Automated biochemical analyzer

SPOTCHEM™ EZ

SP-4430 | Operating Manual

arkray,inc.

Premise

This manual contains important information on the functions of the SPOTCHEM EZ SP-4430

This manual is issued by: ARKRAY, Inc.
Read carefully prior to starting up the unit.
It is recommended to retain this manual for future use.

This product conforms to the EMC Standard EN61326-2-6:2006.
Class of emission: CISPR 11 Class A
This instrument is an IVD medical instrument.

CE

This product conforms to European Directive 98/79/EC

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

The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

Introduction

The SP-4430 is an automated biochemical analyzer using a dry chemistry system.

Before operating the SP-4430, read this manual carefully.
This manual contains outlines, instructions for the operation, maintenance and troubleshooting for the SPOTCHEM SP-4430.
Follow the instructions in this manual in order not to defeat the purpose of protective features of the instrument.
It is recommended to retain this manual for future use.

For the purchase of reagents, consumables or other optional items, refer to the after-sales parts and consumables list that comes with the instrument, or contact your distributor.

- **Always be careful when handling blood samples or waste reagent strips. Incorrect or imprecise procedures may result in exposure to pathogenic microbes.**
- **This analyzer must only be operated by those trained in proper procedures for clinical testing and handling of hazardous waste. Anyone who operates the analyzer for the first time must be assisted by a trained person.**
- **If blood sample is spilt, the user has responsibility for carrying out appropriate decontamination.**
- **Never touch the Reagent Table, Centrifuge-equipped Multi Rack, or other places where sample residue may collect with bare hands. When performing maintenance, always wear protective gloves to prevent exposure to pathogenic microbes.**
- **Separate used samples, tips and protective gloves from general waste and discard them according to local regulation on biohazardous waste.**
- **This analyzer may become infectious in the course of use. Discard the product in accordance with local regulations for biohazardous waste.**

Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the instrument.

Caution Marks

The following symbols are used in this manual and labels on this instrument to call your attention to specific items.

■Regarding accident resulting in injury or death.

To prevent infection of yourself or others from pathogenic microbes, follow the instructions given herein.

To prevent injuries to yourself or others, or material damages, follow the instructions described.

■Regarding damage and performance of products.

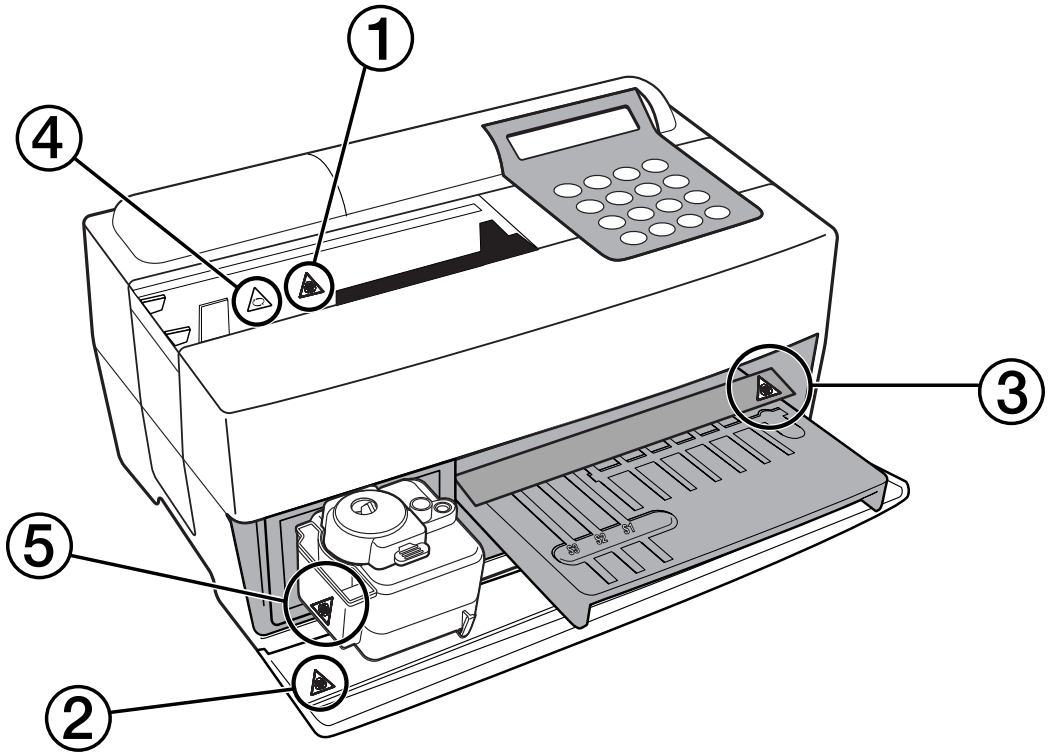
IMPORTANT **Failure to follow the instructions may lead to incorrect results.**

NOTE **To prevent damage to the unit and assist you in making best use of the capabilities of the analyzer, additional explanations and notes are provided herein.**

Reference information on operation, additional explanations and related functions are provided herein.

Caution Labels

Caution Stickers are adhered to the SP-4430 to prevent accidents as below.
The descriptions are given on the following pages.



① Nozzle

Do not touch the nozzle with bare hands. When cleaning the nozzle, wear protective gloves to prevent exposure to pathogenic microbes.

② Internal system components

When touching the internal system components, wear protective gloves to prevent exposure to pathogenic microbes.

③ Reagent table

Do not touch the reagent table with bare hands. When cleaning the reagent table is required, wear protective gloves to prevent exposure to pathogenic microbes.

④ Centrifuge

The centrifuge rotates at high speed. Keep hands off when measurement is in progress.

⑤ Tip waste case

The tip waste case holds tips to which samples are adhered. When discarding tips or cleaning the case, wear protective gloves to prevent exposure to pathogenic microbes.

Contents

Automated biochemical analyzer, SP-4430

MEMO

Chapter 1

INTRODUCTION

The SP-4430 is an automated biochemical analyzer using a dry chemistry system. This chapter contains the information on the functions and measurement principles of the SP-4430.

1-1 Outline

1-1-1 Features

■Compact and lightweight design

The footprint of the SP-4430 is as small as that of a notebook computer. It weighs only 5 kg and can be easily carried by one person. The small unit contains various components such as a display, printer, 1-sample centrifuge and automatic tip disposal mechanism. No water supply or drainage system is required, therefore it is suitable for examinations in schools or bedside in hospitals. Power consumption is greatly reduced.

■Energy-saving design

Power consumption per 1 hour is approximately 50 W on average (AC 100V, 60Hz when continuous measurements are conducted).

■Automatic Sampling

The analyzer automatically absorbs samples set on the Centrifuge-equipped Multi Rack and drops them on reagent strips. Manual operation is not necessary, so that the sampling amount becomes constant and stable measurement results can be obtained.

■Built-in centrifuge for 1 sample

The analyzer has a built-in centrifuge for 1 sample. By placing the whole blood sample in the centrifuge tube and setting it on the Centrifuge-equipped Multi Rack, the operation, centrifugation→suction→sampling is conducted automatically. This saves centrifugation of whole blood samples before measurement.

■Simple calibration using magnetic cards

Calibration using magnetic cards(Reagent Card are provided with the Reagent Strips)is possible, without using the SPOTCHEM Calibrator Kit. By inserting magnetic cards into the magnetic card reader, differences between reagent strip lot number and daily deviations are automatically calibrated.

■Sample Control by Bar code

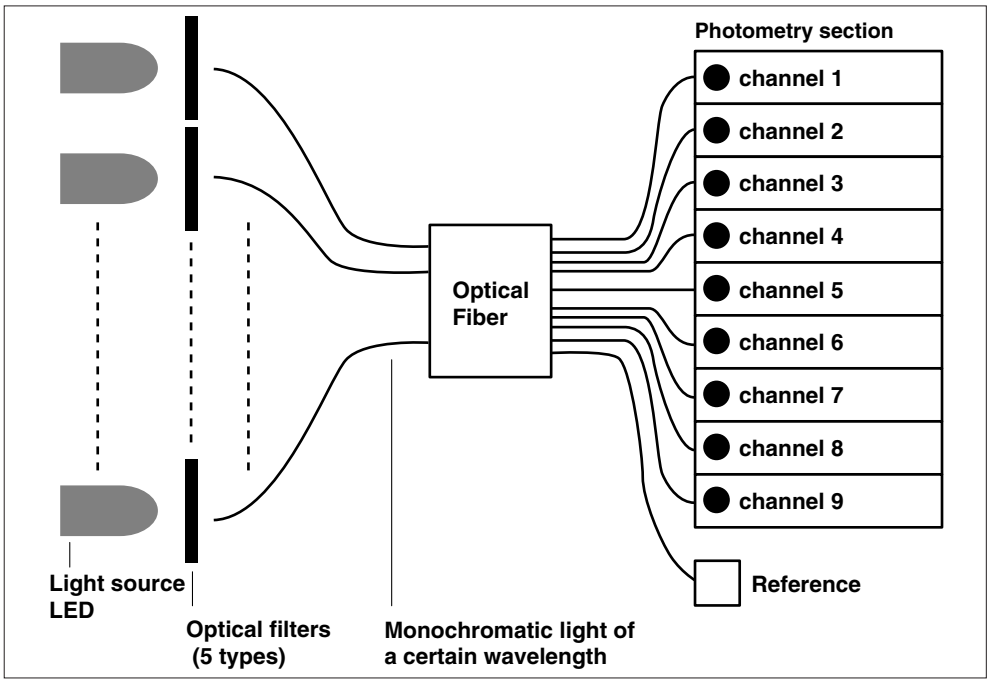
Optional Hand-held Bar Code Reader is available. By reading the bar code of each sample, the bar code is automatically allocated as patient ID.

■Online Network through two-way Transmission

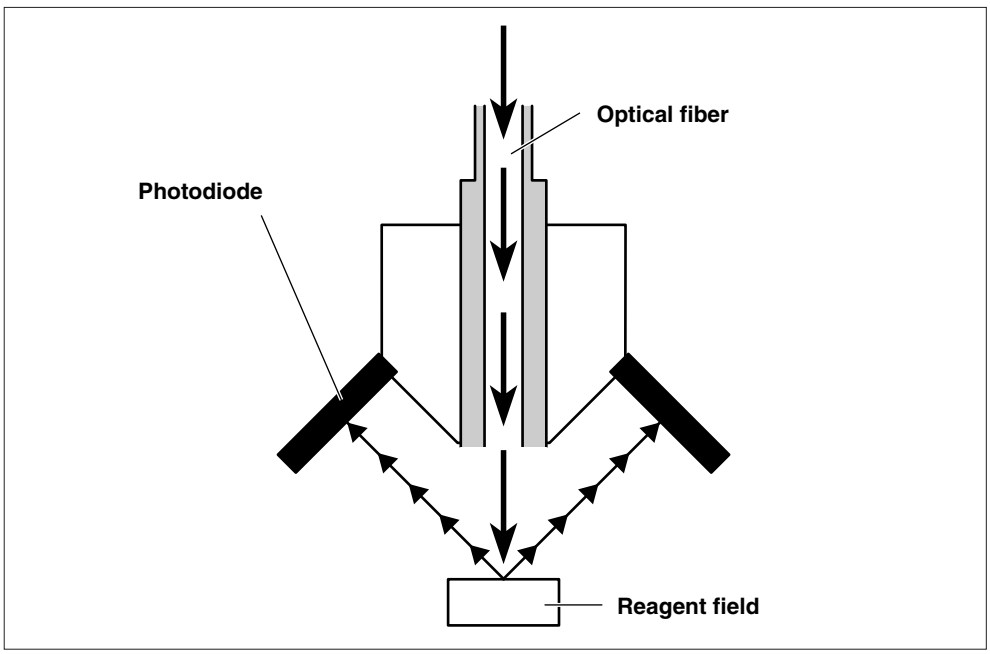
With the optional Data Management Software and external devices, remote control of measurement results and remote update of parameter settings are possible.

1-1-2 Measurement principles

The light emitted from LED becomes monochromatic light of a certain wavelength after passing through an optical fiber (Five different types of optical filters are provided, and the optimum wavelength is selected for each test item). Monochromatic light is separated and transmitted to the photometry section of each channel by ten optical fibers.



In each photometry section, the monochromatic light transmitted by the optical fibers is irradiated on the reagent fields, which has a color reaction after sampling. Its reflected light is read with 2 photodiodes, and the system calculates measurement results by end-point assay (EPA) or reaction-rate assay (RRA).



1-1-3 Specifications

Sample	Serum, Plasma, Whole blood (Only Hb)
Measurement item	General biochemical measurement items, 22 items
Measurement wavelength	5 wavelengths (405, 550, 575, 610 and 820 nm)
Measurement principle	Optical measurement of reflection intensity of reagent color reaction
Measurement Range	Set for sach measurement item
Reagent Strip	SPOTCHEM Ⅱ Reagent Strip
Processing speed	63 items per hour
Minimum sample volume	6 × the number of measurement items + 38 μL: serum, plasma
Sample consumption	4-6 μL(per 1 measurement item): serum, plasma
Sample container	Whole blood: exclusive whole blood sample tube (Orange cap) Centrifuge tube Serum, plasma: exclusive serum sample tube (Blue cap)
Simultaneous measurement	3 Single Reagent Strips or 1 Multi Reagent Strip Maximum of 9 test items of continuous measurement using Single Reagent Strips and a Multi Reagent Strip is available.
Reagent reaction temperature	37 ℃
Light source	LED and Interference filter
Calibration method	Calibration by magnetic card (Reagent Card) Calibration by Calibrator Kit
Data storage volume	100 tests
Display	20 digits×2 lines LCD
Built-in Printer	36-character thermal printer (58 mm width)
External Output	RS-232C interface
Transmission Method	Single or Two-way Transmission
Transmission Rate	300, 600, 1200, 2400, 4800, 9600bps
Measurement conditions	Temperature: 10-30℃ Humidity: 20-80 % RH (Non-condensing)
Environment during transport	Temperature: -10-60℃ Humidity: 20-80% RH (Non-condensing)
Storage environment	Temperature 1-30℃ Humidity: 20-80% RH (Non-condensing)
Max. RPM of centrifuge	10000 ± 500 rpm
Power supply	AC100-120V, 220-240V (Main power supply voltage variation must be within ±10%) 50/60Hz(AC adapter method)
Power input	Max. 100VA
Dimensions	338 mm(W)×203 mm(D)×167 mm(H)
Weight	Approximately 5.4 kg
Sound pressure level	Less than 85 dB
Location of use	Indoor use only
Altitude	2,000 m
Pollution degree	2
Over voltage category	Ⅱ
Expected life	5 years(according to company data)

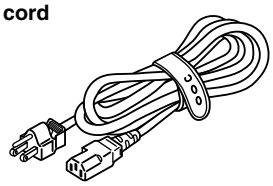
1-2 Shipping Carton

1-2-1 Analyzer

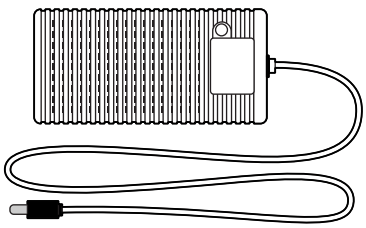
The following items are included with this instrument. Check that all of these items are included. If any items are missing or defective, please contact your distributor.

1 · Analyzer (S-4430)

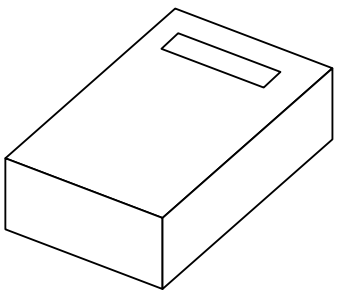
2 · Power cord



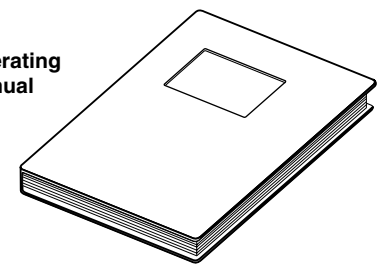
3 · AC adapter



4 · Accessory case



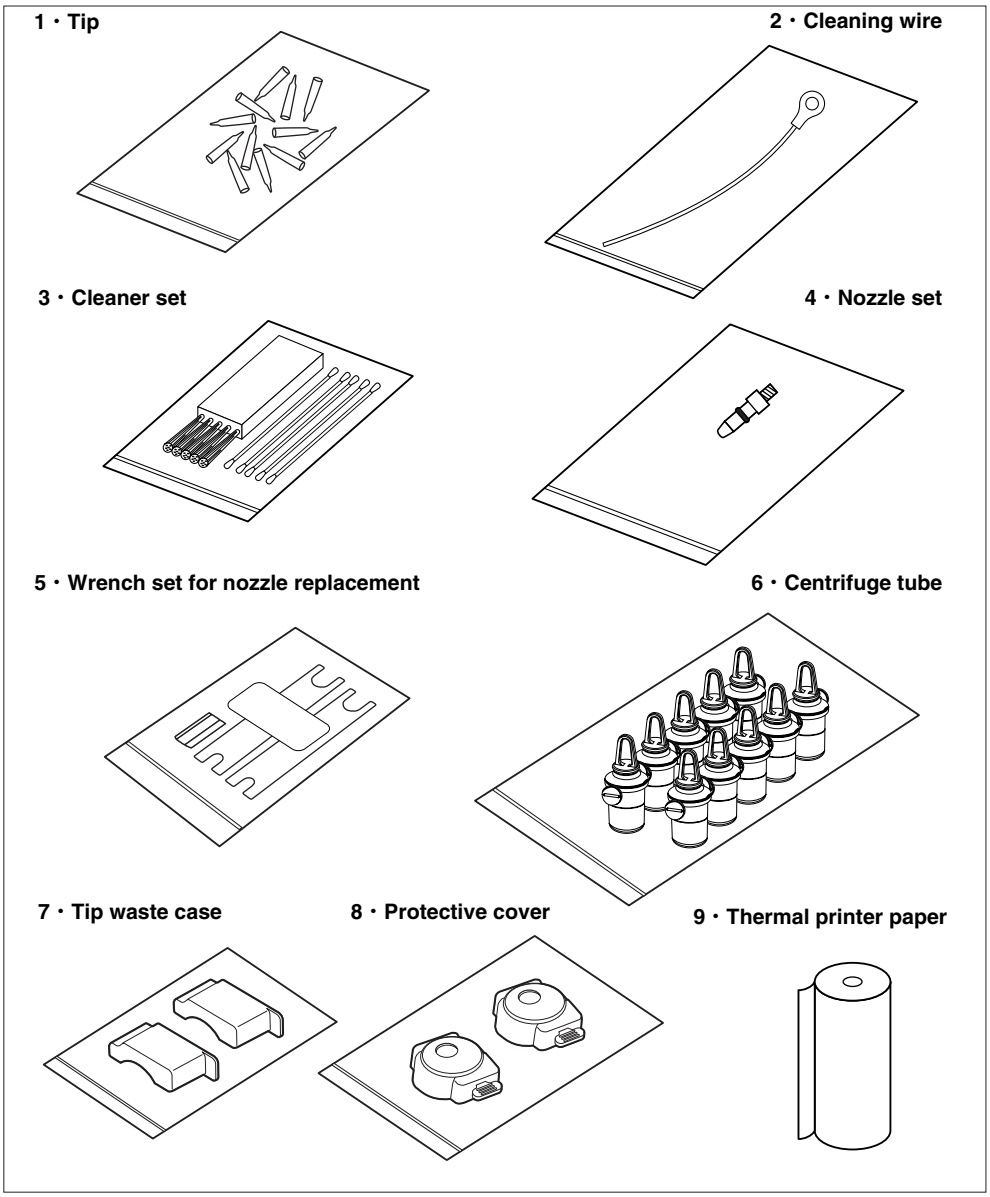
5 · Operating manual



NO.	Item	Description	Qty.
1	Analyzer	SP-4430	1
2	Power cord		1
3	AC adapter		1
4	Accessory case		1
5	Operating manual	This book	1

1-2-2 Accessories

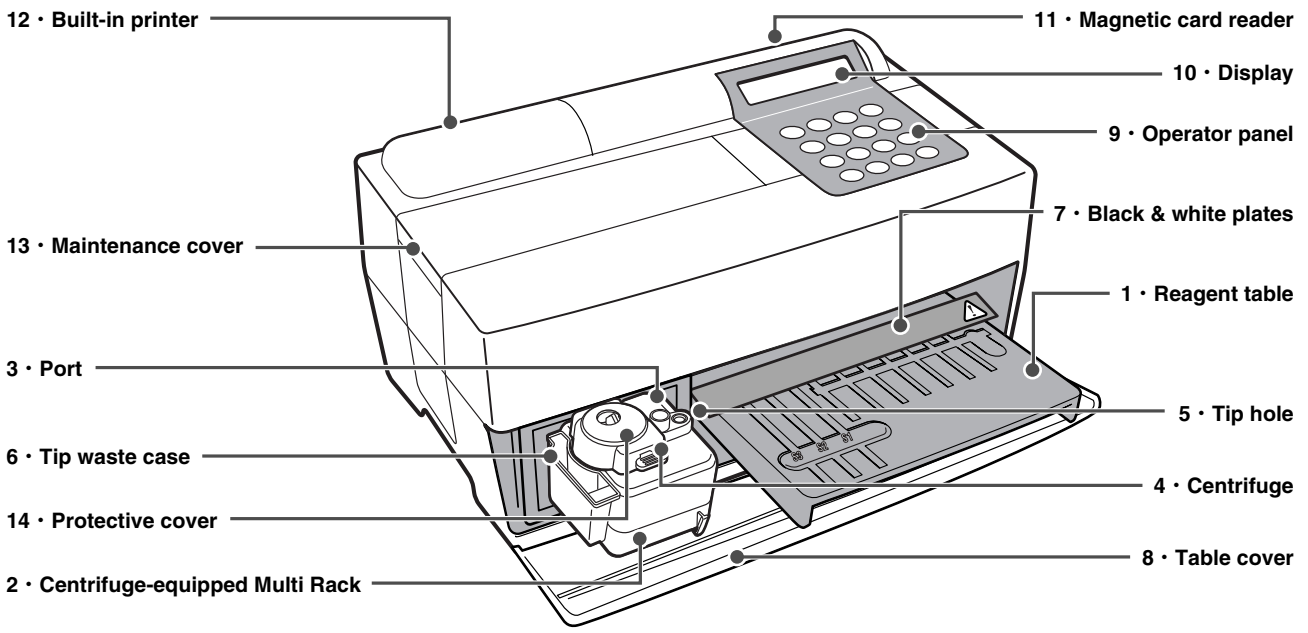
Open the package and confirm that all items are included.



NO.	Item	Description	Qty.
1	Tip	10 tips	1 Set
2	Cleaning wire	Nozzle cleaning	1 Set
3	Cleaner set	Brush, Cotton swab	1 Set
4	Nozzle set (EZ)	Nozzle with O-ring	1 Set
5	Wrench set for nozzle replacement	2 Wrench, Adapter	1 Set
6	Centrifuge tube	10 pieces	1 Set
7	Tip waste case	2 pieces	1 Set
8	Protective cover	2 pieces	1 Set
9	Thermal printer paper	width 58 mm	1 Set

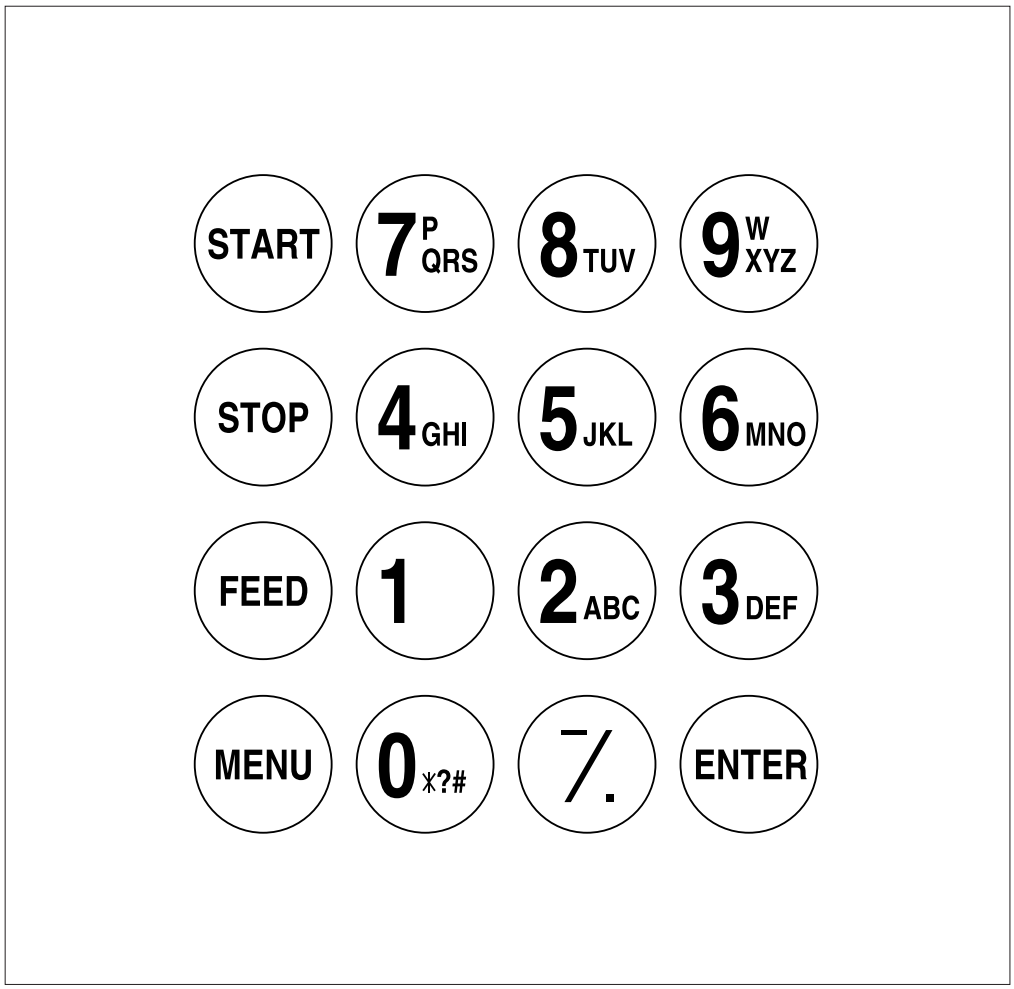
1-3 Parts Description and Function

1-3-1 Front of the analyzer



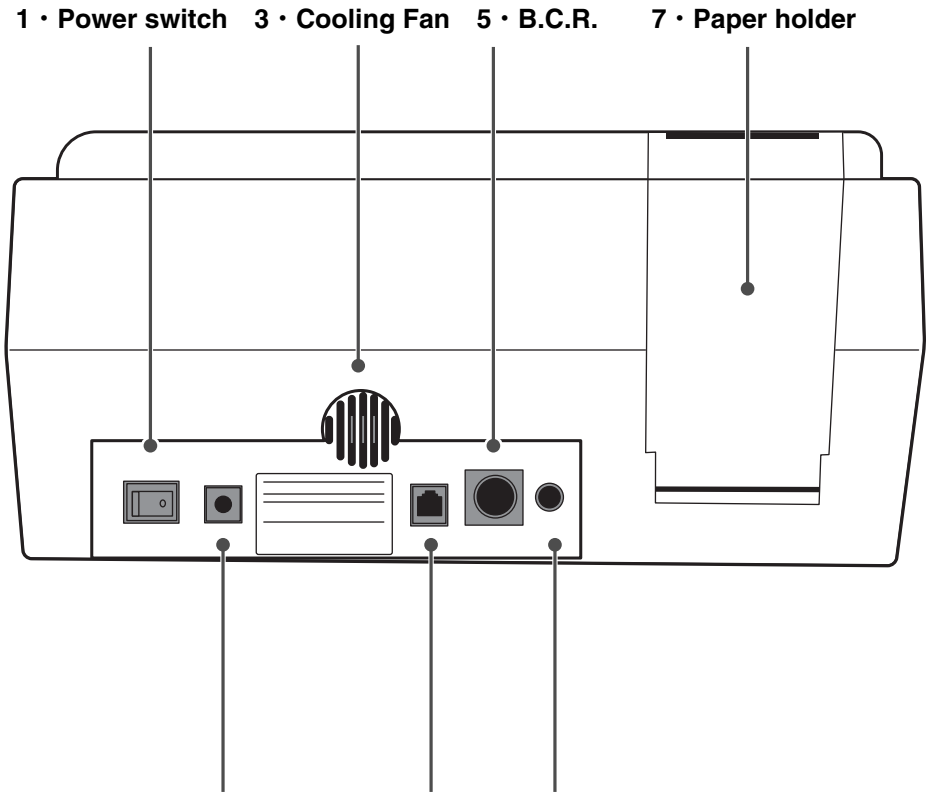
NO.	Item	Function
1	Reagent table	For setting the Reagent Strip. The temperature is kept at 37℃ for the reaction conditions of Reagent.
2	Centrifuge-equipped Multi Rack	For setting the samples and tips. The centrifuge for 1 sample is built in.
3	Port	For setting the samples.
4	Centrifuge	For setting the whole blood samples that have not been centrifuged.
5	Tip hole	For setting tips.
6	Tip waste case	The container for used tips automatically discarded after sampling. Filled with 5 measurements.
7	Black & white plates	The standard reflection plates used for measurement of reflectivity.
8	Table cover	Prevents entering the external light. Slide forward the Reagent Table and Centrifuge-equipped Multi Rack to open.
9	Operator panel	For starting or stopping measurement and entering IDs.
10	Display	Displays information such as operating state of the unit and error messages.
11	Magnetic card reader	For inserting magnetic cards: Reagent Card and Calibration Cards.
12	Built-in printer	Thermal-type printer. Prints out measurement results and setting conditions.
13	Maintenance cover	Protects the Nozzle Driving Units. Also prevents the operator from contacting the nozzle during measurement. There are top and side covers.
14	Protective cover	Prevents the operator from contacting the Centrifuge Tube. Also protects spilling of samples.

