Automated Hematology Analyzer

XE-5000

Instructions for Use

Sysmex Corporation

KOBE, JAPAN

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1. Introduction

The Sysmex XE-5000 is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories.
The XE-5000 can analyze and output the results for 67 parameters.
WBCs, nucleated RBCs and reticulocytes are analyzed by the optical detector block based on the fluorescence flow cytometry method using semiconductor laser.
RBCs and platelet count are analyzed by the RBC detector using the Hydro Dynamic Focusing method based on the fluorescence flow cytometry method.
Hemoglobin (HGB) is analyzed by the HGB detector based on the SLS hemoglobin determination method.
The existence of immature cells are analyzed by the IMI detector based on the RF/DC detection method and the DIFF channel using fluorescence flow cytometry.
Analysis data is displayed on the panel keypad LCD screen and the screen of the Information Processing Unit (IPU).

Note:
Data generated by the XE-5000 is not intended to replace professional judgment in the determination of a diagnosis or in monitoring patient therapy.

Note:
Operate the instrument as instructed. Reliability of test results cannot be guaranteed if there are any deviations from the instructions in this manual. If the instrument fails to function properly as a result of either the user's operation not specified in the manual or the user's utilization of a program not specified by Sysmex, the product warranty would not apply.

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Contact Address

Manufacturer

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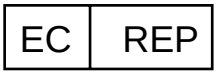
JAPAN

Authorized Representative



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Ordering of Supplies and Replacement Parts

If you need to order supplies or replacement parts, please contact your local Sysmex representative.

Service and Maintenance

Please contact the Service Department of local Sysmex representative.

CE-mark

The IVD-system described in this manual is marked with a CE-mark which confirms the observance of the essential requirements of the following European directive:

98/79/EC IVD Directive

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1.1 Hazard information in this manual

Note, Information, Caution and Warning statements are presented throughout this manual to call attention to important safety and operational information. Non-compliance with this information compromises the safety features incorporated in the analyzer.

Risk of infection

This symbol indicates a possible hazardous situation which, if not avoided, may result in infection by pathogens and others.

Warning!

High risk. Ignoring this warning could result in personal injury to the operator.

Caution, Hot!

Indicates a potential risk of burns or other physical damage in the event of incorrect operation or failure to observe the content.

Caution!

Ignoring this warning could result in property damage or incorrect results. To avoid damage and incorrect measuring results, this caution must be followed.

Information

Minor risk. Considerations that should be observed when operating this instrument.

Caution!

Indicates a potential risk of physical damage to functions of the instrument caused by static electricity discharge of the human body, in the event of incorrect operation or failure to observe the content.

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Note:
Background information and practical tips.

1.2 Protected names

- Sysmex is a registered trademark of SYSMEX CORPORATION.
- STROMATOLYSER, CELLPACK, SULFOLYSER, RET SEARCH and CELLCLEAN are registered trademarks of SYSMEX CORPORATION.
- CELLSHEATH is a trademark of Sysmex.
- SMI and SMI Micro/Pettor are registered trademarks of Scientific Manufacturing Industries, Inc.
- VENOJECT and VENOJECT II are registered trademarks of TERUMO Corporation.
- Windows is a registered trademark of Microsoft Corporation.

Other trademarks referenced are property of their respective owners.
TM and ® are not specified in this manual.

1.3 Measurement parameters

The XE-5000 can analyze the following 67 parameters:

37 Diagnostic Parameters

1 WBC
2 RBC
3 HGB
4 HCT
5 MCV
6 MCH
7 MCHC
8 PLT
9 RDW-SD
10 RDW-CV
11 PDW
12 MPV
13 P-LCR
14 PCT
15 NEUT%
16 LYMPH%
17 MONO%
18 EO%
19 BASO%
20 NEUT#

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21 LYMPH#
22 MONO#
23 EO#
24 BASO#
25 IG% Immature Granulocyte Percent
26 IG# Immature Granulocyte Count
27 HPC# Hematopoietic Progenitor Cell Count
28 NRBC%
29 NRBC#

Note:
XE-5000 automatically analyzes NRBC if an analysis order is assigned to any of the WBC 5 differential counts or percent data.

30 RET%
31 RET#
32 HFR
33 MFR
34 LFR
35 IRF Immature Reticulocyte Fraction
36 RET-He Reticulocyte Hemoglobin Equivalent
37 IPF Immature PLT fraction

6 Body Fluid Mode Parameters
1 WBC-BF WBC body fluid
2 MN% Mononuclear cell percent
3 MN# Mononuclear cell count
4 PMN% Polymorphonuclear cell percent
5 PMN# Polymorphonuclear cell count
6 RBC-BF RBC body fluid

24 Pre-Diluted Mode Parameters
1 WBC
2 RBC
3 HGB
4 HCT
5 MCV
6 MCH
7 MCHC
8 PLT
9 NEUT%
10 LYMPH%
11 MONO%
12 EO%
13 BASO%
14 NEUT#
15 LYMPH#
16 MONO#
17 EO#

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18	**BASO#**	
19	**IG%**	Immature Granulocyte Percent
20	**IG#**	Immature Granulocyte Count
21	**NRBC%**	
22	**NRBC#**	
23	**RET%**	
24	**RET#**	

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2. Safety Information

2.1 Specified conditions of use

The Sysmex XE-5000 is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories. Only human blood, human body fluids or control blood should be run. Any other use is regarded as non-specified.
Use only the reagents and rinse solutions mentioned in this manual.
The specified conditions of use also entail the observance of the cleaning and maintenance procedures described in these instructions.

2.2 General information

Before operating this instrument, carefully read this manual, and strictly follow its instructions.
Keep this manual for future reference after reading.

Warning!

- Unpacking, installation, and confirmation of initial operation must be done by Sysmex technical representative.
- Keep your fingers, clothes and hair etc. away from the instrument while it is in operation. There is a risk of injury from becoming tangled or trapped in the machinery.
- If the instrument emits an abnormal odor or smoke, turn off the power switch immediately and disconnect the power cord from the Main Unit. If the instrument is used continuously in this condition, fire, electrical shock or injury may result. Contact promptly your Sysmex technical representative.
- Take care not to spill any fluids, or drop wire staples or paper clips into the instrument. This might cause a short circuit resulting in smoke emission. If such an incident occurs, turn off the power switch immediately and disconnect the power cord from the Main Unit. Contact your Sysmex technical representative.
- Do not remove the outer cover while the instrument is in use. There is a risk of electrical shock or instrument failure.
- Do not touch the electrical circuits inside the cover, particularly if your hands are wet. Electrical shock may result.

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Warning!
- Never put the power plug in any socket other than the specified voltage. When installing the instrument, be sure to ground it. Otherwise, fire or electrical shock may result.
- Take care not to damage the power cord, not to place a heavy device on it and not to pull it forcibly. Otherwise, the wire may break causing fire or electrical shock.
- When connecting the instrument to a peripheral (host computers and printer etc.), be sure to turn off the power switch beforehand. Otherwise, electrical shock or instrument failure may result.

2.3 Installation

Caution!
- Install the instrument in a place which is not subject to water splash.
- Install the instrument in a place which is not subject to adverse effects of high temperature, high humidity, dust, direct sunlight, etc.
- Do not give the instrument a strong vibration or impact.
- Install in a well-ventilated area.
- Do not install near devices that cause signal noise, such as radios and centrifugal machines.
- Do not install the instrument near a chemical storage or a place where a gas is generated.
- Do not use this instrument in any operating environment which has electro-conductive or flammable gases, including oxygen, hydrogen and anesthetic.
- This instrument was designed for indoor use only.

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2.4 Electromagnetic compatibility (EMC)

This instrument complies with the following IEC (EN) standards.

- IEC61326-2-6:2005 (EN61326-2-6:2006)
- EMI (Electromagnetic Interference)
  For this standard the requirements of class A are fulfilled.
- EMS (Electromagnetic Susceptibility)
  For this standard the minimum requirements with regards to immunity are fulfilled.

2.5 Avoidance of infection

Risk of infection

- In principle, all parts and surfaces of the instrument must be regarded as infective.
- Never touch waste or parts having been in contact with waste, with bare hands.
- Should you inadvertently come in contact with potentially infective materials or surfaces, immediately rinse skin thoroughly with water, then follow your laboratory's prescribed cleaning and decontamination procedures.
- Be careful when handling samples and control blood. Use of personal protective equipment is strongly recommended when operating, maintaining, servicing or repairing the instrument.
- If patient samples of control material contact your eyes, wash the area with plenty of water and immediately contact a physician.
- Be careful when handling waste. If you get it on your skin or clothes, wash with disinfectant.

Revised January 2010

2.6 Handling of reagents

Warning!

- Do not directly touch reagents. Reagents can cause irritation of the eyes, skin and mucous membranes.
- Should you inadvertently come in contact with reagent, immediately rinse skin thoroughly with water.
- If a reagent should get in your eyes, immediately rinse thoroughly with water and see a physician immediately.
- If reagent is accidentally swallowed, follow recommendations on Material Safety Dade Sheets (MSDS) and see a physician immediately.
- CELLPACK diluent is electrically conductive. If diluent is spilled inadvertently near electrical cables or appliances, there is a risk of electrical shock. Switch the instrument off, unplug it and remove the liquid.
- CELLCLEAN is a strong alkaline detergent. It should not come in contact with skin or clothing. If it happens nevertheless, rinse skin or clothing with plenty of water to avoid injury or damage.
- CELLCLEAN contains sodium hypochlorite. If CELLCLEAN comes in contact with the instrument's surfaces, there may be a possibility of corrosion. Immediately wipe up CELLCLEAN with a damp cloth.
- Make sure the reagents used with the instruments are kept level or below the Main Unit of the instrument. Do not put reagents on top of the instrument.

Caution!

- Follow directions on reagent containers.
- Avoid letting reagents come in contact with dust, dirt or bacteria especially when installing new cubes.
- Reagents must not be used after their expiration date.
- Handle reagents gently to avoid bubbling. Never shake reagents. Do not use reagents immediately after moving them.
- Take care not to spill reagents. If a reagent is spilled, wipe up with a damp cloth.

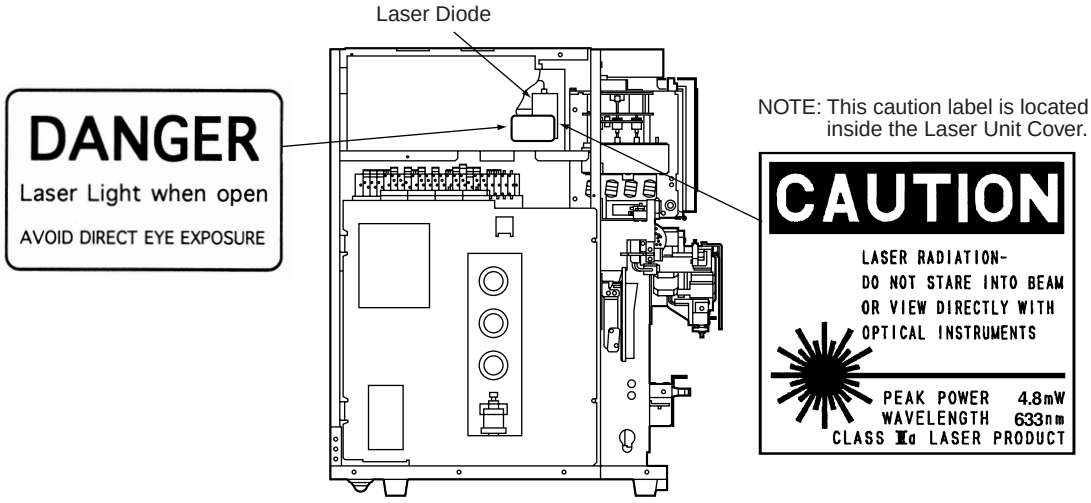
Revised July 2007

2.7 Quality control materials

Caution!
- Do not inject or ingest.
- Follow directions on control material package insert.
- Avoid letting the control material come in contact with dust, dirt or bacteria.
- Control material must not be used after their expiration date.
- Take care not to spill control material. If spilled, follow your laboratory's prescribed cleaning and decontamination procedures.

2.8 Laser

Warning!
The XE-5000 contains the semiconductor laser unit. This semiconductor laser unit is shielded with the shield box cover, and is provided with an interlock system that prevents laser from oscillation if the cover is removed. Do not open this cover. Otherwise, the laser beam can damage your eyes.



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2.9 Maintaining the instrument

Risk of infection

Always wear protective clothing, gloves and eyeglasses when performing maintenance or inspection to prevent contact with blood contaminated parts. Wash your hands thoroughly following maintenance.

Information

When performing maintenance, use only the tools specially provided for such work. All cleaning and maintenance procedures as described in this manual must be observed for optimal performance.

2.10 Disposal of waste fluids, disposables and instruments

Risk of infection

Use of gloves is strongly recommended when handling waste fluids or instrument consumables. Wash your hands thoroughly following maintenance.

Warning!

Waste fluids, instrument consumables and other waste materials must be disposed of appropriately in accordance with local laws, with due consideration of medical, infectious and industrial wastes.

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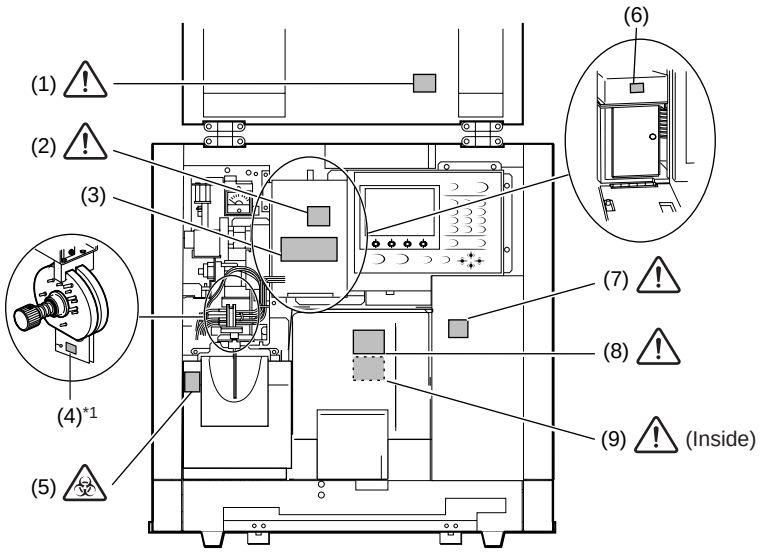
2.11 Marking on the instrument

Main Unit - Front View



(1)

WARNING

Be sure to set the stop bar when opening to avoid injury.

(2)

WARNING

Never touch the detector when the power of the Main Unit is turned ON. Otherwise, electrical shock may result.

(3)

CAUTION

1. Dye solution replacement method
   - For SNR, always replace dye solution and lyse reagent simultaneously.
   - For RED, always replace dye solution and diluent simultaneously.
   - For FFS, the message “Replace FFS” is displayed after the analysis of 2000 cycles. When doing so, always press Reagent or Confirm after replacing with new FFS.
2. When the message “Execute Rinse Flowcell” is displayed, always perform Maintenance – 4. Rinse Flowcell.
3. To clean the IMI detector aperture, first run Maintenance – 1. Drain IMI, then turn off the main unit power.

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(4)

CAUTION

When installing this instrument, remove the constant-pressure screw, then take out the anti-sticking spacers which are inserted between the sample rotor valves. At that stage, rinse the surface of each valve cleanly before setting them in place.
The fluid channel inside the instruments are rinsed with diluent before shipping from the factory. Background count may be high immediately after unpacking, so rinse thoroughly.

*1: After installing, remove the anti-sticking spacers.

(5) 

RISK OF INFECTION

In principle, all parts and surfaces of the instrument must be regarded as infective.

(6)

Always keep the switch in the analysis position.

(7) 

WARNING

Never touch the detector when the power of the Main Unit is turned ON. Otherwise, electrical shock may result.

(8) 

WARNING

Do not remove this cover when the power to the Main Unit is ON. Doing so may result in injury.

(9) 

WARNING

Do not put your fingers inside when the power to the Main Unit is ON. Doing so may result in injury.

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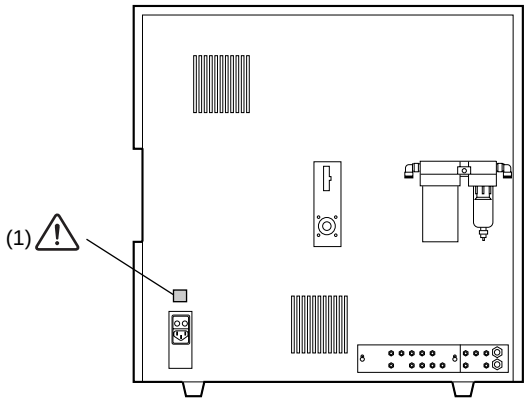
Main Unit - Rear View



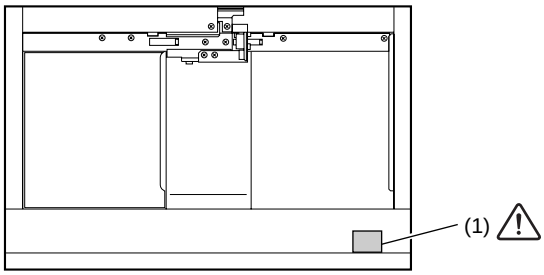
(1)

CAUTION

- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

Fuse Rating
3.15A 250V
Time Lag

Sampler



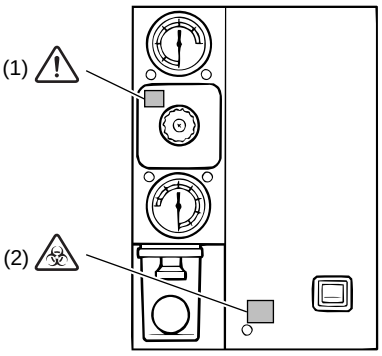
(1)

Do not push in the rack by hand.
There is a small risk that such handling could cause a mismatch between sample numbers and analysis results.

Precautions on setting the sampler

1. Check that the sample tubes fit smoothly into the rack.
2. Check that the rubber stoppers are firmly capped on the sample tube.
3. Insert the sample tube securely all the way to the bottom of the rack.

Pneumatic Unit - Front View



(1)

0.25 MPa regulator

(2)

RISK OF INFECTION
In principle, all parts and surfaces of the instrument must be regarded as infective.

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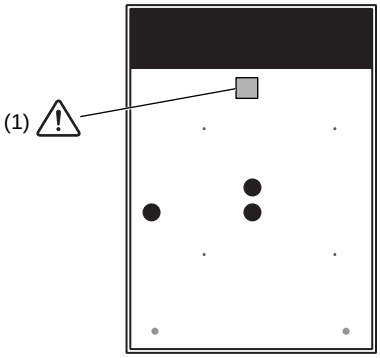
Pneumatic Unit - Rear View

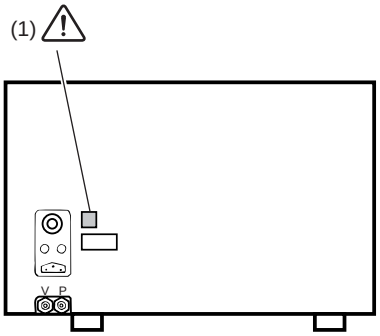


(1)

CAUTION

Do not block the exhaust vent on the rear of the pneumatic unit.

Pneumatic Unit - Right View



(1)

WARNING

Instrument must be grounded.

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2.12 Personnel

Caution!

- This instrument may only be operated by trained personnel having been instructed in its operation.
- Only appropriately trained persons must perform maintenance and repair work. Follow troubleshooting instructions in the manual.
- Unpacking, installation, and confirmation of initial operation must be done by Sysmex technical representative.

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2.13 Computer viruses

Warning!

Although our software has already been checked for computer viruses, the configuration of a specific user environment may make it prone to computer virus infections via the Internet or a network.
We recommend that our customers consider computer virus countermeasures that suit their computer operating environment. Customers that use antivirus software in their operating environment should take the following precautions.

1. Use the antivirus software to periodically check for viruses.
   (1) Use antivirus software designed for your operating system to periodically check for viruses.
   (2) Disable the antivirus software during instrument software operation as it may adversely affect instrument operation.
   (3) Disable functions that check file access.
   (4) Disable firewalls and any other functions that protect or control data transfers.
2. Do not install any software other than the antivirus software.
3. USB memory sticks, CD-Rs and other external memory devices should be checked for viruses before use.
4. Do not open files attached to email or files of unknown origin without first performing a virus check.
5. Do not download files from the Internet or other sources that are not required for instrument operation. However, the virus definition files used by the antivirus software are not subject to this restriction.
6. Always check for viruses before accessing files in a folder shared with other computers.
7. Check effectiveness of computer virus countermeasures used on other computer systems in your laboratory, and select the most effective for use on this instrument.
8. The customer must take sole responsibility when connecting to an external network (for example, the Internet).

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2.14 Use of other software

Warning!

- Do not install any software other than that preinstalled on the instrument. And do not run any other software on the instrument. However, this restriction does not include the installation of antivirus software.
- Note that we will accept no liability whatsoever for any malfunctions arising from use of other software.

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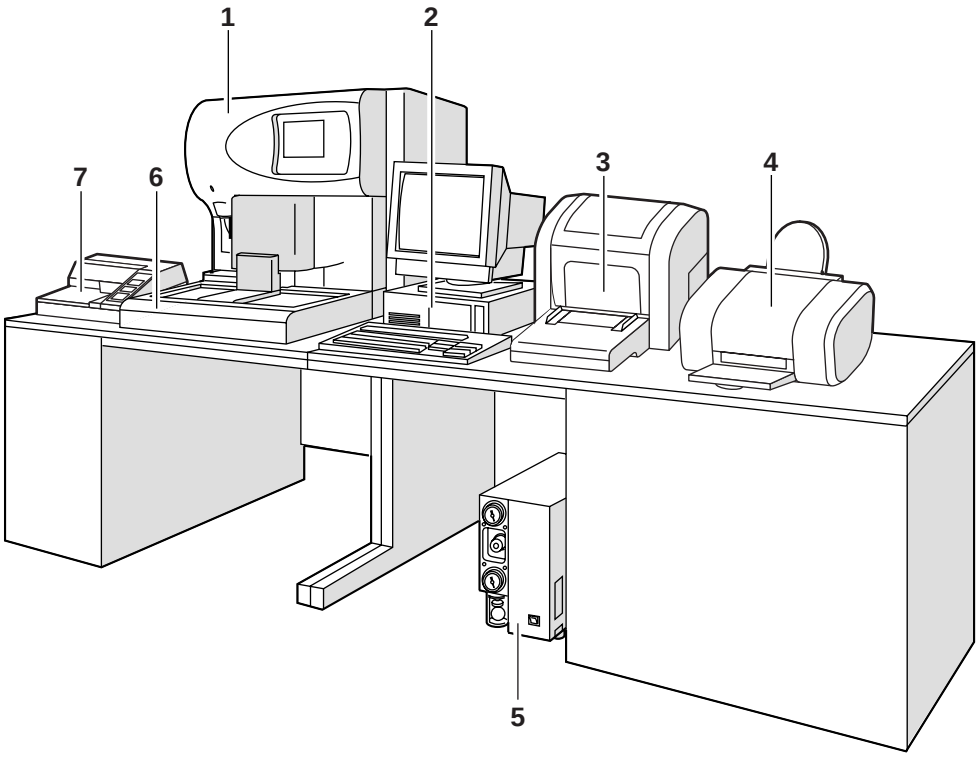
3. Design and Function

3.1 Overview



1 Main Unit
Analyzes and controls samples.

2 Information Processing Unit (IPU)
Processes data which it receives from the Main Unit.

3 Ledger printer (option)
Prints lists of analysis information or results.

4 Color graphic printer (option)
Prints a hardcopy of analysis results or screen of histograms, scattergrams, etc.

5 Pneumatic unit
Supplies pressure and vacuum used by the Main Unit.

6 Sampler unit
Supplies samples to the Main Unit automatically.

7 Data printer (option)
Prints analysis data in the examination ticket format.

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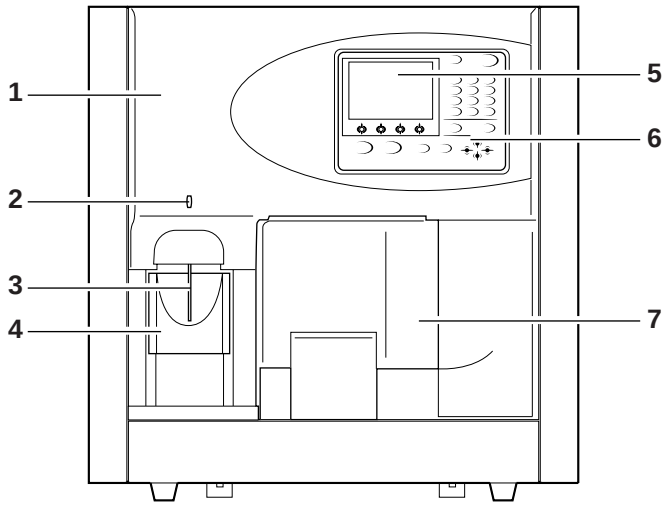
3.2 Main Unit

Front View



1 Front cover
Can be opened upward by hand. Open the cover to inspect or clean inside the Main Unit.

> **Warning!**
> When inspecting inside the Main Unit with the front cover opened, be sure to set the stop bar in advance.
> Otherwise, the cover can drop down and injure your head.

2 READY LED
Lights up when the Main Unit enters Ready status.

3 Manual aspiration pipette
Used to aspirate a sample in manual or capillary mode.

4 START switch
Used to start an analysis in manual, capillary or manual closed mode.

5 LCD screen
Displays the status of the Main Unit, sample ID number and analysis data.

6 Panel Keypad
Used to perform basic operation, such as inputting sample ID number, starting the sampler analysis and selecting the analysis parameter. For details, see “Panel keypad” .

7 CP cover
This is the protection cover of cap piercing unit.

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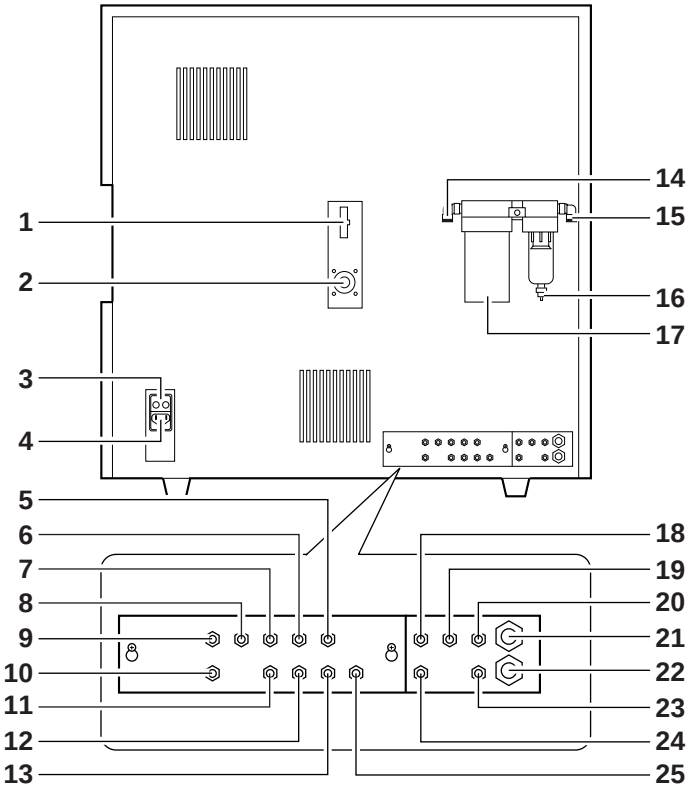
Rear View



1 Float switch connector
Connected to the float switch of each reagent.

2 Pneumatic Unit control output connector
Used as output connector for controlling ON/OFF of the Pneumatic Unit power. Connected to the connector on the rear panel of the Pneumatic Unit.

3 Fuse holder
This is a 250V, 3.15A (time lag) fuse.

> **Warning!**
> • To avoid electrical shock, disconnect supply before servicing.
> • For the continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

4 AC power supply
Supplies power using the provided power cable.

5 ESE inlet nipple (ESE-1)
CELLSHEATH is aspirated via this nipple. Connected to the lower nipple of the CELLSHEATH float switch.

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6 SIM aspiration nipple (SIM-1)
STROMATOLYSER-IM is aspirated via this nipple. Connected to the lower nipple of the STROMATOLYSER-IM float switch.

7 SLS inlet nipple (SLS)
SULFOLYSER is aspirated via this nipple. Connected to the container of SULFOLYSER.

8 FFD reagent inlet nipple (FFD)
STROMATOLYSER-4DL is aspirated via this nipple. Connected to the container of STROMATOLYSER-4DL.

9 FBA inlet nipple (FBA)
STROMATOLYSER-FB is aspirated via this nipple. Connected to the container of STROMATOLYSER-FB.

10 SNR reagent inlet nipple (SNR)
STROMATOLYSER-NR (L) is aspirated via this nipple. Connected to the container of STROMATOLYSER-NR (L).

11 RED diluent inlet nipple (RED)
RET SEARCH (II) diluent is aspirated via this nipple. Connected to the container of RET SEARCH (II) diluent.

12 SIM air bubbles outlet nipple (SIM-2)
Air bubbles inside the float switch of STROMATOLYSER-IM are discharged via this nipple. Connected to the upper nipple of the STROMATOLYSER-IM float switch.

13 ESE air bubbles outlet nipple (ESE-2)
Air bubbles inside the float switch of CELLSHEATH are discharged via this nipple. Connected to the upper nipple of the CELLSHEATH float switch.

14 Air drier outlet nipple
Outputs pressure after removing dust or moisture by the air drier. Connected to the pressure supply nipple.

15 Air drier inlet nipple
Connected to the pressure outlet nipple of the Pneumatic Unit.

16 Air drier drain nipple
Connected to the drain outlet nipple.

17 Air drier
Removes dust or moisture from the air (at PRESSURE side) supplied by the Pneumatic Unit.

18 EPK inlet nipple (EPK-1)
CELLPACK is aspirated via this nipple. Connected to the lower nipple of the CELLPACK float switch.

19 Drain outlet nipple (D)
Water droplets from the air drier are discharged via this nipple to the waste line.

20 Vacuum supply nipple (V)
Connected to the vacuum outlet nipple of the Pneumatic Unit.

21 Waste level detection nipple (P2)

22 Waste level detection nipple (P1)
When the optional waste monitoring sensor is provided, the waste volume is monitored by detecting differential pressure between the waste level detection nipples P1 and P2. Connected to the detection tube of the waste container.

23 Pressure supply nipple (P)
Connected to the air drier outlet nipple.

24 Waste outlet nipple (W)
Waste fluid is discharged via this nipple. Connected to the sewer or the waste container.

25 EPK air bubbles outlet nipple (EPK-2)
Air bubbles inside the float switch of CELLPACK are discharged via this nipple. Connected to the upper nipple of the CELLPACK float switch.

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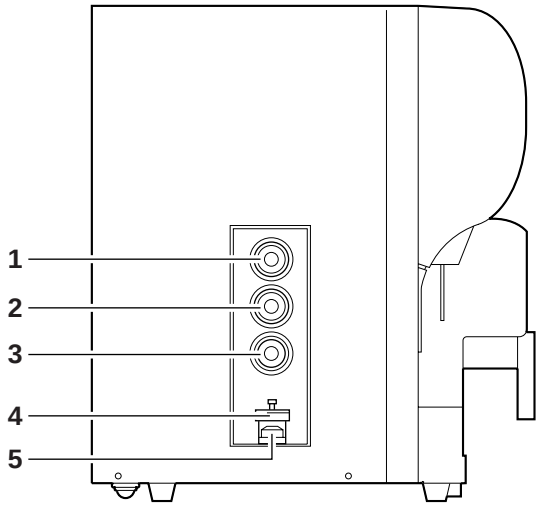
Left Side View



1 0.16 MPa regulator
Adjusts the pressure to 0.16 MPa.

2 0.07 MPa regulator
Adjusts the pressure to 0.07 MPa.

3 0.03 MPa regulator
Adjusts the pressure to 0.03 MPa.

4 Air filter
Prevents dust from entering the bellows unit.

5 Bellows Unit
Adjusts the bellows pressure to -0.04 MPa.

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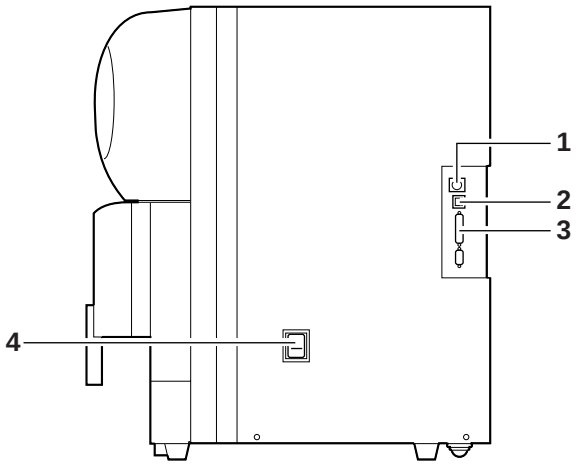
Right Side View



1 Handheld barcode scanner connector
Connected to the optional handheld barcode scanner required to input sample ID numbers.

2 IPU connector
The communication connector with the IPU. Connects to the connector of the IPU using the provided cable.

Caution!
When connecting the communications cable (LAN cable) to the Information Processing Unit (IPU), there is a risk of damage to communications equipment due to static electrical charges on human body. Touch something else to discharge static before connecting the cable.

3 DP connector
Connected to the data printer.

4 Power Supply Switch
Turns the power ON and OFF.

Note:
Do not turn the power ON and OFF repeatedly in a short period of time.
This can cause an overload to blow the fuse.

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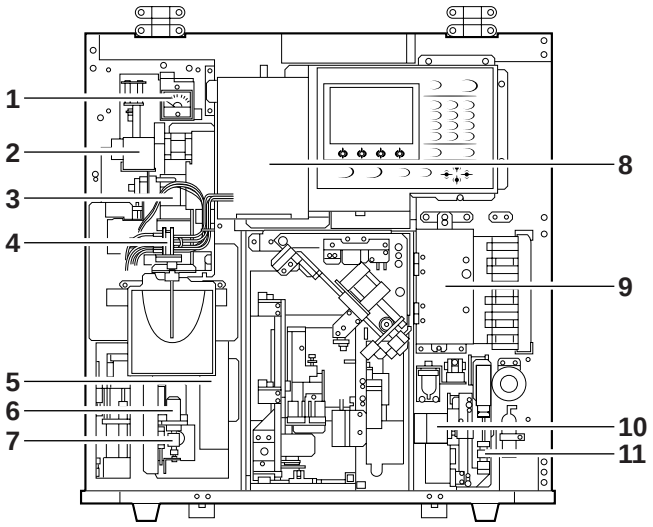
Front Interior



1 RF tuning meter
Displays the status of radio-frequency voltage for the IMI detector.

2 Reaction chamber
Prepares a diluted sample for analyzing WBC/BASO, 4DIFF, NRBC and RET. The sample is retained at a constant temperature for a certain period of time, and sent to the optical detector block.

3 Blood aspiration sensor
Monitors the aspiration status of whole blood in the sampler mode or the manual closed mode.

4 Sample rotor valve (SRV)
Measures the predetermined volume of the aspirated whole blood sample.

5 HGB detector block
Includes the HGB analyzer.

6 Whole blood aspiration pump
Aspirates a whole blood sample.

7 Whole blood aspiration motor
Drives the whole blood aspiration pump.

8 IMI detector block
Includes the IMI detector.

9 RBC detector block
Includes the RBC detector.

10 Sheath motor
Drives the sheath injector piston.

11 Sheath injector piston
Supplies a constant amount of diluted sample (1:500) to the RBC detector.

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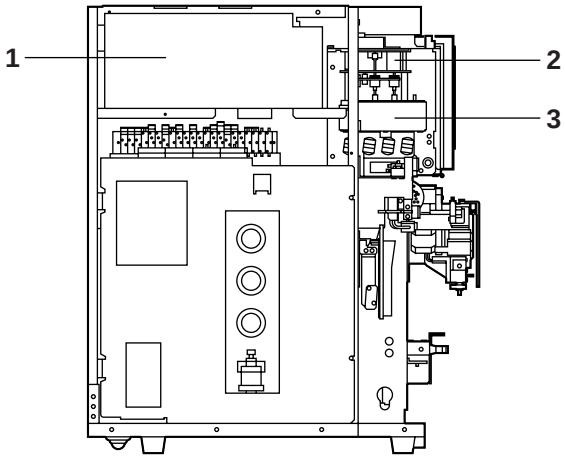
Left Interior



1 WBC detector block
Includes the WBC detector.

2 Reaction chamber mixing motor
Mixes a diluted sample for analyzing WBC/BASO, 4DIFF, NRBC and RET.

3 Reaction chamber
Prepares a diluted sample for analyzing WBC/BASO, 4DIFF, NRBC and RET. The sample is retained at a constant temperature for a certain period of time, and sent to the optical detector block.

Caution!
Do not open the left cover unless the instruction is given by your Sysmex technical representative.

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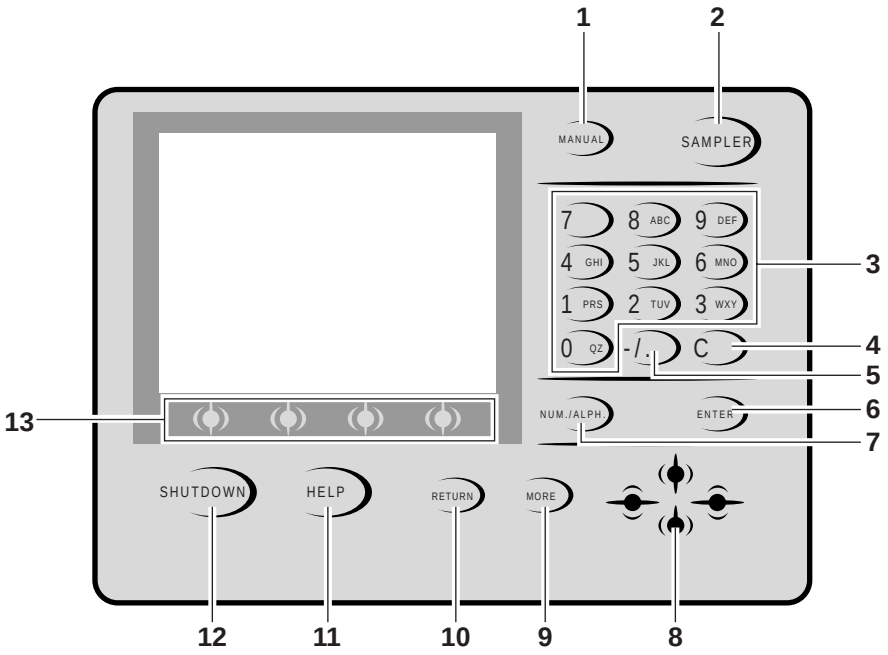
Panel keypad



No.	Function
1	Used to enter the sample ID No. in manual mode, capillary mode, HPC mode, body fluid mode and manual closed mode. The sample ID No. setting screen is displayed. In additional to the sample ID No., the discrete test profile and the analysis mode can be selected.
2	Used to start analysis in sampler mode. When the sampler key is pressed, the sample ID No. setting screen is displayed, and you can set sample ID No., rack No., and tube position from which the analysis has to start.
3	Used to specify sample ID No. and menu No.
4	Used to delete one character during key entry, or to stop the alarm.
5	Used to input hyphen [-] during sample ID No. entry, or decimal point during numeric entry.
6	Used to confirm the entered sample ID No.
7	Used to change input modes.
8	Used to change the LCD screen, or to move the selected parameter.
9	Used to change the function menu display on the screen which has five or more selectable function menu items.
10	Used to cancel the execution of the menu and return to the status before selecting the menu.
11	In the presence of an error, pressing HELP will display the error message, probable cause and corrective action to take.
12	Used to execute the shutdown sequence.
13	Used to select the function menu displayed at the bottom of the LCD screen.

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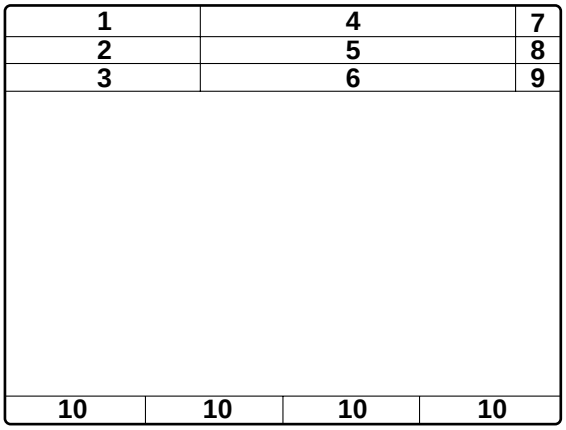
Panel Keypad LCD



1 Displays the mode to be used next.
There are the following four kinds of modes.
- Manual mode (Normal mode: Displayed as “Manual”)
  (HPC analysis mode: Displayed as “HPC Manual”)
  (Body fluid analysis mode: Displayed as “BF Manual”)
- Capillary mode (displayed as “Capillary”)
- Sampler mode (displayed as “Sampler”)
- Manual closed mode (displayed as “Closed”)

2 Displays the discrete setting for next analysis.
There are the following five kinds of discrete settings.
- CBC (displayed as “C”)
- CBC+NRBC (displayed as “C N”)
- CBC+RET (displayed as “C R”)
- CBC+DIFF+NRBC (displayed as “CDN”)
- CBC+DIFF+NRBC+RET (displayed as “CDNR”)

3 Displays the status of the Main Unit.
Any of the following status is displayed.
- Ready
- Not Ready
- Running
- S-Ready
- Stat
- S-Not Ready

4 Displays the manual sample ID No. to be analyzed next.

5 Displays the sample ID No. for DP printing.

6 Displays the present error content which has the highest priority.
When the error under the display is reset, the error with the next highest priority is displayed.
If several errors occur, press the HELP key, and select Error List from the function menu. All the errors are displayed.

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7 Displays the input status by numeric keys.
Alphabet and hyphen in addition to numerals can be used for sample ID No.
By pressing the NUM./ALPH. key on the panel keypad, you can change the input mode in this order: "Numeric" → "Uppercase Alphabet" → "Lowercase Alphabet". The display contents are as follows:
Num: Numeric mode
ALP: Uppercase Alphabet
alp: Lowercase Alphabet

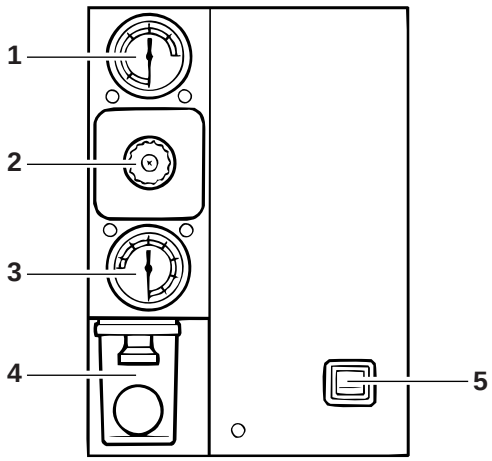
8 Displays the status of the DP.
DP: DP is connected and no error has occurred.
No indication: DP is not connected.
DP (reversing display): DP is set to be connected, but an error has occurred.

9 Displays the implementation status of $\overline{X}_M$ QC.
Xm: $\overline{X}_M$ QC is ON.
No indication: $\overline{X}_M$ QC is OFF.

10 Displays the function menu.
The contents of the function menu differ with each other.

3.3 Pneumatic Unit

Front View



1 Pressure Indicator 1 (0.25 MPa)
Indicates pressure to be supplied to the Main Unit. The normal range is 0.25 ± 0.03 MPa. If pressure comes out of the normal range, the instrument may not operate properly.

2 0.25 MPa regulator
Regulates the 0.25 MPa pressure to be supplied to the Main Unit.

3 Vacuum Indicator 2
Indicates vacuum to be supplied to the Main Unit. The normal range is -0.05 MPa or over. If vacuum is less than -0.05 MPa, the instrument may not operate properly.

4 Pneumatic unit trap chamber
Prevents reagent, etc. from flowing into the compressor when an abnormality has occurred in the instrument.

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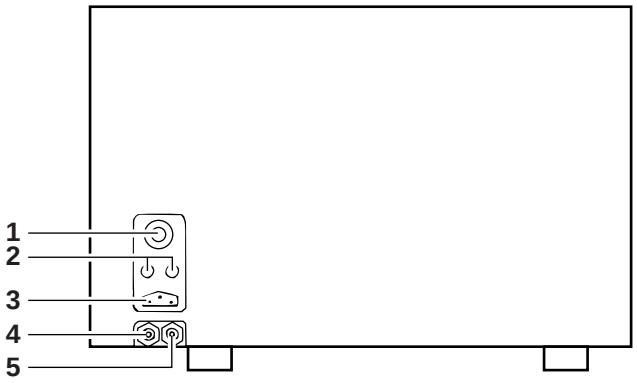
5 Power supply switch
Turns the power ON and OFF.

> **Note:**
> Do not turn the power ON and OFF repeatedly in a short period of time.
> This can cause an overload to blow the fuse.

Right Side View



1 Pneumatic Unit control input connector
The input connector for controlling the Pneumatic Unit ON/OFF. Connects to the Pneumatic Unit control output connector of the Main Unit.

2 Fuse
This is a 250V, 3.15A (time lag) fuse.

> **Warning!**
> • To avoid electrical shock, disconnect supply before servicing.
> • For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

3 Power supply connector
Supplies power with the power cord provided.

4 Vacuum outlet nipple
Supplies vacuum to the Main Unit. Connects to the vacuum supply nipple of the Main Unit.

5 Pressure outlet nipple
Supplies pressure to the Main Unit. Connects to the air drier inlet nipple of the Main Unit.

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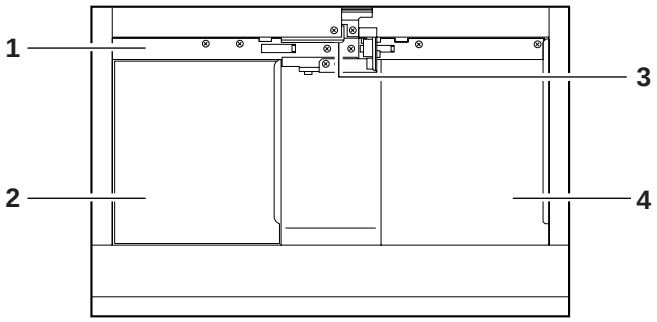
3.4 Sampler Unit



1 Analysis line
A rack automatically shifts to the left once per cycle in an amount equivalent to one sample. On this line, the ID is read and the sample is caught by the hand.

2 Left rack pool
The rack shifts from the analysis line to this pool.

3 Blood volume monitoring sensor
Monitors the volume of blood in the sample tube. If the volume is insufficient, the sample cannot be analyzed.

4 Right rack pool
The racks are set in this pool. Up to 10 racks can be set at a time. Press the **SAMPLER** key to feed the rack automatically to the analysis line.

Caution!
Do not manually push (or move) the sample rack forward while instrument is in operation.
There is a small possibility that sample numbers and analysis results could become misaligned.

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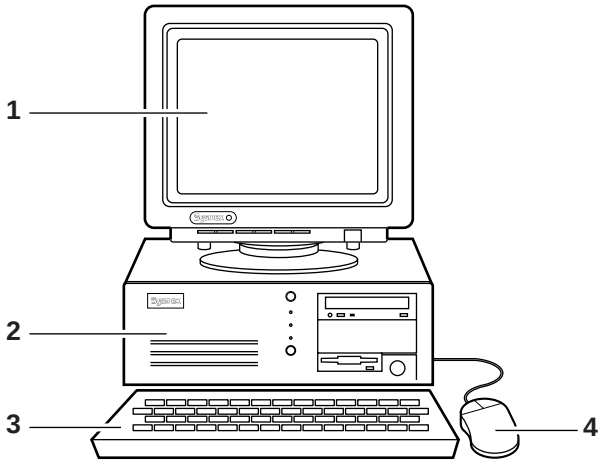
3.5 Information Processing Unit (IPU)

Front View



1 TFT display
SVGA compatible TFT multi-scan display.

2 Main body
IPU Main Unit of the personal computer.

3 Keyboard
Used to input data to the IPU.

4 Mouse
Used to operate the various functions of the IPU.

Information
The IPU illustrations shown in this manual are for reference only. Refer to the manual included with the computer for the layout of connection ports and other details.
For further details, contact your Sysmex technical representative.

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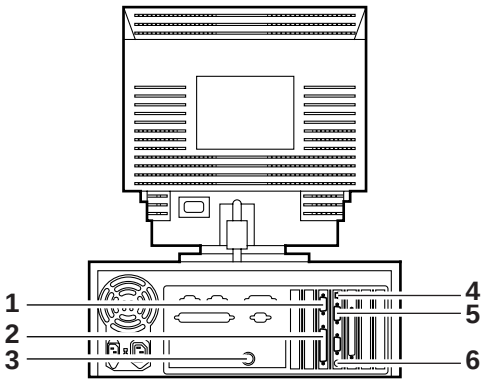
Rear View



1 LP connector (LP: COM1)
Printer connector for printing out the ledgers.

2 GP connector (GP)
Printer connector for printing out the graphics.

3 Keyboard connector
Connector for the keyboard.

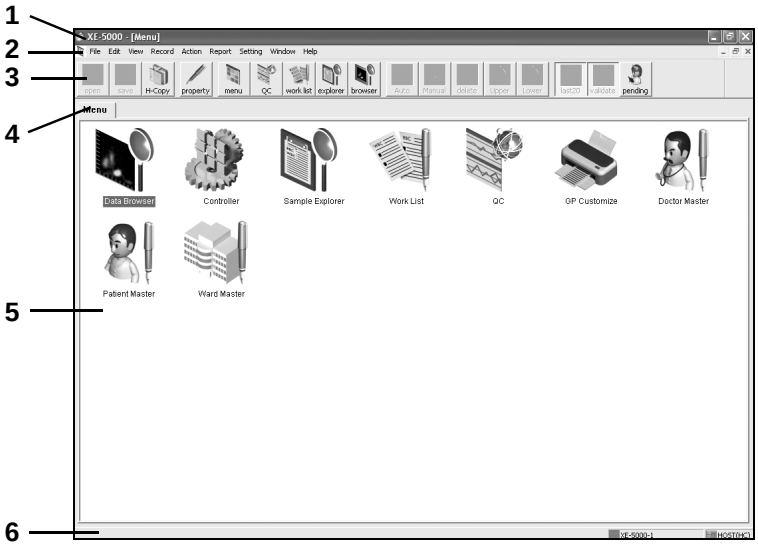
4 Main Unit connector (MAIN UNIT)
Connector for the XE-5000 Main Unit.

5 HOST connector (HOST: COM2)
Connector for the host computer.

6 Mouse connector
Connector for the mouse.

Revised April 2007

Summary of the Information Processing Unit (IPU) display screen



1 Title bar

Displays the instrument name, display window name, No. of stored data, etc.

2 Menu bar

Displays the following:

- File
- Edit
- View
- Record
- Action
- Report
- Settings
- Window
- Help

There are submenus for each menu item. A pull down menu will be displayed when the mouse is left clicked over the menu item.

