Sysmex

AUTOMATED HEMATOLOGY ANALYZER

pocH-100iV Diff

INSTRUCTIONS FOR USE

For Veterinary Use

SYSMEX CORPORATION
KOBE, JAPAN

Code No. 461-2406-6
PRINTED IN JAPAN
Date of Last Revision: March 2007
Software Version: 00-17 and onwards

INSTRUCTIONS FOR USE *pocH-100iV Diff*

Sysmex

Before operating the instrument, carefully read this manual.
Keep this manual for reference. For further information, please contact your Sysmex representative.

- The contents of the screens illustrated in this manual may differ from the actual screens displayed on the instrument.
- We reserve the right of continuous product enhancement. Design and specifications may be subject to change due to further product development. This may result in deviation of actual product properties against the properties stated in this manual.

Operate the instrument as instructed. Reliability of test results cannot be guaranteed if instructions in this manual are not followed. If the instrument fails to function properly as a result of either the user failing to operate the system as specified in the manual or the user's utilization of a program not specified by Sysmex, the product warranty will not apply.

- The Sysmex pocH-100*i*V Diff is an automated hematology analyzer for use in veterinary laboratories, and veterinarian office laboratories. The pocH-100*i*V Diff is a veterinary blood cell counter for screening purpose, and shall only be used for in vitro analysis of veterinary blood samples such as dog, cat, cattle, horse and other specific species and artificial control blood.
- The pocH-100*i*V Diff is equipped with a rinse cup, and after aspirating a sample or control blood, the pipette is automatically cleaned. It is not necessary to wipe the sample pipette.

Carefully read "Safety information" and "Measures for personnel" (page 76).

For explication of warning signs used in the manual see chapter "Symbols" (page 3).

This instrument carries the CE Mark according the directives 89/336/EEC and 73/23/EEC.

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INDEX OVERVIEW

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ADDRESSES

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- **Ordering of supplies and replacement parts**
  To order supplies or replacement parts, please contact your local Sysmex representative.

- **Service and maintenance**
  Please contact the Service Department at your local Sysmex representative.

SYMBOLS

Symbols to indicate biological risks, warnings and helpful information are presented throughout this manual to call to attention important information on safety and handling. Non-compliance with this information compromises the safety features incorporated in the analyzer.

Biological risks
Indicates the risk of serious injury or death by biohazardous materials or conditions.

Warning, hot
Indicates that the marked component can be hot. Do not touch.

Danger, electric shock
High voltage exceeding 1 kV.

Incorrect analysis results
If steps indicated by this sign are ignored, analysis results may produce erroneous data.

Warning
If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which may result in injury of an operator.

Important
Indicates what you need to know in order to maintain instrument performance and to prevent damage.

Note
Indicates information which is useful in operating the instrument.

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ABBREVIATIONS / UNITS

Abbreviations

- CBC: Complete Bloodcell Count
- LD: Lower Discriminator
- LL: Lower Limit
- QC: Quality Control
- T1: Trough Discriminator 1
- T2: Trough Discriminator 2
- UD: Upper Discriminator
- UL: Upper Limit

Unit

- dL: deciliter (0.1 liter)
- fL: femtoliter (10^{-15} liter)
- µL: microliter (10^{-6} liter)
- pg: picogram (10^{-12} gram)

Analysis parameters

This instrument provides results for the following parameters:

- WBC: Number of white blood cells
- RBC: Number of red blood cells
- HGB: Hemoglobin concentration
- HCT: Hematocrit value: Red blood cell ratio of total blood volume
- MCV: Mean corpuscular volume
- MCH: Mean corpuscular hemoglobin
- MCHC: Mean corpuscular hemoglobin concentration
- PLT: Number of platelets
- LYM% (Dog/Cat/Cattle/Horse mode): % of small white blood cells to total WBC
  They are assumed to be equivalent to lymphocytes.
- OTHR% (Dog/Cat mode): % of middle white blood cells to total WBC
  They are assumed to be equivalent to neutrophils, monocytes, and basophils.
- OTHR% (Cattle/Horse mode): % of middle and large white blood cells to total cells
  They are assumed to be equivalent to WBC other than lymphocyte.
- EO% (Dog/Cat mode): % of large white blood cells to total WBC
  They are assumed to be equivalent to eosinophils.
- LYM# (Dog/Cat/Cattle/Horse mode): Absolute number of small white blood cells
  They are assumed to be equivalent to lymphocytes.
- OTHR# (Dog/Cat mode): Absolute number of middle white blood cells
  They are assumed to be equivalent to neutrophils, monocytes, and basophils.
- OTHR# (Cattle/Horse mode): Absolute number of middle and large white blood cells
  They are assumed to be equivalent to WBC other than lymphocyte.
- EO# (Dog/Cat mode): Absolute number of large white blood cells
  They are assumed to be equivalent to eosinophils.
- W-SCR (OTHER1-13 mode): % of small white blood cells to total WBC (white blood cell-small cell ratio).
- W-MCR (OTHER1-13 mode): % of middle white blood cells to total WBC (white blood cell-middle cell ratio).
- W-LCR (OTHER1-13 mode): % of large white blood cells to total WBC (white blood cell-large cell ratio).
- W-SCC (OTHER1-13 mode): Absolute number of small white blood cells (white blood cell-small cell count).
- W-MCC (OTHER1-13 mode): Absolute number of middle white blood cells (white blood cell-middle cell count).
- W-LCC (OTHER1-13 mode): Absolute number of large white blood cells (white blood cell-large cell count).
- RDW-SD: Calculated distribution width of red blood cells, standard deviation
- RDW-CV: Calculated distribution width of red blood cells, coefficient of variation
- PDW (except Cat mode): Calculated distribution width of platelets, standard deviation
- MPV (except Cat mode): Mean platelet volume
- P-LCR (except Cat mode): Ratio of large platelets (volume exceeding 12 fL) to the total number of platelets

NAMES

WARRANTY

All Sysmex instruments are warranted against defective material or workmanship for a period of one year, commencing on the installation date on the customer's premises.

This warranty does not cover any defect, malfunction or damage due to:

- Accident, neglect or wilful mistreatment of the product.
- Failure to use, operate, service or maintain the product in accordance with the applicable Sysmex Instructions for Use.
- Failure to use the appropriate reagents and consumables specified for the product.

FUNCTIONAL DESCRIPTION

ANALYSIS

An exact volume of sample is aspirated with the aspirating pipette. This volume of the sample is then transferred (together with a defined volume of diluent) to the mixing chamber and from there automatically to the transducer.

All parameters are analyzed using the same transducer in the order:
(1) WBC/HGB
(2) RBC/PLT

For WBC/HGB analysis, the WBC/HGB lyse is added to the measuring chamber to provide further dilution and hemolysis of the sample's RBC. This process takes about ten seconds.

During this reaction period, the red blood cells are dissolved under the influence of the lysis, hemoglobin is released and is converted into acid methemoglobin. The white blood cells remain intact.

The volume and number of the white blood cells (WBC) are determined by the DC detection method. In the HGB detector, the hemoglobin concentration is photometrically measured.

For RBC/PLT analysis, the diluted sample is transferred from the mixing chamber to the transducer, and the volume and blood cell count for red blood cells and platelets are analyzed by the DC detection method.

TECHNICAL BASICS

- The calculation of indices is based on international principles in hematology.
- The method for counting blood cells is based on the electric resistance detection principle.
- Hemoglobin concentration is determined by a photometric measuring method.

SYSTEM OVERVIEW, TECHNICAL INFORMATION & SETUP

CONTENTS:

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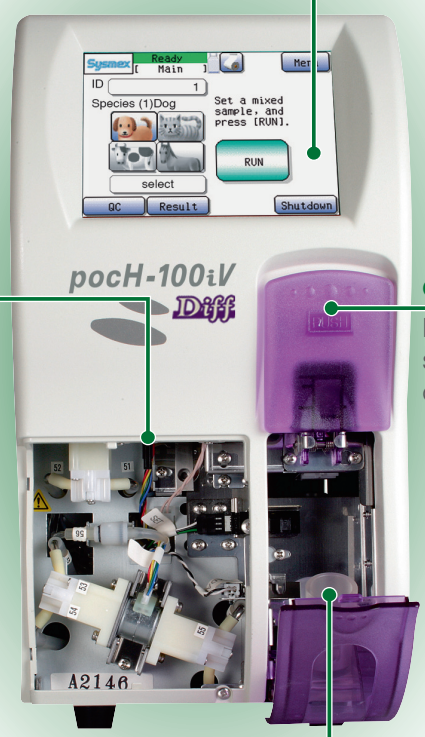
SYSTEM OVERVIEW

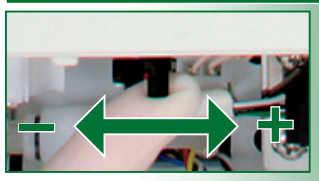
The instrument

Before starting setup and analysis, please read through the following overview to get familiar with the instrument's parts and their description.



Color LCD screen

Contrast adjustment knob



Adjust LCD screen contrast.

Open button

Press to open the sample position compartment.

Sample position

Holds the adapter for the analysis sample tube.

System fuses

AC power supply

AC 100 V
AC 240 V

Float switch connector for waste bottle

Monitors the level in the waste bottle.

Diluent inlet nipple

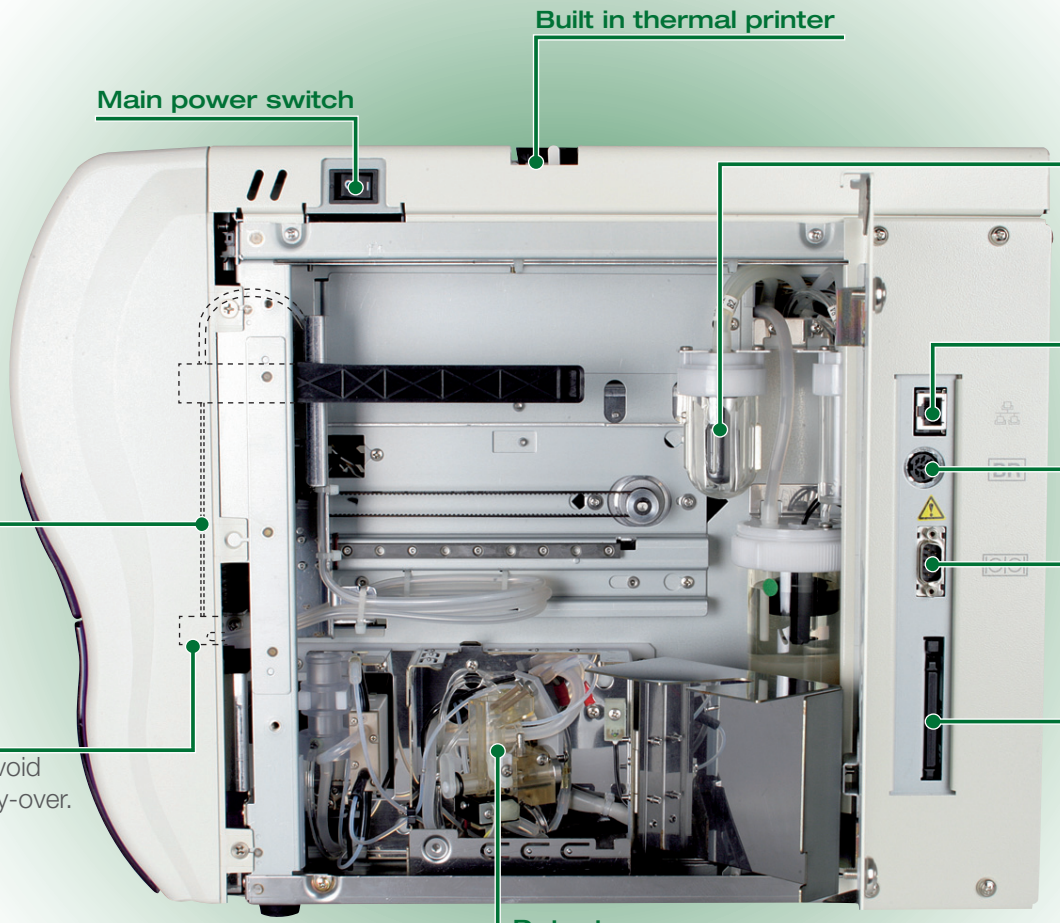
Aspirates diluent.

Lyse inlet nipple

Aspirates lyse reagent.

Waste outlet nipple

Discharges waste.



Built in thermal printer

Main power switch

Trap chamber
In case of malfunction ,avoids reagents' reflux into the vacuum pump.

Socket for LAN
Communication with host computer, etc.

Socket for Barcode-Reader

Aspirating pipette
Aspirates sample.

Serial port
9-pin D-SUB serial interface connector (communication with host computer, etc.).

Card slot
Inserts a program card specified by Sysmex.

Rinse cup
Rinses the pipette to avoid sample-to-sample carry-over.

Detector
RBC transducer, WBC transducer and Hemoglobin detector.

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The reagents

	Purpose & methodology	Storage & shelf life	Composition	Important	Additional equipment
 **pocH-pack D**	• Diluent for hematology analyzers. • Ready-to-use diluent for DC detection and whole blood absorbance analysis.	Expiration date is shown on the outer packaging. • Unopened packs can be stored for 12 months. Store at 1-30 °C. • Opened, reagent stability is max. 60 days. Use at 15-30 °C. **Warning** Replace any pocH-pack D showing signs of contamination or instability. Using it can result in incorrect analysis results.	• Sodium Chloride 6.38 g/L • Boric acid 1.0 g/L • Sodium Tetraborate 0.2 g/L • EDTA-2K 0.2 g/L	Use whole blood sample collected in EDTA anticoagulant.	• Use pocH-pack D only with Sysmex reagents and analyzers. • The performance of Sysmex instruments cannot be guaranteed if using other reagents.
 **pocH-pack LVD**	• Reagent that lyses RBC for accurate WBC count and hemoglobin determination. • Allows white blood cell count and volume distribution analysis by the DC detection method.	Expiration date is shown on the outer packaging. • Unopened packs can be stored for 12 months. Store at 2-35 °C. • Opened, reagent stability is max. 90 days. Use at 15-30 °C. **Warning** Replace any pocH-pack LVD revealing signs of contamination or instability. Using it can result in incorrect analysis results. Do not use once it was frozen.	• Sodium Chloride 4.0 g/L • Org. quart. ammoniumsalt 3.3 g/L	Use whole blood sample collected in EDTA anticoagulant.	• Use pocH-pack LVD only with Sysmex reagents and analyzers. • The performance of Sysmex instruments cannot be guaranteed if using other reagents.

	Purpose & methodology	Storage & shelf life	Composition	Important	Additional equipment
 **CELLCLEAN**	• Strong alkaline detergent. • Removes lyse reagents/ cellular residuals and blood proteins from the hydraulic systems, transducer, whole blood aspiration pipette and the Hgb flow cell.	Expiration date is shown on the outer packaging. • Store in a dark place at 15-30 °C. • Use opened reagent within 60 days.	Sodium Hypochlorite 5.00%	**Warning** • Avoid contact with skin and eyes. • In case of skin contact, rinse with water. • In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice and follow MSDS.	• Use CELLCLEAN only with Sysmex reagents and analyzers. • The performance of Sysmex instruments cannot be guaranteed if using other detergent.
 **EIGHTCHECK 3WP**	Control blood EIGHTCHECK • 3WP-N (Normal level) • 3WP-L (Low level) • 3WP-H (High level) test the precision of automated/semi-automatic hematology analyzers. **Important** Do not use for the calibration of the system!	Expiration date is shown on the outer packaging. • Store at 2-8 °C before and after opening. • Once opened, the product is stable for 7 days if returned to the refrigerator promptly after use. • Control materials provide stable parameter values after at least 12 hours at room temperature (25 °C).	EIGHTCHECK contain stabilized animal red blood cells, fixed animal white blood cells and a platelet component in a medium containing preseratives.	**Biological risks** This product, based on animal blood, should be considered potentially capable of transmitting infectious disease.	• Use EIGHTCHECK only with Sysmex reagents and analyzers. • The performance of Sysmex instruments cannot be guaranteed if using other control material.

