sysmex

Automated Hematology Analyzer
XS series

XS-1000*i*/XS-500*i*
Instructions for Use

Sysmex Corporation
KOBE, JAPAN

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1. Introduction

- The Sysmex XS-1000*i* and XS-500*i* are automated hematology analyzers for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XS-1000*i* and XS-500*i* can analyze and output the results of 24 (for Europe, or 21 for Americas) parameters of a blood sample.
- The Sysmex XS-1000*i* and XS-500*i* perform analysis of WBC and differential with an optical detector block based on the flow cytometry method, using a semiconductor laser. The RBC's and platelets are analyzed by the RBC detector using the Hydro Dynamic Focusing method. Analysis data is displayed on the Information Processing Unit (IPU). Hemoglobin (HGB) is analyzed by the HGB detector based on the SLS hemoglobin detection method.

- The screens shown in these instructions are XS-1000*i* screens. On the XS-500*i* screens, XS-500*i* is displayed for the instrument name at the top left of the screen, and for the Main Unit model name at the lower left. Any other differences will be described in detail on each occasion. Analysis parameters and principles are the same for the XS-1000*i* and the XS-500*i*.

- The XS-1000*i* and XS-500*i* are compact instruments, and their operations are easy to learn. For each operating step, online help is available for support. Quality control material is used to monitor the performance of the analyzer over time.
- The XS-1000*i* and XS-500*i* are equipped with a rinse cup to provide automatic cleaning of the sample probe after sample or control blood aspiration. It is not necessary to wipe the sample probe.
- Sysmex instrumentation generates minimal noise. To ensure quiet laboratory operations during non-operating, the compressor can be switched off.
- Using individual settings, the user can adapt the instrument to their needs or existing laboratory conditions.
- Before operating XS-1000*i* and XS-500*i*, read this manual carefully. Pay special attention to the safety information. Keep this manual for future reference.

- For further information, please contact the Sysmex representative in your country.

Note:

- Data generated by the XS-1000*i* and XS-500*i* is not intended to replace professional judgment in the determination of a diagnosis or in monitoring patient therapy.
- 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

SYSMEX CORPORATION
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JAPAN

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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.

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1.1 Hazard Information in this Manual

Note, Important, 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

Indicates the presence of a biohazardous material or condition.

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!

Average risk. Ignoring this warning could result in property damage. To avoid damage and incorrect measuring results.

Important!

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

Caution!

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

Note:

Background information and practical tips.

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1.2 Protected Names

- Sysmex® is a registered trademark of SYSMEX CORPORATION, Japan.
- CELLPACK, CELLCLEAN, *e*-CHECK (XS), STROMATOLYSER-4DL, -4DS, SULFOLYSER are trademarks of SYSMEX CORPORATION.
- Cubitainer is a registered trademark of Hedwin Corporation.
- ISBT128 (International Society of Blood Transfusion) is copyrighted by and is used under License Agreement with ICCBBA, Inc.

The fact that a trademark is not explicitly mentioned in this manual does not authorize its use.

1.3 Analysis Parameters

The XS-1000*i*/XS-500*i* provides results for the following parameters:

WBC	Number of all leukocytes
RBC	Number of all erythrocytes
HGB	Hemoglobin concentration
HCT	Hematocrit value: Erythrocyte ratio of total blood volume
MCV	Mean erythrocyte volume in total sample
MCH	Mean hemoglobin volume per RBC
MCHC	Mean hemoglobin concentration of erythrocytes
PLT	Number of all platelets
NEUT%	Neutrophil Percent
LYMPH%	Lymphocyte Percent
MONO%	Monocyte Percent
EO%	Eosinophil Percent
BASO%	Basophil Percent
NEUT#	Neutrophil Count
LYMPH#	Lymphocyte Count
MONO#	Monocyte Count
EO#	Eosinophil Count
BASO#	Basophil Count
RDW-SD	Calculated distribution width of erythrocytes, standard deviation
RDW-CV	Calculated distribution width of erythrocytes, coefficient of variation
PDW	Calculated distribution width of platelets
MPV	Mean platelet volume
P-LCR	Platelet-Large Cell Ratio
PCT	Plateletcrit
IG%	Immature Granulocyte Percent (Research only)
IG#	Immature Granulocyte Count (Research only)

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1.4 Abbreviations used throughout this manual

CBC	Complete Blood Count
dL	deciliter (0.1 liter)
EPK	CELLPACK
FCM	Flow cytometry
FFD	STROMATOLYSER-4DL
FFS	STROMATOLYSER-4DS
fL	femtoliter (10^{-15} liter)
µL	microliter (10^{-6} liter)
pg	picogram (10^{-12} gram)
QC	Quality Control
SLS	SULFOLYSER

1.5 Device Overview

- The XS-1000*i*/XS-500*i* is automated hematology analyzer equipped with WBC 5 part differential functionality. The device performs measurements via flow cytometry using a semiconductor laser and via SLS hemoglobin methodology. The RBCs and platelets are analyzed by the RBC detector using the Hydro Dynamic Focusing method. The XS-1000*i*/XS-500*i* is structured with the principal components as follows:

- XS-1000*i*/XS-500*i* Main Unit: measures & controls samples.
- Information Processing Unit (IPU): Processes data generated by the measuring device.
- Model variations and their features are shown below.

	Sample tube	Cap piercer	Sampler (with ID reader)	Optional hand-held bar code reader
XS-1000*i*	Open & Closed	Yes	Optional	Optional
XS-500*i*	Open	No	No	Optional

1.6 Reference Intervals

Reference intervals (Normal Population Reference Ranges) were developed for the XS-1000*i*/XS-500*i* using normal individuals. The range for each parameter is calculated for 95% confidence intervals.

Parameter	Range for Females n = 133	Range for Males n = 182	Units
WBC	3.98 - 10.04	4.23 - 9.07	$x10^3/\mu L$
NEUT%	34.0 - 71.1	34.0 - 67.9	%
LYMPH%	19.3 - 51.7	21.8 - 53.1	%
MONO%	4.7 - 12.5	5.3 - 12.2	%

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Parameter	Range for Females n = 133	Range for Males n = 182	Units
EO%	0.7 - 5.8	0.8 - 7.0	%
BASO%	0.1 - 1.2	0.2 - 1.2	%
NEUT#	1.56 - 6.13	1.78 - 5.38	$x10^3/\mu L$
LYMPH#	1.18 - 3.74	1.32 - 3.57	$x10^3/\mu L$
MONO#	0.24 - 0.86	0.30 - 0.82	$x10^3/\mu L$
EO#	0.04 - 0.36	0.04 - 0.54	$x10^3/\mu L$
BASO#	0.01 - 0.08	0.01- 0.08	$x10^3/\mu L$
RBC	3.93 - 5.22	4.63 - 6.08	$x10^6/\mu L$
HGB	11.2 - 15.7	13.7 - 17.5	g/dL
HCT	34.1 - 44.9	40.1 - 51.0	%
MCV	79.4 - 94.8	79.0 - 92.2	fL
MCH	25.6 - 32.2	25.7 - 32.2	pg
MCHC	32.2 - 35.5	32.3 - 36.5	g/dL
RDW-CV	11.7 - 14.4	11.6 - 14.4	%
RDW-SD	36.4 - 46.3	35.1 - 43.9	fL
PLT	182 - 369	163 - 337	$x10^3/\mu L$

Note:

Sysmex recommends that each laboratory establish its own expected reference intervals based upon the laboratory's patient population encountered during daily operation. Expected reference intervals may vary due to the differences in sex, age, diet, fluid intake, geographic location, etc. The CLSI Document C28-A "How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline" contains guidelines for determining reference values and intervals for quantitative clinical laboratory tests.

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2. Safety Information

2.1 Intended Use

The Sysmex XS (XS-1000*i* / XS-500*i*) is an Automated Hematology Analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratory. Operate the instrument as instructed. Reliability of test results cannot be guaranteed if there are any deviations from the instructions in this manual. Use only the reagents mentioned 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.

2.2 General Information

Read the manual before operating the XS-1000*i*/XS-500*i*.
Keep this manual for future reference.

Warning!

- The unpacking, setup and confirmation of correct initial operation is performed under the direction of Sysmex technical service.
- Take care to keep long hair, fingers and clothing away from rotating parts.
- Should the instrument emit any unusual odors or smoke, turn the main switch OFF immediately and unplug the power cable. Contact Sysmex service representative.
  Using the instrument any further bears the risk of fire, electrical shock or personal injury.
- Do not spill blood samples or reagents onto the instrument and take care not to let anything metal, such as needles and/or clips get into it.
  Doing so could cause a short-circuit.
  Should the instrument malfunction, turn the main switch OFF immediately and unplug the power cable. Contact Sysmex service representative.
- The operator should not touch any electrical circuitry inside the cover. The danger of electrical shock is particularly high when one's hands are wet.
- This instrument must not be connected to a power outlet rated at anything other than specified in the rated plate. Please note that the instrument must be grounded.
  Failure to do so may cause a fire or electrical shock.
- Avoid damage to the power cable: do not place any heavy object on the power cable or pull on it.
  Doing so may cause a fire or shock due to electrical short or broken wiring.
- Switch OFF the power supply before connecting any peripheral devices (host computer, printer).
  This is to prevent electrical shock hazard.

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2.3 Set Up

Caution!

- The instrument should be installed in a well-ventilated location, away from water, dust, direct sunlight. Do not install in an area of elevated temperature and vibration.
- The instrument must be located in a place where it will not be splashed by water.
- Install the instrument in a location free from high temperature and humidity, dust and direct sunlight.
- Install so it will be free of any strong shock or vibration.
- Avoid installation of the instrument near devices that emit electrical interference, such as radio, centrifugal separator, etc.
- Do not install this instrument in places where chemicals are stored or gas can develop.
- Do not use this instrument in any operating environment which has electro-conductive or flammable gases, including oxygen, hydrogen, and anesthesia.
- This instrument was designed for indoor use only.

2.4 Electromagnetic compatibility (EMC)

This instrument complies to 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 potentially infectious.
- Never touch waste, or parts that have come in contact with waste, with your 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.
- Take appropriate care in handling samples. Use of protective garments and gloves is strongly recommended when operating, maintaining, servicing or repairing the instrument. If something should get in your eyes or an open wound, rinse thoroughly with water and then contact your doctor immediately.
- Control blood must be regarded as potentially infectious. When performing quality controls, use protective garments and gloves. If something should get in your eyes or an open wound, rinse thoroughly with water and then contact your doctor immediately.
- Take appropriate care in handling waste fluids. If you get them on your skin or clothes, wash them.

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2.6 Handling of reagents

Warning!

- 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.
- Avoid direct contact with 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, rinse thoroughly with water and contact your doctor immediately.
- If a reagent is accidentally swallowed, vomit or induce vomiting by drinking copious amounts of warm, salty water and contact your doctor immediately.
- CELLPACK diluent is a good electrical conductor. If diluent is spilled inadvertently near electrical cables or appliances, there is a risk of electrical shock. Switch the instrument off, unplug it and wipe-up the liquid.
- CELLCLEAN is a strong alkaline cleaning agent. 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, respectively.
- CELLCLEAN contains sodium hypochlorite. If CELLCLEAN comes in contact with the instrument's surfaces, it will affect the surface finish and there is danger of corrosion. Immediately wipe up CELLCLEAN with a damp cloth.

Caution!

- Follow directions on reagent containers.
- Avoid letting the reagent come in contact with dust, dirt or bacteria.
- 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.

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2.7 Quality Control Materials

Caution!

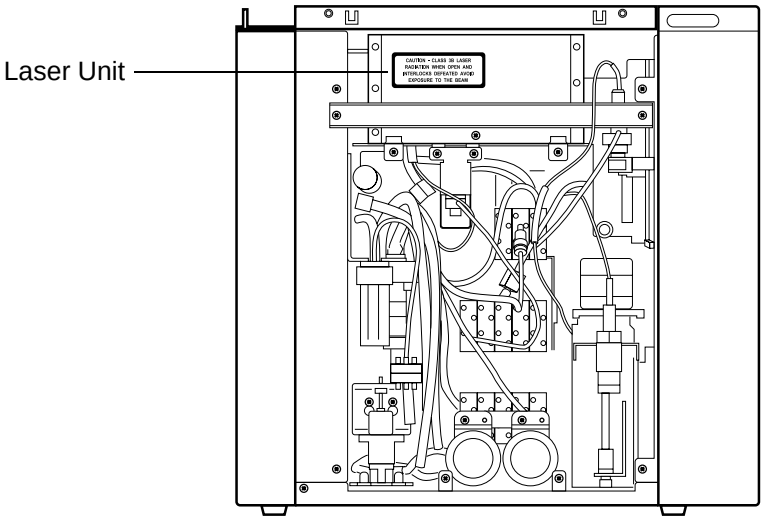
- Do not inject or ingest.
- Follow directions on QC material containers.
- Avoid letting the QC material come in contact with dust, dirt or bacteria.
- QC materials must not be used after their expiration date.
- Handle QC materials gently to avoid bubbling. Never shake reagents. Do not use QC materials immediately after moving them.
- Take care not to spill QC materials. If a QC material is spilled, wipe up with a damp cloth.

2.8 Laser

Warning!

The analyzer of the XS-1000*i*/XS-500*i* uses a semiconductor laser unit. This laser unit is shielded with a sealed box cover. The operator must not remove the cover. If one does remove the cover the unit is equipped with an interlock system that prevents laser oscillation. There is a danger causing eye pain or damage if one looks into the laser beam.

Left side interior view



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2.9 Maintenance

Risk of infection

- Always wear protective garments and gloves when processing with the instrument and during maintenance. After completion of work, wash hands. The danger of contracting infectious from an infectious samples does exist.
- All cleaning and maintenance procedures as described in this manual must be observed for optimal performance.

Important!

When performing maintenance, use only the tools specially provided for such work.

2.10 Disposal of the waste, disposables and instruments

Risk of infection

Use of protective garments and gloves is strongly recommended when handling waste fluid or instrument consumables. After finishing work, wash your hands. There is a risk of infection by pathogens, etc.

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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Waste Disposal

Risk of infection

After becoming waste at end-of-life, this instrument and its accessories are regarded as infectious. They are therefore exempted from EU directive 2012/19/EU (Waste Electrical and Electronic Equipment Directive) and may not be collected by public recycling to prevent possible risk of infection of personnel working at those recycling facilities.

Warning!

- Do not dispose the instrument, accessories and consumables via public recycling!
- Incineration of contaminated parts is recommended!
- Contact your local Sysmex service representative and receive further instructions for disposal! Follow local legal requirements at all times.

Caution!

Waste effluents from the instrument may contain dangerous substances in it and decision about disposal only has to be made by local water authority.

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Decontamination

Warning!

Before decontaminating the instrument, be sure to turn off the power supply and unplug the power cord. This is necessary to avoid the risk of electric shock. When cleaning the instrument, always wear protective gloves and gown. Also, wash hands after decontamination carefully with antiseptic solution first and with soap afterwards. Do not open the instrument for decontamination inside. This is executed only by Service Technician.

Important!

- To ensure decontamination of the instrument outer surfaces, clean the instrument surface at the end of the daily work. This has to be executed in the following three situations;
  - Regularly, at the end of a daily work,
  - Immediately, during contamination with potentially infectious material, and
  - In advance of repair or maintenance by the field technical service representative
- Wipe off the instrument surfaces using a cloth soaked with a suitable decontamination solution. Please use one-way cloths, e.g. made of paper or cellulose. The cloth may be moistened in a way only that no wetness may reach the inside of the instrument.
- The indicated residence time of the decontamination solution shall be observed.
- If required, you may afterwards remove normal contaminations with commercial neutral detergent, in case these could not be removed by the decontaminant.
- As a last step the instrument shall be dried with a dry one-way cloth.

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2.11 Markings on the instrument

Front of the Main Unit

(1)

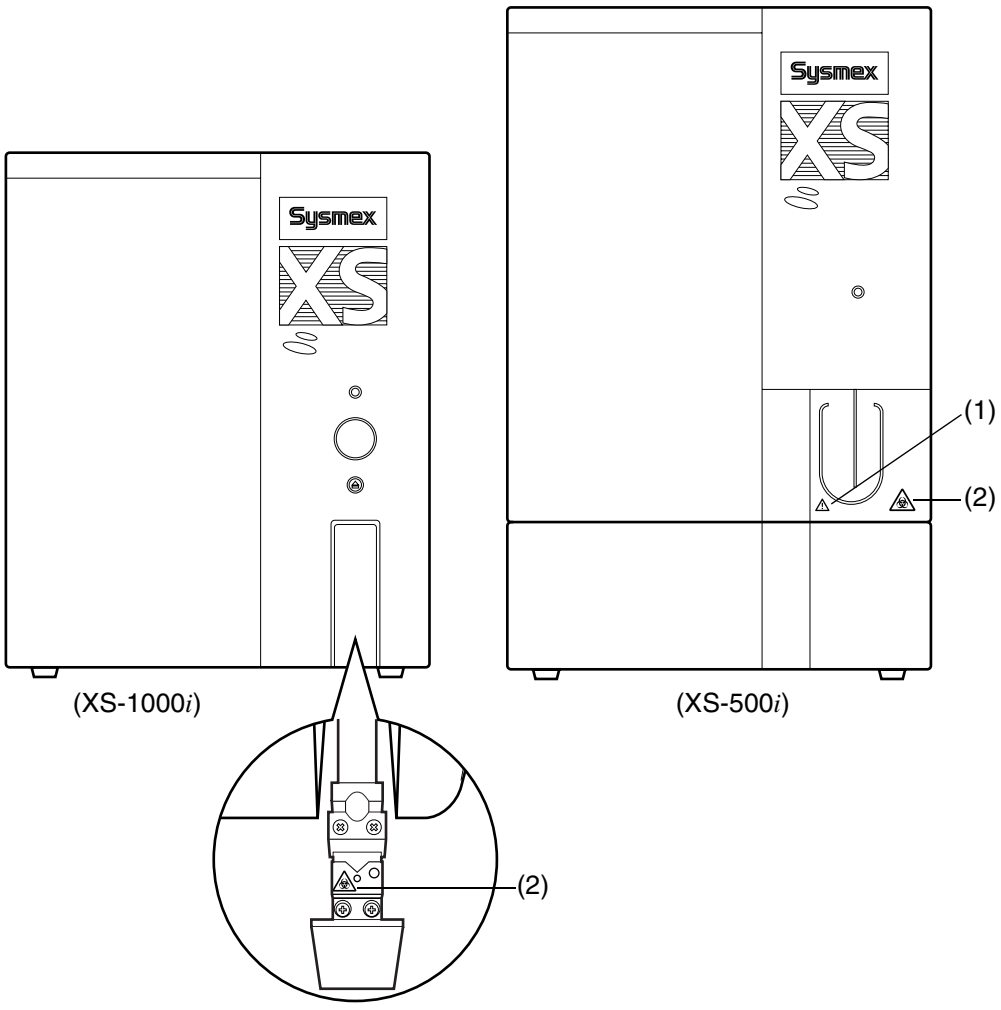
WARNING

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

(2)

RISK OF INFECTION

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



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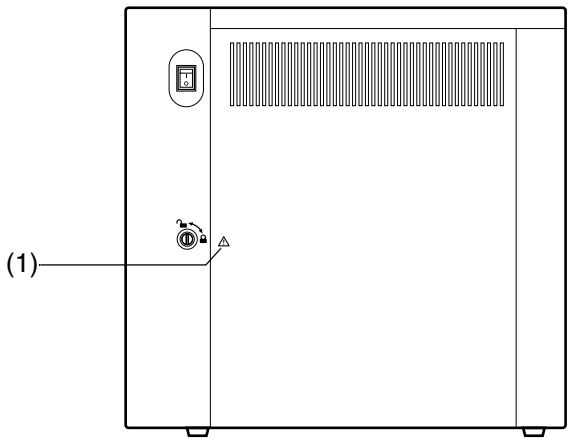
Right side of the Main Unit

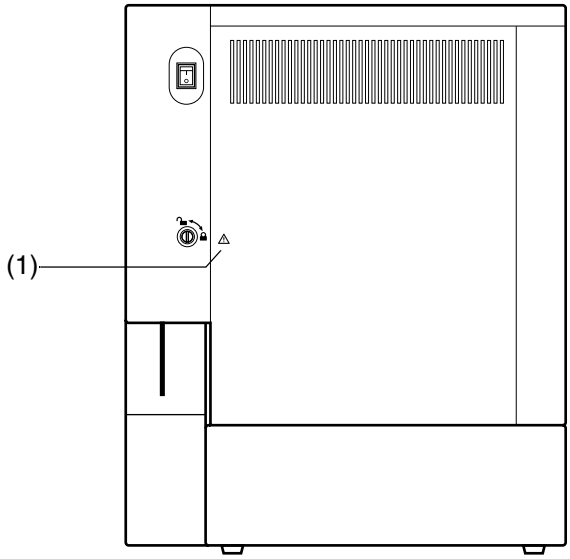
(1)

WARNING

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



(XS-1000*i*)



(XS-500*i*)

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Interior right side of the Main Unit

(1) ⚠

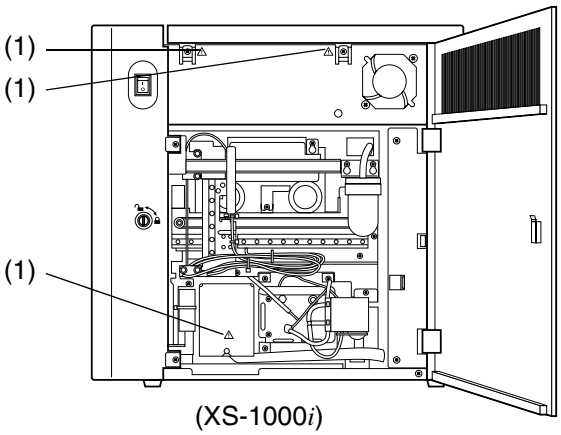
WARNING

- To avoid electrical shock, unplug the cord before servicing. Otherwise, electrical shock may result.

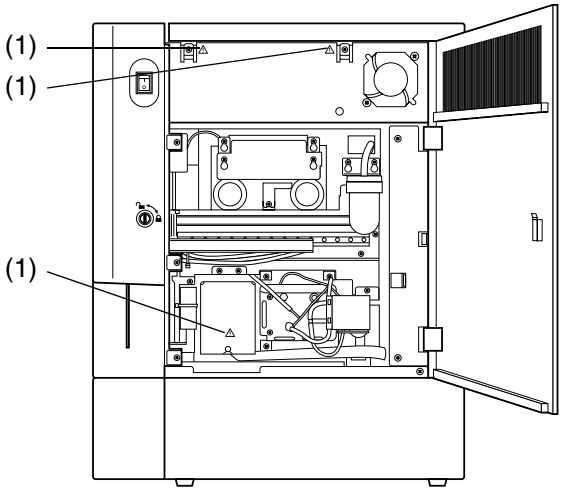
(2) ☣

RISK OF INFECTION

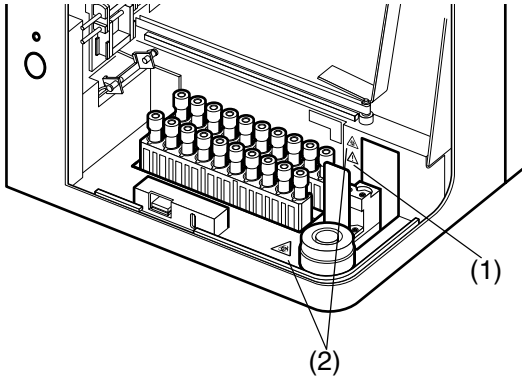
In principle, all parts and surfaces of the instrument must be regarded as infective.



(XS-1000*i*)



(XS-500*i*)



(XS-1000*i* with Sampler)

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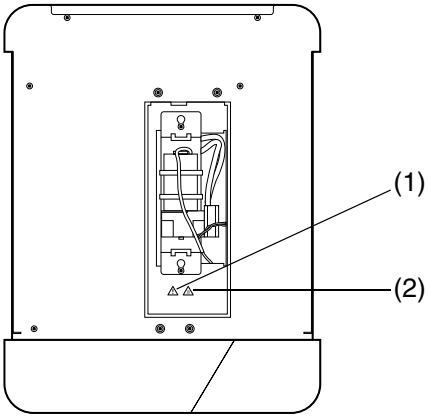
Top interior of the Main Unit



(1)

WARNING

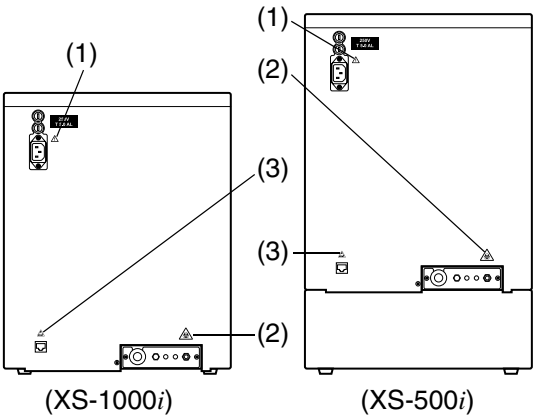
To avoid electrical shock, unplug the cord before servicing. Failure to remove the cord prior to servicing may result in electrical shock.

(2)

CAUTION, HOT!

Do not touch the air pump directly because the surface is hot. There is a risk of burns.

Rear of the Main Unit



(XS-1000*i*) (XS-500*i*)

(1)

WARNING

- To avoid electrical shock, unplug the cord before servicing.
- Replace only with fuses of the specified type and current rating.

FUSE RATING
5.0 A L 250 V
(Time Lag low breaking capacity)

(2)

RISK OF INFECTION

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

(3)

CAUTION!

There is a potential risk of damage to parts of the instrument caused by static electricity discharged from the human body, in the event of incorrect operation or failure to observe the content.

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2.12 Personnel

Caution!

- Personnel with no or limited experience in using this instrument must be instructed by and receive training from fully experienced personnel.
- In the event that a malfunction of the instrument occurs, the person responsible for the instrument may take the measures indicated in the Instructions for Use Manual, but any further steps that need to be taken must be referred to your Sysmex technical representative.
- The unpacking, setup and confirmation of correct initial operation is to be performed by the Sysmex technical representative.
- This instrument may only be operated by trained personnel having been instructed in its operation. Only those with appropriate training may perform maintenance and repair work.

2.13 Computer Virus

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.

2.15 HOST Connection

Caution!

When orders are downloaded from HOST, start operation after all orders of the racks to be analyzed have been completely downloaded. If analysis is started before the order downloading is completed, the sample may be analyzed based on default settings.

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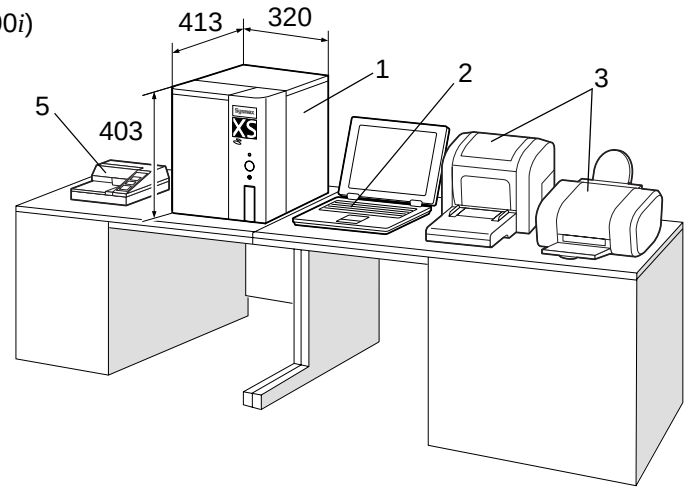
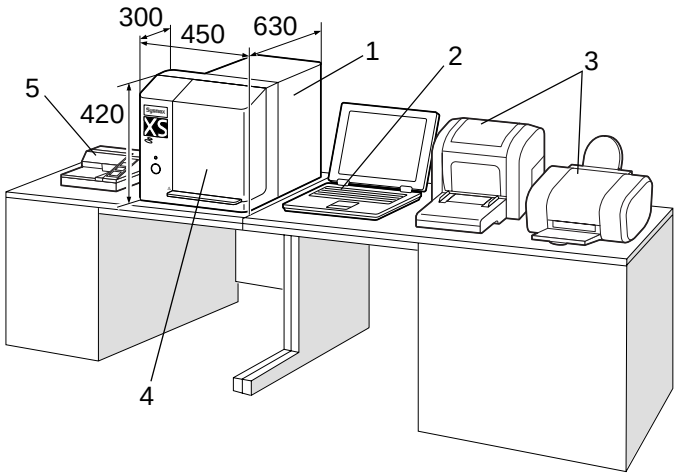
3. Design and Function

3.1 Overview

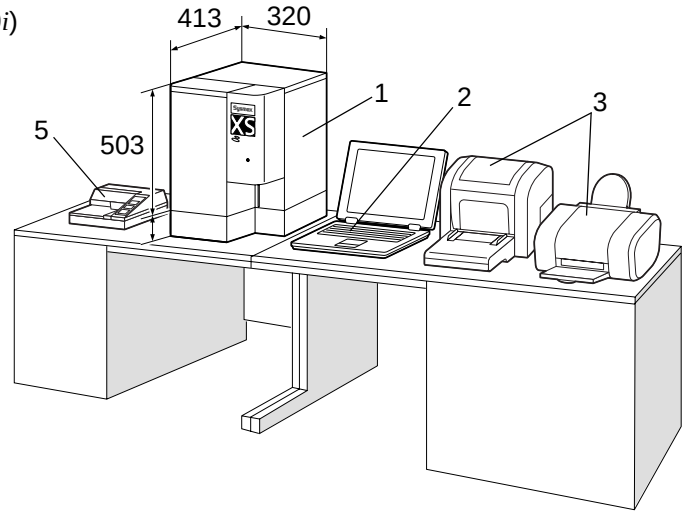
(XS-1000*i*)



(XS-1000*i* with Sampler)



(XS-500*i*)



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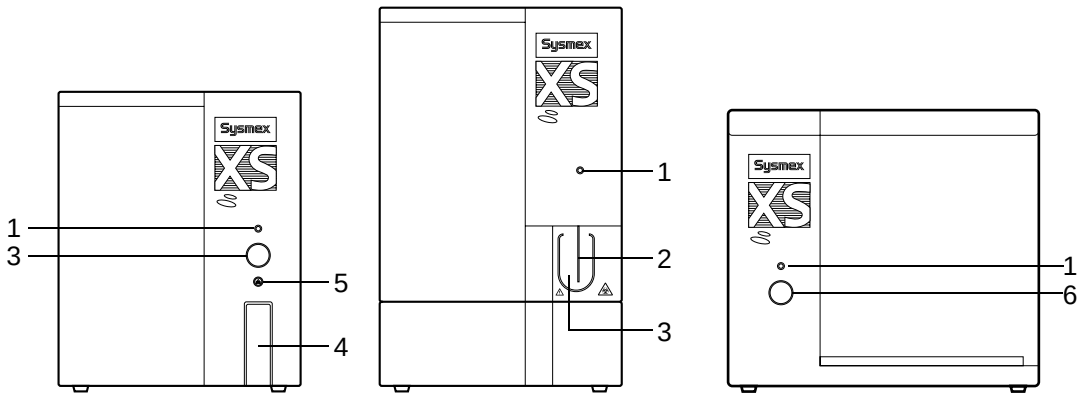
1 **XS-1000*i*/XS-500*i* Main Unit**
Analyzes patient and control samples.
2 **Information Processing Unit (IPU)**
Processes data generated by the Main Unit.
3 **List Printer (LP)/Graphic Printer (GP) (Optional)**
- Prints lists of analysis information or results.
- Prints a hardcopy of analysis results or screen of histograms, scattergrams, etc.

4 **Sampler Unit (Optional for XS-1000*i*)**
Supplies samples to the Main Unit automatically.
5 **Data Printer (Optional)**
Prints analysis data in the examination ticket format.

3.2 XS-1000*i*/XS-500*i* Main Unit

Front View



1 **READY LED**
Lights up when the Main Unit enters Ready status.
2 **Aspiration Probe (only for XS-500*i*)**
Used to aspirate a sample in manual or capillary analysis mode.
3 **Start Switch**
Used to start an analysis in manual or capillary mode.
4 **Sample Position Cover (only for XS-1000*i*)**
This is the protective cover of the sample position.
5 **Open/Close Switch (only for XS-1000*i*)**
Opens and closes the sample position.
6 **Sampler Start/Stop Switch (only for XS-1000*i*)**
Starts and stops the sampler mode analysis.

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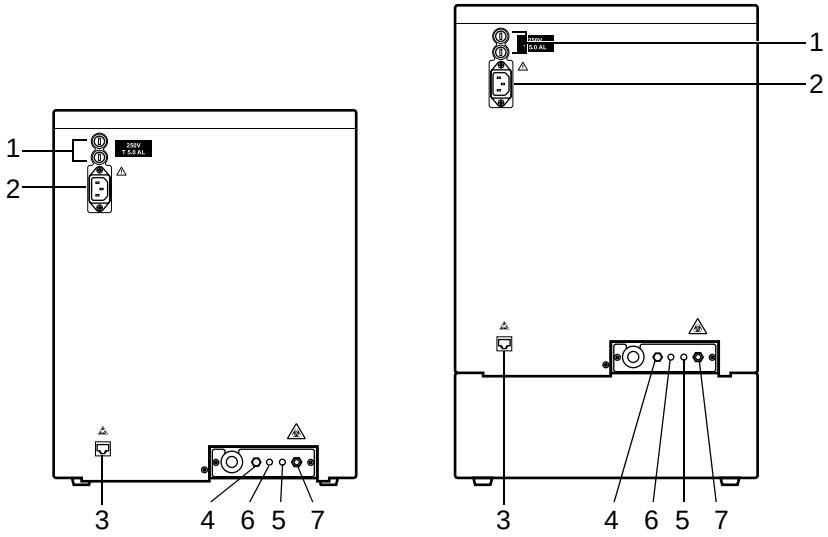
Rear View



1 Fuse Holder
Holds 250V T 5.0A L (Time Lag low breaking capacity) fuses.

Warning!

- To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.
- For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

2 AC Power Inlet
Supplies power using the provided power cable.

3 IPU Connector
The communication port with the IPU. Connect to the port of the IPU using the provided cable.

Caution!

When the cable (LAN cable) is connected to the IPU, there is a risk of damage to the communication functions of the instrument caused by static electricity discharged from the human body. Touch something to discharge static electricity and then connect the cable.

4 EPK Aspiration Nipple
CELLPACK is aspirated via this nipple. Connected to the container of CELLPACK.

5 FFD Reagent Inlet Nipple
STROMATOLYSER-4DL is aspirated via this nipple. Connected to the container of STROMATOLYSER-4DL.

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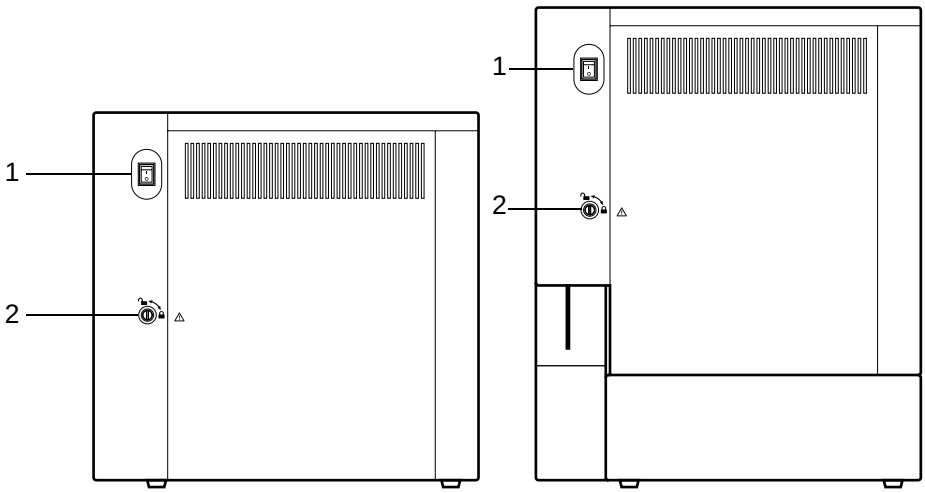
6 SLS Inlet Nipple
SULFOLYSER is aspirated via this nipple. Connected to the container of SULFOLYSER.

7 Waste Fluid Outlet Nipple
Waste fluid is discharged via this nipple. Connected to the drain or the waste container.

Right View



(XS-1000*i*) (XS-500*i*)

1 Main Power Switch
Turns the power ON / OFF.

Note:

Avoid turning this switch ON and OFF repeatedly in a short time.
This will overload the fuse and may cause a fuse to blow.

2 Lock
This is the lock for opening and closing the right side cover.

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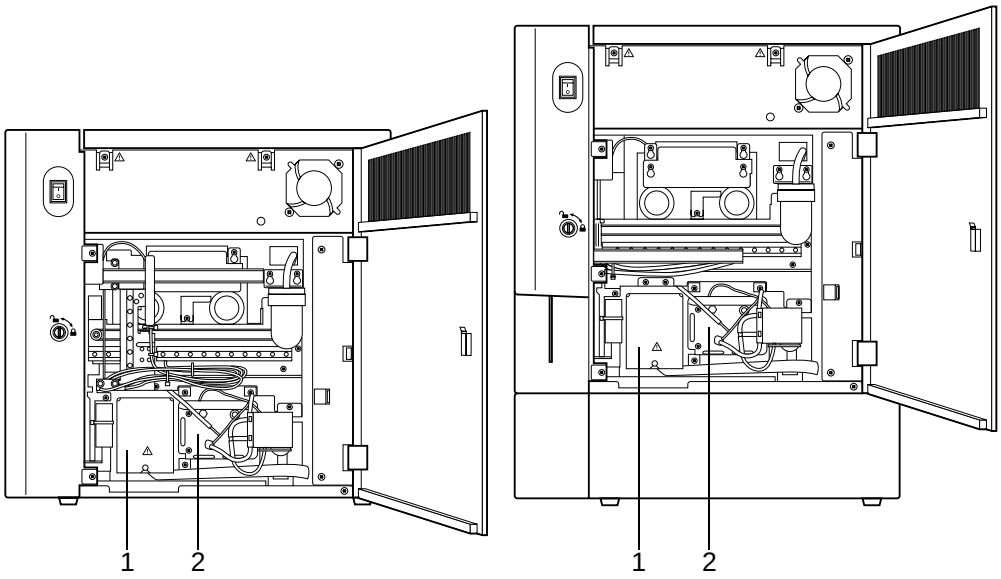
Right Interior



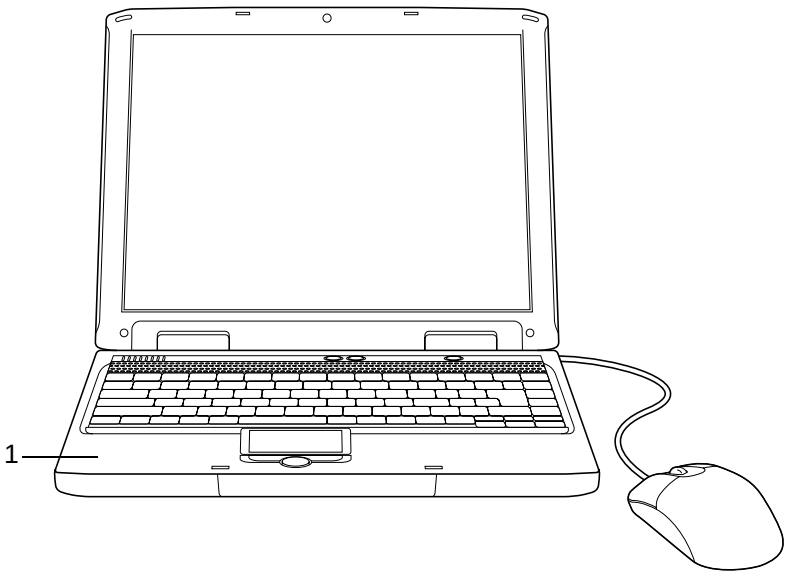
(XS-1000*i*) (XS-500*i*)

1 RBC Detector
Equipped with a RBC optical detector.

2 WBC Reaction Chamber
Prepares 5 DIFF sample.

3.3 Information Processing Unit (IPU)

Front View



1 IPU Main Unit
Main Unit of IPU.

Important!

The IPU illustration shown is for reference only. Refer to the manual included with the computer for the layout of connection ports and other details.
For further details, contact Sysmex service representative.

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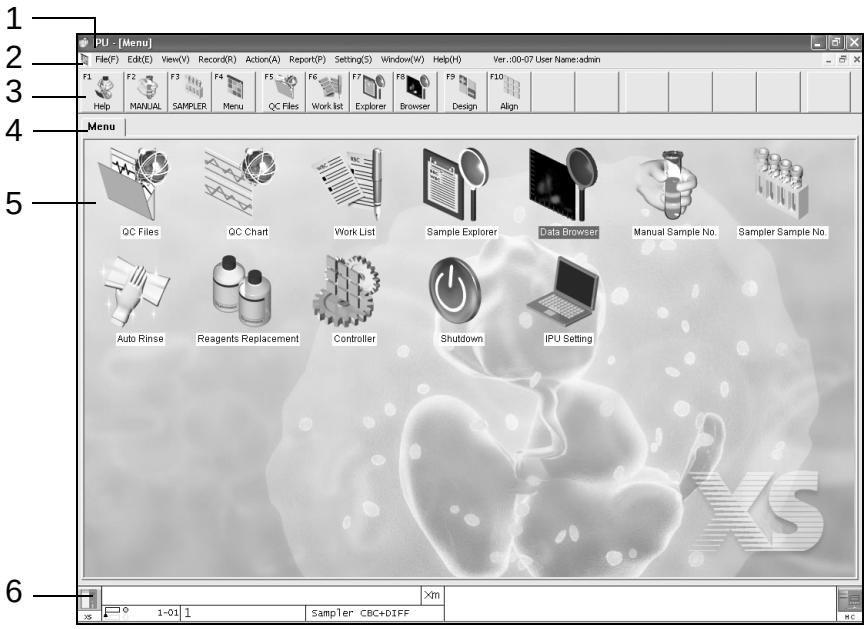
Overview of Display Screens



1 Title Display
The instrument name, display window name and number of samples in memory are shown here.

2 Menu Bar
There are submenus for each menu item. A pull down submenu can be displayed with a left mouse click.

3 Toolbar
The toolbar contains those pull down submenu items that are used regularly. Clicking on a toolbar button will immediately execute the corresponding submenu action. Inactive toolbar buttons are displayed in gray.

4 Tabs
The names of windows indicating menu icons are displayed. When there are several windows, select the desired tab to open that window.

5 View (all windows)
Areas for performing basic processes and operations.

6 System Status Display Area
The following state are displayed:

- Sample No.
- Error message
- Main Unit status
- Analysis mode
- Discrete
- X-barM status
- Host computer connection status

Important!

The explanatory screens shown in this manual are the XS-1000*i* screens. In the XS-500*i* screens, the XS-500*i* is displayed for the instrument name in the title display, and for the Main Unit name in the system status display.

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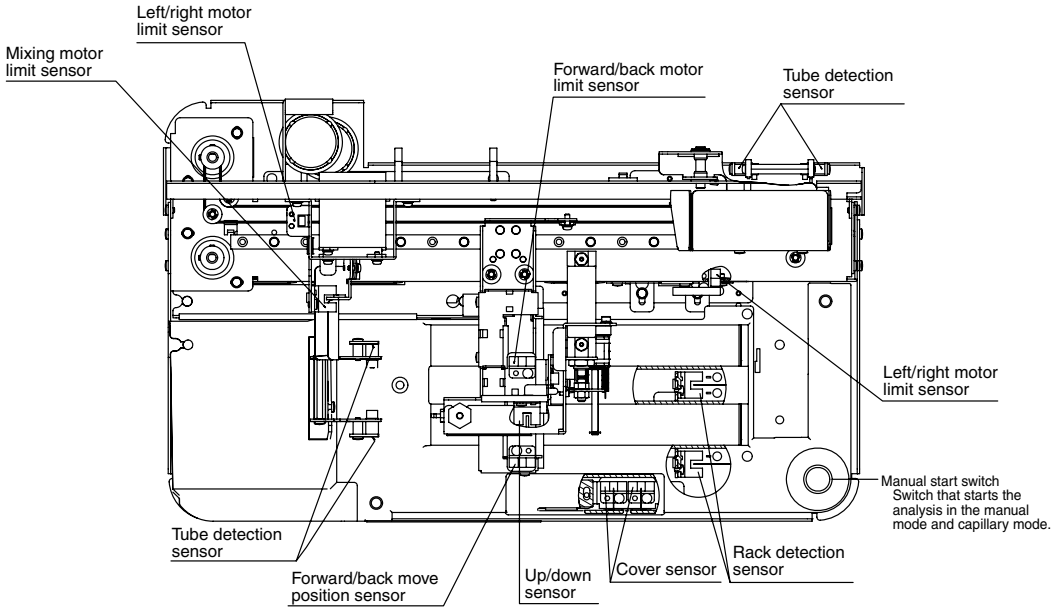
3.4 Sampler Unit (Optional for XS-1000*i*)



3.5 System Status Display Field

The System status area displays icons, etc. with information about the Main Unit status, Analysis mode, Discrete, X-barM status, and Host computer connection status. The meaning of each status display is shown below.

Main Unit status	
Not Displayed	Main Unit power OFF
 (Green)	READY status
 (Orange)	Analyzing
 (Red)	Analysis not possible/Not READY Status
Analysis mode	
Manual	Manual Mode
Capillary	Capillary Mode
Sampler	Sampler Mode (Optional for XS-1000*i*)
Discrete	
CBC	CBC
CBC+DIFF	CBC+DIFF
X-barM status	
(Not displayed)	X-barM OFF
Xm	X-barM ON

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Host computer connection status	
 (Green)	Host computer communication possible
 (Orange)	Communicating with host computer
 (Red)	Host computer communication not possible
None	Not connected

 **Note:**

The Host computer connection status icon is displayed only when Host (HC) Connect is set to ON at Host (HC) Setting. For setting procedures, see Software Guide Chapter 5: 5.2: 9. Host (HC) Setting.

