Automatic Glycohemoglobin Analyzer

ADAMS™ A1c Lite

HA-8380V | Operating Manual

arkray, inc.

1 Premise

Thank you for purchasing our automatic glycohemoglobin analyzer, ADAMS™ A1c Lite HA-8380V.

This operating manual contains important information on the functions of the ADAMS A1c Lite HA-8380V.
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 Lite HA-8380V instrument is intended for the quantitative and automated measurement of HbA1c 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. 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.
For the purchase of reagents, consumables or other optional items, refer to the after-sales parts and consumables list that comes with the instrument, or contact your distributor.

- TAKE THE UTMOST CARE WHEN HANDLING BLOOD. This instrument uses blood as sample and controls. Blood may be contaminated by pathogenic microorganisms that can cause infectious diseases. Improper handling of blood may cause infection to the user or other individuals by pathogenic microorganisms.
- 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 the sample may adhere with unprotected hands. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used samples, liquid waste, column, 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.
- If sample, eluent or hemolysis washing solution spills onto the instrument, wipe it up with a dry cloth. If the spilled liquid is out of reach, contact your distributor.
- 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.

NOTE:
This product is a precision instrument. Handle the instrument with care. **Do not** subject the instrument to strong impact or vibration.

3 Symbols

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

■For your safety

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

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.

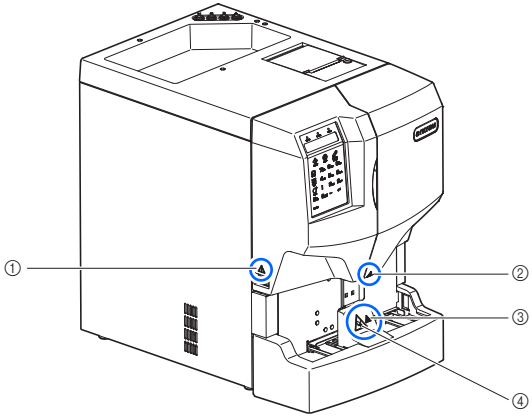
■Symbols used for the product

Symbol	Description
~ (tilde)	Represents the AC rating.

4 Caution Labels

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

■Front



① Power switch

This switch turns the power on/off. Turn off the power after finishing all measurements for the day.

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 microorganisms while cleaning these parts.

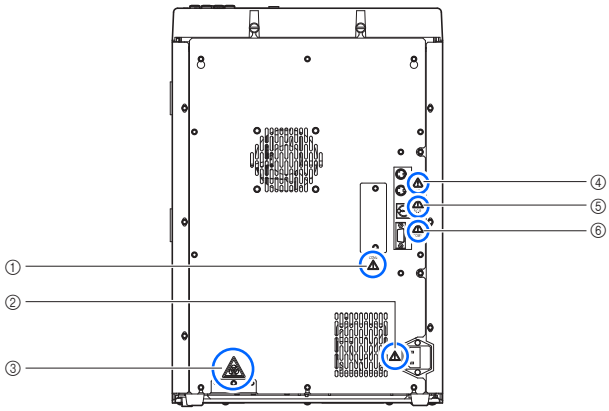
③ Sample aspirating unit

Never touch the piercing nozzle where sample may adhere with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microorganisms when cleaning the nozzle.

④ Sample aspirating unit

The piercing nozzle is located near the label. When measurement operations start, the tip of the nozzle descends to aspirate sample. 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.

■Rear



① **COM2 terminal (optional)**

Connect the specified LAN cable to this terminal. The instrument does not function properly if the wrong cable is connected to this terminal.

② **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.

③ **Drain joints (D1: For the optical unit, D2: For liquid waste)**

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

④ **DRAIN terminal**

Connect the fluid level detection sensor cord for the optional liquid waste bottle to this terminal. The instrument does not function properly if the wrong cord is connected to this terminal.

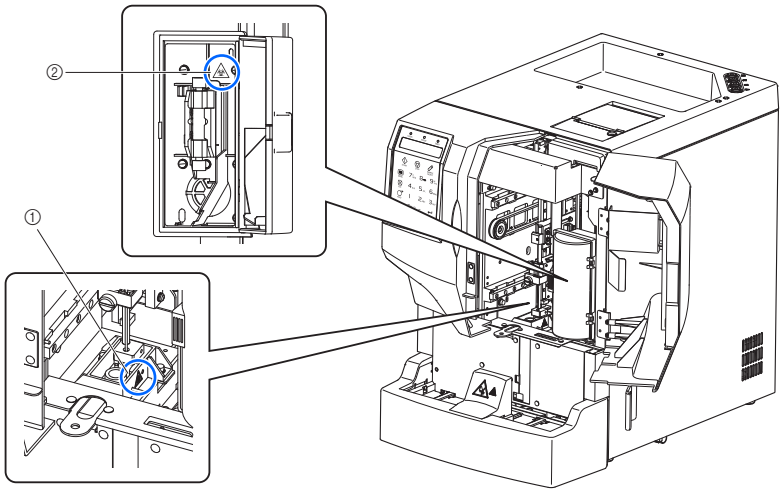
⑤ **B.C.R. terminal**

Connect the optional hand-held barcode reader to this terminal. The instrument does not function properly if the wrong cable is connected to this terminal.

⑥ **COM1 terminal**

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

■Front (inside)



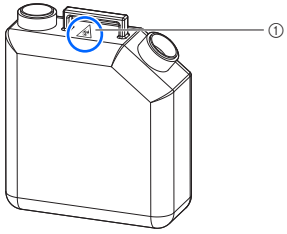
① **Dilution container unit**

Do not touch the dilution container unit with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microorganisms while cleaning the unit.

② **Inside of the column box**

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

■Liquid waste bottle (optional)



① **Liquid waste bottle (optional)**

Liquid waste is collected in this bottle. When discarding liquid waste, wear protective gloves to prevent exposure to pathogenic microbes.

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-8380V measures HbA1c glycated hemoglobin and provides information necessary for controlling blood glucose in diabetics. It can measure stable HbA1c(S-A1c,HbA1c) and HbF. Measurements made with the HA-8380V are accurate because labile HbA1c(L-A1c), carbamylated Hb and acetylated Hb are eluted separately from stable HbA1c peak.

■Sample measurement (normal measurement)

The instrument can measure hemolysis samples that have been diluted with DILUENT 80 as well as whole blood samples. Multiple samples are continuously measured using the normal racks. One normal rack can hold up to 5 samples. Load the normal racks with samples onto the sampler and press START. The instrument then automatically moves the racks and measures the samples sequentially.

Two measurement modes, Variant and Fast: In addition to measuring HbA1c and HbF, this instrument can detect variant Hb, HbS and HbC, in the Variant mode. If HbS and HbC detection is unnecessary, setting the Fast mode shortens measurement time.

For anemia sample: Select the <ANEMIA> as the type of sample to measure whole blood samples from patients previously diagnosed as anemic. Samples are measured at a lower dilution ratio than samples measured in the whole blood measurement. This prevents abnormal low value errors.

■HbA1c control measurement

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.

■HbA1c calibration

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 setup

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

1.1.2 Features

- 160 seconds per sample measurement in the Variant mode, and 100 seconds in the Fast mode

It takes 160 seconds to measure HbA1c and HbF and detect HbS and HbC (Variant mode). Tests for just HbA1c and HbF are completed in 100 seconds (Fast mode).

- Continuous measurements for up to 10 samples

The instrument can store a maximum of 10 samples by loading two normal racks (5 samples for each rack) onto the sampler.

- 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 printed on measurement result reports and calibration result reports to show that the proper reagents were used for measurements.

- 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.

- Highly accurate measurement results

Measurements are performed by high performance liquid chromatography (HPLC), a technique that provides accurate data on HbA1c. A column is used to remove L-A1c. S-A1c and HbF values can be obtained.

- Easy maintenance

Daily maintenance can usually be performed without tools as parts can be easily replaced and tightened by hand.

- Fluid level detection function to prevent reagent shortages during measurement

To prevent reagent shortages during measurements, the remaining reagent volume is detected and a message is displayed before the instrument runs out of reagent.

- Two-way online communications

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

- Wide array of options available

ARKRAY makes available a wide array of options including a hand-held barcode reader and software for the database processing of measurement results.

1.1.3 Specifications

Name	ADAMS A1c Lite HA-8380V
Configuration	Instrument and accessories
Measurement objects	Whole blood or hemolysis sample
Column	COLUMN UNIT 80
Reagents	ELUENT 80A, ELUENT 80B, ELUENT 80CV and HEMOLYSIS WASHING SOLUTION Lite H
Measurement item	HbA1c (stable HbA1c, S-A1c) and HbF (HbS and HbC can be detected in the Variant mode.)
Measurement range[*1]	HbA1c: 3 - 20%, 9 - 195 mmol/mol HbF: 0 - 100%
Guaranteed measurement ranges[*2]	HbA1c: 4.6 - 14.2%, 27 - 132 mmol/mol HbF: 0.1 - 5.0%
Measurement principle	Reversed-phase cation exchange chromatography
Measurement wavelength	420 nm/500 nm (Dual-wavelength colorimetry)
Sample supply	Piercing sampling
Sample transportation	Transported in racks
Resolution	0.1% Ratio, 1 mmol/mol
Processing speed	Variant mode: 160 seconds/test Fast mode: 100 seconds/test
Sample consumption	Whole blood sample: Approximately 4 μL Anemia sample: Approximately 8 μL Hemolysis sample: Approximately 350 μL
Required sample volume	Sample tube: Minimum 10 mm away from the bottom of the tube Sample cup: 400 μL or more
Sample container	Sample tube: (12.3 or 15 mm in outer diameter) × (75 to 100 mm in height) Sample cup: 500 μL
Compatible rack type	ARKRAY racks (for 5 samples)
Number of measurement samples	Maximum 10 samples
Column temperature	Approximately 40°C
Warm-up time	Maximum 30 minutes
Display	20 digits × 2 lines LCD
Printer	For use with 58-mm width thermal printer paper
Memory capacity	300 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 600, 1200, 2400, 4800, 9600 and 19200 bps Ethernet: 10BASE-T, 100BASE-TX (Auto recognition)
Operating environment	Temperature: 10 - 30°C; Humidity: 20 - 80% RH (No condensation)
Measurement environment	Temperature: 10 - 30°C; Humidity: 20 - 80% RH (No condensation)
Storage environment	Temperature: 1 - 35°C; Humidity: 20 - 80% RH (No condensation)
Environment during transport	Temperature: 1 - 60°C; Humidity: 20 - 80% RH (No condensation)

Dimensions	330 (W) × 515 (D) × 485 (H) mm (Not including protrusions, eluent packs and hemolysis washing solution bottle)
Weight	Approximately 35 kg
Power requirements	AC 100 - 240 V±10%, 50/60 Hz
Power input	300 VA
Sound pressure level	Less than 80 dB
Location of use	For indoor use only
Altitude	Up to 2000 m
Pollution degree	2
Over voltage category	II
Temporary overvoltage	Short-Term : 1440 V Long-Term : 490 V
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-8180V Variant 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-8380V measures HbA1c 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

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

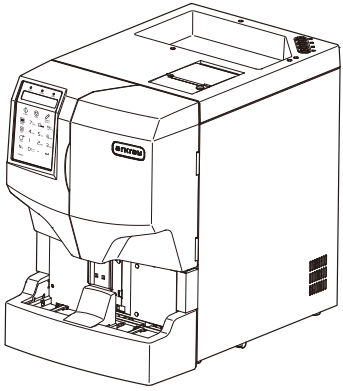
NOTE:

The following items are not included with the instrument:

ELUENT 80A, ELUENT 80B, ELUENT 80CV, HEMOLYSIS WASHING SOLUTION Lite H, COLUMN UNIT 80, CONTROL DILUTION SET 80, CALIBRATOR Lite, 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, gauze, beaker, distilled water, plastic bag, cell washing kit, sodium hypochlorite solution (approximately 0.75%), 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.

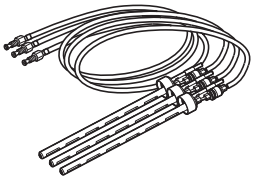
1.2.1 Instrument



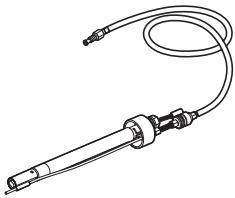
①Instrument

Item	Description	Qty.
① Instrument	ADAMS A1c Lite HA-8380V	1

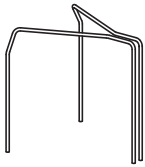
1.2.2 Accessories



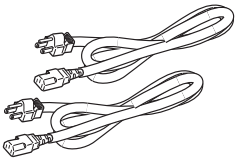
①Bottle caps with nozzle for eluents



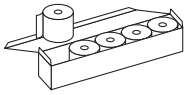
②Bottle cap with nozzle for hemolysis washing solution H



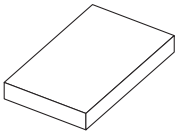
③Eluent pack guides



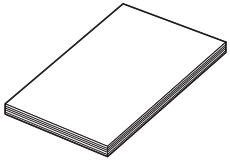
④Power cords



⑤Printer paper



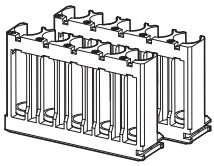
⑥Accessory case



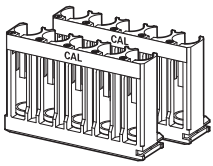
⑦Operating Manual

Item	Description	Qty.
① Bottle caps with nozzle	For eluent A, eluent B and eluent CV	3
② Bottle cap with nozzle	For hemolysis washing solution H	1
③ Eluent pack guides		2
④ Power cords	Rating: 125V 13A (A Type Plug, maximum cable length: 2.6m) and 250V 10A (C Type Plug, maximum cable length: 2.6m) Please use the appropriate power cord for your region's power voltage.	2
⑤ Printer paper	58 mm (W) × 25 m (L), 5 rolls per box	1
⑥ Accessory case	See "1.2.3. Accessory Case" on page 1-8.	1
⑦ Operating Manual		1

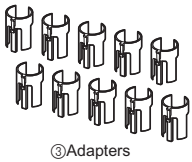
1.2.3 Accessory Case



①Normal racks

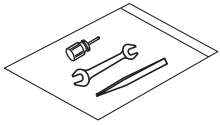


②Calibration racks

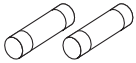


③Adapters

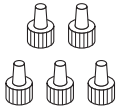
④Piercing nozzle



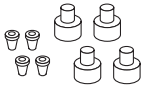
⑤Tool kit



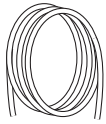
⑥Fuses



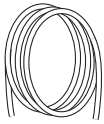
⑦Push screws (circle type)



⑧Joints 1x2



⑨Optical unit drain tube

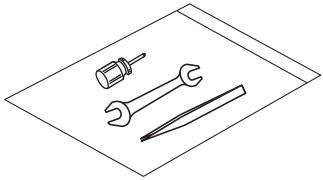


⑩Liquid waste drain tube

⑪Aluminum packs

Item	Description	Qty.
① Normal racks	2 racks	1
② Calibration racks	2 racks for HbA1c calibration	1
③ Adapters	Gray, 10 per pack	1
④ Piercing nozzle	With protective tube	1
⑤ Tool kit	See “1.2.4. Tool Kit” on page 1-9.	1
⑥ Fuses	T4AE 250V~, 2 per pack	1
⑦ Push screws (circle type)	For column IN/OUT tubes, 5 per pack	1
⑧ Joints 1×2	For eluent nozzles M6 flat seal fitting ø2, push screws and ferrules, 4 per pack	1
⑨ Optical unit drain tube	Silicone tube for installation, 2 mm (i.d.) × 4 mm (o.d.), 3 m	1
⑩ Liquid waste drain tube	Silicone tube for installation, 3 mm (i.d.) × 6 mm (o.d.), 3 m	1
⑪ Aluminum packs	For maintenance when the instrument is not to be used for extended periods of time	3

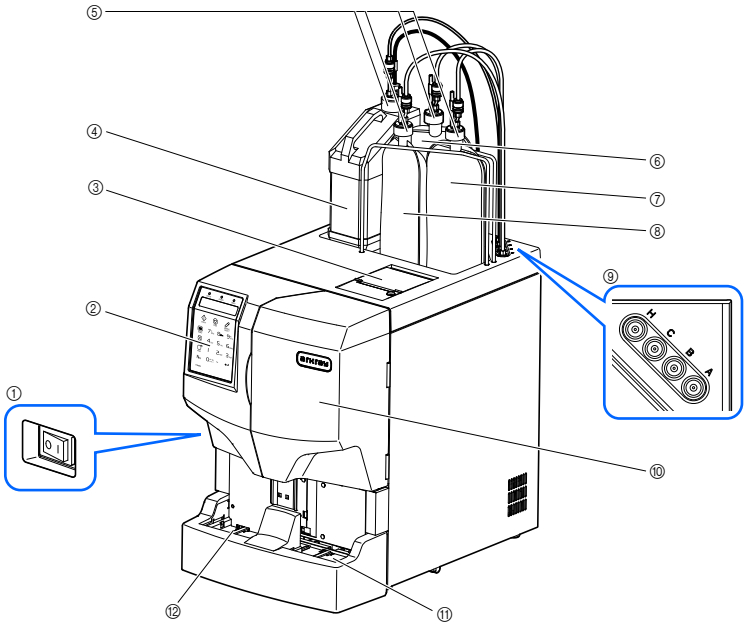
1.2.4 Tool Kit



Item	Description	Qty.
Double open end wrench	6 - 8	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

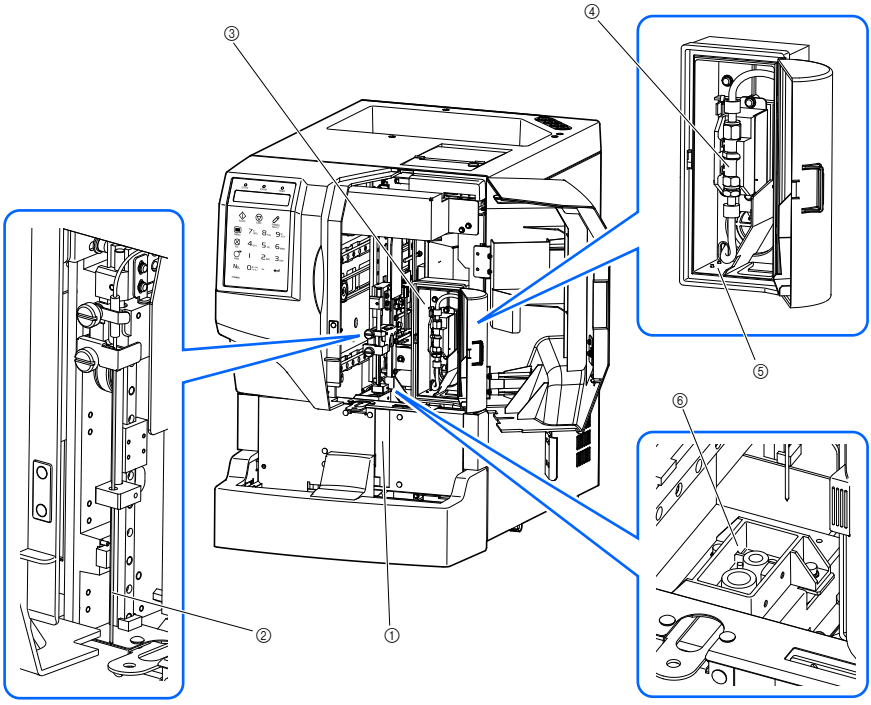


Drive units are housed inside the instrument. Power is shut off automatically if the front cover is opened during instrument operation. Do not open this cover unless necessary.

Name	Description
① Power switch	Used to turn on or off the power.
② Operator panel	See “1.7. Basic Operations” on page 1-34.
③ Printer	Thermal printer. Prints measurement results and other information.
④ Hemolysis washing solution bottle	Contains HEMOLYSIS WASHING SOLUTION Lite H.
⑤ Bottle caps with nozzle (× 4)	Attach these caps to eluent packs and hemolysis washing solution bottle. Eluent A: Blue, Eluent B: Red, Eluent CV: Yellow Hemolysis washing solution bottle: Colorless
⑥ Eluent CV pack	Contains ELUENT 80CV.
⑦ Eluent B pack	Contains ELUENT 80B.

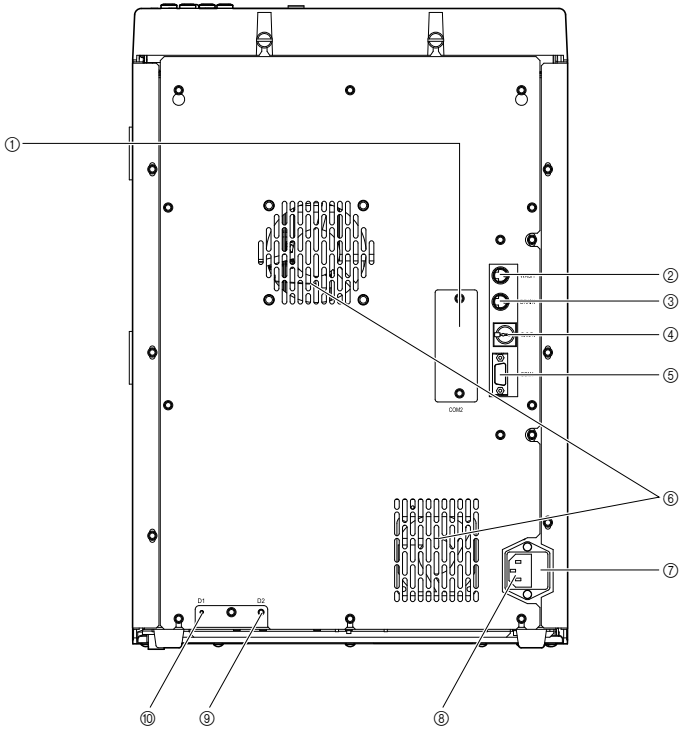
Name	Description
⑧ Eluent A pack	Contains ELUENT 80A.
⑨ Reagent joints	Connect the tubes from the bottle caps with nozzle of the reagents. A: Eluent A, B: Eluent B, C: Eluent CV, H: Hemolysis washing solution
⑩ Front cover	Protects the dilution container unit, column box and other parts. Measurement cannot be performed while the front cover is open.
⑪ Sampler (loading side)	Load sample racks with sample here.
⑫ Sampler (unloading side)	Sample racks exit here after sample aspiration.

■Inside view



Name	Description
① Internal barcode reader	The internal barcode reader is installed here.
② Piercing nozzle	Cap-piercing nozzle for aspirating samples
③ Column box	Keeps the column at a proper temperature.
④ Column	Fractionates sample into multiple hemoglobin components.
⑤ Leak detector	Collects leaking liquid from the high pressure tube for leak detection. Measurement cannot be performed if a leak is detected.
⑥ Dilution container unit (dilution container and washing container)	Dilutes sample and washes the piercing nozzle.

1.3.2 Rear View



Name	Description
① COM2 terminal	The instrument can be connected to a LAN when the optional Ethernet board is installed here. For more information, contact your distributor.*
② WASH terminal (Not used)	This terminal is not usually used. For more information, contact your distributor.
③ DRAIN terminal	Connects to the fluid level detection sensor cord for the optional liquid waste bottle.
④ B.C.R. terminal	Connects to the optional hand-held barcode reader.*
⑤ COM1 terminal	Connects to a communication cable (sold separately) from an external device that has an RS-232C interface.*
⑥ Cooling fan (× 2)	Removes hot air to protect the inside of the instrument from excessive heat.
⑦ Fuse box	Fuses are housed here.
⑧ Power input terminal	Connects to the power cord that comes with the instrument.
⑨ D2 (drain joint)	Connects to the liquid waste drain tube.
⑩ D1 (drain joint)	Connects to the optical unit drain tube.

* See “1.4.5. Connecting Peripheral Devices (when needed)” on page 1-21.

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 cover open. High voltage parts are located inside. Contact with these parts may be dangerous.

- This instrument weighs about 35 kg. Determine a location for the instrument and assemble it in that location. For safety reasons, always move and install the instrument with the help of at least one other person. Carefully hold the bottom of the instrument with both hands when carrying it. (**Do not** hold the bottom of the sampler.) Dropping may cause damage to the instrument or personal injury.

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

- Ensure at least 20 cm clearance between the wall and the rear panel. 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.

- Ensure at least 10 cm clearance between the wall and the right panel (viewed from the front). The air exhaust vents are located on the right side of the instrument. Inadequate clearance between the instrument and wall may cause trouble to the instrument or inaccurate measurement results.

- Ensure at least 15 cm clearance between the wall and the left panel (viewed from the front). Inadequate clearance between the instrument and wall may make it difficult for the users to access the power switch and disconnect the power cord in daily use.

- Install the instrument where temperature and humidity can be maintained in the following ranges:
  Temperature: 10 - 30°C
  Humidity: 20 - 80%
  Installation in the environment outside these ranges may cause 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. If the instrument falls from heights or topples over, it may be damaged or cause personal injury.

- **Do not** install the instrument near:
  - Places that store chemicals;
  - Equipment that generates corrosive gas or electrical noise; or
  - Equipment that may bring the instrument out of the operating temperature and humidity ranges. These factors 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.

- **Do not** use the instrument at elevations of 2000 m or higher. Excessively high elevations will cause inaccurate measurement results.

- Be careful not to pinch your fingers when closing the front cover, column box or printer cover. Pinching may result in personal injury.

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

- In order to prevent electric shocks, always use the power cord that comes with the instrument, and connect the instrument to a grounded outlet. If a grounded outlet is not available at the installation site, contact your distributor.

- Connect the instrument's power cord directly to a single outlet. Shared outlets may lead to instrument damage and malfunctions, personal injury or inaccurate measurement results. The power supply for the instrument is 300 VA. If you use a power strip, make sure it is grounded. Also, check if the power capacity for the power strip is within the specification range.

- Use the specified RS-232C cross cable to connect an external device to the standard 9-pin COM1 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 COM2 terminal (optional Ethernet board). Use of other cables may cause electric shock or fire. For more information, contact your distributor.

- **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 microorganisms 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 microorganisms.

- Use accessories supplied by your distributor for accessories that are to be connected to the product.

1.4.2 Unlocking the Instrument

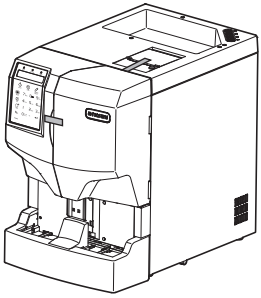
To prevent the instrument from being damaged during transport, various parts are fixed in place before shipping from the factory. Remove the fixing tape and bracket before installing the instrument. Read “1.4.1. Precautions in Instrument Installation” on page 1-13 before installing the instrument.

REFERENCE:

Keep the removed fixing bracket in the accessory case. This bracket should be reused when the instrument is transported.

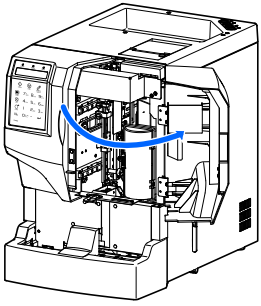
1 Remove the fixing tape.

❶ Remove the fixing tape from the front cover and printer cover.



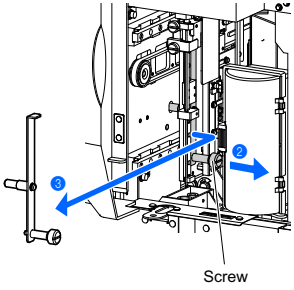
2 Unlock the nozzle drive unit.

❶ Open the front cover.



❷ Loosen the screw by hand.

❸ Slide the fixing bracket to the right as viewed from the front of the instrument and pull it to the front.
- This unlocks the nozzle drive unit.



❹ Close the front cover.

1.4.3 Setting Up Eluent Packs and Hemolysis Washing Solution Bottle

> ⚠ Be careful to avoid contact between skin, eyes or mouth and eluent or 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.

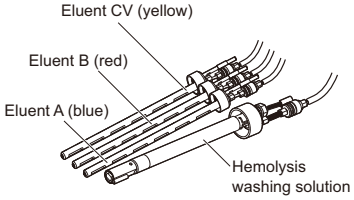
> **IMPORTANT:**
> If eluents and hemolysis washing solution are stored in a refrigerator, allow them to adjust to the same environment as the instrument for at least one hour before using them with the instrument.

Prepare: ELUENT 80A, ELUENT 80B, ELUENT 80CV, HEMOLYSIS WASHING SOLUTION Lite H, eluent pack guides (× 2), bottle caps with nozzle (for ELUENT 80A, ELUENT 80B, ELUENT 80CV, HEMOLYSIS WASHING SOLUTION Lite H) and wrench

1 Identify the types of bottle caps with nozzle.

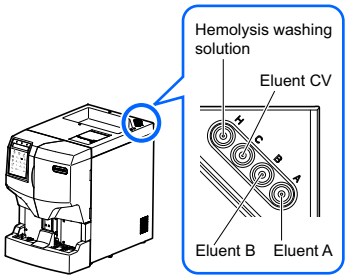
> **NOTE:**
> Check the type of bottle cap with nozzle so as to correctly attach them to the eluent packs and hemolysis washing solution bottle.

❶ Check the identification label on each bottle cap with nozzle.



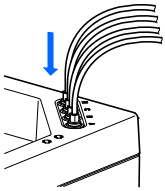
2 Connect the tubes.

NOTE:
Check the marking at each reagent joint so that you can connect the tubes to the proper joints.



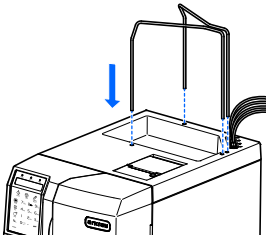
❶ Screw the end of the tube from the bottle cap with nozzle in the correct reagent joint on the instrument.

❷ Tighten the screws securely using the wrench.



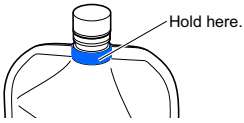
3 Place the eluent pack guides.

❶ Insert the eluent pack guides into the holes on the instrument.



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

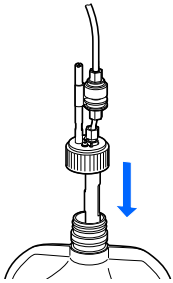
❶ Hold the eluent A pack by the hard plastic neck and remove the cap from the pack.



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

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

❷ Insert the nozzle of the bottle cap for eluent 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 and eluent CV pack.

- See steps **4**-❶ and ❷.

❹ Install the hemolysis washing solution bottle.

- See steps **4**-❶ and ❷.

❺ 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.

5 Place the packs and bottle on the bottle tray.

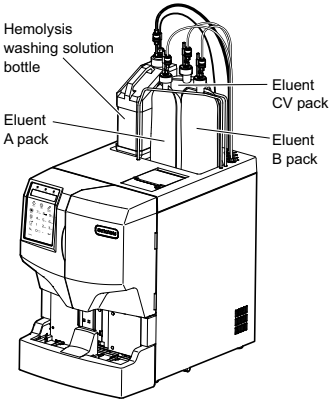
❶ Neatly arrange the tubes to prevent twisting or tangling.

❷ Place the eluent packs and hemolysis washing solution bottle on the bottle tray.

- Position the packs and bottle as shown on the right.

IMPORTANT:

Place the packs between the eluent pack guides.



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.

1.4.4 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.
- **Do not** touch liquid waste with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microorganisms when discarding liquid waste in the bottle.

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) , scissors and protective gloves.

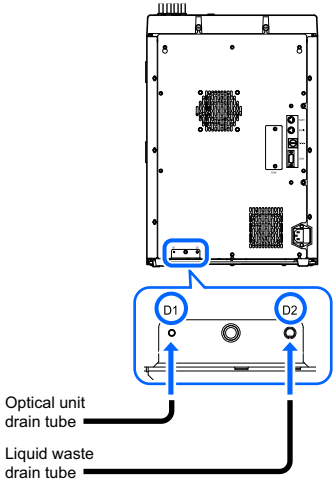
1 Connect the drain tubes to the instrument.