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TECHNICAL INFORMATION

Performance characteristic - Specifications

Ambient temperature	15 – 30 °C (ideal operating temperature at 23 °C) (59 – 86 °F)
Relative humidity	30 – 85 %
Main Unit dimensions	Width: 185 mm (7.3 in.) Depth: 460 mm (18.1 in.) Height: 350 mm (13.8 in.) Weight: approx. 14 kg (30.8 lb.)
Power supply	100 – 240 VAC (±10 %), 50/60 Hz
Power consumption	150 VA or less
Analysis Parameters	see Chapter "Abbreviations/Units" (page 4)
Display range	WBC: 0.0 – 999.9 ($\times 10^3$/µL) RBC: 0.00 – 99.99 ($\times 10^6$/µL) HGB: 0 – 999.9 (g/dL) PLT: 0 – 9999 ($\times 10^3$/µL)
Background limits	WBC: 0.3 ($\times 10^3$/µL) RBC: 0.02 ($\times 10^6$/µL) HGB: 0.1 (g/dL) PLT: 10 ($\times 10^3$/µL)
Analysis time	Approx. 125 seconds (After starting an analysis until displaying the analysis report)
Analysis principle	WBC: DC detection method RBC/PLT: Hydrodynamic Focusing DC detection method HGB: Non-cyanide HGB method
Required temperature compensation	Approx. 512 BTU/h (Approx. 130 kcal/h)
Class of electric shock protection measures	Class I Equipment
EMC characteristics	Conforms with IEC 61326-1 (Class B, Group 1, Industrial environment)
Safety	Conforms with IEC 61010-1 (Overvoltage category II, Pollution degree 2, Portable equipment)

	Parameter	Whole blood mode	
Reproducibility (With 95% reliability limit)	WBC (≥ 4.0 × 10^3/µL)	3.5% or less	
	RBC (≥ 3.00 × 10^6/µL)	2.0% or less	
	HGB	2.0% or less	
	HCT	2.0% or less	
	MCV	2.0% or less	
	MCH	2.0% or less	
	MCHC	2.0% or less	
	PLT (≥ 100 × 10^3/µL) (for dog, cattle or horse blood)	10.0% or less	
	PLT (≥ 100 × 10^3/µL) (for cat blood)	30.0% or less	
	LYM#	30.0% or less	
	OTHR#	15.0% or less	
	EO# (≥ 0.2 × 10^3/µL)	50.0% or less	
	LYM% (≥ LYM 15%)	30.0% or less	
	OTHR%	15.0% or less	
	EO% (≥ EO 2%)	50.0% or less	
	RDW-SD	4.0% or less	
	RDW-CV	6.0% or less	
	PDW (for dog, cattle or horse blood)	12.0% or less	
	MPV (for dog, cattle or horse blood)	5.0% or less	
	P-LCR (for dog, cattle or horse blood)	20.0% or less	
Linearity	WBC (RBC < 7.00 ×10^6/µL) (for dog, cattle or horse blood)	1.0 – 99.9 (×10^3/µL)	± 0.3 (×10^3/µL) or less, or ± 5% or less
	WBC (RBC < 7.00 ×10^6/µL) (for cat blood)	1.0 – 75.0 (×10^3/µL)	± 0.3 (×10^3/µL) or less, or ± 5% or less
	RBC	0.3 – 13.00 (×10^6/µL)	± 0.03 (×10^6/µL) or less, or ± 5% or less
	HGB	0.1 – 25.0 (g/dL)	± 0.2 (g/dL) or less, or ± 5% or less
	HCT	10.0 – 60.0 (HCT%)	± 1 (HCT%) or less, or ± 5% or less
	PLT (RBC < 7.00 ×10^6/µL)	10 – 1200 (×10^3/µL)	± 10 (×10^3/µL) or less, or ± 10% or less

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Carry-over	WBC: 3% or less RBC: 1.5% or less HGB: 1.5% or less HCT: 1.5% or less PLT: 5% or less	
Consumables	Reagents: Detergent: Control material:	pocH-pack D, pocH-pack LVD CELLCLEAN EIGHTCHECK-3WP
Aspirated sample volume	approx. 15 µL	
Number of analyses that can be performed with 1 reagent bottle	pocH-pack D: pocH-pack LVD: (These figures assume 10 measurements per day, and include the background check, shutdown and other processes.)	Approximately 30 Approximately 235

System limitations – Interferences

Note

The abnormal sample conditions listed here are known to affect test results. The majority of the listed sample conditions are not measured quantitatively because these conditions vary due to animal species, diagnosis, age, medications, etc. Laboratories can perform studies in order to show how their specific animal species are affected by various conditions.

WBC: false high white blood cell count

Cause:	Potential Detection:
Lyse resistant red blood cells:	Abnormal WBC histogram (WL flag)
Cold agglutinins:	Increased MCV, increased MCHC due to decreased HCT and RBC
Platelet aggregation / cryoglobulin:	Abnormal WBC histogram (WL flag) and Abnormal PLT histogram (PU flag)
Nucleated red blood cells:	Abnormal WBC histogram (WL flag)

RBC: false low red blood cell count

Cause:	Potential Detection:
Cold agglutinins:	Increased MCV, increased MCHC due to decreased HCT
Microcytosis (severe):	Low MCV
Fragmented red blood cells:	Abnormal RBC histogram (RL flag) and Abnormal PLT histogram (PU flag)

HCT: false low haematocrit measurement

Cause:	Potential Detection:
Cold agglutinins:	Increased MCV and increased MCHC
Fragmented red blood cells:	Abnormal RBC histogram (RL flag) and abnormal PLT histogram (PU flag)

HCT: false high haematocrit measurement

Cause:	Potential Detection:
Leukocytosis:	Very high white blood cell count with low red blood cell count present

PLT: false low platelet count

Cause:	Potential Detection:
Platelet aggregation:	Abnormal PLT histogram (PU flag)
Giant platelets:	Abnormal PLT histogram (PU flag)

PLT: false high platelet count

Cause:	Potential Detection:
Microcytic red blood cells:	Low MCV
Fragmented red blood cells:	Abnormal RBC histogram (RL flag) and abnormal PLT histogram (PU flag)

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SETUP

Check parts

Important

- Move and handle carefully. If the packaging is damaged, open the package in the presence of a representative from the logistics company. Please state the damage clearly on the receipt.

- **Prerequisites for installation**
  - Ensure that power is available.
  - Place on a table which can support the device's weight (17 kg).
  - Provide sufficient space for proper cooling, maintenance or service work.
    The distance from the right side, rear, and top panels to walls should be at least 15 cm (6 in.).
  - The instrument must be installed in a dry and dust-free location.
  - Device must be protected against water.

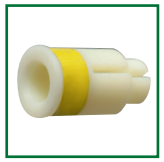
- **Safety instructions for installation**
  - Do not expose the instrument to excessive temperature fluctuation and direct sunlight.
  - Avoid shock and vibrations.
  - The installation location must be well ventilated.
  - Avoid installation near devices causing potential interference, such as radios, centrifuges, computer monitors, wireless communication equipment or similar devices.
  - Installation of this instrument in places where chemicals are stored or hazardous gas may be present is not permitted.

1x
Transducer brush
No. 3
462-3523-6

1x
Adapter
(for 11 mm diameter)
green
033-0891-1

1x
Thermal paper
CL6040
462-4846-1

1x
Power cord
4622-007-0092 (Europe)
265-4731-5



1x
Adapter
(for 9 mm diameter)
yellow
033-0871-7

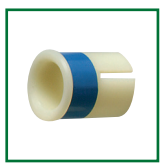
2x
Mini pipette No.10
(1mL)
423-1776-2

1x
Sample tube adapter
13 mm cream
442-3047-7

1x
Adapter
cream
442-3044-6

2x
Fuse 250V T3.15A H
Time lag
266-5330-1

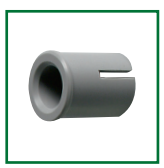
1x
Sample tube adapter
cream (Control blood)
442-3045-0



1x
Adapter
(for 11 mm diameter)
blue
033-0881-4

1x
Container spout kit
No.7 (pocH-pack LVD)
orange
033-0413-9

1x
Adapter
(for 8 mm diameter)
purple
033-0861-0



1x
Adapter
(for 10 mm diameter)
grey
442-3042-9

1x
Container spout kit
No.5 (pocH-pack D)
blue
023-2441-5

Check parts (continued)

1x
Waste bottle assy POCH (C1/WITH FSW)
033-0041-1

1x
Reagent tray
367-2170-9

1x
Coil tube SS-10
266-7110-2

1x
Screwdriver (+)
462-2381-8

1x
Screwdriver (–)
462-2390-1

1x
Sticker
(For Veterinary Use)
369-5172-1

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Optional adapters

Important

- When using micro tubes, be sure to place them in the correct adapter.
- Be sure to remove the cap.

Adapter name	Product code	Adapter color
Sample tube adapter (for 15 mm diameter tube)	442-3032-1	Black
Sample tube adapter (S-MONOVETTE (SARSTEDT) 2.7 mL)	442-3038-3	Red

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Putting the sticker

Put the provided sticker on the front cover.

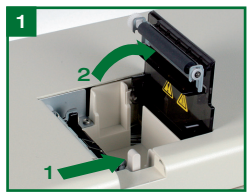
Insert paper roll

Warning, Hot

The printer head can get very hot. Do not touch!

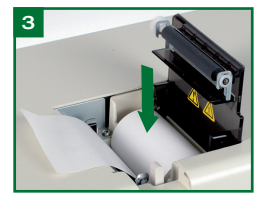
Important

Static electricity may damage the printer head. Do not touch.



Open paper holder by pushing the knob.

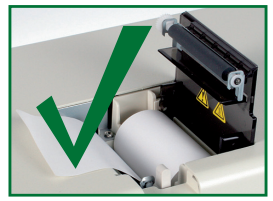
Remove the tape.

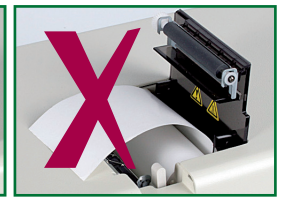


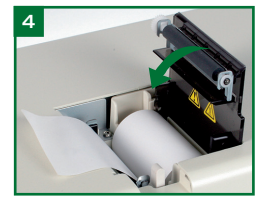
Insert paper.

Important

Insert the paper correctly. If inserted at an angle, the paper may jam.







Close lid.

Note

The printer cover must be closed ("clicking" sound). If the cover is not closed completely, an error message will be displayed.

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Connect reagents

Biological risks

To avoid infections, wear protective garments and gloves for cleaning and/or maintenance. After completion of work, wash hands with disinfectant.

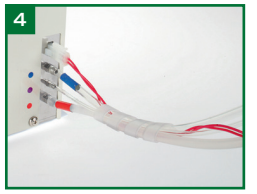
Important

- Connect the tubes to the correct nipples.
- Do not to touch the tubes that enter the reagent.
- Prevent the reagents from spilling.

Set bottles into holder and remove caps.

Insert container spout kits/float switch into the correct bottle and reapply the caps.

Connect the tubes to the appropriate nipples.



Fix tubes together.

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Barcode reader (optional)

Important

- Disconnect the instrument's mains before connecting the peripheral device. Else, the two devices may not interchange any data.
- In identifying samples, maximum integrity of data is required.
  To avoid barcode identification mistakes, use a check digit whenever the sample bar code is used. If a check digit is not used, the chances of the bar code being misread increase.

Note

The bar code reader is not included as a standard accessory. Refer to the barcode reader manual for detailed information on the connection of the barcode reader.

Scans the barcode on the sample collection tube and automatically enters the sample number into the system.

Plug cable into "BR" connection.

Turn the main switch ON, press the trigger switch and check red LED.

ID Barcode specifications

Barcode labels' specifications must match the requirements for the barcode reader.

Symbol	Check digit	Number of digits
ITF	None	Max. 14 digits (sample ID)
	Modulus 10	Max. 14 digits (sample ID) + 1 digit (check digit) = Max. 15 digits
NW-7	None	Max. 15 digits (sample ID)
	Modulus 11-16	Max. 15 digits (sample ID) + 1 digit (check digit) = Max. 16 digits
CODE 39	None	Max. 15 digits (sample ID)
	Modulus 43	Max. 15 digits (sample ID) + 1 digit (check digit) = Max. 16 digits
CODE 128	Modulus 103	Max. 15 digits (sample ID) + 1 digit (check digit) = Max. 16 digits
JAN-8	Modulus 10	Max. 7 digits (sample ID) + 1 digit (check digit) = Max. 8 digits
JAN-13	Modulus 10	Max. 12 digits (sample ID) + 1 digit (check digit) = Max. 13 digits

Power cord

Danger, electric shock

Improper grounding of the instrument can cause electrical shock.

Important

The instrument runs on 100-240V AC, 50/60Hz.

Insert cable into socket.

Insert cable into an AC outlet.

Switch ON

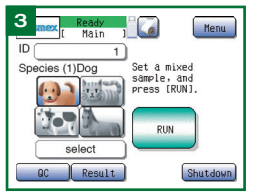
When the main switch is turned ON the first time, supply the reagents into the instrument.

Note

In this section, only the settings relevant for installation are described. For details on all possible settings see "**Settings & Calibration**" **page 55**.

Switch ON.

The instrument performs:
1. a rinse cycle
2. a background check



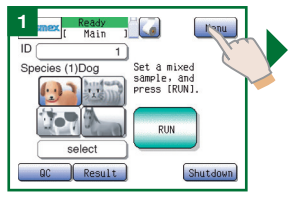
Ready after 6-11 minutes.

Set language

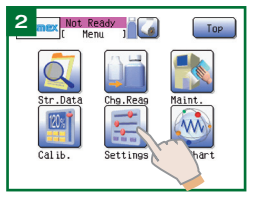
Default setting is English.

Note

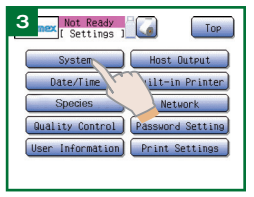
In this section, only the settings relevant for installation are described. For details on all possible settings see "**Settings & Calibration**" **page 55**.



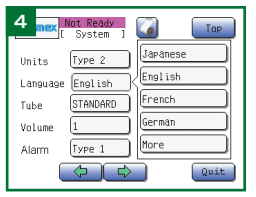
Press "Menu".



Press "Settings".

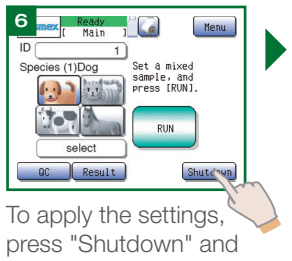


First press "System", then "Language".



Select the language.

Press "Quit" and then "OK" to update the settings.



To apply the settings, press "Shutdown" and follow instructions.

After completion of the shutdown process, Switch OFF.

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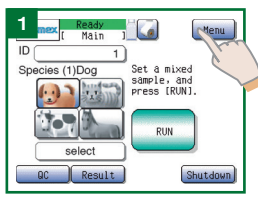
Date & Time

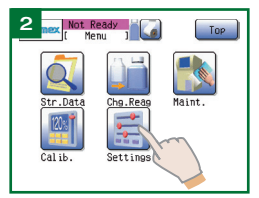
To be able to identify analysis results properly, set time and date correctly.