Information

There may be some menu that cannot be selected, depending on the functions currently effective.
Only menu items displayed in black may be selected.

3 Tool bar

The tool bar contains those pull down submenu items that are used comparatively often. Double-click the icon on the tool bar will immediately execute that submenu action. Inactive tool bar buttons are displayed in gray.

4 Tab

The names of windows indicating menu icons are displayed.
When there are several windows, select a desired tab to change over the windows.

5 Window (View)

Operations are performed in these areas or windows.

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6 System status display area
The following status will be displayed:
- Main Unit status (Displays the status of up to 4 Main Units which can be connected to one IPU).
- Host computer connection status

3.6 Analysis mode

Manual mode
In manual mode, the cap of the sample tube is manually removed and each sample is aspirated individually via the whole blood aspiration pipette.

Capillary mode
In capillary mode, the sample diluted to 1:5 is aspirated manually via the whole blood aspiration pipette, analyzed, displayed and reported.

Sampler mode
The sampler automatically mixes, aspirates and analyzes samples without removing their caps. Up to 100 samples can be loaded at a time and analyzed automatically.

Manual closed mode
In manual closed mode, the sampler is used to aspirate the sample, without opening the cap of the sample tube. This mode is basically the same as manual mode; mixing and continuous analysis can not be performed automatically.

Note:
HPC analysis and body fluid analysis can only be performed in manual mode.

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4. Reagents

4.1 General information

All reagents used in this instrument are specialized reagents for use in Sysmex instruments. Please do not use these reagents for other purposes. Please follow the warnings for handling and using each of the reagents correctly.

Note:
To ensure both customers safety and optimal system performance, the manufacturer recommends that all reagents boxes are placed at a level even with or below the instrument base.

4.2 CELLPACK

Intended Use

Diluent for use in hematology analyzers.

Storage and Shelf Life after first Opening

Store CELLPACK at +1 to +30°C and out of direct sunlight.
If once frozen, mix it well after thawing.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

CELLPACK is a reagent for measuring the numbers and sizes of RBC and platelets by the hydro dynamic focusing (DC Detection). With the addition of the specified lyse reagent for hemoglobin concentration determination, it can also be used to analyze hemoglobin concentration.

4.3 CELLSHEATH

Intended Use

Sheath fluid for use in hematology analyzers.

Storage and Shelf Life after first Opening

Store CELLSHEATH at +1 to +30ºC and out of direct sunlight.
If once frozen, mix it well after thawing.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.

Revised January 2010

Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

CELLSHEATH, in combination with the specified diluent, is a reagent for analyzing the numbers and sizes of RBC and platelets by the hydro dynamic focusing (DC Detection).

4.4 STROMATOLYSER-FB

Intended Use

A lyse reagent for the WBC/BASO channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-FB at +30°C or lower temperature and out of direct sunlight.
If it freezes, mix it well after thawing.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

STROMATOLYSER-FB is a reagent for analyzing basophil counts and WBC counts by the flow cytometry method, using a semiconductor laser.

4.5 STROMATOLYSER-4DL

Intended Use

Diluent for the DIFF channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-4DL at +2 to +35°C and out of direct sunlight.
Do not use reagent that may have frozen.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

STROMATOLYSER-4DL is a reagent used in combination with the specified dye solution (STROMATOLYSER-4DS) to classify WBC by the flow cytometry method, using a semiconductor laser.

Revised January 2010

4.6 STROMATOLYSER-4DS

Intended Use

Dye solution for the DIFF channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-4DS in a dark place at +2 to +35°C.
Do not use reagent that may have frozen.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

STROMATOLYSER-4DS is a reagent used in combination with the specified lyse reagent (STROMATOLYSER-4DL) to classify WBC by the flow cytometry method, using a semiconductor laser.

4.7 STROMATOLYSER-NR(L)

Intended Use

Lyse reagent for the NRBC channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-NR(L) at +2 to +35°C and out of direct sunlight.
Do not use reagent that may have frozen.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

STROMATOLYSER-NR(L) is a reagent using in combination with STROMATOLYSER-NR(S) to analyze erythroblast count and ratio by the flow cytometry method, using a semiconductor laser.

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4.8 STROMATOLYSER-NR(S)

Intended Use

Dye solution for the NRBC channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-NR(S) at +2 to +35°C and out of direct sunlight.
Do not use reagent that may have frozen.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

STROMATOLYSER-NR(S) is a reagent using in combination with STROMATOLYSER-NR(L) to analyze erythroblast count and ratio by the flow cytometry method, using a semiconductor laser.

4.9 SULFOLYSER

Intended Use

A cyanide-free lyse reagent for the hemoglobin determination in hematology analyzers.

Storage and Shelf Life after first Opening

Store SULFOLYSER at +1 to +30°C and out of direct sunlight.
If it has frozen, thaw it in warm water at 30°C or below, and mix it thoroughly before use.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

SULFOLYSER is a reagent used in combination with the specified diluent to analyze the hemoglobin concentration dissolved out of RBCs by the SLS-hemoglobin method.

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4.10 STROMATOLYSER-IM

Intended Use

A lyse reagent for the IMI channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-IM at +30°C or lower temperature and out of direct sunlight.
If it freezes, mix it well after thawing.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

STROMATOLYSER-IM is a reagent for detecting immature cells by the RF/DC detection method.

4.11 RET SEARCH (II) (diluent) RET SEARCH (II) (dye solution)

Intended Use

Lyse reagent and dye solution for the RET channel of hematology analyzers.

Storage and Shelf Life after first Opening

Store RET SEARCH (II) in a dark place at +2 to +35°C.
Do not use reagent that may have frozen.
If the container is unopened, it may be used up to the expiry date stated on the reagent container.
Please refer to the product labeling (package insert or outer package) for the open stability.

Usage

RET SEARCH (II) is a reagent using in the combination of RET SEARCH (II) (diluent) and RET SEARCH (II) (dye solution) to analyze reticulocytes and optically analyzed platelets by the flow cytometry method, using a semiconductor laser.

Revised January 2010 EU

4.12 CELLCLEAN

Intended Use

CELLCLEAN is a strong alkaline detergent to remove lyse reagents, cellular residuals and blood proteins remaining in the hydraulics of Sysmex automated hematology analyzers.

Warnings and Precautions

Warning!

1. Avoid contact with skin and eyes.
2. In case of skin contact, flush the area with water.
3. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
4. If accidentally swallowed, seek medical advice immediately.

Storage and Shelf Life after first Opening

Store CELLCLEAN in a dark place at +1 to +30°C.
Avoid exposing direct sunlight, or the chlorine component may deform and lose its effectiveness, depending upon the period of exposure.

Usage

CELLCLEAN is a detergent to clean and remove cellular residuals and blood proteins from the hydraulic systems, detector, whole blood aspiration line tube and other parts in the blood cell analysis instrument.

Revised January 2010 EU

4.13 Control blood (*e*-CHECK(XE))

Intended Use

e-CHECK(XE) is a hematology control material primarily for intralaboratory quality control of automated, semiautomated and manual procedures that measure components of blood. Additionally, *e*-CHECK(XE) can be used in external quality assessment.

Warnings and Precautions

Risk of infection

When using control blood, use personal protective equipment. After completion of the analysis, be sure to wash your hands with disinfectant.

Warning!

Potentially Infectious Material-All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B9(HbsAg), negative by tests for antibodies to HIV(HIV-1/HIV-2) and Hepatitis C9(HCV), non-reactive for HIR-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis(STS) using techniques specified by the U.S Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.

Storage and Shelf Life after first Opening

Store control material as per product insert at +2 to +8°C. If unopened, *e*-CHECK(XE) may be used up to the expiration date shown on the container. Once opened, it should be used within 7 days.

4.14 Labeling

Important information about the handling of reagents and quality control material is noted on the package insert and containers. Please read the labels and package insert prior to use.

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4.15 Symbols used on the labels

IVD	In Vitro Diagnostic
	Consult instructions for use
LOT 1234	Lot-number
22-Nov-2000	Use by
	Storage temperature
CE	CE conformity sign as per directive 98/79/EC
 Xn	Hazardous Class in EU
	Manufacturer
EC REP	Authorized representative in the European community

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5. Before Using

5.1 Storage prior to transport and installation

- Once the instrument is delivered, check the condition of its packaging as soon as possible.

> **Information**
> If the packaging has been damaged in any way, contact your Sysmex technical representative as soon as possible.

- Store the instrument as packaged in a dry place until installation. Do not turn it over or store it upside down.

> **Information**
> A Sysmex technical representative will perform the initial setup of this instrument. Thereafter, if you wish to move it to another location, please contact your Sysmex technical representative.

5.2 Preparation

- Install the XE-5000 in a dry and dust-free environment.
- It should be located in a space large enough to be used safely. If additional equipment is to be connected to it, further desk space will be required.
- The instrument weighs approximately 93 kg. Be sure to use a table or desk that can support that amount of weight.
- Leave a space of 50 cm or more between the walls and the side, rear and top panels to allow for heat dissipation. Also, leave enough space when installing for maintenance and service work to be performed.
- Do not install this equipment near any devices that emit high-frequency signals or noise (radios, centrifuges, etc.).
- The power cable for this instrument is 1.8 m long. Use a nearby outlet that is designed for it.

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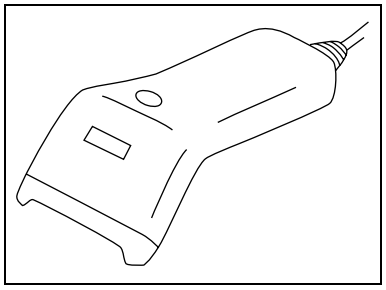
5.3 Peripherals

Caution!
- Turn the power switch of the instrument OFF before connecting peripherals.
- Each peripheral device that is connected will need its own power outlet. Do not plug multiple devices into extensions and adaptors. Such wiring could cause fire.

Ledger printer (option)
Color graphic printer (option)
Data printer (option)
(For the functions of the printers, see “Chapter 3: 3.1 Overview”).

Note:
The ledger printer, color graphic printer and data printer are optional.
Refer to the corresponding printer manuals for details of their installation.

5.4 Additional components



Handheld barcode scanner (option)
A handheld barcode scanner scans the barcode on the sample tube and automatically inputs the sample number.

Note:
The handheld barcode scanner is optional.
Refer to the handheld barcode scanner manuals for the connection method.

Waste sensor unit (option)
Informs the operator that the waste container is full.

Note:
The waste sensor unit is optional.

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Uninterruptible power supply (UPS) (option)
A backup power supply which allows the IPU to operate for a maximum of 5 minutes in the event of power failure. In case of momentary power interruption caused by a thunder storm, the UPS protects the IPU hard disk.

Note:
The uninterruptible power supply (UPS) is optional.

5.5 Basic equipment settings

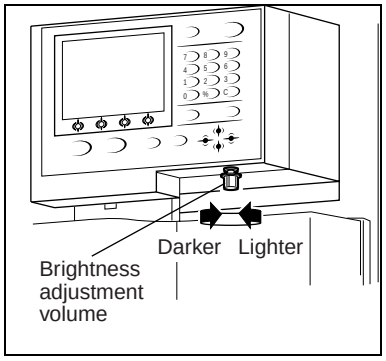
Note:
This chapter only explains the settings related to the initial operations. For more detailed information about other settings, see “Chapter 5: Instrument Setup” in the Software Guide.

Date and Time

Set the date and time accurately, using the Windows date and time adjustment function on the Information Processing Unit (IPU).

Information
The date and time cannot be set from the XE-5000 setup program.

Brightness adjustment of panel keypad LCD screen



1. Open the front cover of the Main Unit.
2. The LCD brightness can be adjusted using the brightness adjustment volume under the panel keypad.
   Turn to the right: Darker
   Turn to the left: Lighter
3. Close the front cover of the Main Unit.

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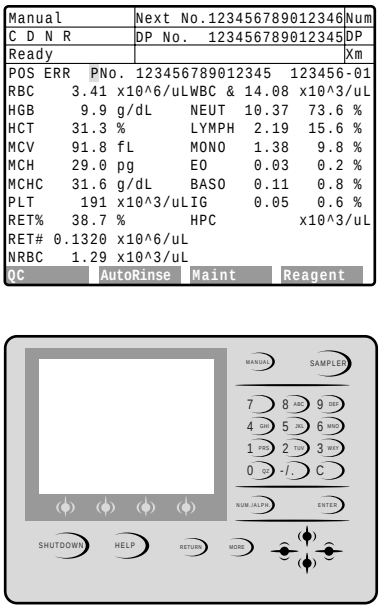
6. Operation

6.1 Summary of Main Unit operation

Various functions can be activated by selecting them from menus on the panel keypad of the Main Unit.
On the LCD screen, the functions that are usable from each menu are displayed on submenu. Information such as the status of the instrument and the setting status of the next sample to be analyzed is displayed at the top of the screen.

Main Menu



The function menu of the main menu is displayed on the bottom of the main menu screen.

- If there are five or more function menus, press the **MORE** key to display the remaining function menus.
- To select a function menu, press the corresponding selection key below the LCD screen.
- To return to the main menu screen from another screen, press the **RETURN** key.

> **Note:**
> To return to the main menu screen, depending on the currently displayed screen, it may be necessary to press the **RETURN** key several times.

Submenu selection

When an item on the main menu is selected, the submenu available for that item is displayed.
The following methods can be selected, depending on the submenu.

- When using a submenu of the function menu, press the corresponding selection key below the LCD screen.
- If there is a submenu with a menu number, press the number key for that menu number, or use the cursor keys to select the menu.

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Entering numbers and characters

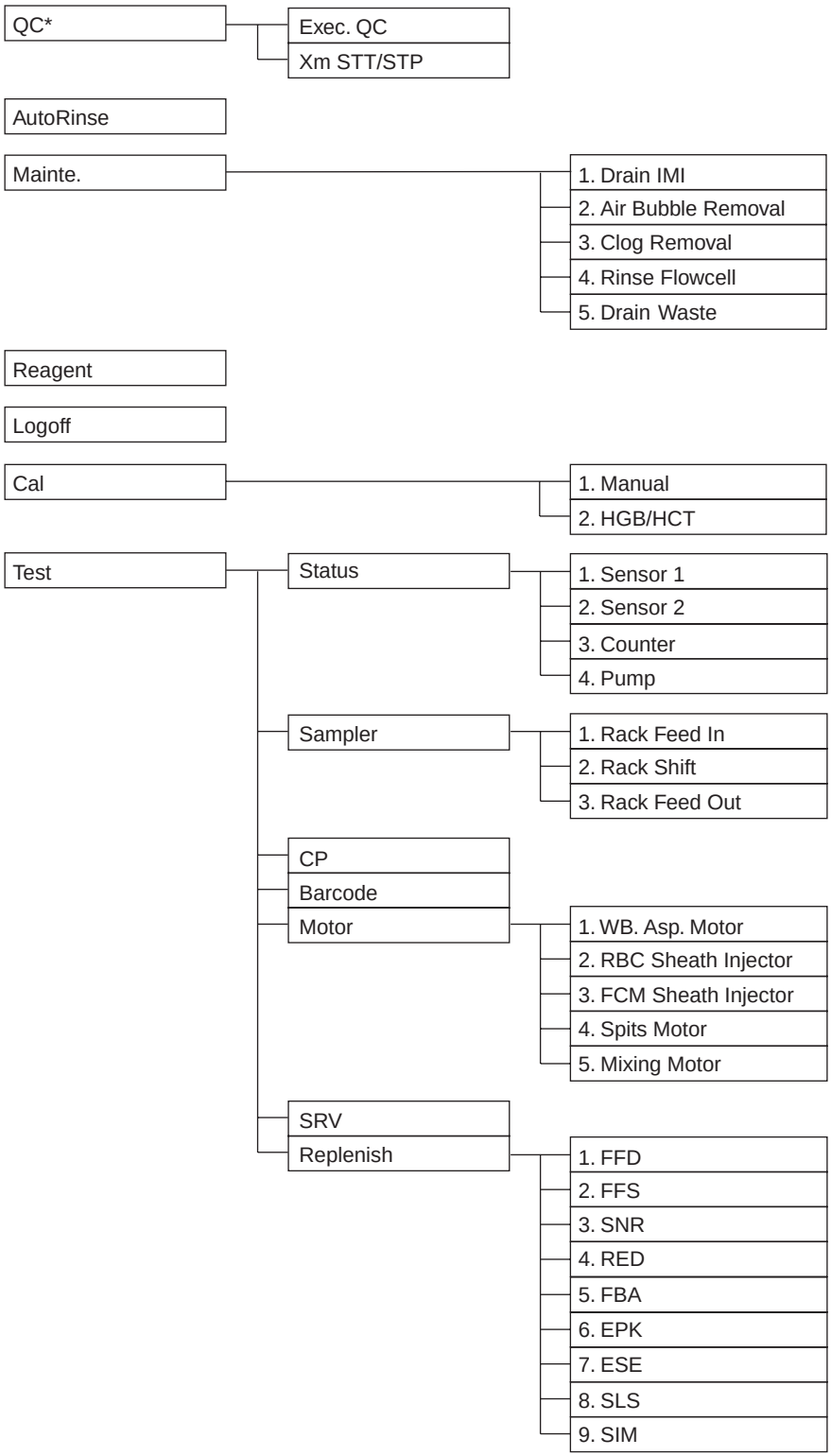
Sample numbers or the like can be entered from the panel keypad.

By pressing the **NUM./ALPH.** key on the panel keypad, you can change the input mode in this order: “Numeric” → “Uppercase Alphabet” → “Lowercase Alphabet”.

- Press the corresponding number keys to enter numbers.
- To enter characters, press the corresponding number key repeatedly until the intended character appears.
- Press the **C** key to delete a character.
- Press the **ENTER** key to confirm input.

Revised April 2007

6.2 Main unit menu tree



* : “B-Check” will be displayed instead of “QC” in the body fluid mode.
“B-Check” means background check.

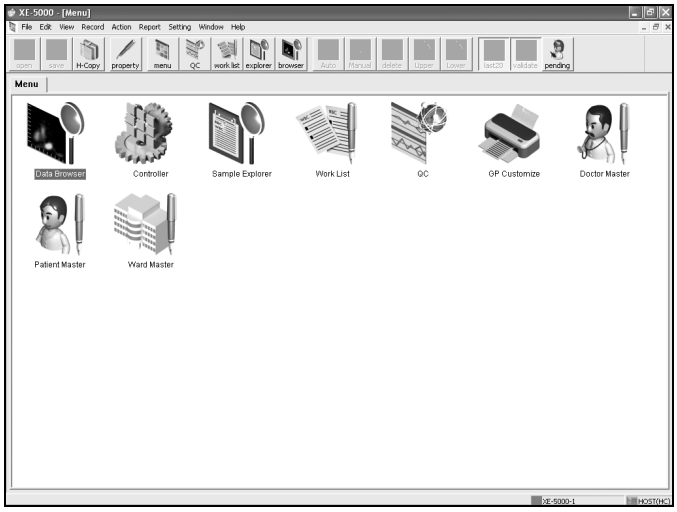
Revised June 2008

6.3 Summary of Information Processing Unit (IPU) operation

Caution!
- The Information Processing Unit (IPU) is to be used exclusively with the XE-5000 and can not be used as a regular computer.
- Operation not covered in this manual or use of programs not specified by Sysmex renders the warranty invalid and may cause the Information Processing Unit (IPU) to perform incorrectly.

Menu screen

The menu screen appears after the Information Processing Unit (IPU) is turned on and the user logs in to the application program.



Note:
The menu screen is customizable. Therefore, the screen displays presented in this manual may differ from the actual screen displays on the instrument. For details of screen customization, see “Chapter 5: Instrument Setup” in the Software Guide.

Menu selection

The following three methods may be used to select an item on the menu.
- Double-click the icon on the tool bar.
- Click on the menu, then select the submenu item from the pull down.
- Double-click the icon on the menu screen.

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Dialog box

The dialog box is displayed when a specified menu or command button is selected.

6.4 Information Processing Unit (IPU) menu bar

Menu	Submenu	Menu Function
File	Open	Opens the data browser (only when the sample explorer is running).
	Close	Closes the window.
	Save	Overwrites and save the presently selected item record.
	Print	Prints the screen.
	Log Off	Logs off (To the logoff screen.)
	Exit	Quits the application. (To the quit confirmation screen.)
Edit	Select All	Selects all records.
	Find	Displays the search window.
	Property	Changes the tab title.
View	Toolbar	Displays or close the tool bar.
	Status Bar	Displays or close the status bar.
	Menu	Starts Menu.
	QC	Starts QC.
	Work List	Starts Work List.
	Sample Explorer	Starts Sample Explorer.
	Data Browser	Starts Data Browser.
Record	Sort	Realigns the displayed patient records. (To sort condition input dialog box.)
	Filter	Selects displayed patient record. (To filter condition input dialog box.)
	Auto Add	Adds new records.
	Manual Add	Adds new records.
	Delete	Deletes selected record.
	Backup	Backs up selected record to the hard disk or USB device.
	Restore	Lists up information saved to the hard disk or USB device.
	Download	Downloads from the host computer.
	First	Moves to the top record.
	Upper	Moves to the previous record.
	Lower	Moves to the next record.
	Last	Moves to the last record.
	Output (CSV format)	Outputs the selected data as a file in CSV format.
Action	Validate	Validates the displayed sample.
	Pending List	Displays the pending work list.
	Last20	Displays the latest 20 samples.
Report	Host (HC)	Transfers the selected analysis results to the host computer (HC).
	Ticket (DP)	Prints the selected analysis results on a ticket printer (DP).
	Report (GP)	Prints the selected analysis results on a report printer (GP).
	Ledger (LP)	Prints the selected analysis results on a ledger printer (LP).
	Report for Lab. Use Only	Prints the selected analysis results on a report printer (GP) with laboratory-use-only format.

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Menu	Submenu	Menu Function
Setting	Date Format	Starts Setting/System.
	Auto Validate	Starts Setting/Auto Validate.
	Auto Output	Starts Setting/Auto Output.
	Discrete	Starts Setting/Discrete.
	Analysis Ordering	Starts Setting/Analysis Ordering.
	User Administration	Starts Setting/User Administration.
	Host (HC) Setting	Starts Setting/Host (HC) Setting.
	Report (GP) Setting	Starts Setting/Report (GP) Setting.
	Ledger (LP) Setting	Starts Setting/Ledger (LP) Setting.
	Categories	Starts Setting/Categories.
	Reference Interval	Starts Setting/Reference Interval.
	Units	Starts Setting/Item Attributes.
	Reference Limit	Starts Setting/Sampler Stop Limit Setting.
	CSV Output Setting	Starts Setting/CSV Output Setting.
	Backup	Starts Setting/Backup.
Window	Cascade	Displays the presently displayed windows cascade style.
	Tile	Displays parallels in above and below, left and right.
	Split	Splits window display.
Help	About XE-5000	Displays the application version. (To version display dialog box.)

6.5 Alarm sound

In the XE-5000, three types of alarm sounds are used to alert the operator:

Key Entry Alarm (single beep)
Sounds about 0.1 second when a key is pressed on the panel keypad.

Input Error Alarm (short beep)
Sounds about 1 second when a wrong key is pressed on the panel keypad.

Analysis Error Alarm (long beep)
Sounds when an error occurs in the Main Unit and continues until the **C** key or **HELP** key is pressed on the panel keypad.

6.6 Operator checks

1. Reagent check

Make sure that there is a sufficient amount of reagent for the day's samples. If the amount is insufficient, prepare replacement reagent. If reagent runs out during an analysis, the system automatically stops and alerts the operator to replace the insufficient reagent. Analysis cannot be restarted until replacement is completed. The following shows the approximate number of cycles that can be analyzed per container of reagent.

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● **Samples Analyzed per Reagent Container**

Reagent	Abbreviation	No. of cycles/ container	Capacity per container
CELLPACK	EPK	Approx. 660 cycles	20.0 L
CELLSHEATH	ESE	Approx. 7300 cycles	20.0 L
STROMATOLYSER-FB	FBA	Approx. 2750 cycles	5 L
STROMATOLYSER-4DL	FFD	Approx. 2750 cycles	5 L
STROMATOLYSER-4DS	FFS	Approx. 2000 cycles	42 mL
STROMATOLYSER-NR(L)	SNR	Approx. 2000 cycles	3.6 L
STROMATOLYSER-NR(S)		Approx. 2000 cycles	43 mL
SULFOLYSER	SLS	Approx. 10000 cycles	5 L
STROMATOLYSER-IM	SIM	Approx. 3200 cycles	10 L
RET SEARCH (II) (Diluent)	RED	Approx. 550 cycles	1 L
RET SEARCH (II) (Dye solution)		Approx. 550 cycles	12 mL

- The number of cycles per container refers to the number of cycles that can be run in CBC+DIFF+RET+NRBC analysis mode.

● **Replacing the Reagent**

Caution!
- Use reagent that has been left at room temperature (15–30°C) for at least 24 hours.
- In handling a reagent that may have frozen, follow the precautions given on the package. Otherwise analysis may not be performed correctly.
- When replacing the reagent container, make sure that no dust adheres to the cubitainer spout kit. Otherwise analysis may not be performed correctly.
- After opening a reagent container, make sure that no dust, dirt or bacteria comes into the container. Otherwise analysis may not be performed correctly.

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2. Printer paper

Make sure that there is a sufficient amount of printer paper for the day's samples.

3. Equipment

Check the tubings and cables. Make sure that the tubing is not bent and the power cord is securely plugged into the outlet.

4. Sampler

Make sure that there are no racks in the analysis line. Remove any rack from the line. Make sure that the left and right rack pools and analysis line are clear.

5. Waste fluid

Discard any waste fluid that has collected in a waste container (if applicable).
For the procedure for disposing of waste, see "Chapter 9 Cleaning and Maintenance".

6.7 Turning ON the power

Turn ON the power switches in the following order: 1) IPU, 2) Main Unit (after the logon screen of the IPU program appears), 3) Printer.

Information
Do not turn OFF the power of the Main Unit while displaying the message "PLEASE WAIT."

Note:
The power for the Pneumatic Unit is controlled by the Main Unit; thus, you can normally leave the Pneumatic Unit power switch ON.

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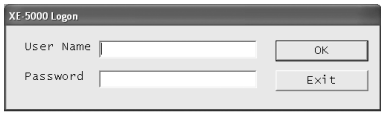
6.8 Logging on to the Information Processing Unit (IPU)



1. Apply the power of the IPU.
2. The Windows system starts up, and the user is automatically logged on to the Windows system as “XE-5000”.
3. The logon dialog box for the XE-5000 application program is displayed.
4. Input a User Name and Password, and click **OK**.
   Logon will be performed with the input User Name and Password. Operation will be possible within the permission set for that User Name.
   To discontinue Logon, click **Exit**.

Information

- Logon can be performed with “Admin” in the condition set at the shipment from the factory.
- “m107m” is the password for the “Admin” user on shipment from the factory.
- Before using the unit, set a user name, password, and permission.
  Also, change the password for “Admin”.

Note:

See “Chapter 5: Instrument Setup” in the Software Guide for the setting and changing procedures of the password and permission.

User Name and Password are very important for proper system management and should be correctly managed.
If you forget the User Name or Password, contact your Sysmex technical representative.

6.9 Self-checks

The instrument performs a self-check operation automatically after the power of the Main Unit is turned ON. The following checks are performed in order: microprocessor check, temperature check, mechanical parts check and background check.
If a failure occurs during a self-check, see “Chapter 10: Troubleshooting”.

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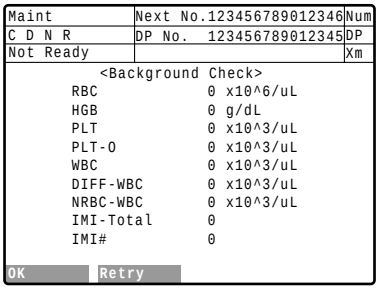
Background check

WBC	0.10 [×10^3/μL]
DIFF-WBC	0.20 [×10^3/μL]
IMI-TOTAL	300
IMI#	5
NRBC-WBC	0.20 [×10^3/μL]
RBC	0.02 [×10^6/μL]
HGB	0.1 [g/dL]
PLT	5 [×10^3/μL]
PLT-O	10 [×10^3/μL]

For the background check, the background check screen will appear. Then, the background value is checked by repeating the background check for up to 3 times. If the background value is less than or equal to that shown in the table, the background check is completed.

If the background value does not become lower than the specified value, the message “Background Error” will be displayed on completion of the background check.
The “+” mark will indicate on the background check screen for the parameter which did not become lower than the specified value.

Caution!
In the case of a background error, the analysis can be performed by selecting **“OK”** on the function menu. However, the measured values tend to be higher and correct results may not be obtained for some analysis parameters.



Note:
- When a background error occurs, the error parameter will be displayed on the screen.
- The progress status of background check is indicated with an asterisk.
- During the background check, “Background Check” is displayed in the sample No. column.

In the case of a background error, select **“Retry”** on the function menu of the Background Check screen to perform a background check again. If the value is not lower than the acceptable background value, “+” is displayed to the right of the value. To resolve background error, see “Chapter 10: Troubleshooting”.

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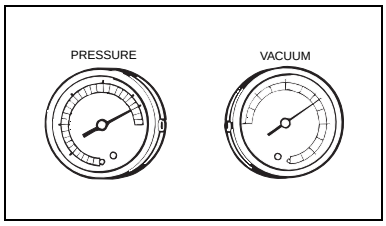
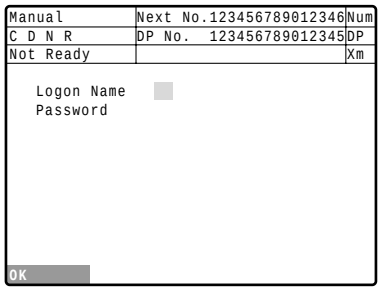
6.10 Pressure and vacuum gauges check



The pressure and vacuum gauges should reach their specified levels approximately 30 seconds after the power of the Main Unit is turned ON.
Confirm that the gauges indicate the values shown below. If they do not, adjust them to the acceptable range.
(Only the pressure can be adjusted on the Pneumatic Unit. See “Chapter 9: Cleaning and Maintenance” for adjustment procedure.)

Pressure	0.25±0.03 MPa
Vacuum	-0.05 MPa or higher

6.11 Logging on the Main Unit



When the background check is completed, the logon screen is displayed on the Main Unit LCD screen.
Enter the registered logon name and password, and select the **“OK”** on the function menu of the logon screen.

Use the ◆ and ◆ keys to changeover the input parameter.
By executing logon, the menu corresponded to the permission set at the Information Processing Unit (IPU) will become executable. See “Chapter 5: Instrument Setup” in the Software Guide.

6.12 Auto output settings check

If Auto Output is desired, before starting an analysis, make sure that the instrument is set to automatically transmit/print. See “Chapter 5: Instrument Setup” in the Software Guide.

6.13 Quality control

Quality control ensures the reliability of the instrument and reagents. QC will be used for long-term monitoring of the stability of analysis values. It can also detect problems early, or prevent them entirely.
Always run the quality control before analyzing samples. For details, see “Chapter 7: Quality Control”.

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6.14 Conditions for sample analysis

Sample types

Venous Blood and body fluids.
If using micro collection systems, follow the manufacturer package inserts and use relevant standards for collecting small samples.

Collection conditions

Blood is collected in EDTA anticoagulant. Analyze samples within 4 hours of collection.
If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2-8°C until it can be analyzed.
Return a refrigerated sample to room temperature before analyzing it (for at least 15 minutes). Next, mix the sample for at least 2 minutes.

Note:
All performance claims given in this manual were generated using samples in EDTA anticoagulant. Results may be affected by the use of other anticoagulants. Therefore, each laboratory should develop protocols for handling samples collected in these anticoagulants.

6.15 Analysis mode

With the XE-5000, the analysis can be performed in six modes: manual, HPC, body fluid, capillary, sampler and manual closed modes.

- Manual, HPC and body fluid modes
  In these modes, the caps of sample tubes are manually removed and each sample is aspirated via the whole blood aspiration pipette.

- Capillary mode
  In capillary mode, an analysis is performed after diluting the sample to 1:5 ratio. This mode is used in analyzing a minute amount of blood collected from the earlobe or fingertip. The method used to aspirate the sample is the same as that used in manual, HPC and body fluid modes.

- Sampler mode
  The sampler automatically mixes, aspirates and analyzes samples without removing their caps. Up to 100 samples can be loaded at a time and analyzed automatically.

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- Manual closed mode
  In manual closed mode, the sampler is used to aspirate the sample, without opening the cap of the sample tube. This mode is basically the same as manual, HPC and body fluid modes; mixing and continuous analysis can not be performed automatically.

Note:
HPC analysis and body fluid analysis can only be performed in manual mode.

6.16 Preparing sample analysis

Samples

- Collect the specified amount of blood (corresponding to the amount of EDTA anticoagulant).
- Using CELLPACK dispensed ahead of time, dilute the sample to a 1:5 ratio for capillary mode.
- Sample volumes
  Manual, capillary and manual closed mode

Analysis mode	Manual	Capillary	Manual Closed
Required Sample	1.0 mL or more	40 µL or more	1.0 mL or more
Aspirated Sample	Approx. 130 µL	Approx. 130 µL	Approx. 200 µL

HPC analysis and Body fluid analysis

Analysis mode	HPC	Body fluid
Required Sample	1.0 mL or more	500 µL or more
Aspirated Sample	Approx. 130 µL	Approx. 130 µL

Sampler mode

	Diameter of Sample Tube	
	12 mm	15 mm
Required Sample	1.0 to 5 mL	1.0 to 7 mL
Aspirated Sample	200 µL	

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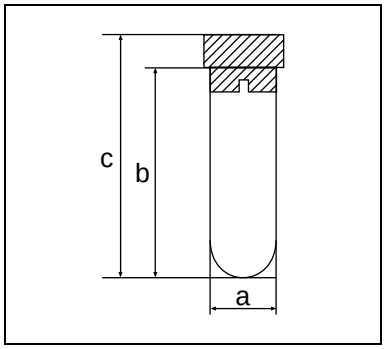
Sample tubes

- For manual mode analysis, the length of the sample tube should be 75 mm or shorter.
- Use the type of vacuum sampling tube shown below for sampler analysis and manual closed analysis.



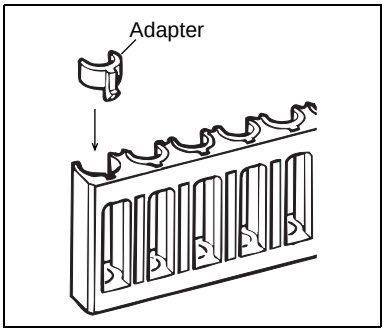
Diameter (a)	12-15 mm
Length (b)	75 mm or shorter
Length including cap (c)	82 mm or shorter

Examples of suitable tubes
- VENOJECT II (TERUMO)
- Hemoguard (BD)
- VACUETTE (greiner)
- Monovette (SARSTEDT)

Do not use reusable caps.

Note:
When VENOJECT II blood collection tube is used, a stopper No. 167 (367-2309-1) is required. For details, contact your Sysmex technical representative.

Sample tube adapters



If tubes have diameters of less than 14 mm, attach adapters to the rack.

Diameter of Sample Tube	Adapter
12 mm	Adapter No. 58
13 mm	Adapter No. 56
14 mm	None
15 mm	None

Affix a barcode label

Make sure that the label is in the proper location so that the barcode can be correctly read. Affix the barcode label as shown in the figure below.
Also, when setting a sample tube in the rack, make sure that all of the barcodes can be seen through the rack slits.
The rack number barcode labels come in 2 sheets as a set. So, affix another barcode label on the side face of the rack.

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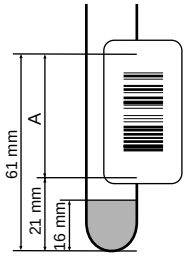
Sample Tube

(Sample ID number bar code label)

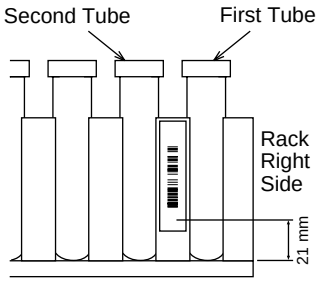


Affix label so that bar code enters range indicated by A.

Area for blood volume sensor (Do not affix bar code label here.)

Rack

(Rack number bar code label)



Affix the rack label between the first and the second tubes, aligning to the top of the rack.

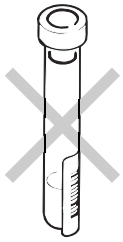
Warning!

Affix the barcode label so that the bars on the label are horizontal when the rack is placed on the sampler. If the barcode label is affixed slanted, the potential of the misreading of the barcode label will be increased.

Caution!

- Sample tubes with multiple labels, or labels which are not flat and smooth against the tube, may cause interference with sampling. The sampler is likely to jam, and in extreme circumstances, the sampler may not be able to properly release the tube back into its original rack position. This could result in sample misidentification.

  To prevent this occurrence, it is recommended to:
  - Affix labels in the correct position;
  - Place no more than two labels on the sample tube;
  - Assure labels are flat and smooth against the tube, without creases or flaring;
  - Assure label does not peel off the tube;
  - Sample tubes with barcode labels affixed must slide smoothly in and out of the racks.



Information

- Affix the rack number barcode label in line with the sample tube barcode label.
- If the barcode is affixed in the area for the blood volume sensor, the volume of sample cannot be accurately monitored.
- The barcode label must never protrude beyond the bottom of the sample tube. If it does, the sample tube may be picked up incorrectly, and the instrument could be damaged.

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Sample number input

- You can enter up to 15 alphanumeric characters and hyphens for the Sample ID number.
- When using alphabetic characters in sample ID number setting, press **NUM./ALPH.** key to change to the alphabetic input mode.
  (Each time you press the **NUM./ALPH.** key, the input mode will change in the following order. “Numerical ”→ “Uppercase alphabetic” → “Lowercase alphabetic”.)
  Examples are given below:
  Ex. 1: For “SYSMEX” **[1]**, **[1]**, **[1]**, **[3]**, **[3]**, **[3]**, **[1]**, **[1]**, **[1]**, **[6]**, **[9]**, **[9]**, **[3]**, **[3]**
  Ex.2: For “ABC” **[8]**,**[****]**,**[8]**,**[8]**,**[****]**,**[8]**, **[8]**,**[8]**,
  (If separators are required, press the key).
  Ex.3: For “No-” **[6]**, **[6]**, **[NUM./ALPH.]**, **[6]**, **[6]**, **[6]**, **[NUM./ALPH.]**, **[-/.]**
  (It is possible to change the input mode during input).
- When a sample ID number includes alphabetic characters or a hyphen, the digits after the first alphabet or hyphen as counted from the numerical last digit are added automatically.
  (1A-B98 is followed by 1A-B99 and 1A-B00.)
- Rack number and tube position number can consist of numerals only.
- Rack numbers (RACK NO.) increase by 1 as each new rack arrives at the analysis line.
- The blood sample tube position number (TUBE POS. NO.) shows the location of the tube on the rack.
  Because the initial value is 1, this setting is not needed when beginning the analysis with the sample on the far left of the rack.

Information

Do not use zero as the sample ID number since the result will not be stored. If the ID number is set to zero, the short beep sounds during aspiration.

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6.17 Sample analysis in manual mode

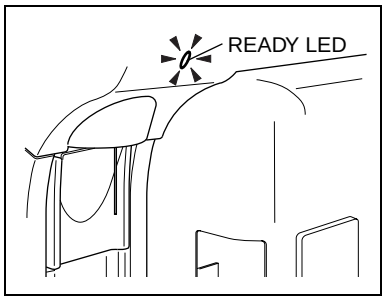
Risk of infection

When analyzing samples, be sure to wear gloves. After completion of the analysis, be sure to wash your hands with disinfectant.

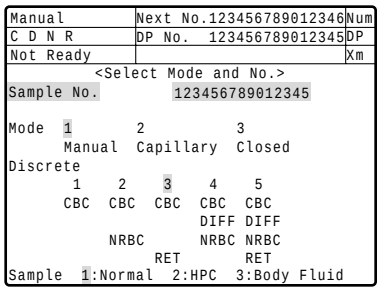
If your hands or body are contaminated by blood, etc., you might be infected by pathogen, etc.

Note:

Refer to “Chapter 6: 6.23 HPC analysis” when performing HPC analysis, and to “Chapter 6: 6.24 Body fluid analysis” when performing body fluid analysis.



1. Make sure that the instrument is in READY status. The READY LED should be lit.
2. Press the **MANUAL** key on the Main Unit panel keypad. The Sample No. Setting screen will appear on the LCD.



3. Using the numeric keys, input the sample ID number. Or, read the barcode using a handheld barcode scanner (option).
4. When analysis mode is not set in manual mode, press the ◆ key and change the set item to “Mode”. Then using the ◆ and ◆ keys, set the manual mode.
5. Check the discrete setting, and if necessary, press ◆ key to change the set item to “Discrete”. Then using the ◆ and ◆ keys, set the discrete.
6. Use the ◆ key to change the setting parameter to “Sample”, then use the ◆ and ◆ keys to set to Normal.
7. After all the settings are completed, press the **ENTER** key to confirm.

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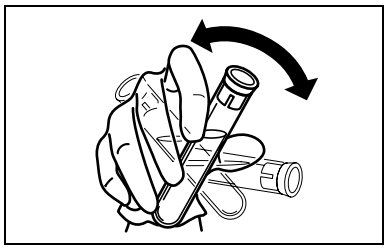
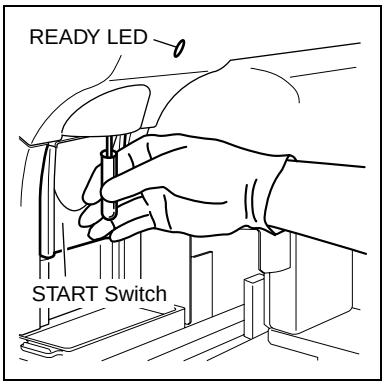


8. Mix the sample tube thoroughly by inverting the tube.



9. Remove the cap carefully in order not to splash the blood.
10. Hold the sample tube under the manual aspiration pipette so that the tip of the pipette is at the bottom of the sample tube; then press the START switch.
    Do not remove the sample tube while the READY LED is blinking; the sample is being aspirated.
11. After the READY LED turns off (and a short beep sounds two times), remove the sample tube.

Caution!
To remove the sample tube, pull straight down to prevent bending the manual aspiration pipette. Otherwise the blood may scatter.

Note:
The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

12. When the READY LED turns on again, prepare the next sample and repeat steps 8 - 11.

Information
If a message calling for reagent replacement is displayed during analysis, replace with new reagent. If the replace reagent sequence is executed when reagent amount is insufficient, bubbles may occur, resulting in higher background value.

Revised July 2007

Note:
- If sample ID number is not set, they are automatically assigned sequentially. (Automatic increment function)
- When settings are made as shown below, analysis order, etc. are inquired after the input of the sample ID number.
  Real time Request (Manual Mode)
  [Sample ID]
- When the sample ID number is incremented automatically for each analysis, the analysis order and patient information are not inquired.

6.18 Sample analysis in capillary mode

Risk of infection

When preparing a sample for capillary analysis, and when analyzing a sample, be sure to wear gloves. After completion of the analysis, be sure to wash your hands with disinfectant.
If your hands or body are contaminated by blood, etc., you might be infected by pathogen, etc.

Preparing 1:5 dilution of the sample

Caution!

Prepare and analyze the 1:5 diluted sample as soon as possible after blood dispensing and dilution to minimize platelet agglutination. Also, if diluent is dispensed ahead of time, measurement errors are generated because of evaporation and contamination; therefore, prepare new diluted sample each time an analysis is performed.

Prepare 1:5 diluted sample using the following materials.
- Diluent (CELLPACK)
- Microtube (MT-40, etc.)
- Pipette [40 µL] (SMI Micro Pettor 40 µL, Type 1058-D40 etc.)
- Pipette [160 µL] (SMI Micro Pettor 50-250 µL, Type 1200-J etc.)
- Diluent dispensing container (mayer, beaker, etc.)
- Diluent dispensing equipment (injector, etc.)

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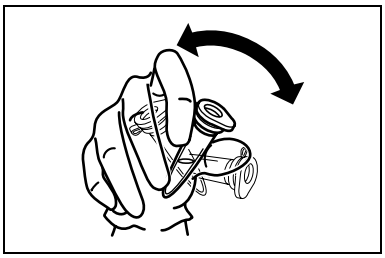
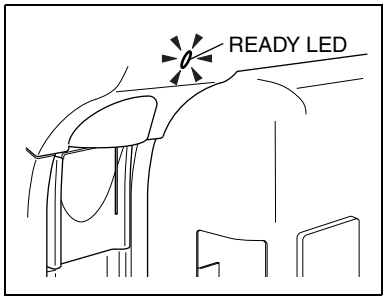
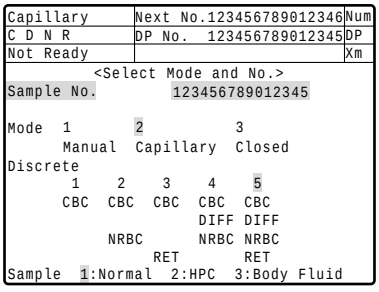
1. Rinse a diluent dispensing container (mayer, beaker, etc.) with CELLPACK to remove dust, etc.
2. Dispense CELLPACK into the diluent dispensing container.
3. Use a pipette (160 µL) to dispense 160 µL of CELLPACK into a microtube.
4. Use a pipette (40 µL) to dispense 40 µL of blood into a microtube.
5. Cap and mix the microtube well.



Sample analysis





1. Make sure that the instrument is in READY status. The READY LED should be lit.
2. Press the **MANUAL** key on the Main Unit panel keypad. The Sample No. Setting screen will appear on the LCD.
3. Using the numeric keys, input the sample ID number. Or, read the barcode using a handheld barcode scanner (option).
4. When analysis mode is not set in capillary mode, press the ◆ key and change the set item to “Mode”. Then using the ◆ and ◆ keys to set the capillary mode.
5. Check the discrete setting, and if necessary, press ◆ key to change the set item to “Discrete”. Then using the ◆ and ◆ keys, set the discrete.
6. After all the settings are completed, press the **ENTER** key to confirm.

Information

- HPC analysis and body fluid analysis are not possible in capillary mode.
- Interpretative Messages like Blasts?, Immature Granulocytes?, Left Shift?, Atypical Lymphocytes?, Abnormal Lymph/L-Blasts?, RBC-Lyse resistance?, and most of the RBC- and PLT interpretative messages are not displayed upon analysis in capillary mode.

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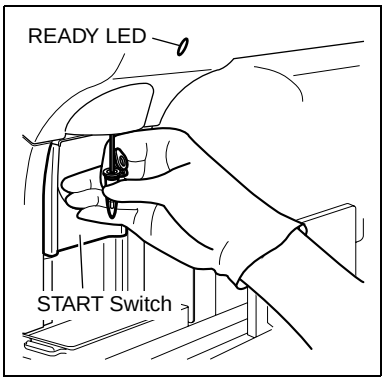


7. Remove the cap carefully in order not to splash the blood.
8. Hold the sample tube under the manual aspiration pipette so that the tip of the pipette is at the bottom of the sample tube; then press the START switch.
   Do not remove the microtube while the READY LED is blinking; sample is being aspirated.
9. After the READY LED turns off (and a short beep sounds two times), remove the microtube.

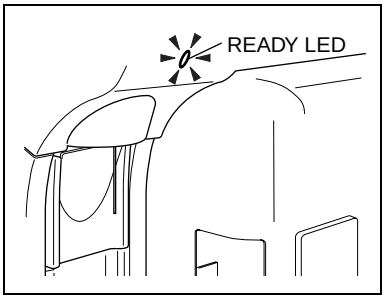
Caution!
To remove the microtube, pull straight down to prevent bending the manual aspiration pipette.
Otherwise the blood may scatter.

Note:
The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

10. When the READY LED turns on again, prepare a next sample and repeat steps 7-9.

Note:
- If sample ID number is not set, they are automatically assigned sequentially. (Automatic increment function)
- For the parameters that can be analyzed in capillary mode, see “Chapter 1: 1.3 Measurement parameters”.
- IMI channel analysis is not performed in capillary mode.

6.19 Sample analysis in sampler mode



1. Make sure that the instrument is in READY status.
   The READY LED should be lit.
2. Press the **SAMPLER** key on the Main Unit panel keypad.
   The Sampler Setting screen will appear on the LCD.

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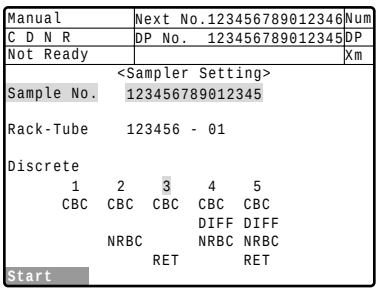
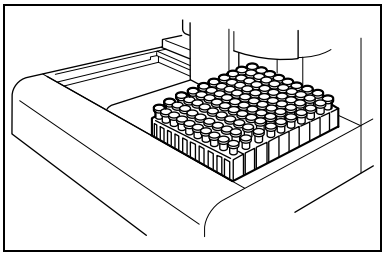


3. Using the numeric keys, input the sample ID number.
4. Check the first sample rack number and tube position number. If it is necessary to change them, press the ◆ key to change the set item; then input the numeral.
5. Check the discrete setting, and if necessary, press ◆ key to change the set item to “Discrete”. Then using the ◆ and ◆ keys, set the discrete.



6. Put the sample tubes in the rack, and set the rack in the right rack pool of the sampler.
   Up to 10 sample racks can be loaded at a time.

Caution!
If a sample is left in a stable condition for more than 4 hours and its blood cell and plasma are separated, correct analysis results may not be obtained due to insufficient mixing. Therefore, in case of analyzing such samples, make sure to mix the samples thoroughly before setting them on the sampler.

7. From the Sampler Setting screen, select **“Start”** on the function menu or press the **SAMPLER** key again. The sampler analysis will start.

Caution!
- Do not touch or remove the cover of the CP Unit during the sampler is in operation.
  You could be injured by the mechanical parts.
  (If the cover is opened, analysis will be interrupted by the monitoring switch.)
- Do not manually push (or move) the sample rack forward during sampler analysis.
  There is a small possibility that sample numbers and analysis results could become misaligned.
- Do not touch the rack on the analysis line during sampler analysis.
- Make sure there is no dirt or foreign substance on the bottom of the rack. Also make sure there is no breakage or deformation of the rack.

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Information

- When the manual closed mode is selected, it is impossible to perform sampler analysis. To carry out the sampler analysis, select the manual mode.
- After sample No. or rack No. is input, move the cursor to the tube position. Otherwise, it is impossible to start the sampler analysis. Once the cursor is moved, the sampler analysis can be started even when the cursor is not at the tube position.
- HPC analysis and body fluid analysis are not possible in sampler mode.

Note:

When the SAMPLER key is pressed during sampler analysis, the sampler stops and STAT analysis (manual or capillary analysis) can be performed.

