AUTOMATED HEMATOLOGY ANALYZER

pocH-100i

INSTRUCTIONS FOR USE

SYSMEX CORPORATION

KOBE, JAPAN

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AUTOMATED HEMATOLOGY ANALYZER

pocH-100i INSTRUCTIONS FOR USE

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

Carefully read "Safety information" and "Measures for personnel" page. 7-2.
For explication of warning signs used in the manual see chapter "Symbols" page. 1.

- The Sysmex pocH-100*i* is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories and physician office laboratories. The pocH-100*i* shall only be used for in vitro analysis of human blood or artificial control blood. Any other use is regarded as non-specified.
  Only reagents and cleaning solutions stated in this manual are permitted for use.
  Observe all cleaning and maintenance procedures at the required intervals.

- 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.

- Data generated by the pocH-100*i* do not replace professional judgment in the determination of a diagnosis or in monitoring patient therapy.

- Operate the instrument as instructed. Reliability of test results cannot be guaranteed if 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 pocH-100*i* is equipped with a rinse cup, and after aspirating a sample or control blood, the piercer (pipette) is automatically cleaned. It is not necessary to wipe the sample pipette (aspirating piercer).

CE-mark

CE

The system described in this manual is marked with a CE-mark which confirms the compliance with the essential requirements of the following European Directives:
98/79/EC (IVD Directive)
2011/65/EU (RoHS Directive)

Overview and Initial settings

Operation

Maintenance/Troubleshooting/Safety

INTRODUCTION

ADDRESSES

Head Office Japan
SYSMEX CORPORATION
1-5-1 Wakinohama-Kaigandori
Chuo-ku, Kobe 651-0073
JAPAN

Americas
SYSMEX AMERICA, Inc.
577 Aptakisic Road
Lincolnshire, IL 60069, U.S.A.
Phone: +1-224-543-9500
Fax: +1-224-543-9505

Europe
European Representative
SYSMEX EUROPE GmbH
Bornbarch 1
22848 Norderstedt, Germany
Phone: +49 40 5 27 26-0
Fax: +49 40 5 27 26-100

Asia-Pacific
SYSMEX ASIA PACIFIC PTE LTD.
9 Tampines Grande, #06-18,
Singapore 528735
Phone: +65-6221-3629
Fax: +65-6221-3687

- **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
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.

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

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

Danger, electric shock
High voltage exceeding 1 kV.

Note
Indicates information which is useful in operating the instrument.

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

ABBREVIATIONS / UNITS

Abbreviations

- CBC : Complete Bloodcell Count
- LD : Lower Discriminator
- LL : Lower Limit
- PD : Pre-diluted mode
- QC : Quality Control
- T1 : Trough Discriminator 1
- T2 : Trough Discriminator 2
- UD : Upper Discriminator
- UL : Upper Limit
- WB : Whole Blood mode

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 leukocytes
- RBC : Number of erythrocytes
- HGB : Hemoglobin concentration
- HCT : Hematocrit value: Erythrocyte ratio of total blood volume
- MCV : Mean corpuscular volume
- MCH : Mean corpuscular hemoglobin
- MCHC : Mean corpuscular hemoglobin concentration
- PLT : Number of platelets
- LYM%/ W-SCR : % of small leukocytes to total WBC
  They are assumed to be equivalent to lymphocytes (white cell-small cell ratio).
- MXD%/ W-MCR : % of middle leukocytes to total WBC
  They are assumed to be equivalent to monocytes, eosinophils, and basophils (white cell-middle cell ratio).
- NEUT%/ W-LCR : % of large leukocytes to total WBC
  They are assumed to be equivalent to neutrophils (white cell-large cell ratio).
- LYM#/ W-SCC : Absolute number of small leukocytes
  They are assumed to be equivalent to lymphocytes (white cell-small cell count).
- MXD #/ W-MCC : Absolute number of middle leukocytes
  They are assumed to be equivalent to monocytes, eosinophils, and basophils (white cell-middle cell count).
- NEUT#/ W-LCC : Absolute number of large leukocytes
  They are assumed to be equivalent to neutrophils (white cell-large cell count).
- RDW-SD : Calculated distribution width of erythrocytes, standard deviation
- RDW-CV : Calculated distribution width of erythrocytes, coefficient of variation
- PDW : Calculated distribution width of platelets
- MPV : Mean platelet volume
- P-LCR : Ratio of large platelets (volume exceeding 12 fL) to the total number of platelets

When analyzing in the pre-diluted mode, only the following eight parameters are output: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT.

NAMES

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INTRODUCTION

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 willful 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 piercer (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 and (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 erythrocytes are dissolved under the influence of the lysis, hemoglobin is released and is converted into red methemoglobin. The leukocytes remain intact.

The volume and number of the leukocytes (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 erythrocytes and platelets are analyzed by the DC detection method.

TECHNICAL BASICS

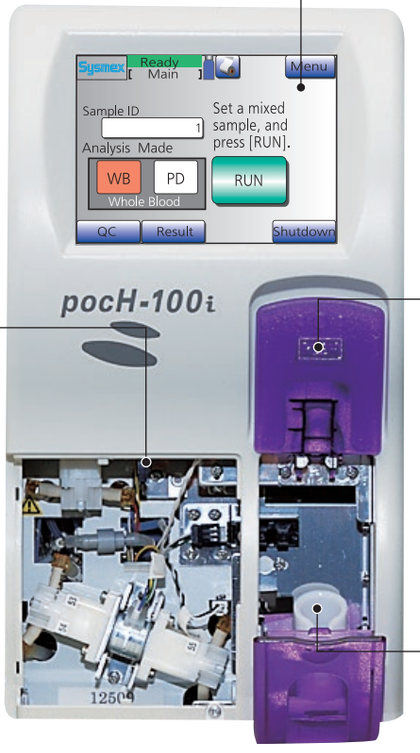
- The calculation of indices is based on international principles in hematology.
- The method for counting blood cells is based on the electric resistance detection principle.
- Hemoglobin concentration is determined by a photometric measuring method.

1.SYSTEM OVERVIEW,TECHNICAL INFORMATION & SETUP : CONTENTS

1.1. SYSTEM OVERVIEW

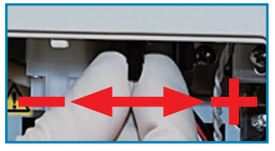
1.1.1. The instrument

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.

Lysing reagent inlet nipple

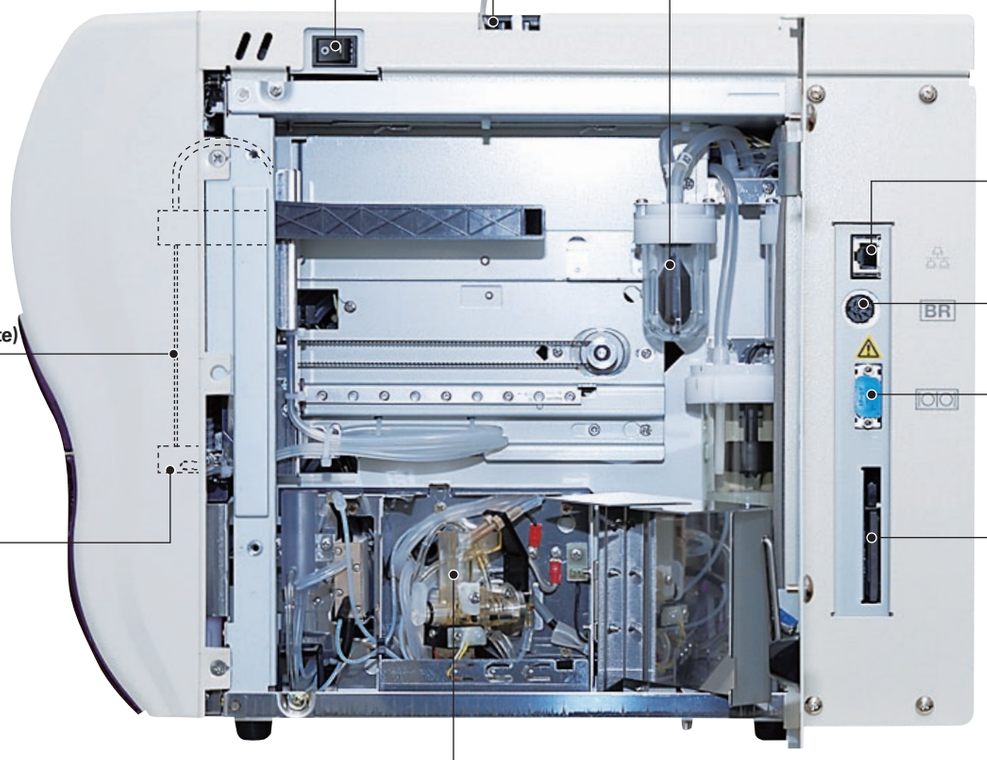
Aspirates lyse reagent.

Waste outlet nipple

Discharges waste.

1.1.SYSTEM OVERVIEW

1.1.1.The instrument



1.1.2. The reagents

pocH-pack 65

Purpose & methodology	Storage & shelf life	Composition
Diluent (blue) • Diluent for use in hematology analyzers. • Ready-to-use diluent for DC detection and whole blood absorbance analysis. **Lysing reagent (purple)** • Reagent for lysing RBC for accurate WBC count and hemoglobin determination • The reagent is colorless, transparent and contains no cyanide. • This is a lysing reagent to lyse the erythrocytes, allows a leukocyte count and volume distribution analysis by the DC detection method. • Hemoglobin is released during RBC lysis, and is converted to the red methemoglobin. • Optional pocH-pack 65XL can be used. The purpose & methodology, Storage & shelf life, and Composition are same with the pocH-pack 65. • A portion of this diluted sample is transferred automatically to the hemoglobin detector, where the absorbance of the red pigment is measured to provide the blood hemoglobin concentration.	Expiration date is shown on the outer packaging. • Unopened packs can be stored for 12 months. Store at 2-30 °C. • Opened, reagent stability is max. 60 days. Use at 15-30 °C.	**Diluent (blue)** • Sodium Chloride 6.38 g/L • Boric acid 1.0 g/L • Sodium Tetraborate 0.2 g/L • EDTA-2K 0.2 g/L **Lysing reagent (purple)** • Sodium Chloride 0.6g/L • Org. quart. ammoniumsalt 8.5g/L

*This is image of the pocH-pack 65. The pocH-pack 65XL does not have waste container.

Warning

Replace any pocH-pack 65/pocH-pack 65XL showing signs of contamination or instability. Using it can result in incorrect analysis results. Do not use once it was frozen.

Incorrect analysis results

- Use whole blood sample collected in EDTA anticoagulant.
- Use pocH-pack 65/pocH-pack 65XL only with Sysmex reagents and analyzers.
- The performance of Sysmex instruments cannot be guaranteed if using other reagents.

1.1. SYSTEM OVERVIEW

1.1.2. The reagents

CELLCLEAN

Purpose & methodology	Storage & shelf life	Composition
• Strong alkaline detergent. • Removes lyse reagents/cellular residuals and blood proteins from the hydraulic systems, transducer, whole blood aspiration piercer (pipette) and the Hgb flow cell.	Expiration date is shown on the outer packaging. • Store in a dark place at 1-30 °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.

Incorrect analysis results

- Use CELLCLEAN only with Sysmex reagents and analyzers.
- The performance of Sysmex instruments cannot be guaranteed if using other detergent.

EIGHTCHECK 3WP

Purpose & methodology	Storage & shelf life	Composition
Control blood EIGHTCHECK • 3WP-N (Normal level) • 3WP-L (Low level) • 3WP-H (High level) test the precision of automated/ semi-automatic hematology analyzers.	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 erythrocytes, fixed animal white blood cells and a platelet component in a medium containing preserratives.

Biological risks

- This product, based on animal blood, should be considered potentially capable of transmitting infectious disease.

Incorrect analysis results

- Use EIGHTCHECK only with Sysmex reagents and analyzers.
- The performance of Sysmex instruments cannot be guaranteed if using other control material.

Important

Do not use for the calibration of the system!

1.2. TECHNICAL INFORMATION

1.2.1. Performance characteristic - Specifications

Ambient temperature	15 °C to 30 °C (ideal operating temperature at 23 °C) (59 °F – 86 °F)
Relative humidity	30% to 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 lbs)
Power supply	100-240 VAC (±10%), 50/60 Hz
Power consumption	150 VA or less
Analysis Parameters	see Chapter "Abbreviations/Units".
Display range	WBC: 0.0 – 299.9 (× 10^3/µL) RBC: 0.00 – 19.99 (× 10^6/µL) HGB: 0 – 25.0(g/dL) PLT: 0 – 1999 (× 10^3/µL)
Background limits	WBC: 0.3 (×10^3/µL) RBC: 0.02 (× 10^6/µL) HGB: 0.1 (g/dL) PLT: 10 (× 10^3/µL)
Analysis time	Approx. 148 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)

1.2. TECHNICAL INFORMATION

1.2.1. Performance characteristic - Specifications

	Parameter	Whole blood mode	Pre-diluted mode
Repeatability (With 95% reliability limit)	WBC (≥ 4.0× 10^3/µL) RBC (≥ 3.00 × 10^6/µL) HGB HCT MCV MCH MCHC PLT (≥ 100 × 10^3/µL) LYM# MXD# (≥ 1.0 × 10^3/µL) NEUT# LYM% MXD% (≥ 12%) NEUT% RDW-SD or RDW-CV PDW MPV P-LCR	3.5% or less 2.0% or less 1.5% or less 2.0% or less 2.0% or less 2.0% or less 2.0% or less 6.0% or less 15.0% or less 30.0% or less 15.0% or less 15.0% or less 30.0% or less 15.0% or less 4.0% or less 12.0% or less 5.0% or less 20.0% or less	6.0% or less 3.0% or less 2.5% or less 3.0% or less 3.0% or less 3.0% or less 3.0% or less 9.0% or less — — — — — — — — — —
Accuracy	WBC RBC PLT	± 3% or ± 0.2 × 10^3/µL or less ± 2% or ± 0.03 × 10^6/µL or less ± 5% or ± 10 × 10^3/µL or less	± 5% or ± 0.3 ×10^3/µL or less ± 3% or ± 0.05 ×10^6/µL or less ± 8% or ± 15 × 10^3/µL or less (Excluding the dilution error at sample preparation.)
Linearity in whole blood mode (applies, when RBC < 7.00 ×10^6/µL)	WBC	1.0 – 9.9 (×10^3/µL) 10.0 – 99.9 (×10^3/µL)	± 0.3 (×10^3/µL) or less ± 3% or less
	RBC	0.3 – 0.99 (×10^6/µL) 1.00 – 7.00 (×10^6/µL)	± 0.03 (×10^6/µL) or less ± 3% or less
	HGB	0.1 – 10.0 (g/dL) 10.0 – 25.0 (g/dL)	± 0.2 (g/dL) or less ± 2% or less
	HCT	10.0 – 33.3 (HCT%) 33.3 – 60.0 (HCT%)	± 1.0 (HCT%) or less ± 3% or less
	PLT	10 – 199 (×10^3/µL) 200 – 999 (×10^3/µL)	± 10 (×10^3/µL) or less ± 5% or less

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: pocH-pack 65/pocH-pack 65XL Detergent: CELLCLEAN Control material: EIGHTCHECK-3WP
Aspirated sample volume	in whole blood mode: approx. 15 µL in pre-diluted mode: approx. 200 µL of the diluted sample; a minimum of 20 µL capillary blood is required.
Number of analyses that can be performed with 1 pocH-pack 65/pocH-pack 65XL	pocH-pack 65: Approximately 65 pocH-pack 65XL: Approximately 240 (These numbers are cycle counts.)

1.2.2. System limitations – Interferences

	Cause	Potential Detection
WBC: false high leukocyte count	Lyse resistant erythrocytes	Abnormal WBC histogram (WL flag)
	Cold agglutinins / cryoglobulins	Increased MCV, increased MCHC due to decreased HCT and RBC
	Platelet aggregation	Abnormal WBC histogram (WL flag) and Abnormal PLT histogram (PU flag)
	Nucleated erythrocytes	Abnormal WBC histogram (WL flag)
RBC: false low erythrocyte count	Cold agglutinins	Increased MCV, increased MCHC due to decreased HCT
	Microcytosis (severe)	Low MCV
	Fragmented erythrocytes	Abnormal RBC histogram (RL flag) and Abnormal PLT histogram (PU flag)
HGB: false high haemoglobin measurement	Lipaemia	MCHC > 36.5 g/dL in severe cases
	Abnormal protein	MCHC > 36.5 g/dL in severe cases
	Leukocytosis	WBC >100,000/µL
HCT: false low haematocrit measurement	Cold agglutinins	Increased MCV and increased MCHC
	Fragmented erythrocytes	Abnormal RBC histogram (RL flag) and abnormal PLT histogram (PU flag)
HCT: false high haematocrit measurement	Leukocytosis	Very high leukocyte count with low erythrocyte count present
PLT: false low platelet count	Platelet aggregation	Abnormal PLT histogram (PU flag)
	Giant platelets	Abnormal PLT histogram (PU flag)
PLT: false high platelet count	Microcytic erythrocytes	Low MCV
	Fragmented erythrocytes	Abnormal RBC histogram (RL flag) and abnormal PLT histogram (PU flag)

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 patient population, patient diagnosis, age, medications, etc. Customers can perform studies in order to show how their specific patient populations are affected by various conditions.

