Automated Hematology Analyzer MEK-9100 Operator's Manual

Operator's Manual

Celltac G

Automated Hematology Analyzer

MEK-9100

1st Edition: 25 Sep 2015
2nd Edition: 08 Mar 2016

0614-907468B

Printed: 2016/03/14

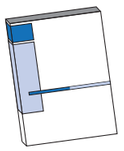
About This Manual

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

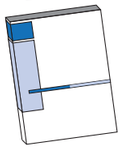
Keep this manual near the instrument or in the reach of the operator and refer to it whenever the operation is unclear.

Accompanying Documentation

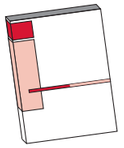
The MEK-9100 automated hematology analyzer comes with the following manuals. Refer to the manual depending on your needs.



Operator's Manual (This Manual)
Describes the operation and settings of the MEK-9100 automated hematology analyzer. Read this manual before use.



Data Management and Setting Guide
Describes the setting procedures performed by administrators. Analyzer administrators should read the Operator's Manual together with this guide.
Manage this guide so that it can only be accessed by analyzer administrators.



Service Manual
For qualified service personnel. Describes information on servicing the analyzer.
Only qualified service personnel can service the analyzer.

This product stores personal patient information. Manage the information appropriately.

Patient names on the screen shots and recording examples in this manual are fictional and any resemblance to any person living or dead is purely coincidental.

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

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

---

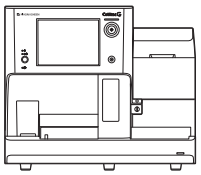
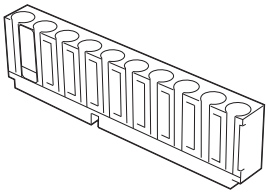
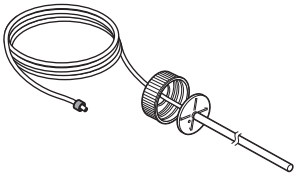
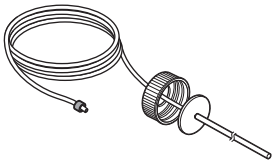
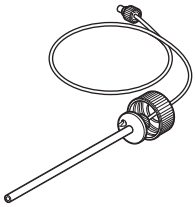
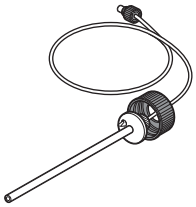
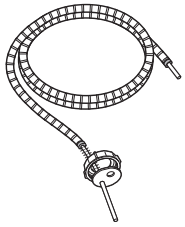
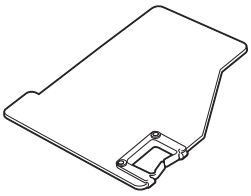
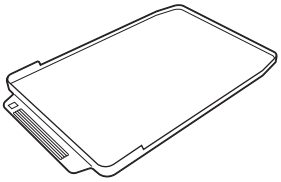
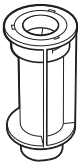
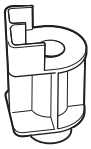
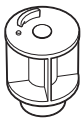
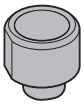
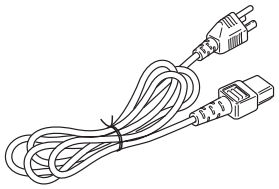
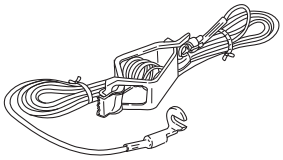
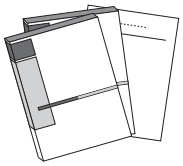
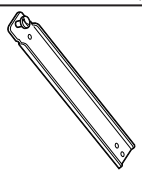
CE

Contents

Unpacking

Check that all the items are included in the package. If there are any missing items, contact your Nihon Kohden representative.

The name and quantity are described under the illustration.

 Hematology analyzer (1)	 Rack (8)	 ISOTONAC tube assy (1)	 CLEANAC tube assy (1)
 HEMOLYNAC•310 tube assy (1)	 HEMOLYNAC•510 tube assy (1)	 Waste tube assy (1)	 Partition plate (1)
 Overflow tray (1)	 Sample tube adapter (1)	 Mini collect adapter (1)	 Micro tube adapter (1)
 Detergent adapter (1)	 Maintenance brush (1)	 Power cord W (1)	 Ground lead D (1)
 6.3 A time-lag fuse (2)	 Barcode reader (1)	 Manuals	 Certification (1)
 Waste container (1) (Selectable option, 10 or 20 L)	 Stopper plate (1)		

For the standard accessories and for consumables such as power cord and reagents, only use Nihon Kohden specified parts and accessories to satisfy the safety and performance.

For the model, code number and supply code of the standard accessories, refer to the “Consumables” page of Section 1 and “Options and Consumables” page of Section 11 in this manual.

Conventions Used in this Manual and Instrument

Warnings and Cautions

Level	Description
⚠ WARNING	A warning alerts the user to the 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.

Icons in this Manual

Icon	Description
	Gives additional information and alternative operation methods.
	Indicates related pages in this or other manuals which give more details.

Safety Standards

Safety Standard Classification of the Analyzer

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 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

ME EQUIPMENT type:

STATIONARY type

1 General

Introduction

MEK-9100 is a fully automatic hematology analyzer that can measure 24 parameters including WBC 5-part differential.

Samples can be measured automatically by setting them in the sample rack (hereafter rack) and pressing the Measurement button (Auto Measurement).

You can also measure a sample manually during standby mode or automatic measurement by touching the Manual Measurement key on the screen (Manual Measurement).

Measured Parameters

Measured Parameters	Name	Note
White Blood Cell Count	WBC	Electrical resistance detection
Neutrophil Percent	NE%	Calculated from scattergram
Lymphocyte Percent	LY%	
Monocyte Percent	MO%	
Eosinophil Percent	EO%	
Basophil Percent	BA%	
Neutrophil Count	NE	
Lymphocyte Count	LY	
Monocyte Count	MO	
Eosinophil Count	EO	
Basophil Count	BA	
Red Blood Cell Count	RBC	Electrical resistance detection
Hemoglobin Concentration	HGB	Colorimetric method
Hematocrit	HCT	Calculated from RBC histogram $HCT\ (\%) = \frac{\text{Red blood cell volume}}{\text{Blood volume}} \times 100$
Mean Corpuscular Volume	MCV	$MCV\ (fL) = \frac{HCT\ (\%) \times 1000}{RBC\ (\times 10^4/\mu L)}$
Mean Corpuscular Hemoglobin	MCH	$MCH\ (pg) = \frac{HGB\ (g/dL)}{RBC\ (\times 10^4/\mu L)} \times 1000$
Mean Corpuscular Hemoglobin Concentration	MCHC	$MCHC\ (g/dL) = \frac{HGB(g/dL)}{HCT\ (\%)} \times 100$
Red Blood Cell Distribution Width in Coefficient of Variation	RDW-CV	Calculated from RBC histogram
Red Blood Cell Distribution Width in Standard Deviation	RDW-SD	
Platelet Count	PLT	Electrical resistance detection
Platelet Crit	PCT	Calculated from PLT histogram
Mean Platelet Volume	MPV	Calculated from PLT and PCT
Platelet Distribution Width	PDW	Calculated from PLT histogram
Platelet Large Cell Ratio	P-LCR	Calculated from PLT histogram

Symbols

The following symbols are used with the analyzer.

The names and descriptions of each symbol are as shown in the table below.

Analyzer

Symbol	Description
	AC power off
	AC power on
	Stand-by
	“Off” only for part of the equipment
	“On” only for part of the equipment
	Laser on
	Reset
	Start
	Do not touch
	Caution
	Consult instructions for use
	Inlet
	Outlet
ISO 3/4	ISOTONAC•3/4 inlet
CLN 710	CLEANAC•710 inlet
HEMO 310	HEMOLYNAC•310 inlet

Symbol	Description
HEMO 510	HEMOLYNAC•510 inlet
WASTE	WASTE
	Alternating current
	Equipotential terminal
	Fuse
	USB socket
IVD	In vitro diagnostic medical device
	Biohazard
	LAN socket
	Serial interface
	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.
	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.

On Screen and Printed Data

Screen Keys

Symbol	Description
	Home key
	Information key
	Manual Measurement key

Symbol	Description
	Eject key
	Change Operator key

Measurement Data

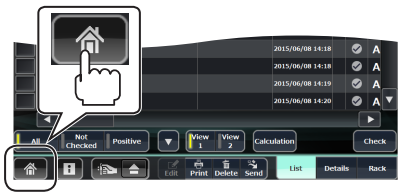
A data identifier is added to the related parameters according to the detected measurement message and abnormal flag.

- “Measurement Messages” (p. 10-2)
- Data Management and Setting Guide: “Viewing Flags” in Section 4

Classification	Data Identifier	Measurement Value	Description
Data cannot be analyzed	None	Related parameter measurement value not displayed	The data cannot be analyzed.
Measurement condition error detected	None	Related parameter measurement value not displayed	Measurement operation error is detected.
Data with low reliability (Error found during measurement)	?	Measurement value displayed	The analyzer condition is out of the specified range and the reliability of the data is low. The measurement value is the reference value.
Data with low reliability (Abnormal flag detected)	! *	Measurement value displayed	Abnormal flag is detected in the sample. The reliability of measured data is low because abnormal cells exist. If the WBC and PLT values are low, count them with a blood smear.
	C	Measurement value displayed	The reliability of measured data is low because PLT clumps are detected.
Out of normal range	H	Measurement value displayed	The measurement value is out of the upper and lower limits range set in the “Sample Type” in System Setting.
	L		
Out of measuring range	None	“OVER” message displayed	The measurement value exceeds the measurable range.

Display

Home Screen



When the power is turned on, the Home screen appears.

"Turning On the Analyzer" (p. 5-5)

If you are in another window, touch [⌂] at the lower left to open the Home screen.

Screen Configuration

Home Screen

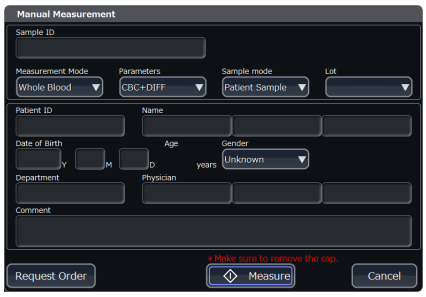
The initial window.

“Home Screen” (p. 1-5)

[ ]: Manual Measurement window

Perform manual measurement.

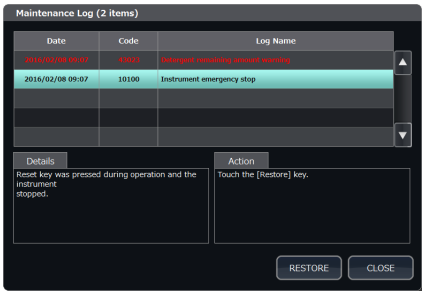
“Performing Manual Measurement” (p. 5-10)



[ ]: Maintenance Log window

Displays messages.

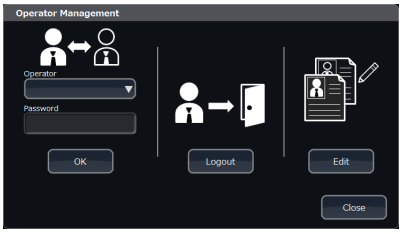
“Measurement Messages” (p. 10-2)



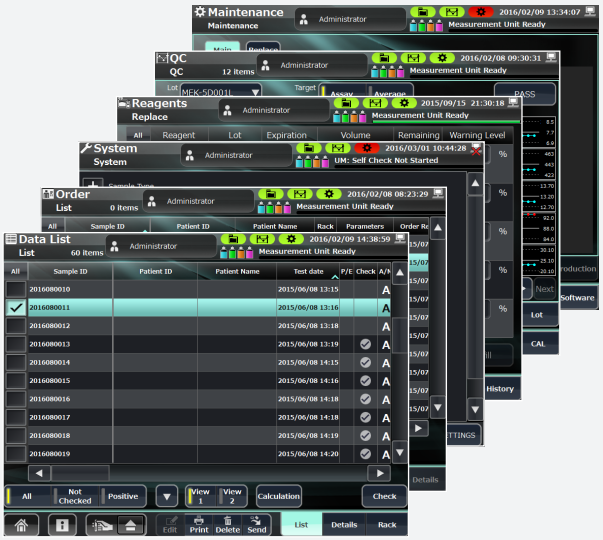
[ ]: Operator Management window

Change or edit operator or log out.

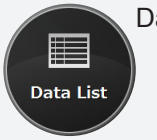
Data Management and Setting Guide: Section 2 “Operator Management”



Touch the icon to open the window.



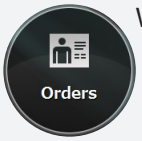
Data List window



Check the measurement data saved in the internal memory of the analyzer.

Data Management and Setting Guide: Section 4 “Data Review”

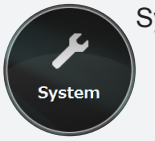
Work Order window



Manages the work order.

Data Management and Setting Guide: Section 3 “Work Orders”

System window



Change the settings.

Data Management and Setting Guide: Section 5 “System Settings”

Reagent Management window

Manages the amount of reagent and waste fluid.

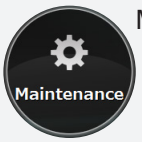
Section 8 “Reagent Management”

QC window

Performs quality control.

Section 6 “Quality Control”

Maintenance window



Performs maintenance related operations.

Section 9 “Maintenance”

Basic Operations

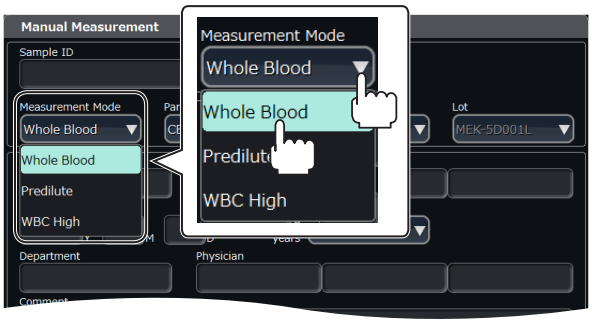
The analyzer has a touch screen display for easy operation.

Touchscreen keys are enclosed in square brackets in this manual.

Changing Settings

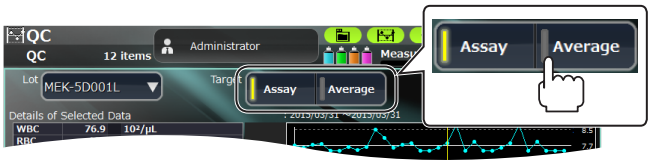
Drop-down Menu

Touch [▼] to open the menu, and select the items.



Setting Key

Touch the key to change the settings.



Entering Letters and Numbers

Touching any characters or numerical items displays either the numeric keyboard or the full keyboard, depending on the displayed value.

Enter characters or numbers and touch [OK] or [Enter].

Touching [Shift] on the full keyboard toggles between uppercase/lowercase and numbers/symbols.

Operator Management

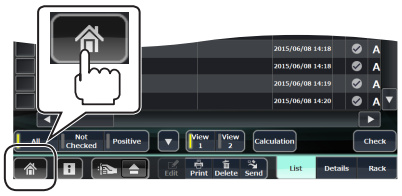
The analyzer user can be set and managed as the operator.

Privileges can be assigned for each operator type and individually for each operator to prevent unauthorized operation.

For details, refer to the Data Management and Setting Guide.

Data Management and Setting Guide:
"Operator Management" in Section 2

Changing Operator



Change the operator of the analyzer.

1 Open the Home screen.

If you are in another window, touch [⌂] at the lower left.

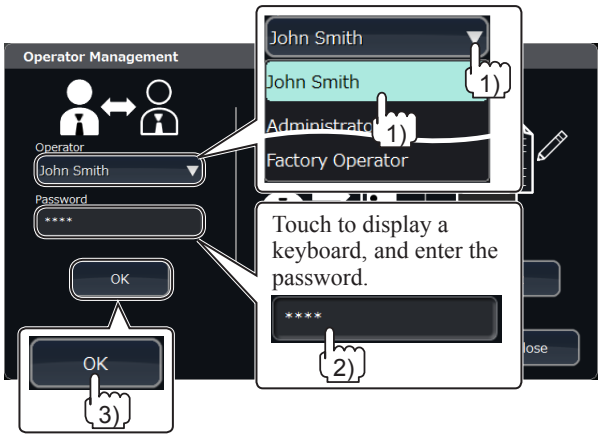
2 Touch [→▯]. The Operator Management window opens.

3 Change the operator.

1) Select the name of the operator to change.

2) Enter the password for the selected operator.

3) Touch [OK].



4 Make sure that the name of the operator shown on the upper part of the screen is changed.

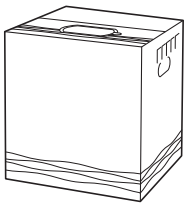
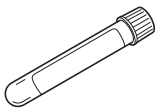
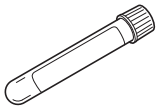
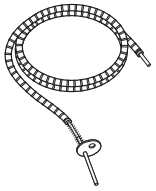
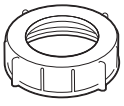
Consumables

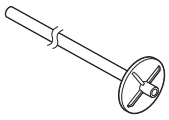
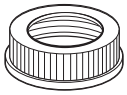
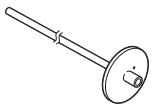
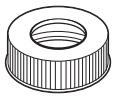
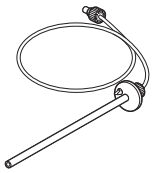
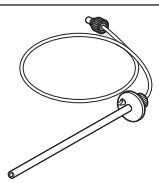
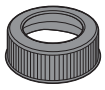
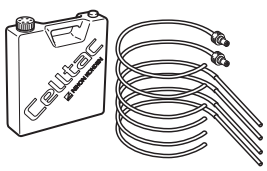
⚠ CAUTION

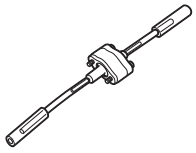
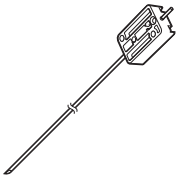
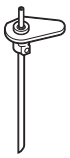
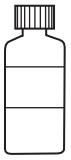
Only use Nihon Kohden specified reagents and consumables. Otherwise the measurement result cannot be guaranteed and incorrect reagent concentration can cause equipment damaged.

Contact your Nihon Kohden representative.

Refer to the provided manuals for the options.

Model and Code No.			Supply Code	Packing Unit
	ISOTONAC•3 diluent	MEK-640	T436D	18 L
	ISOTONAC•4 diluent	MEK-641	—	20 L
	CLEANAC•710 detergent	MK-710W	T438H	2 L
			—	3 L
	CLEANAC•810 detergent	MK-810W	T438R	15 mL × 3
	HEMOLYNAC•310 hemolysing reagent	MK-310W	T493D	250 mL
	HEMOLYNAC•510 hemolysing reagent	MK-510W	T496D	250 mL
	Hematology control	MEK-5DN	—	3 mL × 2
		MEK-5DL	—	
		MEK-5DH	—	
	Hematology calibrator	MEK-CAL	T457	1
	Waste tube (with red collars)		T463B	1
	Waste container cap		T723B	1

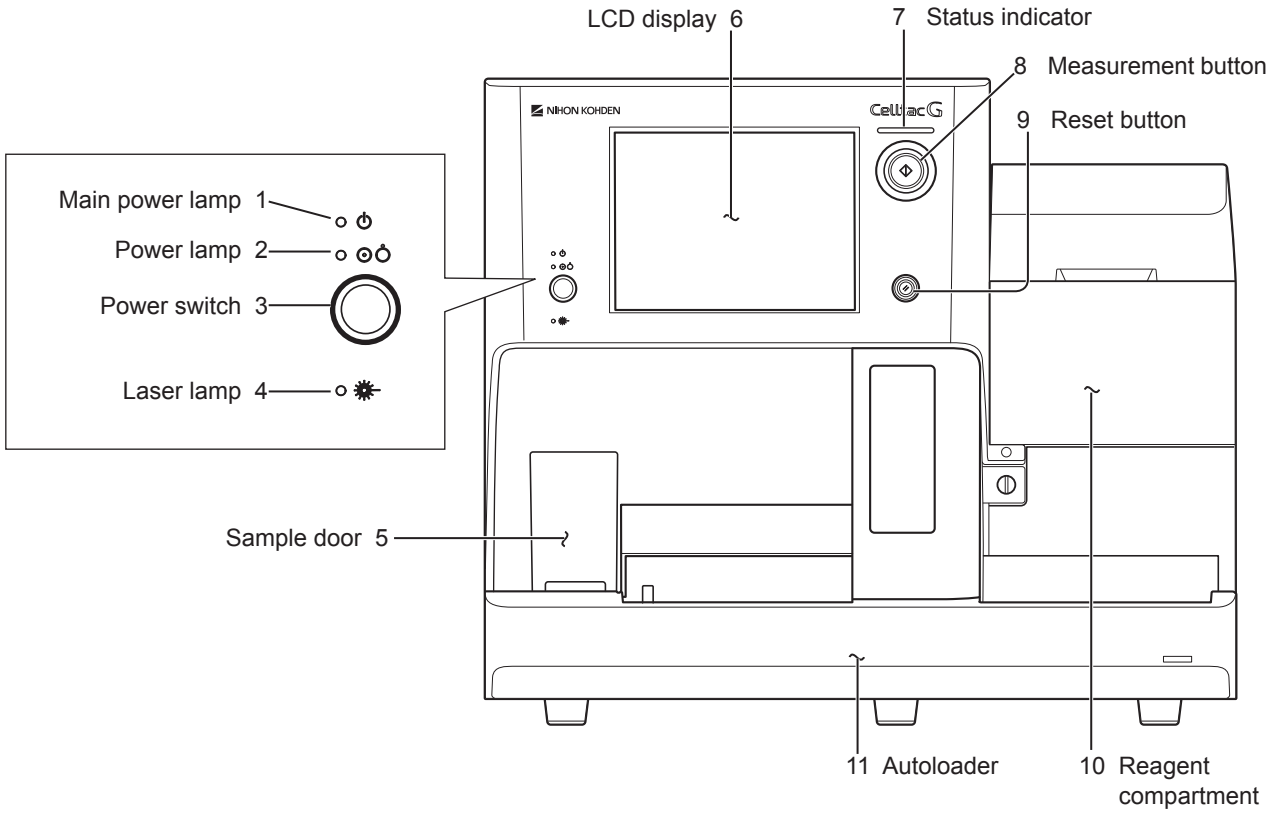
Model and Code No.			Supply Code	Packing Unit
 Example is 10 L	Waste container	10 L	T417B	1
		20 L	T417C	1
	Diluent tube (with blue collar) (for ISOTONAC•3/4 diluent)		T463A	1
	18 L tube assy 3 (for ISOTONAC•3/4 diluent)		T461D	1
	18 L cap (for ISOTONAC•3/4 diluent)		T723A	1
	Detergent tube (with green collar) (for CLEANAC•710 detergent)		T464E	1
	Tube assy (for CLEANAC•710 detergent)		T470A	1
	3 L tube assy (for CLEANAC•710 detergent)		T461E	1
	MEK cap (for CLEANAC•710 detergent)		T469	1
	HEMOLYNAC•310 tube (joint: orange)		T473B	1
	HEMOLYNAC•310 cap (orange)		T447D	1
	HEMOLYNAC•510 tube (joint: purple)		T585B	1
	HEMOLYNAC•510 cap (purple)		T447E	1
	Cleaning kit 2		T414A	1
	SARSTEDT micro tube, 72.699J or the equivalent		T800B	1000

Model and Code No.			Supply Code	Packing Unit
	GREINER BIO-ONE mini collect, 450480 or the equivalent		T401	100
	Micro cap		T812	1
	WBC filter assy		T802A	1
	Sampling nozzle assy		T444E	1
	Releace noz zle assy		T449C	1
	Maintenance brush		T603A	1
	7 µm polymer microsphere suspensions[1]	YZ-0194	T905	80 mL

[1] Maintenance consumables. Contact your Nihon Kohden representative for details.

2 Panel Description

Front Panel



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 switch on the front panel are turned on.

3 Power switch

Turns the analyzer power on or off when the Main power switch on the rear panel is turned on.

4 Laser lamp

Lights when the laser switch is turned on.

5 Sample door

Opens during manual measurement, and the sample tube holder slides out. After you set the sample tube and touch [Measure], the sample tube holder slides in and measurement begins.
After blood aspiration, the sample door opens automatically and the sample tube holder is ejected.

6 LCD display

Displays messages, ID numbers, measured parameters, measurement values and setting values. It has a touchscreen function for changing settings.

7 Status indicator

The indicator color displays the status of the analyzer such as standby, normal operation, out of reagent, or paused with error.

"Status Indicator" (p. 5-7)

8 Measurement button (Auto measurement)

When the button is pressed, measurement of the sample set in the rack begins.

9 Reset button

Stops operation when pressed during operation.

10 Reagent compartment

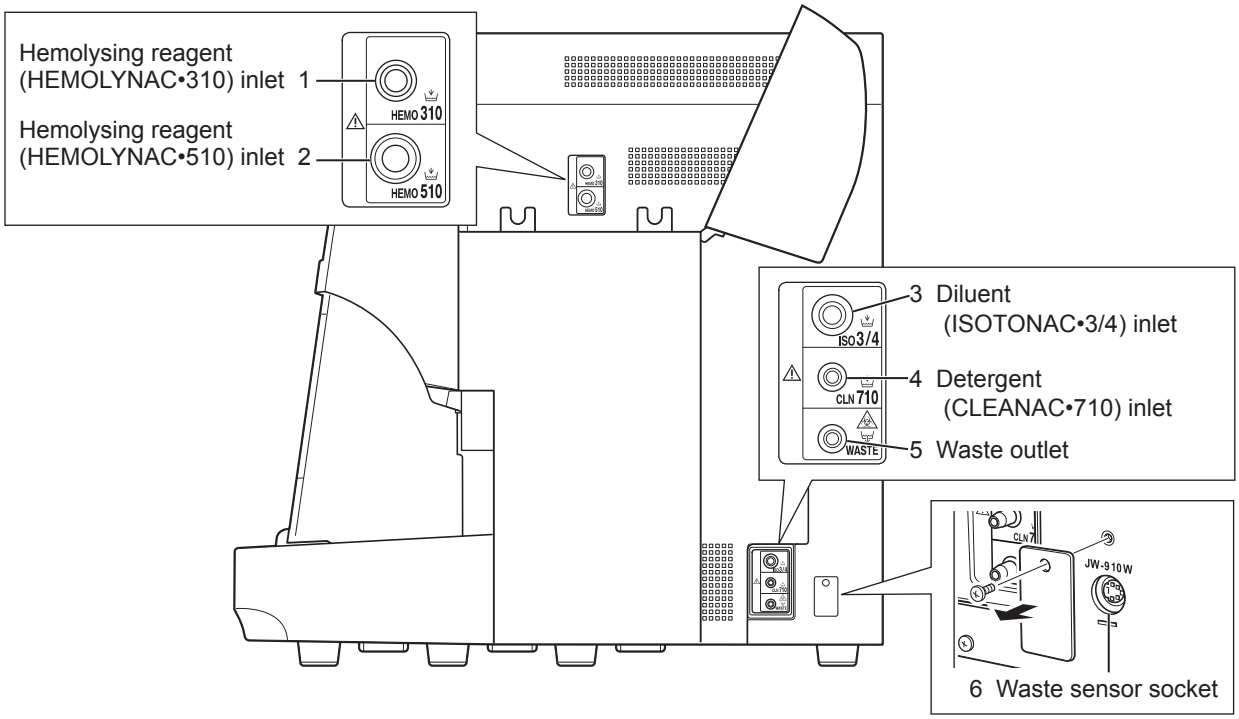
Stores the hemolysing reagent container.

11 Autoloader

Sets the rack.

Side Panel

Right Side Panel



1 Hemolysing reagent (HEMOLYNAC•310) inlet

Connects the hemolysing reagent container (HEMOLYNAC•310) using the provided HEMOLYNAC•310 tube assy.

2 Hemolysing reagent (HEMOLYNAC•510) inlet

Connects the hemolysing reagent container (HEMOLYNAC•510) using the provided HEMOLYNAC•510 tube assy.

3 Diluent (ISOTONAC•3/4) inlet

Connects the diluent container (ISOTONAC•3/4) using the provided ISOTONAC tube assy.

4 Detergent (CLEANAC•710) inlet

Connects the detergent container (CLEANAC•710) using the provided CLEANAC tube assy.

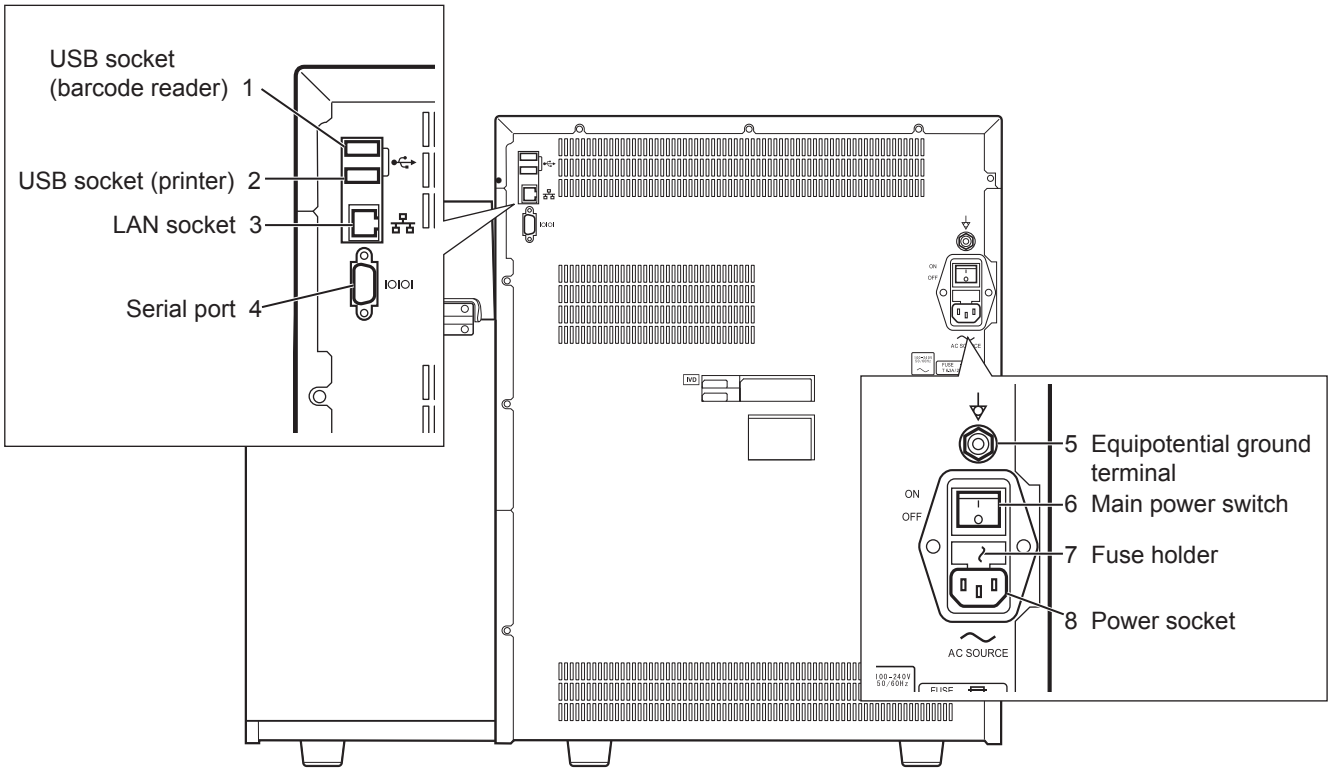
5 Waste outlet

Discharges the used diluent, detergent and aspirated sample. Connects the waste container using the provided waste tube assy.

6 Waste sensor socket

Connects the optional waste sensor.

Rear Panel



1 USB socket (barcode reader)

Connects to a ZK-910W bar code reader.

2 USB socket (printer)

Connects to an optional WA-714W impact printer or the equivalent.

3 LAN socket

Connects to the hospital network and sends/receives order info and measurement data to and from the system.

4 Serial port

Connects to an optional WA-461V card printer with serial communication.

5 Equipotential ground terminal

Used when the analyzer is grounded equipotentially to other devices using the provided earth.

6 Main power switch

Supplies power to the analyzer when it is turned on. Under normal conditions, keep this switch turned on.

7 Fuse holder

Contains the time lag fuse. To replace the fuse, contact your Nihon Kohden representative.

8 Power socket

Connects the AC power cord to supply AC power (100 V) to the analyzer.

3 Safety Information

Precautions

General Handling Precautions

This device is intended for use only by qualified medical 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. This includes, but is not limited to, batteries, recording paper, pens, extension cables, electrode leads, input boxes and AC power.

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 sulphuric 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 a proper grounding facility is available.

3. **Before Operation**

   (1) Check that the instrument is in perfect operating order.

   (2) Check that the instrument is grounded properly.

   (3) Check that all cords are connected properly.

   (4) Pay extra attention when the instrument is combined with other instruments to avoid misdiagnosis or other problems.

   (5) All circuitry used for direct patient connection must be doubly checked.

   (6) Check that battery level is acceptable and battery condition is good when using battery-operated models.

4. **During Operation**

   (1) Both the instrument and the patient must receive continual, careful attention.

   (2) Turn power off or remove electrodes and/or transducers when necessary to assure the patient's safety.

   (3) Avoid direct contact between the instrument housing and the patient.

5. **To Shutdown After Use**

   (1) Turn power off with all controls 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 at least every one year.

   (2) If stored for extended periods without being used, make sure prior to operation that the instrument is in perfect operating condition.

   (3) Technical information such as parts list, descriptions, calibration instructions or other information is available for qualified user technical personnel upon request from your Nihon Kohden representative.

9. **When the instrument is used with an electrosurgical instrument, pay careful attention to the application and/or location of electrodes and/or transducers to avoid possible burn to the patient.**

10. **When the instrument is used with a defibrillator, make sure that the instrument is protected against defibrillator discharge. If not, remove patient cables and/or transducers from the instrument to avoid possible damage.**

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 his/her 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 for such deviation.

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.

5. Use with radiation therapy equipment:

   When the equipment and/or system is used in a radiotherapy room, it may cause failure or malfunction due to electromagnetic radiation or corpuscular radiation. When you bring the equipment and/or system into a radiotherapy room, constantly observe the operation. Prepare countermeasures in case of failure or malfunction.

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: 2002 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 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.

Caution Labels and Caution Marks

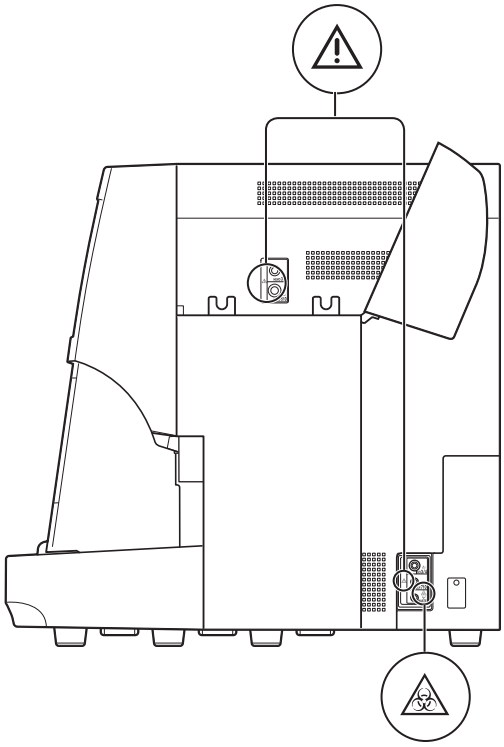
This section provides information on caution labels and caution marks on the analyzer.

To use the analyzer safely and properly, read the page of each description.

Analyzer

Right Side Panel

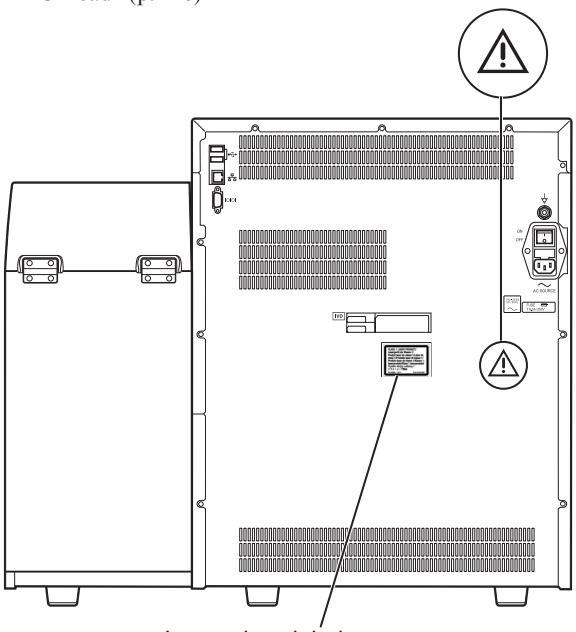
"Connecting the Reagent and Waste Container" (p. 4-10)



"Waste and Waste Fluid" (p. 3-9)

Rear Panel

"Connecting the AC Power Cord and Grounding Lead" (p. 4-8)

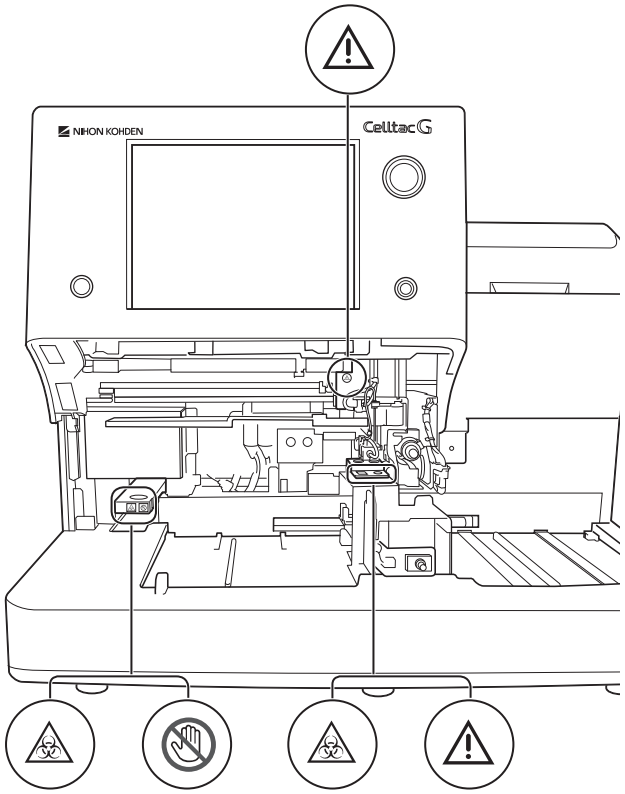


Laser class label

The analyzer is a class 1 laser product.

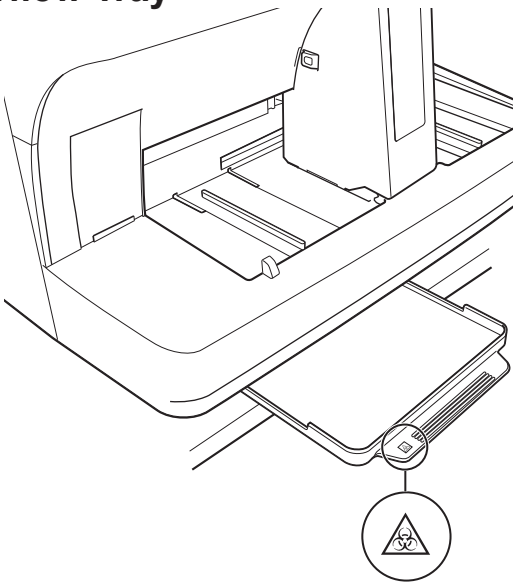
Inside the Front Cover

"Replacing the Sampling Needle" (p. 9-14) and
"Replacing the Venting Needle" (p. 9-19)



"Measurement" (p. 3-8)

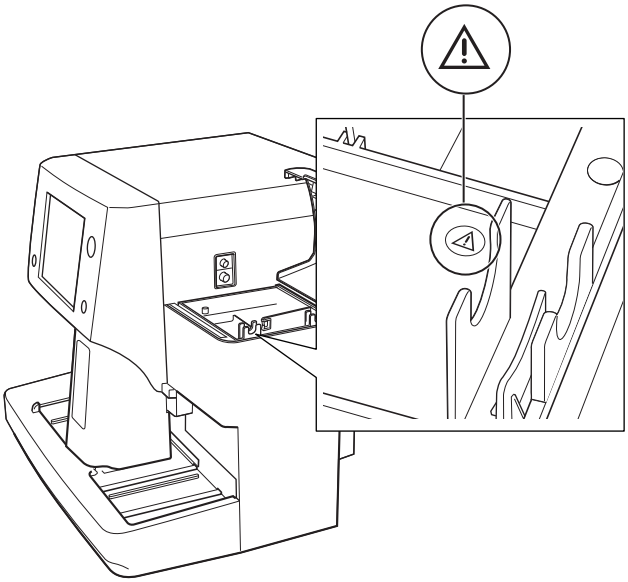
Overflow Tray



"Waste and Waste Fluid" (p. 3-9)

Reagent Bottle Compartment

"Connecting the Reagent and Waste Container" (p. 4-10)



Warnings and Cautions

Medical Devices Used with Analyzer

⚠ 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.

⚠ WARNING

Do not use the analyzer near an ESU. Noise from the ESU may cause the analyzer to malfunction.

Analyzer

⚠ WARNING

Do not diagnose a patient based only on data acquired by the analyzer. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the analyzer and by reading the biomedical signals acquired by other instruments.

Measurement

⚠ WARNING

Always wear rubber gloves to protect yourself from infection.

⚠ CAUTION

Do not put your hand on the rack or sample tube holder during measurement.

⚠ CAUTION

A measurement result with a message might not be correct because of analyzer error or sample error. Do not diagnosis the patient based on the result especially when “!” appears on the measurement result.

⚠ CAUTION

Set the ID correctly. Otherwise, the examination data may be mixed up with data of another examination.

Consumables

⚠ CAUTION

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

⚠ CAUTION

Do not reuse disposable parts and accessories.

Laser

⚠ WARNING

Do not disassemble anything unless specified by the operator's manual. This may result in exposure to laser radiation.

The analyzer complies with IEC 60825 (Class 1 laser products) which is the international standard for laser and there is no hazard of exposure to laser radiation. Laser is radiated inside the analyzer but it is contained within the evacuated enclosure and cover. There is no exposure to laser radiation as long as the analyzer is used as specified in the operator’s manual.

Maintenance

⚠ WARNING

- Be careful not to directly touch any place where blood sample is or may have contacted.
- Always wear rubber gloves to protect yourself from infection.

⚠ WARNING

The sampling needle and venting needle are sharp and potentially contaminated with infectious materials. Be careful when handling the sampling needle and venting needle.

⚠ CAUTION

Before maintenance, perform strong cleaning, drain the cups, and turn off the analyzer main power. If the analyzer is lifted or tilted without draining, the liquid in the cups may spill and damage the electronic circuit or the operator may receive electrical shock. If maintenance is performed while the power is on, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

⚠ CAUTION

Before moving the analyzer, do the following.

- Perform strong cleaning and drain the cups. If the analyzer is lifted or tilted without draining, the liquid in the cups may spill and damage the electronic circuit or the operator may receive electrical shock.
- Turn off the analyzer main power and disconnect the power cord from the AC outlet. If the analyzer is moved while the power is on, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

Waste and Waste Fluid

⚠ WARNING

- Dispose of the analyzer, replaced parts (such as sampling needle and venting needle), 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 needle and venting needle from the analyzer.
  If the above warning is not followed, it causes infection or environmental contamination.

⚠ WARNING

Always wear rubber gloves to protect yourself from infection.

⚠ CAUTION

If the waste fluid contacts the skin, eyes or mouth, wash thoroughly and immediately with water and see a physician.

Reagents

For the analyzer, use the reagents listed in the following table.

When using reagents, observe the precautions for each reagent.

Manuals provided with reagents

Name and Model		Supply Code	Packing Unit
Diluent	ISOTONAC•3 MEK-640	T436D	18 L
	ISOTONAC•4 MEK-641	—	20 L
Detergent	CLEANAC•710 MK-710W	T438H	2 L
	CLEANAC•810 MK-810W	T438R	15 mL× 3
CBC lysing reagent	HEMOLYNAC•310 MK-310W	T493D	250 mL
DIFF lysing reagent	HEMOLYNAC•510 MK-510W	T496D	250 mL

- Performance cannot be guaranteed when an unspecified reagent is used.
- When setting and using a reagent, do not let dust enter the reagent container. If dust gets in the analyzer, correct measurement data may not be acquired or the analyzer may get damaged.
- If dust gets in the reagent container, wash the inside of the container with diluent.
- The usage environment of the reagents is between 15 and 30°C (59 to 86°F). Use reagents within this range. For diluents in particular, be careful not to exceed this temperature range in order to obtain stable data.
- Reagents should be used in accordance with the expiration date and effective period after opening, which are displayed on the package or label.
- Use reagents only in the specified examination room.
- Never use reagents in ways other than specified.
- Use the specified cap when using reagents.

Diluent
MEK-640 ISOTONAC•3
MEK-641 ISOTONAC•4

- Do not drink the diluent.
- If diluent gets in the eyes or mouth, wash it out immediately with plenty of water.
- Use diluent at room temperature.
- If the diluent is frozen, thaw it at room temperature and stir well.

- Handle the diluent as follows. Otherwise the measurement data may be inaccurate due to background noise.
  - Do not leave the diluent container with the diluent tube inserted and the cap opened. Do not put the diluent tube on a desk.
  - When changing the diluent, do not let dust or germs get inside the diluent container.
  - Do not mix fresh diluent and old diluent in the same container.
- Store the diluent at 1 to 30°C (34 to 86°F).

Detergent
MEK-710W CLEANAC•710

⚠ CAUTION
- Wear protective gloves when handling the reagent.
- Do not swallow the reagent. If swallowed, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the reagent contacts the eyes or mouth, wash immediately with plenty of water and see a physician.
- If the reagent contacts the skin, wash with plenty of water.

- Store the detergent at 1 to 30°C (34 to 86°F).

Detergent
MEK-810W CLEANAC•810

⚠ WARNING
- If the detergent contacts the eyes, wash immediately with plenty of water for at least 15 minutes and see a physician. The detergent can cause blindness.
- Do not inhale fumes from the detergent. If detergent fumes are inhaled, move to fresh air and take a rest.
- Do not swallow the detergent. If the detergent is swallowed or contacts the mouth, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the detergent contacts the skin, wash with plenty of water. See a physician if there are skin abnormalities.

⚠ CAUTION
- Wear protective equipment when handling the detergent.
- Do not mix the detergent with acid. This produces chlorine gas.

- Store the detergent at 2 to 8°C (36 to 46°F) in a dark place.
- Use new CLEANAC•810 for each protein cleaning procedure.

CBC Lysing Reagent
MEK-310W Hemolynac•310

⚠ CAUTION
- Wear protective gloves when handling the reagent.
- Do not swallow the reagent. If swallowed, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the reagent contacts the eyes or mouth, wash immediately with plenty of water and see a physician.
- If the reagent contacts the skin, wash with plenty of water.

- Do not mix fresh reagent and old reagent in the same container.
- Store the diluent at 1 to 30°C (34 to 86°F).

DIFF Lysing Reagent
MEK-510W Hemolynac•510

⚠ CAUTION
- Wear protective gloves when handling the reagent.
- Do not swallow the reagent. If swallowed, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the reagent contacts the eyes or mouth, wash immediately with plenty of water and see a physician.
- If the reagent contacts the skin, wash with plenty of water.

- Do not mix fresh reagent and old reagent in the same container.
- Store the diluent at 1 to 30°C (34 to 86°F).

Hematology Control

Use the hematology control listed in the following table for analyzer quality control. Observe the precautions for each hematology control when using them.

Manual provided with the hematology control

Name and Model		Packing Unit
Hematology control	MEK-5DN	3 mL × 2
	MEK-5DL	
	MEK-5DH	

- Do not use a hematology control which is past its expiration date.

