Tosoh Automated Glycohemoglobin Analyzer

HLC-723®G11

Operator's Manual
(Variant Analysis Mode)

Rev. H

This manual was written to ensure safe and proper use of the analyzer. Before using the analyzer, read this manual carefully in order to realize the full capacities of the system. Also, if you have something unclear during daily use or when a problem occurs, please refer to this manual.

TOSOH CORPORATION

BIOSCIENCE DIVISION

About This Manual

This Operator's Manual is designed to ensure that you can operate the Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 safely and correctly.

In this manual, Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 might be abbreviated as HLC-723G11.

This manual is geared to operators who have acquired all the technical qualifications required for working with the HLC-723G11.

It is recommended for users to carefully read and familiarize themselves with the information in this manual and operate the HLC-723G11 in strict accordance with the instructions provided. Keep this manual in a safe, easily accessible location for reference purposes.

Users must strictly adhere to all safety precautions outlined in this manual.

This manual presented is subject to change without prior notification due to ongoing enhancements to system performance and functionality.

Be sure to include this manual whenever selling or relocating the HLC-723G11.

Should you notice any discrepancies, errors or omissions in the information provided, you are requested to immediately notify Tosoh local representatives.

TRADEMARKS

Preface

It is recommended that both Super Users and Operators carefully read and familiarize themselves with the following safety precautions to ensure safe and correct operation of the analyzer. The information displayed using "WARNING" and "CAUTION" signs in this manual are provided for the purposes defined below.

WARNING Indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.

CAUTION Indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

Installation Precautions

WARNING

- **Operate only in accordance with the procedures described in this manual.**
  - Attempts to operate the HLC-723G11 using procedures not prescribed in this manual may adversely affect the integrity of assay results and cause system malfunctions.
  - Refer to the Instructions For Use of the TSKgel G11 Variant and G11 Variant Elution Buffers for detailed instructions.

- **Use only Tosoh designated columns, buffers, solutions, components and accessories for use with the HLC-723G11.**
  - Do not use columns, buffers, solutions or calibrators that have not been specified for use on the HLC-723G11.
  - Tosoh cannot be held liable for any consequences coming forth of the use of non-specified Column, Buffers, Solutions, components or accessories.
  - Use only accessories and consumables (supplies) listed in "**2.1 Parts Inspection**".
  - Only materials obtained from Tosoh should be used. Materials obtained elsewhere should not be substituted since assay performance is characterized based strictly on Tosoh materials.
  - To obtain an overview of the reagents, components and accessories specified for use on the HLC-723G11 please contact Tosoh local representatives.

- **Avoid making clinical judgments only based on the result obtained with the HLC-723G11.**
  - Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested.
  - In order to ensure quality and reliability of the assay, it is recommended to measure the commercially available control simultaneously at the time of the assay of a specimen.
  - Commercially available controls shall be run at least once per day. It is recommended that at least two levels of controls, normal and abnormal, be used.

- **Connect the analyzer to a suitable power supply.**
  - Make sure to connect the analyzer to a power supply with a sufficiently high power rating that is free of voltage fluctuations.
  - Power supplies that have an insufficient power rating or significant fluctuations in voltage may cause fire.

- **Carefully check the ground connections.**
  - Failure to properly ground the analyzer may cause an electrical shock.
  - Grounding the analyzer helps prevent a malfunction due to noise other than an electrical shock.
  - Do not connect the analyzer ground line to gas pipes, water pipes, lightning rod, or the telephone system ground line.

Gas pipes:	can ignite fires and cause explosions
Water pipes:	are not effective grounds
Lightning rod and telephone lines:	are a potential source of danger when lightning strikes

CAUTION

- **Select the installation site with care.**
  - Refer to "**2.4 Installation locations**" to select a suitable site for installation of the analyzer.

- **Do not change the power cable, nor use an extension cable, nor plug many cables into the same socket.**
  - They may cause fire or an electrical shock.
  - Make sure to unplug and insert the power cable several times a year.
  - Contamination by dust, failure to insert the plug firmly into the inlet socket, or a loose connection may cause an electrical shock or fire.

Precautions for Use

WARNING

- **Handle biohazards with care.**
  - Only personnel with sufficient knowledge of clinical laboratory tests and the procedures for handling infectious waste materials are allowed to operate the analyzer
  - There is always the possibility that the specimen may have been contaminated by infectious agents. Mistakes of operation and handling may cause the transmission of agents to the operator and nearby personnel. It is recommended that all specimens are handled with the utmost care and that the proper protective clothing (goggles, gloves, mask etc.) are worn at all times during maintenance.
  - Used columns, filters, sampling needles and cups may have been contaminated. It is recommended that the proper protective clothing (goggles, gloves, mask etc.) are worn at all times and that waste materials are disposed of in accordance with the relevant laws and regulations to protect the surrounding environment and the health.

⚠ CAUTION

- **Check for an eluent leakage**
  - Elution Buffer or Hemolysis & Wash Solution leakage may cause fire, an electrical shock or corrosion.
  - When an eluent or diluent leakage is found, stop the operation, unplug the power cable, put on appropriate protection, and then wipe off the eluent or diluent and stop the leakage after making sure of no leakage in tube connections.
  - Contact Tosoh local representatives when the leakage cannot be stopped.

- **Immediately shutdown the system and unplug the power plug when the problem occurs (such as burning smell) and contact Tosoh local representatives.**
  - Continuing to operate the instrument that is still malfunctioning may cause an electrical shock or fire.

- **Do not place fingers, rods, or other objects into moving or driving units during operation.**
  - The motor is contained inside the unit. Fingers or other objects may get caught and get injured.

- **Close the cover and the door during operation.**
  - Keep the cover and front door closed during operation. The interior of the analyzer contains high-temperature components and high-voltage circuitry.
  - Fingers and hands can easily get snared or tangled in the mechanisms, resulting in lacerations, burns and electrical shock, resulting in personal injury.

- **Do not try to add any sample or sample rack during operation.**
  - Except for the STAT port, do not add any sample or sample rack during operation.

- **Do not shutdown or start the system by simply unplugging or inserting the power plug.**
  - This may cause fire or an electrical shock.
  - Always use the POWER key located on the front or main power switch on the left side of the analyzer.

⚠ CAUTION

- **Do not damage the power cable.**
  - The power cable may be damaged by excessive stretching, bending, or anchoring. It may cause fire or an electrical shock.
  - When unplugging the power cable, make sure to hold the plug .

- **Do not touch the analyzer with wet hands.**
  - It may cause an electrical shock.

- **Do not perform any operation daily required to maintain the unit by those who are not trained with this analyzer.**
  - It may cause infectious disease by injury or contaminated blood samples unless an operator understands what procedure is required such as putting on protection (glasses, gloves, mask) during the daily maintenance.
  - When the sampling needle is replaced, it may damage the analyzer if the needle is moved too forcefully without turning the main power off. Make sure to turn the main power off prior to conducting any maintenance, and be careful of needle tip not to pierce your fingers during the needle replacement.
  - If you have any question about maintenance, contact Tosoh local representatives.

- **Dispose of waste materials properly.**
  - Take appropriate steps to separate all the used sample cups, filter elements, columns and buffers. Always wear protective gloves to avoid direct contact with them. Waste materials must be disposed of in accordance with the relevant laws and regulations to protect the surrounding environment or health.

- **Always wear protective clothing.**
  - Always wear the protective clothing (goggles, gloves, mask etc.) to prevent infection when working with the specimen, reagents, and waste materials.

- **Centrifuge samples under mild conditions in the case of assaying some centrifuged samples.**
  - If the sample has been subjected to a centrifuge to measure blood glucose prior to being assayed by the analyzer, make sure that the centrifugation is done at less than 500G/ 5min.

CAUTION

- **Place fluid containers only in designated locations.**
  - If the reagent are dropped or spilled inside the analyzer, it may cause the short circuits and result in an electrical shock.

Removal of Equipment from Use for Repair or Disposal

WARNING

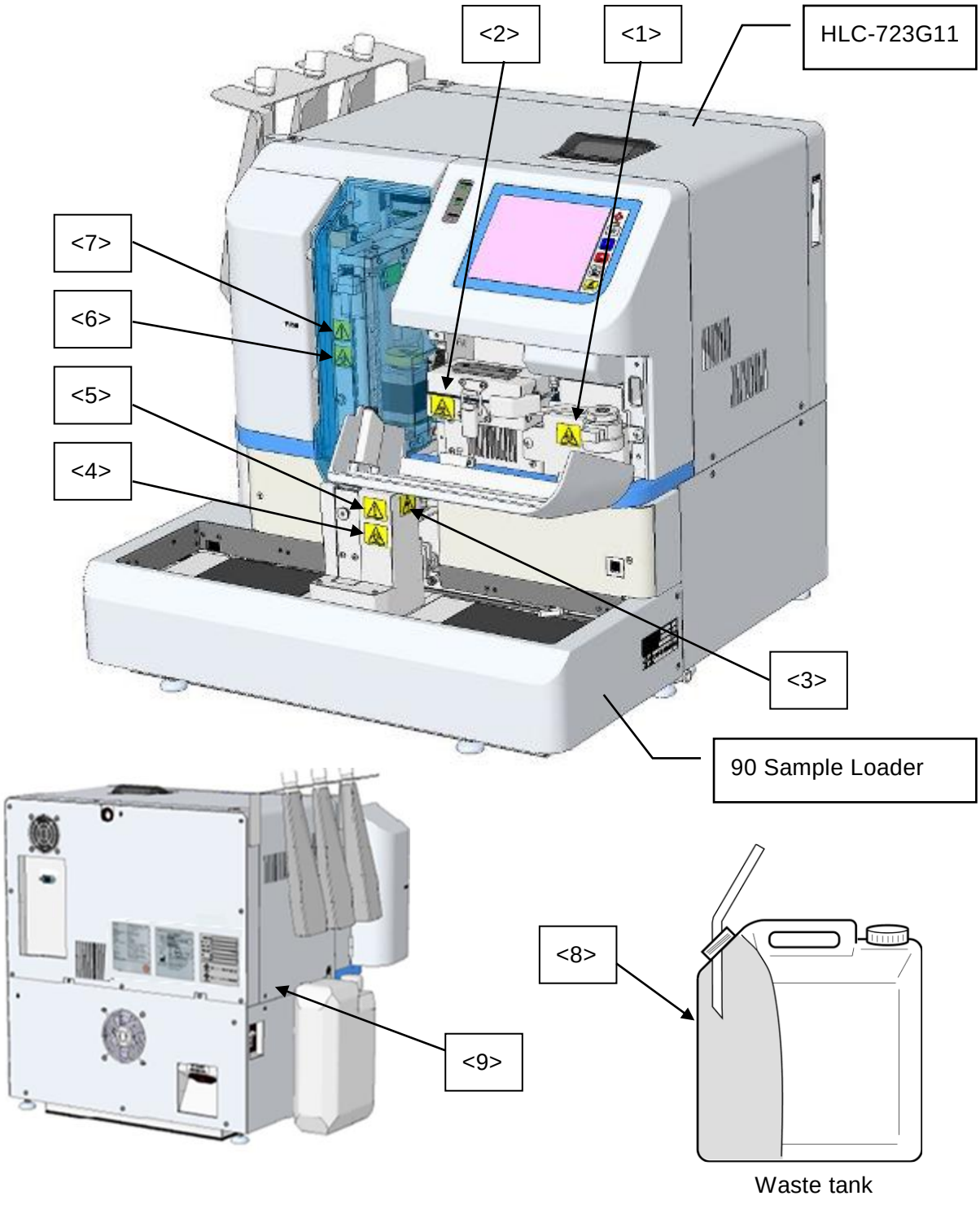
- **Use only trained maintenance personnel.**
  - Maintenance work must be performed by personnel with proper knowledge of system maintenance procedures and who are equipped with proper protective clothing (goggles, gloves, mask etc.). Physical injuries sustained during maintenance work can result in infections from specimens. Therefore, it is important that maintenance personnel conduct work in accordance with the procedures outlined in this manual and only after they have received sufficient training in maintenance procedures.
  - Please contact Tosoh local representatives for information on maintenance procedures.

- **Contact Tosoh local representatives.**
  - There is always a risk that the instrument could be contaminated by blood or body fluid including some infectious agents. When repairing, moving, or disposing the instrument, contact Tosoh local representatives.

Other Precautions

- The caution labels are attached to the unit. Read the instruction thoroughly and follow them.

Placements of warning and caution labels



<1> Filter Unit Biohazard Label

Be sure to wear appropriate protective clothing, such as gloves, when handling the filter unit, as filter element has been contaminated by potentially infectious specimens.

<2> Column Oven Biohazard Label

Be sure to wear appropriate protective clothing, such as gloves, when handling the column oven, as column has been contaminated by potentially infectious specimens.

<3> Injuries Caution Label

Do not place your fingers or any other object into the sampling area of the sample loader. The downward movement of the sampling needle may cause injuries.

<4> STAT Port Biohazard Label

Be sure to wear appropriate protective clothing, such as gloves, when handling the STAT port, as the inside of the STAT port has been contaminated by potentially infectious specimens.

<5> Needle Damage Caution Label

Never open the STAT port during a STAT assay to avoid damaging the sampling needle.

<6> Sampling Needle Biohazard Label

Be sure to wear appropriate protective clothing, such as gloves, when handling the sampling units, as the sampling needle has been contaminated by potentially infectious specimens.

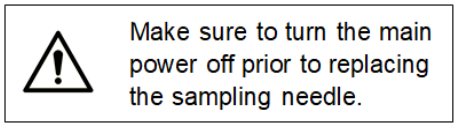
<7> Moving Units Caution Label

Those persons who have not been trained for the needle replacement must not open the needle cover and replace the needle.
Moving units of auto sampler could cause injuries if you replace the sampling needle without turning the main power off.

<8> Waste tank Biohazard Label

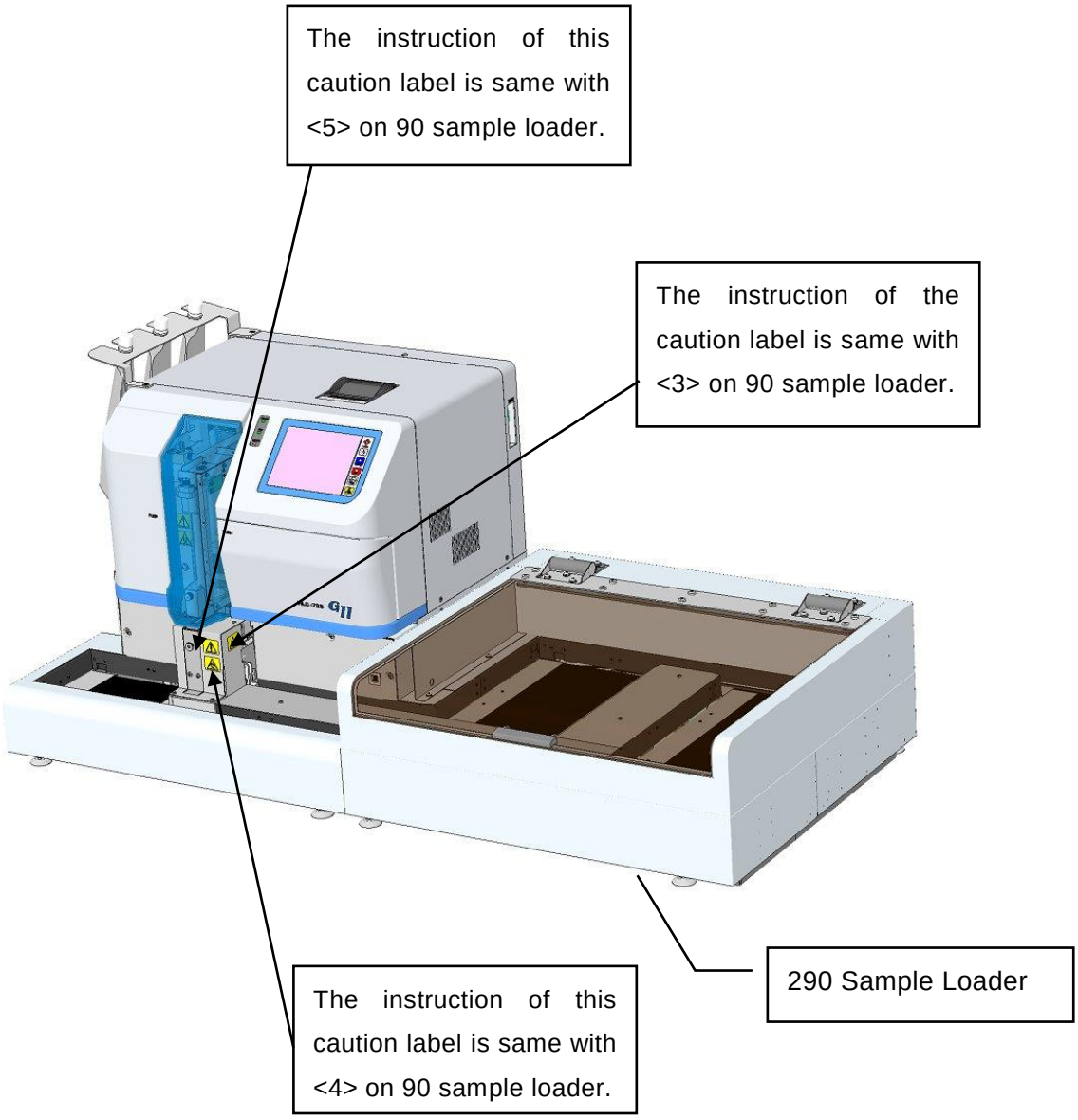
Be sure to wear appropriate protective clothing, such as gloves, when handling the waste tank, as waste liquid has been contaminated by potentially infectious specimens.

<9> Moving Units Caution Label



Moving units of auto sampler could cause injuries if you replace the sampling needle without turning the main power off.

- The caution labels attached to the 290 sample loader are the same as those attached to the 90 sample loader. Read the above instruction thoroughly and follow them.



- When the caution labels have become faded, have dropped off or become illegible, contact your Tosoh local representative.

- Keep this manual with the instrument so that you can read it when necessary.

Contact Tosoh local representatives when repairing the analyzer.

・Improper disassembly, repair or modification work may cause an electrical shock or fire.

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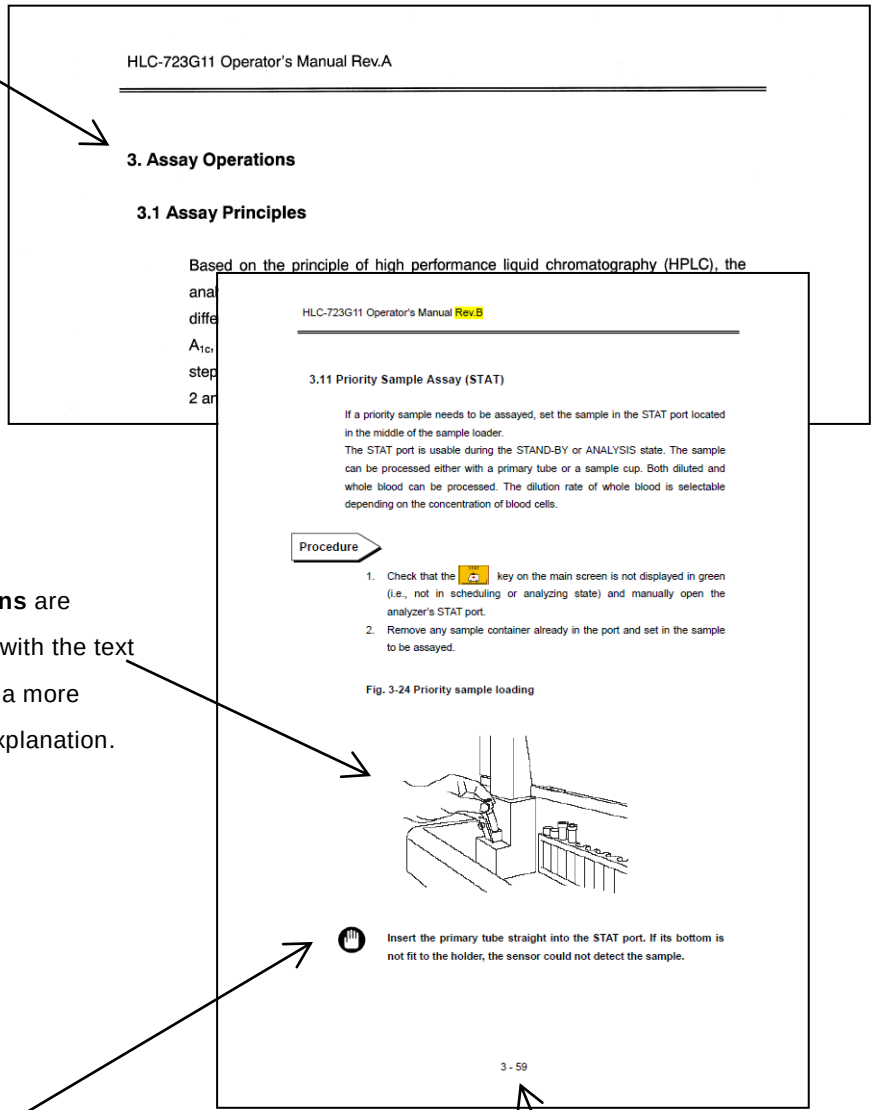
How to Use This Manual

This manual is designed to ensure that users can operate HLC-723G11 system correctly and safety.