8. When all of the racks have moved to the left rack pool of the sampler, the READY LED turns on.

STAT analysis in sampler mode

1. Press the **SAMPLER** key to interrupt the sampler analysis. “STAT” appears at the upper left of the LCD screen. When the sampler analysis is interrupted and the message “STAT READY” appears at the upper left of the LCD screen, manual/capillary analysis can be performed.
2. Press the **MANUAL** key and input the sample ID number for the STAT analysis. Or, read the barcode using a handheld barcode scanner (option).
3. Analyze a sample in the same procedure as with ordinary analysis.
4. After the STAT analysis is completed, the message “STAT READY” will appear at the upper left of the LCD screen again; press the **SAMPLER** key. The message “SAMPLER MODE” will appear on the LCD screen, and sampler analysis will resume.

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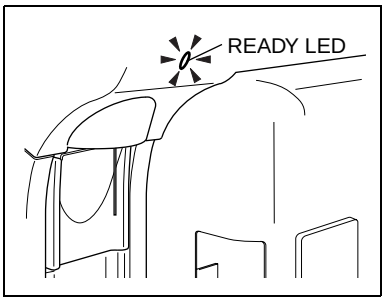
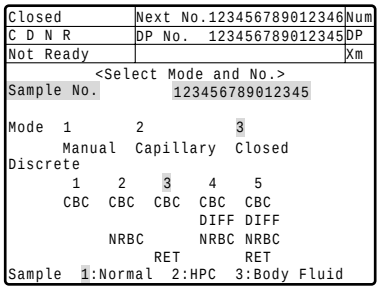
6.20 Sample analysis in manual closed mode



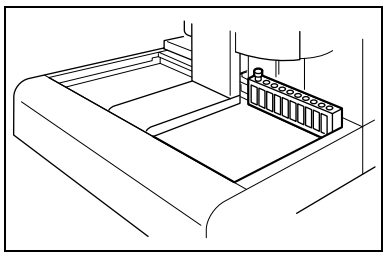
1. Make sure that the instrument is in READY status. The READY LED should be lit.
2. Press the **MANUAL** key on the Main Unit panel keypad. The Sample No. Setting screen will appear on the LCD.



3. Using the numeric keys, input the sample ID number. Or, read the barcode using a handheld barcode scanner (option).
4. When analysis mode is not set in closed mode, press the ◆ key and change the set item to “Mode.” Then using the ▲ and ▼ keys, set the closed mode.
5. Check the discrete setting, and if necessary, press ◆ key to change the set item to “Discrete.” Then using the ▲ and ▼ keys, set the discrete.
6. Use the ◆ key to change the setting parameter to “Sample”, then use the ▲ and ▼ keys to set to Normal.
7. After all the settings are completed, press the **ENTER** key to confirm.
8. Mix the sample thoroughly by inverting the tube; then insert it into the far left position of the rack (tube position No. 1).

Information

- In manual closed mode, a sample is not mixed automatically. Be sure to perform mixing manually before analysis.
- HPC analysis and body fluid analysis are not possible in manual closed mode.



9. Set the rack at the rightmost position of the analysis line in the sampler’s right rack pool.
10. Press the START switch to start the analysis. The rack is transferred to the aspiration point, and aspiration and analysis are performed automatically.

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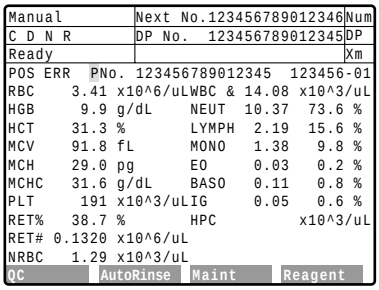
Caution!
Do not touch or remove the cover of the CP Unit during sampler analysis.
You could be injured by the mechanical parts.
(If the cover is opened, analysis will be interrupted by the monitoring switch.)

11. When the READY LED is lit, remove the remaining rack in the analysis line, prepare the next samples, and repeat the steps 8-10.

Information
If a message calling for reagent replacement is displayed during analysis, replace with new reagent. If the replace reagent sequence is executed when reagent amount is insufficient, bubbles may occur, resulting in higher background value.

6.21 Display analysis results

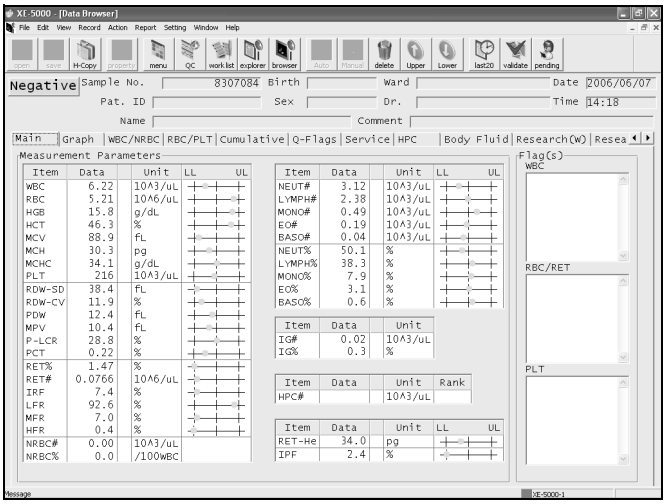


The analysis results – numeral information of latest samples - can be displayed on the Main Menu screen of the Main Unit LCD.
The Main Menu screen is made up of five pages that can be switched using ⊖ and ⊖ keys.

Caution!
- The Positive/Negative display is intended for use only in the clinical laboratory and are not for patient diagnosis.
- POSITIVE or ERROR judgments indicate the possibility of sample abnormality. Such results should be reviewed carefully and may require further examination in accordance with the protocol of your laboratory.

Revised April 2007

The Data Browser screen on the IPU displays details of analysis results.
For the display selection method and the display content, see “Chapter 3: Stored Samples (Explorer)” and “Chapter 4: Data Browser” in the Software Guide.



6.22 Analysis result output

If automatic output has been set up, the analysis results will be sent to the Graphic Printer, Data Printer and/or Host Computer.
If automatic output has not been set up, the operator must select the data and destination for output. See “Chapter 3: Stored Samples (Explorer)” in the Software Guide.

Information
Analysis results in body fluid analysis mode cannot be validated automatically, so they are not subject to automatic output, regardless of the setting.

Revised April 2007

6.23 HPC analysis

Summary of HPC analysis

Intended Use: The HPC (hematopoietic progenitor cell) parameter on the IMI Channel on the Sysmex XE-5000 for in vitro diagnostics is used as a screen for the optimal presence of hematopoietic progenitor cells in peripheral blood and cord blood samples.

Information

Please take into consideration the clinical picture when using the HPC parameter.
The clinician must make the final judgment in the use of the HPC results.

Specimen type

Peripheral blood (PB)
Umbilical cord blood (UCB)

Analysis parameters

HPC#: The count of cells appearing in the Hematopoietic Progenitor Cell (HPC) area of the IMI channel. The sample type is peripheral blood collected from PBSCT (peripheral blood stem cell harvesting) patients.

Anticoagulants

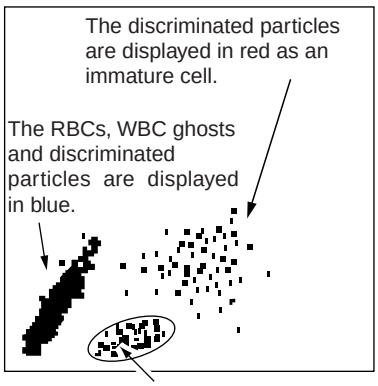
EDTA (Studies were performed on EDTA-3K)

Environment temperature

20 – 30ºC

Revised April 2007

HPC analysis mode



When cord blood or peripheral blood are analyzed in HPC analysis mode, the HPC# is displayed.

Information
When leukemia samples are analyzed, cells other than HPC may appear in the HPC area.

Note:
The HPC detection area exists as a special area on the IMI scattergram.

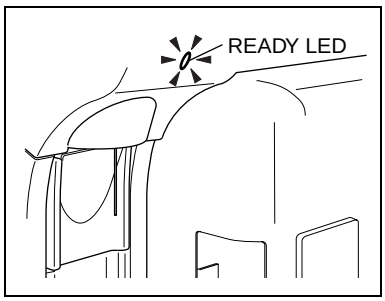
Sample analysis in HPC analysis mode

The HPC mode needs to be selected on the Main Unit, prior to performing the HPC analysis. The method for selecting HPC analysis mode and performing the analysis is explained below.

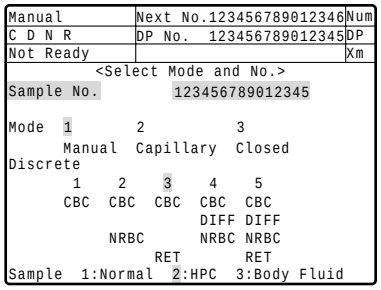
Risk of infection
When analyzing samples, be sure to wear gloves. After completion of the analysis, be sure to wash your hands with disinfectant.
If your hands or body are contaminated by blood, etc., you might be infected by pathogen, etc.

Information
- Samples should be measured immediately after being drawn.
- Prior to sample analysis, ensure that the white blood cell (WBC) concentration is no greater than the linearity limit stated in this manual. The HPC result can be used if it is within the HPC linearity limit.

Revised April 2007



1. Make sure that the instrument is in READY status. The READY LED should be lit.
2. Press the **MANUAL** key on the Main Unit panel keypad. The Manual Sample No. Setting screen will appear on the LCD.



3. Using the numeric keys, input the sample ID number. Or, read the barcode using a handheld barcode scanner (option).
4. When analysis mode is not set in manual mode, press the ◆ key and change the set item to “Mode.” Then using the ◆ and ◆ keys, set the manual mode.

> **Information**
> HPC analysis is only performed in manual mode. It cannot be performed in sampler, capillary or manual closed modes.

5. Use the ◆ key to change the setting parameter to Discrete, then use the ◆ and ◆ keys to set to any of the following.
   4 CBC+DIFF+NRBC
   5 CBC+DIFF+NRBC+RET

> **Information**
> The IMI detector is used for HPC analysis. HPC analysis is not possible if the discrete setting does not include DIFF analysis.

6. Use the ◆ key to change the setting parameter to “Sample”, then use the ◆ and ◆ keys to set to HPC.
7. After all the settings are completed, press the **ENTER** key. The analysis preparation sequence is performed.

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Information

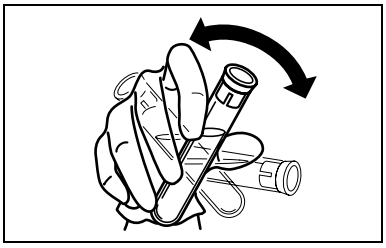
- If the analysis order is already complete, and HPC analysis mode is set, HPC analysis is performed regardless of the results of the analysis order.
- The basic analysis procedure is the same as that for normal mode, but HPC analysis requires preparation of the IMI detector, and of the reaction system for the reagents. The analysis preparation sequence is performed automatically. The time taken to complete the analysis preparation sequence varies according to the installation environment, but does not exceed approximately four minutes.
- In HPC analysis mode, analysis ready status is maintained for approximately three minutes from the last operation. If the Main Unit performs no operation during this time interval, the analysis preparation sequence will start automatically before the next sample analysis.
- Use the reset sequence to return from HPC analysis mode to normal mode. The time taken to complete the sequence varies according to the installation environment.

Note:

The patient ID must be registered in the work list in order to display consecutive data for HPC#. Use any of the methods below to register the patient ID. For details, see “Chapter 2: Work List” in the Software Guide.

- Query the host computer for analysis information.
- Register under patient registration.

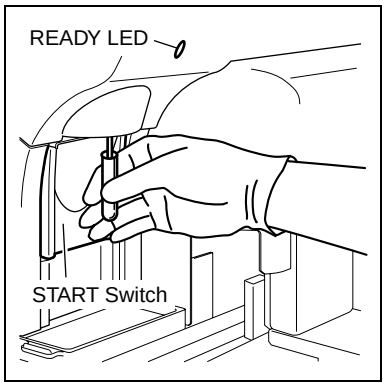
8. Once the HPC analysis preparation sequence is complete, the READY LED lights, and the Main Unit enters HPC analysis ready status.
9. Mix the sample tube thoroughly by inverting the tube.



Information

Sample should be mixed gently.

Revised April 2007



10. Remove the cap carefully in order not splash the blood.
11. Hold the sample tube under the manual aspiration pipette so that the tip of the pipette is at the bottom of the sample tube; then press the START switch.
    Do not remove the sample tube while the READY LED is blinking; sample is being aspirated.

> **Information**
> • Analysis requires an adequate sample volume. Correct analysis results cannot be obtained if the instrument does not aspirate an adequate sample volume. For required sample volumes, see “Chapter 6: 6.16 Preparing sample analysis”.

12. After the READY LED turns off (and a short beep sounds two times), remove the sample tube.

> **Caution!**
> To remove the sample tube, pull straight down to prevent bending the manual aspiration pipette. Otherwise the blood may scatter.

> **Note:**
> The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

13. Once analysis is complete, set “Sample” to “Normal” on the Sample No. Setting screen to return to normal mode.

> **Information**
> • If the value of HPC# is low, we recommend performing multiple analysis.
> • A sample to be used for any purpose other than HPC analysis should be analyzed in normal mode.
> • Abnormal judgments and sampler stop conditions do not apply to HPC#.

Display analysis results

HPC# analysis results are displayed on the main menu screen of the Main Unit LCD screen. The results are also displayed on the sample explorer and data browser screens of the Information Processing Unit (IPU).
Analysis results analyzed in HPC analysis mode are marked with an “H” to the left of the sample No. on the Main Unit LCD screen.
“H” is displayed in the analysis mode display on the sample explorer and data browser screens.

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Note:
Analysis results for HPC# are not displayed if the analysis was performed in normal mode.

The sample explorer and data browser screens display HPC rank.
HPC rank is indicated as shown below.

+++: Displayed if the conditions for “+++” indication, as set on the Rank Limit setting screen, are satisfied.
++: Displayed if the conditions for “++” indication, as set on the Rank Limit setting screen, are satisfied.
+: Displayed if the conditions for “+” indication, as set on the Rank Limit setting screen, are satisfied.
-: Displayed if none of the conditions for “+++”, “++” and “+” indication, as set on the Rank Limit setting screen, are satisfied.

For details of the display methods on the Information Processing Unit (IPU), see “Chapter 3: Stored Samples (Explorer)” and “Chapter 4: Data Browser” in the Software Guide.
See also “Chapter 5: Instrument Setup” in the Software Guide for the setting of HPC rank limits.

Information
The laboratory should perform additional testing if more specific or sensitive limitation information is needed.

Reference intervals

In normal pediatric and adult populations there is an absence to extremely low levels of HPC.
Sysmex recommends that each laboratory establish its own expected reference intervals based upon the laboratory’s patient population. The CLSI document* C28-A2 contains guidelines for determining reference intervals and intervals for quantitative laboratory tests.

* : How to Define and Determine Reference Intervals in the Clinical Laboratory;
Approved Guideline - Second Edition, CLSI document C28-A2, (ISBN P56238-269-I), CLSI (Clinical and Laboratory Standards Institute), 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 2000.

Revised April 2007

6.24 Body fluid analysis

Summary of body fluid analysis

The body fluid analysis mode of the XE-5000 uses the 4DIFF scattergram and the RBC distribution obtained from a specialized analysis sequence to calculate and display the WBC counts, mononuclear cell (MN)/ polymorphonuclear cell (PMN) counts and percentages, and RBC (RBC-BF) counts found in the body fluid.

Specimen type

Serous fluids, synovial fluids, cerebrospinal fluids (CSF) with EDTA, as needed.

> **Information**
> Since fibrin may be precipitated when measuring body fluid, add EDTA anticoagulant in the measurement as necessary.

Analysis parameters

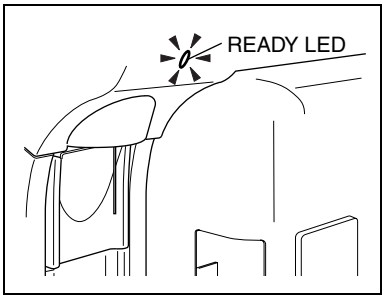
WBC-BF, RBC-BF, MN#, MN%, PMN#, PMN%

Sample analysis under body fluid analysis mode

To perform body fluid analysis, the body fluid analysis mode needs to be selected. The method for selecting body fluid analysis mode and performing the analysis is explained below.

> **Risk of infection**
> When analyzing samples, be sure to wear gloves. After completion of the analysis, be sure to wash your hands with disinfectant.
> If your hands or body are contaminated by blood, etc., you might be infected by pathogen, etc.

> **Information**
> Samples should be measured immediately after being drawn.



1. Make sure that the instrument is in READY status. The READY LED should be lit.
2. Press the **MANUAL** key on the Main Unit panel keypad. The Manual Sample No. Setting screen will appear on the LCD.

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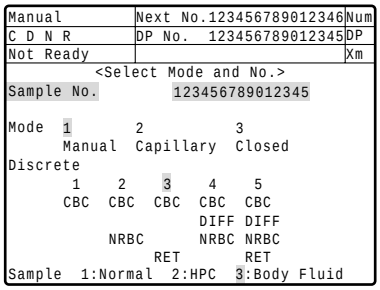

3. Using the numeric keys, input the sample ID number. Or, read the barcode using a handheld barcode scanner (option).
4. When analysis mode is not set in manual mode, press the ◆ key and change the set item to "Mode." Then using the ◆ and ◆ keys, set the manual mode.

> **Information**
> Body fluid analysis is only performed in manual mode. It cannot be performed in sampler, capillary or manual closed modes.

5. Use the ◆ key to change the setting parameter to Discrete, then use the ◆ and ◆ keys to set to any of the following.
   4 CBC+DIFF+NRBC
   5 CBC+DIFF+NRBC+RET

> **Information**
> - In body fluid analysis, the discrete setting must include DIFF analysis.
> - Whichever of the above discrete settings is chosen, it will change to CBC+DIFF when the ENTER key is pressed to confirm the input.

6. Use the ◆ key to change the setting parameter to "Sample", then use the ◆ and ◆ keys to set to Body fluid.
7. After all the settings are completed, press the **ENTER** key to confirm.

> **Information**
> When the ENTER key is pressed, the input sample number is used as the order key to query the analysis information from the work list, or from the host computer. Patient information and sample comments are acquired at that stage, but only the six parameters of WBC-BF, RBC-BF, MN#, MN%, PMN# and PMN% are analyzed, without reference to the analysis order.

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WBC-BF	0.001 [×10^3/μL]
RBC-BF	0.003 [×10^6/μL]

8. When the **ENTER** key is pressed, a background check is run at the same time. Background check analysis is repeated three times for the background check. If the background value is lower or equal to that shown in the table on the left, the background check is completed.

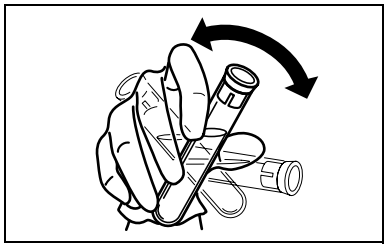
   If the background value does not become lower or equal to the specified value, the message “Background Error” will be displayed on completion of the background check.

> **Information**
> In the case of a “Background Error”, the analysis can be performed by selecting **“OK”** on the function menu. However, the measured values tend to be higher and correct results may not be obtained.

   In the case of a “Background Error”, select **“Auto Rinse”** on the function menu of the Background Check screen to perform an automatic cleaning. If the value after the automatic cleaning is not lower than the acceptable background value, “+” is displayed to the right of the value. To resolve background error, see “Chapter 10 Troubleshooting”.

> **Information**
> - The basic analysis procedure is the same as for normal mode, but for body fluid analysis it is necessary to reliably eliminate background influences. That is why the background check is performed automatically.
> - When the system is in body fluid mode, it cannot perform QC analysis or calibration. Sampler analysis and manual closed analysis are unavailable. Analysis orders will not be accepted from a transportation system (if one is connected).

9. If the result of the background check is such that the background value is lower or equal to the acceptable limit, the READY LED lights and the Main Unit enters body fluid analysis ready status.



10. Mix the contents of the test tube gently but thoroughly.

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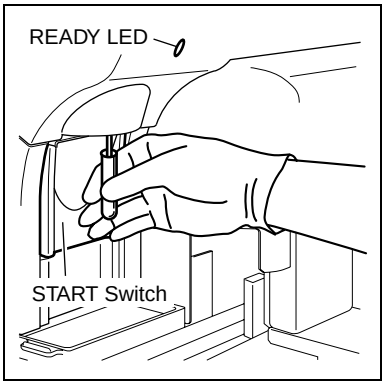
Information
Excessive mixing can break blood cells in the body fluid, making it impossible to obtain accurate results. Take care not to mix sample excessively.



11. Remove the cap carefully in order not to splash the sample.
12. Hold the test tube under the manual aspiration pipette so that the tip of the pipette is at the bottom of the sample tube; then press the START switch.
    Do not remove the test tube while the READY LED is blinking; sample is being aspirated.

Information
- Analysis requires an adequate sample volume. Correct analysis results cannot be obtained if the instrument does not aspirate an adequate sample volume. For required sample volumes, see “Chapter 6: 6.16 Preparing sample analysis”.

13. After the READY LED turns off (and a short beep sounds two times), remove the sample tube.

Caution!
To remove the sample tube, pull straight down to prevent bending the manual aspiration pipette. Otherwise the blood may scatter.

Note:
The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

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14. Once analysis is complete, set Sample to Normal on the Sample No. Setting screen to return to normal mode.

WBC-BF	1.000 [×10^3/μL]
RBC-BF	1.000 [×10^6/μL]

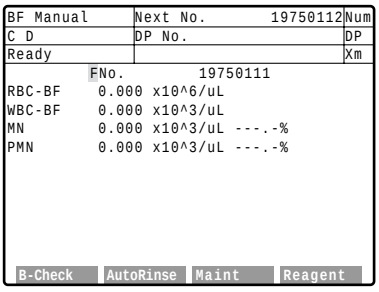
Caution!

If either of the analysis values from body fluid analysis (WBC-BF and RBC-BF) is high, there is the possibility of carryover on the analysis results for the next sample. If analysis results for WBC-BF and RBC-BF exceed the values in the table on the left, the “Execute Background check” error is displayed, asking operater to perform a background check before analyzing the next sample. Analyze the next sample after performing the background check by pressing the “B-Check” function menu on the Main Unit.
Make sure to correct the “Execute Background check” error before analyzing next sample.

Information

- Only analyze body fluid in body fluid analysis mode. Always use normal mode for analyzing human blood.
- Body fluid analysis is not compatible with negative judgment.
- Body fluid analysis results are not subject to $\overline{X}$m control.

Display analysis results



The analysis results of Body fluid analysis mode are displayed on the main menu screen of the Main Unit LCD screen. The results are also displayed on the sample explorer and data browser screens (the Body Fluid tab) of the Information Processing Unit (IPU).
Analysis samples analyzed in body fluid analysis mode are marked with an “**F**” mark to the left of the sample No. on the Main Unit LCD screen.
“**F**” is displayed in the analysis mode display column of the sample explorer and data browser screens.

Information

- Analysis results from the analysis performed without canceling an “Execute Background check” error are marked with an “**F**” mark on a red background on the IPU, and an asterisk “*” is displayed on the left of the “**F**” mark on the main unit LCD screen.
- Results analyzed in body fluid analysis mode are not subject to automatic validation, regardless of the automatic validation setting. Check the display status of the “**F**” mark and perform validation carefully.

Note:

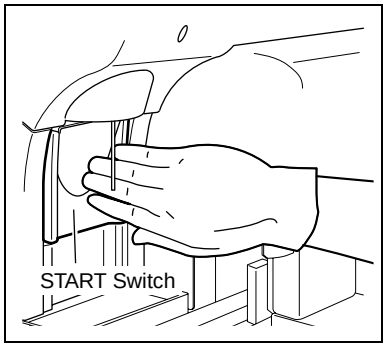
- Analysis parameter results other than WBC-BF, RBC-BF, MN#, MN%, PMN# and PMN% are not displayed, if the analysis was performed in the body fluid analysis mode.
- Even if a patient ID is attached to the analysis results obtained through body fluid analysis, the results will not be subject to the cumulative data display.

For details of the display methods on the Information Processing Unit (IPU), see “Chapter 3: Stored Samples (Explorer)” and “Chapter 4: Data Browser” in the Software Guide.

6.25 Timer processing

When timer mode is used, the Pneumatic Unit power automatically turns OFF if the Main Unit does not detect any operation within a preset amount of time. When the backlight on the LCD of the Main Unit is kept on for the specified time, brightness becomes darker in order to protect the LCD screen.
For the setting method, see “Chapter 5: Instrument Setup” in the Software Guide.

Recovery procedure



- When the start switch is pressed, the brightness of the LCD screen resets. The Pneumatic Unit also resets at the same time.
- When a numeric key on the panel keypad is pressed, the brightness of the LCD screen resets. The Pneumatic Unit also resets at the same time.

Revised April 2007

Information
As for the timer mode, the Pneumatic Unit and the LCD screen interlock.
When you press the START switch or a numeric key, both the timer modes will restart at the same time.

6.26 Shutdown

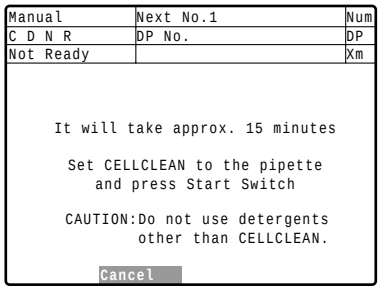
By executing shutdown, the detector and dilution lines are cleaned. Execute shutdown at the end of each day's analysis. When the instrument is used continuously, shut it down at least once every 24 hours or 500 sample analysis.

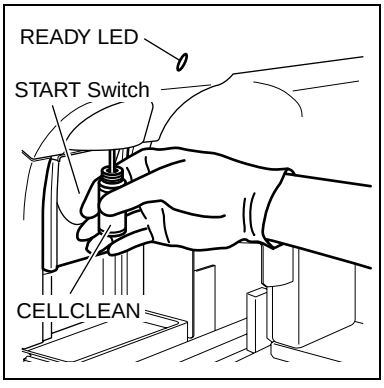
Caution!
- Be sure to execute shutdown to clean the instrument. Otherwise analysis may not be performed correctly.
- To execute shutdown, use CELLCLEAN only.

Main Unit shutdown

1. Press the **SHUTDOWN** key on the Main Unit panel keypad.
2. The shutdown screen appears on the Main Unit LCD screen.

   To cancel shutdown, press the **RETURN** key or select **"Cancel"** on the function menu of the Set CELLCLEAN Message Screen to return to Ready status.





3. Set CELLCLEAN to the manual aspiration pipette as shown in the figure; then press the START switch in that status.
   While the READY LED is blinking and the buzzer is sounding, aspiration is in progress. Keep holding CELLCLEAN in the current status.

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Warning!
CELLCLEAN is a strong alkaline detergent. Pay careful attention not to let it adhere to your body or clothes. If CELLCLEAN adheres to your body or clothes, wash it away immediately with plenty of water. Otherwise, it can damage your skin or clothes.

4. After the READY LED turns off and buzzer stops, remove the CELLCLEAN.

Caution!
When removing the CELLCLEAN container, pull it down straight not to bend the manual aspiration pipette.
Otherwise CELLCLEAN may scatter.

Note:
The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

5. The shutdown sequence in the Main Unit will start.
6. When the shutdown sequence is completed, the message “Turn OFF Main Unit” will appear.
7. If you wish to complete the analysis, turn OFF the Main Unit power in the current status.

Note:
If you wish to continue an analysis with the Main Unit left ON, select “Restart” on the function menu of the Shutdown Completion screen.
After executing an automatic rinse and background check, the system returns to the READY status.

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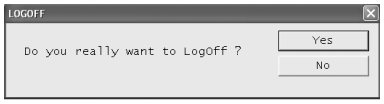
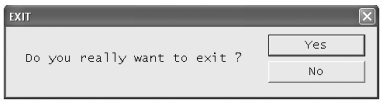
Logging off from the XE-5000 application program

To change a user, logoff from the XE-5000, and then logon again.



1. From the **"file(F)"** menu, select **"Logoff (L)"**.
2. The Logoff confirmation dialog box will be displayed.
3. Click **"Yes"** or **"No"**.
   Yes: The system will perform the Logoff procedure and the XE-5000 Logon dialog box will be displayed.
   No: Logoff procedure will be canceled.

Closing the XE-5000 application



1. To close the XE-5000 application, click on **"Close"** from the **"File (F)"** menu.
2. The Exit confirmation dialog box will be displayed.
3. Click **"Yes"** or **"No"**.
   Yes: The application will end.
   No: The application quit operation will be canceled.

Shutting down the Windows system

1. Use the mouse to click on the Start button on the task bar in the window to display the Start menu, then select **"Shutdown (U)"**.
   The dialog box for Windows shutdown will appear on the screen.
2. Select **"XE-5000 Logoff"**, then click on **"OK"** to display the Windows logon screen.
   Select **"Shut down"**, then click on **"OK"** to shut down the Information Processing Unit (IPU) and turn the power Off.
   Select **"Restart"**, then click on **"OK"** to restart the Information Processing Unit (IPU) and automatically logon to Windows as XE-5000 user after the restart is complete.
   Click on **"Cancel"** to close the Windows shutdown dialog box and return to the state which preceded its opening.
   Click on **"Help (H)"** to display the Help screen. (The Windows shutdown dialog box closes).

Caution!
- Do not turn the power OFF while attempting the shutdown preparation.
  If the power is turned OFF during this task, the data may be saved improperly and the system may get damage.
- Execute the shutdown at least once per week.
  For details, contact your Sysmex technical representative.

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7. Quality control

Quality control is performed in order to monitor an instrument's performance over time. *e*-CHECK(XE) is the quality control material recommended by Sysmex to monitor the performance of XE-5000 analyzer. As the manufacturer, our recommendation is in accordance with the CLIA standard of 2 levels of control, once everyday of instrument operation or as your laboratory policy dictates. It should be noted that for troubleshooting purposes, additional control runs may be necessary.

7.1 Quality control materials

Use control blood.
Use *e*-CHECK(XE) for the control blood.

Information
Do not use any material other than the specified control blood. The control blood is specifically tailored to the analysis technology employed by the instrument.

7.2 Quality control methods

There are two QC methods for the XE-5000, one using control blood and one using normal samples.

QC using control materials
- $\overline{X}$ control: Control blood is analyzed twice, and the mean value of the two analysis is used to evaluate analyzer performance.
- L-J control: Control blood is analyzed once and the result is used as control data.
  It can monitor changes over time.

QC using normal samples
- $\overline{X}_M$ control: This program calculates the summation average of batches of samples (usually 20) using Bull's algorithm, and plots the resulting value as control data.

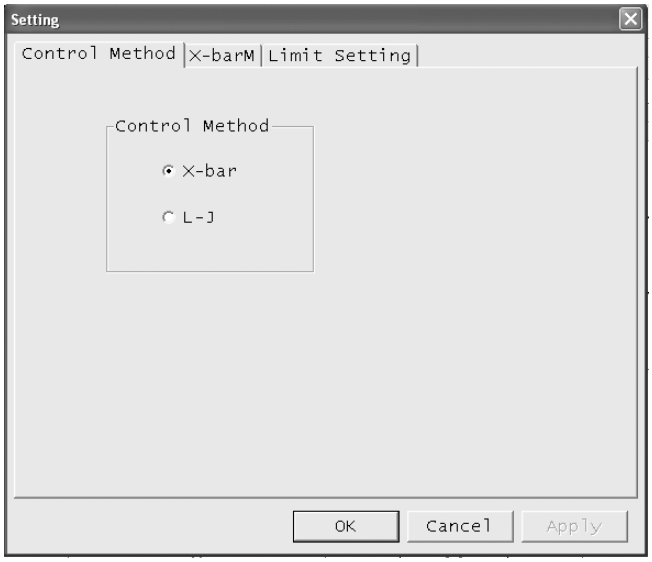
Revised June 2008

7.3 Preparation

Switch on the Information Processing Unit (IPU) and the Main Unit and wait for them to turn into the Ready status.

QC method setting

1. Start quality control from the Information Processing Unit (IPU).
2. Click the **"Setting"** button.
   The QC Setting dialog box will be displayed.
3. Click the **"Control Method"** tab.
   The Control Method screen will be displayed.



4. Click the radio button to select the Control Method.
   X-bar: This method performs two consecutive analysis of control blood, and takes the mean (average) value as control data.
   L-J: This method takes the data from a single analysis of control blood as the control data.
5. After completing settings, click on **"OK"**, **"Cancel"** or **"Apply"**.
   OK: Sets the new settings and closes the dialog box.
   Cancel: Cancels the new settings and closes the dialog box.
   Apply: Sets the new settings.

Revised April 2007

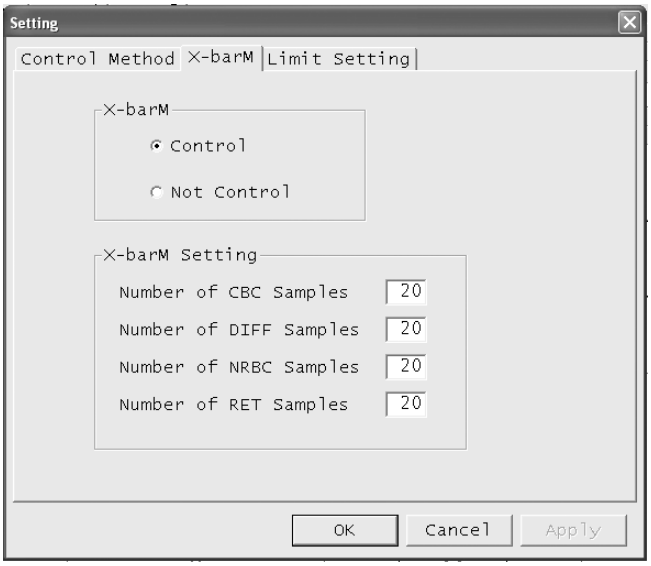
X-barM control setting

1. From the Main Menu screen on the Main Unit, select **"QC"** on the function menu.
   The QC Menu screen will appear.
2. From the QC Menu screen, select **"Xm STT/STP"** on the function menu.
   - If Xm is displayed in the upper right of the LCD screen, it indicates that $\overline{X}_M$ control is ON.
   - If Xm is not displayed in the upper right of the LCD screen, it indicates that $\overline{X}_M$ control is OFF.

> **Information**
> Even if X-barM control is canceled in this menu when "Execute X-barM control" is set in the IPU, X-barM control is executed automatically after the power is turned on again. Use the menu only when you analyze a sample in which control error may occur.

Settings for $\overline{X}_M$ control can be changed as described below.

1. Start quality control from the Information Processing Unit (IPU).
2. Click the **"Setting"** button.
   The QC Setting dialog box will be displayed.
3. Click the **"X-barM"** tab.
   The X-barM Setting screen will be displayed.

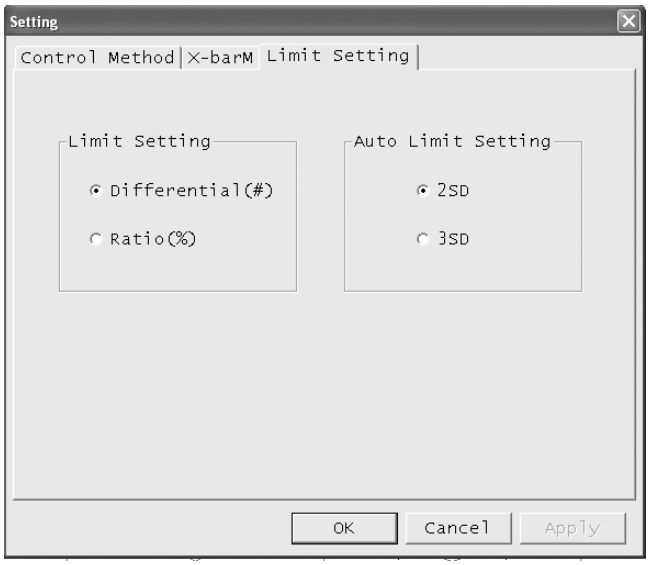


Revised April 2007

4. Perform X-barM setting.
   The setting parameters are as follows:
   X-barM: Sets whether or not to use $\overline{X}_M$ control. Click the **"Control"** radio button to use and the **"Not Control"** radio button not to use this QC.
   X-barM Setting: Sets the number of samples in a batch by discrete.
5. After completing settings, click on **"OK"**, **"Cancel"** or **"Apply"**.
   OK: Sets the new settings and closes the dialog box.
   Cancel: Cancels the new settings and closes the dialog box.
   Apply: Sets the new settings.

Limit setting

1. Start quality control from the Information Processing Unit (IPU).
2. Click the **"Setting"** button.
   The QC Setting dialog box will be displayed.
3. Click the **"Limit Setting"** tab.
   The Limit Setting screen will be displayed.



Revised April 2007

4. Perform limit setting.
   The setting parameters are as follows:
   Limit Setting: Sets the limit display method.
   "Differential (#)" is SV method which calculates the QC limit value as a numeral value with regard to the average value (TARGET).
   "Ratio (%)" is CV method which calculates the QC limit value as a percent with regard to the average value (TARGET).
   Auto Limit Setting: Sets the limit condition used to set limits automatically.
   2SD: Sets the control limit as SD × 2 (or when set, CV × 2).
   3SD: Set the control limit as SD × 3 (or when set, CV × 3).
   For information on auto limit setting, see "Chapter 7: 7.9 Target/Limit".
5. After completing settings, click on **"OK"**, **"Cancel"** or **"Apply"**.
   OK: Sets the new settings and closes the dialog box.
   Cancel: Cancels the new settings and closes the dialog box.
   Apply: Sets the new settings.

7.4 Quality control analysis

Risk of infection

When analyzing control material, be sure to wear gloves. After completion of the analysis, be sure to wash your hands with disinfectant. If your hands or body are contaminated by blood, etc., you might be infected by pathogen, etc.

Note:

$\overline{X}$ control analyzes the control material twice in succession, and the average data is used. Execute L-J, on the other hand, uses the results from one analysis as one control data.

QC analysis in manual mode

1. From the Main Menu screen on the Main Unit, select **"QC"** on the function menu.
   The QC Menu screen will appear.
2. From the QC Menu screen, select **"Exec. QC"** on the function menu.
   The QC Selection screen will appear.

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3. The QC Selection screen displays a list of the QC files. Select the file by Lot No., mode and level into which you wish to save analysis results and press **"Select"** on the function menu.
4. Analyze control blood with reference to "Chapter 6: 6.17 Sample analysis in manual mode".

QC analysis in sampler mode

"Execute L-J" can be performed in sampler mode if either a specified control sample is used or barcode labels (for QC file use) are affixed on a sample tube.

1. Prepare control blood.
2. Affix the barcode label to the correct position on the sample tube.

> **Note:**
> For instructions on how to affix barcode labels, see "Chapter 6: 6.16 Preparing sample analysis".

3. Analyze control blood with reference to "Chapter 6: 6.19 Sample analysis in sampler mode".
   After analysis is completed, the results are recorded automatically in the file designated by the barcode.

QC analysis in manual closed mode

QC analysis can be performed in closed mode if control blood is used.

1. From the Main Menu screen on the Main Unit, select **"QC"** on the function menu.
   The QC Menu screen will appear.
2. From the QC Menu screen, select **"Exec. QC"** on the function menu.
   The QC Selection screen will appear.
3. The QC Selection screen displays a list of the QC files. Select the file by Lot No., mode and level into which you wish to save analysis results and press **"Select"** on the function menu.
4. Analyze control blood with reference to "Chapter 6: 6.20 Sample analysis in manual closed mode".

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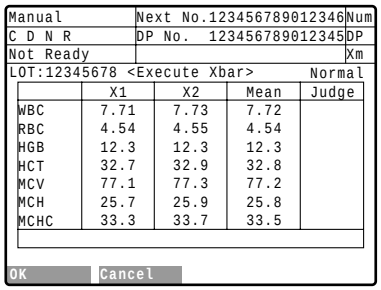
7.5 QC data display

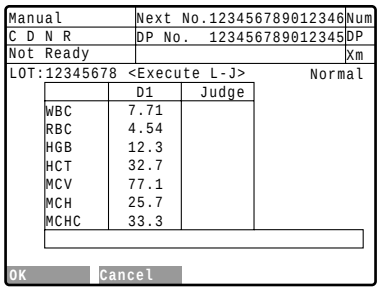
After the analysis is completed, the results are displayed. If $\overline{X}$ control is used as control data, the data in the “Mean” column is stored; in the L-J control, the latest data is stored. The control data will be stored when it is displayed on the LCD screen.


Manual | Next No.123456789012346 | Num
C D N R | DP No. 123456789012345 | DP
Not Ready | | Xm
LOT:12345678 <Execute Xbar> Normal

	X1	X2	Mean	Judge
WBC	7.71	7.73	7.72	
RBC	4.54	4.55	4.54	
HGB	12.3	12.3	12.3	
HCT	32.7	32.9	32.8	
MCV	77.1	77.3	77.2	
MCH	25.7	25.9	25.8	
MCHC	33.3	33.7	33.5	

OK Cancel

$\overline{X}$ control display


Manual | Next No.123456789012346 | Num
C D N R | DP No. 123456789012345 | DP
Not Ready | | Xm
LOT:12345678 <Execute L-J> Normal

	D1	Judge
WBC	7.71	
RBC	4.54	
HGB	12.3	
HCT	32.7	
MCV	77.1	
MCH	25.7	
MCHC	33.3	

OK Cancel

L-J control display

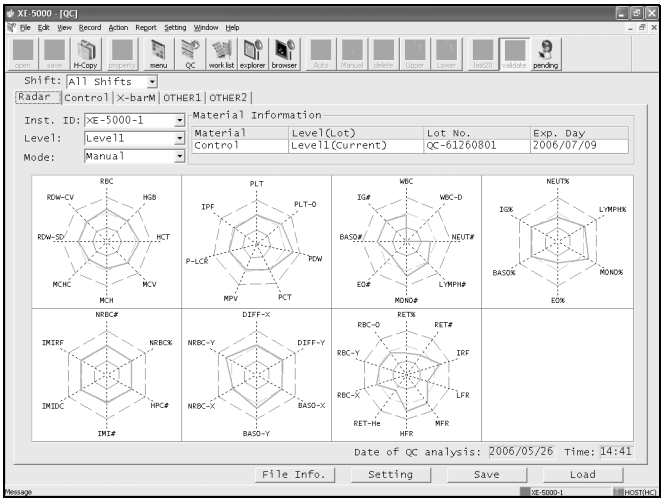
If the message “CHECK CONTROL CHART” appears in the action message column, the analyzed data has exceeded the control limit. If the message “REANALYZE CONTROL” appears, the analyzed data is more than 3 times the limit. The “+” and “-” signs in the judgment column indicate which parameters are outside the control limits and which are above or below the limits. (When analyzed data is more than 3 times the limit, “+” and “-” will be highlighted.)

Revised April 2007

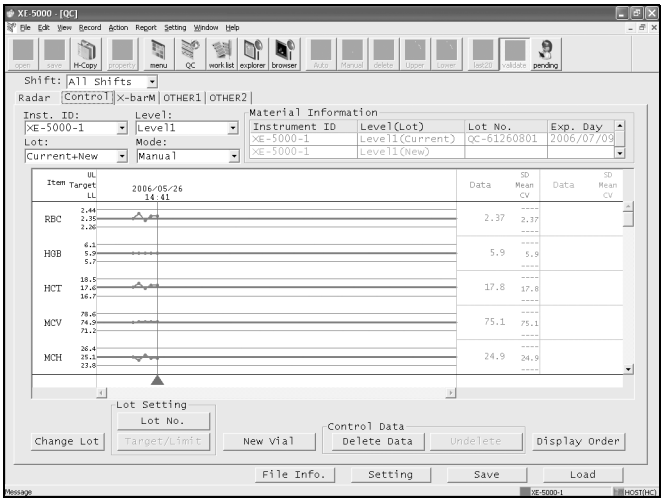
QC assessment

Detailed information on quality control can be displayed on the Information Processing Unit (IPU).

1. Start quality control from the Information Processing Unit (IPU).
   The QC Rader chart screen will appear.



2. Click the **"Control"** tab.



3. If multiple Main Units are connected, select the Main Unit which performed the quality control.
4. Select the level of the control blood displayed in the radar chart.
5. Select the lot of the control blood displayed in the radar chart.
6. Select the analysis mode of the control blood.

Revised April 2007

QC data range selection function

The QC data range selection function can be used to perform the following operations from the QC chart screen in the IPU.

- Select a range and display the Mean, SD, and CV.
- Select a range and use the data in the range to set automatic targets and automatic limits.
- Select a range and delete the data within it.
- Select a range and output the contents to the GP, LP or host computer.

Range selection procedure

Use the operations listed below to select a range on the QC chart screen.

Operation	Result
[←] key	Moves the cursor one plot to the left.
[→] key	Moves the cursor one plot to the right.
[Shift] + [←] key	Expands the selected range to the left. The cursor does not move.
[Shift] + [→] key	Expands the selected range to the right. The cursor does not move.
Mouse left click	Moves the cursor to the mouse pointer location. If an area was selected, the selection changes to a single point.
Shift + Mouse left click	Expands the selected range to the mouse pointer location. The cursor does not move.
Drag	Selects a range.
[Ctrl] + [A] key	Selects all data for the range. The cursor moves to the position of the newest data.

Deleting QC data

If there appears to be a problem with the QC analysis results, or if incorrect control blood was used, the control data can be deleted.

- To delete all control data selected with the QC data range selection function, click **"Delete Data"**.
- To cancel the delete, click **"Undelete"**.

Information

Plots that have been deleted will disappear from the display, but they are retained in internal data until the tab is changed or the QC chart screen is closed, so undo is possible.
Once the tab has been changed or the QC chart has been closed, the plots can no longer be undeleted.

Revised April 2007

Output to printers or host computer

The selected range on the Control, Other1/Other2 and X-barM charts can be output.

Graph print output

1. Use the range selection function to specify the range to print from the QC chart.
2. When **"Report (GP) (R)"** is selected from the **"Output (P)"** menu, the selected area of chart is printed as a graph. (If no range is specified, the plot at the current cursor position is printed).

Ledger print output

1. Use the range selection function to specify the control data to print from the QC chart.
2. When **"Ledger (LP) (L)"** is selected from the **"Output (P)"** menu, the selected area of the control data is printed as a ledger format. (If no range is specified, the control data at the current cursor position is printed).

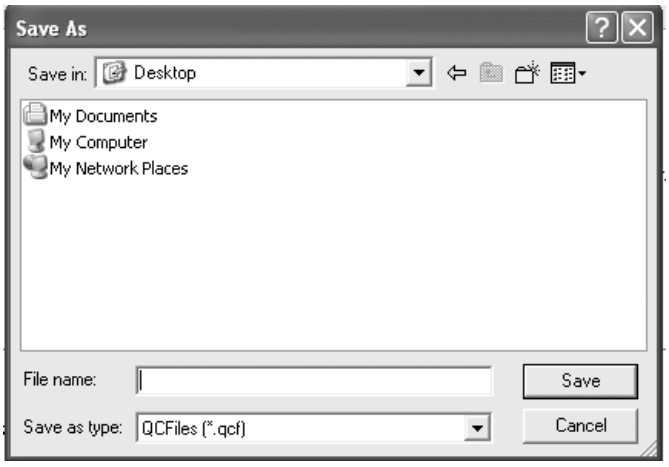
HC (Output to Host Computer)

1. Use the range selection function to specify the control data from the QC chart to output to the host computer.
2. When **"Host Computer HC(H)"** is selected from the **"Output (P)"** menu, the selected area of the control data is output to the host computer. (If no range is specified, the control data at the current cursor position is output to the host computer).

Save

Save the lot information and QC data.

1. To save the QC-files on a removable media, place a memory stick in the USB slot and select a corresponding drive (F: or higher).
2. Click the **"Save"** button.
   The Save dialog box will be displayed.



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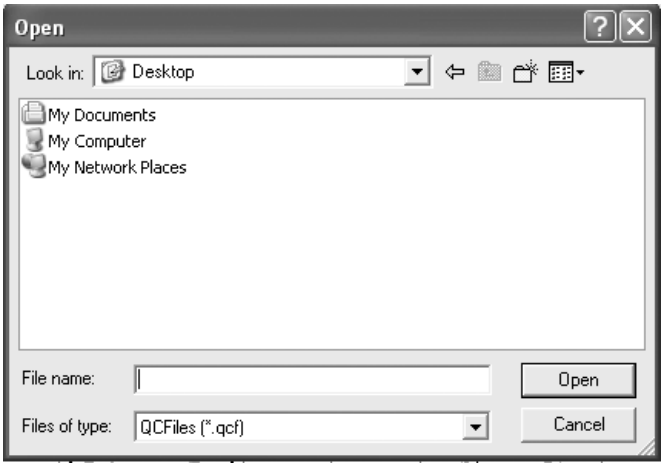
3. Input the name of the file that you wish to save.
4. Click **"Save (S)"** to save all recorded lot information and QC data under the input file name.
   Click **"Cancel"** to cancel the save.

> **Information**
> The C drive is used for system programs. Use a drive other than C for saving data.

Load

Load QC data for review of previous stored QC-files.

1. Place the USB memory stick with the QC-files (*qcf into the USB slot).
2. Click the **"Load"** button.
   The Load dialog box will be displayed.



3. Select the name of the file that you wish to load.
4. Click **"Open (O)"** to display the saved lot information and QC data.
   Click **"Cancel"** to cancel the load.

> **Information**
> - When load is executed, previously stored QC data are imported from memory stick and displayed temporarily. When the QC chart screen is closed then opened again, the current lot information and QC data will reappear.
> - When the load is executed, "Data loaded from a saved file is being displayed" message will be displayed on the QC chart screen.

Revised April 2007

7.6 Troubleshooting

This section explains actions against errors which occur during quality control analysis.

- If the message “CHECK CONTROL CHART” or “REANALYZE CONTROL” appears, check the analysis data on the LCD of the Main Unit. When **“Cancel”** is selected, the data are not sent to the IPU and the QC sample can be reanalyzed. When the **“OK”** button is selected, the data are sent to the IPU. After this, review the rader chart and note the parameters in which the error occurred. Check the detailed data on the Levy-Jennings chart (Control Tab).

Control chart definition

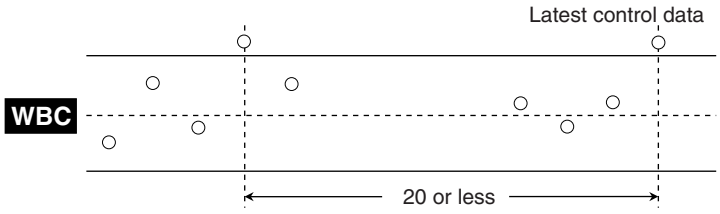
In the XE-5000, the Levy-Jennings method is used as a basic principle for reading the $\overline{X}$/L-J control chart. If the latest control data point is outside the control limits, the last 20 (including the latest) data points are searched for a point that is outside the same limit as the latest data point. If there are data beyond limits, it is judged as an L-J control (or $\overline{X}$ control) error. If there is no data outside the control limits, run the $\overline{X}$/L-J control again. If that result is within the control limits, there is no error. Naturally, if the repeat control result is outside the same limit as the previous result, the quality control is judged abnormal.

> **Note:**
> The computing method to calculate control errors in the $\overline{X}$/L-J control charts is the same as in the $\overline{X}_M$ (moving calculation) control chart.