NOTE:

Do not force tubes into drain joints. The tubes may rip.

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

❷ Fit one end of the liquid waste drain tube into drain 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 with scissors to a suitable length if they are too long.

● For lab drainage system

Insert the tubes into lab drainage system. Make sure to cut the tubes long enough so that they do not come off from the drainage system.

● For the optional liquid waste bottle

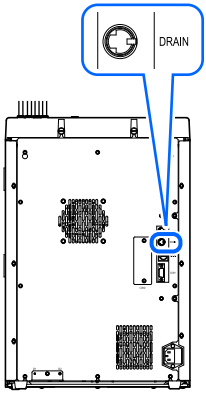
Connect the tubes to the cap of the liquid waste bottle. Make sure to cut the tubes long enough so that the bottles do not fall over.

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.



1.4.5 Connecting Peripheral Devices (when needed)

- Connecting the optional 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 (COM1) for connecting to an external device.

> Use the RS-232C cross 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:

Attach the Ethernet terminal (optional Ethernet board) to the COM2 terminal. For more information, contact your distributor.

Prepare: RS-232C cross cable

1 Connect the cable.

❶ Connect one end of the cable to the COM1 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.

❶ After performing steps in “2.3.2. Turning On the Power” on page 2-10, set <Ext. output> to <ON> to activate the external output. See “3.5.3. Setting Up External Output” on page 3-21.

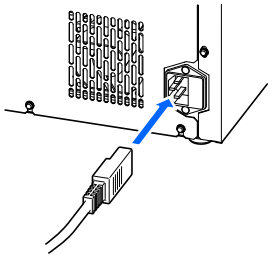
1.4.6 Connecting the Power Cord

> Use the power cord that comes with the instrument for the electrical connection to prevent electric shocks and fire. Always connect the instrument to a grounded outlet to prevent electric shocks. If a grounded outlet is not available at the installation site, contact your distributor.

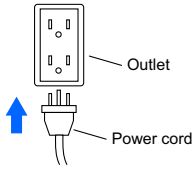
Prepare: Power cord

❶ Ensure the power switch is in the off position.
- The power switch should be pressed to the "O" (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.

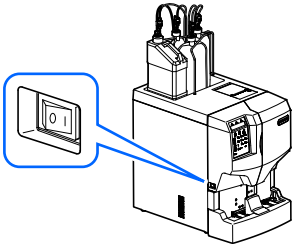


This completes installation of the instrument.

1.5.1 Attaching the Piercing Nozzle

Follow the instructions described below to attach the piercing nozzle to the instrument.

❶ Press and hold [7] on the operator panel and press the " | " side of the power switch.



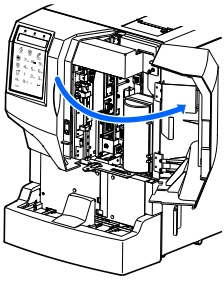
- The piercing nozzle unit will move forward.

```
Piercing nozzle
moving
```

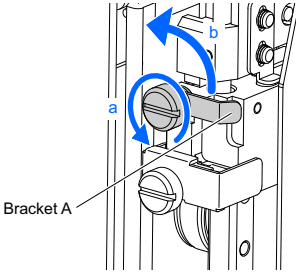
❷ Wait for the screen shown on the right to appear, and then open the front cover.

- The mechanical sections will power off.

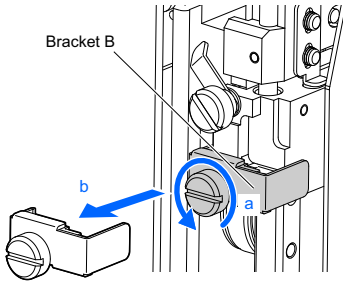
```
Open front cover.
Close when finished.
```



❸ Loosen the screw of the bracket A by hand (a) and then turn the bracket A in the direction of the arrow (b).



❹ Loosen the screw of the bracket B by hand (a) and then remove the bracket B (b).



❺ Attach the piercing nozzle to the instrument.

- See step **3** in "4.4.4. Replacing the Piercing Nozzle [Every 20000 measurements]" on page 4-26.

❻ Close the front cover.

- The mechanical sections will power on and initialize.

```
Initializing...
      Please wait.
```

NOTE:

Be sure to close the front cover to initialize the mechanical sections.

❼ Make sure that initialization has finished and the screen shown on the right appears.

```
Main power OFF
```

❽ Press the "○" side of the power switch.
The display and power will turn off.

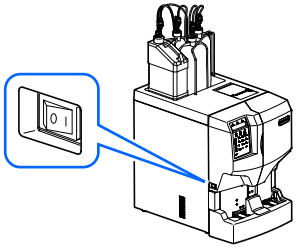
1.5.2 Turning On the Power

NOTE:

Check that eluent A, B and CV, and the hemolysis washing solution are all set before turning on the power.

Follow the instructions described below to turn on the instrument. It will take at most 30 minutes for the instrument to complete initialization of the mechanical sections, warm-up and priming.

❶ Press the " | " side of the power switch.



- The product name and version will appear.

```
  ADAMS A1c Lite
HA-8380V V01.00
```

- The mechanical sections will be initialized and the instrument will start warm-up.

Initializing — STATE (blue): Flashing

```
Initializing...
      Please wait.
```

Warming up

```
Warming up...  30'00
      Please wait.
```

Priming

```
Priming...      5'00
      Please wait.
```

❷ Make sure the standby screen is displayed.

Standby screen

```
Standby[WHOLE ] 0001
-Variant-      C:0000
```

STATE (blue): Continuously lit

1.5.3 Installing the Column

Prepare: COLUMN UNIT 80 and tissue paper

1 Perform priming.

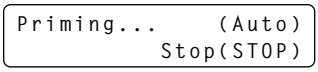
❶ On the standby screen, press PRIMING.

Standby screen

```
Standby[WHOLE ] 0001
-Variant-      C:0000
```

❷ Select <1) Auto>.

- Priming will start.
- After completion, the screen shown in step **1**-❷ will appear again.



❸ Select <2) Pump>.
- Fluid pumping will start.

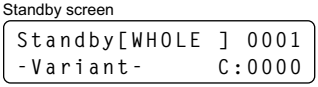
❹ About 3 minutes after pumping starts, press STOP.
- Pumping will stop and the screen shown in step **1**-❸ will appear again.

❺ Press ESC one or more times to return to the standby screen.

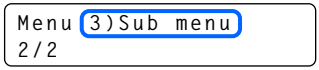
2 Prepare for column installation.

❶ On the standby screen, press MENU twice.

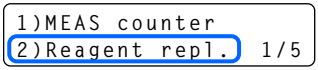
Standby screen



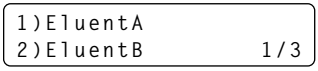
❷ Select <3) Sub menu>.



❸ Select <2) Reagent repl.>.

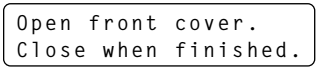


❹ Press MENU twice.



❺ Select <5) Column>.

❻ Make sure that the screen shown on the right appears.



3 Open the column box.

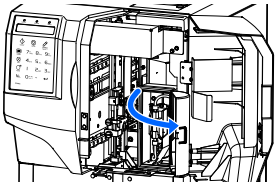
❶ Open the front cover.
- The mechanical sections will power off.

REFERENCE:

If “W-062 Front cover is open” appears:

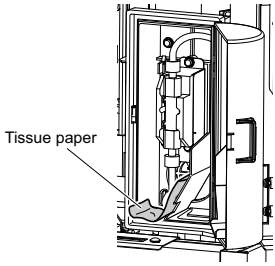
Close the front cover and repeat from step **2**.

❷ Open the column box.



❸ Lay out some tissue paper in the column box.

- The tissue paper blots up any liquid that leaks while installing the column.



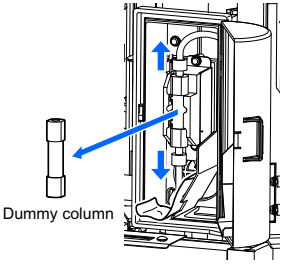
4 Install the column.

❶ Remove the dummy column.

- Follow the instructions for detaching the column. See step **3** in “4.4.2. Replacing the Column” on page 4-19.

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 step **4** to **8** “4.4.2. Replacing the Column” on page 4-19

❸ Press ESC one or more times to return to the standby screen.

REFERENCE:

If “W-062 Front cover is open” appears:

Close the column box and front cover, and press ↵.

1.5.4 Setting Up the Instrument

Check the following before starting measurement:

❶ Printer paper: See “4.3.3. Replacing the Printer Paper” on page 4-16.

❷ Date and time: See “3.5.1. Setting the Date and Time” on page 3-19.

❸ Measurement mode: See “2.3.3. Selecting the Measurement Mode” on page 2-11.

❹ Reagent information: See “3.9. Reagent Information Settings” on page 3-39.

NOTE:
- Set reagent information on eluent A, B and CV, and hemolysis washing solution.
- You can skip this step and go to step ❺.

❺ HbA1c calibration: See “2.6.1. Performing Automatic Calibration” on page 2-29.

NOTE:
Perform HbA1c calibration before the instrument is used for the first time after installation.

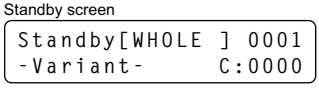
The instrument is now ready for sample measurement.

1.5.5 Turning Off the Power

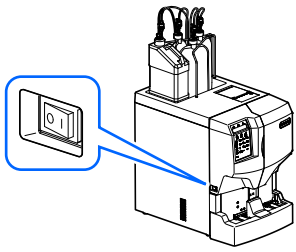
Follow the instructions described below to turn off the power to the instrument in daily use.

❶ Make sure the standby screen is displayed.
- If a different screen is displayed, press ESC one or more times until the standby screen appears.

Standby screen



❷ Press the “○” side of the power switch.
- The display, status indicator lamps, and power will turn off.



1.6 Relocation

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

NOTE:
The instrument 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 "1.10.1. Draining Fluid from the Tubes" on page 1-30). Moving the instrument with solution in the tubes may damage the instrument.

- Turn off the power. 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 CV pack
  - Eluent pack guides
  - Hemolysis washing solution bottle
  - Bottle and tubes for liquid waste
  - Hand-held barcode reader
  - Communication cable for the external device

- Make sure that the front cover is closed before relocating the instrument. Moving the instrument with the cover open may result in exposure to pathogenic microorganisms and/or damage to the instrument.

- 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 1-13 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.

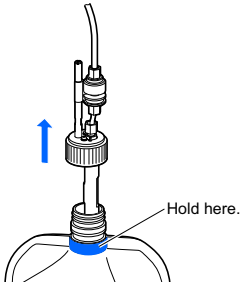
Prepare: Caps for eluent packs (that were originally on the packs before opening, ×3), cap for hemolysis washing solution bottle (that was originally on the bottle before opening, ×1) and gauze

1 Remove the eluent packs.

❶ Lay out some gauze near the instrument.

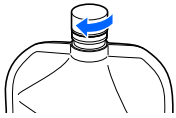
❷ Remove the eluent A pack from the bottle tray.

❸ Hold the pack by the hard plastic neck and remove the bottle cap with nozzle 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 aluminum 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 and eluent CV packs in the same procedure.
- See steps **1**-❷ to **1**-❺.

❼ Wrap the bottle caps with gauze and place them in the bottle tray.

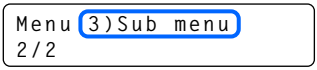
2 Drain fluid from the tubes.

❶ On the standby screen, press MENU twice.

Standby screen

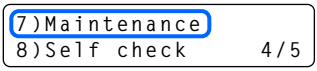
```
Standby[WHOLE ] 0001
-Variant-      C:0000
```

❷ Select <3) Sub menu>.



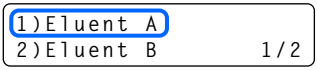
❸ Press MENU three times.

❹ Select <7) Maintenance>.

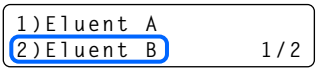


❺ Press MENU.

❻ Select <4) Drain>, and then <1) Eluent A>.
- Eluent A will be drained from the tube.
- After completion, the screen shown on the right will appear again.



❼ Select <2) Eluent B> to drain eluent B.
- Eluent B will be drained from the tube.
- After completion, the screen shown on the right will appear again.



❽ Press MENU and select <3) Eluent CV> to drain eluent CV.
- Eluent CV will be drained from the tube.
- After completion, the screen shown on the right will appear again.

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

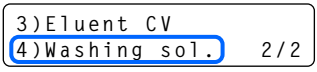
❶ Remove the hemolysis washing solution bottle.
- See step **3** in “4.3.2. Replacing the Hemolysis Washing Solution Bottle” on page 4-13.

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

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

❹ Wrap the bottle cap with gauze and place it in the bottle tray.

❺ Select <4) Washing sol.>.
- Hemolysis washing solution will be drained from the tube.
- After completion, the screen shown on the right will appear again.



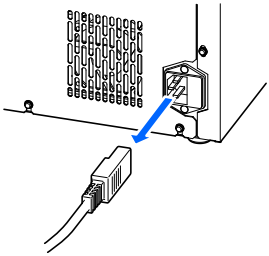
❻ Press ESC one or more times to return to the standby screen.

1.6.3 Unplugging the Power Cord

❶ Make sure the standby screen is displayed and press the "○" side of the power switch.
- The display, status indicator lamps, and power will turn off.

❷ Unplug the power cord from the outlet.

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



1.6.4 Disconnecting the Tubes, Cables and Eluent Pack Guides

Remove the bottle for liquid waste, cable of the external device and eluent pack guides from the instrument.

- When removing the tubes and bottle for liquid waste, wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used protective gloves and liquid waste in accordance with local regulations for biohazardous waste.

Prepare: Wrench and protective gloves

1 Remove the tubes and bottle for liquid waste.

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

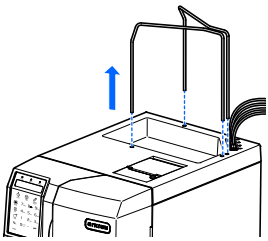
❷ When using the optional liquid waste bottle, disconnect the fluid level detection sensor cord from the DRAIN terminal on the rear panel.

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., COM1 and/or COM2 terminals on the rear panel.

3 Remove the eluent pack guides.

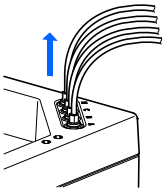
❶ Remove the eluent pack guides from the bottle tray.



4 Remove the tubes of the eluents and hemolysis washing solution.

❶ Loosen the screws on the reagent joints with a wrench and remove all of the tubes from their joints.

❷ Wrap the bottle caps with gauze and place them in the bottle tray.



NOTE:

Be careful not to bend the tubes when placing the bottle caps in the bottle tray.

1.6.5 Relocating the Instrument

Make sure that the front cover is closed before relocating the instrument. Moving the instrument with the front cover open may result in exposure to pathogenic microorganisms and/or damage to 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. (**Do not** hold the bottom of the sampler.) Be careful not to impact or shake the instrument. Rough handling may damage the instrument.

❶ Move the instrument to its new location.

- The instrument must be boxed for shipping to other locations.

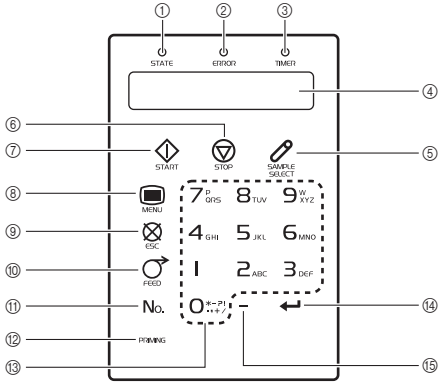
❷ Install the instrument in its new location.

- See “1.4. Installation” on page 1-13.

1.7 Basic Operations

This section explains basic operations you should learn to perform measurement and make parameter settings from the operator panel.

1.7.1 Components on the Operator Panel



- Status indicator lamps and display

Name	Description
① STATE (blue)	Continuously lit: Standby, Flashing fast: Measuring, Flashing slowly: Warm-up
② ERROR (red)	Continuously lit: Warning or error, Flashing: Trouble
③ TIMER (yellow)	Continuously lit: The startup timer is scheduled.
④ Display	Status information, active buttons, setup items or messages are displayed here.

- Operation buttons

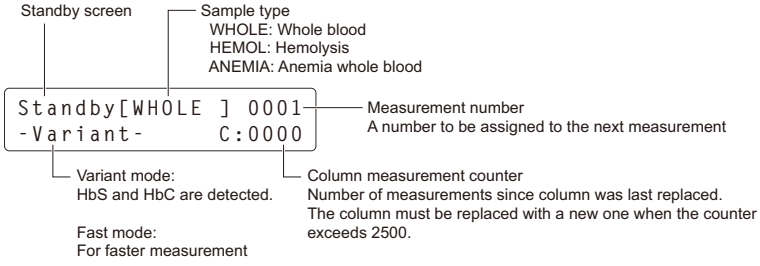
Name	Icon	Description
⑤ SAMPLE SELECT	SAMPLE SELECT	Selects the sample type from whole blood, hemolysis, and anemia whole blood.
⑥ STOP	STOP	Stops measurement, printing or other current operation.
⑦ START	START	Starts measurement.
⑧ MENU	MENU	Displays the main menu. Goes to the next page of the menu.

Name	Icon	Description
⑨ ESC	ESC	Returns you to the standby screen when pressed while either of the main menu screens is being displayed. Returns you to the screen one menu level higher when pressed at one of the sub menu screens or at a screen lower than the sub menu screens. Cancels your entries or settings, and returns you to the previous screen when pressed while the setup screen is being displayed.
⑩ FEED	FEED	Advances printer paper.
⑪ No.	No.	Sets the measurement start number and sample ID.
⑫ PRIMING	PRIMING	Removes air from the tubes.
⑬ Alphanumeric buttons	0~9	Enters numeric values, letters and symbols. Selects options from the menu screens.
⑭ ENTER	↵	Confirms your entries, selections or settings, and goes to the next setup item if there is any. Cancels warnings, errors or trouble.
⑮ Hyphen button	−	Changes the setting (e.g. <ON> or <OFF>). Moves the cursor to the next digit or setup item on the right. Toggles between plus and minus.

1.7.2 Basic Operations

■Standby screen

The standby screen appears after the power has been turned on and the instrument has completed warm-up and priming. After finishing settings or measurement, always return to the standby screen by pressing ESC one or more times.



■Menu screens

● To access the main menu:

On the standby screen, press MENU.

● To go to the next page of the main menu:

Press MENU.

- The next page appears each time you press MENU.

● To access the sub menu:

On the [Main menu screen 2/2], press [3].

● To go to the next sub menu page:

Press MENU.

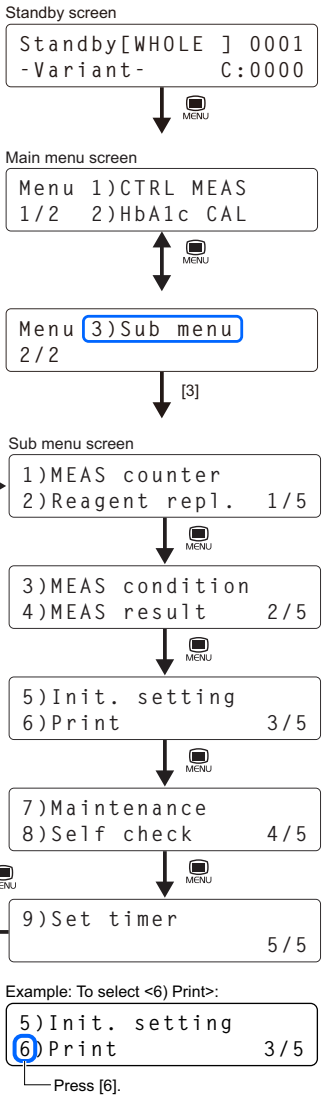
- The next page appears each time you press MENU.

REFERENCE:

- For the sub menu functions, see "Chapter 3. Auxiliary Operations".
- To return to the main menu: Press ESC.

● To select an option from the menu:

Press the number corresponding to the item you want.

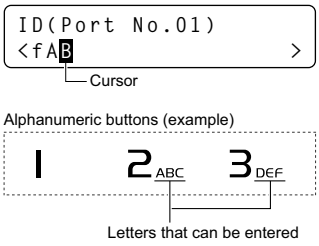


■Entering numbers, letters and symbols

A cursor appears in the field ready for entry.

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

- Entering different characters assigned to the same buttons

Press [-] to move the cursor to the right digit.

Example: To enter “AB”:

1) Press [2] twice to enter “A”.
2) Press [-] to move the cursor.
3) Press [2] three times to enter “B”.

- Correcting an entry

Press [-] to move the cursor to the character you want to correct. Then, enter a new character to overwrite it.

- Moving the cursor

Press [-] to move the cursor to the right digit. If [-] is pressed with the cursor on the right-most digit, the cursor will return to the left-most digit.

- Confirming your entries, selection or settings

Press ↵. The cursor will move to the next entry field or the next screen will appear.

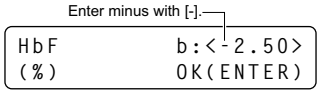
- Canceling your entry

Press ESC. This will cancel your entry and return you to the previous screen.

■Setup screen

● Entering numeric values

Use the alphanumeric buttons to enter numeric values.



To toggle between plus and minus, press [-].

A decimal point does not need to be manually entered.

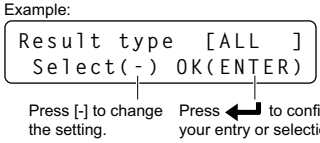
Example: To enter “-2.50”:
Press [-], [2], [5] and [0] in that order.

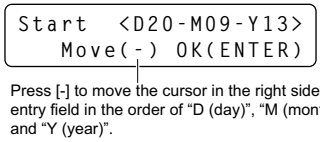
● Button operation

The functions and buttons will appear as shown below.

Example:

Example:



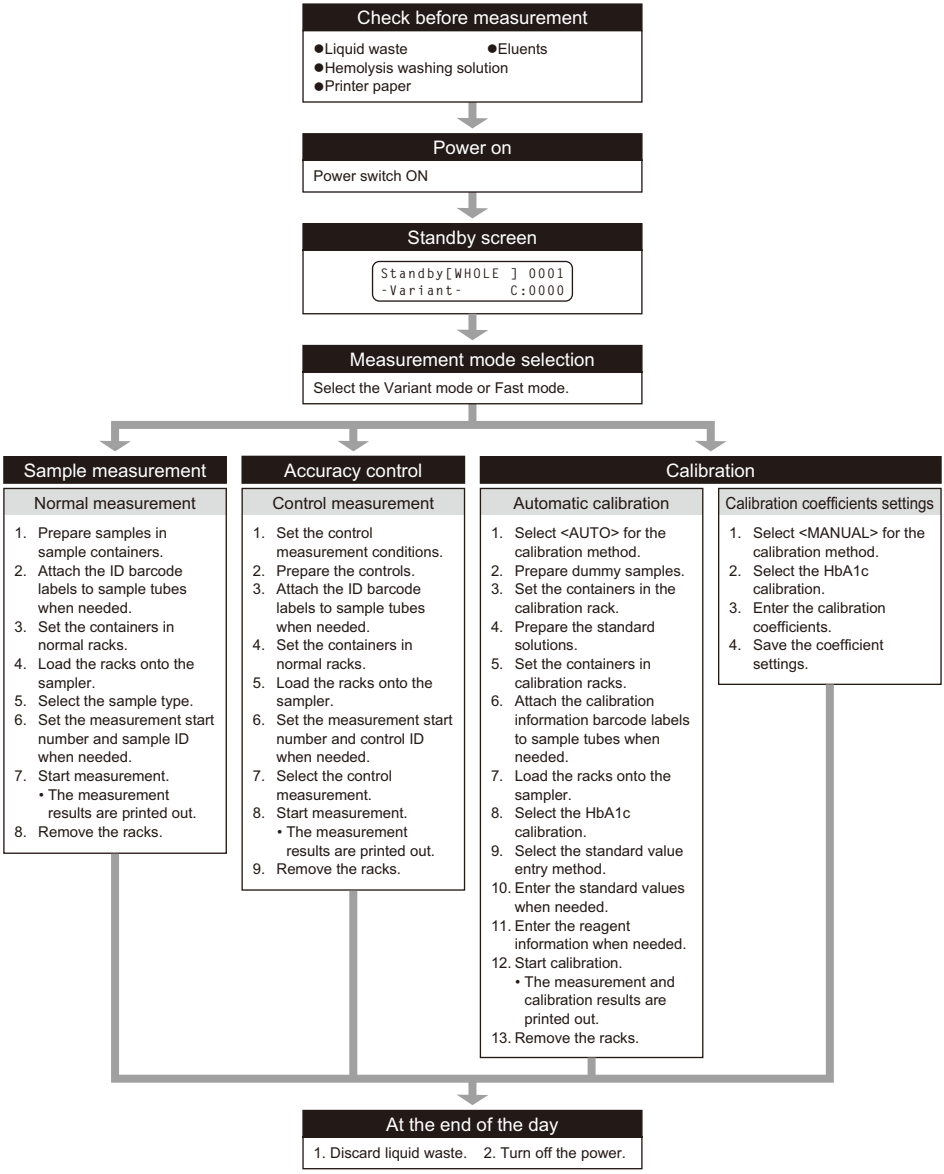


Chapter 2 Measurement

This chapter describes how to perform normal measurement, HbA1c control measurement and HbA1c automatic calibration. Examples of measurement result reports are provided at the end of this chapter.

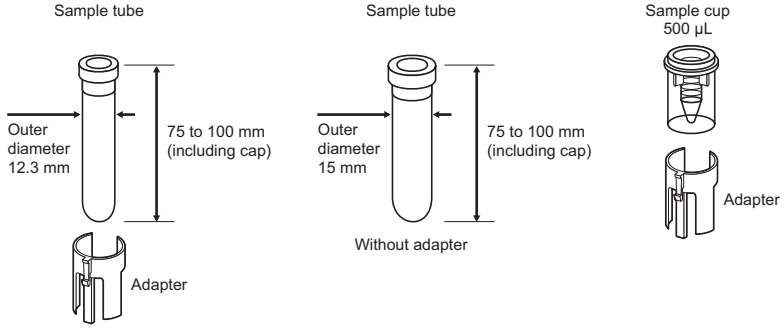
2.1 Before Measurement

2.1.1 Measurement Procedure



2.1.2 Sample Containers

The following are the sample containers that can be used with this instrument.



Sample container	Sample type	ID entry
Sample tube with cap (12.3 or 15 mm in outer diameter)	Whole blood (including anemia samples)	• Internal barcode reader • Hand-held barcode reader (optional) • Alphanumeric buttons
Sample tube with/without cap (12.3 or 15 mm in outer diameter)	Hemolysis	
Sample cup	Whole blood (including anemia samples) Hemolysis	• Hand-held barcode reader (optional) • Alphanumeric buttons

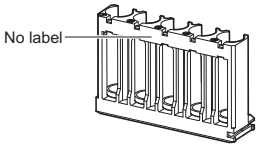
When measuring whole blood in sample tubes, make sure the caps are on the tubes tightly. If a tube is not capped, cap it with a resealable cap. Performing measurements with uncapped tubes may cause sample to splatter inside the instrument, possibly jeopardizing subsequent measurements. It may also cause infection to the user or other individuals by pathogenic microorganisms.

NOTE:

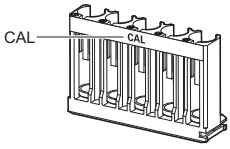
Use sample containers that meet the specifications shown in the figures above.

2.1.3 Sample Racks

There are two types of sample racks: normal racks and calibration racks. Use sample racks suitable for your purposes.



Normal rack



Calibration rack

■Normal rack [No label]

Use	Normal measurement (sample measurement), HbA1c control measurement, HbA1c reproducibility test (whole blood sample, hemolysis sample), automatic tube washing
Object	Whole blood sample, hemolysis sample
Adapter	Adapters are not attached at the time of shipment. Attach gray adapters if needed according to the type of sample containers to be used.
Sample container	Sample tube, sample cup

■Calibration rack [CAL]

Use	HbA1c automatic calibration
Object	Dummy sample (whole blood), standard solutions

Order for loading onto the sampler	Port	Adapter	Sample container	Use
First	1, 2	Blue	Sample tube	For calibration information barcode labels
	3, 4	Gray	Sample tube	Dummy sample
	5	Orange	Sample cup	Standard solution (Low) *
Second	1, 2	Orange	Sample cup	Standard solution (Low) *
	3 to 5	Orange	Sample cup	Standard solution (High) *

* Automatic calibration standard solution measurement count: 3

IMPORTANT:

- Set sample containers for calibration information barcode labels, dummy samples and standard solutions in their specific ports. Inaccurate measurement results may be obtained if they are set in the wrong ports.
- **Do not** set whole blood samples in ports with orange adapters 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.

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 the clinical testing and 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 microorganisms.
- Be sure to close the front cover before performing measurement. **Do not** open the front cover during measurement.
- Discard used samples, liquid waste, column, parts and instrument in accordance with local regulations for biohazardous waste.

- Always connect the instrument to a grounded outlet to prevent electric shocks. If a grounded outlet is not available at the installation site, contact your distributor.
- Read “1.4.1. Precautions in Instrument Installation” on page 1-13 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. See “Chapter 4. Maintenance”.
- If you detect abnormal odors or noise, immediately turn off the 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 80CV” as eluents for use with the ADAMS A1c Lite HA-8380V. 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 CV pack. Connecting the wrong bottle cap to the wrong pack will cause mixing of eluents, resulting in inaccurate measurement results. If the wrong bottle cap is attached, wash the nozzle, then attach the correct bottle cap (see “5.5.2. If Eluent Packs Are Incorrectly Attached” on page 5-22).
- When storing the eluents:
  Store unopened eluent packs at a temperature between 3°C and 30°C, away from direct sunlight. Once opened, use the eluents within one month even if they are still within their expiration dates.
- Observe the expiration date.
  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. Replace the pack to supply new eluent. Adding new eluent to the old pack may 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 aluminum bag. Eluent may spill and damage the instrument.
- Regardless of whether the Variant mode or Fast mode is selected, always perform operations with all eluents (A, B and CV) set in the instrument.

2.2.3 Hemolysis Washing Solution

IMPORTANT:

- Use only hemolysis washing solution specified for the instrument.
  ARKRAY provides “HEMOLYSIS WASHING SOLUTION Lite H” as hemolysis washing solution for use with the ADAMS A1c Lite HA-8380V. 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, away from direct sunlight. Once opened, use them within one month, even if they are still within their expiration dates.
- Observe the 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. Replace the bottle to supply new solution. Adding new solution to the old bottle may 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

- **Do not** touch the column with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microorganisms 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 80” as columns for use with the ADAMS A1c Lite HA-8380V. 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 “4.7.1. Preparing the Instrument Before Extended Periods of Disuse” on page 4-39). 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 the expiration date.
  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.
  Connect the IN side of the column to the IN column tube, and the OUT side, to the OUT column tube of the instrument. Check the IN and OUT sides of the column when installing it in 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.
  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 BIOLOGICAL SAMPLES INCLUDING BLOOD. This instrument uses blood as sample. Blood may be contaminated by pathogenic microorganisms that can cause infectious diseases. Improper handling of blood may cause infection to the user or other individuals by pathogenic microorganisms.
- 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 45 mg/dL and 140 mg/dL (standard: 94 mg/dL). If the concentration does not fall within this range, an error may occur or the reproducibility may deteriorate. If this happens, change the dilution ratio appropriately to adjust the concentration before performing a measurement again. (This instrument dilutes whole blood 161 times before measuring it.)
- Samples without plasma
  Samples without plasma cannot be diluted to the proper hemoglobin concentration, resulting in inaccurate measurement results. To measure such samples, dilute them with DILUENT 80 before measurement and select <HEMOL> as the sample type.
- 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.

- 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 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 there is any 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 “4.3.1. Replacing the Eluent Packs” on page 4-9.
  See “4.3.2. Replacing the Hemolysis Washing Solution Bottle” on page 4-13.