This manual is organized according to the layout rule as below. Use this as a reference when reading this manual.

Section Headings show the name of section.



Illustrations are combined with the text to provide a more detailed explanation.

Page numbers

Icon

Stop signs warn the user of potential operational mistakes.

Point

Key Points provide helpful tips for mastering operation.

Chapter 1 Introduction

Chapter 2 Before Use

Chapter 3 Assay Operations

Chapter 4 Screen Operations

Chapter 5 Maintenance Procedures

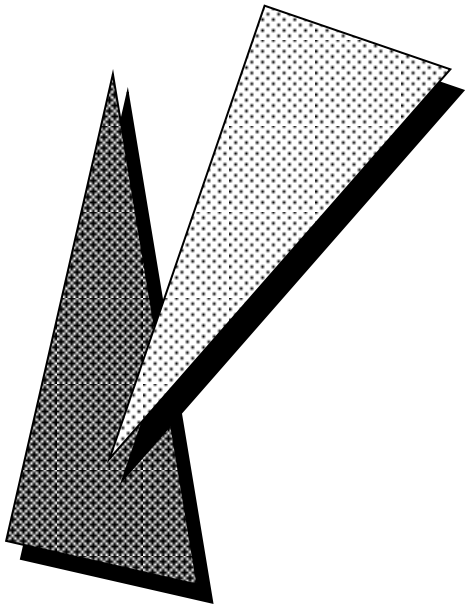
Chapter 6 Troubleshooting

Chapter 7 Appendix

Note

Chapter 1

Introduction



1 Introduction

1.1 Intended Use

The HLC-723G11 is intended for *IN VITRO* DIAGNOSTIC USE for the quantitative percent determination of hemoglobin A1c (HbA1c) in whole blood samples, in the clinical management of diabetes to assess the long-term efficacy of diabetic control in human subjects, based on the principle of high-performance liquid chromatography. The HLC-723G11 is intended for healthcare Professional Use Only.

1.2 Test Principle

The HLC-723G11 is intended to assay HbA1c (% or mmol/mol) out of the total hemoglobin in blood for *in vitro* diagnostic use based on High Performance Liquid Chromatography principle with the cationic non-porous ion exchanger using the ionic difference.

To use the analyzer, simply place the primary tube on the rack of the sample loader, and the analyzer will assay for HbA1c (% or mmol/mol) every 1 minute with sampling and dilution.

This operator's manual is provided to help you better understand and correctly use the analyzer. Read this manual carefully and make sure you thoroughly understand its contents prior to using the analyzer.

Refer to this manual whenever you encounter problems or unclear points.

The analyzer is referred to in this manual as HLC-723G11.

You must use the dedicated column, elution buffers, and Hemolysis and Wash solution for this system. No other column or reagents will work. Let us remind you that it is your responsibility to use any other column or reagent than ours on the system.

The dedicated column for the Tosoh Automated Glycohemoglobin Analyzer HLC-723G11:

TSKgel G11 Variant

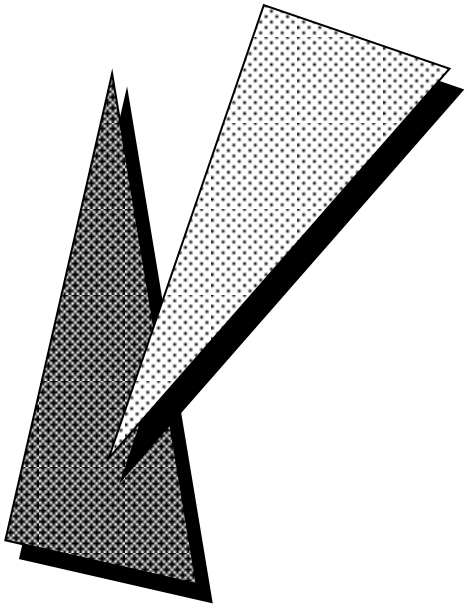
The dedicated buffers for the Tosoh Automated Glycohemoglobin Analyzer HLC-723G11:

G11 Variant Elution Buffer No.1 (S)
G11 Variant Elution Buffer No.2 (S)
G11 Variant Elution Buffer No.3 (S)
HSi Hemolysis & Wash Solution (L) and (LL)

NOTE

Chapter 2

Before Use



2 Before Use

A TOSOH or authorized service representative with sufficient training will install the analyzer units.

A service representative will remove the panel of the main unit during installation, uncovering high-voltage assemblies. These are extremely dangerous to touch. Never attempt to install or unpack the device yourself. Also, make sure to contact your TOSOH or authorized service representative to move the unit, irrespective of the distance to be moved.

2.1 Parts Inspection

The analyzer components are packaged separately and consist of the main unit, accessories, and the sample loader. Two types of sample loader, 90SL with 9 racks and 290SL with 29 racks, are available. Each component comes with the accessories indicated below. Check that all accessories are present.

1) Main Unit (HLC-723G11)

- Warranty Card 1
- Inspection Certificate 1
- Power cable for the Main Unit 2 m 1
- Waste Tank 10 L 1
- Waste Tube Silicone 9 mm × 12 mm × 1.6 m 1
- Bandage CV-150 5
- Wrench 1/4" × 5/16" 1
- Wrench 8 × 10 mm 1
- Cross slot screwdriver 100 mm 1
- Hexagonal Wrench 3 mm 1
- Hexagonal Wrench 2.5 mm 1
- Sample Cup 20
- Printer Paper (Thermal paper roll) 1
- System USB stick 1
- Holder for reagent pack 1
- 4 L Bottle Cap 1
- Accessory box 1
- Handy connector 1

2) 90 Sample Loader (G11-90SL)

- Warranty Card 1
- Inspection Certificate 1
- Sample Rack (TOSOH) 9
- Cup Adapter 10
- End Marker 2
- Mounting Screw 4

3) 290 Sample Loader (G11-290SL)

- Warranty Card 1
- Inspection Certificate 1
- Sample Rack (TOSOH) 30
- Cup Adapter 10
- End Marker 2
- Mounting Screw 4

4) Consumables and Optional components

- Column, Reagents

Part Number	Part Name	Description	Unit
0023478	TSKgel G11 Variant	1 piece	1 box
0023479	G11 Variant Elution Buffer No. 1 (S)	800 mL × 10 packs	1 box
0023480	G11 Variant Elution Buffer No. 2 (S)	800 mL × 10 packs	1 box
0023481	G11 Variant Elution Buffer No. 3 (S)	800 mL × 10 packs	1 box
0018431	HSi Hemolysis & Wash Solution (L)	2000 mL × 5 bottles	1 box
0019550	HSi Hemolysis & Wash Solution (LL)	4000 mL × 2 bottles	1 box
0018767	Hemoglobin A1c Calibrator Set	CAL(1), (2) (4 mL) × 5 each	1 box
0021974	Hemoglobin A1c Control	Level 1, 2 (0.5 mL) × 4 each	1 box
0023502	HbA1c Calibrator Set (S)	CAL(1), (2) (1 mL) × 4 each	1 box
0023503	HbA1c Diluting Solution	100 mL × 2 bottles	1 box

- The expiration dates for column and buffers are noted on their product labels.

- Consumables

Part Number	Part Name	Description	Unit
0023861	Filter Element with flange	5 pieces	1 bag
0019508	Sample Cup (500 pcs)	500 cups	1 bag
0023862	Printer Paper	10 rolls	1 box
0017092	Needle Wash Block O-ring (*1)	5 pieces	1 bag
0018517	Plunger Seal	1 piece	1 bag
0018723	Suction Filter	1 piece	1 bag
0024382	Co-Ni needle (3-sided tip) (*1)	1 piece	1 box
0023866	Rotor Seal for 0023865 valve	1 piece	1 bag
0019495	AS Valve Rotor Seal	1 piece	1 bag
0023864	Sample Loop	1 piece	1 bag
0023933	Waste filter	1 piece	1 box

(*1: Please confirm there is a carved mark "A" on the top of the wash block, if the wash block on the system does not have a carved mark "A", do not use part number 0024382 and contact your Tosoh representative to replace the wash block.)

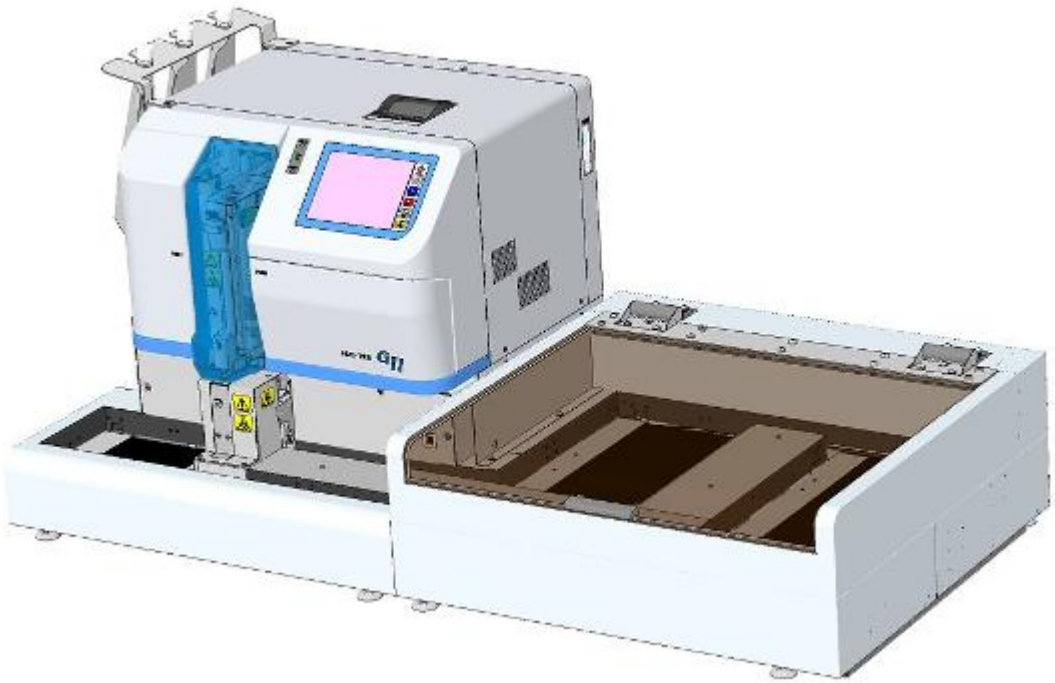
- Optional components

Part Number	Part Name	Description	Unit
0016320	Waste Tank	10 L	1 bottle
0021641	Silicon Tube	15 m for waste fluid	1 piece
0021639	TOSOH Sample Rack	1 piece	1 bag
0018432	Sample Rack (without adapter) SYSMEX 424-3303-3	1 piece	1 bag
0018433	ϕ13 adapter for SYSMEX sample rack	10 pieces	1 bag
0018496	ϕ12 adapter for SYSMEX sample rack	10 pieces	1 bag
0018497	ϕ14 adapter for SYSMEX sample rack	10 pieces	1 bag
0018808	Adapter (rotation prevention)	50 pieces	1 bag
0022944	Barcode Scanner	1 piece	1 box
0023929	Laser barcode reader	1 piece	1 box
0023930	Laser BCR with attachment for 90SL	1 piece	1 box
0023932	LED signal Tower kit for G11	1 piece	1 box
0019509	Cup adapter for SYSMEX sample rack	10 pieces	1 bag
0020101	Sample Cup Adapter	10 pieces	1 bag

2.2 Analyzer Configuration

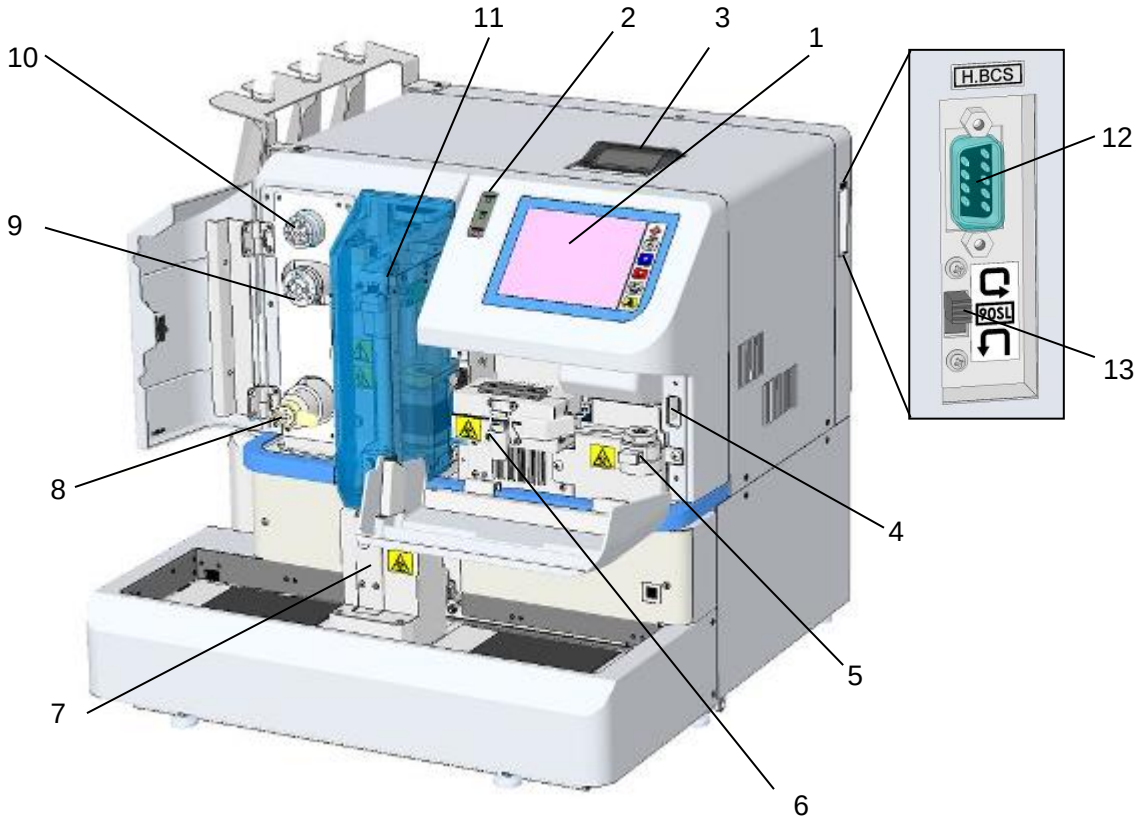
Fig. 2-1 External appearance (with 90SL connected)

Fig. 2-2 External appearance (with 290SL connected)



2.3 Units and Functions

Fig. 2-3 Front view (unit location)



1. Operation panel

   The operation panel is a color LCD touch panel. Various settings can be made on the screen.

   Individual basic function keys such as POWER, START, STOP, HOME and ERROR RESET are provided on the right side of the display. Routine operations are executed with these keys.

2. LED panel

   Three kinds of Light Emitting Diodes (LEDs) indicate the analyzer status: POWER, RUN, and ERROR.

3. Printer

   The printer needs a heat-sensitive paper roll. It prints out assay results, error messages and parameter status. The assay results can be printed out in several kinds of formats. About 270 assay results can be printed out with one paper roll which depends upon the print format.

4. USB memory socket

   The analyzer is equipped with an external USB port. It is used to store assay results, backup parameters and update the program.

   Note that the necessary memory capacity for one set of assay results is 5 kB. This means that a 1 GB memory can store roughly 200 thousand sets of assay results.

   The last 800 sets of assay results are also automatically saved to the analyzer's internal memory.

1. **The number of sets of assay results that can be stored in the USB stick depends upon the file format, the capacity of the USB stick, and the types of files stored. Furthermore, the number of those in a USB stick which is new or used previously in other applications may be smaller because of a different format. When saving the assay results, use a USB stick that has enough space required for them.**
2. **External memory devices other than USB sticks are unusable.**
3. **Secure USB sticks are unusable.**

5. Line filter

   The line filter prevents impurities (such as particles from a worn valve seal) from entering the assay line. The filter element can easily be replaced by hand.

6. Column oven

   The column oven contains a column, which is a critical component in assaying.

   The column must be kept at a constant temperature at all times to prevent fluctuation in temperature from affecting the assay results. The column oven maintains the constant temperature as long as the main power switch (the breaker at the side of the instrument) is turned on. The column can be connected to the pipe without using any tools.

7. STAT port

   Place a priority sample here. A dedicated sample cup or a primary tube is available. Do not open the STAT port during sampling.

Total height of a primary tube including a cap should be less than 110 mm.

8. Drain valve

   If bubbles enter the pump, open this valve to expel the bubbles by a drain flush. Do not open this valve during an assay.

9. Injection valve

   This valve is used to inject a diluted sample into the assay line.

   The sample loop volume is 5 µL.

10. Rotary valve

    The rotary valve is used to switch flow paths during sampling and elution buffer priming.

11. Sampling mechanism

The analyzer automatically recognizes the type of sample containers placed into it and takes in a whole blood sample. The whole blood sample is automatically diluted and introduced into the assay line. When the assay begins, the sample rack is transferred and sampling continues until the metal end marker, which indicates the last rack, or an empty rack on the loader is detected.

When samples with barcodes are set on racks and requests are received from a host computer, only the samples requested by the host computer will be measured.

12. Handheld barcode scanner connector

This connector is used to connect an optional handheld barcode scanner (P/N: 0022944) to the analyzer. Users can input reagents information into the analyzer by handheld barcode scanner. Refer to "**3.12 How to Use Handheld Barcode Scanner**" in this manual.

13. Sample rack rotation switch

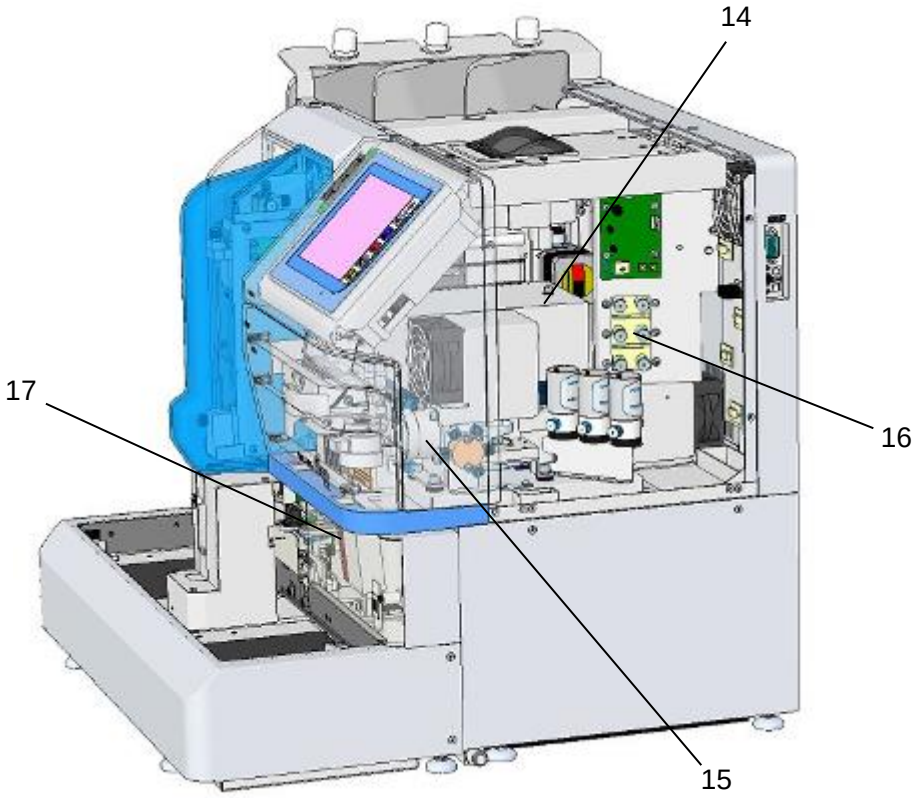
This switch changes the setting of the sample rack rotation (only when G11-90SL is connected). Please read the instructions below.

 : Rotation (Sample racks are rotated)

 : No Rotation (Sample racks are not rotated)

Before changing the setting, make sure to turn the main power off. Refer to ''**3.8 Samples - Sample Rack Rotation**" for details

Fig. 2-4 Right side view (unit location)



14. Detector

The detector is used to detect changes in the absorbance level of hemoglobin in the sample separated with the column. The light source is a blue LED. The temperature of both the detector and the column is controlled by the column oven.