1.3. SETUP

1.3.1. Check parts

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

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

1x
Spacer No.192
(13 mm)
365-9452-9
*1

1x
Sample tube adapter
13 mm Sysmex white
CJ296916

1x
Sample tube adapter
green (Control blood)
442-3051-2

1x
Sample tube adapter
red (S-MONOVETTE
SARSTEDT 2.7mL)
AA155506

1x
Thermal paper
CL5840
AH042068

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

2x
Fuse 02153.15MXP
250V T 3.15A H
AL039459

1x
Container spout kit
No.7
purple (Lysing reagent)
033-0414-2

1x
Container spout kit
No.6
blue (Diluent)
033-0403-1 for pocH-pack 65
033-0405-9 for pocH-pack 65XL

1x
Container spout kit
No.7
purple (Lysing reagent)
033-0412-5

1x
Waste bottle
assy POCH
(C1/WITH FSW)
033-0041-1
*2

1x
Container Spout Kit
No.6
red (Waste)
033-0404-5

1x
Tube polyurethane
4MMID × 6MMOD
442-5338-7

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

1x
Wiring cord
No.2188
963-0801-5

1x
Screwdriver (+)
A6002 Philips
462-2387-0

1x
Screwdriver (-)
A6012 Standard
462-2388-3

- Instructions for Use
  CG184474

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 (17.5kg).
  -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.

*1 This part is for open pipette.

*2 The waste bottle assy POCH (C1/WITH FSW 033-0041-1) might be necessary in case of using pocH-pack 65XL (optional).

1.3.2. Optional adapters

Adapter name	Product code	Adapter color
Micro tube adapter (BD Microtainer tube with EDTA, Product No. 365975)	CA392678	Orange
Micro tube adapter (BD Microtainer tube with EDTA, Product No. 365955)	CH515979	Purple
Micro tube adapter (CAPIJECT (TERUMO))	CE466834	Yellow
Micro tube adapter (MICROVETTE (SARSTEDT))	BP006581	Blue
Sample tube adapter (for 15mm diameter tube)	AJ501289	Black

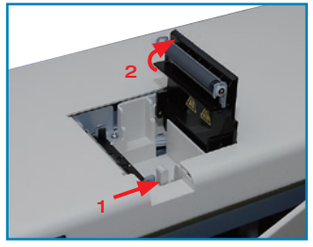
Important

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

1.3. SETUP

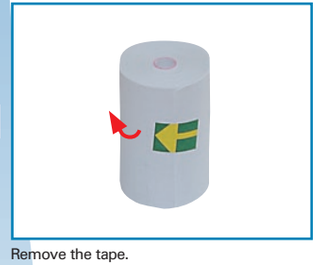
1.3.3. Insert paper roll

1 **Open the paper holder.**



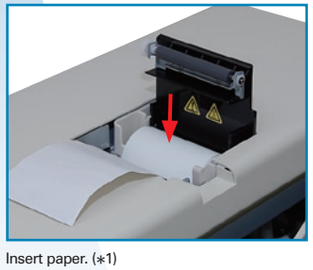
Open paper holder by pushing the knob.

2 **Remove the tape.**



Remove the tape.

3 **Insert paper.**



Insert paper. (∗1)

4 **Close the pepar holder.**

Close lid. (∗2)

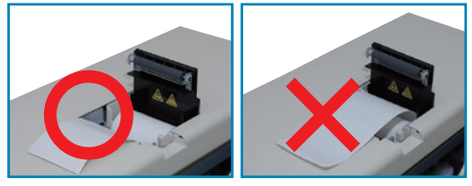
Warning, Hot

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

Important

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

∗1. Insert the paper correctly. If inserted at an angle, the paper may jam.



Note

∗2. The printer cover must be closed ("clicking" sound). If the cover is not closed completely, an error message will be displayed.

1.3.4. Connect the pocH-pack 65/pocH-pack 65XL

pocH-pack 65

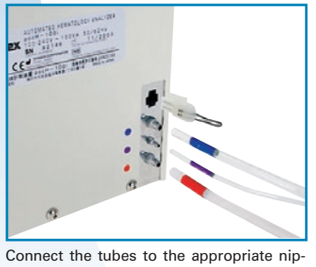
1 **Set the reagents and remove caps.**

Set the reagents and remove caps.

2 **Insert container spout kits/ float switch and reapply the caps.**

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

3 **Connect the tubes to the nipples.**



Connect the tubes to the appropriate nipples. Connect the wiring cord.

pocH-pack 65XL

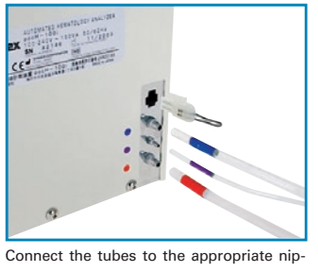
Set the reagents and remove caps.

Set the reagents and remove caps. *

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

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

Connect the tubes to the nipples.



Connect the tubes to the appropriate nipples. Connect the wiring cord.

4 **Fix tubes together.**

Fix tubes together.

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.

* The pocH-pack 65XL does not have waste container.

1.3. SETUP

1.3.5. Barcode reader (optional)

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

1 **Plug cable into "BR" connection.**

Plug cable into "BR" connection.

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

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 Modulus 10	Max. 14 digits (sample ID) Max. 14 digits (sample ID) + 1 digit (check digit) = Max. 15 digits
NW-7	None Modulus 11-16	Max. 15 digits (sample ID) Max. 15 digits (sample ID) + 1 digit (check digit) = Max. 16 digits
CODE 39	None Modulus 43	Max. 15 digits (sample ID) 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

Important

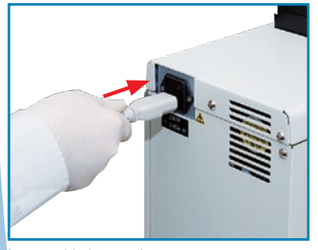
- Disconnect the instrument's mains before connecting the peripheral device. Else, the two devices may not interchange any data.
- In identifying patient samples, maximum integrity of data is required.
  To avoid barcode identification mistakes, use a check digit whenever the sample barcode is used.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

Note

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

1.3.6. Power cord

1 **Insert cable into socket.**



Insert cable into socket.

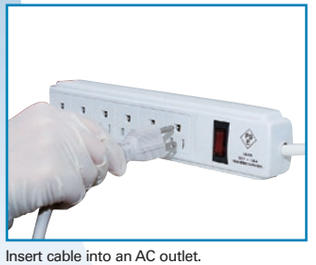
Danger, electric shock

Improper grounding of the instrument can cause electrical shock.

Important

The instrument runs on 100-250V AC, 50/60Hz.

2 **Insert cable into an AC outlet.**

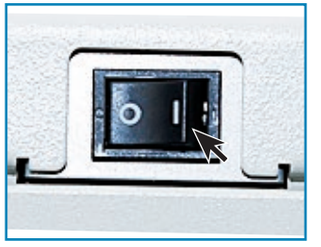


Insert cable into an AC outlet.

1.3.7. Switch ON

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

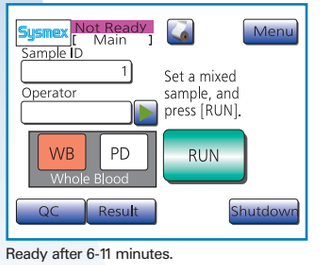
1 **Switch ON.**



Switch ON.

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

3 **Ready after 6-11 minutes.**



Ready after 6-11 minutes.

Note

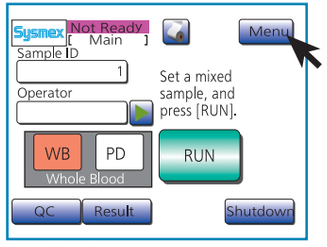
In this section, only the settings relevant for installation are described. For details on all possible settings see "Settings & Calibration" page 5-1.

1.3. SETUP

1.3.8. Set language

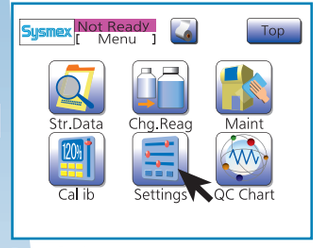
Default setting is English.

1 **Press "Menu".**



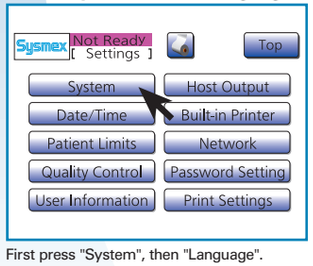
Press "Menu".

2 **Press "Settings".**



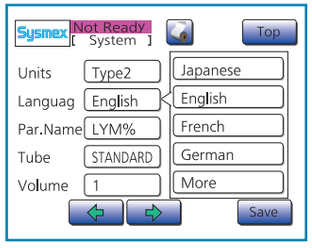
Press "Settings".

3 **Press "System", then "Language".**



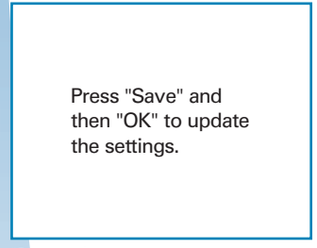
First press "System", then "Language".

4 **Select the language.**



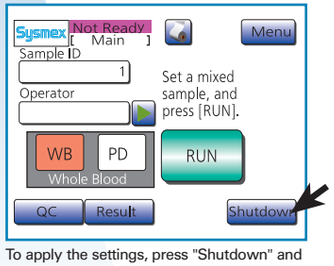
Select the language.

5 **Press "Save".**



"Save" settings.

6 **To apply the settings, press "Shutdown".**



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

7 **After completion of the shutdown process, Switch OFF.**

After completion of the shutdown process, Switch OFF.

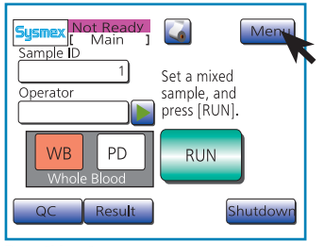
Note

In this section, only the settings relevant for installation are described. For details on all possible settings see "Settings & Calibration" page 5-1.

1.3.9. Date & Time

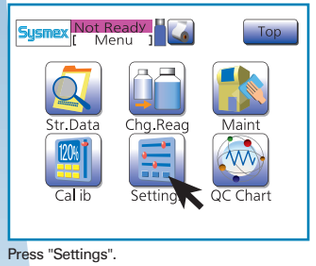
To be able to identify analysis results properly, set time and date correctly.

1 **Press "Menu".**



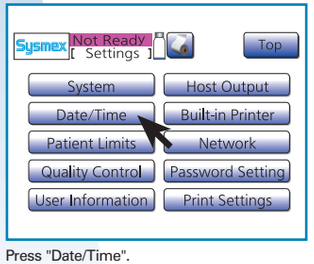
Press "Menu".

2 **Press "Settings".**



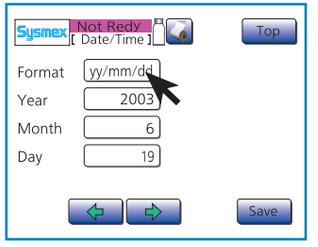
Press "Settings".

3 **Press "Date/Time".**



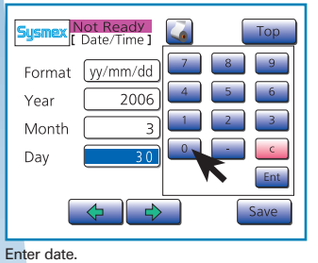
Press "Date/Time".

4 **Choose Format.**



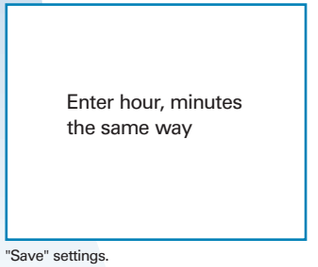
Choose Format. (∗1)

5 **Enter date.**



Enter date.

6 **Press "Save".**



"Save" settings.

Note

- In this section, only the settings relevant for installation are described. For details on all possible settings see "Settings & Calibration" page 5-1.
- When time switches to "standard or daylight saving time" respectively, the clock must be set accordingly.

∗1. 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.

1.3. SETUP

1.3.10. LCD contrast

Adjust the LCD contrast to your comfort.

1 **Open front cover.**

Open front cover.

2 **Adjust contrast.**

darker brighter

Adjust contrast.

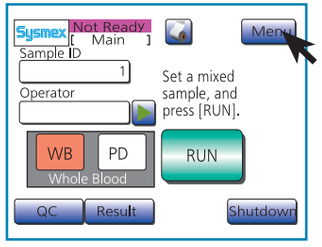
Important

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.

1.3.11. Sample collection tube

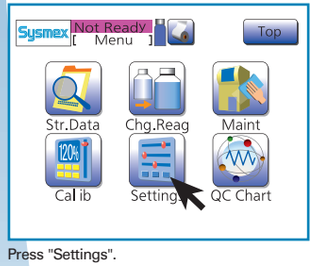
S-MONOVETTE (SARSTEDT) tube has a different bottom shape compared to the other sample tubes.

1 **Press "Menu".**



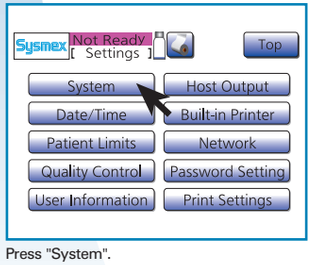
Press "Menu".

2 **Press "Settings".**



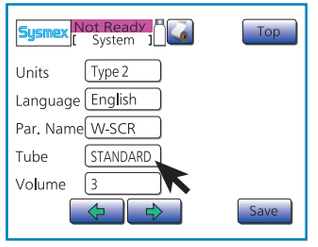
Press "Settings".

3 **Press "System".**



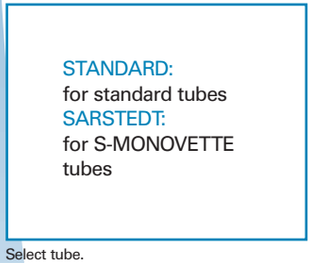
Press "System".

4 **Press "Tube".**



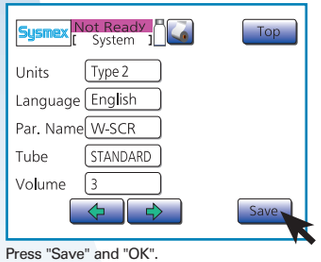
Press "Tube".

5 **Select tube.**



Select tube.

6 **Press "Save" and "OK".**



Press "Save" and "OK".

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 5-1.

2. ANALYSIS : CONTENTS

2.1. ANALYSIS

2.1.1. Screen display

The LCD screen shows the available functions and submenus.

Screen name

Remaining reagent volume indicator

Use this indicator only as a guide.

Paper feed

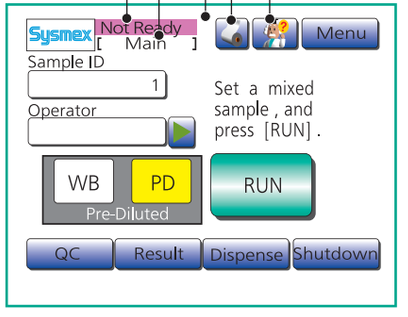
Feed paper on any screen.

Help

Blinks in case of an error.

Instrument status indicator

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



Alarm

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

Timer functions

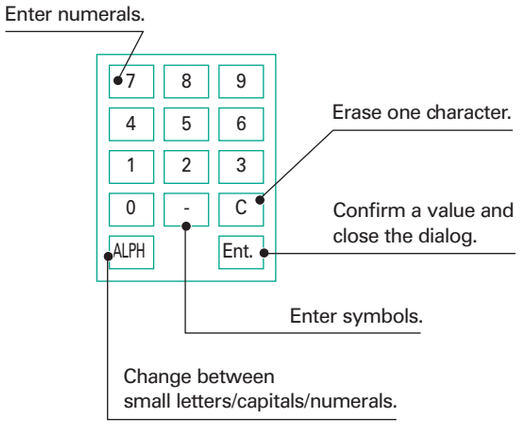
LCD backlight dimmer	Dims backlight after 10 min.
Automatic rinse timer	Prevents drying up of the hydraulic lines, after 2 hours of non operation.
Shutdown warning timer	Reminder to shut down the device after 24h of continuous operation.

Important

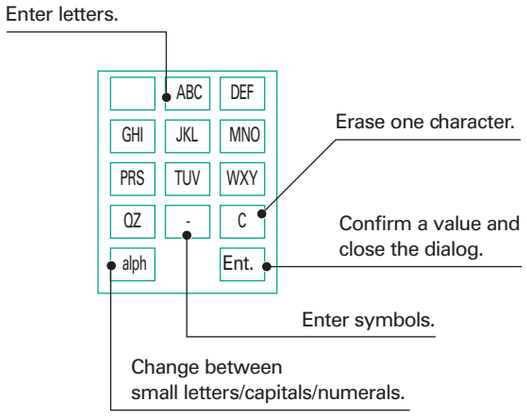
The alarm can be stopped by pressing "OK" on the error dialog box. Pressing the -button displays the help menu. All other buttons are not functional during an alarm.

