Automatic Glycohemoglobin Analyzer

ADAMS™ A1C

HA-8180T | Operating Manual

arkray,inc.

1 Premise

Thank you for purchasing our automatic glycohemoglobin analyzer, ADAMS™ A1C HA-8180T.

This operating manual contains important information on the functions of the ADAMS A1C HA-8180T.
This operating manual is issued by ARKRAY, Inc.
Read carefully prior to starting up the unit.
It is recommended to retain this operating manual for future use.

■Intended Purpose

The ADAMS A1c HA-8180T instrument is intended for the quantitative and automated measurement of HbA1c and HbA2 in whole blood and hemolysis samples. HbA1c measurements are used for screening, monitoring and as an aid to diagnosis of diabetes and prediabetes, for individuals diagnosed with or at risk of developing diabetes or prediabetes. HbA2 measurements are used for screening of β thalassemia, for individuals suspected of having this condition. For *in vitro* diagnostic use and professional use only.

This product conforms to the EMC Standard IEC61326-2-6:2012.
Class of emission: CISPR 11 Class A
This instrument is an IVD medical instrument.

CE

This product conforms to Regulation (EU) 2017/746.

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 operating 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.

2 Introduction

Read this operating manual thoroughly before using the instrument. This operating manual gives an overview of the instrument and the proper procedures for operation and maintenance.
Follow the instructions in this operating manual in order not to defeat the purpose of the protective features of the instrument.

If you have had or could have had any serious incident related to the device, please report it directly to the manufacturer or through the authorised representative and to your local regulatory authority.

If you want to obtain information included in this operating manual in a language other than English, contact your distributor.

- TAKE THE UTMOST CARE WHEN HANDLING BLOOD. This instrument uses blood as sample and as an ingredient of control solutions. Blood may be contaminated by pathogenic microbes that can cause infectious diseases. Improper handling of blood may cause infection to the user or other individuals by pathogenic microbes.
- This instrument is to be operated by qualified persons only. A qualified person is one having adequate knowledge of clinical testing and the disposal of infectious waste. Thoroughly read this operating manual before use.
- Never touch the piercing nozzle, tubes, liquid waste bottle or other parts where sample may adhere with unprotected hands. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples, liquid waste, parts and instrument in accordance with local regulations for biohazardous waste.

- This product contains natural rubber latex which may cause allergic reactions. If you feel unwell, immediately stop using the product and consult a doctor.
- If eluent or hemolysis washing solution spills onto the countertop or floor, immediately and carefully wipe it up with a cloth, then rinse the collected liquid from the cloth with plenty of water. If the spilled liquid dries and crystallizes, wipe up the spill using a cloth moistened with water. Then, rinse the collected liquid from the cloth with plenty of water. Never contact crystals with reducing agents such as alcohol or ascorbic acid.
- Dilute any remaining reagent in eluent packs and hemolysis washing solution bottles with plenty of water, before discarding.
- Each measurement result includes a patient ID so that the result can be associated with its personal health information. Measurement results should be viewed, printed, output or deleted by authorized persons only and always handled with extreme care by every operator. The authorized persons mentioned above do not require any special IT skills or training, but should read the operating manual before first use for a proper understanding.

3 Symbols

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

■For your safety

Follow the instructions given here to prevent exposure to pathogenic microbes.

Follow the instructions given here to prevent injury and property damage.

■For optimal performance

IMPORTANT:
Follow the instructions given here to obtain accurate measurement results.

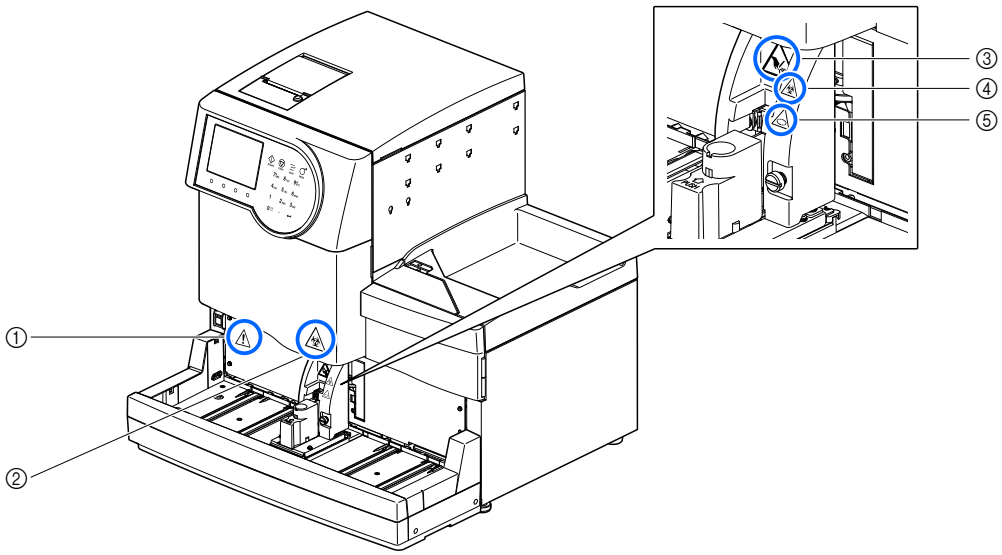
NOTE:
Information useful for preventing damage to the instrument or parts, and other important information you should keep in mind.

REFERENCE:
Additional explanations that help you make the best use of the instrument and information on related functions.

4 Caution Labels

This instrument has several caution labels on the areas that have potential dangers. Please learn the potential dangers shown by each label and observe the precautions described below.

■Front



① Standby switch

This switch turns the power on/off. A separate main power switch is located on the instrument's rear panel. If the instrument is not to be used for extended periods of time, turn off the power by pressing the standby switch, then the main power switch.

② Front cover

The parts inside the front cover can be contaminated by samples. **Do not** touch these parts with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microbes while cleaning these parts.

③ Sample aspirating unit

The piercing nozzle is located near the label. When measurement operations start, the tip of the nozzle descends to aspirate samples. Keep your hands off to avoid injury. **Do not** try to touch the sample racks that are moving on the sampler while measurement is in progress. Injury may result if the moving sample rack hits your hands.

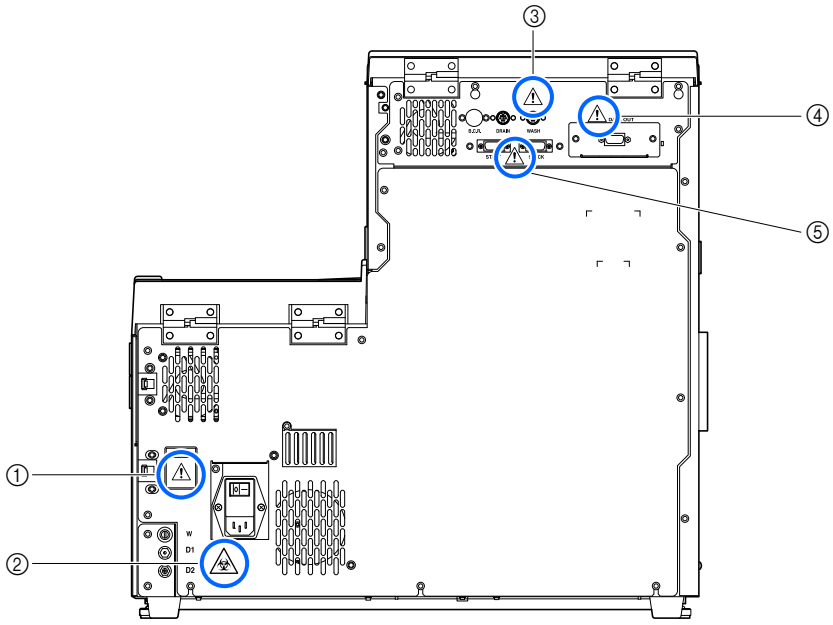
④ STAT port cover

The STAT port cover can be contaminated by samples. **Do not** touch the STAT port cover with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microbes when handling this cover.

⑤ Sample tube spinning unit

Rollers are located near the label. When measurement operations start, the rollers rotate the sample tube to stir the sample. Be sure to attach the STAT port cover to the proper position before starting measurement. Keep your hands off during measurement to avoid injury.

■Rear



① Power input terminal

The power cord (supplied) is plugged in here. Use of other cords may cause electric shock or fire. The fuse holders are also located here. Prepare fuses of the specified capacity for replacement.

② Drain joints (D1: For the optical unit, D2: For liquid waste)

Liquid waste is drained through these joints into the bottle for liquid waste. **Do not** touch the tubes and liquid waste with unprotected hands since the drainage contains samples. Wear protective gloves to prevent exposure to pathogenic microbes when handling the drain tubes and bottle.

③ WASH and DRAIN terminals

Connect the fluid level detection sensor cord for the hemolysis washing solution bottle to the WASH terminal, and that for the optional liquid waste bottle to the DRAIN terminal. The instrument does not function properly if the wrong cords are connected to these terminals.

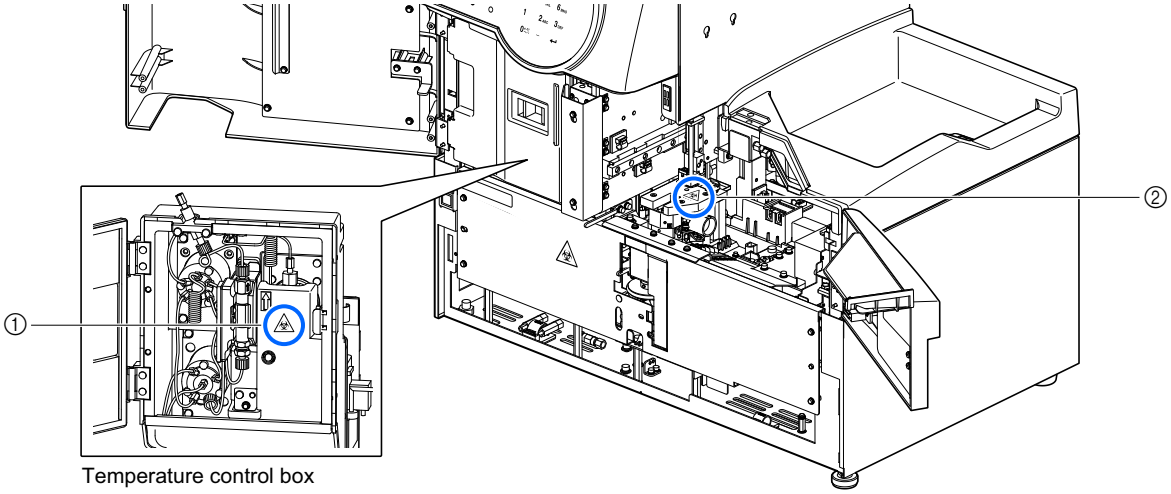
④ DATA OUT terminal

Connect the specified RS-232C cross cable (double-shielded cable) to this terminal. The instrument does not function properly if the wrong cable is connected to this terminal.

⑤ START and STOCK terminals

Connect the optional side sampler to these terminals as instructed in the manual that comes with the product. The instrument does not function properly if the wrong cables are connected to these terminals.

■Front (inside)



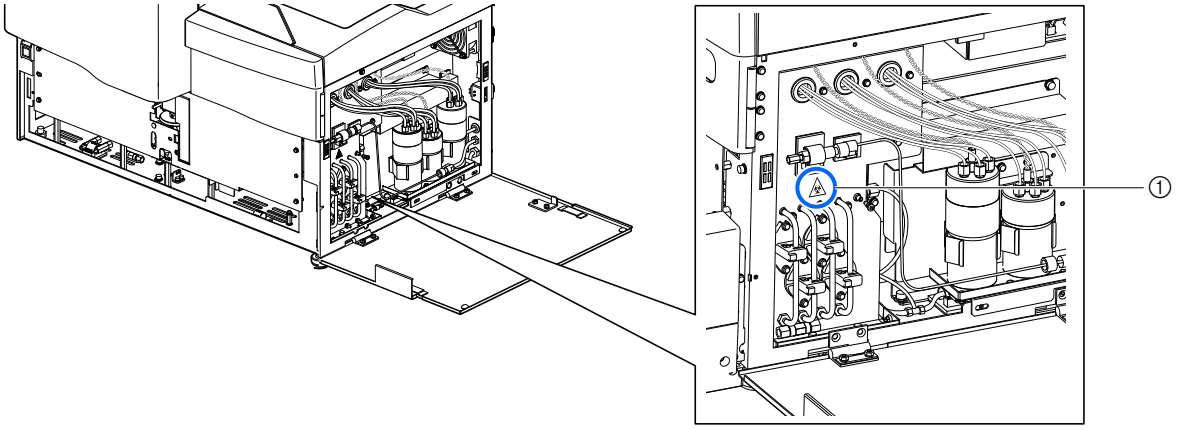
① Temperature control box

Do not touch the tubes and connections with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microbes while cleaning or replacing these parts.

② Dilution container and washing container

Do not touch the dilution container and washing container with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microbes while cleaning these parts.

■Inside of the side cover



① Drain pinch valves

Do not touch the drain pinch valves with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microbes while cleaning or replacing these parts.

5 Table of Contents

Chapter 1 Before Use

This chapter describes information you should know before using the instrument.

1.1 Overview

1.1.1 Main Functions

The HA-8180T measures stable HbA1c (S-A1c or HbA1c), HbA2 and HbF, and provides information useful for diagnosing and monitoring diabetes, and for screening β-thalassemia. It produces more accurate measurement results for HbA1c because it elutes and removes labile HbA1c (L-A1c), carbamylated Hb and acetylated Hb, and elutes variant hemoglobins, HbS, HbC, HbE and HbD.

■Sample measurement

The instrument can measure hemolysis samples that have been diluted with CONTROL DILUTION SET 80 as well as whole blood samples.

Sample measurements can be performed in the following two ways:

- Normal measurement

Normal measurement continuously measures multiple samples using sample racks. One sample rack can hold up to 10 samples. Load the sample racks with samples onto the sampler and press ◇. The instrument then automatically moves the racks and measures the samples sequentially.

> **For anemia sample:** A special rack is supplied to measure whole blood samples from patients previously diagnosed as anemic. Samples on the anemia rack are measured at a lower dilution ratio than samples on the normal racks. This avoids abnormal low value errors to occur.

- STAT measurement

You can measure a single sample by setting it in the STAT port. This allows you to interrupt normal measurement in an emergency to perform a measurement.

■Control measurements for HbA1c, HbA2 and HbF

Control measurements should be carried out at regular intervals to check the accuracy of measurement results. Use commercially available controls that are specified by your distributor.

■Calibrations for HbA1c, HbA2 and HbF

Periodically calibrating the instrument can eliminate measurement errors caused by changes in environmental conditions. Calibration can be performed in the following two ways:

- Automatic calibration

Calibration coefficients (operation coefficients) for correcting measurement results are automatically calculated by measuring two standard solutions.

- Calibration coefficient setting

You can enter calibration coefficients using the numeric buttons on the operator panel.

1.1.2 Features

- Effective for diabetes monitoring and β-thalassemia screening

The HA-8180T simultaneously measures the diabetes-indicator, glycated hemoglobin, and the β-thalassemia-indicators, HbA2 and HbF.

- 210 seconds per sample measurement

The processing speed of the HA-8180T is 17% faster than that of the earlier model.

- Highly accurate measurement results

Measurements are performed using high performance liquid chromatography (HPLC), a technique that provides accurate data on HbA1c, HbA2 and HbF. In addition, variant hemoglobins, HbS, HbC, HbE and HbD are eluted to obtain more accurate measurement results. A column is used to remove labile HbA1c. Stable HbA1c values, HbA2 values, HbF values and chromatograms can be obtained.

- Managing reagent information

Just by entering 10-digit reagent codes, you can store the expiration dates and lot numbers of the reagents (eluents, hemolysis washing solution and calibrator) in the instrument. An error message appears on the screen if you try to enter an incorrect or invalid code. Reagent information can be added to measurement result reports to show that the proper reagents were used for measurements.

- Sample tube stirring

Samples are automatically stirred before measurement, so stable measurement results can be obtained without variations due to blood sedimentation.

- Easy to use

Priming before measurements is automated, so no action is needed from the time when power is activated to the time when measurements start. A large color LCD makes measurement conditions and menu settings easy to read and identify, which makes operation easy. Measurement results, instrument status and operating procedures are displayed, while the remaining volume of reagent is shown on electronic graphs. Chromatograms can also be viewed along with measurement results.

- Fluid level detection sensor to prevent reagent shortages during measurement

Reagent levels are measured and, if low levels are detected, messages are displayed to notify the user. Measurement continues until a reagent is used up, at which point measurement automatically stops.

- Timer-triggered automatic starting/shutdown

Startup times can be set for each day of the week. Sleep mode automatically activates if the standby screen appears for a user-set amount of time.

- Easy maintenance

Daily maintenance can usually be performed without tools as parts can be easily replaced and tightened by hand. In addition, the prefilter is incorporated into the column, removing the need for prefilter replacement (as was necessary with earlier models).

- Wide array of options available

ARKRAY makes available a wide array of options including the hand-held barcode reader, Ethernet board and the side sampler.

● Continuous measurements for up to 100 samples (when set to loop transportation)

The instrument can measure a maximum of 50 consecutive samples if sample rack transportation is set to “one-way transportation”, and 100 samples if it is set to “loop transportation”.

* Sample rack transportation is set to “one-way transportation” at the time of shipment. If you prefer “loop transportation”, contact your distributor.

● On-the-spot STAT measurement

A port specifically for STAT measurements is provided. So normal measurements can be interrupted to measure one specific sample. STAT measurement can also be performed while the standby screen is displayed.

● Two-way online communications

An ordering system using barcode IDs can be built by connecting to a host terminal.

1.1.3 Specifications

Product	ADAMS A1c HA-8180T
Configuration	Main body, sampler (with sample tube spinning unit) and accessories
Measurement objects	Whole blood or hemolysis sample
Column	COLUMN UNIT 80T
Reagents	ELUENT 80A, ELUENT 80B, ELUENT 80CT and HEMOLYSIS WASHING SOLUTION 80H
Measurement items	HbA1c (stable HbA1c, S-A1c), HbA2 and HbF (HbS, HbC, HbE and HbD can be detected.)
Measurement ranges *1	HbA1c: 3 - 20%, 9 - 195 mmol/mol HbA2: 2 - 10% HbF: 0 - 100%
Guaranteed measurement ranges *2	HbA1c: 4.2 - 12.9%, 22 - 117 mmol/mol HbA2: 2.4 - 6.3% HbF: 0.1 - 14.3%
Measurement principle	Reversed-phase cation exchange chromatography
Measurement wavelength	420 nm/500 nm (Dual-wavelength colorimetry)
Sample supply	Sampler
Resolution	0.1% Ratio, 1 mmol/mol
Processing speed	210 seconds/test
Sample consumption	Approximately 14 µL (Whole blood)
Required sample volume	Sample tube: Minimum 10 mm away from the bottom Sample cup: 400 µL or more
Sample container	Sample tube: (12.3/15 mm diameter) × (75 to 100 mm length) Sample cup: 500 µL
Compatible rack type	ARKRAY racks
Number of measurement samples	One-way transportation (factory-set): Maximum 50 samples Loop transportation: Maximum 100 samples
Column temperature	Approximately 39°C
Warm-up time	Maximum 30 minutes
Display	Large color LCD with backlight
Printer	For use with 58-mm width thermal printer paper
Memory capacity	500 measurement results (including calibration results)
External output	Serial 1 port (Can be optionally used as an Ethernet port.)
Communication system	RS-232C compliant (Switchable between one-way and two-way communications.)
Transmission speed	RS-232C: Selectable from 300, 600, 1200, 2400, 4800, 9600 and 19200 bps Ethernet: 10BASE-T
Operating environment	Temperature: 15 - 30°C; Humidity: 20 - 80% RH (No condensation)
Measurement environment	Temperature: 15 - 30°C; Humidity: 20 - 80% RH (No condensation)
Storage environment	Temperature: 1 - 30°C; Humidity: 20 - 80% RH (No condensation)
Environment during transport	Temperature: 1 - 60°C; Humidity: 20 - 80% RH (No condensation) (The humidity should not exceed the absolute humidity; 40°C/85% RH.)
Dimensions	530 (W) × 530 (D) × 530 (H) mm (Not including the hemolysis washing solution bottle)
Weight	Main body: Approximately 39 kg, Sampler: Approximately 4 kg
Power requirements	100 - 240 V AC ± 10%, 50/60 Hz
Power input	Maximum 300 VA
Sound pressure level	Less than 85 dB

Location of use	For indoor use only
Altitude	Up to 2000 m
Pollution degree	2
Over voltage category	II
Expected life	5 years (According to company data) *3

*1: Error-free measurement ranges

*2: Guaranteed ranges for obtaining results equivalent to those from HA-8160 TP mode measurement

*3: The manufacturing date is included in the serial number as shown below.

- 2nd and 3rd digits of the serial number: The last 2 digits of the manufacturing year
- 4th and 5th digits of the serial number: The manufacturing month

1.1.4 Measurement Principle

The HA-8180T measures HbA1c, HbA2 and HbF in blood using reversed-phase cation exchange chromatography. Blood sample diluted with the hemolysis washing solution is sent to the column, which fractionates the sample into several hemoglobin components based on high performance liquid chromatography (HPLC). Each component eluted from the column is measured by the dual-wavelength colorimeter, and the result is processed by a micro computer to obtain peak identification and content.

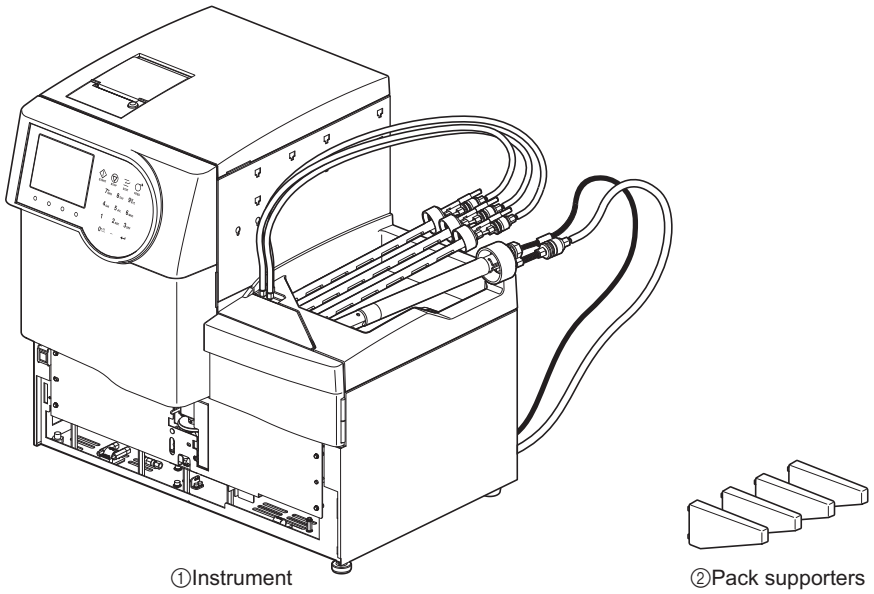
1.2 Unpacking

The system comes in three boxes. Unpack the boxes and make sure you have all items listed in this section. If anything is missing or damaged, contact your distributor.

NOTE:

The following items are not included with the instrument:
ELUENT 80A, ELUENT 80B, ELUENT 80CV, HEMOLYSIS WASHING SOLUTION 80H, COLUMN UNIT 80, CONTROL DILUTION SET 80, CALIBRATOR 80, extendSURE Haemoglobin F and A2 Calibrators, controls for HbA1c measurement, dummy sample, sample cup, sample tube, sample, diluent, sample container, barcode label, protective gloves, tissue paper, piercing nozzle (for replacing), purified water, cotton swab, filter and O-ring for elect., washing solution for tubes, neutral detergent, gauze, beaker, distilled water, plastic bag, 70% isopropanol, bottle for liquid waste, scissors, RS-232C cross cable (double-shield cable) and flat-head screwdriver
These items are underlined in the “Prepare:” sections in “1.4. Installation” and later.

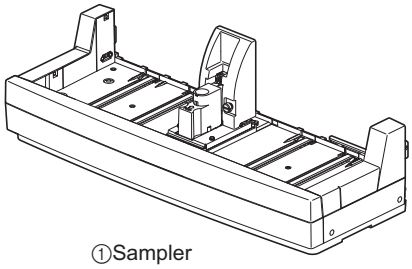
1.2.1 Instrument



①Instrument ②Pack supporters

No.	Item	Description	Qty.
①	Instrument	ADAMS A1C HA-8180T	1
②	Pack supporters	For installation, 4 per pack	1

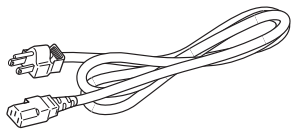
1.2.2 Sampler



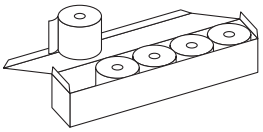
①Sampler

No.	Item	Description	Qty.
①	Sampler	With sample tube spinning unit	1

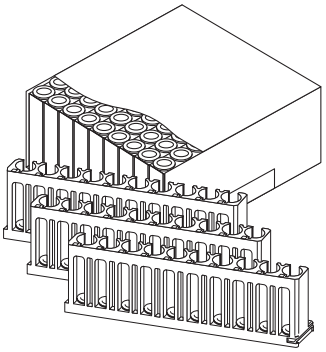
1.2.3 Accessories



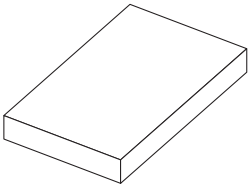
①Power cord



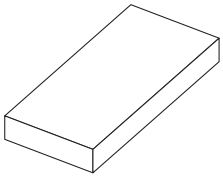
②Printer paper



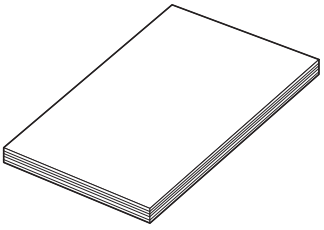
③Rack set



④Accessory case



⑤Tool kit

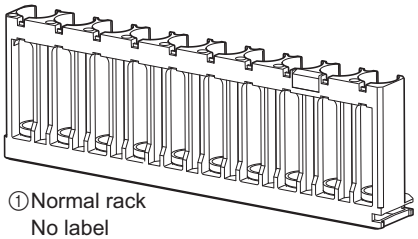


⑥Operating Manual

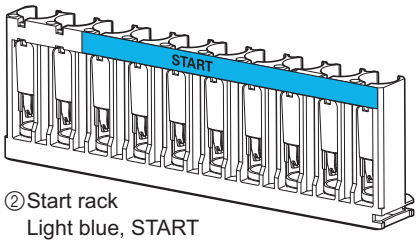
No.	Item	Description	Qty.
①	Power cord	Rating: 250V 10A	1
②	Printer paper	58 mm (W) × 25 m (L), 5 rolls per box	1
③	Rack set	See “1.2.4. Rack Set” on page 1-9.	1
④	Accessory case	See “1.2.5. Accessory Case” on page 1-10.	1
⑤	Tool kit	See “1.2.6. Tool Kit” on page 1-11.	1
⑥	Operating Manual		1

1.2.4 Rack Set

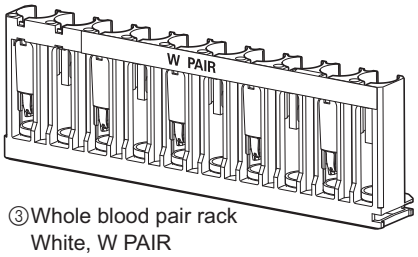
Sample rack types can be identified by the label color and name on the front of the rack. For more information, see “2.1.3. Sample Racks” on page 2-4.



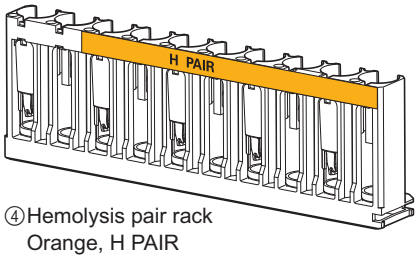
①Normal rack
No label



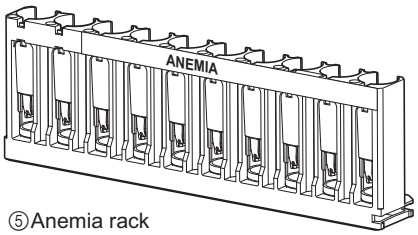
②Start rack
Light blue, START



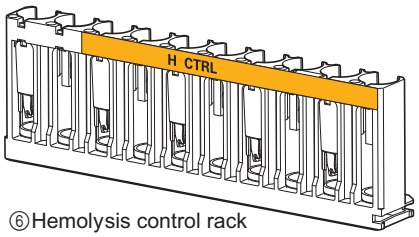
③Whole blood pair rack
White, W PAIR



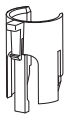
④Hemolysis pair rack
Orange, H PAIR



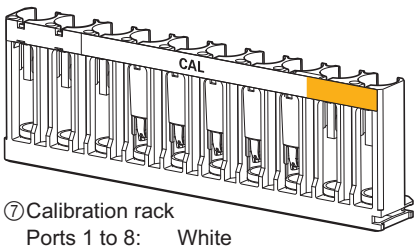
⑤Anemia rack
White, ANEMIA



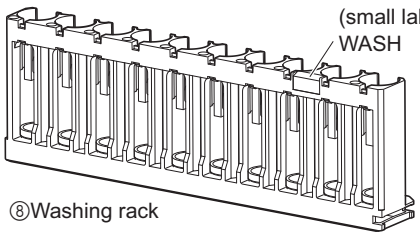
⑥Hemolysis control rack
Orange, H CTRL



⑨Conventional adapter



⑦Calibration rack
Ports 1 to 8: White
Ports 9 and 10: Orange
CAL

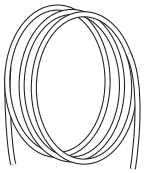


⑧Washing rack

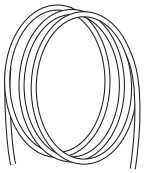
⑩Spinning unit adapter

No.	Rack name	Description	Qty.
①	Normal racks	For normal measurement of whole blood samples, 9 per set	1
②	Start rack	For normal measurement of whole blood samples	1
③	Whole blood pair rack	For normal measurement	1
④	Hemolysis pair rack	For normal measurement	1
⑤	Anemia rack	For normal measurement of anemia samples (whole blood)	1
⑥	Hemolysis control rack	For control measurement	1
⑦	Calibration racks	For calibration	2
⑧	Washing rack	For washing tubes	1
⑨	Conventional adapters	For sample cups, gray, 10 per pack	1
⑩	Spinning unit adapters	For sample tubes (12.3 mm diameter) set in normal racks, transparent, 10 per pack	10

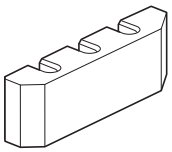
1.2.5 Accessory Case



①Optical unit drain tube



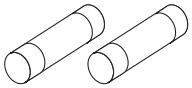
②Liquid waste drain tube



③Tube guide

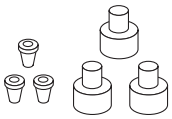
④Conventional adapter

⑤Protective tube

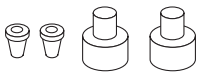


⑥Fuses

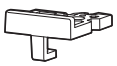
⑦O-rings



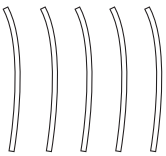
⑧Joints 1x2



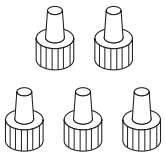
⑨Joints 2x3



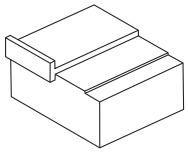
⑩Cover plate



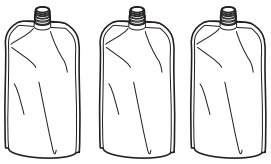
⑪Spare tubes



⑫Push screws (circle type)



⑬Nozzle adjusting block

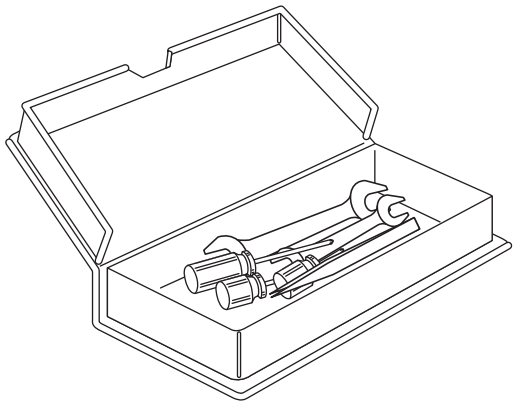


⑭Aluminium packs

No.	Item	Description	Qty.
①	Optical unit drain tube	Silicone tube for installation, 2 mm (i.d.) × 4 mm (o.d.), 3 m	1
②	Liquid waste drain tube	Silicone tube for installation, 3 mm (i.d.) × 6 mm (o.d.), 3 m	1
③	Tube guide	For installing eluent packs	1
④	Conventional adapter	For STAT port, ϕ13, gray	1
⑤	Protective tube	For piercing nozzle maintenance	1
⑥	Fuses	2 per pack	1
⑦	O-rings	For nozzle washing block, 5 per pack	1

No.	Item	Description	Qty.
⑧	Joints 1×2	For eluent nozzles, M6 flat seal fitting ϕ2, push screws and ferrules, 3 per pack	1
⑨	Joints 2×3	For hemolysis washing solution nozzle, M6 flat seal fitting ϕ3, push screws and ferrules, 2 per pack	1
⑩	Cover plate	O-ring presser plate for piercing nozzle	1
⑪	Spare tubes (for valves)	2 mm (i.d.) × 4 mm (o.d.), 10 cm, 5 per pack	1
⑫	Push screws (circle type)	For column IN/OUT tubes, 5 per pack	1
⑬	Nozzle adjusting block	For service person use	1
⑭	Aluminium packs	For maintenance when the instrument is not to be used for extended periods of time	3

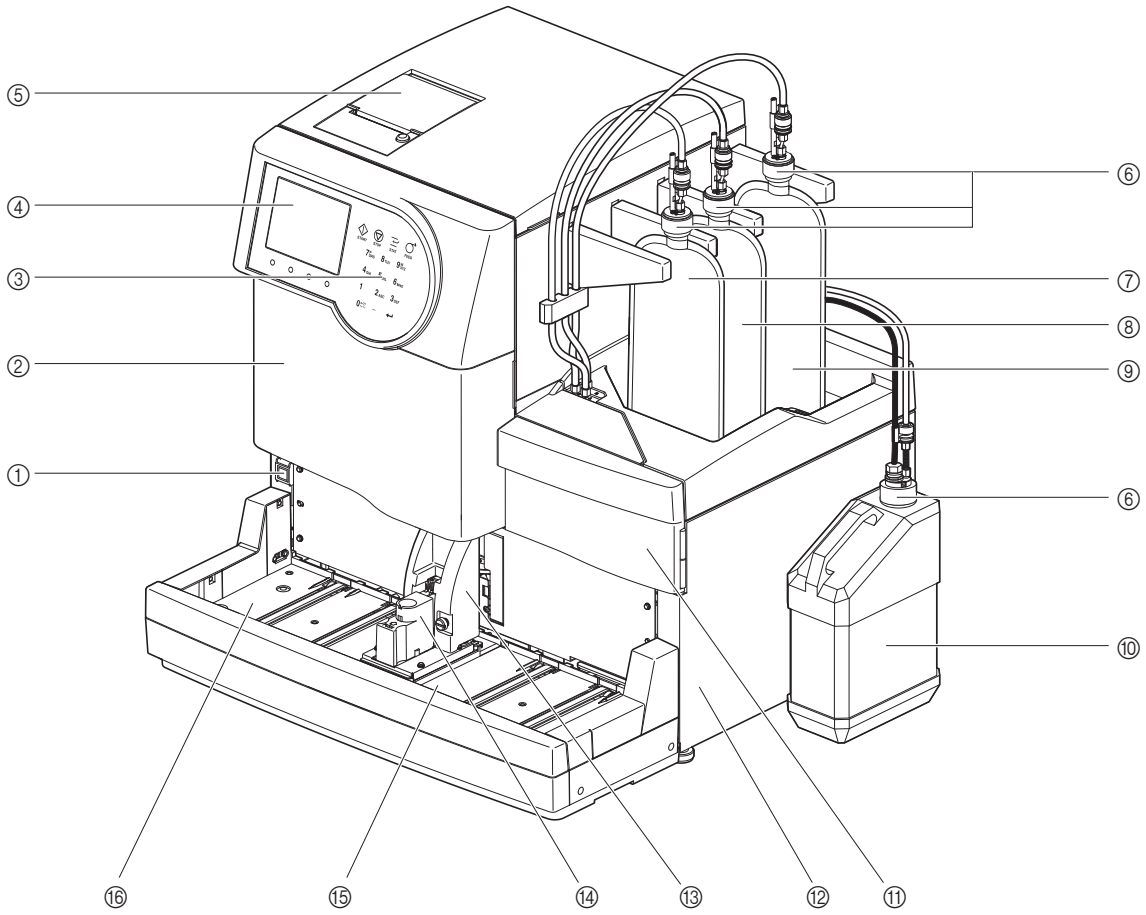
1.2.6 Tool Kit



Item	Description	Qty.
Double open end wrench	6-8	1
Double open end wrench	10-13	1
Phillips screwdriver	No.2, insulated plastic	1
Stubby screwdriver	No.6200-1, insulated plastic	1
Stubby screwdriver	No.1200-2, insulated plastic	1
Tweezers AA	L125	1

1.3 Part Names and Functions

1.3.1 Front and Right Side Views

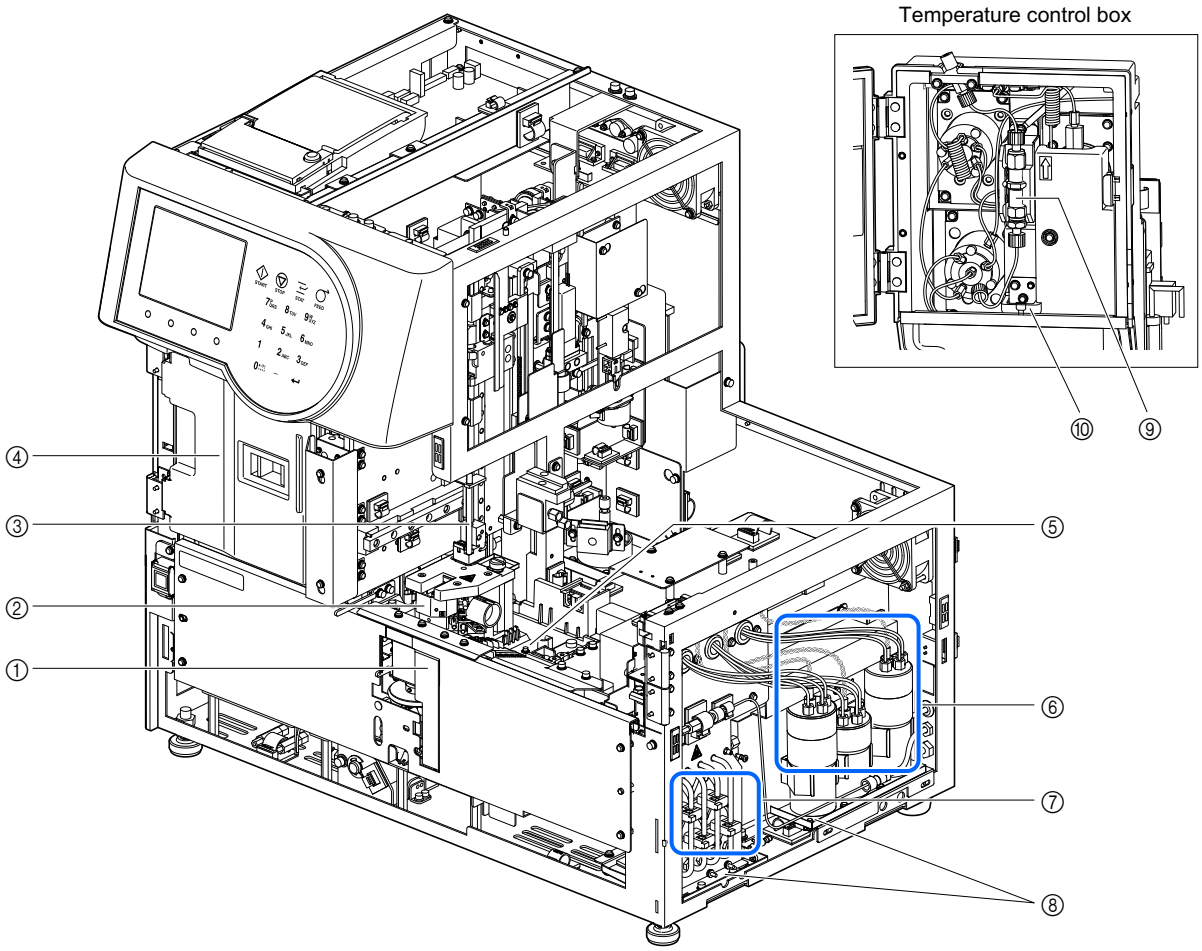


Drive units are housed inside the instrument. Power is shut off automatically if the front cover, maintenance cover or side cover is opened during instrument operation. **Do not** open these covers unless necessary.

No.	Component	Description
①	Standby switch	Used to turn the instrument on/off for daily use. The switch is fitted with a cover to prevent accidental operation. Immediately after power turns on: Orange While power is on: Green In sleep mode: Orange
②	Front cover	Protects the measurement unit including the temperature control box. Measurements cannot be made if this cover is open.
③	Operator panel	See “1.7. Basic Operations” on page 1-41.
④	Display	Status information, measurement results and warning/error/trouble messages are displayed here.
⑤	Printer	Thermal printer. Prints measurement results and other information.
⑥	Bottle caps with nozzle (× 4)	Attach these caps to eluent packs and hemolysis washing solution bottle. For use with eluent A pack (bottle cap A): Blue For use with eluent B pack (bottle cap B): Red For use with eluent CT pack (bottle cap CT): Gray For use with hemolysis washing solution bottle (bottle cap H): Colorless, with fluid level detection sensor

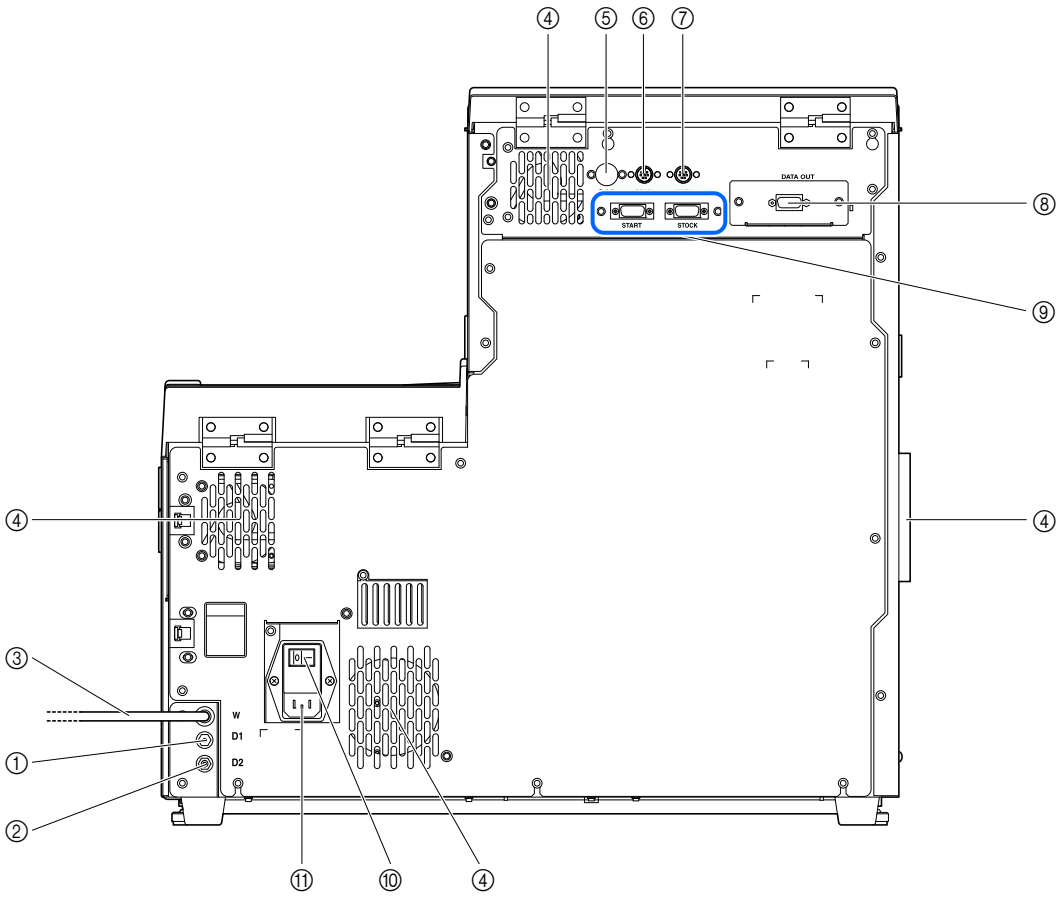
No.	Component	Description
⑦	Eluent A pack	Contains ELUENT 80A.
⑧	Eluent B pack	Contains ELUENT 80B.
⑨	Eluent CT pack	Contains ELUENT 80CT.
⑩	Hemolysis washing solution bottle	Contains HEMOLYSIS WASHING SOLUTION 80H.
⑪	Maintenance cover	Protects the dilution container unit. Measurements cannot be made if this cover is open.
⑫	Side cover	Protects the chamber unit and drain unit. Measurements cannot be made if this cover is open.
⑬	STAT port cover	Prevents the user from touching the sample tube while it is spinning and the piercing nozzle when it is aspirating sample from the STAT port. It also protects the user from splattering sample if the sample tube is not capped.
⑭	STAT port	Sample for STAT measurement is set here.
⑮	Rack loading side	Sample racks with sample are loaded here.
⑯	Rack unloading side	Sample racks exit here after sample aspiration. If sample rack transportation has been set to “loop transportation”, you can load 5 more sample racks to be measured here.

■Inside view



No.	Component	Description
①	Internal barcode reader	The barcode reader unit is connected here.
②	Dilution container unit (dilution and washing containers)	Dilutes sample in the dilution container and washes the piercing nozzle in the washing container.
③	Piercing nozzle	Cap-piercing nozzle for aspirating samples
④	Temperature control box	Keeps the column at a proper temperature.
⑤	Leak tray (below dilution container)	Collects leaking liquid from the dilution container for leak detection. Measurements cannot be performed if a leak is detected.
⑥	Chamber	Detects the levels of Eluents 80A, 80B and 80CT to show a message when the levels are low. Removes large air bubbles.
⑦	Drain pinch valve	Controls flow of liquid waste.
⑧	Leak tray (for drain unit)	Collects leaking liquid from the drain pinch valve tubes and/or the chambers for leak detection. Measurements cannot be performed if a leak is detected.
⑨	Column	Fractionates sample into multiple hemoglobin components.
⑩	Leak tray (below column)	Collects leaking liquid from the high pressure tube for leak detection. Measurements cannot be performed if a leak is detected.

1.3.2 Rear View



No.	Component	Description
①	D1 (drain joint)	Connects to the optical unit drain tube.
②	D2 (drain joint)	Connects to the liquid waste drain tube.
③	Hemolysis washing solution tube (W)	Carries hemolysis washing solution to the instrument.
④	Cooling fan (× 4)	Removes hot air or intakes air to protect the inside of the instrument from excessive heat.
⑤	B.C.R. terminal	Connects to the optional hand-held barcode reader.
⑥	DRAIN terminal	Connects to the fluid level detection sensor cord for the optional liquid waste bottle.
⑦	WASH terminal	Connects to the fluid level detection sensor cord for the hemolysis washing solution bottle.
⑧	DATA OUT terminal	Connects to a communication cable for an external device. * This terminal can be replaced with an Ethernet terminal (optional Ethernet board) to connect the instrument to a LAN. For more information, contact your distributor.
⑨	START and STOCK terminals	Connects to the optional side sampler.
⑩	Main power switch	Used to turn on or off the main power supply. Keep this switch on for daily use, and turn it off before you start maintenance tasks or if the instrument is not to be used for extended periods of time.
⑪	Power input terminal	Connects to the power cord that comes with the instrument.

1.4 Installation

1.4.1 Precautions in Instrument Installation

Before installation of the instrument, read the following notes and always take proper safety precautions.

> ⚠ Install the instrument under the supervision of a service person. It is dangerous to handle the instrument with the covers open. High voltage parts are located inside. Contact with these parts may be dangerous.

- The main body weighs about 39 kg and the sampler about 4 kg. Determine a location for the instrument and assemble it in that location. **Do not** carry the main body with the sampler attached. Separate the two units before moving. For safety reasons, always transport and assemble the instrument with the help of at least one other person. Hold the bottom of the instrument with both hands when carrying it.

- During installation, be careful not to pinch your hands under the instrument.

- Install the rear of the instrument at least 20 cm away from the wall. Inadequate clearance between the instrument and wall may cause overheating of the instrument or undesirable load on cable connections, thus resulting in fire or inaccurate measurement results.

- Install the right side (viewed from the front) of the instrument at least 10 cm away from the wall. Inadequate clearance between the instrument and wall may make it impossible for the users to open the side cover for maintenance tasks. Also, the users will have trouble trying to turn off the main power switch and unplug the power cord in the event of errors or trouble.

- Install the instrument where temperature and humidity can be maintained in the following ranges:
  Temperature: 15 - 30°C
  Humidity: 20 - 80%
  Installation in a measurement environment outside these ranges may result in inaccurate measurement results.

- Install the instrument on a level, vibration-free sturdy platform. Operation of the instrument in an unstable place may cause trouble with or malfunction of the instrument resulting in personal injury. **Do not** install the instrument where it may fall off or topple over.

- **Do not** install the instrument near places that store chemicals or near equipment that generates corrosive gas or electrical noise. Chemicals, corrosive gases and electrical noise may cause trouble with or malfunction of the instrument resulting in personal injury, or may otherwise cause inaccurate measurement results.

- Install the instrument in a place where condensation, direct sunlight or wind can be avoided. These factors may cause inaccurate measurement results, as well as deformation of or damage to the instrument.

- Apply the correct voltage (100 to 240 V AC ± 10%) and frequency (50/60 Hz) to the instrument. The wrong voltage and frequency may result in fire or damage to the instrument and consequently lead to personal injury.

- Use the power cord that comes with the instrument for the electrical connection to avoid electric shock and fire.

- Connect the instrument's power cord directly to a single outlet, without using an extension cord or power tap. The power supply for the instrument is a maximum of 300 VA.

- Use the specified RS-232C cross cable (double-shielded cable) to connect an external device to the 9-pin data output terminal of the instrument. Use of other cables may cause electric shock or fire. For more information, contact your distributor.

- Use the specified Ethernet cable to connect an external device to the Ethernet terminal that is provided when the optional Ethernet board is installed in the instrument. Use of other cables may cause electric shock or fire. For more information, contact your distributor.

- The START and STOCK terminals are used to connect an optional side sampler. Connecting to other devices may cause damage to the instrument. For the installation and operating precautions of the side sampler, contact your distributor. Install the side sampler under the supervision of a service person. Confirm operating precautions with the service person before use.

- **Do not** disassemble the instrument unless required for installation. **Do not** modify the instrument. Disassembly and modification of the instrument may result in exposure to pathogenic microbes or cause fire or damage to the instrument and consequently lead to personal injury.

- If you need to disassemble the instrument after use, wear protective gloves to prevent exposure to pathogenic microbes.

1.4.2 Unlocking the Instrument

To prevent the instrument from being damaged during transport, various parts are fixed in place before shipping from the factory. Remove the fixing tape and brackets before installing the instrument. Read “1.4.1. Precautions in Instrument Installation” on page 1-16 before installing the instrument.

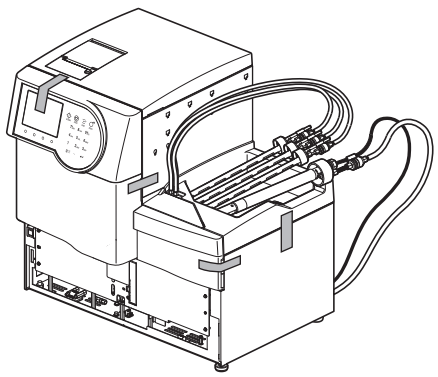
REFERENCE:

Keep the removed fixing brackets and screws in the accessory case. These parts should be reused when transporting the instrument.

Prepare: Phillips screwdriver

1 Remove the fixing tape.

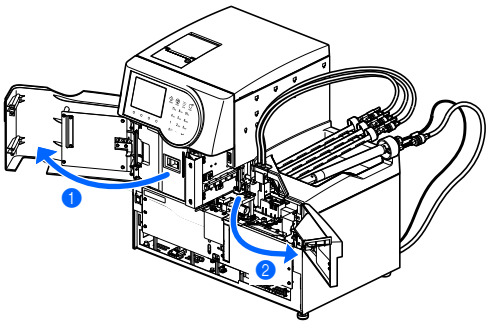
❶ Remove the fixing tape from the printer cover, front cover, maintenance cover and side cover.



2 Unlock the nozzle drive unit.

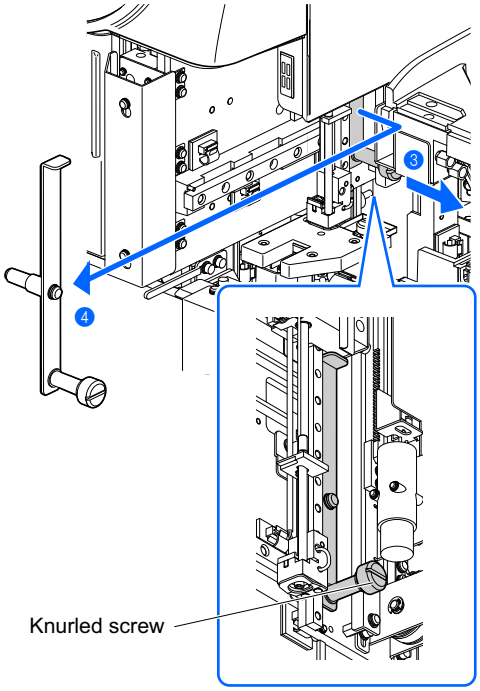
❶ Open the front cover.

❷ Open the maintenance cover.



❸ Loosen the knurled screw by hand.

❹ Slide the fixing bracket to the right as viewed from the front of the instrument and pull it to the front.

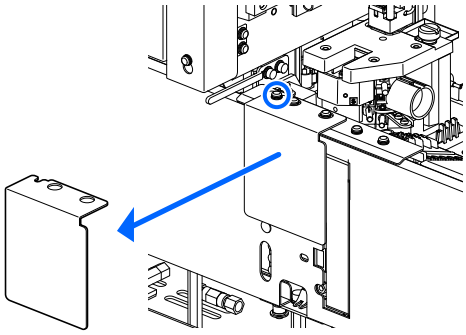


3 Unlock the sample tube spinning unit.

❶ Loosen one screw with the Phillips screwdriver and slide the fixing bracket forward to remove it.

❷ Tighten the loosened screw.

❸ Close the maintenance cover, then the front cover.

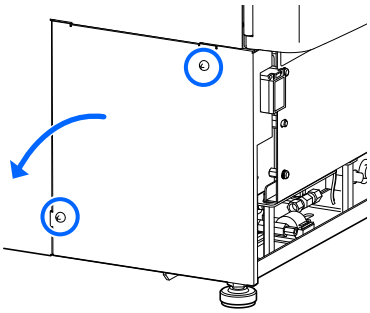


1.4.3 Attaching the Sampler

Prepare: Sampler, Phillips screwdriver, stubby screwdriver (No.6200-1) and double open end wrench (10-13)

1 Remove the wiring box cover.

❶ Loosen the two screws on the left side panel of the main body using the stubby screwdriver and remove the wiring box cover.

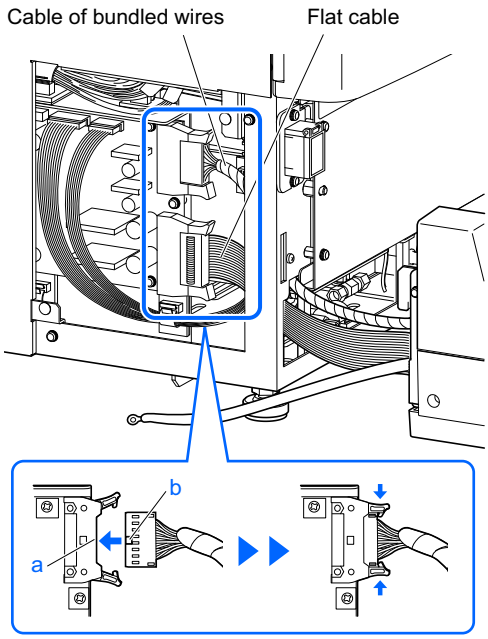


2 Connect the sampler cables to the main body.

❶ Place the sampler in front of the main body.

❷ Feed the two sampler cables through the slot on the main body.

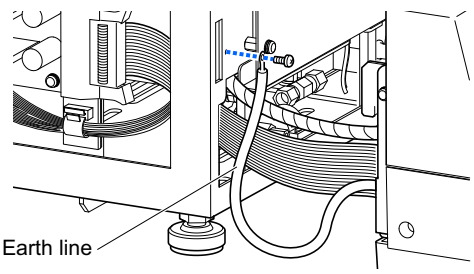
❸ Connect the two sampler connectors to the matching connectors on the main body.



- Match the projection (b) of the sampler connector to the recess (a) of the main body connector, and insert the sampler connector into the main body connector.
- Check that the top and bottom levers are closed and locked.

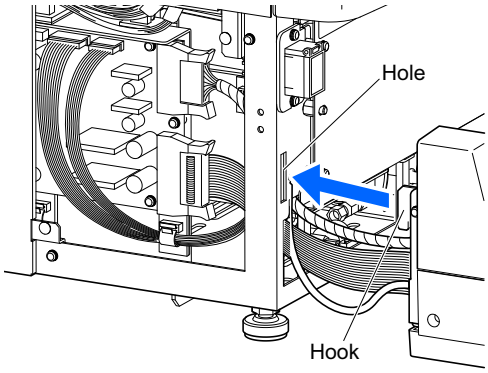
❹ Remove the earth fixing screw with the Phillips screwdriver.

