



OPERATOR'S MANUAL
AUTOMATED HEMATOLOGY ANALYZER
KX-21

CHAPTER 1: INTRODUCTION
CHAPTER 2: SAMPLE ANALYSIS
CHAPTER 3: DISPLAY AND PROCESSING OF ANALYSIS RESULTS
CHAPTER 4: MAINTENANCE AND SUPPLIES REPLACEMENT
CHAPTER 5: QUALITY CONTROL
CHAPTER 6: CALIBRATION
CHAPTER 7: TROUBLESHOOTING
CHAPTER 8: ADJUSTMENT
CHAPTER 9: FUNCTIONAL DESCRIPTION
CHAPTER 10: INSTRUMENT SETUP
APPENDIX A: INSTALLATION
APPENDIX B: TECHNICAL INFORMATION
INDEX

SYSMEX CORPORATION
KOBE, JAPAN

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RECEIVING INSTRUCTIONS

The KX-21 has been thoroughly tested before shipment, and has been packaged carefully to prevent damage from shipping and handling. Reagents and options have also been sent and will arrive at approximately the same time as the analyzer. Follow these guidelines when the system arrives:

- Check to see that the arrows on the sides of the packages are pointing up. If the arrows do not point up, remark this information on the bill of lading.
- Visually inspect the outside of the package for rips, dents, or possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. *This is for your protection!*
- Notify your service representative that the KX-21 system and its components have arrived.
- Wait for your service representative to unpack the system and open the packages.
- Follow the unpacking and storage instructions provided on the outside of the package. Special requirements such as refrigeration are clearly marked on the outside of the carton and will be included in the unpacking instructions and package inserts.

WARRANTY INFORMATION

All instruments manufactured by Sysmex® are warranted against defective materials or workmanship for a period of one year commencing on the installation date at the customer's required location.

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

1. Accident, neglect or willful mistreatment of the product
2. Failure to use, operate, service, or maintain the product in accordance with the applicable Sysmex Operator's Manual
3. Failure to use the appropriate reagents or chemicals specified for the product

ENSURE SAFE OPERATION OF THE INSTRUMENT

Before operating this instrument, carefully read the "Ensure Safe Operation of the Instrument" and OPERATOR'S MANUAL, and strictly follow the instructions given in them.

This manual carries a variety of illustrations to make sure that the product can be used safely and correctly, thus preventing you and others from suffering injuries and damage to property.

The illustrations and meaning are described in the following.

Do understand what they mean before proceeding to the text of the MANUAL.

Meaning of Signs



WARNING • If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which could result in death or serious injury of an operator, or grave property damage.



CAUTION • 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, adverse effect on output results, or will cause property damage.

Caution on Diagnosis



CAUTION • This product is a clinical instrument for screening of abnormalities. Clinical judgments by physicians should take into account results from clinical examinations and other test results besides hematology result.

 **WARNING**

- **In the event the instrument emits abnormal odor or any smoke, turn off the power immediately and disconnect the power plug from the wall socket.**
If the instrument is used continuously in that state, there is a hazard that fire, electrical shock, or injury may result.
Contact your Sysmex service representative for inspection.
 - **Take care not to spill blood or reagent, or drop wire staples or paper clips into the instrument.**
Those might cause short circuit or smoke emission. If such trouble should occur, turn off the power supply immediately and pull off the power plug from the wall socket. Then contact Sysmex service representative for inspection.
 - **Do not touch the electrical circuits inside the cover. Especially if your hands are wet, there is a hazard that electrical shock may result.**
 - **Always wear rubber gloves when performing maintenance work or inspection. Use specified tools and parts. After work is over, wash your hands with disinfectant.**
There is a possibility that those areas of the hand which came in contact with blood could suffer infection, electrical shock, or burn.
 - **Be careful when handling samples.**
Always wear rubber gloves; otherwise infection by bacteria could result. If bacteria happen to enter your eye or a cut, wash it off with plenty of water, and immediately see a doctor.
 - **When discarding waste liquid, or disassembling/assembling the related parts, do not touch the waste liquid.**
If it is contaminated with blood, infection of bacteria may result. If you should touch the waste liquid inadvertently, wash it off with disinfectant first, then wash it off with soap.
- When Handling Reagent**
- **If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.**
 - **If you should swallow it inadvertently, call for a doctor immediately, drink plenty of water, and throw up.**
 - **If it happens to adhere to the hand or the skin of other area, wash it off using plenty of water.**
 - **When discarding waste liquid and instrument consumable, take proper disposing steps as medical, ineffective, and industrial wastes.**
If they are contaminated with blood, infection of bacteria may result.
 - **Do not modify the instrument. (Modification is prohibited by Pharmaceutical Affairs Law in Japan.) Check the regulations that apply to laboratories in your country.**

 **WARNING**

Power Supply, Connection, and Grounding

- **Never put the power plug in any socket other than the specified voltage.**
Otherwise, fire or electrical shock will result.
- **When installing the instrument, be sure to ground it.**
Otherwise, fire or electrical shock will result.

Handling Power Supply Cord

- **Take care not to damage the power cord, place a heavy device on it, or pull it forcibly.**
Otherwise, the wire may break causing fire or electrical shock.
- **When connecting the instrument to a peripheral (host computer), be sure to switch off the power supply beforehand.**
Otherwise, electrical shock or instrument failure may result.



CAUTION

Use of Reagents

- After unpacking, be sure not to allow dust, dirt, or bacteria to come in touch with the reagent.
- Do not use reagents which are out of the expiration date.
- Handle a reagent gently to prevent formation of bubbles.
- Take care not to spill a reagent. If it spills, wipe it off immediately using a wet cloth or the like.
- Follow other instructions described on the Package Insert on each reagent.

Use of Instrument

- When performing maintenance work or inspection, use specified tools and parts. Do not use substitute parts, or modify the instrument. It is hazardous.
- Do not bring your body or clothes close to the instrument.
- Those who have no or only limited experience in using reagents are recommended to have guidance or assistance of those with sufficient experience.
- If the instrument has developed a trouble by any chance, a person in charge of it should take steps within the range specified in the OPERATOR'S MANUAL. As to troubles other than mentioned in it, contact Sysmex service representative for repair.
- Unpacking, installation, and confirmation of initial operation must be done by Sysmex service representative.

Environment for Use

- Install the instrument in a place which is not subject to water splash.
- Install the instrument in a place which is not subject to adverse effects of high temperature, high humidity, dust, direct sunlight, etc.
- Do not give the instrument a strong vibration or impact.
- Do not install the instrument near a chemical storage or a place where a gas is generated.

STRUCTURE OF THIS MANUAL

Read this manual carefully so you will be able to use the instrument to its full extent, and operate it correctly. This manual contains ten Chapters and APPENDICES as listed in the following:

Chapter 1:	Introduction	Describes overview of this instrument, including the outline of the instrument, operation procedure, and messages, and cautions during installation.
Chapter 2:	Sample Analysis	Describes procedures for start-up of the instrument, measurement of the sample, and shut-down. Summarizes the operation method for analyzing the sample.
Chapter 3:	Display and Processing of Analysis Results	Describes the displayed content of the analysis data, and the process of the latest sample/stored data. Also describes the manual analysis and the external output.
Chapter 4:	Maintenance and Supplies Replacement	Describes scheduled maintenance and replacement method of supplies such as reagent.
Chapter 5:	Quality Control	Describes execution procedures of the \bar{X} control and L-J control for quality control.
Chapter 6:	Calibration	Describes procedures for automatic/manual calibration.
Chapter 7:	Troubleshooting	Describes error messages and troubleshooting.
Chapter 8:	Adjustment	Describes the method of pressure adjustment based on the troubleshooting.
Chapter 9:	Functional Description	Describes the analyzing principles of this instrument and names of the components.
Chapter 10:	Instrument Setup	Describes the system environment setting such as date, time, and unit, and the data analysis setting such as data error judgment.
Appendix A:	Installation	Describes the installation method of the KX-21.
Appendix B:	Technical Information	Technical reference data describing the specification for host output format. (The host output function is an option.)

INTRODUCTION

Thank you for purchasing the Sysmex® Automated Hematology Analyzer KX-21. Carefully read the OPERATOR'S MANUAL for correct use of the unit. Keep this MANUAL handy after reading. It will continue to be of your service in finding specific information about this instrument.

PREMISES FOR SIGNS

Meaning of Signs



WARNING • If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which could result in death or serious injury of an operator, or grave property damage.



CAUTION • 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, adverse effect on output results, or will cause property damage.

CAUTION:

- Indicates what we would like you to know to maintain instrument performance and prevent its damage.

NOTE:

- Indicates information which will come handy in operating the instrument.

Document Conventions

In explaining operation, this manual uses the conventions as shown below.

- The keys on the panel keyboard are expressed within square brackets.
For example: [SELECT], [ENTER], [▲]
- The display on LCD appears within quotation marks.
For example: "Stand-by," "WB"
- The name of menu appears within quotation marks.
For example: "2: Quality Control," "6: Settings"

NOTE:

- LCD and printing described in this manual may differ from that in practice.
- Due to the improvement of the product, the content of this manual may not conform with the product.

KX-21 OPERATOR'S MANUAL

TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION

1.	INTRODUCTION.....	1-1
2.	OVERVIEW OF INSTRUMENT.....	1-2
3.	OPTION UNITS.....	1-3
4.	OUTLINE OF OPERATION.....	1-3
5.	AUTOMATIC STOP FUNCTION OF PNEUMATIC UNIT.....	1-3
6.	ANALYSIS PARAMETERS.....	1-4
7.	PANEL KEYBOARD.....	1-6
8.	GRAPHIC SCREEN.....	1-7
	8.1 Contents of Display.....	1-7
	8.2 Status Display Messages.....	1-8
	8.3 LCD Brightness Adjustment.....	1-11
9.	EMERGENCY STOP PROCEDURE.....	1-11
10.	ALARM SOUNDS.....	1-11
11.	CONTENTS OF PACKAGE.....	1-11
12.	INSTALLATION ENVIRONMENT.....	1-12
	12.1 Installation and Relocation.....	1-12
	12.2 Grounding.....	1-12
	12.3 Installation Space.....	1-13
	12.4 Installation Environment.....	1-14
13.	INSTRUMENT SPECIFICATIONS.....	1-15
14.	MENU TREE.....	1-18

CHAPTER 2: SAMPLE ANALYSIS

1.	INTRODUCTION.....	2-1
	1.1 Overview of Analysis Modes.....	2-1
	1.2 Analysis Procedure Flow Chart.....	2-2
2.	START-UP PROCEDURE.....	2-3
	2.2 Inspection before Turning ON the Power.....	2-3
	2.2 Turning ON the Power and Self-Check.....	2-5
3.	QUALITY CONTROL.....	2-8
4.	PROCEDURES IN EACH ANALYSIS MODE.....	2-9
	4.1 Whole Blood (WB) Mode.....	2-9
	4.2 Pre-Diluted (PD) Mode.....	2-16
5.	DISPLAY AND PRINTING OF ANALYSIS RESULT.....	2-24
	5.1 Display of Analysis Result.....	2-24
	5.2 Printing of Analysis Result.....	2-25
6.	LIMITATIONS.....	2-26
	6.1 Cell Count Parameters.....	2-26
	6.2 Limitation of Hemoglobin.....	2-27
7.	EXPECTED RESULTS.....	2-28
8.	STOPPING THE PNEUMATIC UNIT.....	2-29
9.	EXECUTION OF SHUTDOWN.....	2-30
	9.1 Shutdown Procedure.....	2-30

CHAPTER 3: DISPLAY AND PROCESSING OF ANALYSIS RESULTS

1.	INTRODUCTION.....	3-1
2.	PROCESSING LATEST SAMPLES.....	3-2
2.1	Display of Analysis Result	3-2
2.2	Manual Discrimination	3-6
2.3	Printing.....	3-10
2.4	Print Paper Feed	3-10
3.	PROCESSING STORED DATA.....	3-11
3.1	Executing and Quitting Stored Data Processing Program.....	3-11
3.2	Stored Data Screen	3-12
3.3	Deletion	3-15
3.4	Printing.....	3-16
3.5	HC Output (Option)	3-16
3.6	Correcting a Sample Number	3-17

CHAPTER 4: MAINTENANCE AND SUPPLIES REPLACEMENT

1.	INTRODUCTION.....	4-1
2.	KX-21 MAINTENANCE CHECKLIST	4-2
3.	DAILY MAINTENANCE AND PROCEDURE	4-4
3.1	Clean TD Chamber and Diluted Sample Line (Shutdown)	4-4
3.2	Check Trap Chamber Level and Discard.....	4-6
4.	WEEKLY MAINTENANCE AND PROCEDURE	4-7
4.1	Clean SRV Tray	4-7
5.	MONTHLY MAINTENANCE AND PROCEDURE.....	4-9
5.1	Clean Waste Chamber (Rinse Sequence).....	4-9
5.2	Clean Transducer (Rinse Sequence)	4-12
6.	EVERY 3-MONTH MAINTENANCE AND PROCEDURE.....	4-16
6.1	Clean Sample Rotor Valve (SRV).....	4-16
6.2	Reset SRV Cycle Counter	4-22
7.	AS-NEEDED MAINTENANCE AND PROCEDURE.....	4-24
7.1	Auto Rinse.....	4-24
7.2	Clean Rinse Cup	4-26
7.3	Clean WBC/RBC Transducer Aperture	4-28
7.4	Replace Waste Tank.....	4-32
8.	SUPPLIES REPLACEMENT	4-33
8.1	Replenish Reagent.....	4-33
8.2	Replace Fuse	4-36
8.3	Replace Printer Paper	4-37
8.4	Supplies List.....	4-40
9.	CONFIRMATION OF CYCLE NUMBER.....	4-41
9.1	Operation Procedure	4-41

CHAPTER 5: QUALITY CONTROL

1.	INTRODUCTION.....	5-1
1.1	\bar{X} Control	5-1
1.2	Levy-Jennings Control (L-J)	5-1
1.3	QC Chart Screen	5-2
2.	QC ANALYSIS PROCEDURE.....	5-4
2.1	QC Analysis Procedure Flow Chart.....	5-4
2.2	Execute QC Program.....	5-5
2.3	Select QC File.....	5-5
2.4	Erase All	5-6
2.5	Set TARGET/LIMIT Values.....	5-7
2.6	Execute \bar{X} Control.....	5-9
2.7	Execute L-J Control	5-18
2.8	Exit from QC Control Program.....	5-24
3.	DELETION.....	5-25
4.	PRINT.....	5-27
5.	HC OUTPUT (OPTION)	5-29

CHAPTER 6: CALIBRATION

1.	INTRODUCTION.....	6-1
1.1	Calibration Execution Timing	6-1
1.2	Samples Used for Calibration.....	6-1
1.3	Reference Values	6-1
1.4	Calibration Flow Chart.....	6-2
2.	AUTOMATIC CALIBRATION	6-3
2.1	Executing Automatic Calibration Program	6-3
2.2	Automatic Calibration Procedure.....	6-4
3.	MANUAL CALIBRATION	6-9
3.1	Calculating Calibration Value	6-9
3.2	Manual Calibration Procedure	6-10

CHAPTER 7: TROUBLESHOOTING

1.	INTRODUCTION	7-1
2.	WHEN YOU SUSPECT A TROUBLE.....	7-2
2.1	Alphabetical List of Error Messages Displayed on Analysis Screen.....	7-3
2.2	Alphabetical List of Error Messages Displayed on HELP Screen ..	7-4
2.3	Functional List of Error Messages.....	7-5
3.	TROUBLESHOOTING GUIDE	7-7
3.1	Pressure/Vacuum Errors	7-7
3.2	Chamber Errors	7-10
3.3	Motor Errors	7-13
3.4	Transducer Errors	7-15
3.5	Temperature Errors	7-16
3.6	Analysis Errors	7-17
3.7	Memory Errors	7-23
3.8	Others.....	7-25
3.9	Maintenance Errors	7-27
3.10	Built-in Printer Errors	7-30
3.11	External Device Errors (When this option is incorporated).....	7-33
4.	STATUS DISPLAY	7-34

CHAPTER 8: ADJUSTMENT

1.	INTRODUCTION	8-1
2.	ADJUSTMENT OF PRESSURE AND VACUUM.....	8-2
2.1	Location of Control Knobs	8-2
2.2	Pressure and Vacuum Display	8-3
2.3	Adjusting Pressure to 0.5 kg/cm ²	8-5
2.4	Adjusting Vacuum to 250 mmHg	8-6

CHAPTER 9: FUNCTIONAL DESCRIPTION

1.	INTRODUCTION.....	9-1
2.	DETECTION PRINCIPLE.....	9-2
	2.1 DC Detection Method.....	9-2
	2.2 Non-Cyanide Hemoglobin Analysis Method.....	9-2
3.	MEASURING UNIT HYDRAULIC SYSTEM BLOCK DIAGRAM.....	9-4
4.	CBC ANALYSIS.....	9-5
	4.1 WBC/HGB Analysis Flow.....	9-5
	4.2 RBC/PLT Analysis Flow.....	9-7
	4.3 Calculation of RBC Constant.....	9-9
5.	BLOOD CELL DISCRIMINATION CIRCUIT.....	9-10
	5.1 WBC Discriminator.....	9-10
	5.2 RBC Discriminator.....	9-10
	5.3 PLT Discriminator.....	9-10
6.	ANALYSIS OF HISTOGRAM.....	9-11
	6.1 Analysis of WBC Histogram.....	9-11
	6.2 Analysis of RBC/PLT Histogram.....	9-20
7.	ELECTRIC SYSTEM.....	9-28
8.	NAMES AND FUNCTIONS OF INSTRUMENTS.....	9-30
	8.1 Front Panel.....	9-30
	8.2 Front Interior.....	9-31
	8.3 Right Side Panel.....	9-32
	8.4 Left Side Panel.....	9-33
	8.5 Left Side Interior.....	9-34
	8.6 Rear Panel.....	9-35

CHAPTER 10: INSTRUMENT SETUP

1.	INTRODUCTION.....	10-1
2.	SYSTEM SETUP.....	10-2
3.	DATE/TIME SETTINGS.....	10-7
4.	PATIENT LIMIT.....	10-10
5.	QC SETTINGS.....	10-13
6.	HOST SETTINGS (OPTION).....	10-16
7.	PRINTER SETTINGS.....	10-21
8.	PRINT SET VALUES.....	10-24
9.	PERIPHERAL SETTINGS.....	10-25
10.	FACTORY SETTINGS.....	10-27

APPENDIX A: INSTALLATION

1.	INTRODUCTION.....	A-1
2.	CHECK BEFORE INSTALLATION	A-2
3.	INSTALLATION SPACE.....	A-3
4.	REMOVE SHIPPING CLAMPS.....	A-4
5.	CONNECT TUBE.....	A-6
	5.1 Prepare Reagent.....	A-6
	5.2 Connect CELLPACK	A-6
	5.3 Connect STROMATOLYSER-WH.....	A-8
	5.4 Connect Waste Line.....	A-9
6.	SET PRINTER PAPER.....	A-10
7.	CONNECT POWER CORD.....	A-12
8.	TURN POWER ON.....	A-12

APPENDIX B: TECHNICAL INFORMATION

1.	OUTPUT FORMAT FOR HOST COMPUTER (Option).....	B-1
	1.1 Hardware.....	B-1
	1.2 Software.....	B-3

INDEX

CHAPTER 1

INTRODUCTION

1.	INTRODUCTION	1-1
2.	OVERVIEW OF INSTRUMENT.....	1-2
3.	OPTION UNITS.....	1-3
4.	OUTLINE OF OPERATION.....	1-3
5.	AUTOMATIC STOP FUNCTION OF PNEUMATIC UNIT.....	1-3
6.	ANALYSIS PARAMETERS.....	1-4
7.	PANEL KEYBOARD.....	1-6
8.	GRAPHIC SCREEN.....	1-7
8.1	Contents of Display.....	1-7
8.2	Status Display Messages.....	1-8
8.3	LCD Brightness Adjustment.....	1-11
9.	EMERGENCY STOP PROCEDURE.....	1-11
10.	ALARM SOUNDS	1-11
11.	CONTENTS OF PACKAGE.....	1-11
12.	INSTALLATION ENVIRONMENT.....	1-12
12.1	Installation and Relocation.....	1-12
12.2	Grounding	1-12
12.3	Installation Space.....	1-13
12.4	Installation Environment	1-14
13.	INSTRUMENT SPECIFICATIONS.....	1-15
14.	MENU TREE.....	1-18

1. INTRODUCTION

The Sysmex® KX-21 is an automatic multi-parameter blood cell counter *for in vitro diagnostic use* in clinical laboratories.

The KX-21 processes approximately 60 samples an hour and displays on the LCD screen the particle distribution curves of WBC, RBC, and platelets, along with data of 18 parameters, as the analysis results.

Chapter 1 introduces the overview of the instrument, analysis procedure, etc. that we recommend you to read before using the KX-21. The main contents of Chapter 1 are as follows:

Overview of Instrument

The important functions of the KX-21 and the options for efficient operation are explained.

Main Points of Analysis Procedure

Explanation is given on the procedure for implementing each analysis mode, descriptions and functions of the keys on panel keyboard, and the messages on the LCD screen.

Precautions at Time of Installation

Explanation is given on the matters that need to be confirmed before installation, such as installation space, required equipment, environmental conditions.

Instrument Specifications

The instrument specifications are described.

Menu Tree

This chapter describes the KX-21 menu tree and the corresponding chapters which explain the usage of the menus.

2. OVERVIEW OF INSTRUMENT

The KX-21 performs speedy and accurate analysis of 18 parameters in blood and detects the abnormal samples. To assure easy sorting of abnormal samples in the laboratory, the instrument displays abnormal analysis data with abnormal marks attached on the LCD screen. Thus displayed analysis data allows detecting those samples which are outside the tolerance and need further analysis and reconsideration.

The KX-21 employs three detector blocks and two kinds of reagents for blood analysis. The WBC count is measured by the WBC detector block using the DC detection method. The RBC count and platelets are taken by the RBC detector block, also using the DC detection method. The HGB detector block measures the hemoglobin concentration using the non-cyanide hemoglobin method.

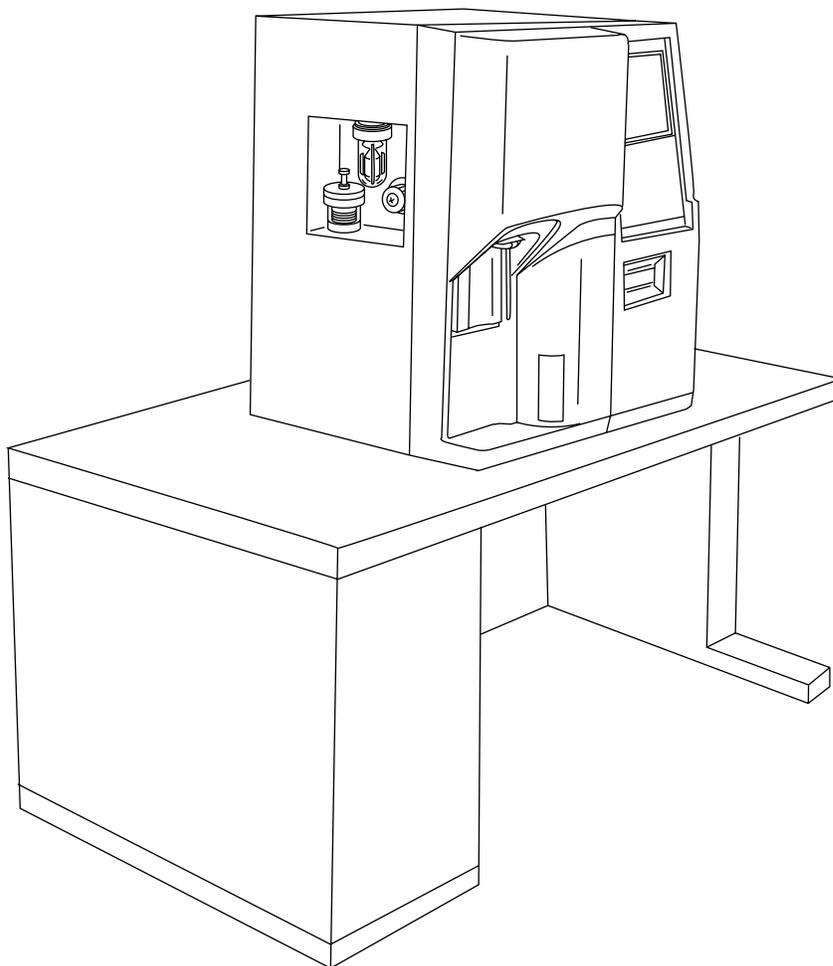


Figure 1-2-1: Overview of KX-21

3. OPTION UNITS

This instrument offers several option units to ensure its efficient operation. The options that can be used with the KX-21 are:

- Serial interface: Outputs analysis data and QC data to the host computer. Ordering Information: OUTPUT UNIT NO. 1 KX-21 (Part No. 973-4531-1)

4. OUTLINE OF OPERATION

Two analysis modes are available with the KX-21: whole blood mode and pre-diluted mode. Analysis procedures in these modes are listed below.

Whole blood mode	Pre-diluted mode
Check before turning ON the power.	
Turn ON the power.	
<ul style="list-style-type: none"> • Self-check • Background check 	
Ready	
Select whole blood mode.	Select pre-diluted mode.
Set sample No.	Prepare analysis samples in pre-diluted mode (1:26 dilution).
	Set sample No.
Set sample to the sample probe.	
Press the start switch.	
<ul style="list-style-type: none"> • Execute analysis. • End analysis. 	
Ready	
Check after analysis.	
Execute shutdown.	
Turn off the power.	

Table 1-4-1: Outline of Operation

- The work by an operator is shown in shaded cells.
- **Ready**: "Ready" is displayed on the LCD screen. In this state, various operations including analysis, settings, and data processing can be performed.

5. AUTOMATIC STOP FUNCTION OF PNEUMATIC UNIT

The KX-21, when left non-operating for 15 minutes, automatically stops the pneumatic unit. This function saves power consumption and extends component service life. In addition, with this function, analysis-ready status can be resumed faster than by turning on the power. It is also possible to manually stop the pneumatic unit through the Select Menu screen.

6. ANALYSIS PARAMETERS

This instrument analyzes the following parameters using three detector blocks and two kinds of reagents:

- 1) Whole WBC (white blood cell) (Analysis principle: DC detection method)
WBC count in 1 μ L of whole blood
- 2) LYM% [W-SCR] (WBC-Small Cell Ratio)
Ratio (%) of lymphocytes (small cells) to whole WBC
- 3) MXD% [W-MCR] (WBC-Middle Cell Ratio)
Ratio (%) of the summation of basophils, eosinophils and monocytes (middle cells) to whole WBC
- 4) NEUT% [W-LCR] (WBC-Large Cell Ratio)
Ratio (%) of neutrophils (large cells) to whole WBC
- 5) LYM# [W-SCC] (WBC-Small Cell Count)
Absolute count of lymphocytes (small cells) in 1 μ L of whole blood
- 6) MXD# [W-MCC] (WBC-Middle Cell Count)
Absolute count of the basophils, eosinophils and monocytes (middle cells) in 1 μ L of whole blood
- 7) NEUT# [W-LCC] (WBC-Large Cell Count)
Absolute count of neutrophils (large cells) in 1 μ L of whole blood
- 8) RBC (red blood cell) (Analysis principle: DC detection method)
RBC count in 1 μ L of whole blood
- 9) HGB (Hemoglobin) (Analysis principle: Non-Cyanide hemoglobin analysis method)
Volume (gram) of hemoglobin in 1 dL of whole blood
- 10) HCT (Hematocrit value) (Analysis principle: RBC pulse height detection method)
Ratio (%) of whole RBC volume in whole blood
- 11) MCV (Mean RBC volume)
Mean RBC volume (fL) in whole blood, which is calculated by Hct/RBC.
- 12) MCH (Mean RBC hemoglobin)
Mean hemoglobin volume (pg) per RBC, which is calculated by Hgb/RBC.
- 13) MCHC (Mean RBC hemoglobin concentration)
Mean hemoglobin concentration (g/dL), which is calculated by Hgb/Hct.

- 14) RDW-CV (RBC distribution width - CV)
RBC distribution width (%) calculated from the points defining 68.26% of the entire area spreading from the peak of the RBC particle distribution curve.
- 15) RDW-SD (RBC distribution width - SD)
The distribution width (fL) at the height of 20% from the bottom when the peak RBC particle distribution curve is taken as 100%.
- 16) PLT (Platelet) (Analysis principle: DC detection method)
Platelet count in 1 μ L of whole blood
- 17) PDW (Platelet distribution width)*
The distribution width (fL) at the height of 20% from the bottom with the peak of platelet particle distribution curve taken as 100%.
- 18) MPV (Mean platelet volume)
Mean volume of platelet (fL)
- 19) P-LCR (Large platelet ratio) *
Ratio (%) of large platelet volume exceeding 12 fL to the platelet volume

NOTE:

- When analyzing in the pre-diluted mode, only the CBC8 parameters are output.
- The RBC distribution width is the switchover type between RDW-SD and RDW-CV.

* For Investigational Use Only in the United States of America.
Not a reportable parameter.

7. PANEL KEYBOARD

The KX-21 is provided with the 22-key panel keyboard.

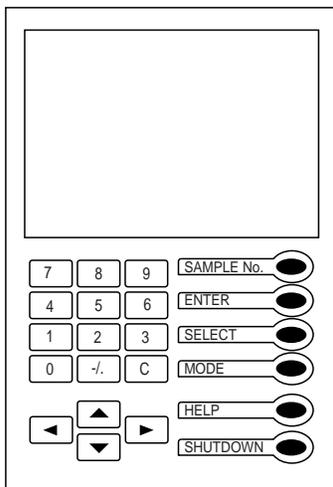


Figure 1-7-1: Panel Keyboard

Name	Function
SAMPLE No.	Used to set a sample No. and QC File No.
ENTER	Used to fix a sample No., selected menu, etc.
SELECT	Used to select a menu. Press this key to display the Select Menu screen. When you press it while the Select Menu screen is displayed, the Analysis screen returns.
MODE	Used to changeover analysis mode (whole blood mode/pre-diluted mode).
HELP	Used when an error has occurred.
SHUTDOWN	Used to execute shutdown program.
0 - 9	Used to enter numerics such as a sample No., QC File No., and set value.
-./.	Used to enter "-" (hyphen) of a sample No., the decimal point of a set value.
C	Used to delete characters when entering numerics, and stop the alarm.
▲, ▼	Used to select a menu. Each time a key is pressed, the cursor moves to the previous or the next item.
◀, ▶	Used to select conditions when setting, and to select Manual Discriminator.

Table 1-7-1: Functions of Panel Keyboard

CAUTION:

- When the alarm is sounding after an error, etc. occurred, press [C] key to stop it or press [HELP] key to display the HELP screen. By pressing [HELP] key, the alarm stops and the HELP screen appears. While the alarm is sounding, the keys other than [C] key and [HELP] key cannot be used.

8. GRAPHIC SCREEN

8.1 Contents of Display

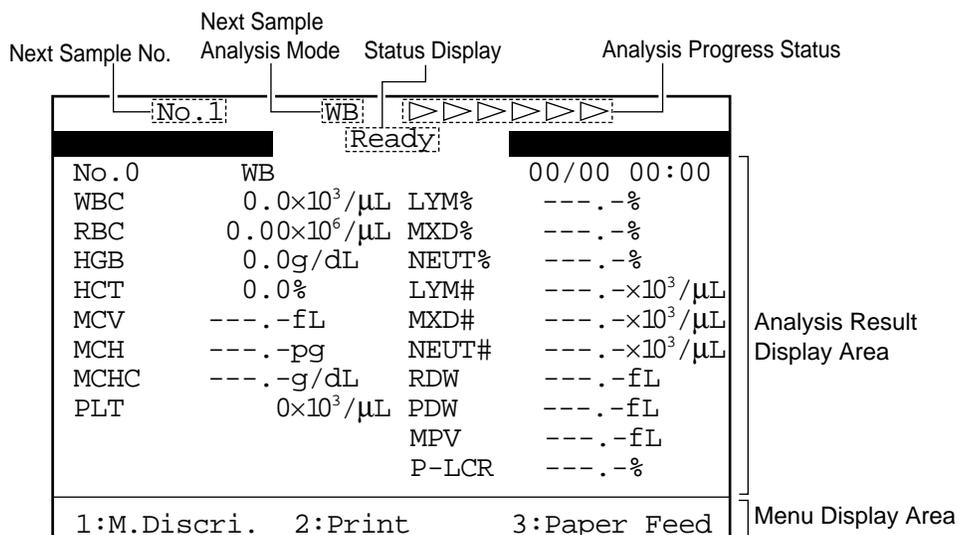


Figure 1-8-1: Graphic LCD

Name	Function
Next Sample No.	Displays the sample No. to be analyzed next.
Next Sample Analysis Mode	Displays the analysis mode for the sample to be analyzed next. WB: whole blood mode PD: pre-diluted mode
Analysis Progress Status	With the start-to-end analysis progress classified into six steps, the present progress status is displayed.
Status Display	Status of the unit is displayed.
Menu Display Area	Useable menus for each screen are displayed.
Analysis Result Display Area	The area for displaying analysis result

Table 1-8-1: Contents of Display

8.2 Status Display Messages

The KX-21 displays instrument status message on the LCD screen. This section gives the meanings of status messages displayed on the LCD screen.

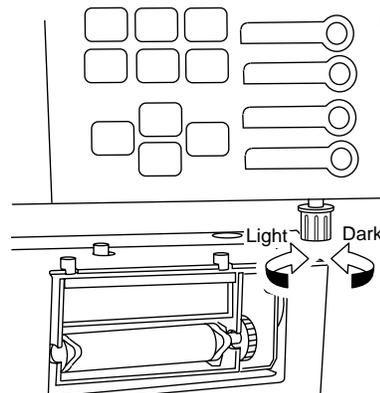
Display Message	Meaning
<div style="border: 1px solid black; padding: 10px; margin: 5px;"> <p style="text-align: center;">Sysmex KX-21</p> <p style="text-align: right;">[00-01]</p> </div>	<p>The instrument is making self-check. When the power is turned ON, the instrument checks itself automatically. When the power is turned ON, [00-01] appears briefly in the right lower corner, which indicates the version of the unit control program.</p>
<div style="border: 1px solid black; padding: 10px; margin: 5px;"> <p style="text-align: center;">*Auto Rinse*</p> <p style="text-align: center;">Please wait.</p> </div>	<p>The hydraulic system is undergoing Auto Rinse. When the power is turned ON, the instrument starts self-check and motor check, followed by auto rinse of the hydraulic system. Auto rinse is also performed when "5: Auto Rinse" in the Select menu is executed and when [SHUTDOWN] key is pressed. When an automatic background check shows a background count exceeding the permissible background count level, rinse sequence is automatically extended.</p>

Display Message	Meaning
<pre> No.1 WB >>>>>>>> Ready No.0 WB 00/00 00:00 WBC 0.0x10³/μL LYM% ---.-% RBC 0.00x10⁶/μL MXD% ---.-% HGB 0.0g/dL NEUT% ---.-% HCT 0.0% LYM# ---.-x10³/μL MCV ---.-fL MXD# ---.-x10³/μL MCH ---.-pg NEUT# ---.-x10³/μL MCHC ---.-g/dL RDW ---.-fL PLT 0x10³/μL PDW ---.-fL MPV ---.-fL P-LCR ---.-% 1:M.Discri. 2:Print 3:Paper Feed </pre>	<p>The instrument is ready for analysis in the whole blood mode. "No." in the left upper corner indicates the sample No. to be analyzed next.</p>
<pre> No.1 PD >>>>>>>> Ready No.0 PD 00/00 00:00 WBC 0.0x10³/μL LYM% ---.-% RBC 0.00x10⁶/μL MXD% ---.-% HGB 0.0g/dL NEUT% ---.-% HCT 0.0% LYM# ---.-x10³/μL MCV ---.-fL MXD# ---.-x10³/μL MCH ---.-pg NEUT# ---.-x10³/μL MCHC ---.-g/dL RDW ---.-fL PLT 0x10³/μL PDW ---.-fL MPV ---.-fL P-LCR ---.-% 1:M.Discri. 2:Print 3:Paper Feed </pre>	<p>The instrument is ready for pre-diluted mode analysis. "No." in the left upper corner shows the sample No. to be analyzed next.</p>
<pre> FILE No.1 QC >>>>>>>> Ready x1 x2 x̄ Judgement WBC RBC HGB HCT MCV MCH MCHC PLT </pre>	<p>The instrument is ready for \bar{X} control. "FILE No. 1" in the left upper corner shows QC file No.</p>
<pre> FILE No.1 QC >>>>>>>> Ready Data Judgement WBC RBC HGB HCT MCV MCH MCHC PLT </pre>	<p>The instrument is ready for L-J control. "FILE No. 1" in the left upper corner shows QC file No.</p>

Display Message	Meaning
<p>*Change Mode*</p> <p>Please wait.</p>	<p>The whole blood mode is turning into the pre-diluted mode, or the pre-diluted mode is turning into the whole blood mode.</p>
<p>No.123457 WB ▶▶▶▶▶▶▶▶ Aspirating</p>	<p>The sample is being aspirated in whole blood mode analysis.</p>
<p>No.123457 PD ▶▶▶▶▶▶▶▶ Aspirating</p>	<p>The sample is being aspirated in pre-diluted mode analysis.</p>
<p>No.123457 WB ▶▶▶▶▶▶▶▶ Analyzing</p>	<p>Samples are being aspirated, diluted, and counted in whole blood mode (or pre-diluted mode).</p>
<p>No.123457 WB ▶▶▶▶▶▶▶▶ Rinsing</p>	<p>Hydraulic line in the whole blood mode (or pre-diluted mode) is being rinsed.</p>
<p>No.123457 WB Replenish Diluent Not Ready</p>	<p>An error occurs, making analysis impossible. (When an error occurs, the error message appears in reversed display in the right upper area of the LCD screen.)</p>
<p>No.123457 WB PU Sleeping Not Ready</p>	<p>When operation has been suspended over 15 minutes, the compressor power is turned OFF and this message is displayed. Press the [START] switch to get ready for analysis.</p>
<p>Momentary power failure occurred.</p>	<p>When the power is turned off without making shutdown process or when power outage caused the instrument to stop, this message appears when the unit is started next time.</p>
<p>WB ▶▶▶▶▶▶▶▶ * Ready</p>	<p>When data is automatically output to the host computer, " * " mark lights up in the right upper corner of the screen. This applies only when an optional serial interface is incorporated.</p>

8.3 LCD Brightness Adjustment

Open the front cover of the instrument. LCD brightness can be adjusted using the brightness adjustment knob under the panel keyboard. Turning to the right brightens the light and turning to the left dims it.



9. EMERGENCY STOP PROCEDURE

When there arises the need to stop the instrument urgently because of power outage, etc., in the laboratory, turn off the instrument power switch.

10. ALARM SOUNDS

The KX-21 indicates different situations by five kinds of alarm sounds:

1. Key sound (single beep)
Sounds about 0.1 second when a key on the panel keyboard is pressed.
2. Input error sound (short beep)
Sounds about 1 second when a wrong key is pressed on the panel keyboard.
3. Analysis error sound (long beep)
Sounds when an error occurs in the instrument and continues until you press [C] key or [HELP] key on the panel keyboard.
4. Sound at sample aspiration
Usually: A single "beep" when the start switch is pressed; "beep, beep" when aspiration is finished.
Sample No. "0" or in pre-diluted mode: Beep sounds (beep, beep, ...) continue from pressing the start switch until aspiration ends.

11. CONTENTS OF PACKAGE

The instrument is fully inspected before leaving the factory and carefully packed to withstand shocks in transit. Upon arrival, check the package to see that there is no external damage. Sysmex service representative will unpack, install the instrument, and make initial settings. To confirm the contents of the package, refer to *"Appendix A: Installation."*

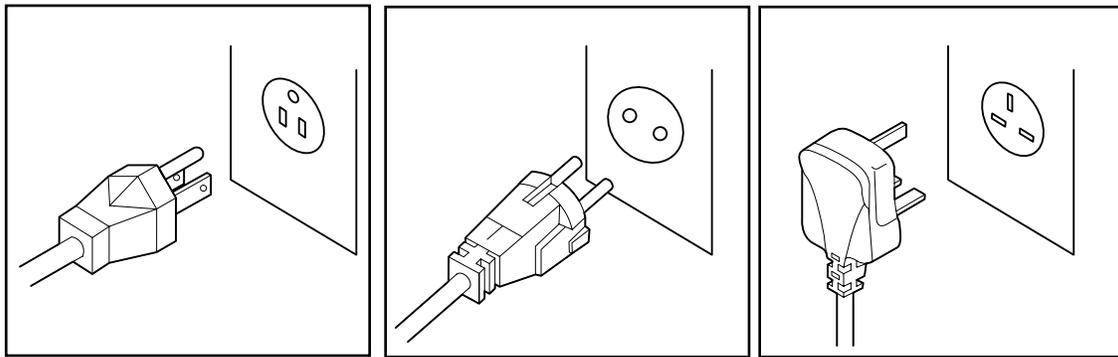
12. INSTALLATION ENVIRONMENT

12.1 Installation and Relocation

The KX-21 is installed by Sysmex Service representative. In case relocation becomes necessary after installation, contact your Sysmex service representative. Pay careful attention to this because if relocation, etc. of the instrument should be conducted by the customer, resulting in any trouble, warranty would not be applied even in the warranty period.

12.2 Grounding

The instrument power supply cord uses the 3-prong plug. When the power supply socket is 3-prong with grounding, simply plug it to the socket.



117 VAC Spec.

220 VAC Spec.

240 VAC Spec.

Figure 1-12-1: Plugs



WARNING • Make sure to ground the instrument. Inadequate grounding could cause electrical shocks.

NOTE:

• The number of power supply sockets required is one.

12.3 Installation Space

To ensure that the instrument fulfills its function, it is important to install it at an appropriate place:

- Choose a place that is close to the power supply and proper waterway.
- Secure a place spacious enough for maintenance and service. Giving consideration to heat radiation by the instrument, provide at least 50 cm distance from the wall to side, rear, and top panels.
- Choose a place where reagent is easy to handle.

The instrument dimensions are shown below. The power supply cord is 1.8 m long, the waste tube up to 6 m long, and the diluent (CELLPACK) tube up to 2 m long.

	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	420	355	480	28

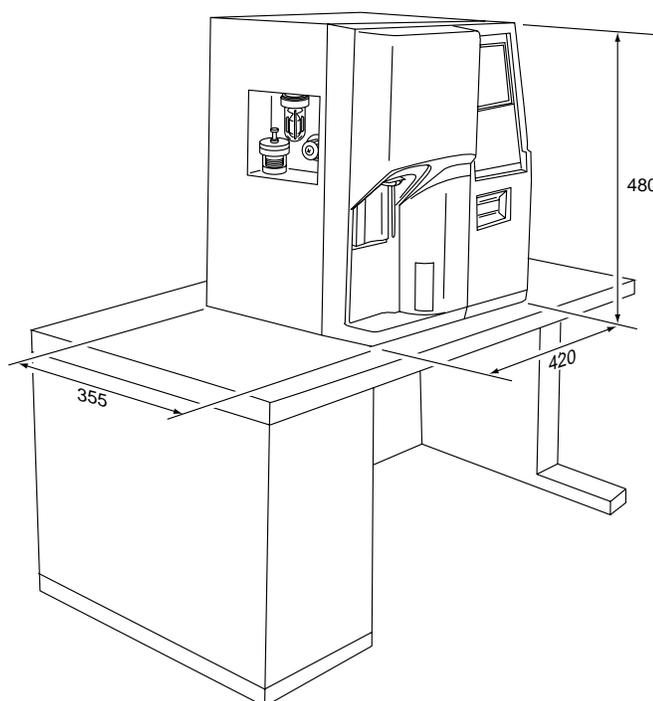


Figure 1-12-2: Instrument Dimensions

CAUTION:

- When the diluent (CELLPACK) tube is more than 2 m long, it may be impossible to have reagent aspirated. Avoid setting CELLPACK at a level higher than the instrument; otherwise, reagent may flow into the vacuum line, possibly damaging the instrument.

12.4 Installation Environment

- Use the instrument at an ambient temperature of 15°C - 30°C (optimum: 23°C).
- Use it at a relative humidity range of 30% - 85%.
- When air conditioning is used, the maximum cooling capacity of about 172 kcal/hour is required to offset the heat from the instrument.
- Avoid a place that can become extremely hot or cold.
- Avoid a place that can be exposed to direct sunlight.
- Choose a well-ventilated place.
- Avoid a place close to a wireless telegraph or communication facility where high frequency waves can be generated or radio interference can occur.

13. INSTRUMENT SPECIFICATIONS

Analysis parameters:

WBC (White Bloodcell Count), RBC (Red Bloodcell Count), HGB (hemoglobin), HCT (hematocrit), MCV (mean corpuscular volume), MCH (mean corpuscular hemoglobin), MCHC (mean corpuscular hemoglobin concentration), PLT (platelet), RDW-SD (RBC distribution width-standard deviation), RDW-CV (RBC distribution width-coefficient of variation), PDW (platelet distribution width)*, MPV (mean platelet volume), P-LCR (platelet large cell ratio)*, LYM% (W-SCR), MXD% (W-MCR), NEUT% (W-LCR), LYM# (W-SCC), MXD# (W-MCC), NEUT# (W-LCC) (RDW-SD or RDW-CV: Switch over type) However, the parameters in pre-diluted mode are eight: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT.

* For Investigational Use Only in the United States of America.
Not a reportable parameter.

Display range

WBC	0.0 - 299.9 ($\times 10^3/\mu\text{L}$)
RBC	0.00 - 19.99 ($\times 10^6/\mu\text{L}$)
HGB	0 - 25.0 (g/dL)
PLT	0 - 1999 ($\times 10^3/\mu\text{L}$)

Reagent

Diluent: CELLPACK
WBC/HGB lyse reagent: STROMATOLYSER-WH

Detergent

CELLCLEAN

Consumption of reagent (per sample)

Diluent (CELLPACK): Approx. 30 mL
WBC/HGB lyse reagent (STROMATOLYSER-WH): Approx. 1.0 mL

Throughput

Approx. 60 samples/hour

Analysis principle

WBC: DC detection method
RBC: DC detection method
HGB: Non-cyanide hemoglobin analysis method

Reproducibility

Reproducibility is within the following range at the reliability level of 95%.

1) Whole blood mode	
WBC ($4.0 \times 10^3/\mu\text{L}$ or over)	3.5% or less
RBC ($4.00 \times 10^6/\mu\text{L}$ or over)	2.0% or less
HGB	1.5% or less
HCT	2.0% or less
MCV	2.0% or less
MCH	2.0% or less
MCHC	2.0% or less
PLT ($100 \times 10^3/\mu\text{L}$ or over)	6.0% or less
LYM# (W-SCC)	15.0% or less
MXD# (W-MCC) ($1.0 \times 10^3/\mu\text{L}$ or over)	30.0% or less
NEUT# (W-LCC)	15.0% or less
LYM% (W-SCR)	15.0% or less
MXD% (W-MCR) (12% or over)	30.0% or less
NEUT% (W-LCR)	15.0% or less
RDW-SD or RDW-CV	4.0% or less
PDW	12.0% or less
MPV	5.0% or less
P-LCR	20.0% or less
2) Pre-diluted mode	
WBC ($4.0 \times 10^3/\mu\text{L}$ or over)	6.0% or less
RBC ($4.00 \times 10^6/\mu\text{L}$ or over)	3.0% or less
HGB	2.5% or less
HCT	3.0% or less
MCV	3.0% or less
MCH	3.0% or less
MCHC	3.0% or less
PLT ($100 \times 10^3/\mu\text{L}$ or over)	9.0% or less

Accuracy

1) Whole blood mode	
WBC:	$\pm 3\%$ or $\pm 0.2 \times 10^3/\mu\text{L}$ or less
RBC:	$\pm 2\%$ or $\pm 0.03 \times 10^6/\mu\text{L}$ or less
PLT:	$\pm 5\%$ or $\pm 10 \times 10^3/\mu\text{L}$ or less
2) Pre-diluted mode	
WBC:	$\pm 5\%$ or $\pm 0.3 \times 10^3/\mu\text{L}$ or less
RBC:	$\pm 3\%$ or $\pm 0.05 \times 10^6/\mu\text{L}$ or less
PLT:	$\pm 8\%$ or $\pm 15 \times 10^3/\mu\text{L}$ or less

Linearity

1) Whole blood mode		
WBC:	1.0 - 9.9 ($\times 10^3/\mu\text{L}$)	± 0.3 ($\times 10^3/\mu\text{L}$) or less
	10.0 - 99.9 ($\times 10^3/\mu\text{L}$)	$\pm 3\%$ or less
RBC:	0.30 - 0.99 ($\times 10^6/\mu\text{L}$)	± 0.03 ($\times 10^6/\mu\text{L}$) or less
	1.00 - 7.00 ($\times 10^6/\mu\text{L}$)	$\pm 3\%$ or less
HGB:	0.1 - 10.0 (g/dL)	± 0.2 (g/dL) or less
	10.0 - 25.0 (g/dL)	$\pm 2\%$ or less
HCT:	10.0 - 33.3 (HCT%)	± 1.0 (HCT%) or less
	33.4 - 60.0 (HCT%)	$\pm 3\%$ or less
PLT:	10 - 199 ($\times 10^3/\mu\text{L}$)	± 10 ($\times 10^3/\mu\text{L}$) or less
	200 - 999 ($\times 10^3/\mu\text{L}$)	$\pm 5\%$ or less
	(However, RBC < $7.00 \times 10^6/\mu\text{L}$)	

Carryover

WBC:	3% or less
RBC:	1.5% or less
HGB:	1.5% or less
HCT:	1.5% or less
PLT:	5% or less

Blood volume aspirated

Whole blood mode:	Approx. 50 μL
Pre-diluted mode:	Approx. 200 μL (Diluted blood sample)
	Blood volume required for the pre-dilution is 20 μL or over.

Power supply

117/220/230/240 VAC $\pm 10\%$ or less (50/60 Hz)

Power consumption

Approx. 230 VA or less

Heat Compensation Required

Approx. 785 BTU/h (198 kcal/h)

Dimensions

Main Unit: 420 (W) \times 355 (D) \times 480 (H) mm

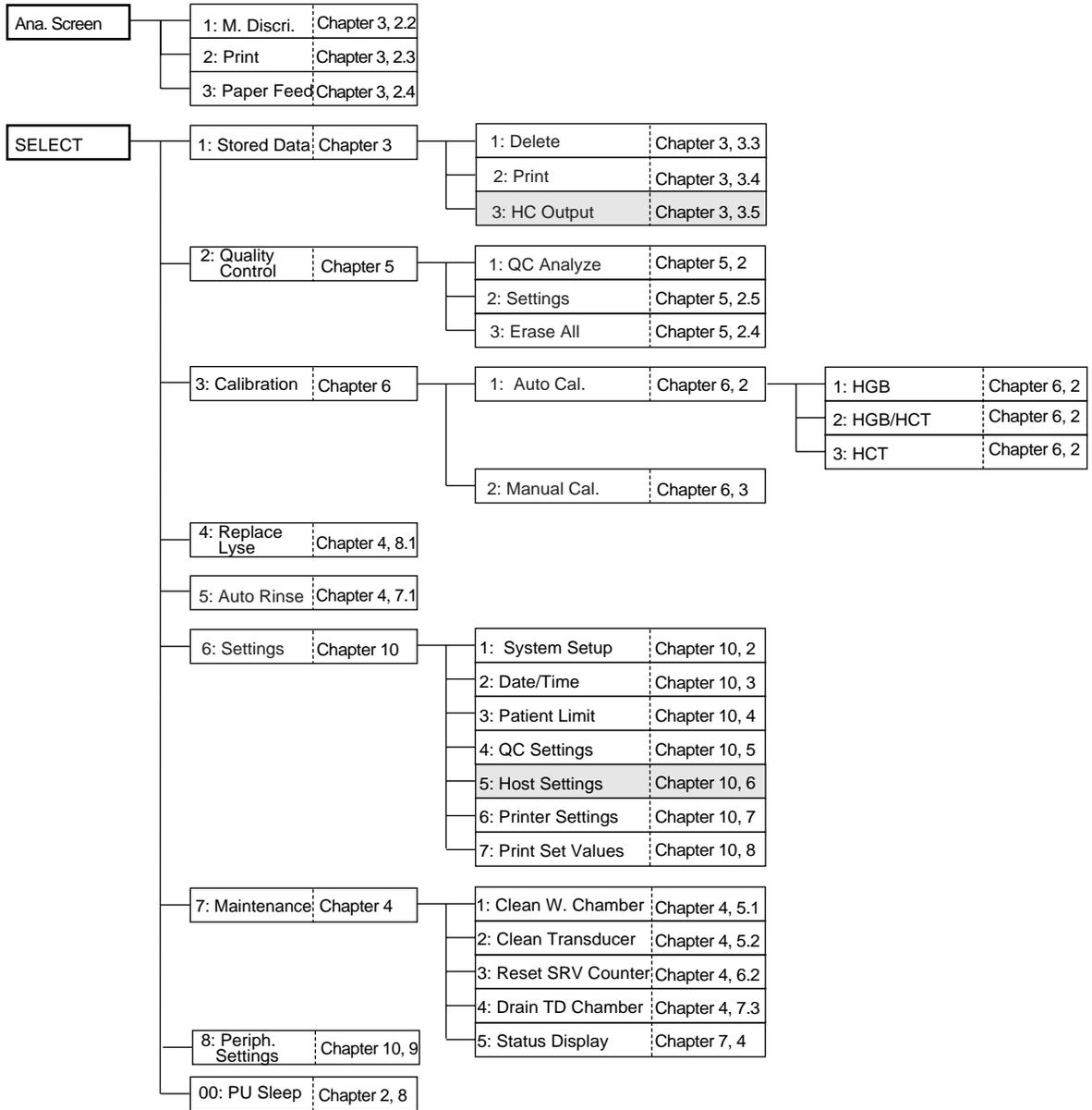
Weight

Main Unit: Approx. 28.0 kg

Classification

According to the type of protection against electric shock:	Class I Equipment
According to the degree of protection against electric shock:	Type B Equipment

14. MENU TREE



SAMPLE No. Chapter 2, 4

MODE Chapter 2, 4

HELP Chapter 7, 1

SHUTDOWN Chapter 2, 6

: Applicable when the option is provided.

CHAPTER 2

SAMPLE ANALYSIS

1.	INTRODUCTION	2-1
1.1	Overview of Analysis Modes.....	2-1
1.2	Analysis Procedure Flow Chart.....	2-2
2.	START-UP PROCEDURE.....	2-3
2.2	Inspection before Turning ON the Power.....	2-3
2.2	Turning ON the Power and Self-Check.....	2-5
3.	QUALITY CONTROL	2-8
4.	PROCEDURES IN EACH ANALYSIS MODE	2-9
4.1	Whole Blood (WB) Mode.....	2-9
4.2	Pre-Diluted (PD) Mode.....	2-16
5.	DISPLAY AND PRINTING OF ANALYSIS RESULT	2-24
5.1	Display of Analysis Result.....	2-24
5.2	Printing of Analysis Result	2-25
6.	LIMITATIONS.....	2-26
6.1	Cell Count Parameters.....	2-26
6.2	Limitation of Hemoglobin.....	2-27
7.	EXPECTED RESULTS.....	2-28
8.	STOPPING THE PNEUMATIC UNIT	2-29
9.	EXECUTION OF SHUTDOWN	2-30
9.1	Shutdown Procedure	2-30

1. INTRODUCTION

This instrument works in two analysis modes: whole blood mode and pre-diluted mode. This chapter describes the general operation procedures from instrument start-up to shutdown, with the procedures in respective analysis modes.

1.1 Overview of Analysis Modes

- Whole blood mode
This is the mode of analyzing collected blood sample in the whole blood status. The tube cap is opened and the sample is aspirated through the sample probe one after another.
- Pre-diluted mode
This mode is used in analyzing a minute amount of child's blood, for instance, collected from the earlobe or fingertip. In this mode, blood sample diluted into 1:26 before analysis is used. The sample aspiration procedure is the same as in the whole blood mode.

NOTE: <ul style="list-style-type: none">• In the pre-diluted mode, particle distribution curve and particle distribution analysis data are not output, and the output is confined to only the CBC8 parameter.
--

1.2 Analysis Procedure Flow Chart

Shown below is the Flow Chart for the operation procedure with pages to refer to.