1-3-2 Operator panel



Item	Function
START	Starts measurement. Select "Yes" from the Yes/No option.
STOP	Stops measurement. Select "No" from the Yes/No option. Cancels entry.
FEED	Feeds the built-in printer with paper while pressed.
MENU	Switches the page on each menu display.
0~9 (ten key)	Selects the menu number. Enter numerical values and ID.
-/.(hyphen/period)	Selects item, move cursor , switch the page on the display, and enter minus sign and decimal point.
ENTER	Determines the entry. Check message to proceed to the operation.

1-3-3 Rear of the analyzer

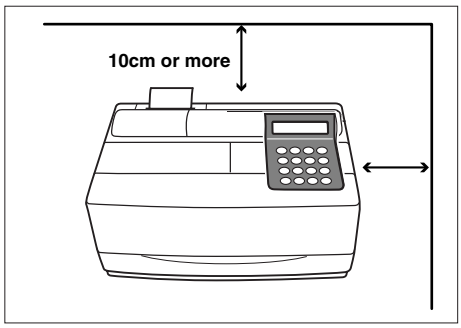


NO.	Item	Function
1	Power switch	For turning on and off the power supply to the analyzer.
2	Power input terminal	For the supplied AC adapter.
3	Cooling Fan	For Ventilating heated air in the unit to prevent overheating.
4	COM.	For the cable of the optional external device.
5	B.C.R.	Jack for the bar-code reader (option).
6	CONT.	For adjusting screen contrast. Turning clockwise to make the screen darker, counterclockwise makes it brighter.
7	Paper holder	For setting thermal printer paper.

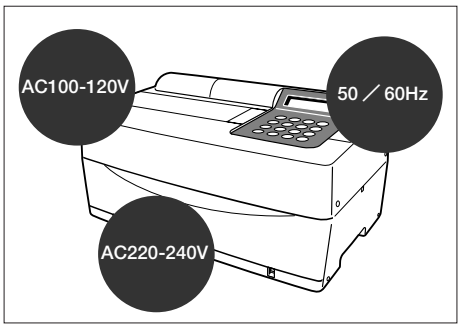
1-4 Setting up the Analyzer

1-4-1 Cautions

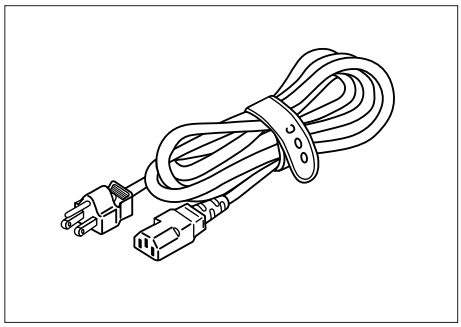
Before setting up the analyzer, read the following notes and always take proper safety precautions.



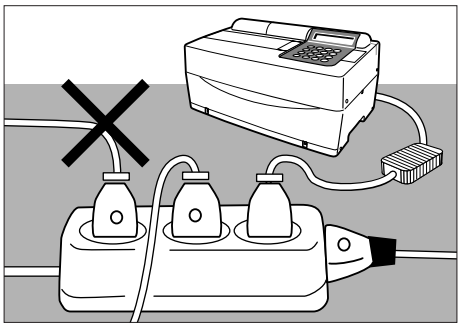
● Allow a space of 10 cm or more between the rear of the analyzer and the wall. Failure to do so may cause overheating. Excessive load on the cable connection may cause fire or incorrect measurement results.
Also, you will have trouble trying to turn off the power switch and disconnect connectors in the event of errors or trouble.



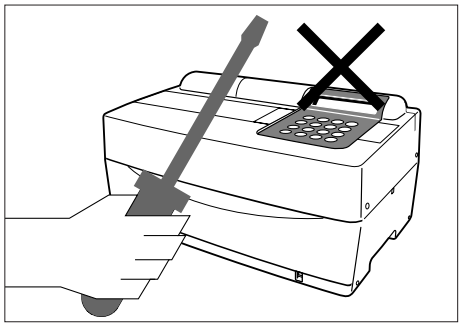
● Operate the analyzer with power of the correct voltage and frequency.
Otherwise fire or damage may result.



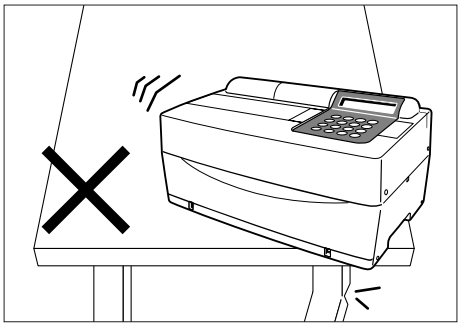
● To avoid electric shock and/or fire, use the attached power cord to connect with a power outlet. For details, contact your distributer.



● Connect the power plug directly to an outlet, not via an extension cord or power tap. The power supply for the analyzer is 100 VA. Before turning on the power switch, make sure that the total input of devices connected to a receptacle of the same circuit doesn't exceed 1500 VA (100V, 15A).

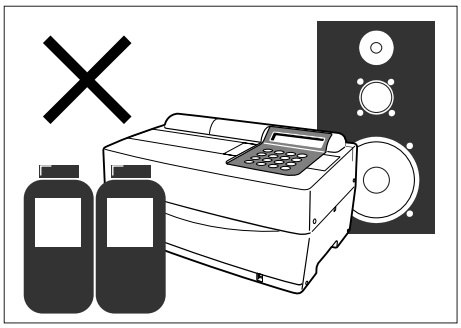


● Do NOT unnecessarily disassemble or modify the analyzer. Such actions may invite danger of exposure to pathogenic microbes, and cause fire or damage.

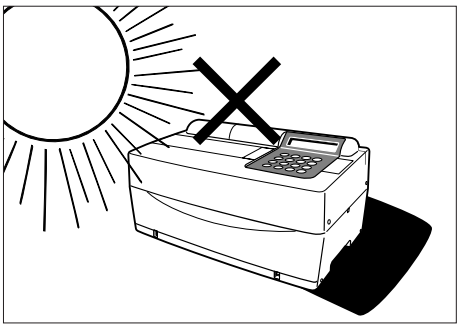


● Place the analyzer on a stable and level surface free of vibration. Failure to do so may damage the analyzer, correct measurement results may not be obtained, and injury may result. Do NOT place the analyzer where there is a risk of falling.

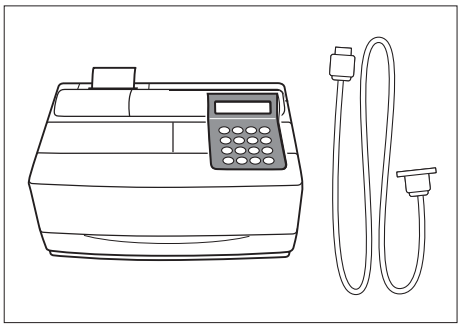
Before setting up the analyzer, read the following notes and always take proper safety precautions.



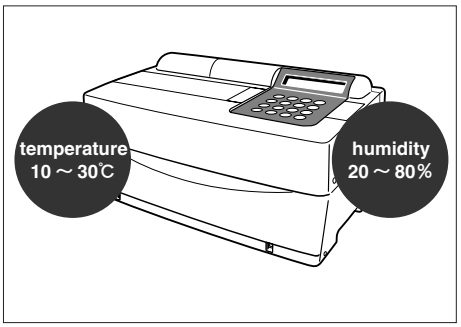
● Do NOT set up the analyzer where chemicals are stored nearby, or where corrosive gases or electrical noise are generated. They may damage the analyzer, and malfunctions and/or injury may occur. Correct measurement results may not be obtained.



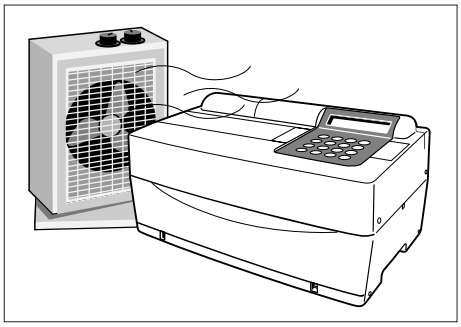
● Avoid exposing the analyzer to direct sunlight, condensation and wind. Otherwise, correct measurement results may not be obtained, and may cause deformation or malfunction of the analyzer.



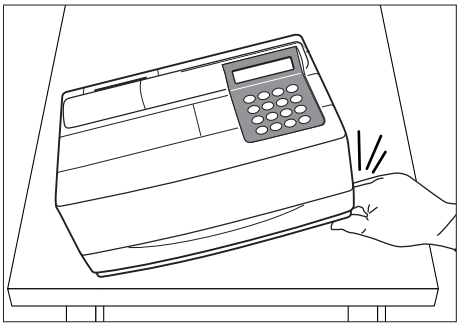
● To connect the analyzer to external devices, be sure to use proper cables to avoid electric shock and/or fire. For details, contact your distributor.



● Place the analyzer in a room at temperatures between 10℃ and 30℃ with humidity between 20% and 80%. Otherwise, correct measurement results may not be obtained.



● Make sure that the room is well ventilated when a large amount of carbon dioxide is generated (when gas stoves, oil heaters and instantaneous water heaters are used in the room). This is because the pH of the Reagent Strips, which use an alkaline reaction reagent, decreases under the influence of carbon dioxide and correct measurement data may not be obtained.



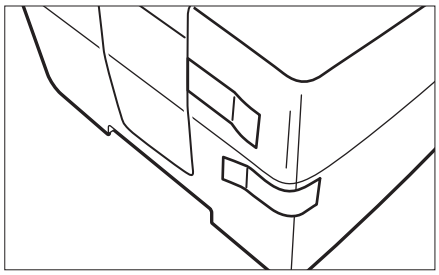
● Be careful not to be put hands under the analyzer.

1-4-2 Setting up the analyzer

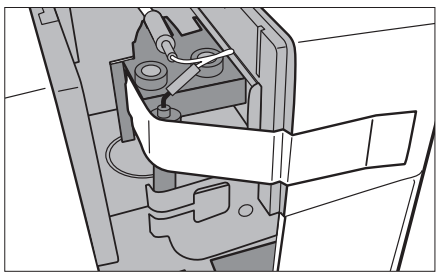
The parts in the analyzer are secured firmly in order to prevent scratches and/or damage due to transportation. Remove the fixing tapes before setting up the analyzer. Read 1-4-1 "Cautions on installation" carefully before setting up the analyzer.

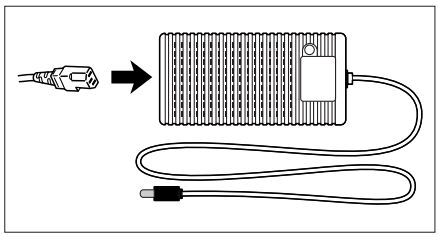
1. Remove the fixing tape.

- Remove the tape fixing the table cover.



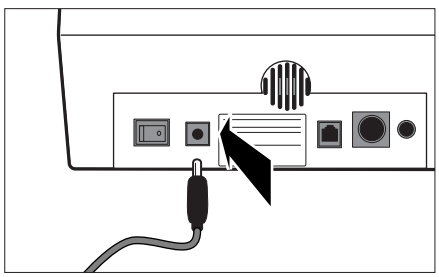
- Open the maintenance cover and remove the tape fixing the nozzle.
- Reattach the maintenance cover.





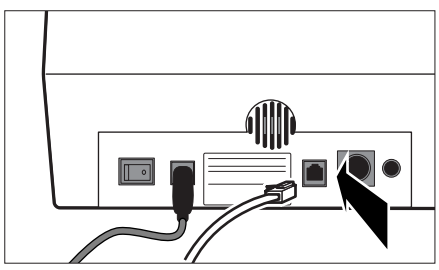
2. Connect the power cord.

- Make sure that the power switch on the rear of the analyzer is OFF.
- Connect the AC adapter to the power cord.
- Connect the AC adapter to the receptacle on the rear panel of the analyzer, and plug the other end of the cord into the AC outlet.



3. Connecting an external device (if necessary)

- When using an external device, connect the exclusive connecting cable to COM on the rear panel of the analyzer.



1-4-3 First operation after setting up

This section explains the way to load thermal printer paper, and set data and time after turning on the power switch.

1. Turn on the power.

- Turn on the power switch on the rear panel of the analyzer.
  "I" is displayed.

```
SPOTCHEM EZ
SP-4430 VXXXX
```

- After the analyzer name and system version are displayed, warm-up starts.

```
Warming up...
```

► For error correction or troubleshooting, "see Chapter 5 Troubleshooting".

- About 10 minutes after (room temperature at 25℃), warm-up is completed and the MAIN MENU is displayed as shown at right.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

2. Set the thermal printer paper.

- Set the attached thermal printer paper (See 4-3-1 "Thermal printer paper replacement").

3. Confirm the time and date.

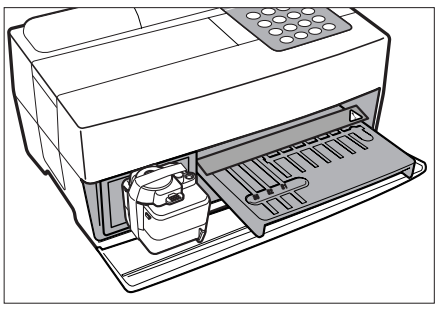
- Set the date and time (see "3-6 Built-in Clock Adjustment").

IMPORTANT

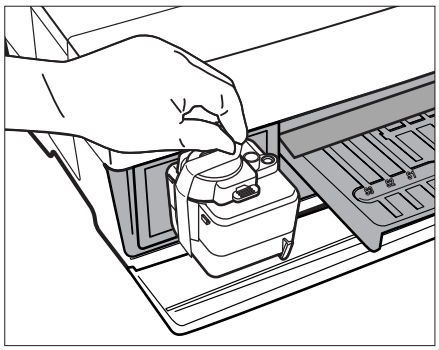
If the date is not set correctly, correct measurement results may not be obtained and an error may occur.

4. Remove the fixing tape on the protective cover.

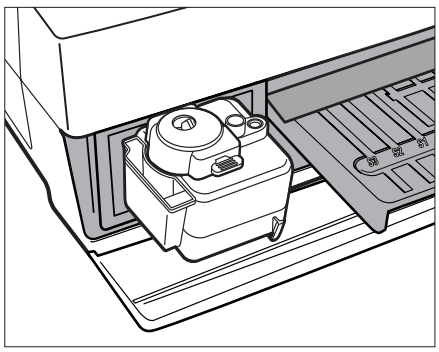
- Press [1] on the MAIN MENU.
  The Table Cover opens and the Reagent Table and Centrifuge-equipped Multi Rack slide forward.



● Remove the tape fixing the protective cover.



● Set the maintenance cover and the tip waste case.



● Press [STOP] to close the table cover.

```
Cover is closing. /
```

```
Cover is closing.
          Stop(STOP)
```

► If no key entry is made within 3 minutes after the Table Cover is opened, an alarm beeps and the Table Cover is closed.
If [STOP] key is pressed while the message "CANCEL" is displayed, the Table Cover remains open and the Standby screen is restored.

► After the Table Cover is closed, a message shown at the right is displayed.
To restore the MAIN MENU, press [STOP] key.
When [ENTER] key is pressed, the Table Cover opens and the Standby screen is restored.

```
Back to MENU(STOP)
Back to MEAS(ENTER)
```

5. Turn off the power.

● When terminating the operation or setting, turn off the power after making sure that the MAIN MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

1-4-4 Precautions in Instrument Relocation

Read the precautions below carefully and always be mindful of safety when transporting the system.

- **Turn off the power and disconnect the power cable before transporting the system. Failure to do so may cause system malfunction.**

- **Transport the system with the front cover closed. Transporting the system with the front cover open may result in exposure to pathogenic microbes or system malfunction.**

- **Check that there are no reagents, tips, or samples remaining in the system before transporting the system. Transporting the system with used reagents, tips, or samples remaining in the system may cause contamination of the internal components by pathogenic microbes.**

- **When transporting the system, handle the system with both hands and avoid exposing the system to impacts or vibrations. Failure to do so may cause system malfunction.**

1-4-5 Notes at transportation

When carrying the analyzer in cars, use an exclusive carrying case. The carrying case is optional. Follow the following procedures to prevent exposure to pathogenic microbes and damage to the analyzer.

Wear protective gloves to prevent exposure to pathogenic microbes.

1. Inspect the inside of the analyzer.

- Press [1] on the MAIN MENU. The Table Cover opens and the Reagent Table and Centrifuge-equipped Multi Rack slide forward.
  The Standby screen is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

```
Standby  2000-06-10
        ID(1) INFO(2)
```

- Make sure that there are no used Reagent Strips or samples. If any, discard them.

- When there are used tips in the Tip Waste Case, discard them.

- Press [STOP] to return to the MAIN MENU and turn off the power switch.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

2. Placing analyzer into carrying case.

- Place the analyzer, AC adapter and power code in the carrying case.

Chapter 2

MEASUREMENT

The normal measurement and two types of calibration can be done with the SP-4430. This chapter describes the outline and operating procedures of each measurement.

2-1 Outline of Measurement

2-1-1 SPOTCHEMⅡ Reagent Strips

SPOTCHEMⅡ Reagent Strips (optional) must be used with this analyzer. There are two types of SPOTCHEM Reagent Strips. Use the correct type of strips for the measurement purpose.

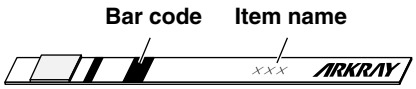
● Multi Reagent Strip

A Multi Reagent Strip has 5~6 reagent fields for analyzing various items including normal screening, and liver or renal function screening.

Multi Reagent Strip

● Single Reagent Strip

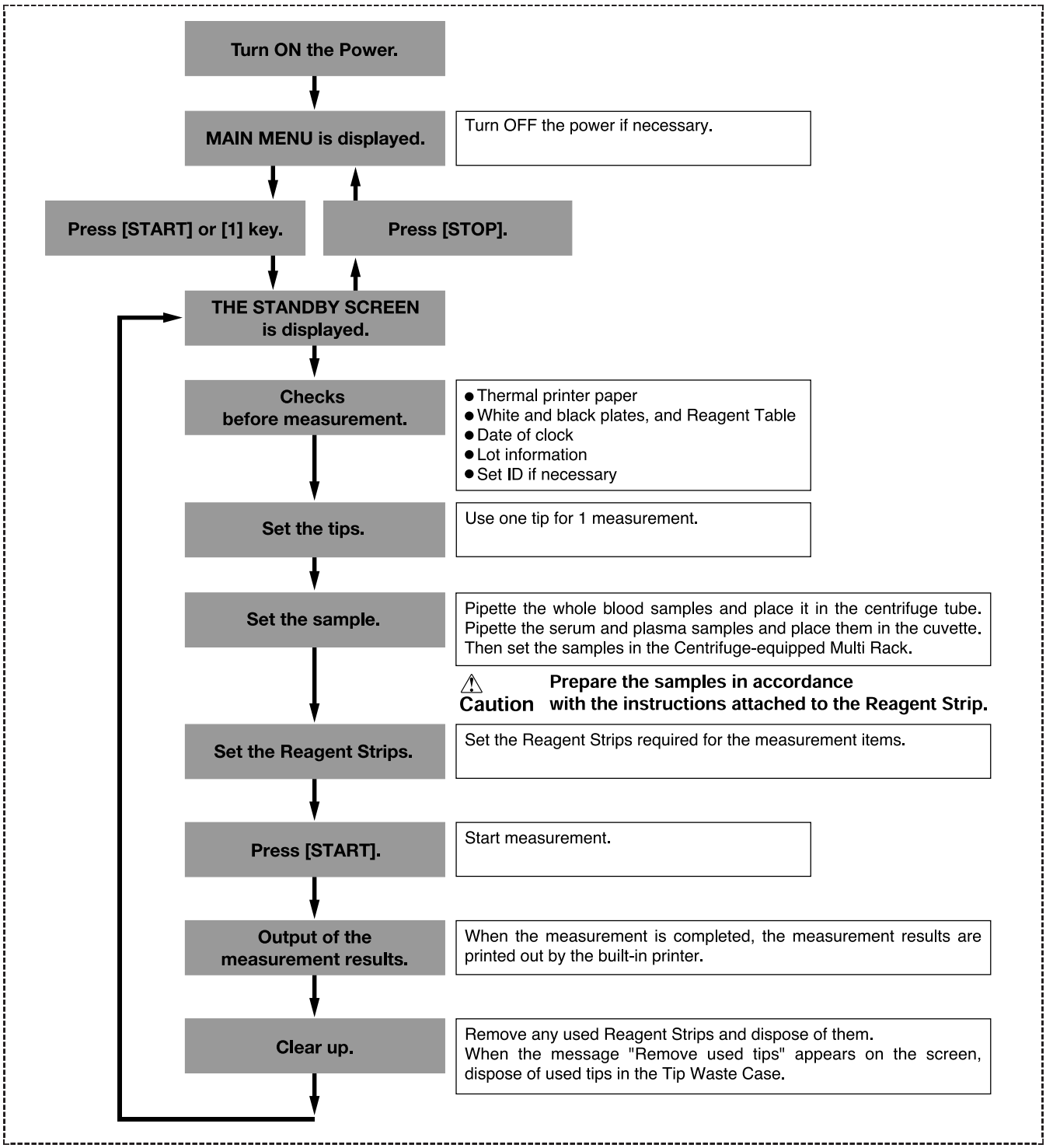
A Single Reagent Strip has only one reagent field on it. Several different reagent items of Single Reagent Strips can be measured for one sample.



Single Reagent Strips

2-1-2 Normal measurement

In normal measurement, more than one item can be measured at a time for one sample. The Reagent Strip Table can hold three Single Reagent Strips and one Multi Reagent Strip, so that simultaneous measurement of up to nine items is available. The operating procedure of normal measurement is described as shown below.



2-1-3 Calibration

This analyzer provides two types of calibration: Calibration by magnetic card (Reagent Card) and Calibration by Calibrator. Calibration must be performed for all fields of Reagent Strips (see "2-5-1 Outline of calibration" for details).

For calibration by Calibrator, the following two types of Calibrator Kit and Magnetic Card (Calibration Card) are used.

■SPOTCHEM Calibrator Kit

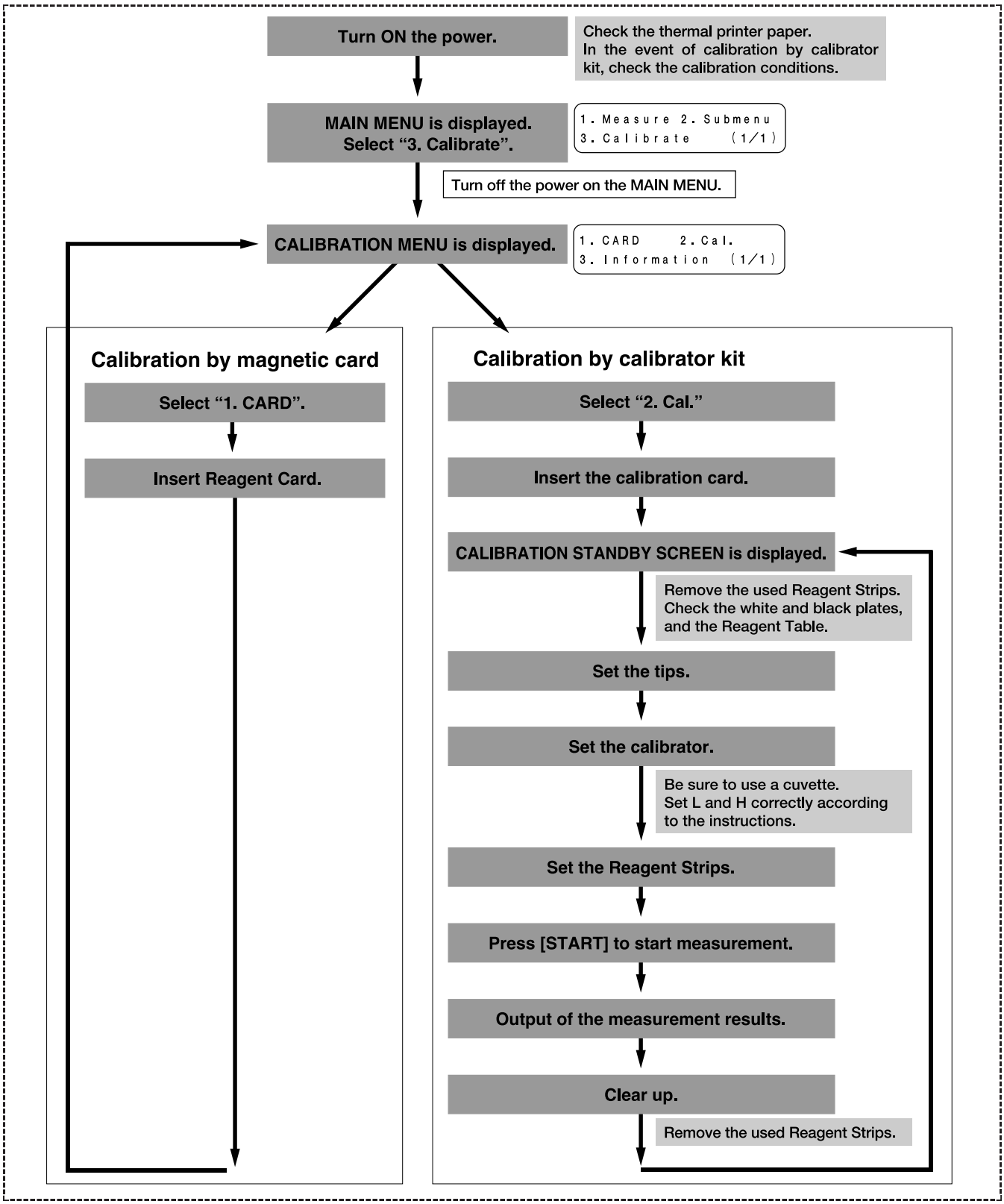
For use with all items except Hemoglobin

■SPOTCHEM Calibrator Hb Kit

For use with Hemoglobin

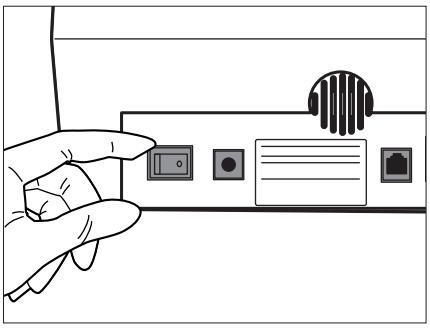
Each Calibrator Kit contains Low and High lyophilized serum and a Calibration Card. For detailed procedures, see the package insert of the Calibrator Kit.

The flowchart of calibration.

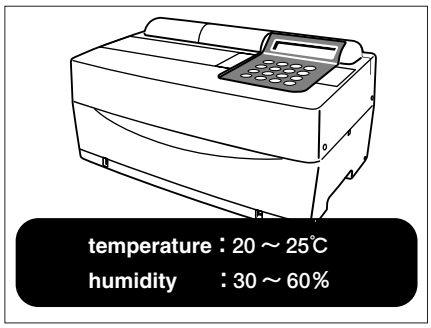


2-2 Cautions

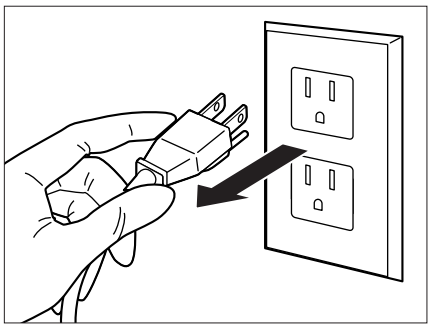
2-2-1 Cautions



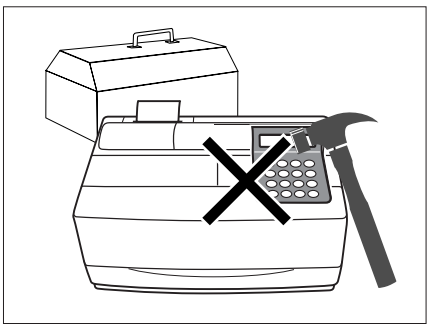
● Before turning ON the power, reconfirm "1-4-1 Cautions" so that the analyzer is always operated under proper conditions.



