Automated Hematology Analyzer
XN-L series

XN-530/XN-430 /XN-330

General Information
(North American Edition)

This manual provides important safety information and specifications of the instrument.
Read this manual before using the instrument.

The following manuals are provided as Instructions for Use:

- General Information
- Basic Operation
- Troubleshooting

Sysmex Corporation
KOBE, JAPAN

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Software version: Ver. 3

Changes are listed below:

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5.1 Performance specifications/characteristics	59, 61, 62, 63, 64, 65, 69
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Chapter 1 Introduction

Thank you for purchasing the Automated Hematology Analyzer XN-L series.
Please read this manual carefully before operating this product.
Keep this manual in a safe place for future reference.

Note:

Operation of instruments and devices outside of recommended manufactures guidelines may result in inaccuracies.

US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

Contact Addresses

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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

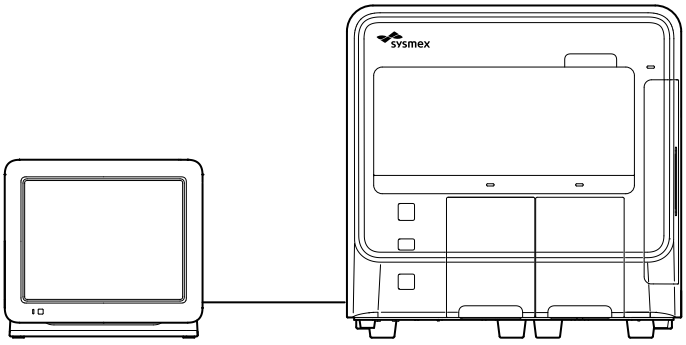
Please contact the Service Department of your local Sysmex representative.

1.1 Intended use

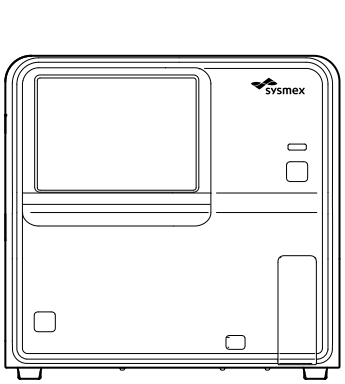
The Sysmex XN-L Automated Hematology Analyzer is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates the following parameters in venous and capillary whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in cerebrospinal, peritoneal, pleural, and synovial fluids. Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

1.2 Overview of the system

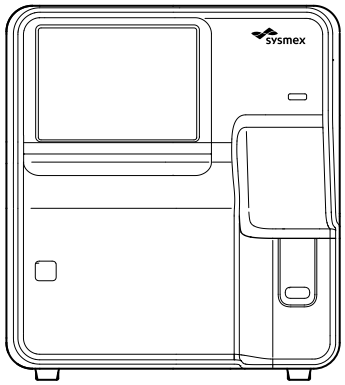
This instrument is a hematology analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories.
This instrument enables quantitative, identification, and existence ratio analysis of tangible components of blood and body fluid (red blood cells, white blood cells, platelets and other cells) by means of electrical impedance, laser light scattering and fluorescent labeling.



XN-530



XN-430



XN-330

		XN-530 Sampler analysis type	XN-430 Closed analysis type	XN-330 Open analysis type
Channels	CBC+DIFF	✓		
	RET	Option		
Analysis mode other than Whole Blood mode	Pre-Dilution	✓		
	Low WBC	Option		
	Body Fluid	Option		

1.3 Reportable parameters

This instrument reports the following parameters.

● Reportable parameters

[Whole Blood] mode / [Low WBC] mode*1 / [Pre-Dilution] mode	
Detector/Channel	Parameter
WDF	WBC, NEUT#, LYMPH#, MONO#, EO#, BASO#, NEUT%, LYMPH%, MONO%, EO%, BASO%, IG#, IG%
RBC/PLT	RBC, HCT, MCV*2, MCH*2, MCHC*2, PLT, RDW-SD*3, RDW-CV*3, MPV*2
HGB	HGB
RET	RET%*1, RET#*1, IRF*1,2, RET-He*1,2
[Body Fluid] mode*1	
Detector/Channel	Parameter
WDF	WBC-BF, MN#, MN%, PMN#, PMN%, TC-BF#
RBC/PLT	RBC-BF

*1 The availability of functions depends on your system configuration.

*2 Parameter calculated from an equation. For details, see the following.

(➤**P.83** "Chapter 5: 5.6.3 Reportable parameters and channels")

*3 Parameters calculated from an equation from the distribution. For details, see the following.

(➤**P.83** "Chapter 5: 5.6.3 Reportable parameters and channels")

1.4 About the manuals

1.4.1 List of manuals

The following manuals are provided with this instrument.

Type		Description
Instructions for Use	**General Information (this manual)**	This manual provides important safety information and specifications of the instrument. Read this manual before using the instrument.
	Basic Operation	Read this manual to operate the instrument. The explanations in this manual assume that you have already read "General Information".
	Troubleshooting	Read this manual when you encounter a problem, and to perform instrument maintenance. The explanations in this manual assume that you have already read "General Information".

1.4.2 Points to note about the manuals

- You may not reprint the contents of the manuals in whole or in part without permission.
- The names of patients, doctors, etc., mentioned in the manuals do not represent actual people in any way.
- Images in these instructions for use related to the product are for illustration purposes only and may not exactly match with what is found on the product itself.
- While we have taken all possible precautions to ensure quality in the content of this manual, please contact the Service Department of your local Sysmex representative if you find any errors or omissions.

1.5 Symbols used in the manuals

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!

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

Caution, Hot!

Indicates risk of burns and other injuries if the warning is not observed.

Caution, Electric!

Failure to observe this warning may result in instrument damage due to electrostatic discharge from your body.

Information

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

Note:

Background information and practical tips.

1.6 Trademarks

- Sysmex is a registered trademark of SYSMEX CORPORATION, Japan.
- CELLPACK, CELLCLEAN, Fluorocell, SULFOLYSER, and Lysercell are trademarks of SYSMEX CORPORATION.
- ISBT128 (International Society of Blood Transfusion) is copyrighted by and is used under License Agreement with ICCBBA, Inc.
- Windows is a trademark or registered trademark of Microsoft Corporation in the United States and other countries.
- Other company names and product names in the manuals are the registered trademarks or trademarks of their respective owners.

The fact that a trademark is not explicitly indicated in this manual does not authorize its use.
TM and ® are not explicitly indicated in the manuals.

Chapter 2 Safety Information

This chapter explains precautions for safe use of this instrument.

2.1 General information

⚠ Warning!

- Keep your hair, fingers and clothing away from the instrument that are in operation.
  You may get injured if caught in the instrument.
- Do not spill blood samples or reagents into the instrument, or get any metals such as staples or clips, inside the instrument.
  Risk of short-circuiting and smoke emission.
- The operator should not touch any electrical circuitry inside the cover.
  The risk of electrical shock is especially high when your hands are wet.
- The instrument must not be connected to a power outlet other than that specified on the rating plate.
  Please note that the instrument must be grounded.
  Failure to do so may result in 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 fire or shock due to an electrical short or break in the wiring.
- In the unlikely event that the instrument emits an unusual odor or smoke, immediately turn OFF the main switch and unplug the power cable. Then contact your Sysmex service representative.
  Continued use of the instrument in such conditions could result in fire, electrical shock or personal injury.

⚠ Caution!

- When handling the sampler adapter (XN-530) and sample tubes, take care not to spill the sample.
- Do not lean against the instrument.
  The resulting impact could damage the instrument or cause it to tip over.
- For maintenance tasks that require a washing solution, always use CELLCLEAN AUTO. If CELLCLEAN AUTO is not used, the instrument will not be cleaned sufficiently and problems may result.
- Do not analyze coagulated blood.

cTÜVus Certification symbol indicates that the equipment is tested and certified to comply with the electrical and fire safety regulations controlled by the US and Canadian governments.
Those tests were conducted thoroughly by TÜV Rheinland that is accredited as a Nationally Recognized Testing Laboratory (NRTL) by OSHA (The Occupational Safety and Health Administration) in the United States, and by SCC (Standards Council of Canada) in Canada.

2.2 Installation

Warning!

- Your Sysmex technical representative will unpack, install, and test initial operation of the instrument.
- This instrument must not be connected to a power outlet rated at anything other than specified on the rating plate. Please note that the instrument must be grounded.
  Failure to do so may result in fire or electrical shock.
- Switch OFF the power supply before connecting any peripheral devices (host computer, printer, etc.).
  Failure to do so may result in electrical shock or failure. In addition, an abnormal stop may occur if a device is connected while the instrument is running.

Caution!

- Install in a location where water will not splash or spray onto the instrument.
- Install in a location where the instrument will be protected from high temperature, humidity, dust and direct sunlight.
- Do not install in a location subject to vibration.
- Do not subject the instrument to intense shock or vibration.
- Install the instrument in a well-ventilated place.
- Avoid installing the instrument near equipment that emits electrical interference, such as a radio or centrifuge.
- Do not install the instrument near an area where chemicals are stored or gases are emitted.
- Do not use the instrument in a location where electroconductive gases, flammable gases, or anesthetics that contain oxygen, hydrogen, or other flammable gases are present.
- Install the instrument indoors.
  The instrument is intended for indoor use only.
- Install the reagent at a height no more than 1 m above or below the bottom of the analyzer. Do not place reagents on top of the instrument.
- The instrument uses the common reagents for the XN series; however, a different dispensing set is used. Be sure to use the correct dispensing set.

2.3 Electromagnetic compatibility (EMC)

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

- IEC61326-2-6:2005 (EN61326-2-6:2006)
  Electrical equipment for measurement, control and laboratory use - EMC requirements
- 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 susceptibility are fulfilled.
- This equipment has been designed and tested to CISPR11 Class A. In a domestic environment, it may cause a radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the equipment. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

The equipment is equipped with an RFID reader/writer that uses radio waves.
Depending on the location and application, there is a risk that this may affect medical equipment.
To mitigate possible effects, observe the following precaution.
Patients who have a modular type RFID implanted medical device must keep the antenna of the modular RFID device at least 22 cm away from the part of the body where the device is implanted.

Installed RFID device
Model: PC1160002
Specification number: No. AC-14056

⚠ Caution!

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

2.4 Avoiding infection

Risk of infection

- When performing any task on the instrument, such as testing, maintenance, preparation, or post processing, be sure to wear protective garments and gloves. Wash your hands with antiseptic solution after completing the task.
  Risk of infection.
- Never touch waste, or parts that have come in contact with waste, with your bare hands.
  If you inadvertently come in contact with potentially infectious materials or surfaces, immediately rinse the skin with large amounts of water, and then follow your laboratory's prescribed cleaning and decontamination procedures.
- Use appropriate care when handling samples and quality control materials.
  In the event that an infectious material gets in the eyes or an open wound, rinse with large amounts of water and seek immediate medical attention.
- Exercise caution when handling waste fluid. If waste fluid comes in contact with your body or clothes, wash thoroughly.
- Do not dispose of waste fluid while analysis is in progress.

2.5 Handling of reagents and quality control materials

Warning!

- CELLPACK diluent is an electrical conductor. Risk of electrical shock if diluent is spilled near electrical cables or appliances. Switch OFF the instrument, unplug the power cable, and wipe off the liquid.
- Be sure to use CELLCLEAN AUTO only when rinsing the inside of the instrument.
- CELLCLEAN AUTO contains sodium hypochlorite.
  Risk of corrosion if CELLCLEAN AUTO comes in contact with the surface of the instrument.
  Immediately wipe off with a damp cloth.

Caution!

Follow the directions on the reagent container.

For other cautionary points, see Chapter 7.
(➤**P.89** "Chapter 7 Reagents")

2.6 Laser

Warning!

The analyzers have a semiconductor laser unit that is located inside the instrument. To avoid physical risk of injury from the laser, access is limited to authorized Sysmex technical representative.

2.7 Maintenance

Information

When performing maintenance, use only the tools specially authorized by Sysmex.

2.8 Disposal of materials

2.8.1 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.

This symbol is affixed by the requirement by Article 14. (4) of the WEEE Directive (2012/19/EU), and indicates the waste end-of-life equipment should not be disposed as unsorted municipal waste and to be collected such equipment separately.

2.8.2 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.

Information

- 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.

2.9 Operators

⚠ Caution!

- The instrument must only be used by properly trained personnel.
- In the event that a malfunction of the instrument occurs, take the measures indicated in the Instructions for Use. Further resolution should be referred to your Sysmex technical representative.

2.10 Computer viruses

⚠ Warning!

It has been verified that the instrument you have purchased is free of computer viruses. Antivirus software has been preinstalled in the instrument; however, before using an external memory device such as a USB memory stick, always verify that the device is free of viruses.

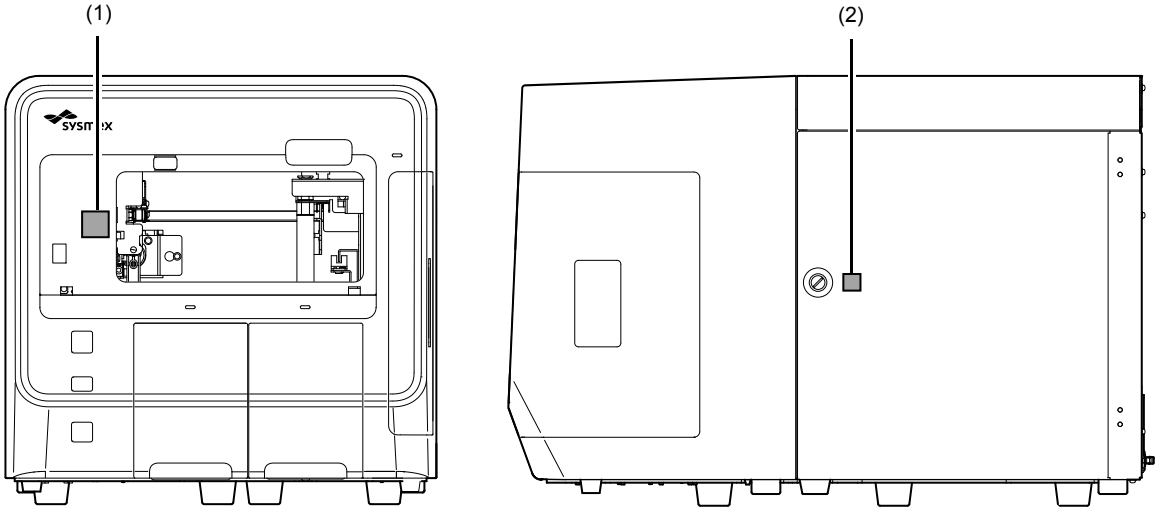
2.11 Use of other software

⚠ Warning!

- Do not install any software other than the software that is preinstalled on the instrument. Never run other software on the instrument.
- Note that we bear no liability whatsoever for any malfunctions arising from the use of other software.

2.12 Markings on the instrument

Front and side views (XN-530)



(1) Surfaces

Risk of infection

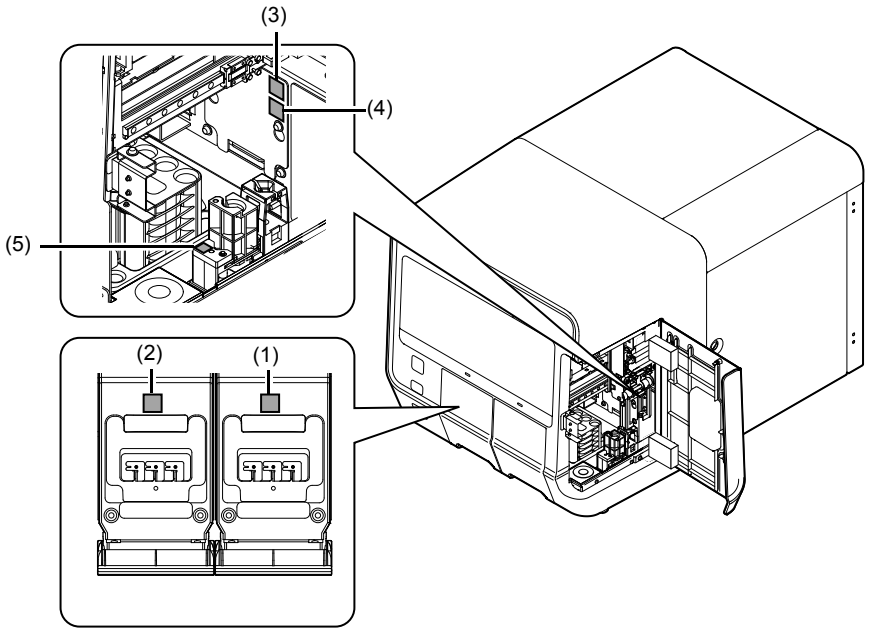
Treat all parts and surfaces of the instrument as posing a risk of infection.

(2) Right view

Warning!

Never insert your hand when the power of the analyzer is turned ON. Risk of injury.

Interior view (XN-530)



(1) Sampler adapter holder (right)

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

(2) Sampler adapter holder (left)

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

(3) Sampler adapter holder (interior)

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

(4) Sampler adapter holder (interior)

Warning!

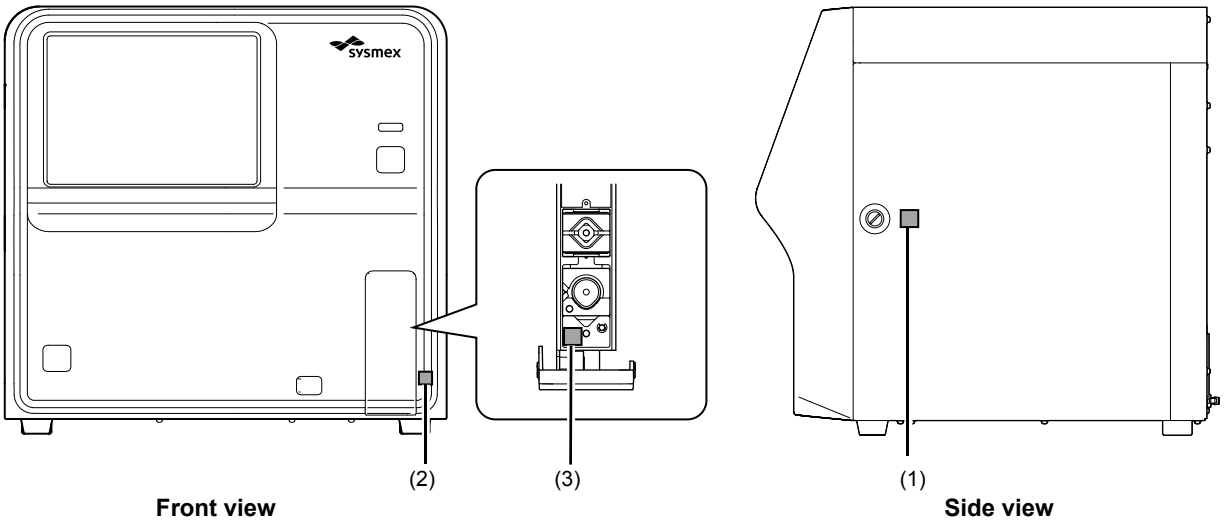
Never insert your hand when the power of the analyzer is turned ON. Risk of injury.

(5) Sample tube holder

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

Front, interior, and side views (XN-430)



Front view **Side view**

(1) Right view

Warning!

Never insert your hand when the power of the analyzer is turned ON. Risk of injury.

(2) Side of sample tube holder

Caution!