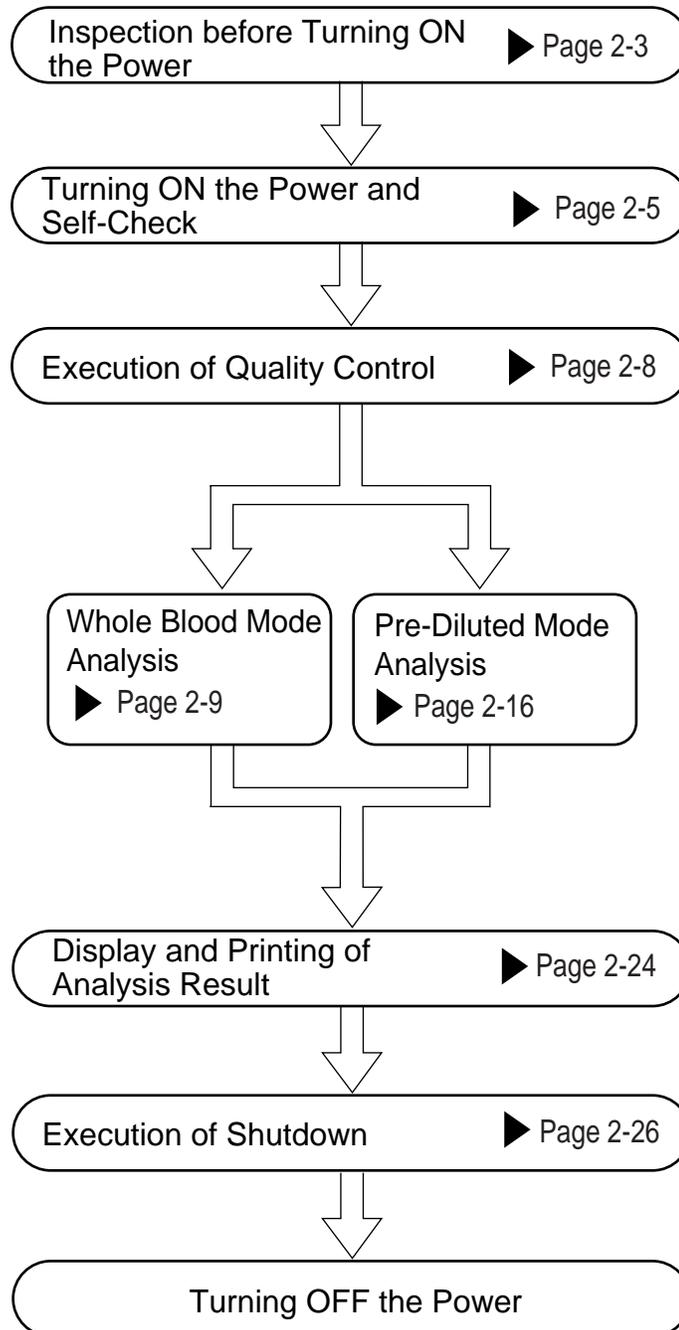


Table 2-1-1: Analysis Procedure Flow Chart

2. START-UP PROCEDURE

2.1 Inspection before Turning ON the Power

1. Inspection of reagents

Check to see that the reagents needed for the number of the samples to be processed for the day are available. If the number available is such as might become short during the day, make ready the reagents for use in replenishment. When reagents run out during analysis, the instrument will automatically come to a stop. Replenish the reagent that gave an error. Until replenishment is completed, analysis cannot be resumed. The number of samples that can be analyzed with one pack of reagent is listed below:

- Number of the samples that can be analyzed with one pack of reagent
 CELLPACK: Approx. 600 samples/20 L (cubitainer)
 STROMATOLYSER-WH: Approx. 470 samples/500 mL (bottle)
 (The above values are the result of continuous analyses performed in one day in the whole blood mode. Depending on the use conditions of the instrument, the result may differ.)
- Replenishing reagent
 - Make ready a new reagent and make sure that it has not passed its expiration date. (For detail, refer to *Chapter 4, Section 8: SUPPLIES REPLACEMENT.*)

 **CAUTION**

- Use a reagent that has been left at room temperature (15 - 30°C) for more than 24 hours.
- If CELLPACK that has just arrived is used, "Background Error" may occur.
- After replenishing a reagent, make sure that its background count is low before starting sample analysis.
- As to a reagent that may have frozen, handle it in accordance with the precautions stated on the Package Insert. Otherwise, there is a possibility that proper analysis cannot be performed.
- When replacing the reagent container, take care not to have dust adhere to the cubitainer spout kit.
- After unpacking, take care to prevent entry of dust, dirt, bacteria, etc. which could impair proper analysis.

CELLPACK	20 L	60 days
STROMATOLYSER-WH	500 mL	90 days

Table 2-2-1: Expiration After Opening the Seal

- We recommend preparing "Reagent Replenishment Record" in which to enter date of replenishment, name of reagent, reagent lot No., expiration date, name of person who replenished. Such record would come handy.
2. **Inspection of the instrument**
Inspect the connection of tubings and cords to see that there are no broken tubes and the power cord is properly plugged in the outlet.
 3. **Inspection of waste**
If waste is found to have collected in the trap chamber on the left side of the unit and the waste tank (when provided), discard the waste.
 4. **Inspection of printer paper**
Open the front cover and check if printer paper needed for processing the samples for the day is available.

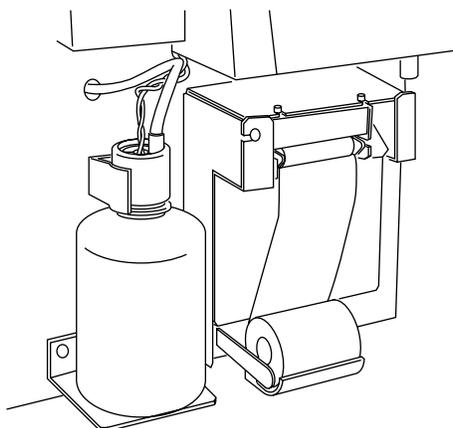


Figure 2-2-1: Inspection of Printer Paper

<p>CAUTION:</p> <ul style="list-style-type: none">• Use the printer paper specified by Sysmex. Avoid using print paper that has its end fixed to the core. Such paper can cause failure.

2.2 Turning ON the Power and Self-Check

Turn ON the power switch on the right side of the unit. Self-check, auto rinse, and background check will be automatically performed, and the "Ready" (ready for analysis) will appear.

1. Turn ON the power switch

- (1) The initial display appears on the LCD screen. The program version (Example: [00-01]) appears at the right lower area of the screen.

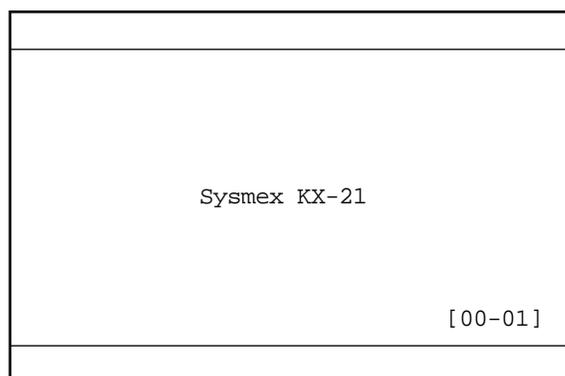


Figure 2-2-2: Initial Display

- (2) Next, the instrument makes self-check of motor operation, scheduled maintenance items, etc. The LCD screen displays "Please wait." during this period.

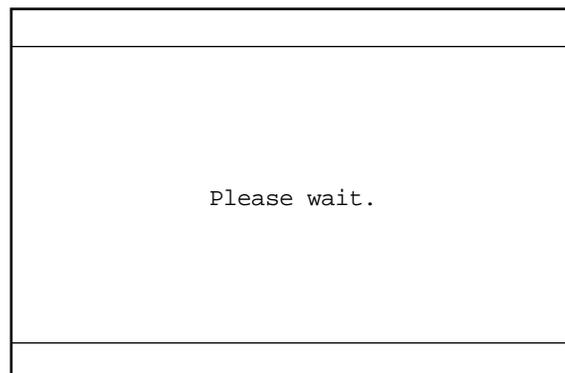


Figure 2-2-3: LCD Screen during Self-check

CAUTION:

- When self-check reveals any error, an error message will appear on the LCD screen. In this case, turn OFF the power once, then turn it ON again. If the error still occurs, contact Sysmex service representative.
- To ensure optimum operation of the instrument, service counters are provided for the components which require scheduled maintenance. If upon the power turn-on, the counter is found exceeding the predetermined times, the screen advising scheduled maintenance is displayed. When the Scheduled Maintenance screen appears, press [C] key to stop the alarm sound, then perform maintenance operation by following the instructions on the screen.
For detail, refer to *Chapter 4: INSTRUMENT MAINTENANCE AND SUPPLIES REPLACEMENT.*

- (3) When self-check is normally completed, auto rinse and background check are performed.

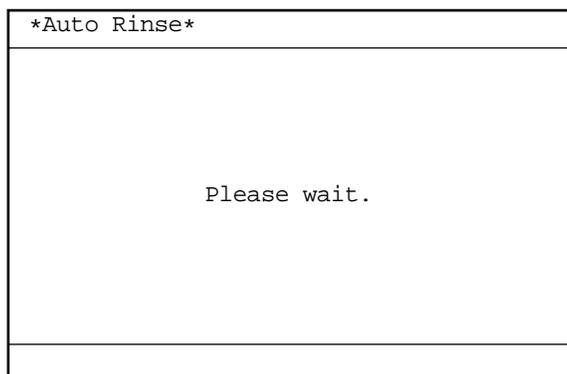


Figure 2-2-4: LCD Screen during Auto Rinse

NOTE:

- Auto rinse is repeated 3 - 5 times. If the background count of any parameter exceeds tolerance after rinsing a maximum of 5 times, the message "Background Error" is displayed and the alarm sounds. In this case, press [HELP] key to stop the alarm and display the Action Message screen. In accordance with the Action Message screen, take an appropriate action.
(Refer to *Chapter 7: TROUBLESHOOTING.*)

- Permissible background counts

WBC	0.3 [$\times 10^3/\mu\text{L}$] or less
RBC	0.02 [$\times 10^9/\mu\text{L}$] or less
HGB	0.1 [g/dL] or less
PLT	10 [$\times 10^3/\mu\text{L}$] or less

2. Confirming the "Ready"

When auto rinse and background check are normally completed, the buzzer (single beep) sounds briefly and "Ready" is displayed. The LCD screen displays the result of background check (sample No. "0").

No.1	WB	▷▷▷▷▷▷▷▷
Ready		
No.0	WB	00/00 00:00
WBC	0.0×10 ³ /μL	LYM% ---.-%
RBC	0.00×10 ⁶ /μL	MXD% ---.-%
HGB	0.0g/dL	NEUT% ---.-%
HCT	0.0%	LYM# ---.×10 ³ /μL
MCV	---.-fL	MXD# ---.×10 ³ /μL
MCH	---.-pg	NEUT# ---.×10 ³ /μL
MCHC	---.-g/dL	RDW ---.-fL
PLT	0×10 ³ /μL	PDW ---.-fL
		MPV ---.-fL
		P-LCR ---.-%
1:M.Descri. 2:Print 3:Paper Feed		

Figure 2-2-5: Ready Status

NOTE: • When the power is on, the next sample No. is displayed "1."

3. QUALITY CONTROL

Quality control is of great importance for obtaining highly reliable data over a long period of time, as is the constant monitoring of the instrument for preventing troubles or for early detection of problems. Before starting sample analysis, analyze control blood (EIGHTCHECK-3WP) using \bar{x} control or L-J control program. The analysis mode used in analyzing control blood is described below.

- Analysis mode to analyze a control blood
Control blood is analyzed in the QC analysis mode. For analysis procedure and examination of analysis result, refer to *Chapter 5: QUALITY CONTROL*.

4. PROCEDURES IN EACH ANALYSIS MODE

With this instrument, sample mixing, cap removal, and tube setting are performed manually. Sample analysis can be executed when the instrument is in the Ready status.

4.1 Whole Blood (WB) Mode

Samples are processed in the following steps:

1. Collecting and preparing samples
2. Selecting whole blood mode
3. Inputting sample No.
4. Analyzing samples

1. Collecting and preparing samples

A specified amount of sample, corresponding to the amount of EDTA anticoagulant, is collected from the vein.



- CAUTION**
- Some anticoagulants alter test results due to their effects on RBC hemolysis or platelet agglutination. As anticoagulant, use EDTA-2K, EDTA-3K, or EDTA-2Na.
 - In the case of refrigerated blood, leave the blood taken from the refrigerator for 30 minutes until it is equilibrated to room temperature.
 - When the reagent might have frozen, handle it according to the precautions stated on the Package Insert of each reagent. Otherwise, improper analysis may result.

Tubes up to 80 mm in height should be used. The volume of sample that can be aspirated is as follows:

Volume of sample aspirated	Approx. 50 μ L
----------------------------	--------------------

2. Selecting whole blood mode

When "PD" is indicated in the system status area on the LCD screen, the pre-diluted (PD) mode is in use for analysis, so change it over to the whole blood (WB) mode by the following procedure:

- (1) Confirm the Ready status.
- (2) Press [MODE] key to display the Change Mode screen.

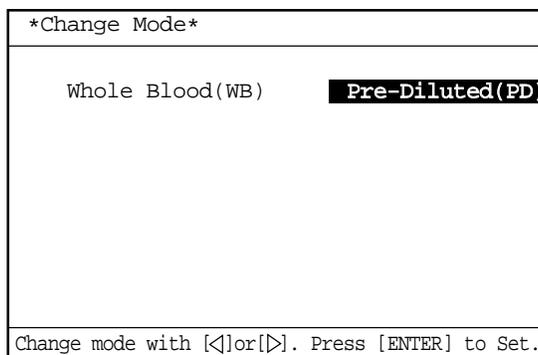


Figure 2-4-1: Change Mode Screen

- (3) Press [◀] or [▶] key to select "Whole Blood (WB)."

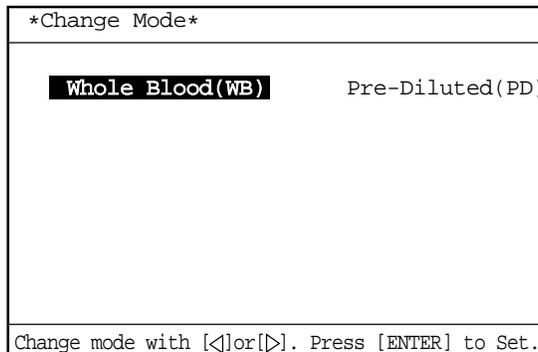


Figure 2-4-2: Selecting WB Mode

- (4) Press [ENTER] key to changeover the analysis mode and return to the Analysis screen.

NOTE:

- The analysis mode selected here is maintained after completion of analysis, until it is switched to the other analysis mode.
- At the time of turning-on the power, the system is in the whole blood mode.

3. Inputting sample No.

- Input from the panel keyboard
- (1) Press [SAMPLE No.] key in the Ready status. In the system status area on the LCD screen, the next sample No. turns to the reverse display and the system is waiting for Sample No. input (in the "Not Ready" status).

No. 1	WB	▷▷▷▷▷▷▷▷
Not Ready		
No. 0	WB	00/00 00:00
WBC	0.0×10 ³ /μL	LYM% ---.-%
RBC	0.00×10 ⁶ /μL	MXD% ---.-%
HGB	0.0g/dL	NEUT% ---.-%
HCT	0.0%	LYM# ---.×10 ³ /μL
MCV	---. -fL	MXD# ---.×10 ³ /μL
MCH	---. -pg	NEUT# ---.×10 ³ /μL
MCHC	---. -g/dL	RDW ---. -fL
PLT	0×10 ³ /μL	PDW ---. -fL
		MPV ---. -fL
		P-LCR ---.-%
1:M.Discri. 2:Print 3:Paper Feed		

Figure 2-4-3: Inputting Sample No.

- (2) The cursor appears under sample No. Input sample No. using the numeric keys.

[Example] Input of sample No. 5

Press [5] key on the numeric keys.

CAUTION:

- Sample No. "0" (zero) is treated as a special sample number.
 - 1) Judgement on patient limit is not made for analysis data.
 - 2) Analysis data is not stored.
 - 3) Data is not transferred to the host computer.
 - 4) Sample No. is not incremented.
 - 5) Judgment on abnormal histogram is not made.
 - 6) When one attempts to make analysis with the sample No. of "0" (zero), the buzzer sounds during sample aspiration.

NOTE:

- When entering the sample No. (on the screen of the previous page), press [C] key first. This will clear the entire sample No. Then, enter a new sample No.
- In the course of entering the sample No., each time you press [C] key, one character disappears with the cursor moving to the left.
- A sample No. of a maximum of six digits, comprising numerics and a hyphen, can be used.
- The hyphen cannot be used at the first or last digit of a number, and two or more hyphens cannot be entered in succession.
[Example] NG -123
 NG 123-
 NG 1--23
- Any number beginning with "0" (zero) cannot be entered.
[Example] NG 0123

- (3) Press [ENTER] key. This will fix the sample No. and the status becomes Ready, namely, ready for analysis.

NOTE:

- When all sample Nos. are cleared, [ENTER] key is not accepted. When you attempt to do so, an alarm sounds.
- In the status of waiting for sample No. input ("Not Ready"), press [SAMPLE No.] or [SELECT] key. The screen returns to the Analysis screen without updating sample No.

4. Analyzing samples

**WARNING**

- When analyzing samples, always wear rubber gloves. After completion of work, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria can occur.

- (1) Mix the sample sufficiently.

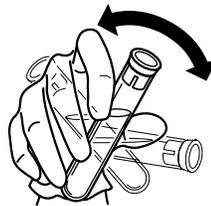


Figure 2-4-4: Mixing the Sample

- (2) Remove the plug while taking care not to allow blood scatter.

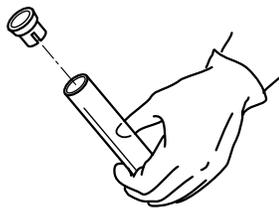


Figure 2-4-5: Removing the Plug

- (3) Set the tube to the sample probe, and in that condition, press the start switch.

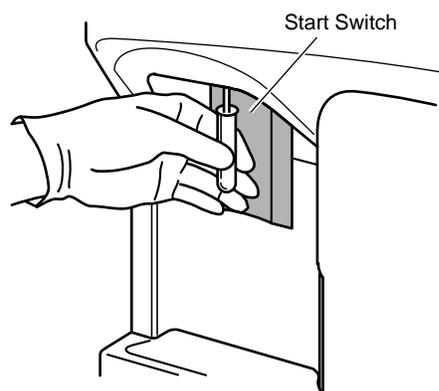
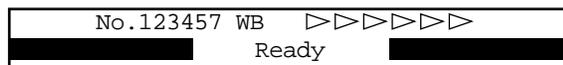


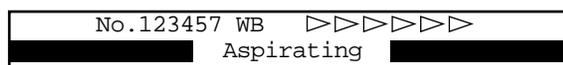
Figure 2-4-6: Pressing the Start Switch

- (4) The buzzer sounds two times - "beep, beep" - and when the LCD screen displays "Analyzing," remove the tube. After that, the unit executes automatic analysis and displays the result on the LCD screen. Then the unit turns to the Ready status, becoming ready for analysis of the next samples.
The screens from the start to the end of analysis are as shown in the following:

(Ready)



(Aspirating)



(Analyzing)



(Rinsing)



(Ready)



Figure 2-4-7: LCD Screen (in WB Mode)



CAUTION

- While the LCD screen is displaying "Aspirating," keep holding the tube in the aforementioned status. If the tube is removed during its display, correct analysis result may not be obtained.

CAUTION:

- Several seconds after the buzzer sounds "beep, beep" and "Aspirating" appears on the LCD screen, the rinse cup lowers. By that time, remove the tube.
- To remove the tube, lower it straight down. Take care not to bend the sample probe.

NOTE:

- The sample probe is automatically rinsed, so there is no need to wipe it clean.

- (5) When the LCD screen displays "Ready," prepare the next samples and repeat the procedure (1) to (4).

NOTE:

- Sample No., if not changed, is automatically incremented by 1, although "0" (zero) is not incremented.

[Example] 123 → 124
999999 → 1
12-3 → 12-4
12-999 → 12-000

4.2 Pre-Diluted (PD) Mode

In this mode, a sample is diluted into 1:26 before analysis. This mode is applied in analyzing a capillary blood collected from the earlobe or fingertip. Samples are processed by the following steps:

1. Collecting and preparing samples
2. Preparing analysis samples in PD mode (dilution of 1:26)
3. Selecting Pre-Diluted mode
4. Inputting sample No.
5. Analyzing samples

1. Collecting and preparing samples

Dilute samples to the ratio of 1:26 using CELLPACK dispensed beforehand in containers.

[Example]

20 μ L of blood is diluted in 500 μ L of CELLPACK.



CAUTION

- A capillary blood collected from the earlobe or fingertip is prone to platelet agglutination, so dilute and analyze it within 30 minutes. Otherwise, correct analysis result may not be obtained.
- With a sample of blood collected from the earlobe or fingertip, blood cell count is generally higher than normal, with lower reproducibility. If possible, analyze the same diluted sample twice and compare the results. When the blood collection tube containing a commercial anti-coagulant is used, there is a possibility that RBC hemolysis or platelet agglutination occurs depending on the types of anticoagulant, with a consequent change in analysis result. As anti-coagulant, use EDTA-2K, EDTA-3K, or EDTA-2Na.

Tubes up to 80 mm in height should be used. The volume of sample is as follows:

Volume of whole blood required	Approx. 20 μ L or more
Volume of sample aspirated	Approx. 200 μ L

2. Preparing analysis samples in PD mode (1:26 Dilution)

- (1) Clean a container such as erlenmeyer flask, beaker, etc. with CELLPACK and remove any dirt.
- (2) Using a syringe, etc., take CELLPACK into a cleaned container.
- (3) Using a 500 μ L transfer pipette, dispense 500 μ L of CELLPACK into a micro-tube.
- (4) Using a capillary tube, etc., collect 20 μ L of blood and dispense it into the micro-tube.
- (5) Attach the cap and mix well.

**WARNING**

- When preparing PD-mode analysis samples, always wear rubber gloves. After completion of work, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria or the like can occur.

**CAUTION**

- A 1:26 dilution sample is prone to platelet agglutination. So, analyze the sample within 30 minutes after blood dispensing and diluting. If diluent is dispensed in advance, evaporation and dirt mixing will result in errors in analysis values. Therefore prepare one sample at a time.

When preparing a 1:26 dilution sample, use the tools listed below:

- Diluent (CELLPACK)
- Micro-tube (MT-40, etc.)
- Capillary tube
- A 500 μ L transfer pipette
- A container, such as erlenmeyer flask or beaker
- A syringe

3. Selecting Pre-Diluted mode

When "WB" is displayed in the system status area on the LCD screen, the whole blood (WB) mode is in use for analysis, so change it over to the pre-diluted (PD) mode by the following procedure:

- (1) Confirm the Ready status.
- (2) Press [MODE] key to display the Change Mode screen.

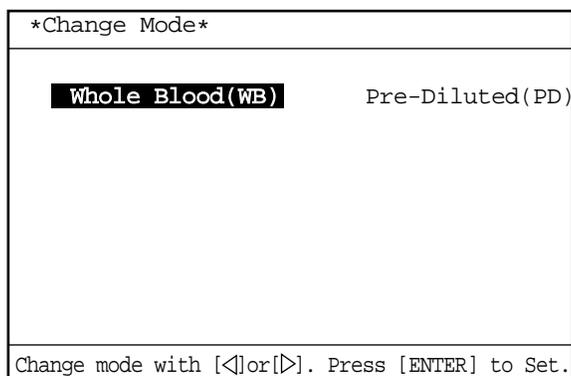


Figure 2-4-8: Change Mode Screen

- (3) Press [◀] or [▶] key to select "Pre-Diluted (PD)."

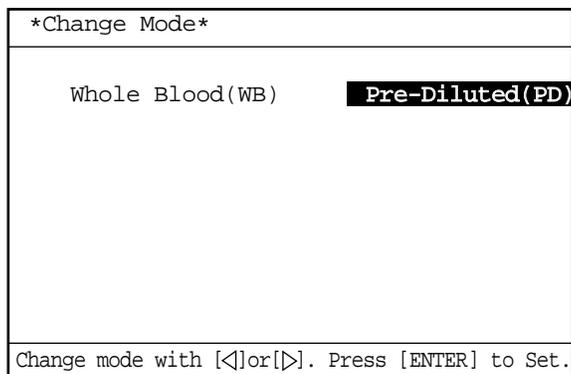


Figure 2-4-9: Selecting PD Mode

- (4) Press [ENTER] key to changeover the analysis mode and return to the Analysis screen.

NOTE:

- The analysis mode selected here is maintained after completion of analysis, until it is switched to the other analysis mode.
- At the time of turning-on the power, the system is in the whole blood mode.

4. Inputting sample No.

- Input from the panel keyboard
- (1) Press [SAMPLE No.] key in the Ready status. The next Sample No. in the system status area on the LCD screen turns to the reverse display and the system waits for Sample No. input (in the "Not Ready" status).

No. 1		PD	▷▷▷▷▷▷▷▷	
Not Ready				
No.0	PD		00/00	00:00
WBC	0.0×10 ³ /μL	LYM%	---	-%
RBC	0.00×10 ⁵ /μL	MXD%	---	-%
HGB	0.0g/dL	NEUT%	---	-%
HCT	0.0%	LYM#	---	×10 ³ /μL
MCV	---. -fL	MXD#	---	×10 ³ /μL
MCH	---. -pg	NEUT#	---	×10 ³ /μL
MCHC	---. -g/dL	RDW	---	-fL
PLT	0×10 ³ /μL	PDW	---	-fL
		MPV	---	-fL
		P-LCR	---	-%
1:M.Discr. 2:Print 3:Paper Feed				

Figure 2-4-10: Inputting Sample No.

- (2) The cursor appears under sample No. Input sample No. using the numeric keys.

[Example] Input of Sample No. 5

Press [5] key on the numeric keys.

CAUTION:

- Sample No. "0" (zero) is treated as a special sample number.
 - 1) Judgement on patient limit is not made for analysis data.
 - 2) Analysis data is not stored.
 - 3) Data is not transferred to the host computer.
 - 4) Sample No. is not incremented.
 - 5) Judgment on abnormal histogram is not made.
 - 6) When one attempts to make analysis with the sample No. of "0" (zero), the buzzer sounds during sample aspiration.

NOTE:

- When entering the sample No. (on the screen of the previous page), press [C] key first. This will clear the entire sample No. Then, enter a new sample No.
- In the course of entering the sample No., each time you press [C] key, one character disappears with the cursor moving to the left.
- A sample No. of a maximum of six digits, comprising numerics and a hyphen, can be used.
- The hyphen cannot be used at the first or last digit of a number, and two or more hyphens cannot be entered in succession.
[Example] NG -123
 NG 123-
 NG 1--23
- Any number beginning with "0" (zero) cannot be entered.
[Example] NG 0123

- (3) Press [ENTER] key. This will fix the sample No. and the status becomes Ready, namely, ready for analysis.

NOTE:

- When all sample Nos. are cleared, [ENTER] key is not accepted. When you attempt to do so, an alarm sounds.
- In the status of waiting for sample No. input ("Not Ready"), press [SAMPLE No.] or [SELECT] key. The screen returns to the Analysis screen without updating sample No.

5. Analyzing samples

 WARNING	<ul style="list-style-type: none"> • When analyzing samples, always wear rubber gloves, and after completion of work, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria can occur.
--	--

- (1) Mix the sample sufficiently.

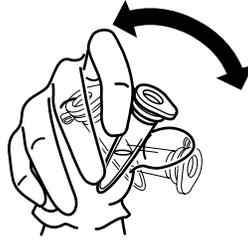


Figure 2-4-11: Mixing the Sample

- (2) Remove the plug while taking care not to allow blood scatter.



Figure 2-4-12: Removing the Plug

- (3) Set the micro-tube to the sample probe, and in that condition, press the start switch.

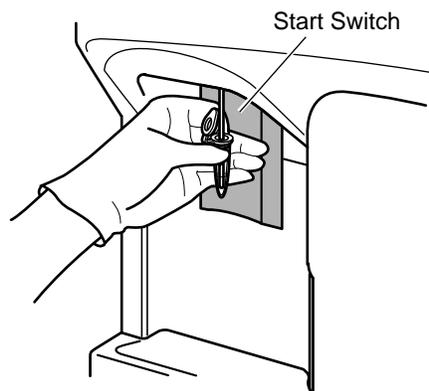


Figure 2-4-13: Pressing the Start Switch

- (4) The buzzer sounds two times - "beep, beep" - and when the LCD screen displays "Analyzing," remove the micro-tube. After that, the unit executes automatic analysis and displays the result on the LCD screen. Then the unit turns to the Ready status, becoming ready for analysis of the next samples.
The screens from the start to the end of analysis are as shown in the following:

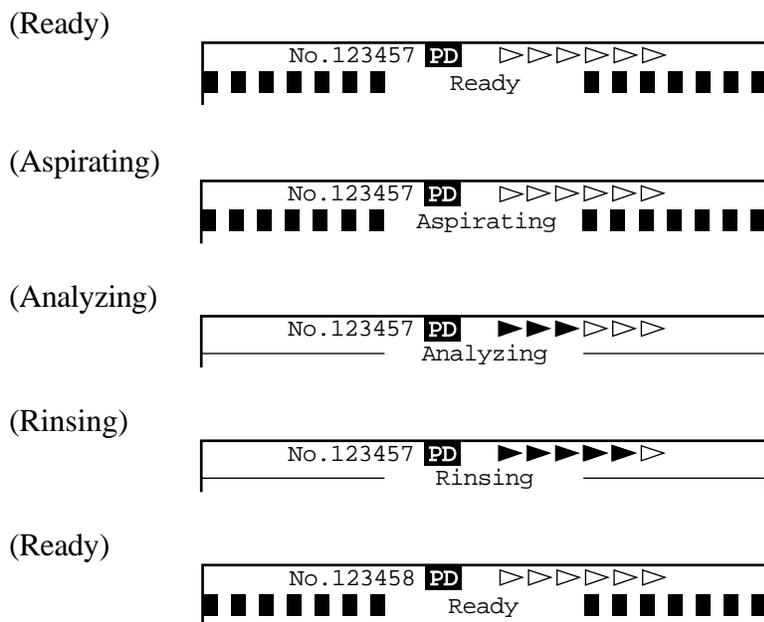


Figure 2-4-14: LCD Screen (in PD Mode)

CAUTION • While the LCD screen is displaying "Aspirating," keep holding the micro-tube in the aforementioned status. If the micro-tube is removed during its display, correct analysis result may not be obtained.

CAUTION:

- Several seconds after the buzzer sounds "beep, beep" and "Aspirating" appears on the LCD screen, the rinse cup lowers. By that time, remove the micro-tube.
- To remove the micro-tube, lower it straight down. Take care not to bend the sample probe.

NOTE:

- The sample probe is automatically rinsed, so there is no need to wipe it clean.

- (5) When the LCD screen displays "Ready," prepare a next sample and repeat the procedure (1) to (4).

NOTE:

- Sample No., if not changed, is automatically incremented by 1, although "0" (zero) is not incremented.

[Example] 123 → 124
999999 → 1
12-3 → 12-4
12-999 → 12-000

5. DISPLAY AND PRINTING OF ANALYSIS RESULT

5.1 Display of Analysis Result

The result of each analysis is displayed on the LCD screen.

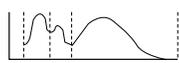
The display screen of analysis result consists of three pages, and pages are turned over by using [◀] or [▶] key.

No.123458 WB ▷▷▷▷▷▷▷▷			
Ready		31/12 23:59	
No.123457 WB			
WBC	7.1×10 ³ /μL	LYM%	31.2%
RBC	3.97×10 ⁶ /μL	MXD%	19.6%
HGB	14.7g/dL	NEUT%	49.2%
HCT	32.8%	LYM#	2.2×10 ³ /μL
MCV	- 82.6fL	MXD#	1.4×10 ³ /μL
MCH	37.0pg	NEUT#	3.5×10 ³ /μL
MCHC	+ 44.8g/dL	RDW	- 25.6fL
PLT	180×10 ³ /μL	PDW	- 7.9fL
		MPV	9.3fL
		P-LCR	- 9.5%

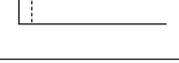
1:M.Discri. 2:Print 3:Paper Feed

No.123459 PD ▷▷▷▷▷▷▷▷			
Ready		31/12 23:59	
No.123458 PD			
WBC	7.1×10 ³ /μL	LYM%	-----%
RBC	3.97×10 ⁶ /μL	MXD%	-----%
HGB	14.7g/dL	NEUT%	-----%
HCT	32.8%	LYM#	----.×10 ³ /μL
MCV	- 82.6fL	MXD#	----.×10 ³ /μL
MCH	37.0pg	NEUT#	----.×10 ³ /μL
MCHC	+ 44.8g/dL	RDW	----.fL
PLT	180×10 ³ /μL	PDW	----.fL
		MPV	----.fL
		P-LCR	----.-%

1:M.Discri. 2:Print 3:Paper Feed

No.123458 WB ▷▷▷▷▷▷▷▷			
Ready		31/12 23:59	
No.123457 WB			
WBC		LYM%	31.2%
		MXD%	19.6%
		NEUT%	49.2%
RBC		LYM#	2.2×10 ³ /μL
		MXD#	1.4×10 ³ /μL
		NEUT#	3.5×10 ³ /μL
PLT		RDW	- 25.6fL
		PDW	- 7.9fL
		MPV	9.3fL
		P-LCR	- 9.5%

1:M.Discri. 2:Print 3:Paper Feed

No.123459 PD ▷▷▷▷▷▷▷▷			
Ready		31/12 23:59	
No.123458 PD			
WBC		LYM%	-----%
		MXD%	-----%
		NEUT%	-----%
RBC		LYM#	----.×10 ³ /μL
		MXD#	----.×10 ³ /μL
		NEUT#	----.×10 ³ /μL
PLT		RDW	----.fL
		PDW	----.fL
		MPV	----.fL
		P-LCR	----.-%

1:M.Discri. 2:Print 3:Paper Feed

No.123458 WB ▷▷▷▷▷▷▷▷			
Ready		31/12 23:59	
No.123457 WB			
WBC	7.1×10 ³ /μL		
RBC	3.97×10 ⁶ /μL		
HGB	14.7g/dL		
HCT	32.8%		
MCV	- 82.6fL		
MCH	37.0pg		
MCHC	+ 44.8g/dL		
PLT	180×10 ³ /μL		

1:M.Discri. 2:Print 3:Paper Feed

No.123459 PD ▷▷▷▷▷▷▷▷			
Ready		31/12 23:59	
No.123458 PD			
WBC	7.1×10 ³ /μL		
RBC	3.97×10 ⁶ /μL		
HGB	14.7g/dL		
HCT	32.8%		
MCV	- 82.6fL		
MCH	37.0pg		
MCHC	+ 44.8g/dL		
PLT	180×10 ³ /μL		

1:M.Discri. 2:Print 3:Paper Feed

(Whole Blood Mode)

(Pre-diluted Mode)

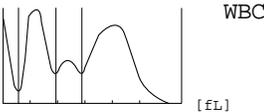
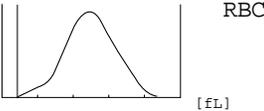
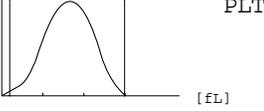
Figure 2-5-1: Analysis Result Display Screen

5.2 Printing of Analysis Result

Analysis result can be printed out on the built-in printer.

NOTE: • One print format can be selected from among Types 1, 2, and 3. For the selecting procedure, refer to *Chapter 10, Section 7: Printer Output Setting*.

[Type 1]

No.	123457
Date	31/12/97 10:02
Mode	WB
WBC	7.3 ×10 ³ /μL
RBC	4.52 ×10 ⁶ /μL
HGB	14.8 g/dL
HCT	36.2 %
MCV	80.1 fL
MCH	32.7 Pg
MCHC	40.9 g/dL
PLT	206 ×10 ³ /μL
	
LYM%	27.2 %
MXD%	13.4 %
NEUT%	59.4 %
LYM#	2.0 ×10 ³ /μL
MXD#	1.0 ×10 ³ /μL
NEUT#	4.3 ×10 ³ /μL
	
RDW	98.3 fL
	
PDW	8.3 fL
MPV	9.1 fL
P-LCR	14.8 %

[Type 2]

No.	123457
Date	31/12/97 10:02
Mode	WB
WBC	7.3 ×10 ³ /μL
RBC	4.52 ×10 ⁶ /μL
HGB	14.8 g/dL
HCT	36.2 %
MCV	80.1 fL
MCH	32.7 Pg
MCHC	40.9 g/dL
PLT	206 ×10 ³ /μL
LYM%	27.2 %
MXD%	13.4 %
NEUT%	59.4 %
LYM#	2.0 ×10 ³ /μL
MXD#	1.0 ×10 ³ /μL
NEUT#	4.3 ×10 ³ /μL
RDW	98.3 fL
PDW	8.3 fL
MPV	9.1 fL
P-LCR	14.8 %

[Type 3]

No.	123457
Date	31/12/97 10:02
Mode	WB
WBC	7.3 ×10 ³ /μL
RBC	4.52 ×10 ⁶ /μL
HGB	14.8 g/dL
HCT	36.2 %
MCV	80.1 fL
MCH	32.7 Pg
MCHC	40.9 g/dL
PLT	206 ×10 ³ /μL

Figure 2-5-2: Printing of Analysis Result

6. LIMITATIONS

6.1 Cell Count Parameters

Some abnormal samples may give incorrect results by automated cell counting methods. The following table shows examples of specific specimens that could cause errors.

Parameter	Specimen	Error	Possible Indication of Error
WBC	Cold Agglutinin	(+)	↑MCV, ↓HCT, red cell clumping on smear
	Platelet aggregation	(+)	Platelet aggregates on smear
	Erythroblastosis	(+)	Erythroblasts on smear
	Nucleated RBC	(+)	NRBC on smear
	Cryoglobulins	(+)	
RBC	Cold Agglutinin	(-)	↑MCV, ↓HCT, red cell clumping on smear
	Severe Microcytosis	(-)	
	Fragmented RBC	(-)	
	Leukocytosis (>100,000/μL)	(+)	Elevation of WBC
HGB	Leukocytosis (>100,000/μL)	(+)	Elevation of WBC
	Lipemia	(+)	↑MCHC, "milky" appearance of plasma
	Abnormal Protein	(+)	↑MCHC, Lysed Hgb/WBC sample turns cloudy
HCT	Cold Agglutinin	(-)	↑MCV, ↓HCT, red cell clumping on smear
	Leukocytosis (>100,000/μL)	(+)	Elevation of WBC
	Abnormal Red Cell Fragility	(?)	
	Spherocytosis	(?)	↓MCV, spherocytes on smear
PLT	Pseudothrombocytopenia	(-)	Platelet Satellitism on smear
	Platelet Aggregation	(-)	Platelet Aggregation on smear
	Increased Microcytosis	(+)	↓MCV
	Megalocytic Platelets	(-)	

(+): Instrument count is affected by an increase in the result.

(-): Instrument count is affected by a decrease in the result.

(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

CAUTION: • WBC results may be elevated erroneously due to unlysed red cells in patients with hemoglobinopathies, severe liver disease or in neonates.

6.2 Limitation of Hemoglobin

1. Hemoglobin measurements may be falsely elevated due to the influences of abnormal samples including leukocytosis above 100,000/ μ L, lipemia or abnormal proteins in blood plasma. The affect of lipemia and abnormal proteins may be removed by plasma replacement or plasma blank procedures.
2. Performance specifications for hemoglobin results are assured only when instrument environment and sample requirements are observed.
3. The hemoglobin method available for this analyzer cannot detect sulfhemoglobin, verdohemoglobin choleglobin or other unusual degradation products of hemoglobin.

7. EXPECTED RESULTS

Reference intervals (normal population reference ranges) were developed for the KX-21 using normal individuals. The ranges for each parameter --- WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, RDW-CV, RDW-SD, Platelet, PDW*, MPV, P-LCR*, Lym% and #, Mxd% and #, and Neut% and # were determined and displayed in Table 1-16-1.

- * For Investigational Use Only in the United States of America.
Not a reportable parameter.

Parameter	Range for Females n=117	Range for Males n=124
WBC	3.1 - 10.3	2.6 - 8.8
RBC	3.2 - 4.6	3.6 - 5.3
Hgb	9.9 -13.6	11.3 - 15.7
Hct	30.2 - 42.3	32.6 - 47.5
MCV	78.6 - 102.2	80.3 - 103.4
MCH	25.2 - 34.7	26 - 34.4
MCHC	31.3 - 35.4	31.8 - 36.3
Plt	128 - 434	134 - 377
Lym%	15 - 45.8	17.5 - 47.9
Mxd%	1.3 - 25.9	1.9 - 24.6
Neut%	43.7 - 77.1	38.3 - 69
Lym#	0.9 - 2.8	0.8 - 2.7
Mxd#	0.1 - 1.6	0.1 - 1.5
Neut#	1.6 - 6.9	1.2 - 5.3
RDW-CV	10.6 - 15.7	10.8 - 14.9
RDW-SD	35.3 - 48.9	33.4 - 49.2
PDW	9.4 - 18.1	9.8 - 18.0
MPV	8.5 - 12.4	8.1 - 12.4
P-LCR	14.3 - 44	10.7 - 45.0

Table 2-7-1: Normal Population Reference Ranges

NOTE:

- The age range for females was 17 - 66 years with a mean age of 33.4.
- The age range for males was 17 - 72 years with a mean age of 42.2.

Sysmex recommends that each laboratory establish its own expected reference intervals based upon the laboratory's patient population encountered during daily operation. Expected reference intervals may vary due to differences in sex, age, diet, fluid intake, geographic location, etc. The NCCLS Document C28A¹, "How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline". This document contains guidelines for determining reference values and intervals for quantitative clinical laboratory test.

¹ NCCLS, 771 East Lancaster Avenue, Villanova, PA 19085, USA.

8. STOPPING THE PNEUMATIC UNIT

The KX-21, when left non-operating for 15 minutes, automatically stops the pneumatic unit. It is also possible to manually stop the pneumatic unit using the following procedures:

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] key or [▼] key, move the cursor to select "00: PU Sleep."

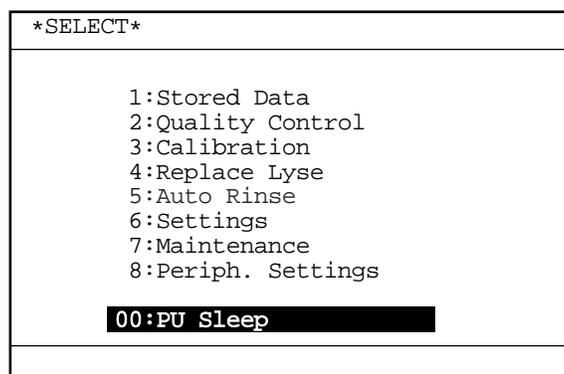


Figure 2-8-1: Select Menu Screen

- (3) Press [ENTER] key. This stops the pneumatic unit.

NOTE: • Press the start switch to return to the ready status.

9. EXECUTION OF SHUTDOWN

When analyses of all samples are finished, execute shutdown before turning the power off. By executing shutdown, the TD chamber and diluted sample line are cleaned. Execute shutdown after the day's work is finished, and also when this instrument is used continuously, shut it down at least once in 24 hours.

CAUTION: • If the power is turned OFF before executing shutdown, failures could occur, such as fluid dripping from the rinse cup and crystals forming around the rinse cup.

9.1 Shutdown Procedure

- (1) Press [SHUTDOWN] key in the Ready status. The Shutdown screen appears.

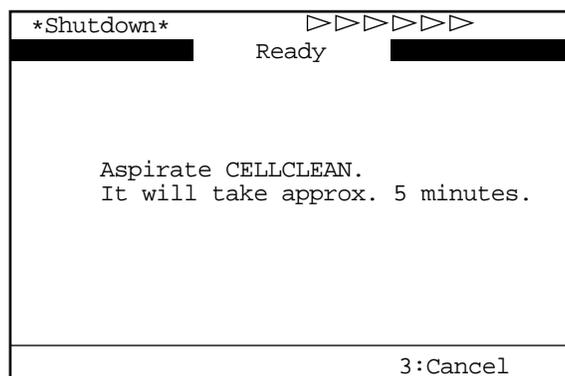


Figure 2-9-1: Shutdown Screen

NOTE: • When [3] key is pressed, shutdown is canceled and the Analysis screen returns.

- (2) When executing shutdown, set CELLCLEAN to the sample probe and press the start switch in that status. While "Aspirating" is being displayed on the screen, keep holding CELLCLEAN in the same status.

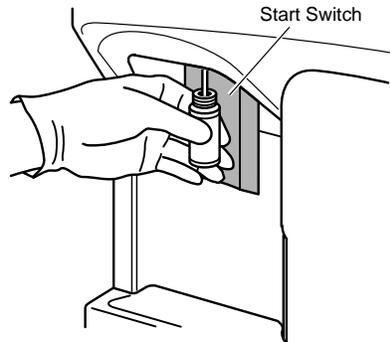


Figure 2-9-2: Pressing the Start Switch

	<p>WARNING</p> <ul style="list-style-type: none"> • Because CELLCLEAN is a strong alkaline detergent, take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.
--	---

<p>NOTE:</p>	<ul style="list-style-type: none"> • Once shutdown is executed, it cannot be canceled until it is completed.
---------------------	---

- (3) When the buzzer sounds two times - beep, beep- , informing the completion of aspiration, remove CELLCLEAN from the sample probe. After that, shutdown is executed automatically.

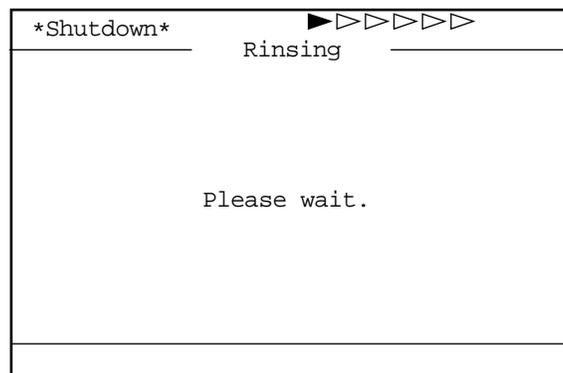


Figure 2-9-3: Shutdown Execution Screen

<p>CAUTION:</p>	<ul style="list-style-type: none"> • To remove CELLCLEAN, lower it straight down. Take care not to bend the sample probe.
------------------------	--

- (4) When shutdown is finished and the following message is displayed, turn off the power switch on the right side of the unit.

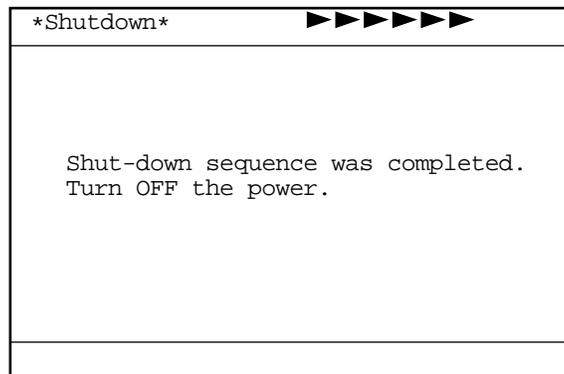


Figure 2-9-4: Shutdown Completion Message Screen

NOTE:

- Shutdown will take approximately 5 minutes.

CHAPTER 3 DISPLAY AND PROCESSING OF ANALYSIS RESULTS

1.	INTRODUCTION	3-1
2.	PROCESSING LATEST SAMPLES	3-2
2.1	Display of Analysis Result.....	3-2
2.2	Manual Discrimination.....	3-6
2.3	Printing.....	3-10
2.4	Print Paper Feed.....	3-10
3.	PROCESSING STORED DATA	3-11
3.1	Executing and Quitting Stored Data Processing Program.....	3-11
3.2	Stored Data Screen.....	3-12
3.3	Deletion.....	3-15
3.4	Printing.....	3-16
3.5	HC Output (Option).....	3-16
3.6	Correcting a Sample Number.....	3-17

1. INTRODUCTION

This instrument displays analysis result and information that assists in breaking down analysis result and outputs such data to external devices. This chapter describes the processing of analysis result, such as displaying latest or stored data on the screen or outputting them to external devices. The gist of the contents is as follows:

Processing of Latest Samples

When analysis is finished, analysis result is displayed in three kinds of screens. The display contents of Analysis Result screen, what they mean, and how to process them are explained here.

Processing of Stored Data

The analysis data stored in the instrument can be read at anytime. Description is made on the display contents of stored data, what they mean, deletion by marking, and output to external devices.

2. PROCESSING LATEST SAMPLES

2.1 Display of Analysis Result

The analysis result is displayed in the Analysis Result Display Area on the LCD screen. In the Analysis Result Display Area, the analysis result is displayed each time a new sample is analyzed. When the analysis result is displayed, the menu display area displays the menu of "1: M. Discr.," "2: Print," and "3: Paper Feed," which can each be executed using the numeric keys.

The Analysis screen consists of three pages that differ from each other in "Analysis Result Display Area."

Use [◀] key or [▶] key to change over pages.

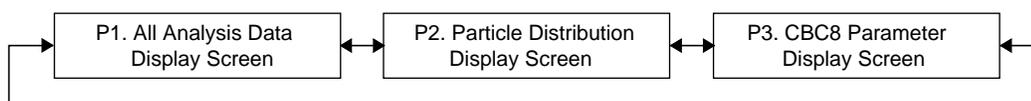


Figure 3-2-1: Page Selection in the Analysis Screen

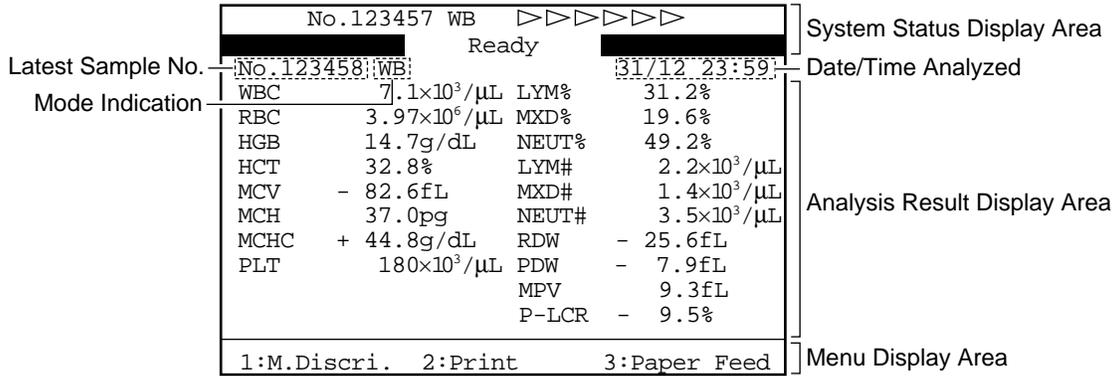


Figure 3-2-2: All Analysis Data Display Screen

NOTE:

- When analysis is made in the pre-diluted mode, particle distribution analysis parameters are displayed in "- - - -." The particle distribution curve is not displayed.

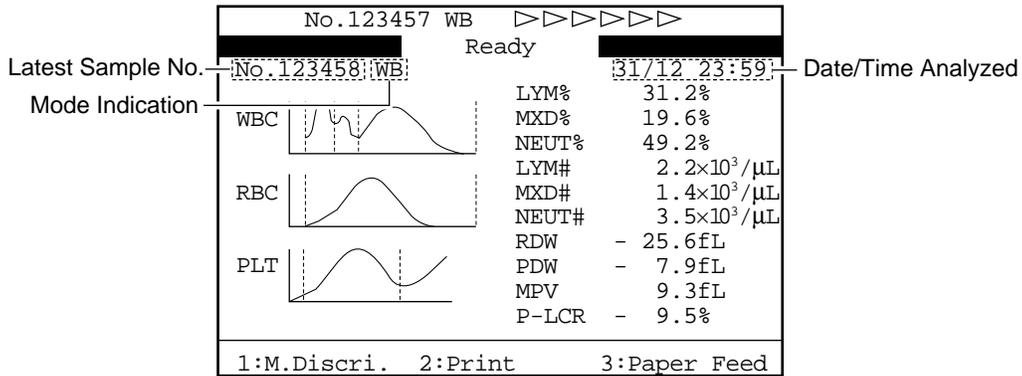


Figure 3-2-3: Particle Distribution Display Screen

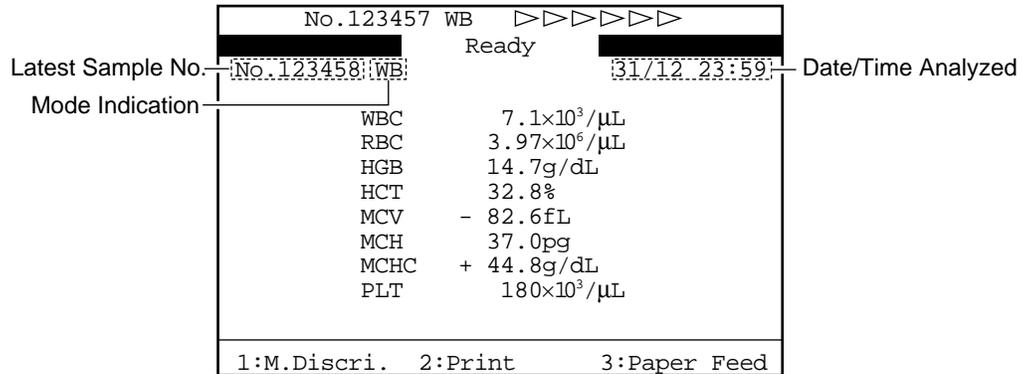


Figure 3-2-4: CBC8 Parameter Display Screen

Display Contents of Analysis Data Display Screens

1) System Status Display Area

This area displays the status of the instrument. For details, refer to *Chapter 1, Section 8.1: Contents of Display*.

2) Latest Sample No.

The latest sample No. is displayed.

3) Mode Indication

The latest sample's analysis mode is displayed.
The whole blood mode is displayed as "WB" and the pre-diluted mode as "PD."

4) Date/Time Analyzed

Date and time when analysis result was obtained are displayed.

5) Analysis Data

The analysis data of the following 18 parameters or part of them are displayed depending on the screen:

Analysis parameters (8): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT

Calculation parameters (10): LYM%, MXD%, NEUT%,
LYM#, MXD#, NEUT#, RDW, PDW, MPV, P-LCR

NOTE:

- As for RDW, either RDW-CV or RDW-SD is output.
When shipped from factory, it is set at RDW-SD
When you want to display RDW-CV, refer to *Chapter 10, Section 2: System Setup*.
- The instrument can be set to block out PDW and P-LCR. Contact Sysmex service representative for assistance.

The marks to the left of analysis data indicate the following:

1. ! : The data is out of the linearity limit.
2. + : The data exceeds the upper Mark Limits.
- : The data exceeds the lower Mark Limits.
3. * : The data is low in reliability.

NOTE:

- The marks are added with the priority order of 1, 2, and 3.
- The Mark Limits with "+" and "-" can be set by the customer. For details, refer to *Chapter 10, Section 4: Patient Limit*.

When an analysis error, etc. has caused errors in analysis data, the marks below are attached to the affected data:

1. + + +. +: When data has exceeded the display range.
2. * * *. *: When data could not be calculated due to instrument failure.
3. - - -. -: When data could not be calculated due to data error.

NOTE: • When analysis is made in the pre-diluted mode, particle distribution analysis parameters are displayed in "- - -. -."

When an error is found in particle distribution, a histogram error flag among the following is displayed:

1. WL: Relative frequency of WBC-LD has exceeded the range.
2. WU: Relative frequency of WBC-UD has exceeded the range.
3. T1: T1 discriminator position cannot be determined.
4. T2: T2 discriminator position cannot be determined.
5. F1: Relative frequency of T1 has exceeded the range.
6. F2: Relative frequency of T1 or T2 has exceeded the range.
7. F3: Relative frequency of T2 has exceeded the range.
8. RL: Relative frequency of RBC-LD has exceeded the range.
9. RU: Relative frequency of RBC-UD has exceeded the range.
10. DW: Distribution width cannot be calculated.
11. MP: There are multiple peaks.
12. PL: Relative frequency of PLT-LD has exceeded the range.
13. PU: Relative frequency of PLT-UD has exceeded the range.
14. AG: The particle count equal to or less than WBC-LD has exceeded the range.

NOTE: • When analysis is made in the pre-diluted mode, no flag is displayed to particle distribution analysis parameters. For details, refer to *Chapter 9, Section 6: Particle Distribution Analysis*.

6) Menu Display Area

The Menu is displayed in accordance with the screen. For details, refer to *Chapter 1, Section 8.1: Contents of Display*.

7) WBC Particle Distribution Chart

The WBC Particle distribution chart is displayed.

8) RBC Particle Distribution Chart

The RBC Particle distribution chart is displayed.

9) PLT Particle Distribution Chart

The PLT Particle distribution chart is displayed.

2.2 Manual Discrimination

This menu allows relocation of particle distribution discrimination position and re-calculation of data.

CAUTION: • Manual Discrimination can be performed only on the latest sample displayed on the Analysis screen, but not on the data with sample number 0.

NOTE: • "1: M. Discr." on the menu is valid only for the analysis result in the whole blood mode.

Execution of Manual Discrimination

- Press [1] key on the Analysis screen displaying analysis result and select "1: M. Discr."
The Manual Discrimination screen (WBC) appears.