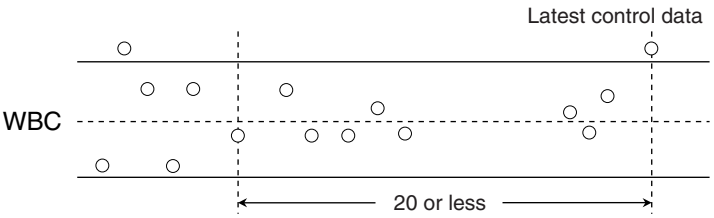
How abnormality is displayed

If the quality control is judged abnormal, the relevant parameter name appears backlit.

Example displays: Abnormality judged



Example displays: No abnormality judged



Revised June 2008

7.7 Change lot

When the change lot is executed, the QC data of the current lot are deleted, and that of the new lot are moved to the current lot file.
Click **"Change Lot"** to display the save confirmation dialog box for the current lot data.
If saving is necessary, click **"Yes (Y)"** in the save confirmation dialog box to store the data in the external storage device.

Information
When the change lot is executed, the QC data in the current lot file are lost.
When it is necessary to store, save the data to an external storage device (a USB memory stick or CD-ROM etc.), then execute the change lot.

Note:
XE-5000 manages the control lots by using two data files; the current lot and the new lot. The current lot contains the daily routine Quality Control data, and the new lot is prepared when the QC material lot is being switched to the new lot of the control material.
When the control material is to be switched to the new lot, register in the new lot the lot information by using the "Lot No." program (refer to the Section 7.8). Then, the new control material shall be temporarily run using both the current lot and the new lot. After examining a few plots or days, if there is no problem running the new control material, execute the "Change Lot" function to move the lot information of the new lot to the current lot.

7.8 Lot No.

Assay values from new lots can be imported by reading the files from CD-ROM (Read File Function) or by manual entry via the keyboard.

Note:
The files which have been set or changed in the Lot No. dialog box are recorded to the New Lot.

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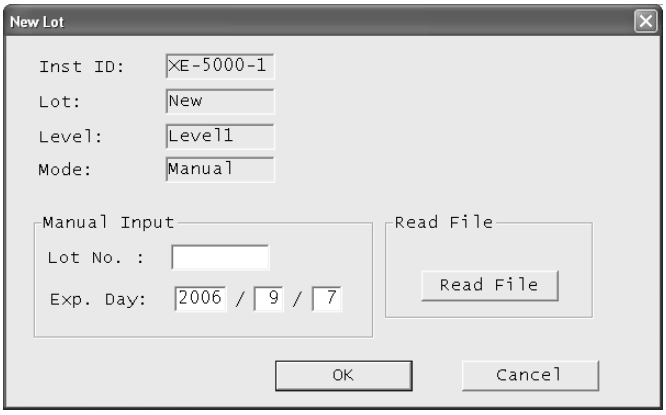
Manual entry

1. Click the **"Lot No."** button.
   The New Lot dialog box will be displayed.



2. Input lot information.
   Lot No.: Inputs the control blood lot number.
   Exp. Day: Inputs the control blood expiry date.
3. Click **"OK"** to register the input lot information and close the new lot dialog box.
   Click **"Cancel"** to cancel the register and close the new lot dialog box.

> **Information**
> Do not register a same lot No. to multiple lots.
> If a same lot No. is registered to multiple lots, data may not be plotted to the target lot.

Read file

1. Insert the CD-ROM provided with the control blood into the CD-ROM drive in the Information Processing Unit (IPU).
2. Click the **"Lot No."** button.
   The new lot dialog box will be displayed.

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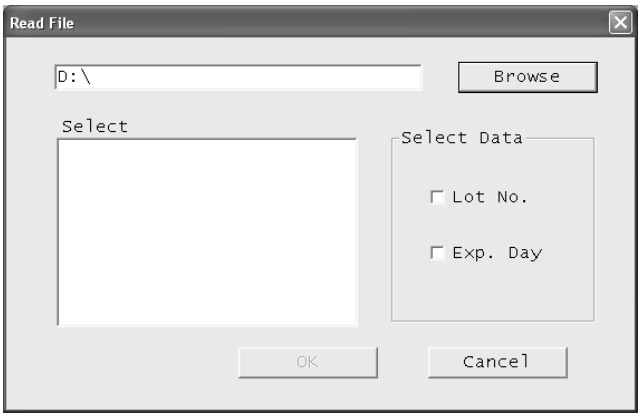
3. Click the **"Read File"** button.
   The Read File dialog box will be displayed.



4. The list of files stored on the CD-ROM for lot selection will be displayed.
   If the file location is not on a CD-ROM, click the **"Browse"** button for the folder containing the file, then select the file from the folder selection that is displayed. Select the desired file by clicking.

5. Click the radio button of the parameter you wish to read.
   Lot No.: Reads the control blood lot number.
   Exp. Day: Reads the control blood expiry date.

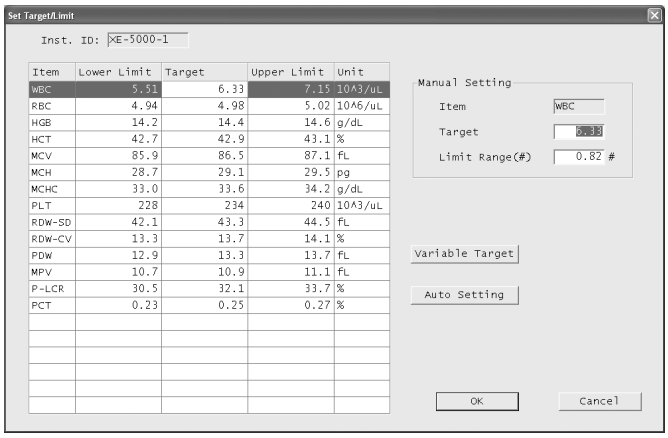
6. Click **"OK"** to execute reading and return to the new lot dialog box.
   Click **"Cancel"** to cancel reading and return to the new lot dialog box.

7. Click **"OK"** in the new lot dialog box to register the restored lot information and close the new lot dialog box.
   Click **"Cancel"** to cancel the record and close the new lot dialog box.

Revised April 2007

7.9 Target/Limit

Set targets and limits for the file displayed.
Click the **"Target/Limit"** button on the Control, OTHER1/ OTHER2 or X-barM chart screen to display the Set Target/ Limit dialog box.
Instrument ID and file information will be displayed in the upper section of the dialog box.



Manual setting

1. Click a parameter you wish to set in the list.
   The selected parameter will be displayed in the Manual Setting column at the upper right of the dialog box.
2. Input the setting values under **"Target, Limit range"**.
   If (%) is displayed in the limit range column, it means that the percentage form is currently used. If (#) is displayed, it means that the numerical value form is currently used.
   See "Chapter 7: 7.3: Limit setting".

Revised April 2007

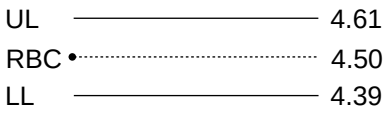
Variable target

The variable target function serves to calculate a control target value automatically from the data stored in the control file. The variable target function operates in both $\overline{X}$/L-J control and $\overline{X}_M$ when the target value is set as space.
The variable target value calculated by this function does not appear in the Set Target/Limit dialog box. It appears only in the Target column of the QC charts.

How target values are calculated
The target value calculation operation is explained in an example using an empty file (file with no control data) as follows:
In this example, the parameter selected is RBC, the target is set at 0 and the limit (%) is set at 2.3%. The limits above and below this target are calculated from the following equation. (The limit values thus obtained are rounded up. UL = upper limit, LL = lower limit.)

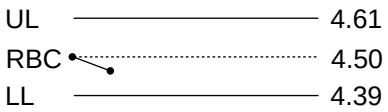
Range (UL and LL) = Target X Limit(%) / 100

N=1, UL-TARGET=0.11



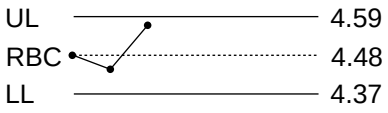
1. 4.5 million is input as the first RBC control data. The variable target will be set at 4.50, and the QC Chart will show the values in the figure on the right.

N=2, UL-TARGET=0.11



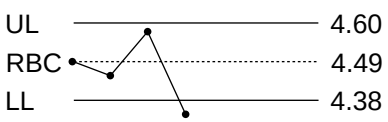
2. 4.45 million is input as the second RBC control data. The variable target remains the same, because the denominator (N-1) in the equation X/N-1 is 1 in this instance.

N=3, UL-TARGET=0.11



3. 4.52 million is input as the third RBC control data. The variable target changes to 4.48 (= (4.50 + 4.45) / 2).

N=4, UL-TARGET=0.11



4. 4.21 million is input as the fourth RBC control data. The variable target, calculated using all three of the previous control data, changes to 4.49 (= (4.50 + 4.45 + 4.52) / 3).

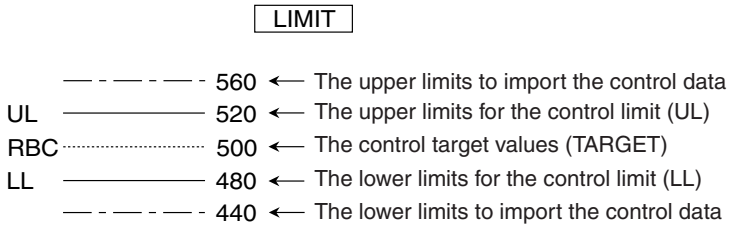
The variable target function is useful for setting control target values when the instrument is monitored using control blood (the analyzed values for which, unlike calibrator, are not reliable in an absolute sense).

Revised April 2007

Variable target function and erroneous data

In the $\overline{X}$/L-J control, there are restrictions on the import of control data into the control chart to ensure the smooth operation of the variable target function. The specific restriction is that control data beyond three times the range of the control range set in advance must not be imported.

Example:



Assume that the control limits are the values given above, with the implementation of $\overline{X}$/L-J control. If the control data is 5.21 million, the message “Check QC Chart” will be displayed, but the data can be entered on the chart. If the control data is 5.61 million however, it should not be entered on the QC Chart, and the message “Reanalyze sample” will be displayed.

Setting variable target

1. Click a parameter you wish to set in the list.

> **Information**
> - When **“Variable Target”** is selected for quality control, set the limits manually or read the assay limits from the CD-ROM.
> - When “Current + New” is selected in the Lot column, the target and limit range cannot be changed or set using the **“Target/Limit”** button (it is inactive). Select a lot you wish to change or set: “Current” or “New”.

2. Click the **“Variable Target”** button.
   The selected parameters are set for variable target. The target column of the list is left blank for parameters set for variable target .

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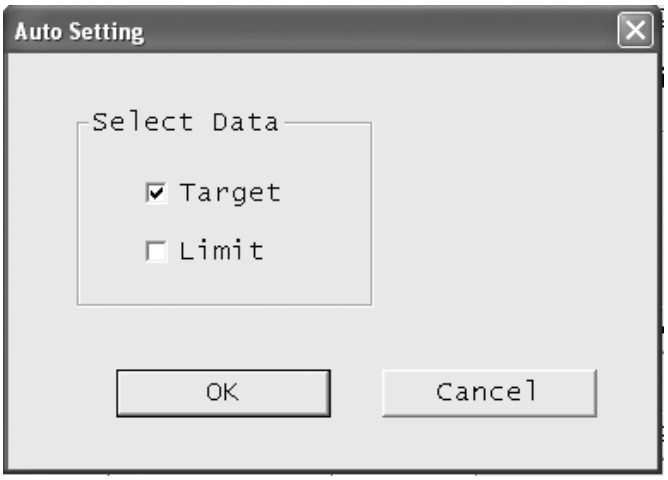
Auto setting

Information
The automatic calculation of Target/Limit according to auto setting employs the control data selected by the range selection function in the chart. (If no range is specified, it is calculated from one control data.

1. Click a parameter in the list to select.
2. Click the **"Auto Setting"** button.
   The Auto Setting dialog box will be displayed.



3. Click the **"Target"** and/or **"Limit"** check box to select.
4. Click on **"OK"** to automatically calculate the target or limit for the selected parameter, based on the control data selected with the range selection function in the chart. Click **"Cancel"** to cancel the auto calculation procedure.

Note:
Automatic calculation is executed on the basis of the limit which was set in "Chapter 7: 7.3 Limit setting".

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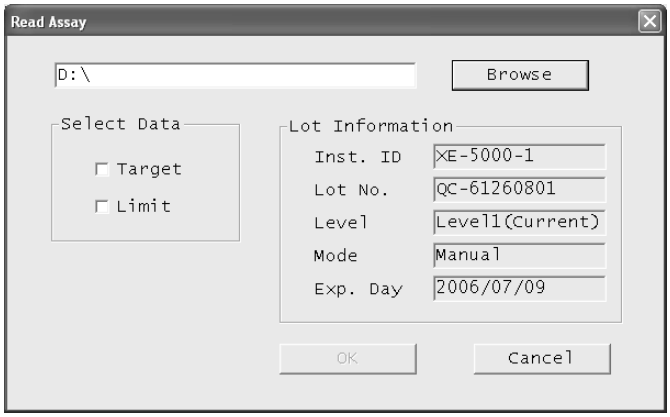
Read assay

1. Insert the CD-ROM provided with the control blood into the CD-ROM drive in the Information Processing Unit (IPU).
2. Select parameters for which you wish to read the assay value from the list. Normally select all parameters.
3. Click the **"Read assay"** button.
   The Read Assay dialog box will appear.
   The new lot information to be imported will be displayed on the right side of the dialog box.



4. Click the **"Target" and/or "Limit"** check box to select.
   If the file location is not on a CD-ROM, click on the **"Browse"** button for the folder containing the file, then select the file from the drive selection that is displayed.
5. Click **"OK"** to read the assay values for the selected data from the CD-ROM.
   Click **"Cancel"** to cancel the load.
6. Click **"File Info"** to check the entered Lot No. if desired (See "Chapter 7: 7.11 File Information").

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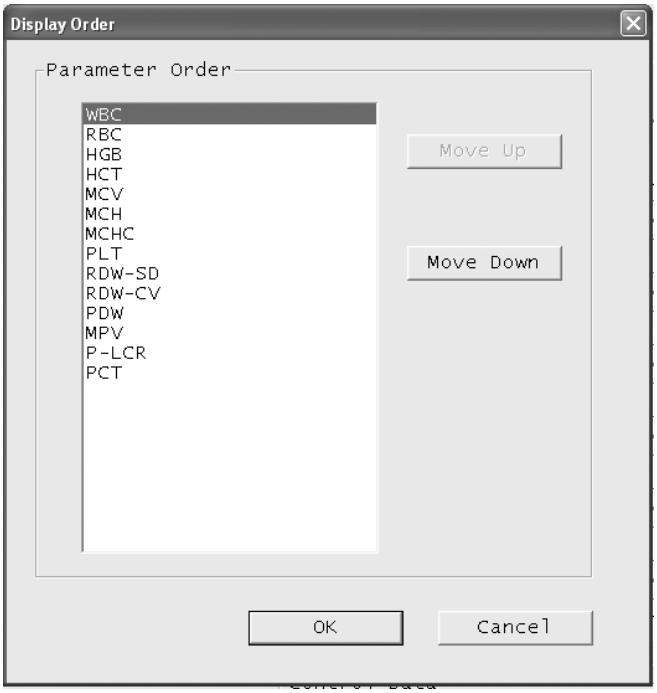
7.10 Display order

The display order of items on the QC screen can be altered.

1. Click the **Display Order** button on the Control, OTHER1/ OTHER2 or X-barM chart screen.
   The Display Order dialog box will be displayed.



2. The list will be displayed in the present order.
   Select the parameter to be changed (reordered).
3. Click the **"Move Up"** or **"Move Down"** button to change the order of the selected parameter.
   Move Up: The selected parameter scrolls up by one line.
   Move Down: The selected parameter scrolls down by one line.
4. Click **"OK"** to close the Display Order dialog box and display the chart with the altered order.
   Click **"Cancel"** to cancel the display order and close the Display Order dialog box.

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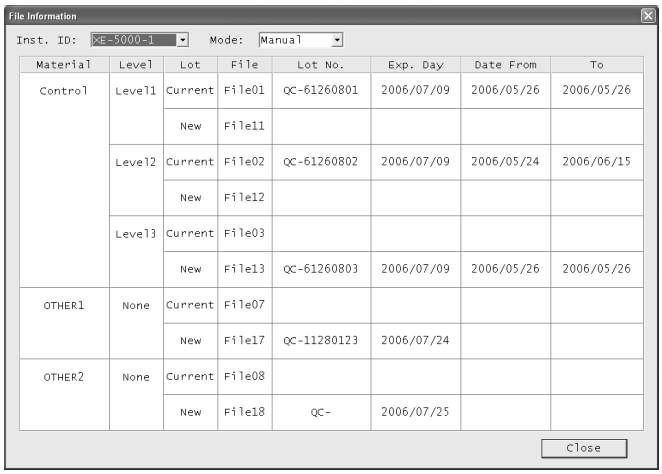
7.11 File Information

A list of the file information can be displayed according to analysis type.

1. Start quality control from the Information Processing Unit (IPU).
2. Click the **"File Info."** button.
   The QC File Information dialog box will appear.



3. When two or more Main Units are connected to one IPU, click the Inst. ID combo box and select the instrument in which you wish to display a list of file information.
4. Click the Mode combo box, and select the analysis mode in which you wish to display a list of the file information.
5. Click **"Close"** to close the dialog box.

> **Note:**
> It is impossible to change the file information on the File Information screen.
> To set or change the file information, see "Chapter 7: 7.8 Lot No.".

Revised April 2007

8. Calibration

Calibration is performed to compensate for any inaccuracies of the pneumatic, hydraulic, and electric systems which will affect analysis results. This is very important in maintaining the system accuracy.
Calibration is carried out by entering calibration values into the unit.
Your Sysmex technical representative will perform initial calibration of your unit at installation. After the installation, the operator should make periodical calibration and proper quality control to maintain the accuracy.
This chapter describes calibration procedure.

8.1 Calibration execution timing

Calibration is not required at specific intervals, but when QC data varies with time, HGB and HCT calibration should be checked. When abnormal QC data occur as a result of instrument problem, reagent degradation or degeneration of control blood, however, do not perform calibration.

8.2 Samples used for calibration

For calibration, use five to ten samples of fresh normal blood that meets the following conditions:
- Blood of a healthy person who is not taking any medicine
- Blood added with appropriate anticoagulant
- Per-sample whole blood to exceed 2 mL
- HGB value to exceed 10.0 g/dL
- HCT value to be within 35.5% – 55.5%

Note:
Do not use control blood for calibration. Control blood is specially produced for the purpose of quality control, not for calibration.

8.3 Reference values

Five or more normal blood samples selected for calibration of HGB and HCT should be analyzed accurately three times consecutively according to the reference method:
HGB value: Cyanmethemoglobin method
HCT value: Microhematocrit method

Revised April 2007

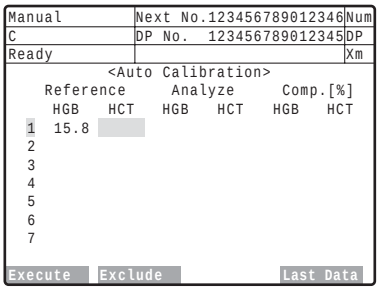
8.4 Automatic calibration

In the XE-5000, five fresh, normal blood samples are used for automatic calibration of HGB and HCT values.

Executing the automatic calibration program

1. From the Main Menu screen on the Main Unit, select **"Calibration"** on the function menu.
   The Calibration Menu screen will appear.

> **Note:**
> When the **"Calibration"** on the function menu is not displayed on the Main Menu screen, press the MORE key to change over the function menu.



2. Select **"Auto Calibration"** on the function menu of the Calibration Menu screen.
   The Automatic Calibration screen (P1) will appear.

   To cancel the automatic calibration, press the **RETURN** key. The Calibration Interruption screen will appear. Select **"OK"** or **"Cancel"** on the function menu.

   OK: Ends the automatic calibration and returns the system to the Main Menu screen.

   Cancel: Returns the system to the Automatic Calibration screen. And the operation can be continued.

Entering reference values

1. Using the ◆ and ◆ keys, move the cursor to select the line in which you wish to enter the value.

> **Note:**
> The Automatic Calibration screen consists of two pages.
> To display the Automatic Calibration screen (P2), press the ◆ key on the lowermost line (7) of the Automatic Calibration screen (P1). To display the Automatic Calibration screen (P1), press the ◆ key on the uppermost line (8) of the Automatic Calibration screen (P2).

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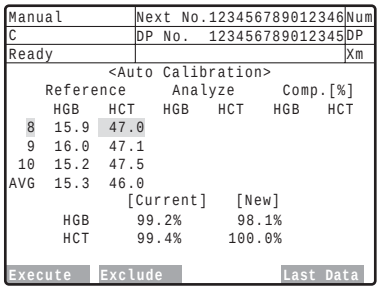

2. Using the ◈ and ◈ keys, move the cursor to select HGB and HCT.
3. Using the numeric keys, enter the HGB or HCT reference value obtained by the standard method.
4. Press the **ENTER** key.
   The entered value is set and the cursor will move to the next column.

   When one or more reference values of HGB and HCT are set, each average is calculated automatically, and displayed in the **"AVG"** column of the Automatic Calibration screen (P2).
   When the sample has been already analyzed, the compensation rate is calculated automatically, and displayed in the **"New"** column of the Automatic Calibration screen (P2).

Analyzing samples

The sample used for analyzing the reference value is analyzed by the XE-5000.

1. Using the ◈ and ◈ keys, move the cursor to select the line to analyze.
2. Carry out the analysis in manual or manual closed mode.

> **Note:**
> Discrete becomes CBC automatically during the automatic calibration analysis.

3. After completion of analysis, the analysis result will appear, and the cursor will move to the next line.

   When one or more samples of HGB and HCT are analyzed, each average is calculated automatically, and displayed in the **"AVG"** column of the Automatic Calibration screen (P2).
   When the values have been already set, the compensation rate is calculated automatically, and displayed in the **"New"** column of the Automatic Calibration screen (P2).

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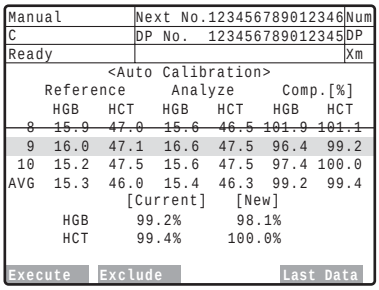
Exclusion

When the compensation rate is far away from 100% because of insufficient mixing or analysis error, the data can be excluded from calibration calculation. If necessary, the excluded data can be restored.

Exclusion



1. Using the (♦) and (♦) keys, move the cursor to select the data to exclude.
2. Select **"Exclude"** on the function menu of the Automatic Calibration screen.
   The data directed by the cursor will be crossed off, and the cursor will move to the next line. The averages of the reference value, analysis value and compensation rate will be calculated again and displayed.

Canceling the exclusion

1. Using the (♦) and (♦) keys, move the cursor to select the data whose calibration value you wish to recalculate.
2. Select **"Exclude"** on the function menu of the Automatic Calibration screen.
   The line on the data will disappear, and the cursor will move to the next line. The averages of the reference value, analysis value and compensation rate will be calculated again and displayed.

Executing the calibration

Update the compensation rate to the new compensation rate calculated from the averages of the reference value and analysis value.

1. Select **"Execute"** on the function menu of the Automatic Calibration screen.
   The calibration will be executed, and the new compensation rate will appear in the **"New"** column.

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Note:

- Comp. [%] in the right of the screen is calculated as follows:

$$\text{Comp.}[\%] = \frac{\text{Reference}}{\text{Analyze}} \times 100[\%]$$

- The new compensation rate is calculated as follows:

$$\text{New compensation rate (\%)} = \frac{\text{Current comp. rate (\%)} \times \text{Avg. comp. rate (\%)}}{100}$$

- When the new compensation rate exceeds the following allowable range, the Calibration Error message will appear, and the compensation rate will not be updated.
  New compensation rate ≥ 120%
  New compensation rate ≤ 80%
  New compensation rate - Current compensation rate ≥ ±5%
- Manual calibration can be carried out when the difference between the new compensation rate and the current compensation rate exceeds ±5%, but the new compensation rate is within 100±20%.

When the Calibration Error message is displayed, select **"OK"** on the function menu to return the system to the last screen. The automatic calibration can be continued.

2. Reanalyze the sample used for the calibration using the XE-5000. Confirm that the analysis value is within the allowable range and does not vary greatly from the reference value.
   Recalibrate if HGB and HCT values are consistently higher or lower overall than the reference value. If, after re-calibration, the analysis values are still outside the allowable range, or if abnormal data is found, check the samples for abnormalities such as abnormal blood coagulation, blood cell morphology, patient medicinal use and old blood. If no abnormality is found on the samples, contact your Sysmex technical representative.

Revised April 2007

8.5 Displaying the last sample data

1. Select **"Last Data"** on the function menu of the Automatic Calibration screen.
   The value of last analysis sample will appear.
2. Select **"OK"** on the function menu of the Last Sample Analysis Data screen. The system will return to the Automatic Calibration screen.

8.6 Manual calibration

In manual calibration, the HGB and HCT calibration values obtained by calculation can be entered by the numeric keys.

Calculating the calibration value

1. Analyze five to ten samples, three times each, by the standard method to obtain average HGB and HCT values.
2. Mix the same samples sufficiently and analyze them in manual or manual closed mode with the Main Unit (XE-5000).
3. When there is a difference between the data obtained by XE-5000 analysis and the reference values obtained by the standard method, calculate new calibration values using the following equation:

$$\text{New compensation rate} = \frac{\text{Current compensation rate} \times \text{Reference mean}}{\text{Instrument mean}}$$

[Example]
Average of HGB values from standard method = 15.6 g/dL
Average of HGB values from XE-5000 analysis = 15.5 g/dL
Old calibration value of HGB = 100.0%

$$100.0 \times \frac{15.6}{15.5} \times 100.65 \cong 100.7\%$$

Therefore, the new calibration value of HGB needs to be set at 100.7%. This means that the calibration value increased 0.7%.

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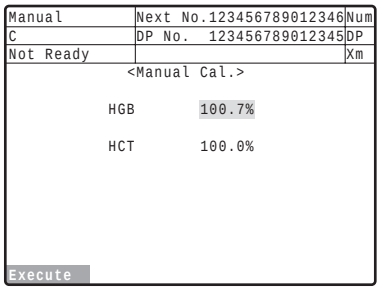
Executing the manual calibration program

1. From the Main Menu screen on the Main Unit, select **"Calibration"** on the function menu.
   The Calibration Menu screen will appear.

> **Note:**
> When the **"Calibration"** on the function menu is not displayed on the Main Menu screen, press the **MORE** key to change over the function menu.



2. Select **"Manual Cal."** on the function menu of the Calibration Menu screen.
   The Manual Calibration screen will appear.

Entering the calibration values

1. Using the ◆ and ◆ keys, move the cursor to select HGB or HCT.
2. Using the numeric keys, enter the calibration value obtained by calculation.

> **Note:**
> Input calibration values in the range 80.0 – 120.0 to the first decimal place.

3. Press the **ENTER** key.
   The entered value is set and the cursor will move to the next parameter.

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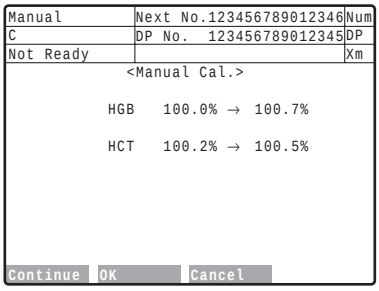
Updating the calibration values



1. After entering the calibration value, select **"Execute"** on the function menu of the Manual Calibration screen.
2. Both the old and updated calibration values of HGB and HCT will appear on the Manual Calibration Setting screen.
3. Select **"Continue"**, **"OK"** or **"Cancel"** on the function menu.
   Continue: Returns the system to the Manual Calibration screen and the operation can be continued.
   OK: Sets the updated calibration value and returns the system to the Calibration Menu screen.
   Cancel: Cancels the updated calibration value and returns the system to the Manual Calibration screen.

Note:
- If you press the **RETURN** key, the updated calibration value will be canceled, and the system will return to the Calibration Menu screen.
- When the updated calibration value exceeds 100±20%, the Calibration Error message will be displayed and the Manual Calibration Setting screen will not appear.
- When a calibration over ±20% is necessary, contact your Sysmex technical representative.

When the Calibration Error message is displayed, select **"OK"** on the function menu to return the system to the Manual Calibration screen. The calibration can be continued.

4. Reanalyze the sample used for the calibration using the XE-5000. Confirm that the analysis value is within the allowable range and does not vary greatly from the reference value.
   Recalibrate if HGB and HCT values are consistently higher or lower overall than the reference value. If, after re-calibration, the analysis values are still outside the allowable range, or if abnormal data is found, check the samples for abnormalities such as abnormal blood coagulation, blood cell morphology, patient medicinal use, and old blood. If no abnormality is found on the samples, contact your Sysmex technical representative.

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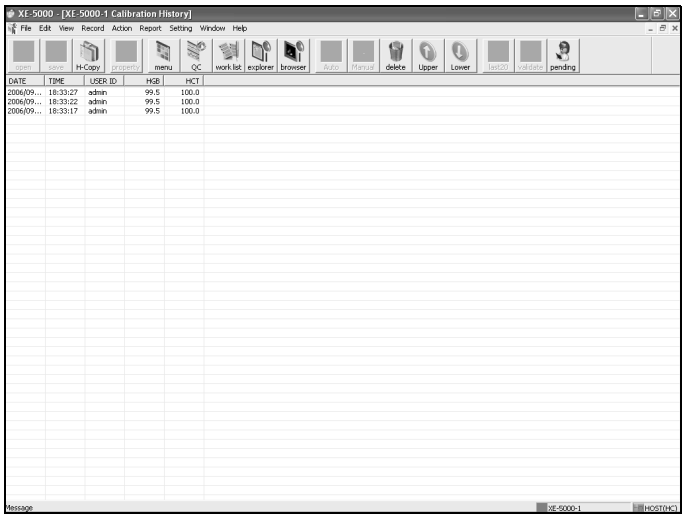
8.7 Calibration history

The Calibration History display screen shows a maximum of 10 calibrations in order of occurrence.
Older calibrations will automatically be deleted if the total number of calibrations exceeds 10.

1. Double-click the **"Controller"** icon on the Information Processing Unit (IPU) menu screen.
   The controller menu will be displayed.
2. Double-click the **"Calibration History"** icon on the controller menu. The Calibration History screen appears.



Deleting calibration history

Calibration history can be deleted.

1. From the Calibration History screen, select a record to delete by clicking on it.
2. From **"Record (R)"** on the menu bar, select **"Delete (D)"**, or double-click the **"Delete"** icon on the tool bar.
3. The Confirm Delete dialog box will be displayed.
4. Click **"OK"** to delete the selected record and close the dialog box.
   Click **"Cancel"** to cancel deletion.

> **Note:**
> Multiple calibration histories cannot be selected nor deleted at a time.

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9. Cleaning and Maintenance

To ensure that the instrument can function in its best state, it is necessary to give scheduled maintenance.
Perform maintenance according to the schedule below and record the result in the maintenance checklist.

Daily maintenance

- Execute shutdown (detector chamber and dilution line are cleaned automatically).
- Remove fluid from the Pneumatic Unit trap chamber.

Periodical SRV maintenance

- Clean the sample rotor valve when the message “Clean the SRV” is displayed:
  Depending on the service contract, your Sysmex technical engineer will perform the cleaning of the SRV.

As-needed maintenance

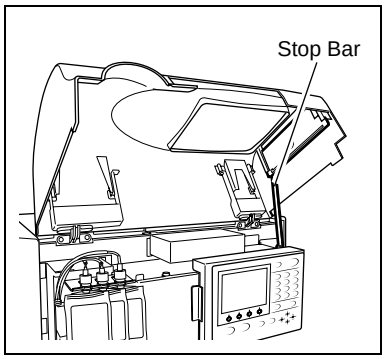
- Clean the manual rinse cup.
- Clean the sample rotor valve tray.
- Clean the piercer tray.
- Removing Clogs. (Clog Removal Sequence)
- Clean the IMI detector aperture.
- Clean the RBC detector aperture.
- Remove flow cell air bubbles in the optical detector block.
- Clean the flow cell in the optical detector block.
- Replace the waste container. (option)

Supplies replacements

- Replace reagents.
- Replace piercer.
- Replace hand clipper.
- Replace the rubber plate No. 39.
- Replace the HEPA filter.
- Replace fuses.

Adjustment of pressure and vacuum

- Adjust the pressure to 0.25 MPa.
- Adjust the pressure to 0.16 MPa.
- Adjust the pressure to 0.07 MPa.
- Adjust the pressure to 0.03 MPa.
- Pneumatic Unit vacuum
- Vacuum: Adjust the vacuum to -0.04 MPa.



Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

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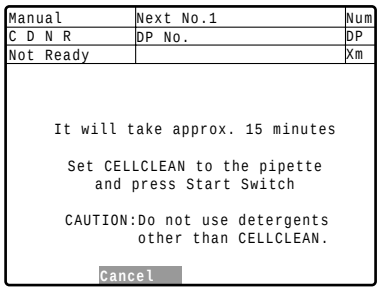
9.1 Execution of shutdown

By executing shutdown, the detector chamber and dilution line are cleared. Execute shutdown every 500 samples or at the end of each day's analysis, and also at least once every 24 hours when you use this instrument continuously.

> **Note:**
> When the analyzed sample exceeds 500 samples in a day, the message prompted to shutdown will appear.

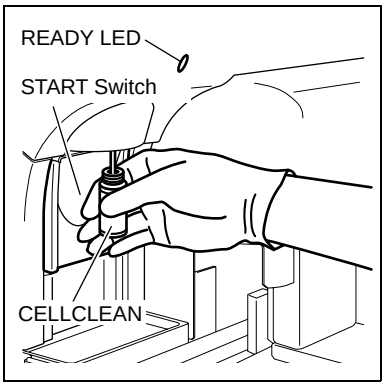
1. Press the **SHUTDOWN** key on the Main Unit panel keypad.



2. The shutdown screen appears on the Main Unit LCD screen.

> **Caution!**
> • Be sure to execute shutdown to clean the instrument. Otherwise analysis may not be performed correctly.
> • To execute shutdown, use CELLCLEAN only.

To cancel shutdown, press the **RETURN** key or select **"Cancel"** on the function menu of the shutdown screen to return to Ready status.



3. Set CELLCLEAN to the manual aspiration pipette as shown in the figure; then press the START switch in that status.
While the READY LED is blinking and the buzzer is sounding, aspiration is in progress. Keep holding CELLCLEAN in the current status.

> **Warning!**
> CELLCLEAN is a strong alkaline detergent. Pay careful attention not to let it adhere to your body or clothes. If CELLCLEAN adheres to your body or clothes, wash it away immediately with plenty of water. Otherwise, it can damage your skin or clothes.

4 After the READY LED turns off and buzzer stops, remove the CELLCLEAN.

> **Note:**
> The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

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5. The shutdown sequence in the Main Unit will start.
6. When the shutdown sequence is completed, the message “Turn OFF Main Unit” will appear.
7. If you wish to complete the analysis, turn OFF the Main Unit power.

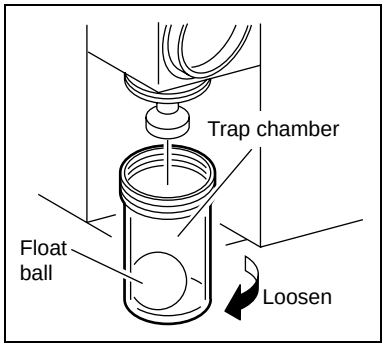
Note:
If you wish to continue an analysis with the Main Unit left ON, select “Restart” on the function menu of the Shutdown Completion screen.
After executing an automatic rinse and background check, the system returns to the READY status.

9.2 Removing fluid from the Pneumatic Unit trap chamber

At the end of each day’s analysis, check the fluid level in the Pneumatic Unit trap chamber; then discard any fluid that has collected.

Risk of infection
When discarding the trap chamber fluid, always wear gloves. And after completion of the analysis, be sure to wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

Caution!
If fluid collects everyday, the Main Unit may have a technical problem.
Please contact your Sysmex technical representative.



1. Turn OFF the power of Pneumatic Unit and make sure that the Pneumatic Unit pressure gauge shows “0”.
2. Turn the trap chamber counterclockwise and remove.
3. Discard the fluid, then reattach the chamber. Make sure there is a float ball inside.

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9.3 Cleaning the sample rotor valve

Have the SRV cleaned periodically (at least twice-thrice per year).

Risk of infection

When cleaning the sample rotor valve, always wear gloves. Also, after completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

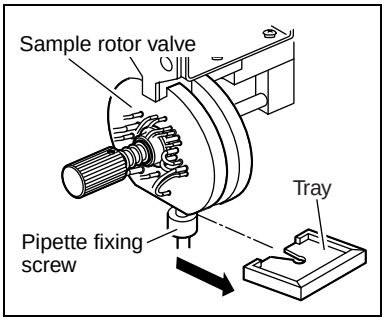
Warning!

- Be sure to set the stop bar when opening to avoid injury.
- CELLCLEAN is a strong alkaline detergent. Pay careful attention not to let it adhere to your body or clothes. If CELLCLEAN adheres to your body or clothes, wash it away immediately with plenty of water.
  Otherwise, it can damage your skin or clothes.

Note:

After cleaning the sample rotor valve, when the analyzed sample exceeds 60,000 samples, the message prompted to perform the maintenance will appear at supplying the power.

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and wait several minutes until the pressure gauge points at “0”.
2. Open the Main Unit front cover.
3. Remove the tray from the sample rotor valve.



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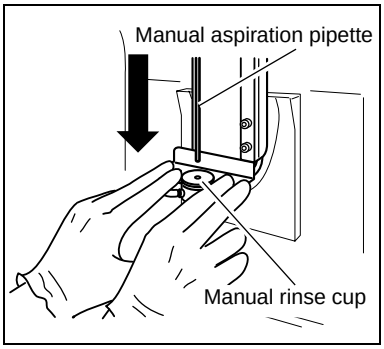
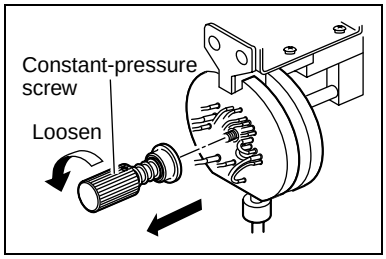
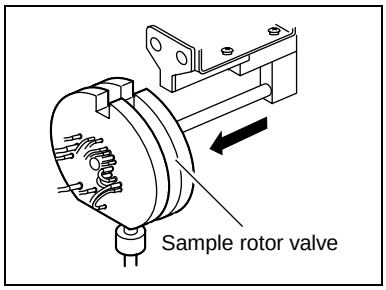


4. Gently push down the manual rinse cup with both hands. Make sure that the manual rinse cup is completely removed from the manual aspiration pipette.

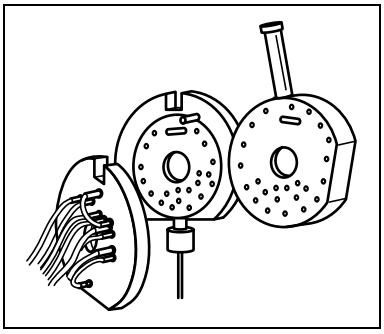
> **Information**
> If the manual rinse cup is not completely removed from the manual aspiration pipette, there is a possibility that the manual aspiration pipette may bend when the sample rotor valve is removed.



5. Remove the constant-pressure screw.



6. Remove the sample rotor valve assembly.



7. Remove the rotary valve.

> **Caution!**
> Do not pull out the valve excessively. This is to prevent excess force from applying to the tube that is connected to the rear fixed valve.

> **Information**
> - When removing the fixed valve, reagent can leak from the tube. Have a paper towel ready to wipe reagent.
> - When pulling out the valve, take care not to bend the manual aspiration pipette.

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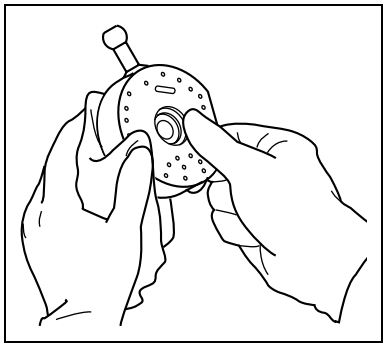
Note:
The valves are in close contact with each other. They can be easily removed when you lightly pull, gently twist, then slide them.



8. Clean the surface of the fixed and rotary valves using distilled water or 1:10 dilution of CELLCLEAN detergent. Make sure to clean them with distilled water after cleaning with CELLCLEAN.
9. Clean the removed tray in running water.

Caution!
Take care not to inflict flaws or scratches on the sample rotor valve surfaces. Do not use each valve with dust or dirt adhered on its surface.
These can cause blood leakage and incorrect analysis results.

Information
Be sure to use CELLCLEAN only. Although the sample rotor valve is corrosion-resistant against CELLCLEAN, wipe it off completely to prevent troubles to the unit or other components.

10. Make sure that the valve contact surfaces are thoroughly free from dirt or dust.
11. Assemble the sample rotor valve in the reverse order of disassembly. And gently push up the manual rinse cup with both hands.

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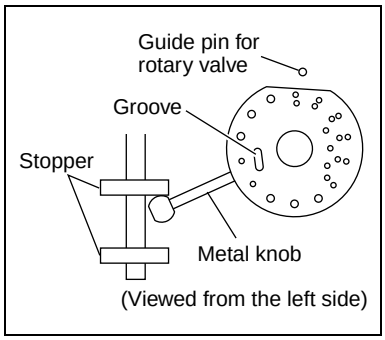

Information

- Place the rotary valve with the notch facing upward and the metal knob positioned between the stoppers.
- Confirm the metal knob is placed between the stoppers.
  If it is not, malfunction can occur.
- Make sure that the manual rinse cup is pushed all the way up with the manual aspiration pipette inserted. If the power is ON with the rinse cup staying lowered, “Rinse Motor Error” will occur, making it impossible to continue the operation.

12. Turn ON the power of the Main Unit. Background check will start automatically. Make sure that all background values are within acceptable.
13. Make sure by quality control that the instrument has no performance problem.

Information

If you spill reagents on the coated surface of the instrument, immediately wipe it off using wet cloth or the like.

14. Reset the SRV counter.
    See “Chapter 10: 10.5 Status”.

9.4 Cleaning the manual rinse cup

If blood adheres to the manual rinse cup or any clogging is found, clean the manual rinse cup by the following procedure.

Risk of infection

When cleaning the manual rinse cup, always wear gloves. After completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

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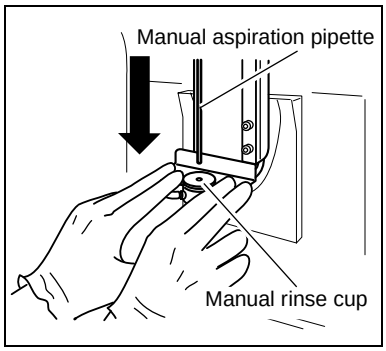
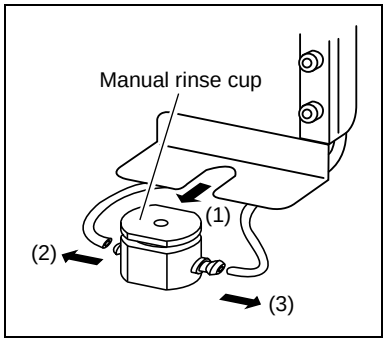
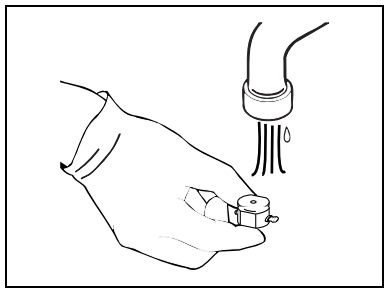
Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and wait several minutes until the pressure gauge points at “0”.
2. Open the Main Unit front cover.
3. Gently push down the manual rinse cup with both hands. Make sure that the manual rinse cup is completely removed from the manual aspiration pipette.



4. Remove the manual rinse cup in the order of (1), (2) and (3).





5. Wash the manual rinse cup with running water.
6. Make sure that no dirt remains in the manual rinse cup and wipe off moisture.
7. Assemble the manual rinse cup in the reverse order of disassembly. Install so that the small tubes pass behind the manual rinse cup.
8. Gently push up the manual rinse cup all the way using both hands.

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Information
Make sure that the rinse cup is pushed all the way up with the manual aspiration pipette inserted.
If the power is turned on with the manual rinse cup lowered, an error will occur, making it impossible to continue operation.

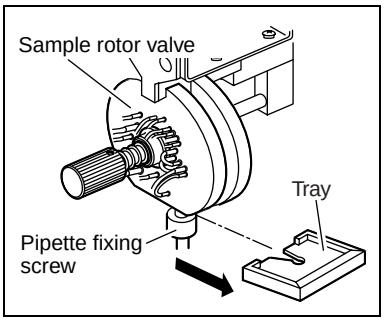
9.5 Cleaning the sample rotor valve tray

If the sample rotor valve tray has dirt, clean the tray by the following procedure.

Risk of infection
When cleaning the sample rotor valve tray, always wear gloves. After completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and wait several minutes until the pressure gauge points at “0”.
2. Open the Main Unit front cover.
3. Remove the sample rotor valve tray.



Caution!
When removing the tray, take care not to loosen the pipette fixing screw.
If an analysis is made with the screw loosened, air bubbles can enter the pipette and affect the data.

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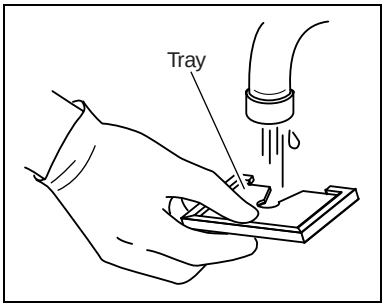

4. Clean the sample rotor valve tray using running water.
5. Make sure that no dirt remains in the sample rotor valve tray and wipe off moisture.
6. Install the sample rotor valve tray to its original position.

Caution!
After installing the tray, make sure that the pipette fixing screw is not loose.
If an analysis is made with the screw loosened, air bubbles can enter the pipette and affect the data.

Information
Install the sample rotor valve tray properly as to the face/bottom and direction.

7. Close the Main Unit front cover.

9.6 Cleaning the piercer tray

If the piercer tray has dirt, clean the piecer tray by the following procedure.

Risk of infection
When cleaning the piercer tray, always wear gloves. After completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and wait several minutes until the pressure gauge points at “0”.
2. Open the Main Unit front cover.
3. Remove the CP cover.

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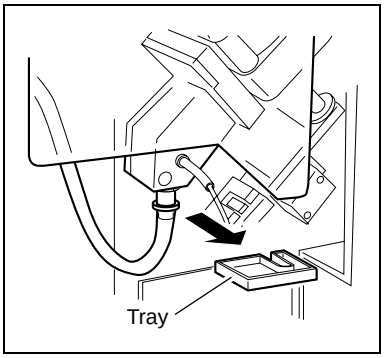
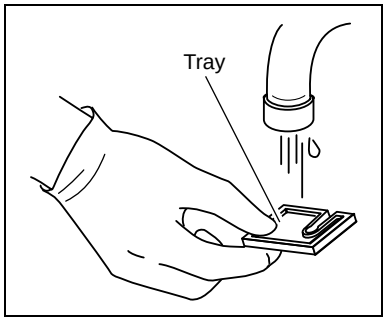


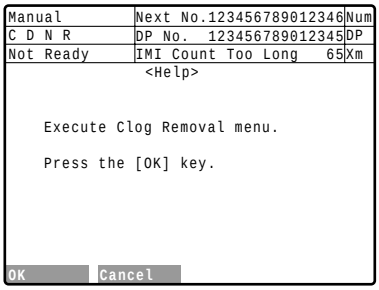
4. Remove the piercer tray.



5. Clean the piercer tray using running water.
6. Make sure that no dirt remains in the piercer tray and wipe off moisture.
7. Install the piercer tray to its original position.
8. Install the CP cover.
9. Close the Main Unit front cover.

9.7 Removing clogs (clog removal sequence)

When the message indicating clogging of RBC or IMI detector is displayed, execute the clog removal sequence by the following procedure.



1. When the error message indicating clogging is displayed, press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.
2. If you select **"OK"** on the function menu of the HELP screen, the clog removal sequence will start.

You can also execute the clog removal sequence by the following procedure.

1. Select **"Maint"** on the function menu of the main menu screen.
   The Maintenance Sequence screen will appear.
2. Using the ↑ and ↓ keys, move the cursor to select **"3. Clog Removal"**.
3. If you select **"Execute"** on the function menu of the Maintenance Sequence screen, the clog removal sequence will start.

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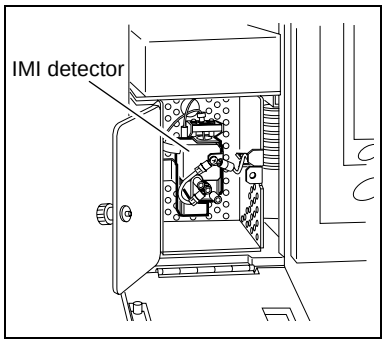
9.8 Cleaning the IMI detector aperture

When clogs are not removed after executing the clog removal sequence, clean the IMI detector aperture by the following procedure.

Risk of infection
When cleaning the aperture, always wear gloves.
After completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

1. Select **"Maint"** on the function menu of the main menu screen.
   The Maintenance Sequence screen will appear.
2. Using the ⇕ and ⇕ keys, move the cursor to select **"1.Drain IMI."**
3. If you select **"Execute"** on the function menu of the Maintenance Sequence screen, the sample inside the IMI detector is drained.
4. Turn OFF the power of the Main Unit and Pneumatic Unit, and wait several minutes until the pressure gauge points at "0".
5. Open the Main Unit front cover.
6. Open the IMI detector cover, and check that the sample is drained.



Warning!
Never touch the detector when the power of the Main Unit is turned ON.
Otherwise, electrical shock may result.

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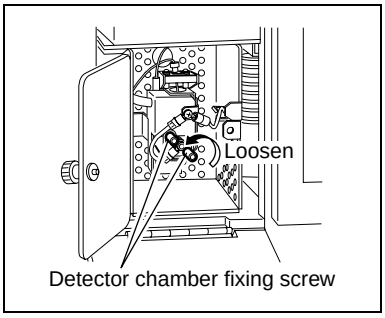
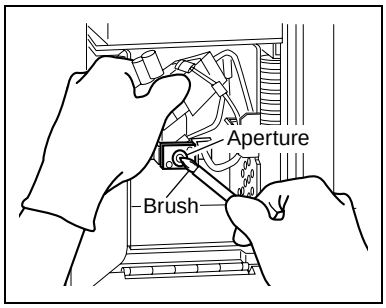


7. Loosen the detector chamber fixing screw, and remove the chamber.

Information
When removing the detector chamber, take care not to apply excessive force to the tube that is connected to the detector chamber.



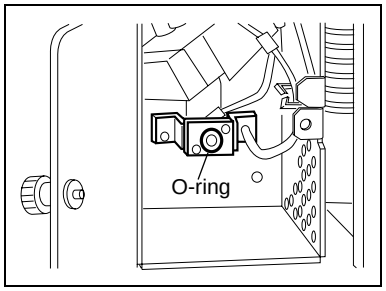
8. Apply CELLCLEAN on the brush provided, and dab by lightly prodding the brush against the aperture.