15. Pump

The pump uses the plunger method to deliver the Elution Buffer required for the assay. The pump operates continuously to deliver the Elution Buffer during the assay and feeds three Elution Buffers of different salt concentration in a 1-minute cycles by switching the solenoid valves. It also forms a gradient (concentration gradient), and the hemoglobin fractions are separated by the column.

16. Degassing unit

    The degassing unit removes air bubbles in the pumped Elution Buffer. The vacuum pump runs intermittently to keep a constant vacuum pressure in the chamber.

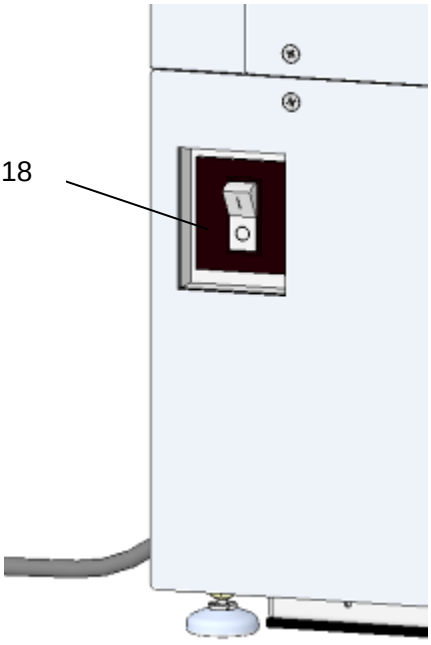
17. Barcode reader

    The barcode reader reads the barcode label on the primary tube and the analyzer prints it on the report in the ID field. Assay information can be requested from the host using the barcode. When you are using a sample cup, attach a barcode label on a cup adapter, set the adapter in the rack, and place the sample cup in the adapter.

18. Main power switch

    The main power switch also acts as a breaker. Usually, the main unit power stays on and using the POWER key on the right side of the display, the instrument can be switched on and off.

Fig. 2-5 Left side face

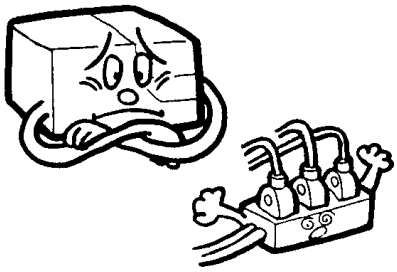


2.4 Installation Locations

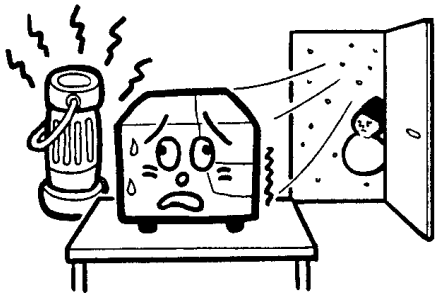
Installation Location

Do not install the unit in the following locations.
Otherwise the result may not be reliable.

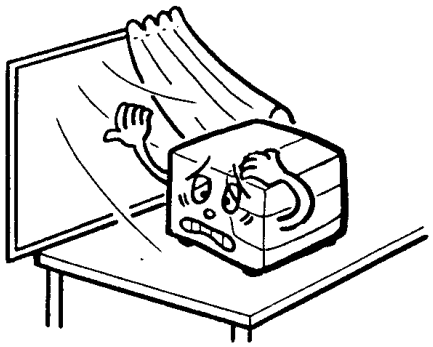
- **Locations with large fluctuations in the power source**



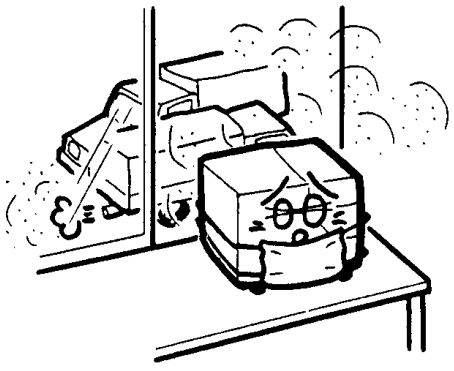
- **Locations with rapid temperature changes**



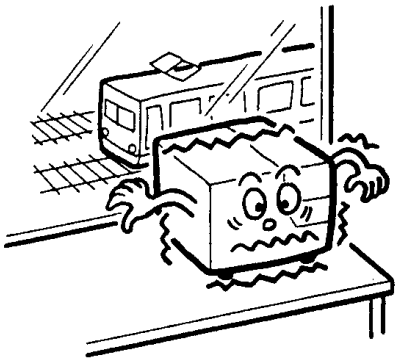
- **Locations in the path of direct air currents**



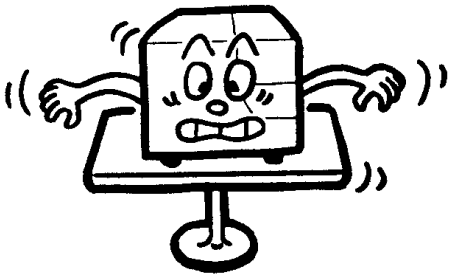
- **Locations with large amounts of dust or dirt**



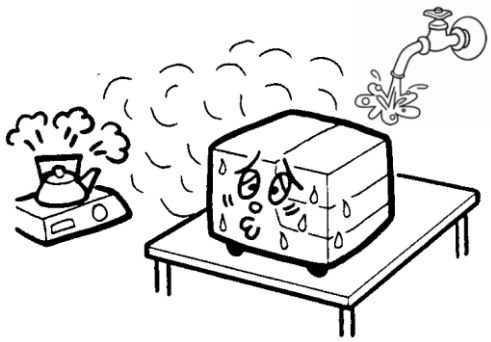
- **Locations with excessive vibration**



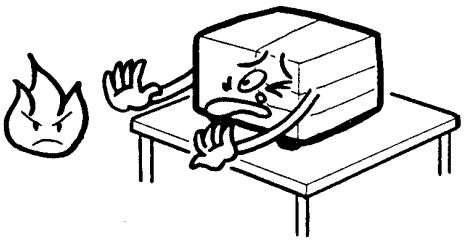
- **Unstable locations**



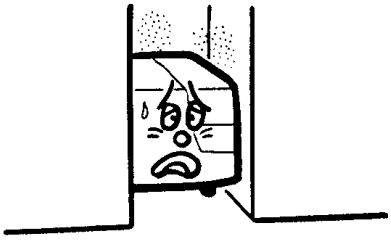
- **Locations with high humidity (>80%)**
- **Locations near water sources, such as a sink**



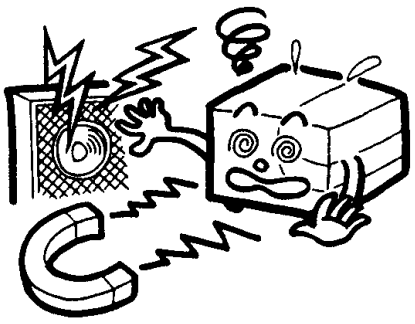
- **Locations with flame nearby**



- **Locations with poor ventilation**



- **Locations where strong magnetic fields or high frequencies may be generated.**



Installation Environment

Install the unit on an even table top without direct sunlight, air currents, poisonous gases, dust or vibration.
Operate the unit under the conditions indicated below.

Environmental conditions

Temperature:	15 °C to 30 °C
Humidity:	40 % to 80 % (no condensation)
Overvoltage Category:	II
Pollution Degree:	2
Dust:	About the quality in an office
Maximum Altitude:	2,000 m
Other:	Instrument should not be installed near water sources, such as a sink.

Caution

Do not use in an environment with sharp temperature fluctuations. Condensation may cause a malfunction and a short circuit.

Environment of Transportation and Storage

Transport and store under the following conditions.

Temperature:	0 °C to 50 °C
Humidity:	80 % or less (no condensation)
Other:	Keep dry and store indoors

The analyzer should only be moved by two or more people using both hands to grasp the bottom section of the analyzer (Fig. 2-6).

Fig. 2-6 Position to grasp the analyzer when moving it

Required Installation Space

Refer to figures below and be sure to secure sufficient space around the analyzer to prevent the fan on the back from being blocked. Also, provide a height of about 880 mm, equal to 400 mm plus the height of the main unit (480 mm). In addition, avoid direct ventilation from other instruments.

Point **The filter handle sticks out from the instrument when the filter element is replaced. Install the instrument with enough space at the right side when setting the G11-90SL.**

Fig. 2-7 Installation space (main unit + 90SL)

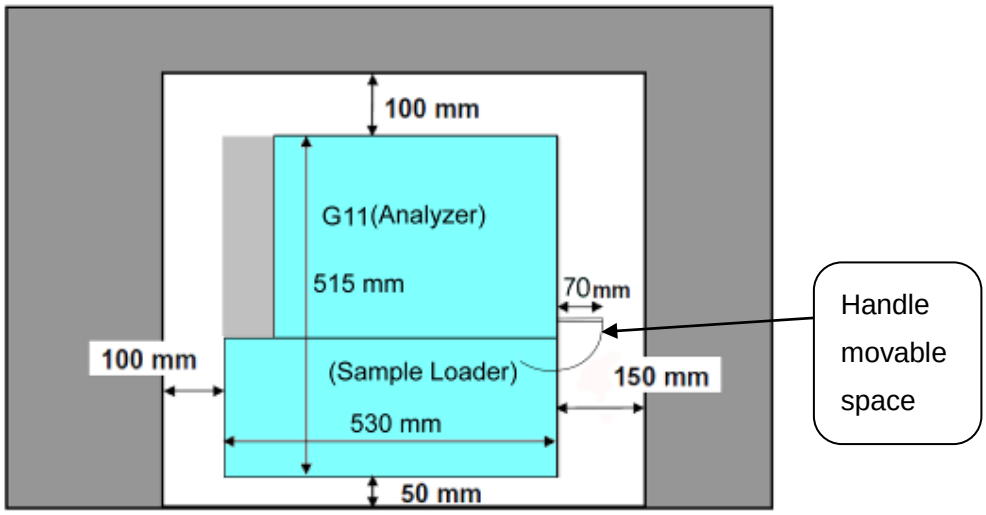
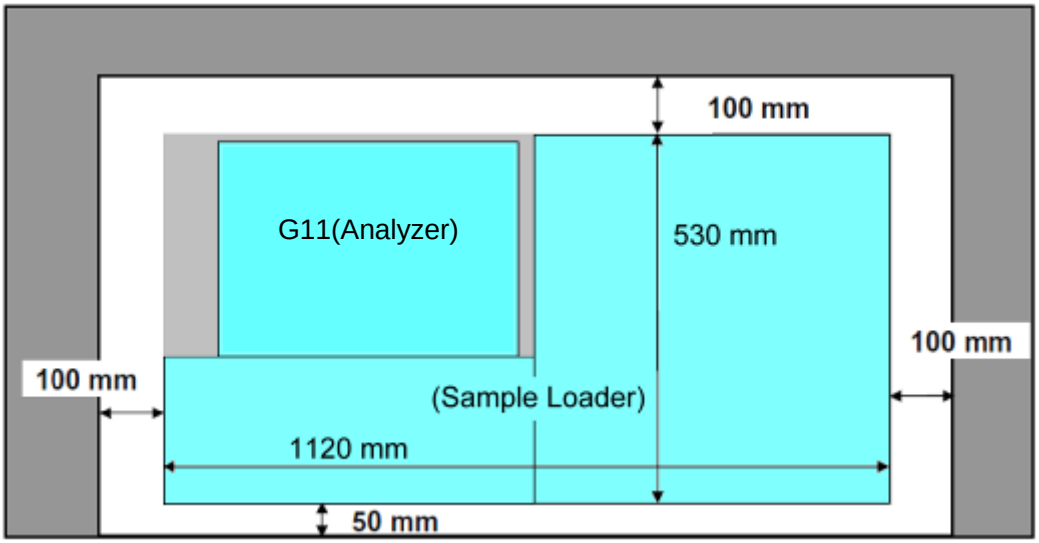


Fig. 2-8 Installation space (main unit + 290SL)



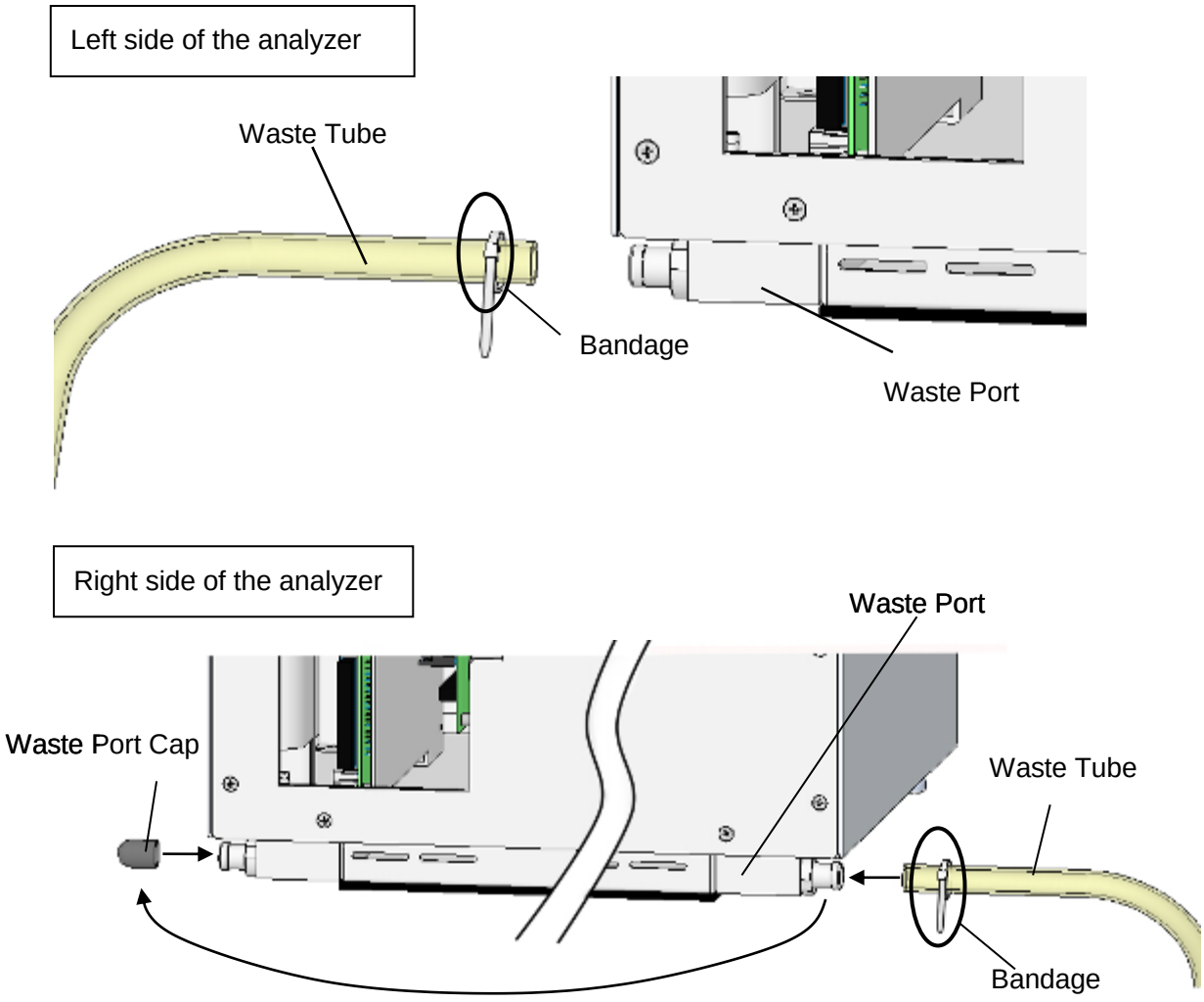
2.5 Connections

Waste Tube

Insert the waste tube firmly into the waste port located on the bottom of the main unit. (Refer to Fig. 2-9). Securely tighten the waste tube with the bandage provided in the accessory box.
Insert the other end of the tube into the waste tank.

Note: if the waste tube is bent, the waste eluent may not drain out smoothly. Adjust (cut) the tube length below 5 m and keep the tube end above the waste eluent level.

Fig. 2-9 Waste tube connection



When moving the analyzer to another location, ensure that the waste tube is not bent and that the waste eluent is discharged smoothly.
When relocating the analyzer, the sample loader should be detached from the main units. Contact Tosoh local representatives in advance.

If the waste tube is bent, the waste eluent may not drain out smoothly and the waste eluent sensor may stop the analysis. Do not lift or move the waste tube during analysis.

Point

The pump drains the waste eluent automatically. It is not a problem that there are waste eluent bubbles in the waste tube.

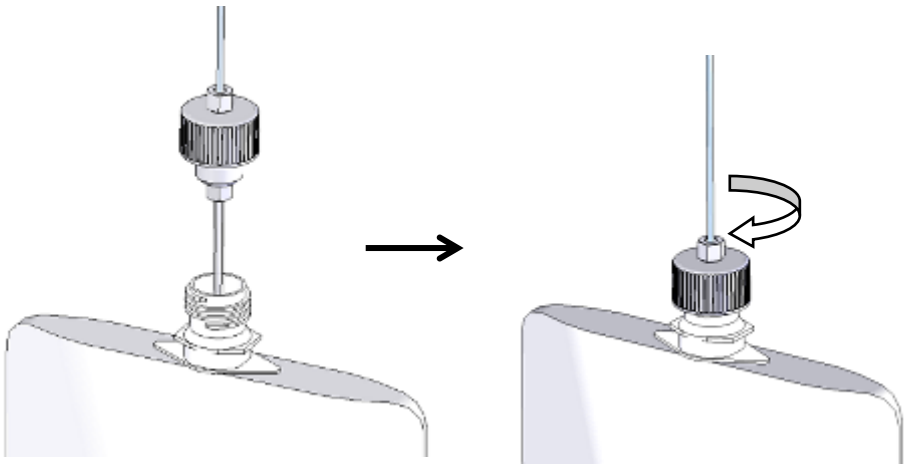
Elution Buffer Tube

Match the color mark of the tube with the label color of the No. 1, 2, and 3 elution buffers, insert the tube into the aluminum bag, and tightly seal the bottle cap. A suction filter is connected to the tip of the elution buffer tube to prevent foreign matter from entering the analyzer.

No. 1 elution buffer: green
No. 2 elution buffer: red
No. 3 elution buffer: yellow

Point **If the tube is bent, the tip may not reach the bottom of the aluminum bag. Connect the tube after straightening any bends.**

Fig. 2-10 Elution buffer tube connection



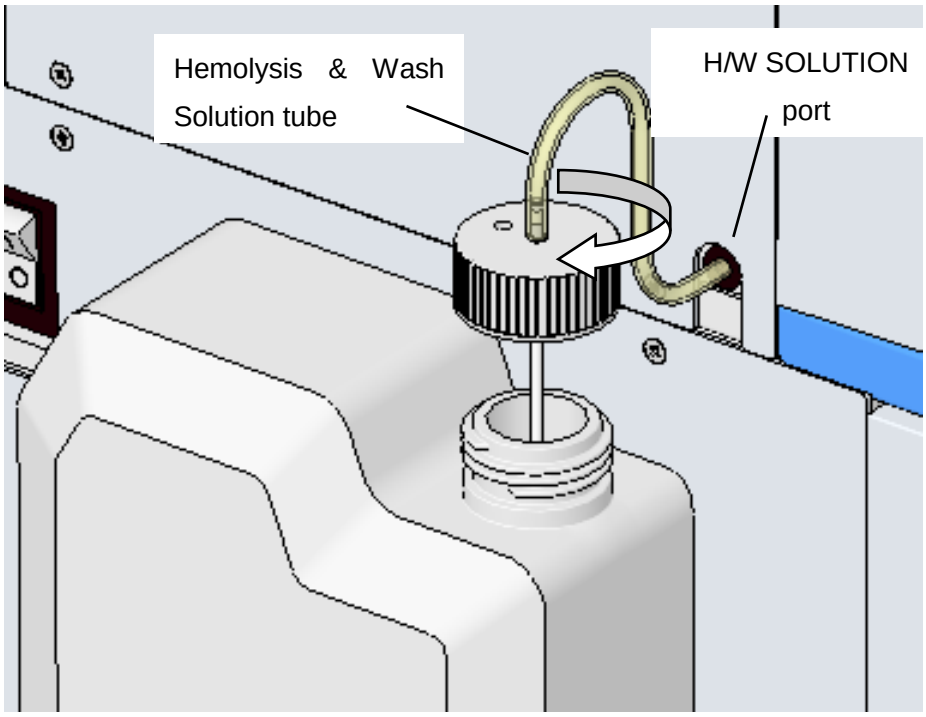
When connecting the tube to the aluminum bag, partially close the cap and push out excess air from the bag using your hands before sealing the cap tightly.
Excess air in the bag may cause buffer degradation or poor suction.