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 “4.3.3. Replacing the Printer Paper” on page 4-16.

2.3.2 Turning On the Power

See “1.5.2. Turning On the Power” on page 1-24.

2.3.3 Selecting the Measurement Mode

Refer to the table below and determine the measurement mode, Variant or Fast.

Mode	Measurable items	Measurement time	Description
Variant	HbA1c, HbF (Detectable items: HbS, HbC)	160 seconds/test	Default setting
Fast	HbA1c, HbF	100 seconds/test	The HbA1c value may be lower than the actual value if the measured sample contains HbS or HbC.

REFERENCE:

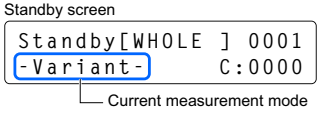
All measurements (normal, HbA1c control and HbA1c calibration) can be performed in both the Variant and Fast modes.

1 Check the current measurement mode.

❶ On the standby screen, check the current mode.

- To use the current mode, go to the relevant section of the measurement procedures.
- To change the mode, go to step **2**.

Standby screen



2 Change the mode.

❶ Press MENU twice, and select <3) Sub menu>.

❷ Press MENU.

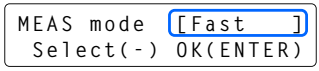
❸ Select <3) MEAS condition>.

❹ Press MENU.

❺ Select <4) MEAS mode>.

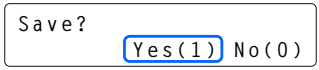
❻ Select the mode you want.

- [-]: Changes the mode.



❼ Press [1] .

- This saves your new setting.

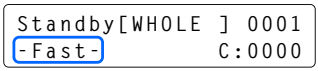


NOTE:

Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❽ Press ESC one or more times to return to the standby screen.

❾ On the standby screen, check that the mode has been changed.



3 Perform control measurement and calibration.

❶ Perform control measurement.

- See “2.5. HbA1c Control Measurement” on page 2-22.

NOTE:

Always perform control measurement after changing the mode.

❷ Perform HbA1c automatic calibration when needed.

- See “2.6.1. Performing Automatic Calibration” on page 2-29.

2.4 Normal measurement

In normal measurement, multiple samples can be continuously measured using normal racks.

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

NOTE:

Perform HbA1c automatic calibration before the instrument is used for the first time after installation (see “2.6.1. Performing Automatic Calibration” on page 2-29).

2.4.1 Preparing Sample in Sample Containers

IMPORTANT:

Samples without plasma cannot be diluted to the proper hemoglobin concentration, resulting in inaccurate measurement results. To measure such samples, dilute them with DILUENT 80 before measurement and select <HEMOL> as the sample type.

NOTE:

There are 3 sample types (whole blood, hemolysis, and anemia whole blood samples). Different types of sample cannot be measured in the same batch.

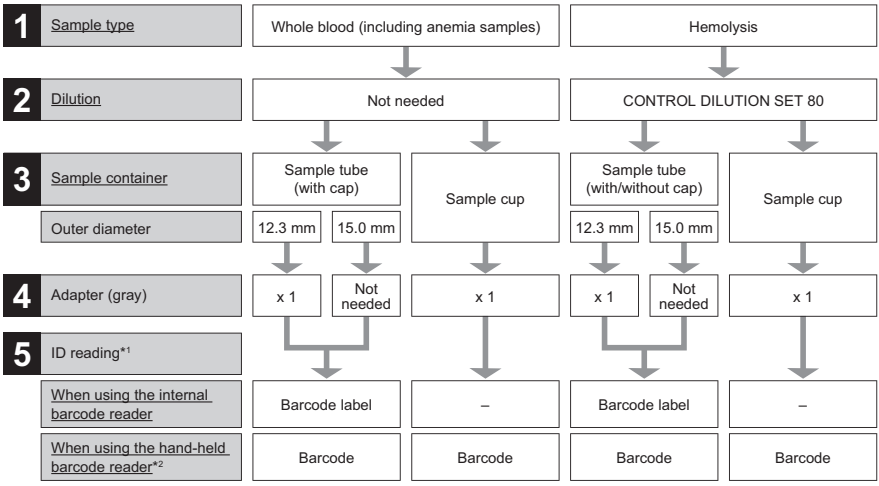
REFERENCE:

Both sample tubes and sample cups can be set in the same normal rack.

Prepare: Normal racks and protective gloves

* Prepare other required items, referring to the table below.

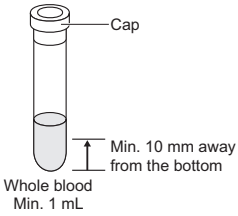
The underlined items are not included with the instrument.



*1: IDs can also be entered by using the alphanumeric buttons. *2: Optional product

■Preparing whole blood sample (including anemia sample) in a sample tube

❶ Add the volume of sample shown on the right to the sample tube.



❷ Make sure that the sample tube is capped.

- If not capped, cap the tube with a resealable cap.

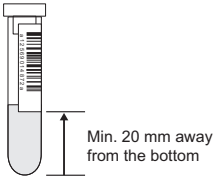
Performing measurements with uncapped tubes may cause sample to splatter inside the instrument, possibly jeopardizing subsequent measurements. It may also cause infection to the user or other individuals by pathogenic microorganisms.

NOTE:

Special notes on recapping samples

- Use rubber resealable caps recommended by the sample tube manufacturer. Other unrecommended caps may damage the nozzle during measurement operations.
- When recapping sample tubes containing excessive volume of whole blood sample, pierce the cap with a syringe needle so that outside air can penetrate the tube and equalize the pressure inside. High pressure inside sample tubes will trigger Abnormal-15 and Abnormal-18 errors during measurement and inaccurate measurement results will be obtained.

❸ To read the sample ID with the internal barcode reader, attach the barcode label to the position shown on the right.



IMPORTANT:
- Make sure that the entire barcode label adheres tightly to the sample tube. If the barcode label comes off, reattach it.
- **Do not** attach one barcode label on top of another.

■Preparing whole blood sample (including anemia sample) in a sample cup

Add the volume of sample shown on the right to a sample cup.

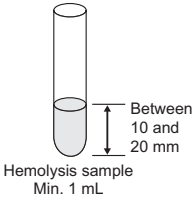
NOTE:
Do not attach barcode labels to sample cups.

■Preparing hemolysis sample in a sample tube

❶ Use DILUENT 80 of CONTROL DILUTION SET 80 to dilute sample.

IMPORTANT:
- Inaccurate measurement results will be obtained if samples are diluted with other diluents.
- Prepare samples so that the hemoglobin concentration is between 45 mg/dL and 140 mg/dL (standard: 94 mg/dL). Inaccurate measurement results will be obtained if the sample's hemoglobin concentration is outside this range.

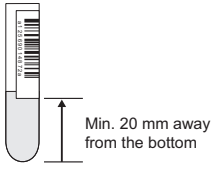
❷ Add the volume of sample shown on the right to a sample tube.



IMPORTANT:
When using sample tubes to measure hemolysis sample, make sure that the sample tube contains 1 mL of sample at minimum as shown on the right. Inaccurate measurement results will be obtained if the sample volume (height) is over 20 mm.

REFERENCE:
You can use either capped or uncapped sample tubes.

❸ To read the sample ID with the internal barcode reader, attach the barcode label to the position shown on the right.



IMPORTANT:
- Make sure that the entire barcode label adheres tightly to the sample tube. If the barcode label comes off, reattach it.
- **Do not** attach one barcode label on top of another.

■Preparing hemolysis sample in a sample cup

❶ Use DILUENT 80 of CONTROL DILUTION SET 80 to dilute sample.

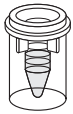
IMPORTANT:

- Inaccurate measurement results will be obtained if samples are diluted with other diluents.
- Prepare samples so that the hemoglobin concentration is between 45 mg/dL and 140 mg/dL (standard: 94 mg/dL). Inaccurate measurement results will be obtained if the sample's hemoglobin concentration is outside this range.

❷ Add the volume of sample shown on the right in a sample cup.

NOTE:

Do not attach barcode labels to sample cups.



Hemolysis sample
Min. 400 µL

2.4.2 Loading the Sample Containers onto the Sampler

1 Set the sample containers in the normal racks.

NOTE:

There are 3 sample types (whole blood, hemolysis, and anemia whole blood samples). Different types of sample cannot be measured in the same batch.

REFERENCE:

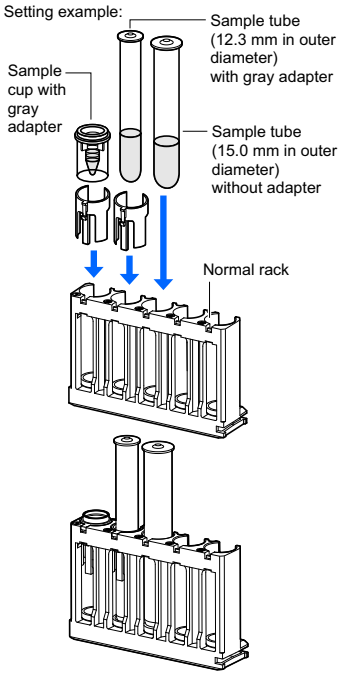
Both sample tubes and sample cups can be set in the same normal rack.

❶ Set the gray adapters in the ports of the normal rack.

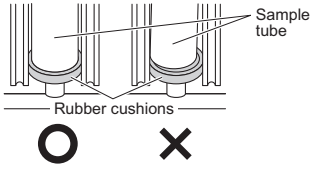
NOTE:

Do not set the adapters in the ports intended for sample tubes of 15 mm outer diameter.

❷ Set the sample containers in the ports.



Fit the bottom of the sample tubes into the bottom of the rubber cushions so that the tubes stand straight. If the tube is tilted, it may cause damage to the piercing nozzle.



NOTE:

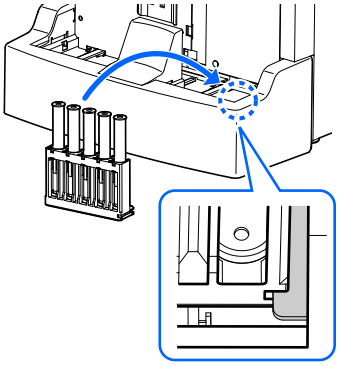
For sample tubes with barcodes:
To enable the internal barcode reader to read barcodes successfully, labels on the tubes must be facing the rear of the normal rack.

2 Load the normal racks onto the sampler.

NOTE:

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

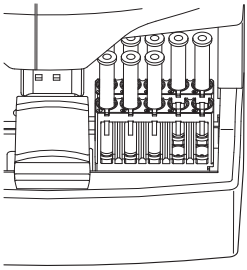
❶ Slightly tilt the normal rack forward, and load it onto the loading side of the sampler.



- Fit the recess at the lower right of the rack into the guide inside the loading side.

- Up to 2 normal racks can be loaded onto the loading side.

Example:
2 normal racks are loaded onto the sampler.



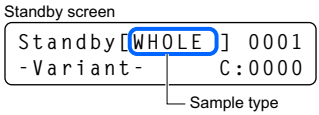
2.4.3 Measuring the Samples

1 Select the sample type.

❶ Make sure the standby screen is displayed.

❷ Press SAMPLE SELECT if you want to change the displayed sample type.

- <WHOLE> : Whole blood
  <HEMOL> : Hemolysis
  <ANEMIA> : Anemia whole blood



IMPORTANT:

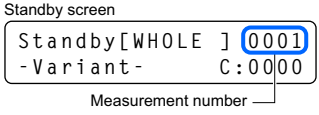
- Inaccurate measurement results will be obtained if the sample type does not match the selection in this step.
- If whole blood sample (including anemia sample) is measured with <HEMOL> selected, it will seriously degrade the column, causing inaccurate measurement results.
- Once <HEMOL> has been selected, any type of sample is measured as hemolysis even if the instrument receives orders for whole blood measurement from the host computer through two-way communication.

❸ Check the measurement mode setting.

- To change the mode, see "2.3.3. Selecting the Measurement Mode" on page 2-11.

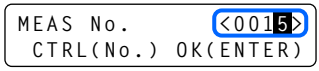
2 Set the measurement start number (when needed).

❶ On the standby screen, press No. .



❷ Enter a new measurement start number.

- Settable range: 0001 to 9999



❸ Press ↵.

- To enter sample IDs using the alphanumeric buttons or optional hand-held barcode reader: Go to step **3**.

- To skip sample ID entry, or to enter sample IDs using the internal barcode reader:

  Press and hold ↵ without entering anything on the screen shown on the right. The standby screen will appear.
  Go to step **4**.

```
ID(Port No.01)
<------------------>
```

NOTE:
If you enter an ID on this screen and it does not match the ID read from the internal barcode reader, a warning will occur and measurement will not be performed.

3 Enter the sample IDs (using the alphanumeric buttons or hand-held barcode reader).

❶ Make sure that the screen shown on the right is displayed.
- If the standby screen is displayed, press No., and then ↵.

```
ID(Port No.01)
<------------------>
```

❷ Enter the ID for the sample set in port 1.
- Up to 18 digits of numbers, letters and symbols can be used.
- The optional hand-held barcode reader can also be used.

```
ID(Port No.01)
<1234567890ABC----->
```

REFERENCE:
- On the screens for empty ports or for ports that do not need sample ID entry, go to step ❸ without entering anything.
- To move the cursor:
  Press [-].
- To delete all the entered characters:
  Press and hold [-].
- To return to the previous screen:
  Press ESC.
- <Port No.> corresponds to the number marked on the top face of normal racks.
  Port Nos. 01 to 05: Ports 1 to 5 of the first normal rack
  Port Nos. 11 to 15: Ports 1 to 5 of the second normal rack

❸ Press ↵.
- The screen for the next port will appear.

❹ Enter the IDs for the samples in the remaining ports.
- Repeat steps **3**-❷ and **3**-❸.

```
ID(Port No.02)
<1234567890DEF----->
```

❺ When all sample IDs have been entered, press and hold ↵.
- You do not need to proceed to the screen for port 15.
- The standby screen will appear again.

NOTE:
If you return to the standby screen without pressing and holding ↵ in step ❺, all of your entries will be deleted.

4 Start measurement.

> Be careful not to pinch your fingers while the rack lever is operating. Pinching may result in personal injury.

❶ On the standby screen, press START.
- The normal rack will move to the aspiration position, and sample will be aspirated.
- Measurement will start.

Standby screen

```
Standby[WHOLE ] 0015
-Variant-      C:0001
```

Measuring sample

```
MEAS WHOLE          1'40
No.0001/P.0001
```

Measurement number/port number (or ID)

Remaining time

REFERENCE:
- For port numbers, see “6.2. Glossary” on page 6-10.
- When IDs have been entered:
  The ID will appear at the lower left of the screen.
- To stop measurement:
  Press STOP.

5 When the measurement result is obtained:

- The obtained measurement results will be printed out.
- See “2.7.1. Measurement Result Report” on page 2-38.

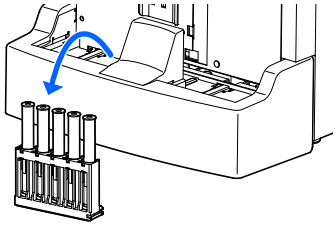
6 Once measurements are complete for all set samples:

- The end process is performed and will return you to the standby screen.

Standby screen

```
Standby[WHOLE ] 0016
-Variant-      C:0001
```

❶ Remove the normal racks from the unloading side of the sampler.
- Slightly tilt the normal rack forward to remove it from the sampler.



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

7 At the end of the day:

❶ Discard liquid waste.
- See “4.2.1. Discarding Liquid Waste [Every day]” on page 4-4.

❷ Turn off the power.

2.5 HbA1c Control Measurement

2.5.1 Quality Control

Control measurement should be performed at regular intervals to check the status of the instrument and accuracy of measurement results. After changing the measurement mode (Variant or Fast), always perform control measurement. Use Canterbury HbA1c control (extendSURE Haemoglobin A1c Lyophilised Controls, assignment of standard values is based on JCCRM411) or commercially available controls that are specified by your distributor. For more information, contact your distributor.

2.5.2 Control Measurement

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

IMPORTANT:

- The typical method for dissolving and diluting controls are explained here.
- Carefully read the package insert that comes with the control before use.
- Dissolve controls as described in the package insert that comes with the controls so that the hemoglobin concentration falls between 45 mg/dL and 140 mg/dL.
- Use controls before their expiration dates. Inaccurate measurement results will be obtained if controls are used beyond their expiration dates. Use of 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.

Prepare: Controls for HbA1c measurement, CONTROL DILUTION SET 80 (RECONSTITUENT 80, DILUENT 80), purified water, barcode label [when using the internal barcode reader], sample containers (see step **2**), normal racks and protective gloves

1 Set the HbA1c control measurement conditions.

See “3.3.4. Setting the HbA1c Measurement Conditions” see page 3-12. If you have already set the measurement conditions correctly, skip to step **2**.

❶ Set the control expected values (Exp. val.).

- This setting is required if the control has a lot number different from that used in the previous control measurement.

❷ Make the settings listed below as needed.
- Control error range (CTRL ERR range: Default is IFCC L 3 mmol/mol, H 4 mmol/mol)
- Action in case of error (CTRL ERR act.: Default is STOP)

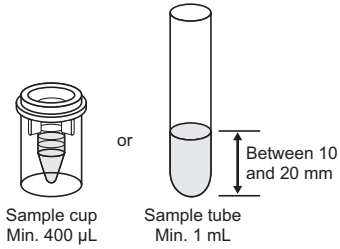
2 Prepare controls.

There are two types of controls (e.g. CTRL1 and CTRL2).

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 controls to sample containers.
- The volume of control as shown on the right is required for measurement.



IMPORTANT:

When using sample tubes to measure controls, make sure that the sample tube contains 1 mL of sample at minimum. Inaccurate measurement results will be obtained if the sample volume (height) is over 20 mm.

NOTE:

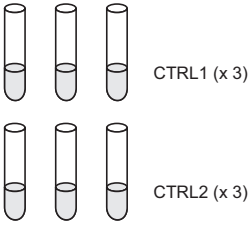
Use sample tubes to read control IDs with the internal barcode reader.

- Add CTRL1 and CTRL2 to the desired number of sample containers.

REFERENCE:

The same number of sample containers is not required for CTRL1 and CTRL2.

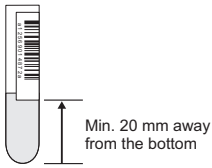
Example:
To measure CTRL1 and CTRL2 three times respectively:



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

Control IDs can be read from barcodes with the internal barcode reader. If you want to enter control IDs with the alphanumeric buttons, skip to step **4**.

❶ Attach the barcode labels to the sample tubes that contain controls.

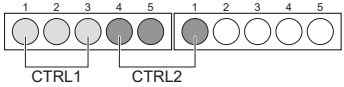


IMPORTANT:
- Make sure that the entire barcode label adheres tightly to the sample tube. If the barcode label comes off, reattach it.
- **Do not** attach one barcode label on top of another.

4 Set the controls in the normal racks.

❶ Set CTRL1 and CTRL2 in the normal rack(s).

Example:
To measure CTRL1 and CTRL2 three times respectively:

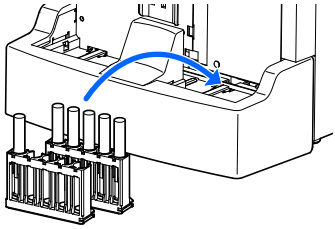


NOTE:
- Controls can be set in any port and in any order of the normal rack.
- For sample tubes with barcodes:
  Barcode labels on the tubes must be facing the rear of the normal rack.

5 Load the normal racks onto the sampler.

❶ Load the normal racks onto the loading side of the sampler properly.

Example:
To measure CTRL1 and CTRL2 three times respectively:



6 Check the measurement mode.

❶ On the standby screen, check the measurement mode (Variant or Fast).
- To change the mode, see “2.3.3. Selecting the Measurement Mode” on page 2-11.

IMPORTANT:
- Measurement accuracy is controlled separately for the Variant mode and Fast mode.
- Accuracy control reports can be printed for each mode or both modes (see “3.7.3. Printing Accuracy Control Reports” on page 3-30).

7 Set the control measurement start number (when needed).

❶ On the standby screen, press No..

Standby screen

```
Standby[WHOLE ] 0001
-Variant-      C:0000
```

❷ Press No. again.

```
MEAS No.        <0001>
 CTRL(No.) OK(ENTER)
```

❸ Enter the measurement start number for control measurement.

- Settable range: 0001 to 9999

```
CTRL No.        <0015>
 MEAS(No.) OK(ENTER)
```

❹ Press ↵.

- To enter control IDs using the alphanumeric buttons or optional hand-held barcode reader:
  Go to step **8**.

- To skip control ID entry, or to enter control IDs using the internal barcode reader:
  Press and hold ↵ without entering anything on the screen shown on the right. The standby screen will appear.
  Go to step **9**.

```
ID(Port No.01)
<------------------->
```

NOTE:

If you enter an ID on this screen and it does not match the ID read from the internal barcode reader, a warning will occur and measurement will not be performed.

8 Enter the control IDs (using the alphanumeric buttons or hand-held barcode reader).

❶ Make sure that the screen shown on the right is displayed.

- If the standby screen is displayed, press No., and then ↵.

```
ID(Port No.01)
<------------------->
```

❷ Enter the ID for the control set in port 1.

- Up to 18 digits of numbers, letters and symbols can be used.
- The optional hand-held barcode reader can also be used.

```
ID(Port No.01)
<1234567890ABC-----> 
```

REFERENCE:

- On the screens for empty ports or for ports that do not need control ID entry, go to step ❸ without entering anything.
- To move the cursor:
  Press [-].
- To delete all the entered characters:
  Press and hold [-].
- To return to the previous screen:
  Press ESC.
- <Port No.> corresponds to the number marked on the top face of normal racks.
  Port Nos. 01 to 05: Ports 1 to 5 of the first normal rack
  Port Nos. 11 to 15: Ports 1 to 5 of the second normal rack

❸ Press ↵.

- The screen for the next port will appear.

❹ Enter the IDs for the controls in the remaining ports.

- Repeat steps **8**-❷ and **8**-❸.

```
ID(Port No.02)
<1234567890DEF----->
```

❺ When all control IDs have been entered, press and hold ↵.

- You do not need to proceed to the screen for port 15.
- The standby screen will appear again.

NOTE:

If you return to the standby screen without pressing and holding ↵ in step ❺, all of your entries will be deleted.

9 Select the control measurement.

❶ On the standby screen, press MENU.

Standby screen

```
Standby[WHOLE ] 0001
-Variant-      C:0000
```

❷ Select <1) CTRL MEAS>.

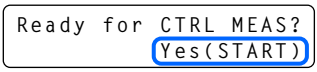
```
Menu 1)CTRL MEAS
1/2  2)HbA1c CAL
```

- The screen shown on the right will appear.

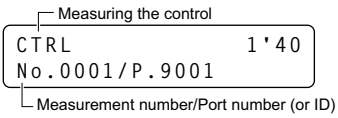
```
Ready for CTRL MEAS?
          Yes(START)
```

10 Start control measurement.

❶ Press START.



- The normal rack will move to the aspiration position and then the control will be aspirated.
- Measurement will start.



REFERENCE:

- When an ID has been entered:
  The ID will appear on the lower left of the screen.
- To stop measurement:
  Press STOP.

11 When the measurement results are obtained:

❶ The obtained measurement results will be printed out.

- See “2.7.1. Measurement Result Report” on page 2-38.

REFERENCE:

You can view information on control measurement performed in a certain period of time (see “3.7.3. Printing Accuracy Control Reports”on page 3-30

12 Once the control measurements are complete:

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

2.6 HbA1c Calibration

Calibration provides operation coefficients (calibration coefficients) for correcting measurement results. Use ARKRAY calibrator (CALIBRATOR Lite, assignment of standard values is based on JCCRM411).

- When calibration is required

When required	Description
After installing the instrument	Perform HbA1c 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 HbA1c control measurement results deviate from control expected values	
If HbA1c control measurement results obtained after changing the measurement mode are out of the control expected values.	
If “AUTO CAL is required” is displayed	
After optical unit cell washing has finished	

REFERENCE:

Deviations in control measurement results can be detected by setting the control expected values and control error range appropriately (see “3.3.4. Setting the HbA1c Measurement Conditions” on page 3-12).

- 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 alphanumeric buttons, or • Reading the calibration information barcodes during measurement (when using the internal barcode reader).
Calibration coefficients settings	Set coefficients “a” and “b” of the HbA1c correction formula, “Y=aX+b”, using the alphanumeric buttons.

2.6.1 Performing Automatic Calibration

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used standard solutions, dummy sample 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 racks for automatic calibration.

REFERENCE:
Dummy samples are measured before standard solutions to obtain stable measurement results.

Prepare: Dummy sample (whole blood), sample tubes (for dummy sample, × 1 or 2, with caps), CALIBRATOR Lite, sample cups (for standard solutions, × 2 to 6), calibration racks (CAL, × 2) and protective gloves
* [When reading the standard values from barcodes]
Calibration information barcode labels (come with the calibrator) and sample tubes (× 2)

1 Set the calibration method to <AUTO>.

❶ Set the calibration method (CAL mode) to "automatic (AUTO)".
- See "3.3.4. Setting the HbA1c Measurement Conditions" on page 3-12.

❷ Set the following setup items as needed. If you do not want to change the settings, skip to step **2**.
- Error range for automatic calibration (CAL ERR range : Default is 3.0)
- Standard solution measurement count for automatic calibration (STD sol. count: Default is "3")

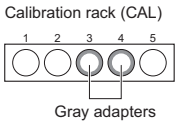
2 Prepare dummy samples.

❶ Add dummy sample (whole blood) to sample tubes and cap the tubes.
- Prepare 1 or 2 tubes with sample.
- See "2.4.1. Preparing Sample in Sample Containers" on page 2-13.

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

3 Set dummy samples in the calibration racks.

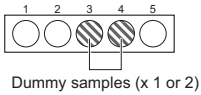
❶ Check the calibration rack for setting dummy samples.



IMPORTANT:

Use the calibration rack (CAL) with gray adapters in ports 3 and 4.

❷ Set the dummy samples in ports 3 and/or 4 (with gray adapters) of the calibration rack.



IMPORTANT:

Do not set dummy samples in ports other than ports 3 and 4 to avoid seriously degrading the column. If dummy samples are accidentally measured in these ports, it is recommended to replace the column with a new one.

NOTE:

Remove the adapter to set a sample tube of 15 mm outer diameter.

REFERENCE:

Use either port 3 or 4 when you have one dummy sample.

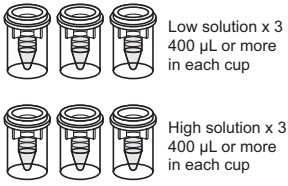
4 Prepare the standard solutions.

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

❷ Add Low and High solutions to the number of sample cups as required by the set standard solution measurement count for automatic calibration.

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

Example:
Standard solution measurement count for automatic calibration: 3



5 Set the standard solutions in the calibration racks.

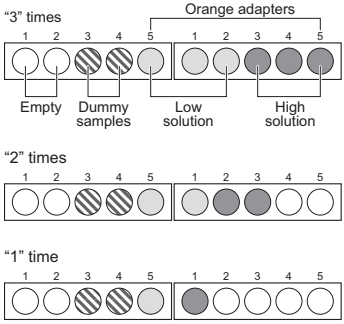
❶ Set the standard solutions in the ports (with the orange adapters) of the calibration racks (CAL).

- Place the standard solutions in the correct ports as required by the set standard solution measurement count for automatic calibration.

IMPORTANT:

Do not set the standard solutions in the ports with blue or gray adapters (ports 1 to 4 of the first rack). If the solutions are set in these ports, calibration may not be performed correctly.

When the standard solution measurement count for automatic calibration is:



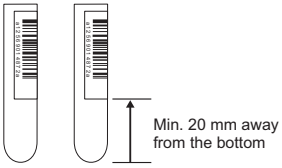
6 Label the sample tubes with calibration information barcode labels (to read the standard values with the internal barcode reader).

The following information can be read from the calibration information barcode labels with 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 alphanumeric buttons instead of the internal barcode reader, skip to step **7**.

❶ Attach the calibration information barcode labels to each of two empty sample tubes.



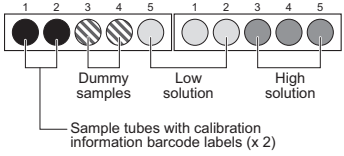
❷ Set these sample tubes in ports 1 and 2 of the first calibration rack.

- You can set either of the two sample tubes in either port 1 or 2.

NOTE:

To enable the internal barcode reader to read barcodes successfully, labels on the tubes must be facing the rear of the calibration rack.

Example:
Standard solution measurement count for automatic calibration: 3



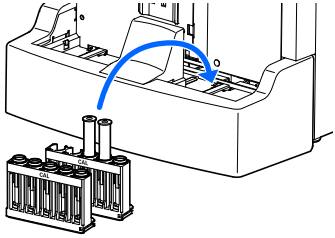
7 Load the calibration racks onto the sampler.

IMPORTANT:

Check again to make sure that the standard solutions are set in the proper ports. Calibration cannot be performed if the standard solutions are set in the wrong ports (see the figures in step **5**).

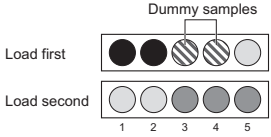
❶ Load the calibration racks onto the loading side of the sampler.

Example:
Standard solution measurement count for automatic calibration: 3



NOTE:

Load the calibration rack that holds the dummy samples first.



8 Check the measurement mode (Variant or Fast).

IMPORTANT:

Calibration coefficients are stored separately for the Variant and Fast modes. Make sure that the instrument is in the correct mode.

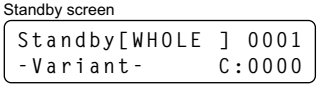
❶ On the standby screen, check the measurement mode (Variant or Fast).

- To change the mode, see “2.3.3. Selecting the Measurement Mode” on page 2-11.

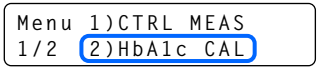
9 Select the HbA1c calibration.

❶ On the standby screen, press MENU.

Standby screen



❷ Select <2) HbA1c CAL>.



10 Select the standard value entry method.

❶ Select the method for entering the standard values.

- [1] : Use the alphanumeric buttons.
  Go to step **11**.

  [0] : Read from calibration information barcode labels.
  Go to step **14**.

```
CAL INFO input mode?
Button(1) Barcode(0)
```

REFERENCE:

When you press [1] in step **10**-❶, standard values entered with the alphanumeric buttons are accepted even if sample tubes with calibration information barcode labels are set in the rack.

11 Enter the standard values of the standard solutions and coefficients with the alphanumeric buttons.

IMPORTANT:

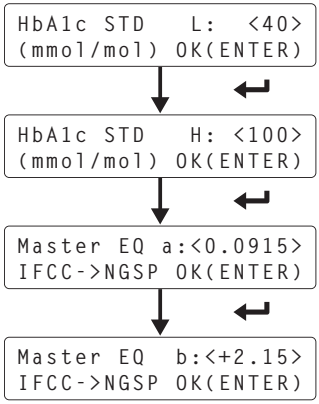
- Enter the standard values written on the standard value sheet that comes with the calibrator.
- Enter coefficients “a” and “b” written on the standard value sheet that comes with the calibrator.

REFERENCE:

A different screen appears depending on the HbA1c value output mode. For the current setting, contact your distributor.

❶ Enter the standard values and coefficients.
- ↵: Goes to the next setup item.

Example:
HbA1c value output mode: IFCC&NGSP*



Standard values

Setup item	Displayed item	Settable range (default)
Standard value for the Low solution	HbA1c STD L: (mmol/mol)	0 to 99 (0)
Standard value for the High solution	HbA1c STD H: (mmol/mol)	0 to 200 (0)

Coefficients for the master equation (from IFCC to NGSP)

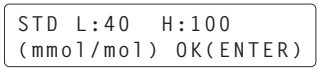
Setup item	Displayed item	Settable range (default)
Coefficient “a”	Master EQ a: IFCC->NGSP	0.0000 to 0.1500 (the value previously entered)
Coefficient “b”	Master EQ b: IFCC->NGSP	-5.00 to 5.00 (the value previously entered)

* The output format differs depending on the current HbA1c value output mode. For the current setting, contact your distributor.