3.6 Analysis mode

Manual Mode (XS-500*i*)

In manual mode, the cap of the sample tube is manually removed and each sample is aspirated via the probe.

Capillary Mode (XS-500*i*)

In capillary mode, an analysis is performed after manually diluting the sample to 1:7 dilution. This mode is used for analyzing a minute amount of blood collected from the earlobe or fingertip.

Manual Mode (XS-1000*i*)

In manual mode, after mixing a sample manually, place the sample tube in the sample position without removing the cap. Press the Start switch to start analysis.

Capillary Mode (XS-1000*i*)

In capillary mode, an analysis is performed after manually diluting the sample to 1:7 dilution. This mode is used for analyzing a minute amount of blood collected from the earlobe or fingertip. Set a sample tube with the cap open in the sample set position, then press the start switch to begin measurement.

Sampler Mode (Optional for XS-1000*i*)

The sampler automatically mixes, aspirates, and analyzes samples without removing their caps. Up to 20 samples can be loaded at a time and analyzed automatically.

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4. Reagents

4.1 General Information

Four types of reagent are used with this instrument. All of them are specialized reagents for use in Sysmex equipment. Please follow the warnings for handling and using each of the reagents correctly.

Note:

To ensure both customer safety and optimal system performance, the manufacturer recommends that all reagent 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.
If the cubitainer is unopened, CELLPACK can be used up to the expiration date shown on the cubitainer.
Please refer to the product labeling (package insert or outer package) for the open stability.

Additional Special Equipment

CELLPACK is a Sysmex reagent and is specially designed for use in analyzers. The performance of Sysmex equipment cannot be guaranteed if anything else is used for dilution.

Methodology

CELLPACK is a ready-to-use diluent for analyzing blood by impedance and photo electrical analysis.

Active ingredients

Sodium Chloride - 0.64%
Boric Acid - 0.10%
Sodium Tetraborate - 0.02%
EDTA-2K - 0.02%

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4.3 STROMATOLYSER-4DL

Intended Use

Lysing reagent for use in blood analyzers.

Storage and Shelf Life after first Opening

Store STROMATOLYSER-4DL at +2 to +35°C.
If the cubitainer is unopened, STROMATOLYSER-4DL can be used up to the expiration date shown on the cubitainer.
Please refer to the product labeling (package insert or outer package) for the open stability.
Replace STROMATOLYSER-4DL showing signs of contamination or instability, such as cloudiness or color change.

Methodology

STROMATOLYSER-4DL is a ready-to-use diluent for analyzing blood by resistance measurement and photometric measurement.

Active ingredients

Non-ionic surfactant - 0.18%
Organic quaternary Ammonium salt - 0.08%

4.4 STROMATOLYSER-4DS

Intended Use

STROMATOLYSER-4DS is used to stain the leukocytes in diluted and lysed blood samples. It serves for the determination of 5-part differential count (Neut, Lymph, Mono, Eo, Baso) with selected Sysmex 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, STROMATOLYSER-4DS is stable up to the expiration date shown on the container.
Please refer to the product labeling (package insert or outer package) for the open stability.
Replace STROMATOLYSER-4DS showing signs of contamination or instability, such as cloudiness or color change.

Methodology

The following steps are automatically performed by the analyzer.
After sample aspiration, a part of the whole blood sample is diluted to 1:50 with lysing reagent STROMATOLYSER-4DL and then STROMATOLYSER-4DS dye is added.
After a predefined response time the stained sample is introduced into the detector, where forward light scatter and side fluorescent emission are measured. From this, five leukocyte populations are computed: neutrophil count (NEUT#), lymphocyte count (LYMPH#), monocyte count (MONO#), eosinophil count (EO#) and basophil count (BASO#), as well as neutrophil percentage (NEUT%), lymphocyte percentage (LYMPH%), monocyte percentage (MONO%), eosinophil percentage (EO%) and basophil percentage (BASO%).

Active ingredients

Polymethine dye - 0.002%
Methanol - 3.00%
Ethylene glycol - 96.90%

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4.5 SULFOLYSER

Intended Use

SULFOLYSER is a cyanide-free reagent used for the determination of hemoglobin.

Storage and Shelf Life after first Opening

Store SULFOLYSER at +1 to +30°C.
If the container is unopened, SULFOLYSER is stable up to the expiration date shown on the container.
Please refer to the product labeling (package insert or outer package) for the open stability.
Replace SULFOLYSER showing signs of contamination or instability, such as cloudiness or color change.

Methodology

SULFOLYSER is a ready-to-use diluent for analyzing blood by colorimetric method.

Active ingredients

Sodium Lauryl Sulphate - 0.17%

4.6 CELLCLEAN

Intended Use

CELLCLEAN is a strong alkaline detergent to remove lysing 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 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.

Methodology

CELLCLEAN is a detergent to clean the instrument, to remove residuals of lysing reagents, cellular residuals and blood proteins from the hydraulic systems, detector and whole blood aspiration tube

Active ingredients

Sodium Hypochlorite - 5.00%

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4.7 *e*-CHECK (XS)

Intended Use

e-CHECK (XS) is a quality control material. Quality Control is performed in order to monitor an instrument's performance over time.

Warnings and Precautions

Risk of infection

Always use protective garments and gloves when using *e*-CHECK (XS). Also, after completion of operation, wash your hands. As with all blood products, if your hands are contaminated by blood, etc., there is a risk of infection.

Storage and Shelf Life after first Opening

Store control material as per product insert at +2°C to +8°C.
If unopened, *e*-CHECK (XS) may be used up to the expiration date shown on the container.
Once opened, it should be used within 14 days.

4.8 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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4.9 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 this instrument is delivered, check the condition of its packaging as soon as possible.

Important!

If the packaging has been damaged in any way, contact Sysmex representative as soon as possible.

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

Important!

Under direction of a Sysmex technical representative initial setup of this instrument will be performed. Before moving the analyzer, please contact the Sysmex technical representative.

5.2 Preparation

- The XS-1000*i*/XS-500*i* is to be installed in a dry, dust-free location.
- It should be located in a space large enough to be used safely. If additional equipment is to be attached/connected to it, additional desk space will be required.
- This instrument weighs approximately 24 kg. Be sure to use a table or desk that can support that amount of weight.
- Leave a space of 50 cm between the walls and the side, rear and top panels to allow for heat dissipation.
- 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.

5.3 Peripheral Equipment

- List Printer (LP)
- Graphic Printer (GP)
- Data Printer (DP)

For the functions and usage of each printer, refer to Chapter 3, 3.1: Overview in this manual.

Caution!

Turn OFF the XS-1000*i*/XS-500*i* before connecting peripheral equipment.
The above peripheral equipment may be connected to the XS-1000*i*/XS-500*i*.

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Important!

- Each device that is connected will need its own power outlet. Do not plug multiple devices in together as doing so may cause a fire.
- The list printer, graphics printer and data printer are not standard equipment. For detailed information, refer to the respective printer manual when installing the printer.

5.4 Additional Components

Bar Code Reader
A bar code reader scans the sample tube and automatically inputs the sample ID number.

Important!

The bar code reader is not standard equipment. For detailed information, refer to the bar code reader manual when installing the bar code reader.

5.5 Basic Equipment Settings

Caution!

This chapter only explains the settings related to the initial operations. See Software Guide Chapter 5 for more detailed information about other settings.

Date & Time

- Sets the correct date and time. The analysis data accompanies the data and time when the analysis results were obtained.

Important!

If an error occurs, an alarm will sound. There are 3 tones (1, 2, 3) that may be set. When shipped, the alarm tone is set to 1.

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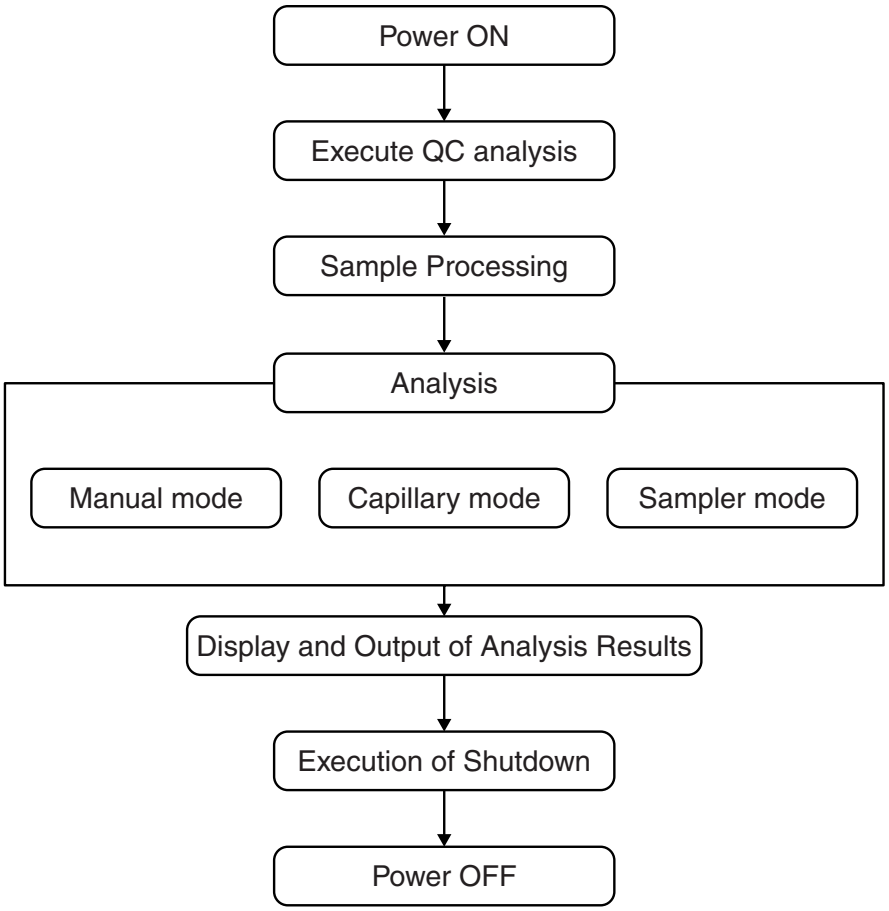
6. Operation

6.1 Overview of Operation

This system is comprised of an IPU (Information Processing Unit) for data processing, a main unit for measurement, and peripherals such as a printer and bar code reader. Power up by turning on the printer, IPU, Main Unit and other Components.
Once the unit goes into READY after turning the power ON, follow the flowchart below to carry out quality control, analysis and output, shutdown and then turn the power OFF.



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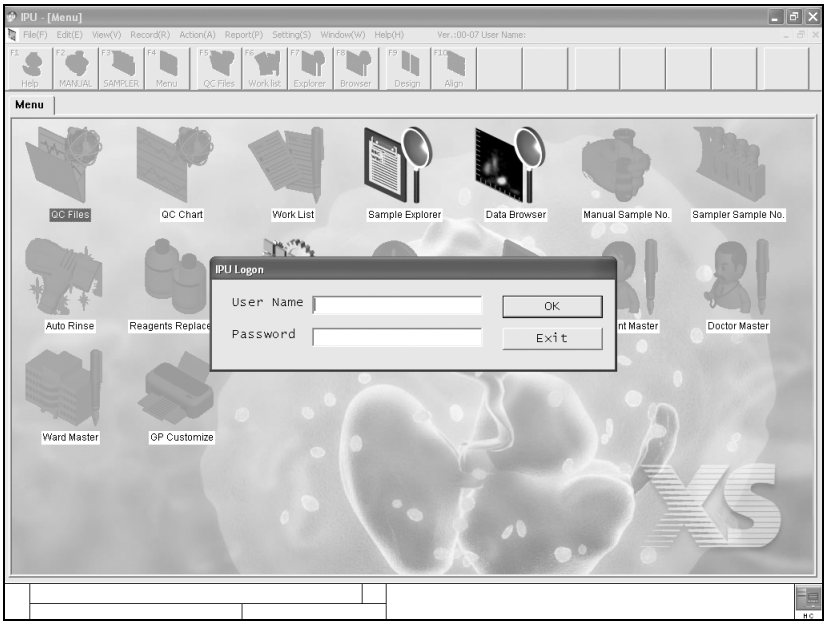
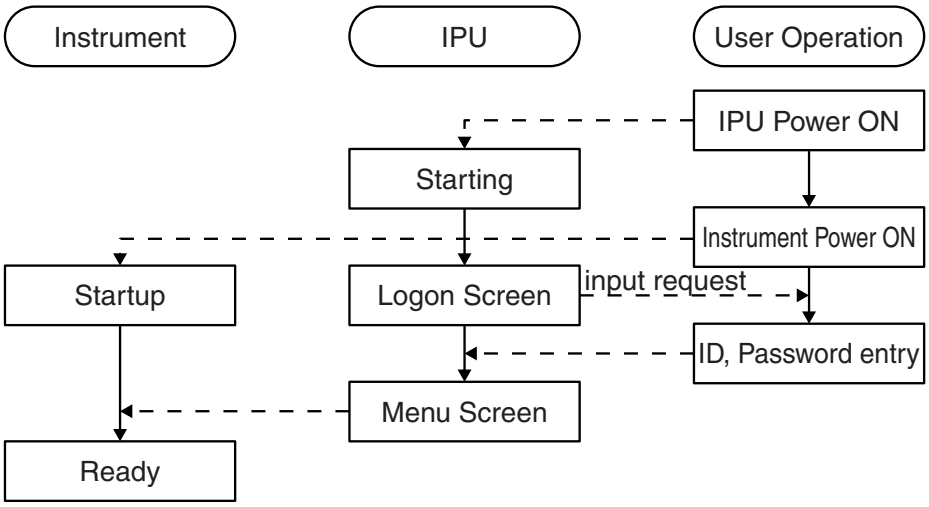
6.2 Passwords

We recommend that the customer set the user names (logon names) and passwords. Setting passwords allows limitation of the people able to use the instrument, and enables safe handling of internally stored data.



The flowchart below shows the relationships between the user, the instrument and the IPU in the procedure from turning on the power (startup) to the password entry stage.



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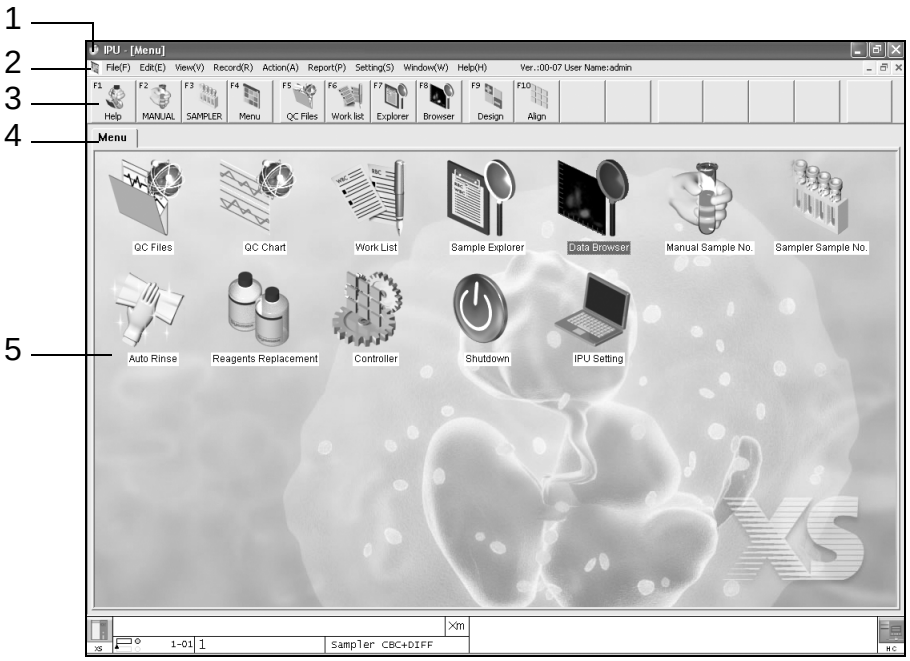
Important!

- With the factory defaults, it is possible to log on using “admin” as the user name and “m101m” as the password.
- The password can be changed. For details, please See Software Guide Chapter 5 System Settings.
- Before using the instrument, set user names, passwords and permissions. The password “admin” should also be changed.

6.3 Screen Composition and Menu Tree

The following is an explanation of the composition (nomenclature) of the overview screen, and the composition of each layer.

1. Overview of Display Screens



1. Title bar
   The menu level is displayed to indicate the user's current position in the menu.
2. Menu bar
   Each menu has submenus. Click on the menu to display its submenus.
   Select a submenu item to execute its function. Submenus which are grayed out cannot be executed.
   Double click on a menu icon in a window (view) to execute the same function.
3. Toolbar
   The buttons immediately below the menu bar are tools.
   Items that are common to all screens are assigned to buttons F1 - F8.
   The remaining nine buttons vary between screens.

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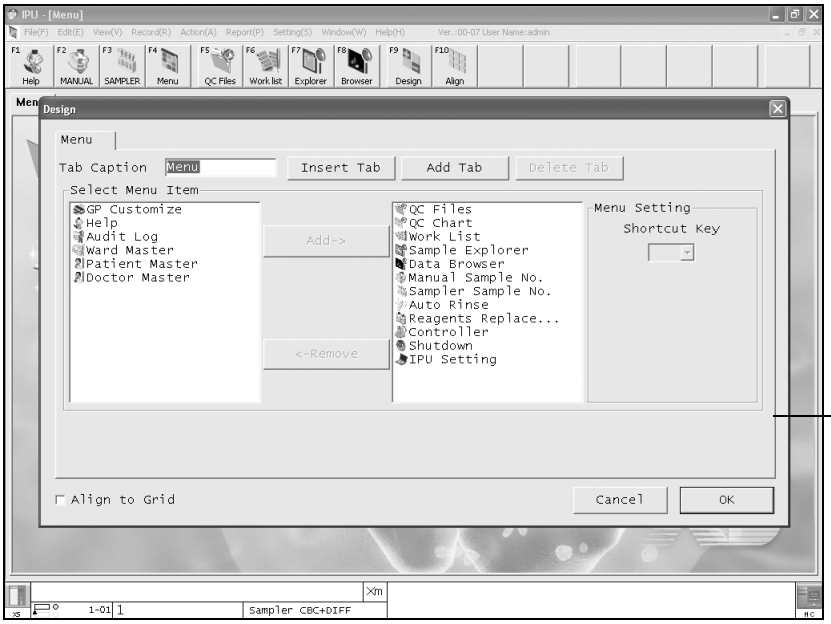
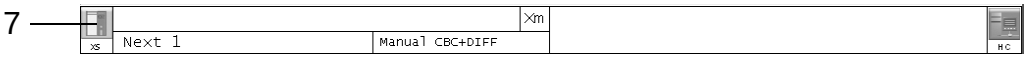
4. Tabs
   Tabs may be displayed within the view. Tabs can be selected to change the content displayed within the view.

5. View (all windows)
   Area for doing actual processing and operations.



6. Dialog boxes
   Dialog boxes may be displayed within the view. Dialog boxes are displayed in front of the active window to prompt the user for decisions and confirmation.
   Display content differs between dialogs.



7. Status bar (system status) display area.
   The bar displayed at the bottom of the window is the status bar. It displays the state of the main unit, the sample number and type of analysis.
   The status of the host computer communication is also displayed on the right side of the status bar.

   - Normal display items

     • Main unit status
     • Sample number
     • Analysis mode
     • Discrete
     • Instrument nickname
     • X-barM status
     • Host computer communication status

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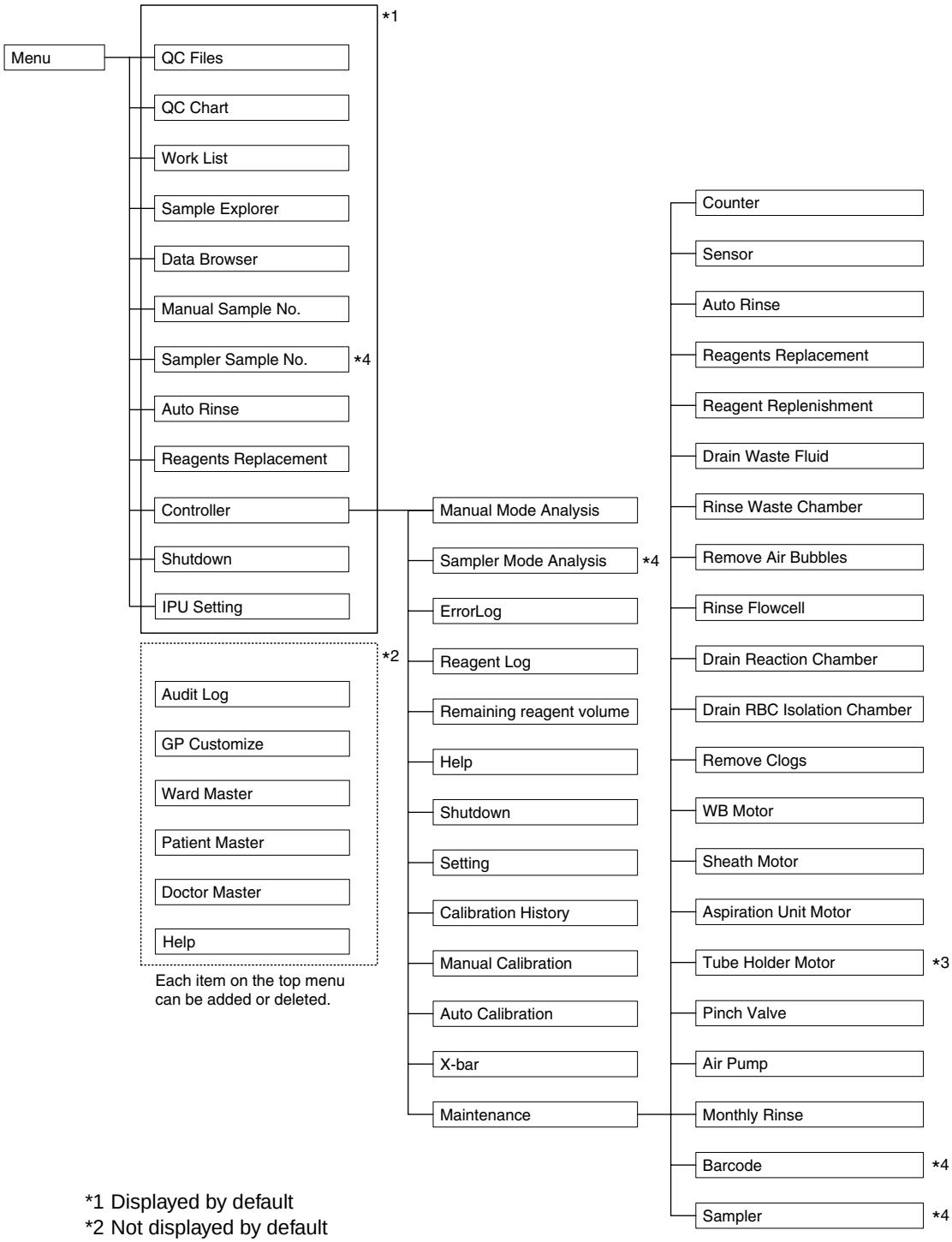
2. Menu tree

Icons for several menu screens are displayed on the IPU. The icons serve as reminders of the functions, and can be double-clicked to call the menu screen. The menu tier diagram is shown as below.



*1 Displayed by default
*2 Not displayed by default
*3 For XS-1000*i* only
*4 Displayed when Sampler is connected

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6.4 Alarm sound

You can set the alarm for the instrument. The alarm sounds for notification when an error occurs.

- There are three types of sounds. For details, please see Software Guide Chapter 5 System Settings.

Note:

Press the F1 button on the IPU (PC) to stop the alarm sound. For details, please See Software Guide Chapter 5 System Settings.

6.5 Checks prior to turning power on.

Be sure to check following items 1~3 before turning the power on to obtain correct analysis results.

1. Reagent inspection

The amounts of reagent used vary between analysis modes. Estimate the volume which will be required for the day, and get it ready, allowing an extra margin.
The instrument will stop automatically if it runs out of a reagent during analysis. In that case, replace the reagent that ran out.
Re-start analysis once replacement is complete.

- The following shows the reagent container capacity.

Reagent name	Abbreviation	Container capacity
CELLPACK	EPK	10 L
STROMATOLYSER-4DL	FFD	2 L
STROMATOLYSER-4DS	FFS	42 mL
SULFOLYSER	SLS	500 mL

- Volume of reagent used per analyzed sample (in continuous analysis)

Discrete mode	CBC	CBC + DIFF
Total reagent volume	Approx. 34.5 mL	Approx. 34.5 mL
CELLPACK	Approx. 32 mL	Approx. 32 mL
STROMATOLYSER-4DL	Approx. 2 mL	Approx. 2 mL
SULFOLYSER	Approx. 0.5 mL	Approx. 0.5 mL
STROMATOLYSER-4DS	0 mL	Approx. 0.03 mL

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- Volume of reagent used for rinsing

Total reagent volume	Approx. 77 mL
CELLPACK	Approx. 72 mL
STROMATOLYSER-4DL	Approx. 4 mL
SULFOLYSER	Approx. 1 mL
STROMATOLYSER-4DS	Approx. 0.06 mL

* If no analysis has been conducted for 12 hours or more, an automatic rinse is carried out when the system restores from timer operation.

- Volume of reagent used when the power is turned on
  This is the same as the volume of reagent used for rinsing.

- Volume of reagent used on shutdown

CELLPACK	Approx. 17 mL

- Replacing the Reagent

Caution!

- Only use reagents that have been left at room temperature (15°C - 30°C) for at least 24 hours.
- When using a reagent which may have been frozen, observe the precautions listed on the package insert. In some cases, correct analysis may not be possible.
- After opening a reagent container, make sure that no substance such as dust, dirt, or bacteria enters the container. These substances may prevent correct analysis.

2. Instrument inspection

Check the tubing and cable connections.
Make sure that the tubing is not bent nor kinked.
Make sure the power cord is securely plugged into the outlet.

3. Waste fluid

Discard waste fluid that has been collected in the waste container (if applicable).
For the waste fluid discharging procedure, see Chapter 9 Cleaning/Maintenance.

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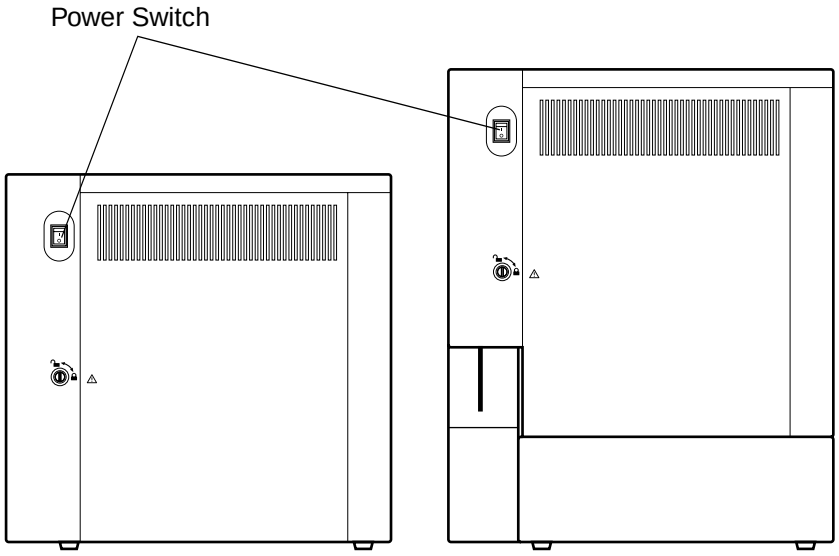
6.6 Turning on the power

Turn on the power for each connected device.

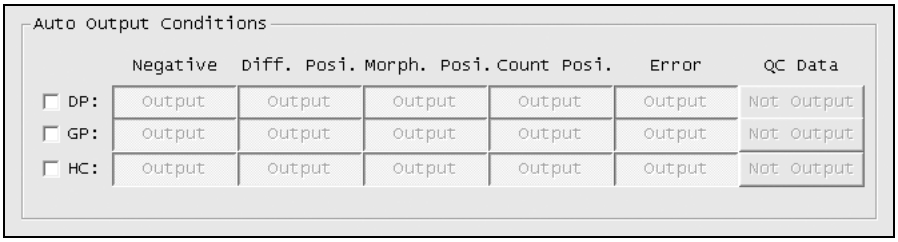


(XS-1000*i*) (XS-500*i*)

6.7 Auto Report

The following three Auto Output settings can be made:
- DP (Print on Ticket Printer)
- GP (Print on Report Printer)
- HC (Output to Host Computer)

1. Select **Settings (S)** – **IPU (I)** on the menu bar.
2. Click **Auto Output** on the **IPU Setting** tree.
3. Selecting auto processing and auto report creation will display the current settings on the Auto Output screen.



4. Click the check box to check the required type of Auto Output (DP, GP, HC).

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5. Click on the sample to select for Auto Output.
   Sample output data can be set as follows: Output sample data conditions may be set to overlap though.

Negative	This indicates that the sample analysis data does not exceed reference intervals or that there are no abnormalities or analysis errors detected (except for ID read error).
Diff. Posi.	This indicates abnormality in the WBC differential parameters.
Morph. Posi.	This indicates abnormal cell morphology.
Count Posi.	This indicates abnormal blood cell count(s).
Error	This indicates that an analysis error has occurred (except for ID bar code read error).
QC data	This indicates sample analysis data used for quality control.

Note:

Even if error data items are set to not output, analysis data will be output for samples affected by an analysis error, if other conditions are applicable.

6. After completing the settings, click **OK**, **Cancel** or **Apply**.
   OK Saves the new settings and closes the window.
   Cancel Cancels the new settings and closes the window.
   Apply Saves the new settings.

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6.8 QC

Quality control assures the reliability of the instrument and reagents system. Quality control allows long-term monitoring of the stability of analysis values. It can also identify problems at an earlier stage and prevent them.

Always run quality control according to laboratory licensing agency specifications.

Quality control is analyzed using X-bar Control or the L-J Control program.
The data is saved in the quality control file.

- Quality control using control blood to monitor daily change over time.
  X-bar control: The control sample is analyzed twice in succession, and the average data is used as the control data.
  L-J (Levy-Jennings) Control: Takes the data from a single analysis of control blood as the control data.

  Refer to the package insert for details of how to handle control blood.

- Quality control using normal patient samples to monitor daily change over time.
  X-barM Control: A weighted average is taken for every 20 consecutively analyzed samples, and the result is used as control data.

6.9 Analysis mode

This instrument supports the following three analysis modes:

- Manual Mode
  In this mode, samples are aspirated one at a time, using the probe. The XS-500*i* aspirates from sample tubes with the cap opened.
- Capillary Mode
  In capillary mode, an analysis is performed after manually diluting the sample to 1:7 dilution.
  This mode is used for analyzing a minute amount of blood collected from the earlobe or fingertip.

- Sampler mode (optional)
  The sampler automatically mixes, aspirates, and analyzes samples without removing their caps. Up to 20 samples can be automatically analyzed in a batch.
  * This operation is possible using the optional sampler unit of the XS-1000*i*.

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6.10 Conditions for samples to be analyzed

Sample type

Use venous and capillary blood.

Sample collection conditions

Mix venous blood with anti-coagulant (EDTA-2K, EDTA-3K or EDTA-2Na). After drawing the sample, analyze it within 4 hours.
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.
Allow refrigerated samples to revert to room temperature before analyzing (allow from 15 minutes to 30 minutes). Then gently invert the sample 10 times.
Capillary blood can be collected in anticoagulated micro-container tubes.

Note:

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

6.11 Analysis of samples

1. Common operations

Caution!

If the dialog box has not closed 30 minutes after the power was turned ON, there may be a problem with the instrument. If this happens, turn the power OFF and contact Sysmex service representative.

1. Turn on power to the printer, IPU (personal computer) and main unit in order.
2. Enter the password and click on **OK**.
   When the instrument is brand new, the logon name is set to “Admin” and the password is the number on the back of the CD case.

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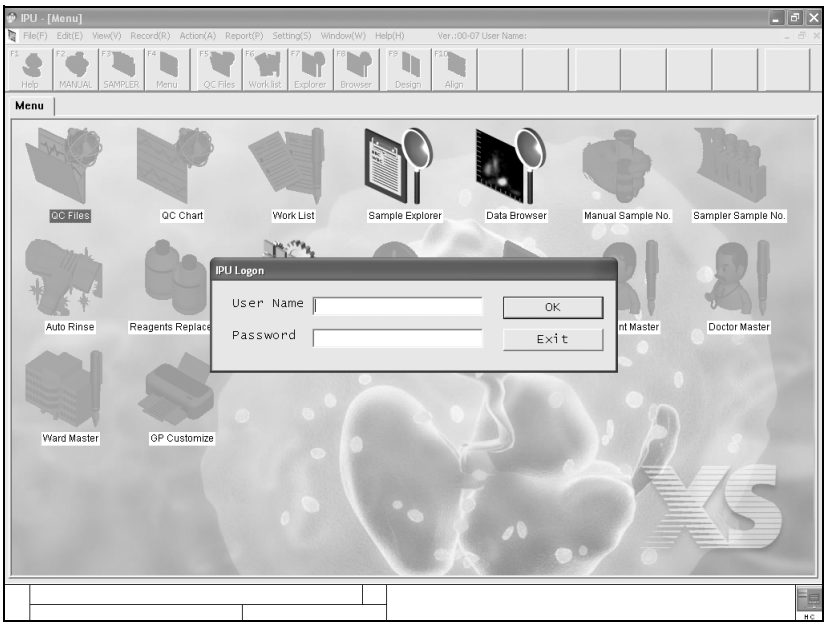
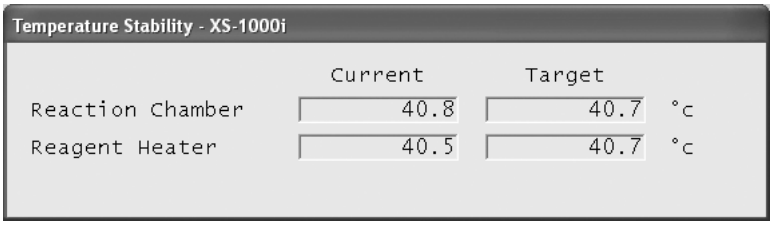


3. Self-tests
The instrument performs a self-check automatically.
When the Main Unit power is turned ON, the following operations are performed in this order: Self-Check, Main Unit control program download, initialization of mechanical and hydraulic parts, a rinsing sequence, waiting for temperature stabilization, and a background check.

   If an error message appears during this series of operations, see Chapter 10 Troubleshooting.

   - Waiting for temperature stabilization



   Analysis starts after the temperature inside the instrument reaches the required value.
   The temperatures of the reaction chamber and reagent heater are displayed in the Temperature Monitoring dialog box. The system waits for these to stabilize at their target temperatures.
   When they have stabilized at their target temperatures, the Temperature Monitoring dialog box is closed automatically.

   - Target temperature (varies with room temperature)

Reaction chamber	Approx. 41°C
Reagent heater	Approx. 42°C

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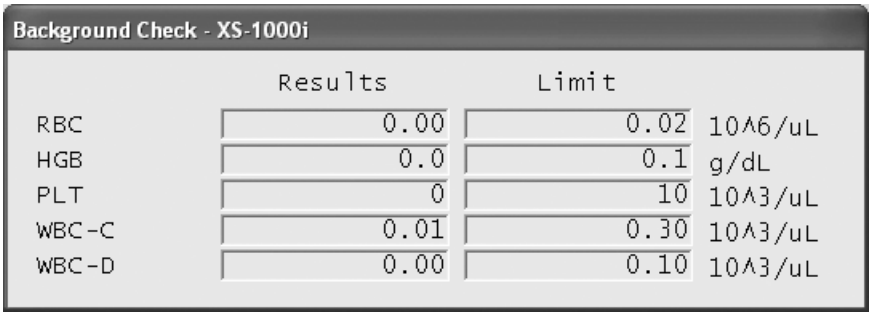
- Background check

Once temperature stabilizes, the Background check dialog box appears. Background analysis is performed up to three times for the background check. If the background value is at or below the values shown in the table below, the background check is completed.

RBC	0.02 [x10^6/µL]
HGB	0.1 [g/dL]
PLT	10 [x10^3/µL]
WBC-C	0.30 [x10^3/µL]
WBC-D	0.10 [x10^3/µL]

Caution!

- If the background values are not at or below the acceptable values, a **Background Error** results, and a Help dialog box appears. Values for parameters not at or below the acceptable values are displayed in red in the Background Check dialog box.
- If all parameters are below the acceptable background values, the dialog box closes automatically after three seconds.
- Even if the values are not at or below the acceptable background values, analysis can still be done by clicking Cancel on the Help dialog box. The measured values may be higher, and there may be parameters for which correct analysis results cannot be obtained.



Note:

- The sample number for the background check data is “BACKGROUNDCHECK.”
- Of the background check data, the data which is not at or below the acceptable values is handled as a sample error (Func.). For details see Software Guide Chapter 3: 3.2 Sample Explorer Screen display content.

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If the background values are not at or below the acceptable value, clicking **OK** on the Help dialog box will close the dialog box and start automatic rinse. If the parameters are still not within the acceptable range, see Chapter 10 Troubleshooting.

- Automatic rinsing can be run by clicking on Controller, then on Auto Rinse.

4. Auto Output Settings Check
   If Auto Output is necessary, check that the instrument is set for automatic transmission/printing before starting analysis. See Software Guide Chapter 5 System Settings.

2. QC analysis

Quality control analysis can be carried out in the manual analysis mode.
Control blood is analyzed by the X-bar or L-J Control programs, and the data is stored in the specified quality control file.

Follow the manufacturer's instructions for handling the control blood samples.
Before performing quality control analysis, see Chapter 7: 7.5 Execute QC analysis.

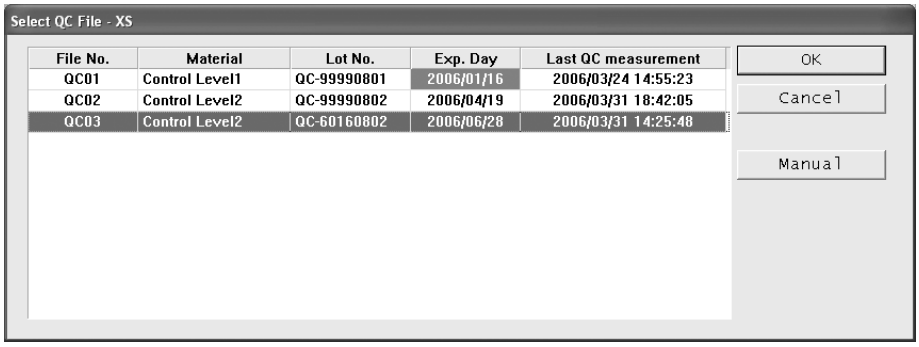
a. QC Analysis: Manual Mode

Follow the procedure below to perform QC analysis in manual mode.

Risk of infection

Always wear protective garments and gloves when analyzing control blood.
Also, wash your hands after completing the process.
There is a risk of infection with pathogens etc.

1. Check that the READY LED (green) on the Main Unit is lit.
   * If it is not lit, or it is flashing red, there is a possibility that an error has occurred. Check the error status using the **HELP** button of the IPU.
2. Select **Manual** from the tool bar, then click the **QC** button for the Manual Mode Analysis dialog box to open and display the Select QC File dialog box.



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3. Select the QC file for quality control analysis (QC1~QC20), then click **OK**.
   OK Open the selected QC file.
   Manual Return to the preceding dialog box.
   Cancel Cancel the order and close the dialog box.

4. (For the XS-500*i*)
   Mix the control blood thoroughly and remove the cap of the sample tube, then set it in the aspiration port, then press the Start switch on the Main Unit to carry out QC analysis.
   (For the XS-1000*i*)
   Mix the control blood thoroughly, then set it in the sample set position, then press the Start switch on the Main Unit to carry out QC analysis.
   For details, see Chapter 6: 6.11: 3: c. Manual mode analysis: XS-1000*i*.

   To create and register a new QC file, select “Create file”, “Register new lot” and “Set target / limit”. For details, see Chapter 7: 7.5 Execute QC analysis.

Note:

Using X-bar Control, the control sample is analyzed twice in succession, and the average data is used as the control data. The L-J Control method, on the other hand, uses the result from one analysis as one control data point.

b. Checking QC analysis results

Once QC analysis is complete, the QC analysis results are automatically displayed in the QC Analysis Results dialog box.

The QC Analysis Results dialog box has the following functions:

- It displays QC analysis results.
- It takes QC analysis results as QC data.
- It notifies the user of abnormal data.
- If X-bar control is used, it displays the average value.

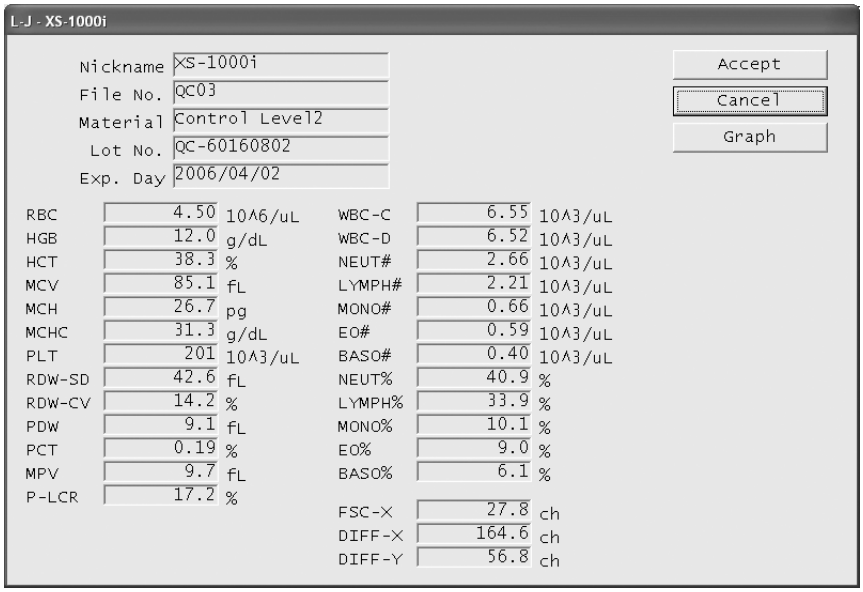
Note:

• If L-J Control is selected
[1] Select the QC file
[2] Mix the control blood thoroughly.
[3] Set the control blood in the aspiration port and press the Start switch.
[4] Check the analysis results.
[5] Accept: QC analysis complete.

• If X-bar Control is selected
[1] Select the QC file.
[2] Mix the control blood thoroughly.
[3] Set the control blood in the aspiration port and press the Start switch.
[4] Check the analysis results.
[5] Accept: Repeat [2] - [4] once more.
[6] Accept: QC analysis complete.

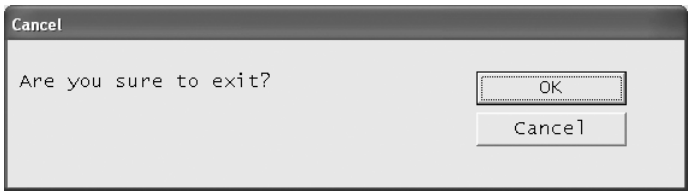
c. L-J control, after analysis

If QC analysis was carried out under the L-J Control setting, the results are automatically displayed in the QC Analysis Results dialog box on completion of the analysis, so that they can be checked.



Accept L-J analysis results are taken and plotted in the QC chart.
In the Sample Explorer, analysis results are stored with the sample number as the QC file number.
Sample number and Discrete are restored to their condition before the QC analysis.

Cancel The Cancel Confirmation dialog box appears.



OK QC analysis is canceled, the Cancel Confirmation dialog box closes, and the results are not plotted as QC data. However, the analysis results are stored in the Sample Explorer with the sample number as the QC lot number.
Sample number and Discrete are restored to their condition before the QC analysis.

Cancel The Cancel Confirmation dialog box is closed. The screen returns to the QC Analysis dialog box.

Graph A graph of the L-J analysis results is displayed in front of the QC Analysis Results dialog box.

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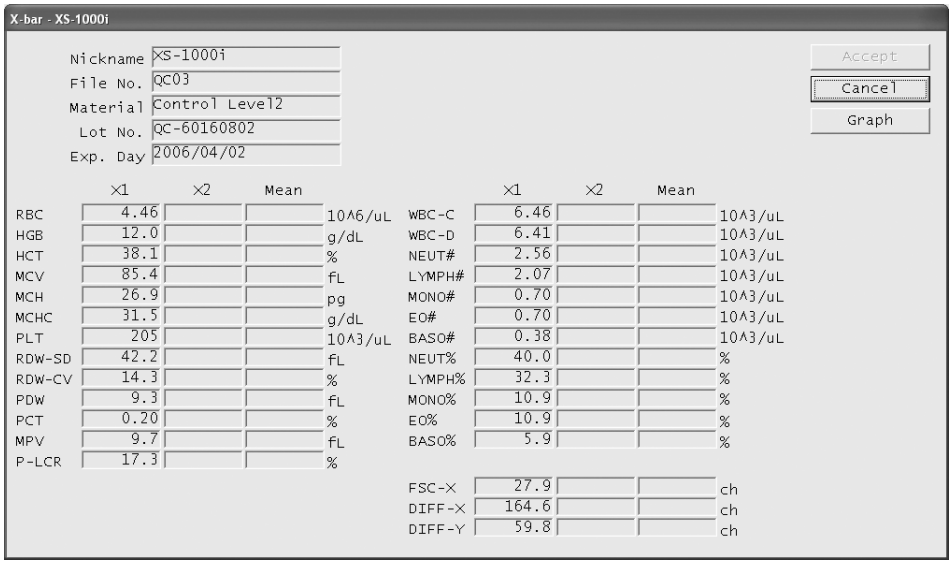
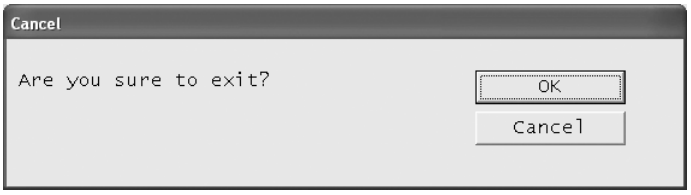
d. X-bar Control, after the first analysis

If QC analysis was carried out under the X-bar Control setting, the first analysis results are automatically displayed in the QC Analysis Results dialog box on completion of the analysis, so that they can be checked.