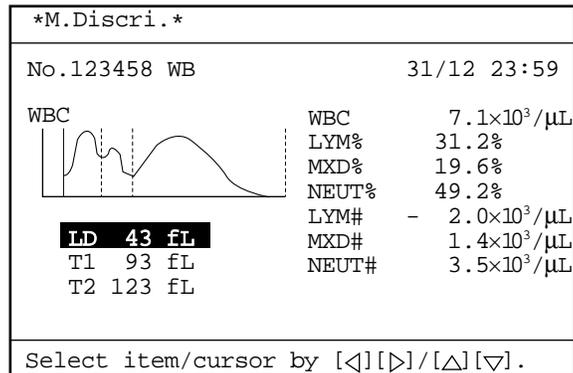


Figure 3-2-5: P1. M. Discr. Screen (WBC)

- Using [◀] key or [▶] key, select a desired page of the M. Discr. screen. The M. Discr. screen consists of three pages.

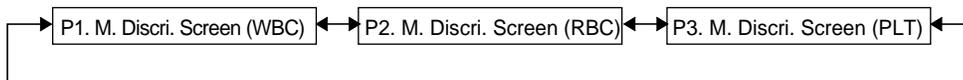


Figure 3-2-6: Page Selection in the M. Discr. Screen

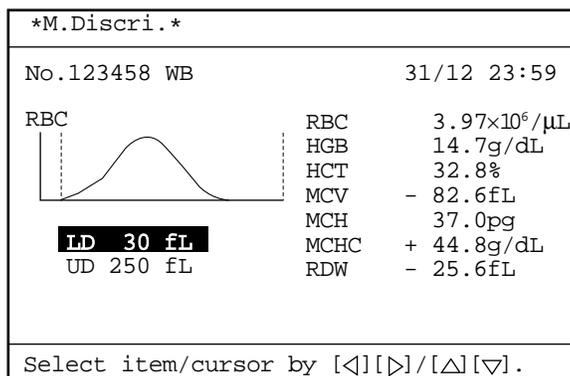


Figure 3-2-7: P2. M. Discr. Screen (RBC)

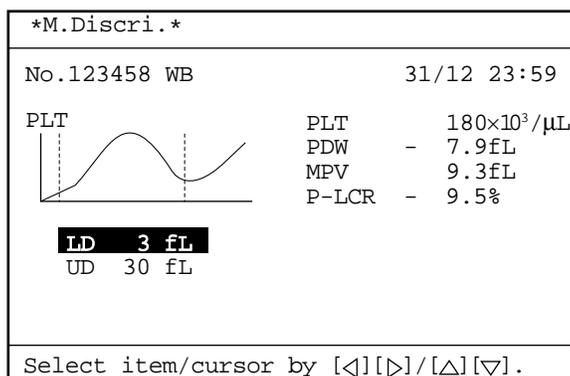


Figure 3-2-8: P3. M. Discr. Screen (PLT)

- (3) Using [▲] key or [▼] key, move the cursor to select the discriminator for manual discrimination.
- (4) Press [ENTER] key.
The discriminator for manual discrimination is set and the discriminator selected on the Particle Distribution Chart is shown with solid line.

- (5) Using [◀] key or [▶] key, move the Discr. position on the Particle Distribution Chart. The Discr. position relocated is displayed.
The range within which each Discr. position can move is shown below.

Table 3-2-1: M. Discr. Screen (WBC)

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

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

Table 3-2-2: M. Discr. Screen (RBC)

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

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

Table 3-2-3: M. Discr. Screen (PLT)

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

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

- (6) After Discr. movement, press [ENTER] key.
The Discr. position is set and analysis data is re-calculated on the basis of new Discr. position.
When [SELECT] key is pressed without pressing [ENTER] key, the Discr. position is not changed, and the status returns to the Discr. position selection status.
- (7) When you want to change another Discr., repeat the above (2) - (6) operation.

- (8) When Discri. change is finished, press [SELECT] key. The Setting Change Confirmation Message appears.



Figure 3-2-9: Setting Change Confirmation Message

- (9) Using [◀] key or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel," then press [ENTER] key.

[Cont.]: Returns to the M. Discri. screen and allows M. Discri. operation.

[Set]: Updates the contents and returns to the Analysis screen.

[Cancel]: Cancels the changed contents and returns to the Analysis screen.

- (10) When you update the contents, analysis values changed in M. Discri. on the Analysis screen are reverse-displayed.

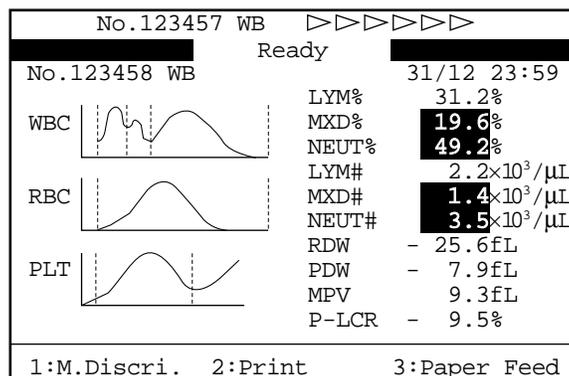


Figure 3-2-10: Analysis Screen

2.3 Printing

This menu can be used to output the latest sample's analysis result from the built-in printer.

Printing of Latest Sample

- (1) Press [2] key on the Analysis screen and select "2: Print."
The built-in printer starts printing analysis result.

NOTE:

- For printing format, refer to *Chapter 2, Section 5.2: Printing of Analysis Result*. To change the printing format, refer to *Chapter 10, Section 7: Printer Settings*.

Contents of Printing

No.	123456	Sample No.
Date	31/12/97 23:59	Date/Time Analyzed
Mode Indication	Mode WB; [W][R][P]	Parameter Discriminated Manually
WBC	WL+11.3 ×10 ³ /μL	
RBC	+3.80 ×10 ⁶ /μL	
HGB	+11.5 g/dL	
	⋮	

Figure 3-2-11: Example of Printing

- 1) **Sample No.**
The latest sample No. is printed.
- 2) **Mode Indication**
The mode in which sample was analyzed is printed. The whole blood mode is printed as "WB" and the pre-diluted mode as "PD."
- 3) **Date/Time Analyzed**
Date and time when analysis result was obtained are printed.
- 4) **Parameter Discriminated Manually**
When M. Discr is used, the parameter discriminated manually are printed.

2.4 Printer Paper Feed

- (1) Press [3] key on the Analysis screen and select "3: Paper Feed." While the key is being held in, paper feed continues.

3. PROCESSING STORED DATA

This instrument is capable of storing data of up to 240 samples. The stored data is retained after the power is turned off and can be called up unless deleted.

- NOTE:**
- The particle distribution chart is not stored.
 - When the stored data exceeds 240, the oldest data are automatically deleted.

3.1 Executing and Quitting Stored Data Processing Program

Executing the Program

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] key or [▼] key, move the cursor to select "1: Stored Data."
- (3) Press [ENTER] key. The Stored Data screen [1/5] appears.

Stored Data					
No.		WBC	RBC	HGB	HCT
123451*		7.7+	3.97	14.7	32.8
QC01		7.5	4.51	14.1	34.7
123453		7.5+	3.85	13.8	30.5
123454	PD	7.1	4.30+	12.2	29.5-
123455*	PD	7.2	3.91	14.3	32.0
123456	PD	5.5-	3.90	15.1	40.2+
123457		7.0	4.05	18.5	31.4
123451*		7.6+	3.98	15.0	35.1
Date 31/12/97 12:59					[1/5]
[ENTER] to mark, [SELECT] to exit.					

Figure 3-3-1: Stored Data Screen

Quitting the Program

- (1) Press [SELECT] key on the Stored Data screen. The Analysis screen returns.

- NOTE:**
- The sample No. and analysis mode on the Analysis screen return to the status before the execution of the stored data processing program.

3.2 Stored Data Screen

The Stored Data screen lists data of up to eight samples in the order of analysis. When the first Stored Data screen is displayed after turning on the power, the data of the last eight samples on the list are displayed. When a new sample is analyzed, its data is automatically added to the last line of the list.

As to analysis data, four parameters are displayed on one page. And there are five pages in total. Using [◀] key or [▶] key, a page with four parameters can be changed over to the next page.

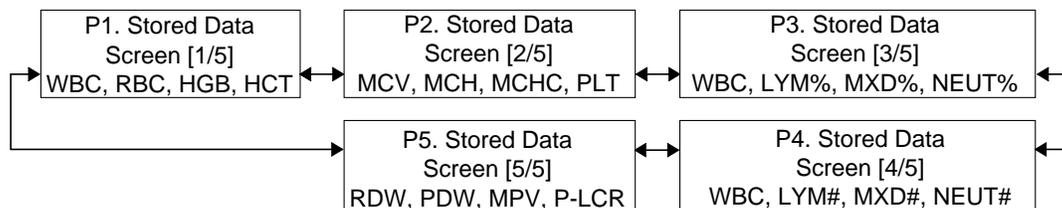


Figure 3-3-2: Page Selection in the Stored Data Screen

Stored Data					
No.		WBC	RBC	HGB	HCT
123451*		7.7+	3.97	14.7	32.8
QC01		7.5	4.51	14.1	34.7
123453		7.5+	3.85	13.8	30.5
123454	PD	7.1	4.30+	12.2	29.5-
123455*	PD	7.2	3.91	14.3	32.0
123456	PD	5.5-	3.90	15.1	40.2+
123457		7.0	4.05	18.5	31.4
123451*		7.6+	3.98	15.0	35.1
Date 31/12/97 12:59					[1/5]
[ENTER] to mark, [SELECT] to exit.					

Figure 3-3-3: Stored Data Screen

Key Operation for Stored Data Screen

- [▲] key: Moves up the underline cursor by one sample. When the underline cursor is at the top, the list scrolls down.
- [▼] key: Moves down the underline cursor by one sample. When the underline cursor is at the bottom, the list scrolls up.
- [◀], [▶] key: Changes over the page.
- [ENTER] key: Attaches or deletes marks.
- [SAMPLE No.] key: Allows you to correct the sample number at the underline cursor.

Marking

To mark the analysis data, specify an analysis data using the underline cursor and press [ENTER] key.

The marked analysis data has a ■ added to its left end and the underline cursor moves to the next analysis data. When an analysis data is marked, the Menu Display Area displays: "1: Deletion," "2: Print," "3: HC Output." When the mark is already attached, press [ENTER] key to delete it.

NOTE:

- When you keep pressing [ENTER] key, the marking is made continuously.
- When you return to the Analysis screen, all the marks on analysis data are deleted.
- "3. HC Output" on the Menu is displayed only when the optional Serial Interface is incorporated.

Stored Data				
No.	WBC	RBC	HGB	HCT
123451*	7.7+	3.97	14.7	32.8
QC01	7.5	4.51	14.1	34.7
■123453	7.5+	3.85	13.8	30.5
■123454 PD	7.1	4.30+	12.2	29.5-
123455* PD	7.2	3.91	14.3	32.0
123456 PD	5.5-	3.90	15.1	40.2+
123457	7.0	4.05	18.5	31.4
123451*	7.6+	3.98	15.0	35.1
Date 31/12/97 12:41				[1/5]
1:Delete		2:Print		3:HC Output

Figure 3-3-4: Marking the Data

Display Contents of Stored Data Screen

1) Sample No.

The sample No. of stored data is displayed.

Identical sample Nos. processed on an identical analysis date are marked with * at the ends of the Nos. QC data are displayed in the format of "QC + File No."

2) Mode Indication

The analysis mode for stored data is displayed.

"PD" is indicated for the pre-diluted mode while no indication is given for the whole blood mode.

3) Analysis Data

Analysis data of 18 parameters are displayed in a group of four parameters on five pages:

- Stored Data Screen [1/5]: WBC, RBC, HGB, HCT
- Stored Data Screen [2/5]: MCV, MCH, MCHC, PLT
- Stored Data Screen [3/5]: WBC, LYM%, MXD%, NEUT%
- Stored Data Screen [4/5]: WBC, LYM#, MXD#, NEUT#
- Stored Data Screen [5/5]: RDW, PDW, MPV, P-LCR

The marks on the left of analysis data indicate the following:

1. ! : The data is out of the linearity limit.
2. + : The data exceeds the upper Mark Limits.
- : The data exceeds the lower Mark Limits.
3. * : The data is low in reliability.

NOTE:

- The marks are added with the priority order of 1, 2, and 3.
- The Mark Limits with "+" and "-" can be set by the customer. For details, refer to *Chapter 10, Section 4: Patient Limit*.

When an analysis error, etc. has caused errors in analysis data, the marks below are attached to the affected data:

1. + + +. +: When data has exceeded the display range.
2. * * *. *: When data could not be calculated due to instrument failure.
3. - - -. -: When data could not be calculated due to data error.

NOTE:

- When analysis is made in the pre-diluted mode, particle distribution analysis parameters are displayed in "- - -. -."

4) Date Analyzed

The date when the analysis data in the underline cursor position was analyzed is displayed.

5) Manual Discrimination Data

As to data changed through manual discrimination, analysis values are reverse-displayed.

6) **Not-output Data**

If the optional serial interface has been mounted, the **H** mark will appear next to the data which has not been output to the host computer. This mark disappears when the data output is completed.

Stored Data					
No.		WBC	RBC	HGB	HCT
123451*	PD	7.7+	3.97	14.7	32.8
QC01	PD	7.5	4.51	14.1	34.7
123453	PD	7.5+	3.85	13.8	30.5
123454*	H PD	7.1	4.30+	12.2	29.5-
123455*	H PD	7.2	3.91	14.3	32.0
123456*	H PD	5.5-	3.90	15.1	40.2+
123457*	H PD	7.0	4.05	18.5	31.4
123451*	H PD	7.6+	3.98	15.0	35.1
Date 31/12/99 12:59					[1/5]
[ENTER] to mark, [SELECT] to exit.					

Figure 3-3-5: Not-Output Data

3.3 Deletion

This menu allows deletion of marked analysis data from stored data.

Execution of Deletion

- Using the underline cursor, specify the analysis data you want to delete and press [ENTER] key. This puts the mark on the analysis data.
- Press [1] key to select "1: Deletion." The Deletion Confirmation message appears.

Delete?	YES	NO
---------	-----	-----------

Figure 3-3-6: Deletion Confirmation Message

- Using [◀] key or [▶] key, move the cursor to select "Yes" or "NO."
[Yes]: Deletes the marked analysis data.
[NO]: Cancels deletion.
- Press [ENTER] key to execute the selected process.
When you press [SELECT] key, the process is canceled.

NOTE: • Before deleting data, make sure the KX-21 completes any output operation to the printer or host computer.

3.4 Printing

This menu allows the marked analysis data to be printed by the built-in printer.

Execution of Printing

- (1) Using the underline cursor, specify the analysis data you want to print and press [ENTER] key. This puts the mark on the analysis data.
- (2) Press [2] key to select "2: Print." The built-in printer starts printing the marked analysis data.

NOTE:

- For print format, refer to *Chapter 2, Section 5.2: Printing of Analysis Result.*
- In printing stored data, Type 2 print is performed even when Type 1 print format is selected. (Particle distribution is not printed.)

3.5 HC Output (Option)

This menu allows outputting the marked analysis data to the host computer, if an optional serial interface is incorporated.

NOTE:

- "3: HC Output" on the Menu is displayed only when the optional serial interface is incorporated.

Execution of HC Output

- (1) Using the underline cursor, specify the analysis data you want to output to the host computer and press [ENTER] key. This puts the mark on the analysis data.
- (2) Press [3] key to select "3: HC Output."
Analysis data is output to the host computer in the order of marking.
During output to the host computer, the * mark blinks at the right top edge of the system status display area.

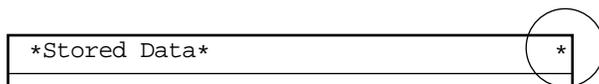


Figure 3-3-7: Screen during Output to Host

NOTE:

- Output to the host computer cannot be interrupted.

3.6 Correcting a Sample Number

Use the [SAMPLE No.] key to correct a sample number of analysis data.

- (1) Use the underline cursor to select the desired analysis data, then press the [SAMPLE No.] key. The selected sample number will be highlighted.
- (2) Use the numeric keypad to enter a new sample number, then press the [ENTER] key.
- (3) When the confirmation message appears, select the [Set] button.

CHAPTER 4 MAINTENANCE AND SUPPLIES REPLACEMENT

1.	INTRODUCTION	4-1
2.	KX-21 MAINTENANCE CHECKLIST	4-2
3.	DAILY MAINTENANCE AND PROCEDURE	4-4
3.1	Clean TD Chamber and Diluted Sample Line (Shutdown).....	4-4
3.2	Check Trap Chamber Level and Discard	4-6
4.	WEEKLY MAINTENANCE AND PROCEDURE.....	4-7
4.1	Clean SRV Tray.....	4-7
5.	MONTHLY MAINTENANCE AND PROCEDURE	4-9
5.1	Clean Waste Chamber (Rinse Sequence).....	4-9
5.2	Clean Transducer (Rinse Sequence).....	4-12
6.	EVERY 3-MONTH MAINTENANCE AND PROCEDURE	4-16
6.1	Clean Sample Rotor Valve (SRV).....	4-16
6.2	Reset SRV Cycle Counter	4-22
7.	AS-NEEDED MAINTENANCE AND PROCEDURE.....	4-24
7.1	Auto Rinse	4-24
7.2	Clean Rinse Cup	4-26
7.3	Clean WBC/RBC Transducer Aperture	4-28
7.4	Replace Waste Tank	4-32
8.	SUPPLIES REPLACEMENT.....	4-33
8.1	Replenish Reagent	4-33
8.2	Replace Fuse.....	4-36
8.3	Replace Printer Paper.....	4-37
8.4	Supplies List.....	4-40
9.	CONFIRMATION OF CYCLE NUMBER.....	4-41
9.1	Operation Procedure	4-41

1. INTRODUCTION

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

- **Daily Maintenance**
Clean the TD chamber and diluted sample line. (Execute shutdown.)
Check trap chamber level, and discard if necessary.

- **Weekly Maintenance**
Clean the sample rotor valve (SRV) tray.

- **Monthly Maintenance (or Every 2500 Samples)**
Clean the waste chamber (rinse sequence).
Clean the transducer (rinse sequence).

- **Every 3-Month Maintenance (or Every 7500 Samples)**
Clean the sample rotor valve (SRV).

- **As-Needed Maintenance**
Auto Rinse
Clean the rinse cup.
Clean WBC/RBC transducer aperture.
Replace the waste tank.

This chapter describes supplies replacement together with these maintenance items.

- **Supplies Replacement**
Replenish reagent.
Replace fuses.
Replace printer paper.

2. KX-21 MAINTENANCE CHECKLIST

Year: _____ Month: _____

Maintenance Item	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Execute shutdown																																
Check trap chamber level and drain																																
Signature																																

As-Needed Maintenance

Maintenance item	Date, Signature	Date, Signature
Auto rinse		
Clean rinse cup		
Clean WBC/RBC transducer aperture		
Replace waste tank		

Supplies Replacement

Maintenance item	Date, Signature	Date, Signature
Replenish reagent		
Replace fuse		
Replace printer paper		

Weekly Maintenance

Maintenance Item	Week	1	2	3	4	5
Clean sampling valve (SRV) tray						
Signature						

Monthly Maintenance

Maintenance item	Date, Signature
Clean waste chamber (Rinse sequence)	
Clean transducer (Rinse sequence)	

Every 3-Month Maintenance

Maintenance item	Date, Signature
Clean sample rotor valve (SRV)	

Reagent Replenishment Record

Month _____ Year _____

CELLPACK							
Lot No.	Date	Expiry	Signature	Lot No.	Date	Expiry	Signature

STROMATOLYSER-WH							
Lot No.	Date	Expiry	Signature	Lot No.	Date	Expiry	Signature

3. DAILY MAINTENANCE AND PROCEDURE

3.1 Clean TD Chamber and Diluted Sample Line (Shutdown)

By executing shutdown, the transducer chamber and diluted sample line are cleaned. Perform shutdown after completion of the day's work, and also at least once every 24 hours when this instrument is used continuously.

- (1) Press [SHUTDOWN] key in the Ready status. The Shutdown screen appears.

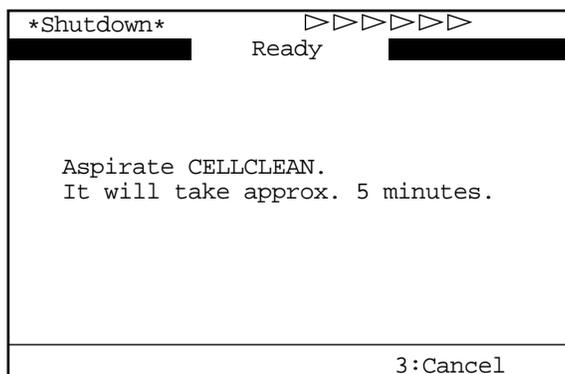


Figure 4-3-1: Shutdown Screen

NOTE: • When [3] key is pressed, shutdown is canceled and the Analysis screen returns.

- (2) In executing shutdown, set CELLCLEAN to the sample probe and press the start switch in that status. While "Aspirating" is being displayed on the screen, keep holding CELLCLEAN in the same state.

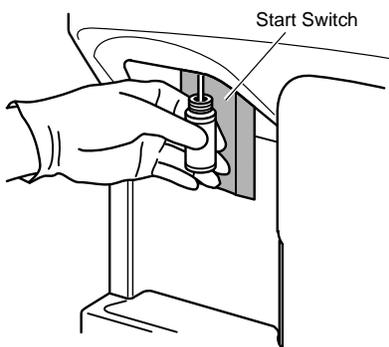


Figure 4-3-2: Pressing the Start Switch

WARNING • Because CELLCLEAN is a strong alkaline detergent, take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.

NOTE: • Once shutdown is executed, it cannot be canceled until completed.

- (3) When the buzzer sounds two times - beep, beep, - informing the completion of aspiration, remove CELLCLEAN from the sample probe. After that, shutdown is executed automatically.

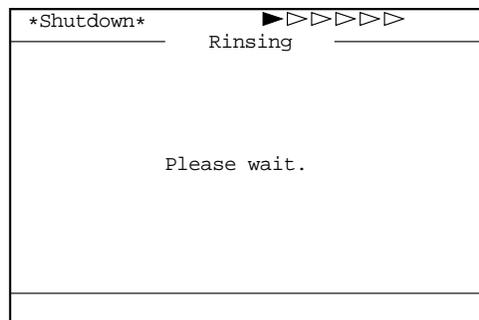


Figure 4-3-3: Shutdown Execution Screen

CAUTION: • To remove CELLCLEAN, lower it straight down. Take care not to bend the sample probe.

- (4) When shutdown is completed and the following message is displayed, turn off the power switch on the right side of the unit.

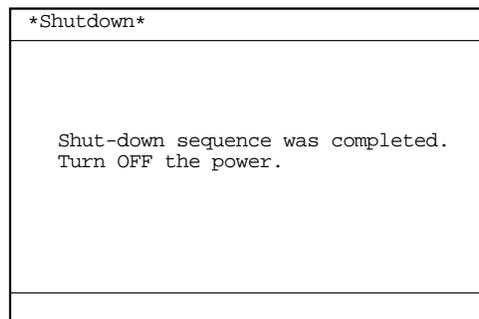


Figure 4-3-4: Shutdown Completion Message Screen

NOTE: • Shutdown will take approximately 5 minutes.

3.2 Check Trap Chamber Level and Discard

After completion of analyses for the day, check trap chamber level and discard any liquid that has collected.

- (1) Turn off the power and wait approximately 30 seconds.
- (2) Turn the chamber on the left side of the unit counterclockwise and remove.

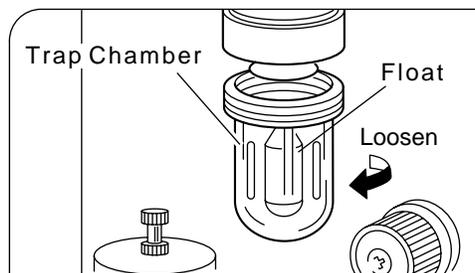


Figure 4-3-5: Checking the Trap Chamber

- (3) After discarding the liquid, mount the chamber. Make sure the float is inside.



WARNING

- When discarding the trap chamber liquid, always wear rubber gloves. After completion of operation, wash hands with disinfectant. If your hands are contaminated by the liquid, infection of bacteria or the like can occur.



CAUTION

- If liquid collects everyday, the hydraulic system may have failed. Contact Sysmex service representative.
- Pay attention to the direction of the float in the chamber. Place it with its pointed end facing upward.

4. WEEKLY MAINTENANCE AND PROCEDURE

4.1 Clean SRV Tray

Clean the sample rotor valve (SRV) tray once a week in the following procedure:

! WARNING • When cleaning the SRV tray, always wear rubber gloves. After completion of operation, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria or the like can occur.

- (1) Turn off the power of the main unit and wait approximately 30 seconds.
- (2) Open the front cover of the main unit.
- (3) Remove the SRV tray.

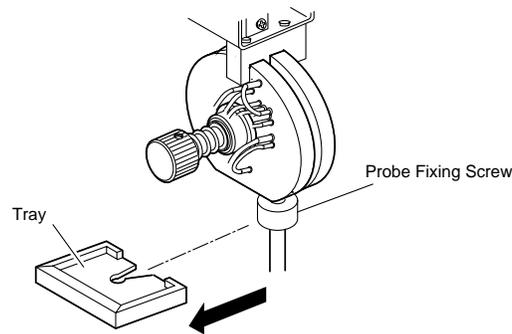


Figure 4-4-1: Removing the SRV Tray

! CAUTION • When removing the tray, take care not to loosen the probe fixing screw. If analysis is made with the screw loosened, air can enter the system and affect the data.

- (4) Wash the SRV tray using tap water.

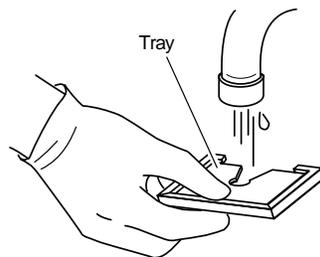


Figure 4-4-2: Washing the SRV Tray

- (5) Make sure no contaminants remain, then wipe off water.
- (6) Re-mount the SRV tray to the original state.



CAUTION • After mounting the tray, make sure the probe fixing screw is not loose. If analysis is made with the screw loosened, air can enter the system and affect the data.

CAUTION: • Mount the SRV tray properly as to the face/bottom and the direction.

- (7) Close the front cover of the main unit.

5. MONTHLY MAINTENANCE AND PROCEDURE

5.1 Clean Waste Chamber (Rinse Sequence)

When the power is turned on, the message is displayed once a month or for every 2500 samples to instruct the scheduled maintenance.

Scheduled Maint.	
Clean the Waste Chamber. It will take approx. 15 minutes.	
Cycle No. after cleaning.	2567
Date last serviced	31/12/97
1:Exec.Clean	3:Cancel

Figure 4-5-1: Scheduled Maintenance Message Screen

When this message appears, press [1] key to select "1: Exec. Clean," and clean the waste chamber by the following procedure:

NOTE:

- When you press [3] key and select "3: Cancel," the start-up process continues without cleaning the waste chamber. Until the waste chamber is cleaned, the above message is displayed at start-up.
- Even when the above message is not displayed, you can execute the waste chamber cleaning by choosing "7: Maintenance" on the Select Menu screen, then "1: Clean W. Chamber" on the Maintenance Menu screen.

- (1) Press [1] key to select "1: Exec. Clean" on the Scheduled Maintenance Message screen. The Clean W. Chamber screen will display the message instructing the following operation:

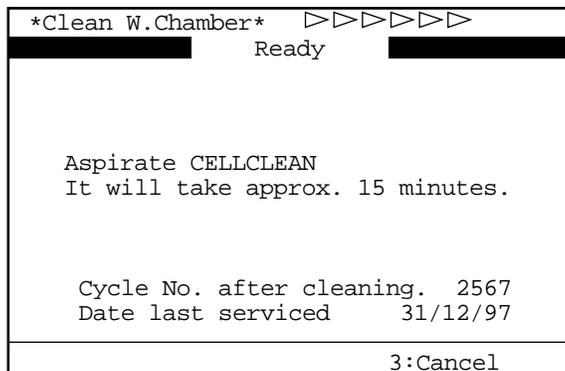


Figure 4-5-2: Clean W. Chamber Screen

NOTE:

- When you press [3] key and select "3: Cancel," the start-up process continues without cleaning the waste chamber. Until the waste chamber is cleaned, the above message is displayed at start-up.

- (2) Set CELLCLEAN to the sample probe and press the start switch in that status. While "Aspirating" is being displayed on the screen, keep holding CELLCLEAN in the same status.

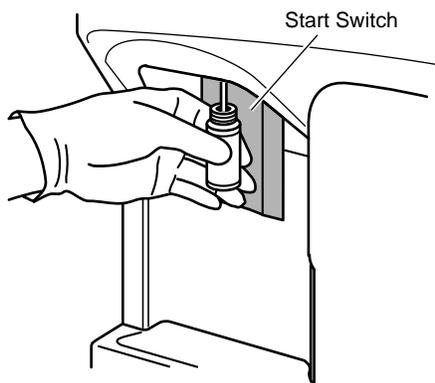


Figure 4-5-3: Pressing the Start Switch



WARNING

- Since CELLCLEAN is a strong alkaline detergent, take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.

- (3) When the buzzer sounds two times - beep, beep , - informing completion of aspiration, remove CELLCLEAN from the sample probe. After that, the waste chamber cleaning is executed automatically.

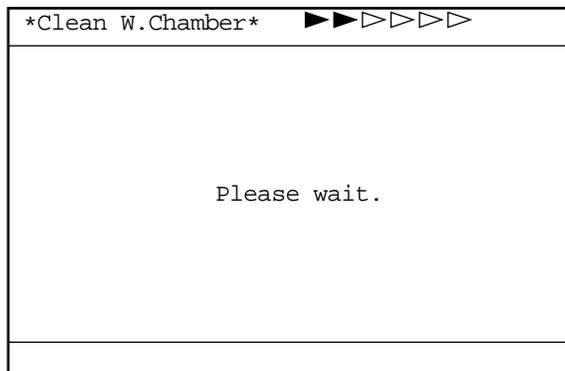


Figure 4-5-4: Screen during Waste Chamber Cleaning

CAUTION: • To remove CELLCLEAN, lower it straight down. Take care not to bend the sample probe.

- (4) When the waste chamber cleaning is completed, the auto rinse and background check are executed, then the system turns to the Ready status.
- (5) Check to see that no background error occurs. Should background error occur, execute the auto rinse.

NOTE: • When this operation is completed, the waste chamber cycle counter is automatically reset. For the confirmation of waste chamber cycle number, refer to *Chapter 4, Section 9: CONFIRMATION OF CYCLE NUMBER*.

5.2 Clean Transducer (Rinse Sequence)

When the power is turned on, the message is displayed once a month or for every 2500 samples to instruct the scheduled maintenance.

Scheduled Maint.	
Clean the Transducer. It will take approx. 7 minutes.	
Cycle No. after cleaning.	2567
Date last serviced	31/12/97
1:Exec. Clean	3:Cancel

Figure 4-5-5: Scheduled Maintenance Message Screen

When this message appears, press [1] key to select "1: Exec. Clean," and clean the transducer by the following procedure:
In addition, the error message of clogging is displayed. Even when the clogging is not removed, clean the transducer using the same procedure.

NOTE:

- When you press [3] key and select "3: Cancel," the start-up process continues without cleaning the transducer. Until the transducer is cleaned, the above message is displayed at start-up.
- Even when the above message is not displayed, you can execute the transducer cleaning by choosing "7: Maintenance" on the Select Menu screen, then "2: Clean Transducer" on the Maintenance Menu screen.
- If this rinse sequence fails to remove clogging, clean with the brush. Regarding cleaning with the brush, refer to *Chapter 4, Section 7.3: Clean WBC/RBC Transducer Aperture.*

- (1) Press [1] key to select "1: Exec. Clean" on Scheduled Maintenance Message screen. Fluid in the transducer is drained and the Clean Transducer screen appears.

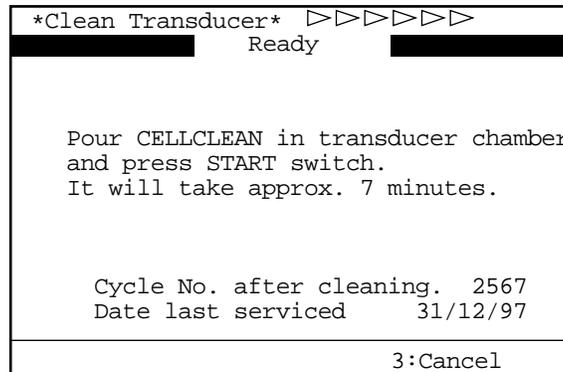


Figure 4-5-6: Clean Transducer Screen

NOTE:

- When you press [3] key and select "3: Cancel," the start-up process continues without cleaning the transducer. Until the transducer is cleaned, the above message is displayed at start-up.

- (2) Open the front cover of the main unit.
- (3) Open the transducer cover.

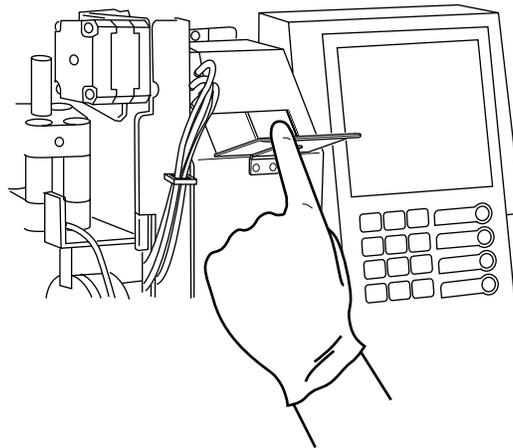


Figure 4-5-7: Opening the Transducer Cover

- (4) Using the filler provided with the unit, pour approximately 1 mL each of CELLCLEAN into the WBC transducer and RBC transducer.

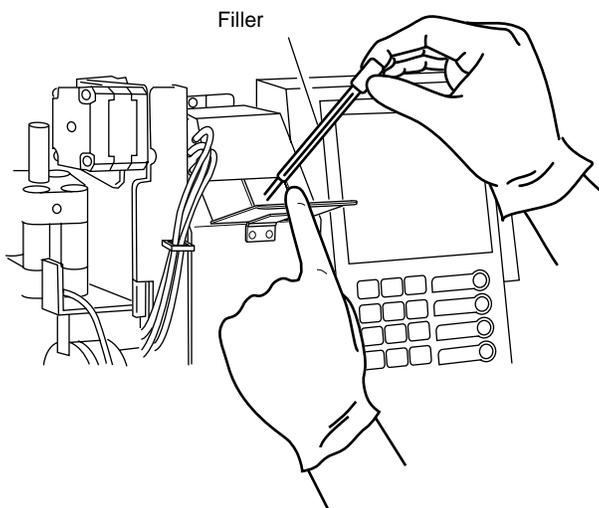


Figure 4-5-8: Pouring CELLCLEAN

! WARNING • Since CELLCLEAN is a strong alkaline detergent, take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.

! CAUTION • Do not pour more than 1 mL of detergent (CELLCLEAN) into the chamber. It may overflow, possibly causing electric shocks or leakage.

CAUTION: • Take care not to have detergent (CELLCLEAN) adhere to the chamber side wall.

- (5) Close the transducer cover.
(6) Close the front cover of the main unit.

- (7) Press the start switch. The transducer cleaning is executed.

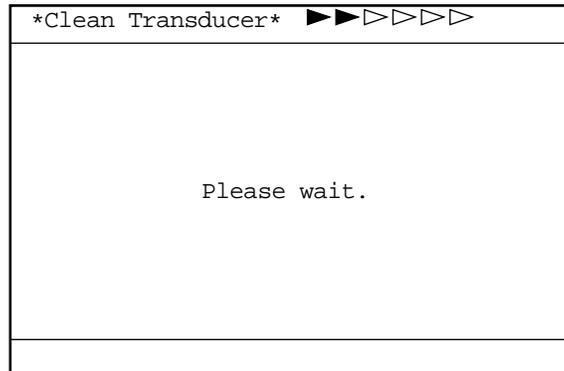


Figure 4-5-9: Screen during Transducer Cleaning

- (8) When the transducer cleaning is completed, the auto rinse and background check are executed, then the system turns to the Ready status.
- (9) Check to see that no background error occurs. Should background error occur, execute the auto rinse.

NOTE:

- When this operation is completed, the transducer cycle counter is automatically reset. For the confirmation of transducer cycle number, refer to *Chapter 4, Section 9: CONFIRMATION OF CYCLE NUMBER.*

6. EVERY 3-MONTH MAINTENANCE AND PROCEDURE

6.1 Clean Sample Rotor Valve (SRV)

When the power is turned on, the message is displayed once every three months or for every 7500 samples to instruct the scheduled maintenance.

Scheduled Maint.	
Clean the SRV.	
[1] Reset the cycle counter for SRV, and you can turn OFF the power.	
[3] Continue to start up. SRV cycle counter will not be reset.	
Cycle No. after cleaning. 7567	
Date last serviced 31/12/97	
1:Exec.Clean	3:Cancel

Figure 4-6-1: Scheduled Maintenance Message Screen

When this message appears, press [1] key to select "1: Exec. Clean," and reset the cycle counter. Then clean the sample rotor valve (SRV) by the following procedure:

 <p>WARNING</p>	<ul style="list-style-type: none"> • When cleaning the sample rotor valve (SRV), always wear rubber gloves. After completion of operation, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria or the like can occur. • Because CELLCLEAN is a strong alkaline detergent, take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.
---	--

<p>NOTE:</p>	<ul style="list-style-type: none"> • When you press [3] key and select "3: Cancel," the start-up process continues without cleaning the sample rotor valve (SRV). Until the sample rotor valve (SRV) is cleaned, the above message is displayed at start-up. • When you want to clean before this message appears, or when you selected "3: Cancel" on the Scheduled Maint. screen and executed cleaning when the power was off, reset the cycle counter, making reference to <i>Chapter 4, Section 6.2: Reset SRV Cycle Counter</i>.
---------------------	---

- (1) Press [1] key to select "1: Exec. Clean" on the Scheduled Maintenance Message screen. The SRV cycle counter is reset and the unit is ready to be turned off.

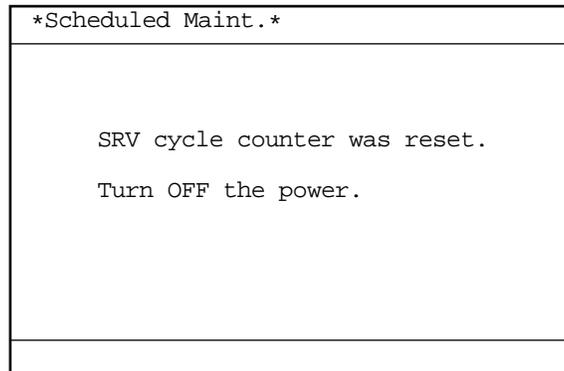


Figure 4-6-2: Clean SRV Screen

CAUTION: • Before turning the power off, always select "1: Exec. Clean," making the unit ready to be turned off.

- (2) Turn off the power of the main unit and wait approximately 30 seconds.
- (3) Open the front cover of the main unit.
- (4) Remove the sample rotor valve (SRV) tray.

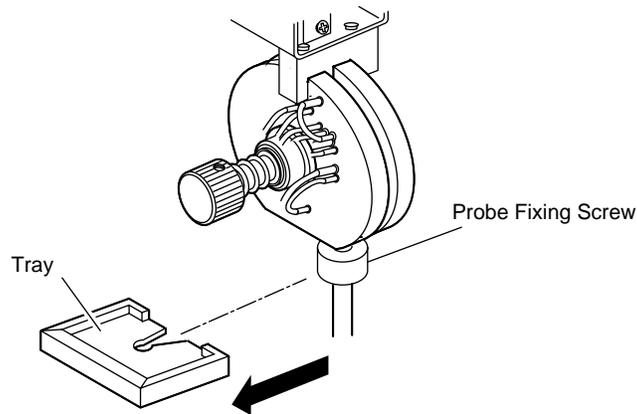


Figure 4-6-3: Removing the Tray

CAUTION • When removing the tray, take care not to loosen the probe fixing screw. If analysis is made with the screw loosened, air can enter the system and affect the data.

- (5) Gently push down the rinse cup using both hands. Make sure the rinse cup is removed completely from the sample probe.

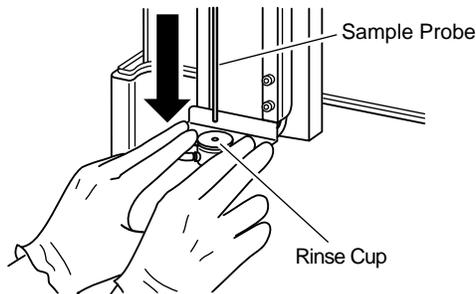


Figure 4-6-4: Pushing Down the Rinse Cup

CAUTION: • If the rinse cup is not completely removed from the sample probe, there is a possibility that the sample probe may bend when the sample rotor valve (SRV) is removed.

- (6) Remove the SRV fixing screw.

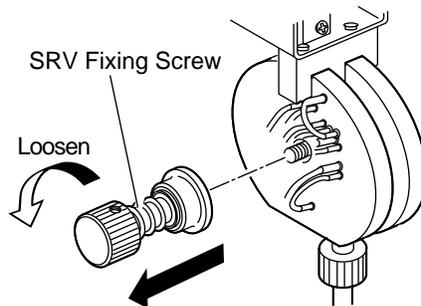


Figure 4-6-5: Removing the SRV Fixing Screw

- (7) Remove the entire sample rotor valve (SRV).

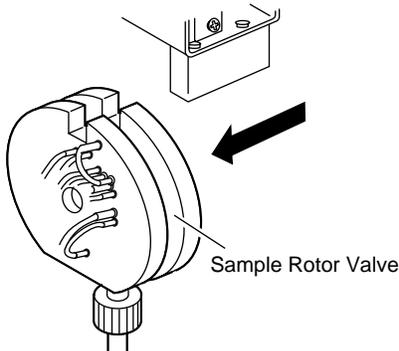


Figure 4-6-6: Removing the Entire SRV

CAUTION:

- Take care not to pull out the valve excessively. This is to prevent applying excess force to the tube connected to the valve.
- When removing the valve, take care not to bend the sample probe.

- (8) Remove the rotary valve.

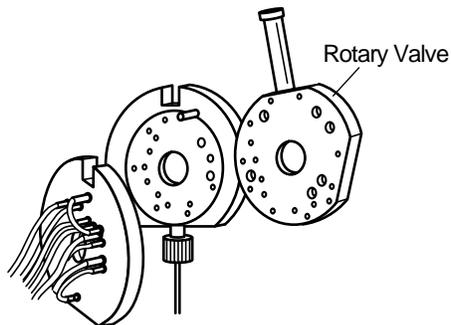


Figure 4-6-7: Removing the Rotary Valve



CAUTION

- When removing the valve, reagent could leak from the tube. If it does, wipe it clean using cloth. If left as it is, it can cause current leakage or electric shocks.

NOTE:

- The valve components are in close contact with one another. They can be easily removed when you gently twist and slide each one.

- (9) Clean the rotary valve using distilled water or 1:10 dilution of CELLCLEAN detergent. After cleaned with CELLCLEAN, always clean it with distilled water.
- (10) Clean the contact surfaces of the fixed and rotary valves using a gauze moistened with distilled water. By using CELLCLEAN together with distilled water, stuck objects, dirt, etc. can be removed easily.



Figure 4-6-8: Cleaning the Contact Faces



CAUTION • Take care not to inflict flaws or scratches on valve surfaces, since flaws or scratches can cause blood leakage and incorrect analysis results.

CAUTION:

- Do not use any detergent other than CELLCLEAN. Although the sample rotor valve (SRV) is corrosion-resistant against CELLCLEAN, wipe it off completely to prevent troubles to the unit or other components.

- (11) Make sure the valve contact surfaces are completely free from dirt or dust.

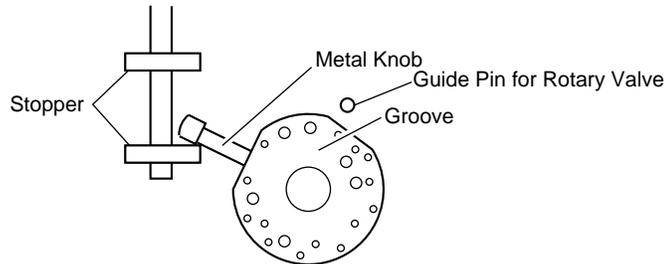


CAUTION • If the device is used with dirt or dust attaching on valve contact surfaces, blood leakage can occur and correct analysis results may not be obtained.

- (12) Install one each valve at a time, and assemble the sample rotor valve (SRV) in the reverse order to disassembly.

CAUTION:

- Mount the rotary valve with the notch facing upward and the metal knob coming between the stoppers.



(View of Left Side)

Figure 4-6-9: Rotary Valve

- Confirm that the metal knob is between the stoppers. If it is not, malfunction will occur.

- (13) Mount the SRV tray to the original position and gently push up the rinse cup to the top using both hands.

CAUTION:

- Mount the SRV tray properly as to its face/bottom and the direction.
- Make sure the rinse cup is pushed all the way up with the sample probe inserted in the hole. If the power is turned on with the rinse cup staying lowered, "Rinse Motor Error" will occur, making it impossible to continue the operation.

- (14) Close the front cover of the main unit.
- (15) Turn on the main unit and make sure that the background error has not occurred.
- (16) Perform quality control and make sure that there is no functional problem.

NOTE:

- When this operation is completed, the SRV cycle counter is automatically reset. For confirmation of SRV cycle number, refer to *Chapter 4, Section 9: CONFIRMATION OF CYCLE NUMBER.*

6.2 Reset SRV Cycle Counter

If you have cleaned the SRV other than the time when instructed on the Scheduled Maintenance screen, always reset the SRV cycle counter manually.

NOTE:

- If you continue using the unit without resetting the SRV cycle counter, the message will instruct you to perform scheduled maintenance within three months (or before analyzing 7500 samples).
- For SRV cleaning procedure, refer to *Chapter 4, Section 6.1: Clean Sample Rotor Valve (SRV)*.

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Use [▲] key or [▼] key, move the cursor to select "7: Maintenance."
- (3) Press [ENTER] key. The Maintenance Menu screen appears.

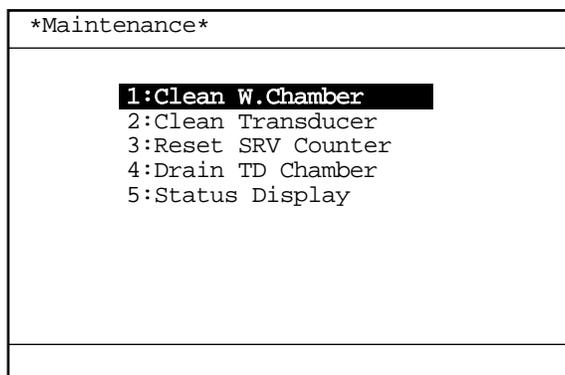


Figure 4-6-10: Maintenance Menu Screen

- (4) Use [▲] key or [▼] key, move the cursor to select "3: Reset SRV Counter."
- (5) Press [ENTER] key. The Rest SRV Counter screen appears.

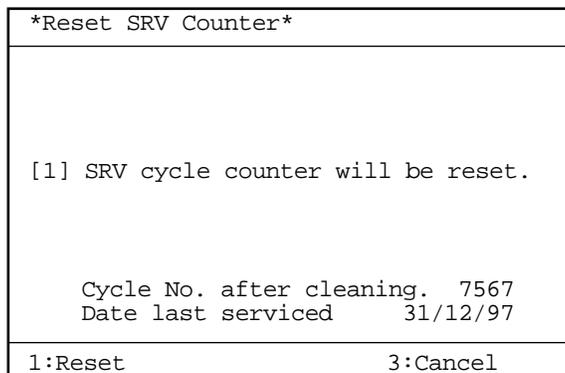


Figure 4-6-11: Reset SRV Counter Screen

- (6) Press [1] key to select "1: Reset." "Cycle No. after cleaning" is reset to "0," the date of the present day is entered in the "Date last serviced" column, then the Analysis screen returns.

NOTE:

- Press [3] key to select "3: Cancel." The cycle counter is not reset, and the Analysis screen returns.
- For confirmation of SRV cycle counter, refer to *Chapter 4, Section 9: CONFIRMATION OF CYCLE NUMBER.*

7. AS-NEEDED MAINTENANCE AND PROCEDURE

When the transducer is clogged or the waste tank becomes full, perform the necessary maintenance.

7.1 Auto Rinse

Execute the Auto Rinse at background check or when the unit has been left idle without shutdown performed. The Auto Rinse cleans all the lines in the unit and drains all waste. Background check is also implemented to allow checking whether the unit is in normal status or not.

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] key or [▼] key, move the cursor to select "5: Auto Rinse."

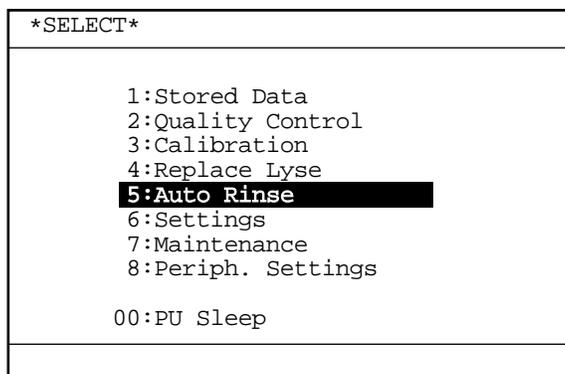


Figure 4-7-1: Select Menu Screen

- (3) Press [ENTER] key. Auto Rinse and background check are performed.

NOTE: • On the Menu screen, each menu can be selected directly by entering a numeral from the numeric keys.

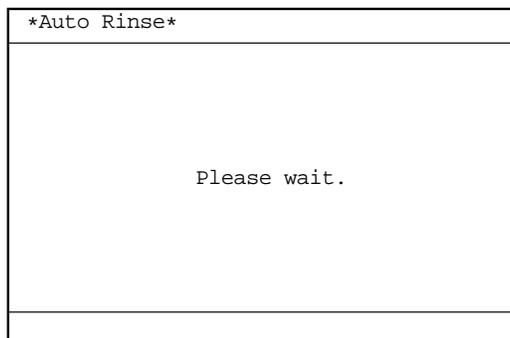


Figure 4-7-2: Auto Rinse Execution Screen

NOTE:

- After Auto Rinse, background check is executed. When the background value of any parameter exceeds tolerance, background check is repeated a maximum of twice. In case background value still exceeds tolerance, the message "Background Error" appears while the alarm starts sounding. Press [HELP] key. This stops the alarm and the Action Message screen appears. Follow the Action Message screen and take appropriate action. (Refer to *Chapter 7: TROUBLESHOOTING*).

- **Background tolerance**

WBC	0.3 [$\times 10^3/\mu\text{L}$] or less
RBC	0.02 [$\times 10^6/\mu\text{L}$] or less
HGB	0.1 [g/dL] or less
PLT	10 [$\times 10^3/\mu\text{L}$] or less

Table 4-7-1: Background tolerance

7.2 Clean Rinse Cup

When the rinse cup has any blood on it or is clogged, clean it by the following procedure:

WARNING • When cleaning the rinse cup, always wear rubber gloves. After completion of operation, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria or the like can occur.

- (1) Turn off the power of the main unit and wait approximately 30 seconds.
- (2) Open the front cover of the main unit.
- (3) Gently push down the rinse cup using both hands. Make sure the rinse cup is removed completely from the sample probe.

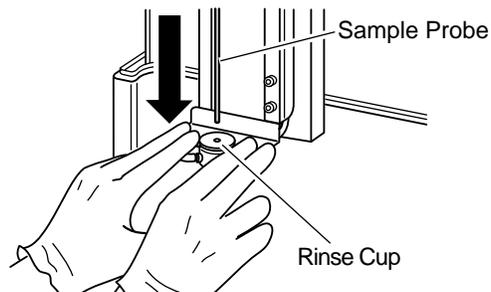


Figure 4-7-3: Pushing Down the Rinse Cup

- (4) Remove the rinse cup in the order of 1, 2, and 3 as shown below.

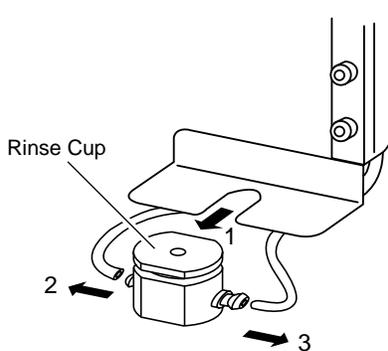


Figure 4-7-4: Removing the Rinse Cup

- (5) Clean the rinse cup using tap water.

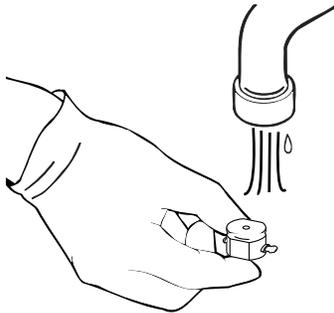


Figure 4-7-5: Cleaning the Rinse Cup

- (6) Make sure no contaminant remains on the rinse cup and wipe off water.
- (7) Mount the rinse cup in the reverse order of removal. Route the thin tubes around the rear of the rinse cup.

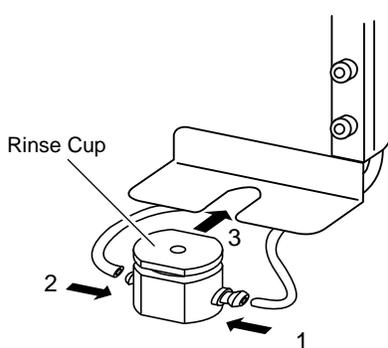


Figure 4-7-6: Mounting the Rinse Cup

- (8) Gently push up the rinse cup to the top using both hands.

CAUTION:

- Make sure the rinse cup is pushed all the way up with the sample probe inserted in the hole. If the power is turned on with the rinse cup staying lowered, "Rinse Motor Error" will occur, making it impossible to continue the operation.

7.3 Clean WBC/RBC Transducer Aperture

If the transducer aperture clogging persists, clean the transducer aperture using the brush by the following procedure:

! WARNING

- When cleaning the aperture, always wear rubber gloves. After completion of operation, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria or the like can occur.
- Since CELLCLEAN is a strong alkaline detergent, take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.

1. Preparation

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Use [▲] key or [▼] key, move the cursor to select "7: Maintenance."
- (3) Press [ENTER] key. The Maintenance Menu screen appears.

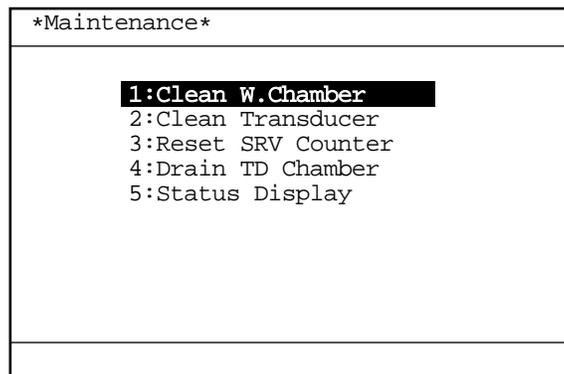


Figure 4-7-7: Maintenance Menu Screen

- (4) Use [▲] key or [▼] key, move the cursor to select "4: Drain TD Chamber."
- (5) Press [ENTER] key. Reagent in the transducer chamber is automatically drained.

NOTE:

- On the Menu screen, each menu can be selected directly by entering a numeral from the numeric keys.

- (6) When reagent in the transducer chamber is drained, the message instructing turning-off of the power is displayed, which indicates that it is ready for cleaning with the brush.

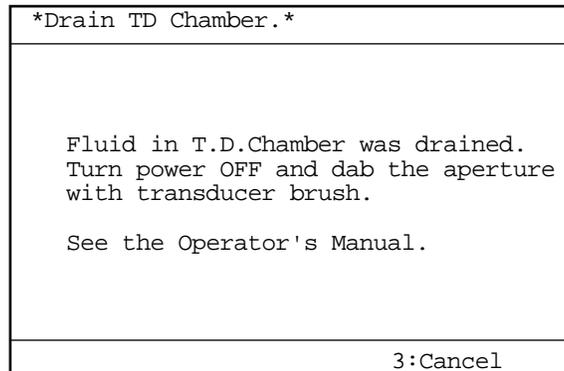


Figure 4-7-8: Drain TD Chamber Screen

NOTE:

- When you press [3] key, cleaning with brush is canceled and the Analysis screen returns.

2. Clean Transducer Aperture

- (1) Turn off the power and wait approximately 30 seconds.
- (2) Open the front cover of the main unit.
- (3) Loosen the screw and open the transducer cover.

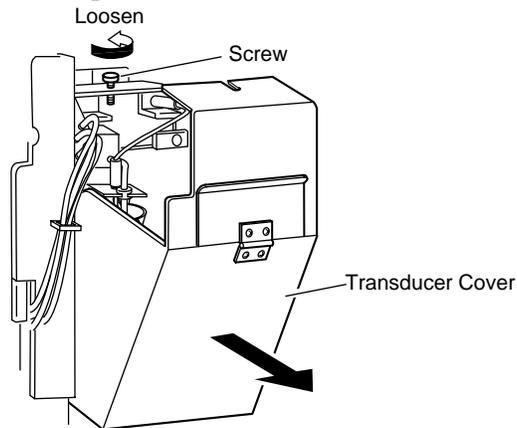


Figure 4-7-9: Opening the Transducer Cover



WARNING • When the power is on, never open the transducer cover. This is to prevent possible electric shocks.