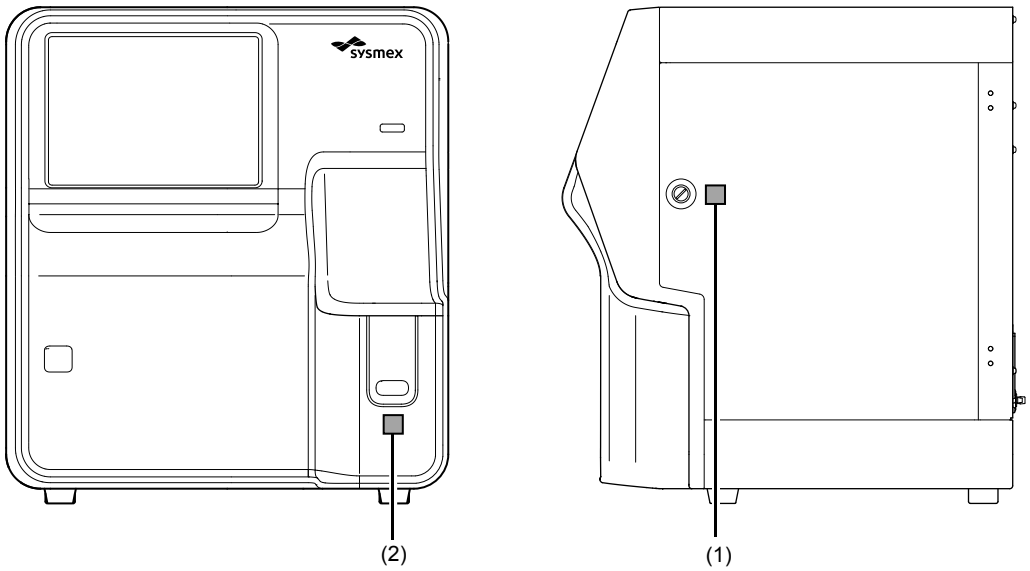
Never insert your hand. Risk of injury.

(3) Sample tube holder

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

Front and side views (XN-330)



Front view **Side view**

(1) Right view

Warning!

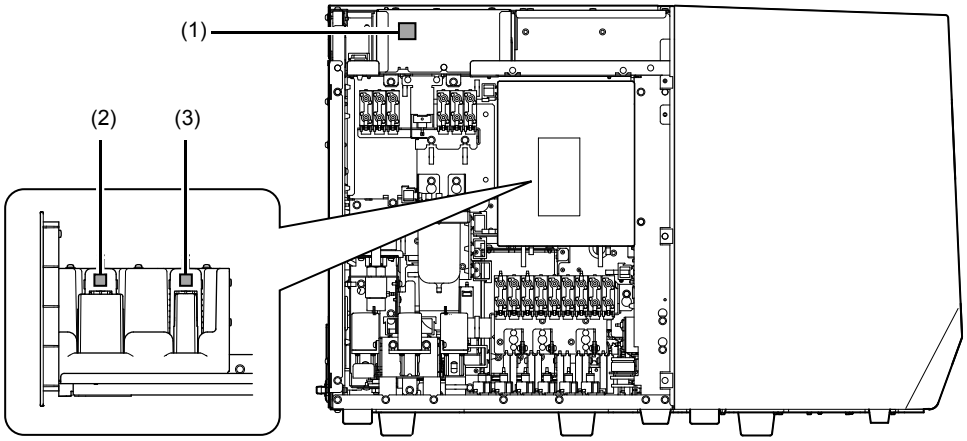
Never insert your hand when the power of the analyzer is turned ON. Risk of injury.

(2) Surfaces

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

Left interior (Common)



Example: XN-530

(1) Semiconductor laser unit

Warning!

The analyzers have a built-in semiconductor laser unit. To avoid the risk of eye injury, the laser is covered by a protective shielded box cover to prevent access by other than service technicians.

(2) Fluorocell WDF dye cover

Warning!

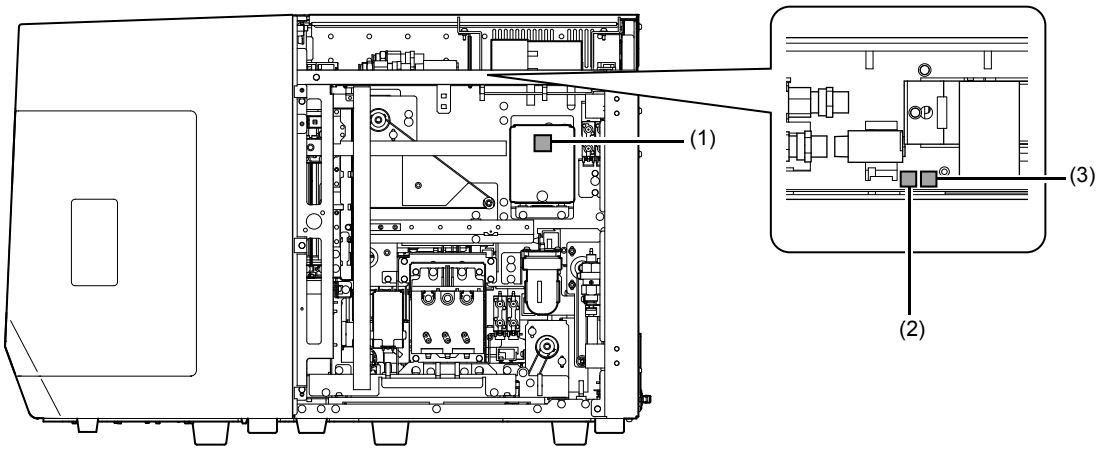
Do not touch the nozzle.
Risk of injury.

(3) Fluorocell RET dye cover

Warning!

Do not touch the nozzle.
Risk of injury.

Right interior and top interior (Common)



Example: XN-530

(1) RBC detector cover

Warning!
To avoid electrical shock, unplug the power cable before servicing. Risk of electrical shock.

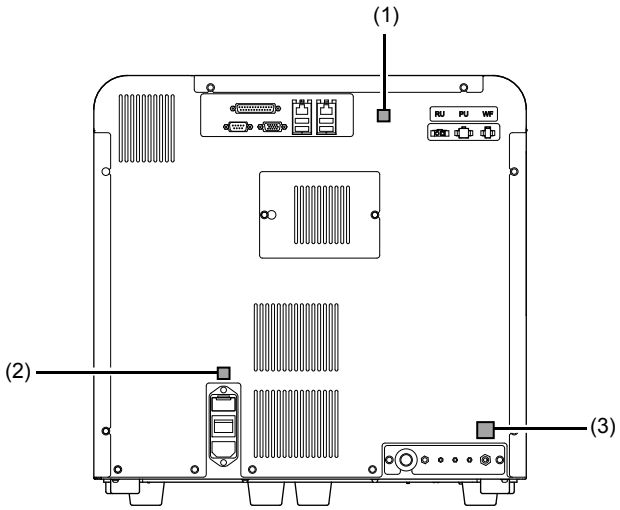
(2) Air pump unit (top)

Warning!
To avoid electrical shock, unplug the power cable before servicing. Risk of electrical shock.

(3) Air pump unit (top)

Caution, Hot!
The surface of the air pump is hot. Do not touch. Risk of burn injury.

Rear view (Common)



Example: XN-530

(1) Interface connector

Caution, Electric!

Failure to observe this warning may result in instrument damage due to electrostatic discharge from your body.

(2) Periphery of main power supply

Warning!

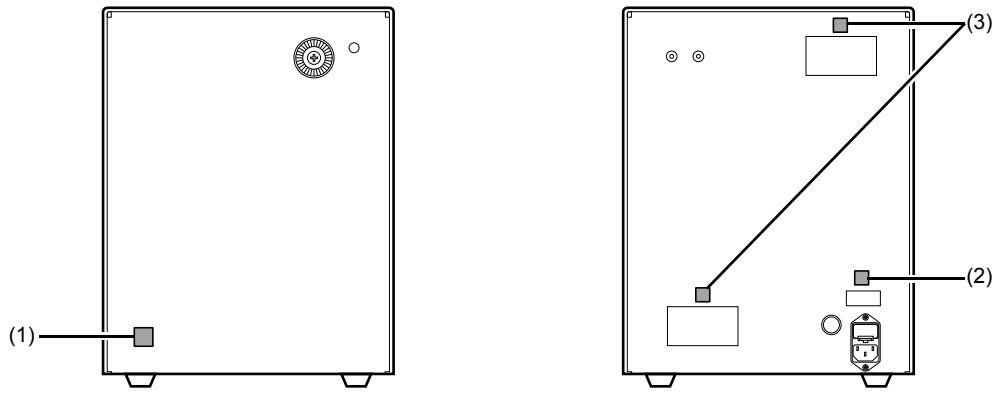
- To avoid electrical shock, unplug the power cable before servicing. Risk of electrical shock.
- Replace only with fuses of the specified type and current rating.

(3) Waste fluid outlet nipple

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

Pneumatic unit (Option)



Front view **Rear view**

(1) Pneumatic unit

Risk of infection

Treat all parts and surfaces of the instrument as posing a risk of infection.

(2) Power connector

Warning!

- To avoid electrical shock, unplug the power cable before servicing.
  Risk of electrical shock.
- Use only a fuse of the specified type and rating.
  Risk of smoke emission and fire.

(3) Exhaust vent

Caution!

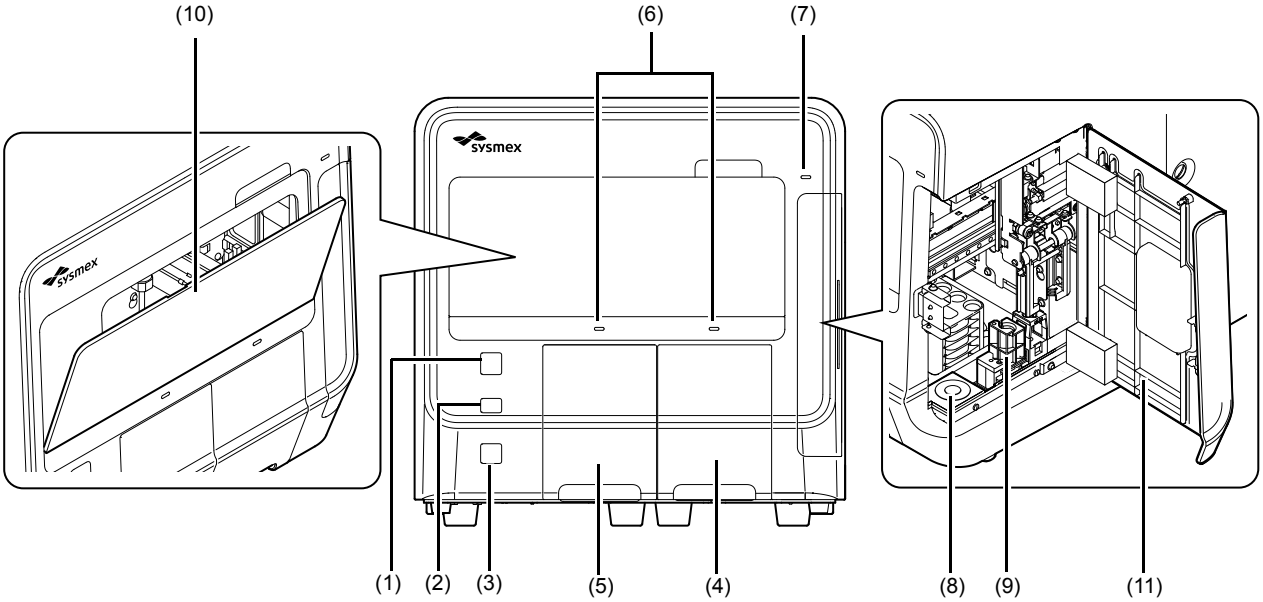
Do not obstruct the exhaust vent on the back of the pneumatic unit.

Chapter 3 Part Names and Functions

This chapter explains an external view and overview of the instrument.

3.1 Analyzer

Front view (XN-530)



(1) Sampler start/stop switch
Press to start sampler analysis. Press to stop sampler analysis while sampler analysis is in progress.

(2) Mode switch
Press to switch between manual analysis mode and sampler analysis mode. Press while sampler analysis is in progress to change to manual analysis mode after analysis of the current sample is completed.

(3) Power switch
Turn the instrument power ON.
For procedures on turning OFF the instrument power, see "Basic Operation".
(➤Basic Operation, "Chapter 1: 1.3 Shutdown")

(4) Sampler adapter holder (right)
Use to load sample tubes for sampler analysis mode.

(5) Sampler adapter holder (left)
Use to load sample tubes for sampler analysis mode.

(6) Sampler adapter status indicator LED

Indicates the status of the sampler adapter holder (right) / (left).

Not lit	All sample tubes in the sampler adapter have been analyzed, or there is no sampler adapter in the sampler adapter holder. The sampler adapter holder can be opened.
Green	Sampler adapter received state The sampler adapter holder can be opened.
Flashing green	Analysis in progress The sampler adapter holder cannot be opened. Wait until analysis is finished and then open the sampler adapter holder.
Red	Error occurring The sampler adapter holder can be opened.
Flashing red	Error occurring The sampler adapter holder cannot be opened. Wait until the sampler adapter status indicator LED lights solid red and then open the sampler adapter holder. For details on errors, see "Troubleshooting". (➤Troubleshooting, "Chapter 1: 1.1 Error message list (in alphabetical order)")

(7) Manual analysis status indicator LED

Indicates the status of manual analysis.

Not lit	Sampler analysis mode
Green	Manual analysis is possible.
Flashing green	Aspirating a sample (during manual analysis).
Red	Error occurring

(8) Start switch

Press to start manual analysis.

(9) Sample tube holder

Use to load sample tubes for manual analysis mode.

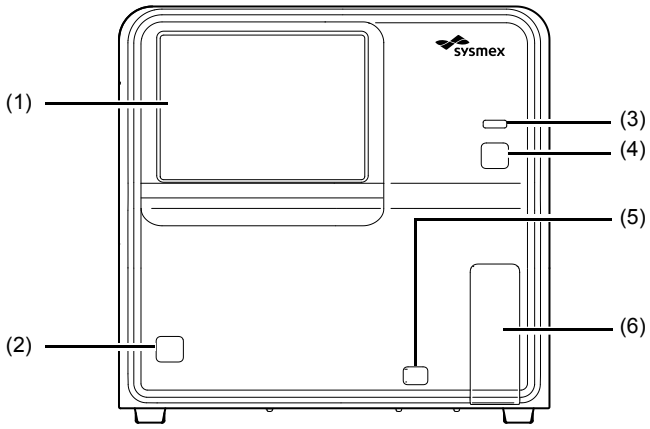
(10) Sampler cover (front)

The cover can be removed for maintenance. The cover is not secured at the bottom. Take care not to drop the cover when removing it.

(11) Sampler cover (manual unit)

Open to load sample tubes for manual analysis mode.

Front view (XN-430)



(1) Touchscreen
Use to operate the instrument and configure settings. The instrument status and analysis results can also be checked.

(2) Power switch
Turn the instrument power ON.
For procedures on turning OFF the instrument power, see "Basic Operation".
(➤Basic Operation, "Chapter 1: 1.3 Shutdown")

(3) Analysis status indicator LED
Indicates the status of the analysis.

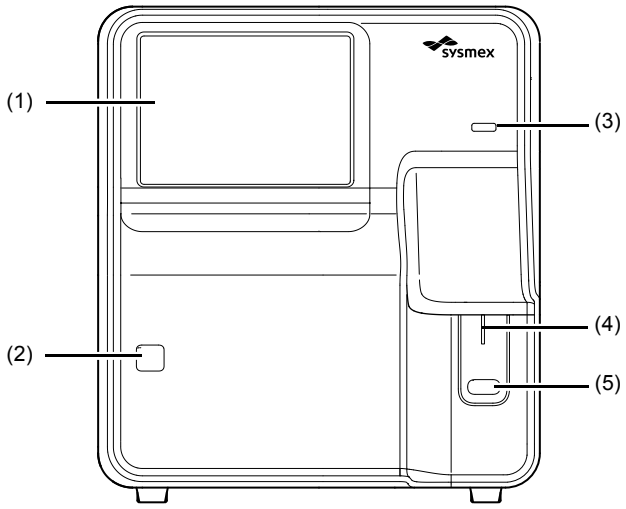
Green	Analysis is possible.
Flashing green	Aspirating a sample.
Red	Error occurring

(4) Start switch
Press to start analysis.

(5) Sample tube holder open/close switch
Press to open and close the sample tube holder.

(6) Sample tube holder
Open to load sample tubes.

Front view (XN-330)



(1) Touchscreen

Use to operate the instrument and configure settings. The instrument status and analysis results can also be checked.

(2) Power switch

Turn the instrument power ON.

For procedures on turning OFF the instrument power, see "Basic Operation".

(➤Basic Operation, "Chapter 1: 1.3 Shutdown")

(3) Analysis status indicator LED

Indicates the status of the analysis.

Green	Analysis is possible.
Flashing green	Aspirating a sample.
Red	Error occurring

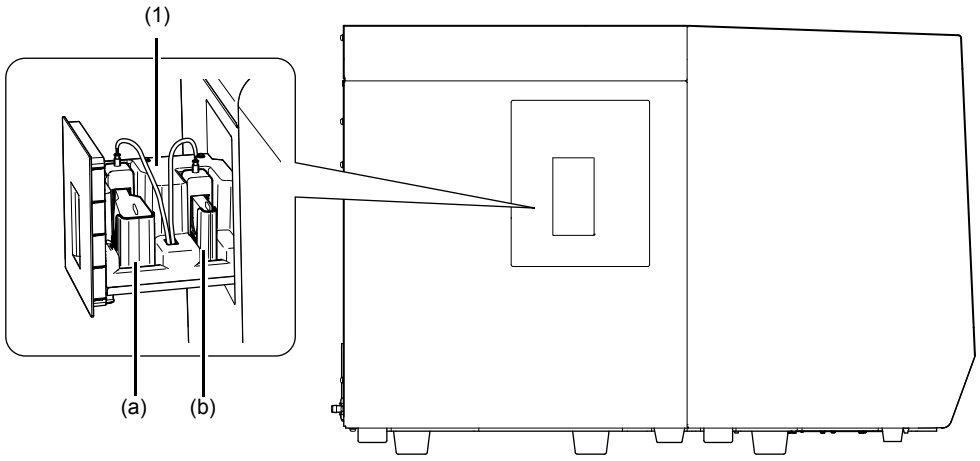
(4) Aspiration pipette

Aspirates a sample.

(5) Start switch

Press to start analysis.

Left view (Common)



Example: XN-530

(1) Dye holder

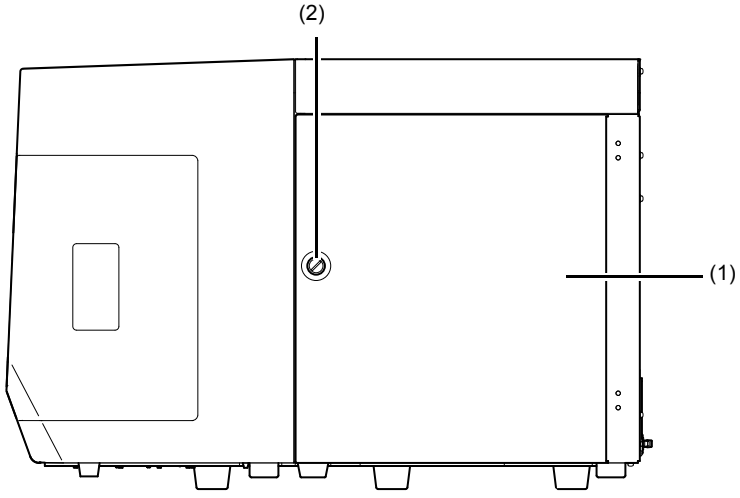
Holds the fluorescence reagents.

(a) Fluorocell WDF holder

(b) Fluorocell RET holder*

* The availability of functions depends on your system configuration.