Hemolysis & Wash Solution Tube

Open the bottle cap on the Hemolysis & Wash Solution, insert the Hemolysis & Wash Solution tube (with the anchor and the bottle cap), and close the bottle cap. Check that the anchor reaches the bottom of the bottle.

When you use the Hemolysis & Wash Solution (LL), use the bottle cap for 4 L bottle (standard accessories) and change the ''H/W BOTTLE TYPE'' setting on the PARAMETER screen(refer to "**4.9 Parameter Setting**" for details).

Fig. 2-11 Hemolysis & Wash Solution tube connection



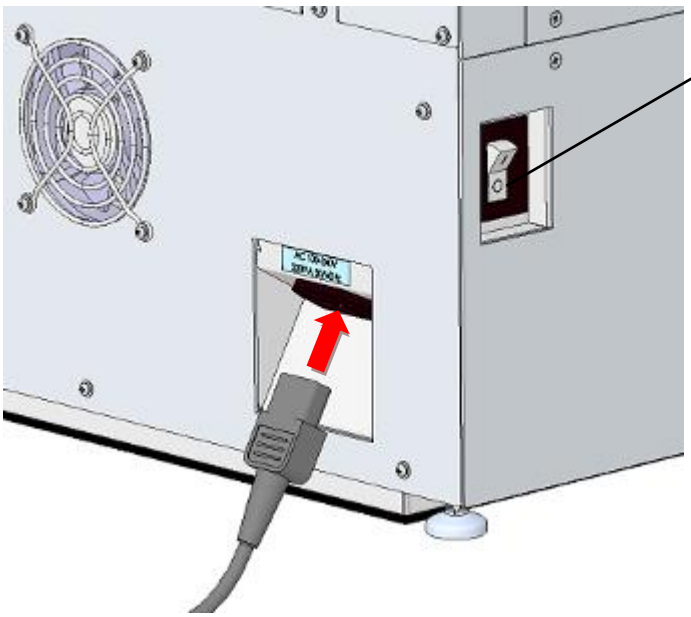
Power Source

Securely connect the power cable to the AC inlet of the main unit.

Make sure that the main power switch is off (O) before inserting the plug into the socket.

The power source requires a capacity over 10A and more than 2 pins with a grounding terminal.

Fig. 2-12 Power Cable Connection



Confirm that the main power is off (O).

Caution

1. **Do not use the same power source as that used for high capacity equipment such as a refrigerator or a compressor.**
2. **Do not touch the power source with wet hands. This may cause electrical shocks.**
3. **Be sure to ground the unit.**
4. **To allow the power to be easily switched off in an emergency, do not place anything in front of the main power switch.**
5. **Leave enough space to allow the power cable to be unplugged from the AC inlet.**
6. **Do not use an extension cord and a power distribution adapter.**

2.6 Column

The dedicated column for HLC-723G11 is the TSKgel G11 Variant.
Never use this column with any other instrument than HLC-723G11.

Refer to the Instructions For Use of TSKgel G11 Variant, and "**5.9 Column Replacement**" of this manual for information on how to connect the column.
Be sure to check for any damage to the package or packaging components before use. If any damage is observed, contact a Tosoh local representative.
Next, confirm that the following inserts are included with the column.

- Instructions For Use 1
- Column Inspection Report 1

Column Connection

Procedure

1) Let the column return to room temperature before use.
2) Take the column out of the box and remove the end plugs on both ends. Do not throw away these plugs, as they are needed for storage.
3) Be sure that eluent delivery has been completely stopped (the status "STAND-BY" is displayed on the MAIN screen). Open the column oven and disconnect the flow line, and remove the used column.
4) Press the  key located on the lower right side of the screen. The key for manual eluent delivery is displayed. Press the 

key to run the pump and confirm that eluent is being delivered from the column flow line end. Press the 

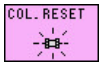
key to stop the pump. Be careful not to spill the eluent draining from the flow line onto the unit. Wipe with paper if necessary.
5) Check the proper column flow direction which is stated on the label of the column, (←) direction, and connect the flow line to the inlet side of the column. Press the screen key to run the pump and check that eluent is draining from the outlet side of the column. Stop the pump and connect the outlet side of the column to the flow line.

6) Press the 

key on the MAIN screen (first screen) and select the 

key to open the REAGENT CHANGE screen. Press the 

key to execute column washing. Check that the pressure is rising quickly and that there is no leakage at the flow line connections. After that, close the column oven.

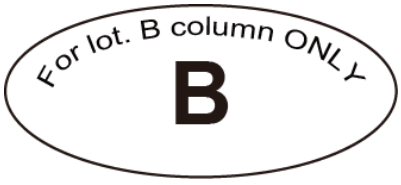
7) Press the 

key on the REAGENT CHANGE screen to reset the column counter to zero.

Column Use Cautions

1) This Operator's Manual must be read together with the Instructions For Use (IFU) of the relevant HLC-723G11 reagents.
2) After you change the column, assay a whole blood samples three times and check the chromatograms.
3) The column must be used with the same lot of G11 Variant Elution Buffer. The column lot ID is shown a single uppercase alphabetical character (A, B, etc.) on the column label. The elution buffer label displays an alphabetic character corresponding to column lot number, as shown below.

Fig. 2-13 Lot ID Identification



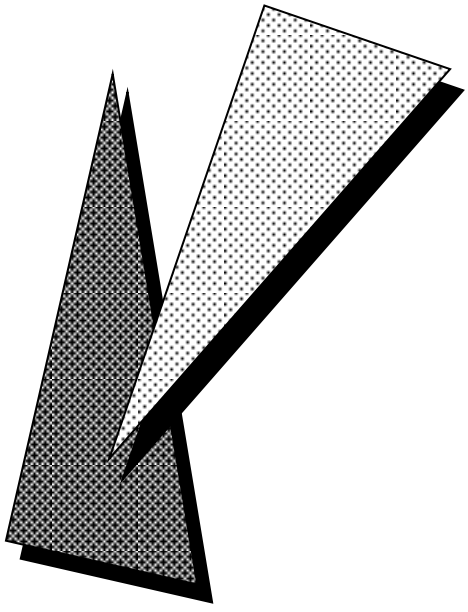
4) The column must follow the flow direction indicated by the arrow on the label and must never flow in the opposite direction.
5) When the column is not used for a long period of time (a week or more), remove it from the unit and secure the protective plugs to protect it from drying out and store in cool dark place at 4 to 15 °C.
6) Handle the column with care. Do not drop or bump the column.
7) If the pressure is more than the pressure (which is indicated on the column inspection report) +4 MPa, first replace the filter element. If

the pressure still does not drop, replace column.

8) The used column has been in contact with blood samples. Wear protective clothing (glasses, glove, mask, etc) and take sufficient care to prevent potential infection during installation and handling.
9) If you use the column registration information on the HLC-723G11, please enter the barcode information printed on the box label with an optional handheld barcode scanner.

Chapter 3

Assay Operations



3 Assay Operations

3.1 Assay Principles

Based on the principle of high performance liquid chromatography (HPLC), the analyzer uses a cation exchange column to separate hemoglobin components by different ionic charge. The various fractions of hemoglobin, including hemoglobin A1c, are quickly (1 minute per sample) separated into 6 fractions and assayed. A step gradient with three different salt concentrations (G11 Variant Elution Buffer No. 1, No. 2 and No. 3) is used for separation.

Each Elution Buffer is degassed by the on-line degassers and switched by the solenoid valves as programmed, then delivered by the pump to the column after passing through an injection valve and filter. Approximately 3 µL of the whole blood sample in the primary tube is aspirated into a piercing nozzle and diluted by the Hemolysis & Wash Solution in the dilution port. Next, the diluted sample is aspirated into the nozzle and injected into the assay line then delivered to the column.

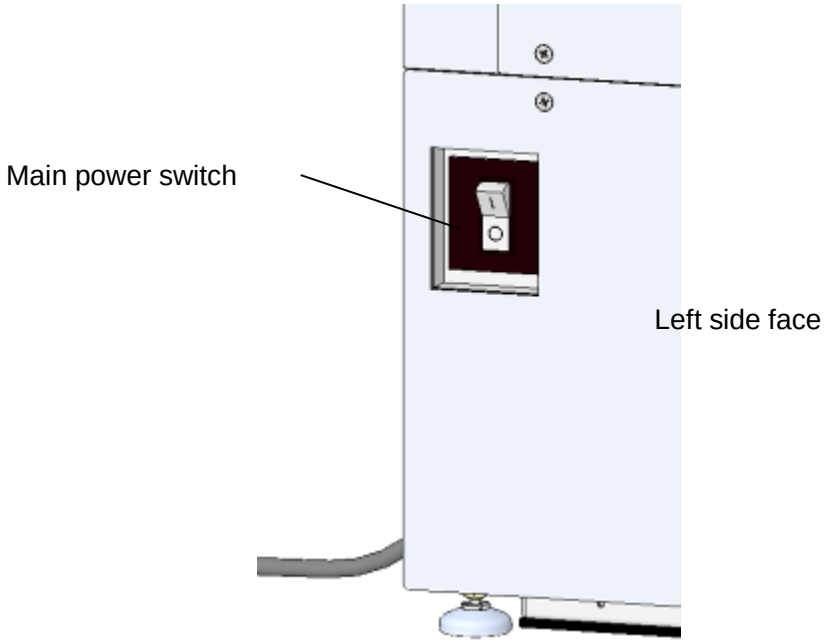
The absorbances of the various hemoglobin components, separated in the column, are then continuously monitored by the detector. After the assay is complete, results for the various hemoglobin fractions are output to the printer as percentages along with the chromatogram.

3.2 Power On

Turning Main Power On

The main power switch of the analyzer is located at the left side face.
The side marked "**I**" indicates power on, and the side marked "**O**" indicates power off.

Fig. 3-1 Turning main power on



The main power switch also acts as a breaker. If the main power switch is turned off immediately after the power is turned on, the analyzer may be short-circuited. If this should occur, be careful not to touch any metal parts of the analyzer. Immediately turn the main power off, unplug the power cable from the power socket and contact Tosoh local representatives.

Caution **Do not touch the power source, operation key, or screen with wet hands. You could receive an electric shock.**

The memory is cleared when the analyzer is shipped. When you start the analyzer for the first time, insert the system USB stick in advance in order to read the system program.
If the system has been already installed, please make sure that there is no system USB stick in the USB socket or a USB stick for saving the results is installed in the socket before startup.

Procedure

1. Turn on the main power.
   The analyzer beeps at startup and Screen 3-1 is displayed.
   Then the analyzer automatically executes a check of its internal circuits. The messages on Screen 3-2 will appear, and the backlight on the screen will temporarily dim.

Screen 3-1 Just after turning on the main power

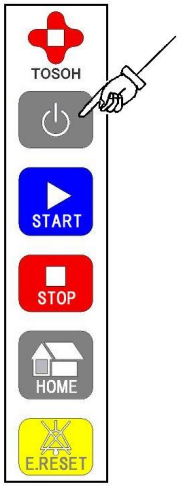
Screen 3-2 Display after main power is turned on, before the POWER key is pressed (normal operation)

2. Please make sure that there is no system USB stick in the USB socket or a USB stick for saving the results is installed in the socket before startup.

If a system USB stick is in the socket, it will be read during startup, and the internal memory will be overwritten.

3. Press the POWER key located at the top of the operation key on the right side of the control panel.

Fig. 3-2 Pressing POWER key on



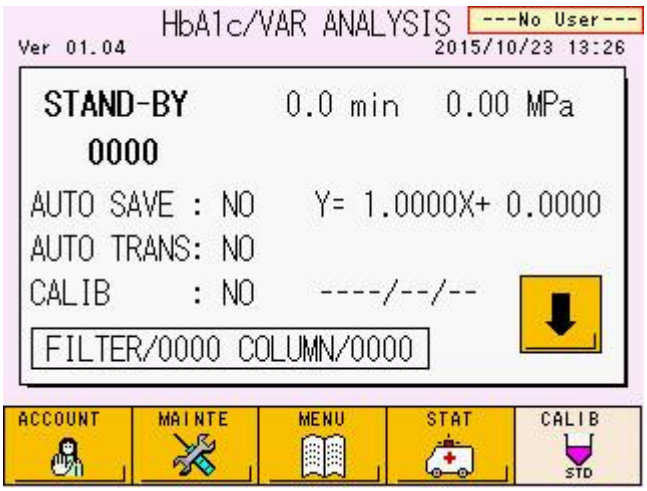
4. The system program, AS (Auto Sampler) program and backup parameters will all be automatically checked.

Screen 3-3 Display after POWER key is on and before system startup (normal operating status when system USB stick is not read)

```
        ######## SYSTEM LOADER ########

                                  BOOT  01.00

Memory Test ..... OK  Printer Test ..... OK
MJ  Trans Test ... OK  EXB Trans Test ... OK
PRT Trans Test ... OK  HBCR Trans Test... OK
LCD Trans Test ... OK  AS  Trans Test ... OK
HST Trans Test ... OK  LC  Trans Test ... OK
      Sampler(AS) ........ 01.00
      Searching AS ....... Not Found


      Searching System ... Not Found

      Checking Result .... Alive
      Checking Param ..... Alive

            Launching System...
```

5. If there are no problems with the backup program or other parameters, the analyzer automatically starts and the main screen appears.

Screen 3-4 Main screen (first screen)



If the main power switch is turned on and the screen does not display, or if a problem occurs during startup, or if an error is displayed, the analyzer may have a problem. Turn off the main power switch and follow the procedures from Step 1 in the above mentioned procedure. If the analyzer still doesn't start, contact Tosoh local representatives.

About the Battery Backup

The analyzer uses an internal battery to store the following information, even if the main power switch is turned off.

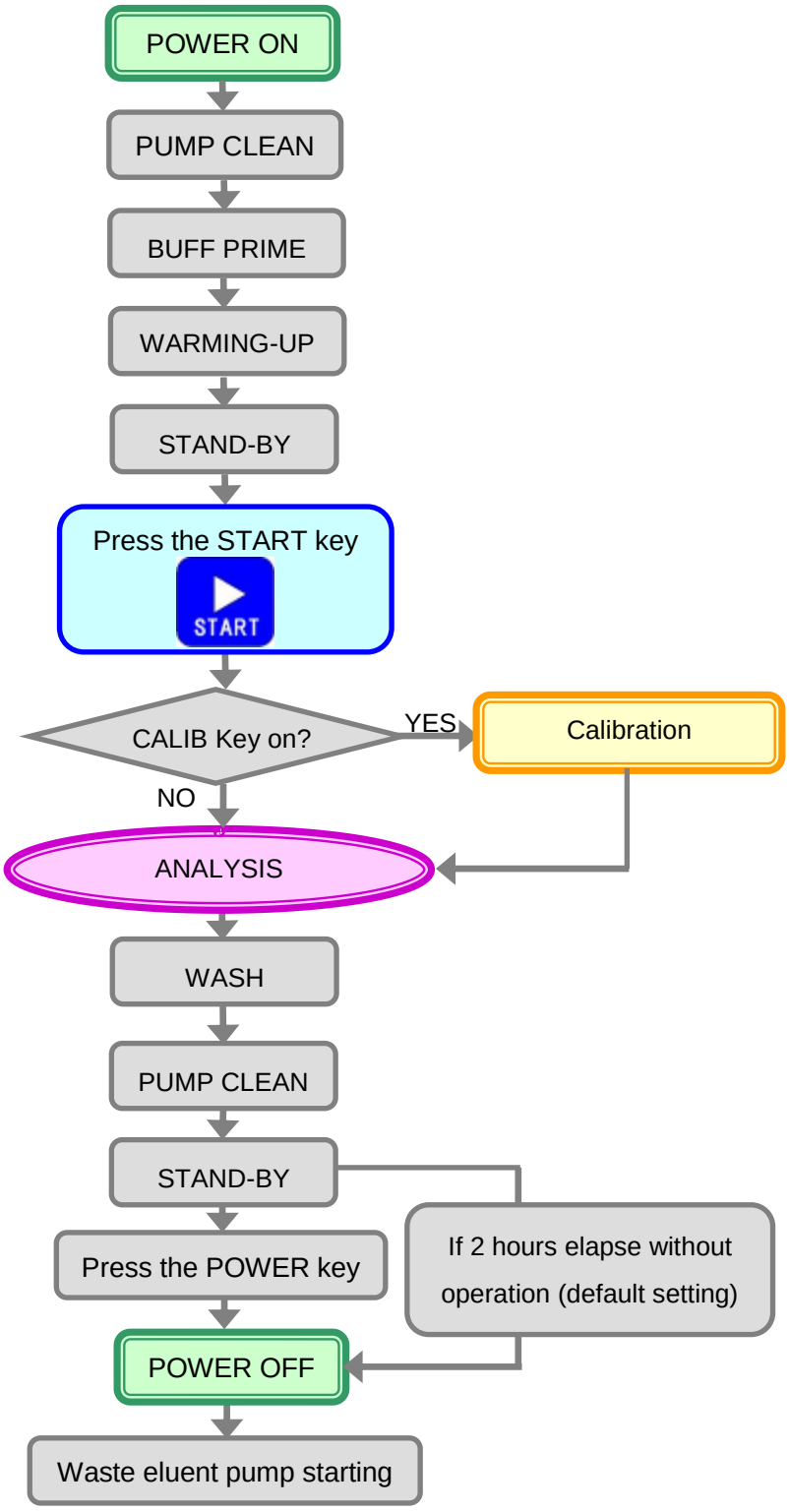
- System Program
  (program for operating the entire analyzer)
- AS Program
  (program for operating the sampling unit and sample loader)
- Assay Parameters
  (parameter files related to analyzer operating conditions)
- Result data
  (assay results stored in the main unit memory)

Therefore, there is no need to load system information from the system USB stick, except when upgrading the system program. The internal battery has a life span of approximately 5 years. This may vary depending on usage. If battery power fails, the information indicated above will not be backed up when the main power is turned off. A message indicating that no system program was loaded may appear when the analyzer is started under these circumstances. If this happens, you must install the system program using the USB stick.
Refer to "**7.1 Downloading Files from the USB Stick**" for details regarding how to load programs and data from USB stick. Even if the batteries are no longer functional, as long as the main power switch is on, the information indicated above is backed up and operation can be executed normally. Contact Tosoh local representatives for battery replacement.

3.3 Assay Flow

The flow of standard assay operations is shown below.

Fig. 3-3 Assay flow chart



3.4 Operation Status

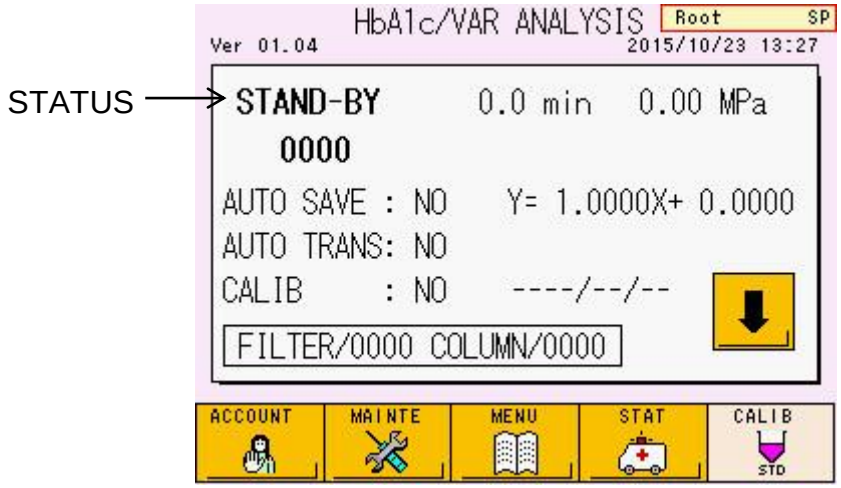
After the POWER key is pressed, the first screen displayed is the main screen (first screen). HbA1c / VAR ANALYSIS is displayed at the top of the screen. During analysis, the main screen should remain displayed. The current operation status is displayed in the upper left of the screen. The following status indications are displayed.

Status

- WARMING-UP
- STAND-BY
- ANALYSIS
- WASH
- COL.WASH
- BUFF PRIME
- PUMP CLEAN
- PURGING

Refer to the following pages for further details.