- (4) Confirm that reagent in the transducer chamber has been drained.

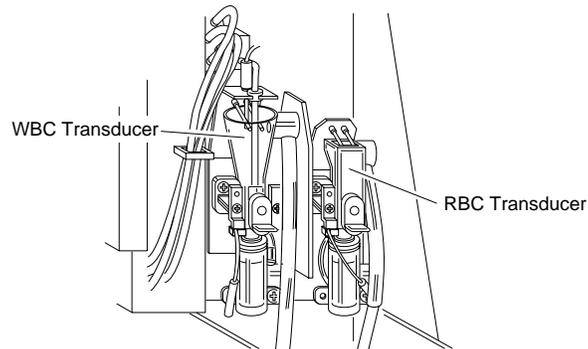


Figure 4-7-10: Checking the WBC/RBC Transducer

- (5) Remove the transducer chamber plug.

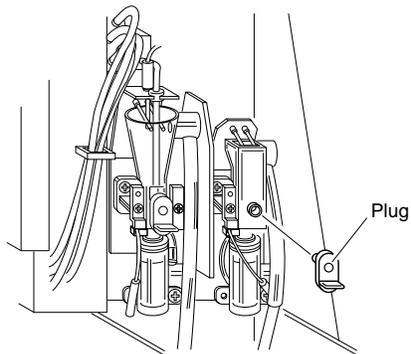


Figure 4-7-11: Removing the Plug

CAUTION • A small volume of reagent occasionally remains. When reagent has leaked, wipe it off immediately using wet cloth or the like. If left as it is, it can cause current leakage or electric shocks.

- (6) Apply CELLCLEAN on the brush provided, and dab by lightly prodding the brush against the transducer aperture.

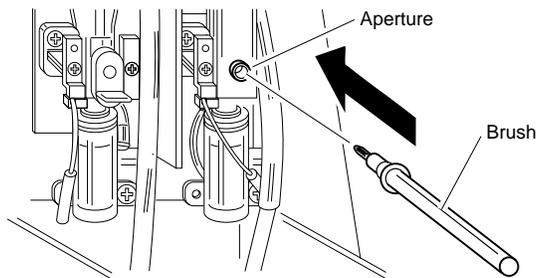


Figure 4-7-12: Cleaning the Aperture

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

(7) Mount the transducer chamber plug.



CAUTION • The transducer chamber plug should be mounted securely. Otherwise, current leakage or electric shocks can occur.

(8) Close the transducer cover and main unit front cover. Then turn on the power.

(9) Check to see that background error has not occurred.

7.4 Replace Waste Tank

When the waste tank has become full, replace it by the following procedure:

WARNING • When replacing the waste tank, always wear rubber gloves. After replacing, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria or the like can occur.

- (1) Turn off the power of the main unit and wait approximately 30 seconds.
- (2) Make ready an empty waste container and remove the cap.
- (3) Pull the tube off the waste container.
- (4) Insert the tube in the new waste container and fix it using tape or the like.

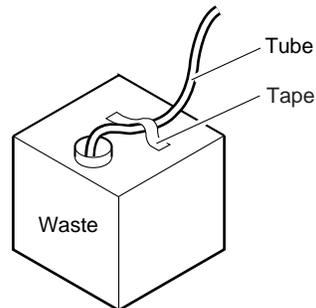


Figure 4-7-13: Waste Container

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

8. SUPPLIES REPLACEMENT

8.1 Replenish Reagent

When reagent becomes insufficient during analysis, the instrument comes to a stop, while the screen displays the error message. Press [HELP] key to change to the replenishment operation.

Error Message (Analysis Screen)	HELP Screen	Reagent to Replenish
Replenish Diluent	<pre> *Help* Replenish Diluent Container. [1] Reaspirating Diluent ERR CODE:XXXXX.X.X 1:Asp. Reag. 3:Cancel </pre>	CELLPACK
Replenish Lyse	<pre> *Help* Replenish Lyse Container. [1] Reaspirating Lyse ERR CODE:12490.0.0 1:Asp.Reag. 3:Cancel </pre>	STROMATOLYSER-WH

NOTE:

- Press [3] key on the HELP screen and select "3: Cancel" to return to the Analysis screen. Although Analysis screen displays the Not Ready status, the processing, etc. of stored data can be performed.

- (1) Make ready a new reagent and check to see that expiration date is not passed.

CAUTION

- CELLPACK, if used just after delivery via transit, sometimes develop a background error.
- In handling a reagent that may have frozen, follow the precautions given on the Package Insert. Otherwise, correct analysis result may not be obtained.
- Leave the reagent at room temperature (15 - 30°C) for at least 24 hours before using.
- After unpacking, take care to prevent entry of dirt, dust, and bacteria.

CELLPACK	20 L	60 days
STROMATOLYSER-WH	500 mL	90 days

Table 4-8-1: Expiration After Opening the Seal

- (2) Remove the cap from the new reagent bottle.
- (3) Remove the cap from the empty reagent bottle and pull out the cubitainer spout set straight up.
- (4) Insert the cubitainer spout set straight down into the new reagent bottle and tighten the cap.

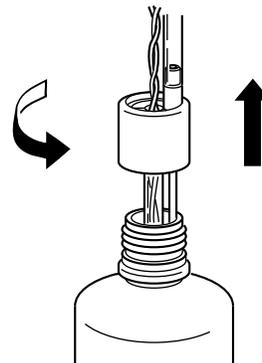


Figure 4-8-1: Pulling Out the Cubitainer Spout Set

CAUTION

- Take care not to grasp the tube dipping into the reagent and not allow dust, etc. to adhere to the tube. If dust, etc. adheres to the tube, wash it away with reagent in use before mounting. Otherwise, correct analysis results may not be obtained.
- Replace only fresh and fully bottled lyse reagent. Old or collected lyse reagent will affect the analysis results.
- Take care not to spill reagent. If it spills, wipe it off immediately using wet cloth, etc. to prevent the floor color fading.
- When replacing lyse, you do not need to disconnect the float switch. If disconnected, connect it securely in prior to starting analysis. Starting analysis with disconnected float switch will give you an error message "No Lyse".

- (5) When reagent replenishment is over, follow the instruction on the screen and press [1] key to select "1: Asp. Reag." Reagent is automatically aspirated, and then background check is performed. The check is made here to see that background error has not occurred.
- (6) Enter the contents of replenishment in Reagent Replenishment Record.

<p>NOTE:</p> <ul style="list-style-type: none">• If you replenish lyse before error message "No Reagent" appears, execute "4: Replace Lyse" on the Select Menu screen.

8.2 Replace Fuse

The main unit employs overcurrent protective fuses. When a fuse is blown, replace it by the following procedure:

- (1) Disconnect the power cord on the right side of the main unit.

! WARNING • Before replacing the fuse, always turn off the power and disconnect the power cord to prevent possible electric shocks.

- (2) Pressing the notch upward with a regular screwdriver, remove the fuse cap holder.

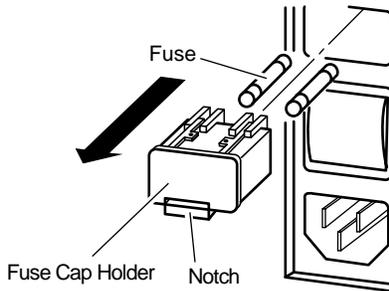


Figure 4-8-2: Removing the Fuse Cap Holder

- (3) Replace the fuse and mount the fuse cap holder.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5109-1	Fuse 250 V 3.15 A ST4-3.15A-N1	Time Lag
220/240 VAC	266-5292-6	Fuse 250 V 2 A No. 19195	Time Lag

Table 4-8-2: Fuse Rating

! CAUTION • For continued protection against risk of fire, use the fuse of the specified type and rating.

8.3 Replace Printer Paper

When the "No Printer Paper" message appears on the screen, press [HELP] key and replace printer paper by the following procedure:

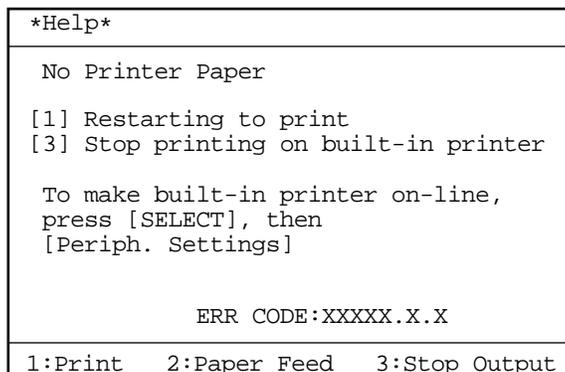


Figure 4-8-3: "No Printer Paper" Message Screen

NOTE:

- On the HELP screen, press [3] and select "3: Stop Output" to stop printing on built-in printer. Analysis is executed as usual but printing is not. When you want to use built-in printer again, select "8: Periph. Settings" to set. (Refer to *Chapter 10, Section 9: Peripheral Settings.*)

- (1) Open the front cover of the main unit.
- (2) Turn the release lever up to free the paper.

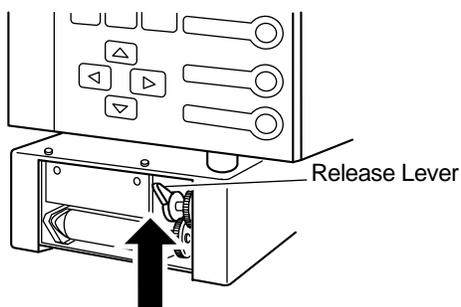


Figure 4-8-4: Releasing the Lever

- (3) Remove the bare paper core and mount a new printer paper.

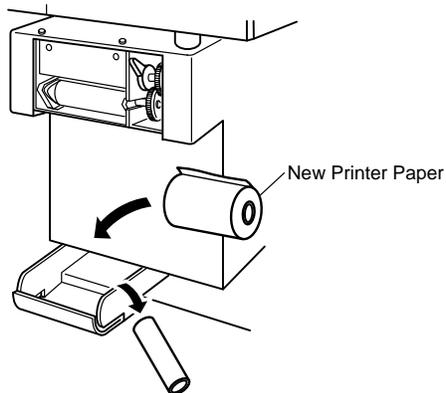


Figure 4-8-5: Mounting a New Printer Paper

NOTE:

- When any printer paper remains, remove it together with the paper core.

- (4) Pass the printer paper as shown below, and turn the release lever down to secure.

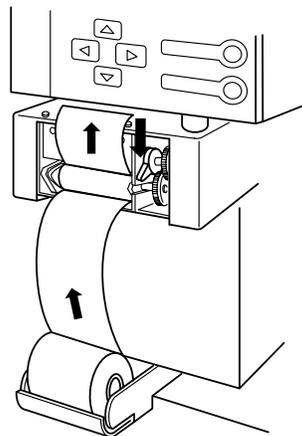


Figure 4-8-6: Securing the Release Lever

- (5) Cut off any printer paper extending from the upper part of the printer.

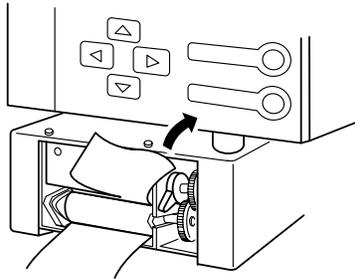


Figure 4-8-7: Cutting Off Paper

- (6) Close the front cover of the main unit.
- (7) Press [1] key and output any print data that is remaining on the memory.

8.4 Supplies List

1. Reagents List

Product Code	Product Name	General Name
834-0161-8	CELLCLEAN (50 mL)	Detergent
884-0871-1	CELLPACK (20 L)	Diluent
974-0521-6	STROMATOLYSER-WH (500 mL × 3)	WBC/HGB Lyse

Table 4-8-3: Reagents List

2. Consumable List

Product Code	Product Name	Chapter & Section for Reference
933-3601-9	Brush No. 1 Assembly	Chapter 4, Section 7.3: Clean WBC/RBC Transducer Aperture.
943-1781-1	Cubitainer Spout Kit No. 1	Chapter 4, Section 8.1: Replace Reagent (Replacement of spout kit is suggested if background count will not drop when diluent has been replaced.)
973-3041-7	Float Switch No. 23	Chapter 4, Section 8.1: Replace Reagent (Replacement of float switch is suggested if WBC/HGB background count will not drop when lyse has been replaced.)
266-5292-6	Fuse 250 V, 2 A No. 19195	Chapter 4, Section 8.2: Replace Fuse (220/240 VAC Spec.)
266-5109-1	Fuse 250 V, 3.15 A ST4-3.15A-N1	Chapter 4, Section 8.2: Replace Fuse (117 VAC Spec.)
921-0351-8	Paper Thermal F1-2 Heat-Sensitive Paper (5 rolls per pack)	Chapter 4, Section 8.3: Replace Printer Paper

Table 4-8-4: Consumable List

9. CONFIRMATION OF CYCLE NUMBER

To let you know when to perform maintenance, this unit has the functions of cycle No. display and automatic reset. As to the waste chamber, transducer, and sample rotor valve (SRV), the next maintenance period is informed in accordance with the operation cycle No. or date, whichever comes first.

Cleaning of waste chamber	Every 2500 cycles or every month
Cleaning of transducer	Every 2500 cycles or every month
Cleaning of sample rotor valve (SRV)	Every 7500 cycles or every 3 months

Table 4-9-1: Maintenance Timing

Current cycle No. of each item can be checked by the following procedure:

9.1 Operation Procedure

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] key or [▼] key, move the cursor to select "7: Maintenance."
- (3) Press [ENTER] key. The Maintenance Menu screen appears.

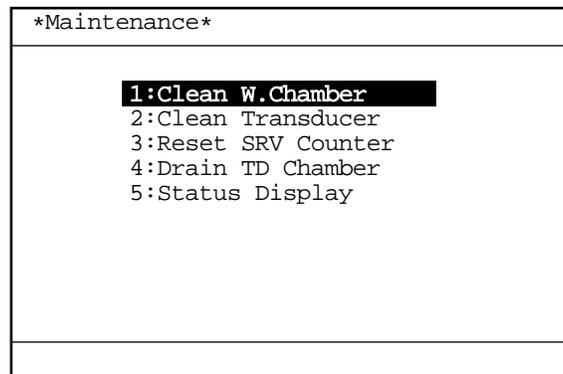


Figure 4-9-1: Maintenance Menu Screen

- (4) Using [▲] key or [▼] key, move the cursor to select "5: Status Display."
- (5) Press [ENTER] key. The Status Display screen 1 appears.

NOTE: • On the Menu screen, each menu can be selected directly by entering a numeral from the numeric keys.

CHAPTER 5

QUALITY CONTROL

1.	INTRODUCTION	5-1
1.1	\bar{x} Control.....	5-1
1.2	Levy-Jennings Control (L-J)	5-1
1.3	QC Chart Screen	5-2
2.	QC ANALYSIS PROCEDURE.....	5-4
2.1	QC Analysis Procedure Flow Chart	5-4
2.2	Execute QC Program	5-5
2.3	Select QC File	5-5
2.4	Erase All.....	5-6
2.5	Set TARGET/LIMIT Values.....	5-7
2.6	Execute \bar{x} Control	5-9
2.7	Execute L-J Control.....	5-18
2.8	Exit from QC Control Program.....	5-24
3.	DELETION	5-25
4.	PRINT.....	5-27
5.	HC OUTPUT (OPTION)	5-29

1. INTRODUCTION

Quality Control checks are performed to monitor an instrument's performance over time. EIGHTCHECK-3WP is the quality control material recommended by Sysmex to monitor the performance of the KX-21 analyzer. This product is supplied with three control levels, at least two levels should be run every 8 hours of operation or in accordance to regulations applicable to your laboratory. Quality control material should be run after component replacement or after a service call. The KX-21 has two quality control methods.

1.1 \bar{X} Control

In \bar{X} control, control blood is analyzed twice and the mean of the two is used to evaluate analyzer performance.

1.2 Levy-Jennings Control (L-J)

The L-J control uses the data from a single control blood analysis to evaluate analyzer performance.

<p>NOTE:</p> <ul style="list-style-type: none">• Selection of the one of the two methods can be performed using QC method in the QC Settings program. Refer to "<i>Chapter 10, Section 5: QC Settings.</i>"
--

1.3 QC Chart Screen

When the QC program is executed, the QC Chart screen appears first. The QC Chart screen displays a QC chart selected from six QC Files. Just after execution of the QC Chart program, File No. 1 Control Chart appears. Its Menu Display Area displays "1: QC Analyze," "2: Settings," and "3: Erase All." The menu can be executed using the numeric keys.

The QC Chart can display QC data up to the latest 60 points. When a new data comes in, the oldest data is erased.

The control parameters indicated in the QC Chart are CBC8 parameters displayed on three pages.

[▲] key or [▼] key can be used to change over the screen.

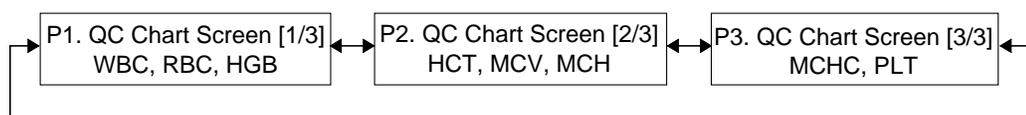


Figure 5-1-1: Page Selection in QC Chart Screen

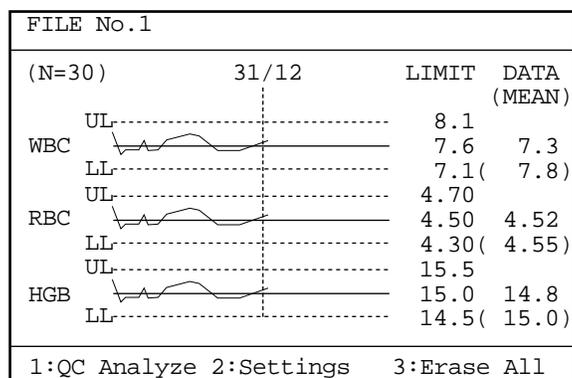


Figure 5-1-2: QC Chart Screen

The QC Chart screen displays QC data as shown below:

- 1) **FILE No.**
FILE No. of QC Chart displayed on the screen
- 2) **Control parameter**
Analysis parameters of control data (CBC8 parameters) are displayed on three pages:
QC Chart screen [1/3]: WBC, RBC, HGB
QC Chart screen [2/3]: HCT, MCV, MCH
QC Chart screen [3/3]: MCHC, PLT
- 3) **N**
The number of control data plotted currently. In the case of \bar{X} control, the average represents a data.

- 4) **LIMIT (UL)**
The upper control limit. An analysis value exceeding this limit is a QC error.
- 5) **LIMIT (LL)**
The lower control limit. An analysis value exceeding this limit is a QC error.
- 6) **Target value**
QC Target value
- 7) **DATA**
The QC data of the plot specified by the vertical line cursor. In the case of \bar{X} control, it is the mean value of two consecutive analyses.
- 8) **MEAN**
The mean of QC data plotted currently
- 9) **Line Cursor**
The vertical line cursor can be moved to the right or left using [◀] key or [▶] key.
The QC data of the plot shown by the line cursor, along with analysis date, are displayed.

2. QC ANALYSIS PROCEDURE

2.1 QC Analysis Procedure Flow Chart

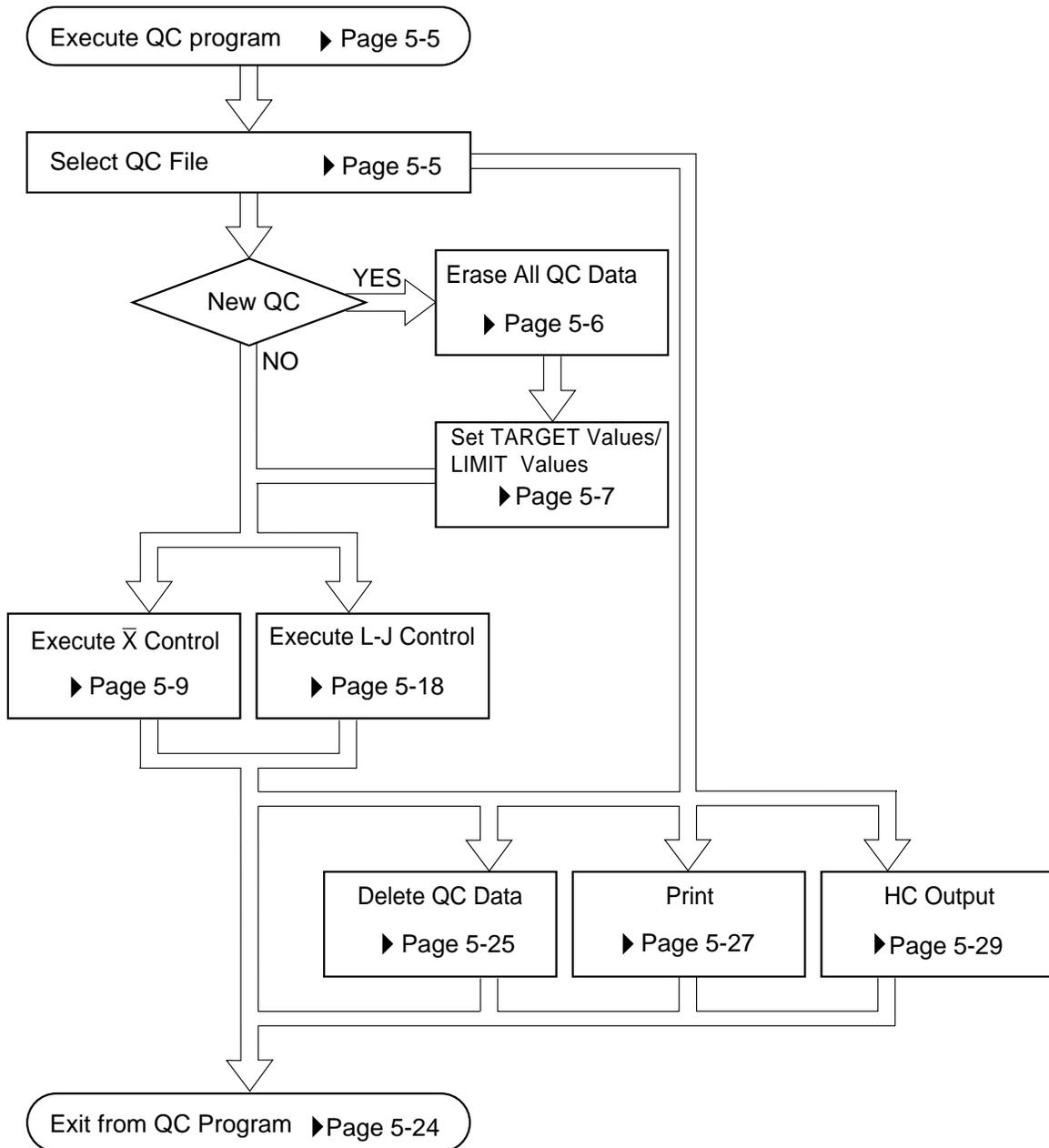


Figure 5-2-1: QC Analysis Procedure Flow Chart

2.2 Execute QC Program

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] key or [▼] key, move the cursor to select "2: Quality Control."
- (3) Press [ENTER] key. The QC Chart screen appears.

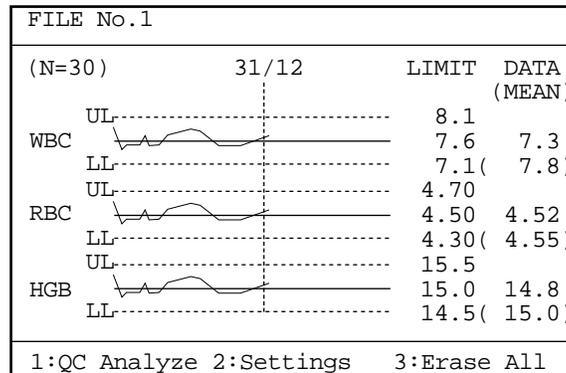


Figure 5-2-2: QC Chart Screen

2.3 Select QC File

This instrument stores six QC Files. To execute QC analysis, settings, file erasing, or HC output, display the QC Chart screen for a desired file as follows.

How to Select QC File

- (1) Press [SAMPLE No.] key on the QC Chart screen.
This causes the FILE No. in the system status area to be reverse-displayed and ready for entry of File No.

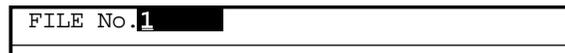


Figure 5-2-3: Entry of File No.

- (2) The cursor comes to right of the FILE No. Use the numeric keys to enter a FILE No.

NOTE:

- In entering a File No. (in the status of the above screen). Press [C] key first to clear it and enter a new FILE No.
- Pressing [C] key erases the character and causes the cursor to move to the left.
- Numerics of 1 - 6 can be entered as a FILE No. Any other numerics cannot be entered.

(3) Press [ENTER] key. The QC Chart screen for the selected QC file appears.

NOTE:

- When no FILE No. is present, [ENTER] key is not accepted. When you attempt to do so, an alarm sounds.
- When you press [SAMPLE No.] key or [SELECT] key in the status of waiting for FILE No. input, the system cancels change of QC File and returns to the previous QC Chart screen.

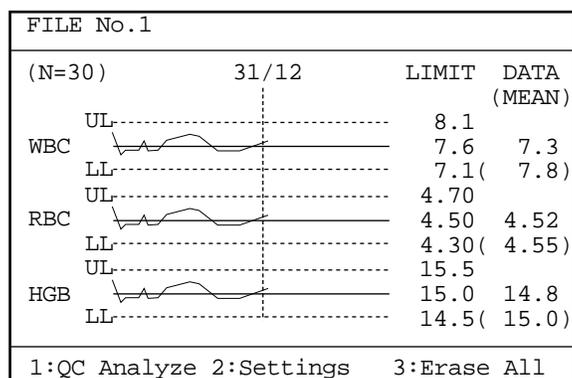


Figure 5-2-4: QC Chart Screen

2.4 Erase All

To start quality control newly, the control data in the QC File has to be erased. When a control blood lot has changed, use the menu of "3: Erase All" to erase all control data in the QC File.

How to Erase All QC Data

- (1) Display the QC Chart screen for the QC File you want to erase.
For how to select the QC File, refer to *Section 2.3: Select QC File* in this chapter.
- (2) Press [3] key to select "3. Erase All." The Erase All Confirmation message appears.

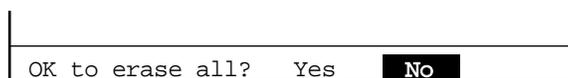


Figure 5-2-5: Erase All Confirmation Message

- (3) Using [◀] key or [▶] key, move the cursor to select "Yes" or "No."
 [Yes]: Erases the plot display on the QC Chart screen and displays the second Erase All Confirmation message.
 [No]: Cancels the erasing of the plot display on the QC Chart screen and returns to the QC Chart screen.

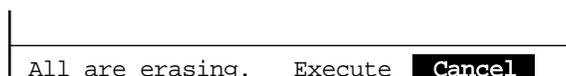


Figure 5-2-6: Second Erase All Confirmation Message

- (4) Using [◀] key or [▶] key, move the cursor to select "Execute" or "Cancel."
 [Execute]: Completely erases QC data and returns to the QC Chart screen.
 [Cancel]: Cancels QC data erase and returns to the QC Chart screen.
- (5) Press [ENTER] key to execute the selected process.

2.5 Set TARGET/LIMIT Values

Before executing Quality Control anew, you have to set TARGET and LIMIT values for the QC File using "2: Settings" on the menu.

How to Set QC File

- (1) Display the QC Chart screen for the QC File you want to set.
 For how to select the QC File, refer to *Section 2.3: Select QC File* in this chapter.
- (2) Press [2] key to select "2: Settings."
 The QC File Setting screen appears.

FILE No. 1			
	TARGET	LIMIT	
WBC	0.0	0.0	×10 ³ /μL
RBC	0.00	0.00	×10 ⁶ /μL
HGB	0.0	0.0	g/dL
HCT	0.0	0.0	%
MCV	0.0	0.0	fL
MCH	0.0	0.0	pg
MCHC	0.0	0.0	g/dL
PLT	0	0	×10 ³ /μL

Press [SELECT] to exit.

Figure 5-2-7: QC File Setting Screen

- (3) Using [▲] key or [▼] key, move the cursor to select control parameters. Eight parameters can be set.

- (4) Using [◀] key or [▶] key, move the cursor to select "TARGET" or "LIMIT."
- (5) Enter the set values using the numeric keys.

NOTE:

- As a set value, up to five digits including decimal point can be entered.
- The decimal point position is linked to the Unit System established in System Setup. For detail, refer to *Chapter 10: INSTRUMENT SETTING, Section 2: System Setup*.
- Each time you press [C] key in the middle of entering, one character disappears and the cursor moves to the left.

- (6) Press [ENTER] key.
The contents of settings are set and the cursor moves to the next item.

NOTE:

- The contents of settings are also set when [▲] key, [▼] key, [◀] key, or [▶] key is pressed after entering.

- (7) When settings are completed, press [SELECT] key. The Setting Confirmation message appears.



Figure 5-2-8: Setting Confirmation Message

- (8) Using [◀] key or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
[Cont.]: Returns to the QC File Setting screen. And the setting operation can be continued.
[Set]: Updates the settings and returns to the QC Chart screen.
[Cancel]: Cancels the changed settings and returns to the QC Chart screen.
- (9) Press [ENTER] key to execute the selected process.

NOTE:

- QC chart will be drawn only if the TARGET and LIMIT values are both entered appropriately.

2.6 Execute \bar{X} Control

The \bar{X} control method for analyzing control blood is described here.

- (1) Display the QC Chart screen for the QC File in which to enter QC data. For how to select the QC File, refer to *Chapter 2.3: Select QC File* in this chapter.

NOTE:

- QC analysis is executed by control method (\bar{X} control or L-J control) set in QC Settings. For setting procedures, refer to *Chapter 10, Section 5: QC Settings*.
- While the \bar{X} Control Analysis screen is displayed, the QC File cannot be changed.

- (2) Press [1] key to select "1: QC Analyze." The \bar{X} Control Analysis screen appears.

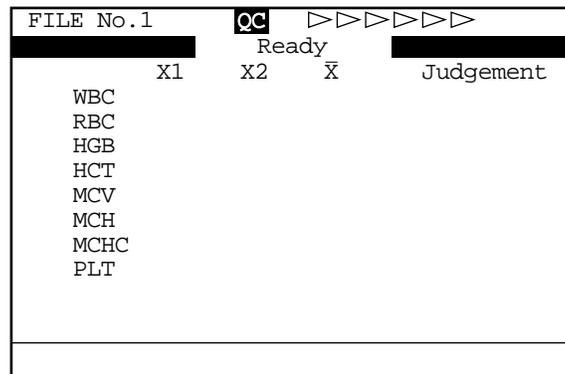


Figure 5-2-9: \bar{X} Control Analysis Screen

NOTE:

- QC analysis is made in the whole blood mode. When the pre-diluted mode is selected as analysis mode, the Mode Change Sequence is activated to change over to the whole blood mode.

- (3) Confirm that "Ready" is displayed for QC analysis.

 **WARNING** • In analyzing control blood, always wear rubber gloves. After completion of work, wash the hands with disinfectant. If your hands are contaminated by blood, etc., infection of pathogenic bacteria can occur.

- (4) Mix control blood sufficiently.

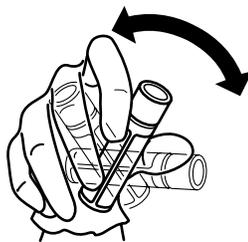


Figure 5-2-10: Mixing the Control Blood

- (5) Remove the cap while taking care not to allow blood to scatter.



Figure 5-2-11: Removing the Cap

- (6) Set the control blood container to the sample probe and press the start switch in that status.

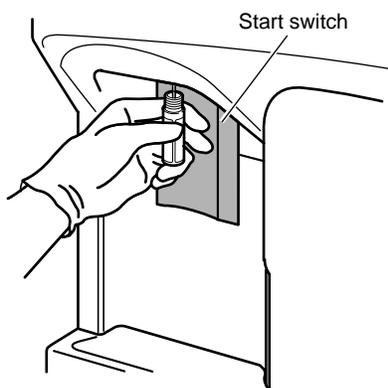


Figure 5-2-12: Pressing the Start Switch

- (7) When the buzzer sounds two times - beep, beep, - and "Analyzing" is displayed on the \bar{X} Control Analysis screen, remove the control blood container. Then, automatic analysis is executed.

The screens from the start to the end of analysis are as shown below.

(Ready)



(Aspirating)



(Analyzing)



(Rinsing)



Figure 5-2-13: \bar{X} Control Analysis Screen

CAUTION • While the screen is displaying "Aspirating," keep holding the control blood container in the aforementioned status. If the container is removed during its display, correct analysis may not be obtained.

CAUTION:

- Several seconds after the buzzer sounds "beep, beep" and "Analyzing" appears on the screen, the rinse cup lowers. Remove the control blood container by that time.
- To remove the container, lower it straight down. Take care not to bend the sample probe.

NOTE:

- The sample probe is automatically rinsed, so there is no need to wipe it clean.

- (8) Under the "X1" column on the Analysis Result screen, the 1st time analysis result is displayed.
 The analysis result comprises three screens which can be changed over by pressing [◀] key or [▶] key.

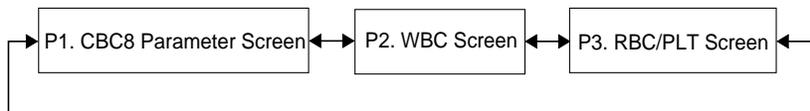


Figure 5-2-14: Page Selection in QC Analysis Result Screen

FILE No.1		QC		
	X1	X2	\bar{X}	Judgement
WBC	7.3			
RBC	4.52			
HGB	14.8			
HCT	36.2			
MCV	80.1			
MCH	32.7			
MCHC	40.9			
PLT	206			
Accept Data?				
1:OK		2:NG		3:Print

Figure 5-2-15: P1. CBC8 Parameter Screen

FILE No.1		QC		
No. QC01-1		31/12 10:02		
WBC		WBC	7.3×10 ³ /μL	
		LYM%	27.2%	
		MXD%	13.4%	
		NEUT%	59.4%	
		LYM#	2.0×10 ³ /μL	
		MXD#	1.0×10 ³ /μL	
		NEUT#	4.3×10 ³ /μL	
Accept Data?		W-SMV	56.3fL	
		W-LMV	172.4fL	
1:OK		2:NG		3:Print

Figure 5-2-16: P2. WBC Screen

FILE No.1		QC		
No. QC01-1		31/12 10:02		
RBC		RBC	4.52×10 ⁶ /μL	
		MCV	80.1fL	
		RDW-SD	27.4fL	
		RDW-CV	11.4%	
PLT		PLT	206×10 ³ /μL	
		PDW	8.3fL	
		MPV	9.1fL	
		P-LCR	14.8%	
Accept Data?				
1:OK		2:NG		3:Print

Figure 5-2-17: P3. RBC/PLT Screen

If the data is acceptable, press [1] key to confirm. Press [2] key to reject.
 Press [3] key and select "3: Print" to print the contents of analysis result on the built-in printer.

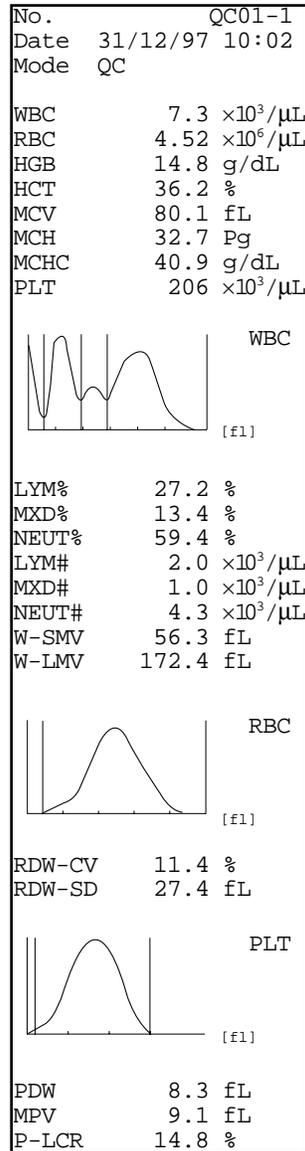


Figure 5-2-18: Example of Analysis Result Printing

NOTE:

- Print of analysis result is valid until the data is set. If the data is set by pressing [1] key or [2] key, analysis result cannot be printed.
- This print format cannot be changed since it is the special format for QC analysis.

- (9) Set the data using [1] key or [2] key.
[1: OK]: Accepts analysis result as the 1st time QC data. And the system turns to be ready for the 2nd analysis.
[2: NG]: Cancels the 1st time analysis result. And the system remains to be ready for another 1st time analysis.

CAUTION:

- When an error occurs during QC analysis, error message is displayed in the system status area. Analysis data in which error occurred is masked, which cannot be accepted as QC data. When you press [1] key to select "1: OK" in response to the data confirmation screen, the alarm sounds and "1: OK" is unacceptable. Press [HELP] key and perform the error recovery process. For the error recovery process, refer to *Chapter 7: TROUBLESHOOTING*.

When you press [SELECT] key before setting the 1st QC data, the QC Cancel Confirmation message is displayed.

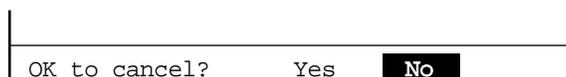


Figure 5-2-19: QC Cancel Confirmation Message

Using [◀] key or [▶] key, move the cursor to select "Yes" or "No."

[Yes]: Rejects analysis result, exits from QC program, and returns to the Analysis screen.

[No]: Returns to the QC Analysis screen and allows continuous QC analysis.

Press [ENTER] key to execute the selected process.

- (10) When the 1st analysis data is accepted, the (3) - (7) procedure is repeated for the 2nd analysis.
- (11) The 2nd analysis result is displayed under "X2" on the Analysis Result screen, the mean values of the 1st and the 2nd analyses under " \bar{X} ," and the comparison result with control limits under the "Judgment" column.
The Analysis Result screen, as in the 1st analysis, can be changed over using [◀] key or [▶] key.
The data confirmation message is displayed and you are asked to decide whether or not to accept the analysis result as QC data.

FILE No. 1		QC		
	X1	X2	\bar{X}	Judgement
WBC	7.3	7.5	7.4	
RBC	4.52	4.49	4.51	
HGB	14.8	14.7	14.8	
HCT	36.2	35.6	35.9	
MCV	80.1	79.3	79.7	
MCH	32.7	32.7	32.7	
MCHC	40.9	41.3	41.1	
PLT	206	209	208	
Accept Data?				
1:OK		2:NG		3:Print

Figure 5-2-20: Analysis Result Screen

A parameters in which the mean of the 1st and the 2nd analyses fell outside the control limits is indicated with **+** or **-** under the "Judgment" column, while the alarm sounds and the QC error message appears.

FILE No. 1		QC			QC Error
	X1	X2	\bar{X}	Judgement	
WBC	7.3	7.5	7.4		
RBC	4.52	4.49	4.51		
HGB	14.8	14.7	14.8		
HCT	42.5	43.0	42.8	+	
MCV	94.0	95.8	94.9	+	
MCH	32.7	32.7	32.7		
MCHC	34.8	34.1	34.5	-	
PLT	106	109	108	-	
Accept Data?					
1:OK		2:NG		3:Print	

Figure 5-2-21: QC Error Message Screen

- (12) Set the data using [1] key or [2] key.
 [1: OK]: QC data is accepted and the plot is entered to the QC Chart. This QC data (mean) is kept in the stored data also.
 [2: NG]: Cancels the 2nd analysis result. And the system remains to be ready for the 2nd analysis again.

CAUTION:

- When an error occurs during QC analysis, the error message appears in the system status area. The analysis data in which the error occurred is masked, which does not undergo mean calculation or judgment, and is not accepted as QC data. When you press [1] key to select "1: OK," in response to the data confirmation screen, the alarm sounds and "1: OK" cannot be accepted. Press [HELP] key and perform the error recovery process. For the error recovery process, refer to *Chapter 7: TROUBLESHOOTING*.

- (13) When the built-in printer is specified for the output device, the set data (mean) is printed on the built-in printer.

No.	QC01
Date	31/12/97 10:02
Mode	QC
WBC	7.4 ×10 ³ /μL
RBC	4.51 ×10 ⁶ /μL
HGB	14.8 g/dL
HCT	35.9 %
MCV	79.7 fL
MCH	32.7 Pg
MCHC	41.1 g/dL
PLT	208 ×10 ³ /μL
LYM%	27.2 %
MXD%	13.4 %
NEUT%	59.4 %
LYM#	2.0 ×10 ³ /μL
MXD#	1.0 ×10 ³ /μL
NEUT#	4.3 ×10 ³ /μL
W-SMV	56.3 fL
W-LMV	172.4 fL
RDW-CV	11.4 %
RDW-SD	27.4 fL
PDW	8.3 fL
MPV	9.1 fL
P-LCR	14.8 %

Figure 5-2-22: Example of Printing

NOTE:

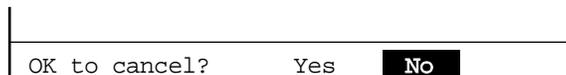
- Printing in QC settings is valid only when the "Built-in Printer" is selected. For detail, refer to *Chapter 10, Section 5: QC Settings*.
- This print format cannot be changed since it is the special format for QC analysis.

- (14) When the serial interface (option) is incorporated, set data (mean) is output to the host computer.

NOTE:

- Transmission to the host is valid only when the "Host Output" is selected. For detail, refer to *Chapter 10, Section 5: QC Settings*.
- As to the host output format, refer to *Appendix B: Technical Information*.

When you press [SELECT] key before setting the 2nd QC data, the QC Cancel Confirmation message appears.



OK to cancel?	Yes	No
---------------	-----	-----------

Figure 5-2-23: QC Cancel Confirmation Message

Using [◀] key or [▶] key, move the cursor to select "Yes" or "No."

[Yes]: Rejects analysis result, exits from the QC program, and returns to the Analysis screen.

[No]: Returns to the QC Analysis screen and allows continuous QC analysis.

Press [ENTER] key to execute the selected process.

2.7 Execute L-J Control

How to analyze control blood by L-J control is described here.

- (1) Display the QC Chart screen for the QC File in which to enter QC data. For how to select the QC File, refer to *Chapter 2.3: Select QC File* in this chapter.

NOTE:	<ul style="list-style-type: none"> • QC analysis is executed by control method (\bar{X} control or L-J control) set in QC Settings. For setting procedures, refer to <i>Chapter 10, Section 5: QC Settings</i>. • While the L-J Control Analysis screen is displayed, the QC File cannot be changed.
--------------	---

- (2) Press [1] key to select "1: QC Analyze." The L-J Control Analysis screen appears.

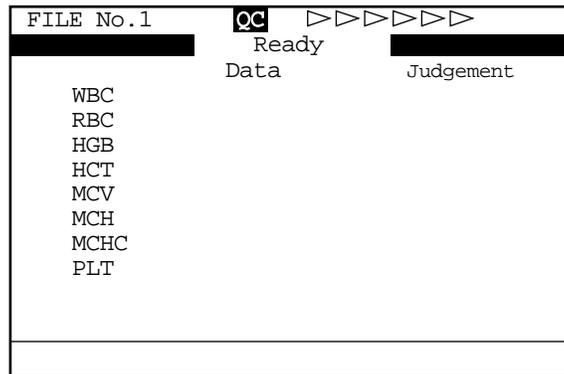


Figure 5-2-24: L-J Control Analysis Screen

NOTE:	<ul style="list-style-type: none"> • QC analysis is made in the whole blood mode. When the pre-diluted mode is selected as analysis mode, the Mode Change Sequence is activated to change over to the whole blood mode.
--------------	--

- (3) Confirm that "Ready" is displayed for QC analysis.

 WARNING	<ul style="list-style-type: none"> • In analyzing control blood, always wear rubber gloves. After completion of work, wash the hands with disinfectant. If your hands are contaminated by blood, etc., infection of pathogenic bacteria can occur.
--	---

- (4) Mix control blood sufficiently.

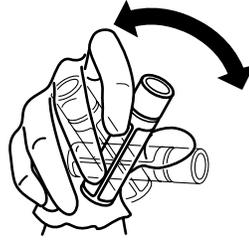


Figure 5-2-25: Mixing the Control Blood

- (5) Remove the cap while taking care not to allow blood to scatter.



Figure 5-2-26: Removing the Cap

- (6) Set the control blood container to the sample probe and press the start switch in that status.

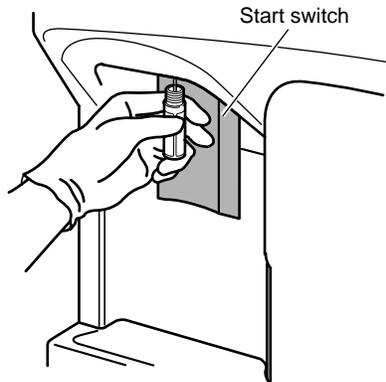


Figure 5-2-27: Pressing the Start Switch

- (7) When the buzzer sounds two times - beep, beep, - and "Analyzing" is displayed on the L-J Control Analysis screen, remove the control blood container. Then, automatic analysis is executed.

The screens from the start to the end of analysis are as shown below.

(Ready)



(Aspirating)



(Analyzing)



(Rinsing)



Figure 5-2-28: L-J Control Analysis Screen



CAUTION

- While the screen is displaying "Aspirating," keep holding the control blood container in the aforementioned status. If the container is removed during its display, correct analysis may not be obtained.

CAUTION:

- Several seconds after the buzzer sounds "beep, beep" and "Analyzing" appears on the screen, the rinse cup lowers. Remove the control blood container by that time.
- To remove the container, lower it straight down. Take care not to bend the sample probe.

NOTE:

- The sample probe is automatically rinsed, so there is no need to wipe it clean.

- (8) Analysis result is given under the "Data" column on the Analysis Result screen and comparison result with QC limits under the "Judgement" column. The analysis result comprises three screens which can be changed over by pressing [◀] key or [▶] key.

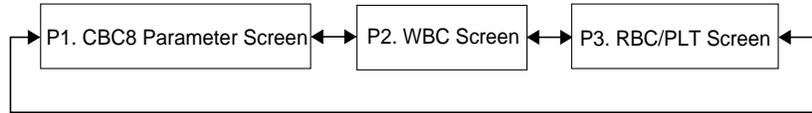


Figure 5-2-29: Page Selection in QC Analysis Result Screen

FILE No.1		QC
	Data	Judgement
WBC	7.3	
RBC	4.52	
HGB	14.8	
HCT	36.2	
MCV	80.1	
MCH	32.7	
MCHC	40.9	
PLT	206	
Accept Data?		
1:OK	2:NG	3:Print

Figure 5-2-30: P1. CBC8 Parameter Screen

FILE No.1		QC
No. QC01-1		31/12 10:02
WBC		WBC 7.3×10 ³ /μL
		LYM% 27.2%
		MXD% 13.4%
		NEUT% 59.4%
		LYM# 2.0×10 ³ /μL
		MXD# 1.0×10 ³ /μL
		NEUT# 4.3×10 ³ /μL
Accept Data?		W-SMV 56.3fL
		W-LMV 172.4fL
1:OK	2:NG	3:Print

Figure 5-2-31: P2. WBC Screen

FILE No.1		QC
No. QC01-1		31/12 10:02
RBC		RBC 4.52×10 ⁶ /μL
		MCV 80.1fL
		RDW-SD 27.4fL
		RDW-CV 11.4%
PLT		PLT 206×10 ³ /μL
		PDW 8.3fL
		MPV 9.1fL
		P-LCR 14.8%
Accept Data?		
1:OK	2:NG	3:Print

Figure 5-2-32: P3. RBC/PLT Screen

As to those parameters whose analysis fell beyond control limits, **+** or **-** is displayed under the "Judgment" column, while the alarm sounds with the QC error message displayed.

FILE No.1		QC	QC Error
	Data	Judgement	
WBC	7.5		
RBC	4.49		
HGB	14.7		
HCT	43.0		+
MCV	95.6		+
MCH	32.7		
MCHC	34.1		-
PLT	109		-
Accept Data?			
1:OK		2:NG	
		3:Print	

Figure 5-2-33: QC Error Message Screen

If the data is acceptable, press [1] key to confirm. Press [2] key to reject. Press [3] key and select "3: Print" to print the contents of analysis result on the built-in printer.

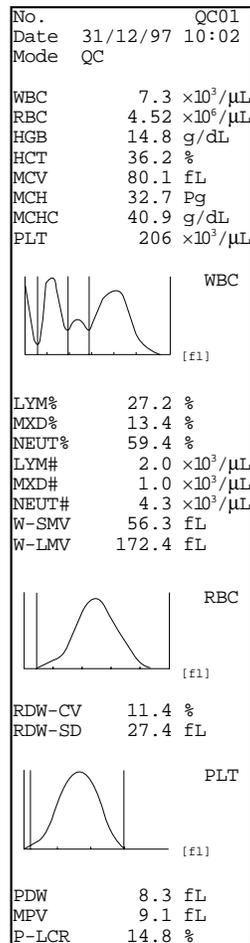


Figure 5-2-34: Example of Analysis Result Printing

CAUTION:

- Print of analysis result is valid until the data is set. If the data is set by pressing [1] key or [2] key, analysis result cannot be printed.
- This print format cannot be changed since it is the special format for QC analysis.

- (9) Set the data using [1] key or [2] key.
- [1: OK]: Sets QC data, and the plot is entered to the QC Chart. This QC data is kept in the stored data.
- [2: NG]: Cancels the analysis result, and the system remains to be ready for another analysis.

CAUTION:

- When an error occurs during QC analysis, error message is displayed in the system status area. Analysis data in which error occurred is masked, which cannot be accepted as QC data. When you press [1] key to select "1: OK" in response to the data confirmation message, the alarm sounds and "1: OK" is unacceptable. Press [HELP] key and perform the error recovery process. For the error recovery process, refer to *Chapter 7: TROUBLESHOOTING*.

- (10) The set data is printed.

No.	QC01
Date	31/12/97 10:02
Mode	QC
WBC	7.3 ×10 ³ /μL
RBC	4.52 ×10 ⁶ /μL
HGB	14.8 g/dL
HCT	36.2 %
MCV	80.1 fL
MCH	32.7 Pg
MCHC	40.9 g/dL
PLT	206 ×10 ³ /μL
LYM%	27.2 %
MXD%	13.4 %
NEUT%	59.4 %
LYM#	2.0 ×10 ³ /μL
MXD#	1.0 ×10 ³ /μL
NEUT#	4.3 ×10 ³ /μL
W-SMV	56.3 fL
W-LMV	172.4 fL
RDW-CV	11.4 %
RDW-SD	27.4 fL
PDW	8.3 fL
MPV	9.1 fL
P-LCR	14.8 %

Figure 5-2-35: Example of Printing

NOTE:

- Printing in QC settings is valid only when the "Built-in Printer" is selected. For detail, refer to *Chapter 10, Section 5: QC Settings*.
- This print format cannot be changed since it is the special format for QC analysis.

(11) When the serial interface (option) is incorporated, set data is output to the host computer.

NOTE:

- Transmission to the host is valid only when the "Host Output" is selected. For detail, refer to *Chapter 10, Section 5: QC Settings*.
- As to the host output format, refer to *Appendix B: Technical Information*.

When you press [SELECT] key before setting the QC data, the QC Cancel Confirmation message appears.

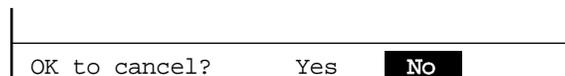


Figure 5-2-36: QC Cancel Confirmation Message

Using [◀] key or [▶] key, move the cursor to select "Yes" or "No."

[Yes]: Rejects analysis result, exist from the QC program, and returns to the Analysis screen.

[No]: Returns to the QC Analysis screen and allows continuous QC analysis.

Press [ENTER] key to execute the selected process.

2.8 Exit from QC Control Program

(1) Press [SELECT] key on the QC Chart screen. The Analysis screen returns.

NOTE:

- The sample No. and analysis mode on the Analysis screen return to those displayed before execution of the QC program.

3. DELETION

Using this menu, QC data in the line cursor position can be deleted.

How to delete QC Data

- (1) Display the QC Chart screen of QC file that contains the data you want to delete.
For how to select QC file, refer to *Chapter 2.3: Select QC File* in this chapter.
- (2) Using [◀] key or [▶] key, move the line cursor to the position of the data to be deleted.

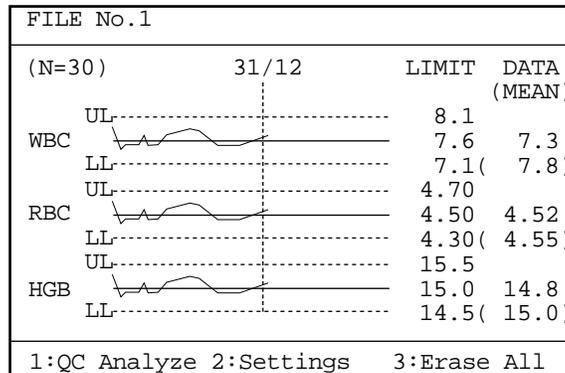


Figure 5-3-1: QC Chart Screen

- (3) Press [ENTER] key.
The line cursor changes from dotted line to solid line, and the menu in the Menu Display Area changes over to "1: Delete," "2: Print," "3: HC Output."

NOTE:

- Press [ENTER] key again, and the line cursor returns to dotted line and the menu in the Menu Display Area change to the original status.
- The line cursor that has changed to solid line cannot be moved.
- "3: HC Output" on the menu is displayed only when the serial interface (option) is incorporated.

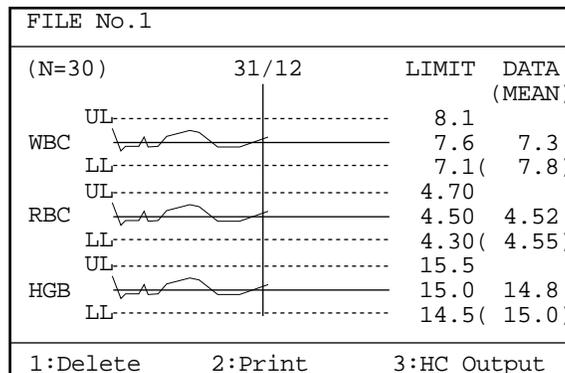


Figure 5-3-2: Deletion Menu Screen

- (4) Press [1] key to select "1: Delete."
The Deletion confirmation message appears.

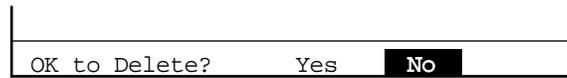


Figure 5-3-3: Deletion Confirmation Message

- (5) Using [◀] key or [▶] key, move the cursor to select "Yes" or "No."
[Yes]: Deletes QC data of the plot shown by the line cursor and returns the line cursor to the dotted line.
[No]: Cancels deletion of QC data and returns the line cursor to the dotted line.
- (6) Press [ENTER] key to execute the selected process.

4. PRINT

Using this menu, QC data in the line cursor position can be printed out from the built-in printer.

How to print QC Data

- (1) Display the QC Chart screen of QC file that contains the data you want to print. For how to select QC file, refer to *Chapter 2.3: Select QC File* in this chapter.
- (2) Using [◀] key or [▶] key, move the line cursor to the position of the data to be printed.

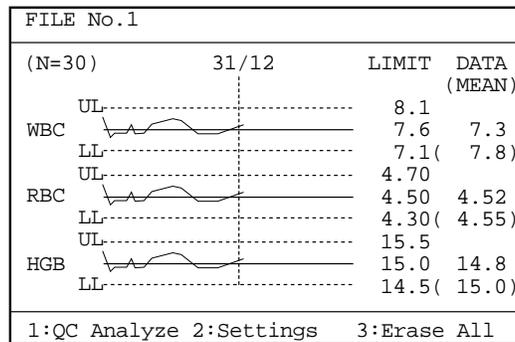


Figure 5-4-1: QC Chart Screen

- (3) Press [ENTER] key. The line cursor changes from dotted line to solid line, and the menu in the Menu Display Area changes over to "1: Delete," "2: Print," "3: HC Output."

NOTE:

- Press [ENTER] key again, and the line cursor returns to dotted line and the menu in the Menu Display Area change to the original status.
- The line cursor that has changed to solid line cannot be moved.
- "3: HC Output" on the menu is displayed only when the serial interface (option) is incorporated.

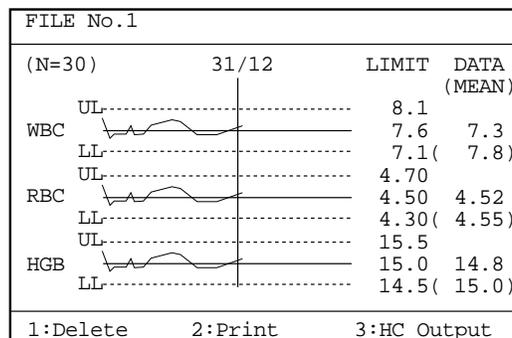


Figure 5-4-2: Print Menu Screen

- (4) Press [2] key to select "2: Print."
The Built-in Printer prints QC data of the plot shown by the line cursor.