Note

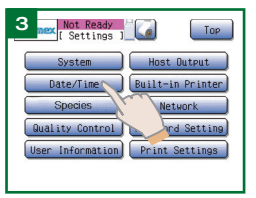
- In this section, only the settings relevant for installation are described. For details on all possible settings see "**Settings & Calibration**" **page 55**.
- When time switches to "standard or daylight saving time" respectively, the clock must be set accordingly.



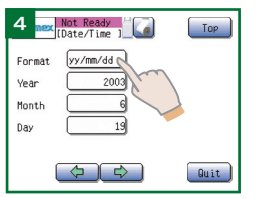
Press "Menu".



Press "Settings".



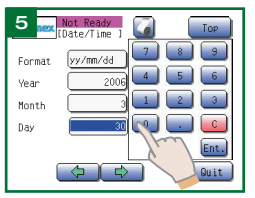
Press "Date/Time".



Choose Format.

Note

If an implausible date has been entered (e.g. 4/31 or 2/29 in a year which is not a leap year), it will be indicated by a beep. Enter the correct date.



Enter date.

6

Enter hour, minutes the same way

"Save" settings.

LCD contrast

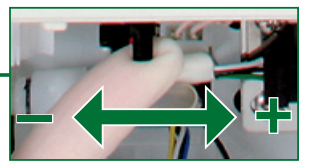
Adjust the LCD contrast to your comfort.

Important

If no operation is performed on the LCD screen for a certain period of time, the LCD backlight will decrease automatically to save power (backlight saving timer function). Touch the LCD screen to relight.

Open front cover.

Adjust contrast.



darker brighter

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Sample collection tube

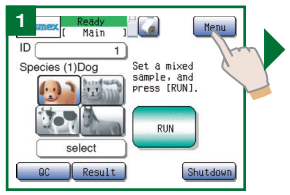
S-MONOVETTE (SARSTEDT) tube has a different bottom shape compared to the other sample tubes.

Important

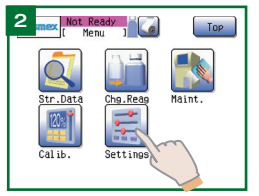
- When SARSTEDT is selected, use "S-MONOVETTE EDTA K" collection tubes manufactured by SARSTEDT.
- S-MONOVETTE (SARSTEDT) sample collection tubes cannot be used together with other sample collection tubes.
  If this is ignored, the instrument will not work.

Note

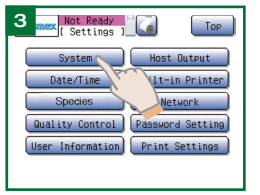
In this section, only the basic and relevant installation settings are described. For details on all possible settings see "**Settings & Calibration**" **page 55**.



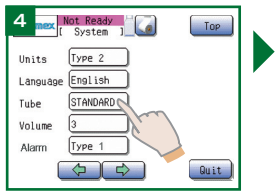
Press "Menu".



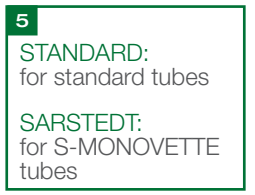
Press "Settings".



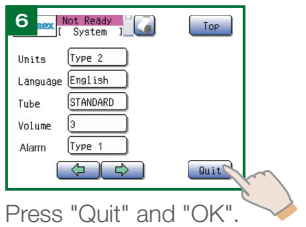
Press "System".



Press "Tube".



Select tube.



Press "Quit" and "OK".

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ANALYSIS

CONTENTS:

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Screen display

The LCD screen shows the available functions and submenus.

Important

- When setting the species, be sure the status display indicates "Ready".
- The analysis data of the "OTHER1" – "OTHER13" mode is for research.
- This setting is kept until the species is selected in the next time or the power switch is turned OFF then ON again. Always check the species selection before performing analysis.
- The alarm can be stopped by pressing "OK" on the error dialog box. Pressing the -button displays the help menu. All other buttons are not functional during an alarm.

Note

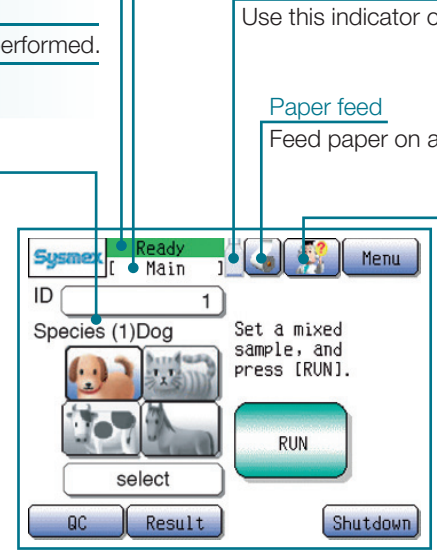
Regarding the species setting,
see "Species specific settings" page 57.

Instrument status indicator

Ready	Analysis can be started.
Aspirating	Sample is being aspirated.
Running	Analysis operation is being performed.
Not Ready	Analysis cannot be started.

Setting the species

	Dog blood is to be analyzed.
	Cat blood is to be analyzed.
	Cattle blood is to be analyzed.
	Horse blood is to be analyzed.
select	Any other species blood are to be analyzed. Press "select" and select species by pressing the desired species button (OTHER1 etc.).



Alarm

Short beep (< 1sec)	Pressing a button
Long beep (> 1sec)	Input error
Continuous beep	Instrument error

Timer functions

LCD backlight dimmer	Dims backlight after 10 minutes.
Automatic rinse timer	Prevents drying up of the hydraulic lines, after 2 hours of non operation.
Shutdown warning timer	Reminder to shut down the device after 24 hours of continuous operation.

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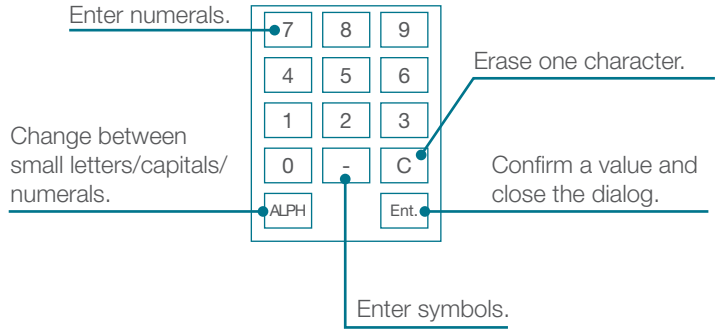
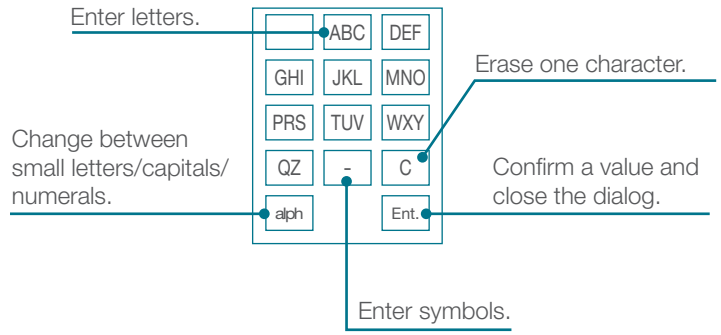
Numerical keys dialog



Alphabetical keys dialog



If you want to enter two letters which are located on the same button one after another, confirm your input by pressing "Ent." after entering the first letter.
For example: desired input "AB".
1. Enter "A".
2. confirm by pressing "Ent.".
3. Enter "B".

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Prior to analysis

Biological risks

- Always wear protective garments and gloves when handling the waste fluid. After work is completed, wash hands with disinfectant.
- When handling (disposing) the waste fluid, dispose it appropriately in accordance to local laws and regulations, which considers for the disposal of medical waste and infectious waste.

Important

- Use only printer paper recommended by Sysmex. Low quality paper may shorten the life of the printer head.
- If the waste bottle is nearly full, dispose the waste fluid.

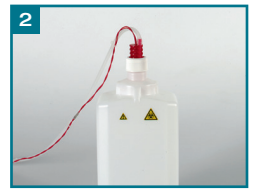
Note

If there is an error, press "OK" and follow the screen instructions.

1

Check if power cable is connected.

2

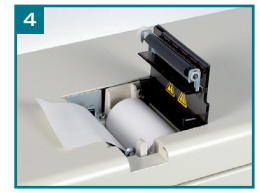


Check if the waste bottle is not full and has enough room for a day's work.

3

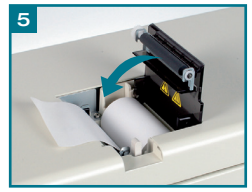
Make sure the cap is fit. Check that the tube is not bent.

4



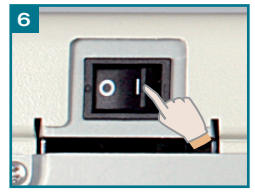
Check if there is sufficient paper.

5



Check if the paper is properly aligned, then close printer cover.

6

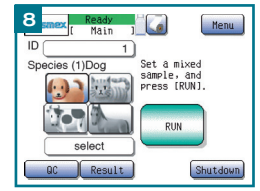


Switch ON.

7

The instrument performs:
1. a rinse cycle
2. a background check

8



READY after 6 – 11 minutes.

9

Perform mandatory quality check prior to operation. **See "Quality control" page 39.**

Analysis: Sample tubes

Check blood with added EDTA anticoagulant, aspirated sample volume ~15µL.

Incorrect analysis results

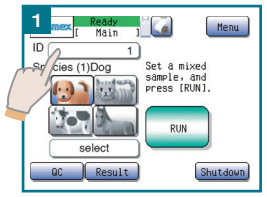
All performance data cited in this manual were generated using specimens in EDTA anticoagulant. Results may differ using other anticoagulants.

Important

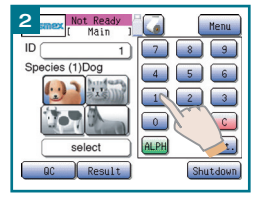
- Be sure to use the correct adapter for the sample tube being used.
- When a sample tube with a cap is used, manually remove the cap before analysis. The pipette might be permanently damaged, if the cap was not removed.

Note

The sample ID can be set up to 15 characters. If a sample's ID is set to "0", the result for this sample will not be stored.



Press "ID".



Enter the ID manually or by bar code reader and press "Ent.".

Open sample position.

Insert the correct adapter.

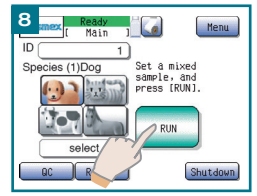
Gently mix the sample.

Remove the cap.

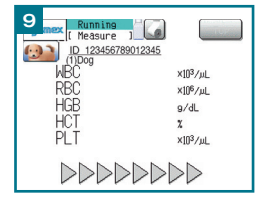
Insert sample tube and close the door.

Important

Do not open the sample position while aspirating!



Press "RUN".



The analysis starts. The results are displayed within approx. 90-125 seconds and are stored automatically.

Analysis results are automatically printed/ sent to host computer according to settings (from page 56).

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Analysis: Micro tubes

Check blood with added EDTA anticoagulant, aspirated sample volume ~15µL.

Incorrect analysis results

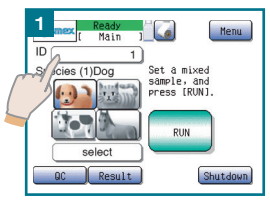
All performance data cited in this manual were generated using specimens in EDTA anticoagulant. Results may differ using other anticoagulants.

Important

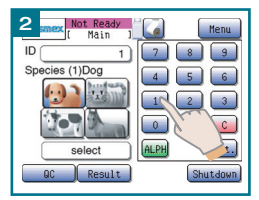
- When using a micro tube attached with a cap, such as Eppendorf tube, set the cap part close toward you to avoid mechanical problems.
- When using micro tubes, place them in the correct adapter and make sure the cap is removed.
- When a sample tube with a cap is used, manually remove the cap before analysis.
  The pipette might be permanently damaged, if the cap was not removed.
- Do not open the sample position while aspirating!

Note

The sample ID can be set up to 15 characters.
If a sample's ID is set to "0", the result for this sample will not be stored.



Press "ID".



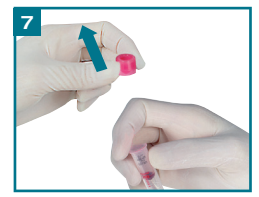
Enter the ID manually or by bar code reader and press "Ent.".

Open sample position.

Set the correct adapter.

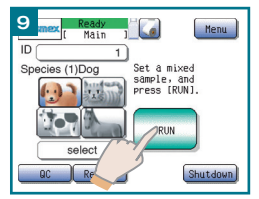
Insert the correct adapter.

Gently mix the sample.

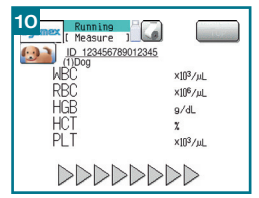


Remove the cap.

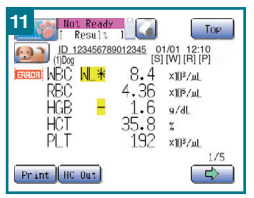
Insert sample tube and close the door.



Press "RUN".



The analysis starts. The results are displayed within approx. 90-125 seconds and are stored automatically.



Analysis results are automatically printed/ sent to host computer according to settings (from page 56).

Adapters are optional parts:

Product code	Adapter	shape and color
033-0861-0	Purple	Fits with micro tubes of which diameter is approx. 8 mm and length 35 mm or more
033-0891-1	Green	Fits with micro tubes of which diameter is approx. 11 mm
033-0871-7	Yellow	Fits with micro tubes of which diameter is approx. 8.5 mm
442-3044-6	Cream	Fits with micro tubes of which diameter is approx. 8 mm and length less than 35 mm
033-0881-4	Blue	Fits with micro tubes of which diameter is approx. 11 mm with higher or thick bottom
442-3042-9	Gray	Fits with micro tubes of which diameter is approx. 10 mm

Display analysis results

- After each analysis the results are displayed on the LCD screen.
- This instrument can store analysis results and histograms for up to 20 samples.
- Values outside the specified upper and lower limits are marked, for further analysis and checking.

Important

The analysis data of the "OTHER1" – "OTHER13" mode is for research.

Note

- When the analysis was performed in the "OTHER1" – "OTHER13" mode, LYM%, OTHR%, EO%, LYM#, OTHR# and EO# are displayed as W-SCR, W-MCR, W-LCR, W-SCC, W-MCC and W-LCC respectively.
- When the analysis was performed in the "Cat" mode, PDW , MPV and P-LCR are displayed as spaces.
- When the analysis was performed in the "Cattle" or "Horse" mode, EO% and EO# are displayed as spaces.

First screen
Displays analysis results of WBC, RBC, HGB, HCT and PLT parameters.

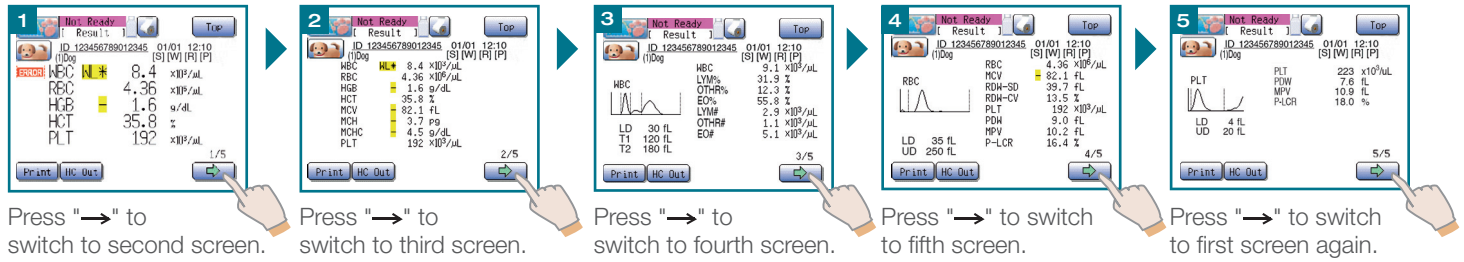
Second screen
Displays analysis results of WBC, RBC, HGB, HCT, MCV, MCH, MCHC and PLT parameters.

