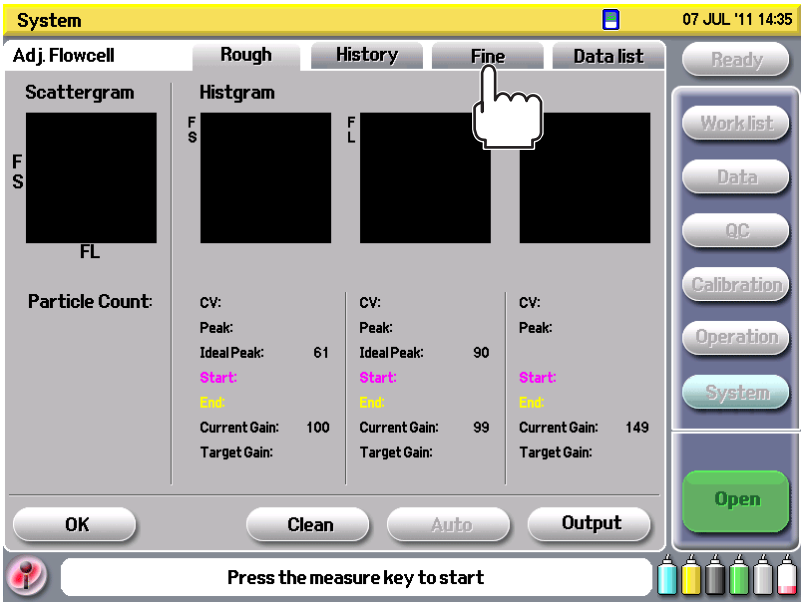
Do fine optical adjustment using MEK-CAL measurement data to sort the WBC in 5 part correctly. Adjust the optical sensitivity using the center peak of the MEK-CAL scatter and move the scattergram distribution to the optimum place.

- Average Peak: Average peak of the two or more MEK-CAL centers
- Ideal Peak: Ideal peak of the optimum center peak
- Current Peak: Latest registered MEK-CAL center peak
- Gain: Gain for optical adjustment
- Target Gain: Optimum target gain
- Current Gain: Currently set gain
- Edit Gain: Gain for manual adjustment

NOTE

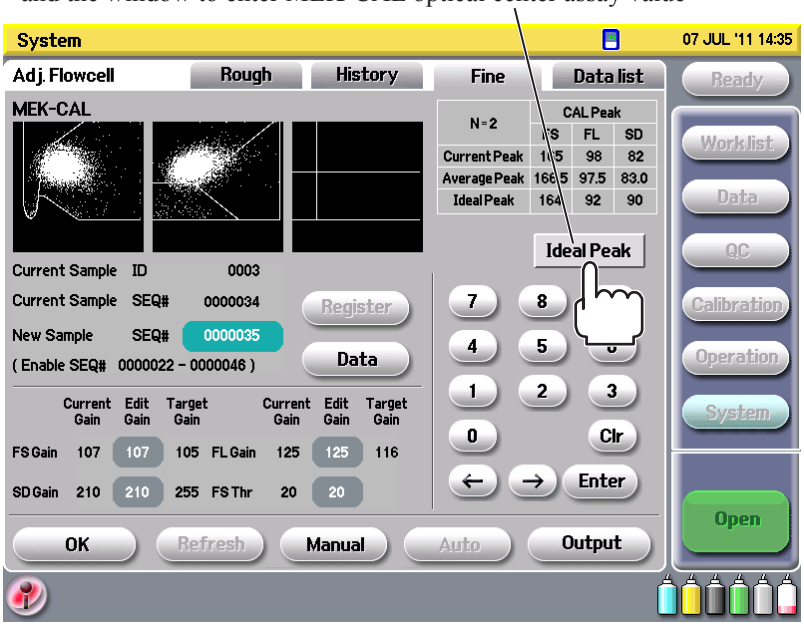
- Before fine adjustment, do rough optical adjustment. Measure MEK-CAL 3 to 5 times.
- Use MEK-CAL for fine optical adjustment. You cannot adjust it correctly with human blood.
- Use MEK-CAL before the expiration date and follow the storage condition.

1. Press the Fine tab on the Adj. Flowcell window.



2. Press the Ideal Peak key to display the MEK-CAL Ideal Peak window.

Switches between the window to register data for fine optical adjustment and the window to enter MEK-CAL optical center assay value

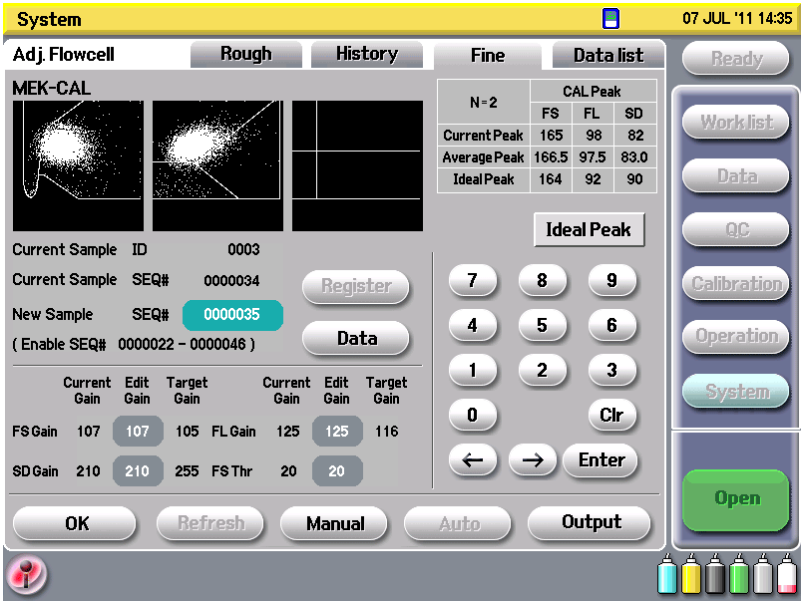


3. Enter the FS, FL and SD ideal peak and FS threshold. Enter the ideal peak on the assay sheet of the MEK-CAL.
   i) Touch the desired item.
   ii) Enter the number with the numeric key pad and press the Enter key.

4. Press the Ideal Peak key to return to the Fine window.

5. Enter the SEQ# of MEK-CAL measurement data to use sensitivity adjustment.

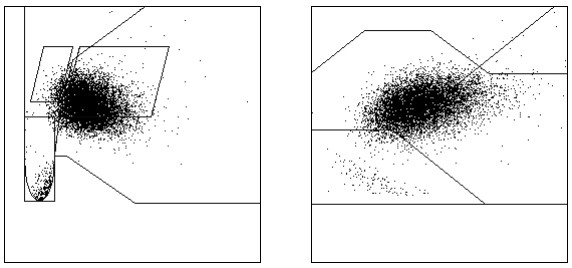
6. Press the Data key to load the measurement data of the New Sample SEQ#. The scattergram is displayed.



7. Check that the displayed scattergram is optimum for optical adjustment.

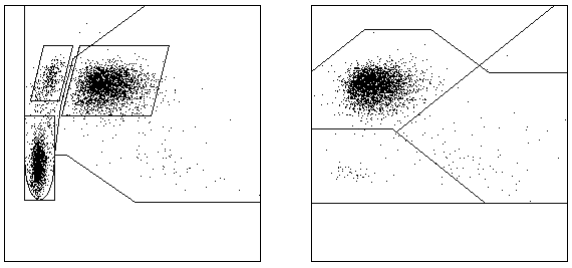
Scattergrams which can be used for optical adjustment

- Scattergrams are distributed in a circle.
- Distribution concentrates in a single center.

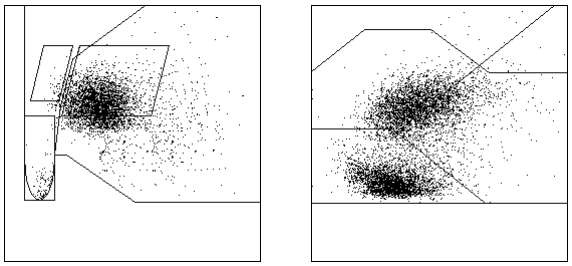


Scattergrams which cannot be used for optical adjustment

- When measuring human blood



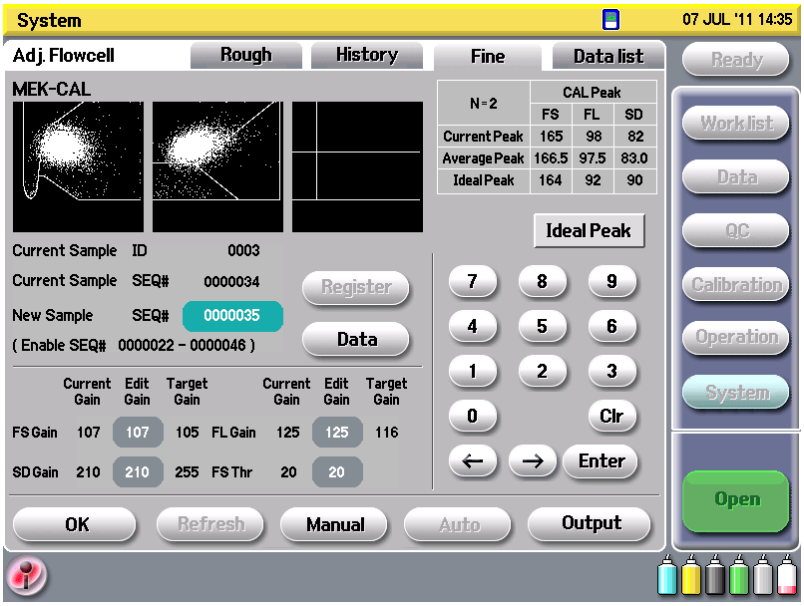
- When measuring expired MEK-CAL



- There are ghosts on the lower part.
- There are two or more distributions.

8. When the sample is optimum, press the Register key to register the measurement data to the data list. Check that the Average Peak is within ±2 of the assay value.

9. If the Average Peak is not within ±2 of the assay value, adjust the gain.



• Auto adjustment

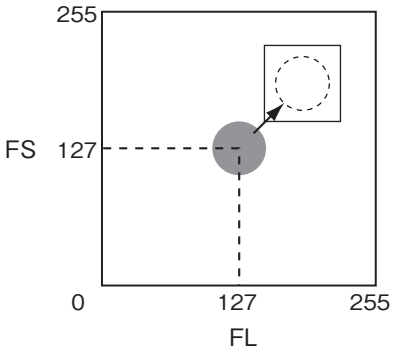
Press the Auto key. The Target Gain is automatically adjusted and set to Current Gain.

• Manual adjustment

Enter the value for Edit Gain. Use the arrow keys to move the cursor. Press the Manual key to set the value entered in Edit Gain to the Current Gain.

When adjusting the vertical axis of the scattergram, adjust the FS Gain. When adjusting the horizontal axis, adjust the FL Gain and SD Gain.

Example: FS-FL scattergram



To adjust the distribution to the square area, increase the FS and FL Gain.

10. Press the Refresh key and check the settings. The scattergrams are displayed again using the ratio of Edit Gain and Current Gain.

11. Press the Yes key to return to the Ready screen.

Calculating Target Gain

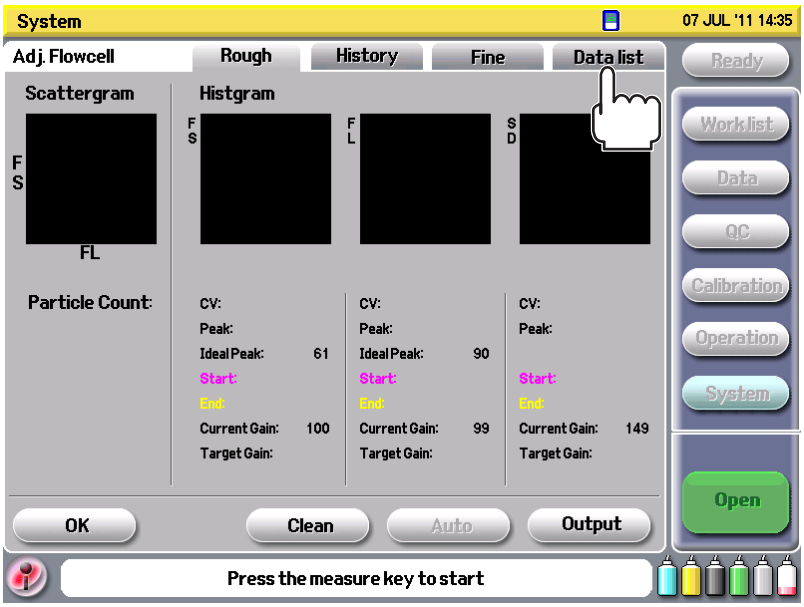
In the Fine tab of the Adj. Flowcell window, the center of the MEK-CAL is calculated from the scattergram of the data which is registered to the data list. The Target Gain is calculated from this Average Peak, Ideal Peak and Current Gain. When the Auto key is pressed, the current gain is changed to the value of Target Gain and saved.

If the Target Gain is out of the 0 to 255 range or the center of the MEK-CAL is not calculated, an "Out of range" message is displayed, Target Gain is not displayed and the Auto key is not available. In this case, do rough adjust flow cell again.

Checking the Value of the Data List

When the data that can be used for optical adjustment is registered, check that there is no difference larger than ±2 between Average Peak and Ideal Peak on the Data List window.

1. Press the Data List tab on the Adj. Flowcell window.



2. Check that "CAL" is displayed on Mode.

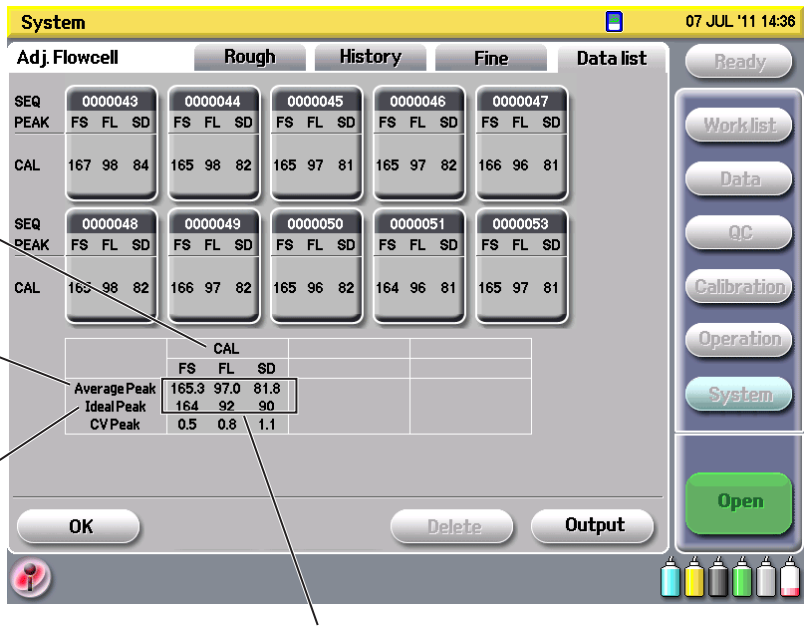
3. Check that there is no difference larger than ±2 between Average Peak and Ideal Peak.

   If there is a difference larger than ±2, delete bad data from the list or adjust the gain.

Mode
Check that the “CAL” is displayed.

Average Peak
The average value of the data registered to the list.

Ideal Peak
The peak target value set on the optical sample setting window.



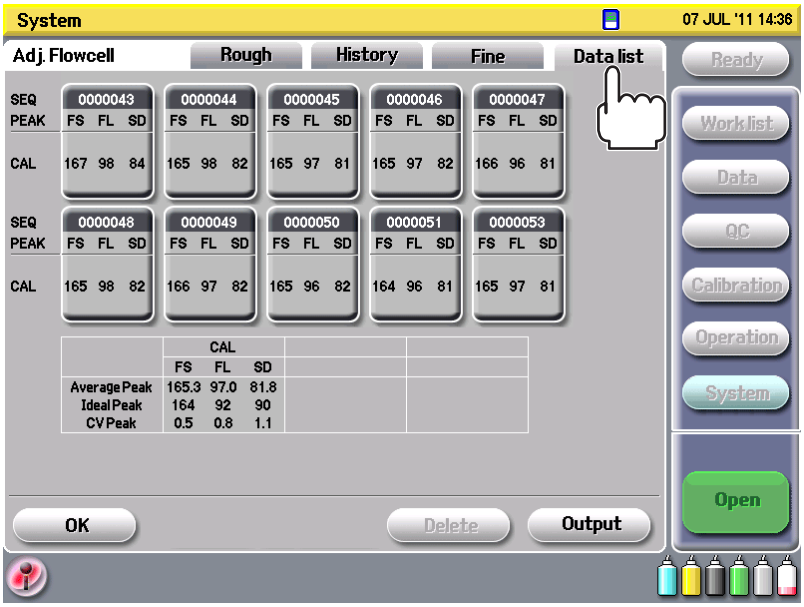
Check that there is no difference larger than ±2 between Average Peak and Ideal Peak.

Checking the Center of the MEK-CAL

Check that there is no difference larger than ±2 between the Average Peak and Ideal Peak on the Fine window or Data list window.

Displaying the Data List Window

Press the Data list tab on the Adj. Flowcell screen to display Data list window. The registered data is displayed in list.



Deleting Data

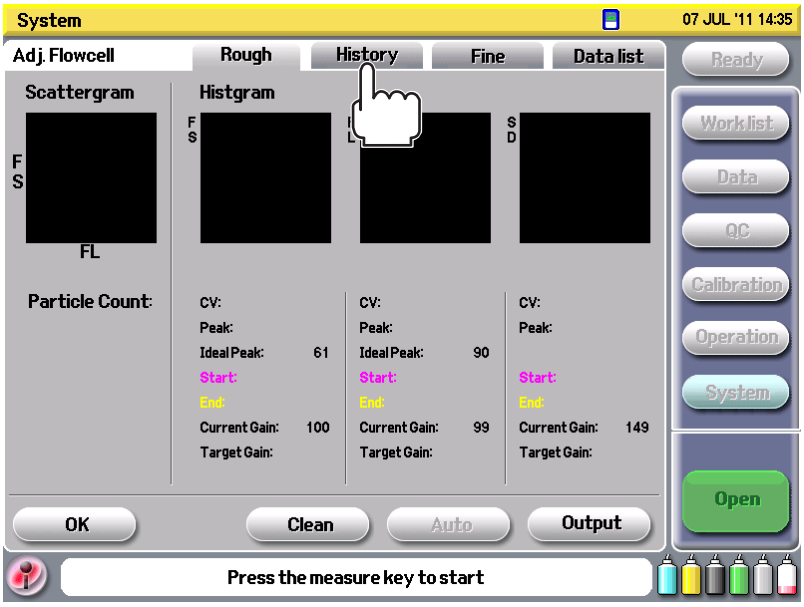
- To delete one data, select the desired data to delete and press the Delete key.

- To delete all data, press the Delete key without selecting data. When a confirmation message appears, press the Yes key to delete all data.

Displaying the Optical Adjustment History

When doing optical adjustment and changing the gain, the SEQ#, Date, Operator and values of the latest data are saved as history. Up to 13 histories can be saved.

Press the History tab to display the History window.

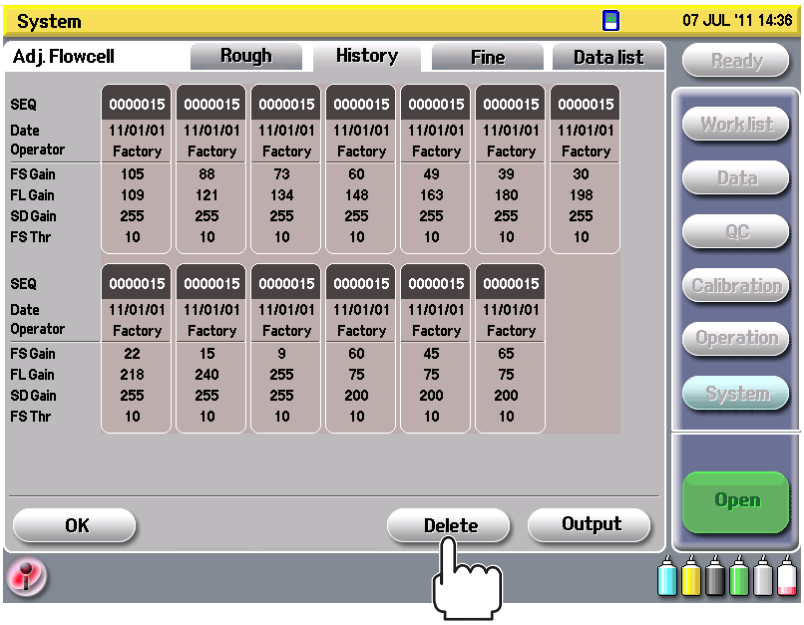


Deleting Optical Adjustment History

NOTE

When the operator is set to User, history cannot be deleted.

1. Press the Delete key on the History window of the Adj. Flowcell screen. A confirmation message appears.



2. Press the Yes key to delete all data.

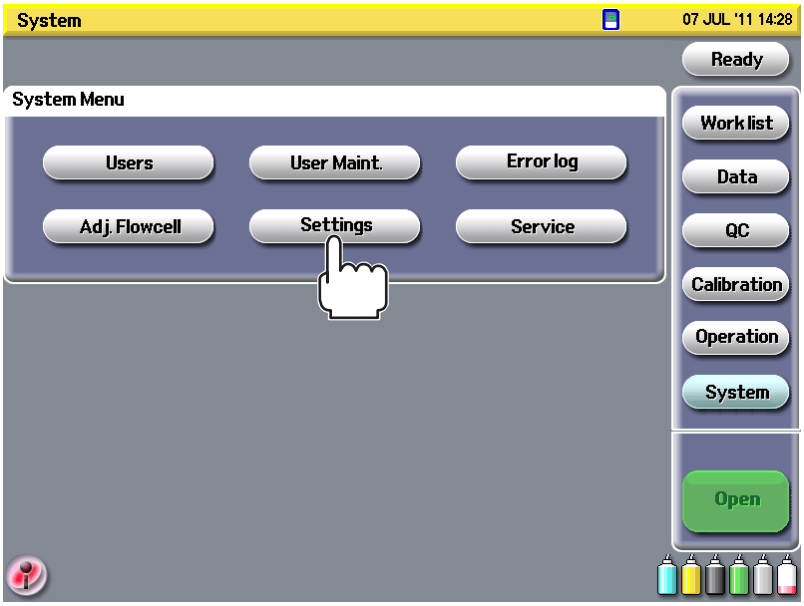
   Press the No key to cancel.

Settings Screen

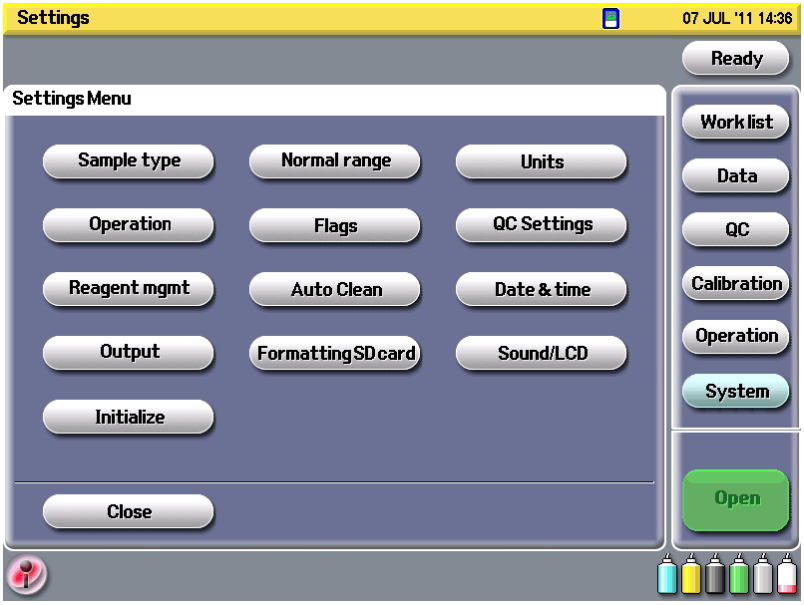
Set the necessary settings before measurement such as measurement condition and data printing format on the Settings screen.

Displaying Settings Screen.

1. Press the Settings key to display the Settings screen.



2. Press the key for the desired settings. The window of the touched key appears.



3. Set the settings. Refer to the following sections.

4. Press the Close key to return to the System screen.

Set the following items on the Settings screen of the System screen. You can also initialize settings on the Initialize screen.

Item	Description
Sample type	Selects sample types and labels each sample type.
Normal range	Sets the upper and lower limits for each parameter. These limits are used as criteria to decide abnormal values.
Units	Selects the units.
Operation	Sets the operation when turning on the analyzer and sets the reagent management function On or Off.
Flags	Selects the flags to highlight ID and set the threshold for the flags.
QC Settings	Sets the quality control settings.
Reagent mgmt	Manages the reagent and waste volume.
Auto clean	Sets a time of day to automatically clean or prime the analyzer.
Date & time	Sets the date and time.
Output	Selects the printer or computer to which the data will be automatically transferred after measurement or when pressing the Output key.
Formatting SD card	Formats the SD card.
Sound/LCD	Sets the sound during measurement and the brightness of the display.
Initialize	Initializes the settings to the factory default settings and deletes stored data.

There are setting screens which can only be entered when the type of user is “Lab technician” or “Service”. For details, refer to the “Assigning Users and Passwords” section.

Labeling and Selecting Sample Types

You can select the sample type before each measurement on the Ready screen. You can label and select sample types to be displayed in the selection list on the Ready screen and other setting screens.

Labeling Sample Types

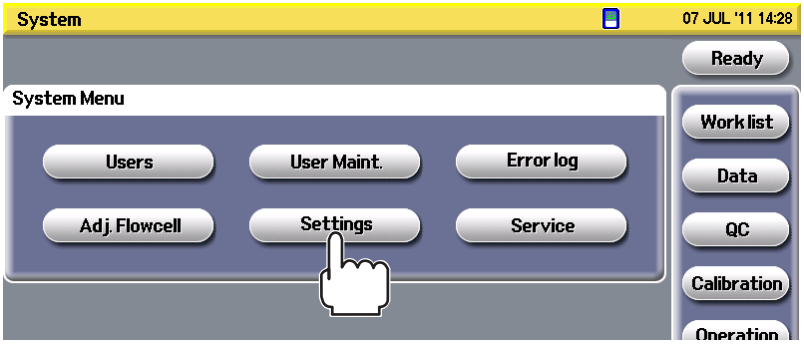
You can label different sample types. Up to 10 sample types can be set, but one of them is fixed to “Control” and cannot be changed. These sample labels appear on the Ready screen so you can select the sample type before measurement. To label sample types, the type of user must be either Lab technician or Service.

When the labels are changed, the new labels are also applied to the stored data. For example, when the “Male” label is changed to “Internal”, the sample type of all sample data with the “Male” sample type are changed to “Internal”.

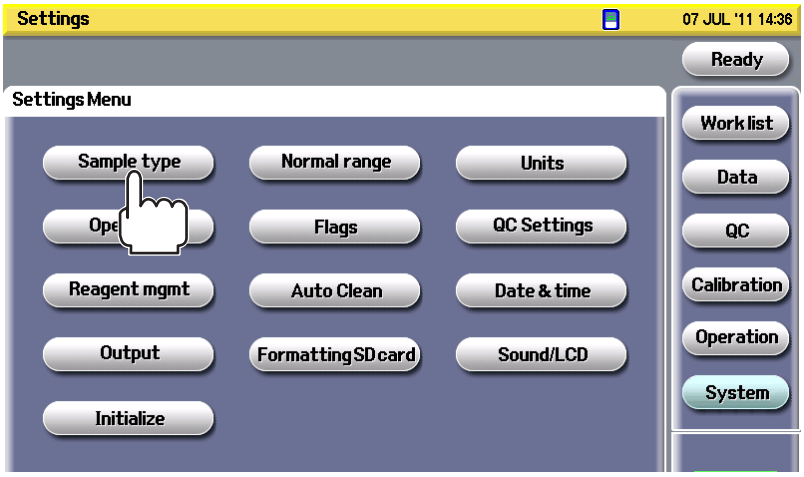
NOTE

It is recommended to delete stored data before changing the sample type labels. Otherwise, it becomes difficult to distinguish the stored data.

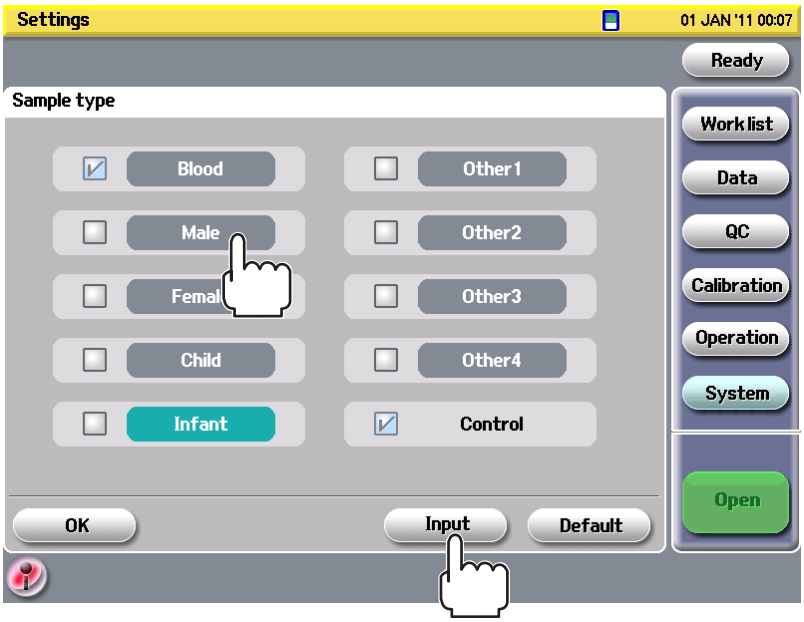
1. Press the Settings key on the System window.



2. Press the Sample Type key on the Settings screen to display the Sample Type screen.

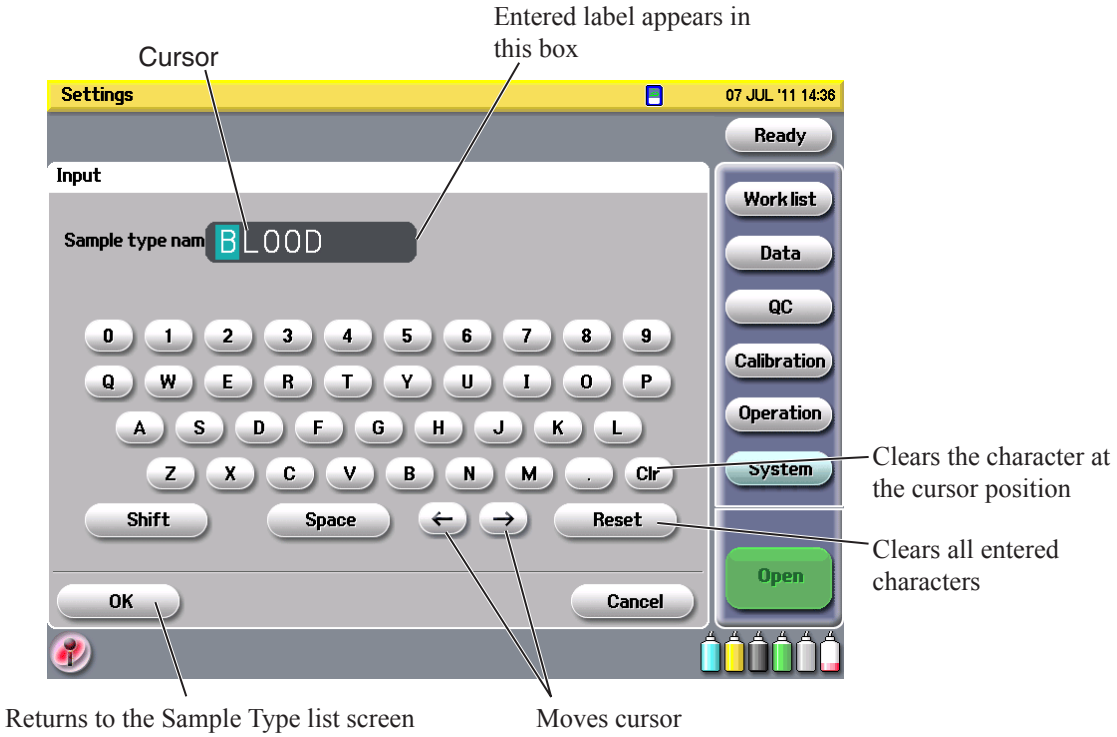


3. Select the sample type for the label to be changed. “Control” cannot be changed.



4. Press the Input key to display keypads for entering the sample label.

5. Edit the sample label using numeric and alphabet keys. You can edit the sample labels using numeric and alphabet keys. Each label can have up to 8 characters.



6. Press the OK key to register the sample label and return to the Sample Type list screen.
   When the Cancel key is pressed, the entered label is cancelled and the screen returns to the Sample Type list screen.

   The entered sample label is registered to the label position you have chosen in step 3.

   When a sample type is selected and the Default key is pressed on the Sample Type screen, the selected sample type label is reset to the factory default setting.

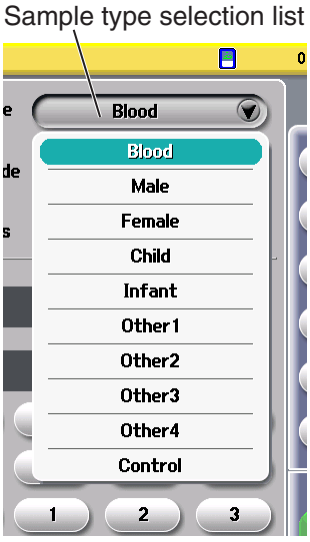
7. Press the OK key to return to the Settings screen.

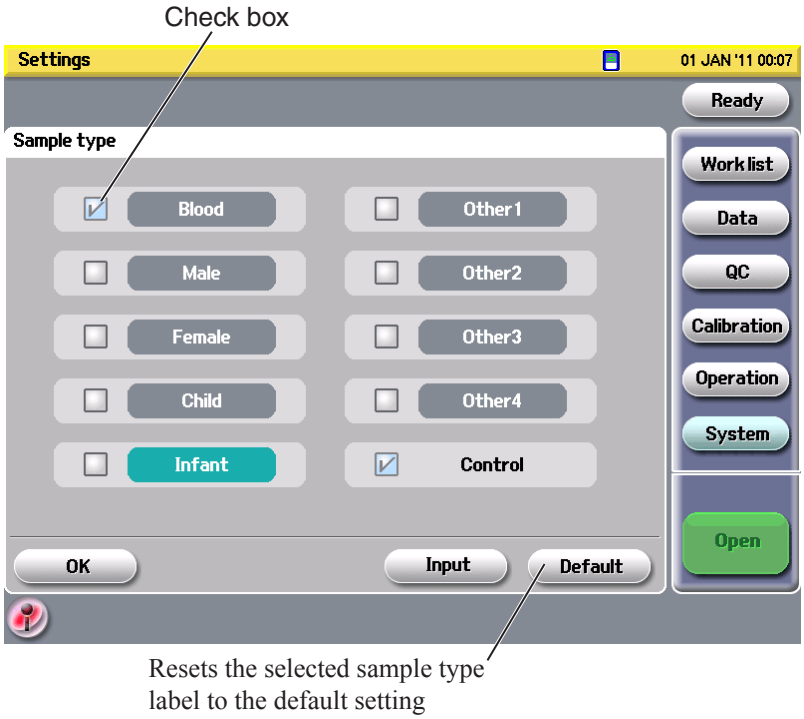
Selecting Sample Types for the Sample Type Selection List

You can set the sample types to be displayed in the sample type selection list. The sample type selection list appears on the Ready, Normal Range, Sens/Thresh, Details (Edit) screen of the Data screen and Search screens.

Press the check box beside the sample type you want to enter for the sample type selection list.

To cancel, press the check box again.





Setting Normal Range Upper and Lower Limits

Each parameter has a normal range. Values outside the normal range can be automatically marked with an H (beyond the upper limit) or L (below the lower limit) mark. The upper and lower limits can be set individually for each parameter. You can set the upper and lower limits individually for different sample types.

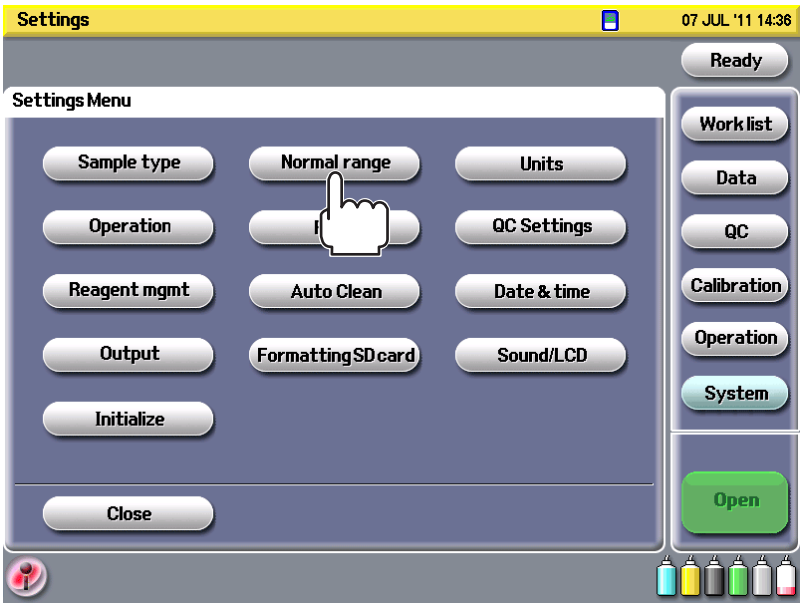
Default Settings of Upper and Lower Limits

Parameter	Default Setting		Variable Range
	Lower Limit	Upper Limit	
WBC ($10^3/\mu L$)	4.0	9.0	0 to 99.9
RBC ($10^6/\mu L$)	3.80	5.30	0 to 14.99
HGB (g/dL)	12.0	18.0	0 to 29.9
HCT (%)	36.0	56.0	0 to 99.9
MCV (fL)	80.0	100.0	20.0 to 199
MCH (pg)	27.0	32.0	10.0 to 50.0
MCHC (g/dL)	32.0	36.0	10.0 to 50.0
PLT ($10^3/\mu L$)	120	380	0 to 1490
NE%	42.0	85.0	0 to 99.9
LY%	11.0	49.0	0 to 99.9
MO%	0.0	9.0	0 to 99.9
EO%	0.0	6.0	0 to 99.9
BA%	0.0	2.0	0 to 99.9
NE ($10^3/\mu L$)	1.7	7.7	0 to 99.9
LY ($10^3/\mu L$)	0.4	4.4	0 to 99.9
MO ($10^3/\mu L$)	0	0.8	0 to 99.9
EO ($10^3/\mu L$)	0	0.6	0 to 99.9
BA ($10^3/\mu L$)	0	0.2	0 to 99.9
RDW-CV (%)	10.0	16.5	0 to 50.0
RDW-SD (fL)	39.0	46.0	0.0 to 199
PCT (%)	0.10	1.00	0 to 2.90
MPV (fL)	5.0	10.0	0 to 20
PDW (%)	12.0	18.0	0 to 50.0

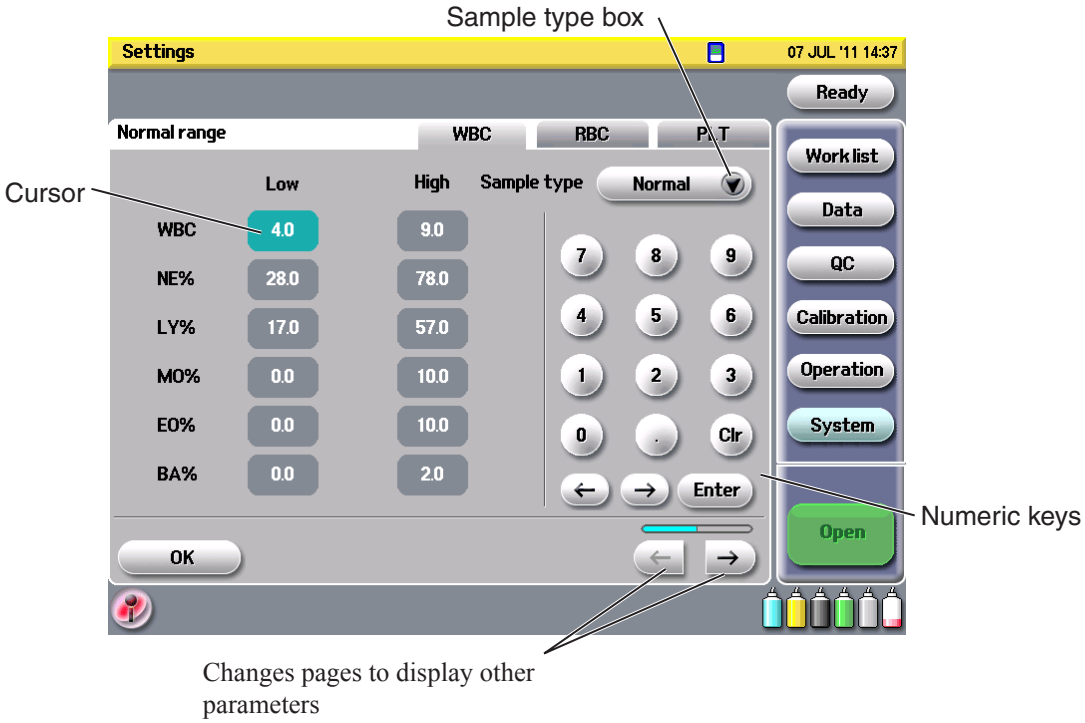
Changing the Limits

To change the limits, the type of user must be either Lab technician or Service.

1. Press the Normal range key on the Settings screen to display the Normal range screen.



2. Select the sample type in the <Sample type> box.



3. Touch the setting value or use the arrow keys to move the cursor to the setting value you want to change.
   Press the ← or → key to display other parameters.

4. Enter the desired value using the numeric keys.

5. Press the Enter key to register the value. The cursor moves to the next parameter.

6. Repeat steps 3 to 5 to change the normal range limits for other sample types.

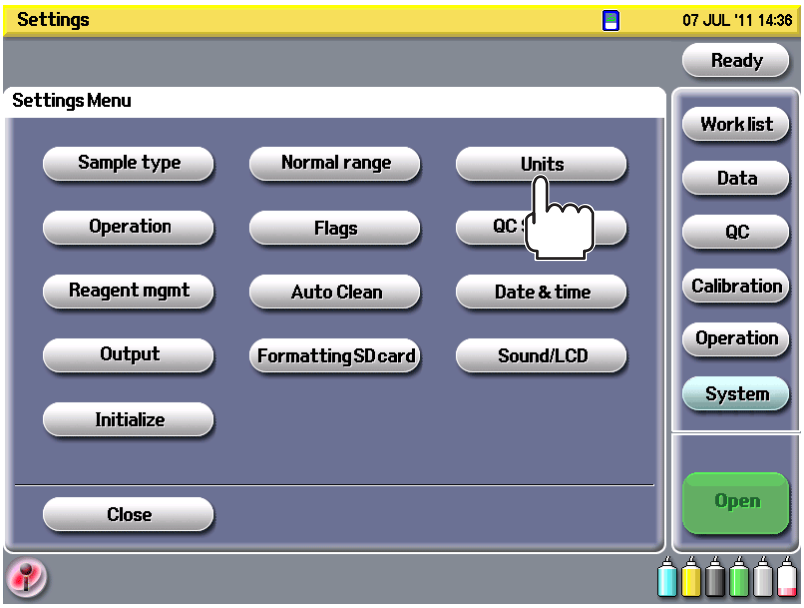
7. When you finish changing the settings, press the OK key to return to the Settings screen.

Selecting Units

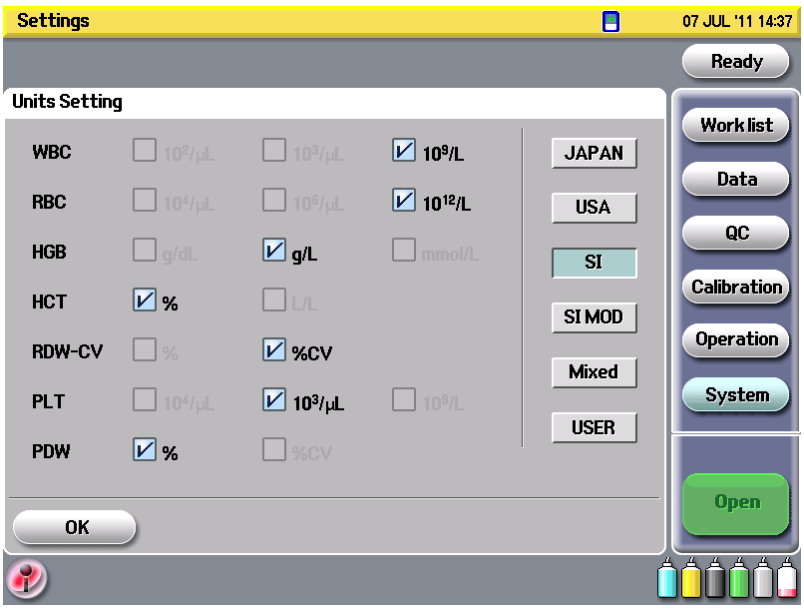
You can select the counting units from JAPAN, USA, SI, SI MOD and Mixed (refer to the table in the "Counting Unit Table" section). You can select different units for different parameters (customize units). These units apply not only to data display but also to printing and sending data. To change the settings, the type of user must be either Lab technician or Service.

Selecting Unit Type

1. Press the Units key on the Settings screen to display the Units screen.



2. Select the unit type on the right side of the window. The unit for each parameter changes according to the selected unit type.



To set your own unit settings, refer to the "Customizing Units" section.

3. Press the OK key to return to the Settings screen.

Counting Unit Table

Parameter	JAPAN	USA	SI	SIMOD	Mixed
WBC	10^2/μL	10^3/μL	10^9/L	10^9/L	10^9/L
RBC	10^4/μL	10^6/μL	10^{12}/L	10^{12}/L	10^{12}/L
HGB	g/dL	g/dL	g/L	mmol/L*	g/L
HCT	%	%	%	%	%
MCV	fL	fL	fL	fL	fL
MCH	pg	pg	pg	fmol	pg
MCHC	g/dL	g/dL	g/L	mmol/L*	g/L
PLT	10^4/μL	10^3/μL	10^3/μL	10^9/L	10^9/L
NE%	%	%	%	%	%
LY%	%	%	%	%	%
MO%	%	%	%	%	%
EO%	%	%	%	%	%
BA%	%	%	%	%	%
NE	10^2/μL	10^3/μL	10^9/L	10^9/L	10^9/L
LY	10^2/μL	10^3/μL	10^9/L	10^9/L	10^9/L
MO	10^2/μL	10^3/μL	10^9/L	10^9/L	10^9/L
EO	10^2/μL	10^3/μL	10^9/L	10^9/L	10^9/L
BA	10^2/μL	10^3/μL	10^9/L	10^9/L	10^9/L
RDW-CV	%	%	%CV	%CV	%CV
PCT	%	%	%	%	%
MPV	fL	fL	fL	fL	fL
PDW	%	%	%	%CV	%
RDW-SD	fL	fL	fL	fL	fL

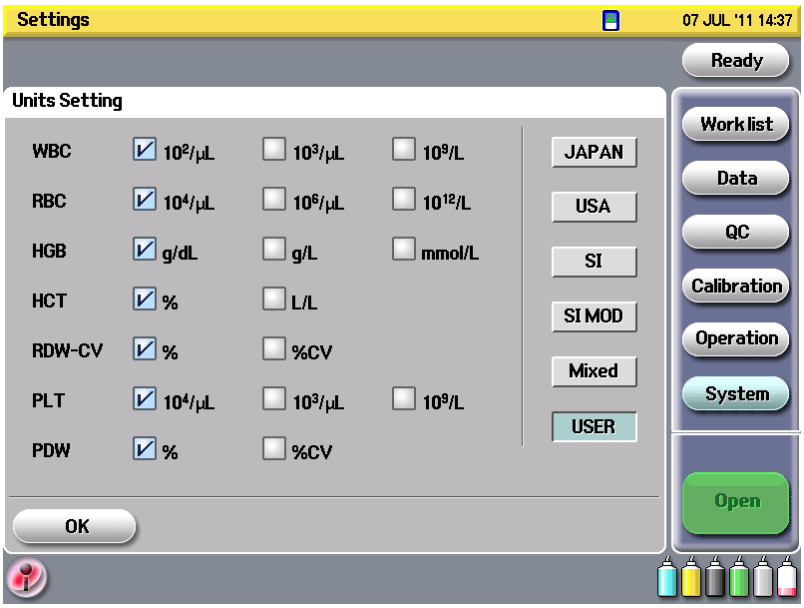
* 1 mmol/L = 1.611 g/dL

Customizing Units

You can select unit for each parameter as shown in the table below.

Item	Settings	Default
WBC	10^2/µL, 10^3/µL, 10^9/L	10^3/µL
RBC	10^4/µL, 10^6/µL, 10^{12}/L	10^6/µL
HGB	g/dL, g/L, mmol/L	g/dL
HCT	%, L/L	%
PLT	10^3/µL, 10^4/µL, 10^9/L	10^3/µL
RDW-CV	%, %CV	%
PDW	%, %CV	%

1. On the Units screen, select “USER” on the right side of the window.



2. Select desired units for each parameter.

3. Press the OK key to return to the Settings screen.

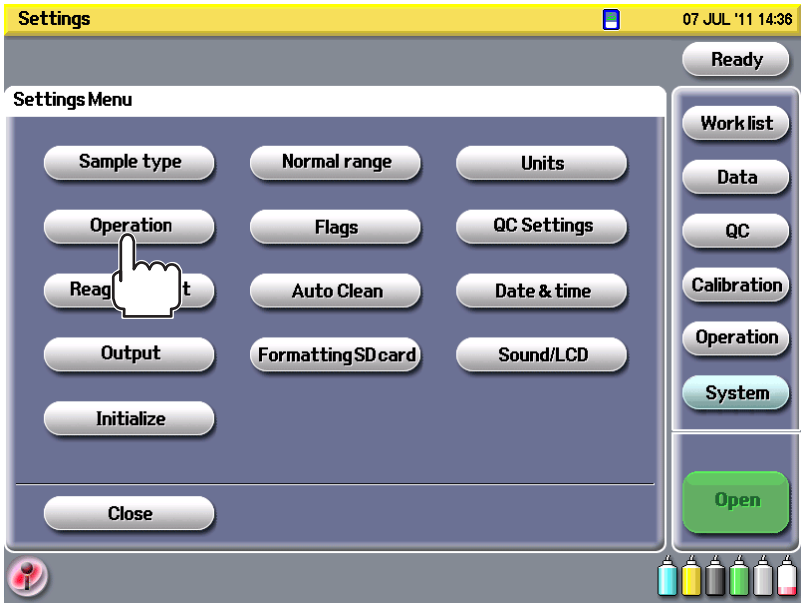
Operation Settings

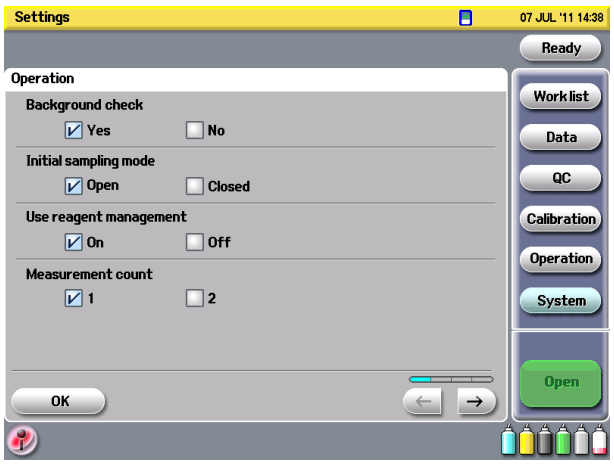
The following items can be set on the Operation window.

Items		Description	Settings	Default
First page	Background check	Select whether or not to perform background measurement during checking after power on.	Yes, No	Yes
	Initial sampling mode	Select closed or open mode. When the power is turned off, the sampling mode returns to this setting.	Closed, Open	Closed
	Use reagent management	Select whether or not to use the reagent management function.	On, Off	Off
	Measurement count	Select to count a sample either once or twice.	1, 2	1
Second page	Display alarm on recount	Select whether or not to display an alarm when recounting a sample.	Yes or No	No
	Measurement result display format	Select whether to display all parameters or CBC eight parameters.	Show all, Show CBC	Show all
	PLT advanced count threshold	Select the threshold under which additional count is performed for the PLT parameter. When "None" is selected, an additional count is not performed. Refer to "Advanced Count" later in this section.	$15 \times 10^4/\mu L$, $10 \times 10^4/\mu L$, $5 \times 10^4/\mu L$ or None	$15 \times 10^4/\mu L$
Third page	Continue dilution mode	Select whether or not to continue measurement in the same dilution mode.	Yes or No	No
	Pre-dilution volume	Select the pre-dilution blood measuring volume.	10 µL or 20 µL	20 µL
	Sync date and time with PC at power on	Select whether or not to synchronize the date and time when the power is turned on. **NOTE** To synchronize the date and time, the analyzer must be connected with the QP-822V data management software.	On, Off	Off
Fourth page	Reset auto ID at power on	Select whether or not to reset ID to 0001 when the power is turned off.	On, Off	On
	Number of digits for ID	Select the digits of the ID.	4-digit, 13-digit	13-digit
	ID Settings	Select the ID display position.	Auto, Left, Right, None	Auto
	Patient ID Setting	Select whether or not to use the patient ID.	On, Off	Off

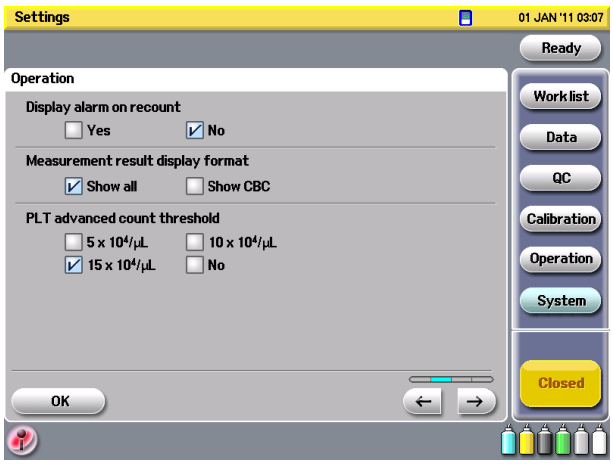
To change the settings, the type of user must be either lab technician or service.

1. Press the Operation key on the Settings screen to display the Operation window.

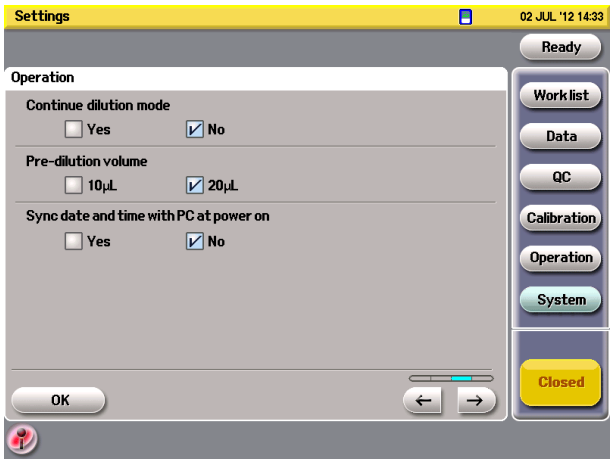




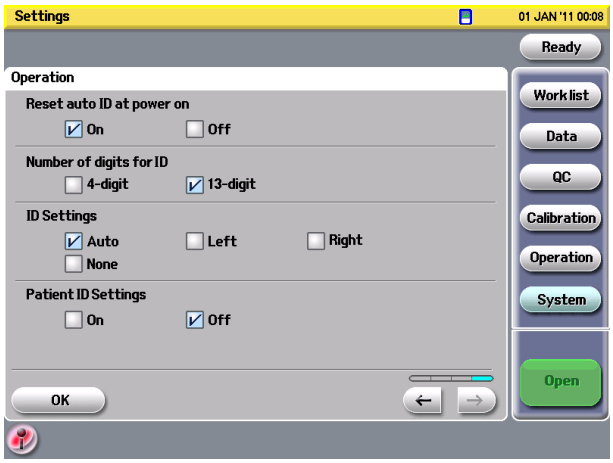
First page



Second page



Third page



Fourth page

2. Select the setting for each item by touching the check box. To change displayed items, press the arrow keys.

3. Press the OK key to return to the Settings screen.

ID Settings and ID Display Format

ID display format differs depending on the ID setting. Refer to the following tables. The setting is on the second page of the Operation setting.

When you set the ID Settings to Auto, only the last 4 digits are incremented. When the last 4 digits are “9999”, the ID is incremented to “0001” for the next sample.

<ID Settings>	<Number of digits for ID>		ID No.	
	4 digits	13 digits	After pressing the Reset key	After measurement
Auto	Right aligned	Left aligned	0001	Increments automatically
Left	Left aligned		No ID assigned, assign an ID manually.	
Right	Right aligned			
No	ID not displayed			

Flag Settings

You can set the standard value for flag display. The analyzer displays flags when the measurement value is out of the setting range. You can also select the flags to highlight in red on the Result or Data screen.

About Settings

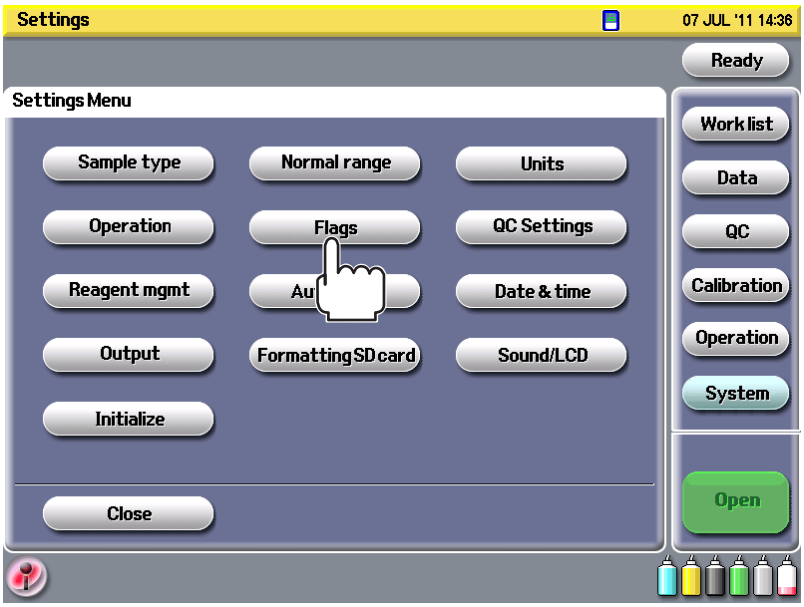
The flag screen has Highlighted, WBC, and RBC*PLT windows. Each window has the following settings.

- Highlighted window: Select the flags to highlight in red on the Result or Data screen.
- WBC window: Select the standard value to display WBC flags.
- RBC*PLT window: Select the standard value to display RBC and PLT flags.

Selecting Flags to Highlight

Select the flags to highlight in red on the Result or Data window.

1. Press the Flags key to display Flags window on the Settings screen.



2. Press the Highlighted tab.

3. Select WBC or RBC*PLT by pressing the WBC or RBC*PLT key.

4. Select the flags to highlight in red on the Result or Data screen by touching the check box. You can select or unselect all the flags by touching the WBC, RBC or PLT check box.

When <Output with "Output" key> setting on the SD Card setting is set to "On", you can capture the window and send it to the SD card by pressing the Output key.

5. Press the OK key to return to the Settings screen.

Setting Items

- WBC

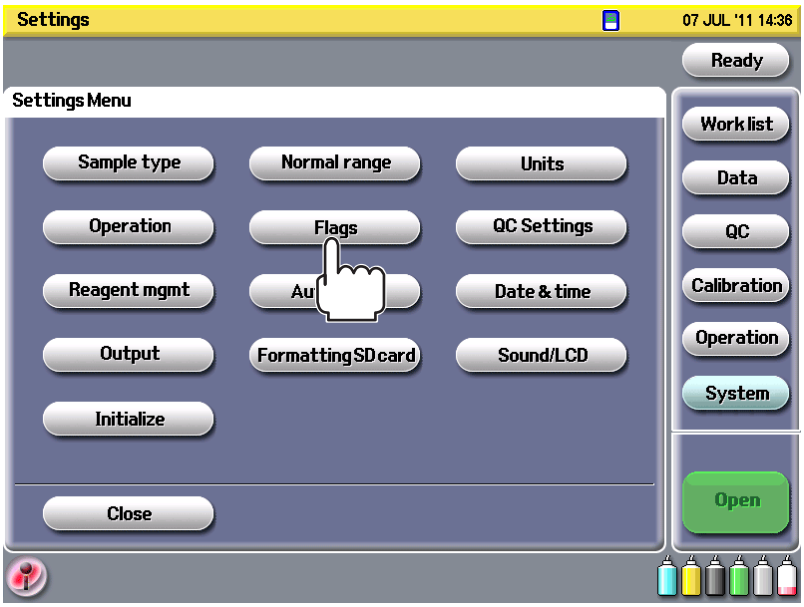
Item	Default	Item	Default
Leukocytosis	Off	Blasts	On
Leukopenia		Immature Gr	
Neutrophilia		Left Shift	
Neutropenia		Atypical Ly	Off
Lymphocytosis		Poor Hemolyzation	On
Lymphopenia		Small Nucleated Cells	Off
Monocytosis		Ly-Mo Interference	
Eosinophilia		Ne-Eo Interference	
Basophilia			

- RBC*PLT

Item	Default	Item	Default
RBC			
Erythrocytosis	Off	Macrocytosis	Off
Anemia		Hypohromia	
Anisocytosis		Abnormal MCHC	
Microcytosis			
PLT			
Thrombocytosis	Off	PLT clumps	On
Thrombocytopenia		PLT-RBC Interfere	Off

Setting the Standard Value to Display Flags

1. Press the Flags key to display Flags window on the Settings screen.



2. Press the WBC or RBC*PLT tab to display WBC or RBC*PLT window.

3. Display the desired flags by pressing the arrow keys and set the value.
   i) Touch the desired value to change. The cursor moves to the value.
   ii) Enter the value with numeric key pad.
   iii) Press the Enter key to set the value. The cursor move to the next value.

When <Output with "Output" key> setting on the SD Card setting is set to "On", you can capture the window and send it to the SD card by pressing the Output key.

4. Press the OK key to return to the Settings screen.

Setting Items

WBC window

Item		Description		Default
First page	Leukocytosis	Leukocytosis flag appears when the WBC value is larger than this setting.	0 to 99.9 ($10^3/\mu L$)	WBC > 18
	Leukopenia	Leukopenia flag appears when the WBC value is smaller than this setting.		WBC < 2.5
	Neutrophilia	Neutrophilia flag appears when the NE value is larger than this setting.		NE > 11
	Neutropenia	Neutropenia flag appears when the NE value is smaller than this value.		NE < 1
	Lymphocytosis	Lymphocytosis flag appears when the LY value is larger than this setting.		LY > 4
Second page	Lymphopenia	Lymphopenia flag appears when the LY value is smaller than this setting.		LY < 0.8
	Monocytosis	Monocytosis flag appears when the MO value is larger than this setting.		MO > 1
	Eosinophilia	Eosinophilia flag appears when the EO value is larger than this setting.		EO > 0.7
	Basophilia	Basophilia flag appears when the BA value is larger than this setting.		BS > 0.2

RBC*PLT window

Item		Description		Default
RBC	Erythrocytosis	Erythrocytosis flag appears when the RBC value is larger than this setting.	0 to 14.99 (10^6/µL)	RBC > 6.5
	Anemia	Anemia flag appears when the HGB value is smaller than this setting.	0.0 to 29.9 (g/dL)	HGB < 10.0
	Anisocytosis	Anisocytosis flag appears when the RDW-CV value is larger than this setting.	0.0 to 99.9 (%)	RDW-CV > 20.0
	Microcytosis	Microcytosis flag appears when the MCV value is smaller than this setting.	0 to 199 (fL)	MCV < 70.0
	Macrocytosis	Macrocytosis flag appears when the MCV value is larger than this setting.		MCV > 110
	Hypohromia	Hypohromia flag appears when the MCHC value is smaller than this setting.	0.0 to 49.9 (g/dL)	MCHC < 29.0
PLT	Thrombocytosis	Thrombocytosis flag appears when the PLT value is larger than this setting.	0.0 to 1490 (10^3/µL)	PLT > 600
	Thrombocytopenia	Thrombocytopenia flag appears when the PLT value is smaller than this setting.		PLT < 60

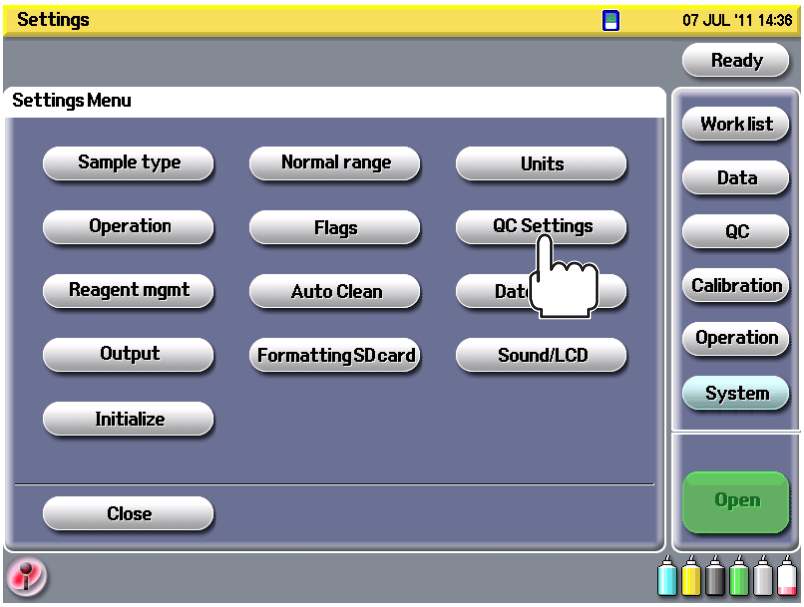
QC Settings Window

Setting Items

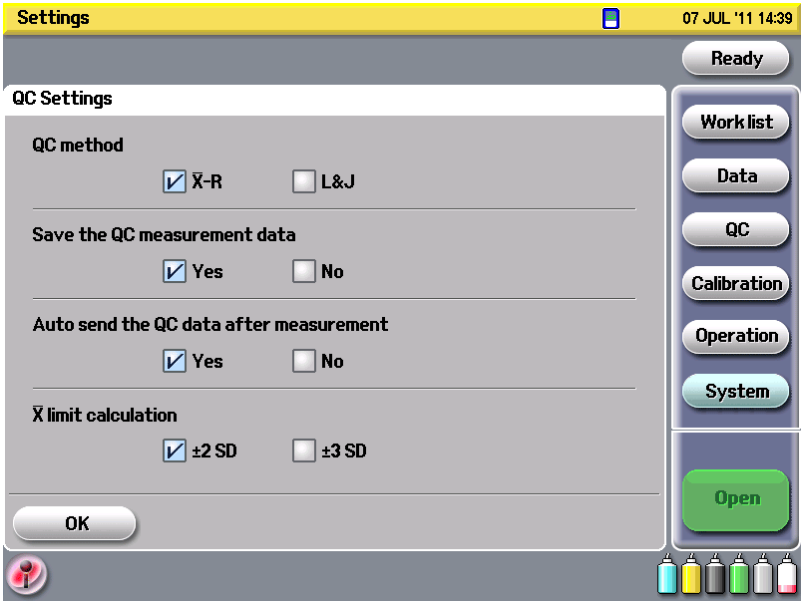
Items	Description	Settings	Default
QC method	Select either $\overline{X}$-R or L&J for the quality control method.	$\overline{X}$-R or L&J	$\overline{X}$-R
Save the QC measurement data	Select whether or not to save the hematology control measurement data on the Data screen.	Yes or No	Yes
Auto send the QC data after measurement	Select whether or not to automatically send the hematology control measured data to the connected instrument after each measurement.	Yes or No	Yes
$\overline{X}$ limit calculation	Select either ±2 SD or ±3 SD for $\overline{X}$ limit calculation.	±2SD or ±3SD	±2SD

Setting the QC Setting

1. Press the QC Settings key to display QC Settings window on the Settings screen.



2. Change settings by touching the check box.



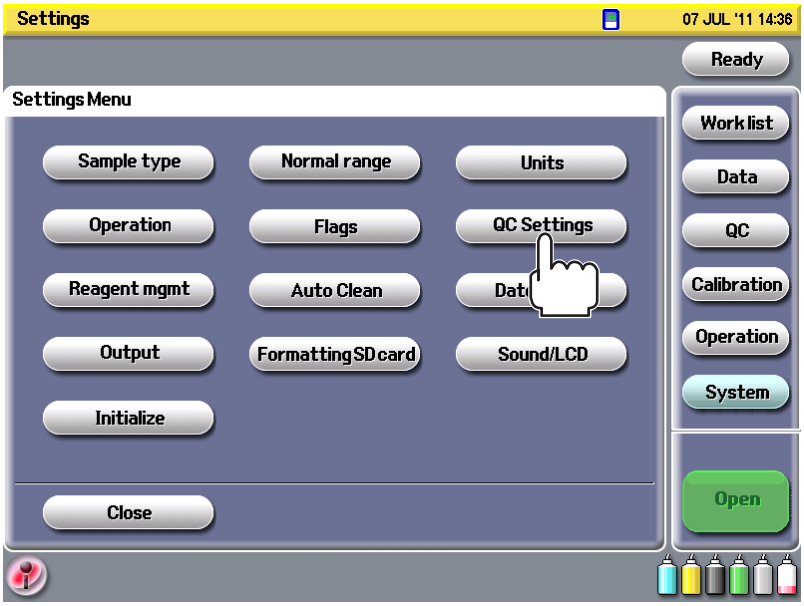
3. Press the OK key to return to the Settings screen.

Setting Reagent Management

You can set the analyzer to display a warning when the reagent or waste reaches the warning level. To change the settings, the type of user must be either Lab technician or Service.

Displaying Reagent Management Window

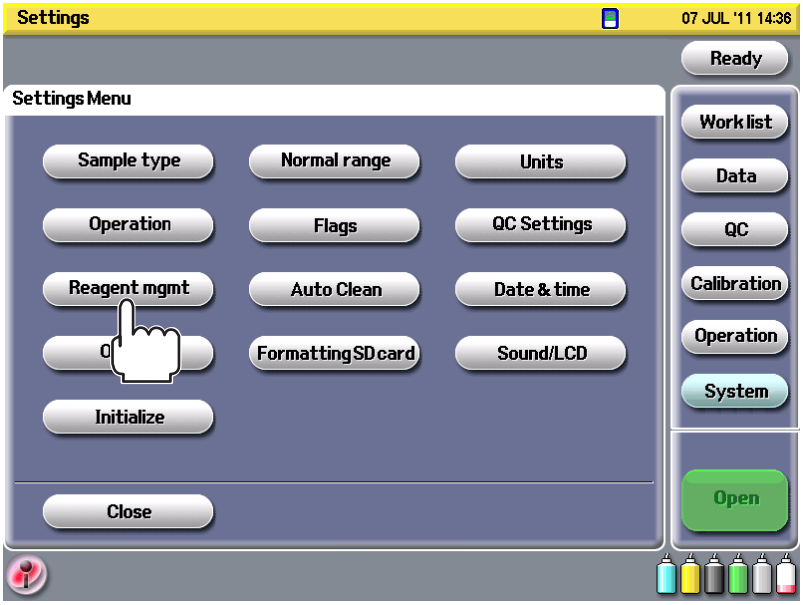
1. Press the QC Settings key to display QC Settings window on the Settings screen.



2. Press the OK key to return to the Settings screen.

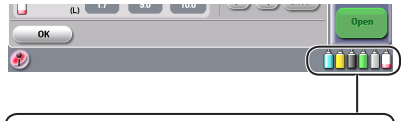
Setting the Warning Level

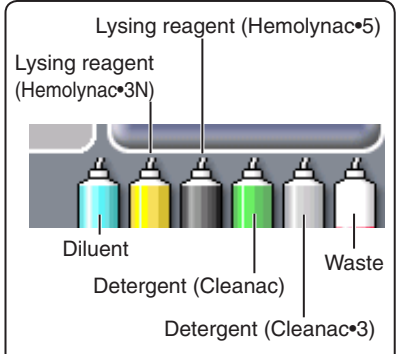
1. Press the Reagent mgmt key on the Settings screen.



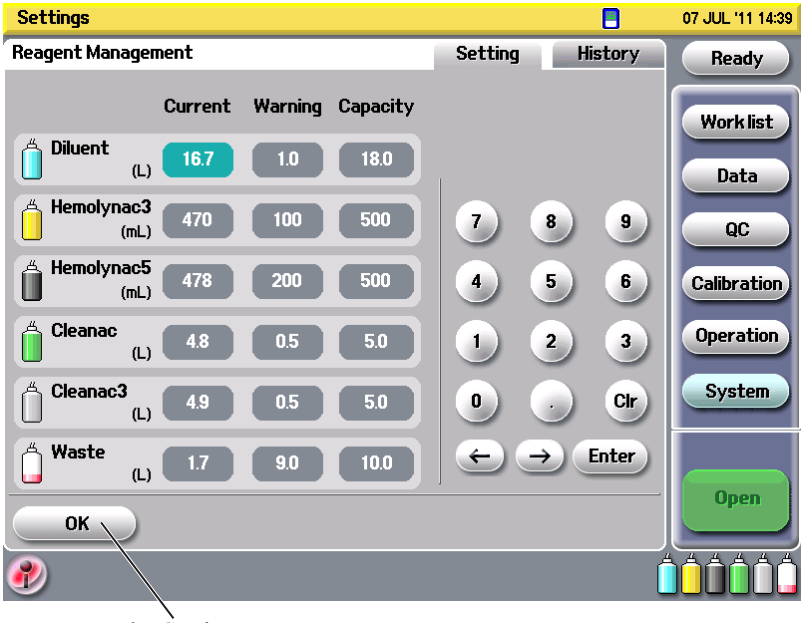
2. Change the setting.
   i) Press the desired value to change. The value is highlighted in green.
   ii) Enter the value with the numeric keypad.
   iii) Press the Enter key to set the value. The cursor moves to the next item.

The reagent bar graph indicates the remaining amount of each reagent and waste level.





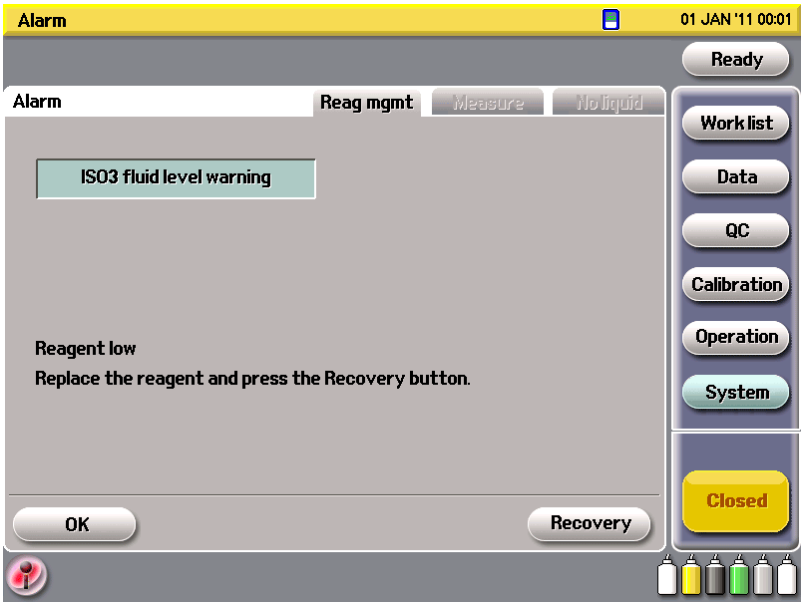
Color of the bar graph	
Diluent (Isotonac•3)	Blue
Lysing reagent (Hemolynac•3N)	Yellow
Lysing reagent (Hemolynac•5)	Black
Detergent (Cleanac)	Green
Detergent (Cleanac•3)	Gray
Waste	Red



Returns to the Settings screen

3. Press the OK key to return to the Settings screen.

When the reagent reaches the warning level, an alarm window is displayed.

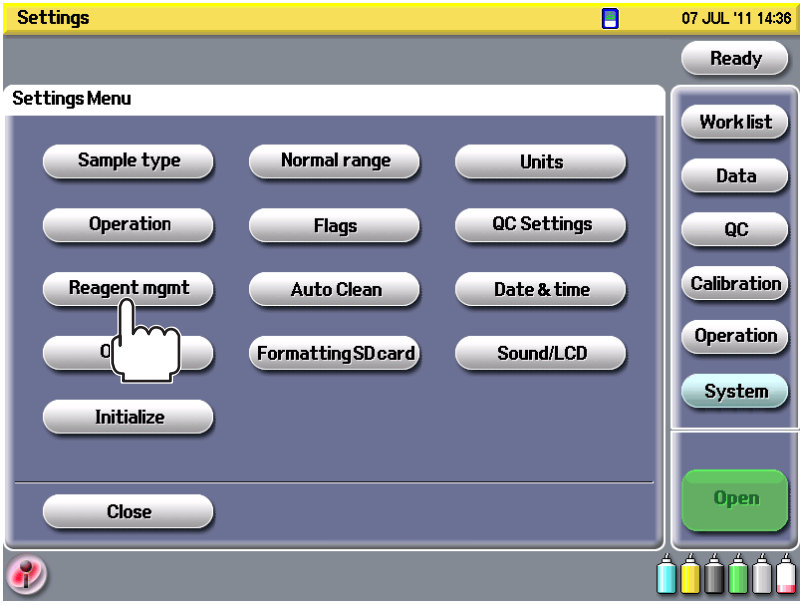


4. After refilling the reagent, change the current reagent level on the Reagent Management window. Set the level on the bottle or package of the reagent.

Checking Reagent Management History

You can check the type, expiration date and replacement date of the reagent on the History window.

1. Press the Reagent mgmt key on the Settings screen.

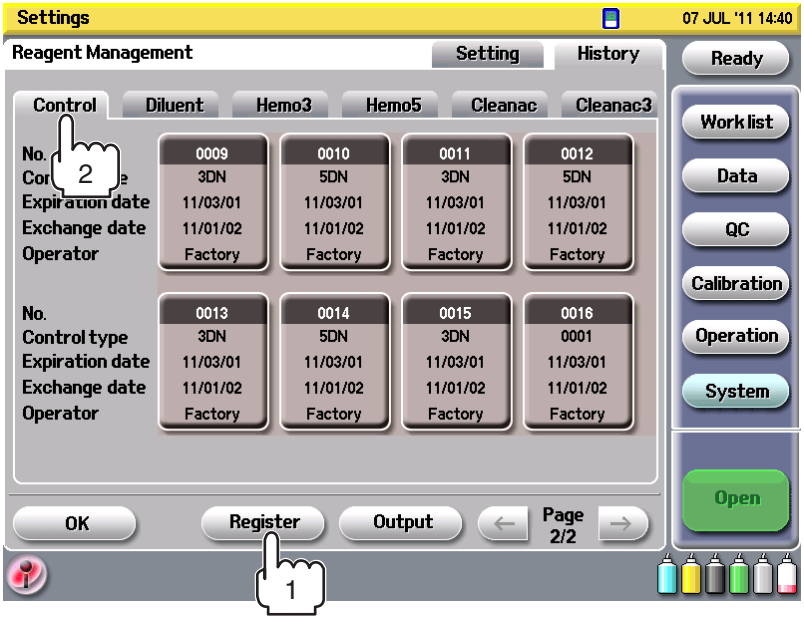


2. Press the History tab to display History window.

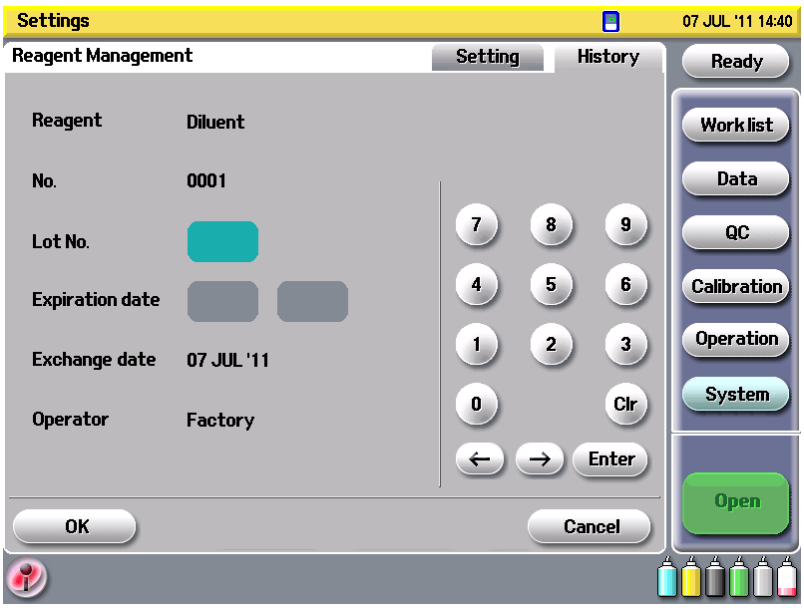
Registering the Reagent Management Information

1. Press the desired reagent tab to register.

2. Press the Register key.



3. Enter the Control type, Lot No. and Expiration date.
   i) Press the item to enter. The item is highlighted in green.
   ii) Enter the value with the numeric keypad.
   iii) Press the Enter key to set the value. The cursor moves to the next item.

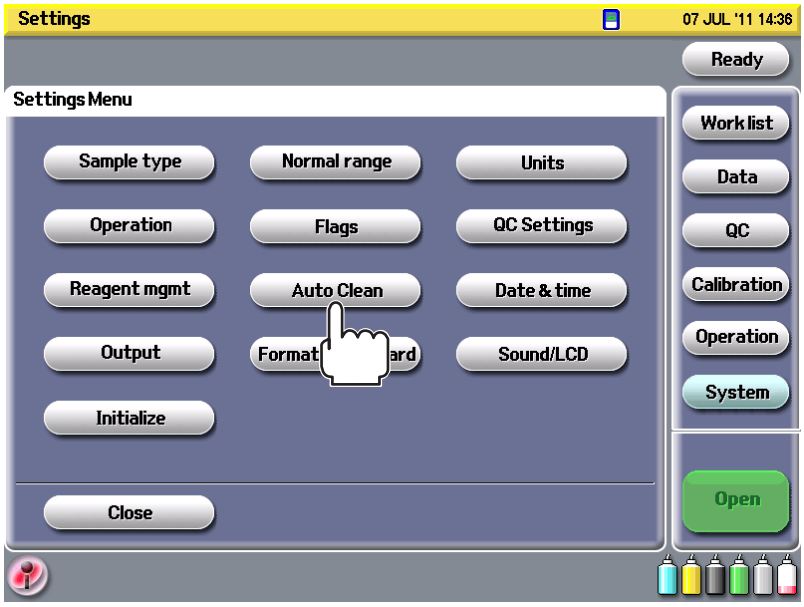


4. Press the OK key to return to the Settings screen.

Setting Auto Priming/Cleaning

To maintain the optimum condition, you can set the analyzer to automatically perform priming or cleaning at a certain time of the day. You can schedule auto priming/cleaning for up to 4 times a day. To change the settings, the type of user must be either Lab technician or Service.

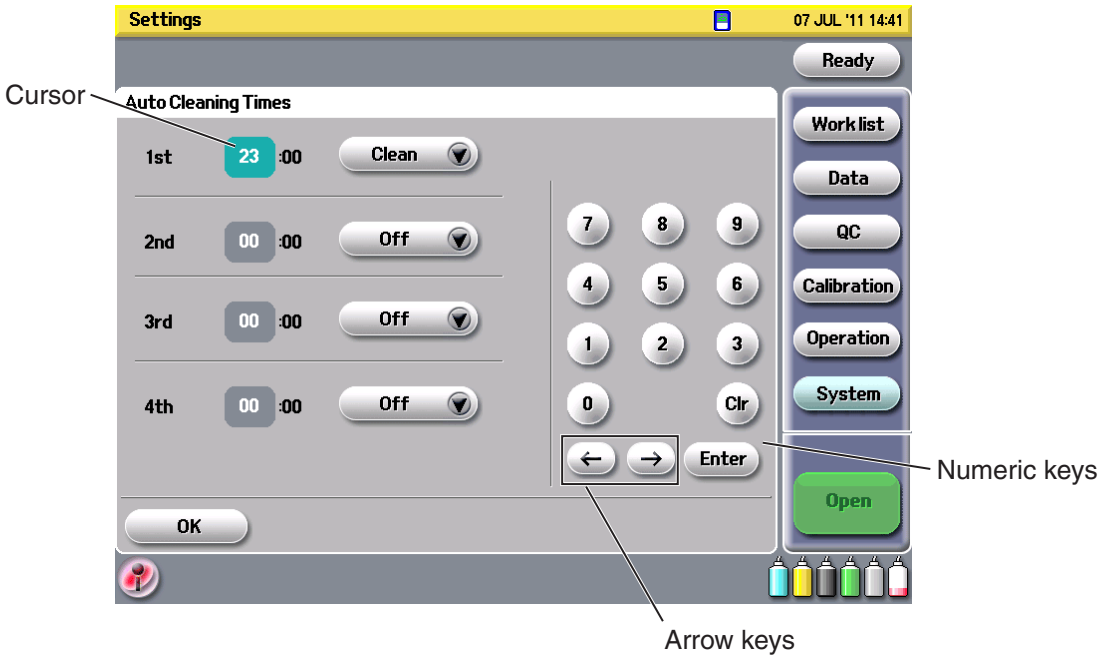
1. Press the Auto Clean key on the Settings screen to display the Auto Clean screen.



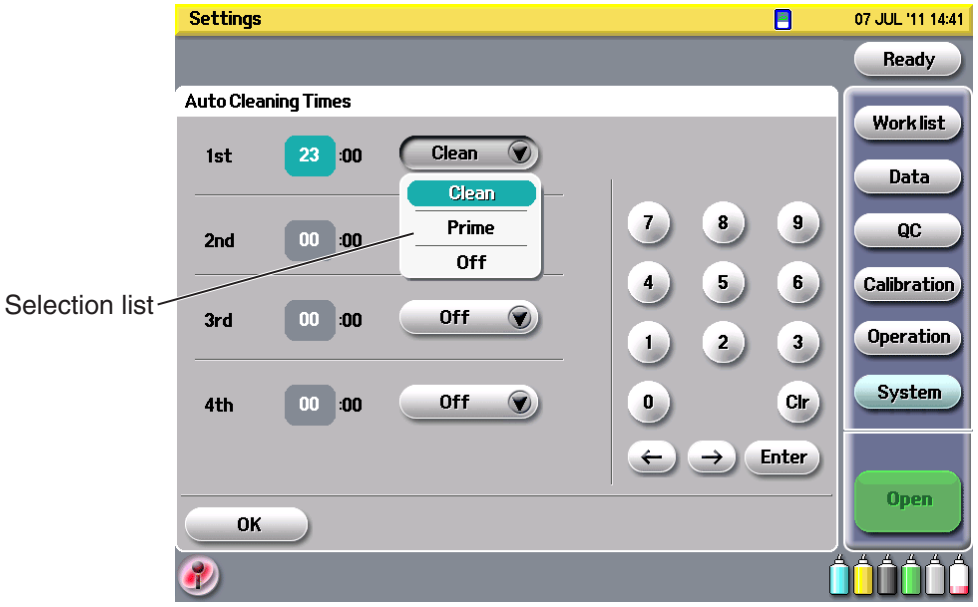
2. Set the time for the schedule.
   i) Touch the setting value or use the arrow keys to move the cursor to the setting value you want to change.
   ii) Enter the desired time with the numeric keys. Use the 24 hour format. (e.g. 17:00)
   iii) Press the Enter key to register the time.

NOTE

You cannot set two or more operations at the same time.



3 Select “Clean”, “Prime” or “Off” from the selection list for each schedule.



4. Press the OK key to return to the Settings screen.

NOTE

- If the analyzer is performing other operations at a scheduled time, priming/cleaning is not performed.
- When setting the auto cleaning and/or priming, check the remaining amount of the reagents and waste level with the reagent management function.

Setting Date and Time

The date and time of the internal clock can be set. The built-in backup circuit maintains the date and time when the analyzer is turned off. You can also select the date format.

NOTE

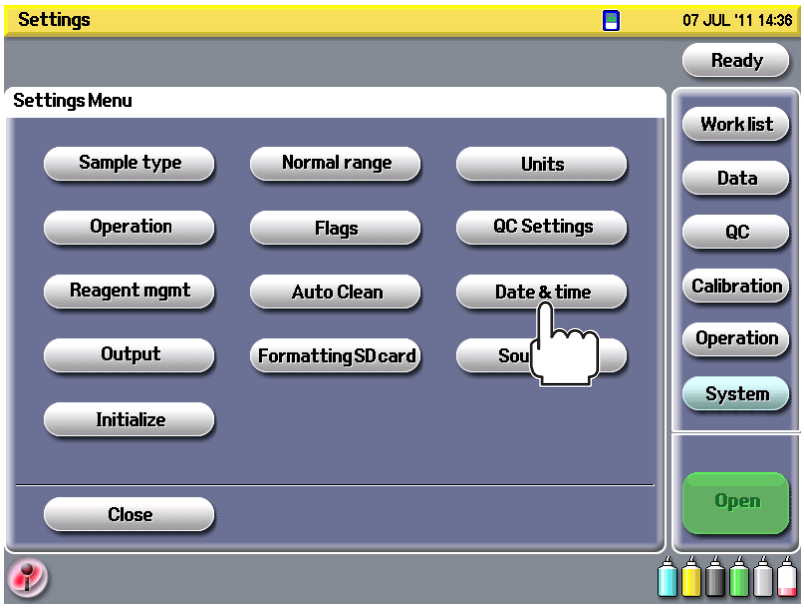
At the start of the day, check that the date and time settings are correct.

Ranges you can set for the date and time are as follows:

Date format:	YY/MM/DD, DD/MM/YY, 'YY MM DD, DD MM 'YY, DD MMM 'YY, MMM DD 'YY
Year:	0 to 99
Month:	1 to 12
Day:	1 to 31
Hour:	0 to 23
Minute:	0 to 59

To change the settings, the type of user must be either Lab technician or Service.

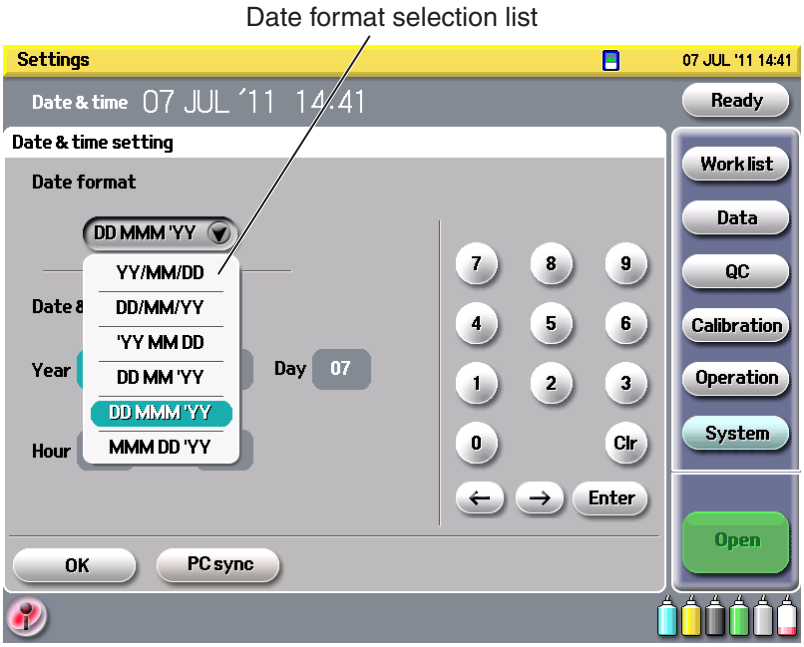
1. Press the Date & time key on the Settings screen to display the Date & time screen.



2. Select the date format in the <Date format> box.

NOTE

The selected date format is also used in stored data, printing, sending and history.