Cancel The Cancel Confirmation dialog box appears.



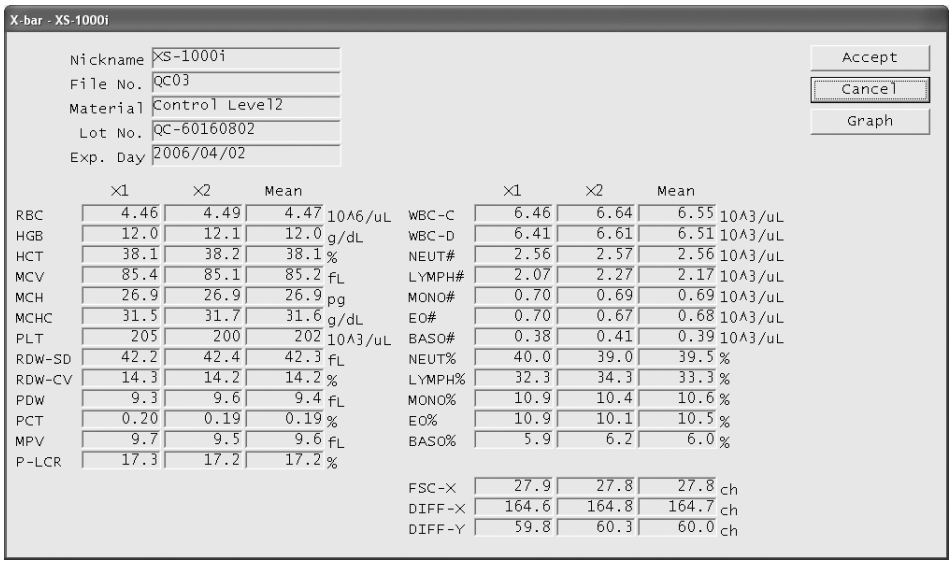
OK Cancel QC analysis and close the Cancel Confirmation dialog box and the QC Analysis Results dialog box. The results will not be plotted as QC data. However, the first analysis results are stored in the Sample Explorer with the sample number as the QC lot number.
Sample number and Discrete are restored to their condition before the QC analysis.

Cancel The Cancel Confirmation dialog box is closed. The screen returns to the QC Analysis dialog box.

Graph A graph of the first run of X-bar QC analysis results is displayed in front of the QC Analysis Results dialog box.

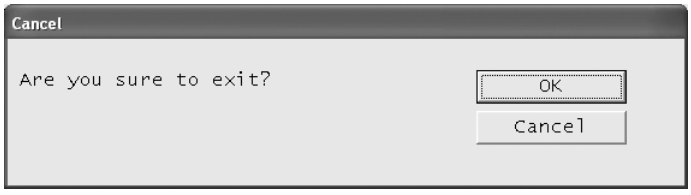
e. X-bar Control, after the second analysis

If QC analysis was carried out under the X-bar Control setting, the second analysis results are automatically displayed in the QC Analysis Results dialog box on completion of the analysis, together with the average of the first and second runs, so that they can be checked.



Accept The first and second runs of X-bar analysis results are confirmed, becoming QC data.
The second analysis results are stored in the Sample Explorer with the sample number as the QC lot number, but the average values are not stored in the Sample Explorer.
Close the QC Analysis Results dialog box.
Sample number and Discrete are restored to their condition before the QC analysis.

Cancel The Cancel Confirmation dialog box appears.



OK Cancel QC analysis and close the Cancel Confirmation dialog box and the QC Analysis Results dialog box. The results will not be plotted as QC data.
However, the second run analysis results are stored in the Sample Explorer with the sample number as the QC lot number.
Sample number and Discrete are restored to their condition before the QC analysis.

Cancel The Cancel Confirmation dialog box is closed. The screen returns to the QC Analysis dialog box.

Graph A graph of the second run of QC analysis results is displayed in front of the QC Analysis Results dialog box.

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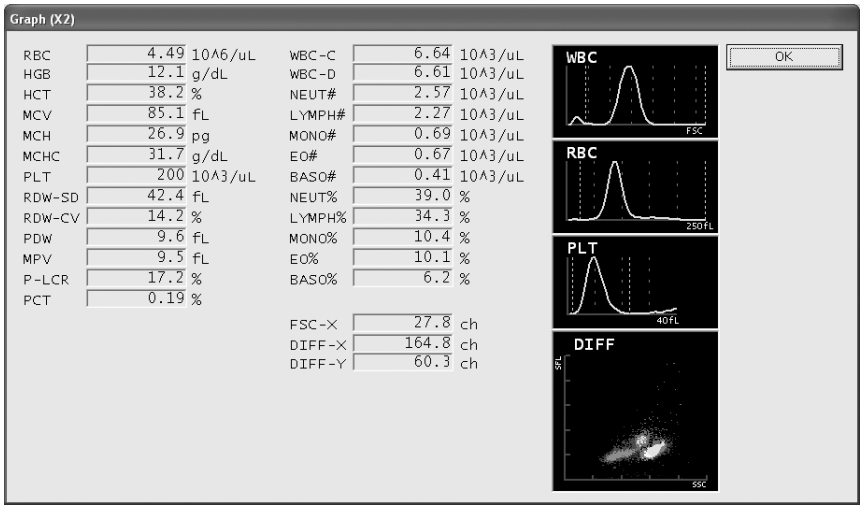
f. QC analysis results graph

The dialog box below appears when the Graph button on the QC Analysis Results dialog box is clicked.



OK Close the QC Analysis Results Graph dialog box.

g. Running X-barM Control

X-barM Control can be started and stopped from the X-barM dialog box.
When a sample that is expected to cause an X-barM Control error is going to be analyzed, and in similar situations, X-barM Control can be canceled.
Double-click on the X-barM icon or press the Enter key to open the X-barM dialog box.

X-barM

The current setting for X-barM status is displayed when the screen starts up.

ON

Run X-barM Control. Only negative samples are used as X-barM data.

OFF

Cancel X-barM Control.

OK

The settings are applied, and the X-barM dialog box is closed.

Cancel

The settings are discarded, and the X-barM dialog box is closed.

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3. Sample analysis

There are two types of sample analysis: Manual/ Capillary mode (using closed piercing on the XS-1000*i* and open pipetting on the XS-500*i*) and Sampler mode (only as an option on the XS-1000*i*). Either mode is run when the instrument's status is Ready or Manual Aspiration Ready.

a. Manual mode analysis: XS-500*i*

Analysis in manual mode can be performed when the Main Unit is in Manual Aspiration Ready status.
All operations are manual.

Risk of infection

Be sure to wear protective garments and gloves when analyzing the sample. Also, wash your hands after completing the process.
There is a risk of infection with pathogens etc.

Caution!

- Depending on the anticoagulant used, hemolysis and platelet aggregation can occur, preventing correct results. Use of EDTA-2K, EDTA-3K or EDTA-2Na anticoagulant is recommended for blood samples.
- Before processing, refrigerated samples should be allowed to equilibrate to the room temperature (approximately 30 minutes).
  Failure to do so may prevent correct analysis.
- To remove the blood collecting tube, pull it straight down to avoid bending the aspiration probe. There is a risk of blood spatter.

Important!

- If a message appears during analysis to ask for reagent replacement, replace the reagent concerned. If the reagent replacement sequence is run when the reagent level is low, bubbling could occur which would raise the blank value.
- If zero is set as the sample number, the analysis results will not be stored. If the sample number is set to zero, a warning beeping will sound during sample aspiration.
- Mix sample thoroughly by inverting the sample tube.
- Remove the cap carefully so as not to spatter blood.

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1. Sample collection and preparation.
   Draw the specified amount of blood as per the package insert of the tube used.

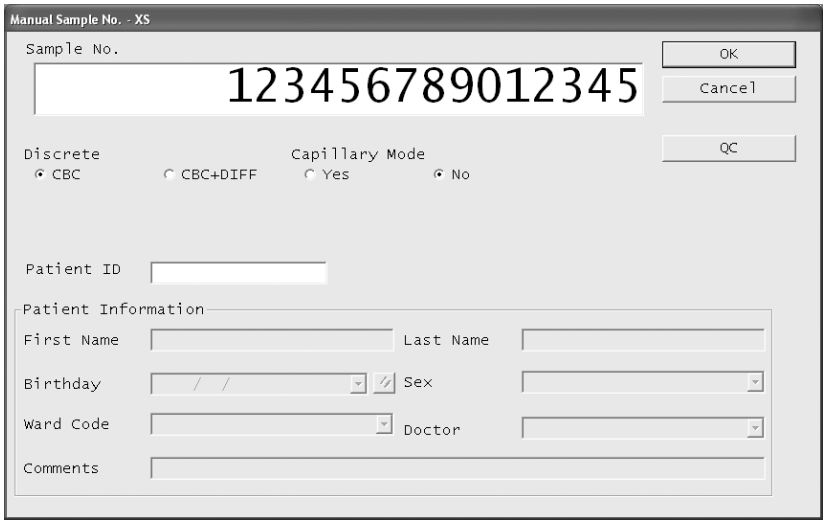
   Use a sample tube of length 85 mm or less. Sample volumes are as stated below.

Vacuum tube	500 µL or more
Aspirated sample volume	Approx. 20 µL

Caution!

The instrument is equipped with a Blood Aspiration Sensor. However, there is a potential that corrects results may not be obtained, if the sample volume is low and the sensor could not detect a "Short Sample" or "Sample Not Asp Error".

2. Startup
   Select the Manual Mode icon on the Controller Menu, then double-click or press the Enter key to start the Manual Mode screen. (It can also be started either from the **Manual** button on the toolbar, or by pressing function key F2.)



3. Data input
   Input the necessary parameters with reference to the table below.

Parameter	Meaning
Sample No.	Enter the sample number to be analyzed.
Discrete	Specify the analysis method for the sample from the Main Unit.
Capillary Mode	Specify whether to analyze diluted samples.
Patient ID	Enter the patient ID.
First Name/Last Name	Alphabet can be used. A maximum of 20 characters may be used for each name.

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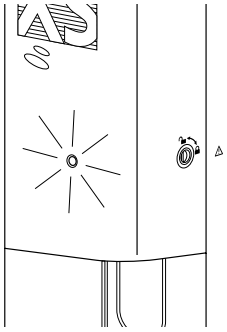
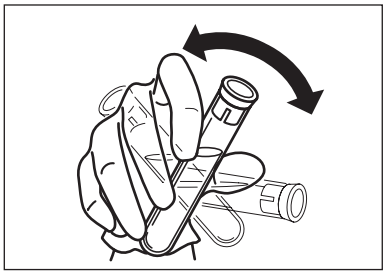
Birthday	Input a patient's date of birth following the "Date format".
Ward Code	Click the combo box and select a ward that has been recorded in the Ward Master.
Sex	Click the combo box and select Male or Female.
Doctor	Click the combo box and select a doctor that has been recorded in the Doctor Master.
Comments	Input comments about the patient.

*: This cannot be selected if there was an error related to reagents for DIFF analysis. When an error has occurred, Discrete is automatically switched to CBC.

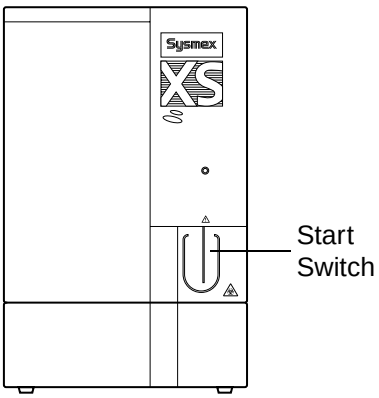
4. Click **OK**.
   The READY LED on the Main Unit changes to green, indicating that it is in Manual Aspiration Ready status.



5. Mix sample thoroughly by inverting the sample tube.



6. Taking care to avoid blood spattering, remove the cap from the sample tube, insert the probe to the bottom of the sample tube, and press the Start switch.



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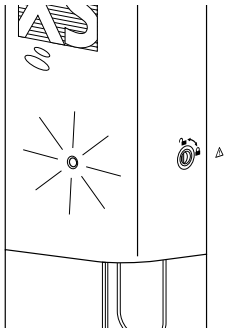
7. The green READY LED flashes during sample aspiration, then the buzzer beeps to indicate the end of aspiration, and the READY LED goes out.



8. Remove the sample tube carefully so as not to bend the probe.
9. The fact that the READY LED is not lit indicates that analysis is in progress.
10. When the READY LED lights green again, the next sample can be analyzed. Check that the READY LED is green, indicating Manual Aspiration Ready status, then carry out steps 2~6.

Note:

- If sample numbers are not set, they are automatically assigned sequentially. (Automatic increment function)
- The lowest digit to be incremented excludes alphabetical characters.
- A maximum of 15 alphanumeric characters and hyphens can be entered for the sample number.
- If the setting below is made, then after the sample number is input, the system will automatically inquire to the host computer the analysis order.
  Real-time Request (Manual Mode) [Sample Number].
- If an automatic increment is set for the sample number of each analysis, then the system will not automatically inquire to the host computer the analysis order and patient information.

b. Capillary mode analysis: XS-500*i*

Analysis in Capillary mode can be performed when the Main Unit is in Manual Aspiration Ready status.
All operations are manual.

Risk of infection

Be sure to wear protective garments and gloves when preparing a sample for capillary analysis.
Also, wash your hands after completing the process.
There is a risk of infection with pathogens etc.

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Caution!

- Small blood samples collected from earlobes or fingertips are prone to clotting, so they should be diluted and analyzed as quickly as possible. Failure to do so may prevent correct analysis results.
- Samples collected from earlobes or fingertips generally have high blood cell counts, which diminish reproducibility. If possible, diluted samples should be analyzed twice and the results compared. If sample tubes containing general anticoagulant are used, hemolysis and platelet aggregation can occur, depending on the anticoagulant used, preventing correct results.
  Use of EDTA-2K, EDTA-3K or EDTA-2Na anticoagulant is recommended.
- Platelet agglutination tends to occur quickly in the 1:7 dilution sample. Perform analysis immediately after adding the blood to make the diluted sample. Prepare diluted samples one at a time for each analysis. If the diluent is dispensed too much ahead of time, measurement errors will result from evaporation and contamination.
- To remove the blood collecting tube, pull it straight down to avoid bending the aspiration probe. There is a risk of blood spatter.

Important!

- If a message appears during analysis to ask for reagent replacement, replace the reagent concerned. If the reagent replacement sequence is run when the reagent level is low, bubbling could occur which would raise the blank value.
- If zero is set as the sample number, the analysis results will not be stored. If the sample number is set to zero, a warning beeping sounds during sample aspiration.
- Gently invert the sample 10 times.
- Remove the cap carefully so as not to spatter blood.

1. The sample is collected and prepared.
   Using CELLPACK dispensed ahead of time, dilute the sample to a 1:7 ratio.

   Sample volumes are as shown below.

Aspirated sample volume	Approx. 67 µL

2. Preparing the Sample for Capillary Analysis (1:7 dilution)
   (1) Rinse a diluent-dispensing container (Erlenmeyer flask, beaker, etc.) with CELLPACK) to remove dirt and dust.
   (2) Dispense CELLPACK into the diluent-dispensing container.
   (3) Use a probe to dispense 120 µL of CELLPACK into the sample tube.
   (4) Use a probe to dispense 20 µL of blood into the sample tube.
   (5) Cap the microtube and mix well.

   Prepare the following materials when making the 1:7 dilution sample.
   - Diluent (CELLPACK)
   - Sample tube (Microtube MT-40 or similar item)

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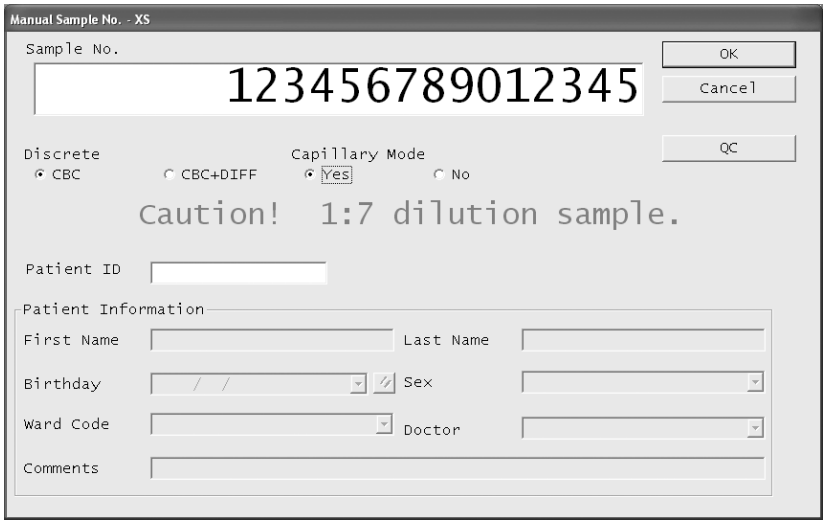
- Probe (20 µL)
- Probe (120 µL)
- Diluent-dispensing container (Erlenmeyer flask, beaker, etc.)
- Diluent-dispensing tool (syringe or similar item)

3. Startup
Select the Manual Mode icon on the Controller Menu, then double-click or press the Enter key to start the Manual Sample No. screen. (It can also be started either from the **Manual** button on the toolbar, or by pressing function key F2.)



In capillary analysis, always click on **Yes** for capillary mode analysis on the screen, then choose CBC or CBC + DIFF and click on **OK** on the screen.

4. Data input
Input the necessary parameters with reference to the table below.

Parameter	Meaning
Sample No.	Enter the sample number to be analyzed.
Discrete	Specify the analysis method for the sample from the Main Unit.
Capillary Mode	Specify whether to analyze diluted samples.
Patient ID	Enter the patient ID.
First Name/Last Name	Alphabet can be used. A maximum of 20 characters may be used for each name.
Birthday	Input a patient's date of birth following the "Date format".
Ward Code	Click the combo box and select a ward that has been recorded in the Ward Master.
Sex	Click the combo box and select Male or Female.
Doctor	Click the combo box and select a doctor that has been recorded in the Doctor Master.
Comments	Input comments about the patient.

*: This cannot be selected if there was an error related to reagents for DIFF analysis. When an error has occurred, Discrete is automatically switched to CBC.

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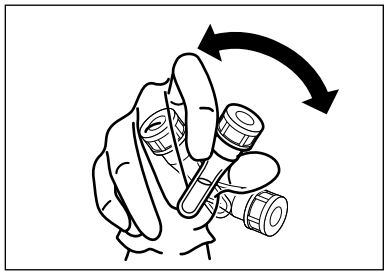
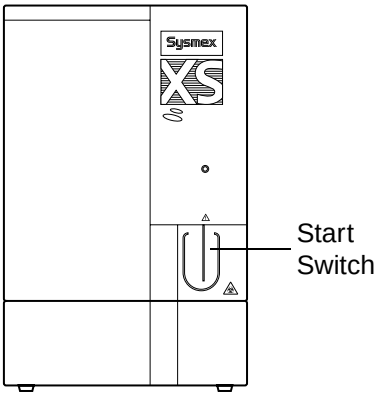
5. Click **OK**.
   The READY LED changes to red and probe rinsing starts.
   After the probe has been housed and rinsed once inside the Main Unit, it returns to the original position.
   The READY LED changes to green, and the system changes to Manual Aspiration Ready status.

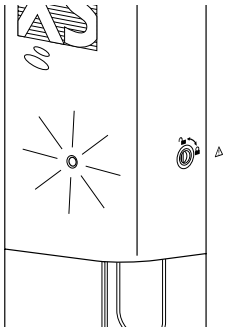
6. Mix sample thoroughly by inverting the sample tube.



7. Taking care to avoid blood spattering, remove the cap from the sample tube, insert the probe to the bottom of the sample tube, and press the Start switch.



8. The green READY LED flashes during sample aspiration, then the buzzer beeps to indicate the end of aspiration, and the READY LED goes out.
9. Remove the sample tube carefully so as not to bend the probe.
10. The fact that the READY LED is not lit indicates that analysis is in progress.



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11. When the READY LED lights green again, the next sample can be analyzed. Check that the READY LED is green, indicating Manual Aspiration Ready status, then carry out steps 3~8.

Note:

- If sample numbers are not set, they are automatically assigned sequentially. (Automatic increment function)
- The lowest digit to be incremented excludes alphabetical characters.
- A maximum of 15 alphanumeric characters and hyphens can be entered for the sample number.
- If the setting below is made, then after the sample number is input, the system will automatically inquire to the host computer the analysis order.
  Real-time Request (Manual Mode) [Sample Number].
- If an automatic increment is set for the sample number of each analysis, then the system will not automatically inquire to the host computer the analysis order and patient information.

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c. Manual mode analysis: XS-1000*i*

Analysis in manual mode can be performed when the Main Unit is in READY status.

Risk of infection

Be sure to wear protective garments and gloves when analyzing the sample.
Also, wash your hands after completing the process.
There is a risk of infection with pathogens etc.

Caution!

- Depending on the anticoagulant used, hemolysis and platelet aggregation can occur, preventing correct results. Use of EDTA-2K, EDTA-3K or EDTA-2Na anticoagulant is recommended for blood samples.
- Before processing, refrigerated samples should be allowed to equilibrate to the room temperature (approximately 30 minutes).
  Failure to do so may prevent correct analysis.

Important!

- If a message appears during analysis to ask for reagent replacement, replace the reagent concerned. If the reagent replacement sequence is run when the reagent level is low, bubbling could occur which would raise the blank value.
- If zero is set as the sample number, the analysis results will not be stored. If the sample number is set to zero, beeping will sound during sample aspiration.
- Gently invert the sample 10 times.
- Remove the cap carefully so as not to spatter blood.

1. Sample collection and preparation
   Draw the specified amount of blood as per the package insert of the tube used.

   Use a sample tube of length 85 mm or less (14 mm diameter). Sample volumes are as stated below.

Required sample volume in the vacuum tube	Approx. 500 µL or more*
Aspirated sample volume	Approx. 20 µL

* When using a sample tube for micro collection device with adapter: Approx. 90 µL or more

Caution!

The instrument is equipped with a Blood Aspiration Sensor. However, there is a potential that correct results may not be obtained, if the sample volume is less than that stated in the above mentioned "required sample volume in the vacuum tube" and the sensor could not detect a "Short Sample" or "Sample Not Asp Error".

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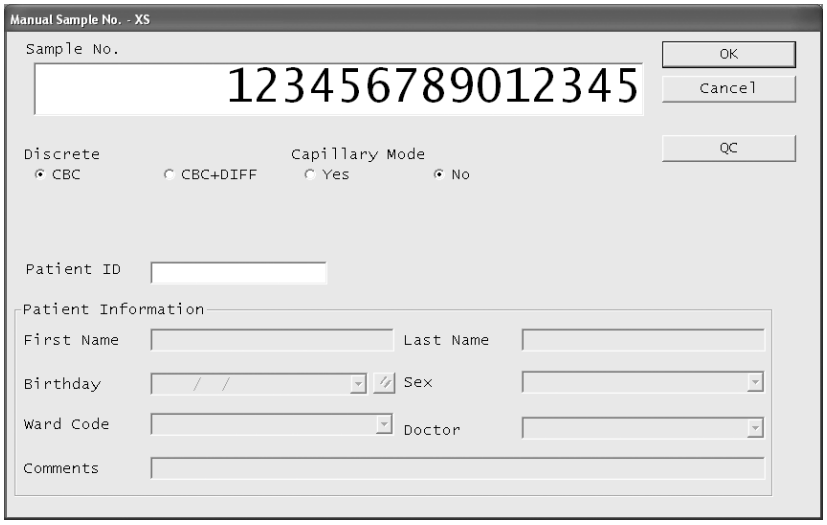
2. Startup
   Select the Manual Sample No. icon on the Controller Menu, then double-click or press the Enter key to start the Manual Sample No. screen. (It can also be started either from the **Manual** button on the toolbar, or by pressing function key F2.)



3. Data input
   Input the necessary parameters with reference to the table below.

Parameter	Meaning
Sample No.	Enter the sample number to be analyzed.
Discrete	Specify the analysis method for the sample from the Main Unit.
Capillary Mode	Specify whether to analyze diluted samples.
Patient ID	Enter the patient ID.
First Name/Last Name	Alphabet can be used. A maximum of 20 characters may be used for each name.
Birthday	Input a patient's date of birth following the "Date format".
Ward Code	Click the combo box and select a ward that has been recorded in the Ward Master.
Sex	Click the combo box and select Male or Female.
Doctor	Click the combo box and select a doctor that has been recorded in the Doctor Master.
Comments	Input comments about the patient.

*: This cannot be selected if there was an error related to reagents for DIFF analysis. When an error has occurred, Discrete is automatically switched to CBC.

4. Click **OK**.
   The Main Unit READY LED changes to green, and the system changes to Ready status.

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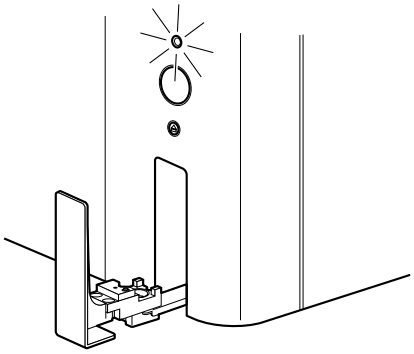
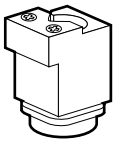
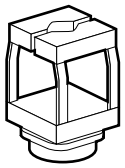
5. Press the Open/Close switch to open the sample position.



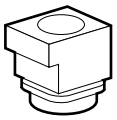
6. Selecting the sample tube adapter
   Adapters for major types of sample tube are ready for use in the sample position of the XS-1000*i*.
   Check the size of the sample tube used, and choose the corresponding provided part or optional adapter.



(For standard sample tubes)



(For micro sample tubes)

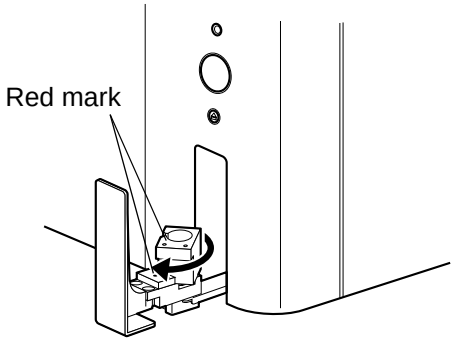


(For control blood)

- Types of sample tube adapters provided as standard parts.
  - Adapter for standard sample tubes: For standard sample tubes with height 79~85 mm and outer diameter up to 14 mm.
  - Adapter for micro sample tubes
  - Adapter for control blood: For QC materials.

- Optional adapters
  - Adapter for sample tubes with 15 mm outer diameter.

7. Sample tube adapter selection and attachment
   Select an adapter from the sample tube adapters, and place it in the sample setting area of the XS-1000*i* to align the red mark, as shown in the diagram, then turn it to the right until there is a click (turn about 45°) to attach it.



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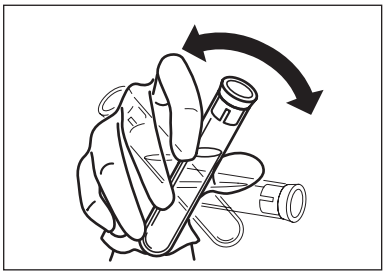
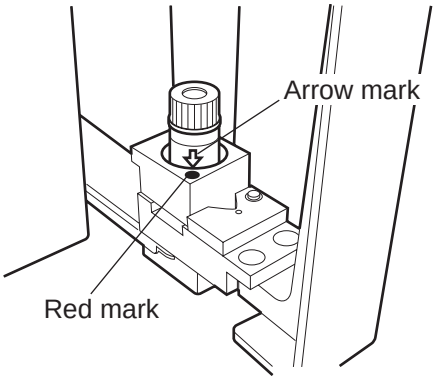
8. Gently invert sample 10 times. Then place it into the sample position.
   At that stage, check again that there is no large gap between the sample tube and the adapter. Check that you are using the right size of adapter. When using micro tubes (adaptor), be sure to open the cap first.
   When analyzing *e*-CHECK (XS), align the arrow marked on the vial label with the red mark on the control blood adapter to decrease the damage to the cap.





Note:

Piercing the same tube repeatedly could cause coring of the rubber cap, resulting in fragments that could block the aspiration or vent portion of the needle. It is recommended that each tube be pierced no more than five times before discarding.

9. When the Start switch is pressed, the sample position goes back inside the instrument and the READY LED flashes green, indicating that the sample is being aspirated.
10. When sample aspiration is complete, the buzzer beeps and the READY LED goes out. The fact that the READY LED is not lit indicates that analysis is in progress. When the READY LED lights again in green, the sample position protrudes, and the next analysis can be performed.

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11. To analyze the next sample, replace the tube with the next sample, making sure the appropriate tube adaptor is installed, and press the Start switch.

Note:

- If sample numbers are not set, they are automatically assigned sequentially. (Automatic increment function)
- The lowest digit to be incremented excludes alphabetical characters.
- A maximum of 15 alphanumeric characters and hyphens can be entered for the sample number.
- If the setting below is made, then after the sample number is input, the system will automatically inquire to the host computer the analysis order.
  Real-time Request (Manual Mode) [Sample Number].
- If an automatic increment is set for the sample number of each analysis, then the system will not automatically inquire to the host computer the analysis order and patient information.

● Finding the status of the Main Unit

Check the status of the Main Unit from the state of the READY LED, or from the icon at the lower left of the screen.

Main Unit status	READY LED display	Status of the icon at the lower left of the IPU screen
Ready	Lit in green	Icon green
Ready for analysis	Lit in green	Icon green or orange
Analyzing	Not lit	Icon orange
Malfunction	Lit red + warning sound	Icon red or yellow

* Error messages on the IPU screen are displayed in order of priority.

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d. Capillary mode analysis: XS-1000*i*

Capillary mode analysis is possible when the Main Unit is in READY status.

Risk of infection

Be sure to wear protective garments and gloves when preparing a sample for capillary analysis. Also, wash your hands after completing the process.
There is a risk of infection with pathogens etc.

Caution!

- Small blood samples collected from earlobes or fingertips are prone to clotting, so they should be diluted and analyzed as quickly as possible. Failure to do so may prevent correct analysis results.
- Samples collected from earlobes or fingertips generally have high blood cell counts, which diminish reproducibility. If possible, diluted samples should be analyzed twice and the results compared. If sample tubes containing general anticoagulant are used, hemolysis and platelet aggregation can occur, depending on the anticoagulant used, preventing correct results.
  Use of EDTA-2K, EDTA-3K or EDTA-2Na anticoagulant is recommended.
- Platelet agglutination tends to occur quickly in the 1:7 dilution sample. Perform analysis immediately after adding the blood to make the diluted sample. Prepare diluted samples one at a time for each analysis. If the diluent is dispensed too much ahead of time, measurement errors will result from evaporation and contamination. It is recommended that diluent be covered at all times.
- When placing the sample tube in the sample set area, always remove the cap of the tube.

Important!

- If a message appears during analysis to ask for reagent replacement, replace the reagent concerned. If the reagent replacement sequence is run when the reagent level is low, bubbling could occur which would raise the blank value.
- If zero is set as the sample number, the analysis results will not be stored. If the sample number is set to zero, a warning beeping sounds during sample aspiration.
- Gently invert the sample 10 times.
- Remove the cap carefully so as not to spatter blood.

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1. The sample is collected and prepared.
   Using CELLPACK dispensed ahead of time, dilute the sample to a 1:7 ratio.

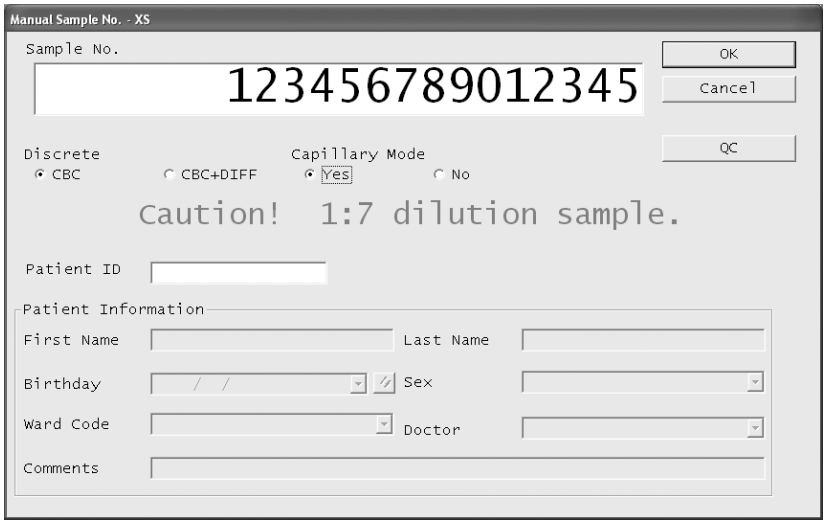
   Sample volumes are as shown below.

Required sample volume	140 µL or more (When using a sample tube for collecting small samples)
Aspirated sample volume	Approx. 67 µL (1:7 dilution)

2. Preparing the Sample for Capillary Analysis (1:7 dilution)
   (1) Rinse a diluent-dispensing container (Erlenmeyer flask, beaker, etc.) with CELLPACK to remove dirt and dust.
   (2) Dispense CELLPACK into the diluent-dispensing container.
   (3) Use a pipette to dispense 120 µL of CELLPACK into the sample tube.
   (4) Use a pipette to dispense 20 µL of blood into the sample tube.
   (5) Cap the sample and mix well.

   Prepare the following materials when making the 1:7 dilution sample.
   - Diluent (CELLPACK)
   - Sample tube (Microtube MT-40 or similar item)
   - Pipette (20 µL): It is recommended to use a pipette that has been calibrated to dispense blood volumes.
   - Pipette (120 µL)
   - Diluent-dispensing container.
   - Diluent-dispensing tool (syringe or similar item)

3. Startup
   Select the Manual Sample No. icon on the Controller Menu, then double-click or press the Enter key to start the Manual Sample No. screen. (It can also be started either from the **Manual** button on the toolbar, or by pressing function key F2.)



   In capillary analysis, always click on **Yes** for capillary analysis on the screen, then choose CBC or CBC+DIFF and click on **OK** on the screen.

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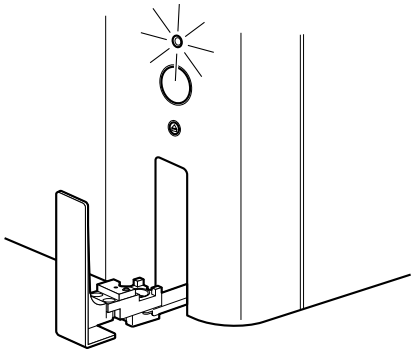
4. Data input
   Input the necessary parameters with reference to the table below.

Parameter	Meaning
Sample No.	Enter the sample number to be analyzed.
Discrete	Specify the analysis method for the sample from the Main Unit.
Capillary Mode	Specify whether to analyze diluted samples.
Patient ID	Enter the patient ID.
First Name/Last Name	Alphabet can be used. A maximum of 20 characters may be used for each name.
Birthday	Input a patient's date of birth following the "Date format".
Ward Code	Click the combo box and select a ward that has been recorded in the Ward Master.
Sex	Click the combo box and select Male or Female.
Doctor	Click the combo box and select a doctor that has been recorded in the Doctor Master.
Comments	Input comments about the patient.

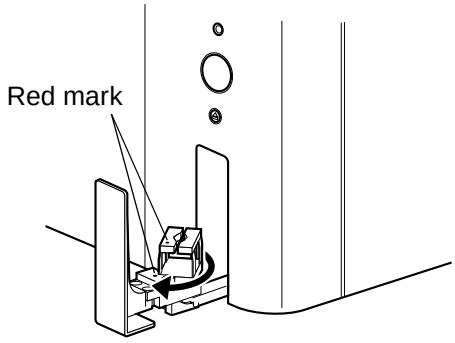
   *: This cannot be selected if there was an error related to reagents for DIFF analysis. When an error has occurred, Discrete is automatically switched to CBC.

5. Click **OK**.
   The Main Unit READY LED changes to green, and the system changes to Manual Aspiration Ready status.

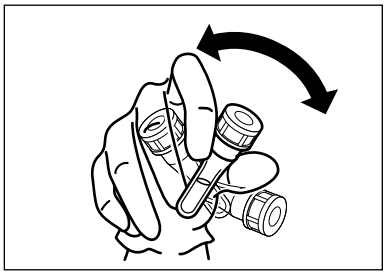
6. Press the Open/Close switch to open the sample position.

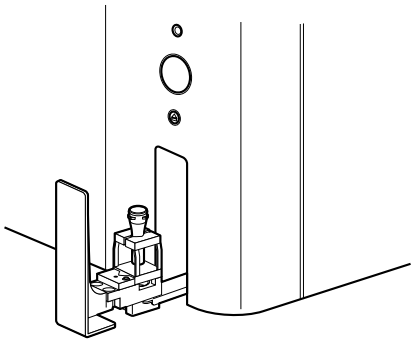


7. Sample tube adapter selection and attachment
   Select a micro tube adapter from the sample tube adapters, and place it in the sample setting area of the XS-1000*i* to align the red mark, as shown in the diagram, then turn it to the right until there is a click (turn about 45°) to attach it.



8. Gently invert sample 10 times, remove the cap, then fit the tube into the sample position.
   At that stage, check again that there is no large gap between the sample tube and the adapter, and check that the adapter used is the right size.





9. When the Start switch is pressed, the sample position goes back inside the instrument and the READY LED flashes green, indicating that the sample is being aspirated.
10. When sample aspiration is complete, the buzzer beeps and the READY LED goes out. The fact that the READY LED is not lit indicates that analysis is in progress. When the READY LED lights again in green, the sample position protrudes, and the next analysis can be performed.

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11. To analyze the next capillary sample, set the tube containing the new sample and press the Start switch.

Note:

- If sample numbers are not set, they are automatically assigned sequentially. (Automatic increment function)
- The lowest digit to be incremented excludes alphabetical characters.
- A maximum of 15 alphanumeric characters and hyphens can be entered for the sample number.
- If the setting below is made, then after the sample number is input, the system will automatically inquire to the host computer the analysis order.
  Real-time Request (Manual Mode) [Sample Number].
- If an automatic increment is set for the sample number of each analysis, then the system will not automatically inquire to the host computer the analysis order and patient information.

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e. Sampler mode: XS-1000*i* with sampler (optional)

Sampler mode analysis can be performed when the Main Unit is in READY status.
In this mode, sample mixing, aspiration, and analysis are all performed automatically.
The sample tube with rubber cap can be placed in the rack for analysis.
* Capillary analysis is not possible in this mode.

Warning!

Affix the bar code label so that the bars on the label are arranged horizontally when the rack is placed on the sampler. If the bar code label is affixed slanted, the potential of an incorrect reading of the bar code label will be increased.

Caution!

Do not open the cover when the Sampler is working.
There is a potential of injury from the mechanical parts.
(If the cover is removed, the monitor switch is activated and analysis stops.)

Important!

- Use the check-digit wherever possible, when using sample bar codes. If the check-digit cannot be used, the potential of the incorrect reading of the bar code label may be increased.
- To avoid sample misidentification, it is recommended to keep the following points when affixing a bar code label.
  - Labels must be affixed in the proper position.
  - Do not affix multiple labels. (See 2. Affixing Bar Codes.)
  - Label surfaces must not be wrinkled.
  - Bar code labels must not peel off the tube.
    (Do not use bar code labels that easily peel off.)
  - Make sure that the labeled tubes could be smoothly picked up from and restored to the rack.

1. Collecting the sample
   Draw the specified amount of blood (corresponding to the amount of anticoagulant) from a vein.
   - Depending on the anticoagulant used, hemolysis and platelet aggregation can occur, preventing correct results. Use of EDTA-2K, EDTA-3K or EDTA-2Na anticoagulant is recommended.
   - Before processing, refrigerated samples should be allowed to equilibrate to the room temperature (approximately 30 minutes).
     Incorrect handling may prevent correct analysis.

   ● The required sample volumes for analysis are shown below.

Required sample volume	Approx. 1.0 mL
Aspirated sample volume	Approx. 20 µL

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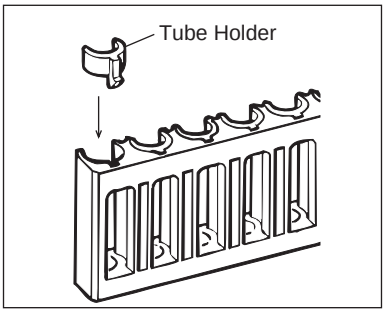
Caution!

The instrument is equipped with a Blood Aspiration Sensor. However, there is a potential that correct results may not be obtained, if the sample volume is less than that stated in the above mentioned "required sample volume in the vacuum tube" and the sensor could not detect a "Short Sample" or "Sample Not Asp Error".

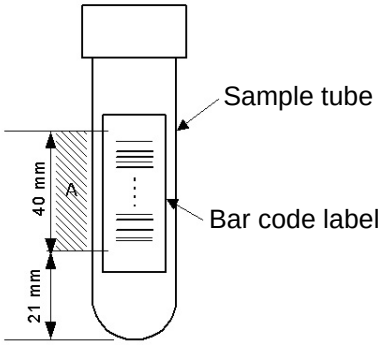
For sampler analysis, use the evacuated blood collection tubes listed below.
Diameter a: 12 - 15 mm
Length b: 75 mm
c: Max. 82 mm
Note:
• VENOJECT II (TERUMO)
• Hemoguard (BD)
• VACUETTE (greiner)
• Monovette (SARSTEDT)
Do not use reusable caps.

Use sample tubes with a length of 75 mm and diameters of 12 - 15 mm. If the diameter of the tubes is less than 14 mm, attach holders to the rack.



Sample tube diameter	Tube Holder
12 mm	No. 58
13 mm	No. 56
14 mm	None
15 mm	None

2. Affixing bar code labels
Make sure that the bar code label must be affixed in the range A in the figure below so that the bar code will be correctly read.



For information on setting up bar codes, see Software Guide Chapter 5: 1.3 Bar Code Reader Settings.

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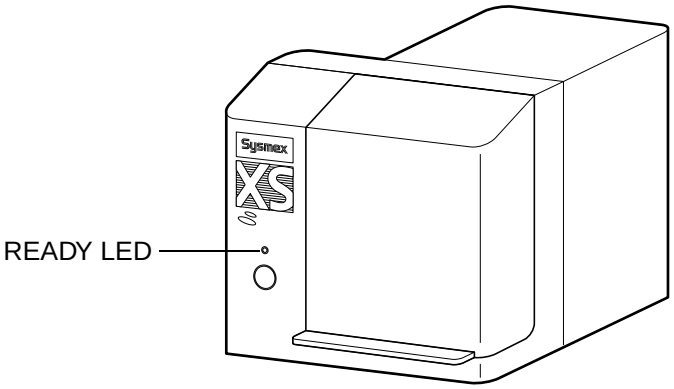
- Precautions for sample analysis
  If a sample is left in a stable condition for 4 hours or more, and its blood cells and plasma have separated, then correct results may not be obtained due to insufficient mixing of the sample. If such samples are to be analyzed, manually mix them thoroughly by hand before setting them in the sampler.

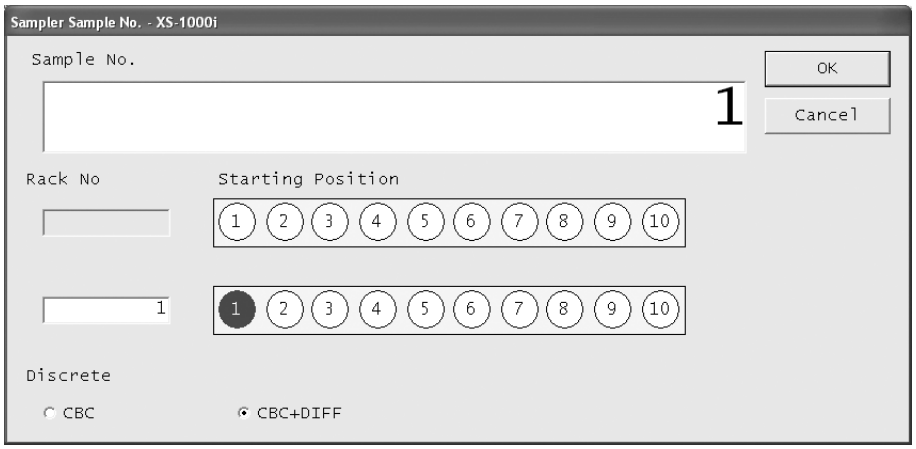
3. Startup
   When the Main Unit is in Ready status (READY LED lit with green), use any of the methods below to open the **Sampler Analysis** dialog box.
   - Click on the **Sampler** button on the toolbar.
   - Press the F3 key.
   - Double-click the **Sampler Sample No.** icon on the **Menu** screen.

   If there was any sampler-related error, both the icon and the F3 key are disabled and cannot be used.



Note:

- The icon is not displayed if no sampler is connected. The F3 key is also disabled.
- If the Main Unit is not in Ready status, the error warning will sound and the screen will not open.



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During sampler analysis, analysis registrations and order and patient information from the host computer can be queried, using the Sample No. or the Rack No. and Tube Position.
If the system is set to not make queries, or if a query is made but the subject was not registered, the analysis will follow the discrete selected on the upper screen.