Third screen
Displays analysis results of WBC, LYM%, OTHR%, EO%, LYM#, OTHR# and EO# parameters.

Fourth screen
Displays analysis results of RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD and RDW-CV parameters.

Fifth screen
Displays analysis results of PLT, PDW, MPV and P-LCR parameters.

The analysis result screen is composed of 5 LCD screen pages.



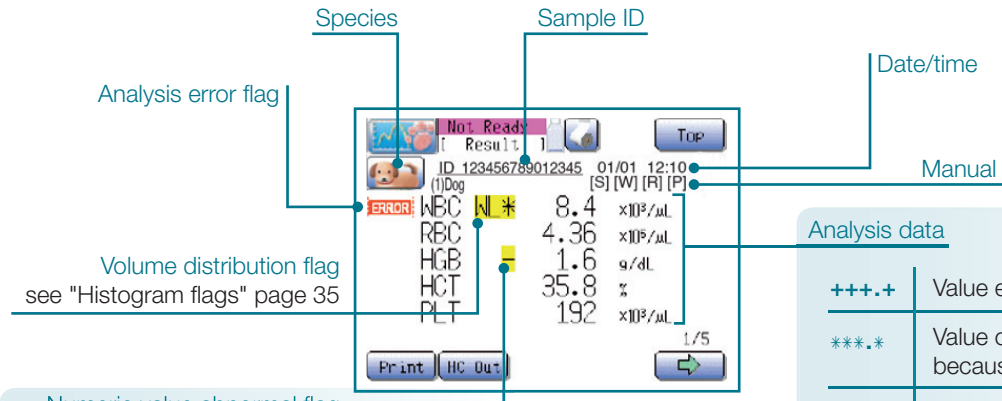
Press "→" to switch to second screen.

Press "→" to switch to third screen.

Press "→" to switch to fourth screen.

Press "→" to switch to fifth screen.

Press "→" to switch to first screen again.



!	Value is out of the linearity limit.
+	Result exceeds the upper reference limit.
-	Result exceeds the lower reference limit.
*	Result is unreliable.

+++.+	Value exceeds display range.
***.*	Value could not be calculated because of analysis error.
---.-	Value could not be calculated due to data error.

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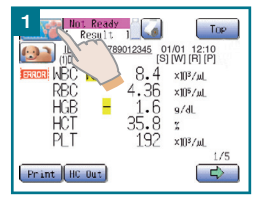
Manual Analysis

This menu allows the following:
- Re-selection of species and re-calculation of data.
- Relocation of particle distribution discrimination position and re-calculation of data.

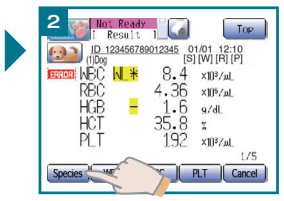
Important
- Manual Analysis can not be performed on the data with sample number 0.
- When "Save" is pressed, the analysis data is overwritten.

Note
- When species are changed, the species name is reverse-displayed, and the manual analysis flag [S] is displayed.
- Analysis values changed by re-calculations are reverse-displayed.
- The complete display consists of 4 screen pages. Switch the pages by pressing "→".

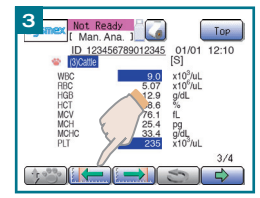
Re-selection of species



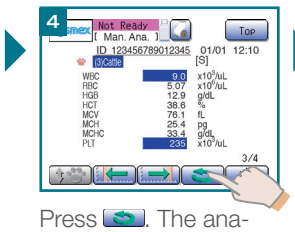
Press .



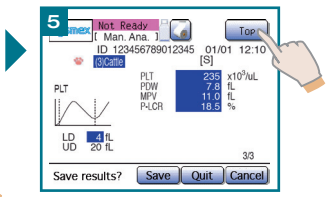
Press "Species".



Press or to select the species.



Press . The analysis data is re-calculated on the basis of new species.



Check the re-calculated analysis data and press "Top". Press "Save" to update the results and return to the Analysis screen.

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Important

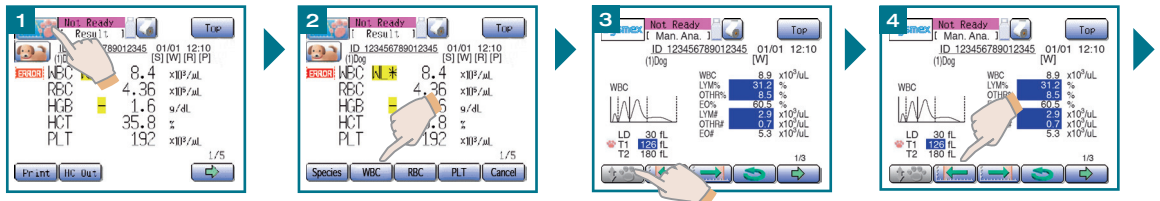
Manual Analysis can not be performed on the data with sample number 0.

Note

When the discrimination positions are changed, these are reverse-displayed, and the manual analysis flags are displayed.

[W] Move the discri. positions of WBC
[R] Move the discri. positions of RBC
[P] Move the discri. positions of PLT

Relocation of discrimination position



Press .

Select a desired particle distribution.

Press to select the discriminator.

Press or to move the discrimination position.

The range within which each discrimination position can move is shown below.

WBC

Discri. to Move	Lower Limit	Upper Limit
LD	6 fL (0ch)	T1
T1	LD	T2
T2	T1	UD (49ch)

WBC particle distribution covers 50 channels of 0 to 49 (6 fL per channel), and the channel changes by one at a time. The relation between WBC particle distribution channel and fL display is as follows:
Discri. position (fL) = (Channel No. + 1) x 6

RBC

Discri. to Move	Lower Limit	Upper Limit
LD	5 fL (0ch)	UD
UD	LD	250 fL (49ch)

RBC particle distribution covers 50 channels of 0 to 49 (5 fL per channel), and the channel changes by one at a time. The relation between RBC particle distribution channel and fL display is as follows:
Discri. position (fL) = (Channel No. + 1) x 5

PLT

Discri. to Move	Lower Limit	Upper Limit
LD	1 fL (0ch)	UD
UD	LD	40 fL (39ch)

PLT particle distribution covers 40 channels of 0 to 39 (1 fL per channel), and the channel changes by one at a time. The relation between PLT particle distribution channel and fL display is as follows:
Discri. position (fL) = (Channel No. + 1) x 1

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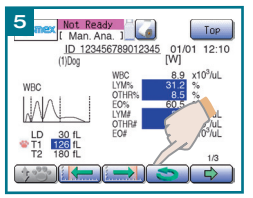
Important

When "Save" is pressed, the analysis data is overwritten.

Note

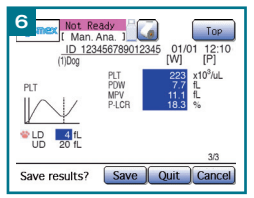
Analysis values changed by re-calculations are reverse-displayed.

5



After Discri. movement, press .

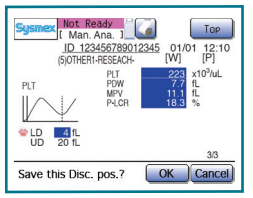
6



Check the re-calculated analysis data and press "Top". Press "Save" to update the results and return to the Analysis screen.

Note

When the analysis data of the "OTHER1" – "OTHER13" mode is saved, the discrimination position save confirmation dialog will appear.

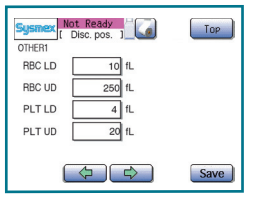


Press "OK" to store new discrimination positions and return to the Analysis screen.

From the next measurement, particle distributions of the other mode are discriminated with the new positions.

Note

Discrimination positions for the other mode can be set in the "Settings" - "Species" menu.



Histogram flags

The pocH-100*i*V Diff extracts the characteristics of the histogram and displays them as histogram flags.
If there are histogram flags, repeat analysis. If flags are still displayed, one of the following problems may apply.

Flag	Probable sample cause	Correction
WL	Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids.	• Check smear. • Warm sample and repeat analysis. • If incomplete lysing is suspected, perform a 1:5 dilution of the sample (50 µL of whole blood added to 200 µL of diluent) and re-analyze. Adjust the results for the dilution factor.
RL	Presence of fragmented red blood cells, increase in large platelets, platelet aggregation or agglutination, presence of micro-red blood cells.	• Check smear. • Warm sample and repeat analysis. • Manual count.
PL	Effects of cryoglobulins, fragmented red blood cells or cellular fragments of white blood cells.	• Check smear. • Warm sample and repeat analysis. • Manual count.
WU	Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc.	• Check smear. • Dilute sample and repeat analysis. • If incomplete lysing is suspected, perform a 1:5 dilution of the sample (50 µL of whole blood added to 200 µL of diluent) and re-analyze. Adjust the results for the dilution factor.
RU	Effects of cold agglutinin, inclusion of white blood cells.	• Check smear. • Warm sample and repeat analysis.
PU	Increase in large platelets, inclusion of fragmented red blood cells, effects of cryoglobulins, platelet aggregation or agglutination, presence of micro-red blood cells.	• Check smear. • Warm sample and repeat analysis. • Manual count. • Take another blood sample.
DW (RBC)	Significant anisocytosis, etc.	Check smear.

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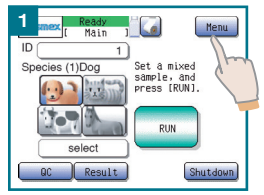
Flag	Probable sample cause	Correction
DW (PLT)	Inclusion of fragmented red blood cells, nonuniformity in size of platelets, effects of cryoglobulins, etc.	• Check smear. • If cyroglobulins are suspected, first warm the sample and repeat analysis. If error message persists, perform a plasma replacement (remove plasma and replace with equal volume of diluent) and repeat analysis.
MP (RBC)	Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes.	Check smear.
MP (PLT)	Platelet aggregation, low platelet count.	
T1	Presence of immature white blood cells, incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC-Histogram not to be separated.	
T2	Presence of immature white blood cells, incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC-Histogram not to be separated.	• Check smear. • If incomplete lysing is suspected, perform a 1:5 dilution of the sample (50 µL of whole blood added to 200 µL of diluent) and re-analyze. Adjust the results for the dilution factor.
F1, F2, F3	Presence of immature white blood cells, incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC-Histogram not to be separated.	

Note

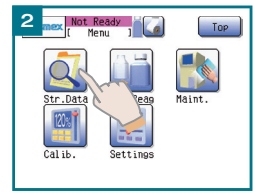
Since cat platelets are known to be difficult to discriminate from the red blood cells, it is a common problem in the cell counters and a PU flag is often reported.

Stored data

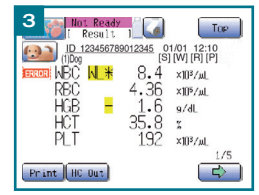
The most recent 20 analysis results are automatically stored and can be recalled. If there are 20 results stored, the fresh set will cancel the oldest.



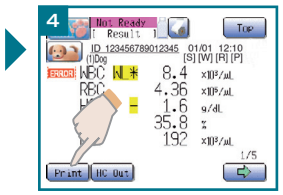
Press "Menu".



Press "Str. Data".



The stored data screen appears.



Press "Print".

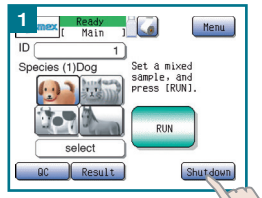
Shutdown

Incorrect analysis results

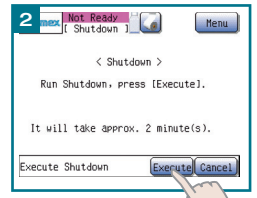
- If the instrument is used continuously without shutting it down periodically, protein build-up on the internal parts may inhibit correct analysis results, and may damage the instrument.
- If the instrument is turned OFF without executing a shutdown, water droplets may seep from the pipette or deposits may build-up on the rinse cup.

Important

Execute a shutdown at least every 24 hours. This may prevent damage to the instrument.

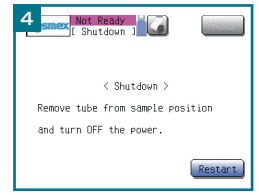


Press "Shutdown".

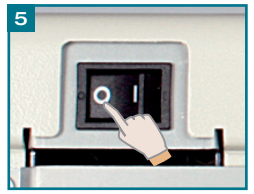


Press "Execute".

Shutdown begins. Process takes approx. 2 minutes.



Shutdown completed.



Switch OFF the instrument.

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2. ANALYSIS

QUALITY CONTROL

CONTENTS:

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PERFORMING QUALITY CONTROL

STEP 1: Settings for control blood information (quality control file)

Incorrect analysis results

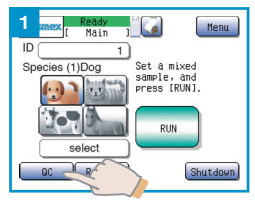
The operator must ensure the control blood is not beyond expiration date. The analyzer does not check the expiration dates entered in the QC file.

Important

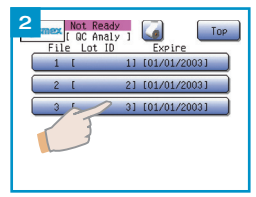
- Before using new control blood, enter the control blood information: Control blood lot ID and Expiration date. For each control parameter enter: **Target value** and **Limit value**.
- Control blood must always be stored in an upright position – irrespective of whether the vial has been opened or is still closed.

Note

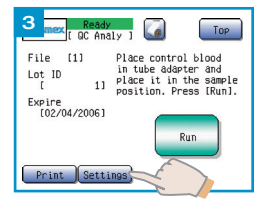
Changes in the analysis results over time must be recorded either by printing results or by other means such as storing the data on PC.



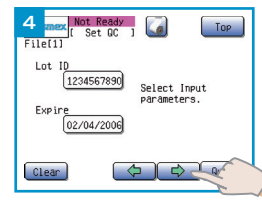
Press "QC".



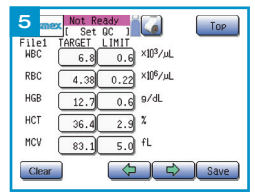
Select analyzing File.



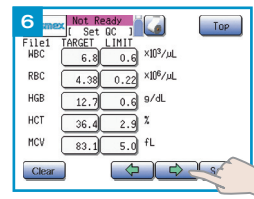
Press "Settings".



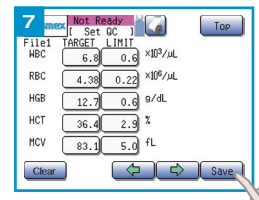
Enter "Lot ID" and "Expire" manually or by bar code reader. Press "→".



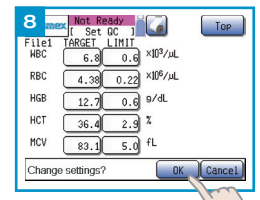
Enter TARGET and LIMIT value for each parameter manually or by bar code reader.



Press "→" to switch to remaining 5 QC file setting screens.



After completion of entering all parameters, press "Save".



Press "OK".

STEP 2: Preparing control blood

Biological risks

- To avoid infections, wear protective garments and gloves for cleaning and/or maintenance.
- After completion of work, wash hands with disinfectant.