3. Touch the setting value or use the arrow keys to move the cursor to the setting value you want to change.

4. Enter the value using the numeric keys.
When setting <Hour>, use the 24 hour format. e.g. 17:00

5. Press the Enter key to register the value. The cursor moves to the next item.

6. Repeat steps 3 to 5 to enter other items.

7. Press the OK key to return to the Settings screen. The new date and time is applied.

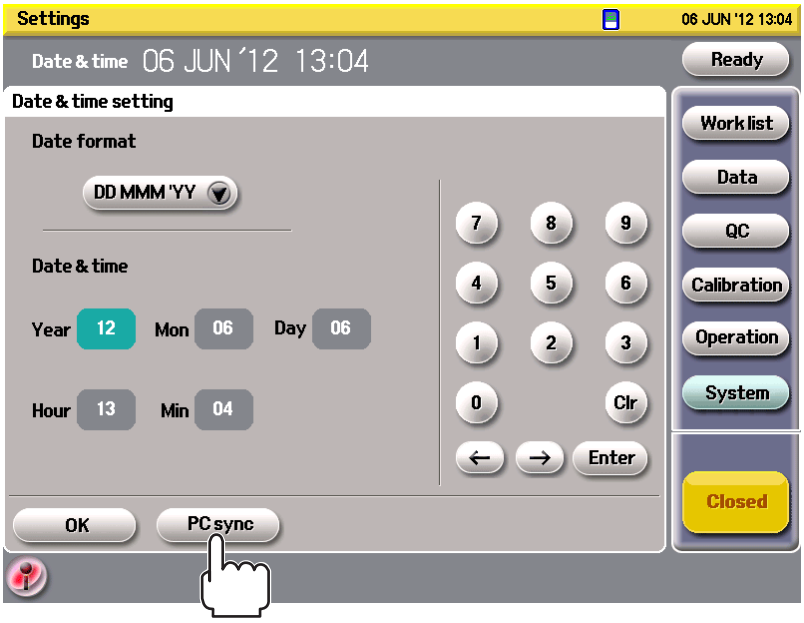
Synchronizing the Date and Time

The date and time of the analyzer can be synchronized with the connected computer.

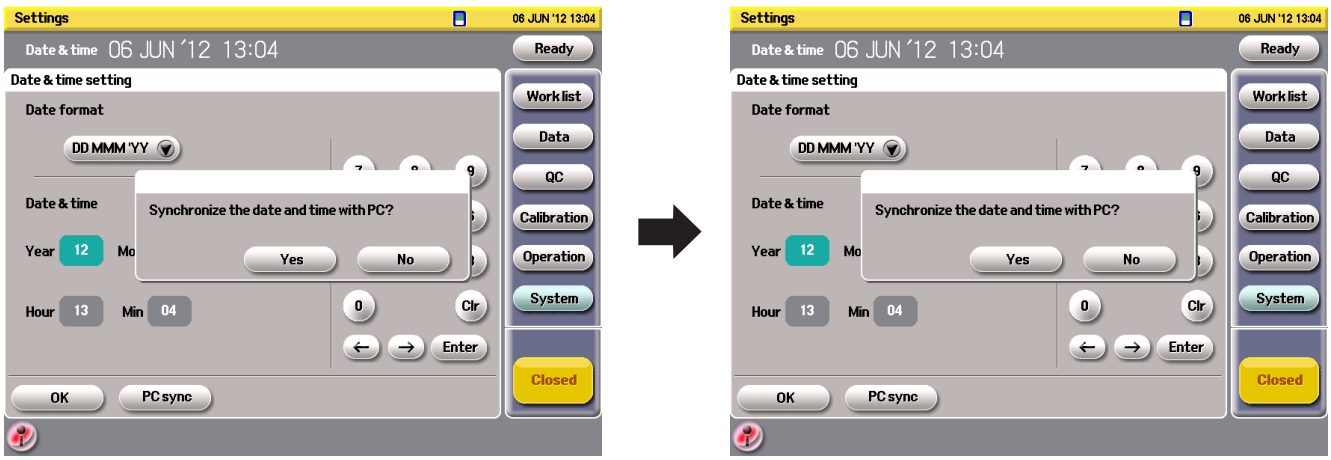
NOTE

- To synchronize the date and time, the QP-822V data management software is required.
- When receiving the data from a PC, the current date and time are overwritten and deleted.
- Connect the PC correctly using the USB socket (device).
- Start the data management software and check that the analyzer and PC are connected.

1. Press the PC sync key on the Date & time setting screen.

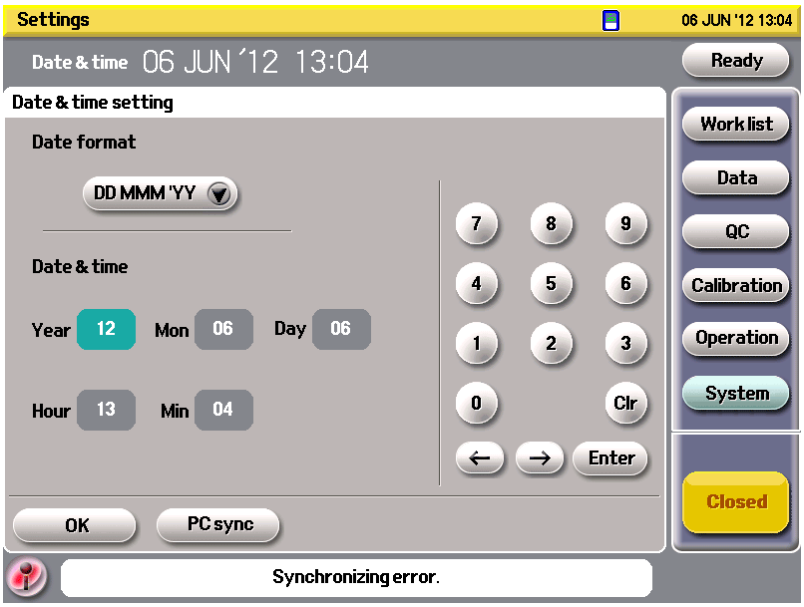


2. Press the Yes key to synchronize the date and time. Press the No key to cancel the synchronization.



3. After synchronization, there is a completion sound and the date and time screen is displayed. Check that the date and time are synchronized correctly.

If the date and time are not synchronized, a “Synchronizing error” message is displayed.



Check the following and synchronize the date and time again.

- The analyzer is correctly connected to the QP-822V data management software.
- The cable is correctly connected to the USB socket (device).

You can synchronize the date and time when the analyzer starts by setting “Sync date and time with PC at power on” to ON on the Operation screen.

Changing Output Format

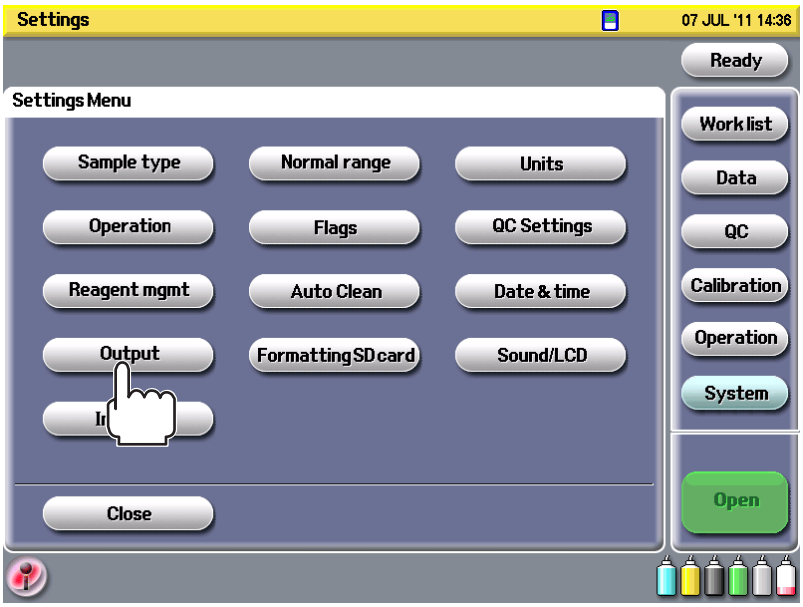
You can select the printers or external devices to which the data will be output. Also, you can automatically send the data to an assigned device after each measurement. To change the settings, the type of user must be either lab technician or service.

Setting Items

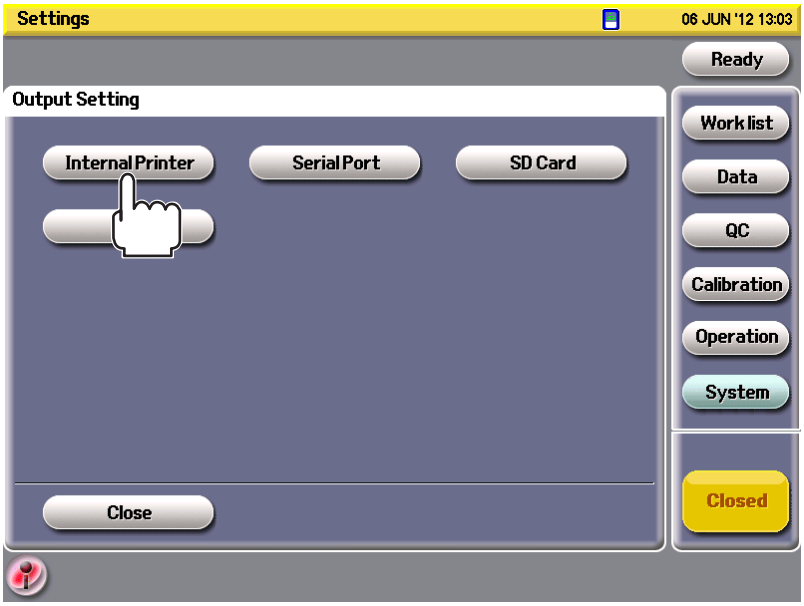
Item	Description
Internal Printer	Settings for printing the data on the internal printer.
Serial Port	Settings for outputting the data to the external device or printer.
SD Card	Settings for outputting the measurement data or settings to the SD memory card.
USB	Settings for transferring the data to the connected PC and analyzer name when receiving the work list.

Changing Settings for Internal Printer

1. Press the Output key on the Settings screen to display the Output window.

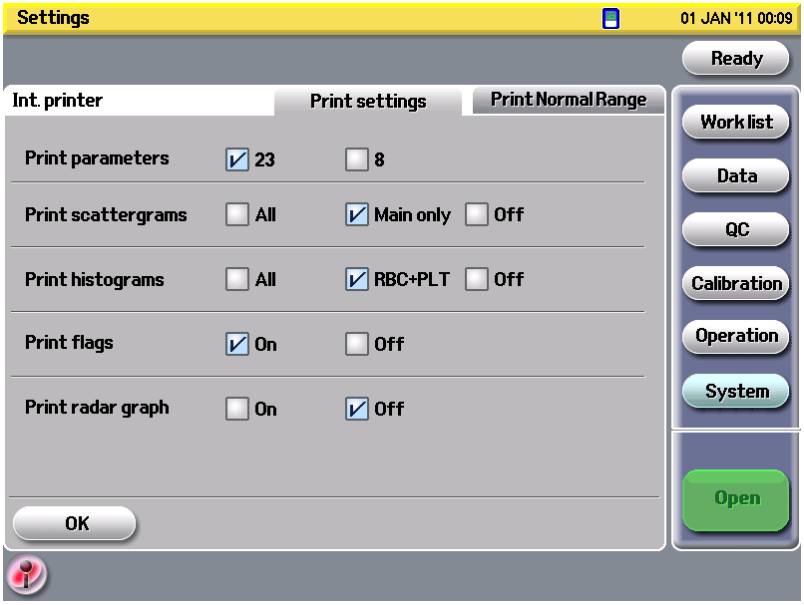


2. Press the Internal Printer key.



3. Touch the Print settings or Print Normal Range tab.

4. Change the settings by pressing the check box.



5. Press the OK key to return to the Output Setting screen.

6. Press the Close key to return to the Ready screen.

Setting Items

Print settings tab

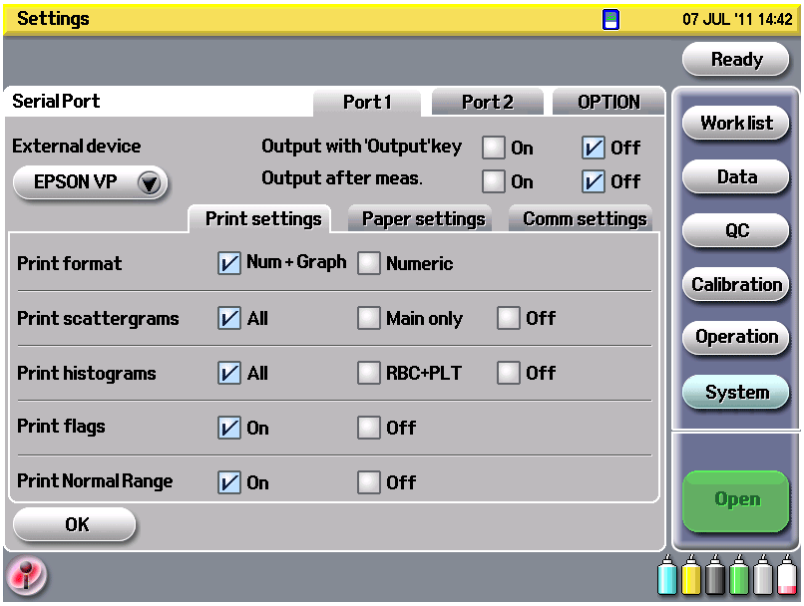
Item	Description		Default
Print parameters	Select number of parameters for printing numeric data.	23, 8	23
Print scattergrams	Select whether or not to print scattergrams.	All, Main only, Off	Main only
Print histograms	Select whether or not to print histograms.	All, RBC+PLT, Off	RBC + PLT
Print flags	Select whether or not to print the flags when they appear.	On, Off	On
Print radar graph	Select whether or not to print chart.	On, Off	Off

Print Normal Range tab

Item	Description		Default
Print Normal Range	Select whether or not to print normal range for each parameter.	WBC, NE, LY, MO, EO, BA, NE%, LY%, MO%, EO%, BA%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PCT, MPV, PDW	Off for all parameters

Changing Serial Port Settings

When transferring data from the serial port, change the serial port settings to match the receiving instrument. There are three ports: port 1, port 2 and OPTION port. The setting is on the Serial Port window of the Output screen. There are common settings and individual settings for each port.



Common Settings

Item	Description		Default
External device (Port 1 and Port 2)	Select the external device to connect to the serial port.	EPSON VP, Card Printers, PC, Other	Port 1: EPSON VP Port 2: PC
Output after meas.	Select whether or not to automatically print data after measurement.	On, Off	Port 1, Port 2: Off OPTION: On
Output with "Output" key	Select whether or not to output data when you press the Output key on the screen.	On, Off	Port 1, Port 2: Off OPTION: On

Individual Settings

Settings for EPSON VP

Item	Description		Default
Print settings			
Print format	Select to print numerical data only or numerical data and graph	Num+Graph, Numeric	Num+Graph
Print scattergrams*	Select whether or not to print scattergrams.	All, Main only, Off	All
Print histograms*	Select whether or not to print histograms.	All, RBC+PLT, Off	All
Print flags*	Select whether or not to print flags.	On, Off	On
Print Normal Range*	Select whether or not to print normal range.	On, Off	On
Paper settings			
Paper length	Select the length of the recording paper.	1 to 255 Data/ Page	66
Paper width	Select the width of the recording paper.	Wide, Narrow	Wide

Item	Description		Default
Comm settings			
Baud rate	Select the data transmission speed.	1200, 2400, 4800, 9600, 19200	19200
Data bits	Select data bits.	7, 8	8
Parity	Select parity bit.	Odd, Even, None	None
Stop bits	Select stop bits.	1, 2	1

* Only available when the Print format is set to Num+Graph.

Settings for Card Printers

Item	Description		Default
Print settings			
Print parameters	Select the number of parameters for printing numeric data.	23, 8	23
Print Item Names	Select whether or not to print item names.	23, DIFF only, Off	DIFF only
Top space	Select the number of blank lines at the top of the recording paper.	1 to 50 lines	5
Left space	Select the amount of blank space at the left side of the recording paper.	0 to 26	0
Row size	Select the width of the row.	5 to 60 inches	10
Comm settings			
Baud rate	Select the data transmission speed.	1200, 2400, 4800, 9600, 19200	9600
Data bits	Select data bits.	7, 8	8
Parity	Select parity bit.	Odd, Even, None	Even
Stop bits	Select stop bits.	1, 2	1

Settings for PC

Item	Description		Default
Comm settings			
Baud rate	Set the data transfer format to the connected instrument.	1200, 2400, 4800, 9600, 19200	19200
Data bits		7, 8	8
Parity		Odd, Even, None	None
Stop bits		1, 2	1

Settings for Other

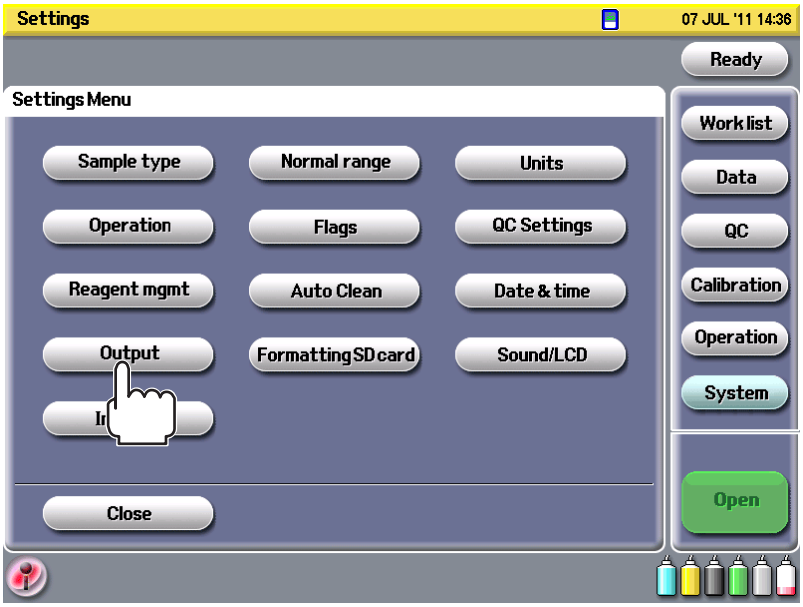
Item	Description		Default
Comm settings			
Baud rate	Set the data transfer format to the connected instrument.	1200, 2400, 4800, 9600, 19200	9600
Data bits		7, 8	8
Parity		Odd, Even, None	Even
Stop bits		1, 2	1

Settings for OPTION window

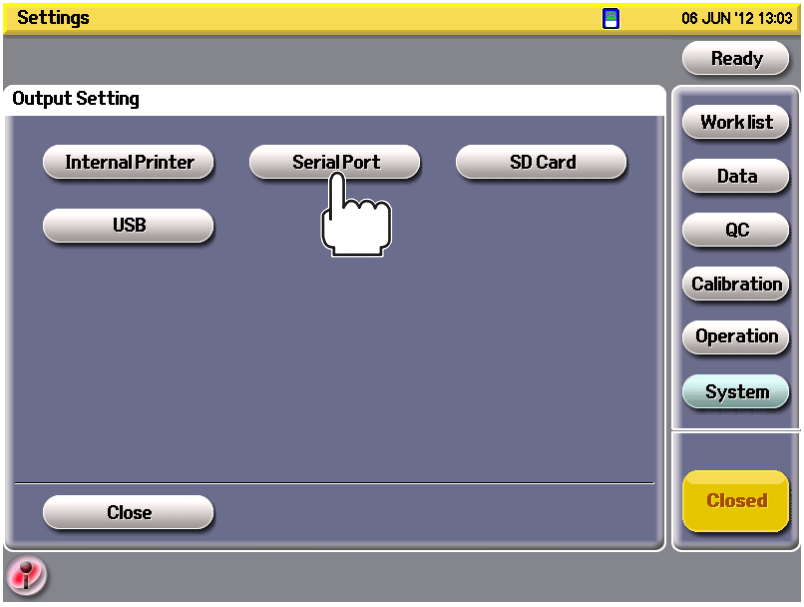
Item	Description		Default
Output settings			
Output setting	Select the data format for communication	Other, Card printer	Other
Comm settings			
Baud rate	Set the data transfer format to the connected instrument.	1200, 2400, 4800, 9600, 19200	9600
Data bits		7, 8	8
Parity		Odd, Even, None	Even
Stop bits		1, 2	1

Changing Settings for Serial Port

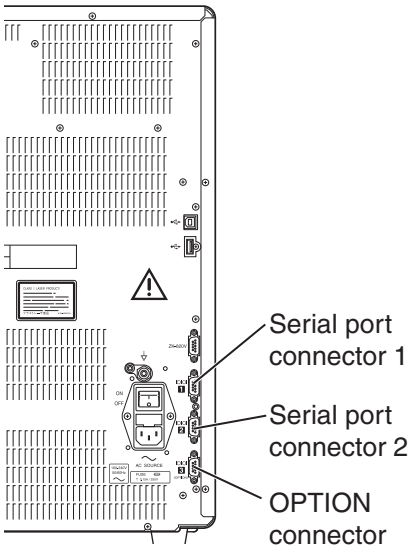
1. Press the Output key on the Settings screen to display the Output window.



2. Press the Serial Port key.

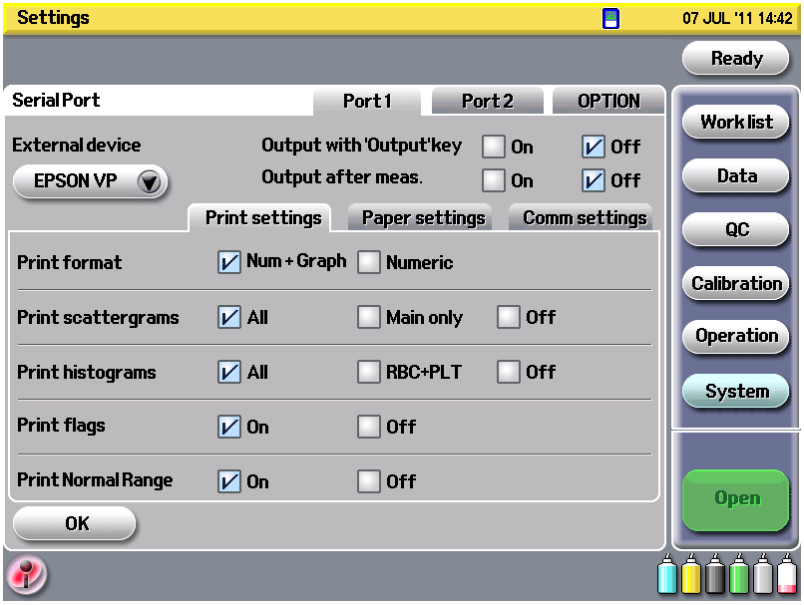


Rear panel



3. Press the desired tab to display setting window.
   Port 1: Settings for output signal from serial port connector 1.
   Port 2: Settings for output signal from serial port connector 2.
   OPTION: Settings for output signal from OPTION connector.

4. Change the settings by pressing the check boxes.

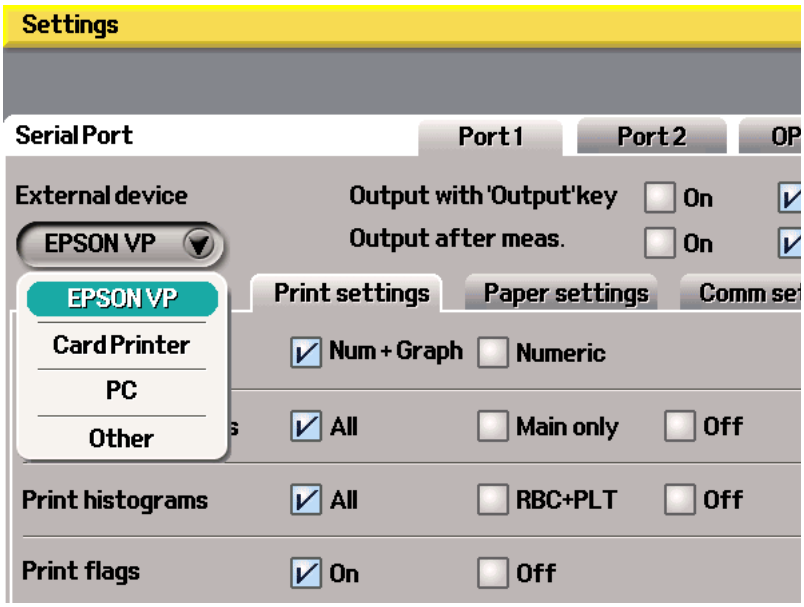


5. Press the OK key to return to the Output screen.

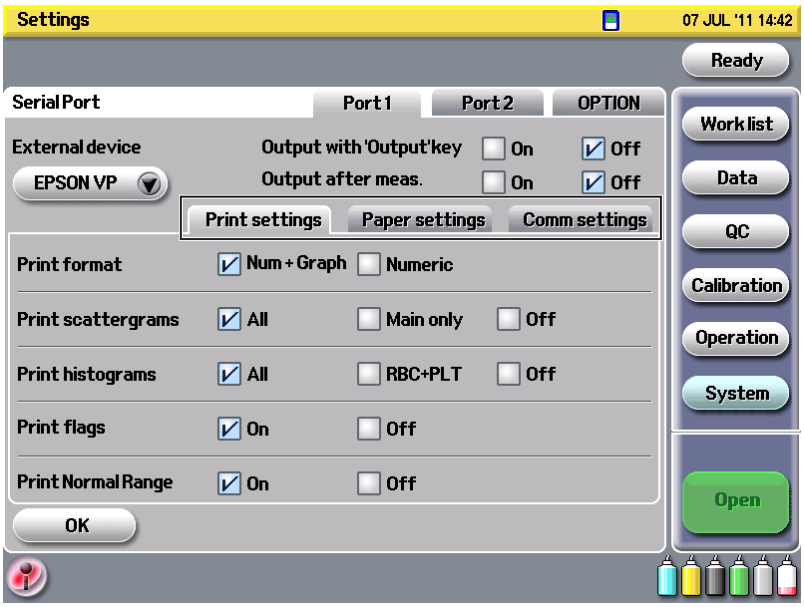
Changing Settings

1. Press the desired tab to change settings.

2. Select the connected instrument in the <External device> box. The settings changes depending on the selected instrument.



3. Press the desired setting tab and change the settings by pressing the check box.

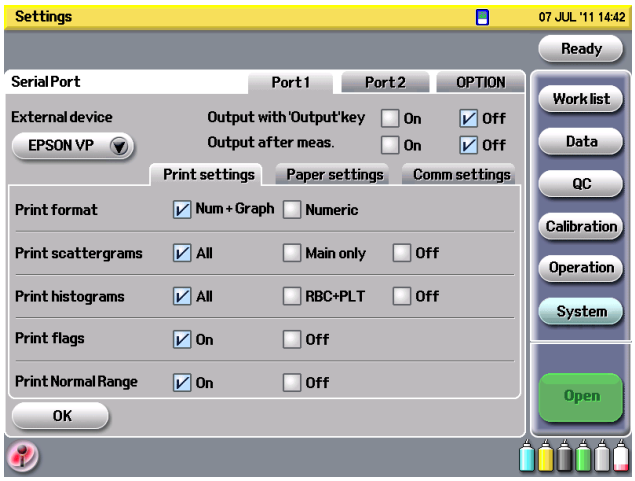


4. Press the OK key to return to the Output screen.

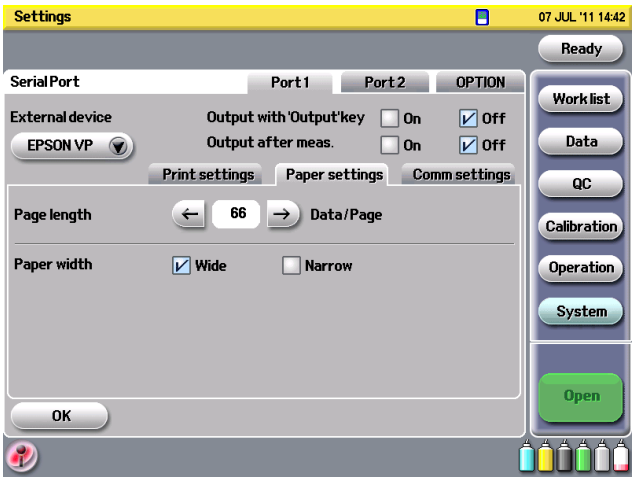
Screen Example

EPSON VP

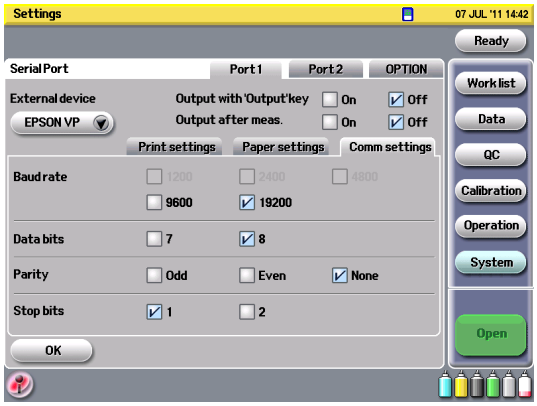
Print settings tab



Paper settings tab

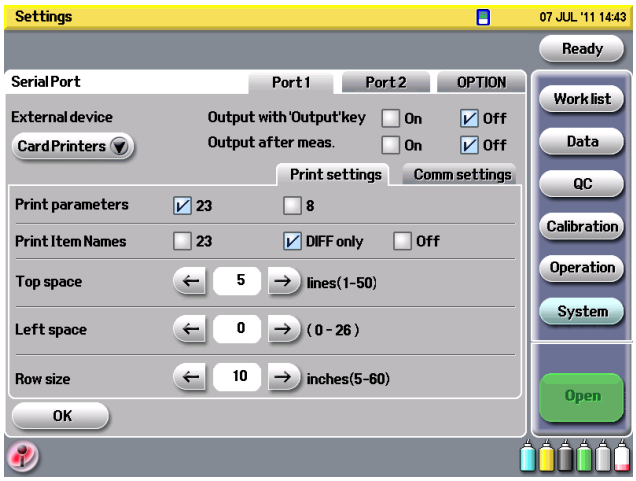


Comm settings tab

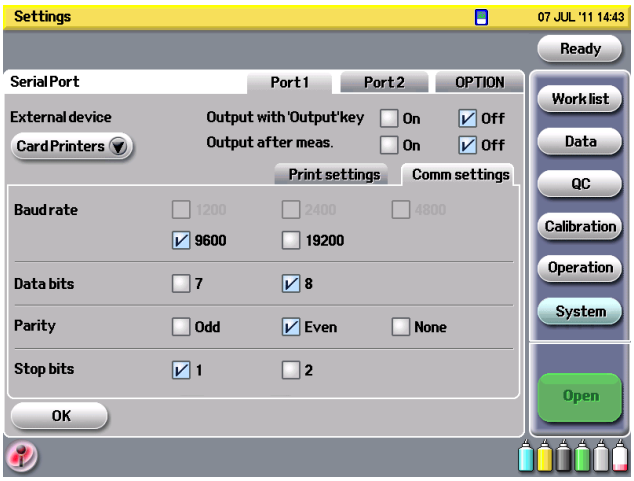


Card Printers

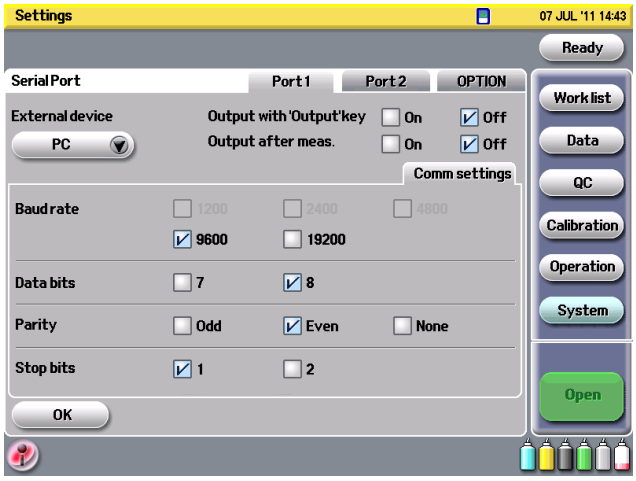
Print settings tab



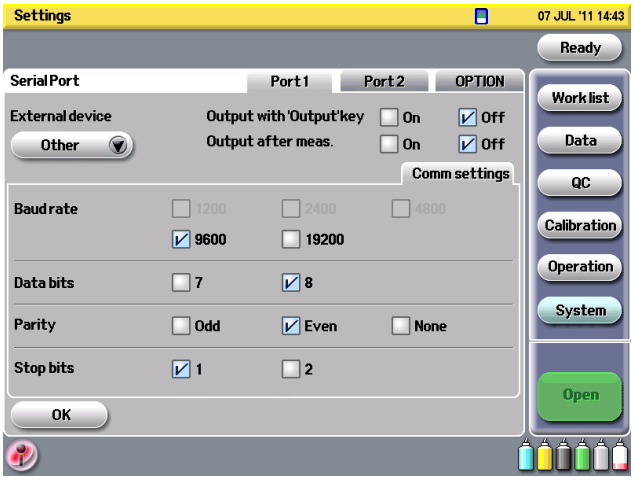
Comm settings tab



PC

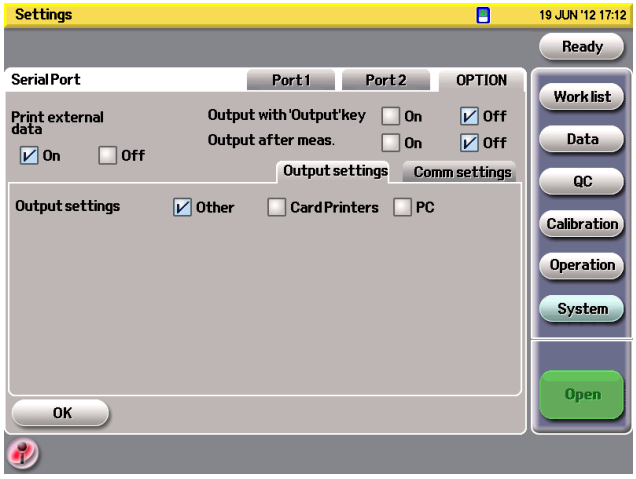


Other

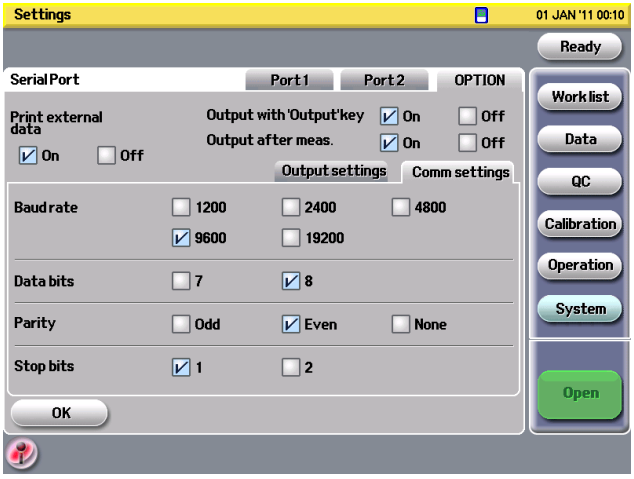


OPTION tab

Output settings tab



Comm settings tab

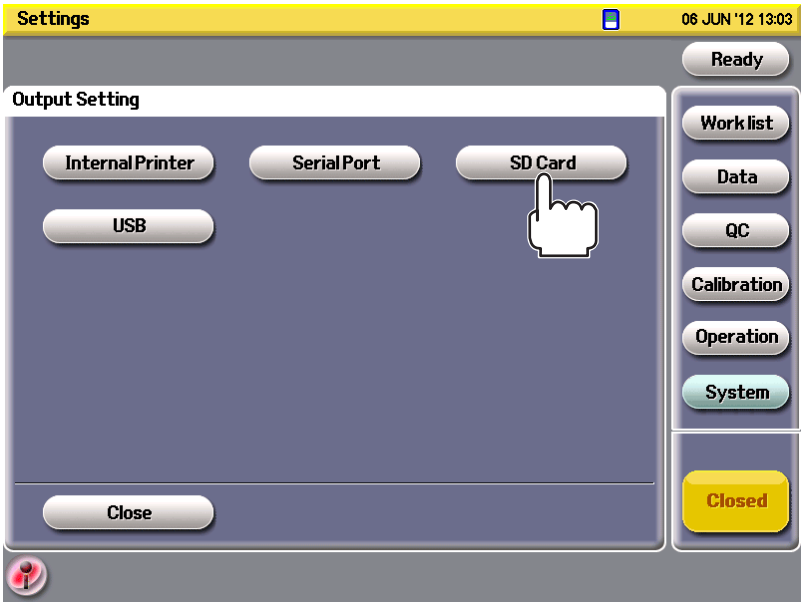


SD Card Setting Items

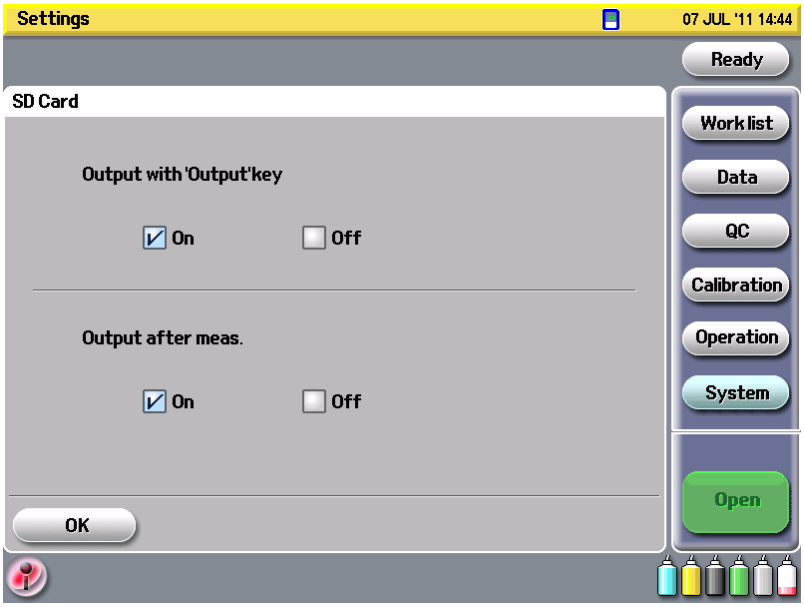
Item	Description		Default
Output with "Output" key	Select whether or not to send data when you press the Send key on the screen.	On, Off	On
Output after meas.	Select whether or not to automatically output data after measurement.	On, Off	Off

Changing SD Card Settings

1. Press the SD Card key to display SD Card window.



2. Change the settings by pressing the check box.



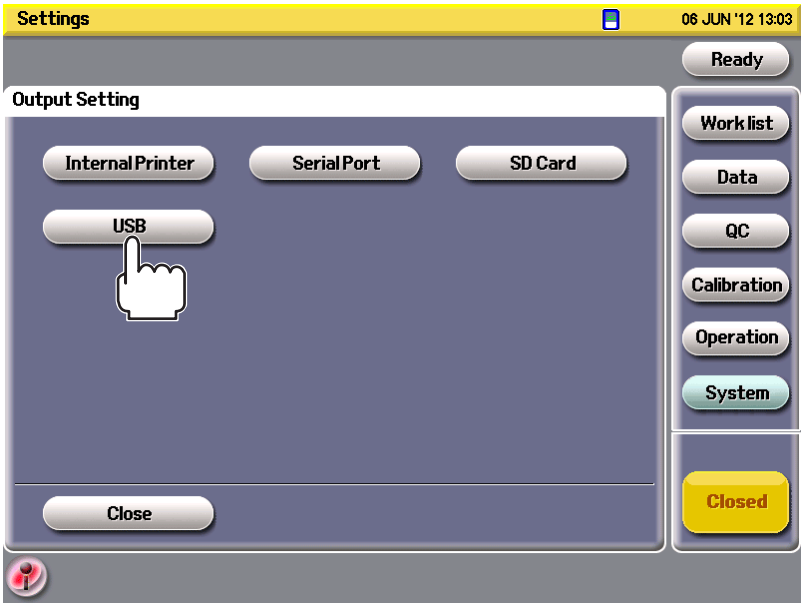
3. Press the OK key to return to the Output Setting screen.

USB Setting Items

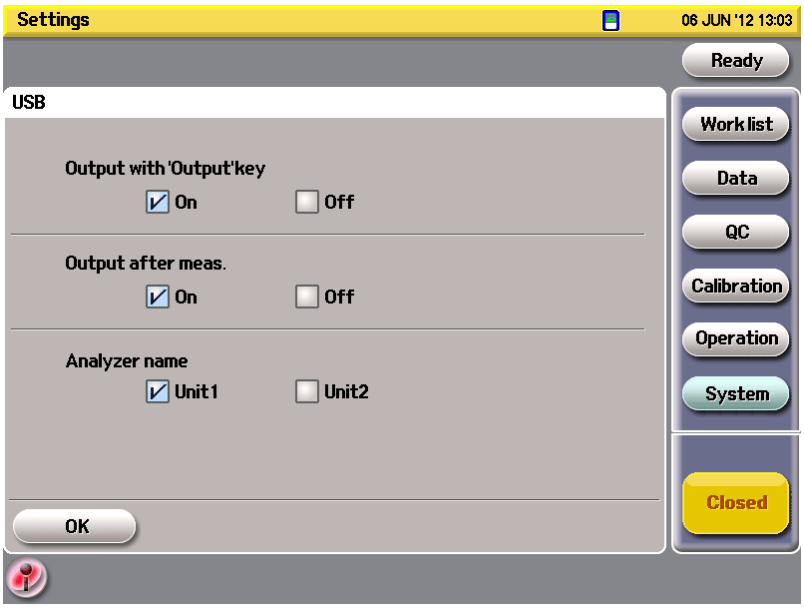
Item	Description		Default
Output with "Output" key	Select whether to send data when you press the Send key on the screen.	On, Off	On
Output after meas.	Select whether to automatically output data after measurement.	On, Off	Off
Analyzer name	Set the analyzer name when two analyzers are connected to a PC.	Unit 1, Unit 2	Unit 1

Changing USB Settings

1. Press the USB key to display the USB window.



2. Change the settings by pressing the check box.

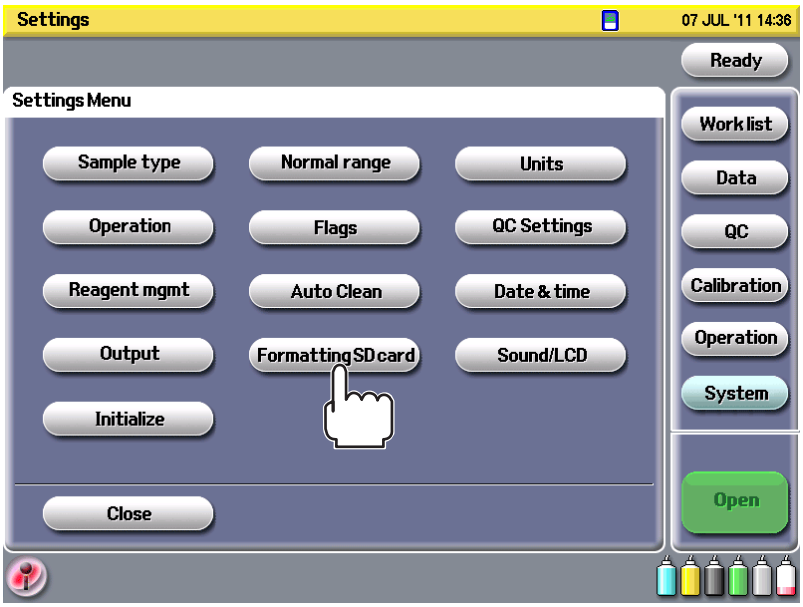


3. Press the OK key to return to the Output Setting screen.

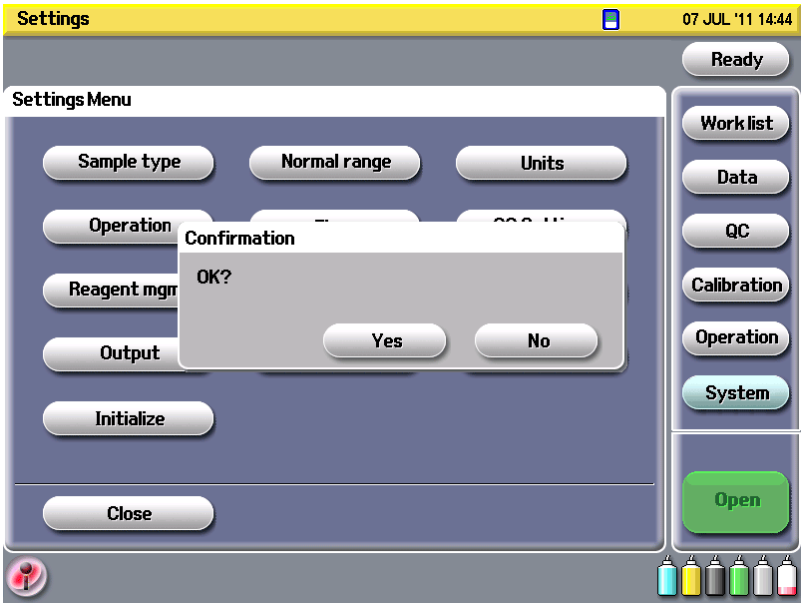
Formatting SD Card

Format the SD card. Otherwise, the measurement data cannot be saved.

1. Press the Formatting SD card key on the Settings screen. A confirmation message appears.



2. Press the Yes key. The SD card is formatted and the window closes.



Precaution about Format

When a SD card is formatted, the folder composition is as follows. Back up the data because all the save data is deleted.

Volume label: MEK-SD

File system: FAT

Folder composition of the SD card

MEK-SD

├ DATA	folder to save the measurement data
├ LOG	folder to save the log file
├ SETTINGS	folder to save the setting information
└ SNAPSHOT	folder to save the screen data

Precautions about Backup

The measurement data is saved in hierarchical year/month/day folder in the DATA folder. Check the following:

- When backing up the data with the external instrument, copy the data or folder.
- When backing up the data, do not change the folder composition or delete the folder. The analyzer cannot read and display the data correctly. If changing the folder composition or deleting the folder, format the SD card once again.
- By transferring the backup data to the appropriate folder, the analyzer can display the data. But do not write the other file from the external instrument to the folder. The analyzer cannot display a data correctly.

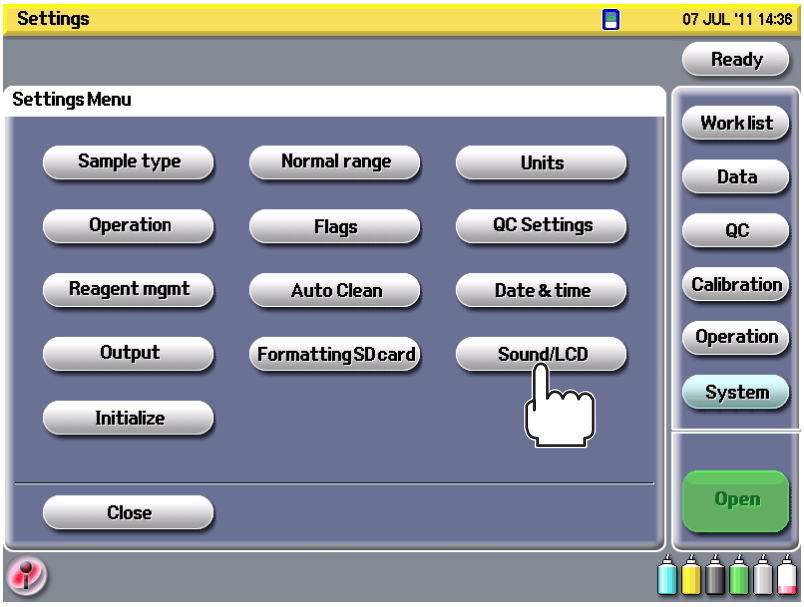
Changing Sound and LCD Settings

Setting Items

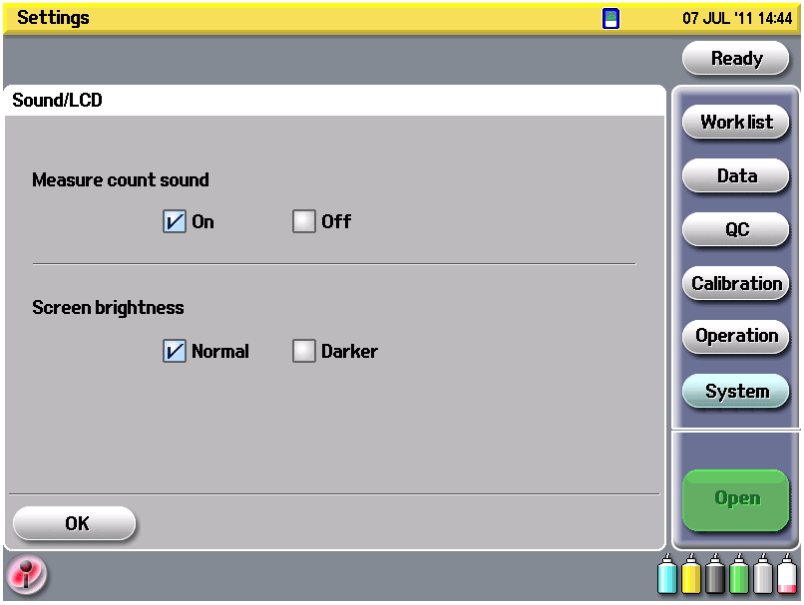
Item	Description		Default
Measure count sound	Select whether or not to create a sound during measurement.	On, Off	On
Screen brightness	Select the screen brightness.	Normal, Darker	Normal

Changing Sound and LCD Settings

1. Press the Sound/LCD key on the Settings screen to display the Sound/LCD window.



2. Change the settings by pressing the check box.



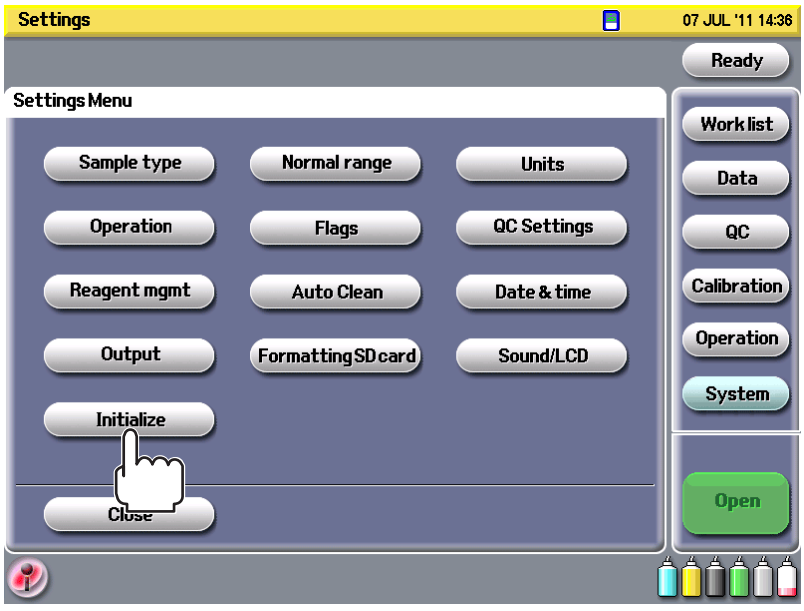
3. Press the OK key to return to the Settings screen.

Initializing the Analyzer

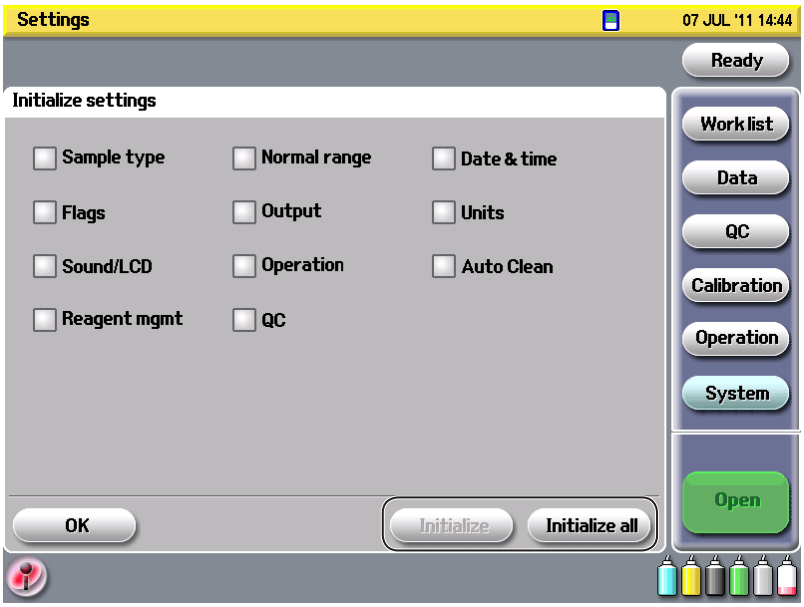
The following items can be initialized.

- Sample type
- Normal range
- Date & time
- Flags
- Output
- Units
- Sound/LCD
- Operation
- Auto Clean
- Reagent mgmt
- QC

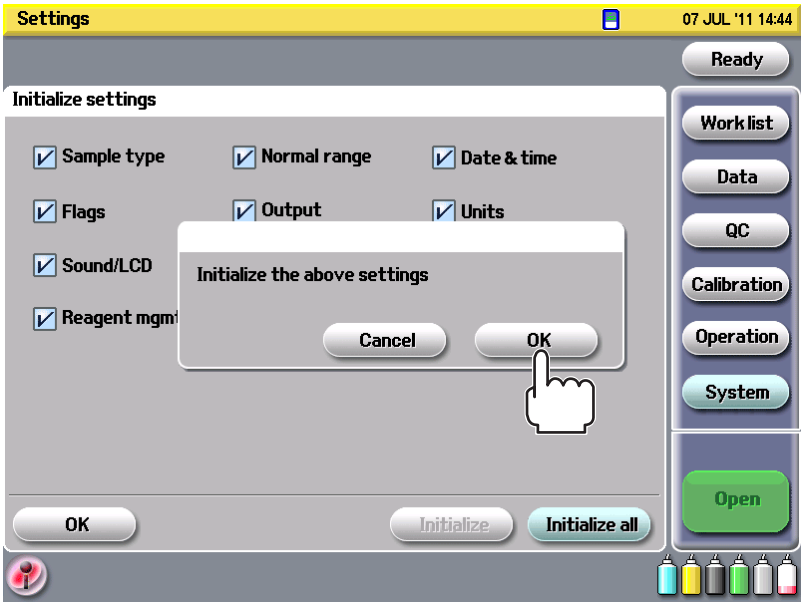
1. Press the Initialize key on the Settings screen to display the Initialize window.



2. Select the items to initialize and press the initialize key. When initializing all the items, press the Initialize all key. A confirmation message appears.



3. Press the OK key to initialize the items.



Interference Substances

WBC: **Unlysed red cells**

In some rare occasions, the RBC in the blood sample may not completely lyse and these non-lysed RBC may be detected as WBC and cause increase in WBC count.

Leukemia

WBC may be fragile in leukemia patients and WBC may be destroyed during measurement. These WBC fragments may also interfere with WBC differential measurement.

Chemotherapy

Cytotoxic and immunosuppressive drugs cause low WBC count.

Cryoglobulins

Cryoglobulin may be increased in patients who are pregnant or have myeloma, cancer, leukemia, macroglobulinemia, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, aneurysm, thromboembolic phenomena, diabetes, etc, which cause increase in WBC, RBC or PLT counts and HGB concentration. In such cases, warm the blood sample to 37°C (98.6°F) in a water bath for 30 minutes and measure the sample immediately.

RBC: **Leukemia**

An increase in WBC in leukemia patient causes increase in RBC.

Agglutinated RBC

Agglutinated RBC may decrease RBC count. This can be checked by abnormal MCH and MCHC values and examination of the stained blood film.

Cold agglutinins

IgM immunoglobulins which are elevated in cold agglutinin disease may decrease RBC and PLT counts and increase MCV.

HGB: **Turbidity of the blood sample**

Any physiologic and/or therapeutic factors may increase HGB. In such a case, determine the cause of turbidity and follow the appropriate method below.

1. Increased lipids
   The blood sample may be milky when there is excessive lipids. This may occur with hyperlipidemia, hyperproteinemia, etc. Accurate HGB measurement can be achieved by manual methods and a plasma blank.
2. Increased turbidity
   When the sample is poor hemolyzation or hyperbilirubinemia, turbidity may increase causing increase in HGB. Observe if MCH and MCHC values are abnormal. HGB result affects MCH and MCHC result.
3. High WBC levels
   Turbidity of blood increases and the hemoglobin concentration becomes high if WBC level of the blood sample is high. MCH and MCHC levels also become high.

HCT: **Agglutinated RBC**

RBC agglutination may cause erroneous HCT and MCV values. Observe if MCH and MCHC values are abnormal. In such a case, measure manually.

MCV: **Agglutinated RBC**

RBC agglutination may cause erroneous HCT and MCV values. Observe if MCH and MCHC values are abnormal. In such a case, measure manually.

Excessive number of large PLT

Excessive number of large PLT and/or excessively high WBC may affect the MCV value. Check by careful examination of the stained blood film.

MCH: MCH is determined from HGB and RBC values. Therefore, the limitations for HGB and RBC also affect MCH value.

MCHC: MCHC is determined from HGB and HCT values. Therefore, the limitations for HGB and HCT also affect MCHC value.

RDW-CV:

RDW-CV is determined from RBC value. Therefore, the limitations for RBC also affect RDW-CV value.

Agglutinated RBC

Agglutinated RBC may decrease RBC count and erroneous RDW-CV. This can be checked by abnormal MCH and MCHC values and examination of the stained blood film.

Nutritional deficiency or blood transfusion

Iron and/or cobalamin and/or folate deficiency may increase RDW-CV.

PLT: **Very small fragments**

Very small RBC, RBC fragments and WBC fragments may be the cause in increased PLT count.

Agglutinated RBC

PLT may be trapped in the agglutinated RBC resulting in decrease in PLT. This can be checked by abnormal MCH and MCHC values and examination of the stained blood film.

Very large PLT

Large PLT may exceed the PLT threshold and might not be counted which results in low PLT count.

Hemolysis

Hemolyzed specimens contain red cell stroma which may increase PLT count.

Anticoagulated blood

Blood anticoagulated with acid-citrate-dextrose may have clumped PLT which may cause decrease in PLT count.

Agglutinated PLT

Clumped PLT may decrease PLT count and/or increase WBC count. For such sample, collect the sample in sodium citrate anticoagulant and measure only PLT.

MPV: **Very large PLT**

Large PLT may exceed the PLT threshold and not be counted which results in low MPV.

Very small fragments

Very small RBC, RBC fragments and WBC fragments may interfere with MPV measurement.

Agglutinated RBC

PLT may be trapped in the agglutinated RBC resulting in erroneous MPV. This can be checked by abnormal MCH and MCHC values and examination of the stained blood film.

WBC 5 part differential parameters are derived from the WBC count, therefore, the limitations for WBC also affect these parameters.

LY and LY%: Erythroblasts, certain parasites and RBC that are resistant to lysis may interfere with an accurate LY count.

MO and MO%: Large lymphocytes, atypical lymphocytes, blasts and excessive number of basophils may interfere with an accurate MO count.

NE and NE%: Excessive eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may interfere with an accurate NE count and NE%.

EO and EO%: Abnormal granules may interfere with an accurate EO count.

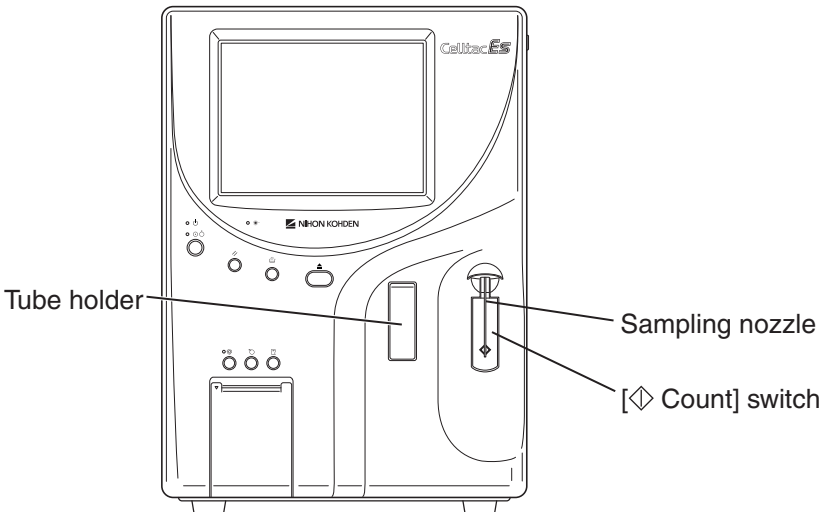
BA and BA%: Immature cell, metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may interfere with an accurate BA count and BA%.

Measurement

General

Open and Closed Sampling Modes

The analyzer has two sampling modes, open mode and closed mode. In closed mode, you put a sample in a capped tube into the tube holder. In open mode, you hold a sample container with whole blood under the sampling nozzle and press the [◇ Count] switch to aspirate the sample.



Front panel

Dilution Modes

There are five dilution modes: normal, pre-dilution, high dilution, higher dilution and low dilution modes. Pre-dilution is only for open sampling mode.

- **Normal mode**
  In normal dilution mode, 55 µL sample volume is measured.

- **Pre-dilution mode**
  For pre-dilution blood measurements, you can specify the pre-dilution blood measuring volume (10 µL or 20 µL) on the Operation screen of the Settings screen. Refer to “Operation Settings” earlier in this section. Pre-dilution mode is for open sampling mode only.

- **High dilution mode**
  When a blood sample’s WBC seems to be high, the sample can be measured in high dilution mode. In high dilution mode, 10 µL of blood sample is aspirated and diluted three times the usual dilution ratio.

- **Low dilution mode**
  When a blood sample's WBC or PLT seems to be low, the sample can be measured in low dilution mode. The low dilution mode reduces the recount and measurement data is stable.

Sample Types

You can specify the sample type before each measurement. This allows you to assign different normal ranges to different samples or to retrieve specific data.

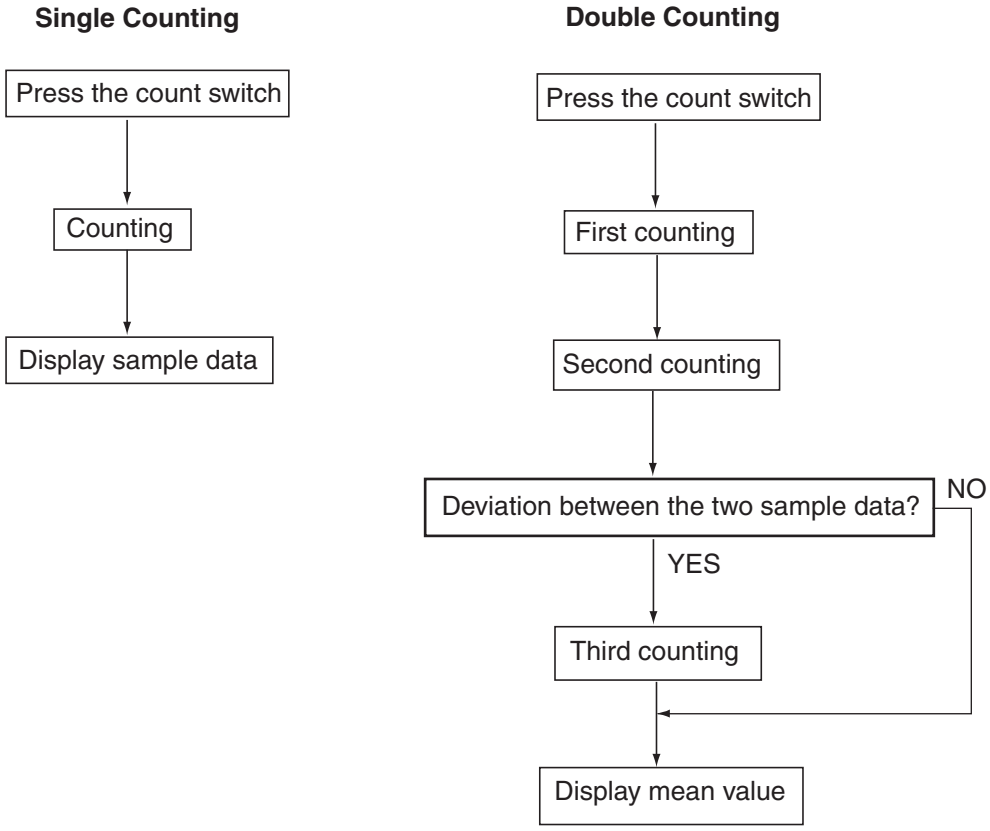
Single and Double Counting

In single counting mode, each sample is counted once.

In double counting mode, the analyzer automatically counts the sample twice and displays and stores the mean value. Only the mean value is printed, displayed and stored in memory. If there is a significant deviation (more than 10%) between the two counts, a third counting is automatically performed and the mean of the two closest counts is used.

When displaying or printing histograms of a double counted sample, the first count data is printed for the WBC and the second count data is printed for the RBC and PLT.

To set double count, refer to "Operation Settings" earlier in this section.



ID Number

Each sample must have its own ID number. You can set any ID number for any sample. Refer to “Assigning an ID to a Sample and Patient” later in this section.

During measurement, the ID number can be automatically incremented by one for each sample.

Alarm Display

The analyzer automatically recounts a sample up to 3 times when an alarm occurs during measurement. If measurement is still unusable after 3 counts, the analyzer displays an alarm with the measurement results. Refer to “Alarm Display” in “Description of the Results Screen” later in this section. You can also set the analyzer to display an alarm while recounting the sample. This helps you find where the trouble is when there are frequent recounts. Refer to “Operation Settings” earlier in this section. In normal operation, set this to “Off”.

CAUTION

When an alarm occurs, the acquired data might not be correct, especially when a “ ! ” or “sample error” message appears. Do not use the data for diagnosis. Recount the sample.

Data Storage

The analyzer stores all measured and calculated data for the latest 400 samples and histograms of up to 50 samples. After that, the oldest sample data is deleted when a new sample is measured.

If you want to save data, use the auto print mode to save data as a printout, especially the histograms.

Quality control data ($\overline{X}$ and CV) and calibration data is also stored. For details, refer to Section 6 and Section 11, respectively.

Printing and Sending Data

The acquired data can be printed on an external printer and sent to a personal computer. When the auto printing or data transfer function is set to on, the data can be automatically printed on the printer or sent to the personal computer. Refer to “Printing and Sending Results” and “Changing Output Format” in this section.

Advanced Count

The analyzer performs additional measurement (advanced count) when WBC or PLT is extremely low. The advanced count is performed when WBC is 3500/μL or less or PLT is 15×10^4/μL or less. The PLT threshold can be changed on the Operation window.

Counting Special Case Samples

- WBC Count
  To measure a blood sample from a patient with serious hepatopathy, it may be necessary to use a method other than the blood cell counter. This is because the RBC membrane's resistance against lysing reagent is increased (insufficient hemolysing) and it will cause an increase of the WBC count when the blood is measured with the blood cell counter. " ! " appears beside the WBC count.

  For a sample that has more than 10^5/μL WBC, use WBC high mode. The result is "OVER" in normal mode.

  For a sample that has less than 400/μL WBC, it is recommended to make a blood specimen and observe it with a microscope

  When the "OVER" message is displayed, measure the background noise and check that the background noise is decreased.

- PLT Count
  The PLT count may be decreased because of pseudothrombocytopenia or incorrect procedure in sampling blood. It is recommended to make a blood specimen and observe it with a microscope when the PLT count is below 50,000/μL.

Assigning an ID to a Sample and Patient

All samples must have an ID. Otherwise, you cannot identify which sample the displayed or saved data corresponds to. All saved and displayed data is identified by an ID number.

When you set an ID, the analyzer automatically assigns it to the next counted sample and increments the ID for each sample after that. Only the last 4 digits are incremented. When the last 4 digits are "9999", the ID is incremented to "0001" for the next sample.

You can also enter an ID manually for each sample and patient.

You can enter up to 13 characters for the ID, but the last 4 digits must be numbers.

When using the optional ZK-820V Hand-held bar code reader, the bar code label of the sample can be read by the bar code reader and this code is entered as the sample ID.

You can also choose to not assign an ID to a sample and patient, such as in background noise measurement.

For ID settings, refer to “Operation Settings” in this section.

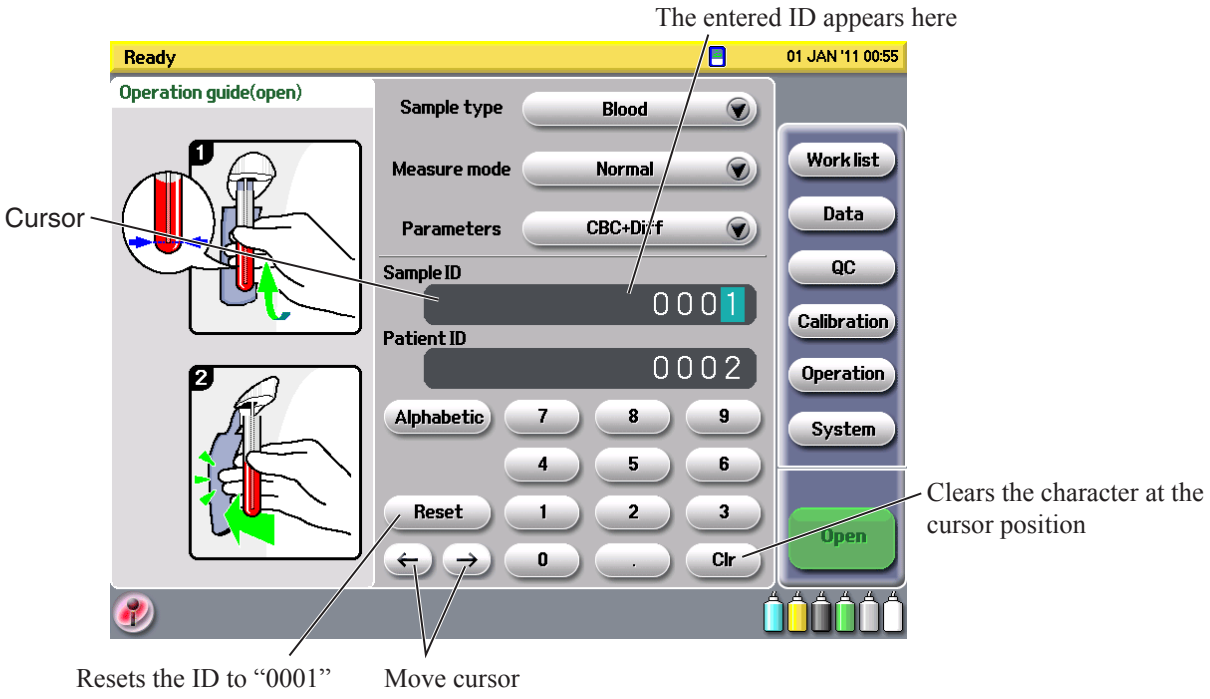
To edit an ID of already saved data, refer to “Editing ID of a Saved Data” later in this section.

<ID Settings>	ID display position		ID No.	
	4 digits	13 digits	After pressing the Reset key	After measurement
Auto	Right aligned	Left aligned	0001	Increments automatically
Right	Right aligned		No ID assigned. Assign an ID manually.	
Left	Left aligned			
No	ID not displayed			

1. Check the <ID Settings>.

2. Select Sample ID or Patient ID by pressing the column.

3. Enter an ID with the keypad. The entered number or letter appears in the <ID> box. For the last 4 digits, only numbers can be entered.



CAUTION

To prevent mixing up the examination data, check that the sample and patient ID are set correctly.

Not Assigning an ID

To not assign an ID, select “No” for <ID Settings>. For details, refer to “Operation Settings” in this section.

Using Bar Codes

The optional ZK-820V Hand-held bar code reader can be used to read the sample bar code label to establish the Sample ID.

To enter the ID by using the hand-held bar code reader, display the Ready, ID, Results or ID Edit screen and read the bar code of the sample.

NOTE

- Up to 13 digits can be entered for an ID. If the bar code has more than 13 digits, the digits after the 13th digit are deleted.
- A bar code ID might not be read properly due to poor printing quality of the label or the label is torn or detached. For such a sample, edit the ID on the ID Edit screen of the Data screen after measurement (refer to "Editing ID of a Saved Data" later in this section). Be careful not to mix up such samples. For details about bar code labels, refer to the "Bar Codes for Using the ZK-820V Hand-held Bar Code Reader" in Appendix B.
- When CODABAR (NW-7) is used for the bar code type, a letter from "a" to "d" is assigned to the beginning and end of the ID. If there are more than 13 digits in the ID because of these start/stop characters or when you do not want these letters to be included in the sample ID, read "Do not send" bar code. Refer to "Bar Codes for Using the ZK-820V Hand-held Bar Code Reader" in Appendix B.
- Ids from the ITF bar code type may be frequently misread by the bar code reader compared to other types of bar codes, especially when the printing quality of the label is poor. Be careful not to mix up samples when using ITF bar codes.

Measurement in Closed Mode

WARNING

Always wear rubber gloves to protect yourself from infection when handling and measuring blood samples.

CAUTION

Avoid blood sample contact with the skin. If it contacts the skin or eyes, wash thoroughly with water and see a physician immediately.

NOTE

Pre-dilution samples cannot be measured in closed mode.

Preparing a Sample

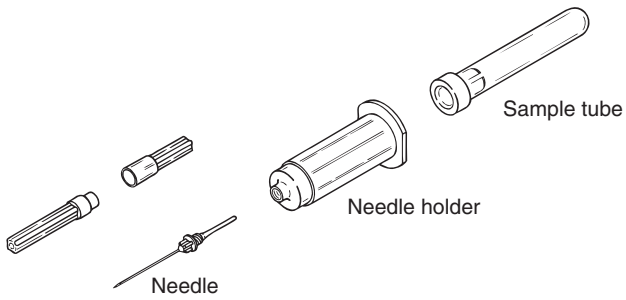
Use vacuum blood sample tubes which contain EDTA-2K anticoagulant. The following vacuum sample tubes can be used. For details, contact your Nihon Kohden representative. Blood samples in these sample tubes can be counted without removing the cap.

Manufacturer	Description	Q'ty
Nihon Kohden	Sampling tube T440B	75 × 12.3 diameter (for 2 mL)
TERUMO	VENOJECT VT-052DK	75 × 12.4 diameter (for 2 mL)
	VENOJECT II VP-DK052	78 × 13.2 diameter (for 2 mL)
NIPRO	NEO-TUBE NP-EK0205	75 × 12.3 diameter (for 2 mL)
BECTON DICKINSON	VACUTAINER 360004	75 × 13 diameter (for 2 mL)

NOTE

Attach a label on the vacuum sample tube so it does not come off.

Prepare 2 mL of collected sample blood in the sample tube.

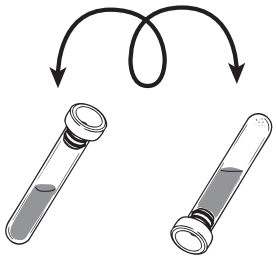


CAUTION

Use only EDTA (ethylenediamine tetra-acetic acid) as an anticoagulant. Do not use heparin as an anticoagulant. It affects white blood cell and platelet measurement.

NOTE

- Check that the sample is between 1.0 to 2.0 mL.
- For reliable data, measure the blood sample within 8 hours. If the blood sample is stored at room temperature for more than 8 hours, the white blood cell membrane resistance against lysing reagent decreases and the white blood cell will contract more (decrease of cell volume) just after the lysing reagent is added to the diluted sample. This causes the total WBC count to decrease.
- Keep the blood samples in room temperature. Do not keep them in a refrigerator.
- When measurement cannot be performed properly due to poor hemolyzation, measure the blood sample at least 30 minutes after collection.
- If the blood sample is measured within 30 minutes after collection, false-positive flags may increase.
- Gently and thoroughly shake the blood sample again before measurement.
- Do not stir the sample excessively because it generates unwanted bubbles and cause hemolyzation.
- Do not use aggregated or coagulated blood. Otherwise the analyzer may be damaged.
- Wipe the blood off the sample cap when counting the same sample again.

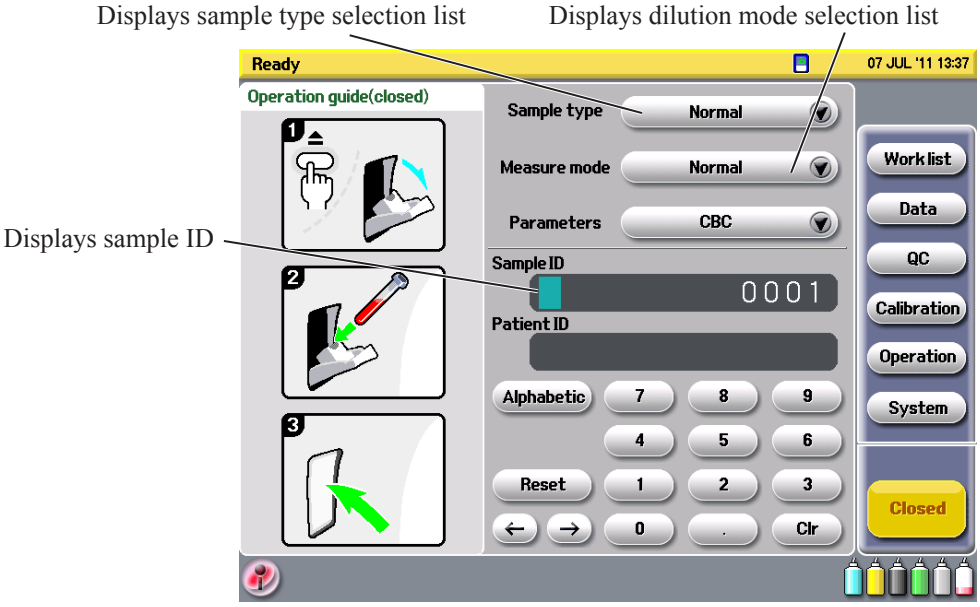


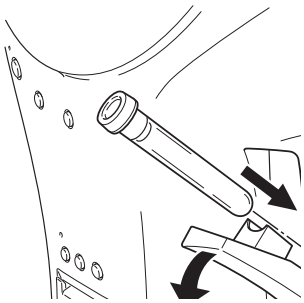
Measuring a Sample in Closed Mode

Measurement in Normal Dilution Mode

1. Agitate the sample and anticoagulant thoroughly by turning the sample tube upside down at least 20 times so that the blood sample and anticoagulant are mixed.

2. On the Ready screen, check the <Sample ID>, <Patient ID> and <Sample type> setting and check that “Normal” is selected for <Measure mode> and “Closed” is selected for sampling mode.



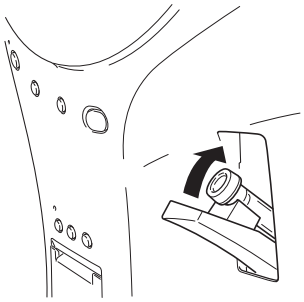


3. Press the [⏏ Eject] key on the front panel to open the tube holder.

NOTE

Before closing the tube holder, fully open the holder.

4. Set the vacuum sealed sample tube in the tube holder.

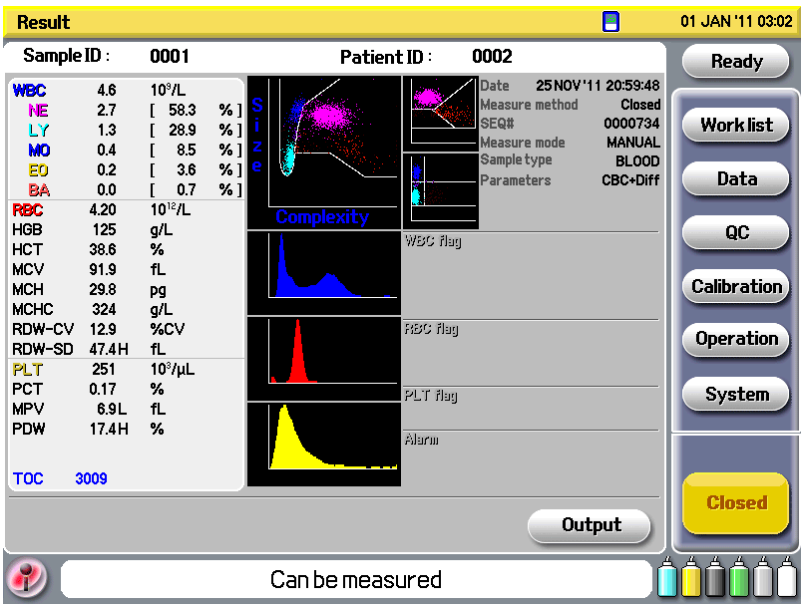


5. Close the tube holder. Measurement automatically starts after the tube holder closes.

   The tube holder automatically opens after finishing the measurement.

   If you close the tube holder without setting a sample tube, measurement is not performed.

   When measurement is completed, the measurement data is stored in memory and the numeric result and histogram appear on the screen. For details on the Result screen, refer to the “Description of the Results Screen” later in this section.



To continue measuring samples, repeat the procedure.

When the <ID Settings> is set to Auto, the ID is automatically incremented when another sample tube is set in the tube holder and the tube holder is closed.

NOTE

When measuring the same sample again, touch the Ready key to display the Ready screen, set the same ID and count the sample.

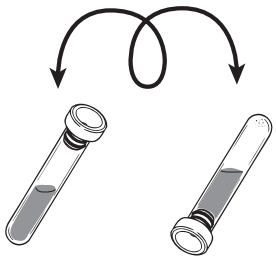
When the <ID Settings> is set to Left, Right or No, touch the Ready key to display the Ready screen and count the new sample.

When a PC or optional printer is connected to the analyzer and auto output or auto print is set to "On" on the Output screen, the measurement data is sent to the PC or printed on the printer. Refer to "Changing Output Format" in this section.

Measurement in WBC Low/High Dilution Mode

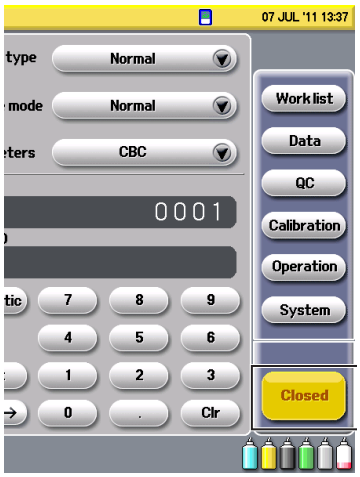
When a blood sample's WBC seems to be high, the sample can be measured in high dilution mode. In high dilution mode, 10 µL of blood sample is aspirated and diluted three times the usual dilution ratio.

When a blood sample's WBC or PLT seems to be low, the sample can be measured in low dilution mode in which 55 µL of blood sample is aspirated and diluted half the usual dilution ratio.



- WBC High: To measure a sample 1000 × 10^2/µL or more
- WBC Low: To measure a sample 35 × 10^2/µL or less

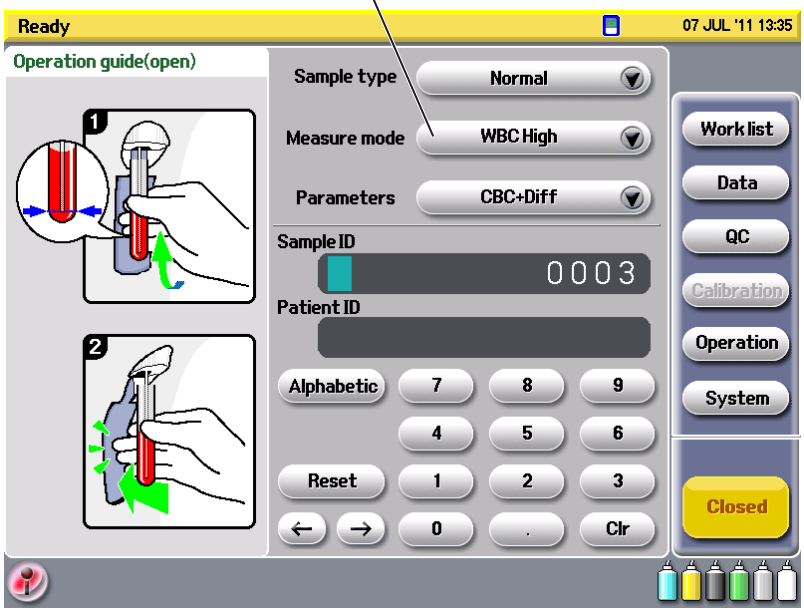
1. Agitate the sample and anticoagulant thoroughly by turning the sample tube upside down at least 20 times so that the blood sample and anticoagulant are mixed.

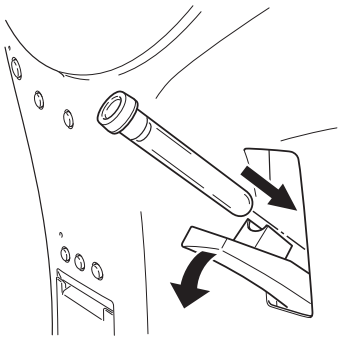


2. On the Ready screen, check the <Sample ID>, <Patient ID> and <Sample type> settings and check that “Closed” is selected for sampling mode.

3. Select “High”, “Higher” or “Low” for <Measure mode>.

Displays dilution mode selection list



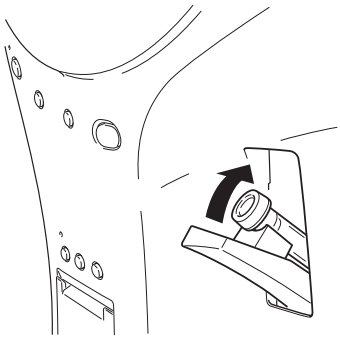


4. Press the [⏏ Eject] key on the front panel to open the tube holder.

NOTE

Before closing the tube holder, fully open the holder.

5. Set the vacuum sealed sample tube in the tube holder.

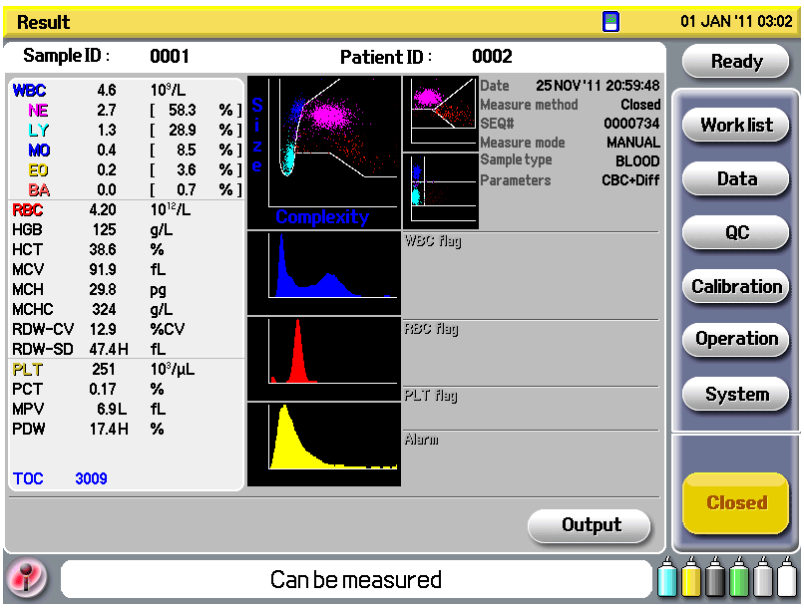


6. Close the tube holder. Measurement automatically starts after the tube holder closes.

   The tube holder automatically opens after finishing the measurement.

   If you close the tube holder without setting a sample tube, measurement is not performed.

   When measurement is completed, the measurement data is stored in memory and the numeric result and histogram appear on the screen. For details on the Result screen, refer to the “Description of the Results Screen” later in this section.



The dilution mode returns to “Normal” after low/high mode measurement. When <Continue dilution mode> is set to “Yes” on the Operation screen of the Settings screen, the dilution mode does not return to “Normal” and you can continue to measure in your selected dilution mode.

When the <ID Settings> is set to Auto, the ID is automatically incremented when another sample tube is set in the tube holder and the tube holder is closed.

NOTE

When measuring the same sample again, touch the Ready key to display the Ready screen, set the same ID and count the sample.

When the <ID Settings> is set to Left, Right or No, touch the Ready key to display the Ready screen and count the new sample.

When a PC or optional printer is connected to the analyzer and auto output or auto print is set to “On” on the Output screen, the measurement data is sent to the PC or printed on the printer. Refer to “Changing Output Format” in this section.

Measurement in Open Mode

WARNING

Always wear rubber gloves to protect yourself from infection when handling and measuring blood samples.

CAUTION

Avoid blood sample contact with the skin. If it contacts the skin or eyes, wash thoroughly with water and see a physician immediately.

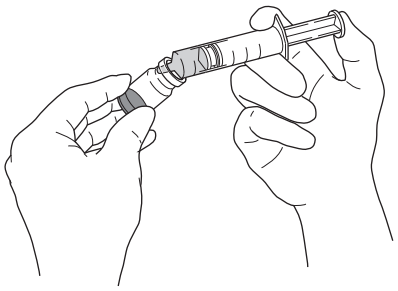
Both venous and pre-dilution samples can be measured in open mode.

Sample in any type of container can be measured in open mode. In the following procedure, a sample container listed in "Consumables" in Appendix A is used as an example.

Measuring a Venous Sample in Normal Dilution Mode

Preparing a Venous Sample

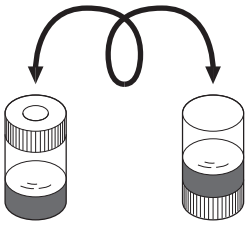
1. Put 2 mL of collected whole blood in a sample container which contains anticoagulant.



CAUTION

Use only EDTA (ethylenediamine tetra-acetic acid) as an anticoagulant. Do not use heparin as an anticoagulant. It affects white blood cell and platelet measurement.

2. Gently shake the covered sample container up and down more than 20 times.



CAUTION

Do not shake the sample excessively because it makes unwanted bubbles and cause hemolyzation.

NOTE

For reliable data, measure the blood sample within 8 hours. If the blood sample is stored at room temperature for more than 8 hours, the white blood cell membrane resistance against lysing reagent decreases and the white blood cell will contract more (decrease of cell volume) just after the lysing reagent is added to the diluted sample. This causes the total WBC count to decrease.

Measuring a Venous Sample

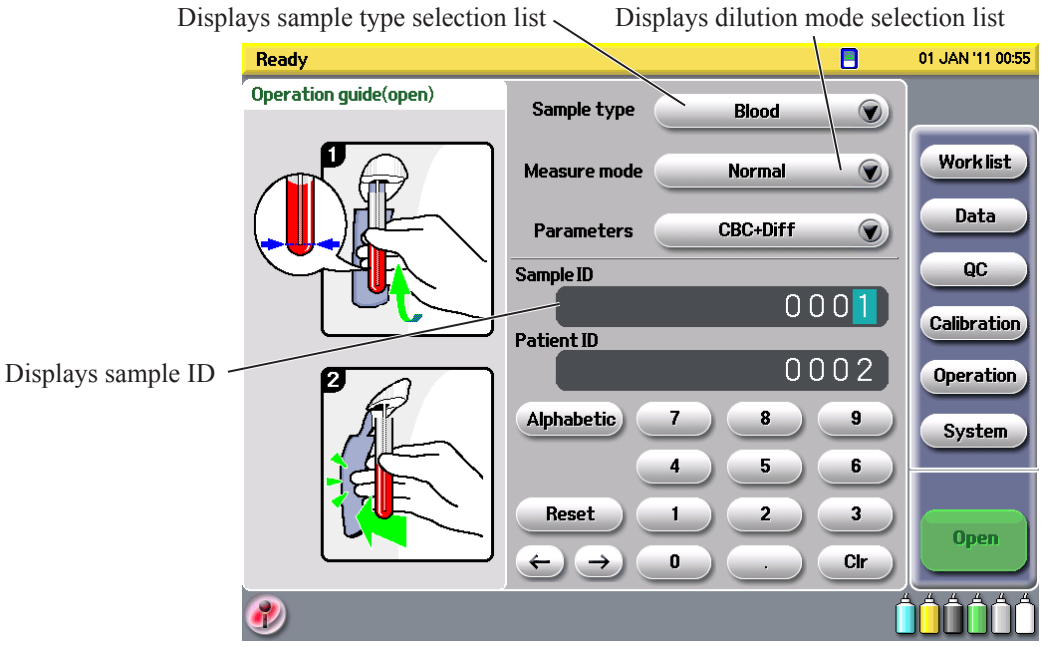
CAUTION

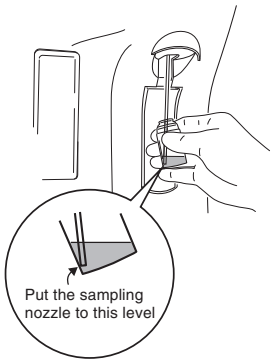
Do not use aggregated or coagulated blood. Otherwise the instrument may be damaged.