  Unopened: expiration date on the label or package

  Opened: 14 days after opening

- Store the control between 2 to 8°C (36 to 46°F). Do not freeze the control.
- Use the control once it has returned to room temperature.
- Mix the hematology control by gently turning it upside down several times before measurement.
- Read the manual of the hematology control thoroughly and follow the precautions.

Barcode Label

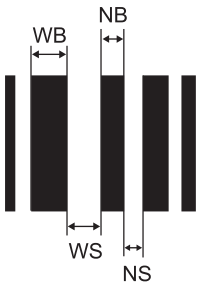
For sample IDs, use only characters supported by the following codes. Unsupported characters might not be read correctly.

NOTE: For sample ID, characters which are available on the on-screen keyboard of the analyzer can be used.

- Code39
- Code128
- NW-7
- Industrial2of5
- ITF
- UPC
- EAN/JAN

Barcode Structure

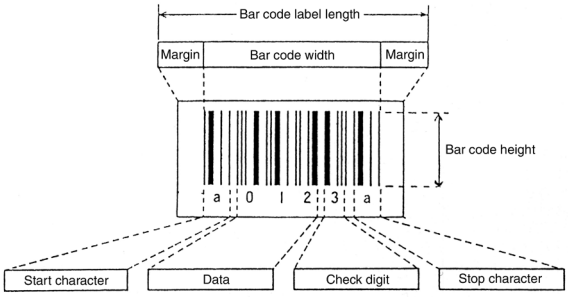
A barcode is a combination of wide and narrow bars and spaces.



NB: Narrow Bars
WB: Wide Bars
NS: Narrow Spaces
WS: Wide Spaces

- The width of the wide bars and wide spaces depends on the width of the narrow bars.
  NB:WB = NS:WS = 1:2 to 1:3
  (Usually 1:2.5)
- The width of the narrow bars, which are called narrow widths, is a reference to describe the specifications of the barcode reader.

The extra spaces on the right and left of the barcode symbol are called the margin. Keep the margin more than 10 times the narrow width for barcode labels that are to be read by the analyzer. If the margin is insufficient, the scan might not be performed successfully.

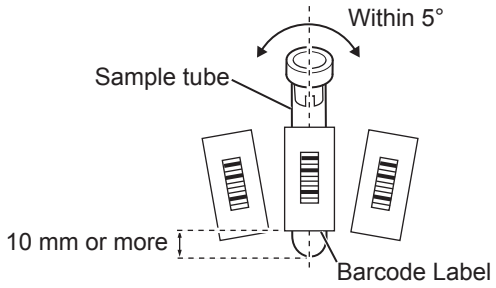


Precautions when Attaching a Barcode Label

When attaching a barcode label on a sample tube, pay attention to the following points.

- The barcode label length must be within 60 mm.
- The narrow bars must be at least 0.125 mm.
- The barcode symbol length must be 35 mm, and equal-width margins must be on both sides. The left and right margins must be 10 times the width of the narrow bars. If the margin is insufficient, the scan cannot not be performed successfully. Contact your Nihon Kohden representative for details.

- Attach the barcode label so that it varies by no more than 5° from the sample tube direction.
- Attach the barcode label at least 10 mm from the bottom of the sample tube.



When the barcode cannot be read properly:

If the barcode cannot be read properly by the barcode reader, check the following points.

Barcode Label

- Barcode is dirty or damaged.
- Margin on the barcode is too small. The left and right margins must be 10 times wider than the narrow bars.
- Barcode print is faint.
- The barcode is printed in silver or is covered by laminate film.
- The barcode printing quality is poor.

NOTE: The printing quality is poor especially when printed on a dot printer or ink jet printer. When printing on such a printer, narrow bars must be as wide as possible. Successful scans cannot be performed with narrow widths. If the barcode type is JAN or CODE128, the code might not be read properly. For JAN and CODE128, the bar sizes are divided into 4 levels, so printout from a printer with low print quality might not be read correctly.

Installation and Connection

General

⚠ WARNING

Install the analyzer and external instruments outside the patient environment (IEC 60601-1-1). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ 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 patient or operator may receive electrical shock or injury, data may be lost or the instrument may malfunction.

⚠ CAUTION

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

Connection to External Instruments

⚠ CAUTION

Connect only the specified instrument to the analyzer and follow the specified procedure.

⚠ 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.

Network

⚠ CAUTION

Connect the analyzer to the network as specified. Otherwise the operator may receive electrical shock or injury and cybersecurity may be compromised. To connect the network, contact your Nihon Kohden representative.

⚠ CAUTION

Do not use a damaged network cable. The operator may receive electrical shock when the damaged part is touched.

Environmental Requirements

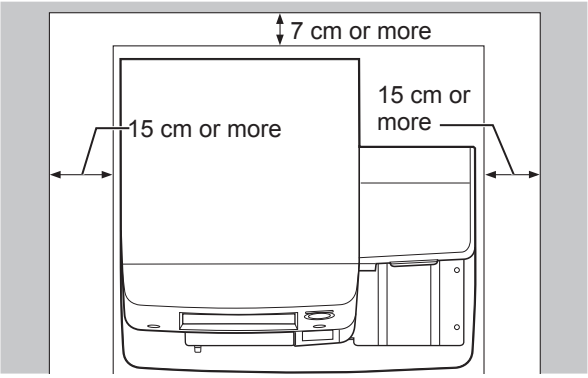
When deciding where to install the analyzer, pay attention to the following points.

- The operating environment is 15 to 30°C (59 to 86°F) for both the room temperature and liquid temperature. Use the analyzer within this range. For diluents in particular, it is necessary to not to greatly exceed this temperature range in order to obtain stable data.

  Operating environment

Temperature:	15 to 30°C (59 to 86°F) (Analyzer and reagents)
Humidity:	30 to 85%
Atmospheric pressure:	700 to 1060 hPa

- Measurement cannot be performed in a dusty place because the aperture cap is extremely fine. Place the analyzer in a place where there is little dust.
- Avoid places near windows where direct sunlight falls upon the analyzer, as it uses an optical sensor.
- Do not put containers of reagent or water on the analyzer. Also avoid places where water splashes, such as near a sink. Otherwise it may damage the circuit or cause an electric shock.
- Make sure that there is more than 7 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. If the vent is blocked, the temperature inside the analyzer goes up, resulting in inaccurate operation or shorter analyzer life.
- Maintain a 15 cm or greater distance from the right side of the analyzer to the wall or other instruments, as you will need to place tubes on the right side of the analyzer when replacing reagents.



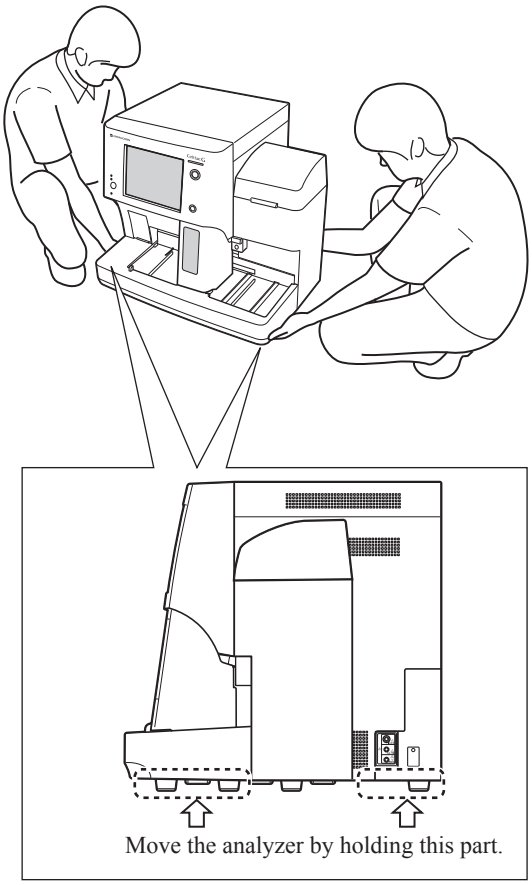
- Choose a stable, horizontal, vibration-free bench as the site for the analyzer.
- The analyzer must not share an AC outlet with noise-generating equipment such as a centrifuge, constant temperature bath (thermostat) or air conditioner.
- Keep enough space around the analyzer so that in emergency the AC power cord can be immediately unplugged from the outlet.

Carrying the Analyzer

The analyzer must be carried carefully by holding the left and right of the bottom panel.

⚠ CAUTION

Use more than one person to move or install the hematology analyzer. Otherwise, it may cause injury from dropping the hematology analyzer.



Cutting Off the Power Supply to the Analyzer

To cut off the power supply to the analyzer, disconnect the power cord of the analyzer from the wall AC outlet.

When installing the analyzer, position the analyzer so that it is easy to disconnect the power cord from the wall AC outlet.

SD Card

When using an SD card, pay attention to the following points.

⚠ WARNING

Do not leave the SD card near the patient or in reach of children. This may lead to an accident such as the patient or child swallowing the SD card.

NOTE: Be careful not to apply static electricity to the SD card.

Handling and Storage

- Never disassemble or modify the SD card.
- Do not give impact to the SD card by dropping or bending.
- Do not handle the SD card while eating or drinking. Do not get the SD card wet.
- Do not touch the terminal of the SD card.
- Do not peel off the label of the SD card or attach another label.
- Never use the SD card in unspecified instruments.
- Keep the SD card slot clean. If dust gets into the slot, the SD card will not function.
- When the SD card is removed from the instrument, be careful not to lose the SD card. Do not let the patient swallow the SD card.
- Do not store the SD card where corrosive gas is generated.
- Observe the following recommendations during storage. Do not expose the SD card to direct sunlight or leave it in a hot and humid place.

  Environment

  - Transport and Storage Environment

    Temperature: –20 to +60°C (–4 to +140°F)

    Humidity: 10 to 95% (noncondensing)

    Atmospheric pressure: 700 to 1060 hPa

  - Operating environment: same as the analyzer

Reading/Writing Data

- Only write data to the SD card in a Nihon Kohden specified instrument. Otherwise the SD card might become unusable.
- Never remove the SD card from the instrument while data is being written to or read from the card, or while pressing the Reset button. Otherwise the SD card may be damaged.

SD Card for Storing Backup Data

- The operation of a mini or micro SD card with conversion adapter cannot be guaranteed.
- An SDHC or SDXC memory card cannot be used.

4 Preparation

Installation and Connection

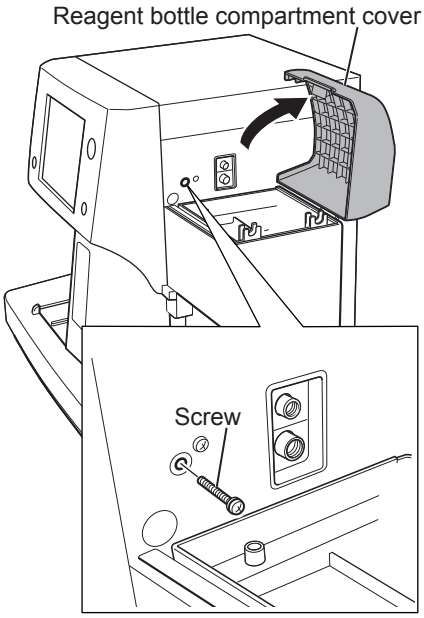
Installation

Install the analyzer. Refer to Section 3 “Safety Information”.

“Installation and Connection” (p. 3-13)

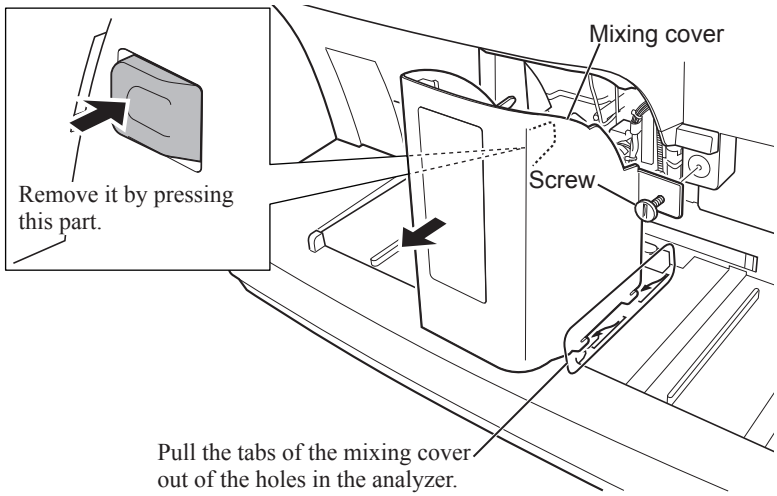
Removing Fixing Screws and Transport Metal Fitting

NOTE: Keep the removed screws and fixing screws for transport together with the standard accessories. The screws will be needed if the analyzer is transported again.

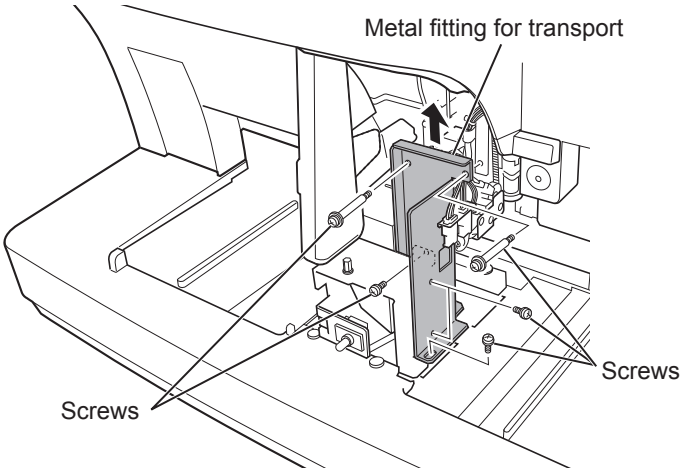


1 Open the reagent bottle compartment cover, and remove the fixing screw shown in the figure.

2 Loosen the screw on the front panel, and remove the mixing cover.

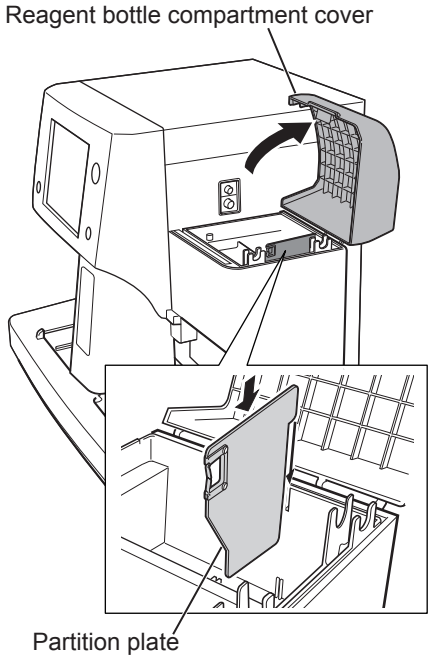


3 Remove the 6 screws shown in the figure, and remove the metal fitting for transport.



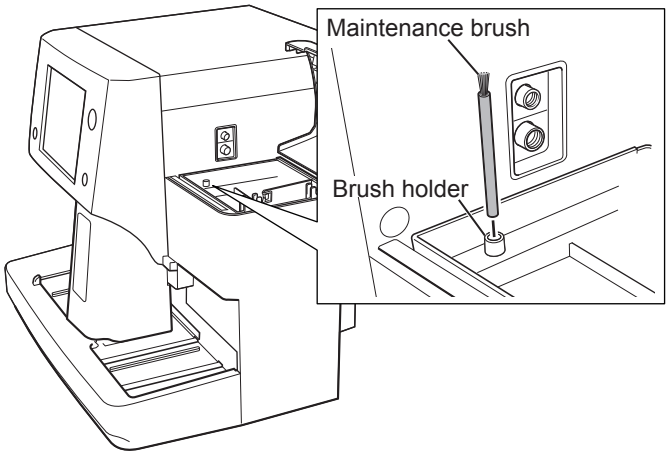
4 Reattach the mixing cover and tighten it with the screw which was loosened in step **2**.

Attaching the Partition Plate



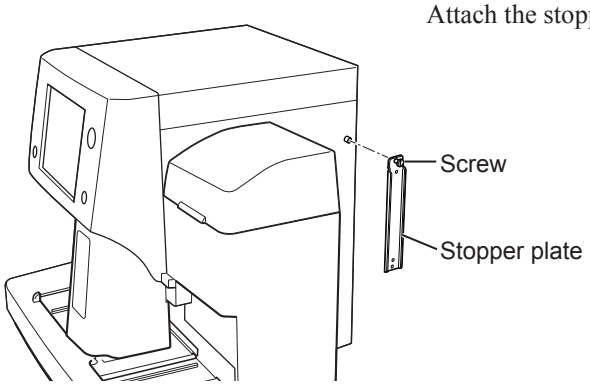
Open the reagent bottle compartment cover and attach the partition plate that comes with the analyzer.

Insert the provided maintenance brush into the brush holder as shown in the figure.



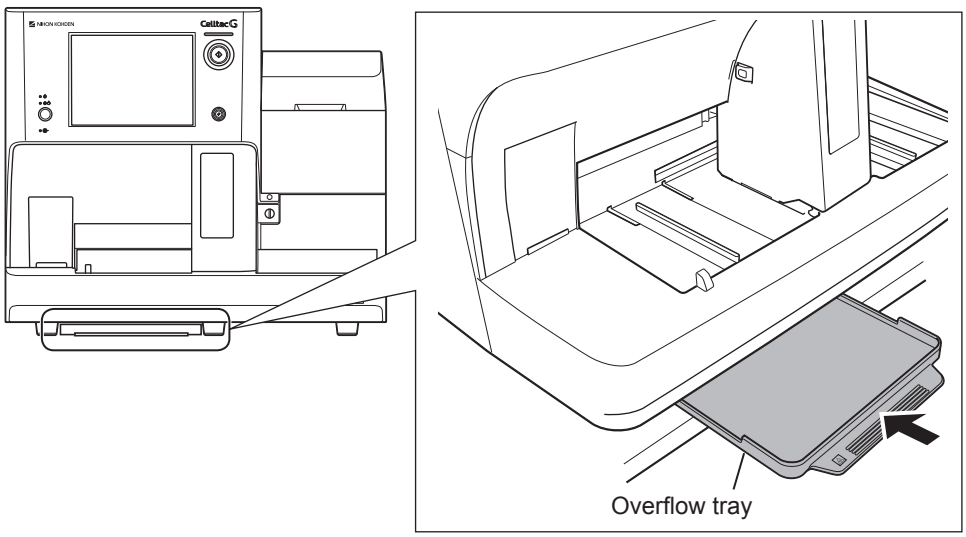
Attaching the Stopper Plate

Attach the stopper plate as shown in the figure and fix it with a screw.



Inserting the Overflow Tray

Insert the provided overflow tray at the position shown in the figure so that it can receive liquid overflowing from inside the analyzer when a liquid leak occurs during a failure.

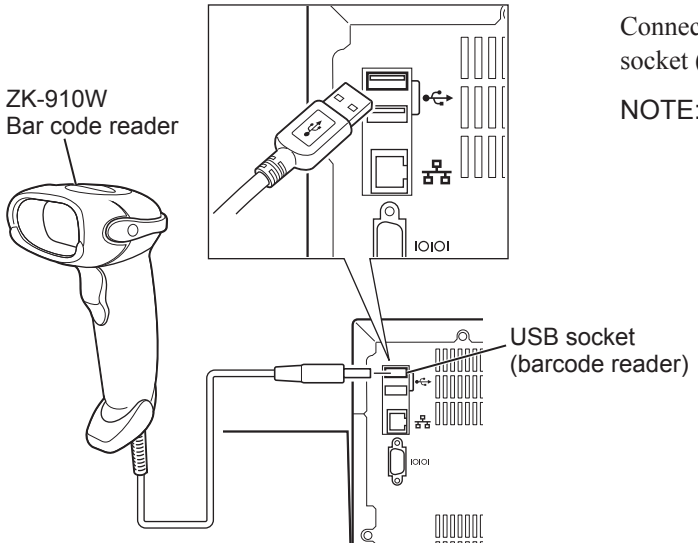


Connecting an External Instrument

For precautions for connecting external instruments, refer to Section 3 “Safety Information”.

“Installation and Connection” (p. 3-13)

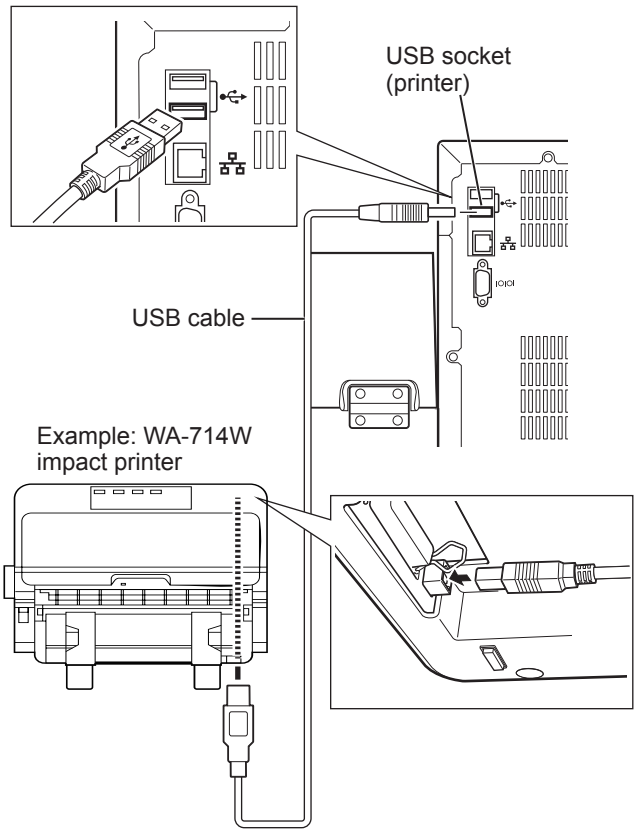
Connecting the Barcode Reader



Connect the provided ZK-910W bar code reader to the USB socket (barcode reader) on the rear panel.

NOTE: Do not connect it to the USB socket (printer).

Connecting an Optional Impact Printer



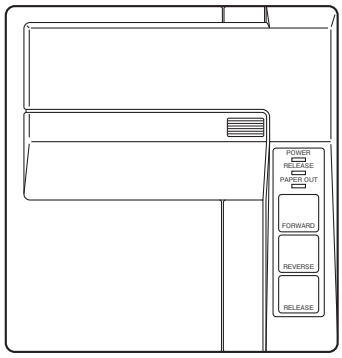
With an optional WA-714W impact printer or the equivalent (Seiko Epson VP-500 and LQ-310), the inspection date, measured values, scattergram, histogram, normal range, etc. can be printed on plain paper or continuous recording paper.

Connect the impact printer to the USB socket (printer) on the rear panel using a USB connection cable.

Connecting an Optional Card Printer

With an optional WA-461V card printer connected to the serial port on the rear panel, data can be printed out.

Connecting an Optional Card Printer



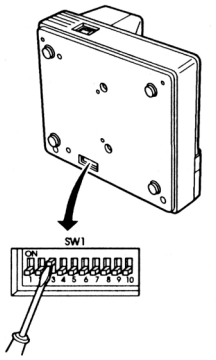
With the WA-461V card printer, the inspection date, ID numbers, measured values, etc. can be printed on special hematology data cards.

Connect the WA-461V card printer to the serial port on the rear panel using the following cable.

- YZ-0318 connection cable (serial)

The YZ-0318 connection cable (serial) is provided with WA-461V card printer.

When a Seiko Epson TM-U295 or the equivalent is used, set the bit switch on the bottom as follows.

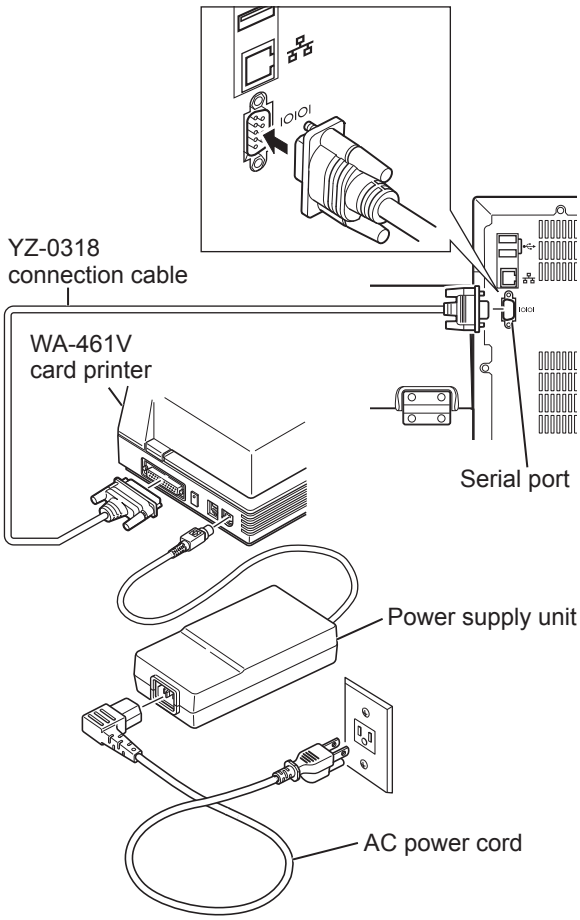


DIP SW1	Setting
1	OFF
2	OFF
3	OFF
4	OFF
5	ON
6	ON
7	OFF
8	OFF

Specifications

- Printing method: Shuttle impact dot matrix
- Power requirements: 24 V DC
- Operating environment: 5 to 40°C (41 to 104°F), 30 to 85% RH
- Dimensions and Weight
  - Main unit: 180 W × 190 D × 101 H (mm), 1.6 kg
  - Power supply unit: 80 W × 160 D × 40 H (mm), 0.4 kg

Connection



1 Connect the card printer to the serial port on the rear panel using the YZ-0318 connection cable provided with WA-461V card printer.

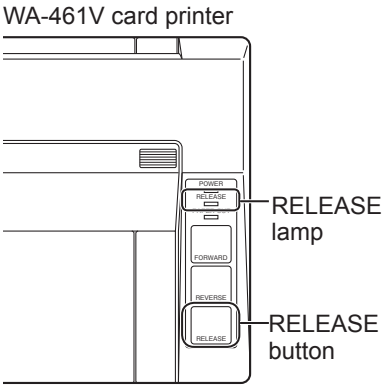
2 Connect the AC power cord.

1) Connect the power output connector of the power supply unit to the DC 24V connector on the rear panel of WA-461V card printer.

2) Plug the provided AC power cord to the power socket of the power supply unit, and connect the plug on the opposite end to an AC outlet on the wall.

NOTE: Use the provided AC power cord for supplying power (AC 100 V) to the power supply unit.

Printing

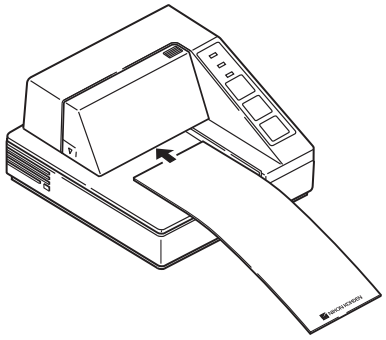


1 Turn on the power to the analyzer and WA-461V card printer.

2 Press the RELEASE button of the WA-461V card printer to turn on the RELEASE lamp.

3 Display the data you want to print on the Data Details window, and touch the Print key to print it.

Data Management and Setting Guide: Section 4 “Data Review”



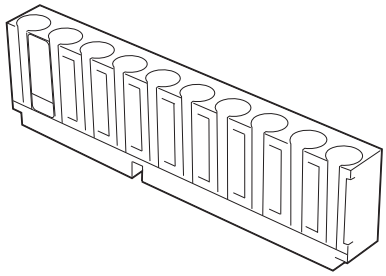
4 Insert a hematology data card, aligning the right side of the card with the guide on the printer.

Printing starts automatically.

5 After printing, remove the hematology data card.

NOTE: The data sent to the printer is stored in the printer memory until it is printed. Therefore, if printing is not performed each time measurement is performed, the data displayed on the analyzer and the printed data will not match. To delete the data in the printer memory, turn the printer off then back on before performing measurement.

Preparing a Rack



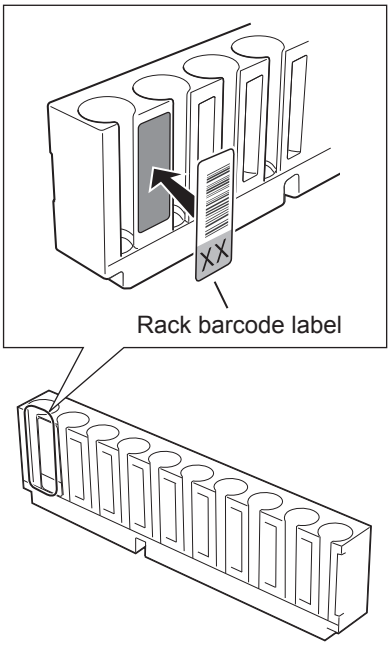
Prepare the provided rack.

Racks in 8 colors (No. 01 to 08) are provided with the analyzer.

The optional extra sample racks are also available.

"Options" (p. 11-18)

Preparing Extra Sample Racks

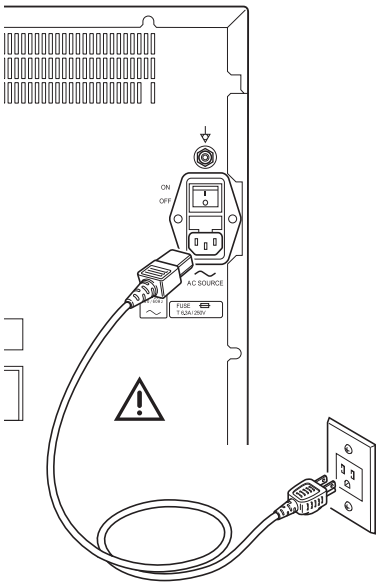


When an optional extra sample rack is used, attach a sample rack label to the position shown in the figure.

NOTE • Attach the same color label as the rack.
• Be careful not to attach the label in the wrong direction.

Connecting the AC Power Cord and Grounding Lead

Connecting the AC Power Cord

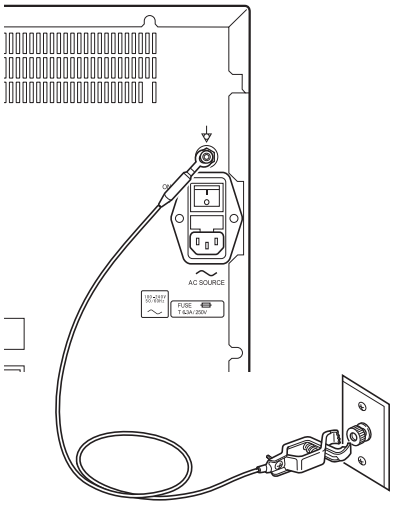


Plug the connector of the provided AC power cord with a 3-pin plug into the power socket on the rear panel, and connect the opposite end to an AC outlet on the wall.

The analyzer is grounded automatically when the AC power cord with a 3-pin plug is connected to a grounded 3-pin AC outlet.

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

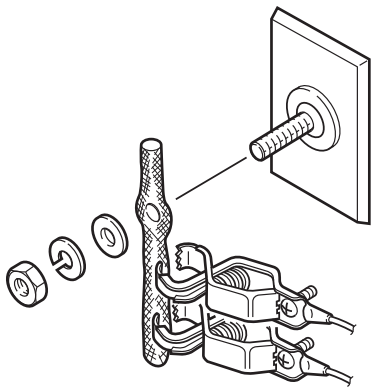
Equipotential Grounding



When the analyzer is used in a place where equipotential grounding is needed, connect the equipotential terminal (the terminal with the ⏚ mark) on the rear panel and a wall ground terminal using the provided grounding lead.

> ⚠ **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.

NOTE: Also, when the analyzer is used while a printer is connected to it, if there is an electrical potential difference between instruments, noise enters through the I/O cable from the AC power source line, resulting in the analyzer malfunctioning. Make sure to use equipotential grounding for the printer in order to prevent an electrical potential difference between instruments.



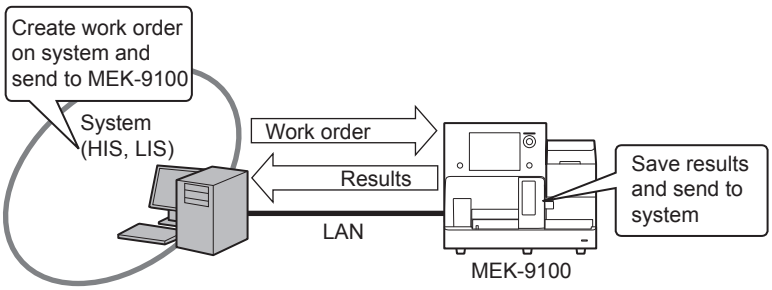
Necessity of Equipotential Grounding

Electrical potential difference between instruments must be prevented from occurring when more than one electrical instrument are used together. If there is an electrical potential difference, the current may flow depending on the voltage and the operator get an electrical shock. Use equipotential grounding whenever possible. For equipotential grounding, securely connect the ground terminal using a thick braided wire as shown in the figure.

If more than one grounding lead is connected to the terminal directly, it becomes easier for the grounding leads to get disconnected, making it more dangerous.

Connecting to the Network

When the analyzer is connected to the network, it can request work orders and send measurement results. Contact your Nihon Kohden representative for details.



When connecting the analyzer to the network, the connection and installation methods depend on where the analyzer is installed and the types and installation sites of the other instruments on the network.

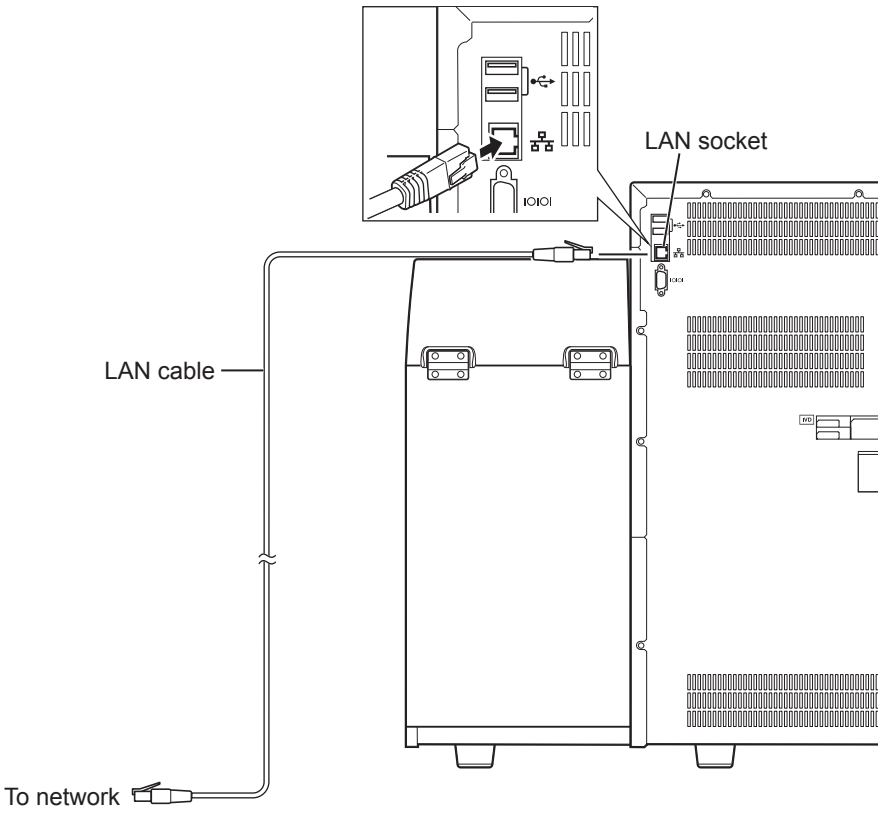
For precautions for connecting to the network, refer to Section 3 “Safety Information”.

“Installation and Connection” (p. 3-13)

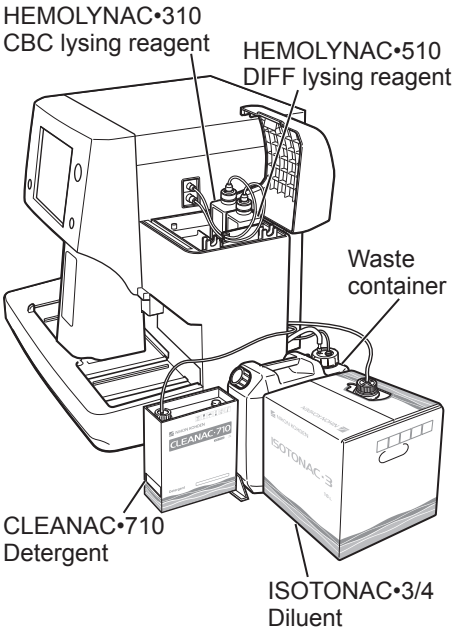
Connect the LAN cable to the LAN socket on the rear panel.

⚠ CAUTION

Do not use a damaged network cable. The operator may receive electrical shock when the damaged part is touched.



Connecting the Reagent and Waste Container

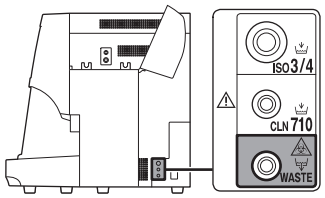
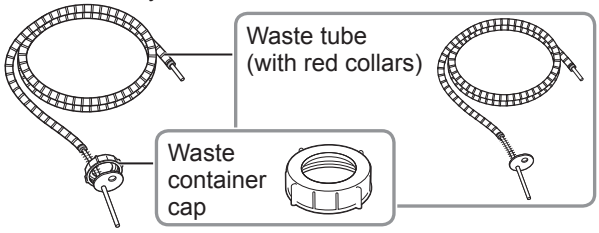


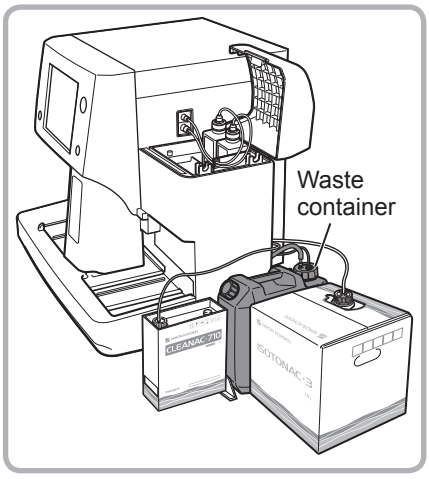
NOTE
- Place the reagents where they do not block the fan vent.
- When connecting the tubes for each reagent or replacing reagents, be careful not to let dust, germs, bacterias, etc. get into the inlet or container. Otherwise the analyzer may malfunction.
- Do not squeeze or bend the tubes. The tube may be accidentally disconnected or the analyzer may be damaged.
- Use only the provided tube for hemolysing reagents and detergents. When you need tubes for hemolysing reagents and detergents, contact your Nihon Kohden representative.
- For information about handling diluent and detergents, refer to the precautions written on their package.
- Follow the manual for hemolysing reagents when handling them.

Name and Model		Supply Code
Hemolysing reagent, HEMOLYNAC•310	MK-310W	T493D

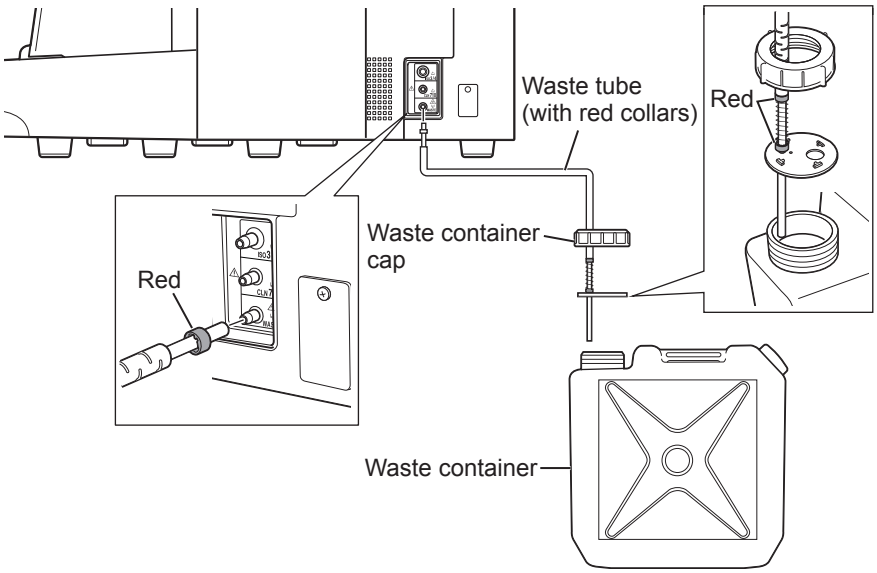
- After connecting each container, be careful not to cover the vent hole on the container cap.

Connecting the Waste Container

Connection on the Analyzer Side	Tube	Reagent, Container
Waste outlet 	Waste tube assy 	Waste container 10 L or 20 L (Option)  Example is 10 L



Connect the waste container to the waste outlet of the analyzer.



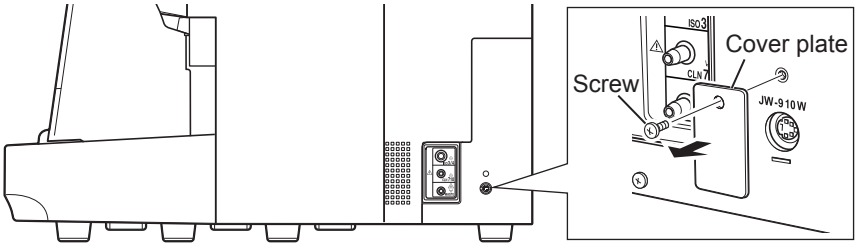
Connecting an Optional Waste Sensor

When an optional JW-910W waste sensor is used, connect it as follows.

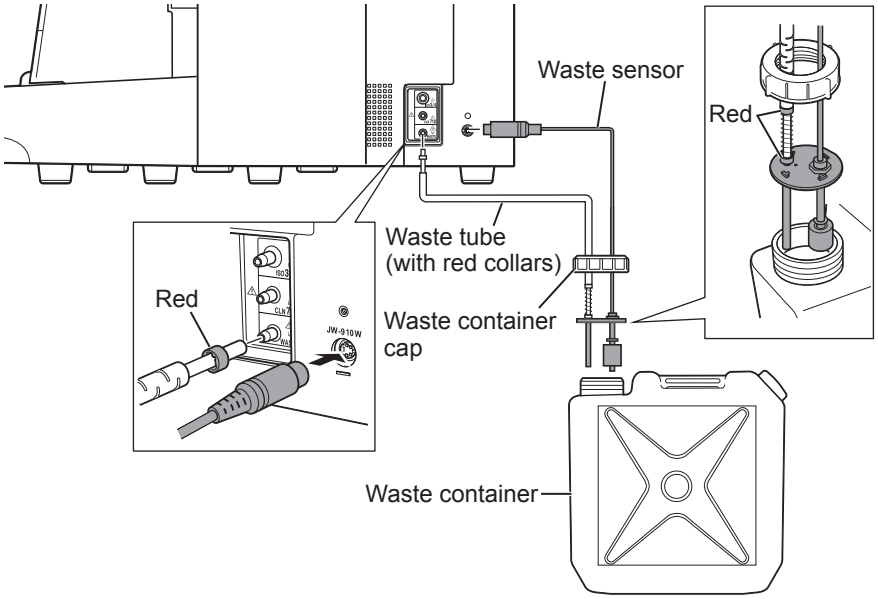
NOTE: When using the JW-910W waste sensor, set [Waste sensor] to "ON" in System > [Waste sensor] > [Reagent Management].

Data Management and Setting Guide:
Section 5 "System Settings"

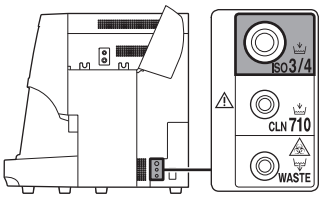
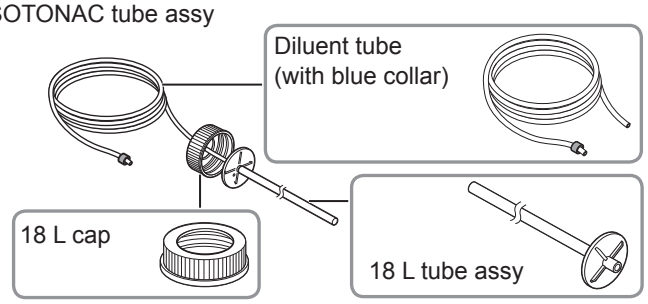
1 Remove the screw on the analyzer, and remove the cover plate of the waste sensor socket.



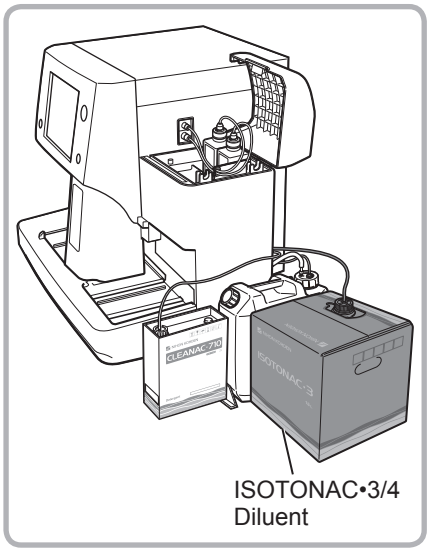
2 Connect the optional JW-910W waste sensor to the waste sensor socket of the analyzer and the waste outlet.



Connecting the Diluent Container

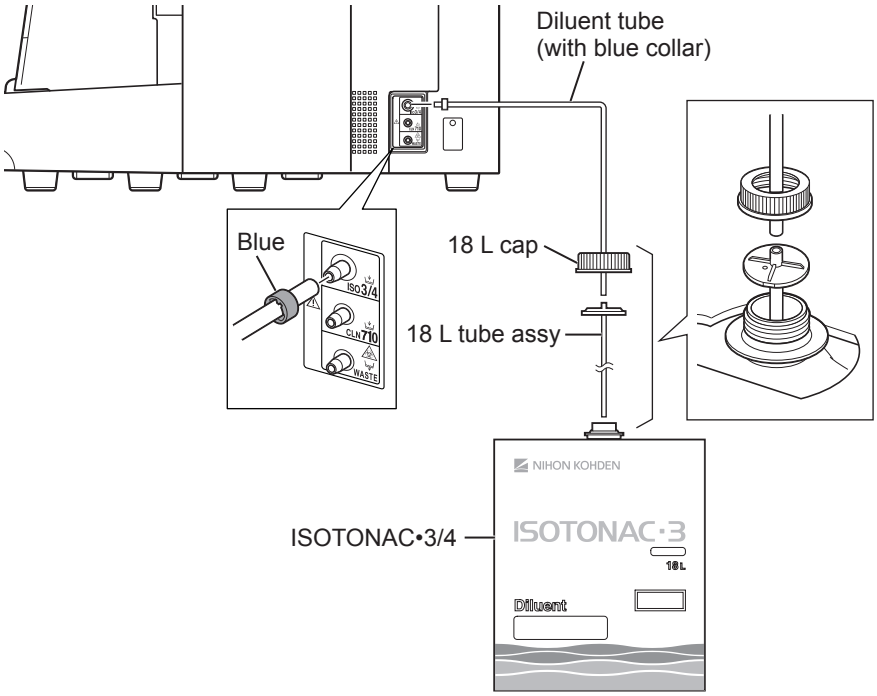
Connection on the Analyzer Side	Tube	Reagent, Container
Diluent (ISOTONAC•3/4) inlet 	ISOTONAC tube assy 	ISOTONAC•3 (MEK-640) ISOTONAC•4 (MEK-641)

ISOTONAC•3 (MEK-640)/ISOTONAC•4 (MEK-641)



NOTE: After opening the diluent, be careful not to let dust or germs get inside the diluent container. Otherwise the measurement data may be inaccurate.