❷ Press ↵.

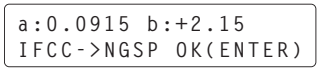
12 Check the calibration information you entered.

❶ Check if the displayed standard values are correct.
- If the values are incorrect, press esc one or more times and retry from step **10**-❶.



❷ Press ↵.

❸ Check if the displayed coefficients are correct.
- If the coefficients are incorrect, press esc one or more times and retry from step **10**-❶.



❹ Press ↵.

13 Set the reagent information on the calibrator.

❶ Enter reagent code.

- The reagent code is a 10-digit number written on the standard value sheet.
- The optional hand-held barcode reader can also be used.

```
Code     <8142480012>
Calibrator OK(ENTER)
```

REFERENCE:

- If you want to skip reagent code entry, press ↵ without entering anything and go to step **14**. You can enter the code later. See "3.9.2. Setting Reagent Information As Needed" on page 3-40.
- To delete all the entered characters:
  Press [-]. The hyphens (---) will appear.

❷ Press ↵.

- The reagent information will appear when your entry is accepted.

REFERENCE:

If "W-037 Incorrect RGNT type" appears:

Your entry is invalid. Enter the correct reagent code.

❸ Check the lot number and expiration date and press ↵.

- The calibration standard values and reagent information on the calibrator will be printed out.

```
Lot No.C180A01
Ex.2015-03 OK(ENTER)
```

14 Start calibration.

❶ Press ◇ START.

- The calibration racks will move to the aspiration position and the dummy sample will be aspirated.

```
Ready for CAL MEAS?
          Yes(START)
```

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

```
                Measuring the standard solution
CAL                    1'40
No.0001/P.9005
└ Measurement number/port number
```

REFERENCE:

To stop measurement:

Press ▽ STOP.

15 When the calibration result is obtained:

- The obtained measurement results will be printed out.
- See "2.7.6. Calibration Results Report" on page 2-43

16 Once the calibration is complete:

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

2.6.2 Setting the Calibration Coefficients

1 Set the calibration method to <MANUAL>.

IMPORTANT:

Calibration coefficients are stored separately for the Variant and Fast modes. Make sure that the instrument is in the correct mode.

❶ Set the calibration method (CAL mode) to <MANUAL>.

- See "3.3.4. Setting the HbA1c Measurement Conditions" on page 3-12.

2 Select the HbA1c calibration.

❶ On the standby screen, press MENU .

Standby screen

```
Standby[WHOLE ] 0001
-Variant-      C:0100
```

❷ Select <2) HbA1c CAL>.

```
Menu 1)CTRL MEAS
1/2  2)HbA1c CAL
```

3 Enter coefficients.

IMPORTANT:

Enter coefficients "a" and "b" written on the standard value sheet that comes with the calibrator.

REFERENCE:

A different screen appears depending on the HbA1c value output mode. For the current setting, contact your distributor.

❶ Enter the coefficients.

- ↵ : Goes to the next setup item.

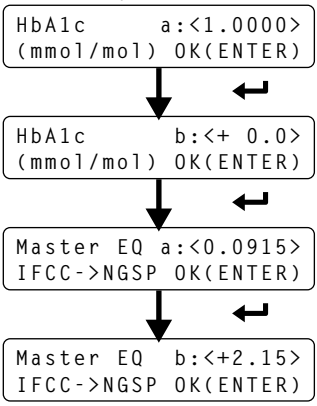
Coefficients for the HbA1c correction formula

Setup item	Displayed item	Settable range (default)
Coefficient “a”	HbA1c a: (mmol/mol)	0.0000 to 1.5000 (1.0000)
Coefficient “b”	HbA1c b: (mmol/mol)	-50.0 to 50.0 (0.0)

Coefficients for the master equation (from IFCC to NGSP)

Setup item	Displayed item	Settable range (default)
Coefficient “a”	Master EQ a: IFCC->NGSP	0.0000 to 0.1500 (the value previously entered)
Coefficient “b”	Master EQ b: IFCC->NGSP	-5.00 to 5.00 (the value previously entered)

Example:
HbA1c value output mode: IFCC&NGSP*



* The output format differs depending on the current HbA1c value output mode. For the current setting, contact your distributor.

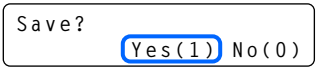
4 Save the coefficients.

❶ Press [1].

- This saves your new settings.

REFERENCE:

To cancel the settings, press [0].



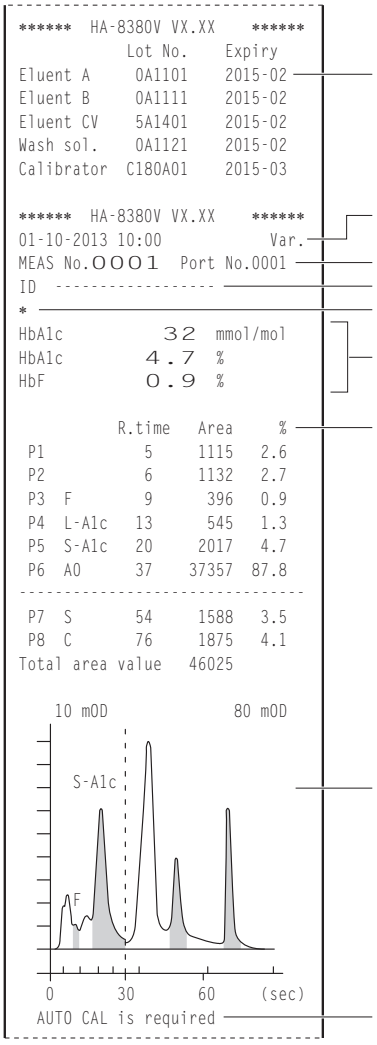
❷ Press ESC one or more times to return to the standby screen.

2.7 Printed Reports

2.7.1 Measurement Result Report

The instrument automatically prints out a measurement result report each time it obtains a result in normal/HbA1c control measurements and HbA1c automatic calibration. This report can be reprinted if needed. See “3.4.1. Printing/Transmitting Results” on page 3-16

Example



Reagent information
This information appears here when the <Reagent INFO> setting is <Batch>.
* When the <Reagent INFO> setting is <MEAS>, this information appears on the end of each measurement result report.

Measurement date and time,
current measurement mode: Var. (Variant) or Fast

Type of measurement, measurement number and port number

ID

Column replacement symbol

HbA1c and HbF measurement results

Peak information
(peak number, peak name, retention time, area value, area ratio)
* All detected peaks are printed out.

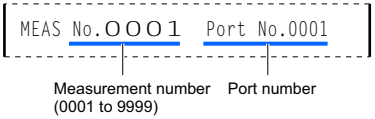
Chromatogram
The number of seconds differs depending on the measurement mode in use.

This message appears when automatic calibration is needed.

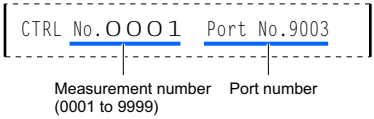
- Type of measurement, measurement number, port number

  For information on measurement numbers and port numbers, see “6.2. Glossary” on page 6-10.

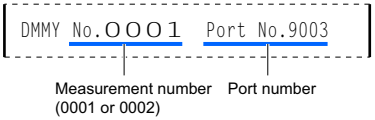
Normal measurement



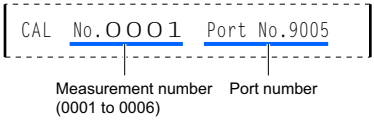
HbA1c control measurement



HbA1c automatic calibration (dummy sample)



HbA1c automatic calibration (standard solution)



REFERENCE:

Normal measurements are serially numbered for the Variant and Fast modes.

- ID

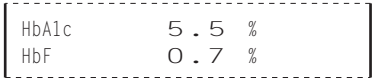
  The ID of the sample or control. This field is padded with hyphens (-) if no ID has been entered or if the number of digits is less than 18.

- Column replacement symbol

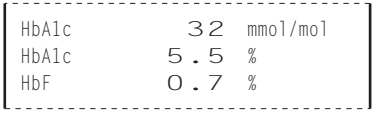
  Usually, nothing is printed, but an “*” appears as in the example when it is time to replace the column.

- HbA1c and HbF measurement results

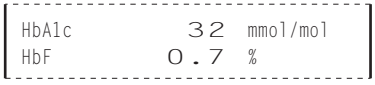
NGSP



IFCC&NGSP (default)



IFCC



- Message that appears when automatic calibration is needed

  Usually, the message “AUTO CAL is required” is not printed on reports. It is printed only when automatic calibration is needed.

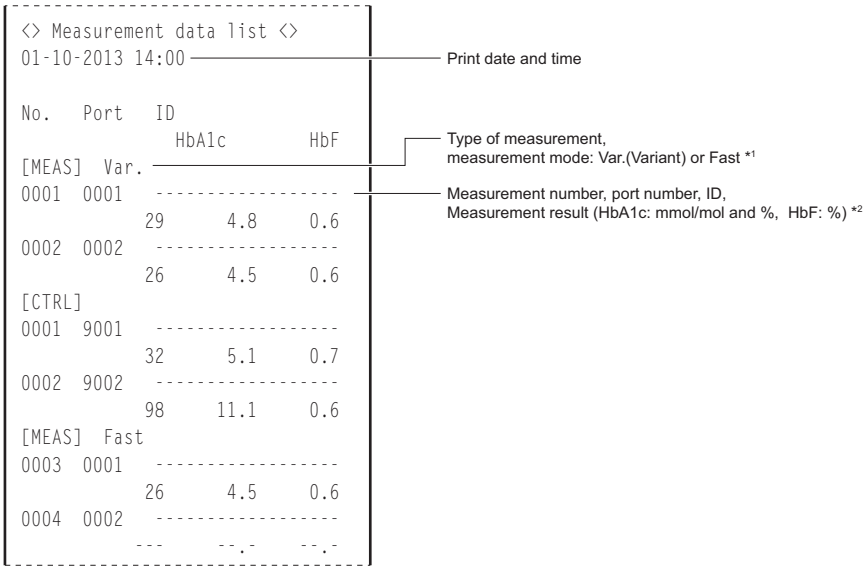
2.7.2 List of Measurement Results

This list contains past measurement results for each type of measurement.

REFERENCE:

See “3.4.1. Printing/Transmitting Results” on page 3-16.

Example



*1: Measurement mode in which the measurement results (shown below each mode) were obtained.

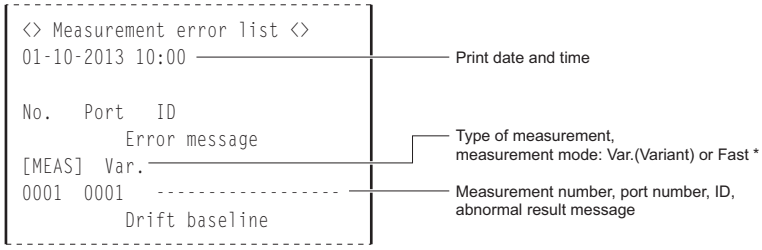
*2: HbA1c value output mode: IFCC&NGSP

2.7.3 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.

REFERENCE:
- See "3.6.3. Printing a List of Abnormal Results" on page 3-25.
- See "5.4. Abnormal Result Messages" on page 5-17.

Example



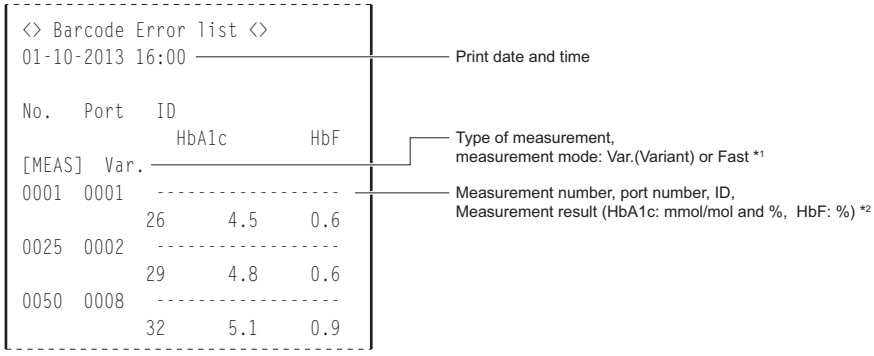
* Measurement mode in which the measurement results (shown below each mode) were obtained.

2.7.4 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 when measurement with the sample racks is complete. You can reprint this report as needed.

REFERENCE:
See "3.6.2. Printing a List of Barcode Errors" on page 3-24.

Example



*1: Measurement mode in which the measurement results (shown below each mode) were obtained.
*2: HbA1c value output mode: IFCC&NGSP

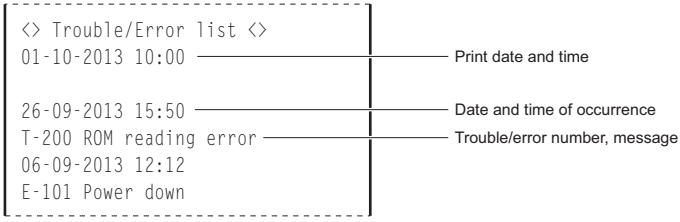
2.7.5 Error/Trouble History

REFERENCE:
- See “5.2. If an Error Occurs” on page 5-8.
- See “5.3. If Trouble Occurs” on page 5-11.

■During measurement

REFERENCE:
See “3.6.1. Printing Error/Trouble History” on page 3-23.

Example



■Not during measurement

Information on error/trouble is printed each time it occurs while the instrument is starting up, the standby screen appears on the display, or menu functions are being used.

Example

2.7.6 Calibration Results Report

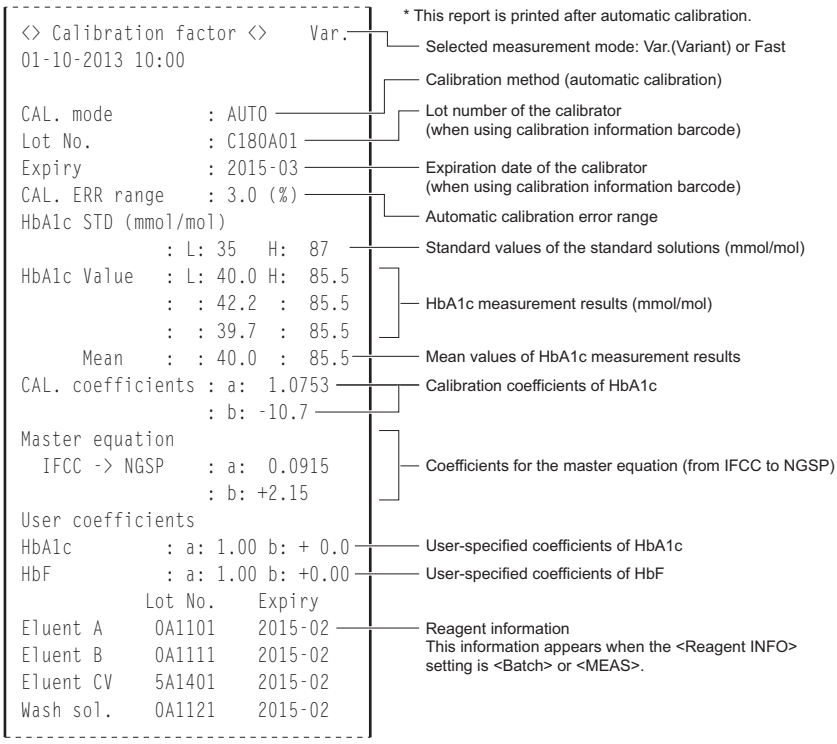
The instrument automatically prints calibration results report in the following cases:

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

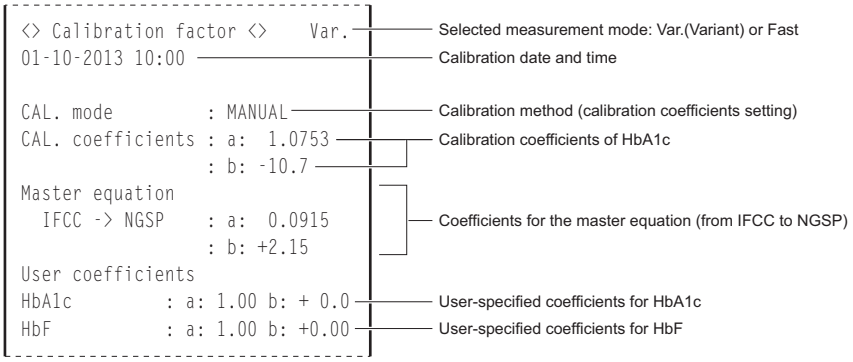
You can reprint this report as needed.

REFERENCE:
See “3.6.4. Printing Calibration Result Report” on page 3-26.

Example: Automatic calibration



Example: Calibration coefficients setting



Chapter 3 Auxiliary Operations

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

3.1 Sub Menu Screen

■Sub menu

From the sub menu, you can make instrument settings, print and transmit measurement results and perform operations necessary for maintenance tasks.

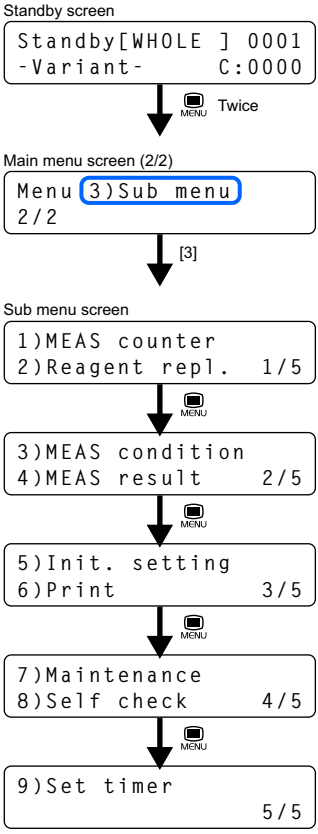
- To access the sub menu:

❶ On the standby screen, press MENU twice.

❷ Select <3) Sub menu>.

- To change the pages of the sub menu:

Press MENU.



■Options on the sub menu

- 1) MEAS counter

Description	Page
Sets the column measurement counter to a desired number.	3-8

- 2) Reagent repl.

Option	Description	Page
1) Eluent A	Makes preparations needed to replace the eluent A pack.	4-9
2) Eluent B	Makes preparations needed to replace the eluent B pack.	
3) Eluent CV	Makes preparations needed to replace the eluent CV pack.	
4) Washing sol.	Makes preparations needed to replace the hemolysis washing solution bottle.	4-13
5) Column	Makes preparations needed to replace the column, and after replacement, sends fluid through the column.	4-19
6) Edit RGNT INFO	Sets reagent information on eluents, hemolysis washing solution and calibrator.	3-40

- 3) MEAS condition

Option	Description (default bolded)			Page
1) User coef.	Set coefficients “a” and “b” of the correction formula for HbA1c and HbF, “Y=aX+b”.			3-9
	HbA1c a: 0.00 to 1.50 (**1.00**), b: -50.0 to 50.0 (**0.0**) * HbA1c value output mode: IFCC&NGSP (default setting) HbF a: 0.00 to 3.00 (**1.00**), b: -5.00 to 5.00 (**0.00**)			
2) Timer setup	Selects whether or not to use the startup timer. When using the timer, set the startup days and times.			3-10
	Startup timer: **ON** (Use), OFF (Not use) Mo to Su: Selects whether or not to start up the instrument on each day of the week. 1 (Use), **0** (Not use) Startup time: **00:00** to 23:59			
3) A1c MEAS setup	1) CTRL MEAS	1) Exp. val.	Control expected values L: 0 to 99 (**IFCC 0 mmol/mol**) H: 0 to 200 (**IFCC 0 mmol/mol**)	3-12
		2) CTRL ERR range	Control error range L: 0 to 99 (**IFCC 3 mmol/mol**) H: 0 to 99 (**IFCC 4 mmol/mol**)	
		3) CTRL ERR act.	Action in case of error **STOP**: Stops measurement. NON: No action WARN: Issues warning.	
	2) PRESS unit	Column pressure unit (**kg/cm2**, MPa)		
	3) CAL mode	Calibration method **AUTO**: Automatic calibration MANUAL: Calibration coefficient settings		
	4) CAL ERR range	Error range for automatic calibration 0.0 to 9.9% (**3.0%**)		
	5) STD sol. count	Standard solution measurement count for automatic calibration 1 to 3 times (**3 times**)		
	6) Col/CAL msg.	Notification of column degradation and automatic calibration request **ON(1st)**: Only once ON(ALL): At each startup and the end of measurement. OFF: No notification		
	7) BC misread	Count of misread barcodes (**0** to 150 times) If set to “0”, measurement does not stop regardless of the number of times that the error occurs.		
4) MEAS mode	Switches between the measurement mode (**Variant**, Fast).			2-11

- 4) MEAS result

Option	Description (default bolded)	Page
1) Print	Prints out measurement results and chromatograms.	3-16
	Start: Start date of the measurement date range (01-01-00 to 31-12-99) End : End date of the measurement date range (01-01-00 to 31-12-99) MEAS mode:Measurement mode (**Current measurement mode**) Variant, Fast, V & F (Variant and Fast) MEAS type: Measurement type **ALL** (all measurements), MEAS (normal measurement), CTRL (control measurement) Result type: Measurement result type **ALL** (all measurement results), NOML (normal results only), ABNML (normal results and abnormal results except results for which the barcodes were misread) Number type: The condition to search for measurement results using numbers **ALL** (all results), No.(results specified by measurement number), ID (results specified by ID)	
2) Print (list)	Prints out a list of measurement results. For information on the setup items, see <1) Print> above.	
3) Transmit	Transmits measurement results to the external device. For information on the setup items, see <1) Print> above.	
4) Delete	Deletes measurement results and error/trouble history from the memory.	3-18
	Deletion item: Types of data to be deleted **ALL** (all measurement results and error/trouble history), MEAS (normal measurements), CTRL (control measurements), ER/TR (error/trouble history)	

- 5) Init. setting

Option	Description (default bolded)	Page
1) Date & Time	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**)	3-19
2) Printer setup	Makes printer settings. Printer use: **ON** (Use), OFF (Not use) Peak INFO: Peak information on measurement result reports **ON** (Prints), OFF (Not print) Chromatogram: Chromatogram on measurement result reports **ON** (Prints), OFF (Not print) Data list: Automatic print of a list of measurement results and other data at the end of each batch **ON** (Prints), OFF (Not print) Reagent INFO: Reagent information on measurement result reports and calibration result reports Batch (On the first measurement result report of each batch and on every calibration result report), MEAS (On every measurement result report and calibration result report), **OFF** (Not print)	3-19
3) Ext. output	Activates or deactivates external output. ON: Use, **OFF**: Not use	3-21

Option	Description (default bolded)	Page
4) Beeper volume	Controls the volume of the beeper that sounds if a warning, error or trouble occurs, and when buttons are operated. Beeper volume: 0 to 4 (**2**)	3-22

- 6) Print

Option	Description (default bolded)	Page
1) ERR & Trouble	Prints out the history of errors and troubles that occurred in a specified period. Start: Start date of the specified period (01-01-00 to 31-12-99) End: End date of the specified period (01-01-00 to 31-12-99)	3-23
2) Barcode ERR	Prints out a list of measurement results for which the barcodes were misread. Measurement date (01-01-00 to 31-12-99) MEAS mode: Measurement mode (**Current measurement mode**) Variant, Fast, V & F (Variant and Fast)	3-24
3) ABNML result	Prints out a list of measurement numbers and messages of abnormal measurement results. Measurement date (01-01-00 to 31-12-99) MEAS mode: Measurement mode (**Current measurement mode**) Variant, Fast, V & F (Variant and Fast)	3-25
4) CAL result	Prints out the most recent calibration result report. MEAS mode: Measurement mode (**Current measurement mode**) Variant, Fast, V & F (Variant and Fast)	3-26
5) Setting INFO	Prints out a list of the current parameter settings of the instrument.	3-27

- 7) Maintenance

Option	Description			Page
1) Tube wash	Washes the tubes automatically.			4-4
2) Pierc. nozzle	1) Cleaning	Makes preparations needed to clean the piercing nozzle.		4-7
	2) Replacement	Makes preparations needed to replace the piercing nozzle.		4-26
3) Dil. & wash.	Makes preparations needed to clean the dilution container unit.			4-17
4) Drain	1) Eluent A	Drains eluent A from the tube.		1-30
	2) Eluent B	Drains eluent B from the tube.		
	3) Eluent CV	Drains eluent CV from the tube.		
	4) Washing sol.	Drains hemolysis washing solution from the tube.		
5) Cell washing	Washes the optical unit cell.			4-31
6) Log	1) Pierc. nozzle	1) Cleaning	Allows you to record the date when the piercing nozzle was last cleaned.	4-37
		2) Replacement	Allows you to record the date when the piercing nozzle was last replaced.	
	2) Dil. & wash.	Allows you to record the date when cleaning the dilution container unit.		
	3) Mesh filters	Allows you to record the date when replacing the mesh filters for the eluents and hemolysis washing solution.		
7) Print (log)	Prints maintenance history.			4-38

- 8) Self check

Option	Description (default bolded)		Page
1) Flow test	1) ALL	Tests the motor drive unit and drain flow once each.	3-28
	2) Drive unit	Tests the motor drive unit.	3-29
	3) Drain	Tests the drain flow.	
2) Accuracy CTRL	Prints out statistical information on control measurements and sample measurements. Start: Start date of the measurement date range (01-01-00 to 31-12-99) End: End date of the measurement date range (01-01-00 to 31-12-99) MEAS mode: Measurement mode (**Current measurement mode**) Variant, Fast, V & F (Variant and Fast)		3-30
3) Monitor print	Prints out the changes in optical unit light absorption over the last 10 minutes.		3-31
4) Analysis sect.	Performs a check measurement for the analysis section.		3-32
5) Repro. test	1) WHOLE sample	Performs reproducibility tests for whole blood sample.	3-33
	2) HEMOL sample	Performs reproducibility tests for hemolysis sample.	3-35

- 9) Set timer

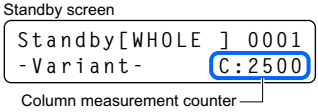
Description	Page
Activates the startup timer. The instrument enters sleep mode and is scheduled to start up and prepare for measurement at a set time on set days.	3-11

3.2 Column Measurement Counter Setup

This section describes how to set the column measurement counter. Usually, the counter should be reset to "0000" after the column has been replaced with a new one.

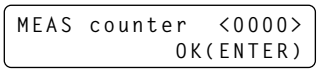
If you wrongly reset the counter, follow the instructions described below to set the counter to a desired number.

Standby screen



❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

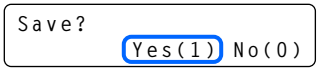
❷ Select <1) MEAS counter>.



❸ Enter a number.
- Settable range: 0000 to 9999

❹ Press ↵.

❺ Press [1].
- This saves your new setting.



NOTE:
Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❻ Press ESC one or more times to return to the standby screen.

3.3 Measurement Conditions

3.3.1 Setting the User-specified Coefficients

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

❶ On the standby screen, check if the instrument is in the measurement mode you want (Variant or Fast).

- To change the mode see “2.3.3. Selecting the Measurement Mode” on page 2-11.

IMPORTANT:

User-specified coefficients are stored separately for the Variant and Fast modes. Make sure that the instrument is in the mode you want.

❷ On the standby screen, press MENU twice, and select <3) Sub menu>.

❸ Press MENU.

❹ Select <3) MEAS condition>, and then <1) User coef.>.

❺ Enter coefficients.

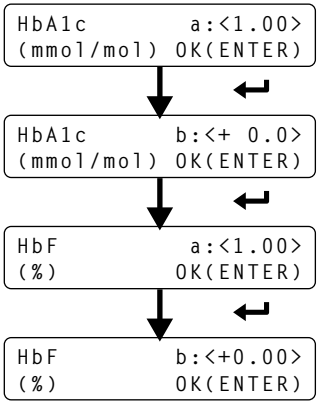
- ↵ : Goes to the next setup item.

HbA1c

Output mode*	Setup item	Displayed item	Settable range (default)
NGSP(%)	HbA1c Coefficient “a”	HbA1c a:	0.00 to 1.50 (1.00)
	Coefficient “b”	HbA1c b:	-5.00 to 5.00 (0.00)
IFCC (mmol/mol)	HbA1c Coefficient “a”	HbA1c a:	0.00 to 1.50 (1.00)
	Coefficient “b”	HbA1c b:	-50.0 to 50.0 (0.0)

* The output format differs depending on the current HbA1c value output mode. For the current setting, contact your distributor.

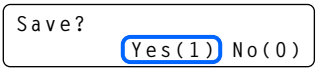
Example:
HbA1c value output mode: IFCC&NGSP*



HbF

Setup item	Displayed item	Settable range (default)
HbF(%) Coefficient “a”	HbF a:	0.00 to 3.00 (1.00)
Coefficient “b”	HbF b:	-5.00 to 5.00 (0.00)

❻ Press [1].
- This saves your new settings.



NOTE:
Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❼ Press ESC one or more times to return to the standby screen.

3.3.2 Setting Up the Startup Timer

The startup timer automatically starts up the instrument at a set time on set days. The instrument will be on standby by the set time, so you can start measurements right away. To use the startup timer, set the startup days and times as in the following steps.

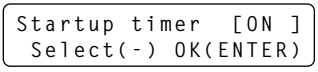
REFERENCE:
To activate the startup timer, see “3.3.3. Activating the Startup Timer” on page 3-11.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU.

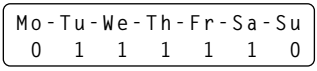
❸ Select <3) MEAS condition>, and then <2) Timer setup>.

❹ Select one of the following options:
- <ON>: Uses the startup timer.
  <OFF>: Does not use the startup timer.
- [-]: Changes the setting.



❺ Press ↵.
- When <OFF> is selected, skip to step ❿.

❻ Select one of the following options for each day of the week.
- <1>: Uses the startup timer.
  <0>: Does not use the startup timer.
- [-]: Selects the day of the week.



❼ Press ↵.
- The first day of the week that the startup timer will be used appears on the screen.

❽ Enter the startup time.
- Settable range: 00:00 to 23:59
- [-]: Moves the cursor.

```
(Tuesday)     <09:00>
   Move(-) OK(ENTER)
```

❾ Press ↵.
- Repeat steps ❽ and ❾ to set the startup time for other days.

❿ Press [1].
- This saves your settings.

```
Save?
          Yes(1) No(0)
```

NOTE:
Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

⓫ Press ESC one or more times to return to the standby screen.

3.3.3 Activating the Startup Timer

■Activating the Startup Timer

Once the startup timer has been activated, the instrument enters sleep mode and is scheduled to automatically start up and prepare for measurement at a set time on a set day. The instrument will be on standby by the set time, so you can start measurements right away. It is convenient to activate the startup timer at the end of the day's work for the next day's work.

REFERENCE:
Prior to activating the startup timer, set the times and days that the instrument is to start up (see "3.3.2. Setting Up the Startup Timer" on page 3-10).

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU four times.

❸ Select <9) Set timer>.
- The next startup day and time will appear.

❹ Change the next startup day if necessary.
- [-]: Selects the day of the week.

```
Start up[MON](09:00)
 Select(-) OK(ENTER)
```

❺ Press ↵.

- The yellow TIMER lamp will be lit and the instrument will enter sleep mode.

REFERENCE:

If “No timer setup” appears:

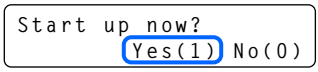
Set the startup time for each day of the week (see “3.3.2. Setting Up the Startup Timer” on page 3-10).

■To cancel the startup timer

❶ While the yellow TIMER lamp is lit, press any button.

❷ Press [1].

- The startup timer will be canceled and the instrument will start up.