NOTE

- When measurement cannot be performed properly due to poor hemolyzation, measure the blood sample at least 30 minutes after collection.
- If the blood sample is measured within 30 minutes after collection, false-positive flags may increase.
- Measure blood samples within 8 hours after collection.
- Keep the blood samples in room temperature. Do not keep them in a refrigerator.
- Gently and thoroughly shake the blood sample again before measurement.

1. On the Ready screen, check the <Sample ID>, <Patient ID> and <Sample type> setting and check that "Normal" is selected for <Measure mode> and "Open" is selected for <Sampling mode>.





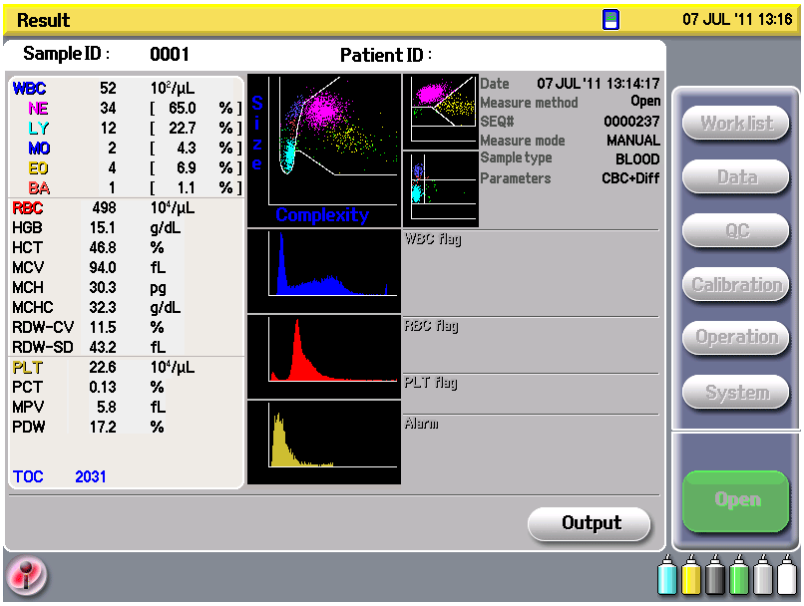
2. Put the sampling nozzle into the sample container of the sample blood so that the tip of the sampling nozzle comes near but does not touch the bottom of the sample container.

NOTE

Do not let the sampling nozzle touch the bottom of the sample container. This may prevent aspiration of the sample.

3. Press the [◇ Count] switch. The sample is aspirated and measurement starts. The "Measuring" message appears on the screen.

When measurement is completed, the measurement data is stored in memory and the numeric result and histogram appear on the screen. For details on the Result screen, refer to “Description of the Results Screen” later in this section.



To continue measuring samples, repeat the procedure.

When the <ID Settings> is set to Auto, the ID is automatically incremented when the [◇ Count] switch is pressed.

NOTE

When measuring the same sample again, touch the Ready key to display the Ready screen, set the same ID and count the sample.

When the <ID Settings> is set to Left, Right or No, touch the Ready key to display the Ready screen and count the new sample.

When a PC or optional printer is connected to the analyzer and auto output or auto print is set to “On” on the Output screen, the measurement data is sent to the PC or printed on the printer. Refer to “Changing Output Format” in this section.

Measuring a Pre-Dilution Sample

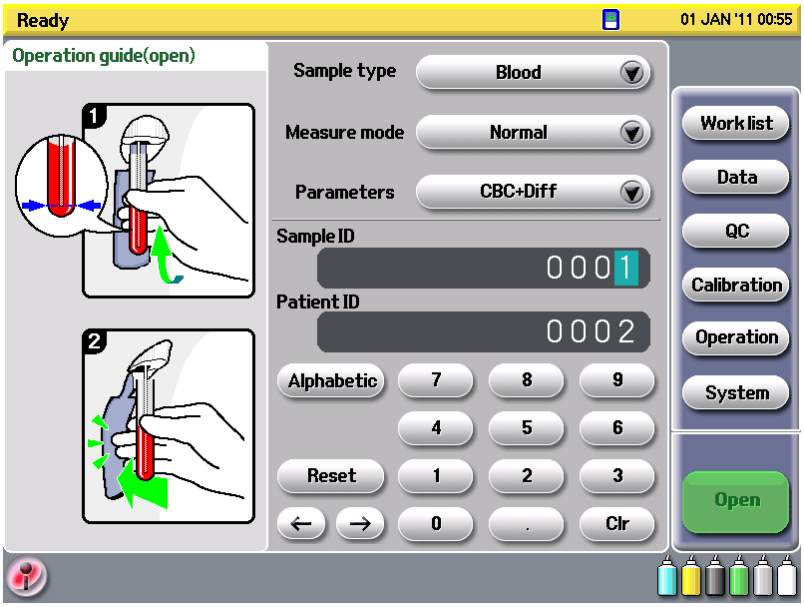
Preparing a Pre-Dilution Sample

NOTE

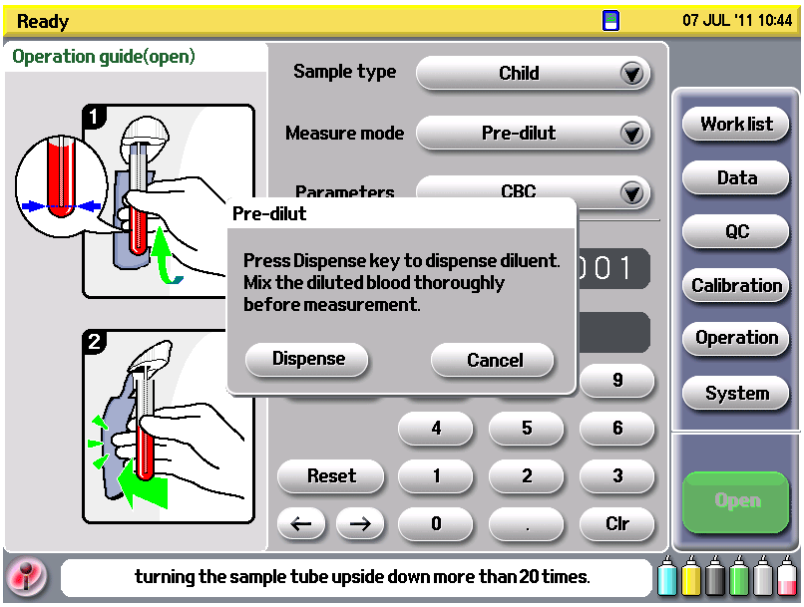
- Rapidly and carefully perform the following procedures to collect and dilute pre-dilution blood from an earlobe or a finger tip. When pre-dilution blood is measured, data accuracy depends on careful performance of these processes, i.e. collecting and diluting the blood sample.
- For neonates and infants, collect pre-dilution blood from a finger tip or heel. Measuring an earlobe pre-dilution blood may not be accurate.
- For each parameter, the values for earlobe pre-dilution blood may be almost 5 to 10% higher than that of a venous sample. If tissue gets into the sample, the WBC value is excessively high.
- When using a sahli pipette, clean and completely dry it before use.
- Pre-dilution samples cannot be measured in closed mode. Open mode must be selected.
- WBC distribution is not available for some pre-dilution samples.

You can select pre-dilution blood measuring volume (10 or 20 µL) on the 3rd page of the Operation window on the Settings screen. For details, refer to "Operation Settings" earlier in this section.

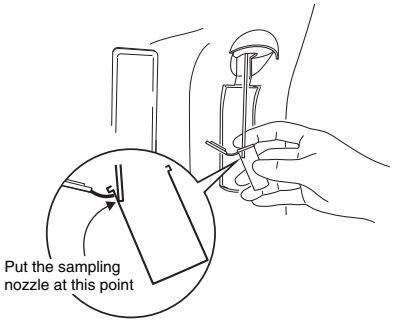
1. On the Ready screen, check the <Sample ID>, <Patient ID> and <Sample type> setting and check that "Open" is selected for sampling mode.



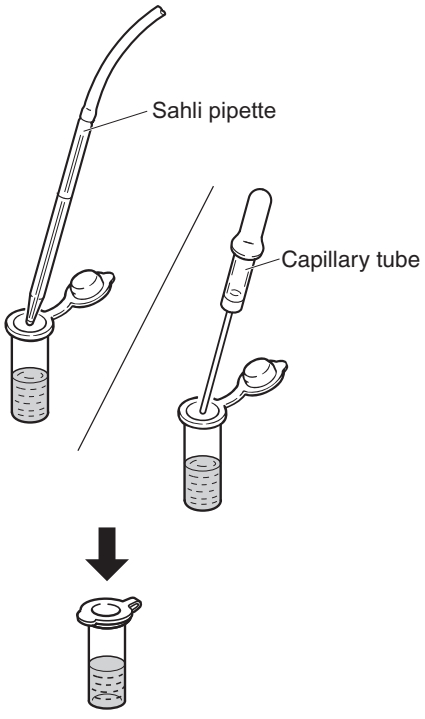
2. Select “Pre-dilut” for <Measure mode>. The Dispense key appears on the screen.



3. Put the sampling nozzle into an empty sample cup so that the tip of the sampling nozzle touches near the rim of the sample cup as shown in the figure.



4. Press the Dispense key on the Ready screen to dispense the diluent into the sample cup.

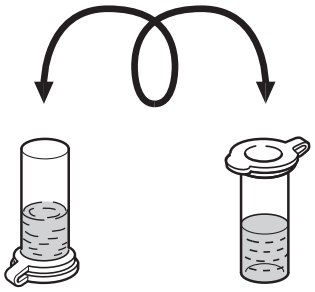


5. Collect 10 or 20 µL of whole blood with a sahli pipette or capillary tube.

NOTE

When wiping the blood off the surface of the sahli pipette or capillary tube, take extreme care not to wipe the blood inside the sahli pipette or capillary tube.

6. Put the pre-dilution blood into the sample cup with the dispensed diluent. Be careful not to create any bubbles. Put the cap on the sample cup.



7. Gently shake the sample cup up and down more than 10 times.

CAUTION

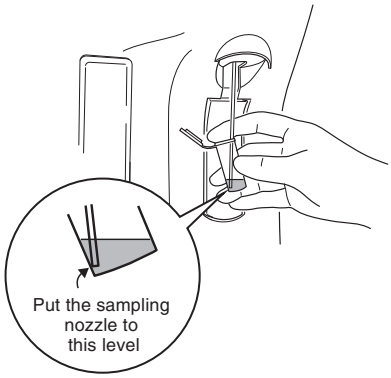
Do not shake the sample excessively because it makes unwanted bubbles and cause hemolyzation.

NOTE

- To prevent evaporation, put the cap on the sample cup when not measuring immediately.
- When measuring blood which is left more than 1 minute after collecting, gently shake the blood again before measurement.

To continue preparing more pre-dilution samples, repeat the procedure from step 3.

Measuring a Pre-Dilution Sample



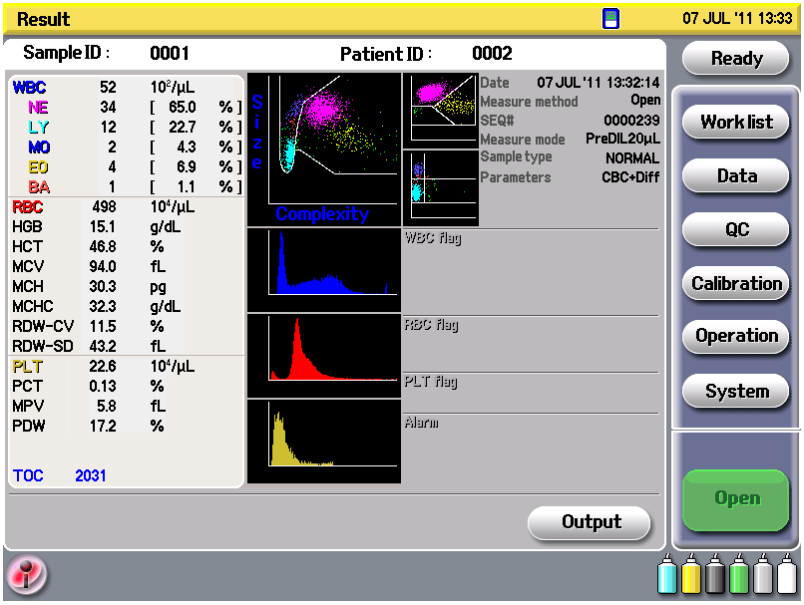
1. Put the sampling nozzle into the sample cup containing the pre-dilution sample so that the tip of the sampling nozzle comes near but does not touch the bottom of the sample cup.

NOTE

- Do not press the sampling nozzle too hard against the bottom of the sample cup. This decreases the aspirating volume.
- In pre-dilution mode, about 1 mL of sample is aspirated. Make sure that the sampling nozzle is near the bottom of the sample cup so that the correct volume of the sample can be aspirated.

2. Press the [◇ Count] switch. The sample is aspirated and measurement starts.

   When measurement is completed, the measurement data is stored in memory and the numeric result and histograms appear on the screen. For details on the Result screen, refer to “Description of the Results Screen” later in this section.



The dilution mode returns to “Normal” after pre-dilution mode measurement. When <Continue dilution mode> is set to “Yes” on the Operation screen of the Settings screen, the dilution mode does not return to “Normal” and you can continue to measure in your selected dilution mode. For details, refer to “Operation Settings” earlier in this section.

To continue measuring pre-dilution samples when <Continue dilution mode> is set to “No”, select “Pre-dilute” for <Measure mode> on the Ready screen. The instructions for making pre-dilution blood sample appears on the screen. When you have already prepared the pre-dilution blood samples, press the [◇ Count] switch and measure the sample.

When the <ID Settings> is set to Auto, the ID is automatically incremented when the [◇ Count] switch is pressed.

NOTE

When measuring the same sample again, touch the Ready key to display the Ready screen, set the same ID and count the sample.

When the <ID Settings> is set to Left, Right or No, touch the Ready key to display the Ready screen and count the new sample.

When a PC or optional printer is connected to the analyzer and auto output or auto print is set to “On” on the Output screen, the measurement data is sent to the PC or printed on the printer. Refer to “Changing Output Format” in this section.

Measuring a Venous Sample in WBC Low/High Dilution Mode

NOTE

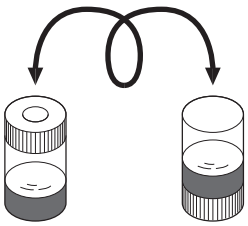
WBC distribution is not available for some low/high dilution samples.

When a blood sample's WBC seems to be high, the sample can be measured in high dilution mode. In high dilution mode, 10 µL of blood sample is aspirated and diluted three times the usual dilution ratio. In higher dilution mode, 5 µL of blood sample is aspirated and diluted six times the usual dilution ratio.

When a blood sample's WBC or PLT seems to be low, the sample can be measured in low dilution mode.

- WBC High: To measure a sample 1000 × 10^2/µL or more
- WBC Low: To measure a sample 35 × 10^2/µL or less

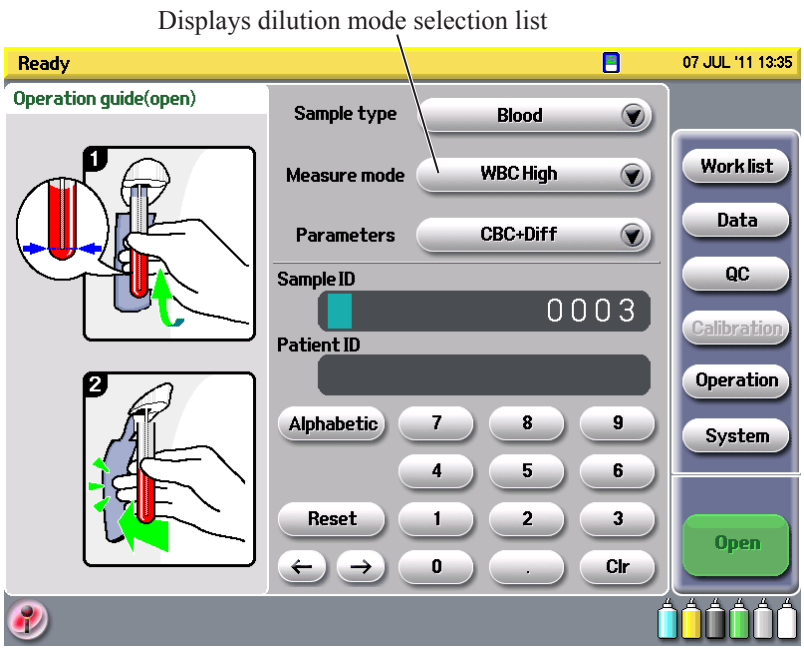
Low/high dilution mode measurement is not available for pre-dilution samples.



1. Agitate the sample and anticoagulant thoroughly by turning the sample container upside down at least 20 times so that the blood sample and anticoagulant are mixed.

2. On the Ready screen, check the <ID> and <Sample type> setting and check that "Open" is selected for sampling mode.

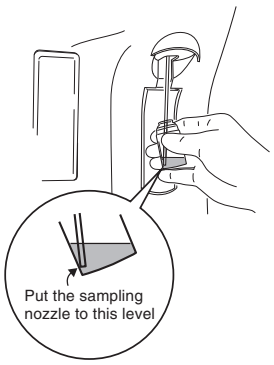
3. Select "WBC High" or "WBC Low" for <Measure mode>.



4. Put the sampling nozzle into the sample container of the sample blood so that the tip of the sampling nozzle comes near but does not touch the bottom of the sample container.

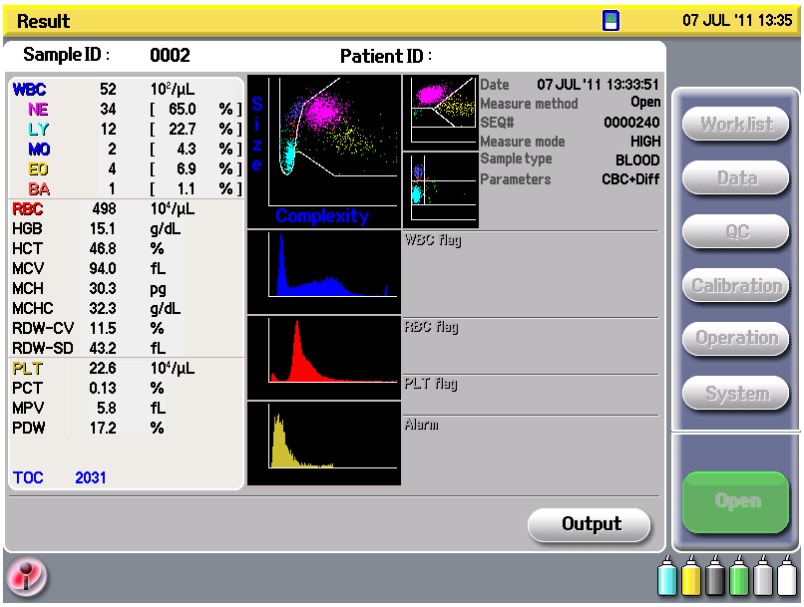
NOTE

Do not let the sampling nozzle touch the bottom of the sample container. This may prevent aspiration of the sample.



5. Press the [◇ Count] switch . The sample is aspirated and measurement starts. The “Measuring” message appears on the screen.

When measurement is completed, the measurement data is stored in memory and the numeric result and histogram appear on the screen. For details on the Result screen, refer to “Description of the Result Screen” later in this section.



The measure mode returns to “Normal” after low/high mode measurement. When <Continue dilution mode> is set to “Yes” on the Operation screen of the Settings screen, the dilution mode does not return to “Normal” and you can continue to measure in your selected dilution mode.

When the <ID Settings> is set to Auto, the ID is automatically incremented when the [◇ Count] switch is pressed.

NOTE

When measuring the same sample again, touch the Ready key to display the Ready screen, set the same ID and count the sample.

When the <ID Settings> is set to Left, Right or No, touch the Ready key to display the Ready screen and count the new sample.

When a PC or optional printer is connected to the analyzer and auto output or auto print is set to “On” on the Output screen, the measurement data is sent to the PC or printed on the printer. Refer to “Changing Output Format” in this section.

Auto Recount

There are two types of auto recount.

- Recount on alarm
- Recount on PLT count

Recount on Alarm

When an alarm occurs during measurement, the sample is automatically recounted up to three times. The same aspirated portion of the sample is recounted. You can set to display alarm upon auto recount to distinguish the problem when <Display alarm on recount> is set to "Yes" on the Operation screen of the Settings screen. To change the setting, refer to "Changing Settings" earlier in this section. For details on the alarm display, refer to the "Alarm Display" later in this section.

Recount on PLT Count

The analyzer automatically recounts a sample when PLT is extremely low. RBC, HCT, PLT, MCV, PCT, MCH, MCHC and RDW are recounted. The same aspirated portion of the sample is recounted. You can select $5 \times 10^4/\mu L$, $10 \times 10^4/\mu L$ or $15 \times 10^4/\mu L$ as the threshold under which a sample is recounted. When "None" is selected, a sample is not recounted. For normal operation, select $15 \times 10^4/\mu L$. To change the setting, refer to "Changing Settings" earlier in this section.

Work Lists

General

A work list lets you enter the patient information, including ID, physician name, measuring parameters and comments for the samples before measurement so that during measurement you only need to prepare the blood samples. To use a work list for measurement, select a data on the work list and press the Count switch. Measurement is performed according to the work list data. Up to 50 data can be entered in the work list. If more than 50 data are entered, the oldest data is deleted.

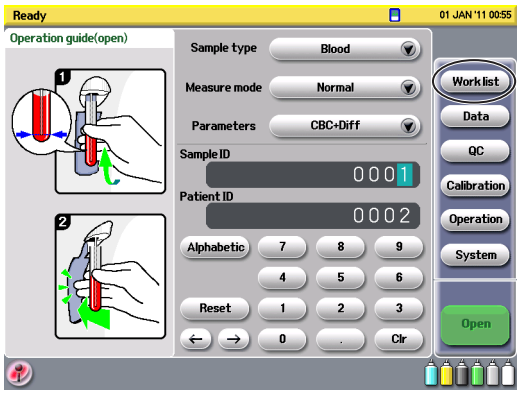
When a PC with the optional Data Management Software is connected to the USB socket on the hematology analyzer, the hematology analyzer can receive work list data from the data management software. For details on the Data Management Software, contact your Nihon Kohden representative.

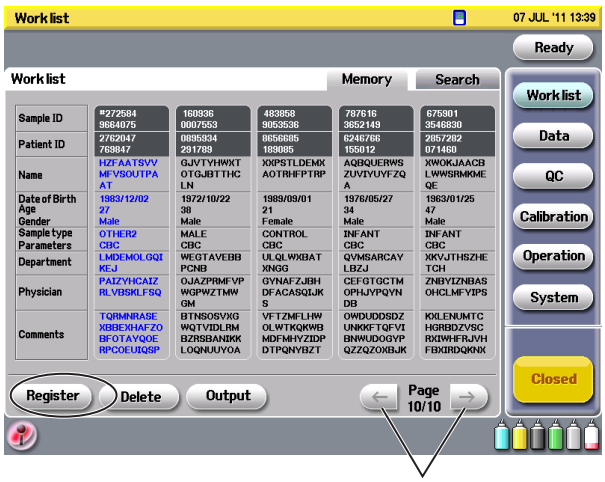
NOTE

- Data from the PC cannot be received if the hematology analyzer power is turned on after the data management software is started. In such a case, close the data management software, turn on the hematology analyzer power then restart the data management software.
- The work list data can only be received from the hematology analyzer when the hematology analyzer is not performing measurement.
- Previous work list data on the hematology analyzer is deleted if new work list data is received from the hematology analyzer.

Entering New Work List Data

1. Press the Work list key to display the Work list screen.





Displays other work list data

2. Press the Register key to enter a new work list data. The screen for entering sample ID appears.

Displays screen for entering patient name

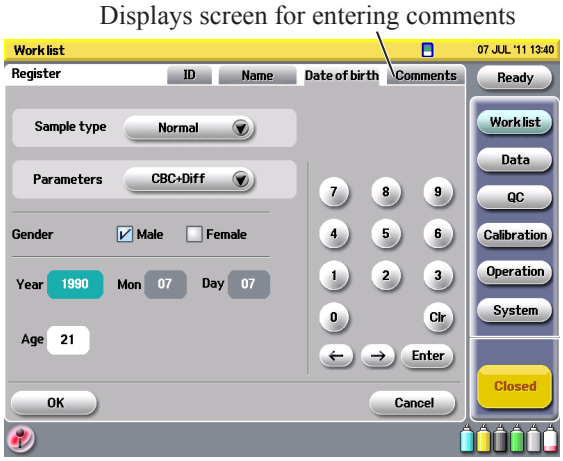
3. Enter the sample ID (up to 13 alphanumeric characters).

When the ZK-820V handy bar code reader is connected to the hematology analyzer, the ID can be entered by reading the bar code on the sample tube by the bar code reader when the screen for entering ID is displayed.

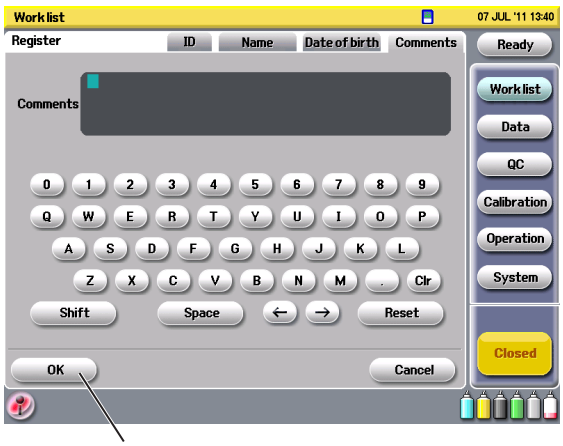
4. Press the Name tab to display the screen for entering the patient name.

Displays screen for entering date of birth

5. Enter the patient name (up to 26 alphanumeric characters) and press the Date of birth tab to display the screen for setting the patient's date of birth, age and sex.



6. Select the sample type, parameters, gender and enter the date of birth. Press the Comments tab to display the screen for entering comments.



7. Enter comments (up to 128 alphanumeric characters) and press the OK key to register the entered data in the work list.

   To not register data, press the Cancel key on any setting screen.

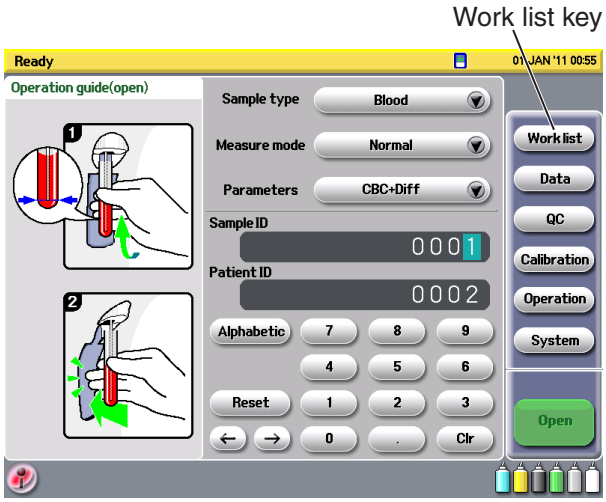
Receiving Work List Data

The work list data can be received from the PC that is connected to the USB socket (device) of the analyzer.

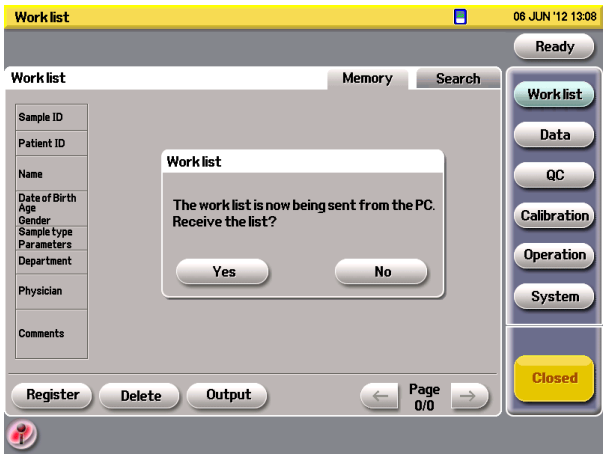
NOTE

- To create and send the work list on the PC, the QP-822V data management software is required. For creating and sending the data, refer to the data management software operator's manual.
- When receiving the work list from the PC, the previous work list is overwritten and deleted.
- Exit the software on the PC before turning off the analyzer.

1. Press the Work list key on the Ready screen to display the Work list screen.

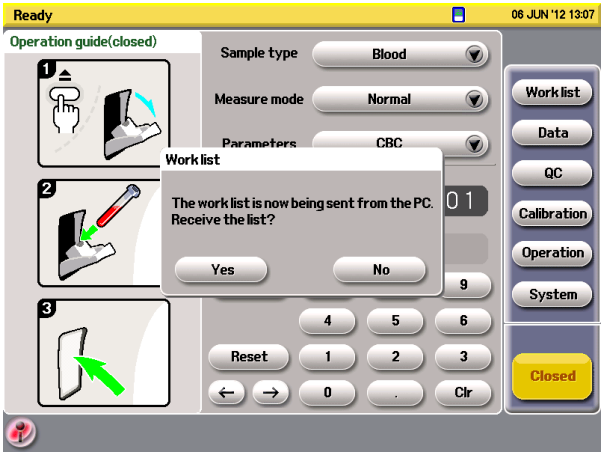


2. Send the work list data from the USB connected PC. When the data is sent from the PC, a confirmation message to receive the data is displayed.



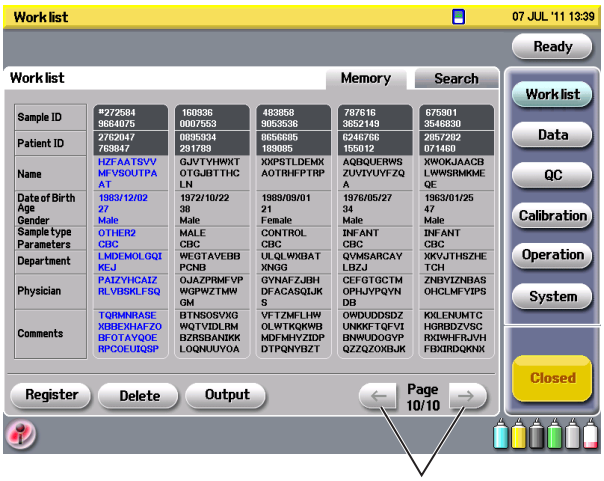
3. Press the Yes key to receive the work list data. The received data overwrites the current work list. Press the No key to cancel receiving and return to the Work list screen.

The work list can be received on the Ready screen.



Editing Work List Data

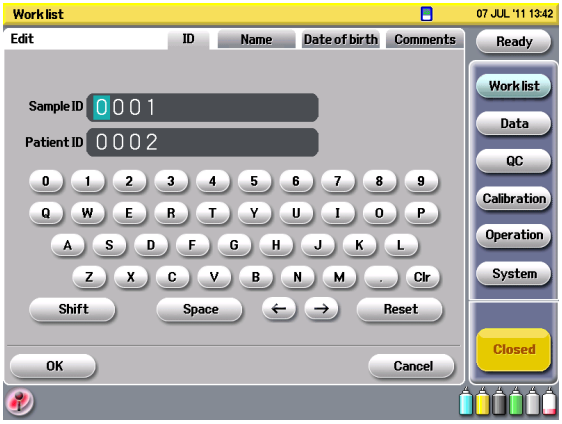
1. Press the Work list key to display the Work list screen.



Displays other work list data

2. Press the desired work list.

3. Press the Edit key. The edit screen of the data is displayed.



NOTE

The Edit key does not appear when the work list data received from PC is selected and cannot be edited.

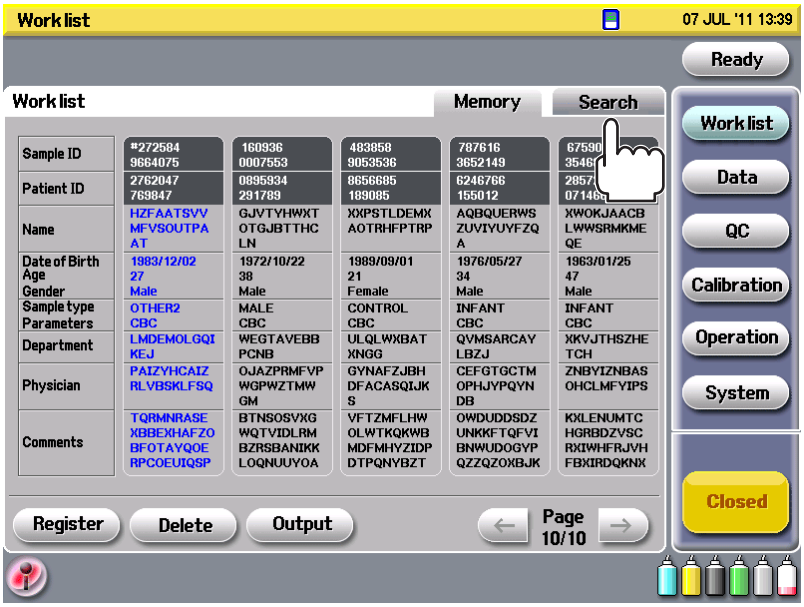
4. Press the tab of the data you want to change. The screen for entering the selected item appears.

5. Change the data. Refer to “Enter New Work List Data” section.

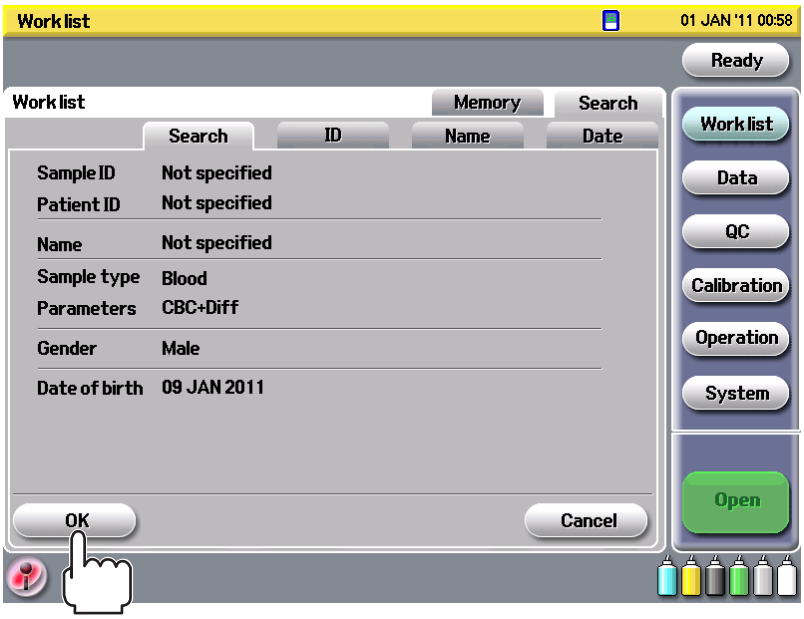
6. Press the OK key to return to the Work list screen.

Searching for Work List Data

1. Press the Search tab on the Work list window. The search conditions are displayed.



2. Check the search condition and press the OK key. When changing the condition, refer to the following procedure.



Search conditions:

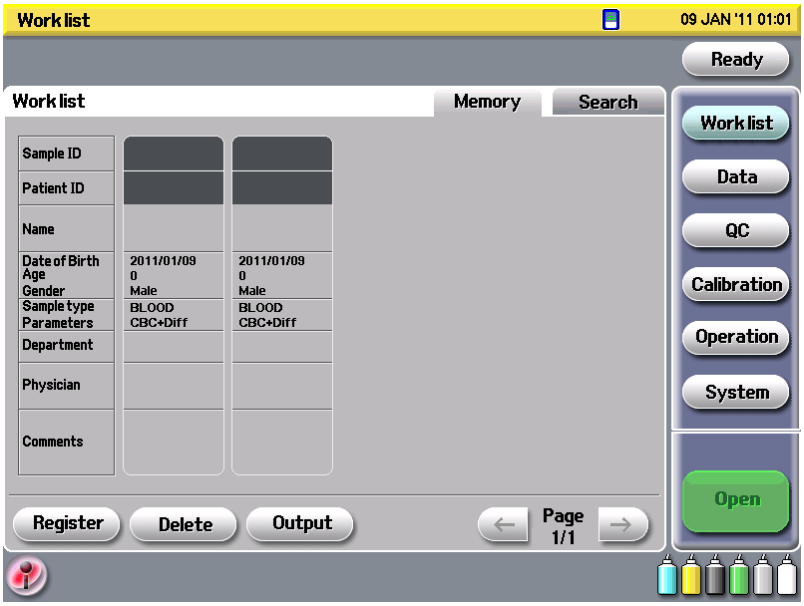
- Only perfectly matching data is found. Partial matches are not found.
- The search is case sensitive.

Changing the Search Conditions

i) Press the ID, Name or Date tab. Set the search condition.

ii) Press the Search condition tab. Check the search condition and press the OK key.

3. Check that all search conditions are correct and press the OK key.

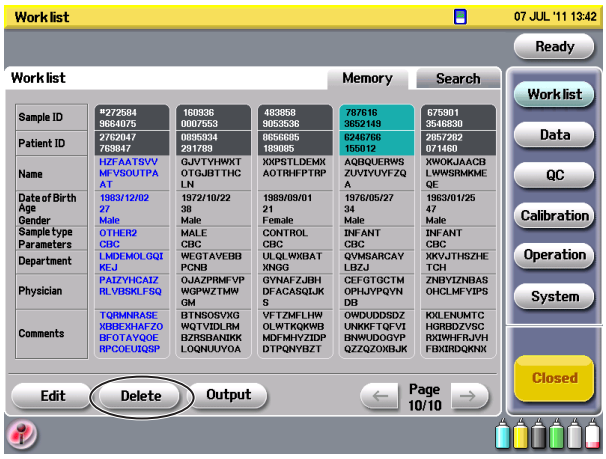


4. Press the Memory tab to display the search results.

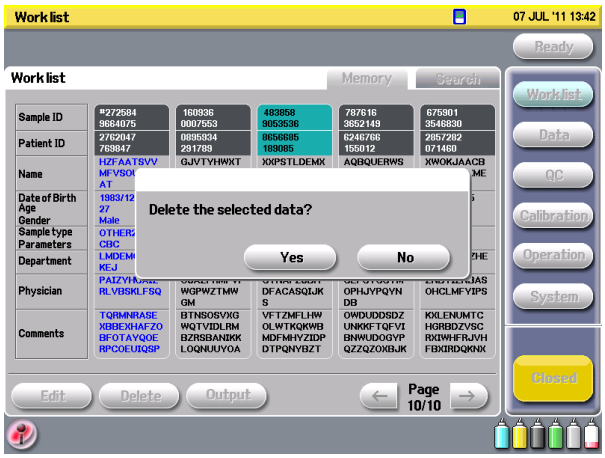
Deleting Work List Data

To Delete One Data

1. On the Work list screen, press the ID of the data to be deleted.



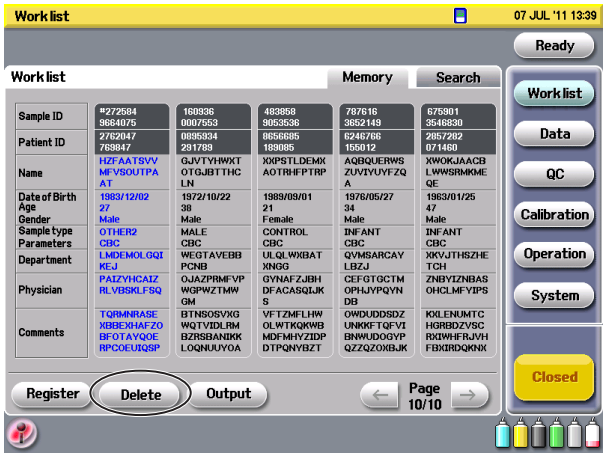
2. Press the Delete key. A confirmation message appears.

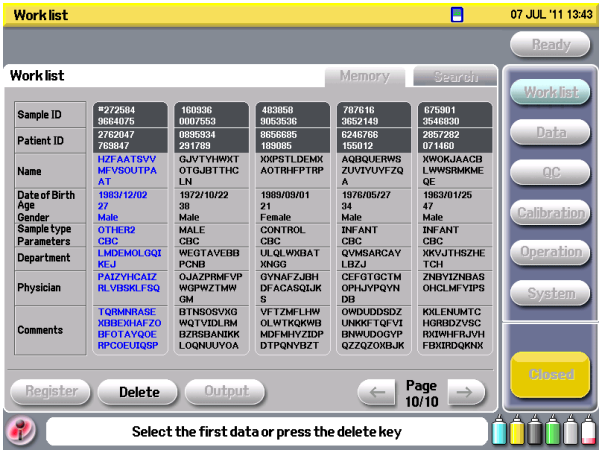


3. Press the Yes key to delete data.
   Press the No key to not delete data.

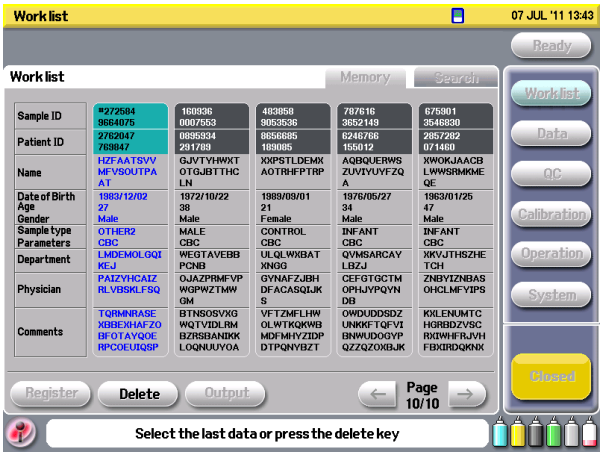
To Delete Several Consecutive Data

1. Press the Delete key. The “Select the first data or press the delete key” message appears on the screen.

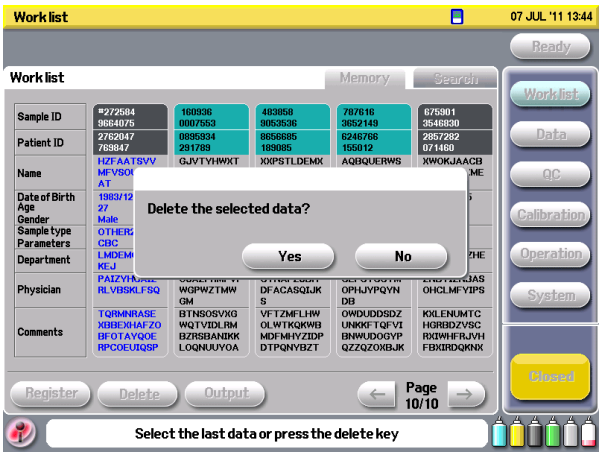




2. Find the first desired data using the arrow keys and press the ID key of the data. The “Select the last data or press the delete key” message appears.



3. Find the last data using the arrow keys and press the ID key of the data. All data between the first and last ID will be deleted. A confirmation message appears.



If the first and last selected data have the same ID, only the selected data will be deleted.

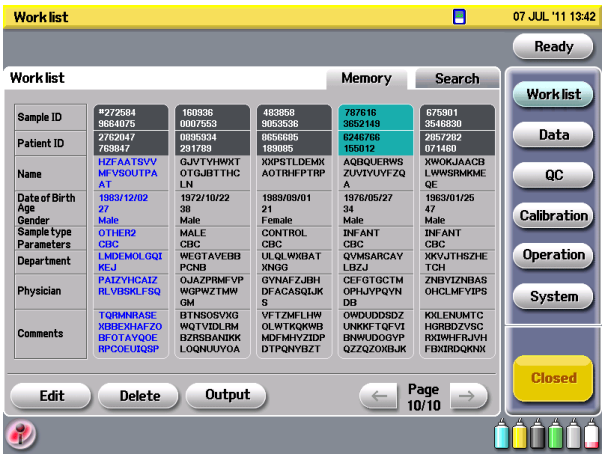
4. Press the Yes key to delete the selected data. The screen returns to the Work list screen.
Press the No key to not delete data. The process is canceled and the screen returns to the Work list screen.

Measuring a Sample Using the Work List

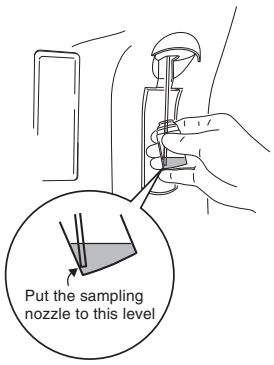
1. If necessary, check the data on the Work list screen.

2. Press the Work list key to display the Work list screen.

3. Select the work list data to be measured by pressing the ID key.



4. Check that the ID is the same as the data selected on the Work list screen.



5. Put the sampling nozzle into the sample cup containing the sample for the selected work list data so that the tip of the sampling nozzle comes near but does not touch the bottom of the sample cup.

NOTE

Do not press the sampling nozzle too hard against the bottom of the sample cup. This decreases the aspirating volume.

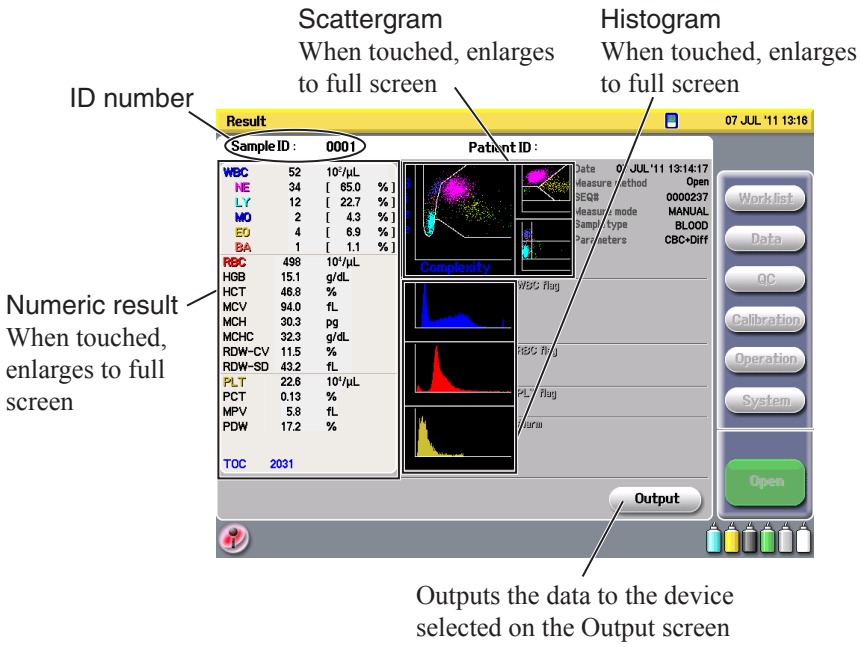
6. Press the [Count] switch. The sample is aspirated and measured according to the setting on the Work list screen.

When measurement is completed, the measurement data is stored in memory and the numeric result and histograms appear on the screen. For details on the Result screen, refer to the “Description of the Results Screen” section.

When a PC or optional printer is connected to the hematology analyzer and Auto is selected on the Output screen, the measurement data is transferred to the PC or printed on the printer.

Description of the Results Screen

When the measurement is completed, the measured data is displayed on the Result screen. On the Result screen, WBC, RBC and PLT histograms and numeric data are displayed. You can enlarge the items by touching them.



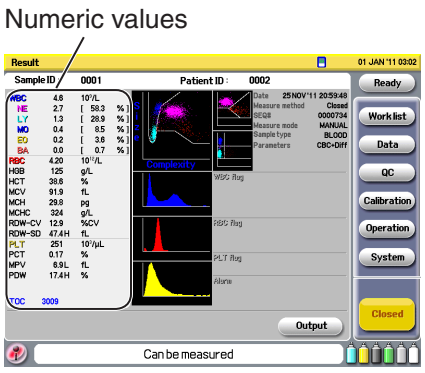
When Measurement result display format is set to Show CBC, only the CBC eight parameters are displayed.

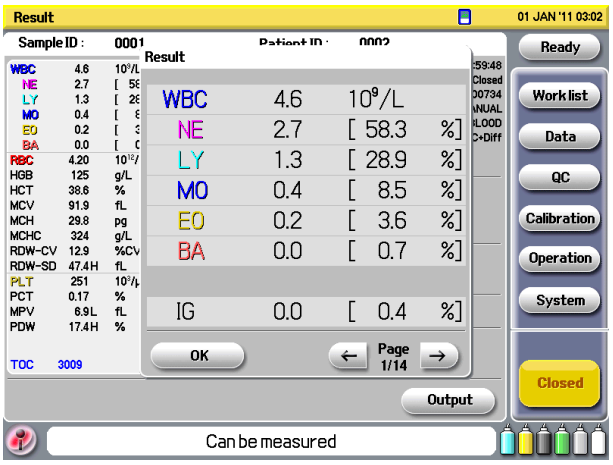
Enlarging Measurement Results

Touch the numeric values on the Results screen to enlarge them. Enlarged scattergram and histogram can be displayed by touching the arrow keys.

Large Numerics

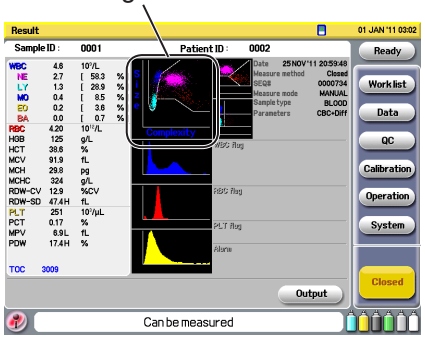
Touch the numeric values on the Results screen to enlarge them. Touch the OK key to return to the Results screen.



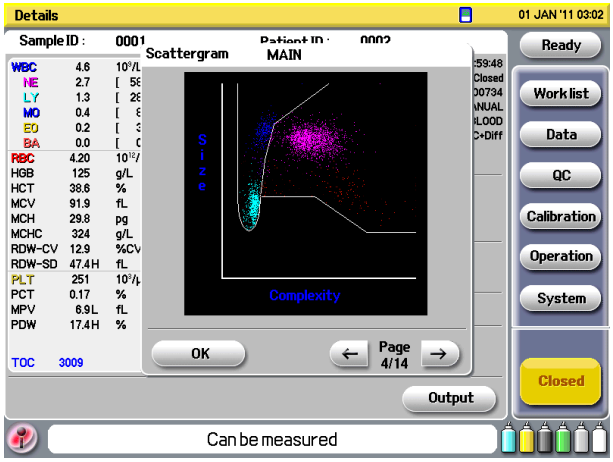


Large Scattergram

Scattergram

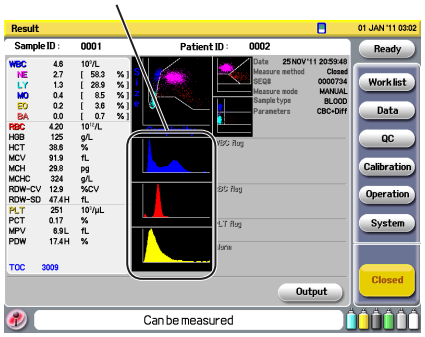


Touch the scattergram on the Results screen to enlarge it. Touch the OK key to return to the Results screen. You can also display the large scattergram by touching the arrow keys on the large numerics window.

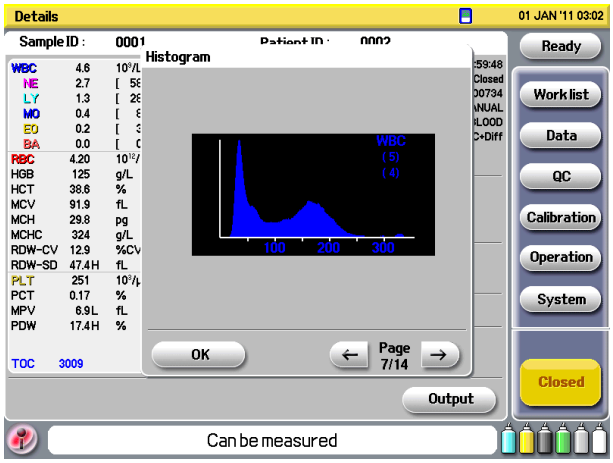


Large Histogram

Histogram



Touch the histogram on the Results screen to enlarge it. Touch the OK key to return to the Results screen. You can also display the large histogram by touching the arrow keys on the large numerics window.



Measuring Units

You can select the measuring units for each parameter or edit them on the Units screen of the Settings screen. For details, refer to “Selecting Units” earlier in this section. The factory default settings are shown in the following table.

Parameter	Units	Parameter	Units
WBC	$10^3/\mu L$	HGB	g/dL
LY%	%	HCT	%
MO%	%	MCV	fL
NE%	%	MCH	pg
EO%	%	MCHC	g/dL
BA%	%	PLT	$10^3/\mu L$
LY	$10^3/\mu L$	RDW-CV	%
MO	$10^3/\mu L$	PCT	%
NE	$10^3/\mu L$	MPV	fL
EO	$10^3/\mu L$	PDW	%
BA	$10^3/\mu L$	RDW-SD	fL
RBC	$10^6/\mu L$		

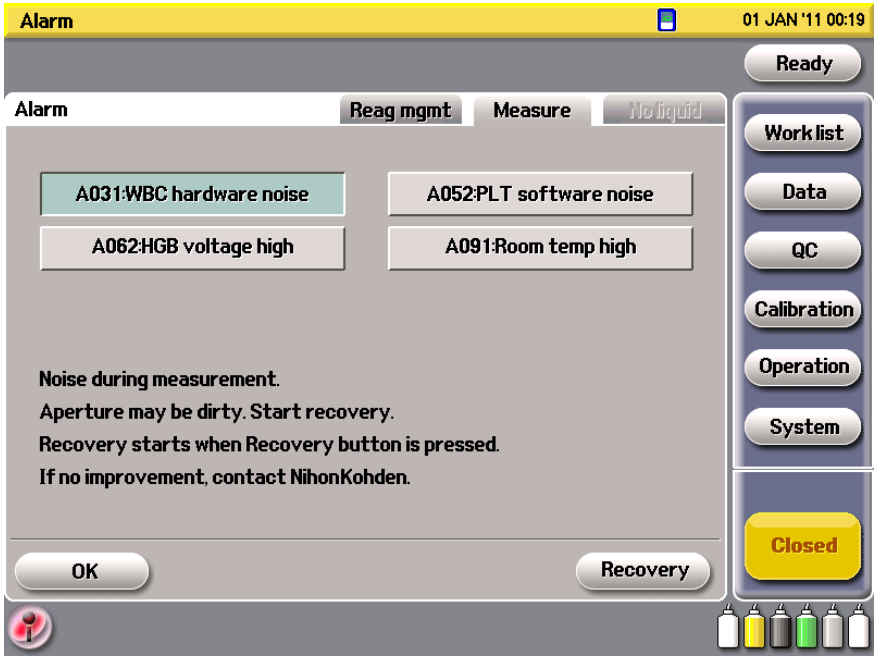
Alarm Display

When trouble occurs during counting, alarms such as “clogged”, “bubble”, “fluid level”, “sample error”, or “ ! ” are displayed and sounded. If an alarm occurs, remove the cause by referring to Section 10 “Messages and Troubleshooting”.

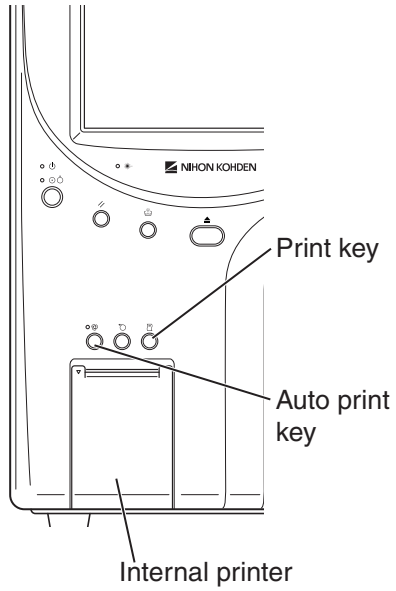
CAUTION

When an alarm occurs, the acquired data might not be correct, especially when a “ ! ” or “sample error” message appears. Do not use the data for diagnosis. Recount the sample.

Touch the information button on the lower left of the screen to display the alarm window. Press the Recovery button to remove the cause of the alarm.



Printing and Sending Results



When an optional printer or PC is connected to the analyzer, the measurement result can be printed on the printer or sent to the PC.

Auto Printing/Sending after Measurement

When an optional printer or PC is connected to the analyzer and auto print or auto output is set to "On" on the Output screen of the Settings screen, the measurement data is printed on the printer or sent to the PC when the measurement is complete. The data selected on the Output screen are printed or sent. For details on printing/sending settings, refer to "Changing Output Format" earlier in this section.

To perform auto print on the internal printer, set <Auto output after measurement> on the Int. printer screen of the Output screen to "Yes" or press the [Auto print] key on the front panel to on.

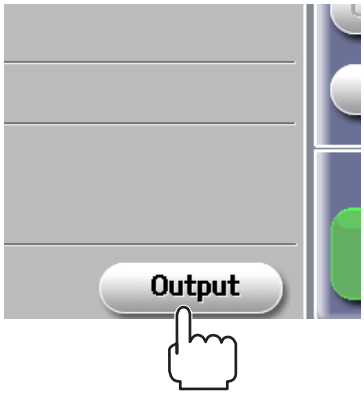
To perform auto print on the external printer, set <Auto output after measurement> on the Serial Port screen of the Output screen to "Yes" or press the [Auto print] key on the front panel to on.

To perform auto print on the card printer or auto send to the PC, set <Auto output after measurement> to "Yes" on the PORT 1 or PORT 2 screen to which the card printer or PC is connected.

Printing by Pressing [Print] Key

When the [Print] key on the front panel is pressed on the Result screen, the displayed data is printed on the printer. The data selected on the Int. printer screen are printed.

Sending Data to PC



When the Output key on the Result screen is pressed, the displayed data is sent to the PC for which <Output with "Output" key> is set to "Yes" on the Serial Port screen. The data selected on the Serial Port screen are sent.

Handling Data

General

The analyzer stores all measured and calculated data for the latest 400 samples and histograms of up to 50 samples. The stored data can be printed, transferred to a personal computer and deleted. Sample IDs can be edited.

When the sample has histograms, these can be displayed and printed.

When the type of user is Other User, the user cannot delete data.

The data is saved in backup memory after the power is turned off.

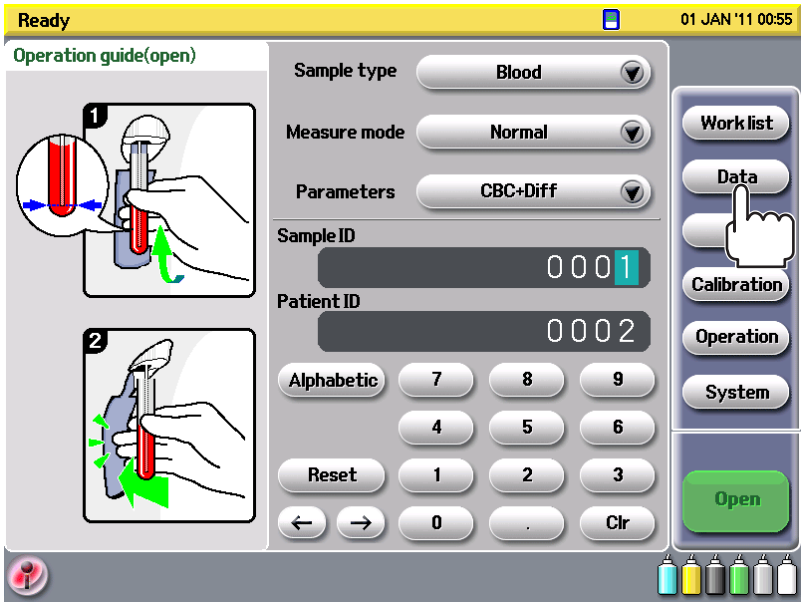
Displaying Saved Data

You can display any saved numeric data. Numeric data for up to 400 samples can be stored in memory.

You can also display histograms. Up to 50 samples can be stored in memory. An asterisk (*) mark in front of the ID means that there are also histograms.

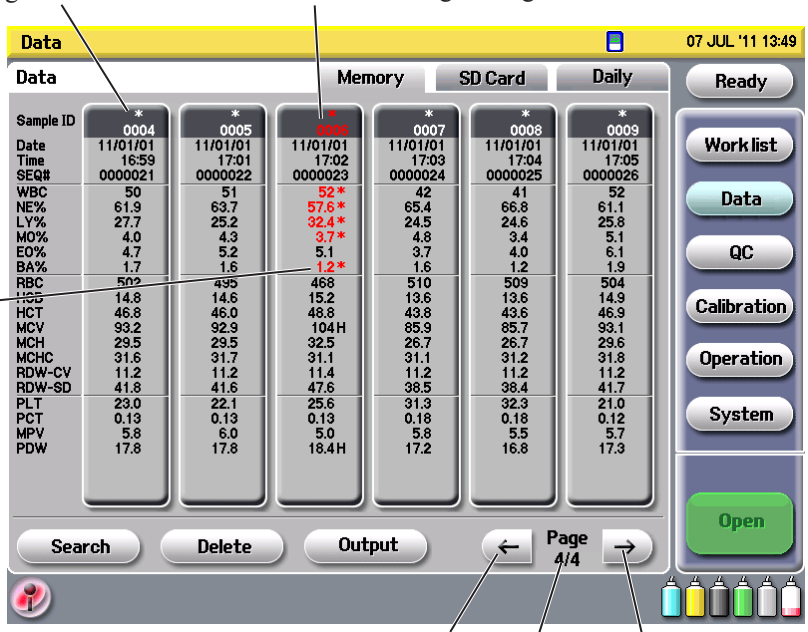
To print data, refer to the “Printing and Sending Data” later in this section.

1. Press the Data key to display the Data screen. The numeric data for the latest six samples is listed.



ID number in red indicates that the data has flags which are selected for <Select flags to display in red> on the Flags screen of the Settings screen. Refer to “Flag Settings” earlier in this section.

Asterisk (*) indicates that the data has histograms



Alarmed parameter is displayed in red

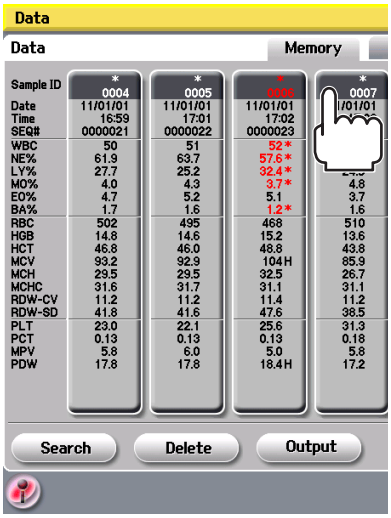
Displays older data

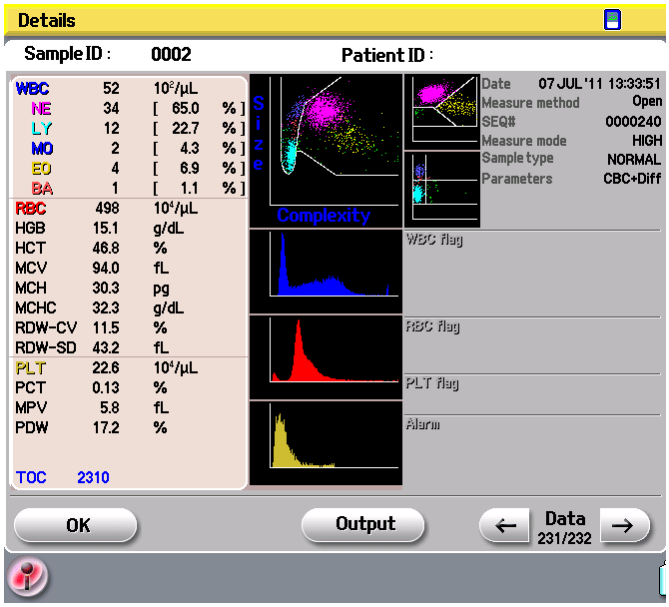
Displays newer data

Up to 100 pages can be created. 100/100 is the latest data page and 1/100 is the oldest data page.

2. Use the arrow keys to display the desired data.
   Press the ← key to display the previous page.
   Press the → key to display the next page.

3. To view the detailed data, press the ID key of the desired data and press the Details key. If the ID has an asterisk (*) mark, the histograms are displayed with the numeric data.





The data displayed on the Details screen is the same as the Results screen. For details about the Results screen, refer to “Description of the Results Screen” earlier in this section.

Press the [Print] key on the front panel to print the displayed data.

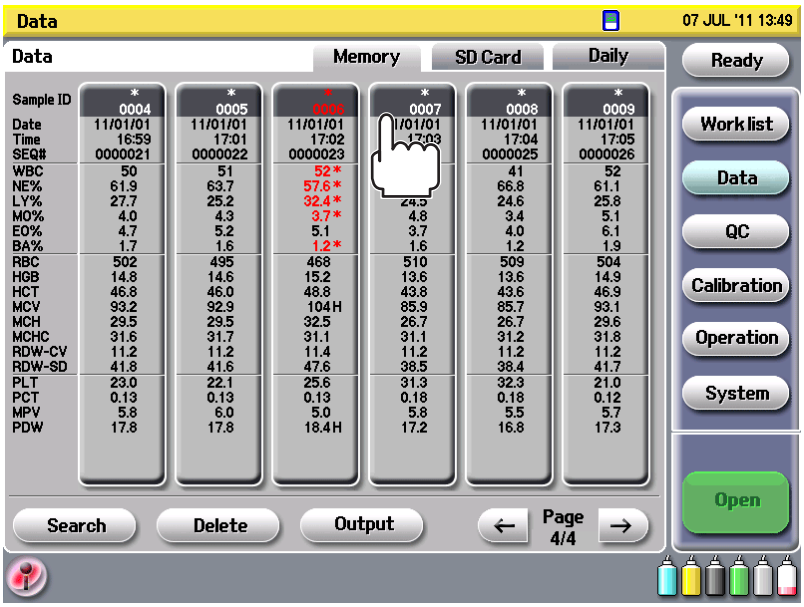
Press the Output key to send the displayed data to the connected PC.

Press the OK key to return to the Data screen.

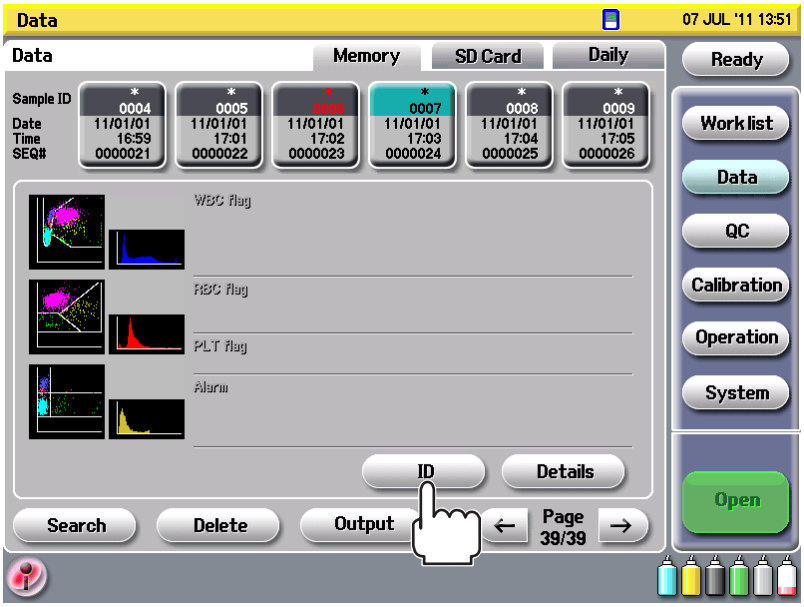
Editing the ID of Saved Data

You can change the ID of any saved data.

1. On the Data screen, select the data you want to edit.



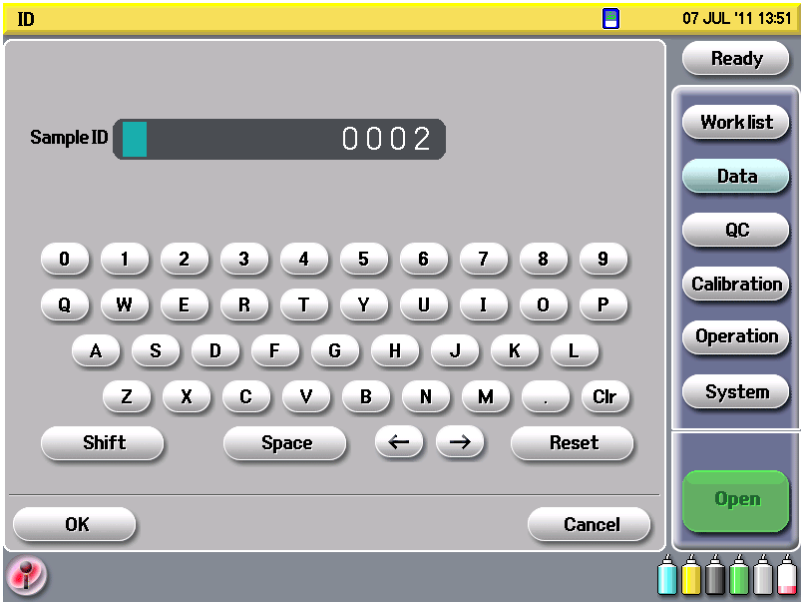
2. Press the ID key to display the ID screen.



3. Edit the ID using the alphanumeric keys. This screen functions the same as the ID screen. For details, refer to “Assigning an ID to a Sample and Patient” earlier in this section. When editing the ID, letters can be used for the last 4 digits.

CAUTION

To prevent mixing up the examination data, check that the sample and patient ID are set correctly.

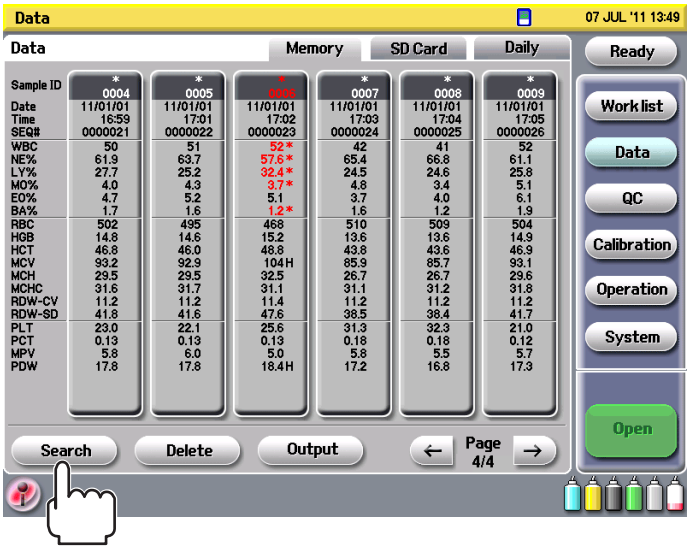


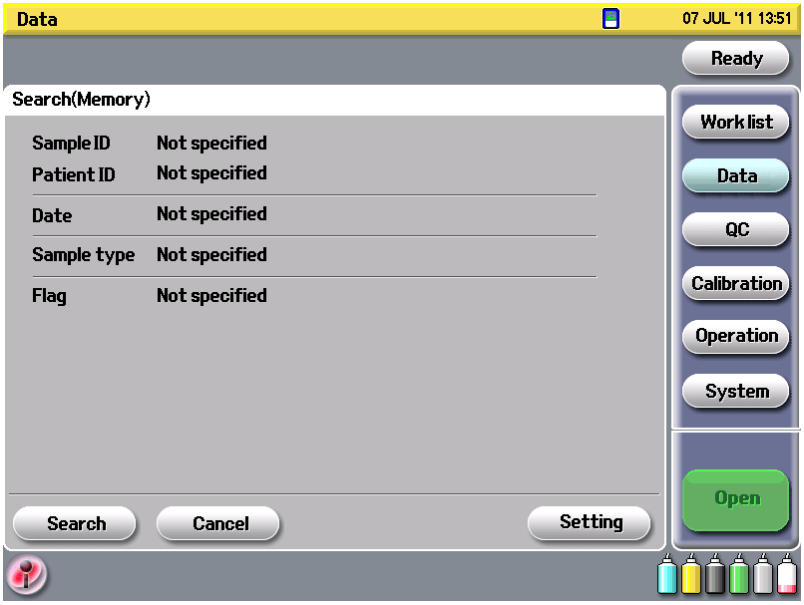
4. Press the OK key to return to the Data screen.

Searching for Saved Data

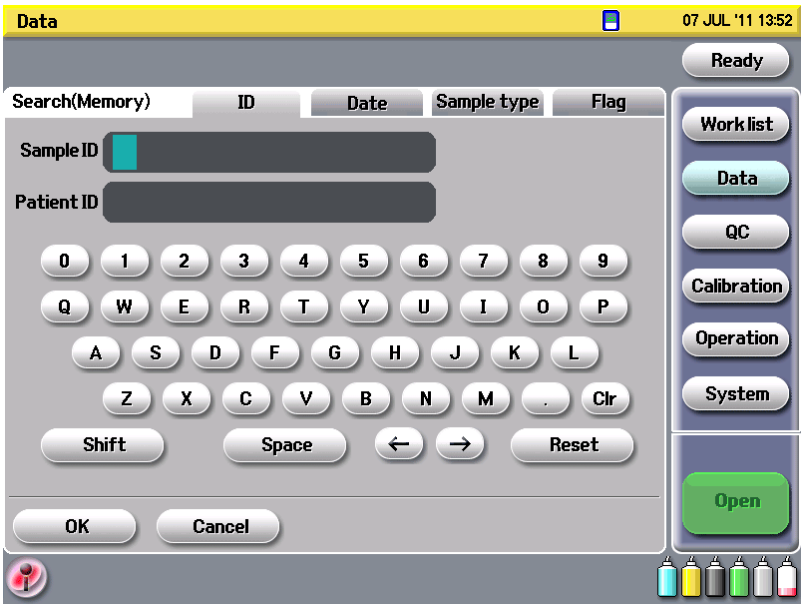
You can search for data by ID, measurement date, sample type and flags. The searched result can be printed, sent or deleted. You can also edit the ID or view the details of the searched samples.

1. On the Data screen, press the Search key to display the Search screen.





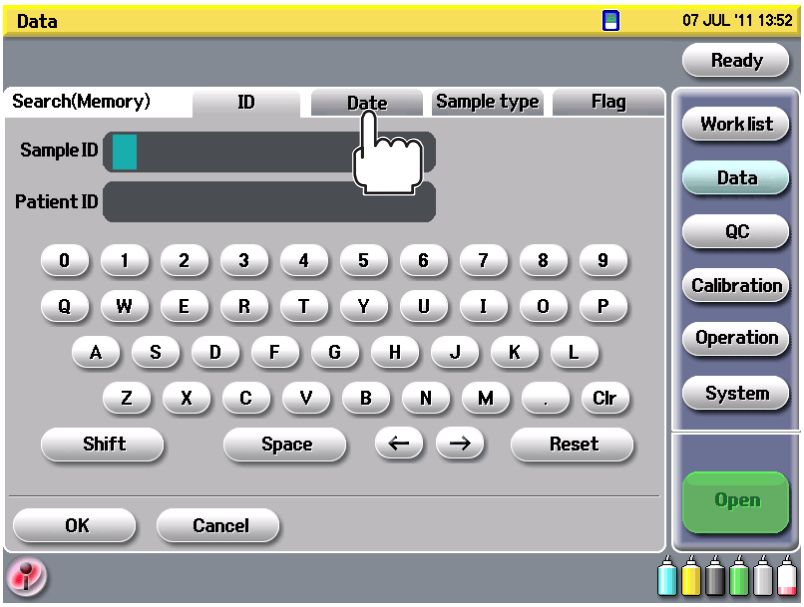
2. Enter the search criteria.
   To specify ID:
   i) Press the Setting key in the Search window to display the screen for entering ID.

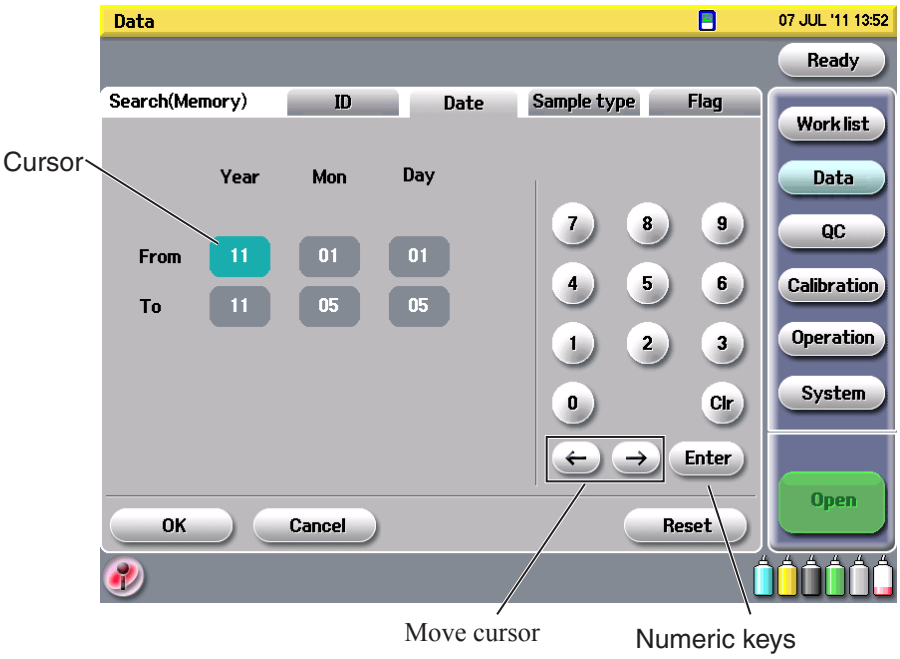


   ii) Enter the ID by using the alphanumeric keys. This screen functions the same as the ID screen. For details, refer to “Assigning an ID to a Sample” earlier in this section.
   iii) Press the OK key to return to the Search screen.

To specify measurement date:

i) Press the Date tab to display the screen for setting dates.



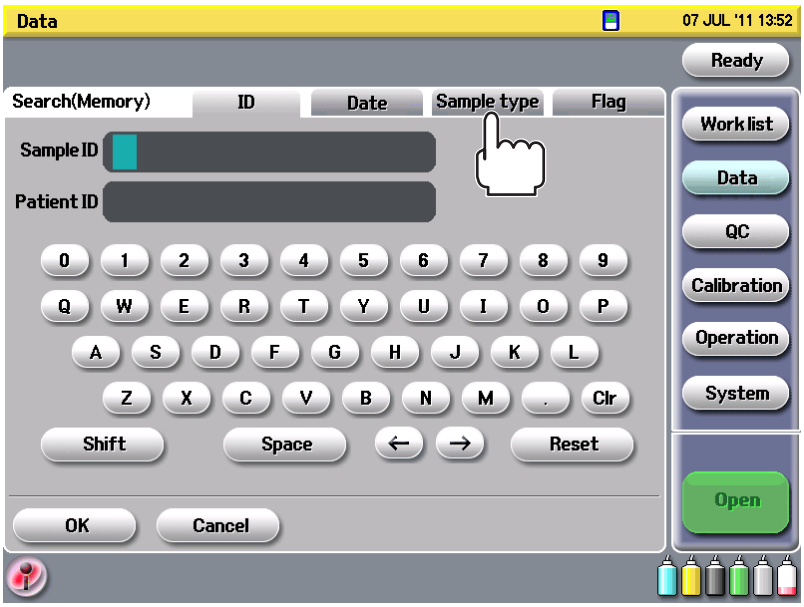


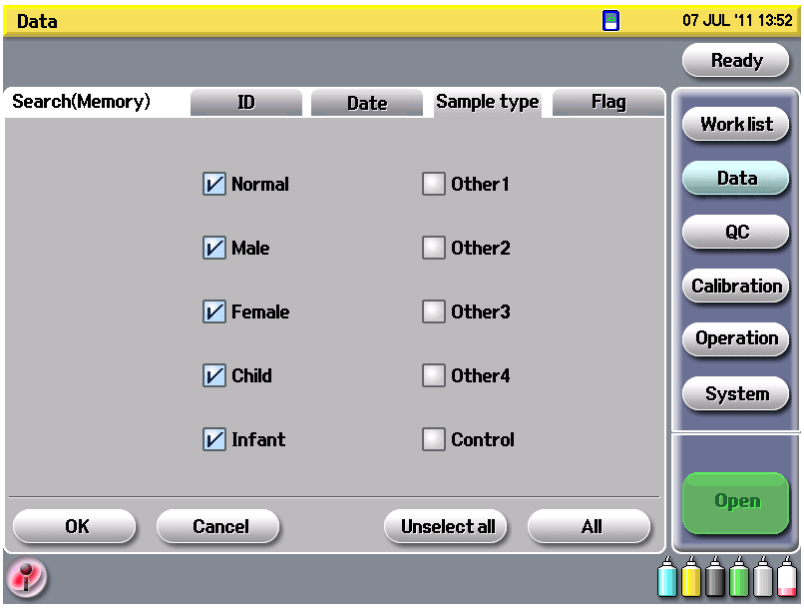
ii) Specify the date range in the <From> and <To> sections. Touch the setting value or use the arrow keys to move the cursor to the setting value you want to set. Enter the number using the numeric keys and press the Enter key to register the number. If you omit the <From> section, the search starts from the oldest stored data. If you omit the <To> section, the search ends with the latest stored data. When the Reset key is pressed, both dates are deleted.

iii) Press the OK key to return to the Search screen.

To specify the sample type:

i) Press the Sample type tab to display the screen for setting sample types.

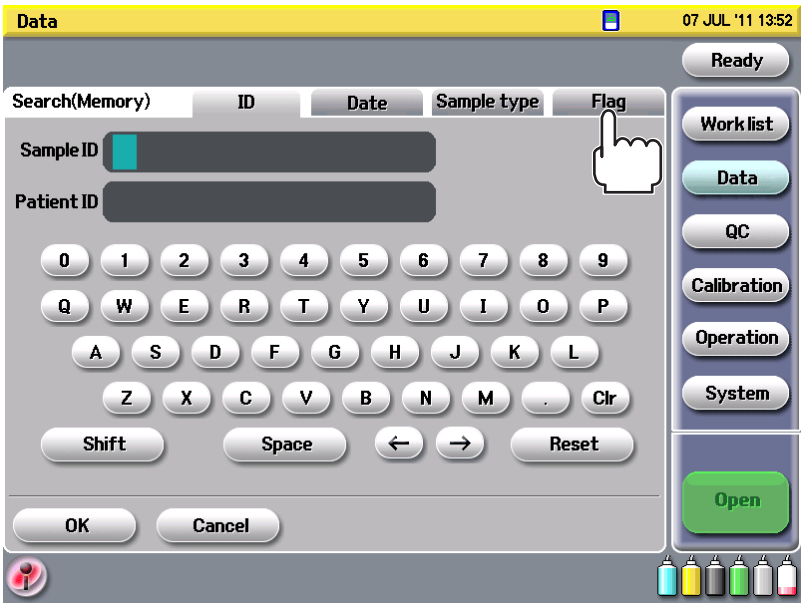




ii) Select the sample type by pressing the check box. When the All key is pressed, all sample types are selected.

To specify flags:

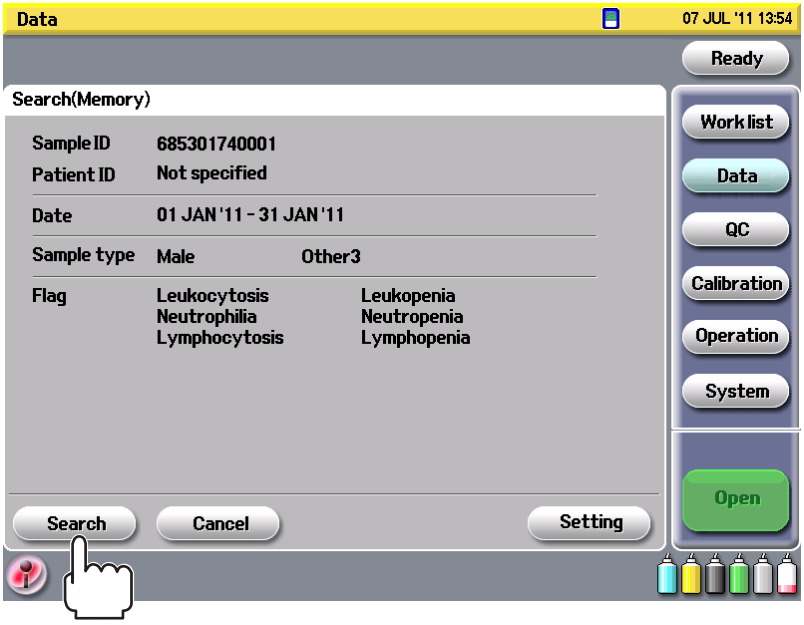
i) Press the Flag tab to display the screen for specifying flags.



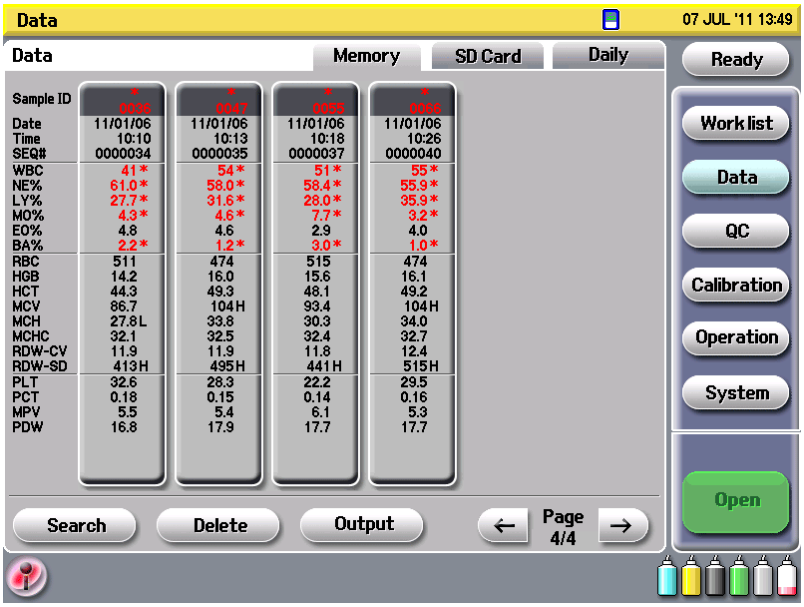
ii) Select the desired flags by pressing the check box. When the All key is pressed, all flags are selected.

iii) Press the OK key to return to the Search screen.

3. Press the Search key on the Search screen.



The search starts and the search results appear on the screen. The search results screen provides the same functions as the Data screen.



Printing and Sending Saved Data

You can print one or more stored data on the following optional printers.

Printer	Printing Data
Card Printer	Numeric data
Internal Printer	Numeric data and histograms
External Printer	Numeric data and histograms

The numerical data and histograms can also be sent to a PC.

Change the necessary settings for printing and sending data on the Output screen of the Settings screen. Refer to “Changing Output Format” earlier in this section.

Automatic Printing and Sending Data after Measurement

When auto output is selected, the data is automatically printed on the printer or sent to the connected PC after every measurement. Refer to the “Changing Output Format” and “Printing and Sending Results” earlier in this section.

Printing and Sending Stored Data

NOTE

Printing and sending data is performed according to the settings on the Output screen of the Settings screen. For example, if histogram is set not to be output, then histogram is not output to the printer or PC.

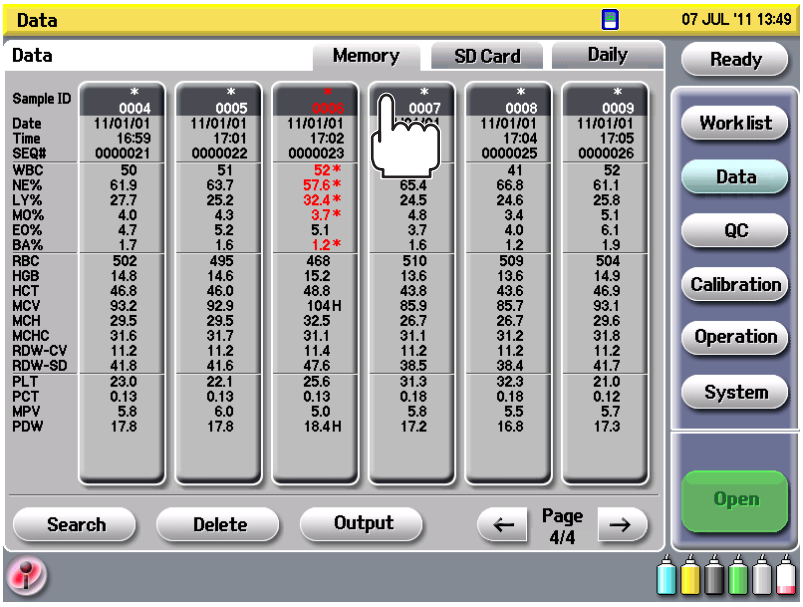
Printing or Sending Single Data

You can print or send one data individually.

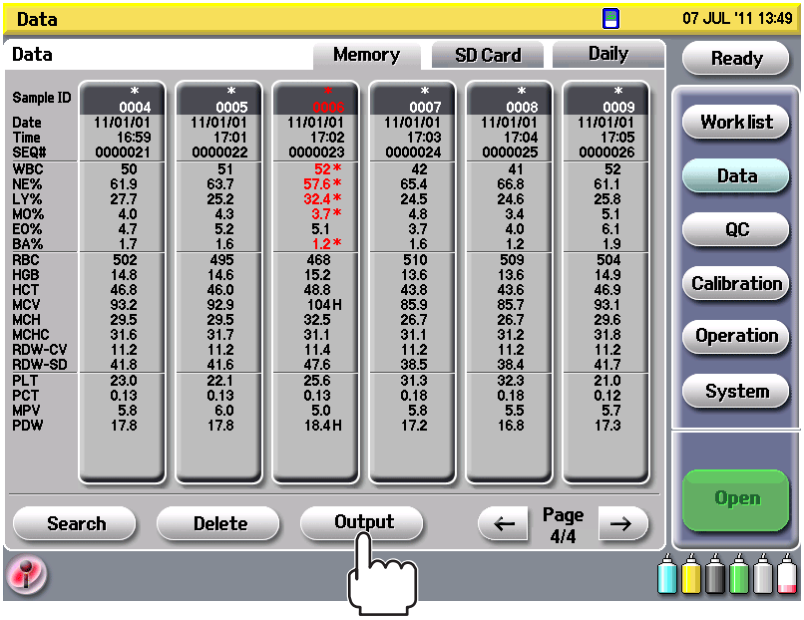
NOTE

Histograms cannot be printed on the card printer.

1. On the Data screen, press the ID key of a desired data to print or send.



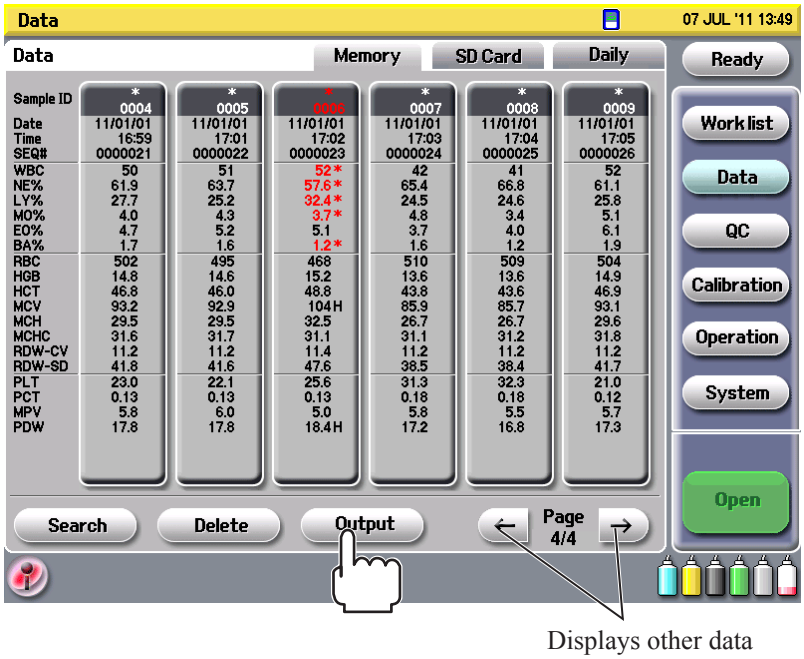
2. Press the Output key. The selected data is printed or sent to the PC.