4. Enter the necessary parameters as prompted by the dialog box, with reference to the table below.

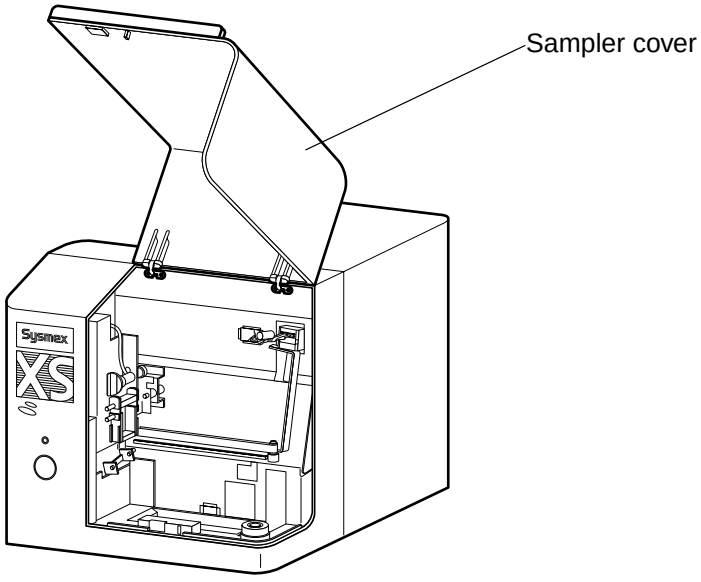
   - Sampler Analysis dialog box List of setting parameters

Parameter	Contents
Sample No.	Enter the starting number for automatic allocation of numbers by the Main Unit. This area is highlighted when the dialog opens.
Rack No.	Enter the number of one rack in the sampler.
Analysis start position	Select the analysis start tube position from the combo box.
Discrete	Specify the default analysis method.

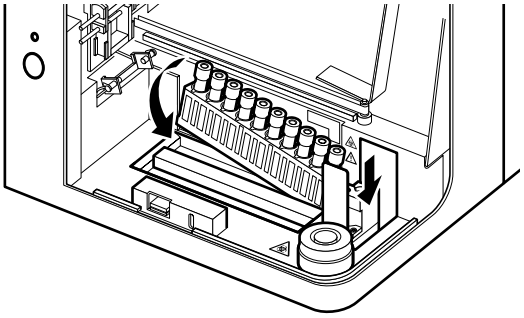
   *:If there is an error to the reagent for DIFF analysis, sampler analysis cannot be made.

5. Click **OK**.
   The Main Unit READY LED changes to green, and the system changes to Manual Aspiration Ready status.

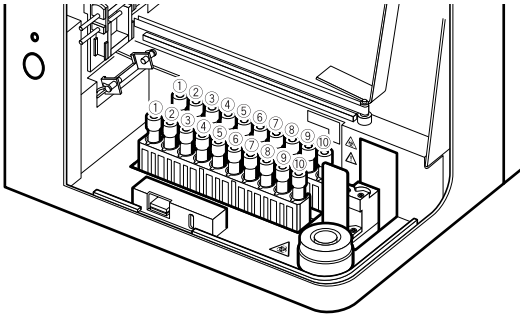
6. Open the Sampler cover.



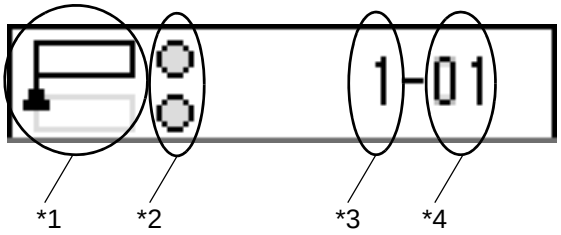
7. Set the samples in the sampler rack, then place the racks to the sampler as shown in the diagram, starting from the interior.



- The rack at the left back side is sample No.1, with numbers rising sequentially to the right, and the sample No. in the front rack left side starts with No.1 again.

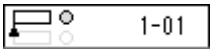
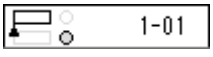
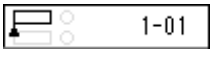


8. Close the Sampler cover.
   When the sampler cover is closed, the following icon is displayed on the lower left of the IPU screen.



*1 When the Sampler's Start switch has been pressed, the position of the sample on which analysis will start is indicated by ▲.

*2 Indicates the status of the racks that are currently installed.

	Racks are installed in both the front and back of the Sampler
	A rack is installed only in the back of the Sampler
	A rack is installed only in the front of the Sampler
	No racks are installed in the Sampler

*3 This means the rack number.

*4 This means the position number (sample number) of the sample, which is written on the bottom diagram of step 7.

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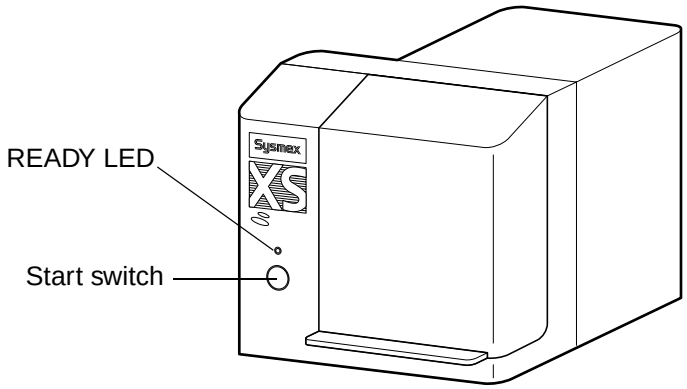
9. Press Start switch in the Sampler.
   (The READY LED flashes green.)



- Sampler analysis starts, on the system moves into Ready status on completion (the READY LED lights in green).
- During sampler analysis, analysis registrations, order and patient information from the host computer can be queried, using the sample number or the rack number and sample tube position.
  If the system is set not to make queries, or if a query was made but the subject was not registered, the analysis will follow the set default order.

* If the instrument suffers an error, the READY LED flashes red, and an Error dialog box appears on the screen of the IPU at the same time.

- If this happens, click on the **Execute** button in the Error dialog box to run the error restoration.
- In the event of multiple errors, repeat the above action, clicking on the **Execute** button, until there are no more Error dialog boxes.
- If automatic restoration is not possible, contact a Symex service representative.

10. When the sampler analysis is complete, a dialog box will open and a chime will sound.

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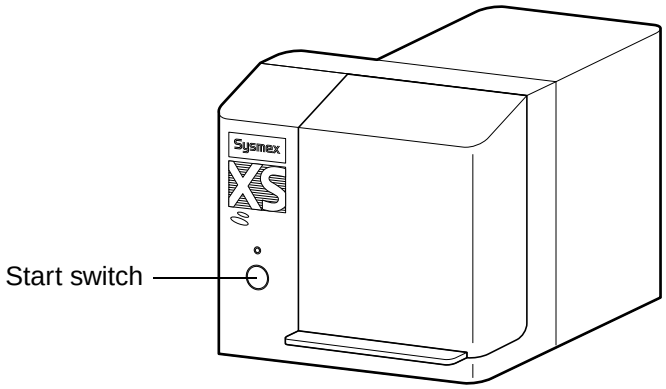
f. Sampler analysis stop: XS-1000*i* with sampler (optional)

1. Press the Sampler Start switch during Sampler analysis to stop analysis.
2. The READY LED flashes in orange when the system is trying to suspend the sampler mode analysis.
3. Then the READY LED lights in green after completing the sampler mode analysis has been suspended.



4. The next can be analyzed if the sampler rack has not been removed.
   - Check that the sampler rack has not been removed, then press the Start switch.
   - Analysis starts, and the system enters Ready status on completion.

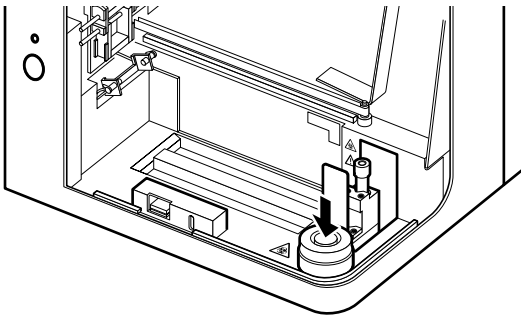
g. Manual analysis: XS-1000*i* with sampler (optional)

On an XS-1000*i* with Sampler, manual analysis is possible while the sampler cover is open.

These operation procedures are the same as those for the standard XS-1000*i*.
- Manual analysis
- Capillary analysis

For details, refer to the operation methods described in “c. Manual mode analysis: XS-1000*i*” and “d. Capillary mode analysis: XS-1000*i*”.
When operating under manual analysis, bar codes cannot be read.

* The Start switch is behind the sampler cover.
Refer to the diagram below for details.



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6.12 Ending of sample analysis (shutdown)

When shutdown is performed, the detector and dilution line are cleaned.
You should run the instrument through a shutdown cycle at the end of each day's analyses or at least once every 24 hours if running the instrument continuously.

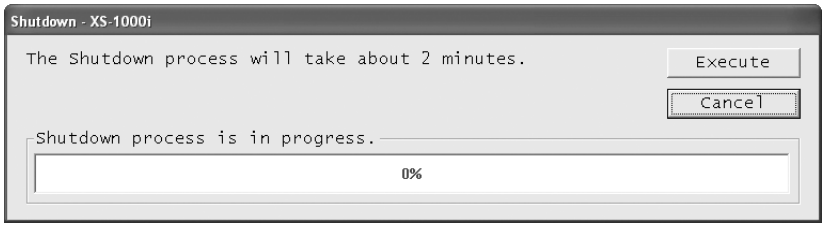
Caution!

- Be sure that cleaning is done by performing shutdown. Failure to do so may prevent correct analysis results.
- Do not use CELLCLEAN during shutdown.

1. Main Unit shutdown

The procedure for shutting down the instrument is: Run Main Unit shutdown sequence → turn main unit power off.

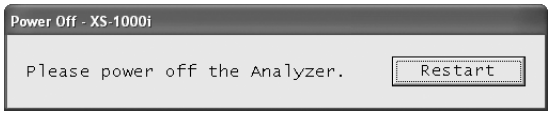
1. Double-click the **Shutdown** icon on the Menu screen.
   The Shutdown dialog box will appear.



   * To cancel shutdown, click **Cancel** on the Shutdown dialog box. The system will return to Ready status.

2. Click **Execute**.
   The Main Unit shutdown sequence begins.

3. After the shutdown sequence is completed, the Shutdown dialog box closes, and the Power Off dialog box appears.



4. If analysis is completed, turn off the power to the Main Unit.
   The information processing unit (IPU) can still be used.

Note:

To continue analysis without turning off the power to the Main Unit, click Restart on the Power Off dialog box. The Power Off dialog box will be closed and the Main Unit will be restarted.

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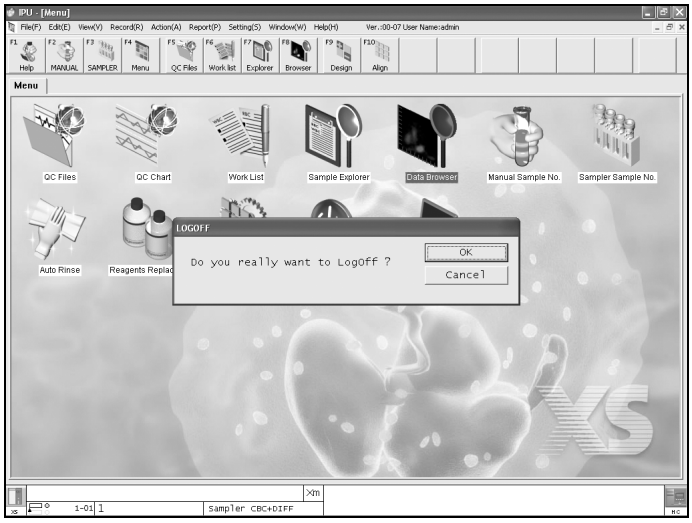
2. Logging Off from the XS-1000*i*/XS-500*i* Program

To change the current user name, first log off from the XS-1000*i* program (XS-500*i* program for the XS-500*i*), and then log on again.

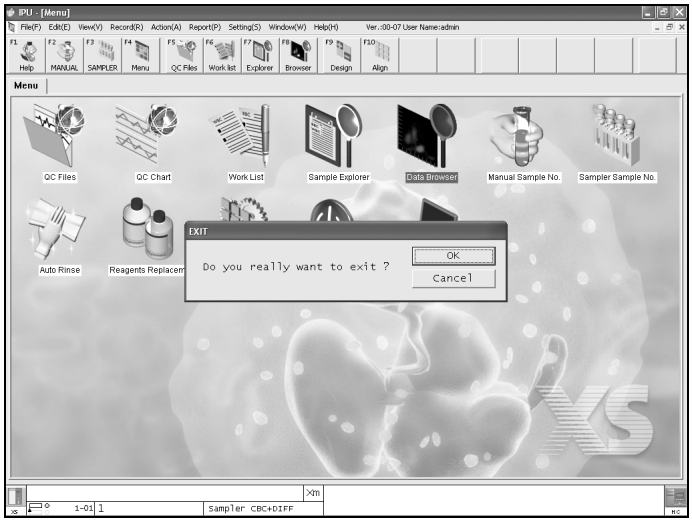
1. Select **Log Off (L)** from the **File (F)** menu. The Log Off Confirmation dialog box will appear.



2. Click **OK** or **Cancel**.
   OK The user is logged off, and the IPU Logon dialog box appears.
   Cancel Log off is canceled.

3. Closing down the Information Processing Unit (IPU)

1. To exit the IPU application, select **Exit (X)** from the **File (F)** menu.
   The Exit Confirmation dialog box will appear.



2. Click **OK** or **Cancel**.
   OK The application closes.
   Cancel Cancels the application exit.

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3. Click the **Start** key on the screen taskbar to display the start menu. Select **Shut Down (U)**.
   The Windows Shut Down dialog box will appear.
4. Select **Shut Down** by clicking on the combo box and click **OK**. The IPU power will be turned OFF.
   - If Restart is selected, the XS-1000i program (XS-500i program for the XS-500i) will start automatically after the restart procedure is finished.

Note:

With some models of PC, the power may not be turned OFF automatically when **Shut Down** is selected.

6.13 Sleep (timer) mode

If there is no operation of the Main Unit within a certain period, the READY LED starts slowly flashing green.
For the setting method, see Software Guide Chapter 5: System Settings.

1. Recovery method

Press the Start Switch to restart the Main Unit.

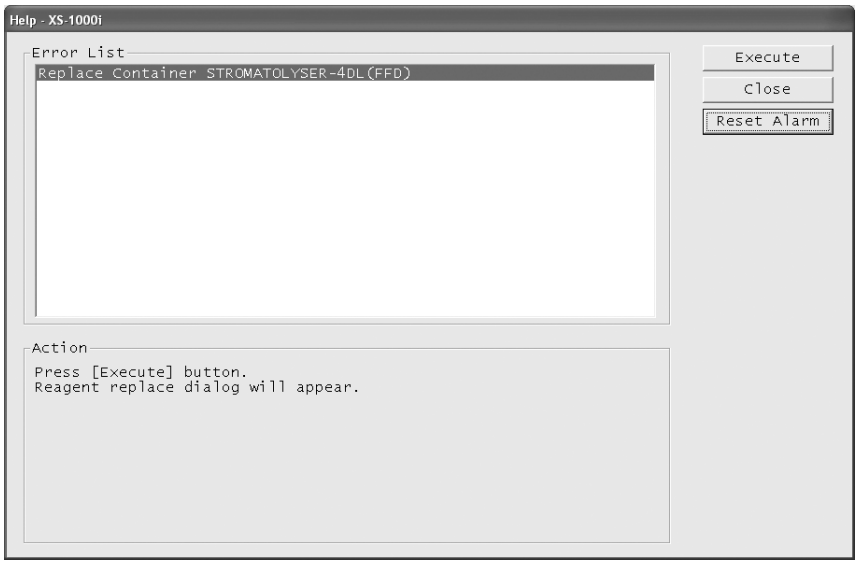
Note:

If the Main Unit has not operated within a certain period, it will perform auto rinsing when it is restored.

6.14 Main Unit Help

When an error occurs with the Main Unit, it sounds an alarm and the Help dialog box appears automatically.
Current errors are displayed in order of priority, with the most urgent first. The error selected from the error list can be processed for restoration.

1. Select the Help icon on the **Controller** menu, then double-click or press the Enter key.
   Alternatively, press the F1 key or the **Help** button on the toolbar.
2. The Help dialog box starts.



- Items and their content

Item	Contents
Error List	All current errors are listed in order of priority. When the Help dialog box is first opened, the cursor is positioned over the error with the highest priority. If an error occurs while the Help dialog box is displayed, the error list is updated but the cursor position does not change. If no error has occurred, the error list is blank and the cursor is not displayed.
Action	Countermeasures for the error selected in the error list are displayed.

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- Buttons and their description

Item	Contents
Excute For an error that can only be checked and requires solution, the button appears as “Accept”.	Stops the alarm and runs the recovery process corresponding to the error. Once the recovery process is complete, the error is removed from the error list.
Close	Stops the alarm and closes the Help dialog box without running the error restoration process.
Reset Alarm	Stop the Main Unit alarm if it is sounding.

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7. Quality Control

Quality Control is performed in order to monitor an instrument's performance over time. *e*-CHECK is the quality control material used to monitor the performance of the XS analyzer. Quality Control should be run according to licensing agency regulations. It should be noted that for troubleshooting purposes, additional control runs may be necessary.

7.1 Quality Control Material

Use control blood.

Important!

Only use the specified control blood. Control blood is specially tailored to the analysis technology of the instrument.

7.2 Method

The XS has two quality control methods for control material: X-bar and L-J (Levy-Jennings).

- QC methods using control material
  - X-bar control: Control blood is analyzed twice and the mean value of the two analyses is used to evaluate analyzer performance.
  - L-J control: Data from a single analysis of control blood is used to monitor analyzer performance daily.
- QC using normal samples
  - X-barM: This program calculates a weighted average of batches of patient samples (usually 20) and plots the resulting value as control data.

7.3 Preparation

- Turn on the Main Unit power and wait for the Main Unit mode to change to Standby.
- When the instrument is shipped from the factory, nothing is registered in the QC file.
- Create a QC file from the QC file screen.

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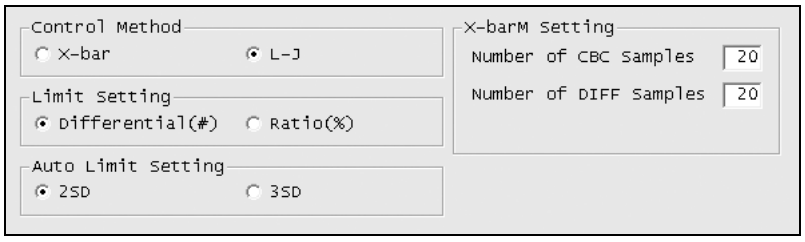
7.4 QC File

The QC file function is used to display various information for the user to judge that QC was carried out correctly, and to make QC settings.

1. Setting

QC-related settings can be made. If a user who is not authorized to carry out quality control operations or calibration is logged in, the settings are unavailable and cannot be altered.

1. Select **Settings (S)** → **IPU (I)** from the Menu bar. Or double-click **IPU Setting** icon on the Menu screen.
2. Clicking **QC** on the IPU Setting tree displays the following screen.



Control Method Set the QC method.
- **X-bar** Select to use X-bar as the QC method.
- **L-J** Select to use L-J as the QC method.

X-barM setting Make settings related to X-barM.
- **Number of CBC Samples** Input the number of samples per plot for the CBC parameters under X-barM.
- **Number of DIFF Samples** Input the number of samples per plot for the DIFF parameters under X-barM.

Limit Setting Make settings related to limit value.
- **Defferential (#)** (SD) calculates the QC limit value as a numeral value with regard to the average value (Target).
- **Ratio(%)** The (CV) method calculates the QC limit value as a ratio with regard to the average value (Target).

Auto Limit Setting Select the limit as a multiple of SD (CV).
- **2SD** Select to make the limit range 2SD (CV).
- **3SD** Select to make the limit range 3SD (CV).

3. Click **OK** to confirm the input.
   Click **Cancel** to cancel the input.

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2. X-barM

X-barM Control can be started and stopped from the X-barM dialog box. When a sample that is expected to cause an X-barM Control error is going to be analyzed, and in similar situations, X-barM Control can be canceled.

1. Double-click on the Menu screen **Control** → **X-barM** (or press Enter key) to start the following dialog box.

X-barM The current setting for X-barM status is displayed when the screen starts up.
ON Run X-barM Control.
OFF Cancel X-barM Control.

OK The settings are applied, and the X-barM dialog box is closed.

Cancel The settings are discarded, and the X-barM dialog box is closed.

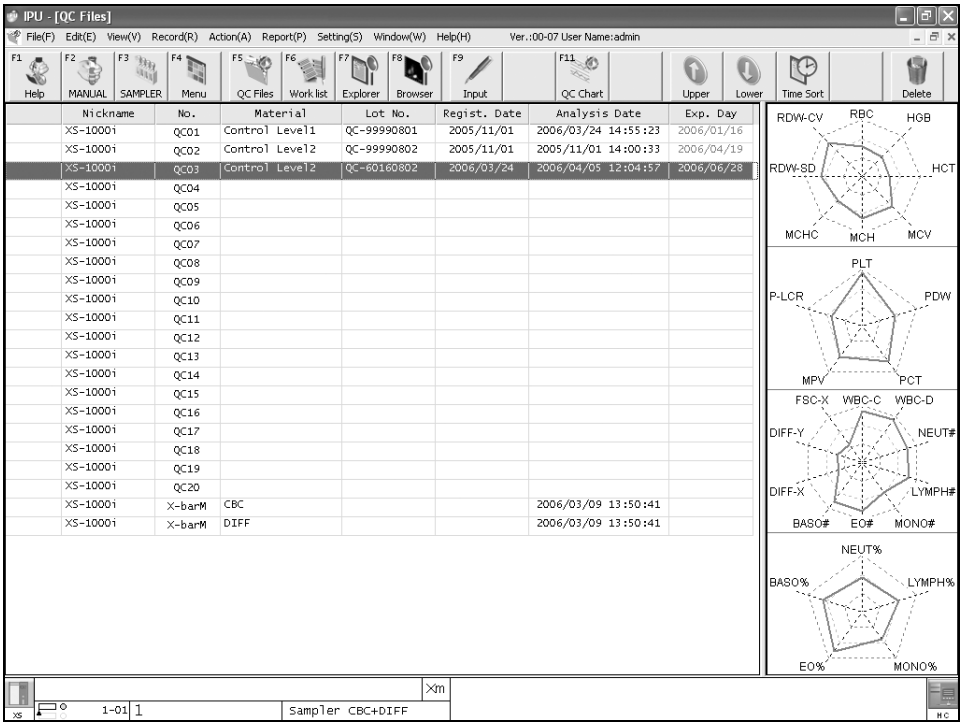
3. QC file screen

The list of QC files can be displayed on the QC File screen for the purpose of running quality control.

- Registrations and alterations of control files, display of lot information and the latest QC analysis results are available.
- The QC File screen comprises the menu bar, tool bar, file list, radar chart and lot information.

The QC File screen can be started by any one of the following methods:

- Select **QC File (F)** from the **View (V)** menu.
- Click the **QC Files** button on the tool bar.
- Press the F5 key.
- Double-click the **QC Files** icon on the Menu screen.

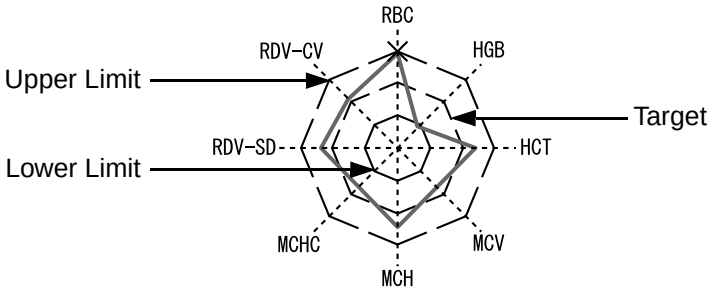


4. Radar chart

The latest plot data from the selected QC file is displayed on the radar chart. If there are no plots in the selected QC file, only the outline and parameter names are displayed.

Parameter names	Displayed in white text on a red background if the latest QC data falls outside the QC limit values. Displayed in black text on white background if the latest QC data falls within the QC limit values.
Inner red line	Lower limit value
Outer red line	Upper limit value
Central black line	Target value
Blue line	Latest QC data from the QC file selected in the file list

For points which fall beyond the upper or lower limit, a red “X” is plotted on the upper or lower limit.



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The following parameters are plotted on the radar chart:

- For QC-01~20

Radar chart name	Parameter
Radar chart 1	RBC
	HGB
	HCT
	MCV
	MCH
	MCHC
	RDW-SD
	RDW-CV
Radar chart 2	PLT
	PDW
	PCT
	MPV
	P-LCR
Radar chart 3	WBC-C
	WBC-D
	NEUT#
	LYMPH#
	MONO#
	EO#
	BASO#
	DIFF-X
	DIFF-Y
	FSC-X
Radar chart 4	NEUT%
	LYMPH%
	MONO%
	EO%
	BASO%

- For X-barM (CBC)

Radar chart name	Parameter
Radar chart 1	WBC
	RBC
	HGB
	HCT
	MCV
	MCH
	MCHC
	RDW-SD
	RDW-CV
Radar chart 2	PLT
	PDW
	PCT
	MPV
	P-LCR

- For X-barM (DIFF)

Radar chart name	Parameter
Radar chart 1	NEUT#
	LYMPH#
	MONO#
	EO#
	BASO#
	DIFF-X
	DIFF-Y
Radar chart 2	NEUT%
	LYMPH%
	MONO%
	EO%
	BASO%

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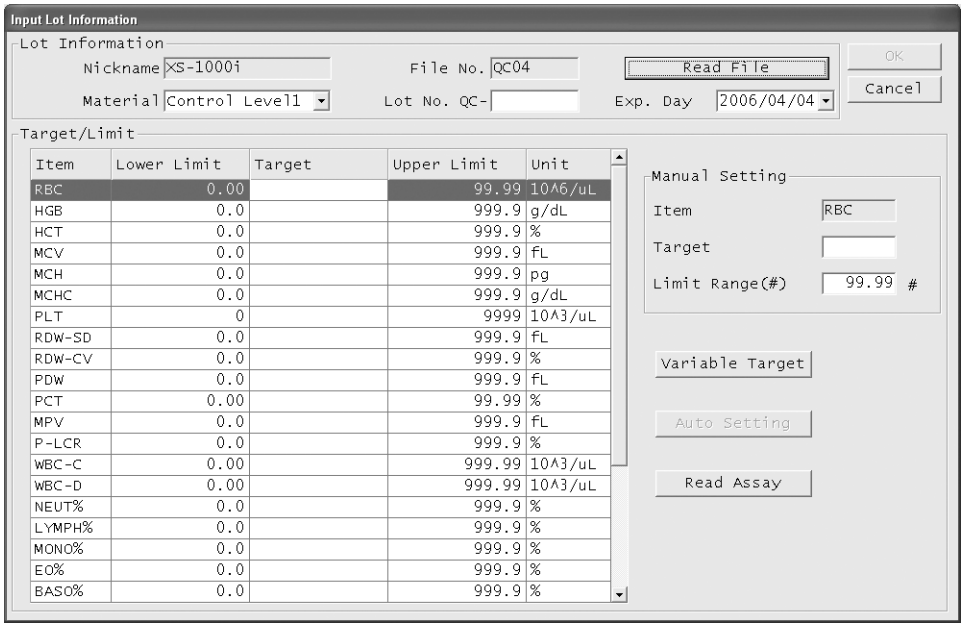
5. Lot information input

QC file lot information can be input from the Lot Information Input dialog box. (Lot information for up to 20 files can be input).

Select the line in the file list on the QC File screen for the QC file number for which you want to input lot information, then start the Lot Information Input dialog box by one of the methods below.

- Left click the **Input** button on the tool bar.
- Press the F9 key.



- Lot Information Input dialog box List of setting parameters

Parameter	Contents
Material	• Select the QC material from the combo box.
Lot No.	• Input the lot number for the QC material.
Exp. Day	• Input the expiration date for the QC material.
Target	• Input the target value.
Limit Range (#) Or **Limit Range (%)**	• Input the limit range. • If the limit range setting is numerical (#), input the numerical value of the range from the target to the limit. • If the limit range setting is a ratio (%), input it as a ratio between the target and the limit.

- Lot Information Input dialog box List of buttons

Parameter	Contents
Read File	• Load lot information, targets and limits from the assay value file.
Variable Target	• Set variable targets for the targets of all the parameters selected in the list. This operation is not possible if limit values have not been set for all selected parameters. Parameters set for variable targets have blanks displayed for the targets on the left side of the screen and manual setting targets, and the manual setting target column and automatic setting button are not usable.
Auto Setting	• The Automatic Setting dialog box is displayed to select whether or not to use automatic calculation for the target, the limit, or both. • If the QC data contains less than 3 plots, then it is not possible to provide statistical calculations.
Read Assay	• Read target and limit values for the parameters selected in the list from the assay value file.
OK	• Confirm the input, register the lot information in the QC file, and close the dialog box. This is not possible if any of the parameters have not yet been input. • Expiration date is checked when the **OK** button is pressed. If the date outside the range is input, automatically corrected date will be displayed.
Cancel	• Discard the input and close the dialog box.

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a. Read file

Read material, lot number, expiration date, targets and limits from external media.

1. Click on the **Read File** in the Lot Information Input dialog box.
   Lot information is searched for within the previously loaded folder and the Lot Selection dialog box is displayed.

Read Target/Limit
Click the check box to load the target value and limit range.

2. Select **OK** or **Cancel**.

OK	Read lot information, and return to the Add Lot dialog box.
Cancel	Close the Lot Selection dialog box, and return to the Add Lot dialog box.

3. Use the Browse button to specify the folder containing assay value files.

4. Select **OK** or **Cancel**.

OK	Confirm the selected folder, close the dialog box, and return to the Read Assay Values dialog box to read the assay values.
Cancel	Cancel the folder selection, and return to the Read Assay Values dialog box.

b. Manual Setting

Item	Display the selected parameter name.
Target	Input the target value for the selected parameter.
Limit	Input the limit range for the selected parameter. If the setting is numerical (#) from IPU setting, input the numerical value of the range from the target to the limit. It is displayed as (#) in the title bar. If the limit range setting is a ratio (%) from IPU setting, input it as a ratio between the target and the limit. It is displayed as (%) in the title bar.

c. Variable Target

Set variable targets for the targets of all the parameters selected in the parameter list on the left side of the screen.
Parameters set for variable targets have blanks displayed for the targets on the left side of the screen and manual setting targets.

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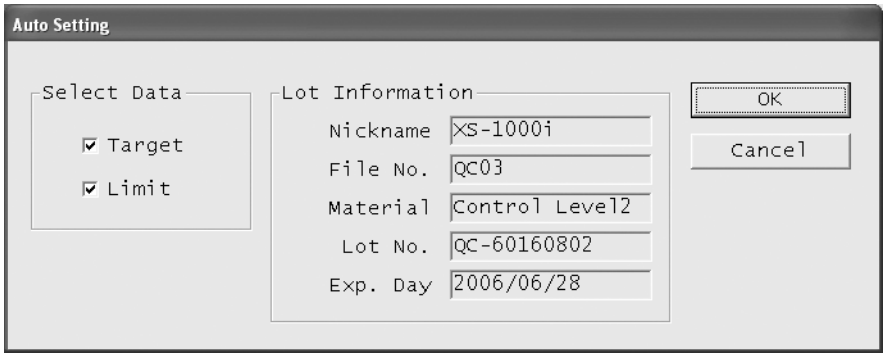
d. Auto Setting

The dialog box is displayed to select whether or not to use automatic calculation for the target, the limit, or both. Limit statistical calculations are not possible, if the QC data contains less than 3 plots, so the limit check boxes cannot be selected.



Target Check the box to calculate targets automatically. Remove the check to prevent automatic calculation of the target.
For automatic target calculation, the average of the QC data is calculated and set as the target value.

Limit Check the box to calculate limits automatically. Remove the check to prevent automatic calculation of the limits.
Automatic calculation of limits is based on the SD of the QC data and the currently set limit standard (2SD or 3SD, depending on the IPU setting), and the calculated values are set as limits.

OK Close the Automatic Setting screen and calculate targets, limits or both, for the check-marked targets or limits of the parameters selected on the left side of the Target/ limit Setting screen. The calculated results are applied as target and limit values.

Cancel Close the Automatic Setting screen without further action.

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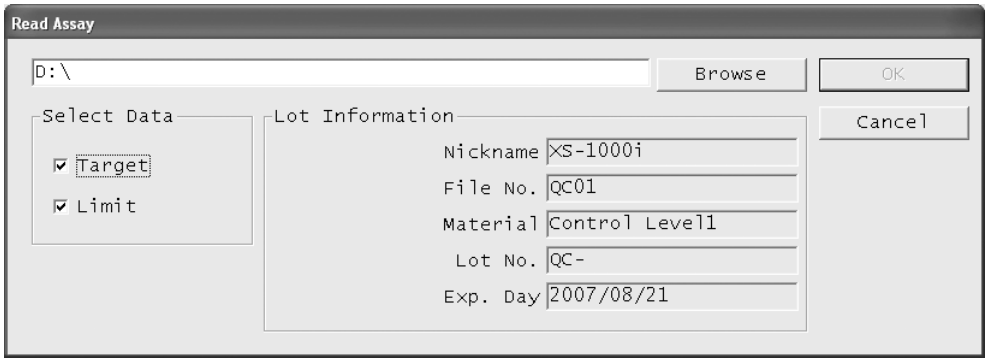
e. Read assay values

Read targets and limits from external media.
Click the Read Assay Values button to search for lot information in the folder from which data was read last and display the Read Assay Values dialog box.



Target Check the box to read targets from the assay value file. Remove the check to prevent reading of targets.

Limit Check the box to read limits from the assay value file. Remove the check to prevent reading of limits.

OK Close the Read Assay Value screen and read from external media the targets, limits or both, for the check-marked targets or limits of the parameters selected on the left side of the Target/ limit Setting screen.

Cancel Close the Read Assay screen.

Browse Specify the folder which contains the assay value file.

OK Confirm the folder selection, close the dialog box, and return to the Read Assay Values dialog box.

Cancel Cancel the folder selection, and return to the Read Assay Values dialog box.

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6. Lot information revision

QC file lot information can be revised from the Lot Information Input dialog box. Select the line in the file list for the QC file number for which you want to revise lot information, then start the Lot Information Input dialog box by one of the methods below.

- Left click the **Input** button on the tool bar.
- Press the F9 key.
    - The Lot Information Input dialog box starts up with the currently selected information displayed.
    - Same as for display parameters, setting parameters and other lot information input.

7. Chronological sort

Sort the QC files into descending order of the date and time of QC analysis. Press the **TimeSort** button again to return to order of the QC file number.

Start by any of the methods below.

- Left click the **TimeSort** button on the tool bar.

8. Move to the top data

Move the cursor on the file list to the top of the list, and select that QC file. If the cursor is already at the top, the button is disabled and cannot be pressed.

Start by any of the methods below.

- Select **Record (R)** → **First (F)** from the menu bar.

9. Move to the next data up

Move the cursor on the file list up one file, and select that QC file. If the cursor is already at the top, the button is disabled and cannot be pressed.

Start by any of the methods below.

- Select **Record (R)** → **Upper (U)** from the menu bar.
- Click the **Upper** button on the tool bar.
- Press the Up cursor key.

10. Move to the next data down

Move the cursor on the file list down one file and select that QC file. If the cursor is already at the bottom, the button is disabled and cannot be pressed.

Start by any of the methods below.

- Select **Record (R)** → **Lower (W)** from the menu bar.
- Click the **Lower** button on the tool bar.
- Press the Down cursor key.

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11.Move to the bottom data

Move the cursor on the file list to the end of the list, and select that QC file. If the cursor is already at the bottom, the button is disabled and cannot be pressed.

Start by any of the methods below.
- Select **Record (R)** → **Last (L)** from the menu bar.

12.Delete

The selected QC file can be deleted. However, the X-barM file cannot be deleted.

How to select the file for deletion
- Use the mouse or Shift + Up cursor, Shift + Down cursor to select multiple lines.
- Select **Edit (E)** → **Select All (A)** from the menu bar.
- Press Ctrl + A to select all QC files.

Select the files for deletion and use one of the methods below to delete them. The QC File Deletion Confirmation dialog box appears.

- Left click the **Delete** button on the tool bar.
- Press the Delete key.

● QC File Deletion Confirmation dialog box List of buttons

Parameter	Contents
OK	• Delete the selected QC files and close the dialog box.
Cancel	• Cancel the QC file deletion and close the dialog box.

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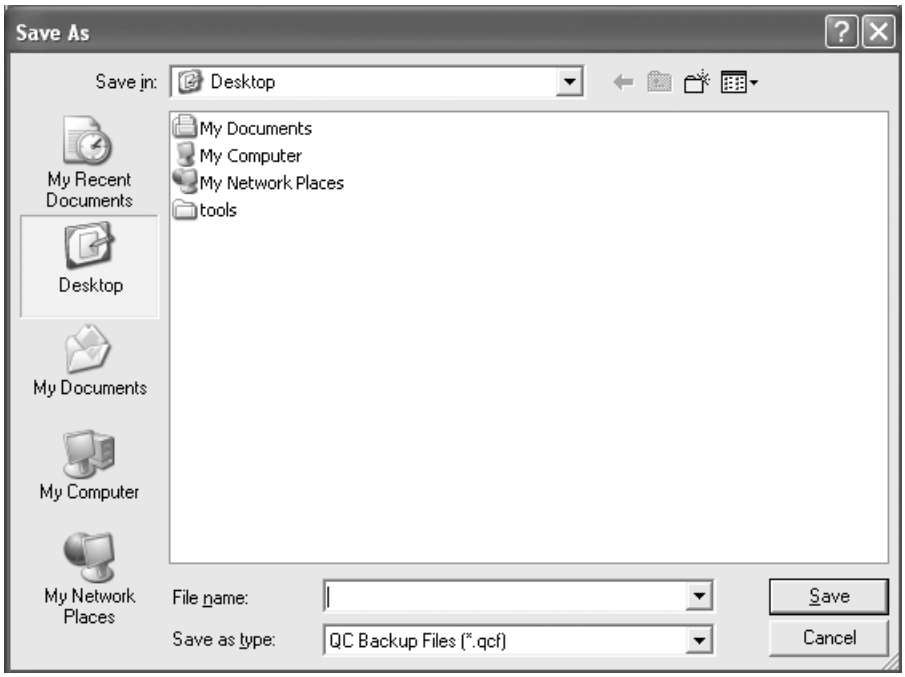
13.Backup

The File Selection screen is displayed to backup lot information and control data. Backup is not available if a user who is not authorized to carry out quality control operations is logged in. The X-barM Control chart cannot be backed up.

Select files to back up on the QC File screen, then follow the method below to perform the backup.

- Select **Control Data (R)** → **Backup (B)** from the menu bar.



- Save As dialog box List of buttons

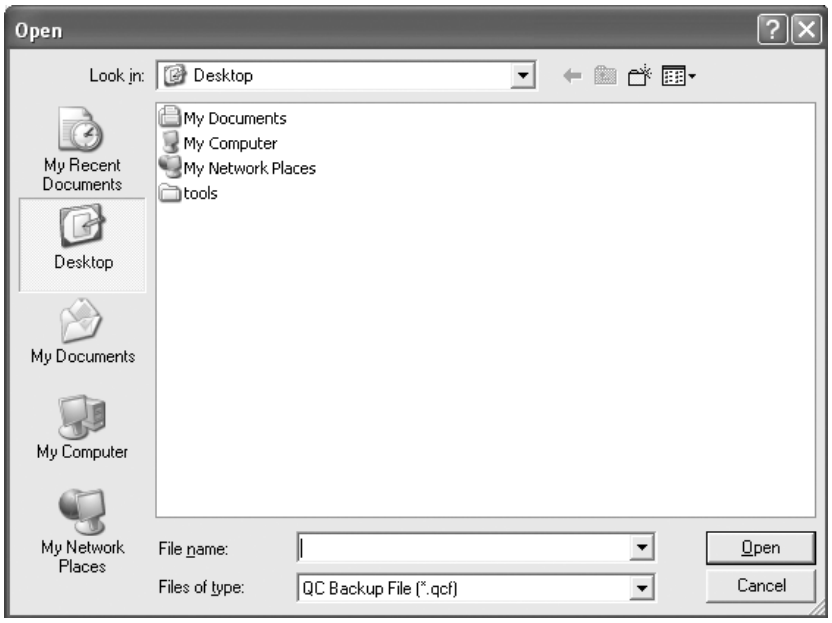
Parameter	Contents
Save	• Specify the file name and destination folder and press the **Save (S)** button. • If a file with that name already exists in that location, the Save As dialog box remains open, and the Overwrite Confirmation dialog box appears. • If there is no file of that name, the QC data is saved to the specified file, and the Save As dialog box closes.
Cancel	• Close the Save As dialog box without saving data.

14.Restore

Read QC data from the QC file specified in the Open File dialog box.

Use one of the methods below to start the Open File dialog box.

- Select the line of the QC file number in the file list of the QC File screen to read data from, then select **Record (R)** → **Restore (R)** from the menu bar.
  * This menu is not available if a user who is not authorized to carry out quality control operations is logged in. Also, if the selected line has already been registered, the menu is disabled and cannot be started.



- Open File dialog box List of buttons

Parameter	Contents
Open	Specify the folder containing the file to read, and the name of the file, then press the **Open (O)** button. Read QC data from the specified QC file, and close the Open File dialog box.
Cancel	Close the Open File dialog box without reading a file.

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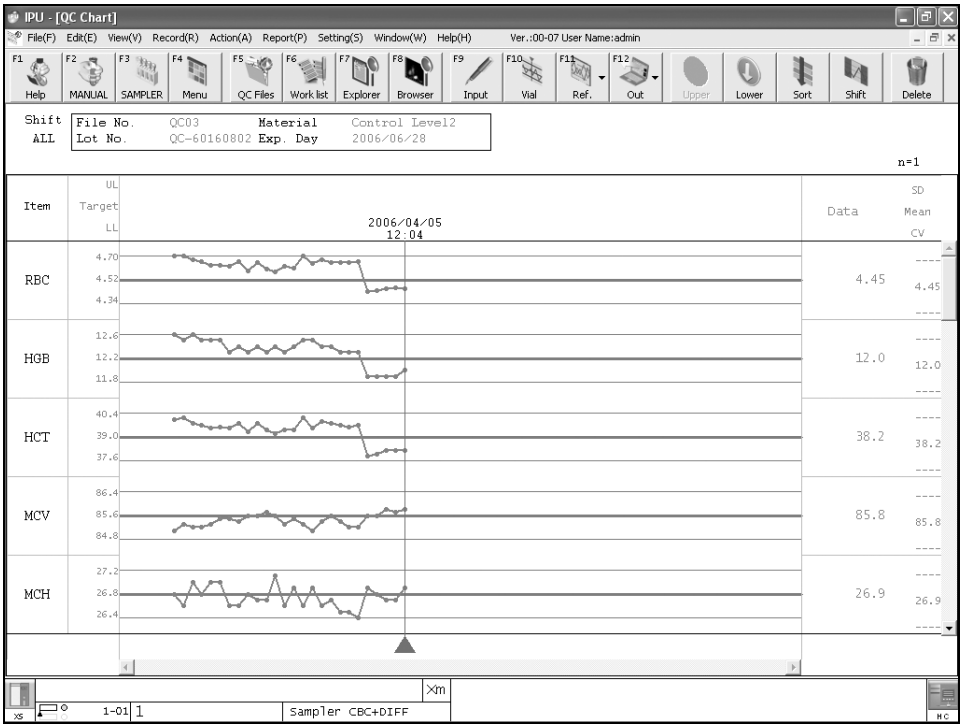
15.QC Chart screen

The QC Chart screen shows the chart for the QC file selected on the QC File screen. One QC file can record and display up to 300 plots. If more are displayed, the excess points are automatically deleted, starting with the oldest.

The QC chart screen is displayed by any of the following procedures:

- Double-click the intended QC file on the QC File screen. (Or press the Enter key)
- Select the intended QC file on the QC File screen, then click the **QC Chart** button on the tool bar.
- Select the intended QC file on the QC File screen, then press the F11 key.

On the QC Chart screen, the QC data from the file selected on the QC File screen is plotted as a time series line graph.
The chart is displayed with blue lines, as shown below.



The QC chart for a different QC file can be displayed superimposed on the current chart by clicking on **Window** → **Ref.** Lines on the superimposed chart are displayed in gray.
At that time, plotted points are only selected from the QC File selected on the QC File screen (the main chart).
Pressing **Vial** from the menu bar can indicate the change of vial to a new one with a blue solid line.
When **Vial** is pressed again on the place where the solid line is displayed, the solid line will disappear. However, this operation cannot be performed in X-barM.

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7.5 Execute QC analysis

Control blood is analyzed by the X-bar or L-J Control program, and the data is stored in a quality control file. Follow the manufacturer's instructions for handling control blood. This section explains how to prepare and handle a quality control file.
For analysis procedure, refer to Chapter 6: 6.11: 2. QC analysis.

1. Creating a quality control file

Create a quality control file (QC file) to save the control data. Input setting parameters with reference to Chapter 7: 7.5: 2. Lot information input, then analyze the control blood.

2. Troubleshooting

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

- If data that exceeds QC limits is displayed with a red background, click on **Graph** in the QC Analysis dialog box to check the analysis data.
  Click on **Accept** in the QC Analysis dialog box to plot the data on the QC chart.
- Check parameters which have recorded errors on the radar chart.
- Check detailed data from the line graph.
- Click on **Cancel** in the QC Analysis dialog box to avoid plotting the data on the QC chart.

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8. Calibration

Calibration is performed to compensate for any reproducible inaccuracies of the system.
The HGB and/or HCT values are corrected by the calibration value.
The initial calibration is carried out by your Sysmex technical representative, at the time of installation. After the initial installation, a customer is requested to perform the calibration when required, and to run a quality control periodically to maintain the accuracy of the instrument system.

8.1 Samples Used for Calibration

For calibration, use five or more samples of fresh normal blood meeting the following conditions:

- Blood of a healthy person who is not taking any medicine;
- Blood added with an appropriate amount of anticoagulant;
- Per-sample whole blood volume to exceed 2 mL;
- HGB value to exceed 10.0 g/dL;
- HCT value to be within 35.5% and 55.5%.

Important!

Control blood is not suitable for calibration. Control blood is specially prepared for quality control, not for calibration.

8.2 Establishing the Reference Values

As reference values for calibration HGB and HCT values are determined by a reference method.