Important

- EIGHTCHECK-3WP-L
  EIGHTCHECK-3WP-N
  EIGHTCHECK-3WP-H
  are used as control materials. These are equivalent to low, normal and high levels.
  For further information see "**The reagents**" **page 10**.
- If other control materials are used, the product performance of Sysmex instruments cannot be guaranteed.

Daily

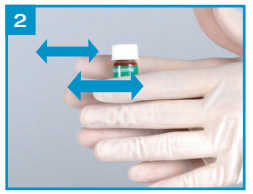
Quality control monitors the stability of the measured values over time.
Problems can be prevented or detected early on. Always perform quality control:

- Before analyzing samples
- After replacement of the reagent
- After maintenance
- If there is any doubt about the accuracy of the analysis values
- As required by regulation(s).

1

Remove small control blood bottles from the refrigerator at least 15 minutes before use.

2



1. Roll 10 times.
2. Turn upside down 10 times.
3. Roll 10 times.
4. Repeat steps 1 – 3 for 2 minutes.

3

Examine vial bottom. If there is a cells pellet on the bottom, repeat whole procedure!

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STEP 3: a) Performing quality control: L-J method (factory setting) Daily

Biological risks

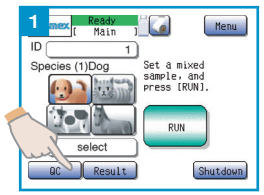
- Wear protective garments and gloves.
- Disinfect hands after work.

Important

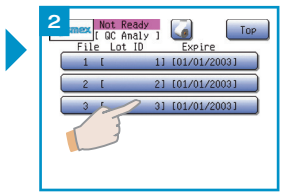
- Do not open the sample position while aspirating!
- Make sure that there are no objects underneath the sample position, because otherwise it cannot be openend fully.
- Use only the supplied sample adapter. Failure to do so may result in serious damage of the instrument.
- When a sample tube with a cap is used, manually remove the cap before analysis. The pipette might be permanently damaged, if the cap was not removed.

Note

The analysis results are automatically saved to "stored data".



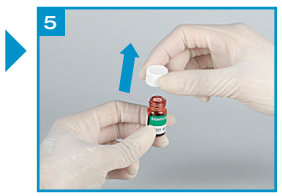
Press "QC".



Select analyzing File.

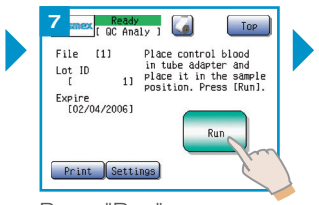
Open sample position.

Insert correct adapter.

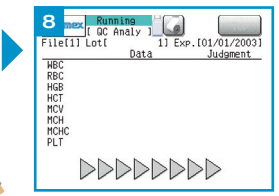


Remove the cap.

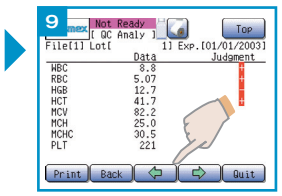
Insert control blood and close door.



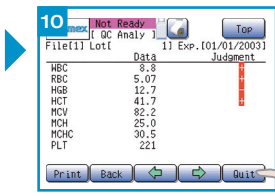
Press "Run".



The analyzing screen will appear.



Press the arrows to scroll the results screens.



Press "Quit" to accept analysis results. Depending on QC settings, results will be printed/sent to host computer automatically.

STEP 3: b) Performing quality control: $\bar{X}$ method — Daily

Biological risks

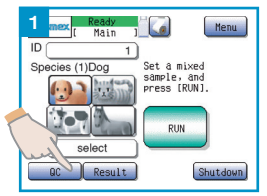
- Wear protective garments and gloves.
- Disinfect hands after work.

Important

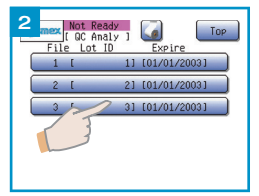
- Do not open the sample position while aspirating!
- Make sure that there are no objects underneath the sample position, because otherwise it cannot be openend fully.
- Use only the supplied sample adapter. Failure to do so may result in serious damage of the instrument.
- When a sample tube with a cap is used, manually remove the cap before analysis. The pipette might be permanently damaged, if the cap was not removed.

Note

The analysis results are automatically saved to "stored data".



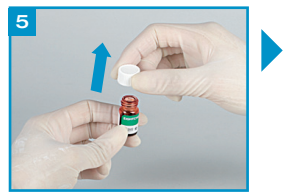
Press "QC".



Select analyzing File.

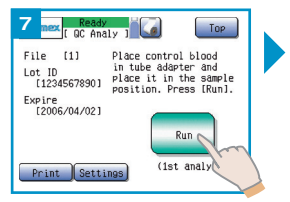
Open sample position.

Insert correct adapter.

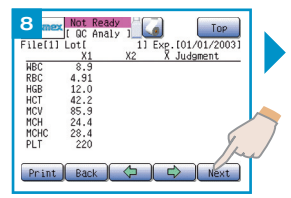


Remove the cap.

Insert control blood and close door.

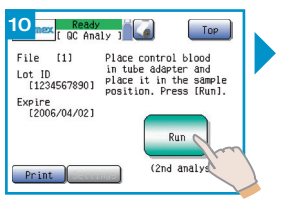


Press "Run".

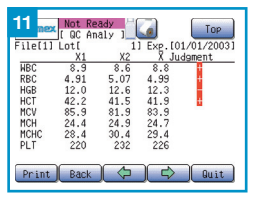


The first analysis results appear. Press "Next" to perform the second analysis.

Remove the control blood, mix well and insert it back into the sample position.



Press "Run" to perform second analysis.



The final results appear. Scroll the results by pressing the arrows and press "Print".

Code No.461-2406-6 Revised March 2007

3. QUALITY CONTROL

CLEANING & MAINTENANCE

CONTENTS:

Code No.461-2406-6 Revised March 2007

CLEANING

Clean instrument surface

- When cleaning the instrument surface or the touch panel, use a "soft dry cloth", "cloth soaked in neutral detergent then wrung tightly" or "soft cloth dampened with ethanol".
- Do not use any organic solvent, acid, or alkaline agent. These will affect the instrument surface's finish and may cause corrosion or discoloration.

Check instrument status

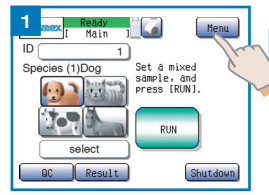
Check operation counter, program version and other information before contacting your Sysmex Service representative.

Biological risks

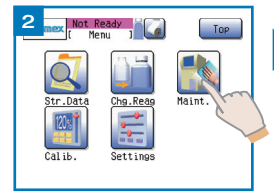
To avoid infections, wear protective garments and gloves for cleaning and/or maintenance. After completion of work, wash hands with disinfectant.

Important

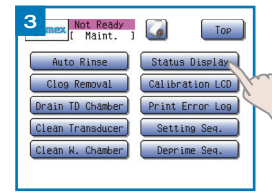
- To ensure proper functioning of the instrument, periodical cleaning and servicing is necessary.
- **Security Information for Using CELLCLEAN:**
  - CELLCLEAN is a strong alkaline cleaning material. It must not come in contact with skin or clothing. Should this happen, rinse skin or clothing with plenty of water to avoid injury or damage.
  - CELLCLEAN cleaning material contains sodium hypochlorite. If CELLCLEAN makes contact with the instrument's surfaces, it will affect the surface finish and there is danger of corrosion. Immediately wipe off CELLCLEAN with a damp cloth.



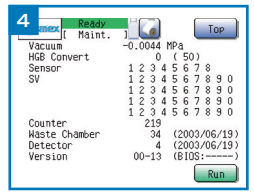
Press "Menu".



Press "Maint.".



Press "Status Display".



The following information is displayed on this screen.

4a

Vacuum	Current vacuum valve
HGB Convert	HGB convert value
Sensor	ON/OFF status of each sensor
SV	ON/OFF status of each solenoid valve
Counter	Number of cycles since instrument production
Waste Chamber	Number of cycles since last cleaning of waste chamber
Detector	Number of cycles since last cleaning of transducer
Version	Program version

Note If "Run" is pressed, analysis operation starts, and the instrument status can be checked during operation.

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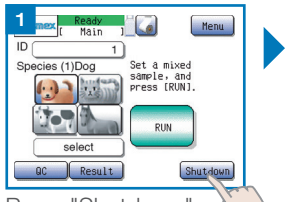
Shutdown

Removes deposits in the instruments tubing.

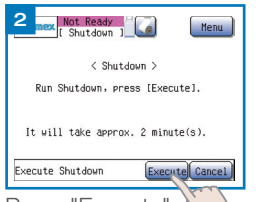
Incorrect analysis results

- Deposits in the instrument's tubing can cause incorrect analysis results. Therefore, the transducer chambers and diluted sample tubes must be cleaned.
- If the instrument is used continuously without performing the shutdown sequence, protein clotting may cause incorrect analysis results or it may damage the instrument.

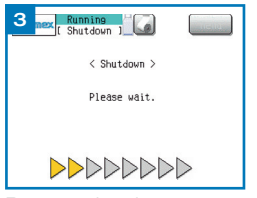
Daily



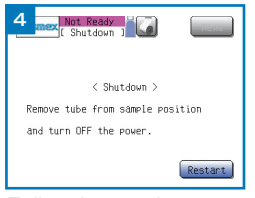
Press "Shutdown".



Press "Execute".



Process begins.



Follow instructions on the screen. Then switch OFF.

Clean transducer

Even if the message "Clean Transducer" is not displayed, this maintenance can be executed by pressing "Menu", "Maint." and then "Clean Transducer".

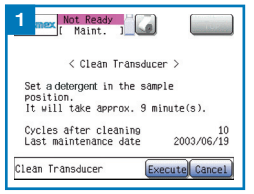
Every 2 weeks or 150 samples

Warning

There is a potential that CELLCLEAN may corrode the container. It is recommended to use a sample tube made of glass or prepare the detergent immediately before cleaning.

Note

A message will appear when either the counter value exceeds 150 or 2 weeks have passed since the last cleaning of the transducer.



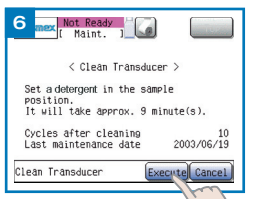
Cleaning instruction message is displayed.

Add 3mL of CELLCLEAN into empty sample tube.

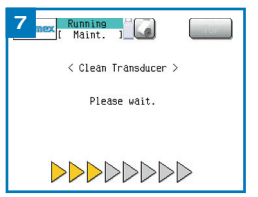
Open sample position.

Insert adapter.

Set CELLCLEAN (without a cap) in place, close door.



Press "Execute".



Process begins. Afterwards **Auto Rinse** and **Background check** will be performed automatically.

When this screen is displayed, remove CELLCLEAN.

Note

After cleaning, the counter resets automatically.

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Clean waste chamber

Even if the message "Clean waste chamber" is not displayed, this maintenance can be executed by pressing "Menu", "Maint." and then "Clean waste chamber".

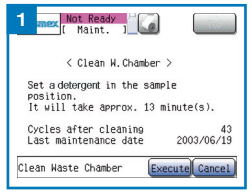
Every 3 months or 1500 samples

Warning

There is a potential that CELLCLEAN may corrode the container. It is recommended to use a sample tube made of glass or prepare the detergent immediately before cleaning.

Note

- A message will appear if either the counter value exceeds 1500 or 3 months have passed since the last "Clean waste chamber".
- After cleaning, the counter resets automatically.

1 

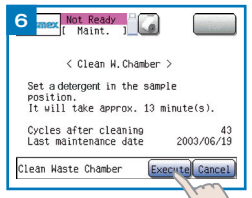
Cleaning instruction message is displayed.

2 
Add 3mL of CELL-CLEAN into empty sample tube.

3 
Open sample compartment.

4 
Insert adapter.

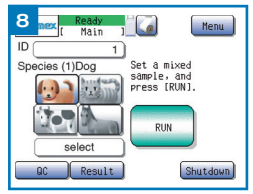
5 
Set CELLCLEAN (without a cap) in place, close compartment.

6 

Press "Execute".

7 

Process begins. Afterwards **Auto Rinse** and **Background check** will be performed automatically.

8 

When this screen is displayed, remove CELLCLEAN.

Clean the sample tube adapter

If sample has spilt into the adapter.

As needed

Biological risks

Always wear protective garments and gloves when handling the waste fluid. After work is completed, wash hands with disinfectant.

1 
Switch OFF.

2 
Remove adapter and clean it.

- Clean with distilled water
or
- Clean with CELLCLEAN diluted 10 times or more.

Rinse the adapter with distilled water afterwards.

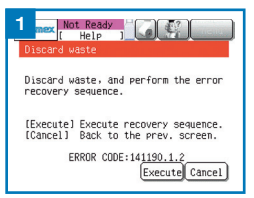
Dispose waste fluid

If the "Discard waste" error message appears, the waste bottle is full and needs to be emptied.

As needed

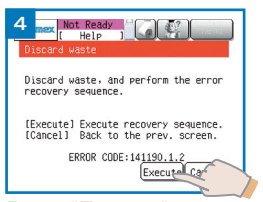
Biological risks

- Always wear protective garments and gloves when handling the waste fluid. After work is completed, wash hands with disinfectant.
- Dispose waste fluid appropriately in accordance to local laws and regulations.
- Ensure that the waste bottle is secure and properly connected before operating the instrument. If the waste fluid is spilt, wipe off immediately with a damp cloth.



- Remove cap.
- Dispose waste fluid.
- Rinse bottle with water.

Insert float switch into empty and cleaned bottle.



Press "Execute"; waste discharge operation starts.

Note

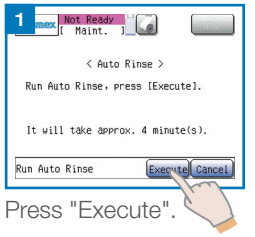
To return to the main screen without performing the waste discharge operation, press "Cancel".

Perform auto rinse

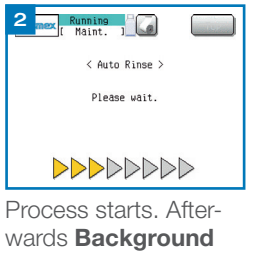
As needed

Clean tubings and drain waste.

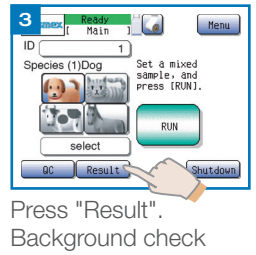
Even if the message "Auto Rinse" is not displayed, auto rinse can be executed by pressing "Menu", "Maint." and then "Auto Rinse".



Press "Execute".



Process starts. Afterwards **Background check** will be performed automatically.



Press "Result". Background check result will appear.

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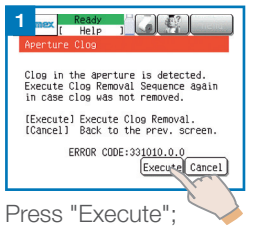
Remove clog from transducer aperture

As needed

If an "Aperture Clog" error occurs, the clog must be removed.
Even if the message "Aperture Clog" is not displayed, automatic clog removal can be executed by pressing "Menu", "Maint." and then "Clog Removal".



Press "Execute"; automatic clog removal starts.

Note

To return to the main screen without performing automatic clog removal, press "Cancel".

Drain reagents

As needed

Perform before moving/shipping the instrument.

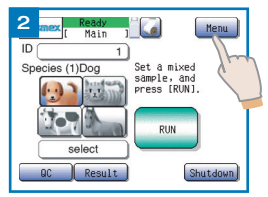
Biological risks

Always wear protective garments and gloves when handling the waste fluid. After work is completed, wash hands with disinfectant.