2.1. ANALYSIS

2.1.2. Numerical keys dialog



2.1.3. 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".

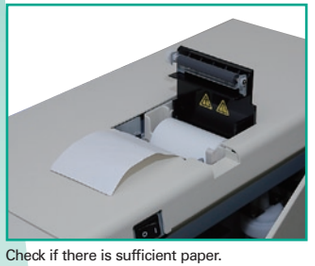
A → Ent. → B → Ent.

2.1.4. Prior to analysis

1 **Check the power cable connection.**

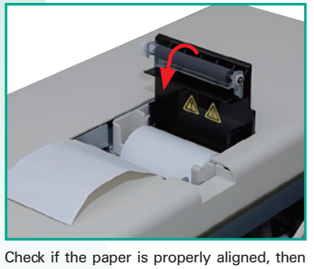
Check if power cable is connected.

2 **Check if there is sufficient paper.**



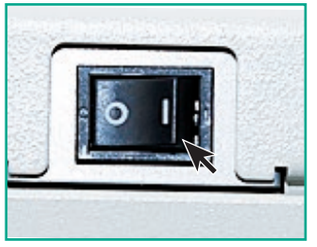
Check if there is sufficient paper.

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



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

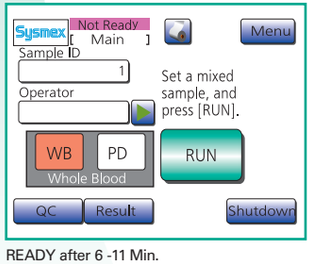
4 **Switch ON.**



Switch ON.

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

6 **READY after 6 -11 Min.**



READY after 6 -11 Min.

7 Perform mandatory quality check prior to operation. See "Quality control" page 3-1.

Important

Use only printer paper recommended by Sysmex. Low quality paper may shorten the life of the printer head.

Note

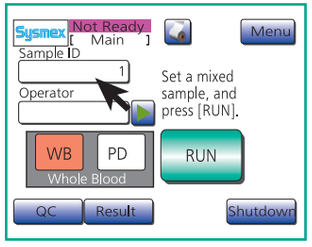
If there is an error, press "OK" and follow the screen instructions.

2.1. ANALYSIS

2.1.5. a) Analysis in whole blood (WB) mode (for close piercer)

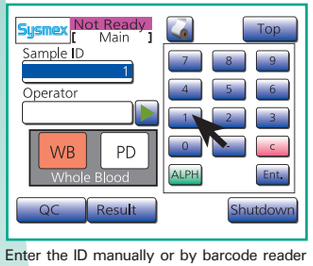
- Check blood with added EDTA anticoagulant, aspirated sample volume ~15µL.
- Required sample volume: >1mL for the ø 13mm tube, > 500µL for the micro tube.

1 **Press "Sample ID".**



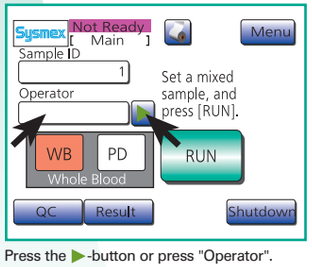
Press "Sample ID".

2 **Enter the ID and press "Ent.".**



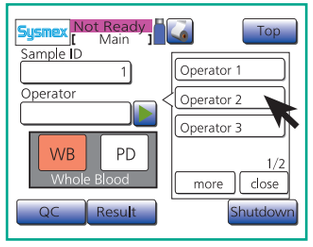
Enter the ID manually or by barcode reader and press "Ent.".

3 **Press the ▶-button or press "Operator".**



Press the ▶-button or press "Operator".

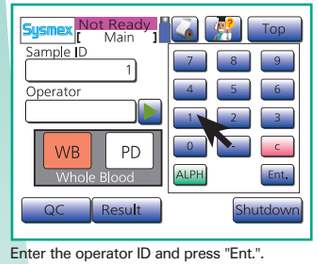
4a **Select a operator ID.**



Select a operator ID.

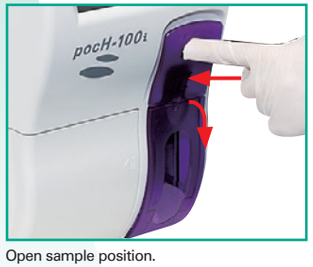
or

4b **Enter the operator ID and press "Ent.".**



Enter the operator ID and press "Ent.".

5 **Open sample position.**



Open sample position.

6 **Insert adapter.**

Insert the correct adapter.

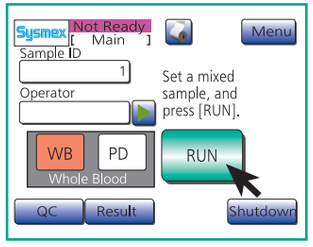
7 **Mix the sample.**

Gently mix the sample. Analyze with or without pierceable cap.

8 **Insert the sample tube and close the door.**

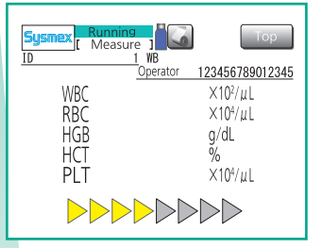
Insert sample tube and close the door. (∗1)

9 **Press "RUN".**



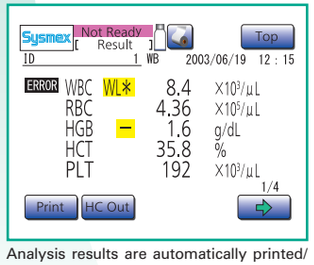
Press "RUN".

10 **The analysis starts.**



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

11 **Analysis results are automatically printed according to settings.**



Analysis results are automatically printed/ sent to host computer according to settings(from page 5-2).

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 micro tubes, place them in the correct adapter and make sure the cap is removed.
- Only use pierceable rubber caps. To avoid introducing rubber fragments from the cap affecting the measurements, use each rubber cap only once.
- Using resin caps may damage the piercer! Do not analyze with resin capped tubes!

*1. Do not open the sample position while aspirating!

Note

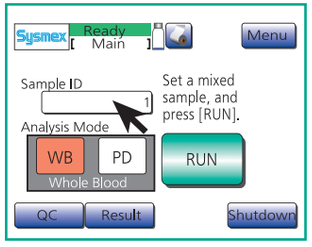
The sample ID can be set up to 15 characters. If a sample's ID is set to „0", the result for this sample will not be stored.

2.1. ANALYSIS

2.1.5. b) Analysis in whole blood (WB) mode (for open pipette)

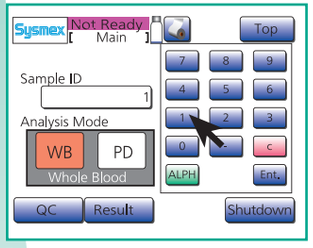
- Check blood with added EDTA anticoagulant, aspirated sample volume ~15µL.
- Required sample volume: >100µL for the ø 13mm tube, > 50µL for the micro tube.

1 Press "Sample ID".



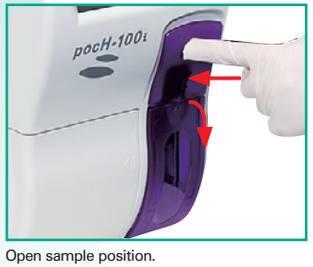
Press "Sample ID".

2 Enter the ID and press "Ent.".



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

3 Open sample position.



Open sample position.

The sample tube caps have to be removed before measurement.

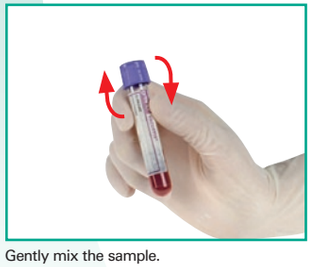
4 Set the spacer to an adapter.

Set the spacer to an adapter.

5 Insert adapter.

Insert the correct adapter.

6 Mix the sample.



Gently mix the sample.

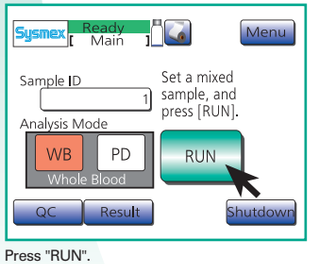
7 Remove the cap.

Remove the cap.

8 Insert the sample tube and close the door.

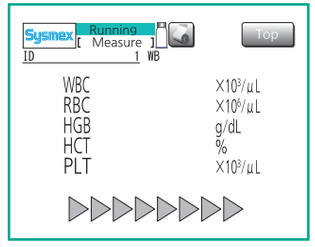
Insert sample tube and close the door. (*1)

9 Press "RUN".



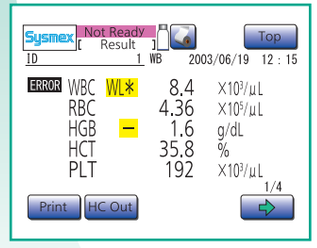
Press "RUN".

10 The analysis starts.



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

11 Analysis results are automatically printed according to settings.



Analysis results are automatically printed/ sent to host computer according to settings (from page 5-2).

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 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.

*1. 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.

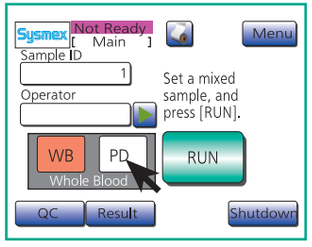
2.1. ANALYSIS

2.1.6. Analysis in pre-diluted blood (PD) mode

- Check blood which has been collected in skin puncture diluted at the ratio 1:26. Aspirated sample volume~200 µL. Use of EDTA anticoagulant.
- Required sample volume: >20 µL for the ø 13mm tube, > 500 µL for the micro tube.

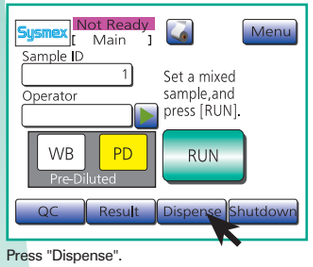
* Steps 11 and 12 are not necessary in case of open pipette.

1 Press "PD".



Press "PD".

2 Press "Dispense".



Press "Dispense".

3 Open sample position.

Open sample position.

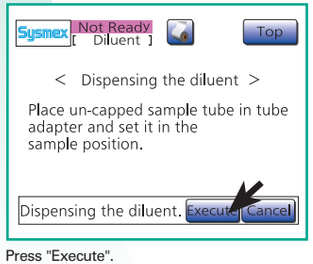
4 Insert adapter.

Insert the correct adapter.

5 Insert an empty micro tube (cap removed) and close the door.

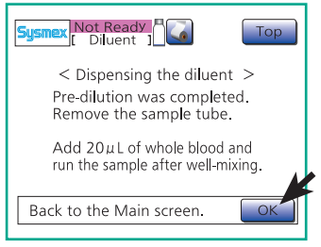
Insert an empty micro tube (cap removed) and close door.

6 Press "Execute".



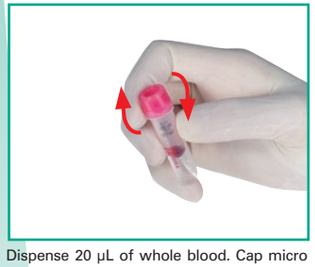
Press "Execute".
500 µL of diluent are dispensed into the tube.

7 After dispensing, press "OK" and remove the micro tube.



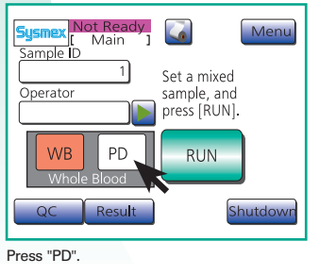
After dispensing, press "OK" and remove the micro tube.

8 Dispense 20 µL of whole blood.



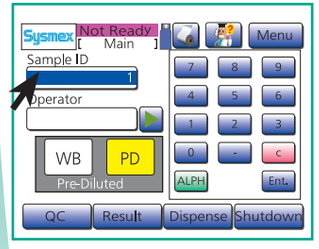
Dispense 20 µL of whole blood. Cap micro tube and mix gently.

9 Press "PD".



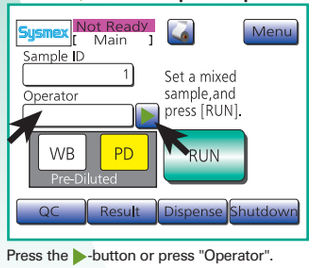
Press "PD".

10 Press "Sample ID". Enter the ID and press "Ent.".



Press "Sample ID", enter the ID manually or by barcode reader and press "Ent.".

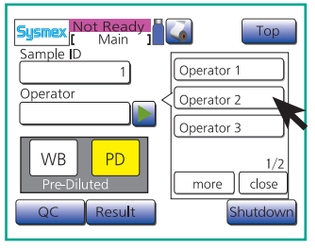
11 Press the ▶ -button or press "Operator".



Press the ▶-button or press "Operator".

12a

Select a operator ID .

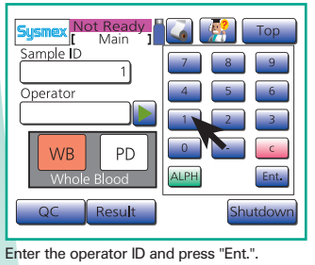


Select a operator ID .

or

12b

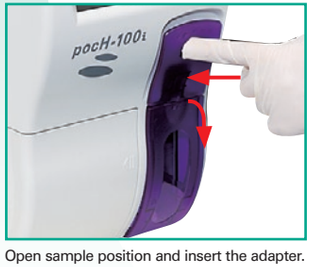
Enter the operator ID and press "Ent.".



Enter the operator ID and press "Ent.".

13

Open sample position and insert the adapter.



Open sample position and insert the adapter.

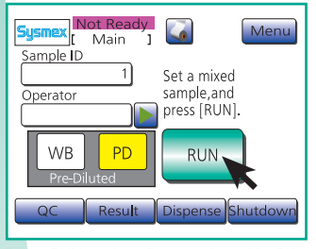
14

Remove the cap, set sample into the adapter and close the door.

Remove the cap, set sample into the adapter and close the door.

15

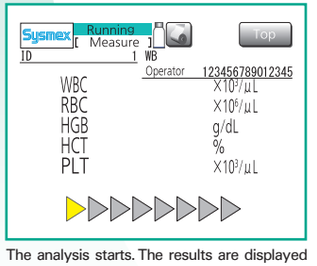
Press "RUN".



Press "RUN" and confirm warning with "OK".

16

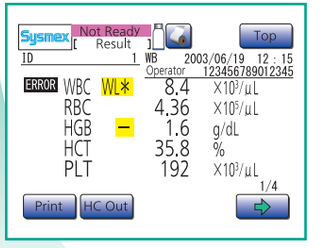
The analysis starts.



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

17

Analysis results are automatically printed according to settings.



Analysis results are automatically printed/ sent to host computer according to settings (from page 5-2).

Incorrect analysis results

- All performance data cited in this manual were generated using specimens in EDTA anticoagulant. Results may differ using other anticoagulants.
- To prevent aggregation, the sample should be diluted and analyzed immediately after collection, else correct analysis results will not be obtained.

Important

- Do not open the sample position while aspirating!
- When using micro tubes, place them in the correct adapter and make sure the cap is removed.

Note

- The sample ID can set be up to 15 characters. If a sample's ID is set to „0" the result for this sample will not be stored.
- In the pre-diluted mode only the 8 CBC parameters are displayed.
- When analyzing in the pre-diluted mode, the histogram curves, distribution analysis data and the distribution flags are not displayed.
  The titles and axes of the Histograms are displayed.

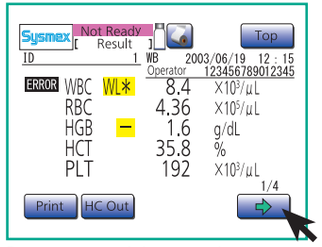
2.1. ANALYSIS

2.1.7. 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 100 samples.
- Values outside the specified upper and lower limits are marked, for further analysis and checking.

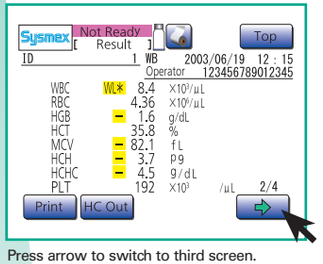
The analysis result screen is composed of 4 LCD screen pages.

The first screen



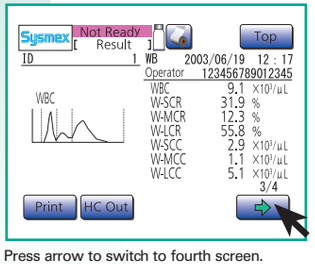
Press arrow to switch to second screen.

The second screen



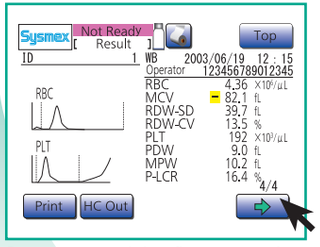
Press arrow to switch to third screen.