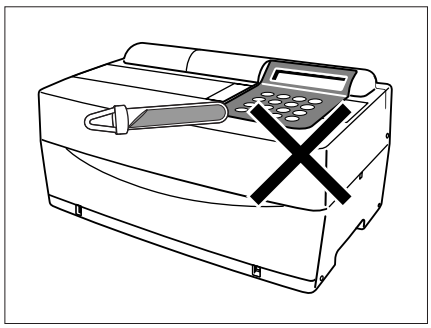
● The analyzer has a temperature control function in order to yield correct measurement results at the room temperature of 10~30℃. For more accurate measurement, measurement at the room temperature of 20~25℃ and at humidity of 30~60% is recommended.



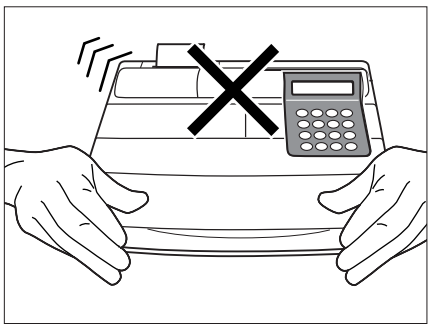
● If there is anything wrong with the analyzer, or in case of odor or smoke, turn OFF the power immediately and unplug. Otherwise the analyzer may be damaged and cause fire.



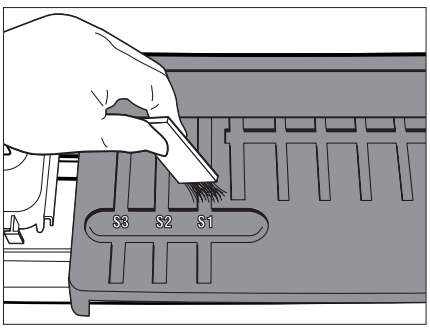
● If the analyzer is out of order, contact your distributor for repair. Do NOT attempt to repair or modify it by yourself. It may damage the analyzer or get injured.



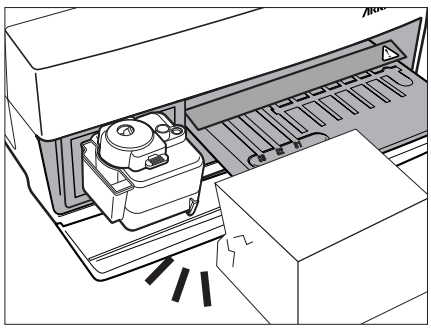
● Do NOT put a container with samples in it on the analyzer. If samples spill on the device, it may damage.



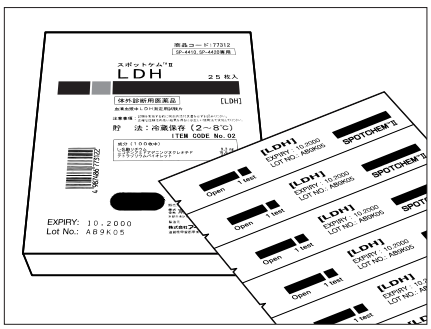
● Do NOT move the analyzer during measurement. Such movement may cause malfunction, resulting in incorrect measurement results.



● Perform proper maintenance following the instruction to ensure high accuracy.

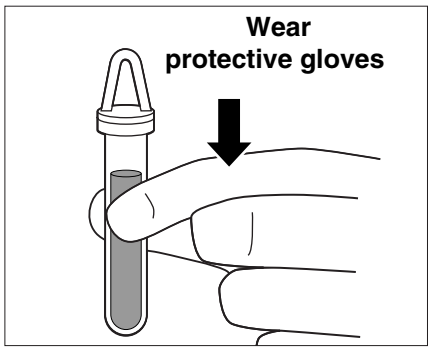


● Do NOT place anything in front of the Table Cover. It automatically opens during operation.

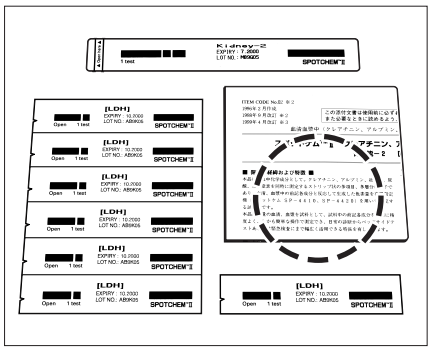


● Use SPOTCHEM Reagent Strips only for the analyzer. The other types of Reagent Strips are unacceptable.

2-2-2 Handling samples

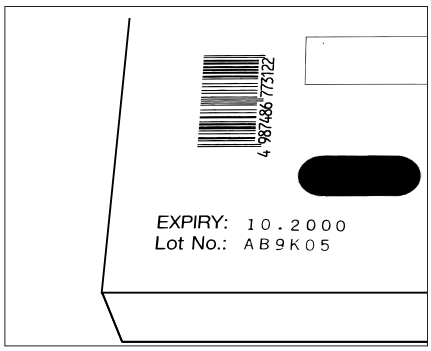


● Blood is used as a measurement sample with this analyzer. Be aware that blood may be contaminated with pathogenic microbes that may cause infectious disease. Exercise utmost care whenever handling blood. Incorrect or imprecise procedures may result in exposure to pathogenic microbes.

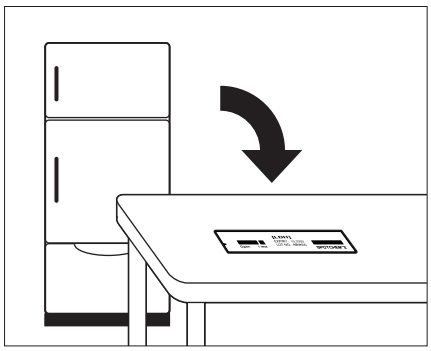


● Handling samples slightly differs depending on test items. Follow the instructions on the package insert of SPOTCHEM Reagent Strips.

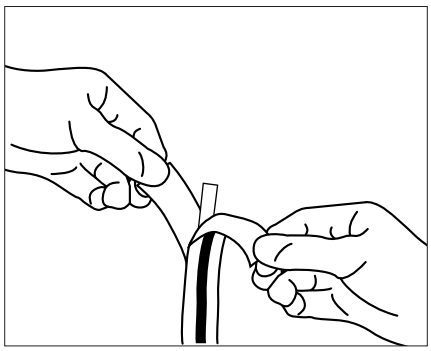
2-2-3 Handling Reagent Strips



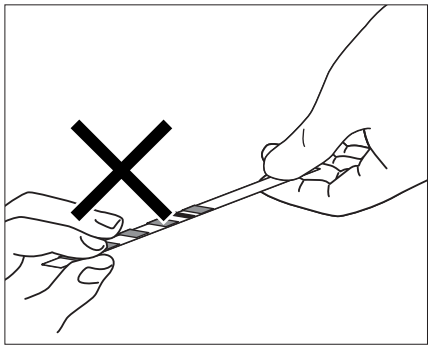
● Do NOT use expired Reagent Strips.
Do NOT use deteriorated strips of which the reagent fields show any sign of discoloration or deformation, even if they are before the expiration date. Otherwise, correct measurement results may not be obtained.



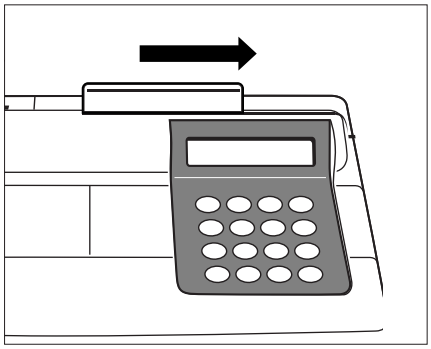
● Take Reagent Strips out of the refrigerator 20 minutes before measurement and allow them to reach room temperature (10 to 30℃). Otherwise, correct measurement results may not be obtained.



● Open a reagent strip package immediately before use. If the opened reagent strip is left for a while, it will absorb water from the air or gather dust, which may result in incorrect measurement results.

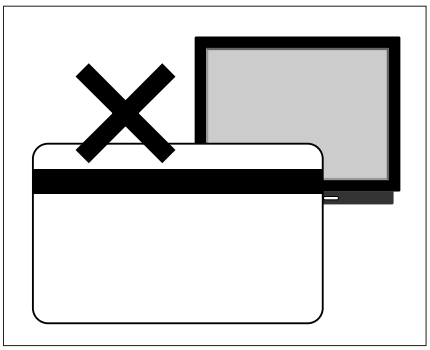


● Do NOT touch the reagent field on the strip with fingers. Sebum on the reagent field may result in incorrect measurement results.

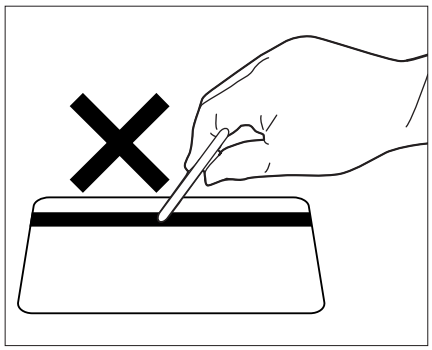


● When a new reagent strip box is opened, perform calibration by magnetic card using the supplied Reagent Card (see 2-5-2).

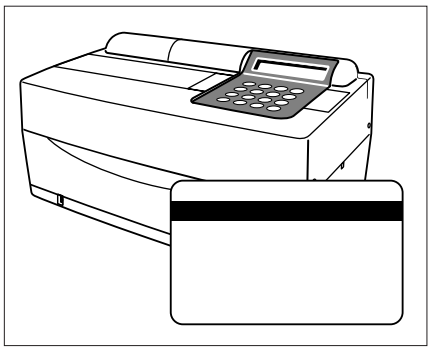
2-2-4 Handling magnetic cards



● Do NOT place a magnetic card close to a magnetic object (magnet, TV set, etc.) Information on the magnetic card may become unreadable.

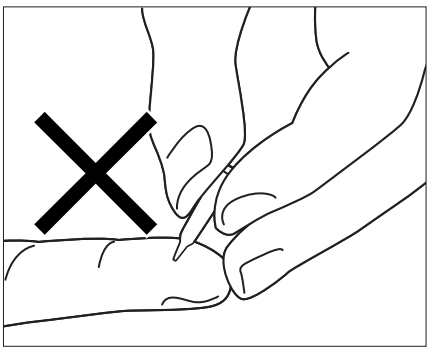


● Do NOT scratch the magnetic surface (stripe). Information on the magnetic card may become unreadable.

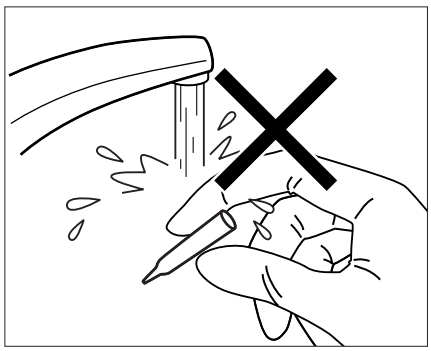


● Do NOT use a magnetic card (supplied with Reagent Strips or Calibrator) for SP-4420 or SP-4430 with other devices. The card may become jammed in the device.

2-2-5 Handling tips

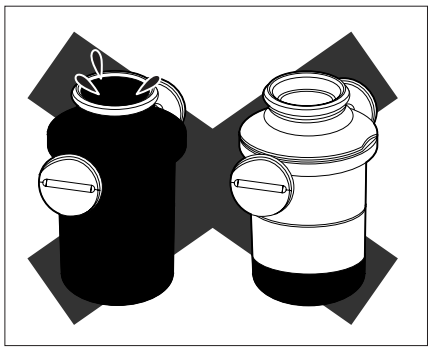


● Do NOT touch the pointed end of a Tip with bare hands. If it becomes soiled, correct sampling may not be possible, resulting in incorrect measurement results.

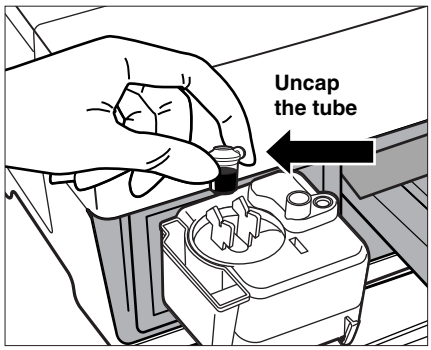


● Do NOT reuse a tip. Water-repellent treatment is applied to each tip so that the sample can be pipetted correctly. If it is rinsed, the coating will come off and correct measurement results may not be obtained.

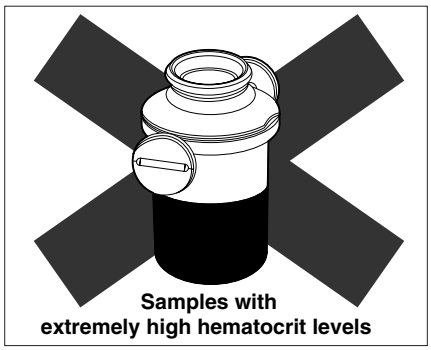
2-2-6 Handling centrifuges



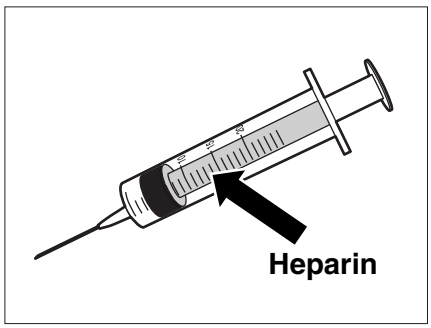
- Pipette 250μL to 270μL of whole blood into the centrifuge tube. Insufficient sample volume may result in incorrect measurement results. Excessive volume may cause blood to stain the cover.



- Heparin is contained as an anticoagulant. Close the cap tightly after setting a sample, and invert it and use the sample after removing the cap.
  Remove air bubbles or skin on the surface of the sample, if any. Otherwise they may cause incorrect measurement results.
  Wipe out the sample attached to the outside of centrifuge tube before placing it to the centrifuge, otherwise it may cause spattering the sample.



- Samples with extremely high hematocrit levels may yield incorrect measurement results.



- When it takes time before blood samples collected are brought into the centrifuge, the samples may begin to coagulate. The samples, which show heavy coagulation or deposition of fibrin, may not be subjected to measurement.
  A syringe containing heparin can be used to prevent coagulation when it takes time before the samples are brought into the centrifuge, although the machinecontains heparin.

2-3 Preparation for Measurement

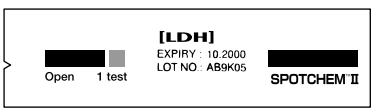
2-3-1 Preparation

Prepare necessary instruments as described in the following table before starting Normal Measurement, Calibration by Magnetic Card or Calibration by Calibrator.

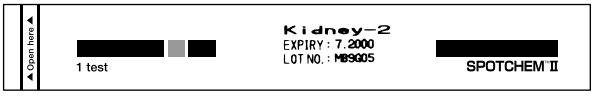
Item	Normal measurement	Magnetic card Calibration	Calibration by calibrator kit
Protective gloves	○	×	○
Centrifuge tube	Used for measurement of whole blood samples	×	×
Whole blood sample tube (Orange cap)	Used for measurement of whole blood samples	×	×
Serum sample tube (Blue cap)	Used for measurement of serum and plasma samples	×	○
Tip	○	×	○
Reagent Strip (Single or Multi)	○	×	○
SPOTCHEM calibrator	×	×	○
Magnetic card (Reagent Card)	×	○	×
Magnetic card (Calibration card)	×	×	○

IMPORTANT

Take the Reagent Strips out of the refrigerator and leave them at room temperature (10～30℃) for 20 minutes.



Single Reagent Strips



Multi Reagent Strip

IMPORTANT

Using Reagent Strips without allowing them to reach room temperature may result in incorrect measurement results.

2-3-2 Startup

The operating procedures from turning ON the power to the MAIN MENU are described below.

NOTE

Before turning ON the power, make sure that the maintenance cover is in position. If light enters into the analyzer during initialization, an error will occur.
Before turning ON the power, make sure that nothing is placed in front of the Table Cover. The Table Cover opens during initialization. If there is an obstruction, a problem may occur.

1. Turn ON the power.

► To obtain the appropriate contrast on the screen, rotate the contrast adjustment knob ("CONT.") on the rear of the analyzer.

- Turn ON the power at the rear of the analyzer. When the power is ON, "|" is displayed

- The name of the analyzer and the system version ("VXXXX" shown at the right) are displayed and warm-up starts.

```
SPOTCHEM EZ
SP-4430 VXXXX
```

- The screen appears during warm-up as shown at the right, and initialization and self-check of each function are performed.

```
Warming up...    /
```

► Warm-up time depends on the room temperature.

- About 10 minutes after (when at 25℃), warm-up is completed and the MAIN MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

2-3-3 Checks before measurement

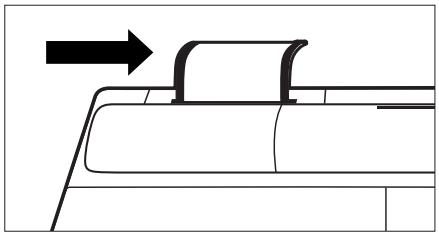
Check each part before performing Normal Measurement or Calibration.

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to the local regulations on biohazardous waste.

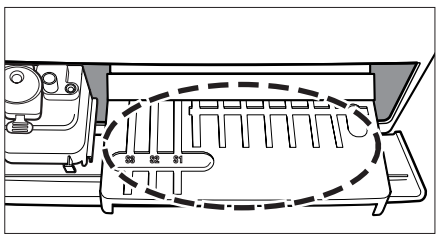
1. Thermal printer paper.

- If a red line appears on both sides of the printer paper, replace it with a new roll (see“4-3-1 Thermal printer paper replacement”).



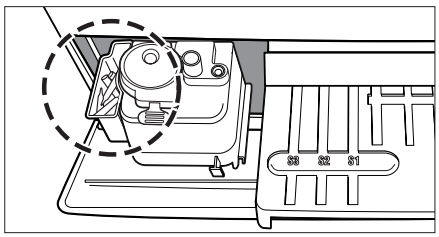
2. Reagent Table.

- Check the Reagent Table and clean it if necessary (see “4-2-1 Cleaning the Reagent Table”).



3. Centrifuge-equipped Multi Rack.

- Make sure that the Centrifuge-equipped Multi Rack has no used samples in it. If any, discard them.
- Install the Tip Waste Case.



4. Setting the parameters.

- Set the parameters as necessary. If the same parameter settings are continuously used, resetting is not necessary. See “Chapter 3 SUB MENU” for details.

IMPORTANT

To check the present parameter settings, print them out (see “3-3-1 Printing parameters”).

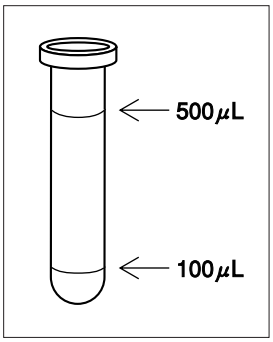
2-3-4 Preparation of samples

Prepare samples as described below except for Hb and HDL-C, which require different procedures (see pages 2-16 and 2-17 for sample preparation for Hb and HDL-C). Test items may be added or changed in the future. Read the package insert of SPOTCHEM Reagent Strips carefully for details on handling samples.

Wear protective gloves to prevent exposure to pathogenic microbes.

► The required volume of a serum or plasma sample is"6x (number of test items)+38 μL".For example, the required volume for 5 test items is : 6 x 5 + 38 μL = 68 μL.

► A Serum or Whole blood Sample Tube has 2 lines marked on it for 100 μL and 500 μL.

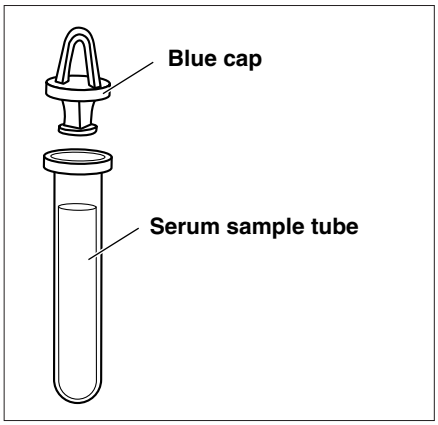


Sample	Sample tube	Required sample amount
Serum or Plasma	Serum sample tube (Blue cap)	6×(number of test items) +38 μL
Whole blood	Whole blood sample tube (Orange cap)	250 μL
Whole blood	Centrifuge tube	250 μL

■ Serum or plasma sample.

Prepare a Serum Sample Tube (blue cap).

Pipette serum or plasma. If measurement is not performed immediately, cap the tube to prevent contamination or evaporation.



IMPORTANT

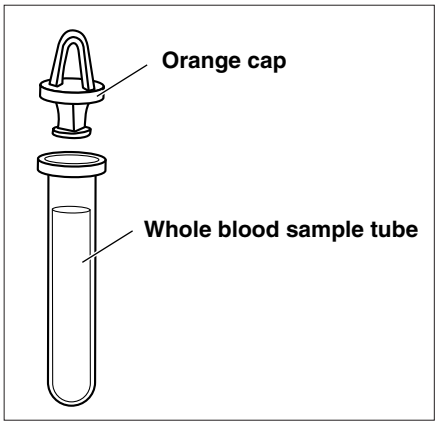
Remove any air bubbles or skin on the surface of the sample.
They may cause incorrect measurement results.

► The Whole blood Sample Tube contains heparin as an anticoagulant.

■ Whole blood.

Prepare a Whole blood Sample Tube (orange cap).
Uncap the tube and pipette whole blood.
Cap the tube tightly.

Invert the sample 5 to 6 times (see "Inverting a sample" on the next page).



► Even if the sample stays at the bottom after being inverted, heparin is well mixed with the sample. Do NOT shake the tube vigorously.

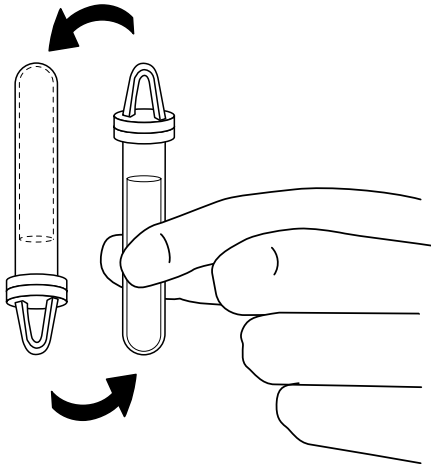
Inverting a sample to mix

1 • Gently invert a sample tube.

2 • In 3 seconds, invert the sample again.

3 • Wait for 3 seconds, and invert it again.

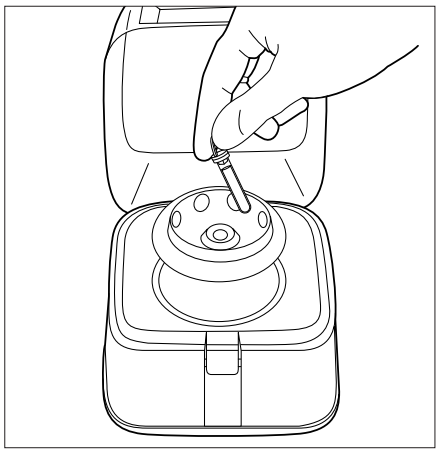
4 • Repeat the above procedure several times.



● To use a whole blood sample tube, prepare a centrifuge.

NOTE

When using an optionally available centrifuge , carefully read the operating manual of the centrifuge.



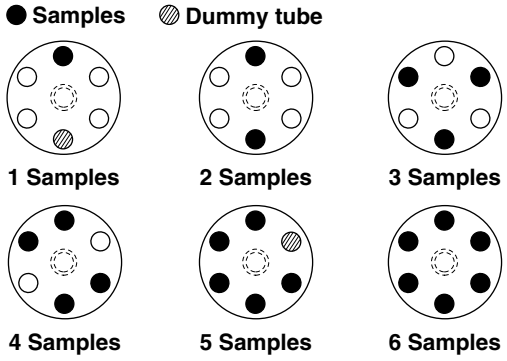
- Place the samples in the centrifuge taking rotor balance into consideration (see the block below).
- Centrifuge the samples for 3 minutes or more. It is not necessary to remove the supernatant from the centrifuged samples. Uncap the tubes and place them directly in the sample rack.

IMPORTANT

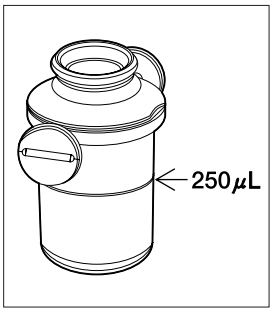
Remove any air bubbles or skin on the surface of the sample.
They may cause incorrect measurement results.

Ensuring rotor balance

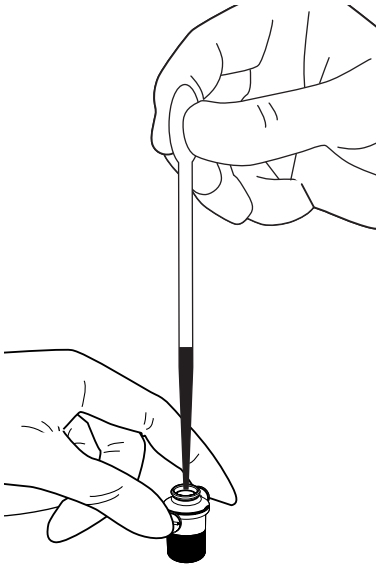
Place sample tubes symmetrically against the rotation axis as illustrated at right. For centrifugation of 1 or 5 samples, use a dummy tube filled with an equal amount of water to make a total of 2 or 6 sample tubes.



► A Centrifuge tube has 1 line marked on it for 250 μL.



Using a centrifuge



- Prepare a centrifuge.
- Uncap the tube and pipette 250μL of heparinized whole blood or plain blood into the centrifuge tube.
- The centrifuge tube includes Heparin as an anticoagulant.
- Close the cap tightly after setting a sample, and invert it.
  Use the sample after removing the cap.
- Wipe out the sample attached to the outside of centrifuge tube before placing it to the centrifuge, otherwise it may spattering the sample.
- Place samples in the centrifuge (see“ 2-4-1 Normal measurement”).

IMPORTANT

Remove any air bubbles or skin on the surface of the sample. They may cause incorrect measurement results.
Wipe out the sample attached to the outside of centrifuge tube before placing it to the centrifuge, otherwise it may cause spattering the sample .

IMPORTANT

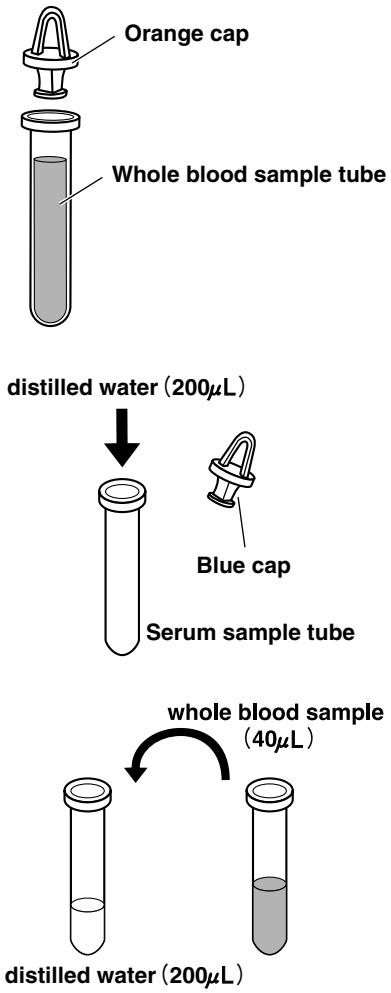
The samples may coagulate when it takes time before the samples collected are brought into the machine. Those showing heavy coagulation or deposition of fibrin sometimes can not be measure. A syringe containing heparin can be used to prevent coagulation when it takes time before the samples are brought into the centrifuge, although the machine contains heparin.

Measuring the Hb

When measuring Hb, dilute whole blood samples 6 times with distilled water.

- Prepare a Whole blood Sample Tube (orange cap).
- Uncap the tube and pipette the whole blood sample into the tube.
- Cap the tube tight.
- Invert the sample several times (see “2-14 Inverting a sample”).

- Prepare a Serum Sample Tube(blue cap). Pipette 200 μL of distilled water.
- Pipette 40μL of the prepared whole blood sample into the above Serum Sample Tube.
- Cap the tube tight.
- Invert the sample several times again.



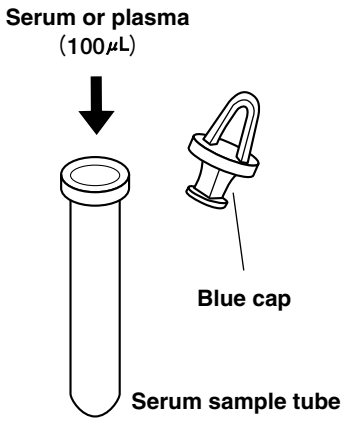
IMPORTANT

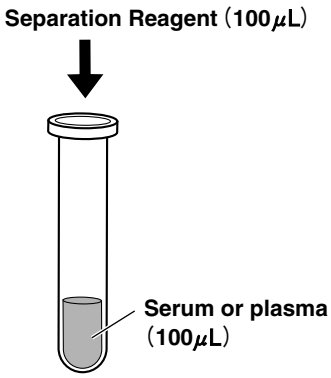
Remove any air bubbles or skin on the surface of the sample.
They may cause incorrect measurement results.