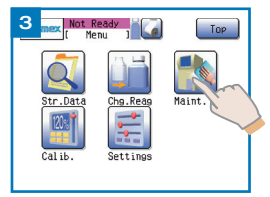
Note

- Place the removed container spout kits on top of a clean cloth or inside a plastic bag, and shield from dust.
- The instrument will be primed automatically the next time it is started up.

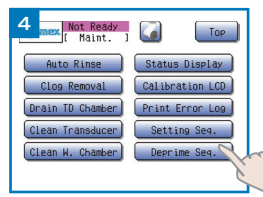
Remove spout kits from pocH-pack D and LVD.



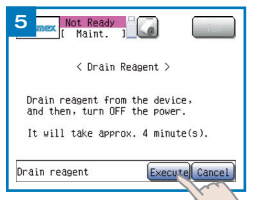
Press "Menu".



Press "Maint.".

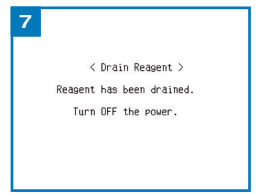


Press "Deprime Seq.".



Press "Execute".

Process begins.



Switch OFF, drain and clean waste bottle.

Calibrate LCD

Calibrate the LCD if panel operation is not properly aligned.

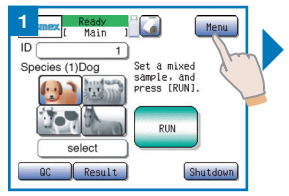
As needed

Important

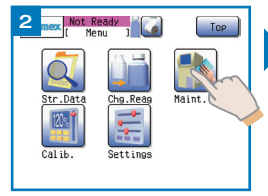
When calibration is performed and a calibration error occurs frequently, there may be a problem with the touch screen. In this case contact your Sysmex service representative for assistance.

Note

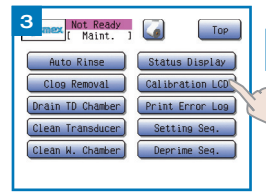
If the input position was outside a regulated range, the calibration error message will appear and the calibration will be discontinued.



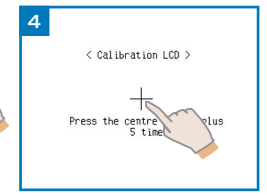
Press "Menu".



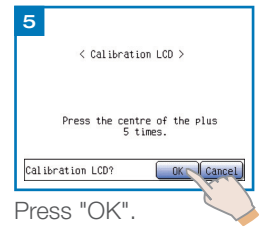
Press "Maint.".



Press "Calibration LCD" and then "OK".



Touch "+" each time it is displayed on the screen (5 times).



Press "OK".

Replace thermal printer paper

Only use paper recommended by Sysmex.

As needed

Warning, Hot

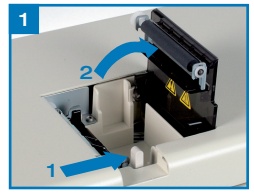
Do not touch the printer head!
It can get very hot.

Important

Static electricity may damage the printer head.
Do not touch.

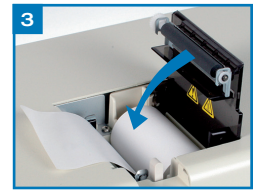
Note

The printer cover must be closed (clicking sound).
If the cover is not closed completely,
an error message will be displayed.



Open paper holder by pushing the knob.

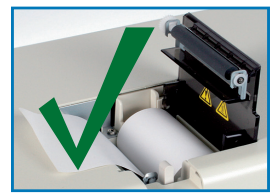
Remove the tape.

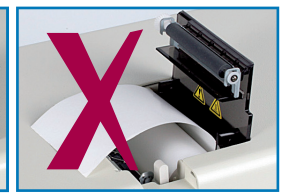


Insert paper.

Note

Insert the paper correctly.
If inserted at an angle,
the paper might jam.





Close lid and remove excess paper.

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Replace reagent

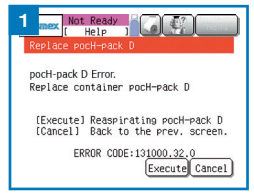
Incorrect analysis results

- Use reagent at 15–30°C.
  Leave reagents at room temperature for at least 24 hours or longer before using. If a refrigerated reagent is used, a correct analysis result will not be obtained.
- For detailed information about storage & shelf life, see "**The reagents**" **page 10**.

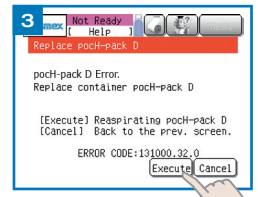
Important

- Do not to touch the pipe with your hands, or to allow dust or other substances to adhere to them. If such substances adhere to the pipe, wash the substance off with reagent first before attaching the container spout kit.
  Failure to do so may lead to erroneous results.
- Be careful to prevent the reagent from spilling.
  If the reagent spills, immediately wipe it off with a damp cloth.

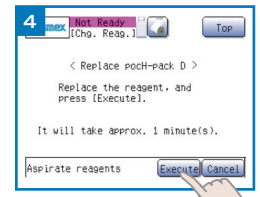
As needed



Insert the container spout kit into the new bottle. Tighten the cap.



Press "Execute".



Press "Execute".

After replace menu process, display shows start screen.

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TECHNICAL MAINTENANCE – Qualified personnel only!

Clean aperture of TD chamber

As needed

If the clogging of the aperture cannot be removed by the automated sequence, the aperture must be cleaned manually with the transducer brush.

Biological risks

Always wear protective garments and gloves for all service and maintenance work. Use only specified tools and parts. After completion of work, wash hands with disinfectant. Instruments that got in contact with blood have infectious potential.

Danger, electric shock

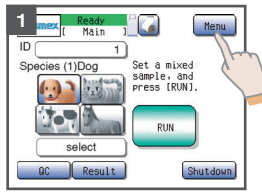
Re-attach the transducer chamber plug securely. Otherwise, reagent leakage might occur, which may cause a short circuit or electrical shock.

Important

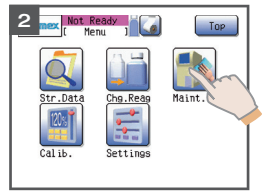
- If the plug is opened with the liquid still in the chamber of the detector, the part might be damaged by the spilling liquid. Remove any residual liquid with the pipette.
- If performing maintenance work, use only the specified tools and parts. Install only such spare or replacement parts intended for this equipment.

Note

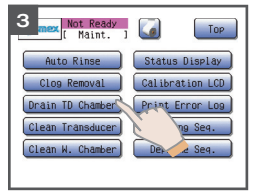
Before storing, rinse the brush with water to completely remove the CELLCLEAN.



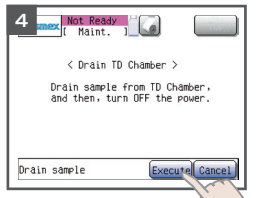
Press "Menu".



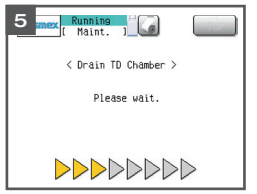
Press "Maint.".



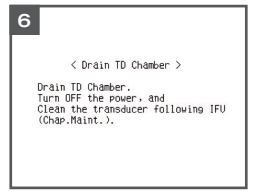
Press "Drain TD Chamber".

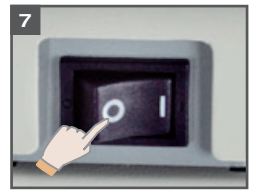


Press "Execute".

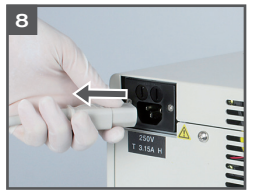


Process starts.





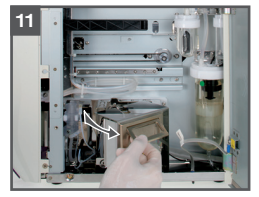
Switch OFF.



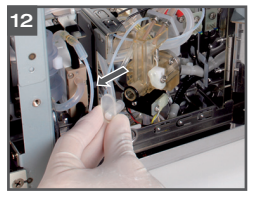
Disconnect power cord to avoid electrical shock.

Unscrew cover by using the supplied screwdriver.

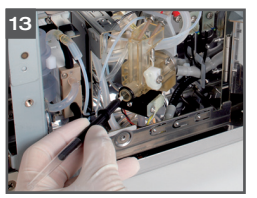
Open side cover and open detector cover.



Check if fluid has been drained. If not, remove it with the pipette.

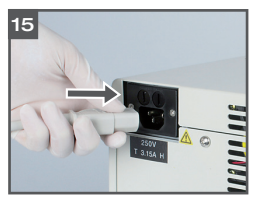


Place cloth under plug and remove plug.



Apply CELLCLEAN to transducer brush, clean aperture gently.

Close all covers. Tighten the screws.



Plug in power cord
Switch ON instrument.

Important

Be sure to turn the main switch ON after completion of the cleaning procedure. If the auto rinsing is not performed after cleaning, the instrument may malfunction.

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System fuse replacement

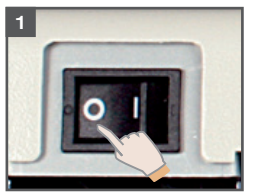
Danger, electric shock

To avoid electrical shock, disconnect power supply before servicing.

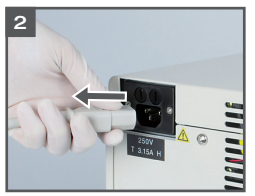
Important

Replace only with fuse of the specified type and correct current specifications.

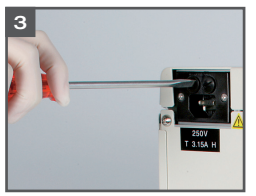
As needed



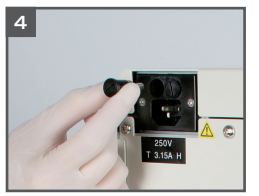
Switch OFF.



Unplug power cable.



Turn fuse holder cap counter-clockwise with screwdriver.



Remove fuse holder cap. Replace fuse(s). Put fuse holder cap back in place.

Plug in power cable.
Switch ON.

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SETTINGS & CALIBRATION

CONTENTS:

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SETTINGS

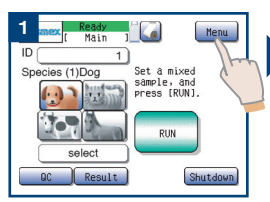
Set up the instrument according to your personal needs or to laboratory requirements.

Change settings

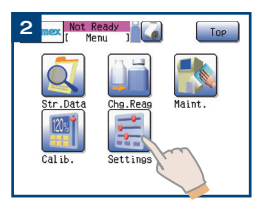
Some parameters are set by factory default. Others (Date/Time) have to be set on initial operation.

Note

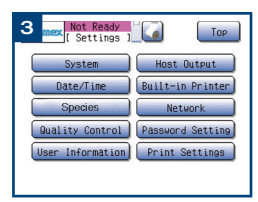
See "**Possible settings**" **pages 56–62** for more detailed information on parameters that can be set manually.



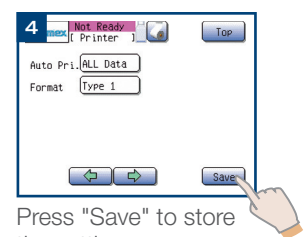
Press "Menu".



Press "Settings".



Select parameter to be changed. (Possible settings to be changed are described on pages 56–62.)



Press "Save" to store the settings.

Possible settings

Important

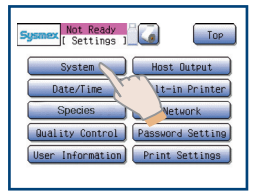
It is not possible to convert the stored data from Dutch SI units to other units for the following 3 parameters: HGB, MCH, MCHC. Do not use stored sample data which was saved before changing the settings. In addition, renew settings for reference limits, and for quality control TARGET and LIMIT values.

Note

The underscored items are factory settings.

System setup

Press "Menu" > "Settings" > "System".



Parameter	Setting
Units	Type1: Japan Type2: General Export Type3: Canada SI Type4: Dutch SI Type5: Standard SI Type6: Hong Kong SI Settings for this parameter will come into effect the next time the main switch is turned ON.
Language	Japanese; English; French; German; Spanish; Italian; Chinese Settings for this parameter will come into effect the next time the main switch is turned ON.
Blood collection tube	STANDARD TYPE: Standard sample tube SARSTEDT TYPE: S-MONOVETTE (SARSTEDT) sample tube
Alarm sound volume	1 Quiet; 2 Medium; 3 Loud
Timbre	Type1: High continuous beep Type2: Repeated high beeps Type3: Repeated high two-tone beeps Type4: Low continuous beep Type5: Repeated low beeps Type6: Repeated low two-tone beeps
ISBT128	Enable; Disable When "Enable" is selected, the ISBT128 bar code will be loaded as a sample ID number with up to 13 characters.

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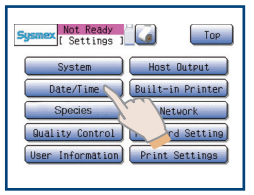
Note

The underscored items are factory settings.

Date/Time For standard or daylight saving time, the clock must be set manually.

Press "Menu" > "Settings" > "Date/Time".



Parameter	Setting
Format	yy/mm/dd; mm/dd/yy; dd/mm/yy
Year	2000 – 2037
Month	1 – 12
Day	1 – 31
Hour	0 – 23
Minute	0 – 59

Note

- The listed values are the initial settings made before shipment from the factory.
- If LL or UL that satisfy the following conditions was entered in the Reference Limit setting screen, a beep sounds and the entering is canceled.
  - LL is higher than UL.
  - UL is lower than LL.

Species specific settings

Press "Menu" > "Settings" > "Species".

Set the folloing parameters for each species.

Species	Parameter
Dog, Cat, Cattle, Horse	Reference limits, Correction values
OTHER1–13	Species name, Reference limits, Correction values, Discrimination positions

Enter the upper and lower limit marks for the analysis results.

Parameter	LL (Lower Limit)	UL (Upper Limit)
WBC	0	0
RBC	0	0
HGB	0.0	0.0
HCT	0.0	0.0
MCV	0.0	0.0
MCH	0.0	0.0
MCHC	0.0	0.0
PLT	0.0	0.0
RDW-SD	0.0	0.0
RDW-CV	0.0	0.0
LYM% (W-SCR)	0.0	0.0
OTHR% (W-MCR)	0.0	0.0
EO% (W-LCR)	0.0	0.0
LYM# (W-SCC)	0	0
OTHR# (W-MCC)	0	0
EO# (W-LCC)	0	0
MPV	0.0	0.0
PDW	0.0	0.0
P-LCR	0.0	0.0

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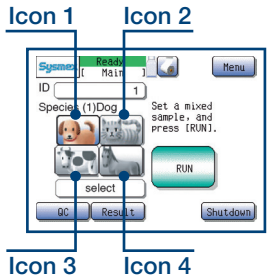
Correction values:
The correction values for HGB and HCT can be set here.
(See the table below for the initial settings.)

Parameter	Dog	Cat	Cattle	Horse	OTHER 1–13
HGB	100.2 %	100.3 %	97.6 %	87.2 %	100.0 %
HCT	92.4 %	78.3 %	89.7 %	92.5 %	100.0 %

Discrimination positions:
The discrimination positions for WBC, RBC, PLT can be set here.
(See the table below for the initial settings.)

Parameter	OTHER1–OTHER13
W-LD	54 fL
W-T1	132 fL
W-T2	144 fL
R-LD	10 fL
R-UD	250 fL
P-LD	1 fL
P-UD	20 fL



The species assigned on the icons in the main screen can be set here.
(See the table below for the initial settings.)

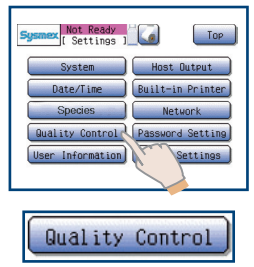
Parameter	Species
Icon1	Dog
Icon2	Cat
Icon3	Cattle
Icon4	Horse

Note
The underscored items are factory settings.