Recommended reference measuring methods:

HGB:	Determination of hemoglobin concentration (DIN 58931)
HCT:	Determination of the concentration of blood corpuscles in blood (DIN 58933)

Important!

Each sample should be analyzed at least three times.
Mark or number the samples and make notes of HGB and HCT values.

8.3 Automatic calibration

In the XS-1000*i*/XS-500*i*, five or more fresh, normal blood samples are used for automatic calibration of HGB and HCT values.

1. Executing the automatic calibration program

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will be displayed.

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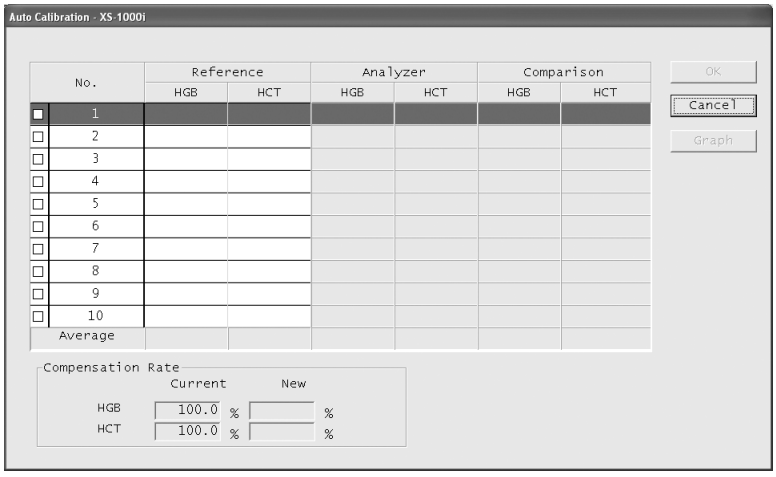
2. Double-click the **Auto Calibration** icon in the Controller Menu.
   The Auto Calibration window will appear.

> **Note:**
>
> Check that the status of the Main Unit is READY.
> If the status of the Main Unit is not READY, the error sound is made and the window will not appear.



3. The following contents are displayed in the Auto Calibration window.

No. Displays the number of the calibration data.

Reference For entering the reference values obtained using the reference method.

Analyzer Displays the data obtained at the Main Unit to be used for automatic calibration.

Comparison Displays the ratios of the reference values to the data obtained at the Main Unit.

Average

- **Reference** Displays the average value of the reference values which were input.
- **Analyzer** Displays the average value of the data analyzed at the Main Unit.
- **Comparison** Displays the average of the ratios of the reference values compose with the data obtained at the Main Unit.

Compensation Rate

- **Current** Displays the current compensation rate.
- **New** Displays the newly-calculated compensation rate.

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2. Reference value input

1. Double-click to select the Reference column to enter values.
   A cursor appears in the selected Reference column.
2. Enter the HGB or HCT reference value obtained by the reference method.
3. To confirm the entered value, press the Enter key or double-click on the next Reference column to enter.

   When one or more reference values of HGB and HCT are set, each average is calculated automatically, and displayed in the Average column of the Auto Calibration window.
   When the sample has been already analyzed, the compensation rate is calculated automatically, and is displayed in the Compensation Rate New column.

3. Analysis

When all reference values have been entered, the instrument is ready for analyzing.

1. Click to select a line in which to display the analysis data.

Important!

If you select a line in which analysis data is already displayed, the displayed data will be overwritten.

2. Carry out the analysis in manual mode. Analyze samples in succession.

Important!

It is important to analyze the sample belonging to the reference value.
The values of the sample to be analyzed are indicated by the underline cursor.

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 Average column of the Auto Calibration window.
   When the values have been already set, the compensation rate is calculated automatically, and is displayed in the Compensation Rate New column.

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4. Exclude

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

a. Exclusion

1. Click the Calibration Data No. checkbox to select. When the box is selected that data is excluded.
   The averages of the reference value, analysis value, and compensation rate will be calculated again and newly displayed.

b. Canceling an Exclusion

1. Click the Calibration Data No. checkbox again to deselect it. When the box is deselected, the excluded data is restored.
   The averages of the reference value, analysis value, and compensation rate will be calculated again and displayed.

5. Updating calibration values

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

1. Click **OK** or **Cancel**.

OK	Applies the compensation rate calculated at automatic calibration to the instrument, makes an addition to the calibration history, and closes the Auto Calibration window.
Cancel	Displays the Cancel Confirmation dialog box. **OK** Cancels changes to the compensation rate, and closes the Cancel Confirmation dialog box and the Auto Calibration window. **Cancel** Closes the Cancel Confirmation dialog box, and returns to the Auto Calibration window.

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Note:

- The compensation rate (%) is calculated as follows:

$$\text{Compensation rate} = \frac{\text{Reference}}{\text{Analyze}} \times 100(\%)$$

- The new compensation rate is calculated as follows:

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

- The OK button is not valid (appears in gray) if the new compensation rate exceeds the allowable range shown below.
  A calibration error is displayed, if
  - the value determined by the analyses exceeds 105% or is less than 95%;
  - the new calibration value exceeds 120% or is less than 80%.
  - 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 must be within 100±20%.

2. Reanalyze the sample used for calibration with the XS-1000*i*/XS-500*i*. Confirm that the analysis value is within the allowable range, and does not vary greatly from the reference values.
   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 blood coagulation, blood cell morphology, patient medicinal use, and aged abnormal blood. If no abnormality is found in the samples, contact your Sysmex service representative.

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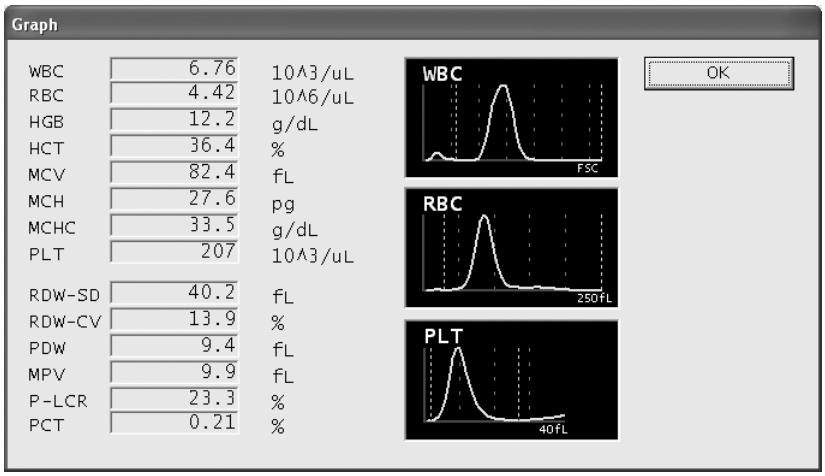
8.4 Displaying the Last Sample Data

1. Click Graph from the Auto Calibration window. The **Graph** display dialog box appears, displaying the newest data obtained by automatic calibration.
2. To close the Graph display dialog box, click **OK** in the dialog box.



8.5 Manual calibration

With manual calibration, calibration can be done by entering HGB and HCT calibration values obtained by calculation.

1. Calculating the Calibration Value

1. Analyze five to ten samples, three times each, by the reference method to obtain the mean HGB and HCT values.
2. Mix the same samples sufficiently and analyze them in manual or manual closed mode with the Main Unit (XS-1000*i*/XS-500*i*).
3. When there is a difference between the data obtained by XS-1000*i*/XS-500*i* analysis and the reference values obtained by the reference method, calculate new calibration values using the following equation:

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

[Example]
Average of HGB values gained by the reference method = 15.6 g/dl
Average of HGB values from XS-1000*i*/XS-500*i* analysis = 15.5 g/dl
Previous calibration value of HGB = 100.0%

Calculation of the new calibration value:
100 x (15.6/15.5) = 100.65% (100.7% rounded off)

The calibration value of HGB has increased by 0.7% and needs to be set at 100.7%.

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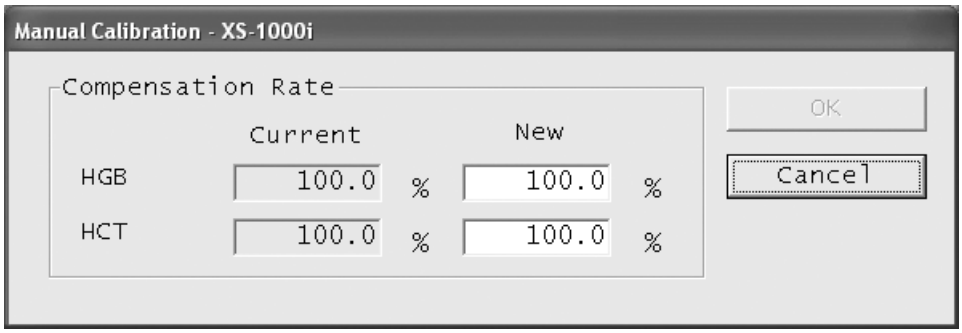
2. Executing the manual calibration program

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will be displayed.
2. Double-click the **Manual Calibration** icon in the Controller Menu.
   The Manual Calibration dialog box will appear.

> **Note:**
>
> Check that the status of the Main Unit is READY.
> If the status of the Main Unit is not READY, the error sound is made, and the dialog box will not appear.



3. The following are displayed in the Manual Calibration dialog box.

HGB

Current	Displays the current calibration value for HGB.
New	Enter a new calibration value for HGB.

HCT

Current	Displays the current calibration value for HCT.
New	Enter a new calibration value for HCT.

3. Entering the Calibration Values

1. Click to select the HGB or HCT **New** column.
2. Enter the new calibration value.

> **Note:**
>
> The entered calibration value can only be in the range of 80.0 to 120.0, and can be entered to one single decimal place.

4. Updating Calibration Values

1. After entering the calibration value, click **OK** or **Cancel**.

OK	Applies the entered calibration value to the instrument, makes an addition to the calibration history, and closes the dialog box.
Cancel	Cancels changes to the calibration value, and closes the dialog box.

Note:

The **OK** button is not valid (appears in gray) if the entered calibration value is not within the range of 80.0 to 120.0.

2. Reanalyze the sample used for calibration with the XS-1000*i*/XS-500*i*. Confirm that the analysis value is within the allowable range, and does not vary greatly from the reference values.
   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 aged blood. If no abnormality is found in the samples, contact your Sysmex service representative.

8.6 Calibration history

The calibration history display screen shows a maximum of 10 calibrations, in the order of occurrence.
The oldest calibration will automatically be deleted if the total number of calibrations exceeds 10.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will be displayed.
2. Double-click the **Calibration History** icon in the Controller Menu.
   The Calibration History screen will be displayed.

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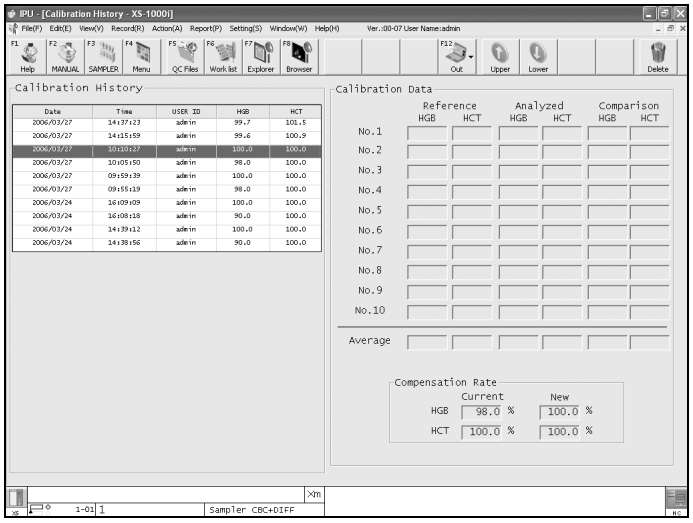
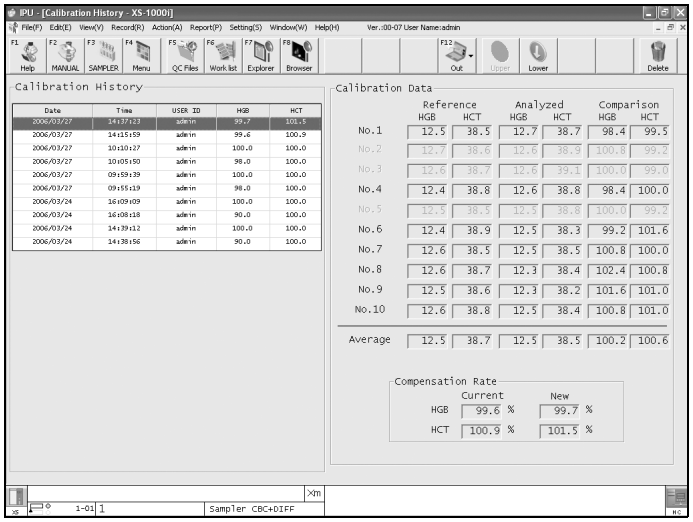
When data of the Manual Calibration is selected, the screen display appears as follows:



When data of the Auto Calibration is selected, the screen display appears as follows:



Analysis data that was excluded from calibration on the Auto Calibration screen is grayed out in the calibration data column.

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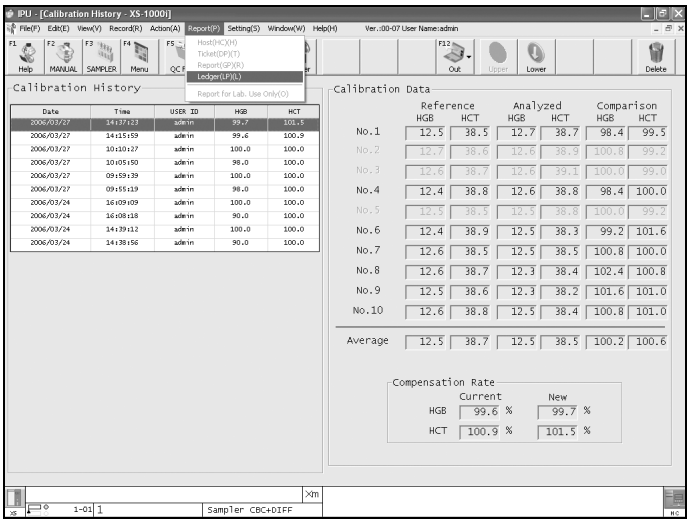
1. Output

Output of data selected in the Calibration history can be carried out.

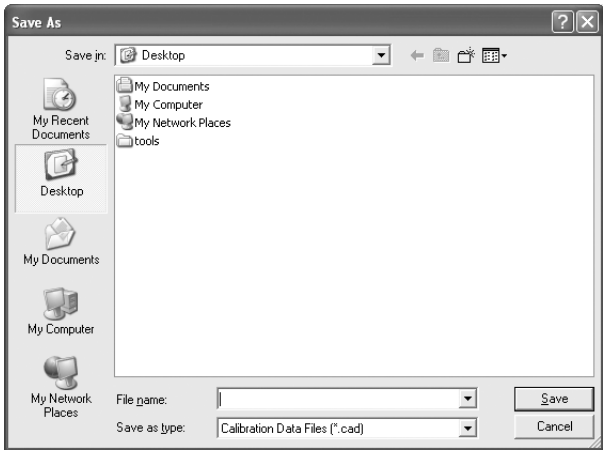


1. Select data to be output from the Calibration History screen.
2. Select **Ledger (LP)** from the **Report** menu bar to start output.
   Ledger (LP) Sends data to connected list printer.

2. Backup

Back up calibration history data in a file.

1. Select data to be backed up on the Calibration History screen.
2. Select **Record** → **Backup** from the menu bar.
3. Backup File Selection dialog box will appear.



4. Click **Save** to backup all the selected calibration history data.
   Click **Cancel** to cancel the backup operation.

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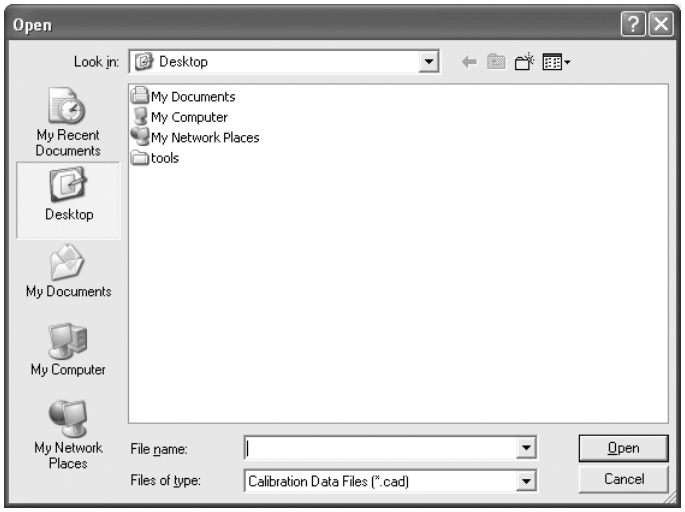
3. Restore

> **Note:**
>
> Restore indicates the calling up of data previously stored.

Restore Calibration history data.

> **Important!**
>
> When over 10 data are restored, the oldest data will be deleted in the order of the analysis date.

1. Select **Record** → **Restore** from the menu bar.
2. The Restore File Selection dialog box will appear.



3. Select the file to be restored.
4. Click **Open (O)** to restore the calibration history data.
   Click **Cancel** to cancel the restore operation.
5. If ten log items have already been recorded, the **Read Confirmation** dialog box appears.

OK	Overwrites the log and the **Read Confirmation** dialog box closes.
Cancel	Cancels to overwrite the log and the **Read Confirmation** dialog box closes.

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4. Delete

Delete calibration history data stored on the hard disk drive.

1. Select data to be deleted from Calibration History list of stored data on the Calibration History screen.
2. Select **Record** → **Delete** from the menu bar, or click the **Delete** button on the toolbar.
3. The Delete Confirmation dialog box will appear.

4. Click **OK** to delete the calibration history data selected in the Calibration History list.
   Click **Cancel** to cancel the delete operation.

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9. Cleaning/Maintenance

This instrument requires regular maintenance if it is to remain in its best condition. Follow the schedule below for maintenance. Make a record of maintenance work performed in the inspection list.

Daily maintenance and inspection points
Run the shutdown process (automatically rinse the detector chamber and dilution line).

Monthly maintenance and inspection points
Running the Monthly Rinse sequence

As-needed maintenance
Replace the waste container (Only if there is a waste container) (See Chapter 9: 9.4: 1)
Drain the waste chamber (See Chapter 9: 9.4: 2)
Automatic Rinsing (See Chapter 9: 9.4: 3)
Clean the waste chamber (See Chapter 9: 9.4: 4)
Remove Air bubbles (See Chapter 9: 9.4: 5)
Clean the flowcell (See Chapter 9: 9.4: 6)
Drain the reaction chamber (See Chapter 9: 9.4: 7)
Drain the RBC isolation chamber (See Chapter 9: 9.4: 8)
Remove an RBC detector clog (See Chapter 9: 9.4: 9)
Clean the RBC detector aperture (See Chapter 9: 9.4: 10)
Rinsing the aspiration unit tray (See Chapter 9: 9.4: 11)

Supplies Replacement
Replace and register reagents (See Chapter 9: 9.5: 1)
Prime reagents (See Chapter 9: 9.5: 2)
Reagent replacement log display function (See Chapter 9: 9.5: 3)
Remaining reagent volume function (See Chapter 9: 9.5: 4)
Replace the piercer (See Chapter 9: 9.5: 5)
Replace the pump (See Chapter 9: 9.5: 6)
Replace fuses (See Chapter 9: 9.5: 7)

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9.1 Maintenance and inspection schedule

The XS-1000*i* and the XS-500*i* require regular cleaning, inspection and maintenance to maintain optimum functionality, so perform maintenance as described in Chapter 9: 9.2 and subsequent sections.

Warning!

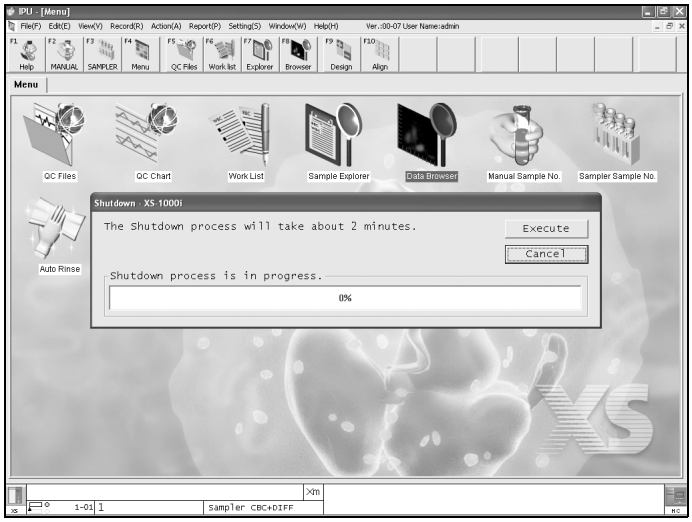
Wear protective garments and gloves for cleaning and maintenance work, to guard against infection and injury. After finishing work, wash your hands.

9.2 Daily maintenance

1. Execution of Shutdown

When shutdown is performed, the detector and dilution line are cleaned. Put the instrument through a shutdown cycle at the end of each day's analyses or at least once every 24 hours if running the instrument continuously.

1. Double-click the **Shutdown** icon on the Menu screen.
   The Shutdown dialog box will appear.



   To cancel shutdown, click **Cancel** on the Shutdown dialog box. The system will return to Ready status.

2. Click **Execute**.
   The shutdown sequence in the Main Unit will start.

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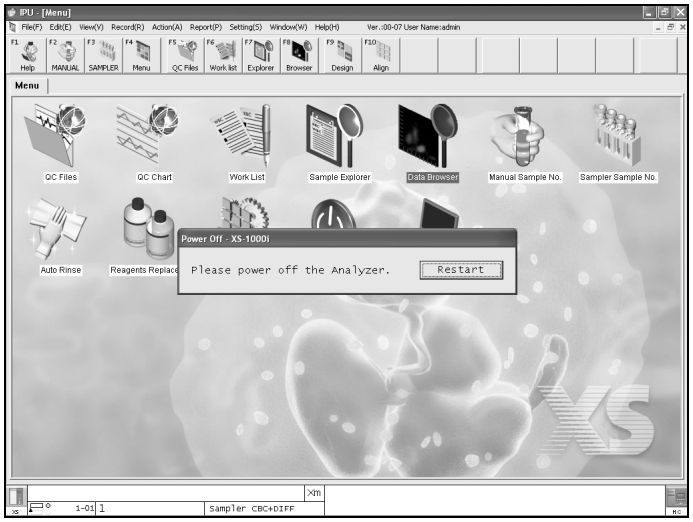
3. After the shutdown sequence is completed, the Shutdown dialog box will be closed and the Power Off dialog box will appear.



4. If you wish to complete the analysis, turn OFF the Main Unit power in the current status.

Note:

- To continue analysis without turning off the power of the Main Unit, click Restart on the Power Off dialog box. The Power Off dialog box will close and the Main Unit will restart.
- When shutting down the Information Processing Unit (IPU), refer to “Chapter 6: 6.12: 3 Closing down the Information Processing Unit (IPU).”

9.3 Monthly maintenance

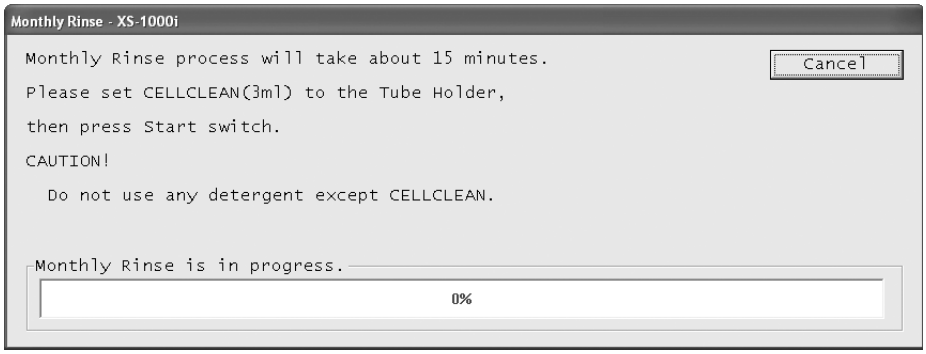
Carry out Monthly maintenance every month, or after every 1,200 analyses.

1. Running the Monthly Rinse sequence

Monthly Rinse runs the Monthly Rinse sequence to wash contaminants from the optical detector block flowcell. The **Monthly Rinse** dialog box appears during the Monthly Rinse sequence.

1. Double-click on the **Controller** icon on the menu screen to display the **Controller** menu.
2. Double-click on the **Maintenance** icon on the **Controller** menu.
   The Maintenace screen appears.
3. Select the **Monthly Rinse** icon on the **Maintenance** screen, then double-click or press the Enter key.
   The Monthly Rinse dialog box will appear.

4. Follow the on-screen prompts to set CELLCLEAN and then press the Start switch to run the Monthly Rinse sequence.
   However, the sequence is only enabled when the instrument is in Ready status. If a process is attempted while the Main Unit is in any other status, the error warning will be sounded at the Main Unit and the screen for the sequence will not open.



   * The screen is for the XS-500*i*. For the XS-1000*i*, the pipette will be the sample position.

5. The Power Off dialog box opens automatically once the Monthly Rinse sequence is complete.
   The dialog closes automatically when the Main Unit power supply is turned off. Click on the Restart button to restart the main unit.

Note:

- The method for CELLCLEAN aspiration differs between the XS-1000*i* and the XS-500*i*.
- The XS-500*i* uses the manual mode procedure to aspirate CELLCLEAN from sample tubes and using the correct adapter.
- When using a XS-1000*i* or XS-1000*i* with Sampler, use the manual mode procedures to dispense CELLCLEAN (3 mL or more) into sample tubes with the caps off, and aspirate through the correct adapter.

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9.4 As-needed maintenance

1. Replace the waste container (only if the instrument has a waste container)

Risk of infection

When replacing the waste container, always wear protective garments and gloves. After replacing, wash hands.
If your hands are contaminated by the waste, there is a risk of infection.

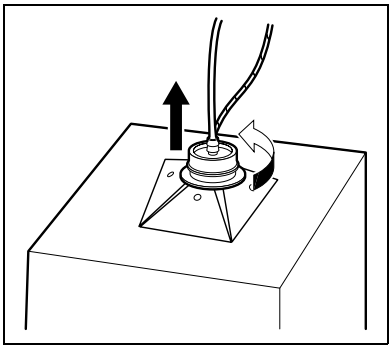
Caution!

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

a. 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. Prepare an empty waste container and remove the cap.
2. Remove the cap of the full waste container, and pull the cap straight up keeping the tube connected.



3. Insert the cap with the tubes into a new waste container, and tighten the cap.

b. When an empty container is used as the waste container

1. Turn OFF the Main Unit power and wait for several minutes.
2. Prepare an empty waste container and remove the cap.
3. Remove the tube from the full waste container.

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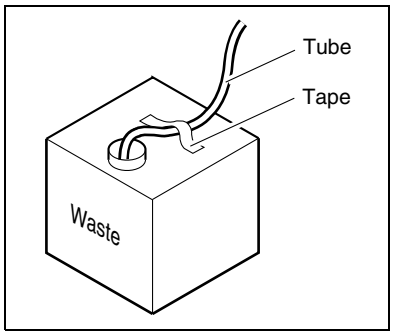
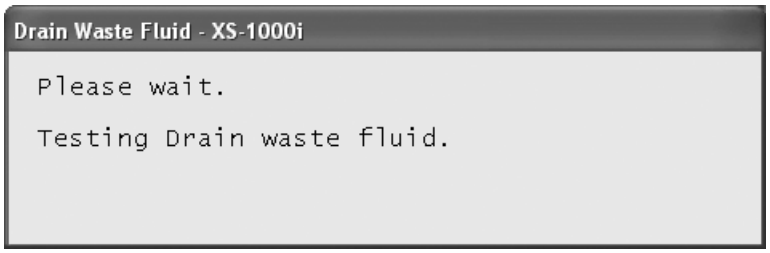
4. Insert the tube into the new waste container, and fasten it in place with tape etc.



2. Drain Waste Fluid

When draining the waste chamber, the waste chamber drainage sequence can be run to drain accumulated waste out of the waste chamber. The Drain Waste Fluid dialog box is displayed while the sequence is running.
Select the Drain Waste Fluid icon on the Maintenance screen and double-click it (or press the Enter key) to run the waste chamber drainage sequence.
For the sequence to run, the instrument must be in Ready status. If a process is attempted while the Main Unit is in any other status, the error warning will be sounded at the Main Unit and the screen for the sequence will not open.

- Drain Waste Fluid dialog box
  This indicates that the waste chamber drainage sequence is in progress. The Drain Waste Fluid dialog box is displayed while the waste chamber drainage sequence is running. It closes once the waste chamber drainage sequence is complete.



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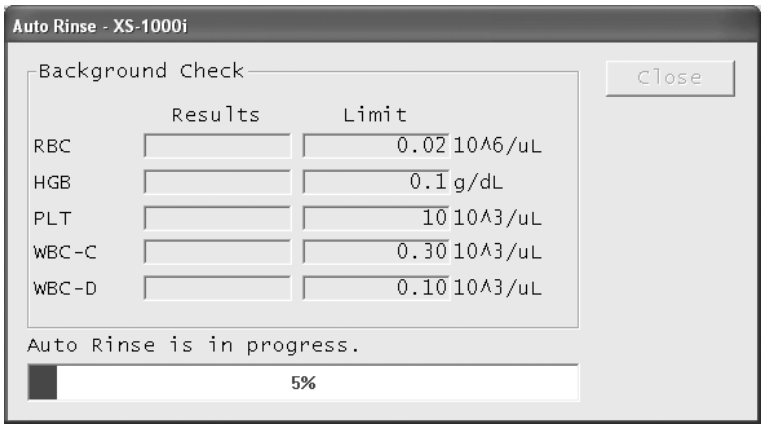
3. Auto Rinse

Select the Auto Rinse icon on the Maintenance screen (double-click the icon or press the Enter key), to start the Auto Rinse dialog box.



Background check	Displays the background value after automatic rinsing is complete. If the background value is higher than the allowable background level, that parameter is displayed with a red background.
Auto Rinse is in progress.	The progress of the auto rinse sequence is displayed.
Close	Close the Auto Rinse dialog box.

4. Waste chamber rinsing

The waste chamber rinse sequence can be run to rinse the chamber. The Rinse Waste dialog box is displayed while the rinse sequence is running.
Select the Rinse Waste icon on the Maintenance screen and double-click it (or press the Enter key) to display the Rinse Waste dialog box, and follow the on-screen prompts to set CELLCLEAN and then press the Start switch.
If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.

- Rinse Waste dialog box
  This indicates that the waste chamber is being rinsed. The Rinse Waste dialog box is displayed while the waste chamber rinse sequence is running. It closes automatically once the waste chamber rinse sequence is complete.

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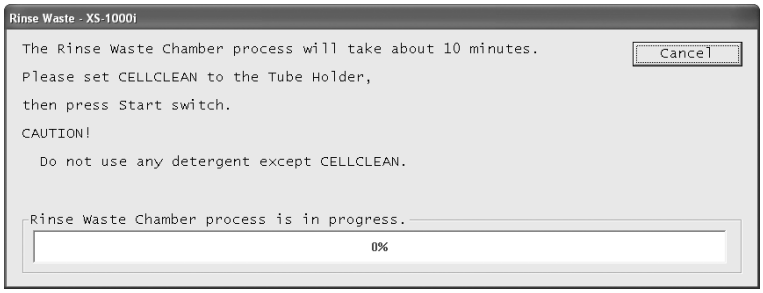


* The screen is for the XS-500*i*. For the XS-1000*i*, the pipette will be the sample position.

Cancel Close the Rinse Waste dialog box without running the rinse sequence. This operation is not available while sthe waste chamber rinse sequence is running.

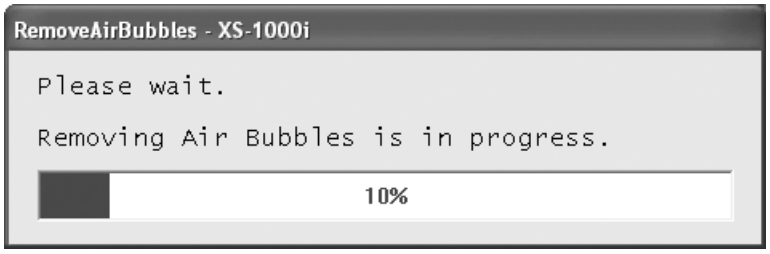
Note:

- The method for CELLCLEAN aspiration differs between the XS-1000*i* and the XS-500*i*.
- The XS-500*i* uses the manual mode procedure to aspirate directly through the probe.
- When using a XS-1000*i* or XS-1000*i* with Sampler, use the manual mode procedures to dispense CELLCLEAN (3 mL or more) into sample tubes with the caps off, and aspirate through the correct adapter.

5. Remove Air Bubbles

The flowcell air bubble removal sequence can be run to remove air bubbles from the flowcell. The Remove Air Bubbles dialog box appears during the flowcell air bubble removal sequence.
Select the Remove Air Bubbles icon on the Maintenance screen and double-click it (or press the Enter key) to run the flowcell air bubble removal sequence.
If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.

- Remove Air Bubbles dialog box
  This indicates that the flowcell air bubbles removal sequence is in progress. The Remove Air Bubbles dialog box appears during the flowcell air bubbles removal sequence. It closes once the flowcell air bubbles removal sequence is complete.



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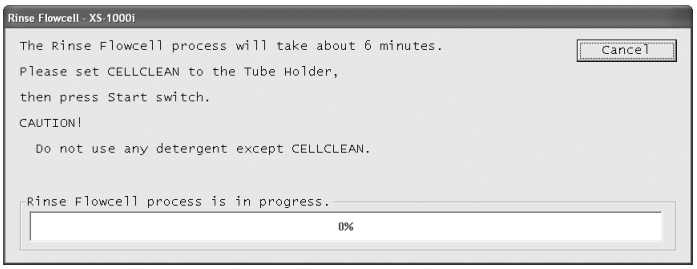
6. Rinse Flowcell

The flowcell rinse sequence can be run to wash contaminants from the optical detector block flowcell. The Rinse Flowcell dialog box appears during the flowcell rinse sequence.
Select the Rinse Flowcell icon on the Maintenance screen and double-click it (or press the Enter key) to display the Rinse Flowcell dialog box, and follow the on-screen prompts to set it to Rinse Flowcell dialog box and then press the Start switch.
If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.

- Rinse Flowcell dialog box
  This indicates that the flowcell rinsing sequence is in progress. The Rinse Flowcell dialog box appears during the flowcell rinsing sequence. It closes automatically once the flowcell rinse sequence is complete.



* The screen is for the XS-500*i*. For the XS-1000*i*, the pipette will be the sample position.

Cancel Close the Rinse Flowcell dialog box without running the rinse sequence.

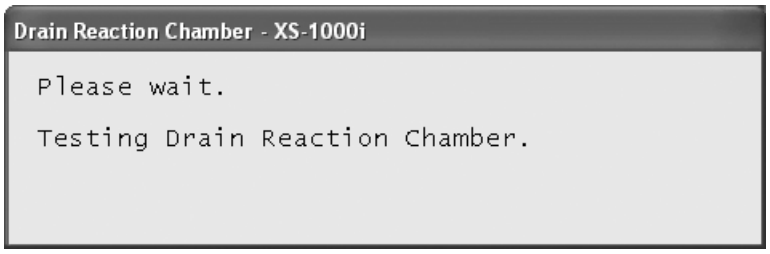
Note:

- The method for CELLCLEAN aspiration differs between the XS-1000*i* and the XS-500*i*.
- The XS-500*i* uses the manual mode procedure to aspirate directly through the probe.
- When using a XS-1000*i* or XS-1000*i* with Sampler, use the manual mode procedures to dispense CELLCLEAN (3 mL or more) into sample tubes with the caps off, and aspirate through the correct adapter.

7. Drain Reaction Chamber

The reaction chamber drainage sequence can be run to drain accumulated reagents out of the reaction chamber. The Drain Reaction Chamber dialog box is displayed while the sequence is running.
Select the Drain Reaction Chamber icon on the Maintenance screen and double-click it (or press the Enter key) to run the reaction chamber drainage sequence.
If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.
If analysis are not going to be done after completing this, run the Auto Rinsing.

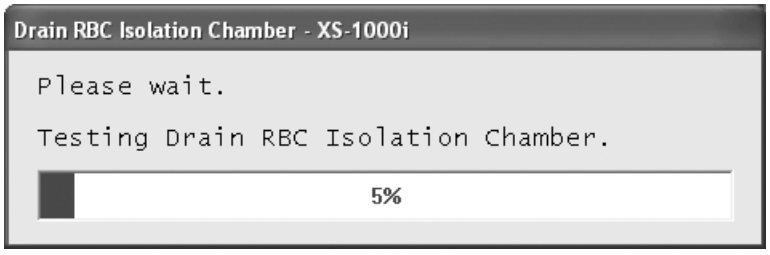
- Drain Reaction Chamber dialog box
  This indicates that the reaction chamber drainage sequence is in progress. the Drain Reaction Chamber dialog box is displayed while the reaction chamber drainage sequence is running. it closes automatically once the reaction chamber drainage sequence is complete.



8. Drain RBC Isolation Chamber

The RBC isolation chamber drainage sequence can be run to drain accumulated reagents out of the RBC isolation chamber. The Drain RBC Isolation Chamber dialog box is displayed while the sequence is running.
Select the Drain RBC Isolation Chamber icon on the Maintenance screen and double-click it (or press the Enter key) to run the RBC isolation chamber drainage sequence.
If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.

- Drain RBC Isolation Chamber dialog box
  This indicates that the RBC isolation chamber drainage sequence is in progress. The Drain RBC Isolation Chamber dialog box is displayed while the RBC isolation chamber drainage sequence is running. It closes automatically once the RBC isolation chamber drainage sequence is complete.



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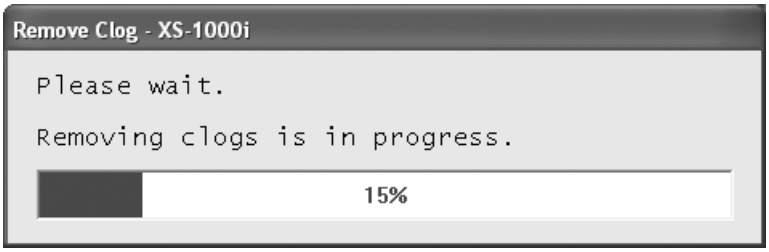
9. Remove Clog

RBC detector clogs can be removed by running the RBC detector clog removal sequence. The Remove Clog dialog box is displayed while the sequence is running. Select the Remove Clog icon on the Maintenance screen and double-click it (or press the Enter key) to run the clog removal sequence.
If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.

- Remove Clog dialog box
  This indicates that the RBC detector clog removal sequence is in progress. The Remove Clog dialog box is displayed while the RBC detector clog removal sequence is running. It closes automatically once the RBC detector clog removal sequence is complete.



10.RBC Detector Aperture Cleaning

If clogging of the aperture cannot be removed by executing the Clog Removal sequence, clean the RBC detector aperture by the following procedure.

Risk of infection

When cleaning the aperture, always wear protective garments and gloves. After completion of the operation, wash your hands.
If your hands are contaminated by the liquid, there is a risk of infection.

Warning!

Never touch the detector when the power of the Main Unit is turned ON.
You could suffer an electrical shock.

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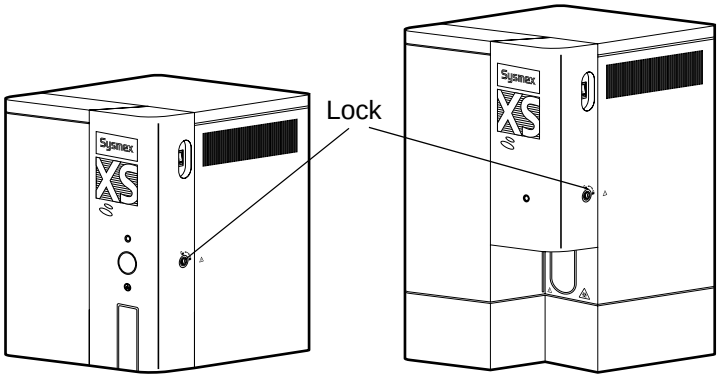
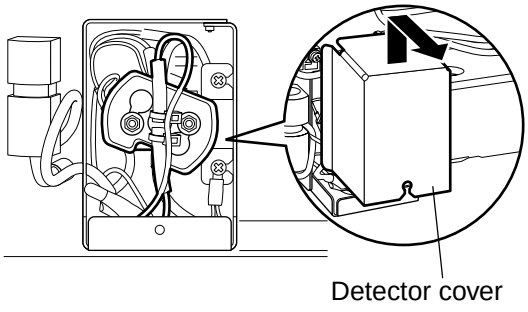
Caution!

- Place a cloth underneath the detector chamber when removing the sheath nozzle to collect any reagent leaking from the detector chamber.
  Spilled diluent could cause ground faults and electrocution.
- As a sheath nozzle is easy to break, do not drop 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.
  Failure to do so may prevent correct analysis.
- Be sure to use CELLCLEAN only.
- When closing the detector cover, take care not to kink the tube.
  Failure to do so may prevent correct analysis.
- When using the transducer brush provided to clean the aperture, poke the aperture gently. Excessive force will damage the aperture.

1. Shut down the instrument and turn OFF the Main Unit power.
2. Use the flathead screwdriver to turn the lock to the left and remove the right side cover.



3. Remove the pin that fastens the RBC detector cover, then remove the cover.



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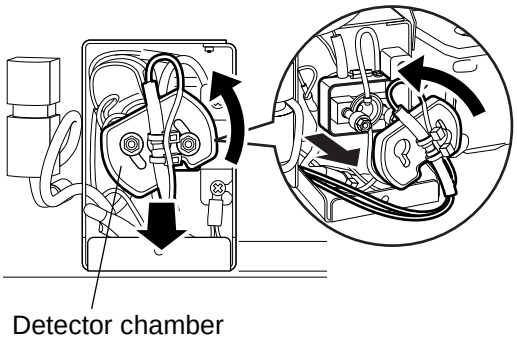
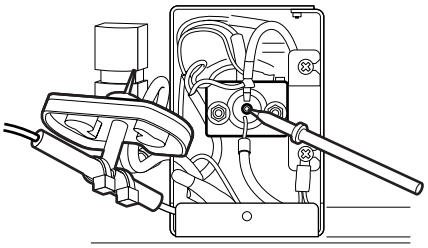
4. Turn the lid of the detector chamber to the left to remove it.



5. Apply CELLCLEAN to the transducer brush provided, and clean by tabbing the brush against the aperture gently.



Note:

- Use a tissue to wipe up spilled cleaning fluid.
- After using the brush, wash it in water thoroughly to remove CELLCLEAN before storing it.

6. Turn the lid of the detector chamber to the right to relock it in place.
7. Close the detector cover and tighten its fixing screw. Then close the Main Unit right side cover.
8. Turn on the power of the Main Unit.
9. Background check starts automatically. Make sure that all background values are within tolerance.

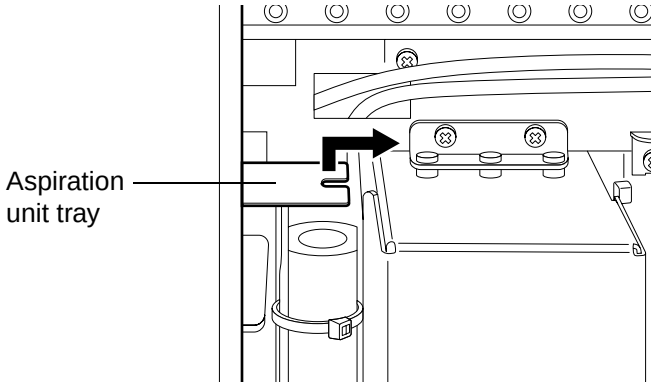
11.Cleaning the aspiration unit tray

If the aspiration unit tray is dirty, clean it according to the procedure below.

Risk of infection

Always wear protective garments and gloves when cleaning the aspiration unit tray. After you have finished cleaning it, wash your hands.
Contact with blood etc. could cause infection with pathogens etc.

1. Run a shutdown from the menu screen according to the “Execution of Shutdown” procedure.
2. Turn off Main Unit power.
3. After opening the right side cover, lift and pull the aspiration unit tray out.



4. Use tap water or alcohol to clean the tray.
5. Check that no dirt remains, then dry the tray.
6. Mount the aspiration unit tray in position and close the right side cover.

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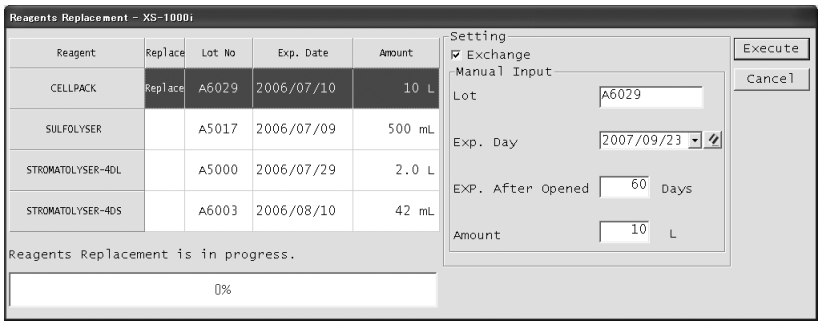
9.5 Supplies Replacement

1. Replace and register reagents

If a reagent amount runs low during analysis, the instrument stops automatically after completing the last analysis and the Help dialog box opens. The error messages below are displayed on the Error List. Replace only the indicated reagent with new reagent. After replacement, execute the reagent replacement sequence for the according reagent from the Reagents Replacement dialog box.

Error Message	Reagent for replacement
Replace Container CELLPACK(EPK)	CELLPACK
Replace Container STROMATOLYZER-4DL(FFD)	STROMATOLYSER-4DL
Replace Container STROMATOLYZER-4DS(FFS)	STROMATOLYSER-4DS
Replace Container SULFOLYSER(SLS)	SULFOLYSER

1. Select the **Reagents Replacement** icon on the **Maintenance** screen, double-click or press the Enter key to start the Reagents Replacement dialog box.
   If the Main Unit is not in Ready status or Sampler Analysis status, the error warning will sound from the Main Unit and the screen for the sequence will not open.