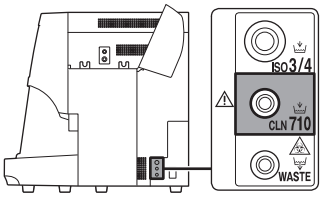
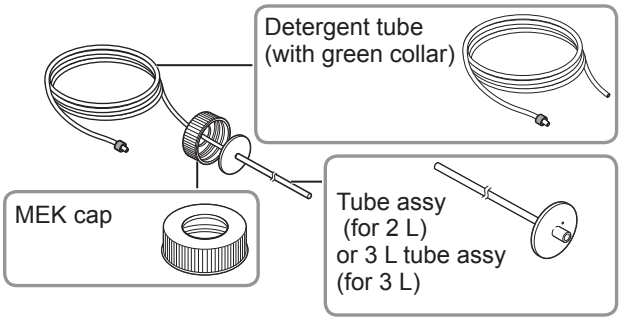
Connect the ISOTONAC•3/4 to the diluent inlet of the analyzer.



Connecting the Detergent Container

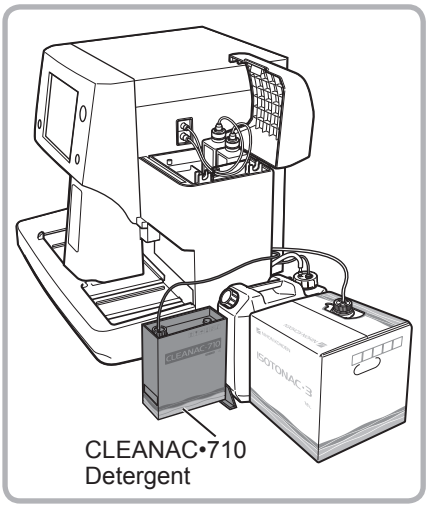
The analyzer uses 2 types of detergent (CLEANAC•710 and CLEANAC•810). Connect the CLEANAC•710 container to the detergent inlet of the analyzer.

Do not connect the CLEANAC•810 container to the analyzer. CLEANAC•810 is taken in from the sample tube holder.

Connection on the Analyzer Side	Tube	Reagent, Container
Detergent (CLEANAC•710) inlet 	CLEANAC tube assy 	CLEANAC•710 (MK-710W) 2 L or 3 L Example is 2 L

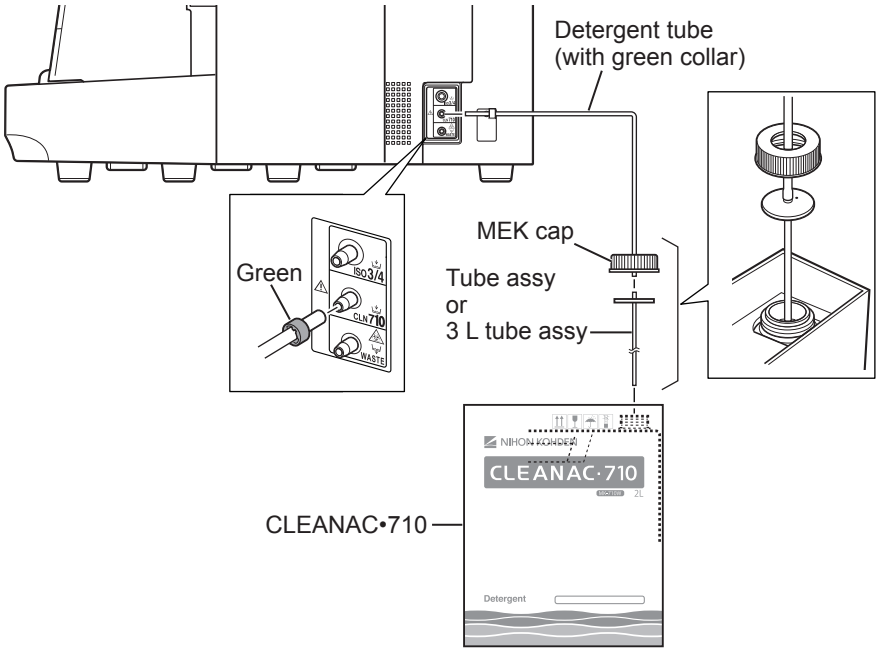
4

CLEANAC•710 (MK-710W)

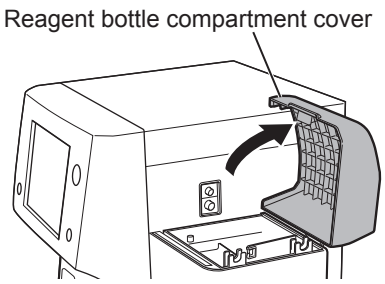


NOTE: Use only the provided tube for detergent connection. When you need tubes for detergents, contact your Nihon Kohden representative.

Connect the CLEANAC•710 to the detergent inlet of the analyzer.



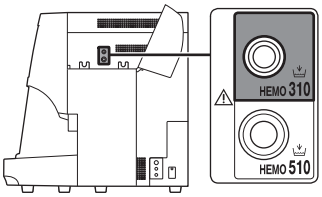
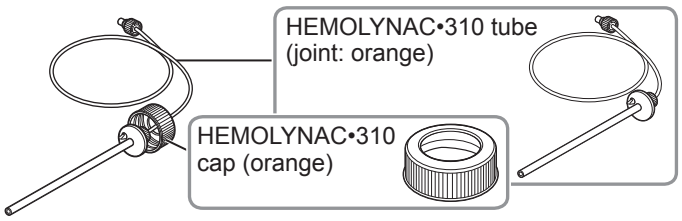
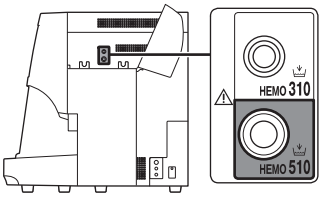
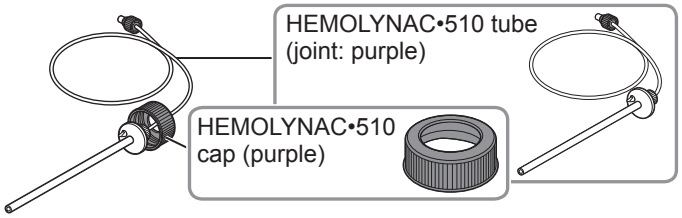
Connecting the Hemolysing Reagent Container



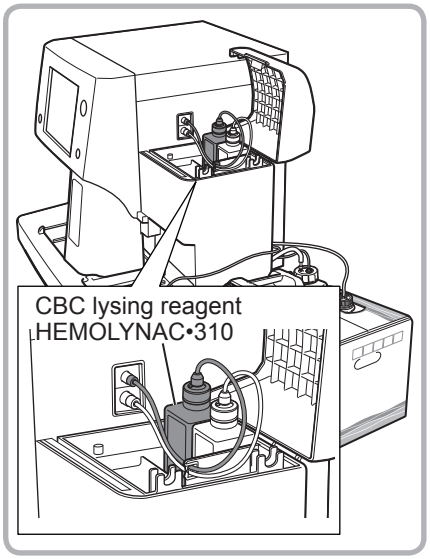
Open the reagent bottle compartment cover, and connect the 2 types of hemolysing reagents (HEMOLYNAC•310 and HEMOLYNAC•510).

NOTE • Be careful not to connect the tubes and containers of HEMOLYNAC•310 and HEMOLYNAC•510 in the wrong way. If you connected them the wrong way, follow steps 1 to 4 below.
1) Remove the hemolysing reagent tubes.
2) Drain the analyzer.
3) Reconnect the hemolysing reagent tubes.
4) Prime the analyzer in the same way as prime on installation.

• Use only the provided tube for connecting the hemolysing reagent container. When you need tubes, contact your Nihon Kohden representative.

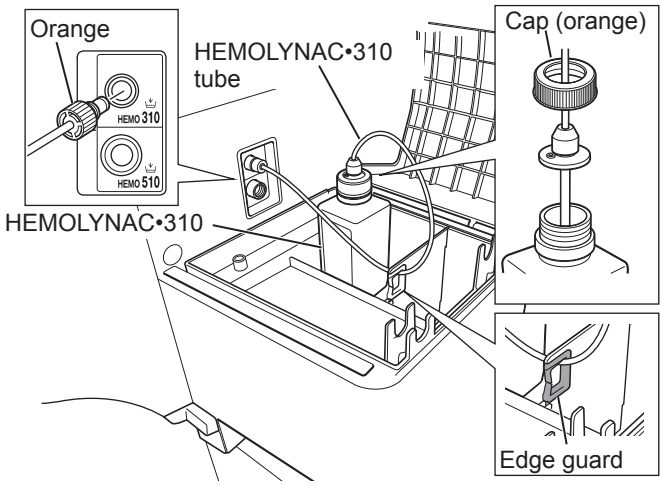
Connection on the Analyzer Side	Tube	Cap	Reagent, Container
HEMOLYNAC•310 inlet 	HEMOLYNAC•310 tube assy 		HEMOLYNAC•310 (MK-310)
HEMOLYNAC•510 inlet 	HEMOLYNAC•510 tube assy 		HEMOLYNAC•510 (MK-510)

HEMOLYNAC•310 (MK-310W: CBC Lysing Reagent)

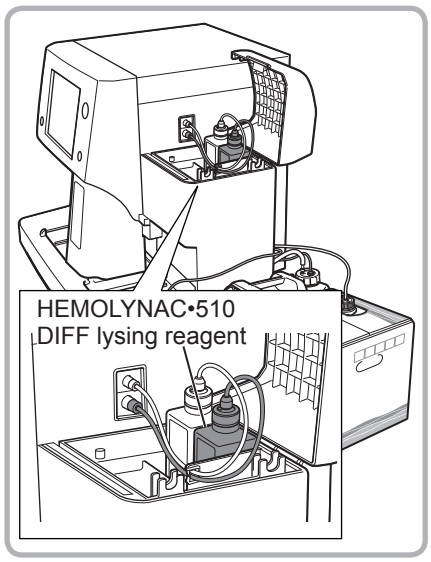


Connect HEMOLYNAC•310 to the hemolysing reagent inlet (HEMOLYNAC•310) of the analyzer.

NOTE: Insert the tube through the edge guard of the partition plate.

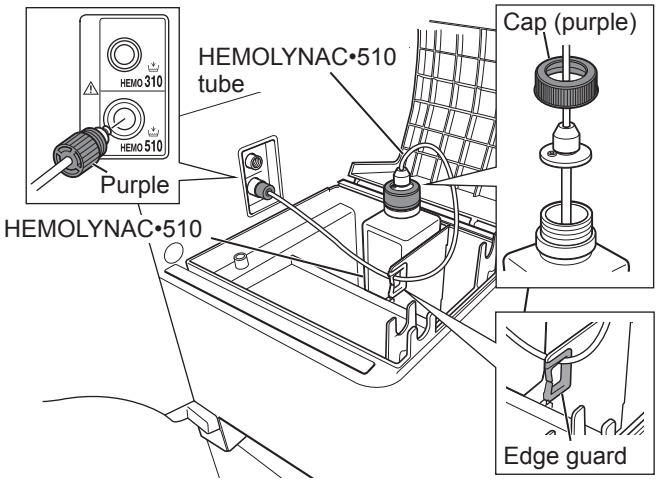


HEMOLYNAC•510 (MK-510W: DIFF Lysing Reagent)

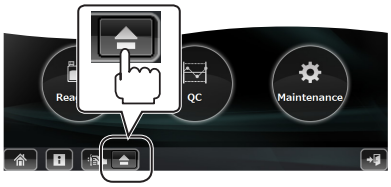


Open the reagent bottle compartment cover, and connect HEMOLYNAC•510 to the hemolysing reagent inlet (HEMOLYNAC•510) of the analyzer.

NOTE: Insert the tube through the edge guard of the partition plate.



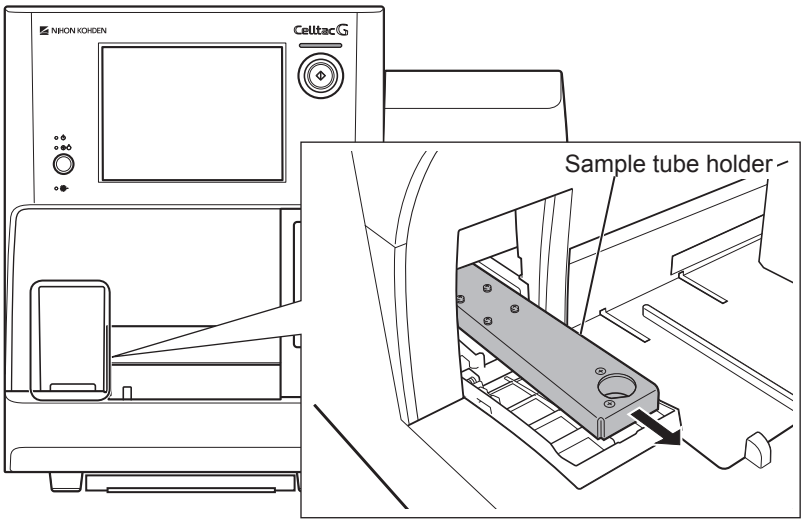
Setting the Adapter for Manual Measurement



1 Turn on the power to the analyzer.

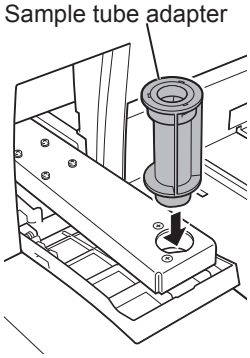
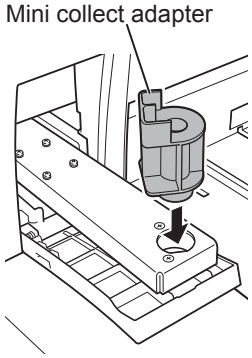
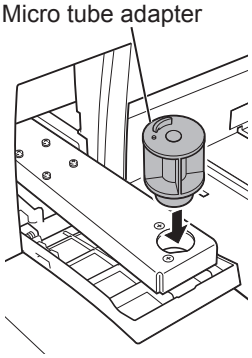
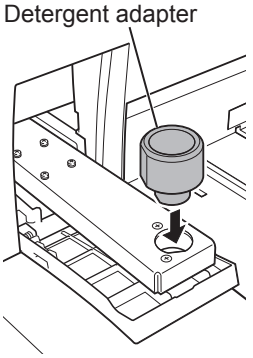
"Turning On the Analyzer" (p. 5-5)

2 Touch [⏏] to eject the sample tube holder.

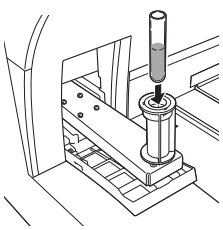
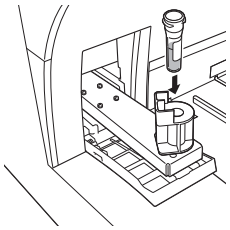
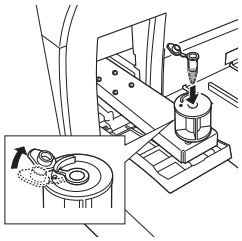
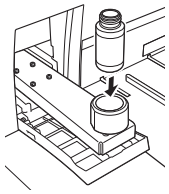


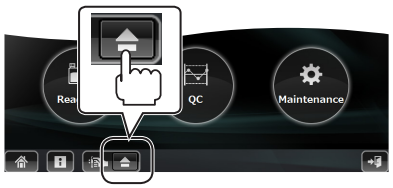
3 Set the adapter depending on the container used in the manual measurement.

NOTE: Push in the adapter until you feel it click.

Sample Tube	Mini Collect	Micro Tube	CLEANAC•810 Detergent
Sample tube adapter 	Mini collect adapter 	Micro tube adapter 	Detergent adapter 

Insert the container into the adapter as follows. For details, refer to the Section 5 "Measurement".

Sample Tube	Mini Collect	Micro Tube	CLEANAC•810 Detergent
			



4 Touch [⏏] to slide in the sample tube holder.

System Settings

You can change settings for administrators in the System Setting window.

To avoid problems caused by unauthorized setting changes, these settings can only be changed by administrators.

For more information about how to change settings, refer to the Data Management and Setting Guide.

Data Management and Setting Guide:
Section 5 “System Settings”

NOTE: When the analyzer is connected to the network, or when a printer or PC is connected to the analyzer, change the items in “External Output” correctly depending on the communication method used in the connection destination.

5 Measurement

General

For precautions during measurement, refer to Section 3 “Safety Information”.

“Warnings and Cautions” (p. 3-8)

Measurement Flowchart

The following 2 types of measurement can be performed with the analyzer.

- Auto measurement: Set the sampling tube in the rack, and measure the samples automatically.
- Manual measurement: Measure a sample individually.

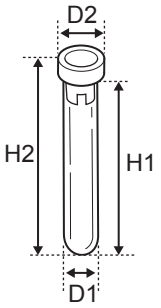
1	**Turning On the Analyzer**	Refer to p. 5-5.
2	**Checking the Status of the Analyzer**	Refer to p. 5-7.
3	**Performing Quality Control**	Refer to p. 5-8.
4	**Performing Auto, Manual, Pre-dilution or WBC High Measurement**	Auto Measurement Refer to p. 5-8. Manual Measurement Refer to p. 5-10. Pre-dilution Measurement Refer to p. 5-13. WBC High Measurement Refer to p. 5-16.
5	**Checking the Measurement Results**	Refer to p. 5-19.
6	**Turning Off the Analyzer**	Refer to p. 5-23.

Measurement Conditions

Measurement Conditions		Description
Measurement mode	Whole blood	After aspirating the sample into the analyzer, dilute and measure it in the analyzer. Use this mode when measuring venous blood.
	Pre-dilution	Manually measure a pre-diluted sample. Use this mode when measuring a small 20 uL blood.
	WBC high	The sample is aspirated and diluted with a higher dilution rate than normal before measurement. If you anticipate that the sample will have a high WBC concentration (WBC:100,000/µL or more), set a higher dilution beforehand to reduce the need for remeasurements and obtain better results.
Parameters	CBC	Measure only the 14 CBC items.
	CBC+DIFF	Measure of 24 items, including 5 WBC differentials.
QC	QC	Measure the hematology control.
	Patient sample	Measure the sample of the patient.

Sample Tubes

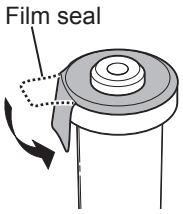
Sample tube dimensions



The following sample tubes can be used with the analyzer.

Manufacturer	Model and Code No.	Dimensions (mm)				Qty
		D1	D2	H1	H2	
TERUMO	VENOJECT II VP-DK052K	ϕ13.2	ϕ17.6	74.6	80.5	2 mL
NIPRO	NEO-TUBE NP-EK0205	ϕ12.5	ϕ17.0	69.0	82.5	
BECTON DICKINSON	VACUTAINER 367846	ϕ12.3	ϕ16.5	62.5	82.0	

When measurement is performed using VENOJECT II, bend the film seal to prevent it from sticking out to the sides before setting it in the rack. Otherwise, the rack might not be transported normally due to seal interference.



If the sample tube is the same dimensions as the available sample tubes which are listed above, contact your Nihon Kohden representative to use the sample tube.

Maximum size of vacuum sample tube that can be used with the analyzer

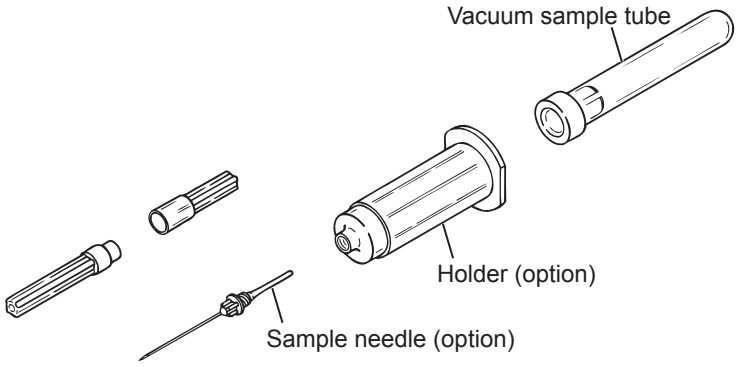
Dimensions (mm)				Qty
D1	D2	H1	H2	
ϕ13.5	ϕ18.0	76.0	83.0	2 mL

NOTE • When attaching a label on the sampling tube, make sure that there is no wrinkling, floating or peeling.

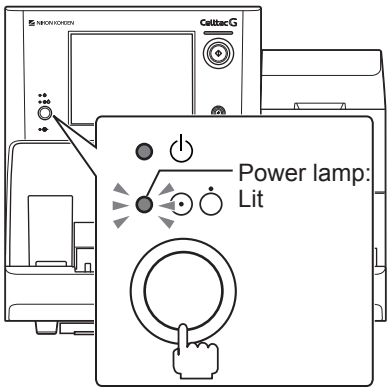
• Do not attach more than one barcode label.

• Attach the barcode label so that there are no wrinkles on the label surface.

"Barcode Label" (p. 3-11)



Turning On the Analyzer



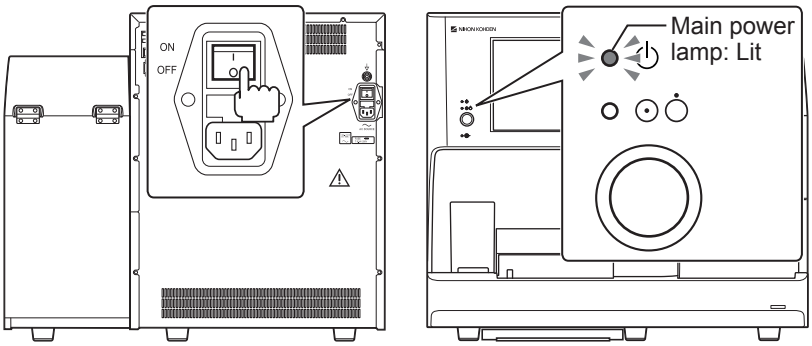
1 Check the surrounding environment, exterior of analyzer, etc. Refer to "Daily Check" in Section 9.

"Check Before Use" (p. 9-2)

2 Turn the main power switch on the rear panel to ON (to |).

The main power lamp on the front panel lights in green.

Leave the main power on except when moving or transporting the analyzer.



3 Press the power switch on the front panel.

The power lamp lights in green.

4 Log into the analyzer.

The following login procedure is not needed when the Auto Login is "ON" in System Setting.

Data Management and Setting Guide: Section 5 "System Settings"

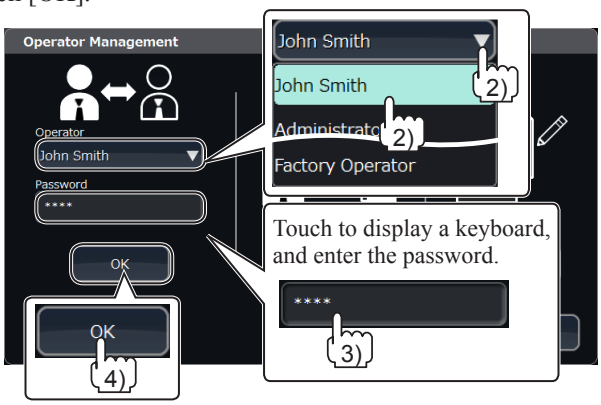
1) Touch [ ] on the Home screen. The Operator Management window opens.

2) Select the operator name to use to log in.

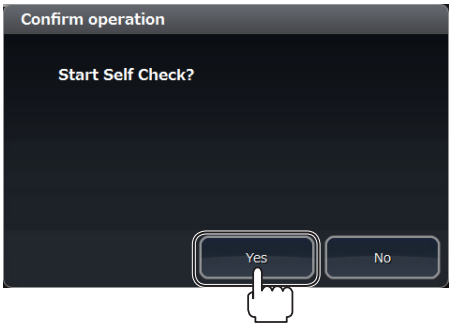
"Operator Management" (p. 1-8)

3) Enter the password of the selected operator.

4) Touch [OK].



5 When the login process is completed, the following Confirm Operation window appears. Touch [Yes] to perform the self check.



If you touch [No] and did not perform the self check, you can perform the self check any time.
"Running Self Check" (p. 9-11)

If any abnormality is detected during the self check, a message appears on the LCD display.
For details, refer to "Screen Messages" (p. 10-2).

6 Check the date and time display. Refer to "Daily Check" in Section 9.

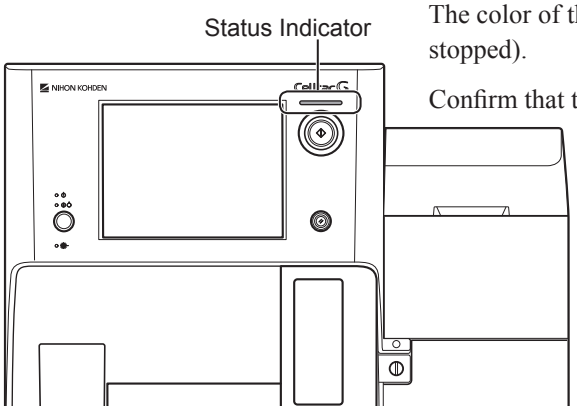
"Check After Turning On the Analyzer" (p. 9-3)

NOTE
- When the analyzer is restarted after power loss or after emergency stop during measurement, some of the previous sample may still remain inside the analyzer. Therefore, do cleaning after the power is turned on again.
- Prime the analyzer after installing the analyzer and after storing it for extended periods.

Checking Analyzer Status

Check the status indicator on the front panel and the status indication at the top of the screen.

Status Indicator

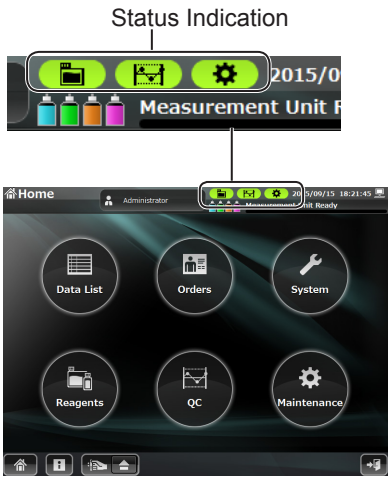


The color of the indicator displays the operation status (starting, operating and stopped).

Confirm that the indicator is green (standby) before a measurement.

Display		Status
Green	Lit	Standby
	Blinking	Operating
Orange or red	Lit	Stopped due to error
Blue	Blinking	Starting
Off		Power off

Status Indication



The status indication at the top of the screen displays the status of the reagents, quality control and user maintenance.

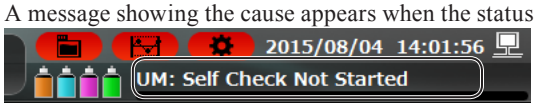
Confirm that all statuses are green before starting a measurement.

Status Indication	Status
Reagent Management 	Green when all the following conditions are met: • All reagents are within the valid period (before their expiration date and expiration after opening date) • All reagents have more than 0% remaining. • The waste amount is below the warning level.
Quality Control 	Green when all the following conditions are met: • Quality control measurement is performed for all control samples in use. • The last quality controlled measured results of all control samples in use meet the quality control judgment criteria or are approved by the operator.
User Maintenance 	Green when all the following conditions are met: • No user inspection items are past their regular user maintenance dates. • No service inspection items are past their regular service maintenance dates. • The analyzer current status does not need any maintenance. • The analyzer self check has been performed and all items passed.

NOTE: Even if the above conditions are met, the quality control and user maintenance status is red if the following conditions apply.

- When power is turned on (when starting)
- More than 24 hours since the last quality control measurement (quality control status) or self check (user maintenance status).

A message showing the cause appears when the status is displayed in red.



Performing Quality Control

Measure the hematology control and perform the quality control.

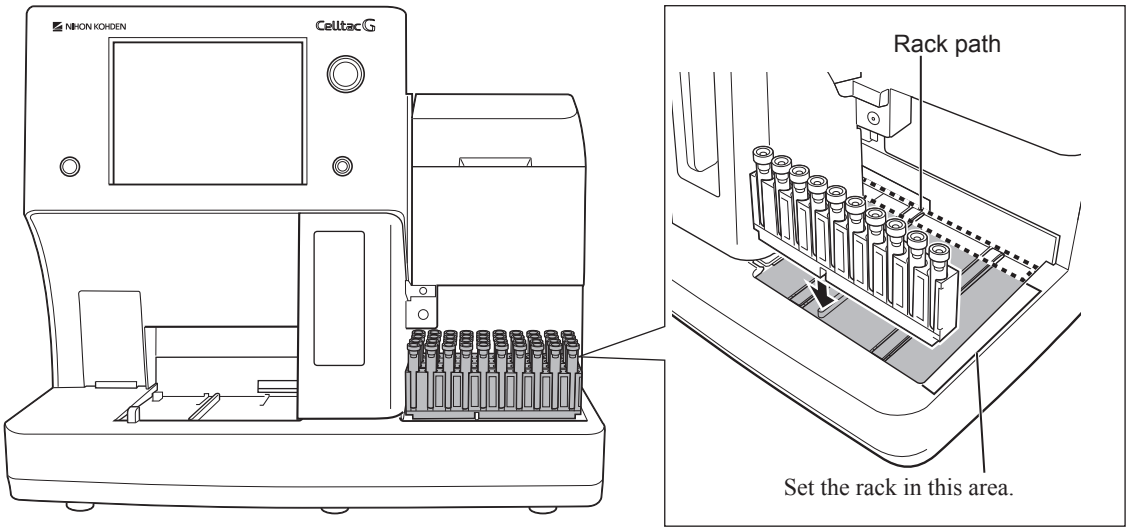
"Quality Control" in Section 6

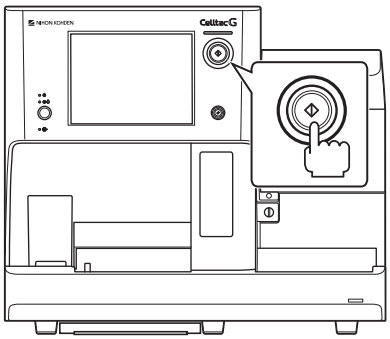
Performing Auto Measurement

1 Put sample tubes in a rack and set the rack on the analyzer.

Do not set the rack on the rack path.
Up to 7 racks can be set at the same time.

NOTE
- Make sure to close the sample tube caps before setting the rack.
- Confirm that the blood amount is 1.0 mL or more.
- Use only EDTA (ethylenediaminetetraacetate) as an anticoagulant. Do not use heparin as an anticoagulant. It affects white blood cell and platelet measurement.
- Depending on the sample, poor hemolyzation may occur when measurement is performed within 30 minutes after collecting the blood. In that case, leave the sample for more than 30 minutes before measuring it.
- For reliable data, measure the blood sample within 8 hours. Refrigerate the samples when storing them, but return them to room temperature before measuring them. Samples collected more than 24 hours ago might not give a correct measurement.
- Do not use aggregated or coagulated blood. This may damage the analyzer.
- When samples are left to stand for more than 2 hours and their blood cells and plasma are separated, accurate result might not be obtained because they are not stirred well enough. When measuring such samples, stir the blood thoroughly before setting them in the rack.





2 Press the Measurement button to start auto measurement.

Auto measurement does the following operations automatically.

The rack on the autoloader slides into the analyzer.

↓

The barcode label on the rack is read.

↓

All samples placed on the rack are measured one by one.

- **The barcode label on the sample tube is read.**
- ↓
- **The sample is agitated by turning the sample tube upside down.**
- ↓
- **Measurement is performed and the result is added on the Data List window.**

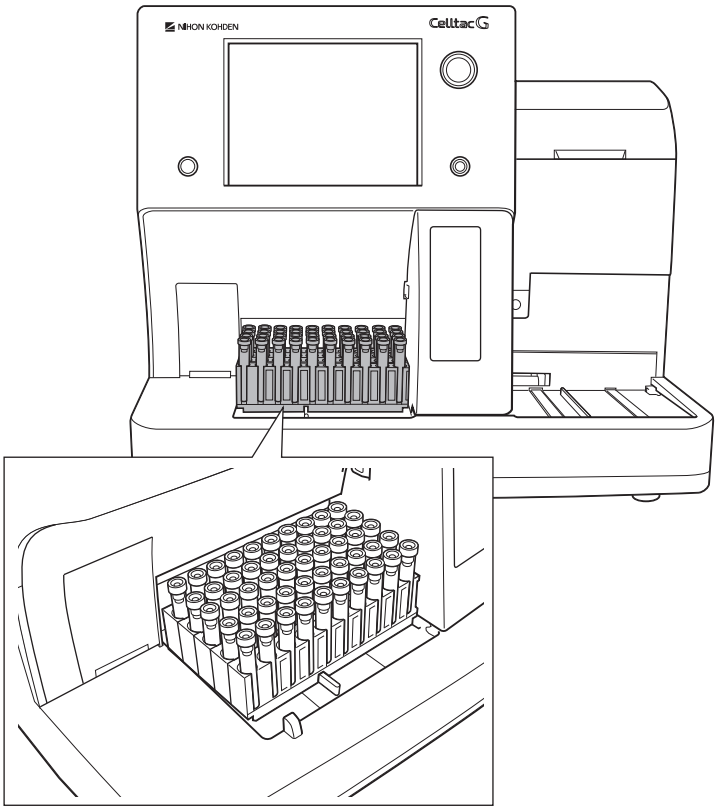
↓

The rack slides out.

> **⚠ CAUTION**
> Do not put your hand on the rack or sample tube holder during measurement.

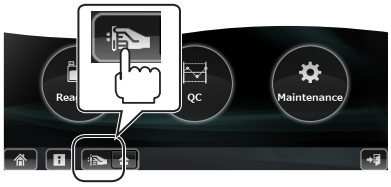
3 The rack with measured samples slides out to the left side of the autoloader.

When a full rack is detected, measurement is paused. Remove the rack in accordance with the displayed message, and resume measurement.

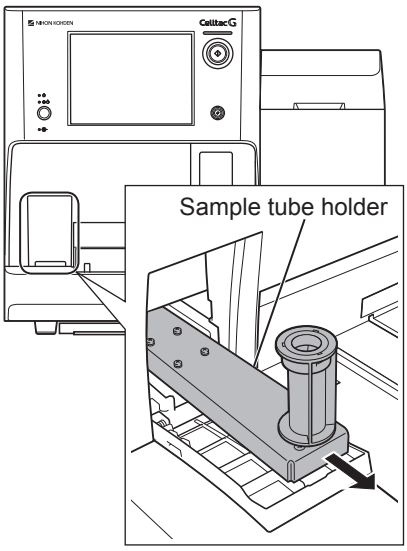


Performing Manual Measurement

NOTE
- Confirm that the blood amount is 1.0 mL or more.
- Use only EDTA (ethylenediaminetetraacetate) as an anticoagulant. Do not use heparin as an anticoagulant. It affects white blood cell and platelet measurement etc.
- Depending on the sample, poor hemolyzation may occur when measurement is performed within 30 minutes after collecting the blood. In that case, leave the sample for more than 30 minutes before measuring it.
- For reliable data, measure the blood sample within 8 hours. Refrigerate the samples when storing them, but return them to room temperature before measuring them. Samples collected more than 24 hours ago might not give a correct measurement.
- Do not use aggregated or coagulated blood. This may damage the analyzer.



1 Touch [ ] to open the Manual Measurement window and eject the sample tube holder.



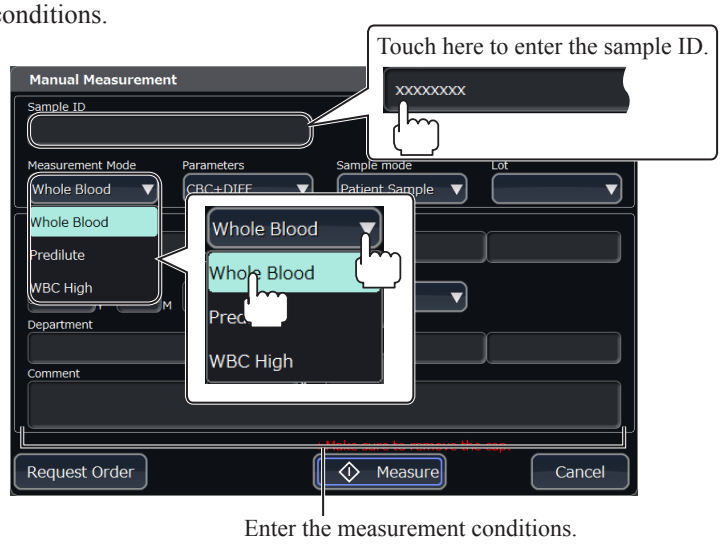
2 Confirm that an adapter for a sample tube or mini collect is set on the sample tube holder that slides out.

"Setting the Adapter for Manual Measurement" (p. 4-16)

Sample Tube	Mini Collect
Sample tube adapter	Mini collect adapter

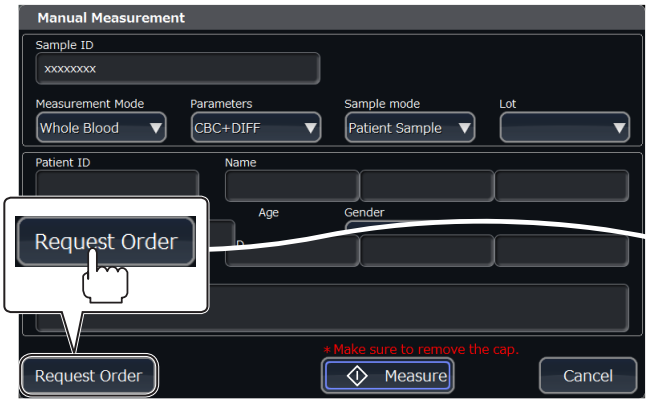
3 Touch “Sample ID” on the Manual Measurement window, and enter the sample ID manually or using a barcode reader.

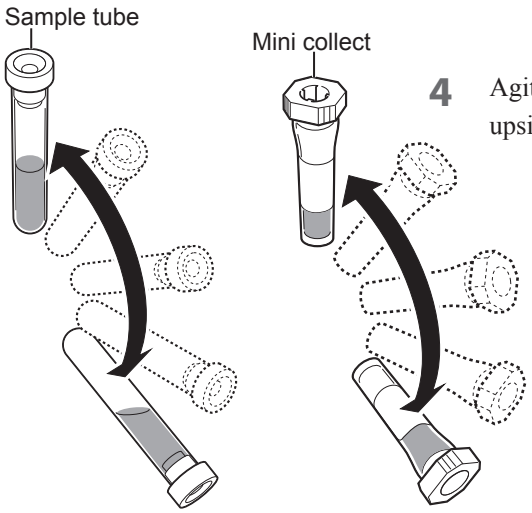
Set the measurement mode to “Whole Blood”, and enter the measurement conditions.



When requesting the order, touch [Request Order] while the sample ID is entered. When there is an order, the order is shown in the Manual Measurement window.

Data Management and Setting Guide:
Section 3 “Work Orders”



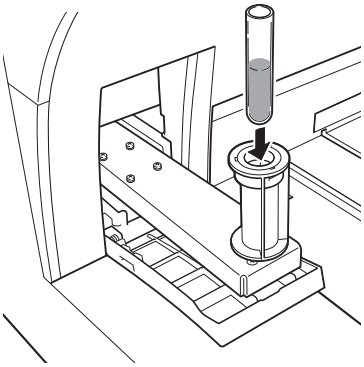
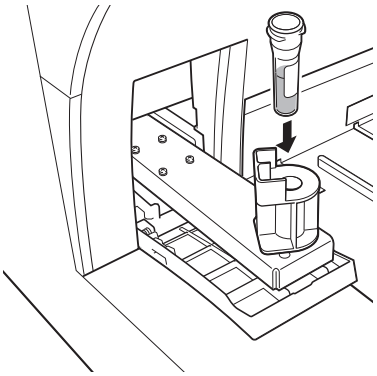


4 Agitate the collected whole blood sample gently by turning the sample tube upside down at least 20 times so that the blood sample is mixed.

5 Remove the cap from the sample tube or mini collect, and insert it into the sample tube holder adapter.

NOTE • Insert the sample tube or mini collect until it contacts the back of the adapter.

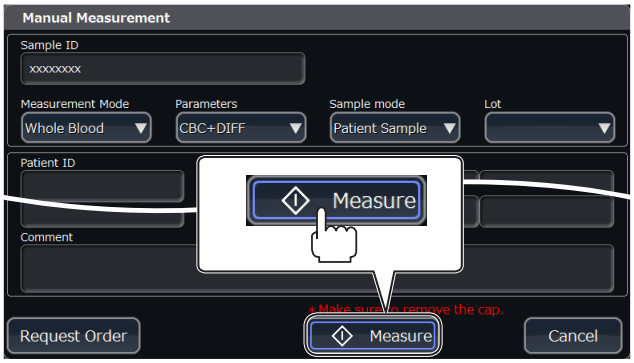
• Make sure to remove the cap.

Sample Tube	Mini Collect
	

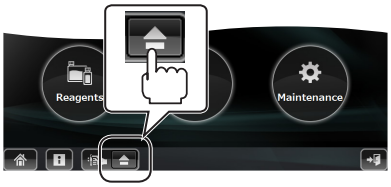
6 Touch [Measure].

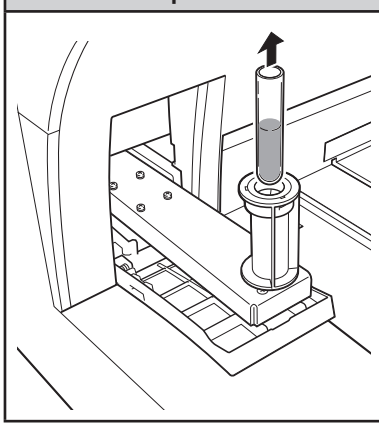
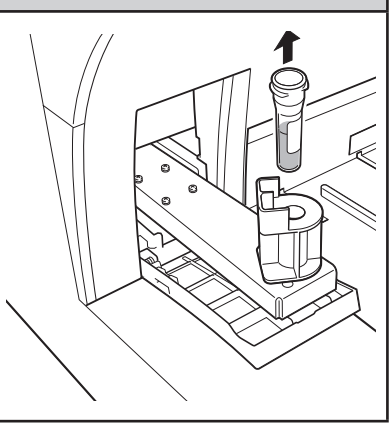
The sample tube holder slides in, and measurement starts.

After the blood is aspirated, the sample tube holder slides out automatically.



7 Remove the sample tube or mini collect from the sample tube holder, and touch [⏏] to slide in the sample tube holder.



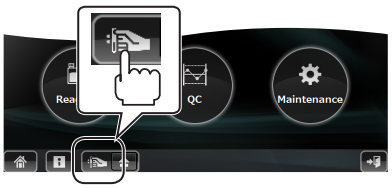
Sample Tube	Mini Collect
	

Performing Pre-dilution Measurement

A small 20 uL blood sample can be manually measured if it is prediluted to a predetermined larger volume.

When performing pre-dilution measurement, the result of WBC 5-part differential is for reference purpose only.

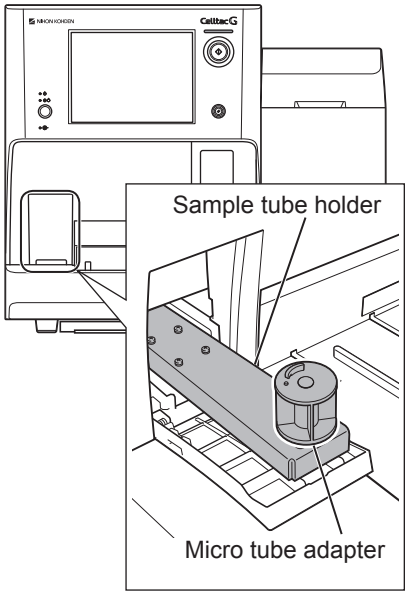
NOTE: Compared to venous blood, the reproducibility of measured data from small blood samples (blood from the earlobe) varies depending on the blood collecting process or diluent procedure. Create samples quickly and carefully.



1 Touch [ ] to open the Manual Measurement window and eject the sample tube holder.

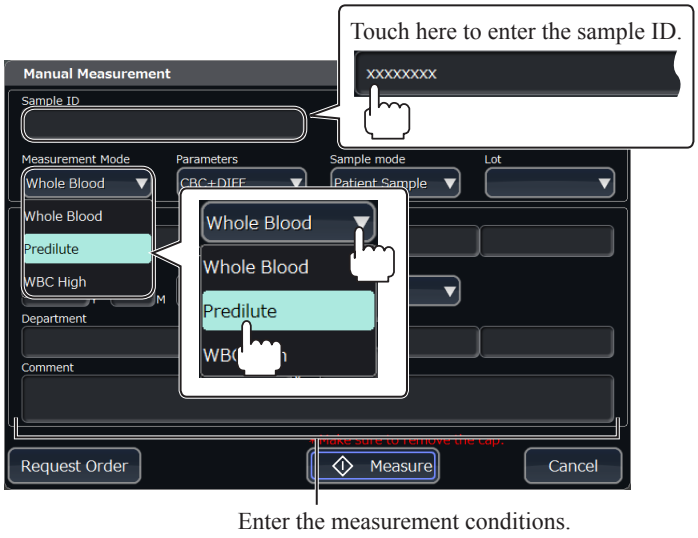
2 Confirm that a micro tube adapter is set on the sample tube holder that slides out.

"Setting the Adapter for Manual Measurement" (p. 4-16)



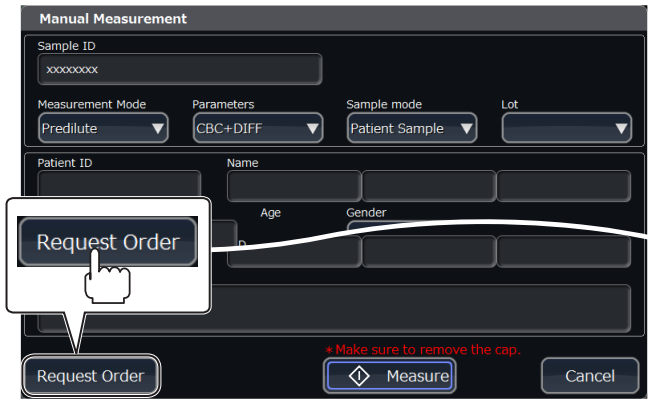
3 Touch "Sample ID" on the Manual Measurement window, and enter the sample ID manually or using a barcode reader.

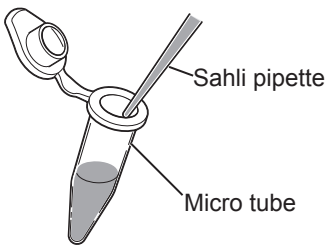
Set the measurement mode to "Pre-dilution", and enter the measurement conditions.



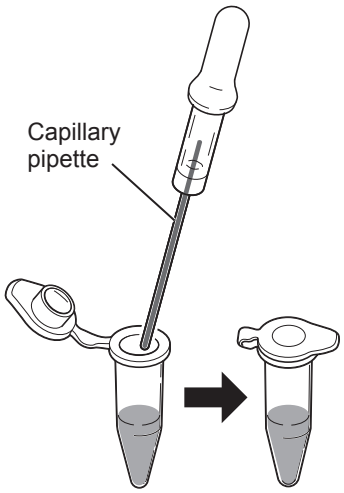
When requesting the order, touch [Request Order] while the sample ID is entered. When there is an order, the order is shown in the Manual Measurement window.

Data Management and Setting Guide:
Section 3 “Work Orders”





4 Dispense 120 µL of diluent (ISOTONAC•3/4) into the micro tube using a sahli pipette.

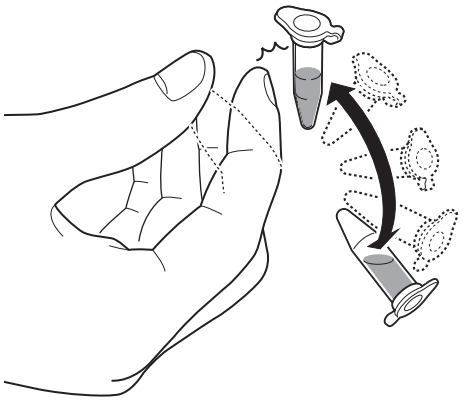


5 Collect 20 µL of blood using a micro cap.

NOTE: Wipe the blood off the capillary tube surface. Take care not to wipe off the blood inside the capillary tube.