❺ Fit the earth fixing screw through the eye of the sampler's earth line and attach the screw to its original position.



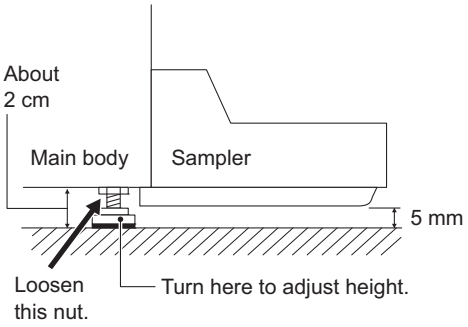
3 Attach the sampler.

❶ Fit the hooks on both sides of the sampler into the holes on the main body.
- Be careful not to pinch the cables.



❷ Loosen the locking nuts on the legs of the main body with the wrench.
- There is one locking nut on each side of the bottom panel.

❸ Turn the adjuster feet by hand until the sampler rises an even 5 mm off the countertop.
- Check that the instrument has a clearance of about 2 cm from the countertop.



❹ Tighten the locking nuts to lock the adjuster feet in place.

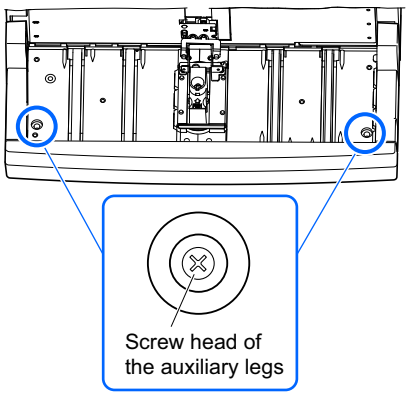
❺ Neatly arrange the cables inside the instrument.

❻ Attach the wiring box cover.

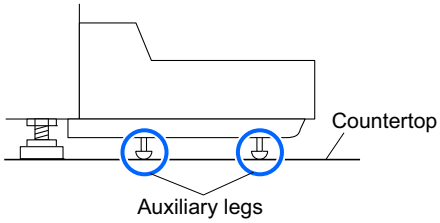
4 Adjust the auxiliary legs of the sampler.

NOTE:
- Lower the auxiliary legs of the sampler until they touch the countertop. Unless the sampler is stable, it can deform under its own weight and the piercing nozzle may become damaged.
- The sampler has one auxiliary leg on the right and left sides of the bottom panel and another one below the STAT port. Lower all three legs to the countertop. The sampler is unstable on only one or two auxiliary legs.

❶ Remove the two black rubber caps from the top of the sampler.
- You can see the screw heads of the auxiliary legs.



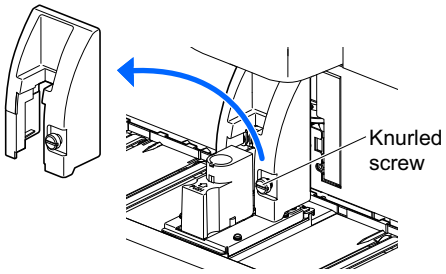
❷ Turn the auxiliary leg screws clockwise with the Phillips screwdriver until the auxiliary legs touch the countertop.



NOTE:
Excessively turning the auxiliary legs will cause the sampler to rise. Stop turning the auxiliary legs when they touch the countertop.

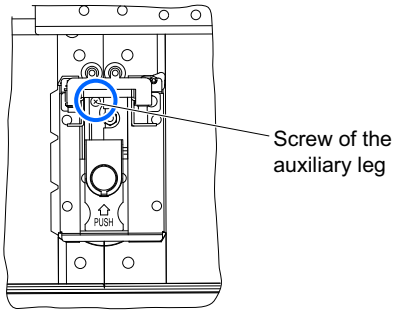
❸ Attach the rubber caps.

❹ Remove the STAT port cover.
- Loosen the knurled screw by hand, and pull the STAT port cover to the front to remove it.



❺ Turn the screw of the auxiliary leg with the Phillips screwdriver until the auxiliary leg below the STAT port touches the countertop.

❻ Attach the STAT port cover.
- Place the STAT port cover in its original position and tighten the knurled screw.



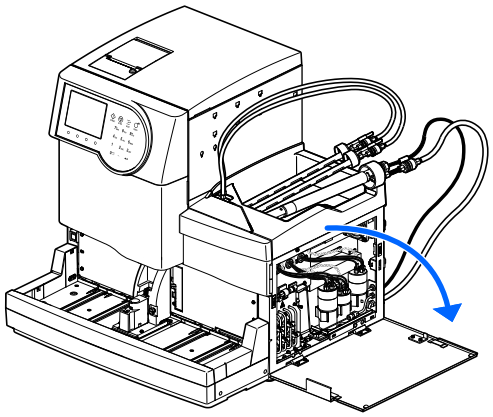
5 Ask a service person for adjustment.

Ask a service person to check that the sample tube spinning unit is in the correct position.

1.4.4 Checking the Tubes of the Drain Pinch Valves

1 Open the side cover.

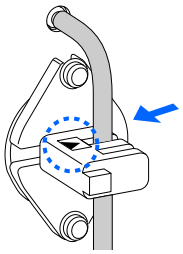
❶ Open the side cover.



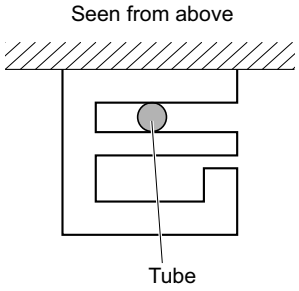
2 Check the tubes.

❶ Check that the four tubes are pinched in the rear hooks.

NOTE:
There are two hooks on each valve. Always check that the tube is pinched in the REAR hook with an arrow mark.



❷ Close the side cover.



1.4.5 Setting Up Eluents and Hemolysis Washing Solution

> ⚠ Be careful to avoid contact between skin, eyes or mouth and eluent or hemolysis washing solution. If any of these reagents make contact with eyes or mouth, immediately wash with plenty of water and consult a doctor. If it makes contact with skin, wash with plenty of water.

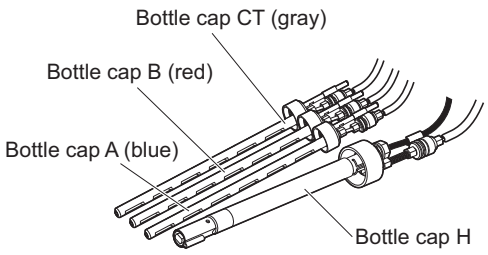
IMPORTANT:
If eluent and hemolysis washing solution are stored in a refrigerator, allow them to adjust to the same environment as the instrument for at least one hour before using them with the instrument.

Prepare: ELUENT 80A, ELUENT 80B, ELUENT 80CT, HEMOLYSIS WASHING SOLUTION 80H, tube guide and pack supporters (× 4)

1 Identify the types of bottle caps with nozzle.

NOTE:
Check the type of bottle cap with nozzle so as to correctly attach them to the eluent packs and hemolysis washing solution bottle.

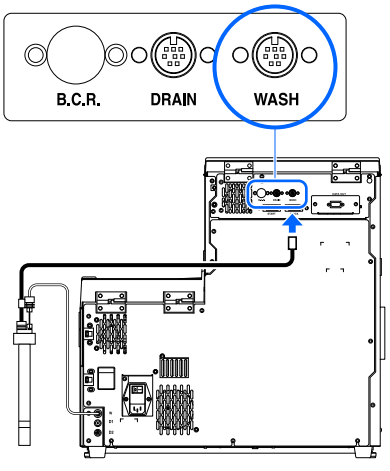
❶ Check the type of bottle cap with nozzle.



2 Connect the fluid level detection sensor cord of hemolysis washing solution bottle.

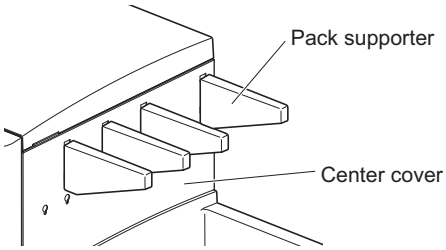
❶ Plug the fluid level detection sensor cord that extends from the bottle cap H, into the WASH terminal on the rear panel.

NOTE:
The DRAIN terminal is for the fluid level detection sensor cord of the optional liquid waste bottle. **Do not** connect the cord of hemolysis washing solution to this terminal.



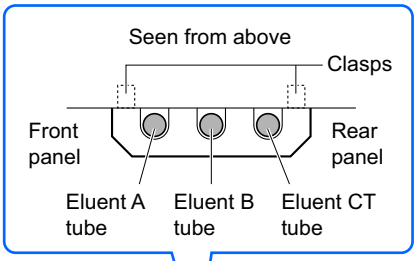
3 Attach the pack supporters.

❶ Attach the four pack supporters to the instrument.
- Hook the pack supporters on the holes in the center cover.

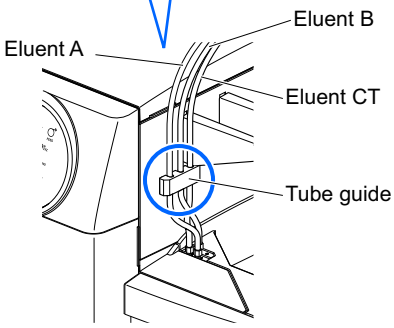


4 Fit the eluent tubes into the tube guide.

❶ Fit the tubes from the bottle caps A , B and CT into the grooves in the tube guide.



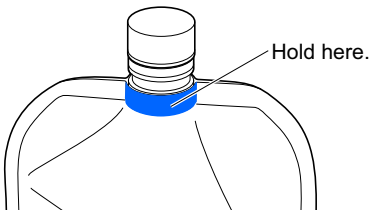
❷ Hook the two tube guide clasps on the two holes in the center cover.



5 Attach the bottle caps with nozzle to the packs and bottle.

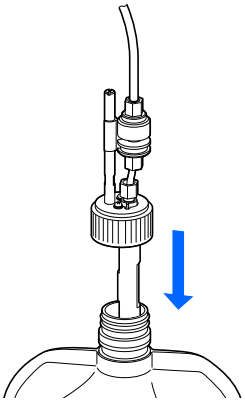
❶ Hold the eluent A pack by the hard plastic neck and remove the cap from the pack.

NOTE:
Do not hold the eluent pack by the soft aluminium bag.
Eluent may spill and damage the instrument.



REFERENCE:
Keep the cap in the accessory case. This cap should be reused when transporting the instrument, or if the instrument is not to be used for extended periods of time.

❷ Insert the nozzle of the bottle cap A into the eluent A pack. Tighten the cap securely.



NOTE:
Attach the bottle caps with nozzle to the packs and bottle somewhere other than above the instrument. Liquid may spill and damage the instrument.

❸ Install the eluent B pack.
- See steps ❶ and ❷.

❹ Install the eluent CT pack.
- See steps ❶ and ❷.

❺ Install the hemolysis washing solution bottle.
- See steps ❶ and ❷.

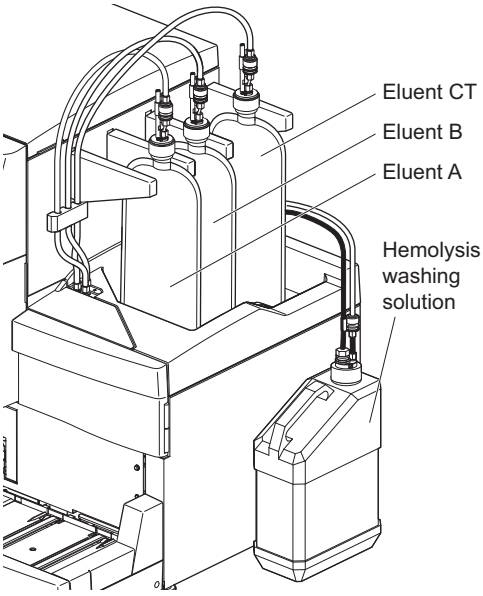
❻ Check that the caps of the eluent packs and hemolysis washing solution bottle are tightened securely.

IMPORTANT:
If the cap is loose, liquid condensation may rise due to evaporation, resulting in inaccurate measurement results.

6 Place the eluent packs and hemolysis washing solution bottle in the specified positions.

❶ Neatly arrange tubes and fluid level detection sensor cord to prevent twisting or tangling.

❷ Place the eluent packs on the bottle tray.
- Position the packs as shown on the right.



NOTE:
Set the packs each between the applicable pack supporters.

❸ Shape the eluent packs into a smooth standing position.

NOTE:
Eluent may not be fully aspirated if the pack is bent over or collapses during measurement.

❹ Place the hemolysis washing solution bottle on the right side of the instrument.

1.4.6 Connecting the Drain Tubes

Connect the instrument to your lab drainage system or bottle for liquid waste. This instrument has two drains: one for the optical unit and the other for liquid waste.

- **Do not** bend or pinch the optical unit drain tube or liquid waste drain tube. Also, keep objects off of the tubes. Tubes may disconnect from the instrument and leak liquid waste if flow is blocked.
- Set the bottle for liquid waste at the same or a lower height than the surface that the instrument sits on. If higher than the instrument base, liquid waste may not drain properly and leak.
- Contacting liquid waste with unprotected hands may result in exposure to pathogenic microbes.

REFERENCE:
When using the optional liquid waste bottle, a message appears on the display if the bottle becomes full.

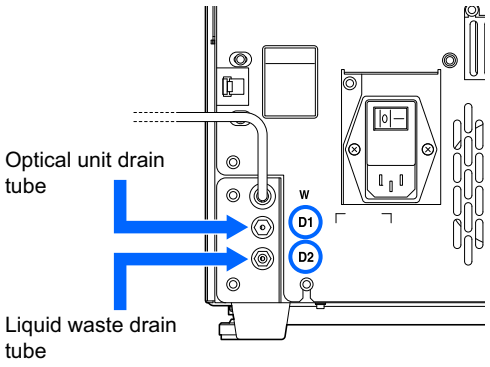
Prepare: Optical unit drain tube, liquid waste drain tube, bottle for liquid waste (when needed) and scissors

1 Connect the drain tubes to the instrument.

NOTE:
- If joint “D1” is capped, remove the cap, taking care not to break the tip of the joint.
- **Do not** force tubes into joints. The tubes may rip.

❶ Fit one end of the optical unit drain tube into joint “D1”.

❷ Fit one end of the liquid waste drain tube into joint “D2”.

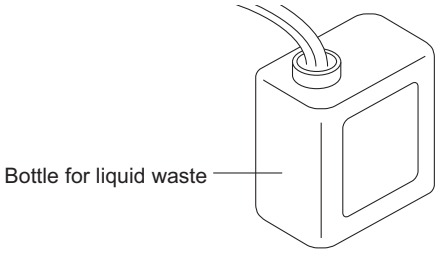


2 Connect the tubes to a liquid waste collection point.

❶ Connect the other ends of the tubes to a collection point.
- Cut tubes to a suitable length if they are too long.

●For the bottle for liquid waste (other than the optional product) or lab drainage system

Insert the tubes into the bottle for liquid waste or lab drainage system. Make sure tubes are long enough when cutting, to prevent them from being pulled from the bottle or drainage system.



●For the optional liquid waste bottle

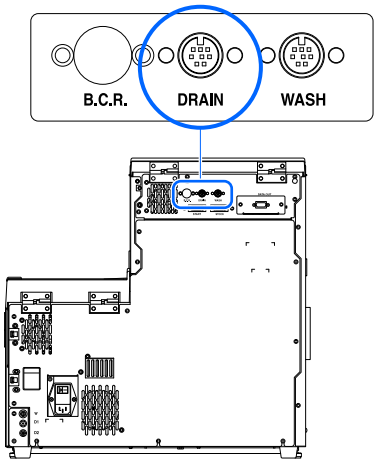
Connect the tubes to the cap of the liquid waste bottle. Make sure tubes are long enough when cutting, to prevent the bottle from falling over.

REFERENCE:

Keep the remaining tubes in the accessory case.

3 Connect the fluid level detection sensor cord.

❶ When using the optional liquid waste bottle, connect the fluid level detection sensor cord to the DRAIN terminal on the rear panel.



Go to the following sections as needed:

- “1.4.7. Connecting Peripheral Devices” on page 1-28.
- “1.4.8. Connecting the Power Cord” on page 1-29.

1.4.7 Connecting Peripheral Devices

● Connecting the hand-held barcode reader

Connect the optional hand-held barcode reader to the B.C.R terminal on the rear panel of the instrument.

● Connecting an external device

This instrument has an RS-232C data output terminal for connecting to an external device.

Use the specified cable to connect an external device to the instrument. Use of other cables may cause electric shock or fire.

REFERENCE:

To connect an Ethernet cable:
Replace the DATA OUT terminal on the rear panel with the Ethernet port (optional Ethernet board). For more information, contact your distributor.

Prepare: RS-232C cross cable (double-shielded cable)

1 Connect the cable.

❶ Connect one end of the cable to the DATA OUT terminal on the rear panel of the instrument.

❷ Connect the other end of the cable to the RS-232C connector on the external device.

2 Activate the external output.

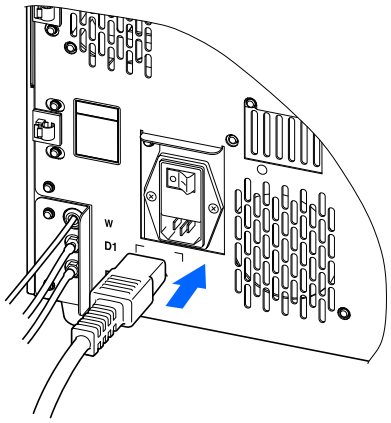
After performing steps in “1.5.1. Turning On the Power for the First Time” on page 1-30, set <External output setup> to <Use> to activate the external output. See “3.5.3. Setting Up External Output” on page 3-24.

1.4.8 Connecting the Power Cord

> Use the power cord that comes with the instrument for the electrical connection to avoid electric shock and fire.

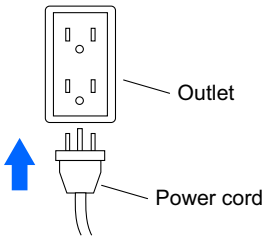
Prepare: Power cord

❶ Ensure the main power switch is in the off position.
- The main power switch should be pressed to the ○ (off) side.



❷ Plug the female connector of the power cord into the power input terminal of the instrument.

❸ Plug the male connector of the power cord into an outlet.



This completes installation of the instrument.

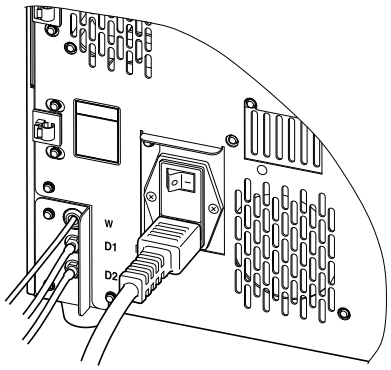
1.5 Starting Up

1.5.1 Turning On the Power for the First Time

It will take at most 30 minutes for the instrument to complete warm-up and priming.

1 Turn on the main power switch.

❶ Press the " – " side of the main power switch.

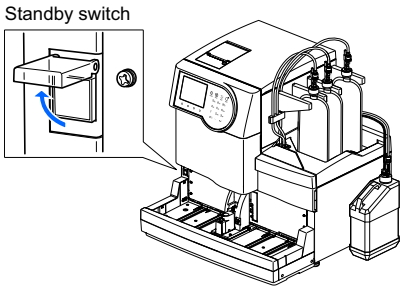


2 Turn on the standby switch.

NOTE:
Check that eluents A, B and CT, and the hemolysis washing solution are all set before turning on the power.

❶ Open the transparent cover and press the standby switch.
- The standby switch will light up orange when power is turned on.
- A few seconds later, the switch will turn green and the instrument will start warm-up.

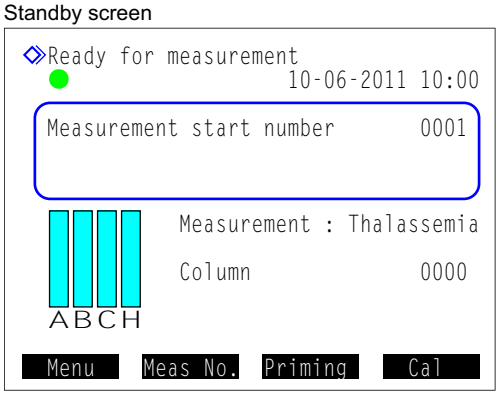
Standby switch



❷ Close the transparent cover.
- Be sure to close the cover to prevent accidental operation.
- Priming will start when the warm-up is complete.

❸ Wait for the standby screen to appear.
- The message "Ready for measurement" and a light green circle (●) will appear.

Standby screen

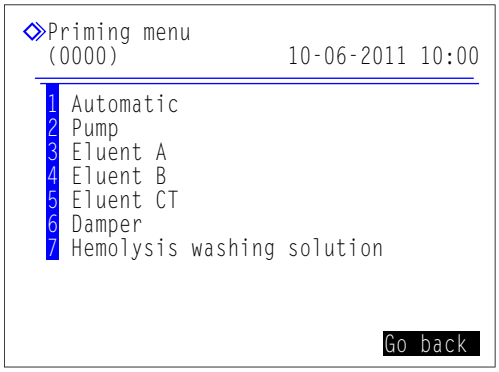


1.5.2 Installing the Column

Prepare: COLUMN UNIT 80T and tissue paper

1 Perform priming.

❶ On the standby screen, press Priming .
- The [Priming menu] screen will appear.



❷ Select <1 Automatic>.
- Priming will start for the eluent A, B and CT tubes, fluid pump and damper.
- After completion, the [Priming menu] screen will appear again.

❸ Select <6 Damper>.
- Priming will start for the fluid pump and damper.
- After completion, the [Priming menu] screen will appear again.

❹ Select <6 Damper> again.
- After completion, the [Priming menu] screen will appear again.

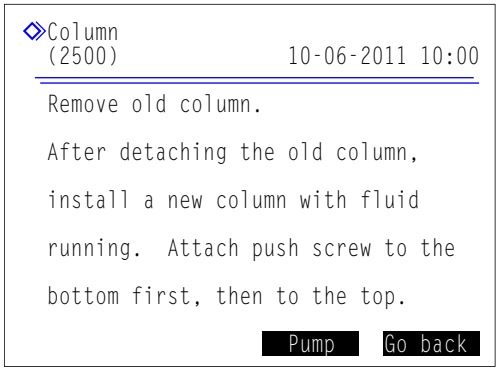
❺ Select <2 Pump>.
- Eluent A will be supplied to the column.

❻ After 3 minutes, press Stop .
- Fluid pumping will stop and the [Priming menu] screen will appear again.

❼ Press Go back to return to the standby screen.

2 Access the maintenance screen.

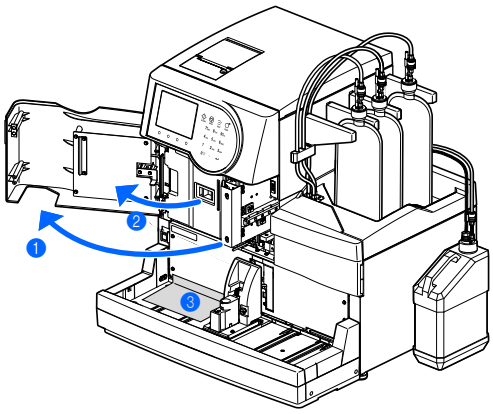
❶ On the standby screen, select Menu , <2 Reagent replacement menu> and <5 Column> in that order.
- The [Column] screen will appear.



3 Open the temperature control box cover.

❶ Open the front cover.
- The mechanical sections will power off.

REFERENCE:
The message “W:062 Front or maintenance cover is open.” appears if the front cover is opened before performing step **2**. Be sure to perform step **2** first.



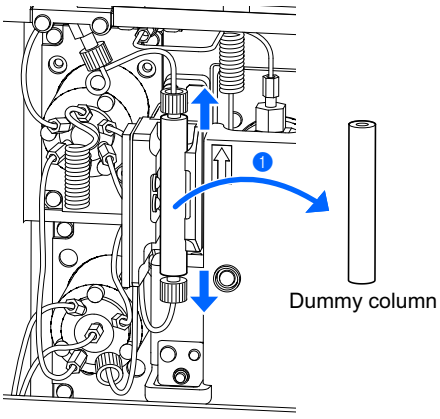
❷ Open the temperature control box cover.
- Push the handle to the left, then pull it to the front to open the box.

❸ Lay tissue paper below the temperature control box.
- The tissue paper blots up any liquids that leak while installing the column.

4 Install the column.

❶ Remove the dummy column.
- Follow the same procedure used to detach the column. See step **3** in “4.2.4. Replacing the Column” on page 4-12.

REFERENCE:
Keep the dummy column in the accessory case. This dummy column should be reused if the instrument is not to be used for extended periods of time.



❷ Install the column.
- See steps **4** to **9** in “4.2.4. Replacing the Column” on page 4-12.

1.5.3 Setting Up the Instrument

Check the following before starting measurement:

❶ Printer paper: See “4.2.3. Replacing the Printer Paper” on page 4-10.

❷ Date and time: See “3.5.1. Setting the Date and Time” on page 3-22.

❸ Reagent information: See “3.8. Reagent Information Settings” on page 3-38.

NOTE:
- Set reagent information on eluents A, B and CT, and hemolysis washing solution.
- You can skip this step and go to step ❹.

❹ Calibration: See “2.7.1. Performing Automatic Calibration” on page 2-35.

NOTE:
Perform calibration before the instrument is used for the first time after installation.

The instrument is now ready for sample measurement.

1.5.4 Turning Off the Power

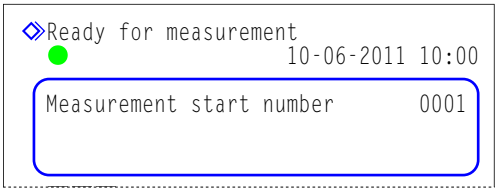
Follow the instructions described below to turn off the power to the instrument in daily use.

REFERENCE:

The instrument can be set so that it automatically enters sleep mode after measurements or tube washing. See “3.3.3. Setting the Timer” on page 3-9.

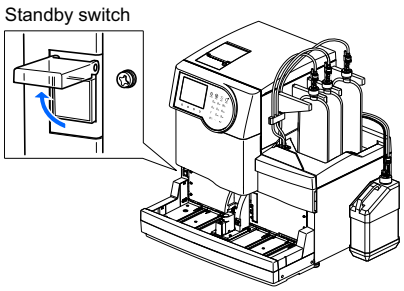
❶ Make sure the standby screen is displayed.

- If a different screen is displayed, press Go back one or more times until the standby screen appears.



❷ Open the transparent cover and press the standby switch.

- The standby switch will light out followed by the display a few seconds later. The power is now off.



❸ Close the transparent cover.

- Be sure to close the cover to prevent accidental operation.

REFERENCE:

For frequent operation, use the standby switch to turn on or off the instrument, while the main power switch on the rear panel is left in the “– (on)” position. Before starting maintenance tasks or if the instrument is not to be used for extended periods of time, first turn off the standby switch and then press the ○ (off) side of the main power switch to shut off the power completely.

1.6 Relocation

This section describes how to move the instrument to another location.

NOTE:
The main body and sampler must be boxed for shipping to other locations. For more information, contact your distributor.

1.6.1 Precautions in Instrument Relocation

Before relocating the instrument, read the following notes and always take proper safety precautions.

- Drain fluid from the tubes (see "1.6.2. Draining Fluid from the Tubes" on page 1-36). Moving the instrument with solution in the tubes may damage the instrument.

- Turn off the power by pressing the standby switch, followed by the main power switch. Then, unplug the power cord from the outlet and unplug the power cord from the instrument.

- Remove the following devices and containers from the instrument:
  - Eluent A pack, eluent B pack and eluent CT pack
  - Hemolysis washing solution bottle
  - Bottle for liquid waste
  - Hand-held barcode reader
  - External device
  - Sampler

- Make sure that the front, maintenance and side covers are closed before relocating the instrument. Moving the instrument with any of the covers open may result in exposure to pathogenic microbes and/or damage the instrument.

- Carry the main body and sampler separately.

- For safety reasons, always move the instrument with the help of at least one other person. Hold the bottom of the instrument with both hands and be careful not to impact or shake the instrument. Rough handling may damage the instrument.

- Read "1.4.1. Precautions in Instrument Installation" on page 1-16 before relocating the instrument.

1.6.2 Draining Fluid from the Tubes

Remove the eluent packs and hemolysis washing solution bottle from the instrument and drain any remaining fluid from the tubes.

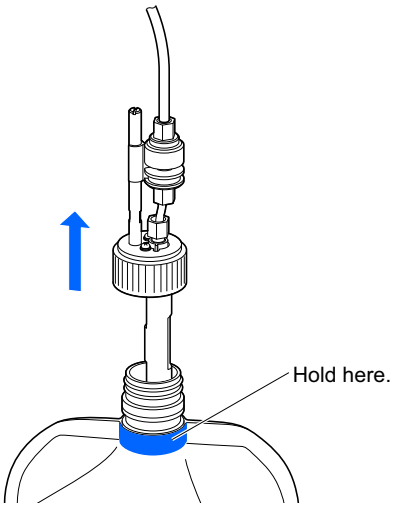
Prepare: Cap for hemolysis washing solution bottle (that was originally on the bottle before opening, × 1), caps for eluent packs (that were originally on the packs before opening, × 3) and gauze

1 Remove the eluent packs.

❶ Lay out some gauze near the instrument.

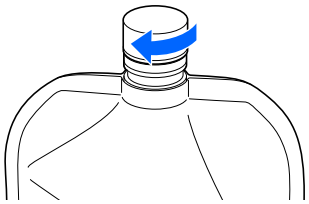
❷ Remove the eluent A pack from the bottle tray.

❸ Hold the pack by the hard plastic neck and remove the bottle cap A from the pack.
- Place the nozzle on the gauze.



NOTE:
- Remove the bottle caps with nozzle from the packs and bottle somewhere other than above the instrument. Liquid may spill and damage the instrument.
- **Do not** hold the eluent pack by the soft aluminium bag. Eluent may spill and damage the instrument.

❹ Attach the cap (that was originally on the pack before opening) to the pack, and tighten it securely.



❺ Wipe any liquid from the nozzle with a new piece of gauze.

❻ Remove the eluent B pack and eluent CT pack in the same procedure as eluent A pack.
- See steps ❷ to ❺.

❼ Wrap the bottle caps A, B and CT with gauze and place them in the bottle tray.

2 Drain fluid from the tubes.

NOTE:
Be sure to drain fluid first from the eluent A, B and CT tubes. Eluents cannot be drained if the hemolysis washing solution is drained first.

❶ On the standby screen, select Menu, <7 Maintenance menu>, <5 Drain menu> and <1 Eluent A> in that order.
- Eluent A will be drained from the tube.
- After completion, the [Drain menu] screen will appear again.

❷ Select <2 Eluent B>.
- Eluent B will be drained from the tube.
- After completion, the [Drain menu] screen will appear again.

❸ Select <3 Eluent CT>.
- Eluent CT will be drained from the tube.
- After completion, the [Drain menu] screen will appear again.

3 Remove the hemolysis washing solution bottle and drain fluid from the tube.

❶ Remove the hemolysis washing solution bottle.
- See **1**-❷ to **1**-❼.

❷ Disconnect the fluid level detection sensor cord from the WASH terminal on the rear panel.

❸ Select <4 Hemolysis washing solution>.
- Hemolysis washing solution will be drained from the tube.
- After completion, the [Drain menu] screen will appear again.

❹ Press Go back three times to return to the standby screen.

1.6.3 Unplugging the Power Cord

❶ Make sure the standby screen is displayed and press the standby switch to turn off the power.

❷ Press the "◯" side of the main power switch on the rear panel to turn off the main power.

❸ Unplug the power cord from the outlet.

❹ Unplug the power cord from the power input terminal on the rear panel.

1.6.4 Disconnecting the Tubes, Sensor Cord and Cables

Remove the bottle for liquid waste, hand-held barcode reader and external device from the instrument.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used protective gloves and liquid waste in accordance with local regulations for biohazardous waste.

Prepare: Protective gloves

1 Remove the bottle for liquid waste.

❶ Disconnect the drain tubes from joints “D1” and “D2” on the rear panel.

❷ When using the optional liquid waste bottle, disconnect the fluid level detection sensor cord from the DRAIN terminal on the rear panel.

2 Remove the hand-held barcode reader and external device.

When the hand-held barcode reader and/or external device are connected to the instrument, disconnect their cables from the B.C.R and/or DATA OUT terminals on the rear panel.

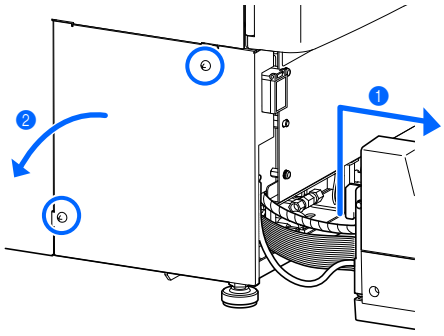
1.6.5 Detaching the Sampler

Prepare: Phillips screwdriver and stubby screwdriver (No.6200-1)

1 Detach the sampler.

❶ Lift the sampler straight upward slowly with both hands and pull to the front.
- This unhooks the sampler in both locations.

❷ Loosen the two screws on the left side panel of the main body using the stubby screwdriver, and remove the wiring box cover.

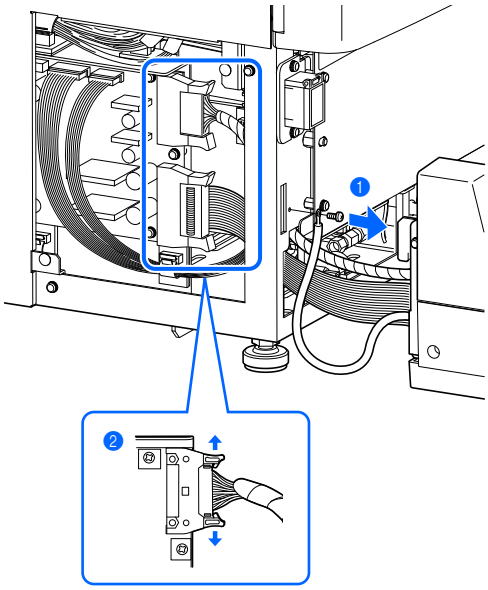


2 Disconnect the sampler cables from the instrument.

❶ Loosen the earth fixing screw with the Phillips screwdriver and disconnect the earth line from the instrument.

❷ Disconnect the two sampler connectors from the main body.
- Press the levers on both sides of the connector on the main body to the outside to disconnect the cable.

The sampler is now detached completely from the instrument.



1.6.6 Relocating the Instrument

Make sure that the front, maintenance and side covers are closed before relocating the instrument. Moving the instrument with any of the covers open may result in exposure to pathogenic microbes and/or damage the instrument.

IMPORTANT:

For safety reasons, always move the instrument with the help of at least one other person. Hold the bottom of the instrument with both hands and be careful not to impact or shake the instrument. Rough handling may damage the instrument.

❶ Move the instrument to its new location.

- Carry the main body and sampler separately.
- The main body and sampler must be boxed for shipping to other locations.

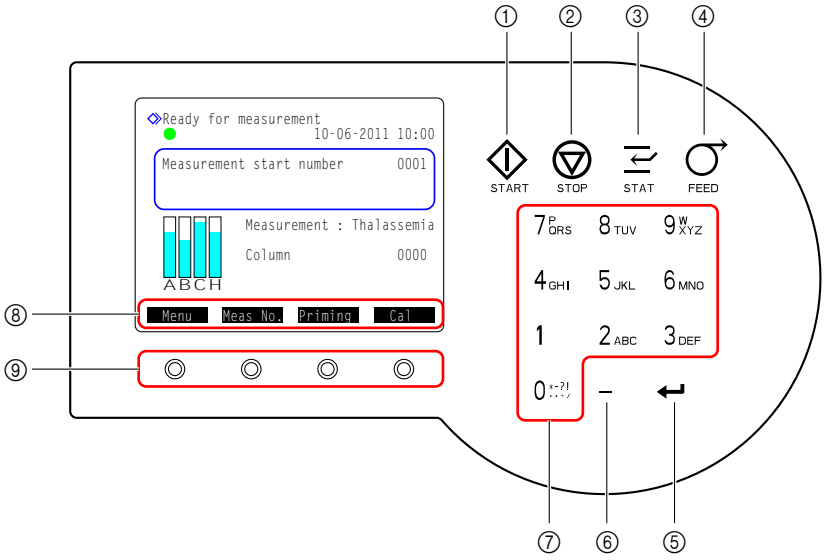
❷ Install the instrument in its new location.

- See “1.4. Installation” on page 1-16.

1.7 Basic Operations

This section describes basic instructions to perform measurement and make parameter settings.

1.7.1 Components on the Operator Panel

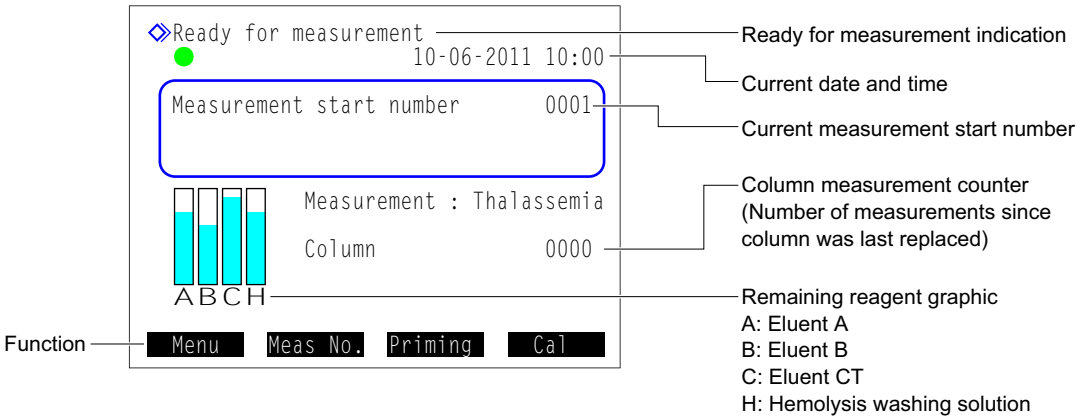


No.	Icon	Name	Description
①		START button	Starts measurement.
②		STOP button	Stops measurement. Stops current operation.
③		STAT button	Reserves STAT measurement.
④		FEED button	Advances printer paper when depressed.
⑤		ENTER button	Confirms your entries, selection or settings. Moves the cursor down.
⑥	–	Hyphen button	Selects options for setup items. Moves the cursor to the next entry field. Used to enter IDs.
⑦	0	Alphanumeric buttons	Enters numeric values. Selects options for setup items on the setup screens. Enters alphabetical characters for IDs.
⑧		Function labels	Functions available for specific operations and situations appear here. As shown below, some labels have the same functions as buttons on the operator panel. Start : Same as the button. Starts measurement. Stop : Same as the button. Stops measurement.
⑨		Function buttons	Corresponds to the function labels. Press the button directly below the function label to activate the corresponding function.

1.7.2 Basic Operations

■Standby screen

The standby screen appears after the power is turned on, and warm-up and priming are complete. Start all operations for measurement, setup and maintenance from the standby screen and return to this screen after completing the tasks.

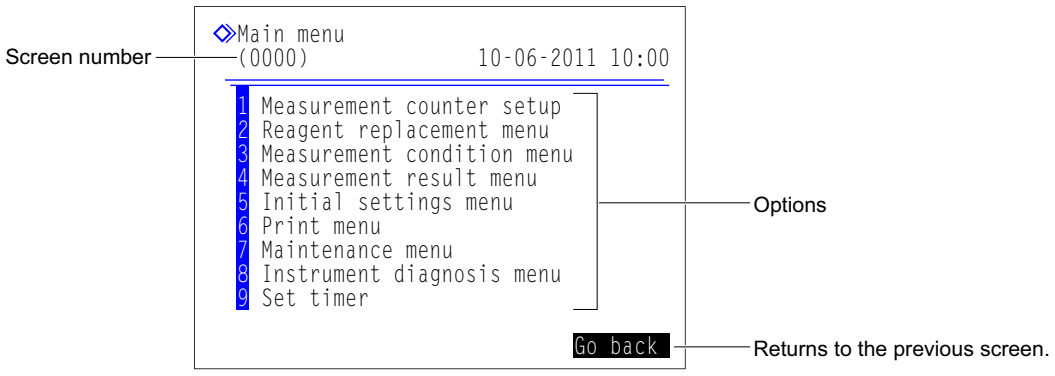


Function	Description
Menu	Goes to the main menu.
Meas No.	Sets the measurement start numbers for normal measurement and control measurement.
Priming	Removes air from eluents and hemolysis washing solution by priming, or pumps these reagents.
Cal	Performs calibration.

■Menu screens

Use the numeric buttons to select options from menu screens.

Example: To select <1 Measurement counter setup>, press the [1] button.

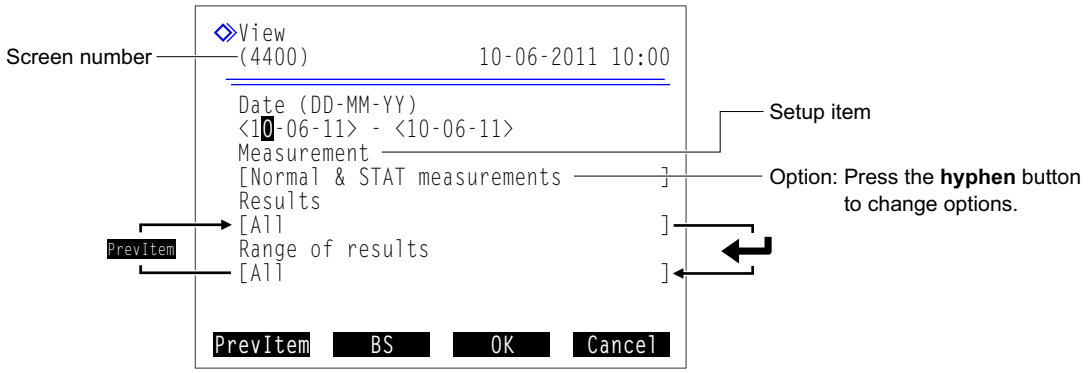


REFERENCE:

Each menu screen has a different screen number. Screen numbers can be referred to when contacting your distributor for service.

■Setup screens

The setup screens are for changing settings, and entering numbers and letters.



Button	Description
Hyphen	Selects options for setup items. Moves the cursor to the next entry field. Used to enter IDs and dates.
↵	Moves the cursor to the next setup item.

Function	Description
PrevItem	Moves the cursor to the previous setup item.
BS	Deletes a number or letter.
OK	Confirms your changes.
Cancel	Cancels your changes and returns to the previous screen.

REFERENCE:

The numeric buttons can be used to select the options.

[8]: Selects the last option.

[2]: Selects the first option.

[4]: Selects the previous option.

[6]: Selects the next option.

NOTE:

The message “Settings changed. Save setting changes?” appears if any changes have been made to setup screens. **Do not** turn off the power while settings are being saved. New settings may not be saved.

■Entering numbers and letters

- Entering numbers

A cursor appears in the right-most digit of entry fields for numeric values. Enter a number with the numeric buttons. Press the **hyphen** button to display the +/- symbol alternately. It is not necessary to enter a decimal point.

Example: To enter “-2.50”:

Press [-], [2], [5] and [0] in that order.

<-2.50>

- Entering dates

Hyphen button: Moves the cursor through the date in the order of "day", "month" and "year".

↵ button: Moves the cursor to the next setup field.

Start date End date

<15-04-11> - <07-11-11>

- Entering the time

Hyphen button: Moves the cursor through the time in the order of "hour" and "minute".

↵ button: Moves the cursor to the next setup field.

- Entering IDs

Use the numeric buttons to assign IDs to samples. An ID can contain up to 18 digits. The characters listed below are entered by pressing buttons a certain number of times.

Example: To enter "f", press [3] seven times.

Button	Once	Twice	3 times	4 times	5 times	6 times	7 times	8 times	9 times	10 times
[0]	0	*	-	?	!	.	,	+	/	Back to "0"
[1]	1									
[2]	2	A	B	C	a	b	c	Back to "2"		
[3]	3	D	E	F	d	e	f	Back to "3"		
[4]	4	G	H	I	g	h	i	Back to "4"		
[5]	5	J	K	L	j	k	l	Back to "5"		
[6]	6	M	N	O	m	n	o	Back to "6"		
[7]	7	P	Q	R	S	p	q	r	s	Back to "7"
[8]	8	T	U	V	t	u	v	Back to "8"		
[9]	9	W	X	Y	Z	w	x	y	z	Back to "9"

REFERENCE:

To enter the same number or character consecutively:Use the **hyphen** button. For example, to enter "AA", press [2], [2], hyphen, [2] and [2] in that order. Use the same method to enter different characters assigned to the same buttons. For example, to enter "NO", press [6], [6], [6], hyphen, [6], [6], [6] and [6] in that order.

- To correct an entry

Press BS. This deletes the right-most digit of your entry. Even if you want to correct a character in the middle of text, you must delete all of characters up to it, and then change the entry.

Example: To change "1302" to "1402":

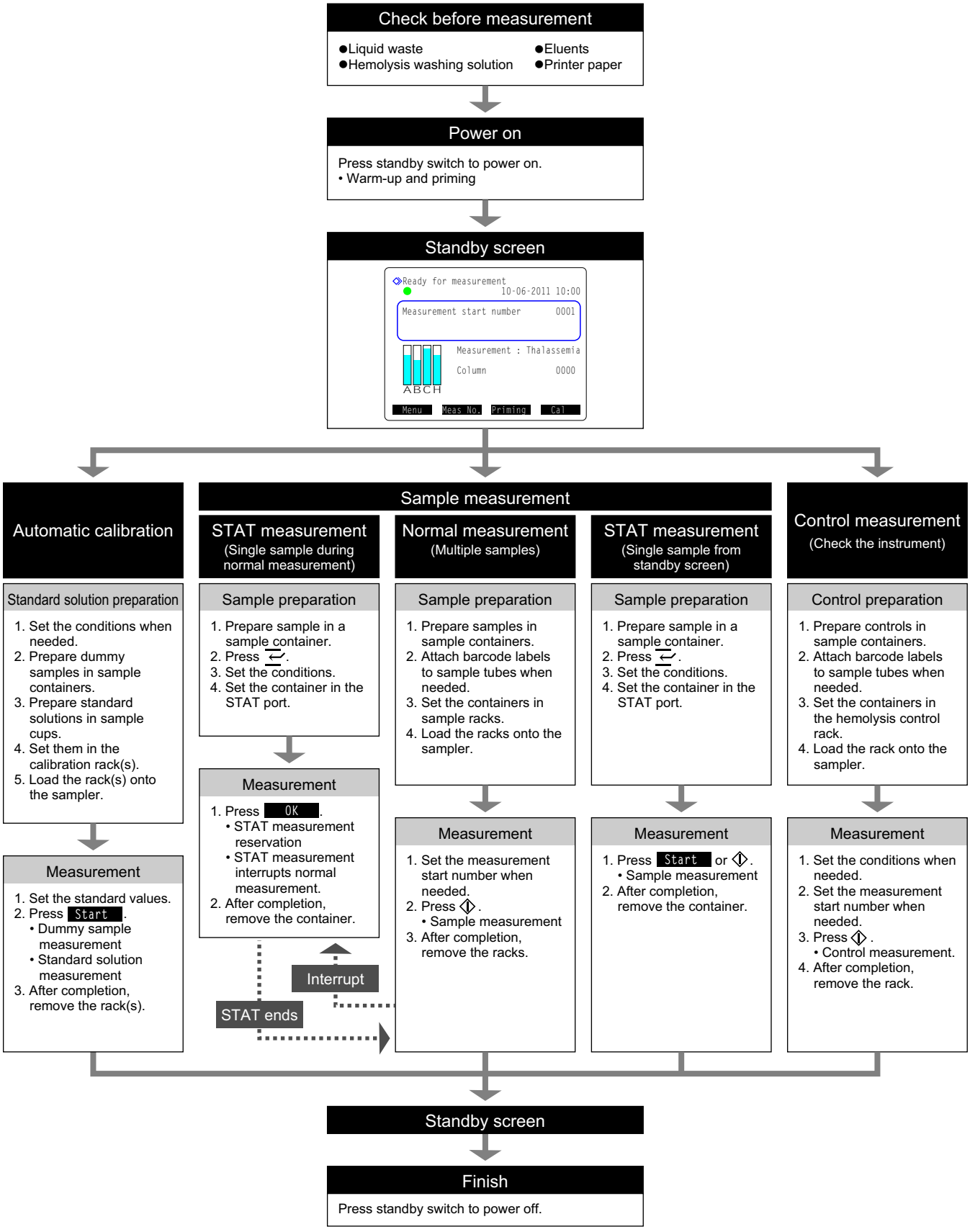
Press BS three times to delete "302". With the field showing "0001", press [4], [0] and [2] in that order.

Chapter 2 Measurement

This chapter describes how to perform normal measurement, STAT measurement, control measurement and calibration. Examples of printed reports showing measurement results and other information are provided at the end of this chapter.

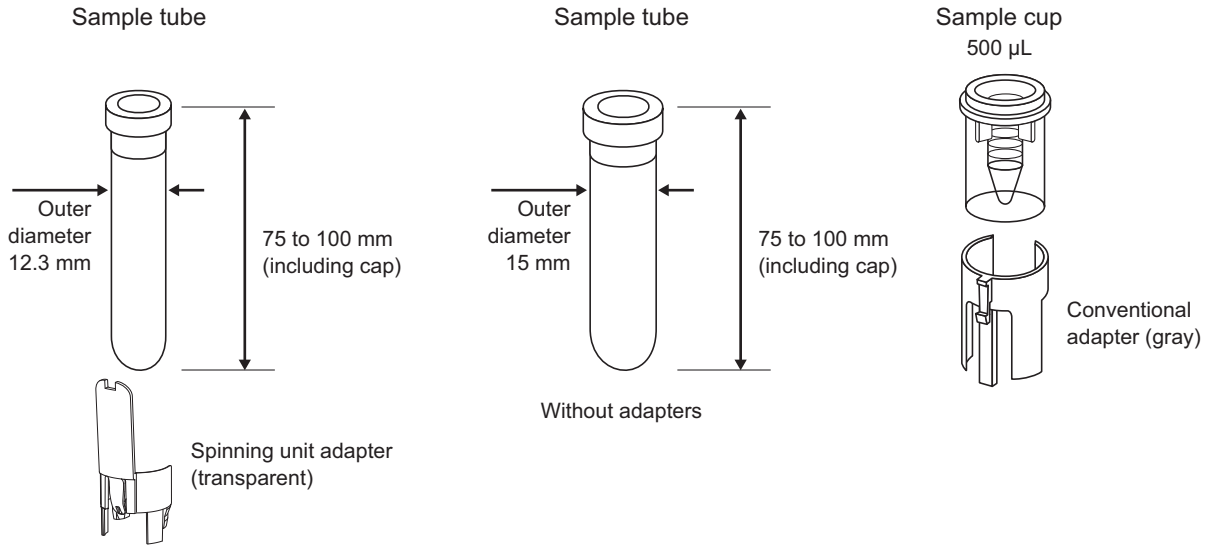
2.1 Before Measurement

2.1.1 Measurement Procedure



2.1.2 Sample Containers

The following are the sample containers that can be used with this instrument, and the adapters required to set these sample containers in the sample racks.



Sample container	Sample setting port	Required adapter	Barcode label*
Sample tube (12.3 mm outer diameter)	Normal rack Start rack Anemia rack STAT port	Normal measurement: Spinning unit adapter (transparent) STAT measurement: Conventional adapter (gray)	Attach directly to the sample tube.
Sample tube (15 mm outer diameter)		None	
Sample cup	Whole blood pair rack Hemolysis pair rack STAT port	Conventional adapter (gray)	Attach to a sample tube and pair it with the sample cup when setting in the rack.

* When using the STAT port, read barcodes with the optional hand-held barcode reader.

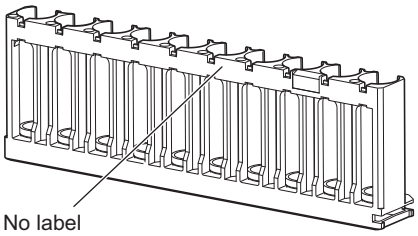
When using sample tubes for normal measurements, make sure the caps are on the tubes tightly. If a tube is not capped, cap it with a resealable cap. Performing measurements with uncapped tubes may cause sample to splatter inside the instrument while spinning, possibly jeopardizing subsequent measurements. It may also cause infection to the user or other individuals by pathogenic microbes.

NOTE:

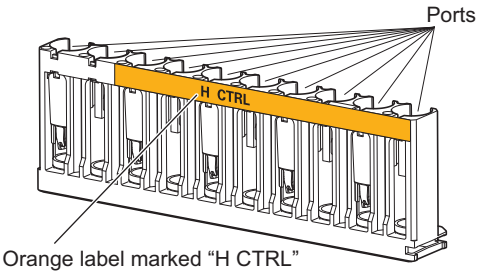
For some sample types and measurement types, either sample tube or sample cup should be used. Confirm the required sample container in “Prepare:” of the specific measurement procedure. Use the correct sample container.

2.1.3 Sample Racks

There are eight types of sample racks in all. These racks can be identified by the label color and name on the front of the rack.



Normal rack



Hemolysis control rack

IMPORTANT:

Use suitable sample racks. Set the samples, control and standard solutions in their specific ports. Inaccurate measurement results will be obtained if measurements are performed with the wrong rack.

REFERENCE:

Set diluted samples such as hemolysis samples, controls and standard solutions in the ports with orange label.

■Normal rack [No label or name]

Use	Normal measurement, reproducibility test (whole blood sample) * Normally use this rack to measure samples.
Object	Whole blood sample
Adapter	Adapters are not attached at the time of shipment. Attach adapters if needed according to the type of sample containers to be used.
Sample container	Sample tube

■Start rack [Light blue, START]

Use	Normal measurement, control measurement, calibration (if sample rack transportation is set to “loop transportation”) Set this rack as the first rack to be measured on the loading side of the sampler. Measurement operation will stop automatically after all samples have been measured and the start rack has returned to its initial position. Example: For normal measurements, set the start rack in the first position, followed by normal racks in the 2nd to 10th positions.
Object	Whole blood sample
Adapter	Spinning unit adapter (transparent)
Sample container	Sample tube

■Whole blood pair rack [White, W PAIR]

Use	Normal measurement. Use this rack to measure whole blood sample in sample cups. IDs are read from the barcode labels attached to sample tubes.
Object	Whole blood sample
Adapter	Odd-numbered ports: Spinning unit adapter (transparent) Even-numbered ports: Conventional adapter (gray)
Sample container	Odd-numbered ports: Sample tubes (for barcode labels) Even-numbered ports: Sample cups (sample)

■Hemolysis pair rack [Orange, H PAIR]

Use	Normal measurement of hemolysis samples. Use sample cups with sample. IDs are read from the barcode labels attached to sample tubes.
Object	Hemolysis sample
Adapter	Odd-numbered ports: Spinning unit adapter (transparent) Even-numbered ports: Conventional adapter (gray)
Sample container	Odd-numbered ports: Sample tube (for barcode labels) Even-numbered ports: Sample cup (sample)

IMPORTANT:

Do not set whole blood samples in the even-numbered ports of the hemolysis pair rack to avoid seriously degrading the column. If whole blood is measured in these ports, it is recommended to replace the column with a new one.

■Anemia rack [White, ANEMIA]

Use	Normal measurement of anemia samples (whole blood)
Object	Whole blood sample
Adapter	Spinning unit adapter (transparent)
Sample container	Sample tube

IMPORTANT:

Use the anemia rack for whole blood samples from patients previously diagnosed as anemic. Measuring non-anemia samples with the anemia rack may cause inaccurate measurement results.

■Hemolysis control rack [Orange, H CTRL]

Use	Control measurements for HbA1c, HbA2 and HbF, reproducibility test (hemolysis sample)
Object	Controls
Adapter	Odd-numbered ports: Spinning unit adapter (transparent) Even-numbered ports: Conventional adapter (orange)
Sample container	**Sample tubes with controls** Odd-numbered ports: Sample tube (control) Even-numbered ports: Empty **Sample cups with controls** Odd-numbered ports: Sample tube (Attach barcode labels to empty sample tubes and set in these ports when using the internal barcode reader.) Even-numbered ports: Sample cup (control) **Port settings (factory-set)** Ports 1 to 6: For HbA1c controls Ports 7 to10: For HbA2/HbF controls These port settings can be changed as needed.

IMPORTANT:

Do not set whole blood samples in the hemolysis control rack to avoid seriously degrading the column. If whole blood is measured with this rack, it is recommended to replace the column with a new one.

■Calibration rack [Ports 1 to 8: White, Ports 9 and 10: Orange, CAL]

Use	Automatic calibration for HbA1c, HbA2 and HbF
Object	Dummy samples (whole blood), standard solutions
Adapter	Ports 1 to 3: Conventional adapter (blue) Ports 4 to 8: Spinning unit adapter (transparent) Ports 9 and 10: Conventional adapter (orange)
Sample container	Ports 1 to 3: Sample tube (for calibration information barcode label) Ports 4 to 8: Sample tube (dummy sample) Port 9: Sample cup (Low solution) Port 10: Sample cup (High solution)

IMPORTANT:

Do not set whole blood samples in ports 9 and 10 of the calibration rack to avoid seriously degrading the column. If whole blood is measured in these ports, it is recommended to replace the column with a new one.

■Washing rack [Blue (small label), WASH]

Use	Tube wash
Object	Washing solution for tubes
Adapter	Conventional adapter (blue)
Sample container	Sample tube

2.2 Measurement Precautions

2.2.1 Precautions for Operation

- This instrument is to be operated by qualified persons only. A qualified person is one having adequate knowledge of clinical testing and the disposal of infectious waste. Thoroughly read this operating manual before use.
- Never touch the piercing nozzle, tubes, liquid waste bottle or other parts where sample may adhere with unprotected hands. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples, liquid waste, column, parts and instrument in accordance with local regulations for biohazardous waste.