► If HDL-C reagent(direct method) is used for measurement, this procedure is unnecessary.

Using HDL-C Kits

- Prepare a Serum Sample Tube (blue cap).
- Pipette 100μL of serum or plasma.
- Gently pipette 100μL of HDL Separation Reagent into the tube.
- Cap the tube tight.
- Invert the sample more than 10 times following to **"** 2-14. Inverting a sample**"** and leave the sample about 5 minutes.
- Centrifuge the samples for 3 minutes, taking rotor balance into consideration(see page 2-14).
  Check if the supernatant is impure or there is any skin or not. Removing the supernatant is not necessary. Uncap the tube and place it directly in the sample rack.





IMPORTANT

Remove any air bubbles or skin on the surface of the sample.
They may cause incorrect measurement results.

2-4 Measurement

2-4-1 Normal measurement

This section describes the operating procedure of Normal Measurement. In Normal Measurement, simultaneous measurement of up to nine items is possible for one sample, using Single and Multi Reagent Strips. Before measurement, make necessary preparation as instructed in "2-3 Preparation for Measurement".

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

Be careful not to spill sample blood when uncapping the tube.

1. Display the Standby screen.

► [START] key can be used instead of [1] key.

- Press [1] key on the MAIN MENU. The Table Cover opens and the Reagent Strip Table and Centrifuge-equipped Multi Rack slide forward.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

- The Standby screen is displayed as shown at the right.

```
Standby  2000-06-10
        ID(1) INFO(2)
```

2. Check the time and date.

- Make sure that the time and date on the Standby screen is correct. If not, set a correct time and date (see "3-6 Built-in Clock Adjustment ").

IMPORTANT

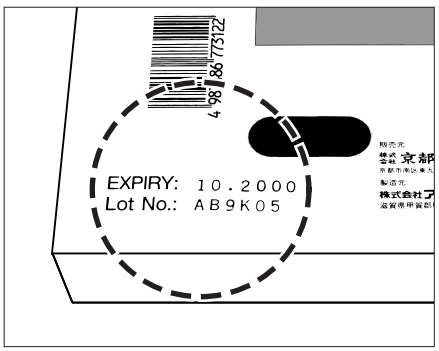
If a wrong date is set, correct measurement results may not be obtained. Before measurement, make sure that the date is correct.

3. Check the lot number of Reagent Strips.

● Press [2] key on the Standby screen.

```
【S-01:GGT        】
( 1/30)【XXXXXX CARD】
```

● The Confirm screen is displayed, which indicates information of Reagent Strips stored in memory. Check that the test items and lot numbers of the Reagent Strips match with those shown on the screen (lot numbers are “XXXXXX” at right). Lot number of a Reagent Strip is printed on the rear side of the aluminum foil package or on the box.



► To check numerous test items at one time, print out the lot numbers of all items.
Press [3] key on the Standby screen to print out all the lot numbers.

IMPORTANT

If the lot numbers of the Reagent Strips are different from those shown on the screen, perform Calibration by magnetic card before measurement.

● Press [hyphen (-)] key to check the information of the reagent strip you are using.

► Besides [hyphen (-)] key, [0], [2], [4], [5], [6], and [8] keys can be used in selecting items.
[0] -> initially displayed item
[2] -> last item
[4] -> previous item
[6] -> next item
[8] -> first item
[5] -> first item of the Multi Reagent Strip

● When confirmation is completed, press [STOP] key. The Standby screen is restored.

```
Standby  2000-06-10
      ID(1) INFO(2)
```

► If no key entry is made within 3 minutes after the Table Cover is opened, an alarm beeps and the Table Cover is closed.
If [STOP] key is pressed while the message “CANCEL” is displayed, the Table Cover remains open and the Standby screen is restored.

```
Cover is closing.
        Stop(STOP)
```

► After the Table Cover is closed, a message shown at the right is displayed.
To restore the MAIN MENU, press [STOP] key.
When [ENTER] key is pressed, the Table Cover opens and the Standby screen is restored.

```
Back to MENU(STOP)
Back to MEAS(ENTER)
```

4. Set measurement No. or ID (if necessary).

ID of up to 13 characters can be set for each measurement. If ID setting is not necessary, move on to procedure 6. Rack slides forward.
The Standby screen is displayed as shown at the right.

- Press [1] key on the Standby screen. The measurement No. screen is displayed.

```
Standby  2000-06-10
      ID(1) INFO(2)
```

- Enter measurement No.. Up to 4 characters can be entered using numbers.

```
No.              <_   >
```

- Press [ENTER] key.
- The entered measurement No. is stored in memory and the ID entering screen is displayed.

```
ID<_                  >
```

- Enter ID. Up to 13 characters can be entered using numbers, letters, and symbols.
- When the barcode reader is used, ID is automatically read by the reader.
- Press [ENTER] key.
- The entered ID is stored in memory and the Standby screen is restored.

► The number of the previous measurement No + 1 is displayed as the initial number. To perform measurement with the number, press [ENTER] key to confirm. Once the power is turned off, the initial number returns to 1.

► The last entered ID is displayed. To perform measurement with the same ID as shown on the screen, press [ENTER] key. If the MAIN MENU is restored, the previous ID is cleared.

► To enter ID, use the numeric keys and [-/.] key.
Example: To enter "EZ"
[3] [3] [3] [9] [9] [9] [9] [9]
Example: To enter "SP"
[7] [7] [7] [7] [7] [-] [7] [7]
The following 12 signs can be entered by using [0] key.
＊ ？ ＃ . , : ; ' ― ＋ / %

► To delete the last character, press [MENU] key and [-/.] key simultaneously.To restore the initially shown ID, press [START] key.

► When the barcode reader (optional) is used, manual entering is not necessary.Read barcode is automatically allocated as ID.

► When the barcode reader is used a message "BARCODE AVAILABLE" is displayed.

► Press [hyphen (-)] key on the Standby screen to switch the operation guidance at the lower part of the screen.

► If no key entry is made within 3 minutes after the Table Cover is opened, an alarm beeps and the Table Cover is closed. If [STOP] key is pressed while the message "CANCEL" is displayed, the Table Cover remains open and the Standby screen is restored.

► After the Table Cover is closed, a message shown at the right is displayed.To restore the MAIN MENU, press [STOP] key. When [ENTER] key is pressed, the Table Cover opens and the Standby screen is restored.

```
Cover is closing.
        Stop(STOP)
```

```
Back to MENU(STOP)
Back to MEAS(ENTER)
```

► No set-up is available where sample type is not registered. The registration can be made on the Parameter Menu.

► The sample type set for basic type is established as an initial value. No setting is needed when not changed.

5. Set the sample type (when necessary).

Sample type can be set for each measurement. When sample type is not registered or measurement is made on the setting of basic type, skip the following and proceed to the Step 6.

● Press [6] key on the Standby screen. The Sample type selecting screen is displayed.

```
Standby  2000-01-19
      ID(1) INFO(2)
```

► Besides [hyphen (-)] key, [4], and [6] keys can be used in selecting sample type.
[4] -> previous sample type
[6] -> next sample type

● Press [hyphen (-)] key to select the sample type to measure.

```
Standby  2000-01-19
      Sample [Man  ]
```

► Pressing [Start] key on the Sample type selecting screen starts measurement with the displayed sample type without returning to the Standby screen.

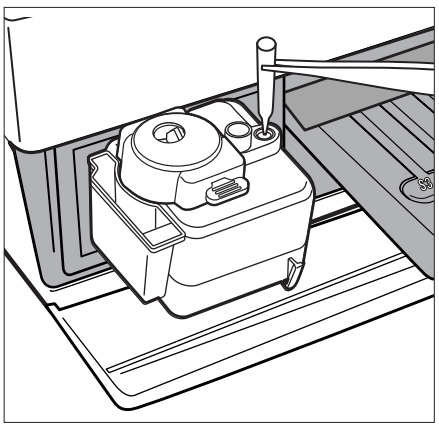
● Press [Enter] key while the selected sample type is displayed.

● The selected sample type is set as the measurement sample type and the Standby screen is restored.

```
Standby  2000-01-19
      ID(1) INFO(2)
```

6. Set the Tip.

● Place the Tip in the Tip hole of the Centrifuge-equipped Multi Rack using a pair of tweezers.



IMPORTANT

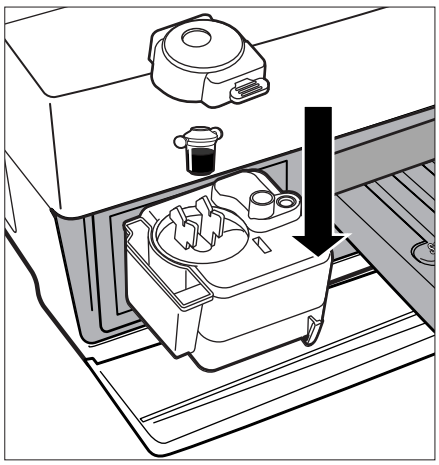
Do NOT touch the pointed end of the Tip with fingers. If it is soiled, correct measurement results may not be obtained.

● Make sure that the Tip Waste Case is set in position.

7. Set the samples.

■ Measurement of uncentrifuged whole blood.

- Open the protective cover and place the uncapped centrifuge tube in position.



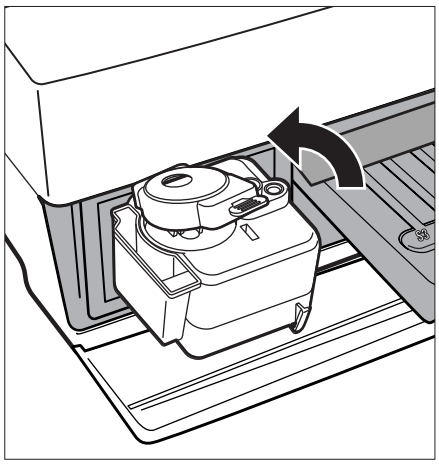
- Close the cover.

⚠CAUTION

If you find any damage to or cracks in the cover, please do not use it.

NOTE

Make sure the sample tubes are uncapped, otherwise it may cause breakage of centrifuge tube and the Nozzle.
Set a sample after removing the cap.

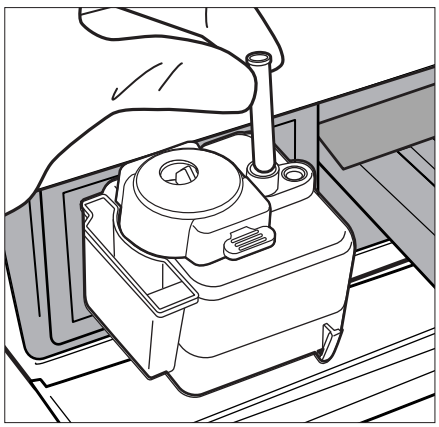


NOTE

Make sure the protective cover is closed properly.
If the protective cover remains open, it may become troubled and correct measurement results may not be obtained.

■ Measurement of serum or plasma, or centrifuged samples.

- Uncap sample tubes and place them to the port of the multi-rack.



NOTE

Make sure the sample tubes are uncapped, otherwise it may cause breakage of the Nozzle.

NOTE

Make sure the protective cover is closed properly.
If the protective cover remains open, it may cause a trouble.

■ Remeasurement (or additional measurement) with a centrifuge.

When measuring the once-measured sample with a centrifuge, such measurement can be done at a reduced centrifugal time.

IMPORTANT

When performing remeasurement or additional measurement , sample quantity may be short. Shortage of sample amount may lead to incorrect results due to sucking of blood cells or trouble because of abnormal rotation of centrifuge. Make sure that the remaining sample amount is enough, and perform remeasurement or additional measurement.

- Press [0] key on the Standby screen. The Centrifuge selecting screen is displayed. [On] is always displayed at the beginning.

```
Standby  2000-01-19
      ID(1) INFO(2)
```

► Every time when [0] key is pressed on the Centrifugation selecting screen, [On], and [Off] are displayed alternately.

- To switch [On] and [Off] of centrifuge, press [0] key on the Centrifuge selecting screen.

```
Standby  2000-01-19
      CNTRFG=[ON ]
```

IMPORTANT

To perform the measurement on the screen of [No centrifugation], be sure to use the centrifuged sample. If uncentrifuged sample is used, correct measurement result may not be obtained.

8. Set the Reagent Strips.

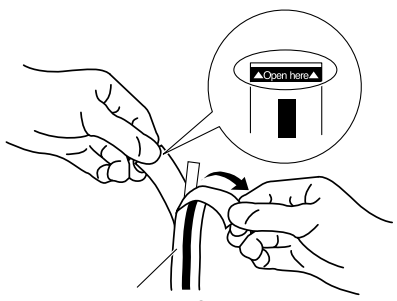
In Normal Measurement, the following three settings are available.

- Multi-type Reagent Strips and Single type Reagent Strip
- Multi-type Reagent Strips only.
- Single-type Reagent Strips only.

Choose one depending on the item to measure.

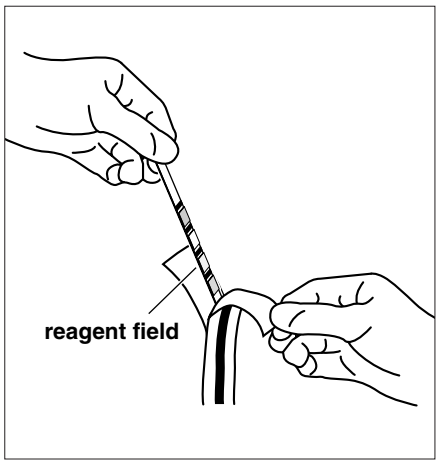
● Set the Multi-type Reagent Strips.

- Open the aluminum foil package from the place written "▲Open here ▲" until two-thirds of the Reagent Strip is exposed.



Multi-type Reagent Strip

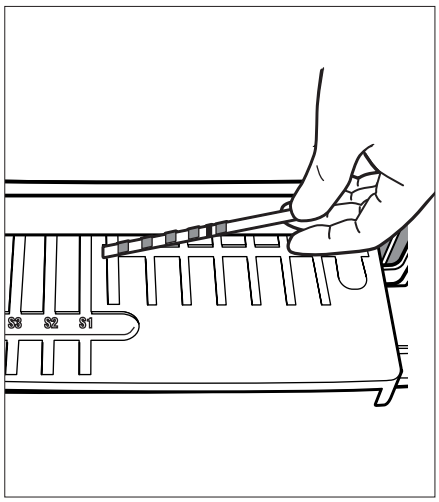
● Remove a Reagent Strip from the aluminum foil package without touching the reagent field with the fingers.



● Place the Reagent Strips on the Reagent Table by holding the right side of the strip.

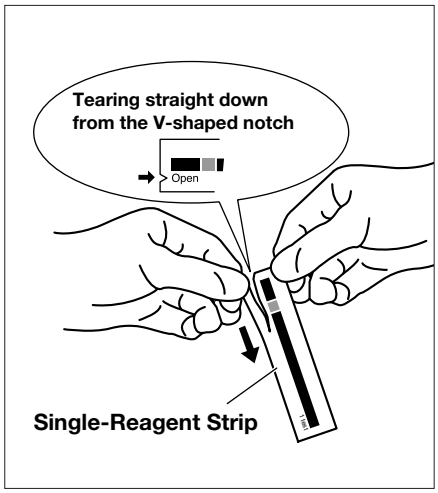
IMPORTANT

Be sure to insert the end of a Reagent Strip into the groove of the Reagent Table so that the Reagent Strip stays firmly in place. If the Reagent Strips are bent or placed out of the groove, it may become jammed or correct measurement results may not be obtained.

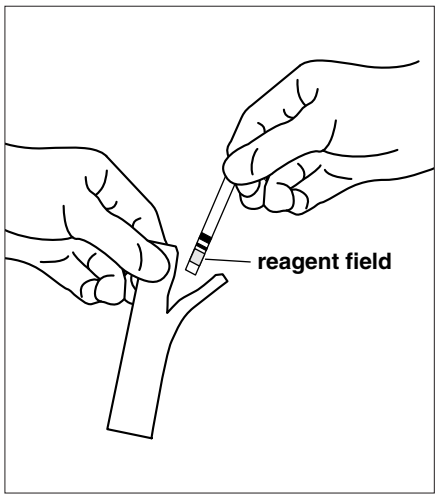


● Set the Single-type Reagent Strips.

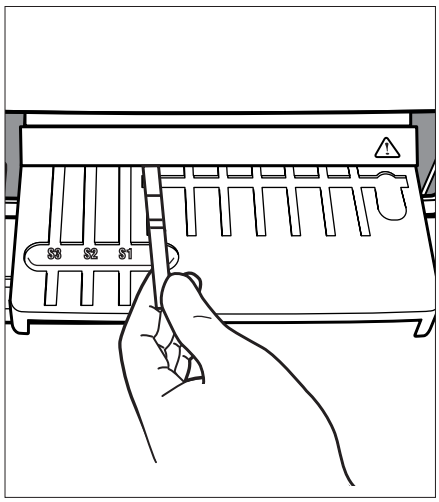
● Open the aluminum foil package of a Reagent Strip by tearing straight down from the V-shaped notch.



● Remove the Reagent Strip from the package without touching the reagent field with fingers.



● Insert Reagent Strips on the Reagent Table as shown at right.



IMPORTANT

Be sure to insert the end of a Reagent Strip into the groove of the Reagent Table so that the Reagent Strip stays firmly in place. If the Reagent Strips are bent or placed out of the groove, it may become jammed or correct measurement results may not be obtained.

9. Start the measurement.

► To discontinue the measurement, press [STOP] key to return to the Standby screen.

● Press [START] key. The Reagent Table and Centrifuge-equipped Multi Rack slide backward and the Table Cover is closed. The message "Measuring . . ." is displayed.

```
Measuring...
          Stop(STOP)
```

● After a while, approximate remaining time is displayed.
The time displayed in [ ] changes at every 30 seconds.

```
Measuring... [3:00]
          Stop(STOP)
```

● As the measurement proceeds, the display of approximate remaining time changes to the ordinary time indication.
The [ ] disappears and the time is counted down by one second.

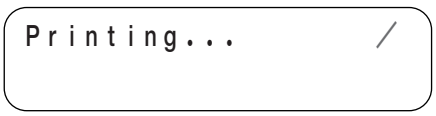
NOTE

Do NOT open the maintenance cover or the Table Cover during measurement. It will cause an error.

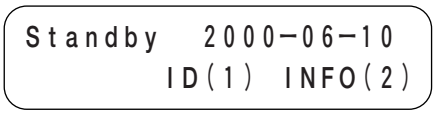
10. End measurement.

► To print another sheet, press [4] key on the Standby screen.

● When measurement is finished, measurement results are printed out. The Table Cover opens and the Reagent Strip Table and the Centrifuge-equipped Multi Rack slide forward.

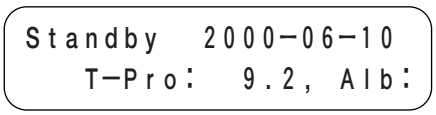


● The Standby screen is restored.



► The measurement result is repeatedly scrolled.

● Where measured results are not printed due to lack of printer paper, press [5] key on the Standby screen to display the latest measurement results.



● Press [5] key again to return the Standby screen.

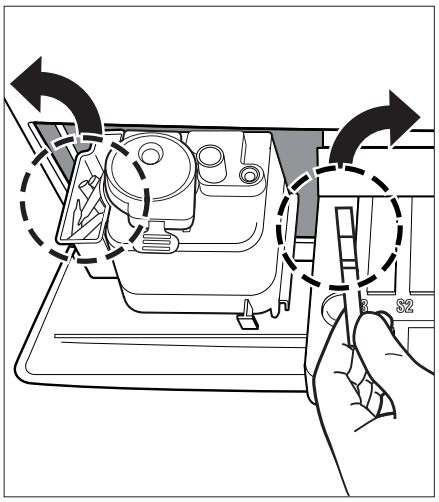
NOTE

Only measurement item and its result are displayed. Channel numbers, unit symbols and others such as ▲▼ are not displayed. When the details are to be confirmed, thermal printer paper is set for allowing the results to be available in print. To check the detailed results, set printer paper and print out the measurement result.

- Remove any used Reagent Strips and discard them.
  When the message “DISCARD TIPS” is displayed, remove the Tip Waste Case and discard used tips.

- Reattach the Tip Waste Case.

- To discontinue measurement, press [STOP] key to return to the MAIN MENU.



Remove used tips.
OK(ENTER)

NOTE

The message “DISCARD TIPS” appears once every five measurements. When the message is displayed, discard the tips. Otherwise, a trouble may occur.

11. End measurement for the day.

- After finishing all measurement for the day, perform daily maintenance (see “4-2 Daily Maintenance”).

2-5 Calibration

2-5-1 Overview of calibration

Calibration is necessary to maintain measurement accuracy.
Calibration reduces unfavorable effects of reagent pack that changes with time, eliminates gaps among lots or facilities, and maintains measurement accuracy to a certain level.

Basically, calibration should be performed using the SPOTCHEM Calibrator Kit for each type of Reagent Strips, but it requires a lot of time to do so for all types of Reagent Strips.
To eliminate such inconvenience, this analyzer is designed to be able to perform calibration for different Reagent Strips by inserting magnetic cards (Reagent Card) storing the lot information of each reagent strip.
There are 2 methods for calibration with SP-4430.

①· Calibration by magnetic card
②· Calibration by calibrator kit (using an exclusive calibrator lit)

①calibration is performed by inserting a magnetic card (Reagent Card) attached to each reagent strip into the magnetic-card reader.
②calibration is performed using an exclusive calibrator. This calibration should be performed every 6 months, when the Reagent Lot is changed or the service representative considers that calibration is necessary. The SPOTCHEM Calibrator Hb Kit is to be used for Hb items. The SPOTCHEM Calibrator Kit is to be used for other items' calibration.

There are two ways of calibration available, one is "1-Point Calibration" using either Low or High Calibrator Solution and the other is "2-Point Calibration" using both of Low and High solution. Make sure to perform calibration according to the calibration conditions of each measurement item by referring to "3-3-2 Entering parameters".

2-5-2 Calibration by magnetic card

By inserting "Reagent Card" attached to Single Reagent Strips or another one attached to Multi Reagent Strips into a magnetic-card reader, differences among lots and changes with time of reagent pack are automatically calibrated.

IMPORTANT

For the lot number of "Reagent Card" for magnetic calibration, use the same lot number as that of the reagent strip currently in use (Magnetic cards attached to the Reagent Strips in use). Calibration can not be performed with magnetic cards with different lot number or magnetic cards with different Reagent Strips.

Requirements	Reagent Card

1. Set the calibration type as by magnetic card.

- When changing the calibration type from calibration by calibrator kit (Cal.) to calibration by magnetic card (CARD), change the setting "see 3-3-2 Enter parameters").
  If the calibration type is already set as calibration by magnetic card, this operation is not necessary.

2. Set the calibration condition.

"CARD" means calibration by magnetic calibration card and "Cal." means calibration by calibrator kit.

- Press [3] key on the MAIN MENU. The CALIBRATION MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

```
1.CARD     2.Cal.
3.Information  (1/1)
```

3. Insert Reagent Card

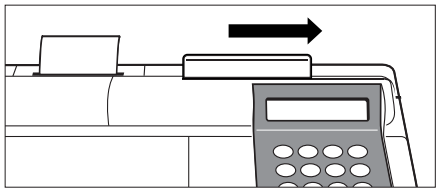
Press [STOP] key to stop the calibration by magnetic card.

- Press [1] key on the CALIBRATION MENU.

```
Insert a card.
                (STOP)
```

There is no order for inserting the stripes. Either stripe can be inserted first.

- Insert a strip of Reagent Card in the magnetic reader and slide the strip to the right.



● When the stripe is inserted, the screen shown at the right is displayed.

```
Insert a card.
The same stripe
```

● Insert the same stripe according the message on the screen.
When the same stripe is inserted twice, item number is displayed.
The inserted stripe number is displayed with ■ on the lower right screen.

```
Insert a card. S-01
Another stripe ■2
```

► Insert the same stripes twice to read the stored information in the magnetic cards.

● Insert the remaining stripes twice according to the message on the screen.
When all stripes are inserted, measurement item and lot numbers are displayed.

```
Insert a card. S-01
【GGT      】【XXXXXX】
```

● About 2 seconds after, the Magnetic card entry screen will be displayed.
Calibration by magnetic card is completed.

4. End of calibration by magnetic card.

● When the discontinuing the calibration, press [STOP] key 3 times to return to the MAIN MENU.

```
1.Measure 2.Submenu
3.Calibrate    (1/1)
```

2-5-3 Calibration by calibrator kit

Use the SPOTCHEM Calibrator Kit for calibration. For Hb items, use the SPOTCHEM Calibrator Hb Kit.

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

Be careful not to spill sample blood when uncapping the tube.

1. Set the calibration type by calibrator kit.

- When changing the calibration type from calibration by magnetic card (CARD) to the calibration by calibrator kit (Cal.), change the setting by referring to "see 3-3-2 Enter parameters").
  If the calibration type is already set for calibrator kit, this operation is not necessary.

2. Display the calibration menu.

► "CARD" means calibration by magnetic calibration card and "Cal." means calibration by calibrator kit.

- Press [3] key on the MAIN MENU.
  CALIBRATION MENU is displayed.

```
1.Measure  2.Submenu
3.Calibrate      (1/1)
```

```
1.CARD     2.Cal.
3.Information  (1/1)
```

3. Prepare the reagent strip and calibrator.

- Prepare the required amount of Reagent Strips according to the following table.

► When performing the calibration by calibrator kit using Multi Reagent Strips, calibration mode of each measurement item (single item) attached to Multi Reagent Strip is used.

Reagent strip	Calibration mode	The number of Reagent Strips	Reagent Strip setting	Required amount
Single-type Reagent Strip	Low,High	The number of calibration times(N) × 2	Set in S1~S3 channels in order.	500 μL
	Low only	The number of calibration times(N)		
	High only	The number of calibration times(N)		
Multi-type Reagent Strip	Low,High	The number of calibration times(N) × 2	Set in the Multi channel	

- To check the calibration mode and the number of calibration times, press [3] key on the CALIBRATION MENU to display the Calibration information checking screen. On this screen, switch the items by pressing [hyphen (-)] key to check calibration mode and the number of calibration times.

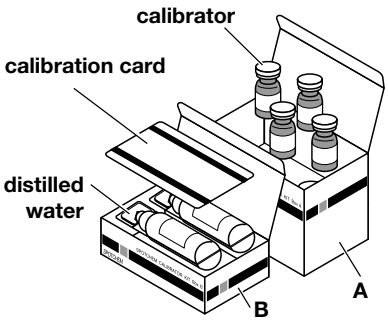
```
【S-01:GGT          】
( 1/30)【L&H N=3     】
```

- Press [STOP] key to return to the CALIBRATION MENU.

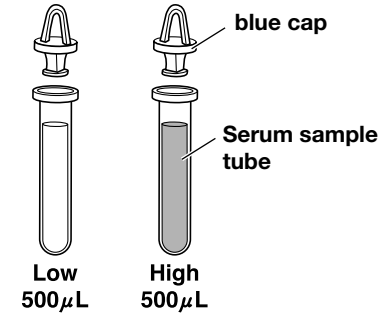
```
1.CARD     2.Cal.
3.Information  (1/1)
```

- Prepare the required equipment and calibrator (see “2-3-1 Preparation”).

- Dissolve Low or High solution according to the instructions on the package insert included in the calibrator kit.



- Place 500μL of Low and High solution in the respective sample tubes. Put the caps back on to prevent evaporation or contamination if calibration is not to be carried out immediately.



IMPORTANT

Remove any air bubbles or skin on the surface of the calibrator, if any. Failure to do so may result in obtaining incorrect measurement results.

4. Insert calibration card.

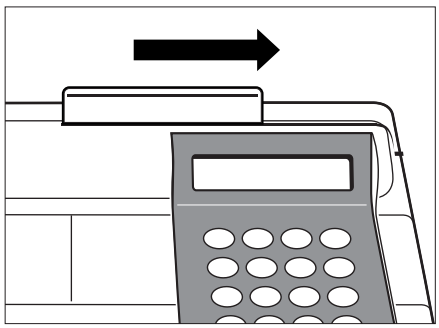
► To stop calibration, press [STOP] key.

- Press [2] key on the CALIBRATION MENU.
  The Magnetic card entry screen is displayed.

```
Insert a card.
The same stripe
```

► There is no order for inserting the stripes. Any stripe can be inserted first.

- Insert the stripe of a calibration card in the magnetic card reader and slide the card to the right.



- When the stripe is inserted, the message shown on the right is displayed.

```
Inseart a card.
The same stripe.
```

► Insert the same stripes twice to surely read the stored information in the calibration cards.

► There is only one stripe for Hb, this screen is not displayed.

- Insert the same stripe again according to the message on the screen.
  When the same stripes are inserted twice, that stripe number is displayed on the lower part of the screen. The entered stripes are displayed as ■.

```
Inseart a card. Cal.
Another stripe ■234
```

- Insert the rest stripes twice according to the message on the screen. When all stripes are inserted, lot number of the calibrator is displayed.
  After that, the Calibration standby screen is displayed.

```
Inseart a card. Cal.
[CAL-CARD  ][XXXXXX]
```

► If no key entry is made within 3 minutes after the Table Cover opens, an alarm sounds and the Table Cover closes.
If press [STOP] key is pressed while **"**CANCEL**"** is displayed, the Standby screen is restored without closing the Table Cover.