REFERENCE:

The startup timer will not be canceled if you press [0] or do not press any buttons for 10 seconds.

3.3.4 Setting the HbA1c Measurement Conditions

Set HbA1c calibration conditions, HbA1c control measurement parameters, pressure unit for the column and error trigger conditions.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU.

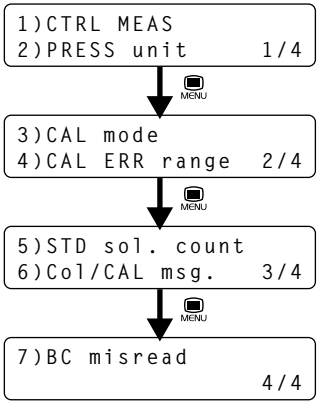
❸ Select <3) MEAS condition>.

❹ Press MENU.

❺ Select <3) A1c MEAS setup>.

❻ Select a setup item from the menu screens shown on the right.

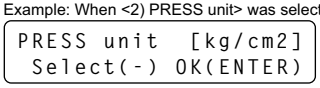
- See “Setup item” in the table on the next page.



❼ Make your settings.

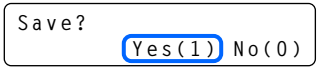
- See “Description” in the table on the next page.
- [-]: Changes the setting.
  ↵: Confirms your changes.

Example: When <2) PRESS unit> was selected:



❽ Press [1] .

- This saves your new settings.



NOTE:

Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❾ Press ESC one or more times to return to the standby screen.

Setup item	Description (default bolded)	
1) CTRL MEAS	1) Exp. val.	Control expected values Enter the expected values written on the package insert of the controls. For NGSP*1 L: Low solution 0.0 to 9.9 % (**0.0 %**) H: High solution 0.0 to 20.0 % (**0.0 %**) For IFCC*1 L: Low solution 0 to 99 mmol/mol (**0 mmol/mol**) H: High solution 0 to 200 mmol/mol (**0 mmol/mol**)
	2) CTRL ERR range	Control error range The warnings “W-011” and “W-071” will be issued if the difference between the obtained control measurement result and the <Exp. val.> value exceeds the range set here. For NGSP*1 L: Low solution 0.0 to 9.9 % (**0.3 %**) H: High solution 0.0 to 9.9 % (**0.4 %**) For IFCC*1 L: Low solution 0 to 99 mmol/mol (**3 mmol/mol**) H: High solution 0 to 99 mmol/mol (**4 mmol/mol**)
	3) CTRL ERR act.	Action in case of error Select the action to take place when the difference between the obtained control measurement result and the <Exp. val.> value exceeds the range set in the <CTRL ERR range> field. **STOP**: Issues a warning and stops measurements. NON: Continues measurements without issuing a warning. WARN: Issues a warning but continues measurements.
2) PRESS unit	Column pressure unit Options: **kg/cm2**, MPa	
3) CAL mode	Calibration method **AUTO**: Automatic calibration MANUAL: Calibration coefficient settings	
4) CAL ERR range	Error range for automatic calibration Set the error detection range for automatic calibration. Settable range: 0.0 to 9.9% (**3.0%**) An error occurs if the measurement result of the Low or High solution is as in the following formula. Example: <CAL ERR range> is set to 3.0% |Measured result – Mean value| > Mean value *2 × 3.0% *2 The mean value is calculated separately for Low and High solutions.	
5) STD sol. count	Standard solution measurement count for automatic calibration Set the number of times to measure each of the Low and High solutions. Settable range: 1 to 3 times (**3 times**)	

Setup item	Description (default bolded)
6) Col/CAL msg.	Notification of column degradation and automatic calibration request <Column degradation notification> When the column measurement counter on the standby screen exceeds 2500, “Replace column.” appears on the screen. <Notification that appears when automatic calibration is needed> “AUTO CAL is required” appears on the screen when the column pressure during measurement exceeds the pressure recorded at the time the instrument was calibrated. **ON(1st)**: Only once ON(ALL): At each startup and the end of measurement OFF: No notification
7) BC misread	Count of 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 the number of times that the error occurs. Settable range: 1 to 150 times (**0 time**)

*1 The output format differs depending on the current HbA1c value output mode. For the current setting, contact your distributor.

3.4 Measurement Results

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

REFERENCE:

- The instrument stores up to 300 results obtained by the following measurements of both measurement modes in the memory: normal measurement, HbA1c control measurement, HbA1c automatic calibration (dummy sample and standard solutions), HbA1c reproducibility test and check measurement for the analysis section.
  If the number of results exceeds 300, 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 3-26.

3.4.1 Printing/Transmitting Results

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

REFERENCE:

- See “2.7.1. Measurement Result Report” on page 2-38.
- See “2.7.2. List of Measurement Results” on page 2-40.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU.

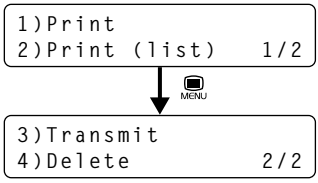
❸ Select <4) MEAS result> .

❹ Select one of the following options:

- <1) Print>: Prints measurement result reports.
  <2) Print (list)>: Prints a list of measurement results.
  <3) Transmit>: Transmits measurement results.

REFERENCE:

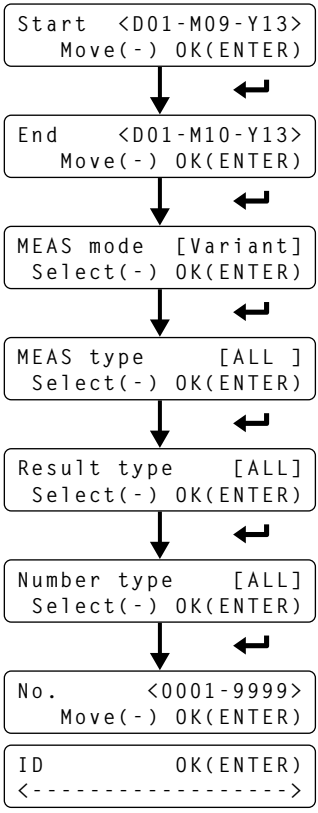
For information on <4) Delete>, see “3.4.2. Deleting Results and Trouble History” on page 3-18.



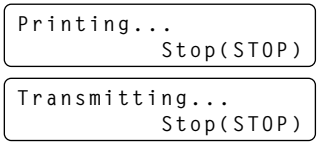
❺ Set the conditions to search for the measurement results you want.

- ↵: Goes to the next setup item.
- [-]: Changes the setting.

Setup item	Description (default bolded)
Start End	Specify the range of measurement dates. The end date must be the same as or later than the start date. [-]: Moves the cursor through the date in the order of “day”, “month” and “year”.
MEAS mode	Select the measurement mode. Variant: Variant mode Fast: Fast mode V & F: Variant and Fast mode (**Current measurement mode**)
MEAS type	Select the measurement type. **ALL**: All measurements MEAS: Normal measurement CTRL: Control measurement
Result type	Select the measurement result type. **ALL**: All results NOML: Normal results only ABNML: Normal and abnormal results (except results with barcode misread)
Number type	Select the condition to search for measurement results using numbers. **ALL**: All results No.: Results specified by measurement number. Go to the <No.> setting. ID: Results specified by sample ID or control ID. Go to the <ID> setting.
No.	This field appears when <Number type> is set to <No.>. Enter the measurement number. Settable range: 0001 to 9999
ID	This field appears when <Number type> is set to <ID>. Enter the sample ID or control ID. The optional hand-held barcode reader can also be used.



- Printing/transmission will start when ↵ is pressed on the last setup screen.



REFERENCE:

- If “W-009 No data” appears:
  No match was found.
  Press ↵ to return to step ❹.
- To stop printing/transmitting:
  Press STOP.

❻ Press ESC one or more times to return to the standby screen.

3.4.2 Deleting Results and Trouble History

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

NOTE:
- Note that deleted data can never be retrieved.
- The results obtained in both the Variant mode and Fast mode are deleted.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU.

❸ Select <4) MEAS result>.

❹ Press MENU.

❺ Select <4) Delete>.

❻ Select one of the following options:
- <ALL>: All measurement results and error/trouble history
  <MEAS>: Normal measurement results
  <CTRL>: Control measurement results
  <ER/TR>: Error/trouble history
- [-]: Changes the setting.

```
Deleting item[ALL  ]
 Select(-) OK(ENTER)
```

❼ Press ↵.

❽ Press [1] .

```
Delete?
        Yes(1) No(0)
```

- This deletes the data.

```
Deleting...
```

❾ Press ESC one or more times to return to the standby screen.

3.5 Initial Settings

3.5.1 Setting the Date and Time

The internal 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 internal clock correctly, since the date and time of measurements are recorded according to the internal clock.

REFERENCE:

The instrument supports three date formats: “YY-MM-DD”, “DD-MM-YY” and “MM-DD-YY”. The default setting is “DD-MM-YY”. If you prefer another date format, contact your distributor.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <5) Init. setting>, and then <1) Date & Time>.

❹ Set the correct date and time.

- [-]: Moves the cursor through the date and time in the order “day”, “month”, “year”, “hour” and “minute”.

<D01-M10-Y13 10:00>
Move(-) OK(ENTER)

❺ Press ↵.

- The new date and time will be recorded.

❻ Press ESC one or more times to return to the standby screen.

3.5.2 Setting Up the Printer

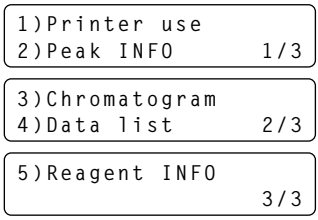
You can deactivate the printer if you do not wish to print anything. When using the printer, you can select whether or not to include peak information and/or chromatograms in individual measurement result reports, to print reagent information on measurement result reports and calibration result reports, and to print reports which list measurement results, abnormal results, barcode errors and error/trouble history at the end of a batch of measurements.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

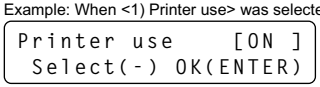
❸ Select <5) Init. setting>, and then <2) Printer setup>.

❹ Select a setup item from the menu screens shown on the right.
- See “Setup item” in the table below.



❺ Make your settings.
- See “Description” in the table below.
- [-]: Changes the setting.

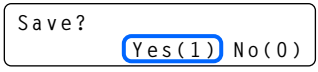
Example: When <1) Printer use> was selected:



Setup item	Description (default bolded)
1) Printer use	**ON**: Use the printer. OFF: Does not use the printer.
2) Peak INFO	**ON**: Includes peak information in measurement result reports. OFF: Does not include peak information.
3) Chromatogram	**ON**: Includes chromatogram in measurement result reports. OFF: Does not include chromatograms.
4) Data list	**ON**: Automatically prints reports which list measurement results, abnormal results, barcode errors and error/trouble history at the end of each batch. OFF: Does not print out the list automatically.
5) Reagent INFO	Batch: Prints reagent information on the first measurement result report of each batch and on every calibration result report. MEAS: Prints reagent information on every measurement result report and calibration result report. **OFF**: Does not print. See “6.1.6. Reagent Information Report” on page 6-8.

❻ Press ↵.

❼ Press [1] .
- This saves your new settings.



NOTE:
Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❽ Press ESC one or more times to return to the standby screen.

3.5.3 Setting Up External Output

Activate external output of the instrument when an external device is connected to the COM1 or COM2 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, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <5) Init. setting>.

❹ Press MENU.

❺ Select <3) Ext. output>.

❻ Select one of the following options:

- <ON>: Uses the external communication.
  <OFF>: Does not use the external communication.
- [-]: Changes the setting.

```
Ext. output    [OFF]
 Select(-) OK(ENTER)
```

❼ Press ↵.

❽ Press [1] .

- This saves your setting, and the screen shown in step ❸ will appear again

```
Save?
        Yes(1) No(0)
```

NOTE:

Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❾ Press ESC one or more times to return to the standby screen.

3.5.4 Adjusting the Beeper Volume

The beeper sounds if a warning, error or trouble occurs, and when buttons are operated. The beeper volume can be adjusted in 5 levels from 0 (mute) to 4 (loudest).

■From the menu screen

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <5) Init. setting>.

❹ Press MENU.

❺ Select <4) Beeper volume>.

❻ Press [2] or [8] to select the level of the beeper volume.
- Settable range: 0 to 4 (0: mute)
- The beeper sounds at the set level each time you press a button.

```
Beeper volume    [3]
 -(2) +(8) OK(ENTER)
```

❼ Press ↵.

❽ Press [1].
- This saves your new setting and return you to the sub menu screen.

```
Save?
          Yes(1) No(0)
```

NOTE:
Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❾ Press ESC one or more times to return to the standby screen.

■From the standby screen

On the standby screen, press and hold STOP, and press [2] or [8] as shown below.

Button	Function
STOP + [2]	Lowers the beeper volume by one level.
STOP + [8]	Raises the beeper volume by one level.

3.6 Print

3.6.1 Printing Error/Trouble History

You can print out the history of errors and troubles that occurred in a specified period. They are listed in the order of oldest first regardless of whether they occurred in the Variant or Fast mode. The instrument stores a total of up to 100 occurrences in the memory.

REFERENCE:
See “2.7.5. Error/Trouble History” on page 2-42.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <6) Print>, and then <1) ERR & Trouble>.

❹ Set the start date of the specified period.
- Settable range: 01-01-00 to 31-12-99
- [-]: Moves the cursor through the date in the order of “day”, “month” and “year”.

```
Start  <D20-M09-Y13>
   Move(-) OK(ENTER)
```

❺ Press ↵.

❻ Set the end date.

REFERENCE:
The end date must be the same as or later than the start date.

```
End    <D01-M10-Y13>
   Move(-) OK(ENTER)
```

❼ Press ↵.
- A list of error/trouble will be printed, starting with the oldest log.

```
Printing...
          Stop(STOP)
```

REFERENCE:
- If “W-009 No data” appears on the display:
  No match was found.
- To stop printing:
  Press STOP.

❽ Press ESC one or more times to return to the standby screen.

3.6.2 Printing a List of Barcode Errors

You can print out a list of measurement results for which the barcodes were misread. Each list contains abnormal results that were obtained on a specified day.

REFERENCE:

See “2.7.4. List of Barcode Errors” on page 2-41.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <6) Print>, and then <2) Barcode ERR>.

❹ Set a measurement date.

- Settable range: 01-01-00 to 31-12-99
- [-]: Moves the cursor through the date in the order of “day”, “month” and “year”.

```
        <D01-M10-Y13>
  Move(-) OK(ENTER)
```

❺ Press ↵.

❻ Select one of the following options:

- <Variant>: Variant mode
  <Fast>: Fast mode
  <V & F>: Variant mode and Fast mode
- [-]: Changes the setting.

```
MEAS mode  [Variant]
 Select(-) OK(ENTER)
```

❼ Press ↵.

- Printing will start.

```
Printing...
          Stop(STOP)
```

REFERENCE:

- If “W-009 No data” appears on the display:
  No match was found.
- To stop printing:
  Press STOP.

❽ Press ESC one or more times to return to the standby screen.

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 measurement result reports. You may use the lists to determine causes of inaccurate measurement results. Each list contains abnormal results that were obtained on a specified day.

REFERENCE:

See "2.7.3. List of Abnormal Results" on page 2-41.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <6) Print>.

❹ Press MENU.

❺ Select <3) ABNML result>.

❻ Set a measurement date.
- Settable range: 01-01-00 to 31-12-99
- [-]: Moves the cursor through the date in the order of "day", "month" and "year".

```
        <D01-M10-Y13>
  Move(-) OK(ENTER)
```

❼ Press ↵.

❽ Select one of the following options:
- <Variant>: Variant mode
  <Fast>: Fast mode
  <V & F>: Variant mode and Fast mode
- [-]: Changes the setting.

```
MEAS mode  [Variant]
 Select(-) OK(ENTER)
```

❾ Press ↵.
- Printing will start.

```
Printing...
          Stop(STOP)
```

REFERENCE:
- If "W-009 No data" appears on the display:
  No match was found.
- To stop printing:
  Press STOP.

❿ Press ESC one or more times to return to the standby screen.

3.6.4 Printing Calibration Result Report

You can print out the most recent HbA1c calibration result report. This report lists either the coefficients obtained by automatic calibration or the manually set coefficients, whichever of the two operations performed last.

REFERENCE:

See “2.7.6. Calibration Results Report” on page 2-43.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU twice.

❸ Select <6) Print>.

❹ Press MENU.

❺ Select <4) CAL result>.

❻ Select one of the following options:

- <Variant>: Variant mode
  <Fast>: Fast mode
  <V & F>: Variant mode and Fast mode
- [-]: Changes the setting.

```
MEAS mode  [Variant]
 Select(-) OK(ENTER)
```

❼ Press ↵.

- Printing will start.

```
Printing...
          Stop(STOP)
```

REFERENCE:

To stop printing:

Press STOP.

❽ Press ESC one or more times to return to the standby screen.

3.6.5 Printing the Current Parameter Settings

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

REFERENCE:

See “6.1.1. Current Parameter Settings” on page 6-2.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

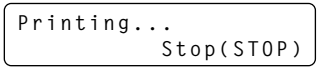
❷ Press MENU twice.

❸ Select <6) Print>.

❹ Press MENU twice.

❺ Select <5) Setting INFO>.

- Printing will start.



REFERENCE:

To stop printing:

Press STOP.

❻ Press ESC one or more times to return to the standby screen.

3.7 Diagnosis

3.7.1 Testing the Whole Flow System

You can run a series of tests on the motor drive units and drain flow once each. Perform these tests to check instrument operation after a problem occurs.

> **NOTE:**
> The same tests are performed for both the Variant mode and Fast mode.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <8) Self check>, <1) Flow test> and <1) ALL> in that order.

- Testing will start.

```
Checking...
          Stop(STOP)
```

REFERENCE:

To stop the test:

Press STOP.

- If "No problem." appears:

  The flow is normal.
  Press ↵.
  Press ESC one or more times to return to the standby screen.

Normal

```
No problem.
          OK(ENTER)
```

- If an error or trouble message appears:

  A problem was detected.
  See the relevant page in "Chapter 5. Troubleshooting" to take the appropriate action.

Abnormal (example)

```
T-430
Main pump
```

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 a problem occurs.

- Motor drive units
- Drain flow

> **NOTE:**
> The same tests are performed for both the Variant mode and Fast mode.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <8) Self check>, and then <1) Flow test>.

❹ Select one of the following options:
- <2) Drive unit>: Motor drive units
  <3) Drain>: Drain flow

❺ Set the number of tests to perform.
- Normally, set it to "1".
- Settable range: 1 to 99 times (default: 1 time)

```
Number of tests < 1>
            OK(ENTER)
```

❻ Press ↵.
- Testing will start.

```
Checking...    01/01
          Stop(STOP)
```

- If "No problem." appears:
  The flow is normal.
  Press ↵.
  Press ESC one or more times to return to the standby screen.

Normal

```
No problem.
            OK(ENTER)
```

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

Abnormal (example)

```
T-430
Main pump
```

3.7.3 Printing Accuracy Control Reports

Accuracy control reports show 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:

See “6.1.2. Accuracy Control Reports” on page 6-4.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <8) Self check>, and then <2) Accuracy CTRL>.

❹ Set the start date of the measurement date range you want.

- Settable range: 01-01-00 to 31-12-99
- [-]: Moves the cursor through the date in the order of “day”, “month” and “year”.

```
Start  <D01-M09-Y13>
   Move(-) OK(ENTER)
```

❺ Press ↵.

❻ Set the end date.

REFERENCE:

The end date must be the same as or later than the start date.

```
End    <D01-M10-Y13>
   Move(-) OK(ENTER)
```

❼ Press ↵.

❽ Select one of the following options:

- <Variant>: Variant mode
  <Fast>: Fast mode
  <V & F>: Variant mode and Fast mode
- [-]: Changes the setting.

```
MEAS mode  [Variant]
 Select(-) OK(ENTER)
```

❾ Press ↵.

- Printing will start.

```
Printing...
           Stop(STOP)
```

REFERENCE:

- If “W-009 No data” appears on the display:
  No match was found.
- To stop printing:
  Press STOP.

❿ Press ESC one or more times to return to the standby screen.

3.7.4 Printing Optical Unit Monitoring Results

Optical unit monitoring results show the changes in optical unit light absorption over the last 10 minutes.

NOTE:
Monitoring is performed for the same duration of time in both the Variant and Fast modes.

REFERENCE:
See “6.1.3. Optical Unit Monitoring Results” on page 6-5.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <8) Self check>.

❹ Press MENU.

❺ Select <3) Monitor print>.
- Printing will start.

```
Printing...
          Stop(STOP)
```

❻ Press ESC one or more times to return to the standby screen.

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, check whether the measurement mode is set to the mode you want to check.
- To change the mode, see "2.3.3. Selecting the Measurement Mode" on page 2-11.

❷ On the standby screen, press MENU twice, and select <3) Sub menu>.

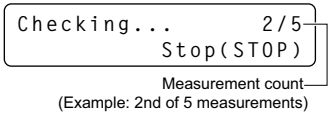
❸ Press MENU three times.

❹ Select <8) Self check>.

❺ Press MENU.

❻ Select <4) Analysis sect.>.
- Measurement will start.

REFERENCE:
- The time required for measurements differs according to the measurement mode in use.
- To stop measurement:
  Press STOP.

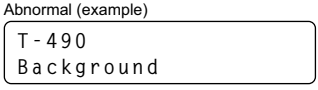


- When "End of MEAS" appears:
  Measurement has finished.
  Press ↵.
  Press ESC one or more times to return to the standby screen.

Normal

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

Abnormal (example)



3.7.6 Testing HbA1c Reproducibility (Whole Blood Sample)

Run a reproducibility test following the instructions described below if the reproducibility of HbA1c measurement results seems to have been reduced in whole blood sample (not including anemia sample) measurements. This test repeatedly measures the same whole blood sample and prints 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.

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

Prepare: Whole blood sample (not including anemia sample), sample tube (×1, with no cap), normal rack and protective gloves

1 Select the reproducibility test for whole blood sample.

❶ On the standby screen, check whether the measurement mode is set to the mode you want to check.
- To change the mode, see "2.3.3. Selecting the Measurement Mode" on page 2-11.

❷ On the standby screen, press MENU twice, and select <3) Sub menu>.

❸ Press MENU three times.

❹ Select <8) Self check>.

❺ Press MENU twice.

❻ Select <5) Repro. test>, and then <1) WHOLE sample>.
- The screen shown on the right will appear.

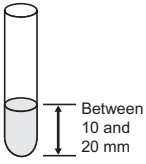
```
Load samples
            OK(ENTER)
```

2 Prepare whole blood sample.

❶ Prepare whole blood sample in a sample tube.
- Make sure the sample tube is uncapped.

IMPORTANT:

When using a sample tube, make sure that the sample tube contains the volume of sample as shown on the right. Inaccurate measurement results will be obtained if the sample volume (height) is over 20 mm.



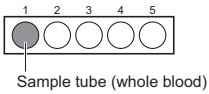
NOTE:

The required sample volume is shown below. Add a sufficient volume of sample to the sample tube to perform the set number of measurements.

(Required sample volume) = 4 µL × (Set number of measurements) + 1 mL

❷ Set the sample tube in port 1 of the normal rack.

❸ Load the normal rack onto the sampler.



3 Start measurement.

❶ Press ↵.

```
Load samples
            OK(ENTER)
```

❷ Set the number of measurements to perform.
- Settable range: 2 to 99 times (default: 3 times)

```
Number of tests < 3>
            OK(ENTER)
```

❸ Press ↵.
- Measurement will start.
- A measurement result report will be printed after each measurement.

```
Running...      01/03
            Stop(STOP)
```

REFERENCE:
- The time required for measurements differs according to the measurement mode in use.
- To stop measurement:
  Press ▽ STOP.

- If "End of MEAS" appears:
  The measurement ended.
  The final measurement result will be printed out.
  Press ↵.
  Press ⊗ ESC one or more times to return to the standby screen.

Normal

```
End of MEAS
            OK(ENTER)
```

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

Abnormal (example)

```
T-481
Low opt. unit light
```

4 When the measurement is complete:

❶ Press ESC one or more times to return to the standby screen.

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

3.7.7 Testing HbA1c Reproducibility (Hemolysis Sample)

Run a reproducibility test following the instructions described below if the reproducibility of HbA1c 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 prints statistical information (average, R, S.D. and C.V.) from those results.

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

REFERENCE:

Number of measurements:
Up to 10 hemolysis samples can be set.

Prepare: Hemolysis sample or hemolysis control (1 type),
Sample containers (the number of sample tubes or sample cups required for measurements to perform), normal racks and protective gloves

1 Select the reproducibility test for hemolysis sample.

❶ On the standby screen, check whether the measurement mode is set to the mode you want to check.
- To change the mode, see “2.3.3. Selecting the Measurement Mode” on page 2-11.

❷ On the standby screen, press MENU twice, and select <3) Sub menu>.

❸ Press MENU three times.

❹ Select <8) Self check>.

❺ Press MENU twice.

❻ Select <5) Repro. test>, and then <2) HEMOL sample>.
- The screen shown on the right will appear.

```
Load samples
            OK(ENTER)
```

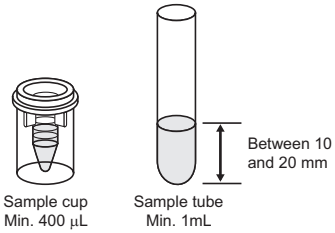
2 Prepare hemolysis samples.

❶ Prepare hemolysis sample in sample tubes or sample cups.

- Divide the same hemolysis sample (or hemolysis control) into the sample containers.
- You can place up to 10 sample tubes or sample cups.

IMPORTANT:

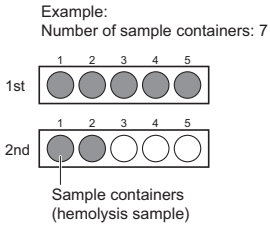
When using sample tubes to measure hemolysis sample, make sure that the sample tube contains 1 mL of sample at minimum as shown by the figure on the far right. Inaccurate measurement results will be obtained if the sample volume (height) is over 20 mm.



❷ Set the sample containers in the normal rack.

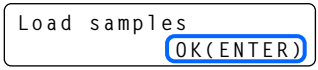
- Set the sample containers in consecutive ports starting from port 1. **Do not** skip any ports.

❸ Load the normal racks onto the sampler.

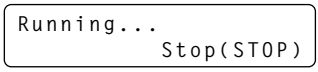


3 Start measurement.

❶ Press ↵.



- Measurement will start.
- A measurement result report will be printed for each measurement.



REFERENCE:

- The time required for measurements differs according to the measurement mode in use.
- To stop measurement:
  Press ▽ STOP.

- If “End of MEAS” appears:
  The measurement ended. The final measurement result will be printed out.
  Press ↵.
  Press ⊗ ESC one or more times to return to the standby screen.

Normal

- If an error or trouble message appears:
  A problem was detected.
  See the relevant page in “Chapter 5. Troubleshooting” to take the appropriate action.

Abnormal (example)

```
T-481
Low opt. unit light
```

4 When measurement is complete:

❶ Press ESC one or more times to return to the standby screen.

❷ Check that the normal racks are not moving, and remove the racks from the unloading side of the sampler.

3.8 Display Contrast Adjustment

Display contrast can be adjusted.
On the standby screen, press and hold STOP, and press [1] or [7] as shown below.

Button	Function
STOP + [7]	Darkens the characters on the display.
STOP + [1]	Lightens the characters on the display.

3.9 Reagent Information Settings

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

• Eluent A • Eluent B • Eluent CV • Hemolysis washing solution • Calibrator

Reagent information settings can be made only by using 10-digit codes supplied with individual reagent products.
A warning 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).

REFERENCE:

Once valid reagent information has been set, it can be printed on measurement result reports and calibration result reports. This serves as proof that the proper reagents were used for measurements (see “3.5.2. Setting Up the Printer” on page 3-19).

3.9.1 Setting Reagent Information When Using New 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 HbA1c automatic calibration.

- For eluents and hemolysis washing solution
  See “4.3.1. Replacing the Eluent Packs” on page 4-9 and “4.3.2. Replacing the Hemolysis Washing Solution Bottle” on page 4-13.

- For calibrator
  See “2.6.1. Performing Automatic Calibration” on page 2-29.

3.9.2 Setting Reagent Information As Needed

You can set reagent information, for example, when:

- You did not make information settings when the new reagent was used; or
- The instrument is started up for the first time after installation. (This does not apply to the calibrator.)

To set reagent information on eluents or hemolysis washing solution, start with step ❷.

❶ To set reagent information for the calibrator, check the following:

- The instrument is in the Variant or Fast mode for which you want to set reagent information.
  See "2.3.3. Selecting the Measurement Mode" on page 2-11.

IMPORTANT:

Reagent information for the calibrator is stored separately for the Variant and Fast modes. Make sure that the instrument is in the correct mode.

NOTE:

Automatic calibration must have been performed and completed in order to enter the reagent information for the calibrator.

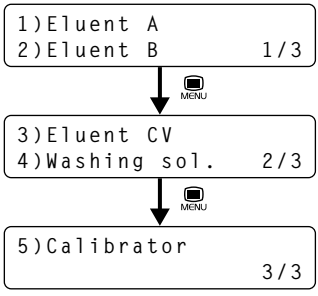
❷ On the standby screen, press MENU twice, and select <3) Sub menu>.

❸ Select <2) Reagent repl.>.

❹ Press MENU twice.

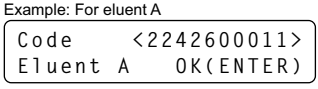
❺ Select <6) Edit RGNT INFO>.

❻ Select the reagent you want.



- The current code will appear.
- Hyphens (---) appear if no information has been set.

Example: For eluent A



❼ 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 sheet.
- The optional hand-held barcode reader can also be used.

REFERENCE:

- If the left-most digit of the reagent code for calibrator is rejected:
  The calibration method (CAL mode) is set to <MANUAL>. Change it to <AUTO>. See “3.3.4. Setting the HbA1c Measurement Conditions” on page 3-12. Perform automatic calibration. See “2.6.1. Performing Automatic Calibration” on page 2-29.
- To delete all the entered characters:
  Press [-]. The hyphens (---) will appear.

❽ Press ↵.

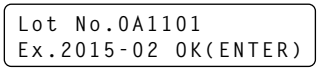
- If your entry is accepted, the lot number and expiration date will appear.

NOTE:

If W-037, W-038 or W-039 appears:
Your entry is invalid. Press ↵ and repeat from step ❼.

❾ Check the reagent information on the screen and press ↵.

- This saves your entries.



❿ To set information on another reagent, repeat from step ❻.

⓫ Press ESC one or more times to return to the standby screen.

Chapter 4 Maintenance

This chapter explains daily maintenance and replacement procedures for consumables such as reagents and printer paper, as well as regular maintenance for the column and piercing nozzle.

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 microorganisms when performing maintenance tasks marked with BIOHAZARD.
- Discard liquid waste, used parts and cleaning tools in accordance with local regulations for biohazardous waste.

Be careful not to pinch your fingers when closing the front cover, column box or printer cover. Pinching may result in personal injury.

- Daily Maintenance

Caution	Maintenance task	Frequency	See page
BIOHAZARD	Liquid waste disposal	Every day	4-4
BIOHAZARD	Automatic tube washing	Every week	4-4
BIOHAZARD	Piercing nozzle cleaning	Every week	4-7

- Replacement of consumables

Caution	Maintenance task	Frequency	See page
	Eluent A pack replacement	If “W-053 No Eluent A” appears About every 90 measurements*1	4-9
	Eluent B pack replacement	If “W-054 No Eluent B” appears About every 550 measurements*1	
	Eluent CV pack replacement	If “W-055 No Eluent CV” appears About every 140 measurements*1	
	Hemolysis washing solution bottle replacement	If “W-052 No washing sol.” appears About every 350 measurements*1	4-13
	Printer paper replacement	When red lines appear along both edges of the printer paper When “W-001 Paper has run out” appears About every 85 measurements*1	4-16

- Regular maintenance

Caution	Maintenance task	Frequency	See page
BIOHAZARD	Dilution container unit cleaning	Every month	4-17
BIOHAZARD	Column replacement	Carefully read the package insert that comes with the column.	4-19
	Mesh filter replacement	Every 2000 measurements (about 6 months)*2	4-23
BIOHAZARD	Piercing nozzle replacement	Every 20000 measurements (about 5 years)*2	4-26
BIOHAZARD	Optical unit cell washing	Every year or every 12000 measurements whichever comes first	4-31

*1: The frequency for these maintenance tasks is for reference only. Actual replacement needs will differ depending on the number of measurements per batch or other conditions. These figures are based on 15 measurements divided into 3 batches (5 measurements per batch on average).