Printing or Sending Multiple Data

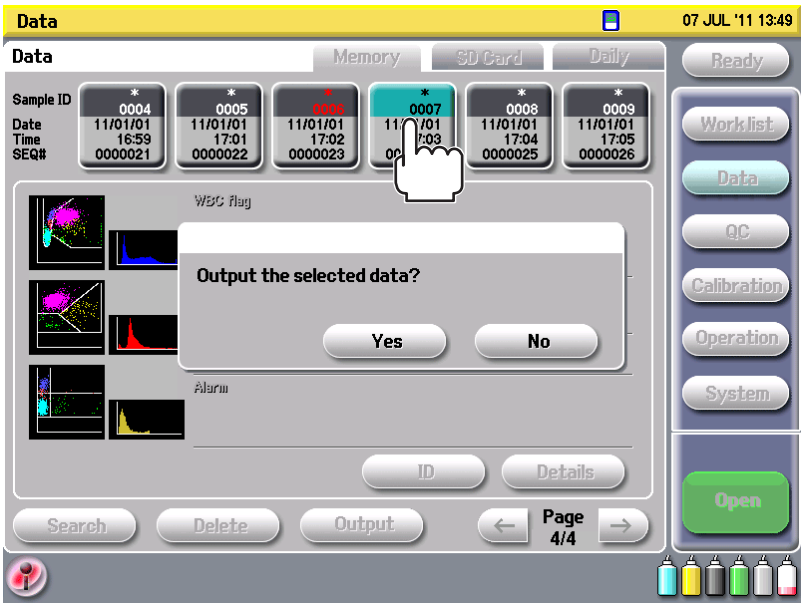
On the Data screen, you can select multiple data to print or send.

1. On the Data screen, press the Output key to send the data. The “Select first data” message appears.



2. Find a desired data using the arrow keys and press the ID key of the data. The “Select last data” message appears.

3. Find the last data using the arrow keys and press the ID key of the data. All data between the first and last ID will be output.
   The “Output the selected data?” message appears.



4. Press the Yes key. The selected data is printed on the printer or sent to the PC. If you press No, the process is canceled and the screen returns to the Data screen.

Printing or Sending Data for All Samples of a Single Day

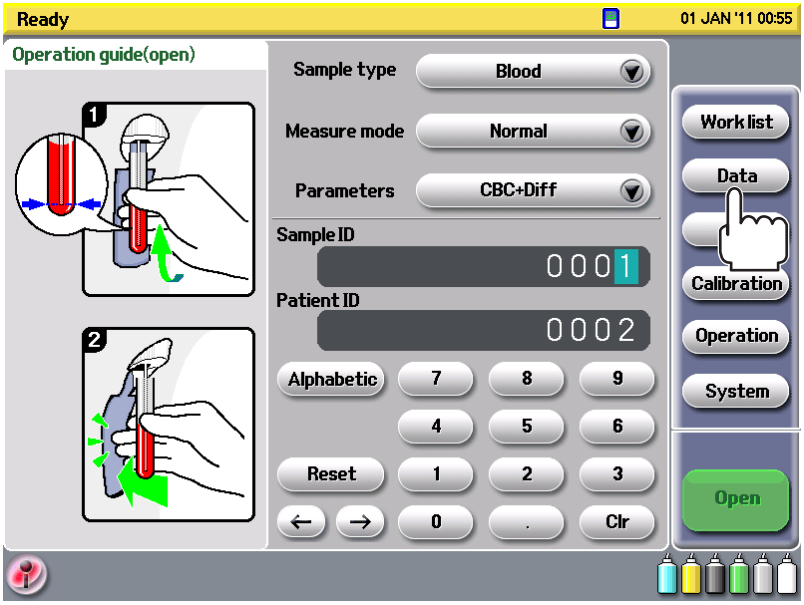
All numerical and histogram data for one day can be printed on the optional printers or sent to the connected PC. This function is not available for the card printer. The data is transferred to the instrument for which Output with “Output” key is set to On on the Serial port and USB settings. Refer to “Changing Output Format” in this section.

When printing, make sure there is enough recording paper in the printer.

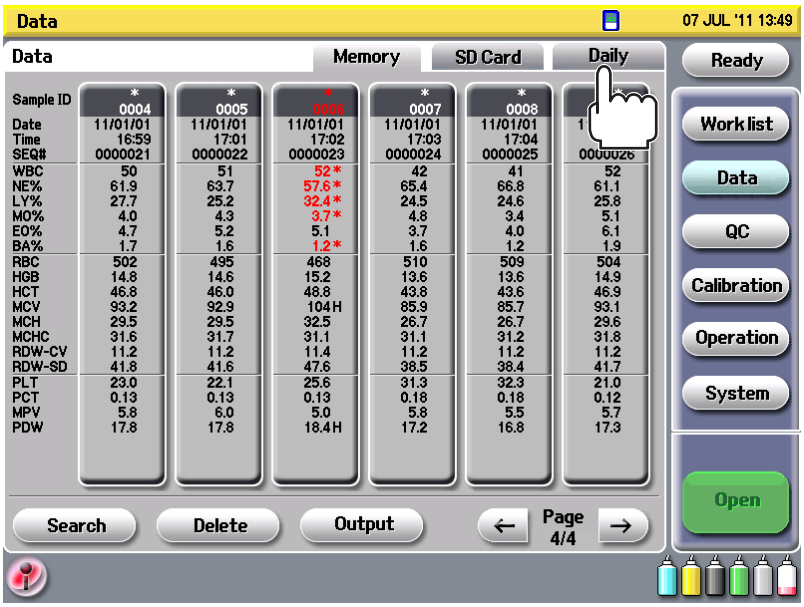
NOTE

- To transfer the data, the communication format must be the same between the instruments. Match the PC and analyzer settings before transferring the data.
- Before transferring the data, prepare the receiving instrument.
- The data of a single day can be sent only when the PC is connected to the USB socket. The data is not sent even if the PC is connected to the serial port.

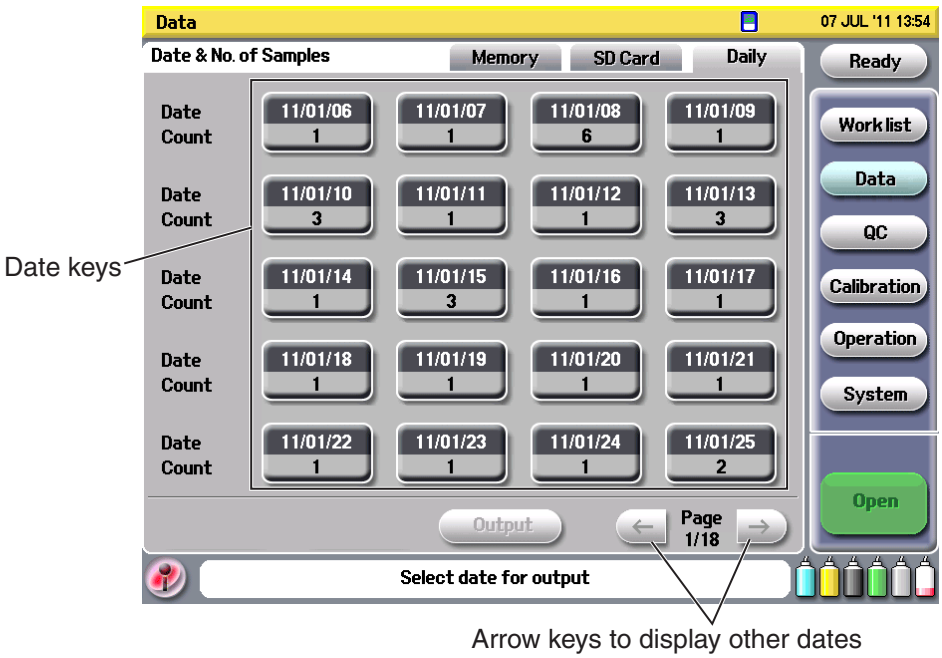
1. Press the Data key.



2. Press the Daily tab on the Data screen.



The screen shows the dates of the stored data and the number of data of each day.



3. Find a desired date using the arrow keys.

4. Press the desired date key to print or send the data.

5. Press the Output key.
   The confirmation message appears.

6. Press the Yes key to print or send all data for the selected date. If you press No, the process is canceled and the screen returns to the Date & No. of Samples screen.

   When printing or sending is complete, the screen returns to the Date & No. of Samples screen.

RS-232C Data Transfer

Sample data can be transferred to the optional printer or a personal computer via the serial ports on the rear panel of the analyzer. This allows you to print or search specific data or perform the statistical work. Sample data can be automatically transferred after each counting.

CAUTION

Only use the 3-prong power cord for the PC.

CAUTION

In order to avoid any safety hazard, only connect personal computers which are approved by UL 60950.

CAUTION

Connect only the specified instruments to the connectors or sockets on the analyzer by following the specified procedure. Otherwise electrical leakage current may harm the operator.

For details about the RS-232C data transfer and format, refer to the Technical Reference Manual of Data Communication Protocol. To obtain this manual, you must sign the license agreement.

Deleting Saved Data

This analyzer can store numeric data for up to 400 samples and histograms for up to 50 samples. If the memory is full and new data is acquired, the oldest data is deleted and the new data is saved.

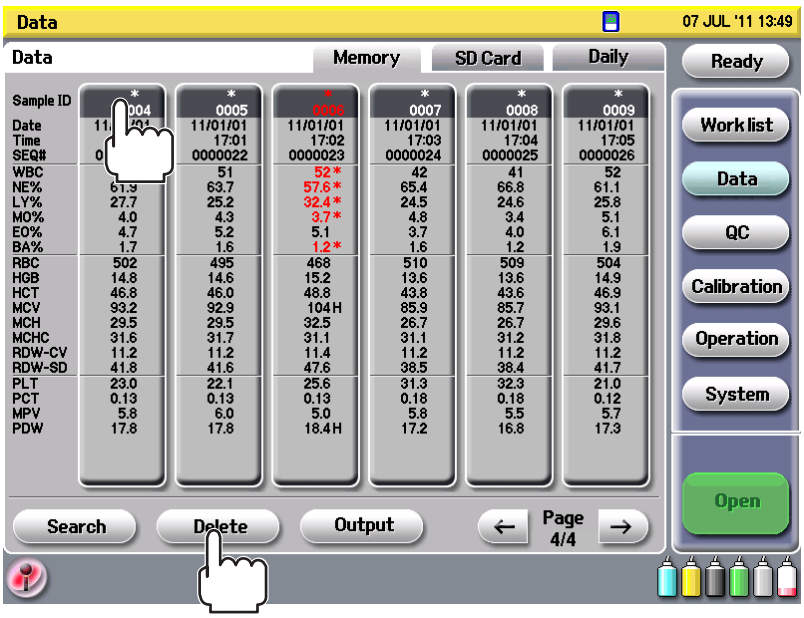
You can delete one data or a block of data together.

To delete data, the type of user must be either Lab technician or Service.

Deleting One Data

1. On the Data screen, press the ID key of the data to be deleted.

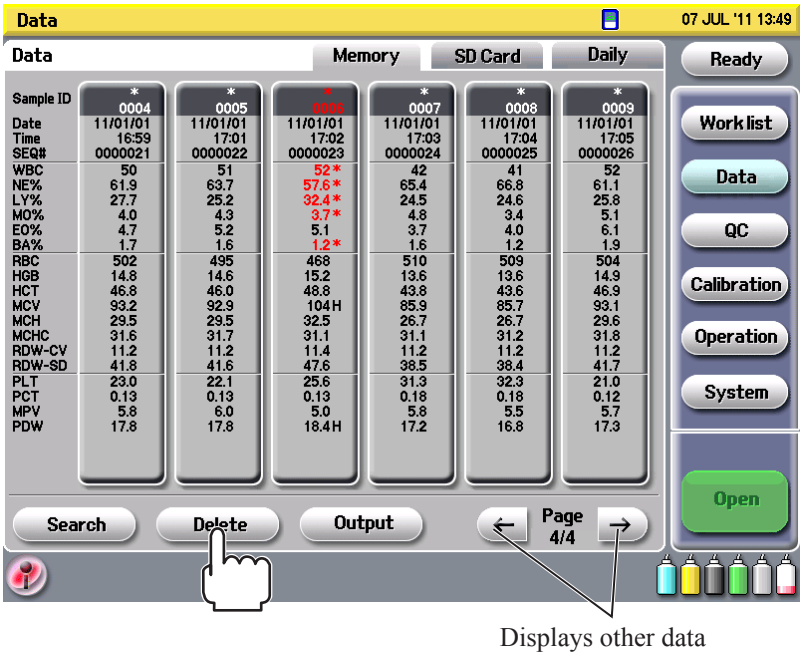
2. Press the Delete key. A confirmation message appears.



3. Press the Yes key to delete the selected data. If you press No, the process is cancelled and the screen returns to the Data screen.

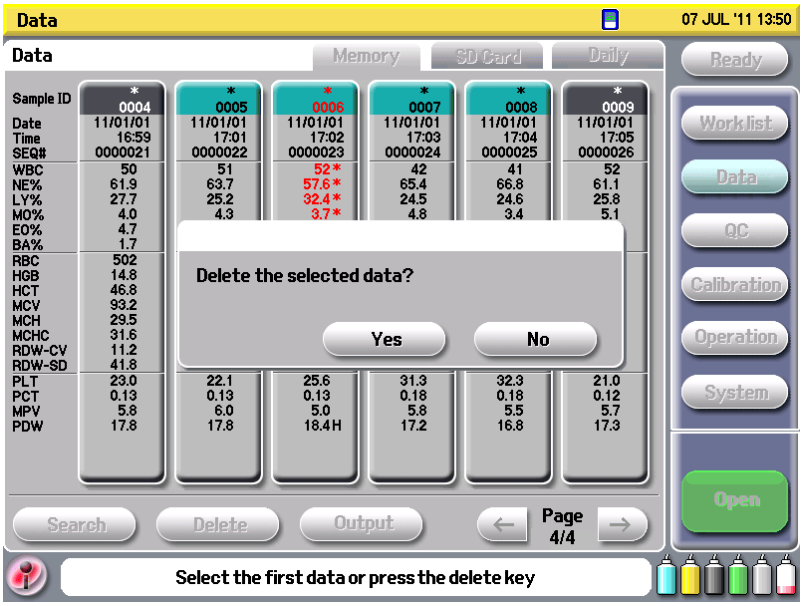
Deleting Multiple Data

1. On the Data screen, press the Delete key. The “Select first data” message appears.



2. Find the first desired data using the arrow keys and press the ID key of the data.
   The “Select last data” message appears.

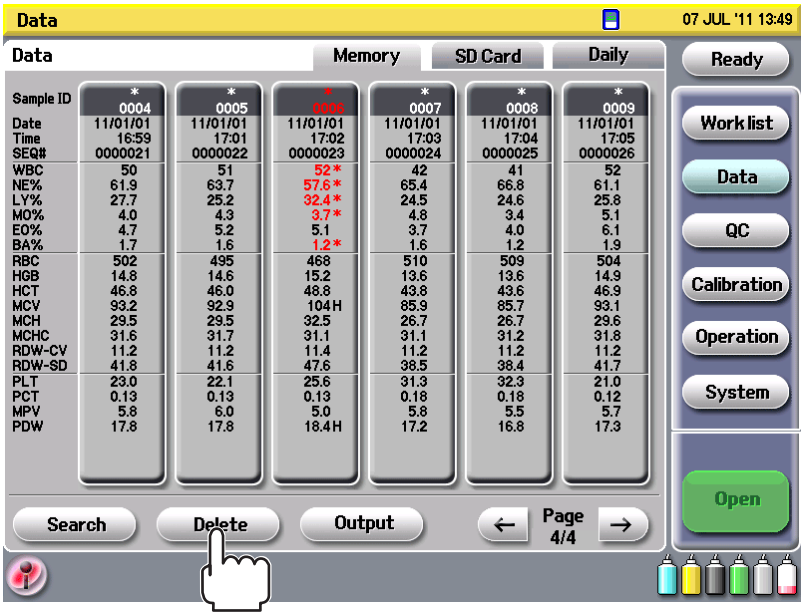
3. Find the last data using the arrow keys and press the ID key of the last data.
   The “Delete the selected data?” message appears. All data between the first and last ID will be deleted.



4. Press the Yes key. The selected data (numeric and histogram) is deleted and the screen returns to the Data screen.
   If you press No, the process is canceled and the screen returns to the Data screen.

Deleting All Stored Data

1. Press the Delete key on the Data screen.



2. Select the latest data then select the oldest data. Use the arrow key to display the oldest data.

3. Press the Yes key to delete all data.

   Press the No key to cancel deleting.

Turning the Power Off

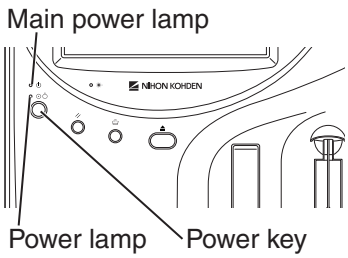
Daily Shutdown

To keep the analyzer in optimum condition, check and clean it after every use. If an error is found during check, clean or replace the item.

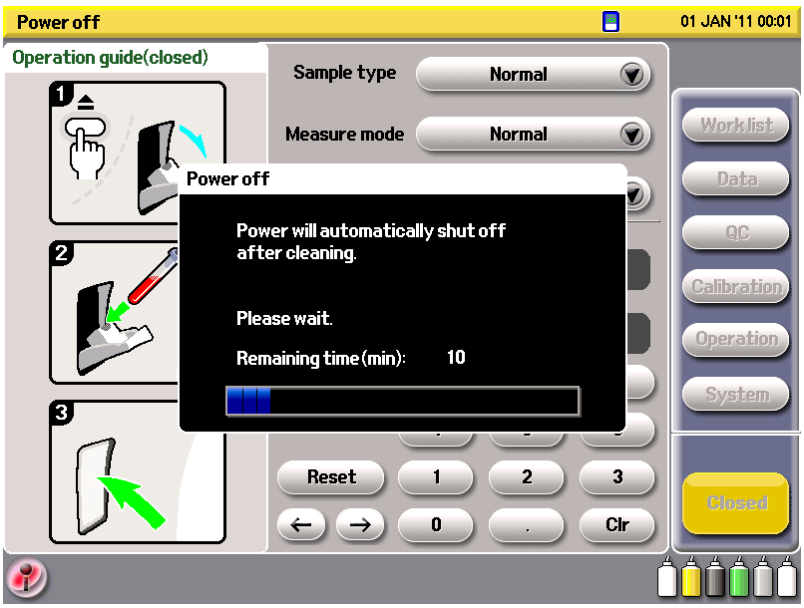
Checking List Before Turning the Power Off

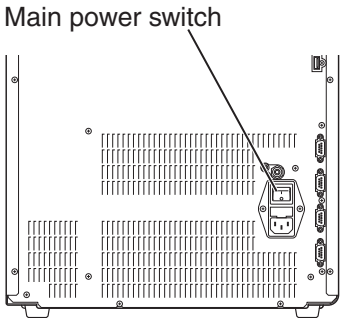
- There is enough lysing reagent, diluent and detergent left in the containers.
- The waste container is empty.
- The waste tube is properly connected.

Turning the Power Off



To turn the power off, press the [Power] key on the front panel. The analyzer automatically performs cleaning and the “Power will automatically shut off after cleaning.” message appears. After the cleaning is completed, the power is automatically turned off.





To turn the main power off, press the [Main power] switch on the rear panel. Check that the [Main power lamp] on the front panel is off.

Always leave the main power on except for storage and transportation of the analyzer.

Check List After Turning Power Off

- There was no leakage during use.
- The outside enclosure of the analyzer is wiped off and clean.
- The fluid path is automatically cleaned when the power is turned off.
- There are no blood clots in the measurement bath or sub bath.

Check List Before Long Term Storage

- The inside of the analyzer has been cleaned with distilled water. For details, refer to “Storing and Transporting Analyzer” in Section 9.
- There is no fluid left inside the analyzer.
- The power is turned off.
- No chemicals or water are placed around the analyzer.
- The analyzer, diluent and detergent are stored properly.
- There is enough lysing reagent, diluent and detergent left in the containers.

Auto Cleaning and Priming when Operating All Night

When operating the analyzer all night and auto priming and/or cleaning is set, check the following:

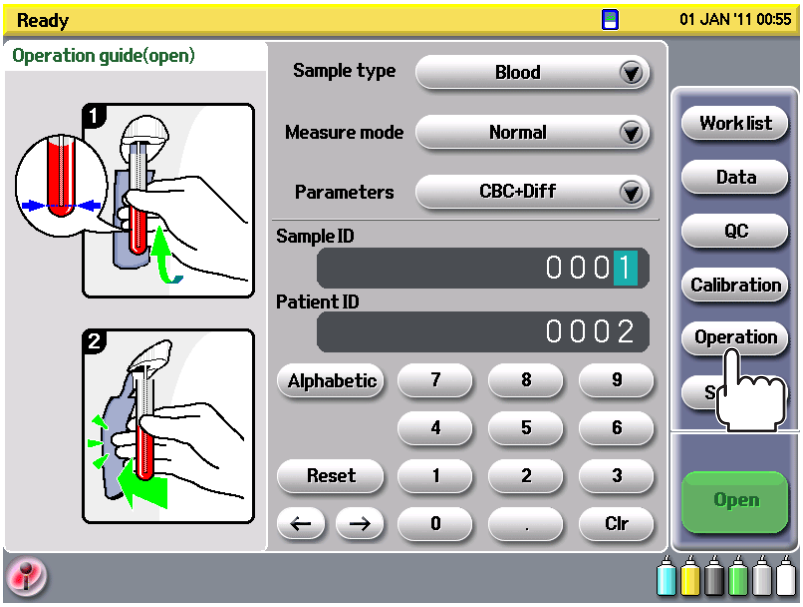
- There is enough diluent and detergent left in the containers.
- The waste container is empty.
- The waste tube is properly connected.

The analyzer is set to clean itself at 23:00 in the factory.

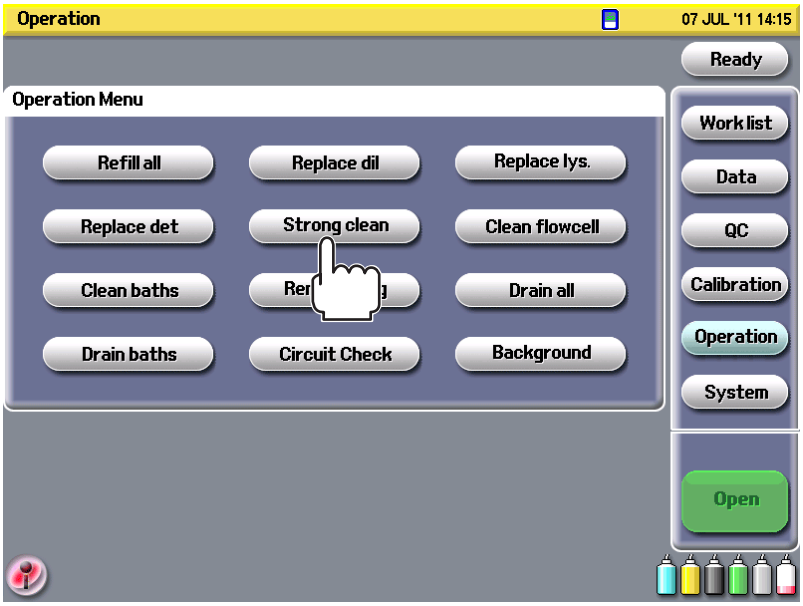
Strong Cleaning

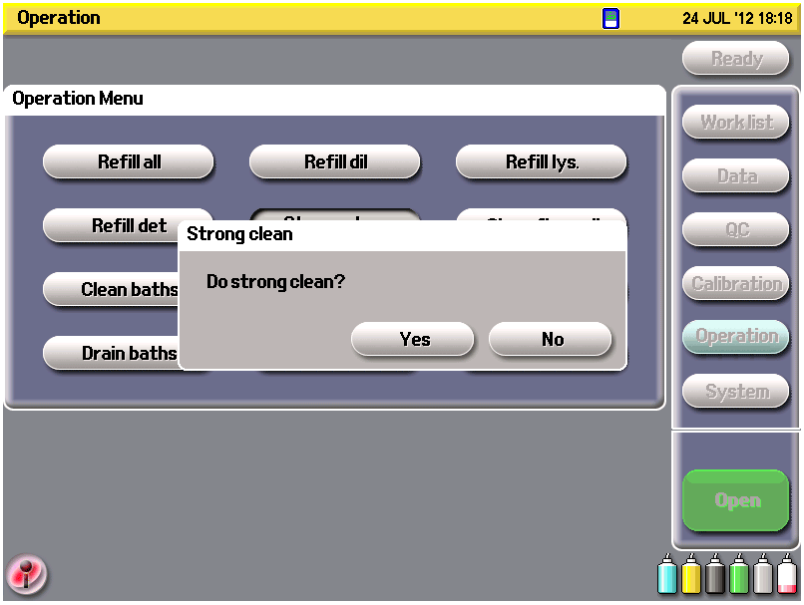
When background counts are out of specification or the clogging message frequently appears, perform strong cleaning to clean the analyzer more thoroughly with CLEANAC•3 detergent containing sodium hypochlorite.

1. Press the Operation key to display the Operation screen.



2. Press the Strong clean key on the Operation screen.





3. Press the Yes key to start strong cleaning. The analyzer starts cleaning and the “Do strong clean?” message appears on the screen.
   Press the No key to cancel the procedure.

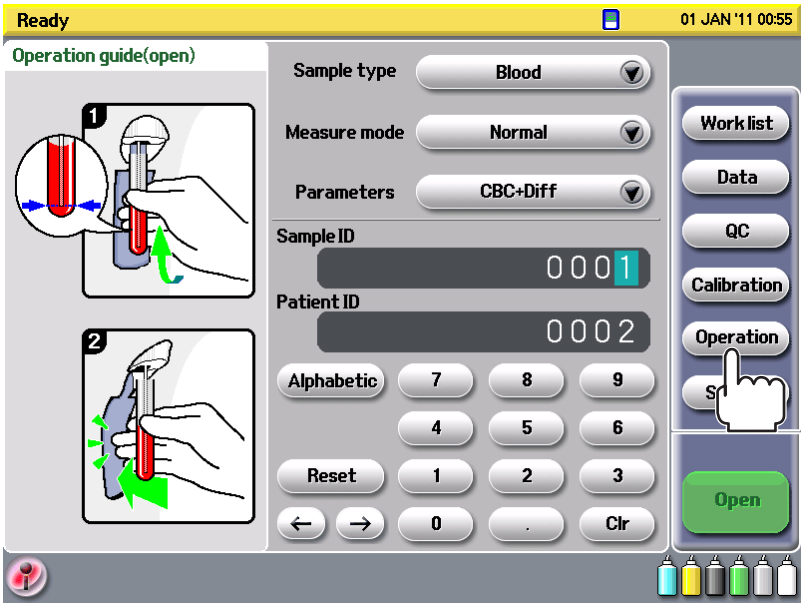
   After cleaning, the screen returns to the Ready screen.

4. After maintenance is complete and the analyzer is turned on again, measure background noise at least twice.

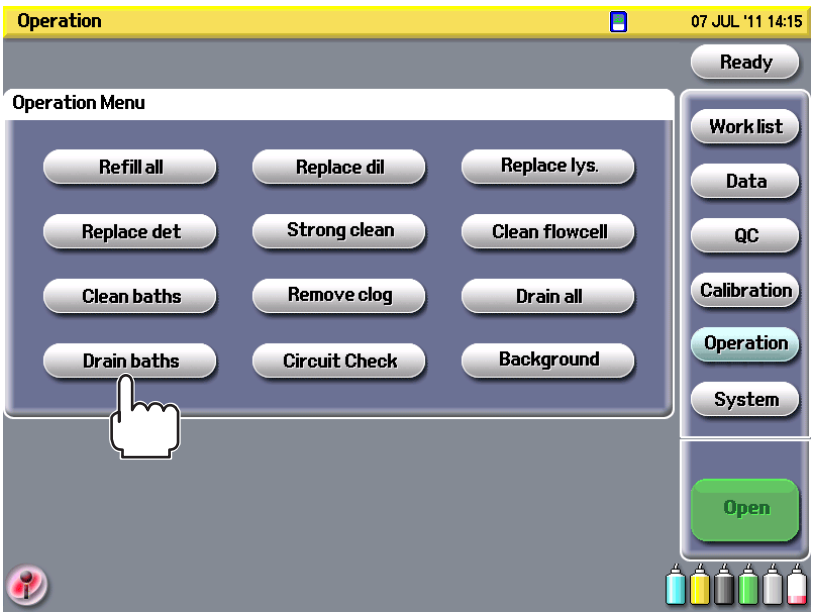
Draining the Measurement Baths and Sub Baths

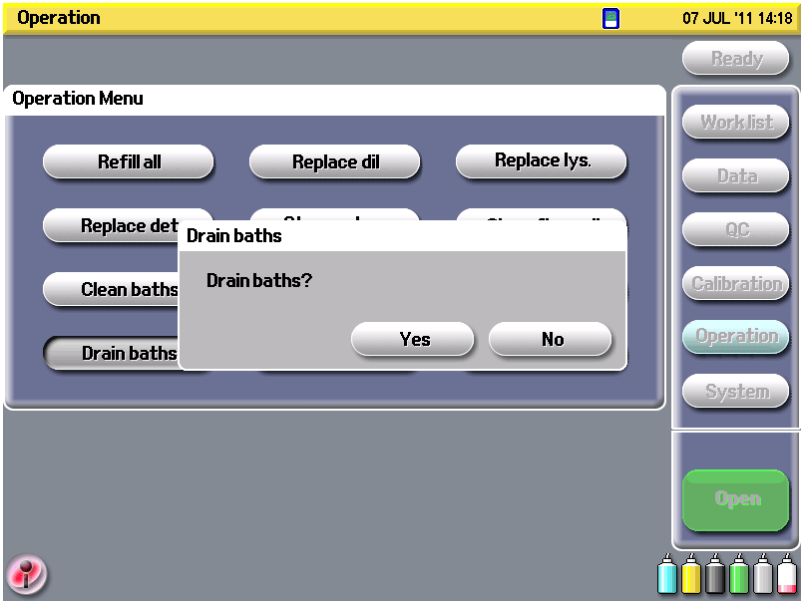
Drain the measurement and sub baths before moving the instrument or before doing maintenance to prevent spilling diluent inside the instrument.

1. Press the Operation key to display the Operation screen.



2. Press the Drain baths key on the Operation screen. The “Drain baths?” message appears.





3. Press the Yes key to start draining. The analyzer starts draining the baths and the “Draining” message appears on the screen.

   Press the No key to cancel the procedure.

   After draining, the screen returns to the Ready screen.

Section 6 Calibration Procedures

General

Calibration is a procedure that confirms the accuracy of the analyzer and must conform to guidelines established by the regulatory agencies in your locality.

The analyzer is initially calibrated at the factory prior to shipment. Calibration must be confirmed during installation by the user. The analyzer is electronically stable and should not require frequent recalibration when it is operated and maintained according to recommendations in this manual.

Calibration can be performed for WBC, RBC, HGB, HCT, PLT, RDW-CV and MPV using the MEK-CAL calibrator. This calibrator must be used within 7 days after opening, stored at 2 to 8˚C (35 to 46˚F) and handled appropriately according to its manual. For higher accuracy, use the calibrator soon after its opening.

The parameters can be calibrated automatically at the same time using the assay values, or individually by selecting the desired parameter. HCT is calibrated from RBC and MCV. Therefore, it is calibrated by calibrating RBC and MCV.

NOTE

- Use the calibrator for calibration.
- When the type of user is set to USER, the numeric keypad is not displayed on the screen and the calibration coefficient cannot be changed. Refer to “Assigning Users and Passwords” in Section 5.

When to Calibrate

Scheduled calibration of the analyzer should conform to any guidelines established by regulatory agencies.

Calibration must be confirmed on a regular basis according to your laboratory’s standards and protocols, and should include daily confirmation on each shift and following a reagent lot number change. Built-in Quality Control programs on the analyzer are designed to provide continual monitoring and confirmation of instrument calibration. The laboratory should make the decision to recalibrate based on the performance of the analyzer in these Quality Control programs.

Calibration is necessary after service adjustments or major component changes. Calibration is necessary when indicated by the results of Quality Control procedures. Calibration is also required after component replacement, software upgrade, preventive maintenance, or reagent changes.

Calibration must be considered the last step in a troubleshooting sequence. Frequent unnecessary recalibrations can mask an underlying problem with the instrument’s performance.

Note on the Calibration Procedure

Calibration can be performed in both closed and open sampling modes. It is only necessary to calibrate in closed mode. When calibration is performed in closed mode, the new calibration coefficient is also applied to open mode and pre-dilution blood mode. However, because the pre-dilution blood samples are diluted manually, the data that is obtained from the different sampling and dilution modes may differ. In such a case, perform calibration in open mode and pre-dilution blood mode.

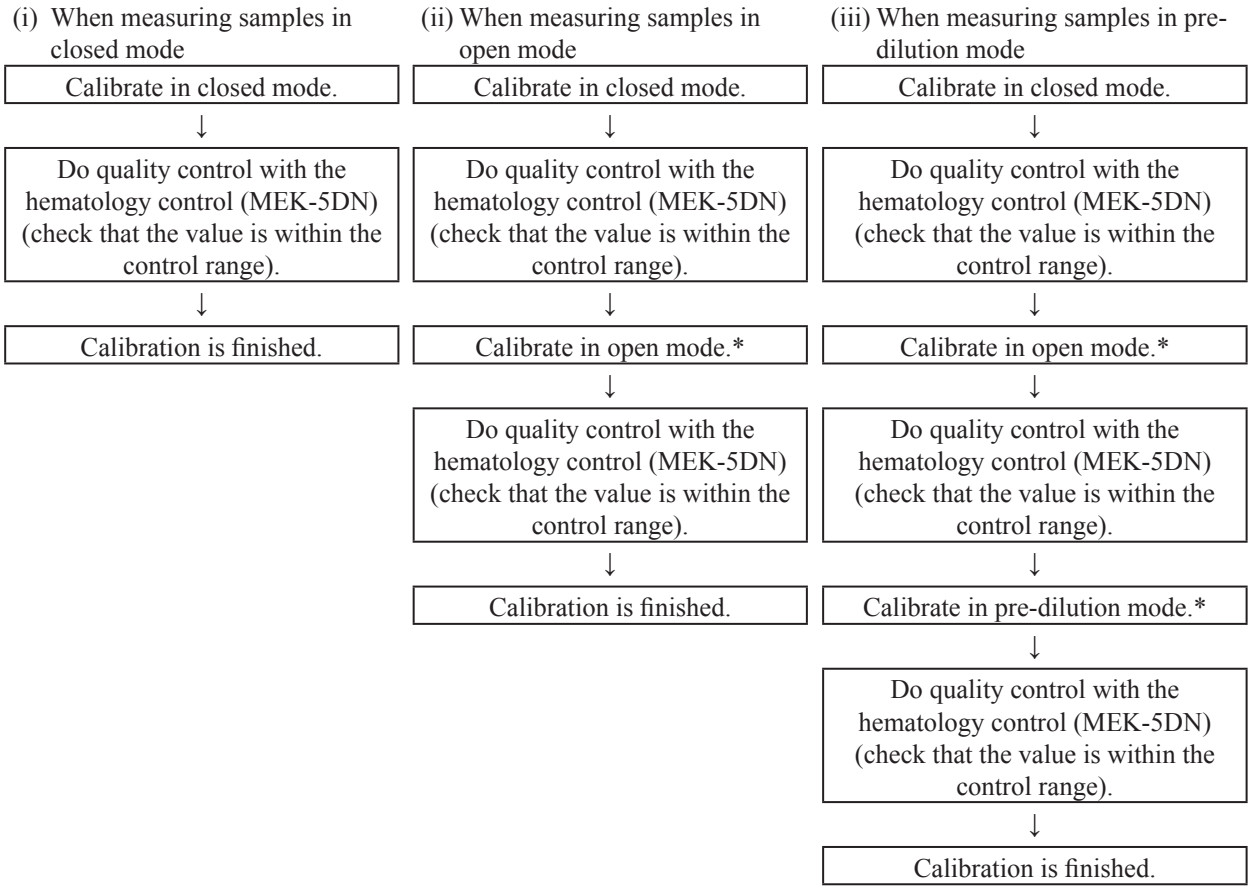
Calibration in closed blood mode must be performed before calibration in open mode and pre-dilution blood mode.

Calibration can only be performed by a lab technician or service user. A user of any other user type can open the Calibration screen but cannot change any settings. For user settings, refer to "Assigning Users and Passwords" in Section 5.

NOTE

You must calibrate in closed mode first even if you measure samples in open and pre-dilution mode.

Flowchart of Calibration



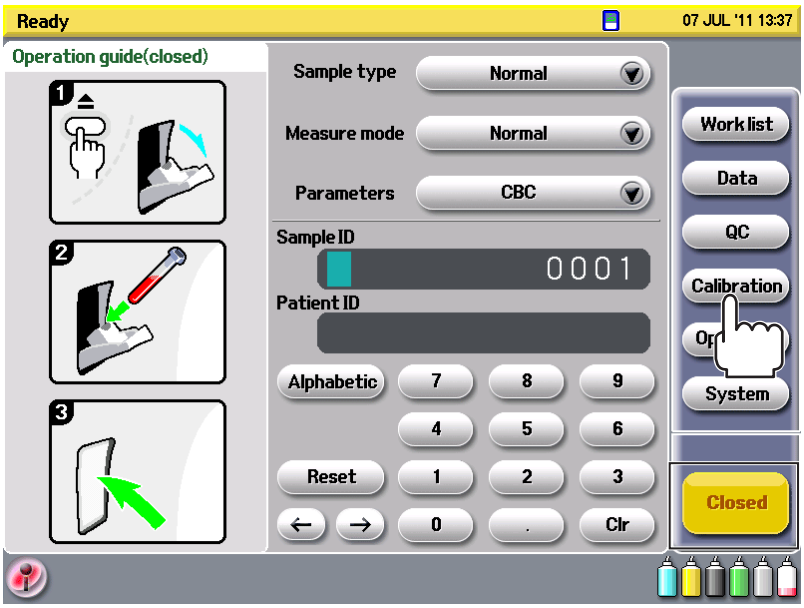
* Perform calibration as needed when the measurement data does not match the calibration value of closed mode.

NOTE

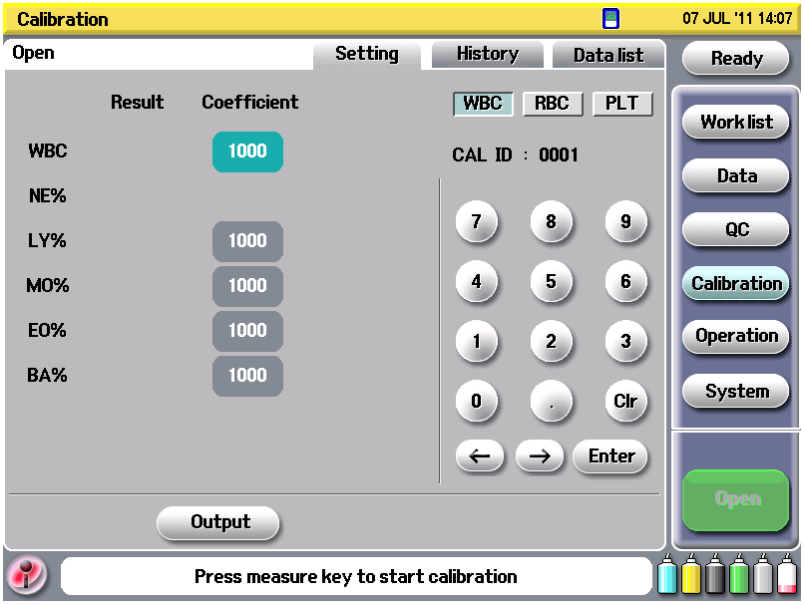
- The calibrator can calibrate WBC, RBC, HGB, HCT, RDW-CV, PLT and MPV but cannot calibrate leukocyte classification. To calibrate leukocyte classification, measure several blood samples that have been stored in room temperature and were drawn within the last 8 hours. Change the calibration coefficient by comparing the result of measurement and manual method. Do not use abnormal samples as the calibrator.
- The WBC 5 part differential is calibrated by checking that the calibration coefficient of LY%, MO%, EO% and BA% is 1000. Only check the calibration coefficient here because the WBC 5 part differential is calibrated correctly by the optical adjustment (fine).
- MEK-5DN hematology control cannot be used as the calibrator. MEK-5DN is only for quality control.
- Do not use calibrator which is past the expiration date.
  Unopened: expiration date on the label or package
  Opened: 7 days after opening
- Store the calibrator between 2 and 8°C (35.6 to 46.4°F) and do not freeze it.
- Use the calibrator after it returns to room temperature.
- Mix the calibrator by gently turning it upside down several times before measurement.
- Read the manual of the calibrator thoroughly and follow the precautions.
- Re-calibrate when there is difference with the reference method. Decide the calibration coefficient from the average of the measured data then enter the coefficient.

Calibration in Closed Mode

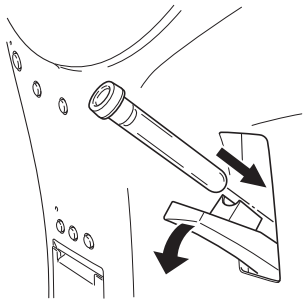
1. On the Ready screen, check that “Closed” is selected for sampling mode.



2. Press the Calibration key to display the Calibration screen.

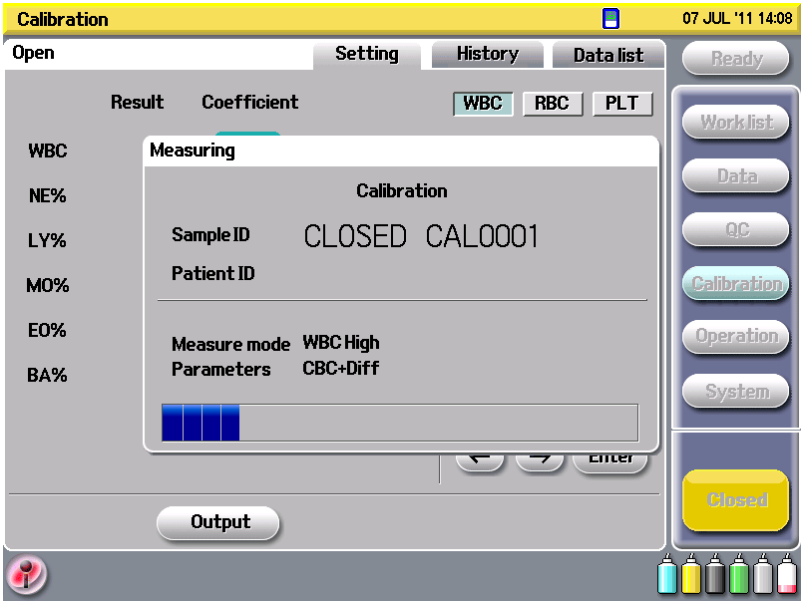


3. Prepare the MEK-CAL calibrator sample in a sample tube. (If the hematology control is taken from a refrigerator, wait at least 10 minutes after the control temperature reaches room temperature.)

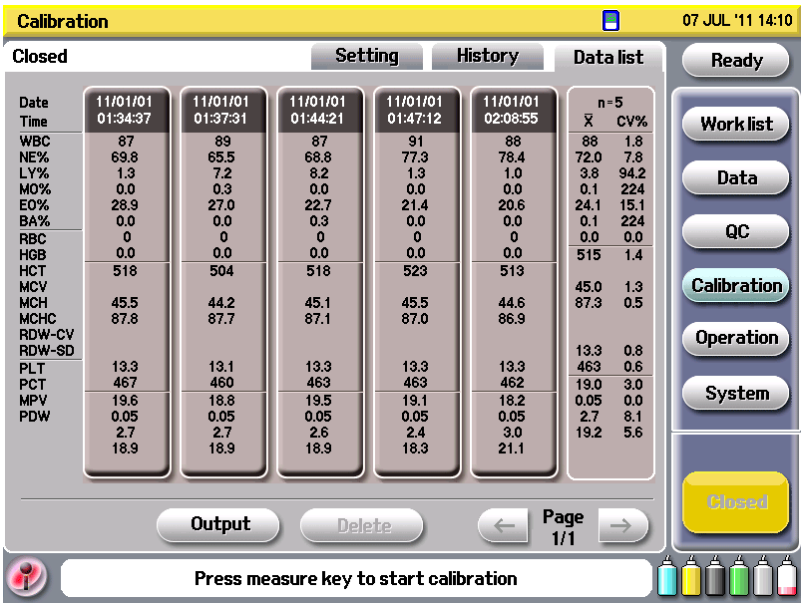


4. Press the [⏏ Eject] key on the front panel to open the tube holder and set the sample tube containing the hematology control.

5. Close the tube holder. The hematology control is measured.



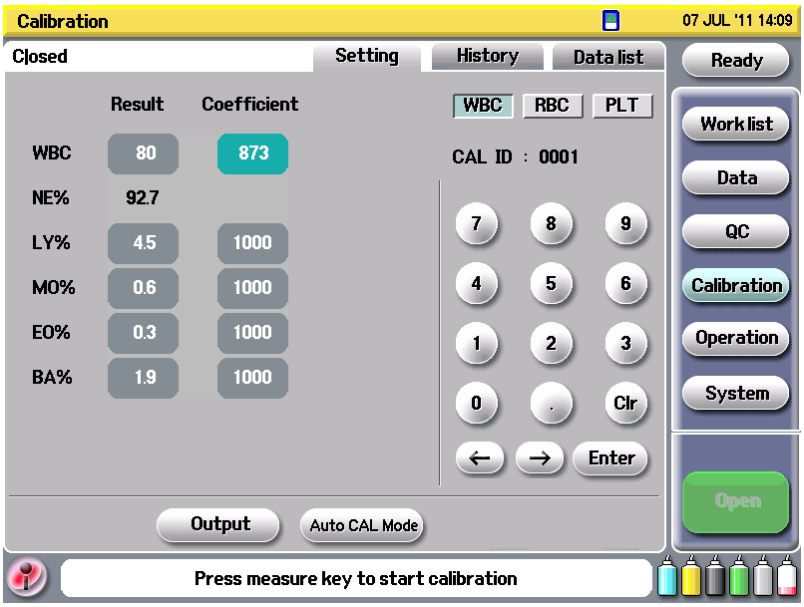
After measurement, the Data list window is displayed and the data is stored in the analyzer.



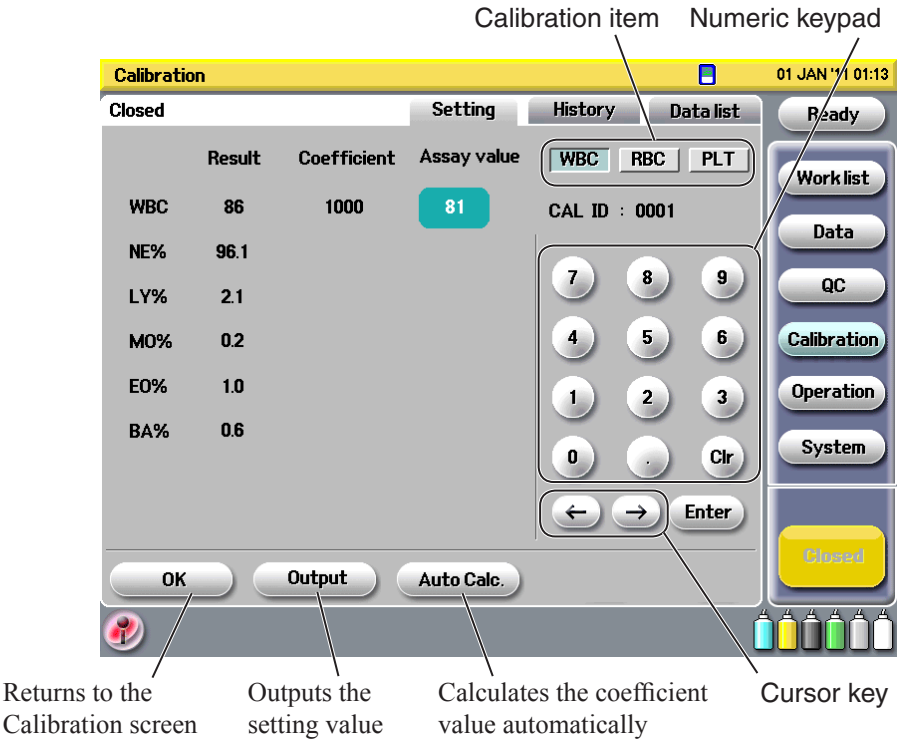
6. Measure the hematology control until you obtain at least 10 optimum data.

   The mean value of all the measurements and CV% are displayed on the screen.

7. Press the Setting tab to return to the Setting window and press the Auto CAL Mode key.



8. In the <Assay value> field, enter the assay value listed in the assay sheet which is attached to the hematology control. Press the Auto Calc. key. The analyzer automatically calculates the calibration coefficient and the value is displayed in the <Coefficient> field.
   i) Press the calibration item you want to change.
   ii) Press the Assay value field you want to change.
   iii) Enter the assay value listed in the assay sheet which is attached to the hematology control.
   iv) Press the Enter key to register the value. The cursor moves to the next item.
   v) Press the Auto Calc. key. The calibration coefficient is automatically calculated and displayed in the Coefficient field.



When the <Output with “Output” key> setting on the SD Card setting is set to “On”, you can capture the window and send it to the SD card by pressing the Output key. Refer to “Changing the Output Format” in Section 5.

9. On the QC screen, measure the MEK-5DN hematology control and check that the value is within the management range. Refer to the Section 11 “Quality Control”.

Reference

The new calibration coefficient is calculated from the equation below.

$$\text{New calibration coefficient} = \text{Previous calibration coefficient} \times \frac{\text{Calibrator assay value}}{\text{Mean measured value}}$$

Calibration in Open Mode and Pre-Dilution Mode

When calibration is performed in closed mode, the new calibration coefficient is also applied to open mode and pre-dilution blood mode. However, because the pre-dilution blood samples are diluted manually, the obtained data may differ between the different sampling and dilution modes. In such a case, perform calibration in open mode and pre-dilution blood mode.

Calibration in closed blood mode must be performed before calibration in open mode and pre-dilution blood mode.

The relationship between the calibration coefficient in pre-dilution blood mode and the measured value is shown in the equation below.

$$\text{Measured value after calibration in pre-dilution blood mode} = \text{Measured value in pre-dilution blood mode} \times \frac{\text{Calibration coefficient in closed mode}}{1000} \times \frac{\text{Calibration coefficient in pre-dilution blood mode}}{1000}$$

CAUTION

Use the hematology control within three days after opening.

CAUTION

Do not use hematology control when the top layer is slightly red or the whole hematology control is red, because the red blood cells in the hematology control are hemolyzed.

CAUTION

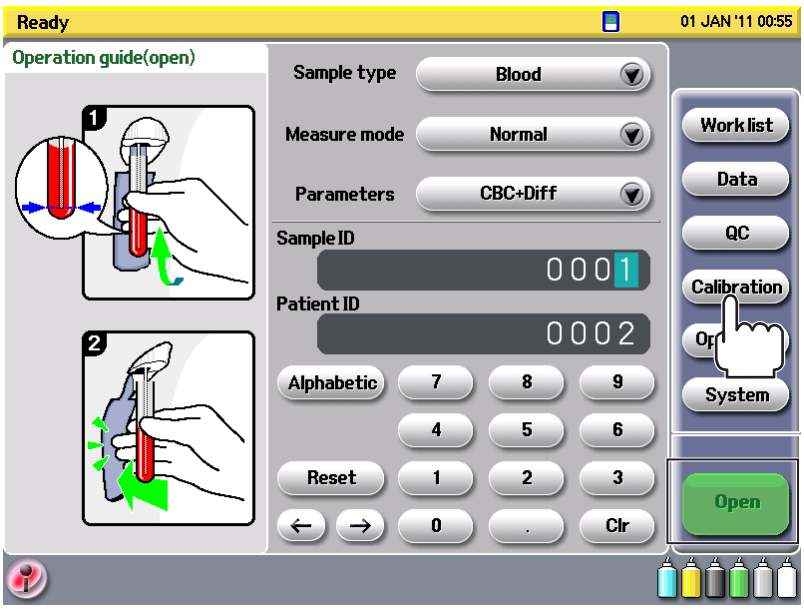
Do not freeze the hematology control because this hemolyses it.

CAUTION

Use and store the hematology control with extreme care according to its instructions.

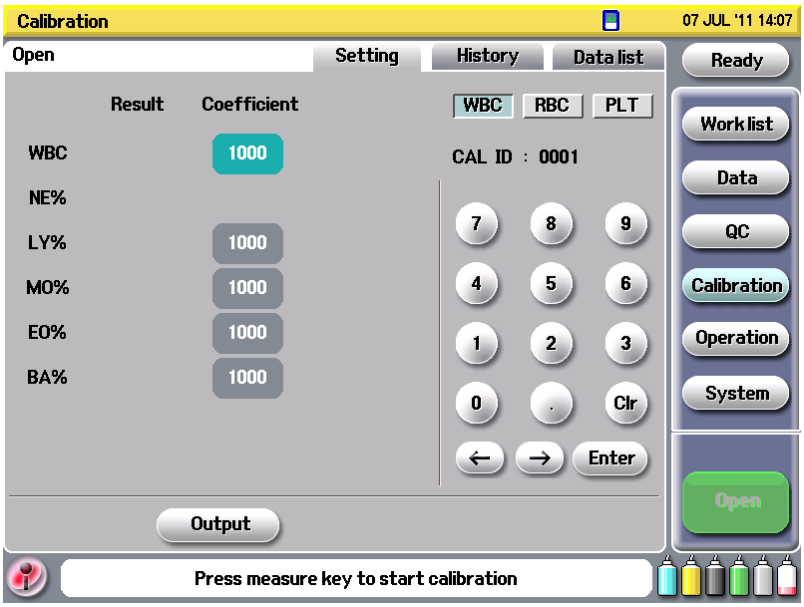
If the hematology control is taken from a refrigerator, wait at least 10 minutes after the control temperature reaches room temperature.

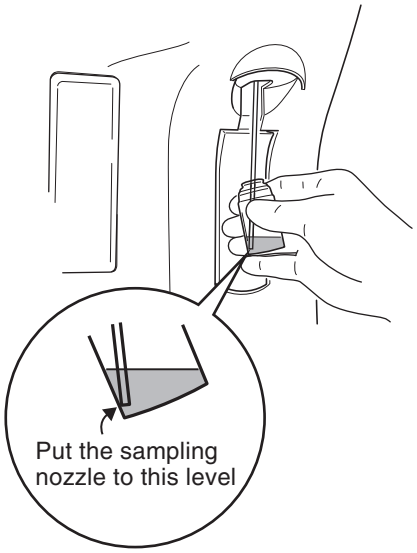
1. On the Ready screen, check that “Open” is selected for sampling mode.



2. Select the Measure mode from the Measure mode list box.

3. Press the Calibration key to display the Calibration screen.



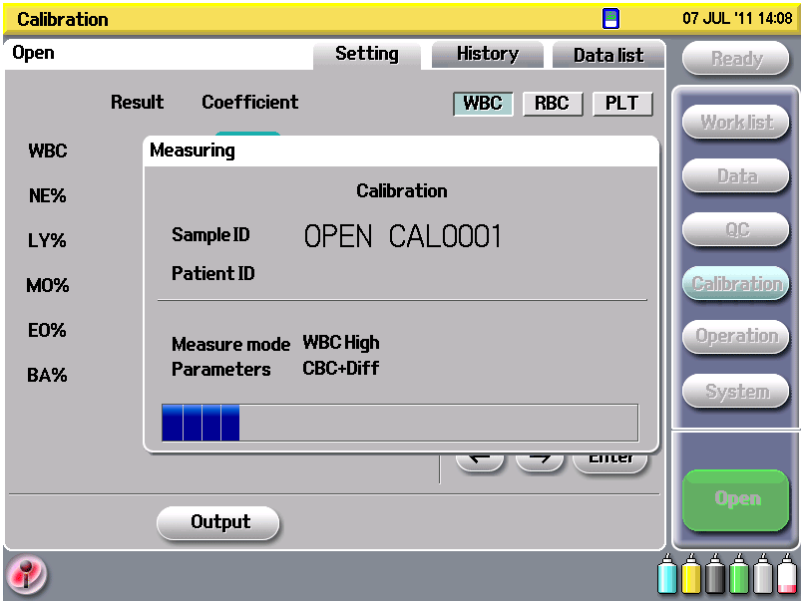


4. Put the sampling nozzle into the hematology control vial so that the tip of the sampling nozzle comes near but does not touch the bottom of the vial.

NOTE

Do not let the sampling nozzle touch the bottom of the vial. This may prevent aspiration of the sample.

5. Press the [◇ Count] switch on the hematology analyzer. The hematology control is aspirated and measurement starts.



After measurement, the Data list window is displayed and the data is stored in the analyzer.

6. Measure the hematology control until you obtain at least 10 optimum data.

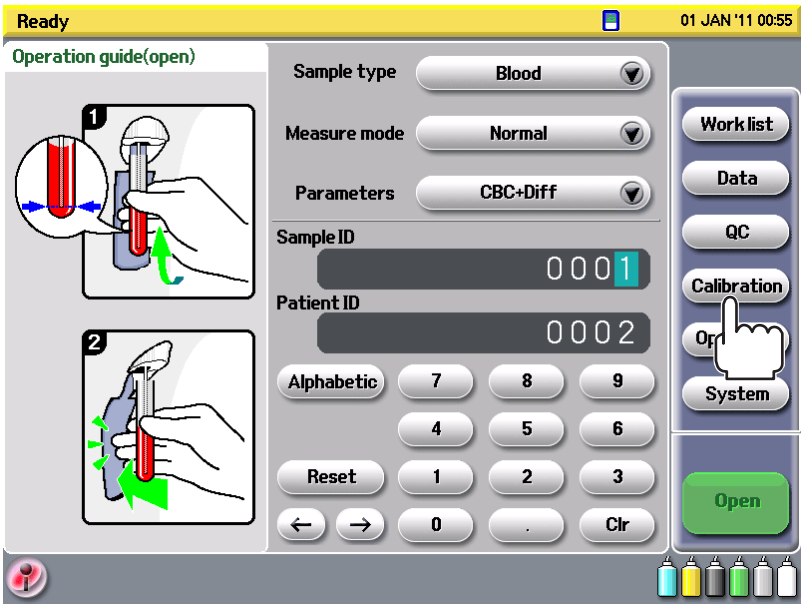
   The mean value of all the measurements is displayed on the screen.

7. Calibrate the analyzer by following the steps 7 to 11 of the “Calibration in Closed Mode”.

Displaying the Calibration Measurement Data List

Up to 15 hematology control measured data can be saved and displayed on the Data List window. The mean and CV of all hematology control measurement can be displayed. You can also delete the measured data.

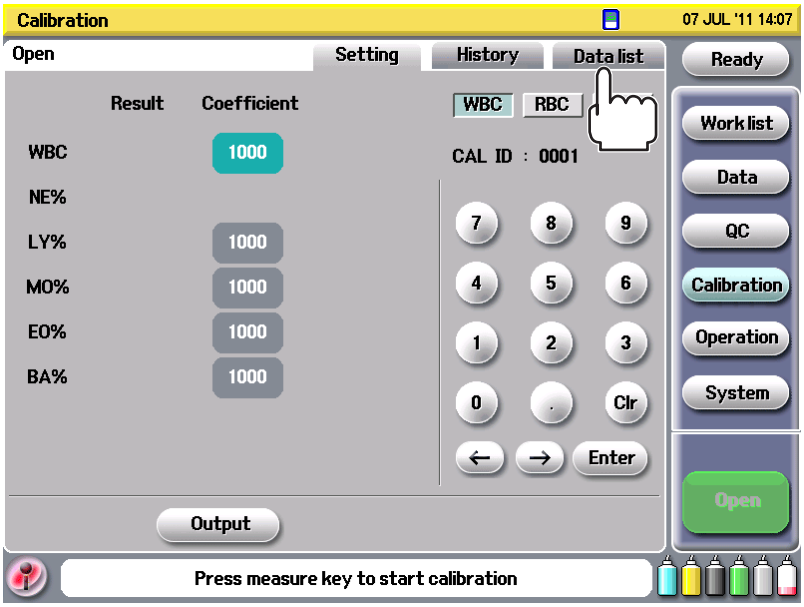
1. Select the Open or Closed sampling mode on the Ready screen.

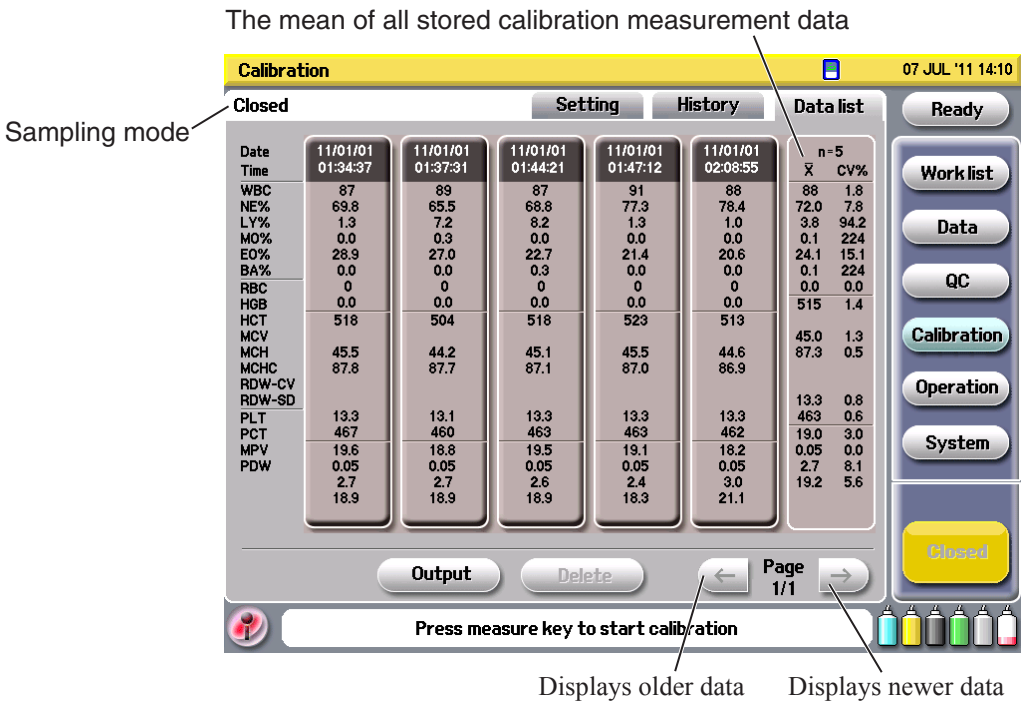


2. Select the Measure mode.

3. Press the Calibration key to display the calibration window.

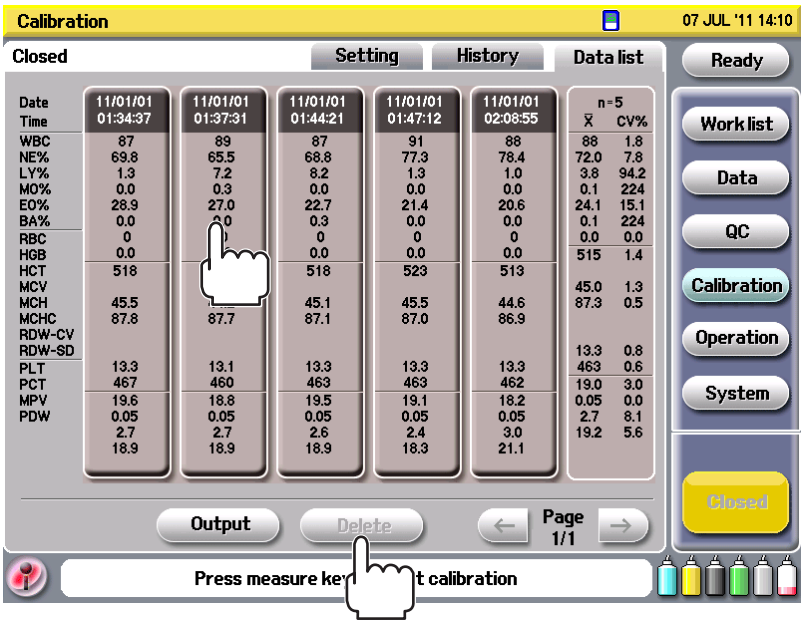
4. Press the Data list tab. The hematology control measured data is listed on the window.



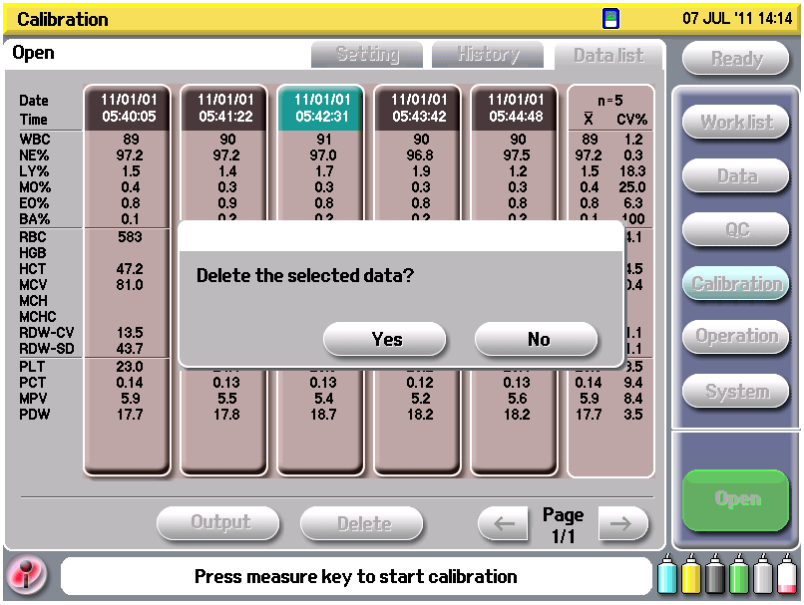


To delete one data:

i) Select the data to be deleted.



ii) Press the Delete key. The confirmation message appears on the screen.



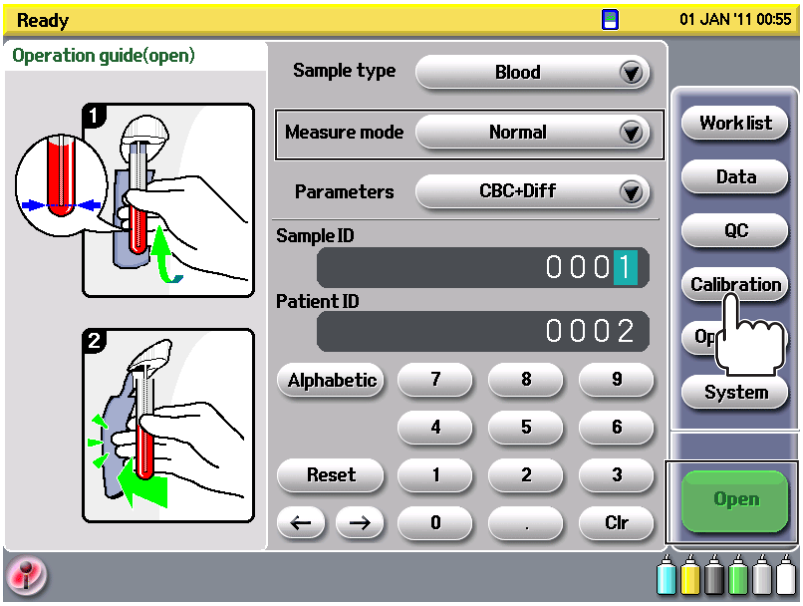
iii) Press the Yes key to delete the selected data. If you press No, the process is canceled.

5. Press the Setting tab to return to the CAL screen.

Displaying and Printing Calibration Data History

The analyzer automatically saves the calibration coefficient every time you perform calibration to create the calibration history record. This allows you to examine the trend of the precision variation of the analyzer or to find a faulty part in the instrument. The data is stored for up to 15 calibrations.

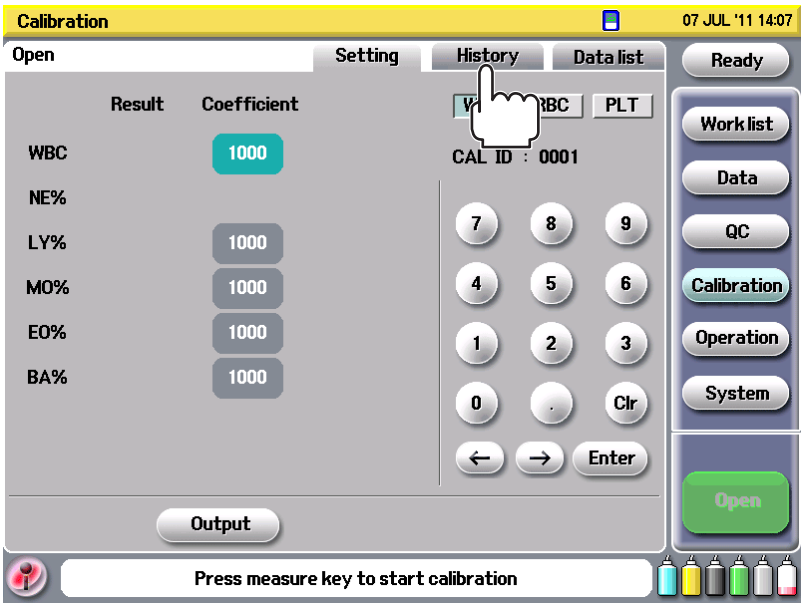
1. Select the Open or Closed sampling mode on the Ready screen.

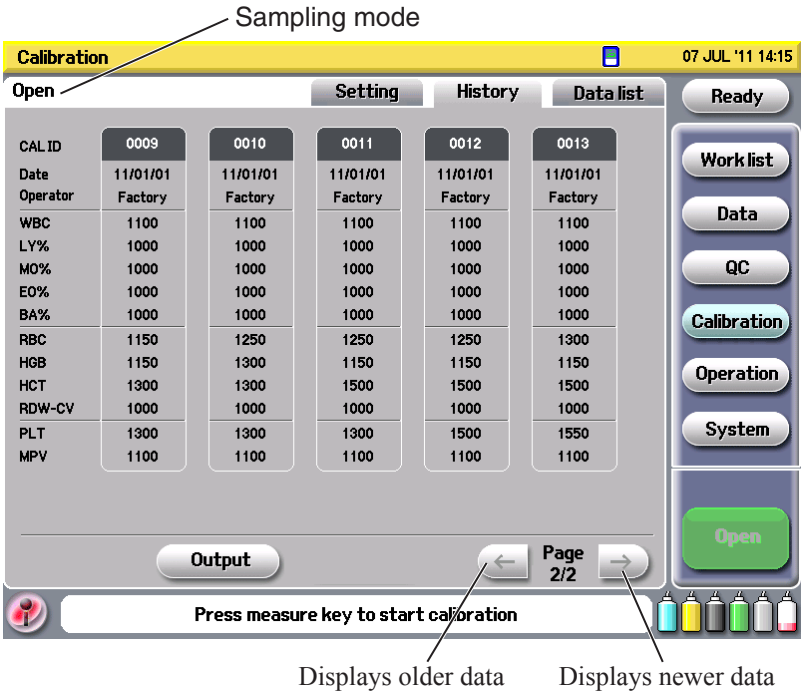


2. Select the Measure mode.

3. Press the Calibration key.

4. Press the History tab on the Calibration screen. The calibration data history for up to five calibrations appears on the screen.





Use the arrow keys to view other data.

To print the data on the printer, press the [Print] key on the front panel.

HGB/HCT Calibration with Human Blood

NOTE

- Refer to “Standardization Analysis Method” in Section 4 and refer to the HGB and HCT references.
- Measurement accuracy with the spectrophotometer and microhematocrit centrifuge depends on the processes, i.e. sampling, diluting and stirring. Perform the processes carefully.

When calibrating with human blood, use both of the following measurement methods.

1. Measurement with the MEK-7300 hematology analyzer

2. Measurement with a spectrophotometer and microhematocrit centrifuge

Calculate the HGB/HCT value with these methods and then calculate the calibration coefficient.

Measurement with the Analyzer

1. Prepare 10 venous blood samples from a healthy person.

2. Count the samples in double counting mode. Refer to Section 5 “Operating Instructions”.

HGB Measurement with a Spectrophotometer

NOTE

Refer to “Standardization Analysis Method” in Section 4 and refer to the HGB reference.

1. Prepare the diluent with lysing reagent specified by International Committee for Standardization in Hematology (ICSH).

2. Make a pair of two 200:1 diluted samples from each sample prepared in step 1 in the above procedure (“Measurement with the Analyzer” section).

3. Set up the spectrophotometer as follows.
   Wavelength: Approx. 540 nm
   Mode: ABS (absorbance) mode

4. Measure the optical density (OD) value of each pair of diluted samples with the spectrophotometer.

5. Calculate the mean value of each pair of samples.

6. Multiply each mean value by 29.3 to obtain the HGB value.

$$29.3 = \frac{64458 \times 200}{44 \times 1000 \times 1 \times 10}$$

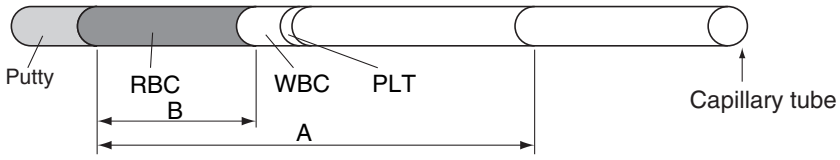
64458: Molecular weight of HGB
200: Dilution ratio
44: Optical density coefficient in mm mol
1000: from mg to g
1: Cell thickness (cm)
10: from g/L to g/dL

HCT Measurement with a Microhematocrit Centrifuge

NOTE

Refer to “Standardization Analysis Method” in Section 4 and refer to the HCT reference.

1. Aspirate the whole blood sample into two-thirds of the capillary tube.
2. Wipe away any blood from the outside of the tube with paper or gauze.
3. Seal the ends of the tubes (blood aspiration side) with putty.
4. Set the microhematocrit centrifuge for 11,000 rpm for 5 minutes.
5. Rotate the tube in the centrifuge.
6. Immediately after rotation stops, measure the length of each layer.



7. Calculate each HCT according to the following formula.

$$HCT = \frac{B}{A} \times 100\ (\%)$$

8. Calculate the mean value of the two HCT values.

Determining the HGB and HCT Calibration Coefficient

1. Fill in each blank in the following table to obtain the HCT calibration coefficient.

NOTE

Whenever calibrating the HGB/HCT, write down the current calibration coefficient on the table because the coefficient shows the variation of the precision in the analyzer.

Sample No.	Manual Measurement (M)	Manual Measurement (I)	Data = $\frac{I - M}{M} \times 100$ (%)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
Mean among the 8 data excluding the highest one data and lowest one data (A)			(%)
Current calibration coefficient (B)			
Revised calibration coefficient (C) $C = B \times (1 - \frac{A}{100})$			

(M): Spectrophotometer and microhematocrit centrifuge
(I): MEK-7300 Hematology Analyzer

2. Calibrate the hematology analyzer by changing the calibration coefficient setting to the revised calibration coefficient (C) in the previous table.

   i) Press the Calibration key on the screen to display the Calibration screen.
   ii) Press the Closed key on the Calibration screen to display the Calibration screen in closed mode.

NOTE

Write down the current settings before changing them.

   iii) In the <Coefficient> field of the desired parameter, enter the new calibration coefficient.
   iv) Press the OK key to return to the Calibration screen.

Hemoglobin Conversion Table (g/dL ↔ %SAHLI)

The analyzer displays the obtained data for hemoglobin in g/dL. To convert the data to %SAHLI units, use the following table.

g/dL	% SAHLI	g/dL	% SAHLI	g/dL	% SAHLI	g/dL	% SAHLI	g/dL	% SAHLI	g/dL	% SAHLI	g/dL	% SAHLI	g/dL	% SAHLI
5.0	31.3	7.0	43.8	9.0	56.3	11.0	68.8	13.0	81.3	15.0	93.8	17.0	106.3	19.0	118.8
5.1	31.9	7.1	44.4	9.1	56.9	11.1	69.4	13.1	81.9	15.1	94.4	17.1	106.9	19.1	119.4
5.2	32.5	7.2	45.0	9.2	57.5	11.2	70.0	13.2	82.5	15.2	95.0	17.2	107.5	19.2	120.0
5.3	33.1	7.3	45.6	9.3	58.1	11.3	70.6	13.3	83.1	15.3	95.6	17.3	108.1	19.3	120.6
5.4	33.8	7.4	46.3	9.4	58.8	11.4	71.3	13.4	83.8	15.4	96.3	17.4	108.8	19.4	121.3
5.5	34.4	7.5	46.9	9.5	59.4	11.5	71.9	13.5	84.4	15.5	96.9	17.5	109.4	19.5	121.9
5.6	35.0	7.6	47.5	9.6	60.0	11.6	72.5	13.6	85.0	15.6	97.5	17.6	110.0	19.6	122.5
5.7	35.6	7.7	48.1	9.7	60.6	11.7	73.1	13.7	85.6	15.7	98.1	17.7	110.6	19.7	123.1
5.8	36.3	7.8	48.8	9.8	61.3	11.8	73.8	13.8	86.3	15.8	98.8	17.8	111.3	19.8	123.8
5.9	36.9	7.9	49.4	9.9	61.9	11.9	74.4	13.9	86.9	15.9	99.4	17.9	111.9	19.9	124.4
6.0	37.5	8.0	50.0	10.0	62.5	12.0	75.0	14.0	87.5	16.0	100.0	18.0	112.5	20.0	125.0
6.1	38.1	8.1	50.6	10.1	63.1	12.1	75.6	14.1	88.1	16.1	100.6	18.1	113.1	20.1	125.6
6.2	38.8	8.2	51.3	10.2	63.8	12.2	76.3	14.2	88.8	16.2	101.3	18.2	113.8	20.2	126.3
6.3	39.4	8.3	51.9	10.3	64.4	12.3	76.9	14.3	89.4	16.3	101.9	18.3	114.4	20.3	126.9
6.4	40.0	8.4	52.5	10.4	65.0	12.4	77.5	14.4	90.0	16.4	102.5	18.4	115.0	20.4	127.5
6.5	40.6	8.5	53.1	10.5	65.6	12.5	78.1	14.5	90.6	16.5	103.1	18.5	115.6	20.5	128.1
6.6	41.3	8.6	53.8	10.6	66.3	12.6	78.8	14.6	91.3	16.6	103.8	18.6	116.3	20.6	128.8
6.7	41.9	8.7	54.4	10.7	66.9	12.7	79.4	14.7	91.9	16.7	104.4	18.7	116.9	20.7	129.4
6.8	42.5	8.8	55.0	10.8	67.5	12.8	80.0	14.8	92.5	16.8	105.0	18.8	117.5	20.8	130.0
6.9	43.1	8.9	55.6	10.9	68.1	12.9	80.6	14.9	93.1	16.9	105.6	18.9	118.1	20.9	130.6

Section 7 Operational Precautions and Limitations

Environmental Requirements

WARNING

Install the analyzer outside the patient environment. If it is installed inside the patient environment, the patient or operator may receive electrical shock.

CAUTION

Use this analyzer under the following conditions.

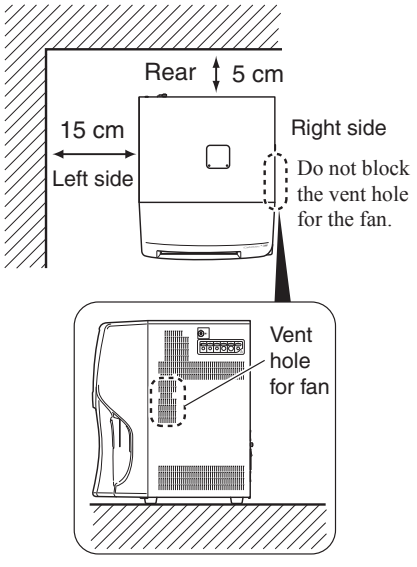
Temperature: 15 to 30°C (59 to 86°F)

Humidity: 30 to 85% (noncondensing)

Air pressure: 70 to 106 kPa

70 kPa air pressure equals 3,000 m above sea level. Do not use the analyzer at altitudes higher than 3,000 m above sea level.

- Operate the analyzer in a room with a temperature range of 15 to 30°C (59 to 86°F). Keep the temperature of diluent and lysing reagent within this temperature in order to obtain reliable data.
- No measurement can be done in dusty areas because the aperture for specimen aspiration is very fine and can get clogged. Therefore, install the analyzer in a dust-free area.
- Do not install the analyzer in direct sunlight.
- Do not place containers of reagent or fluid on the analyzer. To prevent electrical problems or electric shock, avoid spillage in or around the analyzer because the fluid is highly conductive.
- Select a stable, flat buffering stand to set the analyzer on.
- If possible, use an independent AC outlet only for this analyzer. The analyzer must not share an AC outlet with noise generating equipment such as a centrifuge, constant temperature bath (thermostat), refrigerator, air conditioner or ultrasonic cleaner.



- Make sure that there is more than 5 cm of space between the rear panel and the wall and 15 cm of space between the left panel and the wall for adequate ventilation.
- Do not block the vent hole for the fan.
- If there is any problem in the analyzer, turn off the main power immediately and disconnect the power cord from the AC outlet. Take the analyzer out of service and check for damage.

Reagent Storage and Handling

Reagents used with the analyzer require special care as follows:

- Before operating the analyzer for the first time, make sure each reagent line is connected to the appropriate inlet and reagent container.
- Store reagents, calibrators, and controls according to the directions on the label and package inserts.
- Protect reagents from extreme heat and freezing during storage. Temperatures below 0°C (32°F) can cause layering that changes the tonicity and conductivity of the reagent. If freezing occurs, do not use the reagent. Dispose of reagent in accordance with federal, state, and local regulations.
- Protect reagents from direct sunlight, evaporation, and contamination. Use the reagent container cap attached to each inlet tubing to minimize evaporation and contamination.
- Never add remaining reagent from a container being replaced to a freshly opened container. This can contaminate the new reagent.
- Never use a hemoglobin standard designed for use with reference methemoglobin methodology directly on the analyzer. The analyzer uses a modified methemoglobin method which is not designed to analyze these standards.

Section 8 Hazards

Overview

Operation, maintenance, and servicing of automated hematology systems may expose individuals to potential safety and health hazards. All work must be performed as described in the MEK-7300 operator's manual or as directed by your Nihon Kohden representative.

This section provides precautionary warnings and information necessary for the safe use of the analyzer system. Supplementary warnings are inserted throughout this manual and on the analyzer to alert personnel to potential hazards. Whenever hazard symbols are encountered on the analyzer, users must consult the operator's manual to determine the nature of the potential hazard and actions that must be taken.

The standard warning conventions including signal words (e.g., caution) and symbols are described below. Safety symbols appear next to signal words that identify hazards.

Warning Conventions

Signal Words

WARNING: A warning alerts the user to possible injury or death associated with the use or misuse of the analyzer.

CAUTION: A caution alerts the user to possible injury or problems with the analyzer associated with its use or misuse such as analyzer malfunction, analyzer failure, damage to the analyzer, or damage to other property.

NOTE: A note provides specific information, in the form of recommendations, prerequirements, alternative methods or supplemental information.

Safety Icons

The general hazard symbol identifies an activity or area that may present a hazard to personnel or equipment.

The biohazard symbol identifies an activity or area where personnel may be exposed to infectious substances if procedural or engineering controls are not observed.

Hazard Information and Precautions

General

Automated hematology analyzers require the handling of whole blood and blood components by laboratory personnel. In addition, personnel must conduct maintenance to ensure proper performance of the analyzer. These activities result in potential contact with infectious substances and other hazards. The following are warnings, precautions, and standard practices to help prevent injury.

CAUTION

If the analyzer is used or modified in a manner not specified by the manufacturer, the protection provided by the analyzer may be impaired.

Biohazards

WARNING

Potential Biohazard. Consider all clinical specimens, reagents, controls, surfaces, or components that contain or have contacted blood, serum, or other bodily fluid as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910.1030)1 or other equivalent biosafety procedures.

WARNING

Potential Biohazard. The cap pierce nozzle is sharp and potentially contaminated with infectious material. Avoid contact with the tip of the probe.

Spills of potentially infectious materials should be cleaned up in accordance with established biosafety practices. A generally accepted procedure for cleaning such spills is to absorb the spill with toweling or other absorbent material, wipe the area with an appropriate tuberculoidal disinfectant such as 0.5% sodium hypochlorite solution (refer to formula in “Decontamination Protocol” in Section 9).

Prior to maintenance, service, or shipping, the analyzer should be decontaminated in accordance with the procedures specified in “Decontamination Protocol” and/or “Strong and Transporting the Analyzer” in Section 9 as appropriate. Remove and dispose of contaminated disposables in accordance with local, state, and federal regulations.

Handling and Disposing of Biohazardous Material

Dispose of liquid and solid waste in accordance with local, state, and federal regulations. Probes, broken glass, and other sharps that are contaminated with potentially infectious substances should be collected in a “sharps” container for disposal as regulated medical waste. Contaminated gloves, wipes, swabs, and other disposables should be placed in a standard medical waste container.

Chemical Hazards

Prevent exposure to chemicals used in the operation and maintenance of the analyzer (including reagents) by using appropriate personal protective equipment, work procedures, and information on Material Safety Data Sheets (MSDS). For information or Material Safety Data Sheets (MSDS) contact your Nihon Kohden representative. Refer to Section 2 “Installation Procedures and Special Requirements” for an installation procedure for chemical containers.

Electrical Hazards

Basic electrical hazard awareness is essential to the safe operation of any hematology analyzer. To ensure safe operation of the analyzer:

CAUTION

Electrical Hazard. Do not disconnect any electrical connection while the power is ON. Follow instructions for correctly powering OFF the analyzer and all connected equipment before performing maintenance on parts which require protective covers to be removed for access. Use only approved power cords and electrical accessories, such as those supplied with the analyzer, or provided by Nihon Kohden, to protect against electrical shock.

CAUTION

Electrical Hazard. Turn OFF the power to the analyzer and disconnect the power cord before removing any analyzer panel that is securely fastened in place by screws.

CAUTION

If the analyzer is used or modified in a manner not specified by the manufacturer, the protection provided by the analyzer may be impaired.

- Periodically inspect electrical cabling into and on the analyzer for signs of wear or damage.
- When moving equipment, lift all power cables clear of all system components.
- Keep liquids away from all electrical connectors (such as electrical outlets) or communication connectors (such as the serial sockets).
- Keep the floor dry.
- The electrical circuit spacing of the analyzer is based on pollution degree (2) and altitude [up to 3000 m (9800 ft)] as per IEC 61010-1. Pollution degree 2 is defined as normally only nonconductive pollution occurs, temporary conductivity caused by condensation is to be expected.

Physical and Mechanical Hazards

Observe these basic rules for mechanical safety:

- Carefully follow all procedures and instructions.
- Keep all protective covers in place when processing specimens.
- Never allow any part of your body to enter the region of movement of any mechanical component when the analyzer is operating.
- Use caution when performing any maintenance procedure by opening the front panel, as moving parts can pinch.
- Do not wear articles of clothing or accessories that could catch on the system. Keep pockets free of items that could fall into the system. Keep long hair from catching on the system.
- Wear powder-free gloves and safety glasses when maintaining or repairing the analyzer.
- Use assistance or a mechanical lifting device when moving or lifting the analyzer.
- Use proper lifting techniques when moving reagent containers.

Reference

Occupational Safety and Health Administration, 29 CFR Part 1910.1030.
Department of Labor. *Occupational Exposure to Bloodborne Pathogens*.

Section 9 Service and Maintenance

Maintenance

General

This analyzer requires minimal routine maintenance. The operator must routinely perform the scheduled maintenance procedures described in this section in order to ensure optimum performance. Failure to perform the scheduled maintenance procedures may result in inaccurate or imprecise analysis of whole blood samples.

This section describes recommended preventive maintenance procedures and provides instructions for preparing the analyzer for extended periods of inactivity.

NOTE

When performing any maintenance procedure, perform strong cleaning and drain the baths before turning the power off, document the activity, measure background noise (run without a specimen) until results are within specifications, then run quality control. Refer to “Checking Background Noise” later in this section.

The maintenance schedule outlined later in the “Maintenance Schedule” will minimize operational problems with the analyzer. The recommended intervals are based on analyzers operating in laboratories that process samples from a general patient population. These intervals are affected by several factors, including the following:

- Number of samples processed
- Work load schedule
- Operating environment
- Patient population being analyzed

Each laboratory must assess its own situation and modify these recommended intervals as necessary.

A diagram of the inside panel is included in this section to assist in component identification and location. To order any parts, accessories, or consumables, refer to “Standard Accessories” and “Consumables” in Appendix A.

WARNING

- Be careful not to directly touch any place where blood is or may have contacted.
- Protect yourself from infection before cleaning and doing maintenance.

CAUTION

Gloves should be worn during the maintenance procedures. They should be powder-free because powder may cause problems in the instrument.

NOTE

Overdue maintenance is usually indicated by an increase in imprecision of one or more of the directly-measured parameters. This imprecision is due to carryover or dilution/sampling inconsistencies. If this occurs on more than a random basis, perform the appropriate maintenance more frequently than indicated.

Disposing of Waste

Follow your local laws for disposing of medical waste.

WARNING

Dispose of the blood sample and replaced parts by following your local laws for disposing of infectious medical waste.

CAUTION

Avoid blood sample contact with the skin. If it contacts the skin or eyes, wash thoroughly with water and see a physician immediately.

WARNING

Always wear rubber gloves to protect yourself from infection when handling waste.

Disposing of the Analyzer

WARNING

- Dispose of the analyzer, replaced parts (such as sampling nozzles and cap pierce nozzle), waste fluid and parts used for collecting sample blood (such as needles, syringes and vials) according to your local laws for disposing of infectious medical waste (for incineration, melt treatment, sterilization and disinfection).
- Before disposing of the analyzer, perform strong cleaning and remove the sampling nozzles and cap pierce nozzle from the analyzer.

If the above warning is not followed, it causes infection or environmental contamination.

When disposing of the analyzer, contact your Nihon Kohden representative.

Periodic Replacement Parts

- Sampling nozzle
  Replace the sampling nozzle once a year. It may affect the measurement accuracy.
- Pinch valve tube
  Replace the pinch valve tube once a year. It may affect the measurement accuracy. For replacement, contact your Nihon Kohden representative.
- Rinse O ring
  Replace the rinse O ring once a year. It may affect the measurement accuracy. For replacement, contact your Nihon Kohden representative.
- Pump tube
  Replace the pump tube every four months or every 3000 measurements. It may affect the measurement accuracy.
- Filter
  Replace the filter every 1000 measurements. It may affect the measurement accuracy.
- Solenoid valve (replace some valves according to the status of use)
  Replace the solenoid valve every 5 years or 25000 measurements. It may affect the measurement accuracy. The number of measurement can be checked on the third page of the User Maintenance window. For replacement, contact your Nihon Kohden representative.

Refer to the following list for the code number and supply code of the periodic replacement parts.

Periodic replacement parts	Name	Code no.	Supply code
Sampling nozzle (two nozzles)	Sample tube assy	YZ-0341	T444C
Pinch valve tube	Pharmed tube 1 × 3 - 260	6114-924208	—
Pinch valve tube	Pharmed tube 100	6114-094961	—
Rinse O ring	O ring AS568-003	925538	—
Pump tube	Pump tube assy	YS-001B1	T462
Filter (10 filters)	Hemoglobin filter assy	YS-002B2	T802
Solenoid valve	—	—	—

Repair Parts Availability Policy

Nihon Kohden Corporation (NKC) shall stock repair parts (parts necessary to maintain the performance of the instrument) for a period of 7 years after delivery of the instrument. In that period, NKC or its representative will repair the instrument. This period may be shorter than 7 years if the necessary board or part is not available. For discontinuation announcements, contact your Nihon Kohden representative.

Internal Battery

Changing Internal Battery

The analyzer backs up the data and settings by an internal battery. If the battery run out, the data and settings such as date, time and calibration are lost and correct measurement cannot be performed. Write down the settings such as calibration coefficient as a precaution.

When remaining battery power becomes little, a “Check the settings” message is displayed. Turn the power off and on again. If the message is displayed again, contact your Nihon Kohden representative.

NOTE

The message may be displayed, even when the battery has enough remaining power. Then, turn the power off and on again. The message is not displayed.

The lifetime of the internal battery is about six years but depends on operating conditions.

Setting after Battery Change

After changing the internal battery, set the settings again.

1. Initialize the analyzer by pressing the “Initialize” key on the Setting Menu window. Refer to “Initializing Settings” in this section.

2. Set the date and time. Refer to “Setting Date and Time” in Section 5.

3. Measure particles and adjust the optical unit. Refer to “Checking the Flow Cell” in this section.

4. Calibrate the analyzer. Refer to Section 6 “Calibration Procedures”.

5. Set the necessary settings.

When the pressed position and operating position do not match, calibrate the touch screen. Refer to “Calibrating the Touch Screen” in this section.