- The Table Cover opens, and the Reagent Table and the Centrifuge-equipped Multi Rack slide forward.

```
Cover is closing.
          Stop(STOP)
```

► After the Table Cover closes, the message shown on the right is displayed.
To go back to the MAIN MENU, press [STOP] key.
To go back to the Standby screen, press [ENTER] key.

```
 Back to MENU(STOP)
 Back to CAL (ENTER)
```

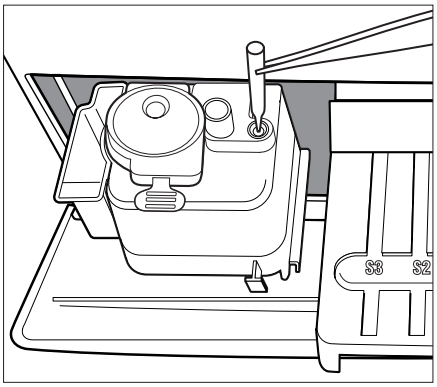
- The Calibration standby screen as shown on the right is displayed.

```
Standby
L=0   H=0   N=?
```

► When performing 1-point calibration (High), proceed to procedure 9.

5. Set the Tip.

● Set the tips in the tip hole of the Centrifuge-equipped Multi Rack using tweezers.



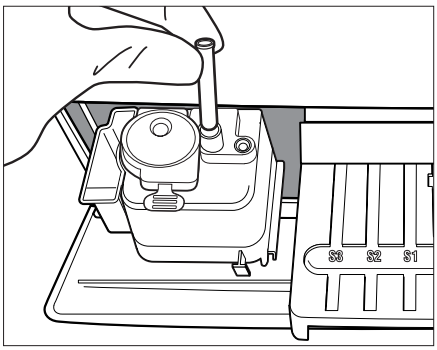
IMPORTANT

Do NOT touch the end of the Tip with bear hands. If the tips are soiled, correct sampling may not be done and this will lead to incorrect calibration results.

● Make sure that the Tip Waste Case is set in position.

6. Set the calibrator "Low".

● Remove the caps and set the calibrator "Low" to the port of the Centrifuge-equipped Multi Rack.



NOTE

Be sure to remove the caps before calibration to avoid damage to the nozzle.

NOTE

Make sure that the protective cover is closed before the measurement. If the protective cover remains open, it may cause a trouble.

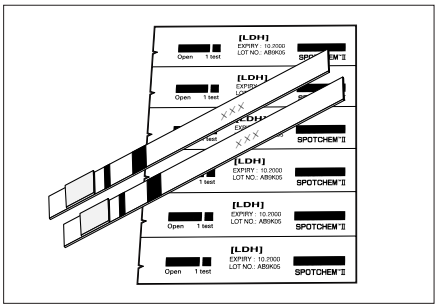
7. Set the Reagent Strips.

IMPORTANT

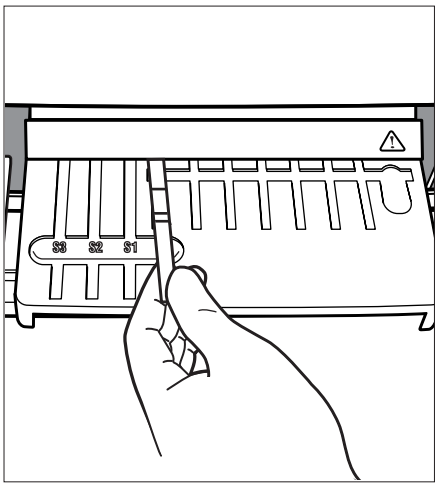
Be sure to insert the tip of the strip in the groove of the reagent table so that the Reagent Strip stays firmly in place. If the strip is placed out of the groove, it may cause jam or correct measurement results may not be obtained.

● Calibration with Single-type Reagent Strips

● Prepare Single-type Reagent Strips. When performing 2-point calibration, prepare twice as many Reagent Strips as the number of times calibration that will be performed. For 1-point calibration, prepare the same number of times calibration that will be performed.



● Insert the Reagent Strips with the same items, starting from the S1 channel on the Reagent Table.
If the number of calibration is set as more than 3 for 2-point calibration, calibration should be sperately performed twice. In this case , set 3 Reagent Strips for the first calibration.
(ex.: When the number of calibration is 4, set 3 Reagent Strips for the first calibration and 1 for the second .)

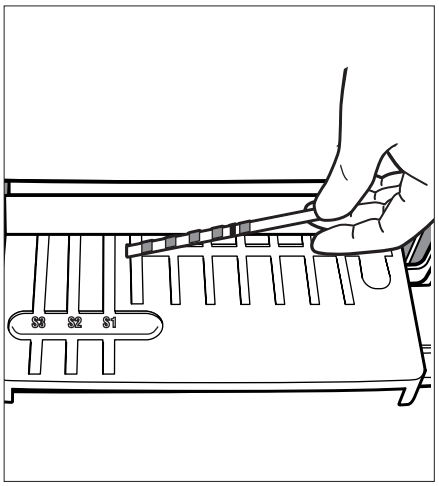


● Calibration with Multi-type Reagent Strips

► With Multi-type Reagent Strips, 1-point calibration cannot be performed.

● Prepare Multi-type Reagent Strips.
Prepare twice as many Multi-type Reagent Strips as the number of the times calibration that will be performed.

● Set the Strip on the Reagent Table from the right hand side.



8. Start measurement of the “Low” calibrator.

► Press [STOP] key to stop the calibration, the Calibration standby screen is restored.

- Press [START] key. The Reagent Table and Centrifuge equipped Multi Rack move inside, and the Table Cover closes. “Measuring…” is displayed.

```
Measuring...
          Stop(STOP)
```

- Approximate remaining time is displayed. The time displayed in [ ], changes at every 30 seconds.

```
Measuring... [3:00]
          Stop(STOP)
```

- As the measurement proceeds, the display of approximate remaining time changes to the ordinary time indication. The [ ] disappears and the time is counted down by one second.

```
Measuring...   01:23
          Stop(STOP)
```

- When “Low” calibration is completed, the Table Cover opens, and the Reagent Table and Centrifuge-equipped Multi Rack move forward. The Calibration standby screen is displayed.

- When the number of calibration is more than 3, repeat the procedure from 5 to 8.

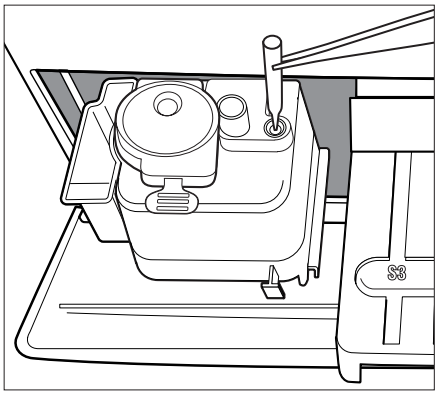
- The Calibration standby screen displays the name of the Reagent Strip being calibrated, the measured number of Low and High (L, H) and the calibration times (N).
  The cursor blinks at L or H according the calibrator (Low or High) to be calibrated next. The examples of the screen at the right shows the number of times of calibration is 2, Low has already measured twice and High will be measured next.

```
Standby  T-Pro
L=2  H=0  N=2
```

► When performing 1-point calibration for "Low" only, proceed to procedure 13.

9. Set the tip.

● Set the tip by following procedure 5.



10. Set the “High” Calibrator.

► Press [STOP] key to stop calibration.
The Calibration standby screen is restored.

● Set the “High” Calibrator by following procedure 6.

11. Set the Reagent Strips.

● Set the Reagent Strips by following procedure 7.

12. Measure the “High” Calibrator.

● Measure the “High” Calibrator by following procedure 8.

13. End the calibration.

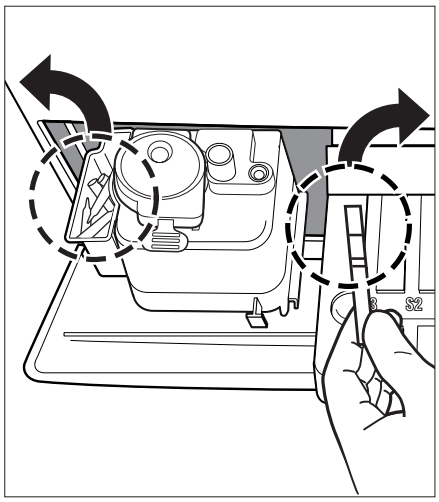
● When calibration is completed, the measurement results are printed. The Table Cover opens, and the Reagent Table and Centrifuge-equipped Multi Rack slide forward. The Calibration standby screen is restored.

```
Printing...
```

```
Standby
L=0   H=0   N=?
```

● Remove the used Reagent Strips and samples, and discard them.

- When a message, “Remove used tips.” is displayed, remove the Tip Waste Case and discard used tips.
- Set the Tip Waste Case again.



Remove used tips.
OK(ENTER)

NOTE

**The message, “Remove used tips.” is displayed every 5 measurements.
When this message is displayed, discard the used tips.
If measurement is continued, it may cause trouble.**

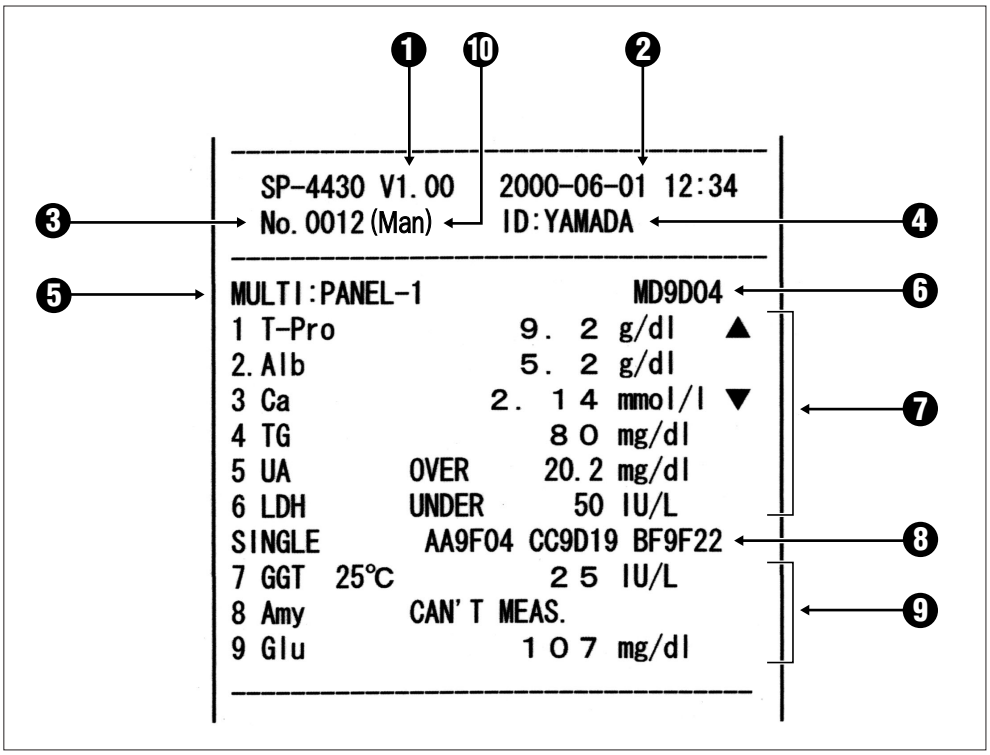
2-6 Interpreting measurement results

2-6-1 Printing normal measurement results

To print out the measurement results, Normal printing and Survey Mode printing are available.
The Survey Mode has the following additional items to the print out of the Normal mode.
These items are printed out when the Survey Mode is ON.

- **Measurement value which temperature conversion, unit conversion or correlation correction is not applied.**
- **Information on temperature conversion (temperature and temperature conversion factor).**
- **Information on unit conversion (unit and unit conversion factor).**
- **Information on correlation correction (coefficient of correlation correction).**

(1) Normal printing



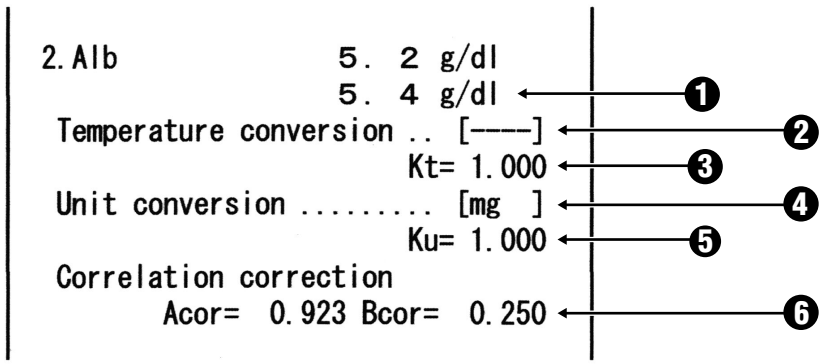
► When "Printing of measurement results" is performed on the Sub Menu, the results are printed according to the parameter settings of the measurement. That is, if the parameters are changed after the measurement (temperature or coefficient of correlation correction), the data after the measurement is printed out.

1 • Version.
2 • Measurement date and time : Date and time when [START] key is pressed.
3 • Measurement number : The number is counted starting from 0001 (When the power is on.)
4 • ID: Printed only when ID is set.
5 • Name of the Multi Reagent Strip.
6 • Lot Number of the Multi Reagent Strip.
7 • Measurement results of the Multi Reagent Strip.
8 • Lot Number of the Single Reagent Strip. Used for S1, S2 and S3 channels from the left.
9 • Measurement results of the Single Reagent Strip.
10 • Sample type : Printed only when set.

5~7 are printed only when the Multi Reagent Strip is measured.
8~9 are printed only when the Single Reagent Strip is measured.

<Details>
The temperature is printed when the temperature is set other than at 37℃ in the enzyme item. (ex.: GGT)
"Over Max. Value" is printed when the measurement result is higher than the upper limit of the measurement range. (ex.: UA)
"Under Min. Value" is printed when the measurement result is lower than the lower limit of the measurement range. (ex.: LDH)
▲ mark is printed when the measurement result is higher than the upper limit of the standard range. (ex.: T-Pro)
▼ mark is printed when the measurement result is lower than the lower limit of the standard range. (ex.: Ca)
When prozone errors occur, the types of errors are printed. (ex.: Amy)
When the unit other than the conventional units is used or a coefficient of correlation correction is entered ▪ is printed on the right of the first number of the measurement result. (ex.: Alb)

(2) Survey Mode printing (for 1 item)



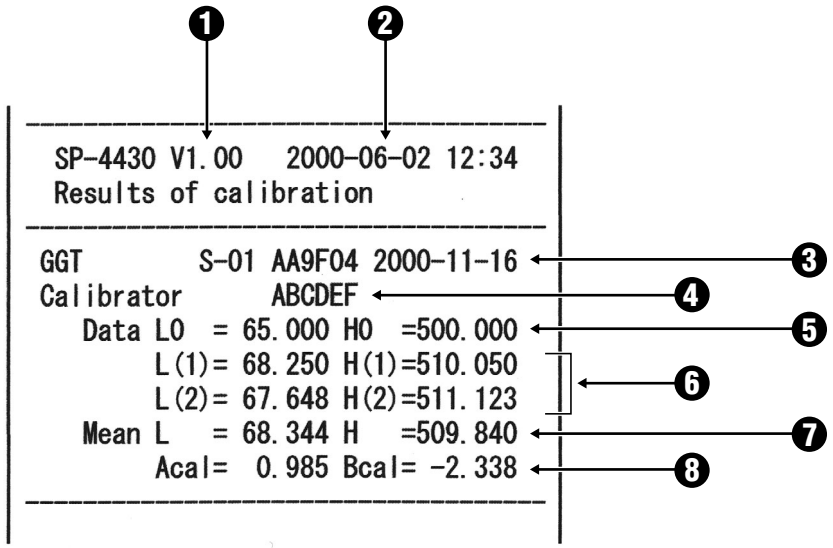
1 • Measurement value which temperature conversion, unit conversion or correlation correction is not applied.
2 • Temperature. Printed out as ….. for the items other than enzyme items.
3 • Temperature conversion factor. Conversion factor when the standard temperature is 37℃.
4 • Unit.“mg” is the conventional unit, “SI” is SI unit and “User” is units set by users.
5 • Unit conversion factor. Conversion factor when the conventional unit is standard.
6 • Coefficient of correlation correction.
Coefficient set in the “Entering parameters” on the Sub Menu.

► Generally, mg (conventional unit) is used for unit. To change the unit, contact your distributor.

2-6-2 Printing calibration results

The calibration results are printed when calibration by calibrator kit is completed. The formats of the Single Reagent Strips and the Multi Reagent Strips are slightly different.
Even when calibration errors (E 30 : Abnormal data) occur during the calibration the calibration results are printed. In this case, Acal and Bcal are printed as ＊＊＊＊＊＊(Calibration factors are not set up.).

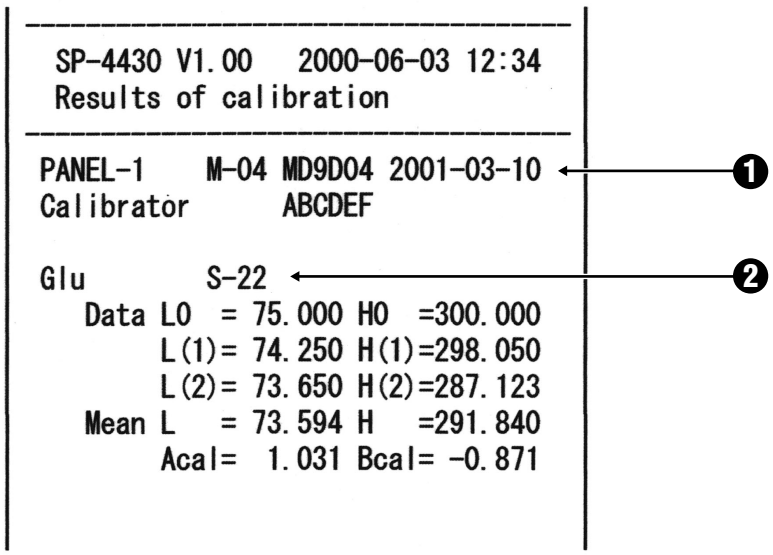
(1) Calibration Result of Single Reagent Strip



1 • Version.
2 • Calibration date: The date when [START] key was pressed for the first time.
3 • From the left, name of Multi Reagent Strip, item symbol, lot number and expiry date.
4 • Lot no. of the calibrator. Read by the calibration card.
5 • Displayed value of calibrator. Read by the calibration card.
6 • Measurement value when calibration is not performed.
Printed out for the number of calibration times.
7 • Average measurement value when calibration is not performed.
8 • Calibration factor.
Factor of linear expression, Y=Acal・X+Bcal to convert the value X of (7) to value Y of (5).

For the items when calibration mode is L, the H part is blank.
For the items when calibration mode is H, the L part is blank.

(2) Calibration Result of Multi Reagent Strip



1 • From the left, name of Multi Reagent Strip, item symbol, lot number and expiry date .
2 • From the left, item name and item symbol.

For the items when calibration mode is L, the H part is blank.
For the items when calibration mode is H, the L part is blank.

MEMO

Chapter 3

SUB MENU

With the SUB MENU, auxiliary operations other than normal measurement and calibration can be performed.
This chapter describes the SUB MENU functions and operating procedure.

3-1 Overview of SUB MENU

3-1-1 Composition of SUB MENU

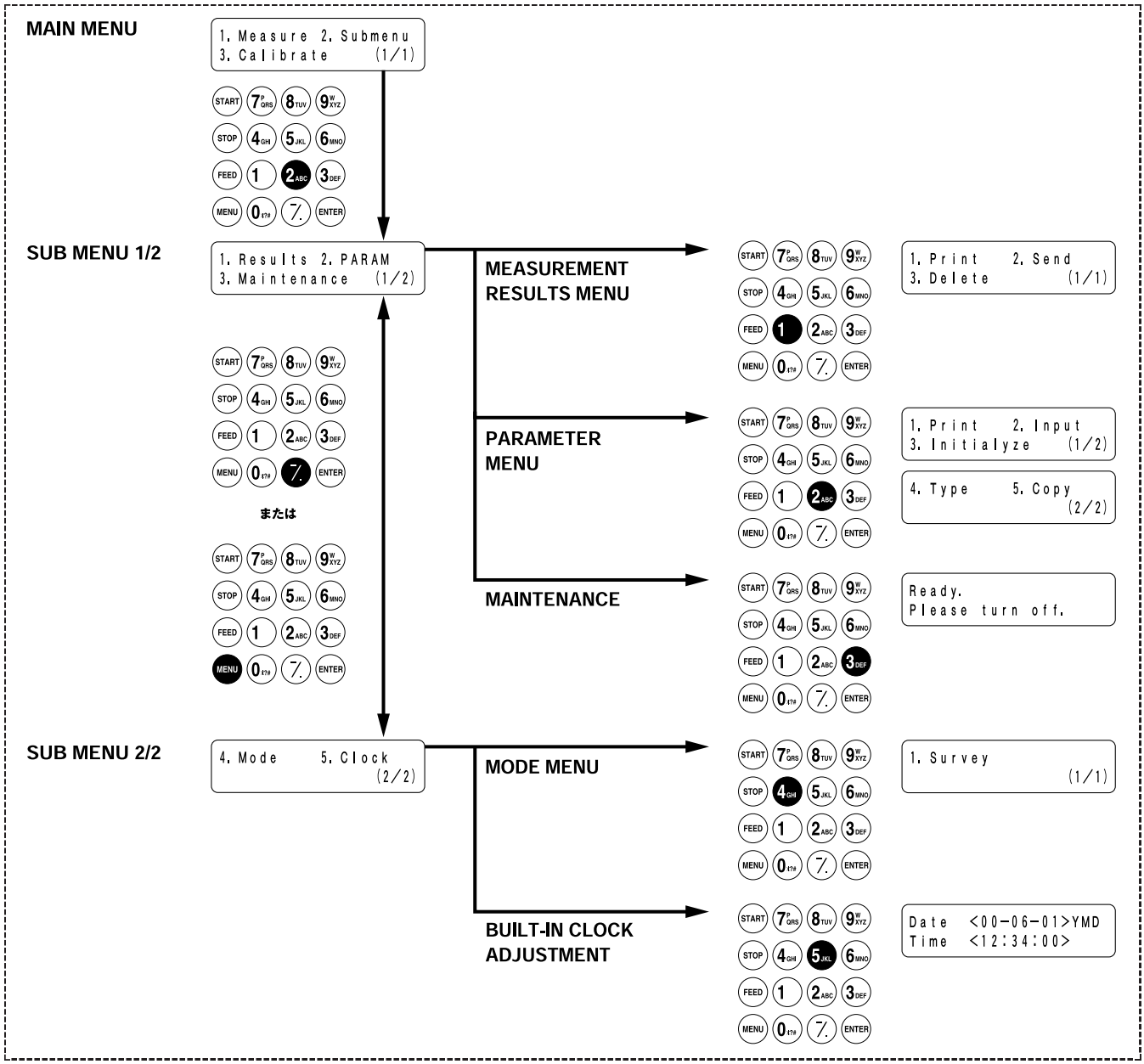
► When [START] key is pressed on any screen of SUB MENU, the MAIN MENU is restored.

■ MAIN MENU

After the power is ON and warm-up is completed, the MAIN MENU is displayed.
In the MAIN MENU, normal measurement, calibration, and the SUB MENU are available.

■ SUB MENU

The SUB MENU consists of 2 pages. Press [MENU] key or [hyphen (-)] key to switch the SUB MENU pages alternately between SUB MENU 1/2 and SUB MENU 2/2.
In the SUB MENU, there are several functions to be set and they are arranged in layers. This chapter partly describes the SUB MENU.



MEASUREMENT RESULTS MENU

Item	Description	Reference term
1. Print Print measurement results	Prints measurement results stored in the memory. Search by date and ID is available.	3-2-1
2. Send Transmit measurement results	Transmits measurement results stored in the memory to the external device. Search by date and ID is available.	3-2-2
3. Delete Delete measurement results	Deletes all the measurement results stored in the memory .	3-2-3

PARAMETER MENU

Item	Description		Reference term
1. Print Print parameters	Prints current setting of each item.		3-3-1
2. Input Input parameters	Temperature	Output converted measurement results to those measured at 25℃, 30℃ or 37℃.	3-3-2
	Coefficient of correlation factor	Enter the coefficient of correlation factor a, b in the regression equation: Y = aX + b.	
	Normal value range	Enter the upper limit and lower limit value of the range.	
	Calibration condition	Sets the calibration type (Cal. or CARD) and the number of times for calibration.	
3. Initialize Initialize parameters	Initializes the setting details for each item.		3-3-3

MAINTENANCE

Item	Description	Reference term
	Performs daily maintenance.	3-4

MODE MENU

Item	Description	Reference term
Survey	Set ON/OFF of the Survey Mode.	3-5

BUILT-IN CLOCK ADJUSTMENT

Item	Description	Reference term
	Sets the date and time.	3-6

3-2 Measurement Results Menu

3-2-1 Print measurement results

► If [STOP] key is pressed during operation, the previous screen is restored.

► In case of reprinting, measurement results are printed starting from the latest result.

Print measurement results stored in the memory (Max. 100 measurements). The following three options for printing are available.

1. LATEST : The latest measurement result (one measurement).
2. ALL : All measurement results (Max. 100 measurements) stored in the memory.
3. SEARCH : The measurement results searched by the date range and/or ID.

1. Display setting screen.

● Press [2] key on the MAIN MENU.
SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

● Press [1] key.
The MEASUREMENT RESULTS MENU is displayed.

```
1.Print   2.Send
3.Delete        (1/1)
```

2. Select measurement results to print.

● Press [1] key.
The Measurement result selecting screen is displayed.

```
1.Latest  2.ALL
3.Search        (1/1)
```

Select the measurement results to print by using the numeric keys.
1. LATEST : the latest measurement result (1 measurement)
2. ALL : all measurement results
3. SEARCH: the searched measurement results by date and ID

● **When LATEST or ALL is selected.**
Printing starts immediately.
After printing is completed, the Measurement result selecting screen is restored.

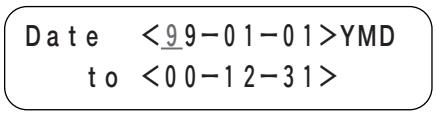
● **When SEARCH is selected.**
The display proceeds to “step 3”.

► If the selected measurement is not found in the data, “No matching data” is displayed as shown on the right.
Press [ENTER] key to return to the Measurement Results selecting screen.

```
No data matched.
          OK(ENTER)
```

3. Enter search condition.

- Enter the dates of starting and finishing measurements by sliding the cursor using [hyphen (-)] key.



► If designation of the range of measurement dates (the dates of starting and finishing measurements) is unnecessary, press [ENTER] key twice to proceed to the next setting screen.

► Be sure to enter correct dates to avoid inconsistencies.

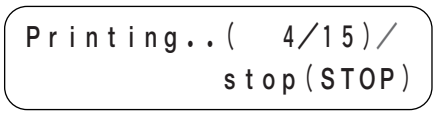
► The 2-digit number of the "year" section of the date indicates the last 2 digits of year and is interpreted as follows:
00~89 -> 2000~2089
90~99 -> 1990~1999

- Press [ENTER] key. The ID entering screen is displayed. Press [ENTER] key when not searched by ID.

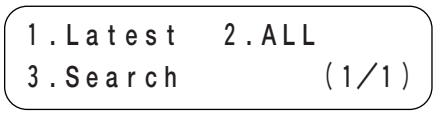
- Enter an ID search pattern for the sample(s) to print by using numbers, alphabets, and symbols up to 13 characters.
Wildcards can be used to enter.

► See 3-09 page for information on wildcards.

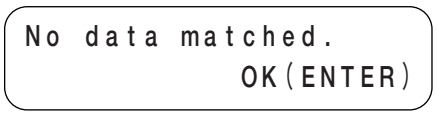
- Press [ENTER] key.
The selected measurement results are printed out.



- When the printing is completed, the Measurement result selecting screen is restored.

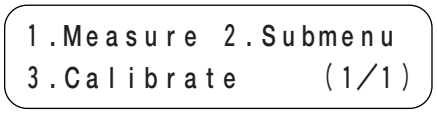


► If the selected measurement result is not found in the data, "No matching data" is displayed as shown on the right.
Press [ENTER] key to return to the Measurement result selecting screen.



4. End printing.

- Press [STOP] key three times to return to the MAIN MENU.



3-2-2 Transmit measurement results

► If [STOP] key is pressed during operation, the previous screen is restored.

► In case of retransmission, measurement results are printed out starting from the latest result.

Transmit measurement results (Max. 100 measurements) stored in the memory.
The following three types for transmission are available.

1. LATEST : The latest measurement result (one measurement).
2. ALL : All measurement results (Max. 100 measurements) stored in the memory.
3. SEARCH : The measurement results searched by the date range and/or ID.