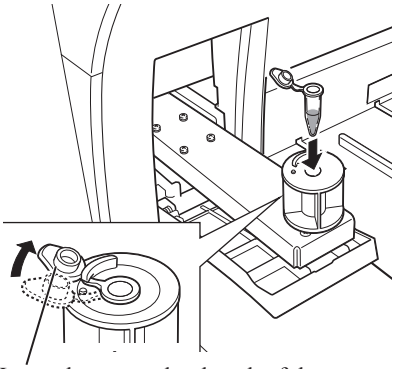
6 Inject the collected blood into the diluent in the micro tube and close the cap securely.

NOTE: Inject the blood carefully so as not to create bubbles, and wash the inside wall of the capillary pipette (capillary tube) carefully so as not to leave blood on the wall.



7 Agitate the collected blood and diluent thoroughly by flipping the micro tube with your finger so that the collected blood and diluent are mixed. Make sure that the sample is not sticking to the top of the micro tube after agitation.

NOTE
- When measuring a sample collected some time ago, agitate it gently again.
- Mix the sample gently. Foam causes hemolyzation.
- When the sample is not used immediately, close the micro tube cap to prevent evaporation.



Insert the cap under the tab of the adapter to secure it.

8 Set the micro tube in the analyzer.

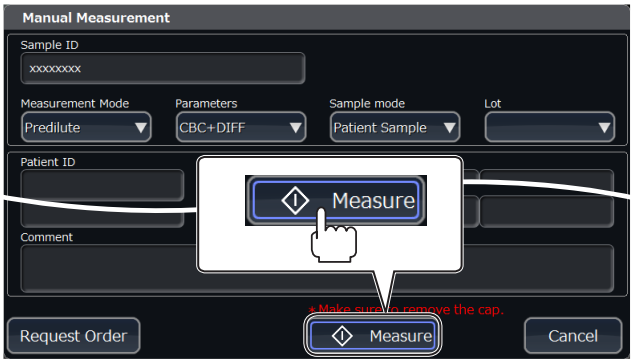
1) Uncap the micro tube.

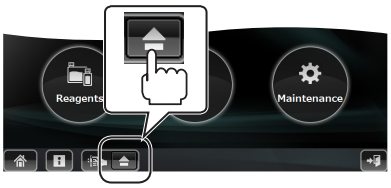
2) Insert the micro tube into the adapter on the sample tube holder and secure it as shown in the figure.

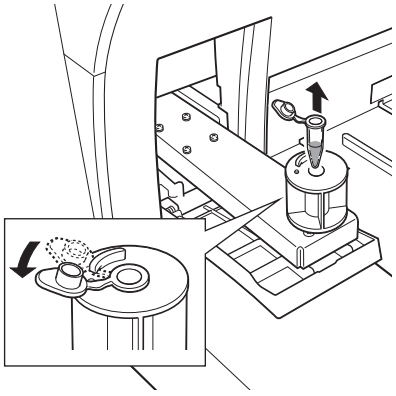
9 Touch [Measure].

The sample tube holder slides in, and measurement starts.

After the blood is aspirated, the sample tube holder slides out automatically.





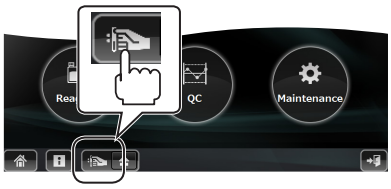


10 Remove the micro tube from the sample tube holder, and touch [⏏] to slide in the sample tube holder.

Performing WBC High Dilution Measurement

The sample is aspirated and diluted with a higher dilution rate than normal before measurement.

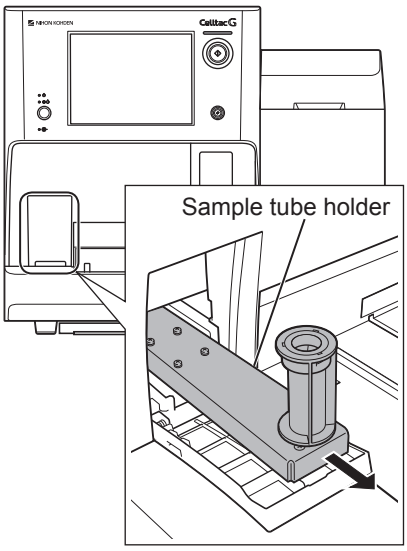
NOTE
- Confirm that the blood amount is 1.0 mL or more.
- Use only EDTA (ethylenediaminetetraacetate) as an anticoagulant. Do not use heparin as an anticoagulant. It affects white blood cell and platelet measurement etc.
- Depending on the sample, poor hemolyzation may occur when measurement is performed within 30 minutes after collecting the blood. In that case, leave the sample for more than 30 minutes before measuring it.
- For reliable data, measure the blood sample within 8 hours. Refrigerate the samples when storing them, but return them to room temperature before measuring them. Samples collected more than 24 hours ago might not give a correct measurement.
- Do not use aggregated or coagulated blood. This may damage the analyzer.



1 Touch [ ] to open the Manual Measurement window and eject the sample tube holder.

2 Confirm that an adapter for a sample tube or mini collect is set on the sample tube holder that slides out.

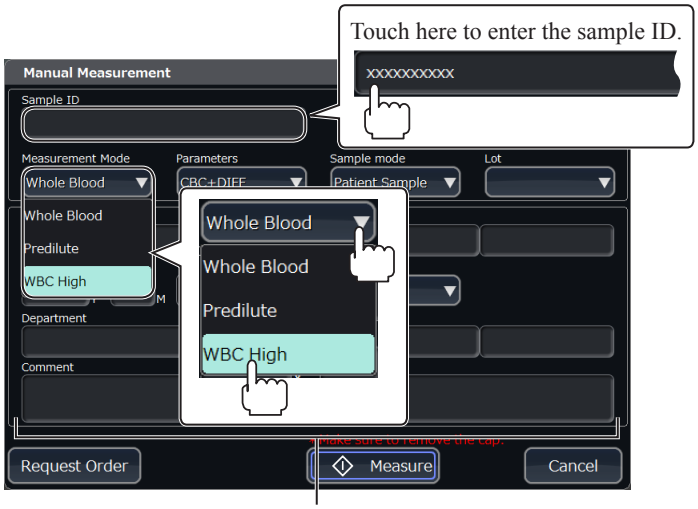
"Setting the Adapter for Manual Measurement" (p. 4-16)



Sample Tube	Mini Collect
Sample tube adapter	Mini collect adapter

3 Touch “Sample ID” on the Manual Measurement window, and enter the sample ID manually or using a barcode reader.

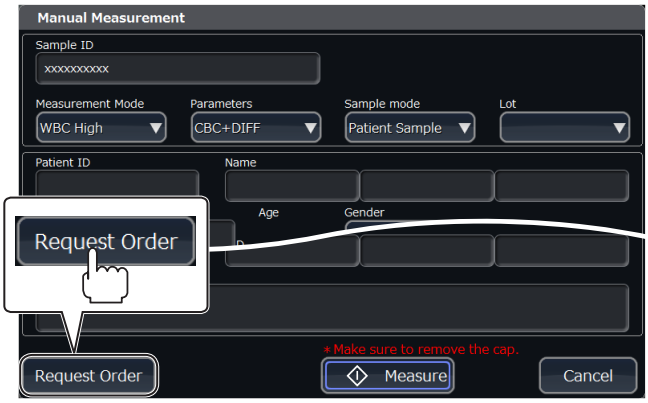
Set the measurement mode to “WBC High”, and enter the measurement conditions.

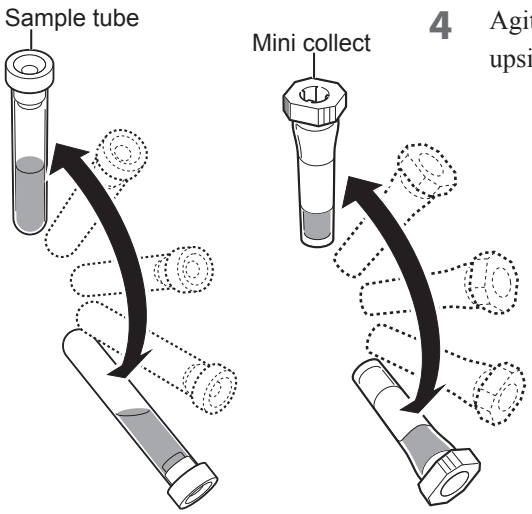


Enter the measurement conditions.

When requesting the order, touch [Request Order] while the sample ID is entered. When there is an order, the order is in the Manual Measurement window.

Data Management and Setting Guide:
Section 3 “Work Orders”



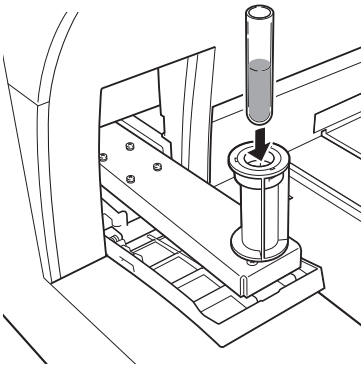
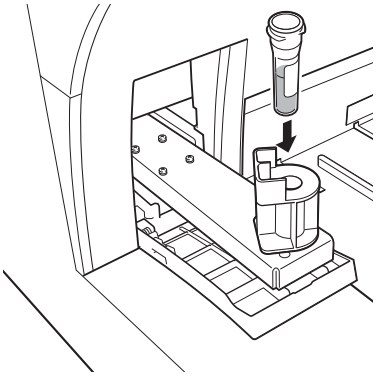


4 Agitate the collected whole blood sample gently by turning the sample tube upside down at least 20 times so that the blood sample is mixed.

5 Remove the cap from the sample tube or mini collect, and insert it into the sample tube holder adapter.

NOTE • Insert the sample tube or mini collect until it contacts the back of the adapter.

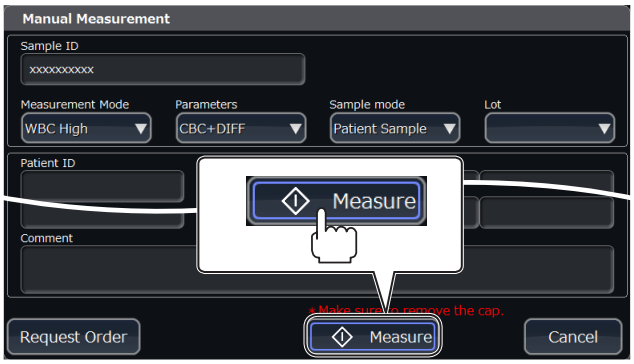
• Make sure to remove the cap.

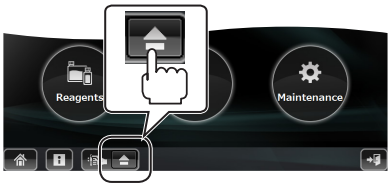
Sample Tube	Mini Collect
	

6 Touch [Measure].

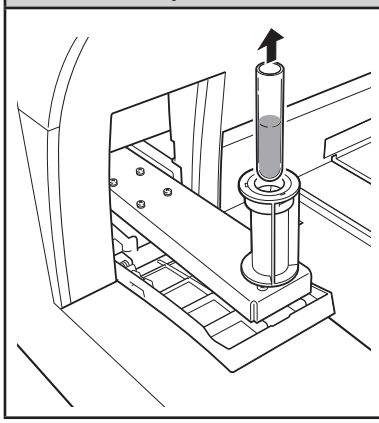
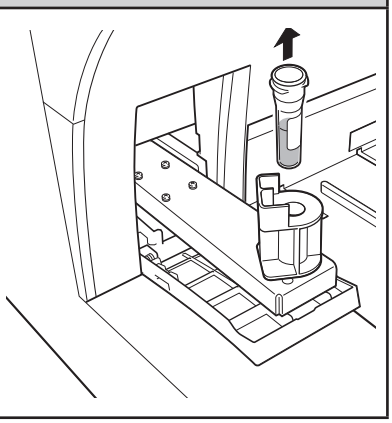
The sample tube holder slides in, and measurement starts.

After the blood is aspirated, the sample tube holder slides out automatically.





7 Remove the sample tube or mini collect from the sample tube holder, and touch [⏏] to slide in the sample tube holder.

Sample Tube	Mini Collect
	

Checking the Measurement Results

Check the measurement results on the Data List window.

Data Management and Setting Guide: Section 4 “Data Review”

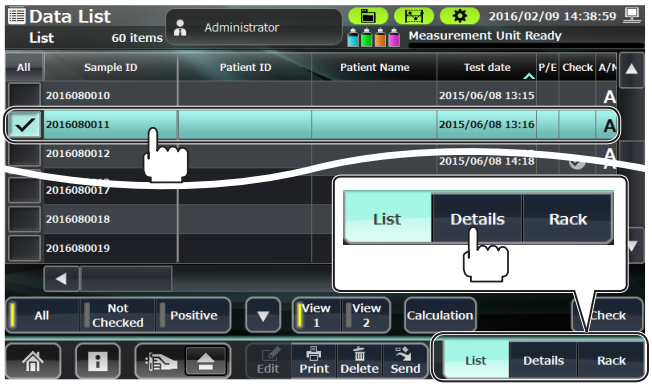
Opening the Data List Window

1 Open the Home screen.

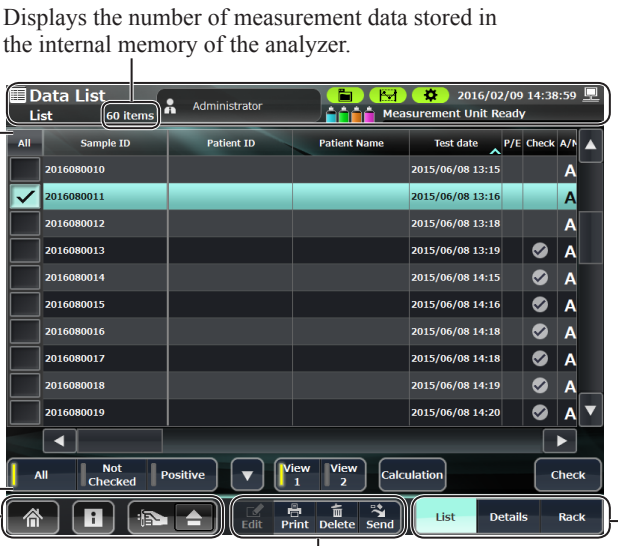
If you are in another window, touch [ ] at the lower left.

2 Touch [Data List] on the Home screen. The Data List window opens.

3 To open the Data Details window and the Rack window, select any work order and touch [Details] or [Rack] to open the windows.



Example: Data List Window



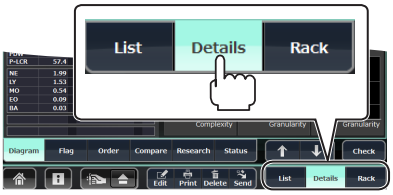
Data List Window

Touch [Data List] on the Home screen or [List] on the Review window to open the Data List window.

The data list window lists the measurement data stored in the internal memory of the analyzer.

Data Management and Setting Guide:
"Data List Window" in Section 4

Data Details Window

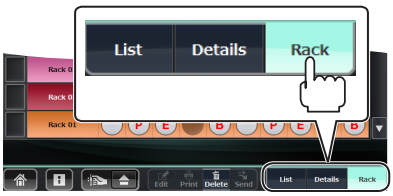


Select any measurement data on the Data List window and touch [Details] to open the Data Details window.

The Data Details window displays detailed information for measurement data.

Data Management and Setting Guide:
"Data Details Window" in Section 4

Rack Window

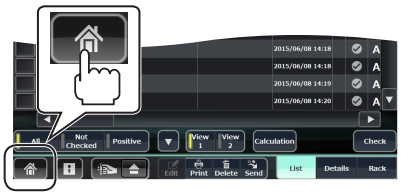


Select any measurement data and touch [Rack] on the Data List window to open the Rack window.

The Rack window displays information such as the rack position for the measurement data.

Data Management and Setting Guide:
“Data Details Window” in Section 4

Turning Off the Analyzer



1 Check the consumables remaining, presence of abnormalities, etc. Refer to “Daily Check” (p. 9-2).

“Check When Turning Off the Analyzer” (p. 9-4)

2 Open the Home screen.

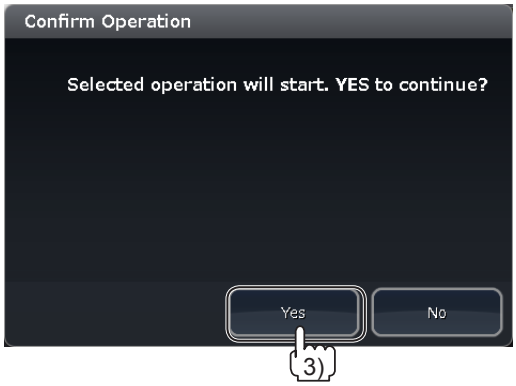
If you are in another window, touch [ ] at the lower left.

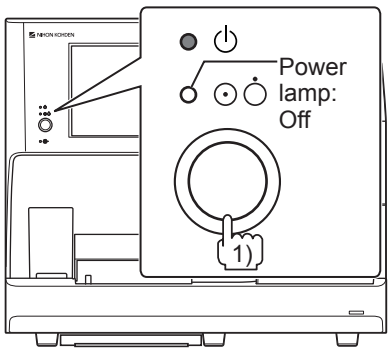
3 Logout.

1) Touch [ ] on the Home screen. The Operator Management window opens.

2) Touch [Logout].

3) When the Confirm Operation window appears, touch [Yes].



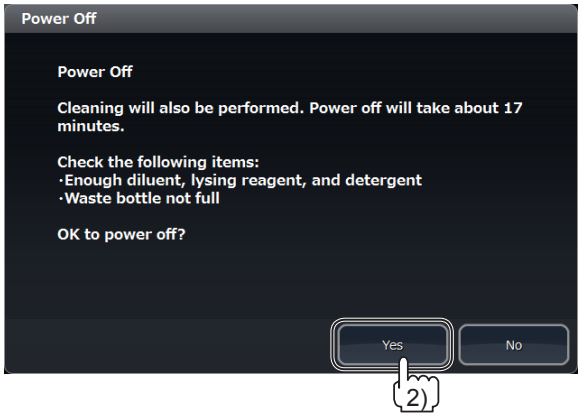


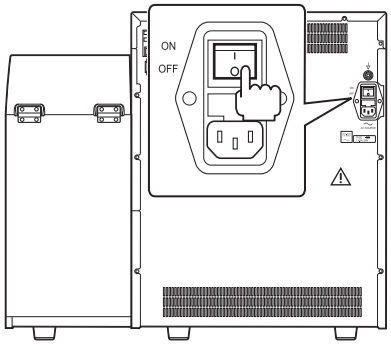
4 Turn off the power.

1) Press the power switch on the front panel of the analyzer.

2) When a confirmation window appears, touch [Yes].

The analyzer performs cleaning automatically, and when it is finished, the power is turned off, then the Power lamp is turned off.





5 When moving or transporting the analyzer, turn the main power switch on the rear panel off (to ○).

6 Quality Control

General

Measure the hematology control to perform quality control.

Use a hematology control listed in the following table for quality control.

For precautions, refer to Section 3 “Safety Information”.

“Hematology Control” (p. 3-11)

Name and Model		Packing Unit
Hematology control	MEK-5DN	3 mL × 2
	MEK-5DL	
	MEK-5DH	

The analyzer has 2 quality control programs, L-J and $\overline{X}$-R.

Set the quality control method and judgment method according to the criteria of the facility or the lab.

Data Management and Setting Guide:
Section 5 “System Settings”

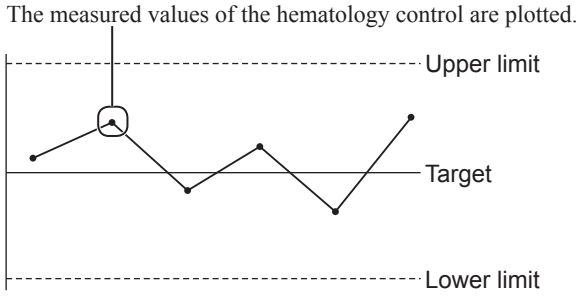
L-J (Levey-Jennings) Control

The analyzer stores quality control data for each set control lot information. Up to 25 items of lot information, and up to 300 measurement data items per lot can be stored.

This quality control method measures the hematology control and checks the measured values.

One sample of hematology control is measured every day, and the measured result is shown in the Trend window and List window of the QC.

Trend Graph



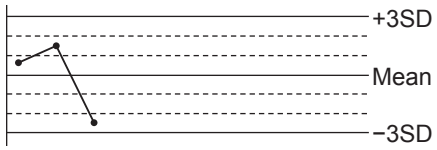
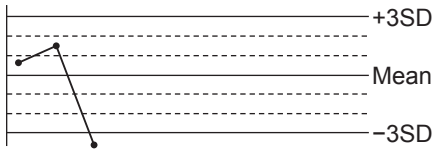
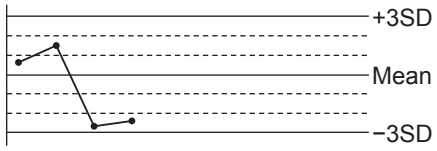
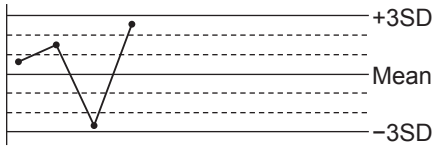
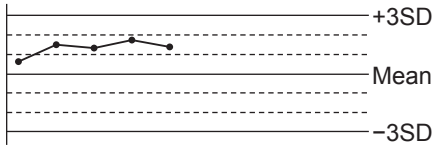
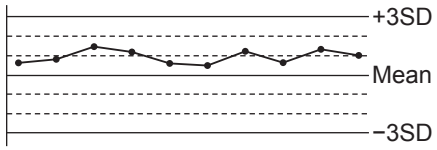
When the measured value exceeds the limit, it fails and the quality control status indication at the top of the window turns red.

The target and limit can be set according to the standard of the facility or lab.

Data Management and Setting Guide:
Section 5 “System Settings”

Westgard Multirule

When “Westgard Multirules” is set to “ON” in System > [Quality Control] > [Auto judgment method], it is judged as fail when the trend graph is as follows and the quality control status indication at the top of the window turns red.

Trend Graph		Description
1-2S		1 measurement exceeds the mean ±2SD
1-3S		1 measurement exceeds the mean ±3SD
2-2S		2 consecutive measurements exceed the mean +2SD or the mean −2SD
R-4S		1 measurement exceeds the mean +2SD and the next measurement exceeds the mean −2SD, or vice versa (total 4SD)
4-1S		4 consecutive measurements exceed the mean +1SD or the mean −1SD
10-X		10 consecutive measurements fall on one side of the mean

- Period average

  The average of all plotted values.
- SD

  SD stands for Standard Deviation.
  Statistically, 95.4% of all measured values fall within the range of the period mean ±2SD and 99.7% of all measured values fall within the range of the period mean ±3SD.

Possible causes of the abnormal results in the above graphs are generally believed to be as follows.

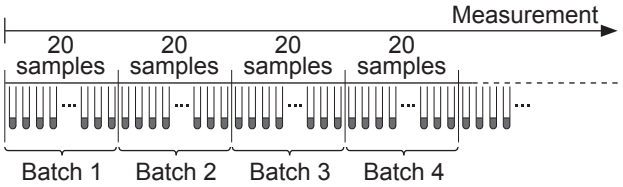
- Change of the reagent or hematology control, or different production lots of the hematology control
- Change of environmental conditions such as room temperature
- Analyzer problems such as dilution ratio error or circuit error
- Insufficient hematology control stirring
- Temperature variation of diluent
- Dirt in measurement system (detector, quantifier and sample cup)

$\overline{X}$B ($\overline{X}$Batch) Management

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 barely affected by differences between samples so they faithfully reflect the precision in the system.

The daily samples data are divided into batches of 20 samples.



For each batch of 20 samples, the $\overline{X}$B value is automatically calculated using the following formula.

$$X(B, i) = X(B, i-1) + SGN[F] \times (F/N)^2$$

$$F = \Sigma SGN[Xj - X(B, i-1)] \times \sqrt{|Xj - X(B, i-1)|}$$

X(B, i): $\overline{X}$B

Xj: Each data in batch

X (B, i–1): $\overline{X}$B of previous batch

SGN [ ]: Sign function

N: Number of samples in batch

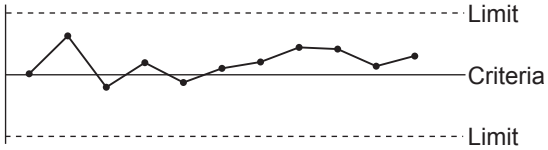
The $\overline{X}$B value of the previous batch is needed to calculate the $\overline{X}$B value of the current batch.

When obtaining the $\overline{X}$B value of the first batch at $\overline{X}$B control introduction, basically a past measured value obtained in the same facility should be used, however, the center value of MCV, MCH and MCHC can be used instead as the $\overline{X}$B value of the previous batch.

NOTE: If the mean value is used as the initial $\overline{X}$B value, the $\overline{X}$B value approaches the real or true value as the number of samples increases. After about 100 samples are counted, the reliability of the $\overline{X}$B value is ensured.

Mean value	MCV:	89.5
	MCH:	30.5
	MCHC:	33.8

The $\overline{X}$B values are plotted on the XB window.



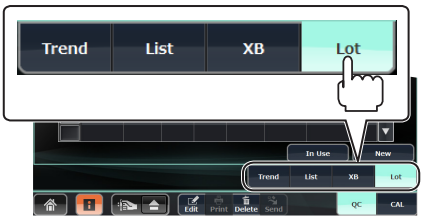
The average $\overline{X}$B value is used as the initial value. The initial value is also determined by the facility or lab staff.

The management limit value should be determined by the facility or lab staff.

Data Management and Setting Guide:
Section 5 “System Settings”

NOTE
- When the mean values of MCV, MCH and MCHC are used as the initial value of $\overline{X}$B, there is no reliability in the plotted graph until the $\overline{X}$B value approaches the true value and becomes stable.
- The calculation of the $\overline{X}$B value is applied to all samples which have an RBC value greater or equal to 500,000 µL. Therefore delete the hematology control data from the stored data in advance. The management data for calibration and $\overline{X}$-R data are excluded from the calculation. Data measured with the QC selection set to “QC” are automatically removed from the target of $\overline{X}$B calculation.
- When the number of samples reaches 2,000 and the window becomes full, do the following procedures.
  - Use each XB data in the last batch as the initial value.
  - Change each initial value on the plotted graph to the mean $\overline{X}$B. (The plotted graph is updated every 20 batches.)
  - Delete all stored data. (Prevents data interference between the new and previous graphs.)

Registering and Editing Hematology Control



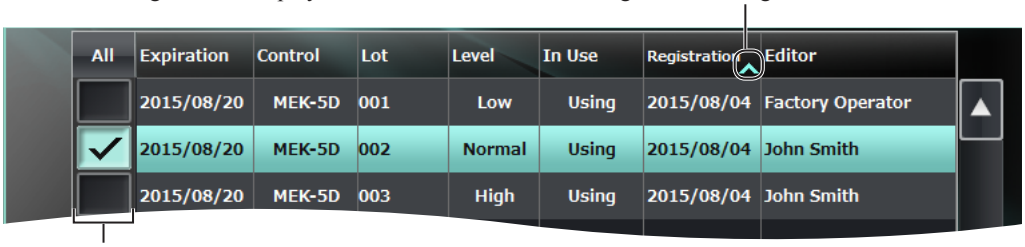
Touch [Lot] in the QC window to open the Lot window.

In the Lot window, you can register the hematology controls to use in quality control, view the list of added hematology controls, and manage the production lots of the hematology controls.

You can also edit or delete hematology control information if necessary.

Item	Description
Expiration	Expiration date of the hematology control.
Control	Name of the material used as the hematology control (MEK-5D)
Lot	Lot number of the hematology control.
Level	Concentration level (Low, Normal, High)
In Use (management target flag)	Indicates whether the hematology control is registered for use in quality control. • Can be used in quality control: In Use • Not used in quality control: Unused
Registration	Date the hematology control is set.
Editor	Name of the operator who registered or edited the hematology control.

Sort icon
Touching sortable displayed items sorts them in ascending or descending order.



Check box
- Touch the hematology control you want to delete or change In Use to select it. A check mark appears.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.

Touch [▲] or [▼] to scroll the list vertically.

[In Use]
Toggles In Use ("Using", "Not Use") for the selected hematology control.

[New]
Sets a new hematology control.

Edits or deletes the information of the selected hematology control.

Registering Hematology Control

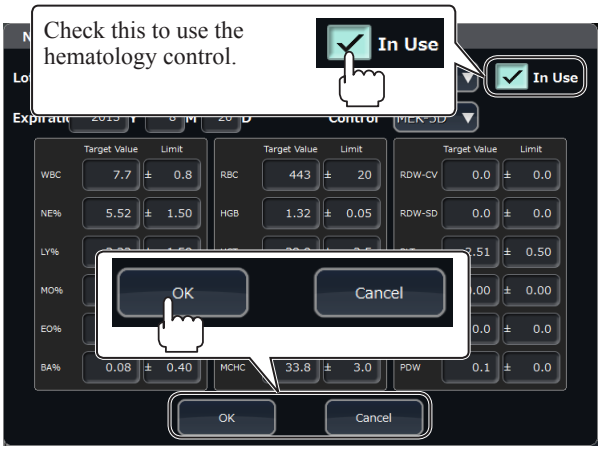
Register the hematology controls.

1 Touch [New] in the Lot window. The New Lot window opens.

2 Read the QR code on the assay sheet of the hematology control with the barcode reader.

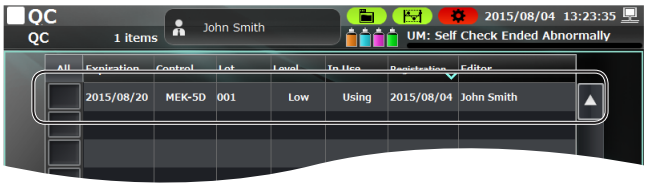
It also can be entered directly by touching the setting item.
(Refer to p. 1-7)

3 To register this hematology control for use in quality control, check “In Use” and touch [OK].



The hematology control is registered to the list.

When “In Use” is checked, In Use is set to “Using”.
When “In Use” is unchecked, In Use is set to “Not Use”.

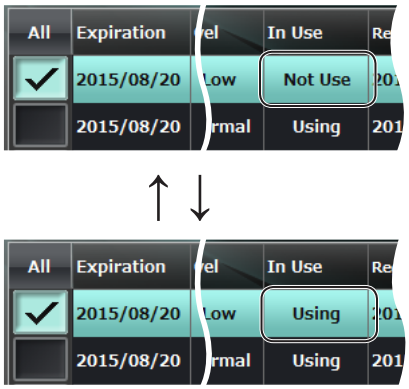


Changing Hematology Control

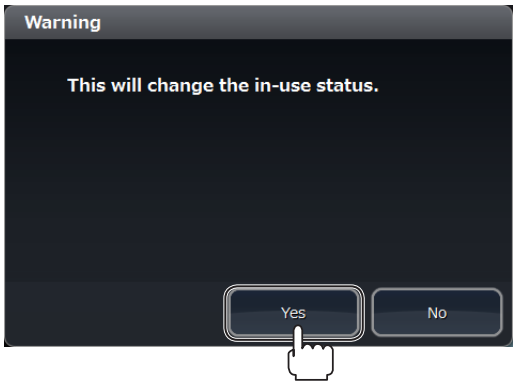
Set whether or not the hematology control can be used in a quality control.

1 Select the hematology control in the Lot window, and touch [In Use].

- To select more than one control, touch the check box.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.



2 When the Warning window appears, touch [Yes] to set “Using”or “Not Use”.



Editing Hematology Control Information

You can edit hematology control information.

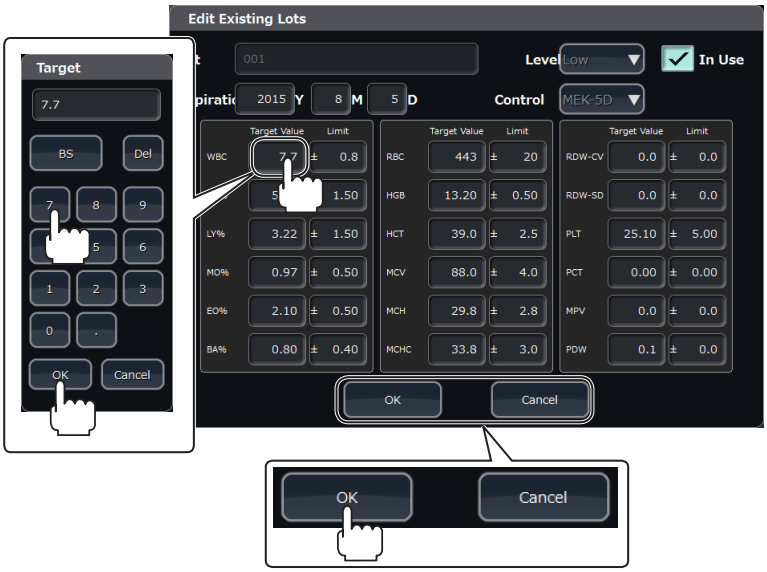
- Level (Low, Normal, High)
- Expiration
- Target and limit of each parameter

1 Select the hematology control and touch [Edit] in the Lot window to open the Edit Existing Lots window.

2 Touch the parameter to edit and change the value, and then touch [OK].

"Basic Operations" (p. 1-7)

Example: Editing the target value of WBC

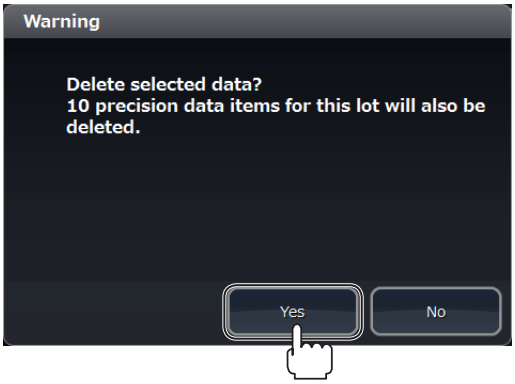


Deleting Hematology Control

1 Select the hematology control to delete in the Lot window, and touch [Delete].

- To select more than one control, touch the check box.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.

2 When the Warning window appears, touch [Yes].



Measuring the Hematology Control

NOTE
- Measure the hematology control at a fixed time every day.
- Observe the expiration date and storage conditions of the hematology control. If the storage conditions of the control are not optimum, hemolyzation or expansion of the blood cells will occur and abnormal data will occur frequently.
- Before measurement, register the hematology control for use in quality control. Even if a hematology control is measured, it's data is not saved as quality control data unless the lot information of the hematology control is registered with the analyzer.
- If the cap of the hematology control gets dirty, wipe it with lint-free paper.

"Registering and Editing Hematology Control" (p. 6-6)

1 Measure the hematology control.

Auto Measurement

Set the control on the rack, and perform an auto measurement. The analyzer reads the barcode, verifies it with the lot information, and saves the data to the lot.

"Performing Auto Measurement" (p. 5-8)

Manual Measurement

Enter the barcode information of the control to the sample ID to verify it with the lot information, and save the data to the lot. Also, by selecting the target lot in the Manual Measurement window and measuring the sample, you can save the quality control data to the selected lot.

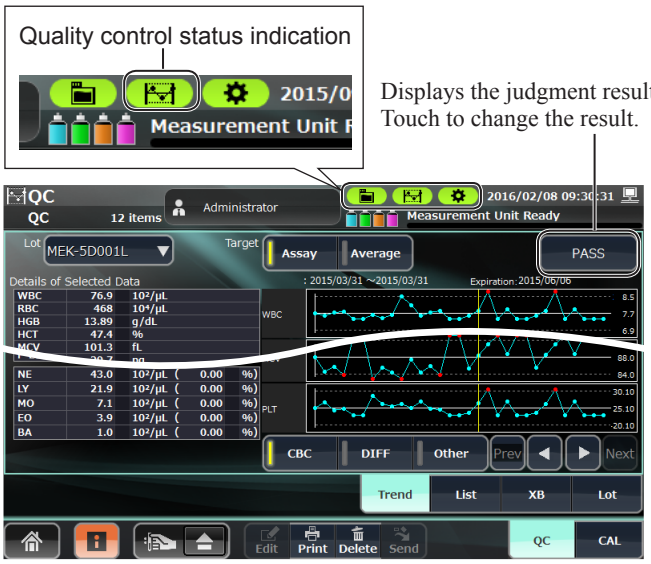
"Performing Manual Measurement" (p. 5-10)

2 Check the measurement result, and perform calibration if necessary.

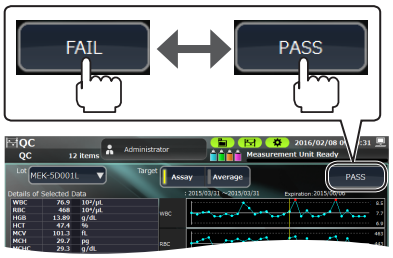
"Performing Calibration" (p. 7-2)

Checking the QC Judgment Result

After the hematology control measurement is completed, the judgment result appears at the top right of the QC window, and the quality control status indication at the top of the window changes.



Status Indication	Status
Quality Control 	Green when all the following conditions are met: • Quality control measurement is performed for all control samples in use. • The last quality controlled measured results of all control samples in use meet the quality control judgment criteria or are approved by the operator.



Pass/fail of the data is judged by the analyzer automatically, but the final decision is made by an operator such as an technician. Automatic judgment results can be changed at the operator's responsibility.

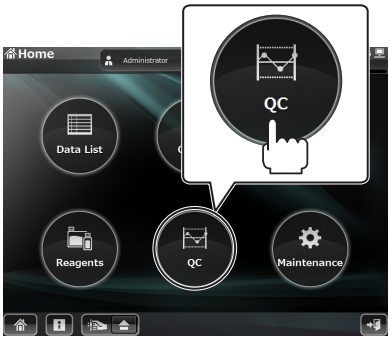
Touch the judgment result to change the result.

Even after approving the judgment result and changing the indication to PASS, data exceeding the limit is still displayed in red on the trend graph.

Opening the QC Window

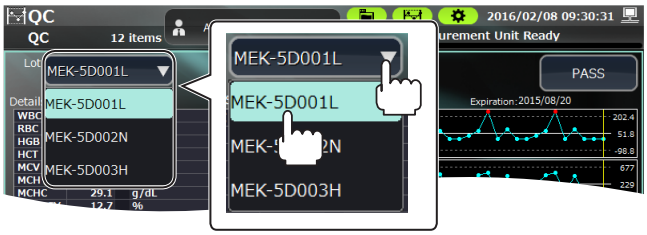
1 Open the Home screen.

If you are in another window, touch [ ] at the lower left.



2 Touch [QC] on the Home screen. The QC window opens.

3 Select the hematology control to be displayed.



4 To open the List window, the XB window, or the Lot window, Touch [List], [XB] or [Lot] respectively to toggle between the windows.

Example: Trend Window

Displays information. (Refer to p. 1-5)

Check the displayed information on each window.

[ ]: Opens the Home screen. (Refer to p. 1-5)
[ ]: Opens the Maintenance Log window. (Refer to p. 10-5)
[ ]: Starts manual measurement. (Refer to p. 5-10)
[ ]: Ejects sample tube holder.

Edits, prints or deletes the selected or displayed data.

Changes the window.

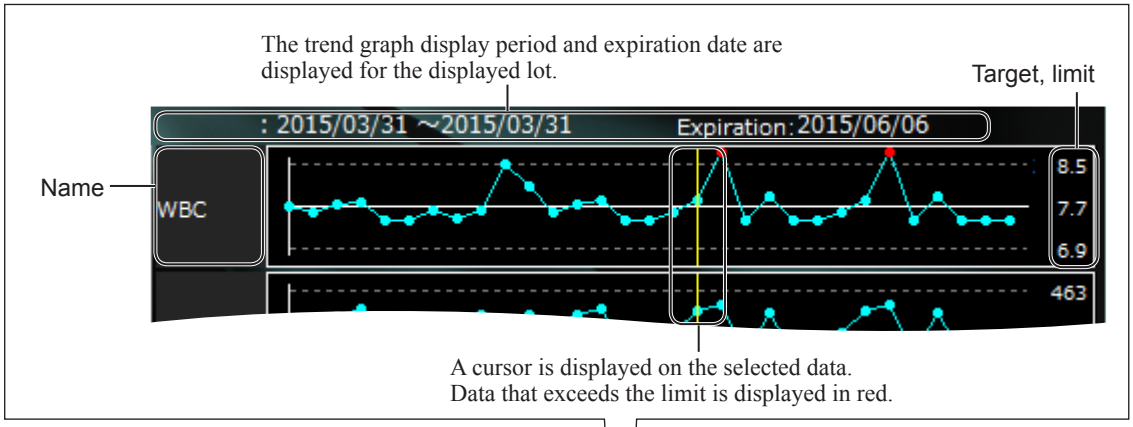
Trend Window

Touch [QC] on the Home screen, or [Trend] on another QC window to open the Trend window.

The Trend window displays the measured data of hematology controls as trend graphs.

Up to 30 data can be displayed on one screen. The latest data is plotted at the right edge.

Data in the Trend window and data in the List window are linked with each other.



Target
Toggles the display of target and limit.

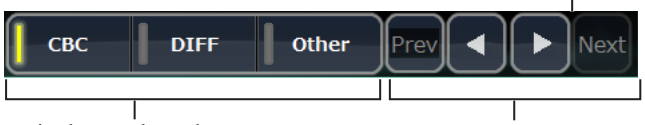
Setting	Target	Limit
Average	Average of all data	±2SD, ±3SD values
Assay	The value set in Lot.	

Displays the judgment result of the latest data. The judgment result can be changed by touching here. (Refer to p. 6-12)

Lot
Selects the hematology control for which a trend graph is displayed.

Details of the Selected Data
Displays the details of the data selected in the trend graph.

Prints or deletes the selected measurement data.



Changes the displayed parameters in the trend graph.
Parameters for [Other] can be set in System Setting window.
[CBC]: WBC, RBC, HGB, MCV and PLT
[DIFF]: NE%, LY%, MO%, EO% and BA%
[Other]: Other

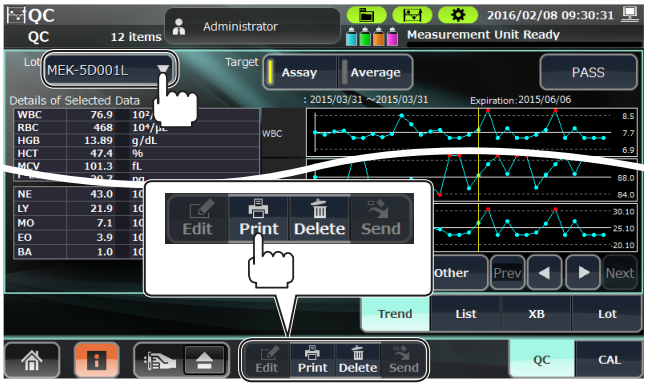
[Prev], [Next]: Scrolls the screen left or right.
[◀], [▶]: Changes the selected data.

Printing Trend Graphs and Measurement Data

You can print the trend graph of the currently used hematology control and measurement data on the external output printer after setting the period.

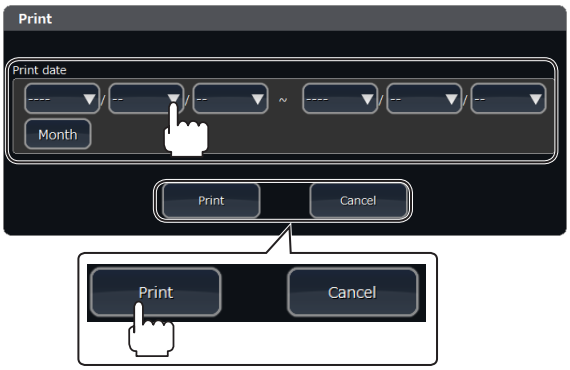
Up to 300 measurement data of trend graph and measurement data in the specified period can be printed.

1 Display the hematology control on the Trend window and touch [Print].

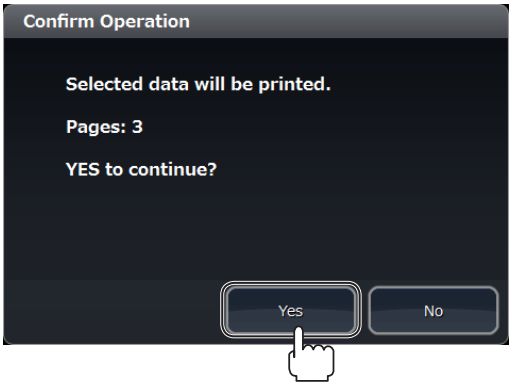


2 When the window to specify the period is displayed, set the date and time of print target and touch [Print].

When [Month] is touched, the date of this month is set automatically.



3 When the Confirm Operation window appears, touch [Yes].



List Window

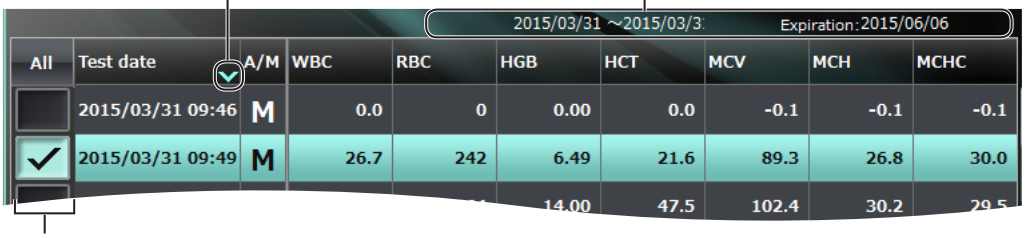
Touch [List] in the QC window to open the List window.

The List window lists the measured data of each hematology control.

Data in the Trend window and List window are linked.

Sort icon
Touching sortable displayed items sorts them in ascending or descending order.

The display period and expiration date of the list are displayed for the displayed lot.



Check box
- Touch the data you want to delete to select it. A check mark appears.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.

Target
Toggles the display of target and limit.

Setting	Target value	Range
Average	Average of all data	±2SD, ±3SD values
Assay	The value set in Lot.	

Displays the judgment result of the latest data. The judgment result can be changed by touching here. (Refer to p. 6-12)

Lot
Select the hematology control for which a list is displayed.

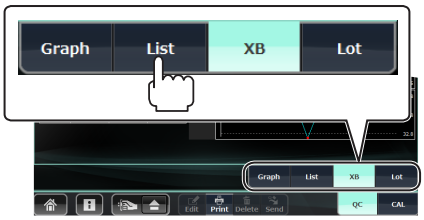
Touch [▲], [▼], [◀] or [▶] to scroll the list vertically or horizontally.

Statistics
Lists the statistical data of each measured parameter.

Average:	Averages of each parameter
2SD:	Two standard deviations of the sample
CV:	Sample standard deviation divided by the mean (expressed as %)
Target value:	The assay value or average that is set in Lot
Range:	The limit that is set in Lot, or 2SD or 3SD value
Difference:	The difference between the selected data and the average.