2. Next, input the parameters as shown in the table.

Parameter name	Meaning	Explanation
Reagent information		
Reagent	Reagent name	
Replace	If a reagent is subject to replacement, “Replace” is displayed by it.	The selections of reagents subject to replacement (checked in the boxes) or not (unchecked) can be switched using the check boxes displayed under the setting items. If the reagent information was input using a hand-held barcode reader, or if it was input manually, the reagent is automatically set as subject to replacement.
Lot No.	Registered lot No.	
Exp. Date	The limit of use for the registered reagents.	Displayed in the date display format set in the Date Format settings. The expiry date is displayed.
Amount	Displays the remaining amount of the registered reagents.	For reagents which include the dye and bottle as a set, the display indicates the volume in the bottle.
Manual Setting		
Lot	Registered lot No.	
Exp. Day	The limit of use for the registered reagents.	
EXP. After Opened	Period of validity after opening.	Input the period of validity after opening, in days.
Amount	Content volume. Displays the current remaining volumes of each reagent when the screen opens.	For reagents which include the dye and bottle as a set, the display indicates the volume in the bottle.
Reagent replacement progress		
Reagents Replacement is in progress.	Indicates the progress of reagent replacement.	Displays at the same time as the progress bar that was displayed on the Reagents Replacement screen.

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3. Click **Execute** or **Cancel**.

Execute Registers reagent information. Also, the reagent subject to replacement is aspirated.
Once the reagent replacement sequence is complete, the Reagents Replacement dialog box closes automatically.

Cancel Delete all of the entered information and return to the previous screen.

- Input from a handy bar code reader
  Bar code input can be used by reading the bar code on the reagent container. However, if the expiration date has passed, or if anything other than the reagent barcode was read, the following dialog box appears and the information is not input. In either case, press the Accept button to close the dialog.

  • If the expiration date has passed

  • If a bar code other than the reagent bar code was read

a. CELLPACK, SULFOLYSER and STROMATOLYSER-4DL (FFD) Replacement Procedure

Caution!

- Use a 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 in the package insert.
  Failure to do so may prevent correct analysis.
- When replacing the reagent container, take care not to have dust, etc. adhere to the container dispenser set.
  Failure to do so may prevent correct analysis results.
- After unpacking, take care to prevent entry of dirt, dust and bacteria.
  Failure to do so may prevent correct analysis.
- Be careful not to touch, or allow dirt to adhere, to any tube that will enter a reagent. If there is such contaminant on the tube, wash it off with reagent and then attach the tube.
  Failure to do so may prevent correct analysis.
- Do not spill reagent. If reagent does spill, wipe off immediately with a wet cloth. The floor could be stained.

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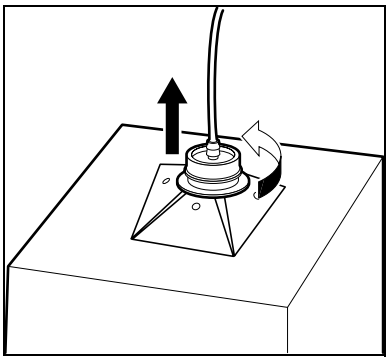
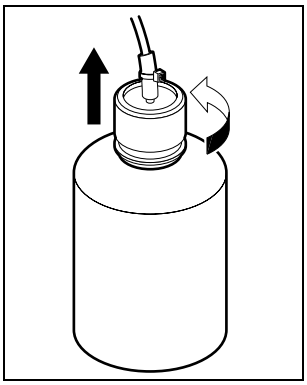
1. Prepare a new reagent and make sure its expiration date has not expired.
2. Remove the cap from the new reagent container.
3. Remove the cap of the empty reagent container, and pull the dispenser kit straight out.





4. Insert the dispenser kit straight into the new reagent container and tighten the cap.
5. Open the Reagents Replacement dialog box and execute the Reagent Replacement sequence.
   For details about the Reagent Replacement dialog box, see Chapter 9: 9.5: 1. Replace and register reagents.

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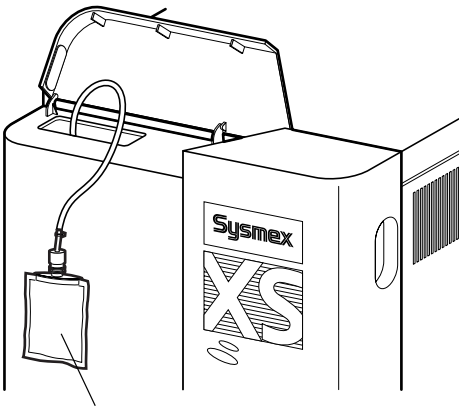
b. STROMATOLYSER-4DS (FFS) Replacement Procedure

Important!

The STROMATOLYSER-4DS must be replaced every 1,200 analyses, and a replacement message will appear accordingly.
Always click OK after replacing the STROMATOLYSER-4DS.

1. Prepare a new reagent and confirm that its expiration date has not expired.
2. Open the cover.
3. Remove the empty STROMATOLYSER-4DS bag from the holder.
4. Remove the cap of the empty STROMATOLYSER-4DS bag, and pull the probe out straight up.
5. Open the cap of new STROMATOLYSER-4DS bag, insert the probe straight in, and close the cap.
6. Insert it fully into the holder.
7. Close the cover.
8. Open the Reagents Replacement dialog box and execute the Reagent Replacement sequence.
   For details about the Reagent Replacement dialog box, see Chapter 9: 9.5: 1 Replace and register reagents.

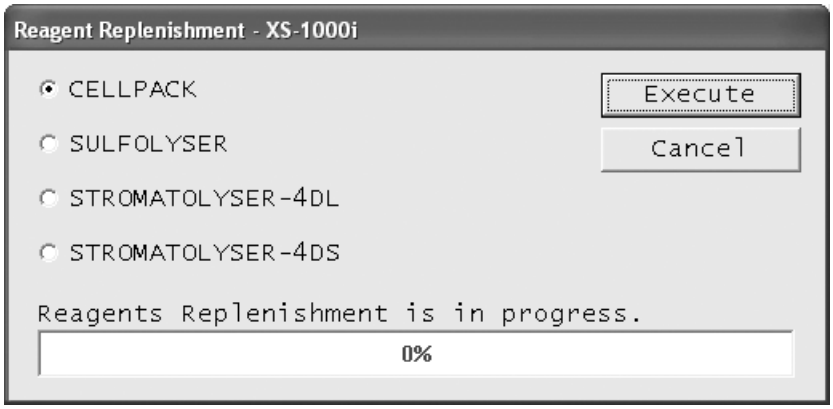


STROMATOLYSER-4DS

2. Replenishing reagents

Select the reagent from the **Reagent Replenishment** dialog box to replenish it.

1. Select the **Reagent Replenishment** icon on the **Maintenance** screen, then double-click or press the Enter key to start the **Reagent Replenishment** dialog box.
   If the Main Unit is not in Ready status, the error warning will sound from the Main Unit and the screen for the sequence will not open.



2. Click on **OK** or **Cancel**.
   OK Replenish the selected reagent.
   Cancel Reagent replenishment is canceled and the Reagents Replenishment dialog box is closed.
   Reagents Replenishment is in progress
   The progress of the reagent replenishment sequence is displayed.

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3. Reagent replacement log display function

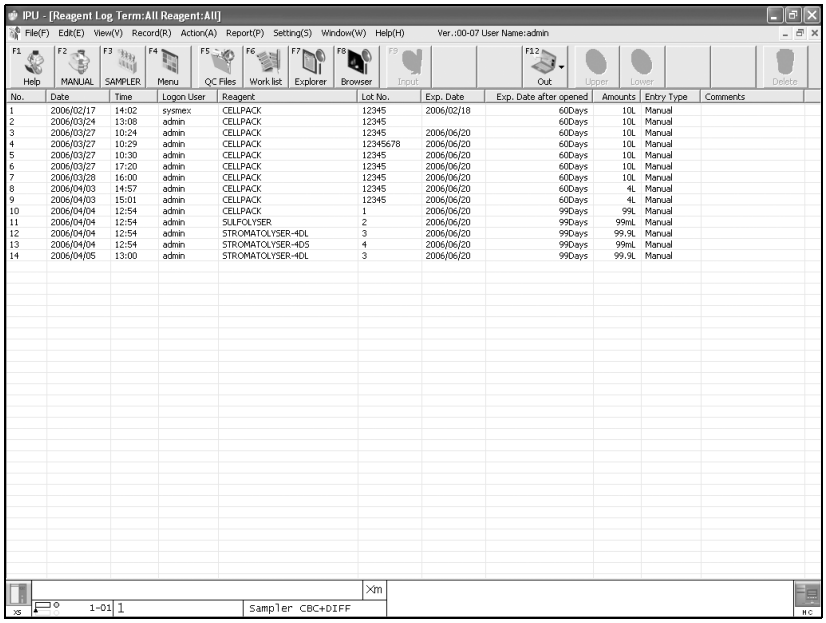
This function displays the replacement history for the reagents registered with the reagent registration function. Comments can be added to the data stored in the reagent replacement log. The log information can be printed out using a Ledger printer and output in a csv file.

a. Displaying the reagent replacement log screen

Reagent Replacement Log Screen can display and delete the reagent replacement log of up to 1000 reagents at maximum that are saved on the hard disk drive.

> **Important!**
>
> When the number of reagent replacement log exceeds 1000, 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.



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No. Sequential numbers beginning with 1.

Date Displays the date when the new reagent was registered.

Time Displays the time when the new reagent was registered.

Logon User
Displays the name of the user who was logged-on to the Main Unit when the new reagent was registered.

Reagent Displays the registered reagents in their “reagent name (abbreviated)” format.

Lot No. Displays the lot numbers of the registered reagents.

Exp. Date
Displays the expiry dates of the registered reagents.

Exp. Date After Opened
Displays the expiry date of the registered reagents after each reagent is opened.

Amounts
Displays the amounts of the registered reagents.

Entry Type
Displays the methods used to register the reagents.
Barcode Entered by reading from barcode.
Manual Entered manually.

Comments
Displays comments concerning the registered reagents.

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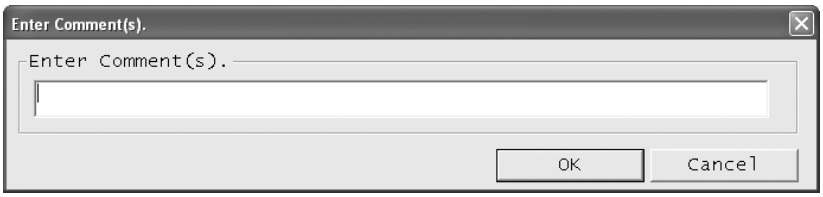
b. Entering comments

Comments concerning the registered reagents can be entered.

> **Important!**
>
> 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 less. The comments which had already been entered are not displayed in the dialog box.

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.
4. After entering the comment, click **OK** button or **Cancel** button.
   OK The entered comment is saved and the dialog box is closed.
   Cancel The entered comment is deleted and the dialog box is closed.

c. Deleting

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** on the **Record** menu, or press the Delete key.
3. The Confirm Delete dialog box appears.

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

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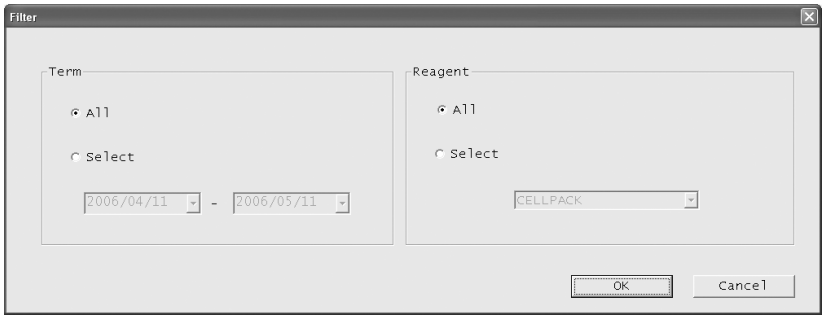
d. Filter

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

1. Select **Filter** on the **Record** menu of the Reagent Replacement Log screen.
2. The current filter conditions are displayed in the Filter dialog box.



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

Term

Parameter	Contents
All	The reagent replacement records saved for all terms are displayed.
Select	The reagent replacement records for the selected term are displayed. Enter the dates to select in the edit boxes.

Important!

The older of the two dates can be entered in either the right or left columns when selecting a term.
A check is made of the entered dates when the cursor is moved away from the column. 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

Parameter	Contents
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.

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4. After setting the filter conditions, click **OK** button or **Cancel** button.
   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.

e. 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** menu to print.

Note:

- The contents to be printed are linked with the filter. Therefore, the records currently displayed are printed.
  If a comment has been entered, it is printed on the following line.
- In case a Graphic Printer (GP) is connected to the instrument, you can only print out the Reagent Replacement Log by selecting the “Ledger (LP)”.

f. Output data in csv file format

Reagent Replacement Log can be output in a csv file format.

Important!

The system uses C:\ drive. It is recommended to save files to a drive other than C:\ where available.
When C:\ drive (system drive) storage capacity is reaching the drive's 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 file data can be retrieved using spreadsheet software commercially available supporting csv file format.

1. Select **csv File Output** in the **Record** menu on Reagent Replacement Log Screen.
2. Saving dialog box appears.
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 **Save** to save the Reagent Replacement Log in the csv file format.
   Click **Cancel** to cancel the save.

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.

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4. Remaining reagent volume function

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

Important!

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.
If a partially-used reagent is set, manually enter the reagent container volume.
The remaining reagent volume should be used as a guide only.

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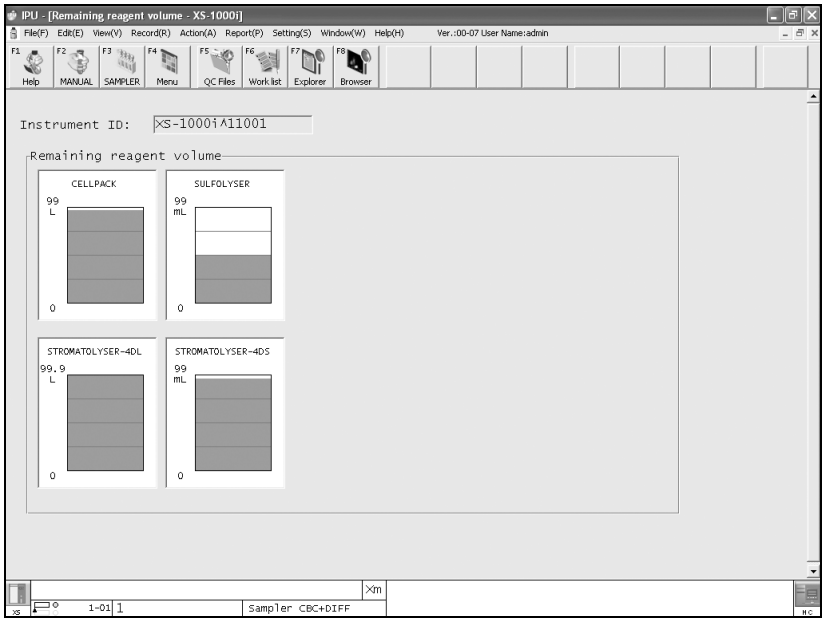
a. Remaining reagent volume screen

The remaining reagent volume can be checked with the Remaining Reagent Volume screen.

1. Double-click the **Controller** icon from the Menu screen to display the Controller menu.
2. Double-click the **Remaining Reagent Volume** icon on the Controller menu. The Remaining Reagent Volume screen appears.

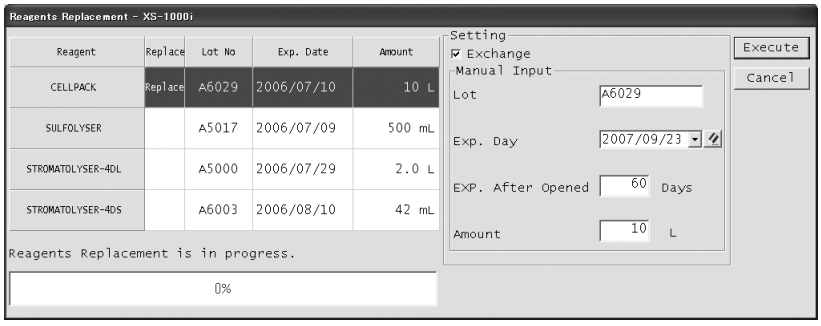


b. Display of the remaining reagent volume on reagents replacement screen

The remaining reagent volume can be checked with the Reagents Replacement screen.

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.

This function does not make insufficient reagent errors. Insufficient reagent errors are detected by sensors and predetermined analysis cycles.

[Example of amount display]

For STROMATOLYSER-4DL:

2.0 →1.8 →1.6 → … →0.4 →0.2 → < 0.2

Reagent name	Display units	Reduction units	Reagent volume*1
CELLPACK	** L	1 L	10 L
SULFOLYSER	*** mL	50 mL	500 mL
STROMATOLYSER-4DL	**.* L	0.2 L	2.0 L
STROMATOLYSER-4DS	*** mL	5 mL	42 mL

*1 The reagent volume listed above are defaults. The volume may differ from the reagent size currently being used.

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5. Piercer replacement

- XS-1000*i*

It is recommended to replace the piercer when the number of the piercings reaches 30,000 cycles. When the piercing operation count exceeds 30,000 cycles, the message "**Replace Piercer**" appears.

Risk of infection

When replacing the probe, use biohazard precautions. After completion of the operation, wash your hands. If your hands become contaminated, there is a risk of infection.

Note:

When piercing has exceeded 30,000 cycles, the piercer needle tip will wear down, potentially breaking or causing other problems. It is recommended to replace the piercer when the number of the piercing reaches 30,000 cycles.
However, depending on the blood collection tubes and conditions, the piercer could wear out before reaching 30,000 cycles.

a. Removing and installing the piercer

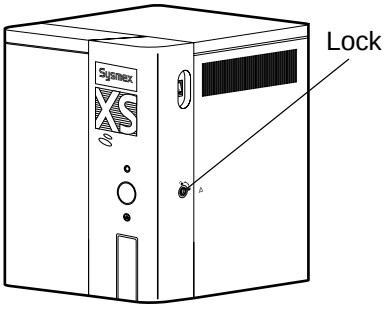
Important!

Another tube is fitted inside one of the tubes. The replacement part of this inner tube is attached to the new piercer set. Remove the inner tube together with the outer tube.

b. Procedures for replacing the piercer

Prepare a No.7 piercer/probe set (consumable part).

1. Shut down the instrument and turn OFF the Main Unit power.
2. Use the flathead screwdriver to turn the lock to the left and remove the right side cover.



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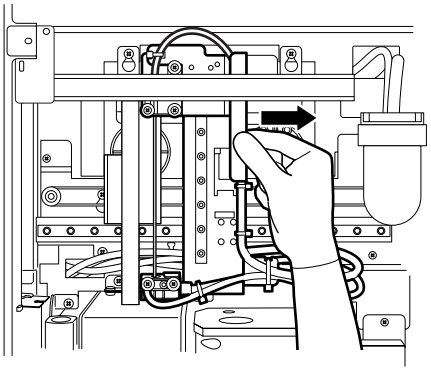
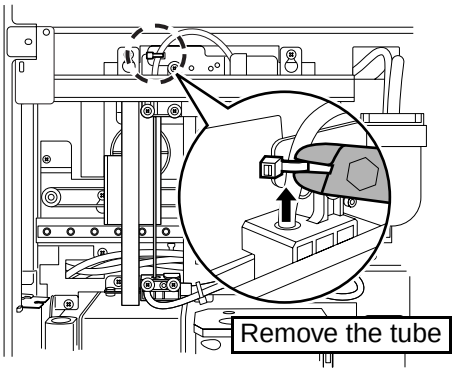
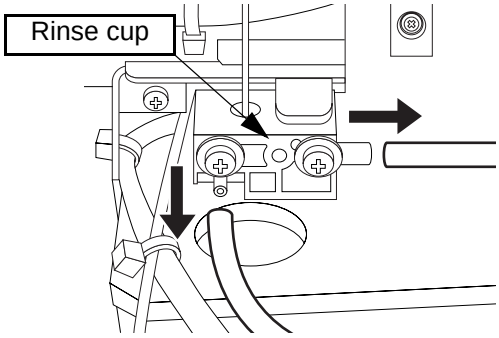
3. Move the piercer by hand to a position so it is easy to work on it.



4. Cut the tie wrap holding the tube sticking out from the top of the piercer and remove the tube.



5. Cut the tie wraps off the tubes from the rinse cup (bottom of piercer) tube in 2 places, then disconnect the tubes.



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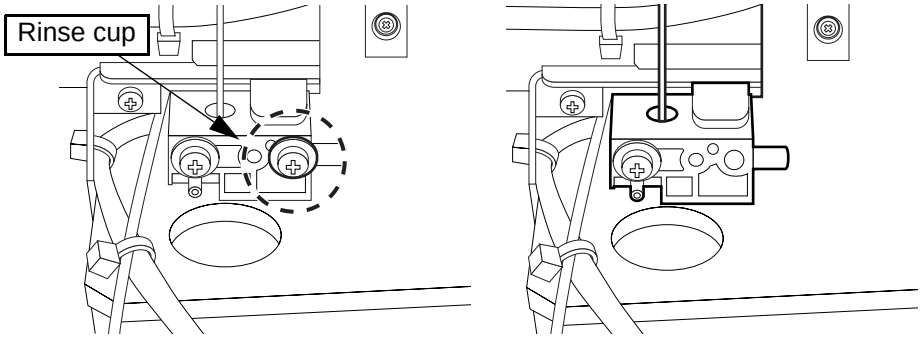
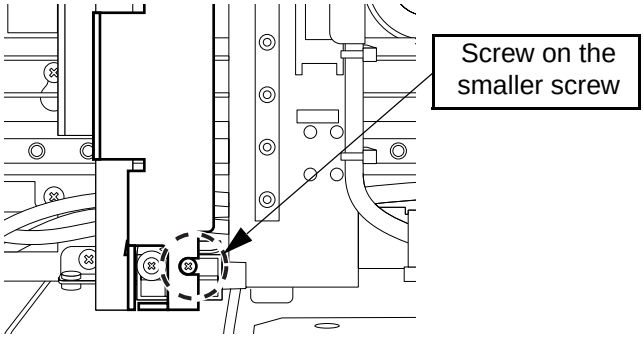
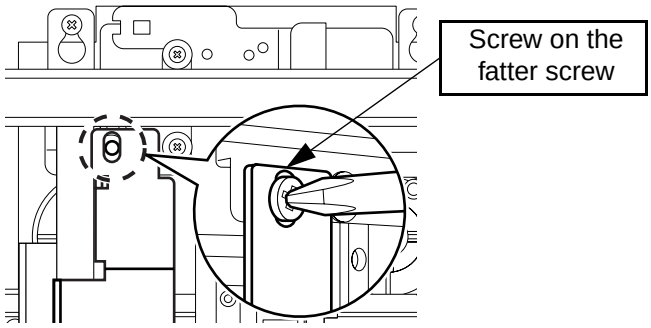
6. Remove the screws on the right side of the rinse cup.



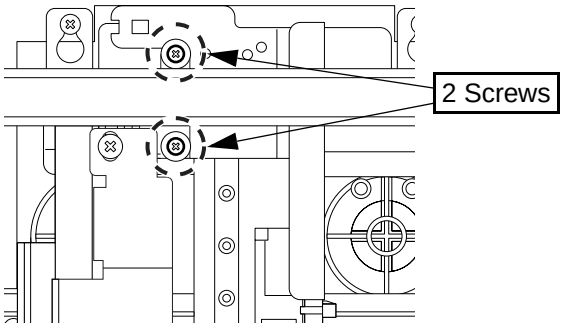
7. Attach a replacement plate



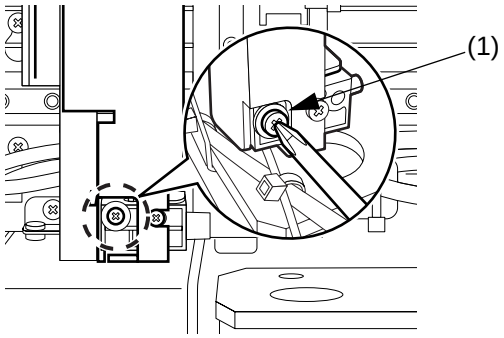
8. Align the hole on the top of the piercer and the fixed slit and fasten the screw.



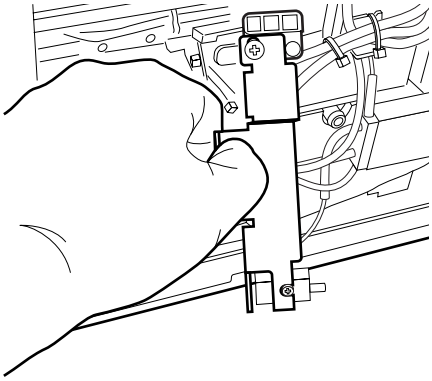
9. Remove the piercer's screws.



10. Remove the rinse cup screw (1). (left screw)



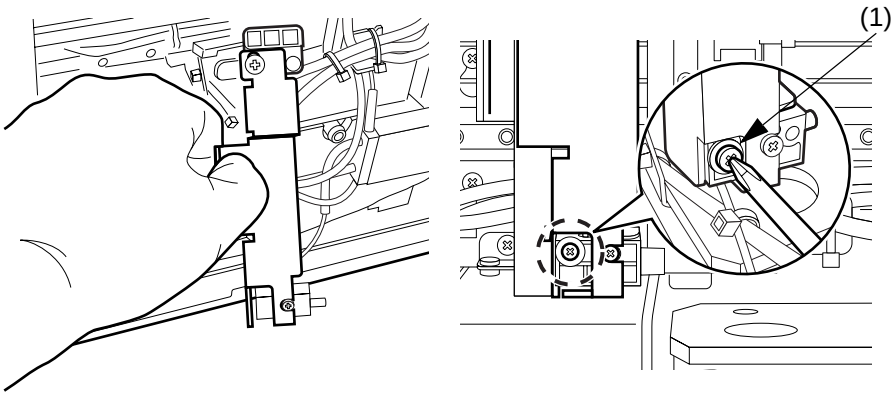
11. This completes removal.



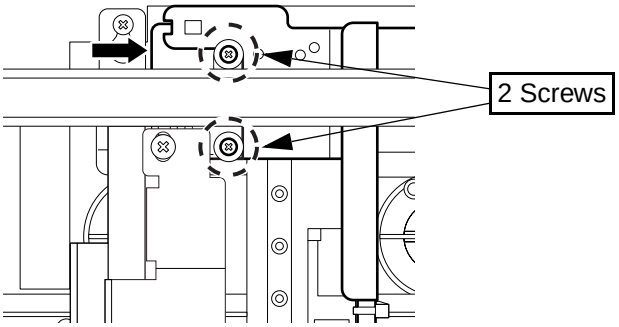
c. Procedures for installing a piercer

Take a new piercer out from the set and install in a reverse way.

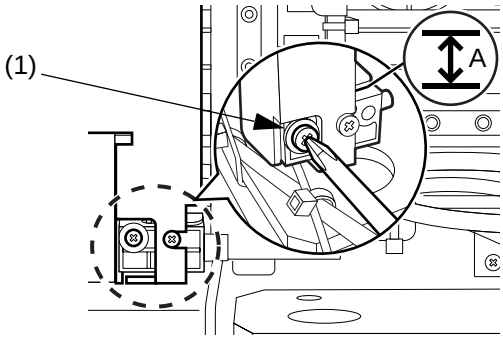
1. Attach a tube to the top of the new piercer.
2. Screw on the left screw (1) on the rinse cup (do not tighten the screw; leave it loose.)



3. Tighten down the 2 screws while holding the upper part of the piercer to the right.



4. Hold the rinse cup up so there isn't a gap at (A) and tighten down the screw (1).



5. Unscrew the 2 screws holding the metal plate and remove the plate.

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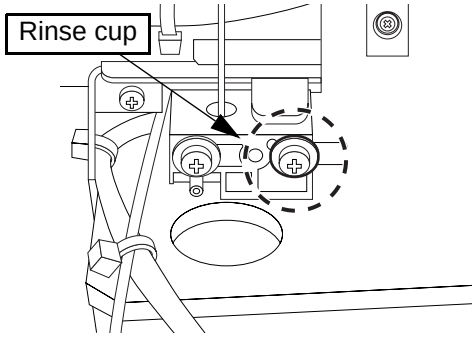
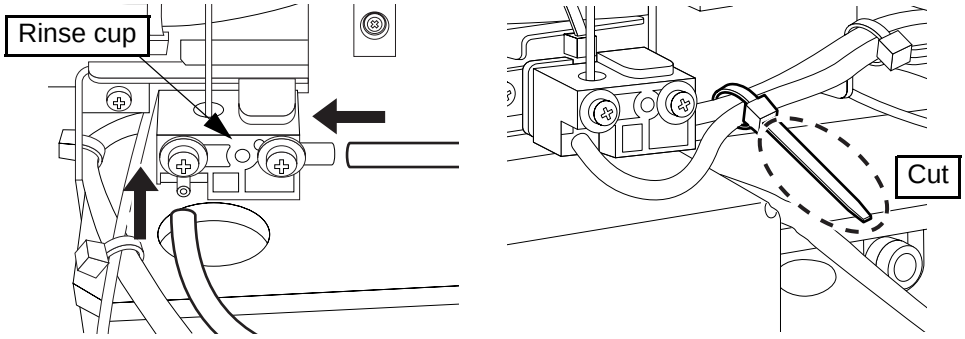
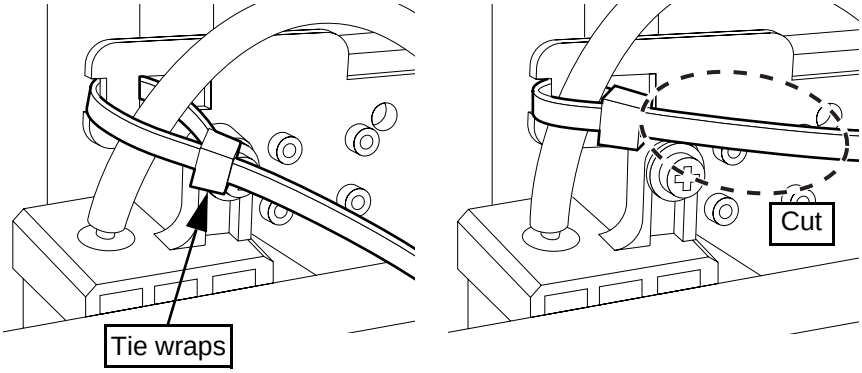
6. Fasten the screws on the right side of the rinse cup.



7. Attach the 2 tubes to the rinse cup, and bind with tie wraps.
   After pulling the tie wraps so that they bind the tubes firmly, cut off their excess length. When tightening the tie wraps, take care not to crush the tubes by tightening the tie wraps too much.



8. Tie up the tubes to the piercer top with tie wraps.
   After getting the tie wraps securely in place, cut off the loose ends.
   When tightening the tie wraps, take care not to crush the tubes by tightening the tie wraps too much.



9. Dispose of the old probe as per your laboratory policy for disposal of biohazards.
10. Turn the instrument on and reset the piercer operation cycle counts.
    For the method to reset the operation cycle counts, refer to “Chapter 10: 10.3: 2 Counter”.

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6. Replacement of the pump unit

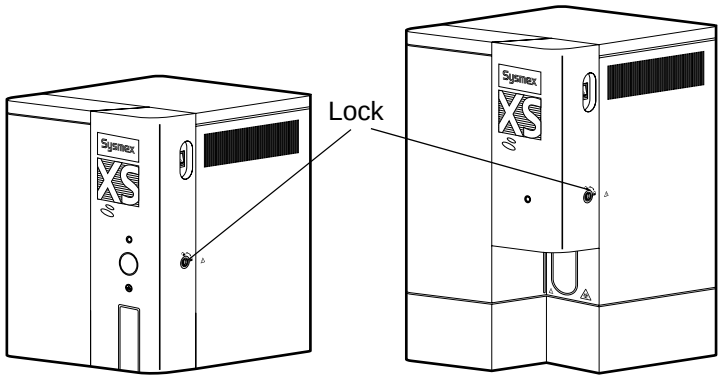
The "**Exchange the Air Pump**" message appears after 30,000 pump operations.

> **Caution!**
>
> Continued use without replacing the air pump could break the circuit board, so always replace the pump when the message appears.

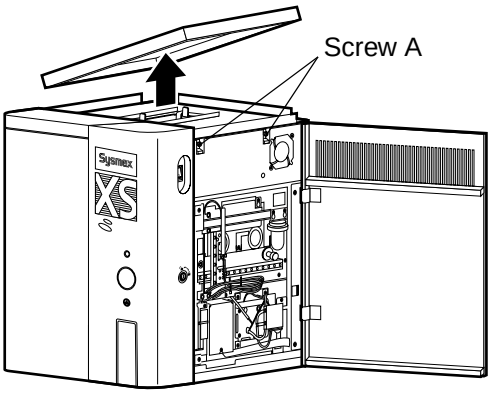
Turn off the Main Unit power switch, and unplug the power cable. Follow the procedure below to replace the pump unit.

> **Cautin, Hot!**
>
> If the pump is hot because of the state of the Main Unit, wait for it to cool down before you start work. There is a risk of burns.

1. Use a flathead screwdriver to turn the lock to the left, then open the right side cover.



2. Remove two screws A and open the top cover.



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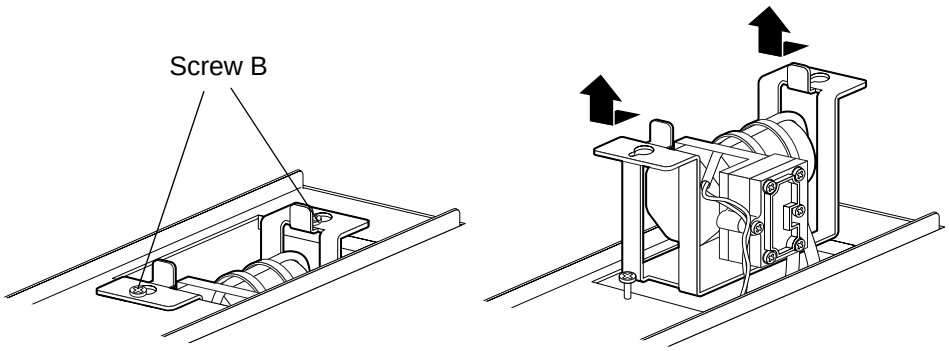
3. Loosen two screws B, slide the air pump unit in the direction of the arrow, and lift it out.



4. Detach the connectors and tube (red: upper, blue: lower), which are connected to the pump unit.
5. Replace with a new pump unit.
6. Reverse the removal process to mount the new pump unit.
7. Turn the instrument on and reset the air pump operation cycle counts.
   For the method to reset the operation cycle counts, refer to “Chapter 10: 10.3: 2 Counter”.

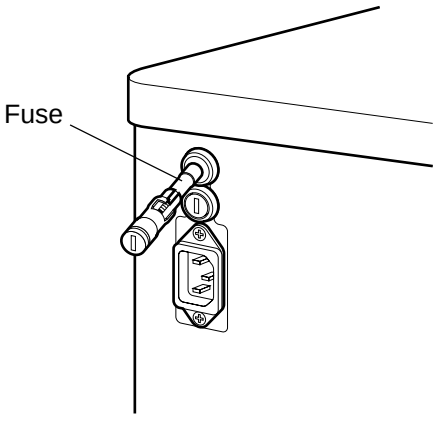
7. Replace fuses

Over-current protection fuses are used in the Main Unit. When a fuse is blown, replace it by the following procedure.

Warning!

- To avoid risk of electrical shock, disconnect the power supply cord before replacing the fuse.
- To avoid risk of fire, use the fuse of the specified type and current rating.

1. Turn OFF the power of the Main Unit and IPU. Unplug the power cable of the unit to which the fuse is to be replaced.
2. Remove the fuse cap holder. To remove the fuse cap holder, use a flathead screwdriver or similar tool to turn it counterclockwise and remove it.
3. Replace the fuse and attach the fuse cap holder.



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- Fuse used in the Main Unit

Specification	Part No.	Names	Fuse Type
100 - 240 VAC	266-7769-4	Fuse 250V 5.0A No. 19195	Time Lag

8. List of supplies

- Reagents List

Description
CELLPACK
STROMATOLYSER-4DL
STROMATOLYSER-4DS
SULFOLYSER
CELLCLEAN

- Consumable Parts

Part Number	Description	Reference number
051-0481-9	Piercer Set No. 7	Chapter 9: 9.5: 5
366-1792-2	Tube Holder No. 56 (White)	Chapter 6: 6.11: 3
366-1789-1	Tube Holder No. 58 (White)	Chapter 6: 6.11: 3
424-3333-5	Sample Rack No. 5-2 (White)	Chapter 6: 6.11: 3
266-7769-4	Fuse 250V 5.0A No. 19195	Chapter 9: 9.5: 7
462-3520-5	Transducer Brush	Chapter 9: 9.4: 10
051-0471-1	Air pump No. 1 Assembly	Chapter 9: 9.5: 6

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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																															
Initial:																															

MONTHLY MAINTENANCE:

Procedure:	Date/Int.	Date/Int.	Date/Int.	Date/Int.
Running the monthly cleaning sequence				

AS NEEDED MAINTENANCE:

Procedure:	Date/Int.	Date/Int.
Replace the waste container		
Automatic Rinsing		
Rinsing the aspiration unit tray		
Remove RBC detector clogs		
Clean RBC detector aperture		
Remove air bubbles		
Clean flowcell		

REPLACEMENTS:

Procedure:	Date/Int.	Date/Int.
Replace reagents		
Replace piercer		
Replace air pump		
Replace fuses		

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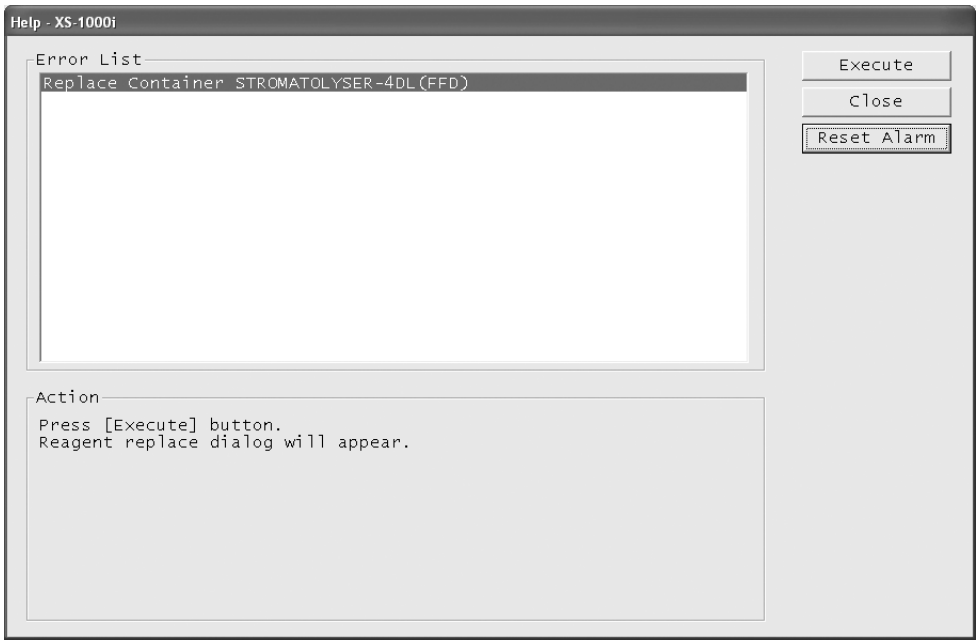
10.Troubleshooting

When an error occurs in the Main Unit, the Help dialog box is displayed automatically on the Information Processing Unit (IPU).
The Help dialog box displays an Error List, showing the errors which occurred, in order of priority.



Note:

The highest-priority error is also displayed on the Status Bar.

When the alarm sounds because an error has occurred, click **Reset Alarm** on the Help dialog box to stop the alarm sound.

In order to clear the error, first select the **Error** in the “Error List” of the dialog box by clicking on it. An explanation of the error and the countermeasures will appear below the “Action” header.
Clicking **Excute** will execute the error correction, or will display the screen necessary for the error correction.
Follow the countermeasures which are displayed under the “Action” header. If Ready status is still not restored, see Chapter 10: 10.2 Troubleshooting Guide and take the appropriate corrective actions.

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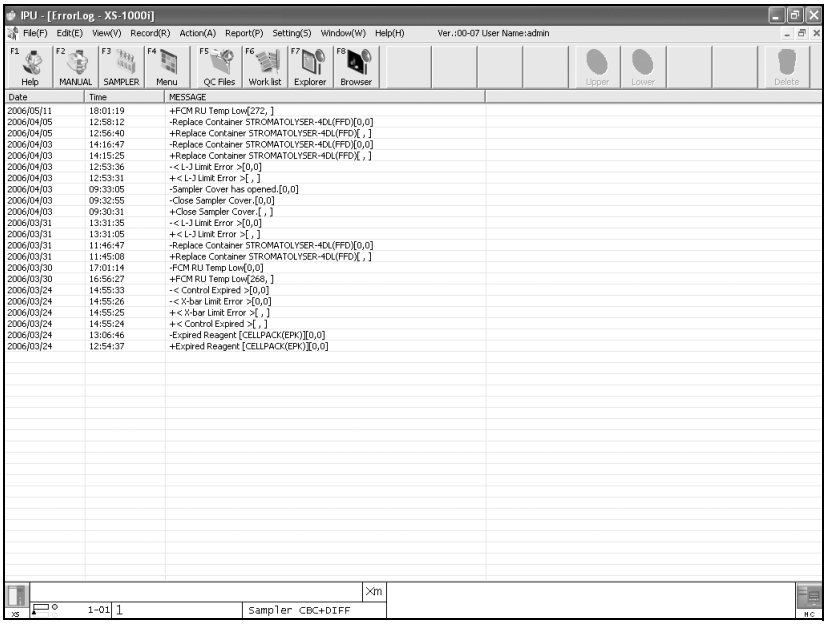
Error Log

The error log displays a maximum of 500 errors in order of their occurrence.
The oldest error will automatically be deleted if the total number of errors exceeds 500.
The error log consists of the error messages and the error parameters.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **ErrorLog** icon on the Controller Menu.
   The Error Log screen will appear.



10.1 Error message list

- Error messages and the pages explaining them are outlined below.

1. Alphabetical Error Message Index

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2. Error Messages Listed by Function

1. Pressure Errors

2. Temperature Errors

3. Reagent and Chamber Errors

4. Motor Errors

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10.2 Troubleshooting Guide

Note:

Errors are classified as follows:

1. Error caused by analysis error
   Analysis Error-Data of an 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. Error - System goes to **Not Ready** status.
   Sample analyses that are in progress will continue, but when all analysis sequences have been completed, the instrument will stop.
   Not Ready and error messages will be displayed.
3. Errors caused by analysis error/ **Not Ready** errors
   There are two cases: (1) Analysis data of an abnormal status is displayed and stored, or (2) An error message alone is displayed. When all analysis sequences have been completed, the instrument will wait without executing the following analyses. 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. Error-indicating warning messages
   If an analysis can be performed, but caution should be applied, a message will be displayed accordingly.
   When the need to act with caution no longer exists, the message will disappear.
5. Emergency stop
   If such an error occurs, the analysis operations will immediately be discontinued, and all 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 comprising an error will be displayed as "********" or "**----.**"

Note:

About error messages in this manual

- If you see the following messages under **Status**:, the Main Unit stops analyzing when an error occurs.
  Not Ready: Analysis cannot be performed after an error occurs.
  Sampler Stop: Sampler analysis is stopped after an error occurs.
  Emergency Stop: All analysis and sequences stop immediately in an emergency.
- **Category**: indicates error types.
  Hardware error: Instrument malfunctions or over limit values
  Analysis error: Analysis results abnormal
  Caution message: Reminder for caution
  Maintenance: Reminder for maintenance

1. Pressure Errors

Error message: Pressure Lower Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Reduce pump performance **Corrective Action** 1. After inspection, select the error in the **Help** dialog box and click **Execute** to perform a test of the pump.
Error message: 0.06 MPa Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. 0.06MPa relief valve defective **Corrective Action** 1. After inspection, select the error in the **Help** dialog box and click **Execute** to perform a test of the pump.
Error message: -0.03 MPa Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. -0.03MPa relief valve defective **Corrective Action** 1. After inspection, select the error in the **Help** dialog box and click **Execute** to perform a test of the pump.

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2. Temperature Errors

Error message: RH Temp High RH Temp Low **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Temperature of 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 Sysmex technical representative for more information.
Error message: FCM RU Temp High FCM RU Temp Low **Status:** Not Ready **Category:** Hardware 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 Sysmex technical representative for more information.
Error message: Env Temp High Env Temp Low **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The environmental temperature is not within the prescribed range. **Corrective Action** 1. Set room temperature between 15°C and 30°C.
Error message: RH Therm Sens ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. One of the thermal sensors for reagent heater might be defective. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error message: FCM RU Therm Sens ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. One of the thermal sensors for reaction chamber might be defective. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error message: Env Therm Sens ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. One of the thermal sensors for detecting the environmental temperature might be defective. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.

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Error message: FCM Sheath Sens ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. One of the thermal sensors for controlling the temperature of the FCM sheath reagent may be defective. **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.