Right view (Common)



Example: XN-530

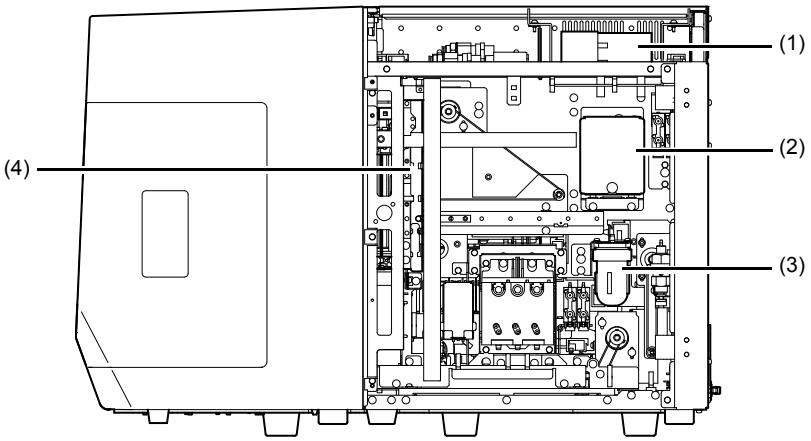
(1) Right cover

Open to inspect and perform maintenance on the inside of the analyzer.

(2) Lock

Lock for opening/closing of the right cover.

Right interior (Common)



Example: XN-530

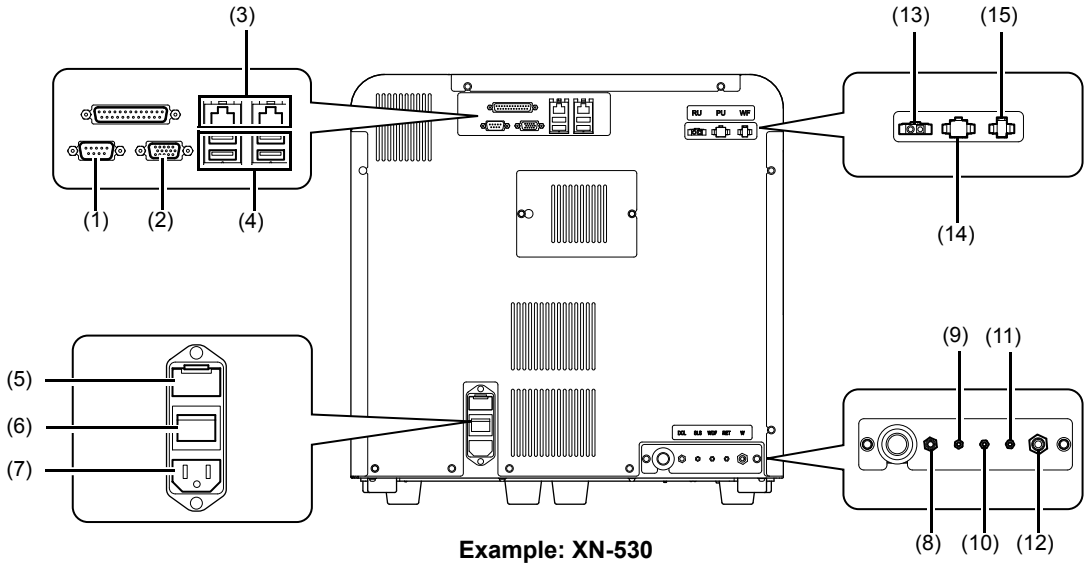
(1) Air pump unit
Adjusts the air pressure that is supplied inside the instrument.

(2) RBC detector cover
Contains an RBC detector.

(3) Pneumatic trap chamber
Prevents reagent and other fluids from flowing into the air pump unit when an abnormality occurs in the instrument.

(4) Piercer (XN-530/XN-430)
The piercer moves to the sample tube to aspirate the sample during analysis.

Rear view (Common)



Example: XN-530

(1) RS-232C port
Use to connect the instrument to a host computer.

(2) Monitor connection port (VGA)
Use to connect to a monitor (XN-530 only).

(3) LAN port
Use to connect to a host computer or SNCS (option).

(4) USB port
Use to connect to a monitor (XN-530 only), hand-held barcode reader (option), or printer (option). Insert a USB memory stick to back up and restore various types of files.

(5) Fuse holder
Use a 250 V, 10 A (time lag) fuse.

(6) Main power switch
Turn the main power of the instrument ON/OFF.

> **Caution!**
> Do not turn this switch ON/OFF repeatedly within a short time.
> This may overload the fuse and cause it to blow.

(7) AC power inlet
Supplies power using the provided power cable.

(8) DCL aspiration nipple
CELLPACK DCL or diluted CELLPACK DST is aspirated through this nipple.

(9) SLS aspiration nipple
SULFOLYSER is aspirated through this nipple. Connect to a SULFOLYSER container.

(10) WDF aspiration nipple
Lysercell WDF is aspirated through this nipple. Connect to a Lysercell WDF container.

(11) DFL aspiration nipple
CELLPACK DFL is aspirated through this nipple. Connect to a CELLPACK DFL container.

(12) Waste fluid outlet nipple
Waste fluid is discharged through this nipple. Connect to a drain or waste container.

(13) RU-20 tank sensor connection port
Used for communication with the RU-20 tank sensor.

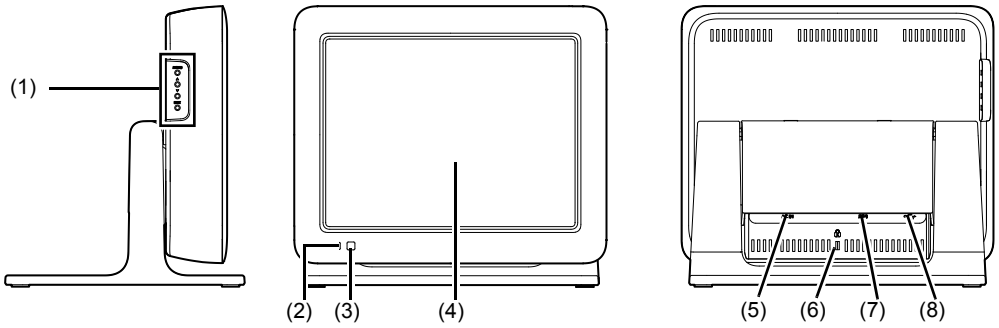
> **Information**
> If the RU-20 supply tank is not connected, connect an anti-static electricity connector to the RU-20 tank sensor connection port. Do not remove this connector.

(14) Port for pneumatic unit control
Output port for turning the pneumatic unit (option) ON/OFF. Connects the pneumatic unit control input connector of the pneumatic unit.

(15) Port for waste container full sensor
Connect to the waste container full sensor (option).

> **Information**
> If the waste container full sensor (option) is not connected, connect an anti-static electricity connector to the port for the waste container full sensor. Do not remove this connector.

3.2 Monitor (XN-530)



Left view **Front view** **Rear view**

(1) OSD (on-screen display) operation buttons

Use to adjust the image quality.

(➤Troubleshooting, "Chapter 2: 2.16 Adjusting the monitor image quality (XN-530)")

(2) Status LED

Indicates the status of the monitor.

Not lit	Power OFF
Green	Power ON, video signal input
Orange	Power ON, no video signal input*

* When there is no video signal input, [NO SIGNAL] appears and then the monitor enters the non-display state.

(3) Power switch

Turns the power of the monitor ON/OFF.

(4) Monitor (touchscreen)

Use to operate the instrument and configure settings. The instrument status and analysis results can also be checked.

(5) AC power inlet

Supplies power using the provided power cable.

(6) Security slot

Use to connect a commercially available anti-theft cable.

(7) RGB port

Connect the monitor to the analyzer. (Video signal)

(8) USB port

Connect the monitor to the analyzer. (Touchscreen signal)

Chapter 4 Installation

This chapter provides information regarding installation of the instrument.

4.1 Preparing for installation

The instrument is installed or moved by Sysmex service representatives. The following is a list of things to do beforehand to prepare for the installation or move.

- Secure ample space for installation, with safety considerations.
  For the installation space, see the following.
  (➤**P.39** "4.2.4 Installation space").
- Note the weight of this instrument. Make sure that the floor and/or the equipment on which the instrument is to be installed can withstand the weight.
- The power cable for this instrument is 2.0 m long. Use a nearby dedicated power outlet.
- Once this instrument is delivered, check the condition of its packaging as soon as possible.

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

- Keep the instrument in its packaging in a dry place until it is time for installation. Store upright.

4.2 Installation

4.2.1 Cautions on installation

The instrument and associated equipment are installed by your Sysmex technical representative. In case relocation becomes necessary after installation, contact your Sysmex technical representative.
Problems resulting from moving of the instrument by anyone other than a Sysmex technical representative are not covered by the Warranty even within the warranty period.

4.2.2 Grounding

The instrument power supply cord uses a 3-prong plug. When the power supply socket is provided with grounding, simply plug it to the socket. If the socket does not provide grounding, use an adapter to ground the power supply safely.

⚠ Warning!

- Be sure to ground this instrument.
  Improper grounding may cause electrical shock.
- Never exceed socket capacity.
  Risk of fire.

⚠ Caution!

Use the power cable that comes with the instrument. Do not use the power cable to supply power to any equipment other than the instrument.

4.2.3 Installation environment

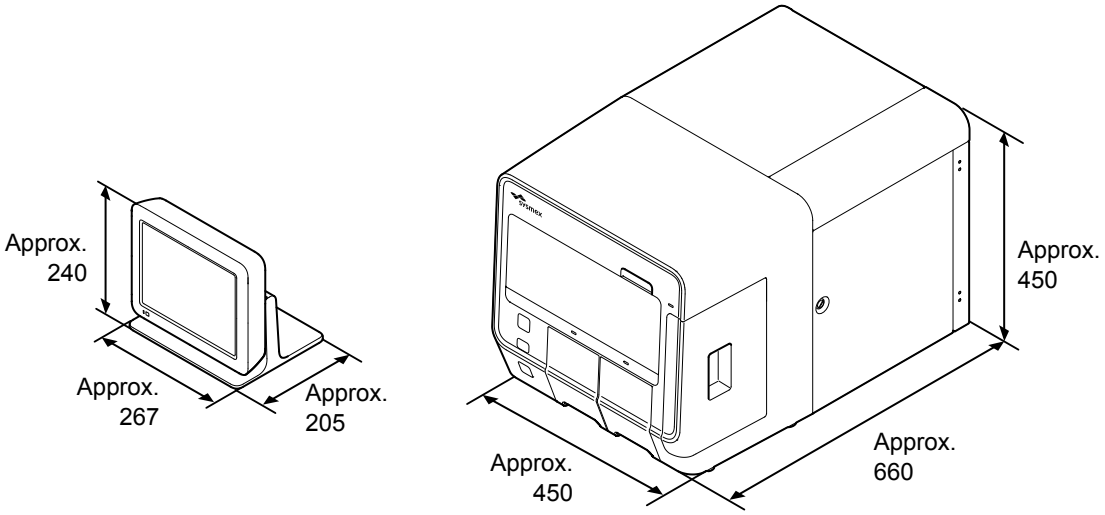
- Use the instrument in an ambient temperature within the range of 15 to 35°C.
- Relative humidity should be within the range of 20 to 85%.
- If ambient temperature and relative humidity are not within the suggested range, air-condition the environment.

For other conditions, see Chapter 2. (➤**P.14** "Chapter 2: 2.2 Installation")

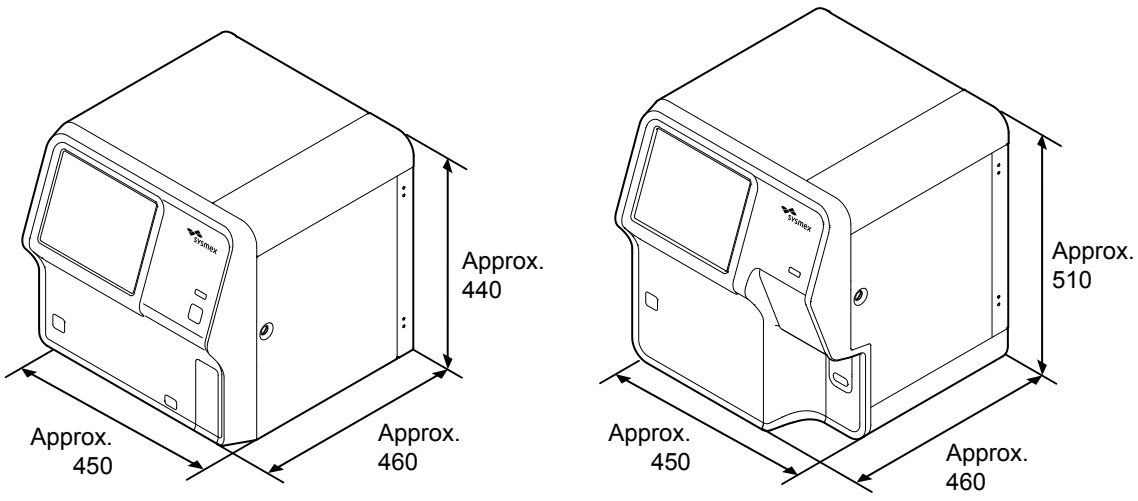
4.2.4 Installation space

To allow sufficient space for maintenance, install the monitor unit on the left side of the analyzer. (XN-530 only)
Install the instrument with a clearance of at least 30 cm at the back.

Component	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Analyzer (XN-530)	Approx. 450	Approx. 660	Approx. 450	Approx. 53
Monitor (XN-530)	Approx. 267	Approx. 205	Approx. 240	Approx. 3
Analyzer (XN-430)	Approx. 450	Approx. 460	Approx. 440	Approx. 35
Analyzer (XN-330)	Approx. 450	Approx. 460	Approx. 510	Approx. 35



XN-530



XN-430 **XN-330**

Chapter 5 Instrument Specifications

This chapter explains technical information such as specifications and principles.

5.1 Performance specifications/characteristics

Physical specifications (Analyzer)

Dimensions and weight	XN-530: Approx. 450 (W) x Approx. 660 (D) x Approx. 450 (H) mm, Approx. 53 kg XN-430: Approx. 450 (W) x Approx. 460 (D) x Approx. 440 (H) mm, Approx. 35 kg XN-330: Approx. 450 (W) x Approx. 460 (D) x Approx. 510 (H) mm, Approx. 35 kg
Electrical rating	Voltage: 100 to 240 V AC Frequency: 50/60 Hz Power consumption: XN-530: 250 VA XN-430/XN-330: 235 VA Protection type: Class I
Operating environment	Ambient temperature: 15 to 35°C (also applies to supplied reagents*) Relative humidity: 20 to 85% Atmospheric pressure: 70 to 106 kPa * Excluding CELLPACK DST.
Noise level	60 dB or less Excludes sound during clamping and release of sample tubes, and alarm sounds.
Storage conditions	Ambient temperature: -10 to 60°C Relative humidity: 10 to 95% (no condensation) Atmospheric pressure: 70 to 106 kPa
Laser class	Class I (IEC60825-1:2007)
Safety standards	IEC61010-1:2001, IEC61010-2-081:2001+A1, IEC61010-2-101:2002

Physical specifications (Monitor (XN-530))

Dimensions and weight	Approx. 267 (W) x Approx. 205 (D) x Approx. 240 (H) mm, Approx. 3 kg Monitor thickness: 52.5 mm
Electrical rating	Voltage: 100 to 240 V AC Frequency: 50/60 Hz Power consumption: 36 VA Protection type: Class I, limited to indoor use Over-voltage category: Category II
Storage conditions	Ambient temperature: -10 to 60°C Relative humidity: 10 to 95% RH Max (no condensation) Atmospheric pressure: 70 to 106 kPa
I/F specifications	Video signal I/F: Analog RGB signal (0.7 VP-P) Touch signal I/F: USB 2.0 compliant
I/F connectors	Video signal (analog RGB) input: Mini Dsub 15 pin (female) Touchscreen signal I/F (USB): USB 2.0 B connector AC power input: 3-prong plug
Supported resolutions	SVGA 800 x 3 (H) x 600 (V)
Screen size	26.4 cm (10.4 type) diagonal
Display colors	16,200,000 colors
Brightness	315 cd/m^2 or more (typ 450 cd/m^2)
Contrast ratio (CR)	900:1
Angle of view	-60° to 80° (vertical), -80° to 80° (horizontal)
Backlight	LED
Touch detection method	4-wire analog resistive film type

Throughput

[Whole Blood] mode	When using the XN-530, the values below are for the case where the barcode reading function and Repeat/Rerun/Reflex function are not used. CBC: approx. 60 samples/hour (approx. 70 samples/hour[*1]) CBC+DIFF: approx. 60 samples/hour (approx. 70 samples/hour[*1]) CBC+RET[*2]: approx. 35 samples/hour CBC+DIFF+RET[*2]: approx. 35 samples/hour *1 The throughput depends on your system configuration. *2 The availability of functions depends on your system configuration.
[Low WBC] mode[*]	CBC+DIFF: approx. 55 samples/hour CBC+DIFF+RET[*]: approx. 30 samples/hour * The availability of functions depends on your system configuration.
[Pre-Dilution] mode	CBC: approx. 60 samples/hour CBC+DIFF: approx. 60 samples/hour CBC+DIFF+RET[*]: approx. 30 samples/hour * The availability of functions depends on your system configuration.
[Body Fluid] mode[*]	Approx. 30 samples/hour * The availability of functions depends on your system configuration.

Aspirated sample volume

[Whole Blood] mode / [Low WBC] mode[*]	Sampler analysis:	25 µL
	Manual analysis:	25 µL
	Micro sample analysis:	25 µL
	Analysis using a micro collection tube:	25 µL
	Analysis using an RBT micro collection tube:	25 µL
	* The availability of functions depends on your system configuration.	
[Pre-Dilution] mode	Micro sample analysis:	70 µL
	Analysis using a micro collection tube:	70 µL
[Body Fluid] mode[*]	Manual analysis:	70 µL
	Micro sample analysis:	70 µL
	Analysis using a micro collection tube:	70 µL
	* The availability of functions depends on your system configuration.	

Reportable parameters

For reportable parameters, see Chapter 1. (➤**P.9** "Chapter 1: 1.3 Reportable parameters")

Reportable range and display range

Reportable Range (Limit of Quantitation) – The actual amount of an analyte that can be reliably detected, and at which the total error meets the requirements for accuracy that is acceptable for clinical use.

Reference: CLSI Document EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition; 2012

Reportable Range is the range over which the analyzer will report, display, print and transmit results.

Parameters	Reportable range*4	Display range	Units
[Whole Blood] mode			
WBC*4	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
RBC*4	0.02 to 8.60	0.00 to 99.99	x 10^6/µL
HGB*4	0.1 to 26.0	0.0 to 30.0	g/dL
HCT*4	0.2 to 74.5	0.0 to 100.0	%
MCV	NA*2	0.0 to 999.9	fL
MCH	NA*2	0.0 to 999.9	pg
MCHC	NA*2	0.0 to 999.9	g/dL
PLT*4	2 to 5,000	0 to 9,999	x 10^3/µL
RDW-SD	NA*3	0.0 to 999.9	fL
RDW-CV	NA*3	0.0 to 999.9	%
MPV	NA*2	0.0 to 999.9	fL
NEUT#	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
LYMPH#	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
MONO#	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
EO#	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
BASO#	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
NEUT%	0.0 to 100.0	0.0 to 100.0	%
LYMPH%	0.0 to 100.0	0.0 to 100.0	%
MONO%	0.0 to 100.0	0.0 to 100.0	%
EO%	0.0 to 100.0	0.0 to 100.0	%
BASO%	0.0 to 100.0	0.0 to 100.0	%
IG#	0.04 to 440.00	0.00 to 999.99	x 10^3/µL
IG%	0.0 to 100.0	0.0 to 100.0	%
RET%*1,4	0.11 to 30.00	0.00 to 99.99	%
RET#*1	0.0100 to 0.4576	0.0000 to 0.9999	x 10^6/µL
IRF*1	0.0 to 100.0	0.0 to 100.0	%
RET-He*1	NA*2	0.0 to 999.9	pg

*1 The availability of functions depends on your system configuration.

*2 Not applicable, as this parameter is calculated from an equation.

*3 Not applicable, as this parameter is calculated using an equation from a distribution.