Contents of Print

No.	QC01	File No.
Date	31/12/97 10:02	Date/Time Analyzed
Analysis Mode	Mode: QC	
WBC	7.3 ×10 ³ /μL	
RBC	4.52 ×10 ⁶ /μL	
HGB	14.8 g/dL	
HCT	36.2 %	
MCV	80.1 fL	
MCH	32.7 Pg	
MCHC	40.9 g/dL	
PLT	206 ×10 ³ /μL	

Figure 5-4-3: Contents of Print

- 1) **File No.**
File No. of QC file is printed.
- 2) **Analysis Mode**
In the case of QC data, "QC" is printed.
- 3) **Date/Time Analyzed**
Printed is the date and time when analysis result was obtained.

NOTE:	• Printout from the stored QC Chart is only CBC8 parameters.
--------------	--

5. HC OUTPUT (OPTION)

Using this menu, QC data in the line cursor position can be output to the host computer (option).

How to output QC Data to HC

- (1) Display the QC Chart screen of QC file that contains the data you want to output to the host computer.
For how to select QC file, refer to *Chapter 2.3: Select QC File* in this chapter.
- (2) Using [◀] key or [▶] key, move the line cursor to the position of the data you want to output to HC.

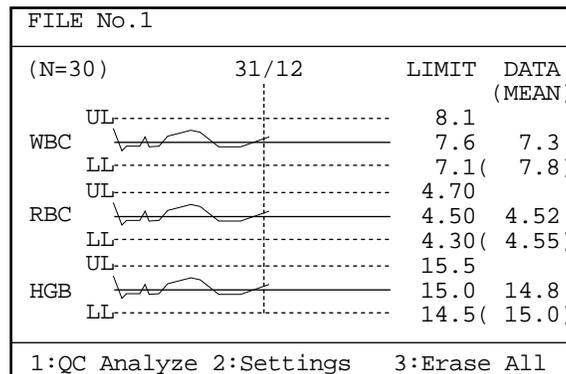


Figure 5-5-1: QC Chart Screen

- (3) Press [ENTER] key.
The line cursor changes from dotted line to solid line, and the menu in the Menu Display Area changes over to "1: Delete," "2: Print," "3: HC Output."

NOTE:

- Press [ENTER] key again, and the line cursor returns to dotted line and the menu in the Menu Display Area change to the original status.
- The line cursor that has changed to solid line cannot be moved.
- "3: HC Output" on the menu is displayed only when the serial interface (option) is incorporated.

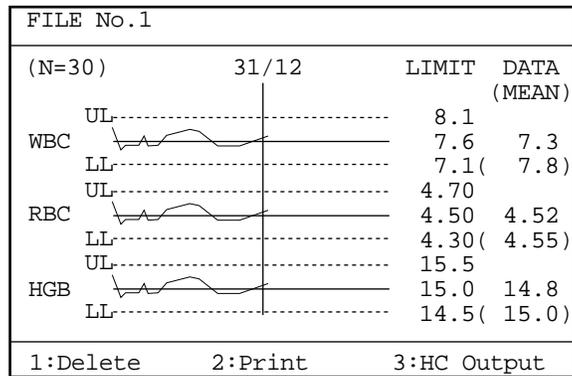


Figure 5-5-2: HC Output Menu Screen

- (4) Press [3] key to select "3: HC Output."
 QC data of the plot shown by the line cursor is output to the host computer.

NOTE:

- Data that can be output from the QC Chart are only data of CBC8 parameters. All other data are output with "* 0000."
 For the output format, refer to *Appendix B: Technical Information*.

1.	INTRODUCTION	6-1
1.1	Calibration Execution Timing.....	6-1
1.2	Samples Used for Calibration	6-1
1.3	Reference Values.....	6-1
1.4	Calibration Flow Chart.....	6-2
2.	AUTOMATIC CALIBRATION.....	6-3
2.1	Executing Automatic Calibration Program.....	6-3
2.2	Automatic Calibration Procedure.....	6-4
3.	MANUAL CALIBRATION	6-9
3.1	Calculating Calibration Value.....	6-9
3.2	Manual Calibration Procedure	6-10

1. INTRODUCTION

Calibration is performed to compensate for any inaccuracies of the pneumatic, hydraulic, and electric systems which will affect analysis results. This is very important in maintaining the system accuracy.

Calibration is carried out by entering calibration values into the unit. Your Sysmex service representative will perform initial calibration of your unit at installation. After installation, the operator should make periodical calibration and proper quality control to maintain the accuracy. This chapter describes calibration procedure.

1.1 Calibration Execution Timing

Calibration need not be performed in specified intervals, but when QC data varies with time, HGB and HCT should be calibrated. When abnormal QC data occur as a result of instrument problem, reagent degradation, or deterioration of control blood, however, do not perform calibration.

1.2 Samples Used for Calibration

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

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

NOTE: • For calibration, do not use EIGHTCHECK-3WP, which was not prepared for calibration but for the use as control blood.

1.3 Reference Values

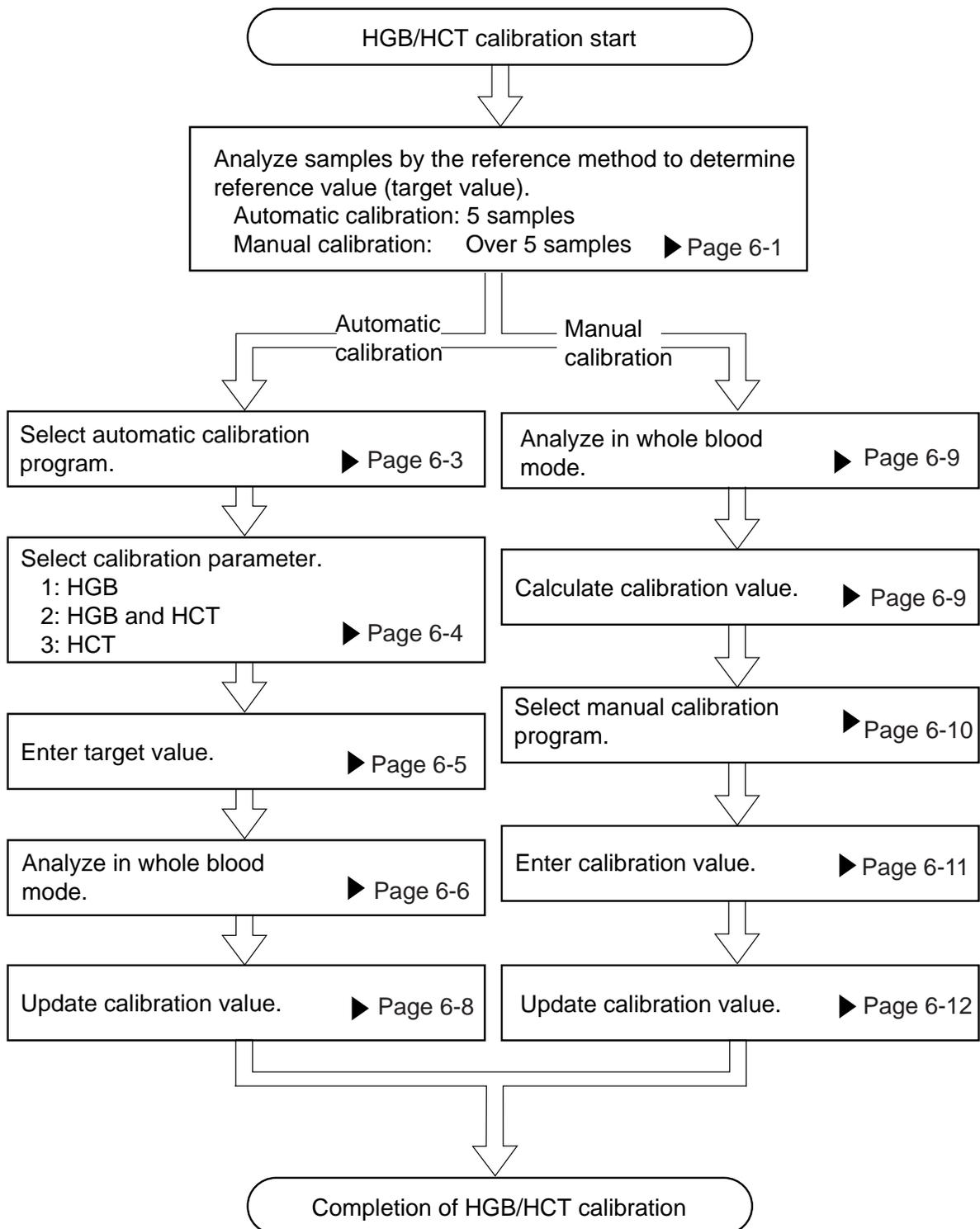
Five or more normal blood samples prepared for calibration of HGB and HCT should be accurately analyzed three times each in accordance with the reference method. The measurements thus obtained are used as reference values.

HGB values: Cyanmethemoglobin method

HCT values: Microhematocrit method

(Five samples are used for automatic calibration.)

1.4 Calibration Flow Chart



2. AUTOMATIC CALIBRATION

In automatic calibration, five or more fresh, normal blood samples are used for automatic calibration of HGB and HCT values.

2.1 Executing Automatic Calibration Program

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "3: Calibration."
- (3) Press [ENTER] key. The Calibration Menu screen appears.

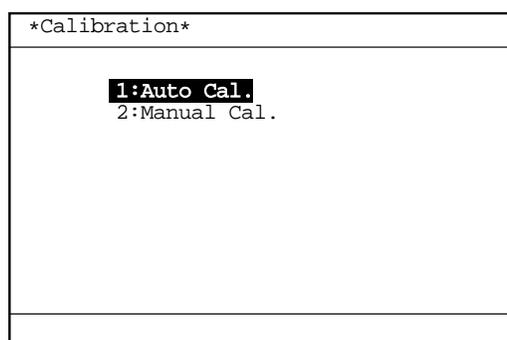


Figure 6-2-1: Calibration Menu Screen

- (4) Using [▲] or [▼] key, move the cursor to select "1: Auto Cal."
- (5) Press [ENTER] key. The Automatic Calibration Menu screen appears.

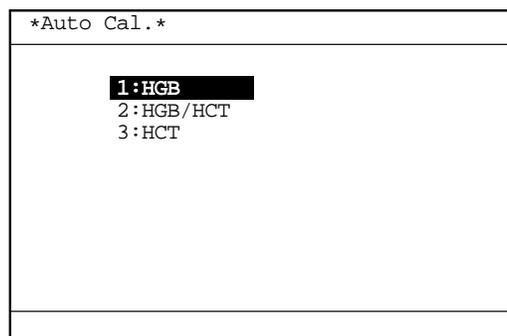


Figure 6-2-2: Automatic Calibration Menu Screen

On the Automatic Calibration Menu screen, an automatic calibration parameter can be selected from among "1: HGB," "2: HGB/HCT," and "3: HCT."

NOTE: • Each menu can be selected directly by entering a numeral from the numeric keys.

2.2 Automatic Calibration Procedure

1. Selecting Automatic Calibration Parameter

- (1) Using [▲] or [▼] key, move the cursor to select an automatic calibration parameter on the Automatic Calibration Menu Screen:
 [1: HGB]: Calibrates HGB alone.
 [2: HGB/HCT]: Calibrates two parameters of HGB and HCT at the same time.
 [3: HCT]: Calibrates HCT alone.

NOTE: • Each menu can be selected directly by entering a numeral from the numeric keys.

- (2) Press [ENTER] key.
 The Automatic Calibration screen for the selected parameter appears.

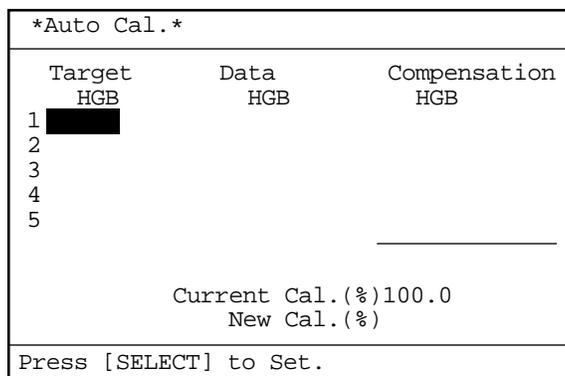


Figure 6-2-3: HGB Automatic Calibration Screen

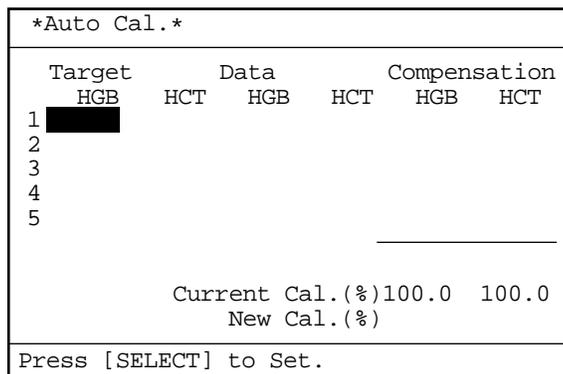


Figure 6-2-4: HGB/HCT Automatic Calibration Screen

Auto Cal.		
Target	Data	Compensation
HCT	HCT	HCT
1	█	
2		
3		
4		
5		
Current Cal.(%)100.0		
New Cal.(%)		
Press [SELECT] to Set.		

Figure 6-2-5: HCT Automatic Calibration Screen

2. Entering Target Values

- (1) Using the numeric keys, enter the HGB or HCT reference values obtained by the reference method in the target column.

NOTE: • Press [C] key to delete one letter at a time.

- (2) Press [ENTER] key to fix the entered value and move the reverse display to the next target column.

Auto Cal.					
Target	Data		Compensation		
HGB	HCT	HGB	HCT	HGB	HCT
1	12.5	█			
2					
3					
4					
5					
Current Cal.(%)100.0 100.0					
New Cal.(%)					
Press [SELECT] to Set.					

Figure 6-2-6: Entering Target Values

NOTE:

- After entering the 5th target value, pressing [ENTER] key does not move the reverse display to the next target column.
- An entered value can be set also by pressing [▲] or [▼] key after entering the target value.

- (3) When all target values have been entered, press [SELECT] key. The Target Value Setting Confirmation message appears.



Figure 6-2-7: Target Value Setting Confirmation Message

- (4) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
 [Cont.]: Returns to the status for entering target values. And the setting operation can be continued.
 [Set]: Sets target values and charges to the Sample Analysis Waiting status.
 [Cancel]: Cancels automatic calibration and returns to the Analysis screen.
- (5) Press [ENTER] key to execute the selected process.

3. Analysis for Automatic Calibration

- (1) When the target values are set, the system turns to the Ready status for automatic calibration analysis.

NOTE: • Automatic calibration analysis is performed in the whole blood mode. When the analysis mode is set in the pre-diluted mode, the mode changeover sequence is activated to switch to the whole blood mode.

Auto Cal.		WB		▷▷▷▷▷▷▷▷	
		Ready			
	Target	Data		Compensation	
	HGB HCT	HGB	HCT	HGB	HCT
1	12.5 50.0				
2	13.0 45.2				
3	13.5 51.5				
4	11.0 40.8				
5	15.0 52.5				
		Current Cal.(%)		100.0	100.0
		New Cal.(%)			

Figure 6-2-8: Automatic Calibration Screen (Before Analysis)

- (2) Analyze the samples used for determining the standard value. The sample being analyzed is indicated by the underline cursor.

- (3) After completion of analysis, analysis result appears in the data column and compensation rate in the compensation column, then the underline cursor moves to the next sample. Upon completion of more than one sample, average compensation rate is automatically calculated and displayed at the bottom of the compensation column.

Auto Cal.			WB >>>>>>>			
			Ready			
	Target		Data		Compensation	
	HGB	HCT	HGB	HCT	HGB	HCT
1	12.5	50.0	13.0	48.0	96.2	104.2
2	13.0	45.2	13.7	43.9	94.9	103.0
3	13.5	51.5	14.1	50.0	95.7	103.0
4	11.0	40.8				
5	15.0	52.5				
					95.6	103.4
					Current Cal.(%)	100.0 100.0
					New Cal.(%)	

Figure 6-2-9: Automatic Calibration Screen (After Analysis)

CAUTION:

- When an error occurs during automatic calibration analysis, the error message appears in the system status display area. The result of analysis in which an error has occurred is masked with "---.-," which is not calculated for compensation rate and not used for average compensation rate calculation, either.
- If "0" is input to the target value, compensation rate for the sample is not calculated and the analysis result is not used for average compensation rate calculation, either.

4. Updating Calibration Value

- (1) When all analyses are finished, press [SELECT] key.
New compensation values will be calculated and the Calibration Value Change Confirmation message will appear.

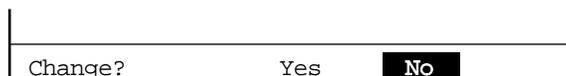


Figure 6-2-10: Calibration Value Change Confirmation Message

NOTE:

- The new compensation value is calculated as follows:

$$\text{New compensation value (\%)} = \frac{\text{Current compensation value (\%)} \times \text{Average compensation rate (\%)}}{100}$$

- When the compensation rate exceeds the following range, "Calibration Error" is displayed and the Calibration Value Change Confirmation message does not appear.
 - Average compensation rate > 105%
 - Average compensation rate < 95%
 - New compensation value > 120%
 - New compensation value < 80%



Figure 6-2-11: Calibration Error Message

About calibration errors, refer to *Chapter 7: TROUBLESHOOTING*.

- (2) Using [◀] or [▶], move the cursor to select "YES" or "NO."
 [YES]: Updates the calibration value and returns to the Analysis screen.
 [NO]: Does not update the calibration value and returns to the Analysis screen.
- (3) Press [ENTER] key to execute the selected process.

3. MANUAL CALIBRATION

In manual calibration, calculated calibration value can be entered using the numeric keys.

3.1 Calculating Calibration Value

- (1) Analyze more than five samples, each three times, by the reference method and average HGB and HCT values.
- (2) Gently mix the same samples sufficiently and analyze them in the whole blood mode.
- (3) When there is a difference between data gained by analysis with this instrument and the reference value gained by the reference method, use the following formula to calculate the new calibration value:

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

[Example]

Average of HGB values gained by the reference method = 15.6 g/dL

Average of HGB values gained by this instrument = 15.5 g/dL

Previous calibration value of HGB = 100.0%

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

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

3.2 Manual Calibration Procedure

- (1) Press [SELECT] key in the Ready status. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "3: Calibration."
- (3) Press [ENTER] key. The Calibration Menu screen appears.

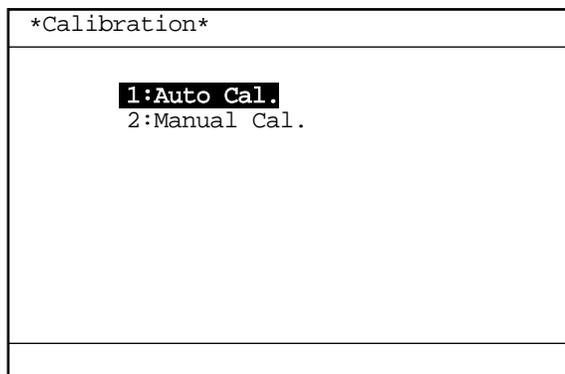


Figure 6-3-1: Calibration Menu Screen

- (4) Using [▲] or [▼] key, move the cursor to select "2: Manual Cal."
- (5) Press [ENTER] key. The Manual Calibration screen appears.

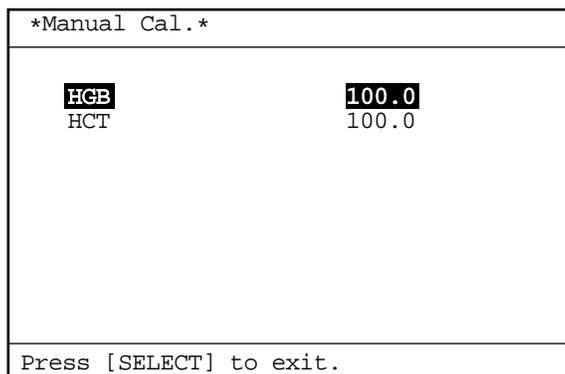


Figure 6-3-2: Manual Calibration Screen

NOTE: • Each menu can be selected directly by entering a numeral from the numeric keys.

1. Entering Calibration Value

- (1) Using [▲] or [▼] key, move the cursor to select "HGB" or "HCT."
- (2) Using the numeric keys, enter the calibration value obtained by calculation.

NOTE: • Press [C] key to delete one letter at a time.

- (3) Press [ENTER] key to set the entered value and move the reverse display to the next parameter.

Manual Cal.	
HGB	100.7
HCT	100.0
Press [SELECT] to exit.	

Figure 6-3-3: Entering Calibration Value

NOTE:

- An entered value can be set also by pressing [▲] or [▼] key after entering the calibration value.
- If no input is made or a space is input, it cannot be set.

2. Updating Calibration Value

- (1) When all calibration values are entered, press [SELECT] key. The Calibration Value Change Confirmation message appears.

Change?	Yes	No
---------	-----	-----------

Figure 6-3-4: Calibration Value Change Confirmation Message

NOTE:

- When there is no calibration value changed, the Calibration Value Change Confirmation message is not displayed and the system returns to the Analysis screen.
- When the compensation rate exceeds the following range, "Calibration Error" is displayed and the Calibration Value Change Confirmation message does not appear.

$$\text{Compensation rate} = \frac{\text{Average of values gained by reference method}}{\text{Average of values gained by this instrument}} \times 100$$

Compensation rate > 105%

Compensation rate < 95%

New compensation value > 120%

New compensation value < 80%

Manual Cal.	Calibration Error
---------------	--------------------------

Figure 6-3-5: Calibration Error Message

About calibration errors, refer to *Chapter 7: TROUBLESHOOTING*.

- (2) Using [◀] or [▶], move the cursor to select "YES" or "NO."
 [YES]: Updates the calibration value and returns to the Analysis screen.
 [NO]: Does not update the calibration value and returns to the Analysis screen.
- (3) Press [ENTER] key to execute the selected process.

CHAPTER 7

TROUBLESHOOTING

1.	INTRODUCTION.....	7-1
2.	WHEN YOU SUSPECT A TROUBLE	7-2
2.1	Alphabetical List of Error Messages Displayed on Analysis Screen	7-3
2.2	Alphabetical List of Error Messages Displayed on HELP Screen	7-4
2.3	Functional List of Error Messages	7-5
3.	TROUBLESHOOTING GUIDE	7-7
3.1	Pressure/Vacuum Errors.....	7-7
3.2	Chamber Errors.....	7-10
3.3	Motor Errors	7-13
3.4	Transducer Errors	7-15
3.5	Temperature Errors.....	7-16
3.6	Analysis Errors	7-17
3.7	Memory Errors	7-23
3.8	Others.....	7-25
3.9	Maintenance Errors.....	7-27
3.10	Built-in Printer Errors.....	7-30
3.11	External Device Errors (When this option is incorporated).....	7-33
4.	STATUS DISPLAY	7-34

1. INTRODUCTION

If the running instrument develops any symptom that you suspect to be a trouble, check it making reference to "2. *WHEN YOU SUSPECT A TROUBLE*" which begins from the next page. When there is not any item that confirms to the trouble in question or if "Action" fails to eliminate the symptom, contact your Sysmex service representative for assistance.

When a trouble occurs, the instrument displays an error message on the LCD screen. When there occurs an error unique to a sample analyzed, analysis data is displayed with a flag.

This chapter describes the cause of a trouble on which an error message is displayed, along with actions that the customer can take in checking and repairing.

HELP Function

When a trouble has occurred, the warning alarm sounds and an error message is displayed on the screen. By pressing [HELP] key on the panel keyboard, you can stop the alarm and change over to the HELP screen that shows what action to take against the error.

Supplementary explanation for that function is given here.

In the event multiple errors occur at the same time, press [HELP] key. The errors that have occurred are listed in the order from higher priority.

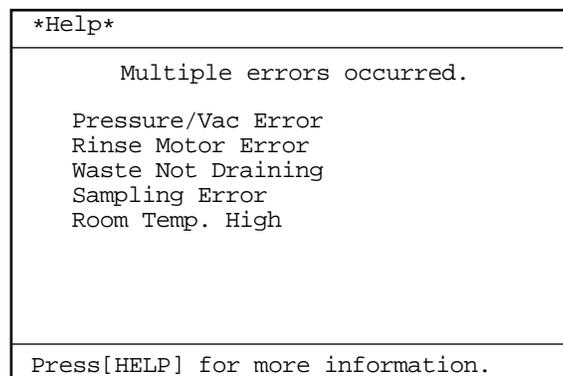


Figure 7-1-1: Help Screen (Error List)

Press [HELP] key again. The screen changes to the HELP screen for the error listed at top.

NOTE:

- When you contact your Sysmex service representative, inform him of "ERR CODE" given on the HELP screen. By doing so, you can inform him of the instrument's status easier and more correctly.

**WARNING**

- When you repair in accordance with TROUBLESHOOTING, be sure to turn the power OFF except when you have to confirm displays and instructions on the screen. If you repair with the power turned ON, you have a risk of electric shock hazard and you may give a permanent damage to electric parts.

2. WHEN YOU SUSPECT A TROUBLE

<p>1. Turning the power ON does not start the unit.</p>	<ul style="list-style-type: none"> • Is the power cord connected securely? • Isn't the fuse blown? Refer to <i>Chapter 4, Section 8.2: Replace Fuse.</i> • Is the power supplied to AC outlet?
<p>2. When the power is ON, nothing is displayed and "beep" keeps sounding.</p>	<ul style="list-style-type: none"> • There is a possibility that memory error has occurred. Turn OFF the power, and turn it ON again 1 - 2 minutes later.
<p>3. The screen displays nothing.</p>	<ul style="list-style-type: none"> • Isn't LCD brightness properly adjusted? Refer to <i>Chapter 1, Section 8.3: LCD Brightness Adjustment.</i>
<p>4. The screen displays "PU Sleeping" message and no key entry is accepted.</p>	<ul style="list-style-type: none"> • Timer mode turned OFF the pneumatic unit power. To return the instrument to the ready status, press the [SELECT] key to return to the analysis result screen, and then the [Start] switch.
<p>5. Fluid leaks from the unit.</p>	<ul style="list-style-type: none"> • Turn OFF the power and wipe off leaking fluid. If fluid leakage persists after turning ON the power, contact your Sysmex service representative.
<div style="border: 1px solid black; padding: 10px;">  <p>WARNING • When operating, always wear rubber gloves. After completion of work, wash hands with disinfectant. If your hands are contaminated by blood, etc., infection of bacteria can result.</p> </div>	
<p>6. Data has error.</p>	<ul style="list-style-type: none"> • Check QC data of control blood. • Referring to <i>Chapter 4: INSTRUMENT MAINTENANCE AND SUPPLIES REPLACEMENT</i>, conduct the maintenance below: Chapter 4, Section 5.2: Clean Transducer Chapter 4, Section 6.1: Clean SRV
<p>7. An error occurs.</p>	<p>Search the following message lists for an error in question and refer to the corresponding pages in TROUBLESHOOTING:</p> <ol style="list-style-type: none"> 1) Message List To search the pages, the error messages are listed in "Alphabetical" and "Functional" orders. 2) TROUBLESHOOTING Cause and action for each trouble are described for respective error message.

2.1 Alphabetical List of Error Messages Displayed on Analysis Screen

[A]	
Analysis Error -----	7-21
[B]	
Background Error -----	7-17
[C]	
Calibration Error-----	7-26
Clean SRV. -----	7-27
Clean Transducer-----	7-29
Clean Waste Chamber. -----	7-28
[H]	
HGB Error -----	7-20
Host Comm. Error (when serial interface is incorporated)-----	7-33
[M]	
Memory Error-----	7-23
[N]	
No Printer Paper-----	7-31
[P]	
Pressure/Vac Error -----	7-7, 7-8, 7-9
Print Error-----	7-30
Printer Error-----	7-32
[Q]	
QC Error-----	7-25
[R]	
RBC Aperture Clog -----	7-15
Replenish Diluent-----	7-11
Replenish Lyse -----	7-12
Rinse Motor Error-----	7-13, 7-14
Room Temp. High -----	7-16
Room Temp. Low-----	7-16
[S]	
Sampling Error -----	7-18, 7-19
Set Value Error -----	7-23
[W]	
Waste Not Draining -----	7-10
WBC Aperture Clog -----	7-15

2.2 Alphabetical List of Error Messages Displayed on HELP Screen

0.5 kg/cm ² Pressure Error-----	7-7
0.5 kg/cm ² Pressure Error at Count-----	7-9
250 mmHg Vacuum Error-----	7-8
[A]	
Abnormal detection sensitivity-----	7-22
[B]	
Background count exceeds tolerance.-----	7-17
[C]	
Calibration value is out of range. -----	7-26
Clean the SRV. -----	7-27
Clean the Transducer. -----	7-29
Clean the Waste Chamber. -----	7-28
Clog in the aperture (RBC)-----	7-15
Clog in the aperture (WBC)-----	7-15
[E]	
Error has occurred during counting (PLT). -----	7-18
Error has occurred during counting (RBC). -----	7-18
Error has occurred during counting (WBC).-----	7-18
Error occurred during HGB analysis. -----	7-20
Error on Built-in Printer (Print Error)-----	7-30
Error on Built-in Printer (Printer Error) -----	7-32
Error on Rinse Cup -----	7-13
[H]	
Host Output Error (When serial interface is incorporated) -----	7-33
[M]	
Memory error occurred. (Repairing) -----	7-23
Memory error occurred. (Turn OFF then ON the power.) -----	7-23
Momentary power failure occurred.-----	7-24
[N]	
No Printer Paper-----	7-31
[Q]	
QC data falls out of control limits. -----	7-25
[R]	
Replenish Diluent Container. -----	7-11
Replenish Lyse Container. -----	7-12
Room Temp. Error -----	7-16
[S]	
Sampling Error has occurred. -----	7-19
[W]	
Waste Not Drained-----	7-10
WBC/HGB Analysis Error-----	7-21

2.3 Functional List of Error Messages

NOTE: • [] indicates error naming that is displayed on the Analysis screen.

1. **Pressure/Vacuum Errors**
 - 0.5 kg/cm² Pressure Error [Pressure/Vac Error] -----7-7
 - 250 mmHg Vacuum Error [Pressure/Vac Error] -----7-8
 - 0.5 kg/cm² Pressure Error at Count [Pressure/Vac Error] -----7-9
2. **Chamber Errors**
 - Waste Not Drained [Waste Not Draining]----- 7-10
 - Replenish Diluent Container. [Replenish Diluent]----- 7-11
 - Replenish Lyse Container. [Replenish Lyse] ----- 7-12
3. **Motor Errors**
 - Error on Rinse Cup [Rinse Motor Error]----- 7-13
4. **Aperture Errors**
 - Clog in the aperture (WBC) [WBC Aperture Clog]----- 7-15
 - Clog in the aperture (RBC) [RBC Aperture Clog] ----- 7-15
5. **Temperature Errors**
 - Room Temp. Error [Room Temp. High]----- 7-16
 - Room Temp. Error [Room Temp. Low]----- 7-16
6. **Analysis Errors**
 - Background count exceeds tolerance. [Background Error] ----- 7-17
 - Error has occurred during counting. (PLT) [Sampling Error] ----- 7-18
 - Error has occurred during counting. (RBC) [Sampling Error] ----- 7-18
 - Error has occurred during counting. (WBC) [Sampling Error]----- 7-18
 - Sampling Error has occurred. [Sampling Error]----- 7-19
 - Error occurred during HGB analysis. [HGB Error] ----- 7-20
 - WBC/HGB Analysis Error [Analysis Error]----- 7-21
 - Abnormal detection sensitivity [Analysis Error]----- 7-22
7. **Memory Errors**
 - Memory error occurred. (Turn OFF then ON the power.) [Memory Error]----- 7-23
 - Memory error occurred. (Repairing) "Set Value Error"----- 7-23
 - Memory error occurred. (Turn OFF then ON the power.) [Set Value Error] ----- 7-24
 - Momentary power failure occurred. [-]----- 7-24
8. **Others**
 - QC data falls out of control limits. [QC Error]----- 7-25
 - Calibration value is out of range. [Calibration Error] ----- 7-26

9. Maintenance Errors	
Clean the SRV. [Clean SRV.]-----	7-27
Clean the Waste Chamber. [Clean Waste Chamber.]-----	7-28
Clean the Transducer. [Clean Transducer.]-----	7-29
10. Built-in Printer Errors	
Error on Built-in Printer [Print Error]-----	7-30
No Printer Paper [No Printer Paper]-----	7-31
Error on Built-in Printer [Printer Error]-----	7-32
11. External Option Errors (When serial interface is incorporated)	
Host Output Error [Host Comm. Error]-----	7-33

3. TROUBLESHOOTING GUIDE

3.1 Pressure/Vacuum Errors

Error Message	Meaning of Message
<p>"Pressure/Vac Error"</p> <pre>*Help* 0.5kg/cm2 Pressure Error 0.35 [0.40 - 0.60] Adjust 0.5kg/cm2 Pressure. [1] Restarting to monitor the pressure ERR CODE:XXXXX.X.X 1:End of Adj</pre>	<p>0.5 kg/cm² is out of the monitor range in Ready status. Monitor range: 0.40 - 0.60 kg/cm²</p>
Cause	<ol style="list-style-type: none"> 1) 0.5 kg/cm² pressure adjustment error 2) Pneumatic unit pressure error 3) Air leakage from pressure line
Action	<ol style="list-style-type: none"> 1) Adjust Pressure to 0.5 kg/cm². The HELP screen displays pressure value in real time. Adjust pressure referring to <i>Chapter 8, Section 2.3: Adjusting Pressure to 0.5 kg/cm²</i>. 2) Check Pressure Line Check the pressure line for loosened nipple or tube, or breakage. If any abnormality is noted, reconnect or replace. After adjustment or check, press [1] key to return to the original screen.
Analysis after error occurrence	Not Ready until the error is resolved.

Error Message		Meaning of Message
<p>"Pressure/Vac Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>250 mmHg Vacuum Error</p> <p>215 [230 - 270]</p> <p>Adjust 250mmHg Vacuum.</p> <p>[1] Restarting to monitor the vacuum</p> <p>ERR CODE:XXXXX.X.X</p> <p>1:End of Adj</p> </div>		<p>250 mmHg vacuum is out of the monitor range in Ready status.</p> <p>Monitor range: 230 - 270 mmHg</p>
Cause	<ol style="list-style-type: none"> 1) 250 mmHg vacuum adjustment error 2) Fluid back-flows into the trap chamber. 3) Pneumatic unit vacuum error 4) Air leakage from vacuum line 	
Action	<ol style="list-style-type: none"> 1) Adjust Vacuum to 250 mmHg The HELP screen displays vacuum value in real time. Adjust vacuum referring to <i>Chapter 8, Section 2.4: Adjusting Vacuum to 250 mmHg.</i> 2) Discard fluid in Trap Chamber Discard fluid if collected. Refer to <i>Chapter 4, Section 3.2: Check Trap Chamber Level and Discard.</i> 3) Check Vacuum Line Check the vacuum line for loosened nipple or tube, or breakage. If any abnormality is noted, reconnect or replace. After adjustment or check, press [1] key to return to the original screen. 	
Analysis after error occurrence	<p>Not Ready until the error is resolved.</p>	

Error Message		Meaning of Message
<p>"Pressure/Vac Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>*Help*</p> <p>0.5kg/cm2 Pressure Error at count</p> <p>Turn OFF then ON the power.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p style="text-align: right;">3:Ana.Screen</p> </div>		<p>0.5 kg/cm² pressure is out of the monitor range during analysis.</p> <p>Monitor range: 0.30 - 0.70</p>
Cause	<ol style="list-style-type: none"> 1) 0.5 kg/cm² pressure adjustment error 2) Pneumatic unit pressure error 3) Air leakage from pressure line 	
Action	<ol style="list-style-type: none"> 1) Adjust Pressure to 0.5 kg/cm² Turn the power OFF, and turned it ON again. Then adjust pressure referring to <i>Chapter 8, Section 2.3: Adjust 0.5 kg/cm² Pressure.</i> 2) Check Pressure Line Check the pressure line for loosened nipple or tubing, or breakage. If any abnormality is noted, reconnect or replace. After adjustment or check, press [1] key to return to the original screen. 	
Analysis after error occurrence	The power needs to be turned OFF then ON again.	
<p>NOTE: • Press [3] key to return to the Analysis screen. The status is not ready for analysis, but the processing, etc. of stored data in Select Menu can be performed.</p>		

3.2 Chamber Errors

Error Message		Meaning of Message
<p>"Waste Not Draining"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Waste Not Drained</p> <p>Check kinked or blocked tubings.</p> <p>[1] Retrying to drain the waste</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p>1:Draining 3:Cancel</p> </div>		<p>Waste in the waste chamber can not be drained within the prescribed draining time.</p>
Cause	<ol style="list-style-type: none"> 1) Breakage or clogging of waste chamber or waste line tube 2) Pneumatic unit pressure error 3) Air leakage from pressure line 4) Float switch malfunction 5) Faulty operation of solenoid or master valve 	
Action	<ol style="list-style-type: none"> 1) Check Waste Line Tube Check the waste drain line for breakage, clogging, etc. If any abnormality is present, clean or replace the tube. Specially check for contaminant or clogging near the drain outlet nipple. 2) Check Pressure Line Check the pressure line for loosened nipple or tubing, or breakage. If any abnormality is noted, reconnect or replace. After adjustment or check, press [1] key to return to the original screen. 	
Analysis after error occurrence	<p>Not Ready until the error is resolved.</p>	
<p>NOTE: • Press [3] key to return to the Analysis screen. The status is not ready for analysis, but the processing, etc. of stored data in Select Menu can be performed.</p>		

3.3 Motor Errors

Error Message		Meaning of Message
<p>"Rinse Motor Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <hr/> <p>Error on Rinse Cup</p> <p>Turn OFF then ON the power.</p> <p>If Rinse Cup is out of position, Turn power OFF and correct manually.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <hr/> <p style="text-align: right;">3:Ana.Screen</p> </div>		<p>The rinse cup is at lower position at start-up (This happens only when the power is ON.)</p>
Cause	<p>1) Rinse cup drive motor malfunction 2) The power was turned ON with the rinse cup remaining lowered.</p>	
Action	<p>1) Turn OFF the power, manually raise the rinse cup with both hands to the original top position, then turn ON the power.</p>	
Analysis after error occurrence	<p>The power needs to be turned OFF then ON again.</p>	
<p>NOTE: • Press [3] key to return to the Analysis screen. The status is not ready for analysis, but the processing, etc. of stored data in Select Menu can be performed.</p>		

Error Message		Meaning of Message
<p>"Rinse Motor Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>*Help*</p> <p>Error on Rinse Cup</p> <p>Turn OFF then ON the power.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p style="text-align: right;">3:Ana. Screen</p> </div>		<p>The rinse cup is not operating normally.</p>
Cause	<ol style="list-style-type: none"> 1) Rinse cup drive motor malfunction 2) Error of the rinse cup drive motor controller <p>Faulty operation of CPU due to sudden noise interference, etc.</p>	
Action	<ol style="list-style-type: none"> 1) Turn OFF the power and check to see that tubing, etc. are not in contact with the top or bottom of rinse cup. 2) Turn OFF the power and clean the rinse cup. <p>Refer to <i>Chapter 4, Section 7.2: Clean Rinse Cup.</i></p>	
Analysis after error occurrence	<p>The power needs to be turned OFF then ON again.</p>	
<p>NOTE: • Press [3] key to return to the Analysis screen. The status is not ready for analysis, but the processing, etc. of stored data in Select Menu can be performed.</p>		

3.4 Transducer Errors

Error Message		Meaning of Message
"WBC Aperture Clog" "RBC Aperture Clog"		The monitor value for aperture clog is out of the prescribed range.
<div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Clog in the aperture Parameter: WBC RBC</p> <p>[1] Execute clog removal sequence. If clog persists, press[SELECT], then [Maintenance]->[Clean Transducer] or dab with brush after [SELECT], [Maintenance]->[Drain TD Chamber]</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p>1:Clog Remove 3:Cancel</p> </div>		
Cause	1) Transducer aperture clogging	
Action	1) Remove Aperture Clogging. Press [1] key to execute automatic clog removal sequence. 2) Transducer Rinse Sequence Pour 1 mL each of CELLCLEAN in the transducer chamber to perform auto rinse sequence. Refer to <i>Chapter 4, Section 5.2: Clean Transducer.</i> 3) Clean the Transducer with Brush Clean the aperture with brush. Refer to <i>Chapter 4, Section 7.3: Clean WBC/RBC Transducer Aperture.</i>	
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)	
NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.		

3.5 Temperature Errors

Error Message		Meaning of Message			
"Room Temp. High" "Room Temp. Low"		Temperature in the unit (around the transducer) is out of the monitor range. Monitor range: 10.0 - 40.0°C			
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">*Help*</td> </tr> <tr> <td> Room Temp.Error 41.5°C [10.0 - 40.0] Analysis data has lower reliability. Check the room temperature. </td> </tr> <tr> <td style="text-align: center;">ERR CODE:XXXXX.X.X</td> </tr> <tr> <td style="text-align: right;">3:Return</td> </tr> </table>			*Help*	Room Temp.Error 41.5°C [10.0 - 40.0] Analysis data has lower reliability. Check the room temperature.	ERR CODE:XXXXX.X.X
Help					
Room Temp.Error 41.5°C [10.0 - 40.0] Analysis data has lower reliability. Check the room temperature.					
ERR CODE:XXXXX.X.X					
3:Return					
Cause	1) Temperature in the transducer is high (or low.)				
Action	1) Check the Ambient Temperature Check to see that the ambient temperature is between 15°C - 30°C.				
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)				
NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.					

3.6 Analysis Errors

Error Message		Meaning of Message
<p>"Background Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Background count exceeds tolerance.</p> <p>WBC 0.1 [≤ 0.3] ($\times 10^3/\mu\text{L}$)</p> <p>RBC 0.05 [≤ 0.02] ($\times 10^6/\mu\text{L}$)</p> <p>HGB 0.0 [≤ 0.1] (g/dL)</p> <p>PLT 12 [≤ 10] ($\times 10^3/\mu\text{L}$)</p> <p>Suspected a dirty aperture or SRV.</p> <p>[1] Execute an Auto Rinse.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p>1:Auto Rinse 3:Cancel</p> </div>		<p>In Auto Rinse, background check reveals that the background count of any parameter exceeds the tolerance.</p> <p>Tolerance: WBC $0.3 \times 10^3/\mu\text{L}$ or less</p> <p>RBC $0.02 \times 10^6/\mu\text{L}$ or less</p> <p>HGB 0.1g/dL or less</p> <p>PLT $10 \times 10^3/\mu\text{L}$ or less</p>
Cause	<ol style="list-style-type: none"> 1) Dirty aperture 2) Dirty HGB flow cell 3) Bubbles mixing 4) Faulty reagent 	
Action	<ol style="list-style-type: none"> 1) Auto Rinse Press [1] key to perform Auto Rinse. 2) Clean Transducer Refer to <i>Chapter 4, Section 5.2: Clean Transducer</i> or <i>Chapter 4, Section 7.3: Clean WBC/RBC Transducer Aperture</i>. 3) Clean SRV Refer to <i>Chapter 4, Section 6.1: Clean Sampling Valve (SRV)</i>. 4) Replenish Reagent Faulty lyse will affect background for WBC or HGB. In case diluent is faulty, it will affect all parameters, notably PLT background count. 	
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)	
<p>NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.</p>		

Error Message	Meaning of Message
<p>"Sampling Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Error has occurred during counting. Parameter: WBC PLT Suspected a clogged aperture.</p> <p>[1] Execute clog removal sequence. If clog persists, press[SELECT], then [Maintenance]->[Clean Transducer] or dab with brush after [SELECT] [Maintenance]->[Drain T.D.Chamber] ERR CODE:XXXXX.X.X</p> <p>1:Clog Remove 3:Cancel</p> </div>	<p>Sampling data falls into disorder. Sampling data refers to the count taken every 0.5 seconds during counting. The system monitors the counts.</p>
Cause	<ol style="list-style-type: none"> 1) Dirty aperture 2) Effect of external noise interference
Action	<ol style="list-style-type: none"> 1) Clean Transducer <ol style="list-style-type: none"> 1. Remove Aperture Clogging Press [1] key to execute automatic clog removal sequence. 2. Transducer Rinse Sequence Pour 1 mL each of CELLCLEAN in the transducer chamber to perform auto rinse sequence. Refer to <i>Chapter 4, Section 5.2: Clean Transducer.</i> 3. Clean the Transducer with Brush Clean the aperture using brush. Refer to <i>Chapter 4, Section 7.3: Clean WBC/RBC Transducer Aperture.</i> 2) Remove Source of External Noise Move the noise source away from the unit.
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)
<p>NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.</p>	

Error Message	Meaning of Message
<p>"Sampling Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p style="text-align: center;">*Help*</p> <hr/> <p style="text-align: center;">Sampling Error has occurred.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <hr/> <p style="text-align: center;">3:Retuen</p> </div>	<p>Sampling data falls into disorder. Sampling data refers to the count taken every 0.5 seconds during counting. The system monitors the counts taken.</p>
Cause	1) CPU malfunction due to sudden noise interference, etc.
Action	1) Turn OFF then ON the power again. If the error persists after turning ON the power again, contact your Sysmex service representative.
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)
<p>NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.</p>	

Error Message		Meaning of Message
<p>"HGB Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Error occurred during HGB analysis. Flow Cell may be dirty.</p> <p>[1] Clean TD Chamber will be performed. (It will take approx. 7 minutes.)</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p>1:Exec. Clean 3:Cancel</p> </div>		<p>HGB converted value is out of the prescribed range.</p> <ol style="list-style-type: none"> 1. Blank value is out of the range. 2. Blank value exceeds sample value.
Cause	<ol style="list-style-type: none"> 1) Dirty HGB flow cell 2) Bubbles mixed in HGB sample line 3) Dirty WBC TD chamber 	
Action	<ol style="list-style-type: none"> 1) Clean Transducer Press [1] key to execute the transducer rinse sequence. Refer to <i>Chapter 4, Section 5.2: Clean Transducer.</i> 	
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)	
<p>NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.</p>		

Error Message	Meaning of Message
<p>"Analysis Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p style="text-align: center;">*Help*</p> <hr/> <p style="text-align: center;">WBC/HGB Analysis Error</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <hr/> <p style="text-align: center;">3:Return</p> </div>	<p>WBC (including HGB) analysis error is continuing.</p>
Cause	1) Faulty lyse (STROMATOLYSER-WH)
Action	<p>1) Replenish Lyse</p> <p>After replenishing lyse, always execute "4: Replace Reagent" in the Select Menu, making reference to <i>Chapter 4, Section 8.1: Replenish Reagent</i>. After replenishment and checking, analyze the control blood and confirm that there is no abnormality.</p>
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)
<p>NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.</p>	

Error Message		Meaning of Message
<p>"Analysis Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>*Help*</p> <p>Abnormal detection sensitivity</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p style="text-align: right;">3:Return</p> </div>		<p>Sensitivity in the transducer exceeds the prescribed range.</p>
Cause	1) Faulty diluent (CELLPACK)	
Action	1) Replenish Diluent After replenishing diluent, execute "5: Auto Rinse" in the Select Menu, and perform background check. In addition, analyze the control blood to see that there is no abnormality.	
Analysis after error occurrence	Ready for analysis (although the next sample could be affected)	
<p>NOTE: • Press [3] key to return to the Analysis screen. Although the system is ready for analysis, the error may occur in the next analysis.</p>		

3.7 Memory Errors

Error Message		Meaning of Message
<p>"Memory Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Memory error occurred. Turn OFF then ON the power.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> </div>		<p>Error occurs on the Read Only Memory (ROM) or Random Access Memory (RAM). The alarm keeps sounding.</p>
Cause	1) Momentary power failure, sudden noise interference, etc. causes CPU malfunction.	
Action	1) Turn OFF then ON the power again.	
Analysis after error occurrence	Inoperative (The power could be turned OFF.)	

Error Message		Meaning of Message
<p>"Set Value Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Memory error occurred. Stored data, and QC data</p> <p>[1] will be repaired. Repairing may end incomplete. [2] Deleting files and initializing.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p>1:Repairing 2:Initialize</p> </div>		<p>Errors occur in the set values of the following:</p> <ul style="list-style-type: none"> • Stored data • Quality Control data • Customer-set values
Cause	1) Momentary power failure, sudden noise interference, etc. causes analysis value errors.	
Action	<p>1) Repair Press [1] key to execute repairing.</p> <p>2) Initializing If execution of "1: Repairing" fails to correct the error, initialize using [2] key. Initializing deletes all stored data and QC data, and set values return to initial values. After completion of initializing, perform all settings referring to <i>Chapter 10: INSTRUMENT SETUP</i>.</p>	
Analysis after error occurrence	Not Ready until the error is resolved.	

Error Message		Meaning of Message
<p>"Set Value Error"</p> <div style="border: 1px solid black; padding: 5px;"> <p>*Help*</p> <p>Memory error occurred. Turn OFF then ON the power.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> </div>		<p>Errors occur in the set values of the following:</p> <ul style="list-style-type: none"> • Stored data • Quality Control data • Customer-set values • Factory-set values
Cause	1) Momentary power failure or sudden noise interference causes set value errors.	
Action	1) Turn OFF then ON the power again. If the error persists even after the power is turned OFF then ON, contact your Sysmex service representative for assistance.	
Analysis after error occurrence	Inoperative (The power could be turned OFF.)	

Error Message		Meaning of Message
<p>Momentary Power Failure</p> <div style="border: 1px solid black; padding: 5px;"> <p>Momentary power failure occurred, or [SHUT DOWN]has not been performed in the last time. Perform[SHUT DOWN]in prior to turning OFF the power.</p> <p>[1] Continue to start up.</p> <p>1:Continue</p> </div>		<p>The program had not been normally quitted the last time the power was turned off.</p>
Cause	1) Momentary power failure, etc. caused the unit to stop temporarily. 2) Shutdown had not been performed the last time the unit was turned OFF.	
Action	Press [1] key to start up the unit. Perform SHUTDOWN before turning OFF the power.	
Analysis after error occurrence	Ready for analysis (This error occurs at starting.)	

3.8 Others

Error Message		Meaning of Message
<p>"QC Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p style="text-align: center;">*Help*</p> <hr/> <p style="text-align: center;">QC data falls out of control limits.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <hr/> <p style="text-align: center;">3:Return</p> </div>		<p>This error occurs only when executing Quality Control. Analysis data is out of QC limits.</p>
Cause	<ol style="list-style-type: none"> 1) Control blood aspiration error 2) Control blood insufficient mixing 3) Faulty control blood 4) Instrument failure 	
Action	<ol style="list-style-type: none"> 1) Reanalyze Control Blood Press [3] key to return to the QC screen and perform reanalysis. 2) Analyze using New Vial. 3) Maintenance Service of Unit When the above 1) and 2) steps fail to resolve the error, a hardware problem may be suspected. Refer to <i>Chapter 4: INSTRUMENT MAINTENANCE AND SUPPLIES REPLACEMENT</i> and clean the transducer, SRV, etc. 	
Analysis after error occurrence	Ready for analysis	

Error Message	Meaning of Message
<p>"Calibration Error"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>*Help*</p> <p>Calibration value is out of range.</p> <p>If error persists, >=5% difference from the last calib. Calib. factor is out of 80%-120%.</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> <p style="text-align: right;">3:Return</p> </div>	<p>The set calibration value does not meet the conditions:</p> <ul style="list-style-type: none"> • Difference from the last calibration must not exceed 5%. • Calibration value must be in the range of 80% - 120%.
Cause	<ol style="list-style-type: none"> 1) Input error of target or calibration values 2) Instrument failure caused data to shift.
Action	<ol style="list-style-type: none"> 1) Checking Entered Values Press [3] key to return to the Calibration screen and check the target or calibration value. <ul style="list-style-type: none"> • In case of input error of target value in automatic calibration Select "No" on the Update screen for calibration value and execute Auto Calibration again from the beginning. • In case of input error of calibration value in manual calibration Select "No" on the Update screen for calibration value and enter calibration value again. 2) Maintenance of Instrument Check QC data, and if data is found to have shifted, a hardware problem is conceivable. Referring to <i>Chapter 4: INSTRUMENT MAINTENANCE AND SUPPLIES REPLACEMENT</i>, clean the transducer, SRV, etc.
Analysis after error occurrence	Not Ready until calibration value is fixed.

3.9 Maintenance Errors

Error Message	Meaning of Message
<pre> *Scheduled Maint.* Clean the SRV. [1] Reset the cycle counter for SRV, and you can turn OFF the power. [3] Continue to start up. SRV cycle counter will not be reset. Cycle No. after cleaning. 7567 Date last serviced 31/12/97 1:Exec.Clean 3:Cancel </pre>	<p>It is time to clean the SRV.</p> <p>Three months have passed from the previous cleaning.</p> <p>7500 samples have been analyzed from the previous cleaning.</p>
Cause	
Action	<p>Press [1] key. Following the instructions on the screen, turn OFF the power and clean the sample rotor valve (SRV). (Refer to <i>Chapter 4: Section 6.1: Clean Sample Rotor Valve (SRV)</i>).</p> <p>If you perform cleaning later, press [3] key. This activates the usual startup sequence and makes the system Ready.</p> <p>* The same message will appear the next time you start the unit; it will be displayed at each startup until the cleaning is performed.</p>
Analysis after error occurrence	Ready for analysis
<p>NOTE: • When you clean SRV without pressing [1] key, execute "7: Maintenance," and then "3: Reset Counter" in the Select Menu.</p>	

Error Message		Meaning of Message
<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">*Scheduled Maint*</p> <p>Clean the Waste Chamber. It will take approx. 7 minutes.</p> <p>Cycle No. after cleaning. 2567 Date last serviced 31/12/97</p> <hr/> <p>1:Exec.Clean 3:Cancel</p> </div>		<p>It is time to clean the waste chamber. One month has passed from the previous cleaning. 2500 samples have been analyzed from the previous cleaning.</p>
Cause		
Action	<p>Press [1] key. Following the instructions on the screen, clean the waste chamber. (Refer to <i>Chapter 4, Section 5.1: Clean Waste Chamber</i>).</p> <p>If you perform cleaning later, press [3] key. This activates the usual startup sequence and makes the system Ready.</p> <p>* The same message will appear the next time you start the unit; it will be displayed at each startup until the cleaning is performed.</p>	
Analysis after error occurrence	Ready for analysis	
<p>NOTE: • When the waste chamber rinse sequence has been completed, the cycle counter is automatically reset.</p>		

Error Message	Meaning of Message
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center;">*Scheduled Maint*</p> </div> <div style="border: 1px solid black; padding: 10px; min-height: 150px;"> <p style="text-align: center;">Clean the Transducer. It will take approx. 7 minutes.</p> <p style="text-align: center;">Cycle No. after cleaning. 2567 Date last serviced 31/12/97</p> <p style="text-align: center;">1:Exec.Clean 3:Cancel</p> </div>	<p>It is time to clean the transducer. One month has passed from the previous cleaning. 2500 samples have been analyzed from the previous cleaning.</p>
Cause	
Action	<p>Press [1] key. Following the instructions on the screen, clean the transducer (Refer to <i>Chapter 4, Section 5.2: Clean Transducer</i>). If you perform cleaning later, press [3] key. This activates the usual startup sequence and makes the system Ready.</p> <p>* The same message will appear the next time you start the unit; it will be displayed at each startup until the cleaning is performed.</p>
Analysis after error occurrence	Ready for analysis
<p>NOTE: • When the transducer rinse sequence has been completed, the cycle counter is automatically reset.</p>	

3.10 Built-in Printer Errors

Error Message		Meaning of Message
<p>"Print Error"</p> <pre> *Help* ----- Error on Built-in Printer [1] Press[1]to return the screen, and print again. [3] Stop printing on built-in printer To make built-in printer on-line, press[SELECT],then [Periph. Settings] ERR CODE:XXXXX.X.X ----- 1:Return 3:Stop Output </pre>		<p>Error is found in the memory used for the built-in printer.</p>
Cause	<p>1) Printer memory error occurs due to momentary power failure, sudden noise interference, etc.</p>	
Action	<p>1) Clear the Printer Memory Press [1] key to initialize the printer memory. * In this case, manually print the same sample again from the Analysis screen.</p> <p>2) Make the Built-in Printer Off-line Press [3] key to make the built-in printer off-line. The main unit becomes Ready but cannot print. When you want to try printing again, refer to <i>Chapter 10: INSTRUMENT SETUP</i> and make settings for connecting the built-in printer.</p>	
Analysis after error occurrence	<p>Not Ready until the error is resolved.</p>	

Error Message	Meaning of Message
<p>"No Printer Paper"</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p style="text-align: center;">*Help*</p> <p>No Printer Paper</p> <p>[1] Restarting to print [3] Stop printing on built-in printer</p> <p>To make built-in printer on-line, press[SELECT], then [Periph. Settings]</p> <p style="text-align: center;">ERR CODE:XXXXX.X.X</p> </div> <p style="font-size: small; margin-top: 5px;">1:Print 2:Paper Feed 3:Stop Output</p>	<p>Paper found empty</p>
Cause	1) No printer paper in the built-in printer
Action	<p>1) Replace Print Paper Refer to <i>Chapter 4, Section 8.3: Replace Printer Paper</i>. After replacing, press [1] key to print the data that has not yet printed.</p> <p>2) Make the Built-in Printer Off-line When you press [3], the built-in printer is made off-line. The main unit becomes Ready but cannot print. When you want to try printing, refer to <i>Chapter 10: INSTRUMENT SETUP</i> and make settings for connecting the built-in printer.</p>
Analysis after error occurrence	Not Ready until the error is resolved.
NOTE: • When you press [2] key, paper is fed.	