- Read “1.4.1. Precautions in Instrument Installation” on page 1-16 and ensure the instrument is installed in a proper environment before turning on the power.
- **Do not** place containers or bottles that contain liquid on the instrument. Sample or other liquid that gets inside the instrument may cause trouble.
- Never fail to clean or wash the specified components of the instrument to maintain measurement quality. For more information, see “Chapter 4 Maintenance”.
- If you detect abnormal odors or noise, immediately turn off the standby switch and then main power switch, and unplug the power cord. Continuous operation in such condition may result in fire or damage to the instrument and consequently lead to personal injury.
- In case of instrument trouble, contact your distributor for repairs. Unauthorized servicing or modification may damage the instrument and consequently lead to personal injury.

2.2.2 Eluents

IMPORTANT:

- **Use only eluents specified for the instrument.**
  ARKRAY provides “ELUENT 80A”, “ELUENT 80B” and “ELUENT 80CT” as eluents specifically for the HA-8180T. Before use, read the package insert that comes with each eluent and observe all handling instructions.
- **Avoid mixing of the eluents.**
  Attach the proper bottle cap (with nozzle) to each eluent A pack, eluent B pack and eluent CT pack. Connecting the wrong bottle cap to the wrong pack can cause mixing of eluents, producing inaccurate measurement results. If the wrong bottle cap is attached, wash the nozzle and chamber, then attach the correct bottle cap (see “5.5.2. If Eluent Packs Are Incorrectly Attached” on page 5-25).
- **When storing the eluents:**
  Store unopened eluent packs at a temperature between 3°C and 30°C, avoiding direct sunlight. Once opened, use the eluent within one month, even if it is before expiration date.
- **Observe expiration dates.**
  Do not use eluent packs beyond their expiration dates. The expiration dates are written on both the box and pack label.
- **Replace the pack.**
  Replace the eluent pack with a new one even if a small volume of eluent remains. Adding new eluent to the old pack can cause inaccurate measurement results.
- **Allow eluents to adjust to room temperature before use.**
  If eluents are stored in a refrigerator, allow them to adjust to the same environment as the instrument for at least one hour before placing them on the instrument.

NOTE:

Be sure to hold eluent packs by the hard plastic neck. **Do not** hold the eluent packs by the soft aluminium bag. Eluent may spill and damage the instrument.

2.2.3 Hemolysis Washing Solution

IMPORTANT:

- **Use only hemolysis washing solution specified for the instrument.**
  ARKRAY provides “HEMOLYSIS WASHING SOLUTION 80H” as hemolysis washing solution specifically for the HA-8180T. Before use, read the package insert that comes with the solution and observe all handling instructions.
- **When storing the hemolysis washing solution:**
  Store unopened hemolysis washing solution bottles at a temperature between 3°C and 30°C, avoiding direct sunlight. Once opened, use the hemolysis washing solution within one month, even if it is before expiration date.
- **Observe expiration date.**
  Do not use hemolysis washing solution bottle beyond its expiration date. The expiration date is written on both the box and bottle label.
- **Replace the bottle.**
  Replace the hemolysis washing solution bottle with a new one even if a small volume of solution remains. Adding new solution to the old bottle can cause inaccurate measurement results.
- **Allow hemolysis washing solution to adjust to room temperature before use.**
  If hemolysis washing solution is stored in a refrigerator, allow it to adjust to the same environment as the instrument for at least one hour before placing it on the instrument.

2.2.4 Column

- Wear protective gloves to prevent exposure to pathogenic microbes when replacing the column.
- Discard used columns in accordance with local regulations for biohazardous waste.

IMPORTANT:

- **Use only columns specified for the instrument.**
  ARKRAY provides “COLUMN UNIT 80T” as columns specifically for the HA-8180T. Before use, read the package insert that comes with the column and observe all handling instructions.
- **When storing the columns:**
  - Store unopened column units at a temperature between 3°C and 25°C. It is recommended to keep the column refrigerated. **Do not** freeze.
  - **Do not** leave the instrument with the column installed for extended periods of time. If the instrument is not to be used for one week or more, perform the required maintenance tasks and then store the removed column with both ends sealed at a temperature between 3°C and 25°C (see “4.6.1. Preparing the Instrument Before Extended Periods of Disuse” on page 4-46). It is recommended to keep the column refrigerated. **Do not** freeze. If not properly stored, the filler may dry beyond a level of practical use.
- **Observe expiration dates.**
  Do not use columns beyond their expiration date. The expiration date is written on both the box and the label attached to the OUT side of the column.
- **Install the column in the correct direction.**
  Check the IN and OUT sides of the column when installing it in the instrument. Connect the IN side of the column to the IN column tube, and the OUT side, to the OUT column tube of the instrument.
- **Keep the sealing screws for future use.**
  Keep the sealing screws removed from new columns in the accessory case. These screws should be reused if the instrument is not to be used for extended periods of time.
- **Do NOT introduce anything other than eluents into the column.**
  Do not introduce anything other than eluents into the column. The introduction of surfactant, fat or water-insoluble materials can alter separation, making it impossible for the instrument to measure samples. Even a trace amount of foreign matter can accumulate inside the column and reduce its service-life significantly. (Distilled water or air can also cause the elution conditions to change and produce inaccurate measurement results.)
- **Do NOT disassemble the column.**
  Trouble may occur or inaccurate measurement results may be obtained, if the column is disassembled.
- **Do NOT subject the column to shocks or vibrations.**
  Trouble may occur or inaccurate measurement results may be obtained, if the column is subjected to strong impacts or vibrations.

2.2.5 Samples

- TAKE THE UTMOST CARE WHEN HANDLING BLOOD. This instrument uses blood as sample. Blood may be contaminated by pathogenic microbes that can cause infectious diseases. Improper handling of blood may cause infection to the user or other individuals by pathogenic microbes.
- Discard used samples in accordance with local regulations for biohazardous waste.

IMPORTANT:

- **When using hemolysis samples:**
  If left at room temperature, hemolysis samples gradually degenerate, which will affect measurement. Promptly measure hemolysis samples without leaving them at room temperature for any extended periods of time.
- **Hemoglobin concentration of hemolysis samples**
  Prepare hemolysis samples so that the hemoglobin concentration is between 75 mg/dL and 225 mg/dL (standard: 150 mg/dL). If the concentration does not fall within this range, an error may occur or the reproducibility may become poor. If this happens, change the dilution ratio appropriately to adjust the concentration before performing a measurement again. (This instrument dilutes whole blood 101 times before measuring it.)
- **Samples without plasma**
  Sample racks for whole blood cannot be used to measure samples from which plasma has been removed. With the whole blood racks, samples without plasma cannot be diluted to the proper hemoglobin concentration and consequently produces inaccurate measurement results. To measure such samples, dilute them with Diluent 80 and measure as hemolysis samples.

- Anticoagulant for whole blood

Use one of the following anticoagulants: heparin, EDTA-2Na, EDTA-2K, EDTA-3K or NaF.
Never measure samples that contain iodoacetic acid as an anticoagulant in order to prevent degradation of the column.

- When storing whole blood samples:

Refrigerate whole blood samples at a temperature between 2°C and 8°C. Samples can be stored in stable condition for 3 to 4 days before use.

2.3 Preparation for Measurement

2.3.1 Checking Liquid Waste and Consumables

1 Check liquid waste.

❶ When using an optional liquid waste bottle, discard liquid waste if it is remaining in the bottle. When using the drainage system at your laboratory, check that the drain tubes are connected properly.

Discard liquid waste in accordance with local regulations for biohazardous waste.

2 Check eluents and hemolysis washing solution.

❶ Replace the eluent packs and hemolysis washing bottle if the reagents are running out.

- See “4.2.1. Replacing the Eluent Packs” on page 4-3.
- See “4.2.2. Replacing the Hemolysis Washing Solution Bottle” on page 4-7.

3 Check the printer paper.

❶ The printer paper is running out if two red lines appear on both edges of the paper. If red lines are visible, replace the paper roll with a new one.

- See “4.2.3. Replacing the Printer Paper” on page 4-10.

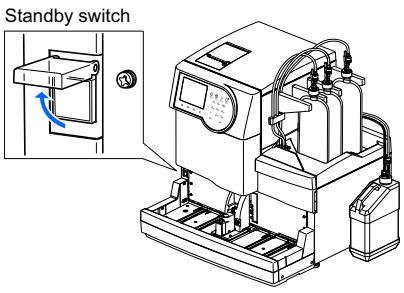
2.3.2 Startup

Follow the instructions described below to start the instrument up. It will take at most 30 minutes from the time when the power is turned on to complete warm-up and priming, and ready itself for measurement.

NOTE:
Check that eluents A, B and CT, and the hemolysis washing solution are all set before turning on the power.

❶ Press the standby switch.

- The standby switch will light up orange when the power is turned on. A few seconds later, it will turn green.



REFERENCE:
If the main power switch on the rear panel is off, set it in the “on” position before pressing the standby switch to turn on the power.

●"Initializing ..."

- The parameter settings will be read and the mechanical sections will be initialized.

●"Warming up ..."

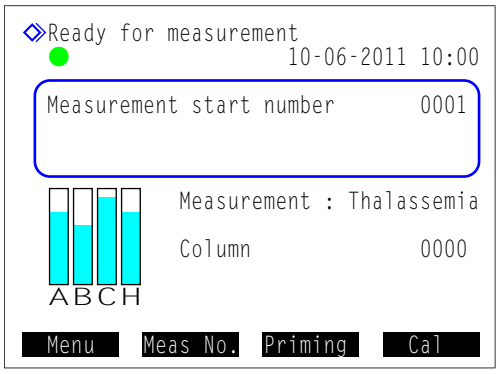
- The instrument is adjusting internal temperature to enable measurement.
- Measurements can be reserved.
- The main menu lists only the options available during warm-up.

●"Removing air ..."

- The tubes are being filled with eluents and hemolysis washing solution to remove air in the tubes.
- Measurements can be reserved.
- The main menu lists only the options available during priming.

●"Ready for measurement"

- The standby screen will appear, indicating that the instrument is now ready for measurement.



REFERENCE:

Indications and functions available during warm-up and priming, and when the instrument is on standby are given below.

Message	"Warming up ..."	"Removing air ..."	"Ready for measurement"
Status	Warm-up	Priming	Standby screen
Icon	–	–	Light green circle (●)
Function	Menu Meas No. Cal	Menu Meas No. Cal	Menu Meas No. Priming Cal
Menu operation	Only available options are listed on the menu.		All options are available.
When press ◇:	Measurement is reserved (measurement starts when warm-up and priming are complete).		Measurement starts immediately.

REFERENCE:

The blue circle (●) flashes when a measurement has been reserved. To cancel the reserved measurement, press ▽.

2.4 Normal Measurement

In normal measurement, multiple samples are continuously measured using the sample racks.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard liquid waste, used samples and protective gloves in accordance with local regulations for biohazardous waste.

NOTE:

Perform calibration before the instrument is used for the first time after installation (see “2.7. Calibration” on page 2-35).

2.4.1 Preparing Samples

IMPORTANT:

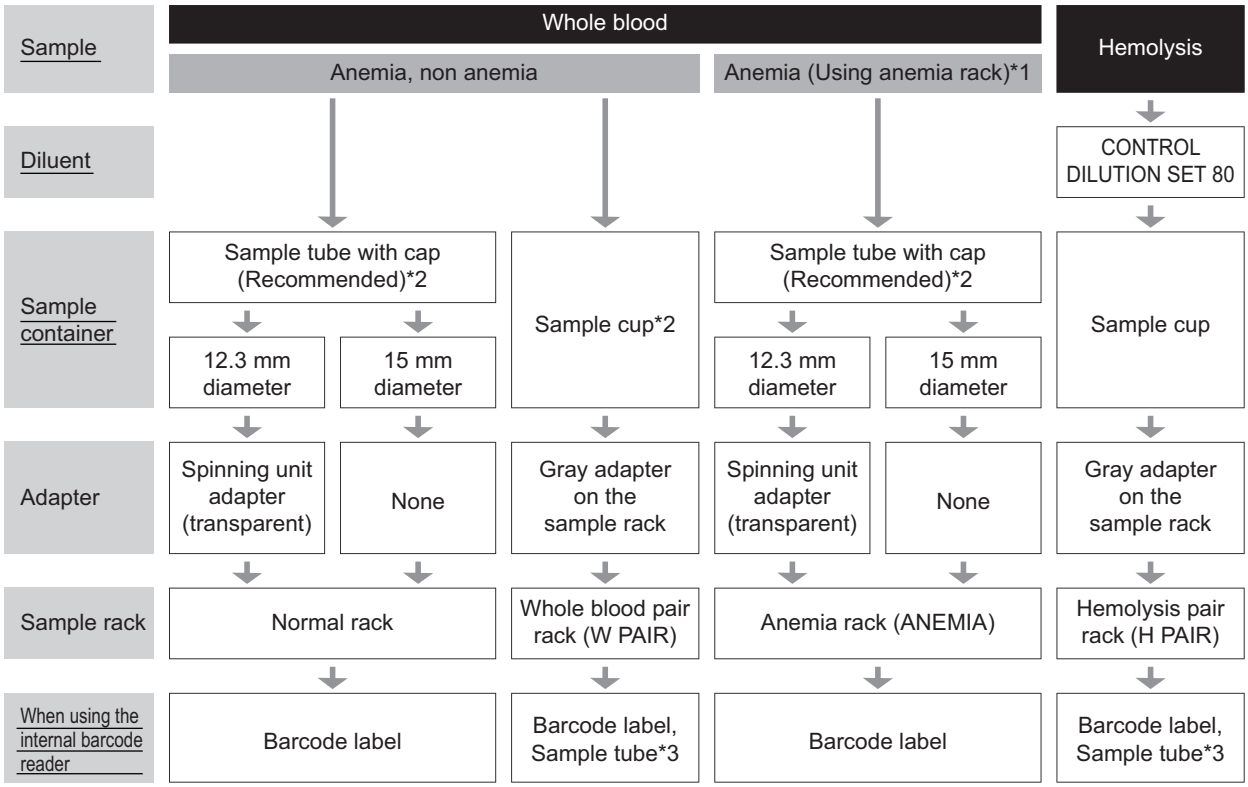
- Samples without plasma cannot be measured. Dilute samples from which plasma has been removed with DILUENT 80 and measure as hemolysis samples. Measuring samples without plasma in a whole blood sample rack will cause inaccurate measurement results.
- Use suitable sample racks. The following may occur if the wrong sample rack is used:
  - Accurate measurement results may not be obtained.
  - Measuring whole blood sample with the hemolysis pair rack or hemolysis control rack may seriously degrade the column. If whole blood is measured with these racks, it is recommended to replace the column with a new one.
  - If a sample tube with a barcode label is mistakenly set in the whole blood pair rack instead of a normal rack, the measurement results of other samples are reported for the IDs of samples in odd-numbered ports.

Prepare: Protective gloves

For sample containers, adapters, sample racks and other required items, see “ Items required for normal measurement” on page 2-15.

Items required for normal measurement

Prepare sample containers, adapters and sample racks for the samples to measure, in the sequence indicated in the following flow chart. The underlined items are not included with the instrument.



*1: Anemia rack

Use the anemia rack for whole blood samples from patients previously diagnosed as anemic.

Samples on the anemia rack are measured at a lower dilution ratio than samples on the normal racks.

*2: Sample containers for whole blood

Sample tube: Recommended. Samples are stirred, so stable measurement results can be obtained without variations due to blood sedimentation.

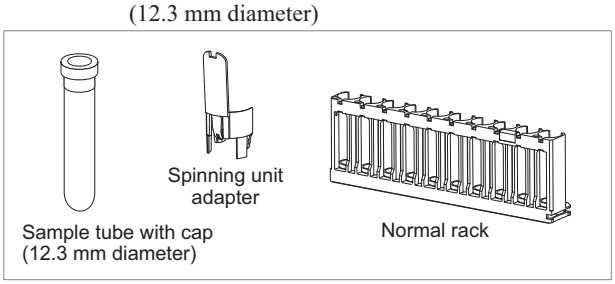
Sample cup: When small volume of sample is available or when measuring few samples. Samples are not stirred.

*3: Barcode labels and sample tubes

Prepare empty sample tubes. IDs are read from the barcode labels attached to the sample tubes.

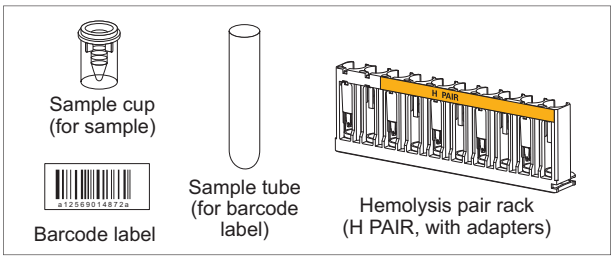
Example 1: Whole blood

When preparing samples in sample tubes (12.3 mm diameter)



Example 2: Hemolysis

When using the internal barcode reader



REFERENCE:

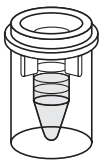
If sample rack transportation is set to “loop transportation”, the start rack (START) is needed in addition to the sample racks specified in the flow chart above.

1 Prepare samples.

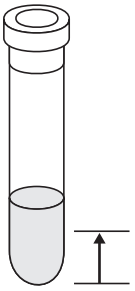
- For whole blood sample (anemia and non-anemia)

❶ Prepare sample in a sample tube or sample cup.
- The volume of sample as shown on the right is required for measurement.

❷ If using a sample tube, make sure the cap is on tight.
- If not capped, cap the tube with a resealable cap.



Sample cup
Min. 400 µL



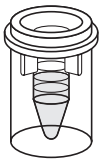
Sample tube (with cap)
Min. 1 mL

Performing measurements with uncapped tubes may cause sample to splatter inside the instrument while spinning, possibly jeopardizing subsequent measurements. It may also cause infection to the user or other individuals by pathogenic microbes.

NOTE:
Use rubber resealable caps recommended by the sample tube manufacturer. Other unrecommended caps may damage the piercing nozzle during measurement operations.

- For hemolysis samples:

❶ Prepare 400 µL or more of sample in a sample cup.



Sample cup
Min. 400 µL

IMPORTANT:
- Prepare hemolysis samples so that the hemoglobin concentration is between 75 mg/dL and 225 mg/dL. Inaccurate measurement results will be obtained if the sample's hemoglobin concentration is outside this range.
- Use DILUENT 80 of CONTROL DILUTION SET 80 to prepare hemolysis samples. Inaccurate measurement results will be obtained if samples are diluted with other diluents.

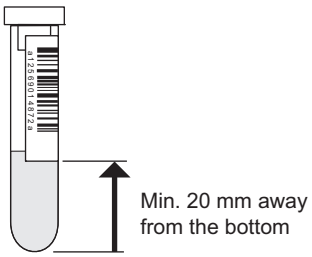
REFERENCE:
Hemolysis samples prepared in sample tubes cannot be measured in normal measurement. Use the STAT port to measure hemolysis samples in sample tubes. See "2.5. STAT Measurement" on page 2-24.

2 Label the sample tubes with barcode labels (when using the internal barcode reader).

Go to step **3** if not using the internal barcode reader.

❶ Label the sample tube with a barcode label.

- Attach the barcode label 20 mm or more above the bottom end of the sample tube, as shown on the right.
- Label sample tubes also when using the whole blood pair rack or hemolysis pair rack.



IMPORTANT:

Make sure that the entire barcode label adheres tightly to the sample tube. **Do not** attach one barcode label on top of another. If the barcode label comes off, reattach it. The label may cause a jam inside the instrument while the sample is stirred, preventing proper stirring.

NOTE:

Barcode labels cannot be attached to sample cups.

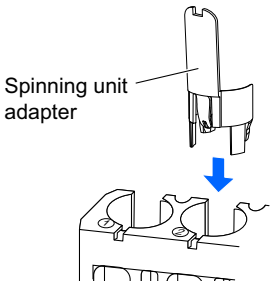
3 Set the samples in the sample racks.

- When preparing sample tubes with sample:

  Use the normal rack (with no label) or start rack (START) for non-anemia samples, and the anemia rack (ANEMIA) for anemia samples.

❶ Set the adapter in the sample rack if needed.

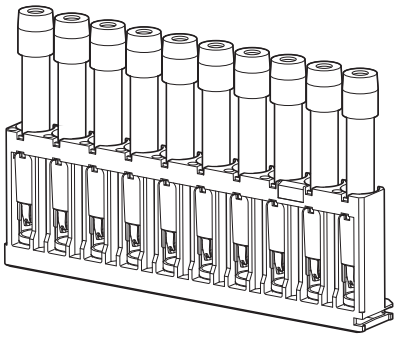
Sample tube	Required adapter
12.3 mm diameter	Spinning unit adapter (transparent)
15 mm diameter	None



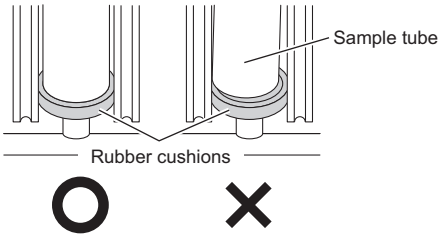
NOTE:

- For sample tubes of a 12.3 mm diameter, set the spinning unit adapter.
- For sample tubes of a 15 mm diameter, remove the spinning unit adapter. Sample tubes of this size cannot fit in the rack due to the adapter.

❷ Set the sample tubes in the ports of the sample racks.

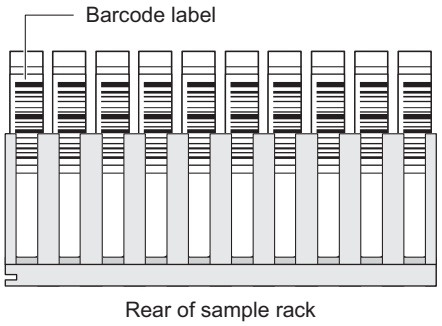


> **Fit the bottom of the sample tubes into the bottom of the rubber cushions so that the tubes stand straight. If the tubes are tilted, they may cause damage to the piercing nozzle.**



NOTE:

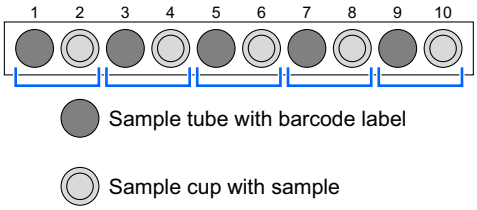
For sample tubes labeled with barcode:To enable the internal barcode reader to read barcodes successfully, labels on the tubes must be facing the rear of the sample rack.



- When preparing sample cups with sample:
  Use the whole blood pair rack (W PAIR) or hemolysis pair rack (H PAIR).

❶ Set sample tubes with barcode labels in the odd-numbered ports.

❷ Set sample cups with sample in the even-numbered ports.
Example: The barcode of port 1 is assigned to the sample in port 2.



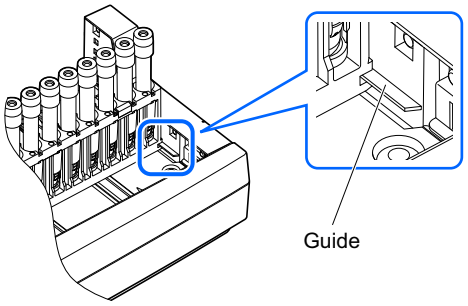
NOTE:

- **Do not** set whole blood samples in the even-numbered ports of the hemolysis pair rack to avoid seriously degrading the column. If whole blood is measured in these ports, it is recommended to replace the column with a new one.
- Set barcoded sample tubes in sample racks with the barcode labels facing the rear of the sample rack.

4 Load the sample racks onto the sampler.

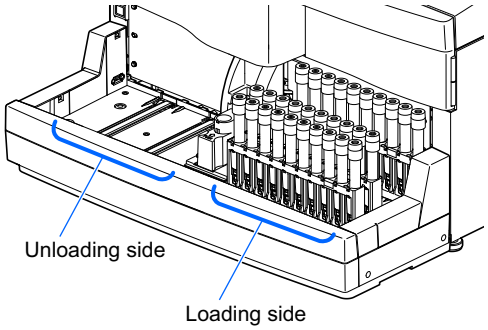
NOTE:
Load sample racks onto the sampler so that they do not fall over. Spilled sample may damage the instrument.

❶ Fit the recess at the side of the rack into the guide inside the rack loading side.



NOTE:

- One-way transportation (initial setting):
  Up to 5 sample racks can be loaded onto the loading side of the sampler. See “One-way transportation” in “6.2. Glossary” on page 6-11.
- Loop transportation:
  Five sample racks can be loaded onto each of the loading and unloading sides of the sampler. Set the start rack as the first rack to be measured on the loading side. See “‘Loop transportation” in “6.2. Glossary” on page 6-12.



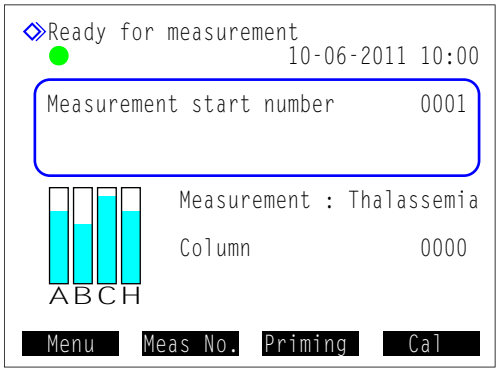
2.4.2 Measuring Samples

Once samples have been prepared, start measurements.

1 Set the measurement start number (if needed).

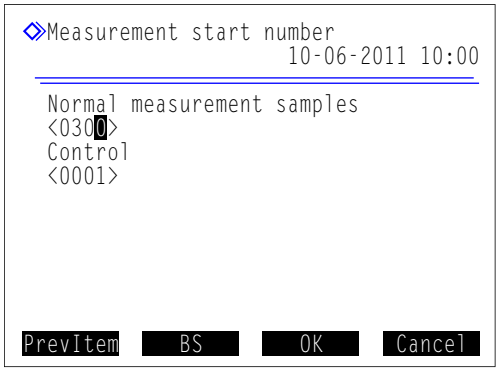
On the standby screen, check the measurement start number. Set a different number if necessary. If you do not change the number, skip to step **2**.

❶ On the standby screen, press Meas No..



❷ Below <Normal measurement samples>, enter a new measurement start number.
- Range: 0000 to 9999

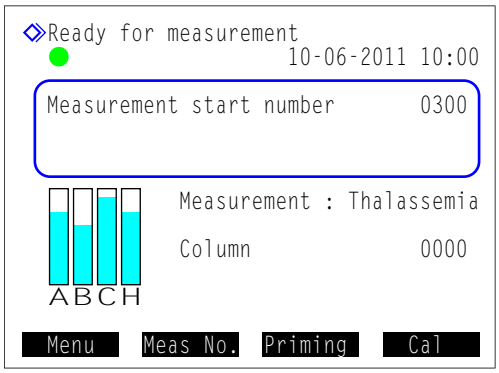
❸ Press OK.
- This saves your entry and will return you to the standby screen.
- The entered number will appear in <Measurement start number> on the standby screen.



2 Start measurement.

NOTE:
This instrument stirs samples before measuring them. Due to a possible risk of injury, **do not** touch the spinning unit or sample container, or insert anything in-between the STAT port cover and front cover while the sample tube is spinning. Also, check that the STAT port cover is attached correctly before starting measurement.

❶ On the standby screen, press ◇.

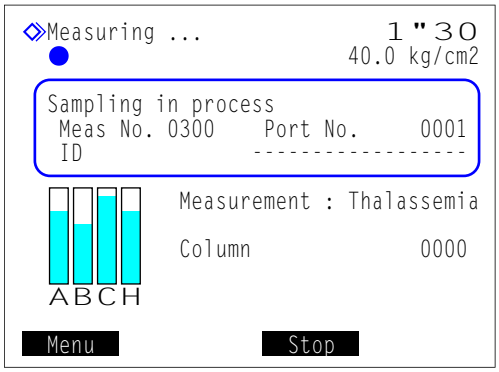


●"Preparing for measurement"

- The sample rack will move to the aspiration position.
- The first sample will be stirred (only if a sample tube is prepared with whole blood).

●"Measuring ..."

- The first sample will be aspirated.
- The measurement number and port number for the sample will be displayed.



REFERENCE:

- The sample's ID appears after the barcode has been read from the sample tube.
- For detailed measurement result reports and timer settings, see "2.4.3. Viewing Measurement Results in Detail" on page 2-22/"3.3.3. Setting the Timer" on page 3-9.

●"Results"

- The obtained measurement result is displayed for 15 seconds.
- At the same time, the measurement result is printed out.
- See "2.8. Displayed and Printed Reports" on page 2-43.

REFERENCE:

To close the measurement result window, press Close.

NOTE:

To stop measurement:

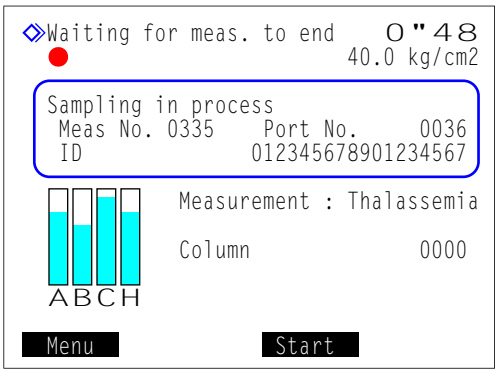
Press Stop or ▽. Depending on when the button is pressed, some samples may be unloaded without being measured. If pressed while measurement is in progress, see the printed measurement results to check if all samples were measured. To restart measurements, press Start or ◇.

⚠ Additional sample racks can be loaded onto the sampler while measurement is in progress. First check that the sample racks are not moving. Touching sample racks during transportation may result in injury and damage to the instrument.

3 Once measurements are complete for all set samples (end of a batch)

● "Waiting for meas. to end"

- The tubes will be cleaned after all sample measurements are complete.
- The standby screen will then appear again.



REFERENCE:

The lists below are printed out when a batch of measurements is complete.

- List of measurement results
- List of abnormal results
- List of barcode errors

❶ Check that the sample racks are not moving.

❷ Remove the sample racks from the rack unloading side of the sampler.

NOTE:
Remove the sample racks so that they do not fall over. Spilled sample may damage the instrument.

4 At the end of the day...

❶ Press the standby switch to turn off the power.

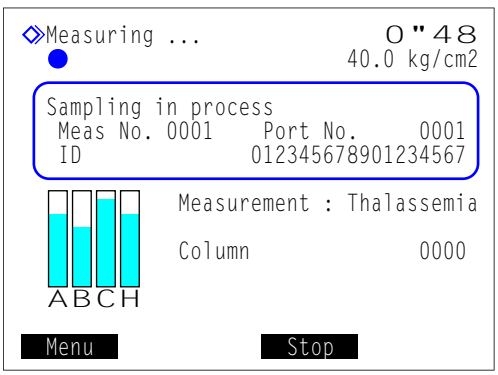
2.4.3 Viewing Measurement Results in Detail

Peak information and chromatograms of measurement results obtained in the current batch can be displayed during measurement.

1 View the measurement results.

❶ While "Measuring ..." is being displayed, press Menu.

- Only available options will appear on the [Main menu] screen.

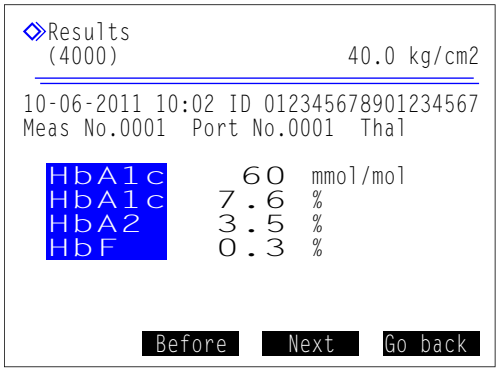


❷ On the [Main menu] screen, select <4 Results>.
- The most recent measurement result will be displayed.

❸ Display the measurement results you want to view.

Button	Description
Before	Returns to the results of the previous sample.
Next	Goes to the results of the next sample.
Go back	Returns to the [Main menu] screen.
↵	Scrolls down the screen to display peak information.

Measurement result

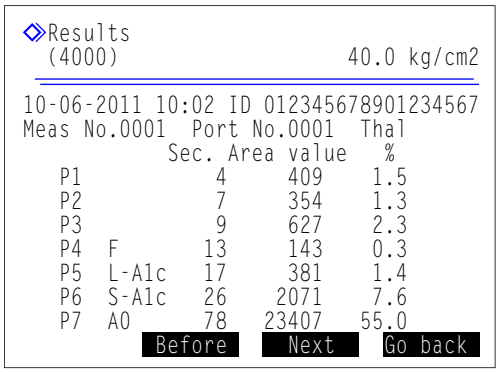


2 View the peak information.

❶ While the measurement result is being displayed, press ↵.
- The retention time and area value for each peak will be listed.

Button	Description
Before	Returns to the results of the previous sample.
Next	Goes to the results of the next sample.
Go back	Returns to the [Main menu] screen.
↵	Scrolls down the screen to display the remaining peak information. A chromatogram appears at the end of the peak information.

Peak information

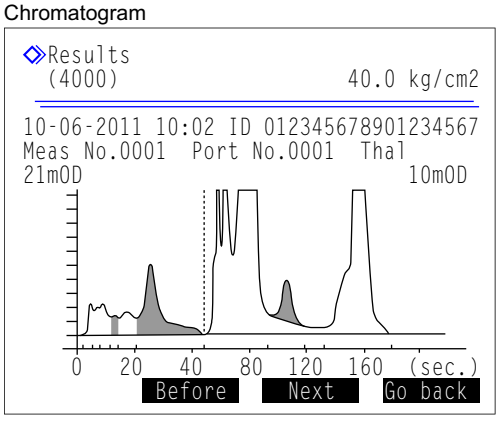


3 View the chromatogram.

❶ At the end of the peak information, press ↵.
- The chromatogram will appear.

Button	Description
Before	Returns to the results of the previous sample.
Next	Goes to the results of the next sample.
Go back	Returns to the [Main menu] screen.
↵	Goes to the results of the next sample.

Chromatogram



2.5 STAT Measurement

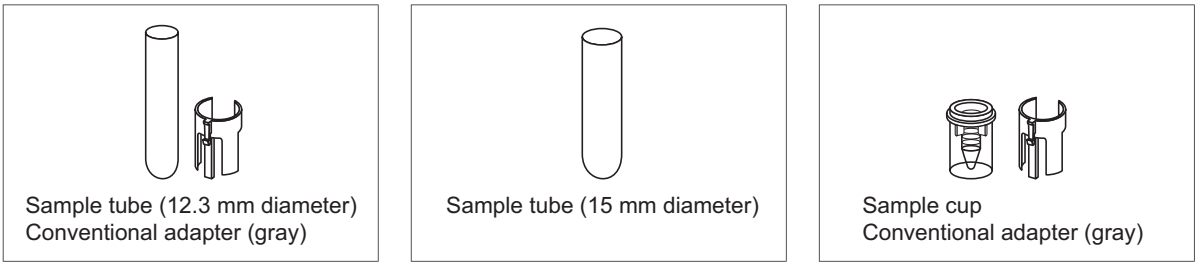
A single sample can be measured by setting it in the STAT port. The STAT port is convenient for interrupting normal measurements to measure an urgent sample or to measure only one sample.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

IMPORTANT:
Samples are not stirred in STAT measurements. If blood has sedimented due to centrifuging, invert the sample tube to mix the sample before performing measurement. Otherwise, inaccurate measurement results will be obtained.

Prepare: Sample container and adapter described below,
CONTROL DILUTION SET 80 (for hemolysis samples) and protective gloves

- Sample containers and adapters



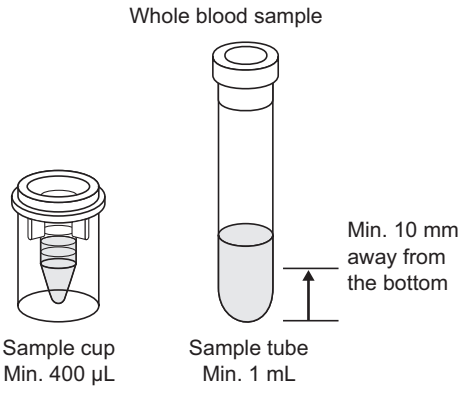
REFERENCE:
Use sample cups when small volume of sample is available.

2.5.1 Measuring a Sample During Normal Measurement

A single sample can be measured by using the STAT port during continuous measurements such as normal measurement. However, STAT measurements cannot be performed during automatic calibration.

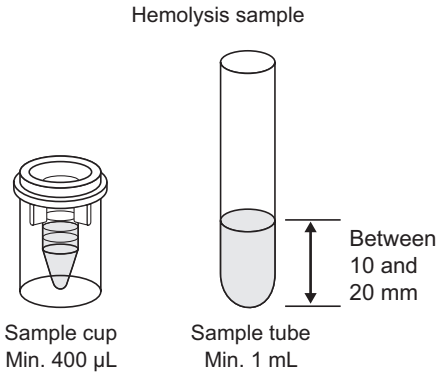
1 Prepare a sample for STAT measurement.

❶ Prepare a sample in a sample tube or sample cup.
- The volume of sample as shown on the right is required for measurement.



IMPORTANT:

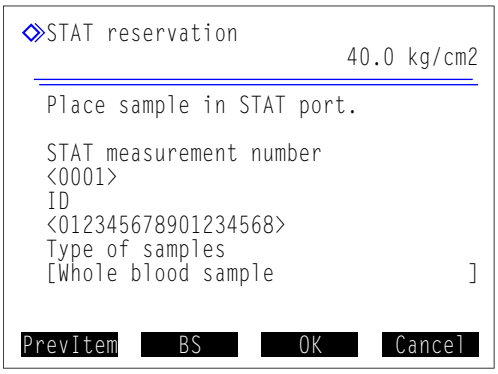
When using sample tubes to measure hemolysis sample, be sure to prepare the volume of sample as shown on the right. Inaccurate measurement results will be obtained if there is too much sample.



2 Set the STAT measurement conditions.

❶ Press ↵ during normal measurement.

❷ Set the STAT measurement conditions.



Setup item	Description
STAT measurement number	Enter a number to be assigned to the STAT measurement sample. The number that initially appears is one higher than the measurement number of the previous STAT measurement. This number is reset to “0001” when the standby screen appears next time. Range: 0000 to 9999
ID	Enter an ID for sample to be measured using the numeric buttons. When using the optional hand-held barcode reader, move the cursor to the <ID> field and read the barcode attached to the sample tube. Measurement can be performed with this field filled with hyphens (-) as initially displayed. Settable characters: Up to 18 digits of numbers and letters
Type of samples	Select the type of sample from <Whole blood sample>, <Hemolysis sample> and <Anemia sample>. Default: Whole blood sample

NOTE:

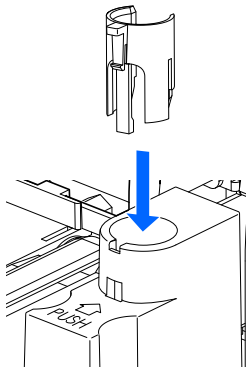
When measuring whole blood samples (anemia and non-anemia):

Be sure to set <Type of samples> to <Whole blood sample> or <Anemia sample> to avoid seriously degrading the column. If whole blood is measured with the <Hemolysis sample> setting, it is recommended to replace the column with a new one.

3 Set the sample in the STAT port.

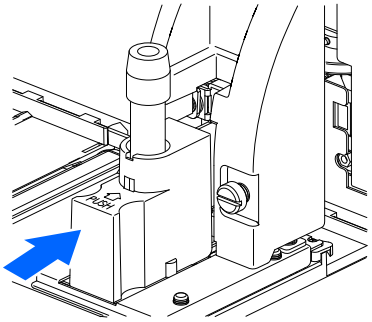
❶ Set the adapter in the STAT port if needed.

Sample container	Required adapter
Sample tube (12.3 mm diameter)	Conventional adapter (gray, in the accessory case)
Sample tube (15 mm diameter)	None
Sample cup	Conventional adapter (gray, in the accessory case)



❷ Set the sample container straight in the STAT port.

NOTE:
Set the sample tube fully to the bottom of the STAT port so that it stands straight. If the tube is tilted, it may cause damage to the piercing nozzle.



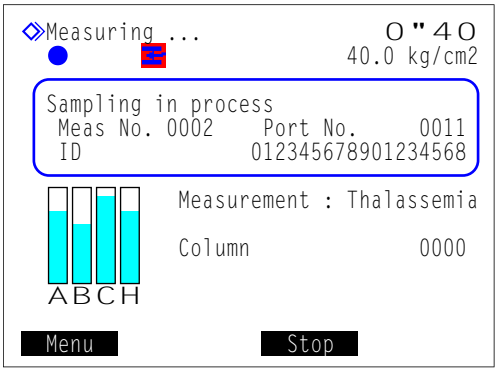
❸ Push the STAT port in the direction of the arrow near "PUSH" by hand until it locks.

❹ Gently pull the STAT port forward to ensure the port is locked.

4 Reserve STAT measurement.

❶ Press OK.

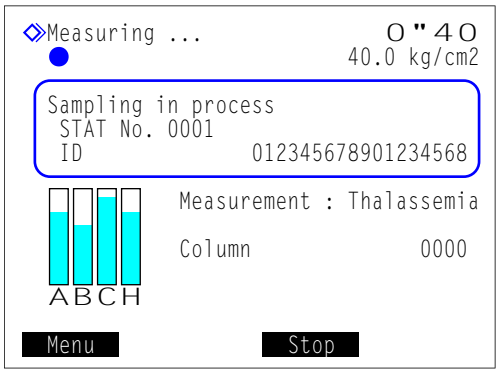
●While the (STAT reservation icon) is flashing:
- STAT measurement has been reserved.
- The STAT measurement is held until normal measurement can be interrupted.



Keep your hands away from the STAT port while STAT measurement is reserved. You may be injured by the piercing nozzle, the sample tube spinning unit or sample racks while they are moving.

●When disappears:

- The beeper will sound and the piercing nozzle will come forward.
- The sample in the STAT port will be aspirated and STAT measurement will start.
- The STAT measurement number will appear at the right side of <STAT No.>.



REFERENCE:

STAT measurement during control measurement:In control measurements, one sample container of control is measured repeatedly according to the number of times you have set on the screen. If STAT measurement is reserved during control measurements, the STAT measurement starts after the completion of the set number of measurements of the sample in the same container.

●"Results"

- The obtained STAT measurement result will be displayed on the screen and printed out.
- See "2.8. Displayed and Printed Reports" on page 2-43.

5 Remove the sample from the STAT port.

❶ Check that the STAT reservation icon has disappeared.

❷ Push the STAT port in the direction of the arrow near "PUSH" by hand until it unlocks, then slide it forward.

❸ Remove the sample from the STAT port.

Setting the next sample:In step **5**-❸, the measured sample can be replaced with another sample to perform the next STAT measurement. Be sure to slide the STAT port forward when replacing the sample. You may be injured by the piercing nozzle or other parts, if you try to replace the sample when the STAT port is still in the aspiration position.

2.5.2 Measuring a Sample During Standby

With the standby screen on the display, one sample can be measured using the STAT port.

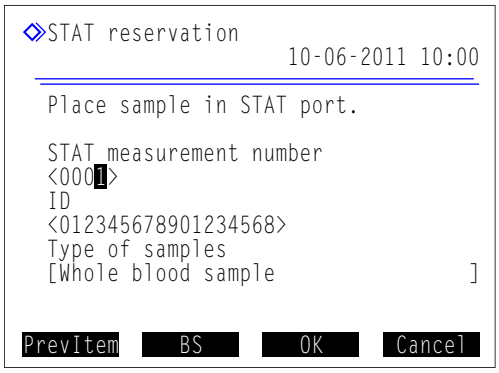
1 Prepare a sample for STAT measurement.

❶ Prepare a sample.
- See step **1** in "2.5.1. Measuring a Sample During Normal Measurement" on page 2-24.

2 Set the STAT measurement conditions.

❶ On the standby screen, press ↵.

❷ Set the STAT measurement conditions.
- See step **2**-❷ in "2.5.1. Measuring a Sample During Normal Measurement" on page 2-25.



NOTE:
When measuring whole blood samples (anemia and non-anemia):
Be sure to set <Type of samples> to <Whole blood sample> or <Anemia sample> to avoid seriously degrading the column. If whole blood is measured with the <Hemolysis sample> setting, it is recommended to replace the column with a new one.

❸ Press OK.
- The settings you have just made will reappear on the display.

❹ Check the settings.
- To make any changes, press Cancel and retry from step **2**-❶.

3 Set the sample in the STAT port.

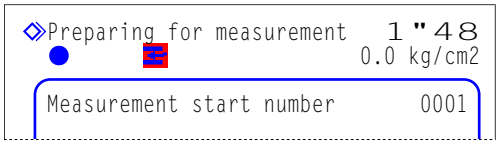
❶ Set the sample in the STAT port.
- See step **3** in "2.5.1. Measuring a Sample During Normal Measurement" on page 2-26.

4 Start STAT measurement.

❶ Press Start or ◇|◇.

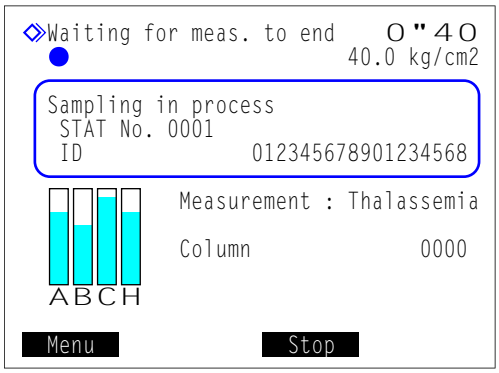
●While the ⇌ (STAT reservation icon) is flashing:

- STAT measurement has been reserved.



●When ⇌ disappears:

- The beeper will sound and the piercing nozzle will come forward.
- The sample in the STAT port will be aspirated and STAT measurement will start.
- The STAT measurement number will appear at the right side of <STAT No.>.



REFERENCE:

To perform another STAT measurement, press ↵ at this point. See step **3** in "2.5.1. Measuring a Sample During Normal Measurement" on page 2-26.

●"Results"

- The obtained STAT measurement result will be displayed on the screen and printed out.
- See "2.8. Displayed and Printed Reports" on page 2-43.

❷ Remove the sample from the STAT port.

- See step **5** in "2.5.1. Measuring a Sample During Normal Measurement" on page 2-27.

2.6 Control Measurement

2.6.1 Quality Control

Control measurement should be performed at regular intervals to check the status of the instrument and accuracy of measurement results. Use Canterbury HbA1c control (extendSURE Haemoglobin A1c Lyophilised Controls, assignment of standard values is based on JCCRM411) and HbA2/F control (extendSURE Haemoglobin F and A2 Controls, assignment of standard values is based on ADAMS A1C HA-8160 TP mode) , or commercially available controls that are specified by your distributor. For more information, contact your distributor.

2.6.2 Control Measurement

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used control and protective gloves in accordance with local regulations for biohazardous waste.

IMPORTANT:

- This section explains general methods for dissolving and diluting controls. For detailed instructions for preparing your controls, contact your distributor. Dilute the controls so that the hemoglobin concentration is between 75 mg/dL and 225 mg/dL.
- Carefully read the package insert that comes with the control before use.
- Prepare controls with a hemoglobin concentration between 75 mg/dL and 225 mg/dL. Inaccurate measurement results will be obtained if the control's hemoglobin level is outside this range.
- Be sure to use DILUENT 80 to dilute controls.
- Use controls before their expiration dates. Inaccurate measurement results will be obtained if controls are used beyond their expiration dates. Using expired controls may also seriously degrade the column, requiring its replacement.
- Store controls properly. Inaccurate measurement results will be obtained if controls are not properly stored. Improperly stored controls may also seriously degrade the column, requiring its replacement.
- Use the hemolysis control rack to measure controls.

Prepare: HbA1c control and/or HbA2/HbF control, CONTROL DILUTION SET 80 (RECONSTITUENT 80, DILUENT 80), sample containers (see step **3**), hemolysis control rack (label: H CTRL), barcode labels (when using the internal barcode reader) and protective gloves

* If sample rack transportation is set to "loop transportation", the start rack (START) is needed in addition to the hemolysis control rack.

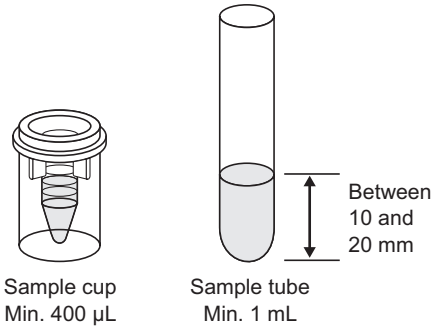
1 Prepare the control.

❶ Dissolve controls as described in the package insert that comes with the controls.

❷ Dilute the control with DILUENT 80.

❸ Add the diluted control to a sample container.

- The volume of control as shown on the right is required for measurement.

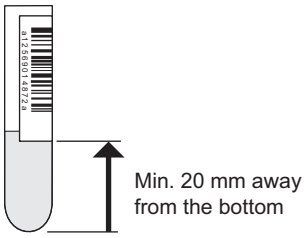


2 Label the sample tubes with barcode labels (when using the internal barcode reader).

Go to step **3** if not using the internal barcode reader.

● For sample cups with control:
Attach barcode labels to empty sample tubes.
See step **2** in "2.4.1. Preparing Samples" on page 2-17.

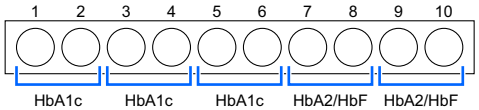
● For sample tubes with control:
Attach barcode labels to the sample tubes with control.
See step **2** in "2.4.1. Preparing Samples" on page 2-17.



3 Set the control in the hemolysis control rack.

❶ Set the sample containers in the correct ports of the hemolysis control rack.

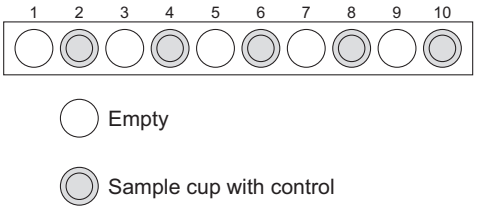
- The ports of this rack are factory-set as follows:
  Ports 1 to 6: For HbA1c controls
  Up to 3 sample containers with controls can be set.
  Ports 7 to10: For HbA2 and HbF controls
  Up to 2 sample containers with controls can be set.
  These port settings can be changed as needed (see "3.3.5. Setting the Measurement Conditions" on page 3-13).



Hemolysis control rack (factory-set)

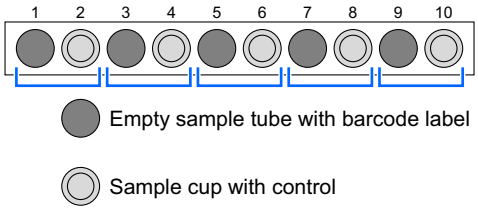
- See "● When preparing sample cups with sample:" ❷ of step **3** in "2.4.1. Preparing Samples" on page 2-18.

● For sample cups with control (when barcodes are NOT set):
Odd-numbered ports: Leave the ports empty.
Even-numbered ports: Sample cups with control



- For sample cups with control (when barcodes are set):

  Odd-numbered ports: Sample tubes with barcode labels
  [12.3 mm diameter]
  Use the adapter on the rack.
  [15 mm diameter]
  Remove the adapter.
  Even-numbered ports: Sample cups with control

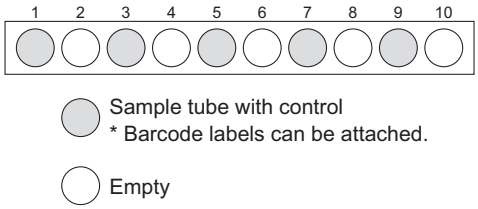


Example: The barcode of port 1 is assigned to the control in port 2.

NOTE:
To perform normal measurements following control measurement, be sure to set the samples in either normal rack, whole blood pair rack or hemolysis pair rack. **Do not** set whole blood samples in the unused ports of the hemolysis control rack to avoid seriously degrading the column. If whole blood is measured with the hemolysis control rack, it is recommended to replace the column with a new one.

- For sample tubes with control:

  Odd-numbered ports: Sample tube with control (attach barcode labels if needed)
  [12.3 mm diameter]
  Use the adapter on the rack.
  [15 mm diameter]
  Remove the adapter.
  Even-numbered ports: Leave the ports empty.



IMPORTANT:
Do not set a sample cup in the port next to a sample tube with control. The sample tube will be recognized for barcode reading and the control in the tube will not be measured. Also, the barcode of the sample tube will be assigned to the sample in the sample cup.

NOTE:
Set sample tubes with barcode labels in the hemolysis control rack with the barcode labels facing the rear of the rack.

4 Load the hemolysis control rack onto the sampler.

❶ Load the hemolysis control rack onto the sampler.

• See step **4** in “2.4.1. Preparing Samples” on page 2-19.

REFERENCE:

- If sample rack transportation is set to “loop transportation”:
  Load the empty start rack and then the hemolysis control rack onto the sampler.
- To perform normal measurements following control measurement:
  Load the hemolysis control rack and then normal racks onto the sampler.

5 Set the control measurement conditions (when needed).

Set the control measurement conditions listed below (see "3.3.5. Setting the Measurement Conditions" on page 3-13). If already set, skip to step **6**.

- Control expected values (required to use the control of a different lot)
- Control measurement count
- Control error range
- Operation if control error occurs

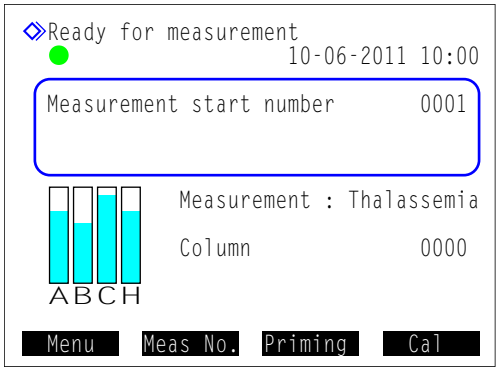
6 Set the measurement start number (when needed).

If you do not change the number, skip to step **7**.

REFERENCE:

- Measurement number assignment:
  In control measurements, the measurement start number is always reset to "0001" each time the standby screen appears, even if <Measurement start number> is set to <Continue from previous batch 1> or <Continue from previous batch 2> on the [Measurement number setup] screen.
- Control measurements are serially numbered for both HbA1c and HbA2/HbF controls. For example, when three controls are measured in the order of HbA1c, HbA2/HbF and HbA1c, these measurements are numbered "Cont A1c 0001", "Cont A2F 0002" and "Cont A1c 0003".

❶ On the standby screen, press Meas No..



❷ Press ↵.

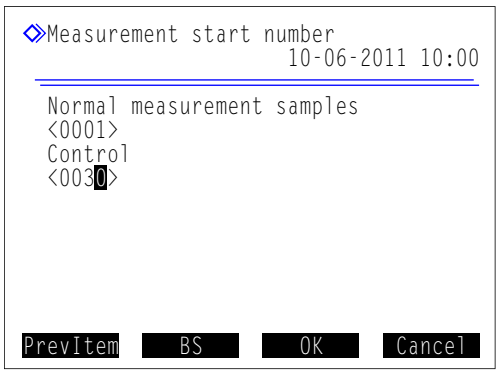
- The cursor will move to the <Control> field.

❸ Below <Control>, enter a measurement start number for control measurement.

- Range: 0000 to 9999

❹ Press OK.

- This saves your entry and will return you to the standby screen.



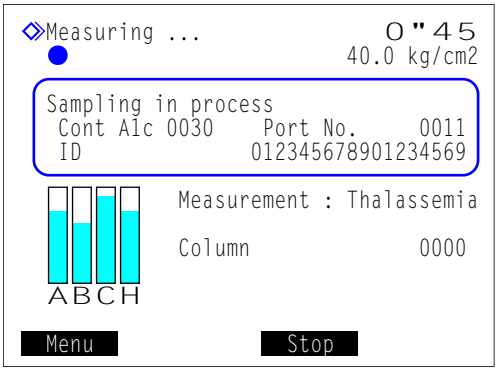
7 Start control measurement.

❶ On the standby screen, press ◇|◇.

- "Preparing for measurement" will appear and the sample rack will move to the aspiration position.

●"Measuring ..."

- One to three measurements will be performed per sample container, as selected in the <Control measurement count> setting (see "3.3.5. Setting the Measurement Conditions" on page 3-13).
- Control will not be stirred.



●"Results"

- The obtained results will be displayed on the screen and printed out.
- <Cont A1c> or <Cont A2F> shows the control measurement number.
- See "2.8. Displayed and Printed Reports" on page 2-43.

8 Once the control measurements are complete

❶ Check that the sample racks are not moving, and remove the sample racks from the rack unloading side of the sampler.

REFERENCE:

Control measurement results can be tabulated everyday and used to check trends in measurement results. See "3.7.3. Printing Accuracy Control Reports" on page 3-31.

2.7 Calibration

Calibration provides operation coefficients (calibration coefficients) for correcting measurement results. Use ARKRAY calibrator (CALIBRATOR 80, assignment of standard values is based on JCCRM411) for HbA1c calibration and use Canterbury calibrator (extendSURE Haemoglobin F and A2 Calibrators, assignment of standard values is based on ADAMS A1C HA-8160 TP mode) for HbA2/F calibration. For more information, contact your distributor.

- When calibration is required

When required	Description
After installing the instrument	Perform calibration before the instrument is used for the first time after installation.
After replacing the column	Measurement errors may occur due to differences among instruments or changes in environmental conditions. Perform calibration to eliminate potential errors.
When restarting the instrument after extended periods of disuse	
If control measurement results deviate from control expected values	

REFERENCE:

Deviations in control measurement results can be detected by setting <Control expected values> and <Control error range> to the appropriate values on the [Measurement condition setup] screen (see “3.3.5. Setting the Measurement Conditions” on page 3-13).

- Calibration methods

Calibration method	Description
Automatic calibration	Normal calibration method. The instrument measures two standard solutions (Low and High solutions), and uses the results to automatically determine the calibration coefficients. Standard values of the standard solutions can be set by: • Entering numbers using the numeric buttons, or • Reading the calibration information barcodes during measurement (when using the internal barcode reader).
User-specified coefficient setup	Set coefficients “a” and “b” of the correction formula, “Y=aX+b”, using the numeric buttons.

2.7.1 Performing Automatic Calibration

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

IMPORTANT:

- Carefully read the package insert that comes with the calibrator before use.
- Use the calibration rack to perform calibration.