The third screen



Press arrow to switch to fourth screen.

The fourth screen



Press arrow to switch to first screen again.

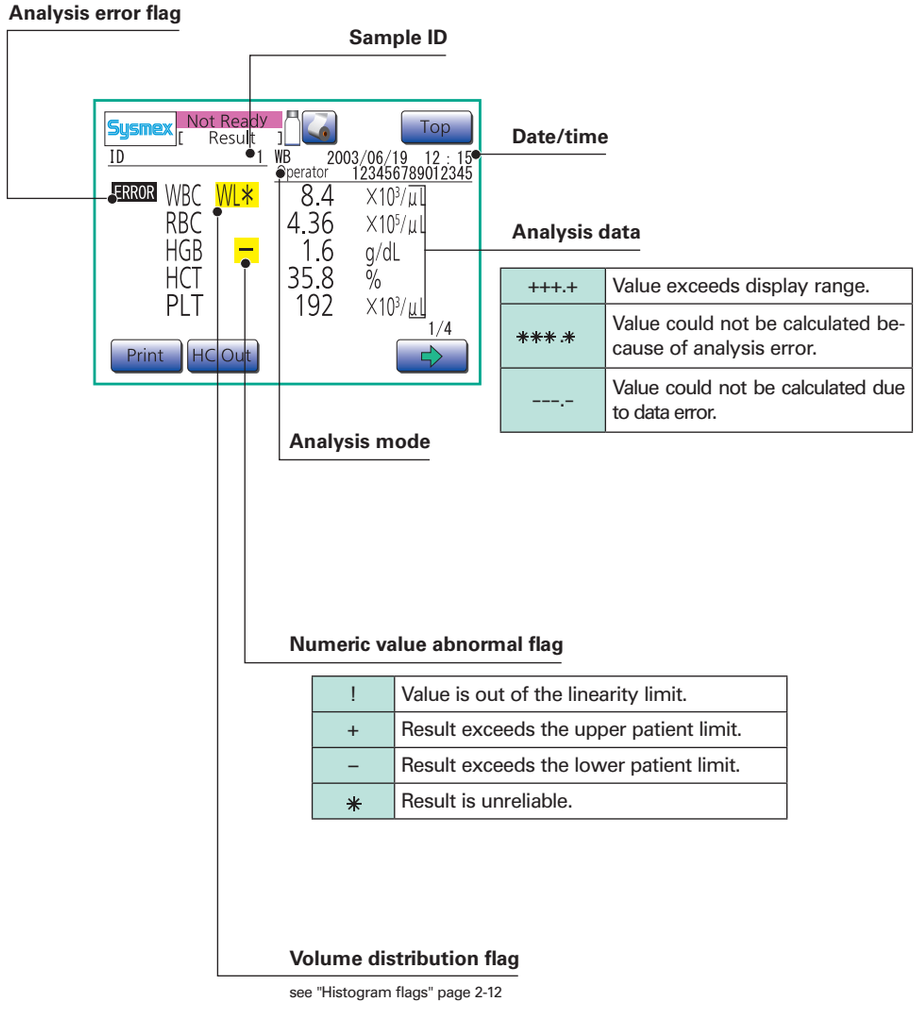
Note

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%, MXD%, NEUT%, LYM#, MXD# and NEUT# parameters, or alternatively WBC, W-SCR, W-MCR, W-LCR, W-SCC, W-MCC and W-LCC parameters.

Fourth screen
Displays analysis results of RBC, MCV, RDW-SD, RDW-CV, PLT, PDW, MPV, and P-LCR parameters.



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

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

2.1.8. Histogram flags

The pocH-100*i* 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.

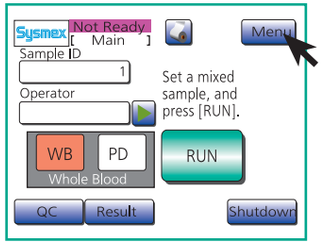
Flag	Probable sample cause	Correction				
		Check smear.	Warm sample and repeat analysis.	Manual count.	Wash blood cells.	
WL	Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase in large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids.	○	○			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-erythrocytes.	○	○	○		
PL	Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells.					
WU	Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc.	○	○			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.	○	○			
PU	Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, platelet aggregation or agglutination, presence of micro-erythrocytes.	○	○	○		
DW (RBC)	Significant anisocytosis, etc.	○				
DW (PLT)	Inclusion of fragmented red blood cells, nonuniformity in size of platelets, effects of cryoglobulins, etc.	○				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.	○				
MP (PLT)	Platelet aggregation, low platelet count.					
T1	Incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC-Histogram not to be separated, presence of CML or other immature granulocytes.	○	○			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.
T2	Aged sample, incomplete lysing of red blood cells, etc., causing the last two WBC populations in the WBC-Histogram not to be separated, presence of CML or other immature granulocytes.					
F1, F2, F3	Sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc., presence of CML or other immature granulocytes.					
AG	Presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids, etc.	○	○		○	

2.1. ANALYSIS

2.1.9. Stored data

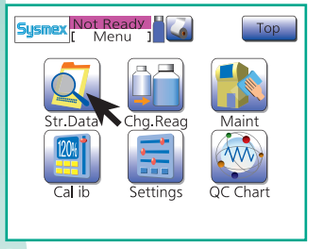
The most recent 100 analysis results are automatically stored and can be recalled.
If there are 100 results stored, the fresh set will cancel the oldest.

1 Press "Menu".



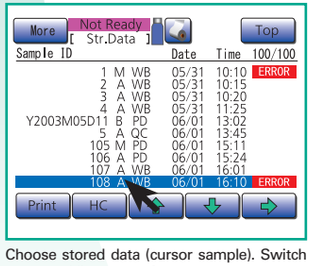
Press "Menu".

2 Press "Str. Data".



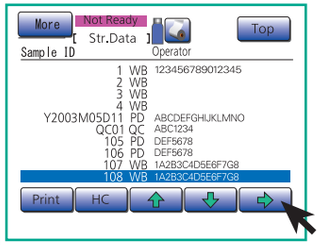
Press "Str. Data".

3 The first list screen



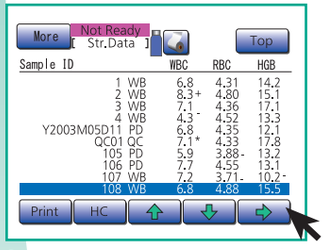
Choose stored data (cursor sample). Switch to second list screen for current cursor sample by pressing "→".

4 The second list screen



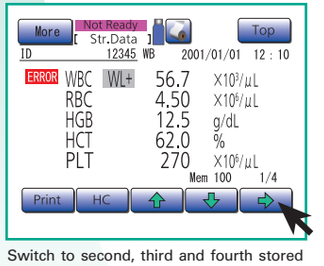
Switch to third list screen for current cursor sample by pressing "→".

5 The third list screen



Switch to fourth list screen, and to first stored data screen for current cursor sample by pressing "→".

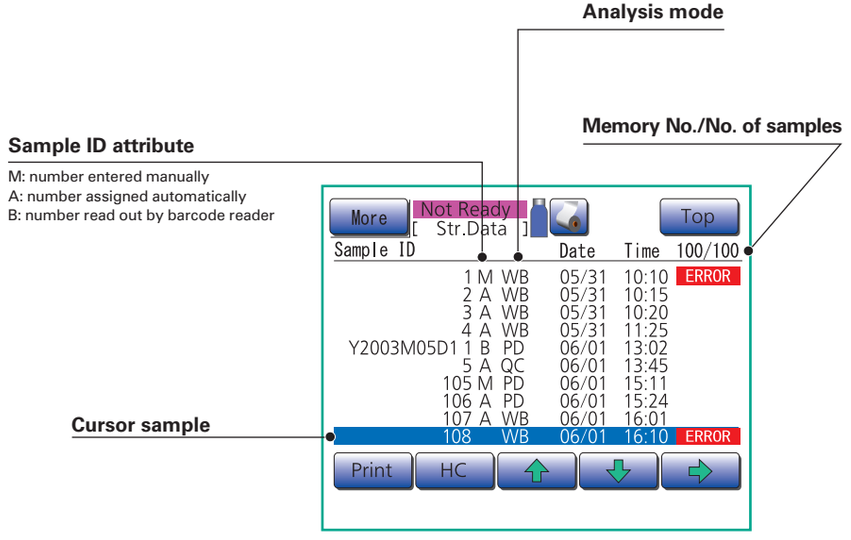
6 First stored data screen



Switch to second, third and fourth stored data screen by pressing "→".

Important

In the list screens and the stored data screens, the data can only be displayed in the order of the operation counter.

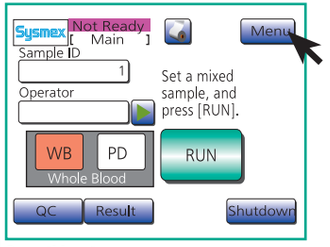


Analysis data for following parameters:

First stored data screen	WBC, RBC, HGB, HCT, PLT
Second stored data screen	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT
Third stored data screen	WBC, LYM% (W-SCR), MXD% (W-MCR), NEUT% (W-LCR), LYM# (W-SCC), MXD# (W-MCC), NEUT# (W-LCC)
Fourth stored data screen	RBC, MCV, RDW-SD, RDW-CV, PLT, PDW, MPV, P-LCR

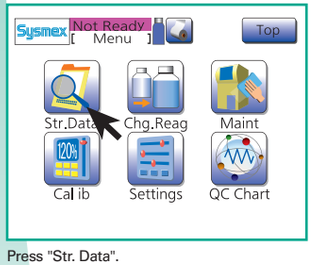
2.1.10. Print automatically stored data

1 **Press "Menu".**



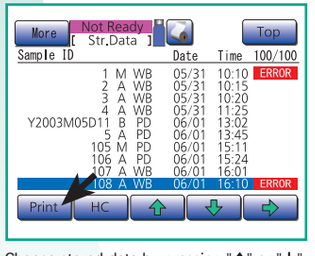
Press "Menu".

2 **Press "Str. Data".**



Press "Str. Data".

3 **Choose stored data and press "Print".**

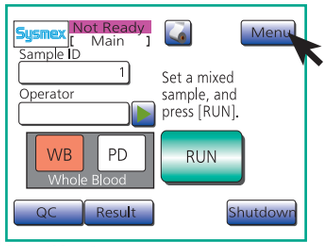


Choose stored data by pressing "↑" or "↓".
Then press "Print".

2.1.11. Send data to host computer

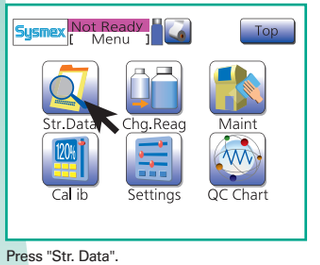
Stored data can be sent to host computer via serial port or LAN.

1 **Press "Menu".**



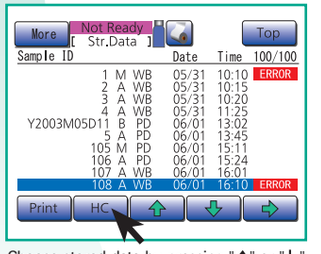
Press "Menu".

2 **Press "Str. Data".**



Press "Str. Data".

3 **Choose stored data and press "HC".**



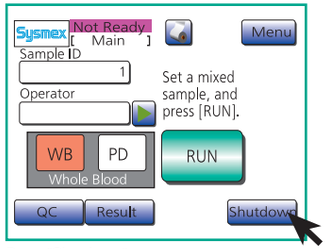
Choose stored data by pressing "↑" or "↓".
Then press "HC".

2.1. ANALYSIS

2.1.12. Shutdown

Press "Shutdown".

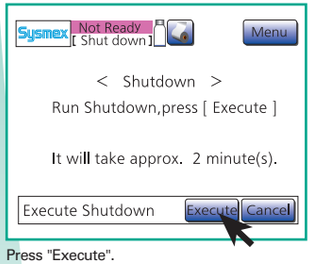
1



Press "Shutdown".

Press "Execute".

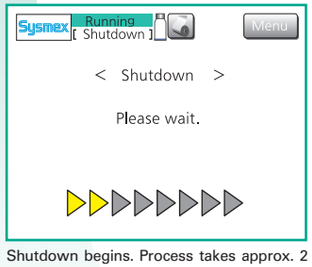
2



Press "Execute".

Shutdown begins.

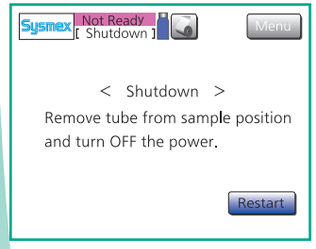
3



Shutdown begins. Process takes approx. 2 min.

Shutdown completed.

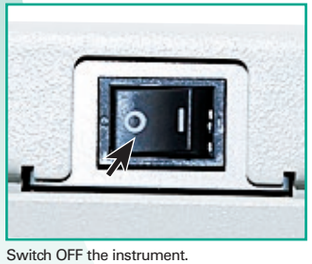
4



Shutdown completed.

Switch OFF .

5



Switch OFF the instrument.

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

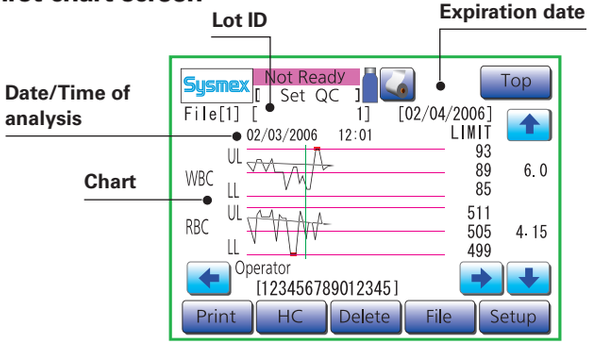
Execute a shutdown at least every 24 hours. This may prevent damage to the instrument.

3. QUALITY CONTROL : CONTENTS

3.1. QUALITY CONTROL

3.1.1. Quality control chart screen

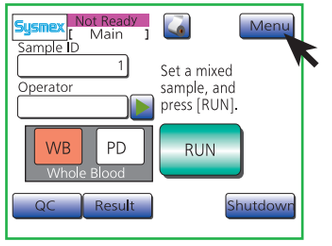
First chart screen



Data for following parameters

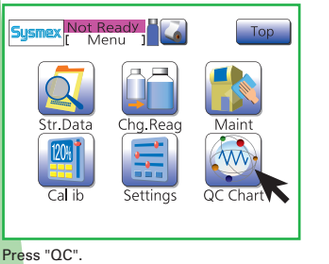
First chart screen	WBC, RBC
Second chart screen	HGB, HCT
Third chart screen	MCV, MCH
Fourth chart screen	MCHC, PLT
Fifth chart screen	LYM%, MXD%
Sixth chart screen	NEUT%, LYM%
Seventh chart screen	MXD#, NEUT#
Eighth chart screen	W-SMV, W-LMV
Ninth chart screen	RDW-SD, RDW-CV
Tenth chart screen	PDW, MPV
Eleventh chart screen	P-LCR

Press "Menu".



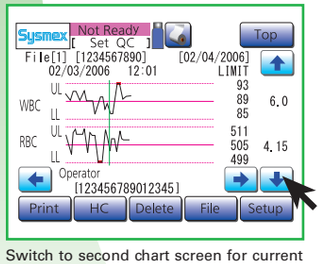
Press "Menu".

Press "QC".



Press "QC".

Switch to second chart screen.

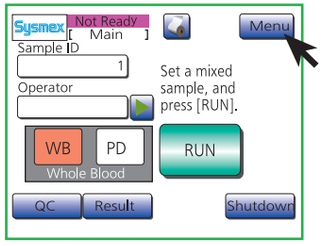


Switch to second chart screen for current cursor sample by pressing "↓".

3.1. QUALITY CONTROL

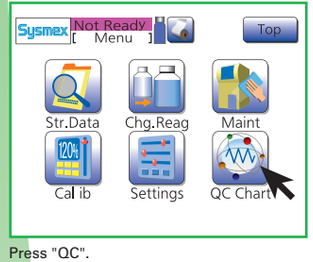
3.1.2. Print control chart

Press "Menu".



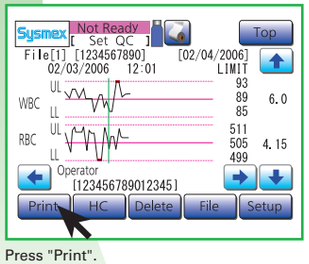
Press "Menu".

Press "QC".



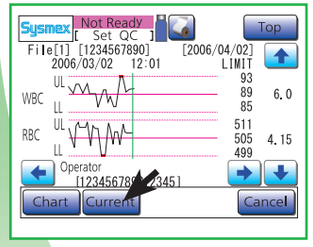
Press "QC".

Press "Print".



Press "Print".

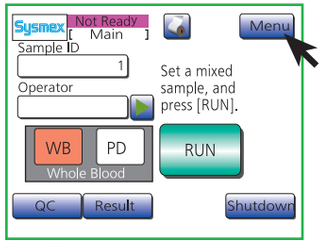
Press "Chart" or "Current".