Error Message	Meaning of Message
<p>"Printer Error"</p> <pre> *Help* ----- Error on Built-in Printer Press the paper guide lever down. [1] Restarting to print [3] Stop printing on built-in printer To make built-in printer on-line, press[SELECT], then [Periph. Settings] ERR CODE:XXXXX.X.X 1:Print 2:Paper Feed 3:Stop Output </pre>	<p>The built in printer has an error.</p>
Cause	1) The paper release lever is not in the secured position.
Action	<p>1) Confirming the Printer Press the paper release lever down. Pressing [1] key resumes printing.</p> <p>2) Make the Printer Off-line When [3] key is pressed, the built-in printer is made off-line. The main unit becomes Ready but cannot print. When you want to try printing, refer to <i>Chapter 10: INSTRUMENT SETUP</i> and make settings for connecting the built-in printer.</p>
Analysis after error occurrence	Not Ready until the error is resolved.
<p>NOTE: • When you press [2] key, paper is fed.</p>	

3.11 External Device Errors (When this option is incorporated)

Error Message	Meaning of Message
<p>"Host Comm. Error"</p> <pre> *Help* ----- Host Output Error *Host ACK Time Out Error* Check Host Condition [1] Retries to transmit to Host [3] Stop transmitting to Host To make Host Computer on-line, press[SELECT], then [Periph.Settings] ERR CODE:XXXXX.X.X ----- 1:Re-sending 3:Stop Output </pre>	<p>Communications cannot be made with the host computer. There are four cases:</p> <ul style="list-style-type: none"> • Host Off-line • Host ACK Time Out Error • Host NAK Retry Error • Host Transmission Time Out Error
Cause	<ol style="list-style-type: none"> 1) Computer connecting cable failure 2) Computer is not turned ON or not ready for communication. 3) Host computer serial interface error
Action	<ol style="list-style-type: none"> 1) Inspect Host Computer Cable 2) Inspect Connection Cable When you press [1] key after inspection, data transmission is resumed. 3) Disconnecting Host Computer When you press [3] key, transmission to the host computer is canceled and the host is off-lined in the main unit. The main unit is now Ready but cannot output to the host computer. To resume transmission to the host computer, refer to <i>Chapter 10: INSTRUMENT SETUP</i> and make settings for connecting the host computer.
Analysis after error occurrence	Not Ready until the error is resolved.

4. STATUS DISPLAY

The unit has the Status Display screen by which you can confirm the status of the instrument. The Status Display screen displays in real time a currently-running sequence, pressure/vacuum readings, sensor status, and solenoid valve operating status. You can also confirm on the screen HGB Converted value, cycle Nos. after performing the last maintenance, and currently-registered cycle No.

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] key or [▼] key, move the cursor to select "7: Maintenance."
- (3) Press [ENTER] key. The Maintenance Menu screen appears.

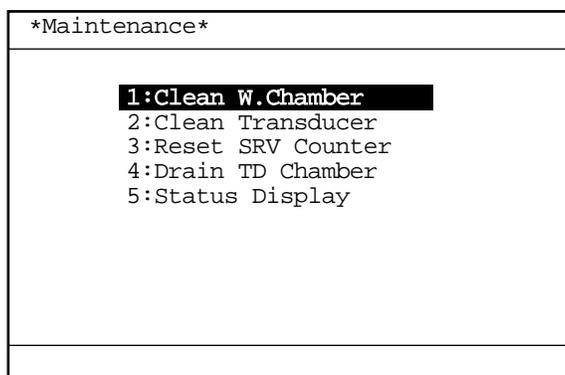


Figure 7-4-1: Maintenance Menu Screen

- (4) Using [▲] key or [▼] key, move the cursor to select "5: Status Display."
- (5) Press [ENTER] key. The Status Display screen appears.

NOTE: • On the Menu screen, each menu can be selected directly by entering a numeral from the numeric keys.

The Status Display screen comprises two pages; you can turn over the pages using [◀] key or [▶] key.

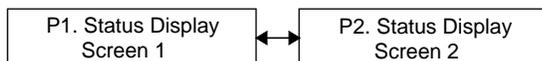


Figure 7-4-2: Page Selection in Status Display Screen

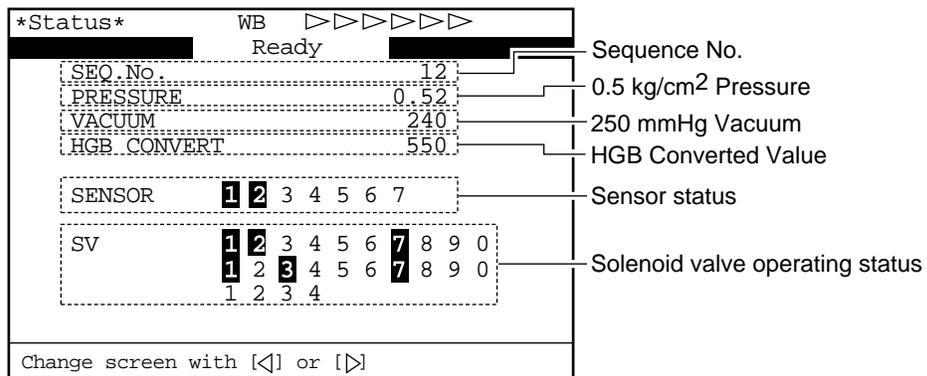


Figure 7-4-3: P1. Status Display Screen 1

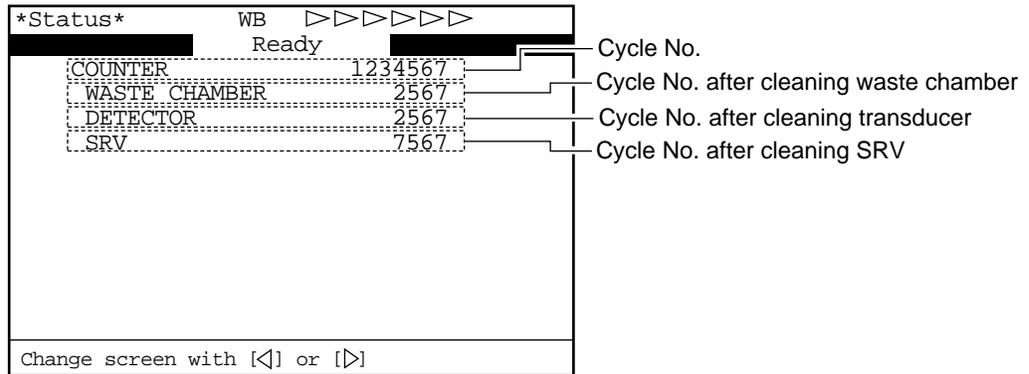


Figure 7-4-4: P2. Status Display Screen 2

CHAPTER 8

ADJUSTMENT

1.	INTRODUCTION.....	8-1
2.	ADJUSTMENT OF PRESSURE AND VACUUM.....	8-2
2.1	Location of Control Knobs.....	8-2
2.2	Pressure and Vacuum Display	8-3
2.3	Adjusting Pressure to 0.5 kg/cm ²	8-5
2.4	Adjusting Vacuum to 250 mmHg	8-6

1. INTRODUCTION

The adjustment procedures described here are important in maintaining accuracy of this instrument. Your Sysmex service representative will perform initial adjustment. Should it require any adjustment subsequently, follow the procedures given below.

The following adjustment procedures are explained in this chapter.

- Pressure: 0.5 kg/cm²
- Vacuum: 250 mmHg

2. ADJUSTMENT OF PRESSURE AND VACUUM

Pressure and vacuum from the built-in Pneumatic Unit are regulated to 0.5 kg/cm² and 250 mmHg. The pressure and vacuum are always monitored by pressure sensors. When an error occurs, an error message is displayed.

If the pressure or vacuum error message is displayed, check tubing connections or the like for any air leakage. If there is no such error, display the Status Display screen and adjust pressure or vacuum as required.

2.1 Location of Control Knobs

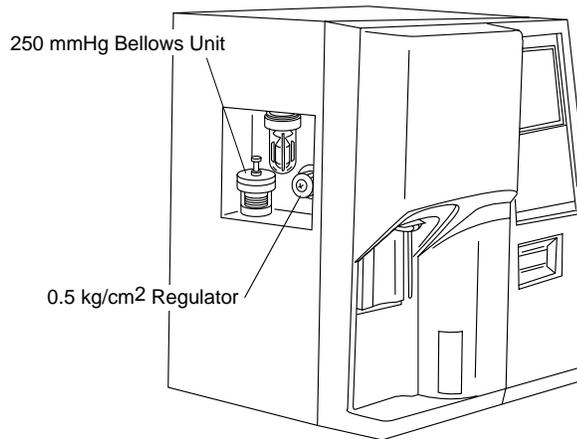


Figure 8-2-1: Location of Control Knobs

NOTE:

- When an error has occurred, press [HELP] key to check pressure or vacuum value on the Help screen.
(Refer to *Chapter 7: TROUBLESHOOTING.*)

```

*Help*
0.5kg/cm2 Pressure Error
    0.35    [0.40 - 0.60]
Adjust 0.5kg/cm2 Pressure
[1] Restarting to monitor the pressure

ERR CODE: XXXX.X.X
1:End of Adj
    
```

Figure 8-2-2: Help Screen

2.2 Pressure and Vacuum Display

- (1) Press [SELECT] key when the status is "Ready." The Select Menu screen appears.
- (2) Move the cursor using [▲] key or [▼] key, and select "7: Maintenance."
- (3) Press [ENTER] key.
The Maintenance Menu screen appears.

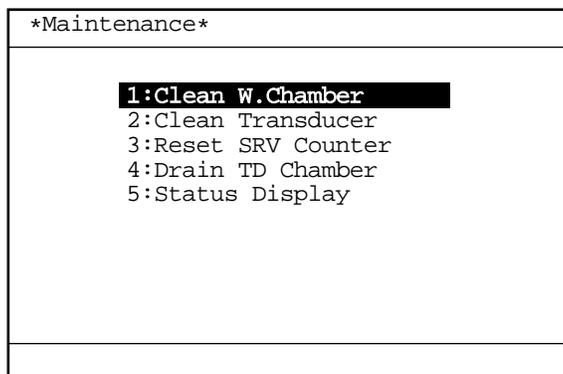


Figure 8-2-3: Maintenance Menu Screen

- (4) Move the cursor using [▲] key or [▼] key, and select "5: Status Display."
- (5) Press [ENTER] key.
The Status Display screen appears.

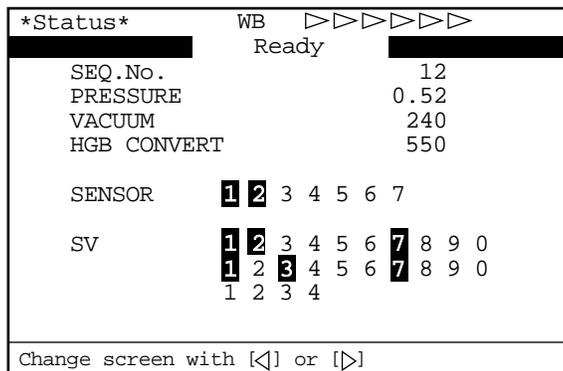


Figure 8-2-4: Status Display Screen

NOTE:

- Each menu can be selected directly on the Menu screen by entering a numeral from the numeric keys.

NOTE:

- The Status Display screen shows current pressure and vacuum.

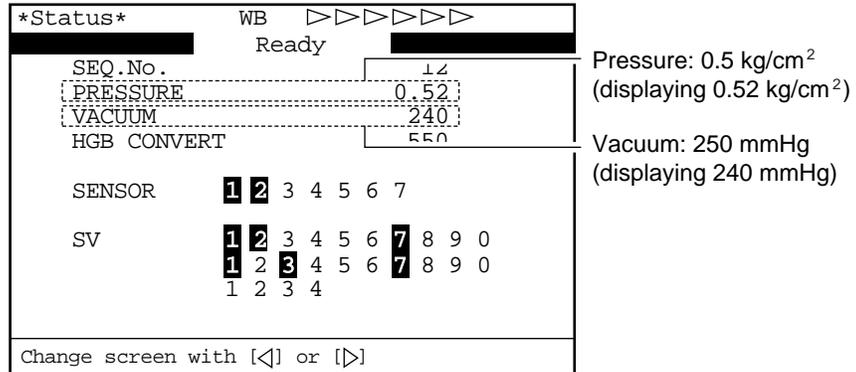


Figure 8-2-5: Status Display Screen

- (6) Adjust the pressure and vacuum by following the procedures given on the next page and later.

2.3 Adjusting Pressure to 0.5 kg/cm²

- (1) Using the procedure of "2.2 Pressure and vacuum Display," display the Status Display screen.
- (2) Loosen the 0.5 kg/cm² regulator locking nut on the left side of the unit.
- (3) While watching the pressure and vacuum indication on the Status Display screen, turn the adjusting knob to regulate pressure and vacuum. Turn the adjusting knob clockwise to increase pressure and vacuum.

Adjustment range: 0.5±0.1 kg/cm²

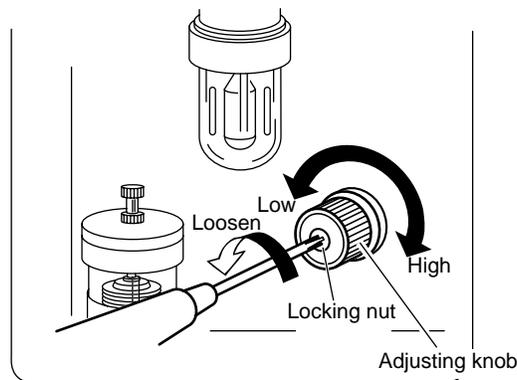


Figure 8-2-6: Adjusting the Pressure

CAUTION:

- Always adjust pressure and vacuum so as to increase to the predetermined levels. Should any of them be too high, lower it to below that level once, then raise it to the set level. Unless adjustment is properly conducted, accurate adjustment may not be possible.

- (4) When adjustment is finished, tighten the locking nut while taking care not to allow the adjusting knob to rotate.
- (5) Press [SELECT] key to return to the Ready status.

2.4 Adjusting Vacuum to 250 mmHg

- (1) Using the procedure of "2.2 Pressure and Vacuum Display," display the Status Display screen.
- (2) By turning counterclockwise, loosen the locking nut for the bellows unit on the left side of the unit.
- (3) While watching the pressure and vacuum indication on the Status Display screen, turn the adjusting knob to regulate pressure and vacuum. Turn the adjusting knob clockwise to increase pressure and vacuum.

Adjustment range: 250 ± 10 mmHg

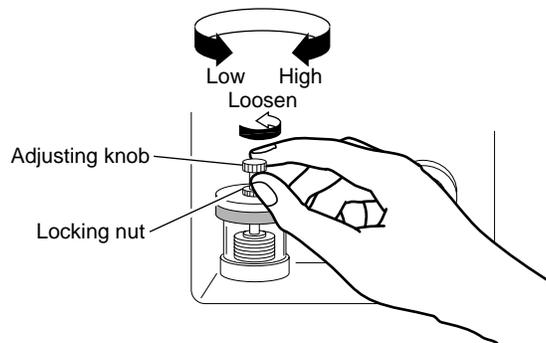


Figure 8-2-7: Adjusting the Vacuum

CAUTION:

- Always adjust pressure and vacuum so as to increase to the predetermined levels. Should any of them be too high, lower it to below that level once, then raise it to the set level. Unless adjustment is properly conducted, accurate adjustment may not be possible.

- (4) When adjustment is finished, tighten the locking nut while taking care not to allow the adjusting knob to rotate.
- (5) Press [SELECT] key to return to the Ready status.

CHAPTER 9 FUNCTIONAL DESCRIPTION

1.	INTRODUCTION	9-1
2.	DETECTION PRINCIPLE	9-2
2.1	DC Detection Method	9-2
2.2	Non-Cyanide Hemoglobin Analysis Method	9-2
3.	MEASURING UNIT HYDRAULIC SYSTEM BLOCK DIAGRAM	9-4
4.	CBC ANALYSIS	9-5
4.1	WBC/HGB Analysis Flow	9-5
4.2	RBC/PLT Analysis Flow	9-7
4.3	Calculation of RBC Constant	9-9
5.	BLOOD CELL DISCRIMINATION CIRCUIT	9-10
5.1	WBC Discriminator	9-10
5.2	RBC Discriminator	9-10
5.3	PLT Discriminator	9-10
6.	ANALYSIS OF HISTOGRAM	9-11
6.1	Analysis of WBC Histogram	9-11
6.2	Analysis of RBC/PLT Histogram	9-20
7.	ELECTRIC SYSTEM	9-28
8.	NAMES AND FUNCTIONS OF INSTRUMENTS	9-30
8.1	Front Panel	9-30
8.2	Front Interior	9-31
8.3	Right Side Panel	9-32
8.4	Left Side Panel	9-33
8.5	Left Side Interior	9-34
8.6	Rear Panel	9-35

1. INTRODUCTION

This chapter describes blood cell count detection principle and analysis method used in this instrument, and flow of individual analysis. Also the hardware elements are explained.

- **Detection Principle:** Principle each of DC detection method and non-cyanide hemoglobin analysis method is described.
- **Flow of Analysis:** Flow of each analysis parameter on the main unit and analysis method for particle distribution are described.
- **Function of Measuring Unit:** Names and functions of the measuring unit's elements are briefly described.

2. DETECTION PRINCIPLE

This instrument performs blood cell count by DC detection method.

2.1 DC Detection Method

Blood sample is aspirated, measured to a predetermined volume, diluted at the specified ratio, then fed into each transducer. The transducer chamber has a minute hole called the aperture. On both side of the aperture, there are the electrodes between which flows direct current. Blood cells suspended in the diluted sample pass through the aperture, causing direct current resistance to change between the electrodes. As direct current resistance changes, the blood cell size is detected as electric pulses. Blood cell count is calculated by counting the pulses, and a histogram of blood cell sizes is plotted by determining the pulse sizes. Also, analyzing a histogram makes it possible to obtain various analysis data.

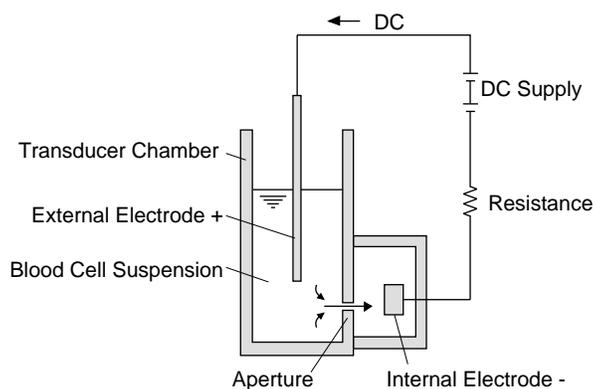


Figure 9-2-1: DC Detection Method

2.2 Non-Cyanide Hemoglobin Analysis Method

To analyze hemoglobin by automated methods, the Cyanmethemoglobin method or Oxyhemoglobin method have so far been the main stream.

Cyanmethemoglobin method was recommended as the international standard method in 1966 by ICSH (International Committee for Standardization in Haematology). This method, however, is so low in hemoglobin conversion rate that it cannot be said an appropriate method in the automated process in which multi-sample processing is the pre-condition. In addition, this method uses the reagent of cyanide compound which is a poisonous substance and requires waste processing; thus, it can hardly be called an environmentally favorable method.

At present, this method cannot be said suitable for a fully-automated instrument which is required to handle a large amount of waste.

The Oxyhemoglobin method, on the other hand, is faster in hemoglobin conversion rate; in fact, blood hemoglobin is converted instantaneously into oxyhemoglobin. Also, it does not contain poisonous substance as cyanmethemoglobin method, making the method suitable for automation. This method, however, is unable to convert methemoglobin into oxyhemoglobin. Consequently, when a great amount of methemoglobin is contained as in control blood, lower-than-real values result, although usual human blood poses no problems.

Non-cyanide hemoglobin analysis method utilizes the advantages of both of the above methods. Non-cyanide hemoglobin analysis method rapidly converts blood hemoglobin as the Oxyhemoglobin method and contains no poisonous substance, making it suitable for automated method.

Being capable of analyzing methemoglobin, this method can accurately analyze control blood, etc. which contain methemoglobin.

3. MEASURING UNIT HYDRAULIC SYSTEM BLOCK DIAGRAM

<Whole Blood Mode>

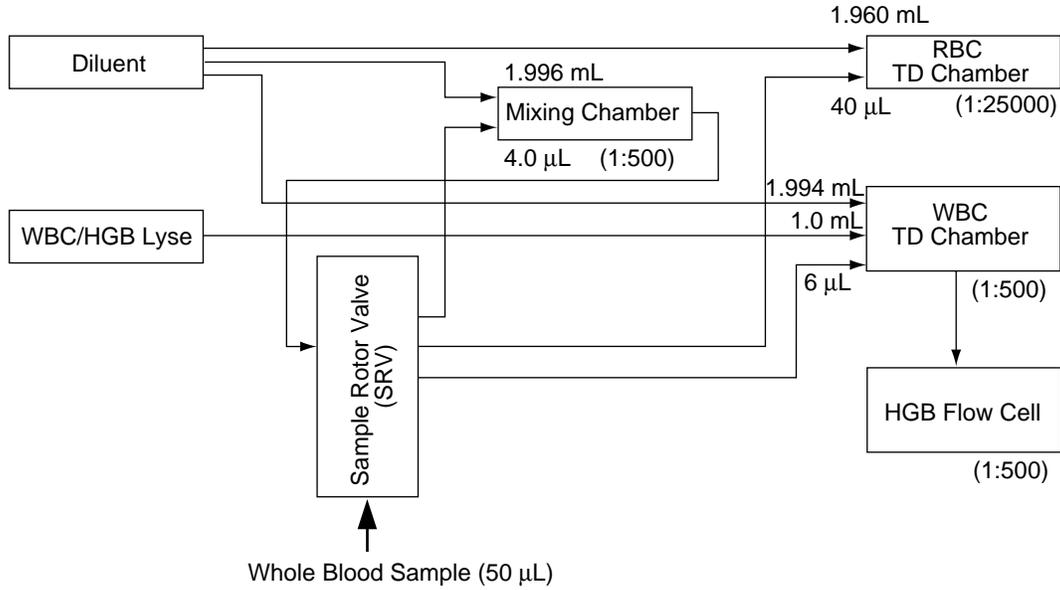


Figure 9-3-1: Hydraulic System in Whole Blood Mode

<Pre-diluted Mode>

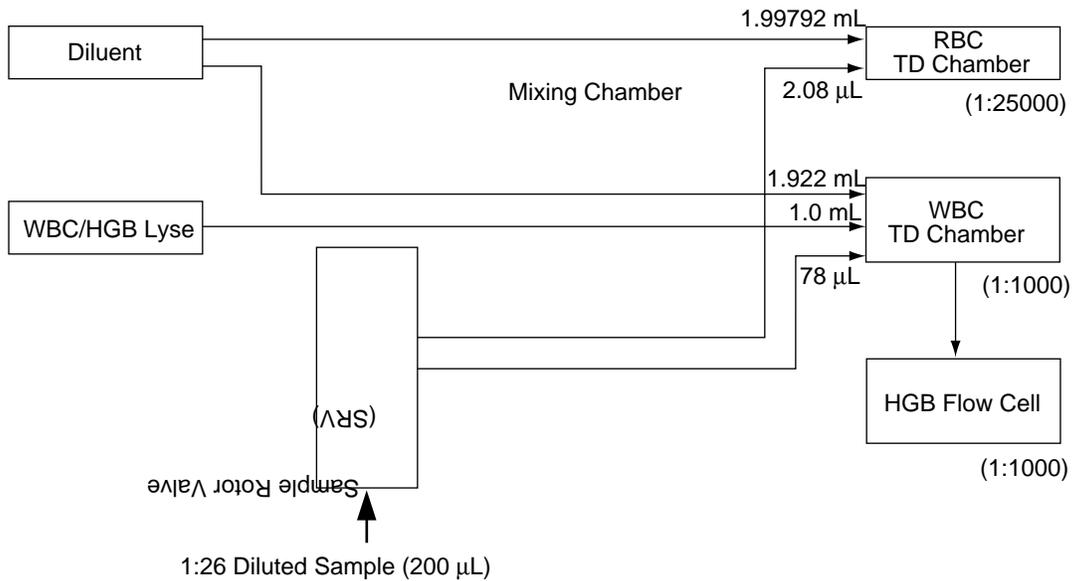


Figure 9-3-2: Hydraulic System in Pre-diluted Mode

4. CBC ANALYSIS

4.1 WBC/HGB Analysis Flow

In WBC and HGB analysis, the volume of WBC and hemoglobin in the blood are measured. The flow of WBC/HGB analysis is described below:

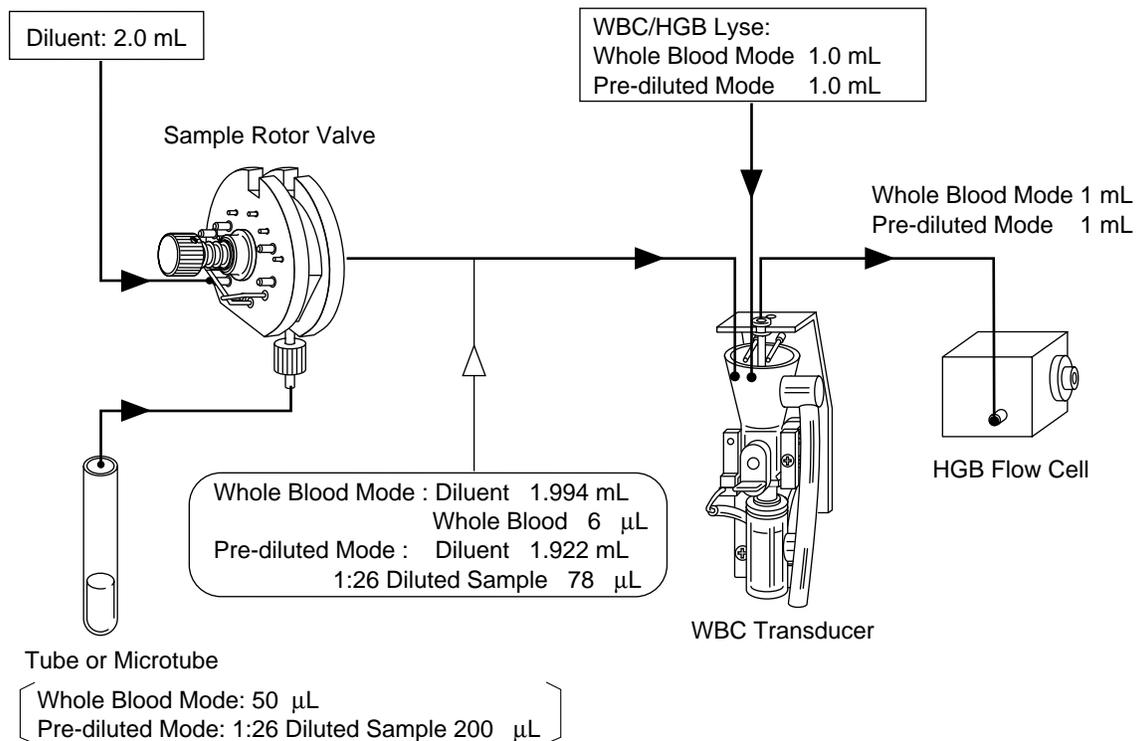


Figure 9-4-1: WBC/HGB Analysis Flow

● Whole Blood Mode

- (1) Blood is aspirated from the sample probe into the sample rotor valve.
- (2) 6 μL of blood measured by the sample rotor valve is transferred to the WBC transducer chamber along with 1.994 mL of diluent. At the same time, 1.0 mL of WBC/HGB lyse is added to prepare 1:500 dilution sample. When the solution is made to react in this status for approximately 10 seconds, RBC is hemolyzed and platelets shrink, with WBC membrane held as they are. At the same time, hemoglobin is converted into red colored methemoglobin.
- (3) Of the diluted/hemolyzed sample in the WBC transducer chamber, approximately 1 mL is transferred to the HGB flow cell.

- (4) 500 μ L of sample in the WBC transducer is aspirated through the aperture. The pulses of the blood cells when passing through the aperture are counted by the DC detection method.
- (5) In the HGB flow cell, 555 nm wavelength beam irradiated from the light emitting diode (LED) is applied to the sample in the HGB flow cell. Concentration of this sample is measured as absorbance. This absorbance is compared with that of the diluent alone that was measured before addition of the sample, thereby calculating HGB (hemoglobin value).

● **Pre-diluted Mode**

- (1) Blood sample that was diluted beforehand to 1:26 dilution using CELLPACK. This sample is aspirated from the sample probe into the sample rotor valve.
- (2) 78 μ L of diluted blood measured by the sample rotor valve is transferred to the WBC transducer chamber along with 1.922 mL of diluent. At this time, 1.0 mL of WBC/HGB lyse is added to prepare 1:1000 dilution sample. When the solution is made to react in this status for approximately 10 seconds, RBC is hemolyzed and platelets shrink, with WBC membrane held as they are. At the same time, hemoglobin is converted into red colored methemoglobin.
- (3) Of the diluted/hemolyzed sample in the WBC transducer chamber, approximately 1 mL is transferred to the HGB flow cell.
- (4) 500 μ L of sample in the WBC transducer chamber is aspirated through the aperture. The pulses of the blood cells when passing through the aperture are counted by the DC detection method.
- (5) In the HGB flow cell, 555 nm wavelength beam irradiated from the light emitting diode (LED) is applied to the sample in the HGB flow cell. Concentration of this sample is measured as absorbance. This absorbance is compared with that of the diluent alone that was measured before addition of the sample, thereby calculating HGB (hemoglobin value).

4.2 RBC/PLT Analysis Flow

In RBC/PLT analysis, RBC and platelet count in the blood are measured. The flow of RBC/PLT analysis is described below:

- Whole Blood Mode

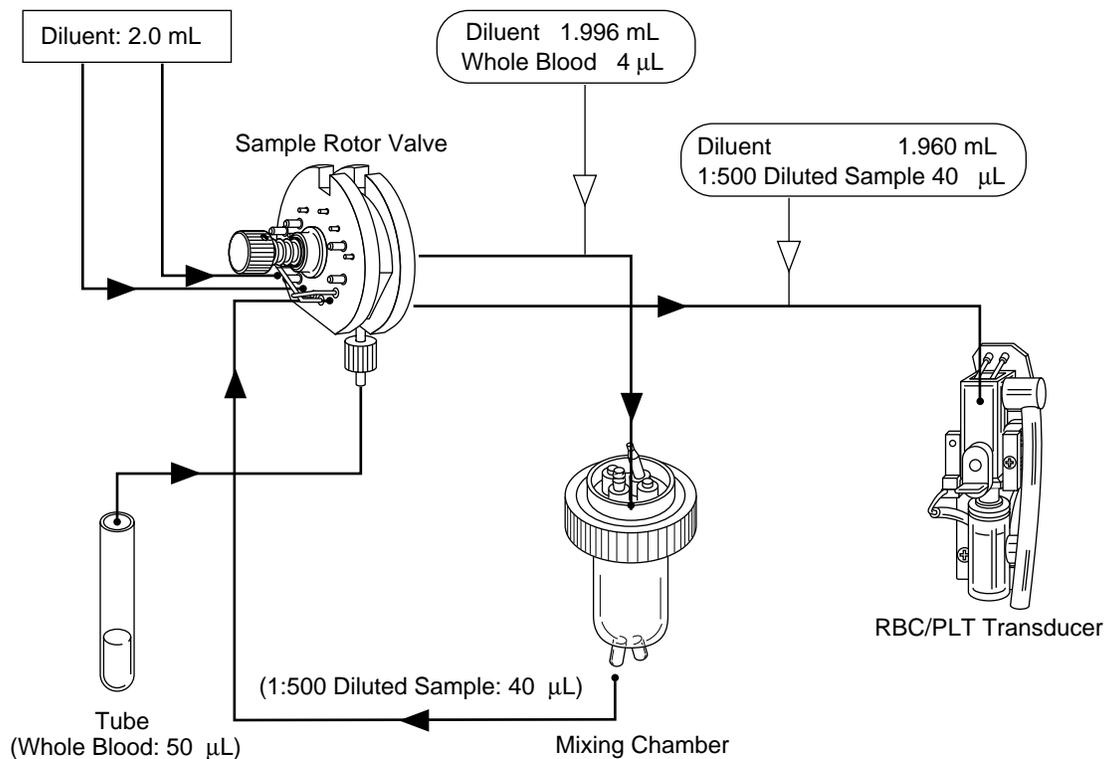


Figure 9-4-2: RBC/PLT Analysis Flow in Whole Blood Mode

- (1) Blood is aspirated from the sample probe into the sample rotor valve.
- (2) 4.0 µL of blood measured by the sample rotor valve is diluted into 1:500 with 1.996 mL of diluent and brought to the mixing chamber as diluted sample. (1st step dilution)
- (3) Out of the 1:500 dilution sample, 40 µL is measured by the sample rotor valve, diluted into 1:25000 with 1.960 mL of diluent, then transferred to the RBC/PLT transducer chamber. (2nd step dilution)
- (4) 250 µL of the sample in the RBC/PLT transducer chamber is aspirated through the aperture. At this time, RBC and PLT are counted by the DC detection method. At the same time, HCT (hematocrit value) is calculated by RBC pulse height detection method.

● Pre-diluted Mode

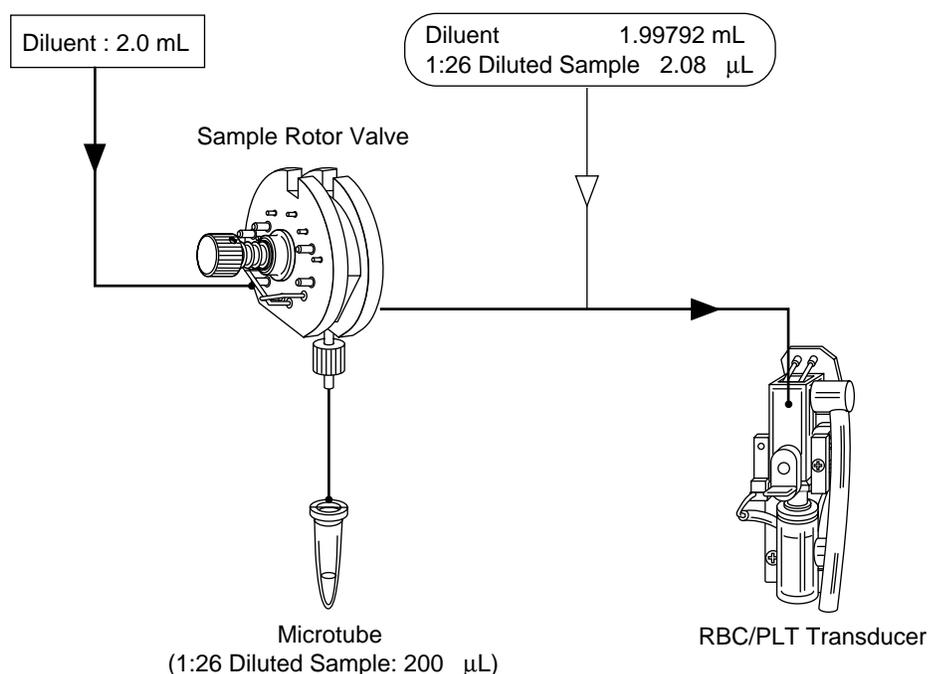


Figure 9-4-3: RBC/PLT Analysis Flow in Pre-diluted Mode

- (1) Blood sample that was diluted beforehand to 1:26 dilution using CELLPACK. This sample is aspirated from the sample probe into the sample rotor valve.
- (2) 2.08 μL of diluted blood measured by the sample rotor valve is transferred in 1.99792 mL of diluent to the RBC/PLT transducer chamber, and is made into 1:25000 dilution sample.
- (3) Of the sample in the RBC/PLT transducer chamber, 250 μL is aspirated through the aperture. At this time, RBC and PLT are calculated by the DC detection method. At the same time, HCT (hematocrit value) is calculated by RBC pulse height detection method.

4.3 Calculation of RBC Constant

RBC constant (mean RBC volume, mean RBC hemoglobin, mean RBC hemoglobin concentration) is calculated from RBC, HGB, and HCT.

1. Mean RBC Volume (MCV)

Calculation is made from RBC and HCT by the formula below:

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

2. Mean RBC Hemoglobin (MCH)

Calculation is made from RBC and HGB by the formula below:

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

3. Mean RBC Hemoglobin Concentration (MCHC)

Calculation is made from HCT and HGB by the formula below:

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

5. BLOOD CELL DISCRIMINATION CIRCUIT

WBC, RBC, and PLT are discriminated and calculated by the following blood cell discriminator.

5.1 WBC Discriminator

As to WBC LOWER discriminator, the optimum position in 30 - 60 fL is automatically determined by the microcomputer. WBC is calculated from the particle counts more than this LOWER discriminator.

5.2 RBC Discriminator

As to RBC LOWER discriminator and UPPER discriminator, the optimum position in 25 - 75 fL and 200 - 250 fL, respectively, are automatically determined by the microcomputer. RBC is calculated from the particle counts between this LOWER discriminator and UPPER discriminator.

5.3 PLT Discriminator

As to PLT LOWER discriminator and UPPER discriminator, the optimum position in 2 - 6 fL and 12 - 30 fL, respectively, are automatically determined by the microcomputer. PLT count is calculated from the particle counts between this LOWER discriminator and UPPER discriminator.

6. ANALYSIS OF HISTOGRAM

Analysis of histogram allows use of the flagging system that suggests sample error or instrument error.

Histograms of WBC, RBC, and PLT can be calculated respectively within the ranges given below.

WBC: Approx. 30 - 300 fL (particle after lyse dripping)
 RBC: Approx. 25 - 250 fL
 PLT: Approx. 2 - 30 fL

6.1 Analysis of WBC Histogram

1. WBC Histogram

The WBC histogram is discriminated into small, middle, and large WBC by 3-part differential method using 4 discriminators. The LOWER discriminator (LD) is automatically determined at an optimum position between 30 and 60 fL. The UPPER discriminator (UD) is fixed at 300 fL, which is used as the monitor for histogram error. The WBC histogram troughs in the (LD)-to-(UD) range are determined; the 1st one is defined TROUGH Discriminator 1 (T1) and the 2nd one TROUGH Discriminator 2 (T2).

• WBC Histogram

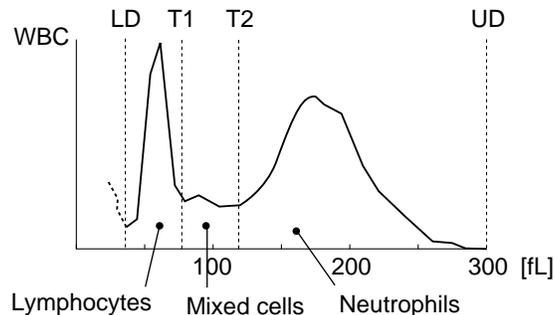


Figure 9-6-1: WBC Histogram

- 1) **LYM# [W-SCC (WBC-Small Cell Count)]**
Lymphocytes between discriminator (LD) and (T1), which is considered highly correlated with lymphocyte count.
- 2) **MXD# [W-MCC (WBC-Middle Cell Count)]**
Mixed cells between discriminator (T1) and (T2), which is considered highly correlated with the sum of monocytes, basophils, and eosinophils.
- 3) **NEUT# [W-LCC (WBC-Large Cell Count)]**
Neutrophils more than discriminator (T2), which is considered highly correlated with neutrophils.

FUNCTIONAL DESCRIPTION

- 4) **LYM% [W-SCR (WBC-Small Cell Ratio)]**
Ratio of lymphocytes to whole WBC
- 5) **MXD% [W-MCR (WBC-Middle Cell Ratio)]**
Ratio of mixed cells to whole WBC
- 6) **NEUT% [W-LCR (WBC-Large Cell Ratio)]**
Ratio of neutrophils to whole WBC

2. WBC Histogram Error Flag

When the WBC histogram is normal with three peaks, there are a lower trough (T1) and a higher trough (T2) between LOWER discriminator (LD) and UPPER discriminator (UD).

- Output Example of Normal WBC Three-Peak Histogram

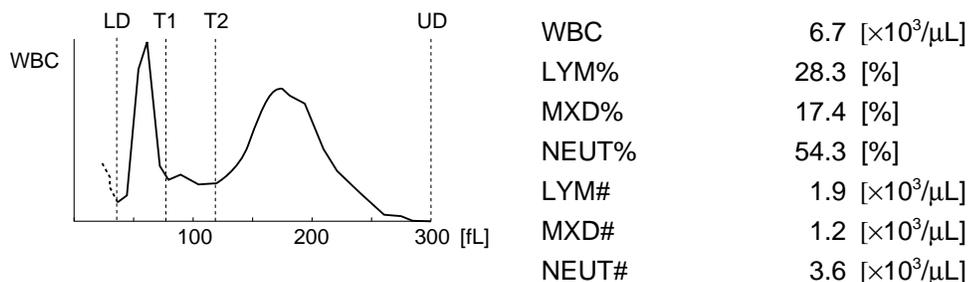


Figure 9-6-2: Normal WBC Three-Peak Histogram

When TROUGH Discriminator (T1) or (T2) cannot be set or when frequency for a set discriminator position is higher than the range, it is flagged as WBC histogram error. Those histogram error flags are listed below in the order of higher priority. If more than one flag are applied, the flag of the highest priority is taken.

- WL: Relative frequency for LOWER discriminator (LD) exceeds the range. Probable cause is inclusion of numerous platelet agglutinations, large platelets, and etc.
- T1: Lower TROUGH Discriminator, that distinguishes lymphocytes and mixed cells, cannot be not determined.
- T2: Higher TROUGH Discriminator, that distinguishes mixed cells and neutrophils, cannot be not determined.
- F1: Small cell histogram error. Relative frequency for T1 exceeds the range.
- F2: Middle cell histogram error. Relative frequency for T1 or T2 exceeds the range.
- F3: Large cell histogram error. Relative frequency for T2 exceeds the range.
- WU: Relative frequency for UPPER discriminator (UD) exceeds the range. Applicable cases are those in which hemolysis is insufficient (for instance, samples whose RBC membrane has extremely strong resistance against lyse) or in which numerous abnormal blood cells are present.
- AG: The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. Therefore, this flag is added to the PLT parameter.

● WBC and Calculation Parameters versus Analysis Value Error Flags

					WBC Histogram Error Flag Output							
Case No.	LD	T1	T2	UD	[1]							[2]
					WBC	LYM%	MXD%	NEUT%	LYM#	MXD#	NEUT#	HOST
1	High	⊘	⊘	⊘	WL	WL	WL	WL	WL	WL	WL	1
2A	○	×	⊘	○		T1	T1	T1	T1	T1	T1	5
2B	○	×	⊘	High	WU	T1	T1	T1	T1	T1	T1	5
3A	○	High	×	○		F1	T2	T2	F1	T2	T2	6
3B	○	High	×	High	WU	F1	T2	T2	F1	T2	T2	6
3C	○	○	×	○			T2	T2		T2	T2	6
3D	○	○	×	High	WU		T2	T2		T2	T2	6
4A	○	High	○	○		F1	F2		F1	F2		7
4B	○	High	○	High	WU	F1	F2		F1	F2		7
4C	○	High	High	○		F1	F2	F3	F1	F2	F3	7
4D	○	High	High	High	WU	F1	F2	F3	F1	F2	F3	7
5A	○	○	High	○			F2	F3		F2	F3	8
5B	○	○	High	High	WU		F2	F3		F2	F3	8
6	○	○	○	High	WU							2
7	(The particle count equal to or less than LD is higher than the range)					PLT parameter is flagged with AG.						2

[1] : Output flag to LCD screen, built-in printer.
 [2] : Output flag to serial interface (if incorporated as option).
 ○ : Analysis result of each discriminator is normal
 High : Frequency for each discriminator is higher than the range.
 × : A trough is not clear and cannot be detected.
 ⊘ : Any of "○", "×," and "High" is applicable.

Table 9-6-1: WBC Histogram Error Flags

NOTE: ● When analyzing in the pre-diluted mode, since CBC8 parameters only are output, flagging is limited to a WBC parameter.

- 1) **1A Histogram having high LD frequency with troughs T1 and T2**
 WL flag is added to all WBC parameters (WBC, LYM%, MXD%, NEUT%, LYM#, MXD#, NEUT#).

● WBC Histogram Error-WL (1A)

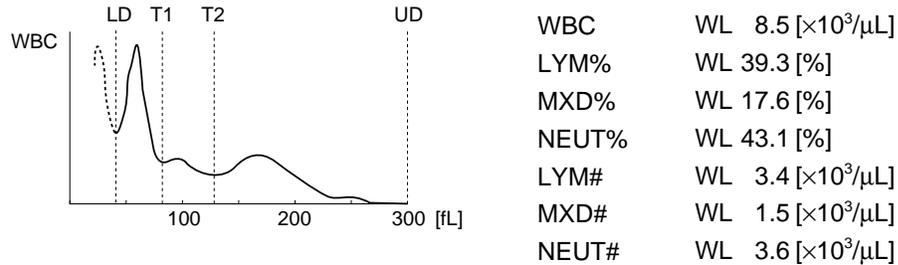


Figure 9-6-3: WBC Histogram Error-WL (1A)

- 2) **1B Histogram with high LD and trough T1 but without T2**
 WL flag is added to all analysis results for WBC, LYM% and LYM#. WL flag is added to mixed cell and neutrophil parameters (MXD%, NEUT%, MXD#, NEUT#) and their data are not output. ([---.])

● WBC Histogram Error-WL (1B)

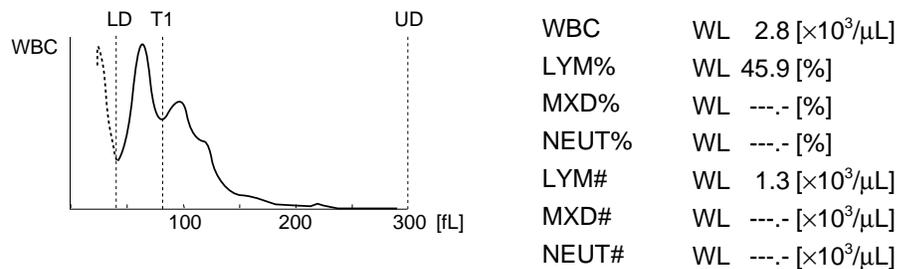


Figure 9-6-4: WBC Histogram Error-WL (1B)

- 3) **1C Histogram with high LD but without T1**
 WL flag is added to WBC and other parameters are not output. Note [+] on WBC numeric data in the example below. This WBC value exceeds the upper Patient Mark Limits mentioned earlier.

● WBC Histogram Error-WL (1C)

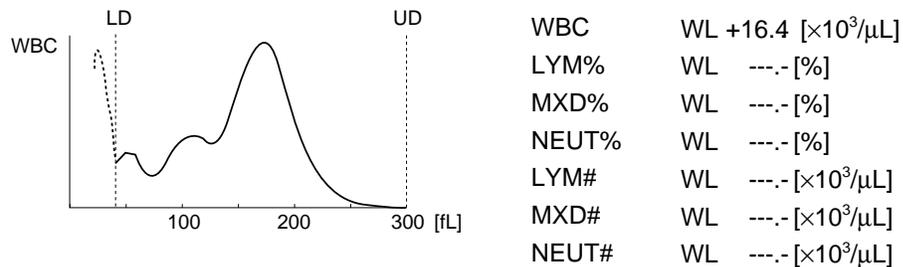


Figure 9-6-5: WBC Histogram Error-WL (1C)

4) **2A Histogram without T1**

Although the histogram error flag is not added to WBC, all other parameters are flagged with T1 and their data are not output. Note that WBC in the graph exceeds the upper Patient Mark Limits.

● WBC Histogram Error-T1 (2A)

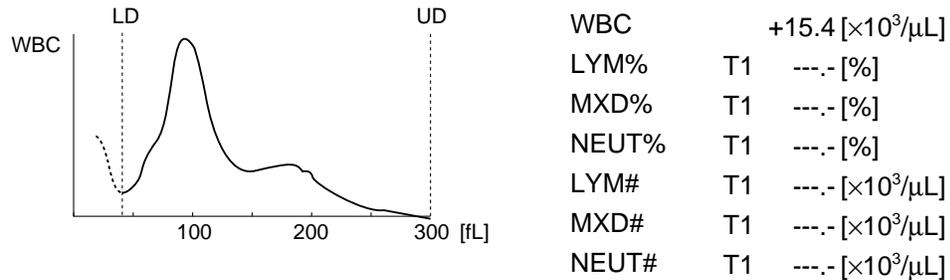


Figure 9-6-6: WBC Histogram Error-T1 (2A)

5) **2B Histogram having high UD but without T1**

WBC is flagged with WU. All other parameters are flagged with T1 and their data are not output.

6) **3A Histogram with high T1 but without T2**

WBC is not flagged. F1 flag is added to lymphocyte parameters (LYM%, LYM#). Mixed cell and neutrophil parameters (MXD%, NEUT%, MXD#, NEUT#) are flagged with T2 and their data are not output.

● WBC Histogram Error-T2 (3A)

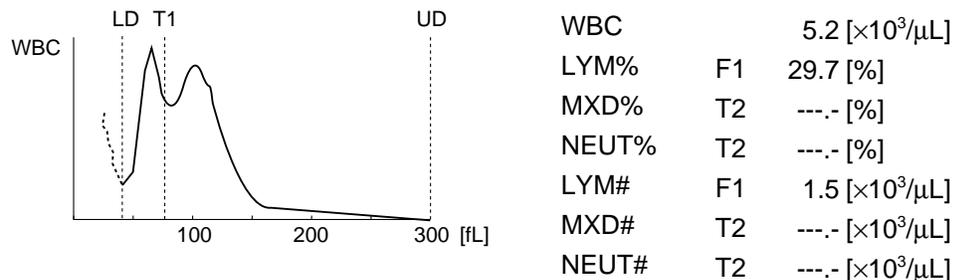


Figure 9-6-7: WBC Histogram Error-T2 (3A)

7) **3B Histogram with high T1 but without T2, and high in UD frequency**

WBC is flagged with WU and lymphocyte parameters (LYM%, LYM#) are flagged with F1. Mixed cell and neutrophil parameters (MXD%, NEUT%, MXD#, NEUT#) are flagged with T2 and their data are not output.

8) **3C Histogram with T1 but without T2**

WBC and lymphocyte parameters (LYM%, LYM#) are not flagged as the histogram error. Mixed cell and neutrophil parameters (MXD%, NEUT%, MXD#, NEUT#) are flagged with T2 and data are not output. WBC shown below exceeds the upper Patient Mark Limits.

● WBC Histogram Error-T2 (3C)

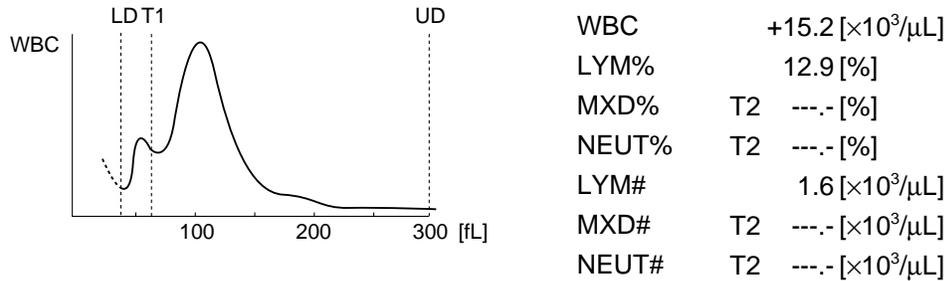


Figure 9-6-8: WBC Histogram Error-T2 (3C)

9) **3D Histogram with high T1 but no T2, and with high UD**

WBC is flagged with WU. Lymphocyte parameters (LYM%, LYM#) are not flagged. Mixed cell and neutrophil parameters (MXD%, NEUT%, MXD#, NEUT#) are flagged with T2 and their data are not output.

10) **4A Histogram with high T1**

WBC and neutrophil parameters (NEUT%, NEUT#) are not flagged. Lymphocyte parameters (LYM%, LYM#) are flagged with F1 and mixed cell parameters (MXD%, MXD#) are flagged with F2.

● WBC Histogram Error - F1 (4A)

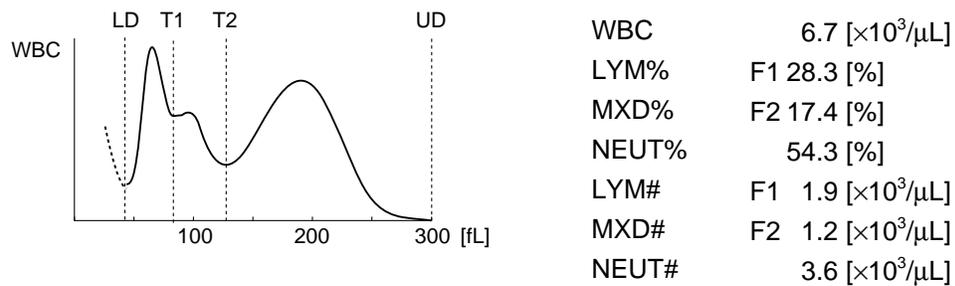


Figure 9-6-9: WBC Histogram Error - F1 (4A)

11) **4B Histogram with high T1 and UD**

WBC is flagged with WU, lymphocyte parameters (LYM%, LYM#) are flagged with F1, and mixed cell parameters (MXD%, MXD#) with F2. Neutrophil parameters (NEUT%, NEUT#) are not flagged.

12) 4C Histogram with high T1 and high T2

WBC is not flagged. Lymphocyte parameters (LYM%, LYM#) are flagged with F1, mixed cell parameters (MXD%, MXD#) with F2, and neutrophil parameters (NEUT%, NEUT#) with F3.

- WBC Histogram Error - F1 (4C)

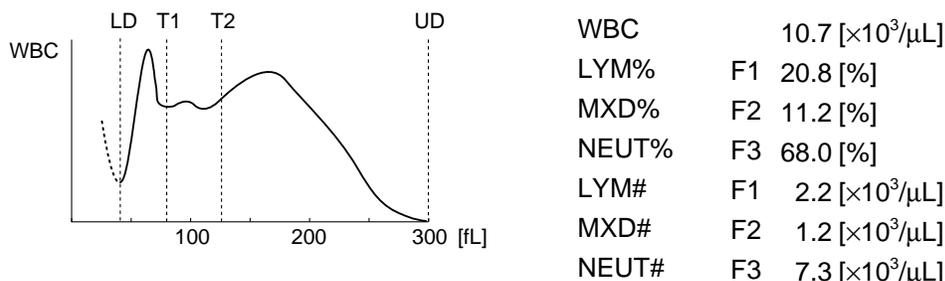


Figure 9-6-10: WBC Histogram Error - F1 (4C)

13) 4D Histogram high in all T1, T2, and UD

WBC data are output with WU flag, lymphocyte parameters (LYM%, LYM#) with F1 flag, mixed cell parameters (MXD%, MXD#) with F2 flag, and neutrophil parameters (NEUT%, NEUT#) with F3 flag.

14) 5A Histogram with high T2

Histogram error flag is not added to WBC and lymphocyte parameters (LYM%, LYM#). Mixed cell parameters (MXD%, MXD#) are flagged with F2, and neutrophil parameters (NEUT%, NEUT#) with F3 flag. WBC and MXD% exceed the upper Patient Mark Limits.

- WBC Histogram Error - F2 (5A)

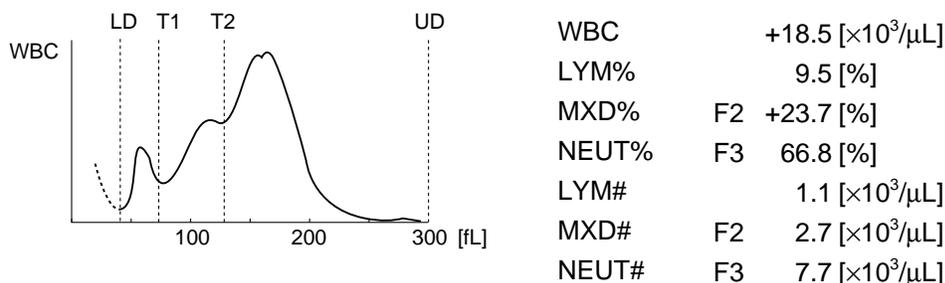


Figure 9-6-11: WBC Histogram Error - F2 (5A)

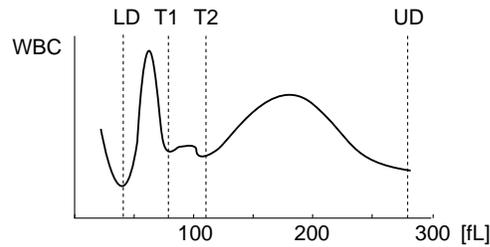
15) 5B Histogram with high T2 and high UD

WBC is flagged with WU and lymphocyte parameters (LYM%, LYM#) are not flagged. Mixed cell parameters (MXD%, MXD#) are flagged with F2, and neutrophil parameters (NEUT%, NEUT#) with F3.