REFERENCE:

- About dummy samples:
  Dummy samples are measured before standard solutions to obtain stable measurement results.
- To perform calibration using both the HbA1c and HbA2/HbF calibrators:
  Use two calibration racks. Set the HbA1c standard solutions in the first calibration rack, and the HbA2/HbF standard solutions in the second calibration rack. Dummy samples are not necessary for the second rack.

Prepare: Protective gloves

For other required items, see " Items required for calibration" on page 2-36.

Items required for calibration

Prepare the correct type of calibrator(s), the correct number of calibration rack(s), and others as listed below depending on the measurement item(s) to calibrate. The underlined items are not included with the instrument.

Measurement item(s) to calibrate	Calibrator *1	Calibration rack (CAL) *2	Dummy sample	Sample cup*3	When reading calibration information from barcodes*4
HbA1c	CALIBRATOR 80	x 1	Whole blood Sample tubes (x 1 to 5)	x 2	HbA1c barcode labels (x 2) Sample tubes (x 2)
HbA2	extendSURE Haemoglobin F and A2 Calibrators*1	x 1	Whole blood Sample tubes (x 1 to 5)	x 2	HbA2 barcode label (x 1) Sample tube (x 1)
HbF	extendSURE Haemoglobin F and A2 Calibrators*1	x 1	Whole blood Sample tubes (x 1 to 5)	x 2	HbF barcode label (x 1) Sample tube (x 1)
HbA1c HbA2	CALIBRATOR 80 extendSURE Haemoglobin F and A2 Calibrators*1	x 2	Whole blood Sample tubes (x 1 to 5)	x 4	HbA1c barcode labels (x 2) HbA2 barcode label (x 1) Sample tubes (x 3)
HbA1c HbF	CALIBRATOR 80 extendSURE Haemoglobin F and A2 Calibrators*1	x 2	Whole blood Sample tubes (x 1 to 5)	x 4	HbA1c barcode labels (x 2) HbF barcode label (x 1) Sample tubes (x 3)
HbA2 HbF	extendSURE Haemoglobin F and A2 Calibrators*1	x 1	Whole blood Sample tubes (x 1 to 5)	x 2	HbA2 barcode label (x 1) HbF barcode label (x 1) Sample tubes (x 2)
HbA1c HbA2 HbF	CALIBRATOR 80 extendSURE Haemoglobin F and A2 Calibrators*1	x 2	Whole blood Sample tubes (x 1 to 5)	x 4	HbA1c barcode labels (x 2) HbA2 barcode label (x 1) HbF barcode label (x 1) Sample tubes (x 4)

*1: For reconstitution and dilution, use the following materials:
Distilled water, CONTROL DILUTION SET 80

*2: If sample rack transportation is set to "loop transportation", the start rack (START) is needed in addition to the calibration rack(s).

*3: These sample cups are used to set standard solutions in the rack(s).

*4: Calibration information barcode labels are supplied with the calibrators.

1 Set the calibration conditions (when needed).

❶ Set <STD. solution measurement count> and <Calibration error range>. If you do not set these setup items, skip to step **2**.

- See "3.3.5. Setting the Measurement Conditions" on page 3-13.

2 Prepare dummy samples.

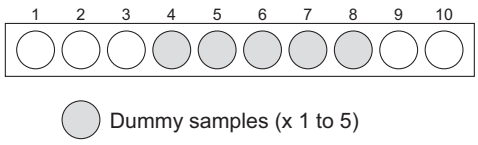
❶ Add dummy sample (whole blood) to sample tubes.

- Prepare 1 to 5 tubes with sample.
- See "2.4.1. Preparing Samples" on page 2-14.

Performing measurements with uncapped tubes may cause sample to splatter inside the instrument while spinning, jeopardizing subsequent measurements. It may also cause infection to the user or other individuals by pathogenic microbes.

❷ Set the dummy samples in ports 4 to 8 of the calibration rack.

- Use any of the ports 4 to 8.
- [12.3 mm diameter] Use the adapters on the rack.
  [15 mm diameter] Remove the adapters.
- When using two calibration racks to measure both the HbA1c and HbA2/HbF standard solutions, dummy samples do not need to be set in the calibration rack for HbA2/HbF.



IMPORTANT:

Do not set dummy samples in ports 9 and 10 to avoid seriously degrading the column. If whole blood is measured in these ports, it is recommended to replace the column with a new one.

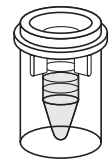
3 Prepare the standard solutions.

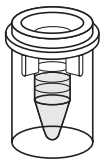
❶ Make sure you have the correct calibrator(s).

- HbA1c calibrator: For HbA1c
  HbA2/HbF calibrator: For both HbA2 and HbF

REFERENCE:

The HbA2/HbF standard solutions are used to perform calibration for HbA2, HbF or both. Select which measurement item(s) to calibrate.


Low solution
Min. 400 µL


High solution
Min. 400 µL

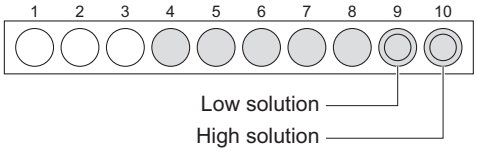
❷ Dissolve and dilute the Low and High solutions included in the calibrator.

❸ Add Low and High solution to separate sample cups.

- Each sample cup requires a minimum of 400 µL of solution.

❹ Set the standard solutions in the calibration rack(s).

- Low solution: Port 9
  High solution: Port 10
- When using two calibration racks, set the HbA1c standard solutions in one rack and the HbA2/HbF standard solutions in another rack.



4 Label the sample tubes with calibration information barcode labels.

The following information can be read from the calibration information barcode labels by the internal barcode reader:

- Standard values of the standard solutions
- Reagent information on the calibrator (lot number and expiration date)

If you want to use the numeric buttons instead of the internal barcode reader, skip to step **5**.

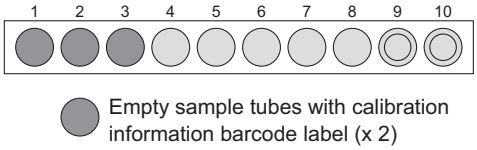
❶ Attach the correct calibration information barcode labels to empty sample tubes.

- Attach one label to each sample tube.

Item to calibrate	Label type
HbA1c	HbA1c barcode labels (x 2)
HbA2	HbA2 barcode label (x 1)
HbF	HbF barcode label (x 1)
HbA2 and HbF	HbA2 barcode label (x 1) HbF barcode label (x 1)

- See step **2** in “2.4.1. Preparing Samples” on page 2-17.

❷ Set the sample tubes in ports 1 to 3 of the calibration rack.



NOTE:
Set sample tubes with barcode labels in the calibration rack(s) with the barcode labels facing the rear of the rack(s).

- Use any of the ports 1 to 3.
- Set barcodes in any order.
- When using two calibration racks, set the labeled sample tubes in the respective racks.

IMPORTANT:
Set the HbA1c barcodes in the rack with the HbA1c standard solutions, and the HbA2 and/or HbF barcodes in the rack with the HbA2/HbF standard solutions. An incorrect combination of the label and rack may cause inaccurate measurement results.

5 Load the calibration rack(s) onto the sampler.

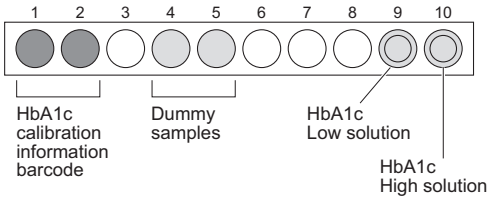
IMPORTANT:

Check again to make sure that the dummy samples and standard solutions are set in the proper ports. Calibration cannot be performed if the samples and solutions are set in the wrong ports.

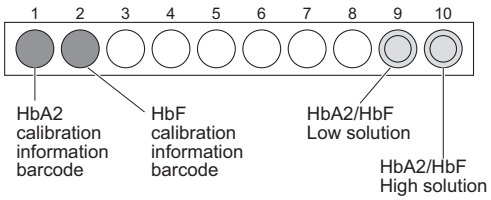
Ports 1 to 3: Calibration information barcode (when needed)
Ports 4 to 8: Dummy sample (whole blood)
Port 9: Low solution
Port 10: High solution

Example) When calibrating HbA1c, HbA2 and HbF

HbA1c: 1st rack



HbA2/HbF: 2nd rack



Dummy samples are not necessary for the 2nd rack.

❶ Load the calibration rack(s) onto the sampler.

- See step **4** in "2.4.1. Preparing Samples" on page 2-19.
- When using two calibration racks, load the rack for HbA1c calibration first, and then the rack for HbA2/HbF calibration.

IMPORTANT:

When measuring both the HbA1c and HbA2/HbF standard solutions, be sure to load the rack with the HbA1c solutions first. Loading the racks in the reverse order may cause inaccurate measurement results.

REFERENCE:

- If sample rack transportation is set to "loop transportation":
  Load the empty start rack and then calibration rack(s) onto the sampler.
- To perform normal measurement following calibration:
  Load the calibration rack(s) and then normal racks onto the sampler.

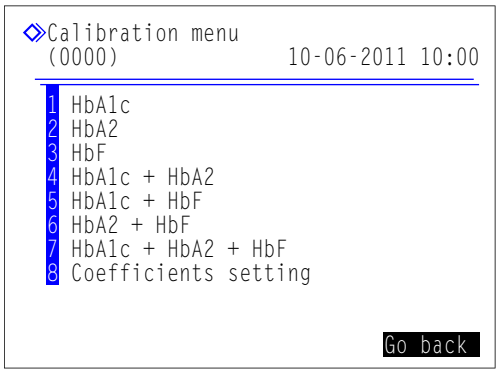
- To read the standard values from the calibration information barcodes:
  Skip to step **7**.

- To enter the standard values with the numeric buttons:
  Skip to step **6**.

6 Set the calibration information. [For the numeric button operation]

❶ On the standby screen, press Cal.

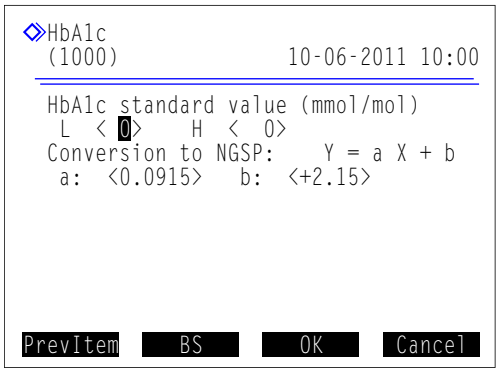
❷ Select an option for the measurement item(s) to calibrate from 1 - 7 on the screen.



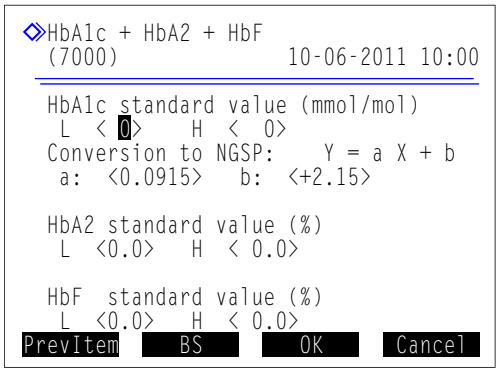
❸ Set the calibration conditions.

- See the table below.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.

When <1 HbA1c> is selected



When <7 HbA1c + HbA2 + HbF > is selected



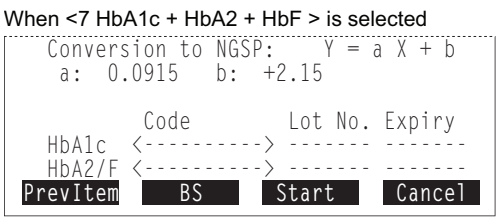
❹ Press OK .

- The current reagent information will appear.

Setup item	Description
HbA1c standard value (mmol/mol) HbA2 standard value (%) HbF standard value (%)	Enter the calibration standard values. Calibration standard values are written on the Standard value lists that come with the calibrators. [HbA1c] L: 0 to 99 (Default: **0**), H: 0 to 200 (Default: **0**) [HbA2] L: 0.0 to 9.9 (Default: **0.0**), H: 0.0 to 20.0 (Default: **0.0**) [HbF] L: 0.0 to 9.9 (Default: **0.0**), H: 0.0 to 20.0 (Default: **0.0**)
Conversion to NGSP	Enter coefficients “a” and “b” of the conversion formula, “Y=aX+b”, to convert HbA1c values from the IFCC unit (mmol/mol) to the NGSP unit (%). a: 0.0000 to 0.1500, b: -5.00 to 5.00 (Default: Those entered the last time)

❺ Below <Code>, check the current reagent code.

When <7 HbA1c + HbA2 + HbF > is selected



❻ To change the reagent code, enter the 10-digit code that is written on the Standard value list.

- If your entry is accepted, the lot number and expiration date will be updated.

NOTE:
If <Lot No.> and <Expiry> are not updated and still contain hyphens (---):
Your entry may be incorrect. Carefully check the reagent code and enter it again.

7 Start calibration.

❶ Start calibration.
- For the barcode operation: Press ◇|◇.
- For the numeric button operation: Press Start.

- The message “Preparing for measurement” will appear and the rack will be transported to the aspiration position.

NOTE:
If an error message appears:
The reagent information is invalid. Press OK. Check the type, expiration date, manufacturing date of the calibrator, and repeat from step **6-❻**.

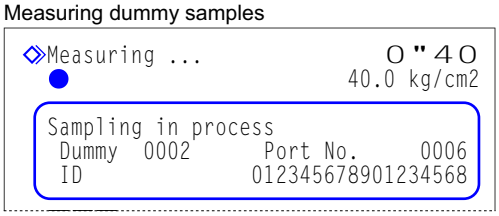
8 Check the measurement results.

● “Measuring ...”

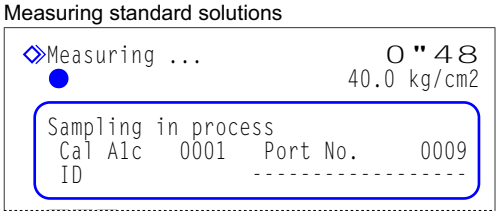
- Dummy samples, Low solution and High solution will be measured in that order.

REFERENCE:
About stirring:
Only dummy samples in sample tubes are stirred. The Low and High solutions are not stirred.

Measuring dummy samples



Measuring standard solutions



● “Results”
- The obtained measurement results will be displayed on the screen and printed out.
- See “2.8. Displayed and Printed Reports” on page 2-43.

9 Once the calibration is complete

❶ Check that the calibration rack(s) is not moving, and remove the rack(s) from the rack unloading side of the sampler.

2.7.2 Setting the Calibration Coefficients

❶ On the standby screen, press Cal, and then select <8 Coefficients setting>.

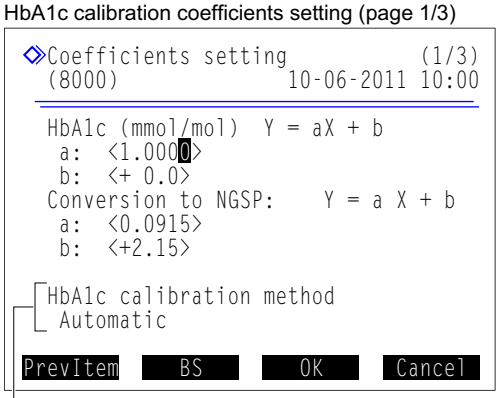
❷ Enter the calibration coefficients (“a” and “b”) as needed.
- See the table below.
- ↵ button: Moves the cursor to the next setup field, or goes to the next page in the order of HbA1c (page 1/3), HbA2 (page 2/3) and HbF (page 3/3).

❸ Press OK.
- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.
- This saves your entry and will return you to the [Calibration menu] screen.

❺ To return to the standby screen, press Go back.

HbA1c calibration coefficients setting (page 1/3)



The calibration method used for the most recent calibration

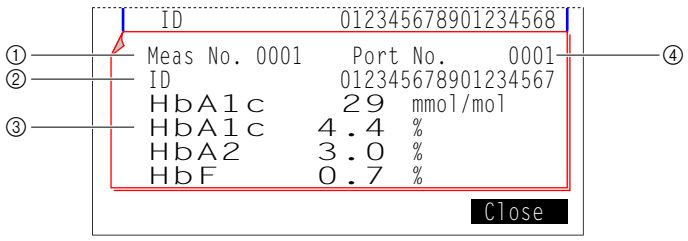
Setup item	Description
HbA1c (mmol/mol) HbA2 (%) HbF (%)	Enter <a> as the gradient and <b> as the intercept of the calibration coefficients. [HbA1c] a: 0.0000 to 1.5000 (Default: **1.0000**), b: -50.0 to 50.0 (Default: **0.0**) [HbA2] a: 0.0000 to 3.2000 (Default: **1.0000**), b: -5.00 to 5.00 (Default: **0.00**) [HbF] a: 0.0000 to 3.0000 (Default: **1.0000**), b: -5.00 to 5.00 (Default: **0.00**)
Conversion to NGSP	Enter coefficients “a” and “b” of the conversion formula, “Y=aX+b”, to convert HbA1c values from the IFCC unit (mmol/mol) to the NGSP unit (%). a: 0.0000 to 0.1500, b: -5.00 to 5.00 (Default: Those entered the last time)

2.8 Displayed and Printed Reports

2.8.1 Displayed Results Report

The instrument displays measurement result reports as shown below when results are obtained in normal measurement, STAT measurement, control measurement and automatic calibration. Press Close to close the result window. A new result window appears each time the next result is obtained even after it is closed.

Example



① Type of samples and measurement number

Measurement numbers (0000 to 9999) assigned to samples, control and standard solutions appear here.

Type of measurement	Indication example
Normal measurement	Meas No. 0001
STAT measurement	STAT No. 0001
Control measurement	Cont A1c 0001 Cont A2F 0001
Automatic calibration (dummy sample)	Dummy 0001
Automatic calibration (standard solution)	Cal A1c 0001 Cal A2F 0001 Cal A2 0001 Cal F 0001

REFERENCE:

- Control measurements are serially numbered for HbA1c and HbA2/HbF.
- Calibrations are serially numbered for HbA1c, HbA2, HbF and HbA2/HbF.

② ID

IDs appear here when the barcode reader reads IDs from barcode labels on sample tubes. Hyphen (-) fills in any unentered column in the ID containing less than 18 digits.

③ Measurement results

HbA1c, HbA2 and HbF measurement results appear here. Abnormal result messages are displayed if inaccurate measurement results were obtained (see “5.4. Abnormal Result Messages” on page 5-21). None of HbS, HbC, HbE and HbD appears here even if detected.

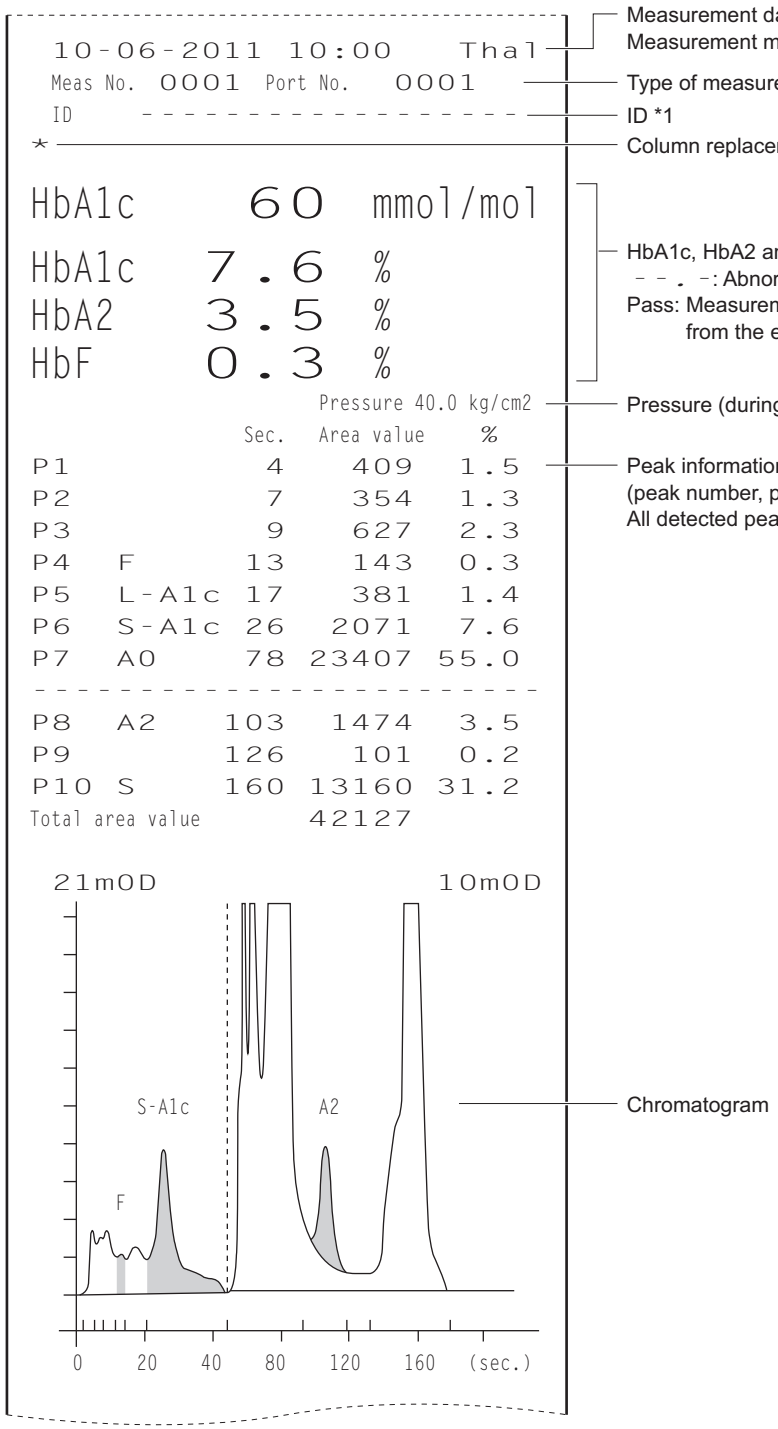
④ Port No.

Port numbers (0000 to 9999) assigned to samples, controls or standard solutions appear here.

2.8.2 Chromatogram Report

The instrument automatically prints out a chromatogram report each time it obtains a result in normal/STAT/control measurements and automatic calibration. The chromatogram report can be reprinted if needed. See “3.4.1. Printing/ Transmitting Results” on page 3-15.

Example



*1: See “2.8.1. Displayed Results Report” on page 2-43.

● Column replacement symbol

Usually, nothing is printed, but an "*" appears as in the example when it is time to replace the column.

● HbA1c, HbA2 and HbF measurement results

The following indications are included in printouts if inaccurate measurement results were obtained.

Indication	Description
--.-	An abnormal measurement result was obtained. "****** Abnormal Fraction ******" will be printed, and then below the chromatogram, a message about the abnormal value will be printed (see "5.4. Abnormal Result Messages" on page 5-21).
Pass	Measurement was not performed due to instructions from the external device.

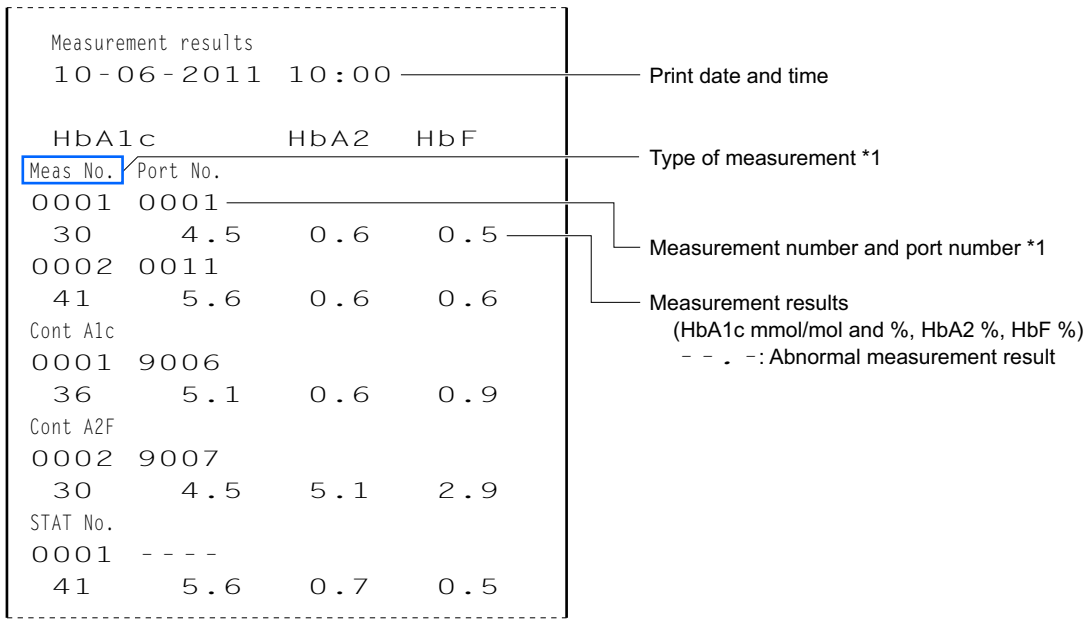
REFERENCE:

Reagent information can be added to the end of the measurement result reports. See "3.8. Reagent Information Settings" on page 3-38.

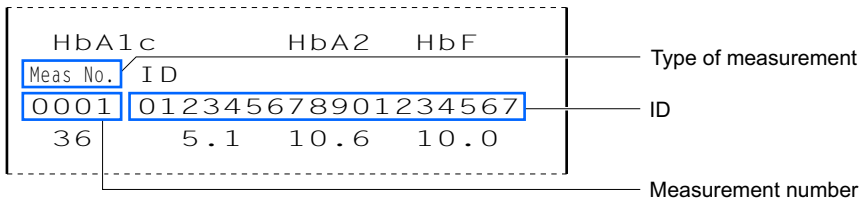
2.8.3 List of Measurement Results

The instrument automatically prints out a list of measurement results at the end of a batch of measurements. This report can be reprinted if needed (See “3.4.1. Printing/Transmitting Results” on page 3-15).

Example



Example (when using the internal barcode reader)



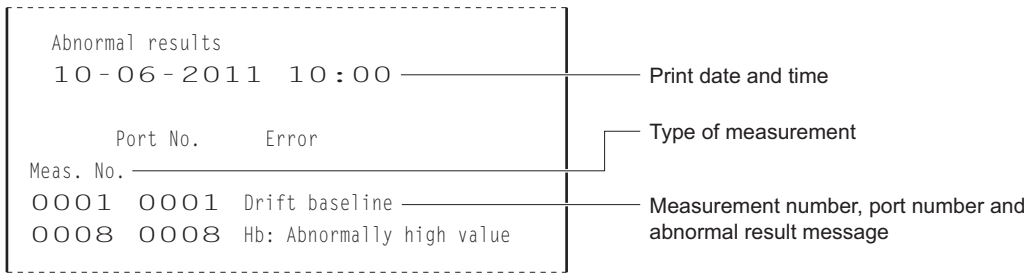
*1: See “2.8.1. Displayed Results Report” on page 2-43.

2.8.4 List of Abnormal Results

The list of abnormal results contains the measurement numbers and messages of the results for which "Abnormal Fraction" appeared on the measurement result reports. The instrument automatically prints this report at the end of a batch. This report can be reprinted if needed. See "3.6.3. Printing a List of Abnormal Results" on page 3-27.

REFERENCE:
Abnormal result messages: See "5.4. Abnormal Result Messages" on page 5-21.

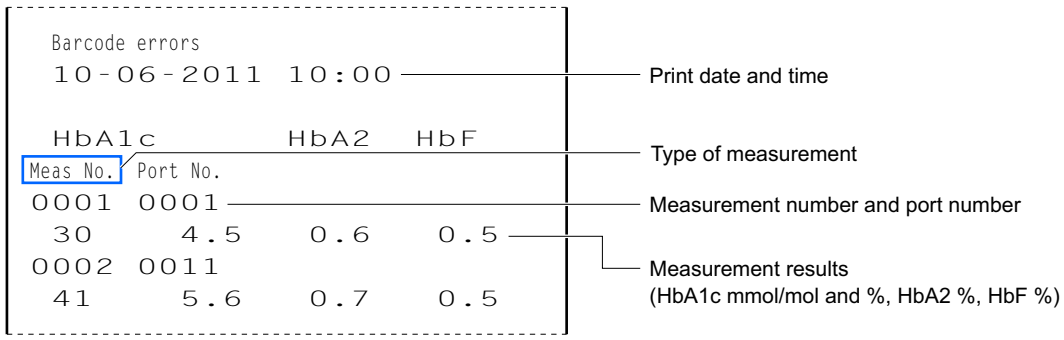
Example



2.8.5 List of Barcode Errors

The list of barcode errors contains measurement results for which the barcode was not correctly read. The instrument automatically prints this report at the end of a batch. This report can be reprinted if needed. See "3.6.2. Printing a List of Barcode Errors" on page 3-26.

Example



2.8.6 History of Warning/Error/Trouble

The history of warning/error/trouble contains the codes and messages of warnings (W:091 to W:095), errors and trouble that occurred.

REFERENCE:

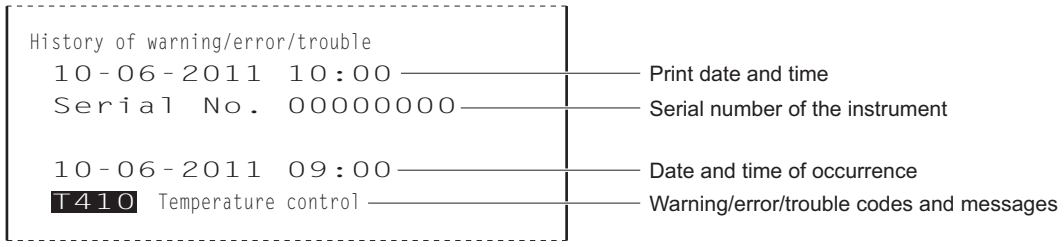
For more information about:

- Warnings, see “5.1. If a Warning Occurs” on page 5-2.
- Errors, see “5.2. If an Error Occurs” on page 5-9.
- Troubles, see “5.3. If Trouble Occurs” on page 5-13.

■During measurement

Warnings, errors and troubles that occur during measurement are printed in a single list when a batch of measurements is complete.

Example



■Outside of measurement

Warnings, errors and troubles are printed each time they occur while the instrument is starting up, the standby screen appears on the display, or menu functions are being used.

Example

■When the history of warning/error/trouble is needed

If needed, warnings, errors and troubles that have occurred at a specified interval can be printed out in a single list . See “3.6.1. Printing History of Warning/Error/Trouble” on page 3-25. For the printed report example, see “■ During measurement” on this page.

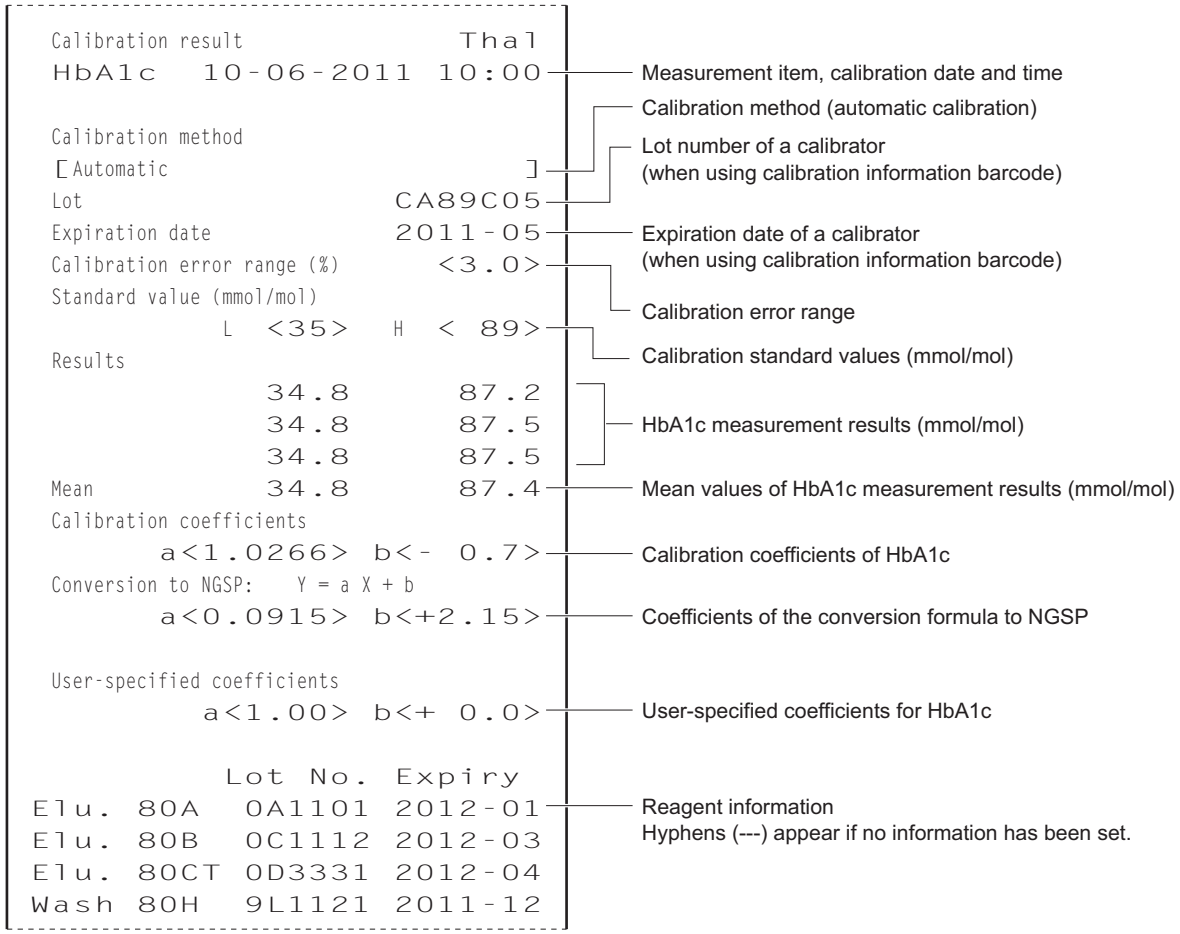
2.8.7 Calibration Results Report

The instrument automatically prints calibration results report in the following cases:

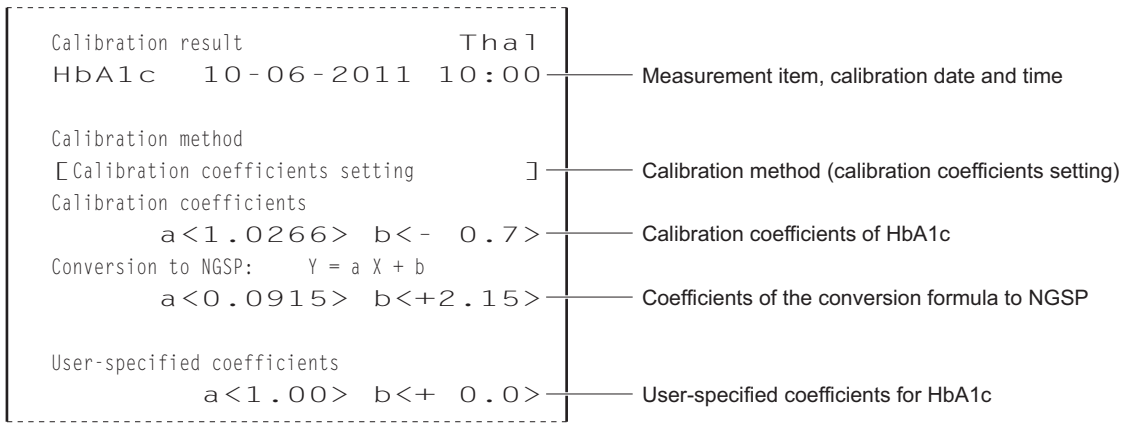
- When calibration results have been obtained after calibration
- Before starting measurement of samples

This report can be reprinted if needed (see “3.6.4. Printing Calibration Result Report” on page 3-28).

Example: Automatic calibration (HbA1c)



Example: Calibration coefficients setting (only HbA1c settings are listed here)



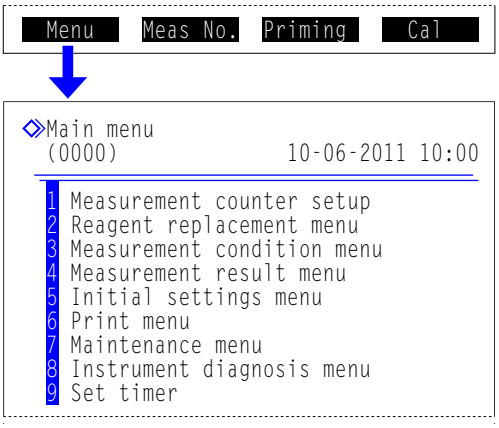
Chapter 3 Auxiliary Operations

This chapter describes auxiliary operations such as how to print and view measurement results, set measurement conditions, set up the instrument, and perform diagnostic checks.

3.1 Main Menu Screen

To go to the [Main menu] screen, press Menu on the standby screen. On the [Main menu] screen, you can make instrument settings, review measurement results and perform operations necessary for maintenance tasks. This section briefly describes the options listed on the [Main menu] screen.

* Screen numbers are given in ( ).



● [Measurement counter setup] screen (1000)

Description	Page
Sets the column measurement counter to a desired number.	3-6

● [Reagent replacement menu] screen (2000)

Option	Description	Page
Eluent A (2100)	Displays precautions on replacing the eluent A pack and automatically resets the remaining reagent graphic on the standby screen after replacement of the pack.	4-3
Eluent B (2200)	Displays precautions on replacing the eluent B pack and automatically resets the remaining reagent graphic on the standby screen after replacement of the pack.	4-3
Eluent CT (2300)	Displays precautions on replacing the eluent CT pack and automatically resets the remaining reagent graphic on the standby screen after replacement of the pack.	4-3
Hemolysis washing solution (2400)	Resets the remaining reagent graphic on the standby screen automatically after replacement of the hemolysis washing solution bottle.	4-7
Column (2500)	Displays instructions on how to replace the column and resets the column measurement counter after replacement of the column.	4-11
Edit reagent information (2600)	Sets information on eluents, hemolysis washing solution and calibrator.	3-38

● [Measurement condition menu] screen (3000)

Option	Description (**default bolded**)	Page
User-specified coefficient setup(3100)	Sets coefficients “a” and “b” of the correction formula for HbA1c, HbA2 and HbF, “Y=aX+b”.	3-7
	HbA1c (mmol/mol) a: 0.00 to 1.50 (**1.00**), b: -50.0 to 50.0 (**0.0**) HbA2 (%) a: 0.00 to 3.00 (**1.00**), b: -5.00 to 5.00 (**0.00**) HbF (%) a: 0.00 to 3.00 (**1.00**), b: -5.00 to 5.00 (**0.00**)	
Timer setup(3200)	Sets the startup and shutdown timers.	3-8
	Startup timer: **Use**, Not use Monday to Sunday: Start, **Not start** (Startup time) **00:00** to 23:59 Shutdown timer: **00:00** (Not use) to 23:59	
Measurement number setup (3300)	Configures the measurement numbering system.	3-11
	Measurement start number: **Continue from previous batch 1** Continue from previous batch 2 Initialize for every batch Measurement number: **Assign to samples**, Assign to ports	

Option	Description (**default bolded**)	Page
Measurement condition setup (3400)	Sets control measurement parameters, calibration conditions, pressure unit for the column and error trigger conditions.	3-13
	Control expected values HbA1c (mmol/mol) L: 0 to 99 mmol/mol (**0 mmol/mol**) H: 0 to 200 mmol/mol (**0 mmol/mol**) HbA2 (%) L: 0.0 to 9.9% (**0.0%**) H: 0.0 to 99.0% (**0.0%**) HbF (%) L: 0.0 to 9.9% (**0.0%**) H: 0.0 to 99.0% (**0.0%**) Control error range HbA1c (mmol/mol) L: 0 to 99 mmol/mol (**3 mmol/mol**) H: 0 to 99 mmol/mol (**4 mmol/mol**) HbA2 (%) L: 0.0 to 9.9% (**0.3%**) H: 0.0 to 9.9% (**0.5%**) HbF (%) L: 0.0 to 9.9% (**0.3%**) H: 0.0 to 9.9% (**0.5%**) Control measurement count: 1 to 3 times (**3 times**) Control solution assignment Port 1-2: **HbA1c**, HbA2/F Port 3-4: **HbA1c**, HbA2/F Port 5-6: **HbA1c**, HbA2/F Port 7-8: HbA1c, **HbA2/F** Port 9-10: HbA1c, **HbA2/F** Operation if control error occurs: **Stop measurement**, No action, Issue warning Pressure unit: **kg/cm2**, MPa STD. solution measurement count: 1 to 3 times (**3 times**) Calibration error range (%): HbA1c: 0.0 to 9.9% (**3.0%**) HbA2: 0.0 to 99.9% (**15.0%**) HbF: 0.0 to 99.9% (**30.0%**) Column degradation: **Use**, Not use Misread barcodes: 0 to 150 times (**0 time**) Sample tube spin failures: 0 to 150 times (**0 time**)	

● [Measurement result menu] screen (4000)

Option	Description (**default bolded**)	Page
Print (4100)	Prints out measurement results and chromatograms.	3-15
	Date (DD-MM-YY): Range of measurement dates (01-01-00 to 31-12-99) Measurement: All, **Normal & STAT measurements**, Normal measurement, STAT measurement, Control measurement Results: **All**, Normal results only, Include abnormal results, Barcode misread Range of results: **All**, Meas. No., Port No., ID	
Print list (4200)	Prints out a list of measurement results. * For information on the setup items, see [Print] above.	3-15
Transmit (4300)	Transmits measurement results to the external device. * For information on the setup items, see [Print] above.	3-15
View (4400)	Displays measurement results stored in the memory of the instrument. You can also edit IDs of measurement results and make settings for control measurement results. * For information on the setup items, see [Print] above.	3-18
Delete (4500)	Deletes measurement results and history of warnings, errors and troubles from the memory.	3-21
	Items to delete: **All**, Normal & STAT measurements, Control measurement, Warning/error/trouble	

● [Initial settings menu] screen (5000)

Option	Description (**default bolded**)	Page
Date and time setup (5100)	Sets the date and time of the internal clock. Date (DD-MM-YY): 01-01-00 to 31-12-99 (**Current date**) Time (24H): 00:00 to 23:59 (**Current time**)	3-22
Printer setup (5200)	Makes printer settings. Use/Not use: **Use**, Not use Peak information: **Print**, Not print Chromatogram: **Print**, Not print Data list: **Print**, Not print Reagent information: Batch, Each measurement, **Not print**	3-23
External output setup (5300)	Activates or deactivates external output. Use/Not use: Use, **Not use**	3-24
Beeper volume setting (5400)	Controls the volume of the beeper that alerts you to a warning, error or trouble. Beeper volume: 00 to 09 (**05**)	3-24

● [Print menu] screen (6000)

Option	Description (**default bolded**)	Page
History of warning/ error/trouble (6100)	Prints out a history of warnings, errors and troubles that have occurred in the set period of time. Date (DD-MM-YY): Range of dates of occurrence (01-01-00 to 31-12-99)	3-25
Barcode errors (6200)	Prints out a list of measurement results for which the barcodes were misread. Date (DD-MM-YY): Measurement date (01-01-00 to 31-12-99)	3-26
Abnormal results (6300)	Prints out a list of abnormal measurement results and messages about the abnormal values. Date (DD-MM-YY): Measurement date (01-01-00 to 31-12-99)	3-27
Calibration result (6400)	Prints out the most recent calibration result (calibration coefficients).	3-28
Parameter settings (6500)	Prints out the current parameter settings of the instrument.	3-28

● [Maintenance menu] screen (7000)

Option	Description	Page
Tube wash (7100)	Washes the tubes.	4-27
Piercing nozzle maintenance (7200)	Moves the piercing nozzle to a position that makes it easy to replace or clean.	4-16 4-31
Dil. and wash. containers cleaning (7300)	Drains the dilution and washing containers in preparation for cleaning them.	4-35 4-38
Sample tube spin unit maintenance (7400)	Moves the sample tube spinning unit to a position that makes it easy to clean.	4-33
Drain menu (7500)	Eluent A (7510): Drains fluid from the eluent A chamber.	1-36 4-48
	Eluent B (7520): Drains fluid from the eluent B chamber.	
	Eluent CT (7530): Drains fluid from the eluent CT chamber.	
	Hemolysis washing solution (7540): Drains hemolysis washing solution from the tube.	

Option	Description	Page
Maintenance log menu (7600)	Piercing nozzle (7610): Allows you to record the dates when maintenance tasks for the piercing nozzle were performed.	4-44
	Dilution and washing containers (7620): Allows you to record the dates when maintenance tasks for the dilution and washing containers were performed.	
	Others (7630): Allows you to record the dates when the nozzle mesh filters and drain pinch valve tubes were replaced.	
Maintenance information (7700)	Displays the dates that maintenance tasks were last performed on parts that require periodic maintenance and the number of measurements since those dates.	4-45

- [Instrument diagnosis menu] screen (8000)

Option	Description (**default bolded**)	Page
Flow test menu (8100)	All (8110): Tests the drive unit, sample introduction flow and drain flow once each.	3-29
	Drive unit test (8120): Tests the drive unit.	3-30
	Sample introduction flow test (8130): Tests the sample introduction flow.	
	Drain flow test (8140): Tests the drain flow.	
Accuracy control (8200)	Prints out statistical information on control measurements and sample measurements.	3-31
	Date: Range of measurement dates (01-01-00 to 31-12-99)	
Monitor print (8300)	Prints out the changes in light absorption of the optical unit over the last 10 minutes.	3-32
Analysis section check (8400)	Checks that the analysis section is working properly.	3-33
Reproducibility test menu (8500)	Whole sample measurement (8510): Repeatedly measures a particular whole blood sample and displays statistical information.	3-34
	Hemolysis sample measurement (8520): Measures the same hemolysis sample or hemolysis control divided into multiple sample containers and displays statistical information.	3-36

- [Set timer] screen (9000)

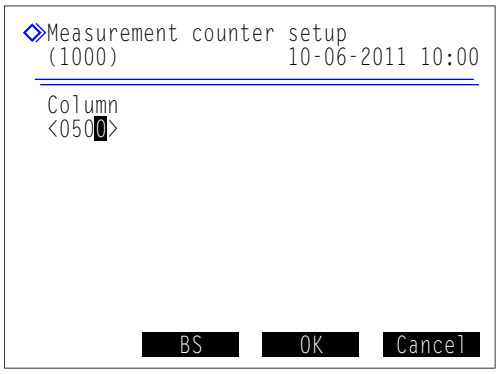
Description	Page
Schedules the instrument to enter sleep mode after measurement and start up automatically at a set time on a set day.	3-9

3.2 Measurement Counter Setup

This section describes how to set the column measurement counter. This counter appears in <Column> on the standby screen. Usually, the counter should be reset to “0000” after the column has been replaced with a new one. If you wrongly reset the counter, follow the instructions described below to set the counter to a desired number.

❶ On the standby screen, select Menu, and then <1 Measurement counter setup>.

❷ Below <Column>, enter a number.



❸ Press OK.
- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.
- This saves your entry and will return you to the [Main menu] screen.

❺ To return to the standby screen, press Go back.

3.3 Measurement Conditions

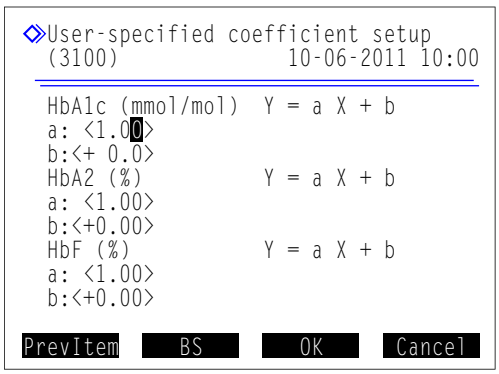
3.3.1 Setting the User-specified Coefficients

Set coefficients “a” and “b” of the correction formula for HbA1c, HbA2 and HbF, “Y=aX+b”.

❶ On the standby screen, select Menu, <3 Measurement condition menu> and <1 User-specified coefficient setup> in that order.

❷ Enter coefficients.

- ↵ button: Moves the cursor to the next setup field.



Setup item	Range (**default bolded**)
HbA1c (mmol/mol)	a: 0.00 to 1.50 (**1.00**)
	b: -50.0 to 50.0 (**0.0**)
HbA2 (%)	a: 0.00 to 3.00 (**1.00**)
	b: -5.00 to 5.00 (**0.00**)
HbF (%)	a: 0.00 to 3.00 (**1.00**)
	b: -5.00 to 5.00 (**0.00**)

❸ Press OK.

- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.

- This saves your entries and will return you to the [Measurement condition menu] screen.

❺ To return to the standby screen, press Go back twice.

3.3.2 Setting the Timer Conditions

● Startup timer

The startup timer starts the instrument up automatically at the set time. Different startup times can be set for each day. The timer can also be set so that the instrument does not start up at all on certain days such as holidays.

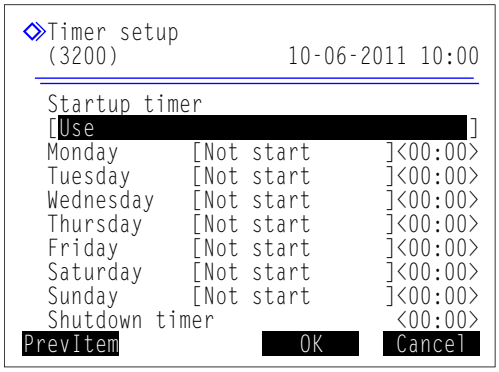
● Shutdown timer

You can set the amount of time until the instrument enters sleep mode when no operations are performed with the standby screen displayed.

❶ On the standby screen, select Menu, <3 Measurement condition menu> and <2 Timer setup> in that order.

❷ Set the startup timer and shutdown timer.

- See the table below.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.



❸ Press OK.

- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.

- This saves your entries and will return you to the [Measurement condition menu] screen.

❺ To return to the standby screen, press Go back twice.

Setup item	Description (**default bolded**)
Startup timer	**Use:** Activates the startup timer. Not use: Does not activate the startup timer.
Monday to Sunday	When <Use> is selected for <Startup timer>, select whether to start up the instrument or not on each day of the week. Start: Automatically starts up the instrument. Enter the startup time. Time range: **00:00** to 23:59 **Not start**: Does not start up the instrument automatically.
Shutdown timer	Set the amount of time until the instrument enters sleep mode when no operations are performed with the standby screen displayed. Set to “00:00” if you do not use the shutdown timer. Range: **00:00** (**Not use**) to 23:59

3.3.3 Setting the Timer

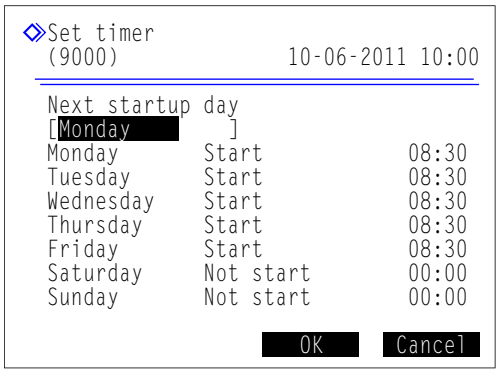
The instrument can be scheduled to enter sleep mode the moment that measurement or tube washing finishes. When using the startup timer, you can select the day to start up the instrument next time. The instrument then turns on automatically at the set time on the day.

■When using the startup timer

Follow the instructions described below when <Startup timer> is set to <Use> on the [Timer setup] screen (see "3.3.2. Setting the Timer Conditions" on page 3-8).

❶ While the standby screen is displayed or during measurement, select Menu, and then <9 Set timer>.

❷ Below <Next startup day>, select the day the next time the instrument starts up.
- **Hyphen** button: Changes the option.



❸ Press OK.

●When starting these steps from the standby screen:
The instrument will immediately enter sleep mode. It starts up automatically at the set time on the day selected in step ❷.

●When starting these steps during measurement:
The standby switch will alternately light green and orange. The instrument will enter sleep mode when measurement or tube washing finishes. It will start up automatically at the set time on the day selected in step ❷.

REFERENCE:
The <Next startup day> setting on this screen overrides the <Startup timer> setting on the [Timer setup] screen. For example, if the startup timer has been set to <Start> on Monday through Friday and you set <Next startup day> to <Thursday> on Monday, the instrument starts up on Thursday but not on Tuesday and Wednesday.

■When NOT using the startup timer

Follow the instructions described below when <Startup timer> is set to <Not use> on the [Timer setup] screen (see "3.3.2. Setting the Timer Conditions" on page 3-8).

REFERENCE:
Press the standby switch to turn off the power while the standby screen is displayed or while the instrument is warming up, instead of using the procedure below.

❶ During measurement, select Menu, and then <9 Set timer>.
- The message "Enter sleep mode?" will appear.

❷ Press OK.
- The instrument will enter sleep mode when measurement or tube washing finishes.

■To cancel the timer setting

The standby switch alternately lights green and orange when the timer is set.

❶ Select Menu, and then <9 Set timer>.
- The timer setting will be canceled and the standby switch will light green.

■To start the instrument from sleep mode

The standby switch lights orange during sleep mode.

❶ Press any button except ⏻.
- The message “Turn on the power?” will appear.

❷ Press OK.
- The instrument starts warming up.

3.3.4 Configuring the Measurement Numbering Method

● Measurement start number

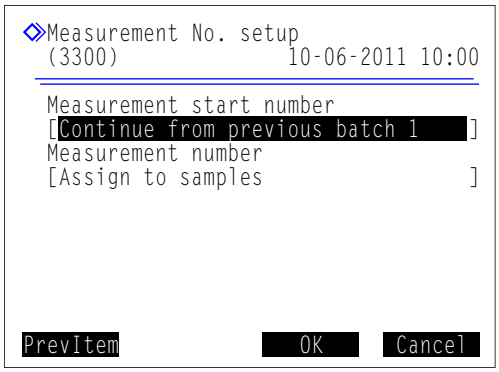
Set how the measurement start number is determined for the next batch.

● Measurement number

Set whether to assign measurement numbers to samples or ports.

❶ On the standby screen, select Menu, <3 Measurement condition menu> and <3 Measurement number setup> in that order.

❷ Set how to assign the measurement start number and measurement numbers.
- See the table below.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.



❸ Press OK.
- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.
- This saves your entries and will return you to the [Measurement condition menu] screen.

❺ To return to the standby screen, press Go back twice.

Setup item	Description (**default bolded**)
Measurement start number	**Continue from previous batch 1**: Sets measurement numbers which continue from the previous batch. The measurement start number is reset to “0001” the next time the power is turned on. Continue from previous batch 2: Sets measurement numbers which continue from the previous batch. The next time the power is turned on, measurement numbers continue from the batch that was in process before the power is turned off. Initialize for every batch: Resets the measurement start number to “0001” at the beginning of each batch.
Measurement number	**Assign to samples**: Assigns measurement numbers to samples. Assign to ports: Assigns measurement numbers to all of the ports regardless of whether the ports have samples in them or not. See [IMPORTANT] on the next page.

IMPORTANT:

Note when setting <Measurement number> to <Assign to ports>:

- If you manually set the measurement start number to any number other than “0001” (see step **1** in “2.4.2. Measuring Samples” on page 2-20), set samples for the first sample rack only in ports of the same number as the last digit in the measurement start number, or in ports of a higher number than that. Samples set in ports of a lower number than the last digit will not be measured. This is because measurement operations are managed so that the port number corresponds to the last digit of the measurement number.

  Example: For a measurement start number of “0005”, the first sample rack is processed as follows:
  Ports 1 to 4: Measurements are not performed. Ports 5 to 10: Measurements are performed.

- If a sample is not set in the port of the same number as the last digit of the measurement start number, the first measurement number is determined as in the following steps:
  1) The last digit of the measurement start number is changed to “0”.
  2) The port number of the first detected sample is added to the number obtained in step 1).

  Example: Measurement start number: 3005, Ports 5 and 6: No samples, Port 7: Sample set
  In this case, the first measurement number is “3007”.

3.3.5 Setting the Measurement Conditions

Set calibration conditions, control measurement parameters, pressure unit for the column and error trigger conditions.

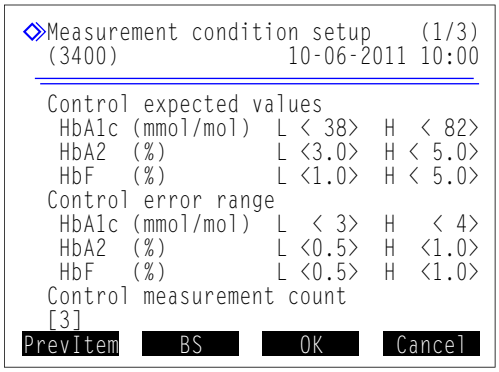
❶ On the standby screen, select Menu, <3 Measurement condition menu> and <4 Measurement condition setup> in that order.

❷ Set the setup items.

- See the table on the next page.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.

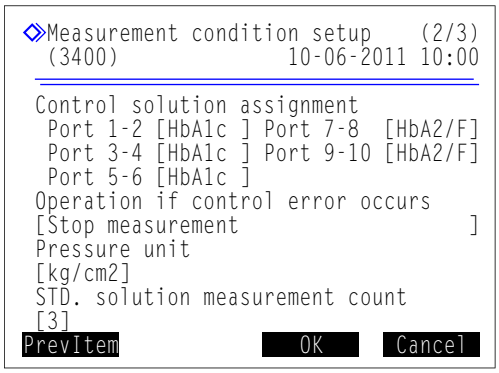
REFERENCE:

- To go to page 2/3:
  Place the cursor in the <Control measurement count> field and press ↵.
- To go to page 3/3:
  Place the cursor in the <HbA1c (mmol/mol) L> field of <Control expected values> and press PrevItem.



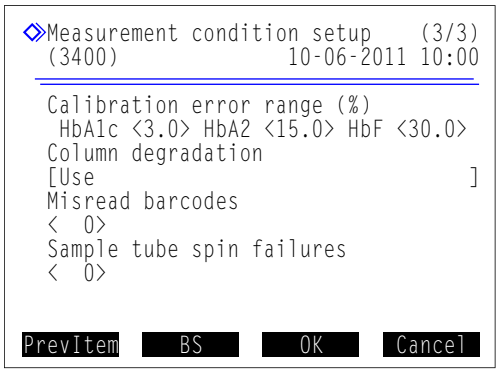
❸ Press OK.