Press "Chart" to print charts of all parameters or "Current" to print data at cursor position.

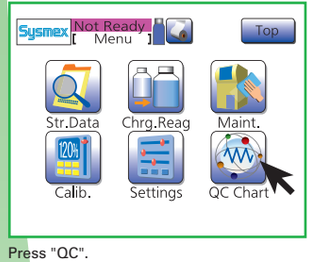
3.1.3. Output to host computer

Press "Menu".



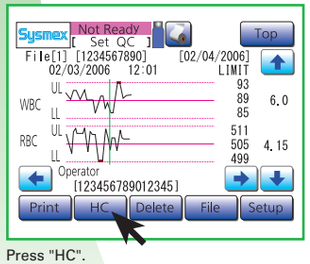
Press "Menu".

Press "QC".



Press "QC".

Press "HC".



Press "HC".

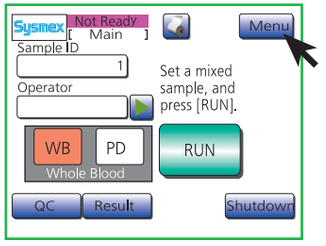
Output to computer.

Serial port (RS-232C) or LAN (Ethernet).

Output to computer.

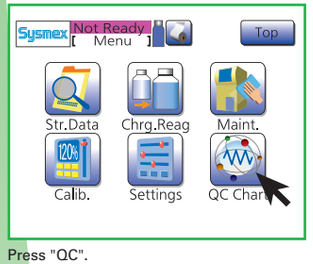
3.1.4. Delete data

1 **Press "Menu".**



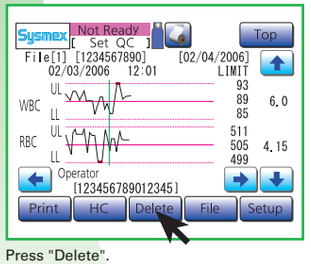
Press "Menu".

2 **Press "QC".**



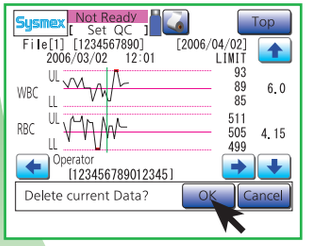
Press "QC".

3 **Press "Delete".**



Press "Delete".

4 **Press "OK".**

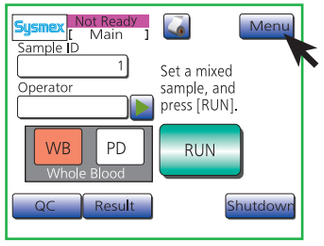


Press "OK".

3.2. PERFORMING QUALITY CONTROL

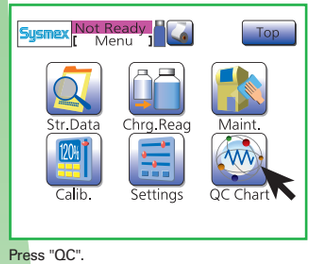
3.2.1. STEP 1: a) Settings for control blood information (quality control file)

1 Press "Menu".



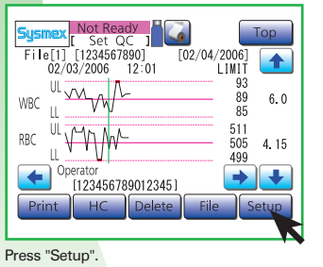
Press "Menu".

2 Press "QC".



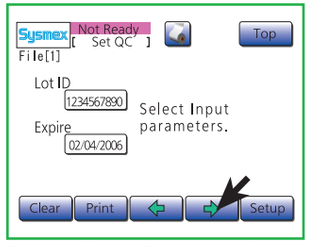
Press "QC".

3 Press "Setup".



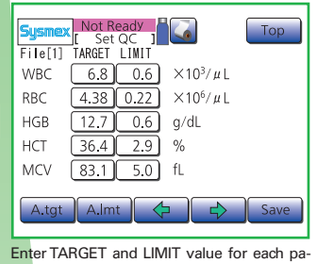
Press "Setup".

4 Enter "Lot ID" and "Expire", then press "→".



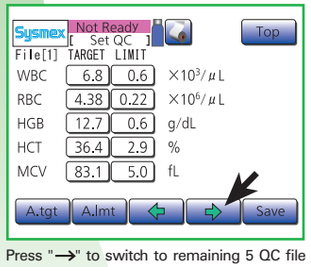
Enter "Lot ID" and "Expire" manually or by barcode reader. Press "→".

5 Enter TARGET and LIMIT value for each parameter.



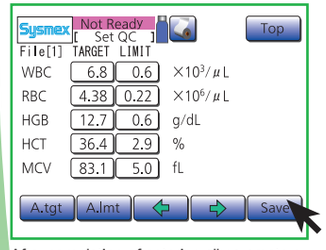
Enter TARGET and LIMIT value for each parameter manually or by barcode reader.

6 Switch to remaining 5 QC file setting screens.



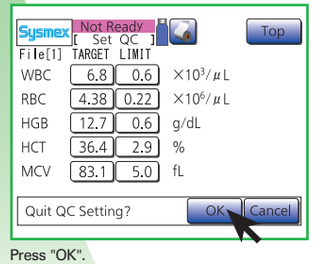
Press "→" to switch to remaining 5 QC file setting screens.

7 Press "Save".



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

8 Press "OK".



Press "OK".

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

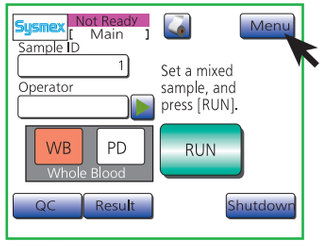
- Before using new control blood, enter the control blood information: Control blood lot ID and Expiration date. For each control parameter enter: Target value and Target Limit
- Control blood must always be stored according to the instructions in the package insert.

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.

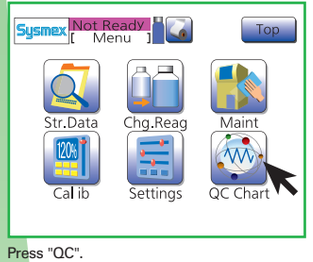
3.2.1. STEP 1: b) Automatic settings

1 **Press "Menu".**



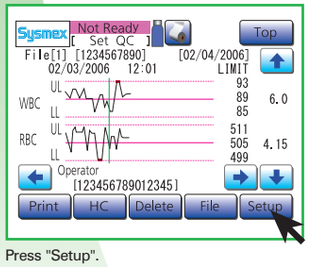
Press "Menu".

2 **Press "QC".**



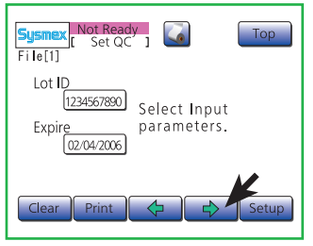
Press "QC".

3 **Press "Setup".**



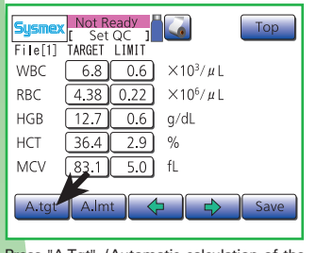
Press "Setup".

4 **Enter "Lot ID" and "Expire", then press "→".**



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

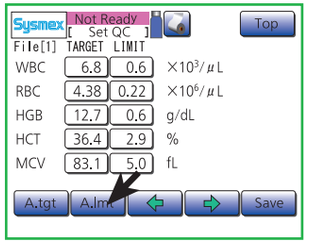
5 **Press "A.Tgt".**



Press "A.Tgt". (Automatic calculation of the average of all plots).

6 No automatic calculation is possible with less than 2 plots.

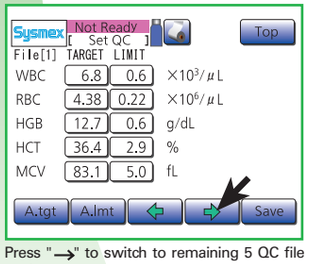
7 **Press "A.Lmt".**



Press "A.Lmt". (Automatic calculation of 2SD or 3SD of all plots).

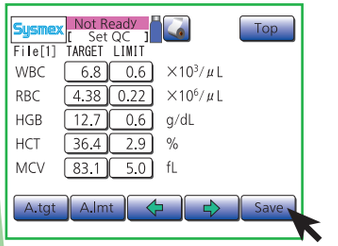
8 No automatic calculation is possible with less than 2 plots.

9 **Switch to remaining 5 QC file setting screens.**



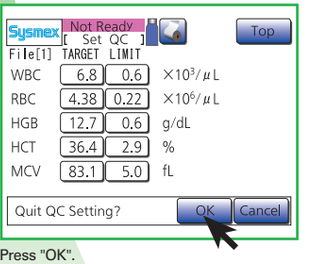
Press "→" to switch to remaining 5 QC file setting screens.

10 **Press "Save".**



After completion of automatic calculation of all parameters, press "Save".

11 **Press "OK".**



Press "OK".

3.2. PERFORMING QUALITY CONTROL

3.2.2. STEP 2: Preparing control blood

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).

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

1

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

Roll 10 times and Turn upside down 10 times. Repeat the action for 2 Min.

2

1. Roll 10 times.
2. Turn upside down 10 times.
3. Roll 10 times.
4. Repeat steps 1-3 for 2 Min.

3

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

Biological risks

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

Important

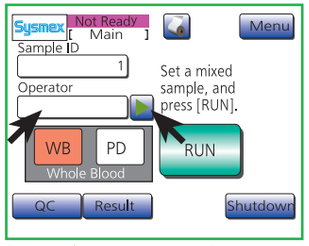
- EIGHTCHECK-3WP-L
  EIGHTCHECK-3WP-N
  EIGHTCHECK-3WP-H
  are used as control materials. These are equivalent to low, normal and high levels.
  For further information see "The reagents" page 1-4.
- If other control materials are used, the product performance of Sysmex instruments cannot be guaranteed.

3.2. PERFORMING QUALITY CONTROL

3.2.3. STEP 3: a) Performing quality control: L-J method (factory setting) (for close piercer)

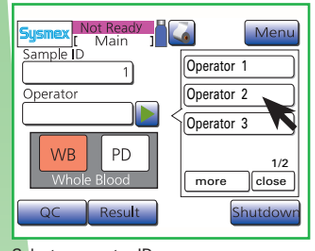
Daily

1 **Press the ▶-button or press "Operator".**



Press the ▶-button or press "Operator".

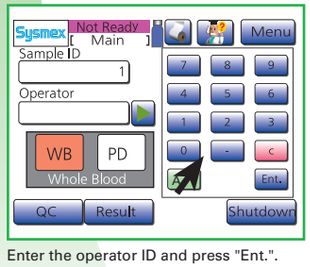
2a **Select a operator ID.**



Select a operator ID.

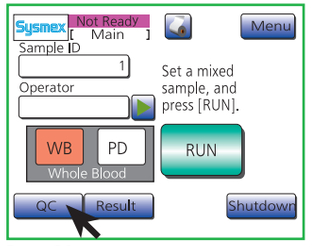
or

2b **Enter the operator ID and press "Ent.".**



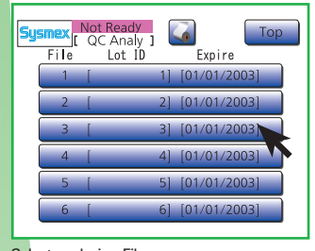
Enter the operator ID and press "Ent.".

3 **Press "QC".**



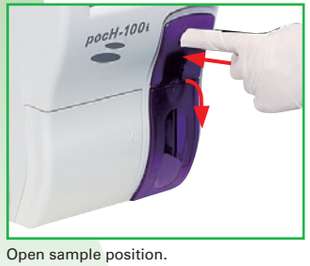
Press "QC".

4 **Select analyzing File.**



Select analyzing File.

5 **Open sample position.**



Open sample position.

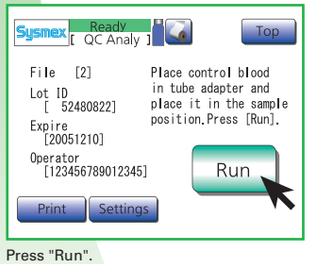
6 **Insert adapter.**

Insert correct adapter.

7 **Insert control blood and close the door.**

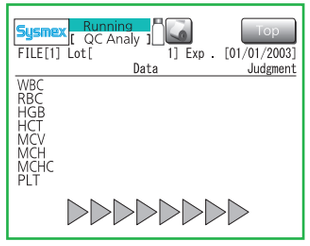
Insert control blood and close door.

8 **Press "Run".**



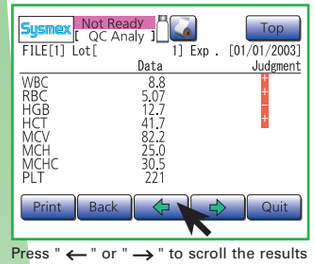
Press "Run".

9 **The analysis starts.**



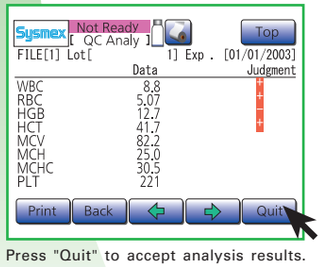
The analyzing screen will appear.

10 **Press " ← " or " → " to scroll screens.**



Press " ← " or " → " to scroll the results screens.

11 **Press "Quit".**



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

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 opened fully.
- Use only the supplied sample adapter. Failure to do so may result in serious damage of the instrument.

Note

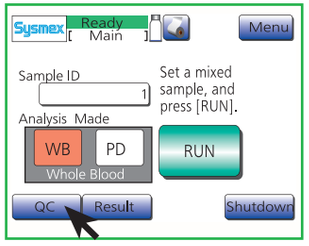
The analysis results are automatically saved to "stored data".

3.2. PERFORMING QUALITY CONTROL

3.2.3. STEP 3: a) Performing quality control: L-J method (factory setting) (for open pipette)

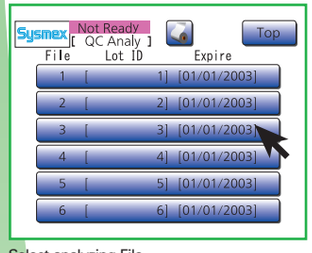
Daily

1 Press "QC".



Press "QC".

2 Select analyzing File.



Select analyzing File.

3 Open sample position.

Open sample position.

The sample tube caps have to be removed before measurement.

4 Set the spacer to an adapter.

Set the spacer to an adapter.

5 Insert adapter.

Insert correct adapter.

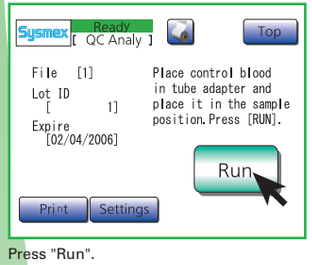
6 Remove the cap.

Remove the cap.

7 Insert control blood and close the door.

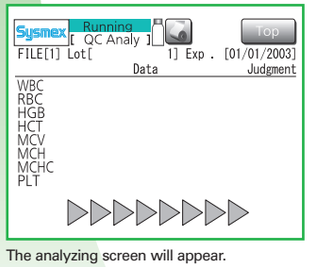
Insert control blood and close door.

8 Press "Run".



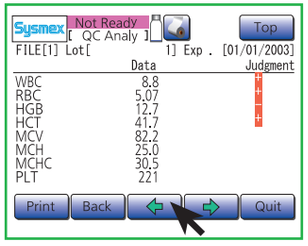
Press "Run".

9 The analysis starts.



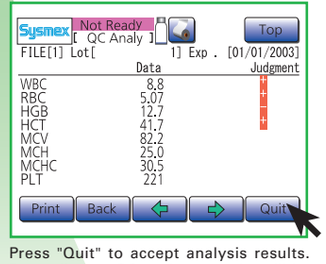
The analyzing screen will appear.

10 Press "←" or "→" to scroll screens.



Press"←" or "→" to scroll the results screens.

11 Press "Quit".



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

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 opened 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

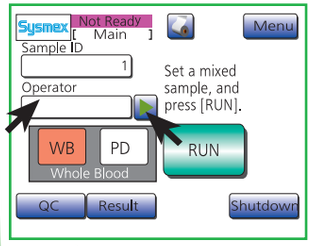
The analysis results are automatically saved to "stored data".

3.2. PERFORMING QUALITY CONTROL

3.2.3. STEP 3: b) Performing quality control: $\bar{X}$ method (for close piercer)

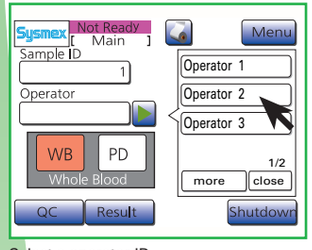
Daily

1 **Press the ▶-button or press "Operator".**



Press the ▶-button or press "Operator".