Screen 3-5 Main screen (first screen)

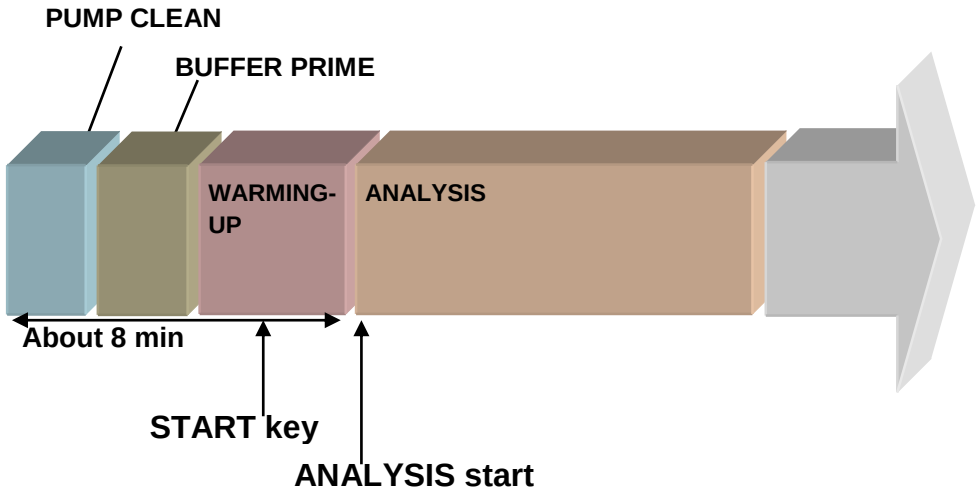


Status

- **WARMING-UP**

  Press the POWER key. After PUMP CLEAN and BUFF PRIME, the pump begins to run and automatically equilibrate the assay lines and analysis column. After pumping each Elution Buffer sequentially for about 8 minutes, the analyzer will enter the STAND-BY state and stop the flow. During this process, the sampling line will be washed twice. Although the WARMING-UP operation can be aborted by pressing the STOP key, always make sure to execute the WARMING-UP operation before the first assay of the day to ensure reliable results. During the WARMING-UP operation, set the samples and calibrators to be assayed and press the START key. The analyzer will go into the ANALYSIS state automatically and start the assays after completing the WARMING-UP operation.

Fig. 3-4 Start command during the WARMING-UP operation

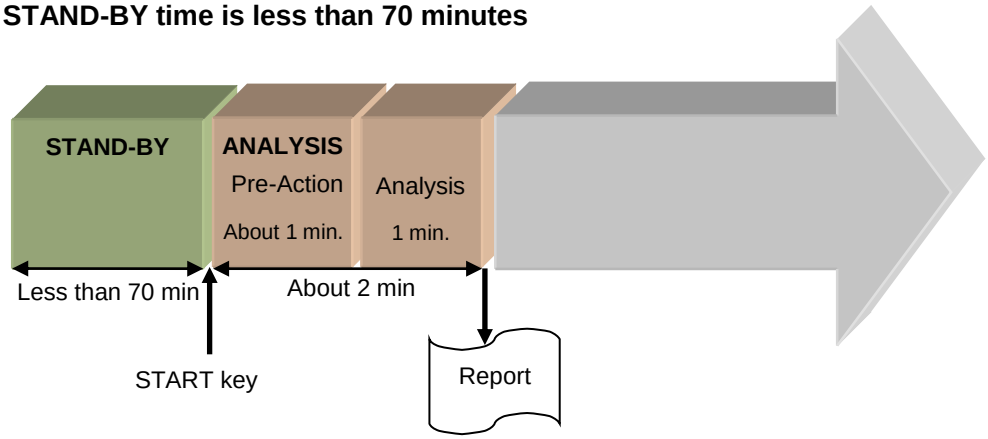


- **STAND-BY**

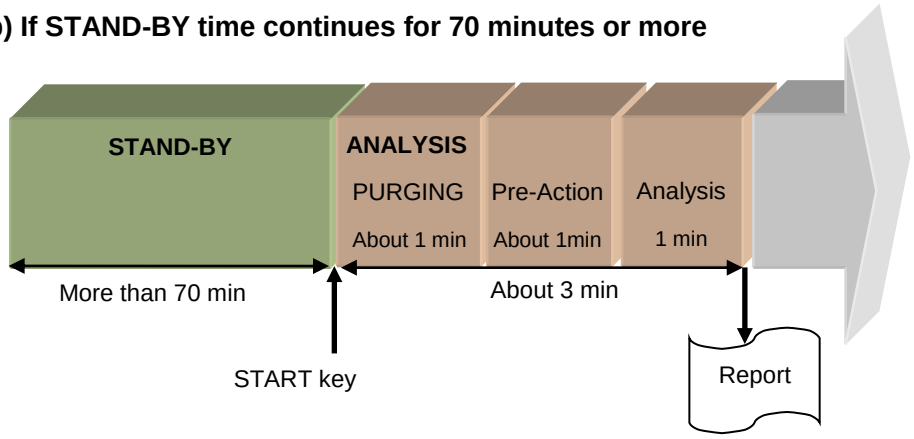
  When the WARMING UP operation is complete, the analyzer goes into STAND-BY. In this state, the pump stops a flow and Elution Buffer is not consumed. If 2 hours (default setting) elapse without pressing any operation key or touch panel, the power will be automatically turned off. The waiting time before power-off can be changed with the OFF TIMER setting on the PARAMETER screen. Refer to "**4.9 Parameter Setting"** for details.

Fig. 3-5 Start command during STAND-BY

a) If STAND-BY time is less than 70 minutes



b) If STAND-BY time continues for 70 minutes or more



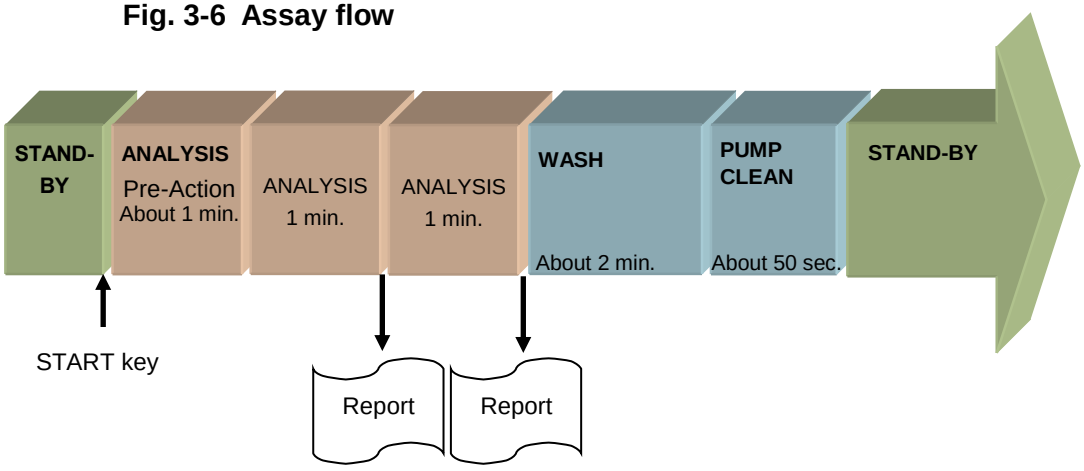
- **ANALYSIS**

  Set the calibrators, controls and samples and press the START key. The assay will start and the analyzer will go into ANALYSIS state. When the system starts from the STAND-BY state, the analyzer begins pumping/sampling when the sample containers are detected. If the sample is whole blood, it is diluted with the Hemolysis & Wash Solution (dilution rate: 1/201) before injection. The diluted sample is then injected into the sample loop. At the same time, pre-action (preliminary reagent flow) in the assay line is run (for a total of about 1 minute) and the assay of the first sample then begins (sample injection). Next, subsequent samples are processed in a 1 minute cycle. The result, including the assay value (HbA1c (%) and/or (mmol/mol)) is output by the printer.

  It takes approximately 2 minutes until the first assay result is printed from the time the first sample container is detected.

  However, if the analyzer has been in the STAND-BY state for 70 minutes or more, a PURGING operation is done to replace Elution Buffer No.1, No.2 and No.3 remaining in the line, and to clean the line. Since the PURGING operation takes approximately 1 minute, it will take a total of approximately 3 minutes until the first assay result is printed in this case.

Fig. 3-6 Assay flow

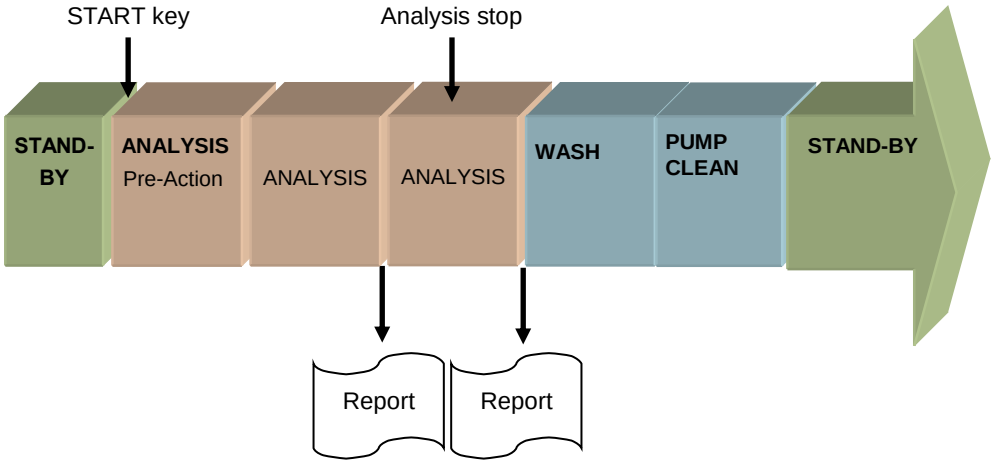


The STOP key can be pressed at any time during ANALYSIS to abort the assay.

A) Analysis stop

- Press the STOP key. The message will be displayed.
- If the OK key or the STOP key is pressed, after the sample currently being assayed is completed, the results for that assay are printed, and the WASH operation is executed

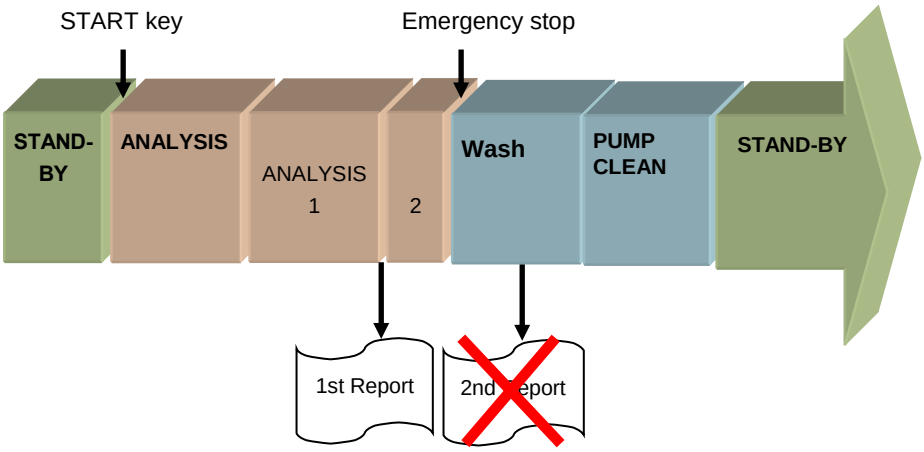
Fig. 3-7 ANALYSIS stop



B) Emergency stop

- If the STOP key is pressed three times in series during ANALYSIS, or one time after "A) Analysis stop" action, an emergency stop is executed. The assay is immediately aborted and the wash operation is started. The result of the sample currently being assayed is not printed.
- If the STOP key is pressed twice during the WASH process, the WASH process is cancelled; the analyzer goes into STAND-BY state, and the flow is stopped.

Fig. 3-8 Emergency stop



When the sensor detects the metallic end marker on the end of a sample rack or an empty rack passes through the sampling position, the analyzer recognizes the end of the assay, outputs the results and executes the WASH operation.

When you use the 90 sample loader with rack circulation switch on or the 290 sample loader, make sure to place an end marker or an empty rack to stop the assay process. If this is not done, samples will be processed again until the stop action is manually operated.
Refer to "3.8 Samples" for details about sample rack circulation and end markers.

Caution

Primary tubes might stay pulled up due to the piercing action after assay. If sampling is done from the tube again in this state, the analyzer's needle could be damaged.

Point

1. **The time that elapses from when the START key is pressed until the sample is detected depends on the location of the sample. To speed up detection, place the sample at the nearest position to the Barcode Reader (BCR). However, the rack placement position is limited to the range indicated in Fig. 3-16 and Fig. 3-17 (refer to "3.8 Samples").**
2. **The assay ends by placing an end marker or an empty rack, or pressing the STOP key.**

- **WASH**

  The analyzer goes into the WASH state after the assay is complete. In this state, Elution Buffer No. 3 automatically runs for 0.5 minutes, and then No. 1 runs for 1.5 minutes to wash the column. Elution volumes for WASH state are 3.3 mL of Elution Buffer No.1 and about 1.1 mL of Elution Buffer No.3. When the "WASH MODE" on the PARAMETER screen is set to "NORMAL", the analyzer goes into the PUMP CLEAN state after the WASH state is complete. When the "WASH MODE" is set to "SIMPLE", the analyzer does only a protective operation for the syringe line without going into the PUMP CLEAN state. Refer to **"4.9 Parameter Setting"** for more details.

  The WASH operation can be cancelled by pressing the STOP key twice; then the analyzer goes in the STAND-BY state and stops the flow.

  Always execute a WASH operation after an assay is complete. If the WASH operations are insufficient, the column life is reduced and results for the next sample to be assayed may be affected. In addition, when an emergency stop is executed during ANALYSIS and flow is stopped (the STOP key is pressed 4 times), the sample currently under assay will remain in the column. In that case, execute the COL.WASH operation not to shorten the column life.

- **COL.WASH**

  The column wash is executed by pressing the 

key on the "REAGENT CHANGE" screen. While washing is taking place, the status of the analyzer is "COL.WASH" and after the system has been washed, the analyzer automatically enters the "STAND-BY" state. Elution volume for the column wash is approximately 1.1 mL of each Elution Buffer No.1, No.2 and No.3.

The COL.WASH operation can be cancelled by pressing the STOP key.

- **BUFF PRIME**

  When the power is initially switched on, the analyzer automatically aspirates and delivers 5 mL of each Elution Buffers in order to replace the buffer in the flow line with fresh liquid (this is called a PRIME operation).

  When the PRIME or CHANGE is executed on the REAGENT CHANGE screen, the BUFF PRIME status will also be displayed during execution.

- **PUMP CLEAN**

  In order to clean contamination or salt precipitated from the pump plunger, the back surface of the plunger seal is automatically washed with Hemolysis & Wash Solution (approximately 5 mL) after the power is turned on or an assay is complete.

- **PURGING**

  When purging air is being executed on the REAGENT CHANGE screen, the PURGING state will be displayed during execution. Elution volumes for PURGING state are 15 mL of Elution Buffer No.1 and 5 mL each of Elution Buffer No.2 and No.3.

3.5 User Setting

Before starting an assay, select the user name displayed on the USER ACCOUNT screen to log on.

You can not execute any operation without log on.

Point

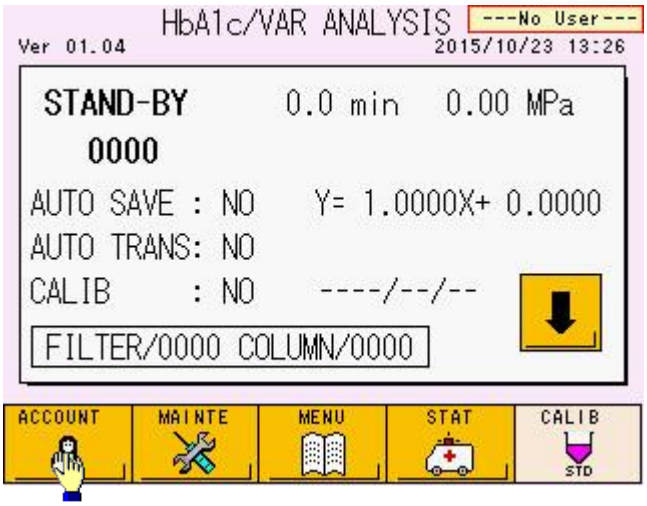
There are two kinds of users, "Super User" and "Operator". "Operator" has limited authorities on some operations compared with "Super User". Refer to "4.2 User Account" for details

- **How to log on**

1. Press 

key on the Main screen to open the USER ACCOUNT screen.

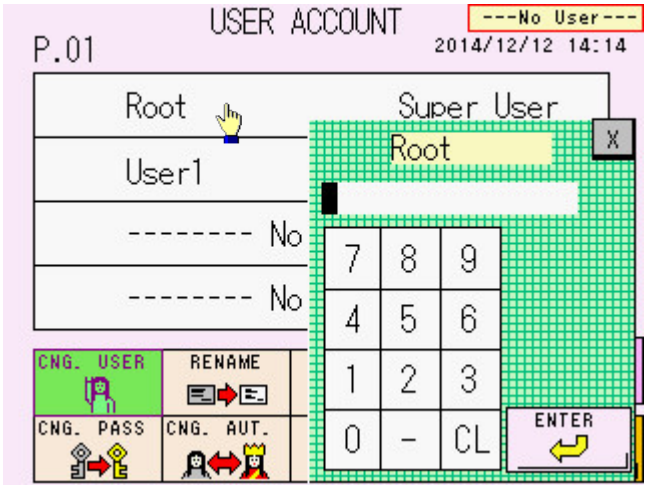
Screen 3-6 Main screen



2. Check that 

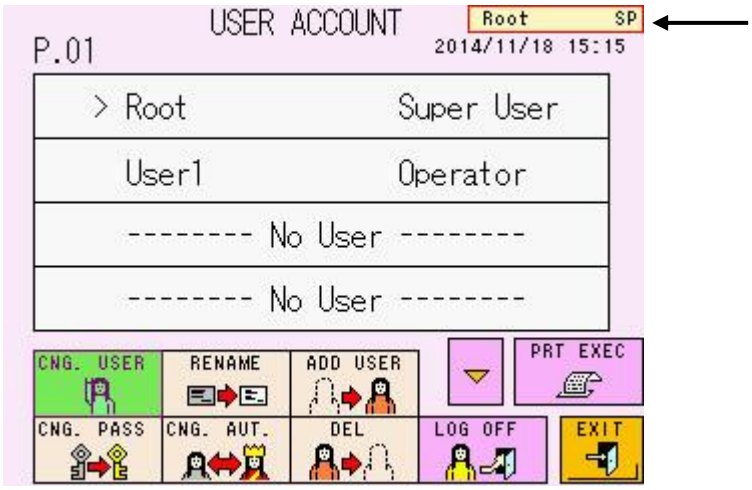
key is displayed in green, and select the registered user name. Enter the password on the numeric keypad.

Screen 3-7 USER ACCOUNT screen



3. After entering the password, confirm the user name displayed on the right top of the screen.

Screen 3-8 USER ACCOUNT screen



Point

If you log on in the WARMING-UP state, you cannot change users. Wait until the analyzer goes in the STAND-BY state.

Point

If an hour (default) elapses without pressing any sheet key or touch panel, the user will be automatically logged off. The delay time before automatic log off can be changed by changing the settings of the LOG OFF TIMER on the PARAMETER screen. Refer to "4.9 Parameter Setting" for more details.

Point

You can change users with an optional handheld barcode scanner. Refer to "3.12 How to Use Handheld Barcode Scanner".

3.6 Checks before Assay

Be sure to check the following items before starting an assay (START command).

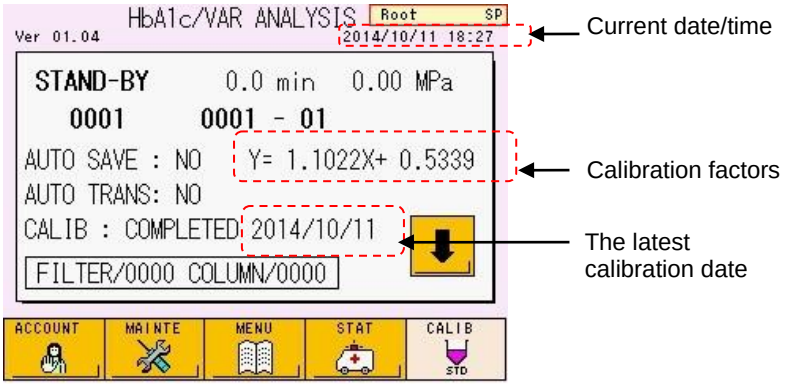
1. Calibration Setting

On the main screen (first screen), check the calibration setting. Be sure to calibrate in the following situations:

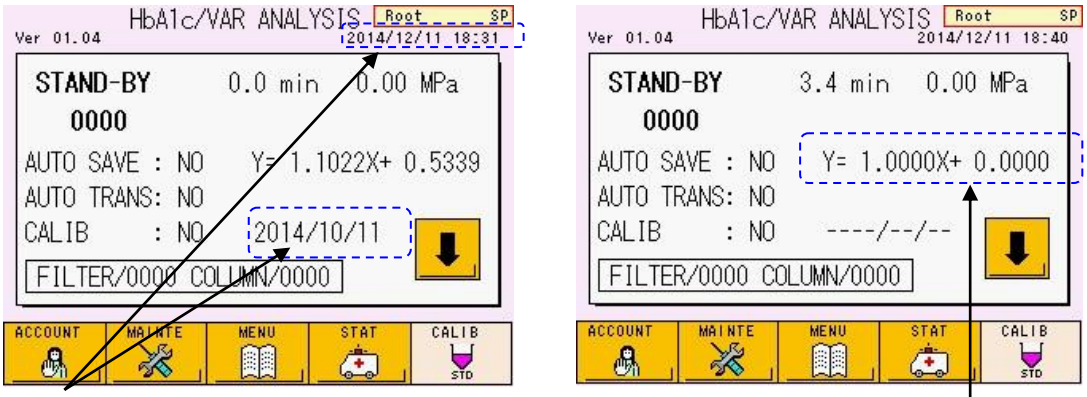
- When calibration factors displayed on the main screen are default values (Y = 1.0000X + 0.0000).
- 30 days or more have passed since the latest calibration.