1. Display setting screen.

● Press [2] key on the MAIN MENU.
SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

● Press [1] key.
The MEASUREMENT RESULTS MENU is displayed.

```
1.Print   2.Send
3.Delete        (1/1)
```

2. Select measurement results to transmit.

● Press [2] key.
The Select Results screen is displayed.

```
1.Latest  2.ALL
3.Search        (1/1)
```

Select the measurement results to transmit by using numeric keys.
1. LATEST : the latest measurement result (1 measurement)
2. ALL : all measurement results
3. SEARCH : the searched measurement results by date and ID

● **When LATEST or ALL is selected.**
Retransmission starts immediately. After retransmission is completed, the Measurement result selecting screen is restored.

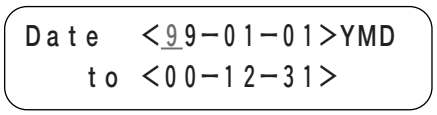
● **When SEARCH is selected.**
The display proceeds to “step 3”.

► If the measurement result selected is not found in the data, “No matching data” is displayed as shown on right. Press [ENTER] key to return to the Measurement result selecting screen.

```
No data matched.
          OK(ENTER)
```

3. Enter searching condition.

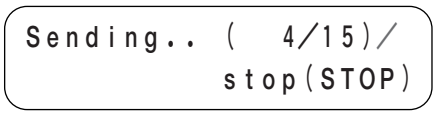
- Enter the dates of starting and finishing measurements by sliding the cursor using [hyphen (-)] key.



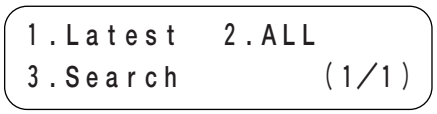
- Press [ENTER] key. The ID entering screen is displayed. Press [ENTER] key when not searching by ID.

- Enter an ID searching pattern for the sample(s) to print by using numbers, alphabets, and symbols up to 13 characters.
  Wildcards can be used to enter.

- Press [ENTER] key.
  The selected measurement results are transmitted.



- When the transmission is completed, the Measurement result selecting screen is restored.



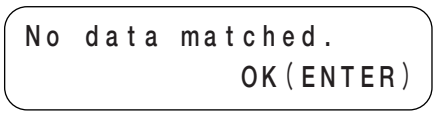
► If designation of the range of measurement dates (the dates of starting and finishing measurements) is unnecessary, press [ENTER] key twice to proceed to the next setting screen.

► Be sure to enter correct dates to avoid inconsistencies.

► The 2-digit number of the "year" section of the date indicates the last 2 digits of year and is interpreted as follows:
00~89 -> 2000~2089
90~99 -> 1990~1999

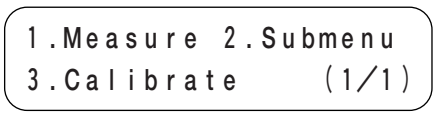
► See 3-09 page for information on wildcards.

► If the selected measurement result is not found in the data, "No matching data" is displayed as shown on the right.
Press [ENTER] key to return to the Measurement result selecting screen.



4. End transmission.

- Press [STOP] key three times to return to the MAIN MENU.



3-2-3 Delete measurement results

Delete all the measurement results stored in memory.

1. Display setting screen.

- Press [2] key on the MAIN MENU.
  SUB MENU1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Press [1] key.
  The MEASUREMENT RESULTS MENU is displayed.

```
1.Print    2.Send
3.Delete         (1/1)
```

2. Delete measurement results.

- Press [3] key. The Password entering screen is displayed.
  Enter password “99”.
  ＊＊ is displayed on the screen.

```
Password <_      >
        Cancel(STOP)
```

- The Delete confirmation screen is displayed.

```
Delete?
 Yes(START) No(STOP)
```

- Press [START] or [STOP].
  If [START] key is pressed, the measurement results are deleted and the MEASUREMENT RESULTS MENU is restored.
  If [STOP] key is pressed, deletion is canceled and the MEASUREMENT RESULTS MENU is restored.

```
1.Print    2.Send
3.Delete         (1/1)
```

3. End Deletion.

- Press [STOP] key three times to return to the MAIN MENU.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

■ Wildcards

Wildcards can be used for ID search. Wildcards have two types of characters, "? " and " ＊", indicating a single or any number of characters.

- " ? " indicates a single character.
- " ＊" indicates any number (including zero) of characters.

For instance, if "????" key is entered, 4-character IDs are retrieved. If "A＊" is entered, IDs starting with "A" are retrieved. The following table shows details.

	Searching Pattern	Meaning
Example 1	? ? ? ? M	5-character ID ending with "M"
Example 2	A B ? Y Z	5-character ID starting with "AB" and ending with "YZ"
Example 3	A B ＊ Y Z	ID starting with "AB" and ending with "YZ"
Example 4	＊ P Q R ＊	ID including "PQR"
Example 5	N ? ? ? ＊	ID of 4 characters or more starting with "N"

This function is upper/lower case sensitive.
The characters "?" key or " ＊" themselves cannot be searched for. (e.g. To search IDs starting with [hyphen (-)] key by entering "?＊", the attempt will fail.)
A searching pattern with more than four asterisks (*) cannot be entered.

3-3 Parameter Menu

3-3-1 Print parameters

Print the present parameter settings by each measurement item for checking.

1. Display setting screen.

● Press [2] key on the MAIN MENU.
SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

● Press [2] key.
The PARAMETER MENU 1/2 is displayed.

```
1.Print   2.Input
3.Initialyze    (1/2)
```

2. Print parameter settings.

● Press [1] key.
The Measurement item selecting screen is displayed.

```
[S-01:GGT         ]
( 1/30)
```

► Besides [hyphen (-)] key, [0], [2], [4], [5], [6], and [8] keys can be used in selecting items.
[0] -> initially displayed item
[2] -> last item
[4] -> previous item
[6] -> next item
[8] -> first item
[5] -> first item of the Multi Reagent Strip

● Select measurement items to print by pressing [hyphen (-)] key.

► If “ALL SINGLE” or “ALL MULTI” is selected, parameter settings of all the items for Single or Multi Regent Strips are printed out respectively.

● Press [ENTER] key.
Printing starts. After printing is completed, the Measurement item selecting screen is restored.

► To stop printing, press [STOP] key. Printing stops and the Measurement item selecting screen is restored.

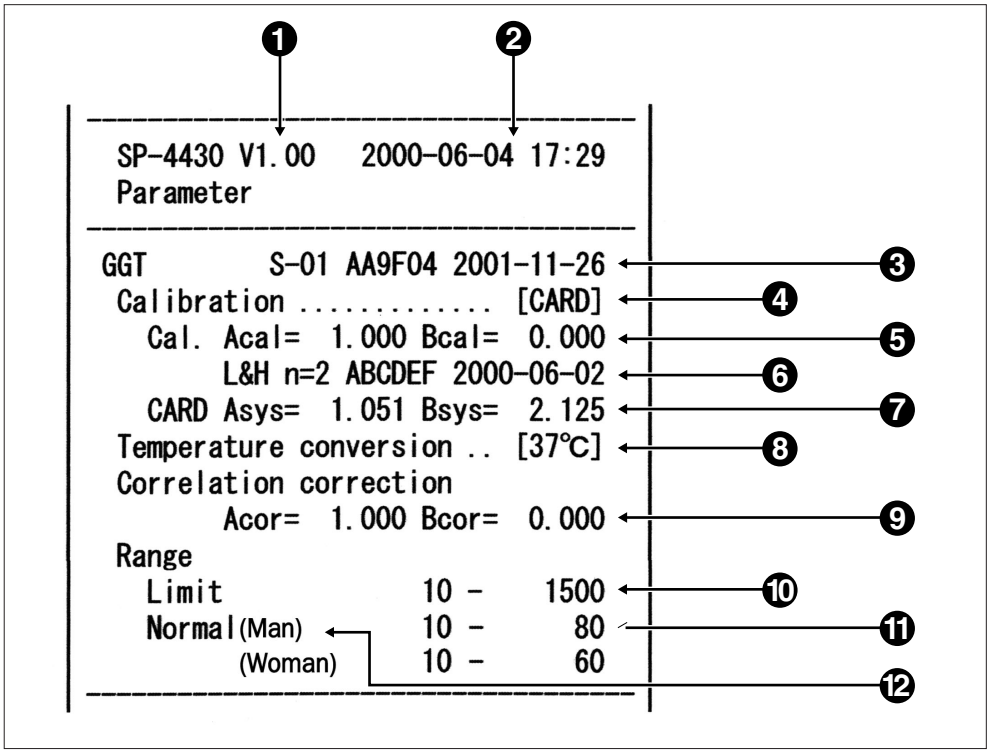
3. End Printing.

● Press [STOP] key to return to the MAIN MENU.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

Parameters can be printed by executing “Printing parameters”.
The formats are slightly different between Single Reagent Strips and Multi Reagent Strips.

(1) Printing of single parameters



1 • Version.

2 • Printed date and time: The date and time when “printing of parameters” is executed.

3 • From the left, item name, item symbol, lot number and expiry date.

4 • Calibration type.
CARD means calibration by magnetic card and Cal. means calibration by calibrator kit.

5 • Calibration factor

6 • From the left, calibration mode (L&H, L, H), the number of calibration times, lot number and calibration date.

7 • Coefficient of system's difference correction(Coefficient to use in the measurement calculates).

8 • Temperature. Printed out as ….. for the items other than enzyme items.

9 • Coefficient of correlation correction.
Coefficient set in the “Entering parameters” in the SUB MENU.

10 • Measurement range. The lower limit and upper limit.

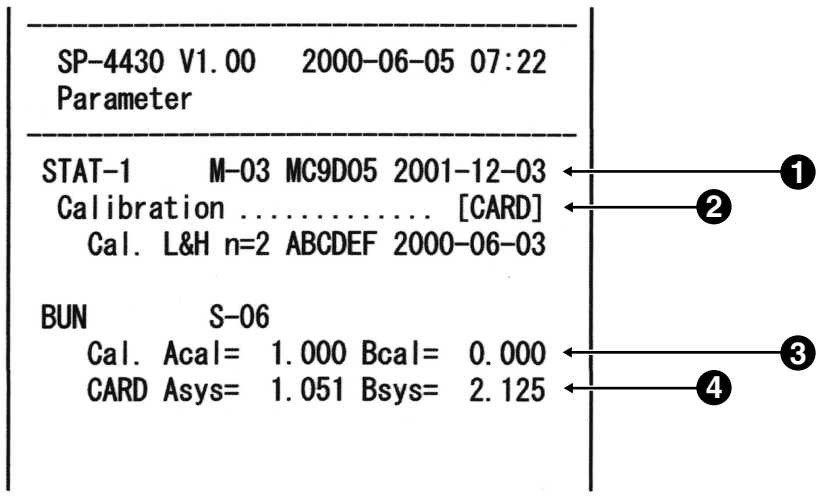
11 • Standard range. The lower limit and upper limit.

12 • Sample types. The lower limit and upper limit of standard range for each sample types set. Printing is available only when sample type is set.

► The lot number and calibration date are printed only when calibration by calibrator kit was performed.

► ▲ mark is not printed when the upper limit of the standard range is the same or higher than the upper limit of the measurement range.
▼ mark is not printed when the lower limit of the standard range is the same or lower than the lower limit of the measurement range.

(2) Printing of multi parameters



1 • From the left, name of Multi Reagent Strip, item symbol, lot number and expiry date.

2 • Calibration type
CARD means calibration by magnetic card and Cal. means calibration by calibrator kit.

3 • Calibration factor.

4 • Coefficient of system's difference correction (Coefficient to use in the measurement calculates).

► The lot number and calibration date are printed only when calibration by calibrator kit was performed.

3-3-2 Enter parameters

► If [STOP] key is pressed during entry, the entry is canceled and the cursor returns to the previous "[ ]" or "< >".

► If the previous setting is not necessary to change, press [ENTER] key to proceed to next "[ ]" or "< >".

Set parameters (measurement conditions) for temperature, coefficient of correlation correction, normal value range, and calibration conditions. Regarding Multi-type Reagent Strips, setting of "calibration conditions" only is possible. The other parameters conform to those preset for Single Reagent Strips.

■Temperature

This device consistently performs measurements under the condition of measurement of 37℃. It can also convert the measurement results to those measured at 30℃ or 25℃ and output the converted results. However, only enzyme values can be converted.

■Coefficient of correlation correction

This function allows your results obtained by this device to match the results by another measurement method (reference method). Apply the regression equation Y = aX + b (X: measurement result of the SP-4430, Y: the result obtained by the reference method.) Enter coefficient values for a and b. For obtaining the coefficients of correlation correction for a and b, contact your distributor.

► ▲ mark is not printed when the upper limit of the standard range is the same or higher than the upper limit of the measurement range.
▼ mark is not printed when the lower limit of the standard range is the same or lower than the lower limit of the measurement range.

■Standard range

When the measurement results are printed, "▲" or "▼", is added on data out of the standard range.

When sample type is set, its corresponding standard range is applied.

■Calibration Conditions

Set the type (calibrator or magnetic card) and the number of times of calibration for each measurement item.

1. Display setting screen.

● Press [2] key on the MAIN MENU. SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

● Press [2] key. The PARAMETER MENU 1/2 is displayed.

```
1.Print    2.Input
3.Initialyze   (1/2)
```

● Press [2] key and the Password entering screen is displayed. Enter password "99".

```
Password <_      >
        Cancel(STOP)
```

● Press [ENTER] key. The Measurement item selecting screen is displayed.

```
[S-01:GGT        ]
( 1/30)
```

2. Select measurement items.

► Besides [hyphen (-)] key, [0], [2], [4], [5], [6], and [8] keys can be used in selecting items.
[0] -> initially displayed item
[2] -> last item
[4] -> previous item
[6] -> next item
[8] -> first item
[5] -> first item of the Multi Reagent Strip

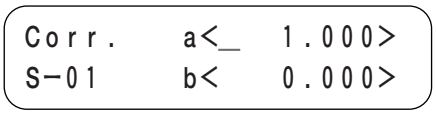
● Select measurement items for parameters by pressing [hyphen (-)] key.

● Press [ENTER] key.
The Temperature setting screen is displayed.

3. Set temperature.

● Select the temperature from 37℃, 30℃, and 25℃ by pressing [hyphen (-)] key.
Note that items other than “enzyme” have only one choice of 37℃.

● Press [ENTER] key.
The Coefficient factor setting screen is displayed.



4. Set coefficient factor.

► To enter minus signs and decimal points , use [-/.] key.
If [-/.] key is pressed first, a minus sign is entered. To enter a decimal point, press [-/.] key after any number is entered.
e.g.) To enter “-12”
Press [-/.] [1] [2]

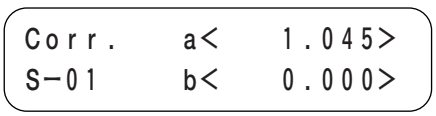
e.g.) To enter “3.4”
Press [3] [-/.] [4]

e.g.) To enter “.5”
press [0] [-/.] [5].
If [-/.] [5] are pressed, the result will be “-5”.

► When the wrong key is pressed, press the MENU key and [-/.] key simultaneously to delete the last entered character.

► If [START] key is pressed, the initially displayed value is restored.

● Enter the coefficient factor “a” by using the numeric keys. Any number from 0 to 10000 can be entered.

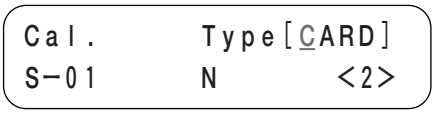


● Press [ENTER] key. The cursor moves to the entry position for “b”.

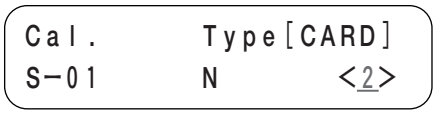
● Enter a coefficient factor “b” and press [ENTER] key. Any number from -10000 to 10000 can be entered.
Press [ENTER] key. The Calibration conditions setting screen is displayed.

5. Set calibration conditions.

● Select “Cal.” or “CARD” by pressing [hyphen (-)] key.
Cal.: Calibration by Calibrator
CARD: Calibration by magnetic card



● Press [ENTER] key.
The cursor moves to the entry position for the number of times of calibration. Any number from 2 to 6 (times) can be entered.



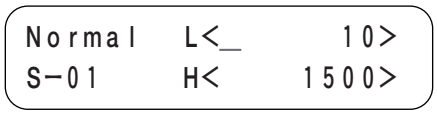
● Press [ENTER] key.
The Standard range setting screen is displayed.

6. Set the standard range.

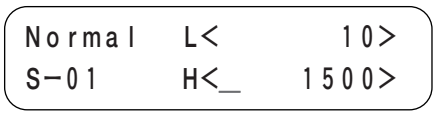
■ When sample type is not set

► ▲ mark is not printed when the upper limit of the standard range is the same or higher than the upper limit of the measurement range.
▼ mark is not printed when the lower limit of the standard range is the same or lower than the lower limit of the measurement range.

● Enter the lower limit of the standard range with the numeric keys.



● Press [Enter] key.
The cursor moves to the entry position for the upper limit value.

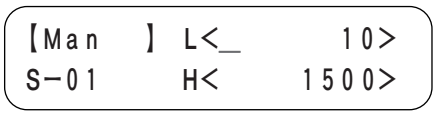


● Enter the upper limit value with the numeric keys.
Press [Enter] key.
The Entry check screen is displayed.

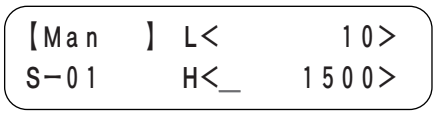
■ When sample type is set

► On the standard range entering screen, a sample type is displayed.

● Enter the lower limit value of the standard range for the sample type1.



● Press [Enter] key to move the cursor to a place for the upper limit value.



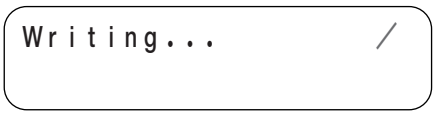
● Enter the upper limit value with the numeric keys and press [Enter] key.

● Similarly, set the standard range for sample types 2 to 5.
The Entry check screen is displayed.

► When the sample type are set only up to two, the standard range entry for the sample types 3 to 5 will be omitted.

7. Store all the parameter settings.

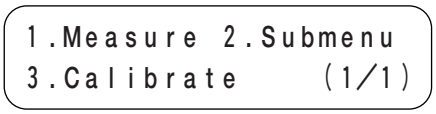
- Press [START] or [STOP].
  If [START] key is pressed, the parameter settings are saved and the Measurement item selecting screen is restored.



- If [STOP] key is pressed, the setting is canceled and Measurement item selecting screen of procedure 1 is restored.

8. End setting.

- If the setting is finished, press [STOP] key three times to return to the MAIN MENU.

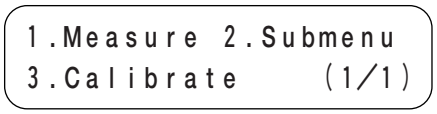


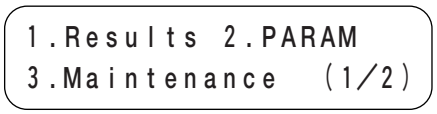
3-3-3 Initialize parameters

Initialize parameter settings to the factory setting values.

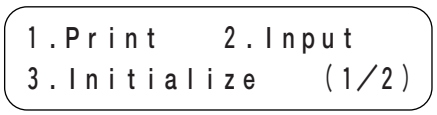
1. Display setting screen.

● Press [2] key on the MAIN MENU.
SUB MENU 1/2 is displayed.

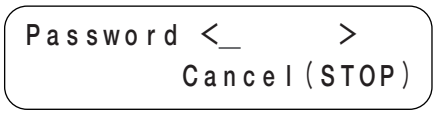




● Press [2] key.
The PARAMETER MENU 1/2 is displayed.



● Press [3] key.
The Password entering screen is displayed. Enter password “99”.
＊＊ is displayed.



● Press [ENTER] key.
The Measurement item selecting screen is restored.

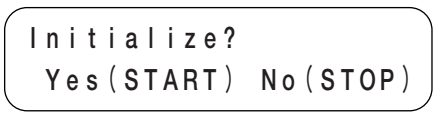
2. Initialize parameters.

► Besides [hyphen (-)] key, [0], [2], [4], [5], [6], and [8] keys can be used in selecting items.
[0] -> initially displayed item
[2] -> last item
[4] -> previous item
[6] -> next item
[8] -> first item
[5] -> first item of the Multi Reagent Strip

► If “ALL SINGLE” or “ALL MULTI” is selected, parameter settings of all the items for Single or Multi Regent Strips are printed out respectively.

● Press [hyphen (-)] key to select a measurement item to initialize.

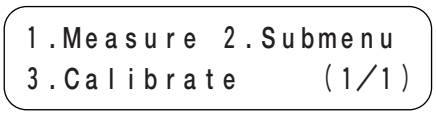
● Press [ENTER] key.
The Initialize confirmation screen is displayed.



● Press [START] key or [STOP] key.
If [START] key is pressed, parameters are initialized and the Measurement item selecting screen is restored.
If [STOP] key is pressed, initialization is canceled and the Measurement item selecting screen is restored.

3. End Initialization.

● If the initialization is finished, press [STOP] key three times to return to the MAIN MENU.



■ Factory setting values

The following measurement conditions are pre-set upon shipment at the factory. Refer to the table when setting parameters.

► The present parameter settings can be printed out (See “3-3-1 Print Parameters”).

Setting item and range			Factory setting value
Temperature	25℃, 30℃, 37℃		37℃
Coefficient of correlation	a : 0 ~ 10000 b : -10000 ~ 10000		a : 1.0 b : 0.0
Standard range	L : 0 ~ 10000 H : -10000 ~ 10000		Measurement range
Calibration	type	Calibration type Cal. or CARD	CARD
	Number of times	2 to 6 (times)	2

3-3-4 Enter sample type

Enter sample types to measure.
The entered types are printed out with the measurement results.
Maximum 5 different types can be set.

1. Display the screen.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Press [2] key.
  The PARAMETER MENU 1/2 is displayed.

```
1.Print   2.Input
3.Initialize    (1/2)
```

- Press [Menu] key or [-] key.

```
4.Type    5.Copy
                (2/2)
```

- Press [4] key.
  The Sample type 1 name entering screen is displayed.

```
REF value 1 name
              <_    >
```

2. Enter the sample type.

- Maximum 5 letters can be entered using numbers, letters, and symbols.

```
REF value 1 name
              <Man  >
```

- Press [Enter] key.
  The Sample type 2 name entering screen is displayed.

```
REF value 2 name
              <_    >
```

- Similarly, enter the sample types 2 to 5.
  When no sample type is set, press [Enter] key, with the space kept blank.

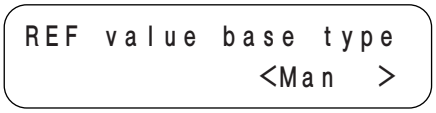
► The numeric keys and [-/.] keys can be used in selecting items. For example, to entry “man” [6][6][2][2][2][2][6][6][6][6][6][6]

[0] key can be used to input the following 12 symbols which are
＊？＃．，：；’ －＋／％

► To delete the name, press [-] key to make it blank. Press [Enter] key.

3. Setting the sample type to use on the basic setting.

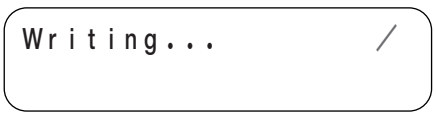
- In the end, set the sample type to use on the basic setting.
  The entered sample type is used as the sample type unless a different type is set at the time of measurement.

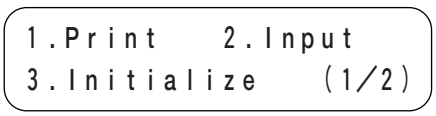


- Press [-] key to select sample type to use as the basic setting, and press [Enter] key.
  The Entry check screen is displayed.

4. Saving the setting contents.

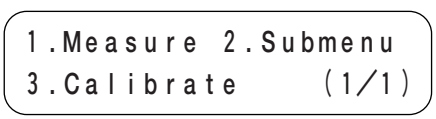
- Press [Start] key or [Stop] key.
  Pressing [Start] key saves the details of the setting, and returns the screen to the PARAMETER MENU 1/2.
  If [Stop] key is pressed, the PARAMETER MENU 1/2 is restored without saving the setting contents.





5. End setting.

- Press [STOP] key twice to return to the MAIN MENU.



3-3-5 Copy standard range setting

The standard range setting for a certain sample type can be copied in all items to one for another sample type.
Copy is available only when two or more sample types are input.

1. Display setting screen.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Press [2] key.
  The PARAMETER MENU 1/2 is displayed.

```
1.Print   2.Input
3.Initialize   (1/2)
```

- Press [Menu] key or [-] key.

```
4.Type    5.Copy
                (2/2)
```

- Press [5] key.
  The Standard range setting copy screen.
  The cursor is in the sample type on the original screen.

```
 PRES SPC>>Next SPC
 [Man  ]    [Man  ]
```

2. Selecting the standard range on the original screen.

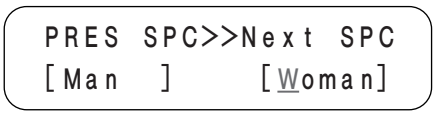
- Press [-] key to select the sample type for which the standard range is set on the original screen.

```
 PRES SPC>>Next SPC
 [Man  ]    [Man  ]
```

- Press [Enter] key.
  The cursor moves to the sample type on the duplicate screen.

3. Selecting the standard range of the duplicate screen.

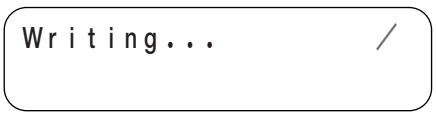
- Press [-] key to select sample type on the duplicate screen for which the standard range setting is required.



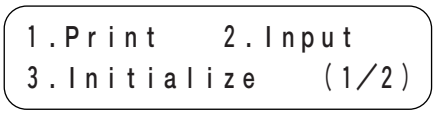
- Press [Enter] key.
  The Entry check screen is displayed.

4. Saving the setting contents.

- Press [Start] key or [Stop] key.
  Press [Start] key to copy and save the standard range. The PARAMETER MENU 1/2 is restored.

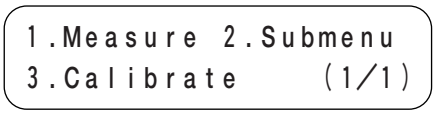


- Press [Stop] key to return the screen to the PARAMETER MENU 1/2, without duplicating the standard range.



5. End setting.

- Press [STOP] key twice to return to the MAIN MENU.



3-4 Maintenance

Proper maintenance is required to maintain the accuracy of the analyzer. Select "Maintenance" on the SUB MENU to perform either daily maintenance or periodical maintenance.

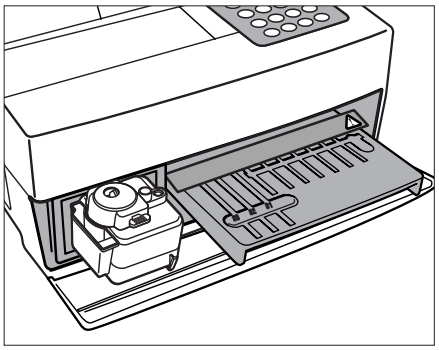
1. Preparation for the maintenance.

- Press [2] key on the MAIN MENU. SUB MENU1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Press [3] key .
  The Table Cover opens, and the Reagent Table and the Centrifuge-equipped Multi rack slide forward.



- When the message is displayed as shown on the right, turn off the power.

```
Ready.
Please turn off.
```

2. Perform maintenance.

- Perform maintenance of each part. (see "Chapter 4 MAINTENANCE")

3. End maintenance.

- Turn ON the power. Warm-up starts, the Reagent Table and the Centrifuge-equipped Multi rack slide back to the original position, and the Table Cover closes.

- After the warm-up is completed, MAIN MENU is restored.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

3-5 Mode Menu

► The Survey Mode is canceled automatically when the power is turned off.

Switch to the Survey Mode. When measurement is performed in the Survey Mode, raw data as well as normal measurement results can be printed out (see 2-6 “Interpreting measurement results” for details of printouts).

1. Display setting screen.

● Press [2] key on the MAIN MENU.
SUB MENU1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

● Press [MENU] key or [-/.] key.
SUB MENU 2/2 is displayed.

```
4.Mode     5.Clock
                (2/2)
```

● Press [4] key.
The MODE MENU is displayed.

```
1.Survey
                (1/1)
```

● Press [1] key.
The Survey mode setting screen is displayed.

```
Survey          [OFF]
```

2. Switch to the Survey Mode.

● Press [hyphen (-)] key.
Turn ON the Survey Mode.

```
Survey          [ ON]
```

● Press [ENTER] key.
The message “Writing...” is displayed and the MODE MENU is restored.

```
Writing...          /
```

3. End the Survey Mode.

● If the setting is finished, press [STOP] key three times to return to the MAIN MENU.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

3-6 Built-in Clock Adjustment

Set the Date and time of the built-in clock. Once the date and time are set, resetting is not necessary. However, resetting may be necessary in a long time of use.