Warning!
CELLCLEAN is a strong alkaline detergent. Pay careful attention not to let it adhere to your body or clothes. If CELLCLEAN adheres to your body or clothes, wash it away immediately with plenty of water. Otherwise, it can damage your skin or clothes.

Caution!
Be sure to use CELLCLEAN only.

Note:
After using the brush, wash it in water thoroughly to remove CELLCLEAN before storing it.

9. Install the detector chamber to its original position, and tighten the fixing screws.



Caution!
When installing the detector chamber, make sure that the O-ring is placed in the specified position.
Tighten the fixing screws alternately and evenly.
Otherwise, analysis may not be performed correctly.

10. Close the detector cover and Main Unit front cover.
11. Turn ON the power of the Main Unit.
12. Background check starts automatically. Make sure that all background values are within acceptable.

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9.9 Cleaning the RBC detector aperture

When clogs are not removed after executing the clog removal sequence, clean the RBC detector aperture by the following procedure.

Risk of infection

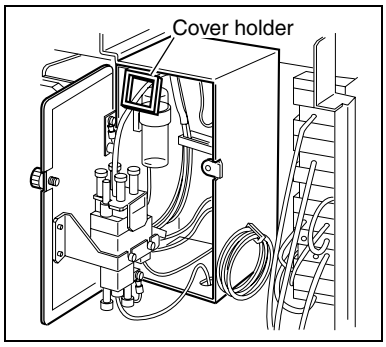
When cleaning the aperture, always wear gloves.
After completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

Warning!

Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

Cleaning the bottom part of aperture

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and wait several minutes until the pressure gauge points at “0”.
2. Open the Main Unit front cover and front right cover.
3. Open the RBC detector cover.
   Rotate the cover holder, and keep the cover open.



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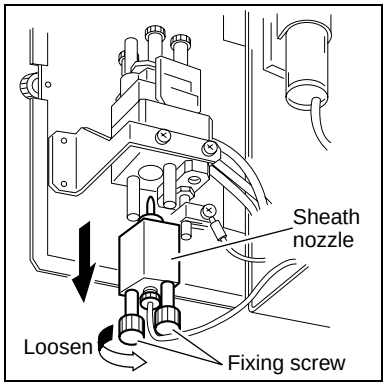
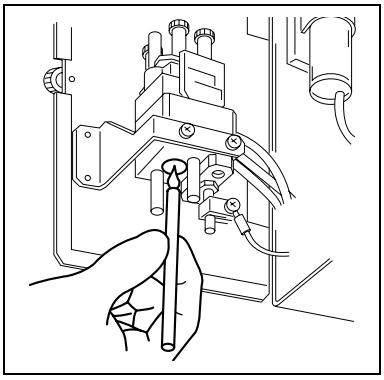


4. Loosen the fixing screw at bottom of the detector chamber, remove the sheath nozzle.

Warning!
Never touch the detector when the power of the Main Unit is turned ON.
Otherwise, electrical shock may result.

Caution!
- When removing the sheath nozzle, reagent can leak from the detector chamber. Place gauze or the like under the detector chamber.
  Otherwise, leakage or electrical shock may result.
- As a sheath nozzle is easy to bend, do not drop or apply impact on it. When removing the detector chamber or sheath nozzle, take care not to apply excessive force to the tube that is connected to the detector chamber.
  Otherwise, analysis may not be performed correctly.



5. Apply CELLCLEAN on the brush provided, and dab by lightly prodding the brush against the aperture.

Caution!
Be sure to use CELLCLEAN only.

Note:
After using the brush, wash it in water thoroughly to remove CELLCLEAN before storing it.

6. Insert the sheath nozzle into the detector chamber, and tighten the fixing screw.

Caution!
When closing the detector cover, take care not to bend the tube.
Otherwise, analysis may not be performed correctly.

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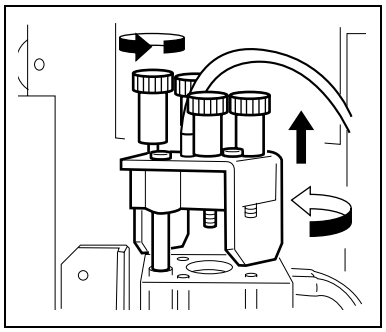
Information
Tighten the fixing screw of the sheath nozzle alternately and evenly.

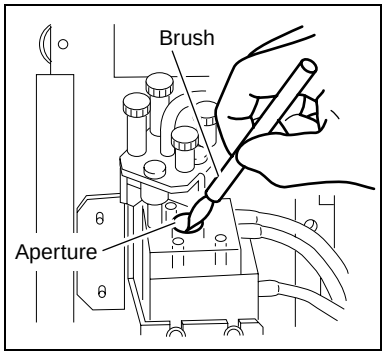
7. Close the detector cover. Then close the Main Unit front cover and front right cover.
8. Turn ON the power of the Main Unit.
9. Background check starts automatically. Make sure that all background values are within acceptable.

Cleaning the top part of aperture

When clogs are not removed after cleaning the bottom of aperture, clean the upper of aperture by the following procedure.

1. Loosen the four fixing screws.
2. Pull up the cap on the detector chamber, and move it in the direction as shown in the figure.





3. Apply CELLCLEAN on the brush provided, and dab by lightly prodding the brush against the aperture.

Caution!
Be sure to use CELLCLEAN only.

4. Return the cap to the original position on the detector chamber.
5. Close the detector cover. Then close the Main Unit front cover and front right cover.
6. Turn ON the power of the Main Unit.
7. Background check starts automatically. Make sure that all background values are within acceptable.

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9.10 Removing air bubbles from the flow cell in the optical detector block

When aggregation status of scattergram analyzed by the optical detector block becomes worse, the air bubbles may adhere to the flow cell in the optical detector block.
In this case, execute air bubble removal sequence by the following procedure.

1. Select **"Maint"** on the function menu of the main menu screen.
   The Maintenance Sequence screen will appear.
2. Using the ◆ and ◆ keys, move the cursor to select **"2. Air Bubble Removal."**
3. If you select **"Execute"** on the function menu of the Maintenance Sequence screen, the air bubble removal sequence will start.
4. During the air bubble removal sequence, the Execution screen will be displayed on the LCD screen.

9.11 Cleaning the flow cell in the optical detector block

When the message "Execute Rinse Flowcell" is displayed, the flow cell in the optical detector may be dirty.
In this case, execute the flow cell rinse sequence by the following procedure.

1. Press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.

Also, the sequence can be executed according to the procedure described below.

1. Select **"Maint"** on the function menu of the main menu screen.
   The Maintenance Sequence screen will appear.
2. Using the ◆ and ◆ keys, move the cursor to select **"4. Rinse Flowcell."**
3. If you set CELLCLEAN to the manual aspiration pipette, and select **"Execute"** on the function menu of the Maintenance Sequence screen, the flow cell rinse sequence will start.
4. During the flow cell rinse sequence, the Execution screen will be displayed on the LCD screen.

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9.12 Replacing the waste container (option)

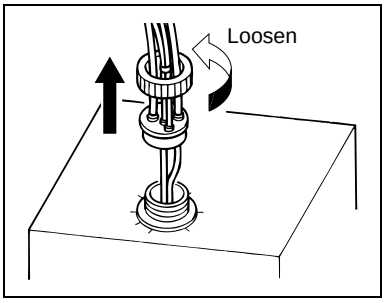
Risk of infection
When replacing the waste container, always wear gloves. Also, after replacing, wash your hands with disinfectant.

Caution!
When using a used reagent container as the waste container, make sure to clearly mark it that it is the waste container.

When the optional waste sensor unit monitoring function is used

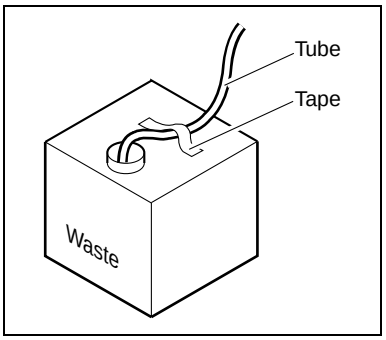
When the message “Exchange Waste Tank” is displayed, replace the waste container by the following procedure.

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and make sure that the pressure gauge indicates “0”.
2. Prepare an empty waste container and remove the cap.
3. Remove the cap of the waste container which has become full, and pull out the cap straight up with the tubes connected.
4. Insert the cap with the tubes to a new waste container straight in, and tighten the cap.



When an empty container is used

1. Turn OFF the power of the Main Unit and Pneumatic Unit, and make sure that the pressure gauge indicates “0”.
2. Prepare an empty waste container and remove the cap.
3. Remove the tube from the full waste container.
4. Insert the tube into a new waste container, and fix it using a tape or the like.



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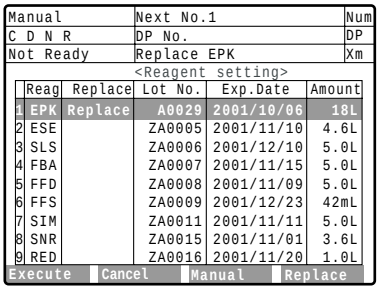
9.13 Replacing and registering reagents

When the reagent runs out during analysis, the instrument stops automatically and an error message shown below is displayed on the screen. Replace the specified reagent with new one. Then, execute the reagent aspiration on the Reagent setting screen.

Error Message	New Reagent
Replace Container EPK	CELLPACK
Replace Container ESE	CELLSHEATH
Replace Container FBA	STROMATOLYSER-FB
Replace Container FFD	STROMATOLYSER-4DL
Replace Container FFS	STROMATOLYSER-4DS
Replace Container SNR	STROMATOLYSER-NR (L) STROMATOLYSER-NR (S)
Replace Container RED	RET SEARCH (II) (Diluent, dye solution)
Replace Container SLS	SULFOLYSER
Replace Container SIM	STROMATOLYSER-IM

Displaying the reagent setting screen



The Reagent setting screen is displayed by either of the processes described below.

- Select **"Reagent"** on the function menu of the Main Menu screen.
- When a reagent replacement error message is displayed, press the **HELP** key, and select **"OK"** on the function menu of the Help screen.

Reagent setting screen display

(Numbers): Displays numbers 1–9.
A reagent can be selected by pressing the corresponding number key to move the cursor to that reagent.

Reag: Displays the reagent names.

Replace: "Replace" appears in this column if the reagent has been designated as a replacement. If the reagent has not been designated as a replacement, nothing appears in this column. If reagent information has been entered manually or by barcode, that reagent will be designated as a replacement automatically, and the cursor will move to that reagent.

Lot No.: Displays the current lot number.

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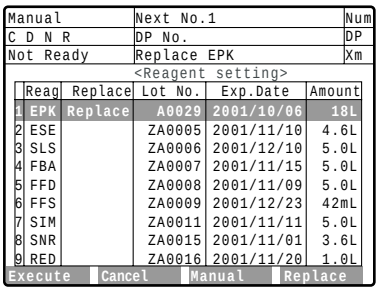
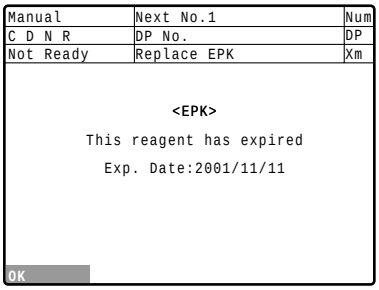
Exp. Date: Displays the expiry limit of the current reagent.
Amount: Displays the current remaining volumes of each reagent.
(For details, see “Chapter 9: 9.15 Remaining reagent volume function”.)

Registering reagent information (barcode entry)



1. Display the Reagent setting screen.
2. Use the handheld barcode scanner to read the barcode that is affixed to the outside of the reagent container, and is marked EAN-128 or Reagent Code.
The cursor moves to the reagent that has been read, and the display is updated with the read reagent information. “Replace” automatically appears for reagents with updated information. These reagents are designated as replacements.



Information
When scanning or entering expired reagent, an Expired Reagent message will be displayed as shown in box, and the information is not updated. Select **“OK”** on the function menu of the Expired Reagent screen to return to the Reagent setting screen.
If the barcode which was read is not a reagent barcode, a beep sounds, and the entry is rejected.

Note:
Selecting **“Replace”** on the function menu alternately designates the reagent as a replacement and removes the designation.

3. Select **“Execute”** on the function menu to register the reagent information and begin reagent aspiration.
Select **“Cancel”** on the function menu to delete all of the read information and return to the previous screen.

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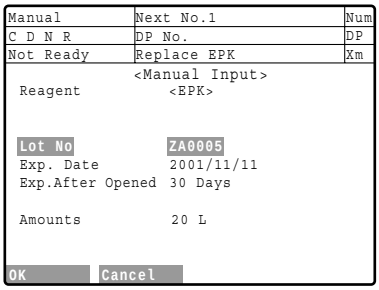
Registering reagent information (manual entry)



1. Display the Reagent setting screen.
2. Press the ▲ and ▼ keys, or the number keys, to select a reagent for manual entry.
3. Select **"Manual"** on the function menu.
   The Manual Input screen appears.

> **Note:**
> While the Manual Input screen is open, it is also possible to use the handheld barcode scanner to read the barcodes that are affixed to the reagent.
> A barcode can also be read for a reagent that is different from the screen that is currently displayed. When a different reagent's barcode is read, the screen changes to the screen for that reagent, and the barcode information appears. If the previous screen contents had been changed, the changes are automatically saved before the screen changes.

4. Press the ▲ and ▼ keys to select the lot No., expiry date, expiry date after reagent is opened or container amount, then enter the appropriate information.

   Lot No.: A maximum of 8 alphanumeric characters can be entered.
   This column may also be left blank.

   Exp. Date: Only numbers can be entered for this item.
   Press the ◀ and ▶ keys to change among the year, month, and day areas.
   This column may also be left blank.

   Exp. After Opened:
   A number from 0–99 can be entered for this item.
   This column may also be left blank.

> **Information**
> After an expiry date, or expiry date after reagent is opened is entered, and the ▲ or ▼ key is pressed, a date check is performed before the cursor moves. If the entered date is invalid, a beep sounds and the cursor does not move.

   Amounts: Numbers and a decimal point (period) can be entered for this item.
   This column may also be left blank.

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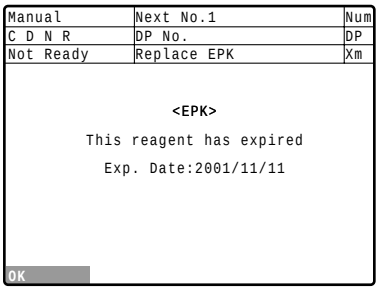
Note:
If a value is entered that exceeds the entry range, the value will be corrected to a value within the entry range when **"OK"** is selected from the function menu in step 5.

Entry ranges for reagent amounts

Reagent name	Entry range	Reagent name	Entry range
EPK	0–99	FFS	0–999
ESE	0.0–99.9	SIM	0.0–99.9
SLS	0.0–99.9	SNR	0.0–99.9
FBA	0.0–99.9	RED	0.0–99.9
FFD	0.0–99.9		

5. After entry is completed, select **"OK"** or **"Cancel"** on the function menu.
   OK: The entered contents are saved, and the screen returns to the Reagent setting screen. When the Reagent setting screen reappears, "Replace" automatically appears at the entered reagent to designate it as a replacement.
   Cancel: The entered contents are deleted and the screen returns to the Reagent setting screen.



Information
When **"OK"** is selected, a check is made using the dates entered for the expiry date and expiry date after reagent is opened. If any reagents have passed the entered expiry limit, the Expired Reagent screen appears.
Select **"OK"** on the function menu of the Expired Reagent screen to return to the previous screen.

Note:
Selecting **"Replace"** on the function menu alternately designates the reagent as a replacement and removes the designation.

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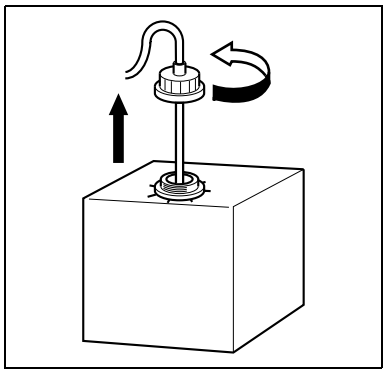
6. Select **"Execute"** on the function menu of the Reagent setting screen to register the reagent information and begin reagent aspiration.
   Select **"Cancel"** on the function menu to delete all of the entered information and return to the previous screen.

Reagent replacement procedure (other than STROMATOLYSER-4DS, STROMATOLYSER-NR (L), STROMATOLYSER-NR(S), RET SEARCH (II), STROMATOLYSER-IM)

1. Prepare a new reagent and confirm that its expiration date has not expired.

Caution!
- Use reagent that has been left at room temperature (15–30°C) for at least 24 hours.
- In handling a reagent that may have frozen, follow the precautions given on the package.
  Otherwise, analysis may not be performed correctly.
- When replacing the reagent container, make sure that no dust adheres to the cubitainer spout kit.
  Otherwise, correct analysis results may not be obtained.
- After opening a reagent container, make sure that no dust, dirt, or bacteria comes into the container.
  Otherwise, analysis may not be performed correctly.
- Be careful not to install the float switch slantwise.
- Make sure that the reagents are kept level or below the Main Unit of the instrument. Do not put reagents on top of the instrument.

2. Remove the new reagent container cap.
3. Remove the cap of the empty reagent container, and pull off straight up the float switch or the cubitainer spout kit.
4. Insert the float switch or the cubitainer spout kit straight into the new reagent container and tighten the cap.



Caution!
- Take care not to grasp the tube dipping into the reagent and not allow dust, etc. to adhere to the tube. If dust, etc. adheres to the tube, wash it away with reagent in use before mounting.
  Otherwise, analysis may not be performed correctly.
- Take care not to spill a reagent. If it spills, wipe it off immediately using a wet cloth or the like.
  Otherwise, the floor could be stained.

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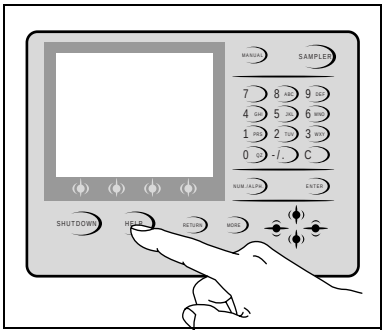
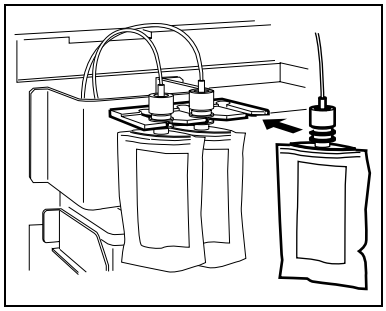


5. Press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.
6. If you select **"OK"** on the function menu of the HELP screen, the Reagent setting screen will appear. See "Chapter 9: 9.13 Replacing and registering reagents" for explanation of the Reagent setting screen.

STROMATOLYSER-4DS (FFS) replacement procedure

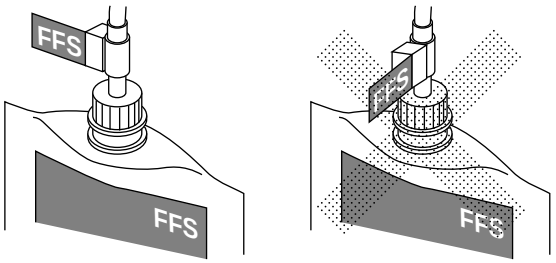
Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

1. Prepare a new reagent and confirm that its expiration date has not expired.
2. Open the Main Unit front cover.
3. Remove the empty STROMATOLYSER-4DS from the holder.
4. Remove the cap of the empty STROMATOLYSER-4DS, and pull out the pipe straight up.
5. Open the cap of new STROMATOLYSER-4DS, and insert the pipe straight in, and close the cap.



6. Insert it all the way into the holder.
7. Close the Main Unit front cover.

Information
To prevent the sensor malfunction, replace the STROMATOLYSER-4DS (FFS) so that two FFS labels will face the same direction.



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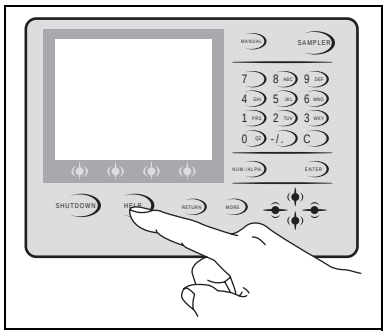

8. Press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.
9. If you select **"OK"** on the function menu of the HELP screen, the Reagent setting screen will appear.
   See "Chapter 9: 9.13 Replacing and registering reagents" for explanation of the Reagent setting screen.

Information
The FFS must be replaced every 2,000 times analysis, an error will appear.
Always select **"OK"** after replacing the FFS.

STROMATOLYSER-NR(L) & STROMATOLYSER-NR(S)(SNR) replacement procedure

Warning!
Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

Caution!
- STROMATOLYSER-NR(L) and STROMATOLYSER-NR(S) should be replaced at the same time. Otherwise, correct analysis results may not be obtained.
- If STROMATOLYSER-NR(S)(dye solution) spills, wipe it off using cloth - preferably moistened with alcohol. This is to prevent discoloration of the instrument coat.

1. Prepare a new reagent and confirm that its expiration date has not expired.
2. Remove the cap of a new STROMATOLYSER-NR(L).
3. Remove the cap of the empty STROMATOLYSER-NR(L).

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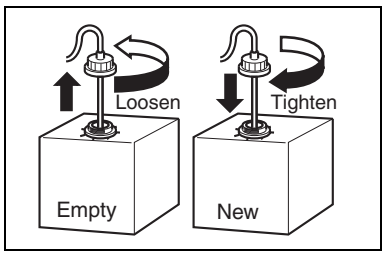
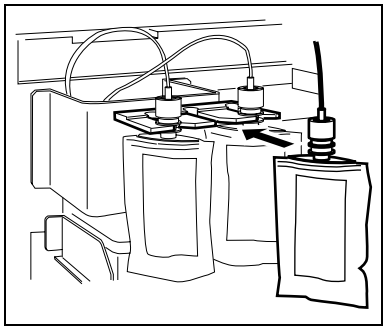


4. Insert the cubitainer spout kit straight into the new STROMATOLYSER-NR(L) and tighten the cap.

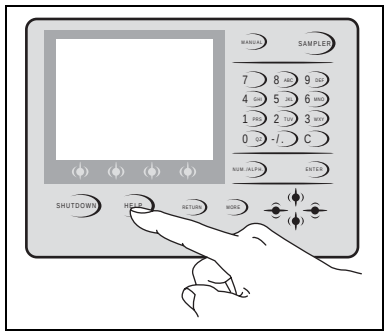
5. Open the Main Unit front cover.
6. Remove the empty STROMATOLYSER-NR(S) from the holder, remove the cap, and pull out the pipe straight up.
7. Remove the cap of a new STROMATOLYSER-NR(S), insert the pipe straight into it, and tighten the cap.



8. Insert it all the way into the holder.

> **Information**
> Insert the STROMATOLYSER-NR(S) all the way into the holder.
> If it slants, air bubbles could enter, making it impossible to obtain correct analysis results.

9. Close the Main Unit front cover.



10. Press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.
11. If you select **"OK"** on the function menu of the HELP screen, the Reagent setting screen will appear.
See "Chapter 9: 9.13 Replacing and registering reagents" for explanation of the Reagent setting screen.

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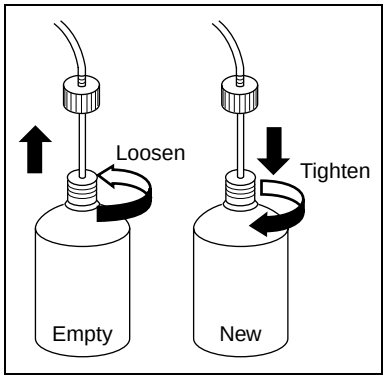
RET SEARCH (II) (diluent, dye solution) (RED) replacement procedure

Warning!
- Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.
- When replacing RET SEARCH (II) dye solution, always wear gloves.If dye solution comes in touch with your skin, it will stain your skin blue, and the stain will be hard to remove.
  Should it adhere to your skin, immediately wash your skin with disinfectant, then with soapy water.

Caution!
- RET SEARCH (II) diluent and RET SEARCH (II) dye solution should be replaced at the same time. Otherwise, correct analysis results may not be obtained.
- If dye solution spills, wipe it off using cloth - preferably moistened with alcohol. This is to prevent discoloration of the instrument coat.

1. Prepare a new reagent and confirm that its expiration date has not expired.
2. Remove the cap of a new reagent or RET SEARCH (II) diluent.
3. Remove the cap of the empty RET SEARCH (II) diluent and pull out the cubitainer spout kit straight up.
4. Insert the cubitainer spout kit straight into the new RET SEARCH (II) diluent and tighten the cap.



5. Open the Main Unit front cover.
6. Remove the empty RET SEARCH (II) dye solution from the holder, remove the cap, and pull out the pipe straight up.

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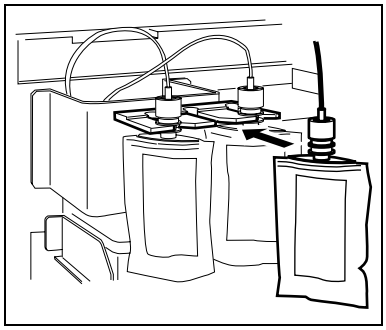
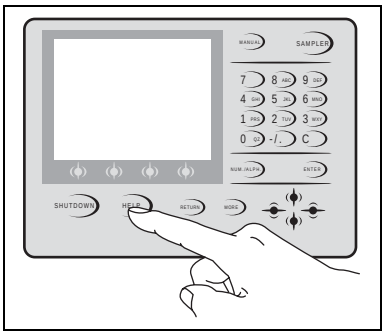


7. Remove the cap of a new RET SEARCH (II) dye solution, insert the pipe straight into it, and tighten the cap.
8. Insert it all the way into the holder.

> **Information**
> Insert the RET SEARCH (II) dye solution all the way into the holder.
> If it slants, air bubbles could enter, making it impossible to obtain correct analysis results.

9. Close the Main Unit front cover.



10. Press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.
11. If you select **"OK"** on the function menu of the HELP screen, the Reagent setting screen will appear.
    See "Chapter 9: 9.13 Replacing and registering reagents" for explanation of the Reagent setting screen.

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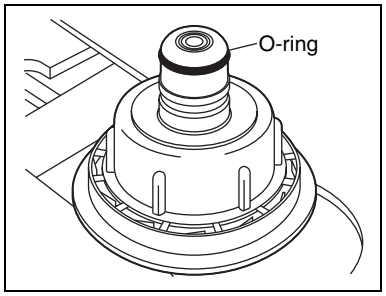
STROMATOLYSER-IM (SIM) replacement procedure

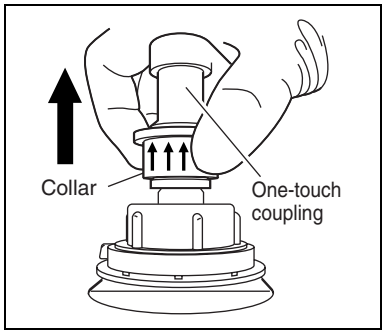
1. Prepare a new reagent and confirm that its expiration date has not expired.

Caution!
- When replacing STROMATOLYSER-IM, always wear gloves.
- Use reagent that has been left at room temperature (15–30°C) for at least 24 hours.
- In handling a reagent that may have frozen, follow the precautions given on the package.
  Otherwise, analysis may not be performed correctly.
- Make sure there is no dust etc. sticking to the joint between the reagent container and the one-touch coupling.Use alcohol (isopropanol 70%) to clean any away.
  Otherwise, analysis may not be performed correctly.
- When changing the reagent container, take care not to pinch or kink the tube.
  Otherwise, analysis may not be performed correctly.

2. Open the seal on the new reagent container.



3. After opening the seal, check that there is an O-ring on the tip of the joint.



4. Pull the collar of the one-touch coupling up, and remove it from the empty reagent container.

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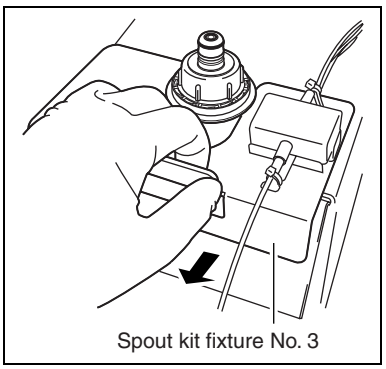
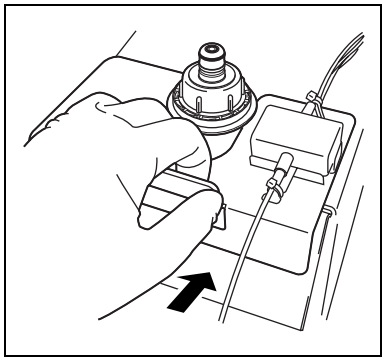
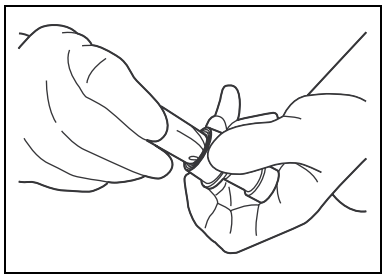


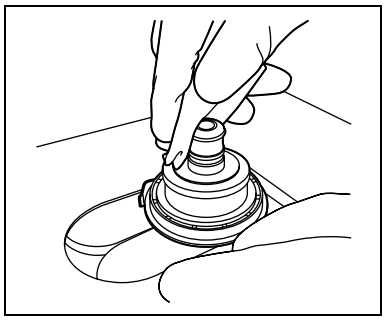
5. Remove spout kit fixture No. 3 from the reagent container.

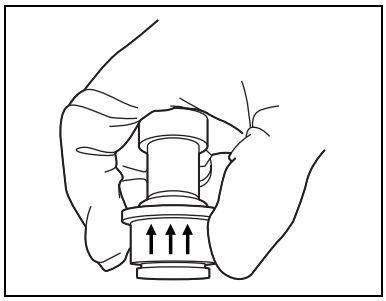


6. Fit spout kit fixture No. 3 onto the new reagent container. Lift up the aspiration port of the reagent container and engage it on spout kit fixture No. 3.
Push it all the way in, to avoid the reagent container from collapsing.



7. Prior to connecting the quick connector to the SIM cubitainer spout, wipe the inside area of the quick connector and the SIM cubitainer spout with a lint-free gauze moistened with ethyl-alcohol. This cleaning will prevent contamination and lubricate the o-ring when connecting.





8. Pull up the collar of the quick connector.

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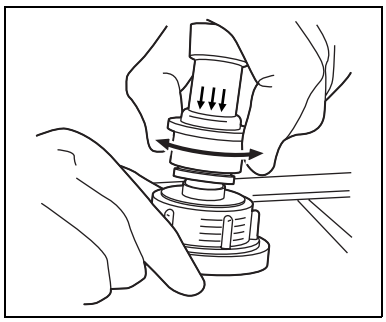
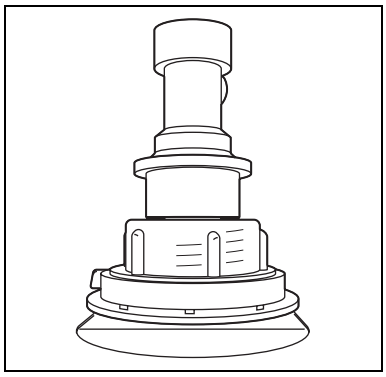
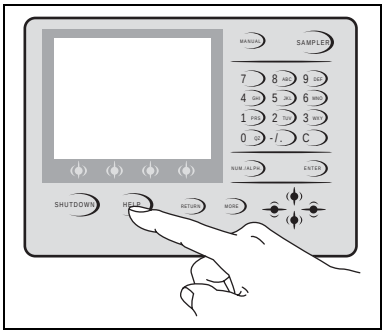


9. When connecting, make sure the quick connector collar is pulled all the way up and gently insert all the way over the cubitainer spout and then release collar. Verify that connector is sealed by gently lifting up on quick connector. If inserting the quick connector to the spout is difficult, wet both the connection ports again with a lint-free gauze moistened with alcohol and try again.



10. Check that the container is connected securely.

> **Caution!**
> - Take care not to spill a reagent.If it spills, wipe it off immediately using a wet cloth or the like.
>   The floor could be stained.
> - Check that the one-touch coupling is connected securely to the reagent container.
>   Analysis may not be performed correctly if the coupling is not connected correctly.
> - After connecting the new reagent container, do not detach the one-touch coupling until the next time the reagent must be replaced.
>   Otherwise, analysis may not be performed correctly.



11. Press the **HELP** key on the Main Unit panel keypad. The HELP screen will appear.
12. If you select **"OK"** on the function menu of the HELP screen, the Reagent setting screen will appear.
    See "Chapter 9: 9.13 Replacing and registering reagents" for explanation of the Reagent setting screen.

9.14 Reagent replacement log display function

This function displays,on the Information Processing Unit (IPU), the replacement history for the reagents registered with the reagent registration function. See "Chapter 9: 9.13 Replacing and registering reagents" for explanation of the reagent registration function.
Comments can be added to the data stored in the reagent replacement log. The log information can be printed out using a Ledger printer and output in a csv file.

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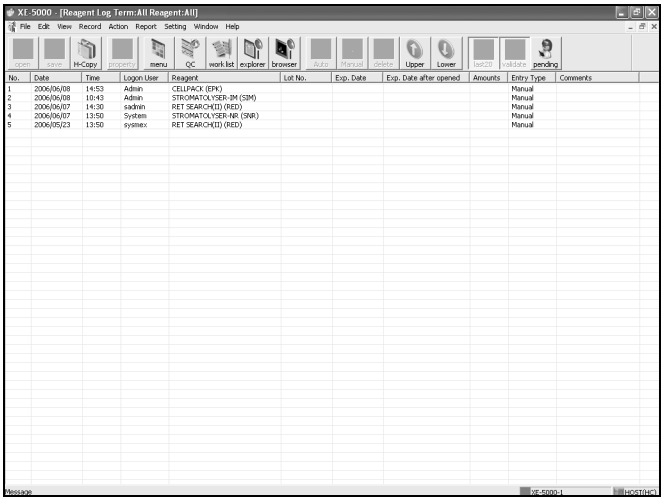
Displaying the reagent replacement log screen

Reagent Replacement Log Screen can display and delete the reagent replacement log of up to 1,000 reagents at maximum that are saved on the hard disk drive.

> **Information**
> When the number of reagent replacement log exceeds 1,000, the system automatically deletes the oldest data.

1. Double-click the **"Controller"** icon on the menu screen.
   The Controller menu appears.
2. Double-click the **"Reagent Log"** icon on the Controller menu.
   The Reagent Replacement Log screen appears.



Entering comments

Comments concerning the registered reagents can be entered.

> **Information**
> Comments cannot be edited or deleted after they are entered. However, additions may be made to a previously-entered comment, provided that the total number of characters remains 50 or fewer. The comments which had already been entered are not displayed in the dialog box.

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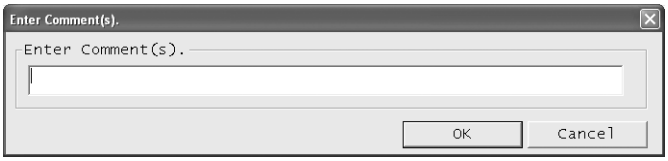
1. From the Reagent Replacement Log screen, select a record, then double-click or press the **Enter** key.
2. The Enter Comment(s) dialog box appears.



3. Enter a comment.
   The comment can be up to 50 characters in length. (Up to 25 2-byte characters)
4. After entering the comment, click **"OK"** or **"Cancel"**.
   OK: The entered comment is saved and the dialog box is closed.
   Cancel: The entered comment is discarded and the dialog box is closed.

Delete

Stored reagent replacement records can be deleted.

1. From the Reagent Replacement Log screen, select a record to delete by clicking on it.
2. Select **"Delete (D)"** on the **"Record (R)"**, or press the **Delete** key.
3. The Confirm Delete dialog box appears.

4. Click **"OK"** to delete the selected record and close the dialog box.
   Click **"Cancel"** to cancel deletion.

> **Note:**
> Multiple reagent replacement records cannot be selected nor deleted at a time.

Filter

The reagents and term for display on the Reagent Replacement Log screen can be set.

1. Select **"Filter (F)"** on the **"Record (R)"** menu of the Reagent Replacement Log screen.

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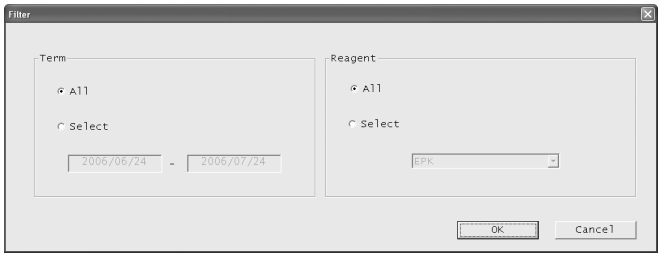
2. The current filter conditions are displayed in the Filter dialog box.



3. Set the filter conditions in the Filter dialog box.
Term

All	The reagent replacement records saved for all dates are displayed.
Select	The reagent replacement records for the selected term are displayed. Enter the dates to select in the respective entry boxes.

Information
The older of the two dates can be entered in either the right or left entry box when selecting dates.
A check is made of the entered dates when the cursor is removed from the entry boxes. If an invalid date was entered, the date returns to the default.
The default date term is from one month before to the current date.

Reagent

All	The reagent replacement records saved for all reagents are displayed.
Select	The reagent replacement records for the selected reagent are displayed. Click on the combo box and select a reagent from the list box.

4. After setting the filter conditions, click **"OK"** or **"Cancel"**.
OK: The set filter conditions are saved and the dialog box is closed. Reagent replacement records are displayed, subject to the selected conditions.
Cancel: The set filter conditions are deleted and the dialog box is closed.

The filter conditions are displayed in the title bar on the Reagent Replacement Log screen.

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LP printout

The reagent replacement log can be printed out using a Ledger printer.
From the reagent replacement log screen, select **"Ledger (LP)"** on the **"Report (P)"** menu to print.

> **Note:**
> The contents to be printed are linked with the filter. If a comment has been entered, it is printed on the following line.

Output data in csv file format

Reagent replacement log can be output in a csv file format.

> **Information**
> The system uses C:\ drive.
> It is recommended to save files to the D:\ drive or to a USB Memory Stick. When C:\ drive (system drive) storage capacity is reaching the limit, the operating system may become unstable.

> **Note:**
> The csv file is a type of data format in which a series of data is enumerated by separating them using a comma (,). A csv files data can be retrieved using spreadsheet software commercially available supporting csv file format.

1. Select **"CSV File Output"** on the **"Record (R)"** menu of the reagent replacement log screen.
2. The file save dialog box will appear.
3. Designate the place to save the file.
   Manually enter the name to save the file if the file name should be changed.
4. Click on **"Save (S)"** to save the reagent replacement record in csv format.
   Click **"Cancel"** to cancel the save operation.

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Note:
- As a csv file synchronizes to the filter, the data output in this process will be the one currently shown on the screen. A comma (,) in the comment column will be automatically transferred after converting into a space in the output file.
- Even when a save process is terminated due to the lack of space in the drive or other reasons, the previous data saved before the error happens will be kept and retained.

9.15 Remaining reagent volume function

The remaining reagent volume is calculated, based on the container volume entered at reagent registration, by using the analysis count to estimate the volume of reagent used.
The remaining reagent volume is displayed as a bar graph on the Remaining Reagent Volume screen at the IPU, and as a numeric value on the Reagent setting screen at the Main Unit.

Information
The remaining reagent volume is calculated based on the container volume which was registered. If an incorrect container volume is entered, the actual reagent volume and the displayed volume may not agree with.
If a partially-used reagent is set, manually enter the reagent container volume. The remaining reagent volume should be used as a guide only.

Note:
If a reagent feeding unit or a similar device is used, it may not be possible to use the remaining reagent volume function.
For reagents (SNR, RED) which include the dye and bottle as a set, the display indicates the volume in the bottle.

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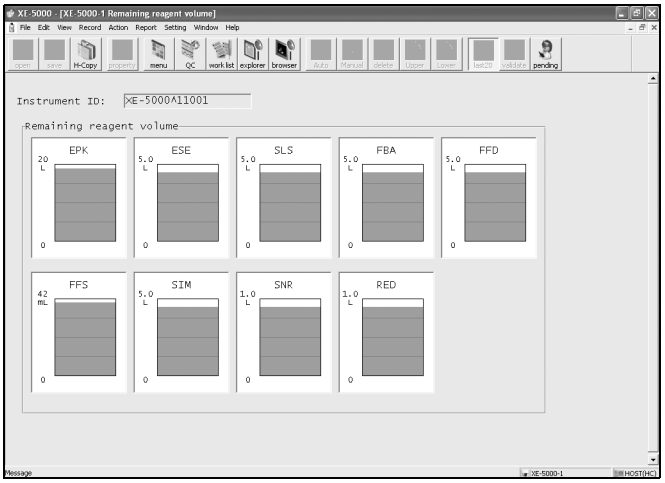
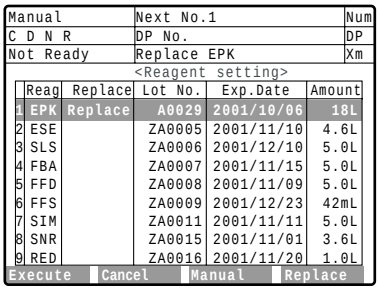
IPU remaining reagent volume function

The remaining reagent volume can be checked with the Remaining reagent volume screen at the IPU.

1. Double-click the **"Controller"** icon on the menu screen.
   The Controller menu appears.
2. Double-click the **"Remaining reagent volume"** icon on the Controller menu.
   The Remaining reagent volume screen appears.



Main Unit remaining reagent volume function



Manual	Next No.1	Num
C D N R	DP No.	DP
Not Ready	Replace EPK	Xm

<Reagent setting>

	Reag	Replace	Lot No.	Exp.Date	Amount
1	EPK	Replace	A0029	2001/10/06	18L
2	ESE		ZA0005	2001/11/10	4.6L
3	SLS		ZA0006	2001/12/10	5.0L
4	FBA		ZA0007	2001/11/15	5.0L
5	FFD		ZA0008	2001/11/09	5.0L
6	FFS		ZA0009	2001/12/23	42mL
7	SIM		ZA0011	2001/11/11	5.0L
8	SNR		ZA0015	2001/11/01	3.6L
9	RED		ZA0016	2001/11/20	1.0L

Execute | Cancel | Manual | Replace

The remaining reagent volume can be checked with the Remaining reagent volume screen at the Main Unit.
The display of remaining reagent volume appears on the screen with the units shown below. The values are rounded down to the nearest unit.
If a reagent has been used and the remaining reagent volume is reduced, the display is reduced in the units shown below.

Note:
"0" (zero) is not displayed for the reagent amounts.When the amount is reduced to less than the smallest display unit, "<" is displayed.
No error occurs, even if the reagent amount becomes 0.
[Example of remaining reagent display]
For ESE
4.6→4.5→4.0→... →1.5→1.0→0.5→ <0.5

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Reagent name	Display units	Reduction units	Reagent container content volume
EPK	** L	1 L	20.0 L
ESE	**.* L	0.5 L	20.0 L
SLS	**.* L	0.5 L	5.0 L
FBA	**.* L	0.5 L	5.0 L
FFD	**.* L	0.5 L	5.0 L
FFS	*** mL	10 mL	42 mL
SIM	**.* L	0.5 L	10.0 L
SNR	**.* L	0.1 L	3.6 L
RED	**.* L	0.1 L	1.0 L

9.16 Replacing the piercer

When sampler analysis (piercing operation) exceeds 30,000 cycles, replace the piercer. After piercing exceeds 30,000 cycles, the message “Change Piercer” will be displayed.

Risk of infection

When replacing the piercer, always wear gloves. Also, after completion of the operation, wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

Warning!

Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

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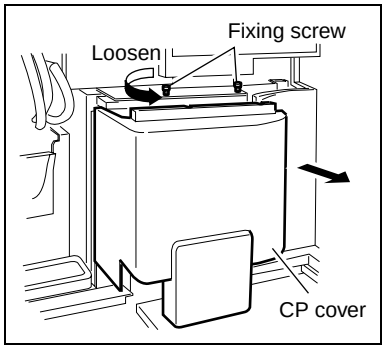
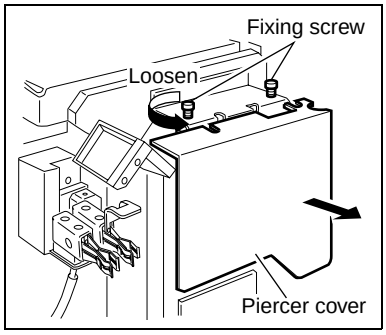
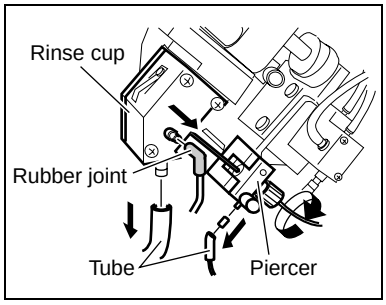
Removing the piercer

1. Turn OFF the Main Unit power and open the front cover.
2. Loosen the fixing screws and remove the CP cover.



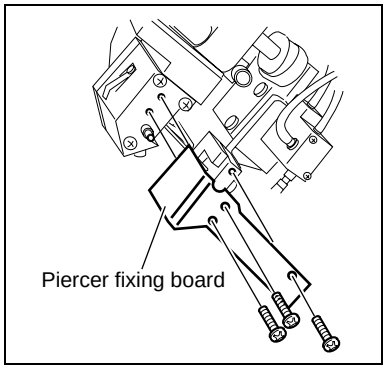


3. Remove the fixing screws of the piercer cover and remove the cover.



4. Remove the tubes and rubber joint which are connected to the rinse cup and piercer.

> **Information**
> Another tube is installed inside one tube. The replacement part of this inner tube is attached to the new piercer set. Remove the inner tube together with the outer tube.



5. Install the fixing board to the piercer using three screws.

> **Warning!**
> Be sure to install the piercer fixing board.
> The piercer needle may pop out during operation and cause injuries.

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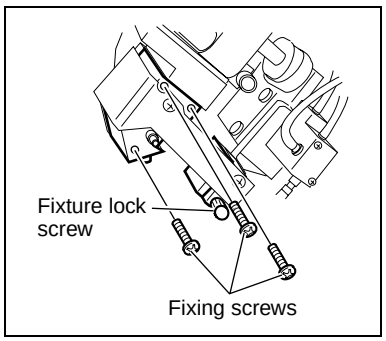
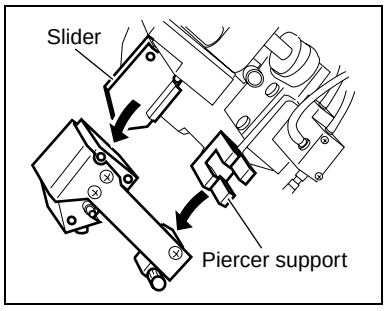
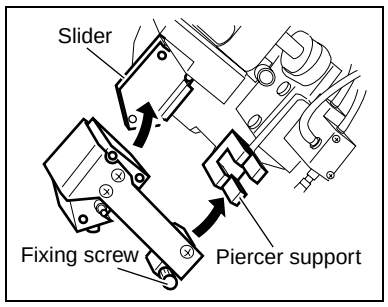


6. Loosen the fixture lock screw, remove three screws which fix the rinse cup.



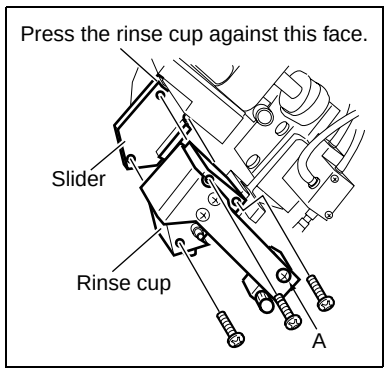
7. Remove the piercer and dispose of it.

Installation



1. Set a new piercer to the slider and piercer support, and tighten the fixture lock screw.

> **Information**
> After tightening the fixture lock screw by hand, retighten it with a screwdriver.



2. Loosen slightly the screw A on the piercer fixing board. Slide the rinse cup and press it against the slider surface, then fix the rinse cup with three fixing screws.

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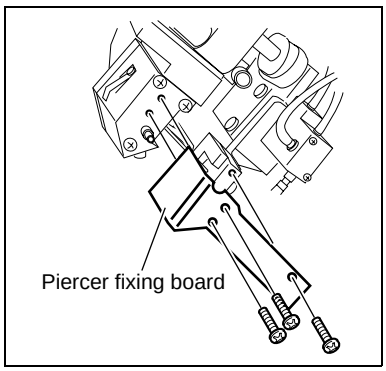
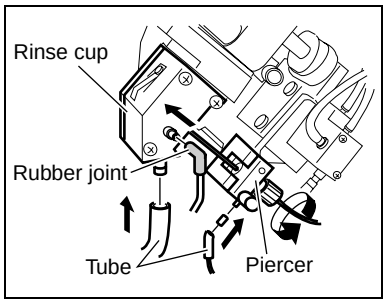


3. Remove three screws on the piercer fixing board and remove the board.



4. Install the tubes and rubber joint which are connected to the rinse cup and piercer.
5. Install the piercer cover and CP cover.

> **Caution!**
> When installing the piercer cover and CP cover, take care not to have the tube caught or bent.
> Otherwise, analysis may not be performed correctly.

6. Close the front cover.
7. Reset the piercer cycle counter.
   See “Chapter 10: 10.5 Status”.

9.17 Replacing the hand clipper

If the hand clipper is deformed and unable to hold the sample tube, replace it in the following procedure:

> **Risk of infection**
> When replacing the hand clipper, always wear gloves. And after completion of the analysis, be sure to wash your hands with disinfectant.
> If your hands are contaminated by blood, you might be infected by pathogen, etc.

> **Warning!**
> Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

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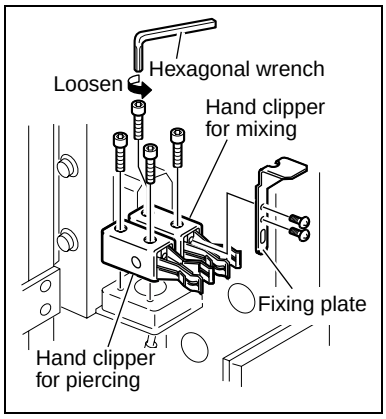
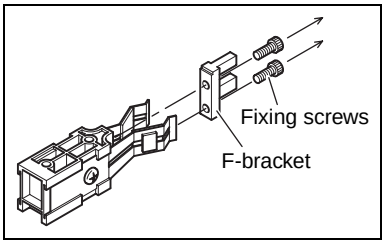


1. Turn OFF the Main Unit power and open the front cover.
2. Loosen the fixing screws and remove the CP cover.
3. Remove the hand clipper fixing screws (2 places) and remove the hand clipper.
4. Hand Clipper for Mixing Only:
   Remove the fixing plate from the old hand clipper for mixing.
   The hand clipper for mixing does not use the F-bracket provided with a new hand clipper.
   Remove the F-bracket from the new hand clipper and attach the fixing plate (just removed) on the new hand clipper for mixing.
5. Install the new hand clipper to the original position using screws removed in step (3).
   Please note:
   Hand clipper for mixing uses fixing plate. Hand clipper for piercing uses F-bracket.