Refer to "**3.7 Calibration**" for information about the input method.

Screen 3-9 Main screen (first screen)



Screen 3-10 Main screen (first screen)
(when calibration should be executed)



More than 30 days have passed since the latest calibration.

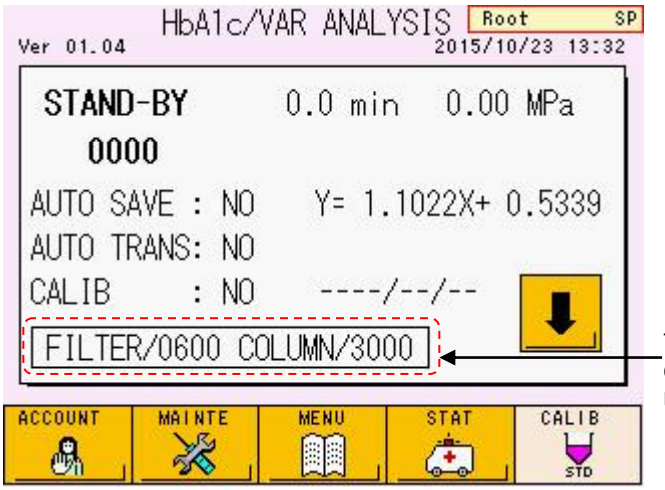
Calibration factors are default values.

2. Column and Filter Count Numbers

Be sure to check the filter count numbers and replace the filter when the following replacement period has passed. The column is replaced as needed. Replacement period of column is as follows. Refer to "**5.8 Filter Replacement**" or "**5.9 Column Replacement**".

[Filter]
Replacement period: 600 injections
[Column]
Replacement period: as needed

Screen 3-11 Main screen (first screen)
(The filter and column count numbers)



The filter and column count numbers after replacement

Caution **Replace the filter when the filter counter reaches 600 injections. Since the life of the filter depend on assay conditions, measure the control sample regularly to confirm that it falls within the standard range or no error occurs.**

3. The Remaining Volumes of Elution Buffers and Hemolysis & Wash Solution

Press the ⬇ key on the right bottom of the main screen (first screen). The screen (second screen) will appear and bar graphs will show the remaining volumes of each buffer.

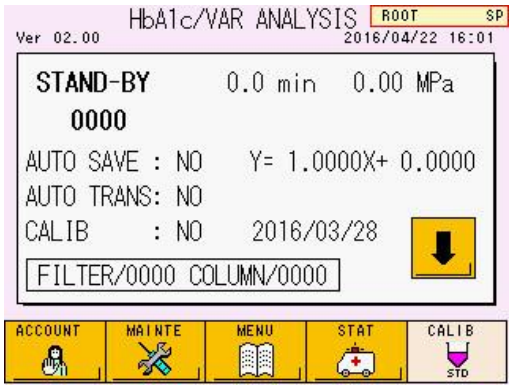
Approximate consumption volumes are shown below for each buffer.

[Consumption volumes of each elution per 1 test]
- G11 Variant Elution Buffer No.1: 0.8 mL/test
- G11 Variant Elution Buffer No.2: 0.9 mL/test
- G11 Variant Elution Buffer No.3: 0.5 mL/test
- Hemolysis & Wash Solution: 4.1 mL/test

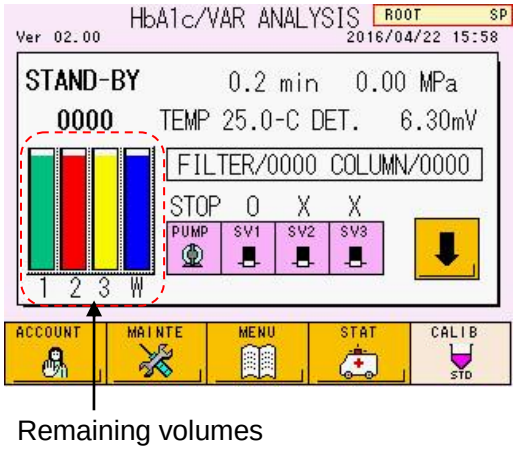
In addition, be aware that some reagents are used in the PUMP CLEAN, BUFF PRIME, PURGING, and COL.WASH operations. Confirm that the remaining volumes are sufficient. Replace Elution Buffers and Hemolysis & Wash Solution as early as possible when remaining volumes are low. Do not reuse remaining Elution Buffer or Hemolysis & Wash Solution or mix remaining reagent with a different or new one.

Refer to "**5.4 Elution Buffers and Hemolysis & Wash Solution Replacement**" for replacement method.

Screen 3-12 Main screen (first screen)



Screen 3-13 Main screen (second screen)

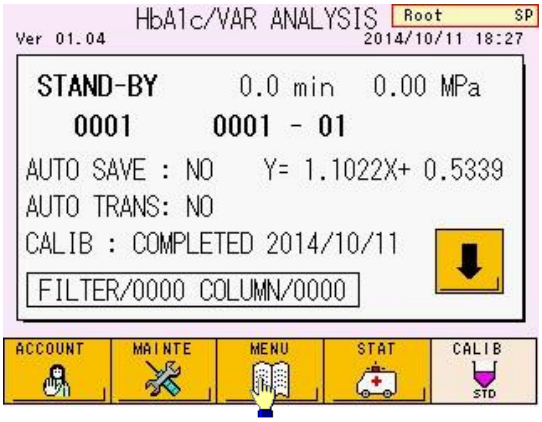


4. USB Sticks for Assay Result Storage

Insert a USB stick into the socket and select the 

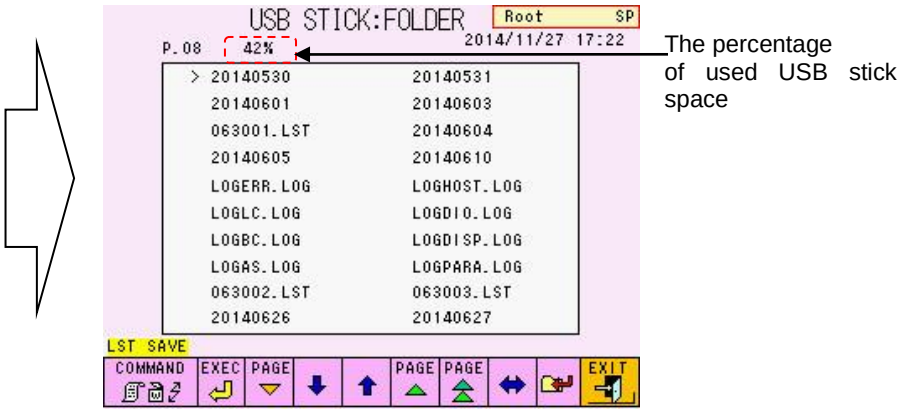
key on the MENU screen. A list of assay result folders stored in the USB stick will appear and the percentage of used USB stick space will be displayed on the upper left of the screen.

Screen 3-14 Main screen (first screen)



Screen 3-15 MENU screen

Screen 3-16 USB STICK: FOLDER screen



The required memory capacity for one set of measurement results (RWV data) is 5 KB. This means that a 1 GB memory can store 200 thousand sets of results. When saving the assay results, use a USB stick that has adequate free space available. Note that when you intend to save the list data as well, the number of sets of data that can be stored will be reduced.

Use the PARAMETER screen to set the type of data to be stored. Refer to "**4.9 Parameter Setting**".

Since assay results are also stored in the RESULT memory in the main unit, saving the results on a USB stick is not absolutely necessary. Up to 800 assay results can be stored in the RESULT memory. When this number is exceeded, existing data is overwritten, starting with the oldest results.

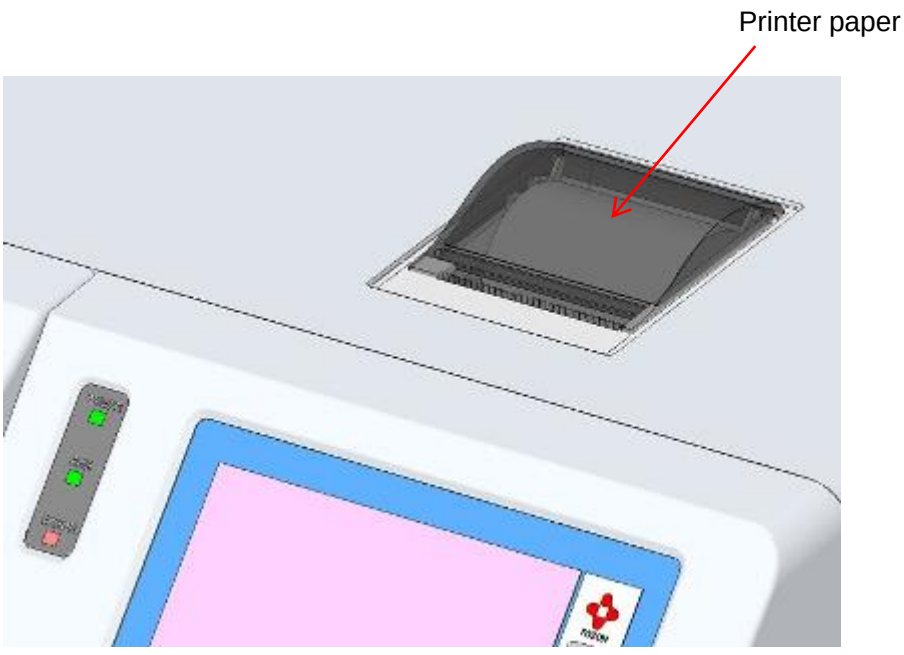
Point

1. The contents displayed on the "USB STICK: FOLDER" screen are the folders and files inside the "G11" folder in the root directory of the USB stick.
2. If data other than the assay data (RWV data) is stored in the USB stick, the number of sets of assay data that can be saved will be reduced. Also, note that you cannot format the USB stick while assay is in progress. Before issuing a start instruction, check the available free space, and before starting assay obtain a formatted USB stick.
3. If the USB stick was used previously in another application, the format may be different. Before using the USB stick, format it to FAT32 format using the analyzer or a PC. The USB stick formatted with the analyzer can be used in a PC.

5. Remaining Printer Paper

Check the remaining volume of printer paper (thermal paper roll).
A colored bar indicates a small volume remaining. Replace the roll with a new roll when this bar appears. After a colored bar appears, about 10 sample results (standard format) can be printed.
Even if the printer paper runs out during an assay, since the results are stored in the RESULT memory in the main unit, the result can be printed using the RECALC (recalculation) after all sample assays are complete. Transmissions to the host will continue regardless of the printer paper status.
A roll can handle about 270 sample results, but it depends upon the format. See "**3.14 Interpretation of Results**".

Fig. 3-9 Printer unit



6. Waste Tank

Be sure to check the volume of the waste fluid before starting an assay. When the tank is filled with the waste fluid, empty the waste tank. Refer to "**2.5 Connections – Waste Tube**".

Caution **If the waste tank is not empty, the waste fluid could overflow during an assay.**

Caution **The waste fluid includes blood components. Never handle the waste tank or waste tube with your bare hands. Always wear protective clothing (goggles, gloves, masks, etc.) to prevent potential infection during handling. Dispose the waste fluid in accordance with your facility's standard procedures.**

7. Expiration Date of the Column and Reagents

The column, Elution Buffers and Hemolysis & Wash Solution each have an expiration date. The expiration date is printed on the following positions. Never use expired reagents, and replace them with new ones. Refer to "**5.9 Column Replacement**" and "**5.4 Elution Buffer and Hemolysis & Wash Solution Replacement**".

[Printed position of expiration date]

Column: Box label, Column label

Elution Buffer: Box label, Aluminum pack label

Hemolysis & Wash Solution: Bottle label

However, the expiration date of the reagent after opening is either "90th day after being opened" or "the expiration date indicated on the label" whichever comes first.

3.7 Calibration

The analyzer is calibrated using HbA1c Calibrator (1) and (2) with different HbA1c aligned values. Use the "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)" for calibration (P/N: 0018767 or 0023502).

Be sure to calibrate in the following situations.

- **When control values assayed are out of range**
  Calibrate when the control assay value falls outside the standard range. Measure the control sample again to confirm that it falls within the standard range before assaying a real sample.
- **After column replacement**
  Never fail to execute calibration after a new column has been installed.
- **After analyzer maintenance**
  Be sure to calibrate after plunger seal replacement or other analyzer maintenance or repair.
- **When set assay conditions of the analyzer are changed**
  Calibrate when a set parameter value of the analyzer such as the flow factor is changed.
- **When calibration factors have expired.**
  The expiration date of calibration factors is 30th day after the latest calibration. If the calibration factors have expired, an error will be displayed when the assay starts.

Each laboratory must carry out the daily test of control samples and check the results for good laboratory practices.
Use the "Hemoglobin A1c Control Set" (P/N: 0021974) together with the calibrators for the daily assay results.

Automatic Calibration

Check the CALIB message on the main screen (first screen). The following messages can be displayed.

- **CALIB: YES**

  Automatic calibration will be executed before the samples are assayed (See Screen 3-18)

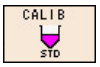
- **CALIB: COMPLETED**

  This indicates that automatic calibration is complete (See Screen 3-19). Subsequently, automatic calibration will not be executed even if the START key is pressed. Set the real samples to start the assay. They will be assayed in accordance with the factors displayed on the screen.

  When the 

key is pressed on the main screen, the display message will change to YES and calibration will be done again. The display will change to NO when the power is turned off with the power key or by the timer.

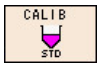
- **CALIB: NO**

  The 

key is not selected. Automatic calibration will not be executed. The assay result will be corrected by the factors displayed on the screen.

  To change the calibration factors for previous assay results, input the new factors in the RECALC screen. Then, recalculate the data stored in the analyzer's memory or on a USB stick

Scheduled Automatic Calibration

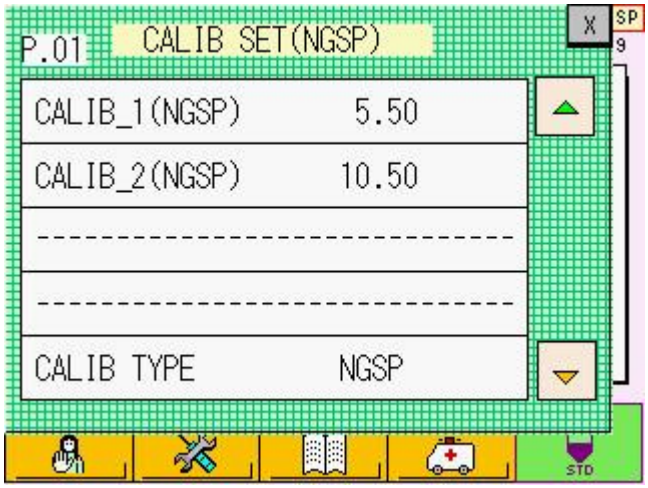
Press the 

key located at the bottom right of the main screen.
The key will be displayed in green, and the calibrator's aligned value input screen will be opened. Confirm the aligned value. If the calibrator's lot has been changed or if the entered value is incorrect, input the correct value. To change the units of assay values, press the "CALIB TYPE" line and select the desired type of assay values.

Point

When a handheld barcode scanner is connected to the analyzer, you can automatically input the calibrator's aligned value by reading barcode sheets attached to the "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)". Refer to "3.12 How to Use Handheld Barcode Scanner" for details.

Screen 3-17 Aligned value input screen (for NGSP unit)



Point

The analyzer accepts aligned values of calibrator both in NGSP (National Glycohemoglobin Standardization Program) units (%) and IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) units (mmol/mol). Aligned values in each unit are printed on the Instructions For Use of "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)".

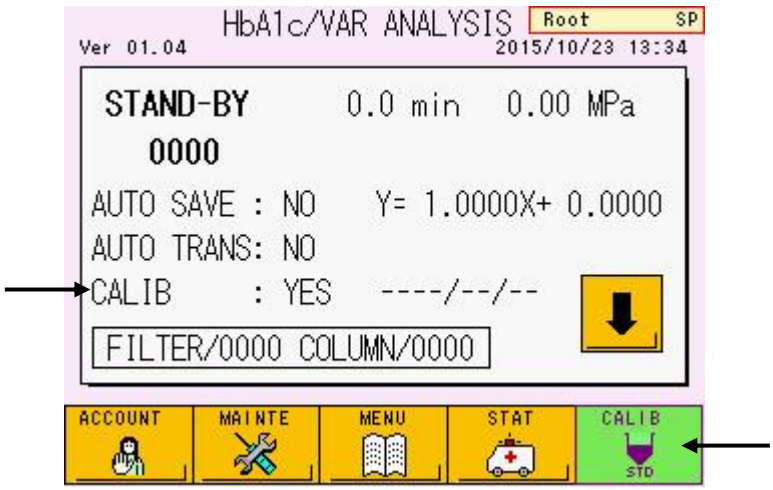
The title line of the Aligned value input screen displays the unit of aligned values which should be entered.

For entering in NGSP units

For entering in IFCC units

After entering aligned values, close the aligned value input screen by pressing the X mark at the top right of the screen. Verify that the key CALIB STD on the main screen is displayed in green and that the CALIB message is YES (See Screen 3-18).

Screen 3-18 Main screen (CALIB: YES)



First set the LEVEL 1 and LEVEL 2 calibrators in the sample cups at the No.1 and No.2 positions of the first rack. Press the START key. The calibration will be processed automatically before samples are assayed.

Once the automatic calibration is complete, the CALIB message will change to COMPLETED with the date of calibration and the CALIB key will be displayed in white.

In addition, CALIBRATION REPORT will be printed. It gives the calibration date, old and new calibration factors, and filter and column count numbers.

The required volume of Calibrator (1) and (2) is described on the Instructions For Use of Calibrator Set. Shortage of them could stop the calibration operation.

Put the Calibrator (1) and (2) into the sample cups on the rack. Calibrators in primary tubes will cause a calibration error.

Screen 3-19 Main screen (CALIB: COMPLETED)

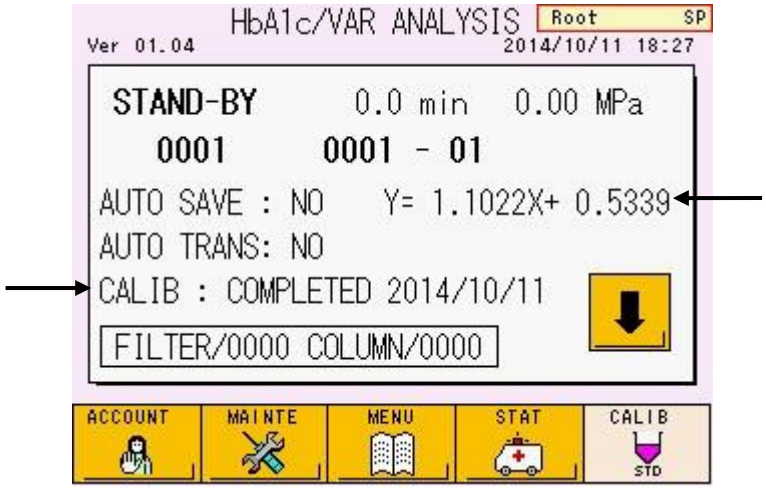
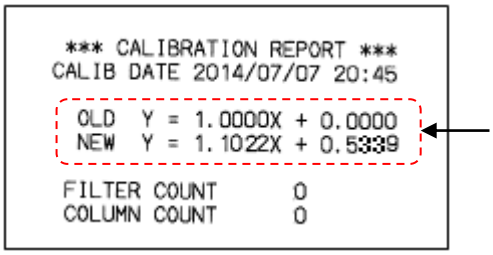


Fig. 3-10 CALIBRATION REPORT



The calculated calibration factors are automatically input in the PARAMETER screen and displayed on the main screen with the date of calibration in the form of Y = AX + B (in case of Screen 3-19, Y = 1.1022X + 0.5339).

Behind the calibrators in the rack, place samples that will be assayed and their values will be corrected using the newly calculated calibration factors.