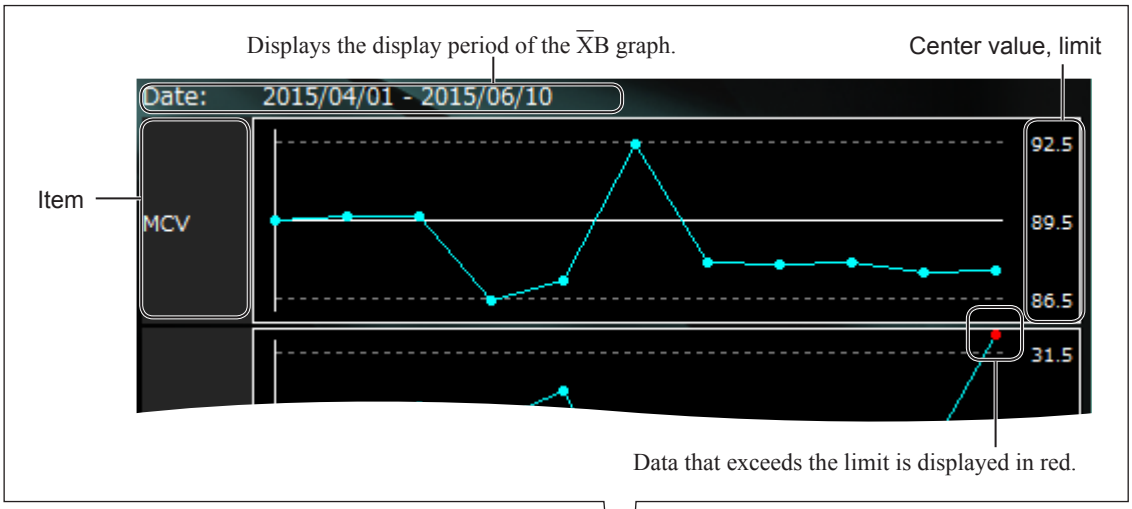
Deletes the selected data.

XB Window



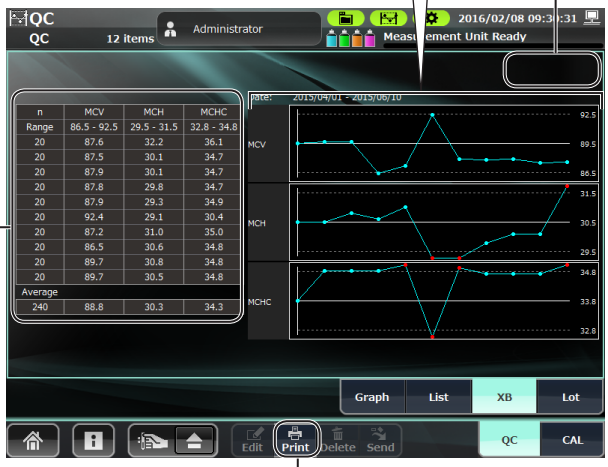
Touch [XB] in the QC window to open the XB window.

The XB window displays the statistic calculation results and $\overline{X}B$ graphs of the MCV, MCH, and MCHC parameters.



Displays the judgment result of the latest data.
The judgment result can be changed by touching here.
(Refer to p. 6-12)

Patient sample statistic data
Displays the statistic calculation result of MCV, MCH, and MCHC parameters using the patient sample measurement data.

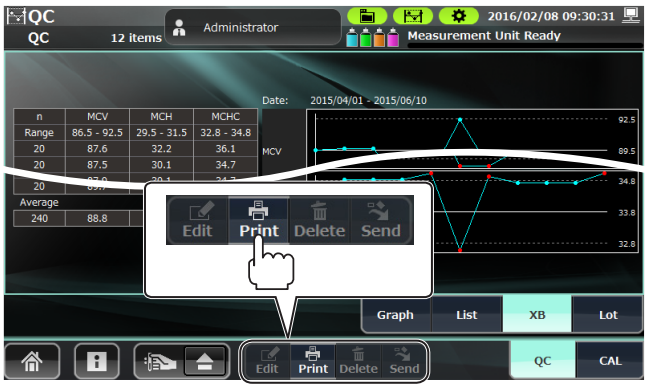


Prints the displayed window.

Printing the XB Window

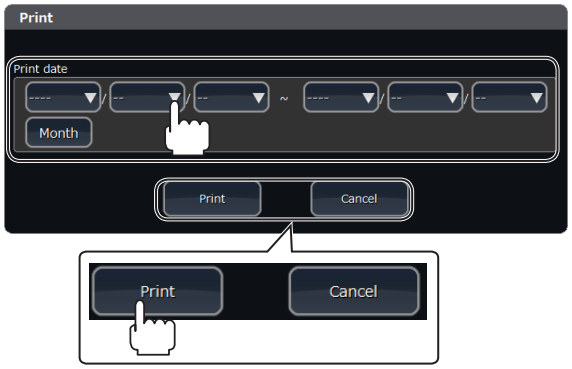
You can print the contents of the XB window on the external output printer.

1 Display the XB window and touch [Print].

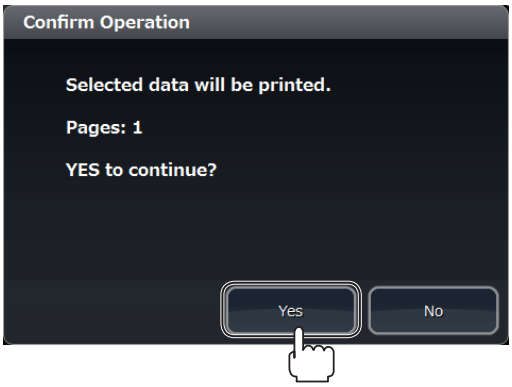


2 When the window to specify the period is displayed, set the date and time and touch [Print].

When [Month] is touched, the date of this month is set automatically.



3 When the Confirm Operation window appears, touch [Yes].



7 Calibration

Performing Calibration

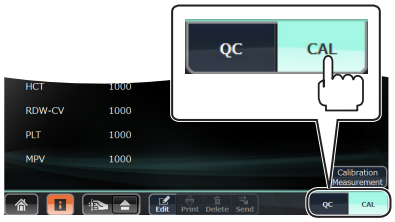
When an unacceptable error is found in a measurement value as a result of quality control, the analyzer needs to be calibrated so that measurements are closer to the true values.

Section 6 “Quality Control”

The analyzer is calibrated with MEK-CAL hematology calibrator.

“HGB, HCT and PLT Calibration with Human Blood” (p. 7-7)

NOTE
- WBC, RBC, HGB, HCT, RDW-CV, PLT and MPV and sensitivity adjustment (FS, FL, SD) of the WBC 5 part differential scattergram can be calibrated with MEK-CAL calibrator.
- The WBC 5-part differential is calibrated by checking that the calibration coefficient of NE%, LY%, MO%, EO% and BA% is 1000. Only check the calibration coefficient here because the sensitivity adjustment of the scattergram allows for precise calibration of the WBC 5-part differential.
- When calibrating with a reference method that uses a calibrator other than the one recommended by Nihon Kohden, measure more than 10 samples collected within the past 8 hours (past 4 hours for WBC differential) and which were stored at room temperature after collection, then adjust the calibration coefficient according to the comparison between the measurement values and the reference method values. Do not use a sample which is suspected to be abnormal as the calibrator.
- The MEK-5DN hematology control cannot be used as a calibrator. MEK-5DN is for quality control.
- Do not use a calibrator past its expiration date.
  Unopened: expiration date on the label or package
  Opened: 7 days after opening
- Store the control between 2 and 8°C (36 and 46°F). Do not freeze the calibrator.
- Use the calibrator once it has returned to room temperature.
- Mix the hematology control by gently turning it upside down several times before measurement.
- Read the calibrator manual thoroughly and follow its 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.



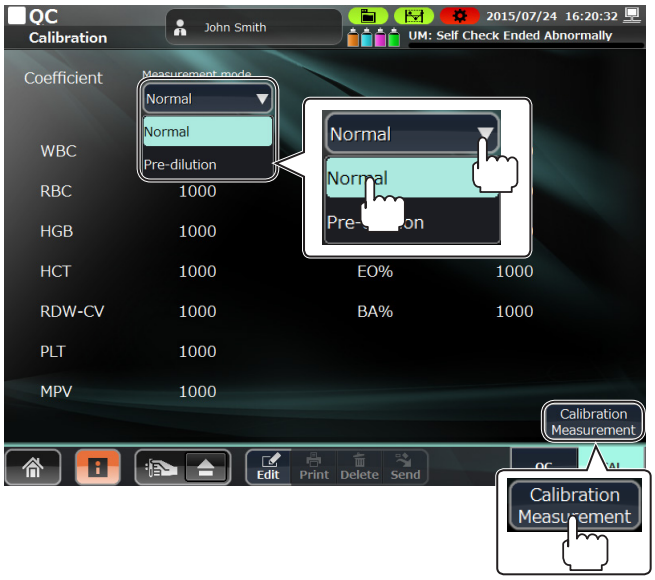
1 Touch [CAL] on the QC window. The Calibration window opens.

“Opening the QC Window” (p. 6-13)

2 Select a measurement mode (Normal or Pre-dilution) and touch [Calibration Measurement]. Check the measurement method to use and select the calibration mode.

Calibration Mode	Auto Measurement	Manual Measurement		
		Whole Blood	Pre-dilution	WBC High
Normal	✓	✓	—	✓
Pre-dilution	—	—	✓	—

- The aspirating position is different between the auto measurement and manual measurement (except pre-dilution) but it uses the same nozzle. Use normal mode for calibration.
- The reagent needs to be prepared in Pre-dilution measurement. Use pre-dilution mode for calibration.

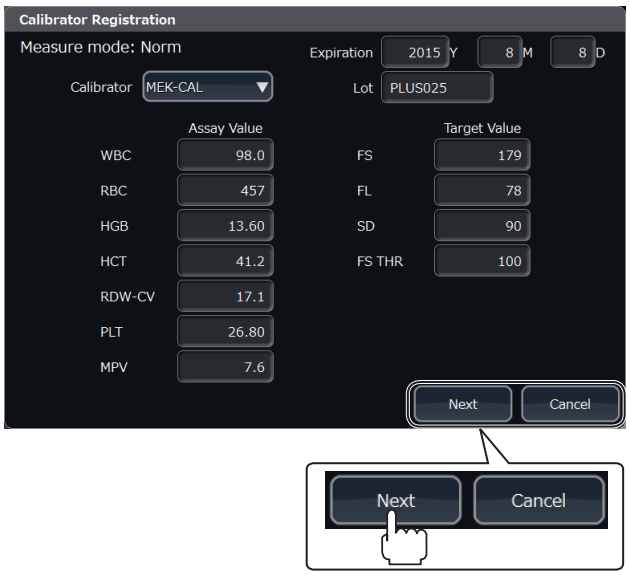


3 After the Calibrator Registration window appears, scan the QR code on the assay sheet of the calibrator with the barcode reader.

The information of the scanned calibrator is set and displayed on the window.

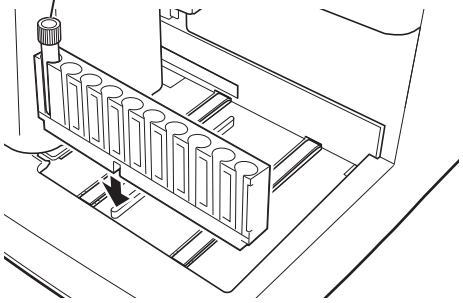
The information can also be entered directly by touching the setting parameter. (Refer to p. 1-7)

4 After checking the information on the window, touch [Next] to open the Auto Calibration window.



Normal mode

Hematology calibrator (MEK-CAL)



5 Measure the calibrator.

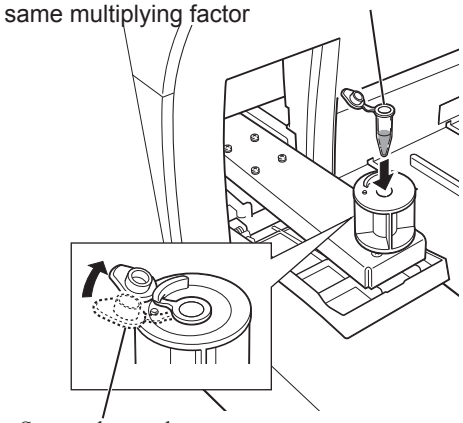
Normal mode:

1) Insert the calibrator into the left end (first position) of the rack.
2) Place the rack with the calibrator in the analyzer, and touch [Measure]. Measure the calibrator 10 times.

"Performing Auto Measurement" (p. 5-8)

Pre-dilution mode

20 µL of the hematology calibrator (MEK-CAL) which were diluted with the same multiplying factor



Secure the cap by inserting the cap under the tab of the adapter.

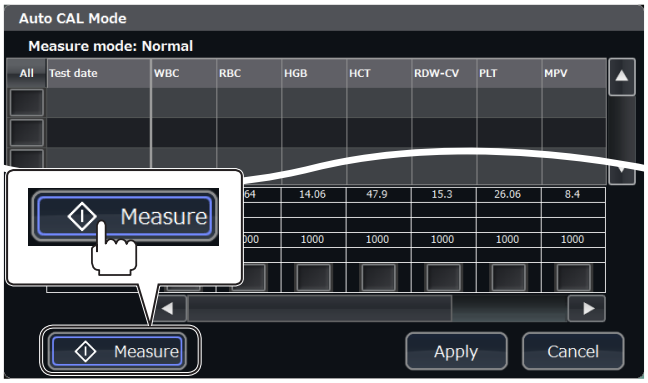
Pre-dilution mode:

1) Refer to steps **4** to **7** in "Performing Pre-dilution Measurement" in Section 5 and prepare 10 samples of 20 µL of MEK-CAL hematology calibrator which were diluted with the same multiplying factor.

"Performing Pre-dilution Measurement" (p. 5-13)

2) Uncap the micro tube, insert it into the adapter of the sample tube holder, and touch [Measure]. Perform manual measurement 10 times.

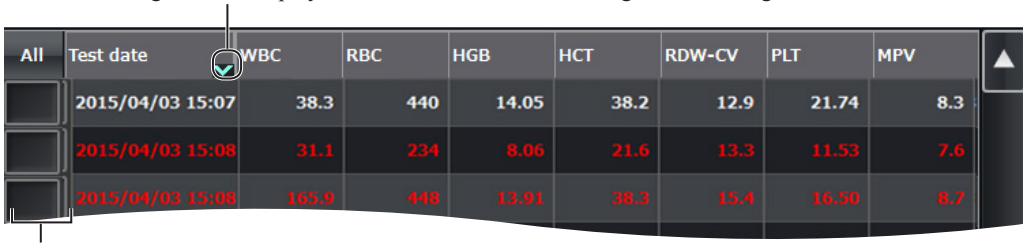
"Performing Manual Measurement" (p. 5-10)



When measurement is complete, the measurement results appear on the screen.

NOTE: When the number of measurement data exceeds 20, the oldest data is overwritten in order to keep the latest 20 data.

Sort icon
Touching sortable displayed items sorts them in ascending or descending order.



Check box
- Touch to select the measurement data to perform statistical calculation. The check icon appears in the box.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.

Measurement mode

Touch [▲], [▼], [◀] or [▶] to scroll the list vertically or horizontally.

Statistical data
Displays the results of the statistical calculation.

Select
Touch to select the parameter to change the calibration coefficient.
The check icon appears in the box.

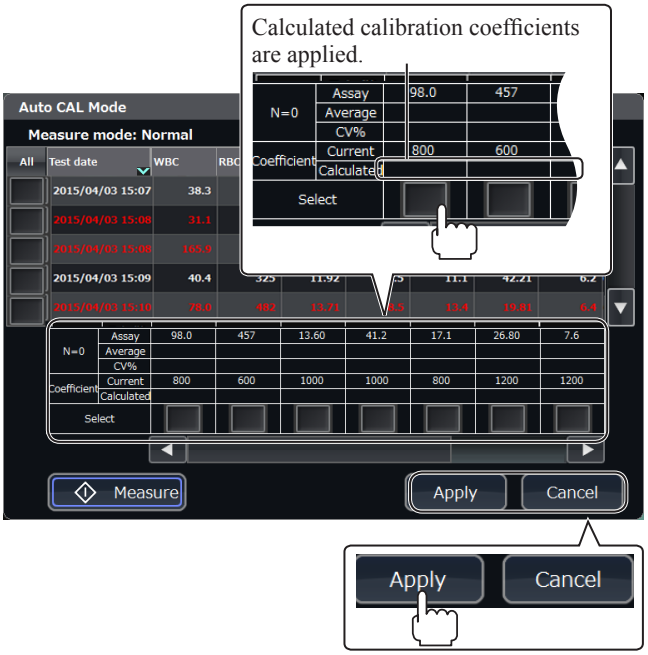
[Apply]: Applies the revised calibration coefficient to the selected parameters.
[Cancel]: Discards all data including the measurement data and returns to the Calibration window.

6 Select 10 or more sets of measurement data to do a statistical calculation.

NOTE: If the number of measurement data is less than 10, repeat measurement.

- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.

7 Check the data, select the parameter column to change the calibration coefficient, and touch [Apply].



8 Check that the calibration coefficient is correctly applied on the Calibration window.

9 Perform a quality control measurement using a hematology control and check that the result is within the control range.

"Measuring the Hematology Control" (p. 6-11)

HGB, HCT and PLT Calibration with Human Blood

Measure 10 human blood samples of healthy persons using the analyzer as well as a spectrophotometer and microhematocrit centrifuge. Calculate the calibration coefficient using the HGB, HCT and PLT values obtained from a spectrophotometer and microhematocrit centrifuge.

1 Prepare 10 human blood samples collected from the veins of 10 different healthy persons.

2 Measure each sample twice with the analyzer.

3 Measure with a spectrophotometer and microhematocrit centrifuge.

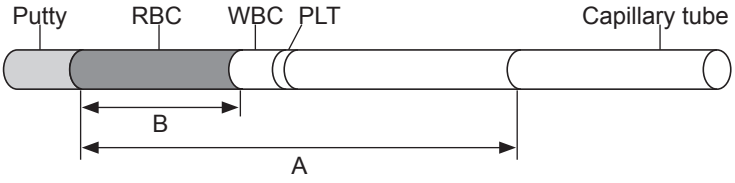
NOTE: Measurement accuracy with the spectrophotometer and microhematocrit centrifuge depends on the processes. Perform the processes carefully.

HCT Measurement

1) Aspirate the whole blood sample into 2/3 of the pre-dilution tube, wipe away any blood from the outside of the tube, and seal the ends of the tubes with putty.

2) Set the microhematocrit centrifuge for 11,000 rpm for 5 minutes and rotate the tube in the centrifuge.

3) Immediately after rotation stops, remove the tube and measure the length of Layers A and B with a microscope. Then calculate each HCT.



$$HCT = \frac{B\ (\text{Red blood cell volume})}{A\ (\text{Blood volume})} \times 100\ (\%)$$

4) Measure 2 tubes for each sample and treat the mean of the measurements as the HCT values with the spectrophotometer and microhematocrit centrifuge method.

HGB Measurement

1) Prepare a lysing reagent in accordance with the International Committee for Standardization in Hematology (ICSH) and use it as a diluent.

2) Make a pair of two 200:1 diluted samples from each sample.

3) Set up the spectrophotometer as follows to measure the 200:1 diluted samples, and calculate HGB values.

- Wavelength: approx. 540 nm
- Mode: ABS (absorbance) mode

Multiply each measured absorbance by 29.3 to obtain the HGB value.

HGB = Measured absorbance × 29.3 (g/dL)

$$29.3 = \frac{64458 \times 200}{44 \times 1000 \times 1 \times 10}$$

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

4) Measure the two 200:1 diluted samples and treat the average of the measurements as the HGB values with the spectrophotometer and microhematocrit centrifuge method.

PLT Measurement

Measure the PLT according to the following international standard.

ICSH/ISLH 2001:

International Council for Standardization in Hematology Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting. Platelet countingby RBC/platelet ratio method. A reference method. Am Journal of Clinical Pathology 115:460-464 2001

4 Calculate the HGB, HCT and PLT calibration coefficients.

1) By filling the following table with the HGB, HCT and PLT values, calculate the mean (A) among the 8 data, excluding the highest one data and the lowest one data.

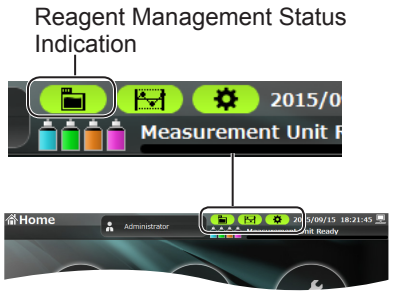
2) By applying the calculated mean (A) and calibration coefficient (B) to the following formula, calculate the revised calibration coefficient (C).

Sample No.	Measurement Value		Data
	Spectrophotometer and microhematocrit centrifuge	Analyzer	$\frac{\text{Analyzer measurement data} - \text{Spectrophotometer and microhematocrit centrifuge measurement data}}{\text{Spectrophotometer and microhematocrit centrifuge measurement data}} \times 100$ (%)
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) $(C) = (B) \times \left(1 - \frac{(A)}{100}\right)$			

5 Open the Calibration window and set the revised calibration coefficient.

8 Reagent Management

General



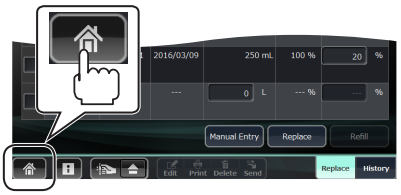
The amount of reagent and waste fluid can be managed on the Reagent Management window.

If reagents are not properly managed, the reagent status indication at the top of the window turns red.

In this case, take the necessary actions to return it to green.

Status Indication	Status
Reagent Management 	Green when all the following conditions are met: • All reagents are within the valid period (before their expiration date and expiration after opening date). • All reagents have more than 0% remaining. • The waste amount is below the warning level.

Opening the Reagents Window

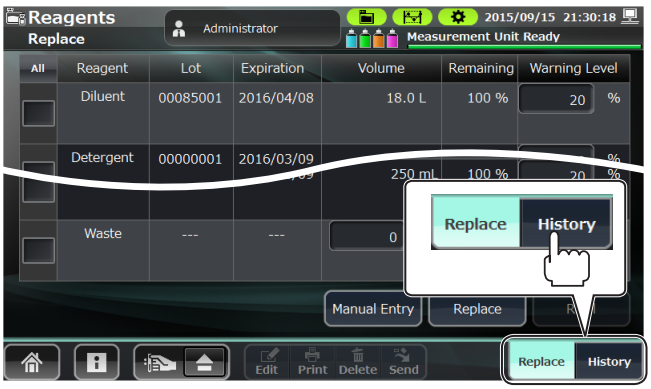


1 Open the Home screen.

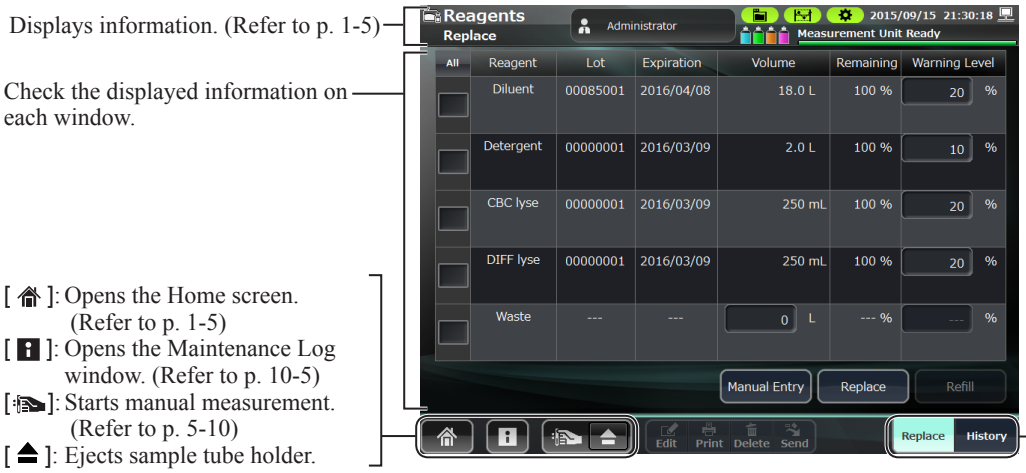
If you are in another window, touch [⌂] at the lower left.

2 Touch [Reagents] on the Home screen. The Replace window opens.

3 To open the History window, touch [History] to change the window.



Example: Replace Window



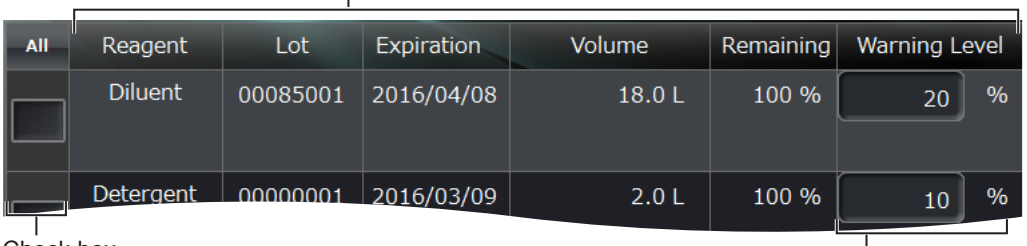
Replace Window

Touch [Reagents] on the Home screen or touch [Replace] on other Reagent Management window to open the Replace window.

The Replace window displays information about the reagent being used and the amount of waste fluid.

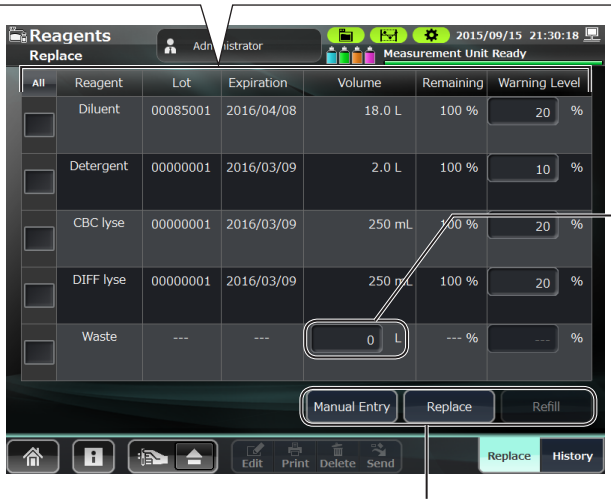
Additionally, when setting, replacing or refilling reagents, set the reagent here.

Displays the reagent information.
- The Expiration displays the earlier of the expiration date or the expiration after opening.
- Once the remaining amount becomes below the warning level, the remaining amount display turns red.



Check box
- Touch to select the reagent to refill. The check icon appears in the box.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.

Warning Level
The warning level is entered here.



The capacity of the waste container is entered here. (Refer to p. 8-4)

[Manual Entry]: Touch to enter the reagent code manually when set or replacing reagents. (Refer to p. 8-4)

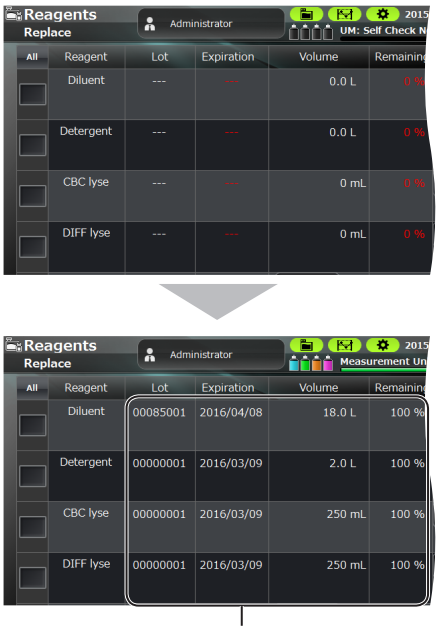
[Replace]: Touch to enter the new reagent when replacing reagents. (Refer to p. 8-5)

[Refill]: Touch to refill the reagent being used. (Refer to p. 8-7)

Registering Reagents

Set the reagents and the capacity of the waste container at the initial startup.

Do not set the reagent information for the CLEANAC•810 (MK-810W) detergent because it is a single-use product.



The information of the scanned reagent appears.

1 Open the Replace window and scan the barcode of the reagent with the barcode reader.

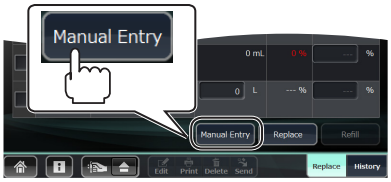
If there is more than one reagent to set, scan them in sequentially.

The information of the scanned reagent is set and displayed on the window.

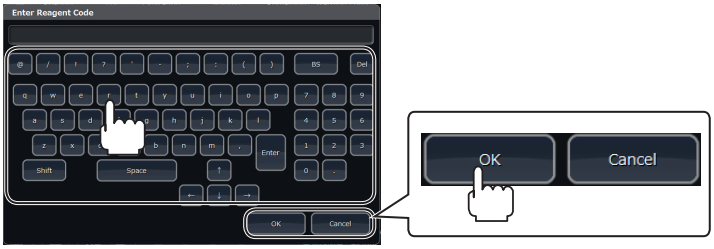
Manual Registration

Do the procedure below to enter reagent codes without using the barcode reader.

1) Touch [Manual Entry]. The Enter Reagent Code window opens.



2) Enter the reagent code and touch [OK].

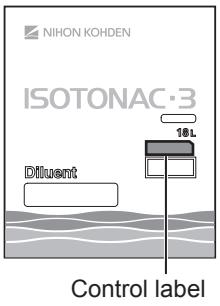
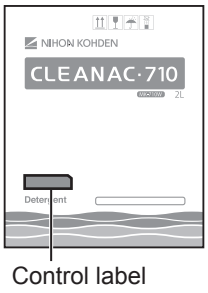


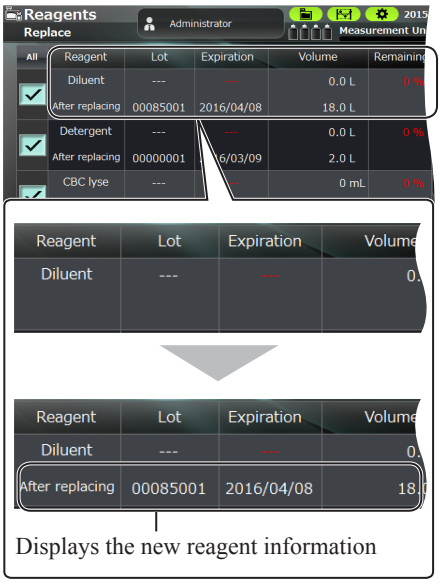
2 Set the capacity of the waste container.

Replacing Reagents

Enter the expiration date and the volume information from the reagent barcode label.

When replacing reagents, scan the control label on the reagent bottle.

ISOTONAC•3/4 Diluent	CLEANAC•710 Detergent	HEMOLYNAC•310 HEMOLYNAC•510 Lysing Reagent
		



1 Open the Replace window and scan the barcode of the new reagent with the barcode reader.

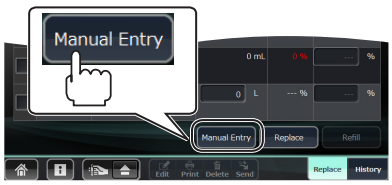
If there is more than one reagent to replace, scan them in sequentially.

The information of the scanned reagent (the new reagent) is displayed on the window.

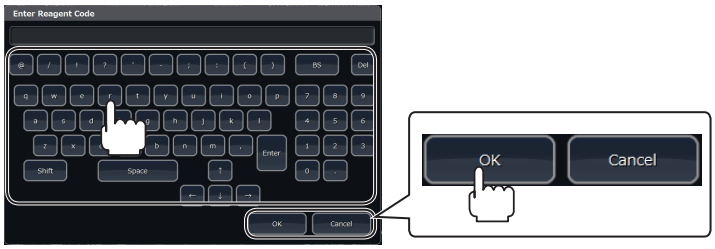
Manual Registration

Do the procedure below to enter reagent codes without using the barcode reader.

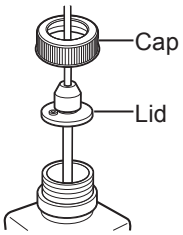
1) Touch [Manual Entry]. The Enter Reagent Code window opens.



2) Enter the reagent code and touch [OK].



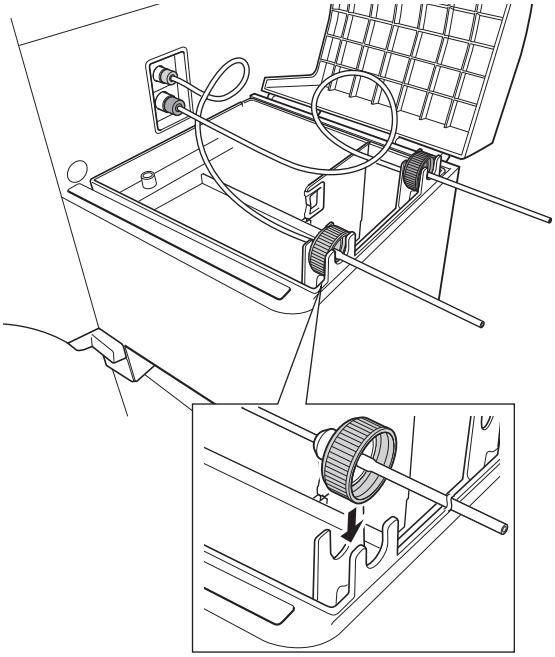
Lysing reagent



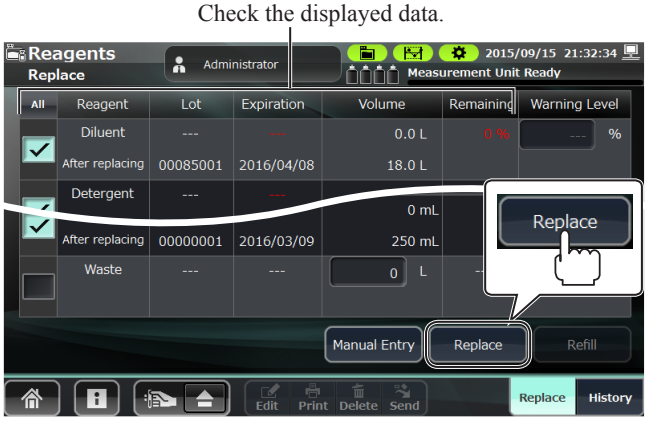
2 Replace the reagent with the new one as described in Section 4 “Connecting the Reagent and Waste Containers”.

Replacing Lysing Reagent

- Remove the cap and the lid of the lysing reagent separately.
- When replacing the lysing reagent, fix the removed cap as shown in the figure.

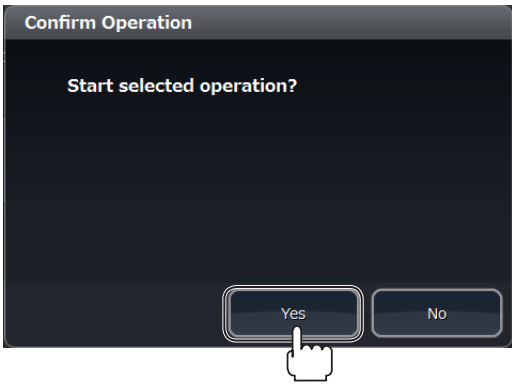


3 Check that the new reagent is appropriate, and touch [Replace].



4 Touch [Yes] on the Confirmation window.

Touching [Yes] starts the replacing operation for the selected reagent.



Refilling Reagents

Refill the reagent that is currently used in the analyzer.

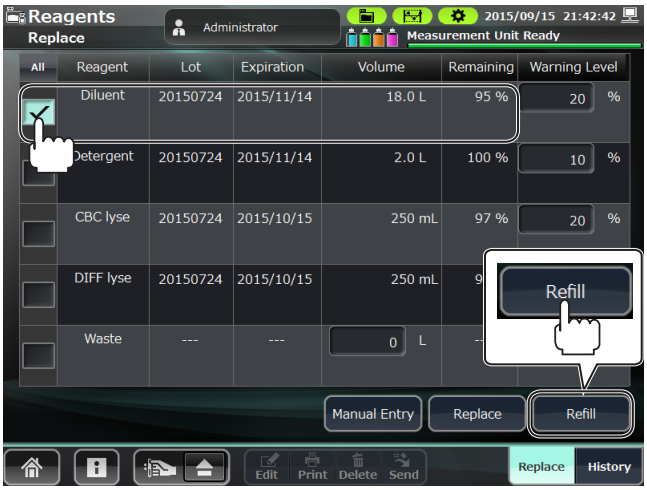
Refilling Reagent is a function that refills the reagents without updating the reagent information.

Use this function after accidental aspiration of bubbles and other situations even when there is enough reagent.

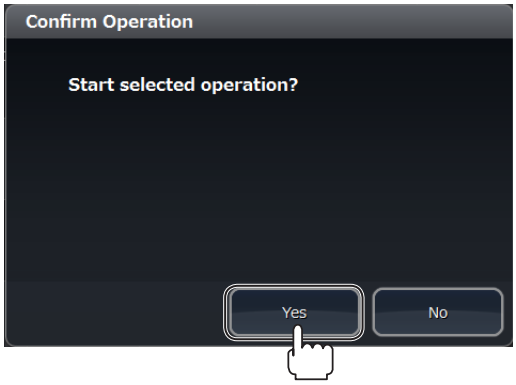
When there is not enough reagent, replace the reagent with a new one.

1 Select the reagent to refill on the Replace window and touch [Refill].

- To select more than one reagent, touch the check boxes.
- To unselect, touch the selected data again.
- Touch [All] to select or unselect all items.



2 Touch [Yes] on the Confirmation window.



History Window

Touch [History] on the Reagent Management window to open the History window.

The History window lists the history of reagent replacements.

Sort icon
Touching sortable displayed items sorts them in ascending or descending order.

Registration Date	Operator	Reagent Type	Lot	Expiration	Valid To	Volume	Entry
2015/08/04 12:48	Factory Operator	Detergent	00000010	2015/11/02	2015/11/02	20.0 L	Barcode
2015/08/04 12:48	Administrator	Diluent	00000009	2015/11/02	2015/11/02	20.0 L	Manual
2015/08/04 12:48	Technical User	DIFF lyse	00000008	2015/11/02	2015/11/02	20000 mL	Barcode

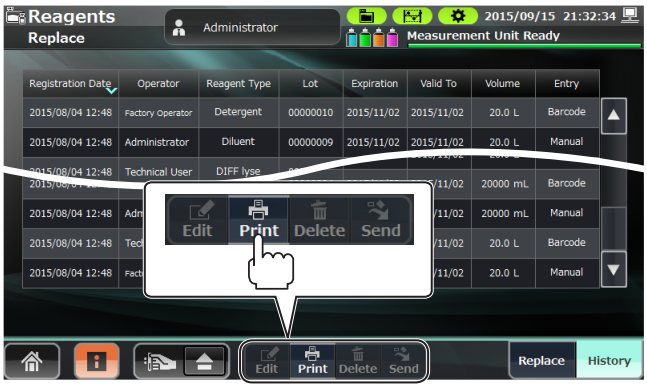
Touch [▲] or [▼] to scroll the list vertically.

Prints the currently displayed page.

Printing Replacement History

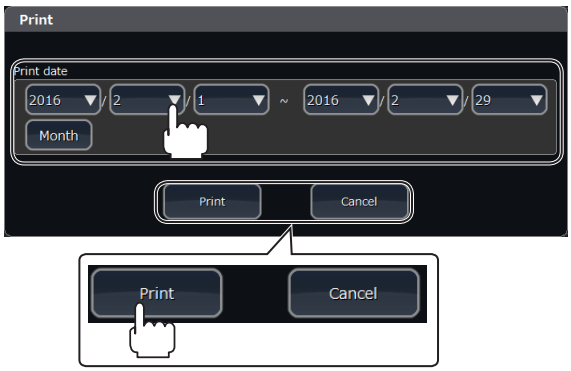
You can print the replacement history on the external output printer.

1 Display the History window and touch [Print].

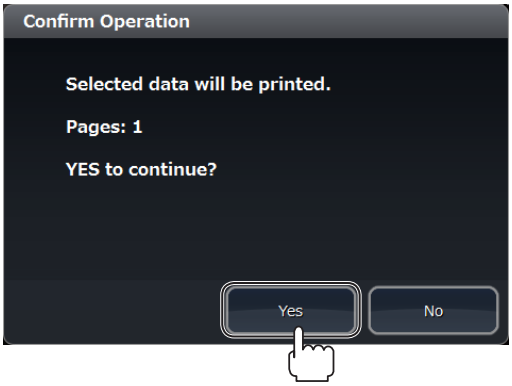


2 When the window to specify the period is displayed, set the date and time of print target and touch [Print].

When [Month] is touched, the date of this month is set automatically.



3 When the Confirm Operation window appears, touch [Yes].



9 Maintenance

Daily Check

Before, during and after use, check that the analyzer can be used in normal and safe condition.

If an abnormality is found, take the proper action.

If the analyzer is suspected to be faulty, attach a “Unusable” or “Repair request” label on it and contact your Nihon Kohden representative.

When there is not enough stock of the consumables, place an order for the necessary consumables with your Nihon Kohden representative.

NOTE: In addition to the daily check, protein must be removed and the surface of the analyzer cleaned at least once a month.

Check Before Use

Item	Description
Accessories and consumables	There is enough Nihon Kohden specified diluent, detergent, hemolysing reagent and other consumables.
Connection and settings	The power cord and grounding lead are connected properly.
	The external instruments are properly connected.
	Enough recording paper in the printer. (when a printer is used)
	Tubes are connected properly.
	Diluent, detergent and lysing reagent bottles are connected.
	The waste container and overflow tray are in place.
Appearance	There are no damaged, dirty parts or leakage from the analyzer.
	No damage to the keys and switches.
	No damage to the AC power cord.
	The waste container is not full.
	The waste fluid is not spilling into the overflow tray.
	Diluent, detergent and lysing reagent bottles have no dust in them.
	The analyzer is completely dry.

Check After Turning On the Analyzer

Item	Description
Turning on the power	The main power lamp, power lamp, laser lamp and status indicator lamp light.
	No fire, smoke or smell.
	There is no electric shock and the analyzer is not too hot.
	No alarm message is displayed on the LCD display.
	The date and time on the LCD display are correct.[1]
	The correct system of units is set.
Basic operation	The screen display is normal. (No abnormal brightness, distortion or color)
	The status indicator lamp is normal.
	Keys and switches operate properly.
	Operations such as measurement work as expected. (No messages appear)
	The measured background noise values are acceptable.
	No messages appear and no abnormal behavior occurs during operation.
Quality control	The measured hematology control values are acceptable.
After long-term storage	Priming on installation is performed.

[1] The accuracy of the IC for the clock used by the analyzer is as follows:

- At an operating temperature of 25°C (77°F), the accuracy is about ±60 seconds per month.

Check that the date and time is correct every time you start using the analyzer.

The date and time must be adjusted if they are not correct.

To change the settings, refer to the Data Management and Setting Guide.

Data Management and Setting Guide:
Section 5 “System Settings”

Check When Turning Off the Analyzer

Always perform the following checks after use.

They will help the next user use the analyzer successfully and smoothly.

When there are not enough consumables in stock, place an order for the necessary consumables with your Nihon Kohden representative.

Item	Description
Before turning off the analyzer	There is enough diluent, detergent and hemolysing reagent.
	The waste container is connected with the tube.
	The waste container is not full.
	The waste fluid is not spilling into the overflow tray.
Abnormalities	There are no abnormalities such as water leakage.
	There is no damage or dirt on the outside of the analyzer.
After turning off the analyzer	The power is automatically turned off after the auto clean operation.
	If the analyzer is wet, liquid is wiped off and the analyzer is thoroughly dried.
	There are enough consumables such as diluent.
	The analyzer power is turned off.
	There is no chemical or water around the analyzer.
	The analyzer, diluent, detergent and lysing reagent are stored properly.
Before long term storage	The analyzer is cleaned with distilled water.
	Any distilled water inside the analyzer is drained out.

Maintenance Inspection

Service personnel should perform the maintenance inspection at least twice every year, make sure that the analyzer operates properly, and replace the consumables.

Repair Parts Availability Policy

Nihon Kohden Corporation (NKC) shall stock repair parts (parts necessary to maintain the performance of the analyzer) for a period of 7 years after delivery of the analyzer.

During that period, NKC or its representatives will repair the analyzer.

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.

Maintenance Operations

Open the User Maintenance window and perform the required cleaning, priming/draining or other operations.

Item	Description	Refer to
Clean	Cleans the fluid path inside the analyzer with CLEANAC•710.	p. 9-6
Clean Protein	Cleans the fluid path inside the analyzer with CLEANAC•810 (sodium hypochlorite).	p. 9-7
Clean Flowcell	Removes dirt and bubbles from the flow cell unit.	p. 9-8
Remove Clog	Removes clogs in the fluid path inside the analyzer.	p. 9-9
Priming on Installation	Refills reagent inside the analyzer.	p. 9-10
Drain All	Drains diluent from the fluid path inside the analyzer.	p. 9-11
Clean MC	Removes dirt and bubbles from the MC.	p. 9-9
Remove MC Aperture Clog	Cleans the aperture cap.	p. 9-29
Self Check	Runs the self check.	p. 9-11
Measuring Background Noise	Measures a sample that only contains diluent.	p. 9-12

Opening the User Maintenance Window

1 Open the Home screen.

If you are in another window, touch [⌂] at the lower left.

2 Open the Maintenance window.

1) Touch [Maintenance] on the Home screen. The Maintenance Self Check window opens.

2) Touch [User]. The User Maintenance window opens.

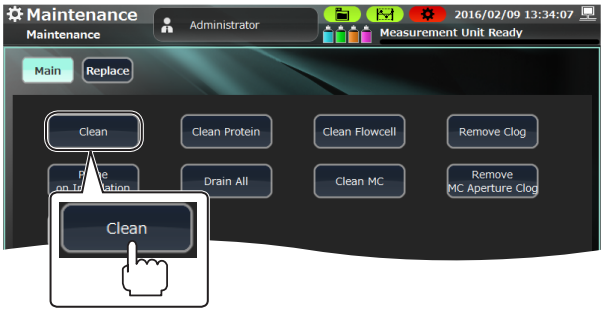
Cleaning

Cleaning

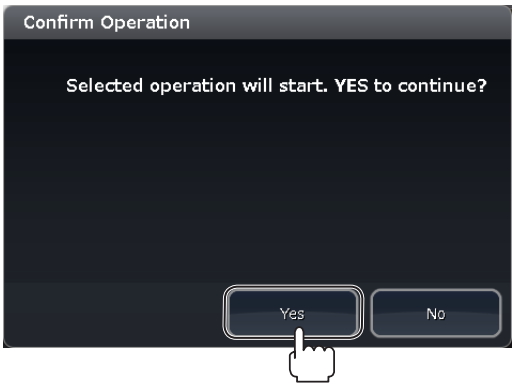
Clean the fluid path inside the analyzer with CLEANAC•710.

1 Open the User Maintenance window and touch [Clean].

"Opening the User Maintenance Window" (p. 9-5)



2 Touch [Yes] on the Confirm Operation window.



Cleaning Protein

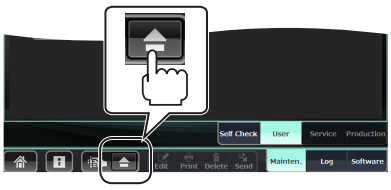
Clean the fluid path inside the analyzer with CLEANAC•810 (sodium hypochlorite).

Do this when normal cleaning was not effective.

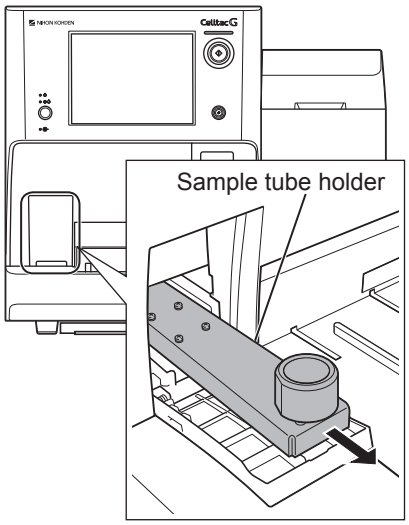
NOTE: Cleaning of protein must be done at least once a month.

1 Open the User Maintenance window and place the CLEANAC•810 detergent on the sample tube holder.

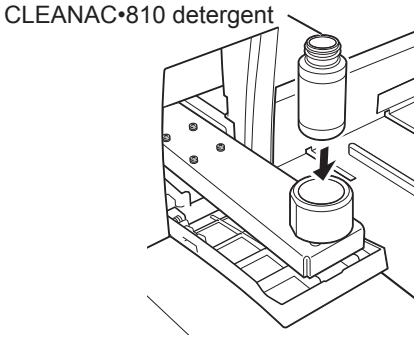
"Opening the User Maintenance Window" (p. 9-5)



1) Touch [⏏] to eject the sample tube holder.