*4 Parameters that exceed the upper limit of the AMR (reportable range) are flagged with "@" beside the result. The sample must be diluted using the system diluent, reanalyzed and multiplied by the dilution factor. The suggested dilution ratio is 1:2. The use of dilution should be noted in the patient report.

Reportable range and display range (continued)

Parameters	Reportable range	Display range	Units
[Body Fluid] mode*			
WBC-BF	0.004 to 10.000	0.000 to 999.999	x 10^3/µL
RBC-BF	0.002 to 5.000	0.000 to 99.999	x 10^6/µL
MN#	0.004 to 10.000	0.000 to 999.999	x 10^3/µL
PMN#	0.004 to 10.000	0.000 to 999.999	x 10^3/µL
MN%	0.0 to 100.0	0.0 to 100.0	%
PMN%	0.0 to 100.0	0.0 to 100.0	%
TC-BF#	0.004 to 10.000	0.000 to 999.999	x 10^3/µL

* The availability of functions depends on your system configuration.

Performance characteristics: Limit of blank, limit of detection, and limit of quantitation

The values below are from evaluation using a stabilized substance.

[Whole Blood] mode

Parameters	Limit of blank (LoB)	Limit of detection (LoD)	Limit of quantitation (LoQ)	Units
WBC	0.00	0.01	0.03	x 10^3/µL
RBC	0.00	0.00	0.00	x 10^6/µL
HGB	0.0	0.0	0.0	g/dL
PLT	0	0	1	x 10^3/µL
HCT	0.0	0.0	0.0	%

[Body Fluid] mode*

Parameters	Limit of blank (LoB)	Limit of detection (LoD)	Limit of quantitation (LoQ)	Units
WBC-BF	0.000	0.002	0.004	x 10^3/µL
RBC-BF	0.000	0.000	0.001	x 10^6/µL
TC-BF#	0.000	0.002	0.004	x 10^3/µL

* The availability of functions depends on your system configuration.

Linearity

Linearity is the ability within a given range to provide results that are directly proportional to the concentration (amount) of the analyte in the test sample. The linearity of a system is measured by testing levels of an analyte which are known by formulation or known relative to each other (not necessarily known absolute); when the systems results are plotted against these values, the degree to which the plotted curve conforms to a straight line is a measure of system linearity.

Reference: CLSI Document EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: Statistical Approach; Approved Guideline. 2003.

Note:

For patient reportable ranges, see reportable range.

[Whole Blood] mode	Linearity can be assessed by testing levels of a parameter with known formulation using peripheral blood or by using commercially available materials qualified for use on the XN-L. WBC: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) RBC: within ±2% or ±0.03 x 10^6/µL (0.00 to 8.00 x 10^6/µL) within ±4% or ±0.06 x 10^6/µL (8.01 to 8.60 x 10^6/µL) HGB: within ±2% or ±0.2 g/dL (0.0 to 26.0 g/dL) HCT: within ±3% or ±1.0 HCT (0.0 to 75.0%) MCV: NA*1 MCH: NA*1 MCHC: NA*1 PLT: within ±5% or ±10 x 10^3/µL (0 to 1000 x 10^3/µL) within ±6% (1001 to 5000 x 10^3/µL) RDW-SD: NA*2 RDW-CV: NA*2 MPV: NA*1 NEUT#: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) LYMPH#: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) MONO#: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) *1 Not applicable, as this parameter is calculated from an equation. *2 Not applicable, as this parameter is calculated using an equation from a distribution.

Linearity (continued)

[Whole Blood] mode	EO#: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) BASO#: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) NEUT%: NA*3 LYMPH%: NA*3 MONO%: NA*3 EO%: NA*3 BASO%: NA*3 IG#: within ±3% or ±0.30 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within ±6% (100.01 to 310.00 x 10^3/µL) within ±11% (310.01 to 440.00 x 10^3/µL) IG%: NA*3 RET%*1: within ±20% or ±0.30 RET% (0.00 to 30.00%) RET#*1: within ±20% or ±0.0150 x 10^6/µL (0.0000 to 0.7200 x 10^6/µL) IRF*1: NA*2 RET-He*1: NA*2 *1 The availability of functions depends on your system configuration. *2 Not applicable, as this parameter is calculated from an equation. *3 Not applicable, as this is a ratio.
[Body Fluid] mode*	Linearity can be assessed by testing levels of a parameter with known formulation using body fluid or by using commercially available materials qualified for use on the XN-L. WBC-BF: within ±0.010 x 10^3/µL (0.000 to 0.050 x 10^3/µL, RBC is less than 1.000 x 10^6/µL) within ±20% (0.051 to 10.000 x 10^3/µL, RBC is less than 1.000 x 10^6/µL) RBC-BF: within ±2% or ±0.010 x 10^6/µL (0.000 to 5.000 x 10^6/µL) TC-BF#: within ±0.010 x 10^3/µL (0.000 to 0.050 x 10^3/µL, RBC is less than 1.000 x 10^6/µL) within ±20% (0.051 to 10.000 x 10^3/µL, RBC is less than 1.000 x 10^6/µL) * The availability of functions depends on your system configuration.

Repeatability

[Whole Blood] mode	Indicated as a coefficient of variation (95% reliability) of peripheral blood (samples with RET-He of RET# 0.0200 x 10^6/μL or more (same day blood)) or control blood analyzed repeatedly 10 times or more. WBC: 3.0% or less (4.00 x 10^3/μL or more) RBC: 1.5% or less (4.00 x 10^6/μL or more) HGB: 1.5% or less HCT: 1.5% or less MCV: 1.5% or less MCH: 2.0% or less MCHC: 2.0% or less PLT: 4.0% or less (100 x 10^3/μL or more) RDW-SD: 3.0% or less RDW-CV: 3.0% or less MPV: 4.0% or less NEUT#: 8.0% or less (1.20 x 10^3/μL or more) LYMPH#: 8.0% or less (0.60 x 10^3/μL or more) MONO#: 20.0% or less (0.20 x 10^3/μL or more) EO#: 25.0% or less, or within ±0.12 x 10^3/μL BASO#: 40.0% or less, or within ±0.06 x 10^3/μL NEUT%: 8.0% or less (30.0 NEUT% or more, WBC 4.00 x 10^3/μL or more) LYMPH%: 8.0% or less (15.0 LYMPH% or more, WBC 4.00 x 10^3/μL or more) MONO%: 20.0% or less (5.0 MONO% or more, WBC 4.00 x 10^3/μL or more) EO%: 25.0% or less, or within ±1.5 EO% (WBC 4.00 x 10^3/μL or more) BASO%: 40.0% or less, or within ±1.0 BASO% (WBC 4.00 x 10^3/μL or more) IG#: 25.0% or less, or within ±0.12 x 10^3/μL (IG# 0.10 x 10^3/μL or more) IG%: 25.0% or less, or within ±1.5 IG% (2.0 IG% or more, WBC 4.00 x 10^3/μL or more) RET%*: 15.0% or less (RBC 3.00 x 10^6/μL or more, RET% 1.00 to 4.00%) RET#*: 15.0% or less (RBC 3.00 x 10^6/μL or more, RET% 1.00 to 4.00%) IRF*: 30.0% or less (RBC 3.00 x 10^6/μL or more, RET% 1.00 to 4.00%, IRF 20.0% or more) RET-He*: 5.0% or less (RET# 0.0200 x 10^6/μL or more) * The availability of functions depends on your system configuration.

Repeatability (continued)

[Body Fluid] mode[*1]	Indicated as a coefficient of variation of a sample of peripheral blood or control blood analyzed repeatedly 10 times or more. WBC-BF: 30.0% or less (0.005 to 0.015 x 10^3/μL) 20.0% or less (0.016 to 0.030 x 10^3/μL) 15.0% or less (0.031 to 0.050 x 10^3/μL) RBC-BF: 40.0% or less, or Max–Min ≤ 0.007 x 10^6/μL (0.003 to 0.050 x 10^6/μL) MN#: 60.0% or less (0.005 to 0.015 x 10^3/μL) 40.0% or less (0.016 to 0.030 x 10^3/μL) 30.0% or less (0.031 to 0.050 x 10^3/μL) PMN#: 60.0% or less (0.005 to 0.015 x 10^3/μL) 40.0% or less (0.016 to 0.030 x 10^3/μL) 30.0% or less (0.031 to 0.050 x 10^3/μL) MN%: NA[*2] PMN%: NA[*2] TC-BF#: 30.0% or less (0.005 to 0.015 x 10^3/μL) 20.0% or less (0.016 to 0.030 x 10^3/μL) 15.0% or less (0.031 to 0.050 x 10^3/μL) *1 The availability of functions depends on your system configuration. *2 Not applicable, as this parameter is calculated from an equation.

Accuracy - [Whole Blood] mode

Blood cell count	Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood, and the value from analysis using a standard instrument. WBC: within ±3% or ±0.30 x 10^3/µL RBC: within ±2% or ±0.03 x 10^6/µL Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument or the international standard method (HGB standard analysis method of the cyanmethemoglobin method based on the ICSH (International Council for Standardization in Haematology) advisory). HGB: within ±2% or ±0.2 g/dL Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument or the international standard method (standard analysis method based on the ICSH (International Council for Standardization in Haematology) advisory). HCT: within ±3% or ±1.0 HCT Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument. MCV: within ±3% or ±2.0 fL MCH: NA*1 MCHC: NA*1 Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument or the international standard method (flow cytometry method based on the ICSH (International Council for Standardization in Haematology) advisory). PLT: within ±5% or ±10 x 10^3/µL Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument. RDW-SD: NA*2 RDW-CV: NA*2 MPV: within ±5% or ±1.0 fL (PLT 100 x 10^3/µL or more) *1 Not applicable, as this parameter is calculated from an equation. *2 Not applicable, as this parameter is calculated using an equation from a distribution.

Accuracy - [Whole Blood] mode (continued)

Differential blood count	Indicated as a correlation coefficient with the control method when 100 or more samples of peripheral blood are analyzed. The control method is a standard instrument or standard analysis method of white blood cell 5 differentiation by flow cytometry. NEUT%: r = 0.90 or more LYMPH%: r = 0.90 or more MONO%: r = 0.75 or more EO%: r = 0.80 or more BASO%: r = 0.50 or more IG%: r = 0.80 or more Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument. NEUT#: within ±3% or ±0.30 x 10^3/µL LYMPH#: within ±3% or ±0.30 x 10^3/µL MONO#: within ±3% or ±0.30 x 10^3/µL EO#: within ±3% or ±0.30 x 10^3/µL BASO#: within ±3% or ±0.30 x 10^3/µL NEUT%: within ±3.0 NEUT% LYMPH%: within ±3.0 LYMPH% MONO%: within ±2.0 MONO% EO%: within ±1.0 EO% BASO%: within ±1.0 BASO% IG#: within ±3% or ±0.30 x 10^3/µL IG%: within ±1.5 IG%
Reticulocyte parameters	Indicated as a correlation coefficient with the control method when 100 or more samples of peripheral blood are analyzed. The control method is analyzed using a standard instrument or the visual observation method. RET%*: r = 0.90 or more RET#*: r = 0.90 or more RET-He*: r = 0.9 or more (At least half of the analysis samples have RET# 0.0200 x 10^6/µL or more.) Indicated as the average of the difference between the value from analysis of at least 100 samples of peripheral blood and the value from analysis using a standard instrument. RET%*: within ±20% or ±0.30 RET% RET#*: within ±20% or ±0.0150 x 10^6/µL IRF*: within ±30% or ±10.0 IRF (within 55.0 IRF when control blood or calibrator is used) * The availability of functions depends on your system configuration.

Performance characteristics:

Accuracy - Correlation coefficient (r-value) and bias limits

Accuracy for the CBC parameters is assessed by comparison of the results from the XN-L and the XN-10. The estimation of the difference is determined as described in CLSI EP09-A2 Method Comparison and Bias Estimation Using Patient Samples. When specimens covering the measuring range with no system error messages are analyzed by both the XN-L and the XN-10 automated hematology analyzer, the XN-L meets specification if the results are within the limits defined in the table below.

Measurand	r-value	Bias Limits
WBC	≥ 0.90	±7.5% or ±0.30 x 10^3/µL
RBC	≥ 0.90	±3.4% or ±0.15 x 10^6/µL
HGB	≥ 0.90	±3.5% or ±0.2 g/dL
HCT	≥ 0.90	±3.1% or ±1.3 HCT
MCV	≥ 0.90	±3% or ±2.0 fL
MCH	(HGB and RBC ≥ 0.90)	NA*1
MCHC	(HGB and RBC ≥ 0.90)	NA*1
PLT	≥ 0.90	±15% or ±15 x 10^3/µL
RDW-SD	(RBC ≥ 0.90)	±10.0% or ±3.0 fL
RDW-CV	(RBC ≥ 0.90)	±10.0% or ±0.5 RDW-CV%
MPV	≥ 0.80	±5% or ±1.0 fL
NEUT%	≥ 0.90	±10% or ±3.0 NEUT%
LYMPH%	≥ 0.90	±10% or ±3.0 LYMPH%
MONO%	≥ 0.75	±10% or ±2.0 MONO%
EO%	≥ 0.80	±10% or ±1.0 EO%
BASO%	≥ 0.50	±10% or ±1.0 BASO%
IG%	≥ 0.80	±10% or ±1.5 IG%
RET%*2	≥ 0.90	±30% or ±0.30 RET%
IRF*2	(RET ≥ 0.90)	±30% or ±10.0 IRF
RET-He*2	≥ 0.90	±10.0% or ±0.2 pg

*1 "NA" means Not Applicable.

*2 These items do not appear on all analyzer types.

Accuracy - [Body Fluid] mode*

Blood cell count	Indicated as a correlation coefficient with the control method and slope of regression line when 50 or more samples of body fluid are analyzed. The control method is analyzed using a standard instrument or the visual observation method. WBC-BF: r = 0.9 or more, and the slope is within 1±0.3. RBC-BF: r = 0.8 or more, and the slope is within 1±0.3.
Differential blood count	Indicated as a correlation coefficient with the control method and slope of regression line when 50 or more samples of body fluid are analyzed. The control method is the visual differentiation of a slide prepared using a standard instrument or the Cytospin method. MN#: r = 0.9 or more, and the slope is within 1±0.5. PMN#: r = 0.9 or more, and the slope is within 1±0.5. MN%: r = 0.7 or more, and the slope is within 1±0.5. PMN%: r = 0.7 or more, and the slope is within 1±0.5. TC-BF#: r = 0.9 or more, and the slope is within 1±0.3.

* The availability of functions depends on your system configuration.

Carryover

[Whole Blood] mode	Carryover is assessed by testing high levels of a parameter from peripheral blood 3 times followed by a peripheral blood with low levels of a parameter. CBC High to Low Carryover is measured per ICSH guidelines and calculated as follows. $\text{Carryover} = \left[\frac{(\text{1st Low} - \text{3rd Low})}{(\text{3rd High} - \text{3rd Low})} \right] \times 100$ WBC: 1.0% or less RBC: 1.0% or less HGB: 1.0% or less HCT: 1.0% or less MCV: NA*2 MCH: NA*2 MCHC: NA*2 PLT: 1.0% or less RDW-SD: NA*3 RDW-CV: NA*3 MPV: NA*3 NEUT#: 2.0% or 0.05 x 10^3/μL or less LYMPH#: 2.0% or 0.05 x 10^3/μL or less MONO#: 2.0% or 0.03 x 10^3/μL or less EO#: 2.0% or 0.03 x 10^3/μL or less BASO#: 2.0% or 0.03 x 10^3/μL or less NEUT%: NA*4 LYMPH%: NA*4 MONO%: NA*4 EO%: NA*4 BASO%: NA*4 IG#: 2.0% or 0.05x10^3/μLor less IG%: NA*4 RET%*1: NA*4 RET#*1: 1.5% or less IRF*1: NA*4 RET-He*1: NA*2 *1 The availability of functions depends on your system configuration. *2 Not applicable, as this parameter is calculated from an equation. *3 Not applicable, as this parameter is calculated using an equation from a distribution. *4 Not applicable, as this is a ratio.

Carryover (continued)

[Body Fluid] mode[*1]	Carryover is assessed by testing high levels of a parameter from body fluids 3 times followed by a body fluid or diluent with low levels of a parameter. High to Low Carryover is measured per ICSH guidelines and calculated as above. WBC-BF: 0.3% or 0.001 x 10^3/µL or less RBC-BF: 0.3% or 0.003 x 10^6/µL or less MN#: 0.3% or 0.001 x 10^3/µL or less PMN#: 0.3% or 0.001 x 10^3/µL or less MN%: NA[*2] PMN%: NA[*2] TC-BF#: 0.3% or 0.001 x 10^3/µL or less *1 The availability of functions depends on your system configuration. *2 Not applicable, as this is a ratio.

Software specifications

Data storage capacity	Samples stored:	10,000 samples
	Patient information:	5,000 records
	Wards registered:	200 wards
	Doctor names registered:	200 names
	Analysis registration function:	1,000 records
	Calibration log:	20 records per analyzer
	QC files:	20 files per analyzer (300 plots per file)
	Reagent replacement log:	500 records
	Maintenance log:	500 records
Quality control (QC)	X-bar control (L-J control):	300 plots x 17 files
	X-barM control:	300 plots x 3 files

Performance Characteristics: Flagging Agreement

The overall goal of any automated differential cell counter is to screen and report normal specimens and to alert the technologist to the presence of abnormalities. Specimens that do not meet software defined decision factors or criteria established by the laboratory are flagged.
The table below shows data from several sites. Results may vary with sample condition and setting of instrument to review criteria established by the laboratory. Results may also vary due to disease abnormalities included in the study, overall patient population and institutional review criteria.

Examples of Flagging Analysis - XN-L compared to XN-10

Sites	Site 1 N=167	Site 2 N=149	Site 3 N=110	Combined Sites N=426
Positive Percent Agreement	95.3	98.1	95.6	96.1
Negative Percent Agreement	93.4	96.8	87.5	93.2
Overall Agreement	94.6	97.3	90.9	94.6

* Variation is dependent upon patient population and sample selection at each site.

Note:

Results can be very heavily biased by the proportion of abnormal or normal specimens in the total number of specimens tested.

Calculations

Predictive value of a positive result indicates the proportion of samples that had positive test results that actually were positive.

$$\text{PV\% Pos} = \frac{TP}{(TP + FP)} \times 100$$

Predictive value of a negative result indicates the proportion of samples that had negative test results that actually were negative.

$$\text{PV\% Neg} = \frac{TN}{(TN + FN)} \times 100$$

Agreement is the overall performance of the instrument in identifying both normal and abnormal specimens.

$$\text{Agreement} = \frac{TP + TN}{\text{Total number}} \times 100$$

Note:

The truth table shows data that challenged the instrument and thus, results may differ due to the difference in patient population and institutional review criteria. Adjustment of Q-flag settings also may factor into the difference in truth tables from site to site.

Whole blood stability

Long term stability is determined by comparing the results of the initial analysis (within two hours of collection) to results from samples stored at controlled room and refrigerated temperature for 48 hours. Upon removal from refrigerated storage, samples were hand mixed by inversion 20 times, allowed to warm to room temperature for a minimum of 30 minutes and then hand mixed by inversion 20 times prior to analysis.

Parameter	Stability Bias Limits	Units	Controlled Room Temperature (RT) (18 to 26°C or 64 to 79°F)	Controlled Refrigerated Temperature (LT) (2 to 8°C or 35.6 to 46.4°F)
WBC	within ±10.0%	x 10^3/µL	24 hours	48 hours
RBC	within ±5.0%	x 10^6/µL	24 hours	48 hours
HGB	within ±5.0%	g/dL	24 hours	48 hours
HCT	within ±8.0% (LT) within ±15.0% (RT)	%	24 hours	24 hours
MCV	within ±8.0% (LT) within ±15.0% (RT)	fL	24 hours	24 hours
PLT	within ±10.0% or ±30 x 10^3/µL	x 10^3/µL	24 hours	48 hours
NEUT%	within ±8.0 NEUT%	%	24 hours	48 hours
LYMPH%	within ±7.0 LYMPH%	%	24 hours	48 hours
MONO%	within ±4.0 MONO%	%	24 hours	48 hours
EO%	within ±3.0 EO%	%	24 hours	48 hours
BASO%	within ±1.0 BASO%	%	24 hours	12 hours
IG%	within ±2.0 IG%	%	24 hours	24 hours
RET%*	within ±20.0% or ±0.3 RET%	%	24 hours	24 hours
IRF*	within ±30.0% or ±10.0 IRF	%	24 hours	24 hours
RET-He*	within ±8.0% (RET# ≥ 0.0100 x 10^6/µL)	pg	24 hours	24 hours

* The availability of functions depends on your system configuration.