Preventive Maintenance Schedule

Maintenance Schedule

Perform the following procedures at the scheduled intervals:

Daily
- Check reagent volume, recording paper and other consumables
- Check sampling nozzle (open mode), switches, keys and outside surface of the analyzer
- Check reagent tube connection
- Check power cord and grounding lead connection
- Check external instrument connection (printer, PC, bar code reader)
- Check screen display and touch screen key function (Calibrate touch screen)
- Check date and time settings
- Check daily accuracy (background noise, measure hematology control)
- Check measurement baths and sub baths
- Check pump tube

Every 200 counts
- Do strong cleaning

Weekly or every 300 counts
- Check filters and filter packings

Monthly or every 1,000 counts, whichever comes first
- Replace filters
- Clean measurement baths and sub baths
- Clean rinse unit and check cap pierce nozzle
- Clean MC tray

Every four months or every 3,000 counts, whichever comes first
- Check sampling nozzles
- Replace pump tube

Every five years or every 25,000 counts, whichever comes first
- Replace solenoid valve

Annually
- Replace pinch valve tube
- Replace rinse O ring

As required
- Replace filter packing
- Clean aperture caps
- Check priming function
- Check draining function
- Check cleaning function

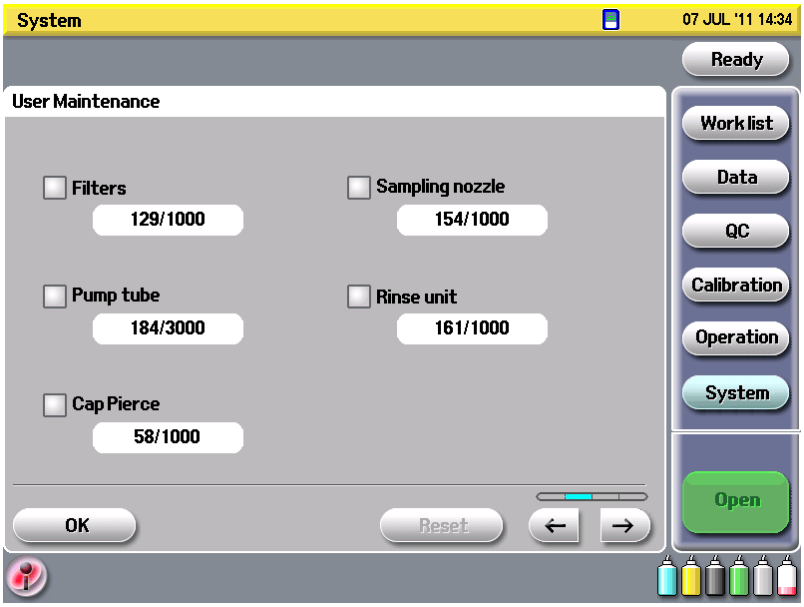
- Check circuit
- Check sensor monitor
- Check external instrument function (printer, PC, bar code reader)
- Decontamination Protocol
- Storing and transporting the analyzer

To keep the analyzer in optimum condition, periodically check, clean and maintain it according to the above schedule. If an error is found during a periodic check, clean or replace the item. If the error persists, contact your Nihon Kohden representative. You can use the User Maintenance screen to keep track of maintenance.

The fluid needs to be drained from the analyzer for some of the above maintenance. For the aperture caps, the fluid must be completely drained from the analyzer (Drain all). After draining, the analyzer power must be turned off. Follow the instructions in this section.

Displaying the User Maintenance Screen

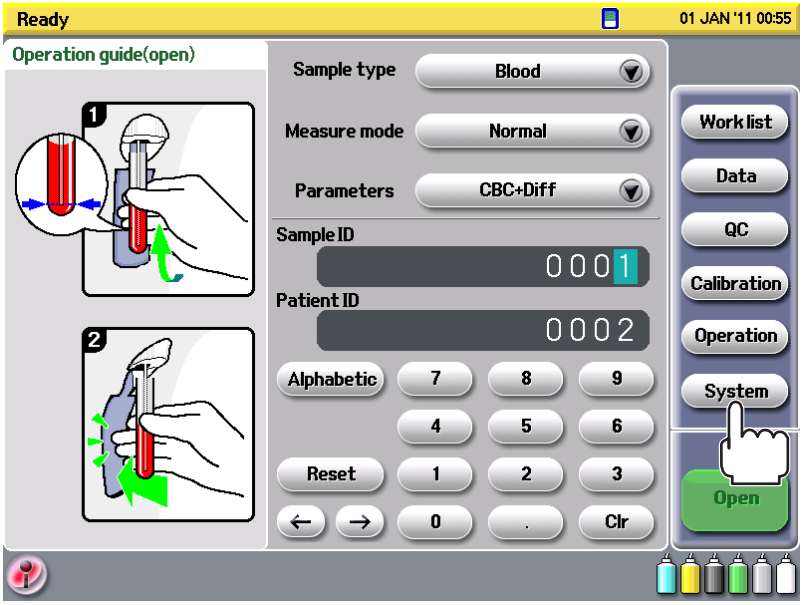
You can display the total operating time (hours), total number of counts, and number of counts used to determine the maintenance schedule for filters, measurement baths, sub baths, pump tube, rinse unit, sampling nozzles, cap pierce nozzle and strong cleaning.



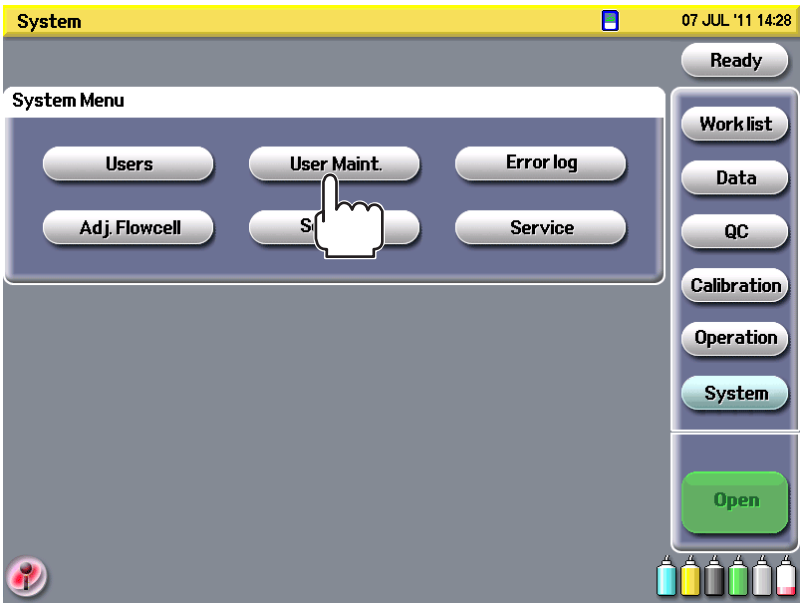
When the filters, measurement baths, sub baths, pump tube, rinse unit, sampling nozzles and cap pierce nozzle are used more than the following number of sample counts, the Message screen appears and prompts you to replace them.

Filters:	1,000 counts
Pump tube:	3,000 counts
Rinse unit:	1,000 counts
Sampling nozzles:	3,000 counts
Cap pierce nozzle:	1,000 counts

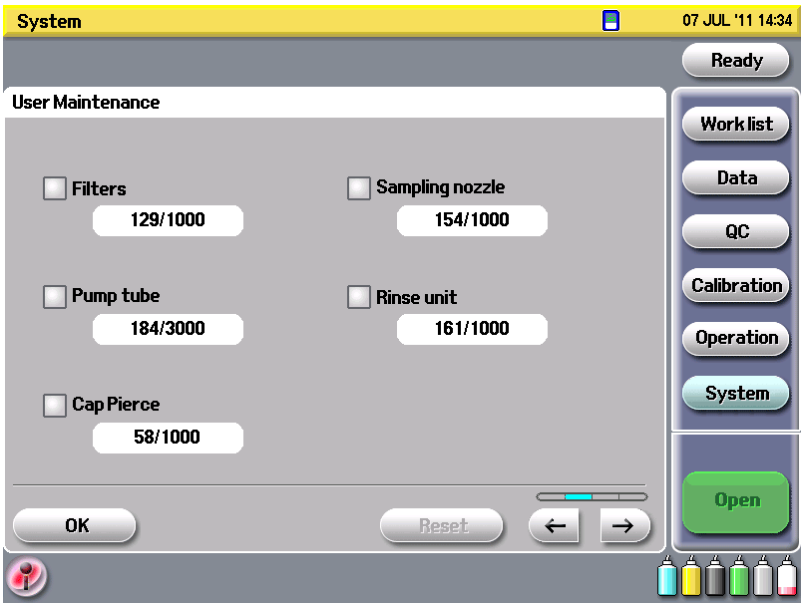
1. Press the System key to display the System screen.



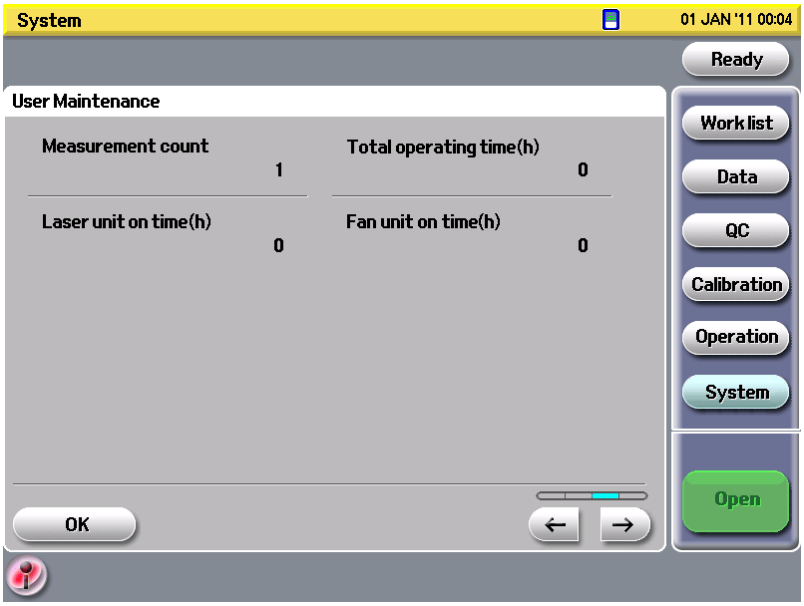
2. Press the User Maint. key to display the User Maintenance screen.



The second page displays the number of counts for filters, pump tube, cap pierce nozzle, sampling nozzles and rinse unit.



The third page displays the total number of counts, laser unit on time, total operating time and fan unit on time (hours).



After checking and replacing the filters, pump tube, rinse unit, sampling nozzles and cap pierce nozzle, reset the counts to zero by pressing the Reset key.

3. Press the OK key to return to the System screen.

Maintenance Check Sheet

It is recommended that operators keep a record of scheduled and unscheduled maintenance procedures using this maintenance check sheet.

Hospital/Organization:_____ Checking Date:_____

Analyzer Model:_____ Analyzer Serial Number:_____

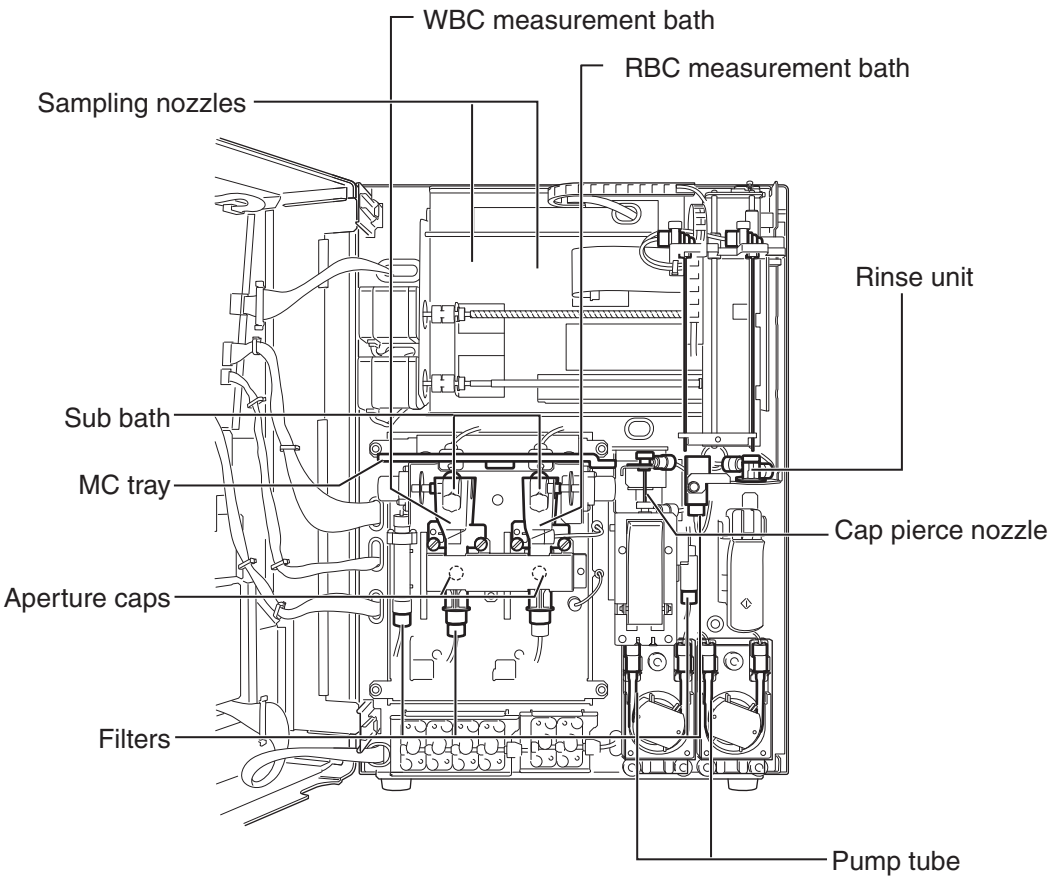
Hardware Revision Number:_____ Software Revision Number:_____

Service Person:_____

Check Item			OK	No
Daily Check				
There are enough Nihon Kohden specified reagent, recording paper and other consumables.				
The reagents are not expired.				
There are no damaged or dirty parts on the outside of the analyzer.				
There is no leakage from the analyzer.				
The sampling nozzle, switches and keys are not damaged.				
The labels are not torn or removed.				
The reagents are properly connected to the analyzer. The tubes are not damaged, bent or clogged.				
The power cord is connected properly. The power cord is not damaged.				
Grounding lead is connected properly.				
The external instruments are properly connected to the analyzer. The connection cables are not damaged.				
No alarms appear when the analyzer is turned on and the Ready screen appears.				
The messages are displayed properly.				
The touch screen keys function properly. Calibrate the touch screen when necessary.				
Date and time are correct.				
Measure background noise	Reference	Enter the value		
	WBC: 0.2 ($\times 10^3/\mu L$)			
	RBC: 0.05 ($\times 10^6/\mu L$)			
	HGB: 0.1 (g/dL)			
	PLT: 10 ($\times 10^3/\mu L$)			
Measure hematology control and check that the obtained data is within the acceptable range on the assay sheet of the hematology control.				
Check that the measurement baths and sub baths are not dirty or damaged.				
Check that the pump tube is not collapsed or damaged.				
Every 200 counts				
Do strong cleaning.				
Weekly or every 300 counts				
Check that filters and filter packings are not damaged.				
Monthly or every 1,000 counts, whichever comes first				
Replace filters.				
Clean sub baths and measurement baths.				
Clean rinse unit and check cap pierce nozzle.				
Clean MC tray.				
Every four months or 3,000 counts, whichever comes first				
Check sampling nozzles.				
Replace pump tube.				
Every five years or 25,000 counts, whichever comes first				
Replace solenoid valve.				

Check Item				OK	No
As required					
Clean aperture caps					
Remove clog from aperture					
Check prime function					
Check draining function					
Check cleaning function					
Check circuit		Reference	Enter the value		
		WBC: 7.6 to 8.4 ($\times 10^3/\mu L$)			
		RBC: 1.52 to 1.68 ($\times 10^6/\mu L$)			
		MCV: 85 to 115 (fL)			
		PLT: 152 to 168 ($\times 10^3/\mu L$)			
		HGB ON: 1.5 to 4.5 V			
		HGB OFF: <0.5 V			
		WBC sensitivity: 5			
		WBC threshold: 4			
		RBC sensitivity: 5			
		RBC threshold: AUTO			
		PLT threshold: 5			
Check sensor monitor	Reference		Enter the value		
	HGB LED On: 1.5 to 4.5 V				
	HGB LED Off: <0.5 V				
	WBC: 17.7 to 18.3 V				
	RBC: 17.7 to 18.3 V				
	Without reagent	WBC manometer upper: >3.5 V			
		WBC manometer lower: >3.5 V			
		RBC manometer upper: >3.5 V			
		RBC manometer lower: >3.5 V			
		Diluent: >3.5 V			
		Lysing reagent: >3.5 V			
	With reagent	WBC manometer upper: <1.5 V			
		WBC manometer lower: <1.5 V			
		RBC manometer upper: <1.5 V			
		RBC manometer lower: <1.5 V			
		Diluent: <1.5 V			
		Lysing reagent: <1.5 V			
	HGB unit (°C or °F)				
	MC unit (°C or °F)				
	Power board (°C or °F)				
Check printer function					
Check bar code reader function					
Check communication function between analyzer and PC.					
Decontamination protocol					
Storing and transporting analyzer					

Inside Panel Components



CAUTION

Do not handle any parts other than specified in this manual.

Daily Maintenance Procedures

Checking Reagents and Other Consumables

WARNING

Potential Biohazard. Follow established biosafety practices when performing maintenance, service or troubleshooting procedures. Refer to Section 8 “Hazards” for additional information.

CAUTION

Only use Nihon Kohden recommended reagents and consumables. Otherwise the measurement result cannot be guaranteed and incorrect reagent concentration can cause equipment damage.

CAUTION

Avoid reagent contact with the skin. If it contacts the skin or eyes, wash thoroughly with water and see a physician immediately.

Check that the following Nihon Kohden specified reagents are used.

- ISOTONAC•3 diluent
- CLEANAC detergent
- CLEANAC•3 detergent (For Strong clean only)
- Hemolynac•3N hemolysing reagent
- Hemolynac•5 hemolysing reagent

Check that these reagents are not expired and are not run out.

When replacing the reagents, dispose the old reagent and connect the new reagent.

NOTE

Do not mix old and new reagents or pour new reagent to the old reagent.

Check that there are enough consumables, such as hematology control, sample containers, sample tubes and sample cups.

When using a printer, check that there is enough recording paper.

Checking the Appearance of the Analyzer

Check the following points.

- There are no damaged or dirty parts on the outside of the analyzer
- The sampling nozzle, switches and keys are not damaged.
- There is no leakage from the analyzer
- The labels are not torn or removed

WARNING

- Be careful not to directly touch any place where blood is or may have contacted.
- Protect yourself from infection before cleaning and doing maintenance.

CAUTION

Turn off the analyzer main power before maintenance. Otherwise, the operator may receive electrical shock and the analyzer may malfunction.

Cleaning the Surface of the Analyzer

To keep the analyzer clean, clean the analyzer by the following procedure on a daily basis.

CAUTION

Never use organic solvents such as thinner or acetone because they damage the enclosure of the analyzer.

NOTE

When wiping the analyzer with a cloth moistened with water, wring out the cloth to prevent water from entering the analyzer.

1. Dilute a neutral detergent with water.
2. Wipe off the dirt with a soft cloth moistened with the diluted neutral detergent.
3. Wipe the analyzer with a dry soft cloth.

Do not wipe the screen with the diluted neutral detergent. Wipe the screen with a dry soft cloth.

Disinfecting the Surface of the Analyzer

Disinfect the analyzer when transporting the analyzer to another place or infectious materials (blood) is attached to the analyzer.

NOTE

Disinfect the sampling nozzle before every maintenance because infectious blood may be adhered to it.

Wipe the analyzer with a cloth moistened with disinfecting ethanol. Disinfect the sampling nozzle (open mode) thoroughly because it touches blood.

Checking the Reagent Connection Tubes

Check that the reagent tubes are not damaged, bent or clogged. For correct tube connection, refer to “Connecting Tubes and Installing Reagents” in Section 2.

Checking the Power Cord and Grounding Lead

Check that the power cord and grounding lead are properly connected and not damaged.

Checking the External Instrument Connection

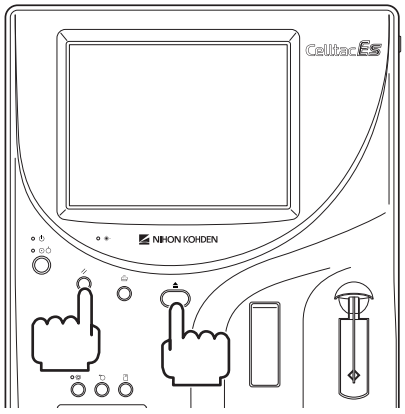
When using an optional printer, PC and ZK-820V hand-held bar code reader, check that they are properly connected to the analyzer. Check that the connection cables are not damaged.

Checking the Power On

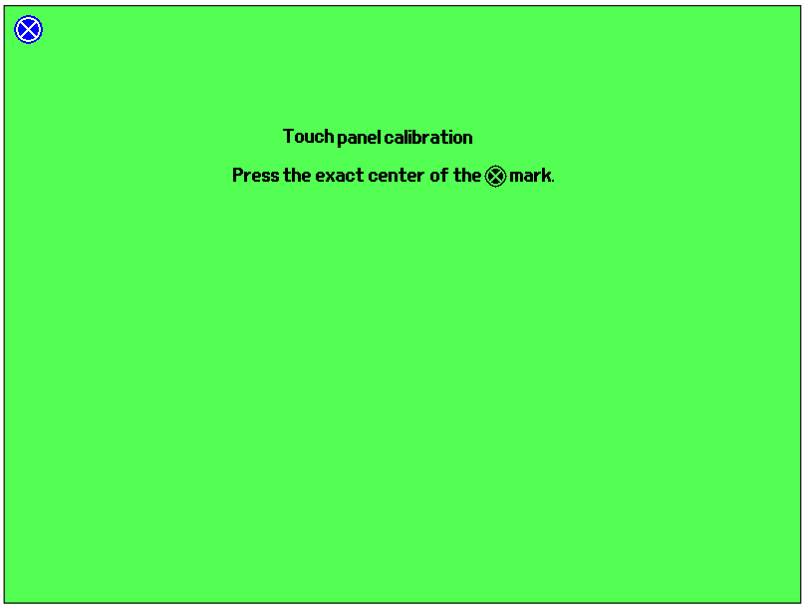
When the analyzer is turned on, check that the self-check is performed and the Ready screen appears. Check that no alarms appear and the touch screen keys function properly. Also check that there is no smell, heat or noise and that there is no leakage from the analyzer.

Calibrating the Touch Screen

Calibrate the touch screen when the pressed position and operating position do not match.



1. Hold down the [⁄⁄ Reset] key until the emergency stop message disappears. Then press the [⏏ Eject] key while holding down the [⁄⁄ Reset] key. The Touch panel calibration screen appears.



2. Follow the instructions on the screen to calibrate the screen.

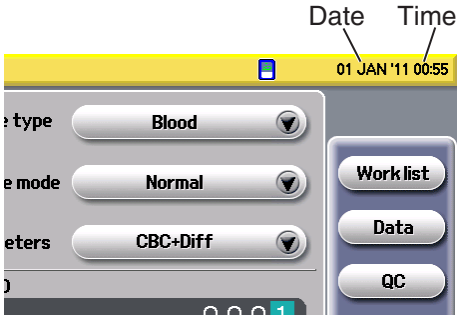
NOTE

Do not use a sharp object to press the mark. Use your finger.

After calibration is completed, the screen returns to the Ready screen.

Checking the Date and Time

Check that the date and time on the screen are correct. To change the date and time, refer to “Setting Date and Time” in Section 5.



Clock Accuracy

At an operating temperature of 25ºC (77ºF), the accuracy of the clock IC of the analyzer is about –39 to +68.7 seconds per month.

At storage temperatures between –20 and +60ºC (–4 and +140ºF), the accuracy of the clock IC of the analyzer is about –7 minutes 24 seconds to +69 seconds per month.

Checking Daily Accuracy

Check the daily accuracy. Refer to “Checking Daily Accuracy” in Section 2.

Checking Measurement Baths and Sub Baths

Refer to the “Checking and Cleaning Measurement Baths and Sub Baths” in the “Monthly/Every 1,000 Counts Maintenance Procedures” later in this section.

Checking Pump Tube

Refer to the “Replacing Pump Tube” in the “Every Four Months/Every 3,000 Counts Maintenance Procedures” later in this section.

Every 200 Counts Maintenance Procedures

Performing Strong Cleaning

Perform strong cleaning every 200 sample counts. Refer to “Strong Cleaning” in Section 5.

Weekly/Every 300 Counts Maintenance Procedures

Checking/Cleaning Filters

Check and clean the filters once a week or every 300 sample counts. Refer to the “Replacing Filters” in the “Monthly/Every 1,000 Counts Maintenance Procedures” later in this section.

Monthly/Every 1,000 Counts Maintenance Procedures

Replacing Filters

Materials Required

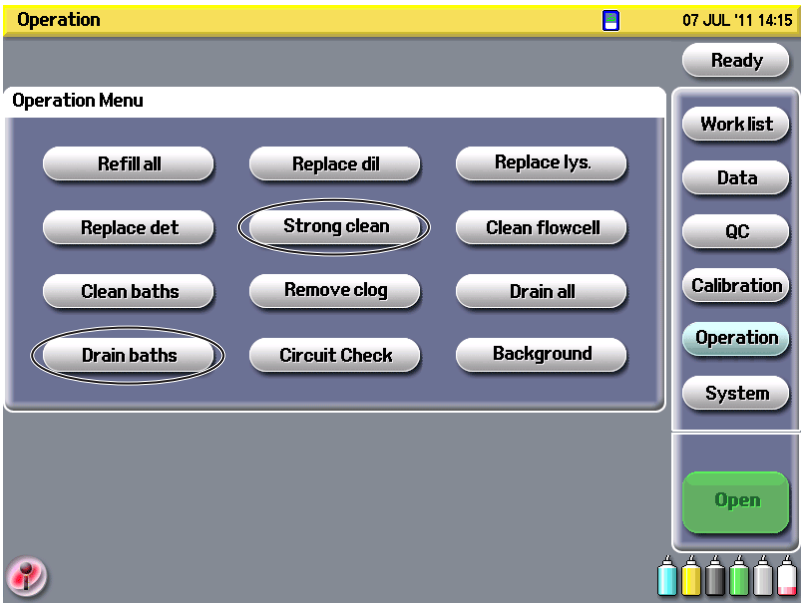
- Powder-free gloves, lab coat, safety glasses
- Phillips screwdriver
- Tweezers

Procedure

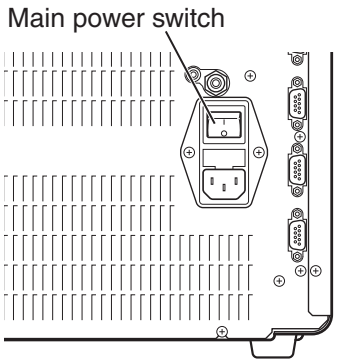
Replace the filters when they are clogged, dirty and/or after every 1,000 sample counts.

Replace the filter packing when they are dirty, deformed or damaged. For replacing the filter packing, contact your Nihon Kohden representative.

1. Press the Strong clean key on the Operation screen to perform strong cleaning to disinfect inside the analyzer. Refer to “Strong Cleaning” in Section 5.



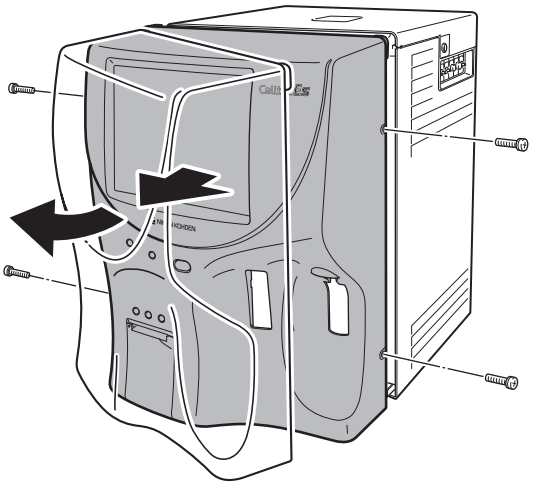
2. Press the Drain baths key on the Operation screen to drain the measurement baths and sub baths. Refer to “Draining Measurement Baths and Sub Baths” in Section 5.



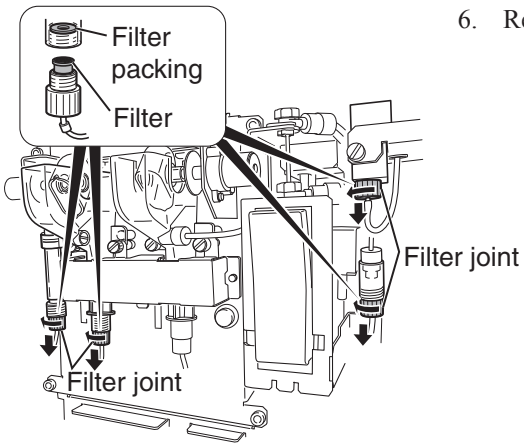
3. Turn off the main power by pressing the main power switch on the rear panel of the analyzer.

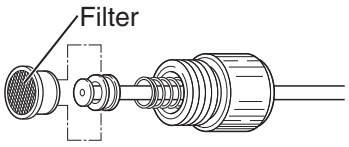
4. Remove the two screws on each side of the front cover of the hematology analyzer.

5. Open the front cover by pulling it from the right side. Check that the tube holder is closed before opening the front cover.



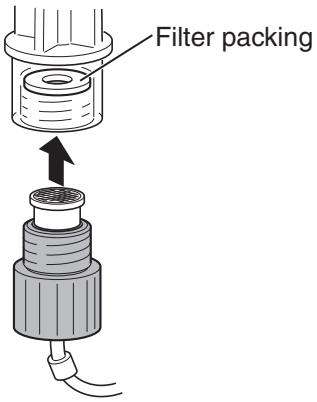
6. Remove the 4 filter joint assemblies by turning the tube connectors.





7. Remove the filter from each assembly. Use tweezers to remove any dust from the filter. If it is still dirty, replace it with a new one.

   Replace the filter packing when they are dirty, deformed or damaged. For replacing the filter packing, contact your Nihon Kohden representative.



8. Reattach the filter joint assemblies to the bottom of the RBC measurement bath and air trap. Make sure that the tube with the same number as the number label on the attaching part is connected back to the original position. Only finger tighten the filter joint.

NOTE

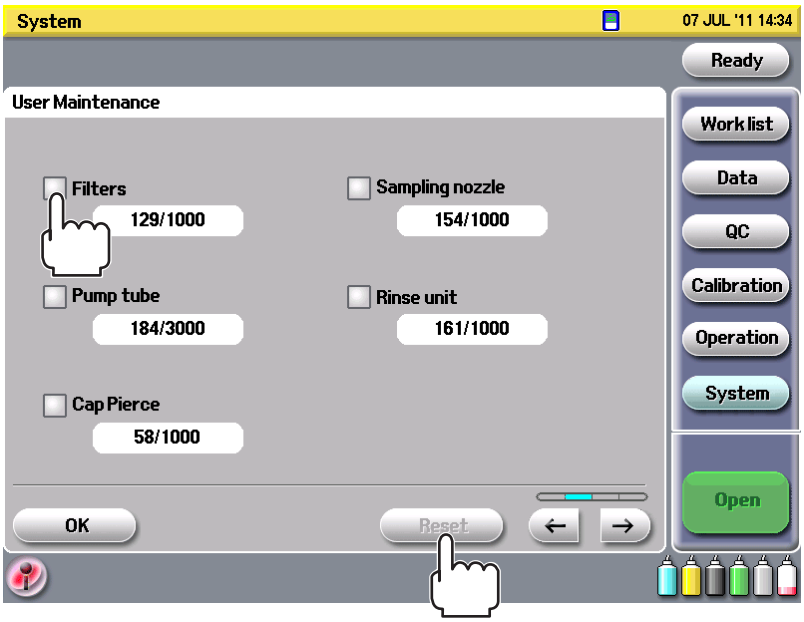
- When attaching the filter joint assembly, be careful not to bend or damage the filter packing at the bottom of the measurement bath.
- If there is leakage noted after installment of the filter, check that there are no scratches or damage around the filter. Damage may occur if a component is overtightened.

9. Reattach the front cover and fasten it with the two screws on each side of the front cover.

10. Press the [Power] key to turn on the power. The analyzer starts priming the fluid pathway.

11. If filters were replaced, reset the filter counter. Before resetting the counter, the measurement baths and sub baths should be cleaned. Refer to the "Checking and Cleaning Measurement Baths, Sub Baths and MC Tray" section.

    To reset the counter, check <Filters> and press the Reset key on the User Maintenance screen to reset the counts to zero.



12. Fill in the Maintenance Check Sheet.

13. Measure background noise at least twice.

14. Run quality controls before running patient samples.

Checking and Cleaning Measurement Baths, Sub Baths and MC Tray

Check the measurement baths, sub baths and MC tray every day.

Clean the measurement baths, sub baths and MC tray when there is any blood or dust on them. (Once a month or every 1,000 sample counts)

Materials Required

- Powder-free gloves, lab coat, safety glasses
- Phillips and flat-blade screwdrivers
- CLEANAC•3 detergent
- Dry lint-free cloth

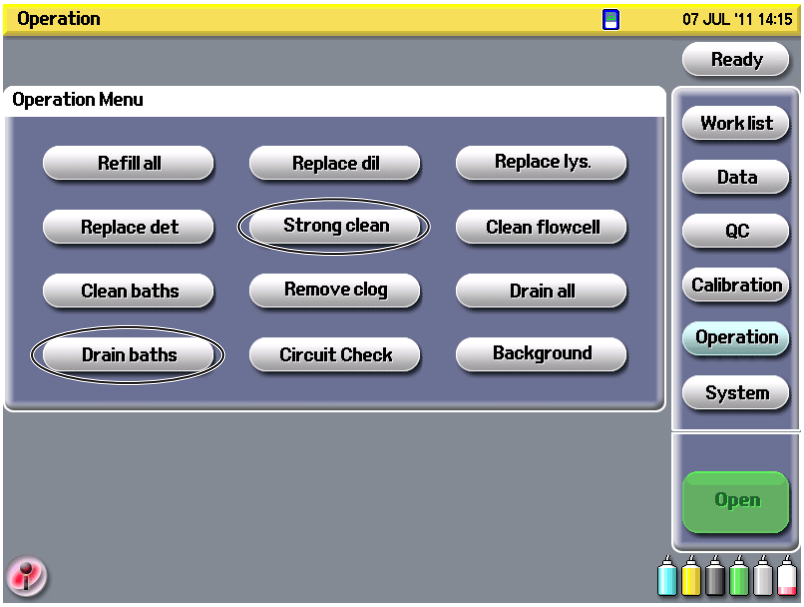
Procedure

NOTE

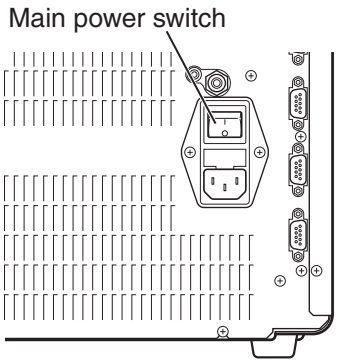
- The sub bath and measurement bath are made of special plastic. When cleaning the sub bath and measurement bath, do not damage the surface (inside). After cleaning, do not touch the surface (inside) with bare hands. It may be the cause of dirt.

- Do not use alcohol to clean the sub bath and measurement bath.

1. Press the Strong clean key on the Operation screen to perform strong cleaning to disinfect inside the analyzer. Refer to “Strong Cleaning” in Section 5.



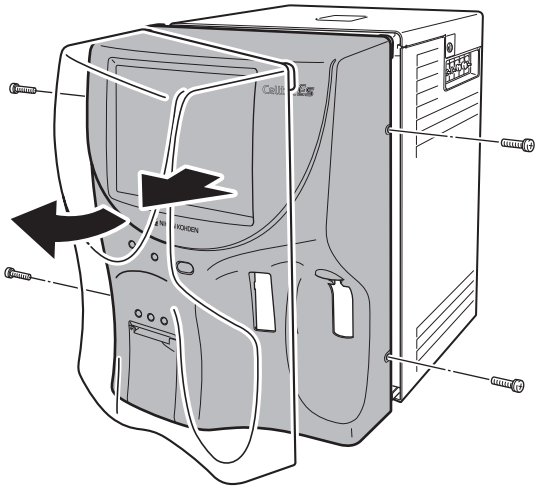
2. Press the Drain baths key on the Operation screen to drain the measurement baths and sub baths. Refer to “Draining Measurement Baths and Sub Baths” in Section 5.

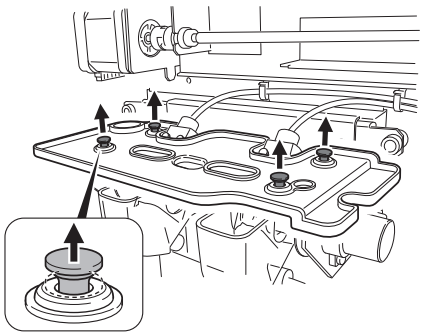


3. Turn off the main power by pressing the main power switch on the rear panel of the analyzer.

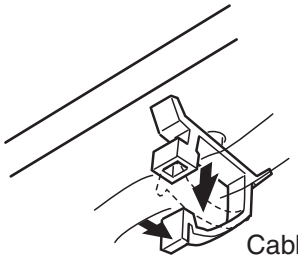
4. Remove the two screws on each side of the front cover of the hematology analyzer.

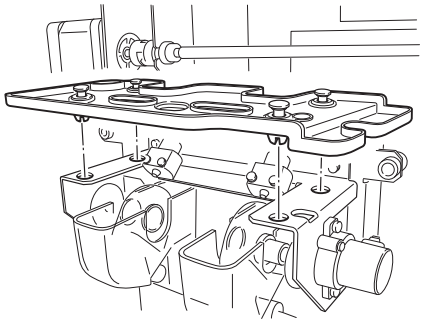
5. Open the front cover by pulling it from the right side. Check that the tube holder is closed before opening the front cover.





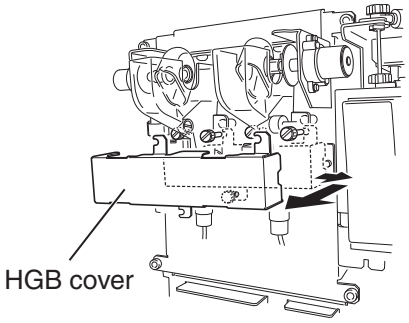
6. Pull up the four tabs of the MC tray until they click and release the cable clamp on the bottom of the tray.





7. Remove the MC tray by pulling up.

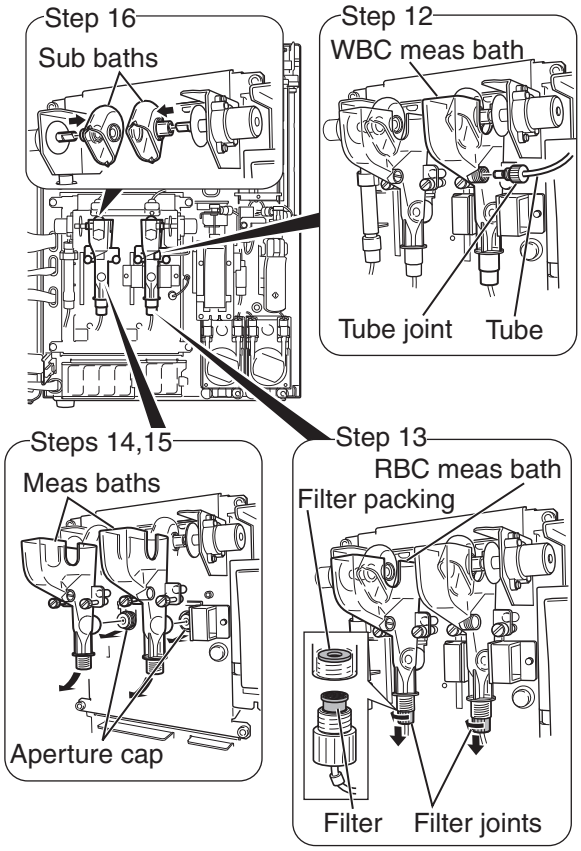
8. Rinse the MC tray with water and wipe it with a dry lint-free cloth.



9. Loosen the two screws beside the measurement bath.

10. Loosen the screw on the HGB cover and remove the HGB cover.

11. Check the WBC and RBC measurement baths and sub baths. If there is any blood or dust on them, remove and clean them taking the following steps.



12. Remove the tube joint connected to the WBC measurement bath by turning the knurl joint.

13. Remove filter joints on the RBC and WBC measurement bath assemblies by turning the tube connectors. The joint with filter is connected to the RBC measurement bath. Remove the filter packing together with the filter joints.

14. Loosen the screws fastening the measurement baths. (The screws cannot be removed from the measurement baths.)

15. Remove the measurement baths by pulling them toward you to remove them from the aperture and then pulling them downward.

16. Remove the sub baths by pulling them to the center.

17. Soak the measurement baths and sub baths in CLEANAC•3 detergent for about 10 minutes.

18. Rinse the measurement baths and sub baths with water and wipe them with a dry lint-free cloth.

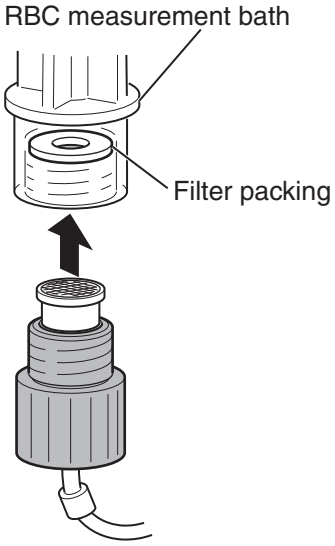
19. Reattach the sub baths to their original positions.

20. Reattach the measurement baths so that the sub bath is in the measurement bath, the shaft of the sub bath is in the tab of the measurement bath, and the round indent of the measurement bath fits the aperture.

21. Tighten the screws which were loosened in step 9 to fasten the measurement baths.

NOTE

Before tightening the screws, check and remove any dirt or rust on and around the screws. If dirt or rust is present, noise alarm may occur during measurement.



22. Reconnect the filter joints to the RBC and WBC measurement bath assemblies by turning the tube connectors. Attach the filter packing to the RBC measurement bath.

NOTE

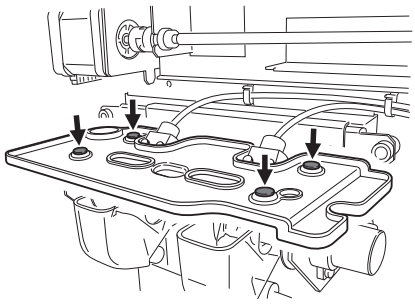
When connecting the filter joints to the RBC measurement bath, check the following:

- The filter packing is not bent or damaged.
- The filter joint is fixed firmly.

- If there is leakage after installing the filter, check that there are no scratches or damage around the filter and connect the joint again.

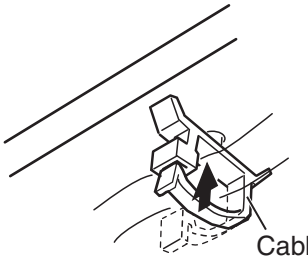
23. Reattach the tube joint to the WBC measurement bath by turning the knurl joint.

24. Reattach the HGB cover and fasten it with three screws.



25. Put the MC tray so that the fixing tabs and holes of the clump match.

26. Push the fixing tab to fix the MC tray and fix the cable with the cable clamp on the bottom of the tray.



27. Reattach the front cover and fasten it with two screws on each side.

28. Press the [Power] key to turn on the power. The analyzer starts priming the fluid pathway.

29. Fill in the Maintenance Check Sheet.

30. Measure background noise at least twice.

31. Run quality controls before running patient samples.

Checking, Cleaning and Replacing the Rinse Unit, Sampling Nozzles, Cap Pierce Nozzle and Sample Cup

Check and clean the rinse unit and cap pierce nozzle once a month or every 1,000 sample counts whichever comes first.

WARNING

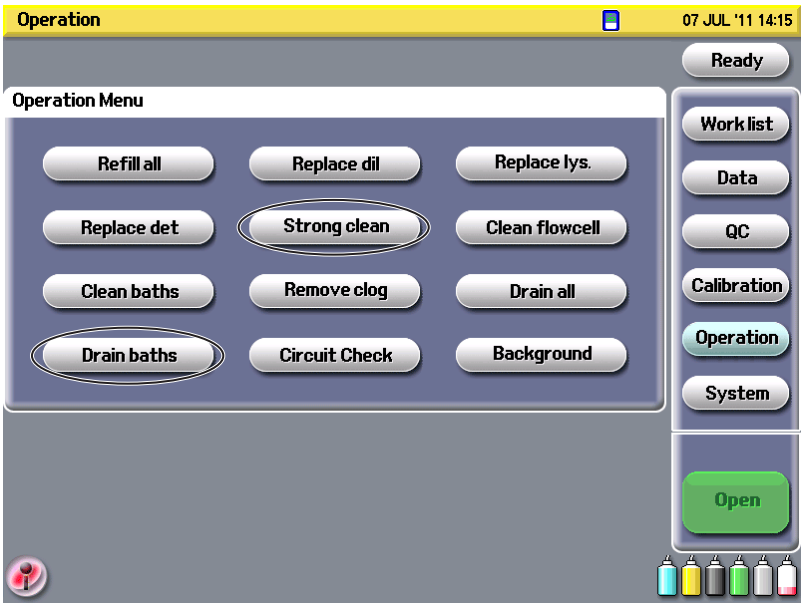
The cap pierce nozzle is sharp and potentially contaminated with infectious materials. Be careful when handling the cap pierce nozzle and performing this procedure.

Materials Required

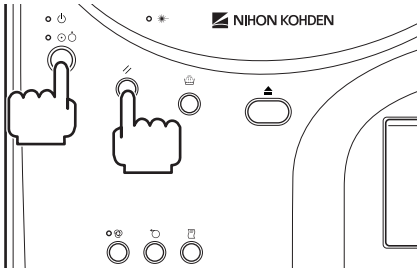
- Powder-free gloves, lab coat, safety glasses
- Phillips and flat-blade screwdrivers
- Cotton swabs
- CLEANAC•3 detergent
- Lint-free pad
- New cap pierce nozzle (when required)

Procedure

1. Press the Strong clean key on the Operation screen to perform strong cleaning to disinfect inside the analyzer. Refer to “Strong Cleaning” in Section 5.



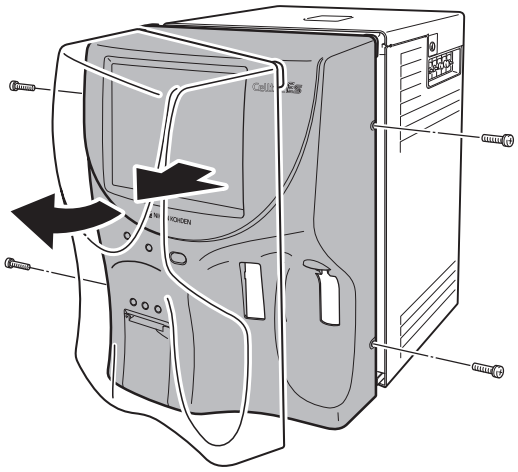
2. Press the Drain baths key on the Operation screen to drain the measurement baths and sub baths. Refer to “Draining Measurement Baths and Sub Baths” in Section 5.



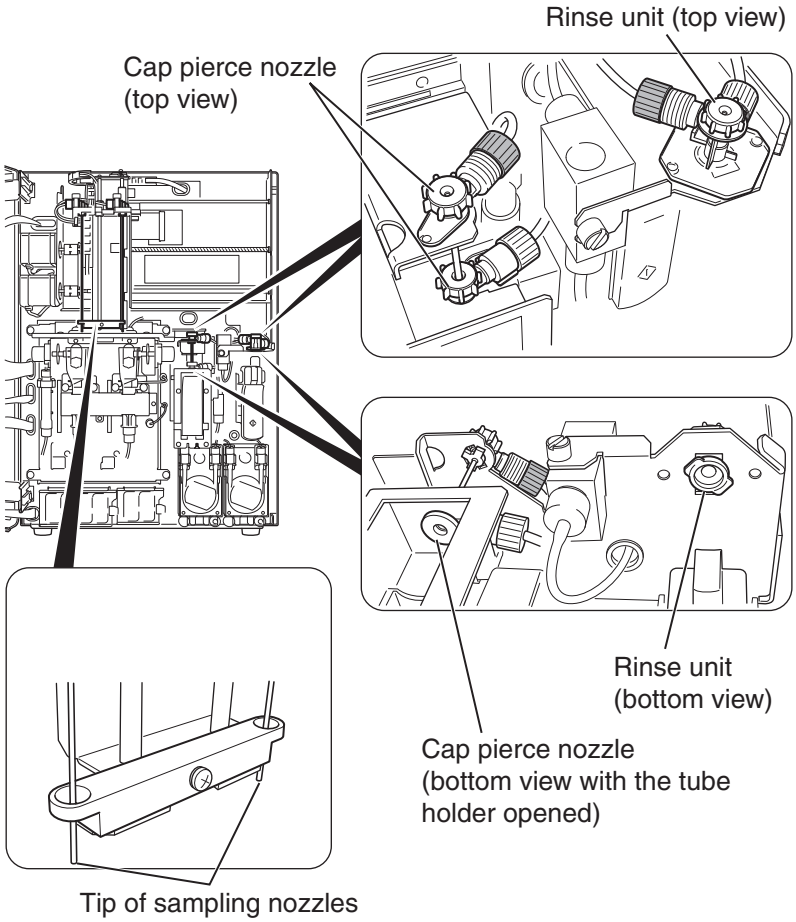
3. Press the [Power] key while holding down the [Reset] key to turn the power off. Check that the power lamp is off.

4. Remove the two screws on each side of the front cover of the hematology analyzer.

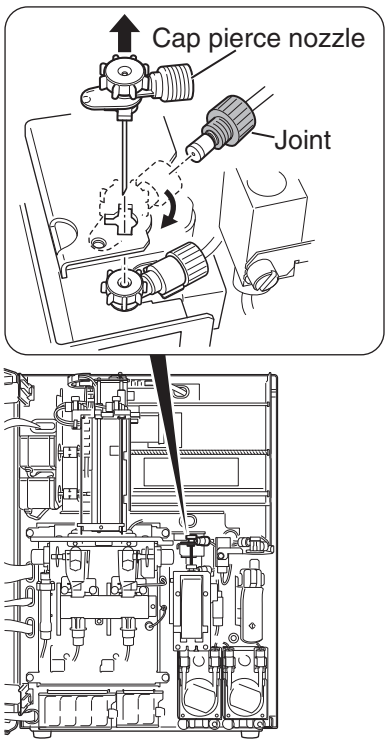
5. Open the front cover by pulling it from the right side. Check that the tube holder is closed before opening the front cover.



6. Check the following parts for dirt or blood clot. Remove blood or salt crystals on the rinse unit and the tip of the cap pierce nozzle and sampling nozzles with a cotton swab or lint-free pad moistened with CLEANAC•3 detergent.



If the cap pierce nozzle is damaged or dirt or blood cannot be removed, replace the cap pierce nozzle with a new one.



To replace the cap pierce nozzle:

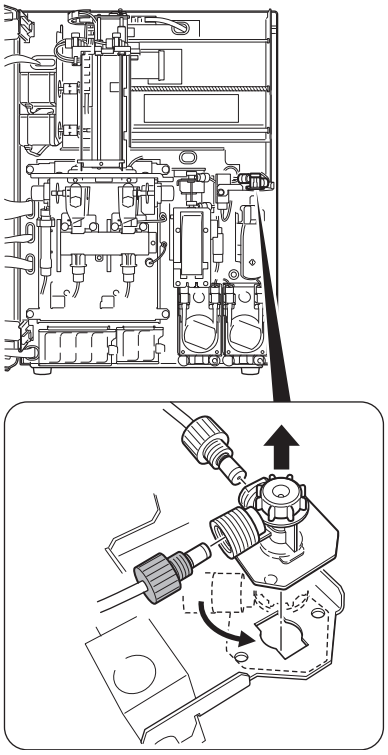
i) Turn the cap pierce nozzle 90º clockwise.

ii) Remove the joint from the cap pierce nozzle.

iii) Pull the cap pierce nozzle up to remove it.

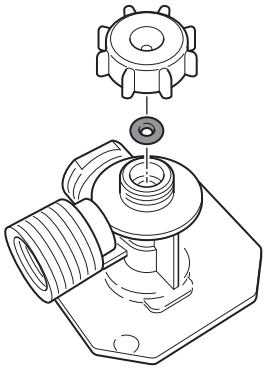
iv) Reattach the joint to the new cap pierce nozzle.

v) Insert the cap pierce nozzle into the cap pierce nozzle guide and turn the cap pierce nozzle 90º counterclockwise.



7. Turn the rinse unit cap counterclockwise to remove the rinse unit.

8. Loosen the joint assemblies to remove the tubes. Be careful not to lose the O-ring from the rinse unit.



9. Insert a cotton swab into the rinse unit from the bottom and push out the O-ring to remove it from the rinse unit.

10. Wipe the inside of the rinse unit and rinse unit cap with a cotton swab moistened with CLEANAC•3 detergent. If they are still dirty, soak them in CLEANAC•3 for about 10 minutes.

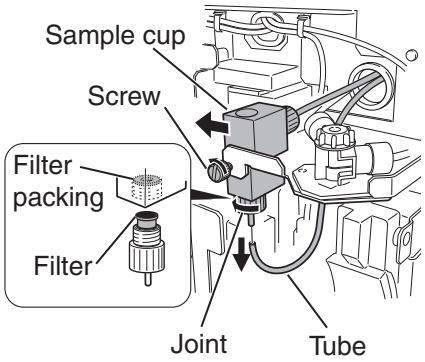
NOTE

Do not use alcohol to clean the rinse unit.

11. Rinse the rinse unit, rinse unit cap and O-ring with water and dry thoroughly with a dry cloth.

12. Reattach the O-ring to the rinse unit and return the rinse unit and rinse unit cap to the original position.

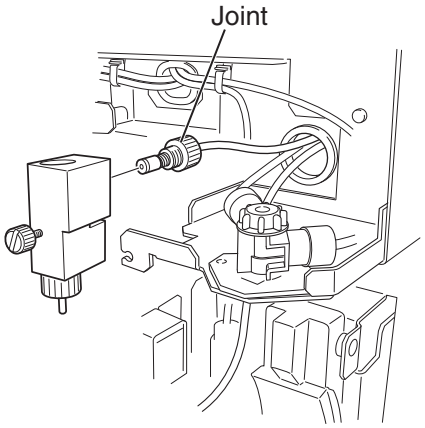
    When replacing the O-ring, clean the rinse unit and rinse unit cap and attach the new O-ring.



13. Remove the tube from the sample cup.

14. Remove the joint from the bottom of the sample cup. Remove the filter and filter packing together with the joint.

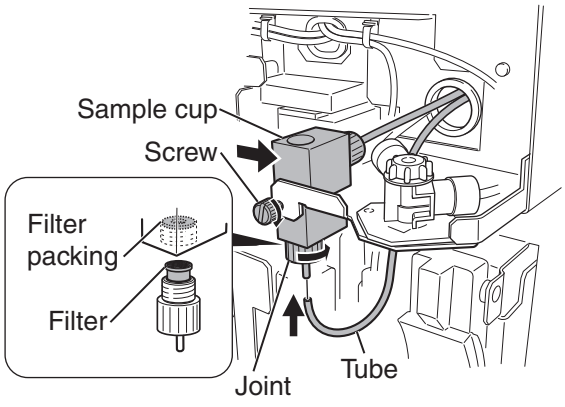
15. Loosen the screw of the sample cup and remove the sample cup by turning the sample cup clockwise.



16. Remove the transparent joint.

17. Soak the sample cup in CLEANAC•3 for about 10 minutes.

18. Rinse the sample cup with water and dry thoroughly with a dry cloth.



19. Reattach the joint which was removed in step 14 to the bottom of the sample cup. Attach the packing inside the sample cup.

NOTE

- Do not bend the packing inside the sample cup.
- Attach the joint firmly.
- If there is a leak, check that the filter is not damaged or cracked and attach the joint again.

20. Reattach the transparent joint.

21. Reattach the sample cup to the original position and fix the cup with screw.

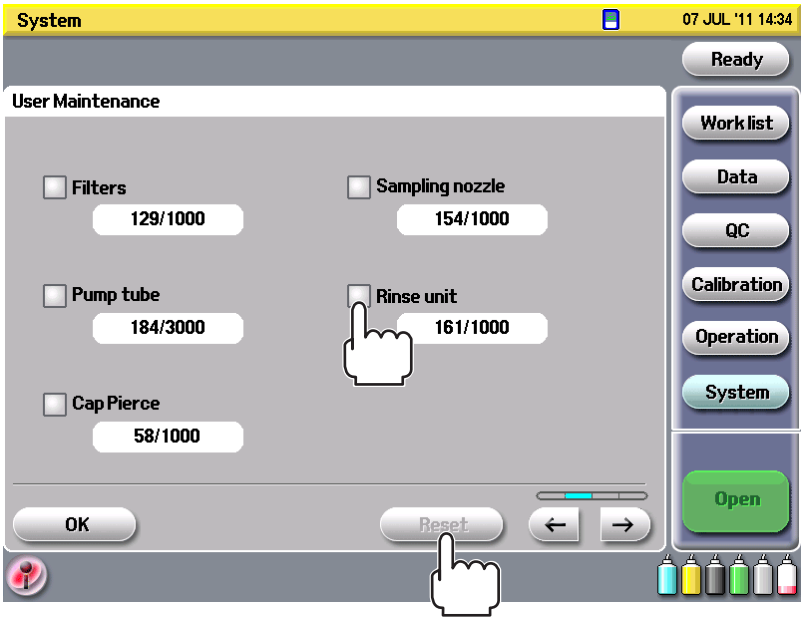
22. Reattach the tube.

23. Reattach the front cover and fasten it with two screws on each side.

24. Press the main power switch on the rear panel to turn on the main power.

25. Press the [Power] key to turn on the power. The analyzer starts priming the fluid pathway.

26. If the rinse unit and cap pierce nozzle were checked and cleaned, the rinse unit and cap pierce nozzle counter will have to be reset. To reset the counter, check <Rinse unit> and/or <Cap Pierce> and press the Reset key on the User Maintenance screen to reset the counts to zero.



27. Fill in the Maintenance Check Sheet.

28. Measure background noise at least twice.

29. Run quality controls before running patient samples.

Every Four Months/Every 3,000 Counts Maintenance Procedures

Checking, Cleaning and Replacing the Sampling Nozzles

Check and clean the sampling nozzles once every four months or every 3,000 sample counts whichever comes first.

When PLT background count increases or the sampling nozzle is bent, replace the sampling nozzles with a new one.

WARNING

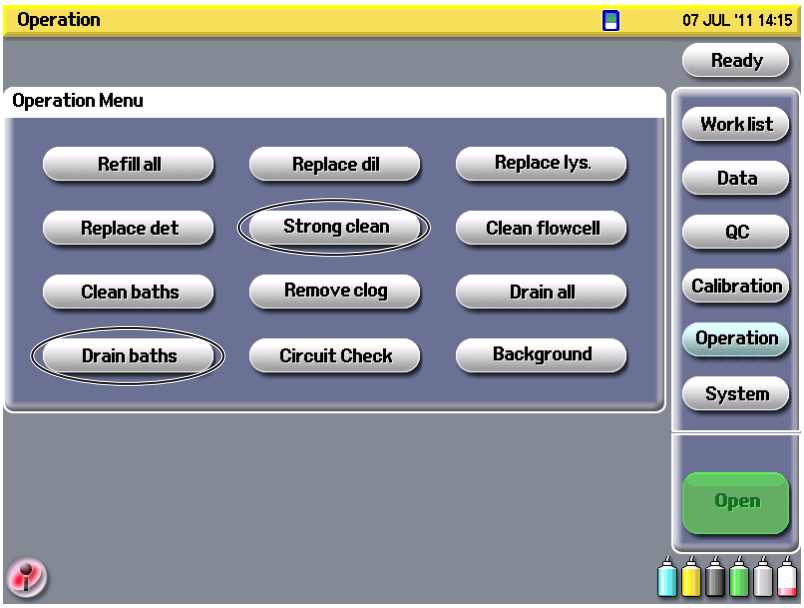
The sampling nozzles are sharp and potentially contaminated with infectious materials. Be careful when handling the sampling nozzles and performing this procedure.

Materials Required

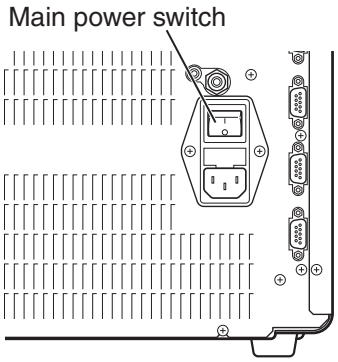
- Powder-free gloves, lab coat, safety glasses
- Phillips and flat-blade screwdrivers
- Cotton swabs
- CLEANAC•3 detergent
- Lint-free pad
- New sampling nozzle(s) (when required)

Procedure

1. Press the Strong clean key on the Operation screen to perform strong cleaning to disinfect inside the analyzer. Refer to “Strong Cleaning” in Section 5.



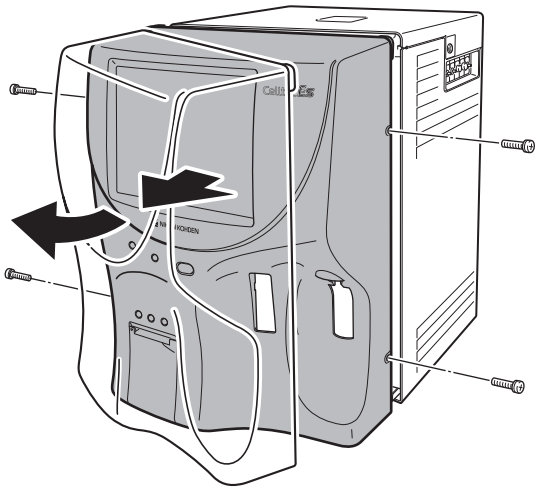
2. Press the Drain baths key on the Operation screen to drain the measurement baths and sub baths. Refer to “Draining Measurement Baths and Sub Baths” in Section 5.



3. Turn off the main power by pressing the main power switch on the rear panel of the analyzer.

4. Remove the two screws on each side of the front cover of the hematology analyzer.

5. Open the front cover by pulling it from the right side. Check that the tube holder is closed before opening the front cover.

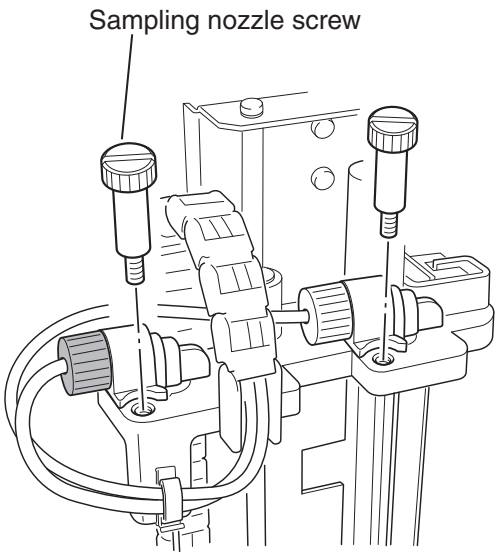


6. Check the sampling nozzles for dirt or blood clot. Remove blood or salt crystals on the tip of the sampling nozzles with a cotton swab or lint-free pad moistened with CLEANAC•3 detergent.

   If the sampling nozzle is damaged or dirt/blood cannot be removed, replace the sampling nozzle with a new one.

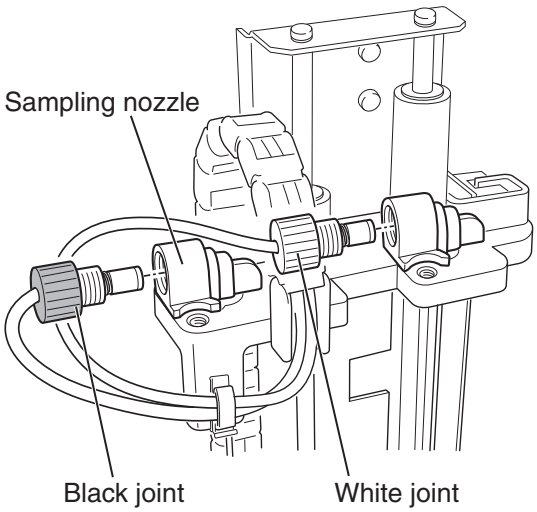
   To replace sampling nozzles:

   i) Loosen the sampling nozzle screw from each of the sampling nozzle.



NOTE

Be careful not to drop the screws into the analyzer.



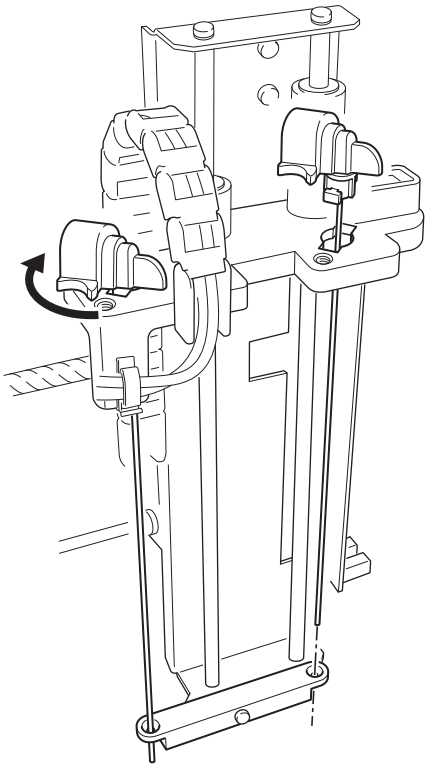
ii) Remove the joint from each sampling nozzle.

NOTE

Diluent may flow out from the sampling nozzle when the joint is removed.

iii) Turn each sampling nozzle 45º clockwise.

iv) Pull the sampling nozzle up to remove it.



v) Attach the new sampling nozzles by reversing the above procedure. Make sure that the white joint is attached to the right sampling nozzle and the black joint to the left sampling nozzle. Fasten the sampling nozzles with the sampling nozzle screws.

NOTE

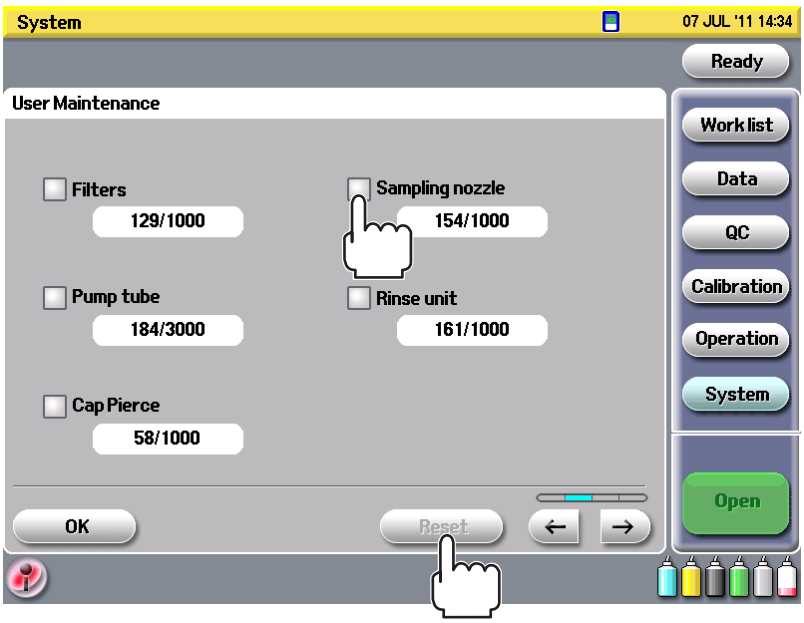
Attach the sampling nozzles correctly by letting the nozzles into the guides.

7. Reattach the front cover and fasten it with the two screws on each side.

8. Press the main power switch on the rear panel to turn on the main power.

9. Press the [Power] key to turn on the power. The analyzer starts priming the fluid pathway.

10. If the sampling nozzles were checked and cleaned, the sampling nozzle counter will have to be reset. To reset the counter, check <Sampling nozzle> and press the Reset key on the User Maintenance screen to reset the counts to zero.



11. Fill in the Maintenance Check Sheet.

12. Measure background noise at least twice.

13. Run quality controls before running patient samples.

Replacing Pump Tube

Check the pump tube for water droplets and leaks every day.

Replace the pump tube when there are water droplets or leaks. (Once every 4 months or every 3,000 sample counts whichever comes first.)

NOTE

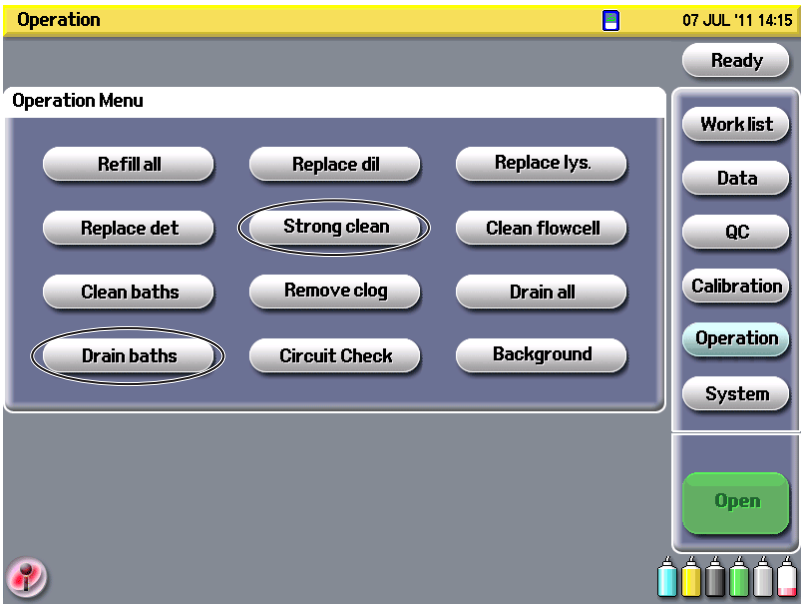
Do not leave the pump tube with water droplets or leaks on it.

Materials Required

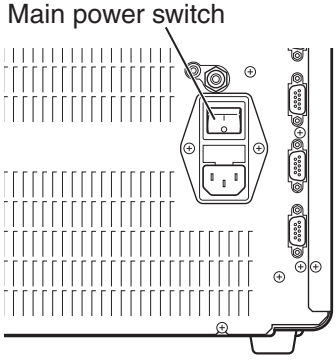
- Powder-free gloves, lab coat, safety glasses
- Phillips screwdriver

Procedure

1. Press the Strong clean key on the Operation screen to perform strong cleaning to disinfect inside the analyzer. Refer to “Strong Cleaning” in Section 5.



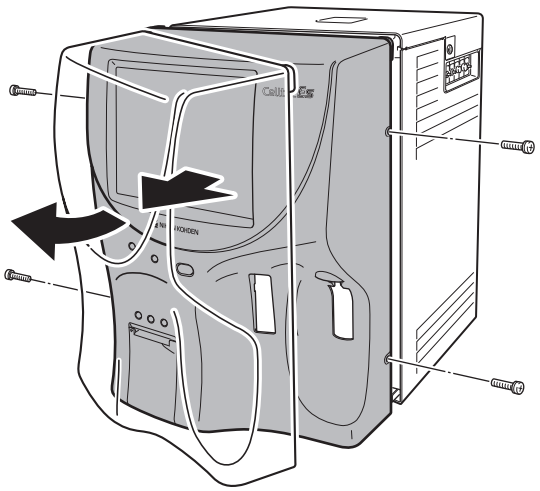
2. Press the Drain baths key on the Operation screen to drain the measurement baths and sub baths. Refer to “Draining Measurement Baths and Sub Baths” in Section 5.

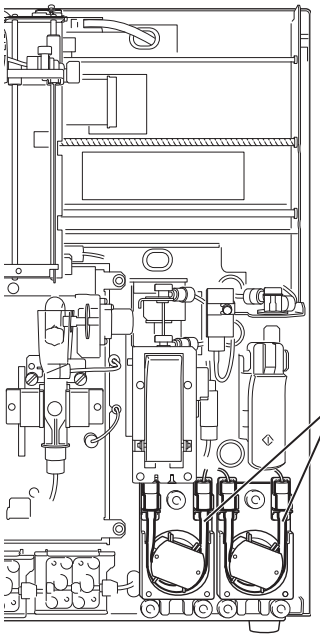


3. Turn off the main power by pressing the main power switch on the rear panel of the analyzer.

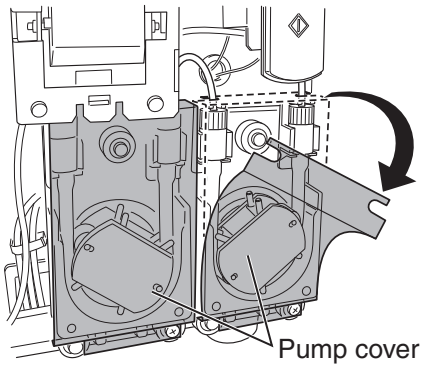
4. Remove the two screws on each side of the front cover of the hematology analyzer.

5. Open the front cover by pulling it from the right side. Check that the tube holder is closed before opening the front cover.

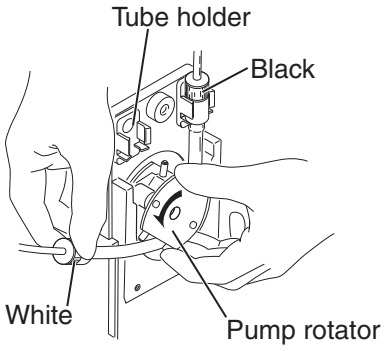




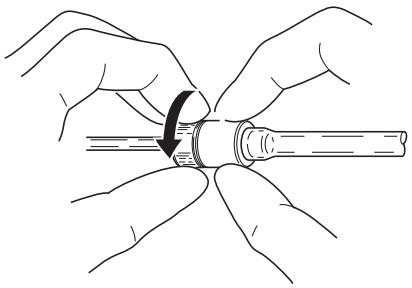
6. Check the pump tube for water droplets and leaks. If any droplet or leak is found, replace the tube with a new one by using the following steps.



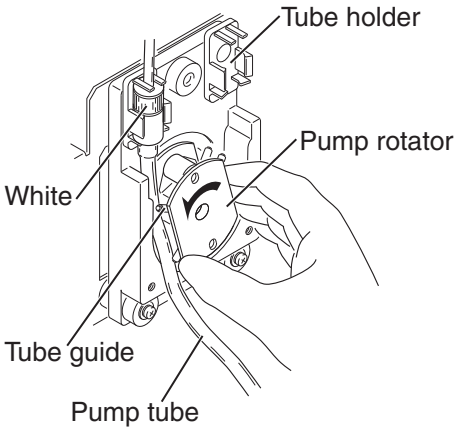
7. Remove the pump covers.



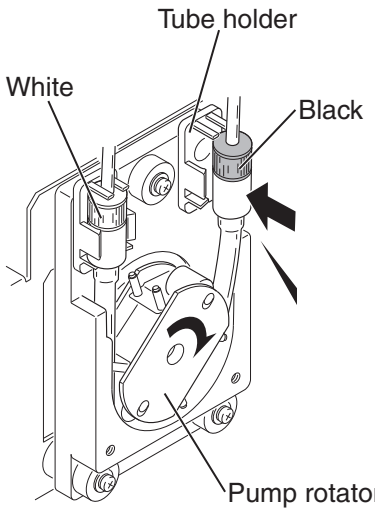
8. Pull out the white tube joint from the tube holder and pull out the pump tube by turning the pump rotator counterclockwise. Then pull the black tube joint out of the tube holder.



9. Remove the white and black tube joints and replace the pump tube.



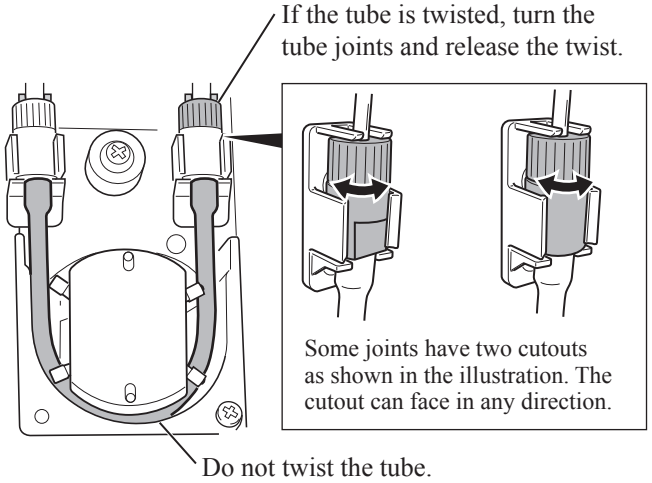
10. Return the white tube joint to the original position and push the pump tube into the tube guide by turning the rotator counterclockwise.



11. Return the black tube joint to the original position.

NOTE

- Be careful not to pinch the new pump tube between the tube guide and housing. This may damage the pump tube.
- Do not attach the black tube joint to the tube holder before the white tube joint because internal compressed air may disconnect the tube.
- Put back the pump tube properly. If the pump tube has slack, remove the slack by turning the rotator clockwise. If the pump tube has slack, it will be damaged by the tube guide.
- Make sure the joints are held properly by the tube holder as shown below. Otherwise, the pump tube may be damaged or the life of the pump tube will be shortened.



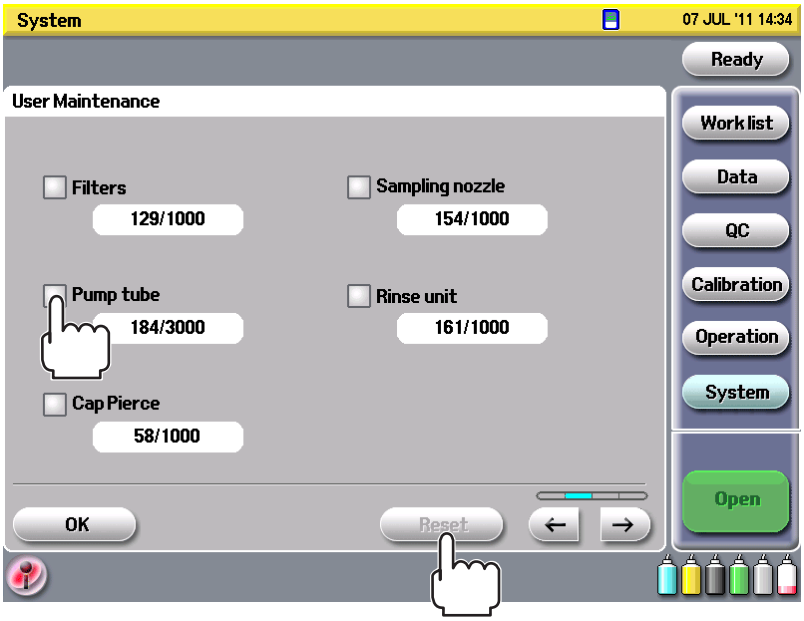
12. Reattach the pump covers.

13. Reattach the front cover and fasten it with the two screws on each side.

14. Press the main power switch on the rear panel to turn on the main power.

15. Press the [Power] key to turn on the power. The analyzer starts priming the fluid pathway.

16. If the pump tube was replaced, the pump tube counter will have to be reset. To reset the counter, check <Pump tube> and press the Reset key on the User Maintenance screen to reset the counts to zero.



17. Fill in the Maintenance Check Sheet.

18. Measure background noise at least twice.

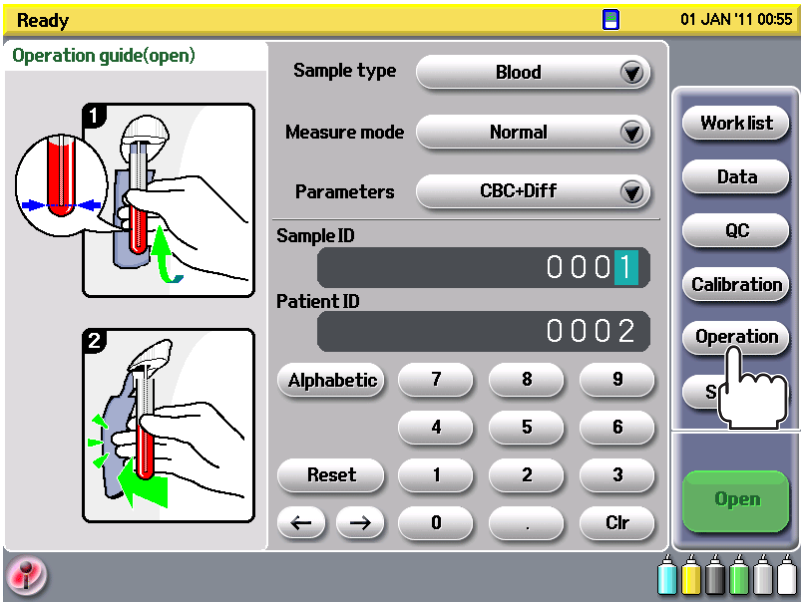
19. Run quality controls before running patient samples.

As-Required Maintenance Procedures

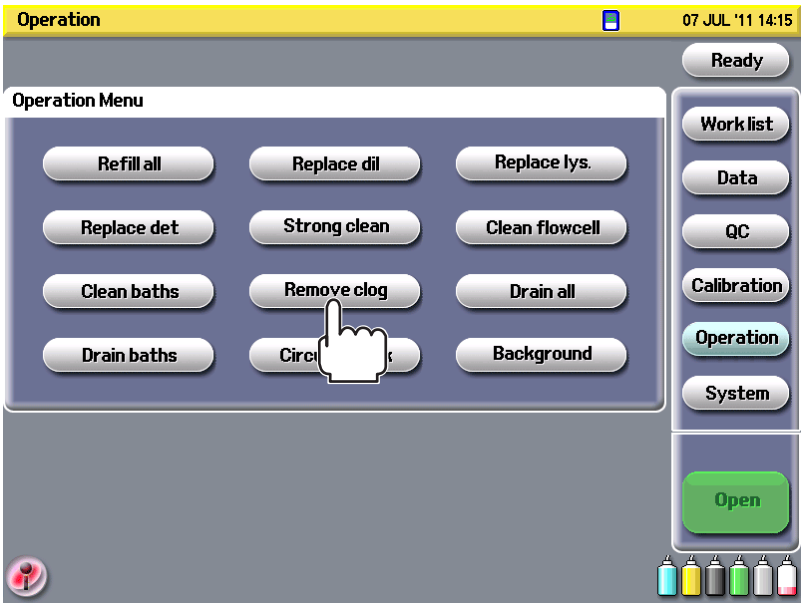
Removing a Clog from the Aperture

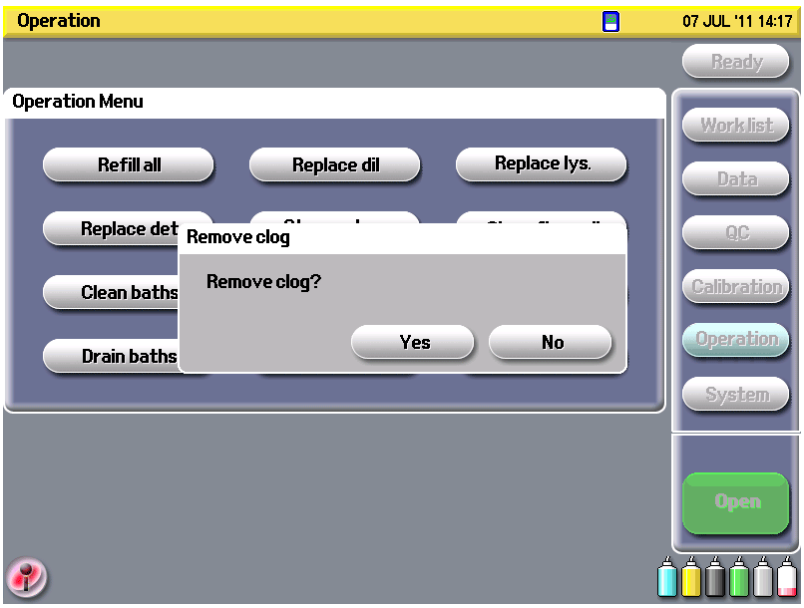
When the “CLOG” alarm occurs, remove the clog by the following procedure.

1. Press the Operation key on the screen to display the Operation screen.



2. Press the Remove clog key on the Operation screen. The confirmation message appears.





3. Press the Yes key to remove the clog from the aperture. The analyzer starts removing the clog and the “Removing clog” message appears on the screen. Press the No key to cancel the procedure.

   After removing the clog, the screen returns to the Operation screen.

Cleaning Aperture Caps

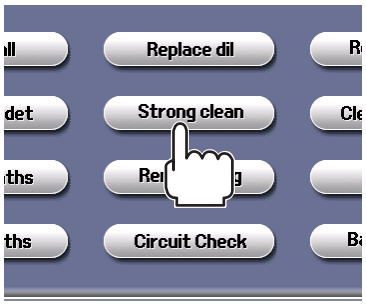
Materials Required

- Powder-free gloves, lab coat, safety glasses
- Phillips and flat-blade screwdrivers
- Dry cloth or tissue paper
- CLEANAC•3 detergent
- Microscope

Procedures

For daily cleaning of the aperture caps, press the [Clean] key on the front panel.

However, if the “CLOG” message frequently appears or the background count is high, clean the aperture caps as directed in the following procedure.

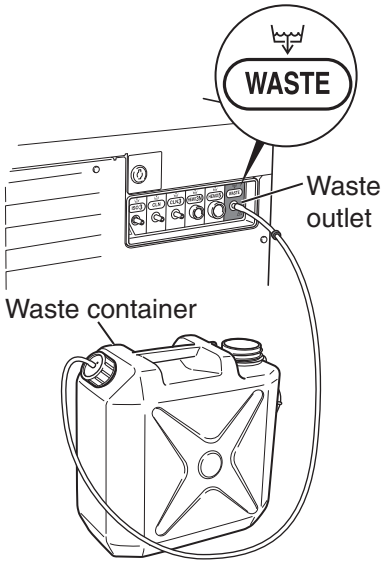


NOTE

The aperture caps are behind the measurement baths.

1. Press the Strong clean key on the Operation screen to perform strong cleaning to disinfect inside the analyzer. Refer to “Strong Cleaning” in Section 5.

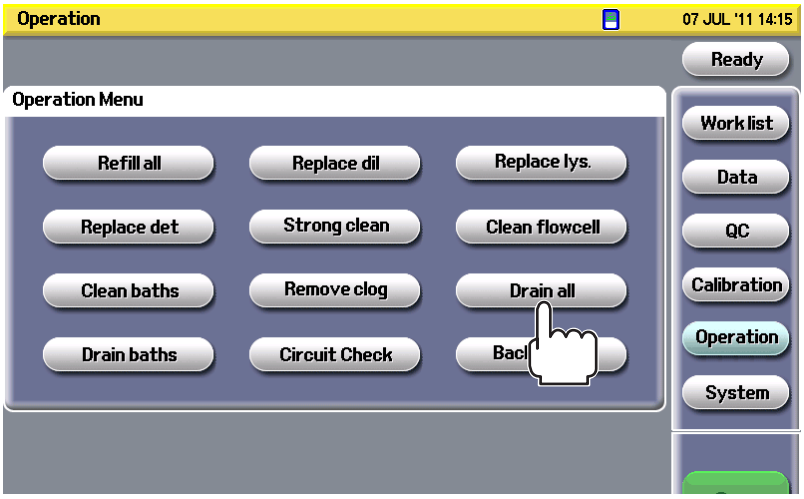
2. Remove the diluent tube from the ISO3 inlet, the hemolysiing reagent tubes from the HEMO3 and HEMO5 inlets, and the detergent tubes from the CLN3 inlets on the right side panel.



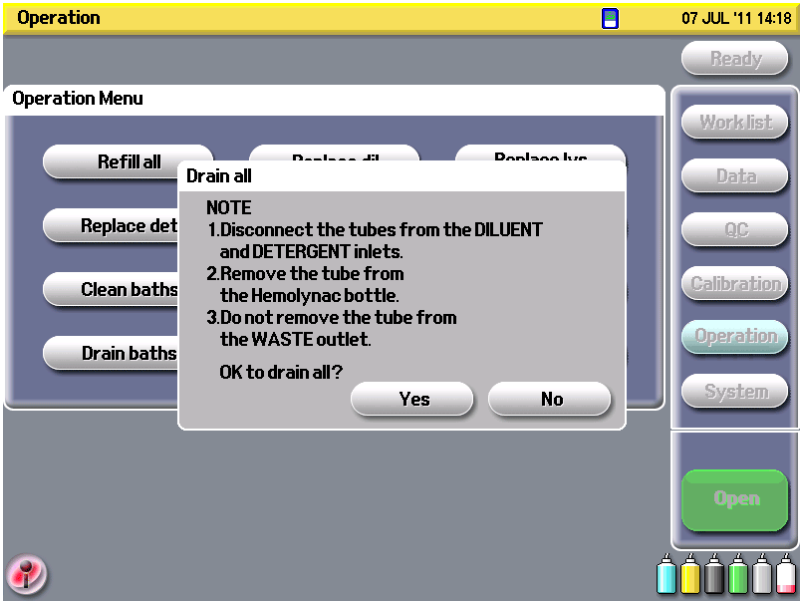
NOTE

Waste comes out from the CLN inlet when Drain all is performed.

3. Press the Drain all key on the Operation screen.



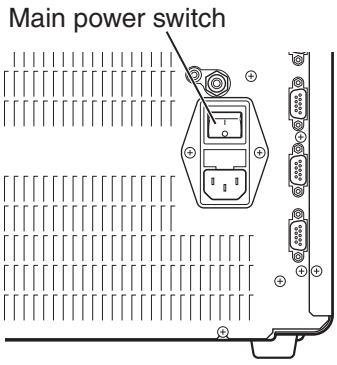
A confirmation message appears on the screen.



4. Press Yes to start draining the analyzer.

NOTE

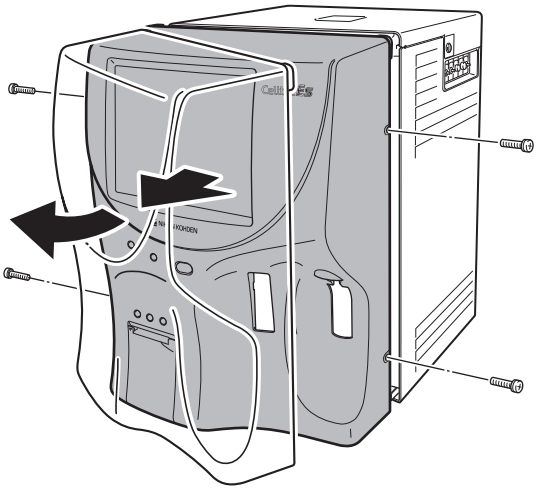
Be sure all reagent has drained into the container. Failure to do so may result in a liquid spill.

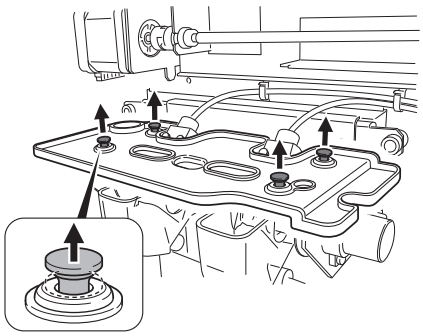


5. After draining, turn off the main power by pressing the main power switch on the rear panel of the analyzer.

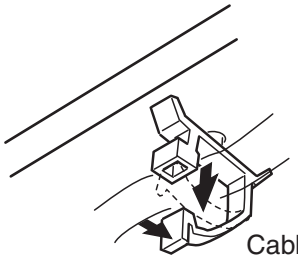
6. Remove the two screws on each side of the front cover of the hematology analyzer.

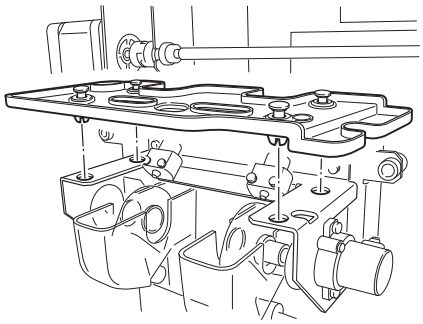
7. Open the front cover by pulling it from the right side. Check that the tube holder is closed before opening the front cover.