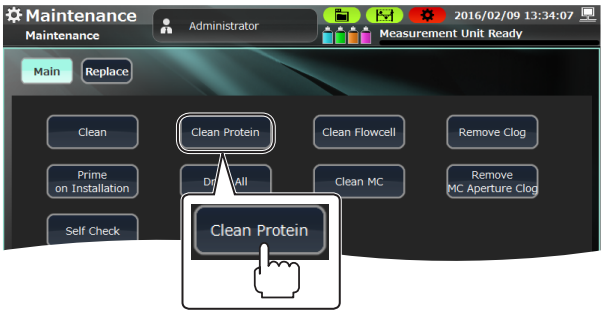
2) Check that the detergent adapter is attached on the ejected sample tube holder.



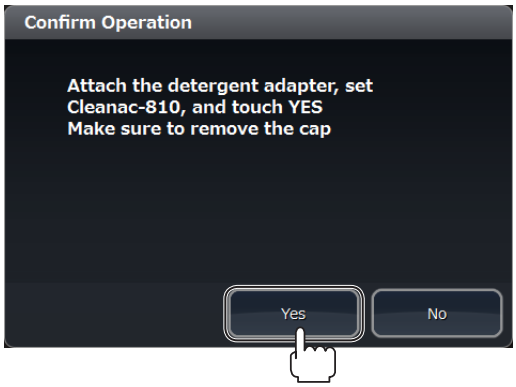
3) Remove the cap from the CLEANAC•810 detergent bottle and insert it into the sample tube holder adapter.

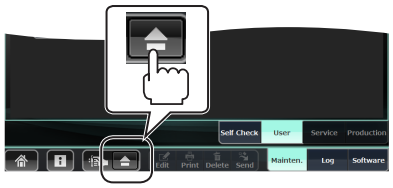
NOTE
- Insert the detergent into the adapter until it stops at the end.
- Make sure to remove the cap.

2 Touch [Clean Protein] on the User Maintenance window.



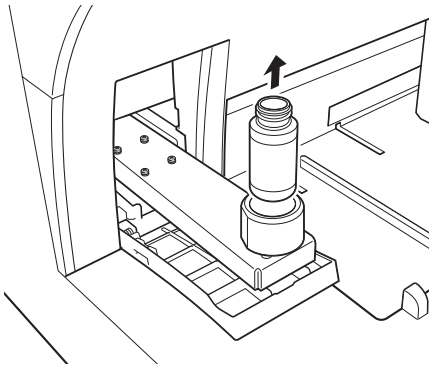
3 Touch [Yes] on the Confirm Operation window.





4 When the cleaning protein operation is completed, the sample tube holder is ejected.

Remove the CLEANAC•810 detergent, and touch [⏏] to slide in the sample tube holder.

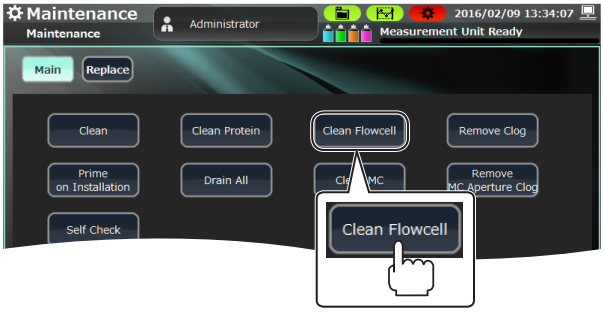


Cleaning the Flowcell

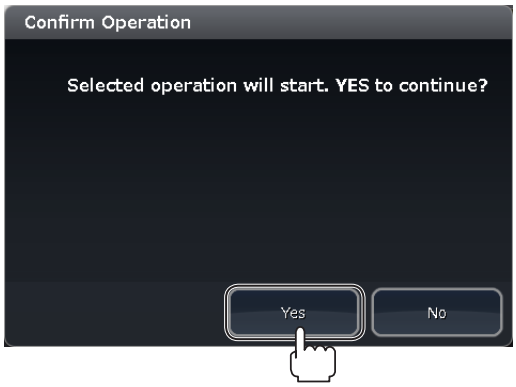
This removes dirt and bubbles from the flow cell unit.

1 Open the User Maintenance window and touch [Clean Flowcell].

"Opening the User Maintenance Window" (p. 9-5)



2 Touch [Yes] on the Confirm Operation window.



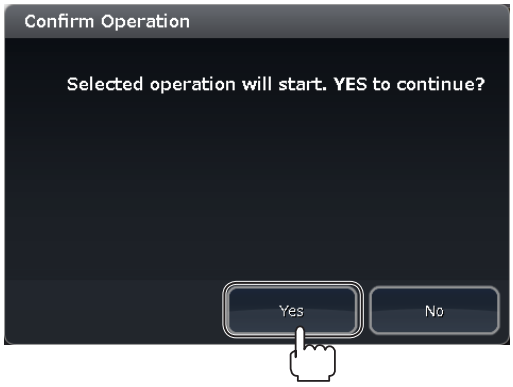
Cleaning the MC

This removes dirt and bubbles from the MC.

1 Open the User Maintenance window and touch [Clean MC].

"Opening the User Maintenance Window" (p. 9-5)

2 Touch [Yes] on the Confirm Operation window.

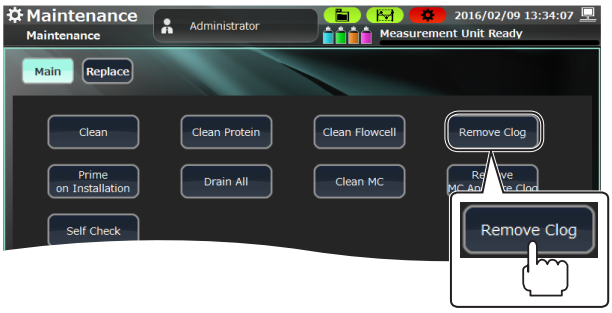


Removing Clogs

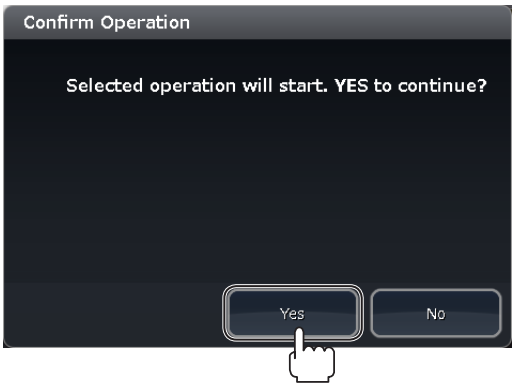
This removes clogs in the aperture cap inside the analyzer.

1 Open the User Maintenance window and touch [Remove Clog].

"Opening the User Maintenance Window" (p. 9-5)



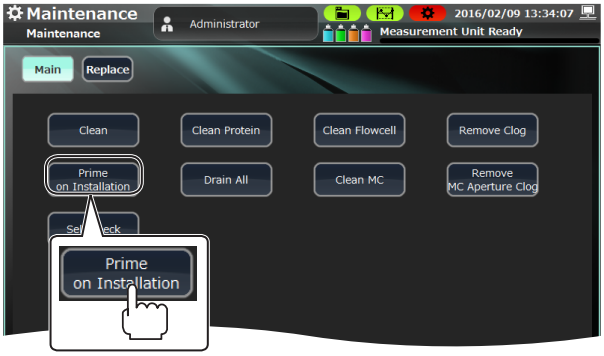
2 Touch [Yes] on the Confirm Operation window.



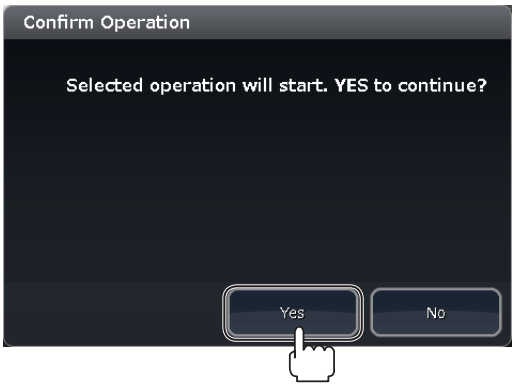
Priming on Installation

1 Open the User Maintenance window and touch [Prime on Installation].

"Opening the User Maintenance Window" (p. 9-5)



2 Touch [Yes] on the Confirm Operation window.



When an analyzer message "21100 Analyzer internal draining status" appears on the Maintenance Log window, touch [RESTORE] to perform priming on installation.

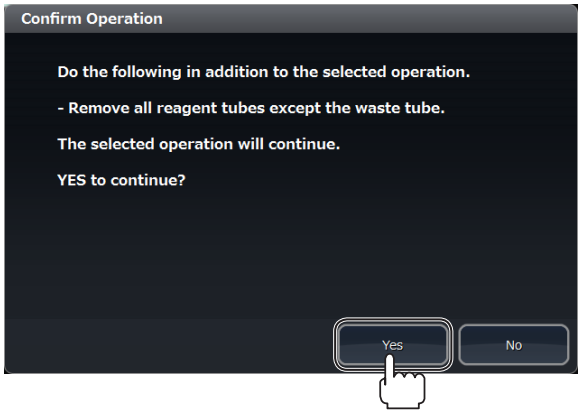
Draining All

This drains diluent from the fluid path inside the analyzer to prepare for maintenance inspection or long term storage.

1 Open the User Maintenance window and touch [Drain All].

"Opening the User Maintenance Window" (p. 9-5)

2 When the Confirm Operation window appears, disconnect all reagent tubes (diluent, CBC lysing reagent, DIFF lysing reagent and detergent) except the waste tube and touch [Yes].

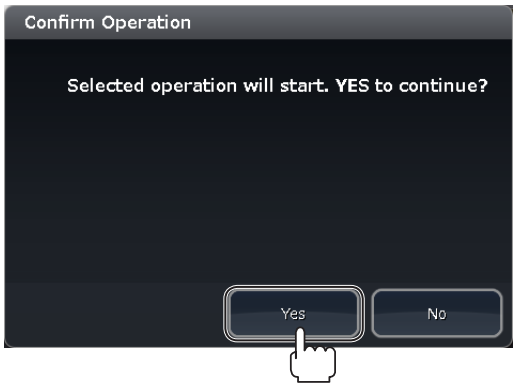


Running Self Check

1 Open the User Maintenance window and touch [Self Check].

"Opening the User Maintenance Window" (p. 9-5)

2 Touch [Yes] on the Confirm Operation window.



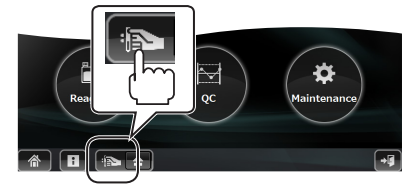
Measuring Background Noise

Measure a sample that only contains diluent.

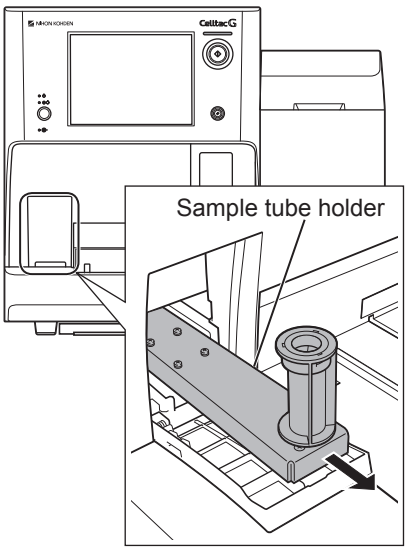
Background noise increases in the following cases.

- The diluent is old.
  Replace the diluent if it is past the expiration period after opening the package.
- There is dirt or dust in the diluent container.
- The diluent temperature is extremely high or low.

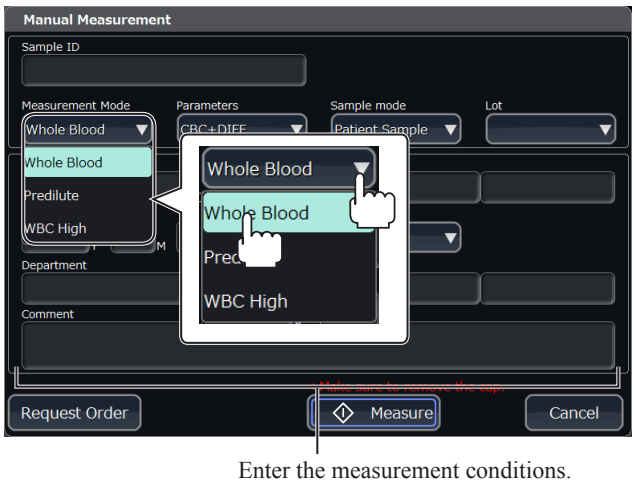
  The normal operating temperature range is 15 to 30°C (59 to 86°F).



1 Touch [ ] to open the Manual Measurement window and eject the sample tube holder.



2 Set the measurement mode to “Whole Blood” on the Manual Measurement window, and enter the measurement conditions.

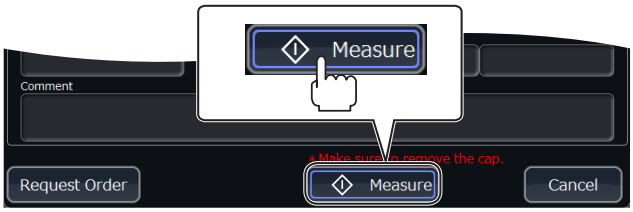


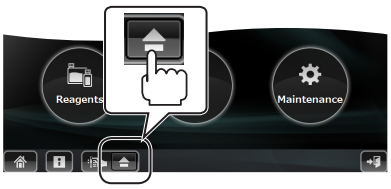
Enter the measurement conditions.

3 Make sure nothing is on the sample tube holder adapter and touch [Measure].

The sample tube holder slides in and measurement starts.

The sample tube holder slides out automatically.





4 Touch [⏏] to slide in the sample tube holder.

5 Check the measured results on the Data List window to confirm that the measured value falls within the following range.

Data Management and Setting Guide: Section 4 “Data Review”

- Measured parameters other than TWBC, RBC, HGB and PLT are not influenced by noise.
- TOC value can be viewed only with “Factory Operator” or “Technical User” operator privileges. Other operators can confirm measured values other than TOC.

Measured Parameters	Normal Range
WBC	2.0×10^{2}/µL or less
RBC	2×10^{4}/µL or less
HGB	0.1 g/dL or less
PLT	1.00×10^{4}/µL or less
TOC	100 count or less

When the check result exceeds the normal value, check the following points and measure background noise again.

- Diluent is not dirty
- There are no bubbles in the diluent

If the measured value exceeds the above range even after it is measured again, refer to “2. High background noise” in Section 10 “Troubleshooting”.

Expiration, Replacement and Disposal

Analyzer

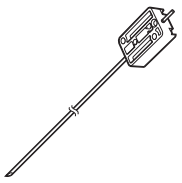
Periodic Replacement Parts

The following components need to be replaced regularly according to the cycle shown below to maintain the functions and performance of the analyzer.

Contact your Nihon Kohden representative for more information or replacing the periodic replacement parts.

Periodic Replacement Parts	Schedule
Analyzer	
Sampling needle	Every 12,000 measurements
Venting needle	
Filter	
Backup battery	Every 4 years

Replacing the Sampling Needle



Sampling needle (Maintenance item: sampling nozzle)

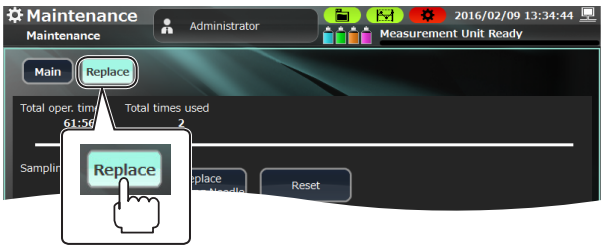
Schedule: **Every 12,000 measurements**

Maintenance item: **Sampling nozzle (supply code: T444E)**

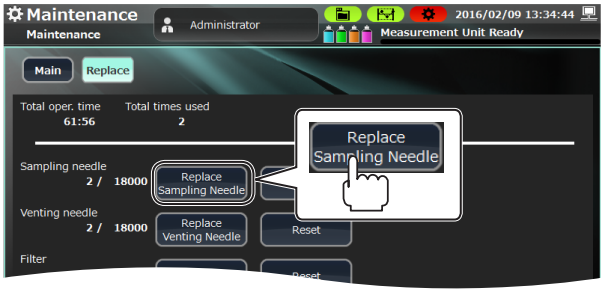
NOTE: Keep the screws that were removed during the replacement for reuse.

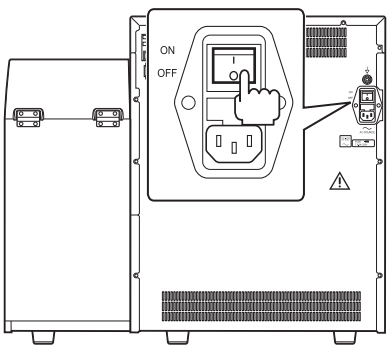
1 Open the User Maintenance window and touch [Replace].

"Opening the User Maintenance Window" (p. 9-5)



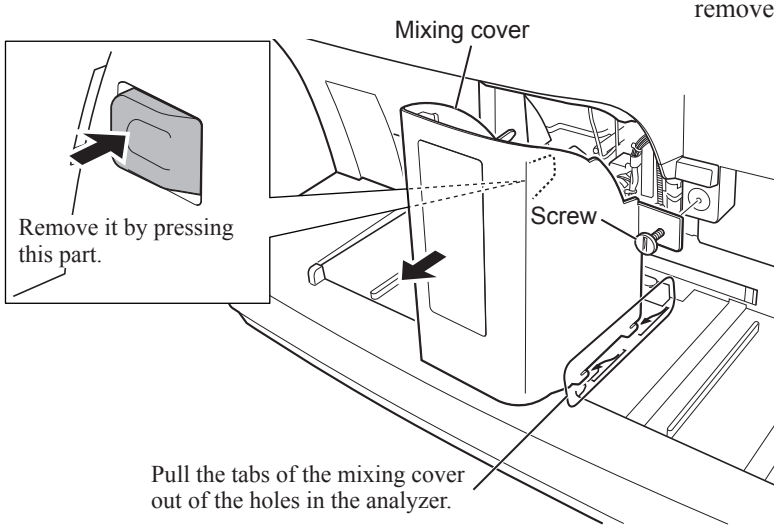
2 Touch [Replace Sampling Needle]. The sampling needle and related fluid paths are drained and the power is automatically turned off.





3 Turn off the Main power switch (to ○) on the rear panel of the analyzer.

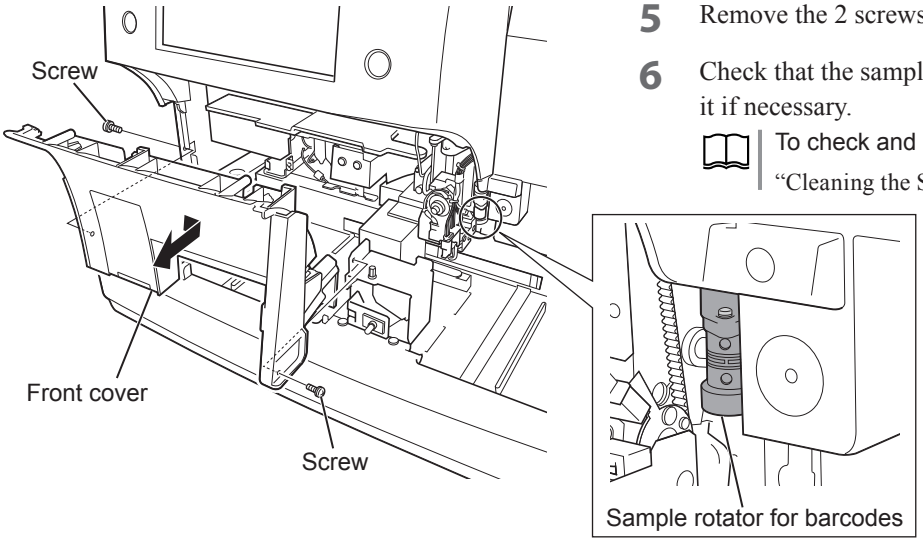
4 Loosen the screw on the front panel of the analyzer to remove the mixing cover.



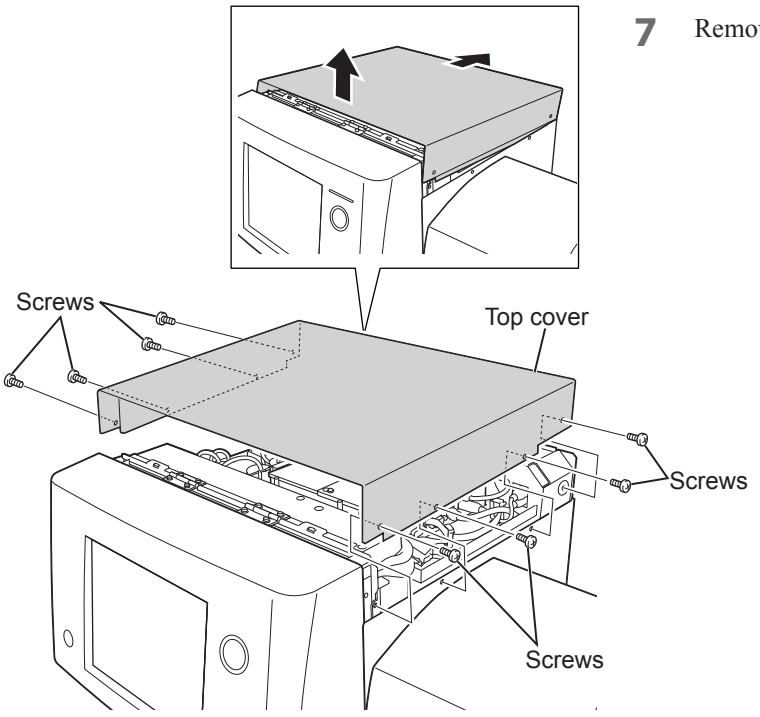
5 Remove the 2 screws to remove the front cover.

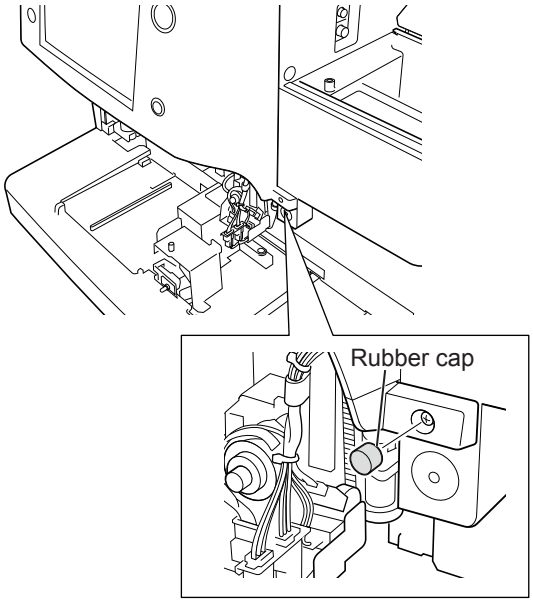
6 Check that the sample rotator for barcodes is clean. Clean it if necessary.

To check and clean sample rotator for barcodes:
"Cleaning the Sample Rotator for Barcodes" (p. 9-28)

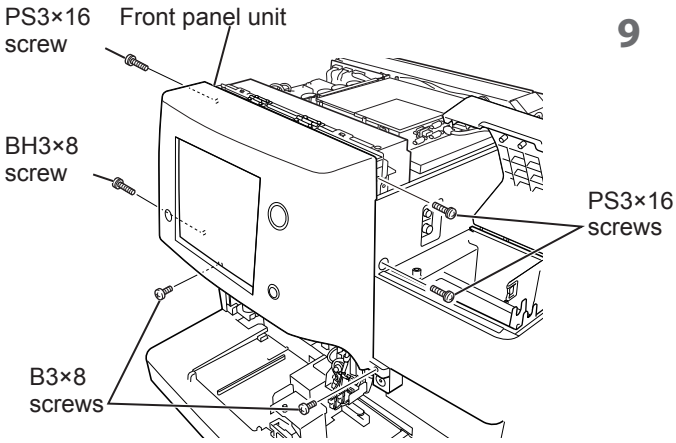


7 Remove the 8 screws to remove the top cover.

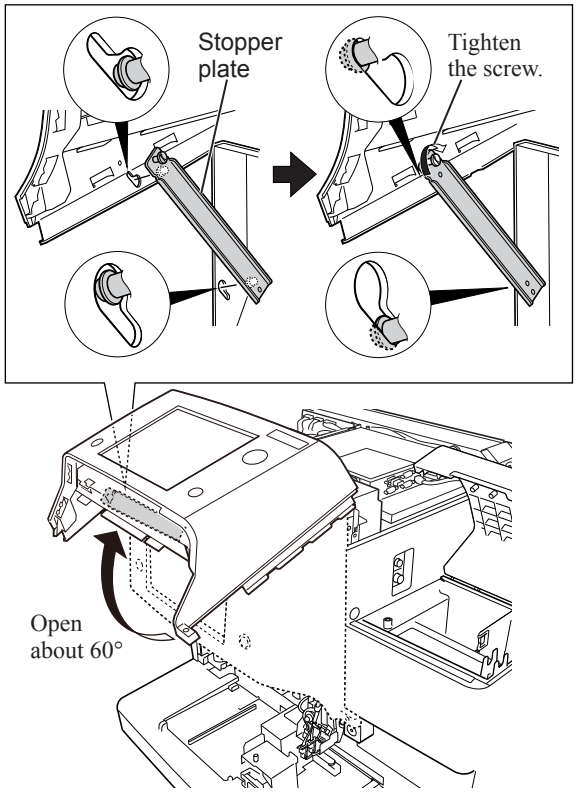




8 Remove the rubber cap.



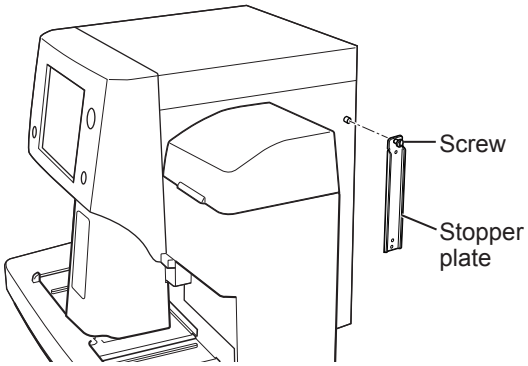
9 Remove the 6 screws to remove the front panel unit.

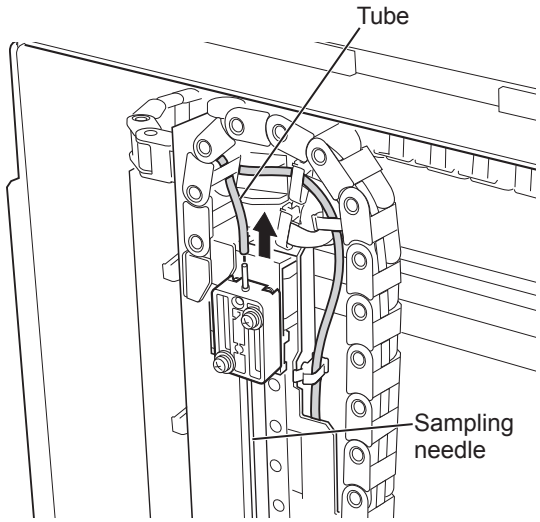


10 Open the front panel unit about 60° and fix it with the provided stopper plate as shown in the figure.

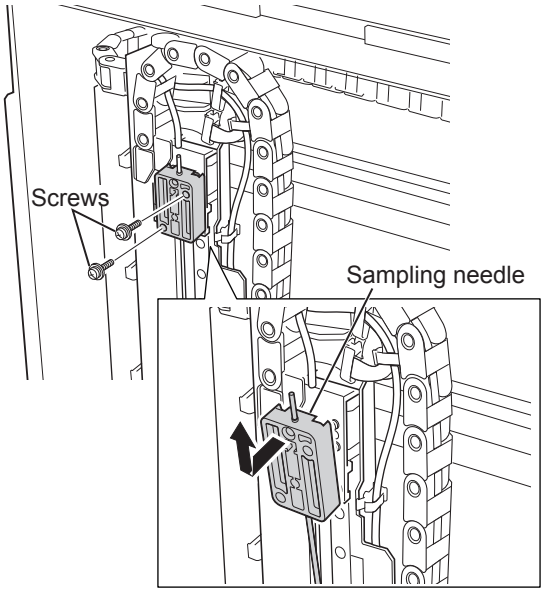
NOTE: Do not open the front panel unit more than 90°. This may damage the analyzer.

The provided stopper plate is fixed with a screw at the position in the figure.





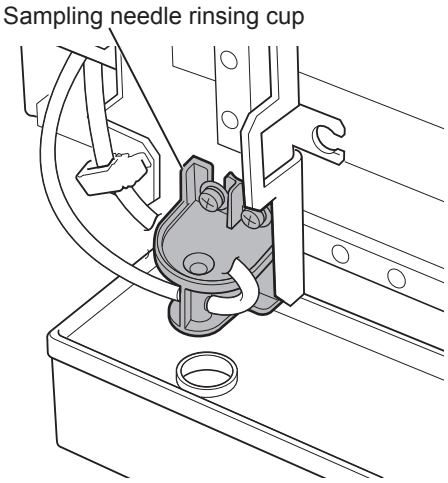
11 Remove the tube from the top of the sampling needle.

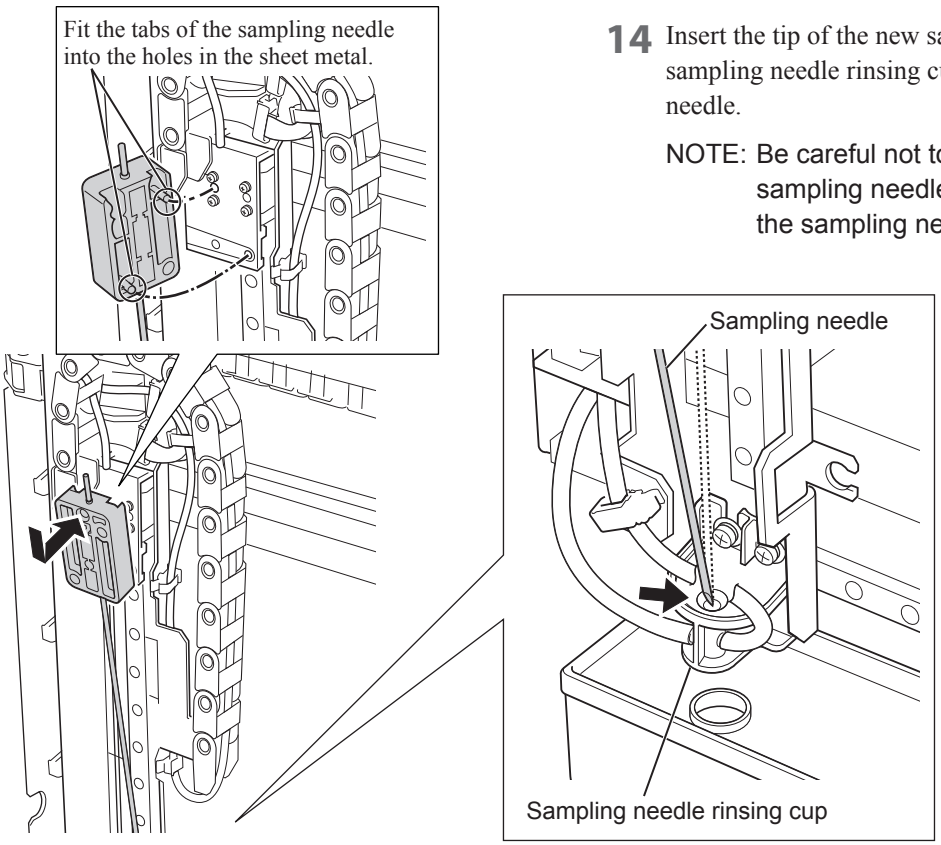


12 Remove the 2 screws to remove the sampling needle.

13 Clean the sampling needle rinsing cup.

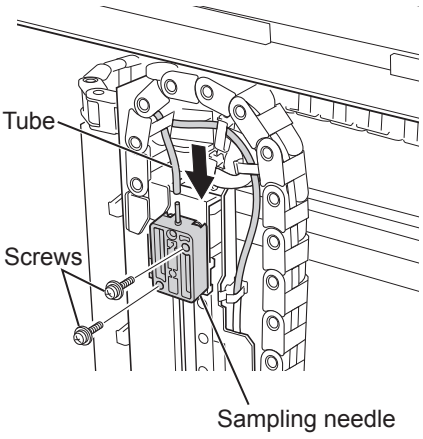
"Cleaning the Sampling Needle Rinsing Cup" (p. 9-27)





14 Insert the tip of the new sampling needle into the sampling needle rinsing cup and then install the sampling needle.

NOTE: Be careful not to damage the tube or the sampling needle rinsing cup when inserting the sampling needle into the rinsing cup.



15 Fix the sampling needle with the 2 screws removed in step **12** and connect the tube.

16 Do steps **4** to **10** in reverse order to return the analyzer to its original state.

17 Turn the analyzer on. Touch [No] on the window to run the self check.

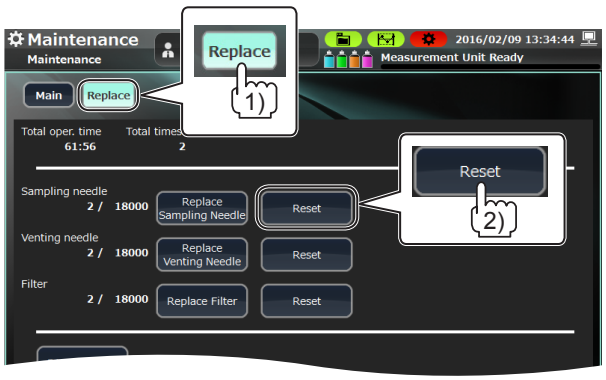
"Turning On the Analyzer" (p. 5-5)

18 Check that the analyzer message "21200 Maintenance part replacement status" appears and touch [RESTORE] on the Maintenance Log window.

"Analyzer Messages" (p. 10-5)

19 Run the self check.

"Running Self Check" (p. 9-11)



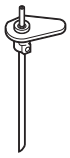
20 Reset the number of times the sampling needle is used.

1) Display the User Maintenance window and touch [Replace].

"Opening the User Maintenance Window" (p. 9-5)

2) Touch [Reset] in Sampling needle.

Replacing the Venting Needle



Venting needle
(Maintenance item:
Release nozzle assy

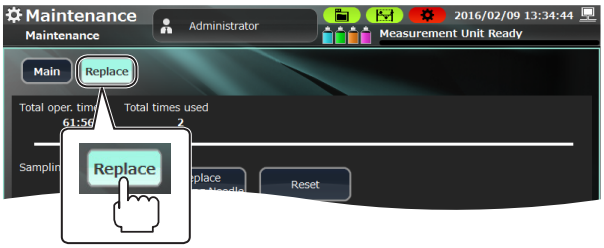
Schedule: **Every 12,000 measurements**

Maintenance item: **Release nozzle assy (supply code: T449C)**

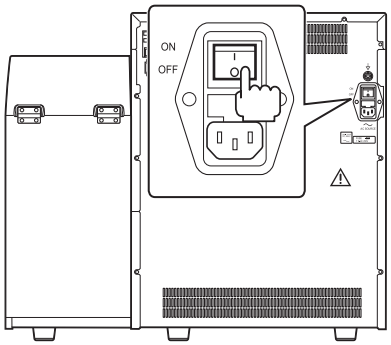
NOTE: Keep the screws that were removed during the replacement for reuse.

1 Open the User Maintenance window and touch [Replace].

"Opening the User Maintenance Window" (p. 9-5)



2 Touch [Replace Venting Needle]. The venting needle and related fluid paths are drained and the power is automatically turned off.



3 Turn off the Main power switch (to ○) on the rear panel of the analyzer.

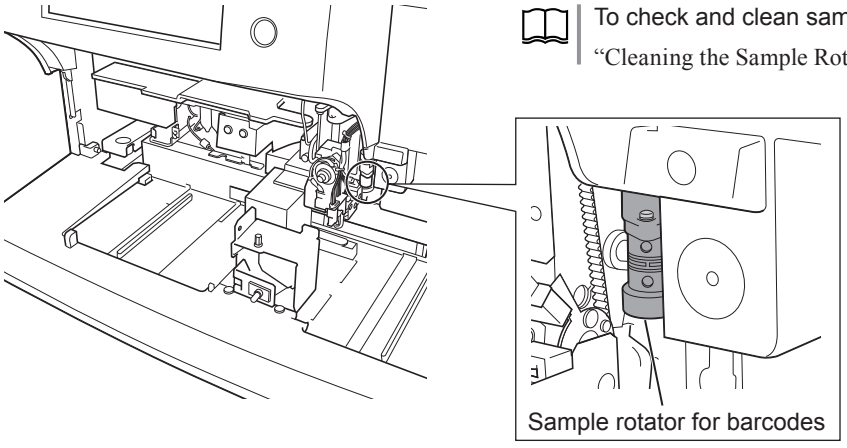
4 Remove the mixing and front covers. Refer to steps **4** and **5** in "Replacing the Sampling Needle".

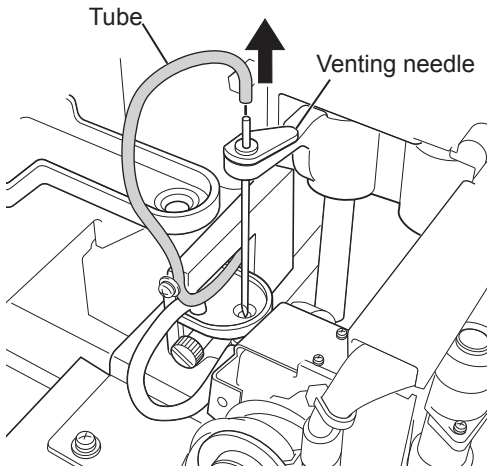
"Replacing the Sampling Needle" (p. 9-14)

5 Check that the sample rotator for barcodes is clean. Clean it if necessary.

To check and clean sample rotator for barcodes:

"Cleaning the Sample Rotator for Barcodes" (p. 9-28)

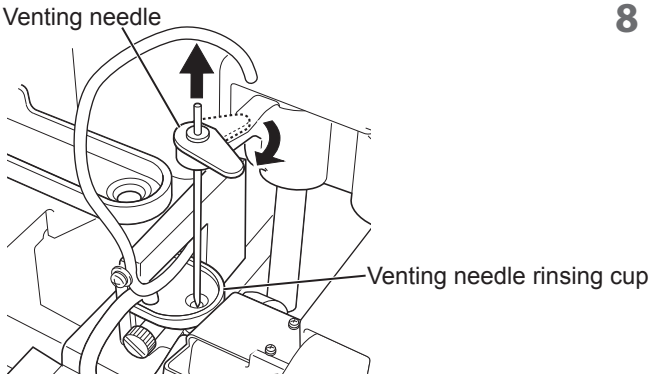




6 Refer to steps **7** to **10** in "Replacing the Sampling Needle" and fix the stopper plate while the front panel unit is opened.

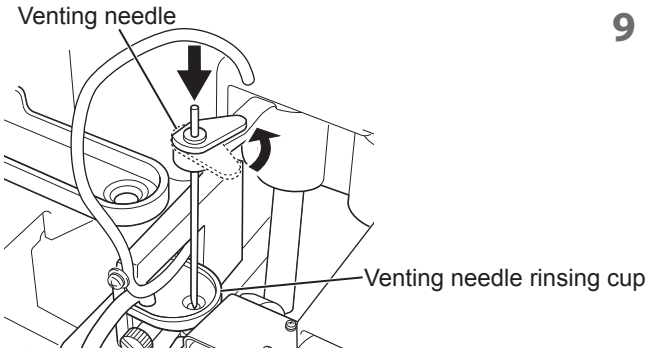
"Replacing the Sampling Needle" (p. 9-14)

7 Remove the tube from the top of the venting needle.



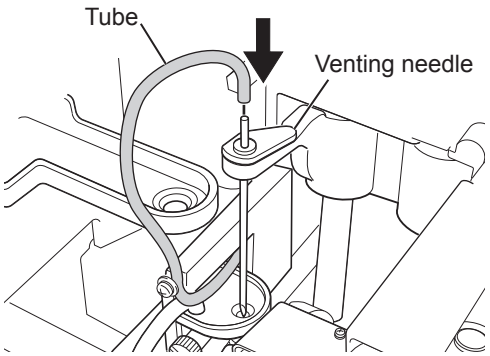
8 Rotate the venting needle to remove it and clean the venting needle rinsing cup.

"Cleaning the Venting Needle Rinsing Cup" (p. 9-28)



9 Insert the tip of the new venting needle into the venting needle rinsing cup and then rotate the venting needle to fix it in place.

NOTE: Be careful not to damage the tube or the venting needle rinsing cup when inserting the venting needle into the rinsing cup.



10 Connect the tube to the top of the venting needle.

11 Do steps **4** to **6** in reverse order to return the analyzer to its original state.

12 Turn the analyzer on. Touch [No] on the window to run the self check.

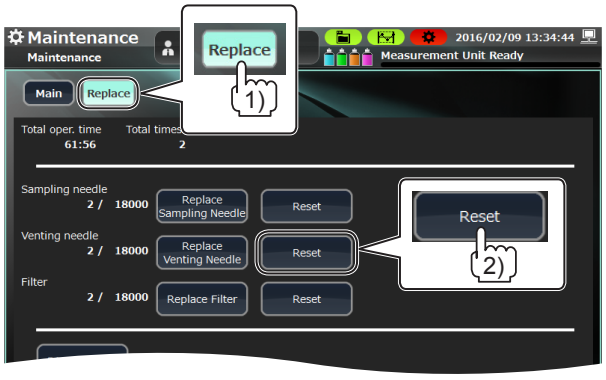
"Turning On the Analyzer" (p. 5-5)

13 Check that the analyzer message "21200 Maintenance part replacement status" appears and touch [RESTORE] on the Maintenance Log window.

"Analyzer Messages" (p. 10-5)

14 Run the self check.

"Running Self Check" (p. 9-11)



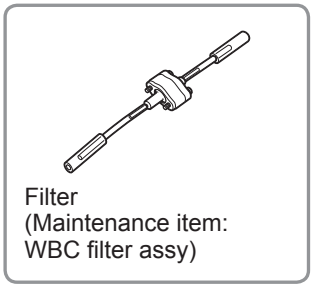
15 Reset the number of times the venting needle is used.

1) Display the User Maintenance window and touch [Replace].

"Opening the User Maintenance Window" (p. 9-5)

2) Touch [Reset] in Venting needle.

Replacing the Filter



Filter
(Maintenance item:
WBC filter assy)

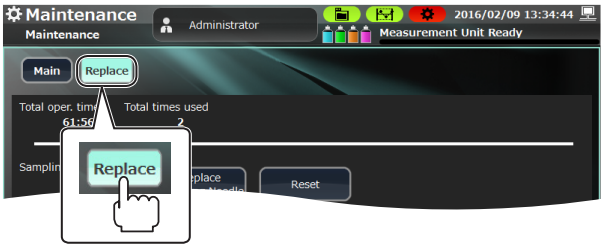
Schedule: **Every 12,000 measurements**

Maintenance item: **WBC filter assy (supply code: T802A)**

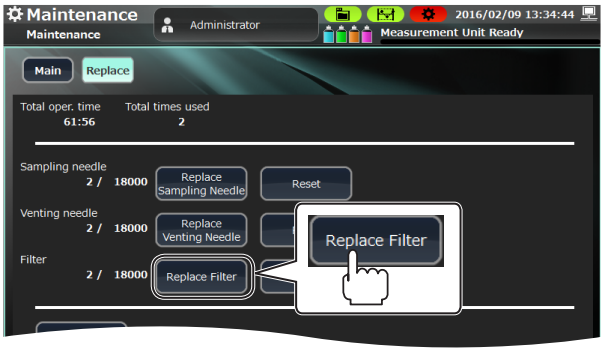
NOTE: Keep the screws that were removed during the replacement for reuse.

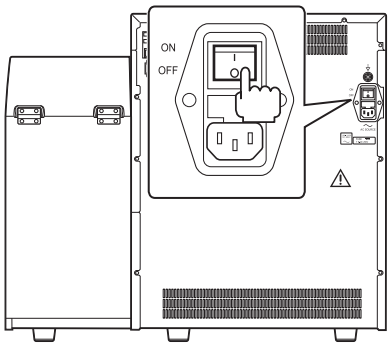
1 Open the User Maintenance window and touch [Replace].

"Opening the User Maintenance Window" (p. 9-5)



2 Touch [Replace Filter]. The filter and related fluid paths are drained and the power is automatically turned off.

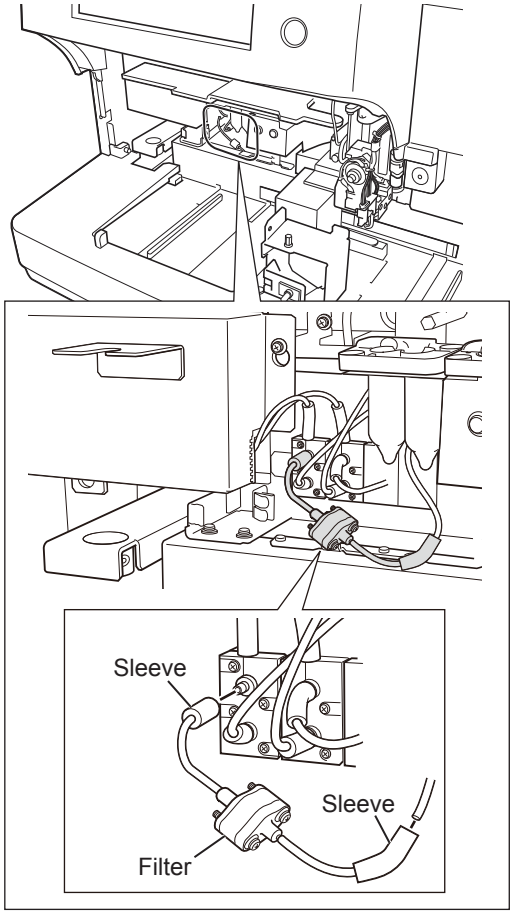


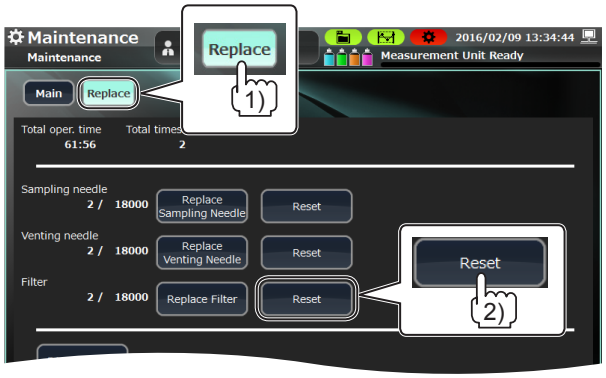


3 Turn off the Main power switch (to ○) on the rear panel of the analyzer.

4 Remove the mixing and front covers. Refer to steps **4** and **5** in "Replacing the Sampling Needle".

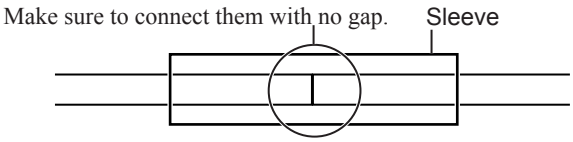
"Replacing the Sampling Needle" (p. 9-14)





5 Remove the filter together with the sleeves and replace it with a new one.

NOTE: Connect the new filter firmly to prevent gaps in the sleeves.



6 Do step **4** in reverse order to put the analyzer back to its original state.

7 Turn the analyzer on. Touch [No] on the window to run the self check.

"Turning On the Analyzer" (p. 5-5)

8 Check that the analyzer message "21200 Maintenance part replacement status" appears and touch [RESTORE] on the Maintenance Log window.