3. Reagent and Chamber Errors

Error message: Replace Container CELLPACK (EPK) Replace Container SULFOLYSER (SLS) Replace Container STROMATOLYSER-4DL (FFD) Replace Container STROMATOLYSER-4DS (FFS) **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Insufficient reagent. 2. Defective float switch. 3. Abnormality in the intake hydraulic lines. **Corrective Action** 1. Replace the reagent. Replace the empty reagent container with a new container. Select the **error** in the Help dialog box and Click **Execute**. If the error persists after replacement, there is probably a defective float switch or an abnormality in the hydraulic system. 2. Inspection of the intake hydraulic lines. Check for kinked, looseness, or tears in the tubing for the reagent indicated by the error message. Next, choose the error from the Help dialog box, then click on Execute to aspirate reagent.  **Note:** CBC analysis are still possible when the **Replace Container STROMATOLYSER-4DS(FFS)** error has occurred.
Error message: Chamber CELLPACK (EPK) Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Tubing between the reagent container and the Main Unit is kinked, clogged or disconnected. **Corrective Action** 1. Check the tubing. Inspect tubes. Then select the **error** in the Help dialog box and click **Execute** to begin reagent aspiration.

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Error message: STROMATOLYSER-4DS (FFS) Aspiration Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Tubing between the reagent container and the Main Unit is kinked, clogged or disconnected. 2. The reagent runs out before the prescribed number of operations (if a new container was not used the last time the reagent was replaced, etc.) **Corrective Action** 1. Check the tubing. Inspect tubes. Then select the **error** in the Help dialog box and click **Execute** to begin reagent aspiration. 2. If the problem recurs even when a new reagent container is used, a defect in the diaphragm pump is the most likely cause. Contact your Sysmex technical representative.
Error message: Waste Chamber 1 Not Draining Waste Chamber 2 Not Draining **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The waste fluid drain line is kinked or clogged. **Corrective Action** 1. Check the drain line tubing. If a kink or clogging is found in the tube connected to the drain outlet nipple, clean or replace the tubing. Especially check for dirt or clogging around the drain outlet at a sewer. After the check, select the **error** in the Help dialog box and click **Execute** to drain the waste chamber.
Error message: Exchange Waste Tank **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Waste container is full. **Corrective Action** 1. Replace the waste container. (See Chapter 9: 9.4 As-needed maintenance)
Error message: RBC/HGB Chamber Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Kink or clog in the RBC/HGB chamber drain tube, or clog in the drain line filter. **Corrective Action** 1. Check the tubing. Inspect for kinks or clogs in the drain tube, or clogging in the filter. After the check, select the error in the **Help** dialog box and click **Execute** to drain the reaction chamber.
Error message: WBC Chamber Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Kink or clog in the WBC chamber drain tube, or clog in the drain line filter. **Corrective Action** 1. Check the tubing. Inspect for kinks or clogs in the WBC chamber drain tube, or clogging in the filter. After the check, select the error in the **Help** dialog box and click **Execute** to drain the WBC chamber.

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4. Motor Errors

Error message: WB Asp Motor Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of WB aspiration pump **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.
Error message: Sheath Motor Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of the sheath syringe **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.
Error message: Aspiration Unit Up Down Motor Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of the Aspiration Unit Up Down Motor **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.
Error message: Aspiration Unit Front Back Motor Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of the Aspiration Unit Front Back Motor **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.
Error message: Rinse Cup Pinch Valve Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of the rinse cup pinch valve **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.
Error message: Waste Chamber 1 Pinch Valve Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of waste chamber 1 pinch valve **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.
Error message: Waste Chamber 2 Pinch Valve Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of waste chamber 2 pinch valve **Corrective Action** 1. Select the **error** in the **Help** dialog box and click **Execute** to confirm the action.

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Error message: Tube Holder Motor Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Malfunction of the sample position motor **Corrective Action** 1. Check that the sample tube adapter is correctly attached. Then select the **error** in the **Help** dialog box and click **Execute** to confirm the action.

5. WB Aspiration and Dilution Errors

Error message: Sample Not Asp Error **Status:** Sampler analysis stop	**Probable Cause** 1. Abnormal blood sample, Blood volume is insufficient: Clots present in blood sample Extremely low concentration of blood 2. The parts below are clogged: Probe Whole blood aspiration line tubing 3. Tubing in the whole blood aspiration line is disconnected. **Corrective Action** 1. Check the whole blood sample, then reanalyze it. 2. Then clean the instrument hydraulics as follows: (1) Use CELLCLEAN to run a monthly rinse process. (2) When the Monthly Rinse sequence is complete, restart the instrument. (3) When the system enters Ready status, reanalyze the sample. (4) If the error still persists, it is assumed that the probe is clogged by clots; replace the probe. (See Chapter 9: 9.5: 5. Piercer replacement.) 3. Tube connection **Note:** When analyzing extremely low concentration blood, disable use of the Aspiration Sensor from the Main Unit setting screen.

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Error message: Short Sample **Status:** Sampler analysis stop	**Probable Cause** 1. Abnormal blood sample,: Clots present in blood sample Extremely low concentration of blood 2. The parts below are clogged: Probe Whole blood aspiration line tubing 3. Tubing in the whole blood aspiration line is disconnected. **Corrective Action** 1. Check the whole blood sample, then reanalyze it. 2. Then clean the instrument hydraulics as follows: (1) Use CELLCLEAN to run a monthly rinse process. (2) When the Monthly Rinse sequence is complete, restart the instrument. (3) When the system enters Ready status, reanalyze the sample. (4) If the error still persists, it is assumed that the probe is clogged by clots; replace the probe. (See Chapter 9: 9.5: 5. Piercer replacement.) 3. Tube connection **Note:** When analyzing extremely low concentration blood, disable use of the Aspiration Sensor from the Main Unit setting screen.
Error message: Blood Asp Sensor Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Bubbles have entered the blood aspiration sensor part. 2. Faulty blood aspiration sensor **Corrective Action** 1. Run automatic rinsing Double-click on the **Auto Rinse** icon on the **Controller** menu to run Auto Rinse. 2. Replace faulty blood aspiration sensor Contact your Sysmex technical representative for more information. The Aspiration Sensor can be set as disabled from the Main Unit setting screen, as an emergency measure to allow analysis. However, aspiration will not be monitored.

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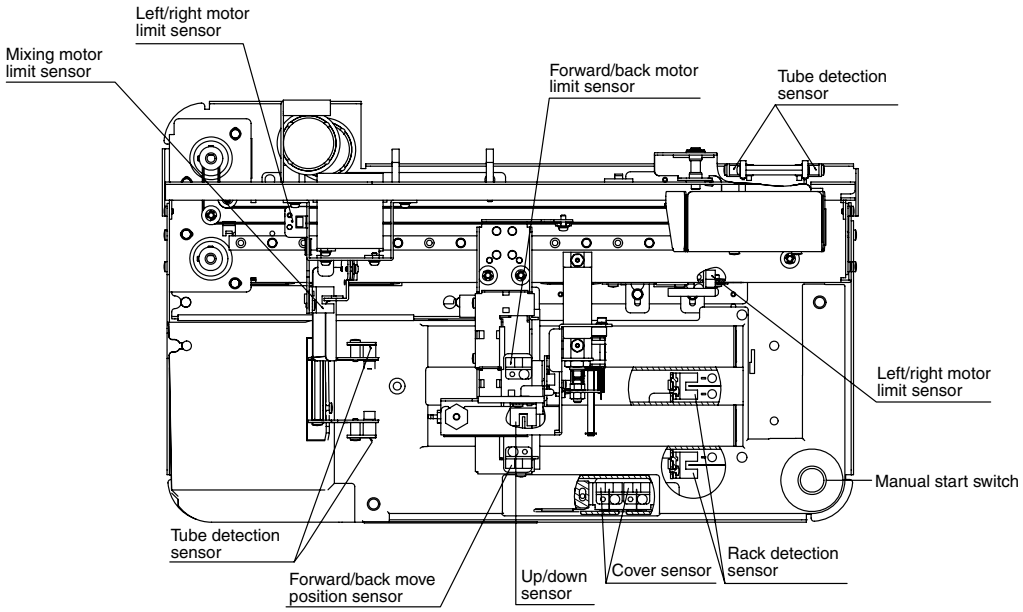
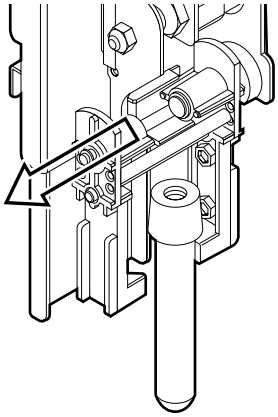
6. Sampler Errors (Sampler is optional)

The names and positions of the various sensors fitted to the Sampler are shown below.



When an error occurs while the catcher is holding a sample tube, open the catcher forward as shown below and remove the sample tube.



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Error message: Close Sampler Cover. **Category:** Hardware error	**Probable Cause** 1. The Start switch was pressed without first closing the sampler cover. **Corrective Action** 1. Close the sampler cover, then press the Start switch again to carry out the analysis.
Error message: Sampler Cover is opened. **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The sampler cover was opened while the sampler was operating. **Corrective Action** 1. Close the sampler cover and repeat the analysis.
Error message: Hand (Front/Back) motor ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Front/Back operation of the catcher of the sampler was not performed normally. **Corrective Action** 1. Open the sampler cover and check whether the catcher is holding a sample tube, and whether a tube has been dropped inside the sampler unit. 2. If a sample tube has fallen inside the instrument, or if it is jammed in the catcher, place the tube back in the rack and repeat the analysis.
Error message: Hand (Left/Right) motor ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Left/Right operation of the catcher of the sampler was not performed normally. **Corrective Action** 1. Open the sampler cover and check whether the catcher is holding a sample tube, and whether a tube has been dropped inside the sampler unit. 2. If a sample tube has fallen inside the sampler unit, or if it is jammed in the catcher, place the tube back in the rack and repeat the analysis.
Error message: Hand (Up/Down) ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Up/Down operation of the catcher of the sampler was not performed normally. **Corrective Action** 1. Open the sampler cover and check whether the catcher is holding a sample tube, and whether a tube has been dropped inside the sampler unit. 2. If a sample tube has fallen inside the sampler unit, or if it is jammed in the catcher, place the tube back in the rack and repeat the analysis.

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Error message: Mixing motor ERR **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The catcher of the sampler did not mix the sample tube normally. **Corrective Action** 1. Open the sampler cover and check whether the catcher is holding a sample tube, and whether a tube has been dropped inside the sampler unit. 2. If a sample tube has fallen inside the sampler unit, or if it is jammed in the catcher, place the tube back in the rack and repeat the analysis.
Error message: Fail to set Tube to Tube Holder **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The catcher of the sampler did not place the sample tube in the sample position normally. **Corrective Action** 1. Open the sampler cover and check whether the sample tube has dropped inside the sampler unit. 2. If a sample tube has fallen inside the sampler unit, or if it is jammed in the catcher, place the tube back in the rack and repeat the analysis.
Error message: Sample tube is still in the tube holder. **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The catcher of the sampler did not pick the sample tube out of the sample position normally. **Corrective Action** 1. Open the sampler cover and check whether the sample tube is still inside the sample position. 2. If the sample tube was left in the sample position, put it back in the rack and repeat the analysis.
Error message: Rack Not Exist **Status:** Sampler analysis stop **Category:** Hardware error	**Probable Cause** 1. No rack was set when analysis was to start. **Corrective Action** 1. Open the sampler cover and check whether the rack is set correctly at the rack setting position.

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7. Analysis Errors

Error message: Background Error **Category:** Analysis error	**Probable Cause** 1. Inclusion of bubbles 2. Dirty aperture 3. Defective reagent **Corrective Action** 1. Perform Auto Rinse. Select the **error** in the Help dialog box and click **Execute** to perform Auto Rinse. 2. Remove the clogging. Double-click the **Remove RBC Detector Clogs** icon on the Maintenance screen to execute the RBC Detector Clog Removal sequence. If the error still occurs, clean the detector aperture with a transducer brush. (See Chapter 9: 9.4 As-needed maintenance.) 3. Replacement of reagents (See Chapter 9: 9.5 Supplies Replacement.)
Error message: RBC Sampling Error PLT Sampling Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. Dirty aperture 2. Error caused by the sample **Corrective Action** 1. Remove the clogging. Double-click the **Remove RBC Detector Clogs** icon on the Maintenance screen to execute the RBC Detector Clog Removal sequence. If the error still occurs, clean the detector aperture with a transducer brush. (See Chapter 9: 9.4 As-needed maintenance.) 2. Perform the analysis again.
Error message: WBC Sampling Error Diff Sampling Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. Clogging or dirt in the optical detector block flow cell 2. Error caused by the sample **Corrective Action** 1. Clean the flowcell in the optical detector block. (See Chapter 9: 9.4 As-needed maintenance.) 2. Perform the analysis again.
Error message: RBC Bubble Error RBC Clog Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. Clogging or air bubble inclusion at RBC detector. **Corrective Action** 1. Remove the clogging from the RBC detector. Select the **error** in the **Help** dialog box and click **Execute** to execute the Detector Clog Removal sequence. If the error still occurs, clean the detector aperture with a transducer brush. (See Chapter 9: 9.4 As-needed maintenance.)

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Error message: Low Count Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. Error caused by the sample 2. Clogging at probe 3. Clogging at WB aspiration line tube **Corrective Action** 1. Perform the analysis again. 2. Rinse the probe. 3. Rinse the WB aspiration line tube
Error message: HGB ERROR **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. Air bubble inclusion in HGB analysis line **Corrective Action** 1. Perform Auto Rinse. Double-click the **Auto Rinse** icon on the Controller Menu to start automatic rinsing.
Error message: WBC-CH Error DIFF-CH Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. Clogging or dirt in the optical detector block flow cell 2. Error due to short sample (Insufficient sample and mixing of air bubbles, etc.) 3. Error due to sample (Platelet aggregation and precipitation of cold agglutinins, etc.) **Corrective Action** 1. Clean the flowcell in the optical detector block. (See Chapter 9: 9.4 As-needed maintenance.) 2. Perform the analysis again. 3. Check the sample by visual inspection of a smear.
Error message: RBC-CH Error PLT-CH Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. The number of RBC/PLT channel particles exceeds the upper limit of display range due to external noise etc. **Corrective Action** 1. Block the noise source. Keep the noise source away from the Main Unit. 2. Perform the analysis again.

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Error message: Data Error **Category:** Analysis error	**Probable Cause** 1. Analysis result exceeds the upper Reference Limit. 2. Error caused by the sample 3. Dirty aperture **Corrective Action** 1. Review the Reference Limits of the information processing unit (IPU). (See Software Guide Chapter 5: 5.1: 2. Sampler Limit Setting.) 2. Perform the analysis again. 3. Remove the clogging. Double-click the **Remove RBC Detector Clogs** icon on the Maintenance screen to execute the RBC Detector Clog Removal sequence. (See Chapter 9: 9.4 As-needed maintenance.) 4. Perform quality control, if necessary.
Error message: Analysis Error **Category:** Analysis error	**Probable Cause** 1. An error occurred which affects data and should stop or cancel sampler analysis **Corrective Action** 1. Run the corrective action for the error that has occurred.
Error message: Right side cover is open. **Status:** Not Ready **Category:** Analysis error	**Probable Cause** 1. The right side cover is open. **Corrective Action** 1. Close the right side cover.
Error message: Right side cover has opened. **Status:** Emergency Stop **Category:** Analysis error	**Probable Cause** 1. Right side cover has opened during analysis. **Corrective Action** 1. Turn the power OFF and back ON once Main Unit operation is complete.
Error message: Tube Holder has opened. **Status:** Emergency Stop **Category:** Hardware error	**Probable Cause** 1. The sample position door has opened during analysis. **Corrective Action** 1. Turn the power OFF and back ON once Main Unit operation is complete.

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8. Laser Errors

Error message: Laser Diode Aged **Category:** Hardware error	**Probable Cause** 1. Laser service life is coming to end. (Analysis is still possible.) **Corrective Action** 1. Turn the power OFF, then ON again. Check whether the error has been resolved. Contact your Sysmex technical representative for more information.
Error message: Laser Power Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. The laser power is out of the laser control range **Corrective Action** 1. Replace the Laser. Contact your Sysmex technical representative for more information.
Error message: Close FCM Detector Cover. **Status:** Not Ready **Category:** Hardware 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 for more information.

9. System Errors

Error message: Barcode Reader Com. Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. Serial communications with the Sampler bar code reader malfunctioned **Corrective Action** 1. Turn the power OFF, then ON again. If the error persists, contact your Sysmex technical representative.
Error message: ID Read Error **Status:** Sampler analysis stop **Category:** Hardware error	**Probable Cause** 1. Dirty ID label 2. ID label is badly printed. 3. ID label is badly positioned. **Corrective Action** 1. Check the ID label. (See Software Guide Chapter 6: 6.2 ID barcode specification.)
Error message: System Configuration Error **Status:** Not Ready **Category:** Hardware error	**Probable Cause** 1. IPU and Main Unit settings do not match. **Corrective Action** 1. Contact your Sysmex technical representative.

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10.QC Errors

Error message: X-barM Limit Error L-J Limit Error X-bar Limit Error **Status:** Sampler analysis stop **Category:** Analysis error	**Probable Cause** 1. An X-barM, L-J, or X-bar control error has occurred. **Corrective Action** 1. Check the quality control chart. 2. Check the analysis data for the parameters that exceeded control limits.
Error message: Control Expired Error **Status**: Sampler analysis stop **Category:** Caution message	**Probable Cause** 1. Control blood has expired. **Corrective Action** 1. Replace the control blood by a new lot.
Error message: Control Entry ERR **Status:** Sampler analysis stop **Category:** Caution message	**Probable Cause** 1. Analysis was performed for unregistered control blood. **Corrective Action** 1. Enter lot information for the control blood.

11.User Maintenance Warnings

Error message: Replace Piercer **Category:** Maintenance	**Probable Cause** 1. It is time to replace the piercer. **Corrective Action** 1. Replace the piercer, and reset the piercer operation count. (See Chapter 9: 9.5 Supplies Replacement.)
Error message: Execute Monthly Rinse **Category:** Maintenance	**Probable Cause** 1. It is time to run the monthly rinse. **Corrective Action** 1. Run the monthly rinse.
Error message: Execute Monthly Rinse (Warning) **Status:** Not Ready **Category:** Maintenance	**Probable Cause** 1. It is time to run the monthly rinse. **Corrective Action** 1. Run the monthly rinse.
Error message: Exchange the Air pump. **Category:** Maintenance	**Probable Cause** 1. It is time to replace the pump. **Corrective Actio**n 1. Replace the pump, and reset the pump operation count. (See Chapter 9: 9.5 Supplies Replacement.)

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Error message: Expired Reagent (CELLPACK (EPK)) **Category:** Maintenance	**Probable Cause** 1. CELLPACK (EPK) has expired. **Corrective Action** 1. Replace CELLPACK (EPK).
Error message: Expired Reagent (SULFOLYSER (SLS)) **Category:** Maintenance	**Probable Cause** 1. SULFOLYSER (SLS) has expired. **Corrective Action** 1. Replace SULFOLYSER (SLS).
E**rror message:** Expired Reagent (STROMATOLYSER-4DL (FFD)) **Category:** Maintenance	**Probable Cause** 1. STROMATOLYSER-4DL (FFD) has expired. **Corrective Action** 1. Replace STROMATOLYZER 4DL (FFD).
Error message: Expired Reagent (STROMATOLYSER-4DS (FFS)) **Category:** Maintenance	**Probable Cause** 1. STROMATOLYSER-4DS (FFS) has expired. **Corrective Action** 1. Replace STROMATOLYZER 4DS (FFS).

10.3 Test

With the XS-1000*i*/XS-500*i*, it is possible to execute test programs to check system operation and find the causes of abnormalities detected in the Main Unit.

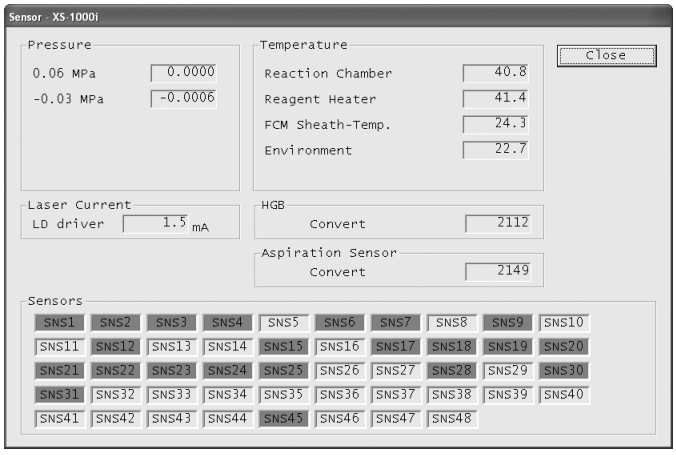
Note:

A test process can only be performed when the Main Unit is in Ready or Stat Ready status. If a test is attempted in any other status, the error warning will be sound on the Main Unit and the process will not be performed. Analysis is not possible during the test process.

1. Sensors

The Sensor dialog box displays the pressure and the temperatures at each part of the Main Unit, and also the data of each sensor.
The data display is updated every 0.5 seconds.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Sensor** icon on the Maintenance screen.
   The Sensor dialog box will appear.



The following information is displayed in the Sensor dialog box.

Pressure

0.06 MPa	Indicates 0.06 MPa
-0.03 MPa	Indicates -0.03 MPa

Temperature

Reaction Chamber	Indicates the temperature inside the reaction chamber.
Liquid Heater	Indicates the temperature of the liquid heater.
FCM sheath-deg	Displays the temperature (°C) of the FCM sheath fluid.
Environment	Indicates the room temperature (°C).

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Laser Current

LD driver Indicates the laser diode driving current (mA).

HGB

Convert Indicates HGB convert value.

Aspiration sensor

Convert Indicates blood aspiration sensor convert value.

Sensors Displays whether sensors No.1~No.48 are ON or OFF. When ON, the background is displayed in red.

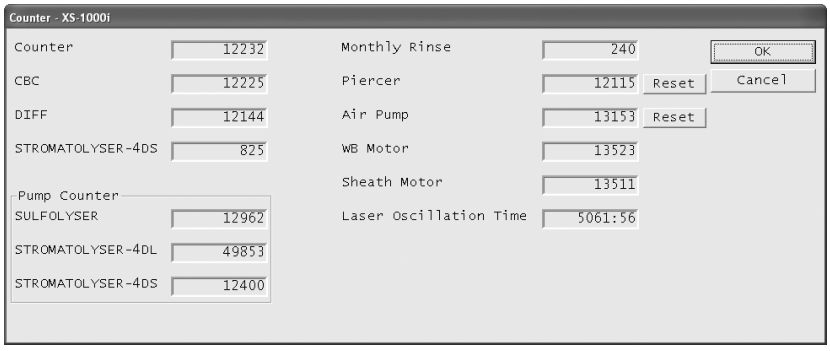
2. Counter

The Counter dialog box displays the operation cycle count (or oscillation time for the laser) for each part unit of the Main Unit.
After completion of the piercer replacement or the pump replacement, reset the operation cycle by the procedure described following.

Important!

Except for the Piercer and Pump, all other operation cycle counts are for reference. They cannot be reset.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Counter** icon on the Maintenance screen.
   The Counter dialog box will appear.



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The following operation cycle counts are displayed in the Counter dialog box.

Counter	Indicates the operation cycles of the instrument.
CBC	Indicates the operation cycles at the CBC analysis mode.
DIFF	Indicates the operation cycles at the DIFF analysis mode.
STROMATOLYSER-4DS	Indicates the number of pump operations after the Stromatolyser-4DS is replaced.
Pump Counter	
SULFOLYSER	Indicates the number of Sulfolyser pump operations.
STROMATOLYSER-4DL	Indicates the number of Stromatolyser-4DL pump operations.
STROMATOLYSER-4DS	Indicates the number of Stromatolyser-4DS pump operations.
Monthly Rinse	Indicates the analysis cycles since executing monthly rinse last.
Piercer	Indicates the piercing operation cycles since replacement of the piercer.
Air Pump	Indicates the operation cycles since replacement of the pump.
WB Motor	Indicates the operation cycles of the Whole Blood Aspiration Motor.
Sheath Motor	Indicates the operation cycles of the Sheath Motor.
Laser Oscillation Time	Indicates the laser oscillation time in hours.

4. Click Reset button for the Piercer or Pump.
   The operation cycle count of the item for which Reset was clicked is reset to 0.
5. Click **OK** or **Cancel**.

OK	Reset is confirmed and the Counter dialog box is closed.
Cancel	Reset is canceled and the Counter dialog box is closed.

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3. Barcode Reader (Only when the XS-1000*i* sampler is connected)

A reading test can be performed for the bar codes affixed to the test tubes on the rack, and for the bar code affixed to the rack.

1. Insert the test tubes, with bar codes affixed, into the rack. Place the rack in the sampler analysis line.
2. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
3. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
4. Double-click the **Barcode** icon on the Maintenance screen.
   The Barcode dialog box will appear.
5. Click **Start** to begin the reading test. If there are results of a previous test displayed in this dialog box, these results will be erased when the test begins.
6. The test results will be displayed in the Bar code dialog box.

Tube Position	Position of the test tube on the rack.
Rack/Sample No.	Indicates the sample number or rack number which was read.
Check Digit	Indicates the check digit of the barcode which was read.
Type	Indicates the symbology type of bar code which was read.

7. Click **Close** to close the Bar code dialog box.

4. Whole Blood Aspiration Motor

An operation test can be performed for the WB Aspiration Motor. When a "**WB Asp Motor Error**" has occurred, the error can be cleared by performing this test, provided the result is normal.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **WB Motor** icon on the Maintenance screen.
4. The WB Aspiration Motor test begins.
   During the WB Aspiration Motor test, the Testing WB Aspiration Motor dialog box appears.
   It closes automatically once the WB Aspiration Motor test is complete.

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5. Sheath Motor

An operation test can be performed for the RBC Sheath Syringe. When a "**Sheath Motor Error**" has occurred, the error can be cleared by performing this test, provided the result is normal.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Sheath Motor** icon on the Maintenance screen.
4. The Sheath Motor test begins.
   During the Sheath Motor test, the Testing Sheath Motor dialog box appears.
   It closes automatically once the Sheath Motor test is complete.

6. Pinch Valve

An operation test can be performed for the Pinch Valves. When a "**Waste Chamber 1 Pinch Valve Error**", "**Waste Chamber 2 Pinch Valve Error**", "**Rinse Cup Pinch Valve Error**" has occurred, the error can be cleared by performing this test, providing the result is normal.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Pinch Valve** icon on the Maintenance screen.
4. The Pinch Valve test begins.
   During the Pinch Valve test, the Testing Pinch Valve dialog box appears.
   It closes automatically once the Pinch Valve test is complete.

7. ASP Motor

An operation test can be performed for the whole blood aspiration unit motors. When a "**Aspiration Unit Up Down Motor Error**", "**Aspiration Unit Front Back Motor Error**" has occurred, the error can be cleared by performing this test, provided the result is normal.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **ASP Motor** icon on the Maintenance screen.
4. The ASP Motor test begins.
   During the ASP Motor test, the Testing ASP Motor dialog box appears.
   It closes automatically once the ASP Motor test is complete.

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8. Sample Set Area Motor

An operation test can be performed for the Sample Set Area motor.
When a "**Tube Holder Motor Error**" has occurred, the error can be cleared by performing this test, provided the result is normal.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Sample Set Area Motor** icon on the Maintenance screen.
4. The Sample Set Area Motor test begins.
   During the Sample Set Area Motor test, the Testing Sample Set Area Motor dialog box appears.
   It closes automatically once the Sample Set Area Motor test is complete.

9. Air Pump

An operation test can be performed for the Pump.
When a "**Pressure Lower Error**", "**0.06MPa Error**", "**-0.03MPa Error**" has occurred, the error can be cleared by performing this test, provided the result is normal.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Air Pump** icon on the Maintenance screen.
4. The Pump test begins.
   During the Pump test, the Testing Air Pump dialog box appears.
   It closes automatically once the Pump test is complete.

10. Sampler (Only when the XS-1000*i* sampler is connected)

An operation test can be performed for the Sampler.

1. Double-click the **Controller** icon on the Menu screen. The Controller Menu will appear.
2. Double-click the **Maintenance** icon on the Controller Menu.
   The Maintenance screen will appear.
3. Double-click the **Sampler** icon on the Maintenance screen.
   The Sampler test begins.
4. The Sampler test begins.
   During the Sampler test, the Testing Sampler dialog box appears.
   It closes automatically once the Sampler test is complete.

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11. Technical Information

11.1 XS-1000*i* Dimensions, weight, throughput

Main Unit dimensions (including Sampler Unit)	Width: 320 mm Height: 403 mm Depth: 413 mm Sampler Unit Width: 450 mm Height: 420 mm Depth: 300 mm (when Main unit is connected: 630 mm)
Main Unit weight (including Sampler Unit)	approx. 24 kg Sampler Unit approx. 14 kg (approx. 38 kg including the Sampler Unit)
Throughput	CBC: approx. 60 samples/hour (Manual Mode) CBC+DIFF: approx. 60 samples/hour (Manual Mode) CBC: approx. 49 samples/hour (Capillary Mode) CBC+DIFF: approx. 49 samples/hour (Capillary Mode) CBC: 20 samples/approx. 23 minutes (Sampler Mode) CBC+DIFF: 20 samples/approx. 23 minutes (Sampler Mode) However, if Real-time Request from the host computer is used, throughput will be reduced by the speed of communication with the host computer.

11.2 XS-500*i* Dimensions, weight, throughput

Main Unit dimensions	Width: 320 mm Height: 503 mm Depth: 413 mm
Main Unit weight	approx. 24 kg
Throughput	CBC: approx. 60 samples/hour (Manual Mode) CBC+DIFF: approx. 60 samples/hour (Manual Mode) CBC: approx. 55 samples/hour (Capillary Mode) CBC+DIFF: approx. 55 samples/hour (Capillary Mode) However, if Real-time Request from the host computer is used, throughput will be reduced by the speed of communication with the host computer.

11.3 XS-1000*i*/XS-500*i* performance/specifications

Ambient temperature	15°C to 30°C (23°C optimum)
Relative humidity	30% to 85%
Power supply	100-117 VAC/ 220-240 VAC ±10% (50/60 Hz)
Power consumption	Main Unit, Sampler Unit: 210 VA or less
Laser class	Class I (IEC60825-1:2007)
Protection type	Class I device (IEC61010-1)
Display range	WBC: 0.00 - 999.99×10^3/μL RBC: 0.00 - 99.99×10^6/μL HGB: 0.0 - 30.0 g/dL HCT: 0.0 - 100.0% PLT: 0 - 9999×10^3/μL

Revised August 2013

Background limits	WBC: RBC: HGB: PLT:	$0.1\times10^3/\mu L$ $0.02\times10^6/\mu L$ 0.1 g/dL $10\times10^3/\mu L$
Precision (Reproducibility) Manual Mode and Sampler Mode	WBC RBC HGB HCT MCV MCH MCHC PLT RDW-SD RDW-CV PDW MPV P-LCR PCT NEUT% LYMPH% MONO% EO% BASO% NEUT# LYMPH# MONO# EO# BASO#	3.0% or less ($4.0\times10^3/\mu L$ or more) 1.5% or less ($4.0\times10^6/\mu L$ or more) 1.5% or less 1.5% or less 1.5% or less 2.0% or less 2.0% or less 4.0% or less ($100\times10^3/\mu L$ or more) 3.0% or less 3.0% or less 10.0% or less 4.0% or less 18.0% or less 6.0% or less 8.0% or less (30.0 NEUT% or more, WBC $4.0\times10^3/\mu L$ or more) 8.0% or less (15.0 LYMPH% or more, WBC $4.0\times10^3/\mu L$ or more) 20.0% or less (5.0 MONO% or more, WBC $4.0\times10^3/\mu L$ or more) 25.0% or less, or within ±1.5EO% (WBC $4.0\times10^3/\mu L$ or more) 40.0% or less, or within ±1.0 BASO% (WBC $4.0\times10^3/\mu L$ or more) 8.0% or less ($1.2\times10^3/\mu L$ or more) 8.0% or less ($0.6\times10^3/\mu L$ or more) 20.0% or less ($0.2\times10^3/\mu L$ or more) 25.0% or less, or within $\pm0.12\times10^3/\mu L$ 40.0% or less, or within $\pm0.06\times x10^3/\mu L$

Revised June 2011

Precision (reproducibility) Capillary Mode	WBC 5.0% or less (4.0×10^3/µL or more) RBC 4.5% or less (4.0×10^6/µL or more) HGB 4.5% or less HCT 4.5% or less MCV 4.5% or less MCH 4.5% or less MCHC 6.0% or less PLT 12.0% or less (100×10^3/µL or more) RDW-SD 6.0% or less RDW-CV 6.0% or less PDW 20.0% or less MPV 8.0% or less P-LCR 36.0% or less PCT 12.0% or less NEUT% 16.0% or less (30.0 NEUT% or more, WBC 4.0×10^3/µL or more) LYMPH% 16.0% or less (15.0 LYMPH% or more, WBC 4.0×10^3/µL or more) MONO% 40.0% or less (5.0 MONO% or more, WBC 4.0×10^3/µL or more) EO% 40.0% or less (WBC 4.0×10^3/µL or more) BASO% 50.0% or less or within ±1.5BASO% (WBC 4.0×10^3/µL or more) NEUT# 16.0% or less (1.2×10^3/µL or more) LYMPH# 16.0% or less (0.6×10^3/µL or more) MONO# 40.0% or less (0.2×10^3/µL or more) EO# 40.0% or less or within $\pm0.12\times10^3$/µL BASO# 50.0% or less or within $\pm0.06\times10^3$/µL
Analysis Parameters	see page 1-4
Blood Cell Count Accuracy in Manual Mode and Sampler Mode	WBC within ±3%, or within $\pm0.2\times10^3$/µL RBC within ±2%, or within $\pm0.03\times10^6$/µL PLT within ±5%, or within $\pm10\times10^3$/µL
Blood Cell Count Accuracy in Capillary Mode	WBC within ±10% RBC within ±8% PLT within ±12%
Blood Cell Type Accuracy (Indicated in correlation with the reference method when 100 or more normal blood samples are analyzed.)	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
Blood Cell Type Accuracy (Mean value of the differences from the analyses by 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%

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Accuracy (differential blood count) Capillary Mode	When more than 100 fresh patient bloods are analyzed the correlation factor with the standard FCM analysis method is shown below. NEUT% r=0.70 or more LYMPH% r=0.70 or more MONO% r=0.60 or more EO% r=0.60 or more BASO% r=0.50 or more
Accuracy (differential blood count) Capillary Mode	The average of the sample values analyzed by a subject instrument by that of the standard instrument is with the following range. 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%
Linearity in Whole Blood Mode	WBC* within ±3% or ±0.3×10^3/µL (0 to 100×10^3/µL) within ±6% (100.01 to 300×10^3/µL) within ±11% (310.01 to 400×10^3/µL) RBC within ±3% or ±0.03×10^6/µL (0 to 8×10^6/µL) HGB ±2% or within ±0.2 g/dL (0.0 to 25.0 g/dL) HCT ±3% or within ±1HCT% (0.0 to 60.0 HCT%) PLT* within ±5% or ±10×10^3/µL (0 to 2000×10^3/µL) within ±16% (2001 to 5000×10^3/µL) (Depending on the RBC density, the value may not be within the range of the above-mentioned.) * The range above 310.00×10^3/µL of WBC and the range above 2000×10^3/µL of PLT are based on the verification with a stable material.
Linearity in Capillary Mode	WBC within ±5% or ±0.5×10^3/µL (0 to 100×10^3/µL) RBC within ±6% and ±0.06×10^6/µL (0 to 8×10^6/µL) HGB ±7% or within ±0.7 g/dL (0.0 to 25.0 g/dL) HCT ±6% or within ±2.0 HCT% (0.0 to 60.0 HCT%) PLT within ±10.0% or ±20×10^3/µL (0 to 1000×10^3/µL) (In some cases the value may not fall within the above range depending on RBC density.)
Carry-over	WBC 1.0% or less RBC 1.0% or less HGB 1.0% or less HCT 1.0% or less PLT 1.0% or less NEUT# 2.0% or 0.05×10^3/µL or less LYMPH# 2.0% or 0.05×10^3/µL or less MONO# 2.0% or 0.03×10^3/µL or less EO# 2.0% or 0.03×10^3/µL or less BASO# 2.0% or 0.03×10^3/µL or less

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Sample Stability with Time after Blood Collection 36 hours	NEUT% LYMPH% MONO% EO%	within ±8 NEUT% within ±7 LYMPH% within ±3 MONO% within ±3 EO%
48 hours	NEUT% LYMPH% MONO% EO%	within ±8 NEUT% within ±7 LYMPH% within ±4 MONO% within ±3 EO%
24 hours	BASO%	within ±1 BASO%
	Important! The samples used were stored at 18 to 26ºC, or in a refrigerator (2 to 8ºC). However, although the samples were preserved at room temperature and refrigerated temperature, the cold preserved samples were returned to room temperature before analyzing (In some cases the value may not fall within the above range depending on preservation status and the individual specimen).	
Sample Volume Required	Manual, Sampler Mode: Capillary Mode:	Approx. 20 µL Approx. 67 µL (The amount of blood necessary for dilution is approx. 20 µL)
Data Storage Capacity	Analysis data with histogram: Scattergram: Patient information: Order information: Quality control (QC) files:	10,000 samples (XS-1000*i*) 8,000 samples (XS-500*i*) 10,000 samples (XS-1000*i*) 8,000 samples (XS-500*i*) 5,000 persons 1,000 samples 20 files
Quality Control	X-bar control (L-J control): X-barM control:	300 points×20 files, 28 parameters 300 points×1 file, 26 parameters
Storage Condition (Transportation)	Ambient temperature: Relative humidity:	-10°C to 60°C 10~95% (but no condensation)

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11.4 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
- 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

PLT

Where the following are present, the platelet count may be reported falsely low.
- Platelet aggregation
- Pseudothrombocytopenia
- Giant platelets

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Where the following are present the platelet count may be reported falsely high.
- Microcytosis
- Fragmented erythrocytes
- Fragmented leukocytes
- Cryoprotein
- Cryoglobulin

11.5 Interface protocol

Data output can be made in different formats via the serial interface. For further information, please contact the Sysmex technical representative.

11.6 Program version

To check the current program version proceed as follows.
Select **Help (H)** → **About IPU (A)** from the menu bar.

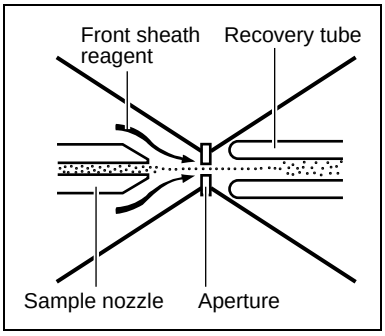
11.7 Functional descriptions

1. Detection principles

This instrument performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.

a. 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 sent to the catcher 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. And because the blood cells pass through the aperture in a line, it also prevents the generation of abnormal blood cell pulses.



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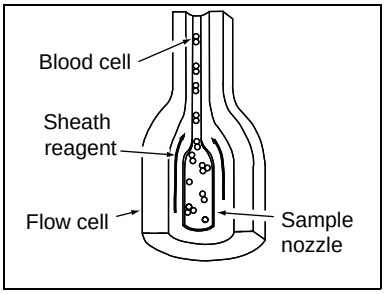
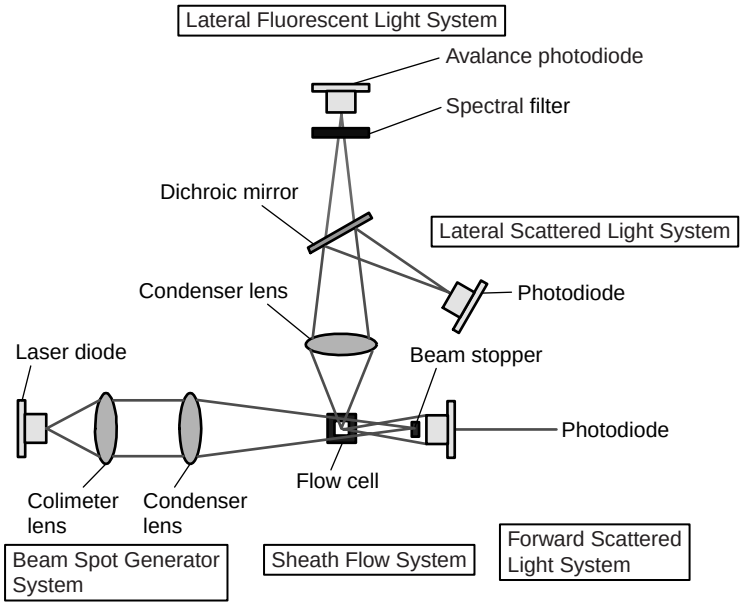
b. Flow Cytometry Method using semiconductor laser

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 flow cells.



A blood sample is aspirated and measured, diluted to the specified ratio, and stained. The sample is then fed into the flow cells.
This Hydro Dynamic Focusing mechanism improves cell count accuracy and reproducibility. And since the blood cell particles pass in a line through the center of the flow cell, the generation of abnormal 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 and lateral scattered light is captured by the photodiode, and the lateral fluorescent light is captured by the avalance photodiode. This light is converted into electrical pulses, thus making it possible to obtain blood cell information.



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(1) Forward Scattered Light and Lateral Scattered Light
When obstacles pass through a light path, the light beam scatters from each obstacle in various directions. This phenomenon is called light scattering. By detecting the scattered light, it is possible to obtain information on cell size and material properties. Likewise, when a laser beam is emitted to blood cell particles, light scattering occurs. 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 interior (such as the size of the nucleus).

(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 increases as the concentration of the stain becomes higher. By measuring the intensity of the fluorescence emitted, you can obtain information on the degree of blood cell staining. Fluorescent light is emitted in all directions; the XS-1000*i*/XS-500*i* detects the fluorescent light that is emitted sideways.

c. SLS-Hemoglobin Method

In the past, the mainstream methods for automatically measuring hemoglobin were the cyanmethemoglobin method and oxyhemoglobin method. But these methods both have advantages and disadvantages when they are used with a fully automatic instrument such as the XS-1000*i*/XS-500*i*.
The cyanmethemoglobin method was recommended by the International Council for Standardization in Hematology (ICSH) in 1966 as an international standard method. But since its hemoglobin conversion speed is slow, this method is not appropriate for automatic analysis in terms of the processing speed. 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 for fully automatic instruments.

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 analyses. 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.
And since it can be used to measure methemoglobin, it can also accurately measure blood containing methemoglobin, such as control blood.