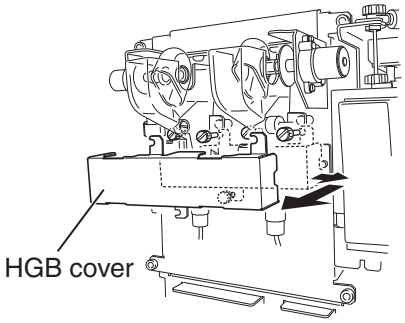


8. Pull up the four tabs of the MC tray until they click and release the cable clamp on the bottom of the tray.



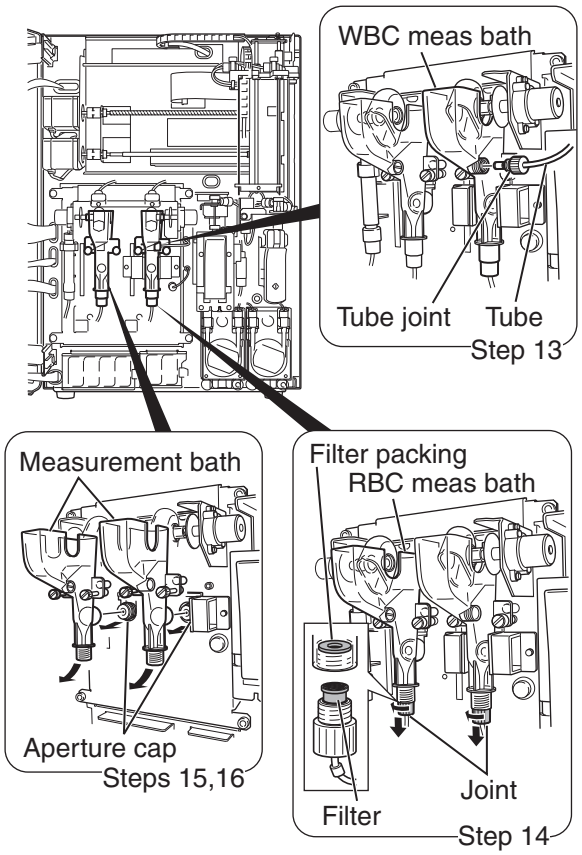


9. Remove the MC tray by pulling it up.



10. Loosen the two screws beside the measurement bath.

11. Remove the screw on the HGB cover and remove the HGB cover.

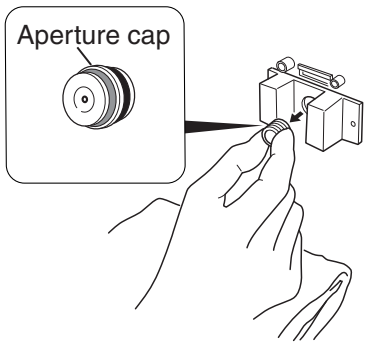


12. Remove the tube joint connected to the WBC measurement bath by turning the knurl joint.

13. Remove the filter joints on the RBC and WBC measurement bath assemblies by turning the tube connectors.

14. Loosen the screws fastening the measurement baths. (The screws cannot be removed from the measurement baths.)

15. Remove the measurement baths by pulling them toward you to remove them from the aperture and then pulling them downward.



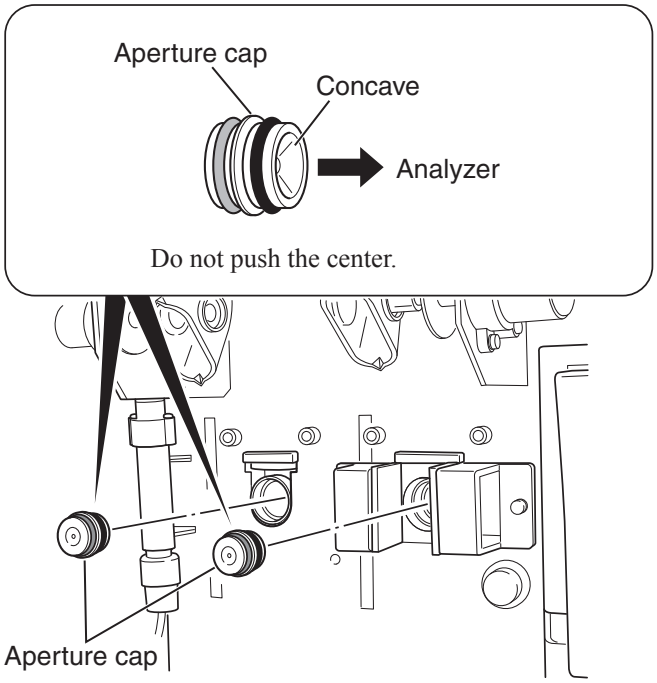
16. Place a cloth or tissue paper under your hand and remove the aperture cap by pulling it toward you. If it is not easy to pull the aperture cap, move it slowly left and right to remove it.

17. Carefully rinse the aperture cap. Remove all protein build-up, especially from the inside. The condition of the aperture cap can be checked with a 100× microscope.

18. If a clog or dust still remains in the aperture caps, soak the aperture caps in CLEANAC•3 detergent for about an hour.

CAUTION

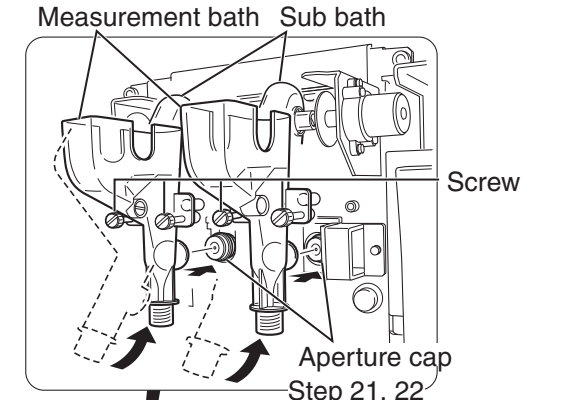
Handle the aperture caps with care. They can be damaged if a sharp object is used to clean them.

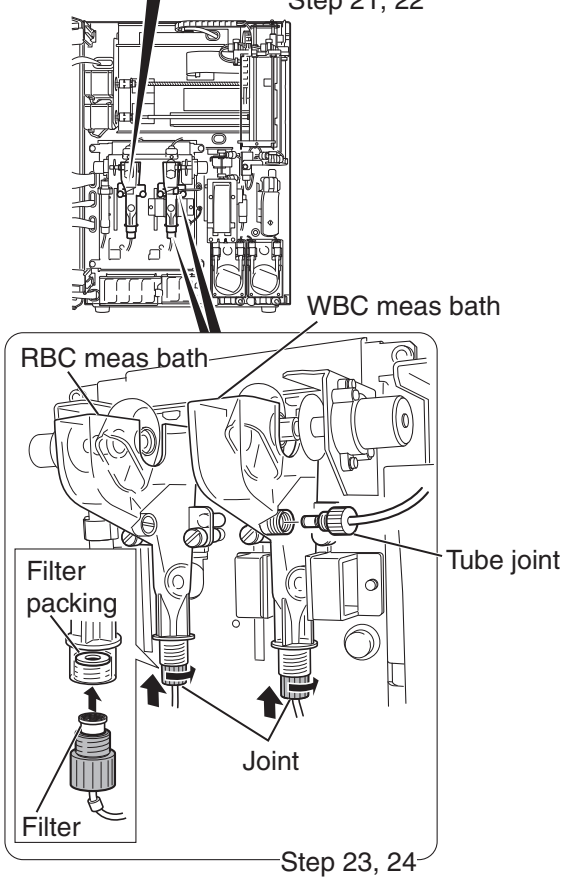


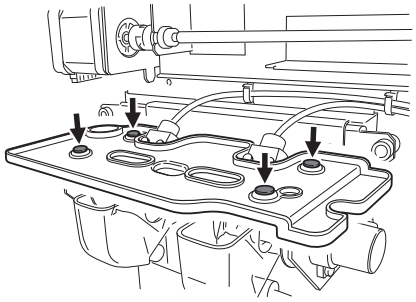
19. Rinse the aperture caps with water and replace them in the original positions. Make sure that the black O-ring is facing the hole (analyzer side).

NOTE

When replacing the aperture cap, do not push the aperture cap with your ball of finger. The aperture cap may be broken.







20. Reattach the measurement baths so that the sub bath is in the measurement bath, the shaft of the sub bath is in the tab of the measurement bath, and the round indent of the measurement bath fits the aperture.

21. Tighten the screws which were loosened in step 15 to fasten the measurement baths.

NOTE

Before tightening the screws, check and remove any dirt or rust on and around the screws. If dirt or rust is present, noise alarm may occur during measurement.

22. Reconnect the filter joints to the RBC and WBC measurement bath assemblies by turning the tube connectors. Attach the filter packing to the RBC measurement bath.

NOTE

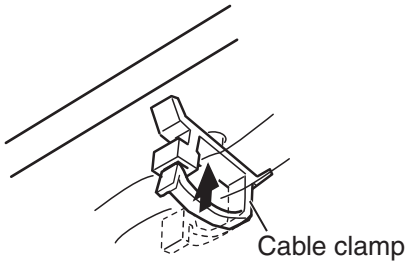
- Do not bend the packing inside the sample cup.
- Attach the joint firmly.
- If there is a leak, check that the filter is not damaged or cracked and attach the joint again.

23. Reattach the tube joint to the WBC measurement bath by turning the knurl joint.

24. Reattach the HGB cover and fasten it with the screw.

25. Put the MC tray so that the fixing tabs and holes of the clump match.

26. Push the fixing tab to fix the MC tray and fix the cable with the cable clamp on the bottom of the tray.



27. Reattach the front cover and fasten it with the two screws on each side.

28. Press the [Power] key to turn on the power. The analyzer starts priming the fluid pathway.

29. Fill in the Maintenance Check Sheet.

30. Measure background noise at least twice.

31. Run quality controls before running patient samples.

Checking the Prime Function

This function fills the fluid path inside the analyzer with diluent.

1. Press the Operation key on the screen to display the Operation screen.

2. Press the Refill all key. The “Refill all?” confirmation message appears.

3. Press the Yes key to prime. The analyzer automatically checks the reagent and starts priming.
   Press the No key to cancel the procedure. The screen returns to the Operation screen.

   During priming, the screen shows the “Priming” message. After priming is completed, the screen returns to the Ready screen.

Checking the Drain Function

Refer to “Draining Measurement Baths and Sub Baths” in Section 5.

Checking the Cleaning Function

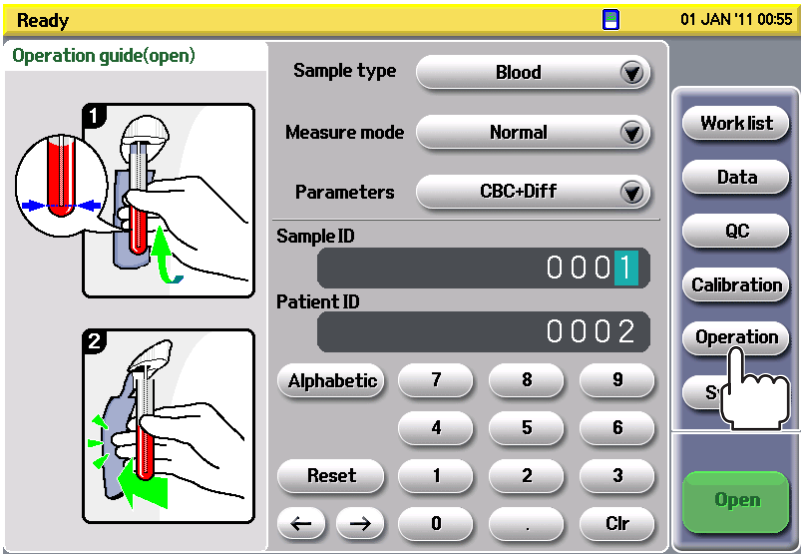
Press the [Clean] key on the front panel to check the cleaning function.
After cleaning, the screen returns to the Ready screen.

For checking the strong cleaning function, refer to “Strong Cleaning” in Section 5.

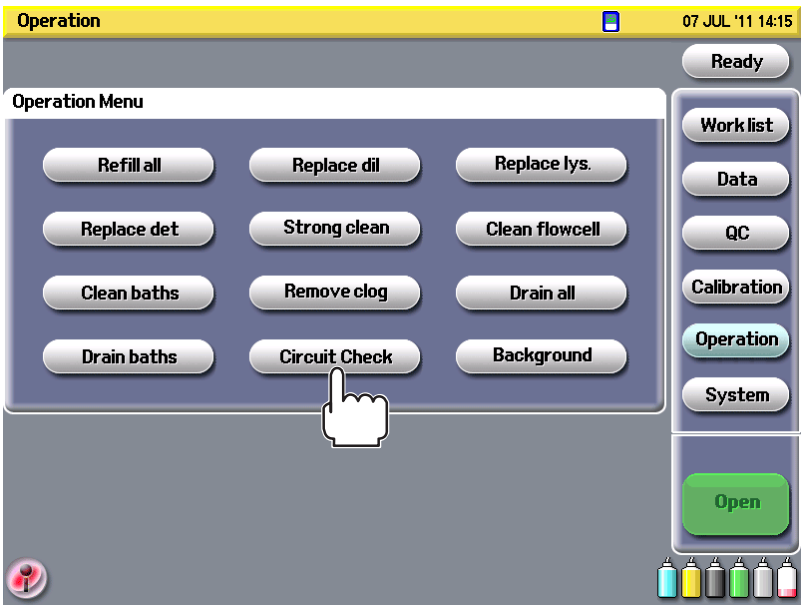
Checking the Electrical Circuits

You can check the analyzer's electrical circuits.

1. Press the Operation key on the screen.

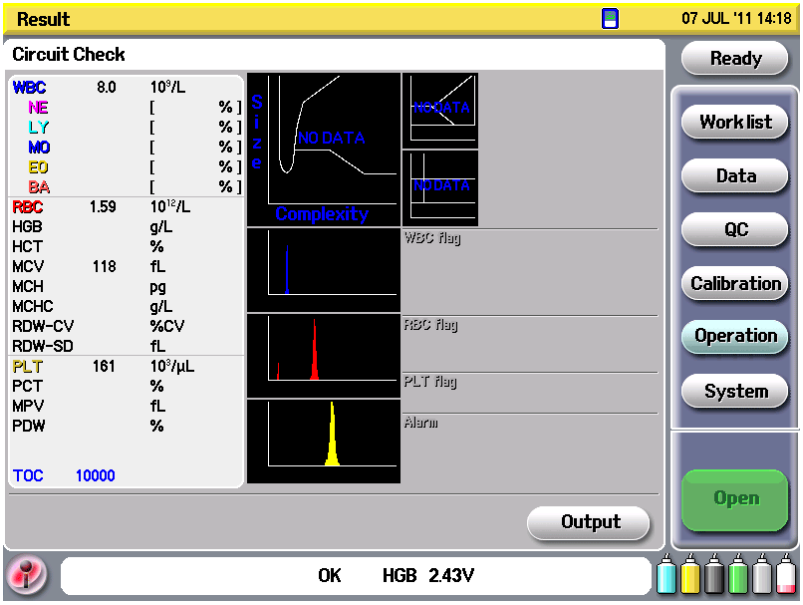


2. Press the Circuit Check key on the Operation screen. The confirmation message appears.



3. Press the Yes key. The analyzer starts checking the circuit and the screen shows the "Checking circuit" message.

   When the check is completed, the result appears.



If the circuits are normal, “OK” and HGB voltage is displayed. If the circuits are abnormal, “NG” and HGB voltage is displayed.

Normal range

WBC: 7.6 to 8.4 (10^3/µL)
RBC: 1.52 to 1.68 (10^6/µL)
MCV: 85 to 115 (fL)
PLT: 152 to 168 (10^3/µL)
HGB ON: 1.5 V to 4.5 V
HGB OFF: less than 0.5 V

- If the HGB value is outside the normal range, clean the WBC measurement bath and recheck the circuit.
- If a check result is outside the normal range, contact your Nihon Kohden representative.
- Also check the sensitivity and threshold setting and write down the settings in the maintenance check sheet.

Checking the Background Noise

Measure only diluent and check that the values are less than or equal to the following values. For details, refer to “Measuring Background Noise” in Section 2.

WBC	0.2 ($\times 10^3$/µL)
RBC	0.05 ($\times 10^6$/µL)
HGB	0.1 (g/dL)
PLT	10 ($\times 10^3$/µL)
TOC*	100 (count)

* Total Optical Count

When the check result exceeds the normal value, an “Abnormal background” message appears on the message area. In this case, check the following points and measure background noise again.

- Diluent is not dirty
- There are no bubbles in the diluent
- Aperture caps are not dirty
- Aperture caps are attached firmly

If the “Abnormal background” message is displayed again, refer to “Inaccurate Counting and Other Problems” in Section 10.

Checking the Flow Cell

Measure particles to check the particle distribution width. If the width is out of the standard, adjust the flow cell position. If most of the WBC distribution of the scattergram is out of the area or WBC flag (Immature Gr, Blasts, Left Shift, Atypical Ly, Neutropenia, Lymphocytosis, Lymphopenia, Monocytosis, Neutrophilia, Basophilia) occurs frequently, check the particle distribution width and perform the optical adjustment.

1. Perform cleaning or flow cell cleaning to remove the dust or bubbles inside the flow cell. Refer to “Cleaning the Flow Cell” in this section.

NOTE

After cleaning, check that no detergent, diluent or lysing reagent alarm occurs. If there is no reagent, replace the reagent and perform cleaning or flow cell cleaning again.

2. Press the System key on the menu to open the system menu window.

3. Press the Adj. flow cell key to open the Adj. Flowcell window.

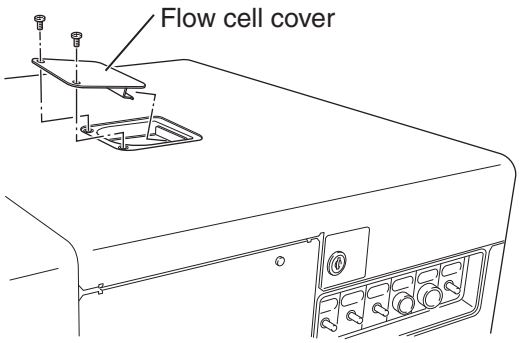
4. Check that the Rough window is displayed. Measure particles by pressing the count switch.

5. After the measurement, check that the CV and peaks are less than or equal to the following values.

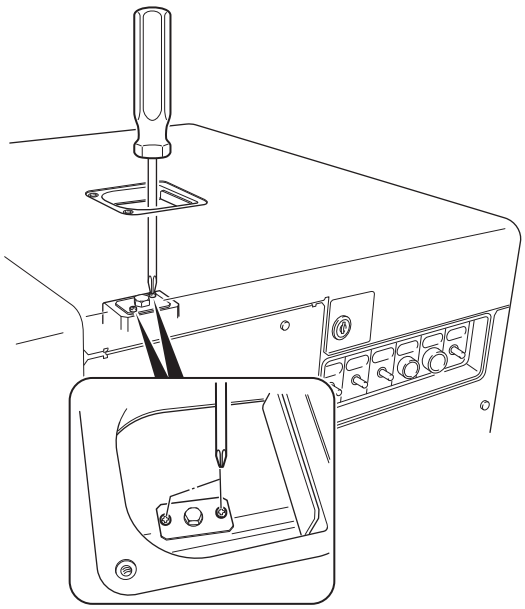
FS CV	7.0%
FS Peak	61 ±6
FL CV	7.0%
FL Peak	90 ±6
TOC	3000 count

If the result is out of the above values, perform flow cell adjustment and optical adjustment (rough and fine). Refer to “Performing an Optical Adjustment” in Section 5 and “Adjusting Flow Cell” later in this section.

Adjusting the Flow Cell



1. Remove the two screws and flow cell cover from the top of the analyzer.



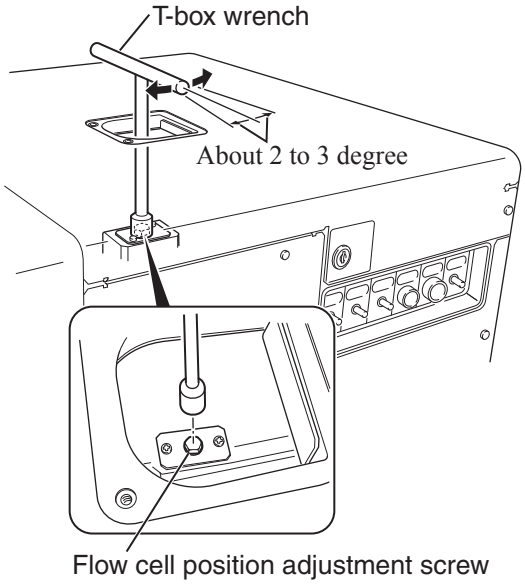
2. Loosen the two screws which are fixing the flow cell position adjustment screw by turning the screws counterclockwise with a Phillips-head screwdriver.

NOTE

Do not remove the screws. Only loosen them.

3. Insert the T-box wrench into the flow cell position adjustment screw.

4. Measure the standard particles.



5. When the particle count starts, turn the T-box wrench about 2 to 3 degrees to the right or left.

6. Press the Clear key and check the particle distribution on the scattergram and histogram.

When the Clear key is pressed, the Count is reset and starts from zero. The scattergram is also cleared so you can check the adjustment condition each time.

If the Clear key is not pressed, the scattergram remains displayed and you cannot check the condition.

7. Compare the particle distribution on the scattergram before and after turning the wrench. When the after distribution is smaller (the width of the FS and FL histogram becomes thinner), turn the wrench about 2 to 3 degrees in the same direction. When the after distribution is larger, turn the wrench in the opposite direction.

8. Press the Clear key and check the distribution as described in step 6.

9. Repeat steps 7 and 8 until the particle distribution on the scattergram becomes smallest (the particle distribution of the histogram becomes thinnest).

10. When the particle distribution on the scattergram becomes smallest, pull out the T-box wrench gently.

11. Fix the two screws which secure the flow cell position adjustment screw clockwise with Pillips-head screwdriver.

12. Measure standard particle and check the CV of FS and FL and Peak value. If the CV of FS and FL is 7.0% or more, contact your Nihon Kohden representative.

13. After checking the CV of FS and FL is less than 7.0%, hook the flow cell cover to the analyzer and attach the cover with the two screws.

14. When the particle is measured, a “Clean flow cell” message is displayed after pressing the OK key on the Adj. flow cell window. Press the OK key and clean the flow cell.

Checking the Optical Sensitivity

NOTE

Check the internal or external printer setting to print the scattergram of the measurement result beforehand.

1. Display the internal or external printer setting window.
   Press the System key → Settings key → Output setting key → Internal printer or Output setting key.

2. Check that the Print scattergrams is set to On.

3. Set the Output after meas. to On.

Checking the Optical Sensitivity (fine)

NOTE

- Before this check, perform the rough adjustment with particle.
- Use MEK-CAL to perform optical fine adjustment in MEK-CAL mode. If human blood is used, optical adjustment cannot be performed correctly.
- Use MEK-CAL before expiration date and under optimum condition.
  Expiration date
  Unopened: expiration date on the label or package
  Opened: 7 days after opening
  Storage temperature: 2 to 8°C (35.6 to 46.4°F)

1. Measure the MEK-CAL in blood and CBC + DIFF sample type.

2. Press the System key and Adj. Flowcell key. The Adjust flow cell window is displayed.

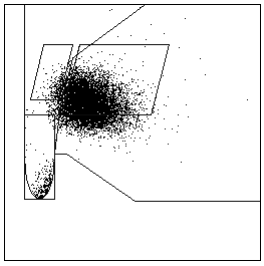
3. Press the Fine tab and register the measured sample.

4. Display the measurement data and check if the data is appropriate by checking the scattergram and peak of the MEK-CAL.

Check point of the scattergram

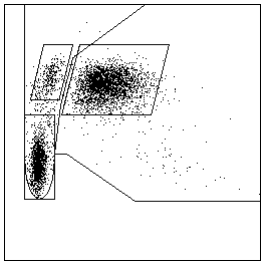
i) The distribution is elliptical
ii) One distribution on the scatter
iii) No ghosts at the bottom of the scattergram

Normal scattergram

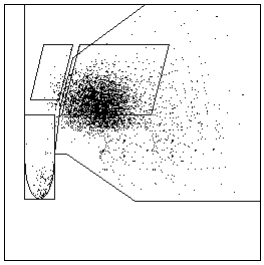


Abnormal scattergram

When human blood is loaded in MEK-CAL mode.



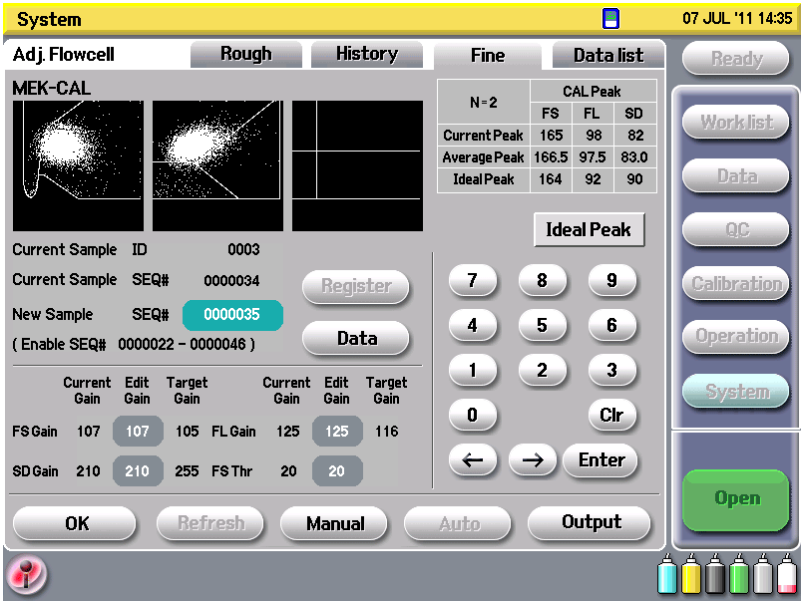
When old MEK-CAL is used.



- There are ghosts on the lower part.
- There are two or more distributions.

Checking the PEAK of the MEK-CAL

Check that the AVE value of the PEAK is within ±5 of the assay value.



5. If the AVE value of the PEAK is not within ±5 of the assay value, perform optical adjustment by referring to “Optical Adjustment with MEK-CAL (fine)” in Section 5.

   If the MEK-CAL is abnormal or the gain is changed largely, the value might not become appropriate by one adjustment.

If the above adjustment does not work, mechanical adjustment of the optical unit is needed. Contact your Nihon Kohden representative.

Checking the $\overline{X}$-R

Check the average ($\overline{X}$) and difference (R) of the two measurement on the $\overline{X}$-R management. When the analyzer is stable, measure MEK-5DN/L/H hematology control two times and check that the average ($\overline{X}$) is within the range of the assay sheet and difference (R) is within the range of the following list. Refer to Section 11 “Quality Control”.

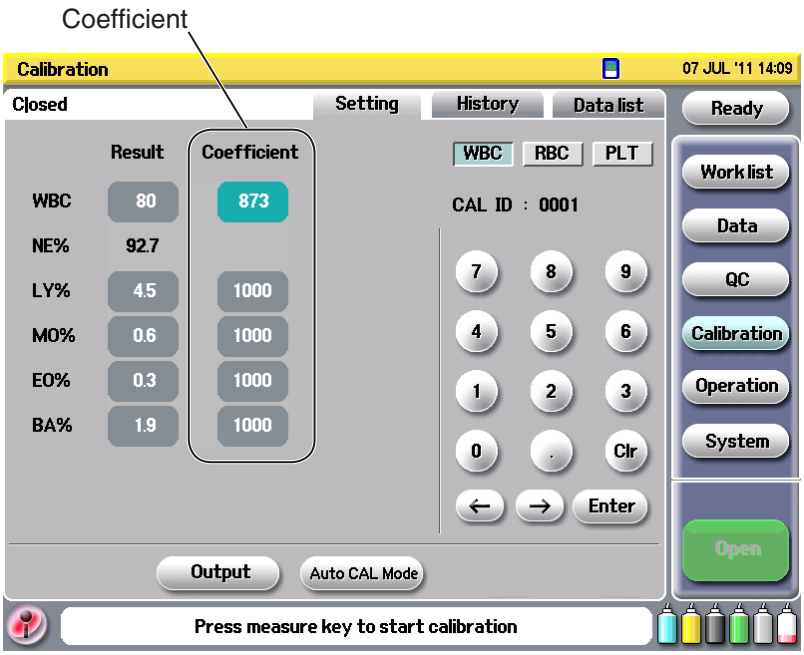
Item	Expected value	Item	Expected value
WBC	≤ 7	BA	—
NE%	≤ 11.4	RBC	≤ 29
LY%	≤ 5.2	HGB	≤ 1.0
MO%	≤ 3.3	HCT	—
EO%	≤ 3.9	MCV	≤ 3.6
BA%	≤ 1.0	MCH	—
NE	—	MCHC	—
LY	—	RDW-CV	—
MO	—	PLT	≤ 3.9
EO	—	MPV	—

The above expected value is statistically calculated as control limit from CV standard of hematology analyzer.

Checking the Current Coefficient

Check the current coefficient. Check the coefficient of following items in closed, open, pre-dilution mode. Confirm that the coefficient of LY%, MO%, EO% and BA% is “1000”. The current coefficient is displayed on the closed, open, pre-dilution calibration window. Refer to Section 6 “Calibration Procedures”.

WBC, LY%, MO%, EO%, BA%, RBC, MCV, HGB, HCT, RDW-CV, PLT, MPV

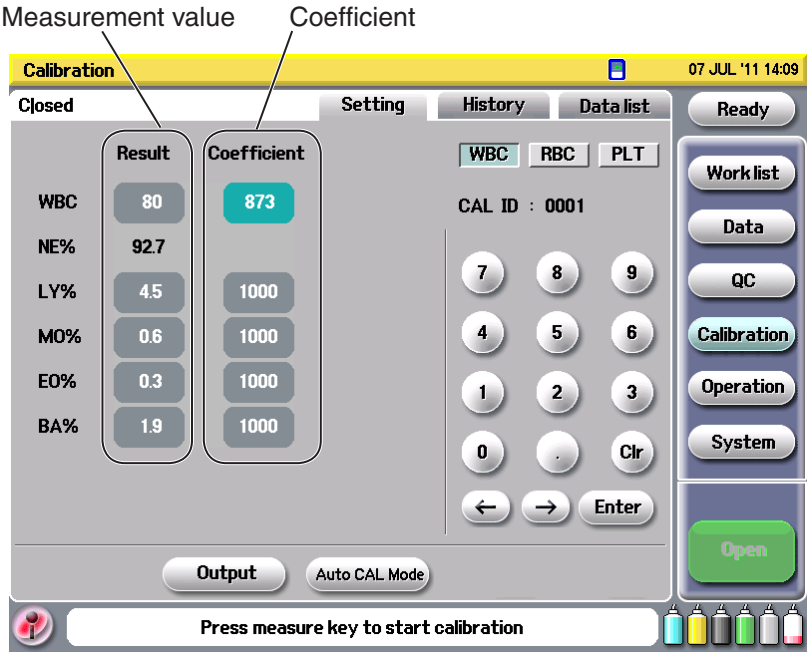


Checking the Coefficient after Calibration

After the calibration, check the newly changed measurement value and coefficient. Check the measurement value and coefficient of the following items in venus blood mode. Refer to Section 6 “Calibration Procedures”.

WBC, RBC, MCV, HGB, HCT, RDW-CV, PLT, MPV

Venus blood calibration window



LY%, MO%, EO% and BA% is calibrated by optical adjustment (fine). So normally check that the coefficient of LY%, MO%, EO% and BA% is “1000”.

Checking the External Instruments

Printers

Check the printer function. Check that data is printed properly and that the print is not faint and no dots missing.

ZK-820V Hand-held Bar Code Reader

Read a sample ID bar code label with the hand-held bar code reader and check that the correct ID appears on the Ready screen.

PC

Send a sample data to PC and check that the data is properly received by the PC.

Decontamination Protocol

Decontaminate the analyzer by rinsing the fluid path with a 0.5% sodium hypochlorite solution. The surfaces of the analyzer should be wiped with a non-abrasive detergent solution to remove any soiling, then wiped with a 0.5% sodium hypochlorite solution.

To calculate the percent (%) sodium hypochlorite concentration desired see the following formula:

A = Percent (%) of sodium hypochlorite solution desired

B = Percent (%) of sodium hypochlorite stock solution (as purchased)

X = Parts of water to be mixed with one part of the sodium hypochlorite stock solution

$$X = \frac{B - A}{A}$$

Example:
If you need a 0.5% sodium hypochlorite solution for a cleaning procedure, and the label on the bottle of bleach states that it is 5.25% sodium hypochlorite, then:

$$X = \frac{5.25 - 0.5}{0.5}$$

$$X = 9.5$$

Add 9.5 parts deionized water to 1 part bleach to obtain a 0.5% sodium hypochlorite solution, or 9.5 mL of deionized water to 1.0 mL of bleach (5.25% sodium hypochlorite) to obtain 10.5 mL of a 0.5% solution of sodium hypochlorite.

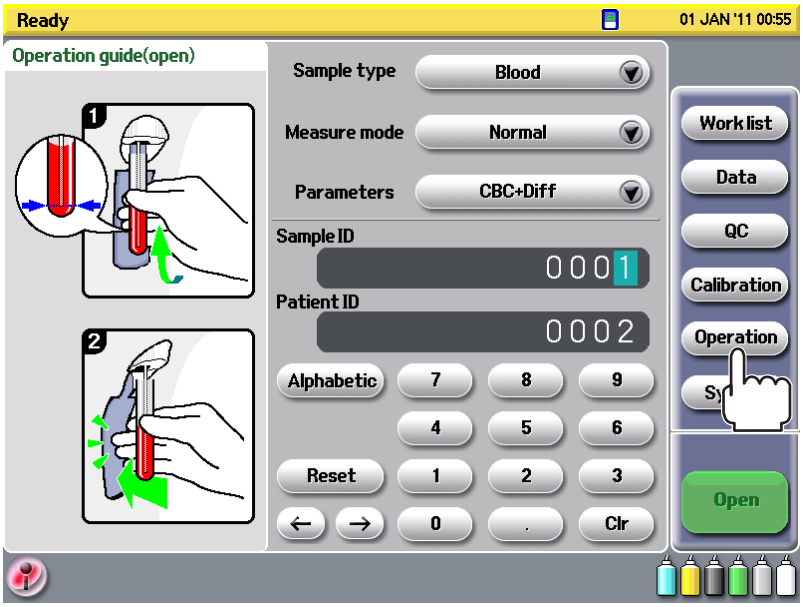
Before servicing by Nihon Kohden Corporation or its representatives, the following Decontamination Protocol must be performed by the relevant qualified laboratory personnel. Failure to perform this protocol may result in the analyzer not being serviced.

CAUTION

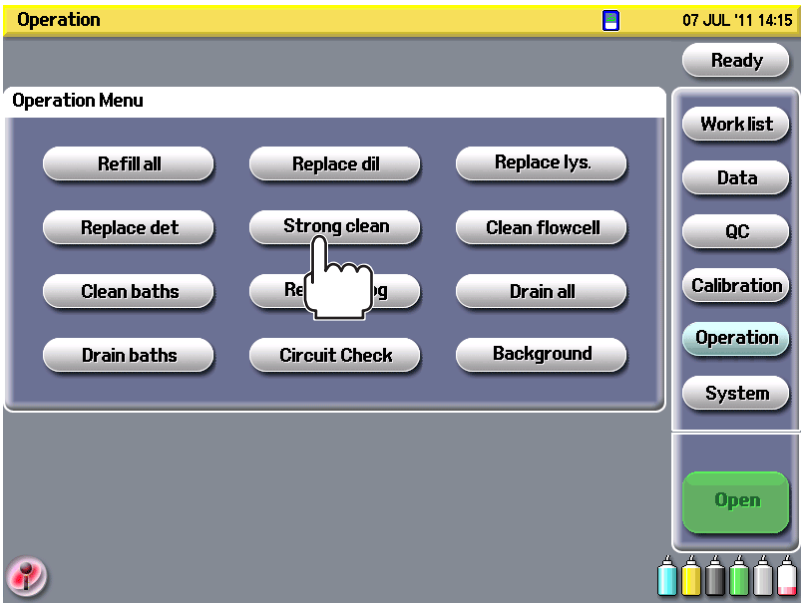
During this procedure, normal precautions regarding the handling of biologically hazardous material must be observed.

Procedure

1. Press the Operation key on the screen to display the Operation screen.



2. Press the Strong clean key on the Operation screen to disinfect inside the analyzer. The confirmation message appears.



3. Press the Yes key to perform strong cleaning. The analyzer starts cleaning and the “Strong cleaning” message appears on the screen.

   When cleaning is complete, the screen returns to the Ready screen.

4. Wipe down all analyzer surfaces with 0.5% sodium hypochlorite solution.

5. Wipe the analyzer surface with a soft cloth moistened with tap water. Wring out the cloth thoroughly.

   When transporting or shipping the analyzer, follow the procedure in “Storing and Transporting the Analyzer” later in this section.

Certification of Decontamination

This instrument

Type: MEK-_____

Serial Number: _____

Has been decontaminated according to the Nihon Kohden recommended protocol.

Date: ___ : ___ : ____

Laboratory Supervisor

Name: _____

Signature: _____

Certification of Decontamination

This instrument

Type: MEK-_____

Serial Number: _____

Has been decontaminated according to the Nihon Kohden recommended protocol.

Date: ___ : ___ : ____

Laboratory Supervisor

Name: _____

Signature: _____

Storing and Transporting the Analyzer

NOTE

When transporting the analyzer, remove the laser key. Otherwise, the analyzer may get damaged or it may cause injury.

Preparing the Analyzer for Long Term Storage or Transport

The fluid pathway can become clogged with salt deposits and reagent residue if the analyzer is not rinsed and drained before a period of inactivity.

Before transporting or storing the analyzer for a long period of time, clean it by the following procedure.

1. Press the Clean key on the front panel to clean the fluid path.

2. Remove the diluent tube from the ISO3 inlet, the hemolysing reagent tubes from the HEMO3N and HEMO5 inlets, and the detergent tubes from the CLN3 and CLN inlets on the right side panel.

   Do not disconnect the waste tube from the WASTE outlet.

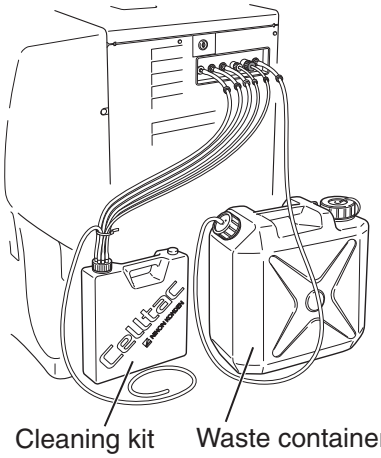
CAUTION

Make sure the tubes are correctly connected.

NOTE

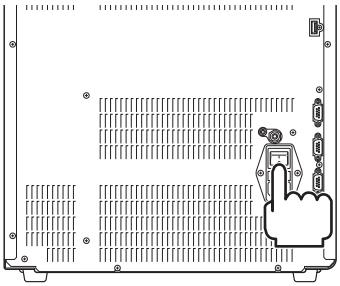
- To handle the diluent container, detergent container and waste container, follow the instructions on each package.
- To handle the Hemolynac•3N and Hemolynac•5 hemolysing reagents, follow the instructions in the operator's manual for each hemolysing reagent.

3. Press the Drain all key on the Operation screen, and press Yes key. The hematology analyzer starts draining all fluid.



4. Connect the spare tubes to the ISO3, HEMO3, HEMO5, CLN and CLN3 inlets and put the other ends of the tubes into the distilled water. (The optional YZ-252 Cleaning bottle kit is available for easy setup.)

5. Press the Clean key on the front panel to prime the hematology analyzer with the distilled water.



6. Repeat steps 2 and 3 to drain all fluid from the hematology analyzer again.

7. Press the main power switch on the rear panel to turn the main power off.

Using the Analyzer after Storage

NOTE

After long term storage (more than 2 weeks), the pump tube may be collapsed or the fluid path may be dirty. Perform the following procedures before using the analyzer.

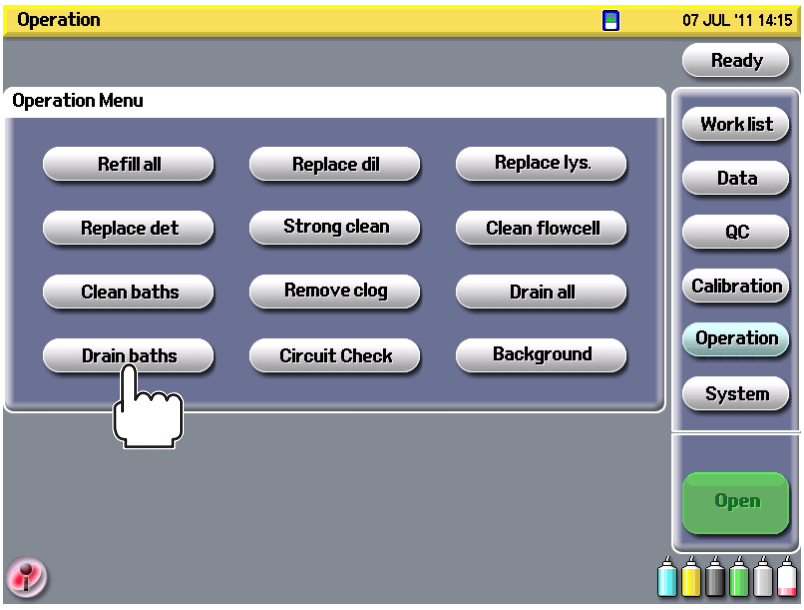
1. Clean the aperture caps by following the procedure in the “Cleaning Aperture Caps” earlier in this section.

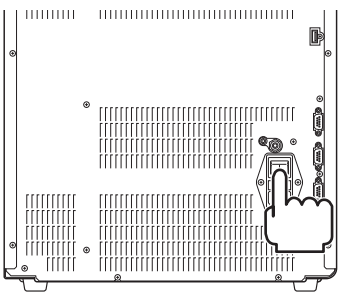
2. Set up the analyzer and turn the power on. Refer to Section 2 “Installation Procedures and Special Requirements”. After automatic draining and priming, the Ready screen appears.

3. Perform strong cleaning by pressing the Strong clean key on the Operation screen.

Preparing the Analyzer for Short Term Transport

1. Press the Drain baths key on the Operation screen to drain the measurement baths and sub baths. Refer to “Draining Measurement Baths and Sub Baths” in Section 5.





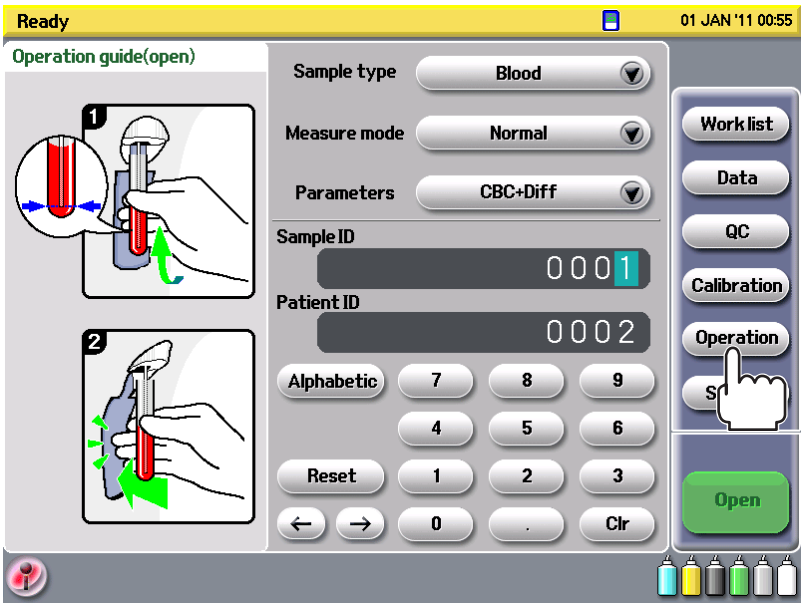
2. Press the [Main power] switch on the rear panel to turn off the analyzer.

Operation Window

Instrument operations for maintenance can be accessed on the Operation window.

Displaying the Operation Window

1. Press the Operation key. The operation window is displayed.



2. Press the desired operation key. The screen for the operation is displayed.

Returns to the Ready screen.

Press the desired operation.

3. Perform the operation by referring to the explanation later in this section.

4. Touch the Ready key to return to the Ready screen.

Operation list

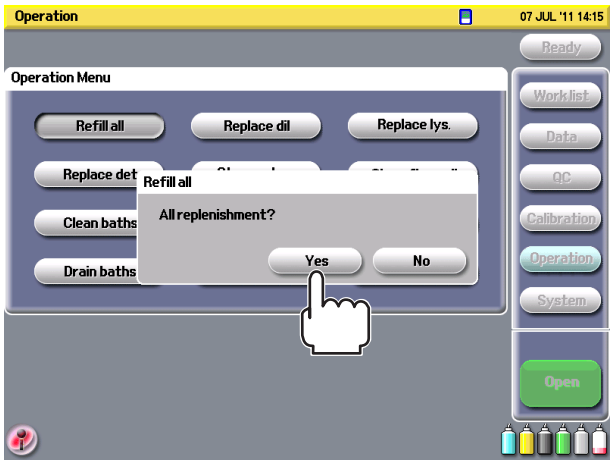
Operation	Function
Refill all	Refill all the reagents.
Refill diluent*	Refill diluent.
Refill hemolynac*	Refill lysing reagent.
Refill det.*	Refill detergent.
Strong clean	Use when the normal cleaning does not work, installing the analyzer or disposing the analyzer.
Clean flow cell	Remove dust or bubbles from the flow cell.
Clean bath	Remove dust or bubbles from the measurement bath.
Remove clog	Use when the clog alarm frequently occurs.
Drain all	Drain the reagents from the fluid path inside the instrument for maintenance or long term storage.
Drain bath	Drain the reagents from the bath inside the instrument for maintenance.
Circuit check	Check the electric circuit inside the instrument.
Background	Check the background noise.

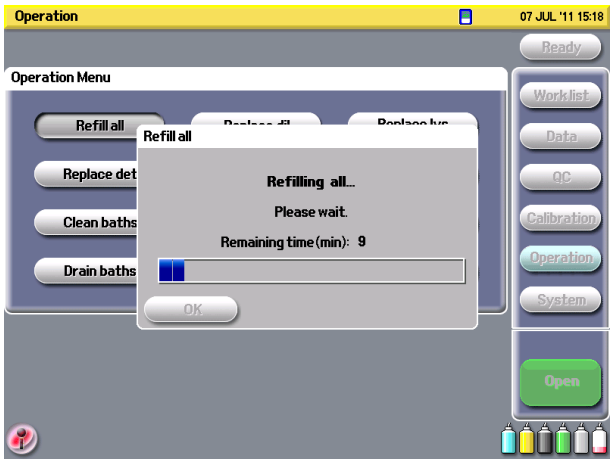
* When the reagent is replaced, do these operations.

Refilling All the Reagents

1. Press the Refill all key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to refill the reagents. A “Refilling all” message and the remaining time are displayed during refilling.



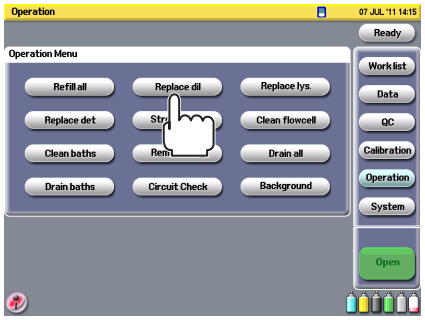


When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

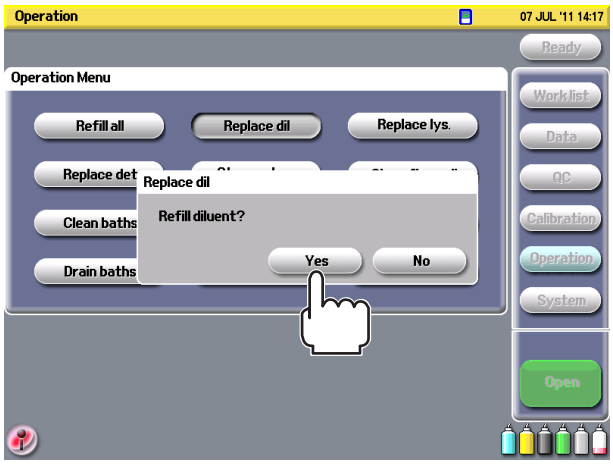
Refilling the Diluent

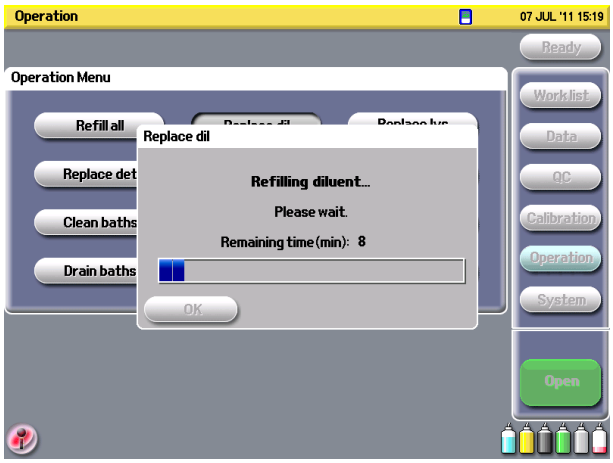
When the diluent is replaced, do this operation.



1. Press the Refill dil key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to refill the diluent. A “Refilling diluent” message and the remaining time are displayed during refilling.





When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

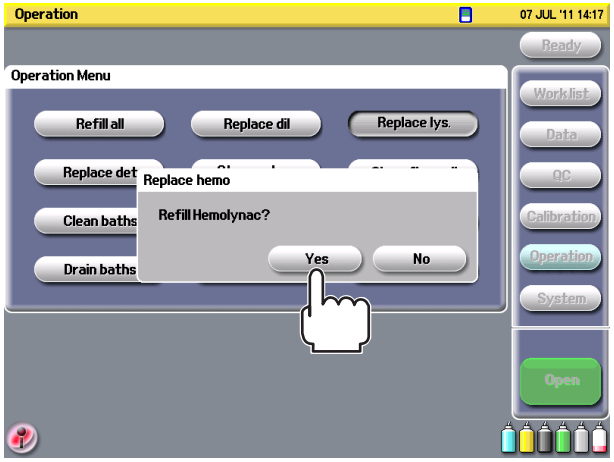
When the operation is performed from the alarm window, the Ready screen is displayed.

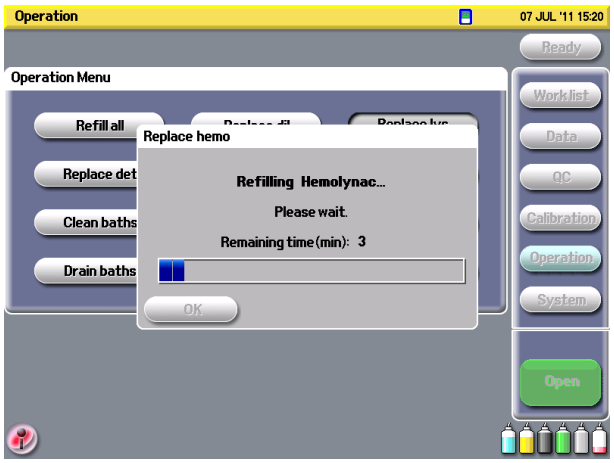
Refilling the Lysing Reagent

When the lysing reagent is replaced, do this operation.

1. Press the Refill lys key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to refill the lysing reagent. A “Refilling Hemolynac” message and the remaining time are displayed during refilling.



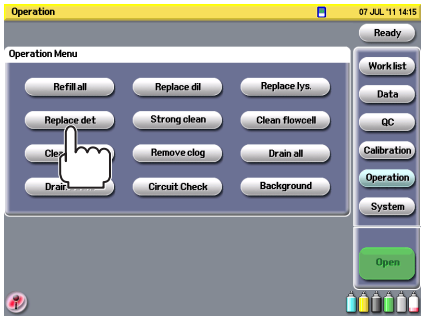


When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

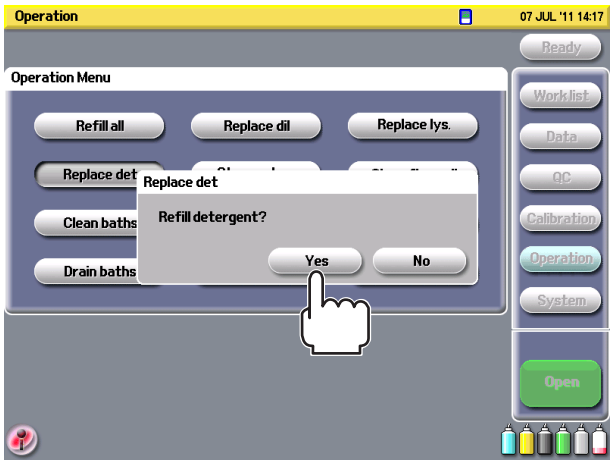
When the operation is performed from the alarm window, the Ready screen is displayed.

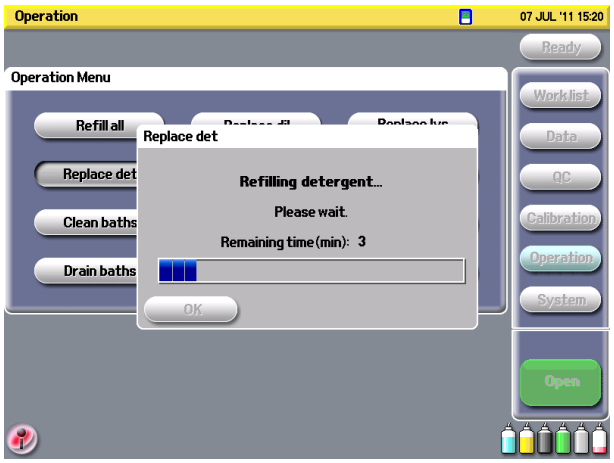
Refilling the Detergent



1. Press the Refill det key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to refill the CLEANAC and CLEANAC•3 detergent. A "Refilling detergent" message and the remaining time are displayed during refilling.





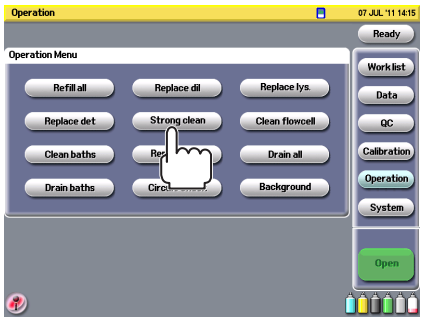
When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

When the operation is performed from the alarm window, the Ready screen is displayed.

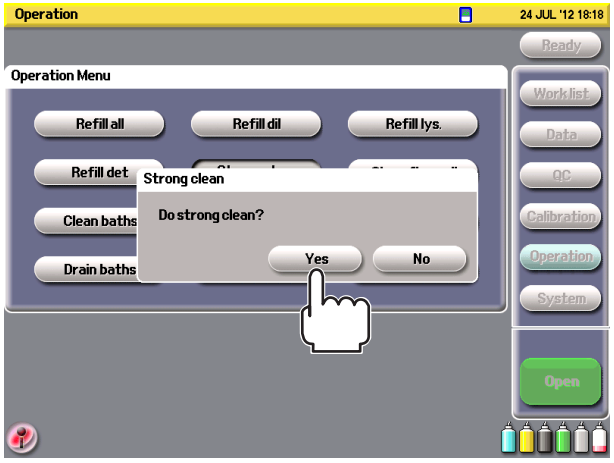
Performing Strong Cleaning

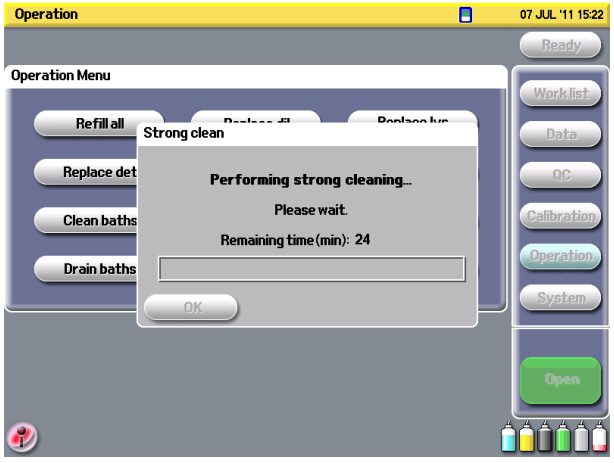
When background counts are out of specification or the clogging message frequently appears, perform strong cleaning to clean the analyzer more thoroughly than normal cleaning with the [Clean] key.



1. Press the Strong clean key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to perform strong cleaning. A "Performing strong cleaning" message is displayed during cleaning.





When the No key is pressed, the window returns to the Operation window.

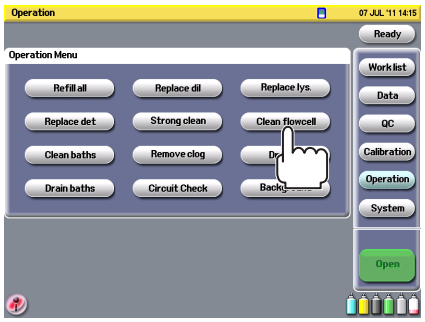
3. Press the OK key to return to the Operation window.

NOTE

Measure background noise at least twice after strong cleaning.

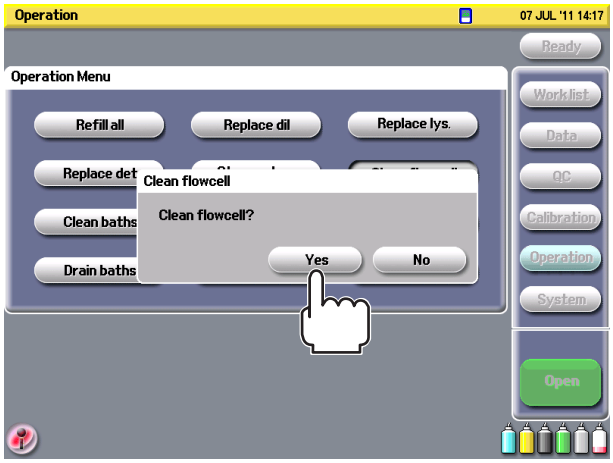
Cleaning the Flow Cell

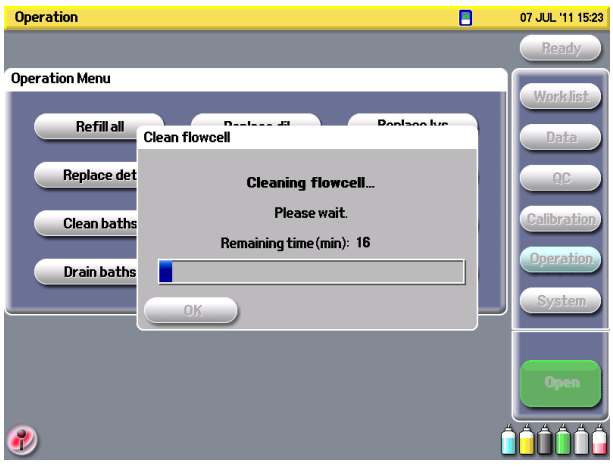
Remove dust or bubbles from the flow cell. Clean the flow cell when the optical unit does not function properly.



1. Press the Clean flow cell key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to start the cleaning of the flow cell. A “Cleaning flow cell” message and the remaining time are displayed during cleaning.



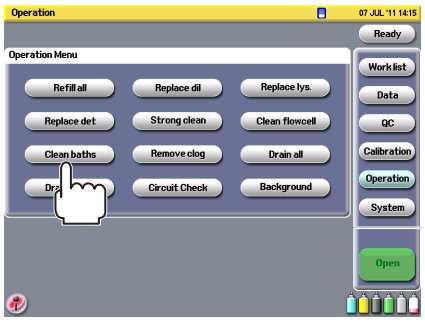


When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

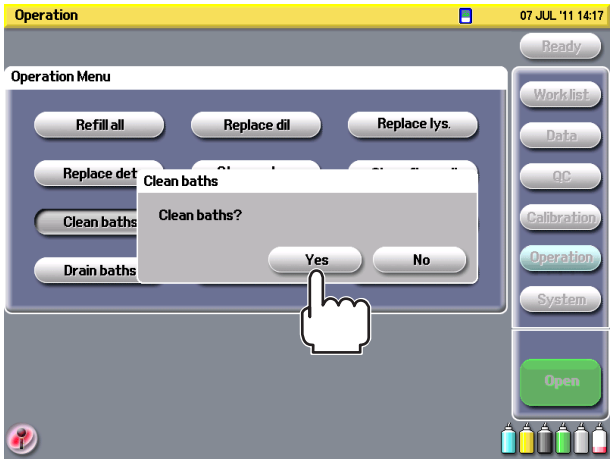
Cleaning the Baths

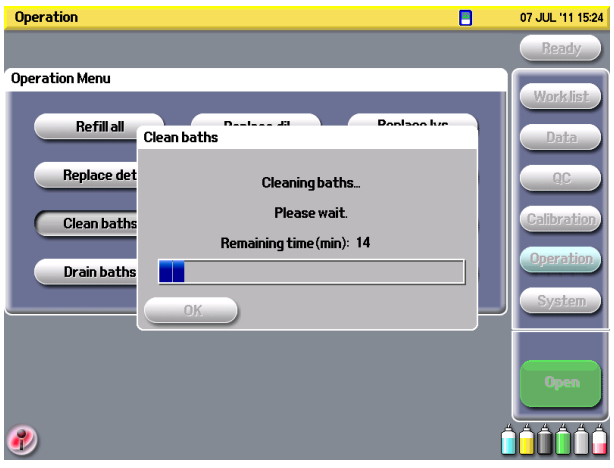
Remove dust from the measurement and sub baths. Clean the baths when the CBC unit does not function properly.



1. Press the Clean baths key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to clean the baths. A “Cleaning baths” message and the remaining time are displayed during cleaning.



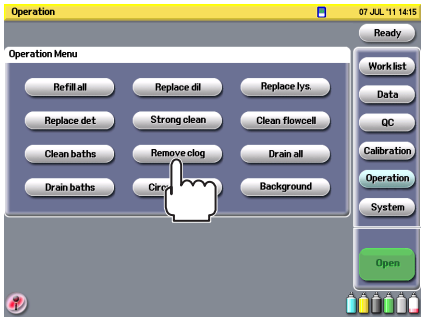


When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

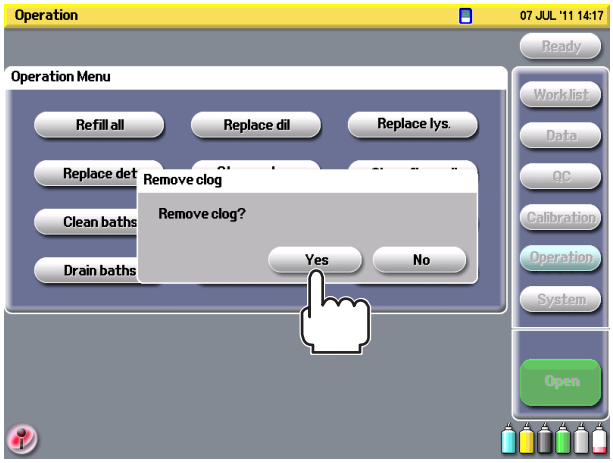
Removing a Clog

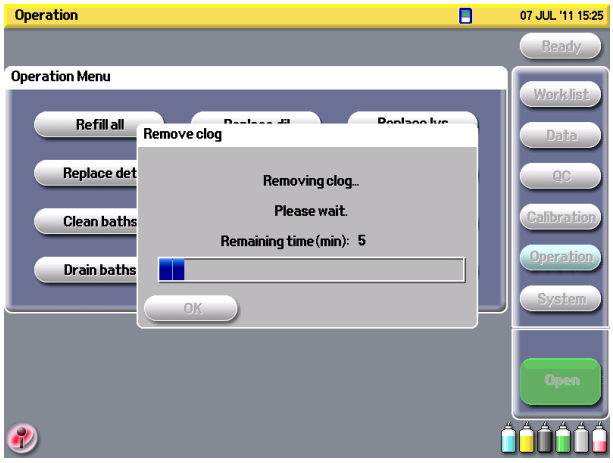
Remove clogs when the clogging alarm frequently appears.



1. Press the Remove clog key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to remove clogs. A “Removing clog” message and the remaining time is displayed during removing.



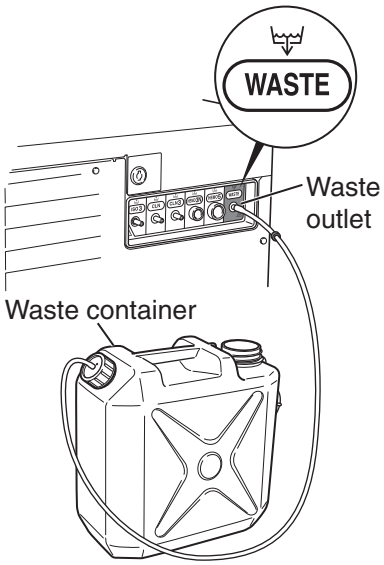


When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

Draining the Analyzer

Drain the reagents from the fluid path of the analyzer before maintenance or long term storage.



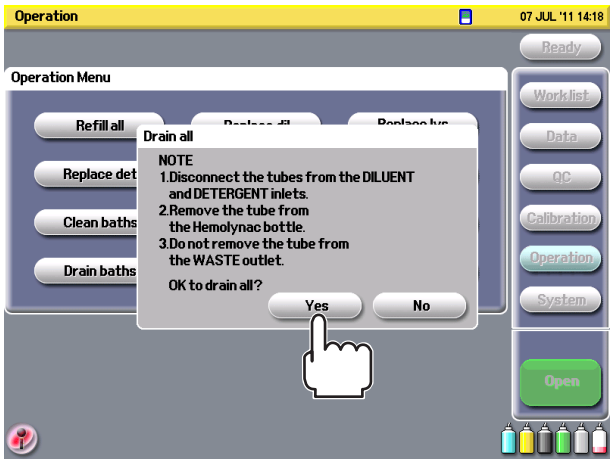
1. Remove the diluent tube from the ISO3 diluent inlet, the hemolysing reagent tube from the HEMO3N and HEMO5 inlets, the detergent tube from the CLN inlet and the cleanac tube 8 from the CLN3 inlet on the right side panel.

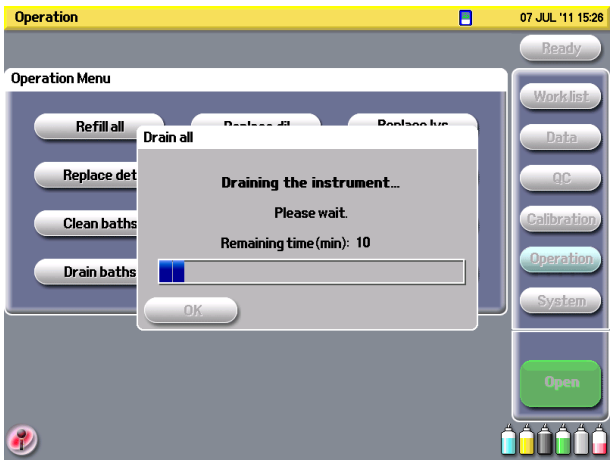
NOTE

Do not remove the waste tube from the waste outlet.

2. Press the Drain all key on the Operation window. A confirmation message is displayed.

3. Press the Yes key to drain the reagents. A “Draining the instrument” message and the remaining time is displayed during draining.





When the No key is pressed, the window returns to the Operation window.

4. Press the OK key to return to the Operation window.

NOTE

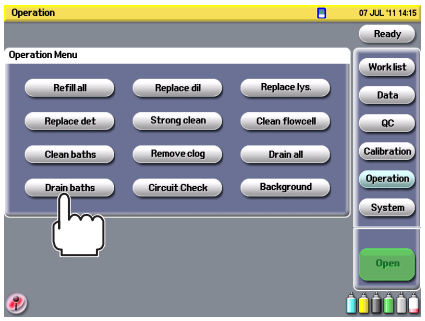
The analyzer must be restarted because the sampler does not move to the measurement standby position after draining.

Draining Baths

Drain the reagent from the measurement baths before maintenance. The analyzer has cupped measurement baths inside and the baths are normally filled to the top with diluent. If you lift or tilt the analyzer, the diluent spills and causes trouble. Drain the baths before moving the analyzer.

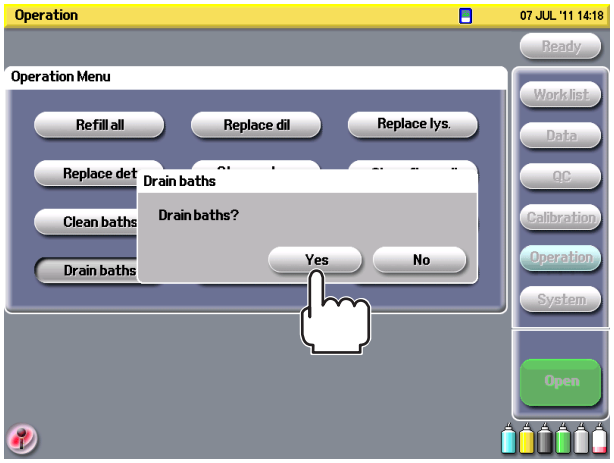
NOTE

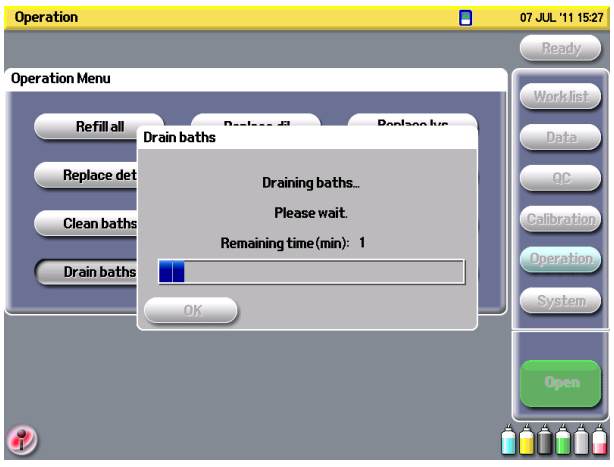
Do not remove the waste tube from the waste outlet.



1. Press the Drain baths key on the Operation window. A confirmation message is displayed.

2. Press the Yes key to drain fluid from the baths.



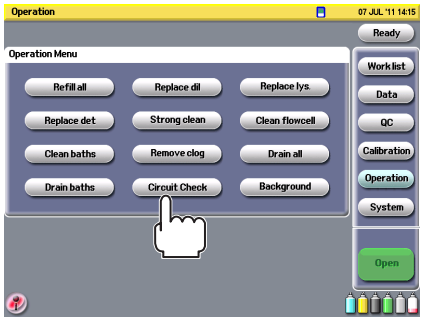


When the No key is pressed, the window returns to the Operation window.

3. Press the OK key to return to the Operation window.

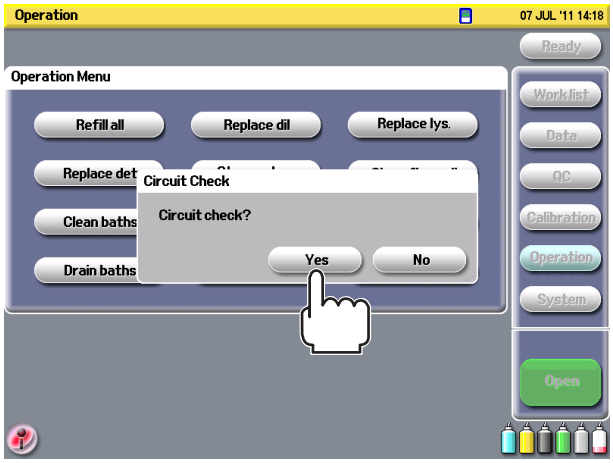
Checking the Circuit

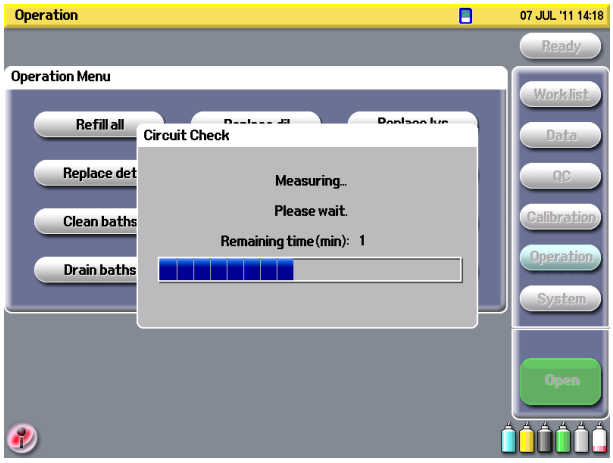
When alarms occur frequently, check the circuit to find the faulty part and do other checks. The circuit check does not check the fluid path and fluid sensor.



1. Press the Circuit check key on the Operation window. A confirmation message appears.

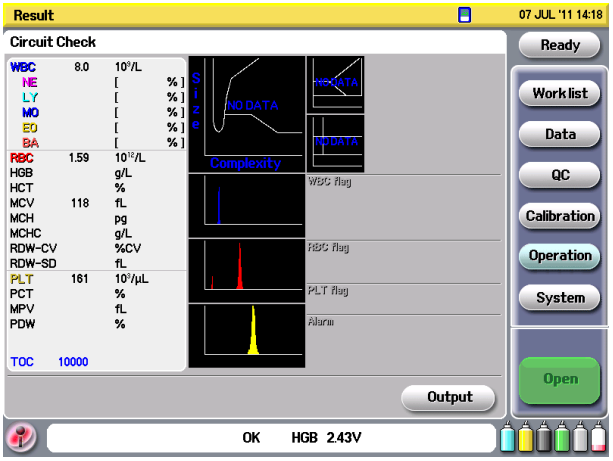
2. Press the Yes key to start checking.





When the No key is pressed, the window returns to the Operation window.

3. After the checking is finished, the Result screen is displayed and the check result is displayed in the message column. When the result is normal, “OK” and HGB voltage are displayed. When the result is abnormal, “NG” and HGB voltage are displayed.



Normal range

WBC: 80 ±5%

RBC: 160 ±5%

HGB: 1.5 V to 4.5 V

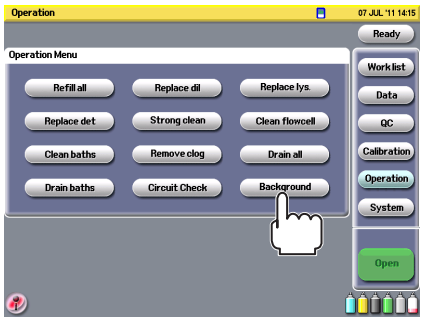
MCV: 118 ±15%

PLT: 16.0 ±5%

If the HGB is out of normal range, clean the WBC measurement bath and check the circuit again.

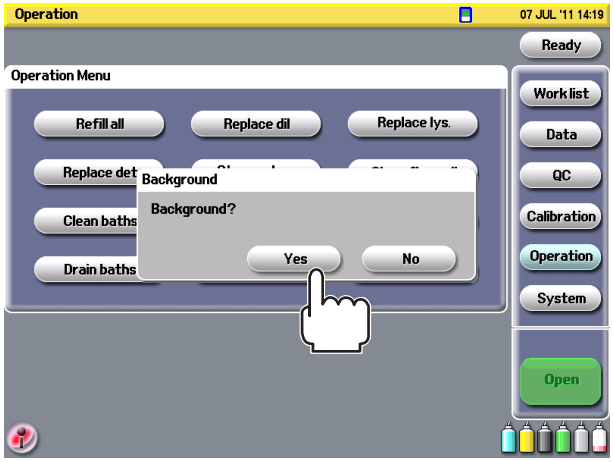
If the result is continuously out of normal range, contact your Nihon Kohden representative.

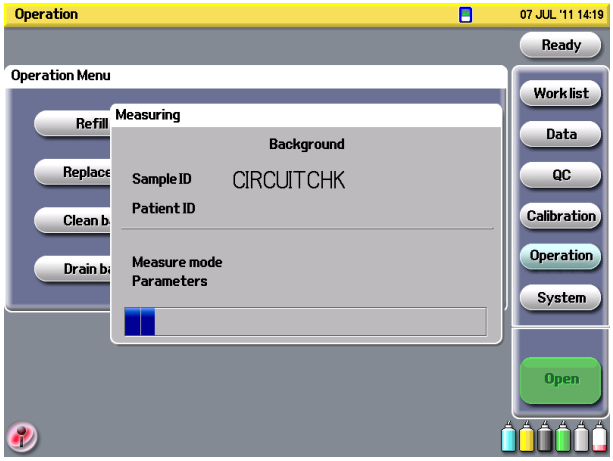
Checking Background Noise



1. Press the Background key on the Operation window. A confirmation message is displayed.

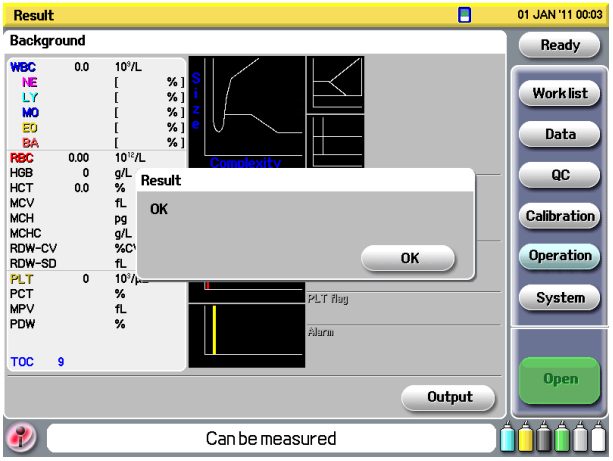
2. Press the Yes key to check background noise.





When the No key is pressed, the window returns to the Operation window.

3. When the background noise check is finished, the Result screen is displayed and the result is displayed in the message column.



Check that the diluent measurement result is in the following range:

- WBC ≤ 0.2 ($\times 10^3/\mu L$)
- RBC ≤ 0.05 ($\times 10^6/\mu L$)
- HGB ≤ 0.1 g/dL
- PLT ≤ 10 ($\times 10^3/\mu L$)
- TOC* ≤ 100 (counts)

* TOC indicates Total Optical Count

4. When the result is out of range, a “Background noise check failed” message is displayed in the message column. Check the following points and measure the background noise again.
   - Diluent is not dirty.
   - Bubbles are not in the diluent.
   - Aperture cap is not dirty.
   - Aperture cap is attached firmly.

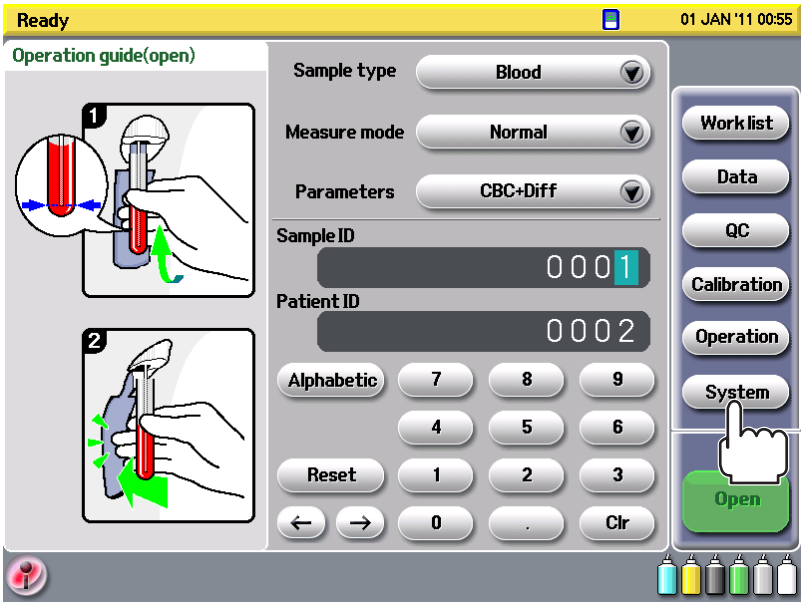
If the check fails again, refer to Section 10 “Messages and Troubleshooting”.

Initializing Settings

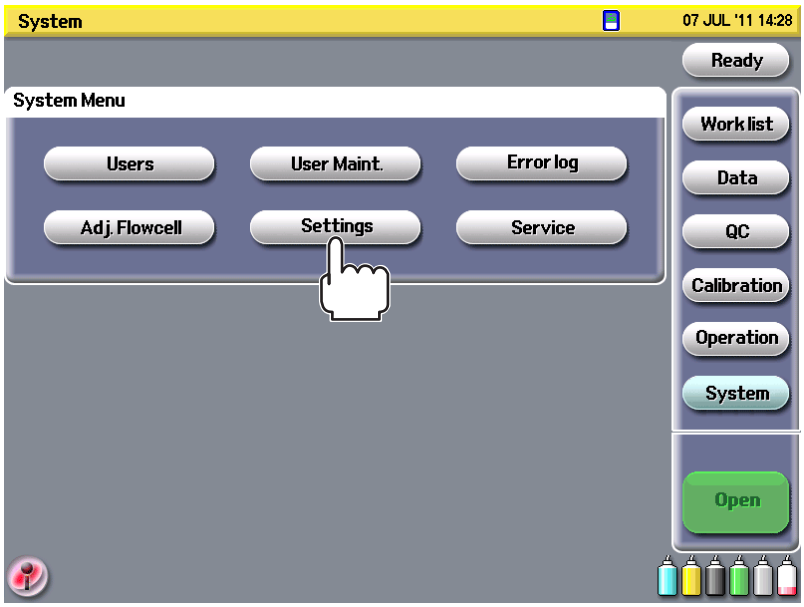
You can initialize the settings to the factory default settings. The factory default settings are shown in Appendix D.

To initialize the settings, the type of user must be either lab technician or service.

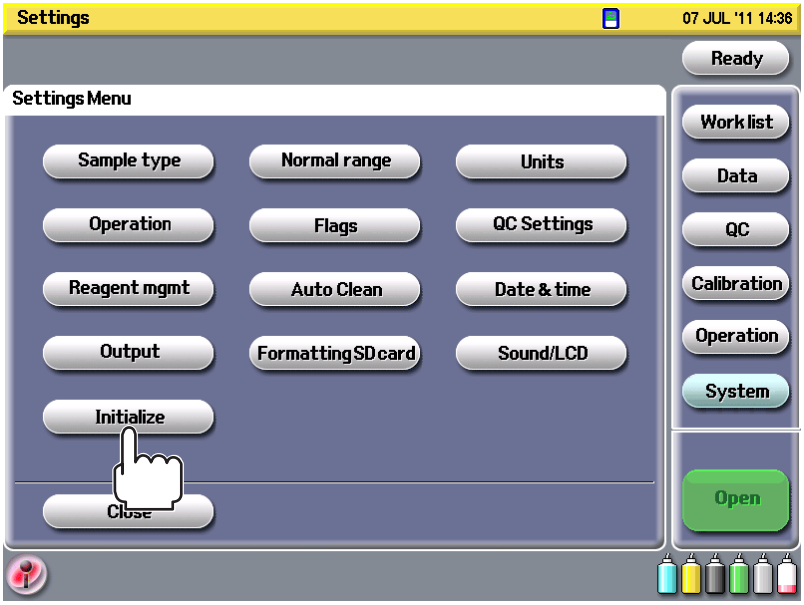
1. Press the System key on the screen.



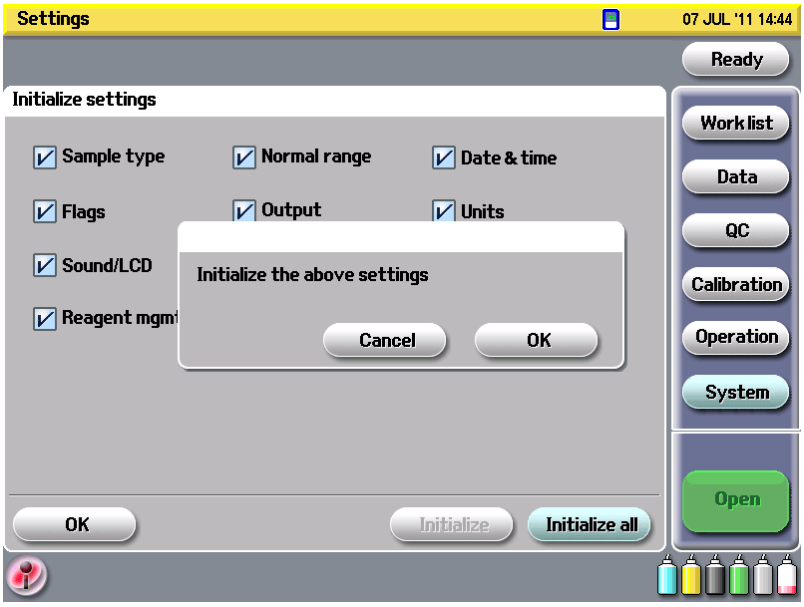
2. Press the Settings key on the System screen.



3. Press the Initialize key to display the Initialize screen. All settings which will be initialized are listed on the screen and a confirmation message appears.



4. Press Yes to start initializing. If you press No, initializing is canceled and the screen returns to the Settings screen.



Section 10 Messages and Troubleshooting

Troubleshooting

This troubleshooting guide provides information to assist in problem identification, isolation, and corrective action. Instructions for obtaining technical assistance are included.

NOTE

Generally, conditions that are analyzer or reagent related will occur on all samples, including controls. Therefore, it is important to confirm analyzer performance by re-running controls.

WARNING

Potential Biohazard. Follow established biosafety practices when performing maintenance, service or troubleshooting procedures. Refer to Section 8 “Hazards” for additional information.

Introduction

Understanding normal analyzer operation is essential for identifying and resolving operational problems. Effective troubleshooting requires a logical, step-by-step approach to problem solving. Logical troubleshooting can be divided into three steps as follows:

1. Problem Identification—requires the operator to investigate not only what is wrong but also to note what is right. The investigation should identify the problem area and eliminate areas that are working correctly. Once this step is done, move to the next step.

2. Problem Isolation—further classifies an analyzer problem. These problems are generally divided into three categories:
   - Measurement related to sample analysis
   - Software related
   - Hardware component related

   Typically, hardware and software problems are operator-correctable with technical assistance. Measurement problems are generally operator-correctable and are further subdivided into problems related to sample handling, maintenance, or calibration.

3. Corrective Action—involves taking appropriate steps to correct the problem. If the operator can correct the problem, with or without technical assistance, normal operation can quickly resume.

Troubleshooting Tips and Techniques

Effective troubleshooting is possible only when the problem is clearly recognized and the probable cause is isolated. This is always facilitated by obtaining sufficient information and data pertaining to the specific problem. Carefully observe the situation. Document the steps that have been taken and record all results.

This troubleshooting guide is designed to guide the operator through a logical series of steps to obtain information regarding the nature of the problem. If it is necessary to call for technical assistance, this information must be communicated to your Nihon Kohden representative.

Obtaining Technical Assistance

If additional information or help is required, technical assistance can be obtained by contacting your Nihon Kohden representative. It is important to provide the representative with a clear and detailed description of the problem.

When assistance is needed, please be prepared to provide the following information:

- Instrument model name
- Serial number of the analyzer
- Software version in use (displayed on OPER HISTORY screen)
- Description of the problem
- The lot numbers and expiration dates of reagents, calibrators, and controls currently in use
- Instrument maintenance history
- Sufficient examples of data to facilitate the discussion including:
- Data from quality control reports as well as data from your last analyzer calibration

Message and Troubleshooting

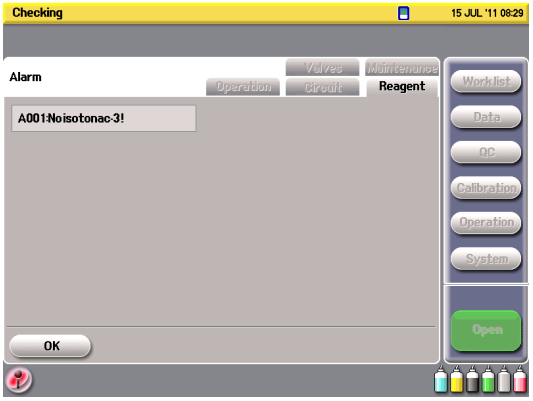
General

If the analyzer detects a problem, it displays an alarm message with an alarm sound. Use the tables in this section for more information, cause of alarm and countermeasures. When the Recovery key is pressed, the analyzer automatically remove the cause of the alarm.

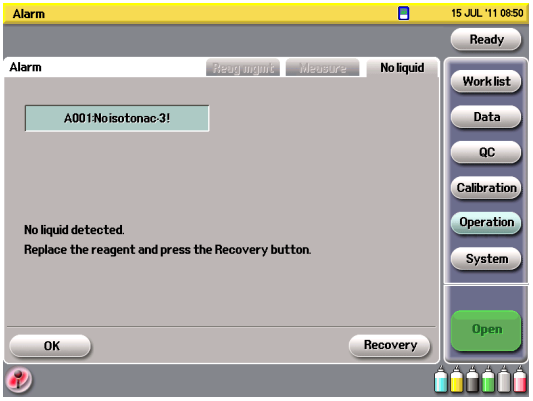
There are two types of alarms:

- After self-check at power on
- During measurement

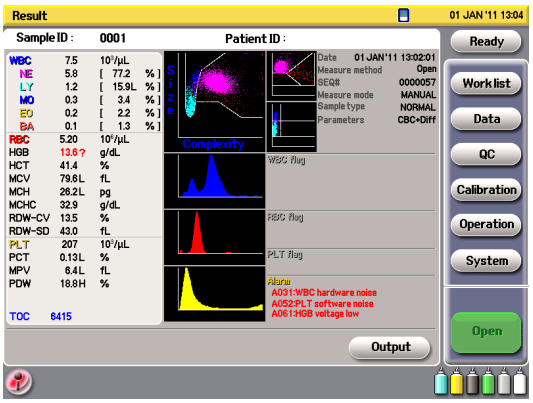
Example: alarm after power on



Example: alarm at cleaning and priming



Example: alarm after measurement

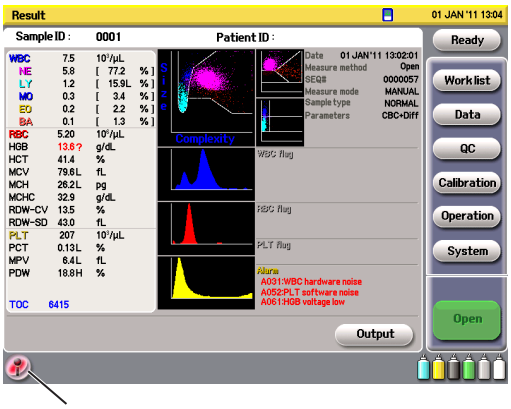


Alarm Window

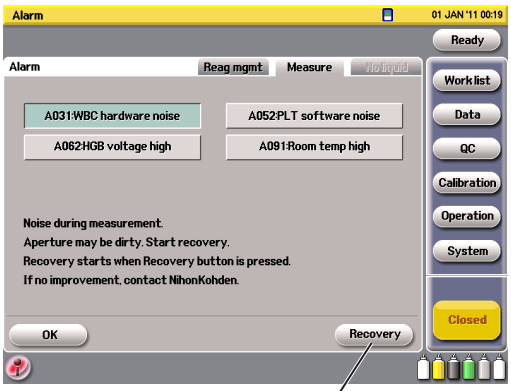
You can display the Alarm window by pressing the information button on the lower left of the window when an alarm occurs.

When you press the Recovery key, the analyzer automatically removes the cause of the alarm.

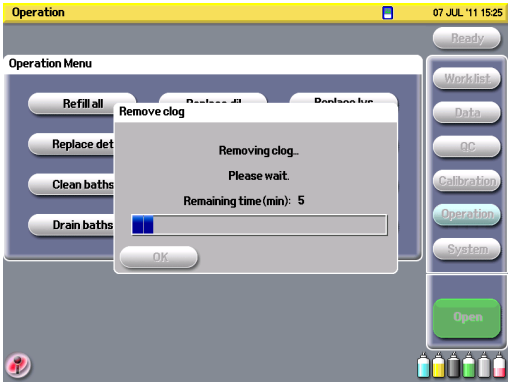
Example: measurement alarm



Press the information key to open the alarm window



Recovery key
Removes the cause of the alarm



Alarm Messages

CAUTION

When an alarm occurs, the acquired data might not be correct, especially when a " ! " or "sample error" message appears. Do not use the data for diagnosis. Recount the sample.

NOTE

When performing the strong cleaning as the countermeasure, after the strong cleaning is completed, press the [◇ Count] switch in open mode without aspirating the diluent from the sampling nozzle. Perform this procedure two or more times so that the diluent replaces the CLEANAC•3 detergent inside the analyzer.