Information
In case of connecting to the HST System, remove the F-bracket.

6. Install the CP cover.

Caution!
When installing the CP cover, take care not to have the tube caught or bent.
Otherwise, analysis may not be performed correctly.

7. Close the front cover.

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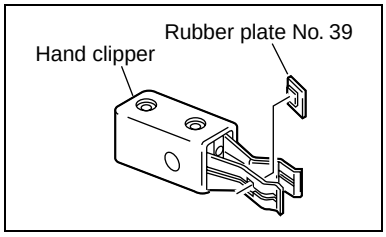
9.18 Replacing rubber plate No. 39

If the hand clipper becomes slippery, replace the anti-slip rubber plate No. 39 in the following procedure:

> **Risk of infection**
> When replacing the rubber plate No. 39, always wear gloves. And after completion of the analysis, be sure to wash your hands with disinfectant.
> If your hands are contaminated by blood, you might be infected by pathogen, etc.

> **Warning!**
> Before operating with the front cover open, be sure to set the stop bar. Otherwise, the cover can drop down and injure your head.

1. Turn OFF the Main Unit power and open the front cover.
2. Loosen the fixing screws and remove the CP cover.
3. Remove the hand clipper fixing screws (2 places) and remove the hand clipper.
4. Remove the rubber plate No. 39.



5. Install a new rubber plate in the reverse order.
6. Install the hand clipper to the original position.
7. Install the CP cover.

> **Caution!**
> When installing the CP cover, take care not to have the tube caught or bent.
> Otherwise, analysis may not be performed correctly.

8. Close the front cover.

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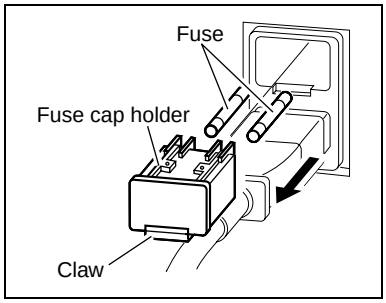
9.19 Replacing the fuses

Over current protection fuses are used in the Main Unit and Pneumatic Unit. When a fuse is blown, replace it by the following procedure.

> **Warning!**
> • To avoid electrical shock, disconnect supply before servicing.

Main Unit

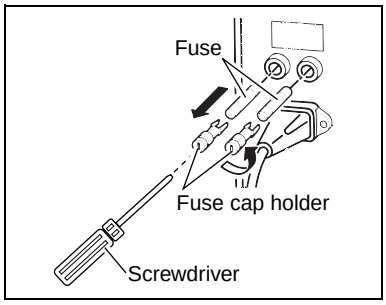


1. Turn OFF the power of the Main Unit, Pneumatic Unit, and IPU, and disconnect the power cord of the Main Unit.
2. Remove the fuse cap holder.
   Remove the fuse cap holder at the rear face of the Main Unit while pushing its claw up using a flat-tip screwdriver.
3. Replace the fuse and attach the fuse cap holder.

Main Unit

Specification	Part No.	Description	Fuse Type
117 VAC	266-5106-0	FUSE 250V 6.3A ST4-6.3A-N1 (N.AMERICA)	Time Lag
220/240 VAC	266-5293-0	FUSE 250V 3.15A NO. 19195 (EUROPE)	Time Lag

Pneumatic Unit



1. Turn OFF the power of the Main Unit, Pneumatic Unit, and IPU, and disconnect the power cord of the Pneumatic Unit.
2. Remove the fuse cap holder.
   Remove the fuse cap holder at the right face of the Pneumatic Unit by turning it counterclockwise using a flat-tip screwdriver.
3. Replace the fuse and attach the fuse cap holder.

Pneumatic Unit

Specification	Part No.	Description	Fuse Type
117 VAC	266-7651-2	FUSE 250V 4A 313004 (N.AMERICA)	Time Lag
220/240 VAC	266-5293-0	FUSE 250V 3.15A NO. 19195 (EUROPE)	Time Lag

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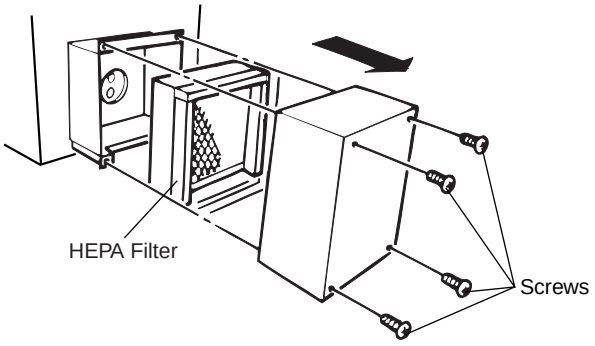
Warning!
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

9.20 Replacing the HEPA filter (option)

When the HEPA filter is used, replace it once a year by the following procedure.

Risk of infection
When replacing the HEPA filter, always wear gloves. And after completion of the analysis, be sure to wash your hands with disinfectant.
If your hands are contaminated by blood, you might be infected by pathogen, etc.

1. Turn OFF the power of Pneumatic Unit and make sure that the Pneumatic Unit pressure gauge shows “0”.
2. Remove the screws of the filter cover and remove the filter cover.



3. Remove the HEPA filter and replace it with a new one. Pay attention to the installation direction.

Information
Install the HEPA filter with its groove facing downward.

4. Install the filter cover and fix it with the screws.

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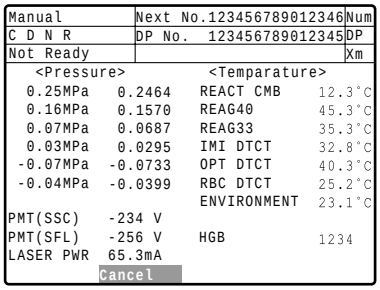
9.21 Adjusting pressure and vacuum

Pressure and vacuum from the Pneumatic Unit are adjusted to 0.25 MPa, 0.16 MPa, 0.07 MPa, 0.03 MPa, and -0.04 MPa by the XE-5000 Main Unit. The pressure and vacuum are monitored by pressure sensors. When an error occurs, an error message is displayed.
If a pressure or vacuum error message is displayed, check the tubing connections for any leakage. When no abnormality is found, display the monitored value on the LCD and adjust the pressure or vacuum as described below.

Displaying the pressure or vacuum

1. Select **"TEST"** on the function menu of the main menu screen of the Main Unit.
   The Test menu screen will appear.
2. Select **"Status"** on the Test function menu.
   The Status screen will appear .
3. From the Status menu screen, select **"Sensor 1"** on the function menu.
   The Sensor 1 screen will appear.
   The Sensor 1 screen displays pressure, temperature, HGB convert, PMT voltage and laser driving voltage.



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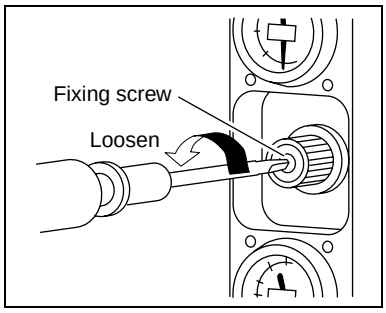
Adjusting the pressure to 0.25 MPa

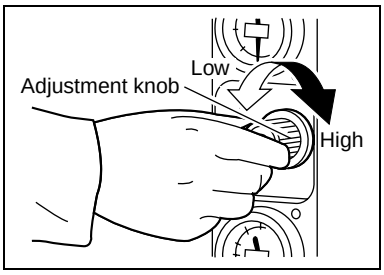
This pressure is used to drive the sample rotor valve and the master valve.

1. Display the Sensor 1 screen on the LCD screen.
   See “Chapter 9: 9.21 Displaying the pressure or vacuum”.

> **Information**
> If the difference between the pressure values displayed on the Sensor 1 screen and on the pressure gauge 1 of Pneumatic Unit is 0.02 MPa or more, check the connecting area of tubing for any leakage.



2. Loosen the fixing screw for the 0.25 MPa regulator of the Pneumatic Unit.



3. Adjust the pressure while watching the pressure gauge on the front panel of the Pneumatic Unit.
   To increase the pressure, turn the knob clockwise.

   Normal range: 0.25 ± 0.01 MPa

> **Information**
> Always adjust pressure so as to increase to the predetermined level.If the pressure is too high, lower it below that level once; then raise it to the set level.

4. Check that the pressure displayed on the Sensor 1 screen is the predetermined pressure.
5. If the displayed pressure does not match the predetermined pressure, adjust it by repeating the operations 3 and 4.
6. When the adjustment is completed, tighten the fixing screw while taking care not to allow the adjustment knob to rotate.

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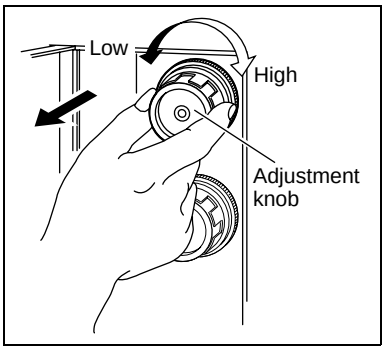
Adjusting the pressure to 0.16 MPa

This pressure is used to supply sheath reagent to the detector block.



1. Display the Sensor 1 screen on the LCD screen.
   See “Chapter 9: 9.21 Displaying the pressure or vacuum”.
2. Pull out the knob for the 0.16 MPa regulator to release the lock.
3. Adjust the pressure while watching the pressure displayed on the Sensor 1 screen.
   To increase the pressure, turn the knob clockwise.

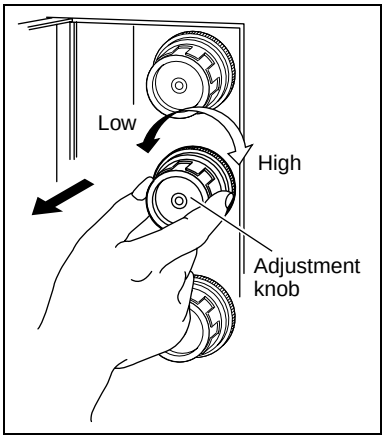
   Normal range: 0.16 ± 0.001 MPa

> **Information**
> Always adjust pressure so as to increase to the predetermined level. If the pressure is too high, lower it below that level once; then raise it to the set level.

4. Check that the pressure displayed on the Sensor 1 screen is the predetermined pressure.
5. If the displayed pressure does not match the predetermined pressure, adjust it by repeating the operations 3 and 4.
6. When the adjustment is completed, press the adjustment knob for the 0.16 MPa regulator to lock.

Adjusting the pressure to 0.07 MPa

This pressure is used to discharge waste fluid and mix the sample.



1. Display the Sensor 1 screen on the LCD screen.
   See “Chapter 9: 9.21 Displaying the pressure or vacuum”.
2. Pull out the knob for the 0.07 MPa regulator to release the lock.
3. Adjust the pressure while watching the pressure displayed on the Sensor 1 screen.
   To increase the pressure, turn the knob clockwise.

   Normal range: 0.07 ± 0.001 MPa

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Information
Always adjust pressure so as to increase to the predetermined level. If the pressure is too high, lower it below that level once; then raise it to the set level.

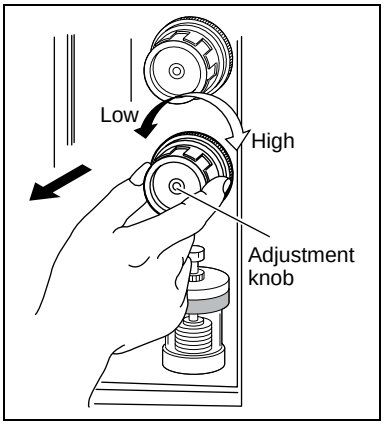
4. Check that the pressure displayed on the Sensor 1 screen is the predetermined pressure.
5. If the displayed pressure does not match the predetermined pressure, adjust it by repeating the operations 3 and 4.
6. When the adjustment is completed, press the adjustment knob for the 0.07 MPa regulator to lock.

Adjusting the pressure to 0.03 MPa

This pressure is supplied to RBC/PLT Sheath detector.

1. Display the Sensor 1 screen on the LCD screen.
   See “Chapter 9: 9.21 Displaying the pressure or vacuum”.
2. Pull out the knob for the 0.03 MPa regulator to release the lock.
3. Adjust the pressure while watching the pressure displayed on the Sensor 1 screen.
   To increase the pressure, turn the knob clockwise.

   Normal range: 0.03 ± 0.001 MPa



Information
Always adjust pressure so as to increase to the predetermined level. If the pressure is too high, lower it below that level once; then raise it to the set level.

4. Check that the pressure displayed on the Sensor 1 screen is the predetermined pressure.
5. If the displayed pressure does not match the predetermined pressure, adjust it by repeating the operations 3 and 4.
6. When the adjustment is completed, press the adjustment knob for the 0.03 MPa regulator to lock.

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Pneumatic Unit vacuum

The Pneumatic Unit vacuum cannot be adjusted with the Pneumatic Unit. If the vacuum indicator on the front panel of the Pneumatic Unit shows below 0.05 MPa, take the following steps:

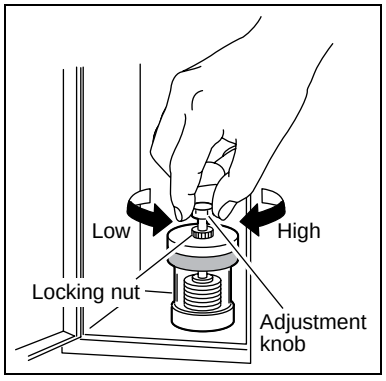
1. Pinch the tube that runs from the Pneumatic Unit to the Main Unit. If the vacuum increases to 0.05 MPa or more, there is leakage in the Main Unit. Contact your Sysmex technical representative.
2. Check the tube between the Main Unit and the Pneumatic Unit or inside the Pneumatic Unit. If any of them is disconnected, connect it securely.

Note:
After a long period of use, the vacuum decreases gradually. In such cases, the vacuum pump may need to be repaired or replaced. Please contact your Sysmex technical representative.

Adjusting the vacuum to 0.04 MPa

This vacuum is used to transfer fluid between the chambers.

1. Display the Sensor 1 screen on the LCD screen.
   See “Chapter 9: 9.21 Displaying the pressure or vacuum”.
2. Loosen the locking nut for the bellows unit.
3. Adjust the pressure while watching the pressure displayed on the Sensor 1 screen.
   To increase the pressure, turn the knob clockwise.



Normal range: 0.04 ± 0.001 MPa

Information
Always adjust pressure so as to increase to the predetermined level. If the pressure is too high, lower it below that level once; then raise it to the set level.

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4. Check that the pressure displayed on the Sensor 1 screen is the predetermined pressure.
5. If the displayed pressure does not match the predetermined pressure, adjust it by repeating the operations 3 and 4.
6. When the adjustment is completed, tighten the locking nut while taking care not to allow the adjustment knob to rotate.

9.22 Supplies and replacement parts

Reagents list

Part Number	Description		Volume
884-0871-1	CELLPACK (PK-30L)		20 L
834-0032-4	CELLSHEATH (SE-90L)		20 L
944-0461-3	STROMATOLYSER-FB (FBA-200A)		5 L
984-1771-2	STROMATOLYSER-4DL (FFD-200A)		5 L
984-1721-6	STROMATOLYSER-4DS (FFS-800A)		3 × 42 mL
064-2881-5	STROMATOLYSER-NR (L) (SNR-210A)	lyse	3.6 L
064-2891-2	STROMATOLYSER-NR (S) (SNR-810A)	dye	43 mL
904-1151-1	SULFOLYSER (SLS-220A)		5 L
934-0671-6	STROMATOLYSER-IM (SIM-220A)		10 L
984-1621-1	RET SEARCH (II) (RED-700A)	diluent	1 L
		dye	12 mL
834-0162-1	CELLCLEAN (CL-50)		50 mL

Replacements list

Part Number	Description	Refer to
971-0583-5	PIERCER SET NO. 1 (XE/STANDARD)	Chapter 9: 9.16
366-1792-2	TUBE HOLDER NO. 56 (WHITE)	Chapter 6: 6.16
366-1789-1	TUBE HOLDER NO. 58 (WHITE)	Chapter 6: 6.16
073-2763-1	SAMPLE RACK PACKAGE ASSEMBLY (WHITE) (6/PACK)	Chapter 6: 6.16
923-8101-4	HAND CLIPPER S#4 ASSY (C1/PIER)	Chapter 9: 9.17
368-0079-6	RUBBER PLATE NO. 39	Chapter 9: 9.18
266-5106-0	FUSE 250V 6.3A ST4-6.3A-N1 (N.AMERICA)	Chapter 9: 9.19
266-7651-2	FUSE 250V 4A 313004 (N.AMERICA)	Chapter 9: 9.19
266-5293-0	FUSE 250V 3.15A NO. 19195 (EUROPE)	Chapter 9: 9.19
443-2224-6	HEPA FILTER (WITH PRE)	Chapter 9: 9.20
462-3520-5	TRANSDUCER BRUSH	Chapter 9: 9.8 Chapter 9: 9.9
983-8861-9	FLOAT SWITCH NO. 25 ASSY (C1/5L)	Chapter 9: 9.13

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9.23 XE-5000 maintenance and inspection check list

DAILY MAINTENANCE:

Month _____ Year _____

Daily:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Execute shutdown																															
Check Trap Chamber Fluid Level																															
Initial:																															

AS NEEDED MAINTENANCE:

Procedure:	Date/Int.	Date/Int.
Clean manual rinse cup		
Clean sample rotor valve tray		
Clean piercer tray		
Remove clogs (Clog removal sequence)		
Clean IMI detector aperture		
Clean RBC detector aperture		
Remove flow cell air bubbles in optical detector block		
Clean flow cell in the optical detector block		
Replace waste container		

SAMPLE ROTOR VALVE MAINTENANCE:

Procedure:	Date/Int.	Date/Int.
Clean sample rotor valve		

REPLACEMENTS:

Procedure:	Date/Int.	Date/Int.
Replace reagents		
Replace piercer		
Replace hand clipper		
Replace rubber plate No. 39		
Replace fuses		
Replace HEPA filter		

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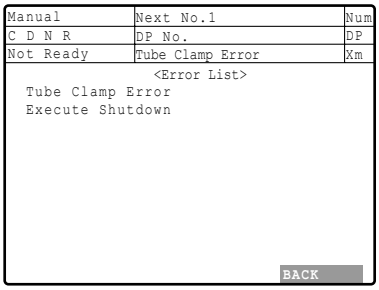
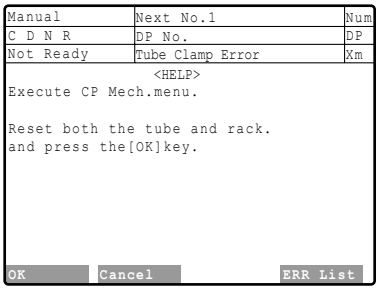
10.Troubleshooting

10.1 HELP screen



When an error occurs, an error message is displayed in the center of the LCD screen of the Main Unit panel keypad.
The LCD screen displays the content of the highest-priority error currently occurring.
If several errors occur, press the **HELP** key on the panel keypad, then select **"Error List"** on the function menu to display the Error List Display Screen.
To return to the Help Screen, select **"BACK"** on the function menu.



When an error occurs, press the **HELP** key on the panel keypad.
The error content and reset method will be displayed.
Follow the indicated recovery procedure and the content of "Chapter 10: 10.4 Troubleshooting guide".
If the recovery procedure does not restore the system to normal condition, contact your Sysmex technical representative.

10.2 Error log

The error log displays a maximum of 100 errors in order of their occurrence.
Older errors will automatically be deleted if the total number of errors exceeds 100.
The error log consists of the error messages and the error parameters.

1. Double-click the **"Controller"** icon on the Information Processing Unit (IPU) menu screen.
   The controller menu will be displayed.

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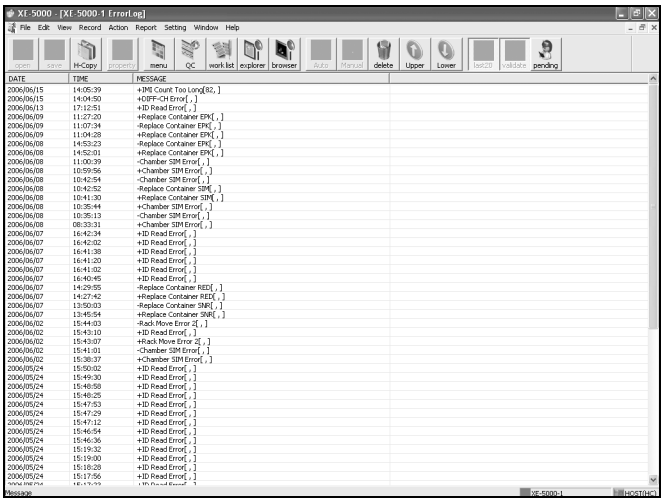
2. Double-click the **"Error log"** icon on the Controller menu. The Error Log screen appears.



Deleting error log

Error log can be deleted.

1. From the Error Log screen, select a record to delete by clicking on it.
2. From **"Record (R)"**on the menu bar, select **"Delete (D)"**, or click on the **"Delete"** button on the tool bar.
3. The Confirm Delete dialog box will be displayed.
4. Click **"OK"** to delete the selected record and close the dialog box.
   Click **"Cancel"** to cancel deletion.

> **Note:**
> Multiple error logs cannot be selected nor deleted at a time.

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10.3 Error message list

Alphabetical error message index

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Functional error message list

1. Pressure and Vacuum Errors

2. Temperature Errors

3. Chamber Errors

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Revised May 2011

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10.4 Troubleshooting guide

Note:

Errors are classified as follows:

1. Error caused by analysis failure
   Data added with abnormal status is displayed and stored. When all sequences have been completed, the system automatically enters Ready status.
   “Analysis Error” and “Check Stored Data” will be displayed.
2. “Not Ready” error
   Sample analysis that are in progress will continue, but when all analysis sequences have been completed, the instrument will wait without executing the following analysis.
   “Not Ready” and error messages will be displayed.
3. Error caused by analysis failure/“Not Ready” error
   There are two cases: (1) Data added with error status is displayed and stored, and(2) An error message alone is displayed. When all sequences have been completed, the instrument will wait without executing the following analysis. The system enters Ready status after confirming that the abnormal condition no longer exists.
   “Not Ready” and “Analysis Error” will be displayed.
   If an error occurs during a sampler analysis, “Analysis Error” and “Check Stored Data” will be displayed.
4. Message urging caution
   If an analysis can be performed, but caution should be urged, a message will be displayed.
   When the need to urge caution no longer exists, the message will disappear.

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Note:

5. Emergency stop
   If an error occurs, the analysis operations will immediately be discontinued, and all the sequences will stop.
   Then the message prompting you to turn OFF the power will appear. To restore the system, turn the power OFF, wait for at least 10 seconds, and then turn it ON again.

• Sample data with an error will be displayed in "----."

1. Pressure and Vacuum Errors

Error messages: 0.25 MPa ERROR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. 0.25 MPa pressure adjustment error 2. Inadequate pressure in the Pneumatic Unit 3. Pressure leakage from tube or nipple **Corrective Action** 1. Adjust pressure of 0.25 MPa. (Refer to Chapter 9: 9.21 Adjusting pressure and vacuum.) 2. Check the Pneumatic Unit power switch and the power cord connection. 3. Check the tube connection and nipple looseness.
Error messages: 0.16 MPa ERROR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. 0.16 MPa pressure adjustment error 2. Defective 0.16 MPa regulator **Corrective Action** 1. Adjust pressure of 0.16 MPa. (Refer to Chapter 9: 9.21 Adjusting pressure and vacuum.) 2. If adjustment of 0.16 MPa pressure fails, the regulator is probably defective. Contact your Sysmex technical representative.
Error messages: 0.07 MPa ERROR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. 0.07 MPa pressure adjustment error 2. Defective 0.07 MPa regulator **Corrective Action** 1. Adjust pressure of 0.07 MPa. (Refer to Chapter 9: 9.21 Adjusting pressure and vacuum.) 2. If adjustment of 0.07 MPa pressure fails, the regulator is probably defective. Contact your Sysmex technical representative.
Error messages: 0.03 MPa ERROR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. 0.03 MPa pressure adjustment error 2. Defective 0.03 MPa regulator **Corrective Action** 1. Adjust pressure of 0.03 MPa. (Refer to Chapter 9: 9.21 Adjusting pressure and vacuum.) 2. If adjustment of 0.03 MPa pressure fails, the regulator is probably defective. Contact your Sysmex technical representative.

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Error messages: -0.07 MPa ERROR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Inadequate vacuum in the Pneumatic Unit 2. Pressure leakage from tube or nipple **Corrective Action** 1. The Pneumatic Unit is probably defective. Contact your Sysmex technical representative. 2. Check the tube connection and nipple looseness.
Error messages: -0.04 MPa ERROR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. -0.04 MPa vacuum adjustment error 2. There is fluid in the Pneumatic Unit trap chamber. 3. Pressure leakage from tube or nipple **Corrective Action** 1. Adjust vacuum to -0.04 MPa. (Refer to Chapter 9: 9.21 Adjusting pressure and vacuum.) 2. Drain fluid from the Pneumatic Unit trap chamber. (Refer to Chapter 9: 9.2 Removing fluid from the Pneumatic Unit trap chamber.) 3. Check the tube connection and nipple looseness.
Error messages: Pressure Lower Error **Status:** Emergency Stop	**Probable Cause** 1. Pneumatic Unit power is OFF during the operation. 2. Pressure connection tube is disconnected. **Corrective Action** 1. Check the Pneumatic Unit power switch and the power cord connection. 2. Check the pressure connection tube.

2. Temperature Errors

Error messages: Close RBC Detect Cover **Status:** Not Ready	**Probable Cause** 1. RBC detector cover is open. 2. The cover sensor of RBC detector has failed. **Corrective Action** 1. Close the RBC detector cover. If the error persists, the cover sensor is probably defective. 2. Replace the cover sensor of RBC detector: Contact your Sysmex technical representative.
Error messages: IMI Detector Cover Open **Status:** Not Ready	**Probable Cause** 1. IMI detector cover is open. 2. The cover sensor of IMI detector has failed. **Corrective Action** 1. Close the IMI detector cover. If the error persists, the cover sensor is probably defective. 2. Replace the cover sensor of IMI detector: Contact your Sysmex technical representative.

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Error messages: RBC Detector Temp High RBC Detector Temp Low **Category:** Analysis Error	**Probable Cause** 1. Temperature of sample in RBC detector is not within 10 to 40°C. **Corrective Action** 1. Check the ambient temperature: Use sample at an ambient temperature of 15 to 30ºC (Optimum: 25°C).
Error messages: IMI Detector Temp High IMI Detector Temp Low **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Temperature of IMI detector is outside the regulation range. **Corrective Action** 1. Wait until the temperature has stabilized inside the regulation range: If this error is still displayed 30 minutes after the power is turned ON, there is probably something defective in the system. Contact your Sysmex technical representative. In this case, CBC and RET can be analyzed even if the error persists.
Error messages: IMI Detector Temp High HPC IMI Detector Temp Low HPC **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Temperature of IMI detector is outside the regulation range for HPC analysis mode. **Corrective Action** 1. Wait until the temperature has stabilized inside the regulation range: If this error is still displayed 30 minutes after switching to HPC analysis mode, there is probably something defective in the system. Contact your Sysmex technical representative. In this case, it is possible to perform analysis in normal mode even if the error persists.
Error messages: 40°C RH Temp High 40°C RH Temp Low **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Temperature of 40°C reagent heater is outside the regulation range. **Corrective Action** 1. Wait until the temperature has stabilized inside the regulation range: If this error is still displayed 30 minutes after the power is turned ON, there is probably something defective in the system. Contact your Sysmex technical representative.
Error messages: 33°C RH Temp High 33°C RH Temp Low **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Temperature of 33°C reagent heater is outside the regulation range. **Corrective Action** 1. Wait until the temperature has stabilized inside the regulation range: If this error is still displayed 30 minutes after the power is turned ON, there is probably something defective in the system. Contact your Sysmex technical representative.

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Error messages: FCM RU Temp High FCM RU Temp Low **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Temperature of reaction chamber is outside the regulation range. **Corrective Action** 1. Wait until the temperature has stabilized inside the regulation range. If this error is still displayed 30 minutes after the power is turned ON, there is probably something defective in the system. Contact your Sysmex technical representative.
Error messages: FCM Detector Temp High FCM Detector Temp Low **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Temperature of optical detector block is outside the regulation range. **Corrective Action** 1. Wait until the temperature has stabilized inside the regulation range. If this error is still displayed 30 minutes after the power is turned ON, there is probably something defective in the system. Contact your Sysmex technical representative.
Error messages: IMI TD Therm Sens ERR **Status:** Not Ready	**Probable Cause** 1. One of the thermal sensors for IMI detector has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error messages: IMI TD Therm Sens ERR HPC **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. One of the thermal sensors for IMI reaction chamber has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative. In this case, it is possible to perform analysis in normal mode even if the error persists.
Error messages: 33°C RH Therm Sens ERR **Status:** Not Ready	**Probable Cause** 1. One of the thermal sensors for 33ºC reagent heater has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error messages: 40°C RH Therm Sens ERR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. One of the thermal sensors for 40ºC reagent heater has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error messages: FCM RU Therm Sens ERR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. One of the thermal sensors for reaction chamber has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.

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Error messages: FCM TD Therm Sens ERR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. One of the thermal sensors for optical detector block has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error messages: Env Therm Sens ERR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. One of the thermal sensors for detecting outside air temperature has broken. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error messages: IMI Reac Temp High HPC IMI Reac Temp Low HPC **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. IMI reaction temperature is outside the regulation range for HPC analysis mode. **Corrective Action** 1. IMI reaction temperature stabilization: Press the **HELP** key on the Main Unit panel keypad. Select **"OK"** on the function menu to execute IMI temperature stabilization sequence. In this case, it is possible to perform analysis in normal mode even if the error persists.
Error messages: Env Temp High HPC Env Temp Low HPC **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. The ambient temperature in which the instrument is used is outside the the regulation range for HPC analysis mode. **Corrective Action** 1. Check the ambient temperature: Keep surrounding temperature within the range 20-30°C, in which HPC analysis mode is usable. In this case, it is possible to perform analysis in normal mode even if the error persists.
Error messages: IMI Temp Stab. ERR **Status:** Not Ready	**Probable Cause** 1. Before the IMI reaction temperature stabilized, the transition to HPC mode was processed, and the HPC sleep restoration process was completed. **Corrective Action** 1. IMI reaction temperature stabilization: Press the **HELP** key on the Main Unit panel keypad. Select **"OK"** on the function menu to execute IMI temperature stabilization sequence. In this case, it is possible to perform analysis in normal mode even if the error persists.

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3. Chamber Errors

Error messages:	**Probable Cause**
Replace Container ESE Replace Container SIM (CBC and RET can be analyzed.) Replace Container EPK Replace Container SLS Replace Container FBA Replace Container FFD (CBC and RET can be analyzed.) Replace Container FFS (CBC and RET can be analyzed.) Replace Container SNR (CBC, DIFF and RET can be analyzed.) Replace Container RED (CBC, DIFF and NRBC can be analyzed.) **Status:** Not Ready	1. Insufficient reagent 2. Defective float switch 3. Abnormality in the hydraulic system **Corrective Action** 1. Replace reagent: Replace the empty reagent container with new one, and press the **HELP** key on the Main Unit panel keypad. A help message will be displayed. Select **"OK"** on the function menu. If the error persists after replacement, there is probably a defective float switch or an abnormality in the hydraulic system. 2. Check the float switch. 3. Check the hydraulic system: Check for bending, looseness or tears of the tube for the reagent indicated by the error message. If an abnormality is found, repair the connections or replace the affected items. **Note:** • When a reagent replacement error occurs during an analysis, analysis is available in the manual mode or capillary mode, but unavailable in the sampler mode. For details, refer to "Chapter 6: 6.17 Sample analysis in manual mode" and "Chapter 6: 6.18 Sample analysis in capillary Mode", and change the discrete. When analysis order inquiry is performed in the manual mode, analysis is unavailable if "Realtime Request (Manual Mode) [Sample ID]" checkbox is checked in the Analysis Ordering Screen. To uncheck, refer to "Chapter 5: 5.2 Information processing unit (IPU) setting, Analysis Ordering" in XE-5000 Software Guide. • When a reagent replacement error occurs at start up, the analysis is unavailable in any mode until the recovery from the error status.

Error messages: Chamber EPK Error Chamber ESE Error Chamber SIM Error (CBC can be analyzed.) Chamber FCM Sheath ERR **Status:** Not Ready	**Probable Cause** 1. Tubing between the reagent container and the Main Unit is bent, clogged or disconnected. **Corrective Action** 1. Check the tubing: Press the **HELP** key on the Main Unit panel keypad. A help message will be displayed. Select **"OK"** on the function menu, then aspirate reagent. **Note:** • When a reagent replacement error occurs during an analysis, analysis is available in the manual mode or capillary mode, but unavailable in the sampler mode. For details, refer to "Chapter 6: 6.17 Sample analysis in manual mode" and "Chapter 6: 6.18 Sample analysis in capillary Mode", and change the discrete. When analysis order inquiry is performed in the manual mode, analysis is unavailable if "Realtime Request (Manual Mode) [Sample ID]" checkbox is checked in the Analysis Ordering Screen. To uncheck, refer to "Chapter 5: 5.2 Information processing unit (IPU) setting, Analysis Ordering" in XE-5000 Software Guide. • When a reagent replacement error occurs at start up, the analysis is unavailable in any mode until the recovery from the error status
Error messages: Waste Chamber 1 Error Waste Chamber 2 Error Waste Chamber 3 Error **Status:** Not Ready	**Probable Cause** 1. Drain line tubing is bent or clogged. **Corrective Action** 1. Check the drain line tubing: If bending or clogging is found on the tube connected to the drain outlet nipple, clean or replace the tubing. Especially check for dirt or clogging around the drain outlet. After the check, press the **HELP** key on the panel keypad of the Main Unit. A help message will be displayed. Select **"OK"** on the function menu, then empty the waste chamber.
Error messages: RBC Chamber Drain Error **Status:** Not Ready	**Probable Cause** 1. RBC sheath drain line tubing is bent or clogged. **Corrective Action** 1. Check the RBC sheath drain line tubing: If bending or clogging is found on the tube connected to the drain outlet nipple, clean or replace the tubing. Especially check for dirt or clogging around the drain outlet. After the check, press the **HELP** key on the panel keypad of the Main Unit. A help message will be displayed. Select **"OK"** on the function menu, then empty the waste chamber.

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Error messages: Exchange Waste Tank **Status:** Not Ready	**Probable Cause** 1. Waste container is full. **Corrective Action** 1. Replace the waste container. (Refer to Chapter 9: 9.12 Replacing the waste container (option).)

4. Motor Errors

Error messages: WB Asp Motor Error **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. The load on the whole blood aspiration pump is abnormally high. **Corrective Action** 1. Check the WB aspiration pump: Check that no fluid switch connector or tubing is touching the upper/lower part of WB aspiration pump. Then press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to check the operation.
Error messages: RBC Sheath Motor Error **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. The load on the RBC sheath injector piston is abnormally high. **Corrective Action** 1. Check the RBC seath injector piston: Check that no fluid switch connector or tubing is touching the upper/lower part of RBC sheath injector piston. Then press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to check the operation.
Error messages: FCM Sheath Motor Error **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. The load on the FCM sheath injector piston is abnormally high. **Corrective Action** 1. Check the FCM seath injector piston: Check that no fluid switch connector or tubing is touching the upper/lower part of FCM sheath injector piston. Then press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to check the operation.
Error messages: Rinse Motor Error **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. The load on the rinse cup driving part is abnormally high. **Corrective Action** 1. Check the rinse cup: Check that no fluid switch connector or tubing is touching the upper/lower part of the rinse cup. Then press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to check the operation.

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Error messages: Mixing Motor Error **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. The load on the reaction chamber mixing motor is abnormally high. **Corrective Action** 1. Check the reaction chamber mixing motor: Check that no tubing is touching the mixing motor. Then press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to check the operation.

5. WB Aspiration and Dilution Errors

Error messages: Low Blood Volume **Category:** Analysis Error	**Probable Cause** 1. Blood volume is short during sampler operation. **Corrective Action** 1. Analyze in manual mode or capillary mode.
Error messages: Sample Not Asp Error **Category:** Analysis Error	**Probable Cause** 1. Abnormal blood sample Clumps present in blood sample. Extremely low concentration blood 2. The parts below are clogged: Piercer Sample rotor valve Whole blood aspiration line tubing 3. Tubing in the whole blood aspiration line is disconnected from the sampler. **Corrective Action** 1. Check the whole blood sample, and reanalyze it. 2. Clean the sampler piercer, SRV and whole blood aspiration line as follows: 1. Perform the shutdown sequence using CELLCLEAN. (Refer to Chapter 9: 9.1 Execution of shutdown.) 2. When the shutdown sequence is completed, perform auto rinse. 3. When the auto rinse is completed and the system enters Ready status, reanalyze the sample. 4. If dirt cannot be removed completely, pour CELLCLEAN into the test tubes and analyze these samples in the sampler mode to clean the piercer and the whole blood aspiration line. 5. If the error still persists, it is assumed that the piercer is clogged by clots, replace the piercer. (Refer to Chapter 9: 9.16 Replacing the piercer.) 3. Reconnect the tubing.

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Error messages: Short Sample **Category:** Analysis Error	**Probable Cause** 1. Blood volume is insufficient. The required volume of blood has not been aspirated. 2. Dirty piercer or whole blood aspiration line **Corrective Action** 1. The required volume of blood has not been aspirated. Analyze in manual mode or capillary mode. 2. If the “Short Sample” error persists although there is enough sample in the test tube, it is suspected that the piercer or the whole blood aspiration line is dirty. Clean it as follows: 1. Perform the shutdown sequence using CELLCLEAN. (Refer to Chapter 9: 9.1 Execution of shutdown.) 2. When the shutdown sequence is completed, perform auto rinse. 3. When the auto rinse is completed and the system enters Ready status, reanalyze the sample. 4. If dirt cannot be removed completely, pour CELLCLEAN into the test tubes and analyze these samples in the sampler mode to clean the piercer and the whole blood aspiration line. 5. If the error still persists, it is assumed that the piercer is clogged by clots, replace the piercer. (Refer to Chapter 9: 9.16 Replacing the piercer.)  **Note:** If the test tube is dirty or the barcode label is affixed on the lower area than the specified position, the sampler unit cannot detect the blood volume. Therefore, even if the blood amount is insufficient, the aspiration will be performed, and the “Short Sample” error will occur.
Error messages: SRV Lower Position ERR SRV Upper Position ERR **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Sample rotor valve has malfunctioned. 2. Dirty sample rotor valve **Corrective Action** 1. Perform test operation: Check that no tubing is touching any rotating part(s) of the sample rotor valve. And press the **HELP** key on the panel keypad of the Main Unit. Then select **“OK”** on the function menu to check the operation. 2. Clean the sample rotor valve, and execute test operation.
Error messages: Blood Asp Sensor Error **Status:** Not Ready	**Probable Cause** 1. The sensor that monitors whether blood is being aspirated normally during sampler operation is defective. **Corrective Action** 1. Replace the blood aspiration sensor: Contact your Sysmex technical representative. As a tentative measure, alter the sampler stop conditions to allow sampler operation to continue.

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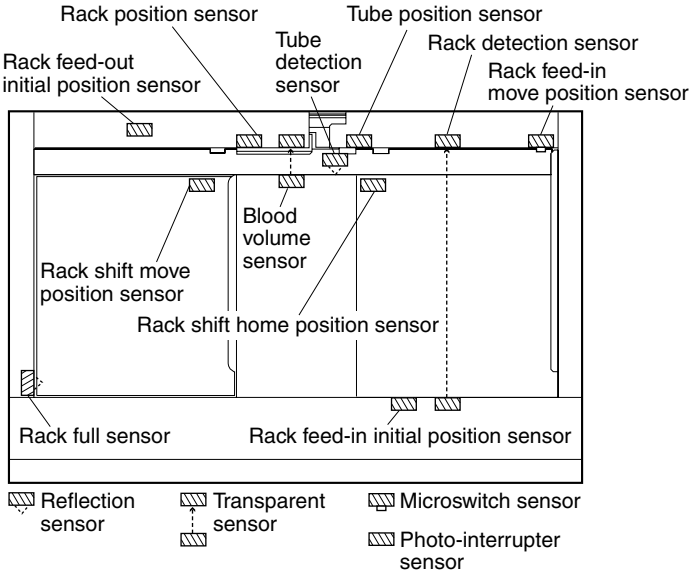
6. Sampler Operation Errors

The names and positions of the various sensors fitted to the sampler are shown below.



Error messages: Set Piercer Cover **Status:** Not Ready	**Probable Cause** 1. CP cover has not been installed. **Corrective Action** 1. Install the CP cover: After the installation, press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to check the operation.
Error messages: Rack Feed In Func Error **Status:** Not Ready	**Probable Cause** 1. Rack feed-in move position sensor has malfunctioned. 2. The rack moves by irresistible force during sampler analysis. **Corrective Action** 1. Remove dirt or dust. 2. There may be an inconsistency between sample number and analysis result. Check the analysis results of all the samples inserted in the rack on the analysis line.
Error messages: Rack Feed In Init. ERR **Status:** Not Ready	**Probable Cause** 1. Rack feed-in initial position sensor has malfunctioned due to dirt or dust. **Corrective Action** 1. Remove dirt or dust.

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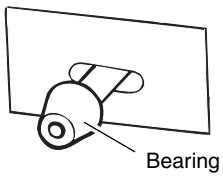
Error messages: Rack Shift Function ERR **Status:** Not Ready	**Probable Cause** 1. Rack shift move position sensor has malfunctioned due to dirt or dust. 2. Actuator bearing of rack position sensor is fixed. 3. The rack moves by irresistible force during sampler analysis.  **Corrective Action** 1. Remove dirt or dust. 2. Apply lubrication oil to the bearing. 3. There may be an inconsistency between sample number and analysis result. Check the analysis results of all the samples inserted in the rack on the analysis line.
Error messages: Rack Shift Home Pos. ERR **Status:** Not Ready	**Probable Cause** 1. Rack shift home position sensor has malfunctioned due to dirt or dust. **Corrective Action** 1. Remove dirt or dust.
Error messages: Rack Removed **Status:** Not Ready	**Probable Cause** 1. While the hand clipper is catching the test tube during sampler analysis, the rack moves by irresistible force. **Corrective Action** 1. Remove the test tube from the hand clipper, and return it to the rack. Reinstall the rack, and perform the analysis again.
Error messages: Rack Move Error 1	**Probable Cause** 1. Rack has not been shifted. **Corrective Action** 1. Reinstall the rack, and perform the analysis again.
Error messages: Rack Move Error 2	**Probable Cause** 1. While the hand clipper has not caught the test tube during sampler analysis, the rack moves by irresistible force. **Corrective Action** 1. Reinstall the rack, and perform the analysis again.
Error messages: Rack Move Error 3	**Probable Cause** 1. When interruption is ready, the rack moves by irresistible force. **Corrective Action** 1. Reinstall the rack, and perform the analysis again.

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Error messages: Rack Feed Out Func ERR Rack Feed Out Init. ERR **Status:** Not Ready	**Probable Cause** 1. Rack feed-out initial position sensor has malfunctioned due to dirt or dust. 2. The rack moves by irresistible force during sampler analysis. **Corrective Action** 1. Remove dirt or dust. 2. There may be an inconsistency between sample number and analysis result. Verify the analysis results of all the samples in the rack on the analysis line as well as all the samples inserted in the rack that has just been fed out.
Error messages: Hand Init Position ERR Hand Move Position ERR **Status:** Not Ready	**Probable Cause** 1. Forward/backward cylinder has malfunctioned. **Corrective Action** 1. Perform test operation. Before the test operation, remove the test tube from the hand clipper, and return it to the rack. Check the hand's forward/backward position for obstacles, and press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to check the operation.
Error messages: Hand Upper Position ERR Hand Lower Position ERR **Status:** Not Ready	**Probable Cause** 1. Up-down cylinder has malfunctioned. **Corrective Action** 1. Perform test operation. Before the test operation, remove the test tube from the hand clipper, and return it to the rack. Check the hand's up/down position for obstacles, and press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to check the operation.
Error messages: Tube Inv. Position ERR **Status:** Not Ready	**Probable Cause** 1. Tube inversion cylinder has malfunctioned. **Corrective Action** 1. Perform test operation. Before the test operation, remove the test tube from the hand clipper, and return it to the rack. Check the hand mixing for error, and press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to check the operation.
Error messages: Tube Sensor Error **Category:** Message urging caution	**Probable Cause** 1. Although there is the test tube containing blood, the tube detection sensor detects that no tube is found. 2. Although there is no test tube, the blood detection sensor detects that blood is found. **Corrective Action** 1. Remove dirt from the tube detection sensor. 2. Remove dirt from the blood volume sensor.

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Error messages: Tube Clamp Error **Status:** Not Ready	**Probable Cause** 1. Clamping failure 2. Hand clipper is bent, and the test tube is not grasped correctly. **Corrective Action** 1. Perform test operation: Before the test operation, remove the test tube from the hand clipper, and return it to the rack. Check the clamping for error, and press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to check the operation. 2. After correcting or replacing the hand clipper, perform the test operation.
Error messages: Rack Full Error	**Probable Cause** 1. Rack full sensor detects that the racks have filled up, and sampler analysis cannot be continued. **Corrective Action** 1. Remove the analyzed racks from the sampler left rack pools.
Error messages: Sampler Start ERR (BSNS) Sampler Start ERR (SNS4) Sampler Start ERR (SNS5) **Status:** Not Ready	**Probable Cause** 1. When there are racks remain on the positions other than the rack set position of the sampler analysis line, the sample analysis has been started. **Corrective Action** 1. Remove the racks from the analysis line, and restart the analysis.
Error messages: Rack Not Exist **Category:** Message urging caution	**Probable Cause** 1. There is no analysis rack in the right rack pool. **Corrective Action** 1. Place the rack in the right rack pool to perform the analysis.

7. Volumetric Block Errors

Error messages: IMI Count Too Long **Category:** Analysis Error	**Probable Cause** 1. Clogging at detector aperture **Corrective Action** 1. Remove clogs: Press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to execute the clog removal sequence. If the error persists, clean the IMI detector aperture with the brush. (Refer to Chapter 9: 9.8 Cleaning the IMI detector aperture.)
Error messages: IMI Count Too Short **Category:** Analysis Error	**Probable Cause** 1. Air bubbles in volumetric block **Corrective Action** 1. Perform auto rinse: Press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to execute the auto rinse.

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8. Analysis Errors

Error messages: Background Error **Category:** Analysis Error	**Probable Cause** 1. Mixing of air bubbles 2. Dirty aperture 3. Faulty reagent **Corrective Action** 1. Perform auto rinse: Press the **HELP** key on the panel keypad of the Main Unit. Then select **"OK"** on the function menu to execute the automatic cleaning. 2. Remove clogs: Select **"Maint"** on the function menu of the Main Unit LCD screen. Then select **"3. Clog Removal"** on the Maintenance screen to execute the clog removal sequence. If the error persists, clean the detector aperture with the brush. (Refer to Chapter 9: 9.8 Cleaning the IMI detector aperture, 9.9 Cleaning the RBC detector aperture.) 3. Replace the reagent. (Refer to Chapter 9: 9.13 Replacing and registering reagents.)
Error messages: RBC Sampling Error PLT Sampling Error **Category:** Analysis Error	**Probable Cause** 1. Dirty aperture 2. Abnormal sample **Corrective Action** 1. Remove clogs: Select **"Maint"** on the function menu of the Main Unit LCD screen. Then select **"3. Clog Removal"** on the Maintenance screen to execute the clog removal sequence. If the error persists, clean the detector aperture with the brush. (Refer to Chapter 9: 9.9 Cleaning the RBC detector aperture.) 2. Perform the analysis again.
Error messages: WBC/BASO Sampling Error DIFF Sampling Error NRBC Sampling Error RET Sampling Error **Category:** Analysis Error	**Probable Cause** 1. Clogging or dirt at optical detector block flow cell 2. Abnormal sample **Corrective Action** 1. Clean the flow cell of optical detector block. (Refer to Chapter 9: 9.11 Cleaning the flow cell in the optical detector block.) 2. Perform the analysis again.
Error messages: RBC CCSD Noise Error PLT CCSD Noise Error IMI CCSD Noise Error FCM CCSD Noise Error **Category:** Analysis Error	**Probable Cause** 1. External noise interference 2. Sudden noise interference **Corrective Action** 1. Interrupt the noise source. Keep the noise source away from the Main Unit. 2. Perform the analysis again.

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Error messages: IMI RF Noise Error **Category:** Analysis Error	**Probable Cause** 1. The level of RF signal noise is high. **Corrective Action** 1. Perform the analysis again. If the error persists, contact your Sysmex technical representative.
Error messages: RBC Bubble Error RBC Clog Error **Category:** Analysis Error	**Probable Cause** 1. Clogging at RBC detector or mixing of air bubbles **Corrective Action** 1. Remove the clogging from the RBC detector: Press the **HELP** key on the panel keypad of the Main Unit. Select **"OK"** on the function menu to execute the clog removal sequence. If the error persists, clean the detector aperture with the brush. (Refer to Chapter 9: 9.9 Cleaning the RBC detector aperture.)
Error messages: Low Count Error **Category:** Analysis Error	**Probable Cause** 1. Abnormal sample 2. Clogging at piercer 3. Clogging at sample rotor valve (SRV) 4. Clogging at WB aspiration tube **Corrective Action** 1. Perform the analysis again. 2. Clean the piercer. 3. Clean the sample rotor valve (SRV). 4. Clean the WB aspiration tube.
Error messages: HGB Error **Category:** Analysis Error	**Probable Cause** 1. Air bubbles are mixed in HGB analysis line. **Corrective Action** 1. Perform auto rinse: Select **"Auto Rinse"** on the function menu to execute the automatic cleaning.
Error messages: HGB Drain Error **Category:** Analysis Error	**Probable Cause** 1. Draining speed of HGB cell background fluid is low. **Corrective Action** 1. Check the drain line tubing of HGB cell. Check that no tubing is bent or clogged.
Error messages: IMI Detector Error **Category:** Analysis Error	**Probable Cause** 1. Dirt or air bubbles in IMI detector **Corrective Action** 1. Clean the IMI detector: Select **"Maint"** on the function menu of the Main Unit LCD screen. Then select **"3. Clog Removal"** on the Maintenance screen to execute the clog removal sequence. If the error persists, clean the detector aperture with the brush. (Refer to Chapter 9: 9.8 Cleaning the IMI detector aperture.)