- The message “Settings changed. Save setting changes?” will appear.



❹ Press OK.

- This saves your entries and will return you to the [Measurement condition menu] screen.



❺ To return to the standby screen, press Go back twice.

Setup item	Description (**default bolded**)
Control expected values (mmol/mol)	Set control expected values of the controls you are using. These values are written on the package inserts of the controls. HbA1c (mmol/mol) L: 0 to 99 mmol/mol (**0 mmol/mol**) H: 0 to 200 mmol/mol (**0 mmol/mol**) HbA2 (%) L: 0.0 to 9.9% (**0.0%**) H: 0.0 to 99.0% (**0.0%**) HbF (%) L: 0.0 to 9.9% (**0.0%**) H: 0.0 to 99.0% (**0.0%**)
Control error range (mmol/mol)	Set the error detection ranges used in control measurements. The instrument issues a warning if the difference between the obtained control measurement result and <Control expected values> exceeds the values set here. HbA1c (mmol/mol) L: 0 to 99 mmol/mol (**3 mmol/mol**) H: 0 to 99 mmol/mol (**4 mmol/mol**) HbA2 (%) L: 0.0 to 9.9% (**0.3%**) H: 0.0 to 9.9% (**0.5%**) HbF (%) L: 0.0 to 9.9% (**0.3%**) H: 0.0 to 9.9% (**0.5%**)
Control measurement count	Set the number of times for measuring the control in a single sample container. Up to 3 measurements can be performed per sample container, so you can reduce the volume of controls used for control measurements. Range: 1 to 3 times (**3 times**)
Control solution assignment	Assign HbA1c or HbA2/F to each port of the control rack. Port 1-2: **HbA1c**, HbA2/F, Port 3-4: **HbA1c**, HbA2/F Port 5-6: **HbA1c**, HbA2/F, Port 7-8: HbA1c, **HbA2/F** Port 9-10: HbA1c, **HbA2/F**
Operation if control error occurs	Select the action to take place when the difference between the obtained control measurement result and <Control expected values> exceeds <Control error range>. **Stop measurement**: Issues W:071, W:072 or W:073 and stops measurements. Issue warning: Issues W:011, W:012 or W:013, but continues measurements. No action: Continues measurements without issuing a warning.
Pressure unit	Select the pressure unit for the column. Options: **kg/cm2**, MPa
STD. solution measurement count	Set the number of times to measure each of the Low and High solutions for automatic calibration. Range: 1 to 3 times (**3 times**)
Calibration error range (%)	Set the error detection ranges used in automatic calibration. HbA1c: 0.0 to 9.9% (**3.0%**) HbA2: 0.0 to 99.9% (**15.0%**) HbF: 0.0 to 99.9% (**30.0%**)
Column degradation	Set whether or not to notify the user by a message that the column requires replacement when the column measurement counter passes a preset number. Options: **Use**, Not use
Misread barcodes	Set the number of misread barcode errors in a batch at which the instrument issues W:081 and stops measurement. If set to “0”, measurement does not stop regardless of times the error occurs. Range: 0 to 150 times (**0 time**)
Sample tube spin failures	Set the number of sample tube spin failures in a batch at which the instrument issues W:082 and stops measurement. If set to “0”, measurement does not stop regardless of times the failure occurs. Range: 0 to 150 times (**0 time**)

3.4 Measurement Results

This section describes how to print, transmit, review and delete measurement results stored in the memory of the instrument.

REFERENCE:

- The instrument stores up to 500 measurement results obtained by the following measurements in the memory: normal measurement, STAT measurement, control measurement, calibration (dummy sample and standard solution), reproducibility test and analysis section check. If the number of results in the memory exceeds 500, the newest result overwrites the oldest one. Note that deleted results can never be retrieved.
- Calibration results printing instructions: See “3.6.4. Printing Calibration Result Report” on page 3-28.

3.4.1 Printing/Transmitting Results

This section describes how to print chromatogram reports and a list of measurement results, and also transmit results to the external device. You can choose to print/transmit all measurement results or individually specified measurements by type or number to allow printing/transmitting specific results only. The same procedure is used for printing and transmission, so the following instructions include the screen images for printing only.

REFERENCE:

Chromatogram report: See “2.8.2. Chromatogram Report” on page 2-44.
List of measurement results: See “2.8.3. List of Measurement Results” on page 2-46.

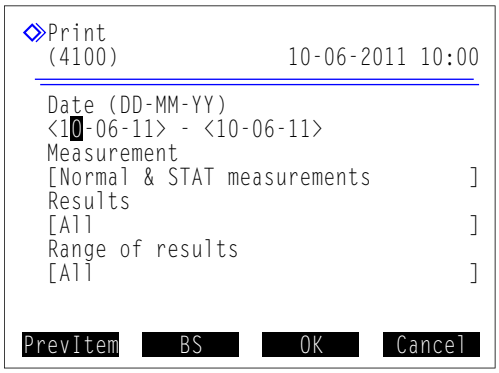
❶ On the standby screen, select Menu, and then <4 Measurement result menu>.

❷ On the [Measurement result menu] screen, select one of the following:

- <1 Print>: Prints chromatogram reports.
  <2 Print list>: Prints a list of measurement results.
  <3 Transmit>: Transmits the results to the external device.

❸ Set the search conditions for the measurement results you want to print/transmit.

- See the table on the next page.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.



Setup item	Description (**default bolded**)
Date (DD-MM-YY)	Set a range of measurement dates. The end (right) date must be the same as or later than the start (left) date. Settable range: 01-01-00 to 31-12-99
Measurement	Select the type of measurement from: **Normal & STAT measurements**, All, Normal measurement, STAT measurement, Control measurement
Results	Select the type of results from: **All**: All results Normal results only: Normal results only Include abnormal results: Normal and abnormal results (Results for misread barcodes are not included.) Barcode misread: Barcode misread results only
Range of results	Select how you want to specify a range of results from: **All**: All results, Meas. No.: Measurement number Port No.: Port number, ID: ID

❹ Press OK.

- If <All> is selected for <Range of results>, printing/transmission will start.
- If another option is selected for <Range of results>, go to step ❺.

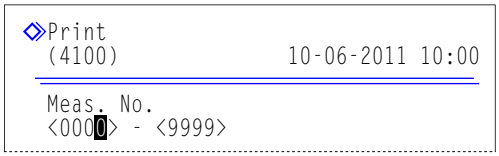
REFERENCE:

- If "None found." appears on the display:
  No match is found in the memory. Press OK to return to the screen shown in step ❸.
- Press Stop or ▽ to stop printing/transmission.

❺ Set the range of measurement results to print/transmit according to the option set in <Range of results>.

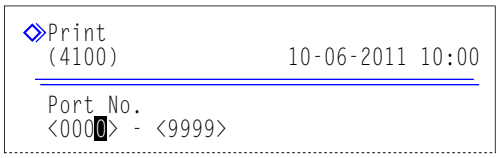
●When <Meas. No.> is selected:

- Set a range of measurement numbers.
- Settable range:0000 to 9999
- ↵ button: Moves the cursor from the start number to the end number.



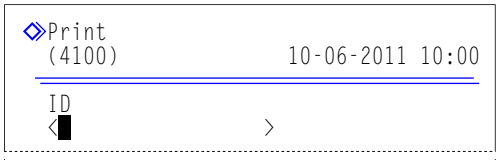
●When <Port No.> is selected:

- Set a range of port number.
- Settable range: 0000 to 9999



●When <ID> is selected:

- Enter an ID.
- See "● Entering IDs" on page 1-44.
- IDs can also be entered with the optional hand-held barcode reader.



❻ Press OK .

- Printing/transmission will start for the selected measurement results.
- The [Measurement result menu] screen will appear again when printing is complete.

REFERENCE:

If “None found.” appears on the display:

No match is found in the memory. Press OK to return to the screen shown in step ❸.

❼ To return to the standby screen, press Go back twice.

3.4.2 Reviewing Results

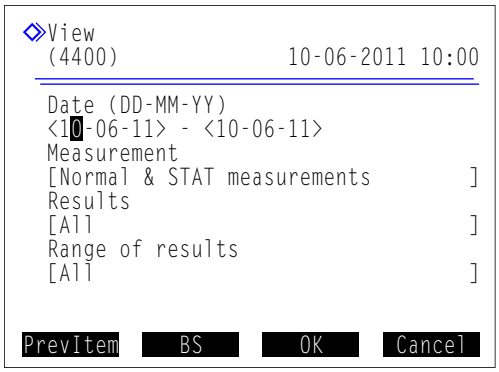
Measurement results stored in the memory can be reviewed on the display. You can choose to view all measurement results in order or individual measurement results specified by type or number of the measurement. Peak information and chromatograms for searched results can also be displayed. IDs shown as a series of hyphens due to barcode misread can be modified. Settings for accuracy control and control expected values can be made for individual control measurement results.

■Reviewing measurement results

❶ On the standby screen, select Menu, <4 Measurement result menu> and <4 View> in that order.

❷ Set the search conditions for the measurement results you want to review.

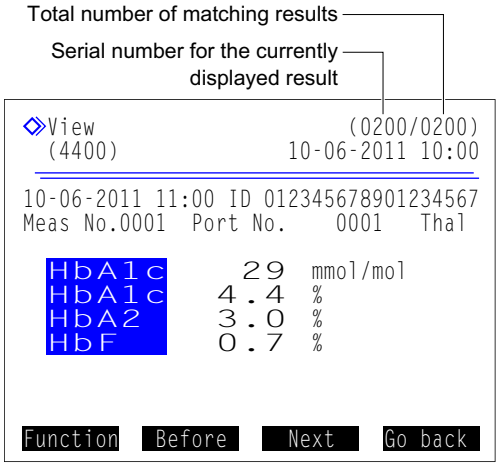
- See steps ❸ to ❺ in "3.4.1. Printing/Transmitting Results" on page 3-15.



❸ Press OK.

- The oldest matching result will be displayed.
- To view other results, see the table below.

REFERENCE:
If "None found." appears on the display:
No match is found in the memory. Press OK to return to the screen shown in step ❷.



- The functions below can be used to view measurement results.

Button	Description
Function	See "■ Printing/transmitting results or setting sample information" on page 3-20.
Before	Returns to the results of the previous sample.
Next	Goes to the results of the next sample.
Hyphen	See "■ Editing IDs" on page 3-19. See "■ Setting parameters for control measurement results" on page 3-19.
↵	Scrolls down the screen to display the peak information and a chromatogram (see steps ❷ and ❸ in "2.4.3. Viewing Measurement Results in Detail" on page 2-23).

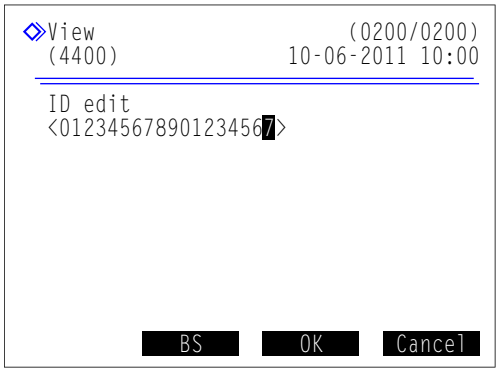
■Editing IDs

❶ Display the result whose ID you want to modify.
- See "■ Reviewing measurement results" on page 3-18.

❷ Press the **hyphen** button. Or, select Function, and then <1 Sample info. edit>.

❸ Enter a correct ID.
- Use the numeric buttons or optional hand-held barcode reader.
- See "● Entering IDs" on page 1-44.

❹ Press OK.
- This saves your entry and will return you to the measurement result screen.

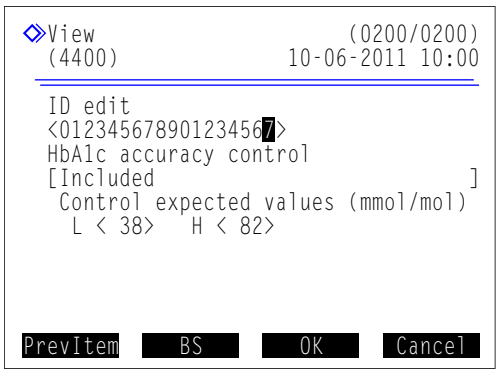


■Setting parameters for control measurement results

❶ Display the control measurement result whose parameters you want to set.
- See "■ Reviewing measurement results" on page 3-18.
- Below <Measurement>, select <Control measurement>.

❷ Press the **hyphen** button.
Or, select Function, and then <1 Sample info. edit>.

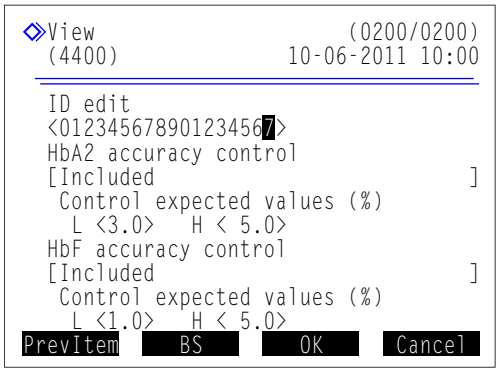
HbA1c control



❸ Set the setup items.
- See the table below.
- ↵ button: Moves the cursor to the next setup field.
Hyphen button: Changes the option.

❹ Press OK.
- This saves your entries and will return you to the measurement result screen.

HbA2/HbF control



Setup item	Description (**default bolded**)
HbA1c accuracy control HbA2 accuracy control HbF accuracy control	**Included**: Includes the selected result in statistical data for accuracy control (see "3.7.3. Printing Accuracy Control Reports" on page 3-31). Not included: Does not include the selected result in statistical data for accuracy control. Select this option if the result was obtained by measuring a control that is not usually used, a sample for a control survey, or a control of a different lot on the same day.
Control expected values	Set control expected values of the controls used for the selected result. Use this setup item when control expected values were not set before performing control measurements. Control expected values are written on the package insert of the controls. HbA1c (mmol/mol) L: Low solution 0 to 99 (**0**) H: High solution 0 to 200 (**0**) HbA2 (%) L: Low solution 0.0 to 9.9 (**0.0**) H: High solution 0.0 to 99.9 (**0.0**) HbF (%) L: Low solution 0.0 to 9.9 (**0.0**) H: High solution 0.0 to 99.9 (**0.0**)

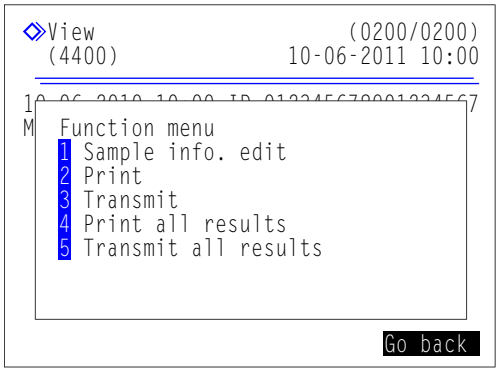
■Printing/transmitting results or setting sample information

❶ Display the measurement result you want.

- See "■ Reviewing measurement results" on page 3-18.

❷ Press Function.

❸ Select one of the options listed below.



Option	Description
1 Sample info. edit	See "■ Editing IDs" on page 3-19. See "■ Setting parameters for control measurement results" on page 3-19.
2 Print	Prints the currently displayed result.
3 Transmit	Transmits the currently displayed result to the external device.
4 Print all results	Prints all matching results.
5 Transmit all results	Transmits all matching results to the external device.

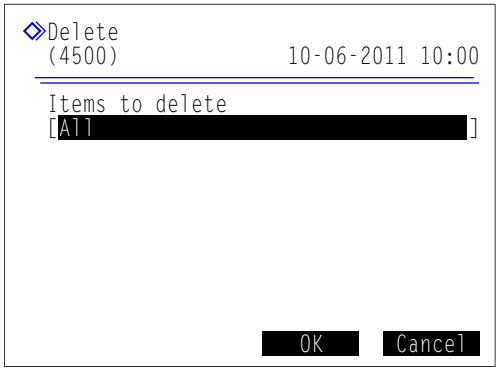
3.4.3 Deleting Results

Measurement results and history of warning/error/trouble stored in the memory can be deleted. You can delete all data at a time or select specific types of data from normal and STAT measurement results, control measurement results and history of warning/error/trouble.

NOTE:
Note that deleted data can never be retrieved.

❶ On the standby screen, select Menu, <4 Measurement result menu> and <5 Delete> in that order.

❷ Select one of the following:
- <All>, <Normal & STAT measurements>, <Control measurement>, <Warning/error/trouble>
- **Hyphen** button: Changes the option.



❸ Press OK.
- The message “Delete data?” will appear.

❹ Press OK.
- This deletes the specified data and will return you to the [Measurement result menu] screen.

❺ To return to the standby screen, press Go back twice.

3.5 Initial Settings

3.5.1 Setting the Date and Time

The internal system clock may not keep the right time after initial installation of the instrument or if the instrument has not been used for extended periods of time. Set the system clock correctly, since the date and time of measurements are recorded according to the system clock.

REFERENCE:

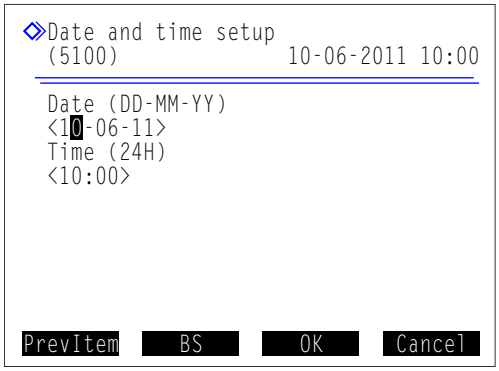
The instrument supports three date formats: “YY-MM-DD”, “DD-MM-YY” and “MM-DD-YY”. The current setting is displayed at the right side of <Date>. The default setting is “DD-MM-YY”. If you prefer another date format, contact your distributor.

❶ On the standby screen, select Menu, <5 Initial settings menu> and <1 Date and time setup> in that order.

❷ Set the correct date and time.

- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Moves the cursor through the date in the order of “day”, “month” and “year” or the time in the order of “hour” and “minute”.

Setup item	Description
Date (DD-MM-YY)	Enter the current date.
Time (24H)	Enter the current time in the 24-hour format.



❸ Press OK.

- This saves your entries and will return you to the [Initial settings menu] screen.

❹ To return to the standby screen, press Go back twice.

3.5.2 Setting Up the Printer

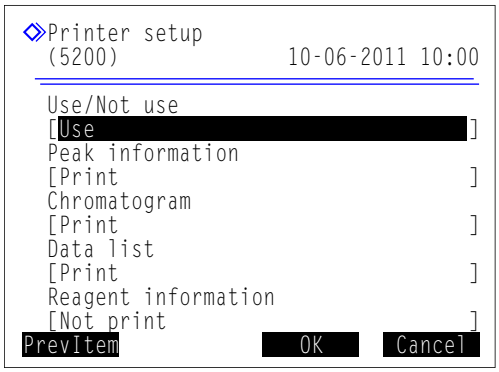
You can deactivate the printer if you do not wish to print anything. When using the printer, you can select whether or not to:

- Include peak information and/or chromatograms in individual measurement result reports,
- Automatically print reports which list measurement results, abnormal results, barcode errors and history of warning/error/trouble at the end of a batch of measurements, and
- Print reagent information at the beginning of batches or add it to individual measurement result reports.

❶ On the standby screen, select Menu, <5 Initial settings menu> and <2 Printer setup> in that order.

❷ Set the setup items.

- See the table below.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.



❸ Press OK.

- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.

- This saves your entries and will return you to the [Initial settings menu] screen.

❺ To return to the standby screen, press Go back twice.

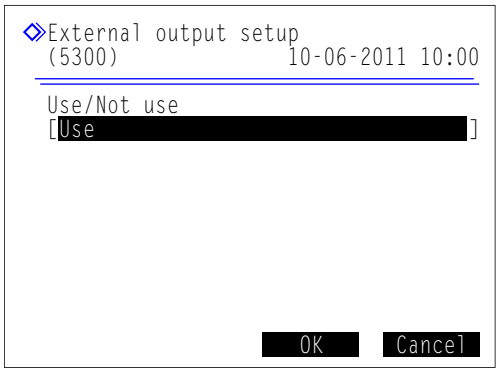
Setup item	Description (**default bolded**)
Use/Not use	**Use**: Uses the printer to print measurement results and information on the instrument. Not use: Does not use the printer. Nothing is printed.
Peak information	**Print**: Includes peak information in printed measurement result reports. Not print: Does not include peak information.
Chromatogram	**Print**: Includes chromatograms in printed measurement result reports. Not print: Does not include chromatograms.
Data list	**Print**: Automatically prints reports which list measurement results, abnormal results, barcode errors and history of warning/error/trouble at the end of each batch. Not print: Does not print these reports automatically.
Reagent information	Batch: Prints at the beginning of each batch. Each measurement: Prints on each measurement result report. **Not print:** Does not print. See “6.1.6. Reagent Information Report” on page 6-9.

3.5.3 Setting Up External Output

Activate external output of the instrument when an external device is connected to the DATA OUT terminal on the rear panel. External output is deactivated as a default, so the instrument cannot communicate with the external device even when connected to it.

❶ On the standby screen, select Menu, <5 Initial settings menu> and <3 External output setup> in that order.

❷ Select either of the following:
- <Use>, <Not use>
- **Hyphen** button: Changes the option.



❸ Press OK.
- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.
- This saves your entry and will return you to the [Initial settings menu] screen.

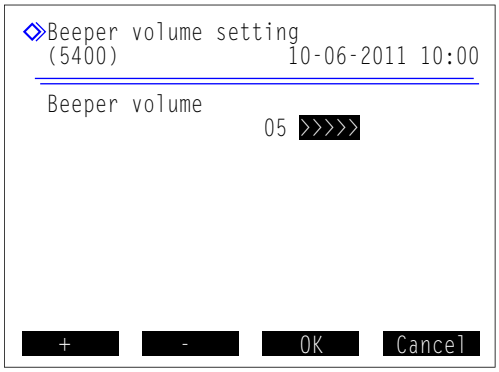
❺ To return to the standby screen, press Go back twice.

3.5.4 Adjusting the Beeper Volume

Beeper sounds when a warning, error or trouble occurs. The volume of the beeper can be adjusted in 10 levels, from 00 (muted) to 09 (max.).

❶ On the standby screen, select Menu, <5 Initial settings menu> and <4 Beeper volume setting> in that order.

❷ Press + or - to select the level of the beeper volume.
- Range: 00 (muted) to 09 (max.). The default is 05.
- The beeper sounds at the set level each time you press a button.



❸ Press OK.
- The message “Settings changed. Save setting changes?” will appear.

❹ Press OK.
- This saves your entry and will return you to the [Initial settings menu] screen.

❺ To return to the standby screen, press Go back twice.

3.6 Print

3.6.1 Printing History of Warning/Error/Trouble

You can print out a history of warnings (W:091 to W:095), errors and troubles that occurred in a specified period. The instrument stores a total of up to 100 occurrences in the memory.

REFERENCE:
Printed report example: See “2.8.6. History of Warning/Error/Trouble” on page 2-48.

❶ On the standby screen, select Menu, <6 Print menu> and <1 History of warning/error/trouble> in that order.

❷ Specify the range of history to print.

- The end (right) date must be the same as or later than the start (left) date.
- Settable range: 01-01-00 to 31-12-99
- **Hyphen** button: Moves the cursor through the date in the order of “day”, “month” and “year”.

↵ button: Moves the cursor from the start date to end date.

❸ Press OK.

- A list of warning/error/trouble will be printed, starting with the oldest log.
- After completion, the [Print menu] screen will appear again.

REFERENCE:

- If “None found.” appears on the display:
  No match is found within the specified range of dates. Press OK to return to the screen shown in step ❷.
- To stop printing, press Stop or ▽.

❹ To return to the standby screen, press Go back twice.

3.6.2 Printing a List of Barcode Errors

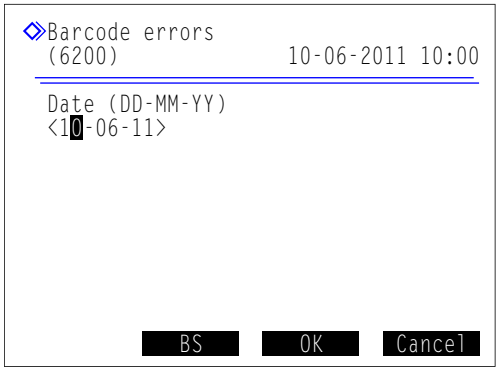
You can print out a list of measurement results for which the barcodes were misread on a specific day.

REFERENCE:
Printed report example: See “2.8.5. List of Barcode Errors” on page 2-47.

❶ On the standby screen, select Menu, <6 Print menu> and <2 Barcode errors> in that order.

❷ Set the setup items.
- See the table below.

Hyphen button: Moves the cursor through the date in the order of “day”, “month” and “year”. Or, changes the option.



❸ Press OK.
- Printing will start.
- The [Print menu] screen will appear again when printing is complete.

REFERENCE:
- If “None found.” appears on the display:
  No match is found for the specified date. Press OK to return to the screen shown in step ❷.
- To stop printing, press Stop or ▽.

❹ To return to the standby screen, press Go back twice.

Setup item	Description
Date (DD-MM-YY)	Set a measurement date. Settable range: 01-01-00 to 31-12-99

3.6.3 Printing a List of Abnormal Results

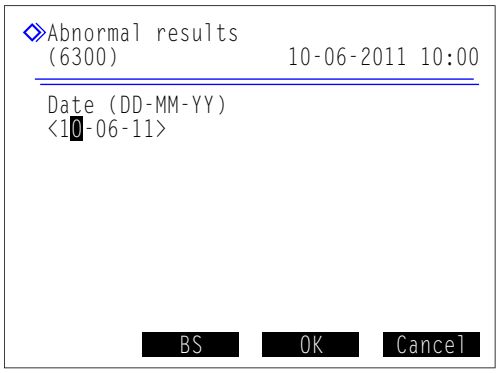
The list of abnormal results contains the measurement numbers and messages of the results for which “Abnormal Fraction” appeared on the chromatogram reports. You may use the lists to determine causes of inaccurate measurement results. Each list contains abnormal results that were obtained on a specific day.

REFERENCE:
Printed report example: See “2.8.4. List of Abnormal Results” on page 2-47.
Messages: See “5.4. Abnormal Result Messages” on page 5-21.

❶ On the standby screen, select Menu, <6 Print menu> and <3 Abnormal results> in that order.

❷ Set the setup items.
- See the table below.

Hyphen button: Moves the cursor through the date in the order of “day”, “month” and “year”. Or, changes the option.



❸ Press OK.
- Printing will start.
- The [Print menu] screen will appear again when printing is complete.

REFERENCE:
- If "None found." appears on the display:
  No match is found for the specified date. Press OK to return to the screen shown in step ❷.
- To stop printing, press Stop or ▽.

❹ To return to the standby screen, press Go back twice.

Setup item	Description
Date (DD-MM-YY)	Set a measurement date. Settable range: 01-01-00 to 31-12-99

3.6.4 Printing Calibration Result Report

You can print out the most recent calibration result report. This report includes results of calibrations for HbA1c, HbA2 and HbF. It lists either the coefficients obtained by automatic calibration or the manually set coefficients, whichever of the two operations performed last.

REFERENCE:
Printed report example: See “2.8.7. Calibration Results Report” on page 2-49.

❶ On the standby screen, select Menu, <6 Print menu> and <4 Calibration result> in that order.
- Printing will start.
- The [Print menu] screen will appear again when printing is complete.

REFERENCE:
To stop printing, press Stop or ▽.

❷ To return to the standby screen, press Go back twice.

3.6.5 Printing the Current Parameter Settings

You can print out a list of the current parameter settings of the instrument.

REFERENCE:
Printed report example: See “6.1.1. Current Parameter Settings” on page 6-2.

❶ On the standby screen, select Menu, <6 Print menu> and <5 Parameter settings> in that order.
- Printing will start.
- The [Print menu] screen will appear again when printing is complete.

REFERENCE:
To stop printing, press Stop or ▽.

❷ To return to the standby screen, press Go back twice.

3.7 Diagnosis

3.7.1 Testing the Whole Flow System

You can run a series of tests on the drive units, sample introduction flow and drain flow once each. Use this whole flow system test to check instrument operation after trouble occurs.

❶ On the standby screen, select Menu, <8 Instrument diagnosis menu>, <1 Flow test menu> and <1 All> in that order.

- Testing will start.

REFERENCE:

To stop the test, press Stop.

●If “No problem was found.” appears:

The flow is normal.

●If an error or trouble message appears:

Trouble was detected somewhere in the flow. See the relevant pages in “Chapter 5 Troubleshooting” to take the appropriate action.

❷ To return to the standby screen, press Go back three times.

3.7.2 Testing Individual Flow Circuit

You can test any of the flow circuits listed below independent of the others. Anywhere between 1 and 99 test cycles can be set. These tests consume less eluents and hemolysis washing solution than used in actual measurements. Perform these tests to check instrument operation after trouble occurs.

- Drive units
- Sample introduction flow
- Drain flow

❶ On the standby screen, select Menu, <8 Instrument diagnosis menu> and <1 Flow test menu> in that order.

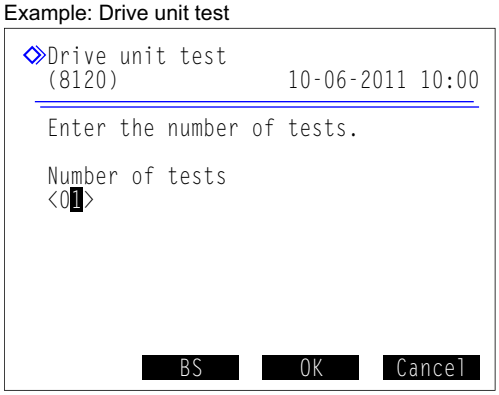
❷ On the [Flow test menu] screen, select one of the following:

- <2 Drive unit test>, <3 Sample introduction flow test>, <4 Drain flow test>

❸ Set the number of tests to perform.

- Normally, set it to "01".
- Range: 01 to 99 times. The default is 01.

Example: Drive unit test



❹ Press OK.
Testing will start.

●If "No problem was found." appears:
The flow is normal.

●If an error or trouble message appears:
Trouble was detected somewhere in the flow. See the relevant pages in "Chapter 5 Troubleshooting" to take the appropriate action.

❺ To return to the standby screen, press Go back three times.

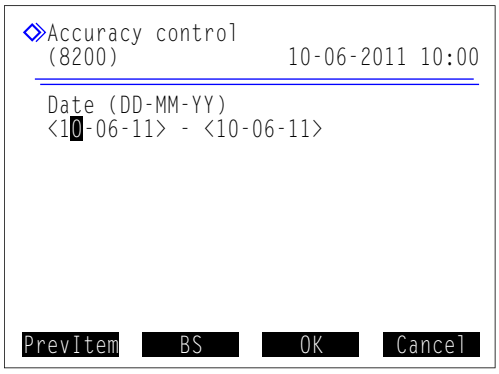
3.7.3 Printing Accuracy Control Reports

You can print out statistical information on control measurements and sample measurements for a specified period of time. Use this report to check the status of accuracy control.

REFERENCE:
Printed report example: See “6.1.2. Accuracy Control Reports” on page 6-4.

❶ On the standby screen, select Menu, <8 Instrument diagnosis menu> and <2 Accuracy control> in that order.

❷ Set the setup items.
- See the table below.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Moves the cursor through the date in the order of “day”, “month” and “year”. Or, changes the option.



❸ Press OK.
- Printing will start.
- The [Instrument diagnosis menu] screen will appear again when printing is complete.

REFERENCE:
If “None found.” appears on the display:
No match is found within the specified range of dates. Press OK to return to the screen shown in step ❷.

❹ To return to the standby screen, press Go back twice.

Setup item	Description
Date (DD-MM-YY)	Specify a range of measurement dates. The end (right) date must be the same as or later than the start (left) date. Settable range: 01-01-00 to 31-12-99

3.7.4 Printing Optical Unit Monitoring Results

The optical unit monitoring result report shows the changes in light absorption of the optical unit over the last 10 minutes.

REFERENCE:
Printed report example: See “6.1.3. Optical Unit Monitoring Results” on page 6-6.

❶ On the standby screen, select Menu, <8 Instrument diagnosis menu> and <3 Monitor print> in that order.
- Printing will start.
- The [Instrument diagnosis menu] screen will appear again when printing is complete.

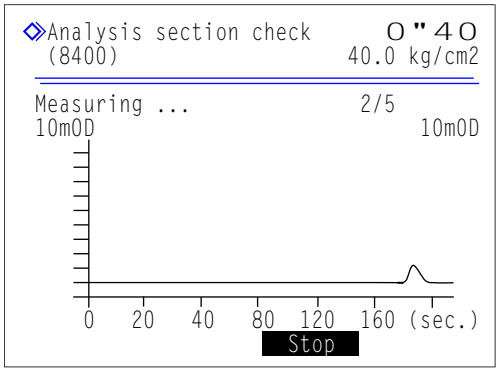
❷ To return to the standby screen, press Go back twice.

3.7.5 Performing Check Measurement for the Analysis Section

Follow the instructions described below to perform a check measurement for the analysis section if measurement results seem inaccurate. This test measures the hemolysis washing solution 5 times in order to check that the analysis section is working properly. Since the solution in the hemolysis washing solution bottle is measured, there is no need to set hemolysis washing solution in the sample rack. This test consumes less hemolysis washing solution than actual sample measurements.

❶ On the standby screen, select Menu, <8 Instrument diagnosis menu> and <4 Analysis section check> in that order.
- The message “Perform check measurement.” will appear.

❷ Press Start.
- Measurement will start.
- A chromatogram will be displayed for each measurement.
- Measurements will be performed 5 times. The current measurement cycle appears in the upper right corner of the display.
  Example: “2/5” (2nd of 5 measurements)



REFERENCE:
To stop measurement, press Stop or ▽.

●If “No problem was found.” appears:
The analysis section is normal.

●If an error or trouble message appears:
Trouble was detected somewhere in the analysis section. See the relevant page in “Chapter 5 Troubleshooting” to take the appropriate action.

❸ To return to the standby screen, press Go back three times.

3.7.6 Testing Reproducibility (Whole Blood Sample)

Run a reproducibility test following the instructions described below if the reproducibility of measurement results seems to have been reduced in anemia or non-anemia whole blood sample measurements. This test repeatedly measures the same whole blood sample and displays statistical information (average, R, S.D. and C.V.) from those results. Since all measurements are performed using sample from a single sample tube, there is no need to divide the sample into multiple sample tubes before setting them.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: For whole blood sample test
Whole blood sample, sample tube (× 1),
normal rack (or start rack for loop transportation) and protective gloves

For anemia sample test
Anemia sample, sample tube (× 1), anemia rack and protective gloves

1 Prepare sample.

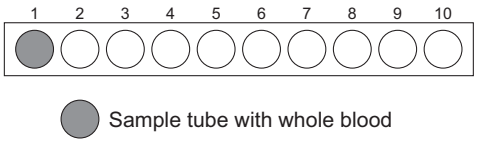
❶ On the standby screen, select Menu, <8 Instrument diagnosis menu>, <5 Reproducibility test menu> and <1 Whole sample measurement> in that order.
• The message “Load samples onto sampler.” will appear.

❷ Prepare sample in a sample tube.
• Make sure the sample tube is capped.

Performing measurements with uncapped tubes may cause sample to splatter inside the instrument while spinning, possibly jeopardizing subsequent measurements. It may also cause infection to the user or other individuals by pathogenic microbes.

NOTE:
The required sample volume (whole blood) is shown below. Add a sufficient volume of sample to the sample tube to perform the set number of measurements.
(Required sample volume) = 14 µL x (Set number of measurements) + 1 mL

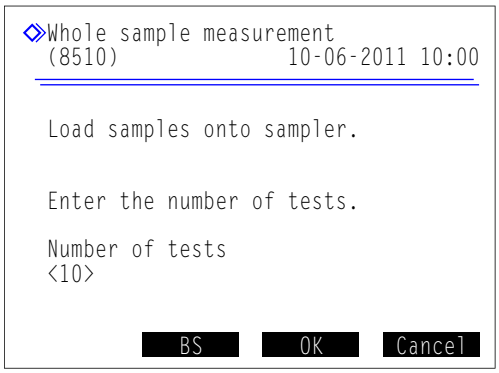
❸ Set the sample tube in port 1 of the specified sample rack.
• For sample tubes of a 12.3 mm diameter, set a spinning unit adapter (transparent) in the port before setting the tube.



❹ Load the sample rack onto the sampler.

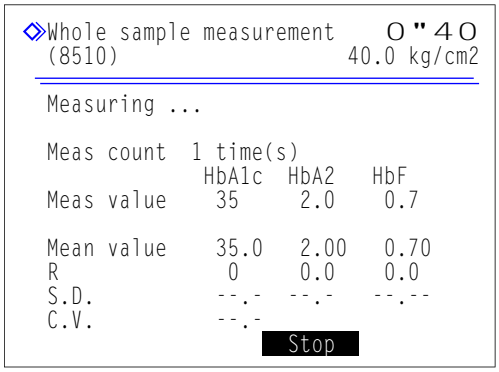
2 Measure the sample.

❶ Set the number of measurements you will perform.
- Range: 2 to 99 times



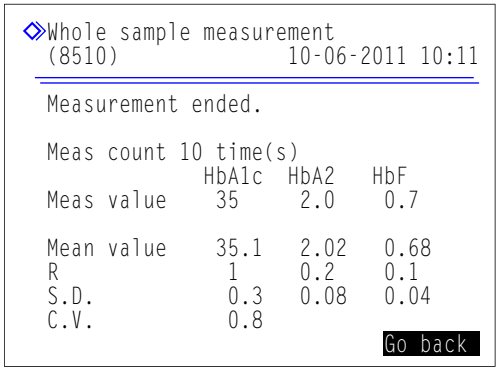
❷ Press OK.
- Measurement will start.
- The obtained result will appear on the display and a chromatogram report will be printed after each measurement.

REFERENCE:
To stop measurement, press Stop or ▽.



●If "Measurement ended." appears:
The most recent result will appear on the display.

●If an error or trouble message appears:
Trouble was detected. See the relevant page in "Chapter 5 Troubleshooting" to take the appropriate action.



❸ To return to the standby screen, press Go back four times.

❹ Check that the sample rack is not moving, and remove the rack from the rack unloading side of the sampler.

3.7.7 Testing Reproducibility (Hemolysis Sample)

Run a reproducibility test following the instructions described below if the reproducibility of measurement results seems to have been reduced in hemolysis sample measurements. This test repeatedly measures the same hemolysis sample or hemolysis control divided into multiple sample containers, and displays statistical information (average, R, S.D. and C.V.) from those results.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

REFERENCE:

Number of measurements:

You can place up to 5 sample containers with hemolysis samples in the hemolysis control rack and up to 3 measurements can be performed per sample container. So, a maximum of 15 measurements can be performed at a time in the reproducibility test (see “Control measurement count” in “3.3.5. Setting the Measurement Conditions” on page 3-14).

Prepare: Hemolysis sample or hemolysis control (1 type), sample containers (sample tube or sample cup, quantity needed for the number of measurements), hemolysis control rack and protective gloves

1 Prepare samples.

❶ On the standby screen, select Menu, <8 Instrument diagnosis menu>, <5 Reproducibility test menu> and <2 Hemolysis sample measurement> in that order.

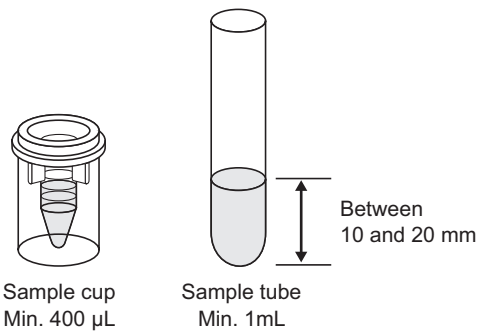
- The message “Load samples onto sampler.” will appear.

❷ Prepare sample in a sample tube or sample cup.

- Divide the same hemolysis sample (or hemolysis control) into the sample containers.
- You can place up to 5 sample tubes or sample cups.

❸ Set the sample containers in the hemolysis control rack.

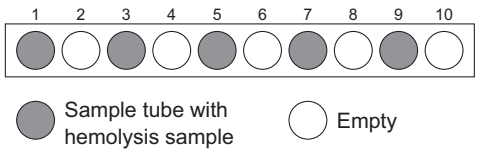
- For sample tubes of a 15 mm diameter, remove the spinning unit adapters before setting the tubes.



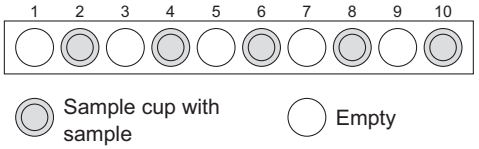
●For sample tubes:

Odd-numbered ports: Sample tube

Even-numbered ports: Empty



●For sample cups:
Odd-numbered ports: Empty
Even-numbered ports: Sample cup

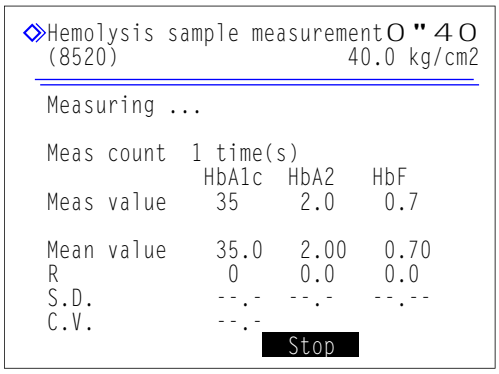


❹ Load the hemolysis control rack onto the sampler.

2 Measure the samples.

❶ Press Start.
- Measurement will start.
- The obtained result will appear on the display and a chromatogram report will be printed after each measurement.

REFERENCE:
To stop measurement, press Stop or ▽.

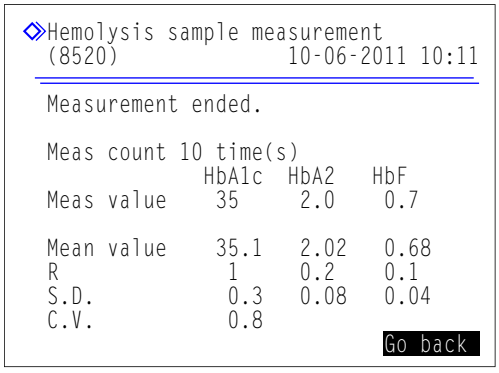


●If "Measurement ended." appears:
The most recent result will appear on the display.

●If an error or trouble message appears:
Trouble was detected. See the relevant page in "Chapter 5 Troubleshooting" to take the appropriate action.

❷ To return to the standby screen, press Go back four times.

❸ Check that the hemolysis control rack is not moving, and remove the rack from the rack unloading side of the sampler.



3.8 Reagent Information Settings

Reagent information includes the lot number, expiration date and manufacturing date of the specific reagent. You can store this information in the instrument for the reagents listed below, and use it to manage your reagents.

Eluent A, eluent B, eluent CT, hemolysis washing solution and calibrator

Reagent information settings can be made just by entering 10-digit codes supplied with individual reagent products. An error message appears on the screen and your entry is rejected if you try to set invalid information (for example, the expiration date has passed or the type of reagent is incorrect). Once valid reagent information has been set, it can be printed on measurement result reports. This serves as proof that the proper reagents were used for measurements (see "3.5.2. Setting Up the Printer" on page 3-23). Follow the instructions described below to set reagent information.

3.8.1 Setting Reagent Information When Replacing the Reagents

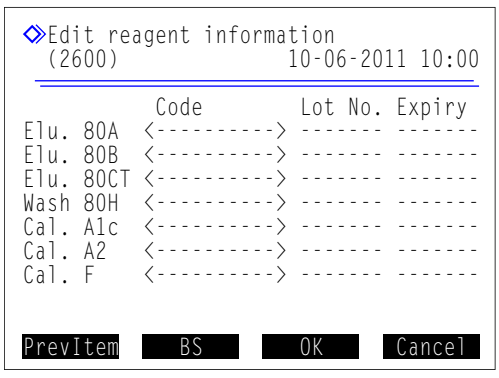
Reagent information can be set for eluents and hemolysis washing solution when replacing packs or bottles. For the calibrator, reagent information can be set when performing calibration.

- For eluents and hemolysis washing solution
  See "4.2.1. Replacing the Eluent Packs" on page 4-3 and "4.2.2. Replacing the Hemolysis Washing Solution Bottle" on page 4-7.
- For calibrator
  See "2.7.1. Performing Automatic Calibration" on page 2-35.

3.8.2 Setting Reagent Information After Replacing the Reagents

You can set reagent information anytime, for example, when:
- You did not make information settings when the reagent was replaced, or
- The instrument is started up for the first time after installation.

❶ On the standby screen, select Menu, <2 Reagent replacement menu> and <6 Edit reagent information>.
- The current information will appear.
- Hyphens (---) appear where no information has been set.



❷ Select a reagent.
- ↵ button: Moves the cursor to the next setup field.

❸ Below <Code>, enter the 10-digit reagent code.
- For eluents and hemolysis washing solution, the code is written on the pack or bottle labels.
- For calibrator, the code is written on the Standard value list.
- If your entry is accepted, the lot number and expiration date will be updated (or appear).

REFERENCE:

- For eluents and hemolysis washing solution, the optional hand-held barcode reader can be used to read the reagent codes.
- To delete the current entry, press the **hyphen** button. Then hyphens (---) appear.

❹ To set information on another reagent, repeat from step ❶.

❺ Press OK.

• This saves your entries and will return you to the [Reagent replacement menu] screen.

NOTE:

- If an error message appears:
  The reagent information is invalid. See the table below to determine the cause. Press OK to return to step ❶ and enter the correct code. Invalid entries will then appear as hyphens (---).
- When setting information for two or more reagents at a time:
  You can go to step ❻ once all of your entries are valid. If invalid information was entered for two or more reagents, repeat steps ❶ to ❺ until no more error messages appear.

❻ To return to the standby screen, press Go back twice.

Error message	Description
Reagent type in reagent information does not match the selected reagent type.	You entered the reagent code of another reagent. For example, you entered the reagent code of Eluent 80B in <Elu. 80A>.
Manufacturing date in reagent information is not consistent with the current date.	The manufacturing date in the reagent information is after the current date.
Expiration date in reagent information has passed.	The expiration date in the reagent information is before the current date.

3.8.3 Printing Reagent Information

Reagent information can be printed out as follows:

- At the beginning of batches
- On individual measurement result reports

REFERENCE:

Printed report example: See “2.8.7. Calibration Results Report” on page 2-49 and “6.1.6. Reagent Information Report” on page 6-9.

Chapter 4 Maintenance

This chapter describes instructions for performing maintenance tasks including replacement of consumables such as reagents and printer paper and cleaning of the piercing nozzle, dilution container and washing container.

4.1 Frequency of Maintenance

This section lists the parts that require maintenance and the standard frequency to perform maintenance tasks. Referring to the table below, clean or replace the parts at recommended intervals.

- Wear protective gloves to prevent exposure to pathogenic microbes when performing maintenance tasks marked with a checkmark (✓).
- Discard liquid waste, used parts and cleaning tools in accordance with local regulations for biohazardous waste.

	Maintenance task	Frequency	See page
✓	Liquid waste disposal	Every day	4-27
	Eluent A pack replacement	About every 90 measurements (*1)	4-3
	Eluent B pack replacement	About every 360 measurements (*1)	4-3
	Eluent CT pack replacement	About every 120 measurements (*1)	4-3
	Hemolysis washing solution bottle replacement	About every 150 measurements (*1)	4-7
	Printer paper replacement	About every 180 measurements (*1)	4-10
✓	Piercing nozzle cleaning	Every week	4-31
✓	Automatic tube washing	Every week	4-27
✓	Sample tube spinning unit cleaning	Every month	4-33
✓	Dilution container and washing container cleaning	Every month	4-35
	Air filter washing	Every month	4-42
✓	Column replacement	At least 2500 measurements (About 6 months *2)	4-11
✓	Nozzle washing block cleaning	Every 1200 measurements (About 3 months *2)	4-16
	Mesh filter replacement for eluent and hemolysis washing solution nozzles	Every 2400 measurements (About 6 months *2)	4-22
✓	Drain pinch valve tube replacement	Every 6 months	4-25
✓	Part cleaning for dilution container and washing container	Every year	4-38
✓	Piercing nozzle replacement	Every 60000 measurements	4-16

*1 The frequency for these maintenance tasks is for reference only. Actual replacement needs will differ according to the number of measurements per batch or other conditions. These figures are based on 20 measurements divided into 10 batches (2 measurements per batch on average).

*2 The frequency for these maintenance tasks is based on the assumption that 20 measurements are performed per day, for 20 days per month.

4.2 Replacement of Consumables

4.2.1 Replacing the Eluent Packs

Replace the eluent pack if “W:053 No Eluent A”, “W:054 No Eluent B” or “W:055 No Eluent CT” appears on the display.

> ⚠ Be careful to avoid contact between skin, eyes or mouth and eluent. If eluent makes contact with eyes or mouth, immediately wash with plenty of water and consult a doctor. If it makes contact with skin, wash with plenty of water.

IMPORTANT:

- Be sure to use eluent A, eluent B and eluent CT specified for the HA-8180T.
- Replace the pack one at a time. Eluents A, B and CT differ in composition. Attaching the wrong nozzle to the wrong pack can cause mixing of eluents, producing inaccurate measurement results. If the wrong bottle cap is attached, wash the nozzle and chamber, then attach the correct bottle cap to the pack (see “5.5.2. If Eluent Packs Are Incorrectly Attached” on page 5-25).
- Replace the pack to supply new eluent. Adding new eluent to the old pack can cause inaccurate measurement results.
- If eluents are stored in a refrigerator, allow them to adjust to the same environment as the instrument for at least one hour before placing them on the instrument.

Prepare: ELUENT 80A, ELUENT 80B or ELUENT 80CT, and gauze

1 Access the maintenance screen.

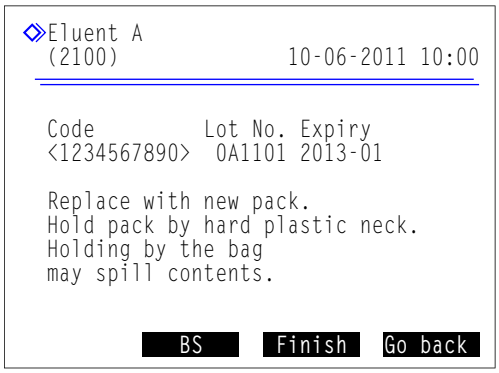
❶ On the standby screen, select Menu, <2 Reagent replacement menu> and <1 Eluent A>, <2 Eluent B> or <3 Eluent CT> in that order.

2 Set the reagent information on a new eluent pack.

You can skip this step and enter the reagent code later. See “3.8. Reagent Information Settings” on page 3-38.

❶ Below <Code>, enter the 10-digit reagent code that is written on the label of a new eluent pack.

- If your entry is accepted, the lot number and expiration date will be updated.

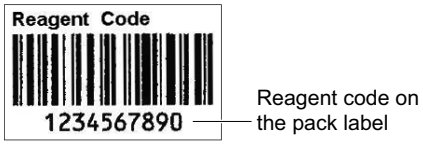


NOTE:

If <Lot No.> and <Expiry> are not updated and still contain hyphens (---):
Your entry may be incorrect. Carefully check the reagent code and enter it again.

REFERENCE:

You can use the optional hand-held barcode reader to read the reagent code.



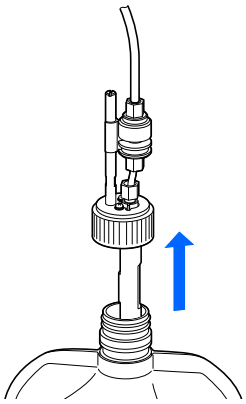
3 Remove the used eluent pack.

❶ Lay out some gauze near the instrument.

❷ Remove the used eluent pack from the bottle tray.

❸ Remove the bottle cap with nozzle from the pack.

- Place the nozzle on the gauze.

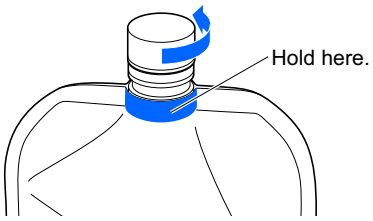


4 Place the new eluent pack.

❶ Hold the new eluent pack by the hard plastic neck and remove the cap from the pack.

NOTE:

Do not hold the eluent pack by the soft aluminium bag.
Eluent may spill and damage the instrument.



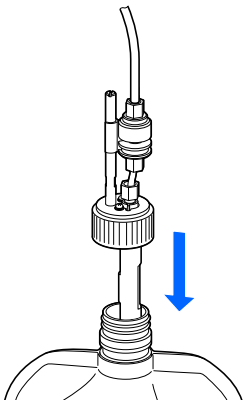
REFERENCE:

Keep the cap in the accessory case. This cap should be reused when transporting the instrument, or if the instrument is not to be used for extended periods of time.

❷ Wipe any liquid from the nozzle with a new piece of gauze.

NOTE:
Remove any lint if it is stuck to the nozzle. Lint may clog the tube.

❸ Insert the nozzle of the bottle cap into the new pack and tighten the cap securely.



NOTE:
Attach the bottle cap with nozzle to the pack somewhere other than above the instrument. Liquid may spill and damage the instrument.

❹ Check that the cap of the eluent pack is tightened securely.

IMPORTANT:
If the cap is loose, liquid condensation may rise due to evaporation, resulting in inaccurate measurement results.

❺ Check the type of the new eluent pack and place the pack in the specified position on the bottle tray.

NOTE:
Set the pack between the applicable pack supporters.

❻ Shape the eluent pack into a smooth standing position.

NOTE:
Eluent may not be fully aspirated if the pack is bent over or collapses during measurement.

5 Reset the remaining reagent graphic for the eluent.

❶ Press Finish.

- This resets the remaining reagent graphic for the eluent.
- The [Reagent replacement menu] screen will appear again.

NOTE:
If an error message appears:
The reagent information is invalid. Press OK to return to step **2**. Check the type, expiration date and manufacturing date of the eluent, and enter the correct reagent code. To replace with another new eluent pack, repeat steps **2** to **4**.

6 Remove air from the eluent by priming.

REFERENCE:

To replace another reagent:

Select the next reagent you want to replace on the [Reagent replacement menu] screen at this point. You can then replace the next reagent without priming the last reagent you replaced. Once all reagents have been replaced, press Go back on the [Reagent replacement menu] screen to start priming for all of the new reagents.

❶ Press Go back .

- Priming will start for the new eluent.
- After completion, the [Main menu] screen will appear again.

❷ To return to the standby screen, press Go back .

- Check that the whole remaining reagent graphic ([A], [B] or [C]) is displayed in light blue. This shows the graphic has been reset.

4.2.2 Replacing the Hemolysis Washing Solution Bottle

Replace the hemolysis washing solution bottle if "W:052 No hemolysis washing solution" appears on the display.

> ⚠ Be careful to avoid contact between skin, eyes or mouth and hemolysis washing solution. If the solution makes contact with eyes or mouth, immediately wash with plenty of water and consult a doctor. If it makes contact with skin, wash with plenty of water.

IMPORTANT:

- Be sure to use hemolysis washing solution specified for the HA-8180T.
- Replace the bottle to supply new solution. Adding new solution to the old bottle may cause inaccurate measurement results.
- A small volume of solution always remains in the bottle for fluid level detection. Replace the bottle with a new one without using the remaining solution.
- If hemolysis washing solution is stored in a refrigerator, allow it to adjust to the same environment as the instrument for at least one hour before placing it on the instrument.

Prepare: HEMOLYSIS WASHING SOLUTION 80H and gauze

1 Access the maintenance screen.

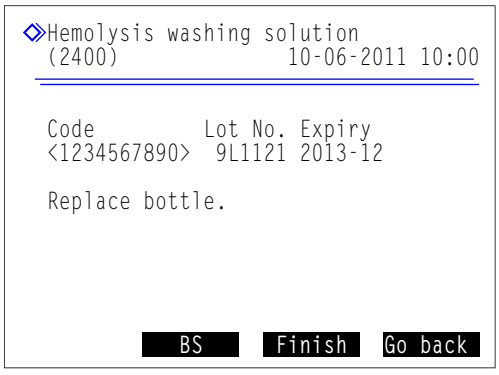
❶ On the standby screen, select Menu, <2 Reagent replacement menu> and <4 Hemolysis washing solution> in that order.

2 Set the reagent information on a new hemolysis washing solution bottle.

You can skip this step and enter the reagent code later. See "3.8. Reagent Information Settings" on page 3-38.

❶ Below <Code>, enter the 10-digit reagent code that is written on the label of a new bottle.

- If your entry is accepted, the lot number and expiration date of that bottle will be updated.



NOTE:

If <Lot No.> and <Expiry> are not updated and still contain hyphens (---):
Your entry may be incorrect. Carefully check the reagent code and enter it again.

REFERENCE:

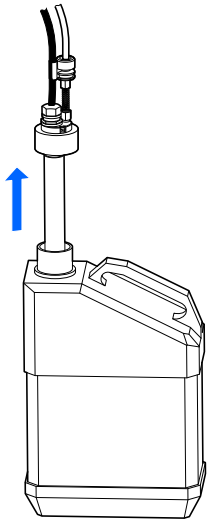
You can use the optional hand-held barcode reader to read the reagent code.

Reagent code on the pack label

3 Remove the used hemolysis washing solution bottle.

❶ Lay out some gauze near the instrument.

❷ Remove the bottle cap with nozzle from the bottle.
- Place the nozzle on the gauze.



4 Place the new hemolysis washing solution bottle.

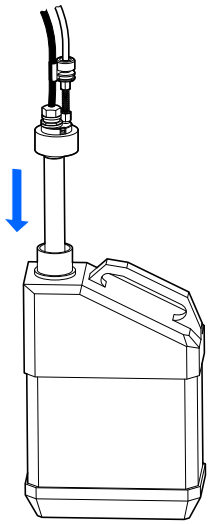
❶ Remove the cap from a new hemolysis washing solution bottle.

REFERENCE:
Keep the cap in the accessory case. This cap should be reused when transporting the instrument, or if the instrument is not to be used for extended periods of time.

❷ Wipe any liquid from the nozzle with a new piece of gauze.

NOTE:
Remove any lint if it is stuck to the nozzle. Lint may clog the tube.