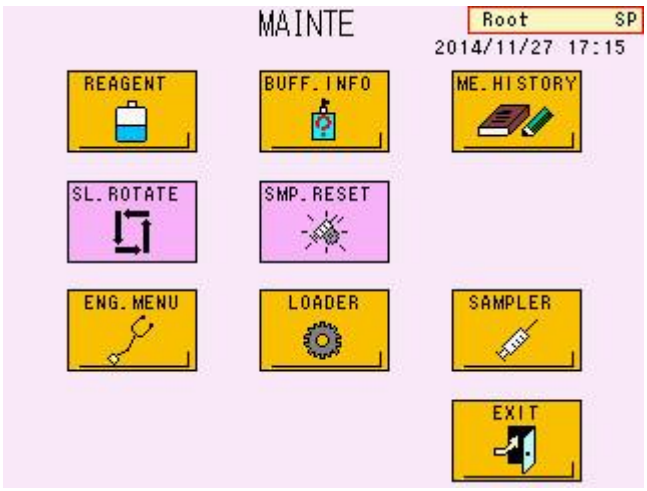
Expiration Date of Calibration Factors

The expiration date of calibration factors is 30 days after the latest calibration. When the calibration factors are expired, an error will be displayed when an assay starts. Execute calibration again

To check the expiration date, press the 

key on the main screen and open the MAINTE screen,

Screen 3-20 MAINTE screen

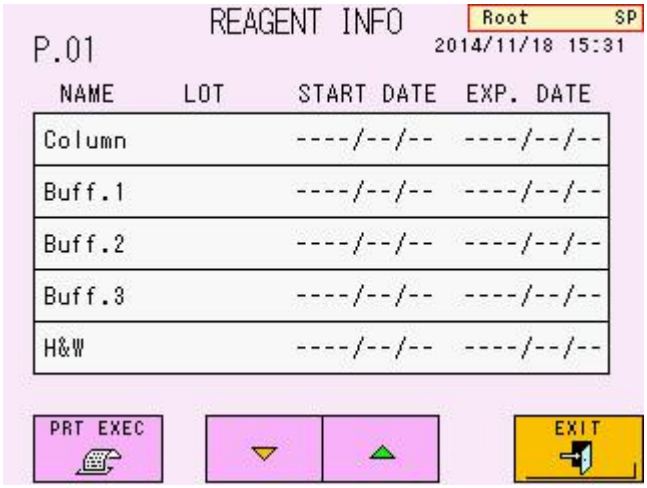


Press the 

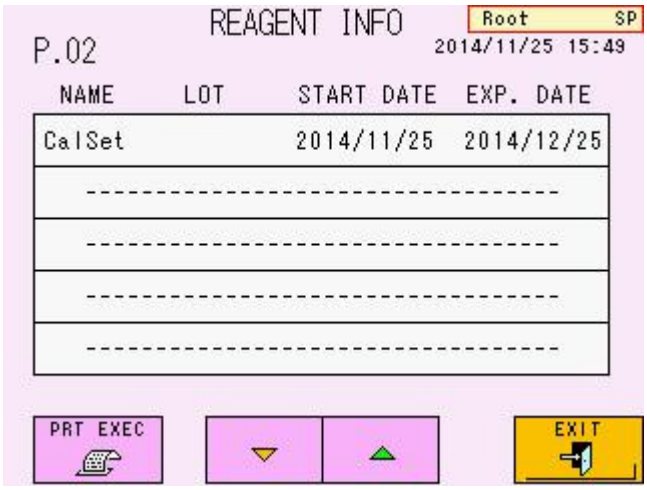
key. The REAGENT INFO screen will be opened.

Move to the second page by pressing  key. The calibration date (start date) and the expiration date of calibration factors will be displayed in the "CalSet" line.

Screen 3-21 REAGENT INFO screen (P.01)



Screen 3-22 REAGENT INFO screen (P.02)
(expiration date of calibration factors)



Calibrator Reconstitution

Refer to the Instructions For Use for details regarding the proper handling of the "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)".
Pay particular attention to the following points:

(1) The calibrator set contains lyophilized human hemoglobin components sealed in vials. Store unopened vials in a refrigerator and use before the expiration date.

When using the calibrator, open the vial and dissolve the material according to the Instructions For Use of "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)".

After the material has sufficiently dissolved, dispense the required volume into a sample cup. Use soon after dissolving and do not leave at room temperature for a long period.

(2) Seal the remaining calibrator in the vial and then store in a refrigerator after use. The stability of reconstituted calibrator is indicated on the Instructions For Use of "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)". Never use the reagent whose expiration date has passed.

Calibrator Procedure to Determine the Factors after Calibration

The following are for a case entering aligned values in NGSP units. For a case entering aligned values in IFCC units, calculations are done in the same way.

Calibrator (1) is the low value calibrator (approximately 6.0 %) and Calibrator (2) is the high value calibrator (approximately 10.8 %). The low value calibrator is assayed 3 times and the high value calibrator is assayed 2 times.
The first assay result for Calibrator (1) is discarded and the average HbA1c % of the 2nd and 3rd assay is calculated as the result for Calibrator (1). The average HbA1c % of the 4th and 5th assay is calculated as the result for Calibrator (2). Based on the assay results and the aligned values, the following linear equation is used to calculate the calibration factors.

Object of correction: HbA1c (%)
Correction formula: (HbA1c (%) after correction)

= A × (HbA1c (%) before correction) + B

A = (CAL(2) aligned value – CAL(1) aligned value) / (CAL(2) assayed value – CAL(1) assayed value)

B = CAL(2) aligned value – (CAL(2) assayed value × A)

When aligned values in IFCC units (mmol/mol) are entered, the calibration factors are calculated in the same way using the above equations.

Calibration Error

A calibration error occurs when the calibrator assay results meet the following conditions.

- Error conditions

1. **The difference in the HbA1c (%) value between the 2nd and 3rd assay result is 0.3 % or more.**
2. **The difference in the HbA1c (%) value between the 4th and 5th assay result is 0.3 % or more.**
3. **The average HbA1c (%) of the 2nd and the 3rd assay results differ(s) more than 30 % from the aligned value.**
4. **The average HbA1c (%) of the 4th and the 5th assay results differ(s) more than 30 % from the aligned value**

In addition, the calibration error will occur when the analyzer recognizes the primary tubes during calibration,
When an error occurs, the assay automatically stops and the analyzer goes in the STAND-BY state. Samples placed behind the calibrator are not assayed. The CALIB message on the main screen changes to "NO" and the 

key is displayed in white. Execute calibration again because it has not been completed.

When aligned values in IFCC units (mmol/mol) were entered, the calibration error will be checked after automatically converting the entered values into NGSP units (%) using the Master eq.:NGSP (%) = 0.09148 x IFCC (mmol/mol) + 2.152.

These errors could be caused by the following.

1. **Calibrator (1) and (2) are placed in wrong positions of the rack.**
2. **The entered aligned value of the calibrator is incorrect.**
3. **The calibrator is not reconstituted according to the correct procedure.**
4. **The expiration date of calibrators has exceeded.**
5. **Samples other than the calibrator were assayed.**
6. **The column lot ID does not match the Elution Buffer lot ID.**
7. **The expiration date of the column or Elution Buffers has exceeded.**
8. **Calibrators are in primary tubes, not in sample cups.**

Execute calibration again after checking positions of the sample cups, checking the entered aligned value, replacing the buffer, filter and column, preparing a new calibrator and confirming samples containers.

3.8 Samples

Sample Containers

Primary tubes and special sample cups can be processed in the analyzer.

- **PRIMARY TUBE**

  Tubes with rubber caps can be directly set in the sample rack. The sizes of tubes that can be directly set are 12 - 15 mm diameter × 75 mm and 12 - 15 mm diameter × 100 mm.

  For safety, a finger guard for 75 mm primary tubes is attached to the analyzer. Remove the finger guard when using 100 mm primary tubes. If you want to remove the finger guard, contact Tosoh local representatives.

  The minimum required sample volume is approximately 1 mL for whole blood. For samples with a low hematocrit, blood cells may not be sampled. It is advisable to use sample cups.

Caution **If the sample has been subjected to centrifugation to measure blood glucose prior to being assayed by the analyzer, make sure that the centrifugation has been done at less than 500 G/5 min.**
You may get different results between centrifuged samples at over 500 G/ 5 min and hand-mixed samples in anemic patients or dialysis patients. It is recommended to use the whole blood mixed by turning the primary tubes upside down thoroughly for correct results.

- When using a SYSMEX Rack

If you use a SYSMEX rack, attach a rack adapter to the sample rack for 12-14 mm diameter primary tubes. The adapter for 13 mm diameter tube is included as a standard accessory. Adapters for 12 mm and 14 mm diameter tubes are available as options.

(ϕ12 adapter: P/N 0018496, ϕ14 adapter: P/N 0018497)

Caution

- **If the primary tube adapter is too loose, the tube may tilt during sampling and the sampling needle may not pierce at the proper location. In the worst case, the needle may be bent or broken. Be sure to use an adapter size that is appropriate for the primary tube diameter.**

- **SAMPLE CUPS**

  Use a sample cup when processing diluted samples, calibrators, control, or small volumes of whole blood.

  When you use a sample cup, make sure to attach a cup adapter (P/N: 0020101).

  If there is only a small amount of sample in the primary tube, preventing blood cells from being sampled, a whole blood sample can be moved to a sample cup (minimum sample volume is 100 µL) or can be diluted in a sample cup manually for an assay in the STAT port (refer to "**3.11 Priority Sample Assay (STAT)**") Follow the procedure below to dilute a whole blood

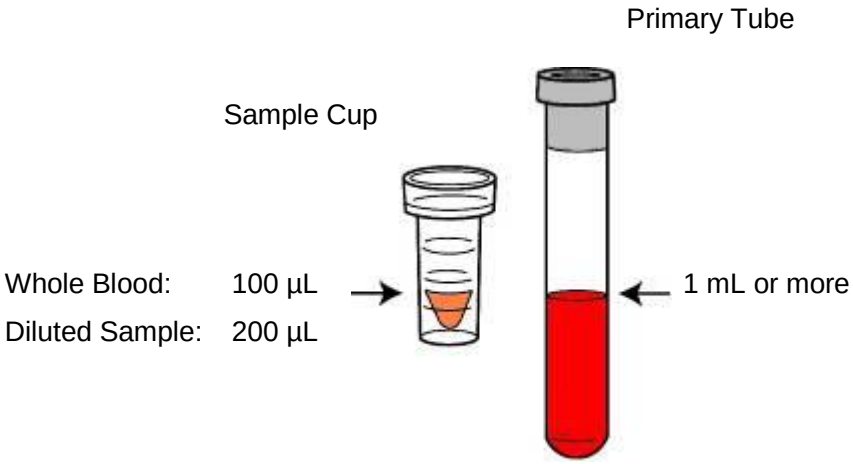
Procedure

1. Dispense 1 mL of Hemolysis & Wash Solution into a sample cup.
2. Add 5 µL of a whole blood and mix thoroughly (dilution rate: 201 times)

When the hematocrit is low, the TOTAL AREA of the assay results may drop below 400. If this happens, dilute 10 µL of whole blood in 1 mL of Hemolysis & Wash Solution (dilution rate: 101 times).

Screen 3-23 LOADER SMP MODE parameter setting

Fig. 3-11 Minimum Sample Volume



The anticoagulants used in primary tubes have no particular influence on assay values.

Generally, a primary tube containing EDTA is used for the HbA1c assay. A primary tube containing EDTA and NaF is used when processing an HbA1c assay and a glucose assay (with another system) with the same primary tube.

Caution

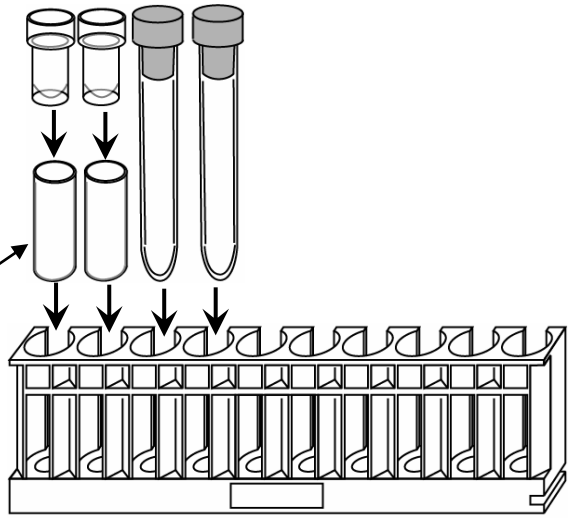
1. **If the primary tubes are loose on the TOSOH rack, adjust the rack's holder to tightly hold the primary tubes. The sampling needle could be bent if the tubes are loose.**
2. **Insert the primary tubes straight into the racks. If the primary tube is not set straight or its bottom is not fit to the rack, the sampling needle could be bent.**
3. **Make sure to place the primary tubes or sample cups from position No.1 of the rack. If there is no sample container in position No.1, loading assays may not start.**
4. **If primary tubes with labels and those without labels are mixed together on the same rack, or when different types of primary tubes from different manufacturers are mixed on the same rack, make sure all the tubes are firmly held in place. If the tubes are excessively loose, prepare racks with different adapter diameters for each primary tube type.**
5. **Maximum sample volume for a sample cup is 1 mL.**
6. **If primary tubes and sample cups are mixed on the same rack and the rack could not be carried smoothly, prepare racks with different sample containers.**

Fig. 3-12 Loading method for primary tubes and sample cups (example)

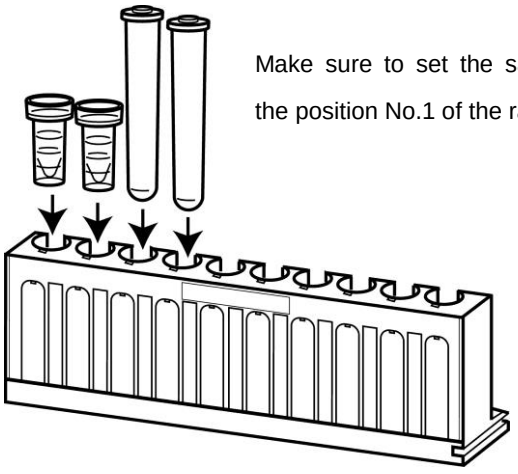
(For TOSOH rack)

Make sure to set the sample containers from the position No.1 of the rack.

Cup Adapter
(P/N: 0020101)



(For SYSMEX rack with ADAPTER)



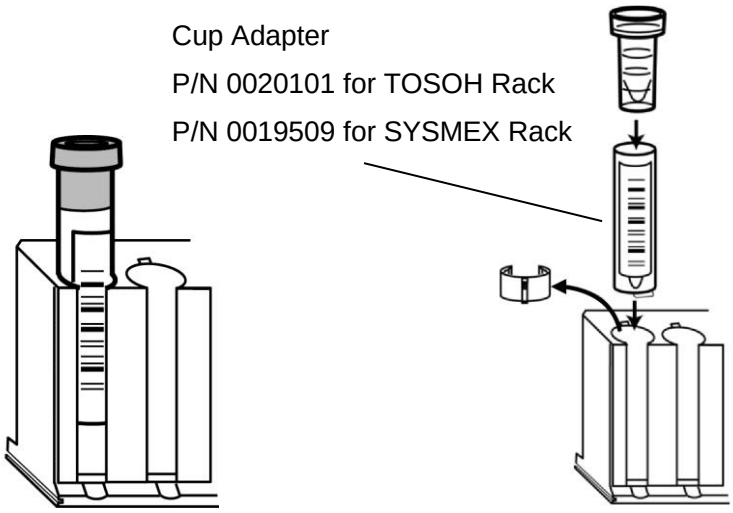
Make sure to set the sample containers from the position No.1 of the rack.

Barcode Label Confirmation

The barcode reader on this analyzer allows reading of the barcode ID on the label attached to the primary tube. Then the analyzer can transfer sample information inquiries and assay results with the read IDs to the host. Barcode ID will also be printed onto the measurement report from the analyzer's built-in printer. If a container with no barcode is processed, the measurement ID will be sent to the host and printed along with the measurement.

When setting primary tubes on the sample rack, the barcode label must be oriented toward the slit (the barcode will therefore face the main unit when the rack is placed in the analyzer). In the case of sample cups, use the optional cup adapter attaching barcode labels.

Fig. 3-13 Label direction and cup adapter setting position in a rack



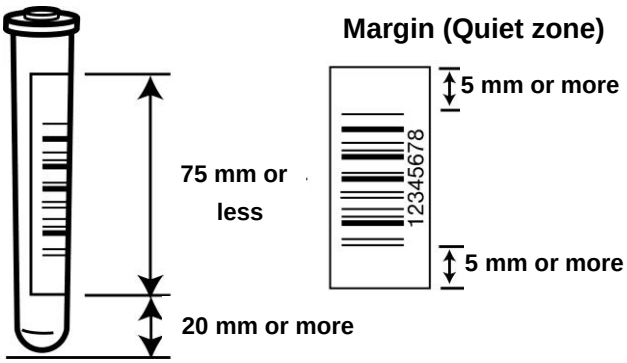
In addition, a 5 mm margin (blank space) is required on the top and bottom of the printed barcode. See Fig. 3-14 below.

The analyzer could detect the barcode label attached to the sample rack as specimen's barcode. Do not attach the barcode label to the sample rack.

If a barcode can not be read or a sample container has no barcode, the rack number and the position on the rack (1 to 10) will automatically be assigned instead. The rack of the first sample from the START is recognized as number 0001 (0001-03, 0008-01, etc.).

Affix the labels vertically as shown in Fig. 3-14. A reading error will occur if the label is set at an angle or if it is wrinkled.

Fig. 3-14 Barcode label attachment position and size



There are strict printing specifications for each standard code used in bar-coding. Labels that do not conform to specifications (lines that are too thin, etc.) will result in a poor reading rate or may be completely unreadable. Contact your label printer manufacturer for information regarding these specifications.
Although the analyzer is compatible with most bar-coding standards, some barcode specifications do not specify an initial setting, and a reset may be required.
Refer to "**7.3 Analyzer Specifications**" for code specifications. Refer to "**4.22 Barcode Reader Settings and Reading Check**" for details on how to change the settings.

The barcode label should not be angled more than 5 °. You should also leave a margin (quiet zone) of 5 mm or more on the left and right of the barcode, as indicated in Fig 3-14.

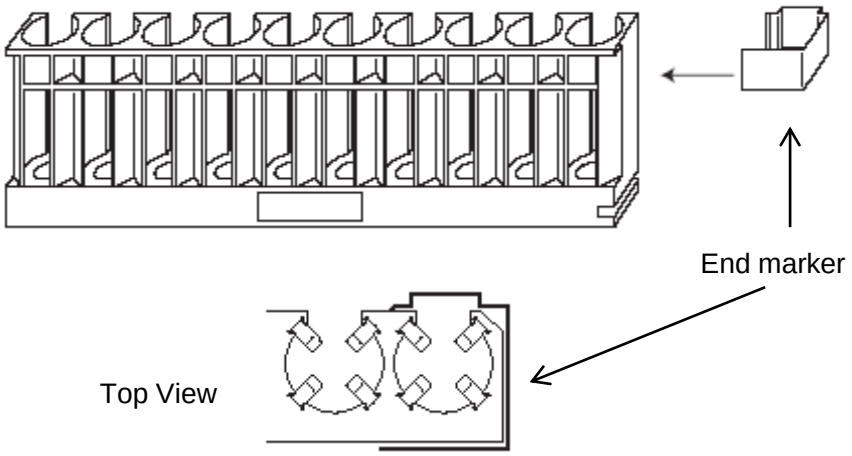
End Marker Attachment

When the end marker is attached to the last rack, the assay automatically ends when the assaying of all samples set in the rack is complete.

Procedure

1. Squeeze the end marker with fingers until the opening is 6 to 8 mm wide.
2. Set the end marker in the position shown in Fig. 3-15.
   - Orientation: Set the flat surface on the front edge (the side with no slit) and the bending surface on the rear edge (the side with a slit).
   - Position: Top of No.10 port on the last rack.

Fig. 3-15 End marker attachment



Attach the correct end marker. An improper end marker could result in improper operation and damage to the machine and its components.

Sample Rack Loading

Caution **Never set racks, or add or remove samples during an analysis. Otherwise users might catch their fingers in the moving parts.**

Procedures

1. Sample racks can be loaded in the rack positions (shaded) shown in Fig. 3-16 and Fig. 3-17. A loader chuck is provided at the slit at the right bottom of the rack to prevent overturning.
2. With the 90 sample loader, the first rack is placed at A and subsequent racks are placed in sequence.
   Up to 9 racks can be set and 1 rack space must remain empty.
3. With the 290 sample loader, the first rack is set at B and subsequent racks are set in sequence. Up to 29 racks can be set.
4. When barcodes are to be read from primary tubes, check that the labels face the rack slit side (main unit side).
5. Attach an end marker to the last rack. An empty rack with no samples may also be set as the last rack.
6. Recheck the rack direction and setting.