Body fluids stability

Per established literature, body fluid samples should be stored at room temperature and analyzed within 1 hour of collection.

Source: Kjeldsberg, C. Body Fluids Third Edition. 1993

Performance Characteristics: Reference Interval

Reference intervals (Normal Population Reference Ranges) were developed using normal individuals. The range for each parameter is calculated for 95% confidence intervals. The table below shows the Normal Population Reference Ranges.

Parameter	Range for Females n=133	Range for Males n=182	Units
WBC	3.98 to 10.04	4.23 to 9.07	x 10^3/µL
NEUT%	34.0 to 71.1	34.0 to 67.9	%
LYMPH%	19.3 to 51.7	21.8 to 53.1	%
MONO%	4.7 to 12.5	5.3 to 12.2	%
EO%	0.7 to 5.8	0.8 to 7.0	%
BASO%	0.1 to 1.2	0.2 to 1.2	%
NEUT#	1.56 to 6.13	1.78 to 5.38	x 10^3/µL
LYMPH#	1.18 to 3.74	1.32 to 3.57	x 10^3/µL
MONO#	0.24 to 0.36	0.30 to 0.82	x 10^3/µL
EO#	0.04 to 0.36	0.04 to 0.54	x 10^3/µL
BASO#	0.01 to 0.08	0.01 to 0.08	x 10^3/µL
NRBC%	0 to 0.2	0 to 0.2	/100WBC
NRBC#	0 to 0.012	0 to 0.012	x 10^3/µL
RBC	3.93 to 5.22	4.63 to 6.08	x 10^6/µL
HGB	11.2 to 15.7	13.7 to 17.5	g/dL
HCT	34.1 to 44.9	40.1 to 51.0	%
MCV	79.4 to 94.8	79.0 to 92.2	fL
MCH	25.6 to 32.2	25.7 to 32.2	pg
MCHC	32.2 to 35.5	32.3 to 36.5	g/dL
RDW-CV	11.7 to 14.4	11.6 to 14.4	%
RDW-SD	36.4 to 46.3	35.1 to 43.9	fL
RET%*	0.5 to 1.7	0.51 to 1.81	%
RET#*	0.0164 to 0.0776	0.026 to 0.095	x 10^6/µL
IRF*	3.0 to 15.9	2.3 to 13.4	%
PLT	182 to 369	163 to 337	x 10^3/µL
MPV	9.4 to 12.3	9.4 to 12.4	fL

Reference values for IG% and IG#

	IG%	IG# (x 10^3/µL)
Mean	0.215	0.0138
SD	0.107	0.0086
N	60	60

Reference intervals for RET-He

RET-He (pg)	Site 1	Site 2	Site 3
Mean	32	32.0	33.7
SD	1.5	1.9	1.4
D	33	122	31
Range	29 to 35	28.0 to 35.7	30.8 to 36.6

Reference:

1) http://www.pubinfo.vcu.edu/pathlabs/print_menu/appendix_hematology_reference_ranges.pdf
2) http://www.sysmex.se/fileadmin/media/f100/Diagnostic_Perspectives/Pekelharing_DiagPersp_Vol1_1-11.pdf
J. M. Pekelharing1, O. Hauss2, R. de Jonge3, J. Lokhoff1, J. Sodikromo1, M. Spaans1, R. Brouwer3, S. de Lathouder3, R. Hinzmann2
3) https://www.healthcare.uiowa.edu/path_handbook/handbook/test299.html
4) http://labhandbook.hitchcock.org/lhb_reference_range.php

Note:

Sysmex recommends that each laboratory verify the reference intervals before use of the XN-L or 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-A3c "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline-Third Edition" contains guidelines for determining reference values and intervals for quantitative clinical laboratory tests.

Performance Characteristics: Verification of Pediatric Reference intervals

Verification of pediatric reference intervals was performed on the XN-L analyzer to demonstrate comparability of whole blood reference ranges for a pediatric population (0-21 years) to the ranges cited from published literature. The range for each parameter was calculated for 95% confidence intervals. The table below shows the 95% confidence intervals of the upper and lower limits of the overlapping two data sets.

Pediatric Reference Ranges – Birth to <2 years

XN-L Automated Hematology Analyzer Reference Intervals – Birth to <2 years				
Measurand	Units	Females	Males	Combined[*1] RI Male/Females
WBC	x 10^3/µL	5.9 – 15.8	6.5 – 16.7	5.9 – 16.7
RBC	x 10^6/µL	3.55 – 4.83	3.24 – 5.08	3.24 – 5.08
HGB	g/dL	10.7 – 16.4	10.2 – 16.6	10.2 – 16.6
HCT	%	30.5 – 47.7	29.1 – 47.4	29.1 – 47.7
MCV	fL	76.6 – 105.4	75.6 – 106.3	75.6 – 106.3
MCH	pg	26.5 – 36.3	26.0 – 36.4	26.0 – 36.4
MCHC	g/dL	33.7 – 35.7	33.6 – 35.7	33.6 – 35.7
PLT	x 10^3/µL	95.0 – 430	120 – 471	95.0 - 471
RDW-SD	fL	34.9 – 65.7	35.3 – 61.7	34.9 – 65.7
RDW-CV	%	13.3 – 17.8	13.5 – 18.2	13.3 – 18.2
MPV	fL	7.3 – 9.9	7.3 – 9.3	7.3 – 9.9
NEUT	x 10^3/µL	2.2 – 11.4	2.2 – 9.4	2.2 – 11.4
NEUT	%	15.7 – 69.3	14.6 – 69.2	14.6 – 69.3
LYMPH	x 10^3/µL	1.2 – 5.7	1.4 – 5.6	1.2 – 5.7
LYMPH	%	8.0 – 70.0	9.0 – 68.0	8.0 – 70.0
MONO	x 10^3/µL	0.1 – 5.0	0.2 – 3.5	0.1 – 5.0
MONO	%	4.0 – 19.0	4.0 – 18.0	4.0 – 19.0
EO	x 10^3/µL	0.0 – 0.4	0.0 – 0.5	0.0 – 0.5
EO	%	1.0 – 6.0	1.0 – 7.0	1.0 – 7.0
BASO	x 10^3/µL	0.0 – 0.1	0.0 – 0.1	0.0 – 0.1
BASO	%	0.0 – 1.0	0.0 – 1.0	0.0 – 1.0
RET	%	0.4 – 3.7	0.4 – 4.8	0.4 – 4.8
RET	x 10^3/µL	35.0 – 120.0	29.0 – 104.0	29.0 – 120.0
RET-He[*2]	pg	23.9 – 30.9	22.5 – 31.8	22.5 – 31.8
IRF	%	11.4 – 35.1	11.4 – 35.1	11.4 – 35.1
IG	%	0.0 – 1.7	0.0 – 1.7	0.0 – 1.7
IG	x 10^3/µL	0.00 – 0.28	0.00 – 0.28	0.0 – 0.28

*1 Combined Reference Intervals (RI) – The lowest and highest value of the above female and male ranges were used to define the lower and upper range for the combined RI for pediatric subgroup birth to <2 years listed in the above table.

*2 RET-He parameter is the same as the Reticulocyte cellular hemoglobin content (CHR) referenced in Sixth Edition, AACC Press, Washington D.C.

Reference Ranges (WBC, RBC, HGB, HCT, MCV, MCH, PLT, RDW-SD, RDW-CV, MPV, NEUT#, NEUT%, LYMPH#, LMPH%, MONO#, MONO%, EO#, EO%, BASO%, RET#, RET%, IRF%, IG#):
Soldin, S.J., Brugnara, C., and Wong, E.C. 2005. Pediatric Reference Intervals, Fifth Edition, AACC Press, Washington, DC.
Reference Ranges (BASO#, IG%, IG #, MCHC, RET-He)
Soldin, S. J.,Brugnara, C., and Wong, E.C. 2007. Pediatric Reference Intervals, Sixth Edition, AACC Press, Washington, DC.

Pediatric Ages 2-12 years

XN-L Automated Hematology Analyzer				Verification of Pediatric Reference Intervals Ages 2-12yrs Sample Range (95% CI)	
Measurand	Units	Proposed RI Females	Proposed RI Males	Females N = 28	Males N = 21
WBC	x 10^3/µL	4.80-13.50	4.80-13.50	5.17-15.15 (7.58, 10.62)	4.16-13.71 (5.9, 8.79)
RBC	x 10^6/µL	3.70-5.40	3.85-5.50	1.75-5.57 (3.77, 4.79)	4.1-6.0 (4.29, 4.70)
HGB	g/dL	10.5-16.0	10.5-16.0	5.9-17.0 (10.7, 13.6)	9.4-15.0 (12.3, 13.3)
HCT	%	29.0-48.0	29.0-48.0	16.3-53.3 (33.2, 40.2)	30.7-44.0 (35.5, 40.3)
MCV	fL	74.0-99.0	75.0-99.0	59.0-103.9 (84.0, 91.3)	60.3-107.3 (81.1, 86.7)
MCH	pg	25.0-32.2	24.0-33.0	17.7-35.2 (28.3, 30.5)	18.0-32.9 (27.5, 30.0)
MCHC	g/dL	31.0-37.0	32.0-36.5	28.4-38.4 (32.0, 34.9)	28.0-36.2 (32.9, 34.7)
PLT	x 10^3/µL	150-450	150-450	127-564 (245, 335)	185-832 (283, 430)
RDW-SD	fL	35.1-46.1	35.1-46.1	37.3-85.7 (40.3, 51.2)	33.7-61.2 (37.8, 42.9)
RDW-CV	%	11.6-14.4	11.5-15.0	11.9-27.5 (13.0, 17.3)	11.0-24.1 (12.2, 13.8)
MPV	fL	7.3-12.4	7.2-12.4	9.3-13.9 (10.5, 11.6)	9.2-13.3 (9.6, 11.1)
NEUT	x 10^3/µL	1.50-8.64	1.50-8.50	2.03-12.42 (3.65, 6.88)	1.19-12.6 (2.28, 4.05)
NEUT	%	33.6-77.5	23.0-76.7	31.4-85.3 (49.0, 70.4)	26.0-91.9 (32.8, 49.0)
LYMPH	x 10^3/µL	0.96-7.29	0.96-7.29	0.3-5.85 (1.77, 2.96)	0.73-6.11 (2.55, 4.08)
LYMPH	%	10.0-59.0	8.0-65.0	4.9-54.3 (20.9, 41.5)	5.4-63.6 (41.3, 55.1)

XN-L Automated Hematology Analyzer				Verification of Pediatric Reference Intervals Ages 2-12yrs Sample Range (95% CI)	
Measurand	Units	Proposed RI Females	Proposed RI Males	Females N = 28	Males N = 21
MONO	x 10^3/µL	0.00-1.20	0.00-1.20	0.29-1.39 (0.48, 0.73)	0.24-0.81 (0.38, 0.61)
MONO	%	4.0-12.5	3.0-9.0	2.9-13.1 (5.4, 8.2)	2.2-13.6 (5.2, 8.0)
EO	x 10^3/µL	0.00-0.50	0.00-0.50	0.00-1.14 (0.08, 0.20)	0.00-1.12 (0.09, 0.22)
EO	%	1.0-4.0	0.0-5.0	0.0-10.7 (1.0, 2.1)	0.0-8.4 (1.4, 4.1)
BASO	x 10^3/µL	0.00-2.80	0.00-2.27	0.02-0.20 (0.05, 0.08)	0.01-0.15 (0.03, 0.06)
BASO	%	0.0-1.0	0.0-1.0	0.1-3.9 (0.6, 0.8)	0.1-2.9 (0.4, 0.9)
RET	%	0.80-2.80	0.70-2.20	0.42-24.3 (1.03, 1.78)	0.52-1.76 (0.81, 1.32)
RET	x 10^6/µL	0.0430-0.0830	0.0290-0.0800	0.0178-0.4253 (0.0439, 0.0668)	0.0219-0.0827 (0.0369, 0.0591)
RET-He	pg	25.1-33.3	23.6-33.9	16.4-37.3 (27.1, 31.7)	17.2-32.7 (29.9, 32.2)
Verification of Reference Intervals				PASS	PASS

Pediatric Ages >12-21 years

XN-L Automated Hematology Analyzer				Verification of Pediatric Reference Intervals Ages >12-21yrs Sample Range (95% CI)	
Measurand	Units	Proposed RI Females	Proposed RI Males	Females N = 53	Males N = 34
WBC	x 10^3/µL	3.90-13.00	3.70-13.00	3.82-18.99 (8.95, 10.47)	1.64-30.72 (6.27, 10.12)
RBC	x 10^6/µL	3.79-6.10	3.74-6.10	3.23-5.50 (4.23, 4.51)	3.48-6.91 (4.81, 5.33)
HGB	g/dL	11.3-18.0	11.0-18.0	9.4-16.1 (12.2, 13.1)	10.7-19.5 (14.0, 15.6)
HCT	%	32.1-52.0	31.4-52.0	30.7-51.3 (37.3, 40.7)	31.6-59.6 (42.5, 46.8)
MCV	fL	78.0-102.0	79.0-99.0	77.9-111.6 (86.6, 93.8)	76.4-104.9 (84.8, 89.5)

XN-L Automated Hematology Analyzer				Verification of Pediatric Reference Intervals Ages >12-21yrs Sample Range (95% CI)	
Measurand	Units	Proposed RI Females	Proposed RI Males	Females N = 53	Males N = 34
MCH	pg	25.0-35.0	25.0-35.0	23.7-33.8 (28.4, 29.5)	24.1-31.9 (28.2, 30.1)
MCHC	g/dL	31.0-37.0	32.0-36.7	26.4-35.5 (31.4, 32.8)	29.3-35.8 (33.0, 33.9)
PLT	x 10^3/µL	150-450	150-450	102-540 (257, 313)	175-561 (249, 275)
RDW-SD	fL	35.1-46.1	35.1-46.1	37.6-74.0 (44.7, 48.8)	37.0-60.5 (40.0, 44.1)
RDW-CV	%	11.5-14.7	11.5-14.6	11.8-20.3 (13.7, 14.7)	11.9-15.5 (13.2, 13.7)
MPV	fL	6.3-12.4	6.1-12.4	9.3-15.4 (10.8, 11.6)	9.6-12.7 (10.3, 11.4)
NEUT	x 10^3/µL	1.90-8.64	1.92-8.64	2.71-16.26 (5.54, 8.41)	1.11-26.62 (3.25, 6.07)
NEUT	%	39.6-80.0	33.0-80.0	42.8-90.1 (66.3, 74.4)	25.3-92.7 (51.0, 67.8)
LYMPH	x 10^3/µL	0.40-3.90	0.40-3.90	0.54-6.33 (1.77, 2.16)	0.35-5.48 (1.91, 2.46)
LYMPH	%	8.0-52.8	8.0-45.8	5.0-49.0 (17.3, 24.0)	2.7-49.8 (24.2, 37.1)
MONO	x 10^3/µL	0.20-0.90	0.20-1.30	0.11-1.65 (0.56, 0.78)	0.12-1.48 (0.49, 0.72)
MONO	%	2.7-12.5	3.0-9.2	2.0-11.9 (6.3, 7.3)	4.0-22.4 (7.1, 8.7)
EO	x 10^3/µL	0.00-0.40	0.00-0.40	0.00-0.30 (0.05, 0.10)	0.00-0.37 (0.07, 0.14)
EO	%	0.5-7.2	0.0-6.2	0.0-4.4 (0.5, 1.1)	0.0-7.5 (0.8, 2.4)
BASO	x 10^3/µL	0.00-0.10	0.00-0.10	0.02-0.31 (0.05, 0.07)	0.01-0.12 (0.03, 0.05)
BASO	%	0.0-1.0	0.0-1.3	0.2-3.1 (0.5, 0.8)	0.2-1.5 (0.4, 0.7)
RET	%	0.80-2.40	0.80-2.70	0.24-2.22 (1.09, 1.41)	0.45-2.57 (0.86, 1.28)
RET	x 10^6/µL	0.0400-0.1020	0.0390-0.1000	0.0109-0.0871 (0.0493, 0.0611)	0.0165-0.1106 (0.0475, 0.0625)
RET-He	pg	27.5-34.2	27.0-35.3	18.2-36.5 (28.5, 31.2)	21.8-34.4 (29.4, 31.4)
Verification of Reference Intervals				PASS	PASS

References:

1 https://www.pubinfo.vcu.edu/pathlabs/.../appendix_hematology_reference_ranges.pdf
2 www.mayomedicallaboratories.com/test-info/pediatric/refvalues
3 https://www.childrensmn.org/references/lab/hematology/cbc-reference-value-table.pdf
4 Sysmex XW-100 Instructions for Use Manual, Pediatric and Adolescent reference ranges
5 http://www.mercynorthiowa.com/cbc-normal-ranges
6 http://www.labcareplus.org/docs/REFERENCE_RANGES.pdf
7 http://www.uams.edu/clinlab/Pediatricnormalrangesfinalupdated%207.15.09.pdf

Reference intervals for body fluids

Due to the unavailability of obtaining normal body fluid samples, it is difficult for laboratories to reference intervals. Adult reference intervals for body fluids are included from a widely known textbook. According to C49-A "Analysis of Body Fluids in Clinical Chemistry", clinical laboratories have not established reference ranges for body fluids.

Adult reference ranges for body fluid types

Body Fluid Type	WBC#	PMN%	PMN#	MN% (Lymphocyte + Monocyte)	MN # (Lymphocyte + Monocyte)	RBC#
CSF	0 to 5 cells / µL[*1]	2% ± 4%[*2]	0.02 cells / µL ± 0.04[*2]	90% ± 20%[*2]	0.90 cells / µL ± 0.20[*2]	None[*2]
Peritoneal	None[*3]	None[*3]	None[*3]	None[*3]	None[*3]	None[*3]
Pleural	None[*4]	None[*4]	None[*4]	None[*4]	None[*4]	None[*4]
Synovial	<200 cells / µL[*5]	<25%[*6]	<0.25 cells / µL[*6]	<75%[*6]	<0.75 cells / µL[*6]	None[*6]

Neonate reference ranges for body fluid types

Body Fluid Type	WBC#	PMN%	PMN#	MN% (Lymphocyte + Monocyte)	MN # (Lymphocyte + Monocyte)	RBC#
CSF	0 to 30 cells / µL[*1]	4% ± 4%[*2]	0.04 cells / µL ± 0.04[*2]	90% ± 20%[*2]	0.90 cells / µL ± 0.20[*2]	None[*2]

Note:

Children have intermediate leukocyte values, less than 20 cells / µL the first year of life and less than 10 cells / µL until adolescence[*1].

*1 Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993. P.67.

*2 Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993. P.72.

*3 Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993. P.223. The peritoneal cavity is not a true cavity, but only becomes so in the presence of disease that causes fluid to accumulate within it. Therefore, no cells are normally present.

*4 Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993. P.159. The pleural cavity is not a true cavity, but only becomes so in the presence of disease that causes fluid to accumulate within it. Therefore, no cells are normally present.

*5 Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993. P.270.

*6 Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993. P.266.

Body fluid application

Intended use

The XN-L series body fluid mode adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid and synovial fluid to the XN-L series, providing enumeration of the WBC counts and the RBC counts.