❸ Insert the nozzle of the bottle cap into the new bottle and tighten the cap securely.



NOTE:
Attach the bottle cap with nozzle to the bottle somewhere other than above the instrument. Liquid may spill and damage the instrument.

❹ Check that the cap of the bottle is tightened securely.

IMPORTANT:
If the cap is loose, liquid condensation may rise due to evaporation, resulting in inaccurate measurement results.

❺ Place the new bottle in the specified position.

5 Reset the remaining reagent graphic for the hemolysis washing solution.

❶ Press Finish .

- This resets the remaining reagent graphic for hemolysis washing solution.
- The <Reagent replacement menu> screen will appear again.

NOTE:

If an error message appears:
The reagent information is invalid. Press OK to return to step **2**. Check the type, expiration date and manufacturing date of the solution, and enter the correct reagent code. To replace with another new bottle, repeat steps **2** to **4**.

❷ Press Go back .

- Priming will start for hemolysis washing solution.
- After completion, the <Main menu> screen will appear again.

❸ To return to the standby screen, press Go back .

- Check that the whole remaining reagent graphic [H] is displayed in light blue. This shows the graphic has been reset.

4.2.3 Replacing the Printer Paper

Red lines appear along both edges of the printer paper when the paper is near the end of the roll. Replace the paper roll as soon as possible. An out-of-paper icon appears on the display if the printer runs out of paper. Promptly set a new roll.

NOTE:
Keep your hands away from the printer head to avoid damage to the printer.

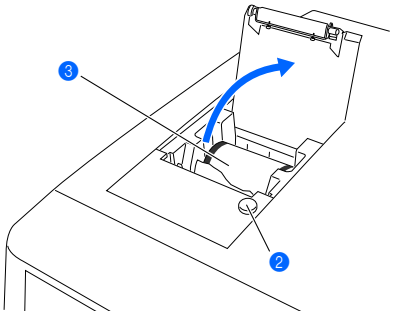
Prepare: Printer paper

1 Remove the remaining printer paper.

❶ Make sure the standby screen is displayed.

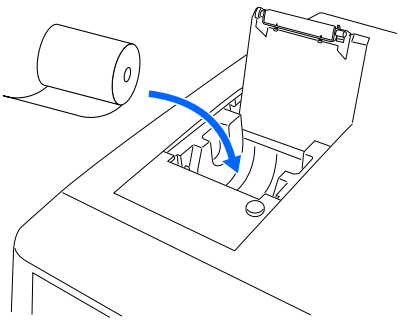
❷ Press the release button to open the cover.

❸ Remove the old roll and remaining paper from the printer.



2 Load a new paper roll.

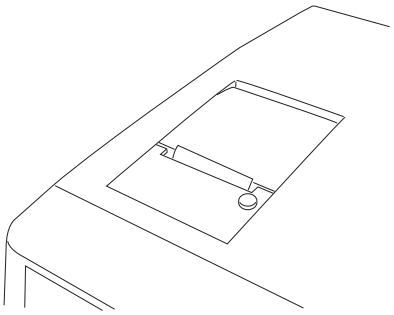
❶ Hold a new paper roll so the paper can unroll from the bottom as shown on the right, and place it in the paper compartment.



❷ Pull the leading edge of paper until drawing a full turn of the roll and carefully press the printer cover to close it.

NOTE:
Print does not appear on the area where the tape was attached.

❸ Feed the drawn paper through the paper cut slot and cut the leading edge.



REFERENCE:
To feed the paper, press .

4.2.4 Replacing the Column

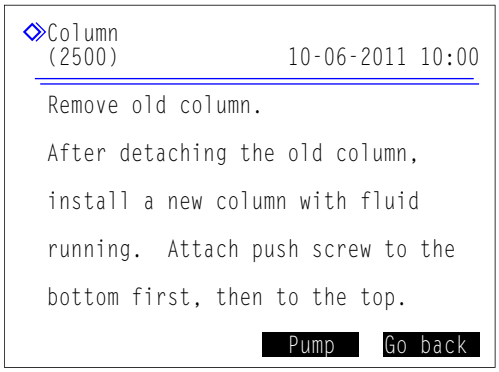
Replace the column with a new one at regular intervals to obtain accurate measurement results. Please follow the instructions from your distributor regarding the column replacement timing.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used columns, cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: COLUMN UNIT 80T, tissue paper and protective gloves

1 Access the maintenance screen.

❶ On the standby screen, select Menu, <2 Reagent replacement menu> and <5 Column> in that order.
- The message “Remove old column.” will appear.



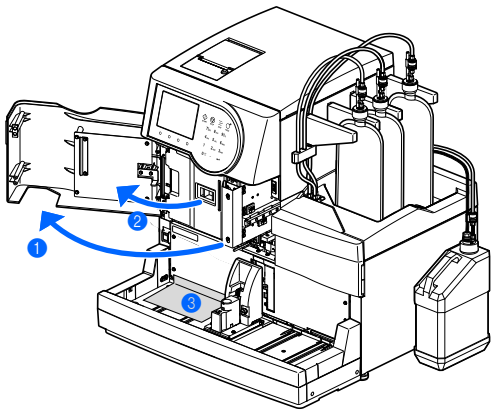
REFERENCE:
- If “Column should be replaced. Replace column now?” has been displayed:
  Press OK to go to the [Column] screen. Pressing No warn. displays the standby screen and clears the message until power is turned on the next time.
- Priming will automatically start after the eluent pack or hemolysis washing solution bottle has been replaced. The [Column] screen appears after priming has finished.

2 Open the temperature control box cover.

❶ Open the front cover.
- The mechanical sections will power off.

REFERENCE:
The message “W:062 Front or maintenance cover is open.” appears if the front cover is opened before performing step **1**-❶. Be sure to perform step **1**-❶ first.

❷ Open the temperature control box cover.
- Push the handle to the left, then pull it to the front to open the box.

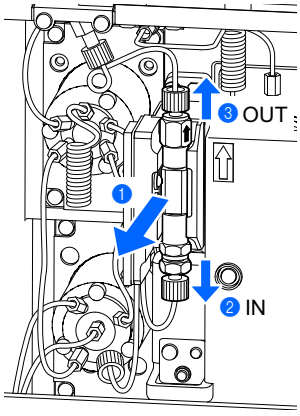


❸ Lay tissue paper on the bottom of the temperature control box.
- The tissue paper blots up any liquids that leak while replacing the column.

3 Detach the old column.

> The column and column holder may be hot. Before touching the column, place your hand near to the column to make sure that it is not hot. If the column is hot, the temperature controlling unit may break. Contact your distributor.

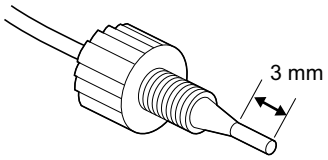
❶ Detach the column from the column holder.
- Place your hand behind the column at the top and push the column to the front.



❷ Wrap the column with tissue paper and turn the push screw on the IN side by hand to disconnect it from the column.

❸ Turn the push screw on the OUT side by hand to detach the column.

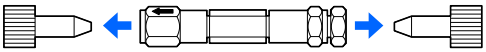
❹ Press the tube until it is protruding about 3 mm from the push screws on both the IN and OUT sides.



NOTE:
Liquid may leak when attaching the column unless the tubes protrude about 3 mm from the push screws.

4 Install a new column.

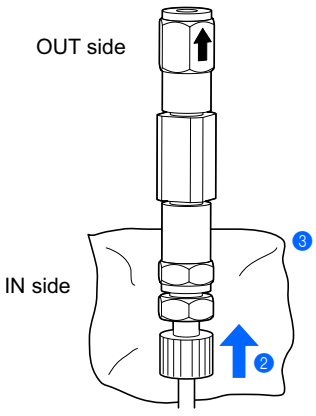
❶ Remove the sealing screws from both ends of a new column.



REFERENCE:
Keep the sealing screws in the accessory case. These screws should be reused if the instrument is not to be used for extended periods of time.

❷ Fit the push screw into the IN side of the new column and tighten it lightly.
- **Do not** fully tighten the push screw at this point.

IMPORTANT:
Install the column with the arrow to the top. **Do not** install the column upside-down.



❸ Wrap the connection between the IN side of the column and push screw with tissue paper.
- The tissue paper blots up any liquid that overflows during priming.

5 Remove air from the column by priming.

❶ Press Pump and wait about 30 seconds.
- Fluid pumping starts, and liquids and bubbles overflow from the connection between the column and push screw.
- Priming is complete (in about 30 seconds) when bubbles are no longer formed and only liquid overflows.

NOTE:
Slightly loosen the push screw if liquid does not overflow from the connection.

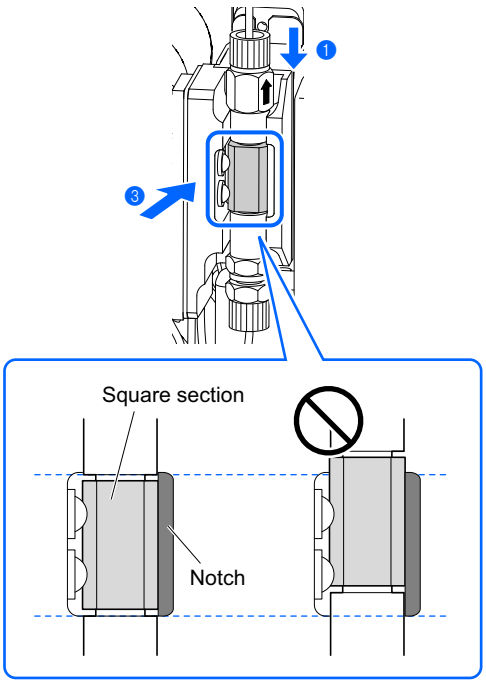
❷ With liquid overflowing from the IN side, securely tighten the IN side push screw by hand and immediately wrap the OUT side of the column with tissue paper.
- Liquid will overflow from the OUT side of the column.

6 Tighten the column fully.

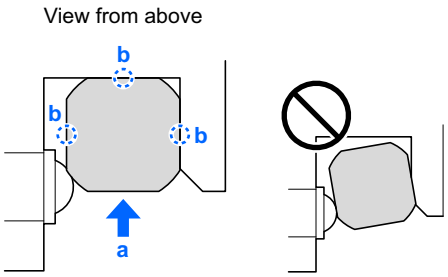
❶ Connect the push screw to the OUT side of the column.
- Insert the tube of the push screw into the column until the tube stops, and then securely tighten the push screw by hand.

❷ Remove the tissue paper.

❸ Insert the column into the holder with the square section fitted in the notch of the holder.



❹ Press the column firmly in place (**a**) to ensure that the 3 square sections are flush with the inside of the holder (**b**), as shown on the right.



⚠ Install the column properly. Inaccurate measurement results will be obtained if the column is not in the correct position.

7 Check for liquid leaks.

❶ Check that liquid does not leak from the connections on the IN and OUT sides of the column.

- Retighten the push screws if liquid leaks.

REFERENCE:

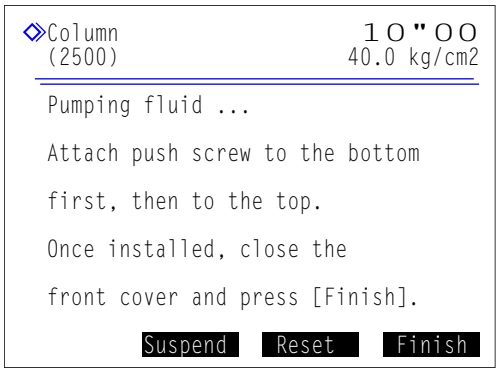
Fluid pumping stops in 10 minutes. To pump more fluid, press Reset. The instrument will continue to pump the fluid for another 10 minutes.

❷ Press Suspend or ▽ when the appropriate column pressure appears on the display.

- Fluid pumping will stop.

REFERENCE:

An appropriate column pressure is near the “Column Pressure (MPa or kg/cm^2)” written on the “CERTIFICATE OF QUALITY” that comes with the column.

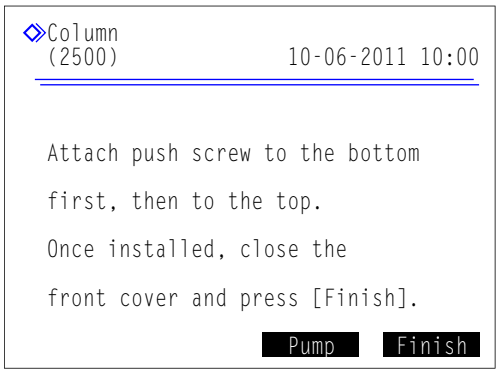


8 Close the covers.

❶ Close the temperature control box cover, then the front cover.

9 Complete maintenance.

❶ Press Finish .



REFERENCE:

The message “W:062 Front or maintenance cover is open.” appears if Finish is pressed with the front cover open. Be sure to close the front cover before pressing Finish .

❷ If “Replaced with new column?” appears, press OK .

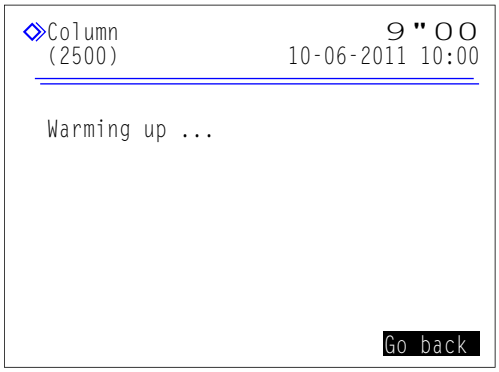
- The instrument will record the maintenance date.
- The calibration information and the column measurement counter are reset and the instrument starts warming up.

REFERENCE:

Press Cancel if you did not replace the column with a new one.

❸ Wait 9 minutes until the column warms up fully.

- A countdown timer will show the remaining warm-up time.
- When the column has warmed up, the [Reagent replacement menu] screen will appear again.



REFERENCE:

During warm-up, you can access menu screens and the standby screen by pressing Go back . However, you cannot start measurement until warm-up finishes.

❹ To return to the standby screen, press Go back twice.

- <Column> reads “0000” if the column has been replaced with a new one.

❺ When the column was replaced, perform calibration.

- See “2.7. Calibration” on page 2-35.

REFERENCE:

Perform calibrations for HbA1c, HbA2 and HbF. If you start measurement without calibrating these items, a warning message will show that measurement operation is disabled.

4.2.5 Replacing the Piercing Nozzle/Cleaning the Nozzle Washing Block

● Cleaning the nozzle washing block and replacing the O-ring

Replace the O-ring of the nozzle washing block every 1200 measurements. Hemolysis washing solution may leak from the nozzle washing block if the O-ring degrades. The piercing nozzle may not be adequately washed as a result. Always clean the bottom of the nozzle washing block when replacing the O-ring.

● Replacing the piercing nozzle

Replace the piercing nozzle every 60000 measurements. A clogged or damaged nozzle also requires replacement. Also replace the O-ring of the nozzle washing block when replacing the piercing nozzle.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used piercing nozzle, O-ring, cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: O-ring (for nozzle washing block), piercing nozzle (when replacing), Phillips screwdriver, tweezers AA, purified water, cotton swabs, gauze, tissue paper, protective tube (for piercing nozzle maintenance) and protective gloves

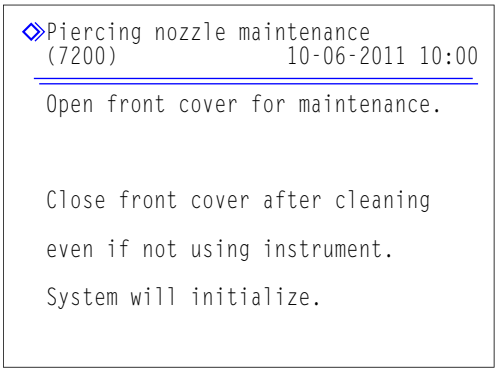
1 Move the piercing nozzle.

❶ On the standby screen, select Menu, <7 Maintenance menu> and <2 Piercing nozzle maintenance> in that order.

❷ Press Start or ◇|.

• Liquid will be drained from the piercing nozzle and the piercing nozzle will move to the front.

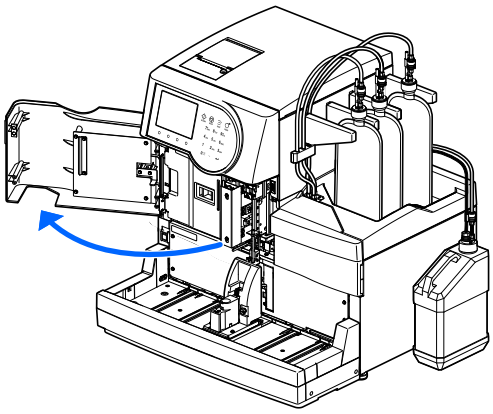
❸ Wait for the screen shown on the right to appear.



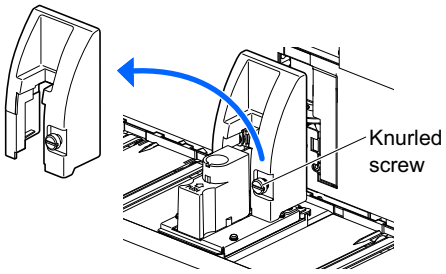
2 Remove the STAT port cover.

❶ Open the front cover.
- The mechanical sections will power off.

REFERENCE:
The message “W:062 Front or maintenance cover is open.” appears if the front cover is opened before performing steps **1**-❶ to **1**-❸. Be sure to perform steps **1**-❶ to **1**-❸ first.



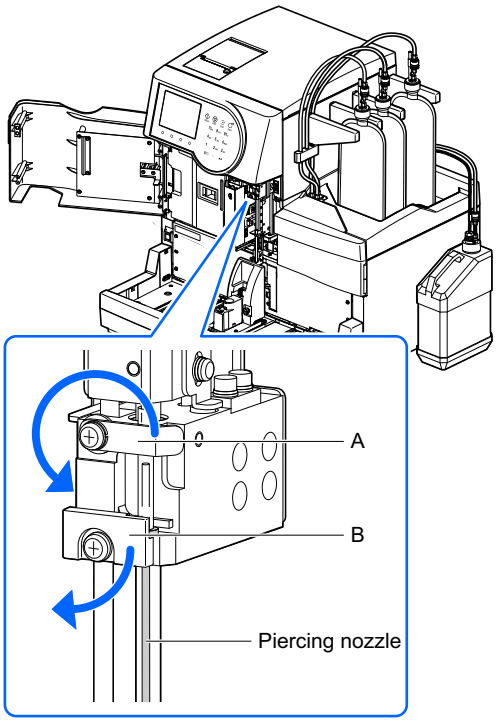
❷ Loosen the knurled screw by hand, and pull the STAT port cover to the front to remove it.



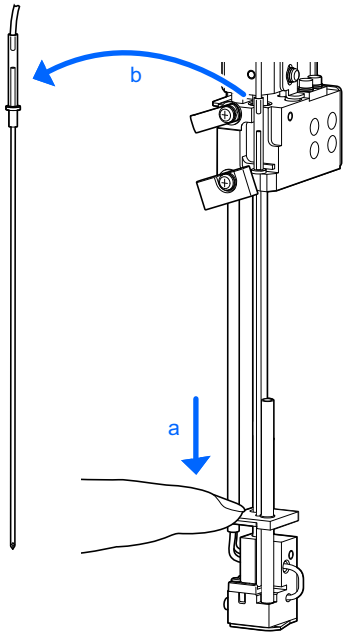
3 Remove the piercing nozzle.

❶ Lay out tissue paper near the instrument.

❷ While holding the piercing nozzle still with one hand, loosen the screws of fixing brackets A and B with the Phillips screwdriver.
- Turn the fixing bracket A counterclockwise and leave downward.
- Turn the fixing bracket B downward.



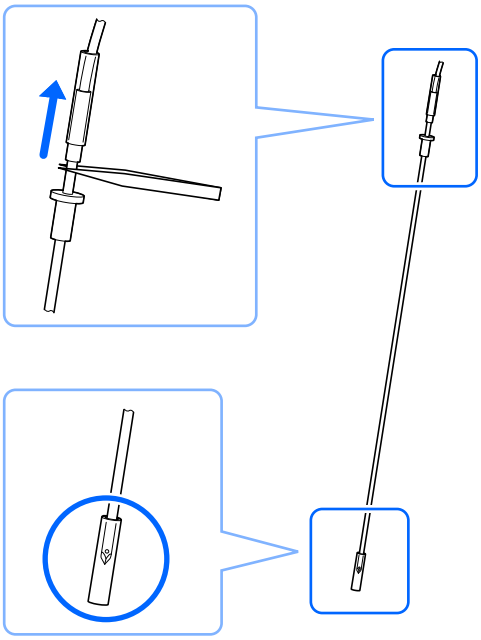
❸ With the nozzle guide held down to where it stops (a), pull the piercing nozzle upward with the other hand and move it to the front (b).



❹ Remove the nozzle tube from the piercing nozzle.

- Using the tip of tweezers AA, lift the nozzle tube up until the tube is removed.

NOTE:
Do not pinch the nozzle tube with tweezers AA. The tube may break.



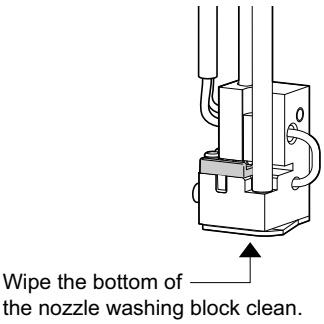
❺ Attach the protective tube to the tip of the piercing nozzle and place the nozzle on the tissue paper.

Place the removed piercing nozzle on tissue paper rather than directly on countertops or other surfaces to prevent exposure to pathogenic microbes.

4 Clean the nozzle washing block.

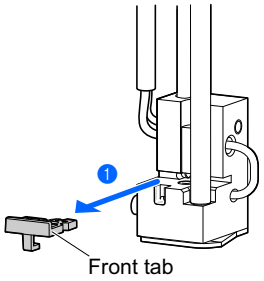
❶ Wipe off dirt from the bottom of the nozzle washing block.

- Use cotton swabs or gauze moistened with purified water.



5 Replace the O-ring.

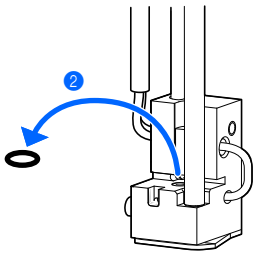
❶ Remove the cover plate.
- While holding the nozzle washing block still with one hand, gently pull the front tab with the other hand to the front.



❷ Remove the old O-ring with tweezers AA.

❸ Wipe off dirt from the groove that holds the O-ring.
- Use cotton swabs moistened with purified water.

❹ Attach a new O-ring using tweezers AA.
- Make sure that the O-ring is level and not rising anywhere.



❺ While holding the nozzle washing block still with one hand, push the cover plate all the way back in with the other hand.

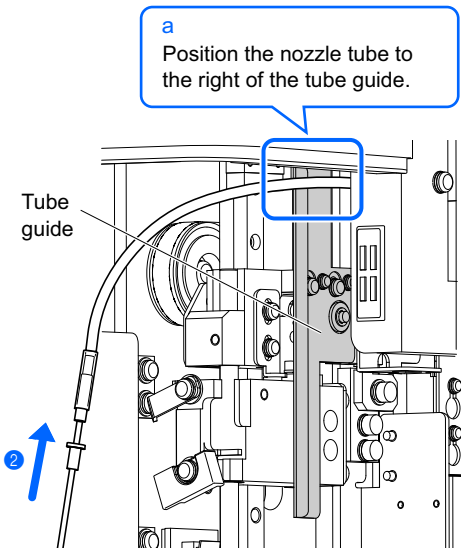
6 Attach the piercing nozzle (or a new piercing nozzle).

If the piercing nozzle removed in step **3** requires replacement, install a new piercing nozzle. Otherwise, install the piercing nozzle removed in step **3**.

❶ Remove the protective tube from the piercing nozzle.
- Keep the protective tube in the accessory case.

❷ Insert the piercing nozzle into the nozzle tube by hand.

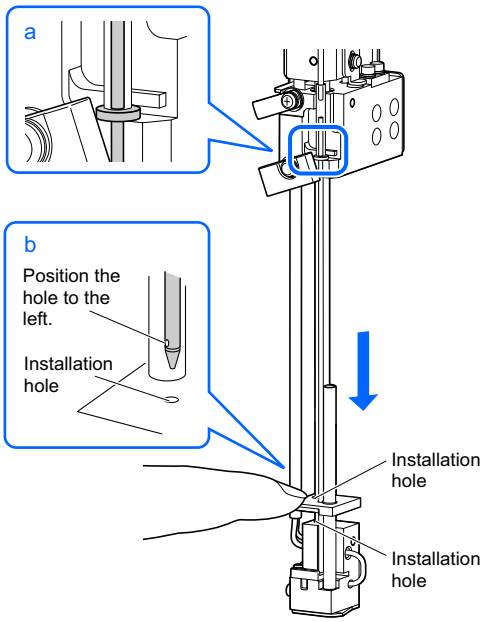
NOTE:
Position the nozzle tube to the right of the tube guide as seen from the front (a).



❸ With the nozzle guide held down to where it stops, pass the tip of the piercing nozzle through the two installation holes.

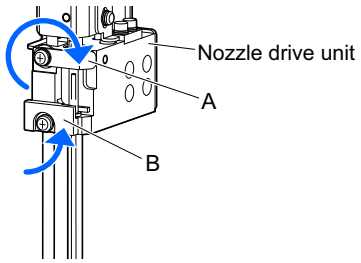
- Fit the projection at the top of the piercing nozzle into the recess in the nozzle holder (a).

NOTE:
Position the piercing nozzle so that the hole near the tip of the nozzle faces the left as seen from the front (b).



❹ While holding the nozzle drive unit still with one hand, return both fixing brackets A and B to their original positions and tighten the screws with the Phillips screwdriver.

- Turn the fixing bracket A clockwise.



7 Attach the STAT port cover.

Be sure to attach the STAT port cover. This reduces sample splattering if sample tubes are not capped.

❶ Place the STAT port cover in its original position and tighten the knurled screw by hand.

❷ Close the front cover.

- The mechanical sections will power on and initialize.

NOTE:
Close the cover to initialize the mechanical sections even if you are not going to perform measurements or other operation right away.

8 Complete maintenance.

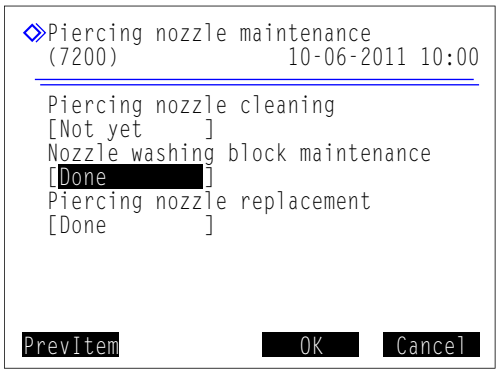
❶ Select <Done> for the maintenance tasks you performed.

- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.

❷ Press OK .

- The instrument will record the maintenance date.
- The [Maintenance menu] screen will appear again.

❸ To return to the standby screen, press Go back twice.



4.2.6 Replacing the Mesh Filters of the Reagent Nozzles

Replace the mesh filters of the nozzles for eluents and hemolysis washing solution every 2400 measurements. Trouble may occur with the flow if the mesh filters become clogged.

IMPORTANT:
Replace the mesh filter for one reagent at a time.

Prepare: Filter and O-ring for elect. (mesh filters and O-rings), tweezers AA, double open end wrench (6-8), gauze, cap for the hemolysis washing solution bottle (that was originally on the bottle before opening, × 1) and caps for the eluent packs (that were originally on the packs before opening, × 3)

1 Remove the tube.

❶ Make sure the standby screen is displayed.

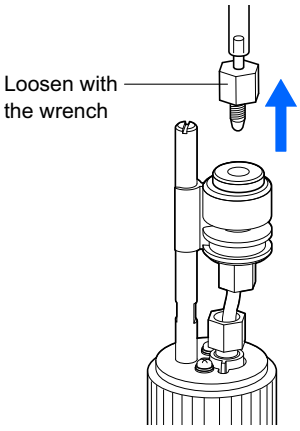
❷ Lay out some gauze near the instrument.

❸ Remove the eluent pack or hemolysis washing solution bottle from the bottle tray.

❹ Remove the bottle cap with nozzle from the pack or bottle.
- Place the nozzle on the gauze.

❺ Attach the cap (that was originally on the pack or bottle before opening it) to the pack or bottle and tighten it securely.

❻ Remove the tube from the bottle cap with nozzle.
- Loosen the push screw with the double open end wrench (6-8) and remove it.



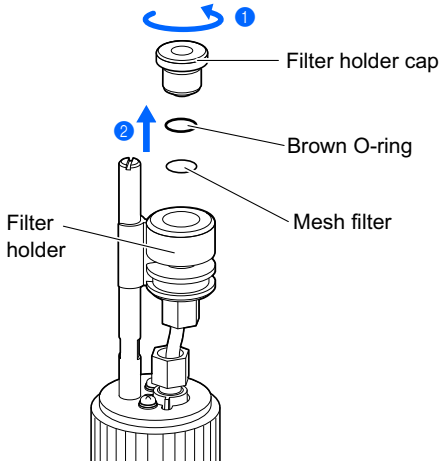
2 Replace the mesh filter.

❶ Turn the cap of the filter holder by hand and remove it.

❷ Remove the old brown O-ring and mesh filter from the holder using tweezers AA.

❸ Put a new mesh filter in the filter holder.

- Position the mesh filter neatly and correctly in the holder using tweezers AA.



NOTE:
The mesh filters are made of easily deformed material. Handle them with great care. Also, liquid may leak if the mesh filters are off the correct position. Position them neatly and correctly.

❹ Attach a new O-ring to the filter holder cap and attach the cap to the filter holder.

❺ Attach the push screw of the tube removed in step **1** to the bottle cap with nozzle. Tighten the screw with the wrench.

NOTE:
Air may enter tubes and prevent solution aspiration if the push screws are loose.

3 Attach the bottle cap with nozzle to the pack or bottle.

❶ Remove the cap from the eluent pack or hemolysis washing solution bottle.

❷ Insert the nozzle of the bottle cap into the pack or bottle. Tighten the cap securely.

4 Place the pack or bottle.

❶ Check that the cap of the eluent pack or hemolysis washing solution bottle is tightened securely.

❷ Neatly arrange the tube and fluid level detection sensor cord to prevent twisting or tangling.

❸ Place the pack or bottle in its original position.

5 Remove air from the tube by priming.

❶ Perform priming for the tube and pump fluid to it.

- Eluent nozzle: Perform priming for the applicable eluent, and then pump fluid to the tube.
  Hemolysis washing solution nozzle: Perform priming for hemolysis washing solution.
- See “4.4. Priming” on page 4-43.

❷ Check that air has not entered the tube from the filter holder.

- If there is air in the tube, further tighten the push screw that was tightened in step **2**-❺ with a wrench.
- If air still enters the tube, retry from step **1**-❶.

REFERENCE:

You can record the date of mesh filter replacement on the instrument. See “4.5.1. Recording the Date of Maintenance” on page 4-44.

4.2.7 Replacing the Tubes of the Drain Pinch Valves

Replace the tubes of the drain pinch valves every 6 months or if the tubes aspirate foreign matter.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used tubes and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: Spare tubes (for valves), gauze and protective gloves

1 Turn off the power.

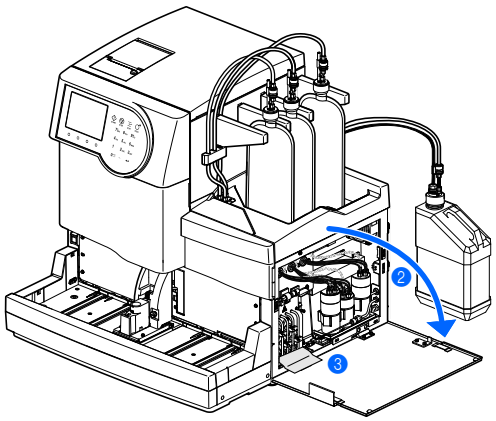
❶ Make sure the standby screen is displayed and press the standby switch.
- The power will be turned off.

2 Open the side cover.

❶ Move the hemolysis washing solution bottle as shown on the right.
- This makes it possible to open or close the side cover.

❷ Open the side cover.

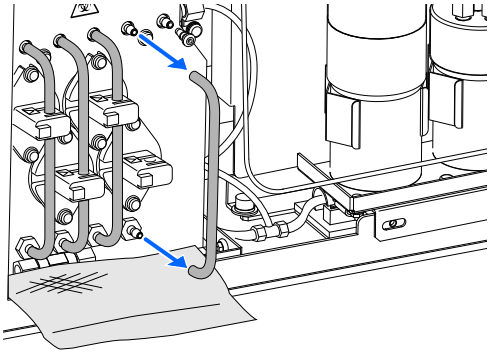
❸ Lay tissue paper below the drain pinch valves.
- The tissue paper blots up any liquid that overflows when removing the old tubes.



3 Replace the tubes.

❶ Remove the four old tubes from the drain pinch valves.

❷ Connect both ends of the new spare tubes to the top and bottom joints of the drain pinch valves.



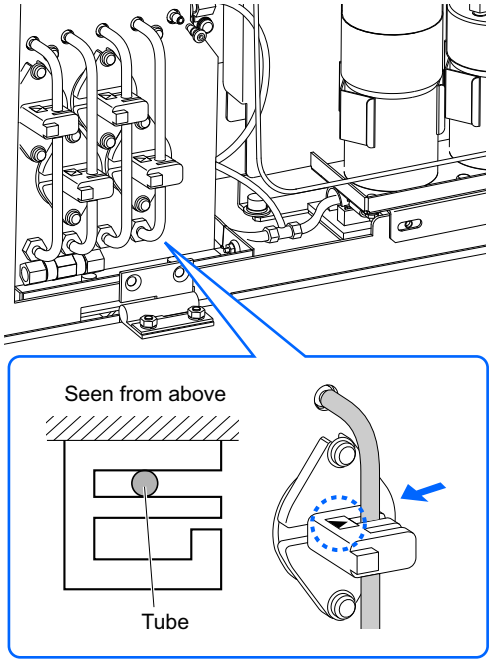
NOTE:

- Connect tubes to the correct joints. Liquid may leak if tubes are connected to the wrong joints or loose. The instrument may be damaged as a result.
- Check tubes are not kinked at the joints. If the tubes are kinked, it may cause liquid waste to obstruct the flow.

❸ Fit the spare tubes into the rear hooks.

NOTE:

There are two hooks on each valve. Be sure to pinch the tube in the REAR hook with an arrow mark.



❹ Wipe up if there is any leaked liquid.

❺ Close the side cover.

REFERENCE:

You can record the date of tube replacement on the instrument. See “4.5.1. Recording the Date of Maintenance” on page 4-44.

❻ Place the hemolysis washing solution bottle in its original position.

4.3 Washing and Cleaning

4.3.1 Discarding Liquid Waste

Discard liquid waste from the bottle for liquid waste before starting the first measurement every day. This instrument drains liquid waste from two drain joints on the rear panel: “D1” for the optical unit and “D2” for liquid waste. During measurements, regularly check the volume of liquid waste in the bottle and discard it before the bottle becomes full.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard liquid waste and used protective gloves in accordance with local regulations for biohazardous waste.

Prepare: Protective gloves

4.3.2 Automatically Washing the Tubes

Wash the tubes once a week. Inaccurate measurement results may be obtained if the tubes are contaminated. This section describes how to wash the tubes automatically. Automatic tube washing starts with the tubes in which sample flows and ends with washing solution drainage.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard liquid waste, used sample tubes and protective gloves in accordance with local regulations for biohazardous waste.

REFERENCE:

Use the following sample tubes for automatic tube washing:

- 15 mm diameter and 75 to 100 mm in height
- 12.3 mm diameter and 100 mm in height

Prepare: Washing solution for tubes, sample tubes (× 2, see “REFERENCE” above.), washing rack (label: WASH) and protective gloves

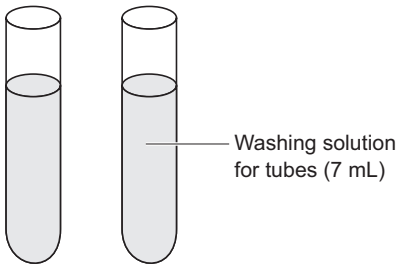
1 Access the maintenance screen.

❶ On the standby screen, select Menu, <7 Maintenance menu> and <1 Tube wash> in that order.

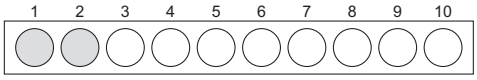
- The following message will appear; “Load washing solution into washing rack, and then load rack onto sampler.”

2 Prepare the washing solution for tubes.

❶ Add 7 mL of washing solution for tubes to each of two sample tubes.



❷ Set the sample tubes in ports 1 and 2 of the washing rack.



NOTE:
Be sure to use the washing rack. Use of other racks may damage the instrument or seriously degrade the column, requiring its replacement.

❸ Load the washing rack onto the sampler.
- See step **4** in "2.4.1. Preparing Samples" on page 2-19.

3 Wash the tubes.

❶ Press Start or ◇|.
- Tube washing will start.

REFERENCE:
To have the instrument enter sleep mode automatically after tube washing:
Press Timer. If the startup timer is set to [Use], select the day the next time the instrument starts up (see "3.3.3. Setting the Timer" on page 3-9).

4 Turn off the power.

NOTE:
If the timer was set by pressing Timer, **do not** turn off the power by pressing the standby switch in step ❷ below. Turning off the power with the standby switch will cancel the timer.

REFERENCE:
The washing solution for tubes will remain in the instrument and will be drained the next time the instrument starts up.

- The message "Tube washing ended. Turn off power." will appear when tube washing is complete.

❶ Check that the washing rack is not moving and remove the rack from the rack unloading side of the sampler.

❷ Press the standby switch to turn off the power.

4.3.3 Automatically Washing the Tubes After Measurement

You can automatically wash tubes after sample measurement by loading a washing rack after sample racks with samples. Set sample tubes with washing solution for tubes in the washing rack.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard liquid waste, used sample tubes and protective gloves in accordance with local regulations for biohazardous waste.

REFERENCE:

Use the following sample tubes for automatic tube washing:

- 15 mm diameter and 75 to 100 mm in height
- 12.3 mm diameter and 100 mm in height

Prepare: Washing solution for tubes, sample tubes (for tube washing, × 2, see "REFERENCE" above.), washing rack (label: WASH), sample containers and racks needed for normal measurement, and protective gloves

1 Prepare samples and the washing solution for tubes.

NOTE:

Be sure to set the washing solution for tubes in the washing rack. Use of other racks may damage the instrument or seriously degrade the column, requiring its replacement.

❶ Prepare samples for normal measurements.

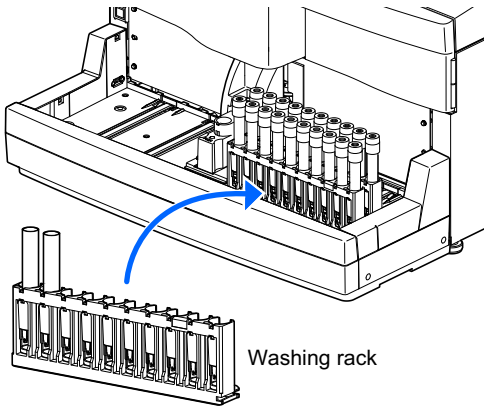
- See steps **1** to **3** in "2.4.1. Preparing Samples" on page 2-16.

❷ Prepare the washing solution for tubes.

- See step **2** in "4.3.2. Automatically Washing the Tubes" on page 4-28.

❸ Load the sample racks for normal measurements onto the sampler.

- See step **4** in "2.4.1. Preparing Samples" on page 2-19.



❹ Load the washing rack onto the sampler.

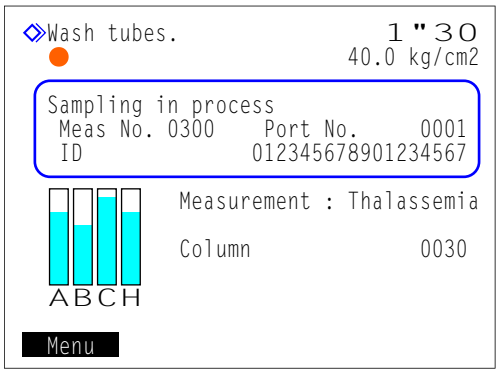
NOTE:

Measurements are not performed if a sample rack is set after the washing rack.

2 Start measurement.

❶ On the standby screen, press ◇|◇.

- Normal measurements will start.
- The message “Wash tubes.” will appear when the washing rack is detected.
- Tube washing will start when normal measurements for all samples are complete.



REFERENCE:

To have the instrument enter sleep mode automatically after tube washing:
Select Menu, and then <9 Set timer>. If the startup timer is set to [Use], select the day the next time the instrument starts up (see “3.3.3. Setting the Timer” on page 3-9).

3 Turn off the power.

NOTE:

If the timer is set (see “REFERENCE” above), **do not** turn off the power by pressing the standby switch in step ❷ below. Turning off the power with the standby switch will cancel the timer.

REFERENCE:

The washing solution for tubes will remain in the instrument and will be drained the next time the instrument starts up.

- The message “Tube washing ended. Turn off power.” will appear when washing is complete.

❶ Check that the sample racks are not moving, and remove the racks from the rack unloading side of the sampler.

❷ Press the standby switch to turn off the power.

4.3.4 Cleaning the Piercing Nozzle

Clean the piercing nozzle once a week. Contaminated piercing nozzle accelerates degradation of the O-ring of the nozzle washing block. If the O-ring degrades, hemolysis washing solution may leak, resulting in inaccurate measurement results.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: Cotton swabs, gauze, purified water and protective gloves

1 Move the piercing nozzle.

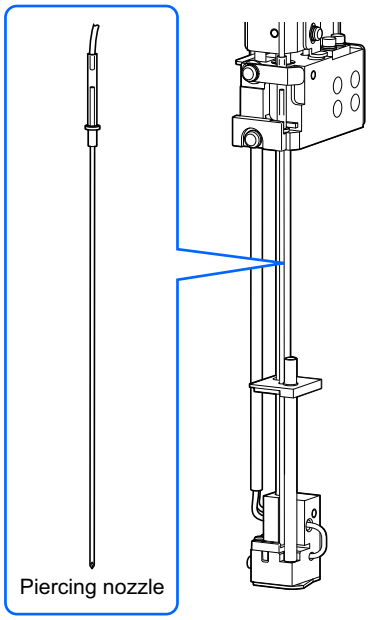
❶ Move the piercing nozzle by menu operation, then remove the STAT port cover.

- See steps **1** and **2** in "4.2.5. Replacing the Piercing Nozzle/Cleaning the Nozzle Washing Block" on page 4-16.

2 Clean the piercing nozzle.

❶ Wipe off dirt from the outside of the piercing nozzle with cotton swabs.

- For stubborn dirt, use gauze moistened with purified water.



3 Attach the STAT port cover.

Be sure to attach the STAT port cover. This reduces sample splattering if sample tubes are not capped.

❶ Place the STAT port cover in its original position and tighten the knurled screw by hand.

❷ Close the front cover.
- The mechanical sections will power on and initialize.

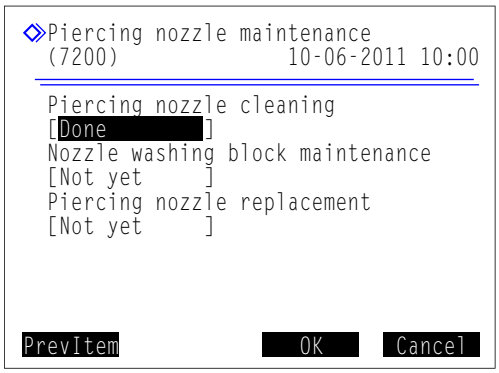
NOTE:
Close the cover to initialize the mechanical sections even if you are not going to perform measurements or other operation right away.

4 Complete maintenance.

❶ Below <Piercing nozzle cleaning>, select <Done>.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.

❷ Press OK .
- The instrument will record the maintenance date.
- The [Maintenance menu] screen will appear again.

❸ To return to the standby screen, press Go back twice.



4.3.5 Cleaning the Sample Tube Spinning Unit

Clean the sample tube spinning unit once a month. The sample tube spinning unit cannot spin sample tubes properly if the rollers are contaminated.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used gauze and protective gloves in accordance with local regulations for biohazardous waste.

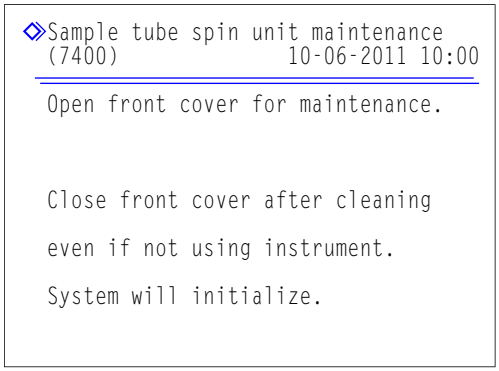
Prepare: Gauze, purified water and protective gloves

1 Move the sample tube spinning unit to the front.

❶ On the standby screen, select Menu, <7 Maintenance menu> and <4 Sample tube spin unit maintenance> in that order.

❷ Press Start.
- The sample tube spinning unit will move to the front.

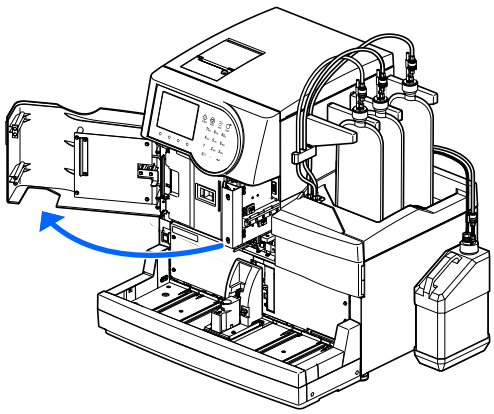
❸ Wait for the screen shown on the right to appear.



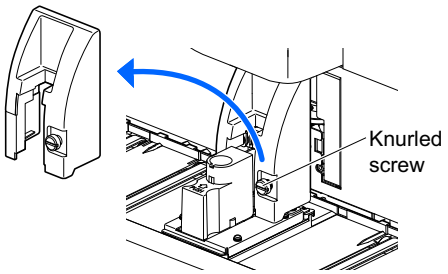
2 Remove the STAT port cover.

❶ Open the front cover.
- The mechanical sections will power off.

REFERENCE:
The message “W:062 Front or maintenance cover is open.” appears if the front cover is opened before performing steps **1**-❶ to **1**-❸. Be sure to perform steps **1**-❶ to **1**-❸ first.



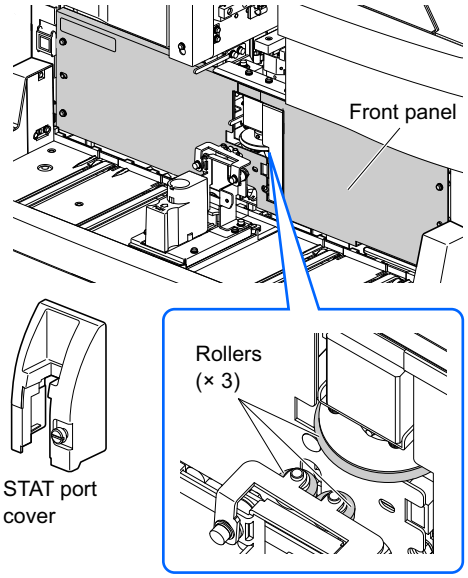
❷ Loosen the knurled screw by hand, and pull the STAT port cover to the front to remove it.



3 Clean the sample tube spinning unit.

❶ Wipe off dirt from the parts listed below using gauze moistened with purified water.

- Front panel
  Rollers (× 3)
  STAT port cover
- Rotate the rollers by hand while cleaning.



4 Attach the STAT port cover.

Be sure to attach the STAT port cover. This reduces sample splattering if sample tubes are not capped.

❶ Place the STAT port cover in its original position and tighten the knurled screw by hand.

❷ Close the front cover.

- The mechanical sections will power on and initialize.
- The instrument will record the maintenance date.
- The [Maintenance menu] screen will appear again.

NOTE:
Close the cover to initialize the mechanical sections even if you are not going to perform measurements or other operation right away.

❸ To return to the standby screen, press Go back twice.

4.3.6 Cleaning the Dilution Container and Washing Container

Wash the dilution container unit and its cover once a month. (The unit consists of both the dilution container and washing container.) Inaccurate measurement results may be obtained if the dilution container and washing container are contaminated.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: Purified water, cotton swabs, gauze and protective gloves

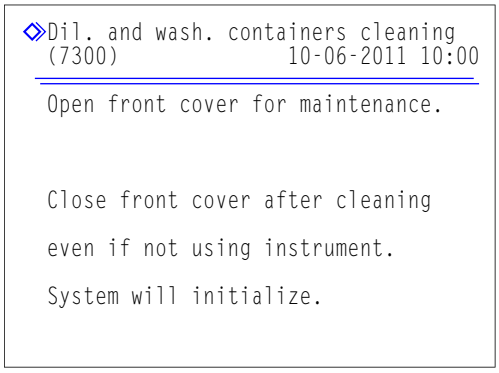
1 Prepare for cleaning.

❶ On the standby screen, select Menu, <7 Maintenance menu> and <3 Dil. and wash. containers cleaning> in that order.

❷ Press Start.

- The piercing nozzle will move to the rear to make it easy to access the dilution container unit. Liquid will be drained from the dilution container and washing container.

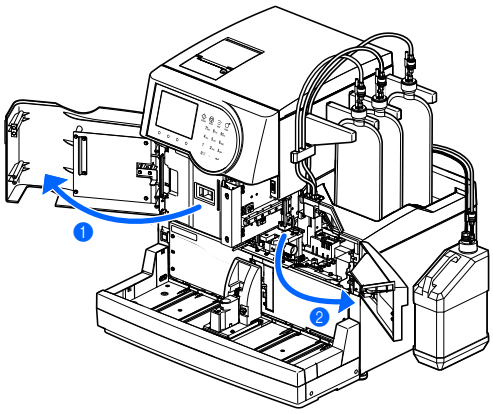
❸ Wait for the screen shown on the right to appear.



2 Remove the dilution container cover.

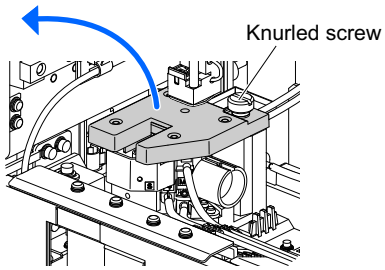
❶ Open the front cover.
- The mechanical sections will power off.

REFERENCE:
The message “W:062 Front or maintenance cover is open.” appears if the front cover is opened before performing steps **1-❶** to **1-❸**. Be sure to perform steps **1-❶** to **1-❸** first.



❷ Open the maintenance cover.

❸ Remove the dilution container cover.
- Loosen the knurled screw by hand and remove the black dilution container cover.

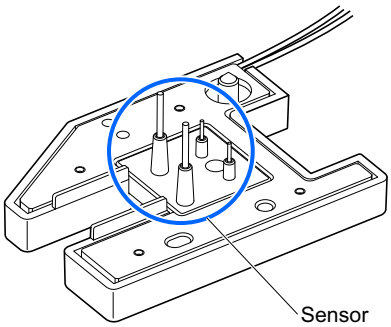


3 Clean the dilution container cover.

❶ Wipe off dirt from the back of the dilution container cover.
- Use cotton swabs or gauze moistened with purified water.
- Be careful in particular not to leave dirt on the sensors.

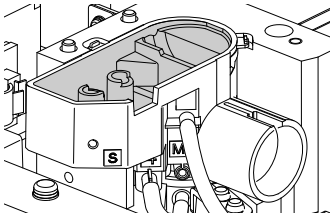
> ⚠ The sensor tips are sharp. Be careful not to injure yourself.

NOTE:
The sensors are fragile. **Do not** apply force to them, for example, by pressing with fingers. If the sensors are bent or broken, the instrument may not work properly and trouble may occur.



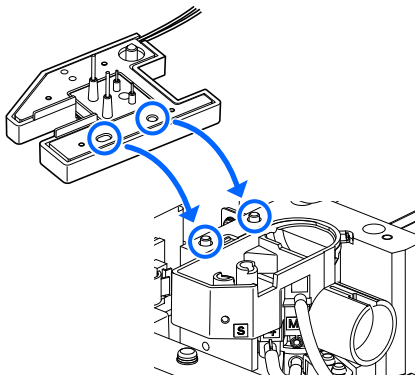
4 Clean the dilution container and washing container.

❶ Blot up any liquid inside the dilution container and washing container, and wipe off any dirt.
- Use cotton swabs or gauze moistened with purified water.



5 Attach the dilution container cover.

❶ Attach the dilution container cover so that the two pins on the left side of the dilution container unit fit into the two holes on the back of the dilution container cover.



NOTE:
Check that the dilution container cover is level as seen from the front. If rising or tilted, the cover may touch other parts and may be damaged during operation.

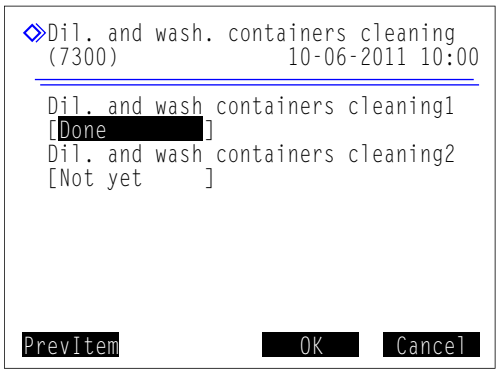
❷ Tighten the knurled screw by hand.

6 Complete maintenance.

❶ Close the maintenance cover, then the front cover.
- The mechanical sections will power on and initialize.

NOTE:
Close the cover to initialize the mechanical sections even if you are not going to perform measurements or other operation right away.

❷ Below <Dil. and wash containers cleaning1>, select <Done>.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.



❸ Press OK.
- The instrument will record the maintenance date.
- The [Maintenance menu] screen will appear again.

❹ To return to the standby screen, press Go back twice.

4.3.7 Cleaning the Parts of the Dilution and Washing Containers

Disassemble the dilution container unit and wash the parts once a year. (The unit consists of both the dilution container and washing container.) Inaccurate measurement results may be obtained if the dilution container and washing container are contaminated.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: Tweezers AA, neutral detergent, cotton swabs, gauze, purified water, beaker and protective gloves

1 Prepare for cleaning and remove the dilution container cover.

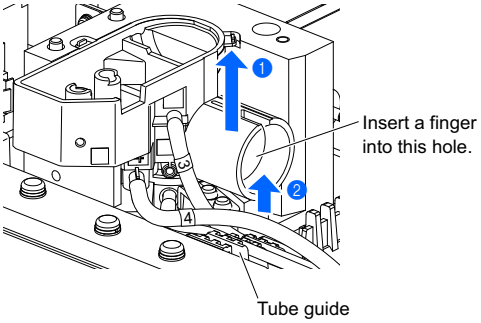
❶ Prepare for cleaning and remove the dilution container cover.

• See steps **1** and **2** in "4.3.6. Cleaning the Dilution Container and Washing Container" on page 4-35.

2 Detach the dilution container unit.

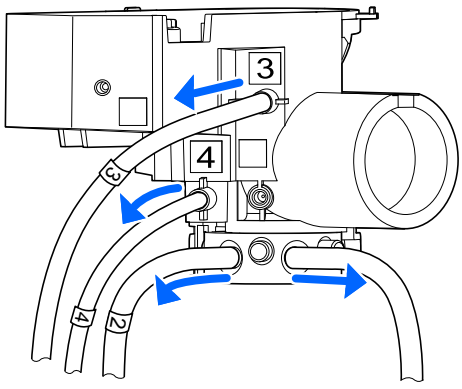
❶ Detach the dilution container unit.

REFERENCE:
The dilution container unit can be easily detached by inserting a finger into the hole on the right side of the unit and lifting the unit straight up.



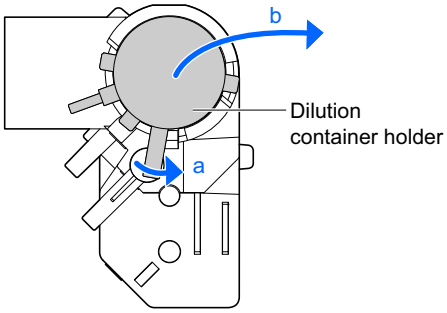
❷ Disconnect the three tubes of the dilution container unit from the tube guide.

❸ Remove all the four tubes from the dilution container unit.



3 Remove the dilution container holder.

❶ Turn the metal dilution container holder on the bottom of the dilution container unit counterclockwise (a) and remove the holder (b).

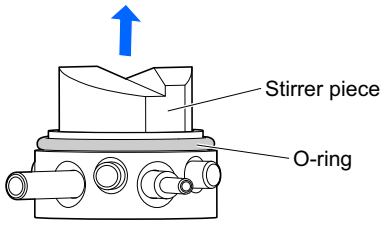


4 Remove the stirrer piece and O-ring.

❶ Remove the white stirrer piece from the dilution container holder.

❷ Pinch the black O-ring with tweezers AA and pull it off the dilution container holder.

NOTE:
If the O-ring breaks, replace it with a new one.



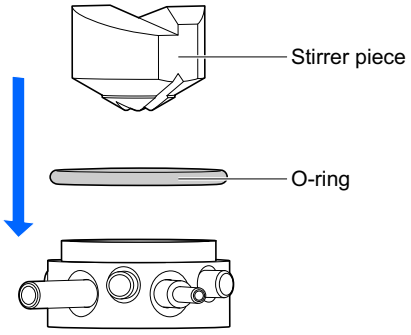
5 Clean the parts.

❶ Clean the dilution container unit, dilution container holder, stirrer piece and O-ring.
- Wipe with cotton swabs or gauze moistened with purified water or rinse with purified water.
- Place the O-ring in a beaker filled with purified water to clean.
- Wipe off stubborn dirt by using gauze moistened with a neutral detergent, and rinse off all detergent on the parts with purified water.