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Error messages: RET Error **Category:** Analysis Error	**Probable Cause** 1. Abnormal sample 2. Clogging, bending or disconnection at RET dye solution and diluent line tubing **Corrective Action** 1. Perform the analysis again. 2. Check the dye solution tubing and the reagent amount.
Error messages: WBC/BASO-CH Error DIFF-CH Error NRBC-CH Error **Category:** Analysis Error	**Probable Cause** 1. Clogging or dirt at optical detector block flow cell 2. Abnormal short sample (Insufficient samples or mixing of air bubbles, etc.) 3. Abnormal sample (Platelet coagulation or sedimentation of cold protein, etc.) **Corrective Action** 1. Clean the flow cell of optical detector block. (Refer to Chapter 9: 9.11 Cleaning the flow cell in the optical detector block.) 2. Perform the analysis again. 3. Check the sample using smear or visually.
Error messages: RBC-CH Error PLT-CH Error **Category:** Analysis Error	**Probable Cause** 1. The number of RBC/PLT channel particles exceeds the upper limit of display range because of external noise. **Corrective Action** 1. Interrupt the noise source. Keep the noise source away from the Main Unit. 2. Perform the analysis again.
Error messages: RET-CH Error **Category:** Analysis Error	**Probable Cause** 1. Abnormal sample 2. Sample rotor valve has clogged. 3. Clogging or dirt at optical detector block flow cell 4. Air bubbles in optical detector block flow cell **Corrective Action** 1. Perform the analysis again. 2. Clean the sample rotor valve. 3. Clean the flow cell of optical detector block. (Refer to Chapter 9: 9.11 Cleaning the flow cell in the optical detector block.) 4. Remove the air bubbles from the flow cell of optical detector block.

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Error messages: DATA Error **Category:** Analysis Error	**Probable Cause** 1. Analysis result exceeds the Reference Limit set on IPU 2. Abnormal sample 3. Dirty aperture **Corrective Action** 1. Reset the Reference Limit of IPU. (Refer to “Chapter 5: Instrument Setup” in the Software Guide.) 2. Perform the analysis again. 3. Remove clogs. Select **“Maint”** on the function menu of the Main Unit LCD screen. Then select **“3. Clog Removal”** on the Maintenance screen to execute the clog removal sequence. 4. Perform the quality control analysis, if necessary.
Error messages: Execute Background check **Category:** Message urging caution	**Probable Cause** 1. If the analysis value is too high in body fluid analysis, there is the risk that the analysis result for the next sample may be affected by carryover. **Corrective Action** 1. Perform a background check. Perform auto rinse if the problem is not solved by the background check.

9. Laser Errors

Error messages: Laser Tube Aged **Category:** Message urging caution	**Probable Cause** 1. Laser life is coming to end. (Analysis is possible.) **Corrective Action** 1. Turn the power OFF, then ON again. Check whether the error has been resolved. If the error persists, contact your Sysmex technical representative.
Error messages: Laser Power Error **Category:** Analysis Error	**Probable Cause** 1. Deteriorated laser **Corrective Action** 1. Perform the analysis again. If the error persists, contact your Sysmex technical representative.
Error messages: Close FCM Detect Cover **Status:** Not Ready **Category:** Analysis Error	**Probable Cause** 1. Optical detector block cover is open. 2. The sensor of optical detector block cover is defective. **Corrective Action** 1. Close the cover of optical detector block. If the error persists, the cover sensor is possibly defective. 2. Replace the sensor of optical detector block cover. Contact your Sysmex technical representative.

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10. Subprocessor Errors

Error messages:	**Probable Cause**
TC Com. Error ID Unit Com. Error (Manual mode analysis unavailable.) Sampler Com. Error (Manual mode analysis unavailable.) **Status:** Not Ready **Category:** Analysis Error	1. Malfunction of CPU is caused by sudden noise interference, etc. **Corrective Action** 1. Turn the power OFF, then ON again. If the same error message is displayed again, contact your Sysmex technical representative.

11. Memory Errors

Error messages:	**Probable Cause**
RAM Error Setup Data Error **Status:** Not Ready **Category:** Analysis Error	1. Malfunction of CPU is caused by sudden noise interference, etc. **Corrective Action** 1. Turn the power OFF, then ON again. If the same error message is displayed again, contact your Sysmex technical representative.

12. External Output Errors

Error messages:	**Probable Cause**
DP Error	**Probable Cause** 1. No DP printer paper 2. DP is in offline status. 3. DP power is OFF. **Corrective Action** 1. Supply DP printer paper. 2. Set the DP to the online status. 3. Turn the DP power ON.
Error messages: IPU Communication Error **Status:** Not Ready	**Probable Cause** 1. The power of IPU is turned OFF during normal operation. 2. XE program of IPU is interrupted during normal operation. 3. Connection cable to the Main Unit is disconnected during normal operation. 4. Other probable causes **Corrective Action** 1. Turn OFF the power of the Main Unit, then turn ON the powers of the IPU and Main Unit again. 2. Turn OFF the power of the Main Unit, and connect the connection cable. Then turn ON the powers of the IPU and Main Unit. 3. Contact your Sysmex technical representative.

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Error messages: IPU Error **Status:** Not Ready	**Probable Cause** 1. When the Main Unit is started, the power of IPU is turned OFF. 2. When the Main Unit is started, the XE program of IPU has not been started. 3. When the Main Unit is started, the connection cable to the Main Unit is disconnected. 4. Other probable causes **Corrective Action** 1. Turn ON the power of the IPU to start the application. Then select **"Retry"** on the "Reconnect?" screen of the Main Unit. 2. Start the XE program of the IPU. Then select **"Retry"** on the "Reconnect?" screen of the Main Unit. 3. Connect the connection cable, and select **"Retry"** on the "Reconnect?" screen of the Main Unit. 4. Contact your Sysmex technical representative.

13. ID Errors

Error messages: ID Read Error Rack ID Read Error	**Probable Cause** 1. Dirty ID barcode 2. Poorly printed ID barcode 3. Incorrect position of ID barcode **Corrective Action** 1. Check the ID barcode. (Refer to Chapter 6: 6.2 ID barcode specifications.)

14. QC Errors

Error messages: Xm Limit Error L-J Limit Error Xb Limit Error	**Probable Cause** 1. $\overline{X}_M$ or L-J, $\overline{X}$ control error has occurred. For details of "control error", see "Chapter 7: 7.6 Troubleshooting control chart definition". **Corrective Action** 1. Check the QC chart. 2. Check the analysis data for the items that exceed control limits. 3. If necessary, perform calibration.
Error messages: Control Expired **Category:** Message urging caution	**Probable Cause** 1. Expiration date of control blood in use has expired. **Corrective Action** 1. Replace the control blood with the new one.
Error messages: Control Entry Err **Category:** Message urging caution	**Probable Cause** 1. New lot information of the control blood has not been registered. **Corrective Action** 1. Register the new lot information of the control blood. (Refer to Chapter 7: 7.8 Lot No.)

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15. Maintenance Errors

Error messages: Replace Piercer **Category:** Message urging caution	**Probable Cause** 1. It is time to replace the piercer. **Corrective Action** 1. Replace the piercer, and reset the piercer operation count. (Refer to Chapter 9: 9.16 Replacing the piercer.)
Error messages: Execute Shutdown **Category:** Message urging caution	**Probable Cause** 1. It is time to execute shutdown. **Corrective Action** 1. Press the **SHUTDOWN** key to execute shutdown. (Refer to Chapter 9: 9.1 Execution of shutdown.)
Error messages: Clean The SRV **Category:** Message urging caution	**Probable Cause** 1. It is time to clean the sample rotor valve. **Corrective Action** 1. Clean the sample rotor valve and reset the counter of the SRV. (Refer to Chapter 9: 9.3 Cleaning the sample rotor valve.)
Error messages: Execute Rinse Flowcell **Category:** Message urging caution	**Probable Cause** 1. It is time to rinse the flow cell in the optical detector. **Corrective Action** 1. Rinse the flow cell in the optical detector. (Refer to Chapter 9: 9.11 Cleaning the flow cell in the optical detector block.)
Error messages: Expired Reagent (EPK) Expired Reagent (ESE) Expired Reagent (SLS) Expired Reagent (FBA) Expired Reagent (FFD) Expired Reagent (FFS) Expired Reagent (SIM) Expired Reagent (SNR) Expired Reagent (RED)	**Probable Cause** 1. The expiry limit of the reagent has expired, according to the limit set when the reagent was registered. **Corrective Action** 1. Replace reagent: Replace the expired reagent with new one. Press the **HELP** key on the Main Unit panel keypad. A help message will be displayed. Select **"OK"** on the function menu, then register the reagent on the displayed reagent setting screen.

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10.5 Test

The XE-5000 is equipped with test processes for checking system operation and finding the causes of abnormalities occurring in the Main Unit.

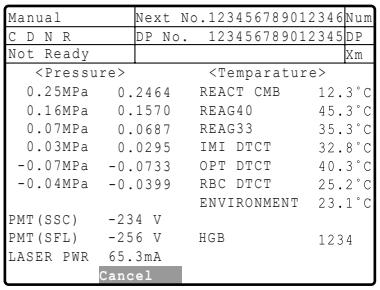
> **Note:**
> The test program can only be executed when the Main Unit is ready. During analysis, a “Wait until READY” message will appear, and the programs will not be executed. Also note that analysis cannot be performed while the test program is in progress.

Status

1. Sensor 1

The Sensor 1 screen displays pressure, temperature, photomultiplier tube voltage, laser power and HGB convert value.

1. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
2. Select **“Status”** on the function menu of the Test Menu screen.
   The Status screen will appear .
3. Select **“Sensor 1”** on the function menu of the Status screen.
   The Sensor 1 screen will appear.



<Pressure>

0.25 MPa:	Indicates 0.25 MPa
0.16 MPa:	Indicates 0.16 MPa
0.07 MPa:	Indicates 0.07 MPa
0.03 MPa:	Indicates 0.03 MPa
-0.07 MPa:	Indicates source vacuum.
-0.04 MPa:	Indicates -0.04 MPa

<Temperature>

REACT CMB:	Indicates temperature of reaction unit.
REAG40:	Indicates temperature of 40°C heater.
REAG33:	Indicates temperature of 33°C heater.
IMI DTCT:	Indicates temperature of IMI detector block.
OPT DTCT:	Indicates temperature of optical detector block.
RBC DTCT:	Indicates temperature of RBC detector block.
ENVIRONMENT:	Indicates ambient temperature.

PMT(SSC): Indicates photomultiplier tube voltage of lateral scattered light channel.

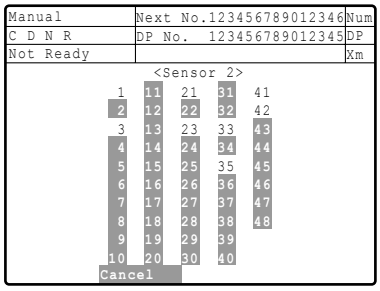
PMT(SFL): Indicates photomultiplier tube voltage of lateral fluorescence channel.

HGB: Indicates HGB convert value.

2. Sensor 2

The Sensor 2 screen displays the status of the sensor and solenoid valve.

1. From the Main Menu screen on the Main Unit, select **"Test"** on the function menu.
   The Test Menu screen will appear.
2. Select **"Status"** on the function menu of the Test Menu screen.
   The Status screen will appear .
3. Select **"Sensor 2"** on the function menu of the Status screen.
   The Sensor 2 screen will appear.

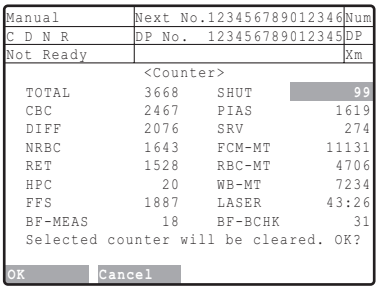


Display On and OFF of the Sensor No. 1 to Sensor No. 48.
When the sensor is ON, the No. of the sensor is displayed highlighted.

3. Counter

This program displays the operation cycle of each unit (oscillation time for the laser) and the counter of the operation cycle.
After completion of the piercer replacement or the sample rotor valve (SRV) cleaning, reset the operation cycle by the procedure described following.

1. From the Main Menu screen on the Main Unit, select **"Test"** on the function menu.
   The Test Menu screen will appear.
2. Select **"Status"** on the function menu of the Test Menu screen.
   The Status screen will appear .
3. Select **"Counter"** on the function menu of the Status screen.
   The Counter screen will appear.



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The following operation cycle is displayed on the Counter screen.

TOTAL: Indicates the operation cycle of the equipment.
CBC: Indicates the operation cycles in the CBC analysis mode.
DIFF: Indicates the operation cycles in the DIFF analysis mode.
NRBC: Indicates the operation cycles in the NRBC analysis mode.
RET: Indicates the operation cycles in the RET analysis mode.
HPC: Indicates the operation cycles in the HPC analysis mode.
FFS: Indicates the operation cycle count of the FFS reagent pump after replacement of the FFS.
SHUT: Indicates the analysis cycle after shutdown execution.
PIAS: Indicates the piercer operation cycle after replacement of the piercer.
SRV: Indicates the analysis cycle after the SRV cleaning.
FCM-MT: Indicates the operation cycles of the FCM sheath motor.
RBC-MT: Indicates the operation cycles of the RBC sheath motor.
WB-MT: Indicates the operation cycle of the whole blood aspiration motor.
LASER: Indicates the laser oscillation cycle.
BF-MEAS: Indicates the operation cycles in the body fluid analysis mode.(except background check)
BF-BCHK: Indicates the operation cycles in the body fluid analysis mode.(background check only)

4. Select PIAS or SRV by moving the cursor with ↓ or ↑ key on the Counter screen.

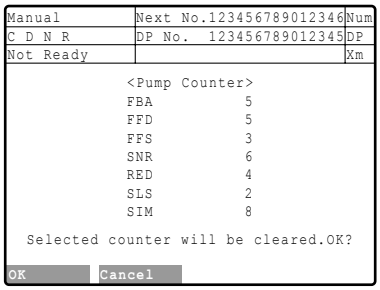
> **Information**
> Only PIAS and SRV are selectable by the cursor, and operation cycle can be reset.
> The other parameters are for the reference.

5. When you select **"OK"** on the function menu of the Counter screen, then select **"OK"** again, the highlighted parameter counter will be reset.
When you wish to cancel the reset operation, select **"Cancel"** on the function menu and return to the Status Menu screen.

4. Pump

This program displays the operation cycle count of each reagent pump.
After replacing the reagents, reset the operation cycle counter by the procedure described following.

1. From the Main Menu screen on the Main Unit, select **"Test"** on the function menu.
   The Test Menu screen will appear.
2. Select **"Status"** on the function menu of the Test Menu screen.
   The Status screen will appear .



3. Select **"Pump"** on the function menu of the Status screen.
   The Pump screen will appear.

   The following operation cycle is displayed on the Pump screen.
   FBA: Indicates the operation cycle count of the FBA reagent pump.
   FFD: Indicates the operation cycle count of the FFD reagent pump.
   FFS: Indicates the operation cycle count of the FFS reagent pump.
   SNR: Indicates the operation cycle count of the SNR reagent pump.
   RED: Indicates the operation cycle count of the RED reagent pump.
   SLS: Indicates the operation cycle count of the SLS reagent pump.
   SIM: Indicates the operation cycle count of the SIM reagent pump.
4. Select the reagent pump by moving the cursor with (♦) or (♦) key on the Pump screen.
5. When you select **"OK"** on the function menu of the Pump screen, then select **"OK"** again, the highlighted parameter counter will be reset.
   When you wish to cancel the reset operation, select **"Cancel"** on the function menu and return to the Status Menu screen.

Sampler

1. Rack Feed In

Select this program to execute the Rack Feed In operation test. Set the rack in place before executing the test.

1. Set the rack in place on the right rack pool.
2. From the Main Menu screen on the Main Unit, select **"TEST"** on the function menu.
   The Test Menu screen will appear.

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3. Select **"Sampler"** on the function menu of the Test Menu screen.
   The Sampler Test screen will appear.
4. Select **"1 Rack feed in"** by moving the cursor with ↓ or ↓ key on the Sampler Test screen.
5. Select **"Execute"** on the function menu of the Sampler Test screen. Rack feed-in operation will start. Check the sampler operation.
6. To cancel the sampler test, select **"Cancel"** on the function menu, or press the **RETURN** key.

2. Rack Shift

Select this program to execute the Rack Shift operation test. Set the rack in place before executing the test.

1. Set the rack in place in the sampler analysis line.
2. From the Main Menu screen on the Main Unit, select **"TEST"** on the function menu.
   The Test Menu screen will appear.
3. Select **"Sampler"** on the function menu of the Test Menu screen.
   The Sampler Test screen will appear.
4. Select **"2 Rack shift"** by moving the cursor with ↓ or ↓ key on the Sampler Test screen.
5. Select **"Execute"** on the function menu of the Sampler Test screen. Rack shift operation will start. Check the sampler operation.
6. To cancel the sampler test, select **"Cancel"** on the function menu, or press the **RETURN** key.

3. Rack Feed Out

Select this program to execute the Rack Feed Out operation test. Set the rack in place before executing the test.

1. Set the rack in place on the left rack pool.
2. From the Main Menu screen on the Main Unit, select **"TEST"** on the function menu.
   The Test Menu screen will appear.
3. Select **"Sampler"** on the function menu of the Test Menu screen.
   The Sampler Test screen will appear.
4. Select **"3. Rack feed out"** by moving the cursor with ↓ or ↓ key on the Sampler Test screen.

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5. Select **"Execute"** on the function menu of the Sampler Test screen. Rack feed-out operation will start. Check the sampler operation.
6. To cancel the sampler test, select **"Cancel"** on the function menu, or press the **RETURN** key.

CP Unit

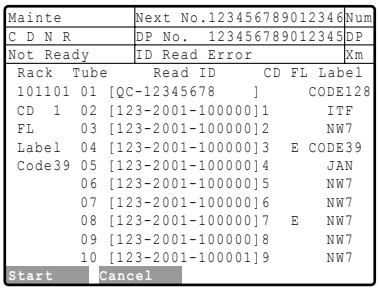
Select this program to execute test operation of the CP (cap piercing) unit. Execute this test when one of the following messages is displayed and sampler analysis cannot be performed: "Tube Inv. Position ERR", "Hand Init Position ERR", "Hand Move Position ERR", "Hand Upper Position ERR", "Hand Lower Position ERR" and "Tube Clamp ERR". If the test is normally completed, sampler analysis can be performed.

1. From the Main Menu screen on the Main Unit, select **"TEST"** on the function menu.
   The Test Menu screen will appear.
2. Select **"CP Unit"** on the function menu of the Test Menu screen, then select **"Execute"**.
   After the CP operation, the hand will return to the initial position.
3. To cancel the CP operation test, select **"Cancel"** on the function menu, or press the **RETURN** key.

Barcode

Select this program to test the ID read function.

1. Place the barcoded tubes in a sampler analysis line.
2. From the Main Menu screen on the Main Unit, select **"TEST"** on the function menu.
   The Test Menu screen will appear.
3. Select **"Barcode"** on the function menu of the Test Menu screen.
   The Barcode Test screen will appear.



4. Select **"Start"** on the function menu of the Barcode Test screen to start ID reading. The sample ID numbers read are displayed on the Barcode Test screen.

   Barcode on all positions within the rack is read.
   The check digit will appear on the CD column.
   When reading error occurs, "E" will appear on the FL column.
   The barcode type will appear on the Label column. (NW7, ITF, JAN, CODE39 or CODE128)
5. To cancel the ID reading test, select **"Cancel"** on the function menu, or press the **RETURN** key.

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Motor

1. WB Aspiration Motor

This program performs test operation of the WB aspiration motor and sets the motor in the correct initial position. Execute this test when a “WB Asp Motor Error” occurs and analysis cannot be performed. If the test is normally completed, analysis will be possible after the system enters the READY status.

1. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
2. Select **“Motor”** on the function menu of the Test Menu screen.
   The Motor Test screen will appear.
3. Select “1. WB Aspiration Motor” by moving the cursor with (♦) or (♦) key on the Motor Test screen.
4. Select **“Execute”** on the function menu of the Motor Test screen. The WB aspiration motor will start running, and the Testing screen will appear.
5. When aspiration is completed, the motor will return to the initial position.
6. To cancel the motor test, select **“Cancel”** on the function menu, or press the **RETURN** key.

2. RBC Sheath Injector

This program performs test operation of the RBC sheath injector and sets the motor in the correct initial position. Execute this test when a “RBC Sheath Motor Error” occurs and analysis cannot be performed. If the test is normally completed, analysis will be possible after the system enters the READY status.

1. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
2. Select **“Motor”** on the function menu of the Test Menu screen.
   The Motor Test screen will appear.
3. Select **“2. RBC Sheath Injector”** by moving the cursor with (♦) or (♦) key on the Motor Test screen.
4. Select **“Execute”** on the function menu of the Motor Test screen. The RBC sheath injector will start running, and the Testing screen will appear.
5. When the analysis operations are completed, the motor will return to the initial position.
6. To cancel the motor test, select **“Cancel”** on the function menu, or press the **RETURN** key.

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3. FCM Sheath Injector

This program performs test operation of the FCM sheath injector and sets the motor in the correct initial position. Execute this test when a “FCM Sheath Motor Error” occurs and analysis cannot be performed. If the test is normally completed, analysis will be possible after the system enters the READY status.

1. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
2. Select **“Motor”** on the function menu of the Test Menu screen.
   The Motor Test screen will appear.
3. Select **“3. FCM Sheath Injector”** by moving the cursor with (♦) or (♦) key on the Motor Test screen.
4. Select **“Execute”** on the function menu of the Motor Test screen. The FCM Sheath Injector will start running, and the Testing screen will appear.
5. When the analysis operations are completed, the motor will return to the initial position.
6. To cancel the motor test, select **“Cancel”** on the function menu, or press the **RETURN** key.

4. Rinse Motor

This program performs test operation of the rinse cup motor and sets the motor in the correct initial position.
Execute this test when a “Rinse Motor Error” occurs and analysis cannot be performed. If the test is normally completed, analysis will be possible after the system enters the READY status.

1. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
2. Select **“Motor”** on the function menu of the Test Menu screen.
   The Motor Test screen will appear.
3. Select **“4. Rinse Motor”** by moving the cursor with (♦) or (♦) key on the Motor Test screen.
4. Select **“Execute”** on the function menu of the Motor Test screen. The rinse cup motor will start running, and the Testing screen will appear.
5. When rinsing is completed, the motor will return to the initial position.
6. To cancel the motor test, select **“Cancel”** on the function menu, or press the **RETURN** key.

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5. Mixing Motor

This program performs test operation of the reaction chamber mixing motor.
Execute this test when a “Mixing Motor Error” occurs and analysis cannot be performed. If the test is normally completed, analysis will be possible after the system enters the Ready status.

1. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
2. Select **“Motor”** on the function menu of the Test Menu screen.
   The Motor Test screen will appear.
3. Select “5. Mixing Motor” by moving the cursor with ◊ or ◊ key on the Motor Test screen.
4. Select **“Execute”** on the function menu of the Motor Test screen. The reaction chamber mixing motor will start running, and the motor revolution speed will be displayed on the Testing screen.

   Normal range: 1300 < Revolution speed < 2000
5. Approximately 30 seconds later, the reaction chamber mixing motor will stop rotating, and the test will be completed.
6. To cancel the motor test, select **“Cancel”** on the function menu, or press the **RETURN** key.

SRV

This program performs test operation of the sample rotor valve (SRV) and sets the valve in the correct initial position.
Execute this test when a “SRV Lower Position ERR” or “SRV Upper Position ERR” occurs and analysis cannot be performed. If the test is normally completed, analysis will be possible after the system enters the Ready status.

1. Open the front cover of the Main Unit.
2. From the Main Menu screen on the Main Unit, select **“Test”** on the function menu.
   The Test Menu screen will appear.
3. Select **“SRV”** on the function menu of the Test Menu screen, then select **“Execute”**.
   The sample rotor valve will start operation and perform volume determination. Then the valve will return to the initial position.
4. To cancel the SRV test, select **“Cancel”** on the function menu, or press the **RETURN** key.

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11. Technical Information

11.1 Performance/specifications of the XE-5000

Ambient temperature	15°C – 30°C
Relative humidity	30% – 85%
Dimensions of Main Unit (including Sampler Unit)	Width: 706 mm Height: 711 mm Depth: 912 mm
Weight of Main Unit (including Sampler Unit)	Approx. 93 kg
Laser class	Class I (IEC60825-1)
Dimensions of Pneumatic Unit	Width: 195 mm Height: 333 mm Depth: 395 mm
Weight of Pneumatic Unit	Approx. 15.5 kg
Power supply	Alternating current between 117, 220 or 240 volts ±10% (50/60 cycles)
Power consumption	Main Unit, sampler unit: Not exceeding 550 VA Pneumatic Unit: Not exceeding 250 VA
Type of protection	Class I device
Display range	WBC: 0.00 – 999.99 × $10^3/\mu L$ RBC: 0.00 – 99.99 × $10^6/\mu L$ HGB: 0.0 – 30.0 g/dL HCT: 0.0 – 100.0% PLT: 0 – 9999 × $10^3/\mu L$ RET%: 0.00 – 99.99% RET#: 0.0000 – 0.9999 × $10^6/\mu L$ RBC-BF: 0.000 – 99.999 × $10^6/\mu L$ WBC-BF: 0.000 – 999.999 × $10^3/\mu L$ MN%: 0.0 – 100.0% MN#: 0.000 – 999.999 × $10^3/\mu L$ PMN%: 0.0 – 100.0% PMN#: 0.000 – 999.999 × $10^3/\mu L$
Acceptable background value	WBC: 0.10 × $10^3/\mu L$ DIFF-WBC: 0.20 × $10^3/\mu L$ IMI-TOTAL: 300 IMI#: 5 NRBC-WBC: 0.20 × $10^3/\mu L$ RBC: 0.020 × $10^6/\mu L$ HGB: 0.1 g/dL PLT: 5 × $10^3/\mu L$ PLT-O: 10 × $10^3/\mu L$ WBC-BF: 0.001× $10^3/\mu L$ RBC-BF: 0.003 × $10^6/\mu L$

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Throughput	CBC:	Approx. 150 samples/hour
	CBC+NRBC:	Approx. 150 samples/hour
	CBC+WBC5DIFF+NRBC:	Approx. 150 samples/hour
	CBC+WBC5DIFF+NRBC+RET:	Approx. 113 samples/hour (if the RET analysis rate is 100%)
	CBC+RET:	Approx. 113 samples/hour (if the RET analysis rate is 100%)
	Body fluid analysis:	Approx. 38 samples/hour

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Precision (reproducibility) Manual mode, sampler mode	WBC	3.0% or less (4.0 × 10^3/μL or more)
	WBC-D	3.0% or less (4.0 × 10^3/μL or more)
	RBC	1.5% or less (4.00 × 10^6/μL or more)
	HGB	1.0% or less
	HCT	1.5% or less
	MCV	1.0% or less
	MCH	1.5% or less
	MCHC	1.5% or less
	PLT	4.0% or less (100 × 10^3/μL or more)
	RDW-SD	2.0% or less
	RDW-CV	2.0% or less
	PDW	10.0% or less
	MPV	3.0% or less
	P-LCR	15.0% or less
	PCT	5.0% or less
	NEUT%	8.0% or less (30.0 NEUT% or more, WBC 4.0 × 10^3/μL or more)
	LYMPH%	8.0% or less (15.0 LYMPH% or more, WBC 4.0 × 10^3/μL or more)
	MONO%	20.0% or less (5.0 MONO% or more, WBC 4.0 × 10^3/μL or more)
	EO%	25.0% or less, or within ±1.5 EO% (WBC 4.0 × 10^3/μL or more)
	BASO%	40.0% or less, or within ±1.0 BASO% (WBC 4.0 × 10^3/μL or more)
	IG%	25.0% or less, or within ±1.5 IG% (WBC 4.0 × 10^3/μL or more, IG% 2% or more)
	NRBC%	25.0% or less, or within ±1.5 NRBC% (WBC 4.0 × 10^3/μL or more)
	NEUT#	8.0% or less (1.20 × 10^3/μL or more)
	LYMPH#	8.0% or less (0.60 × 10^3/μL or more)
	MONO#	20.0% or less (0.20 × 10^3/μL or more)
	EO#	25.0% or less, or within ±0.12 × 10^3/μL
	BASO#	40.0% or less, or within ±0.06 × 10^3/μL
	IG#	25.0% or less, or within ±0.12 × 10^3/μL (IG# 0.1 × 10^3/μL)
	NRBC#	25.0% or less, or within ±0.12 × 10^3/μL
	HPC#*[1]	30% or less, or within ±0.015× 10^3/μL
	RET#	15% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%)
	RET%	15% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%)
	LFR	30% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%, LFR 20% or more)
	MFR	50% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%, MFR 20% or more)
	HFR	100% or less, or within ±2 HFR% (RBC 3.00 × 10^6/μL or more, RET% 1-4%)
	IRF	30% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%, IRF 20% or more)
	RET-He	5% or less (RET#≥ 0.020 × 10^6/μL)
	IPF	25% or less (95% C.I., when PLT is 50 × 10^3/μL or more and IPF is 3% or more) 20% or less (actual CV%, not in 95% C.I., when PLT is 10 to 50 × 10^3/μL and IPF is 10% or more)
	*1: Within-Run Precision is based on 5 consecutive determinations of the sample.	

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Precision (reproducibility) Capillary mode	WBC	9.0% or less (4.0 × 10^3/μL or more)
	RBC	4.5% or less (4.00 × 10^6/μL or more)
	HGB	3.0% 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 (100 × 10^3/μL or more)
	RET#	35% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%)
	RET%	35% or less (RBC 3.00 × 10^6/μL or more, RET% 1-4%)
	WBC-D	9.0% or less (4.0 × 10^3/μL or more)
	NEUT%	24.0% or less (30.0 NEUT% or more, WBC 4.0 × 10^3/μLor more)
	LYMPH%	24.0% or less (15.0 LYMPH% or more, WBC 4.0 × 10^3/μL or more)
	MONO%	60.0% or less (5.0 MONO% or more, WBC 4.0 × 10^3/μL or more)
	EO%	75.0% or less, or within ±4.5 EO% (WBC 4.0 × 10^3/μL or more)
	BASO%	120.0% or less, or within ±3.0 BASO%(WBC 4.0 × 10^3/μL or more)
	IG%	75.0% or less, or within ±4.5 IG% (IG% 2.0% or more, WBC 4.0 × 10^3/μL or more)
	NRBC%	75.0% or less, or within ±4.5NRBC% (WBC 4.0 × 10^3/μL or more)
	NEUT#	24.0% or less (1.20 × 10^3/μL or more)
	LYMPH#	24.0% or less (0.60 × 10^3/μL or more)
	MONO#	60.0% or less (0.20 × 10^3/μL or more)
	EO#	75.0% or less, or within ±0.36 × 10^3/μL
	BASO#	120.0% or less, or within ±0.18 × 10^3/μL
	IG#	75.0% or less, or within ±0.36 × 10^3/μL (IG# 0.1 × 10^3/μL or more)
	NRBC#	75.0% or less, or within ±0.36 × 10^3/μL
Precision (reproducibility) Body fluid analysis mode	WBC-BF	30% or less (CSF: 0.015 - 0.030 × 10^3/μL, other than CSF: 0.030 - 0.050 × 10^3/μL)
	RBC-BF	40% or less, or Max-Min≤0.007 × 10^6/μL (0.003 - 0.050 × 10^6/μL)
Analysis parameters	See “Chapter 1: 1.3 Measurement parameters”.	
Accuracy (cell counts) Manual mode, sampler mode	WBC	Within ±3% or within ±0.20 × 10^3/μL
	WBC-D	Within ±3% or within ±0.20 × 10^3/μL
	RBC	Within ±2% or within ±0.03 × 10^6/μL
	PLT	Within ±5% or within ±10 × 10^3/μL
Accuracy (cell counts) Capillary mode	WBC	Within ±10%
	WBC-D	Within ±10%
	RBC	Within ±8%
	PLT	Within ±8%

Note:

Typical performance characteristics for precision (reproducibility) of body fluid analysis mode were determined during instrument evaluation on a typical instrument, using 14 body fluid samples, counted 10 times consecutively in the body fluid mode and based on the precision profile.

WBC-BF	Reproducibility C.V.25% or less (0.010 – 0.015 × 10^3/μL)
	Reproducibility C.V.20% or less (0.016 – 0.025 × 10^3/μL)
	Reproducibility C.V.15% or less (0.026 – 0.050 × 10^3/μL)
	Reproducibility C.V.10% or less (0.050 × 10^3/μL or more)

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Accuracy (blood cell differentiation)	Accuracy is expressed as the coefficient of correlation to the comparison method for analysis of at least 100 samples (at least 20 samples for NRBC) of normal blood (for NRBC, blood in which nucleated RBCs are manifested). NEUT% r=0.90 or more LYMPH% r=0.90 or more MONO% r=0.75 or more EO% r=0.80 or more BASO% r=0.50 or more IG%*1 r=0.80 or more NRBC% r=0.80 or more *1: Analyze 100 fresh samples that have immature granulocytes for XE-5000 and reference method (FCM) and manual countig method using NCCLSH-20A. Average of deviation from the standard instrument NEUT% Within ±3.0 NEUT% LYMPH% Within ±3.0 LYMPH% MONO% Within ±2.0 MONO% EO% Within ±1.0 EO% BASO% Within ±1.0 BASO% IG% Within ±1.5 IG%
Accuracy (reticulocyte parameters) Manual mode, sampler mode	RET# Within ±20% or within ±0.015 × 10^6/μL RET% Within ±20% or ±0.3 RET% IRF Within ±30% or ±10 IRF% LFR Within ±30% or ±10 LFR% MFR Within ±30% or ±10 MFR% HFR Within ±30% or ±5 HFR%
Accuracy (reticulocyte parameters) Capillary mode	RET# Within ±30% or within ±0.025 × 10^6/μL RET% Within ±30% or ±0.5 RET%
Accuracy (reticulocyte parameter correlation)	RET# r=0.90 or more RET% r=0.90 or more
Accuracy (cell counts) Body fluid analysis mode	Accuracy is expressed as the regression line's slopes and coefficient of correlation to the Fuchs Rosenthal method as reference method, using 50 or more samples. WBC-BF r=0.9 or more, and within slope=1 ±0.3 RBC-BF r=0.8 or more, and within slope=1 ±0.3
Accuracy (blood cell differentiation) Body fluid analysis mode	Accuracy is expressed as the regression line's slopes and coefficient of correlation to the manual count by using Cytospin as reference method, using 50 or more samples. MN% r=0.7 or more, and within slope=1 ±0.5 PMN% r=0.7 or more, and within slope=1 ±0.5 MN# r=0.9 or more, and within slope=1 ±0.5 PMN# r=0.9 or more, and within slope=1 ±0.5

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Linearity Whole blood mode	WBC	Within ±2.0% or ±0.2 × $10^3/\mu L$ (0.00 – 100.00 × $10^3/\mu L$) Within ±6.0% (100.01 – 310.00 × $10^3/\mu L$) Within ±11.0% (310.01 – 440.00 × $10^3/\mu L$)
	WBC-D	Within ±2.0% or ±0.2 × $10^3/\mu L$ (0.00 – 100.00 × $10^3/\mu L$) Within ±6.0% (100.01 – 310.00 × $10^3/\mu L$) Within ±11.0% (310.01 – 440.00 × $10^3/\mu L$)
	RBC	Within ±2.0% or within ±0.03 × $10^6/\mu L$ (0.00 – 8.00 × $10^6/\mu L$)
	HGB	Within ±2.0% or ±0.2 g/dL (0.0 – 25.0 g/dL)
	HCT	Within ±2.0% or ±1.0 HCT% (0.0 – 75.0 HCT%)
	PLT	Within ±5.0% or within ±10 × $10^3/\mu L$ (0 – 2000 × $10^3/\mu L$) Within ±6.0% (2001 – 5000 × $10^3/\mu L$) (the value may not fall within the above ranges, depending on RBC concentration)
	RET%	Within ±20% or ±0.3 RET% (0.00 – 23.00%)
	RET#	Within ±20% or within ±0.015 × $10^6/\mu L$ (0.0000 – 0.7200 × $10^6/\mu L$)
	NRBC%	Within ±20% (0.0 – 464.0/100 WBC)
	NRBC#	Within ±2.0% or within ±2.0 × $10^3/\mu L$ (0.00 – 19.20 × $10^3/\mu L$)
Linearity Capillary mode	WBC	Within ±4.0% or within ±0.4 × $10^3/\mu L$ (0.00 – 440.00 × $10^3/\mu L$)
	RBC	Within ±4.0% or within ±0.06 × $10^6/\mu L$ (0.00 – 8.00 × $10^6/\mu L$)
	HGB	Within ±5.0% or ±0.5 g/dL (0.0 – 25.0 g/dL)
	HCT	Within ±4.0% or ±2.0 HCT% (0.0 – 75.0 HCT%)
	PLT	Within ±10.0% or within ±20 × $10^3/\mu L$ (0 – 5000 × $10^3/\mu L$) (the value may not fall within the above ranges, depending on RBC concentration)
Linearity Body fluid analysis mode	WBC-BF	Within ±10/uL (0 – 0.050 × $10^3/\mu L$) Within ±20% (0.050 – 10.000 × $10^3/\mu L$)
	RBC-BF	Within ±2.0% or within ±0.010 × $10^6/\mu L$(0.000 – 5.000 × $10^6/\mu L$)
		Note: This specification is based on the verification using control blood.
Linearity Range*[1]	HPC#	0.000 – 0.500 × $10^3/\mu L$ Linearity is performed by analyzing a series of dilutions and taking multiple measurements of each dilution. Samples should be diluted with CELLPACK and measured immediately after each dilution is made. *1: Guidance for Premarket Notification for Automated Differentlel Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA. Document issued: November 1, 2000. CDRH, FDA.

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Mode disparity Manual mode, sampler mode	WBC Within ±5.0% or within ±0.4 × 10^3/μL WBC-D Within ±5.0% or within ±0.4 × 10^3/μL RBC Within ±2.0% or within ±0.02 × 10^6/μL HGB Within ±2.0% or within ±0.2 g/dL HCT Within ±2.0% or within ±0.3 HCT% PLT Within ±7.0% or within ±20 × 10^3/μL NEUT% Within ±5.0 NEUT% LYMPH% Within ±4.0 LYMPH% MONO% Within ±3.0 MONO% EO% Within ±2.0 EO% BASO% Within ±1.0% BASO% NRBC% Within ±20% or within ±2.0 NRBC% RET# Within ±20% or within ±0.015 × 10^6/μL RET% Within ±20% or within ±0.3 RET% RBC-O Within ±20% PLT-O Within ±20% LFR Within ±30% or within ±10 LFR% MFR Within ±30% or within ±10 MFR% HFR Within ±30% or within ±5 HFR% IRF Within ±30% or within ±10 IRF%
Mode disparity Capillary mode	NEUT% Within ±9.0 NEUT% LYMPH% Within ±9.0 LYMPH% MONO% Within ±6.0 MONO% EO% Within ±3.0 EO% BASO% Within ±3.0 BASO% IG% Within ±3.0 IG% NRBC% Within ±3.0 NRBC%
Carryover	WBC 1.0% or less WBC-D 1.0% or less RBC 1.0% or less HGB 1.0% or less HCT 1.0% or less PLT 1.0% or less RBC-O*1 Within ±1.5% HPC#*2 1% or less *1: RBC-O is not an official analysis parameter. RBC-O is the RBC count analyzed by the flow cytometry method, using a semiconductor laser, and is provided as research parameter. *2: Guidelines for the evaluation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications. International Committee for Standardization in Haematology (ICSH). Clin. Lab, Haemat 1994, 16,157–174.
Carryover Body fluid analysis mode	RBC-BF 0.3 % or less, or 0.003 × 10^6/μL or less WBC-BF 0.3 % or less, or 0.001 × 10^3/μL or less

Revised April 2007

Stability of blood over time after sampling 36 hours later	NEUT% Within ±8 NEUT% LYMPH% Within ±7 LYMPH% MONO% Within ±3 MONO% EO% Within ±3 EO% BASO% Within ±1 BASO%
48 hours later	NEUT% Within ±8 NEUT% LYMPH% Within ±7 LYMPH% MONO% Within ±4 MONO% EO% Within ±3 EO% BASO% Within ±1 BASO% **Information** Use samples at 18–26°C, or samples that have been kept refrigerated (2–8°C). Samples are at room temperature or refrigerated, and refrigerated samples are returned to room temperature before analysis. Some samples may not enter the above ranges, depending on the state of preservation etc.
Stability of blood over time after sampling 24 hours later	IG% Within ±1.5 IG% RET-He Within ±8% (RET#≥0.010 × 10^6/μL) **Information** Use samples at 18–26ºC, or samples that have been kept refrigerated (4–8ºC). Samples are at room temperature or refrigerated, and refrigerated samples are returned to room temperature before analysis. Some samples may not enter the above ranges, depending on the state of preservation etc. IPF Variation Within 30% or Variation range Within 2.0 IPF (PLT 100.0 (× 10^3/μL) or more and IPF is 2(%) or more.) **Information** Samples should be stored at room temperature.
Aspirated blood volume	Sampler mode: Approx. 200 μL Manual Closed mode: Approx. 200 μL Manual mode: Approx. 130 μL Capillary mode: Approx. 40 μL (the blood volume required for dilution)
Number of stored samples	Analysis data with histograms: 10,000 samples Scattergrams: 10,000 samples Patient information: For 5,000 patients Order information: 1,000 samples
Quality control	$\overline{X}$ control (L-J control): 300 points × 20 files, 51 parameters $\overline{X}_M$ control: 300 points × 1 file, 54 parameters
Storage conditions for transportation	Ambient temperature: -10 – 60ºC Relative humidity: 95% or less (no condensation)

Revised April 2007

11.2 Possible sample interferences

WBC

Where the following are present, the white blood cell count may be reported falsely low.
- Leukocyte aggregation

Where the following are present, the white blood cell count may be reported falsely high.
- Platelet aggregation
- Lyse resistant erythrocytes
- Erythroblasts(when NRBC is not analyzed)
- Erythrocyte aggregation (Cold agglutinin)
- Cryoprotein
- Cryoglobulin
- Fibrin
- Giant platelets (Platelets>1,000,000/μL)

RBC

Where the following are present, the red blood cell count may be reported falsely low.
- Erythrocyte aggregation (Cold agglutinin)
- Microcytosis
- Fragmented erythrocytes

Where the following are present, the red blood cell count may be reported falsely high.
- Leukocytosis (Lymphocytes>100,000/μL)
- Giant platelets (Platelets>1,000,000/μL)

HGB

Where the following are present, the blood cell count may be reported falsely high.
- Leukocytosis (Lymphocytes>100,000/μL)
- Lipemia
- Abnormal protein

HCT

Where the following are present, the hematocrit value may be reported falsely low.
- Erythrocyte aggregation (Cold agglutinin)
- Microcytosis
- Fragmented erythrocytes

Where the following are present, the hematocrit value may be reported falsely high.
- Leukocytosis (Lymphocytes>100,000/μL)
- Severe diabetes
- Uremia
- Spherocytosis

Revised August 2008

PLT

Where the following are present, the platelet count may be reported falsely low.
- Platelet aggregation
- Pseudothrombocytopenia
- Giant platelets

Where the following are present the platelet count may be reported falsely high.
- Microcytosis
- Fragmented erythrocytes
- Fragmented leukocytes
- Cryoprotein
- Cryoglobulin

RET

Where the following are present, the reticulocyte count may be reported falsely high.
- Erythrocyte aggregation (Cold agglutinin)
- Giant platelets
- Platelet aggregation
- Fragmented leukocytes
- Malaria
- Howell-Jolly body

11.3 Interface protocol

Data can be output in various formats via the serial interface or via the TCP/IP network interface to the HOST computer. For details, contact your Sysmex technical representative.

11.4 Program version

To check the current program version, select **"About XE-5000 (A)"** under **"Help (H)"** on the Information Processing Unit (IPU) menu bar.

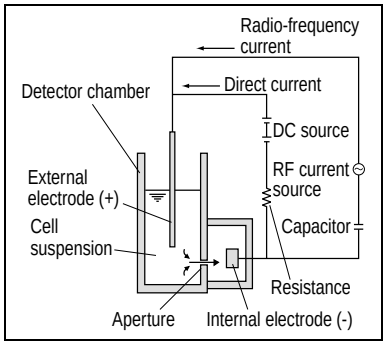
Revised August 2008

11.5 Principles

1. Detection principle

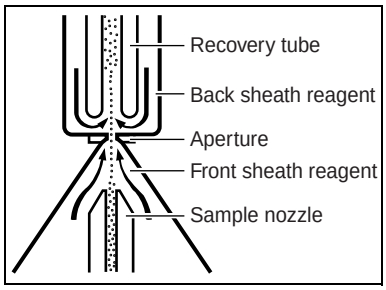
This instrument performs hematology analysis according to the RF/DC detection method, Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.

RF/DC detection method



The RF/DC detection method detects the size of blood cells by changes in direct-current resistance, and the density of the blood cell interior by changes in radio-frequency resistance. A blood sample is aspirated and measured, diluted to the specified ratio, and sent to the applicable detector chamber. Inside the detector chamber is a tiny hole called an “aperture”, on both sides of which are electrodes. Between the electrodes flow direct current and radio-frequency current. Blood cells suspended in the IMI reagent pass through the aperture, changing the direct-current resistance and radio-frequency resistance between the electrodes. The size of the blood cells is detected via changes in the direct-current resistance and the density of the blood cell interior (size of the nucleus and other information) is detected via changes in the radio-frequency resistance, with such detection coming in the form of electrical pulses. Based on the size of these pulses, a two-dimensional distribution (scattergram) of the blood-cell size and internal density can be drawn. Various analysis data can be obtained by analyzing such distributions (scattergram).

Hydro dynamic focusing (DC Detection)

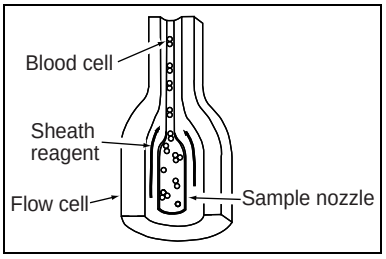


Inside the detector, the sample nozzle is positioned in front of the aperture and in line with the center. After diluted sample is forced from the sample nozzle into the conical chamber, it is surrounded by front sheath reagent and passes through the aperture center.

After passing through the aperture, the diluted sample is surrounded by back sheath reagent and sent to the recovery tube. This prevents the blood cells in this area from drifting back, and prevents the generation of false platelet pulses. The Hydro Dynamic Focusing method improves blood count accuracy and reproducibility. Because the blood cells pass through the aperture in a line, also generation of artifical pulses (interference) is prevented. Hydro Dynamic Focusing method improves the blood count accuracy and reproducibility by minimizing the coincidence error.

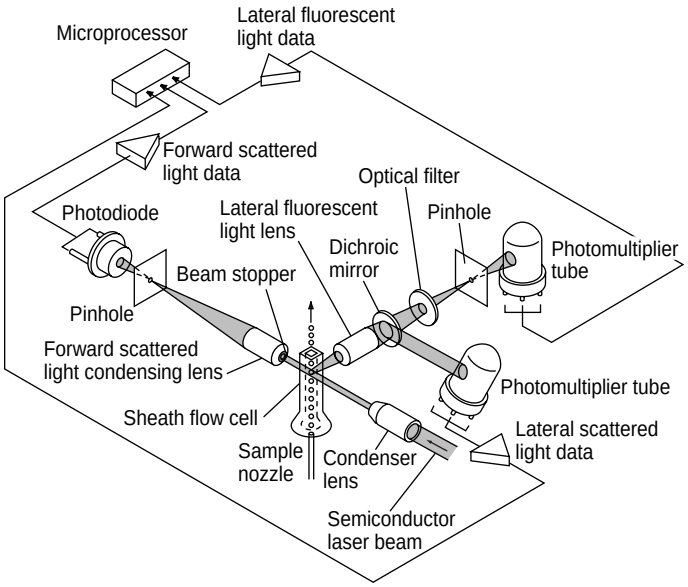
Revised April 2007

Flow cytometry method using semiconductor laser



Cytometry is used to analyze physiological and chemical characteristics of cells and other biological particles. Flow cytometry is used to analyze those cells and particles as they are passed through extremely small and sensitive detecting zones. Fluorescence Flow Cytometry uses light emission from stained proteins (RNA&DNA) in order to separate cell populations through scattergram analysis programs.

A blood sample is aspirated and measured, diluted to the specified ratio and stained. The sample is then fed into the flow cell.
This Hydro Dynamic Focusing mechanism improves cell count accuracy, reproducibility and linearity. And since the blood cell particles pass in a line through the center of the flow cell, the generation of artificial blood pulses is prevented and flow cell contamination is reduced.
A semiconductor laser beam is emitted to the blood cells passing through the flow cell. The forward scattered light is received by the photodiode, and the lateral scattered light and lateral fluorescent light are received by the photomultiplier tubes. This light is converted into electrical pulses, making it possible to perform detailed scattergram analysis.



(1) Forward scattered light and lateral scattered light
When blood cells pass the light-beam, the light scatters from each cell in various directions. This phenomenon is called light scattering. By detecting the scattered light, it is possible to obtain information on cell size and cell surface structure. The intensity of the scattered light depends on factors such as the particle diameter and viewing angle. This instrument detects forward scattered light, which provides information on blood cell size and lateral scattered light, which provides information on the cell complexity.

Revised April 2007

(2) Lateral fluorescent light

When light is emitted to fluorescent material, such as stained blood cells, light of longer wavelength than the original light is produced. The intensity of the fluorescent light proportionally increases with the concentration of the precipitated stain in the blood cells. The intensity of the emitted fluorescent light indicates the degree of blood cell staining and as such the RNA and/or DNA concentration.
Fluorescent light is emitted in all directions; the XE-5000 detects the fluorescent light that is emitted sideways.

SLS-Hemoglobin method

In the past, the mainstream methods for automatically measuring hemoglobin were the cyanmethemoglobin method and oxyhemoglobin method. But these methods have both advantages and disadvantages when they are used with a large, fully automatic instrument such as the XE-5000.
The cyanmethemoglobin method was recommended by the International Committee for Standardization in Haematology (ICSH) in 1966 as an international standard method. But since its hemoglobin conversion speed is slow and multiple-sample processing is an assumed requirement, this method is not really appropriate for automatic analysis. Moreover, since it uses cyanide compounds, which are poisonous as reagents, the liquid waste must be treated, making the method undesirable from an environmental perspective.
Currently, this is not an appropriate analysis method, particularly as a large fully automatic instrument that discharges large amounts of liquid waste.