16) 6 Histogram with high UD

WBC is flagged with WU and other parameters are not flagged. WBC in this instance exceeds the upper Patient Mark Limits.

● WBC Histogram Error - WU (6)



WBC	WU+ 15.4 [$\times 10^3/\mu\text{L}$]
LYM%	24.5 [%]
MXD%	7.5 [%]
NEUT%	68 [%]
LYM#	3.3 [$\times 10^3/\mu\text{L}$]
MXD#	1.0 [$\times 10^3/\mu\text{L}$]
NEUT#	8.1 [$\times 10^3/\mu\text{L}$]

Figure 9-6-12: WBC Histogram Error - WU (6)

17) 7 The particle count equal to or less than LD is higher than the range.

PLT is flagged with AG and other parameters are not flagged.

6.2 Analysis of RBC/PLT Histogram

1. RBC Histogram

As mentioned earlier, RBC are determined as particle counts between two discriminators (LD) and (UD) which are automatically counted in the ranges of 25 - 75 fL and 200 - 250 fL, respectively.

As to histogram, check is made for relative frequency errors on respective discriminator levels, for more than one peak, and for distribution width error.

In addition, this instrument is capable of expressing RBC distribution width (RDW) by two methods below:

RDW-CV (RBC Distribution Width - Coefficient of Variation) is calculated by the formula below, after determining points L1 and L2 for 68.26% of the entire particle area:

- Calculation of RDW-CV

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

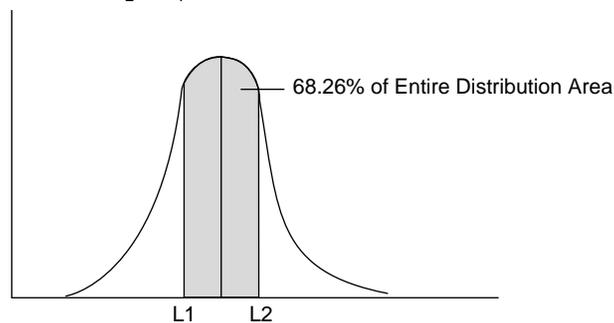


Figure 9-6-13: Calculation of RDW-CV

RDW-SD (RBC Distribution Width - Standard Deviation) is set on 20% frequency level with the peak taken as 100%.

- Definition of RDW-SD

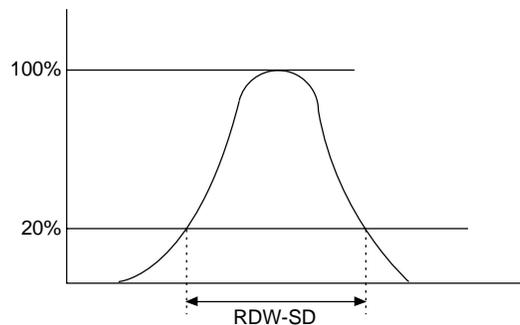


Figure 9-6-14: Definition of RDW-SD

2. PLT Histogram

Platelet histogram is analyzed using three discriminators: two discriminators (LD) and (UD) - determined automatically between 2 - 6 fL and between 12 - 30 fL, respectively -and the fixed discriminator at 12 fL. Regarding PLT histogram, check is made to see that there are no relative frequency errors at discriminators (LD) and (UD), distribution width error, and there is a single peak.

1) PDW (PLT Distribution Width)

PDW is the distribution width on 20% frequency level with the peak taken as 100%. The unit applied is fL (femto = 10⁻¹⁵L).

- Definitions of PDW and P-LCR

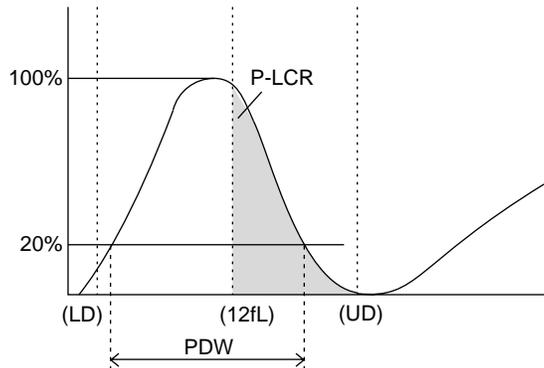


Figure 9-6-15: Definitions of PDW and P-LCR

2) MPV (Mean Platelet Volume)

MPV is calculated by the following formula:

$$MPV (fL) = \frac{PCT (\%)}{PLT (\times 10^3 / \mu L)} \times 1000$$

Where PCT (%) represents the value weighted with PLT frequency and is called platelet-crit or platelet volume ratio. The analysis method used is the same as mentioned in HCT analysis principle 4.2 *RBC/PLT Analysis Flow* in this chapter.

3) P-LCR (Large Platelet Ratio)

This is the ratio of large platelets exceeding 12 fL discriminator and is calculated as the ratio of the particle count between the 12-fL fixed discriminator and Upper discriminator (UD) to the particle count between Lower discriminator (LD) and Upper discriminator (UD).

3. RBC Histogram Error Flag

When RBC histogram is not normal, a histogram error flag is added to the corresponding parameter of the analysis value. Those histogram error flags are listed in the order of higher priority. When two or more flags are applicable to a parameter, the highest-priority flag is used.

RL: Relative frequency for LOWER discriminator (LD) exceeds the range. Probable cause is the effect of noise, RBC morphological change, platelet coagulation, or the like.

RU: Relative frequency for UPPER discriminator (UD) exceeds the range. Probable cause is the effect of noise.

MP: Two or more peaks in histogram.

DW: Particle distribution width error for 20% frequency with the peak taken as 100%. When the 20% frequency does not cross the histogram two times, this flag is attached.

- Matching of eight kinds of RBC histogram error flags

					RBC Histogram Error Flag Output								
					[1]								[2]
Case No.	LD	UD	DW	MP	RBC	HCT	MCV	MCH	MCHC	PLT	RDW-SD	RDW-CV	HOST
1A	High	/	○	○	RL	RL	RL	RL	RL	RL	RL	RL	1
1B	High	/	×	○	RL	RL	RL	RL	RL	RL	DW	RL	1
1C	High	/	/	×	RL	RL	RL	RL	RL	RL	MP	MP	1
2A	○	High	○	○	RU	RU	RU	RU	RU	RU	RU	RU	2
2B	○	High	×	○	RU	RU	RU	RU	RU	RU	DW	RU	2
2C	○	High	/	×	RU	RU	RU	RU	RU	RU	MP	MP	2
3	○	○	×	○							DW		3
4	○	○	/	×							MP	MP	4

[1]: Output flag to LCD screen, built-in printer.
 [2]: Output flag to serial interface (if incorporated as option).
 ○: • When analysis results of LD and UD are normal
 • In the case of DW, when RDW-SD could be analyzed
 • In the case of MP, when RBC histogram has a single peak
 High: Frequencies of LD and UD are higher than the range
 ×: • In the case of DW, when RDW-SD could not be analyzed
 • In the case of MP, when RBC histogram has two or more peaks
 /: Any of "○", "×," and "High" is applicable.

Table 9-6-2: RBC Histogram Error Flags

NOTE: • Since CBC8 parameters only are output in the pre-diluted mode, a flag is not output to RDW-SD or RDW-CV.

1) **1A Histogram with high frequency for LD**

RBC, HCT, MCV, MCH, MCHC, PLT, and particle distribution width data parameters are flagged with RL. MCV and RDW-SD exceed the upper Patient Mark Limits, and MCHC falls below the lower Patient Mark Limits.

● RBC Histogram Error - RL (1A)

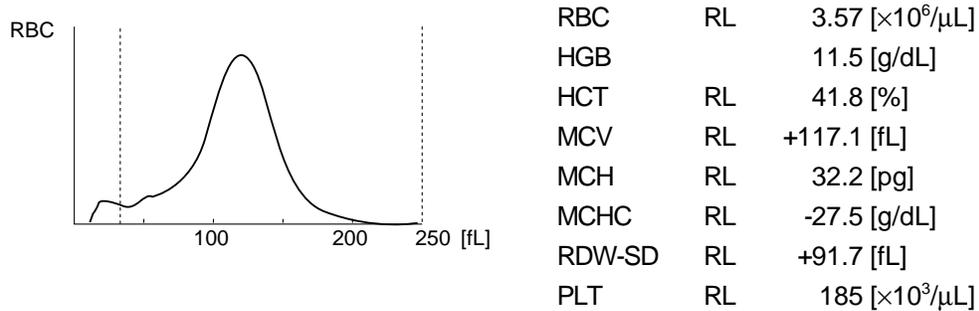


Figure 9-6-16: RBC Histogram Error - RL (1A)

2) **1B High frequency for LD with 20% particle distribution width error**

RBC, HCT, MCV, MCH, MCHC, and PLT parameters are flagged with RL. Of the particle distribution width data, RDW-CV is flagged with RL and its data are output. RDW-SD parameter is flagged with DW and its data are not output.

3) **1C High LD with two or more peaks**

RBC, HCT, MCV, MCH, MCHC, and PLT parameters are flagged with RL. RDW-CV is flagged with MP and its data are output, while RDW-SD is flagged with MP but its data are not output.

4) **2A Frequency high for UD**

RBC, HCT, MCV, MCH, MCHC, PLT, and particle distribution width data parameters are flagged with RU. In this instance, flags to indicate that their data are out of Patient Mark Limits are added to MCV, MCHC, and RDW-SD.

● RBC Histogram Error - RU (2A)

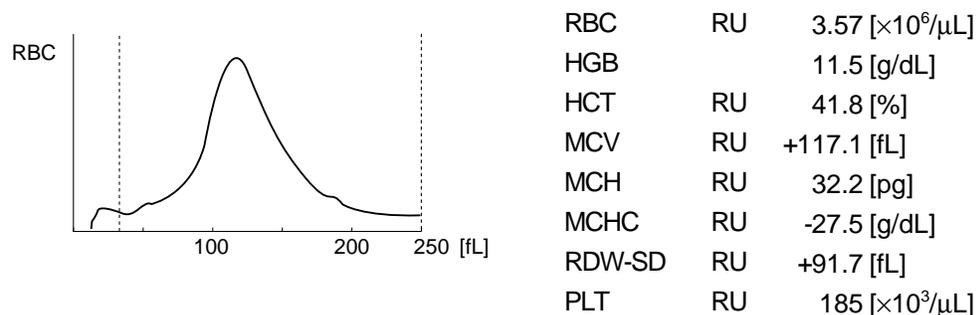


Figure 9-6-17: RBC Histogram Error - RU (2A)

- 5) **2B High UD with 20%-frequency distribution width error**
 RBC, HCT, MCV, MCH, MCHC, and PLT parameters are flagged. Out of the particle distribution width data, RDW-CV is flagged with RU and its data are output.
 RDW-SD is flagged with DW and its data are not output. In this instance, MCV and MCHC are out of Patient Mark Limits.

● RBC Histogram Error - RU, DW (2B)

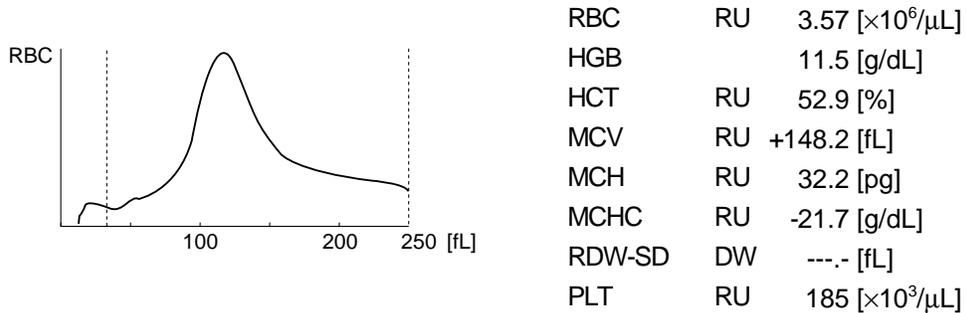


Figure 9-6-18: RBC Histogram Error - RU, DW (2B)

- 6) **2C High UD with two or more peaks**
 RBC, HCT, MCV, MCH, MCHC, and PLT parameters are flagged with RU. As to particle distribution width data, RDW-CV is flagged with MP and its data are output, while RDW-SD is also flagged with MP but its data are not output.
- 7) **3 20%-frequency particle distribution width error**
 RBC, HCT, MCV, MCH, MCHC, and PLT parameters are not flagged. As to the particle distribution width data, RDW-CV data are output without flagging, while RDW-SD data are flagged with DW and their data are not output.
- 8) **4 Two or more peaks**
 RBC, HCT, MCV, MCH, MCHC, and PLT parameters are not flagged. As to the particle distribution width data, RDW-CV data are output with MP flag. RDW-SD is flagged with MP and its data are not output. In this instance, RDW-CV is out of Patient Mark Limits.

● RBC Histogram Error - MP (4)

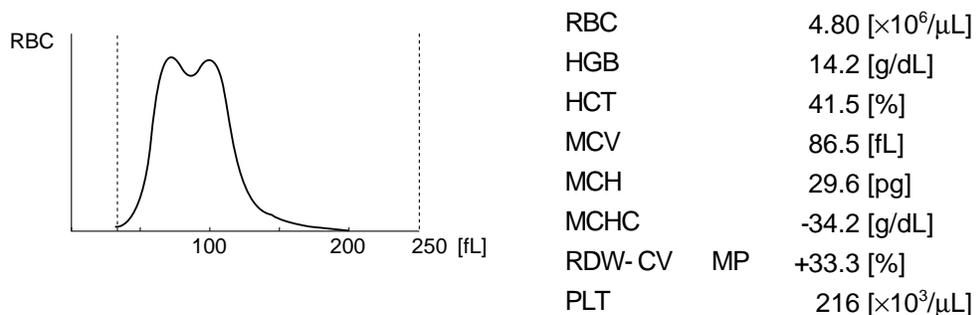


Figure 9-6-19: RBC Histogram Error - MP (4)

4. Platelet Histogram Error Flag

When the platelet histogram is not normal, a histogram error flag is added to the corresponding parameter of the analysis value. Those histogram error flags - used with the particle distribution analysis unit mounted, are listed in the order of higher priority.

When two or more flags are applicable to a parameter, the highest priority flag is used.

PL: Relative frequency for LOWER discriminator (LD) exceeds the range. Probable cause is the effect of noise and etc.

PU: Relative frequency for UPPER discriminator (UD) exceeds the range. Probable cause is the effect of platelet agglutination, noise interference, and etc.

MP: Two or more peaks in histogram

DW: Particle distribution width error for 20% frequency with the peak taken as 100%. When the 20% frequency does not cross the histogram two times, this flag is attached.

- Matching of eight kinds of platelet histogram error flags

Case No.					Platelet Histogram Error Flag Output					
	LD	UD	DW	MP	[1]			[2]		
	PLT	PDW	MPV	P-LCR	HOST					
1A	High	/	○	○	PL	PL	PL	PL	PL	1
1B	High	/	×	○	PL	DW	PL	PL	PL	1
1C	High	/	/	×	PL	MP	PL	PL	PL	1
2A	○	High	○	○	PU	PU	PU	PU	PU	2
2B	○	High	×	○	PU	DW	PU	PU	PU	2
2C	○	High	/	×	PU	MP	PU	PU	PU	2
3	○	○	×	○		DW	DW	DW	DW	3
4	○	○	/	×		MP	MP	MP	MP	4

[1]: Output flag to LCD screen, built-in printer.
 [2]: Output flag to serial interface (if incorporated as option).
 ○: • When analysis results of LD and UD are normal
 • In the case of DW, when PDW could be analyzed
 • In the case of MP, when PLT histogram has a single peak
 High: Frequencies of LD and UD are higher than the range.
 ×: • In the case of DW, when PDW could not be analyzed
 • In the case of MP, when PLT histogram has two or more peaks
 /: Any of "○", "×", and "High" is applicable.

Table 9-6-3: Platelet Histogram Error Flags

NOTE: • Since CBC8 parameters only are output in the pre-diluted mode, flag output is limited to a PLT parameter.

- 1) **1A High frequency for LD**
 PLT, PDW, MPV, and P-LCR parameters are flagged with PL.

- Platelet Histogram Error - PL (1A)

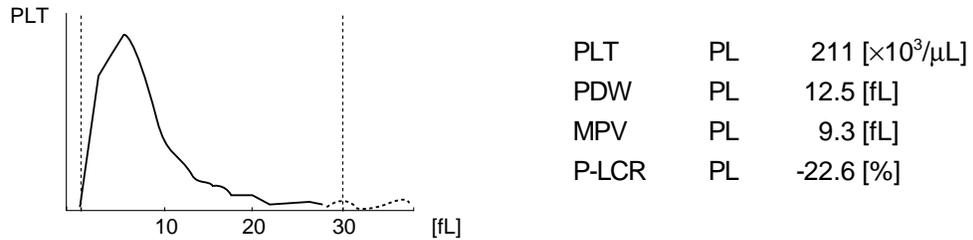


Figure 9-6-20: Platelet Histogram Error - PL (1A)

- 2) **1B High LD with 20%-frequency distribution width error**
 PLT parameter is flagged with PL. Particle distribution width (PDW) is flagged with DW and its data are not output.
 MPV and P-LCR are flagged with PL and their data are not output.

- 3) **1C High LD with two or more peaks**
 PLT parameter is flagged with PL. Particle distribution width (PDW) is flagged with MP and its data are not output.
 MPV and P-LCR are flagged with PL and their data are not output.

- 4) **2A High UD**
 PLT, PDW, MPV, and P-LCR parameters are flagged with PU.

- 5) **2B High UD with 20%-frequency particle distribution width error**
 PLT parameter is flagged with PU. Particle distribution width (PDW) is flagged with DW and its data are not output.
 MPV and P-LCR are flagged with PU and their data are not output.

- Platelet Histogram Error - PU (2B)

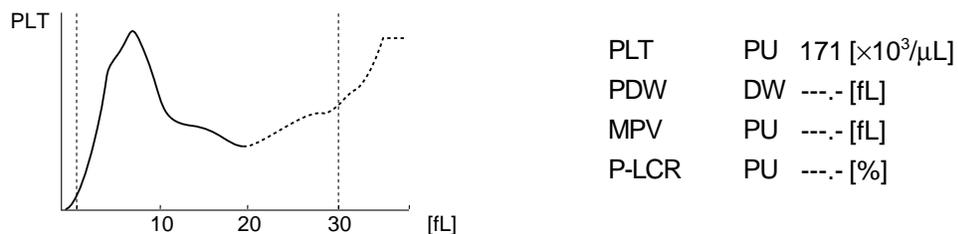


Figure 9-6-21: Platelet Histogram Error - PU (2B)

6) 2C High UD with two or more peaks

PLT parameter is flagged with PU. Particle distribution width (PDW) is flagged with MP and its data are not output. MPV and P-LCR are flagged with PU and their data are not output.

7) 3 20%-frequency particle distribution width error

PLT is not flagged. PDW, MPV, and P-LCR are flagged with DW and their data are not output.

- Platelet Histogram Error - DW (3)

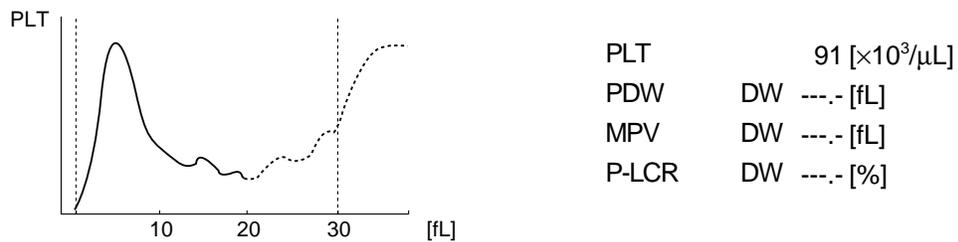


Figure 9-6-22: Platelet Histogram Error - DW (3)

8) 4 Two or more peaks

PLT is not flagged. Other parameters are flagged with MP and their data are not output.

- Platelet Histogram Error - MP (4)

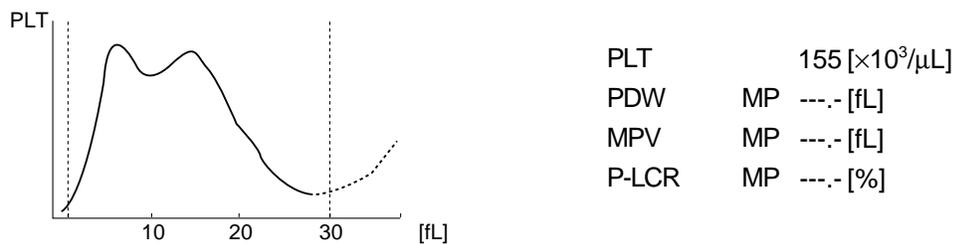


Figure 9-6-23: Platelet Histogram Error - MP (4)

7. ELECTRIC SYSTEM

The microprocessor in the main unit controls the hydraulic system's solenoid valves and master valves, thus regulating the flow of samples, reagents, and waste in the hydraulic system.

Electric signals received from various transducers go through the analogue circuit for electrical waveform-processing, and to the microcomputer. The microcomputer converts the analogue signals into digital signals for the calculation.

The WBC, RBC, and PLT cell signals are sent to the respective waveform-processing circuits in the analogue circuit, where the noise in signals is eliminated to acquire the required cell signals only. The microcomputer converts the A/D-converted cell signals into particle distribution data, and outputs them to the built-in printer or to the host computer (optional).

To calculate HGB, absorbance of only the diluent (background) is deducted from samples' absorbance. The beam that has passed through the fluid is detected by the photo diode. And the signals is photoelectrically converted, A/D converted, and then sent to the HGB counting circuit for the calculation of the absorbance.

Electric Diagram

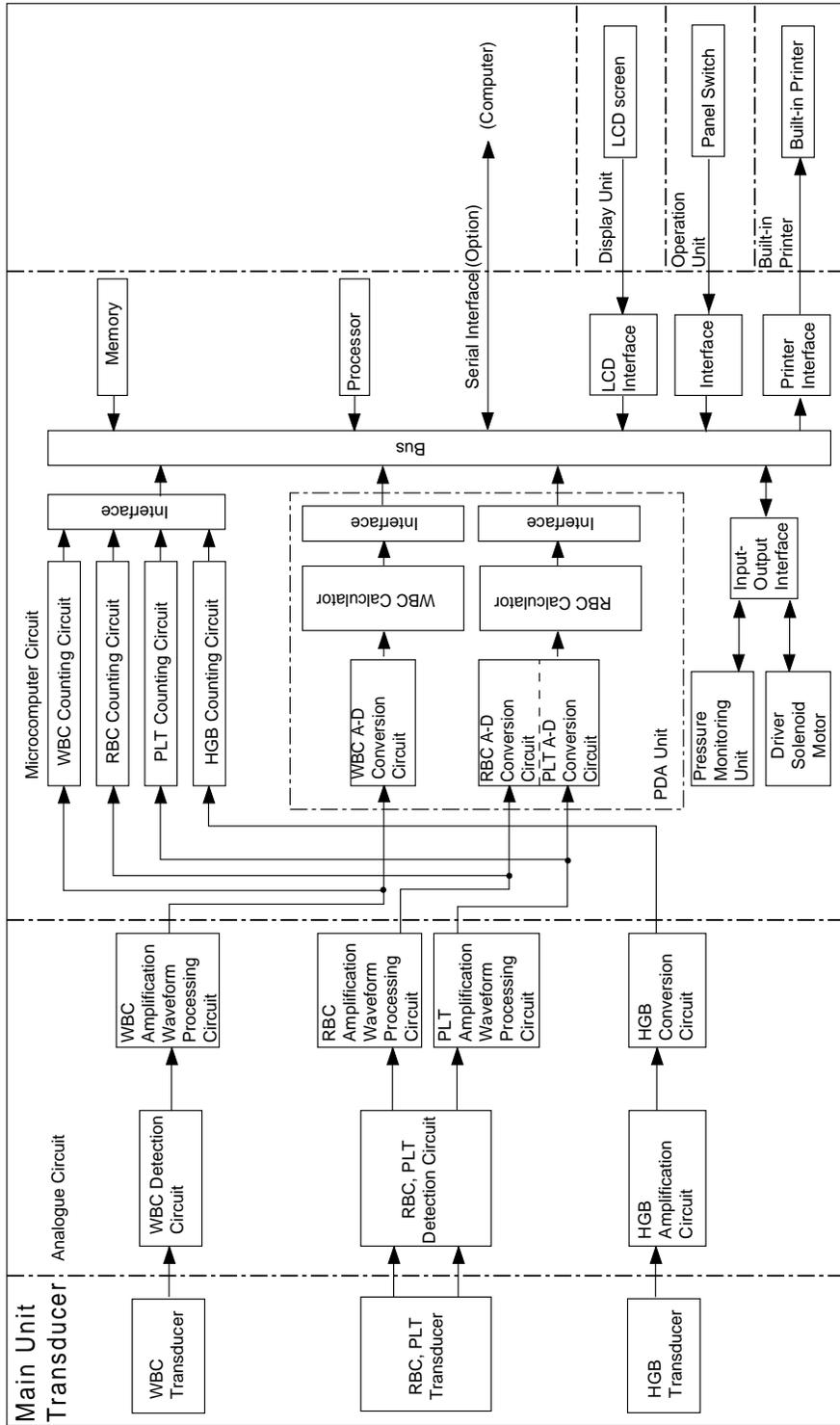


Figure 9-7-1: Electric Diagram

8. NAMES AND FUNCTIONS OF INSTRUMENTS

8.1 Front Panel

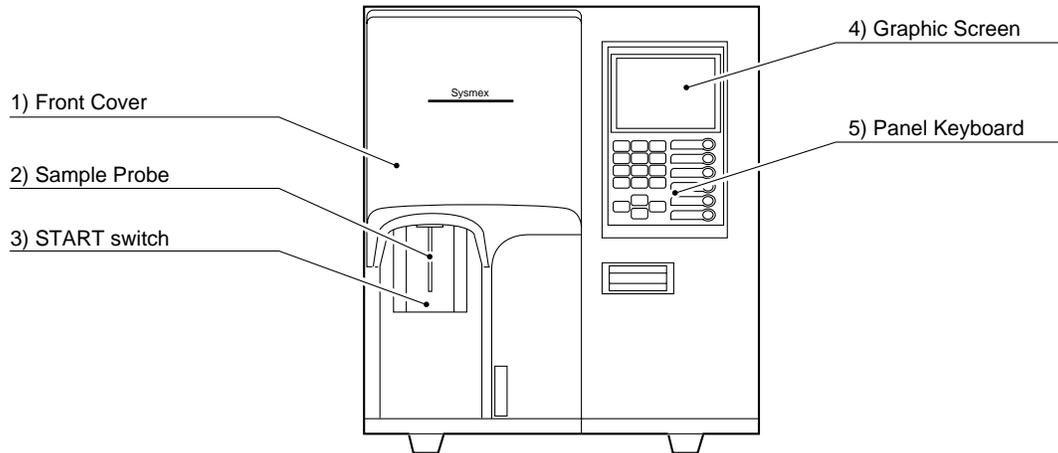


Figure 9-8-1: Front Panel

- 1) **Front Cover**
The front cover can be opened to the right by your hands. It is opened to replace lyse containers, check or clean the interior of measuring unit.
- 2) **Sample Probe**
The sample probe is used to aspirate sample in the whole blood and pre-diluted modes.
- 3) **START Switch**
This switch starts whole blood mode analysis and pre-diluted mode analysis.
- 4) **Graphic Screen**
This displays Sample Nos., analysis results, instrument status, error messages, etc. For detail, refer to *Chapter 1, Section 8: GRAPHIC SCREEN*.
- 5) **Panel Keyboard**
This keyboard allows basic operations such as entry of Sample No. and selection of analysis parameters. For detail, refer to *Chapter 1, Section 7: PANEL KEYBOARD*.

8.2 Front Interior

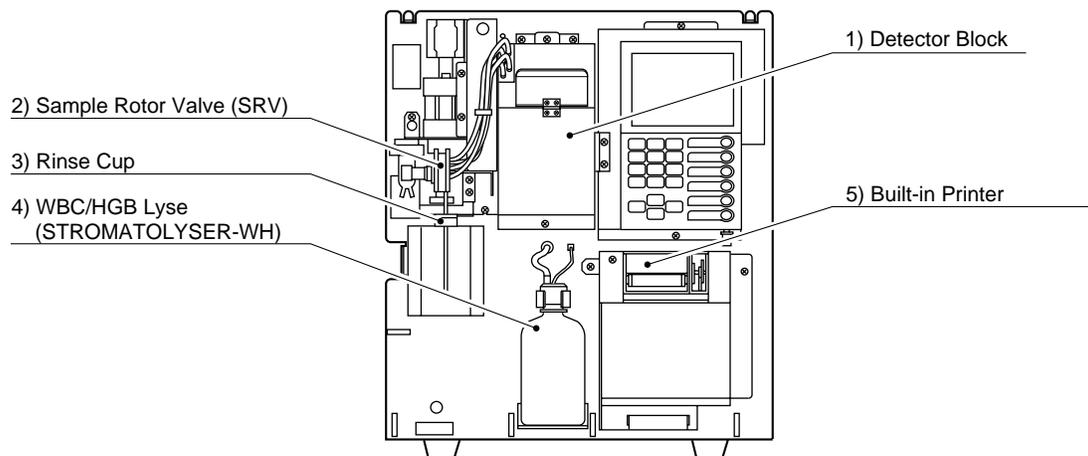


Figure 9-8-2: Front Interior

- 1) **Detector Block**
Incorporates RBC transducer, WBC transducer, and HGB flow cell.
- 2) **Sample Rotor Valve (SRV)**
Makes volumetric measurement of aspirated blood.
- 3) **Rinse Cup**
Cleans the sample probe.
- 4) **WBC/HGB Lyse (STROMATOLYSER-WH)**
Reagent to measure WBC/HGB
- 5) **Built-in Printer**
Prints analysis data, error messages, etc.

8.3 Right Side Panel

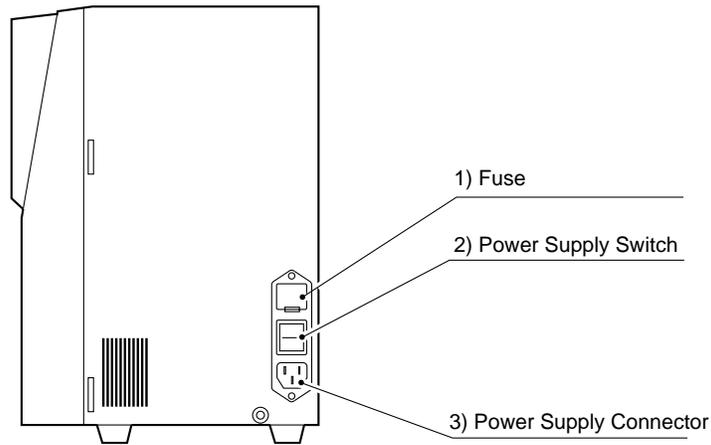


Figure 9-8-3: Right Side Panel

1) Fuse

Replace with provided time-lag type fuse. The rating will be different depending on the instrument specification.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5109-1	Fuse 250 V 3.15 A ST4-3.15A-N1	Time Lag
220/240 VAC	266-5292-6	Fuse 250 V 2 A No. 19195	Time Lag

! WARNING • To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

! CAUTION • For continued protection against risk of fire, use the fuse of specified type and rating.

2) Power Supply Switch

Turns on and off the main unit power supply.

CAUTION: • Avoid turning this switch ON and OFF continuously in short duration. This will overload the fuse and may cause fuse blown.

3) Power Supply Connector

Using the furnished power supply cord, this connector supplies power from the outlet.

8.4 Left Side Panel

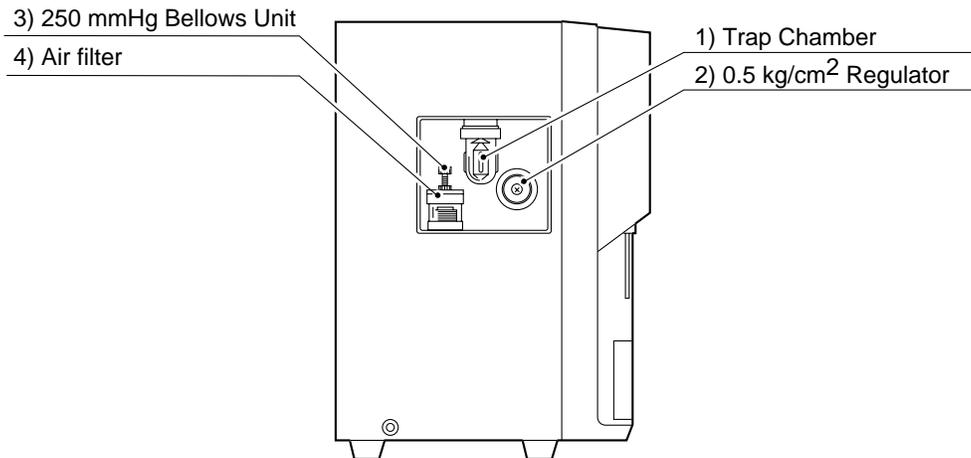


Figure 9-8-4: Left Side Panel

- 1) **Trap Chamber**
Prevents reagent, etc. from flowing into the vacuum pump of the compressor when an error occurs with the instrument.
- 2) **0.5 kg/cm² Regulator**
Regulates pressure to 0.5 kg/cm².
- 3) **250 mmHg Bellows Unit**
Regulates vacuum to 250 mmHg vacuum.
- 4) **Air Filter**
Prevents dirt and dust from entering the bellows.

8.5 Left Side Interior

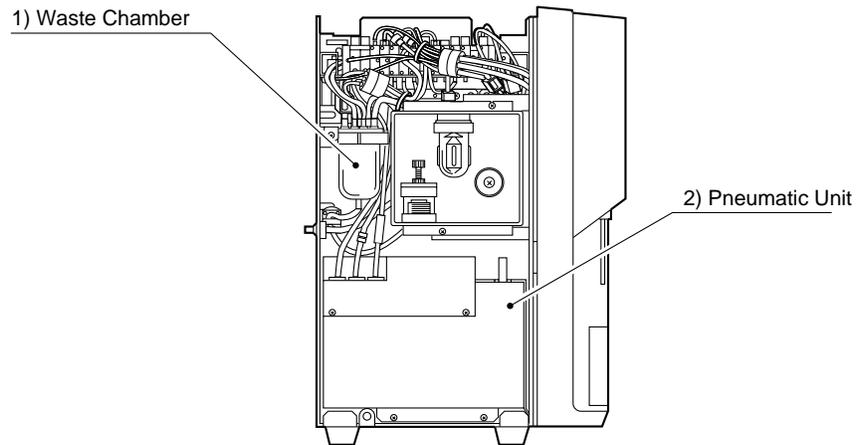


Figure 9-8-5: Left Side Interior

- 1) **Waste Chamber**
Collects wastes from transducers and mixing chambers.
- 2) **Pneumatic Unit**
Supplies pressure and vacuum.

<p>CAUTION: • Do no open the left face unless your Sysmex service representative asks you to.</p>

8.6 Rear Panel

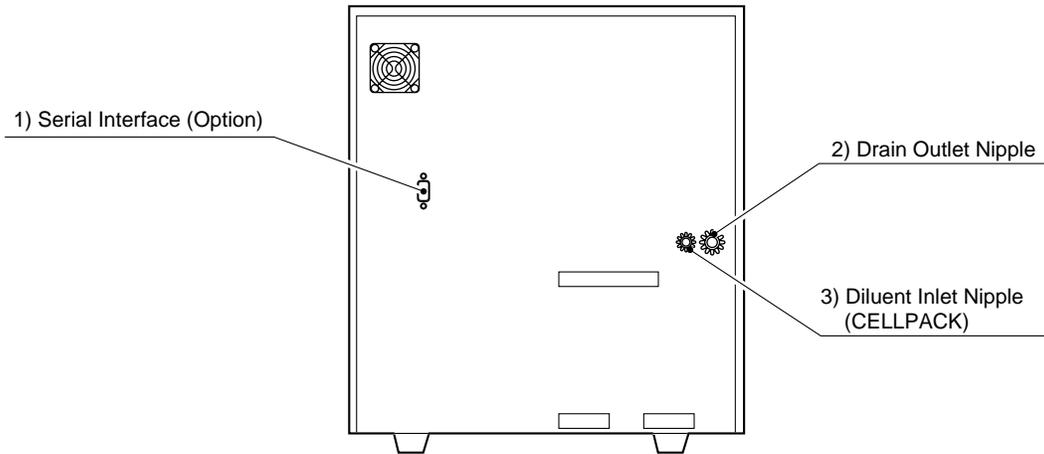


Figure 9-8-6: Rear Panel

- 1) **Serial Interface (Option)**
Connector for communicating with the host computer
- 2) **Drain Outlet Nipple**
This nipple drains waste. It connects with the drain sewer or waste tank.
- 3) **Diluent Inlet Nipple (CELLPACK)**
This nipple aspirates diluent. It connects with the diluent container.

CHAPTER 10

INSTRUMENT SETUP

1.	INTRODUCTION	10-1
2.	SYSTEM SETUP	10-2
3.	DATE/TIME SETTINGS	10-7
4.	PATIENT LIMIT	10-10
5.	QC SETTINGS	10-13
6.	HOST SETTINGS (OPTION)	10-16
7.	PRINTER SETTINGS	10-21
8.	PRINT SET VALUES	10-24
9.	PERIPHERAL SETTINGS	10-25
10.	FACTORY SETTINGS	10-27

1. INTRODUCTION

Your Sysmex service representative performs the settings of the instrument at time of installation. The settings can be changed by using this program. This chapter describes how to use this setting program.

System Setup

Sets up the instrument system status.

Date/Time

Sets date/time of the built-in clock.

Patient Limit

Sets upper and lower Patient Mark Limits to check for error in analysis data.

QC Settings

Selects between \bar{x} control and L-J control as the QC method, and sets the output method of QC data.

Host Settings (when the optional serial interface is incorporated)

Sets the interface conditions for transferring data to the host computer.

Printer Settings

Sets the output selection and output conditions of the built-in printer.

Print Set Values

Prints all the contents of the settings by the built-in printer.

Peripheral Setting

Sets whether to Use or Not Use of the built-in printer or the host computer (option) output.

CAUTION: • The setting program can be run only when the instrument is ready.

NOTE:

- Menu selection method
 - (1) Cursor selection (explained in this Manual)
Using [▲] or [▼] key, move the cursor to a desired program and press [ENTER] key to set.
 - (2) Direct key selection
Using the numeric keys, enter a menu number of the program you want to set, thus selecting the menu.
The menu number is displayed on the Menu screen.
- Change set values and move the cursor to the next parameter using [▲] or [▼] key ([◀] or [▶] key also can be used in Patient Limit setting) or press [ENTER] key. This sets the settings.

2. SYSTEM SETUP

This program is used to set unit system, display language, WBC analysis parameters, and RDW calculation method.

How to Setup System Status

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

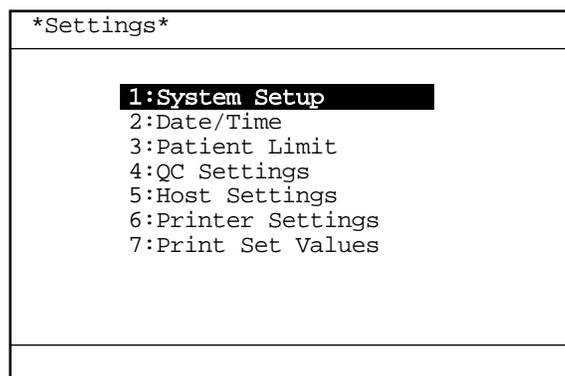


Figure 10-2-1: Setting Menu Screen

NOTE: • "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "1: System Setup."

- (5) Press [ENTER] key. The current setting status is displayed on the System Setup screen.

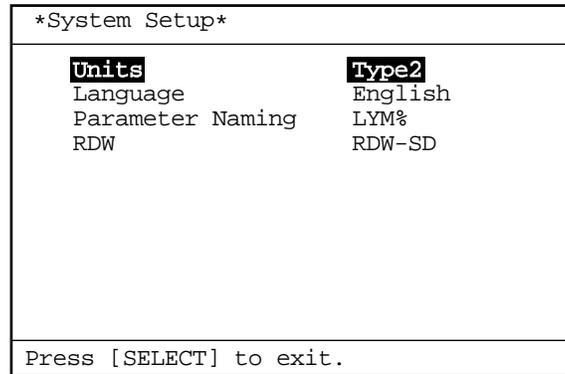


Figure 10-2-2: System Setup Screen

- (6) Using [▲] or [▼] key, move the cursor to select the desired set parameter. For System Setup, four parameters can be set.
- (7) Using [◀] or [▶] key, select the content of settings. Each time you press the key, the content of settings changes.
- (8) Press [ENTER] key. The content of settings is set and the cursor moves to the next set parameter.

NOTE: • The settings can also be set when you press [▲] or [▼] key after changing the content of settings.

1) Unit Setting

Sets the unit system for displaying analysis data. The unit can be selected from the following six kinds:

Settings	Unit System	Settings	Unit System
Type 1	For Japan	Type 4	Dutch SI
Type 2	For General Export	Type 5	Standard SI
Type 3	Canada SI	Type 6	Hong Kong SI

Table 10-2-1: Unit Setting

For the detail of unit system, refer to the following table:

Item	For Japan		For General Export		Canada SI	
	Decimal point	Unit	Decimal point	Unit	Decimal point	Unit
WBC	####	×10 ² /μL	###.#	×10 ³ /μL	###.#	×10 ⁹ /L
RBC	####	×10 ⁴ /μL	##.##	×10 ⁶ /μL	##.##	×10 ¹² /L
HGB	###.#	g/dL	###.#	g/dL	####	g/L
HCT	###.#	%	###.#	%	#.###	L/L
MCV	###.#	fL	###.#	fL	###.#	fL
MCH	###.#	pg	###.#	pg	###.#	pg
MCHC	###.#	g/dL	###.#	g/dL	####	g/L
PLT	###.#	×10 ⁴ /μL	####	×10 ³ /μL	####	×10 ⁹ /L
LYM%	###.#	%	###.#	%	#.###	
MXD%	###.#	%	###.#	%	#.###	
NEUT%	###.#	%	###.#	%	#.###	
LYM#	####	×10 ² /μL	###.#	×10 ³ /μL	###.#	×10 ⁹ /L
MXD#	####	×10 ² /μL	###.#	×10 ³ /μL	###.#	×10 ⁹ /L
NEUT#	####	×10 ² /μL	###.#	×10 ³ /μL	###.#	×10 ⁹ /L
RDW-SD	###.#	fL	###.#	fL	###.#	fL
RDW-CV	###.#	%	###.#	%	#.###	
MPV	###.#	fL	###.#	fL	###.#	fL
PDW	###.#	fL	###.#	fL	###.#	fL
P-LCR	###.#	%	###.#	%	#.###	

Item	Dutch SI		Standard SI		Hong Kong SI	
	Decimal point	Unit	Decimal point	Unit	Decimal point	Unit
WBC	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L
RBC	##.##	×10 ¹² /L	##.##	×10 ¹² /L	##.##	×10 ¹² /L
HGB	###.#	mmol/L	####	g/L	###.#	g/dL
HCT	#.###	L/L	#.###		#.###	
MCV	###.#	fL	###.#	fL	###.#	fL
MCH	####	amol	###.#	pg	###.#	pg
MCHC	###.#	mmol/L	####	g/L	###.#	g/dL
PLT	####	×10 ⁹ /L	####	×10 ⁹ /L	####	×10 ⁹ /L
LYM%	#.###		#.###		###.#	%
MXD%	#.###		#.###		###.#	%
NEUT%	#.###		#.###		###.#	%
LYM#	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L
MXD#	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L
NEUT#	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L	###.#	×10 ⁹ /L
RDW-SD	###.#	fL	###.#	fL	###.#	fL
RDW-CV	#.###		#.###		###.#	%
MPV	###.#	fL	###.#	fL	###.#	fL
PDW	###.#	fL	###.#	fL	###.#	fL
P-LCR	#.###		#.###		###.#	%

Table 10-2-2: Details of Unit System

2) Language Setting

Set the language for displaying on the screen. The language can be selected from the three kinds listed below:

Settings	Display language
Japanese	Japanese
English	English
Chinese	Chinese

Table 10-2-3: Language Setting

3) Parameter Name Setting

Set WBC analysis parameter names. The parameter can be selected from the following two kinds:

Settings	Analysis Parameter Name
W-SCR	W-SCR
	W-MCR
	W-LCR
	W-SCC
	W-MCC
	W-LCC
LYM%	LYM%
	MXD%
	NEUT%
	LYM#
	MXD#
	NEUT#

Table 10-2-4: Parameter Name Setting

4) RDW Setting

Set the RDW calculation method. The RDW calculation method can be selected from the following two kinds:

Settings	RDW Calculation Method
RDW-SD	RDW-SD
RDW-CV	RDW-CV

Table 10-2-5: RDW Setting

NOTE:

- The settings of system setup become valid from the next time you turn ON the instrument power.

- (9) When the setting of each parameter is completed, press [SELECT] key. The Setting Change Confirmation message appears.



Figure 10-2-3: Setting Change Confirmation Message

- (10) Using[◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."

[Cont.]: Returns to the System Setup screen. And the setting operation can be continued.

[Set]: Updates the settings and returns to the Analysis screen.

[Cancel]: Cancels the changed settings and returns to the Analysis screen.

- (11) Press [ENTER] to execute the selected process.

<p>NOTE:</p> <ul style="list-style-type: none">• When you change the system setup, always turn OFF then ON the power. Until you do this, the changed contents of the settings will not be reflected.

3. DATE/TIME SETTINGS

This instrument displays date/time on analysis data, using the built-in clock. This program is used to set the date/time for the built-in clock and date format.

How to Set Date/Time

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

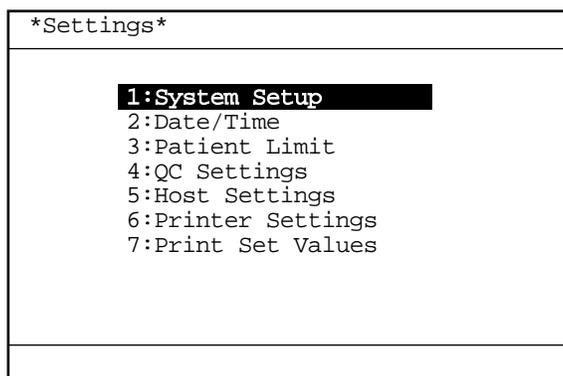


Figure 10-3-1: Setting Menu Screen

NOTE:

- "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "2: Date/Time."

- (5) Press [ENTER] key. The current setting status is displayed on the Date/Time screen.

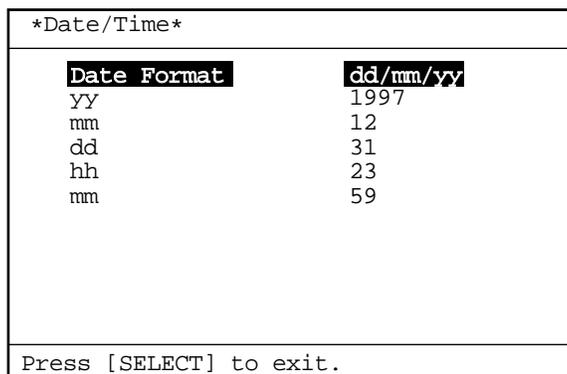


Figure 10-3-2: Date/Time Screen

- (6) Using [▲] or [▼] key, move the cursor to select the desired set parameter.
- (7) Using [◀], [▶], or the numeric keys, set each parameter. In setting the date format, use [◀] or [▶] key. Year, month, day, hour, and minute are entered using the numeric keys.
- (8) Press [ENTER] key. The content of the settings is set and the cursor moves to the next set parameter.

NOTE: • The settings can also be set when you press [▲] or [▼] key after changing the content of settings.

- 1) **Date Format Setting**
 Using [◀] or [▶] key, select the date format. The date format can be selected from the following three types. It changes each time you press the key.

Settings	Example of display
yy/mm/dd	97/12/31
mm/dd/yy	12/31/97
dd/mm/yy	31/12/97

Table 10-3-1: Date Format Setting

- 2) **Year Setting**
 Enter in the dominical year using the numeric keys.
- 3) **Month Setting**
 Enter using 1 - 12 from the numeric keys.

- 4) **Day Setting**
Enter using 0 - 31 from the numeric keys.
 - 5) **Hour Setting**
Enter in the 24-hour system using 0 - 23 from the numeric keys.
 - 6) **Minute Setting**
Enter using 0 - 59 from the numeric keys.
- (9) When the setting of each parameter is completed, press [SELECT] key.
The date entered is checked and when there is no setting error, the Setting Change Confirmation message is displayed.
If there is any setting error, the alarm sounds and the Setting Change Confirmation message is not displayed.

NOTE:

- About the date setting, the following items are checked:
Leap year check: whether 2/29 is set in non-leap year
Month/day check: whether 4/31, e.g., is set

**Figure 10-3-3: Setting Change Confirmation Message**

- (10) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
[Cont.]: Returns to the Date/Time screen. And the setting operation can be continued.
[Set]: Updates the settings and returns to the Analysis screen.
[Cancel]: Cancels the changed settings and returns to the Analysis screen.
- (11) Press [ENTER] key to execute the selected process.

4. PATIENT LIMIT

For Patient Limit, you can set Mark Limits.

The Mark Limits are the values set to determine whether analysis values are within the normal range or not. This program can be used to set the upper and lower Mark Limits for each analysis parameter.

When analysis data exceeds the upper Mark Limit, it is flagged with [+] mark, and when it exceeds the lower Mark Limit, it is flagged with [-] mark. Analysis data output to the built-in printer or the host computer is also attached with either marks.

How to Set Mark Limits

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

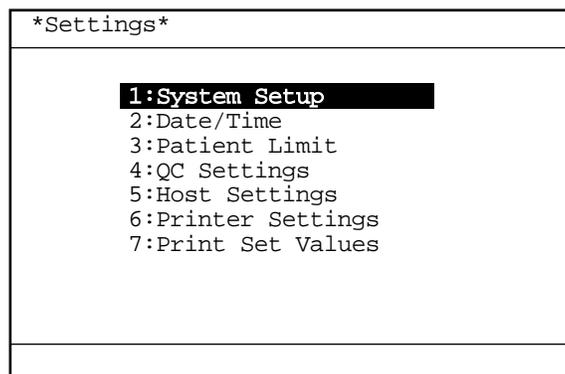


Figure 10-4-1: Setting Menu Screen

NOTE: • "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "3: Patient Limit."

- (5) Press [ENTER] key. The current setting status is displayed on the Patient Limit screen.

Patient Limit		
	LL	UL
WBC	3.0	15.0 ×10 ³ /μL
RBC	2.50	5.50 ×10 ⁶ /μL
HGB	8.0	17.0 g/dL
HCT	26.0	50.0 %
MCV	86.0	110.0 fL
MCH	26.0	38.0 pg
MCHC	31.0	37.0 g/dL
PLT	50	400 ×10 ³ /μL
LYM%	5.0	55.0 %
MXD%	1.0	20.0 %

Press [SELECT] to exit.

Figure 10-4-2: Patient Limit Screen

- (6) Using [▲] or [▼] key, move the cursor to select the desired set parameter.

NOTE:

- Total 19 setting parameters of Patient Limit are displayed. But not all of them can be displayed in one screen at a time. Therefore, scroll the screen using [▲] or [▼] key.

Patient Limit		
	LL	UL
MXD%	1.0	20.0 %
NEUT%	45.0	95.0 %
LYM#	0	0 ×10 ³ /μL
MXD#	0	0 ×10 ³ /μL
NEUT#	0	0 ×10 ³ /μL
RDW-SD	37.0	54.0 fL
RDW-CV	11.0	16.0 %
PDW	9.0	17.0 %
MPV	9.0	13.0 fL
P-LCR	13.0	43.0 %

Press [SELECT] to exit.

Figure 10-4-3: Scrolling the Screen

- (7) Using [◀] or [▶] key, move the cursor to select LL (Lower Limit) or UL (Upper Limit).
- (8) Enter the settings using the numeric keys.

- (9) Press [ENTER] key. The content of settings is set and the cursor moves to the next set parameter.

NOTE:

- When [▲], [▼], [◀], or [▶] key is pressed after entering, the contents of settings are also set.
- When both the upper and lower limits are set at "0," the judgment on patient limit is not executed.

- (10) When the setting of each parameter is completed, press [SELECT] key. When the set values are checked and there is no setting error, the Setting Change Confirmation message is displayed. In case Upper Limit \leq Lower Limit is set, the alarm sounds and the Setting Change Confirmation message is not displayed.



Figure 10-4-4: Setting Change Confirmation Message

- (11) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
[Cont.]: Returns to the Patient Limit screen. And the setting operation can be continued.
[Set]: Updates the settings and returns to the Analysis screen.
[Cancel]: Cancels the changed settings and returns to the Analysis screen.
- (12) Press [ENTER] key to execute the selected process.

5. QC SETTINGS

This program is used to set QC method and output method of QC data. Two kinds of QC methods are available with this instrument: \bar{X} control and L-J control. Select either of them that suits your purpose.

\bar{X} Control: Control blood is subjected to two consecutive analyses and the mean of them is used as the QC data. This method causes little influence on reproducibility in analysis.

L-J Control: This control uses the data from a single analysis of control blood as QC data. The control width in the L-J control is prone to influence in reproducibility in analysis, so that the control width is wider than in the case of \bar{X} control.

How to Set QC Settings

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

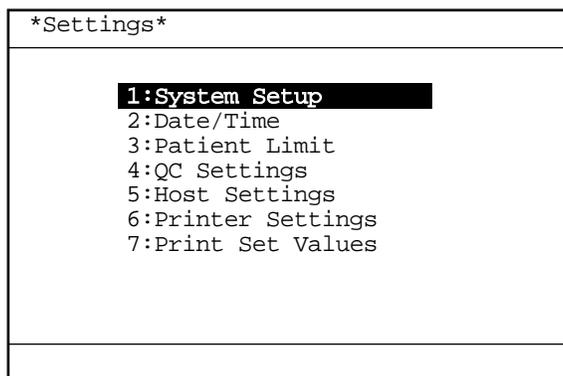


Figure 10-5-1: Setting Menu Screen

NOTE:

- "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "4: QC Settings."

- (5) Press [ENTER] key. The current setting status is displayed on the QC Settings screen.

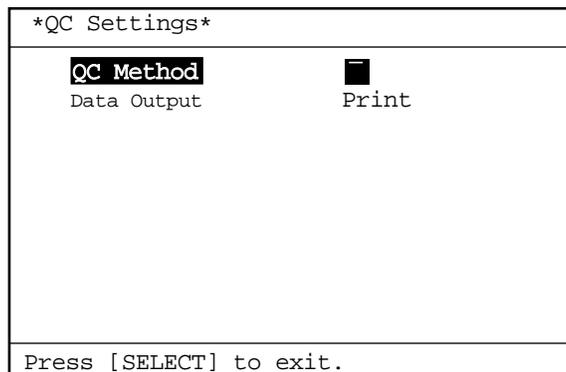


Figure 10-5-2: QC Settings Screen

- (6) Using [▲] or [▼] key, move the cursor to select the set parameter. QC settings can be made on two parameters.
- (7) Using [◀] or [▶] key, select the content of settings. The content of settings changes each time you press the key.
- (8) Press [ENTER] key. The content of setting is set and the cursor moves to the next analysis parameter.

NOTE: • The settings can also be set when you press [▲] or [▼] key after changing the content of settings.

- 1) **QC Method Setting**
Set the QC method. The QC method can be selected from the following two kinds: 17

Settings	QC Method
\bar{X}	\bar{X} Control
L-J	L-J Control

Table 10-5-1: QC Method Setting

2) **Data Output Setting**

Set the QC data output method. The QC data output can be selected from the following four kinds:

Settings	QC data output
None	Not output
Print	Print on built-in printer
Host	Output to host computer
Print, Host	Print on built-in printer and output to host computer

Table 10-5-2: Data Output Setting

NOTE:

- Output to the host computer is valid only when the option is incorporated.
- For print format to the built-in printer, refer to *Chapter 5, Section 2.6: Execute \bar{X} Control* or *Chapter 5, Section 2.7: Execute L-J Control*.
- For output format to the host computer, refer to *Appendix B: Technical Information*.
- The data output format for quality control differs from the format for usual analysis.

- (9) When the setting for each parameter is completed, press [SELECT] key. The Setting Change Confirmation message appears.



Figure 10-5-3: Setting Change Confirmation Message

- (10) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
 [Cont.]: Returns to the QC Settings screen. And the setting operation can be continued.
 [Set]: Updates the settings and returns to the Analysis screen.
 [Cancel]: Cancels the changed settings and returns to the Analysis screen.
- (11) Press [ENTER] key to execute the selected process.

6. HOST SETTINGS (OPTION)

This program is used to set the interface conditions for transferring data to the host computer.

NOTE: • "Host Settings" is displayed only when the optional serial interface is incorporated.