*2: The frequency for these maintenance tasks is based on the assumption that 15 measurements are performed per day, for 20 days per month.

4.2 Daily Maintenance

4.2.1 Discarding Liquid Waste [Every day]

Discard liquid waste from the bottle for liquid waste after all measurements are finished at the end of the 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.

- **Do not** touch liquid waste with unprotected hands. Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard liquid waste and used protective gloves in accordance with local regulations for biohazardous waste.

Prepare: Protective gloves

4.2.2 Automatically Washing the Tubes [Every week]

Wash the tubes once a week. Inaccurate measurement results will be obtained if the tubes are contaminated. This section describes how to wash the tubes automatically.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- 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 in outer diameter, 75 to 100 mm in height
- 12.3 mm in outer diameter, 100 mm in height

Prepare: Washing solution for tubes, sample tube (×1, see "REFERENCE" above), gray adapter (if a sample tube of 12.3 mm outer diameter is used), normal rack and protective gloves

1 Prepare for automatic tube washing.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>, and then <1) Tube wash>.

- Go to either of the following step depending on the message that appears.
  "Use timer after tube wash?": Go to step **2**.
  "Washing?": Go to step **3**.

2 Set the startup timer.

❶ Select whether or not to activate the startup timer after automatic tube washing.

- [1]: Activates the setup timer. On the screen shown on the lower right, use [-] to select the next startup day, and then press ↵.
  [0]: Does not activate the timer.

```
Use timer after tube
wash?   Yes(1) No(0)
```

When [1] is pressed:

```
Start up[MON](09:00)
 Select(-) OK(ENTER)
```

REFERENCE:

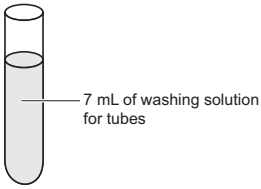
For information on the startup timer, see "3.3.3. Activating the Startup Timer" on page 3-11.

❷ Make sure that the screen shown on the right appears.

```
Washing?
          Yes(1) No(0)
```

3 Prepare the washing solution for tubes.

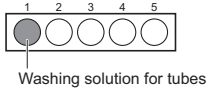
❶ Add 7 mL of washing solution for tubes to a sample tube.



❷ Set the sample tube in port 1 of the normal rack.

NOTE:

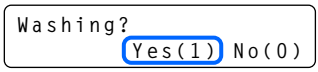
For a sample tube of 12.3 mm outer diameter, set a gray adapter in the port.



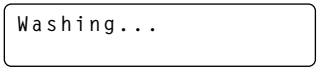
❸ Load the normal rack onto the sampler.

4 Start automatic tube washing.

❶ Press [1].



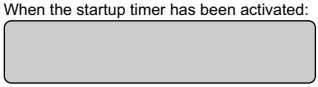
- Automatic tube washing will start.



5 When automatic tube washing is complete:

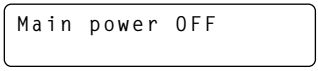
- Either of the screens shown on the right will appear.

When the startup timer has been activated:



Sleep mode: Yellow TIMER lamp is lit.

Others:



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

❷ When “Main power OFF” is displayed, turn off the power.

NOTE:

Do not deactivate the startup timer after automatic tube washing. Otherwise, the tubes will not be properly washed.

REFERENCE:

The washing solution for tubes will remain in the instrument and will be drained the next time the instrument starts up.

4.2.3 Cleaning the Piercing Nozzle [Every week]

Clean the piercing nozzle once a week.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- 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 Prepare for nozzle cleaning.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>, <2) Pierc. nozzle> and <1) Cleaning> in that order.

❹ Press [1].

```
Cleaning?
        Yes(1) No(0)
```

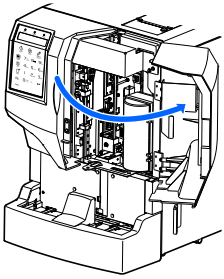
- The piercing nozzle will move to the cleaning position.

```
Piercing nozzle
moving
```

❺ Wait for the screen shown on the right to appear, and then open the front cover.

- The mechanical sections will power off.

```
Open front cover.
Close when finished.
```



2 Clean the piercing nozzle.

❶ Wipe off dirt from the outside of the piercing nozzle with cotton swabs.

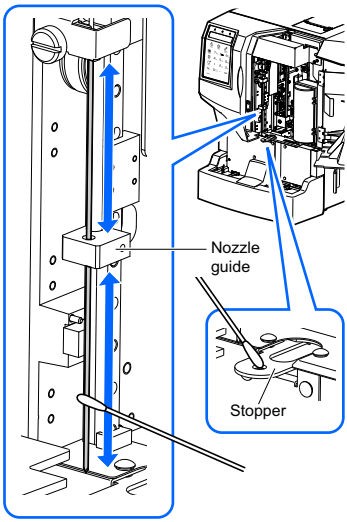
- For stubborn dirt, use gauze moistened with purified water.

NOTE:

Do not clean the piercing nozzle around the nozzle guide. Otherwise, the piercing nozzle may bend or break.

❷ Wipe off dirt from the stopper with cotton swabs.

- Carefully remove dirt from the inner wall of the hole on the stopper and the lower surface of the stopper.
- For stubborn dirt, use gauze moistened with purified water.



3 Log the cleaning date.

❶ Close the front cover.

- The mechanical sections will power on and initialize.

```
Initializing...
      Please wait.
```

NOTE:

Be sure to close the front cover to initialize the mechanical sections.

❷ Press [1].

- This saves the cleaning date.

```
Finished maint.?
        Yes(1) No(0)
```

❸ Press ESC one or more times to return to the standby screen.

4.3 Replacement of Consumables

4.3.1 Replacing the Eluent Packs

Replace the eluent pack if one of the following warning messages appears on the display:

- W-053 No Eluent A
- W-054 No Eluent B
- W-055 No Eluent CV

> Be careful to avoid contact between skin, eyes or mouth and eluent. 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 eluents specified for use with the ADAMS A1c Lite HA-8380V.
- Replace the pack one at a time. Eluents A, B and CV differ in composition. Attaching the wrong nozzle to the wrong pack will cause mixing of eluents, resulting in inaccurate measurement results. If the wrong bottle cap is attached, wash the nozzle, then attach the correct bottle cap to the pack (see “5.5.2. If Eluent Packs Are Incorrectly Attached” on page 5-22).
- Replace the pack to supply new eluent. Adding new solution to the old pack may 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 80CV and gauze

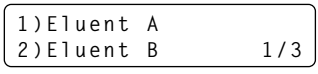
1 Prepare for pack replacement.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Select <2) Reagent repl.>.

❸ Select a type of eluent.

- To go to 2/3, press MENU.



2 Set the reagent information on the new eluent pack.

❶ Enter the reagent code.

- The reagent code is a 10-digit number written on the label of a new eluent pack.
- The optional hand-held barcode reader can also be used.

Example: For eluent A

```
Code     <1234567890>
Eluent A    OK(ENTER)
```

Reagent code on the pack label

REFERENCE:

- If you want to skip reagent code entry, press ↵ without entering anything and go to step **3**. You can enter the code later. See “3.9.2. Setting Reagent Information As Needed” on page 3-40
- To delete all the entered characters:
  Press [-]. The hyphens (---) will appear.

❷ Press ↵.

- The reagent information will appear when your entry is accepted.

REFERENCE:

If “W-037 Incorrect RGNT type” appears:
Your entry is invalid. Enter the correct reagent code.

❸ Check the lot number and expiration date and press ↵.

Example: For eluent A

```
Lot No.0A1101
Ex.2015-02 OK(ENTER)
```

3 Remove the used eluent pack.

❶ Make sure that the screen shown on the right appears.

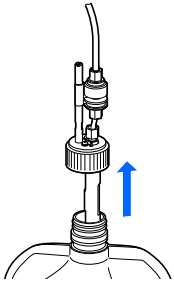
```
Replace pack.
            OK(ENTER)
```

❷ Lay out some gauze near the instrument.

❸ Remove the used eluent pack from the bottle tray.

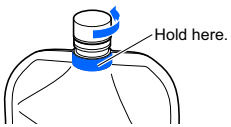
❹ Remove the bottle cap with nozzle from the pack.

- Place the nozzle on the gauze.



4 Place a new eluent pack.

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



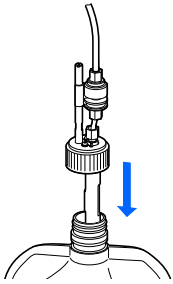
NOTE:
Do not hold the eluent pack by the soft aluminum bag. Eluent may spill and damage the instrument.

REFERENCE:
Keep the cap in the accessory case. This cap should be reused when the instrument is transported, or if it 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 bottle cap 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.

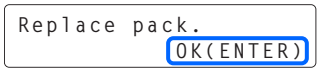
NOTE:
Set the pack between the eluent pack guides.

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.

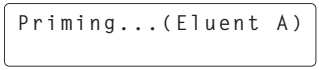
5 Remove air from the eluent by priming.

❶ Press ↵.

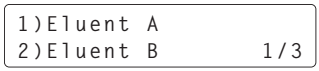


- Priming will start.

For eluent A



- When priming is complete, the screen shown on the right will appear again.



❷ Press ESC one or more times to return to the standby screen.

4.3.2 Replacing the Hemolysis Washing Solution Bottle

Replace the hemolysis washing solution bottle if the following message appears on the display:

- W-052 No washing sol.

> ⚠ 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:

- Use only hemolysis washing solution specified for the HA-8380V.
- 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 Lite H and gauze

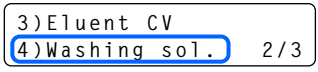
1 Prepare for bottle replacement.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Select <2) Reagent repl.>.

❸ Press MENU.

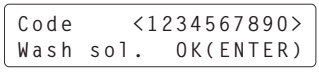
❹ Select <4) Washing sol.>.



2 Set the reagent information on the new hemolysis washing solution.

❶ Enter the reagent code.

- The reagent code is a 10-digit number written on the label of a new bottle.
- The optional hand-held barcode reader can also be used.



Reagent code on the bottle label

REFERENCE:

- If you want to skip reagent code entry, press ↵ without entering anything and go to step **3**. You can enter the code later. See “3.9.2. Setting Reagent Information As Needed” on page 3-40.
- To delete all the entered characters:
  Press [-]. The hyphens (---) will appear.

❷ Press ↵.

- The reagent information will appear when your entry is accepted.

REFERENCE:

If “W-037 Incorrect RGNT type” appears:

Your entry is invalid. Enter the correct reagent code.

❸ Check the lot number and expiration date and press ↵.

```
Lot No.0A1121
Ex.2015-02 OK(ENTER)
```

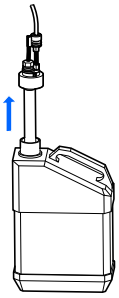
3 Remove the used hemolysis washing solution bottle.

❶ Make sure that the screen shown on the right appears.

```
Replace bottle.
          OK(ENTER)
```

❷ Lay out some gauze near the instrument.

❸ Remove the used hemolysis washing solution bottle from the bottle tray.



❹ Remove the bottle cap with nozzle from the bottle.

- Place the nozzle on the gauze.

4 Place a new hemolysis washing solution bottle.

❶ Remove the cap from a new hemolysis washing solution bottle.

REFERENCE:

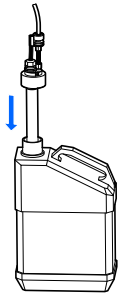
Keep the cap in the accessory case. This cap should be reused when the instrument is transported, or if it is not to be used for extended periods of time.

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 tubes.

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 on the bottle tray.

5 Remove air from the hemolysis washing solution by priming.

❶ Press ↵.

```
Replace bottle.
          OK(ENTER)
```

- Priming will start.

```
Priming...(Wash sol)
```

- When priming is complete, the screen shown on the right will appear again.

```
3)Eluent CV
4)Washing sol.   2/3
```

❷ Press ESC one or more times to return to the standby screen.

4.3.3 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. The following warning message appears on the display if the printer runs out of paper. Promptly set a new roll.

- W-001 Paper has run out

NOTE:
- Keep your hands away from the printer head to avoid damage to the printer.
- Keep your hands away from the paper cutter to avoid injury.

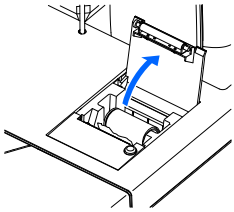
Prepare: Printer paper

1 Remove the remaining printer paper.

❶ Make sure the standby screen is displayed.

❷ Press the release button to open the cover.

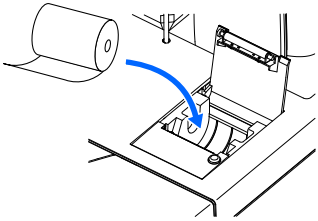
❸ Remove the old roll and remaining paper from the printer.



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.

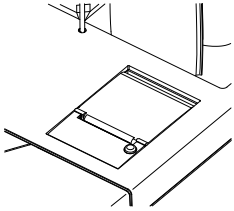
❷ Pull the leading edge of paper until drawing a full turn of the roll and carefully press the printer cover to close it.



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 FEED.



4.4 Regular Maintenance

4.4.1 Cleaning the Dilution Container Unit [Every month]

Wash the dilution container unit once a month. The unit consists of both the dilution container and washing container. Inaccurate measurement results may be obtained if the dilution container unit is contaminated.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- 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, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>.

❹ Press MENU.

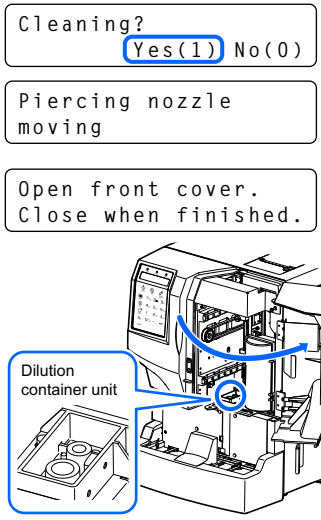
❺ Select <3) Dil. & wash.>.

❻ Press [1].

- The piercing nozzle moves backward so that the dilution container unit can be accessed.

❼ Wait for the screen shown on the right to appear, and then open the front cover.

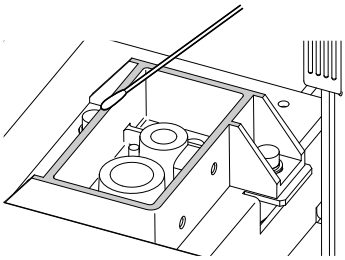
- The mechanical sections will power off.



2 Clean the dilution container unit.

❶ Clean the top of the dilution container unit frame with cotton swabs moistened with purified water.
Blot up any liquid inside the unit, and wipe off any dirt.

- For stubborn dirt, use gauze moistened with purified water.



3 Log the cleaning date.

❶ Close the front cover.

- The mechanical sections will power on and initialize.

```
Initializing...
      Please wait.
```

NOTE:

Be sure to close the front cover to initialize the mechanical sections.

❷ Press [1].

- This saves the cleaning date.

```
Finished maint.?
        Yes(1) No(0)
```

❸ Press ESC one or more times to return to the standby screen.

4.4.2 Replacing the Column

Carefully read the package insert that comes with the column for the replacement of the column. **Do not** use a column beyond its expiration date, since accurate measurement results may not be obtained.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used columns, cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: COLUMN UNIT 80, tissue paper and protective gloves

1 Prepare for column replacement.

NOTE:

Be sure to perform steps **1**-❶ to **1**-❹ first. Otherwise, a warning message will appear when the front cover is opened.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Select <2) Reagent repl.>.

❸ Press MENU twice.

❹ Select <5) Column>.

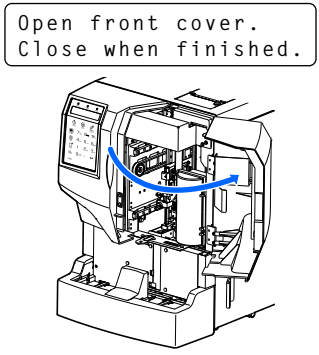
❺ Wait for the screen shown on the right to appear.

- The mechanical sections will power off.

REFERENCE:

If “W-062 Front cover is open” appears:

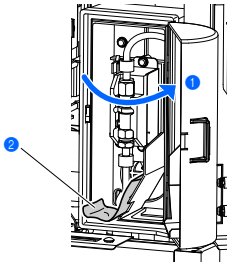
Close the front cover and retry from step **1**-❶.



2 Open the column box.

❶ Open the column box.

❷ Lay out some tissue paper below the column box.
- The tissue paper blots up any liquid that leaks while replacing the column.



3 Detach the old column.

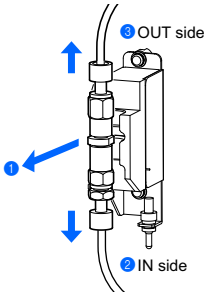
> The column and column holder may be hot. Before touching the column, place your hand near to the column to make sure that it is not hot. If the column is hot, the temperature controlling unit may break. Contact your distributor.

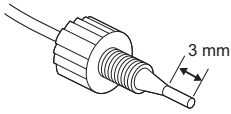
❶ Detach the column from the column holder.
- Place your hand behind the column at the top and push the column to the front.

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.



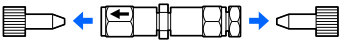


NOTE:

Liquid may leak when attaching the column unless both ends of the tube 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.

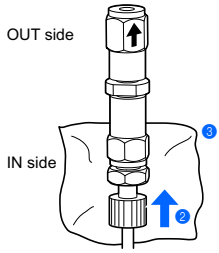


REFERENCE:

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:

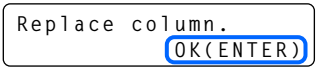
Install the column with the arrow to the top. **Do not** install the column upside-down.

❸ Wrap the connection between the IN side of the column and push screw with tissue paper.

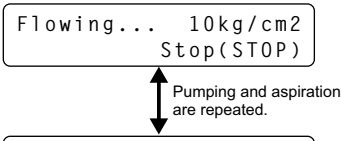
- The tissue paper blots up any liquid that overflows during priming.

5 Remove air from the column by priming.

❶ Press ↵.



- Fluid pumping starts, and liquids and bubbles overflow from the connection between the column and push screw.

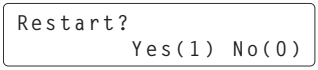


NOTE:

Slightly loosen the push screw if liquid does not overflow from the connection.

REFERENCE:

When “Restart?” appears and pumping stops:
A certain volume of fluid has been pumped. To pump more fluid, press [1]. When pumping is no longer needed, press [0].



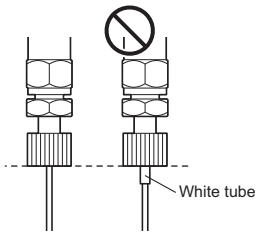
❷ Check that bubbles are no longer formed and only liquid overflows.

- The bubbles will disappear in about 30 seconds.

❸ 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.

❹ Check that the white tube is firmly attached within the push screw on the IN side.

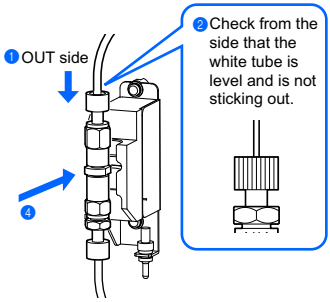


NOTE:

If the white tube is not firmly attached within the push screw:
Remove the push screw from the column, and press the tube until it is protruding about 3 mm from the push screw (see step **3**-❹). Reinsert the push screw into the column and tighten it firmly.

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 Check that the white tube is firmly attached within the push screw on the OUT side (see step **5**-❹).

❸ Remove the tissue paper.

❹ Install the column into the column holder.

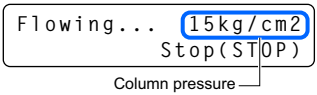
NOTE:

Be careful not to pinch your fingers when installing the column.

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.

❷ Press STOP when the column pressure becomes appropriate.
- 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.

- The screen shown on the right will appear.

8 Reset the column measurement counter and log the column replacement date.

❶ Close the column box, then the front cover.

❷ Press ↵.

```
Close front cover
after inst OK(ENTER)
```

❸ To reset the column measurement counter to "0000", press [1].
- This saves the column replacement date.

```
Reset col. counter?
        Yes(1) No(0)
```

REFERENCE:
If you do not want to reset the counter, press [0].

9 Complete maintenance.

❶ Press ESC one or more times to return to the standby screen.

REFERENCE:
If "W-062 Front cover is open" appears, close the column box and front cover before pressing ↵.

❷ Perform HbA1c automatic calibration.
- See "2.6.1. Performing Automatic Calibration" on page 2-29.

4.4.3 Replacing the Mesh Filters [Every 2000 measurements]

Replace the mesh filters for eluents and hemolysis washing solution every 2000 measurements. A problem 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.

Standby screen

```
Standby[WHOLE ] 0001
-Variant-      C:0000
```

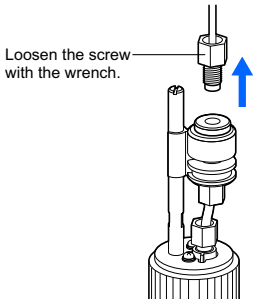
❷ Lay out some gauze near the instrument.

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.

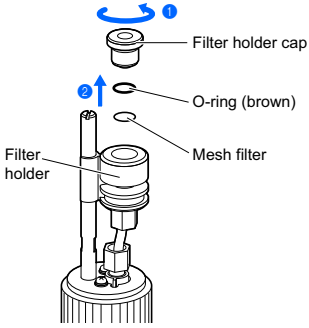


2 Replace the mesh filter.

❶ Turn the filter holder cap by hand and remove it.

❷ Remove the old brown O-ring and mesh filter from the filter 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 screw is loose.

3 Attach the bottle cap with nozzle to the pack or bottle.

❶ Remove the cap from the pack or bottle.

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

❸ To replace the mesh filter of another reagent, repeat from step **1**-❸.

4 Place the packs and/or bottle on the bottle tray.

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

❷ Neatly arrange the tubes to prevent twisting and tangling.

❸ Place the packs and bottle in their original positions on the bottle tray.

5 Remove air from the tubes by priming.

❶ Perform priming for the tube of the reagent for which the mesh filter was replaced and pump fluid through the tube.
- Eluent: Select <4) Eluent A>, <5) Eluent B> or <6) Eluent CV> in “4.5. Priming” on page 4-35.
- Hemolysis washing solution: Select <7) Washing sol.> in “4.5. Priming” on page 4-35.

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.

❸ To perform priming for another reagent, repeat from step **5**-❶.
- Perform priming for every reagent for which the mesh filter was replaced.

REFERENCE:

You can record the date of mesh filter replacement on the instrument. See “4.6.1. Recording the Date of Maintenance” on page 4-37

4.4.4 Replacing the Piercing Nozzle [Every 20000 measurements]

Replace the piercing nozzle every 20000 measurements. A clogged or damaged nozzle also requires replacement.

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

Prepare: Piercing nozzle, tissue paper, protective tube (that was originally attached to the piercing nozzle at the time of shipment) and protective gloves

1 Prepare for nozzle replacement.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>, <2) Pierc. nozzle>, and then <2) Replacement>.

❹ Press [1].

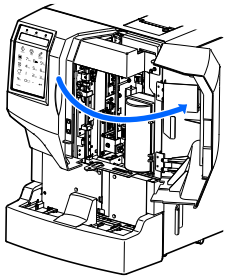
```
Repl. pierc. nozzle?
        Yes(1) No(0)
```

- The piercing nozzle will move to the replacement position.

```
Piercing nozzle
moving
```

❺ Wait for the screen shown on the right to appear, and then open the front cover.
- The mechanical sections will power off.

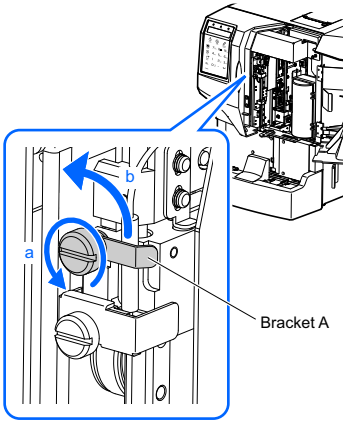
```
Open front cover.
Close when finished.
```



2 Remove the old piercing nozzle.

❶ Lay tissue paper near the instrument.

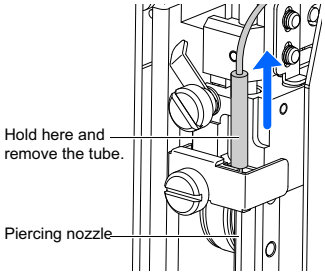
❷ Loosen the screw of the bracket A by hand (a) and then turn the bracket A in the direction of the arrow (b).



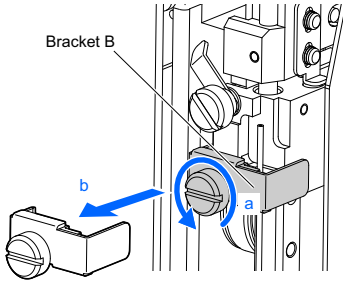
❸ Hold the tube at the top of the piercing nozzle, and pull upwards and remove the tube.

NOTE:

Two different types of tube are used at the top of the piercing nozzle. **Do not** separate them.



❹ Loosen the screw of the bracket B by hand (a) and then remove the bracket B (b).

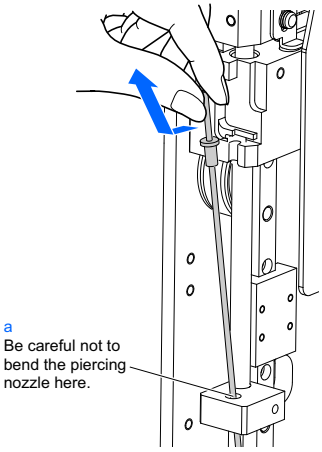


❺ While holding the top of the piercing nozzle, pull the nozzle slightly forward.

NOTE:

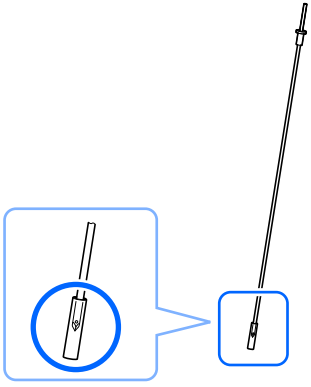
Do not pull the piercing nozzle in any way that may cause it to bend (a) or break.

❻ Pull the piercing nozzle upwards at an angle and remove it.



❼ Attach the protective tube to the tip of the piercing nozzle and place the nozzle on the tissue paper.

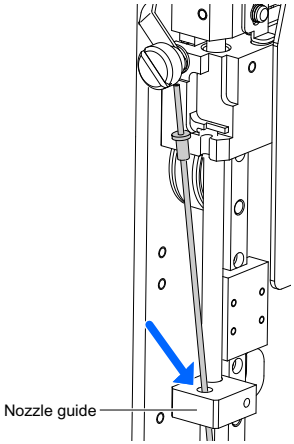
Place the removed piercing nozzle on tissue paper rather than directly on countertops or other surfaces to prevent exposure to pathogenic microorganisms.



3 Attach a new piercing nozzle.

❶ Remove the protective tube from a new piercing nozzle.
- Keep the protective tube in the accessory case.

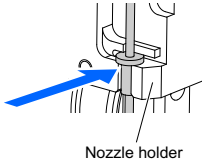
❷ While holding the top of the piercing nozzle, pass the tip through the hole in the nozzle guide.



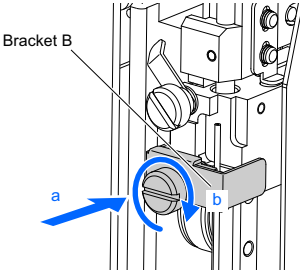
❸ Fit the protrusion at the top of the piercing nozzle into the recess in the nozzle holder.

REFERENCE:

The hole near the tip of the piercing nozzle may face any direction.

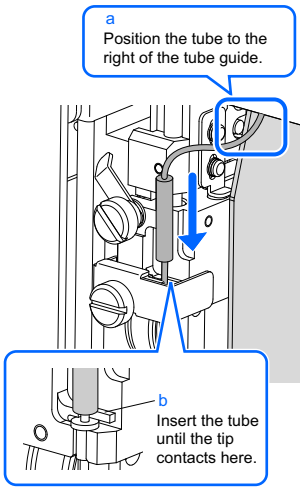


❹ Attach the bracket B to its original position (a) and tighten the screw by hand (b).

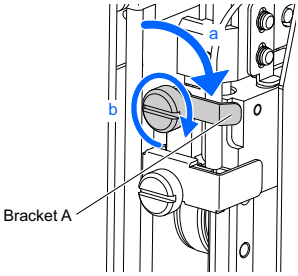


❺ Connect the tube to the top of the piercing nozzle.

NOTE:
- Position the tube to the right of the tube guide as seen from the front (a).
- Insert the tube until the tip contacts the protrusion on the nozzle holder (b).



❻ While holding the tube, return the bracket A to its original position (a) and tighten the screw by hand (b).

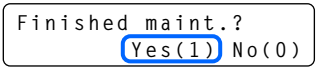


4 Log the nozzle replacement date.

❶ Close the front cover.
- The mechanical sections will power on and initialize.

NOTE:
Be sure to close the front cover to initialize the mechanical sections.

❷ Press [1].
- This saves the nozzle replacement date.



❸ Press ESC one or more times to return to the standby screen.

4.4.5 Washing the Optical Unit Cell [Every year]

Wash the optical unit cell every year or every 12000 measurements, whichever comes first. Inaccurate measurement results may be obtained if the optical unit cell is contaminated.

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

IMPORTANT:

Carefully read the package insert that comes with the cell washing kit (sold separately) and follow the instructions.

Prepare: Cell washing kit (sold separately), sodium hypochlorite solution (approximately 0.75%) and protective gloves

1 Prepare the cell washing set.

❶ Fill the cell washing set with washing solution (sodium hypochlorite solution).

- See the package insert that comes with the cell washing kit.

2 Prepare for optical unit cell washing.

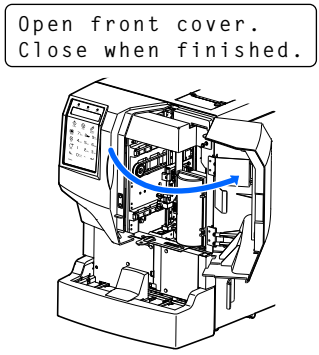
❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>, and then <5) Cell washing>.

❹ Wait for the screen shown on the right to appear, and then open the front cover.

- The mechanical sections will power off.



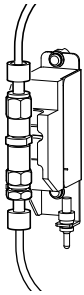
3 Detach the column.

❶ Make sure that the screen shown on the right appears.

```
Install cell washing
set.          OK(ENTER)
```

❷ Detach the column.

- See steps **2** and **3** in "4.4.2. Replacing the Column" on page 4-19.



❸ Seal the both ends of the column with the sealing screws.

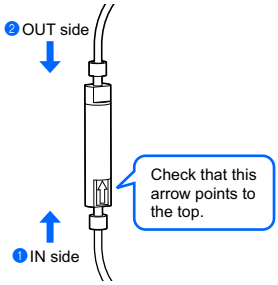
- The sealing screws are stored in the accessory case.

4 Install the cell washing set.

Connect the IN side (bottom) of the cell washing set first.

❶ Remove the sealing screw on the IN side (marked with the arrow) of the cell washing set. Then, attach the push screw on the IN-side tube to the cell washing set. Securely tighten the push screw by hand.