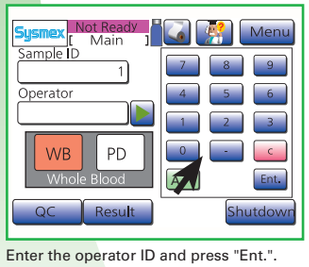
2a **Select a operator ID.**



Select a operator ID.

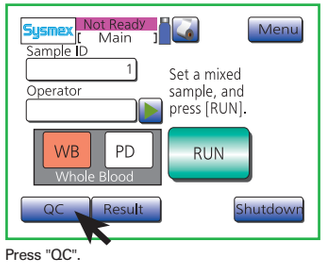
or

2b **Enter the operator ID and press "Ent.".**



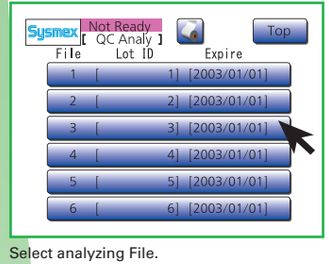
Enter the operator ID and press "Ent.".

3 **Press "QC".**



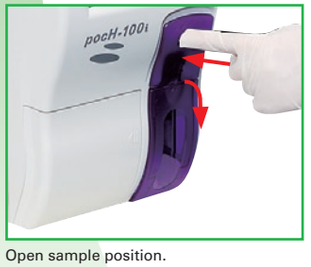
Press "QC".

4 **Select analyzing File.**



Select analyzing File.

5 **Open sample position.**



Open sample position.

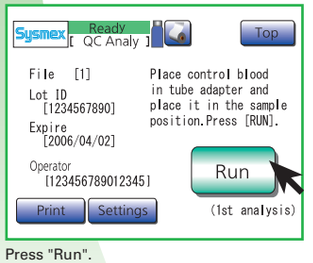
6 **Insert adapter.**

Insert correct adapter.

7 **Insert control blood and close the door.**

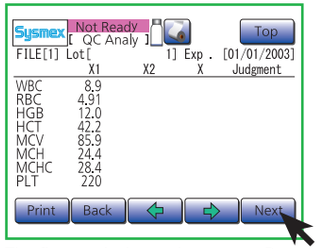
Insert control blood and close door.

8 **Press "Run".**



Press "Run".

9 **Press "Next" to perform the second analysis.**

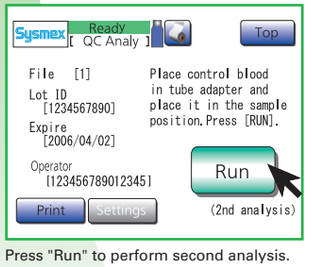


The first analysis results appear. Press "Next" to perform the second analysis.

10 **Mix well and insert it back into the sample position.**

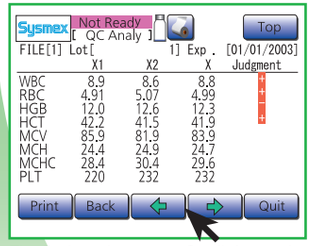
Remove the control blood, mix well and insert it back into the sample position.

11 **Press "Run".**



Press "Run" to perform second analysis.

12 **The final results appear.**



The final results appear. Scroll the results by pressing "←"or "→" and press "Print".

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 opened fully.
- Use only the supplied sample adapter. Failure to do so may result in serious damage of the instrument.

Note

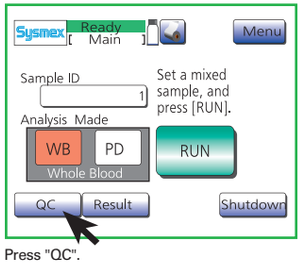
The analysis results are automatically saved to "stored data".

3.2. PERFORMING QUALITY CONTROL

3.2.3. STEP 3: b) Performing quality control: $\bar{X}$ method (for open pipette)

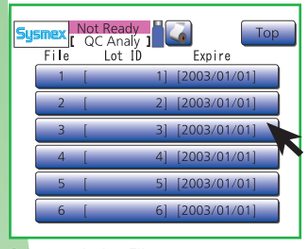
Daily

1 Press "QC".



Press "QC".

2 Select analyzing File.



Select analyzing File.

3 Open sample position.

Open sample position.

The sample tube caps have to be removed before measurement.

4 Set the spacer to an adapter.

Set the spacer to an adapter.

5 Insert adapter.

Insert correct adapter.

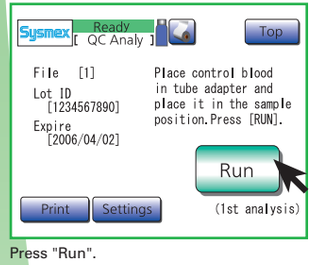
6 Remove the cap.

Remove the cap.

7 Insert control blood and close the door.

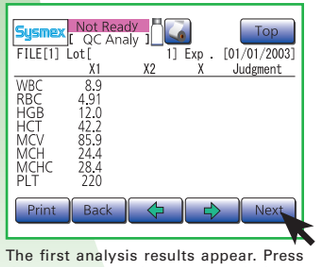
Insert control blood and close door.

8 Press "Run".



Press "Run".

9 Press "Next" to perform the second analysis.

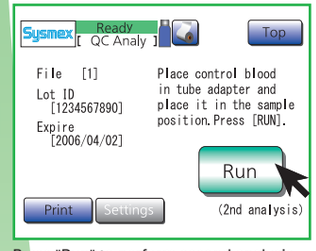


The first analysis results appear. Press "Next" to perform the second analysis.

10 Mix well and insert it back into the sample position.

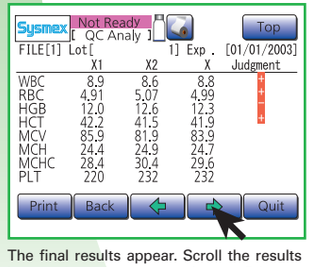
Remove the control blood, mix well and insert it back into the sample position.

11 Press "Run".



Press "Run" to perform second analysis.

12 The final results appear.



The final results appear. Scroll the results by pressing "←" or "→" and press "Print".

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 opened 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".

4. CLEANING & MAINTENANCE : CONTENTS

4.1. CLEANING

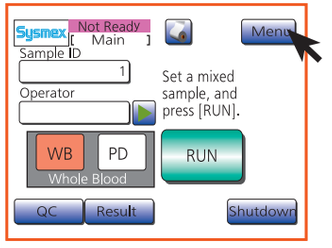
4.1.1. Clean instrument surface

- 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.

4.1.2. Check instrument status

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

1 **Press "Menu".**

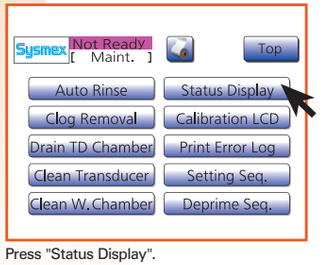


Press "Menu". (∗1)

2 **Press "Maint.".**

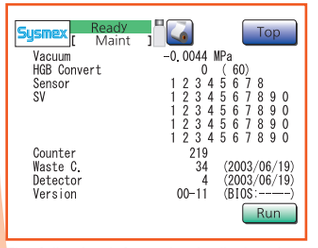
Press "Maint.".

3 **Press "Status Display".**



Press "Status Display".

4 **The screen displays information.**



The following information is displayed on this screen. (∗1)

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

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.

Note

∗1. If "Run" is pressed, analysis operation starts, and the instrument status can be checked during operation.

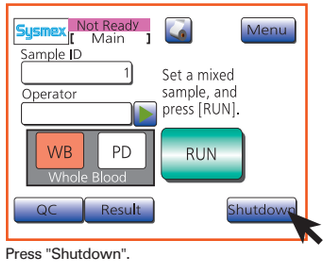
4.1. CLEANING

4.1.3. Shutdown

Removes deposits in the instruments tubing.

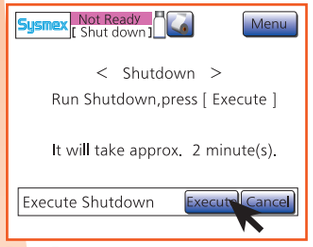
Daily

Press "Shutdown".



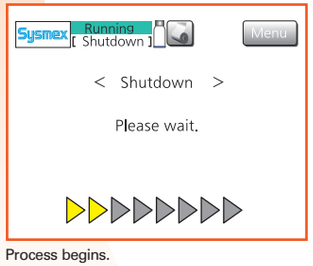
Press "Shutdown".

Press "Execute".



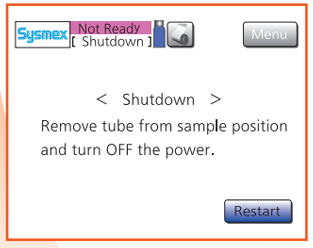
Press "Execute".

Process begins.



Process begins.

Follow instructions on the screen. Then switch OFF.



Follow instructions on the screen. Then switch OFF.

Incorrect analysis results

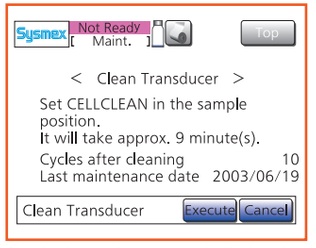
- Deposits in the instrument's tubing can cause incorrect analysis results. Therefore, the transducer chambers and diluted sample tubes must be cleaned.
- If the instrument is used continuously without performing the shutdown sequence, protein clotting may cause incorrect analysis results or it may damage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

4.1.4. 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

1 Cleaning instruction message is displayed.



Cleaning instruction message is displayed.

2 Add 3mL of CELLCLEAN into the sample tube.

Add 3mL of CELLCLEAN into empty sample tube.

3 Open sample position.

Open sample position.

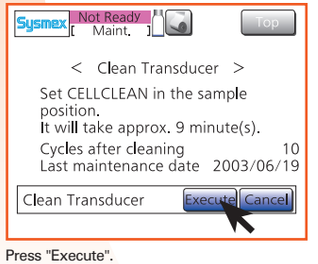
4 Insert adapter.

Insert adapter.

5 Set CELLCLEAN in place, close door.

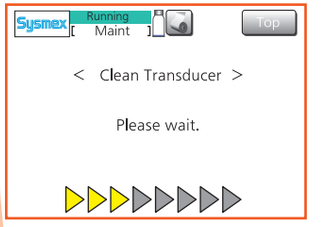
Set CELLCLEAN in place, close door.
* For open pipette, remove a cap.

6 Press "Execute".



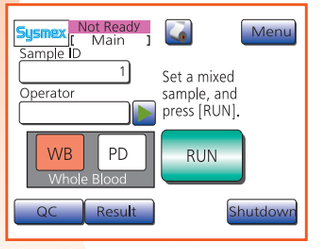
Press "Execute".

7 Process begins.



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

8 Cleaning completed. Remove CELLCLEAN.



When this screen is displayed, remove CELLCLEAN. (*1)

Note

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

*1. After cleaning, the counter resets automatically.

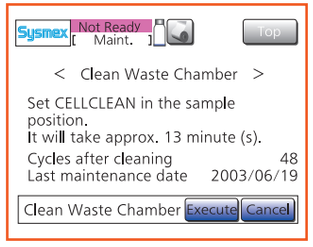
4.1. CLEANING

4.1.5. 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

1 Cleaning instruction message is displayed.

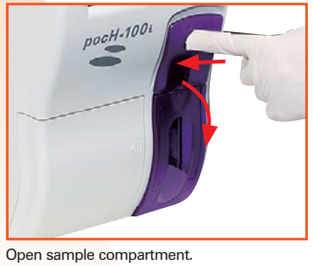


Cleaning instruction message is displayed.

2 Add 3mL of CELLCLEAN into the sample tube.

Add 3mL of CELLCLEAN into empty sample tube.

3 Open sample position.



Open sample compartment.

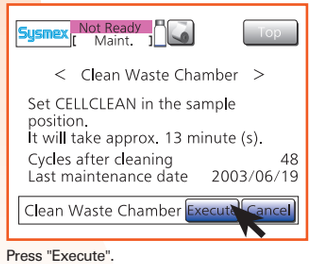
4 Insert adapter.

Insert adapter.

5 Set CELLCLEAN in place, close compartment.

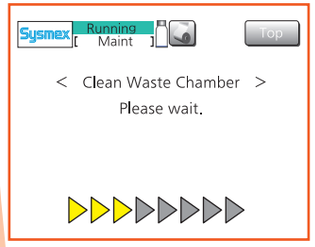
Set CELLCLEAN in place, close compartment.
* For open pipette, remove a cap.

6 Press "Execute".



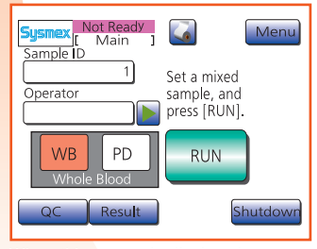
Press "Execute".

7 Process begins.



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

8 Cleaning completed. Remove CELLCLEAN.



When this screen is displayed, remove CELLCLEAN.

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.

4.1.6. Clean the sample tube adapter

If sample has spilt into the adapter.

As needed

Switch OFF.

Switch OFF.

Remove adapter and clean it.

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

Biological risks

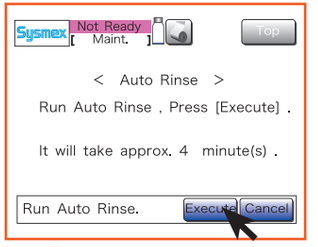
Always wear protective garments and gloves when handling the waste fluid. After work is completed, wash hands with disinfectant.

4.1.7. Perform auto rinse

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".

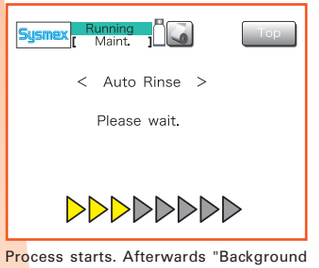
As needed

Press "Execute".



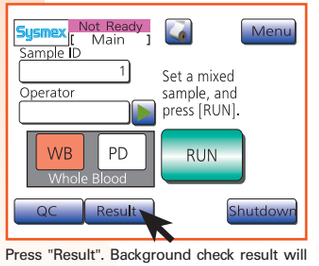
Press "Execute".

Process starts.



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

Background check result will appear.



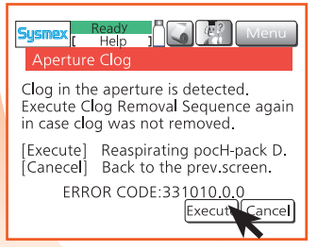
Press "Result". Background check result will appear.

4.1.8. Remove clog from transducer aperture

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".

As needed

1 **Press "Execute".**



Press "Execute";automatic clog removal starts. (∗1)

Note

∗1. To return to the main screen without performing automatic clog removal, press "Cancel".

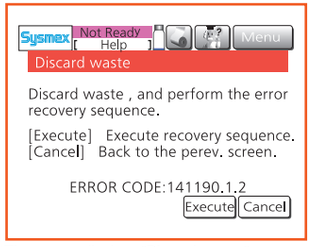
4.1. CLEANING

4.1.9. Dispose waste fluid

If the "Discard waste" error message appears, the waste bottle is full and needs to be emptied.
The waste bottle might be necessary in case of using pocH-pack 65XL.

As needed

1 **The screen displays "Discard waste."**



The screen displays "Discard waste."

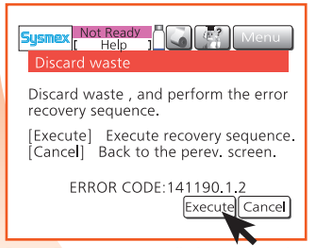
2 **Rinse bottle with water.**

1 Remove cap.
2 Dispose waste fluid.
3 Rinse bottle with water.

3 **Insert float switch.**

Insert float switch into empty and cleaned bottle.

4 **Waste discharge operation starts.**



Press "Execute"; waste discharge operation starts. (∗1)

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.

Note

∗1. To return to the main screen without performing the waste discharge operation, press "Cancel".

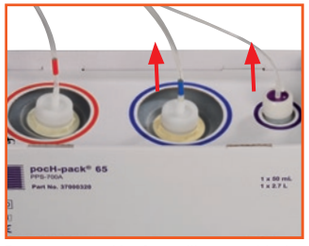
4.1.10. Drain reagents

Perform before moving/shipping the instrument.

As needed

Remove spout kits from diluent and lysing reagent.

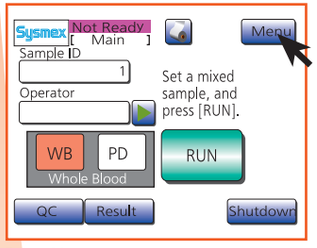
1



Remove spout kits from diluent and lysing reagent.*

Press "Menu".

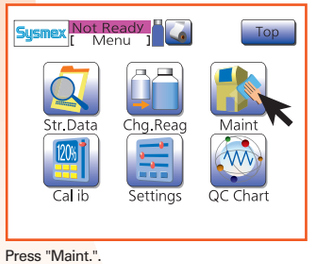
2



Press "Menu".

Press "Maint.".

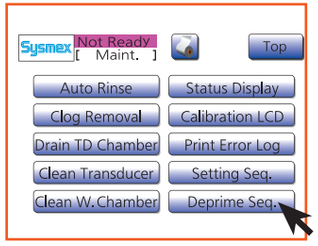
3



Press "Maint.".