1. Display setting screen.

- Press [2] key on the MAIN MENU. SUB MENU1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Press [MENU] key or [-/.] key. SUB MENU 2/2 is displayed.

```
4.Mode      5.Clock
                (2/2)
```

- Press [5] key . The Password entering screen is displayed. Enter password “99”. ＊＊is displayed on the screen.

```
Password <_      >
        Cancel(STOP)
```

- Press [ENTER] key. The Clock adjustment screen is displayed.

```
Date  <00-06-01>YMD
Time  <12:34:00>
```

2. Set the date and time.

- Enter the present date by sliding the cursor with [hyphen (-)] key.

```
Date  <00-06-12>YMD
Time  <12:34:00>
```

- Press [ENTER] key. The cursor moves to the time entry position.

```
Date  <00-06-12>YMD
Time  <12:34:00>
```

- Enter the present time by sliding the cursor with [hyphen (-)] key.

```
Date  <00-06-12>YMD
Time  <12:5_:00>
```

- Press [ENTER] key. The set date and time are stored, and the SUB MENU 2/2 is restored.

```
4.Mode      5.Clock
                (2/2)
```

3. End Setting.

- Press [STOP] key to return to the MAIN MENU.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

► If [STOP] key is pressed during operation, the setting is canceled and the SUB MENU 2/2 is restored.

► If [START] key is pressed, the initially displayed value is restored.

► If [STOP] key is pressed during operation, the setting is canceled and the date setting is restored.

► For the time settings, only the hour and minute can be set. The cursor does not move to the second position.

MEMO

Chapter 4
MAINTENANCE

Proper maintenance is required to maintain satisfactory measurement.
This chapter describes maintenance and replacement of consumables.

4-1 Outline of Maintenance

4-1-1 Frequency of Maintenance

The following table shows the parts requiring maintenance and the frequency of maintenance. Perform daily or periodical maintenance according to the table.

	Cleaning part	Frequency	Page
★	Cleaning of Reagent Table	Daily	4-03
★	Cleaning of Tip Waste Case	Daily	4-06
★	Cleaning of Protective Cover		4-07
	Replacement of Thermal Printer Paper	When a red line appears on both sides of printer paper	4-08
★	Cleaning of Optical Window	Once every 2,000 measurements	4-10
★	Cleaning of Nozzle	Once every 10,000 measurements or once a year	4-13
★	Replacement of Nozzle	When a trouble occurs or once a year	4-16

Cleaning of the parts marked with "★" on the table above requires user to wear protective gloves to prevent exposure to pathogenic microbes.
Discard any replaced parts or used cleaning tools separately from general waste according to local regulations on biohazardous waste.

4-2 Daily Maintenance

4-2-1 Cleaning the Reagent Table

With numerous measurements, residue of sample and Reagent Strips stay on the Reagent Table. When they are adhered to a new Reagent Strip, correct measurement results may not be obtained or Reagent Strips may be jammed inside.
Clean the Reagent Table daily after use to ensure that correct measurement results can be obtained all the time. Also, clean the black and white plates, and the Rubber Plate once a week. If those plates are dusty, correct measurement results may not be obtained. Refer to the next page for cleaning procedures. Perform occasional cleaning between measurements if necessary.

Requirements	Cleaning set (brush , cotton swabs), Distilled water and Protective gloves

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

1. Slide the Reagent Table forward.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

- Press [3] key .
  The Table Cover opens, and the Reagent Table and the Centrifuge-equipped Multi Rack slide forward.

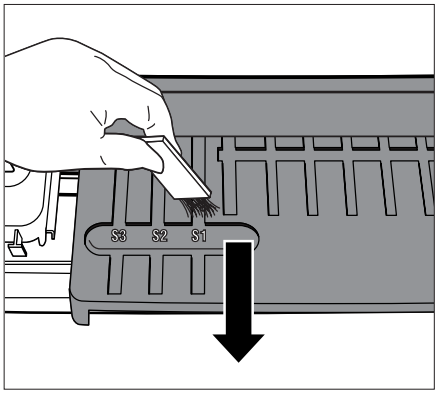
```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Turn OFF the power.

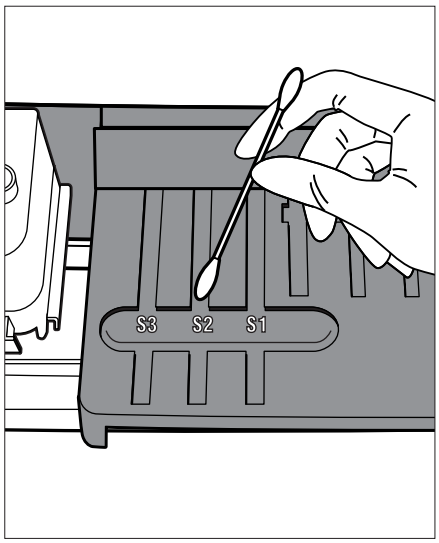
```
Ready.
Please turn off.
```

2. Clean the Reagent Table.

- Brush off dust on the Reagent Table with a cleaning brush toward you. Be sure to brush dust toward you, not toward the analyzer. Otherwise, malfunction of the analyzer may occur.



- Moisten a cotton swab with distilled water and wipe out stains or dust adhered to the Reagent Table. Clean the groove well carefully, not to break the lugs on the tip of the groove.

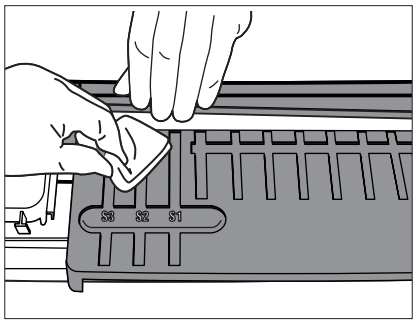


- If the Reagent Table is wet, wipe using a dry cotton swab. If any fiber is remained on the Reagent Table, brush it off with the cleaning brush again. Do not spill water on the analyzer to avoid damage.
- Wipe out dust adhered to the table pins with a cotton swab.
- Clean the black and white plates.

Cleaning the black and white plates (once a week)

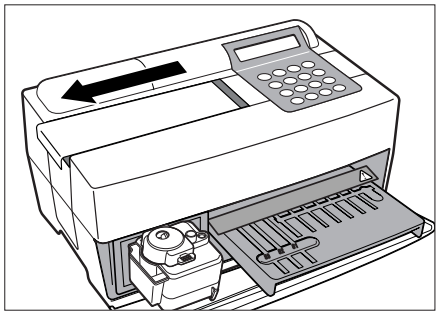
NOTE **The black and white plates are reflectors to measure standard values of reflectivity measurement. Be careful not to leave grease or scratch the plates by touching them with bare hands. Otherwise, correct measurement results may not be obtained.**

- Requirements: soft cloth (cloth for eyeglasses is preferable).
- Carefully wipe out stains or dust adhered to the black and white plates with a soft cloth.
- Do NOT try to blow dust away with your breath, which may cause fogging of the plates. Use a soft cloth, a brush, or a camera blower.

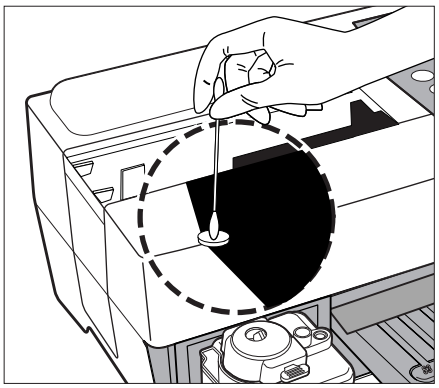


3. Clean the Rubber Plate. (Once a week)

- Remove the top cover by sliding it to the left.



- Moisten a cotton swab with distilled water and wipe out stains or dust adhered to the Rubber Plate.



- If the Rubber Plate is wet, use a dry cotton swab.

- Attach the top cover by sliding to the right.

4. End cleaning.

- Turn ON the power. Warm-up starts and the Reagent Table and the Centrifuge-equipped Multi Rack slide back to the original position, and the Table Cover closes.

```
Warming up...      /
```

- If the operation is completed, turn OFF the power after the MAIN MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

4-2-2 Cleaning the Tip Waste Case and Protective Cover

The Tip Waste Case holds used tips.
Its capacity is for 5 measurements (※) .Discard used tips and wash the Tip Waste Case. Clean the Protective Cover if necessary.
(※) A message suggesting the disposal of used tips is displayed every 5 measurements.

Requirements	Alcohol, Cloth and Protective gloves

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

Alcohol is sometimes used to clean the instrument. Alcohol is readily combustible, therefore handle it carefully and keep away from flames, electrical sparks and sources of heat. Also, ventilate the room sufficiently during use.

1. Slide the Centrifuge-equipped Multi Rack forward.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

- Press [3] key .
  The Table Cover opens and the Reagent Table and the Centrifuge-equipped Multi Rack slide forward.

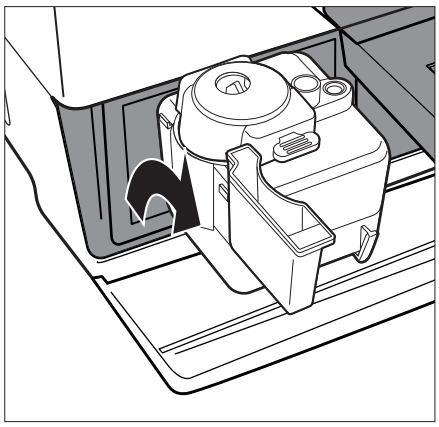
```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

- Turn OFF the power.

```
Ready.
Please turn off.
```

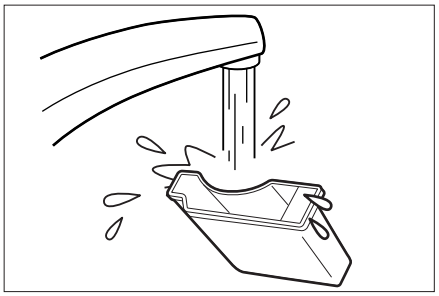
2. Discard Tips.

- Remove the Tip Waste Case from the Centrifuge-equipped Multi Rack.
- Discard tips.



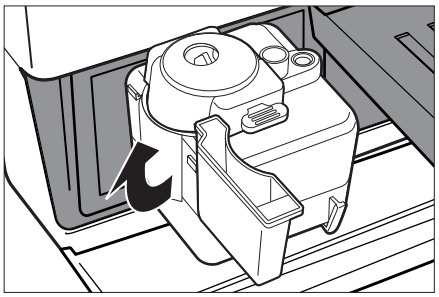
3. Disinfect and wash the Tip Waste Case.

- Disinfect the Tip Waste Case with alcohol and wash it with tap water.
- Wipe it dry with a cloth.



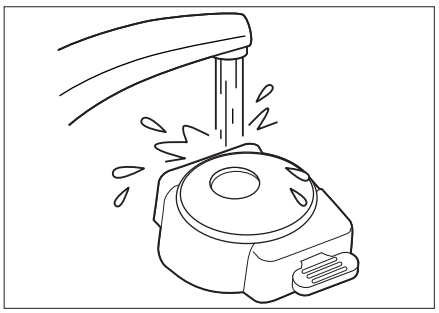
4. Reattach the Tip Waste Case.

- Put the Tip Waste Case into the Centrifuge-equipped Multi Rack.



5. Disinfect and wash the Protective Cover.

- Disinfect the Protective Cover with alcohol and wash it with tap water.
- Wipe it dry with a cloth.



6. End cleaning.

- Turn ON the power.
  Warm-up starts. The Reagent Table and Centrifuge-equipped Multi Rack slide back to the original position and the Table Cover closes.

```
Warming up...      /
```

- If the operation is completed, turn OFF the power after the MAIN MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

4-3 Periodic Maintenance

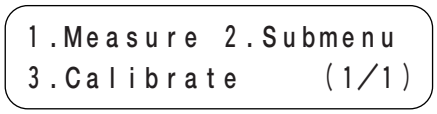
4-3-1 Replacement of Thermal Printer Paper

When the printer paper runs out, a red line appears on both sides of the printer paper. If the line is seen, replace it with a new roll. Approximately 500 measurements can be printed out on one roll of paper.

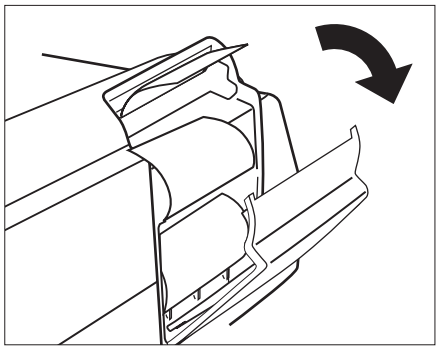
Requirements	New thermal printer paper roll and Scissors

1. Cut printer paper.

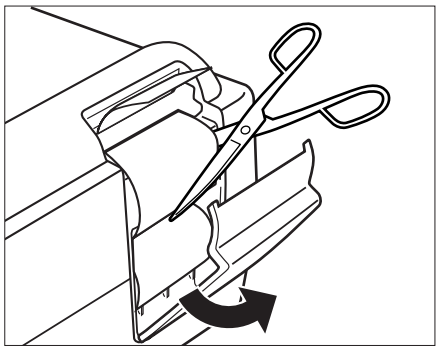
- Make sure that the MAIN MENU is displayed.



- Open the printer cover.

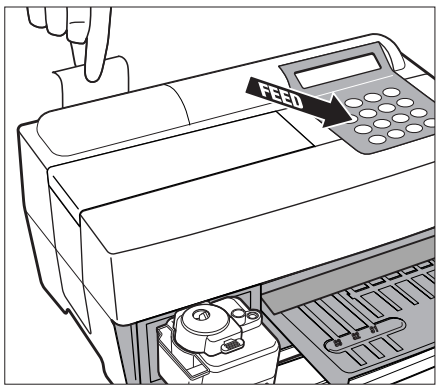


- If paper remains in the printer, cut it off with scissors and remove the remained paper.
  If no paper remains in the printer, remove the tube and proceed to Procedure 3.



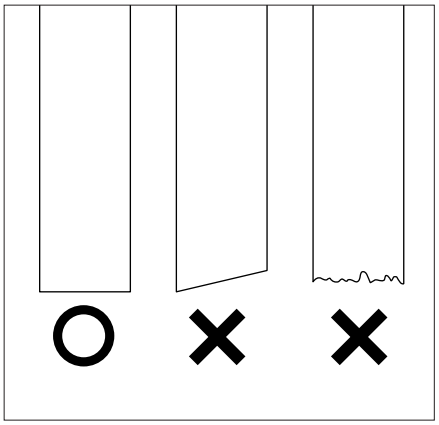
2. Remove the remained paper.

- Press the [FEED] key. Pick and remove the remained paper, as it is fed out.



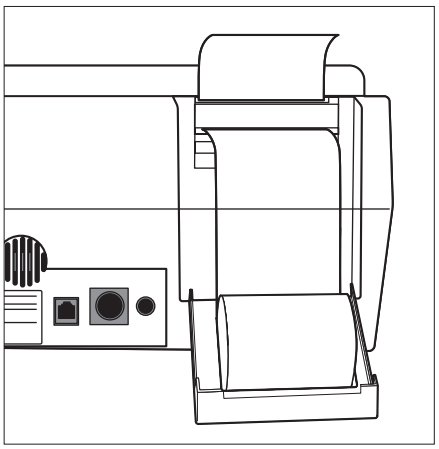
3. Prepare new printer paper.

- Cut off a single turn of the paper of new roll. Cut the top end straight to avoid a paper jam.



4. Set new printer paper.

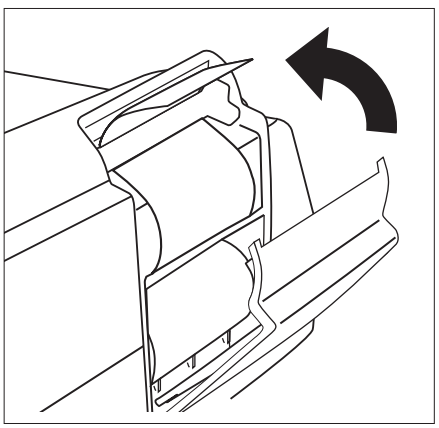
- Place a new roll of paper in the paper holder, with the paper end facing up.
- Insert the top of the paper end into the slot. The paper starts to be rolled and fed automatically.
- Press [FEED] key once.
  The printer becomes ready for printing.



► To make the printer ready for printing, press [FEED] key.

5. Close the printer cover.

- Close the printer cover until it clicks into place.



NOTE

Be careful not to touch the paper cutter to avoid injury.

4-3-2 Cleaning the Optical Window

If dust is adhered to the Optical Window, correct measurement result may not be obtained due to improper detection of reflect on light caused by fluctuation of wavelength. Clean the Optical Window once every 2,000 measurements.

Requirements Cotton swab, Distilled water and Protective gloves

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

1. Move the Nozzle to stand-by position.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

- Press [3] key .
  The Table Cover opens and the Reagent Table and Centrifuge-equipped Multi Rack slide forward. The Nozzle Driving Unit moves to the left end in the analyzer.

```
1.Results 2.PARAM
3.Maintenance  (1/2)
```

```
Ready.
Please turn off.
```

- Turn OFF the power .

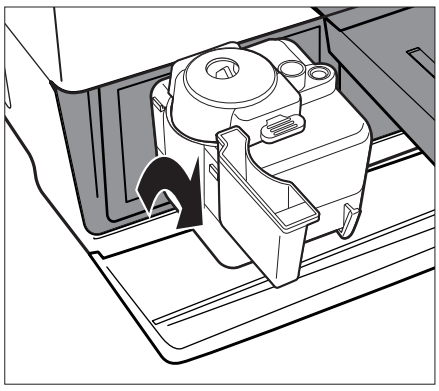
Make sure the power is OFF before moving on to the next procedure. Otherwise, it may cause injury by contacting with the driving unit of the analyzer.

2. Lay the analyzer on its side.

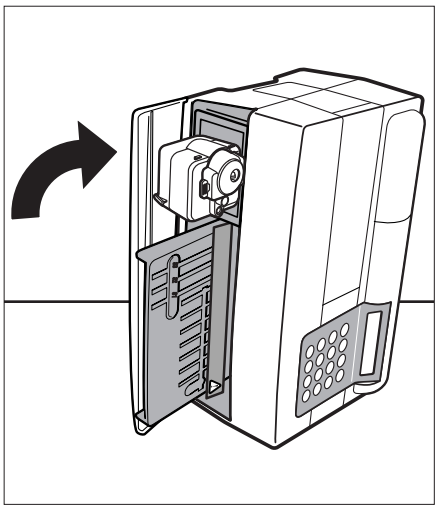
- Remove the Tip Waste Case from the Centrifuge-equipped Multi Rack.

NOTE

Make sure that all used Reagent Strips, samples and tips are removed.



- Turn over the analyzer carefully so that the right side (to which small legs are attached) faces down.
  Do NOT hold the Table Cover while turning the analyzer.

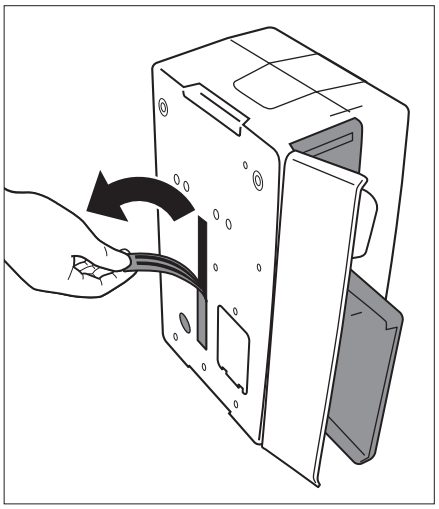


NOTE

Do NOT damage the connecting part of the Table Cover.
Be careful not to tip over the analyzer to avoid damage.

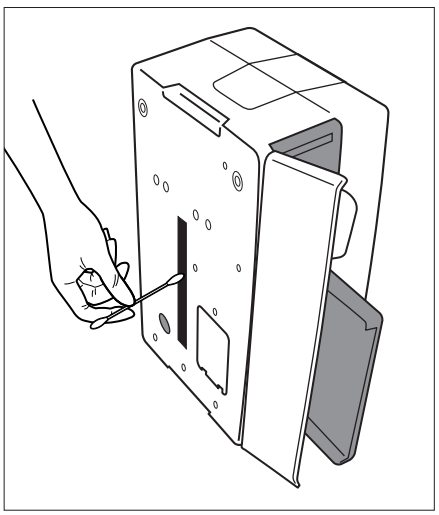
3. Clean the Optical Window.

- Remove the rubber cap on the bottom of the analyzer.



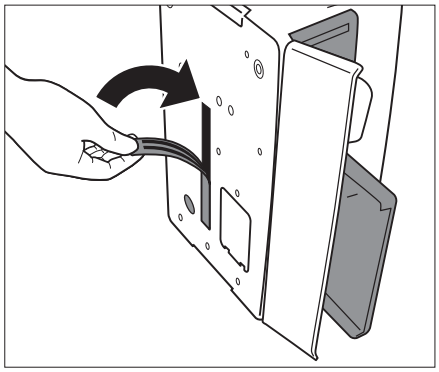
- Wipe out stains and dust adhered to the Optical Window (transparent glass plate) with a cotton swab moistened with distilled water.

- Wipe out remained cotton swab fibers and moisture of the Optical Window with a new dry cotton swab. Check it the Optical Window is clean and dust-free. Use a flashlight to make the checking easier.

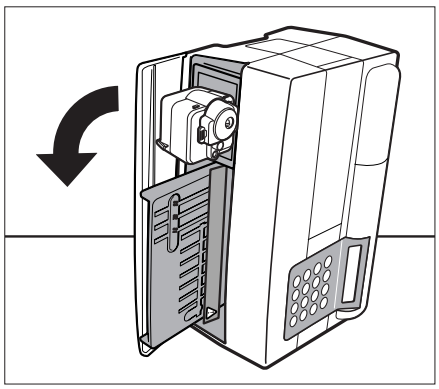


4. Restore the analyzer.

● Reattach the rubber caps firmly to the bottom of the analyzer.



● Carefully turn over the analyzer to the original position, without holding the Table Cover.

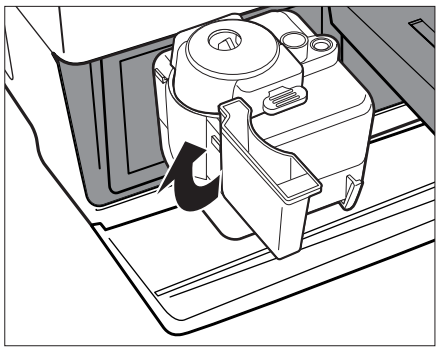


NOTE

Do NOT damage the connecting part of the Table Cover.
Be careful not to tip over the analyzer to avoid damage.

5. End cleaning.

● Attach the Tip Waste Case to the Centrifuge-equipped Multi Rack.



● Turn ON the power.
Warm-up starts.The Reagent Table and Centrifuge-equipped Multi Rack slide back to the original position and the Table Cover closes.

```
Warming up...      /
```

● When the operation is completed, turn OFF the power after the MAIN MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

4-3-3 Cleaning the Nozzle

With numerous measurements, sample blood residue may stay inside the Nozzle and cause clogging.
Clean the Nozzle once every 10,000 measurements or once a year.

Requirements Nozzle cleaning wire, Tweezers,
Tissue paper and Protective gloves

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

1. Move the Nozzle to stand-by position.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate      (1/1)
```

- Press [3] key .
  The Table Cover opens, and the Reagent Table and Centrifuge-equipped Multi Rack slide forward. The Nozzle Driving Unit moves to the left end in the analyzer.

```
1.Results 2.PARAM
3.Maintenance    (1/2)
```

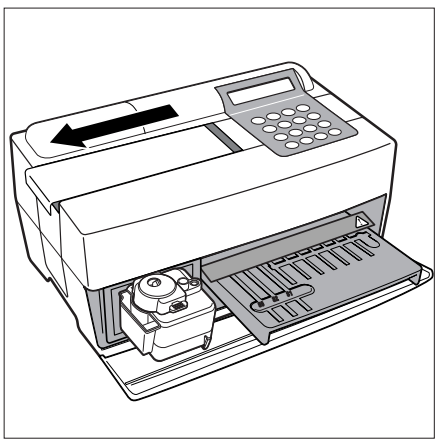
```
Ready.
Please turn off.
```

- Turn OFF the power.

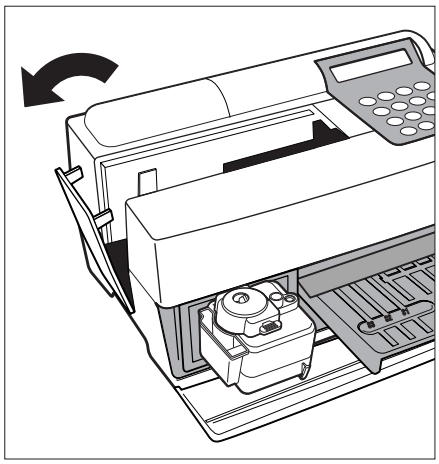
Make sure the power is OFF before moving on to the next procedure. Otherwise, it may cause injury by contacting with the driving unit of the analyzer.

2. Remove the cover.

- Remove the top cover by sliding it to the left.

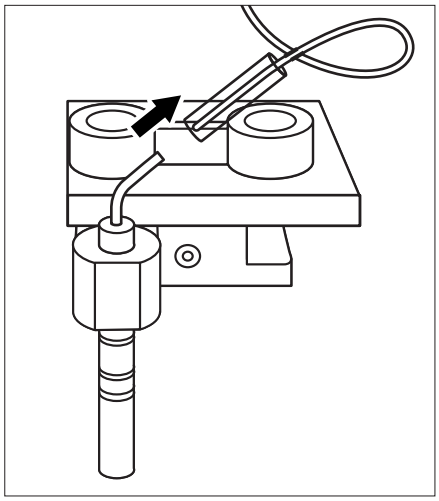


● Remove the side cover.



3. Remove the Nozzle Tube.

● Remove the Nozzle Tube from the Nozzle using tweezers.



NOTE

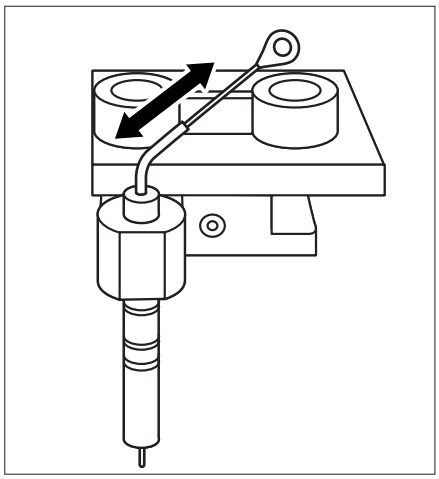
Do NOT scratch or damage the Nozzle Tube.

4. Clean the Nozzle.

● Insert the nozzle cleaning wire into the Nozzle until its tip appears from the other end.

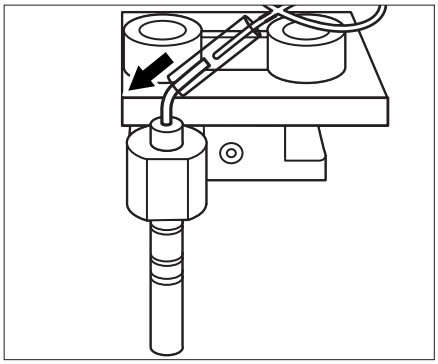
● Clean the inside of the Nozzle by moving the wire up and down a couple of times.

● Wipe out the dust caming out of the tip of the Nozzle with tissue paper.



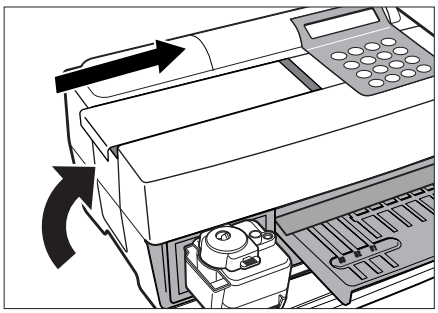
5. Insert the Nozzle Tube.

- Remove the nozzle cleaning wire from the Nozzle.
- Pinch the Nozzle Tube with tweezers and insert it into the tube joint.



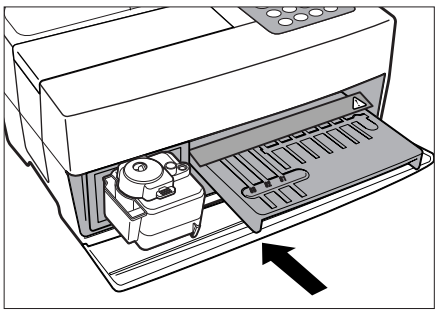
6. Reattach the covers.

- Put the side cover to the analyzer.
- Attach the top cover by sliding to the right.



7. End Cleaning.

- Turn ON the power.
  Warm-up starts. The Reagent Table and Centrifuge-equipped Multi Rack slide back to the original position, and the Table Cover closes.



```
Warming up...      /
```

- When the operation is completed, turn OFF the power after the MAIN MENU is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

NOTE

Before turning ON the power, make sure that the maintenance cover is installed.

4-3-4 Replacement of Nozzle

With numerous measurements, the O-ring attached to the Nozzle becomes deteriorated.

Requirements Nozzle, Nozzle replacement tool and Protective gloves

Wear protective gloves to prevent exposure to pathogenic microbes.

Discard used samples, tips and protective gloves separately from general waste according to local regulations on biohazardous waste.

1. Move the Nozzle to stand-by position.

- Press [2] key on the MAIN MENU.
  SUB MENU 1/2 is displayed.

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

- Press [3] key .
  The Table Cover opens, and the Reagent Table and Centrifuge-equipped Multi Rack slide forward. The Nozzle Driving Unit moves to the left end in the analyzer.