❷ Remove the sealing screw on the OUT side of the cell washing set. Then, attach the push screw of the OUT-side tube to the cell washing set. Securely tighten the push screw by hand.

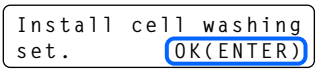


NOTE:

- Check that the cell washing set is installed with the arrow to the top.
- Check that the push screws are firmly tightened.

5 Wash the optical unit cell.

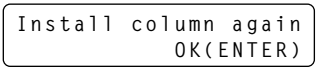
❶ Press ↵ .
- Fluid pumping starts and the optical unit cell is washed for about 18 minutes.



❷ Check that liquid does not leak from the connections between the cell washing set and tubes.
- Retighten the push screws if liquid leaks.

6 Remove the cell washing set.

❶ Make sure that optical unit cell washing has finished and the screen shown on the right appears.

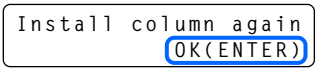


❷ Remove the push screw on the OUT side of the cell washing set, and attach the sealing screw.

❸ Remove the push screw on the IN side of the cell washing set, and attach the sealing screw.

7 Install the column.

❶ Attach the push screw to the IN side of the column detached in step **3**.
- See step **4** in “4.4.2. Replacing the Column” on page 4-19.



❷ Press ↵ .
- Fluid pumping starts, and liquids and bubbles overflow from the connection between the column and push screw (priming).
- Pumping will stop automatically after about 7 minutes.

NOTE:
Slightly loosen the push screw if liquid does not overflow from the connection.

❸ Tighten the column fully.
- See step **5**-❷ to **7**-❶ in “4.4.2. Replacing the Column” on page 4-21.

8 Complete maintenance.

❶ Make sure that pumping has stopped and the screen shown on the right appears.

```
Close front cover
after inst.OK(ENTER)
```

❷ Close the column box, then the front cover.

❸ Press ↵ .

❹ Press ESC one or more times to return to the standby screen.

REFERENCE:

If “W-062 Front cover is open” appears:

Close the column box and front cover before pressing ↵ .

❺ Perform HbA1c automatic calibration.

- See“2.6.1. Performing Automatic Calibration” on page 2-29.

❻ Wash the cell washing kit.

- See the package insert that comes with the cell washing kit.

4.4.6 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

4.5 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) • Main pump
• Eluent A • Eluent B • Eluent CV • Hemolysis washing solution

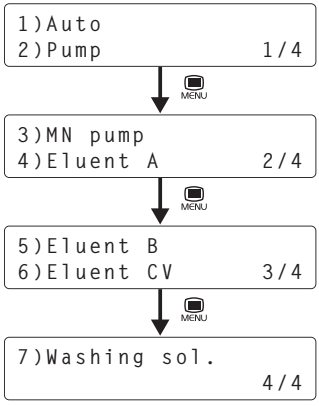
1 Access the priming screen.

❶ On the standby screen, press PRIMING.

2 Start priming.

❶ Select the type of priming to perform.

Option	Description
1) Auto	Removes air from the eluent A tube, eluent B tube, eluent CV tube and main pump by priming, and stops automatically. To manually stop priming, press STOP.
2) Pump	Pumps eluent A to the column. Once fluid pumping has started, wait for at least 30 seconds for the column pressure to reach an appropriate value, and then press STOP. 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) Auto>.
3) MN pump	Removes air from the main pump by priming and stops automatically.
4) Eluent A	Removes air from the eluent A tube by priming and stops automatically.
5) Eluent B	Removes air from the eluent B tube by priming and stops automatically.
6) Eluent CV	Removes air from the eluent CV tube by priming and stops automatically.
7) Washing sol.	Removes air from the hemolysis washing solution tube by priming and stops automatically.



- Priming will start.

Example: When <1) Auto> is selected:

```
Priming...     (Auto)
          Stop(STOP)
```

REFERENCE:

To stop priming:
Press STOP. This action stops priming operations started by <1) Auto> or <2) Pump> only.

❷ When priming is complete, press ESC one or more times to return to the standby screen.

4.6 Maintenance Log

4.6.1 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. 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.

- Piercing nozzle cleaning and replacement
- Dilution container unit cleaning
- Mesh filter replacement

1 Access the maintenance log screen.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>.

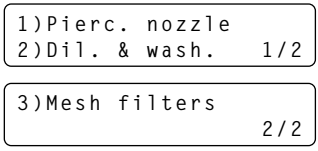
❹ Press MENU twice.

❺ Select <6) Log>.

2 Select the type of maintenance task.

❶ Select the type of maintenance task.

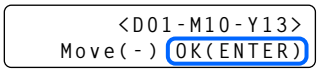
- To go to page 2/2, press MENU.



Option		Description
1) Pierc. nozzle	1) Cleaning	Piercing nozzle cleaning
	2) Replacement	Piercing nozzle replacement
2) Dil. & wash.		Dilution container unit cleaning
3) Mesh filters		Mesh filter replacement

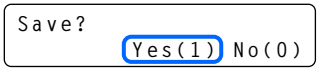
3 Enter the date.

❶ Enter the date.
- [-]: Moves the cursor through the “day”, “month” and “year” fields.



❷ Press ↵ .

❸ Press [1].
- This saves your new settings.



NOTE:
Do not turn off the power while settings are being saved. Otherwise, new settings may not be saved.

❹ Press ESC one or more times to return to the standby screen.

4.6.2 Printing the Maintenance Log

You can print out a maintenance log that lists the dates when reagents were last replaced and parts were last cleaned.

REFERENCE:
See “6.1.7. Maintenance Log Report” on page 6-9.

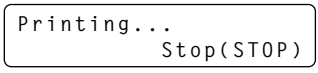
❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>.

❹ Press MENU three times.

❺ Select <7) Print (log)>.
- The maintenance log will be printed out.



4.7 Before/After Extended Periods of Disuse

4.7.1 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 microorganisms.
- 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), aluminum 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

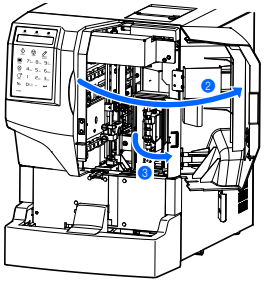
1 Open the column box.

❶ Make sure the standby screen is displayed.

❷ Open the front cover.

REFERENCE:

The message “W-062 Front cover is open” appears, even though there is no problem with the instrument. Proceed without canceling the warning.



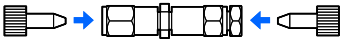
❸ Open the column box.

2 Store the column.

❶ Remove the column from the column holder. Press the tube until it is protruding about 3 mm from the push screws on both the IN and OUT sides.

- See step **3** in "4.4.2. Replacing the Column" on page 4-20.

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.

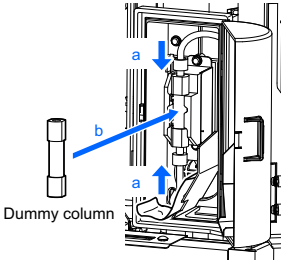
3 Install the dummy column.

❶ Install 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 column box and front cover.

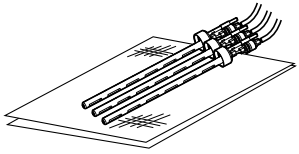
❸ Press ↵.

- Warning "W-062" will be cancelled.

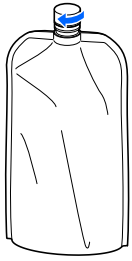
4 Store the eluent packs.

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, away from direct sunlight.

5 Turn off the power.

❶ Press the power switch to turn off the power.

6 Wash the eluent tubes.

❶ Add a small volume of distilled water to an empty aluminum pack and rinse the inside. Use the aluminum 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 aluminum pack with a beaker.

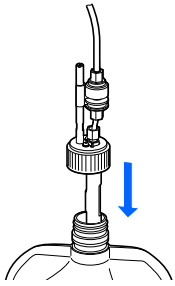
NOTE:

- 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 aluminum pack and tighten the cap securely.

❹ Attach other nozzles to their respective aluminum packs in the same way.

❺ Press the power switch to turn on the power.



❻ On the standby screen, press PRIMING, and then select <1) Auto>.

- Priming will stop automatically when the eluent tubes are filled with distilled water.

❼ Select <2) Pump>.

- The switching valves and optical unit will be washed.

❽ About 3 minutes after pumping starts, press STOP.

- Fluid pumping will stop.

```
Pumping...   15kg/cm2
          Stop(STOP)
```

❾ Press ESC one or more times to return to the standby screen.

7 Drain distilled water from the tubes.

❶ Remove the bottle caps with nozzle from the aluminum packs.
- Place the nozzles on the gauze.

❷ Discard all of the distilled water in the aluminum packs.

NOTE:
- Hold the aluminum pack by the hard plastic neck while discarding the distilled water from the pack.
- Dry the aluminum packs thoroughly, then keep them in the accessory case.

❸ Drain distilled water from the tubes.
- See step **2** in "1.6.2. Draining Fluid from the Tubes" on page 1-30.
- Distilled water will be drained from the eluent tubes.

❹ Press ESC one or more times to return to the standby screen.

8 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, away from direct sunlight.

9 Wash the tube for hemolysis washing solution.

❶ On the standby screen, press MENU twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>.

❹ Press MENU.

❺ Select <4) Drain>.

❻ Press MENU.

❼ Select <4) Washing sol.>.
- The tube for hemolysis washing solution will be washed.
- Tube washing will automatically stop.

❽ Select <4) Washing sol.> again.
- Wait until washing finishes.

❾ Press ESC one or more times to return to the standby screen.

10 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 Perform steps **9**.
- The distilled water will be drained from the hemolysis washing solution tube.

11 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 can remain connected to the instrument.

NOTE:
If you store the nozzles without washing, fluid may crystallize and clog the nozzles.

12 Discard liquid waste.

❶ Discard liquid waste remaining in the bottle for liquid waste.

13 Turn off the power.

❶ Press the power switch to turn off the power.

❷ Unplug the power cord from the outlet.

4.7.2 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 packs of eluent A, B and CV on the bottle tray.
- See step **4** in "4.3.1. Replacing the Eluent Packs" on page 4-9.

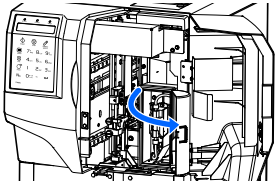
❷ Place the hemolysis washing solution bottle on the bottle tray.
- See step **4** in "4.3.2. Replacing the Hemolysis Washing Solution Bottle" on page 4-13.

NOTE:
If you set a reagent from a different lot, set its reagent information after step **4**. It is also recommended to perform HbA1c calibration after step **6**.

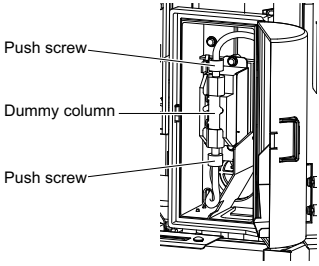
2 Check if the dummy column is installed.

❶ Open the front cover.

❷ Open the column box.



❸ Check the following:
- The dummy column is installed 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 properly installed, liquid may leak, resulting in trouble during fluid pumping.

❹ Close the column box, then the front cover.

3 Turn on the power.

❶ Plug the power cord into an outlet.

❷ Press the power switch.
- The power will turn on.

4 Set the date and time.

❶ Set the correct date and time.
- See “3.5.1. Setting the Date and Time” on page 3-19.

5 Perform priming.

❶ Perform priming.
- See step **1** in “1.5.3. Installing the Column” on page 1-25

6 Install the column.

❶ Install the column.
- See “4.4.2. Replacing the Column” on page 4-19.
- In step **3**, remove the “dummy column” instead of the “old column”.
- In step **8**-❸, **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 and how to replace fuses.

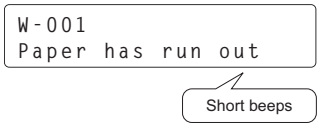
5.1 If a Warning Occurs

Warnings inform you of shortages of reagents and consumables, parts that require replacement and incorrectly set samples. In many cases, you can continue measurement after taking simple remedial action.

5.1.1 From Warning Occurrence to Remedy

If a warning occurs, follow the instructions described below to clear it.

❶ The instrument notifies you of a warning by:
- Emitting short beeps.
- Displaying a warning code and message.



❷ Check the warning code and message, and press ↵.

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 START.
- Measurement will start.

❺ If the warning persists, turn off the power and contact your distributor.

5.1.2 Causes and Remedies

- Wear protective gloves to prevent exposure to pathogenic microorganisms 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	Paper has run out
Cause	① Printer paper has run out. Or, printer paper is not correctly loaded. ② The printer cover is open.
Remedy	Press ↵ to clear the warning. ① Load a new paper roll (see page 4-16). *Printing will automatically restart when paper is loaded. ② Close the printer cover.

W-008	Discard liquid waste
Cause	The optional liquid waste bottle is full of liquid waste.
Remedy 	Press ↵ to clear the warning. Discard liquid waste from the bottle (see page 4-4).

W-009	No data
Cause	There are no measurement results or error/trouble history that matches the search condition.
Remedy	Press ↵ to clear the warning.

W-011	Abnormal CTRL value
Cause	① Control expected values are not set correctly. ② The control error range is not set correctly. ③ Calibration has not been performed correctly. Or, calibration coefficients have not been set correctly. ④ There is a problem with the controls.
Remedy 	Press ↵ to clear the warning. ① Set the control expected values correctly (see page 3-12). ② Set the control error range correctly (see page 3-12). ③ Perform HbA1c automatic calibration (see page 2-29). ④ Retry control measurement using a new control.

W-021	A1c R. time (early) * Printed on measurement result reports as an abnormal result message.
Cause	① Different types of eluents are mixed up because a wrong bottle cap has been fit on a wrong eluent pack. ② Eluent has degraded. ③ The column has degraded.
Remedy 	Press ↵ to clear the warning. ① Clean the nozzle and attach it to the correct eluent pack (see page 5-22). ② Replace the eluent pack with a new one (see page 4-9). ③ Replace the column with a new one (see page 4-19).

W-022	A1c R. time (late) * Printed on measurement result reports as an abnormal result message.
Cause	① The column has degraded. ② Eluent has degraded. ③ Eluent has been diluted. ④ Fluid is leaking from the tubes between the main pump, column and optical unit. ⑤ Air bubbles have formed in the tubes.
Remedy 	Press ↵ to clear the warning. ① Replace the column with a new one (see page 4-19). ② Replace the eluent pack with a new one (see page 4-9). ③ Replace the eluent pack with a new one (see page 4-9). ④ Perform fluid pumping (see page 4-35: select <2) Pump>). Open the column box while pumping fluid, and tighten the tube that is leaking. ⑤ Perform priming for the tube and perform fluid pumping to it (see page 4-35: select <1) Auto> and then <2) Pump>).

W-023 W-024 W-025	A1c R. time change A0 R. time Last peak R. time * Printed on measurement result reports as an abnormal result message.
Cause	① Fluid is leaking from the tubes between the main pump, column and optical unit. ② Air bubbles have formed in the tubes.
Remedy 	Press ↵ to clear the warning. ① Perform fluid pumping (see page 4-35: select <2) Pump>). Open the column box while pumping fluid, and tighten the tube that is leaking. ② Perform priming for the tube and fluid pumping to it (see page 4-35: select <1) Auto>, and then <2) Pump>).

W-037	Incorrect RGNT type
Cause	① The entered reagent code is incorrect. ② An incorrect type of reagent code was entered.
Remedy	Press ↵ to clear the warning. ① Enter the correct reagent code. ② Enter the correct type of reagent code.

W-038	Exp. date has passed
Cause	① The entered reagent code is invalid because the reagent has expired. ② The entered reagent code is incorrect. ③ The date and time of the internal clock do not match the actual date and time.
Remedy	Press ↵ to clear the warning. ① Prepare a new reagent within its expiration date. ② Enter the correct reagent code. ③ Set the date and time correctly (see page 3-19).

W-039	Incorrect MFG date
Cause	① The entered reagent code is incorrect. ② The date and time of the internal clock do not match the actual date and time.
Remedy	Press ↵ to clear the warning. ① Enter the correct reagent code. ② Set the date and time correctly (see page 3-19).

W-041	Light volume is low * Printed on measurement result reports as an abnormal result message.
Cause	① The hemolysis sample was incorrectly diluted. ② Air bubbles have formed in the optical unit cell.
Remedy 	Press ↵ to clear the warning. ① Prepare samples so that the hemoglobin concentration is between 45 mg/dL and 140 mg/dL (standard 94 mg/dL). ② Perform fluid pumping (see page 4-35: select <2) Pump>).

W-043	High pressure * Printed on measurement result reports as an abnormal result message.
Cause	① The tubes between the main pump, column and optical unit are clogged. ② The column has degraded.
Remedy 	Press ↵ to clear the warning. Replace the column with the dummy column (see page 4-39) and perform fluid pumping (see page 4-35: select <2) Pump>). If fluid pumping finishes without any problem, replace the column with a new one (see page 4-19). If the warning persists, turn off the power and contact your distributor.

W-044	Low pressure * Printed on measurement result reports as an abnormal result message.
Cause	① Air is trapped in the tubes between the eluent pack, temperature control box and main pump. ② Fluid is leaking from the tubes between the main pump, column and optical unit.
Remedy 	Press ↵ to clear the warning. After measurement stops, perform the following steps. ① Remove air from the tube by priming (see page 4-35: select <1) Auto>). ② Perform fluid pumping (see page 4-35: select <2) Pump>). Open the column box while pumping fluid, and tighten the tube that is leaking.

W-045 W-046	**Temp. (temp ctrl box)** **Temp. (column block)** *** Printed on measurement result reports as the abnormal result message "Temp. out of range".**
Cause	① The room temperature is outside the measurement environment temperature range of between 10°C and 30°C. ② The column box is open.
Remedy	Press ↵ to clear the warning. ① Adjust the room to a temperature between 10°C and 30°C. ② Close the column box.

W-051	**Calibrator expired**
Cause	① The HbA1c calibrator is beyond its expiration date. ② The date and time of the internal clock do not match the actual date and time.
Remedy	Press ↵ to clear the warning. ① Retry HbA1c automatic calibration using a new HbA1c calibrator (see page 2-29). ② Set the date and time correctly (see page 3-19).

W-052	**No washing sol.**
Cause	The hemolysis washing solution has run out.
Remedy	Press ↵ to clear the warning. Replace the bottle with a new one (see page 4-13).

W-053 W-054 W-055	**No Eluent A** **No Eluent B** **No Eluent CV**
Cause	Eluent A, B or CV has run out.
Remedy	Press ↵ to clear the warning. Replace the indicated eluent pack with a new one (see page 4-9).

W-058	**Liq. waste bot. full**
Cause	The optional liquid waste bottle is full.
Remedy	Press ↵ to clear the warning. Discard liquid waste from the bottle (see page 4-4).

W-060	**HbA1c not calibrated**
Cause	① HbA1c automatic calibration was not performed after instrument installation. ② The HbA1c calibration results have become invalid after column replacement.
Remedy	Press ↵ to clear the warning. Perform HbA1c automatic calibration (see page 2-29).

W-062	Front cover is open
Cause	The front cover is open.
Remedy	Close the cover. Press ↵ to clear the warning.

W-071	Abnormal CTRL value
Cause	① Control expected values are not set correctly. ② The control error range is not set correctly. ③ Calibration has not been performed correctly. Or, calibration coefficients have not been set correctly. ④ There is a problem with the controls.
Remedy 	Press ↵ to clear the warning. ① Set the control expected values correctly (see page 3-12). ② Set the control error range correctly (see page 3-12). ③ Perform HbA1c automatic calibration (see page 2-29). ④ Retry control measurement using a new control.

W-081	Internal BCR
Cause	More barcodes in the batch were misread than the number set in “Count of misread barcodes” under “A1c MEAS setup.”
Remedy 	Press ↵ to clear the warning. Attach the barcode label to the correct position on the sample tube. Set sample tubes so that the barcode labels face the internal barcode reader. Set the sample tubes in the sample racks correctly.

W-085	Incorrect ID entry
Cause	The ID entered on the screen is different from that read from the barcode on the sample tube.
Remedy	Press ↵ to clear the warning. **When reading IDs from barcode labels on the sample tubes:** Do not enter IDs on the ID entry screens for the ports in which the sample tubes are set. **When entering IDs on the screen using the alphanumeric buttons or hand-held barcode reader:** Set the sample tube in the port so that the barcode label is not facing the rear of the rack. Or, remove the barcode label before setting the sample tube in the port.

W-090	Unloading side full
Cause	There are two sample racks with already measured samples in the unloading side of the sampler.
Remedy 	Press ↵ to clear the warning. Remove the sample racks from the unloading side.

5.2 If an Error Occurs

Errors occur due to improper instrument settings or measurement preparations that may affect measurement results. In many cases, you can continue measurement by following simple remedial procedures.

5.2.1 From Error Occurrence to Remedy

If an error occurs, follow the instructions described below to clear it.

❶ The instrument notifies you of an error by:
- Emitting short beeps.
- Displaying an error code and message.
- Printing an error code and message.

❷ Check the error code and message, and press ↵.

❸ Take the necessary action to remove the cause.
- See “5.2.2. Causes and Remedies” on page 5-9 and later.

❹ If measurement results were not obtained for samples due to the error, load those samples onto the sampler again and press START.
- Measurement will start.

❺ If the error persists, turn off the power and contact your distributor.

REFERENCE:
- See “2.7.5. Error/Trouble History” on page 2-42.
- See “3.6.1. Printing Error/Trouble History” on page 3-23.

5.2.2 Causes and Remedies

- Wear protective gloves to prevent exposure to pathogenic microorganisms 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 CPU program was upgraded to a newer version.
Remedy	Press ↵ to clear the error.

E-101	Power down
Cause	The power was turned off during measurement operations.
Remedy 	Press ↵ to clear the error. When the standby screen appears, retry measuring samples for which measurement results were not obtained.

E-102	Date & time
Cause	The date and time are set incorrectly.
Remedy	Press ↵ to clear the error. Set the date and time correctly (see page 3-19).

E-104	Power down(saving)
Cause	The power was turned off while data was being saved.
Remedy	Press ↵ to clear the error. Make settings again if new settings have been cleared.

E-106	Sub ver. change
Cause	The sub CPU program was upgraded to a newer version.
Remedy	Press ↵ to clear the error.

E-107	Racksub ver. change
Cause	The rack sub CPU program was upgraded to a newer version.
Remedy	Press ↵ to clear the error.

E-110	No HbA1c STD value
Cause	The calibration information barcode could not be read.
Remedy 	Press ↵ to clear the error. Attach the calibration information barcode label to the correct position on empty sample tubes. Set the sample tubes in ports 1 and 2 of the first calibration rack, and retry HbA1c automatic calibration (see page 2-29).

E-111	STD sol. loading
Cause	Dummy samples or the standard solutions are not set in the correct ports.
Remedy 	Press ↵ to clear the error. Set dummy samples and the standard solutions in the calibration racks correctly and retry measurement (see page 2-30).

E-112	Abnormal CAL
Cause	① Standard values of the standard solutions are not set correctly. ② The standard solutions were diluted with an incorrect diluent or incorrectly diluted. ③ The calibrator has not been stored properly. ④ The error range for automatic calibration was set incorrectly.
Remedy 	Press ↵ to clear the error. ① Enter the correct standard values for the standard solutions. ② Use the calibrator specified by your distributor to dilute the Low and High solutions in the correct ratio. ③ Use a fresh bottle of calibrator to prepare the standard solutions. ④ Set the error range for automatic calibration correctly (see page 3-12).

E-120	Loading side full
Cause	The loading side of the sampler is full of sample racks.
Remedy 	Remove the sample racks from the loading side. Press ↵ to clear the error.

E-121	Memory full
Cause	① Measurement results for 300 samples are suspended from being printed because the printer paper has run out. ② Measurement results for 300 samples are suspended from being transferred because the external device is not connected to the communication cable. If more measurements are performed, the oldest result will be overwritten with the newest one.
Remedy	Press ↵ to clear the error. ① Load a new paper roll (see page 4-16). Suspended measurement results will be printed out. ② If the communication cable is disconnected, connect it (see page 1-21). Suspended measurement results will be transferred.

E-122	Wash. sol. setting
Cause	① Automatic tube washing was started without first loading the normal rack onto the sampler. ② No sample tube with the washing solution for tubes is set in the normal rack.
Remedy	Press ↵ to clear the error. Set a sample tube with the washing solution for tubes in the normal rack. Load the rack onto the sampler, and then start automatic tube washing.

5.3 If Trouble Occurs

Trouble is indicated if there is a serious problem with the electrical circuits, measurement unit, drive unit or other parts of the instrument.

5.3.1 From Trouble Occurrence to Remedy

If trouble occurs, follow the instructions described below to clear it.

❶ The instrument alerts you to trouble by:
- Two different long tones in series.
- Displaying a trouble code and message.
- Printing a trouble code and message.

❷ Check the trouble code and message, and take the necessary action to remove the cause.
- See “5.3.2. Causes and Remedies” on page 5-12 and later.

❸ If measurement results were not obtained for samples due to the trouble, load those samples onto the sampler again and press START.
- Measurement will start.

❹ If the trouble persists, turn off the power and contact your distributor.

REFERENCE:
- See “2.7.5. Error/Trouble History” see page 2-42.
- See “3.6.1. Printing Error/Trouble History” see page 3-23.

5.3.2 Causes and Remedies

- Wear protective gloves to prevent exposure to pathogenic microorganisms 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-205** **T-215**	**ROM reading error** **ROM writing error** **ROM deleting error**
Cause	There is a trouble with the flash ROM in which data is stored.
Remedy	Turn off the power and contact your distributor.

T-210	**Printer**
Cause	The printer did not operate properly.
Remedy	Remove any jammed printer paper and correctly set the paper roll. If the trouble persists, turn off the power and contact your distributor.

T-224	**Sub-CPU com.**
Cause	Communication with the sub CPU failed.
Remedy	Turn off the power and contact your distributor.

T-227	**Rack sub-CPU com.**
Cause	Communication with the rack sub CPU failed.
Remedy	Turn off the power and contact your distributor.

T-300 **T-307**	**Pierc. nozzle F/B** **Pierc. nozzle U/D**
Cause	① Something is obstructing the piercing nozzle. ② The piercing nozzle did not operate properly.
Remedy 	Remove the obstruction near the piercing nozzle. Press ↵ to clear the trouble. If the trouble persists, turn off the power and contact your distributor.

T-320	**Sample pump**
Cause	There is a problem with the sample pump drive unit.
Remedy 	Turn off the power and contact your distributor.

T-354	Introduced sample
Cause	① Whole blood sample of low hemoglobin concentration was measured. ② The hemoglobin concentration of the hemolysis sample is too low due to an incorrect dilution ratio. ③ The sample volume is insufficient. ④ Hemolysis sample was measured, though <WHOLE> or <ANEMIA> was selected as the sample type. ⑤ Air bubbles have formed while the sample was being aspirated or discharged.
Remedy 	Press ↵ to clear the trouble. ① Prepare samples so that the hemoglobin concentration is between 45 and 140 mg/dL (standard 94 mg/dL), and select <HEMOL> as the sample type before measurement. Select <ANEMIA> as the sample type when measuring anemia samples. ② Prepare samples so that the hemoglobin concentration is between 45 and 140 mg/dL (standard 94 mg/dL). ③ 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. ④ Select the correct sample type (see page 2-19). ⑤ Perform priming (see page 4-35: select <1) Auto>). If the trouble persists, turn off the power and contact your distributor.

T-380	Leak dil. container
Cause	Fluid is leaking in the dilution container unit due to the clogged dilution container or washing container.
Remedy	Turn off the power and contact your distributor.

T-403 T-405	Temp. (temp ctrl box) Temp. (column block)
Cause	① The room temperature is outside the measurement environment temperature range of between 10°C and 30°C. ② The column box is open.
Remedy	Press ↵ to clear the trouble. ① Adjust the room to a temperature between 10°C and 30°C. ② Close the column box. If the trouble persists, turn off the power and contact your distributor.

T-413	Temp. (inside)
Cause	The room temperature is outside the measurement environment temperature range of between 10°C and 30°C.
Remedy	Press ↵ to clear the trouble. Adjust the room to a temperature between 10°C and 30°C. If the trouble persists, turn off the power and contact your distributor.

T-420	Degasser unit
Cause	There is a problem with the degasser unit.
Remedy	Turn off the power and contact your distributor.

T-430	Main pump
Cause	There is a problem with the main pump.
Remedy	Turn off the power and contact your distributor.

T-432 T-433 T-434	Switching valve 1 Switching valve 2 Switching valve 3
Cause	There is a problem with the switching valve drive unit.
Remedy	Turn off the power and contact your distributor.

T-440	Leak temp. cont. box
Cause	Fluid is leaking from the parts or tubes in the temperature control box.
Remedy	Turn off the power and contact your distributor.

T-441	Leak column box
Cause	Fluid is leaking from the column or column tube, and pooling inside the column box.
Remedy 	Turn off the power. Check that the column is properly connected to the IN and OUT sides, and retighten the push screws (see page 4-19). Blot up liquid pooled in the leak detector in the column box. If the trouble persists, turn off the power and contact your distributor.

T-442	Leak main pump
Cause	Fluid is leaking from the main pump.
Remedy	Turn off the power and contact your distributor.

T-443	Leak optical unit
Cause	Fluid is leaking from the optical unit.
Remedy	Turn off the power and contact your distributor.

T-450	ABNML PRESS (high)
Cause	Pressure in the tubes is excessively high.
Remedy	Turn off the power and contact your distributor.

T-457	ABNML PRESS (low)
Cause	① Air is trapped in the tubes. ② Fluid is leaking from the column or column tube.
Remedy 	Press ↵ to clear the trouble. ① Remove air from the tube by priming (see page 4-35: select <1) Auto>). ② Check that the column is properly connected to the IN and OUT sides, and retighten the push screws (see page 4-19). Blot up liquid pooled in the column box. Turn off the power and contact your distributor.

T-472 T-473 T-480	**Temp. (light source)** **Temp. (opt. block)** **Opt. unit detector**
Cause	The room temperature is outside the measurement environment temperature range of between 10°C and 30°C.
Remedy	Press ↵ to clear the trouble. Adjust the room to a temperature between 10°C and 30°C. If the trouble persists, turn off the power and contact your distributor.

T-481	**Low opt. unit light**
Cause	① The hemoglobin concentration of the hemolysis sample is too high. ② Air bubbles have formed in the optical unit cell.
Remedy	Press ↵ to clear the trouble. ① Prepare samples so that the hemoglobin concentration is between 45 and 140 mg/dL. ② Perform fluid pumping (see page 4-35: select <2) Pump>). After 3 minutes, press STOP. If the trouble persists, turn off the power and contact your distributor.

T-482 T-483 T-490	**Strong opt. light** **Optical unit light** **Background**
Cause	Air bubbles have formed in the optical unit cell.
Remedy	Press ↵ to clear the trouble. Perform fluid pumping (see page 4-35: select <2) Pump>). If the trouble persists, turn off the power and contact your distributor.

T-600	**BCR communication**
Cause	Communication with the internal barcode reader failed.
Remedy	Turn off the power and contact your distributor.

T-602	**Sampler**
Cause	There is a problem with the sampler drive unit.
Remedy	Turn off the power and contact your distributor.

T-800	**Serial communication**
Cause	A problem occurred in communications with an external device.
Remedy	Press ↵ to clear the trouble. Connect the cable from the external device to the COM1 terminal on the rear panel of the instrument correctly.

T-811	**No matching ID**
Cause	The external device transmitted an abnormal command for measurement.
Remedy	Press ↵ to clear the trouble. Check if the external device is communicating with the instrument correctly.

T-820	Ethernet com.
Cause	① The external device is not connected to the LAN. Or, the external device cannot communicate through the LAN. ② There is a problem with the LAN cable.
Remedy	Press ↵ to clear the trouble. ① Connect the external device to the LAN. Or, enable LAN communication (for example, by turning on the external device). ② Connect the LAN cable to the COM2 terminal on the rear panel of the instrument correctly.