QC settings

Select Quality Control and data output method.

Press "Menu" > "Settings" > "Quality Control".



Parameter	Selection
QC Method	($\overline{X}$); L-J
Data Output	Disable; Print; HC; Print + HC

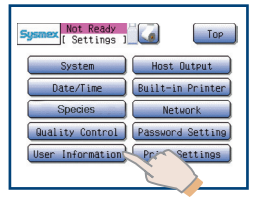
Choose the control method meeting your laboratory's internal regulations:

- L-J Levey-Jennings control method (initial factory setting):
  Only one control blood analysis is performed and compared with the expected range.
- $\overline{X}$ control method:
  Two consecutive analyses are performed and the mean values are compared with the expected range.

User information settings

If several pocH-100*i*V Diff are connected to a host computer, a unique naming can be set to identify each instrument.

Press "Menu" > "Settings" > "User Information".

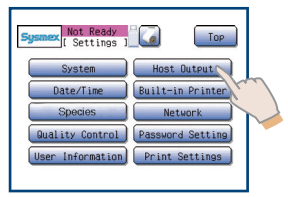


Note
The underscored items are factory settings.

Host settings

To set data output to host computer.

Press "Menu" > "Settings" > "Host Output".



Parameter	Setting
Connect	Disable; Serial; LAN
Automatic Output	Enable; Disable
Format	pocH; KX-21N; ASTM; K-1000
Transfer Rate	1200 bps; 2400 bps; 4800 bps; 9600 bps; 19200 bps
Data Length	7 bits; 8 bits
Stop bit	1 bit; 2 bits
Parity	Even; Odd; Disable
Protocol	Class A; Class B
Transfer Interval	0 s; 2 s; 3 s; 5 s; 7 s; 10 s; 15 s
RTS/CTS	Enable; Disable
ID Pad.	0 pad; SpacePad.
RDW	RDW-SD; RDW-CV
ASTM Rev.	1381-95; 1381-02

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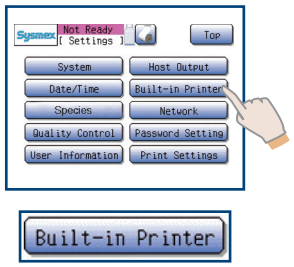
Note
The underscored items are factory settings.

Printer settings

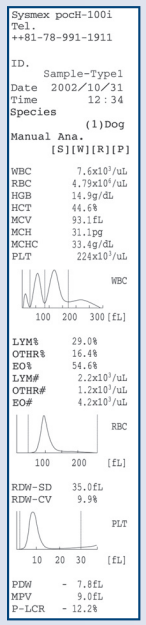
Printing out analysis results can be set here. The print header can be set individually (i.e. containing laboratory name, instrument name etc.).

Press "Menu" > "Settings" > "Built-in Printer".

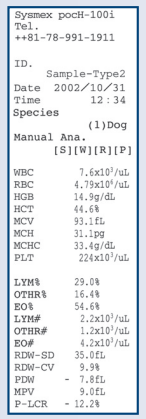


Parameter	Setting
Automatic Print	All Data; Error Data; Disable
Format	Type 1: Prints 19 analysis results and the histograms. Type 2: Prints 19 analysis results. Type 3: Prints only CBC8 analysis results.
[First print header line]	Up to 16 digits of alphanumeric characters
[Second print header line]	Up to 16 digits of alphanumeric characters
[Third print header line]	Up to 16 digits of alphanumeric characters

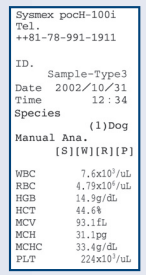
Type 1



Type 2



Type 3



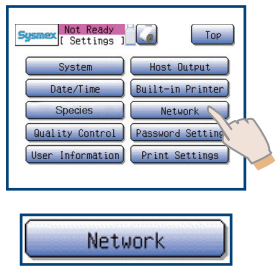
Note

The underscored items are factory settings.

Network settings

Address and other necessary settings can be entered for use of LAN port to communicate with a host computer. In addition, the MAC address can be viewed on this screen.

Press "Menu" > "Settings" > "Network".



Instrument side

Parameter	Setting
IP Address	0 – 255 (common to all columns) Default: "0.0.0.0"
Netmask	0 – 255 (common to all columns) Default: "255.255.255.0"
Default Gateway	0 – 255 (common to all columns) Default: "0.0.0.0"

Host side

Parameter	Setting
IP Address	0 – 255 (common to all columns) Default: "0.0.0.0"
Port Number	0 – 9999 Default: "3000"

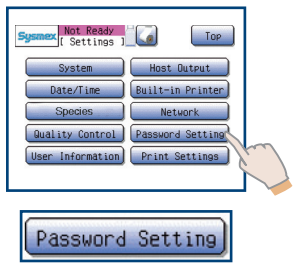
Important

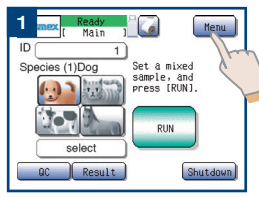
- In case the password has been forgotten, contact your Sysmex service representative.
- Enter maximum 10 digits of numerals (0-9) or hyphens (-) .

Password setting

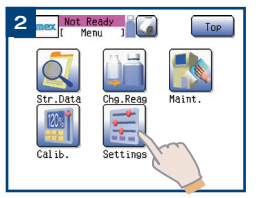
To prevent unauthorized change of the settings, a password can be set.
Password-protected functions: Calibration and Setting.

Press "Menu" > "Settings" > "Password Setting".

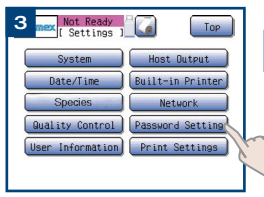




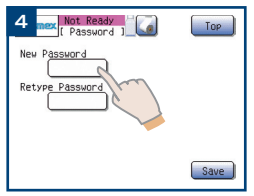
Press "Menu".



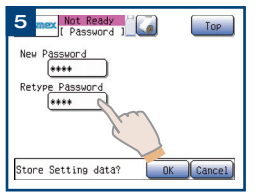
Press "Settings".



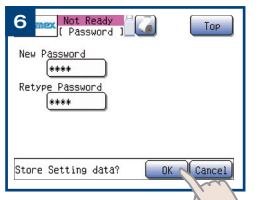
Press "Password Setting".



Press "New Password", the numerical keys dialog will appear. Enter max 10 digits. Press "Ent.".



Press "Retype Password". Repeat password and press "Ent.".



Press "OK".

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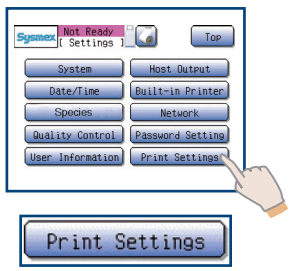
Print settings Print a list of the current settings.

Press "Menu" > "Settings" > "Print Settings".



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CALIBRATION The HGB and/ or HCT values are corrected by a calibration value.

Calibrate the instrument

- If quality control shows repeated deviations in the same direction.
- If a major component of the instrument has been replaced.

Important

- Calibration does not need to be performed at specific intervals. Follow your internal laboratory regulations for performing calibration.
- Calibration is to compensate the analysis results in a way, and all the analysis results will be compensated to add a specific bias.
- Each sample should be analyzed at least three times.
- EIGHTCHECK is not suitable for calibration purposes, but for quality control instead.

Note

Upon calibration, run a QC using control bloods and verify that the analysis results will not exceed the control limits.

Establishing reference values

Recommended measuring methods:

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

Samples used for calibration

Use 5 or more samples of fresh normal human blood meeting the following conditions:

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

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Automatic calibration

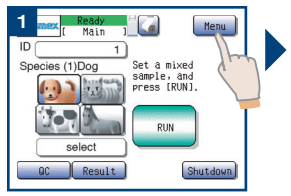
The instrument determines the calibration value automatically by analyzing 5 calibration samples.

Important

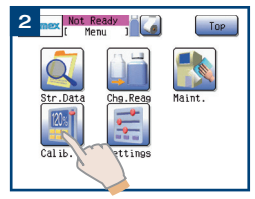
- It is important to analyze the samples according to their reference values. The values of the sample to be analyzed are indicated by the underline cursor.
- Set "0" for any parameter which does not need to be calibrated.
- Do not open the sample position while "Aspirating" is displayed. Only open it when "Running" is displayed.

Note

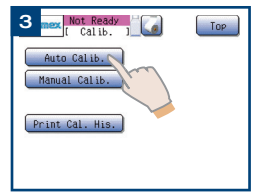
If an error occurs during analysis, press "Cancel" and analyze again.



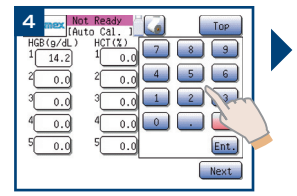
Press "Menu".



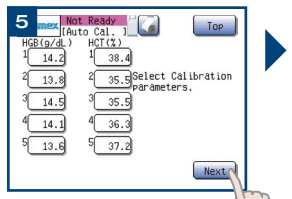
Press "Calib.".



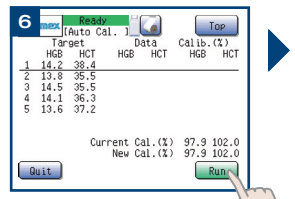
Press "Auto Calib.".



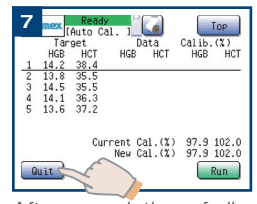
Enter reference values for 5 each sample and press "Ent.".



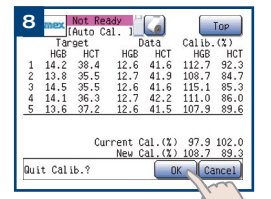
Press "Next" and "OK".



Set first sample and press "Run" and repeat this for the remaining 4 samples.



After completion of all analyses, press "Quit".



Press "OK".

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Manual calibration

The calibration value must be calculated according to the formula shown below and entered manually.
Use normal and fresh human blood of 5 or more samples.

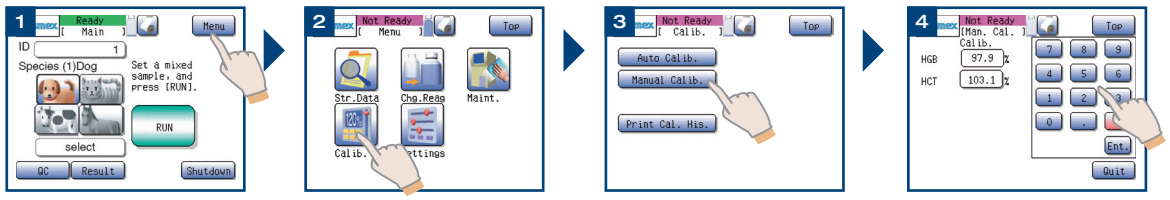
Note

A calibration error is displayed, if the mean calibration value for each analysis exceeds 105% or is less than 95%, or if the new calibration value exceeds 120% or is less than 80%.
The calibration value can be calculated using the following formula:

$$\text{Calibration value} = 100 \times \frac{\text{New calibration value}}{\text{Current calibration value}}$$

1. Establish the reference values.
2. Calculate the mean value.
3. Analyze the samples.
4. Calculate the mean value.
5. Calculate the calibration value using the following formula:

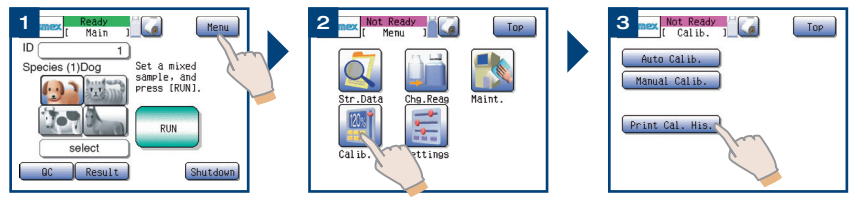
$$\text{New calibration value} = \text{Previous calibration value} \times \frac{\text{Average of values gained by reference method}}{\text{Average of values gained by this instrument}}$$



Press "Menu". Press "Calib.". Press "Manual Calib.". Enter calibration value; press "Ent." and confirm with "OK".

Print calibration history

Print an overview of the five most recent calibration results.



Press "Menu". Press "Calib.". Press "Print Cal. His.".

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5. SETTINGS & CALIBRATION

TROUBLESHOOTING

CONTENTS:

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General errors, instrument failure

Danger, electric shock

Disconnect the power cord before opening the instrument. Otherwise there is a risk of injury by electrical shock and possible damage to the instrument.

Note

If the instrument shows a malfunction, check the following table. If the corresponding item is not found or the procedure listed does not eliminate the problem, contact your Sysmex service representative.

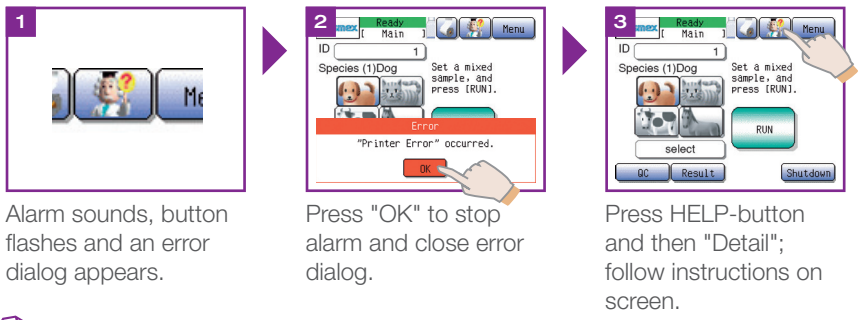
- Other errors are indicated by a beep and a message displayed on the LCD screen.
- If an error affects only a specific analysis result, it will be marked by a flag.

The instrument is switched ON but will not start.	• Check if power cord is plugged in properly. • Use another appliance to check if the outlet is live. • Check fuses and circuit breakers, replace if necessary (**"Technical Maintenance" page 53**).
The logo appears on the LCD screen, however the main screen does not appear.	The program card is not inserted properly. Turn the main power switch OFF, and check whether the program card is securely inserted in the card slot on the right side of the instrument. Then switch ON again.
After turning the main switch ON, the LCD screen remains blank.	Possibility of memory error. Turn the main switch OFF, wait 1 to 2 minutes, then turn the main power switch ON again.
Mechanical operation is heard, but no display appears on LCD screen.	Check whether the LCD screen contrast is set correctly.
Fluid leaks from the instrument.	Turn the main power switch OFF and wipe off the leaked fluid. **Biological risks** Wear protective garments and gloves when working. After completion of work, wash hands with disinfectant.

Error messages

Important

- If you are unable to solve the problem, contact your Sysmex service representative for assistance. Please note the ERROR CODE to enable your service representative to provide quick assistance.
- In case of a power failure during operation, turn the main power switch OFF.



1. Alarm sounds, button flashes and an error dialog appears.
2. Press "OK" to stop alarm and close error dialog.
3. Press HELP-button and then "Detail"; follow instructions on screen.

Note

Multiple errors are displayed ranked by importance. Press "Detail" for displaying the help screen of the first error.

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Error messages, possible causes and actions to resolve the error

Vacuum Error

Possible cause	Defective vacuum pump or air leakage in vacuum line.
Action to resolve the error	• Check if any fluid was collected in the trap chamber. • Press "Execute" to clear the error and perform the recovery process. If the pressure returns to normal, Auto Rinse and back ground check are performed in sequence, and the screen returns to the Main screen. The error message will be displayed again if the pressure has not returned to normal. • Press "Cancel" to return to the previous LCD screen.
Special notes, if error remains	Not ready until the error is resolved.