"Analyzer Messages" (p. 10-5)

9 Run the self check.

"Running Self Check" (p. 9-11)

10 Reset the number of times the filter is used.

1) Display the User Maintenance window and touch [Replace].

"Opening the User Maintenance Window" (p. 9-5)

2) Touch [Reset] in Filter.

Disposing of the Analyzer and Medical Waste

⚠ WARNING

- Dispose of the analyzer, replaced parts (such as sampling needle and venting needle), 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 needle and venting needle from the analyzer.
  If the above warning is not followed, it causes infection or environmental contamination.

⚠ WARNING

Always wear rubber gloves to protect yourself from infection.

Follow your local laws for disposing of medical waste.

Reagents

For information about the diluent, detergent and lysing reagent, refer to the package and manual provided with them.

Options

Refer to the manual provided with the options.

Cleaning and Disinfection

Analyzer

⚠ WARNING

- Be careful not to directly touch any place where blood sample is or may have contacted.
- Always wear rubber gloves to protect yourself from infection.

⚠ CAUTION

Before maintenance, perform strong cleaning, drain the cups, and turn off the analyzer main power. If the analyzer is lifted or tilted without draining, the liquid in the cups may spill and damage the electronic circuit or the operator may receive electrical shock. If maintenance is performed while the power is on, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

NOTE
- Clean and disinfect the analyzer by the following procedure.
- Wipe off moisture with a dry cloth and thoroughly dry before use.
- When using a flammable solvent such as ethanol for cleaning and disinfecting, ventilate the room adequately.

Cleaning the Surface of the Analyzer

Cleaning schedule: At least once a month

Wipe the surface with a soft cloth moistened with disinfecting ethanol (concentration: 76.9 to 81.4 vol% at 15°C (59°F)), neutral detergent diluted with water, or isopropyl alcohol. After cleaning, dry it completely.

Wipe the LCD display with a soft dry cloth.

NOTE
- Do not use volatile liquids such as thinner, benzine or bleach. These will cause the plastic surface to melt or crack.
- If you use a wet cloth with water (or detergent), wring the cloth well to prevent the liquid from spilling into the analyzer.
- Note that disinfecting ethanol or detergent that spills into the analyzer through the gap at the edge of the display may cause a failure.

Disinfecting the Surface of the Analyzer

Disinfecting schedule: When an infectious substance (blood) is present on the surface of the analyzer or when the analyzer is moved to another facility.

Wipe the surface with a soft cloth moistened with disinfecting ethanol (Concentration: 76.9 to 81.4 vol% at 15°C (59°F)).

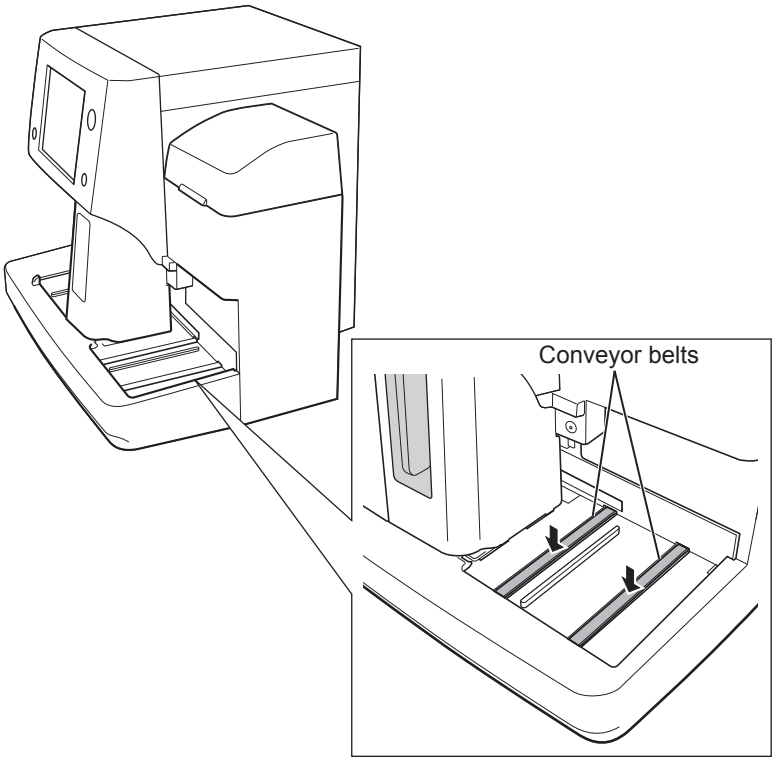
NOTE
- Use disinfectants in the correct concentration.
- Do not use volatile liquids such as thinner, benzine or bleach. These will cause the plastic surface to melt or crack.
- Wipe the analyzer thoroughly after disinfecting it with a sprayer.

Cleaning the Conveyor Belt

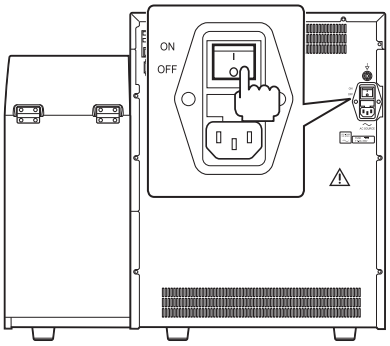
Cleaning schedule: When the conveyor belt is not clean

Wipe the conveyor belt with a soft cloth moistened with disinfecting ethanol (concentration: 76.9 to 81.4 vol% at 15°C (59°F)), neutral detergent diluted with water, or isopropyl alcohol. After cleaning, dry it completely.

NOTE
- Do not use volatile liquids such as thinner, benzine or bleach. These will cause the plastic surface to melt or crack.
- If you use a wet cloth with water (or detergent), wring the cloth well to prevent the liquid from spilling into the analyzer.
- Note that disinfecting ethanol or detergent that spills into the analyzer through the gap may cause a failure.



Cleaning the Rack Path



Cleaning schedule: When the rack path is not clean

1 Turn off the analyzer and switch off (to ○) the main power on the rear of the analyzer.

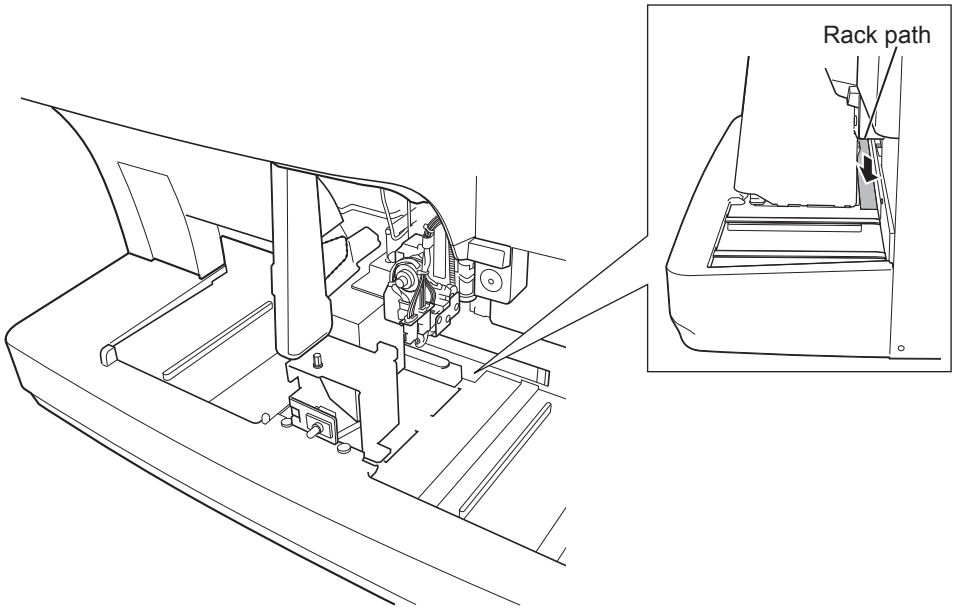
"Turning Off the Analyzer" (p. 5-23)

2 Remove the mixing cover. Refer to step **4** in "Replacing the Sampling Needle".

"Replacing the Sampling Needle" (p. 9-14)

3 Wipe the rack path with a soft cloth moistened with disinfecting ethanol (concentration: 76.9 to 81.4 vol% at 15°C (59°F)), neutral detergent diluted with water, or isopropyl alcohol. After cleaning, dry it completely.

NOTE
- Do not use volatile liquids such as thinner, benzine or bleach. These will cause the plastic surface to melt or crack.
- If you use a wet cloth with water (or detergent), wring the cloth well to prevent the liquid from spilling into the analyzer.
- Note that disinfecting ethanol or detergent that spills into the analyzer through the gap may cause a failure.



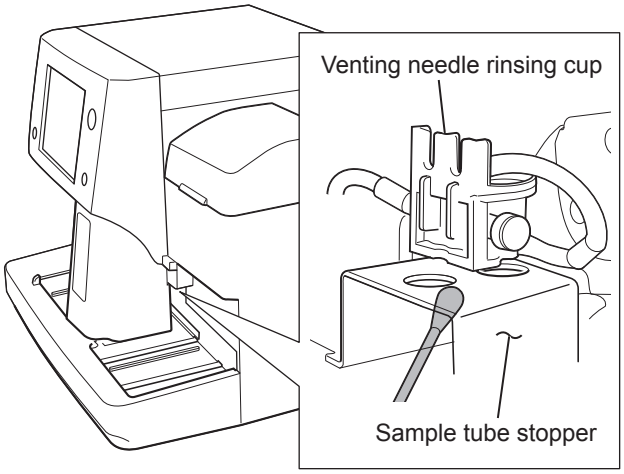
Cleaning the Sample Tube Stopper

Cleaning schedule: When the sample tube stopper is not clean

Check for dirt on the sample tube stopper.

Wipe off the dirt on the surface contacting the sample tubes using a cotton swab moistened with disinfecting ethanol (concentration: 76.9 to 81.4 vol% at 15°C (59°F)) or isopropyl alcohol.

The sample tube stopper is located right below the venting needle rinsing cup. You do not need to remove any covers to clean the stopper.



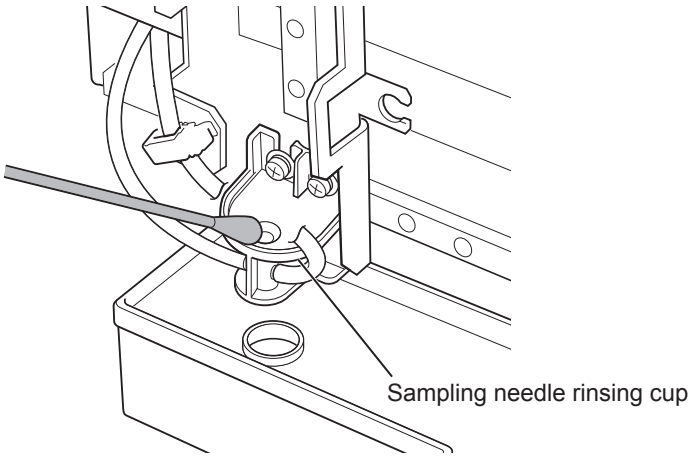
Cleaning the Sampling Needle Rinsing Cup

Cleaning schedule: When replacing the sample needle

After removing the sampling needle, clean the sampling needle rinsing cup with a cotton swab as shown in the figure.

"Replacing the Sampling Needle" (p. 9-14)

NOTE: Do not use disinfecting agents (disinfecting ethanol or isopropyl alcohol) when cleaning the sampling needle rinsing cup.



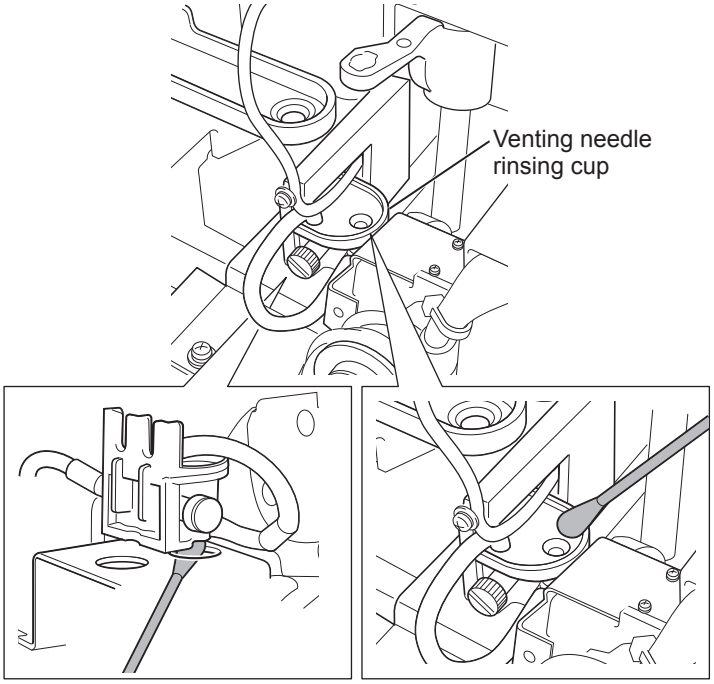
Cleaning the Venting Needle Rinsing Cup

Cleaning schedule: When replacing the venting needle

After removing the venting needle, clean the venting needle rinsing cup with a cotton swab as shown in the figure.

"Replacing the Venting Needle" (p. 9-19)

NOTE: Do not use disinfecting agents (disinfecting ethanol or isopropyl alcohol) when cleaning the venting needle rinsing cup.

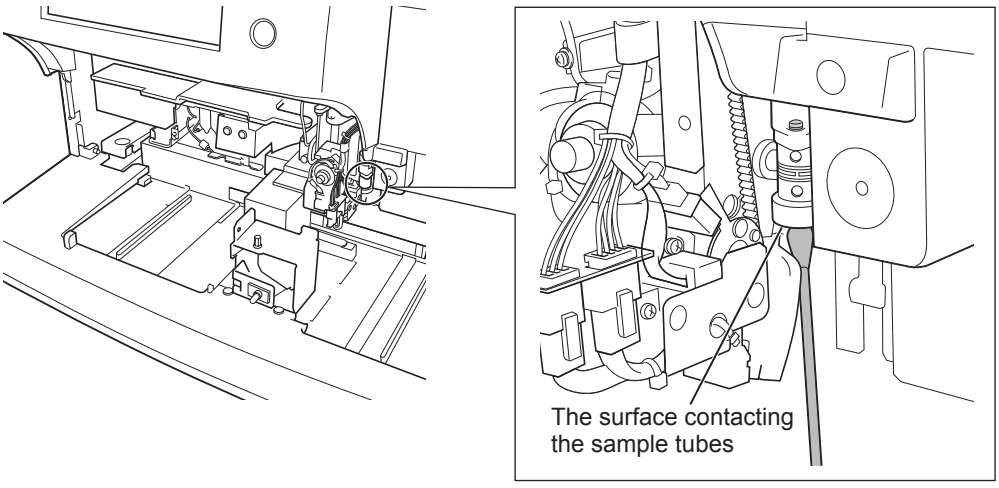


Cleaning the Sample Rotator for Barcodes

Cleaning schedule: When the sample rotator for barcodes is not clean (when replacing the sampling needle or the venting needle)

Check for dirt when replacing the sampling needle or the venting needle.

Wipe off the dirt on the surface contacting the sample tubes using a cotton swab moistened with disinfecting ethanol (concentration: 76.9 to 81.4 vol% at 15°C (59°F)) or isopropyl alcohol.



Cleaning the Aperture Caps

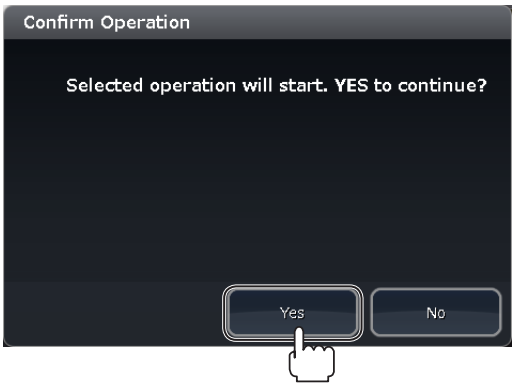
Cleaning schedule: When troubleshooting

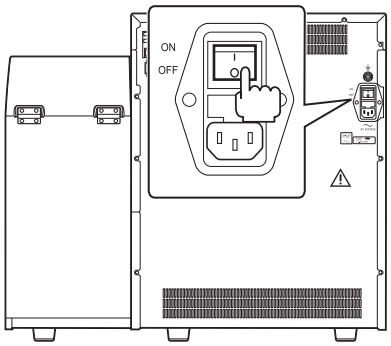
NOTE: Keep the screws that were removed during the cleaning for reuse.

1 Open the User Maintenance window and touch [Remove MC Aperture Clog].

"Opening the User Maintenance Window" (p. 9-5)

2 Touch [Yes] on the Confirm Operation window. MC and related fluid path is drained and the power is automatically turned off.



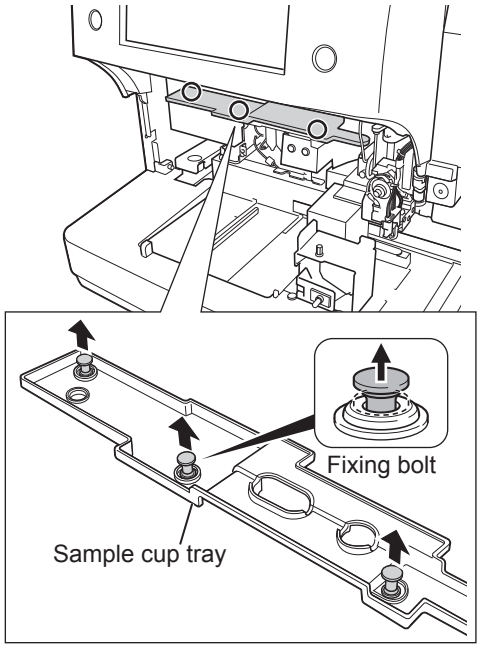


3 Switch off (to ○) the main power on the rear panel of the analyzer.

"Turning Off the Analyzer" (p. 5-23)

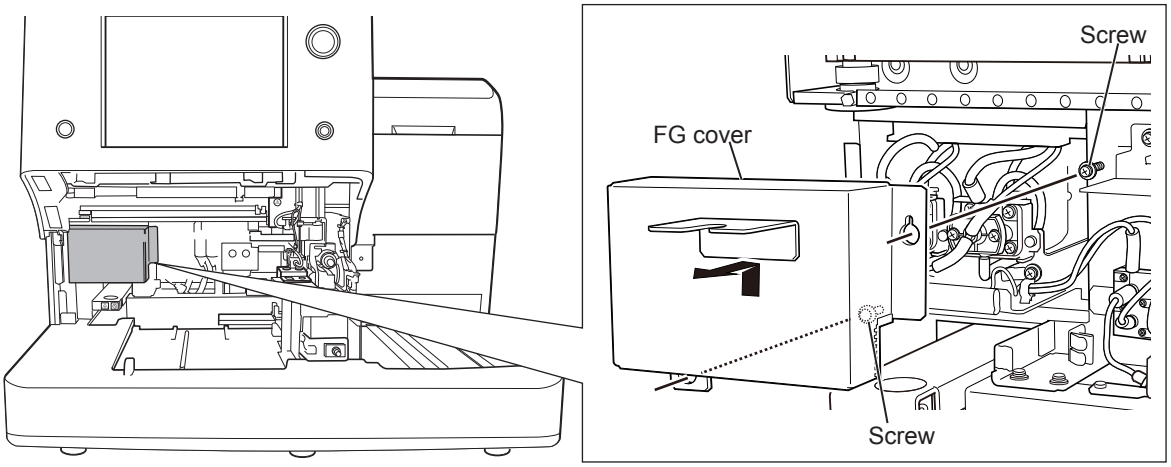
4 Remove the mixing and front covers. Refer to steps **4** and **5** in "Replacing the Sampling Needle".

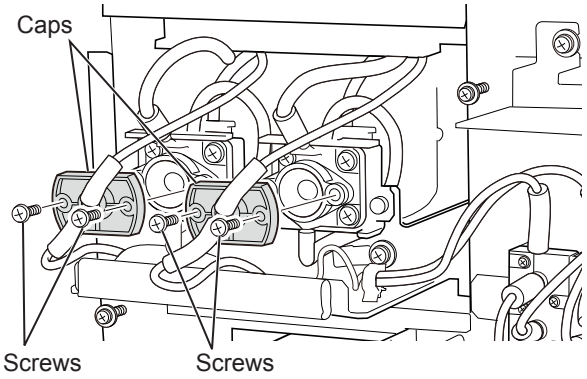
"Replacing the Sampling Needle" (p. 9-14)



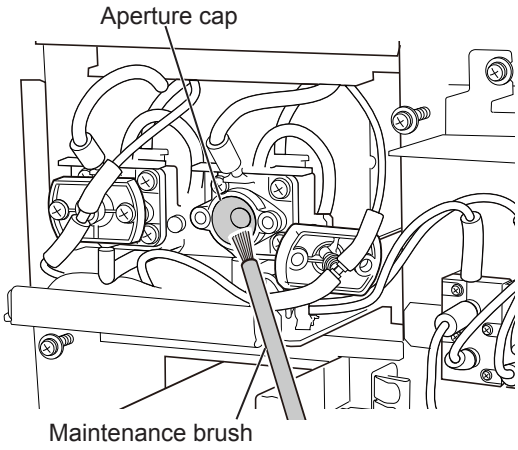
5 Pull up the 3 fixing bolts until they click then remove the sample cup tray.

6 Loosen the 2 screws to remove the FG cover.



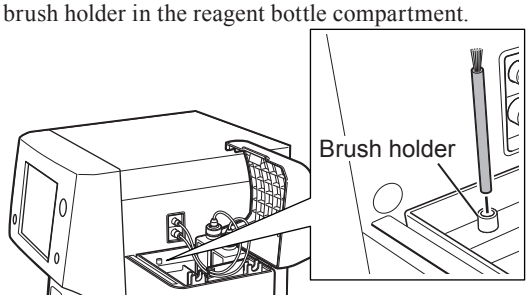


7 Remove the 4 screws to pull out the left and right caps.



8 Using the provided maintenance brush dipped in CLEANAC•810, clean the left and right aperture caps by lightly tapping them.

- The provided maintenance brush is housed in the brush holder in the reagent bottle compartment.



- After cleaning the aperture caps, wash the brush well with tap water, fully dry the tip, and then insert it into the reagent bottle compartment.

9 Do steps **4** to **7** in reverse order to return the analyzer to its original state.

10 Turn the analyzer on. Touch [No] on the window to run the self check.

"Turning On the Analyzer" (p. 5-5)

11 Clean the MC chamber.

"Cleaning the MC" (p. 9-9)

12 Run the self check.

"Running Self Check" (p. 9-11)

Cleaning the Rack

Cleaning schedule: When the rack is not clean

Wipe off the dirt on the rack with a soft cloth moistened with neutral detergent diluted with water.

After cleaning, dry it completely.

NOTE: When cleaning the rack, make sure to avoid peeling off the label (identification barcode) on the rack.

Options

Refer to the manual provided with the options.

Storage and Transport

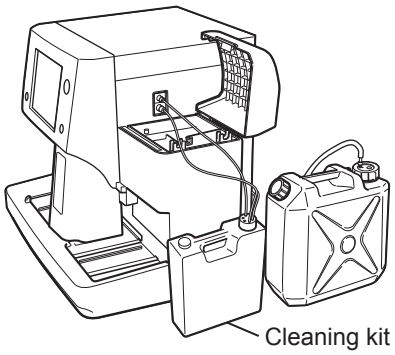
Long Term Storage and Transport

> **⚠ CAUTION**
>
> Before moving the analyzer, do the following.
> - Perform strong cleaning and drain the cups. If the analyzer is lifted or tilted without draining, the liquid in the cups may spill and damage the electronic circuit or the operator may receive electrical shock.
> - Turn off the analyzer main power and disconnect the power cord from the AC outlet. If the analyzer is moved while the power is on, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

In long term storage or transport, if any diluent remains inside the analyzer, the inside of the analyzer will become dirty because of dried diluent crystal or other contaminants. This increases background noise.

If the analyzer needs to be stored for a long time or transported, clean the inside by flushing the fluid path with distilled water and doing the Drain All operation.

If there is no distilled water, commercially available purified water is acceptable.



1 Perform cleaning.

“Cleaning” (p. 9-6)

2 Removing the tubes connected to the diluent inlet, detergent inlet and lysing reagent inlet, leaving only the waste fluid tube connected.

“Connecting the Reagent and Waste Container” (p. 4-10)

3 Perform the draining operation to completely drain all reagent from the inside of the analyzer.

“Draining All” (p. 9-11)

4 Pour distilled water into the bottle of the cleaning kit and connect the tubes of the cleaning kit to the diluent inlet, detergent inlet and lysing reagent inlet.

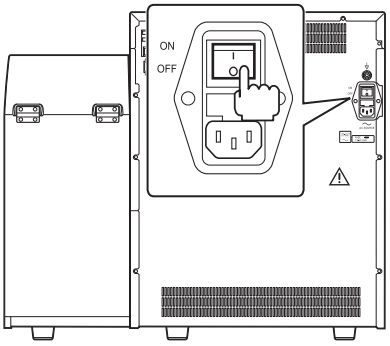
The cleaning kit consists of a distilled water container and tubes.

5 Perform priming on installation to fill the analyzer with distilled water.

When an analyzer message “21100 Analyzer internal draining status” appears on the Maintenance Log window, touch [RESTORE] to start priming on installation.

“Priming on Installation” (p. 9-10)

6 Repeat steps **2** to **3** to drain the analyzer of all the distilled water.



7 Turn off the analyzer and switch off (to ○) the main power on the rear of the analyzer.

"Turning Off the Analyzer" (p. 5-23)

Using the Analyzer After Long Term Storage

NOTE: After long term storage, perform the following procedures before using the analyzer because the fluid path may be dirty.

1 Clean the aperture caps.

"Cleaning the Aperture Caps" (p. 9-29)

2 Turn the analyzer on.

"Turning On the Analyzer" (p. 5-5)

3 Perform priming on installation.

When an analyzer message "21100 Analyzer internal draining status" appears on the Maintenance Log window, touch [RESTORE] to start priming on installation.

"Priming on Installation" (p. 9-10)

10 Troubleshooting

Screen Messages

If the analyzer detects an alarm, the alarm message appears on the window. The alarm message and their causes and their countermeasures are described in the tables on the following pages.

After solving the problem, check that no error messages are displayed and that the analyzer functions properly before use.

NOTE
- If the error message does not disappear after taking the following countermeasures, attach an “Unusable” or “Repair request” label to the analyzer and contact your Nihon Kohden representative.
- Be careful when diagnosing a patient by the measurement results with an error message. The measurement results might not be correct because of analyzer error or sample error.

> **⚠ CAUTION**
>
> A measurement result with a message might not be correct because of analyzer error or sample error. Do not diagnosis the patient based on the result especially when “!” appears on the measurement result.

Measurement Messages

The measurement message indicates a measurement error.

To check the message, touch [Flag] on the Data Details window.
An identifier (? or !) is displayed related to the detected error.

Depending on the detected error, the measurement value of the related parameter might not be displayed.

Measurement messages are displayed

The following data identifiers are added to the parameter on the analyzer. The data identifiers for the measurement messages are "?" and "!".

Abnormal Flags

Data Management and Setting Guide:
"Viewing Flags" in Section 4

Classification	Data Identifier	Measurement Value	Description
Data cannot be analyzed	None	Related parameter measurement value not displayed	The data cannot be analyzed.
Measurement condition error detected	None	Related parameter measurement value not displayed	Measurement operation error is detected.
Data with low reliability (Error found during measurement)	?	Measurement value displayed	The analyzer condition is out of the specified range and the reliability of the data is low. The measurement value is the reference value.
Data with low reliability (Abnormal flag detected)	! *	Measurement value displayed	Abnormal flag is detected in the sample. The reliability of measured data is low because abnormal cells exist. If the WBC and PLT values are low, count them with a blood smear.
	C	Measurement value displayed	The reliability of measured data is low because PLT clumps are detected.
Out of normal range	H	Measurement value displayed	The measurement value is out of the upper and lower limits range set in the "Sample Type" in System Setting.
	L		
Out of measuring range	None	"OVER" message displayed	The measurement value exceeds the measurable range.

10

Measurement Message List

Measurement Message	Cause	Countermeasure
HGB Circuit Message	LED OFF voltage is outside the range.	Contact your Nihon Kohden representative.
SS Circuit Message		
HGB LED Temp. Message	Temperature sensor cable is disconnected or sensor may be damaged.	
Diluent Temp. Message		
SS LED Temp. Message		
SS Cup Temp. Message		
Cup Temp. Message		
Cup Heater Temp. Message		
Tank Temp. Message		
Tank Heater Temp. Message		
Room Temp. Message		
WBC Noise	Detector is dirty or power environment is unstable.	Take the countermeasure on the message displayed on the Maintenance Log window and remeasure the sample with an error.
RBC Noise		
WBC Aperture Clog	Electrode voltage after measurement is outside the range.	
RBC Aperture Clog		

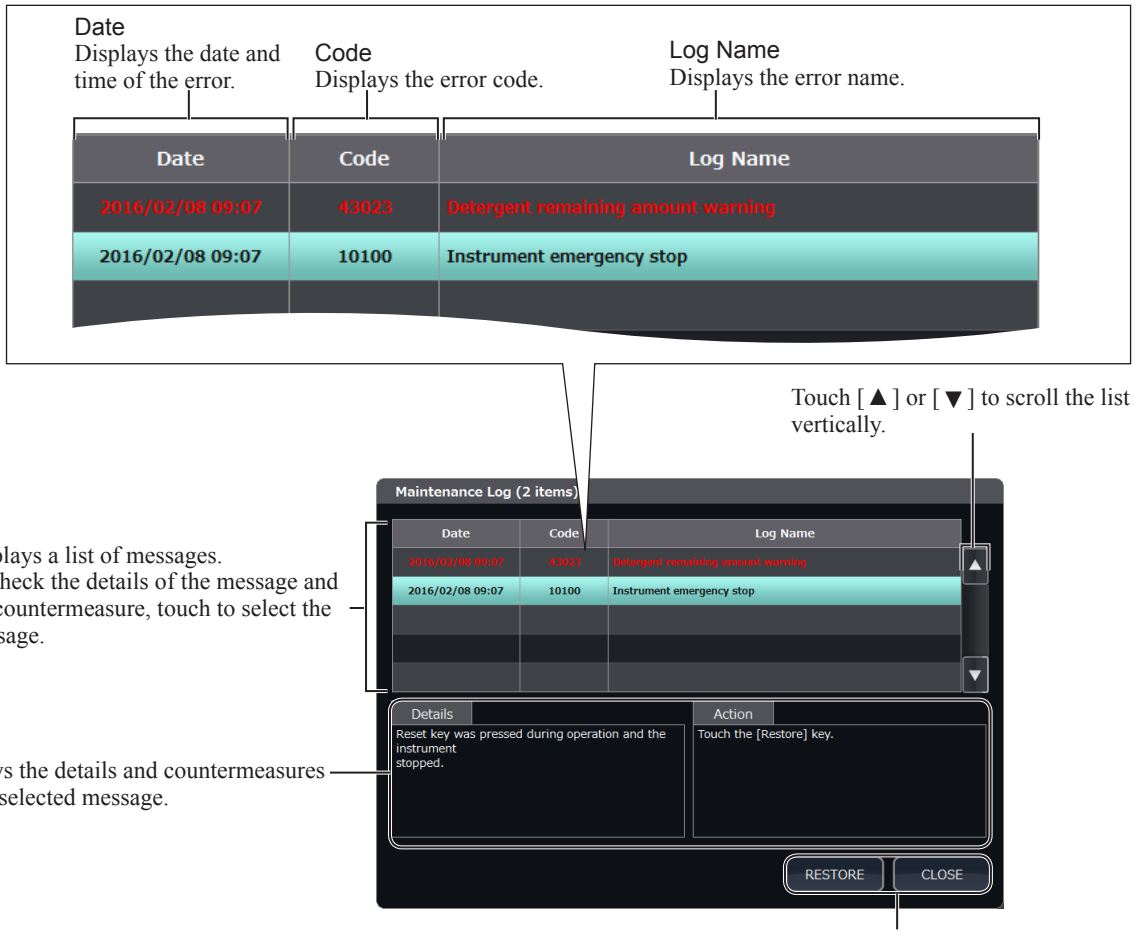
Measurement Message	Cause	Countermeasure
WBC Time-Series Message	Maximum value and minimum value in the time series is outside the range.	Perform the following operation and remeasure the sample with an error. 1. Remove clogs in the aperture cap. "Removing Clogs" (p. 9-9) 2. Clean protein. "Cleaning Protein" (p. 9-7) 3. Clean the aperture cap. "Cleaning the Aperture Caps" (p. 9-29)
RBC Time-Series Message		
PLT Time-Series Message		
LaserKey Off	The laser key is OFF.	Contact your Nihon Kohden representative.
OpticalCount Message	Unspecified operation during optical count	Clean the flow cell. "Cleaning the Flowcell" (p. 9-8)
OpticalCount Low	Optical count is too low and WBC 5-part was not differentiated.	Make a blood smear and count it visually with a microscope.
Short Sample	Blood cannot be discharged in the IWBC cup and OWBC cup.	Remeasure the sample.
Cup Temp. Low	The cup temperature during measurement is out of specified range.	• Locate the analyzer so that the venting hole is not blocked. • Keep the room temperature at 15 to 30C° (59 to 86°F) and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.
Cup Temp. High		
HGB Voltage High	LED ON voltage is outside the range.	Contact your Nihon Kohden representative.
HGB Voltage Low		Keep the room temperature and diluent temperature at 15 to 30C° (59 to 86°F) and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.
HGB LED Temp. Low	HGB LED temperature is outside the specified range.	
HGB LED Temp. High		
Diluent Temp. Low	HGB CAL temperature is outside the specified range.	
Diluent Temp. High		
SS Voltage Low	SS voltage is outside the specified range.	Contact your Nihon Kohden representative.
SS Voltage High		
SS LED Temp. Low	SS LED temperature is outside the range.	Keep the room temperature and diluent temperature at 15 to 30C° (59 to 86°F) and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.
SS LED Temp. High		
SS Cup Temp. Low	The OWBC cup temperature during SS measurement is outside of specified range.	
SS Cup Temp. High		
Cup Heater Temp. Low	The cup heater temperature during measurement is outside of specified range.	
Cup Heater Temp. High		
Tank Temp. Low	The tank temperature during measurement is outside of specified range.	
Tank Temp. High		
Tank Heater Temp. Low	The tank heater temperature during measurement is outside of specified range.	
Tank Heater Temp. High		
Room Temp. Low	The chassis internal temperature during measurement is outside of specified range.	• Locate the analyzer so that the venting hole is not blocked. • Keep the room temperature at 15 to 30C° (59 to 86°F) and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.
Room Temp. High		

Analyzer Messages

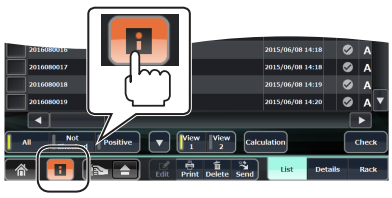
If an error is detected during measurement, the Maintenance Log window appears.

The Maintenance Log window displays a message of the analyzer error and the countermeasures.

- A message right after detection appears in red (unread message status).
- When the message is touched and the details and countermeasures are checked, the message is displayed in white (read message status).



[RESTORE]: Restores operation depending on the error status.
[CLOSE]: Closes the Maintenance Log window.



For messages with low priority listed in the "User Information (4xxxx)" (p. 10-13), [ℹ] on the lower left may become orange without opening the Maintenance Log window. In this case, touch [ℹ] to open the Maintenance Log window.

Restoring Operation

The analyzer can be restored to the normal condition in the following procedure.

1. Select the error message on the Maintenance Log window and display the details and countermeasures.
2. Perform the displayed countermeasure.

   Some messages require the countermeasure on other menu such as on the Reagents window.
3. Touch [RESTORE] on the Maintenance Log window.

Analyzer Message List

Service Messages (0xxxx)

Code	Error	Cause	Countermeasure
00001	Open Voltage Operation Error	Control error for air pressure source condition	Contact your Nihon Kohden representative.
00002	Air Opening Error	During air opening operation, pressure is outside the range	
00003	ISO Chamber Positive Pressure Error	During ISO chamber pressurization, pressure is outside the range	
00004	ISO Chamber Negative Pressure Error	During ISO chamber depressurization, pressure is outside the range	
00005	WC1 Positive Pressure Error	During WC1 pressurization, pressure is outside the range	
00006	WC1 Negative Pressure Error	During WC1 depressurization, pressure is outside the range	
00010	Diluter Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00011	Diluter Operation Error	Pump full stroke did not reach the bottom dead point sensor (sensor timeout)	
00012	Diluter Base Position Error	• At the start of pump operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00013	Diluter End Position Error	• At the end of pump operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00020	Sample Pump Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00022	Sample Pump Base Position Error	• At the start of pump operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00030	RBC Pump Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00032	RBC Pump Base Position Error	• At the start of pump operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00040	WBC Pump Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00042	WBC Pump Base Position Error	• At the start of pump operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00050	X Sampler Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00051	X Sampler Operation Error	Movement of the sensor to the OP position did not reach the OP sensor (sensor timeout)	

Code	Error	Cause	Countermeasure
00052	X Sampler Base Position Error	At the start of sampler movement, the sensor which should be ON is OFF Sensor did not detect it or pump position is incorrect	Contact your Nihon Kohden representative.
00053	X Sampler End Position Error	• At the end of sampler operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00060	Y Sampler Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00061	Y Sampler Operation Error	Movement of the sensor to the full stroke position did not reach the sensor (sensor timeout)	
00062	Y Sampler Base Position Error	• At the start of sampler movement, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00063	Y Sampler End Position Error	• At the end of sampler operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00070	Venting Needle Initialize Error	Initialization movement did not reach the start point sensor (sensor timeout)	
00071	Venting Needle Operation Error	Full stroke did not reach the bottom dead point sensor	
00072	Venting Needle Base Position Error	• At the start of venting needle operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00073	Venting Needle End Position Error	• At the end of venting needle operation, the sensor which should be ON is OFF • Sensor did not detect it or pump position is incorrect	
00090	PV1 Initialize Error	• Error in bulb closing operation (initialization operation) • Sensor did not detect it or bulb position is incorrect (sensor timeout)	
00100	PV2 Initialize Error		
00110	PV3 Initialize Error		
00120	PV4 Initialize Error		
00130	PV5 Initialize Error		
00091	PV1 Close Operation Error	• Error in bulb closing operation • Sensor did not detect it or bulb position is incorrect (sensor timeout)	
00101	PV2 Close Operation Error		
00111	PV3 Close Operation Error		
00121	PV4 Close Operation Error		
00131	PV5 Close Operation Error		

Code	Error	Cause	Countermeasure
00092	PV1 Open Operation Error	• Error in bulb opening operation • Sensor did not detect it or bulb position is incorrect (sensor timeout)	Contact your Nihon Kohden representative.
00102	PV2 Open Operation Error		
00112	PV3 Open Operation Error		
00122	PV4 Open Operation Error		
00132	PV5 Open Operation Error		
00140	Thermistor Abnormality (Cup)	• Thermistor failure • Distribution wire problem • Problem in IC (AD converter) on board	
00141	Thermistor Abnormality (Cup Heater)		
00142	Thermistor Abnormality (Tank)		
00143	Thermistor Abnormality (Tank Heater)		
00144	Thermistor abnormality (HGB temperature sensor)		
00145	Thermistor abnormality (SS temperature sensor)		
00146	Thermistor abnormality (chassis internal temperature sensor)		
00156	Thermistor abnormality (diluent temperature sensor)		
00160	CBC Circuit Abnormality	Circuit inspection result out of range (WBC, RBC, MCV, W-ELE, R-ELE)	
00161	DIFF Circuit Abnormality	Circuit inspection result out of range (TOC)	
00162	HGB Circuit Abnormality	• HGB LED OFF voltage is outside the range • AD circuit abnormality • LED circuit abnormality • AMP circuit abnormality	
00163	SS Circuit Abnormality	• SS LED OFF voltage outside the range • AD circuit abnormality • LED circuit abnormality • AMP circuit abnormality	
00500	Internal communication loss	Communication with measuring part lost and number of retries exceeded	
00600	WBC MCB Error	MCB error	
00601	RBC MCB Error	MCB error	

Code	Error	Cause	Countermeasure
01000	System error	System error	Contact your Nihon Kohden representative.
01001			
08000	Autoloader Continuous Operation Detected	Autoloader power interruption detected	

User Messages (1xxxx)

Code	Error	Cause	Countermeasures
10000	IWBC Cup Draining Error	• IWBC cup draining completion was not detected. • During cup draining, the WC1 pressure was not greater than the specified value.	1. Touch the [RESTORE] key on the Maintenance Log window to drain the cup. 2. Check the overflow tray. Wipe it if there is fluid. If the message frequently appears, contact your Nihon Kohden representative.
10001	RBC Cup Draining Error	• RBC cup draining completion was not detected. • During cup draining, the WC1 pressure was not greater than the specified value.	
10002	OWBC Cup Draining Error	• OWBC cup draining completion was not detected. • During cup draining, the WC1 pressure was not greater than specified value.	
10100	Instrument emergency stop	RESET button was touched during operation and the analyzer stopped	Touch [RESTORE] on the Maintenance Log window to return the analyzer to measurement condition.
10150	Temperature Upper Limit Error (Cup)	Temperature sensor on the cup is outside the range.	Touch [RESTORE] on the Maintenance Log window to return the analyzer to standby. If the message frequently appears, contact your Nihon Kohden representative.
10151	Temperature increase error (cup heater)	Temperature sensor on the cup heater is outside the range.	
10152	Temperature Upper Limit Error (Tank)	Temperature sensor on the tank is outside the specified range.	
10153	Temperature increase error (tank heater)	Temperature sensor on the tank heater is outside the range.	
11000	Waste Chamber 1 Full	WC1 full condition detected	Touch [RESTORE] on the Maintenance Log window to drain the waste chamber. If the message frequently appears, contact your Nihon Kohden representative.
11001	Waste Chamber 2 Full	WC2 full condition detected	
18000	Mixing cover off	Mixing cover detached	1. Refer to the replacement procedure for sampling needle and attach the mixing cover. “Replacing the Sampling Needle” (p. 9-14) 2. Touch [RESTORE] on the Maintenance Log window to return the analyzer to measurement condition.

User Messages (2xxxx)

Code	Error	Cause	Countermeasure
21000	Unexpected shutdown occurred	Without touching the power switch, the analyzer shut down due to power interruption or other reason.	1. Touch [RESTORE] on the Maintenance Log window to initialize the drive part of the analyzer. 2. Do cleaning if power interruption during measurement or cleaning is suspected. "Replacing the Sampling Needle" (p. 9-14)
21050	WBC Detection Hole Clog	WBC aperture cap clog detected	Touch the [RESTORE] key on the Maintenance Log window to do cleaning. If this does not solve the problem, do the following. 1. Do protein cleaning. "Cleaning Protein" (p. 9-7) 2. Clean the aperture cap. "Cleaning the Aperture Caps" (p. 9-29) If the message frequently appears, contact your Nihon Kohden representative.
21051	RBC Detection Hole Clog	RBC aperture cap clog detected	
21052	WBC noise	WBC measurement noise detected	
21053	RBC noise	RBC measurement noise detected	
21110	Analyzer internal draining status	Analyzer internal draining operation was done and the analyzer fluid path was drained	After moving or storing the analyzer, touch [RESTORE] key to do priming on installation.
21200	Maintenance part replacement status	The fluid path of the affected part was drained during [Replace Sampling Needle], [Replace Venting Needle] or [Replace Filter] operation.	After replacement of the parts, touch [RESTORE] on the Maintenance Log window to prime the fluid path of the related maintenance parts.
23000	3-part diff lysing reagent priming error	Out of HEMOLYNAC•310 detected	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to standby. 2. Replace the reagent. "Replacing Reagents" (p. 8-5)
23001	5-part diff lysing reagent priming error	Out of HEMOLYNAC•510 detected	
23002	Detergent priming error	Out of HEMOLYNAC•710 detected	
23003	Diluent priming error	Out of ISOTONAC•3/4 detected	
23030	Waste Bottle Full	JW-910W waste fluid sensor (option) detected waste container full	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to standby. 2. Replace the waste container. "Replacing Reagents" (p. 8-5)
23031	Waste bottle replacement period	Waste fluid amount exceeded warning value	
26100	Self check not done	• After login, measurement was started without self-check • More than 24 hours between self-check and measurement start	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to standby. 2. Do self-check. "Running Self Check" (p. 9-11)
27000	Consumable Parts (Sample Tube)	Sampling needle was used more than the specified number of times	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to standby. 2. Replace the maintenance parts. "Replacing the Sampling Needle" (p. 9-14) "Replacing the Venting Needle" (p. 9-19) "Replacing the Filter" (p. 9-21)
27001	Consumable Parts (Venting Needle)	Venting needle was used more than the specified number of times	
27002	Consumable Parts (Filter)	Filter was used more than the specified number of times	
28001	AL Detection Sensor Error (BU)	The following sensors in the barcode reader unit detected abnormalities at the same time: • No sampling tube detected sensor, sampling tube release sensor	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to initialize the drive part of the analyzer. 2. Manually remove any rack from inside the autoloader. If the message frequently appears, contact your Nihon Kohden representative.

Code	Error	Cause	Countermeasure
28002	AL Detection Sensor Error (AU)	The following sensors in the agitator unit detected abnormalities at the same time: • Agitator rotate down, agitator rotate up • Agitator arm up, agitator arm down	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to initialize the drive part of the analyzer. 2. Manually remove any rack from inside the autoloader. If the message frequently appears, contact your Nihon Kohden representative.
28003	AL Detection Sensor Error (FU)	The following sensors in the feed unit detected abnormalities at the same time: • Feed axle tab eject/tab return • Feed conveyor position 1, 2, 3, 4, 5, 6, end point	
28004	AL Detection Sensor Error (GU)	The following sensors in the pierce guide unit detected abnormalities at the same time: • Pierce guide fixed/release	
28005	AL Detection Sensor Error (TU)	The following sensors in the terminal unit detected abnormalities at the same time: • Rack eject tab eject/tab return	
28010	Tube check arm ascend failure	The following sensors did not detect the operation • Sampling tube release	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to initialize the drive part of the analyzer. 2. Manually remove any rack from inside the autoloader. If the message frequently appears, contact your Nihon Kohden representative.
28011	Agitator grip open failure	The following sensors did not detect the operation • Agitator grip release	
28012	Agitator arm descent failure	The following sensors did not detect the operation • Agitator arm lowering	
28013	Agitator grip down failure	The following sensors did not detect the operation • Agitator rotating down	
28014	Blood sample tube failed to release from pierce guide	The following sensors did not detect the operation • Pierce guide release	
28015	Discharge tab return failure	The following sensors did not detect the operation • Rack eject tab return	
28016	Feed conveyor tab return failure	The following sensors did not detect the operation • Feed axle tab return operation	
28017	Feed conveyor failed to go to start position	The following sensors did not detect the operation • Feed conveyor position 1	
28021	Agitator arm ascend failure	The following sensors did not detect the operation • Agitator arm raising	
28022	Agitator grip up failure	The following sensors did not detect the operation • Agitator raising	

Code	Error	Cause	Countermeasure
28023	Failure of pierce guide to hold sample tube	The following sensors did not detect the operation • Pierce guide fixed	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to initialize the drive part of the analyzer. 2. Manually remove any rack from inside the autoloader. If the message frequently appears, contact your Nihon Kohden representative.
28024	Discharge tab eject failure	The following sensors did not detect the operation Rack eject tab eject	
28025	Feed tab eject failure	The following sensors did not detect the operation FEED axle tab out	
28026	Feed conveyor failed to move to start position	The following sensors did not detect the operation Feed conveyor position 2, 3, 4, 5, 6, end point	
28027	Agitator grip grip failure	The following sensors did not detect the operation Agitator grip release	
28040	Feed conveyor error (measurement/ handling divergence)	The following transport position information did not match in the check before transport operation Sensor detection position (measurement) Control recognition position (management)	
28041	Feed conveyor error (measurement/ target divergence)	The following conveyor position information did not match in the check after conveyor operation Sensor detection position (measurement) Conveyor target position (target)	
28042	Feed conveyor abnormality (target out of control)	A conveyor target position outside the conveyor range was set	
28902 to 28918	AL unexpected catch	System error	1. Touch [RESTORE] on the Maintenance Log window to return the analyzer to initialize the drive part of the analyzer. If the message frequently appears, contact your Nihon Kohden representative.