Analysis principle

Fluorescent flow cytometry using side scattered light and side fluorescent light are used to determine the WBC counts. The DC detection method is used for the RBC counts.

Limitations

1. Failure to properly collect, store and transport specimens may compromise results. To ensure proper collection, storage and transport of specimens Sysmex recommends that you follow CLSI guidance documents or equivalent procedures.
2. Always use good laboratory practices when inspecting specimens for clots, ensuring specimens are properly mixed and verifying results. Follow standard operating procedure for inspecting specimens for clots. Results may be compromised with improper mixing, cellular debris or clotted specimens.
3. Interpretation of results should included total clinical presentation of the patient, clinical history, data from additional tests, smear review, and other appropriate information.
4. Fat globules, crystals and high viscous synovial fluids may cause erroneous or misleading results.
5. Body fluid specimens should be transported to the laboratory promptly at room temperature and analyzed within 1 hour of collection. Delay in processing may lead to erroneous or misleading results as per established literature.
6. Sample results with Error related to WBC-BF, RBC-BF and TC-BF# parameters should not be used.
7. WBC-BF counts < 0.004 x 10^3/μL should be confirmed using an alternate method.
8. RBC-BF counts < 0.002 x 10^6/μL should be confirmed using an alternate method.
9. The laboratory should perform additional testing if more specific or sensitive limitation information is needed.

5.2 System limitations and Interfering substances

Note:

Compromised samples, such as those not properly collected, stored, transported, or contain clots may cause misleading results. Always use good laboratory practices for inspecting specimens for acceptability and verifying results.

Possible sample limitations

● WBC

If any of the following conditions are present, the system may erroneously report a low white blood cell count.

- White blood cell aggregation

If any of the following conditions are present, the system may erroneously report a high white blood cell count.

- Platelet aggregation
- Poor hemolysis
- Erythroblast
- Red blood cell aggregation (cold agglutinin)
- Chylemia
- Cryoprotein
- Cryoglobulin
- Fibrin
- Giant platelets

● RBC

If any of the following conditions are present, the system may erroneously report a low red blood cell count.

- Red blood cell aggregation (cold agglutinin)
- Microcytic red blood cells
- Fragmented red blood cells

If any of the following conditions are present, the system may erroneously report a high red blood cell count.

- Leukocytosis (> 100,000/μL)
- Giant platelets

● HGB

If any of the following conditions are present, the system may erroneously report a high hemoglobin value.

- Leukocytosis (> 100,000/μL)
- Lipemia
- Abnormal protein

HCT

If any of the following conditions are present, the system may erroneously report a low hematocrit value.
- Red blood cell aggregation (cold agglutinin)
- Microcytic red blood cells
- Fragmented red blood cells

If any of the following conditions are present, the system may erroneously report a high hematocrit value.
- Leukocytosis (> 100,000/μL)
- Severe diabetes
- Uremia
- Spherocyte

PLT

If any of the following conditions are present, the system may erroneously report a low platelet count.
- Platelet aggregation
- Pseudothrombocytopenia
- Giant platelets

If any of the following conditions are present, the system may erroneously report a high platelet count.
- Microcytic red blood cells
- Fragmented red blood cells
- Fragmented white blood cells
- Cryoprotein
- Cryoglobulin

RET*

If any of the following conditions are present, the system may erroneously report a high reticulocyte count.
- Red blood cell aggregation (cold agglutinin)
- Giant platelets
- Platelet aggregation
- Fragmented white blood cells
- Malaria
- Howell-Jolly body

Body fluid*

- Excessive mixing of samples
- Debris
- Fat globules
- Crystals
- High viscous synovial fluids
- Bacteria
- Fungi

* The availability of functions depends on your system configuration.

Interfering substances

Whole blood interference - EDTA-2K

Interfering substances studies for Bilirubin C, Bilirubin F, Hemolytic Hemoglobin, Lipemia (intralipid) and Chyle interferents were performed on the XN-L series.

A total of 6 whole blood EDTA-2K samples were collected from 3 donors each. All tubes were centrifuged and 150 µL of plasma removed from each. Each interferent was diluted to (0%, 20%, 40%, 60%, 80%, and 100%) and then 150 µL of each dilution was added to the centrifuged tubes (from a single donor). The tubes were mixed and measured 3 consecutive times for WBC, RBC, HGB, HCT, PLT, RET%/#[*1], IRF[*1], and RET-He[*1] on the XN-L series.

Bilirubin C interference

There was no significant Bilirubin C interference up to a concentration of 42.2 mg/dL for WBC, RBC, HGB, HCT, PLT, RET%/#[*1], and RET-He[*1] parameters. A significant Bilirubin C interference was observed at a concentration of 8.4 mg/dL for IRF[*1] parameter.

Bilirubin F interference

There was no significant Bilirubin F interference up to a concentration of 40.0 mg/dL for WBC, RBC, HGB, HCT, RET%/#[*1], and RET-He[*1] parameters, up to a concentration of 8.0 mg/dL for PLT parameter, and up to a concentration of 24.0 mg/dL for IRF[*1] parameter.

Hemolysis interference

There was no significant hemolysis interference up to a concentration of 1018.0 mg/dL for WBC, RBC, HCT, PLT, RET%/#[*1], and RET-He[*1] parameters, up to a concentration of 203.6 mg/dL for HGB parameter. A significant hemolysis interference was observed at a concentration of 203.6 mg/dL for IRF[*1] parameter.

Intralipid interference

There was no significant intralipid interference up to a concentration of 2.00 g/dL for WBC, RBC, HCT, RET%/#[*1], and RET-He[*1] parameters, up to a concentration of 1.00 g/dL for PLT and IRF[*1] parameters, and up to a concentration of 0.20 g/dL for HGB parameter.

Chyle interference

There was no significant chyle interference up to a concentration of 2800 FTU for WBC[*2], RBC, HGB, HCT, RET%/#[*1], IRF[*1], and RET-He[*1] parameters and up to a concentration of 1680 FTU for PLT parameter.
A significant chyle interference at a concentration of 560 FTU for WBC[*3] parameter.

Allowable change rate:

The Allowable Change Rate is the allowable bias for each measurand. Bias outside the ranges listed below is considered an interference.

	WBC	RBC	HGB	HCT	PLT	RET#[*1]	RET%[*1]	IRF[*1]	RET-He[*1]
Change rate	within ±10.9%	within ±3.2%	within ±2.8%	within ±2.8%	within ±9.1%	within ±11.0%	within ±11.0%	within ±13.0%	within ±10%

The concentration that showed no significant interference was judged by the change rate based on the criteria from the CLSI document H26-A2 under Biological variation (%CV) for all listed parameters except for RET-He[*1]. RET-He[*1] was judged by accuracy acceptance limits for bias percent.

*1 The availability of functions depends on your system configuration.

*2 The white blood cell count calculated from the WDF channel (CBC+DIFF mode).
*3 The total white blood cell count calculated from the forward scattered light and the side scattered light of the WDF channel (CBC mode).

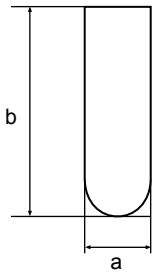
5.3 Supported sample tubes and sampler adapter

This section explains the sample tubes you can use with this instrument.

5.3.1 Supported sample tubes (XN-330)

● Regular sample tubes

Diameter (a)	ϕ11 to 15 mm
Length (b)	85 mm or less

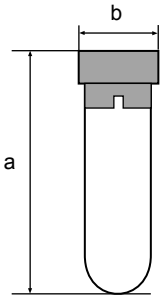


5.3.2 Supported sample tubes (XN-530/XN-430)

● Regular sample tubes

Length including the cap (a)	70 to 85 mm
Diameter including the cap (b)	ϕ11 to 15 mm

With the exception of micro analysis, use the tube with the cap on.



Information

When performing sampler analysis using VENOJECT II (Terumo), fold the film seal so that it does not protrude horizontally before placing in the rack.
Otherwise, there is a risk that the seal will interfere with an adjacent sample tube and cause it to fall from the rack.

Note:

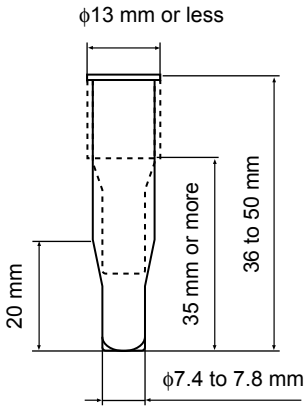
An adapter is needed when using a ϕ15 mm sample tube. For details, please contact your local Sysmex service representative.

- For XN-530 manual analysis / XN-430 analysis: XS adapter_ ASSY (for ϕ15) 05357228
- For XN-530 sampler analysis: Adapter_ASSY No. 14 (15MM DIA) AR970823

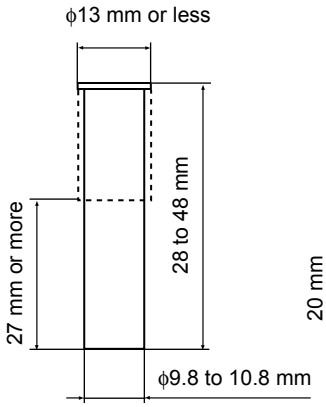
● Micro collection tubes

Standard micro collection tube shapes are shown below.
Compatible dimensions vary depending on the shape of the micro collection tube. The following are guidelines. It will be necessary to check using the actual micro collection tube.

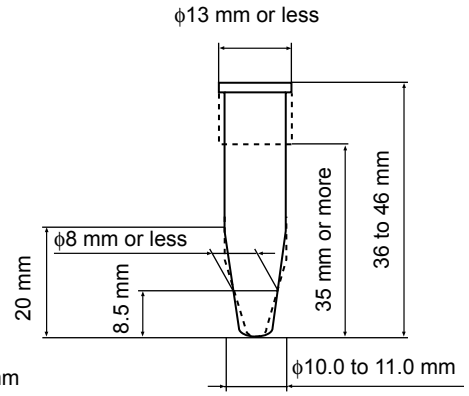
Type A



Type B



Type C



The cap is not included in the dimensions. Open the cap during analysis.

● RBT micro collection tube (RBT: Raised Bottom Tube)

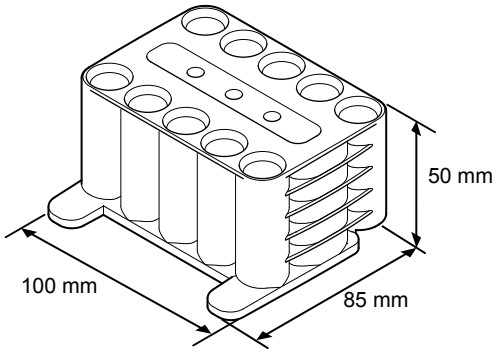
Sample tube for micro-volumes of blood. Can be used for sampler analysis. Allowable dimensions are the same as for regular sample tubes.

⚠ Caution!

Do not use a non-specified sample tube.
For information on using sample tubes not described here, consult your local Sysmex representative.

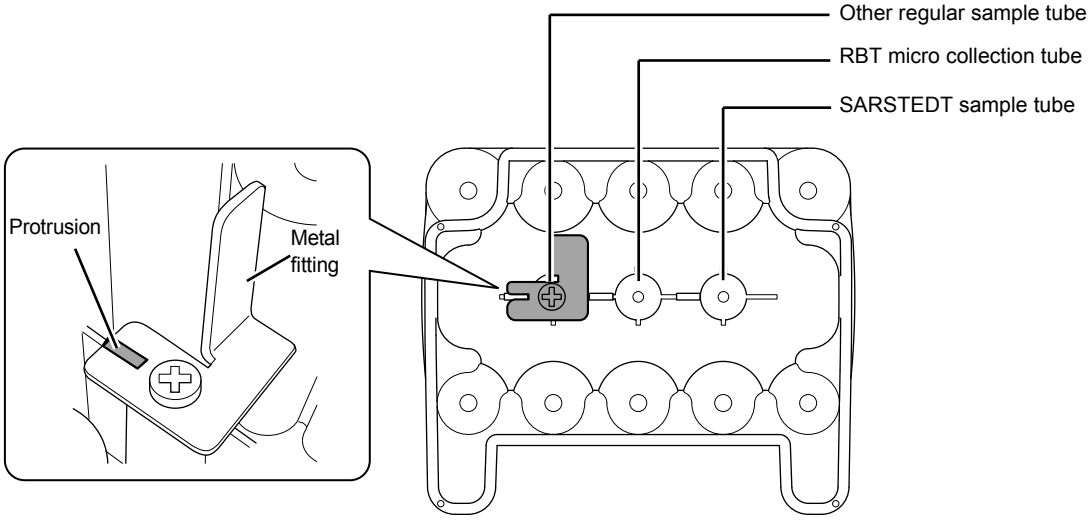
5.3.3 Supported sampler adapter

Regular sample tubes and RBT micro collection tubes can only be used with a Sysmex sampler adapter.



● Sample tube setup

Depending on the sample tube type, the metal fitting must be attached to the back of the sampler adapter.



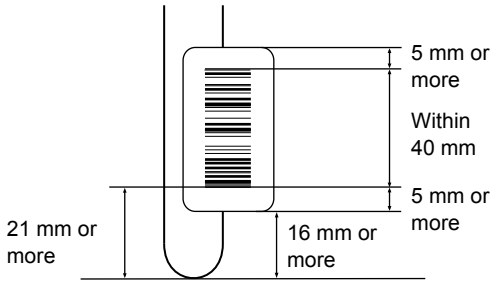
Example: Setup for other regular sample tubes

⚠ Caution!

- Use the sampler adapter with the metal fitting attached in the correct position for your sample tube type.
- Do not remove the attached metal fittings.
  Reattaching metal fittings may cause screw loosening due to enlargement of screw holes.

5.4 Barcode labels (XN-530)

To correctly read a barcode using a sampler, the barcode label must be attached in the correct position.
Attach the barcode label to the sample tube so that the barcode is within the area shown on the right.



Caution!

When attaching barcode labels, pay attention to the points below.
Incorrect attachment may cause barcode misreading and sample mix-ups.

- Attach the label so that the bars of the barcode are horizontal.
- Do not attach multiple labels.
- Do not allow the label to become wrinkled.
- Make sure that the label does not extend past the bottom of the sample tube.
- Make sure that the barcode label does not peel off the sample tube.
- Make sure that the labeled sample tubes can be inserted into and removed from the rack with ease.
- Do not write any text in the margins of a barcode label.

5.5 ID barcode specifications

This section explains the specifications of barcode labels that can be read by the hand-held barcode reader and the barcode reader on the XN-530 sampler.

5.5.1 Acceptable barcodes

The types of barcodes that can be used and check digit support are listed below.

Caution!

For the XN-530 only, use a check digit whenever possible when reading barcodes on sample tubes. There is a risk of incorrect reading of the barcode if a check digit is not used. To set a check digit, see "Basic Operation".
(➤Basic Operation, "Chapter 7: 7.9.4 Barcode reader settings (XN-530)")

Sample numbers

Barcode types	Check digits	Number of digits
ITF	None	Max. 22 digits (sample No.)
	Modulus 10	Max. 22 digits (sample No.) + 1 digit (check digit) = Max. 23 digits
CODABAR/NW7	None	Max. 22 digits (sample No.)
	Modulus 11	Max. 22 digits (sample No.) + 1 digit (check digit) = Max. 23 digits
	Weighted modulus 11	
	Modulus 16	
CODE39	None	Max. 22 digits (sample No.)
	Modulus 43	Max. 22 digits (sample No.) + 1 digit (check digit) = Max. 23 digits
JAN/EAN/UPC	Modulus 10	12 digits (sample No.) + 1 digit (check digit) = 13 digits
ISBT128	Modulus 103	Max. 22 digits (sample No.) + 1 digit (check digit) = Max. 23 digits
CODE128	Modulus 103	Max. 22 digits (sample No.) + 1 digit (check digit) = Max. 23 digits

Information

When using CODE128, do not use function characters.

Note:

In CODE128, any one of the characters "A", "B", "C", "a", "b" or "c" can be used for the start/stop code.

Quality control (QC)

Barcode types	Check digits	Number of digits
CODE128	Modulus 103	3 digits (fixed character string [QC-]) + 8 digits (lot number) + 1 digit (check digit) = 12 digits

Note:

The CODE128 barcode for quality control is a special Sysmex code used for control blood.

5.5.2 Automatic assignment of sample numbers

A sample number is automatically assigned to samples when a barcode label read error occurs or when analysis begins while the analysis order was still being downloaded.
An automatically assigned sample number starts with a symbol that distinguishes it from other sample numbers.

Number starting with [ERR.]	Assigned when a barcode label read error occurs. A barcode label read error also occurs when a number includes characters that cannot be used. When a serial number is assigned and the limit number is exceeded, the number returns to [00....01].
Number starting with [QC]	Assigned to a QC sample with a lot number or to a QC file.
[BACKGROUNDCHECK]	Assigned to a background check sample.
Number starting with [PRE-CHK]	Assigned to a precision check sample.
Number starting with [CAL-CAL]	Assigned to samples calibrated by calibrator calibration.

Information

Sample numbers starting with [QC] whose lower 4 digits are one of the following numbers are assigned.

- "1101", "1102", "1103": XN CHECK
- "1401", "1402", "1403": XN-L CHECK
- "1301", "1302": XN CHECK BF

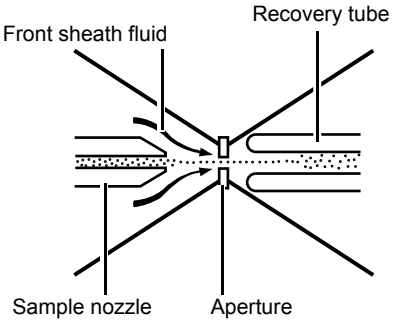
5.6 Functional descriptions

This device performs hematology analyses based on the Hydrodynamically focussed impedance measurement, the flow cytometry method (using a semiconductor laser), and the SLS-hemoglobin method.

5.6.1 Analysis principles

Hydrodynamically focussed impedance measurement

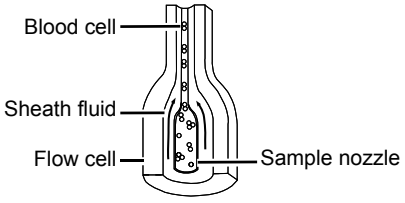
The RBC detector counts RBC and PLT by Hydrodynamically focussed impedance measurement.
At the same time, the hematocrit (HCT) is calculated via the RBC pulse height detection method.
Inside the detector, the sample nozzle is positioned in front of the aperture and in line with the center. After diluted sample is forced from the sample nozzle into the conical chamber, it is surrounded by front sheath fluid and passes through the aperture center.



After passing through the aperture, the diluted sample is sent to the recovery tube. This prevents the blood cells in this area from drifting back, and prevents the generation of pseudo platelet pulses. The Hydrodynamically focussed impedance measurement improves blood cell count accuracy and repeatability. Because the blood cells pass through the aperture in a line, this method also prevents the generation of abnormal blood cell pulses.