Waste C. Error

Possible cause	• Clogging of waste chamber and tubing. • Waste tubing is kinked. • Pinch valve 2 malfunctions. • Pinch valve 2 tubing is blocked. • Defective pressure pump or air leak in pressure line. • Float switch does not work properly.
Action to resolve the error	• Check the clogging of waste chamber and tubing. • Check waste tubing for kinks. • After checking, press "Execute" to clear the error, and the waste chamber drain sequence is executed.
Special notes, if error remains	Not ready until the error is resolved.

Replace pocH-pack D
Replace pocH-pack LVD

Possible cause	Level in pocH-pack D or pocH-pack LVD is insufficient.
Action to resolve the error	• Replace the pocH-pack D or pocH-pack LVD with new one. • Replace with a new reagent and press "OK". The error is cleared and the reagent replacement sequence is executed. • See "Replace reagent" page 52. • An error message will be displayed again, if the reagent replacement sequence was not completed correctly.
Special notes, if error remains	Not ready until the error is resolved.

Drain Error

Possible cause	The waste bottle is full.
Action to resolve the error	• See "Dispose waste fluid" page 49. • After checking, press "Execute" to clear the error, and the recovery sequence is executed.
Special notes, if error remains	Not ready until the error is resolved.

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Piercer MC Error
PinchV1 MC Error
PinchV2 MC Error
Syringe MC Error

Possible cause	Abnormality in the controller for each driving motor.
Action to resolve the error	Turn the main switch OFF, then turn it ON again.
Special notes, if error remains	Not ready until the error is resolved.

Piercer MT Error
Syringe MT Error

Possible cause	Operation of each driving motor is abnormal.
Action to resolve the error	Turn the main switch OFF, then turn it ON again.
Special notes, if error remains	Not ready until the error is resolved.

PinchV1 MT Error

Possible cause	Operation of driving motor is abnormal. The tube is stuck or broken.
Action to resolve the error	Turn the main switch OFF, then turn it ON again.
Special notes, if error remains	Not ready until the error is resolved.

Aperture Clog

Possible cause	Transducer chamber aperture is clogged, or air bubbles have entered the transducer chamber.
Action to resolve the error	• Remove the aperture clog. Execute automatic clog removal (page 50). • Clean the transducer (page 47). • Clean the aperture with the brush (page 53). • Press "Execute" to clear the error, and Clog Removal is executed.
Special notes, if error remains	Ready for next analysis, however, the next sample may be analysed incorrectly.

Temp. Error (H)
Temp. Error (L)

Possible cause	Temperature in the detector block is too high or too low. - "Temp. Error (L)": Detector block temperature is 10 °C or lower - "Temp. Error (H)": Detector block temperature is 40 °C or higher
Action to resolve the error	Set room temperature between 15–30 °C.
Special notes, if error remains	• The ∗ sign (indicates the result is low in reliability) will appear to the left of the analysis results. • If the temperature in the detector block is too high or low, perform shutdown of the instrument. Leave the instrument at an appropriate room temperature for some time, then turn the main switch ON again.

Blank Error

Possible cause	• Instrument has not been operated for several days. • Aperture clogged. • Dirty HGB flow cell. • Air trapped in the system. • Reagent faulty.
Action to resolve the error	• Clean the transducer (page 47). • Replace the reagent (page 52). • Press "Execute" to clear the error, and Auto Rinse is executed.
Special notes, if error remains	Ready for next analysis, however, the following sample results may be incorrect.

HGB Error

Possible cause	• Dirty HGB flow cell. • Bubbles mixed in HGB flow cell. • Dirty WBC Transducer chamber.
Action to resolve the error	Press "Execute" to clear the error, and Clean Transducer is executed.
Special notes, if error remains	Ready for next analysis, however, the following sample results may be incorrect.

QC (L-J) Error
QC ($\overline{X}$) Error

Possible cause	• Aspiration of control blood was incomplete. • Mixing of control blood was insufficient. • Control blood has deteriorated. • Instrument failure. • TARGET value or LIMIT value was entered incorrectly.
Action to resolve the error	• Reanalyze the control blood again. • Confirm TARGET and LIMIT values.
Special notes, if error remains	Ready for next analysis, however, the following sample results may be incorrect.

PLT Smp'g Error
RBC Smp'g Error
WBC Smp'g Error

Possible cause	• Aperture partly clogged. • Air bubbles sticking in transducer aperture. • Effect of external electric noise interference.
Action to resolve the error	• Remove the aperture clog. Execute automatic clog removal (page 50). • Transducer cleaning sequence. Apply CELLCLEAN in the transducer and run Transducer cleaning sequence (page 47). • Clean aperture with transducer brush (page 53). • Separate the source of the electric noise from the instrument. • Press "Execute" to clear the error, and the Clog Removal is executed.
Special notes, if error remains	Ready for next analysis, however, the following sample results may be incorrect.

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QC Data Error
Setting Error
Stored Error

Possible cause	An error occurred in the set values of the stored data or QC data due to momentary power failure, sudden electric noise interference, etc.
Action to resolve the error	Turn the main switch OFF, then turn it ON again.
Special notes, if error remains	• Follow the instructions on the screen to "repair" the data. Then restart instrument. If "repair" is not successful, then "initialize" the data. • When the instrument is initialized, all stored data is deleted. If settings have been initialized, set settings again. • If either "repair" or "initialize" is successful, the program will be started.

RAM and ROM Error

Possible cause	CPU malfunction due to momentary power failure, sudden electric noise interference, etc.
Action to resolve the error	Turn the main switch OFF, then turn it ON again.
Special notes, if error remains	Applications cannot be started.

Tube holder Error

Possible cause	• The sample position was opened while the instrument was operating. • No adapter was set.
Action to resolve the error	After closing the door, press "Execute" to clear the error and the recovery sequence is executed.
Special notes, if error remains	Not ready until the error is resolved.

Setting Seq. Err

Possible cause	At the time the reagent was aspirated inside the instrument (priming), a motor error, chamber error, sample position error, or right side cover error occurred.
Action to resolve the error	• Press "Execute", then turn OFF the main switch. Check connecting the reagents and waste bottle, then restart the instrument. • Press "Cancel" to return to the previous LCD screen.
Special notes, if error remains	Not ready until the error is resolved.

R-Cover Open

Possible cause	The right side cover was opened.
Action to resolve the error	After closing the right side cover, press "Execute" to clear the error, and the recovery sequence is executed. If the recovery process is completed correctly, then Auto Rinse and background check are performed in sequence, and the screen returns to the Main screen.
Special notes, if error remains	Not ready until the error is resolved.

PLT Noise Error
RBC Noise Error
WBC Noise Error

Possible cause	• Effects of external electric noise interference. Control board malfunction. • Hydraulic line or aperture partly clogged.
Action to resolve the error	Separate the source of electric noise from the instrument.
Special notes, if error remains	Ready for next analysis, however, the following sample results may be incorrect.

PPMC Cont. Error

Possible cause	Error in the motor controller circuit.
Action to resolve the error	Turn the main switch OFF, then turn it ON again.
Special notes, if error remains	Not ready until the error is resolved.

HC Buffer Full
LAN Buffer Full
Print Buffer Full

Possible cause	The amount of data for output or printout is too large to be processed.
Action to resolve the error	Press "Back" to clear the error.
Special notes, if error remains	Not ready until the error is resolved.

No Printer Paper

Possible cause	No printer paper in the built-in thermal printer.
Action to resolve the error	• After refilling paper in the built-in thermal printer, press "Retry" to clear the error. The data currently being printed will restart printing from the beginning of that sample. • After refilling paper in the built-in thermal printer, press "Cancel" to cancel the data being printed. Also discard the waiting data and the error is cleared.
Special notes, if error remains	Not ready until the error is resolved.

Printer Error

Possible cause	• The built-in thermal printer has an error. • The printer cover is open.
Action to resolve the error	• Check if the paper is set correctly and close the cover (page 51). • After checking the built-in thermal printer, press "Retry" button to clear the error. The data currently being printed will restart printing from the beginning of that sample. • After checking the built-in thermal printer, press "Cancel" button to cancel the data being printed. Also discard the waiting data and the error is cleared.
Special notes, if error remains	Not ready until the error is resolved.

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HC ACK Timeout
HC Off-line
HC NAK Retry

Possible cause	• Computer connection cable failure. • Computer main switch is not turned on, or computer not ready for communication. • Host computer serial interface error.
Action to resolve the error	• Inspect the host computer's cable. • Inspect the connection cable to host. • Press "Retry" to clear the error, and the transmission to the host computer is restarted. • Press "Cancel" to clear the error. All output queued to host computer is deleted.
Special notes, if error remains	Not ready until the error is resolved. If the retry action does not resolve the problem, take the host transmission off-line in order to return the instrument to ready mode.

LAN no Response

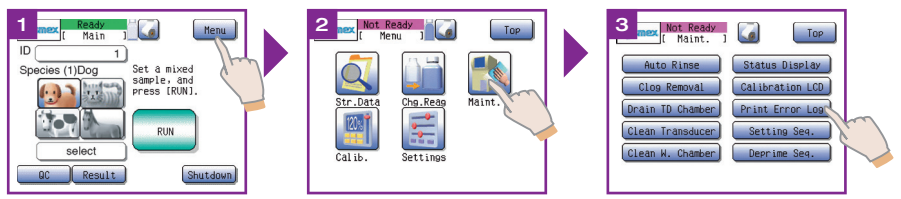
Possible cause	• Computer connecting cable failure. • Computer main switch not turned on, or computer not ready for communication. • LAN connector for host computer failure.
Action to resolve the error	• Check the host computer's cable. • Check the connection cable to host. • Press "Retry" to clear the error, and the transmission to LAN is restarted. • Press "Cancel" to clear the error. All data for LAN output is deleted.
Special notes, if error remains	Not ready until the error is resolved. If the retry action does not resolve the problem, take the host transmission off-line in order to return the Instrument to ready mode.

Print error log

The 10 most recent error messages are printed.

Note

Print error messages prior to contacting your Sysmex service representative.



Press "Menu".

Press "Maint.".

Press "Print Error Log"; the error history will be printed out.

SAFETY INFORMATION & WASTE DISPOSAL

CONTENTS:

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SAFETY INFORMATION

General information

- Before operating this instrument, carefully read this manual. Keep this manual for further reference. Observe all cautionary information in the manual and on the instrument.
- Install and operate this instrument only as instructed in this manual.
- Keep hair, fingers and clothing away from rotating parts.
- If the instrument service is required, contact your Sysmex representative.
- Respecting all first aid steps in your laboratory is essential.

Measures for personnel

- Personnel using this instrument must read the Instructions for Use thoroughly beforehand, and must operate the instrument correctly.
- Personnel who have little or no experience operating the instrument should receive guidance and assistance from an experienced operator.

Hazards of electricity

Risk of electric shock and fire! Danger of life!

- **Never** insert the power plug into power sockets other than AC100-240 V. Please note that the instrument must be grounded.
- Do not touch the electric circuits inside the instrument.
- Avoid damage to the power cable. Do not place any appliances on the power cable. Do not pull the power cord but grip the plug for unplugging.
- **If the instrument emits unusual odors or smoke, or if the instrument leaks:** Switch OFF immediately and unplug the power cable. Contact your Sysmex service representative.

Risk of damage and short-circuit!

- Do not spill blood samples or reagent on the unit.
- Do not put metal objects such as staples or paper clips on the instrument.
- **In the case of a short-circuit:** Switch OFF immediately and unplug the power cable. Contact your Sysmex service representative.
- Before connecting peripheral devices: Switch OFF the devices. Peripheral devices are e.g. a host computer, handheld bar code reader, or the program card.

Biohazards

All parts and surfaces of this instrument must be regarded as potentially infectious, since this instrument analyzes blood. To avoid infections:

- Use of protective garments and gloves when operating, maintaining or servicing the unit.
- **Never** touch waste or parts having been in contact with waste with your bare hands.
- Should you inadvertently come in contact with potentially infectious materials or surfaces, immediately rinse skin thoroughly with water, and follow your hospital or laboratory's prescribed cleaning and decontamination procedures.
- **Control blood** must be regarded as potentially infectious. Wear protective garments and gloves when performing quality control.
- After completion of work, wash hands with disinfectant.

Handling of reagent

Incorrect handling of reagents can cause incorrect analysis results!

- Store the reagents at their specified temperatures.
- Do **not** use reagents after their expiration date.
- Do **not** shake! Do **not** use directly after transport. Handle reagents gently to avoid bubbling.
- Leave the reagent at room temperature (15 – 30°C) for at least 24 hours before using.
- Keep reagent from dust, dirt or bacteria.

Reagents can cause irritation of the eyes, skin and mucous membranes!

- Read the documentation and labeling on all reagents.
- Observe the markings on the reagents' packings as well as the information on the package inserts.
- Avoid direct contact with reagents.
- Should you inadvertently come in contact with a reagent, rinse skin immediately with plenty of water.
- In case of eye contact, rinse at once with plenty of water. See a physician immediately. Observe the material safety data sheet (MSDS).
- If reagent was swallowed, get immediate medical advice. Observe the material safety data sheet (MSDS).

Reagents spilling, risk of electric shock!

- Make sure the reagents used with the instruments are kept level or below the main unit of the instrument. Do **not** put reagents on top of the instrument.
- If reagents are spilt near electrical cables or appliances, there is a risk of electric shock. Switch the instrument off, unplug it and remove the liquid.
- If reagent is spilt, wipe up with a damp cloth.

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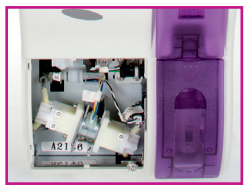
Warning labels on the instrument:

Warning

- This equipment must be grounded.
- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.
- Never open the instrument's cover on the back when the power switch is on. Do not open this cover unless absolutely necessary. There are no user serviceable parts inside.



Warning

Contact with static electricity at the lower left part at the front side may result in abnormal instrument operation.
During operation, do not touch any parts other than the contrast adjustment lever.

Warning, Hot

The printer head may get very hot.

Warning

Static electricity may damage the printer head.
Do not touch.

Warning

When opening the detector cover to clean the transducer aperture, follow the instructions in chapter "Clean aperture of TD chamber" page 53.
Because there is a risk of electric shock, do not open this cover for any other purposes.

Warning

- Static electricity may damage the electronic circuit via the connectors on the right side. Do not touch connector pins with hands.
- Turn the main switch OFF before inserting or removing connectors or program cards.

Electromagnetic compatibility (EMC)

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

- IEC61326-1:1997+A1:1998+A2:2000 (EN61326:97+A1) Equipment for measurement, control and laboratory use EMC Requirements.
- EMS (Electro-magnetic susceptibility (= interference radiation)) For this issue the industrial environment requirements with regards to immunity are fulfilled.
- EMI (Electro-magnetic interference (= resistance to jamming)) For this issue the requirements of class B are fulfilled.

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WASTE DISPOSAL

Instrument and its accessories

- Do not dispose the instrument via public recycling!
- Incineration is recommended!
- Contact your local Sysmex service representative and receive further instructions for disposal!

Biological risks

After becoming waste at end-of-life, this instrument and its accessories are regarded as infectious.
They are exempted from EU directive 2002/96/EC (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.

Stale reagents

Be aware of any warnings and precautions of specific reagents information in this instructions for use.
Disposal procedures shall meet the local legal requirements.

Biological risks

Always wear protective garments and gloves when handling the waste fluid.
After work is completed, wash hands with disinfectant!

Waste fluids of instruments

The waste fluids of instruments contain blood and are therefore regarded as infectious.
Disposal procedures shall meet the local legal requirements.

Biological risks

Always wear protective garments and gloves when handling the waste fluid.
After work is completed, wash hands with disinfectant!

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