User Messages (3xxxx)

Code	Error	Cause	Countermeasure
38010	Feed conveyor entrance full	Rack on the conveyor line does not return to the autoloader entrance	1. Remove the rack from the autoloader entrance. 2. Touch [RESTORE] on the Maintenance Log window to restart auto measurement.
38011	Feed conveyor exit full	Rack on the conveyor line does not exit from the autoloader exit	1. Remove the rack from the autoloader exit. 2. Touch [RESTORE] on the Maintenance Log window to restart auto measurement.
38012	Check feed conveyor exit	Possible foreign object outside the rack in the autoloader exit	1. Check that there is no foreign object in the autoloader exit. 2. Touch [RESTORE] on the Maintenance Log window to restart auto measurement.
38020	Check feed conveyor entrance	Possibility that a rack or other object was manually inserted into the conveyor line from the autoloader entrance side	1. Check there is no rack or foreign object in the conveyor line. If there is a rack or foreign object in the conveyor line, remove it. 2. Touch [RESTORE] on the Maintenance Log window to restart auto measurement.
38021	Check feed conveyor exit	Possibility that a rack or other object was manually inserted into the conveyor line from the autoloader exit side.	
38022	Rack could not be conveyed	• Feed conveyor operated but the rack was not held. • Feed conveyor (conveyor first time) was done but the incoming sensor continually detected it.	1. Put the remaining rack in the autoloader entrance again. 2. Touch [RESTORE] on the Maintenance Log window to restart auto measurement.

10

User Information (4xxxx)

These are messages to notify information to user. There are no recovery operation. If the message is touched and it becomes read condtion, the message is not displayed on the Maintenance Log window.

Code	Error	Cause	Countermeasure
43010	Reagent Expiration (Diluent)	• Attempted to register expired reagent • Registered reagent exceeded the expiration period	Replace with reagent which is within the expiration period. “Replacing Reagents” (p. 8-5)
43011	Reagent Expiration (CBC Lysing Reagent)		
43012	Reagent Expiration (DIFF Lysing Reagent)		
43013	Reagent Expiration (Detergent)		
43020	Diluent remaining amount warning	Remaining reagent dropped below the warning level	Check the remaining reagent level. If necessary, replace it with new reagent. “Replacing Reagents” (p. 8-5)
43021	3-part diff lysing reagent remaining amount warning		
43022	5-part diff lysing reagent remaining amount warning		
43023	Detergent remaining amount warning		

Code	Error	Cause	Countermeasure
44000	Diluent temperature low	Diluent temperature low	Keep the room temperature at 15 to 30C° (59 to 86°F) and remeasure the sample.
44001	Diluent temperature high	Diluent temperature high	
44002	HGB LED temperature low	Room temperature low	
44003	HGB LED temperature high	Room temperature high	
44004	SS LED temperature low	Room temperature low	
44005	SS LED temperature high	Room temperature high	
44006	Chassis internal temperature low	Chassis temperature low	
44007	Chassis internal temperature high	Chassis temperature high	
46300	Protein cleaning period	More than 30, 40, 50, or 60 days since last protein cleaning	Do protein cleaning. “Cleaning Protein” (p. 9-7)
47000	Part Replacement Period (Sample Tube)	Part used more times than the safety period of 12,000, 13,000, 14,000, 15,000, 16,000, 17,000, or 18,000 times	Replace the maintenance part and reset the operation history. • “Replacing the Sampling Needle” (p. 9-14) • “Replacing the Venting Needle” (p. 9-19) • “Replacing the Filter” (p. 9-21)
47001	Part Replacement Period (Venting Needle)		
47002	Part Replacement Period (Filter)		
47003	HGB Voltage Drop	Blank time LED ON voltage is less than the specified value.	Contact your Nihon Kohden representative.
47004	HGB Voltage Increase	Blank time LED ON voltage is more than the specified value.	
47005	SS Voltage Drop	Blank time LED ON voltage is less than the specified value.	
47006	SS Voltage Increase	Blank time LED ON voltage is more than the specified value.	
47007	Background increase	Background measurement value exceeds specifications of the analyzer.	Redo the operation (self check or background measurement). • “Running Self Check” (p. 9-11) • “Measuring Background Noise” (p. 9-12) If this error occurs frequently, do cleaning. “Cleaning” (p. 9-6)
48000	No rack	Rack could not be detected when auto measurement started	Position the rack and restart auto measurement.
48030	Check sampling tube	A sampling tube may be remaining inside the analyzer because it was inside the agitator during auto measurement before an analyzer power interruption.	Check if there is a sample tube remaining in the agitator unit. If there is a sample tube in the agitator unit, do the following. 1. Turn off the analyzer. “Turning Off the Analyzer” (p. 5-23) 2. Remove the mixing cover. “Replacing the Sampling Needle” (p. 9-14) 3. Manually remove the tube and restore the mixing cover.

Code	Error	Cause	Countermeasure
48100	Sample tube barcode reading abnormality	The barcode on the sample tube cannot be read (except the barcode undetected)	If the barcode on the sample tube cannot be read, the measurement cannot be performed following the system setting. If the sample tube is not measured, check the barcode and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.
48101	Sample tube barcode multiple readings	Several barcode are decteced when the barcode on the sample tube is read.	If the several barcode are read from the sample tube, the measurement cannot be performed following the system setting. If the sample tube is not measured, check the barcode and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.
48110	Rack barcode reading abnormality	The barcode on the rack cannot be read (except the barcode undetected)	If the barcode on the rack is not read, the sample tubes in the rack cannot be measured. Check if the barcode on the rack is not diry or peeled off and remeasure the sample. If the message frequently appears, contact your Nihon Kohden representative.

Troubleshooting

The following tables list troubles and their causes and countermeasures.

After doing the countermeasure and after the trouble disappears, confirm that the analyzer operates normally then restart the analyzer.

NOTE: If the following countermeasures do not solve the problem, attach an “Unusable” or “Repair request” label to the analyzer and contact your Nihon Kohden representative.

No.	Problem	Possible Cause	Countermeasure
1	• Power does not turn on • Power was lost during operation (Main power lamp does not light)	Main power is turned off on the rear panel of the analyzer.	Turn on the main power on the rear panel of the analyzer. After the main power lamp lights, press the power switch on the front panel of the analyzer. If the power shuts off during operation, a blood sample may remain in the analyzer. Therefore, clean the inside of the analyzer after the power is restored. “Cleaning” (p. 9-6)
		Power cord disconnected	Check that the power cord is securely connected and turn on the power. If the power shuts off during operation, a blood sample may remain in the analyzer. Therefore, clean the inside of the analyzer after the power is restored. “Cleaning” (p. 9-6)
2	• Noise during measurement • High background noise	Grounding bad	Check that the ground wire is securely connected.
		Nearby device is generating noise	Connect the noise generating device to a separate power outlet.
		Noise from the AC power line	Connect the analyzer to a different power outlet.
		The front cover is open and noise is affecting the measurement unit.	Close the front cover.
		Diluent is dirty	Replace the diluent.
		Filter is dirty	Replace the filter. “Replacing the Filter” (p. 9-21)
		Sample cup is dirty	Do protein cleaning. “Cleaning Protein” (p. 9-7)
		Aperture cap is dirty	Remove clogs in the fluid path. “Removing Clogs” (p. 9-9) Do protein cleaning. “Cleaning Protein” (p. 9-7) If protein cleaning does not improve the problem, clean the aperture cap. “Cleaning the Aperture Caps” (p. 9-29)
		Poor contact of external electrode	Contact your Nihon Kohden representative.
		Dirty inside fluid path	Clean the fluid path. “Cleaning” (p. 9-6)
			Do protein cleaning. “Cleaning Protein” (p. 9-7)

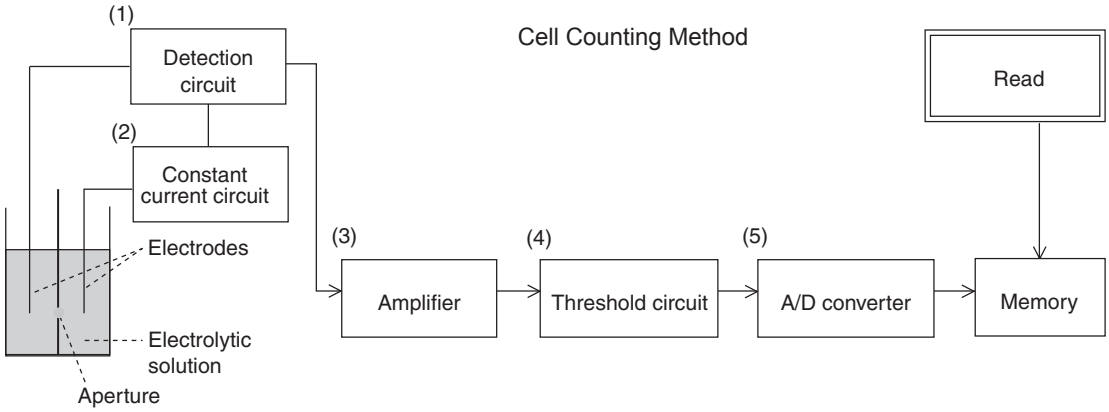
No.	Problem	Possible Cause	Countermeasure
3	Bad reproducibility of cell count values	Insufficient sample stirring	Carefully agitate the sample tube, being careful to preventing bubbles.
		Sample cup is dirty	Do protein cleaning. "Cleaning Protein" (p. 9-7)
		Aperture cap is dirty	Remove clogs in the fluid path. "Removing Clogs" (p. 9-9) Do protein cleaning. "Cleaning Protein" (p. 9-7) If protein cleaning does not improve the problem, clean the aperture cap. "Cleaning the Aperture Caps" (p. 9-29)
		High background noise	Refer to the second countermeasure above on this page.
4	Water leaks from inside the analyzer	Clogged solenoid valve.	Contact your Nihon Kohden representative.
		Clogged filter.	Replace the filter. "Replacing the Filter" (p. 9-21)
5	HGB reproducibility is bad	Dirty HGB cell	Do protein cleaning. "Cleaning Protein" (p. 9-7)
6	Cannot print from printer	No recording paper	Load recording paper.
		Paper jam	Remove the jammed paper.
		Abnormality in electrical circuit	Turn off the printer and wait few minutes, then turn it on again.
7	Actual touched position on touch panel does not match displayed touch position The touch screen keys do not function	Touch panel needs adjustment	Contact your Nihon Kohden representative.
8	Date and time incorrect	Setting error	Correctly set the date and time. Data Management and Setting Guide: Section 5 "System Settings"
9	The following message is displayed and the analyzer cannot be operated ---------- 00C08270: Real Time Clock Error - Check Date and Time settings Press F1 Continue or F2 to Enter Setup ----------	Internal backup battery exceeded lifetime (about 5 years)	Contact your Nihon Kohden representative.
10	• WBC distributions extend outside their areas on the scattergram • Frequent WBC flags	• Bubbles in the flow cell unit • Clog in flow cell unit. • Inappropriate sensitivity for the WBC 5 part differential	Clean the flow cell unit. "Cleaning the Flowcell" (p. 9-8) Calibrate with MEK-CAL hematology calibrator. "Performing Calibration" (p. 7-2) If the problem is not solved with the flow cell cleaning and calibration, contact your Nihon Kohden representative.

11 Technical Information

Principle of Operation

Blood Cell Counting

1. Constant current flows between 2 electrodes on both sides of the aperture cap. The electrolytic solution (sample) containing blood cells is aspirated from the aperture caps.
2. The resistance between the electrodes increases when a blood cell passes through the aperture between the electrodes because the DC resistance of the cells is high.
3. When the resistance changes, the amplifier generates a signal of several volts. The peak voltage is proportional to the volume of the blood cell passing through the aperture.
4. The amplified signal is sent to the threshold circuit (discrimination circuit). Here, a constant voltage is applied (threshold level) to eliminate the signals and electrical noise that are generated by non-blood cell material such as dust particles and only signals that exceed the threshold value are passed.
5. To find the peak values, the blood cell signal are sent to the A/D converter. The acquired data is stored in memory for each individual peak value.
6. The data of the blood cell count is calculated and displayed on the screen.



Platelet Measurement

RBC signals and PLT signals are saved in the analyzer memory in the form of voltage peak values.

This information is ultimately organized into a histogram in the analyzer.

There is no problem if the PLT and RBC distributions are clearly separated as in Fig. 1 but the distributions overlap in the case of small red blood cells (Fig. 2) or large platelets (Fig. 3). In these cases, the analyzer automatically moves the threshold level to the lowest distribution position, changes the PLT volume range, and performs a highly accurate PLT count.

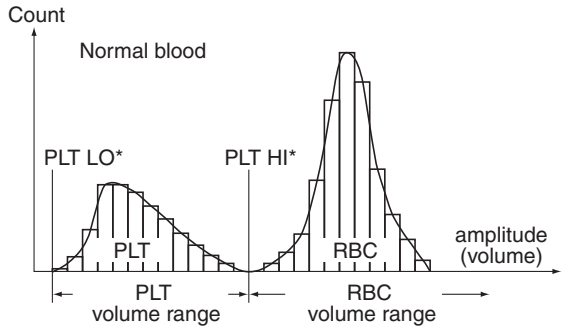


Fig.1

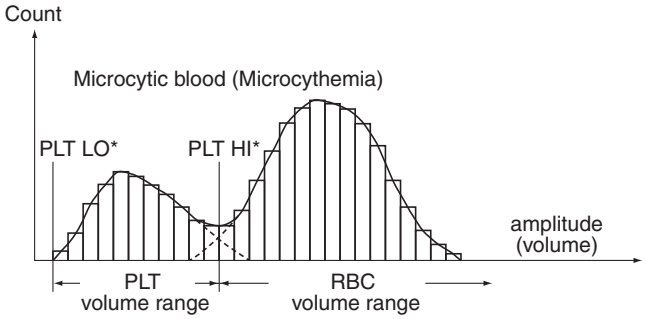


Fig.2

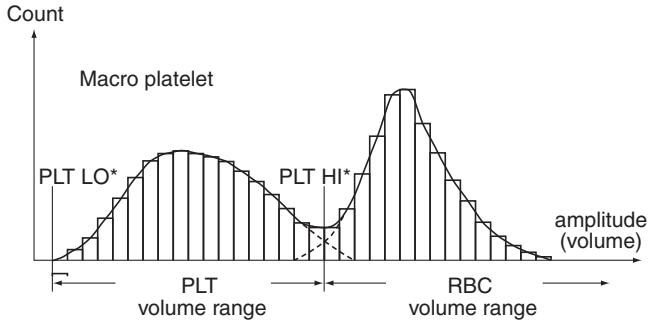


Fig.3

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

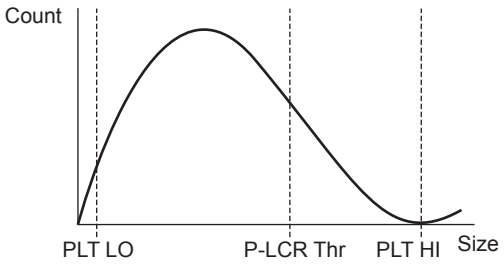
11

P-LCR

P-LCR is the ratio of large platelets larger than P-LCR Thr count to the platelet count.

As shown in the figure below, the ratio of the number of particles between PLT LO and PLT HI (platelet count) to the number of particles between P-LCR Thr and PLT HI (large platelet count) is calculated.

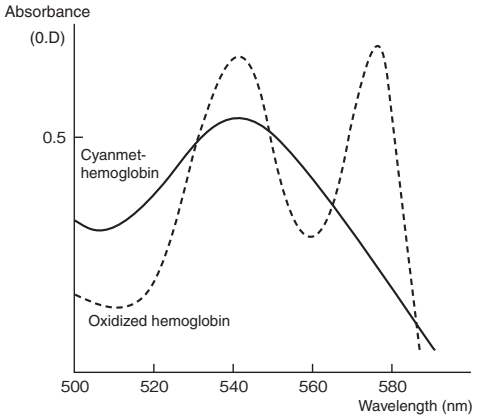
$$\text{P-LCR (\%)} = \frac{\text{Large (P-LCR Thr or more) platelet count}}{\text{Platelet count}} \times 100$$



Hemoglobin Measurement

1. HEMOLYNAC•310 is added to the diluted sample to elute the hemoglobin in the RBC. The eluted hemoglobin reacts with class 4 ammonium salt in the reagent and changes to a hemoglobin compound. The absorbance of the hemoglobin compound is proportional to the hemoglobin concentration so the concentration is determined by measuring the absorbance.
2. The transmittance of light from the LED changes according to the sample in the measurement cell. This light enters the light-receiving element.
3. The light receiving element amplifies the electrical signal corresponding to the light intensity and converts this voltage to a digital value.
4. Measurement of the hemoglobin concentration requires signals of both the diluent and the sample. The sample data is acquired when starting the measurement. The ratio of sample data and diluent data is subjected to logarithmic conversion, multiplied by the coefficient, and displayed on the screen.
5. Samples that are no longer needed are ejected to an direct external device by a pump or a pressure source.
6. 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 with diluent after each measurement.

Hemoglobin absorption characteristics



Principle of WBC Differential

White blood cells in the sample pass through a very thin flow cell one by one, are irradiated with a laser, and the scattered laser light is detected. (Fig. 1)

The strength and direction of the scattered light indicates the volume and complexity of the blood cells (such as the presence or absence of granules or the structure of the nucleus). The lymphocytes, monocytes, neutrophils, eosinophils, and basophils can be classified from the scattergram with 3 parameters: low-angle scattering in the same direction as the laser linear direction ("Size"), large-angle scattering in the same direction as the laser linear direction ("Complexity"), and vertical direction scattering against the laser linear direction ("Granularity"). (Fig. 2)

Size is the size of the blood cells, Complexity is the complexity of the blood cells, and Granularity is the amount of granules in the blood cells.

Fig. 1. White blood cell differential

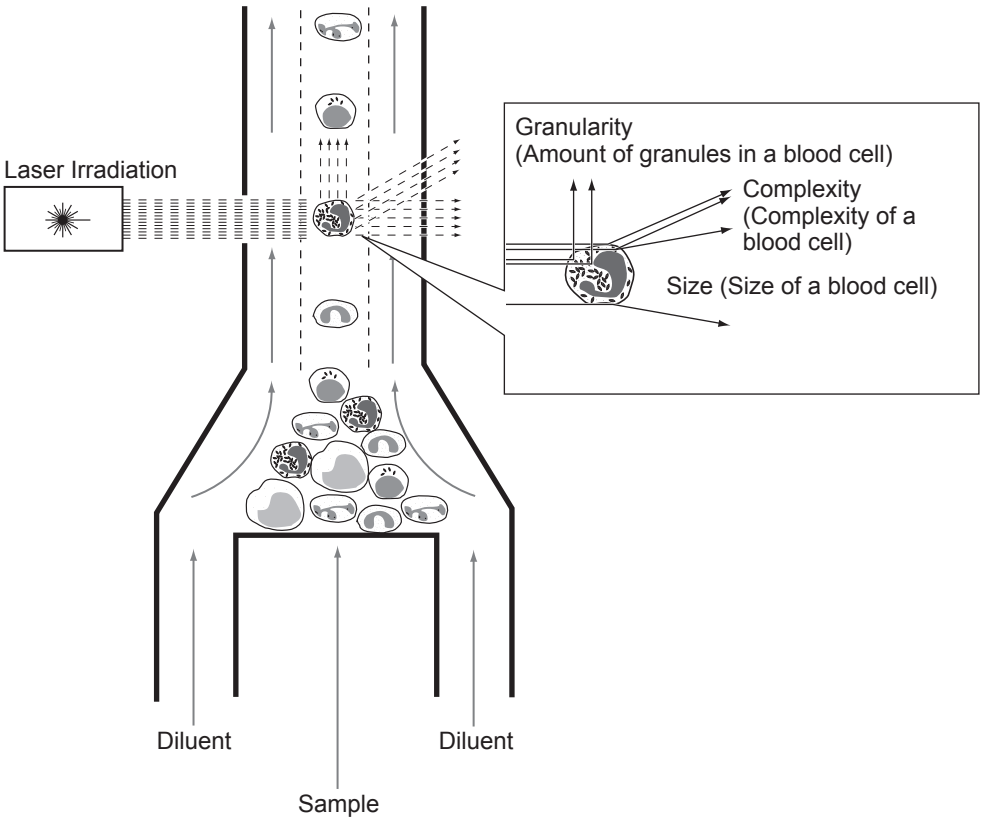
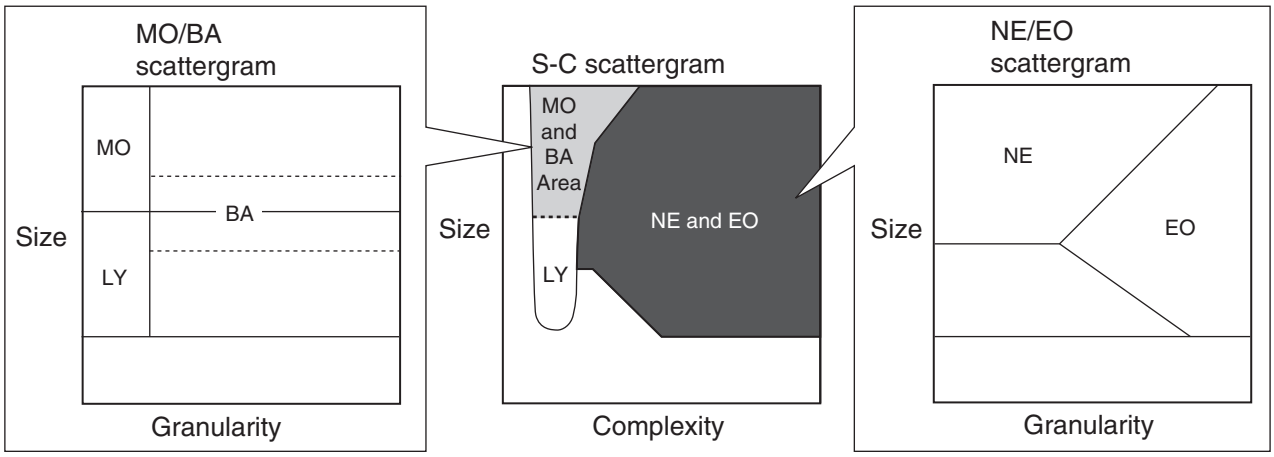


Fig. 2. Scattergram



Name	
NE	Neutrophil Count
LY	Lymphocyte Count
MO	Monocyte Count
EO	Eosinophil Count
BA	Basophil Count

There are scattergrams with Size for the vertical axis and Complexity for the horizontal axis (S-C scattergrams), scattergrams with Size for the vertical axis and monocyte and basophils classifications of Granularity for the horizontal axis (scattergrams for MO/BA classification), and scattergrams with Size for the vertical axis and neutrophil and eosinophil classifications of Granularity for the horizontal axis (scattergrams for NE/EO classification).

Lymphocytes are distributed in the LY area of the S-C scattergram. Monocytes and basophils are distributed in the MO/BA area of the S-C scattergram and when the scattergram for MO/BA classification is expanded, the monocytes are distributed in the MO area and the basophils are distributed in the BA area. Neutrophils and eosinophils are distributed in the NE/EO area of the S-C scattergram. When the scattergram for NE/EO classification is expanded, the neutrophils are distributed in the NE area and the eosinophils are distributed in the EO area.

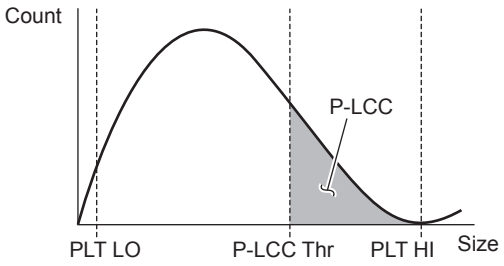
Research Parameters

P-LCC

P-LCC is the number of large platelet cells.

It corresponds to the number of particles between P-LCC Thr and PLT HI.

P-LCC = the number of platelets (P-LCC Thr or more)



Mentzer Index

The Mentzer Index is a parameter related to β-thalassemia and iron deficiency anemia. It is provided for reference purposes.

It is the RBC volume divided by the RBC count.

$$\text{Mentzer Index} = \frac{\text{Red blood cell volume}}{\text{Red blood cell count}}$$

RDWI

RDWI is a parameter related to β-thalassemia and iron deficiency anemia, provided for reference purposes.

It is calculated using the RBC volume, RBC distribution width and RBC count.

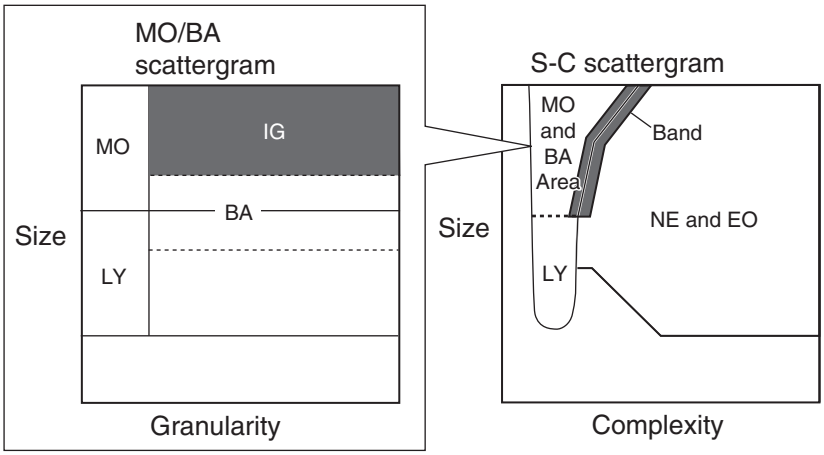
$$\text{RDWI} = \frac{\text{RBC volume} \times \text{RBC distribution width}}{\text{Red blood cell count}}$$

IG, Band, Seg

IG, Band and Seg are parameters related to neutrophils. These are provided for reference purposes.

Name	
IG%	Immature Granulocyte Percent
IG#	Immature Granulocyte Count
Band%	Band Neutrophil Percent
Band#	Band Neutrophil Count
Seg%	Segmented Neutrophil Percent
Seg#	Segmented Neutrophil Count

As shown in the figure below, immature granulocytes are distributed in the IG area of the scattergram for MO/BA classification and band neutrophil are distributed in the Band area of the S-C scattergram.



IG% is calculated from how much the IG area count accounts for in the optical WBC count.

$$IG\% = \frac{\text{IG area count}}{\text{Optical WBC count}}$$

IG# is calculated by the WBC count and the IG%.

IG# = WBC count × IG%

Band% is calculated from how much the Band area count accounts for in the optical WBC count.

$$Band\% = \frac{\text{Band area count}}{\text{Optical WBC count}}$$

Band# is calculated from the WBC count and the Band%.

Band# = WBC count × Band%

Seg% is calculated from the neutrophil ratio and the Band%.

Seg% = NE% − Band%

Seg# is calculated from the neutrophil count and the Band#.

Seg# = NE# − Band#

Interfering Substances

Measuring Parameter and Interfering Substances		Description
WBC	High WBC levels	When WBC is abnormally high and exceeding 100,000/µL, measure the sample in WBC high concentration mode. If the measurement range is exceeded, dilute with diluent and measure again.
	Nucleated erythrocytes	Nucleated erythrocytes are detected as white blood cells and this causes a falsely high WBC count.
	Poor Hemolyzation	On some rare occasions, the red blood cells in the blood sample might not completely lyse. These non-lysed RBC may be detected as WBC and cause increase in WBC count.
	Leukemia	White blood cells may be fragile in leukemia patients and may be destroyed during measurement and this may cause a falsely low WBC count and WBC differential cannot be accurately determined.
	Chemotherapy	White blood cells become fragile due to anti-cancer agents and immunosuppressive agents and may be destroyed during measurement and the WBC count may become a falsely low value and WBC differential cannot be accurately determined.
	Cryoglobulins	Cryoglobulins may increase and cause falsely high values of WBC, RBC, platelets, and hemoglobin. Increase of cryoglobulins is caused by myeloma, cancer, leukemia, macroglobulinemia, lymphoproliferative disorders, metastatic tumors, autoimmune abnormalities, infection, aneurysm, pregnancy, blood clots, diabetes and other conditions. 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 white blood cells in leukemia patients causes an increase in red blood cells. If the WBC count is more than 50,000/µL, correct the number of RBC by subtracting the number of WBC.
	Hemagglutination	If hemagglutination is observed, the RBC count becomes falsely low and MCV becomes falsely high. In such cases, you will notice because the values of MCH and MCHC become abnormal. In such samples, when you observe the tube wall while gently tilting the sample tube, the blood appears to be a rough texture. Hemagglutination can also be confirmed by observing a blood smear.
	Cold agglutinins	If cold agglutination of blood cells is observed, the RBC count becomes falsely low and MCV becomes falsely high. 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. When the cold agglutination value is significantly high, blood appears to clot in the blood smear.
	Hemolysis	When a sample is hemolyzed, RBC becomes falsely low.
HGB	Turbidity of the blood sample	Any physiologic or therapeutic factors may increase HGB concentration.. In such a case, determine the cause of turbidity and take the appropriate action described below. Hemoglobin concentration affects the MCH and MCHC. Therefore, MCH and MCHC values become abnormal. Increased lipids • The plasma of blood with increased lipids is cloudy. This is caused by increased protein and increased lipids. Accurate HGB measurement can be achieved by using a plasma blank. Increased turbidity • When the sample is poor hemolyzation or hyperbilirubinemia, turbidity may increase and cause increase in HGB. Accurate HGB measurement can be achieved by using a plasma blank. High WBC levels • Turbidity of blood increases and the hemoglobin concentration value becomes falsely high if WBC level of the blood sample is abnormally high. Centrifuge the diluted sample and measure the supernatant fluid with a spectrophotometer.
HCT	Hemagglutination	RBC agglutination may cause false HCT and MCV values. This can be checked by abnormal MCH and MCHC values and examination of the blood smear. In this case, measure by centrifugation.
MCV	Excessive number of large PLT	An excessive number of large PLT or excessively high WBC may affect the MCV value. A blood smear observation is required.

Measuring Parameter and Interfering Substances		Description
MCH	Hemoglobin Concentration and RBC count abnormalities	MCH is determined from HGB and RBC values Therefore the limitations for HGB and RBC also affect MCH value.
MCHC	Hemoglobin Concentration and Hematocrit abnormalities	MCHC is determined from HGB and HCT values. Therefore, the limitations for HGB and HCT also affect MCHC value.
PLT	Very small fragments	Fragments of small red blood cells, red blood cells, and white blood cells are counted as platelets, and this may cause a falsely high platelet count.
	Excessive number of large PLT	For Bernard-Soulier syndrome, which is a congenital platelet function disorder, platelets of the same size as RBC will appear. If these large platelets cause PLT to exceed the high threshold of the PLT histogram, the PLT count will be falsely low.
	Hemolysis	Hemolyzed samples contain red cell stroma which may increase PLT count.
	Anticoagulated blood	If blood contains anticoagulant other than EDTA (ethylenediaminetetraacetate), PLT agglutination may cause the PLT count to become falsely low.
	PLT Clumps	The agglutinated PLT count value becomes falsely low, and the WBC count value becomes falsely high. For these samples, use a different anticoagulant such as sodium citrate anticoagulant to re-collect the sample then remeasure the PLT only.
MPV	Very small fragments	Very small RBC, RBC, and WBC fragments may interfere with MPV measurement.
	Excessive number of large PLT	If large PLT exceeds the high threshold of the PLT histogram, the MPV count will be falsely low.
	Hemolysis	Hemolyzed samples contain red cell stroma which may interfere with MPV measurement.
	Anticoagulated blood	If blood contains anticoagulant other than EDTA (ethylenediaminetetraacetate), PLT agglutination occurs, potentially causing interference with the MPV measurement.
	PLT Clumps	Samples with agglutinated PLT may interfere with MPV measurement. WBC differential values are derived from the number of WBC. The WBC count will affect the differential of these values.
LY LY%	NRBC, some type of parasite, Hemolysing reagent resistant red blood cells	NRBC, certain parasites, and RBC that are resistant to lysis may interfere with an accurate LY count.
MO MO%	Large lymphocyte, atypical lymphocytes, blasts, excessive number of basocytes	Large lymphocytes, atypical lymphocytes, blasts, and excessive number of basophils may interfere with an accurate MO count.
NE NE%	A large number of eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts, plasmacyte	Excessive eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts may interfere with an accurate NE count.
EO EO%	Abnormal granules	Abnormal granules may interfere with an accurate EO count.
BA BA%	Juvenile cell, metamyelocyte, myelocytes, promyelocytes, blasts, plasmacyte	Immature cell, metamyelocytes, myelocytes, promyelocytes, blasts, and plasma cells may interfere with an accurate BA count and BA%.

Reference Method

WBC

ICSH 1988

The assignment of values to fresh blood used for calibrating automated blood cell counters. Clin Lab Hematol. 1988;10:203-212

RBC

ICSH 1988

The assignment of values to fresh blood used for calibrating automated blood cell counters. Clin Lab Hematol. 1988;10:203-212

HGB

CLSI H15-A3 Vol.20 No.28;

Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition, 2000

HCT

CLSI H07-A3 Vol.20 No.18;

Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard - Third Edition, 2000

PLT

ICSH/ISLH 2001:

International Council for Standardization in Hematology Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting. Platelet counting by RBC/platelet ratio method. A reference method. Am Journal of Clinical Pathology 115:460-464 2001

WBC Differential

CLSI H20-A2:Vol.27 No.4;

Reference Leukocyte (WBC) Differential Count (proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition, 2007

CLSI H26-A2:Vol.29 No.40;

Validation,Verification,and Quality Assurance of Automated Hematology Analyzers; Approved Standard - Second Edition, 2010

Specifications

Function and Performance

Measured Parameters

- Blood cell count (WBC, RBC, PLT): Electrical resistance detection
- Hemoglobin concentration (HGB): Colorimetric method (surfactant method)
- Hematocrit (HCT): Peak integration method using blood cell pulses (calculated from RBC histogram)
- RBC distribution width (MCV, MCH, MCHC): Calculated from RBC, HGB and HCT
- WBC blood cell differential (NE%, LY%, MO%, EO%, BA%, NE, LY, MO, EO, BA): Calculated from scattergram
- Platelet crit (PCT): Peak integration method using blood cell pulses (calculated from PLT histogram)
- Mean platelet volume (MPV): Calculated from PLT and PCT
- RBC distribution width (RDW-CV, RDW-SD): Calculated from RBC histogram
- Platelet distribution width (PDW): Calculated from PLT histogram
- Platelet large cell ratio (P-LCR): Calculated from PLT histogram

Measuring Range (Display Range)

Measured Parameters	Name	Measuring Range (Display Range)
White Blood Cell Count	WBC	0.0 to 999×10^2/μL 0.0 to 2999×10^2/μL (high concentration mode)
Neutrophil percent	NE%	0.00 to 100%
Lymphocyte Percent	LY%	
Monocyte Percent	MO%	
Eosinophil Percent	EO%	
Basophil Percent	BA%	
Neutrophil Count	NE	0.0 to 999×10^2/μL 0.0 to 2999×10^2/μL (high concentration mode)
Lymphocyte Count	LY	
Monocyte Count	MO	
Eosinophil Count	EO	
Basophil Count	BA	
Red Blood Cell Count	RBC	0 to 999×10^4/μL
Hemoglobin Concentration	HGB	0.00 to 29.9 g/dL
Hematocrit	HCT	0.0 to 99.9%
Mean Corpuscular Volume	MCV	20.0 to 199 fL
Mean Corpuscular Hemoglobin	MCH	10.0 to 50.0 pg
Mean Corpuscular Hemoglobin Concentration	MCHC	10.0 to 50.0 g/dL

Measured Parameters	Name	Measuring Range (Display Range)
Red Blood Cell Distribution Width in Coefficient of Variation	RDW-CV	0.0 to 50.0%
Red Blood Cell Distribution Width in Standard Deviation	RDW-SD	0.0 to 199 fL
Platelet Count	PLT	0.00 to 149×10^4/µL
Platelet Crit	PCT	0.00 to 2.99%
Mean Platelet Volume	MPV	2.0 to 20.0 fL
Platelet Distribution Width	PDW	0.0 to 50.0%
Platelet Large Cell Ratio	P-LCR	0.0 to 100%

Precision (Reproducibility)

- Normal mode (difference from CV or mean value)

  WBC: 2.0% or less (WBC: 40.0 × 10^2/µL or more)
  RBC: 1.5% or less (RBC: 400 × 10^4/µL or more)
  HGB: 1.5% or less
  HCT: 1.5% or less
  MCV: 1.0% or less
  MCH: 2.0% or less
  MCHC: 2.0% or less
  RDW-CV: 3.0% or less
  RDW-SD: 3.0% or less
  PLT: 4.0% or less (PLT : 10.0 × 10^4/µL or more)
  PCT: 6.0% or less
  MPV: 4.0% or less
  PDW: 10.0% or less
  P-LCR: 18.0% or less
  NE%: 5.0% or less (NE%: 30.0% or more AND WBC: 40.0 × 10^2/µL or more)
  LY%: 5.0% or less (LY%: 15.0% or more AND WBC: 40.0 × 10^2/µL or more)
  MO%: 12.0% or less (MO%: 5.0% or more AND WBC: 40.0 × 10^2/µL or more)
  EO%: 20.0% or less OR within ±1.0 Eo% (WBC: 40.0 × 10^2/µL or more)
  BA%: 30.0% or less OR within ±1.0 Ba% (WBC: 40.0 × 10^2/µL or more)
  NE: 8.0% or less (NE: 12.0 × 10^2/µL or more)
  LY: 8.0% or less (LY: 6.0 × 10^2/µL or more)
  MO: 20.0% or less (MO: 2.0 × 10^2/µL or more)
  EO: 25.0% or less OR within ±1.0 × 10^2/µL (WBC: 40.0 × 10^2/µL or more)
  BA: 30.0% or less OR within ±1.0 × 10^2/µL (WBC: 40.0 × 10^2/µL or more)

- Pre-dilution mode (CV)

  WBC: 6.0% or less (WBC: 40.0 × 10^2/µL or more)
  RBC: 4.5% or less (RBC: 400 × 10^4/µL or more)
  HGB: 4.5% or less
  HCT: 4.5% or less
  MCV: 4.5% or less
  MCH: 4.5% or less
  MCHC: 4.5% or less
  PLT: 12.0% or less (PLT: 10.0 × 10^4/µL or more)

Linearity

- WBC: within ±3.0% OR ±3 × 10^2/µL (WBC: 2.0 to 999 × 10^2/µL)
- RBC: within ±3.0% OR ±8 × 10^4/µL (RBC: 2 to 800 × 10^4/µL)
- HGB: within ±1.5% OR ±0.2 g/dL (HGB: 0.10 to 25.0 g/dL)
- HCT: within ± 3.0% OR ±1.0% (HCT: 20.0 to 60.0%)
- PLT: within ±10.0% OR ±2.0 × 10^4/µL (PLT: 1.00 to 149 × 10^4/µL)

(Specifications above applies to the normal mode)

Background Noise

- WBC: 2.0 × 10^2/µL or less
- RBC: 2 × 10^4/µL or less
- HGB: 0.1 g/dL or less
- PLT: 1.00 × 10^4/µL or less
- TOC: 100 count or less

(The background noise of the flow cytometry measurement system is evaluated with Total Optical Count (TOC))

Carryover

- WBC: 1.0% or less
- RBC: 1.0% or less
- HGB: 1.0% or less
- PLT: 1.0% or less
- TOC: 1.0% or less

(The carryover of the flow cytometry measurement system is evaluated with the TOC)

Counting Time

- Auto measurement: 90 samples/hr (40 s/sample)
- Manual measurement : 90 s/sample

Sample Volume

- Normal mode (CBC+DIFF): 40 µL
- Normal mode (CBC): 25 µL
- Pre-dilution mode: 20 µL

Laser

Class 1 (built-in laser class: Class 3B)

Applicable Directives and Standards

Applicable Directives

- IVD directive
- WEEE directive
- RoHS directive

Safety Standards

- IEC 60825-1:2014
- IEC 61010-1:2001
- IEC 61010-2-101:2002
- IEC 61010-2-081:2001 + Amendment 1:2003
- IEC 61326-1:2005
- IEC 61326-2-6:2005
- CISPR 11:2003 Group 1 Class B
- EN 55011:2002 Group 1 Class B
- EN 60825-1:2014
- EN 61010-1:2001
- EN 61010-2-101:2002
- EN 61010-2-081:2001 + Amendment 1:2003
- EN 61326-1:2006
- EN 61326-2-6:2006

Classification

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 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

ME EQUIPMENT type:

STATIONARY type

Environment

Storage Environment

- Temperature: –20 to +60°C (–4 to +140°F)
- Humidity: 10 to 95% (noncondensing)
- Atmospheric pressure: 700 to 1060 hPa

Transport Environment

- Temperature: –20 to +60°C (–4 to +140°F)
- Humidity: 10 to 95% (noncondensing)
- Atmospheric pressure: 700 to 1060 hPa

Operating Environment and Power

Operating environment

- Temperature: 15 to 30°C (59 to 86°F)
- Humidity: 30 to 85%
- Atmospheric pressure: 700 to 1060 hPa

Power Requirements

AC only

- Line voltage: AC 100 to 240 V
- Allowable fluctuation range: ±10%
- AC type: Switching regulator
- Power input: 330 VA
- Line frequency: 50 to 60 Hz
- Allowable fluctuation range: ±5%
- Safety standards for power supply unit: IEC 61010-2-101:2002, IEC 61010-2-081:2001

Noise

IEC 61010-1:2001

Cooling System

Natural cooling

EMC Standards

- CISPR 11:2003 Group 1 Class B
- IEC 61326-1:2005
- IEC 61326-2-6:2005
- EN 55011:2002 Group 1 Class B
- EN 61326-1:2006
- EN 61326-2-6:2006

Dimensions and Weight

- Dimensions: 675 W × 589 D × 576 H (mm) ±10%
  (Main unit only, excluding protruding parts)
- Weight: 66 kg ±10%

Options and Consumables

Standard Accessories

⚠ CAUTION

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

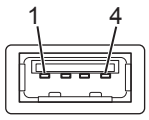
Name and Model		Qty	Supply Code
Power cord W		1	–
Ground lead D		1	–
6.3 A time-lag fuse		2	–
ISOTONAC tube assy		1	–
CLEANAC tube assy		1	–
HEMOLYNAC•310 tube assy		1	–
HEMOLYNAC•510 tube assy		1	–
Waste tube assy		1	–
Waste container (Selectable option, 10 or 20 L)	10 L	1	T417B
	20 L	1	T417C
Open loader adapters set	For samples	1	–
	For micro tubes	1	–
	For mini collects	1	–
	For detergent	1	–
Overflow tray		1	–
Rack		1 set	–
Partition plate		1	–
Maintenance brush		1	T603A
ZK-910W barcode reader		1	–
Stopper plate		1	–

Options

Name and Model	Qty	Supply Code
WA-714W impact printer (Seiko Epson VP-500, LQ-310 or equivalent)	1	–
WA-461V card printer	1	–
JW-910W waste sensor	1	–
Extra sample racks	8	T411A
Serial DB9-DB9 crossover cable	1	–
LAN cable, 2.0 m	1	–
USB cable, 2.0 m	1	–
QS-023W software kit	1	–

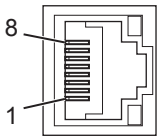
Socket Pin Assignment

USB Socket (Barcode Reader and Printer)



No.	Signal
1	VBus
2	–Data (D–)
3	+Data (D+)
4	GND

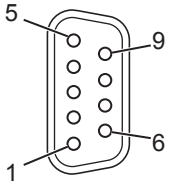
LAN Socket



No.	Signal
1	TD+
2	TD–
3	RD+
4	NC

No.	Signal
5	NC
6	RD–
7	NC
8	NC

Serial Port



No.	Signal
1	NC
2	RxD
3	TxD
4	DTR
5	GND (SG)

No.	Signal
6	DSR
7	RTS
8	CTS
9	NC

Manufacturer
NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai, Shinjuku-ku Tokyo 161-8560, Japan
Phone +81 3-5996-8036
Fax +81 3-5996-8100

North and South America

NIHON KOHDEN AMERICA, INC.
15353 Barranca Parkway, Irvine, CA 92618, U.S.A.
Toll-free +1-800-325-0283
Phone +1 949-580-1555
Fax +1 949-580-1550

NIHON KOHDEN LATIN AMERICA S.A.S
Carrera 16 No.93A-36 Of. 802. Bogota D.C., Colombia
Phone +57 1-300-1742
Fax +57 1-300-1825

NIHON KOHDEN DO BRASIL LTDA.
Rua Diadema, 89, 1º andar, conjuntos 11 a 17, bairro Mauá
no Município de São Caetano do Sul, Estado de São Paulo
CEP 09580-670, Brasil
Phone +55 11-3044-1700
Fax +55 11-3044-0463

Europe

EC REP European Representative
NIHON KOHDEN EUROPE GmbH
Raiffeisenstrasse 10, D-61191 Rosbach, Germany
Phone +49 6003-827-0
Fax +49 6003-827-599

NIHON KOHDEN DEUTSCHLAND GmbH
Raiffeisenstrasse 10, D-61191 Rosbach, Germany
Phone +49 6003-827-0
Fax +49 6003-827-599

NIHON KOHDEN FRANCE SARL
8, rue Francois Delage, 94 230 Cachan, France
Phone +33 1-49-08-05-50
Fax +33 1-49-08-93-32

NIHON KOHDEN IBERICA S.L.
C/Ulises 75A, E-28043 Madrid, Spain
Phone +34 91-7-161080
Fax +34 91-3-004676

NIHON KOHDEN ITALIA S.r.l.
Via Fratelli Bronzetti 28, 24124 Bergamo, Italy
Phone +39 035-219543
Fax +39 035-232546

NIHON KOHDEN UK LTD
Trident Court 118, 1 Oakcroft Road
Chessington, Surrey KT9 1BD, UK
Phone +44 20-8391-6800
Fax +44 20-8391-6809

Asia

SHANGHAI KOHDEN
MEDICAL ELECTRONIC INSTRUMENT CORP.
567 Huancheng Bei Road
Shanghai Comprehensive Industrial Development Zone
Shanghai 201401, China
Phone +86 21-5743-6998
Fax +86 21-5743-6939

NIHON KOHDEN SINGAPORE PTE LTD
1 Maritime Square, #10-34 HarbourFront Centre
Singapore 099253
Phone +65 6376-2210
Fax +65 6376-2264

NIHON KOHDEN INDIA PVT. LTD.
308, Tower A, Spazedge, Sector 47, Sohna Road
Gurgaon-122 002 Haryana, India
Toll-free +91 1800-103-8182
Phone +91 124-493-1000
Fax +91 124-493-1029

NIHON KOHDEN MIDDLE EAST FZE
JAFZA One Tower A, 19th floor, Office No. 1912
P.O. Box 261516, Jebel Ali Free Zone, Dubai, U.A.E
Phone +971 4-884-0080
Fax +971 4-880-0122

NIHON KOHDEN KOREA, INC.
5F Miso Bldg.
890-47 Daechi-dong, Gangnam-gu, Seoul, 135-280 Korea
Phone +82 2-3273-2310
Fax +82 2-3273-2352

Contact information is accurate as of January 2016. Visit www.nihonkohden.com for the latest information.

The model and serial number of your instrument are identified on the rear or bottom of the unit.
Write the model and serial number in the spaces provided below. Whenever you call your representative concerning this instrument, mention these two pieces of information for quick and accurate service.

Model _____ Serial Number _____

Your Representative

MEK-9100_0614-907468B