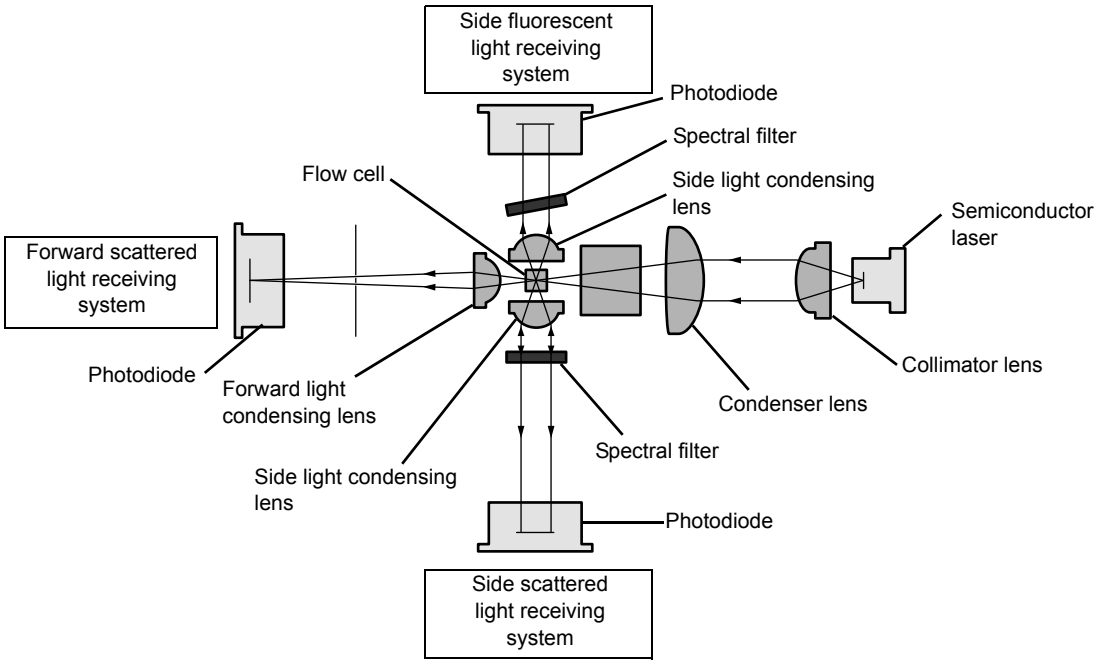
Flow cytometry method using a semiconductor laser

Cytometry is used to analyze physiological and chemical characteristics of cells and other biological particles. Flow cytometry is a method 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 by the sheath flow mechanism.



This mechanism improves cell count accuracy and repeatability. 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 directed onto the blood cells passing through the flow cell. The forward scattered light, side scattered light and side fluorescent light are captured by the photodiode. These lights are converted into electrical pulses, thus making it possible to obtain blood cell information.



- Forward scattered light and side 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 directed onto 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 side scattered light, which provides information on the cell interior (such as the size of the nucleus).

- Side fluorescent light
  When light is directed onto fluorescent material, such as labeled blood cells, light of longer wavelength than the original light is produced. The intensity of the fluorescent light increases as the concentration of the marker becomes higher. By measuring the intensity of the fluorescence emitted, you can obtain information on the degree of blood cell labeling. Fluorescent light is emitted in all directions. This instrument detects the fluorescent light that is emitted sideways.

SLS-hemoglobin method

In the past, the mainstream methods for automatically measuring hemoglobin were the cyanmethemoglobin method and oxyhemoglobin method. These methods have both advantages and disadvantages when they are used with a large, fully automated instrument such as this instrument.
The cyanmethemoglobin method was recommended by the International Council for Standardization in Haematology (ICSH) in 1966 as an international standard method. However, because the hemoglobin conversion speed of this method is slow and multiple-sample processing is a requirement for automation, this method is not appropriate for automatic analysis. Moreover, the method uses cyanide compounds, which are toxic, as reagents, and thus the liquid waste must be treated, making the method undesirable from an environmental perspective.
Currently this is not considered to be an appropriate analysis method for a large fully automatic instrument that discharges large amounts of liquid waste.

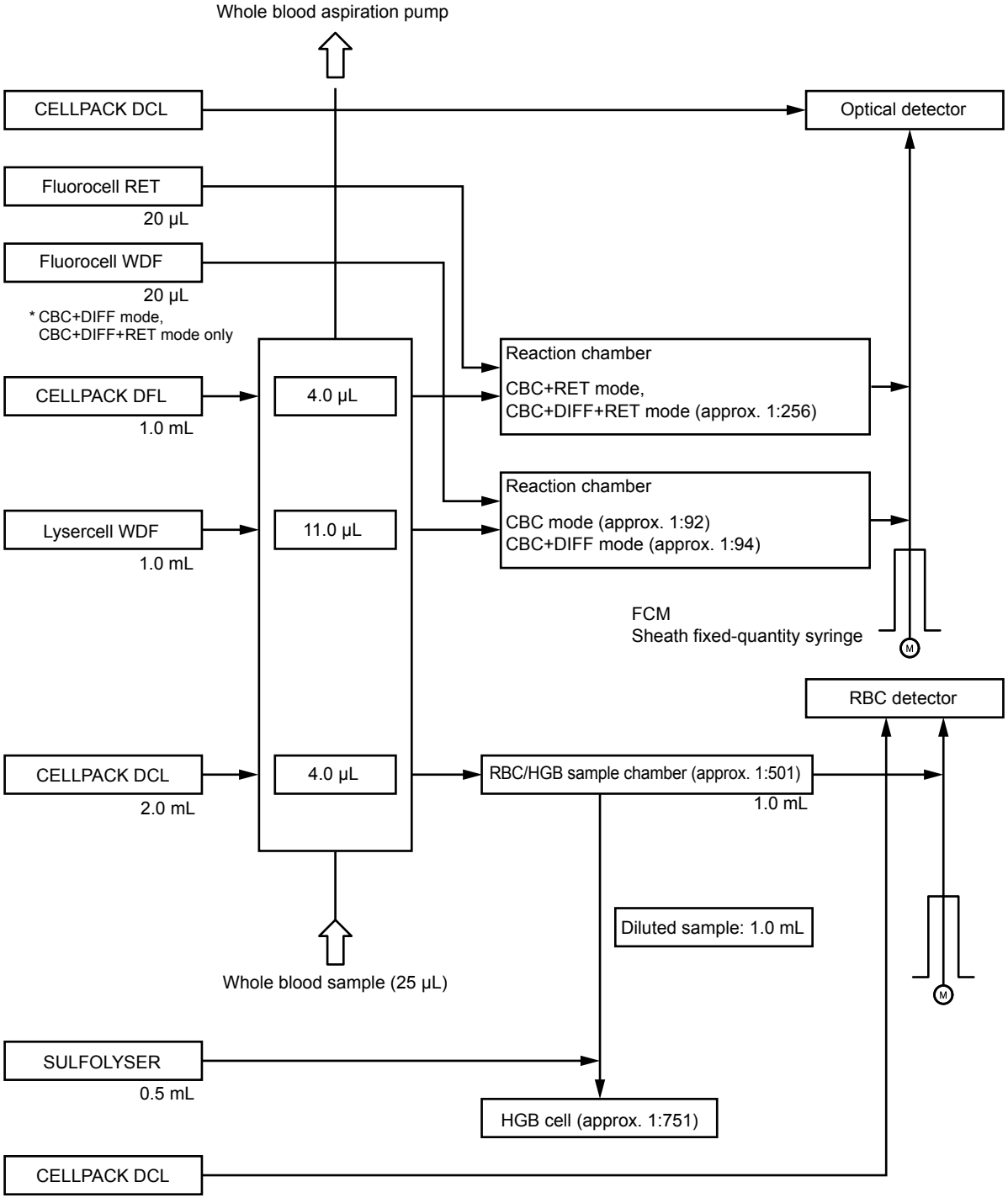
In contrast, the hemoglobin conversion speed of the oxyhemoglobin method is fast, as blood hemoglobin is instantly converted into oxyhemoglobin. In addition, it does not use toxic substances such as cyanide, and thus is a suitable method for performing automatic analysis. The method cannot, however, convert methemoglobin into oxyhemoglobin, which is not a problem for normal human blood, but will result in values that are lower than the true values for samples that contain large amounts of methemoglobin, such as control blood samples.

The SLS-hemoglobin method is an analysis method that makes use of the advantages of the two aforementioned methods.
As with the oxyhemoglobin method, the hemoglobin conversion speed of the SLS-hemoglobin method is fast and the method does not use poisonous substances, making it a suitable method for automation.
Further, since methemoglobin can be analyzed, control samples such as control blood containing methemoglobin can also be accurately analyzed.

5.6.2 Hydraulic diagram

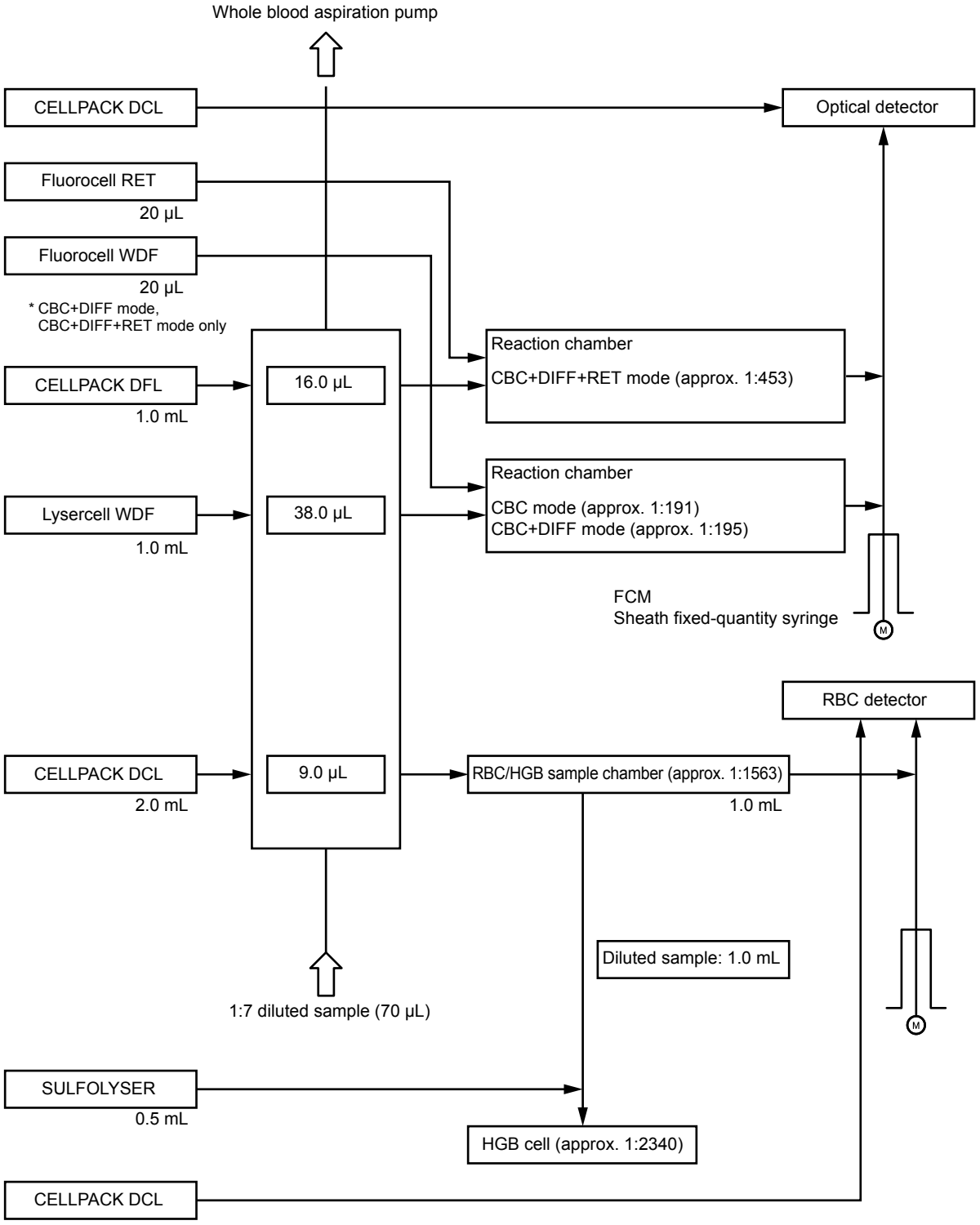
Whole blood mode

The availability of RET analysis function depends on your system configuration.



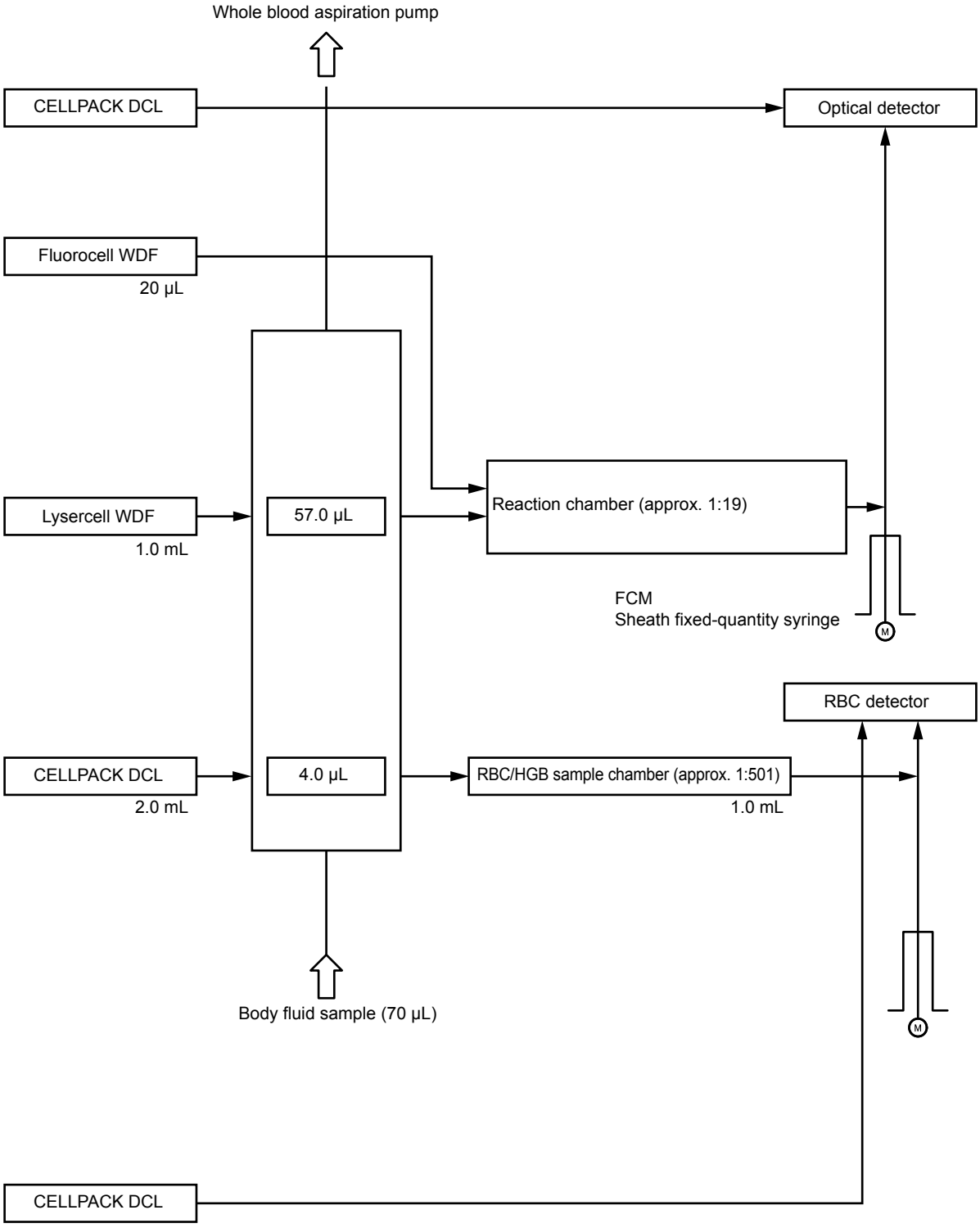
Pre-dilution mode

The availability of RET analysis function depends on your system configuration.



Body fluid mode

The availability of body fluid analysis function depends on your system configuration.

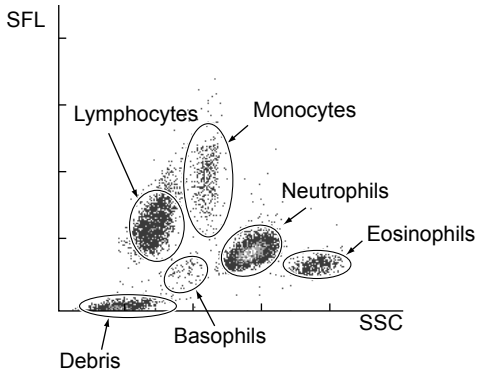


5.6.3 Reportable parameters and channels

WBC analysis

WDF channel

The WDF channel is a channel primarily for classifying white blood cells.
By flow cytometry method using a semiconductor laser, a two-dimensional scattergram is plotted, with the X-axis representing the intensity of the side scattered light (SSC), and the Y-axis representing the intensity of the side fluorescent light (SFL).
This scattergram displays groups of lymphocytes, monocytes, eosinophils, neutrophils, basophils, and debris.



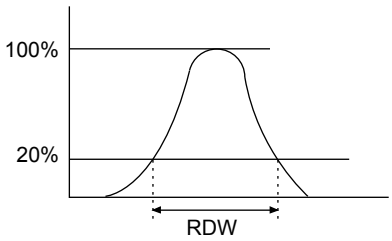
RBC/PLT analysis

RBC distribution

The RBC (red blood cell count) is calculated as a particle count between two discriminators (lower discriminator (LD) and upper discriminator (UD)), which are automatically set up in the ranges of 25 to 75 fL and 200 to 250 fL, respectively.
The particle distribution is checked for abnormal relative frequencies at each discriminator level, abnormal distribution width, and the existence of more than one peak.
In this instrument, the RBC distribution width (RDW) is expressed in the following two ways.

● RDW-SD

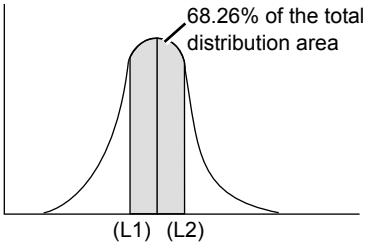
With the peak height assumed to be 100%, the distribution width at the 20% frequency level is RDW-SD.
The unit used is fL (femtoliter) (1 fL = 10^{-15} L).



● 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:

$$\text{RDW-CV (\%)} = \frac{\text{L2-L1}}{\text{L2+L1}} \times 100$$



● MCV (Mean cell volume)

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

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

● MCH (Mean cell hemoglobin)

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

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

● MCHC (Mean cell hemoglobin concentration)

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

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

PLT distribution

The PLT (platelet count) is measured as a particle count between 2 discriminators (lower discriminator (LD) and upper discriminator (UD)), which are automatically set up in the ranges of 2 to 6 fL and 12 to 30 fL, respectively. The PLT distribution is checked for abnormal relative frequencies, abnormal distribution width, and the existence of more than 1 peak at the LD.

● MPV (Mean platelet volume)

The average platelet volume is calculated from the particle size information of the PLT particle distribution.

Distribution expression

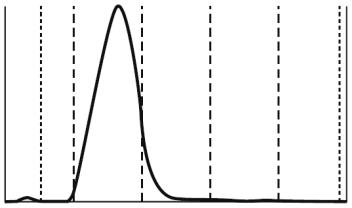
The impression given by a particle distribution can vary greatly, depending on the way in which it is expressed. The width of a particle distribution requires particular attention because it can appear completely different, depending on the expression used for the distribution.
The instrument utilizes a conventional particle distribution expression (normal expression) and a particle distribution expression method that enables the user to obtain a large amount of information from the particle distribution intuitively (normal particle range expression).

● Normal expression

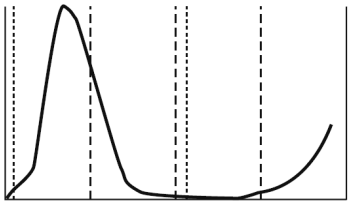
With the peak of the particle distribution set as full scale (maximum height when the particle distribution is displayed), this method of expression normalizes and expresses the distribution.