Press "Deprime Seq.".

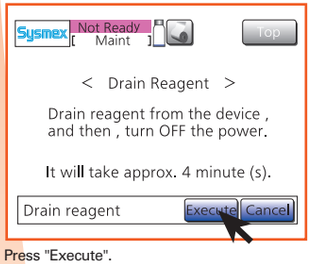
4



Press "Deprime Seq.".

Press "Execute".

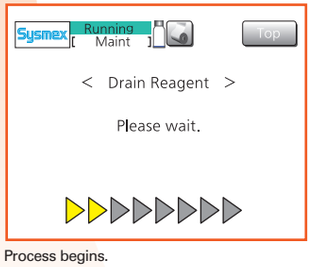
5



Press "Execute".

Process begins.

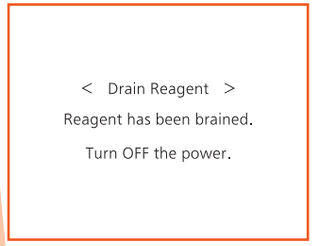
6



Process begins.

The screen of process completed.

7



The screen of process completed.

Switch OFF .

8

Switch OFF, drain and clean waste bottle.

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.

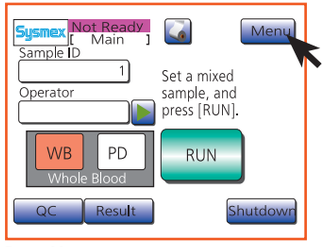
* This is image of the pocH-pack 65. The pocH-pack 65XL does not have waste container.

4.1.11. Calibrate LCD

Calibrate the LCD if panel operation is not properly aligned.

As needed

1 **Press "Menu".**

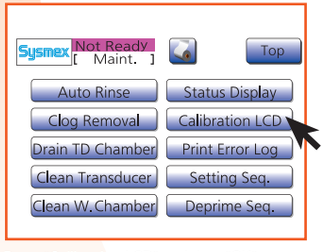


Press "Menu".

2 **Press "Maint.".**

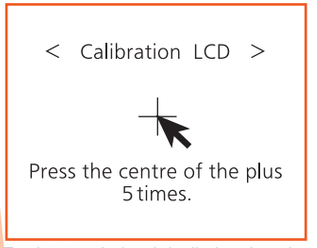
Press "Maint.".

3 **Press "Calibration LCD" and then "OK".**



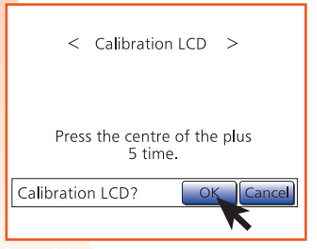
Press "Calibration LCD" and then "OK".

4 **Press the centre of the plus 5 times.**



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

5 **Press "OK".**



Press "OK".

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

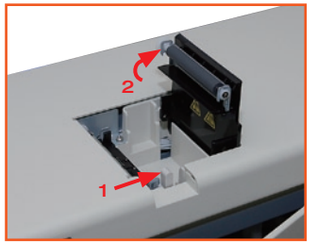
If the input position was outside a regulated range, the calibration error message will appear, and the calibration will be discontinued.

4.1.12. Replace thermal printer paper

Only use paper recommended by Sysmex.

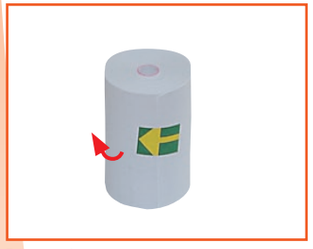
As needed

1 **Open the paper holder.**



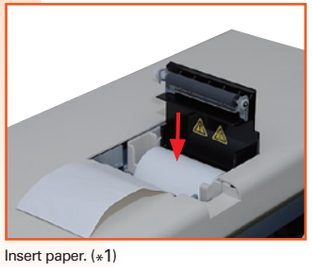
Open paper holder by pushing the knob.

2 **Remove the tape.**



Remove the tape.

3 **Insert paper.**



Insert paper. (*1)

4 **Close lid and remove excess paper.**

Close lid and remove excess paper.

Warning, Hot

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

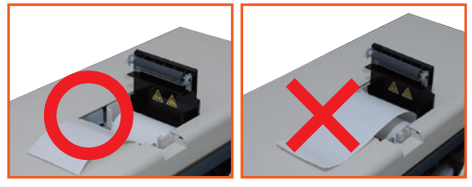
Important

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.

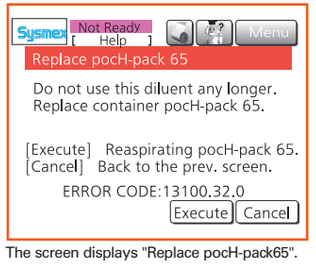
*1. Insert the paper correctly.
If inserted at an angle, the paper might jam.



4.1.13. Replace reagent

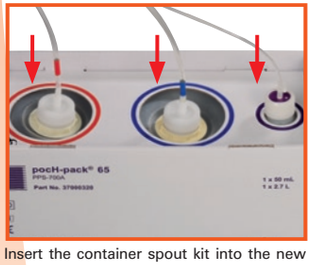
As needed

1 **The screen displays "Replace pocH-pack65".**



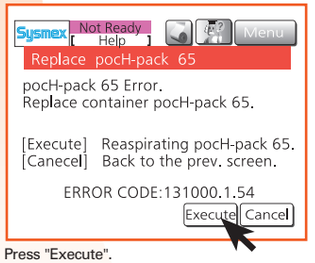
The screen displays "Replace pocH-pack65".

2 **Insert the container spout kit into the new pocH-pack 65.**



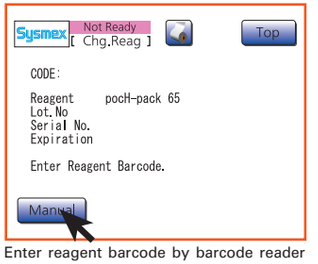
Insert the container spout kit into the new pocH-pack 65. Tighten the cap.*

3 **Press "Execute".**



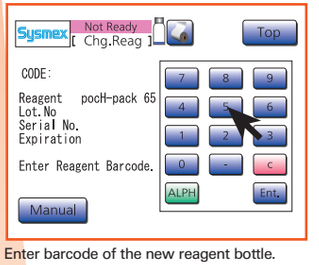
Press "Execute".

4 **Enter reagent barcode by barcode reader and proceed to step 7 or press "Manual".**



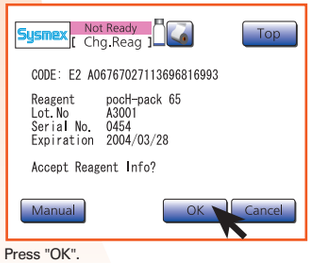
Enter reagent barcode by barcode reader and proceed to step 7 or press "Manual".

5 **Enter barcode of the new reagent bottle**



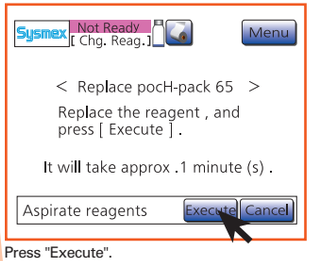
Enter barcode of the new reagent bottle.

6 **Press "OK".**



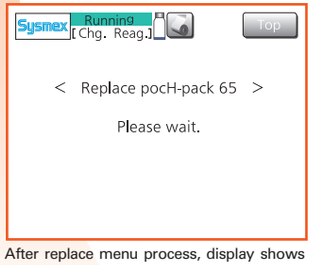
Press "OK".

7 **Press "Execute".**



Press "Execute".

8 **After replace menu process, display shows start screen.**



After replace menu process, display shows start screen.

Biological risks

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.

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, please see "The reagents" page 1-4.

Caution

- Waste fluid may discolor some materials.
- If the waste fluid is spilt, wipe off with the damp cloth immediately.
- Clean spills according to your policies and procedures.

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.

* This is image of the pocH-pack 65. The pocH-pack 65XL does not have waste container.

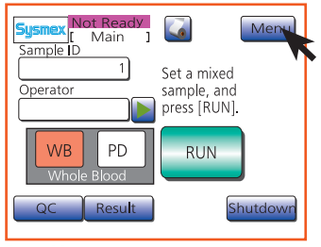
4.2. TECHNICAL MAINTENANCE-Qualified personnel only!

4.2.1. Clean aperture of TD chamber

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

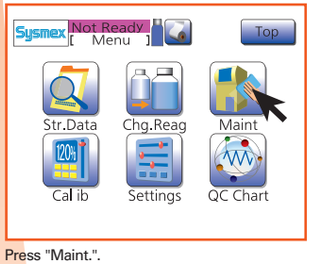
As needed

1 **Press "Menu".**



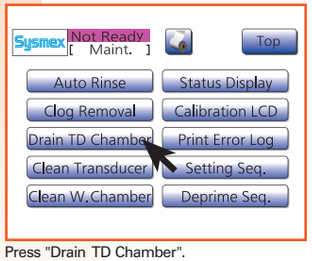
Press "Menu".

2 **Press "Maint.".**



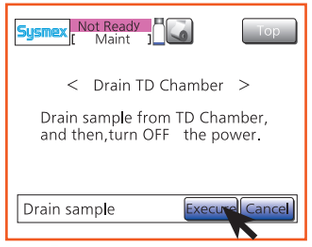
Press "Maint.".

3 **Press "Drain TD Chamber".**



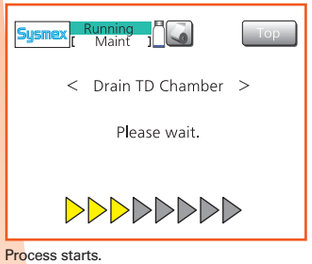
Press "Drain TD Chamber".

4 **Press "Execute".**



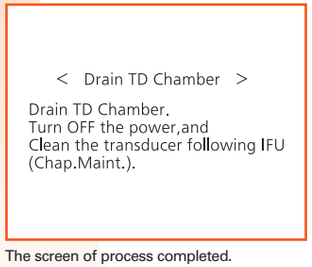
Press "Execute".

5 **Process starts.**



Process starts.

6 **The screen of process completed.**



The screen of process completed.

7 **Switch OFF.**

Switch OFF.

8 **Disconnect power cord.**

Disconnect power cord to avoid electrical shock.

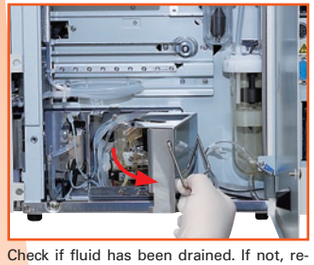
9 **Unscrew cover.**

Unscrew cover by using the supplied screwdriver.

10 **Open side cover and open detector cover.**

Open side cover and open detector cover.

11 **Check if fluid has not been drained.**



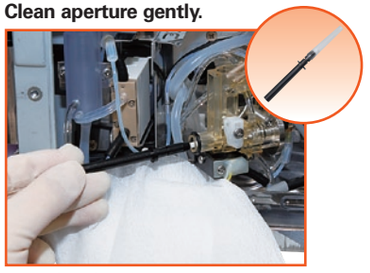
Check if fluid has been drained. If not, remove it with the pipette.

12 **Remove the plug.**

Place cloth under plug and remove plug.

13

Clean aperture gently.



Apply CELLCLEAN to transducer brush, clean aperture gently.

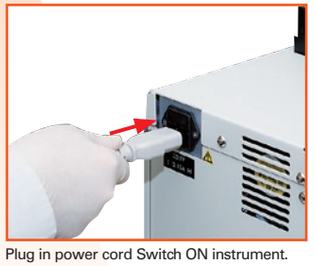
14

Close all covers. Tighten the screws.

Close all covers. Tighten the screws.

15

Switch ON the instrument.



Plug in power cord Switch ON instrument. (∗1)

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 performing maintenance work, use only the specified tools and parts. Install only such spare or replacement parts intended for this equipment.

∗1. 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.

Note

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

4.2. TECHNICAL MAINTENANCE-Qualified personnel only!

4.2.2. System fuse replacement

As needed

Switch OFF.

1

Switch OFF.

Unplug power cable.

2

Unplug power cable.

Turn fuse holder cap counter-clockwise.

3

Turn fuse holder cap counter-clockwise with screwdriver.

Replace the fuse(s).

4

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

Switch ON.

5

Plug in power cable. Switch ON.

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.

5. SETTINGS & CALIBRATION : CONTENTS

5.1. SETTINGS

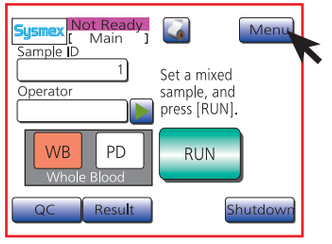
Set up the instrument according to your personal needs or to laboratory requirements.

5.1.1. Change settings

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

1

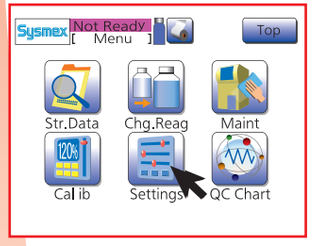
Press "Menu".



Press "Menu".

2

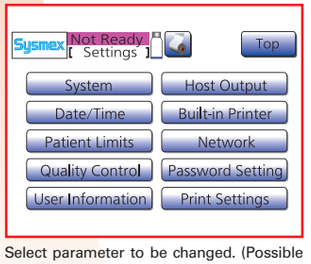
Press "Settings".



Press "Settings".

3

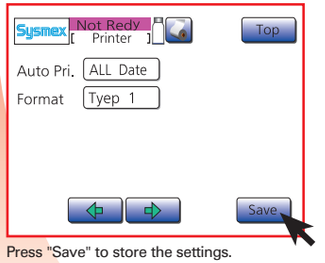
Select parameter to be changed.



Select parameter to be changed. (Possible settings to be changed are described on pages 5-3~5-10.)

4

Press "Save".



Press "Save" to store the settings.

Note

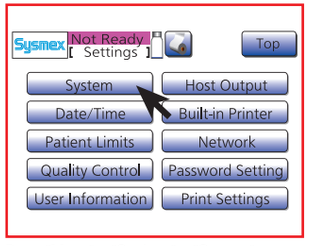
See "Possible settings" pages 5-3~5-10 for more detailed information on parameters that can be set manually.

5.1. SETTINGS

5.1.2. Possible settings

5.1.2.1. System setup

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



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 Settings for this parameter will come into effect the next time the main switch is turned ON.
Parameter Name	W-SCR; LYM% 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 barcode will be loaded as a sample ID number with up to 13 characters.
ID Inc.	Disable / Enable When "Enable" is selected, the sample ID will be incremented automatically.

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 patient limits, and for quality control TARGET and LIMIT values.

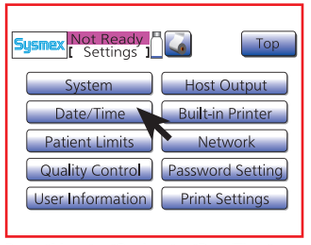
Note

The underscored items are factory settings.

5.1.2.2. Date/Time

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

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



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

Note

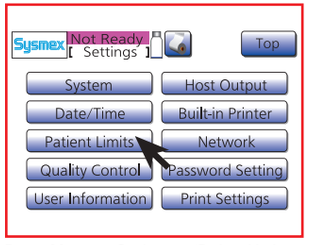
The underscored items are factory settings.

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

5.1.2.3. Patient Limits

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

Press "Menu" > "Settings" > "Patient Limits".



Press "Menu" > "Settings" > "Patient Limits".

Note

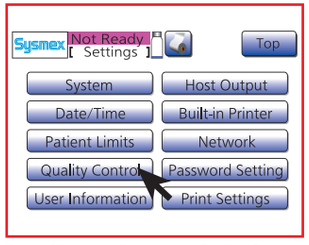
- The listed values are the initial settings made before shipment from the factory.
- If LL or UL that satisfy the following conditions was entered in the Patient Limit setting screen, a beep sounds and the entering is canceled.
  - LL is higher than UL.
  - UL is lower than LL.

Parameter	LL (Lower Limit)	UL (Upper Limit)
WBC	3.0	15.0
RBC	2.50	5.50
HGB	8.0	17.0
HCT	26.0	50.0
MCV	86.0	110.0
MCH	26.0	38.0
MCHC	31.0	37.0
PLT	50	400
RDW-SD	37.0	54.0
RDW-CV	11.0	16.0
LYM% (W-SCR)	5.0	55.0
MXD% (W-MCR)	1.0	20.0
NEUT% (W-LCR)	45.0	95.0
LYM# (W-SCC)	0.0	0.0
MXD# (W-MCC)	0.0	0.0
NEUT# (W-LCC)	0.0	0.0
MPV	9.0	13.0
PDW	9.0	17.0
P-LCR	13.0	43.0

5.1.2.4. QC settings

Select Quality Control and data output method.

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



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

Note

The underscored items are factory settings.