6 Attach the dilution container unit.

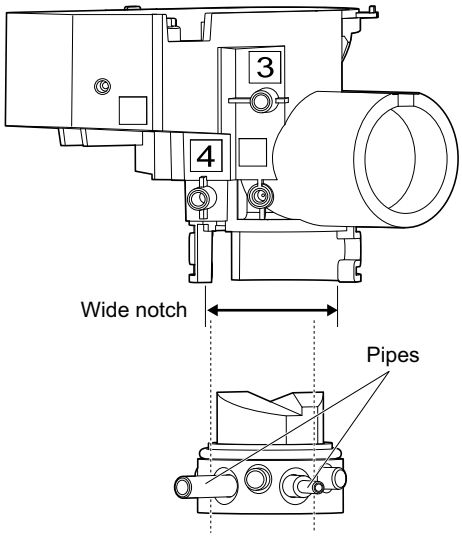
❶ Fit the O-ring over the dilution container holder.

❷ Fit the stirrer piece into the dilution container holder.

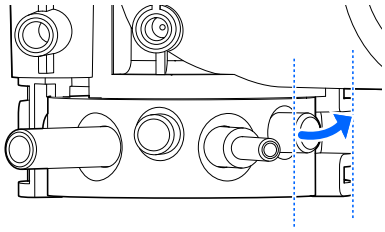


❸ Attach the dilution container holder to the dilution container unit.

- Set the dilution container holder so that the two pipes on it can fit into the wider notch on the bottom of the dilution container unit.

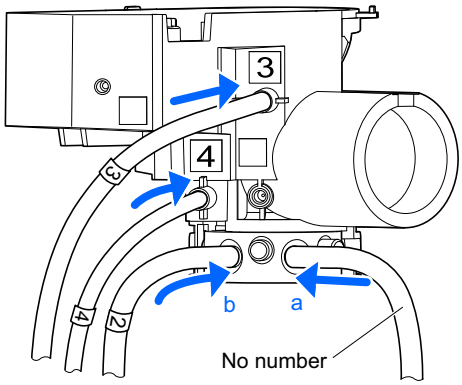


- Turn the dilution container holder counterclockwise until the pin makes contact to lock it in place.



❹ Connect the four tubes.

Connection port location		Tube number
Metal dilution container holder	a (shown in the figure)	No number
	b (shown in the figure)	2
Dilution container unit	3	3
	4	4



NOTE:

Check that the tube number matches the number of the connection port on the dilution container unit before connecting. Connect the tubes securely. The instrument may be damaged if the tubes are connected to the wrong ports or loose.

❺ Place the dilution container unit in its original position.

❻ Fit the tubes (Nos. 2, 3 and 4) into the tube guide.

7 Attach the dilution container cover.

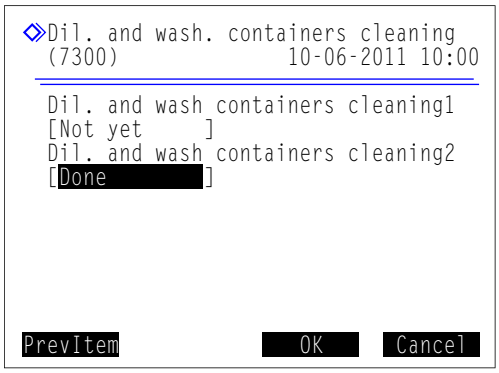
See step **5** in "4.3.6. Cleaning the Dilution Container and Washing Container" on page 4-37.

8 Complete maintenance.

❶ Close the maintenance cover, then the front cover.
- The mechanical sections will power on and initialize.

NOTE:
Close the cover to initialize the mechanical sections even if you are not going to perform measurements or other operation right away.

❷ Below <Dil. and wash containers cleaning2>, select <Done>.
- ↵ button: Moves the cursor to the next setup field.
  Hyphen button: Changes the option.



❸ Press OK.
- The instrument will record the maintenance date.
- The [Maintenance menu] screen will appear again.

❹ To return to the standby screen, press Go back twice.

4.3.8 Washing the Air Filter

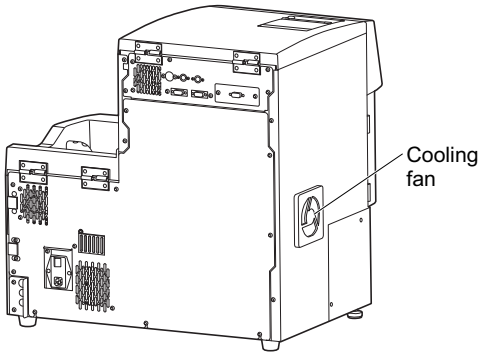
The cooling fan (air intake fan) of the instrument has the air filter that protects the internal mechanism from dust. Accumulation of dust in the filter results in decreased cooling efficiency. Wash the filter once a month.

1 Remove the air filter.

❶ Make sure the standby screen is displayed.

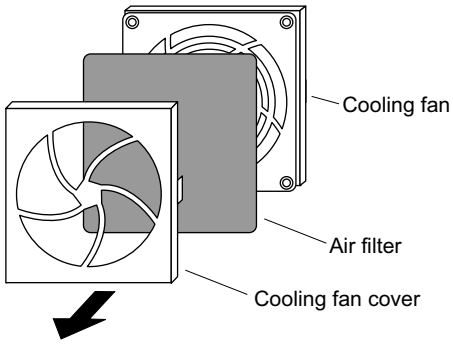
❷ Press the standby switch to turn off the power.
- Make sure the cooling fan has stopped completely.

⚠ Make sure the cooling fan has stopped completely, before proceeding to the next step. Failure to do so may result in injury.



❸ Pull the cooling fan cover toward you and remove it.

❹ Remove the air filter.

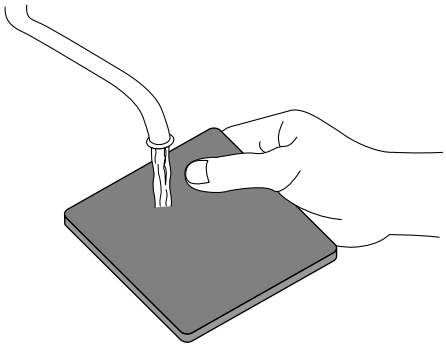


2 Wash the air filter.

❶ Wash the filter thoroughly under running water to remove accumulated dust.

❷ Lightly wring out the air filter to remove water. Dry the filter well.

❸ Reattach the air filter to its original position.



NOTE:
Replace the air filter with a new one if it rips or stubborn stains persist after washing.

4.3.9 Disinfection

For disinfection of the device, lightly wipe the device with a cotton swab or gauze moistened with disinfectant, then wipe off the disinfectant with a cotton swab or gauze moistened with water, and then wipe it dry. Use 70% isopropanol as the disinfectant. Contact your distributor if you use another disinfectant.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: 70% isopropanol, cotton swabs, and gauze

4.4 Priming

Usually, air is automatically removed from the tubes by priming before measurement. Follow the instructions described below when you are instructed to perform priming or fluid pumping after replacing parts, or when remedying warning, error or trouble. Priming can be selected from the seven types listed below.

- Automatic
- Fluid pumping (Supplying eluent A to the column)
- Eluent A
- Eluent B
- Eluent CT
- Damper (Priming for the fluid pump and damper)
- Hemolysis washing solution

1 Access the maintenance screen.

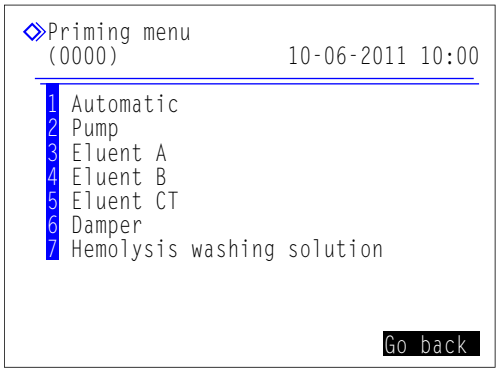
❶ On the standby screen, press Priming .

- The [Priming menu] screen will appear.

2 Select the type of priming.

❶ Select the type of priming to perform.

- Priming will start.
- After completion, the [Priming menu] screen will appear again.



Setup item	Description
1 Automatic	Removes air from the eluent A tube, eluent B tube, eluent CT tube, fluid pump and damper by priming, and stops automatically. To manually stop priming, press Stop .
2 Pump	Pumps eluent A to the column. Press Stop in three or four minutes when the column pressure becomes appropriate. An appropriate column pressure is near the “Column Pressure (MPa or kg/cm^2)” written on the “CERTIFICATE OF QUALITY” that comes with the column. If the column does not reach an appropriate pressure, press Stop and select <1 Automatic> on the [Priming menu] screen.
3 Eluent A	Removes air from the eluent A tube by priming and stops automatically.
4 Eluent B	Removes air from the eluent B tube by priming and stops automatically.
5 Eluent CT	Removes air from the eluent CT tube by priming and stops automatically.
6 Damper	Removes air from the fluid pump and damper by priming. After one minute, priming stops automatically.
7 Hemolysis washing solution	Removes air from the hemolysis washing solution tube by priming, and stops automatically.

❷ To return to the standby screen, press Go back .

4.5 Recording Maintenance

4.5.1 Recording the Date of Maintenance

After replacing or cleaning parts, the instrument automatically records that date. You can use this information as a reference for the next time maintenance is needed. Maintenance dates can also be manually entered after performing tasks that do not provide automatic recording or when you want to change the recorded dates.

1 Access the maintenance screen.

❶ Access the desired screen.

●Piercing nozzle

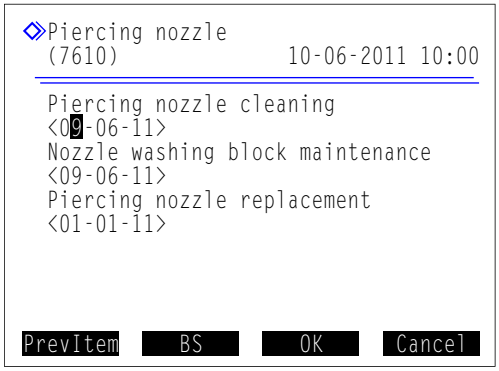
On the standby screen, select Menu, <7 Maintenance menu>, <6 Maintenance log menu> and <1 Piercing nozzle> in that order.

●Dilution container and washing container

On the standby screen, select Menu, <7 Maintenance menu>, <6 Maintenance log menu> and <2 Dilution and washing containers> in that order.

●Mesh filters of reagent nozzles and drain pinch valves

On the standby screen, select Menu, <7 Maintenance menu>, <6 Maintenance log menu> and <3 Others> in that order.



2 Enter the date.

❶ Enter the date.

- **Hyphen** button: Moves the cursor through the date in the order of “day”, “month” and “year”.
  ↵ button: Moves the cursor to the next setup field.

❷ Press OK.

- The message “Settings changed. Save setting changes?” will appear.

❸ Press OK.

- This saves your entries and will return you to the [Maintenance log menu] screen.

❹ To return to the standby screen, press Go back three times.

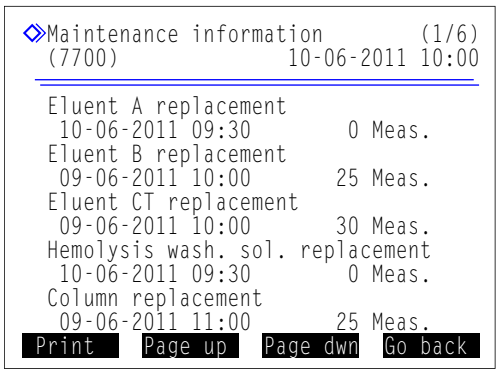
4.5.2 Viewing Maintenance History

You can display the last date of each maintenance task and the number of measurements performed since that date for viewing.

❶ On the standby screen, select Menu, <7 Maintenance menu> and <7 Maintenance information> in that order.

- A maintenance history will appear.
- Items beyond their maintenance frequency are displayed in red.

Print	Prints maintenance history.
Page up	Returns to the previous page.
Page dwn	Goes to the next page.
Go back	Returns to the previous screen.



❷ To return to the standby screen, press Go back three times.

4.6 Before/After Extended Periods of Disuse

4.6.1 Preparing the Instrument Before Extended Periods of Disuse

When you do not intend to use the instrument for one week or more, follow the instructions described below to clean each part. Failure to do so may cause remaining fluid to crystallize and clog the tubes, resulting in damage to the instrument.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard liquid waste, used cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

IMPORTANT:

- After removing eluent packs or the hemolysis washing solution bottle from the instrument, cap them tightly and store them at a temperature between 3°C and 30°C. If not properly stored, inaccurate measurement results may be obtained.
- Squeeze out as much air as possible from eluent packs before capping.

Prepare: Dummy column (that was originally attached to the column installation position at the time of shipment), cap for the hemolysis washing solution bottle (that was originally on the bottle before opening, × 1), caps for the eluent packs (that were originally on the packs before opening, × 3), sealing screws (that were attached to the column when taken from its package, × 2), beakers (500 mL or more capacity: × 1, small enough to hold in one hand: × 1), aluminium packs (× 3, for maintenance when the instrument is not to be used for extended periods of time), gauze, distilled water, plastic bag (large enough to hold the bottle caps with nozzles) and protective gloves

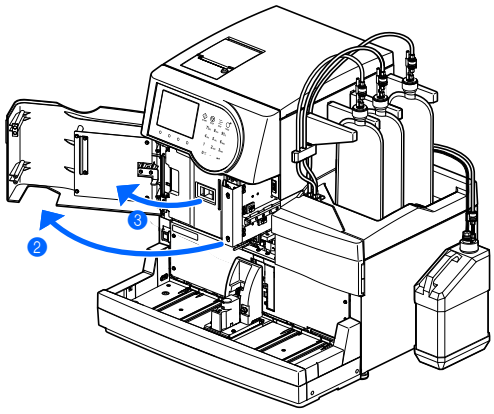
1 Open the temperature control box cover.

❶ Make sure the standby screen is displayed.

❷ Open the front cover.

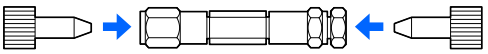
REFERENCE:
The message “W:062 Front or maintenance cover is open.” appears, even though there is no problem with the instrument. Proceed without pressing OK.

❸ Open the temperature control box cover.



2 Store the column.

❶ Detach the column from the column holder and press the tube until it is protruding about 3 mm from the push screws.
- See step **3** in "4.2.4. Replacing the Column" on page 4-12.



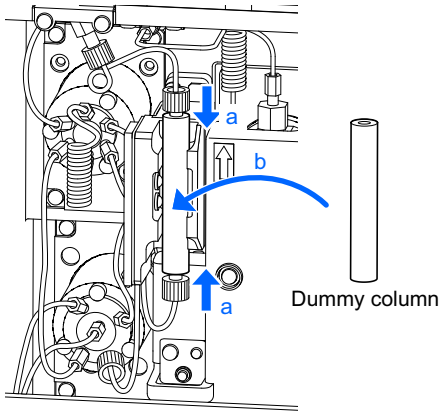
❷ Seal the both ends of the column with the sealing screws.

❸ Store the column at a temperature between 3°C and 25°C.

3 Connect the dummy column.

❶ Connect the dummy column in the place of the removed column.
- Connect the push screws to the both ends of the dummy column (a) and tighten the screws by hand. Then, install the dummy column into the column holder (b).

REFERENCE:
Either end of the dummy column can be set to the top.



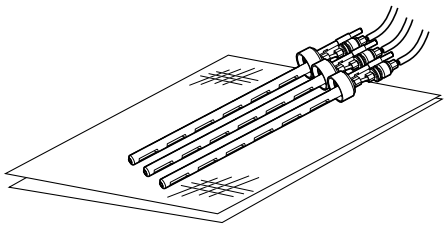
❷ Close the temperature control box cover, then the front cover.

❸ Press OK.
- "W:062" will be cancelled.

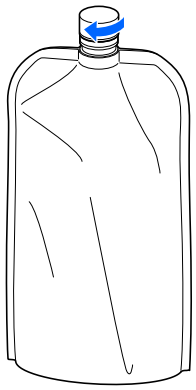
4 Store the eluent packs.

❶ Remove the bottle caps with nozzle from the eluent packs.

❷ Wipe eluent from the nozzles with gauze and place the nozzles on a new piece of gauze.



❸ Squeeze out as much air as possible from the packs.



IMPORTANT:
If air remains in the packs, eluent condensation may rise, resulting in inaccurate measurement results.

❹ Attach the caps (that were originally on the packs before opening) to the packs and tighten them securely.

❺ Store the packs at a temperature between 3°C and 30°C, avoiding direct sunlight.

5 Drain fluid from the chambers.

❶ On the standby screen, select Menu, <7 Maintenance menu>, <5 Drain menu> and <1 Eluent A> in that order.
- Fluid is drained from the eluent A chamber.
- After completion, the [Drain menu] screen will appear again.

❷ Select <2 Eluent B>.
- Fluid is drained from the eluent B chamber.
- After completion, the [Drain menu] screen will appear again.

❸ Select <3 Eluent CT>.
- Fluid is drained from the eluent CT chamber.
- After completion, the [Drain menu] screen will appear again.

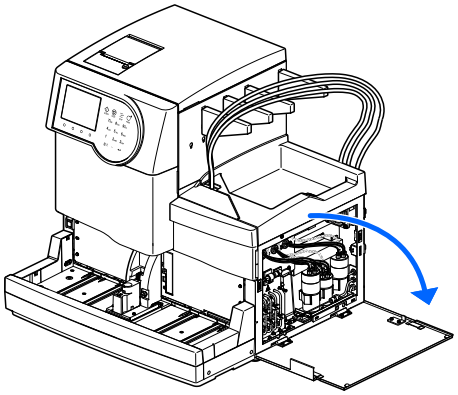
❹ Press Go back three times to return to the standby screen.

6 Turn off the power.

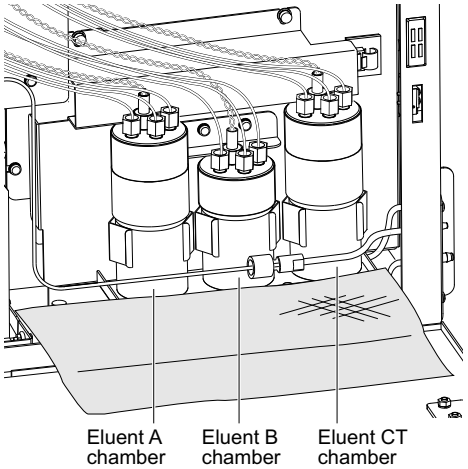
❶ Press the standby switch to turn off the power.

7 Remove the chambers.

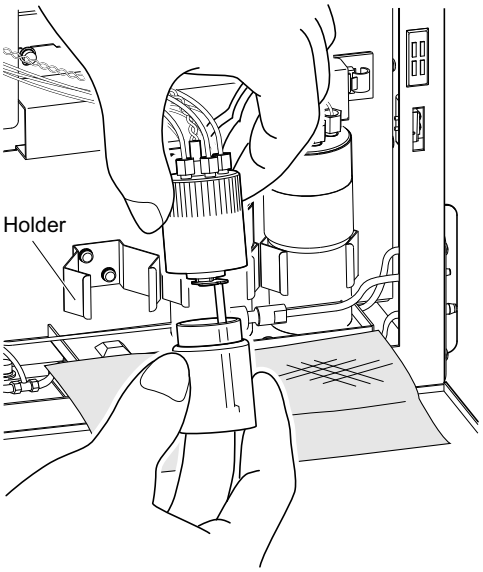
❶ Open the side cover.



❷ Lay out some gauze in front of the chambers.
- The gauze blots up any liquid that is spilled while removing the chambers.



❸ Remove the eluent A chamber from the holder and pull it to the front 2 to 3 cm.



IMPORTANT:
Remove and clean one chamber at a time to prevent confusion.

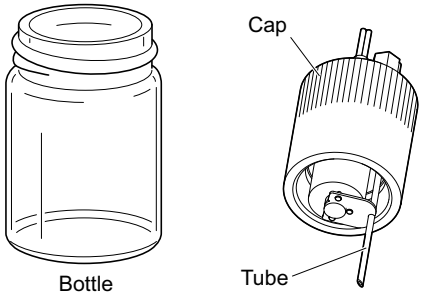
NOTE:
Do not pull the cords or tubes excessively when pulling out the chambers. The sensor cords and tubes may become disconnected.

❹ Holding the cap of the eluent A chamber, turn the bottle until the cap detaches.

8 Clean the chambers.

❶ Dilute any remaining liquid in the bottle of the eluent A chamber with plenty of water, then discard the liquid.

❷ Blot water from the chamber bottle, cap and tube with gauze.



NOTE:
Remove any lint if it is stuck to the bottle, cap or tube. Lint may clog the tube.

❸ Attach the eluent A chamber to its original holder.

NOTE:
Tighten the chamber cap securely. If the cap is loose, the chamber may leak, resulting in damage to the instrument.

❹ Clean the eluent B chamber in the same procedure.
- See steps **7**-❸ to **8**-❸.

❺ Clean the eluent CT chamber in the same procedure.
- See steps **7**-❸ to **8**-❸.

❻ Close the side cover.

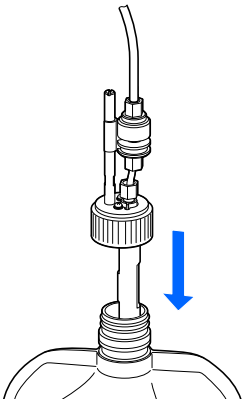
9 Wash the eluent tubes.

❶ Add a small volume of distilled water to an empty aluminium pack and rinse the inside.
- Use the aluminium packs (supplied) for maintenance when the instrument is not to be used for extended periods of time.
- Discard the distilled water after rinsing the pack.

❷ Add 600 mL of distilled water to the aluminium pack with a beaker.

NOTE:
- Use a beaker that can be held with one hand. If the beaker cannot hold 600 mL, add the distilled water in several pourings.
- Hold the beaker in one hand and the pack by the hard plastic neck in the other hand while adding the distilled water. If you fail to do so, the pack may collapse under its own weight.

❸ Insert one of the nozzles on the gauze into the aluminium pack and tighten the cap securely.



❹ Attach other nozzles to other aluminium packs in the same procedure.
- See steps **9**-❶ to **9**-❸.

❺ Press the standby switch to turn on the power.

❻ On the standby screen, press Priming.
- The [Priming menu] screen will appear.

❼ Select <1 Automatic>.
- Priming will stop automatically when the eluent tubes are filled with distilled water. The [Priming menu] screen will then appear again.

❽ Select <6 Damper>.
- The fluid pump and damper will be washed.
- After completion, the [Priming menu] screen will appear again.

❾ Select <6 Damper> again.
- The [Priming menu] screen will appear again when washing is complete.

❿ Select <2 Pump>.
- The valves and optical unit will be washed.

⓫ After three minutes, press OK.
- Pumping will stop and the [Priming menu] screen will appear again.

⓬ Press Go back to return to the standby screen.

10 Drain distilled water from the tubes.

❶ Remove the bottle caps with nozzle from the aluminium packs.
- Place the nozzles on the gauze.

❷ Discard all of the distilled water in the aluminium packs.

NOTE:
- Hold the aluminium pack by the hard plastic neck while discarding the distilled water from the pack.
- Dry the aluminium packs thoroughly, then keep them in the accessory case.

❸ Drain fluid from the chambers.
- See step **5** on page 4-48.
- The distilled water will be drained from the tubes.

11 Store the hemolysis washing solution bottle.

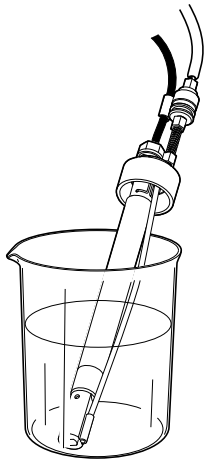
❶ Add distilled water to a beaker (500 mL or more capacity).

❷ Remove the bottle cap with nozzle from the hemolysis washing solution bottle.

❸ Wipe solution from the nozzle with gauge and place the nozzle in the beaker.

❹ Attach the cap (that was originally on the bottle before opening) to the bottle and tighten it securely.

❺ Store the bottle at a temperature between 3°C and 30°C, avoiding direct sunlight.



12 Wash the tube for hemolysis washing solution.

❶ On the standby screen, select Menu, <7 Maintenance menu>, <5 Drain menu> and <4 Hemolysis washing solution> in that order.
- The distilled water will be drained from the tubes for hemolysis washing solution.
- The [Drain menu] screen will appear again.

❷ Select <4 Hemolysis washing solution> again.
- Wait until washing finishes.

❸ Press Go back three times to return to the standby screen.

13 Drain distilled water from the tubes.

❶ Discard all of the distilled water from the beaker in which the bottle cap with nozzle for hemolysis washing solution was placed.

❷ On the standby screen, select Menu, <7 Maintenance menu>, <5 Drain menu> and <4 Hemolysis washing solution> in that order.
- The distilled water will be drained from the tubes for hemolysis washing solution.
- The [Drain menu] screen will appear again.

❸ Press Go back three times to return to the standby screen.

14 Wash the nozzles.

❶ Wash the nozzles for eluents and hemolysis washing solution with distilled water, and blot with gauze.

❷ Wrap the bottle caps with nozzle in gauze, place them in the plastic bag and put the bag on the bottle tray.
- The tubes and fluid level detection sensor cord can remain connected to the instrument.

NOTE:
If you store the nozzles without washing, fluid may crystallize and clog the nozzles.

15 Discard liquid waste.

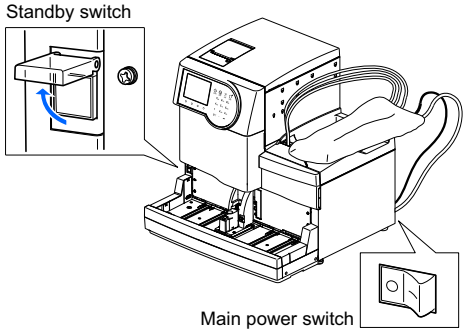
❶ Discard liquid waste remaining in the bottle for liquid waste.

16 Turn off the main power.

❶ Press the standby switch to turn off the power.

❷ Press the "○" side of the main power switch on the rear panel to turn off the main power.

❸ Unplug the power cord from the outlet.



17 Clean the chambers.

❶ Remove and clean the chambers.
- See steps **7** and **8** on pages 4-48 to 4-49.

4.6.2 Starting Up the Instrument After Extended Periods of Disuse

Follow the instructions described below to start up the instrument after one week or more of disuse.

1 Set the eluent packs and hemolysis washing solution bottle.

❶ Place the eluent A, B and CT packs on the bottle tray.
- See step **4** in "4.2.1. Replacing the Eluent Packs" on page 4-4.

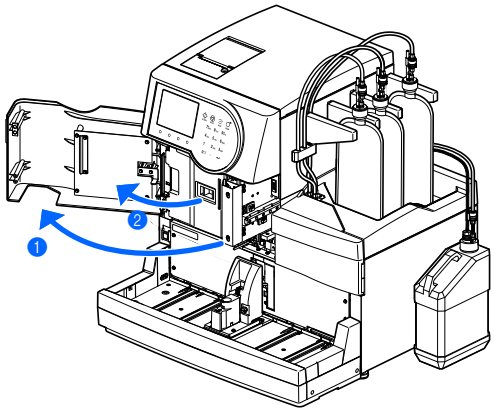
❷ Place the hemolysis washing solution bottle in the specified position.
- See step **4** in "4.2.2. Replacing the Hemolysis Washing Solution Bottle" on page 4-8.

NOTE:
If you set a reagent of a different lot from before, set its reagent information after step **4**. It is also recommended to perform calibration after step **6**.

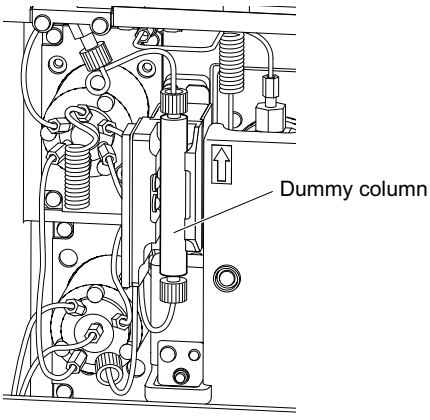
2 Check if the dummy column is connected.

❶ Open the front cover.

❷ Open the temperature control box cover.



❸ Check the following:
- The dummy column is connected in the column installation position.
- The push screws at the top and bottom of the dummy column are firmly tightened.



NOTE:
If the dummy column is not connected, liquid may leak and trigger a warning during fluid pumping.

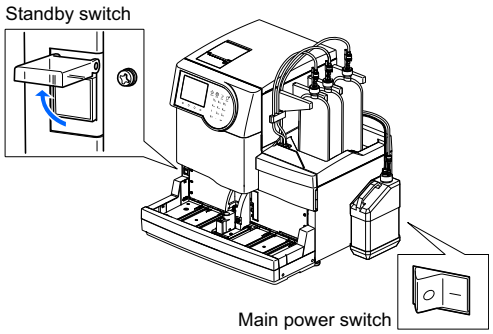
❹ Close the temperature control box cover, then the front cover.

3 Turn on the power.

❶ Plug the power cord into an outlet.

❷ Press the "–" side of the main power switch.

❸ Press the standby switch to turn on the power.



4 Set the date and time.

❶ Check the date and time on the display, and adjust them if necessary.

- See "3.5.1. Setting the Date and Time" on page 3-22.

5 Perform priming.

❶ Perform priming.

- See step **1** in "1.5.2. Installing the Column" on page 1-31.

6 Install the column.

❶ Install the column.

- See "4.2.4. Replacing the Column" on page 4-11.
- In step **3**, remove the "dummy column" instead of the "old column".
- In step **9**-❷, **do not** reset the column measurement counter.

Chapter 5 Troubleshooting

This chapter describes actions you should take if warnings, errors or troubles occur. It also describes what to do if eluent packs are attached to the wrong nozzles.

5.1 If a Warning Occurs

Warnings call your attention to operations required during instrument use via alarms, warning codes, icons and messages. Measurement may be interrupted by some warnings, but the measurement results of aspirated sample are reported when possible. Remeasure samples for which measurement results were not obtained due to a warning, after completing the necessary action.

5.1.1 From Warning Occurrence to Remedy

● W:001 to W:050

Measurements can continue for a while, but take the necessary action as quickly as possible.

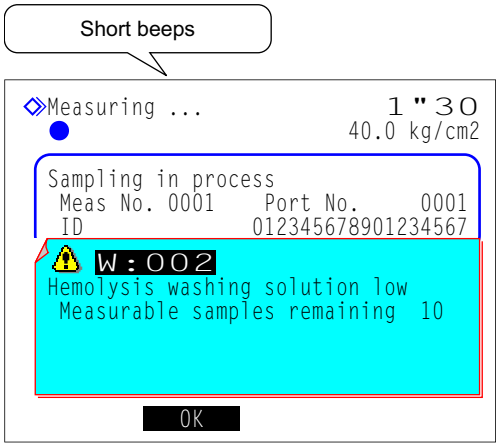
● W:051 to W:095

Immediate action is required. If these warnings occur during measurement, measurement stops.

If a warning occurs, follow the instructions described below to clear it.

❶ An alarm of consecutive short beeps sounds for about 10 seconds, and a warning code and message appear on the display.

- W:001 to W:050
  Even if the warning occurs during measurement, measurement continues without interruption.
- W:051 to W:095
  If the warning occurs during measurement, measurement stops.



Warning code (“W” and 3-digit number) and message

❷ Check the warning code and message, and press OK.

- The alarm is silenced.

❸ Take the necessary action to remove the cause.

- See “5.1.2. Causes and Remedies” on page 5-3 and later.

❹ If measurement results were not obtained for samples due to the warning, load those samples onto the sampler again and press ◇|.

- Measurement will start.

❺ If the warning persists, turn off the power and contact your distributor.

REFERENCE:

History of warning/error/trouble:

Printed report example: See “2.8.6. History of Warning/Error/Trouble” on page 2-48.

Printing instructions: See “3.6.1. Printing History of Warning/Error/Trouble” on page 3-25.

5.1.2 Causes and Remedies

- Wear protective gloves to prevent exposure to pathogenic microbes before any operation that may expose you to samples.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

W:001	**Printer paper has run out. Load new paper.**
Cause	● The printer paper has run out.
Remedy	① Press OK to clear the warning. ② Load a new paper roll (see page 4-10). * Printing will automatically restart when paper is loaded.

W:002	**Hemolysis washing solution low** *** <Measurable samples remaining> shows the number of samples that can be measured before the solution completely runs out.**
Cause	● The hemolysis washing solution is running out. ● The fluid level detection sensor cord of the hemolysis washing solution bottle is disconnected from the instrument.
Remedy	① Press OK to clear the warning. ② If the hemolysis washing solution is running out, replace the bottle with a new one after measurement stops (see page 4-7). ③ If there is enough solution in the hemolysis washing solution bottle, properly connect the fluid level detection sensor cord of the bottle to the WASH terminal on the rear panel.

W:003 **W:004** **W:005**	**Eluent A is running out.** **Eluent B is running out.** **Eluent CT is running out.** *** <Measurable samples remaining> shows the number of samples that can be measured before eluent completely runs out.**
Cause	● Eluent A, B or CT is running out.
Remedy	① Press OK to clear the warning. ② Replace the indicated eluent pack with a new one after measurement stops (see page 4-3).

W:008	**Liquid waste bottle is full. Discard liquid waste after measurement stops.** *** <Measurable samples remaining> shows the number of samples that can be measured before the bottle becomes full.**
Cause	● The optional liquid waste bottle is full of liquid waste.
Remedy 	① Press OK to clear the warning. ② Discard liquid waste from the bottle after measurement stops (see page 4-27).

W:009	**None found.**
Cause	● There are no measurement results or history of warning/error/trouble that match the search condition.
Remedy	Press OK to clear the warning.

W:010	**The STAT port is not set in place.** **Set STAT port as instructed in manual and retry measurement.**
Cause	● The STAT port is not set in the correct position.
Remedy	① Press OK to clear the warning. ② Push the STAT port in the direction of the arrow near “PUSH” by hand until it locks (see page 2-26). Then, retry measurement.

W:011 W:012 W:013	**Abnormal HbA1c control measurement result was obtained.** **Abnormal HbA2 control measurement result was obtained.** **Abnormal HbF control measurement result was obtained.**
Cause	● Control expected values are not set correctly. ● The error detection range for control measurements is not set correctly. ● Measurement results are largely out of the expected values. ● There is a problem with the controls.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② - ⑤. ② Set the expected values correctly (see page 3-13). ③ Set the error detection range correctly (see page 3-13). HbA1c: Default L: 3 mmol/mol, H: 4 mmol/mol HbA2: Default L: 0.3 %, H: 0.5 % HbF: Default L: 0.3 %, H: 0.5 % ④ Perform calibration (see page 2-35). ⑤ If the warning persists, retry control measurement using a new control.

W:021	**S-A1c retention time started early**
Cause	● The eluent has degraded or the wrong bottle cap has been fit on the wrong eluent pack. ● The column has degraded.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② - ④. ② Remove air from the tube by priming (see page 4-43: On the [Priming menu] screen, select <1 Automatic>). ③ If the warning persists, replace the eluent pack with a new one (see page 4-3). ④ If the warning persists, replace the column with a new one (see page 4-11).

W:022	**S-A1c retention time started late.**
Cause	● Fluid is leaking from the eluent tubes or fluid pump. ● Air bubbles have formed in the fluid pump check valve. ● The eluent has degraded. ● The column has degraded.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② - ⑤. ② Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). Open the temperature control box cover while pumping fluid, and tighten the tube that is leaking. ③ If the warning persists, perform priming and then pump fluid to the tubes (see page 4-43: On the [Priming menu] screen, select <1 Automatic>. After completion, select <2. Pump>). ④ If the warning persists, replace the eluent pack with a new one (see page 4-3). ⑤ If the warning persists, replace the column with a new one (see page 4-11).

W:023	**S-A1c retention time fluctuated.**
Cause	● Fluid is leaking from the eluent tubes or fluid pump. ● Air bubbles have formed in the fluid pump check valve. ● The wrong bottle cap has been fit on the wrong eluent pack.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② and ③. ② Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). Open the temperature control box cover while pumping fluid, and tighten the tube that is leaking. ③ If the warning persists, perform priming and then pump fluid to the tubes (see page 4-43: On the [Priming menu] screen, select <1 Automatic>. After completion, select <2. Pump>).

W:024 W:025 W:026	**HbA0 retention time** **Retention time** **HbA2 retention time**
Cause	● Fluid is leaking from the eluent tubes or fluid pump. ● Air bubbles have formed in the fluid pump check valve or optical unit cell. ● The wrong bottle cap has been fit on the wrong eluent pack.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② - ④. ② Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). Open the temperature control box cover while pumping fluid, and tighten the tube that is leaking. ③ If the warning persists, perform priming and then pump fluid to the tubes (see page 4-43: On the [Priming menu] screen, select <1 Automatic>. After completion, select <2 Pump>). ④ If the warning persists, turn off the power and contact your distributor.

W:032	**Sample tube spinning failed.**
Cause	● The barcode label comes off or is displaced from the correct position. ● The correct adapters are not set in the sample rack.
Remedy	① Press OK to clear the warning. ② Reattach the barcode label to the correct position (see page 2-17). ③ Set the correct adapters in the sample rack (see page 2-17), then set the samples in the sample rack.

W:041	**Optical unit light volume low**
Cause	● Whole blood sample was measured with a rack for hemolysis sample. ● The hemoglobin concentration of the sample is too high. ● The light source has degraded. ● Air bubbles have formed in the optical unit cell.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② - ⑤. ② If whole blood sample was measured with a rack for hemolysis sample, it is recommended to replace the column with a new one (see page 4-11). If you do not have a spare column, perform the following as a temporary remedy: 1) Set 10 empty sample tubes or cups in a normal rack and perform normal measurement. 2) After measurement stops due to “T:354 Sample introduction”, perform control measurement. 3) Carefully check that the obtained results are normal. If abnormal results are obtained, **do not** perform measurements until the column is replaced with a new one. ③ Prepare samples so that the hemoglobin concentration is between 75 mg/dL and 225 mg/dL before measurement. ④ Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). After three minutes, press Stop. ⑤ If the warning persists, turn off the power and contact your distributor.

W:043	**Pressure high**
Cause	● The column or tube is clogged.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② - ④. ② Replace the column with the dummy column (see page 4-47) and then pump fluid to the tube (see page 4-43: On the [Priming menu] screen, select <2 Pump>). After five minutes, press Stop. The dummy column was attached to the column installation position at the time of shipment. ③ If fluid pumping finishes without any problem, replace the column with a new one (see page 4-11). ④ If the warning persists, turn off the power and contact your distributor.

W:044	**Pressure low**
Cause	● Air has entered the fluid pump. ● Fluid is leaking from the eluent tubes or fluid pump.
Remedy	① Press OK to clear the warning. After measurement stops, perform steps ② and ③. ② Remove air from the tube by priming (see page 4-43: On the [Priming menu] screen, select <1 Automatic>). ③ If the warning persists, pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). Open the temperature control box cover while pumping fluid, and tighten the tube that is leaking.

W:045 W:046 W:047	**Temperature is outside range**
Cause	● The room temperature is outside the measurement environment temperature range of between 15°C and 30°C. ● The temperature controlling unit did not operate properly.
Remedy	① Press OK to clear the warning. ② Adjust the room to a temperature between 15°C and 30°C. ③ If the warning persists, turn off the power and contact your distributor.

W:050	**Unloading side is full of racks. Remove racks.** 
Cause	● The rack unloading side of the sampler is full of sample racks with already measured samples. ● Something is obstructing the rack detection sensor. * This warning occurs when the optional side sampler is attached to the instrument.
Remedy 	① Press OK to clear the warning. ② Remove the sample racks from the rack unloading side. ③ Remove the obstruction from the front of the rack detection sensor (rear left of the unloading side of the sampler).

W:051	**HbA1c STD solution has passed expiration date. Use new solution and retry.**
Cause	● The standard solution is beyond its expiration date.
Remedy 	① Press OK to clear the warning. ② Retry HbA1c calibration using a new standard solution (see page 2-35).

W:052	**No hemolysis washing solution Replace bottle.**
Cause	● The hemolysis washing solution has run out. ● The fluid level detection sensor cord of the hemolysis washing solution bottle is disconnected from the instrument.
Remedy	① Press OK to clear the warning. ② If the hemolysis washing solution has run out, replace the bottle with a new one (see page 4-7). ③ Properly connect the fluid level detection sensor cord of the hemolysis washing solution bottle to the WASH terminal on the rear panel (see page 1-23).

W:053 W:054 W:055	**No Eluent A Replace pack.** **No Eluent B Replace pack.** **No Eluent CT Replace pack.**
Cause	● Eluent A, B or CT has run out.
Remedy	① Press OK to clear the warning. ② Replace the indicated eluent pack with a new one (see page 4-3).

W:058	**Liquid waste bottle is full. Discard liquid waste in bottle.**
Cause	● The optional liquid waste bottle is full of liquid waste.
Remedy 	① Press OK to clear the warning. ② Discard liquid waste from the bottle (see page 4-27).

W:059	**HbA2/HbF STD solution has passed expiration date. Use new solution and retry.**
Cause	● The standard solution is beyond its expiration date.
Remedy 	① Press OK to clear the warning. ② Retry HbA2/HbF calibration using a new standard solution (see page 2-35).

W:060	HbA1c has not been calibrated. Do calibration before measurement.
Cause	● The HbA1c calibration result is invalid due to column replacement.
Remedy	① Press OK to clear the warning. ② Perform calibration (see page 2-35) and retry measurement.

W:062	Front or maintenance cover is open. Close the cover.
Cause	● The front cover or maintenance cover was opened.
Remedy	① Press OK to clear the warning. ② Close the cover.

W:063	Side cover is open. Close the cover.
Cause	● The side cover was opened.
Remedy	① Press OK to clear the warning. ② Close the side cover.

W:065 W:066	HbA2 has not been calibrated. Do calibration before measurement. HbF has not been calibrated. Do calibration before measurement.
Cause	● The HbA2/HbF calibration result is invalid due to column replacement.
Remedy	① Press OK to clear the warning. ② Perform calibration (see page 2-35) and retry measurement.

W:071 W:072 W:073	Abnormal HbA1c control measurement result was obtained. Abnormal HbA2 control measurement result was obtained. Abnormal HbF control measurement result was obtained.
Cause	● Control expected values are not set correctly. ● The error detection range for control measurements is not set correctly. ● Measurement results are largely out of the expected values. ● There is a problem with the controls.
Remedy	① Press OK to clear the warning. ② Set the expected values correctly (see page 3-13). ③ Set the error detection range correctly (see page 3-13). HbA1c: Default L: 3 mmol/mol, H: 4 mmol/mol HbA2: Default L: 0.3 %, H: 0.5 % HbF: Default L: 0.3 %, H: 0.5 % ④ Perform calibration (see page 2-35). ⑤ If the warning persists, retry control measurement using a new control.

W:081	Barcode could not be read.
Cause	● The number of misread barcode errors in the current batch reached or exceeded the number set for <Misread barcodes> on the [Measurement condition setup] screen.
Remedy	① Press OK to clear the warning. ② Reattach the barcode label to the correct position (see page 2-17) and retry measurement. Or, enter the ID with the numeric buttons (see page 1-44). ③ Set sample tubes in sample racks with the barcode labels facing the rear of the rack.

W:082	Sample tube spinning insufficient
Cause	● The number of sample tube spin failures in the current batch reached the number set for <Sample tube spin failures> on the [Measurement condition setup] screen.
Remedy	① Press OK to clear the warning. ② If the warning persists, turn off the power and contact your distributor.

W:090	**Unloading side is full of racks. Remove racks.** 
Cause	● The rack unloading side of the sampler is full of sample racks with already measured samples. ● Something is obstructing the rack detection sensor.
Remedy 	① Press OK to clear the warning. ② Remove the sample racks from the rack unloading side. ③ Remove the obstruction from the front of the rack detection sensor (rear left of the unloading side of the sampler).

W:091	**Leak below dil. container**
Cause	● Fluid is spilling from the eluent pack or hemolysis washing solution bottle. ● The tube inside the instrument is disconnected or improperly connected. ● The dilution container or washing container is clogged.
Remedy 	① Press OK to clear the warning. ② Properly attach the eluent packs and hemolysis washing solution bottle to the instrument (see page 1-23). Securely tighten the push screw of the tube from the bottle caps with nozzle. Wipe up spilled liquid and blot up pooled liquid in the leak tray below the dilution container (see page 1-14). ③ Properly connect the tubes of the dilution unit (see page 4-40), drain pinch valves (see page 4-25) and piercing nozzle (see page 4-19). Wipe up spilled liquid and blot up pooled liquid in the leak tray below the dilution container (see page 1-14). ④ Disassemble the dilution container and washing container, and clean the parts (see page 4-38). Wipe up spilled liquid and blot up pooled liquid in the leak tray below the dilution container (see page 1-14).

W:092	**Drain unit is leaking.**
Cause	● Fluid is spilling from the eluent pack or hemolysis washing solution bottle. ● The tube inside the instrument is disconnected or improperly connected. ● The chamber cap is not closed.
Remedy 	① Press OK to clear the warning. ② Properly attach the eluent packs and hemolysis washing solution bottle to the instrument (see page 1-23). Securely tighten the push screw of the tube from the bottle caps with nozzle. Wipe up spilled liquid and blot up pooled liquid in the leak tray below the drain unit (see page 1-14). ③ Properly connect the tubes of the drain pinch valves (see page 4-25). Wipe up spilled liquid and blot up pooled liquid in the leak tray below the drain unit (see page 1-14). ④ Tighten the chamber cap securely. Wipe up spilled liquid and blot up pooled liquid in the leak tray below the drain unit (see page 1-14).

W:093	**Temperature control box leaking**
Cause	● Fluid is leaking in the temperature control box.
Remedy	① Press OK to clear the warning. ② If the warning persists, turn off the power and contact your distributor.

W:094	**Column is leaking at the bottom.**
Cause	● The column connections are not securely tightened.
Remedy 	① Press OK to clear the warning. ② Check that the column is properly connected on the IN and OUT sides, and retighten the push screws (see page 4-12). Blot up pooled liquid in the leak tray below the column (see page 1-14). ③ If the warning persists, turn off the power and contact your distributor.

W:095	**Optical unit is leaking.**
Cause	● Fluid is leaking from the optical unit.
Remedy	① Press OK to clear the warning. ② If the warning persists, turn off the power and contact your distributor.

5.2 If an Error Occurs

Errors occur due to problems with the power supply, memory, connections or parameter settings, and are indicated by alarms, error codes and messages. Measurements are interrupted by errors, but the measurement results of aspirated sample are reported when possible. Remeasure samples for which measurement results were not obtained due to an error, after completing the necessary action.

5.2.1 From Error Occurrence to Remedy

If an error occurs, follow the instructions described below to clear it.

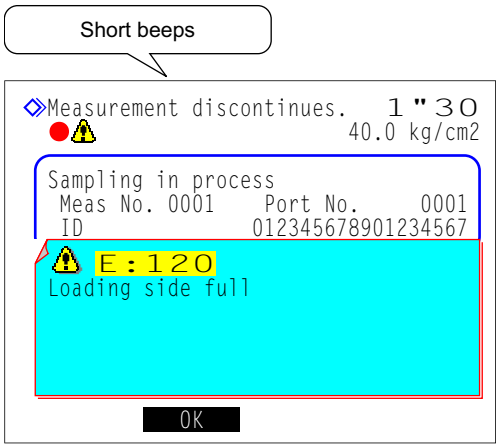
❶ An alarm of consecutive short beeps sounds for about 10 seconds, and an error code and message appear on the display.
- Sample aspiration stops if the error occurs during measurement.

❷ Check the error code and message, and press OK.
- The alarm is silenced.
- Initialization starts. If the error occurs during measurement, initialization starts when measurement is complete for the aspirated sample.

❸ Take the necessary action to remove the cause.
- See “5.2.2. Causes and Remedies” on page 5-10 and later.

❹ If measurement results were not obtained for samples due to the error, load those samples onto the sampler again and press ◇.
- Measurement will start.

❺ If the error persists, turn off the power and contact your distributor.



Error code (“E” and 3-digit number) and message

REFERENCE:
History of warning/error/trouble:
Printed report example: See “2.8.6. History of Warning/Error/Trouble” on page 2-48.
Printing instructions: See “3.6.1. Printing History of Warning/Error/Trouble” on page 3-25.

5.2.2 Causes and Remedies

- Wear protective gloves to prevent exposure to pathogenic microbes before any operation that may expose you to samples.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

E:100	Version change
Cause	● The main ROM was replaced.
Remedy	Press OK to clear the error.

E:101	Power down
Cause	● The power was turned off during measurement operations.
Remedy 	① Press OK to clear the error. ② When warm-up and priming finish and the standby screen appears, retry measuring samples for which measurement results were not obtained.

E:102	Battery voltage
Cause	● The backup battery discharged because power to the instrument was off for several days.
Remedy	① Press OK to clear the error. ② Keep the instrument powered on for at least 25 hours to charge the battery. ③ Set the date and time correctly (see page 3-22).

E:103	Backup data
Cause	● The main ROM was replaced. ● The backup battery discharged because power to the instrument was off for several days.
Remedy	① Press OK to clear the error. ② Keep the instrument powered on for at least 25 hours to charge the battery. ③ Set the date and time correctly (see page 3-22).

E:104	Power down (Saving data)
Cause	● The power was turned off while data was being saved.
Remedy	① Press OK to clear the error. ② Check that changed parameters did not return to their previous settings.

E:111	STD. sol. loading
Cause	● Dummy samples or standard solutions are improperly set in the calibration rack.
Remedy 	① Press OK to clear the error. ② Properly set the dummy samples and standard solutions in the calibration rack and retry calibration (see page 2-37).

E:112	HbA1c calibration
Cause	● Abnormal measurement results were obtained for HbA1c standard solution measurement. ● Reproducibility of the measurement results is low for HbA1c standard solution measurement. ● The error detection range for HbA1c automatic calibration was set too low.
Remedy 	① Press OK to clear the error. ② Check the expiration dates of the standard solution, eluents, hemolysis washing solution and column, and replace any of them that is beyond its expiration date (see pages 4-3, 4-7 and 4-11). ③ Clean anything that requires cleaning (see page 4-45). ④ Set the error detection range correctly (Default: 3.0%) (see page 3-13).

E:113	HbA1c STD. value no entry
Cause	● Standard values of the HbA1c standard solutions are not set. ● The calibration information barcode could not be read.
Remedy 	① Press OK to clear the error. ② **When reading standard values from calibration information barcodes:** Replace wrinkled or dirty calibration information barcode labels with new ones. Set sample tubes in sample racks with the barcode labels facing the rear of the rack, and retry HbA1c calibration. **When entering standard values with the numeric buttons:** Enter correct standard values and retry calibration (see page 2-39).

E:114	HbA2 calibration
Cause	● Abnormal measurement results were obtained for HbA2 calibration. ● Reproducibility of the measurement results is low for HbA2 calibration. ● The error detection range for HbA2 automatic calibration was set too low.
Remedy	① Press OK to clear the error. ② Check the expiration dates of the standard solution, eluents, hemolysis washing solution and column, and replace any of them that is beyond its expiration date (see pages 4-3, 4-7 and 4-11). ③ Clean anything that requires cleaning (see page 4-45). ④ Set the error detection range correctly (Default: 15.0%) (see page 3-13).

E:115	HbA2 STD. value no entry
Cause	● HbA2 standard values are not set. ● The calibration information barcode could not be read.
Remedy	① Press OK to clear the error. ② **When reading standard values from calibration information barcodes:** Replace wrinkled or dirty calibration information barcode labels with new ones. Set sample tubes in sample racks with the barcode labels facing the rear of the rack, and retry HbA2 calibration. **When entering standard values with the numeric buttons:** Enter correct standard values and retry calibration (see page 2-39).

E:116	HbF calibration
Cause	● Abnormal measurement results were obtained for HbF calibration. ● Reproducibility of the measurement results is low for HbF calibration. ● The error detection range for HbF automatic calibration was set too low.
Remedy	① Press OK to clear the error. ② Check the expiration dates of the standard solution, eluents, hemolysis washing solution and column, and replace any of them that is beyond its expiration date (see pages 4-3, 4-7 and 4-11). ③ Clean anything that requires cleaning (see page 4-45). ④ Set the error detection range correctly (Default: 30.0%) (see page 3-13).

E:117	HbF STD. value no entry
Cause	● HbF standard values are not set. ● The calibration information barcode could not be read.
Remedy	① Press OK to clear the error. ② **When reading standard values from calibration information barcodes:** Replace wrinkled or dirty calibration information barcode labels with new ones. Set sample tubes in sample racks with the barcode labels facing the rear of the rack, and retry HbF calibration. **When entering standard values with the numeric buttons:** Enter correct standard values and retry calibration (see page 2-39).

E:120	Loading side full
Cause	● A sixth sample rack was loaded onto the rack loading side of the sampler. ● Sample racks are improperly loaded onto the loading side of the sampler.
Remedy 	① Press OK to clear the error. ② Remove the sixth sample rack from the loading side of the sampler. ③ Properly load the sample racks onto the loading side.

E:121	Memory full
Cause	● Measurement results for 500 samples are suspended from being printed because the printer paper has run out. ● Measurement results for 500 samples are suspended from being transmitted to the external device because the communication cable is improperly connected.
Remedy	① Press OK to clear the error. ② If the printer paper has run out, set a new roll of paper (see page 4-10). Suspended measurement results will be printed out. ③ If the communication cable is disconnected, connect it properly (see page 1-28). Suspended measurement results will be transmitted.

E:122	Wash. solution setting
Cause	● Tube washing was started without first loading the washing rack onto the sampler. ● Sample tubes with the washing solution for tubes are not set in the washing rack.
Remedy 	① Press OK to clear the error. ② Set two sample tubes with the washing solution for tubes in the washing rack. Load the rack onto the sampler, and then start tube washing (see page 4-28).

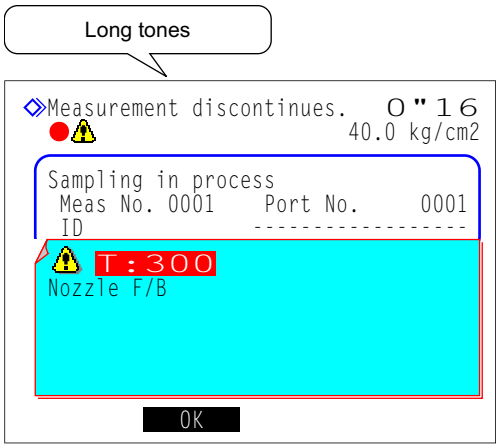
5.3 If Trouble Occurs

Serious problems that occur with the electrical circuits, measurement unit, drive unit or other parts of the instrument are indicated by alarms, trouble codes and messages. Measurements are interrupted by trouble, but the measurement results of aspirated sample are reported when possible. Remeasure samples for which measurement results were not obtained due to the trouble, after completing the necessary action.

5.3.1 From Trouble Occurrence to Remedy

If trouble occurs, follow the instructions described below to clear it.

❶ Two different long tones sound in turn for about one minute, and a trouble code and message appear on the display.
- Sample aspiration stops if the trouble occurs during measurement.



Trouble code (“T” and 3-digit number) and message

❷ Check the trouble code and message, and press OK.
- The alarm is silenced.
- Initialization starts. If the trouble occurs during measurement, initialization starts when measurement is complete for the aspirated sample.

❸ Take the necessary action to remove the cause.
- See “5.3.2. Causes and Remedies” on page 5-14 and later.

❹ If measurement results were not obtained for samples due to the trouble, load those samples onto the sampler again and press ◇.
- Measurement will start.

❺ If the trouble persists, turn off the power and contact your distributor.

REFERENCE:
History of warning/error/trouble:
Printed report example: See “2.8.6. History of Warning/Error/Trouble” on page 2-48.
Printing instructions: See “3.6.1. Printing History of Warning/Error/Trouble” on page 3-25.

5.3.2 Causes and Remedies

- Wear protective gloves to prevent exposure to pathogenic microbes before any operation that may expose you to samples.
- Discard used samples and protective gloves in accordance with local regulations for biohazardous waste.

T:200 - T:209	**Flash ROM**
Cause	● The main ROM was upgraded to a newer version. ● Trouble occurred in the flash ROM in which data is stored.
Remedy	Turn off the power and contact your distributor.

T:210	**Printer**
Cause	● The printer head is hot. ● The printer did not operate properly.
Remedy	① Press OK to clear the trouble. ② Remove any jammed printer paper and correctly set the paper roll. ③ If the trouble persists, turn off the power and contact your distributor.

T:220 - T:227	**Internal communication Turn off power.**
Cause	● Internal communication trouble occurred.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:230 - T:234	**Flash ROM Turn off power.**
Cause	● Trouble occurred in the ROM.
Remedy	Turn off the power and contact your distributor.

T:300 - T:306 **T:307 - T:312**	**Nozzle F/B** **Nozzle U/D**
Cause	● Something is obstructing the piercing nozzle. ● The piercing nozzle did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Remove the obstruction near the piercing nozzle. ③ If the trouble persists, turn off the power and contact your distributor.

T:320, T:321 **T:330, T:331**	**Sampling pump** **Sample introduction pump**
Cause	● The indicated part did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:332 - T:336	Sample introduction flow
Cause	● The piercing nozzle is broken. ● The piercing nozzle is clogged. ● A tube is disconnected or improperly connected. ● The dilution container or washing container is contaminated. ● The dilution container or washing container is clogged. ● Air bubbles have formed in the hemolysis washing solution tube. ● The magnetic valve did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Replace the piercing nozzle if broken (see page 4-16). ③ Remove the piercing nozzle and inject hemolysis washing solution using a syringe to clean inside the nozzle. If the clog cannot be removed, replace the piercing nozzle with a new one (see page 4-16). ④ Properly connect the tubes of the hemolysis washing solution bottle nozzle, piercing nozzle (see page 4-19), dilution unit (see page 4-40) and drain pinch valves (see page 4-25). ⑤ Clean the dilution container and washing container (see page 4-35). ⑥ Disassemble the dilution container and washing container, and clean the parts (see page 4-38). ⑦ Remove air from the hemolysis washing solution by priming (see page 4-43: On the [Priming menu] screen, select <7 Hemolysis washing solution>). ⑧ If the trouble persists, turn off the power and contact your distributor.