- Features: Patterns of particle distributions whose counts are different can be viewed on the same scale.
  Widths of particle distributions can be compared intuitively.
- Supported display area: RBC distribution, PLT distribution

RBC



PLT

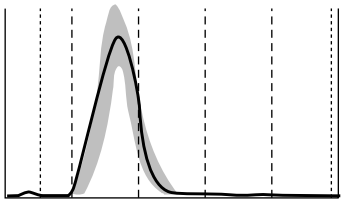


● Normal particle range expression

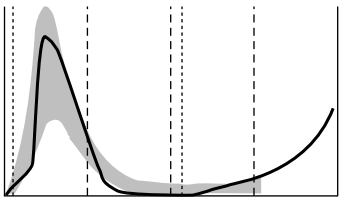
This method of expression does not consider the peak of the particle distribution as the full scale (maximum height when the particle distribution is displayed). Instead, it normalizes the distribution, with the peak of the normal particle range, which was calculated empirically, set as the full scale. At the same time, this method overlays the normal range of the particle distribution.
If, however, the peak of the particle distribution is higher than the peak of the normal particle range, the expression is made with the distribution peak set as full scale. In this case, the normal particle range is smaller in proportion to than the height of the particle distribution peak.
A normal particle range can be obtained by superposing the particle distributions of a large number of healthy people and then utilizing the region from the 10th percentile to the 90th percentile.

- Features: The user can intuitively see the amount of the particle count from the particle distribution.
  If the particle distribution deviates from the normal particle range, the user knows instantly that the particle distribution pattern is abnormal.
- Supported display area: RBC and PLT distributions if settings are preset to normal range

RBC



PLT

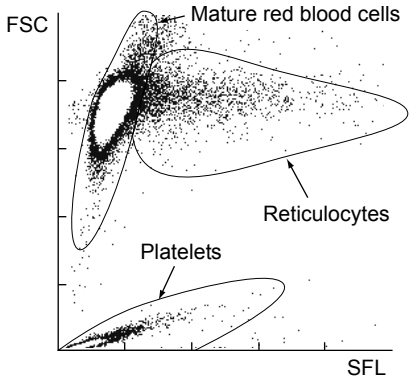


RET analysis

The availability of RET analysis function depends on your system configuration.

RET channel*

By flow cytometry method using a semiconductor laser, a 2-dimensional scattergram is plotted, with the X-axis representing the intensity of the side fluorescent light (SFL), and the Y-axis representing the intensity of the forward scattered light (FSC).
This scattergram displays groups of reticulocytes, mature red blood cells and platelets.
The IRF is obtained as a ratio of reticulocytes count in the area with strong fluorescent light intensity in the RET scattergram (IRF area), to the total reticulocytes count.



- IRF (Immature reticulocytes fraction):

$$\text{IRF} = \frac{\text{Particle count in IRF area}}{\text{Particle count in the reticulocytes area}} \times 100$$

* Cannot be used depending on the analyzer type.

- RET% (Reticulocyte ratio):

$$\text{RET\%} = \frac{\text{Particle count in the reticulocyte area}}{\text{Particle count in the mature red blood cell area} + \text{Particle count in the reticulocyte area}} \times 100$$

- RET# (Reticulocyte count):

$$\text{RET\#} = \frac{\text{RET\%} \times \text{RBC}}{100}$$

- RET-He (Reticulocyte hemoglobin equivalent):
  RET-He is a unique parameter developed by Sysmex that is derived using the reticulocyte scattered light signals and a proprietary Sysmex calculation equation.

Chapter 6 Supplies, Accessories, and Options

This chapter describes the supplies, accessories, and options.

6.1 Supplies

Part number	Item name
26677681	Fuse 50T100H
05104711	Air pump set No. 1

6.2 Accessories

Part number	Item name	Quantity
AA835013	Intake Tube_ASSY No. 58 (For DCL 10 L)	1
CH037047	Intake Tube_ASSY No. 60 (For WDF 2 L bottle)	1
AH953119	Intake Tube_ASSY No. 61 (For DFL 1 L bottle)	1
AE677153	Intake Tube_ASSY No. 62 (For SLS 500 mL bottle)	1
92380928	Power Cable No. 15 Assembly (for general export)*	1 (XN-530: 2)
AK803790	XN-L series Basic Operation (US)	1
BW212660	XN-L series Troubleshooting (US)	1
BV237179	XN-L series General Information (US)	1
46235205	Brush (with cap)	1
46223818	Phillips head screwdriver	1
46223901	Flathead screwdriver	1
46231221	Opener No. 2 (Use to open CELLPACK DCL)	1
26677681	Fuse 50T100H	2
44253387	Tube 6×4	2 m
44253405	Tube 9×6	5 m
26644618	Tie wrap CV-100	10
BL006232	Tray No. 258 (Bottle stand)	1
BT850247	Cap No. 559 (Special opener for CELLCLEAN AUTO)	1
CP976529	Adapter No. 328 (Sampler adapter)	2 (XN-530 only)
BQ750561	Interrupter plate No. 395 (Metal fitting)	2 (XN-530 only)
66387687	Phillips head tapping screw bind M3×6	2 (XN-530 only)
AY707257	TM104-SYX01 (Monitor)	1 (XN-530 only)

Part number	Item name	Quantity
04315817	Cable No. 3497 (Anti-static electricity connector for RU port)	1
96308015	Cable No. 2188 (Anti-static electricity connector for waste container full sensor)	1
BK659140	Label No. 1689	1 (XN-430X/N-330 only)

* Not attached in certain countries and regions.

6.3 Options

Item name	Description
Graphic printer	Prints lists of analysis information and results. Prints distributions, scattergrams and other analysis results, and hard copies of screens.
List printer	
Waste container full sensor	Detects when the waste container is full.
Hand-held barcode reader	Scans a barcode on a sample tube and automatically inputs the sample number.
Pneumatic unit (PU-17)	Supplies positive/negative pressure to the instrument.

Chapter 7 Reagents

This chapter describes the reagents that are used with the instrument.

7.1 General information

All reagents used in this instrument are exclusively for use with Sysmex equipment. Do not use them for any other purpose. Please follow the warnings for handling and using each of the reagents correctly.

7.2 List of specified reagents specifications

● Reagents

Product name	Storage temperature	Usage temperature	Shelf life after first opening	Composition
CELLPACK DCL	2 to 35°C	15 to 35°C	60 days	Sodium chloride 0.7% Tris buffer 0.2% EDTA-2K 0.02%
CELLPACK DST		15 to 30°C	60 days	Sodium chloride 15.7% Tris buffer 4.3% EDTA-2K 0.4%
CELLPACK DFL		15 to 35°C	60 days (1.5 L)	Tricine buffer 0.17%
			70 days (1.0 L)	
SULFOLYSER	1 to 30°C		60 days	Sodium lauryl sulfate 1.7 g/L
Lysercell WDF	2 to 35°C		90 days	Organic quaternary ammonium salts 0.07% Nonionic surfactant 0.17%
Fluorocell WDF			90 days	Polymethine pigment 0.002% Methanol 3.0% Ethylene glycol 96.9%
Fluorocell RET			90 days	Polymethine pigment 0.03% Methanol 7.9% Ethylene glycol 92.0%
CELLCLEAN AUTO	1 to 30°C		—	Sodium hypochlorite (Effective chlorine concentration 5.0%)

● Control blood and calibrator

Product name	Storage temperature	Usage temperature	Shelf life after first opening
XN CHECK	2 to 8°C	15 to 35°C	7 days
XN-L CHECK			15 days
XN CHECK BF			30 days
XN CAL			4 hours

7.3 CELLPACK DCL

General name

Whole blood diluent for use in hematology analyzers

Intended use

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

This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Caution!

1. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use.
2. When replacing the reagent, do not refill and use the same container.
3. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, analysis may not be performed normally.
4. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.
5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
6. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention.

Examination procedure

Use CELLPACK DCL at 15 - 35°C. If an analysis is performed at a temperature over 35°C or under 15°C, you may not be able to obtain accurate results. Connect the CELLPACK DCL container to the designated place on the instrument. For details, see "Troubleshooting". (➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store CELLPACK DCL at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. If frozen, thaw and mix thoroughly before use.

Disposal procedures

1 If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing.

2 Disposal procedures should meet requirements of applicable local regulations.

7.4 CELLPACK DST

General name

Concentrated diluent of reagent unit for use in hematology analyzers

Intended use

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

This reagent is to be used by connecting to a reagent preparation device specified by Sysmex.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Caution!

1. This reagent is a concentrated reagent. Use this reagent by connecting to a reagent preparation device specified by Sysmex.
2. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use.
3. When replacing the reagent, do not refill and use the same container.
4. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, analysis may not be performed normally.
5. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.
6. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
7. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention.

Examination procedure

Use CELLPACK DST at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to obtain accurate results. Connect the CELLPACK DST container to the designated place on the reagent preparation device. For details, see "Troubleshooting".

(➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store CELLPACK DST at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagent specifications.

(➤**P.89** "7.2 List of specified reagents specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen.

Disposal procedures

1 If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing.

2 Disposal procedures should meet requirements of applicable local regulations.

7.5 CELLPACK DFL

General name

Whole blood diluent for use in hematology analyzers

Intended use

CELLPACK DFL is a reagent used in combination with Fluorocell RET. After diluting the blood with CELLPACK DFL, Fluorocell RET is used to label blood cell components and thereby analyze red blood cell count, reticulocyte count, reticulocyte rate, platelet count, low fluorescent light intensity rate, middle fluorescent light intensity rate, high fluorescent light intensity rate, and immature reticulocyte fraction count. This reagent is to be used by connecting to an automated hematology analyzer specified by Sysmex.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Caution!

1. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use.
2. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, analysis may not be performed normally.
3. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.
4. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
5. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention.

Examination procedure

Use CELLPACK DFL at 15 - 35°C. If analysis is performed at a temperature over 35°C or under 15°C, you may not be able to obtain an accurate red blood cell count, reticulocyte count, reticulocyte rate, platelet count, low fluorescent light intensity rate, middle fluorescent light intensity rate, high fluorescent light intensity rate, and immature reticulocyte fraction count. Attach the CELLPACK DFL container to the designated place on the instrument.

(➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store CELLPACK DFL at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagent specifications.

(➤**P.89** "7.2 List of specified reagents specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen.

Disposal procedures

1 If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing.

2 Disposal procedures should meet requirements of applicable local regulations.

7.6 SULFOLYSER

General name

A reagent for the automated determination of hemoglobin concentration of blood

Intended use

SULFOLYSER is a reagent for the automated determination of hemoglobin concentration of blood with Sysmex automated hematology analyzers.

Warnings and precautions (for in vitro diagnostic use only)

> **⚠ Caution!**
>
> Avoid contact with skin and eyes. In case of skin contact, flush the area with water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately.

Examination procedure

1. Allow the container of SULFOLYSER to equilibrate to environmental temperature (15 - 35°C).
2. Loosen and remove the cap on the SULFOLYSER container.
3. Attach the Dispenser Kit to the SULFOLYSER container. Tighten the cap. Connect the SULFOLYSER line from the instrument to the Dispenser Kit.
4. Prime the SULFOLYSER through the hydraulic system of the instrument by cycling the instrument several times in the whole blood mode to fill all SULFOLYSER tubing with reagent and to remove air bubbles in the lines.

For details, see "Troubleshooting". (➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store SULFOLYSER at 1 - 30°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration.

Disposal procedures

1 If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing.

2 Disposal procedures should meet requirements of applicable local regulations.

7.7 Lysercell WDF

General name

A lysing reagent for hematology analyzers

Intended use

Lysercell WDF is a reagent used in combination with Fluorocell WDF. By hemolyzing red blood cells with Lysercell WDF and dyeing the white blood cell components with Fluorocell WDF, the counts and percentages of neutrophils, lymphocytes, monocytes, eosinophils, and basophils are analyzed. This reagent is to be used by connecting to an automated hematology analyzer specified by Sysmex.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Caution!

1. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use.
2. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, analysis may not be performed normally.
3. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.
4. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
5. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention.

Examination procedure

Use Lysercell WDF at 15 - 35°C. If an analysis is performed at a temperature over 35°C or under 15°C, you may not be able to obtain accurate counts and percentages of neutrophils, lymphocytes, monocytes, eosinophils, and basophils. Connect the Lysercell WDF container to the designated place on the instrument. For details, see "Troubleshooting". (➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store Lysercell WDF at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen.

Disposal procedures

1 If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing.

2 Disposal procedures should meet requirements of applicable local regulations.

7.8 Fluorocell WDF

General name

A labeling reagent for hematology analyzers

Intended use

Fluorocell WDF is to be used to label the leukocytes in diluted and lysed blood samples for determination of the WBC differential with Sysmex automated hematology analyzers.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Caution!

1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes.
2. In case of skin contact, rinse immediately with plenty of soap and water.
3. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains. Obtain medical attention.
4. If swallowed, seek medical advice immediately.
5. Do not breathe vapor. In case of accident or you feel unwell, seek medical advice immediately (show the label where possible).

R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.
R68/20/21/22: Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed.
S23: Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
S24/25: Avoid contact with skin and eyes.
S37/39: Wear suitable gloves and eye/face protection.
S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive.

Examination procedure

1. Put a Fluorocell WDF cartridge in the prescribed position and then connect the Fluorocell WDF line.
2. Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label.
3. After setting, reset of the package is not recommended. Removing the reagent cartridge from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film.

For details, see "Troubleshooting". (➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store Fluorocell WDF in a dark place at 2 - 35°C. If the reagent has not been opened, it can be kept until the expiration date printed on the package insert. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications") Do not use a reagent that is suspected to have frozen.

Disposal procedures

1 Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout.

2 Disposal procedures should meet requirements of applicable local regulations.

7.9 Fluorocell RET

General name

A labeling reagent for hematology analyzers

Intended use

Fluorocell RET is to be used to label the reticulocytes in diluted blood sample for the assay of reticulocyte count, reticulocyte percent and platelet count in blood with Sysmex automated hematology analyzers.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Caution!

1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes.
2. In case of skin contact, rinse immediately with plenty of soap and water.
3. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains. Obtain medical attention.
4. If swallowed, seek medical advice immediately.
5. Do not breathe vapor. In case of accident or you feel unwell, seek medical advice immediately (show the label where possible).

R10: Flammable.
R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.
R68/20/21/22: Harmful: possible risk of irreversible effects through inhalation, in contact withskin and if swallowed.
S16: Keep away from sources of ignition - No smoking.
S23: Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
S24/25: Avoid contact with skin and eyes.
S37/39: Wear suitable gloves and eye/face protection.
S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive.

Examination procedure

1. Put a Fluorocell RET cartridge in the prescribed position and then connect the Fluorocell RET line.
2. Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label.
3. After setting, reset of the package is not recommended. Removing the reagent cartridge from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film.

For details, see "Troubleshooting". (➤Troubleshooting, "Chapter 2: 2.12 Replacing the reagent")

Storage and shelf life after first opening

Store Fluorocell RET in a dark place at 2 - 35°C. If the reagent has not been opened, it can be kept until the expiration date printed on the package insert. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications") Do not use a reagent that is suspected to have frozen.

Disposal procedures

1 Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout.

2 Disposal procedures should meet requirements of applicable local regulations.

7.10 CELLCLEAN AUTO

General name

Detergent for fully automated hematology analyzer

Intended use

CELLCLEAN AUTO is to be used as a strong alkaline detergent to remove SYSMEX lysing reagent, cellular residuals and blood proteins remaining in the hydraulics of XN series/XN-L series automated hematology analyzer and SP-10 automated hematology slide preparation unit.

Warnings and precautions (for in vitro diagnostic use only)

⚠ Warning!

Avoid contact with skin and eyes. In case of skin contact, flush the area with water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice immediately.
R31: Contact with acids liberates toxic gas.
R36/38: Irritating to eyes and skin.
S2: Keep out of the reach of children.
S25: Avoid contact with eyes.
Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive.

Storage and shelf life after first opening

Store CELLCLEAN AUTO at 1 - 30°C, away from direct sunlight.

Do not use a reagent that is suspected to have frozen.

Disposal procedures

1 After use, there will be a hole in the film that seals the top of the tube. Exercise caution, as residual fluid may leak from the hole.
2 Disposal procedures should meet requirements of applicable local regulations.

7.11 Control blood (XN CHECK/XN-L CHECK)

Intended use

XN CHECK and XN-L CHECK are used for control and calibration verification of Sysmex XN-L analyzer. It is not, however, intended for actual calibration of this analyzer. Assayed parameters include:
RBC (10^6/µL), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT (10^3/µL), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC (10^3/µL), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# (10^3/µL), LYMPH# (10^3/µL), MONO# (10^3/µL), EO# (10^3/µL), BASO# (10^3/µL), IG# (10^3/µL), RET# (10^6/µL), RET%, IRF%, RET-HE (pg)

Warnings and precautions (for in vitro diagnostic use only)

Risk of infection

Always wear protective garments and gloves when using control blood. Also, wash your hands after completing the process.
The basic blood used in the control blood has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle the control blood with the same level of care you would use when handling other blood samples that may be infectious.

Warnings and precautions

Caution!

1. Minimize the time that the product is left at room temperature.
   Leaving the product at room temperature for a prolonged period of time will cause deterioration.
2. If suspected to have frozen, the product cannot be used, as analysis results will be affected.

Storage and shelf life after first opening

Store the control blood in a dark refrigerated place at 2 - 8°C.
If it has not been opened, the product can be kept until the expiration date printed on the vial label and outer box.
For shelf life after opening, refer to the package insert or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications")

7.12 Control blood (XN CHECK BF)

Intended use

XN CHECK BF is used for control and calibration verification of Sysmex XN-L analyzer. It is not, however, intended for actual calibration of this analyzer. Assayed parameters include:

WBC-BF (10^3/µL), RBC-BF (10^6/µL), MN# (10^3/µL), PMN# (10^3/µL), MN%, PMN%, TC-BF# (10^3/µL)

Warnings and precautions (for in vitro diagnostic use only)

Risk of infection

Always wear protective garments and gloves when using control blood. Also, wash your hands after completing the process.

The basic blood used in the control blood has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle the control blood with the same level of care you would use when handling other blood samples that may be infectious.

Warnings and precautions

Caution!

1. Minimize the time that the product is left at room temperature.
   Leaving the product at room temperature for a prolonged period of time will cause deterioration.
2. If suspected to have frozen, the product cannot be used, as analysis results will be affected.

Storage and shelf life after first opening

Store the control blood in a dark refrigerated place at 2 - 8°C.

If it has not been opened, the product can be kept until the expiration date printed on the vial label and outer box.

For shelf life after opening, refer to the package insert or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications")

7.13 Calibrator (XN CAL)

Intended use

XN CAL is used for calibration and calibration verification of Sysmex XN-L analyzer. Assayed parameters include:

WBC (10^3/µL), RBC (10^6/µL), HGB (g/dL), HCT (%), PLT (10^3/µL), RET (%)

Warnings and precautions (for in vitro diagnostic use only)

Risk of infection

Always wear protective garments and gloves when using calibrator. Also, wash your hands after completing the process.
The basic blood used in the calibrator has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle the control blood with the same level of care you would use when handling other blood samples that may be infectious.

Warnings and precautions

Caution!

1. Minimize the time that the product is left at room temperature.
   Leaving the product at room temperature for a prolonged period of time will cause deterioration.
2. If suspected to have frozen, the product cannot be used, as analysis results will be affected.

Storage and shelf life after first opening

Store the calibrator in a dark refrigerated place at 2 - 8°C.

If unopened, the product can be kept until the expiration date printed on the vial label and outer box.

For shelf life after opening, refer to the package insert or reagent specifications. (➤**P.89** "7.2 List of specified reagents specifications")

7.14 Symbols used on the labels

Signs and symbols used on reagent containers and outer boxes are as follows:

Caution!

Important information about the handling of reagents is noted on their containers, outer boxes and the package insert. Do not use a reagent until you fully understand the information.

In vitro diagnostic medical device

Manufacturer

Authorized representative in the European Community

Consult instructions for use

Temperature limitation

Biological risks

Use by

Batch code

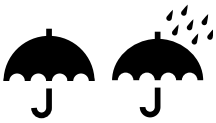
Catalogue number

Concentrated reagent

Keep away from sunlight

Use no hooks

This way up



Keep dry

Stacking limit by number

Fragile; handle with care

Corrugated recycles

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