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

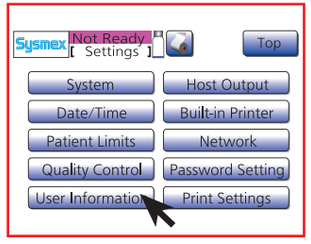
Choose the control method meeting your laboratory's internal regulations:

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

5.1.2.5. User information settings

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

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

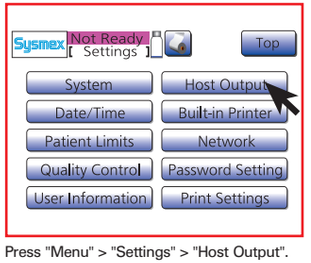


Press "Menu" > "Settings" > "User Information".

5.1.2.6. Host settings

To set data output to host computer.

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



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

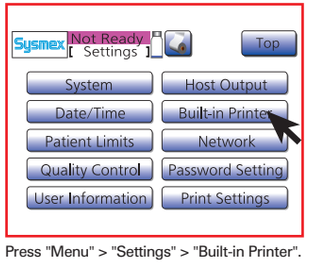
Note

The underscored items are factory settings.

5.1.2.7. 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.)

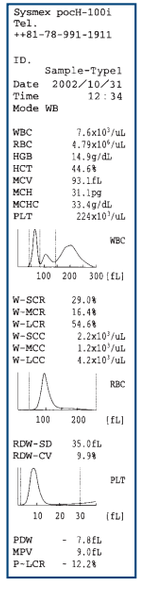
Press "Menu" > "Settings" > "Built-in Printer".



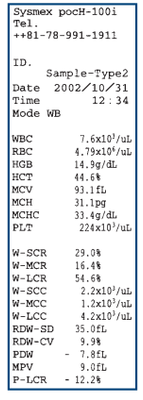
Press "Menu" > "Settings" > "Built-in Printer".

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. (The print format for the analysis result of pre-diluted mode is pre-fixed with Type 3 regardless of the setting.)
[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

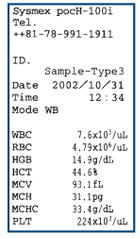
Type 1



Type 2



Type 3



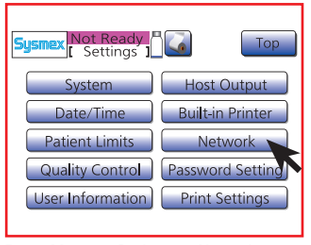
Note

The underscored items are factory settings.

5.1.2.8. 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".



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

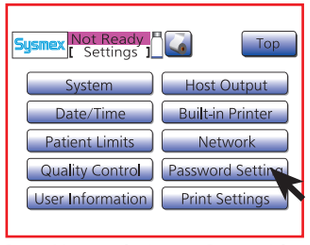
Note

The underscored items are factory settings.

5.1.2.9. Password setting

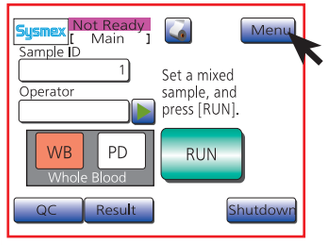
To prevent unauthorized change of the settings, a password can be set.
Password-protected functions: Calibration and Setting.

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



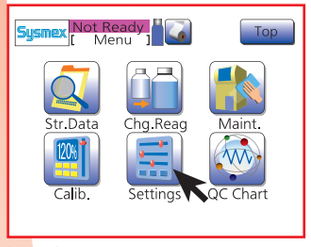
Press "Menu" > "Settings" > "Password Setting".

Press "Menu".



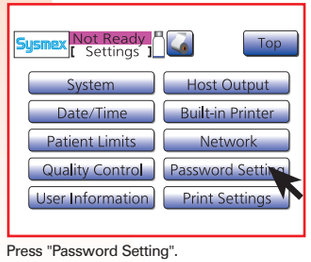
Press "Menu".

Press "Settings".



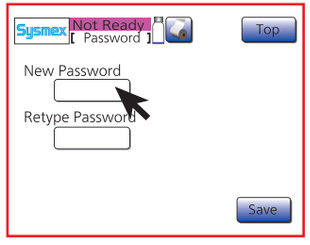
Press "Settings".

Press "Password Setting".



Press "Password Setting".

Enter password and press "Ent.".

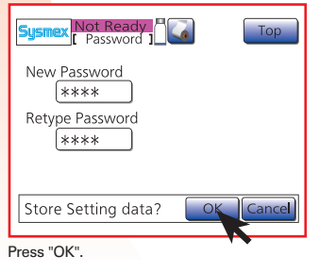


Press "New Password", the numerical keys dialog will appear. Enter max 10 digits. Press "Ent.".

Enter password again for confirmation and press "Ent.".

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

Press "OK".



Press "OK".

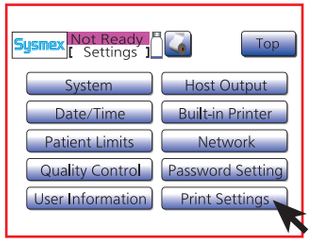
Important

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

5.1.2.10. Print settings

Print a list of the current settings.

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



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

5.2. CALIBRATION

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

5.2.1. Calibrate the instrument

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

Establishing reference values

Recommended measuring methods:

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

Samples used for calibration

Use 5 or more samples of fresh 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%

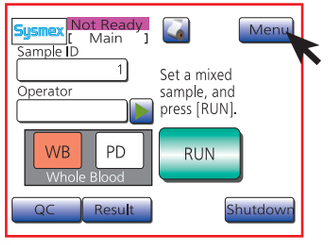
Important

- Calibration does not need to be performed at specific intervals. Follow your internal laboratory regulations for performing calibration.
- Each sample should be analyzed at least three times.
- EIGHTCHECK is not suitable for calibration purposes, but for quality control instead.

5.2.2. Automatic calibration

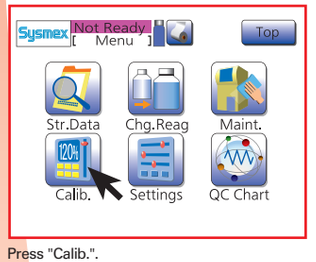
The instrument determines the calibration value automatically by analyzing 5 calibration samples.

1 **Press "Menu".**



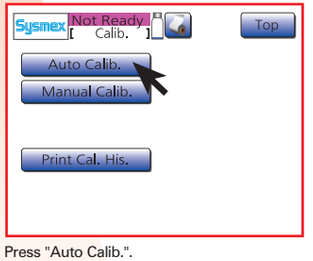
Press "Menu".

2 **Press "Calib.".**



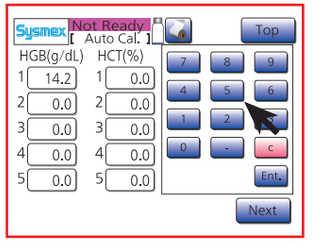
Press "Calib.".

3 **Press "Auto Calib.".**



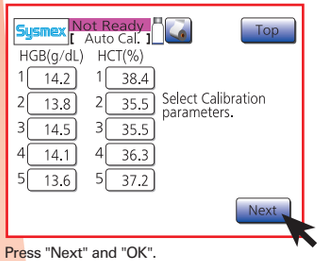
Press "Auto Calib.".

4 **Enter reference values and press "Ent.".**



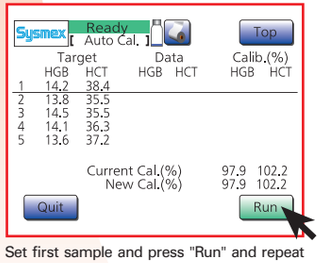
Enter reference values for 5 each sample and press "Ent.".

5 **Press "Next" and "OK".**



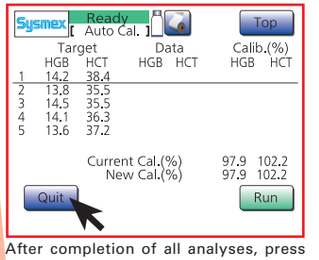
Press "Next" and "OK".

6 **Set first sample and press "Run".**



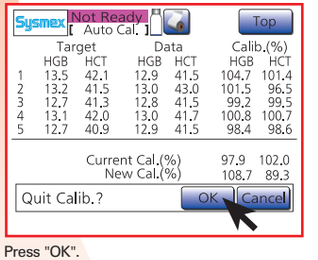
Set first sample and press "Run" and repeat this for the remaining 4 samples.

7 **Press "Quit.".**



After completion of all analyses, press "Quit".

8 **Press "OK".**



Press "OK".

Important

- Automatic calibration is always performed in the WB mode.
- 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.

5.2. CALIBRATION

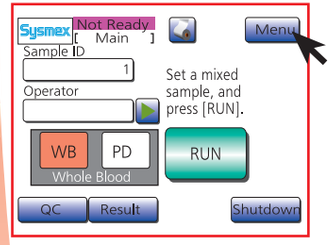
5.2.3. Manual calibration

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

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

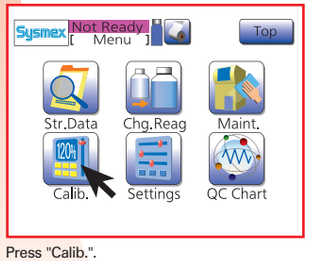
$$\text{New calibration value} = \text{Previous calibration value} \times \frac{\text{Average of values gained by reference method}}{\text{Average of values gained by this instrument}}$$

Press "Menu".



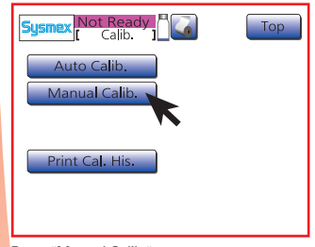
Press "Menu".

Press "Calib.".



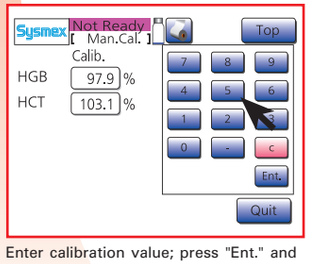
Press "Calib.".

Press "Manual Calib.".



Press "Manual Calib.".

Enter calibration value and press "Ent.".



Enter calibration value; press "Ent." and confirm with "OK".

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:

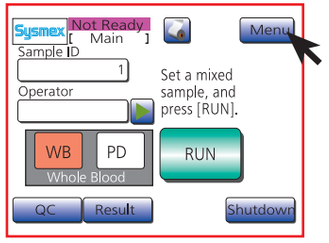
$$\text{Calibration value} = 100 \times \frac{\text{New calibration value}}{\text{Current calibration value}}$$

5.2.4. Print calibration history

Print an overview of the five most recent calibration results.

1

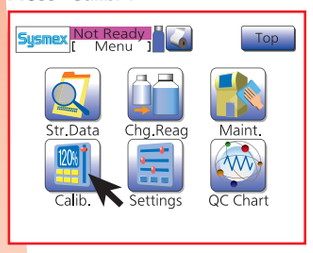
Press "Menu".



Press "Menu".

2

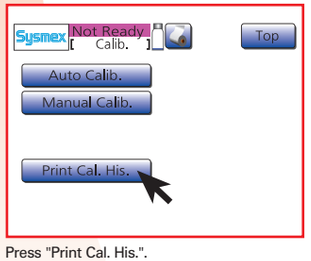
Press "Calib.".



Press "Calib.".

3

Press "Print Cal. His.".



Press "Print Cal. His.".

6. TROUBLESHOOTING : CONTENTS

6.1. GENERAL ERRORS, INSTRUMENT FAILURE

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 (see "Technical Maintenance" page 4-13).
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.

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

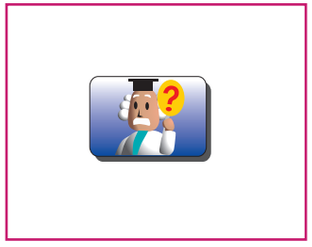
If the instrument shows a malfunction, check the following table. If the corresponding item is not found or the procedure listed does not eliminate the problem, contact your Sysmex service representative.

- 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.

6.2. ERROR MESSAGES

Error dialog.

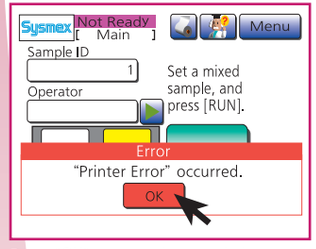
1



Alarm sounds, button flashes and an error dialog appears.

Press "OK".

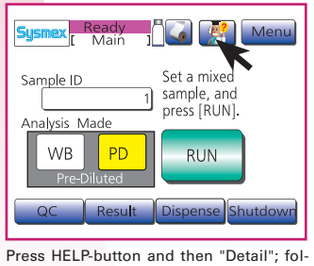
2



Press "OK" to stop alarm and close error dialog.

Press HELP-button and then "Detail".

3



Press HELP-button and then "Detail"; follow instructions on screen. (*1)

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.

Note

*1. Multiple errors are displayed ranked by importance. Press "Detail" for displaying the help screen of the first 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 65

Possible cause	Level in pocH-pack 65/pocH-pack 65XL is insufficient.
Action to resolve the error	• Replace the pocH-pack 65/pocH-pack 65XL 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 4-12. • 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 4-8. • 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.

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.

6.3. ERROR MESSAGES, POSSIBLE CAUSES AND ACTIONS TO RESOLVE THE ERROR

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 (see page 4-7). • Clean the transducer (see page 4-4). • Clean the aperture with the brush (see page 4-13). • 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 14 °C or lower - "Temp. Error (H)": Detector block temperature is 31 °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 (see page 4-4). • Replace the reagent (see page 4-12). • 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 ($\bar{X}$) 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 (see page 4-7). • Transducer cleaning sequence. Apply CELLCLEAN in the transducer and run Transducer cleaning sequence (see page 4-4). • Clean aperture with transducer brush (see page 4-13). • 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.

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 the "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 the "Execute" button 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 (see page 4-11). • 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.

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.

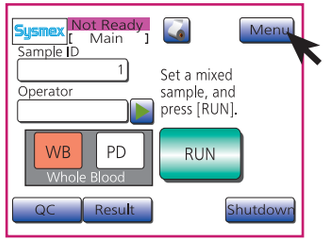
LAN no Response

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.

6.4. PRINT ERROR LOG

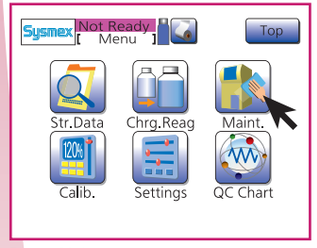
The 10 most recent error messages are printed.

Press "Menu".



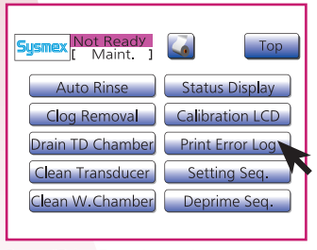
Press "Menu".

Press "Maint.".



Press "Maint.".

Print out error history.



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

Note

Print error messages prior to contacting your Sysmex service representative.

7. SAFETY INFORMATION & WASTE DISPOSAL : CONTENTS

7.1. SAFETY INFORMATION

7.1.1. 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.

7.1.2. 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.
- Training courses
  For further training information, please contact your Sysmex representative.

7.1.3. Hazards of electricity

Risk of electric shock and fire! Danger of life!

- Never insert the power plug into power sockets other than AC100-240V. 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 barcode reader, or the program card.

7.1.4. Biohazards

All parts and surfaces of this instrument must be regarded as potentially infectious, since this instrument analyzes patient 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.

7.1. SAFETY INFORMATION

7.1.5. 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).

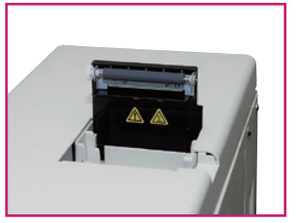
Reagents spilling, risk of electric shock!

- 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.

7.1.6. Warning labels on the instrument

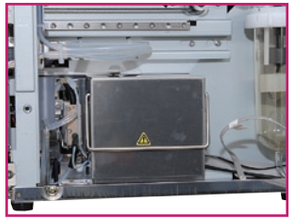
Warning

- 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.



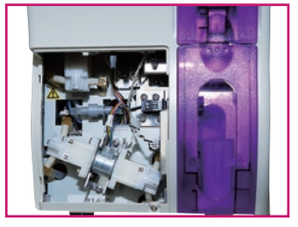
Warning, Hot

The printer head may get very hot.



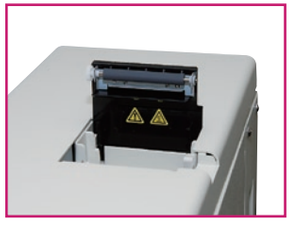
Warning

When opening the detector cover to clean the transducer aperture, follow the instructions in chapter "Clean aperture of TD chamber" page 4-13.
Because there is a risk of electric shock, do not open this cover for any other purposes.



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

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

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.

7.1. SAFETY INFORMATION

7.1.7. 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.

7.2. WASTE DISPOSAL

7.2.1. 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!

7.2.2. 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!

7.2.3. Waste fluids of instruments

The waste fluids of instruments contain patient 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!

Waste Disposal

Biological risks

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

Warning

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

Warning

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

Decontamination

Warning

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

Important

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

8. INDEX