T:340	Stirrer motor rotation
Cause	● Stirrer motor rotations are outside the specified range.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:350 - T:353	Drain flow
Cause	● Tubes inside the instrument are disconnected or improperly connected. ● The dilution container or washing container is contaminated. ● The dilution container or washing container is clogged. ● The magnetic valve did not operate properly. ● The drain pump did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Properly connect the tubes of the dilution unit (see page 4-40) and drain pinch valves (see page 4-25). ③ Clean the dilution container and washing container (see page 4-35). ④ Disassemble the dilution container and washing container, and clean the parts (see page 4-38). ⑤ If the trouble persists, turn off the power and contact your distributor.

T:354	Sample introduction
Cause	● Five consecutive samples had insufficient volume for measurement. ● Hemolysis sample was measured with a rack for whole blood sample. ● The piercing nozzle is clogged. ● The dilution container or washing container is clogged. ● Tubes inside the instrument are clogged. ● The sample tube detection sensor or sample cup detection sensor did not operate properly. ● The magnetic valve did not operate properly. * This trouble occurs if “Hb: Abnormally low value” appears for five consecutive samples.
Remedy 	① Press OK to clear the trouble. ② If sample volume is low, either transfer the sample to a sample cup and remeasure it, or dilute the sample and measure it as a hemolysis sample. ③ Set samples in the suitable sample rack (see page 2-15). ④ Remove the piercing nozzle and inject hemolysis washing solution using a syringe to clean inside the nozzle. If the clog cannot be removed, replace the piercing nozzle with a new one (see page 4-16). ⑤ Disassemble the dilution container and washing container, and clean the parts (see page 4-38). ⑥ Perform automatic tube washing (see page 4-27). ⑦ If the trouble persists, turn off the power and contact your distributor.

T:360 - T:362 T:370, T:371	Magnetic valve Drain flow
Cause	● Tubes inside the instrument are disconnected or improperly connected. ● The dilution container or washing container is contaminated. ● The dilution container or washing container is clogged. ● The magnetic valve did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Properly connect the tubes of the dilution unit (see page 4-40) and drain pinch valves (see page 4-25). ③ Clean the dilution container and washing container (see page 4-35). ④ Disassemble the dilution container and washing container, and clean the parts (see page 4-38). ⑤ If the trouble persists, turn off the power and contact your distributor.

T:372 - T:375	Drain flow
Cause	● Tubes inside the instrument are disconnected or improperly connected. ● The dilution container or washing container is contaminated. ● The dilution container or washing container is clogged. ● The magnetic valve did not operate properly. ● The drain pump did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Properly connect the tubes of the dilution unit (see page 4-40) and drain pinch valves (see page 4-25). ③ Clean the dilution container and washing container (see page 4-35). ④ Disassemble the dilution container and washing container, and clean the parts (see page 4-38). ⑤ If the trouble persists, turn off the power and contact your distributor.

T:400 - T:402	Temperature sensor Turn off power.
Cause	● There is a problem with the temperature sensor.
Remedy	Turn off the power and contact your distributor.

T:403 - T:411	Temperature control
Cause	● The room temperature is outside the measurement environment temperature range of between 15°C and 30°C. ● The temperature controlling unit did not operate properly.
Remedy	① Press OK to clear the trouble. ② Adjust the room to a temperature between 15°C and 30°C. ③ If the trouble persists, turn off the power and contact your distributor.

T:420 T:430, T:431 T:432 - T:435 T:436 - T:439	Degasser unit Fluid pump drive Sample introduction valve Eluent switching valve
Cause	● The indicated part did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:450 - T:452	Excessive pressure
Cause	● The column or tube is clogged.
Remedy	① Press OK to clear the trouble. ② Replace the column with the dummy column (see page 4-47) and pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). After five minutes, press Stop. The dummy column was attached to the column installation position at the time of shipment. ③ If fluid pumping finishes without any problem, replace the column with a new one (see page 4-11). ④ If the trouble persists, turn off the power and contact your distributor.

T:453	Damper high pressure
Cause	● The tube is clogged.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:454	Pressure sensor
Cause	● There is a problem with the pressure sensor.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:455 - T:461	Fluid pumping problem
Cause	● Air has entered the fluid pump. ● Fluid is leaking from the eluent tubes or fluid pump.
Remedy	① Press OK to clear the trouble. ② Remove air from the tube by priming (see page 4-43: On the [Priming menu] screen, select <1 Automatic>). ③ If the trouble persists, pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). Open the temperature control box cover while pumping fluid, and tighten the tube that is leaking. ④ If the trouble persists, turn off the power and contact your distributor.

T:470, T:471	Temperature sensor Turn off power.
Cause	● There is a problem with the temperature sensor.
Remedy	Turn off the power and contact your distributor.

T:472 - T:478	Temperature control
Cause	● The room temperature is outside the measurement environment temperature range of between 15°C and 30°C. ● The temperature controlling unit did not operate properly.
Remedy	① Press OK to clear the trouble. ② Adjust the room to a temperature between 15°C and 30°C. ③ If the trouble persists, turn off the power and contact your distributor.

T:480	Optical unit detector
Cause	● The room temperature is outside the measurement environment temperature range of between 15°C and 30°C. ● The optical unit detector did not operate properly.
Remedy	① Press OK to clear the trouble. ② Adjust the room to a temperature between 15°C and 30°C. ③ If the trouble persists, turn off the power and contact your distributor.

T:481	Low optical unit light
Cause	● Whole blood sample was measured with a rack for hemolysis sample. ● The hemoglobin concentration of the hemolysis sample is too high. ● Air bubbles have formed in the optical unit cell. ● The light source has degraded.
Remedy 	① Press OK to clear the trouble. ② If whole blood sample was measured with a rack for hemolysis sample, it is recommended to replace the column with a new one (see page 4-11). If you do not have a spare column, perform the following as a temporary remedy: 1) Set 10 empty sample tubes or cups in a normal rack and perform normal measurement. 2) After measurement stops due to “T:354 Sample introduction”, perform HbA1c control measurement. 3) Carefully check that the obtained results are normal. If abnormal results are obtained, **do not** perform measurements until the column is replaced with a new one. ③ Prepare samples so that the hemoglobin concentration is between 75 mg/dL and 225 mg/dL. ④ Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). After three minutes, press Stop. ⑤ If the trouble persists, turn off the power and contact your distributor.

T:482 T:483	Strong optical unit light Optical unit light
Cause	● Air bubbles have formed in the optical unit cell. ● The optical unit detector did not operate properly. ● The light source has degraded (T:483).
Remedy	① Press OK to clear the trouble. ② Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). ③ If the trouble persists, turn off the power and contact your distributor.

T:490	Background
Cause	● Eluent has degraded. ● The optical unit cell is contaminated.
Remedy	① Press OK to clear the trouble. ② Replace the eluent pack with a new one (see page 4-3). ③ Pump fluid (see page 4-43: On the [Priming menu] screen, select <2 Pump>). ④ If the trouble persists, turn off the power and contact your distributor.

T:600	BCR communication
Cause	● The barcode reader did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:601	Cannot read rack ID
Cause	● The rack detection sensor did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Load the sample rack properly and retry measurement. ③ If the trouble persists, turn off the power and contact your distributor.

T:602	Measurement-side lever
Cause	● The measurement-side lever of the sampler did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:610 - T:612	Measurement-side lever drive
Cause	● Sample racks are improperly loaded onto the rack loading side of the sampler. ● Something is obstructing the path of the measurement-side lever on the sampler. ● The measurement-side lever did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Load the sample racks onto the rack loading side properly. ③ Remove the obstruction from the path of the measurement-side lever located on the instrument side of the sampler. ④ If the trouble persists, turn off the power and contact your distributor.

T:613, T:614	Return-side lever drive
Cause	● Sample racks are improperly loaded onto the rack unloading side of the sampler. ● Something is obstructing the path of the return-side lever on the sampler. ● The return-side lever did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Load the sample racks onto the unloading side properly. ③ Remove the obstruction from the path of the return-side lever located on the front side of the sampler. ④ If the trouble persists, turn off the power and contact your distributor.

T:620 - T:622	Sample tube spin F/B
Cause	● Something is obstructing the sample tube spinning unit. ● The sample tube spinning unit did not operate properly.
Remedy 	① Press OK to clear the trouble. ② Remove the obstruction from the sample tube spinning unit (towards the rear under the STAT port cover). ③ If the trouble persists, turn off the power and contact your distributor.

T:623	Sample tube spinning
Cause	● The sample tube spinning unit did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:800 T:805	Serial transmission Serial receiving
Cause	● The serial communication board did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:801 - T:804 T:807 - T:810	**Two-way communication**
Cause	● The communication cable of the external device is disconnected or improperly connected.
Remedy	① Press OK to clear the trouble. ② Properly connect the communication cable. ③ If the trouble persists, turn off the power and contact your distributor.

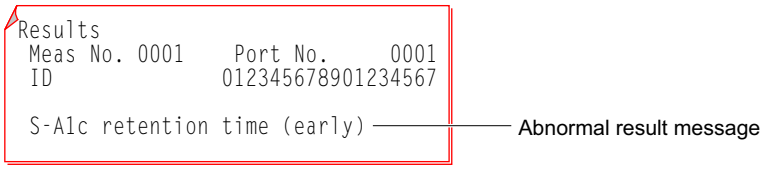
T:811	**No matching ID**
Cause	● The host computer transmitted an abnormal measurement command.
Remedy	① Press OK to clear the trouble. ② Check if the host computer correctly replies to an inquiry from the instrument.

T:820 - T:822	**Ethernet communication**
Cause	● The Ethernet board did not operate properly.
Remedy	① Press OK to clear the trouble. ② Turn off the power and contact your distributor.

T:999	**Other trouble**
Cause	● Other trouble occurred.
Remedy	Take notes of what appears on the screen, and contact your distributor.

5.4 Abnormal Result Messages

The following messages appear on the display if inaccurate measurement results are obtained. Measurements will continue.



Temperature control	
Cause	• The room temperature is outside the measurement environment temperature range of between 15°C and 30°C. • The temperature controlling unit did not operate properly.

Low optical unit light	
Cause	• Whole blood sample was measured with a rack for hemolysis sample. • The hemoglobin concentration of the sample is too high. • Air bubbles have formed in the optical unit cell. • The light source has degraded.

High pressure tube: High pressure	
Cause	• The column or tube is clogged.

High pressure tube: Low pressure	
Cause	• Air has entered the fluid pump. • Fluid is leaking from the eluent tubes or fluid pump.

S-A1c retention time (early)	
Cause	• The eluent has degraded or the wrong bottle cap has been fit on the wrong eluent pack. • The column has degraded.

S-A1c retention time (late)	
Cause	• Fluid is leaking from the eluent tubes or fluid pump. • Air bubbles have formed in the fluid pump check valve. • The eluent has degraded. • The column has degraded.

S-A1c R. time fluctuation	
Cause	• Fluid is leaking from the eluent tubes or fluid pump. • Air bubbles have formed in the fluid pump check valve. • The wrong bottle cap has been fit on the wrong eluent pack.

HbA0 retention time	
Cause	• Fluid is leaking from the eluent tubes or fluid pump. • Air bubbles have formed in the fluid pump check valve or optical unit cell. • The wrong bottle cap has been fit on the wrong eluent pack.

L-A1c tail	
Cause	• The column has degraded.

S-A1c tail	
Cause	• The S-A1c tail rises more than the threshold value.

Drift baseline	
Cause	• The baseline drifted more than the threshold value.

Noise detected	
Cause	• Noise was detected in the chromatogram.

Duplex peaks	
Cause	• Two or more peaks were detected for either HbF, L-A1c or S-A1c.

Hb: Low value	
Cause	• The total area was smaller than the threshold value. • The sample had insufficient volume for measurement. • Hemolysis or anemia sample was measured with a sample rack for whole blood sample.

HbA0: Abnormally high value	
Cause	• The HbA0 area was larger than the threshold value. • Whole blood sample was measured with a rack for hemolysis sample. • The hemoglobin concentration of the hemolysis sample is too high.

Hb: Abnormally low value	
Cause	• The difference between the maximum and minimum volume of light absorption was less than the threshold value. • The sample volume was insufficient. • Hemolysis sample was measured with a rack for whole blood sample.

Abnormal peak count	
Cause	• Less than two peaks could be detected. • Twenty or more peaks were detected. • The first peak showed other than HbA1ab.

Hb: Abnormally high value	
Cause	• Light absorption was higher than the threshold value. • Whole blood sample was measured with a rack for hemolysis sample. • The hemoglobin concentration of the hemolysis sample is too high. • Whole blood sample was measured with a rack for hemolysis sample.

Retention time **HbA2 retention time**	
Cause	• Fluid is leaking from the eluent tubes or fluid pump. • Air bubbles have formed in the fluid pump check valve or optical unit cell. • The wrong bottle cap has been fit on the wrong eluent pack.

HbA0 bottom	
Cause	• The HbA0 bottom rises more than the threshold value.

HbA2 tail	
Cause	• HbA2 tail rises more than the threshold value.

No valid peak detected	
Cause	• HbF or S-A1c peak could not be detected.

5.5 If This Happens

5.5.1 If the Instrument Does Not Start Up (Replacing Fuses)

If the instrument does not start up after turning on both the main power switch and standby switch, there is a possibility that a fuse has blown. The instrument has a pair of fuses and they can be replaced from the rear panel. Replace whichever is blown.

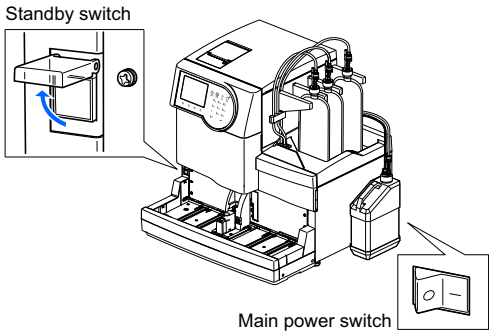
> ⚠ Use only fuses of the specified capacity. Over-rated fuses may result in fire or damage to the instrument.

NOTE:
If the fuses blow soon after the replacement, there is a problem with the instrument. Contact your distributor.

Prepare: Fuse and flat-head screwdriver

1 Turn off the main power.

❶ Press the standby switch to turn off the power.
- Press the standby switch two or three times. The power is ON when the switch remains slightly depressed. Then, press the switch one more time to turn off the power.



❷ Press the main power switch on the rear panel to turn off the main power.
- Press the "○" side of the main power switch.

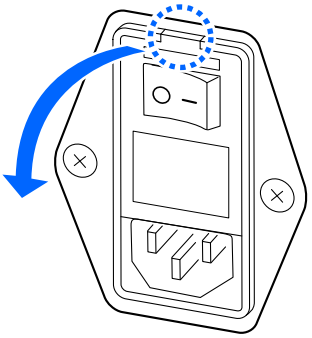
❸ Unplug the power cord from the outlet.

❹ Unplug the power cord from the power input terminal on the rear panel.

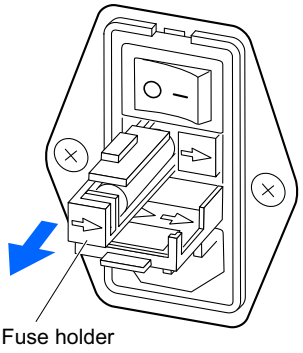
> ⚠ Keep the power cord unplugged unless otherwise instructed in the following steps.

2 Remove the fuse holder.

❶ Pop open the fuse holder cover by working a flat-head screwdriver under the tab (dotted area in the figure).

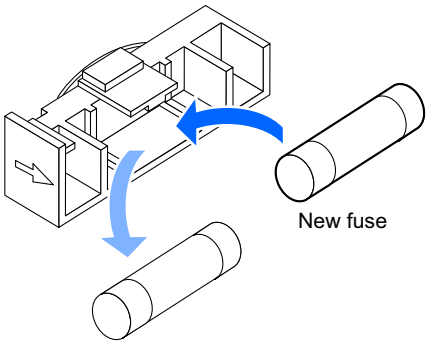


❷ Pull the fuse holder straight to the front.



3 Replace the fuse.

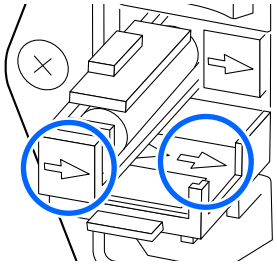
❶ Remove the blown fuse from the fuse holder and set a new fuse.



4 Store the fuse holder.

❶ Insert the holder into its original position.

NOTE:
Align the arrows on the fuse holder and cover, and insert the holder into place.



❷ Close the fuse holder cover.

5 Turn on the power.

❶ Plug the power cord into the power input terminal on the rear panel.

❷ Plug the power cord into an outlet.

❸ Press the main power switch on the rear panel to turn on the main power.

❹ Press the standby switch to turn on the power.
- The standby switch will light up.

5.5.2 If Eluent Packs Are Incorrectly Attached

If you attach the bottle cap (with nozzle) of one eluent to the wrong type of eluent pack, clean the nozzle and chamber inside the instrument, then attach the bottle cap correctly. Eluents A, B and CT differ in composition, so changing nozzles without first cleaning them will cause mixing of eluents, producing inaccurate measurement results.

Prepare: Cap for eluent pack (that was originally on the pack before opening) and gauze

1 Clean the eluent nozzle.

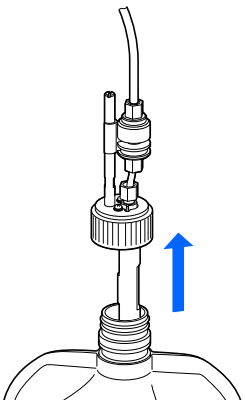
❶ Lay out some gauze near the instrument.

❷ Remove the eluent pack with the wrong nozzle attached from the bottle tray.

❸ Remove the bottle cap with nozzle from the pack.

❹ Wipe any liquid from the nozzle with a new piece of gauze.
- Place the nozzle on the gauze.

❺ Attach the cap (that was originally on the pack before opening) to the pack, and tighten it securely.



2 Drain eluent from the chamber.

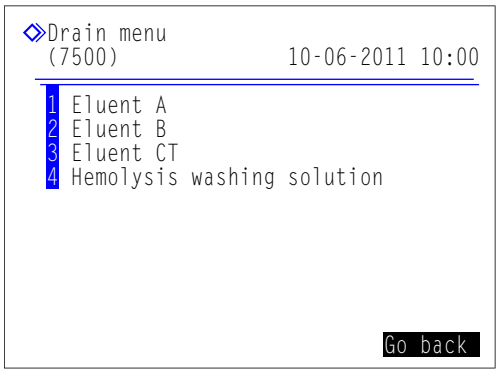
NOTE:
Detaching the chamber without first draining eluent may spill eluent and damage the instrument. Be sure to drain fluid before removing the chamber.

❶ On the standby screen, select Menu, <7 Maintenance menu> and <5 Drain menu> in that order.

❷ On the [Drain menu] screen, select the eluent whose nozzle was inserted into the wrong pack.
- Fluid is drained from the chamber.
- After completion, the [Drain menu] screen will appear again.

REFERENCE:
Repeat from step **1**-❶ if the nozzle of other eluents was also wrongly inserted.

❸ Press Go back three times to return to the standby screen.



3 Turn off the power.

❶ Press the standby switch to turn off the power.

4 Clean the chamber.

❶ Clean the emptied chamber.
- See steps **7**-❶ to **8**-❸ in "4.6.1. Preparing the Instrument Before Extended Periods of Disuse" on page 4-48.
- In step **7**-❸, remove the emptied chamber.
- In step **8**-❸, attach the cleaned chamber.

REFERENCE:
Clean the other chamber in the same procedure if the nozzle of other eluents was also wrongly inserted.

❷ Close the side cover.

5 Attach the nozzle to the correct eluent pack.

❶ Attach the bottle cap with nozzle to the correct eluent pack.
- See steps **5**-❶ to **6**-❸ in "1.4.5. Setting Up Eluents and Hemolysis Washing Solution" on page 1-24.

6 Perform priming.

❶ Press the standby switch to turn on the power.

❷ Perform priming.
- See steps **1**-❶ to **1**-❼ in "1.5.2. Installing the Column" on page 1-31.

Chapter 6 Appendix

This chapter gives you examples of printed reports on the instrument's parameter settings and diagnosis results, and also lists measurement terminology. An index is provided at the end of this chapter.

6.1 Printed Report Examples

This section gives you examples of printed reports on the instrument's parameter settings and diagnosis results.

6.1.1 Current Parameter Settings

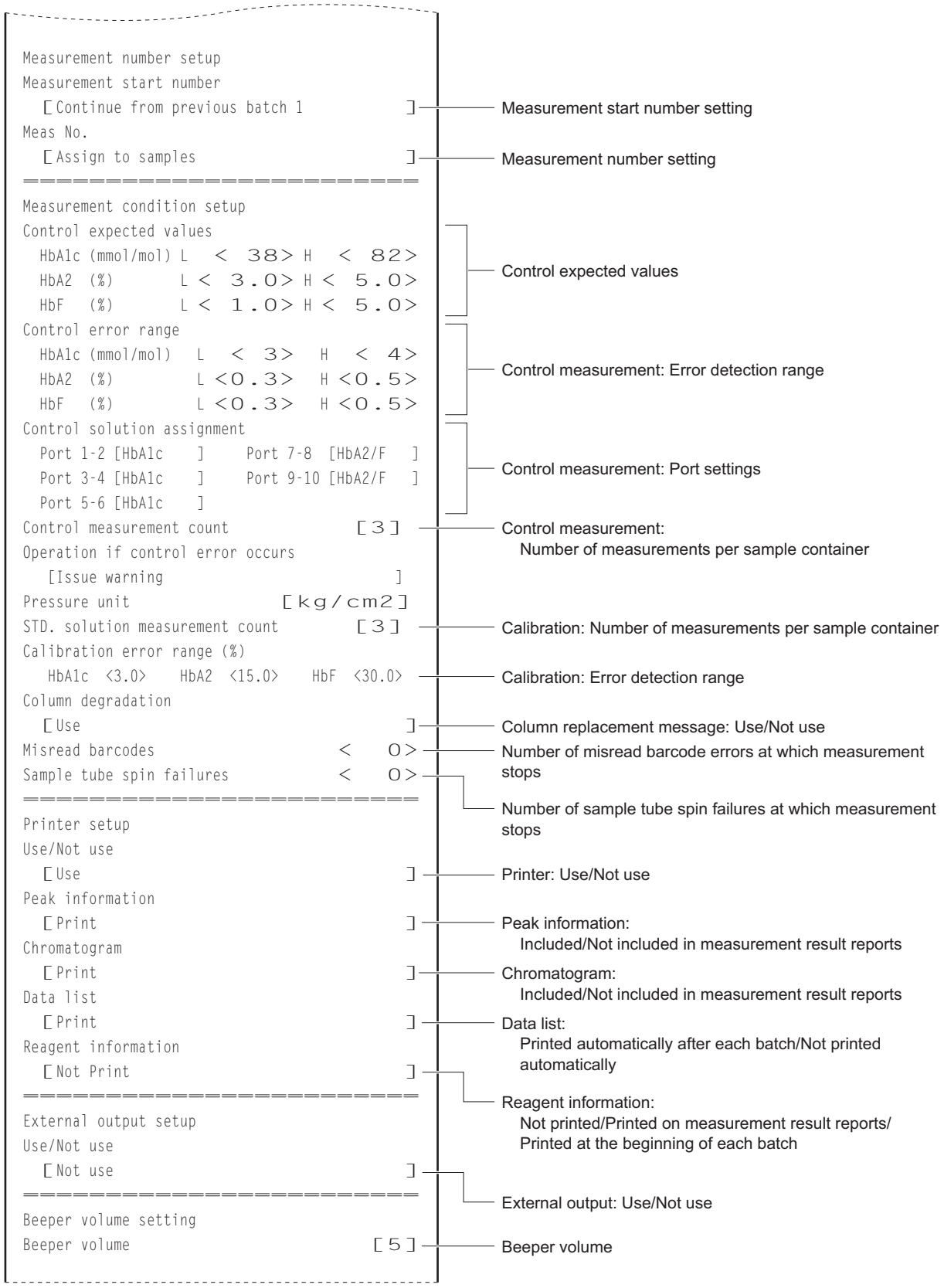
You can view the current parameter settings for timers, column pressure unit, the printer and others.

REFERENCE:
Printing instructions: See "3.6.5. Printing the Current Parameter Settings" on page 3-28.

Example

```
*** HA-8180T VXX.XX  ***
 Parameter settings
 10-06-2011 10:00
 Serial No. 00000000
============================
Counter
Column                  <0672>
Total                <0005773>
Sample               <0005137>
Control              <0000519>
============================
Reagent information
           Lot No. Expiry
Elu. 80A   0A1101 2012-01
Elu. 80B   0C1112 2012-03
Elu. 80CT  0D3331 2012-04
Wash 80H   9L1121 2011-12
Cal. A1c   CA89C05 2012-10
Cal. A2    C289C05 2013-05
Cal. F     C289C05 2013-05
============================
Timer setup
Startup timer
  [Use                     ]
Monday      [Not start    ] <00:00>
Tuesday     [Not start    ] <00:00>
Wednesday   [Not start    ] <00:00>
Thursday    [Not start    ] <00:00>
Friday      [Not start    ] <00:00>
Saturday    [Not start    ] <00:00>
Sunday      [Not start    ] <00:00>
Shutdown timer          <00:00>
============================
```

Print date
Serial number of the instrument
Column measurement counter
Number of measurements for each type of measurement.
Reagent information
Hyphens (---) appear if no reagent information has been set.
Startup timer: Use/Not use
Startup timer: Settings for each day
Shutdown timer setting

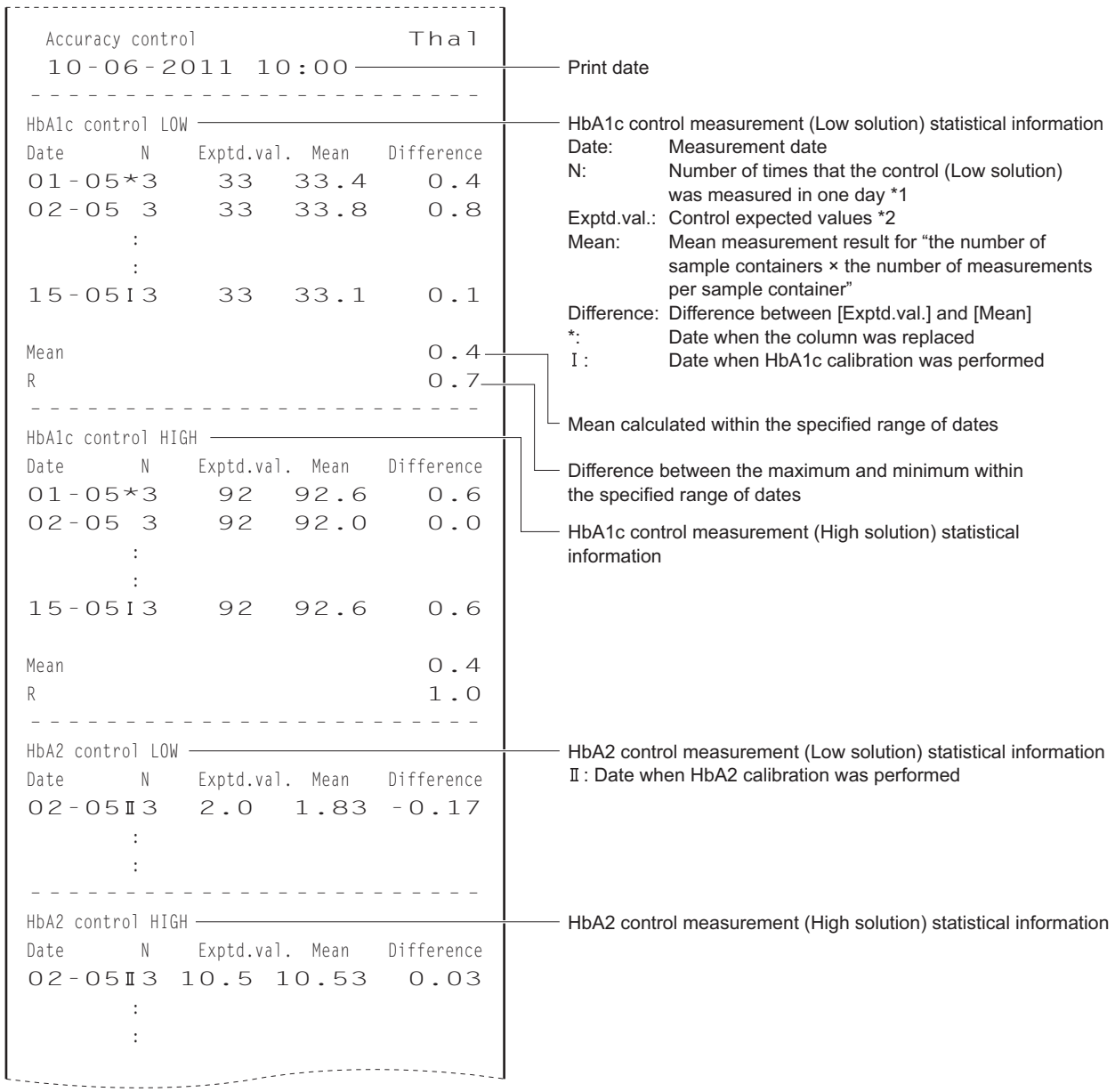

Measurement number setup
Measurement start number
[Continue from previous batch 1]
Meas No.
[Assign to samples]
Measurement condition setup
Control expected values
HbA1c (mmol/mol) L < 38> H < 82>
HbA2 (%) L < 3.0> H < 5.0>
HbF (%) L < 1.0> H < 5.0>
Control error range
HbA1c (mmol/mol) L < 3> H < 4>
HbA2 (%) L <0.3> H <0.5>
HbF (%) L <0.3> H <0.5>
Control solution assignment
Port 1-2 [HbA1c] Port 7-8 [HbA2/F]
Port 3-4 [HbA1c] Port 9-10 [HbA2/F]
Port 5-6 [HbA1c]
Control measurement count [3]
Operation if control error occurs
[Issue warning]
Pressure unit [kg/cm2]
STD. solution measurement count [3]
Calibration error range (%)
HbA1c <3.0> HbA2 <15.0> HbF <30.0>
Column degradation
[Use]
Misread barcodes < 0>
Sample tube spin failures < 0>
Printer setup
Use/Not use
[Use]
Peak information
[Print]
Chromatogram
[Print]
Data list
[Print]
Reagent information
[Not Print]
External output setup
Use/Not use
[Not use]
Beeper volume setting
Beeper volume [5]
Measurement start number setting
Measurement number setting
Control expected values
Control measurement: Error detection range
Control measurement: Port settings
Control measurement:
Number of measurements per sample container
Calibration: Number of measurements per sample container
Calibration: Error detection range
Column replacement message: Use/Not use
Number of misread barcode errors at which measurement stops
Number of sample tube spin failures at which measurement stops
Printer: Use/Not use
Peak information:
Included/Not included in measurement result reports
Chromatogram:
Included/Not included in measurement result reports
Data list:
Printed automatically after each batch/Not printed automatically
Reagent information:
Not printed/Printed on measurement result reports/
Printed at the beginning of each batch
External output: Use/Not use
Beeper volume

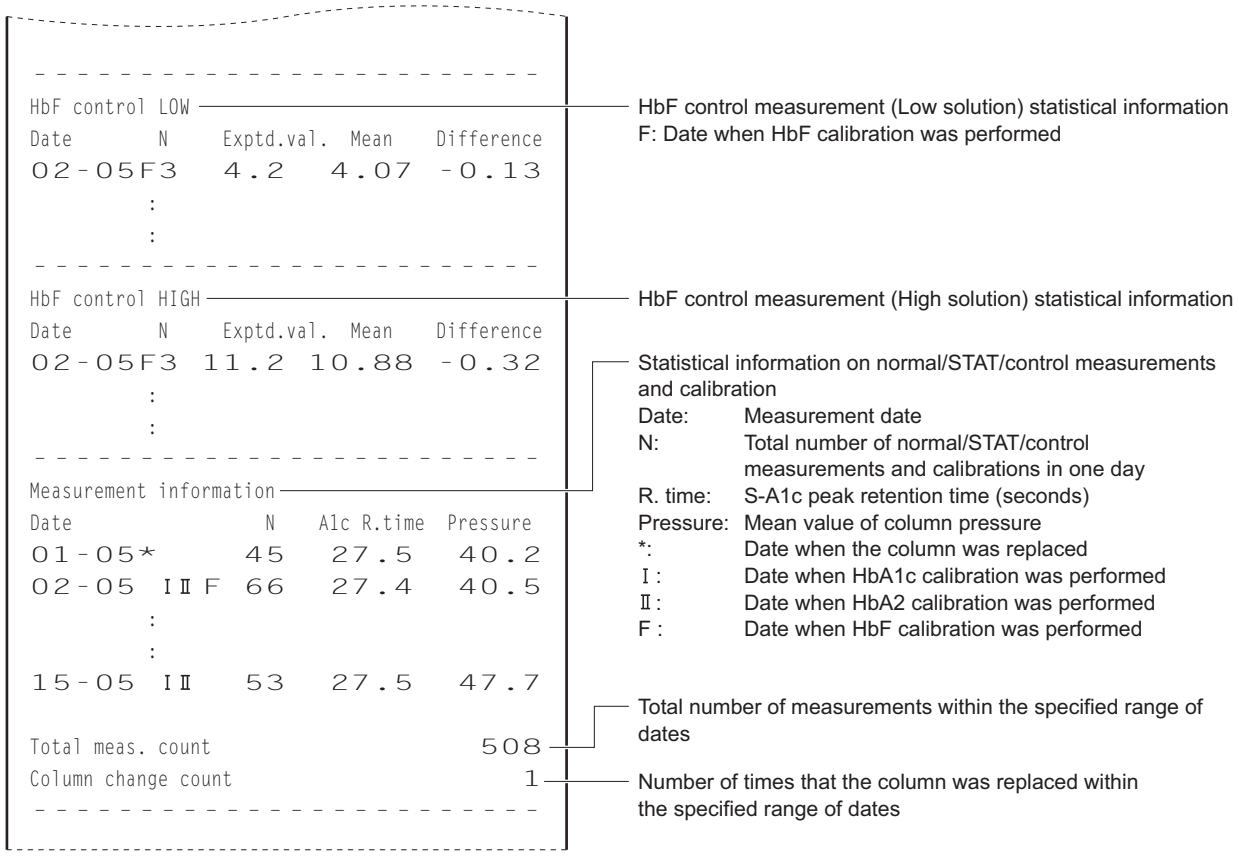
6.1.2 Accuracy Control Reports

Accuracy control reports show statistical information on control measurements and sample measurements for a specified period of time.

REFERENCE:
Printing instructions: See “3.7.3. Printing Accuracy Control Reports” on page 3-31.

Example:





*1: If the control measurement was performed two or more times in one day, the number of times that the Low solution was measured after the following operations appears on the next line:
- Changing expected values
- Calibration

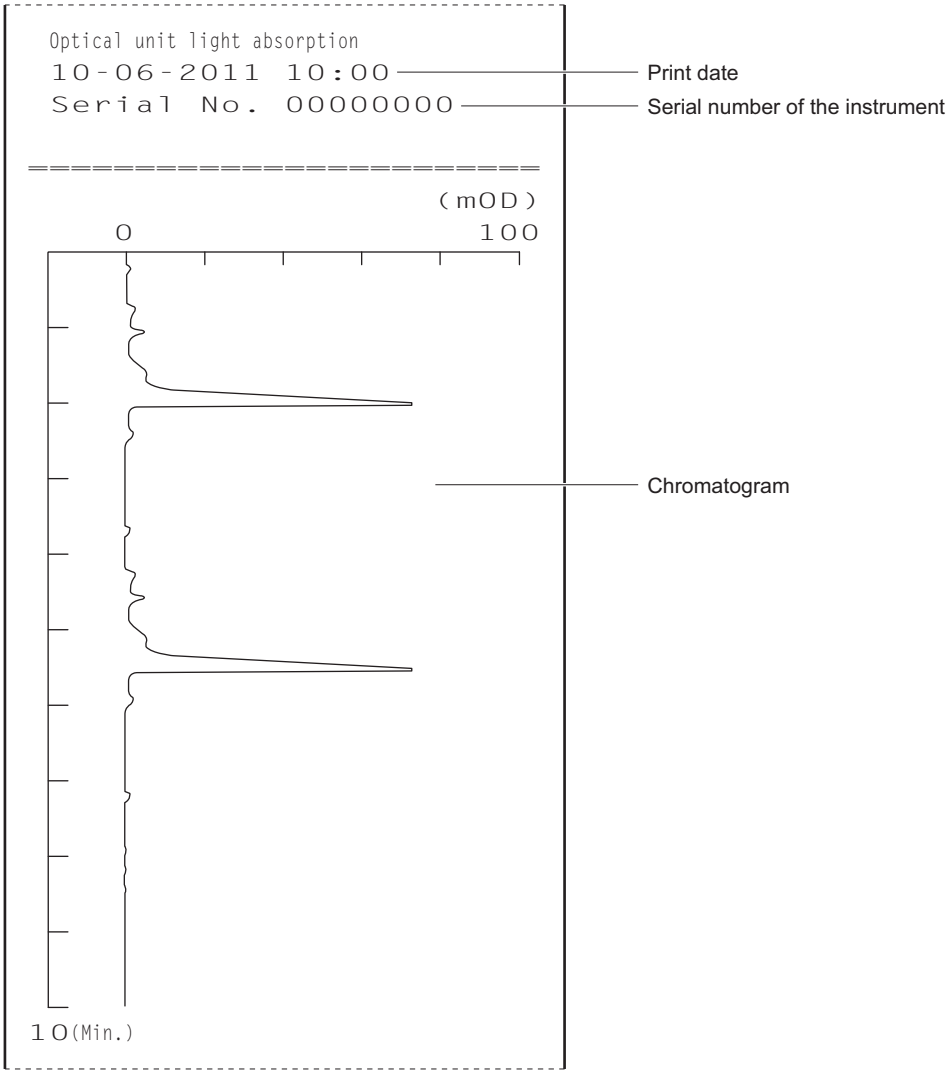
*2: These are the control expected values that were set as <Control expected values> on the <Measurement condition setup> screen when the control measurements were performed. However, if different expected values were later set on the [View] screen for individual measurement results, the newly set values appear here instead.

6.1.3 Optical Unit Monitoring Results

Optical unit monitoring results show the changes in optical unit light absorption over the last 10 minutes.

REFERENCE:
Printing instructions: See “3.7.4. Printing Optical Unit Monitoring Results” on page 3-32.

Example

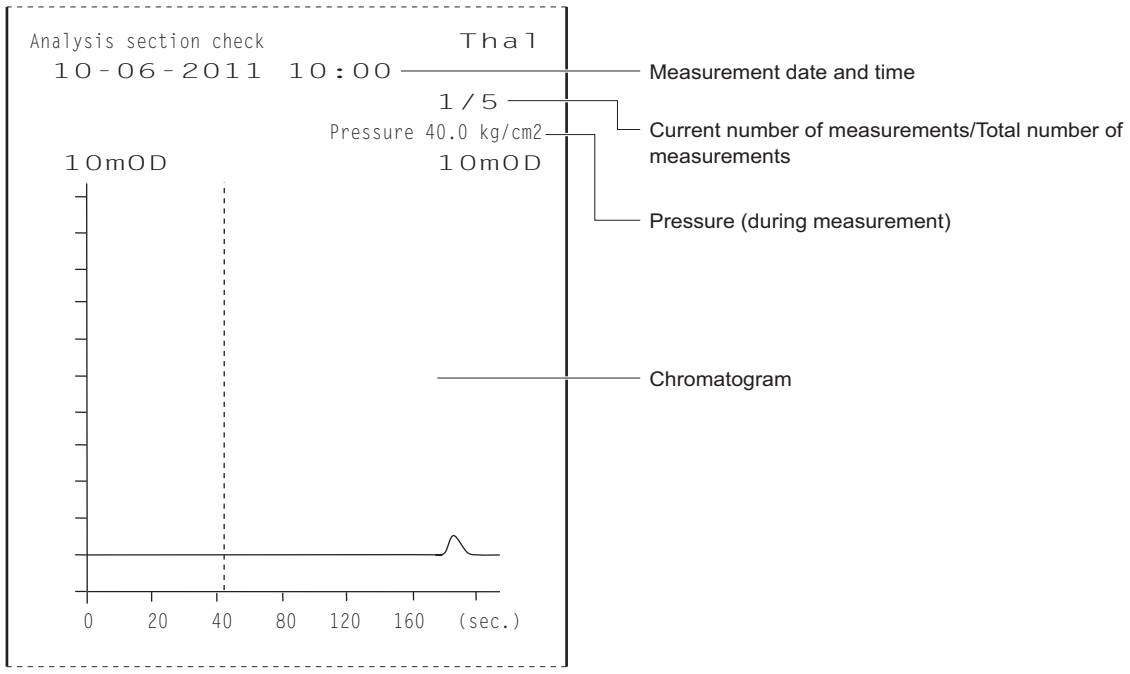


6.1.4 Analysis Section Check Measurement Results

A chromatogram is printed out each time hemolysis washing solution is measured during analysis section check.

REFERENCE:
Printing instructions: See “3.7.5. Performing Check Measurement for the Analysis Section” on page 3-33.

Example



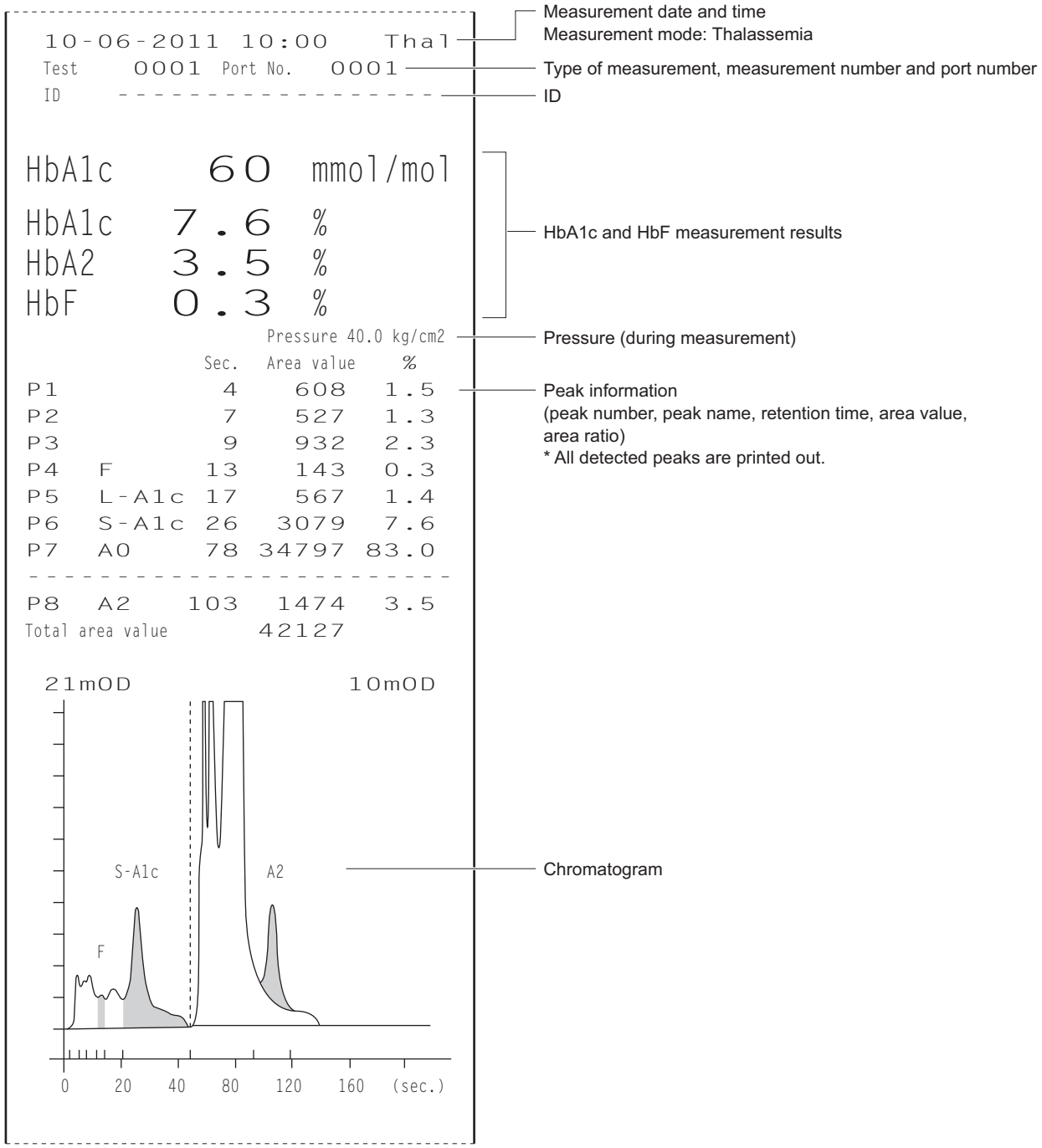
6.1.5 Reproducibility Test Results

A chromatogram is printed out each time sample is measured during reproducibility tests. Diagnosis results are also printed out after the test.

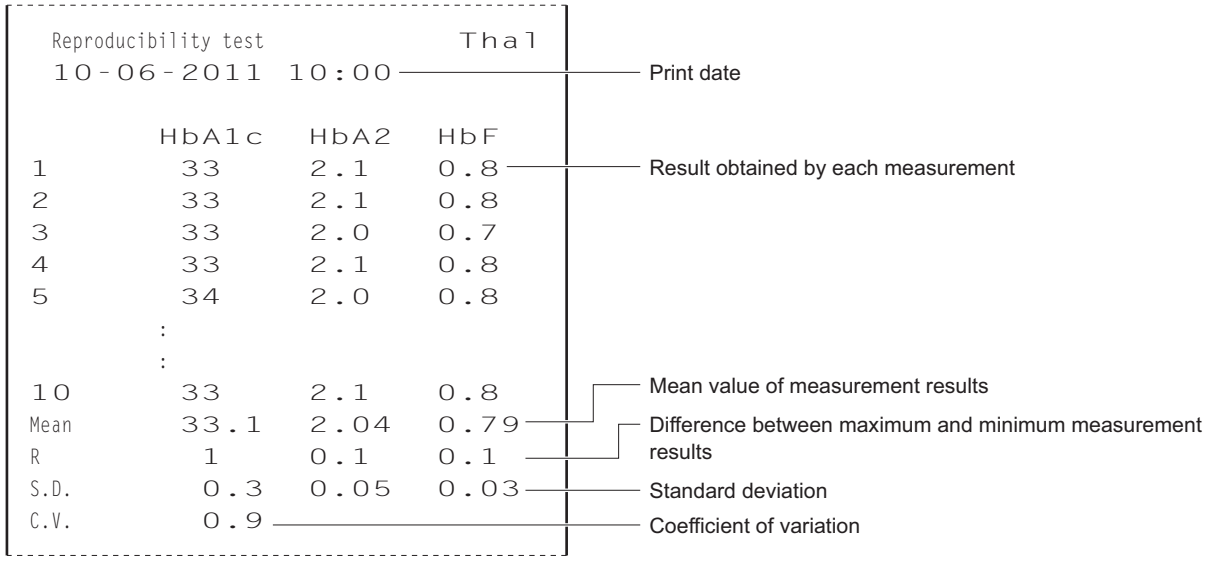
REFERENCE:

Printing instructions: See “3.7.6. Testing Reproducibility (Whole Blood Sample)” on page 3-34 and “3.7.7. Testing Reproducibility (Hemolysis Sample)” on page 3-36.

Example: Chromatogram



Example: Diagnosis results



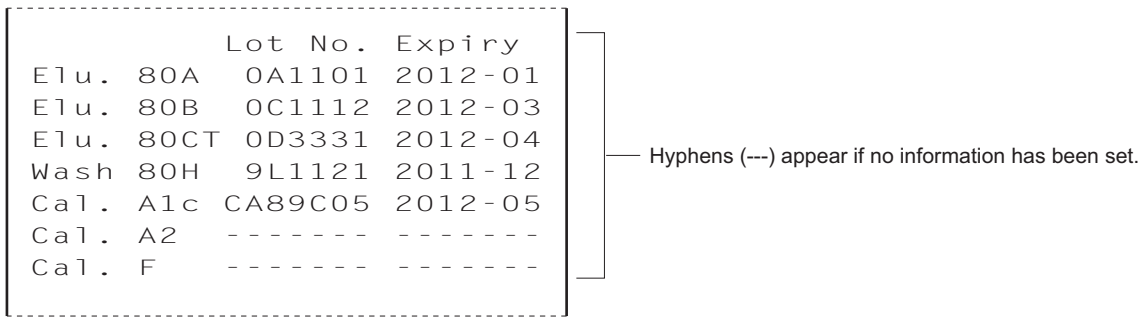
6.1.6 Reagent Information Report

Reagent information can be printed out as follows:

- At the beginning of batches
- On individual measurement result reports

Reagent information is not printed as a default. If needed, change the printer settings (see “3.5.2. Setting Up the Printer” on page 3-23).

Example



6.2 Glossary

● Batch

A batch is a group of samples measured continuously. In an actual operation, a batch means any number of samples measured after the ◇| button has been pressed and until the standby screen appears again.

● Measurement number

A measurement number is a 4-digit code (0000 to 9999) that identifies each measurement result. Measurement numbers are automatically increased by one and assigned to samples in the order of measurements, and displayed and printed along with results. Measurement numbers are indicated differently according to the type of measurement (see the table below). Measurement numbers can be assigned not only to samples but to ports as well (see “3.3.4. Configuring the Measurement Numbering Method” on page 3-11).

Type of measurement	Indication example
Normal measurement	Meas No. 0001
STAT measurement	STAT No. 0001
Control measurement	Cont A1c 0001 Cont A2F 0001
Automatic calibration (dummy sample)	Dummy 0001
Automatic calibration (standard solution)	Cal A1c 0001 Cal A2F 0001 Cal A2 0001 Cal F 0001
Reproducibility test	Test 0001

● Measurement start number

The measurement start number is assigned to the first sample (or port) in a batch of normal or control measurements. At the time of shipment, the instrument is set so that it is always powered up with the measurement start number “0001”. The measurement start number of the next batch is the next number after the last number in the previous batch. The measurement start number can be set to continue from the previous batch even after the power has been turned off and back on, or it can be reset to “0001” for each new batch (see “3.3.4. Configuring the Measurement Numbering Method” on page 3-11). You can also set any measurement start number using the numeric buttons before starting measurement.

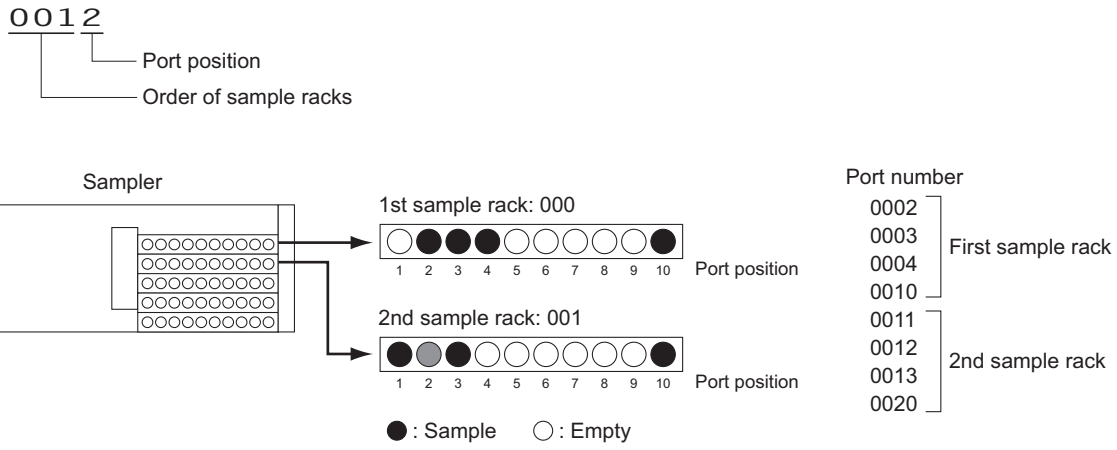
● ID

An ID is a text string that identifies the patient from whom the sample was collected. It consists of up to 18 digits of numbers, letters and symbols. When using the internal barcode reader or optional hand-held barcode reader, IDs can be read from the barcode on the sample tubes during measurements, and displayed, printed and sent to external devices along with measurement results.

● Port number

A port number is a 4-digit code (0000 to 9999) that identifies the port in which sample is set. The last digit indicates the port position (the corresponding number is marked on the top face of the sample rack). Port 10 is indicated as “0”. The first three digits are a sequential number assigned to the sample racks loaded onto the sampler: the first rack on the sampler is indicated as “000” and the second rack, “001”. However, for port 10, the first three-digit number is one larger than that of other ports of the same rack: the first rack is indicated as “001” and the second rack, “002”. Port numbers are displayed and printed along with measurement results.

Example:
Port number marked with a gray circle (●) in the figure below

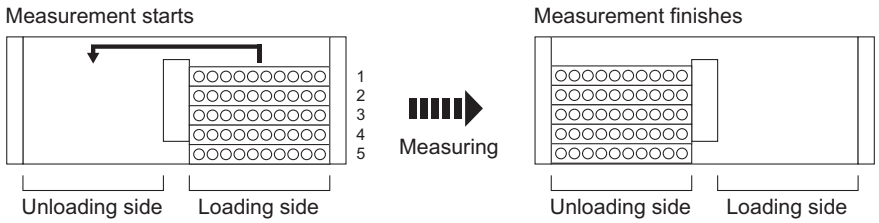


● Sample rack transportation

The instrument supports two methods for transporting sample racks in the sampler: “one-way transportation” and “loop transportation”. To change the rack transportation method, contact your distributor.

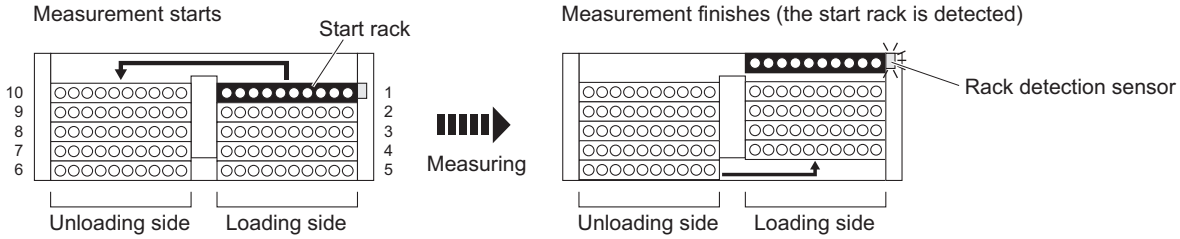
One-way transportation (factory-set)

Up to 5 sample racks (50 samples) can be loaded onto the loading side of the sampler. The racks exit the unloading side in order after sample aspiration has finished.



Loop transportation

Up to 100 samples can be measured continuously by setting 5 racks each on the rack loading and unloading sides of the sampler and circulating these racks. Be sure to place the start rack at the first position of a batch, and normal racks, in the remaining area (numbered 2 to 10 in the figure below). The instrument then starts measurements with the start rack, and stops when it has finished aspiration of all the samples and detected the start rack again.



- **Normal measurement**

In normal measurement, samples are set in racks and measured continuously. It is called “normal measurement” to differentiate it from other measurements for specific purposes such as control measurements and calibrations.

- **Sleep mode**

In sleep mode, the display turns off and power to the mechanical sections shuts off in the same way as when power is turned off. The standby switch lights up orange. The instrument still consumes a small level of power because power is not completely shut off.

- **IFCC value for HbA1c**

HbA1c value compliant with IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) values
Measurement unit: mmol/mol

- **NGSP value for HbA1c**

NGSP (National Glycohemoglobin Standardization Program) values are obtained by converting IFCC values (mmol/mol) with the conversion formula.
Measurement unit: %

- **Reagent information**

Reagent information can be set in the HA-8180T to prove that the right reagents are being used for measurement. The reagent information can be added to printed result reports.

6.3 Performance Characteristics

6.3.1 Analytical Performance

1) Trueness

HbA1c

JCCRM411 (certified reference material)	Difference between the measured value and the certified value
Level 1	0.04%
Level 2	0.01%
Level 3	0.00%
Level 4	-0.07%
Level 5	-0.07%

2) Precision

HbA1c

Precision	C.V.%
Reproducibility (Between-day)	0.21 - 0.48%
Repeatability (Within-run)	0.10 - 0.39%

HbA2

Precision	S.D.%
Reproducibility (Between-day)	0.02 - 0.04%
Repeatability (Within-run)	0.01 - 0.05%

3) Linearity

HbA1c

Difference between the measured value and the theoretical value	-0.10 - -0.01%

HbA2

Difference between the measured value and the theoretical value	-0.03 - 0.02%

4) Interference

Substance	Test concentration with no significant interference
Carbamylated Hb (Sodium Cyanate)	20mg/dL
Aldehyde Hb (Acetaldehyde)	15mg/dL
Labile A1c (Glucose)	2000mg/dL
Bilirubin, conjugated	100mg/dL
Bilirubin, unconjugated	100mg/dL
Ascorbic Acid	200mg/dL

5) Investigation of Variant Hb

All samples containing HbS, HbC, HbD or HbE that were measured were correctly recognized.

6) Method comparison

HbA1c

Correlation coefficient with reference method*	0.9980

HbA2

Correlation coefficient with reference method*	0.993

*ADAMS A_{1C} HA-8160 TP mode measurement

7) Matrix comparison

All available anticoagulants had no effect on the measurements.

6.3.2 Clinical Performance

HbA1c

Positive percent agreement	Negative percent agreement	Overall percent agreement
100.0%	97.1%	98.2%

vs. ADAMS A_{1C} HA-8160 TP mode measurement

REFERENCE:

The clinical cutoff point for diagnosis of diabetes, 6.5% was used for the determination of Positive/Negative.
New WHO criteria on use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus (2011)

6.4 Index

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ARKRAY Factory, Inc.
1480 Koji, Konan-cho, Koka-shi
Shiga 520-3306, JAPAN
https://www.arkray.co.jp/script/mailform/afc-contact_eng

EC REP ARKRAY Europe, B.V.
Prof. J.H. Bavincklaan 2
1183 AT Amstelveen, THE NETHERLANDS
If you need to obtain technical assistance,
please contact ARKRAY Europe, B.V.
TEL: +31-20-545-24-50
FAX: +31-20-545-24-59

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