How to Set Host Output

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

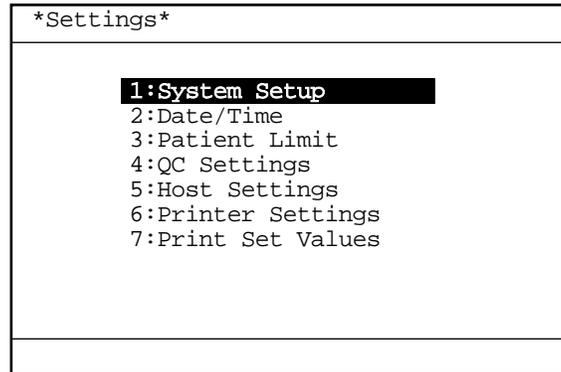


Figure 10-6-1: Setting Menu Screen

NOTE: • "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "5: Host Settings."

- (5) Press [ENTER] key. The current setting status is displayed on the Host Settings screen.

Host Settings	
Connect	
Output Format	K-1000
Auto Output	On
Baud Rate	2400
Data Length	7bits
Stop Bit	2bit
Parity Check	Even
Protocol	Class A
Interval	2
RTS/CTS	Ignore
Press [SELECT] to exit.	

Figure 10-6-2: Host Settings Screen

- (6) Using [▲] or [▼] key, move the cursor to select the desired set parameter. For Host Settings, eight parameters can be set.
- (7) Using [◀] or [▶] key, select the condition. The condition changes each time you press the key.
- (8) Press [ENTER] key. The content of settings is set and the cursor moves to the next set parameter.

NOTE: • The settings can also be set when you press [▲] or [▼] key after changing the content of settings.

- 1) **Connect Settings**
Set whether to connect the host computer or not.

Settings	Connection
Use	Connect
Not Use	Not Connect

Table 10-6-1: Host Output Settings

2) **Output Format Settings**

Set output format of analysis data to the host computer. This can be selected from the following two kinds:

Settings	Output Format
K-1000	ASCII data is output in the published format. Refer to <i>Appendix B: Technical Information</i> .
K-DPS	Binary data is output for connecting with K-DPS. Data format is not published.

Table 10-6-2: Output Format Settings

3) **Auto Output Settings**

Set whether to make auto output to the host computer or not.

Settings	Auto Output
On	Auto Output
Off	Not Auto Output

Table 10-6-3: Auto Output Settings

4) **Baud Rate Settings**

Set the baud rate. This can be selected from the following four kinds:

Settings	Baud Rate
1200	1200 bps
2400	2400 bps
4800	4800 bps
9600	9600 bps

Table 10-6-4: Baud Rate Settings

5) **Data Length Settings**

Set the data length. This can be selected from the following two kinds:

Settings	Data Length
7 bits	7 bits
8 bits	8 bits

Table 10-6-5: Data Length Settings

- 6) **Stop Bit Settings**
Set the stop bit. This can be set selected from the following two kinds:

Settings	Stop Bit
1 bit	1 bit
2 bits	2 bits

Table 10-6-6: Stop Bit Settings

- 7) **Parity Check Settings**
Set the parity check method. This can be set selected from the following three kinds:

Settings	Parity Check
None	None
Odd	Odd
Even	Even

Table 10-6-7: Parity Check Settings

- 8) **Protocol Settings**
Set the protocol. This can be set selected from the following two kinds:

Settings	Protocol
Class A	Class A
Class B	Class B

Table 10-6-8: Protocol Settings

- 9) **Transmission interval Settings**
Select a transmission interval from the following:

Settings	Interval
0	0 second
2	2 seconds
3	3 seconds
5	5 seconds
7	7 seconds
10	10 seconds
15	15 seconds

Table 10-6-9: Transmission Interval

10) RTS/CTS control Settings

Specify whether or not the RTS/CTS flow control takes place.

Settings	RTS/CTS control
Refer	Allowed
Ignore	Not allowed

Table 10-6-10: RTS/CTS control

- (9) When the setting of each parameter is completed, press [SELECT] key. The Setting Change Confirmation message appears.



Figure 10-6-3: Setting Change Confirmation Message

- (10) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
[Cont.]: Returns to the Host Settings screen. And the setting operation can be continued.
[Set]: Updates the settings and returns to the Analysis screen.
[Cancel]: Cancels the changed settings and returns to the Analysis screen.
- (11) Press [ENTER] key to execute the selected process.

7. PRINTER SETTINGS

This program is used to set the output selection and output conditions for the built-in printer.

How to Set Printer Output

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

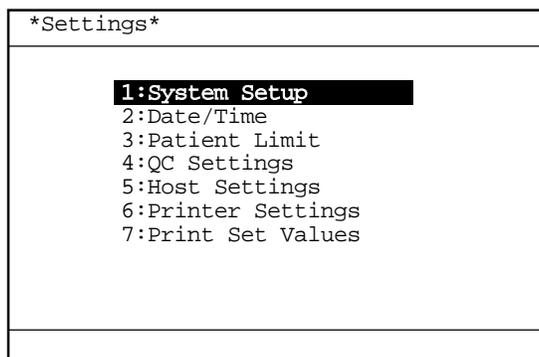


Figure 10-7-1: Setting Menu Screen

NOTE: • "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "6: Printer Settings."
- (5) Press [ENTER] key. The current setting status is displayed on the Printer Settings screen.

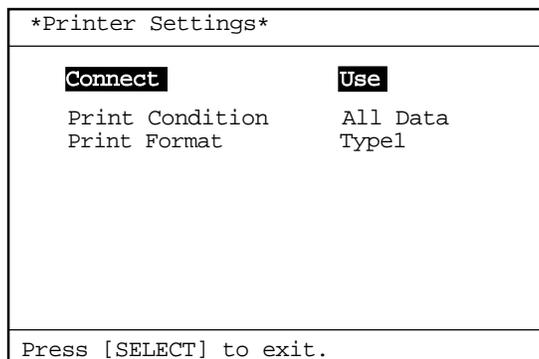


Figure 10-7-2: Printer Settings Screen

- (6) Using [▲] or [▼] key, move the cursor to select the set parameter. Printer settings can be made on three parameters.
- (7) Using [◀] or [▶] key, select the condition. The condition changes each time you press the key.
- (8) Press [ENTER] key. The content of settings is set and the cursor moves to the next set parameter.

NOTE: • The settings can also be set when you press [▲] or [▼] key after changing the content of settings.

- 1) **Connect Settings**
Set whether to connect the built-in printer or not.

Settings	Connection
Use	Connect
Not Use	Not Connect

Table 10-7-1: Built-in Printer Settings

- 2) **Print Condition Settings**
Set the auto print condition for the built-in printer. This can be selected from the following three kinds:

Settings	Auto Print Conditions
All Data	Print All Samples
Abnormal Data	Print Abnormal Data Only
None	Not Auto Print

Table 10-7-2: Print Condition Settings

NOTE:

- Data printed as abnormal data:
 - Data in which analysis error occurred
 - Data in which noise error occurred
 - Data with flags other than Mark Limits
 - Data with histogram flag
 - Data out of the linearity limit
- For print conditions of QC data, refer to *Chapter 10, Section 5: QC Settings*.

3) Print Format Settings

Set the print format for the built-in printer. This can be selected from the following three kinds:

Settings	Print Format
Type 1	Print 18 parameters + histograms.
Type 2	Print 18 parameters.
Type 3	Print 8 parameters.

Table 10-7-3: Print Format Settings

NOTE:

- For print format, refer to *Chapter 2, Section 5.2 Printing of Analysis Result.*
- For print format for quality control, refer to *Chapter 5, Section 2.6: Execute \bar{X} Control* or *Chapter 5, Section 2.7: Execute L-J Control.*

- (9) When the setting of each parameter is completed, press [SELECT] key. The Setting Change Confirmation message appears.



Figure 10-7-3: Setting Change Confirmation Message

- (10) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
 [Cont.]: Returns to the Printer Settings screen. And the setting operation can be continued.
 [Set]: Updates the settings and returns to the Analysis screen.
 [Cancel]: Cancels the changed settings and returns to the Analysis screen.
- (11) Press [ENTER] key to execute the selected process.

8. PRINT SET VALUES

To backup the set values, all the contents of the settings can be printed by the built-in printer.

How to Print Set Values

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.
- (2) Using [▲] or [▼] key, move the cursor to select "6: Settings."
- (3) Press [ENTER] key. The Setting Menu screen appears.

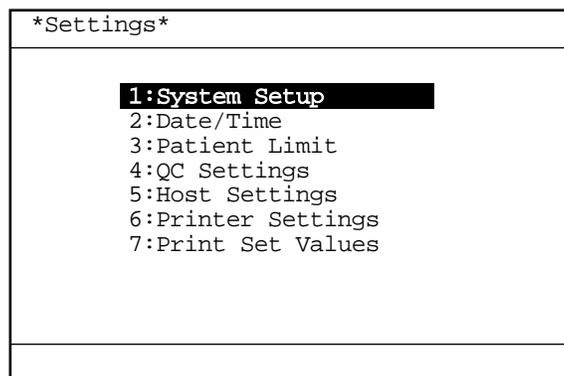


Figure 10-8-1: Setting Menu Screen

NOTE: • "5: Host Settings" is displayed only when the optional serial interface is incorporated.

- (4) Using [▲] or [▼] key, move the cursor to select "7: Print Set Values."
- (5) Press [ENTER] key. The built-in printer starts printing all the set values.

NOTE: • If any faulty operation occurs, contact your Sysmex service representative. Keep the printed contents of the settings in good condition because the service representative may have to confirm the contents of settings.

9. PERIPHERAL SETTINGS

When you want to temporarily cancel external output due to error occurrence, use this program to set "Use" or "Not use" of the built-in printer or optional host computer output.

- NOTE:**
- "Host Output" is displayed only when the optional serial interface is incorporated.
 - For peripheral settings, refer to "5: Host Settings" and "6: Printer Settings" which carry description of similar settings.

How to Set Peripheral Connection

- (1) Press [SELECT] key on the Analysis screen. The Select Menu screen appears.

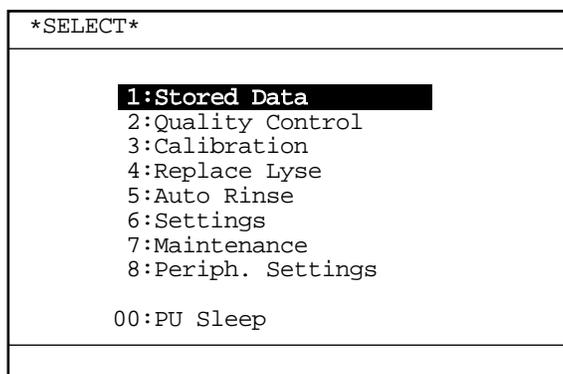


Figure 10-9-1: Select Menu Screen

- (2) Using [▲] or [▼] key, move the cursor to select "8: Periph. Settings."
- (3) Press [ENTER] key. This displays connection status of external devices on the Peripheral Settings screen.

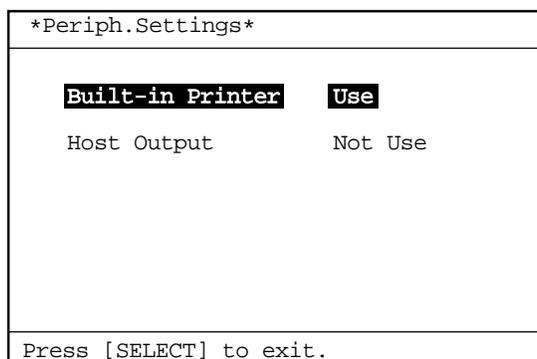


Figure 10-9-2: Peripheral Settings Screen

- (4) Using [▲] or [▼] key, move the cursor to select the desired external device.
- (5) Using [◀] or [▶] key, select "Use" or "Not Use". "Use" and "Not Use" change over each time you press the key.
- (6) Press [ENTER] key. The content of the settings is set and moves the cursor to the next set parameter.

NOTE:	• The settings can also be set when you press [▲] or [▼] key after changing the content of settings.
--------------	--

- (7) Press [SELECT] key. The Setting Change Confirmation message appears.



Figure 10-9-3: Setting Change Confirmation Message

- (8) Using [◀] or [▶] key, move the cursor to select "Cont.," "Set," or "Cancel."
[Cont.]: Returns to the Peripheral Settings screen. And the setting operation can be continued.
[Set]: Updates the settings and returns to the Analysis screen.
[Cancel]: Cancels the changed settings and returns to the Analysis screen.
- (9) Press [ENTER] key to execute the selected process.

10. FACTORY SETTINGS

The settings made at the factory are listed below:

- **System Settings**

Units	Type 2
Language	English
Parameter Naming	LYM%
RDW	RDW-SD

- **Date/Time**

Date Format	dd/mm/yy
-------------	----------

- **Patient Limits**

	LL	UL
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
W-SCR	5.0	55.0
W-MCR	1.0	20.0
W-LCR	45.0	95.0
W-SCC	0.0	0.0
W-MCC	0.0	0.0
W-LCC	0.0	0.0
RDW-SD	37.0	54.0
RDW-CV	11.0	16.0
PDW	9.0	17.0
MPV	9.0	13.0
P-LCR	13.0	43.0

- **QC Settings**

QC Method	\bar{x}
Data Output	Print

- **Printer Settings**

Built-in Printer	Use
Print Condition	All Data
Print Format	Type 1

- **Host Settings**

Host Output	Not use
Output format	K-1000
Auto Output	Off
Baud Rate	2400 bps
Data Length	7 bits
Stop Bit	2 bits
Parity Check	Even
Protocol	Class A
Interval	2
RTS/CTS	Ignore

APPENDIX A: INSTALLATION

1.	INTRODUCTION	A-1
2.	CHECK BEFORE INSTALLATION	A-2
3.	INSTALLATION SPACE	A-3
4.	REMOVE SHIPPING CLAMPS	A-4
5.	CONNECT TUBE	A-6
5.1	Prepare Reagent	A-6
5.2	Connect CELLPACK.....	A-6
5.3	Connect STROMATOLYSER-WH.....	A-8
5.4	Connect Waste Line.....	A-9
6.	SET PRINTER PAPER	A-10
7.	CONNECT POWER CORD.....	A-12
8.	TURN POWER ON	A-12

1. INTRODUCTION

This product is a clinical test instrument. Sysmex representative is responsible for unpacking, installing, and initial setup of the product to ensure its proper and safe operation. The next several pages will give some essential information on this instrument.

NOTE:

- When the optional serial interface function is intended to incorporate to this instrument, following optional part should be ordered in prior to the installation so that Sysmex service representative could install at once.
973-4531-1 OUTPUT UNIT NO. 1 KX-21

2. CHECK BEFORE INSTALLATION

Make sure the KX-21 is free from external damages and check the quantities of the accessories.

No.	Part No.	Description	Q'ty		
			117 V	220 V	240 V
1	461-2263-8	Operator's Manual KX-21 (North American)	1	0	0
1	461-2261-1	Operator's Manual KX-21 (English)	0	1	1
2	923-8092-8	Power Cord No. 15 (C-2/N. Amer)	1	-	-
2	265-4719-0	Power Cord 4622-007-0092 (Europe)	-	1	-
2	265-4728-3	Power Cord No. 7650 (U.K.)	-	-	1
3	943-1781-1	Cubitainer Spout Kit No. 1	1	1	1
4	973-3041-7	Float Switch No. 23	1	1	1
5	367-1051-9	Tray No. 20	1	1	1
6	442-5338-7	Tube Polyurethane 4 mm ID × 6 mm OD	3 m	3 m	3 m
7	442-5340-5	Tube Polyurethane 6 mm ID × 9 mm OD	6 m	6 m	6 m
8	423-1776-2	Mini Pipette No. 10 (1 mL)	2	2	2
9	933-3601-9	Brush No. 1 Assy	1	1	1
10	266-5109-1	Fuse 250V 3.15A ST4-3.15A-N1	2	-	-
10	266-5292-6	Fuse 250V 2A No. 19195 (Europe)	-	2	2
11	266-6743-4	Clamp LWS-8S-2.5W	1	1	1
12	369-8234-6	Caution Mark No.170	1	1	1

Table A-2-1: KX-21 Unpacking Checklist

NOTE:	<ul style="list-style-type: none"> Item No. 4 (973-3041-7 Float Switch No. 23) is pre-installed in the Main Unit Front Interior at the factory.
--------------	--

3. INSTALLATION SPACE

To ensure that the instrument performs to its full extent, it should be installed at an appropriate place.

- Select a place where the power supply is located close.
- Secure a space for maintenance and service. Giving consideration to heat radiation by the instrument, provide at least 50 cm clearance between the wall and the instrument's side rear, and top panels.

Each dimension of the instrument is shown below. The power cord is 1.8 m long.

	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	420	355	480	28

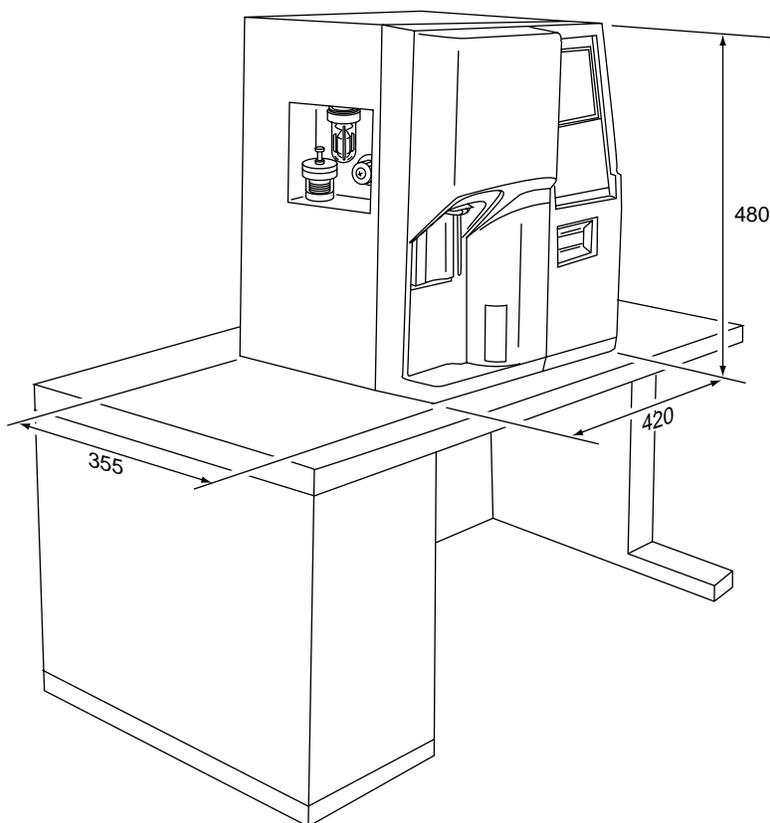


Figure A-3-1: Instrument Dimensions

4. REMOVE SHIPPING CLAMPS

- (1) Peel off the fixing tape of the outer cover gently.

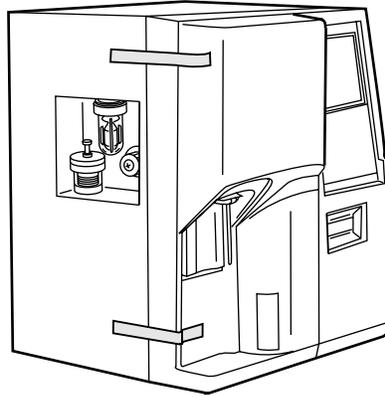


Figure A-4-1: Removing the Tape

- (2) Open the front cover of the main unit.
- (3) Remove the protection sheets of the sampling valve.
 - 1) Remove the SRV fixing screw.
 - 2) With the fixed and rotary valves separated sufficiently, remove the protection sheets.
 - 3) Return the valves and the SRV fixing screw to their original positions.
 - 4) Set the provided sample rotor valve tray.

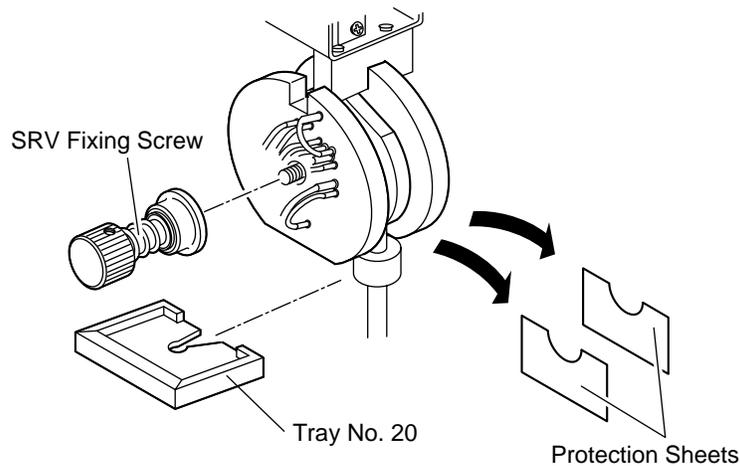


Figure A-4-2: Removing the Protection Sheets

- (4) Remove the pneumatic unit fixing screws (2 pcs). Keep these screws for future use.

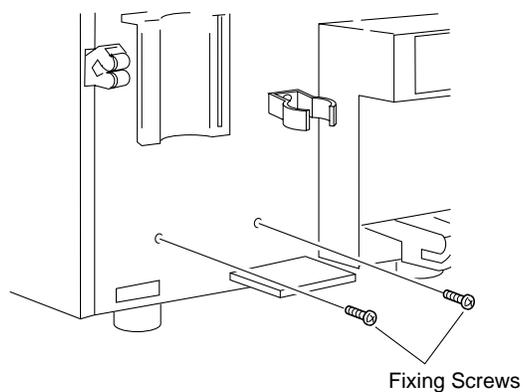


Figure A-4-3: Removing the Screws

- (5) Remove the rubber caps of the reagent connection nipples. Keep these rubber caps for future use.

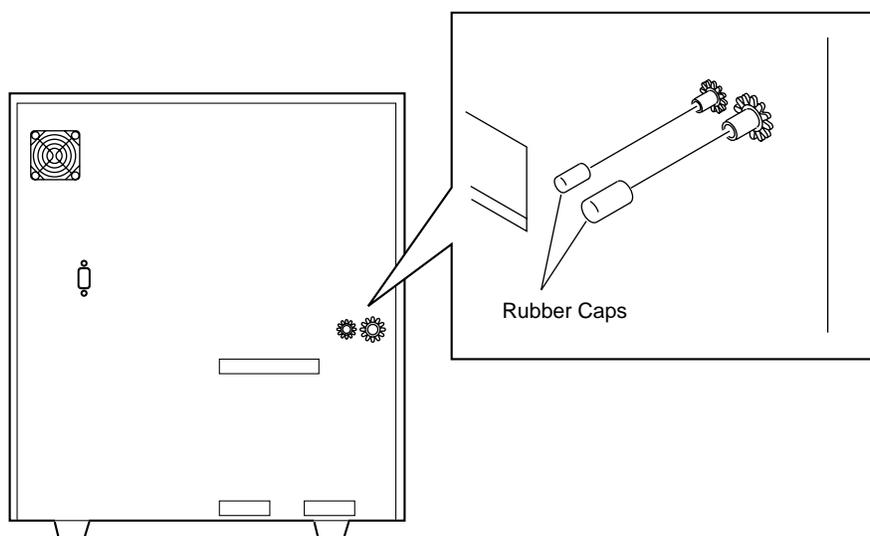


Figure A-4-4: Removing the Rubber Caps

5. CONNECT TUBE

5.1 Prepare Reagent

Prepare the reagents and connection kits shown below.

Reagent Part No.	Type	Part Name	Connection Kit
884-0871-1	PK-30L	CELLPACK	Cubitainer spout kit No. 1 (for 20L)
974-0521-6	SWH-200A	STROMATOLYSER-WH	Float switch No. 23

5.2 Connect CELLPACK

- Prepare the following reagent tube.
Tube Polyurethane 4 mmID × 6 mmOD : 1 pc

<p>NOTE: • Cut the tube to an appropriate length, and connect it.</p>
--

- Connect the diluent (CELLPACK) inlet aspiration nipple behind the unit and the nipple of the cubitainer spout kit No. 1 with the tube polyurethane 4 mmID × 6 mmOD.
- Set the cubitainer spout kit No. 1 to the CELLPACK container.

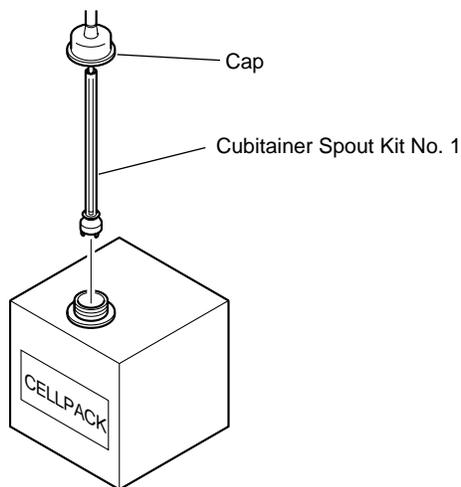


Figure A-5-1: Setting the Cubitainer Spout Kit

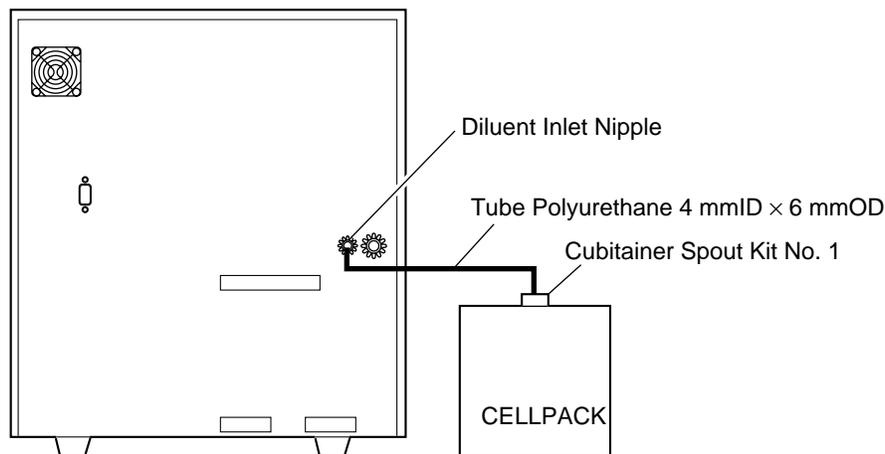


Figure A-5-2: Connecting the CELLPACK

! CAUTION

- Take care not to spill a reagent on to the instrument. If it spills, wipe it off immediately using a wet cloth or the like.
- If it happens to adhere to your skin, wash it off using plenty of water.
- If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.
- After unpacking, be sure not to allow dust or dirt to come into the instrument. Use up CELLPACK within 60 days from the unpacking date, and STROMATOLYSER-WH within 90 days.

CAUTION:

- When the diluent (CELLPACK) tube is more than 2 m long, it may be impossible to have reagent aspirated. Avoid setting CELLPACK at a level higher than the instrument; otherwise, reagent may flow into the vacuum line, possibly damaging the instrument.

CAUTION:

- After connecting the tube, do not pull it by force for reagent replacement.

5.3 Connect STROMATOLYSER-WH

- (1) Gently remove the provided float switch No. 23 from the dust-protection bag.
- (2) Install the float switch No. 23 to STROMATOLYSER-WH. Then, set it to the table.

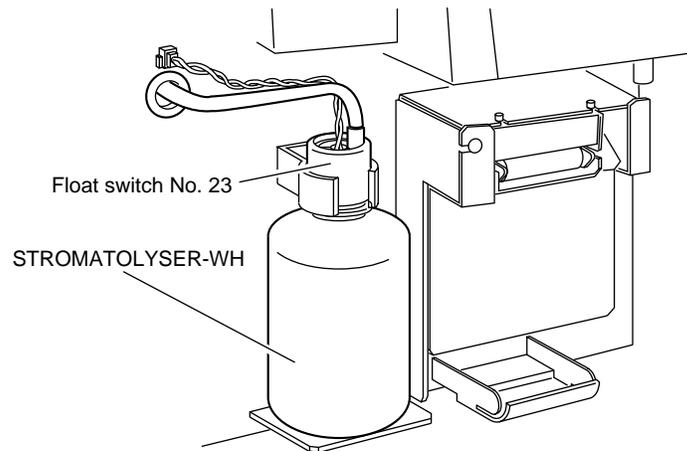


Figure A-5-4: Installing the STROMATOLYSER-WH

5.4 Connect Waste Line

- (1) Prepare the following waste line tube.
Tube Polyurethane 6 mmID × 9 mmOD : 1 pc
- (2) Connect an end of the tube polyurethane 6 mmID × 9 mmOD to the drain outlet nipple behind the unit. Connect the other end of the tube to the waste sewer in the lab.
If the waste sewer is not available, connect it to a waste tank.
The maximum waste line length is 6 m.

NOTE:

- Cut the tube to an appropriate length, and connect it.
- Since waste is removed from the system by pressurized air, the waste tank may be located at the same height as, or lower than, the drain outlet nipple. Otherwise the waste may be flown back into the system, which will result of a malfunction.

- (3) Arrange and tie the diluent and waste line tubings as shown in the figure using the provided clamp.

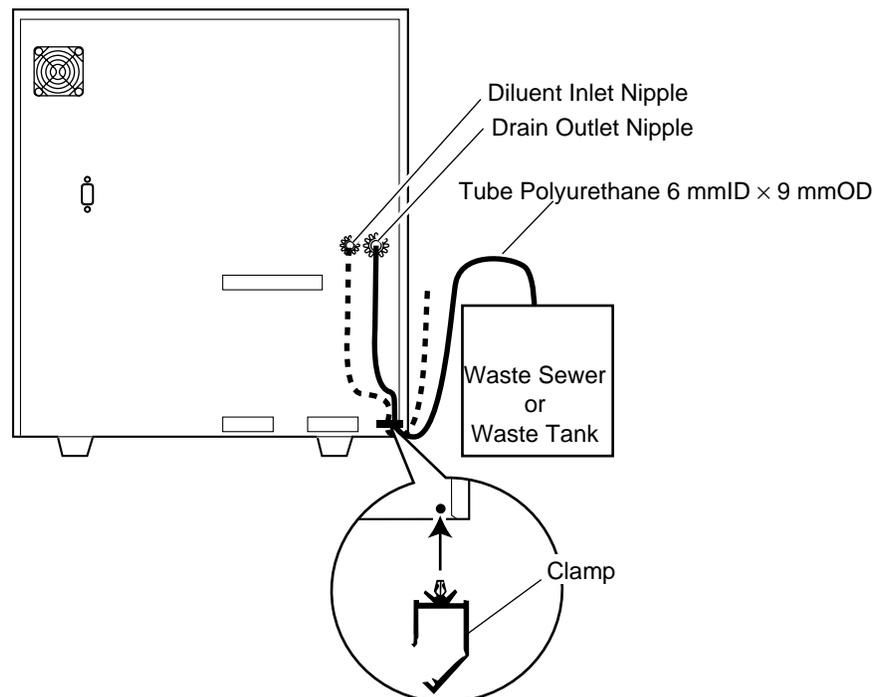


Figure A-5-5: Connecting the Waste Line and Clamping Tubings

6. SET PRINTER PAPER

- (1) Open the front cover of the main unit.
- (2) Turn the release lever up to free the paper.

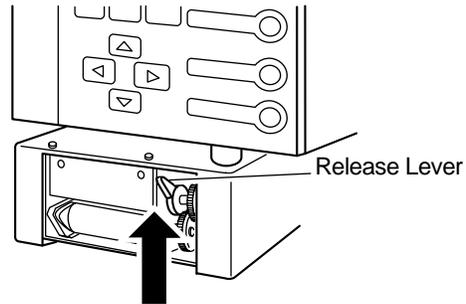


Figure A-6-1: Releasing the Lever

- (3) Mount a printer paper.

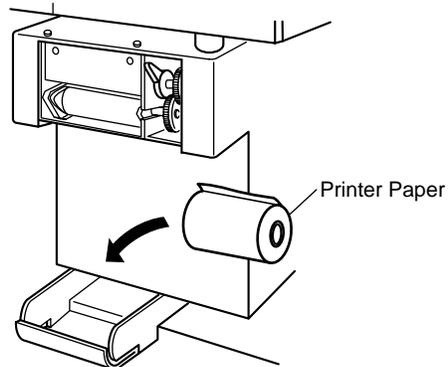


Figure A-6-2: Mounting a Printer Paper

- (4) Pass the printer paper as shown below, and turn the release lever down to secure.

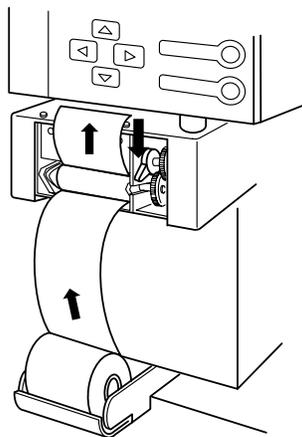


Figure A-6-3: Securing the Release Lever

- (5) Cut off any printer paper extending from the upper part of the printer.

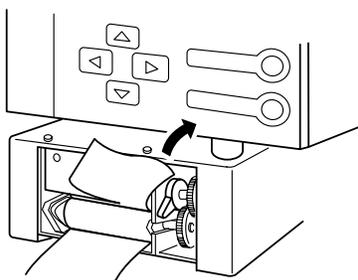


Figure A-6-4: Cutting Off Paper

- (6) Close the front cover of the main unit.

7. CONNECT POWER CORD

Connect the provided power cord to the power supply outlet.

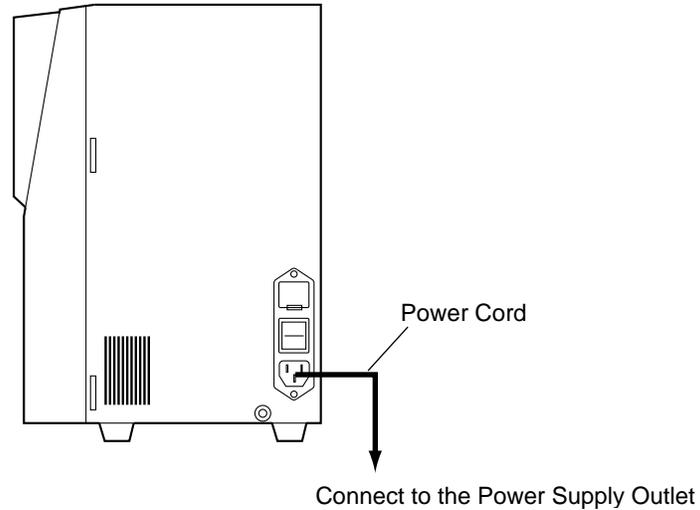


Figure A-7-1: Connecting the Power Cord

8. TURN POWER ON

It is necessary to run the service sequence at the initial start-up.
Your Sysmex service representative is responsible for the operation.

APPENDIX B: TECHNICAL INFORMATION

1.	OUTPUT FORMAT FOR HOST COMPUTER (OPTION).....	B-1
1.1	Hardware.....	B-1
1.2	Software.....	B-3

1. OUTPUT FORMAT FOR HOST COMPUTER (OPTION)

The bit serial voltage type, which conforms to the RS-232C interface, is used for host computer output of the KX-21. The serial interface port for the connection with the host computer is on the rear panel of the main unit, when an option is incorporated.

NOTE:

- When the optional serial interface function is intended to incorporate to this instrument, following optional part should be ordered in prior to the installation so that Sysmex service representative could install at once.
973-4531-1 OUTPUT UNIT NO. 1 KX-21

1.1 Hardware

1. Connector

- The connector for the output to the host computer is located on the rear panel.
- Use a 9-pin D-SUB, female connector.
- Fixing screws for this connector are in inch-specification.

2. Connector Signals

Pin No.	Signal Name	Signal Direction
1		
2	Receive data (RxD)	From Host to KX-21
3	Transmit Data (TxD)	To Host from KX-21
4	Data Terminal Ready (DTR)	To Host from KX-21
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	From Host to KX-21
7	Request to Send (RTS)	To Host from KX-21
8	Clear to Send (CTS)	From Host to KX-21
9		

Table B-1-1: Pin Assignment

3. Communication Format

The data is communicated in the asynchronous, half duplex mode.

4. Signal Level

Signal level conforms to JIS C6361.

Level	Data signal	Control signal
+3V or higher	Logic "0", Start bit	ON
-3V or lower	Logic "1", Stop bit	OFF

Table B-1-2: Signal Level

5. Interface Circuit

- Output circuit

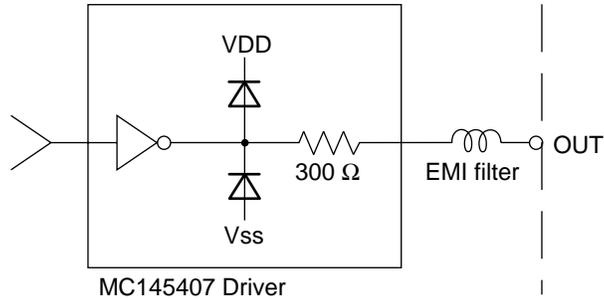


Figure B-1-1: Interface Output Circuit

- Input circuit

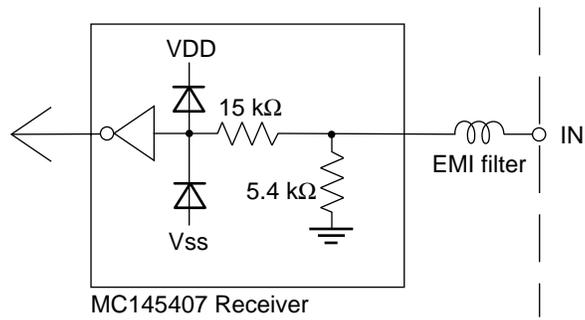


Figure B-1-2: Interface Input Circuit

1.2 Software

1. Communication Format

1) Code

ASCII codes are used for output.
(Except for K-DPS output)

2) Structure of text

"STX" (02 H) is sent prior to data and "ETX" (03 H) is sent at the end of data.
(Except for K-DPS output)

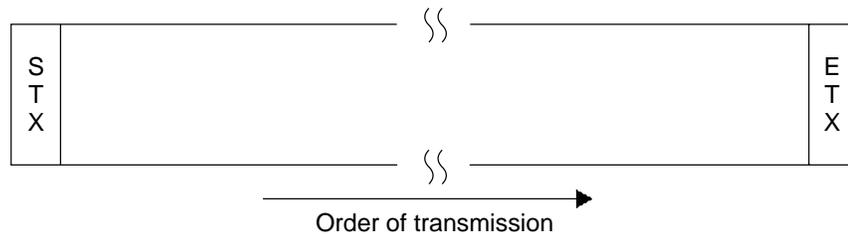


Figure B-1-3: Order of Transmission

3) Communication protocol

The following 2 protocols are provided in the system, and can be selected according to the system status.

- **Class A**

One-way transmission to the host computer without requiring ACK nor NAK from host computer.

- **Class B**

The KX-21 transmits data and then waits for ACK or NAK to complete the data transmission.

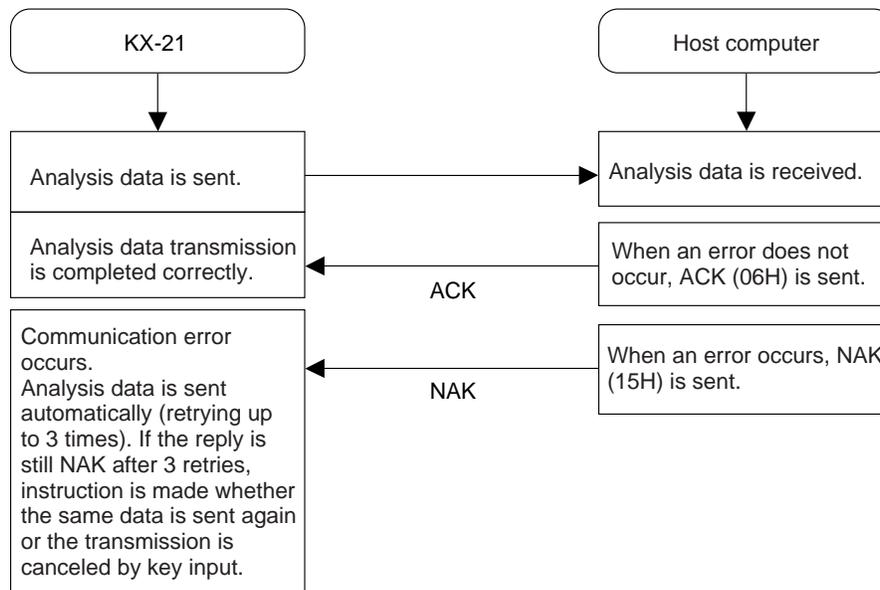


Figure B-1-4: Data Transmission

4) **Transmission errors**

If the KX-21 detects a transmission error, the data transmission is canceled and an error message is displayed. Re-transmission of the data ([1] key) or cancellation of the transmission ([3] key) can be selected. Transmission errors occur in the following situations.

- The computer is off line.
- The control signal DSR is off.
- After the data is transmitted, there is no response from the computer in 15 seconds. (Class B only)
- After the data is transmitted, other than ACK or NAK is sent from the computer. (Class B only)
- After the data is transmitted, the fourth NAK is sent. (Class B only. The KX-21 resends the data automatically up to 3 times when NAK is sent.)

5) **Timing, subject, and content of transmission**

	Serial interface ↓ Host computer
Normal analysis	Analysis data (A)
Quality control	QC data (A)

Table B-1-3: Content of Transmission

- Analysis data includes the date, sample ID No., 18-parameter data, and the flag.
- QC data is \bar{X} or L-J data.
- The setting of the connecting device is changed in the setting program.

2. **Text Format**

The following two types of formats are used for computer output.

- K-1000: Format for connecting to the host computer
- K-DPS: Special format for connecting to K-DPS

NOTE: • K-1000 format is selected at the time of shipping from the factory.

The details of K-1000 format are as follows.

- K-1000 format
 K-1000 format has two formats; one is "analysis data format" for output of the sample data, and the other is "QC data format" for output of the QC data. They differ in length and content of the text. (They are distinguished by the sample distinction code.)
 The text distinction code II is fixed at "1".
 However, when the text exceeds 256 bytes in a future modification, the text is divided into 2 or more blocks. The number in text distinction code II shows the order of the blocks. The ETB (17 H) is not used.

(1) Analysis data format (121 characters)

Parameter	No. of Characters	Example
STX	1	(02 H)
Text distinction code I	1	"D"
Text distinction code II	1	"1"
Sample distinction code	1	"U"
Year (Month or Day)	2	"97"
Month (or Day)	2	"09"
Day (or Year)	2	"30"
Analysis information	1	(O)
Sample ID No.	12	(OOOOOOOOOOOOO)
PDA information	6	(OOOOOO)
RDW select information	1	"S" or "C"
WBC	5	XXX.XF
RBC	5	XX.XXF
HGB	5	XXX.XF
HCT	5	XXX.XF
MCV	5	XXX.XF
MCH	5	XXX.XF
MCHC	5	XXX.XF
PLT	5	XXXXF
LYM% (W-SCR)	5	XXX.XF
MXD% (W-MCR)	5	XXX.XF
NEUT% (W-LCR)	5	XXX.XF
LYM# (W-SCC)	5	XXX.XF
MXD# (W-MCC)	5	XXX.XF
NEUT# (W-LCC)	5	XXX.XF
RDW-SD/CV	5	XXX.XF
PDW	5	XXX.XF
MPV	5	XXX.XF
P-LCR	5	XXX.XF
ETX	1	(03 H)

Table B-1-4: Analysis Data Format

(2) QC data format (99 characters)

Parameter	No. of Characters	Example
STX	1	(02 H)
Text distinction code I	1	"D"
Text distinction code II	1	"1"
Sample distinction code	1	"C"
Data distinction code	1	"X" or "L"
Year (Month or Day)	2	"97"
Month (or Day)	2	"09"
Day (or Year)	2	"30"
Hour	2	"09"
Minute	2	"59"
QC File Number	1	"5"
Not used	1	"0"
RDW select information	1	"C"
WBC $[\times 10^3/\mu\text{L}]$	4	XXX.X
LYM% (W-SCR) [%]	4	XXX.X
MXD% (W-MCR) [%]	4	XXX.X
NEUT% (W-LCR) [%]	4	XXX.X
LYM# (W-SCC) $[\times 10^3/\mu\text{L}]$	4	XXX.X
MXD# (W-MCC) $[\times 10^3/\mu\text{L}]$	4	XXX.X
NEUT# (W-LCC) $[\times 10^3/\mu\text{L}]$	4	XXX.X
RBC $[\times 10^6/\mu\text{L}]$	4	XX.XX
HGB [g/dL]	4	XXX.X
HCT [%]	4	XXX.X
MCV [fL]	4	XXX.X
MCH [pg]	4	XXX.X
MCHC [g/dL]	4	XXX.X
RDW-(CV/SD) [%/fL]	4	XXX.X
PLT $[\times 10^3/\mu\text{L}]$	4	XXXX
PDW [fL]	4	XXX.X
MPV [fL]	4	XXX.X
P-LCR [%]	4	XXX.X
W-SMV [fL]	4	XXX.X
W-LMV [fL]	4	XXX.X
ETX	1	(03 H)

Table B-1-5: QC data format

- (3) Details of the analysis data output in K-1000 format
 - 1) The order of output is from the top parameter to the bottom. The data is sent from the upper line without performing zero suppression.
 - 2) Because the decimal point is not sent, the decimal point specified in each parameter has to be added and represented by numeric value at the host computer.
 - 3) The order of the date conforms to the format in the setting program in the setting program.
 - 4) Analysis information shows the following content of the analysis.

	Manual No. input
WB mode analysis	"0"
Pre-diluted mode analysis	"5"

Table B-1-6: Analysis Information

- 5) The sample ID No. is 6-digit numerals, but 12 digits are output in this format. The upper 6 digits are 0's (zeros). Depending on the usage, "-" (2D H) may be inserted in the numeral column. In this case, "-" is included in the 12 digits.
- 6) PDA information consists of the following 6 items.

Item	No. of Characters
WBC histogram information	1
WBC histogram flag	1
RBC histogram information	1
RBC histogram flag	1
PLT histogram information	1
PLT histogram flag	1

Table B-1-7: PDA Information

Code	Description
"0"	Histogram is normal.
"1"	Histogram is abnormal.
"2"	Manually discriminated

Table B-1-8: Histogram Information

Code	Description
"0"	Normal WBC/RBC/PLT
"1"	(L) discriminator degree is high. WBC/RBC/PLT
"2"	(U) discriminator degree is high. WBC/RBC/PLT
"3"	Analysis is impossible because there is no pair of intersection on the 20% degree level for calculation of DW. RBC/PLT
"4"	Two peaks are recognized in the particle distribution. RBC/PLT
"5"	(T1) discriminator cannot be determined. WBC
"6"	(T2) discriminator cannot be determined. WBC
"7"	(T1) discriminator level is high, and the data is not reliable. WBC
"8"	(T1) or (T2) discriminator level is high, and the data is not reliable. WBC
"9"	(T2) discriminator level is high, and the data is not reliable. WBC
"A"	The particle count equal to or less than (L) discriminator exceeds the range. WBC

Table B-1-9: Histogram Flag

The histogram flag corresponds to the flagging characters of the LCD and the built-in printer as follows.

Particle distribution FLAG	Flagging characters of LCD and built-in printer		
	WBC	RBC	PLT
"0"			
"1"	WL	RL	RL
"2"	WU	RU	RU
"3"		DW	DW
"4"		MP	MP
"5"	T1		
"6"	T2		
"7"	F1		
"8"	F2		
"9"	F3		
"A"			AG

Table B-1-10: Flagging Character

- 7) RDW select information
 It shows whether RDW-CV or RDW-SD is output.
 "C": RDW-CV
 "S": RDW-SD

NOTE:

- RDW-SD is selected at the time of shipping from the factory.
- To output RDW-CV, refer to *Chapter 10, Section 2: System Setup*.

- 8) The numerical data configuration in the Analysis Data Format is as follows.

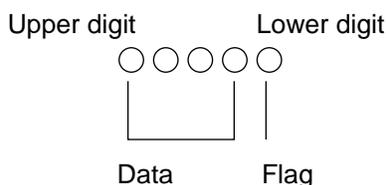


Figure B-1-5: Numerical Data Configuration

Code	Description
"0"	Normal
"1"	Abnormality judgment is "+."
"2"	Abnormality judgment is "-."
"3"	Out of linearity limit
"4"	Reliability is low.

Table B-1-11: Details of Flag

- 9) If the data over-flows, it is indicated as follows:
 *0003
- 10) In case of analysis error, or if the data lacks some data such as the calculation parameter in pre-diluted mode, the data is transmitted as follows:
 *0000

INDEX

0.5 kg/cm² Pressure Error -----7-7
0.5 kg/cm² Pressure Error at count -----7-9
250 mmHg Vacuum Error-----7-8

A

Abnormal Detection Sensitivity----- 7-22
Adjusting Pressure to 0.5 kg/cm² -----8-5
Adjusting Vacuum to 250 mmHg-----8-6
Alarm Sounds ----- 1-11
Analysis Error----- 7-21
Analysis for Automatic Calibration -----6-6
Analysis of Histogram----- 9-11
Analysis of RBC/PLT Histogram ----- 9-20
Analysis of WBC Histogram ----- 9-11
Analysis Parameters-----1-4
Analysis Procedure Flow Chart-----2-2
Analyzing Samples (in PD Mode)----- 2-21
Analyzing Samples (in WB Mode) ----- 2-12
As-Needed Maintenance and Procedure--- 4-24
Auto Rinse----- 4-24
Automatic Calibration -----6-3
Automatic Calibration Procedure-----6-4
Automatic Stop Function of Pneumatic Unit 1-3

B

Background Error ----- 7-17
Bellows Unit -----8-6, 9-33
Blood Cell Discrimination Circuit----- 9-10

C

Calculating Calibration Value-----6-9
Calculation of RBC Constant-----9-9
Calibration Error----- 7-26
Calibration Execution Timing -----6-1
Calibration Flow Chart-----6-2
CBC Analysis -----9-5
Cell-Count Parameters----- 2-26
Check before Installation----- A-2
Check Trap Chamber Level and Discard ---4-6
Clean Rinse Cup----- 4-26
Clean Sample Rotor Valve (SRV) ----- 4-16
Clean SRV Tray -----4-7
Clean TD Chamber and Diluted Sample Line
(Shutdown) -----4-4
Clean Transducer (Rinse Sequence)----- 4-12
Clean Waste Chamber (Rinse Sequence)-----4-9
Clean WBC/RBC Transducer Aperture ---- 4-28
Clog in the aperture----- 7-15

Correcting a Sample Number----- 3-17
Collecting and Preparing Samples-----2-9, 2-16
Confirmation of Cycle Number ----- 4-41
Connect CELLPACK ----- A-6
Connect Power Cord-----A-12
Connect STROMATOLYSER-WH ----- A-8
Connect Tube ----- A-6
Connect Waste Line----- A-9
Contents of Display -----1-7
Contents of Package ----- 1-11

D

Daily Maintenance and Procedure -----4-4
Date/Time Settings ----- 10-7
DC Detection Method -----9-2
Deletion----- 5-25
Deletion (Stored Data)----- 3-15
Detection Principle-----9-2
Display and Printing of Analysis Result --- 2-24
Display of Analysis Result -----2-24, 3-2

E

Electric Diagram ----- 9-29
Electric System----- 9-28
Emergency Stop Procedure----- 1-11
Entering Calibration Value----- 6-11
Entering Target Values-----6-5
Erase All -----5-6
Every 3-month Maintenance and
Procedure----- 4-16
Execute \bar{X} Control-----5-9
Execute L-J Control ----- 5-18
Execute QC Program -----5-5
Executing and Quitting Stored Data
Processing Program----- 3-11
Executing Automatic Calibration Program--6-3
Execution of Shutdown -----2-30
Exit from QC Program ----- 5-24
Expected Results ----- 2-28

F

Factory Settings -----10-27
Front Panel ----- 9-30
Front Interior----- 9-31
Functional List of Error Messages-----7-5

G

Graphic Screen-----1-7
Grounding----- 1-12

H	
Hardware-----	B-1
HC Output (QC Data)-----	5-29
HC Output (Stored Data)-----	3-16
Help -----	7-1
HGB Error-----	7-20
Host Comm. Error-----	7-33
Host Settings-----	10-16
How to Set Mark Limits-----	10-10

I	
Inputting Sample No.-----	2-11, 2-19
Inspection before Turning ON the Power ---	2-3
Inspection of Printer Paper-----	2-4
Inspection of Reagents-----	2-3
Inspection of the Instrument-----	2-4
Inspection of Waste-----	2-4
Installation and Relocation-----	1-12
Installation Environment-----	1-12, 1-14
Installation Space-----	1-13, A-3
Instrument Specifications-----	1-15

K	
KX-21 Maintenance Checklist-----	4-2

L	
Levy-Jennings Control (L-J)-----	5-1
LCD Brightness Adjustment-----	1-11
Left Side Interior-----	9-34
Left Side Panel-----	9-33
Limitations-----	2-26
Limitations on Hemoglobin-----	2-27
Location of Control Knobs-----	8-2

M	
Manual Calibration-----	6-9
Manual Calibration Procedure-----	6-10
Manual Discrimination-----	3-6
Marking-----	3-13
Measuring Unit Hydraulic System Block Diagram-----	9-4
Memory Error-----	7-23
Menu Tree-----	1-18
Momentary power failure occurred-----	7-24
Monthly Maintenance and Procedure-----	4-9

N	
Names and Functions of Instruments-----	9-30
No Printer Paper-----	7-31
Non-Cyanide Hemoglobin Analysis Method	9-2

O	
Operation Procedure-----	4-41
Option Units-----	1-3
Outline of Operation-----	1-3
Output Format for Host Computer (Option)	B-1
Overview of Analysis Modes-----	2-1
Overview of Instrument-----	1-2

P	
Panel Keyboard-----	1-6
Peripheral Settings-----	10-25
PLT Discriminator-----	9-10
Pre-Diluted (PD) Mode-----	2-15
Prepare Reagent-----	A-6
Preparing Analysis Samples in PD Mode -	2-17
Pressure/Vac Error-----	7-7, 7-8, 7-9
Pressure and Vacuum Adjustment-----	8-2
Pressure and Vacuum Display-----	8-3
Print (QC Data)-----	5-27
Print Error-----	7-30
Print Set Values-----	10-24
Printer Error-----	7-32
Printer Paper Feed-----	3-10
Printer Settings-----	10-21
Printing (Latest Sample)-----	3-10
Printing (Stored Data)-----	3-15
Printing of Analysis Result-----	2-25
Procedures in Analysis Modes-----	2-9
Processing Latest Samples-----	3-2
Processing Stored Data-----	3-11
PU Sleeping-----	1-10, 7-2

Q	
QC Analysis Procedure-----	5-4
QC Analysis Procedure Flow Chart-----	5-4
QC Chart Screen-----	5-2
QC Error-----	7-25
QC Settings-----	10-13
Quality Control-----	2-8

R	
RBC Aperture Clog-----	7-15
RBC Discriminator-----	9-10
RBC/PLT Analysis Flow-----	9-7
Rear Panel-----	9-35
Reference Values-----	6-1
Regulator Unit-----	8-5, 9-33
Remove Shipping Clamps-----	A-4
Replace Fuse-----	4-36
Replace Printer Paper-----	4-37
Replace Waste Tank-----	4-32
Replenish Diluent-----	4-33, 7-11
Replenish Lyse-----	4-33, 7-12
Replenish Reagent-----	4-33

Reset Sampling Valve (SRV)	
Cycle Counter	4-22
Right Side Panel	9-32
Rinse Motor Error	7-13, 7-14
Room Temp. High	7-16
Room Temp. Low	7-16

S

Sampling Error	7-18, 7-19
Select QC File	5-5
Selecting Automatic Calibration Parameter	6-4
Selecting Pre-Diluted Mode	2-18
Selecting Whole Blood Mode	2-10
Set Printer Paper	A-10
Set TARGET/LIMIT Values	5-7
Set Value Error	7-23
Shutdown Procedure	2-30
Software	B-3
Start-up Procedure	2-3
Status Display	7-34
Status Display Messages	1-8
Stopping the Pneumatic Unit	2-29
Stored Data Screen	3-12
Supplies List	4-40
Supplies Replacement	4-33
System Setup	10-2

T

Troubleshooting Guide	7-7
Troubleshooting Guide	
(Analysis Errors)	7-17
Troubleshooting Guide	
(Built-in Printer Errors)	7-30
Troubleshooting Guide	
(Chamber Errors)	7-10
Troubleshooting Guide	
(External Device Errors)	7-33
Troubleshooting Guide	
(Maintenance Errors)	7-27
Troubleshooting Guide (Memory Errors)	7-23
Troubleshooting Guide (Motor Errors)	7-13
Troubleshooting Guide (Others)	7-25
Troubleshooting Guide	
(Pressure/Vacuum Errors)	7-7
Troubleshooting Guide	
(Temperature Errors)	7-16
Troubleshooting Guide	
(Transducer Errors)	7-15
Turn Power On	A-12
Turning ON the Power and Self-Check	2-5

U

Updating Calibration Value	
(Manual Calibration)	6-12
Updating Calibration Value	
(Automatic Calibration)	6-8

W

Waste Not Draining	7-10
WBC Aperture Clog	7-15
WBC Discriminator	9-10
WBC/HGB Analysis Error	7-21
WBC/HGB Analysis Flow	9-5
Weekly Maintenance and Procedure	4-7
When You Suspect A Trouble	7-2
Whole Blood (WB) Mode	2-9

X

X Control	5-1
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