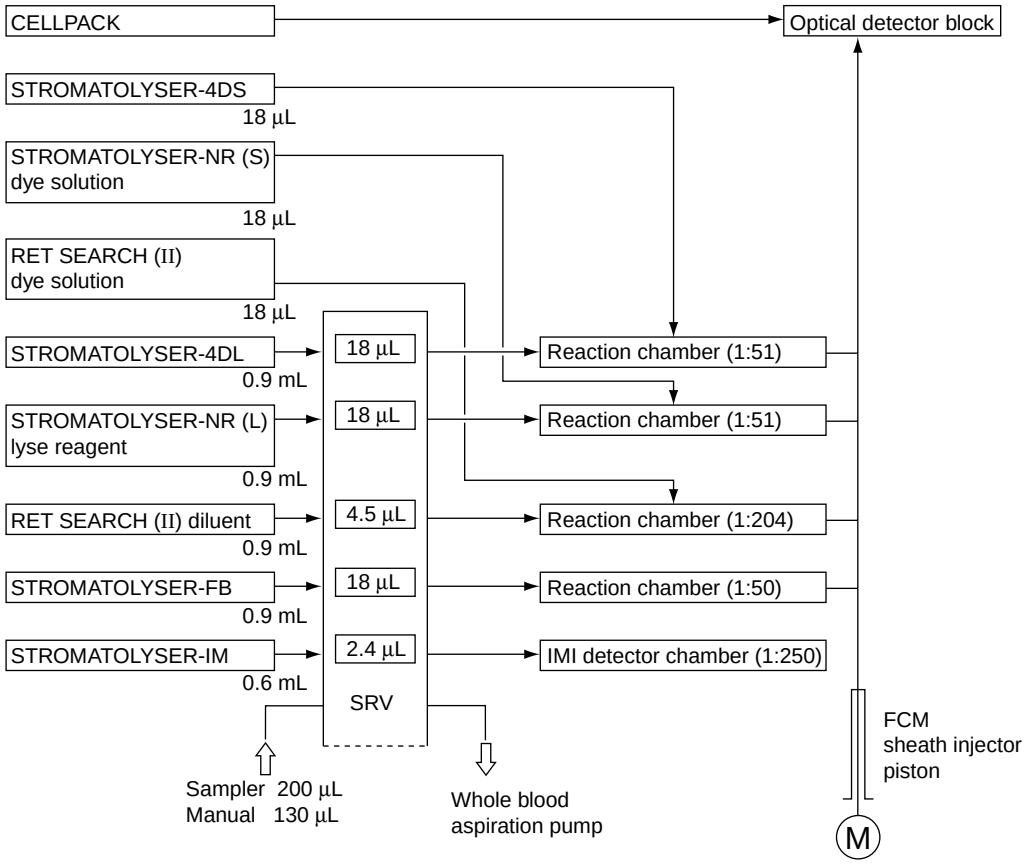
In contrast, the hemoglobin conversion speed of the oxyhemoglobin method is fast, as blood hemoglobin is instantly converted into oxyhemoglobin. And since it does not use poisonous substances such as cyanide, it is a suitable method for performing automatic analysis. It cannot, however, convert methemoglobin into oxyhemoglobin, which is not a problem for normal human blood, but will result in values that are lower than the true values for samples that contain large amounts of methemoglobin, such as control blood samples.

The SLS-hemoglobin method is an analysis method that makes use of the advantages of the two aforementioned methods.
As with the oxyhemoglobin method, the hemoglobin conversion speed of the SLS-hemoglobin method is fast and the method does not use poisonous substances, making it a suitable method for automation.
Further, since methemoglobin can be analyzed, control samples such as blood containing methemoglobin can also be accurately analyzed.

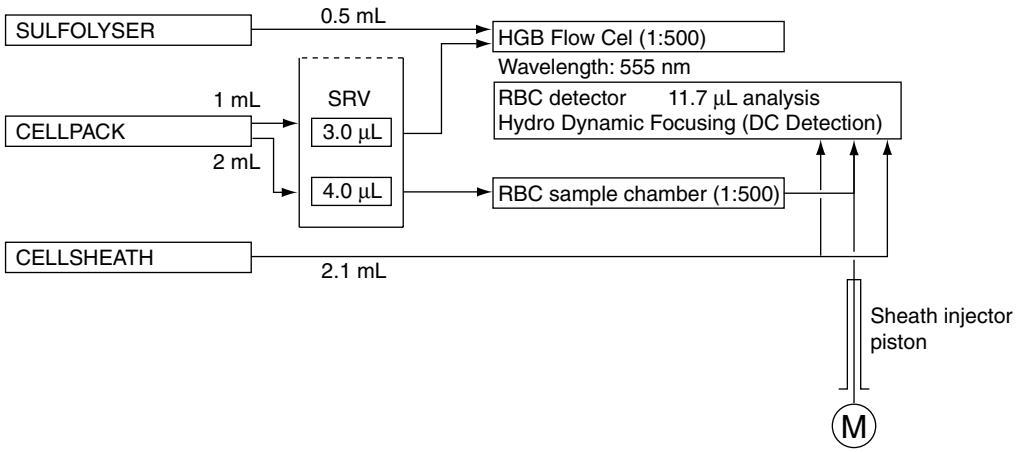
Revised April 2007

2. Hydraulic system block diagram

WBC/RET



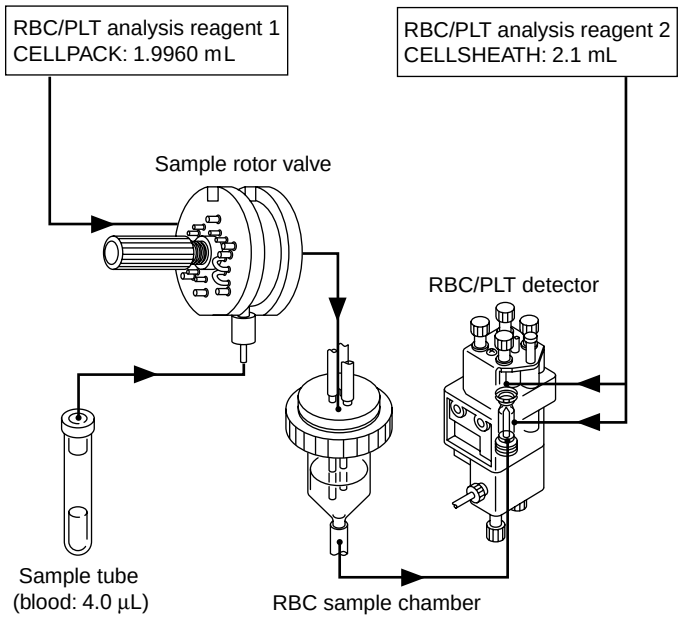
RBC/HGB



3. RBC/PLT and HGB analysis

RBC/PLT analysis procedure

During RBC and PLT analysis, the red blood cells and platelets in the blood are analyzed. The procedure for analyzing RBC/PLT is explained as follows:

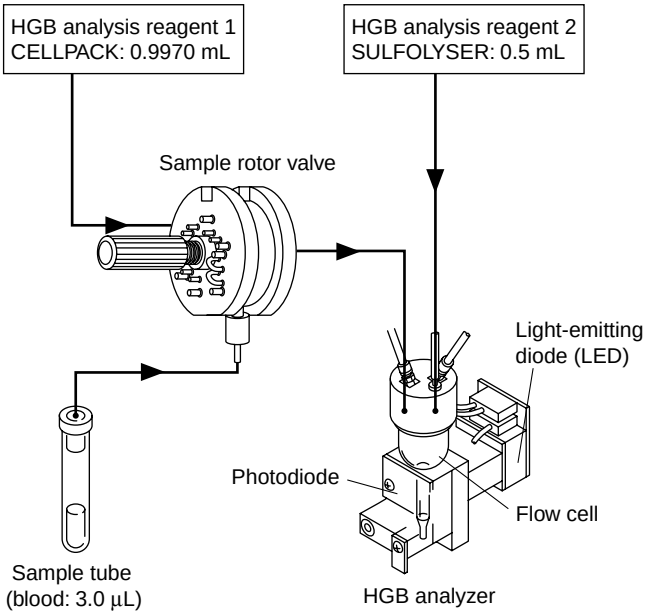


1. Blood is aspirated from the manual aspiration pipette to the sample rotor valve.
2. 4.0 µL of blood, measured by the sample rotor valve, is diluted to a ratio of 1:500 with 1.9960 mL of CELLPACK, and then sent to the RBC sample chamber as the diluted sample.
3. The sheath injector piston sends 11.7 µL of diluted sample slowly to the RBC/PLT detector.
4. The RBC detector counts the RBC and PLT via the Hydro Dynamic Focusing (DC Detection).
   At the same time, the hematocrit (HCT) is calculated via the RBC pulse height detection method.

Revised April 2007

HGB Analysis procedure

During an HGB analysis, the amount of hemoglobin in the blood is analyzed. The procedure for analyzing HGB is explained as follows:



1. Blood is aspirated from the manual aspiration pipette to the sample rotor valve.
2. 3.0 µL of blood, measured by the sample rotor valve, is diluted to a ratio of 1:333 with 0.9970 mL of CELLPACK, and then sent to the flow cell as the diluted sample. At the same time, 0.5 mL of SULFOLYSER is added to hemolyze the red blood cells to make 1:500 diluted sample, and the hemoglobin is converted into SLS-hemoglobin.
3. Light (of wavelength 555 nm) emitted from the light-emitting diode passes through the lens and into the sample in the Hgb cell. The concentration of SLS-hemoglobin is analyzed as light absorbance, and is calculated after substruction of the absorbance of the diluent measured before the sample was added.

Revised January 2010

Calculation of RBC constants

The red blood cell constants (mean cell volume, mean cell hemoglobin, and mean cell hemoglobin concentration) are calculated from the RBC, HGB, and HCT.

Mean cell volume (MCV)

The MCV is calculated from the RBC and HCT, using the following equation:

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

Mean cell hemoglobin (MCH)

The MCH is calculated from the RBC and HGB, using the following equation:

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

Mean cell hemoglobin concentration (MCHC)

The MCHC is calculated from the HCT and HGB, using the following equation:

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

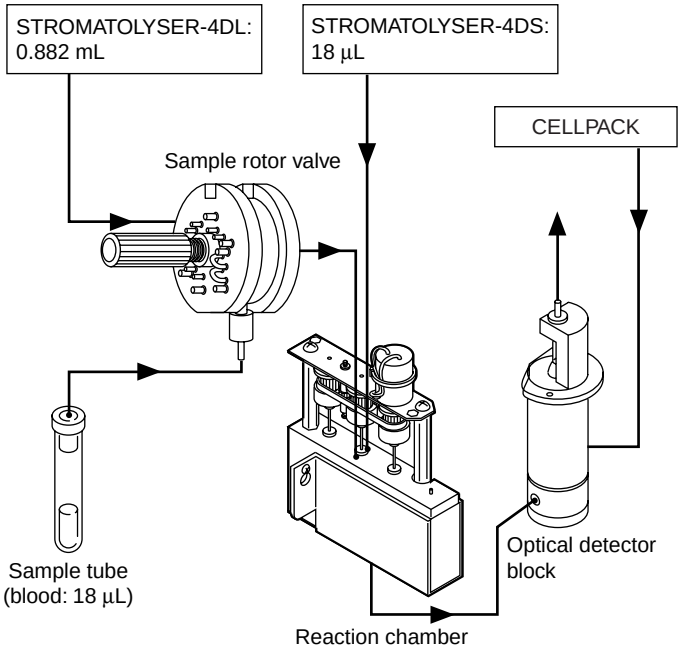
Revised April 2007

4. WBC classification

White blood cells (leukocytes) can be broadly classified as either lymphocytes, monocytes or granulocytes. Granulocytes can be further classified as either neutrophils, basophils or eosinophils, depending on the dye-affinity of the granules. The applicable analysis procedure is explained as follows:

4DIFF analysis procedure

A 4DIFF analysis is used to identify and analyze the following white cell subpopulations: lymphocytes, monocytes, eosinophils, neutrophils, basophils and immature granulocytes. The 4DIFF analysis procedure is explained as follows:

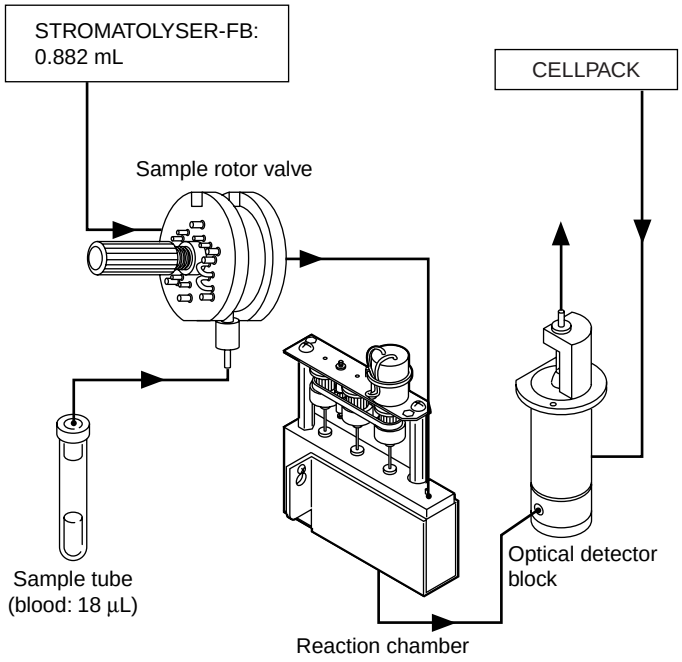


1. Blood is aspirated from the manual aspiration pipette to the sample rotor valve.
2. 18 µL of blood, measured by the sample rotor valve, is diluted with 0.882 mL of STROMATOLYSER-4DL, and then sent to the reaction chamber as the diluted sample. At the same time, 18 µL of STROMATOLYSER-4DS is added to dilute the sample to a ratio of 1:51. After reacting for about 22 seconds in this condition, the red blood cells are hemolyzed and the white blood cells are stained.
3. The sheath injector piston sends 40 µL of diluted sample to the optical detector block.
4. In the optical detector block, the sample is analyzed via flow cytometry method utilizing a semiconductor laser.

Revised April 2007

WBC/BASO analysis procedure

A WBC/BASO analysis is used to analyze the number of white blood cells, as well as the number of basophils at the same time. The WBC/BASO analysis procedure is explained as follows:

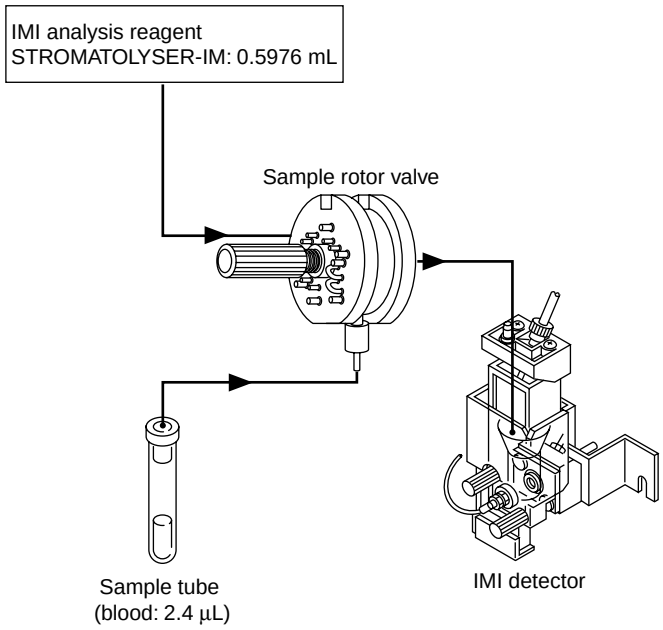


1. Blood is aspirated from the manual aspiration pipette to the sample rotor valve.
2. 18 µL of blood, measured by the sample rotor valve, is diluted to a ratio of 1:50 with 0.882 mL of STROMATOLYSER-FB, and then sent to the reaction chamber as the diluted sample.
   After reacting for about 14 seconds in this condition, the red blood cells are hemolyzed.
3. The sheath injector piston sends 40 µL of diluted sample to the optical detector block.
4. In the optical detector block, the sample is analyzed via flow cytometry method utilizing a semiconductor laser.

Revised April 2007

IMI analysis procedure

IMI (immature information) indicates information on immature cells (granulocytes). The procedure for analyzing IMI is explained as follows:



1. Blood is aspirated from the manual aspiration pipette to the sample rotor valve.
2. 2.4 µL of blood, measured by the sample rotor valve, is diluted with 0.5976 mL of STROMATOLYSER-IM to a ratio of 1:250, and then sent to the IMI detector as the diluted sample.
   After reacting for about 13 seconds in this condition, the red blood cells are hemolyzed and the cytoplasm of white blood cells other than the immature granulocytes is released/dissolved and are reduced in size.
3. The diluted sample is aspirated, via the aperture, and 250 µL is accurately measured by the float-type manometer.
   Detection is performed via the RF/DC detection method.

Revised April 2007

5. WBC differential analysis

4DIFF and WBC/BASO scattergrams

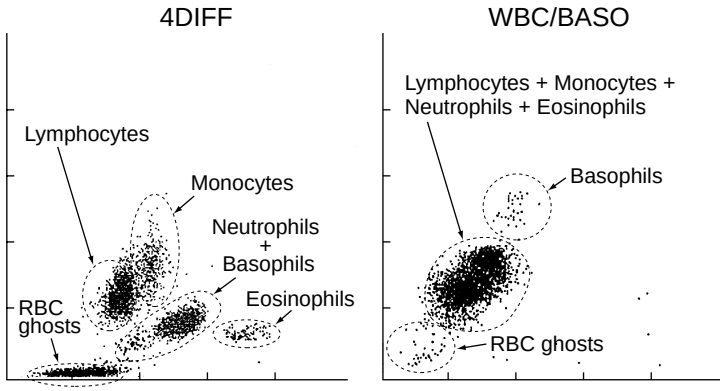
Forward scattered light, lateral scattered light and lateral fluorescent light are detected via fluorescence flow cytometry method utilizing a semiconductor laser, and two-dimensional scattergrams are displayed.

In the 4DIFF scattergram, the X-axis represents the intensity of the lateral scattered light and the Y-axis the intensity of the lateral fluorescent light.

After scattergram Analysis, the 4DIFF scattergram displays the following classified populations: red blood cell ghosts, lymphocytes, monocytes, eosinophils, immature granulocytes(IG), neutrophils and basophils.

In the WBC/BASO scattergram, the X-axis represents the intensity of the lateral scattered light, and the Y-axis the intensity of the forward scattered light.

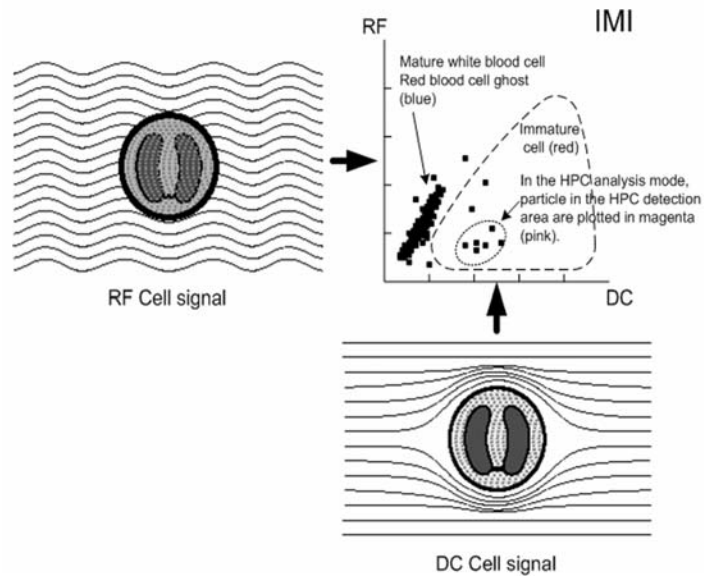
The WBC/BASO analysis scattergram displays the classified populations of red blood cell ghosts, basophils and other remaing white blood cells (lymphocytes + monocytes + neutrophils + eosinophils).



Revised April 2007

IMI scattergrams

Two-dimensional distributions of the cell size and density of the cell interior (such as nucleus size) are drawn via the RF/DC detection method.

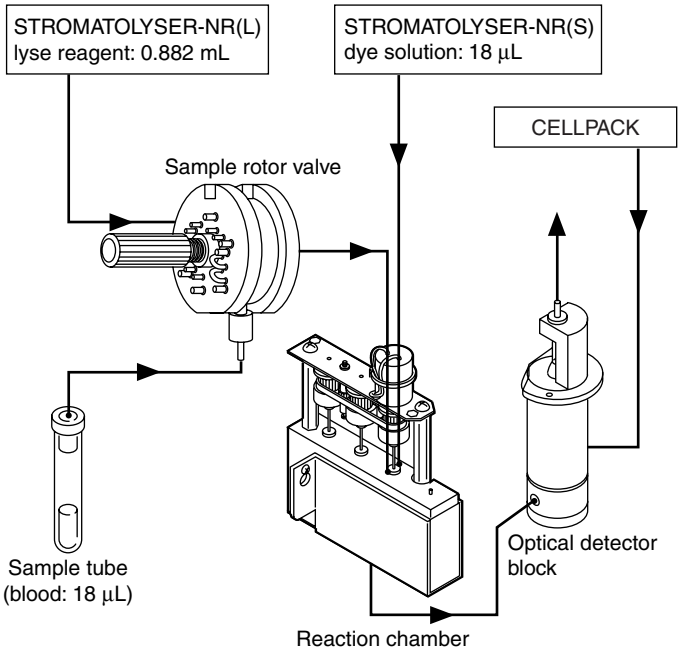


The IMI analysis channel is a channel used to discriminate between immature and mature white blood cells.

6. NRBC analysis

NRBC analysis procedure

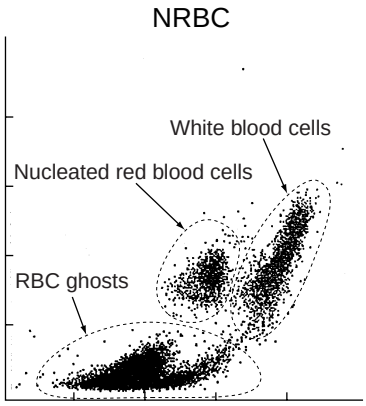
The NRBC analysis is performed to classify and count the nucleated red blood cell population in the blood. The NRBC analysis procedure is explained as follows:



Revised April 2007 EU

1. Blood is aspirated from the manual aspiration pipette to the sample rotor valve.
2. 18 µL of blood, measured by the sample rotor valve, is diluted with 0.882 mL of STROMATOLYSER-NR (L) lyse reagent, and then sent to the reaction chamber as the diluted sample.
   At the same time, 18 µL of STROMATOLYSER-NR (S) dye solution is added to dilute the sample to a ratio of 1:51. After reacting for about 7 seconds in this condition, the red blood cells are hemolyzed and the white blood cells and nucleated red blood cells are stained.
3. The sheath injector piston sends 40 µL of diluted sample to the optical detector block.
4. In the optical detector block, the sample is analyzed via flow cytometry method utilizing a semiconductor laser.

7. NRBC scattergram



Through fluorescence flow cytometry method utilizing a semiconductor laser, a two-dimensional distribution of the forward scattered light and lateral fluorescent light is displayed as a scattergram.
The X-axis of the scattergram represents the intensity of the lateral fluorescent light and the Y-axis the intensity of the forward scattered light.

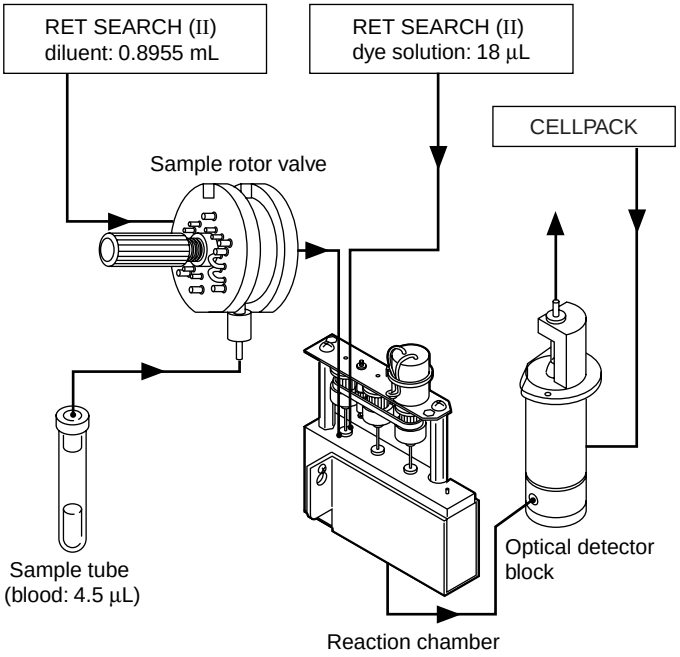
After scattergram analysis, the classified groups of red blood cell ghosts, white blood cells and nucleated red blood cells are displayed.

Revised April 2007 EU

8. RET analysis

RET analysis procedure

A RET analysis is used to classify and analyze groups of red blood cells, platelets, reticulocytes and reticulocyte sub-population in the blood. The RET analysis procedure is explained as follows:



1. Blood is aspirated from the manual aspiration pipette through the sample rotor valve.
2. 4.5 µL of blood, measured by the sample rotor valve, is diluted with 0.8955 mL of RET SEARCH (II) diluent, and then sent to the reaction chamber as the diluted sample. At the same time, 18 µL of RET SEARCH (II) dye solution is added to dilute the sample to a ratio of 1:204.
   After reacting for about 31 seconds in this condition, the diluted sample is stained and analyzed by fluorescence flow cytometry.
3. The sheath injector piston sends 2.8 µL of diluted sample to the optical detector block.
4. In the optical detector block, the sample is analyzed via fluorescence flow cytometry utilizing a semiconductor laser.

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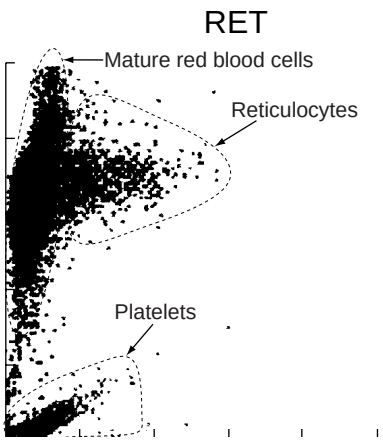
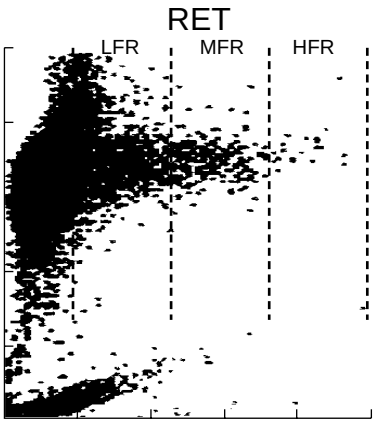
9. RET scattergram



After fluorescence flow cytometry analysis, a two-dimensional distribution of the forward scattered light and lateral fluorescent light is displayed as a scattergram.
In the scattergram, the X-axis represents the intensity of the lateral fluorescent light and the Y-axis the intensity of the forward scattered light.

Scattergram analysis algorythms separate the mature red blood cells, reticulocytes and platelets from each other and calculate reticulocyte ratio's, reticulocyte count, optical red blood cell count and platelet count.



Here, the scattergram is divided into three RET zones based on the intensity of the fluorescent light and the ratio of the reticulocytes in each zone to the total number of reticulocytes is calculated.

Analysis parameters

Reticulocyte Ratio:

$$RET\% = \frac{\text{Particle count in reticulocyte zone}}{\text{Particle count in mature RBC zone + Particle count in reticulocyte zone}} \times 100$$

Reticulocyte Count:

$$RET\# = \frac{RET\% \times RBC}{100}$$

Low Fluorescence Ratio:

$$LFR = 100 - HFR - MFR$$

Middle Fluorescence Ratio:

$$MFR = \frac{\text{Particle count in MFR zone}}{\text{Particle count in reticulocyte zone}} \times 100$$

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High Fluorescence Ratio:

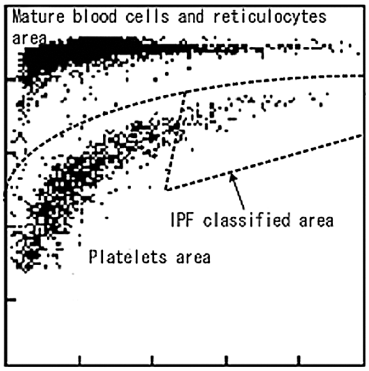
$$HFR = \frac{\text{Particle count in HFR zone}}{\text{Particle count in reticulocyte zone}} \times 100$$

Immature Reticulocyte Fraction:

IRF = MFR + HFR

LFR: Low Fluorescence Ratio
MFR: Middle Fluorescence Ratio
HFR: High Fluorescence Ratio
IRF: Immature Reticulocyte Fraction

RET-He (Reticulocyte Hemoglobin equivalent) :
The RET-He is a unique parameter developed by Sysmex that is derived using the reticulocyte scattered light signals and a proprietary Sysmex calculation equation.



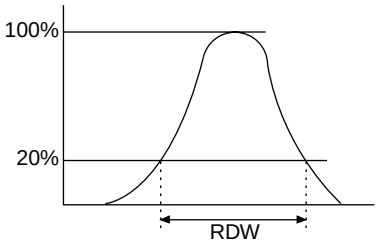
IPF (Immature Platelet Fraction) :

$$IPF = \frac{\text{Particle in IPF classified area in RET channel}}{\text{Platelet count in RET channel}} \times 100$$

10. RBC/PLT particle size distribution analysis

RBC particle size distribution

The RBC (red blood cells) are found between two discriminators, a lower discriminator (LD) and upper discriminator (UD), which are automatically set up between 25 – 75 fL and 200 – 250 fL, respectively.
Particle size distributions are checked for abnormalities, including abnormal relative frequencies at the different discriminator levels, existence of two or more peaks and abnormal distribution widths.
The XE-5000 expresses the RBC distribution width (RDW) according to the two methods shown below.



RDW-SD

With the peak height assumed to be 100%, the distribution width at the 20% frequency level is RDW-SD. Units are expressed in fL (femtoliters), with 1 fL equal to 10^{-15}L.

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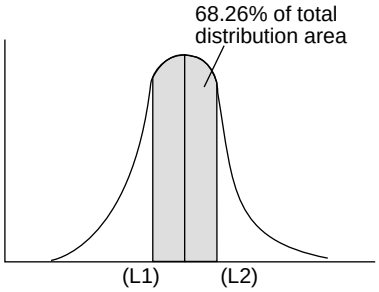


RDW-CV

With points L1 and L2 found at a frequency of 68.26% of the total distribution area, RDW-CV is calculated from the following equation:

$$\text{RDW–CV (\%)} = \frac{L_2 - L_1}{L_2 + L_1} \times 100$$

PLT particle size distribution

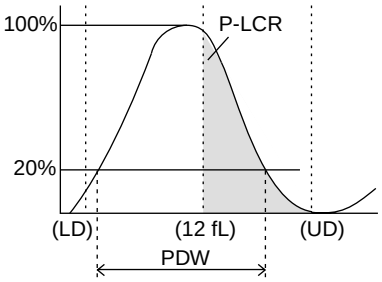
Platelet particle size distributions are analyzed using three discriminators: a lower discriminator (LD) and upper discriminator (UD), which are automatically set up between 2 – 6 fL and 12 – 30 fL, respectively; and a fixed discriminator, which is set at 12 fL.

PLT particle size distributions are checked for abnormalities, including abnormal relative frequencies at the lower discriminator, abnormal distribution widths and the existence of more than one peak.

PDW (PLT Distribution Width)

With the peak height assumed to be 100%, the distribution width at the 20% frequency level is PDW.

Units are expressed in fL (femtoliters), with 1 fL equal to 10^{-15}L.



P-LCR (Platelet Large Cell Ratio)

The P-LCR is the ratio of large platelets from the 12 fL discriminator or larger. It is calculated as a ratio comparing the number of particles between the fixed discriminator and UD, to the number of particles between LD and UD.

MPV (Mean Platelet Volume)

The MPV is calculated from the following equation:

$$\text{MPV (fL)} = \frac{\text{PCT (\%)}}{\text{PLT} (\times 10^3/\mu\text{L})} \times 10000$$

PCT: PCT is called the platelet hematocrit or platelet volume ratio, and is weighted toward the PLT frequency.

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Particle size distribution expression

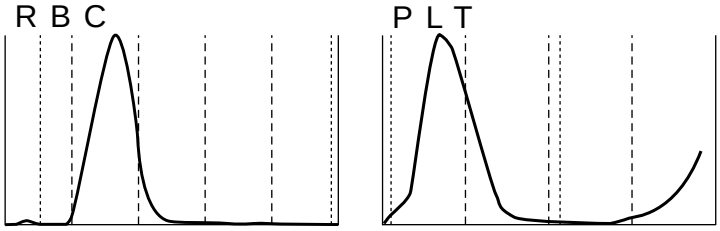
The impression one receives of a particle size distribution can vary greatly, depending on the way in which it is expressed. The width of a particle size distribution requires particular attention, because it can appear completely different, depending on the expression used for the distribution.
The XE-5000 utilizes a conventional particle size distribution expression (normal expression) and a particle size distribution expression method that enables the user to obtain a large amount of information from the particle size distribution intuitively (normal cell size range expression).

Normal expression

With the peak of the particle size distribution set as “full scale” (maximum height when the particle size distribution is displayed), this method of expression normalizes and expresses the distribution.

- Features: Patterns of particle size distributions whose counts are different can be viewed on the same scale. Widths of particle size distributions can be compared intuitively.

- Displays supported: RBC and PLT particle size distributions



Normal cell size range expressions

With the peak of the normal cell size range found experimentally set as full scale rather than the peak of the particle size distribution set as full scale (maximum height when the particle size distribution is displayed), this method of expression normalizes and expresses the distribution. At the same time, it repeatedly expresses the normal range of the distribution.
If, however, the peak of the particle size distribution is higher than the peak of the normal cell size range, the expression is made with the distribution peak set as full scale. In this case, the normal cell size range is proportionally smaller than the height of the particle size distribution peak.
A normal cell size range can be obtained by superposing the particle size distributions of a large normal population of blood samples and then utilizing the region from the 10th percentile to the 90th percentile.

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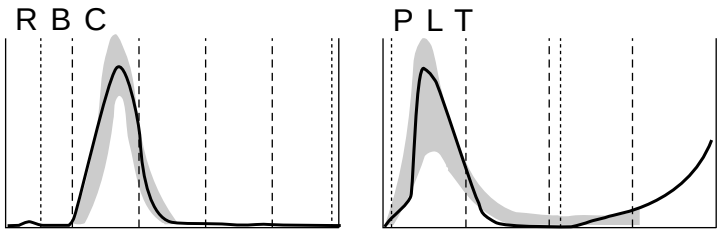
- Features: The viewer can intuitively see the size of the particles from the size distribution.
  If the particle size distribution strays from the normal range, the viewer knows instantly that the particle size distribution pattern is abnormal.

- Displays supported: RBC and PLT particle size distributions if settings are preset to normal range



11. Main Unit electrical system

The microprocessor in the Main Unit controls solenoid valves and master valves in the hydraulic system, thus, it controls the flow of the sample, reagents and waste fluid in the hydraulic system.
The electrical signals received from each detector are processed (waveform processing) at the analog unit and sent to the microcomputer unit. The microcomputer unit converts the analog signals into digital signals, then computes the results.

RBC and PLT cell signals are sent to the applicable waveform processing circuits of the analog unit, where noise is eliminated and the required blood cell signals are picked up. The microcomputer unit converts the analog-to-digital-converted cell signals into particle size distribution data and sends the data to the IPU.

The RF- and DC- signals are sent to the applicable waveform processing circuits of the analog unit, where noise is eliminated and the required blood cell signals are picked up. The microcomputer unit converts the analog-to-digital-converted cell signals into scattergram data and sends the data to the IPU.

HGB is calculated by subtracting the light absorbance of the diluent (background count) from the light absorbance of the sample. The light that is passed through the liquid in the hemoglobin flow cell is received by the photodiode, where it is photoelectrically converted. It is then converted from analog to digital signals, and sent to the IPU.

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The blood cell signals from the optical detector block (which analyzes 4DIFF, WBC/BASO, NRBC and RET) can be obtained by the process mentioned below. Signals from the forward scattered light, lateral scattered light, and lateral fluorescent light are sent to the applicable waveform processing circuits of the analog unit, where noise is eliminated and the required blood cell signals are picked up. The microcomputer unit converts the analog-to-digital-converted cell signals into scattergram data and sends the data to the IPU.

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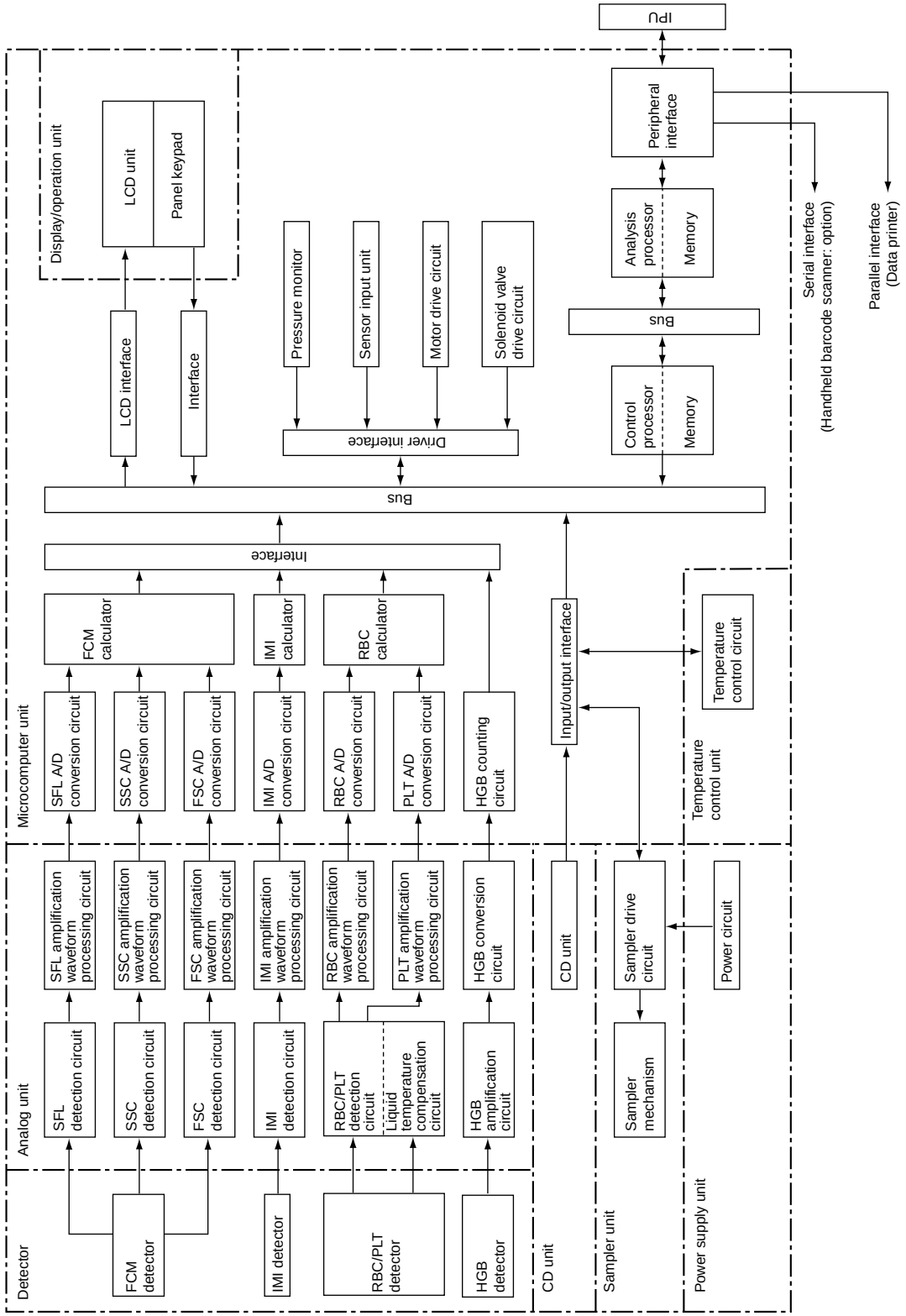
12. Electrical system block diagram



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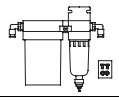
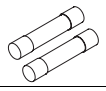
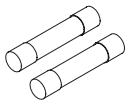
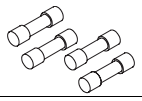
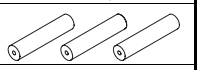
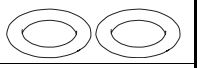
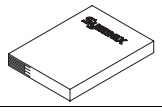
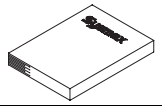
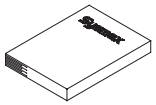
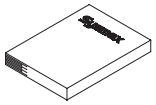
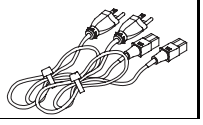
11.6 Contents of the packages

1. Main Unit

Part number	Description	Quantity			Usage	
		117V	220V	240V		
063-7922-1	MAIN COMPLETE XE-5000 (117VAC)	1	0	0		
063-7923-5	MAIN COMPLETE XE-5000 (220VAC)	0	1	0		
063-7924-9	MAIN COMPLETE XE-5000 (240VAC)	0	0	1		
933-1243-6	AIR DRIER NO. 1 ASSY (C3/XE)	1	1	1		
462-2423-7	CUTTING PLIERS B-150 MM	1	1	1		
266-7651-2	FUSE 250V4A 313004 (N.AMERICA)	2	0	0	for PU	
266-5106-0	FUSE 250V6.3A ST4-6.3A-N1 (N.AMERICA)	2	0	0	for Main Unit	
266-5293-0	FUSE 250V3.15A NO. 19195 (EUROPE)	0	4	4	for PU & Main Unit	
442-3362-0	RUBBER JOINT NO. 22	3	3	3		
343-2462-5	O-RING NO. 12	2	2	2		
461-2640-4	XE-5000 Instructions for Use	1	0	0		
461-2642-1	XE-5000 Instructions for Use/EU	0	1	1		
461-2641-8	XE-5000 Software Guide	1	0	0		
461-2643-5	XE-5000 Software Guide/EU	0	1	1		
923-8092-8	POWER CORD NO.15 (C-2/ N.AMERICA)	2	0	0		

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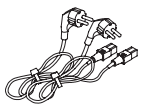
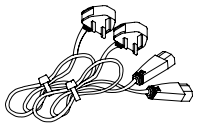
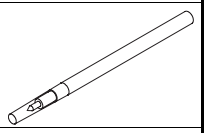
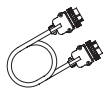
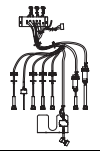
Part number	Description	Quantity			Usage	
		117V	220V	240V		
265-4731-5	POWER CORD 4622-007-0092 (EUROPE)	0	2	0		
265-4733-2	POWER CORD NO. 7687	0	0	2		
462-2381-8	SCREWDRIVER PHILLIPS NO. 1300#2	1	1	1		
346-6568-9	SEAL NO. 18	1	1	1		
266-4461-8	TIE WRAP CV-100	10	10	10		
462-3520-5	TRANSDUCER BRUSH	1	1	1		
442-5343-6	TUBE POLYURETHANE 10 MM × 14 MM	10 M	10 M	10 M		
442-5055-4	TUBE POLYURETHANE 1.8 MM × 3.4 MM	5 M	5 M	5 M		
442-5338-7	TUBE POLYURETHANE 4 MMID × 6 MMOD	5 M	5 M	5 M		
442-5301-0	TUBE SILICONE 3 MMID × 6.5 MMOD	1 M	1 M	1 M		
442-6203-5	TUBE E-PD-2 (2 × 4)	1	1	1		
442-5333-9	TUBE POLYURETHANE 2.4 MM × 4 MM	1 M	1 M	1 M		
442-5415-7	TUBE TEFLON 1.0 MM × 2.0 MM	1 M	1 M	1 M		
442-6483-4	TUBE PHARMED 1/32 × 5/32	200 MM	200 MM	200 MM		
442-5418-8	TUBE TEFLON 0.8 MMID × 1.8 MMOD	1 M	1 M	1 M		
903-0021-3	CONNECTING CABLE NO. 33	1	1	1		
063-4142-1	REAG SUPPLY UNIT NO. 4	1	1	1		

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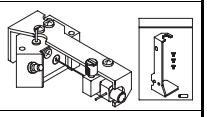
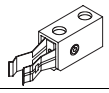
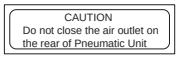
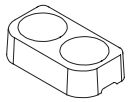
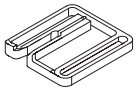
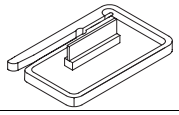
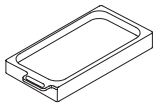
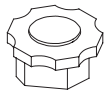
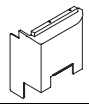
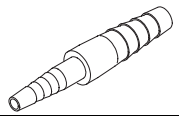
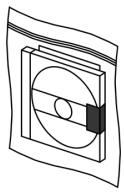
Part number	Description	Quantity			Usage	
		117V	220V	240V		
971-0583-5	PIERCER SET NO. 1 (XE/ STANDARD)	1	1	1		
266-4462-1	TIE WRAP CV-250	4	4	4		
923-8101-4	HAND CLIPPER S#4 ASSY (C1/ PIER)	1	1	1		
369-5013-6	INDICATION MARK NO. 1003	1	1	1		
369-8377-1	CAUTION MARK NO. 188 (WHITE)	1	0	0		
424-3705-2	BOTTLE STAND NO. 17	1	1	1		
367-1058-4	TRAY NO. 27	1	1	1		
367-1059-8	TRAY NO. 28	1	1	1		
367-1109-7	TRAY NO. 26 (WHITE)	1	1	1		
462-3122-1	CUBITAINER CAP OPENER NO. 2	1	1	1		
462-2852-7	HEX KEY TWH-13 2.5 MM	1	1	1		
368-0079-6	RUBBER PLATE NO. 39	4	4	4		
322-4907-6	CP UNIT COVER-A	1	1	1		
322-4309-1	CP UNIT COVER-B	1	1	1		
442-4486-8	TUBE JOINT PD-ML	1	1	1		
063-7622-5	CDR1XE5X	1	1	1		

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2. Pneumatic Unit

Part number	Description	117V	220V	240V
003-0313-7	PU-15 COMPLETE ASSEMBLY (117V/XE)	1	0	0
003-0314-1	PU-15 COMPLETE ASSEMBLY (220V/XE)	0	1	0
003-0315-4	PU-15 COMPLETE ASSEMBLY (240V/XE)	0	0	1

3. Sampler Unit

Part number	Description	Quantity		
		117V	220V	240V
063-7952-3	OPSU-12 MAIN UNIT COMPLETE ASSY (117VAC)	1	0	0
063-7953-7	OPSU-12 MAIN UNIT COMPLETE ASSY (220VAC/240VAC)	0	1	1
073-2763-1	SAMPLE RACK PACKAGE ASSEMBLY (WHITE) (6/PACK)	2	2	2
321-3106-8	CONNECTING ROD NO. 7	2	2	2
348-3926-8	SCREW BINDING M4 × 6(SUS)	3	3	3
368-9781-5	SPILL COVER NO. 37	1	1	1
348-3612-0	SCREW FLAT M3 × 6(SUS)	4	4	4
367-9161-1	BALL CATCHER TL-60-Z-CR TYPE 2	2	2	2

Note:
If you need to order supplies or replacement parts, please contact your local Sysmex representative.

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11.7 Check before installation

The XE-5000 and associated equipment is installed by your Sysmex technical representative. In case relocation becomes necessary after installation, contact your Sysmex technical representative.
Problems resulting from the relocation of the XE-5000 by anyone other than a Sysmex technical representative are not covered by the Warranty even if it is in the warranty period.

11.8 Grounding

The instrument power supply cord uses a 3-prong plug. When the power supply socket is provided with grounding, simply plug it to the socket. If the power supply socket is not provided with grounding, use an adapter plug and ground the ground wire separately.

Warning!
- Always ground this instrument.
  Inadequate grounding creates the danger of electrical shock.
- Take care to stay within the capacity of the socket.
  This is to prevent the risk of a fire.

11.9 Installation environment

- Use sample at an ambient temperature of 15 – 30ºC (20 – 30ºC for HPC analysis mode).
- Relative humidity should be within the range of 30% - 85%.
- If ambient temperature and relative humidity are not within the suggested range, air-condition the environment.
- Avoid a place that can be extremely high or low in temperature.
- Avoid a place that is exposed to direct sunlight.
- Select a well-ventilated place.
- Avoid a place close to a centrifugal machine, wireless communication devices or communication facility where high frequency waves are generated or radio interference can occur.

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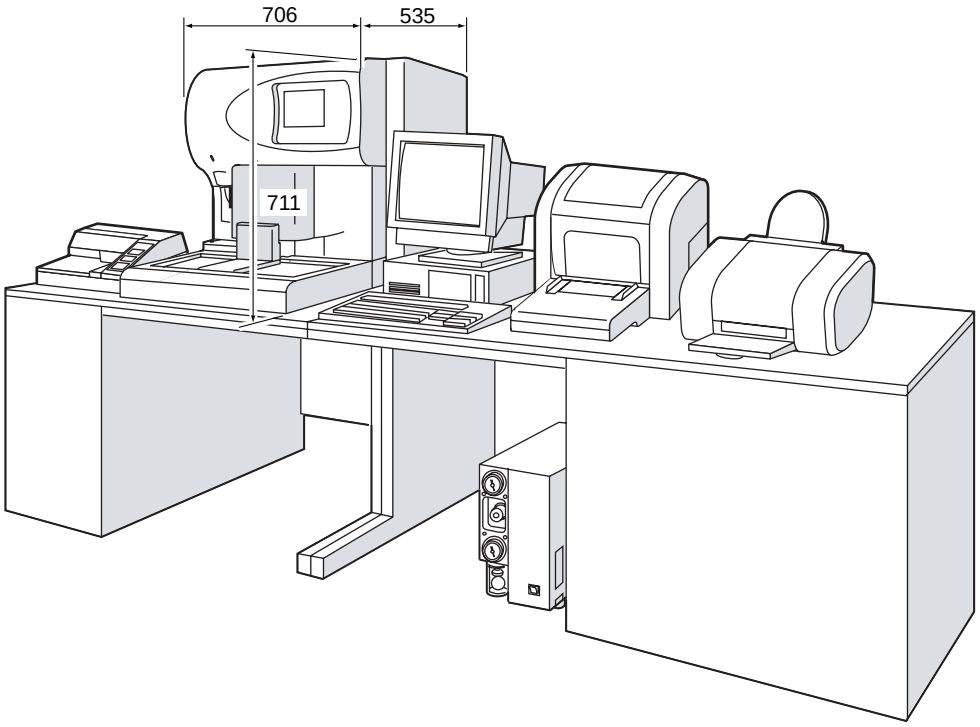
11.10 Installation space

To secure the space required for maintenance, install the IPU on the right side of the Main Unit. The Main Unit should be at least 25 cm away from the CRT of the IPU.
Provide a distance of at least 50 cm behind the instrument.

Component	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	706	535	711	Approx. 81
Sampler	580	377	195	Approx. 12
Pneumatic Unit	195	395	333	Approx. 15.5



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12. Warranty

All Sysmex instruments are guaranteed against defects of material or manufacture for one year from the date of installation on the user's premises. However, this warranty does not cover defects, malfunctions or damage arising for any of the reasons stated below.

- Accidents and improper use of the instrument, whether intentional or unintentional.
- Failure to observe the usage, operation, servicing and maintenance described in the applicable Sysmex Instructions for Use.
- Failure to use suitable reagents and replacements, as specified for the product.

Information

The warranty is no longer applicable if the customer has relocated the instrument or has used it at another location. Contact your Sysmex technical representative before relocating the instrument.

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