```
1.Results 2.PARAM
3.Maintenance   (1/2)
```

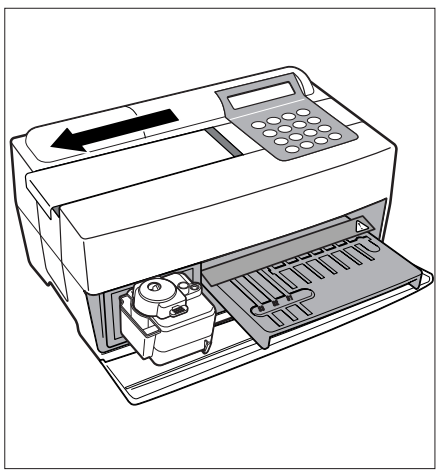
```
Ready.
Please turn off.
```

- Turn OFF the power.

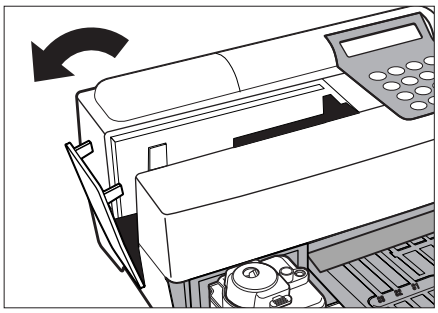
Make sure the power is OFF before moving on to the next procedure. Otherwise, it may cause injury by contacting with the driving unit of the analyzer.

2. Remove the cover.

- Remove the top cover by sliding to the left.



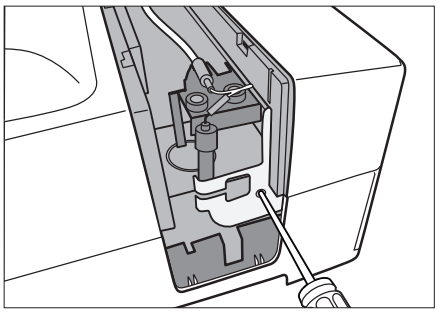
● Remove the side cover.



3. Remove the Tip Waste Case.

● Loosen the fixing screws and remove the tip ejector.

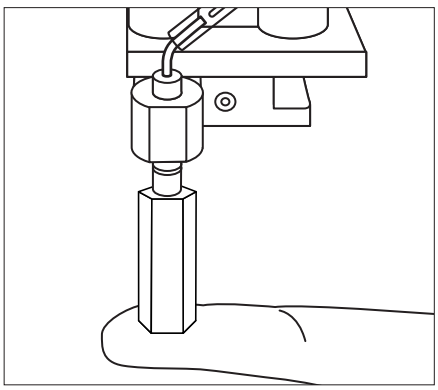
● Remove the Tip Waste Case.



4. Replace the Nozzle.

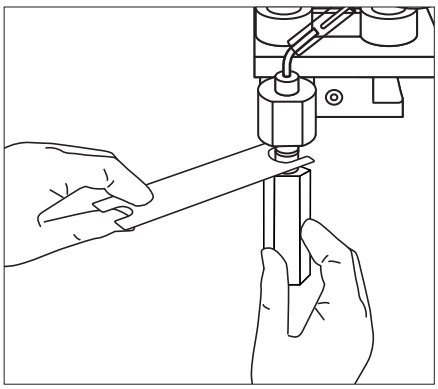
● Fasten the upper part using the narrow side of the wrench.

● Insert the adapter from the bottom and rotate it using the wide side of the wrench.



● Attach a new Nozzle and fasten it lightly by hand.

● Tighten it firmly using two wrenches.

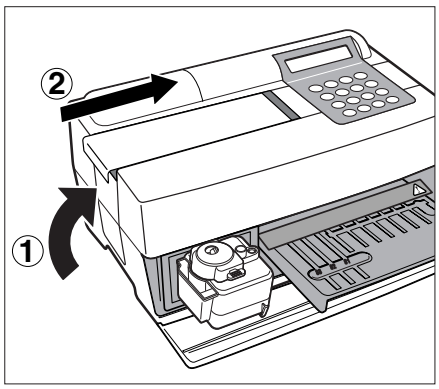


5. Reattach the Tip Waste Case.

- Put the Tip Waste Case by tightening the screws.

6. Reattach the covers.

- Put the side cover to the analyzer.
- Put the top cover to the analyzer by sliding it to the right.

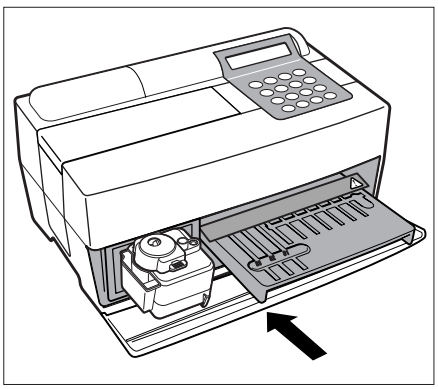


7. End replacement.

NOTE

Before turning ON the power, make sure that the maintenance cover is installed.

- Turn ON the power.
  Warm-up starts. The Reagent Table and Centrifuge-equipped Multi Rack slide back to the original position, and the Table Cover closes.



- When the operation is completed, turn OFF the power after the MAIN MENU is displayed.

```
Warming up...      /
```

```
1.Measure 2.Submenu
3.Calibrate     (1/1)
```

Chapter 5

TROUBLESHOOTING

When there is a failure in operation or a problem with the analyzer, an error or trouble occurs. This chapter describes, the kinds of errors / troubles, causes and remedy.

5-1 Error Messages

When an error occurs, an alarm sounds and the error message appears on the screen.
The error message is automatically printed in order to preserve the error record (The following errors are only displayed, and not printed).

●The following errors are not printed when the magnetic card is inserted.
E15 No MEAS data
E21 Card misread
E24 Wrong card
E25 Wrong stripe

Description and error message	Conditions and causes	Remedy
E02 E02 Cover open OK(ENTER) (T) : Trouble with the table cover. (M) : Trouble with the maintenance cover.	● The table cover was opened during measurement or warm-up. ● The maintenance cover was opened during measurement or warm-up. ● The table cover is not properly closed (Foreign matter is jammed). ● The measurement was started without closing the maintenance cover.	● Close the table cover correctly (Remove the foreign matter). ● Set the maintenance cover in the correct position.
E03 E03 Power down OK(ENTER)	● Power failure has occurred during measurement. ● Power was turned off during measurement. ● The power cable was unplugged during measurement.	● The last measurement was invalid. Restart measurement.
E04 E04 LED unstable OK(ENTER)	● A light source is deteriorated.	● If the same trouble occurs, contact your distributor.
E05 E05 Optical error (9 6 2) OK(ENTER) (1 ～ 9) : Channels with abnormalities	● The white and black plate or window plate is dirty. **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Clean the white and black plate or window plate (see “4-2-1 Cleaning the Reagent Table” and “4-3-2 Cleaning the Optical Window”).
E11 E11 No strips (M) OK(ENTER) (7 ～ 9) : Single type (M) : Multi type Channel with no Reagent Strip in either case. Display is made only in calibration. Usually nothing is displayed during measurement.	● Reagent Strip is not set. ● The bar code was not correctly read due to displacement or bending of the Reagent Strip. ● The Reagent Strip is not set in the channel necessary for calibration. **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Set Reagent Stripes correctly. ● When calibrating, set the necessary numbers.

Description and error message	Conditions and causes	Remedy
E13 E13 Wrong strips (87) OK(ENTER) (7 ～ 9) : Single type (M) : Multi type Channel with a different Reagent Strip in either case.	● When calibrating by calibrator kit, a many Reagent Strip is set. ● The bar code was not correctly read due to displacement or bending of the Reagent Strip. ● Before calibration of an item is completed, another item was attempted to be calibrated.  **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Set the Reagent Strip correctly. ● Return to the menu because the changing item is not allowed during calibration by calibrator kit.
E14 E14 Used strips (9) OK(ENTER) (7 ～ 9) : Single type (M) : Multi type Channel with used Reagent Strip in either case.	● Used Reagent Strip is already used. ● The reagent pad is colored because of old Reagent Strips or inappropriate preservation. ● The reagent pad is dirty. ● The bar code was not correctly read due to displacement or bending of the Reagent Strip.  **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Use a new Reagent Strip. ● Set the Reagent Strip correctly.
E15 E15 No MEAS data (7 M) OK(ENTER) (7 ～ 9) : Single type (M) : Multi type Channel with no information for measurement in either case. The error is not displayed when the magnetic card is inserted.	● Reagent Card for the item to measure is not inserted. ● The bar code was not correctly read due to displacement or bending of the Reagent Strip. ● When this occurs in measurement with a Multi Reagent Strip, Reagent Card for a multi reagent is not inserted for measurement. ● Reagent Card for an item with no information for measurement is inserted.  **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Insert a magnetic card corresponding to the item. ● Set the Reagent Strip correctly.
E16 E16 No CAL data (7 M) OK(ENTER) (7 ～ 9) : Single type (M) : Multi type Channel with no calibration information in either case.	● Wrong calibration card was inserted. ● The bar code was not correctly read due to displacement or bending of the Reagent Strip.  **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Insert the correct calibration card again (Hb is a different card). ● Set the Reagent Strip correctly.

Description and error message	Conditions and causes	Remedy
E17 E17 No sample (CNTRFG) OK (ENTER) Cuvette: when a curette is used for liquid level detection. CNTRFG: When a centrifuge vessel is used.	● A sample vessel is misplaced. ● There is no sample or an insufficient amount of sample. ● A centrifuge tube was used in calibration by calibrator kit.	● Set the sample correctly. ● Confirm the amount of the sample. ● Be sure to use cuvettes in calibration by calibrator kit.
E21 E21 Card misread OK (ENTER)	● The magnetic card was caught when inserted. ● The head of magnetic card reader is dirty.	● Insert the magnetic card again. ● Clean the head of the magnetic card reader.
E24 E24 Wrong card OK (ENTER)	● Wrong magnetic card was used (a calibration card was inserted when the display showed Reagent Card reading or vice-versa).	● Insert a correct magnetic card.
E25 E25 Wrong stripe OK (ENTER)	● The same stripe was inserted.	● Insert a different stripe.
E30 E30 Abnormal data (L1 3) OK (ENTER) PR : Prozone error L 1 : Large difference between the measured and the displayed values of calibrator L. H 1 : Large difference between the measured and the displayed values of calibrator H. L 2 : Large variations between the measured values of calibrator L. H 2 : Large variations between the measured values of calibrator H. LH : No difference between the measured value of calibrator L and that of calibrator H. (1 ～ 6) : Channel with an error. The display is shown only in multi calibration, and nothing is displayed in single calibration.	● During calibration, the difference of the measured value and the display of calibrator is extremely large. ● The variations of the measured values are extremely large in calibration. ● Calibrator L and H might be set oppositely in calibration. ● Incorrect adjustment of calibrator.	● Perform measurement again.

Wear protective gloves in order to avoid exposure to pathogenic microbes.

Description and error message	Conditions and causes	Remedy
E31 E31 Wrong date/time OK(ENTER)	● The clock is not correctly adjusted. ● The power was not connected for a long time (battery is dead).	● Readjust the date and time. (see "3-6 Built-in Clock Adjustment")
E32 E32 Invalid strips (7 M) OK(ENTER) (7 ~ 9) : Single type (M) : Multi type Channel with expired Reagent Strips in either case.	● The Reagent Strip has expired. ● The clock is not correctly adjusted. ● The clock is not correct because the power was not connected for a long time. ● When using a Reagent Strips from new lot, the corresponding magnetic card to the lot of the was not inserted.	● Use a new Reagent Strip. ● Adjust the clock. ● Insert a new magnetic card.
E33 E33 Stray light OK(ENTER)	● External light entered because the table cover or maintenance cover was slightly opened.	● Close the table cover or the maintenance cover firmly. ● Change the direction of the analyzer.
E34 E34 BAR misread (987) OK(ENTER) (7 ~ 9) : Single type Channel which was misread.	● The table is dirty. ● The bar code was not correctly read due to displacement or bending of the Reagent Strip. ● Foreign matter is attached to the Single Reagent Strip. **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Remove dust from the table. ● Reset the Single Reagent Strip correctly. ● Confirm that foreign matter is not attached to the Single Reagent Strip.
E35 E35 BCR error OK(ENTER)	● The setting (such as baud rate) of the hand-held bar code reader is incorrect. ● The hand-held bar code reader is not correctly connected.	● Confirm the setting of the hand-held bar code reader (such as baud rate). ● Connect the hand-held bar code reader correctly.
E36 E36 Battery error OK(ENTER)	● Battery is exhausted.	● Charge the battery.

Description and error message	Conditions and causes	Remedy
E37 E37 Sampling error OK(ENTER)	● When sampling, air bubbles or fibrin was aspirated. ● When sampling, the sample amount was insufficient.  **Wear protective gloves in order to avoid exposure to pathogenic microbes.**	● Remove air bubbles or fibrin. ● Confirm the sample amount.
E38 E38 Tip case not set OK(ENTER)	● Forgot to set the Tip Waste Case. ● The Tip Waste Case is not correctly set.	● Set the Tip Waste Case correctly.
E39 E39 Communication OK(ENTER)	● The cable is not connected. ● The setting (e.g. baud rate) of the connected device (such as PC) is incorrect.	● Connect the cable correctly. ● Confirm the setting (e.g. baud rate) of analyzer connections (e.g. PC).
E40 E40 Sample drop (7 4 1) OK(ENTER) (1～9) : Channels with abnormalities	● Failed to draw the sample and drop it to the reagent correctly due to lack of sample amount or absorbing fibrin. ● Failed to drop the sample to the reagent correctly because the sample adheres around the dropping hole.	● Check the sample amount and remove fibrin if necessary. ● Wipe off the sample adhered to around the dropping hole. ● Measure it with a different tip.
E90 E90 Memory:results OK(ENTER)	● The memory storing the measured results is defective. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs often, contact your distributor.
E91 E91 Memory:history OK(ENTER)	● The memory storing the trouble history is detective. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs often, contact your distributor.
E92 E92 Memory:setup OK(ENTER)	● The memory storing the setup data is defective. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs often, contact your distributor. ● As the user setting value is initialized or is returned to the last measured value, reset it (re-enter it).

5-2 Trouble Messages

When a trouble occurs, an alarm sounds, and a trouble message is displayed. The trouble message is automatically printed in order to preserve the trouble record.

IMPORTANT

When a trouble occurs during measurement, perform the measurement again. It may have influenced the result obtained before the trouble occurred. Perform the measurement again if the result is defective.

Description and trouble message	Conditions and causes	Remedy
T03 T03 Tube pressure OK(ENTER)	● The pressure does not increase since the rubber plate is dirty or deformed. ● The tube or pipe is clogged. ● The tube connecting the nozzle with the pump is disconnected. ● The tube connecting the pump with the pressure-detecting sensor is disconnected.	● Clean the rubber plate. ● Check the tube. ● If the same trouble occurs, contact your distributor. (NOTE: in cases where the abnormality is detected when the power switch is turned on, it is necessary to turn on the power again after maintenance because the measurement could not be started).
T04 T04 Temp control OK(ENTER)	● The temperature inside the analyzer became too high because the fan had stopped. ● The temperature outside exceeds the range (10 ～ 30℃) suitable for operation.	● Confirm if the fan is rotating. ● Confirm the temperature outside. ● If the same trouble occurs, contact your distributor. (NOTE: in cases where the abnormality is detected when the power is turned on, it is necessary to turn on the power again because the measurement cannot be started).
T05 T05 Nozzle U/D OK(ENTER)	● Trouble occurred at the nozzle up-down driving mechanism (hit an obstruction when it moved downward or it was caught in the upward-movement).	● Turn on the power again. ● Confirm that there is no obstruction. ● If the same trouble occurs, contact your distributor.
T06 T06 Nozzle L/R OK(ENTER)	● Trouble occurred in the nozzle right-left driving.	● Turn on the power again. ● Confirm that there is no obstruction. ● If the same trouble occurs, contact your distributor.
T07 T07 Reagent table OK(ENTER)	● The table cannot function because a Reagent Strip is caught in the gap in the table. ● The Reagent Strip table cannot function because there is an obstruction in front of the table cover.	● Turn on the power again. ● Remove the obstruction, if any. ● Confirm that there is no obstruction in front of the table cover. ● If the same trouble occurs, contact your distributor.

Description and trouble message	Conditions and causes	Remedy
T09 T09 Pump OK(ENTER)	● Trouble occurred in the pump-driving mechanism.	● Turn on the power again. ● If the same trouble occurs, contact your distributor.
T12 T12 Optical gain OK(ENTER)	● The optimal gain could not be set.	● Turn on the power again. ● If the same trouble occurs, contact your distributor. (NOTE: If measurement is started though trouble is detected when the power turned on, trouble occurs at the start of measurement, and the measurement cannot be performed).
T13 T13 Calculation OK(ENTER)	● Trouble occurred in the internal calculation operation.	● If the same trouble occurs, contact your distributor.
T14 T14 LED intensity (Low) OK(ENTER) (High): the case in which the counted value is greater than the setup range. (Low): the case in which the counted value is smaller than the setup range.	● LED is not lit. ● LED is deteriorated.	● Turn on the power again. ● If the same trouble occurs, contact your distributor.
T17 T17 Device error (SUB) OK(ENTER) (PMC): When trouble occurs on the PMC. (SUB): When trouble occurs on the sub-CPU.	● Trouble occurred in an electrical component.	● Turn on the power again. ● If the same trouble occurs, contact your distributor.
T20 T20 Tip picking OK(ENTER)	● Forgot to set tips. ● Failure in setting tip mount.	● Set the tip.

Description and trouble message	Conditions and causes	Remedy
T21 T21 Tip ejecting OK(ENTER)	● Failure to discard tip.	● Turn off the power, and remove the tip from the nozzle.
T25 T25 Barcode sensor (8 5 3) OK(ENTER) (1- 5, 7- 9) :Channels with abnormalities	● White plate or black plate is dirty.	● Clean the white plate or black plate. (Note: the case in which trouble is detected when the power is turned on, it is necessary to turn on the power again after maintenance since measurement cannot be started).
T27 T27 Centrifuge OK(ENTER) (Cover) :Protective cover is not attached (Position) :Stop position is not correct	● The rotating rate of centrifuge is defective. ● It cannot rotate due to an obstruction around the centrifuge. ● Forgot to set centrifuge tube. ● Protective cover is not properly attached.	● Remove the obstruction around the centrifuge. ● Turn on the power again. ● If the same trouble occurs, contact your distributor. ● Set the centrifuge tube. ● Attach the protective cover properly.
T28 T28 Centrifuge F/B OK(ENTER)	● Trouble occurred in the centrifuge front-back driving mechanism. ● It cannot operate because of an obstruction in the operating path of the centrifuge base.	● Turn on the power again. ● Confirm that there is no obstruction. ● If the same trouble occurs, contact your distributor.
T90 T90 Memory:product OK(ENTER)	● Trouble with product information memory storage. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs, contact your distributor.
T91 T91 Memory:mechanism OK(ENTER)	● Trouble with mechanism information memory storage. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs, contact your distributor.
T92 T92 Memory:optical OK(ENTER)	● Trouble with optical system information memory storage. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs, contact your distributor.

Description and trouble message	Conditions and causes	Remedy
T93 T93 Memory:parameter (S-03) OK(ENTER) (S- XX): Single type (M- XX): Multi type The parameter item number found defective in either case.	● Trouble with parameter memory storage. ● Power was cut while writing in memory or deleting.	● If the same trouble occurs, contact your distributor.

5-3 After sales service

■Warranty : A warranty is included in this packaging box. This warranty is necessary when the analyzer requires repair. After filling in the necessary items and confirming the described contents, keep the warranty in a safe place.

■Repairs :

When the analyzer does not function well	Contact your distributor.
Repair within the guaranteed period	Repair is made under conditions of the certificate.
Repair after the guarantee has expired	A repair fee is necessary.

Chapter 6

APPENDIX

6-1 Transmission Specifications

6-1 Transmission Specifications

6-1-1 Protocol

Transmission format Start-stop system (asynchronous) unidirectional transmission by serial transmission format (in compliance with JIS X5101).

Data format One character consists of the following 11 bits.
Start bit: 1 bit
Data bit: 7 bits (ASCII code)
Parity bit: 1 bit (even)
Stop bit: 2 bits

Baud rate Baud rate can be selected out of the following 6 rates.
300, 600, 1200, 2400, 4800, 9600bps

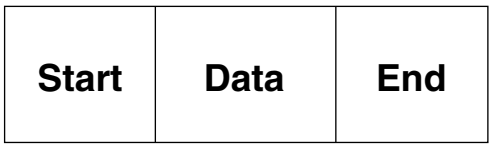
Hand shake Suppression by CFT and RTS are possible. (Suppression is not set by default.) XON/XOFF control is not available.

Time gap 2-second waiting time is inserted between each block (from < ETX > or < ETB > to < STX >).

Forced finish Data transmission is sometimes forced to stop halfway by key operation. It is not promptly stopped by pressing a key, but transmission continues until < ETX > or < ETB > is output.

6-1-2 Format

Block structure is regular. One block consists of start, data and end. This is illustrated below in the following descriptions.



● **Start (S)**

Start of each block is < STX >.

Start of block is expressed as S in the following illustrations.

● **Data**

Data (text) of each block is the main body of transmission contents, and is expressed by arrangement of ASCII characters.

< CR >, < LF >, < RS > or < US > is sometimes involved in data. Characters other than these cannot be involved.

● **End (E)**

End of each block is < RTX > or < ETB >.

< ETX > or < ETB > is distinguished by whether it is in the last block or not.

If it is in the last block, it is < ETX >, and if it is in the middle block, it is <ETB >.

The block end is expressed by E in the following illustrations.

6-1-3 Format for measurement results (format 1)

The measurement result (format 1) is the same as the "regular format" in SP-4410 or SP-4420. The receiving program designed to receive the measurement results of SP-4420 (regular format) can normally receive the measurement results (format 1) of SP-4430.

■ Transmission data of measurement results (format 1)

When transmitting the measurement results with format 1, the number of blocks differs depending on the combination of the reagent strips.

A. When only Multi Reagent Strips are measured.

S	Header	Multi Reagent Strip measurement results	E

B. When only Single Reagent Strips are measured.

S	Header	Single Reagent Strip measurement results	E

C. When Multi and Single Reagent Strips are measured.

S	Header	Multi Reagent Strip measurement results	E

S	Single Reagent Strip measurement results	E

●Format of header

001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019	020	021	022
■	■	／	■	■	／	■	■						■	■	:	■	■			CR	LF
023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044
I	D	#		■	■	■	■	■	■	■	■	■	■							CR	LF

Start	Finish	Description
001	001	Measurement date. Year (The last two digits of year), month (1~12), date (11~31). No zero control. YMD format is always applied regardless of the date setting.
014	018	Measurement date. Time (01~23), Minute (01~59). No zero control.
027	036	When ID is available, ID is output. When there is no ID, only the first 10 digits are output. The measurement number is expressed in 4 digits without zero control. For the measurement number, blank is used for 0311~036.

●Format of Multi Reagent Strip measurement results

001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019	020	021	022
	M	U	L	T	I	:	■	■	■	■	■	■	■	■	■	■				CR	LF
023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
045	046	047	048	049	050	051	052	053	054	055	056	057	058	059	060	061	062	063	064	065	066
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
067	068	069	070	071	072	073	074	075	076	077	078	079	080	081	082	083	084	085	086	087	088
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
089	090	091	092	093	094	095	096	097	098	099	100	101	102	103	104	105	106	107	108	109	110
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF

Start	Finish	Description
008	017	Name of Multi Reagent Strip
023	027	Item name
029	029	Abnormal mark ● Within the range of standard values: Blank (20H) ● Low value: <US>(1FH) ● High value: <RS>(1EH)
030	034	Measurement value
036	041	Unit symbol
042	042	Temperature ● 37℃: Blank(20H) ● 30℃: " + " ● 25℃: " ＊ " ● Items other than enzyme: Blank
045	154	The same repetition as 023~044. When the number of items is less than 6, the redundancy makes up for the blank (20H).

●Format of Single Reagent Strip measurement results

001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019	020	021	022
■	■	■	■	■	■	■														CR	LF
023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
045	046	047	048	049	050	051	052	053	054	055	056	057	058	059	060	061	062	063	064	065	066
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF
067	068	069	070	071	072	073	074	075	076	077	078	079	080	081	082	083	084	085	086	087	088
■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■	CR	LF

Start	Finish	Description
001	007	When only Single Reagent Strips are measured: Blank (20H) When Multi Reagent Strips are measured: Fixed character string “SINGLE”
023	027	Item name
029	029	Abnormal mark ● Within the range of standard values: Blank (20H) ● Low value: <US>(1FH) ● High value: <RS>(1EH)
030	034	Measurement value
036	041	Unit symbol
042	042	Temperature ● 37℃: Blank(20H) ● 30℃: “ + ” ● 25℃: “ ✻ ” ● Items other than enzyme: Blank
045	048	The same repetition as 023~044. No extra output is made. The block length of this block changes according to the number of Reagent Strips (items). For example, if the number of the Reagent Strips are 2 (2 items), the block length is completed as 66 bytes.

●Data errors

In the Multi Reagent Strip and Single Reagent Strip measurement results, data parts for each item (22 bytes including end CR/LF) are output as follows when measurement errors occur.

●Error in range or prozone (OVER)

023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044
■	■	■	■	■		■	■	■	■	■	■	■		■	■	■	■	■	■	CR	LF

Start	Finish	Description
023	027	Item name
029	035	● Over the range: Fixed character string “OVER >” ● Under the range: Fixed character string “UNDER >” ● Prozone (OVER): Fixed character string “OVER >”
037	041	● Over the range: Upper limit of measurement range ● Under the range: Lower limit of measurement range ● Prozone (OVER): Upper limit of measurement range
042	042	Temperature ● 37℃: Blank(20H) ● 30℃: “ + ” ● 25℃: “ ∗ ” ● Items other than enzyme: Blank

●Prozone (CANT' MEAS) or calibration error by magnetic card

023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044
■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	CR	LF

Start	Finish	Description
023	027	Item name
029	041	Error message ● Prozone (CANT' MEAS): “CANT' MEAS ” ● Magnetic card, CAL error, L: “CAL. ERROR L1” ● Magnetic card, CAL error, H: “CAL. ERROR H1”
042	042	Temperature ● 37℃: Blank(20H) ● 30℃: “ + ” ● 25℃: “ ∗ ” ● Items other than enzyme: Blank

6-1-4 Format of measurement results (format 2)

The measurement result (format 2) is the same as the "extended format" in SP-4410 or SP-4420. The receiving program designed to receive the measurement results of SP-4420 (extended format) can normally receive the measurement results of SP-4430 (format 2).

■ Transmission data of measurement results (format 2)

A. When only Multi Reagent Strips are measured.

When transmitting the measurement results with format 2, 1 item is output as 1 block. The order of the items are, Multi Reagent Strip, Single Reagent Strip.

S	Data in Item 1	E	S	Data in Item 2	E	·····	S	Data in Item n	E

※ The end of the block is all block <ETX>.

●Format of "data in item x"

001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019	
■	■	■	■	■	■	■	■	■	■		■		■	■	／	■	■		
020	021	022	023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039
■	■	／	■	■	／	■	■		■	■	:	■	■		■		■	CR	LF
040	041	042	043	044	045	046	047	048	049	050									
■	■	■	■	■	■	■	■	■	■										
051	052	053	054	055	056	057	058	059	060	061	062	063	064	065	066	067	068	069	
■	■	■	■	■		■	■	■	■	■		■	■	■	■	■	■		
070	071	072	072	074	075	076	077	078	079	080	081	082	083	084	085	086	087	088	089
0																		CR	LF

Start	Finish	Description
001	010	When ID is available, ID is output. When there is no ID, only the first 10 digits are output. The measurement number is expressed in 4 digits without zero control. For the measurement number, blank is used for 031~036
012	012	Sample number types . For ID, "1". For number , "0"
014	015	The maximum number of items in the measurement
017	018	The order of the maximum number of items
020	027	Measurement date. Year (The last two digits of year), month (1~12), date (1~31) No zero control. YMD format is always applied regardless of the date setting
029	033	Measurement date, Time (0~23), Minute (0~59). No zero control
035	035	Data error. Normal=0, Under the range=1, Over the range or prozone error (OVER)=2, Low value=3, High value=4, Prozone error (CAN'T MEAS)=5, Calibration error by magnetic card L1=6, Calibration error of magnetic card H1=7
037	037	● 37℃: " 0 " ● 30℃: " 2 " ● 25℃: " 1 " ● Items other than enzyme: " 0 "
040	049	Name of Multi Reagent Strip (For Single Reagent Strip, blank (20H) is used)
051	055	Item name
057	061	Measurement value. When the data error=1, lower value, the data error=2,5,6,7, upper values are applied
063	068	Unit symbol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