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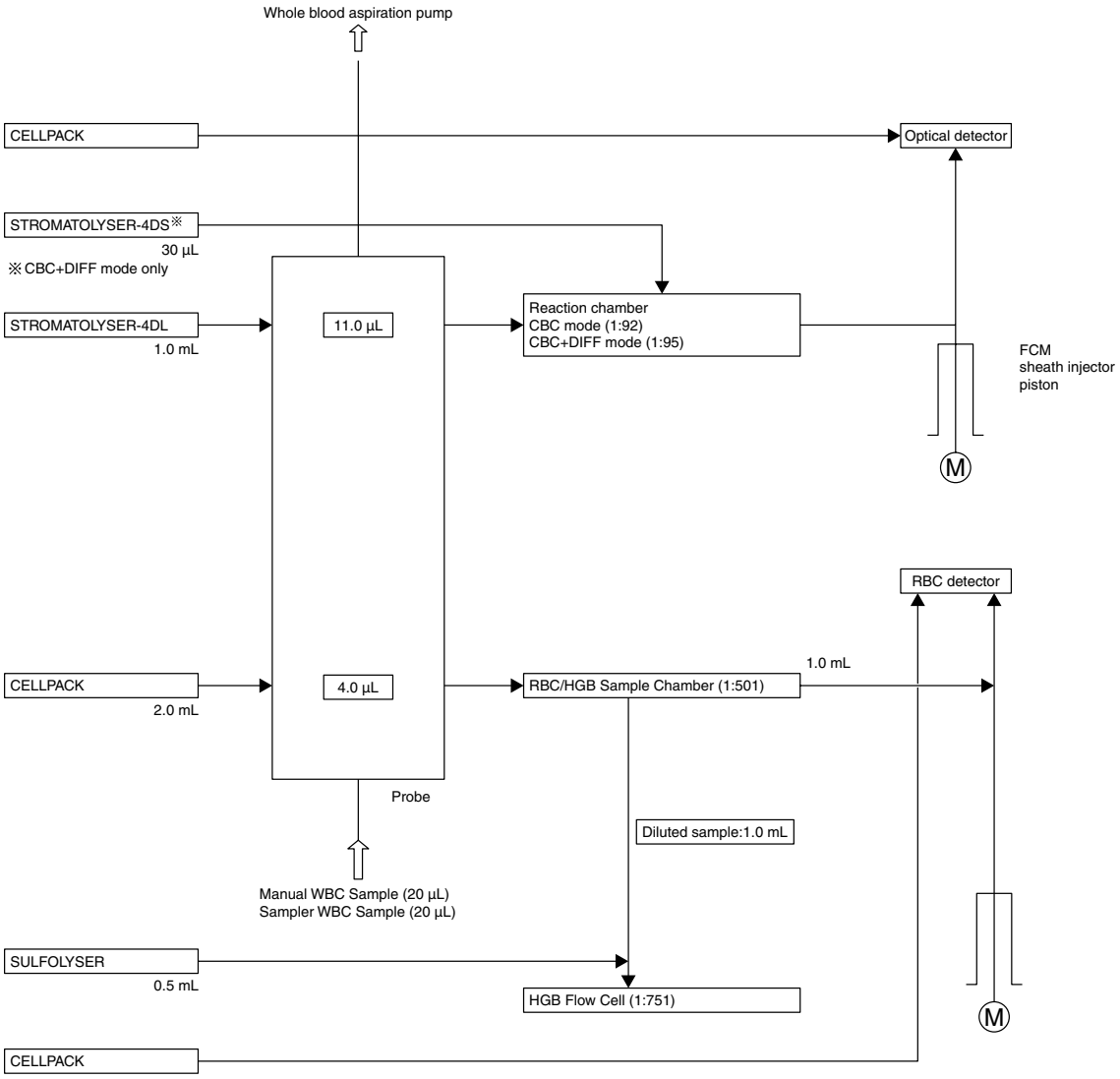
2. Hydraulic System Block Diagram

a. Whole blood mode



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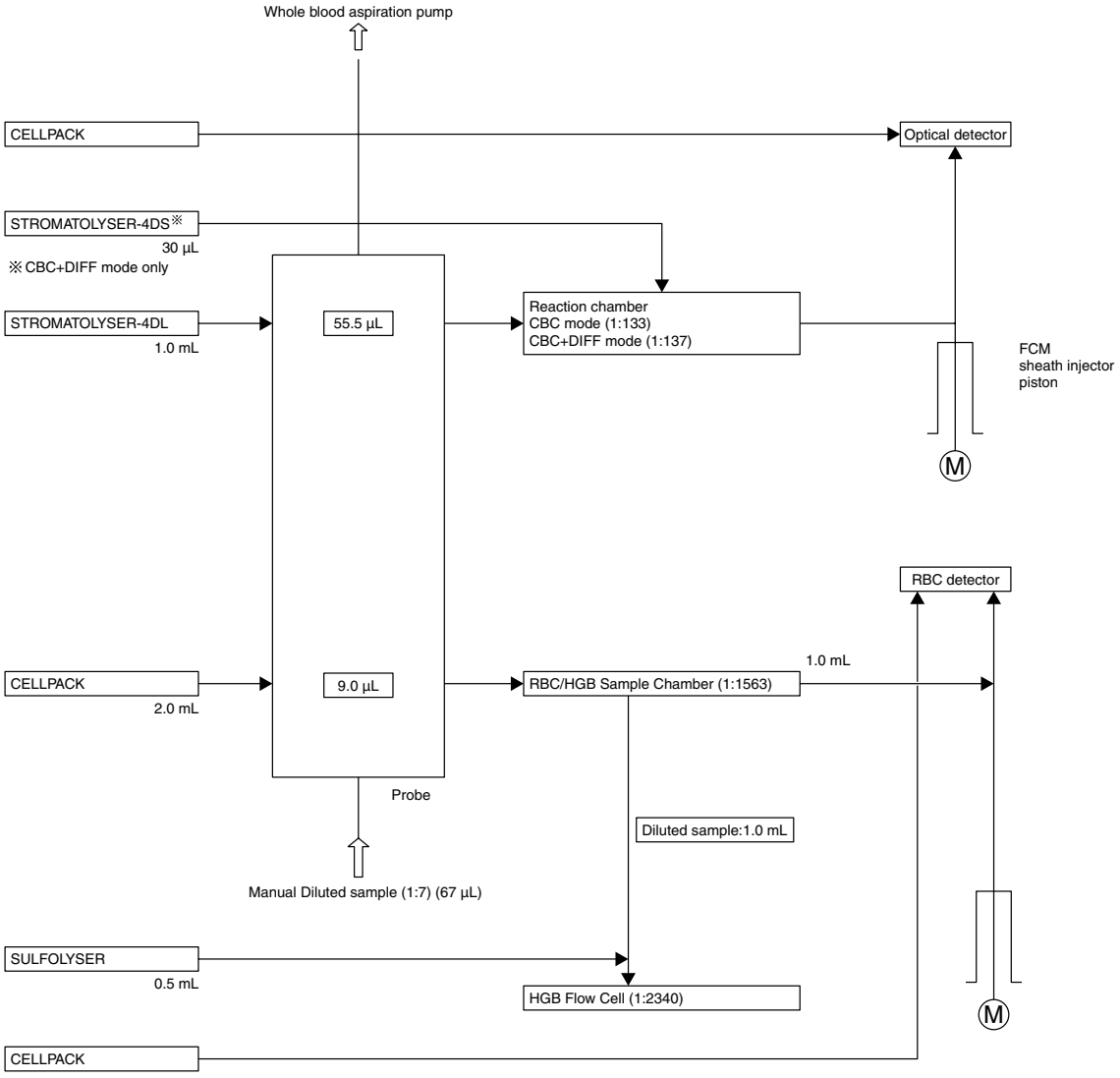
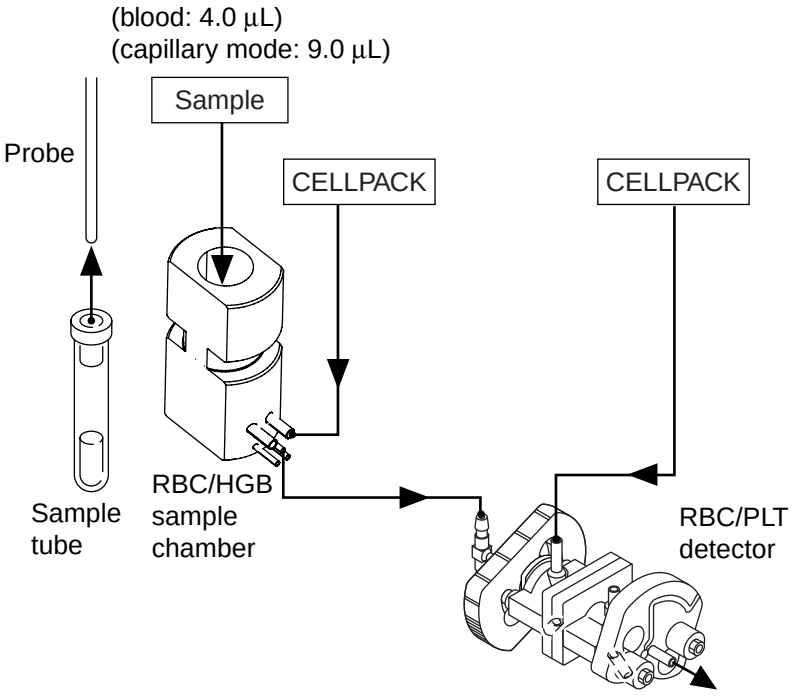
b. Capillary mode



3. RBC/PLT and HGB analysis

a. RBC/PLT Analysis Procedure

During RBC and PLT analysis the red blood cell and platelet in the blood are analyzed. The procedure for analyzing RBC/PLT is explained here.



1. Blood (diluted sample for capillary mode) is aspirated from the probe.
2. 4.0 µL of blood (9.0 µL of diluted sample for capillary mode) and 2.0 mL of CELLPACK are carried into the RBC/HGB sample chamber by the WB aspiration pump and diluted.
3. The sheath injector piston sends 10.3 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.

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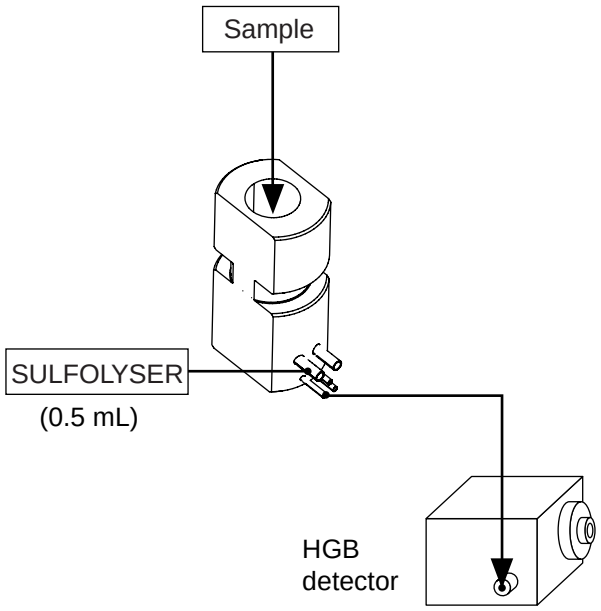
b. HGB Analysis Procedure

During an HGB analysis, the amount of hemoglobin in the blood is measured. The procedure for analyzing HGB is explained here.



1. After the RBC/PLT analysis, 0.5 mL of SULFOLYSER is added to the diluted sample remaining in the RBC/HGB sample chamber, diluting it to 751 times (2340 times for capillary mode), and the red blood cells hemolyze and the hemoglobin is converted to SLS-Hemoglobin.
2. The diluted sample from step 1 is carried into the HGB detector (HGB cell).
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 measured as light absorbance, and is calculated by comparison with the absorbance of the diluent measured before the sample was added.

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c. Computing the Erythrocyte Indices

The red blood cell constants (mean cell volume, mean cell hemoglobin, and mean cell hemoglobin concentration) are calculated from the RBC, HGB, and HCT.

1. Mean cell volume (MCV)

The MCV is calculated from the RBC and HCT, using the following equation:

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

2. Mean cell hemoglobin (MCH)

The MCH is calculated from the RBC and HGB, using the following equation:

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

3. Mean cell hemoglobin concentration (MCHC)

The MCHC is calculated from the HCT and HGB, using the following equation:

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

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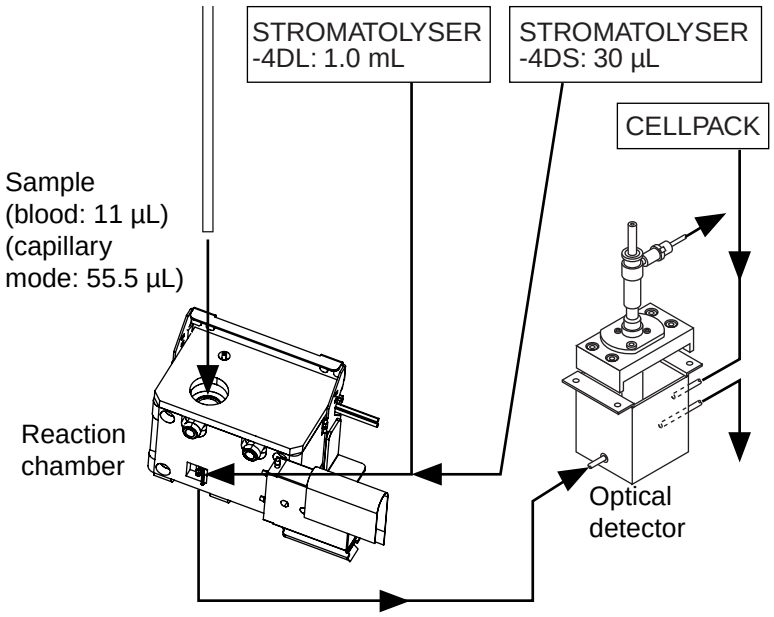
4. WBC Classification (CBC+DIFF mode)

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 here.

A 5DIFF analysis is used to identify and analyze the following white cell groups: lymphocytes, monocytes, eosinophils, neutrophils, and basophils. The 5DIFF analysis procedure is explained here.



1. In the WB aspiration pump, a fixed amount of 11 µL of blood (55.5 µL of diluted sample for capillary mode) is diluted by 1.0 mL of STROMATOLYSER-4DL in the reaction chamber.
   At the same time, 30 µL of STROMATOLYSER-4DS is added to dilute the sample to a ratio of 1:95. (1:137 in capillary mode) After reacting for about 22 seconds in this condition, the red blood cells are hemolyzed and the white blood cells are stained.
2. The sheath injector piston sends 95 µL of diluted sample to the optical detector block.
3. In the optical detector block, the sample is analyzed via flow cytometry method utilizing a semiconductor laser.

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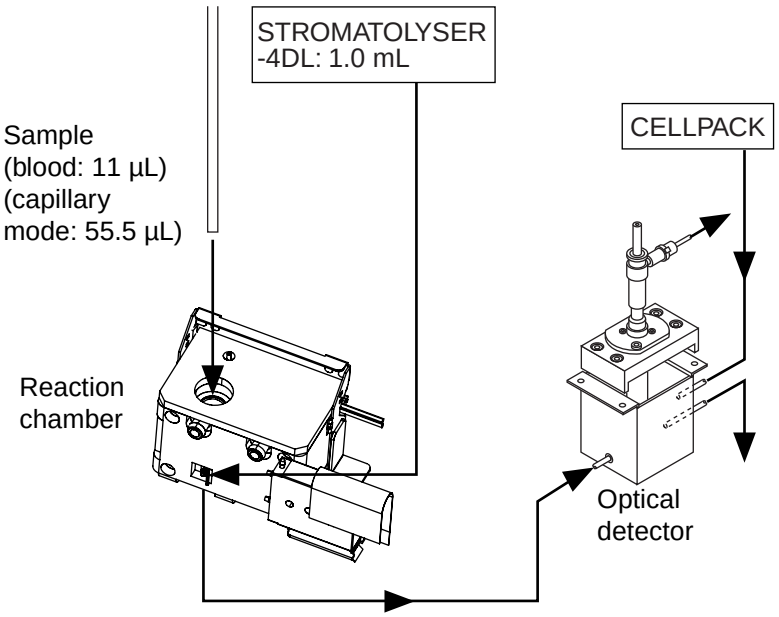
5. WBC Classifications (CBC mode)



1. In the WB aspiration pump, a fixed amount of 11 µL of blood (55.5 µL of diluted sample for capillary mode) is diluted to 92 times (133 times for capillary mode) by 1.0 mL of STROMATOLYSER-4DL in the reaction chamber. This is left to react for approximately 22 seconds. The red blood cells hemolyze.
2. 95 µL of the diluted sample is fed slowly into the optical detector by a sheath injector piston.
3. The fed-in sample is analyzed by the optical detector with the Flow Cytometry Method using a semiconductor laser.

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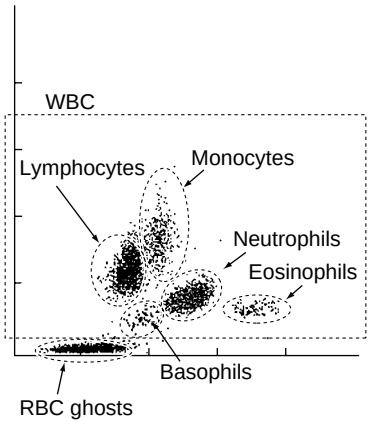
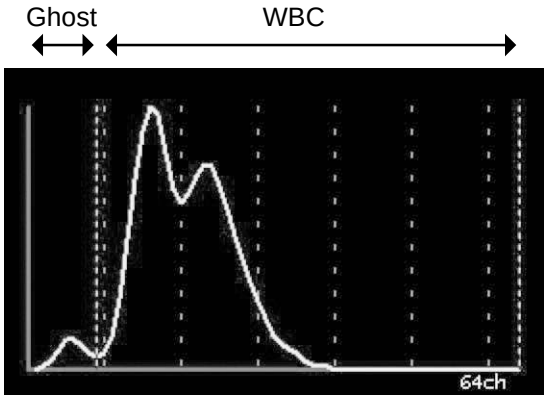
6. WBC analysis

According to the Flow Cytometry Method using a semiconductor laser, forward-scattered light, lateral-scattered light, and lateral fluorescent light are detected and represented in a 2 dimensional scattergram and histogram.
The scattergram in CBC+DIFF mode (DIFF scattergram) shows the lateral-scattered light intensity on the X axis, and the lateral fluorescent light intensity on the Y axis.
The histogram in CBC mode (WBC particle size distribution) shows the forward-scattered light intensity on the X axis, and its frequency on the Y axis.
The scattergram in CBC+DIFF mode shows the fraction of the red blood cell ghost, lymphocyte, monocyte, basophil, neutrophil, and eosinophil groups.
The histogram in CBC mode shows the fraction of the red blood cell ghost and leukocyte groups.

CBC + DIFF mode



CBC mode



Lateral scattered light and lateral fluorescent are detected via flow cytometry method utilizing a semiconductor laser, and two-dimensional scattergrams are drawn.
In a DIFF scattergram, the x-axis represents the intensity of the lateral scattered light, and the y-axis the intensity of the lateral fluorescent light.
A DIFF scattergram displays the classified groups of red blood cell ghosts, lymphocytes, monocytes, eosinophils, neutrophils, and basophils.

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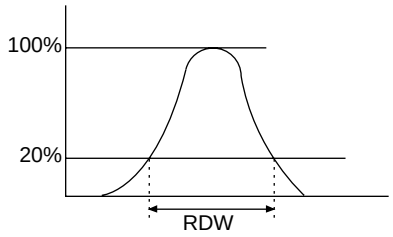
7. RBC/PLT particle size distribution analysis

a. RBC particle size distribution

The RBC (red blood count) is a particle count 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 XS-1000*i*/XS-500*i* expresses the RBC distribution width (RDW) according to the two methods shown below.

1. RDW-SD

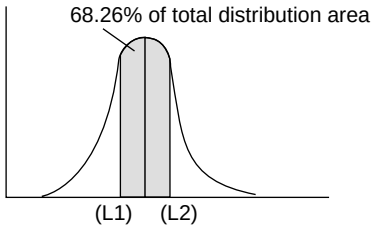
With the peak height assumed to be 100%, the distribution width at the 20% frequency level is RDW-SD. Units are expressed in fL (femtoliters), with 1 fL equal to 10^{-15}L.



2. 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:

$$\text{RDW–CV (\%)} = \frac{L_2 - L_1}{L_2 + L_1} \times 100$$



b. 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.

1. 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.

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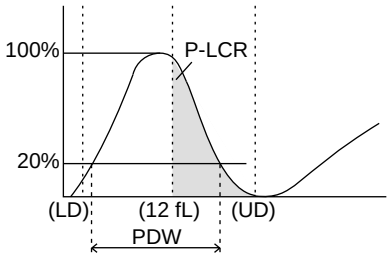
2. P-LCR (Platelet Large Cell Ratio)

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.



3. 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.

c. 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.

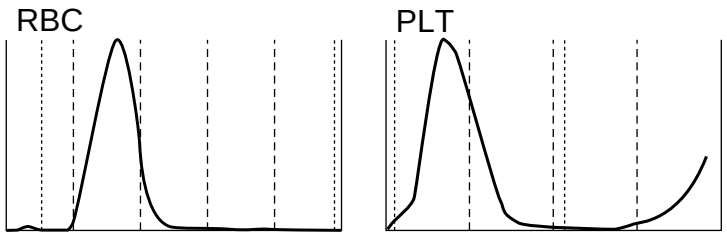
The XS-1000*i*/XS-500*i* utilizes a conventional particle size distribution expression (normal expression) and a particle size distribution expression method that enables the user to obtain a large amount of information from the particle size distribution intuitively (normal cell size range expression).

1. 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



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2. Normal Cell Size Range Expression

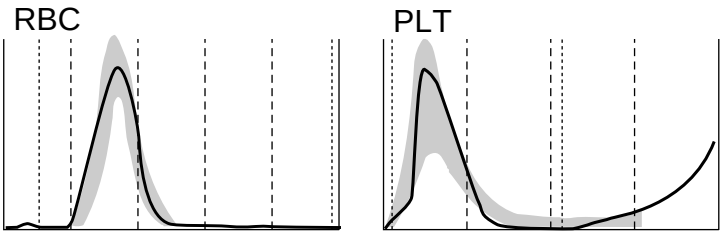
With the peak of the cell size range found experimentally set as full scale rather than the peak of the particle size distribution set as full scale (maximum height when the particle size distribution is displayed), this method of expression normalizes and expresses the distribution. At the same time, 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 number of normal people and then utilizing the region from the 10th percentile to the 90th percentile.

- Features: The viewer can intuitively see the size of the particle count from the particle 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



8. 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 converted from analog signals to digital signals, and sent to the microprocessors unit. The data is then sent from the microprocessors unit to the IPU where the data is processed.

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 digital unit converts the analog-to-digital-converted cell signals into particle size distribution data and sends the data to the microprocessors unit.

HGB is calculated by subtracting the light absorbance of the diluent (background count) from the light absorbance of the sample. As for this light absorbance, light that is passed through the liquid is received by the photodiode, where it is photoelectrically converted. It is then converted from analog to digital signals, and sent to the microprocessors unit.

The blood cell signals from the optical detector block (which analyzes 5DIFF) 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 digital unit converts the analog-to-digital-converted cell signals into scattergram data and sends the data to the microprocessors unit.

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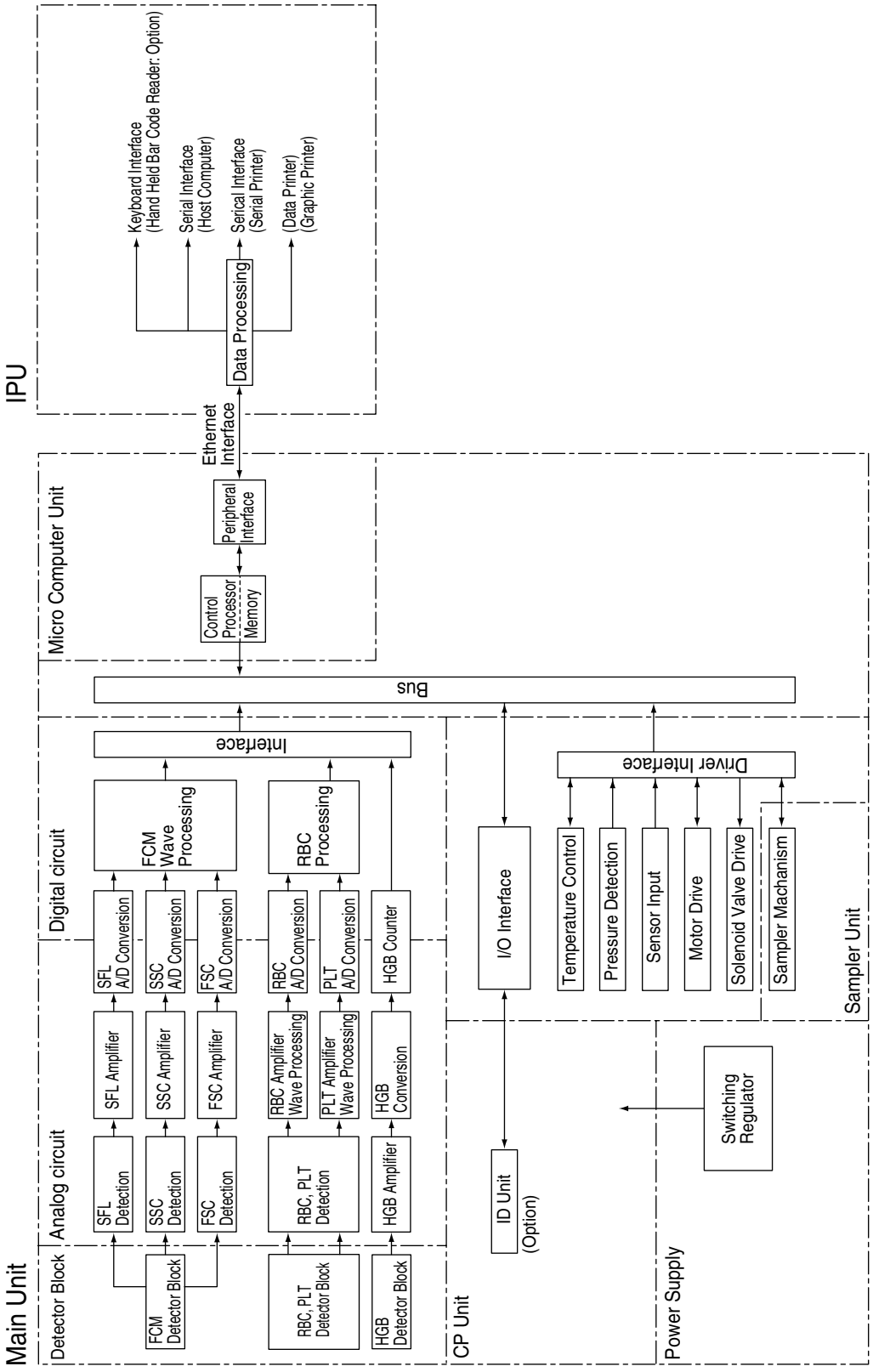
9. Electronic system block diagram



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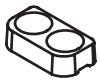
11.8 Unpacking Checklist

Main Unit (XS-1000*i*/XS-500*i* finished product)

Part Number	Names	Quantity		
		XS-1000*i*	XS-500*i*	
053-4241-8	Main Unit Complete assembly (for XS-1000*i*)	1	—	
053-4242-1	Main Unit Complete (for XS-500*i*)	—	1	
266-7769-4 or 266-5296-1	Fuse 50T050H (250V 5A) or Fuse No. 19195 (250V 5A)	2	2	
462-3520-5	Transducer Brush (With cap)	1	1	
462-2381-8	Screwdriver Phillips No. 1300#2	1	1	
462-2390-1	Screwdriver Regular DS-34	1	1	
BG432419	TRAY No.129	1	1	
462-3122-1	Cubitainer Opener No. 2	1	1	
442-5338-7	Tube Polyurethane 4 mm ID × 6 mm OD 2 m	1	1	
442-5340-5	Tube Polyurethane 6 mm ID × 9 mm OD 5 m	1	1	
943-1782-4	Cubitainer Spout Kit No. 1 (10 L)	1	1	
023-2442-9	Cubitainer Spout Kit No. 5	1	1	
033-0411-1	Cubitainer Spout Kit No. 7	1	1	
053-5671-5	Cubitainer Spout Kit No. 10	1	1	
CR163712	XS-1000*i*/XS-500*i* Instructions for Use	1	1	
BR275157	XS-1000*i*/XS-500*i* Software Guide	1	1	
053-4761-0	CDR 1XSi1 Assembly	1	1	
923-8092-8	Power Cord No. 15	1 *1 — *2 1 *3	1 *1 — *2 1 *3	
265-4731-5	Power Cord 4622-007-0092	— *1 1 *2 1 *3	— *1 1 *2 1 *3	

*1 For North America *2 For Europe *3 For Asia Pacific

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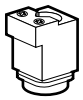
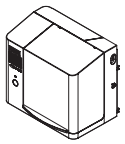
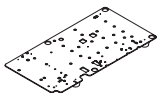
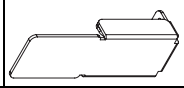
Part Number	Names	Quantity		
		XS-1000*i*	XS-500*i*	
266-4461-8	Tie Wrap CV-100	10	10	
AK061255	XS Adapter (For standard sample tubes)	1	—	
442-3088-0	XS Adapter (For analyzing small samples: 2)	1	—	
442-3085-9	XS Adapter (For Control blood)	1	—	
368-0003-3	Rubber Shoe C-31-4-UL	—	4	
321-4353-8	XS-500*i* Base	—	1	

Sampler Unit (XS-1000*i*)

Part Number	Names	Quantity	
053-6321-6	OPSU-11 Main Unit Complete Assembly	1	
053-6331-3	OPSU-11 Base Assy	1	
322-3919-7	OPSU-11 Sample Position Cover	1	
424-3333-5	Sample Rack No. 5-2 (White)	2	
366-1789-1	Tube Holder No. 58 (White)	20	
368-1577-0	Polyurethane Roll Stock TM-182-832-12	2	
368-0992-4	Clear Bang-Pong TM-180-303 (2 each for spares)	4	
348-3926-8	Philips Screw Binding M4 ×6 (SUS)	3	
348-3935-1	Philips Screw Binding M4 ×30 (SUS)	1	
348-3911-2	Philips Screw Binding M3 ×4 (SUS)	2	
348-3812-1	Philips Screw Binding M3 ×6 (SUS)	2	

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11.9 Check Before Installation

The XS-1000*i*/XS-500*i* 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 XS-1000*i*/XS-500*i* by anyone other than a Sysmex technical representative are not covered by Warranty even within the warranty period.

11.10 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.

Warning!

- Be sure to ground this instrument. Improper grounding may cause electrical shock.
- Be sure not to exceed socket capacity. Failure to do so may cause a fire.

11.11 Installation Environment

- Operate the XS-1000*i*/XS-500*i* within an ambient temperature range of 15°C - 30°C (optimum temperature: 23°C).
- 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 places of extremely high or low temperatures.
- Avoid a place that is exposed to direct sunlight.
- Select a well-ventilated place.
- Avoid a place close to a wireless telegraph or communication facility where high frequency waves are generated or radio interference can occur.

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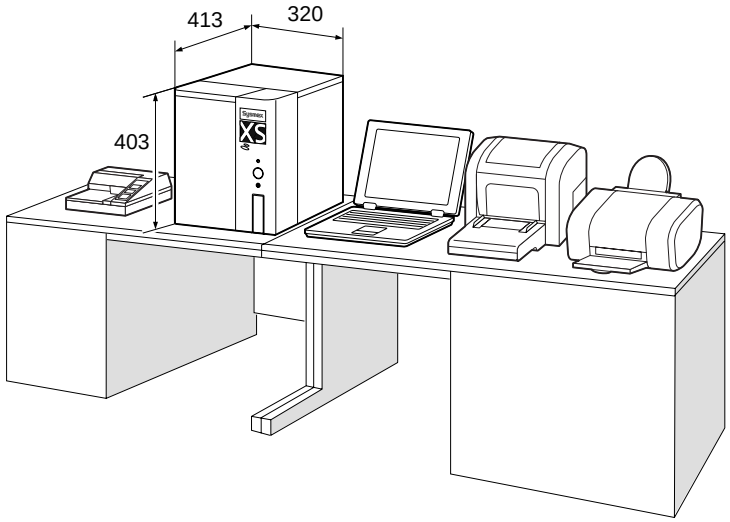
11.12 Installation Space

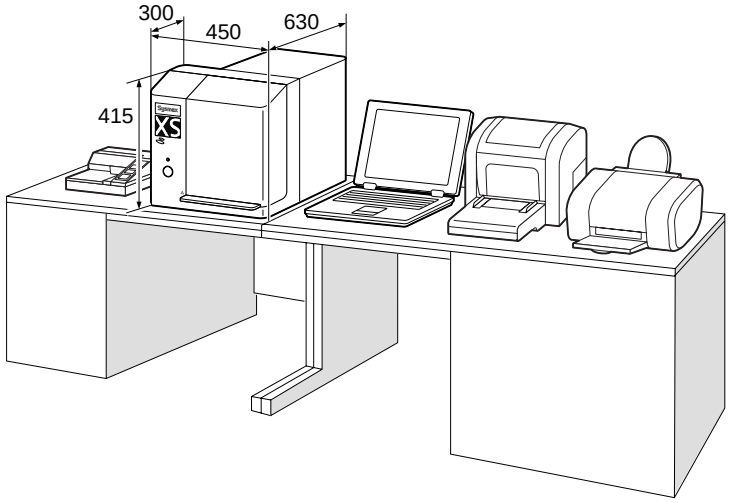
To secure the space required for maintenance, install the IPU on the right side of the XS-1000*i*/XS-500*i*.
Provide a distance of at least 50 cm behind the instrument.

XS-1000*i*

Components	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	320	413	403	Approx. 24
Sampler Unit	450	320 (when Main unit is connected: 630)	415	Approx. 14



XS-1000*i* with Sampler (Optional)



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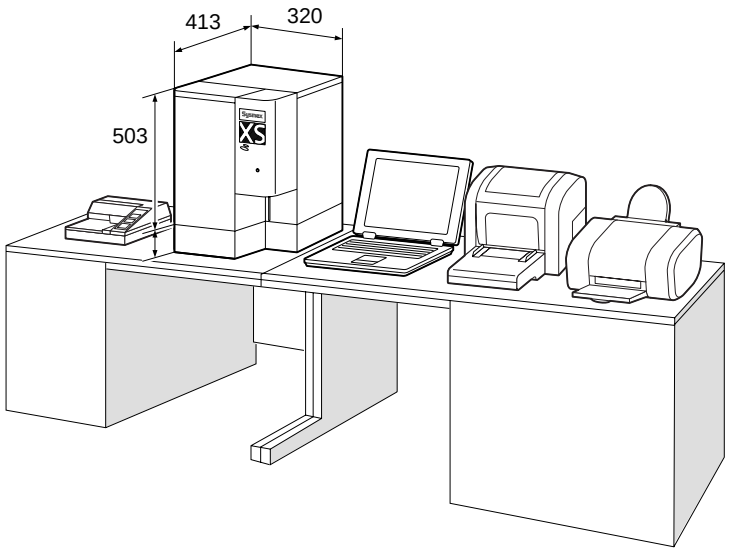
XS-500*i*

Component	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	320	413	503	Approx. 24



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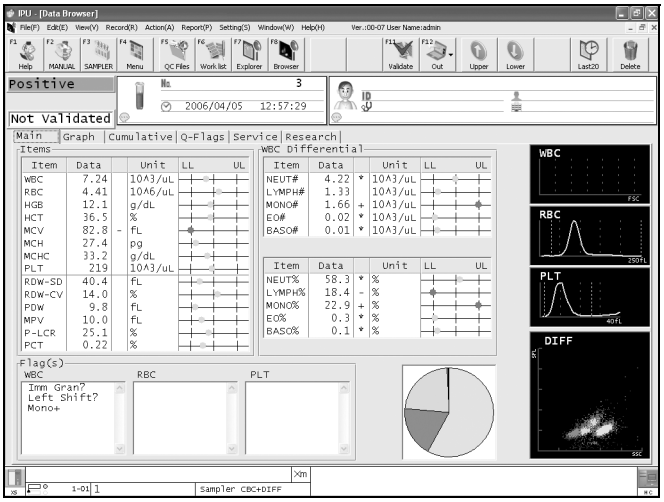
12. IP messages

The IPU, displays and prints hematology information in a format designed to aid in the separation of POSITIVE and NEGATIVE data results.
All analyzed samples without analysis errors can be separated into a POSITIVE or NEGATIVE category according to preset criteria. The system bases its judgments on comprehensive surveys of numerical data, particle size distributions, scattergrams, and provides easy-to-understand flags/messages indicating the instrument's findings. These flags/messages are referred to as "IP (Interpretive Program) messages."



POSITIVE (red backlight) — A POSITIVE result indicates that the sample is judged abnormal according to preset criteria for analysis, numerical values and cell morphology. (Abnormal)

NEGATIVE (green backlight) — A NEGATIVE result indicates that the sample is normal, i.e. has no analysis errors nor IP messages. (Normal)

This system categorizes and flags POSITIVE results as "DIFF Abnormal", "MORPH Abnormal", and/or "COUNT Abnormal" during WBC, RBC, and PLT analysis. These flags appear when abnormal cell populations are detected during computer analysis of the particle size distributions, scattergrams, and 24 parameters.

DIFF Abnormal	Indicates abnormality in the WBC differential parameters.
MORPH Abnormal	Indicates abnormal cell morphology.
COUNT Abnormal	Indicates abnormality in the blood cell numerical count.

These sub-categories (DIFF Abnormal, MORPH Abnormal, and COUNT Abnormal) appear when the field of the POSITIVE flag is double-clicked.

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The IP Message displays either an Abnormal IP Message or Suspect IP Message whenever there is an abnormality relating to the WBC, RBC, or PLT tests.

Abnormal IP messages
Indicates that the sample is definitely abnormal. The IP abnormal message criteria can be set except for some items.

Suspect IP messages
Indicates that there is a possibility that the sample is abnormal.

Important!

Abnormal and suspect IP Messages are intended for use only in the clinical laboratory and are not for patient diagnosis. The purpose of the IP Message is to inform the operator of the possibility of sample abnormality, so special measures or further analysis can be undertaken.
(Additional information) It is recommended to check the data and perform review (re-analysis or close examination.)

The IP Message is displayed on the Data Browser screen, Graph screen, and Research screen flag(s) area.

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When IP messages are flagged, the unit will judge that the analyzed data with the following IP messages have low reliability because of abnormalities. The mark of "*" (or "----") will be displayed at the right of the data.

	WBC	NEUT	LYMPH	MONO	EO	BASO	RBC HCT MCV MCH MCHC	HGB MCH MCHC	RDW SD	RDW CV	PLT	PDW MPV PLCR PCT
WBC Abn. Scattergram												
1) Lymph, Mono		- -	- -	- -								
2) Neut, Eo		- -			- -							
3) Mono, Neut		- -		- -								
4) Lymph, Neut		- -	- -									
5) Lymph, Baso		- -	- -			- -						
6) Mono, Eo		- -		- -	- -							
7) Ghost, Baso	*	- -	- -	- -	- -	- -						
8) Ghost, Lymph	*	- -	- -	- -	- -	- -						
9) Ghost, Neut	*	- -	- -	- -	- -	- -						
10) Bas: Neu, Bas: Lym						*						
11) Neu: Bas		- -				- -						
12) WBC Histogram Abnormality	*											
13) Impossibility of the calculation of 5DIFF data		- -	- -	- -	- -	- -						
14) WBC < 0.5 × 10^3/μL		*	*	*	*	*						
Blasts?		*	*	*								
Immature Gran?		*			*	*						
Left Shift?		*			*							
Atypical Lympho?		*	*	*								
Abn Lympho?		*	*	*								
NRBC?	*	*	*	*	*	*						
RBC Abn Distribution												
1) MP-Flag							*		- -	- -		
2) Abnormal RDW-SD							*		- -	*		
3) Other abnormal distribution Abnormal							*		*	*		
4) RBC < 0.50 × 10^6/μL							*		*	*		
Dimorphic Population							*		- -	- -		
RBC Agglutination?							*					
Turbidity/HGB Interf?								*				
PLT Abn Distribution												
1) Abnormal PDW											*	- -
2) Other abnormal distribution Abnormal											*	*
PLT Clumps?	*	*	*	*	*	*					*	*
PLT Clumps (S)?	*	*	*	*	*	*					*	*

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The IP Message Judgment Details

1. During normal Analysis

The IP Messages will not be displayed in the following cases:

- Quality Control Analysis Data
- Calibration Analysis Data
- Background Check Data
- Blank Data

When WBC < 0.5 × 10^3/µL, no WBC Suspect Message will be generated.

When RBC < 0.5 × 10^6/µL, no messages other than the "**RBC Abn. Distrib.**" will be generated.

When PLT is "**----**," no PLT IP messages will be generated.

If errors prevent the parameters necessary for judgment from being calculated, the IP Messages will not appear (i.e. parameters are marked with "**----**" and "**++++**").

2. For Capillary Analysis

In addition to the conditions of normal analysis, all available parameter data is used for judgment.

Some of the RBC- and PLT- IP Messages are not judged. Refer to “4. Description of IP Messages” for details.

Performs only POSITIVE judgement, not NEGATIVE judgement.

3. For Discrete Analysis

In addition to the conditions of normal analysis, the parameters (" " [Blank]) which are not analyzed by the user settings are not used for judgment.

Revised August 2013

The IP Message categories, meanings and judgments/formula used by the XS-1000*i*/XS-500*i* are listed as follows:

WBC IP Messages		
ABNORMAL		
Message	Meaning	Judgment/Formula
WBC Abn. Scattergram	WBC abnormal scattergram	By the clustering in the DIFF Scattergram
Neutropenia	Low neutrophil count	NEUT# < 1.0 × 10^3/µL
Neutrophilia	High neutrophil count	NEUT# > 11.0 × 10^3/µL
Lymphopenia	Low lymphocyte count	LYMPH# < 0.8 × 10^3/µL
Lymphocytosis	High lymphocyte count	LYMPH# > 4.0 × 10^3/µL
Monocytosis	High monocyte count	MONO# > 1.0 × 10^3/µL
Eosinophilia	High eosinophil count	EO# > 0.7 × 10^3/µL
Basophilia	High basophil count	BASO# > 0.2 × 10^3/µL
Leukocytopenia	Low leukocyte count	WBC < 2.5 × 10^3/µL
Leukocytosis	High leukocyte count	WBC > 18.0 × 10^3/µL
SUSPECT		
Message	Meaning	Judgment/Formula
Blasts?	Possibility that blasts are present	Blast cluster found in the DIFF Scattergram
Immature Gran?	Possibility that immature granulocytes are present	Immature Granulocyte cluster found in the DIFF Scattergram
Left Shift?	Possibility of left shift	Cluster in the upper right of the Granulocytes in the DIFF Scattergram
Abn Lympho?	Possibility of abnormal lymphocytes	Overlapping of the lymphocyte and monocyte population
NRBC?	Possibility of nucleated RBCs present	Spot distribution between ghosts and lymphs in the DIFF Scattergram
Atypical Lympho?	Possibility of atypical lymphocytes	Cluster in the upper left area of the DIFF Scattergram

RBC IP Messages		
ABNORMAL		
Message	Meaning	Judgment/Formula
RBC Abn Distrib.	RBC abnormal distribution	Arithmetic calculation and numerical comparison on a specific analysis parameter
Dimorphic Population	Double-peak RBC distribution	Gap between the high and low points and shape of distribution "peak."
Anisocytosis	Anisocytosis	RDW-SD > 65 fL or RDW-CV > 20.0%
Microcytosis	Microerythrocytes	MCV < 70 fL
Macrocytosis	Macroerythrocytes	MCV > 110 fL
Hypochromia	Hypochromia	MCHC < 29.0 g/dL
Anemia	Anemia	HGB < 10.0 g/dL
Erythrocytosis	Erythrocytosis	RBC# > 6.5 × 10^6/μL
SUSPECT		
Message	Meaning	Judgment/Formula
RBC Agglutination?	Possibility of RBC agglutination	Arithmetic calculation and numerical comparison on a specific analysis parameter
Turbidity/HGB Interf?	Possibility of HGB interference by chylemia	Arithmetic calculation and numerical comparison on a specific analysis parameter
Iron Deficiency?	Possibility of iron deficiency anemia	Arithmetic calculation and numerical comparison on a specific analysis parameter
HGB Defect?	Possibility of HGB abnormality	Arithmetic calculation and numerical comparison on a specific analysis parameter
Fragments?	Possibility of fragmented RBCs	Arithmetic calculation and numerical comparison on a specific analysis parameter
pRBC?*1	Possibility of Parasitized RBC*2	Arithmetic calculation and numerical comparison on a specific analysis parameter

PLT IP Messages		
ABNORMAL		
Message	Meaning	Judgment/Formula
PLT Abn Distrib.	PLT abnormal distribution	Arithmetic calculation and numerical comparison on a specific analysis parameter
Thrombocytopenia	Thrombocytopenia	PLT# < 60.0 × 10^3/μL
Thrombocytosis	Thrombocytosis	PLT# > 600.0 × 10^3μL
SUSPECT		
Message	Meaning	Judgment/Formula
PLT Clumps?	Possibility of PLT clumps	Spot distribution in the lower area of DIFF Scattergram and forward scatter data
PLT Clumps (S)?	Possibility of PLT clumps	Arithmetic calculation and numerical comparison on a specific analysis parameter

*1: License registration only

*2: The flag indicates that red blood cell may be infected with either P. vivax or P. malariae - trophozoite, schizont and gametocyte stages. This is only a suspect flag and NOT definitive or specific for malaria infection.

Revised August 2013

4. Description of IP messages

See the list shown below for the following items.

- Reference to flag No. on the Explorer screen
- IP message output format for display and printing
- Reference to category for Positive/Negative judgment
- IP message for flagging during analysis

	Message		Message on Explorer screen (Flag No.)	Message on Data Browser screen	Message in GP print	Flag categories in Positive/Negative check			Parameters for flagging at discrete analysis		Capillary
						Morph	Count	Diff	CBC	CBC+DIFF	
WBC	Abnormal	WBC Abn Scattergram	1	WBC Abn Scg	WBC ABN Scattergram	●			○	○	○
		Neutropenia	2	Neutro-	Neutropenia			●	×	○	○
		Neutrophilia	3	Neutro+	Neutrophilia			●	×	○	○
		Lymphopenia	4	Lympho-	Lymphopenia			●	×	○	○
		Lymphocytosis	5	Lympho+	Lymphocytosis			●	×	○	○
		Monocytosis	6	Mono+	Monocytosis			●	×	○	○
		Eosinophilia	7	Eo+	Eosinophilia			●	×	○	○
		Basophilia	8	Baso+	Basophilia			●	×	○	○
		Leukocytopenia	9	Leuko-	Leukocytopenia		●		○	○	○
		Leukocytosis	A	Leuko+	Leukocytosis		●		○	○	○
	Suspect	Blasts?	1	Blasts?	Blasts?	●			×	○	○
		Immature Gran?	2	Imm Gran?	Immature Gran?	●			×	○	○
		Left Shift?	3	Left Shift?	Left Shift?	●			×	○	○
		Atypical Lympho?	4	Atypical Ly?	Atypical Lympho?	●			×	○	○
		Abn Lympho?	7	Abn Ly?	Abn Lympho?	●			×	○	○
		NRBC?	5	NRBC?	NRBC?	●			×	○	○
RBC	Abnormal	RBC Abn Distribution	1	RBC Abn Dst	RBC ABN Distribution	●			○	○	×
		Dimorphic Population	2	Dimorph Pop	Dimorphic Population	●			○	○	×
		Anisocytosis	3	Aniso	Anisocytosis	●			○	○	×
		Microcytosis	4	Micro	Microcytosis	●			○	○	○
		Macrocytosis	5	Macro	Macrocytosis	●			○	○	○
		Hypochromia	6	Hypochromia	Hypochromia	●			○	○	○
		Anemia	7	Anemia	Anemia		●		○	○	○
		Erythrocytosis	8	Erythro+	Erythrocytosis		●		○	○	○
	Suspect	RBC Agglutination?	1	RBC Agglut?	RBC Agglutination?		●		○	○	×
		Turbidity/HGB Interference?	2	Turb/HGB?	Turbidity/HGB Interf?		●		○	○	×
		Iron Deficiency?	3	Iron Def?	Iron Deficiency?	●			○	○	×
		HGB Defect?	4	HGB Defect?	HGB Defect?	●			○	○	×
		Fragments?	5	Fragments?	Fragments?	●			○	○	×
		pRBC?*	6	pRBC?	pRBC?	●			○	○	○
PLT	Abnormal	PLT Abn Distribution	1	PLT Abn Dst	PLT ABN Distribution	●			○	○	×
		Thrombocytopenia	2	Thrombo-	Thrombocytopenia		●		○	○	○
		Thrombocytosis	3	Thrombo+	Thrombocytosis		●		○	○	○
	Suspect	PLT Clumps?	1	PLT Clumps?	PLT Clumps?		●		×	○	○
		PLT Clumps(S)?	2	PLT C(S)	PLT Clumps(S)?		●		○	○	×

○: Perform flagging, ×: Does not perform flagging

*: License registration only

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13. Warranty

All Sysmex instruments are warranted against defective material or workmanship for a period of one year, commencing on date of installation at the customer's premises. This warranty does not however cover any defect, malfunction or damage due to:

- Accident, neglect or willful mistreatment of the product;
- Failure to use, operate, service or maintain the product in accordance with the applicable Sysmex Instruction for Use.
- Failure to use the appropriate reagents and consumables specified for the product.

Important!

If the customer relocates the instrument or operates it at a different location, the warranty expires. Contact your Sysmex technical representative before relocating.

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14. Index

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