Invalid Data Identifier

Identifier	Possible Cause/Criteria	Countermeasure
? is displayed to the right of the WBC or RBC measured value	Abnormal sample	Check that the temperature of the diluent is between 15 and 30°C (59 and 86°F). Then recount the sample. Only use the specified diluent. Otherwise, the analyzer may get damaged.
? is displayed to the right of the HGB measured value	The WBC measurement bath is dirty.	Clean the measurement bath.
? is displayed to the right of NE, NE%, LY, LY%, MO, MO%, EO, EO%, BA or BA% measured value	Optical count error	Do the following procedure 1 to 3. If ? is displayed again, contact your Nihon Kohden representative. 1. Clean the flow cell. Refer to "Cleaning the Flow Cell" in Section 9. 2. Perform optical adjustment (rough). Refer to "Performing Optical Adjustment" in Section 5. 3. Measure hematology control. Refer to "Measurement" in Section 5.
! is displayed to the right of WBC measured value	WBC counting error. Poor hemolyzation.	Check the analyzer by counting the hematology control. Then recount the sample.
! is displayed to the right of HGB measured value	HGB voltage adjustment error.	
! is displayed to the right of MCHC measured value	Abnormal RBC. Error occurred when diluting the sample.	
! is displayed to the right of PLT measured value	Background noise is increased.	Replace the diluent and press the [Clean] key to perform cleaning. Then measure the background noise again.
	Other noises are detected during counting.	
* is displayed to the right of HGB measured value	Error in the circuit.	Check the internal circuit by referring to "Checking the Circuit" in Section 9. If an error is detected, refer to the Service Manual.
* is displayed to the right of RBC or PLT measured value	PLT-RBC interference	Check the analyzer by counting the hematology control. Then recount the sample.
* is displayed to the right of PLT measured value	PLT low value (below 50,000/μL)	Prepare a stained blood film and examine it under a microscope.
C is displayed to the right of WBC and PLT measured values	WBC and PLT counting error. Platelet coagulated. (Poor hemolyzation and low PLT)	Check the analyzer by counting the hematology control. Then recount the sample.

Alarm Messages with Alarm Codes

Messages	Possible Cause/Criteria	Countermeasure
A: 001 NO DILUENT A: 005 NO CLEANAC A: 006 NO CLEANAC•3 A: 007 NO HEMOLYNAC•3N A: 008 NO HEMOLYNAC•5	Out of diluent, detergent or hemolysing reagent.	Replace the diluent, detergent or hemolysing reagent. Then press the Refill key on the Operation screen.
A: 009 WBC PRIME ERROR	Insufficient diluent in the manometer or the connection tube is out of position.	Add the diluent or check that the connection tube is connected properly. Then do the following procedure: • Press the Recovery key on the alarm window to recover the analyzer. • Press the Remove clog key on the Operation screen to remove clog.
A: 010 RBC PRIME ERROR		
A: 021 WBC LEVEL 1 A: 022 WBC LEVEL 2	Erroneous operation during counting.	Press the Clean key to perform cleaning. Then recount the sample. If the alarm still occurs, perform strong cleaning, clean the aperture cap and replace the pump tube.
A: 023 WBC LEVEL 3	The WBC aperture cap is clogged.	
A: 024 WBC BUBBLE 1 A: 025 WBC BUBBLE 2 A: 026 WBC BUBBLE 3 A: 027 WBC BUBBLE 4	Air bubbles in WBC manometer.	Press the Clean key to perform cleaning. Then recount the sample.
A: 029 WBC CLOG	The WBC aperture cap is clogged.	Press the Clean key to perform cleaning. Then recount the sample. If the alarm still occurs, perform strong cleaning, clean the aperture cap and replace the pump tube.
A: 030 WBC SAMPLE ERROR	Abnormal sample	Prepare the sample and measure again. Check that the temperature of the diluent is between 15 and 30°C (59 and 86°F).
A: 031 WBC HARD NOISE A: 032 WBC SOFT NOISE	Noise is detected during counting.	Check the grounding, and separate the instrument from other equipment and their power sources. Then recount the sample.
A: 034 UPPER MANO ERROR	The upper part of the manometer is dirty. Manometer sensor output is low.	Press the Clean key to perform the cleaning. Then press the Strong clean key on the Operation screen to perform strong cleaning.
A: 035 LOWER MANO ERROR	The lower part of the manometer is dirty. Manometer sensor output is low.	
A: 041 RBC LEVEL 1 A: 042 RBC LEVEL 2	Erroneous operation during counting.	Press the Clean key to perform cleaning. Then recount the sample. If the alarm still occurs, perform strong cleaning, clean the aperture cap and replace the pump tube.
A: 043 RBC LEVEL 3	The RBC aperture cap is clogged.	
A: 044 RBC BUBBLE 1 A: 045 RBC BUBBLE 2 A: 046 RBC BUBBLE 3 A: 047 RBC BUBBLE 4	Air bubbles in RBC manometer.	Press the Clean key to perform cleaning. Then recount the sample.
A: 049 RBC CLOG	The RBC aperture cap is clogged.	Press the Clean key to perform cleaning. Then recount the sample. If the alarm still occurs, perform strong cleaning, clean the aperture cap and replace the pump tube.
A: 050 RBC SAMPLE ERROR	Abnormal sample	Prepare the sample and measure again. Check that the temperature of the diluent is between 15 and 30°C (59 and 86°F).
A: 051 RBC HARD NOISE A: 052 PLT SOFT NOISE	Noise is detected during counting.	Check the grounding, and separate the instrument from other equipment and their power sources. Then recount the sample.

Messages	Possible Cause/Criteria	Countermeasure
A: 061 HGB VOLTAGE LOW	The WBC measurement bath is dirty.	Clean the measurement bath.
A: 062 HGB VOLTAGE HIGH	HGB voltage adjustment error.	Needs HGB voltage adjustment. Contact your Nihon Kohden representative.
A: 063 HGB CIRCUIT ERROR	Error in the HGB circuit.	Needs check and replacement of the measurement unit. Contact your Nihon Kohden representative.
A: 072 DOOR IS OPEN	The hematology analyzer does not operate because the door of the cap pierce unit is open.	Close the door (tube holder).
A: 073 TUBE IS CONTAINED	Open mode can not be selected because the sample tube is set in the cap pierce unit.	Remove the sample tube and close the door (tube holder).
A: 081 LASER KEY OFF	The laser switch is not turned on.	To measure WBC 5 part differential parameters, turn the laser switch on the right panel to on.
A: 082 OPTICAL COUNT ERROR	The flow cell is dirty.	Press the Clean key to perform cleaning. Then recount the sample.
A: 091 ROOM TEMP OVER	Measurement is performed at temperatures over 30°C (86°F).	Perform measurement at temperatures between 15 and 30°C (59 and 86°F).
A: 092 ROOM TEMP LOW	Measurement is performed at temperatures below 15°C (59°F).	
A: 093 CASE TEMP OVER	Internal temperature is abnormal.	Turn the power off. Then turn the power on to start counting. If the alarm still occurs, contact your Nihon Kohden representative.
A: 094 CASE TEMP LOW		
A: 095 POWER TEMP OVER		
E: 122 CHECK SETTINGS	The backup data is inappropriately changed.	Re-enter the calibration coefficient and all other settings. Then sample counting can be performed. If the error still occurs, contact your Nihon Kohden representative for battery replacement.
E: 123 MEMORY ERROR		Initialize the stored data.
Replace filters	Measurement is performed more than 1000 times.	Replace the filters and reset the operation history.
Replace pump tubes	Measurement is performed more than 3000 times.	Replace the pump tubes and reset the operation history.
Check cap pierce needle	The measurement is performed more than 1000 times in closed mode.	Check or replace the cap pierce needle and reset the operation history.

Other Alarm Messages

Messages	Possible Cause/Criteria	Countermeasure
Background noise check failed	Error occurred during background noise measurement.	Press the [Count] switch and measure background noise again.
Check cap pierce nozzle	The measurement is performed more than 1,000 times in closed mode.	Check or replace the cap pierce nozzle and reset the operation history.
Check filters, baths and sub baths	Measurement is performed more than 1,000 times.	Check filters, baths and sub baths and reset the operation history. Replace filters if necessary.
Check rinse unit	Measurement is performed more than 1,000 times.	Check rinse unit and reset the operation history.
Check sampling nozzle	Measurement is performed more than 3,000 times.	Check sampling nozzle and reset the operation history.
Check settings	The backup data is inappropriately changed.	Re-enter the calibration coefficient and all other settings. Then sample counting can be performed. If the error still occurs, contact your Nihon Kohden representative for battery replacement.
Replace pump tube	Measurement is performed more than 3,000 times.	Replace the pump tube and reset the operation history.

System Error Messages

Messages	Possible Cause/Criteria	Countermeasure
E001: DILUTER INITIALIZE ERROR	The MD-640V combination syringe pump unit cannot be initialized.	Turn the power off then on. If the alarm still occurs, write down the error code and contact your Nihon Kohden representative.
E003: DILUTER ERROR	The MD-640V combination syringe pump unit does not aspirate the sample.	
E021: SAMPLER INITIALIZE ERROR	The MS-640V sampler unit cannot be initialized.	
E022: SAMPLER ERROR	The MS-640V sampler unit does not function.	
E041: SUB BATH INITIALIZE ERROR	The sub bath of the MC-640V measuring unit cannot be initialized.	
E101: BATH DRAIN ERROR	The MP-640V pump unit does not drain the measurement baths.	
E120: WATCH DOG TIMER ERROR	Internal communication error.	
E122: CHECK SETTINGS	The backup data is inappropriately changed.	Re-enter the calibration coefficient and all other settings. Then sample counting can be performed. If the error still occurs, contact your Nihon Kohden representative for battery replacement.
E123: MEMORY ERROR		Delete the stored data.
E124: CIRCUIT ERROR	Circuit error.	Turn the power off then on. If the alarm still occurs, write down the error code and contact your Nihon Kohden representative.
E141: CAP PIERCE INITIALIZE ERROR	The MS-641V cap pierce unit cannot be initialized.	Turn the power off then on. If the alarm still occurs, write down the error code and contact your Nihon Kohden representative.
E142: CAP PIERCE RISING ERROR	The MS-641V cap pierce unit cannot be raised.	
E145: TUBE HOLDER OPERATION ERROR	The tube holder cannot be opened.	

Inaccurate Counting and Other Problems

If operation is not accurate after attempting the countermeasure in the previous sections, check the causes according to the following table.

Problem		Possible Cause/Criteria	Countermeasure
A	• The power cannot be turned on. • The power is turned off during operation (main power lamp is off.	The main power switch on the rear panel is off.	Turn on the main power switch on the rear panel. After the main power lamp lights, press the power switch on the front panel. If the power is turned off during operation, press the clean key to clean inside the analyzer after power on because previous blood sample may remain in the analyzer.
		The power cord is disconnected.	Connect the power cord firmly and turn the power on. If the power is turned off during operation, press the clean key to clean inside the analyzer after power on because previous blood sample may remain in the analyzer.
B	• Noise interference during counting • High background noise	Insufficient grounding.	Make sure the ground is sufficient.
		Equipment near the instrument is generating noise.	Separate the instrument from other equipment and their power sources.
		Noise in the power line.	Use a different power line.
		The front cover is open.	Close the front cover.
		Dirty diluent.	Replace the diluent.
		Dirty sub bath, measurement bath and filters.	Clean the sub bath, measurement bath and filters. Refer to Section 9.
		Dirty aperture caps.	Clean the aperture caps. Refer to Section 9.
		Poor contact of external electrode to the socket of the instrument.	Firmly tighten the measurement bath.
		The fluid path and diluent tube are dirty.	Press the Clean key to clean the fluid path using the CLEANAC detergent. Perform the strong cleaning by selecting Strong clean on the Operation screen.
C	Poor reproducibility of blood cell count	Insufficient stirring of sample.	Stir the sample sufficiently without creating bubbles.
		Dirty sub bath and/or measurement bath.	Clean the sub bath and/or measurement bath. Refer to Section 9.
		Dirty aperture caps.	Clean the aperture caps. Refer to Section 9.
		High background noise.	Reduce the background noise. Refer to Problem B.
D	Water leaks from inside the hematology analyzer	Pump tube is broken.	Replace the pump tube. Refer to Section 9.
		Filter is clogged.	Replace the filter. Refer to Section 9.
E	Poor reproducibility of HGB value	The WBC measurement bath is dirty.	Clean the measurement bath. Refer to Section 9.
F	Incorrect LCD display	Circuit error.	Press the Reset key. If the problem still occurs, turn off the instrument, wait about 10 seconds, then turn it on again.
	Instrument repeats same operation		

	Problem	Possible Cause/Criteria	Countermeasure
G	No printing (auto print)	The recording paper is not set.	Set the paper into the recorder.
		Auto print mode is set to off (auto print mode lamp is off).	Press the auto print key to set the auto print mode to on.
		Paper jammed.	Remove the jammed paper. Refer to the printer manual.
		Circuit error.	Press the Reset key. If the problem still occurs, turn off the instrument, wait about 10 seconds, then turn it on again.
	No printing (print key)	The recording paper is not set.	Set the paper into the recorder.
		Paper jammed.	Remove the jammed paper. Refer to the printer manual.
		Circuit error.	Press the Reset key. If the problem still occurs, turn off the instrument, wait about 10 seconds, then turn it on again.
H	The touch screen keys do not function	The pressed position and operating position do not match.	Calibrate the touch screen. Refer to Section 9.
		Circuit error.	Press the Reset key. If the problem still occurs, turn off the instrument, wait about 10 seconds, then turn it on again.
I	Priming starts suddenly (When noise interferes with the instrument program, priming automatically starts and the Ready screen appears.)	Power cord is not connected properly.	Connect the power cord properly.
		Equipment near the instrument is generating noise.	Separate the instrument from other equipment and their power sources.
		Noise in the power line.	Use a different power line.
J	The time displayed on the upper right corner of the screen is not correct.	The date and time setting is not correct.	Set the correct date and time setting on the DATE & TIME screen. Refer to Section 5.
		The backup battery is old.	Check the date and time setting on the DATE & TIME screen and turn off and on the power of the hematology analyzer. If the time is incorrect, replace the backup battery with a new one. Contact your Nihon Kohden representative.
K	Scattergrams appear outside the alloted area.	Bubbles in the flow cell unit	Clean the flow cell unit. Refer to Section 9.
		Incorrect flow cell position	
	Flags related to WBC 5 part differential frequently appear.	Incorrect gain for WBC 5 part differential parameters	

Data and Symbol Display

The following table shows the relationship between the data classification and display.

Classification	Data Display	Symbol Display	Description
Data cannot be analyzed	None	None	Data cannot be analyzed.
Measurement alarm	Abbreviated alarm message (see the table below)	None	Error found during measurement.
Measurement alarm	Data displayed	"?" beside numeric data	Measurement error due to surrounding temperature out of specified range. Measured data is displayed but measurement accuracy is not reliable. "?" appears beside all WBC 5 part differential parameters when optical count error occurs.
Out of measuring range	"OVER" message displayed	None	Out of measuring range.
Data with low reliability	Data displayed	"*", "!" or "C" beside numeric data	Abnormal flag detected in the sample. Measurement accuracy is not reliable due to abnormal cell. • When WBC flag appears, all WBC parameters are affected by the abnormal cell. "*" is displayed beside the parameter which is greatly affected. • When there is possibility of PLT coagulation, "C" is displayed beside the parameter. • When there is possibility of poor hemolyzation, "!" is displayed beside the parameter.
Out of normal range	Data displayed	"H" or "L" beside numeric data	Out of normal range setting.

Abbreviated alarm messages

Abbreviation		Code No.	Alarm Message
Displayed beside WBC data	Displayed beside RBC data		
LEVEL1		A021	WBC fluid level 1
LEVEL2		A022	WBC fluid level 2
LEVEL3		A023	WBC fluid level 3
BBL1		A024	WBC bubble 1
BBL2		A025	WBC bubble 2
BBL3		A026	WBC bubble 3
BBL4		A027	WBC bubble 4
CLOG		A029	WBC clogged
NOISE2		A031	WBC hardware noise
NOISE1		A032	WBC software noise

	LEVEL1	A041	RBC fluid level 1
	LEVEL2	A042	RBC fluid level 2
	LEVEL3	A043	RBC fluid level 3
	BBL1	A044	RBC bubble 1
	BBL2	A045	RBC bubble 2
	BBL3	A046	RBC bubble 3
	BBL4	A047	RBC bubble 4
	CLOG	A049	RBC clogged
	NOISE2	A051	RBC hardware noise
	NOISE1	A052	RBC software noise

The following table shows the relationship between the flags and symbols.

Flag	Flag Class.	Parameters											
		NE% NE#	LY% LY#	MO% MO#	EO% EO#	BA% BA#	WBC	RBC	HGB	HCT	MCHC	PLT	PCT MPV PDW
Blasts	WBC	*	*	*	*	*							
Immature Gr		*		*		*							
Left Shift		*		*		*							
Atypical Ly			*	*									
Small Nucleated Cell							*						
Ly-Mo Interference			*	*									
Ne-Eo Interference		*			*								
PLT-RBC Interference	RBC/PLT							*				*	
PLT Clumps							C					C	C
PLT Low Value	PLT											*	
WBC OVER	OTHER								*				
Abnormal MCHC	Specimen										!		
Poor hemolyzation							!						

The following table shows the relationship between the alarm messages and symbols.

Alarm Message	Code No.	Parameters										
		NE% NE#	LY% LY#	MO% MO#	EO% EO#	BA% BA#	WBC	RBC	HGB	HCT	MCHC	PLT
WBC SAMPLE ERROR	A030						?					
RBC SAMPLE ERROR	A050							?				?
HGB VOLTAGE LOW	A061								?			
HGB VOLTAGE HIGH	A062								!			
HGB CIRCUIT ERROR	A063								*			
ROOM TEMP OVER	A091	?	?									
ROOM TEMP LOW	A092	?	?	?								
OPTICAL COUNT ERROR	A082	?	?	?	?	?						

Section 11 Quality Control

General

Quality Control (QC) procedures are used to determine the accuracy and precision of the analyzer. These procedures allow the user to consistently and accurately evaluate instrument performance, interpret laboratory data, and ascertain acceptability of analysis results.

We suggest that this information be incorporated into your laboratory's protocol or procedures manual. Refer to your laboratory's standard operating procedures and/or a quality assurance plan to check for and ensure proper instrument performance and analysis accuracy.

When to Run QC

QC testing must be conducted according to established regulations and procedures in your particular state or country. At a minimum, however, it is suggested that QC be conducted as follows:

- After startup procedures are completed
- To confirm calibration
- When a reagent lot number has been changed
- After maintenance or component replacement
- When a new software version has been installed
- When there is an unusual shift or trend in sample results
- When there is a reason to suspect data or results

QC Methods

The analyzer offers the following Quality Control (QC) programs for monitoring and validating instrument performance.

- $\overline{X}$-R
- L & J (Levey and Jennings)
- $\overline{X}$B

These programs automatically calculate the plotting data from the sample data. The data can be displayed and printed as a table and graphs are plotted from the obtained data for each parameter for quality control.

$\overline{X}$-R and L & J programs cannot be used at the same time. Select either of them on the QC Settings screen. Refer to the "Changing the Quality Control Settings" later in this section.

Control Material

Controls usually consist of fixed blood cells with assayed ranges for each measured parameter. There are three levels of hematology controls for each measured parameter —Low, Normal, and High.

Quality Control Procedures

Guidelines for Running Controls

Quality Control (QC) procedures must be carried out in accordance with your laboratory's QC protocol and according to regulatory requirements, using the following general guidelines:

- Prior to running patient specimens, run a minimum of two levels of control on each day a test is run.
- Perform the quality control measurement in the usual measurement mode for your facility (closed mode, open mode or pre-dilution mode).
- Run controls for each measured parameter in the same manner as patient specimens.
- Verify that control results are within the laboratory's acceptable limits and review the data for shifts or trends.
- If the control results fall within acceptable limits, record the results and begin to process patient specimens.
- If QC results fall outside the laboratory's acceptable limits, try another vial from the same lot of control material. If the problem persists, contact your Nihon Kohden representative.
- Do not report patient results if QC results fall outside the laboratory's acceptable limits.
- Verify that the control file being used is the correct file in which means and limits are updated.

Control Material Guidelines

Use the following guidelines for proper handling of control material:

- Check the condition of incoming control material. Be sure the vials are at the proper temperature and are not leaking. Check for gross hemolysis.
- Check the shelf life and open-tube stability dating. Do not use products longer than recommended by the manufacturer, or the results may be compromised.
- Always mix and handle control materials according to the directions given on the package insert. Proper mixing is essential for accurate results.
- Carefully prepare the control product according to the directions on the package insert.
- Never subject controls to excessive cold, heat, or agitation. Store controls at recommended temperatures; if storing controls inside a refrigerator, place in a central location. Do not store control or calibrator material in the refrigerator door.

$\overline{X}$-R Program

General

Overview of $\overline{X}$-R Program and Quality Control Procedure

The $\overline{X}$-R program calculates and displays the daily $\overline{X}$ (mean values of the first and second counting of the same control sample) and R (difference between the values of the first and second counting of the same control sample). The $\overline{X}$-R program also calculates $\overline{\overline{X}}$ and $\overline{R}$ (averaged $\overline{X}$ and R for a number of days). You can use the data from this program to plot the obtained data for each parameter for quality control. The data for the last 120 days is stored in memory.

Every day the analyzer is used, count the control "n" times per day ($n \geq 2$). Continue the counting for k days (more than 10 days).

The analyzer automatically calculates the daily mean and difference and the averaged mean and difference for k days.

The average of $\overline{X}$ ($\overline{\overline{X}}$), ±2 SD and ±3 SD of $\overline{\overline{X}}$, CV of $\overline{\overline{X}}$, the average of R ($\overline{R}$), upper limit of $\overline{R}$ ($\overline{R}$URL) and CV of $\overline{R}$ of the stored $\overline{X}$-R data can be displayed.

CAUTION

Store control in optimum conditions. If the storage conditions of the control are not optimum, hemolyzation or expansion of the blood cells will occur and abnormal data will be frequently obtained on the $\overline{X}$ and R graphs.

CAUTION

Do not use control after the expiration date. If you use control after the expiration date, the obtained $\overline{X}$ and R graphs are not reliable.

NOTE

- Only use the MEK-5D Hematology Control for the $\overline{X}$-R program.
- The internal temperature of the instrument affects the measurement results and internal temperature of the instrument varies with the time of day. Therefore, it is recommended to do the quality control measurement at the same time every day.

Calculation of $\overline{\overline{X}}$ and $\overline{R}$

$$\overline{\overline{X}} = \frac{\Sigma \overline{X}}{k} \qquad \overline{R} = \frac{\Sigma R}{k}$$

$\overline{X}$: Mean for one day
$\overline{\overline{X}}$: Mean for k days

R: Difference for one day
$\overline{R}$: Difference for k days

Calculation of Upper and Lower Limits of $\overline{X}$ and R

The upper and lower limits for quality control are statistically calculated as follows. The 3-sigma statistical method is used. Refer to a statistical reference book.

If the control is counted n (≥2) times every day, the upper and lower limits of $\overline{X}$ are as follows.

$$\text{Upper limit of X (UCL)} = u + 3\frac{\delta}{\sqrt{n}} = \overline{\overline{X}} + 3\frac{\overline{R}}{\sqrt{n}\ d_2}$$

$$\text{Lower limit of X (LCL)} = u - 3\frac{\delta}{\sqrt{n}} = \overline{\overline{X}} - 3\frac{\overline{R}}{\sqrt{n}\ d_2}$$

δ = Standard deviation estimate
u = Truth estimate

The upper limit of R is as follows.

$$\text{Upper limit of R (UCL)} = d_2\delta + 3d_3\delta = \left(1 + 3\frac{d_3}{d_2}\right)\overline{R}$$

Relation between n and d_2 (for $\overline{X}$) or d_2 and d_3 (for R)

n	d_2	$1/d_2$	d_3
2	1.128	0.8862	0.853
3	1.693	0.5908	0.888
4	2.059	0.4857	0.880
5	2.326	0.4299	0.864
6	2.534	0.3946	0.848
7	2.704	0.3698	0.833
8	2.847	0.3512	0.820
9	2.970	0.3367	0.808
10	3.078	0.3249	0.797

$\overline{X}$-R Management Graph

There are two types of graphs for $\overline{X}$-R management graph of the analyzer.

- Multi trendgraph: Refer to “Displaying Multi Trend Graph”.
- Detail graph of measurement items: Refer to “Handling $\overline{X}$-R Graphs”.

To check the overall trend, select multi trendgraph (Trend tab). To check the detail trend of each measurement item, select graph (Graph tab).

$\overline{X}$-R Graph Example

Following are example data and plotted graphs for RBC.

Day	Obtained Data		$\overline{X}$	R
	First	Second		
1	4.82	4.76	4.79	0.06
2	4.79	4.80	4.80	0.01
3	4.80	4.85	4.83	0.05
4	4.71	4.77	4.74	0.06
5	4.80	4.89	4.85	0.09
6	4.82	4.83	4.83	0.01
7	4.77	4.74	4.76	0.03
8	4.77	4.80	4.79	0.03
9	4.68	4.74	4.71	0.06
10	4.91	4.92	4.92	0.01
11	4.73	4.77	4.75	0.04
12	4.79	4.80	4.80	0.01
13	4.77	4.73	4.75	0.04
14	4.77	4.82	4.80	0.05
			$\overline{\overline{X}} = 4.794$	$\overline{R} = 0.0393$

$n = 2$, $d_2 = 1.128$, $d_3 = 0.853$

$\overline{X}$ graph:

$$\text{Upper limit of } \overline{X} = \overline{\overline{X}} + 3 \frac{1}{\sqrt{n}\, d_2} \overline{R}$$

$$= 4.794 + 1.88 \times 0.0393$$

$$= 4.868$$

$$\text{Lower limit of } \overline{X} = \overline{\overline{X}} - 3 \frac{1}{\sqrt{n}\, d_2} \overline{R}$$

$$= 4.794 - 1.88 \times 0.0393$$

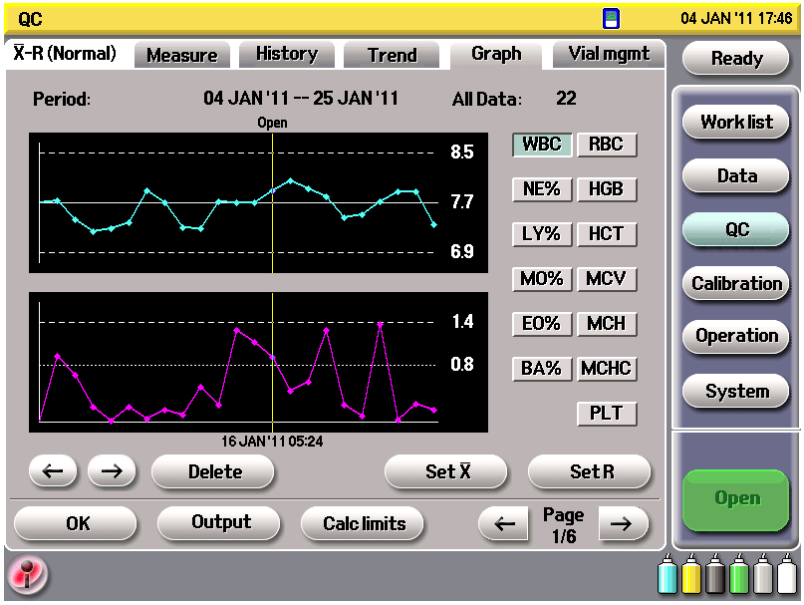
$$= 4.720$$

R graph:

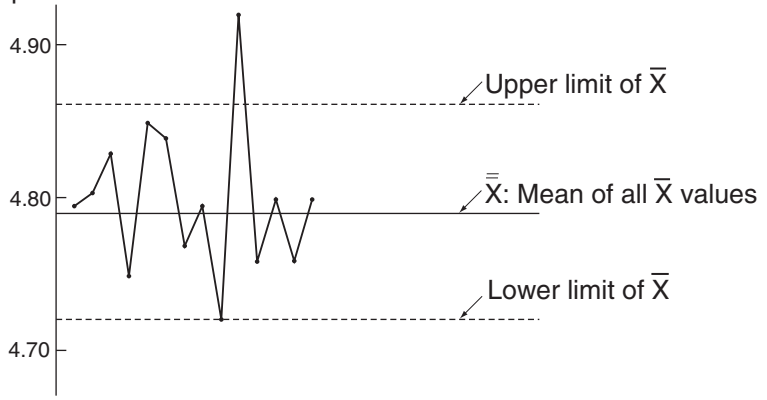
$$\text{Upper limit of R} = \left(1 + 3 \frac{d_3}{d_2}\right) \overline{R}$$

$$= 3.27 \times 0.0393$$

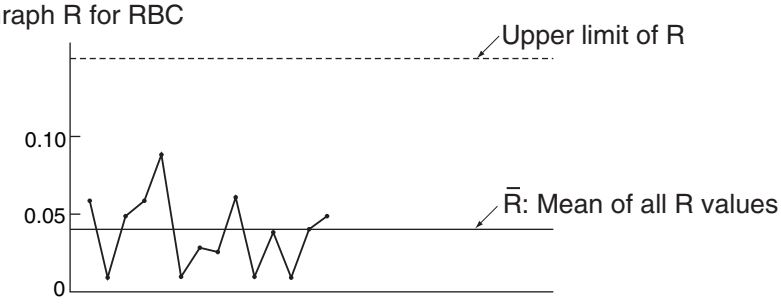
$$= 0.129$$



Graph $\bar{X}$ for RBC



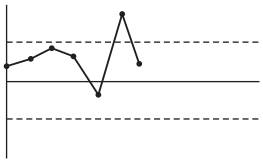
Graph R for RBC



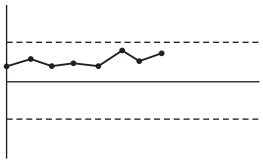
How to Read the $\overline{X}$-R Graph

Refer to the "Data Outside the Limits" section below when these plots appear.

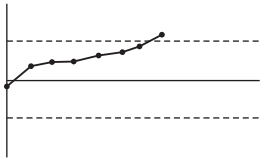
- The plot is outside the upper or lower limit



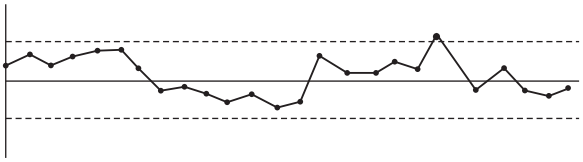
- The $\overline{X}$ plot goes to the plus side or minus side



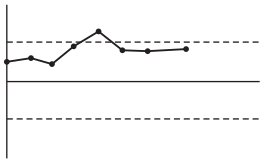
- The plot gradually increases or decreases



- The plot shows a repeated periodic variation



- The plot is close to the upper or lower limit



Data Outside the Limits

Normally, each data plotted on the $\overline{X}$ and R graphs varies within the range between the upper and lower limits of $\overline{X}$, and between zero and upper limit of R, respectively. (See the $\overline{X}$ and R graphs on the previous page.)

If the data exceeds an upper/lower limit, it may be caused by the following.
$\overline{X}$ Graph:

- Diluent, lysing reagent or hematology control chemically degraded or past the expiration date. This can be caused by change of environmental conditions such as humidity or room temperature or unsuitable storage conditions.
- Composition difference between different production lots of control.
- Analyzer trouble.

R Graph:

- Insufficient control stirring.
- Temperature variation of diluent.
- Dirty fluid path such as aperture, manometer, measurement baths or sub baths.
- Analyzer trouble such as dilution ratio error or circuit error.

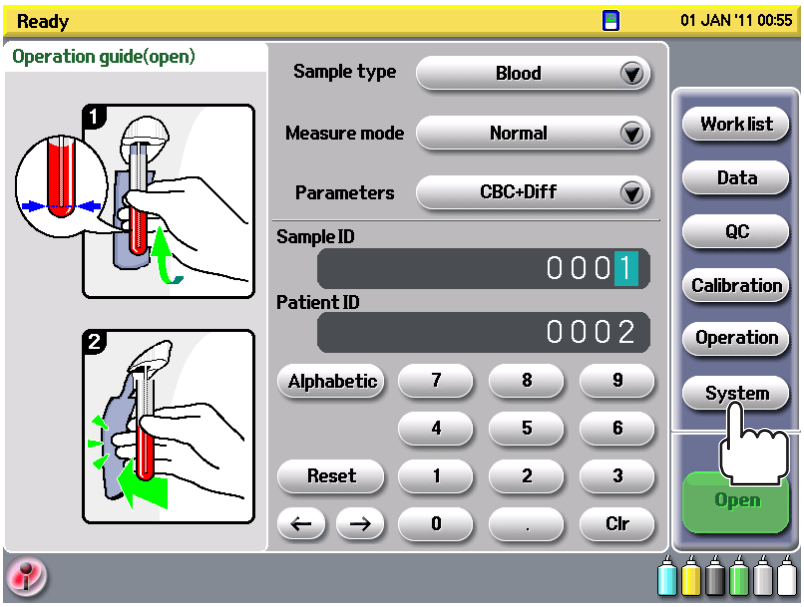
Changing the Quality Control Settings

You can set the following items for $\overline{X}$-R and L & J quality control programs.

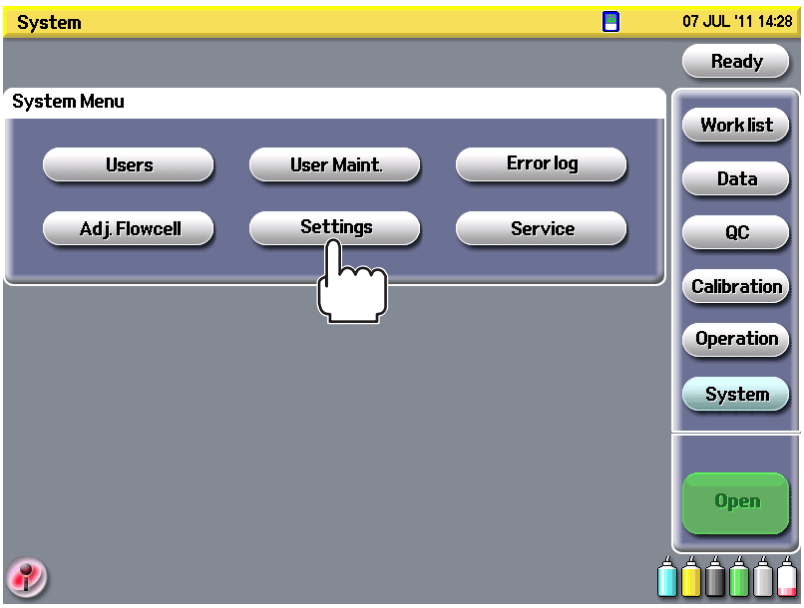
Item	Description	Settings	Default
QC method	Select either $\overline{X}$-R or L & J for the quality control method.	$\overline{X}$-R or L & J	$\overline{X}$-R
Save the QC measurement data	Select whether or not to save the quality control measurement data.	Yes or No	No
Auto send the QC data after measurement	Select whether or not to automatically send the hematology control measured data to the connected instrument after each measurement.	Yes or No	No
$\overline{X}$ limit calculation	Select either ±2 SD or ±3 SD for $\overline{X}$ limit calculation.	±2 SD or ±3 SD	±3 SD

When the $\overline{X}$-R keys do not appear on the QC screen, change the quality control method.

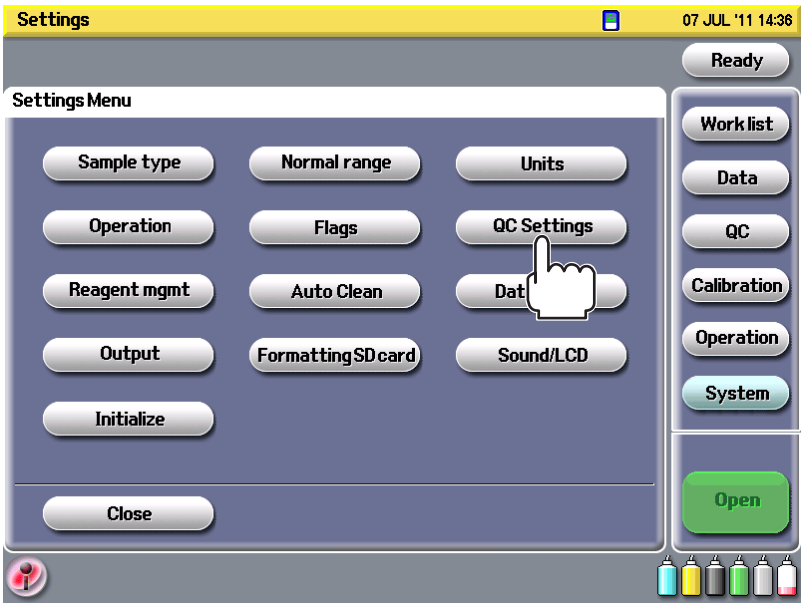
1. Press the System key on the screen.



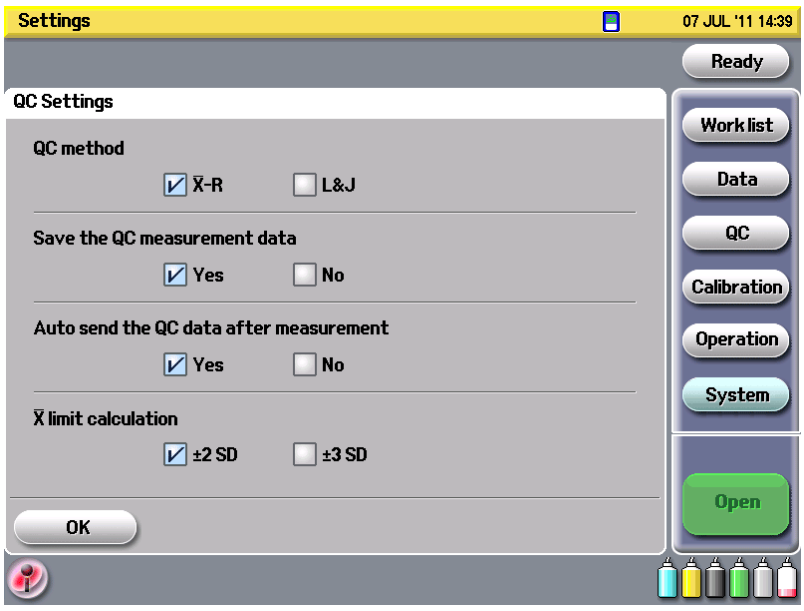
2. Press the Settings key.



3. Press the QC Settings key.

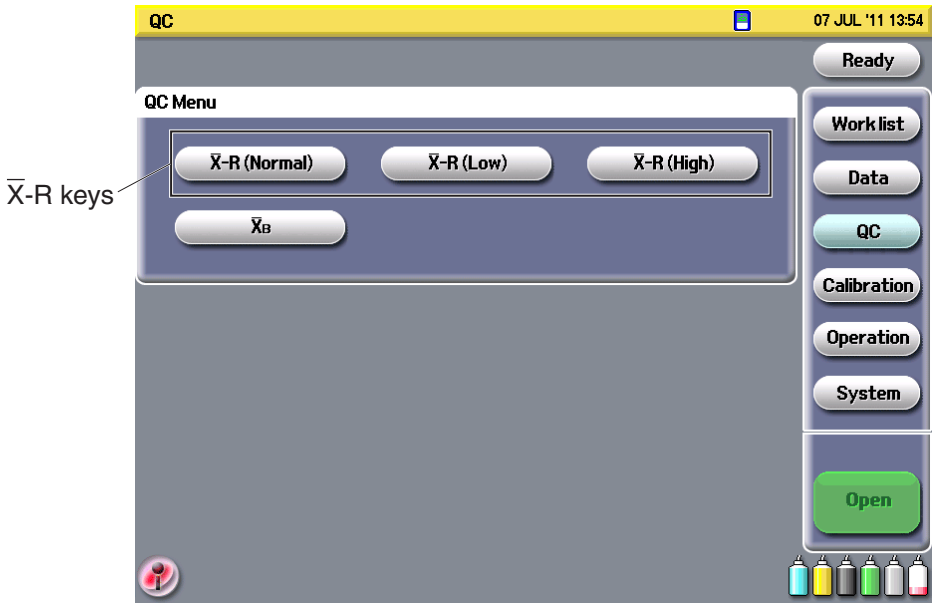


4. Change necessary settings. Select "$\bar{X}$-R" in the <QC method> area.



5. Press the OK key.

6. Press the QC key and check that $\overline{X}$-R keys are displayed on the screen.



Precautions for Hematology Control

When using MEK-5DN, MEK-5DH, MEK-5DL hematology control, observe the following precautions:

- Do not use the hematology control whose expiration date is elapsed.
  Unopened: expiration date on the label or package
  Opened: 14 days after opening
- Store the control in 2 to 8°C (35.6 to 46.4°F) and do not freeze the control.
- Use the control after returning it to the room temperature.
- Shake and mix the control before measurement.
- Refer to the manual of the hematology control and observe the precautions.

Counting the Hematology Control

To ensure accuracy, observe the following cautions.

CAUTION

Store control in optimum conditions. If the storage conditions of the control are not optimum, hemolyzation or expansion of the blood cells will occur and abnormal data will be frequently obtained on the $\overline{X}$ and R graphs.

CAUTION

Do not use control after the expiration date. If you use control after the expiration date, the obtained $\overline{X}$ and R graphs are not reliable.

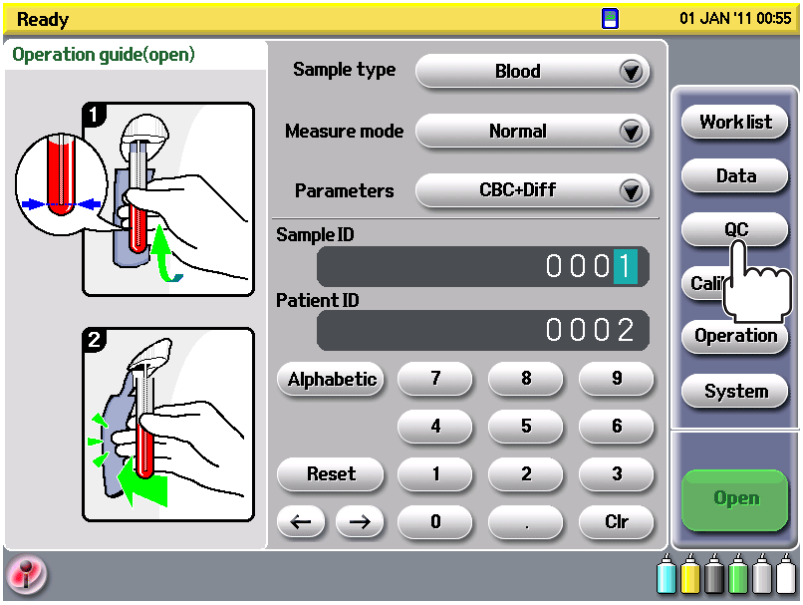
NOTE

The internal temperature of the instrument affects the measurement results and internal temperature of the instrument varies with the time of day. Therefore, it is recommended to do the quality control measurement at the same time every day.

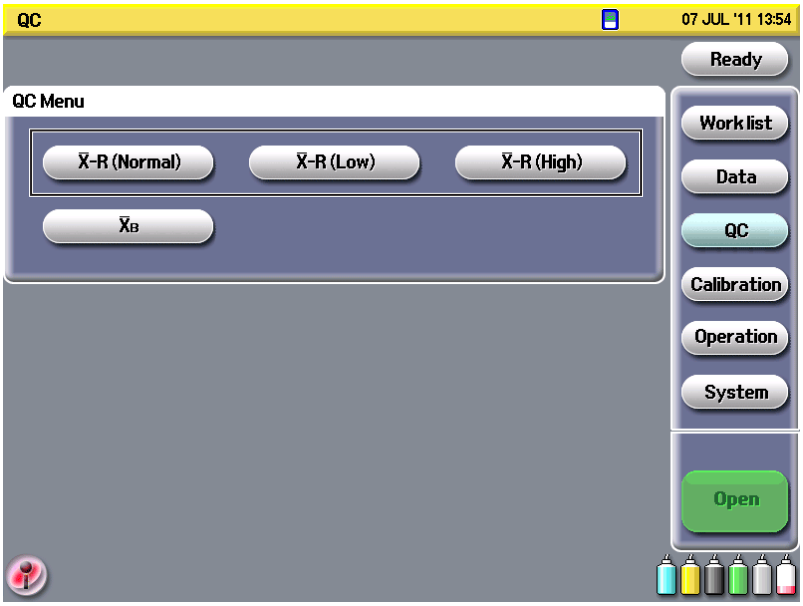
Perform the quality control measurement in the usual measurement mode for your facility (closed mode, open mode or pre-dilution mode).

You can use three types of control: MEK-5DN (Normal), MEK-5DH (High) and MEK-5DL (Low). The analyzer stores data for 120 measurements of each type of control.

1. Press the QC key to display the QC screen.

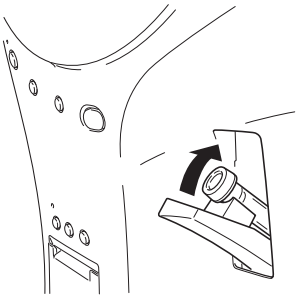


2. Press the $\overline{X}$-R (Normal) key when using the MEK-5DN control, the $\overline{X}$-R (Low) key when using the MEK-5DL control or the $\overline{X}$-R (High) key when using the MEK-5DH control.



The $\overline{X}$-R screen appears. When counting the control for the first time of the day, the "Measure hematology control" message appears.
When the control is already counted, the measurement result of the previous measurement is displayed. When performing another control measurement is necessary, delete the previous measurement data on the History screen of the $\overline{X}$-R screen. To delete data, refer to the "Deleting $\overline{X}$-R Data" later in this section.

If the $\overline{X}$-R keys do not appear on the QC screen, change the quality control method. Refer to the “Changing the Quality Control Settings” earlier in this section.

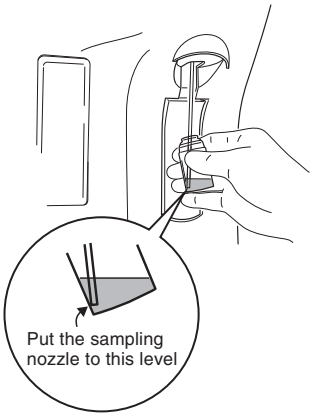


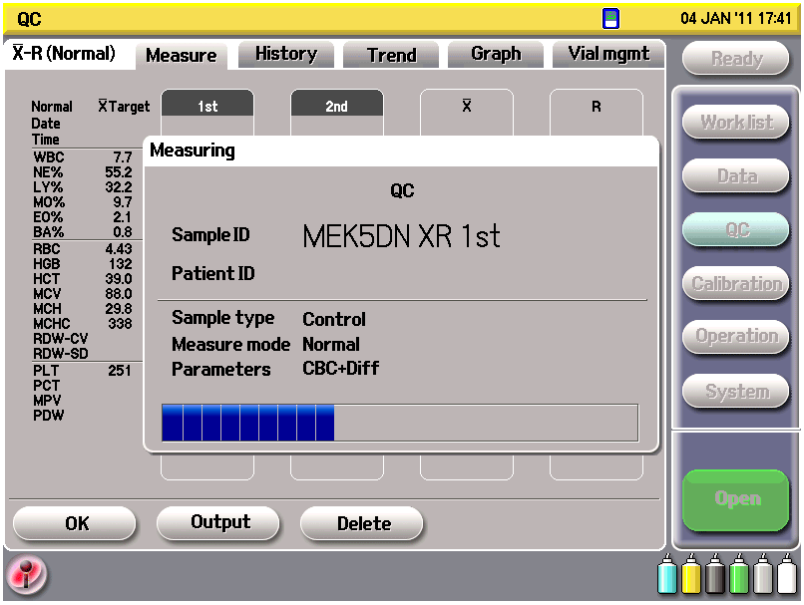
3. Do one of the following.
   - When measuring in closed mode:
     Set the sample tube containing the hematology control in the tube holder and close the tube holder.

NOTE

Before closing the tube holder, fully open the holder.

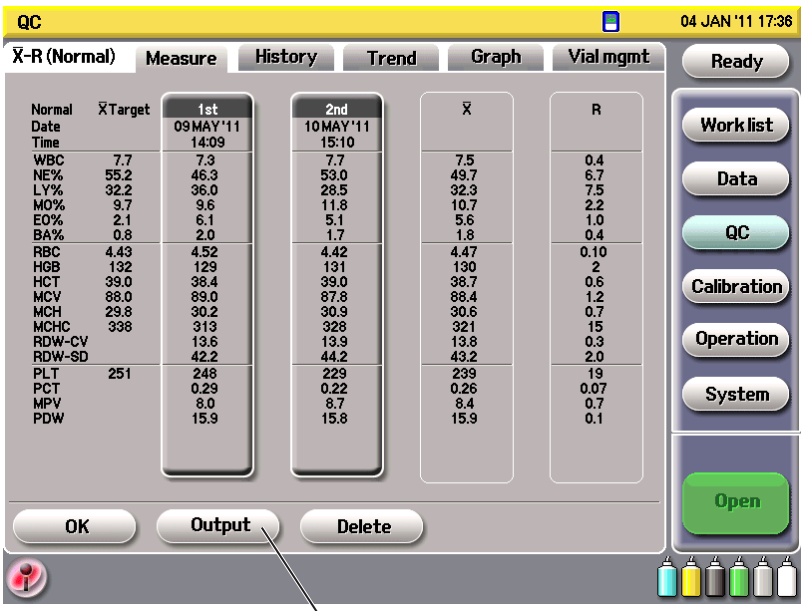
   - When measuring in open mode:
     Put the sampling nozzle into the sample container containing the hematology control and press the [◇ Count] switch.





4. After the first count, the measurement data appears on the screen. Measure the control again.

   After the second count, the $\overline{X}$-R data appears on the screen. The data is automatically saved (for up to 120 samples for each control type).



When <Output with "Output" key> on the Serial Port setting is set to "On" and <External device> is set to "EPSON VP", you can output the data to the EPSON VP printer by pressing the Output key. You can also print the data with the internal printer.

When a PC or optional printer is connected to the analyzer and <Auto send the QC data after measurement> is set to "Yes" on the QC Settings screen, the measurement data is sent to the PC or printed on the printer. Refer to "Changing the Quality Control Settings" earlier in this section.

To display or print the $\overline{X}$-R graph, press the Graph tab. Refer to the "Handling $\overline{X}$-R Graphs" later in this section.

To display stored data, press the History tab. Refer to the next section.

5. Press the OK key to return to the QC screen.

Deleting Quality Control Measurement Data

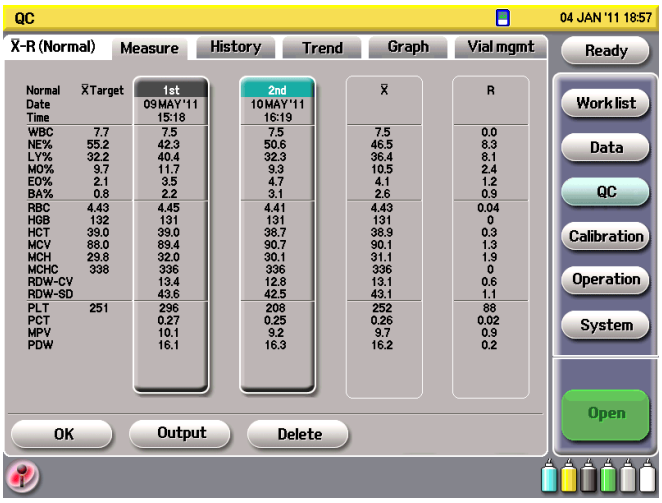
1. Press the data to delete.

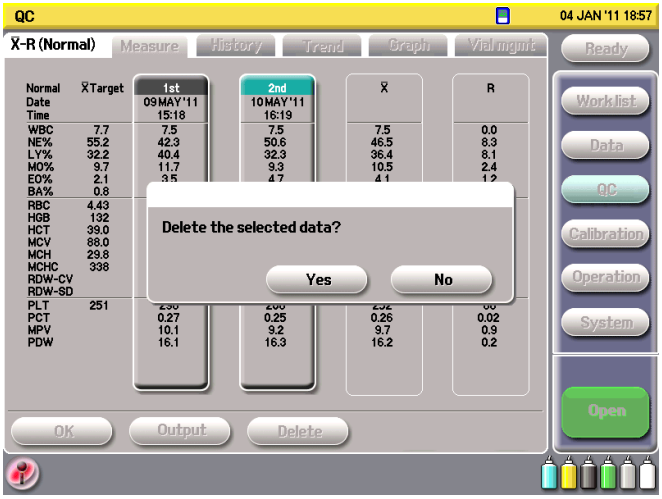
2. Press the Delete key. A “Delete the selected data?” message is displayed.

3. Press the Yes key to delete the data.

NOTE

- When there is second measurement data, only the first measurement data cannot be deleted (the data cannot be selected).
- When the second measurement data is selected, the first measurement data can be selected. By selecting the first and second data, you can delete the two data at the same time. You cannot unselect the second data when the both data is selected. When performing two measurements, $\overline{X}$-R history data is generated from the two data and the history data is not deleted even the second data is deleted. Delete the history data on the $\overline{X}$-R History window.



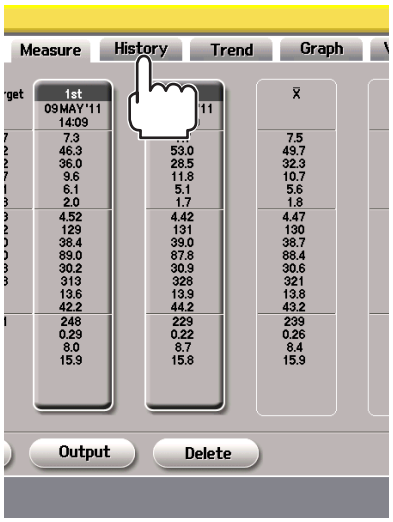


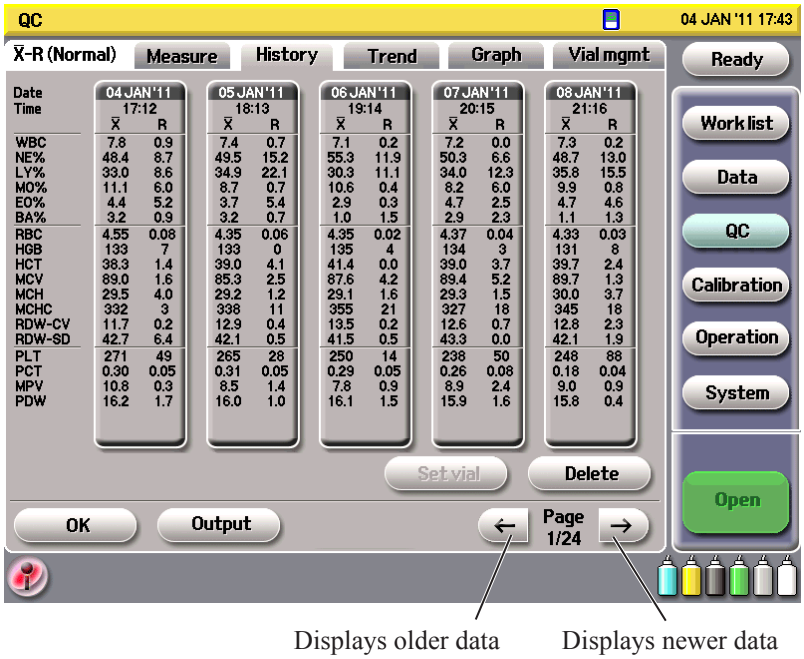
Handling $\overline{X}$-R Data

Displaying the $\overline{X}$-R Data List (History)

You can display stored $\overline{X}$-R data on the History screen.

1. On the $\overline{X}$-R screen, press the History key to display the latest five data.





2. To display other data, use the arrow keys.

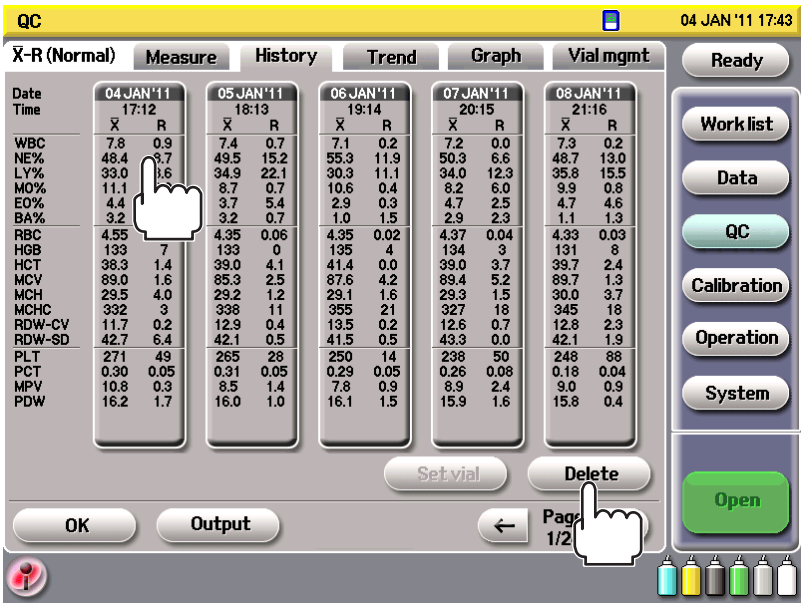
   When <Output with "Output" key> setting on the Serial Port setting is set to "On" and <External device> is set to "EPSON VP", you can output the data to the EPSON VP printer by pressing Output key. You can also print the data with the internal printer.

3. Press OK to return to the $\overline{X}$-R screen.

Deleting X̄-R Data

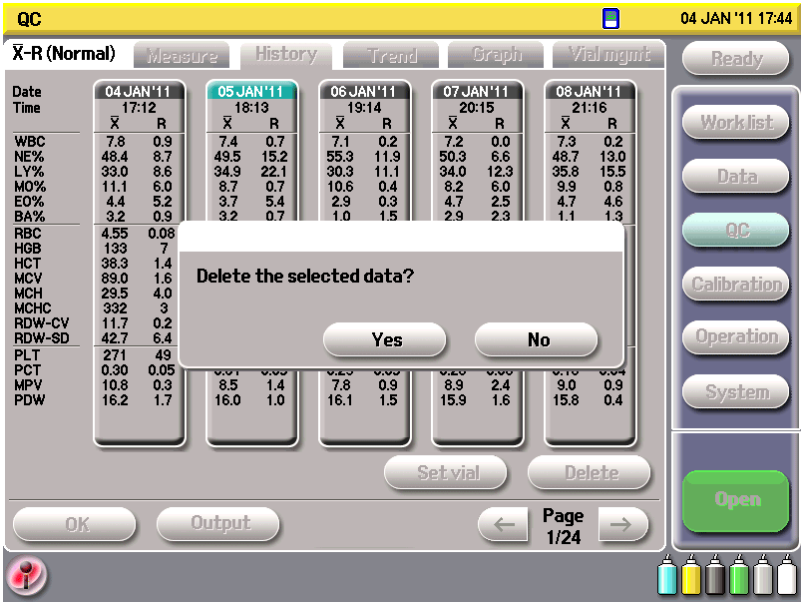
Deleting X̄-R Data Individually

1. On the History window, select one data to be deleted by pressing the desired date key. Use the arrow keys to find the desired data.



2. Press the Delete key.

   A confirmation message appears.

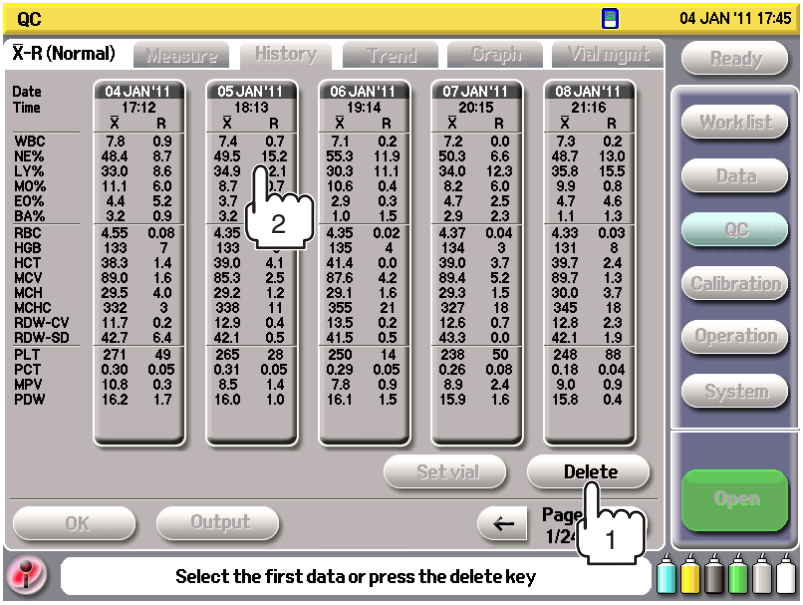


3. Press Yes to delete selected data. Press No to cancel the procedure.

Deleting X̄-R Data Consecutively

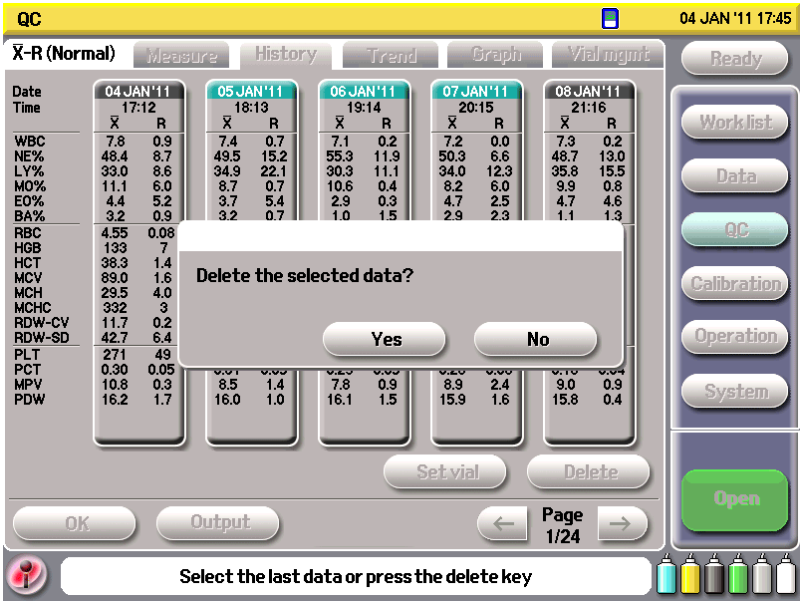
1. Press the Delete key on the History window.

   The “Select the first data or press the delete key” message appears on the screen.



2. Press the date key of the first data. The “Select last data or press the delete key” message appears on the screen.

3. Find the last data using the arrow keys and press the date key of that data. A confirmation message appears on the screen.



4. Press the Yes key. All data between the first and last date will be deleted. Press the No key to cancel the procedure.

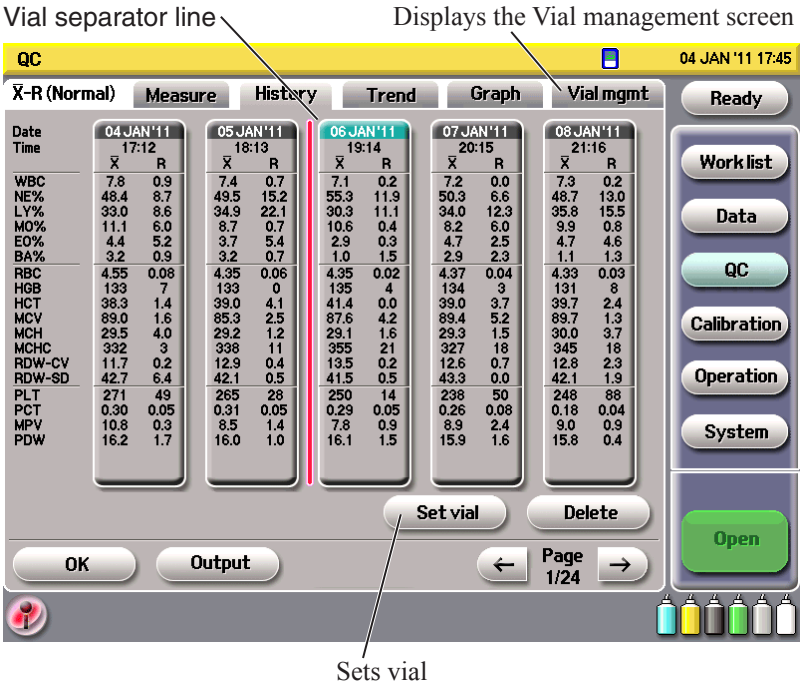
Setting Vial to X̄-R History

You can manage X̄-R History data by vial. Set vial when measuring new MEK-5DN/L/H hematology control.

1. Select the first data of the vial on the X̄-R History screen.

2. Press the Set vial key. A red line is displayed at the left of the selected data. The data from the line to the next line is data for one vial.

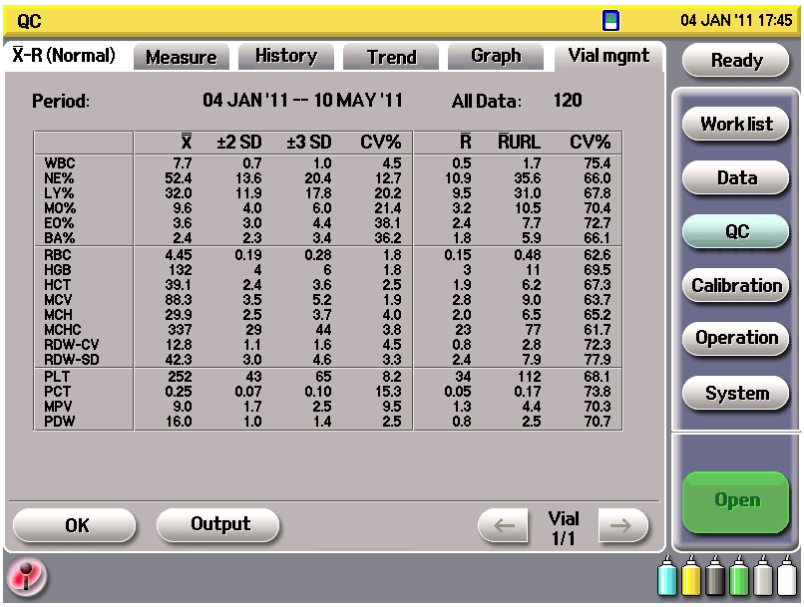
You can delete the line by selecting the data and pressing the Set vial key.



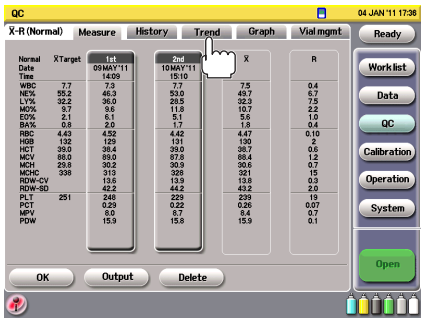
Displaying Vial Management Window

On the Vial Management window, you can display a period average rates of $\overline{X}$-R data ($\overline{\overline{X}}$), 2DS and 3DS of $\overline{\overline{X}}$, CV value of $\overline{X}$, average of the day ($\overline{R}$), upper management limit of R ($\overline{R}$URL), CV value of $\overline{R}$.

Press the Vial mgmt tab to display the Vial Management screen.

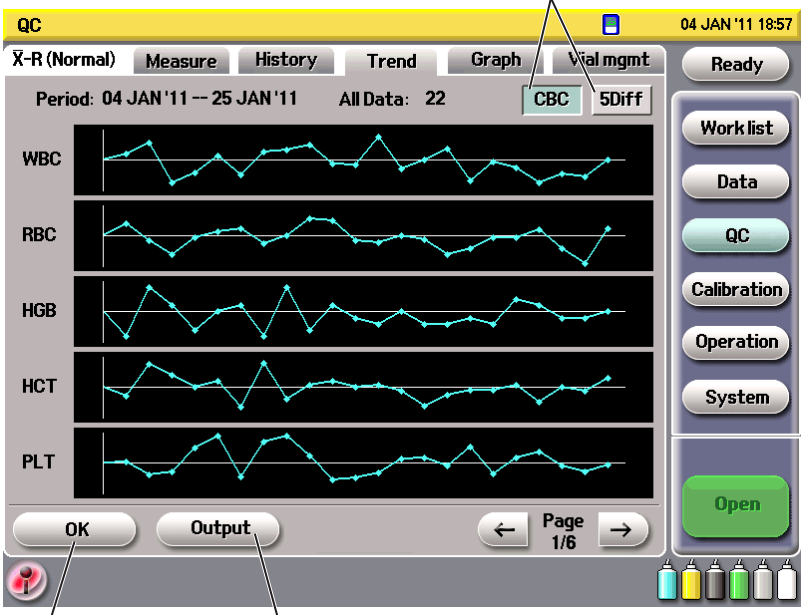


Displaying $\overline{X}$-R Multi Trendgraph



1. Press the Trend tab on the $\overline{X}$-R screen to display the $\overline{X}$-R multi trendgraph.

2. Press the CBC or 5 Diff key to change the graph.
   - CBC: Display the CBC main 5 parameters (WBC, RBC, HGB, HCT, PLT)
   - 5 DIff: Display the 5 part differential parameters (LY%, MO%, NE%, EO%, BA%)



If a value is out of the range, the value is plotted in red on the graph.

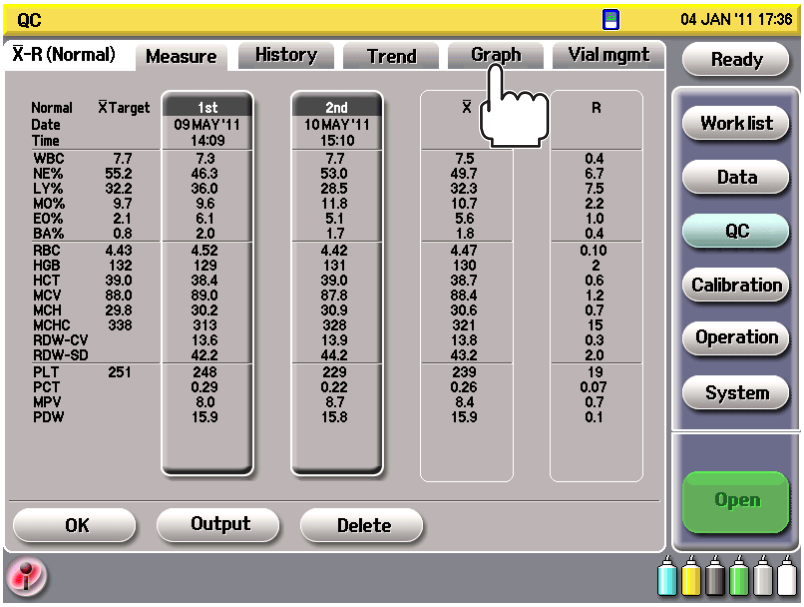
When <Output with "Output" key> setting on the SD Card setting is set to "On", you can capture the window and send it to the SD card by pressing the Output key.

3. Press the OK key to return to the $\overline{X}$-R screen.

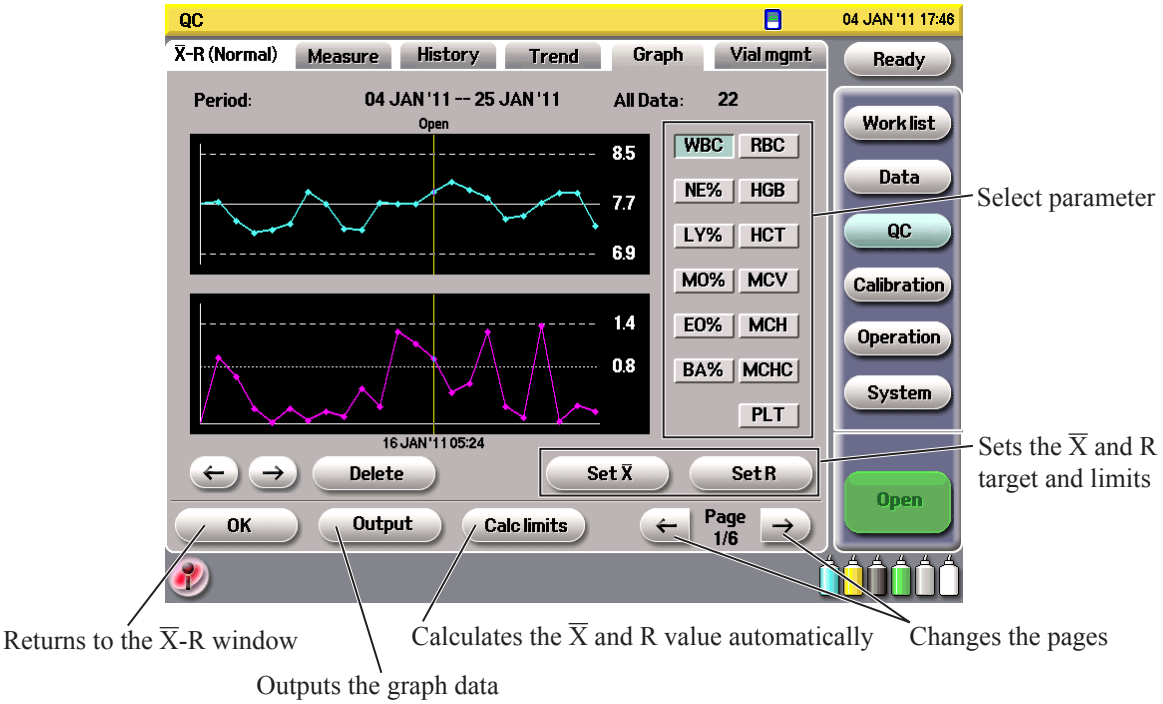
Handling $\overline{X}$-R Graphs

You can display the graph of the $\overline{X}$ and R for each parameter.

1. Press the Graph tab on the $\overline{X}$-R screen.



2. Press the desired parameter key. The graph for that parameter is displayed on the screen.



You can change parameters by pressing the parameter keys at the right side of the screen.

An “Out of range” message appears when the graph goes outside the limits.

When <Output with “Output” key> setting on the Serial Port setting is set to “On” and <External device> is set to “EPSON VP”, you can output the data to the EPSON VP printer by pressing Output key. You can also print the data with the internal printer.

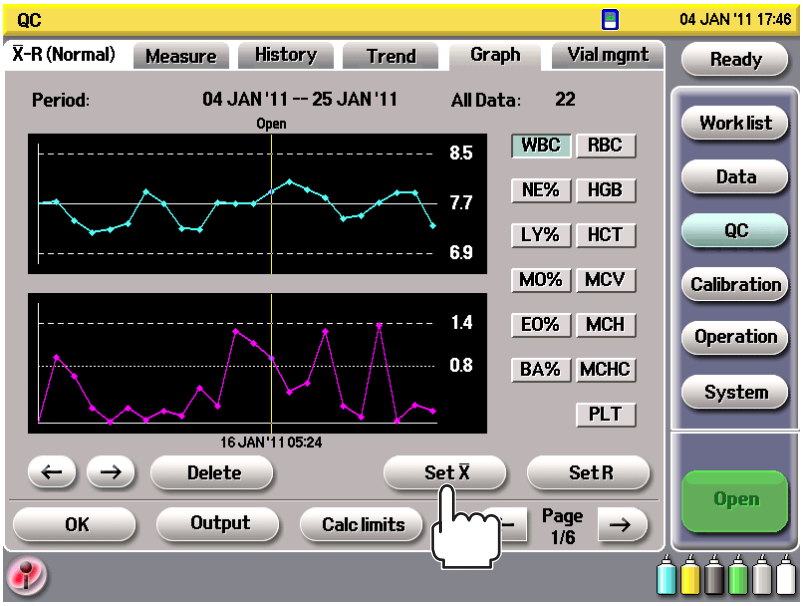
To change the initial and the upper and lower limits of $\overline{X}$ and R values for the $\overline{X}$-R graph, press the Set $\overline{X}$ or Set R key. For details, refer to the next procedure.

3. Press the OK key to return to the previous screen.

Changing the $\overline{X}$-R Limits

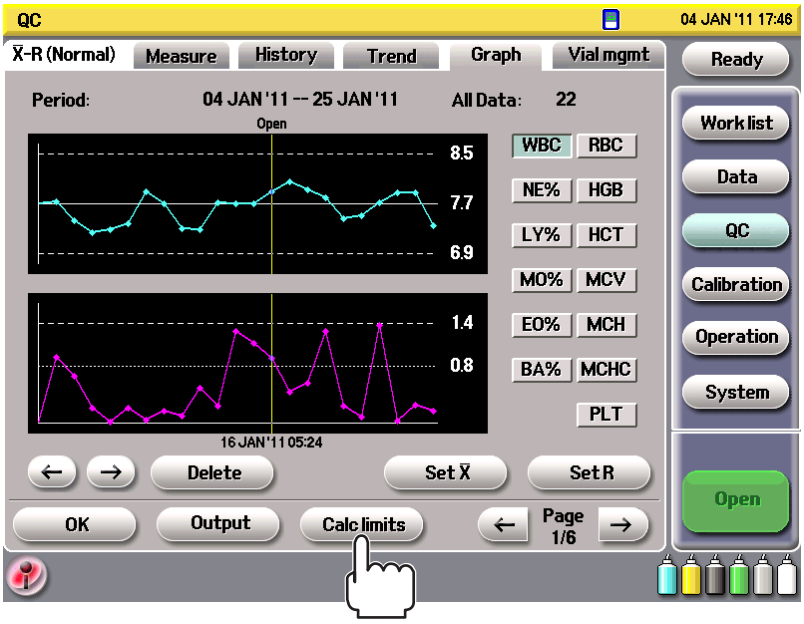
When necessary, you can change the target and the upper and lower limits of $\overline{X}$ and R values for the $\overline{X}$-R graph.

1. Press the Set $\overline{X}$ or Set R key on the $\overline{X}$-R graph screen to display the $\overline{X}$-R limits setting screen.

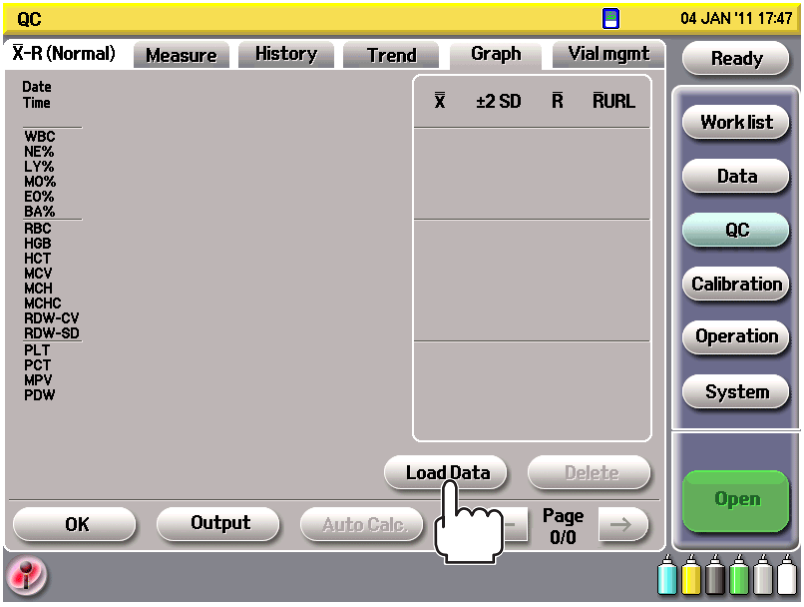


2. To change the limits individually:
   i) Touch the setting value or use the arrow keys to move the cursor to the setting value you want to change.
   ii) Enter the desired value using the numeric keys. Press the Enter key to register the value. The cursor moves to the next field.
   iii) Repeat steps i) and ii) to change other values.

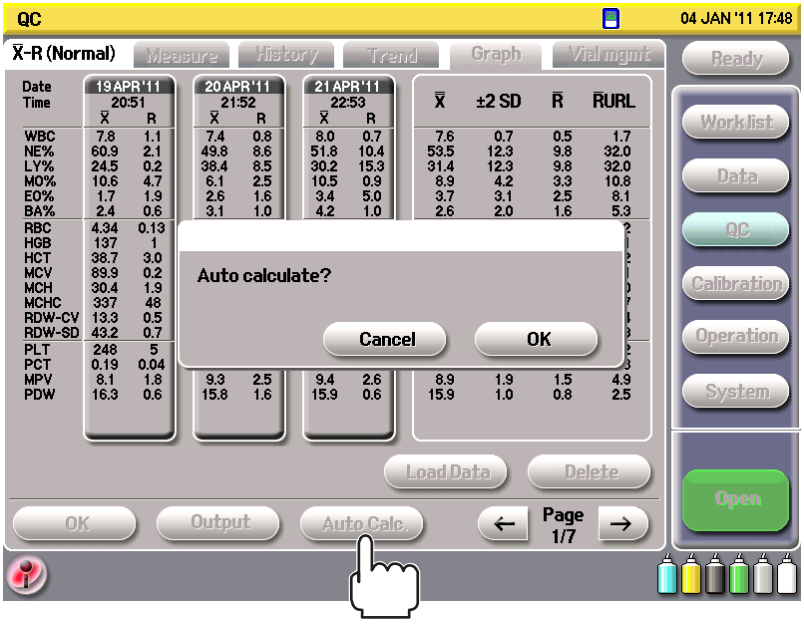
   To automatically calculate the ideal values for all limits:
   i) Press the Calc limits key. The limit calculation screen appears.



   ii) Press the Load Data key to load up to 21 X̄-R measurement data from the newest vial. Limits are calculated and displayed automatically.



iii) Press the Auto Calc. key. A confirmation message is displayed.



iv) Press the OK key to set the limits automatically. $\overline{\overline{X}}$ is set to $\overline{X}$ target value, ±2SD is set to $\overline{X}$ limit, $\overline{R}$ is set to R target value and $\overline{R}$URL is set to R limit.

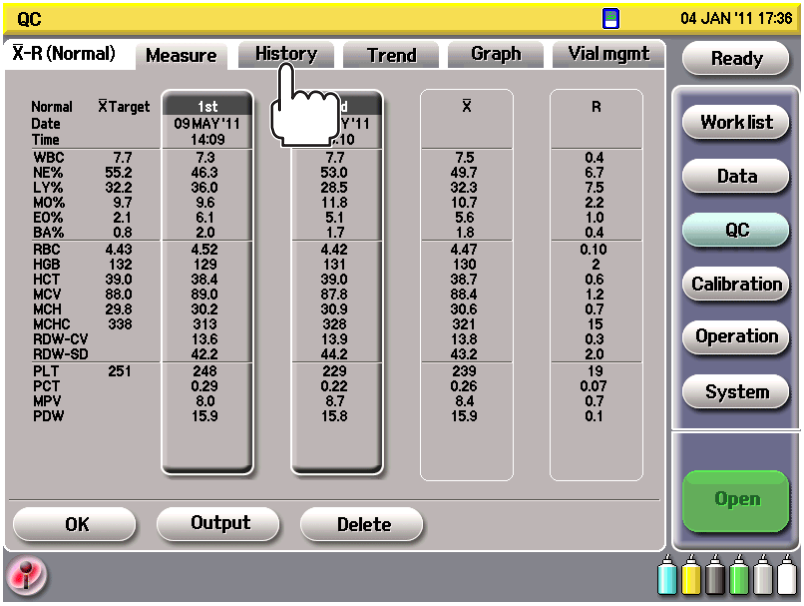
3. Repeat steps 1 and 2 to change limits for R. Select “Set R” in step 1.

4. Press the OK key to return to the $\overline{X}$-R graph screen.

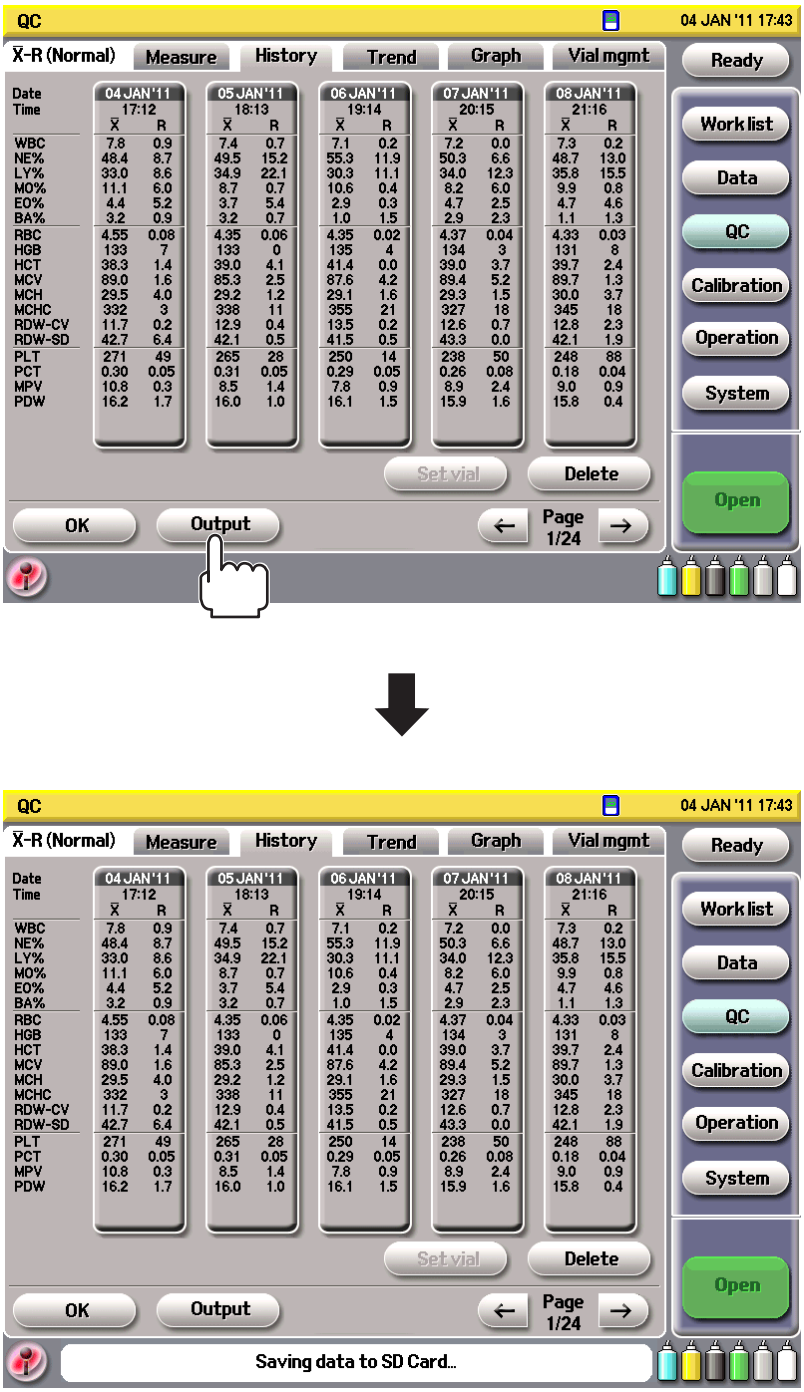
Saving $\overline{X}$-R History Data

You can save the $\overline{X}$-R history data to a SD memory card.

1. Press the History tab.



2. Press the Output key. A “Saving data to SD card...” message appears and the data is saved to the SD memory card.



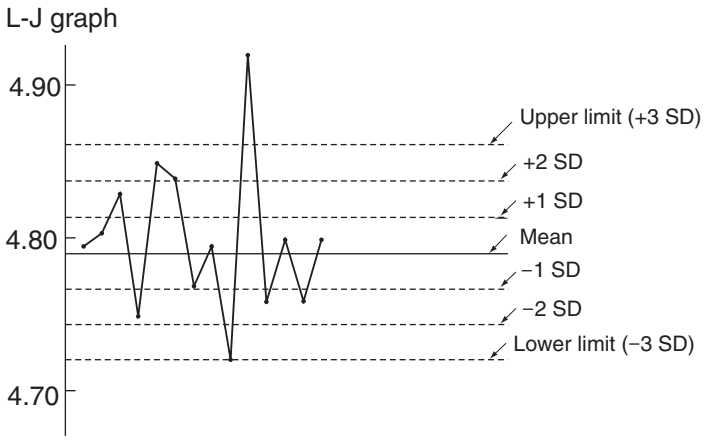
L & J Program (Levey and Jennings)

General

Overview of L & J Program and Quality Control Procedure

The L & J (Levey and Jennings) program* counts one control sample every day and the mean and standard deviation (SD) are automatically calculated to plot L-J chart for quality control. The data for the last 120 days is stored in memory.

* Westgard® Rules are applied to the L & J program.
  Westgard is a registered trademark of Westgard Quality Corporation.



Every day when the analyzer is stable, count the control once. The analyzer automatically calculates the mean and the upper and lower limits.

The mean, ±2 SD, ±3 SD and CV of the stored data can be displayed.

CAUTION

Store control in optimum conditions. If the storage conditions of the control are not optimum, hemolyzation or expansion of the blood cells will occur and abnormal data will be frequently obtained on the L & J graphs.

CAUTION

Do not use the control after the expiration date. If you use control after the expiration date, the obtained L & J graphs are not reliable.

NOTE

- Only use the MEK-5D Hematology Control for the L & J program.
- The internal temperature of the instrument affects the measurement results and internal temperature of the instrument varies with the time of day. Therefore, it is recommended to do the quality control measurement at the same time every day.

Calculation of Upper and Lower Limits

The upper and lower limits for the L & J program is automatically calculated according to the following equations.

Upper limit (+3S) = X + 3σ
Lower limit (−3S) = X −3σ
X = mean σ = standard deviation

L & J Management Graph

There are two types of graphs for the L & J management graph of the analyzer.

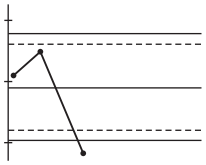
- Multi trend graph: Refer to “Displaying Multi Trend Graph”.
- Detail graph of measurement items: Refer to “Handling L & J Graphs”.

To check the overall trend, select multi trend graph (Trend tab). To check the detail trend of each measurement items, select graph (Graph tab).

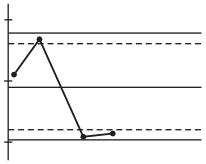
How to Read the L & J Graph

Refer to the “Data Outside the Limits” section when these plots appear.

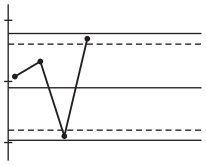
- The plot is outside ±3 SD limit



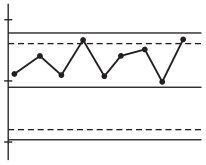
- The plot goes outside ±2 SD limit twice in a row



- Two consecutive plots go from outside +2 SD (or −2 SD) to −2 SD (or +2 SD)



- The plot goes to the plus side or minus side



Data Outside the Limits

Normally, each data are plotted within the range between the upper and lower limits. If the data exceeds an upper/lower limit, an “Out of range” message is displayed. It may be caused by the following.

- Diluent, lysing reagent or hematology control chemically degraded or past the expiration date. This can be caused by change of environmental conditions such as humidity or room temperature or unsuitable storage conditions.

- Composition difference between different production lots of control.
- Insufficient control stirring.
- Temperature variation of diluent.
- Dirty fluid path such as aperture, manometer, measurement baths or sub baths.
- Analyzer trouble such as dilution ratio error or circuit error.

Changing the Quality Control Settings

If the L & J keys do not appear on the QC screen, change the quality control method. Select "L & J" in the <QC method> box on the QC Settings screen. Refer to the "Changing the Quality Control Settings" in "$\overline{X}$-R Program" earlier in this section.

Precautions for Hematology Control

When using MEK-5DN, MEK-5DH, MEK-5DL hematology control, observe the following precautions:

- Do not use the hematology control whose expiration date is elapsed.
  Unopened: expiration date on the label or package
  Opened: 14 days after opening
- Store the control in 2 to 8°C (35.6 to 46.4°F) and do not freeze the control.
- Use the control after returning it to the room temperature.
- Shake and mix the control before measurement.
- Refer to the manual of the hematology control and observe the precautions.

Counting the Hematology Control

To ensure accuracy, observe the following cautions.

CAUTION

Store control in optimum conditions. If the storage conditions of the control are not optimum, hemolyzation or expansion of the blood cells will occur and abnormal data will be frequently obtained on the L & J graphs.

CAUTION

Do not use the control after the expiration date. If you use control after the expiration date, the obtained L & J graphs are not reliable.