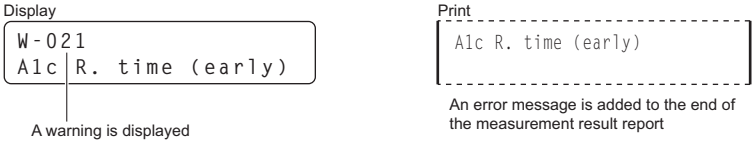
T-999	Other trouble
Cause	Other trouble occurred.
Remedy	Write down the information displayed on the screen, turn off the power and contact your distributor.

5.4 Abnormal Result Messages

A following warning or “Abnormal-(No.)” appears on the display if inaccurate measurement results are obtained. Subsequent measurements will continue even if an abnormal measurement result is obtained.

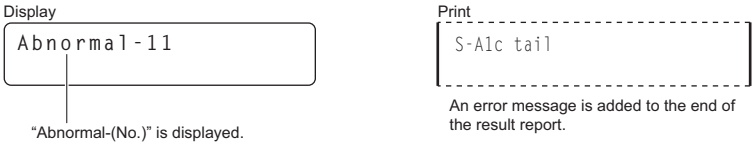
5.4.1 Warning W-021 to W-046

See “5.1.2. Causes and Remedies” on page 5-3 and later.



Display		Print
W-021	A1c R. time (early)	A1c R. time (early)
W-022	A1c R. time (late)	A1c R. time (late)
W-023	A1c R. time change	A1c R. time change
W-024	A0 R. time	A0 R. time
W-025	Last peak R. time	Last peak R. time
W-041	Light volume is low	Light volume is low
W-043	High pressure	High pressure
W-044	Low pressure	Low pressure
W-045	Temp. (temp ctrl box)	Temp. out of range
W-046	Temp. (column block)	

5.4.2 Abnormal-11 to Abnormal-27



Display	Abnormal-11	Print	S-A1c tail
Cause	• The S-A1c tail rises more than the threshold value.		

Display	Abnormal-12	Print	Drift baseline
Cause	• The baseline drifted more than the threshold value.		

Display	Abnormal-13	Print	Noise detected
Cause	• Noise was detected in the chromatogram.		

Display	Abnormal-14	Print	Duplex peaks
Cause	• Two or more peaks were detected for either HbF, L-A1c or S-A1c.		

Display	Abnormal-15	Print	Hb: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. • The hemoglobin concentration is below the lower limit of the range specified for that sample type. • Excessive volume of sample in a recapped sample tube was measured.		

Display	Abnormal-17	Print	HbA0:High value
Cause	• The HbA0 area was larger than the threshold value. • The hemoglobin concentration is over the upper limit of the range specified for that sample type.		

Display	Abnormal-18	Print	Hb:Abnormally low
Cause	• The difference between the maximum and minimum volume of light absorption was less than the threshold value. • The sample volume was insufficient. • The hemoglobin concentration is below the lower limit of the range specified for that sample type. • Excessive volume of sample in a recapped sample tube was measured.		

Display	Abnormal-19	Print	No S-A1c peaks
Cause	• The S-A1c peak could not be detected.		

Display	Abnormal-22	Print	Abnormal peak count
Cause	• Less than two peaks could be detected. • Twenty or more peaks were detected. • The first peak showed a result other than HbA1ab.		

Display	Abnormal-23	Print	Hb:High value
Cause	• Light absorption was higher than the threshold value. • The hemoglobin concentration is over the upper limit of the range specified for that sample type.		

Display	Abnormal-24	Print	L-A1c tail
Cause	• The column has degraded.		

Display	Abnormal-25	Print	Peak(E) detected
Cause	• HbE was detected in the chromatogram.		

Display	Abnormal-26	Print	Peak(D) detected
Cause	• HbD was detected in the chromatogram.		

Display	Abnormal-27	Print	HbA0:Bottom
Cause	• The HbA0 bottom rises more than the threshold value.		

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 the power, there is a possibility that a fuse has blown. The instrument has a pair of fuses that can be accessed and replaced from the rear panel. Replace whichever is blown.

> ⚠ Use only fuses of the specified capacity. Over- or under-rated fuses may lead to fire or damage to the instrument. Make sure you have fuses with the specified capacity before replacement.

NOTE:
If the fuses blow soon after the replacement, there is something wrong with the instrument. Contact your distributor.

Prepare: Fuses (T4AE 250V) and flat-head screwdriver

1 Turn off the power.

❶ Press the power switch to turn off the power.

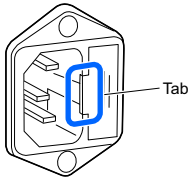
❷ Unplug the power cord from the outlet.

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

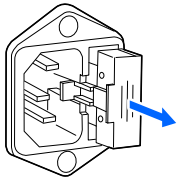
> ⚠ Keep the power cord unplugged until otherwise instructed in this procedure.

2 Open the fuse holder.

❶ Slightly lift up the tab (boxed area shown on the right) with a flat-head screwdriver.

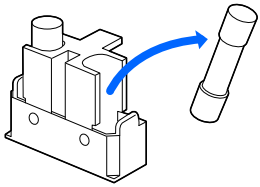


❷ Pull the fuse holder straight to the front.



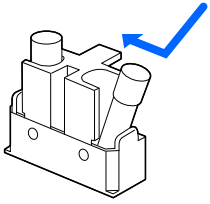
3 Replace the fuse.

❶ Remove the blown fuse from the fuse holder.



❷ Set a new fuse in the fuse holder.

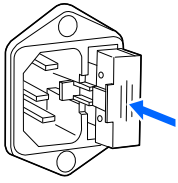
- Tilt the fuse slightly and insert it into the holder, and then stand it upright to correctly install it.



4 Store the fuse holder.

❶ Hold the fuse holder with the tab to the left side, and insert the holder into its original position.

- Push the holder until it stops.



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 power switch.

- The power will turn on.

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 attach the bottle cap correctly. Eluents A, B and CV differ in composition. If you change nozzles without first cleaning them, that will cause mixing of eluents and inaccurate measurement results.

Prepare: Cap for eluent pack (that was originally on the pack before opening) and gauze

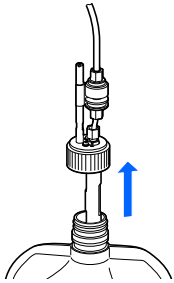
1 Clean the eluent nozzle.

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 fluid from the nozzle.

❶ On the standby screen, press twice, and select <3) Sub menu>.

❷ Press MENU three times.

❸ Select <7) Maintenance>.

❹ Press MENU.

❺ Select <4) Drain>.

❻ Select the type of the nozzle to discharge fluid.
Example: If you removed the nozzle for eluent A from the pack of a different reagent in step 1, select <1) Eluent A>
- Eluent will be drained from the tube.
- After completion, the screen shown on the upper right will appear again.

```
1)Eluent A
2)Eluent B        1/2
```

```
3)Eluent CV
4)Washing sol.    2/2
```

❼ Press ESC one or more times to return to the standby screen.

3 Turn off the power.

❶ Press the standby switch to turn off the power.

4 Attach the nozzle to the correct eluent pack.

❶ Attach the bottle cap with nozzle to the correct eluent pack.

- See step **4** in "1.4.3. Setting Up Eluent Packs and Hemolysis Washing Solution Bottle" on page 1-16.

5 Perform priming.

❶ Press the standby switch to turn on the power.

❷ Perform priming.

- See step **1** in "1.5.3. Installing the Column" on page 1-25

Chapter 6 Appendix

This chapter gives you examples of printed reports on the instrument's parameter settings and self check results, and also lists measurement terminology. An index is provided at the end of this chapter.

6.1 Printed Report Examples

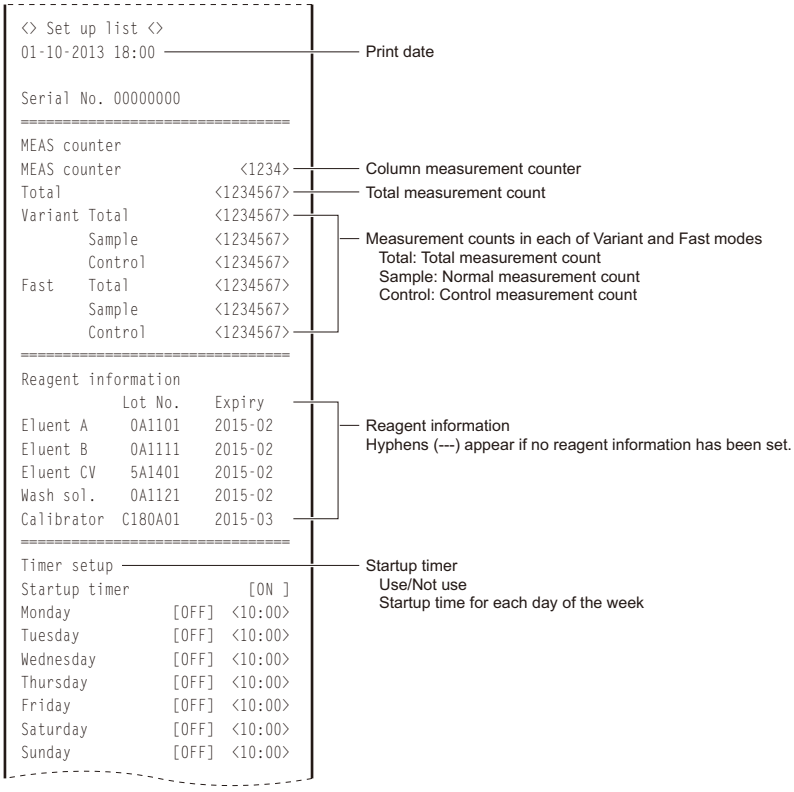
This section gives you examples of printed reports on the instrument's parameter settings and self check results.

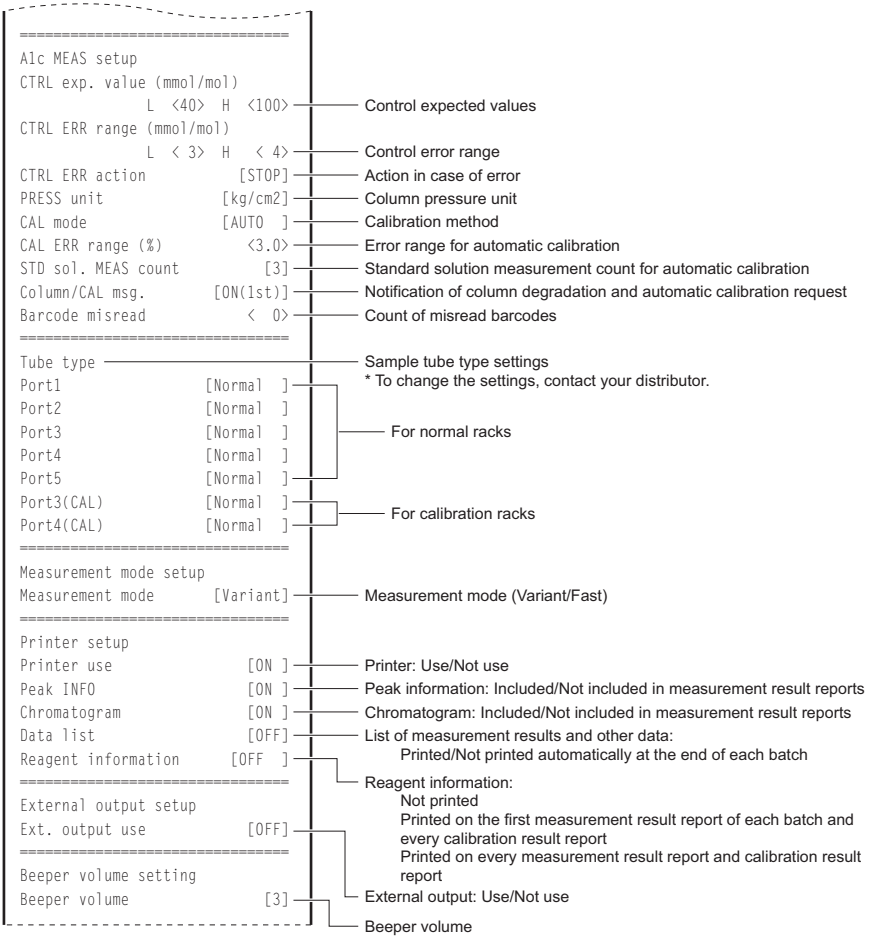
6.1.1 Current Parameter Settings

You can view the current parameter settings for control measurement, calibration, the printer and others.

REFERENCE:
See "3.6.5. Printing the Current Parameter Settings" on page 3-27.

Example




==========
A1c MEAS setup
CTRL exp. value (mmol/mol)
L <40> H <100>
CTRL ERR range (mmol/mol)
L < 3> H < 4>
CTRL ERR action [STOP]
PRESS unit [kg/cm2]
CAL mode [AUTO]
CAL ERR range (%) <3.0>
STD sol. MEAS count [3]
Column/CAL msg. [ON(1st)]
Barcode misread < 0>
==========
Tube type
Port1 [Normal]
Port2 [Normal]
Port3 [Normal]
Port4 [Normal]
Port5 [Normal]
Port3(CAL) [Normal]
Port4(CAL) [Normal]
==========
Measurement mode setup
Measurement mode [Variant]
==========
Printer setup
Printer use [ON]
Peak INFO [ON]
Chromatogram [ON]
Data list [OFF]
Reagent information [OFF]
==========
External output setup
Ext. output use [OFF]
==========
Beeper volume setting
Beeper volume [3]
Control expected values
Control error range
Action in case of error
Column pressure unit
Calibration method
Error range for automatic calibration
Standard solution measurement count for automatic calibration
Notification of column degradation and automatic calibration request
Count of misread barcodes
Sample tube type settings
* To change the settings, contact your distributor.
For normal racks
For calibration racks
Measurement mode (Variant/Fast)
Printer: Use/Not use
Peak information: Included/Not included in measurement result reports
Chromatogram: Included/Not included in measurement result reports
List of measurement results and other data:
Printed/Not printed automatically at the end of each batch
Reagent information:
Not printed
Printed on the first measurement result report of each batch and every calibration result report
Printed on every measurement result report and calibration result report
External output: Use/Not use
Beeper volume

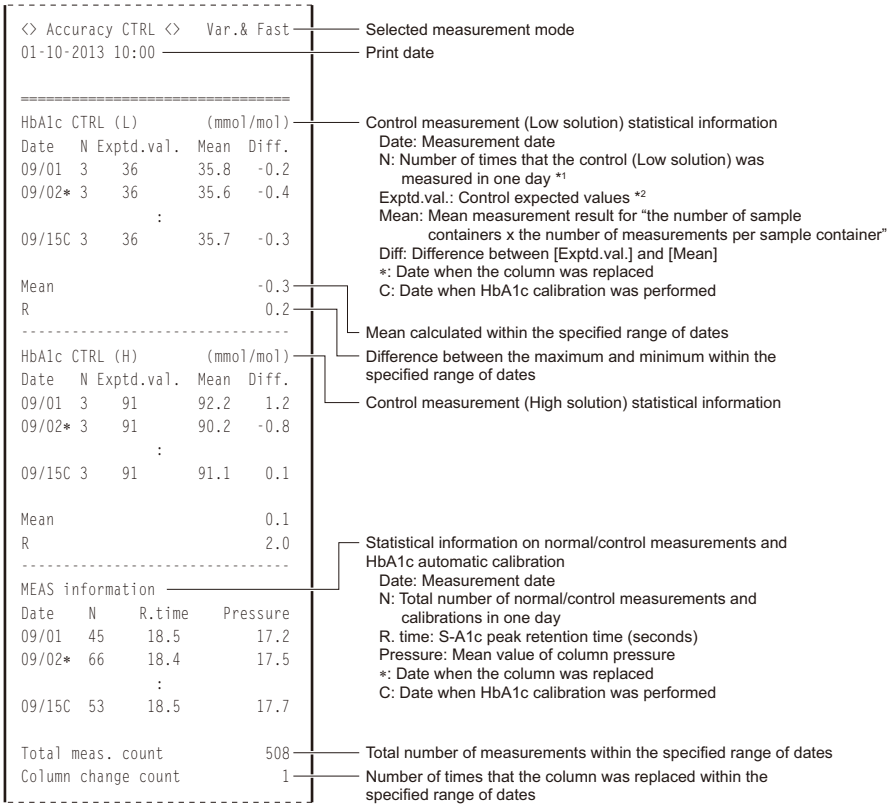
6.1.2 Accuracy Control Reports

Accuracy control reports show statistical information on control measurements and sample measurements for a specified period of time.

REFERENCE:

See “3.7.3. Printing Accuracy Control Reports” on page 3-30.

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

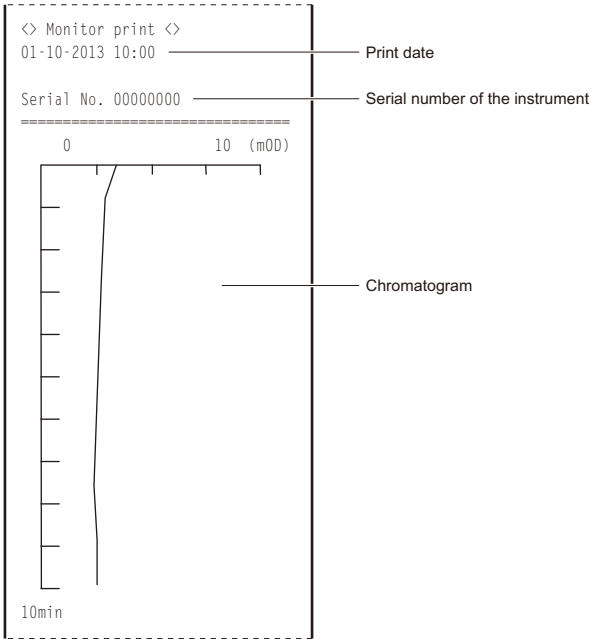
*2: The values set in the <Exp. val.> field are listed here. See “3.3.4. Setting the HbA1c Measurement Conditions” on page 3-12.

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:
See “3.7.4. Printing Optical Unit Monitoring Results” on page 3-31.

Example



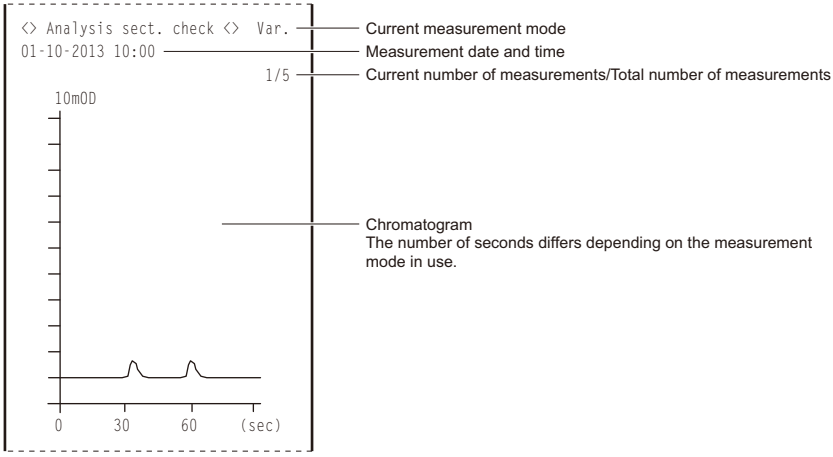
6.1.4 Check Measurement Results for the Analysis Section

A chromatogram is printed out each time hemolysis washing solution is measured during check measurement for the analysis section.

REFERENCE:

See “3.7.5. Performing Check Measurement for the Analysis Section” on page 3-32.

Example



6.1.5 HbA1c Reproducibility Test Results

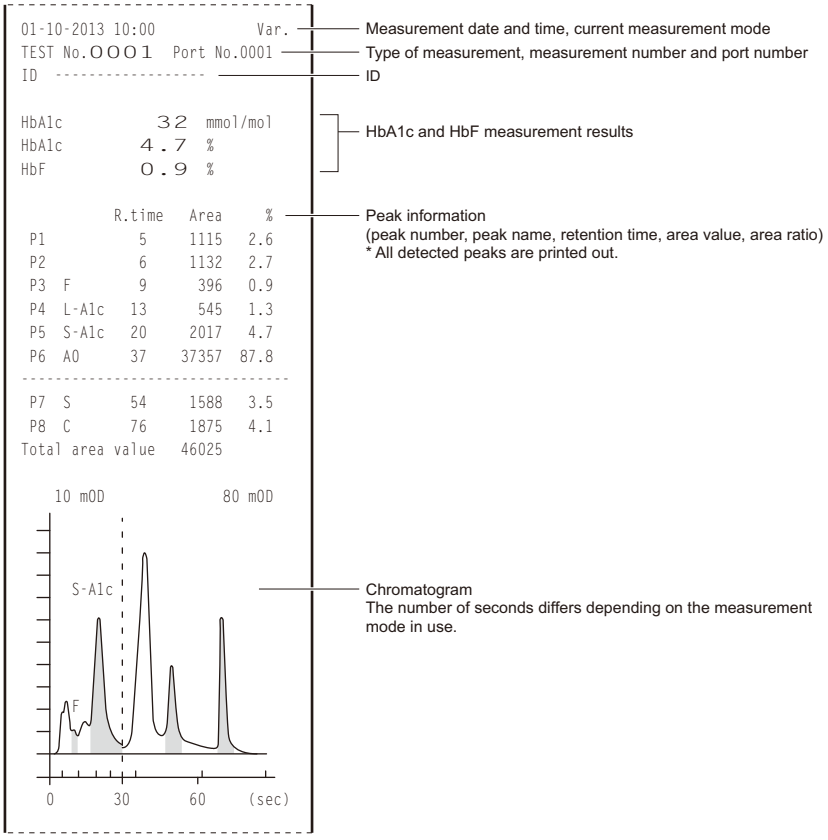
A measurement result report will be printed out each time sample is measured during HbA1c reproducibility tests. Self check results are also printed out after the test.

REFERENCE:

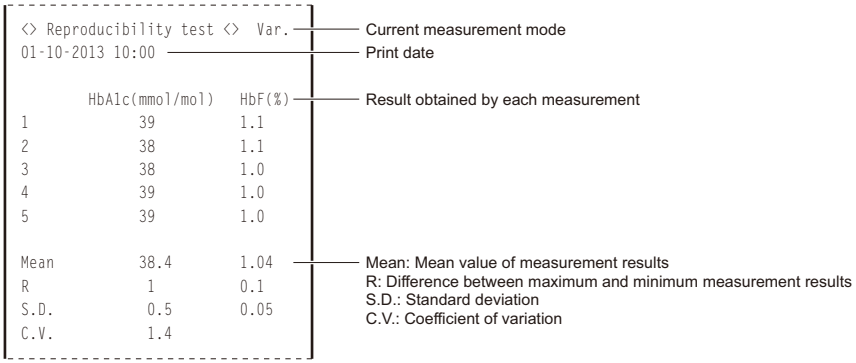
See “3.7.6. Testing HbA1c Reproducibility (Whole Blood Sample)” on page 3-33

and “3.7.7. Testing HbA1c Reproducibility (Hemolysis Sample)” on page 3-35.

Example: Measurement result report



Example: Reproducibility test result report



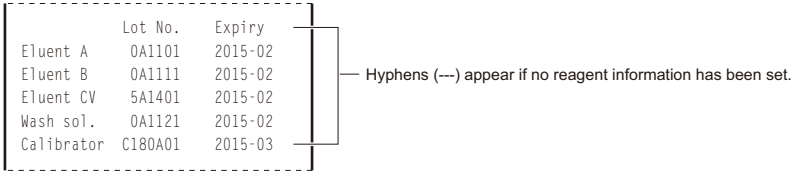
6.1.6 Reagent Information Report

Reagent information can be printed,

- On every calibration result report and,
- On the first measurement result report of each batch, or
- On every measurement result report.

Reagent information is not printed as a default. If needed, change the printer settings (see “3.5.2. Setting Up the Printer” on page 3-19).

Example



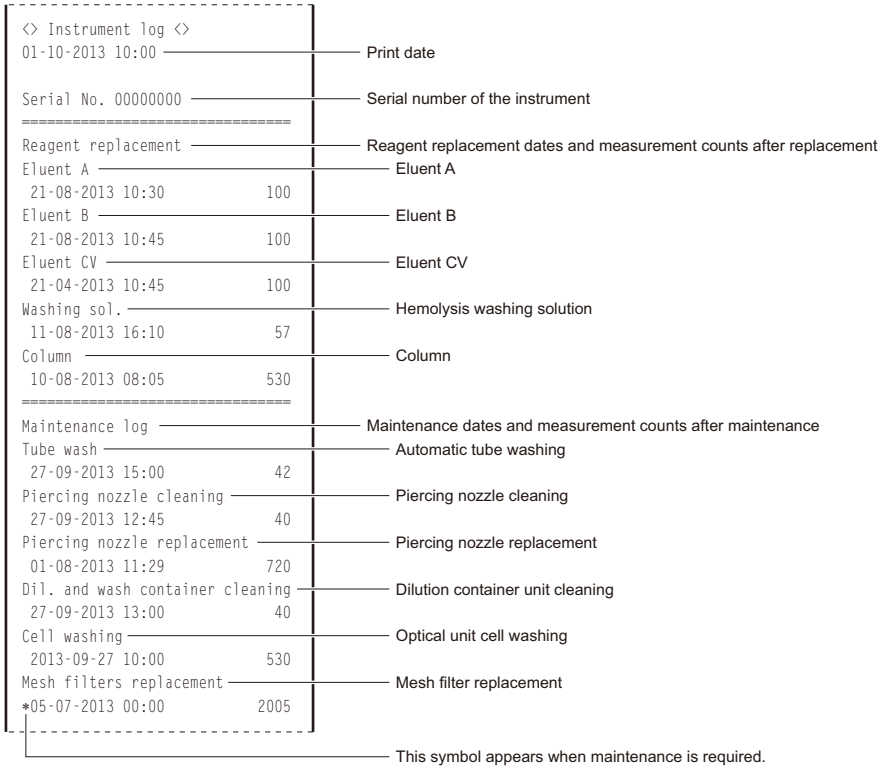
6.1.7 Maintenance Log Report

The maintenance log report lists the dates when reagents were last replaced and parts were last cleaned.

REFERENCE:

See “4.6.2. Printing the Maintenance Log” on page 4-38.

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 START has been pressed and until the standby screen appears again.

- Measurement number

A measurement number is a 4-digit code (0001 to 9999) that identifies each measurement result. Measurement numbers are automatically increased by one and assigned to samples in the order of measurements.

Screen during measurement

Printed measurement results report

Measurement type	Range of measurement numbers	Print example
Normal measurement	0001 to 9999	MEAS No.0001
HbA1c control measurement	0001 to 9999	CTRL No.0001
HbA1c automatic calibration (standard solution)	0001 to 0006	CAL No.0001
HbA1c automatic calibration (dummy sample)	0001, 0002	DMMY No.0001

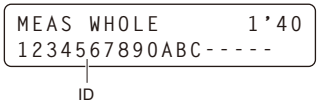
- Measurement start number

The measurement start number is assigned to the first sample in a batch of normal or control measurements. The instrument 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. You can also set any measurement start number using the alphanumeric buttons before starting measurement.

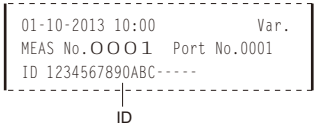
- ID

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. The internal barcode reader can automatically scan the barcode IDs on the labels on the sample tubes. You can also enter IDs using the alphanumeric buttons or the optional hand-held barcode reader.

Screen during measurement



Printed measurement results report

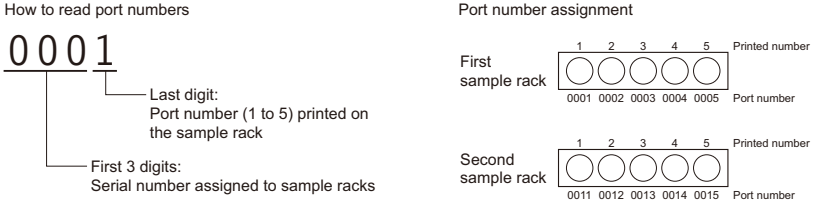


- Port number

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 number (1 to 5) marked on the top face of the sample rack.

The first three digits are a serial number (000 to 999) used to identify sample racks that have been set in the sampler. “000” indicates the first rack to be transported after START is pressed. The first three digits beginning with 9 (900 to 999) are used to identify control measurements and HbA1c automatic calibration results.



- Normal measurement

In normal measurement, samples are set in normal 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 TIMER lamp lights up yellow. 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) reference method
Unit of measure: mmol/mol

- NGSP value for HbA1c

HbA1c value compliant with NGSP (National Glycohemoglobin Standardization Program)
Unit of measure: %

- Measurement mode

The HA-8380V supports two measurement modes: Variant and Fast. The Variant mode detects HbS and HbC in addition to measuring HbA1c and HbF. If HbS and HbC detection is unnecessary, setting the Fast mode shortens measurement time.

- Reagent information

Reagent information can be set in the HA-8380V to prove that the right reagents are being used for measurement. The reagent information can be printed on measurement result reports and calibration result reports.

6.3 Performance Characteristics

6.3.1 Analytical Performance

✣ 1) Trueness

Variant mode

JCCRM411 (certified reference material)	Difference between the measured value and the certified value
Level 1	0.00%
Level 2	-0.01%
Level 3	-0.06%
Level 4	-0.09%
Level 5	-0.06%

IFCC calibrator (certified reference material)	Difference between the measured value and the certified value
Level 1	0.15%
Level 2	0.10%
Level 3	0.07%
Level 4	0.14%
Level 5	0.19%
Level 6	0.19%
Level 7	0.03%
Level 8	-0.07%

Fast mode

JCCRM411 (certified reference material)	Difference between the measured value and the certified value
Level 1	-0.01%
Level 2	-0.07%
Level 3	-0.07%
Level 4	-0.08%
Level 5	-0.08%

IFCC calibrator (certified reference material)	Difference between the measured value and the certified value
Level 1	0.14%
Level 2	0.12%
Level 3	0.13%
Level 4	0.15%
Level 5	0.30%
Level 6	0.29%
Level 7	0.17%
Level 8	0.05%

2) Precision

Variant mode

Precision	C.V.%
Reproducibility (Between-day) Repeatability (Within-run)	0.32 - 0.51% 0.08 - 0.41%

Fast mode

Precision	C.V.%
Reproducibility (Between-day) Repeatability (Within-run)	1.06 - 1.22% 0.21 - 0.32%

3) Linearity

Variant mode

Difference between the measured value and the theoretical value	-0.18 - 0.09%

Fast mode

Difference between the measured value and the theoretical value	-0.15 - 0.17%

4) Interference

Substance	Test concentration with no significant interference
Carbamylated Hb (Sodium Cyanate)	20mg/dL
Aldehyde Hb (Acetaldehyde)	25mg/dL
Labile A1c (Glucose)	2000mg/dL
Bilirubin, conjugated	40mg/dL
Bilirubin, unconjugated	40mg/dL
Ascorbic Acid	200mg/dL

5) Investigation of Variant Hb

All samples containing HbS or HbC that were measured were correctly recognized by Variant mode.

6) Method comparison

Variant mode

Correlation coefficient with reference method *1	0.9993

Fast mode

Correlation coefficient with reference method *2	0.9990

*1 ADAMS A_{1C} HA-8180V Variant mode measurement
*2 ADAMS A_{1C} HA-8180 measurement

7) Matrix comparison

All available anticoagulants had no effect on the measurements.

6.3.2 Clinical Performance

Variant mode

Positive percent agreement	Negative percent agreement	Overall percent agreement
100.0%	100.0%	100.0%

vs. ADAMS A_{1C} HA-8180V Variant mode measurement

Fast mode

Positive percent agreement	Negative percent agreement	Overall percent agreement
98.6%	100.0%	99.0%

vs. ADAMS A_{1C} HA-8180 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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84-08102B


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