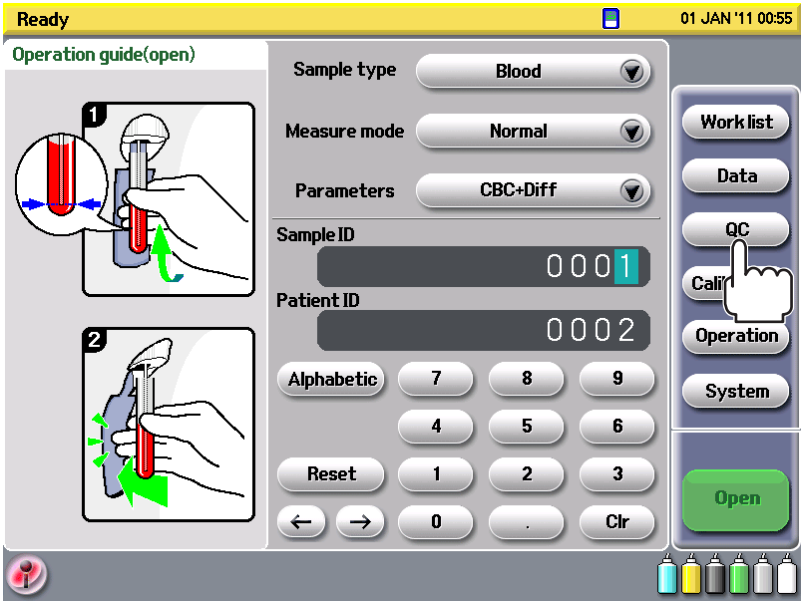
NOTE

The internal temperature of the instrument affects the measurement results and internal temperature of the instrument varies with the time of day. Therefore, it is recommended to do the quality control measurement at the same time every day.

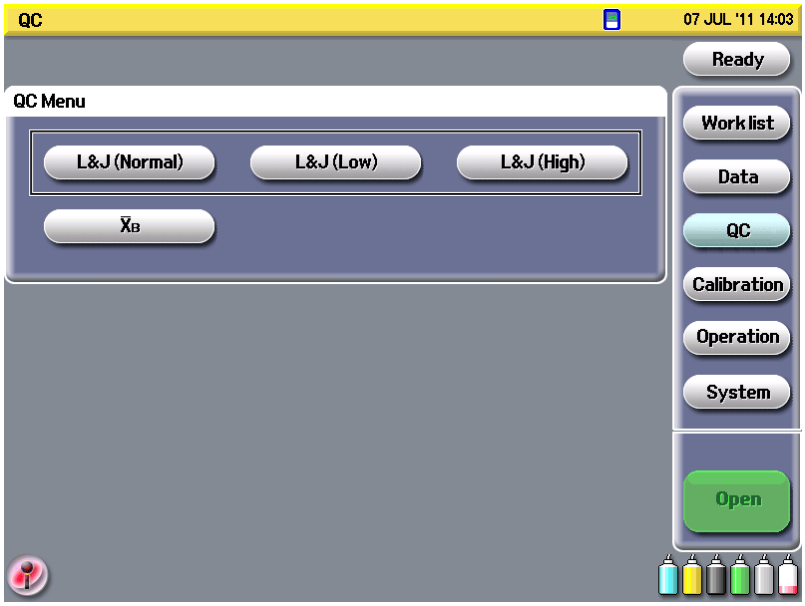
Perform the quality control measurement in the usual measurement mode for your facility (closed mode, open mode or pre-dilution mode).

You can use three types of control: MEK-5DN (Normal), MEK-5DH (High) and MEK-5DL (Low). The analyzer stores data for 120 measurements of each type of control.

1. Press the QC key on the screen to display the QC screen.



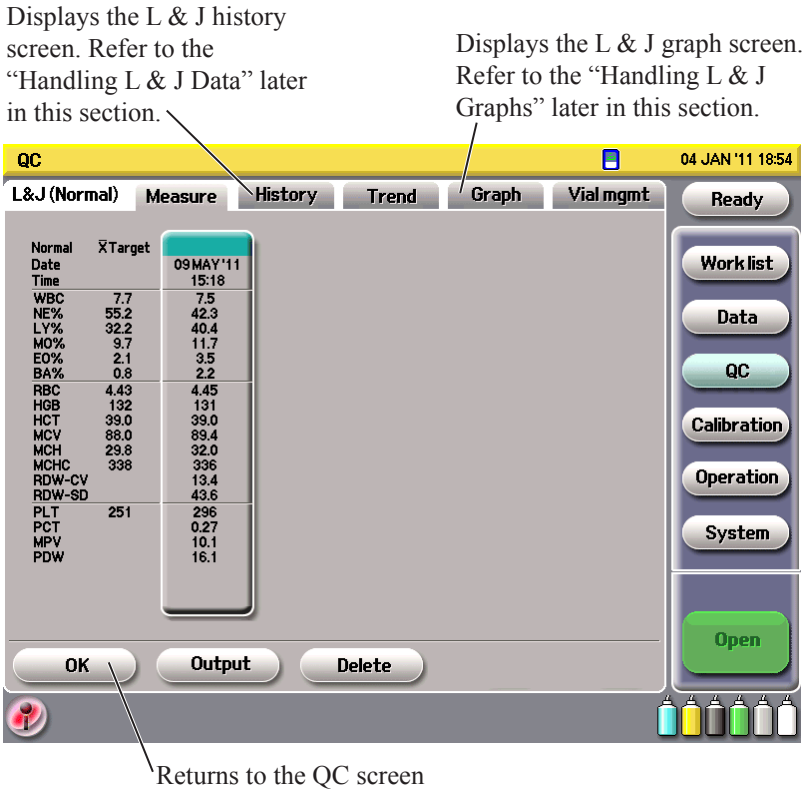
2. Press the L & J (Normal) key when using the MEK-5DN control, the L & J (Low) key when using the MEK-5DL control or the L & J (High) key when using the MEK-5DH control.



The L & J screen appears. When counting the control for the first time of the day, the “Measure hematology control” message appears.

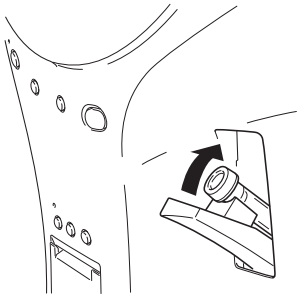
When the control is already counted, the measurement result of the previous measurement is displayed. When performing another control measurement is necessary, delete the previous measurement data on the History screen of the L & J screen. To delete data, refer to the “Deleting L & J Data” later in this section.

When the L & J keys do not appear on the QC screen, change the quality control method. Refer to the “Changing the Quality Control Settings” earlier in this section.



11

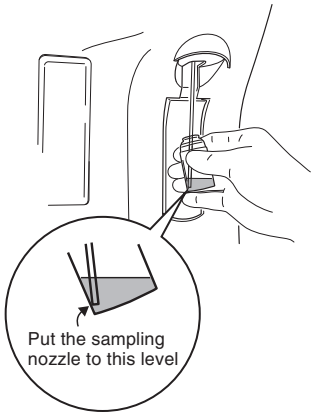
3. When measuring in closed mode:
   Set the sample tube containing the hematology control in the tube holder and close the tube holder.



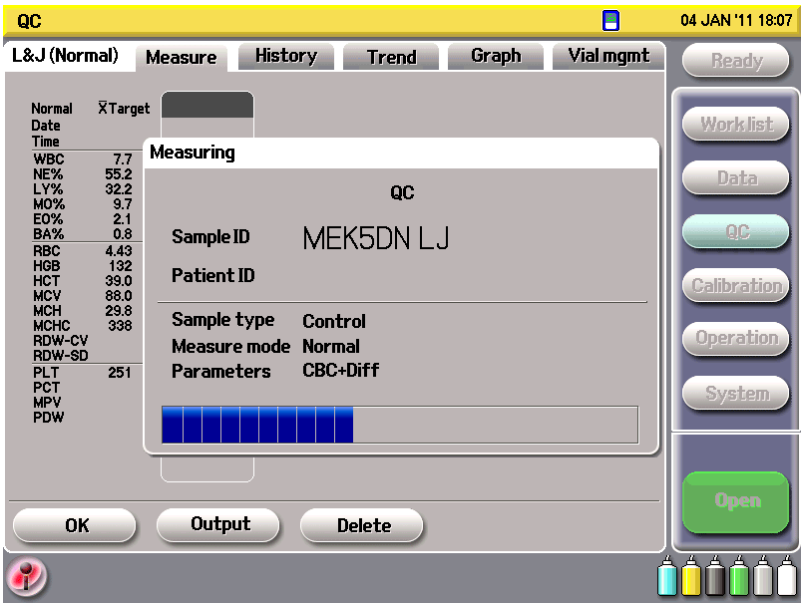
NOTE

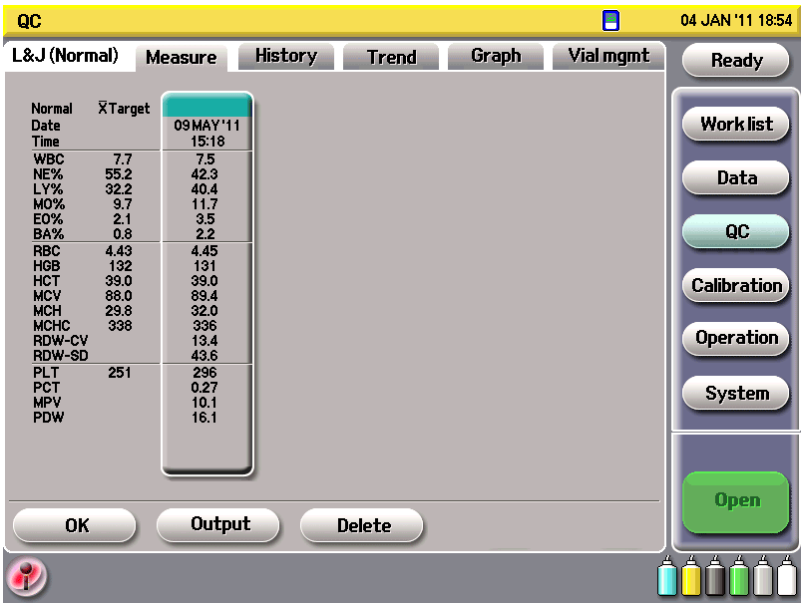
Fully open the holder before closing the tube holder.

When measuring in open mode:
Put the sampling nozzle into the sample container containing the hematology control and press the [◇ Count] switch.



4. After the measurement, the measurement data appears on the screen. The data is automatically saved (for up to 120 samples for each control type).





When <Output with "Output" key> on the Serial Port setting is set to "On" and <External device> is set to "EPSON VP", you can output the data to the EPSON VP printer by pressing Output key. You can also print the data with the internal printer.

When a PC or optional printer is connected to the analyzer and <Auto send the QC data after measurement> is set to "Yes" on the QC Settings screen, the measurement data is sent to the PC or printed on the printer. Refer to the "Changing the Quality Control Settings" earlier in this section.

To display or print the L & J graph, press the Graph tab. Refer to "Handling L & J Graphs" later in this section.

To display stored data, press the History tab. Refer to the next section.

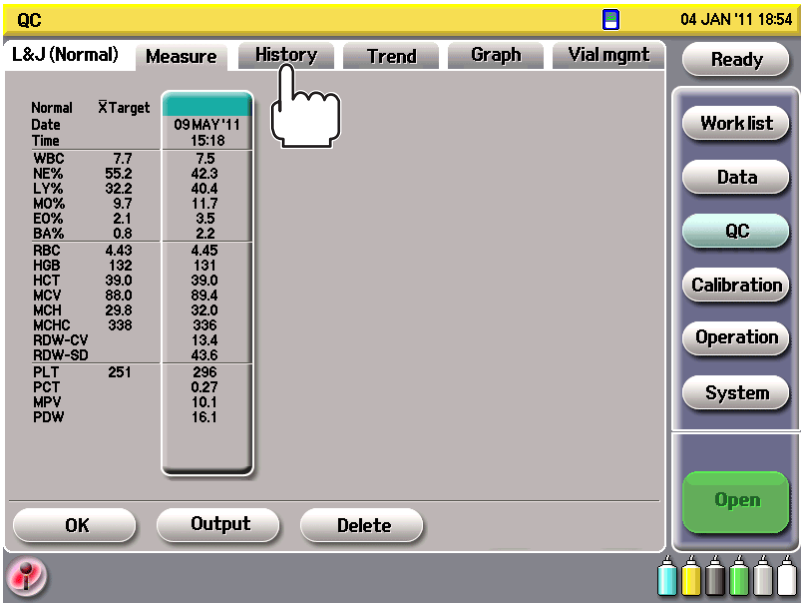
5. Press the OK key to return to the QC screen.

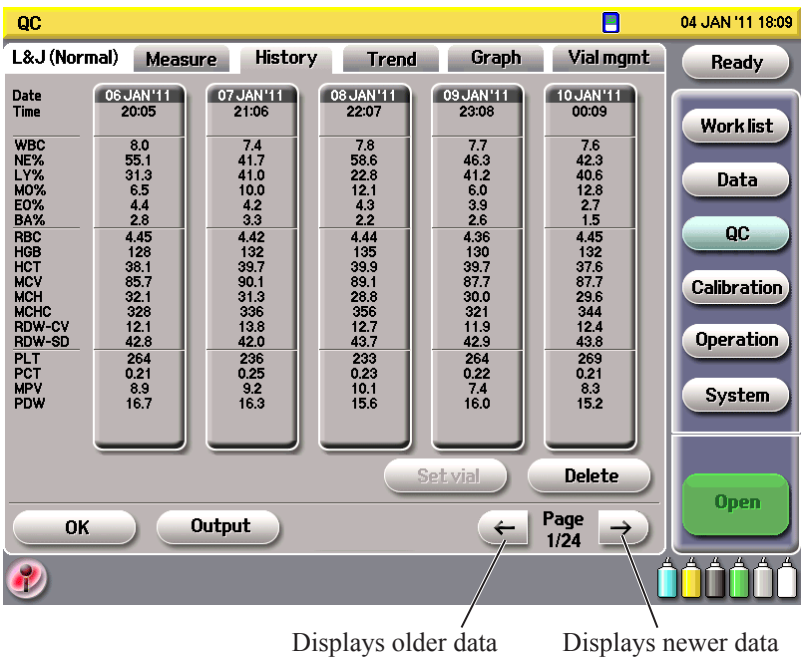
Handling L & J Data

Displaying the L & J Data List (History)

You can display stored L & J data on the History window.

1. On the L & J screen, press the History tab to display the latest five data.





2. To display other data, use the arrow keys.

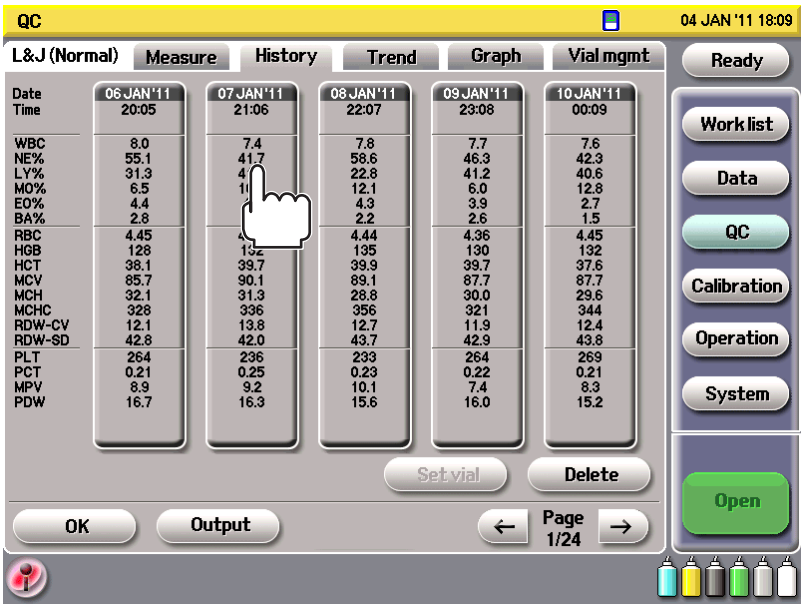
When <Output with “Output” key> on the Serial Port setting is set to “On” and <External device> is set to “EPSON VP”, you can output the data to the EPSON VP printer by pressing Output key. You can also print the data with the internal printer.

3. Press OK to return to the L & J screen.

Deleting L & J Data

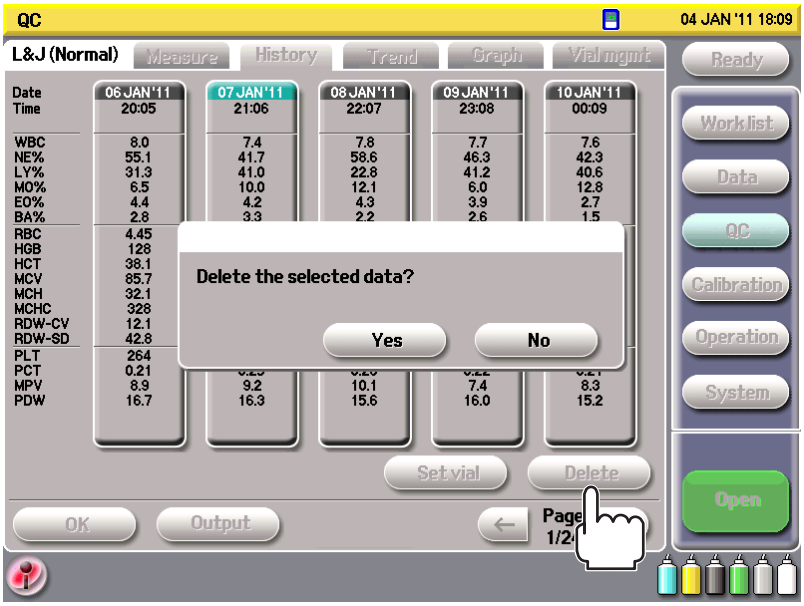
Deleting L & J Data Individually

1. On the History window, select one data to be deleted by pressing the desired date key. Use the arrow keys to find the desired data.



2. Press the Delete key.

   The confirmation message appears.

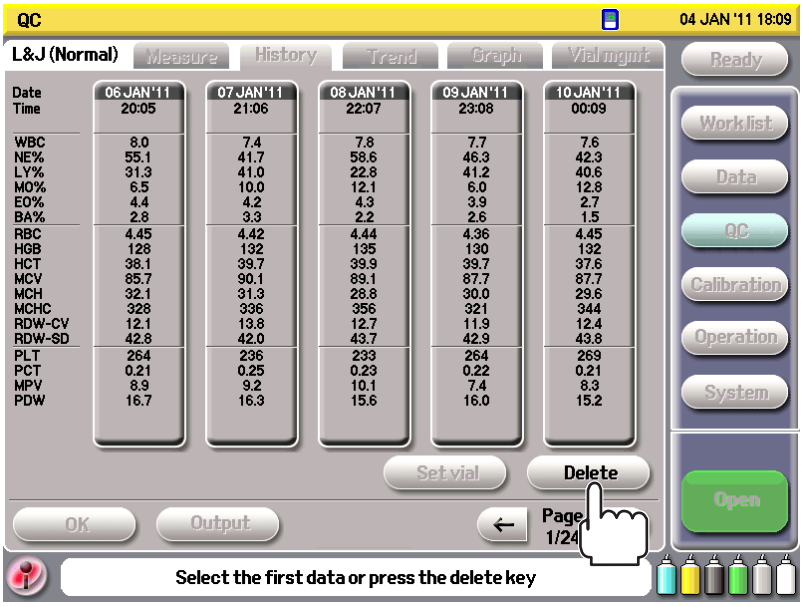


3. Press Yes to delete selected data. Press No to cancel the procedure.

Deleting L & J Data Consecutively

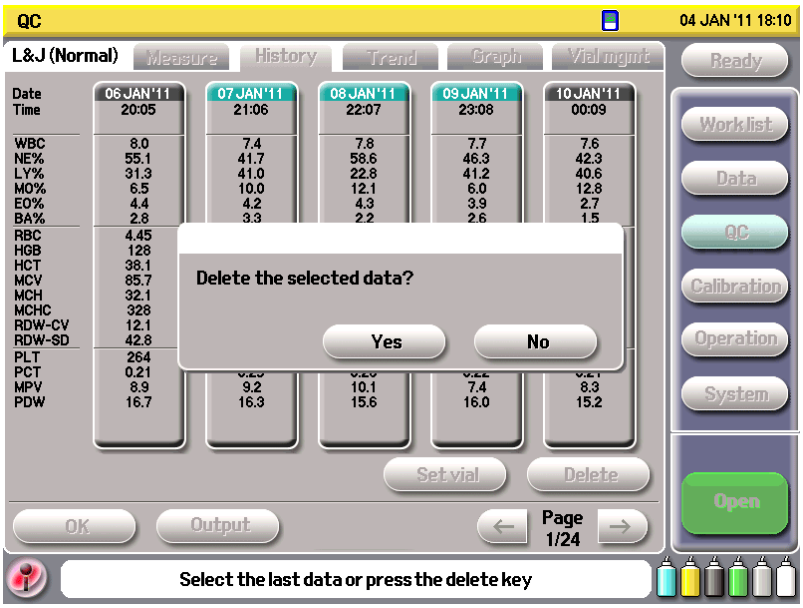
1. Press the Delete key on the History window.

   The “Select the first data or press the delete key” message appears on the window.



2. Press the date key of the first data. The “Select last data or press the delete key” message appears on the screen.

3. Find the last data using the arrow keys and press the date key of that data. A confirmation message appears on the window.



4. Press the Yes key. All data between the first and last date will be deleted. Press the No key to cancel the procedure.

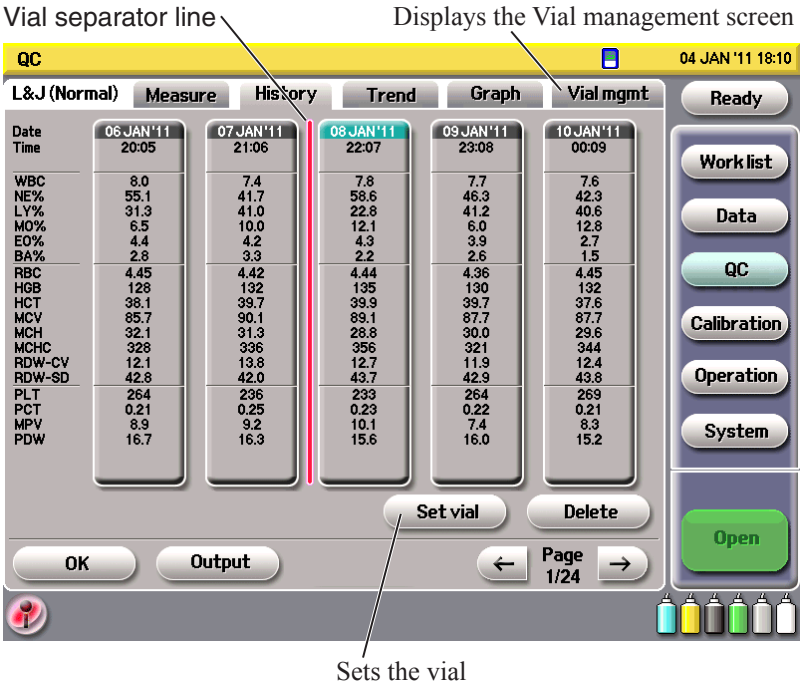
Setting Vial to L & J History

You can manage L & J History data by vial. Set vial when measuring new MEK-5DN/L/H hematology control.

1. Select the first data of the vial on the L & J History window.

2. Press the Set vial key. A red line is displayed at the lift of the selected data. The data from the line to the next line is data for one vial.

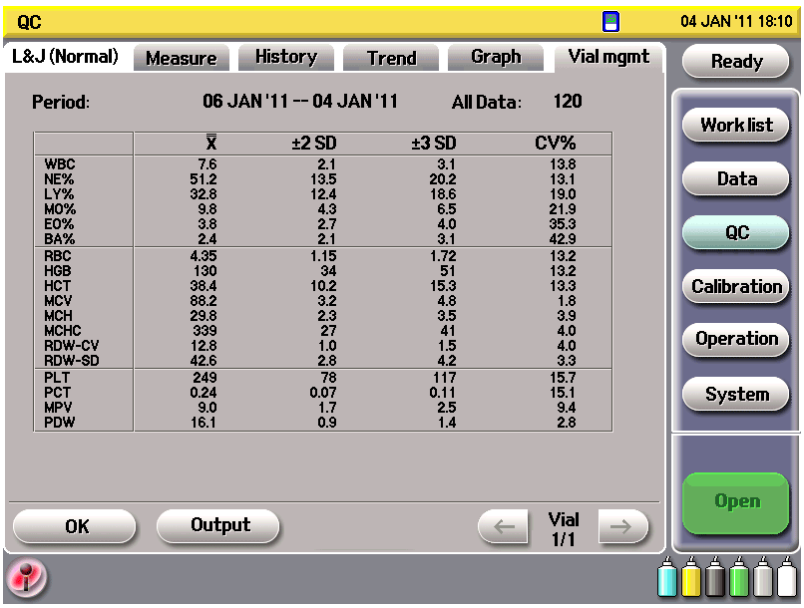
You can delete the line by selecting the data and pressing the Set vial key.



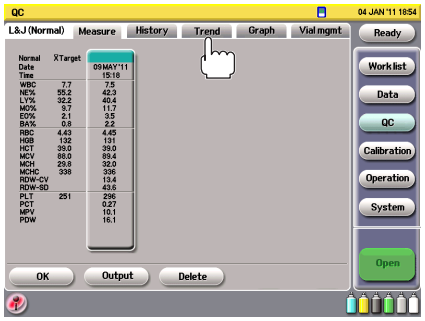
Displaying Vial Management Screen

On the Vial Management screen, you can display an average of L & J data ($\overline{\overline{X}}$), 2SD and 3SD of X, CV value of X.

Touch the Vial mgmt tab to display the Vial Management screen.

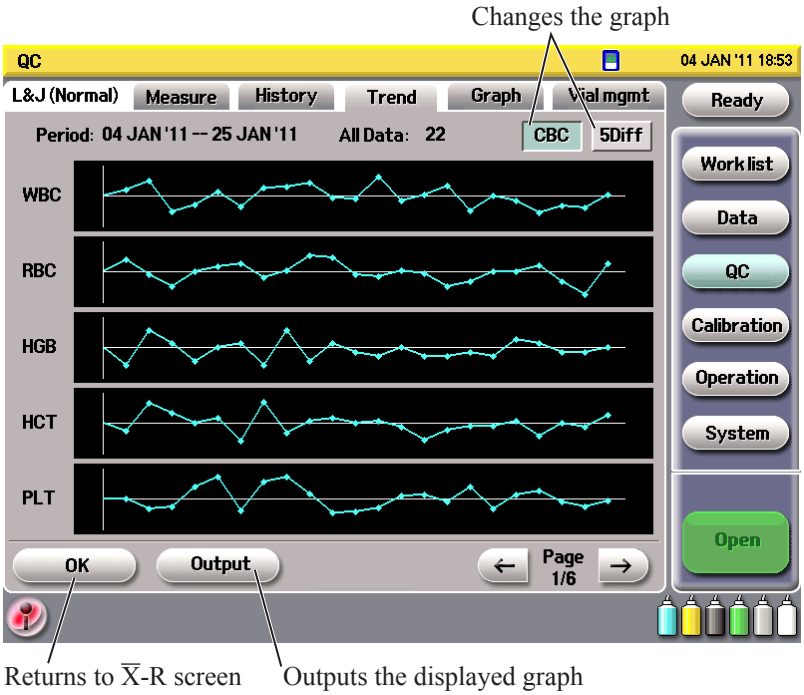


Displaying L & J Multi Trendgraph



1. Press the Trend tab on the L & J screen to display the L & J multi trendgraph.

2. Press the CBC or 5 Diff key to change the graph.
   - CBC: Display the CBC main 5 parameters (WBC, RBC, HGB, HCT, PLT)
   - 5 DIff: Display the 5 part differential parameters (LY%, MO%, NE%, EO%, BA%)



If a value is out of the range, the value is plotted in red on the graph.

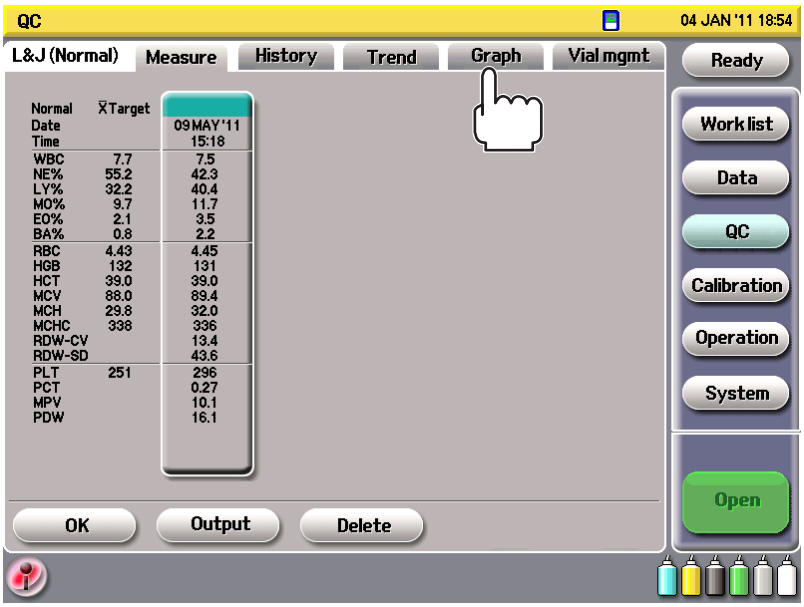
When <Output with “Output” key> on the SD Card setting is set to “On”, you can capture the window and send it to the SD card by pressing the Output key.

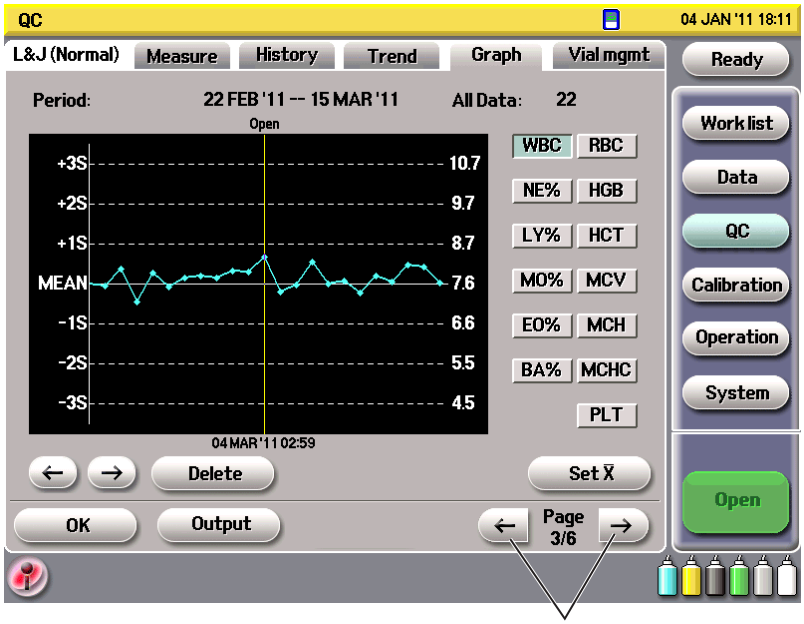
3. Press the OK key to return to the L & J screen.

Handling L & J Graphs

You can display the L & J graph for each parameter.

1. Press the Graph tab on the L & J screen. The graph is displayed on the screen.





Displays graph of other dates
(31 data/page, maximum 4 pages)

You can change parameters by pressing the parameter keys at the right part of the screen.

The “Out of range” message appears when the graph goes outside the limits.

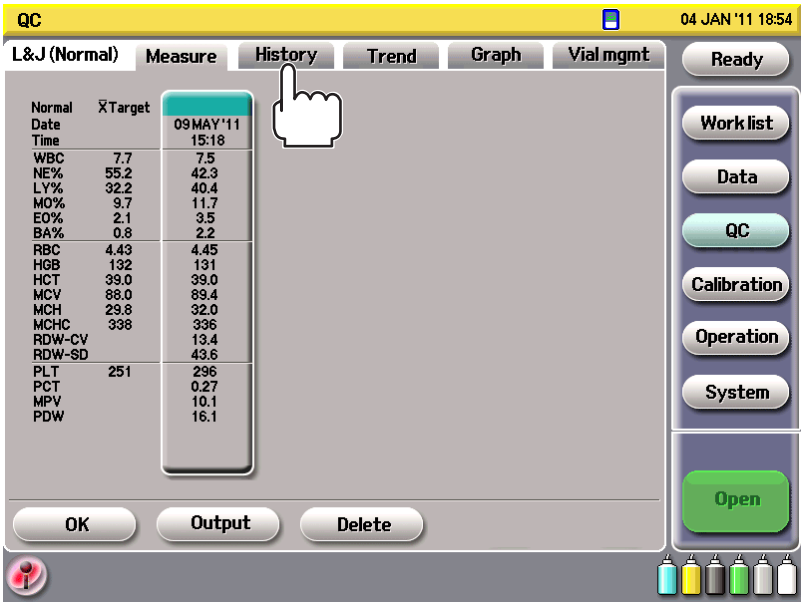
When <Output with “Output” key> on the Serial Port setting is set to “On” and <External device> is set to “EPSON VP”, you can output the data to the EPSON VP printer by pressing the Output key. You can also print the data with the internal printer.

2. Press the OK key to return to the previous screen.

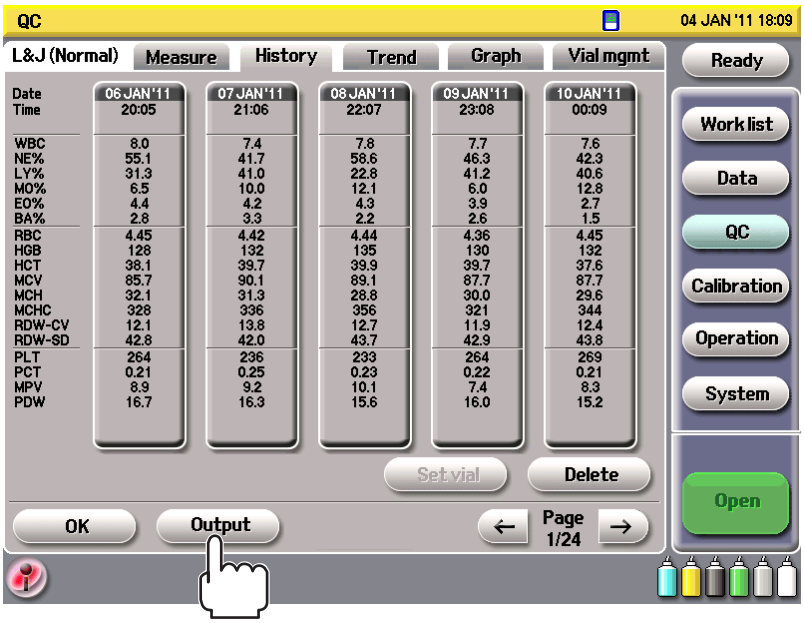
Saving L & J History Data

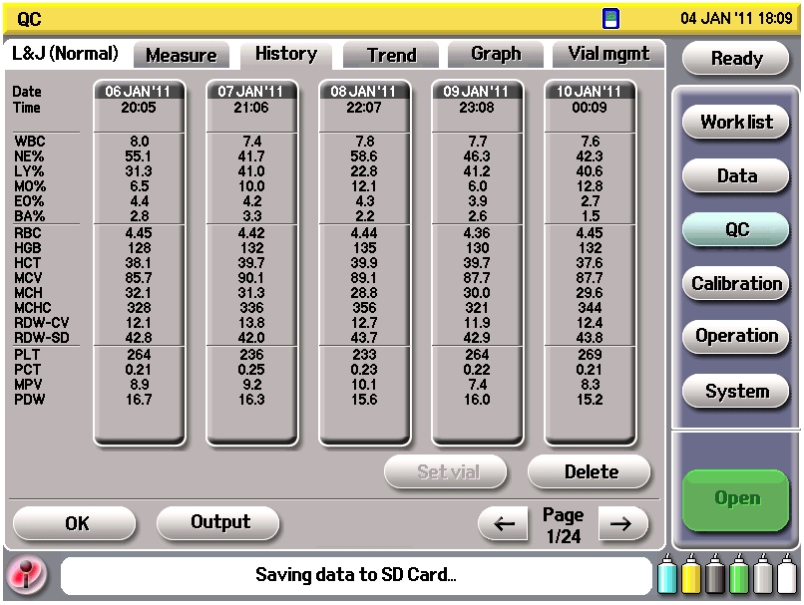
You can save the L & J history data to a SD memory card.

1. Press the History tab.



2. Press the Output key. “Saving data to SD card...” message appears and the data is saved to the SD memory card.




QC
04 JAN '11 18:09
L&J (Normal)
Measure
History
Trend
Graph
Vial mgmt
Ready
Date
Time
06 JAN '11 20:05
07 JAN '11 21:06
08 JAN '11 22:07
09 JAN '11 23:08
10 JAN '11 00:09
WBC 8.0 7.4 7.8 7.7 7.6
NE% 55.1 41.7 58.6 46.3 42.3
LY% 31.3 41.0 22.8 41.2 40.6
MO% 6.5 10.0 12.1 6.0 12.8
EO% 4.4 4.2 4.3 3.9 2.7
BA% 2.8 3.3 2.2 2.6 1.5
RBC 4.45 4.42 4.44 4.36 4.45
HGB 128 132 135 130 132
HCT 38.1 39.7 39.9 39.7 37.6
MCV 85.7 90.1 89.1 87.7 87.7
MCH 32.1 31.3 28.8 30.0 29.6
MCHC 328 336 356 321 344
RDW-CV 12.1 13.8 12.7 11.9 12.4
RDW-SD 42.8 42.0 43.7 42.9 43.8
PLT 264 236 233 264 269
PCT 0.21 0.25 0.23 0.22 0.21
MPV 8.9 9.2 10.1 7.4 8.3
PDW 16.7 16.3 15.6 16.0 15.2
Set vial
Delete
OK
Output
Page 1/24
Work list
Data
QC
Calibration
Operation
System
Open
Saving data to SD Card...

$\overline{X}_B$ ($\overline{X}$ Batch) Program

General

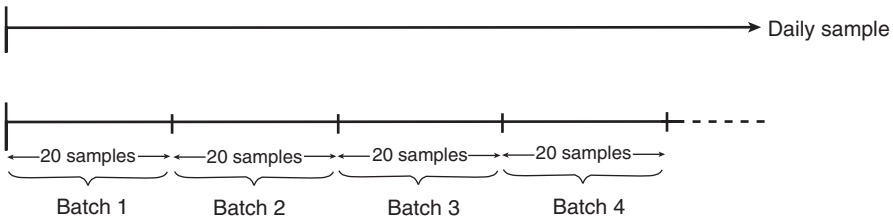
Overview of $\overline{X}_B$

The daily samples data are divided into batches of 20 samples. The data within each batch is averaged. With the mean $\overline{X}_B$ values, the precision in the system can be managed due to the extremely small physiological variation in red blood cell constants of MCV, MCH and MCHC. The $\overline{X}_B$ values are hardly affected by differences between samples so they faithfully reflect the precision in the system.

You can also use the $\overline{X}$D•CV program in conjunction with the $\overline{X}_B$ program. (Refer to the $\overline{X}$D•CV Program later in this section.)

Calculation of $\overline{X}_B$

The analyzer automatically divides the daily sample data into batches of 20 samples each.



For each batch of 20 samples, the $\overline{X}_B$ value is automatically calculated by the following equation.

$$X(B, i) = X(B, i-1) + SGN[F] \times (F/N)^2$$

$$F = \Sigma SGN[X_j - X(B, i-1)] \times \sqrt{|X_j - X(B, i-1)|}$$

- X (B, i) = $\overline{X}_B$ of present batch
- X (B, i-1) = $\overline{X}_B$ of previous batch
- Xj = Each data in batch
- SGN [ ] = Sign function
- N = Number of samples in batch

The $\overline{X}_B$ value of the previous batch is required to calculate $\overline{X}_B$ of the present batch. There are two methods of obtaining the initial $\overline{X}_B$ value of the batch before Batch 1.

i) Use the past obtained value for the same facility.

ii) The simple method is to substitute the mean values of MCV, MCH and MCHC for each initial $\overline{X}_B$ value of the batch before Batch 1.

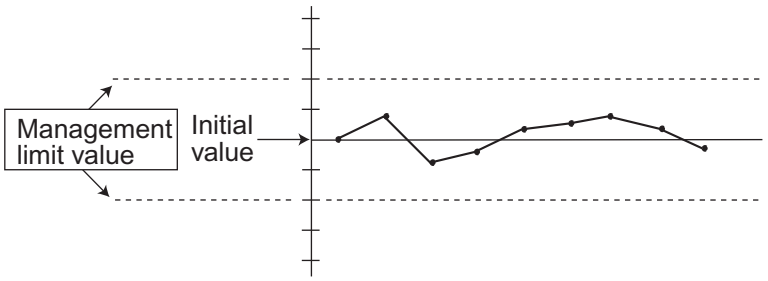
NOTE

If the mean value is used as the initial $\overline{X}_B$ value, the $\overline{X}_B$ value to be obtained gradually comes closer to a real or true value as the samples increase in number.

After about 100 samples are counted, the reliability of the $\overline{X}_B$ value is ensured. Usually, the mean values are somewhere near these values:

MCV: 89.5, MCH: 30.5, MCHC: 33.8

The $\overline{X}_B$ values are plotted on the screen.



The average of $\overline{X}_B$ is used as the initial value. The initial value will also be determined by the facility or examination room staff.

The management limit value should be determined by the facility or examination room staff. (For example, ±3% of the initial value.)

The analyzer provides continuous $\overline{X}_B$ management of up to 20 batches (400 samples). When the number of samples reaches 400 and the table becomes full, do the following procedures.

i) Use each $\overline{X}_B$ data in the last batch as the initial value.
ii) Change each initial value on the plotted graph to the mean $\overline{X}_B$. (The plotted graph is updated every 20 batches.)
iii) Delete all stored data to prevent data interference between the new and previous graphs. Refer to "Deleting Data" in Section 5.

CAUTION

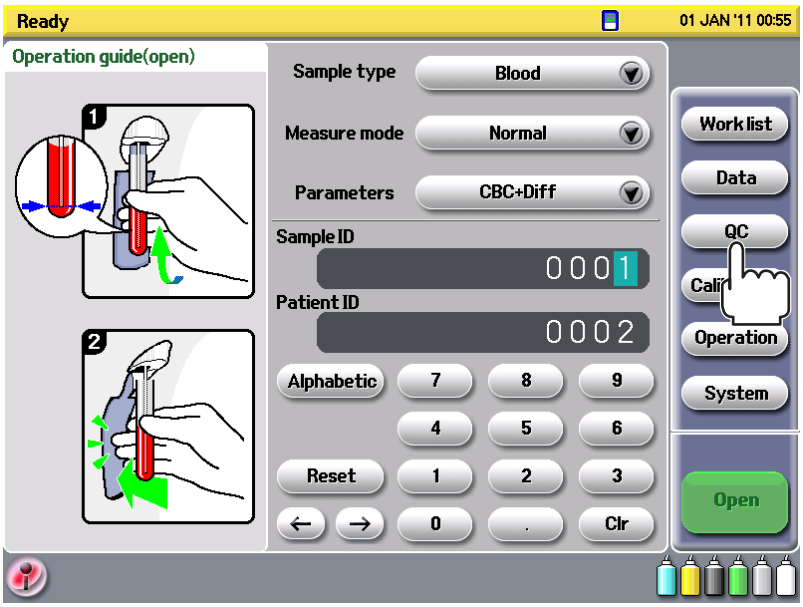
Each $\overline{X}_B$ is calculated from all the samples that have RBC count 500,000/µL or more. Therefore, data of MEK-5D Hematology Control should be deleted from the Data screen beforehand. Any measured data with "Control" as the sample type is excluded from the calculation.

NOTE

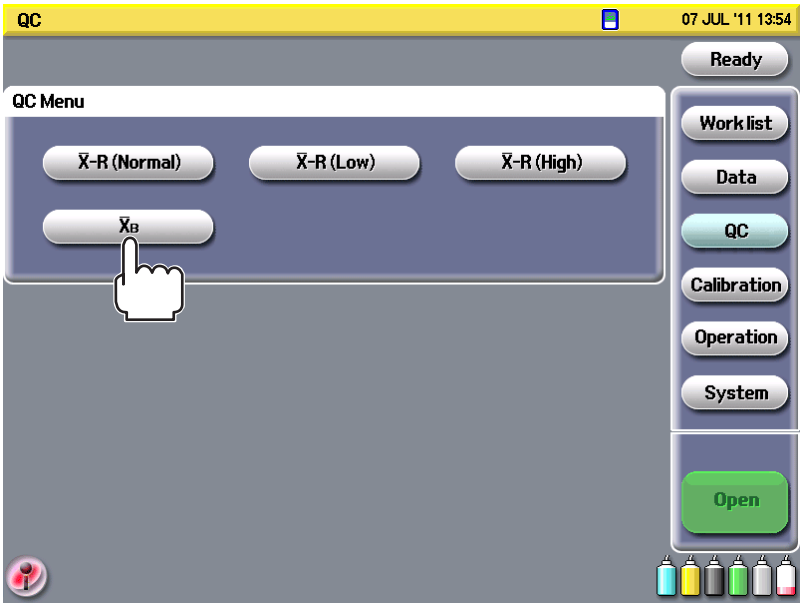
- When each mean value of MCV, MCH and MCHC is used as the initial value of $\overline{X}_B$, there is no reliability in the plotted graph until the $\overline{X}_B$ value comes closer to the true value and becomes stable.
- The management data for calibration and $\overline{X}$-R data are excluded from the calculation.

Handling $\overline{X}_B$ Data

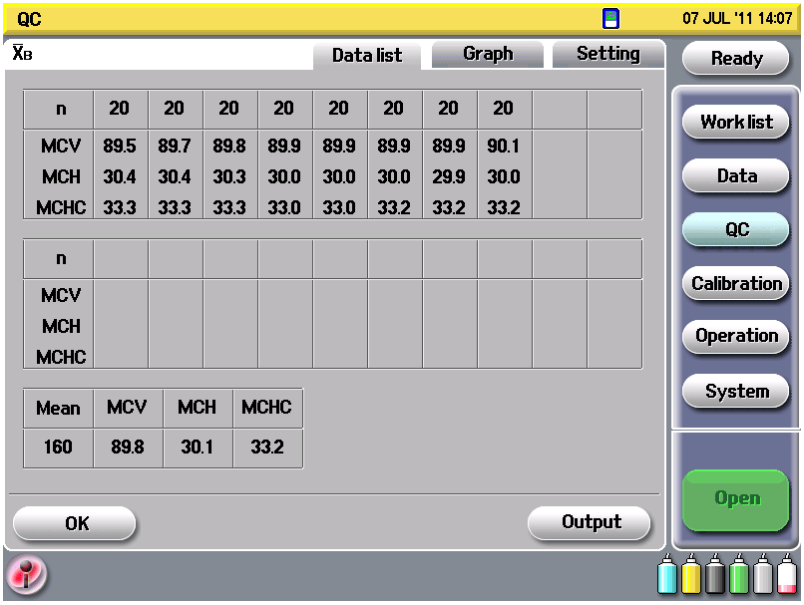
1. Press the QC key on the screen to display the QC screen.



2. Press the $\overline{X}_B$ key on the QC screen to display the $\overline{X}_B$ screen.



The $\overline{X}_B$ screen of the stored measured data is displayed on the screen.



N: Number of samples in each batch

MEAN: Averaged $\overline{X}_B$ for parameter (MCV/MCH/MCHC) and total number of samples

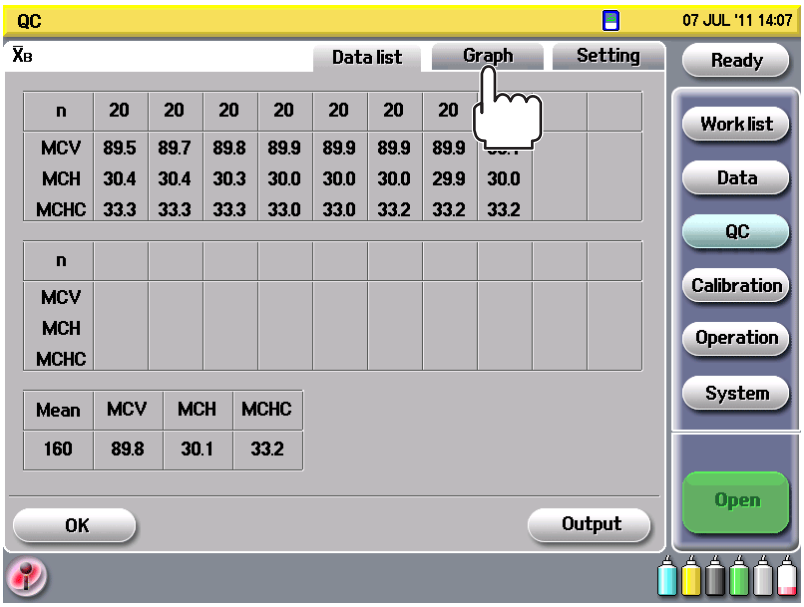
When <Output with "Output" key> on the Serial Port setting is set to "On" and <External device> is set to "EPSON VP", you can output the data to the EPSON VP printer by pressing the Output key. You can also print the data with the internal printer.

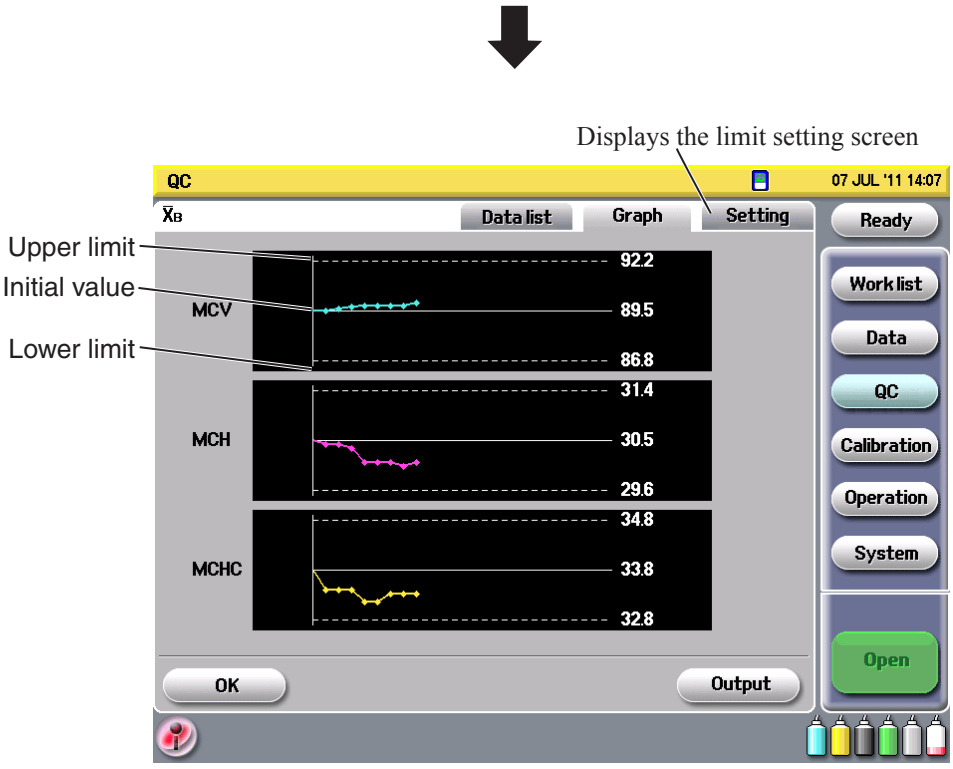
To display $\overline{X}_B$ graph, press the Graph tab. Refer to the "Handling $\overline{X}_B$ Graph" later in this section.

3. Press the OK key to return to the QC screen.

Handling $\overline{X}_B$ Graph

1. Press the Graph tab on the $\overline{X}_B$ screen to display the $\overline{X}_B$ graph screen.





The MCV, MCH and MCHC graphs are plotted on the screen.

When <Output with "Output" key> on the Serial Port setting is set to "On" and <External device> is set to "EPSON VP", you can output the data to the EPSON VP printer by pressing the Output key. You can also print the data with the internal printer.

2. Press the OK key to return to the $\overline{X}_B$ screen.

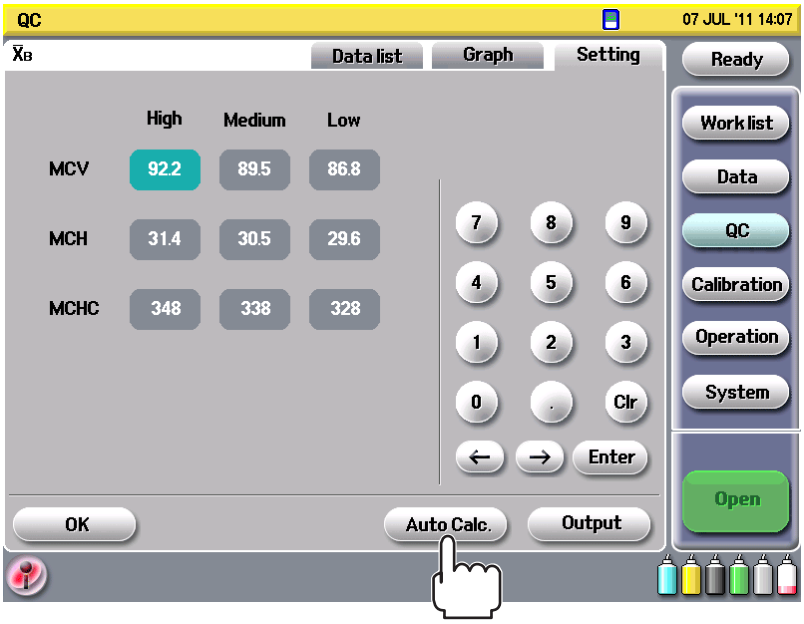
Setting $\overline{X}_B$ Medium and Limit Values

When the $\overline{X}_B$ program is used for the first time, set the $\overline{X}_B$ medium and limit values.

1. Press the Settings tab on the $\overline{X}_B$ screen to display the $\overline{X}_B$ limit setting screen.

2. To change the limits individually:
   i) Touch the setting value or use the arrow keys to move the cursor to the setting value you want to change.
   ii) Enter the desired value using the numeric keys. Press the Enter key to register the value. The cursor moves to the next field.
   iii) Repeat steps i) and ii) to change other values.

   To automatically calculate the ideal values for all values:
   i) Press the Auto Calc. key. The confirmation message appears.



   ii) Press OK to set the ideal values which are automatically calculated based on the stored data. If you press Cancel, the process is canceled and the screen returns to the $\overline{X}_B$ limit screen.

3. Press the OK key to return to the QC screen.

Appendix A Parts and Accessories

Standard Accessories

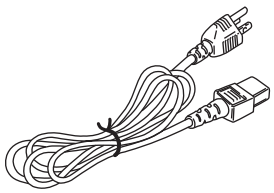
NOTE

- Use only Nihon Kohden specified parts and accessories to assure maximum performance from your instrument.
- When ordering the following accessories and options, specify the supply code no. When the supply code no. is not provided with the accessory, specify the code no.

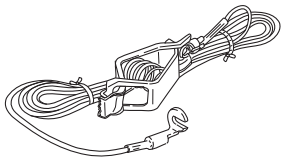
No.	Description	Qty	Model/Code no.	Supply code no.
1	Power cord	1	—	—
2	Ground lead	1	—	—
3	Fuse 3.15 A time-lag	2	346199	—
4	Diluent tube (marked blue)* Detergent tube for CLEANAC (marked green)* Waste tube (marked red)*	1 each	—	—
5	18 L cap	3	—	T723A
6	18 L tube assy 2	1	YZ-0356	T461A
7	18 L tube assy (WASTE)	1	6144-001979	—
8	Cleanac tube 8 for CLEANAC•3 (marked white)	1	—	T464A
9	Cleanac tube assy (8222)	2	0214-011645	—
10	Hemolynac•3 cap (yellow)	1	—	T447B
11	Hemolynac•5 cap (black)	1	—	T447C
12	Hemolynac•3 tube (570) (marked yellow)	1	—	T473A
13	Hemolynac•5 tube (570) (marked black)	1	—	T585A
14	Sampling nozzle	1	—	T479A
15	Filter assy	4	—	T802
16	Pump tube (N) assy	2	YS-001B1	T462
17	Waste container (10 L)	1	YZ-0248	T417
18	Laser key	2	—	—
19	T-wrench TBS-8 (8 mm)	1	9000-005986	—
20	1 L tube assy	1	YZ-001B7	T-464D

* When ordering these tubes for replacement, order YS-002B4 tube A (supply code no. T409, 1.5 m) or connection tube (supply code no. T463, 5.0 m).

1.



2.



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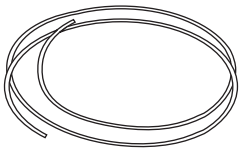

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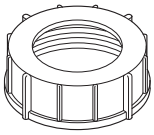

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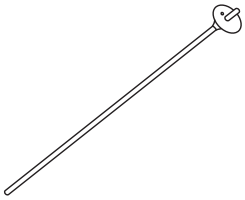

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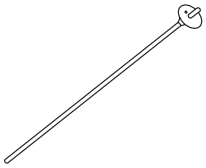

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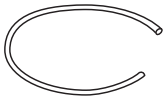

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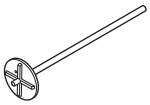

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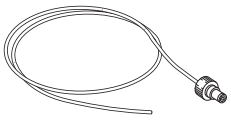

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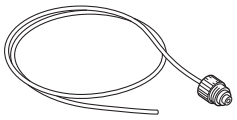

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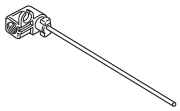

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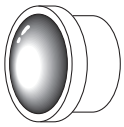

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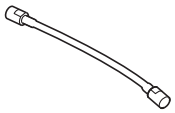

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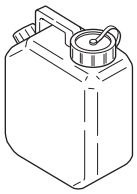

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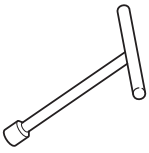


Options

NOTE

- Use only Nihon Kohden specified parts and accessories to assure maximum performance from your instrument.
- When ordering the following accessories and options, specify the supply code no. When the supply code no. is not provided with the accessory, specify the code no.

WA-730VK Printer Unit

Thermal printer. Installed in the hematology analyzer. Prints numeric data, scattergrams, and histograms on thermal roll paper.

WA-713V Printer (Seiko Epson VP-700 or equivalent, PM-730C or equivalent, or Canon BJS-550 or equivalent)

Connected to the printer socket on the rear panel of the hematology analyzer. Prints numeric data, scattergrams, and histograms on normal paper or continuous paper.

WA-461V Card Printer (Seiko Epson TM-U295 or equivalent)

Connected to the serial port on the rear panel of the hematology analyzer. Prints numerical data on a hematology data card.

When using the TM-U295 printer, set the bit switch at the bottom of the printer as follows.

DIP SW 1	Settings	DIP SW 1	Settings
1	OFF	5	ON
2	OFF	6	ON
3	OFF	7	OFF
4	OFF	8	OFF

ZK-820V Bar Code Reader

ZK-820V is a hand-held bar code reader. It can read the bar code label (sample ID number of up to 13 digits) and input to the measurement result by connecting to the ZK-820V bar code reader socket on the rear panel of the analyzer.

The bar code reader can read the following codes:

- Industrial 2 of 5
- ITF
- JAN/EAN/UPC
- NW-7
- CODE 39
- CODE 93
- CODE 128

For details, refer to the ZK-820V bar code reader manual.

For sample ID, use the characters that are supported by each code. Otherwise, the bar code reader cannot read the characters correctly.

QP-822V Data Management Software

This software can be installed in a PC for data communication with the hematology analyzer. You can receive the measured data from a hematology analyzer and edit and print the data on the PC. The work list can be sent from the PC to the hematology analyzer and the measured data according to the work list is sent back to the PC to be edited.

YZ-0318 D9-D25 Cable

For connecting WA-461V/713V card printer to the hematology analyzer.

YZ-0320 USB Cable, 0.7 m

YZ-0321 USB Cable, 2.0 m

YZ-0323 RS-232C Cable

For connecting PC to the hematology analyzer.

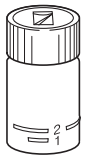
Consumables

NOTE

When ordering the following options/consumables, specify the supply code. When the supply code is not provided with the options or consumables, specify the model or code number.

No.	Description	Packing unit	Supply code no.
1	Sample container set, MEK-435	200 pcs × 5	T435
2	Recording paper for WA-730VK, RQW58-2	10 rolls	A819B
3	Diluent ISOTONAC•3, MEK-640	18 L	T436D
4	Detergent CLEANAC•3, MEK-620 Detergent CLEANAC, MEK-520	5 L	T438D T438
5	Hemolysing reagent HEMOLYNAC•3N, MEK-680 Hemolysing reagent HEMOLYNAC•5, MEK-910	500 mL × 3	T498 T496
6	Hematology control MEK-5DN MEK-5DL MEK-5DH	 3 mL × 2 3 mL × 2 3 mL × 2	 T456 T456L T456H
7	Hemoglobin filter assy set, YZ-0024	10 pcs	T802
8	Pump tube (N) assy, YS-001B1	1 pcs	T462
9	Hematology data card for WA-460V card printer	100 cards × 4 copies	C976
10	Hematology data sheet for WA-710V printer, narrow type Hematology data sheet for WA-710V printer, wide type	1000 sheets 2000 sheets	C975 C962
11	Sampling nozzle, 6114-096103C, YZ-0193	2	T444B
12	7 µm polymer microsphere suspensions, YZ-0194	80 mL × 1	T905
13	Hemolynac•3 tube (570)	1	T473A
14	Hemolynac•5 tube (570)	1	T585A
15	Cleanac tube 8 (1.5 m), 6114-003748	1	T464A
16	Connection tube (5.0 m), 2114-080786D	1	T463
17	18 L diluent container cock, 3455788A	1	T723
18	Tube assy	2	T470A
19	Container cap for detergent and diluent	1	T469
20	QM-001D SD memory card	1	—
21	Reagent bottle set	1	T466A
22	Cleaning bottle kit	1	T414
23	Sample cup (5.0 mL), TA-8	500 pcs	T857
24	Micro cap (20 µL)	100 pcs	T812
25	Micro cap (10 µL)	100 pcs	T813
26	Sahli pipette, (0.02 mL), 2430302	1	T421
27	Sampling nozzle for MS-721V cap pierce unit, 6144-011237A	1	—
28	Cotton swabs	100 pcs	—
29	Vacuum sample tube T-440A	1	T440B
30	Cap pierece needle, YZ-0312	1	—
31	Hematology calibrator, MEK-CAL	1	T457

1.



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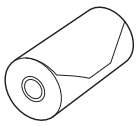

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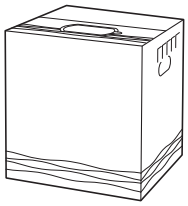

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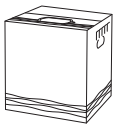

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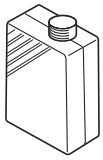

6.

MEK-5DN, MEK-5DL,
MEK-5DH

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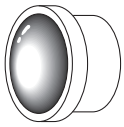

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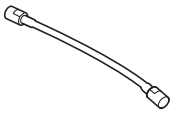

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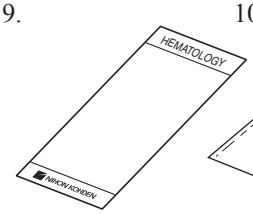

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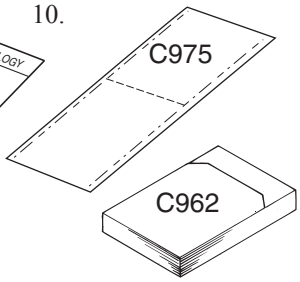

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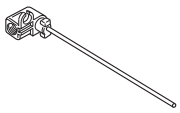

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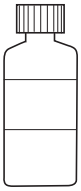

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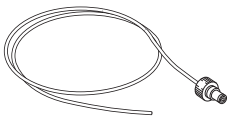

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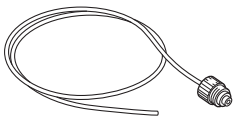

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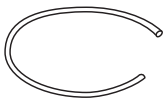

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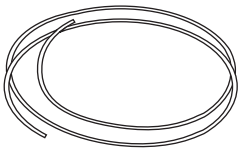

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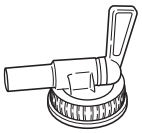

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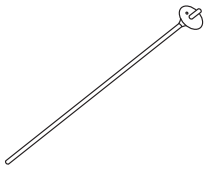
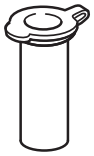


19.

20.

For capillary blood measurement

23.



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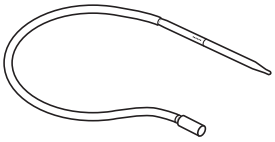
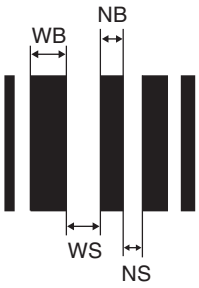


Appendix B Bar Codes

Bar Codes for Using the ZK-820V Hand-held Bar Code Reader

Using Bar Codes



A bar code consists of narrow bars (NB), wide bars (WB), narrow spaces (NS) and wide spaces (WS). The width of the WB and WS depends on the width of the NB. The ratio between NB and WB is NB:WB = NS:WS = 1:2 to 1.3. Usually, it is 1:2.5.

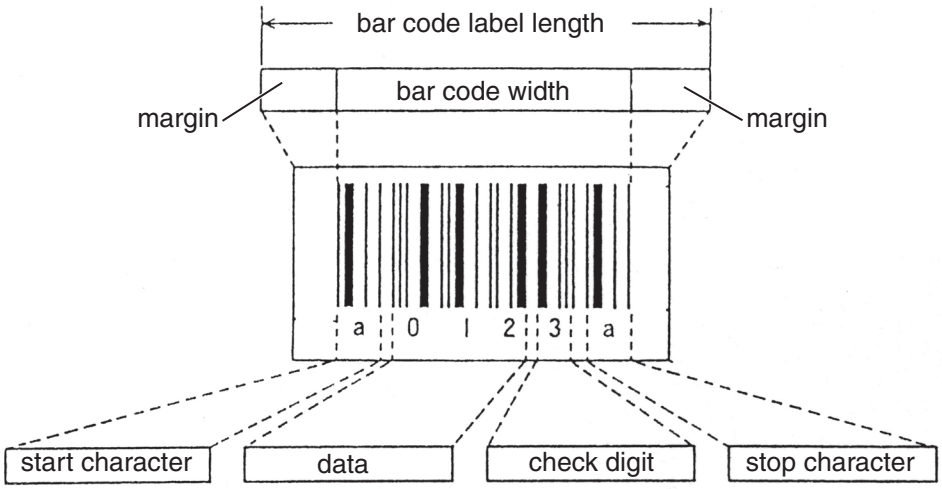
When using the optional ZK-820V Hand-held bar code reader, the bar code label of the sample can be read by the bar code reader and this code is entered as the sample ID.

NOTE

- ID can only be entered up to 13 digits. When the bar code has more than 13 digits, the ID cannot be entered.
- When CODABAR (NW-7) is used for the bar code type, a letter from “a”,“b”,“c” and “d” is assigned to the beginning and end of the ID. When there are more than 13 digits in the ID because of these start/stop characters or when you do not want these letters to be included in the sample ID, read “Do not send” bar code. Refer to the “Changing Settings” in Section 5.
- When using the ITF bar code type, IDs may be frequently misread by the bar code reader when compared to the other types of bar codes, especially when the printing quality of the label is poor. Be careful not to mix up samples when using ITF bar codes.

For the bar code to be read properly by the bar code reader, attach the bar code label to the sample tube checking the following points. (Refer to the illustration below.)

- The bar code label length must be within 60 mm.
- NB must be wider than 0.125 mm.
- The bar code width must be 35 mm.
- The left and right margins must be the same size and 10 times larger than NB.



If the bar code cannot be read properly by the bar code reader, check the following points.

- Bar code is dirty or damaged
- Margin on the bar code is too small
- Bar code print is faint
- Bar code is printed in silver or is covered by laminate film
- The printing quality of the bar code is poor (The printing quality is poor especially when printed on a dot printer or ink jet printer. When printing on such a printer, NB must be as wide as possible. If the bar code type is JAN or CODE128, code may not be read properly.)
- The appropriate bar code type or check digit type is not set on the bar code reader.

Changing the Settings

To change the setting of the BL-N60RK bar code reader, use the following procedure. The setting are saved in an EEPROM.

1. With the bar code reader, read the three bar codes of "Start setting" from top to bottom within 15 seconds of turning the bar code reader power on. The beeper sounds five times to indicate that the bar code reader has entered the setup mode.

2. Read all necessary parameter bar codes of the items to be set.

NOTE

The factory setting is indicated with < >.

3. When setting is complete, read the "Complete setting" bar code. The settings are saved in an EEPROM to exit the setup mode (The beeper sounds five times, indicating completion of this procedure.).

4. After the settings are completed, turn off the bar code reader.

5. Reading the "Initialize" bar code in the setup mode will reset the bar code reader to the factory settings.

6. Reading "Cancel setting" bar code cancels any changes and resets to the settings prior to entering the setup mode.

Example

To change the settings to not read ITF code:

1. Within 15 seconds of turning on the bar code reader, read the three bar codes in the "Start setting" from top to bottom. Beepers sounds five times.
2. Read the "OFF" of ITF.
3. Read the "Complete setting" bar code.
4. Turn off the bar code reader to complete the settings.

Appendix C Printing Examples

Printing Examples

WA-730VK internal printer

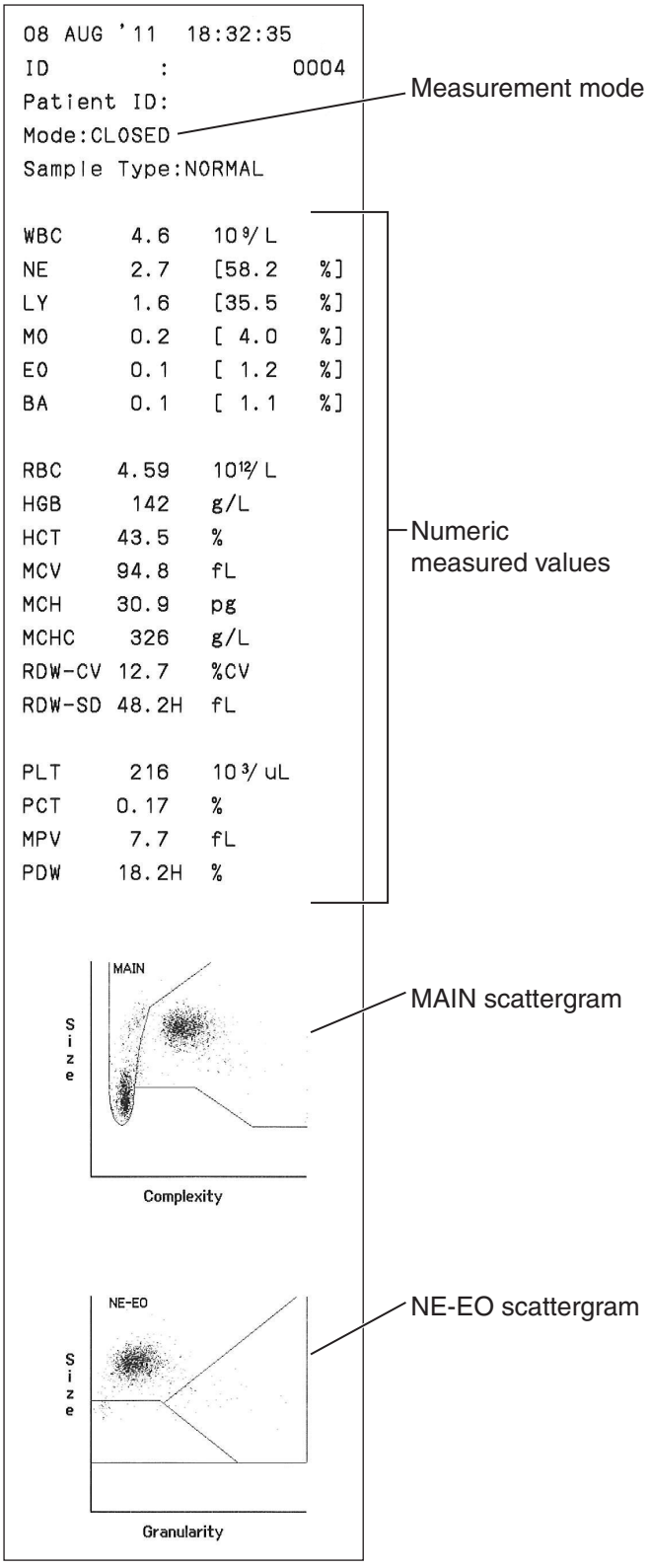
Settings on the Internal Printer screen of the Settings screen

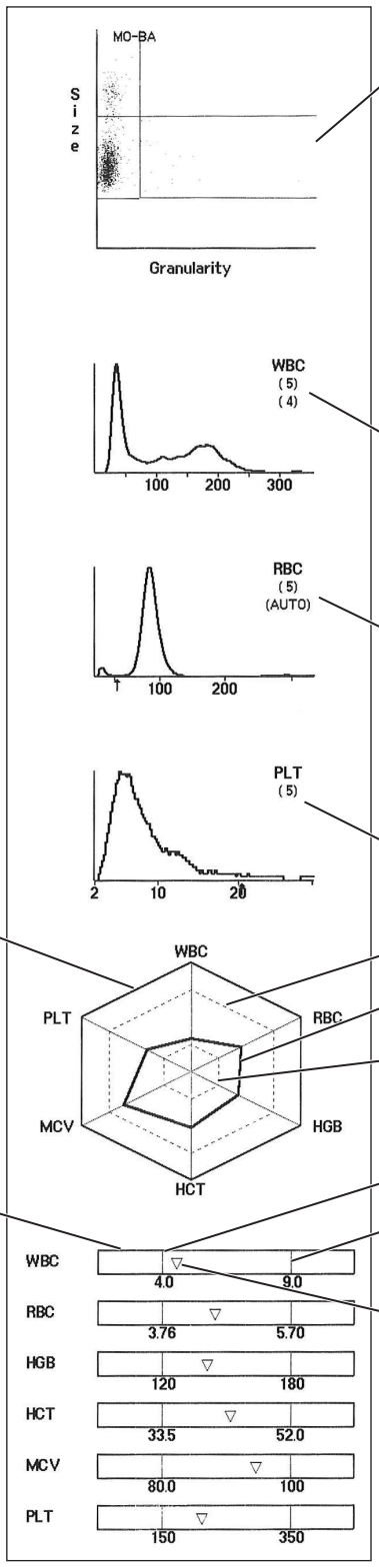
Print settings tab

Print parameters:	23
Print scattergrams:	All
Print histograms:	All
Print flags:	Off
Print radar graph:	On

Print Normal Range tab

On for WBC, RBC, HGB, HCT, MCV and PLT




MO-BA
Size
Granularity
MO-BA scattergram
WBC
(5)
(4)
100
200
300
WBC histogram
RBC
(5)
(AUTO)
100
200
RBC histogram
PLT
(5)
2
10
20
PLT histogram
Radar graph
WBC
PLT
RBC
MCV
HGB
HCT
Normal range upper limit
Measured value
Normal range lower limit
Normal range graph
Normal range lower limit
Normal range upper limit
Measured value
WBC
4.0
9.0
RBC
3.76
5.70
HGB
120
180
HCT
33.5
52.0
MCV
80.0
100
PLT
150
350

External printer

Settings on the Serial Port screen of the Settings screen

External device: EPSON VP

Print format: Numeric

Paper width: Wide

```
DATE        TIME    WBC             RBC     HGB     HCT     MCV     MCH     MCHC    PLT
ID                  NE      NE%     RDW-CV                                          PCT
                    LY      LY%     RDW-SD                                          MPV
                    MO      MO%                                                     PDW
                    EO      EO%
                    BA      BA%

2011/08/08 18:32     4.6            4.59    142     43.5    94.8    30.9    326     216
           0004      2.7    58.2    12.7                                            0.17
                     1.6    35.5    48.2H                                           7.7
                     0.2     4.0                                                    18.2H
                     0.1     1.2
                     0.1     1.1

2011/08/08 20:47     7.9            4.63    138     42.0    90.7    29.8    329     317
           0004      6.0    75.8    14.1H                                           0.17
                     1.2    15.6L   51.2H                                           5.4L
                     0.5     6.3                                                    18.1H
                     0.1     1.4
                     0.1     0.9
```

Settings on the Serial Port screen of the Settings screen

External device: EPSON VP

Print format: Numeric

Paper width: Narrow

Date : 08 AUG 2011 18:32
Sample ID : 0004
CLOSED NORMAL

WBC	4.6	10^9/L	(4.0- 9.0)
NE	2.7	10^9/L	(1.1- 7.0)
LY	1.6	10^9/L	(0.7- 5.1)
MO	0.2	10^9/L	(0.0- 0.9)
EO	0.1	10^9/L	(0.0- 0.9)
BA	0.1	10^9/L	(0.0- 0.2)
NE%	58.2	%	(28.0-78.0)
LY%	35.5	%	(17.0-57.0)
MO%	4.0	%	(0.0-10.0)
EO%	1.2	%	(0.0-10.0)
BA%	1.1	%	(0.0- 2.0)
RBC	4.59	10^{12}/L	(3.76-5.70)
HGB	142	g/L	(120- 180)
HCT	43.5	%	(33.5-52.0)
MCV	94.8	fL	(80.0- 100)
MCH	30.9	pg	(28.0-32.0)
MCHC	326	g/L	(310- 350)
RDW-CV	12.7	%CV	(11.6-14.0)
RDW-SD	48.2H	fL	(39.0-46.0)
PLT	216	$10^3/\mu L$	(150- 350)
PCT	0.17	%	(0.16-0.33)
MPV	7.7	fL	(7.0-11.0)
PDW	18.2H	%	(15.0-17.0)

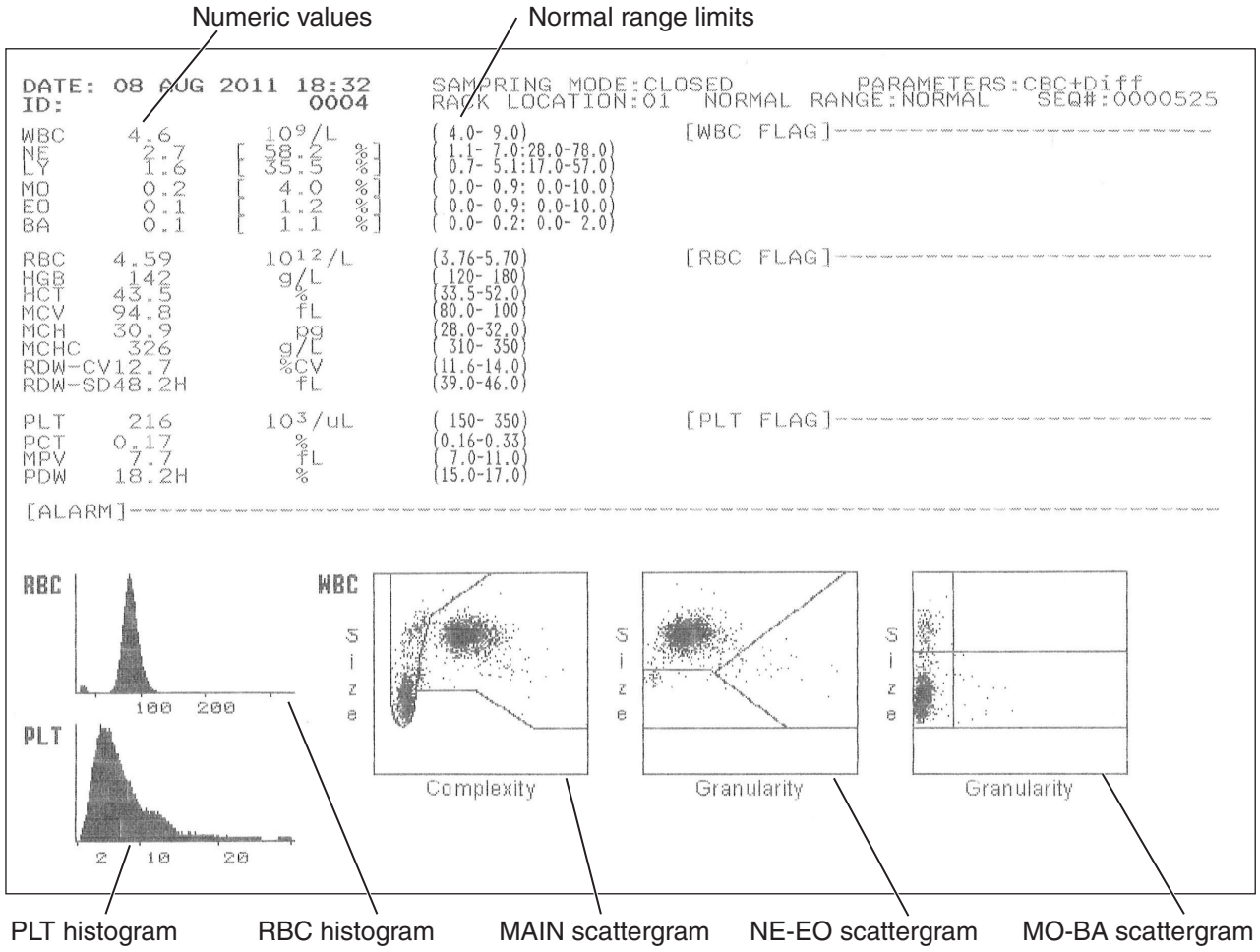
A-C

Settings on the Serial Port screen of the Settings screen

External device: EPSON VP

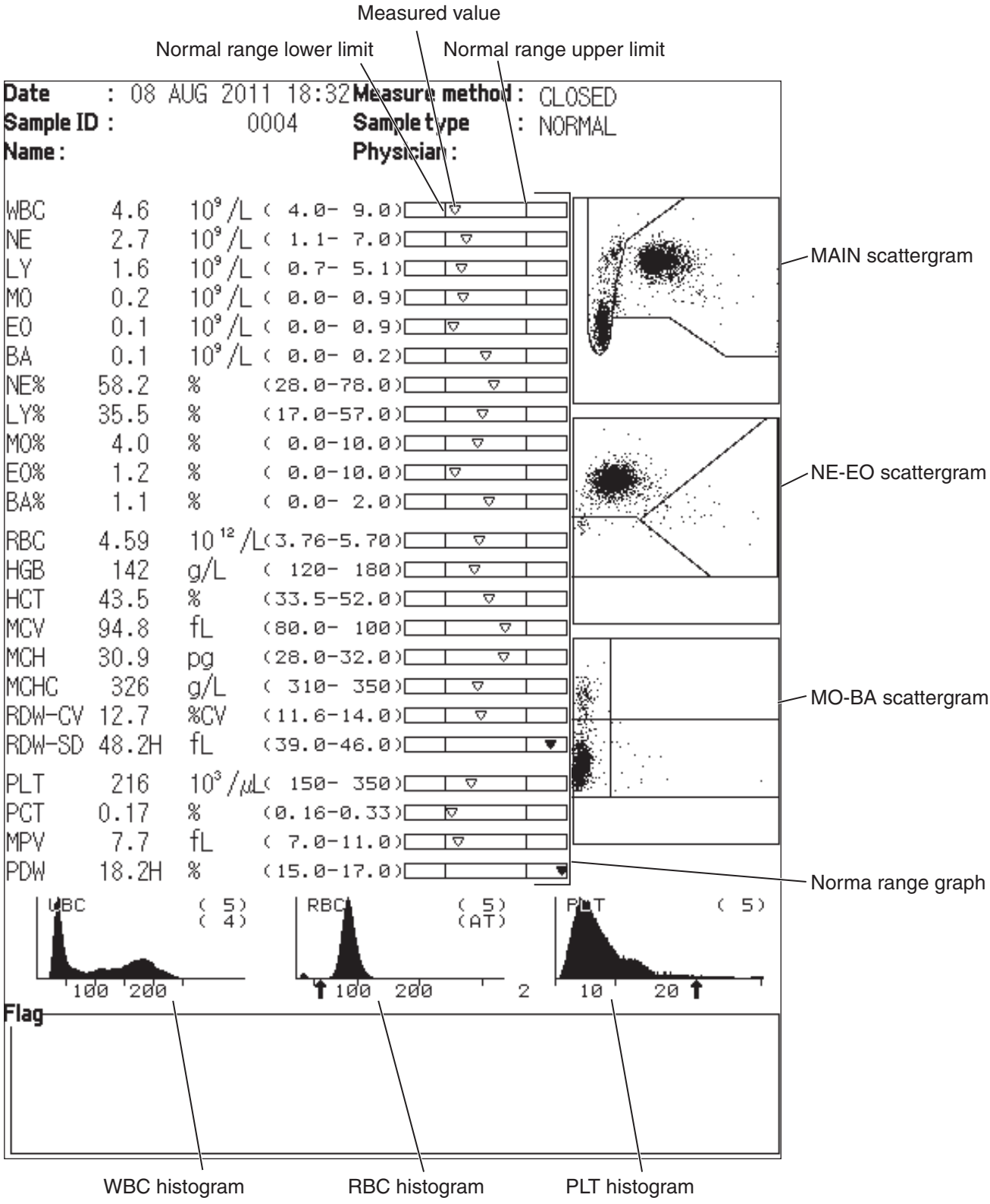
Print format: Num + Graph

Paper width: Wide



Settings on the Serial Port screen of the Settings screen

External device: EPSON VP
Print format: Num + Graph
Paper width: Narrow



Appendix D Factory Default Settings

Sample type

Item	Default
Sample type	Blood, Male, Female, Child, Infant, Other 1, Other 2, Other 3, Other 4, Control

Normal range

Parameter	Lower Limit	Upper Limit	Unit
WBC	4.0	9.0	$10^3/\mu L$
RBC	3.76	5.70	$10^6/\mu L$
HGB	12.0	18.0	g/dL
HCT	33.5	52.0	%
MCV	80.0	100.0	fL
MCH	28.0	32.0	pg
MCHC	31.0	35.0	g/dL
PLT	150	350	$10^3/\mu L$
NE%	28.0	78.0	%
LY%	17.0	57.0	%
MO%	0.0	10.0	%
EO%	0.0	10.0	%
BA%	0.0	2.0	%
NE	1.1	7.0	$10^3/\mu L$
LY	0.7	5.1	$10^3/\mu L$
MO	0	0.9	$10^3/\mu L$
EO	0	0.9	$10^3/\mu L$
BA	0	0.2	$10^3/\mu L$
RDW-CV	11.6	14.0	%
RDW-SD	39.0	46.0	fL
PCT	0.16	0.33	%
MPV	7.0	11.0	fL
PDW	15.0	17.0	%

Units: USA

Operation

Item	Default
Background check	Yes
Initial sampling mode	Closed
Use reagent management	Off
Measurement count	1
Display alarm on recount	No
Measurement result display format	Show all
PLT advanced count threshold	$15 \times 10^4/\mu L$
Continue dilution mode	No
Pre-dilution volume	20 µL
Reset auto ID at power on	On
Number of digits for ID	13-digit
ID Settings	Auto
Use patient ID	Off

Flags

Item	Highlighted	Default
Leukocytosis	Off	18 (10^3/μL)
Leukopenia		2.5 (10^3/μL)
Neutrophilia		11 (10^3/μL)
Neutropenia		1.0 (10^3/μL)
Lymphocytosis		4.0 (10^3/μL)
Lymphopenia		0.8 (10^3/μL)
Monocytosis		1.0 (10^3/μL)
Eosinophilia		0.7 (10^3/μL)
Basophilia		0.2 (10^3/μL)
Blasts	On	—
Immature Gr		
Left Shift		
Atypical Ly		
Poor Hemolyzation		
Small Nucleated Cells	Off	
Ly-Mo Interference		
Ne-Eo Interference		

QC Settings

Item	Default
QC method	$\overline{X}$-R
Save the QC measurement data	Yes
Auto send the QC data after measurement	Yes
$\overline{X}$ limit calculation	±2SD

Reagent mgmt

Item	Current	Warning	Capacity
Diluent (L)	18.0	1.0	18.0
Hemolynac 3N (mL)	500	100	500
Hemolynac 5 (mL)	500	200	500
Cleanac (L)	5.0	0.5	5.0
Cleanac 3 (L)	5.0	0.5	5.0
Waste (L)	0.0	9.0	10.0

Auto Clean

Item	Default
Time	1st: 23:00, 2nd to 4th: 00:00
Operation	1st: Clean, 2nd to 4th: Off

Date & time

Item	Default
Date format	DD/MMM/YY

Output - Internal Printer

Item	Default
Print parameters	23
Print scattergrams	Main only
Print histograms	RBC + PLT
Print flags	On
Print chart	Off
Print Normal Range	Off for all parameters

Output - Serial Port (Port 1, Port 2)

Item	Default
Output with “Output” key	Port 1: Off Port 2: Off
Output after meas.	Port 1: Off Port 2: Off
External device	Port 1: EPSON VP Port 2: PC
<When the External device is set to “EPSON VP”>	
Print format	Num + Graph
Print scattergrams	All
Print histograms	All
Print flags	On
Print Normal Range	On
Paper length	66 Data/Page
Paper width	Wide
Baud rate	19200
Data bits	8
Parity	None
Stop bits	1
<When the External device is set to “Card Printers”>	
Print parameters	23
Print Item Names	DIFF only
Top space	5 lines
Left space	0
Row size	10 inches
Baud rate	9600
Data bits	8
Parity	Even
Stop bits	1
<When the External device is set to “PC”>	
Baud rate	19200
Data bits	8
Parity	None
Stop bits	1
<When the External device is set to “Other”>	
Baud rate	9600
Data bits	8
Parity	Even
Stop bits	1

Output - OPTION

Item	Default
Output setting	Other
Baud rate	9600
Data bits	8
Parity	Even
Stop bits	1

Output - SD Card

Item	Default
Output with “Output” key	On
Output after meas.	Off

Output - USB

Item	Default
Output with “Output” key	On
Output after meas.	On
Analyzer name	Unit 1

Sound/LCD

Item	Default
Measure count sound	On
Screen brightness	Normal

$\overline{X}$R-$\overline{X}$ Value

$\overline{X}$-R Normal

Parameter	$\overline{X}$ Target	$\overline{X}$ Limit	R Target	R Limit	Unit
WBC	7.7	±0.8	0.8	0.6	$10^3/\mu L$
NE%	55.2	±5.0	5.0	10.0	%
LY%	32.2	±5.0	5.0	10.0	%
MO%	9.7	±3.0	3.0	6.0	%
EO%	2.1	±4.0	4.0	8.0	%
BA%	0.8	±1.0	1.0	2.0	%
RBC	4.43	±0.20	0.20	0.40	$10^6/\mu L$
HGB	13.2	±0.5	0.50	1.0	g/dL
HCT	39.0	±2.4	2.4	4.8	%
MCV	88.0	±4.0	4.0	8.0	fL
MCH	29.8	±2.8	2.8	5.6	pg
MCHC	33.8	±3.0	3.0	6.0	g/dL
PLT	251	±40	40	80	$10^3/\mu L$

$\overline{X}$-R High

Parameter	$\overline{X}$ Target	$\overline{X}$ Limit	R Target	R Limit	Unit
WBC	25.9	±2.2	2.2	4.4	$10^3/\mu L$
NE%	79.7	±5.0	5.0	10.0	%
LY%	9.8	±5.0	5.0	10.0	%
MO%	6.9	±3.0	3.0	6.0	%
EO%	2.9	±4.0	4.0	8.0	%
BA%	0.7	±1.0	1.0	2.0	%
RBC	5.39	±0.25	0.25	0.50	$10^6/\mu L$
HGB	17.8	±0.7	0.7	1.4	g/dL
HCT	52.8	±3.0	3.0	6.0	%
MCV	98.0	±4.0	4.0	8.0	fL
MCH	33.0	±2.8	2.8	5.6	pg
MCHC	33.7	±3.0	3.0	6.0	g/dL
PLT	487	±70	70	140	$10^3/\mu L$

$\overline{X}$-R Low

Parameter	$\overline{X}$ Target	$\overline{X}$ Limit	R Target	R Limit	Unit
WBC	2.1	±0.6	0.6	1.2	$10^3/\mu L$
NE%	31.3	±5.0	5.0	10.0	%
LY%	54.8	±6.0	6.0	12.0	%
MO%	11.6	±3.5	3.5	7.0	%
EO%	1.6	±4.0	4.0	8.0	%
BA%	0.7	±1.0	1.0	2.0	%
RBC	2.63	±0.15	0.15	0.30	$10^6/\mu L$
HGB	6.7	±0.4	0.4	0.8	g/dL
HCT	20.3	±2.0	2.0	4.0	%
MCV	77.0	±4.0	4.0	8.0	fL
MCH	25.5	±2.4	2.4	4.8	pg
MCHC	33.0	±3.0	3.0	6.0	g/dL
PLT	45	±20	20	40	$10^3/\mu L$

The default value is a provisional value. Refer to the value on the assay sheet of the MEK-5DN, MEK-5DL and MEK-5DH hematology control.

$\overline{X}_B$ Value

Parameter	High	Medium	Low	Unit
MCV	92.2	89.5	86.8	fL
MCH	31.4	30.5	29.6	pg
MCHC	34.8	33.8	32.8	g/dL