Fig. 3-16 Top view of 90 sample loader

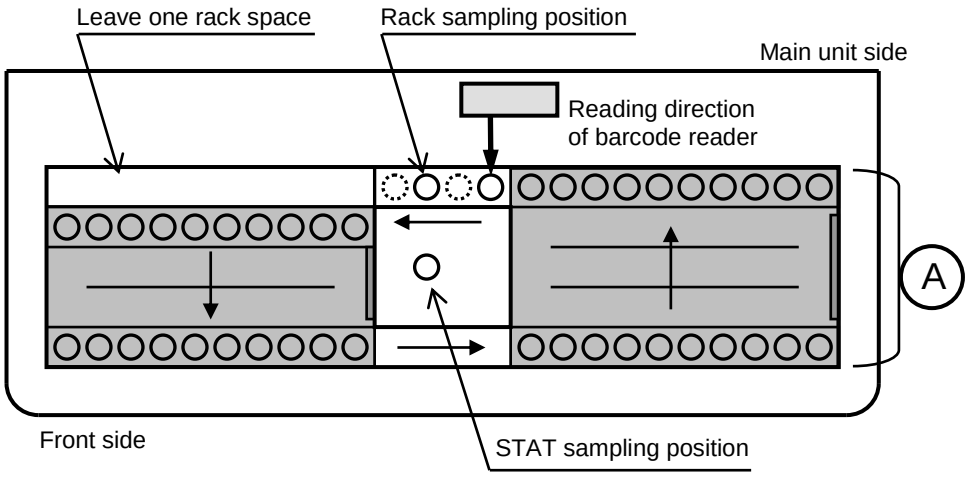
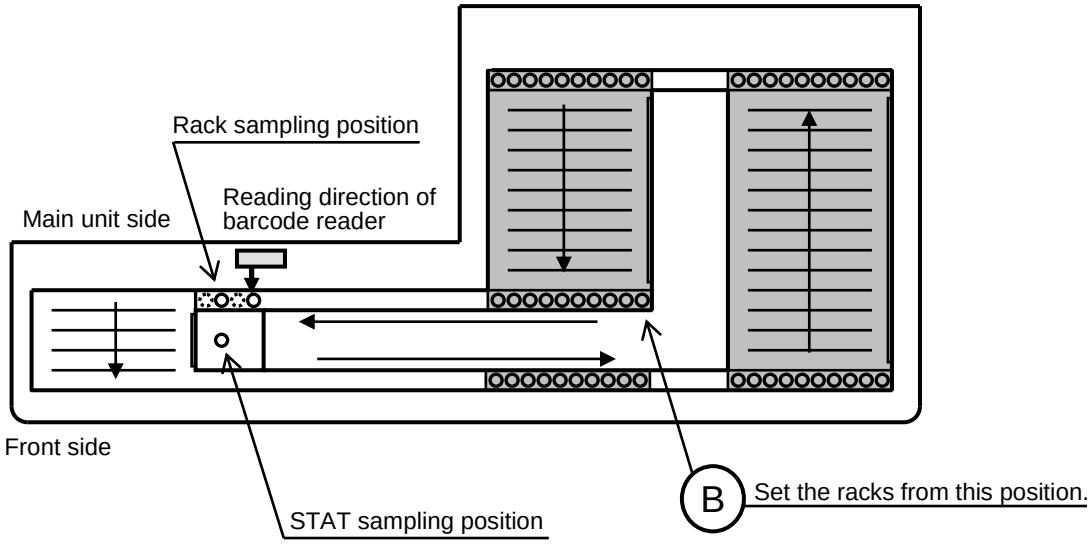


Fig. 3-17 Top view of 290 sample loader



1. **Load the rack when the analyzer is in WARMING-UP or STAND-BY state. During ANALYSIS, if the sensor is activated, a RACK POS ERROR appears and the assay will be aborted. Never set racks, or add or remove samples during an analysis. Make sure to first load all samples and sample racks before pressing START.**

   If you are using the 90 sample loader, the racks can be loaded into any position as long as one rack space is left empty. However, there must be a rack in the A position, as indicated in Fig. 3-16.

   If you are using the 290 sample loader, the assay will not be processed if the racks are loaded anywhere other than the gray area indicated in Fig. 3-17.

2. **When loading racks on the sample loader, be sure to engage the slit on the right lower side of the rack to the chuck on the sample loader for preventing it overturning. Push the racks completely to the right and left ends of the sample loader. If racks are placed in an inappropriate position, a RACK POS ERROR will result, and the assay will stop.**

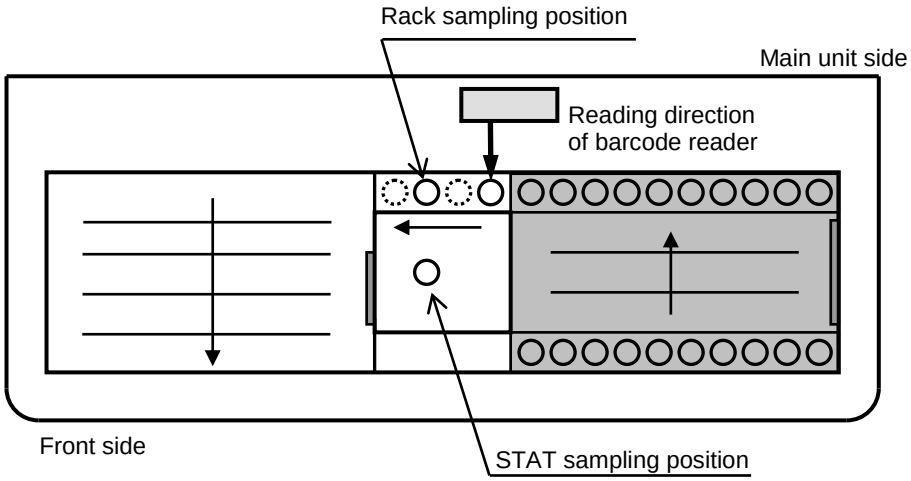
Sample Rack Rotation

When connecting the 90 sample loader, you can change the sample rack rotation settings by using the switch on the right side of the main unit. Under "No Rotation", setting, the assay will automatically end when the analyzer does not detect next sample even without end marker or empty rack.

Caution **Make sure to turn the main power off prior to changing the sample rack rotation setting.**

Under "No Rotation" setting, you can load the sample racks in the positions indicated in Fig 3-18.

Fig. 3-18 Top view of 90 sample loader
(rack loading positions under "No Rotation" setting)

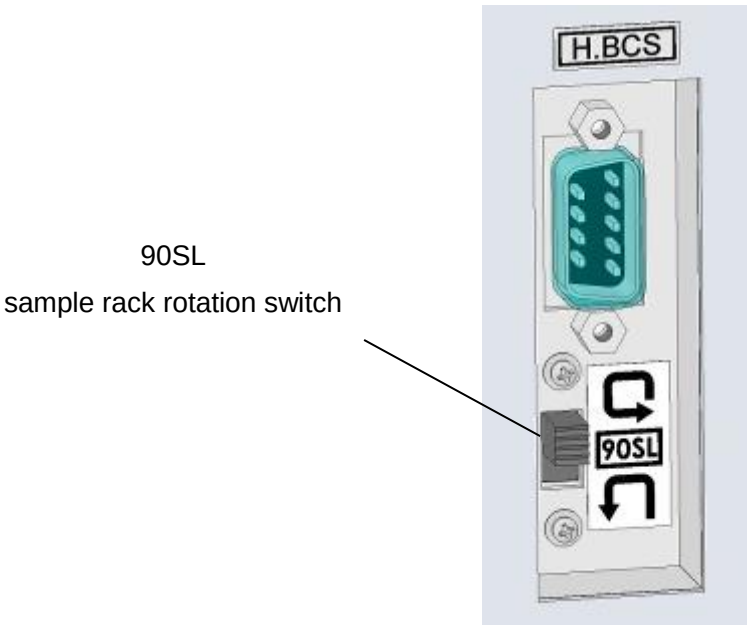


Under "No Rotation" setting, up to 5 sample racks can be loaded.

Procedures

1. Turn the main power off.
2. Change the 90SL sample rack rotation switch on the right side of the main unit. When the switch is in the upper side, the sample rack rotation will be executed. To stop sample rack rotation, shift the switch to the bottom.
3. Turn the main power on.

Fig. 3-19 Sample rack rotation switch for 90SL on the main unit



When connecting the 290 sample loader, the sample rack rotation switch does not work.

Units for reporting and calibration

Assay results are calibrated and reported using the calibration factors determined with the entered aligned calibrator values and units. If the units in which assay results are reported differ from those in which the calibration factors were determined (refer to "**4.9 Parameter Setting**"), correct results will not be reported.

When the units for reporting assay results are changed by "CALIB TYPE" on PARAMETER screen, therefore, calibration should be performed again before assaying.

See "**3.7 Calibration**" for calibration procedures.
See "**4.9 Parameter Setting**" for setting of PRINT OUT FORMAT.

Caution **Assuming the current calibration factors were determined in NGSP units (CALIB TYPE: NGSP), if assays are performed under a setting to report in IFCC units (CALIB TYPE: IFCC), a calibration error will occur, and vice versa.**

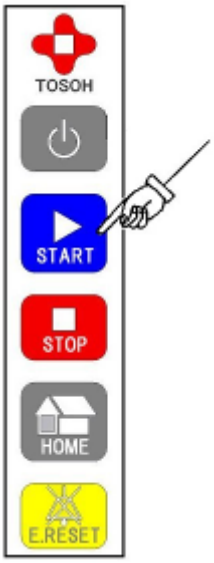
3.9 Assay Start and End

Starting an Assay

After placing samples on the loader correctly, press the START key on the key sheet to start the assay. The RUN LED (green) on the left side of the screen will illuminate and the status display will change from STAND-BY to ANALYSIS.

.

Fig. 3-20 START key



If the START key is pressed during WARMING-UP, the assay will start immediately after WARMING-UP is complete.

Confirm the pressure on the main screen and check the flow status. The target pressure is within range when less than the column pressure (which is indicated on the column inspection report) +4 MPa.

Example: If the column pressure printed in the column inspection report is 12.0 MPa, the target pressure range is 12.0 to 16.0 MPa.

Caution **Never set racks, or add or remove samples during an analysis. Otherwise users might catch their fingers in the moving parts.**

Press the START key only after loading all samples and racks. If you add or remove racks after the assay starts, the sensor may detect a RACK POS ERROR and abort the assay.

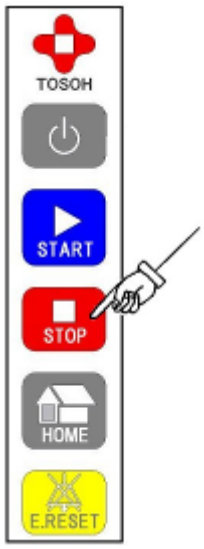
Ending an Assay

Assay results of samples will be printed and the assay will automatically end when the end marker or an empty rack is detected. Thereafter, a WASH will be executed and the analyzer will go in STAND-BY state.

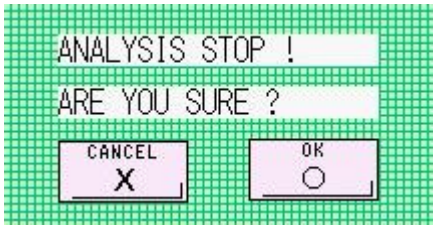
Stopping an Assay

To stop the assays while the assays are in process, press the STOP key. The message below (Screen 3-24) will be displayed. Press the OK key on the screen or press the STOP key again to confirm the stop process. Press the CANCEL key to cancel the stop process.
After the assay currently in process is completed, the result will be output, and the analyzer will go in WASH state.

Fig. 3-21 STOP key



Screen 3-24 The message to stop an assay



If the STOP key is pressed three times, operation will immediately stop and a WASH operation will be executed. Assay results of the sample currently in process will not be reported.
If the STOP key is pressed twice during the WASH process, the WASH operation is cancelled; the analyzer goes in STAND-BY state, and the flow is stopped.

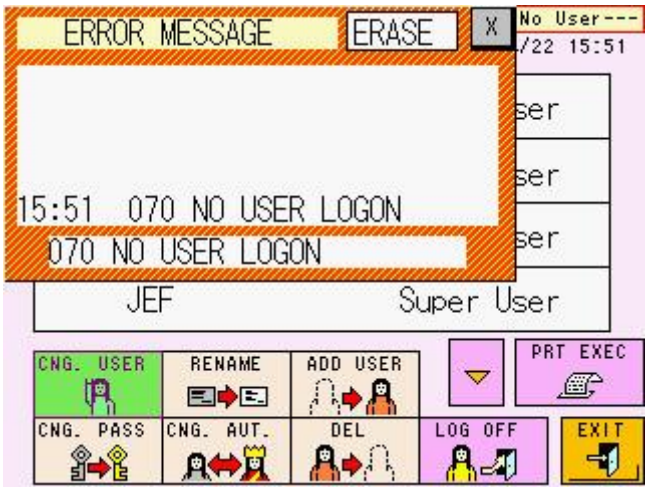
Caution **Always execute a WASH operation after assaying samples.**
If WASH operations are executed insufficiently, sample may remain in the column, which may shorten column life and cause sample carry-over.

Do not immediately remove the samples and racks after you pressed the STOP key to stop the assay. The final sample may still be in the assay after the STOP key has been pressed. If the rack or samples are immediately removed, the sensor will be activated and a RACK POS ERROR will occur, and the assay results for that sample will not be reported.

3.10 Clearing Errors

If an error occurs, a buzzer will sound and an error message will be displayed on the screen.

Screen 3-25 ERROR MESSAGE screen



Follow the procedure below to clear the error.

Procedure

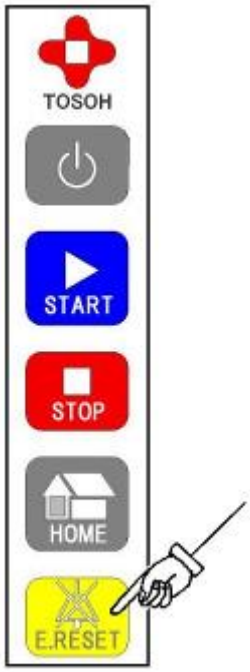
1. Press the E.RESET key on the sheet key. The buzzer will stop.
2. Press the X key to close the ERROR MESSAGE screen.

Make sure to confirm the cause of the error before clearing it. Refer to "6.3 Error Messages" for further details.

Point

After closing the error message screen, you can confirm the cause of the error on the ERROR LOG VIEW screen. Refer to "4.16 Log File Check" for further details.

Fig. 3-22 E.RESET key



3.11 Priority Sample Assay (STAT)

If a priority sample needs to be assayed, set the sample in the STAT port located in the middle of the sample loader.

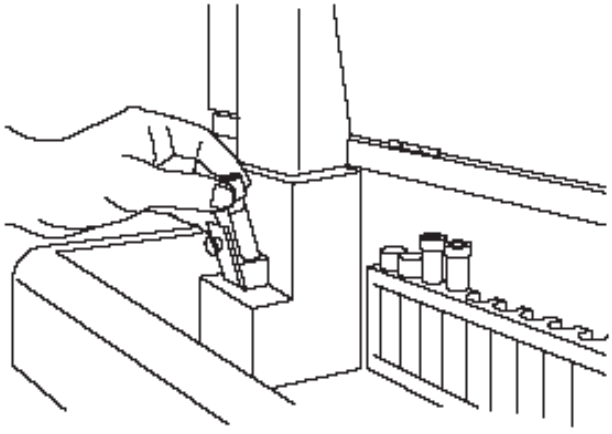
The STAT port is usable during the STAND-BY or ANALYSIS state. The sample can be processed either with a primary tube or a sample cup. Both diluted and whole blood can be processed. The dilution rate of whole blood is selectable depending on the concentration of blood cells.

Procedure

1. Check that the 

key on the main screen is not displayed in green (i.e., not in scheduling or analyzing state) and manually open the analyzer's STAT port.
2. Remove any sample container already in the port and set in the sample to be assayed.

Fig. 3-23 Priority sample loading

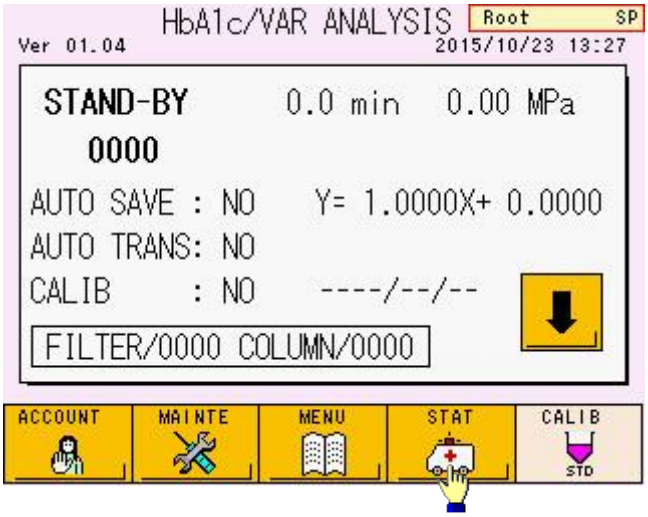


Insert the primary tube straight into the STAT port. If the primary tube does not reach to the bottom of the STAT port, the sensor could not detect the sample.

3. Press the 

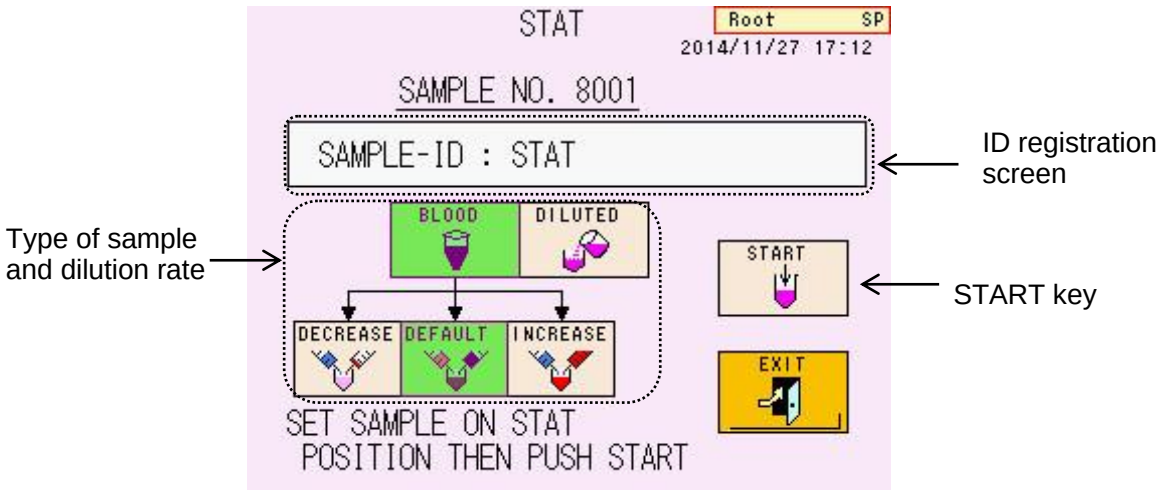
key on the main screen (Screen 3-26).

Screen 3-26 Main screen (first screen)



4. The STAT screen will be displayed (Screen 3-27).
   Register a sample ID as required. Select the type of sample (BLOOD /DILUTED), and dilution rate (DECREASE / DEFAULT / INCREASE) then securely close the STAT port.

Screen 3-27 STAT Screen



5. Press the 

key.
Registration is complete when SCHEDULED is displayed at the bottom of the STAT screen. Press the 

key. The 

key will be displayed in green on the main screen.
6. When the assay currently being processed is completed, the STAT sample is immediately processed. When the sampling is complete, the 

key display will return to normal (with orange color). Open the front door and remove the sample.

Point

1. **When the hematocrit is low, the TOTAL AREA of the assay results may become below 600. If this happens, select the "INCREASE" key. The concentration of diluted sample is approximately 2 times of the DEFAULT setting.**
2. **When the hematocrit is high, the TOTAL AREA of the assay results may become over 3000. If this happens, select the "DECREASE" key. The concentration of diluted sample is approximately 0.5 times of the DEFAULT setting.**
3. **Before starting the STAT assay, you can register a sample ID by handheld barcode scanner (P/N: 0022944). Refer to "3.12 How to Use Handheld Barcode Scanner" for details.**
4. **Press the 

key again to cancel the STAT assay.**

Caution **Never open the STAT port during sampling (while the STAT key is displayed in green). The needle can be bent or can cause injury.**

Before opening or closing the STAT port door, check that the STAT operation has not been scheduled on the main screen (STAT key is not displayed in green), or the STAT assay is not being processed.

3.12 How to Use Handheld Barcode Scanner

This analyzer can manage reagents lot and input calibrator's aligned values with an optional handheld barcode scanner (P/N: 0022944).

Handheld Barcode Scanner Connection

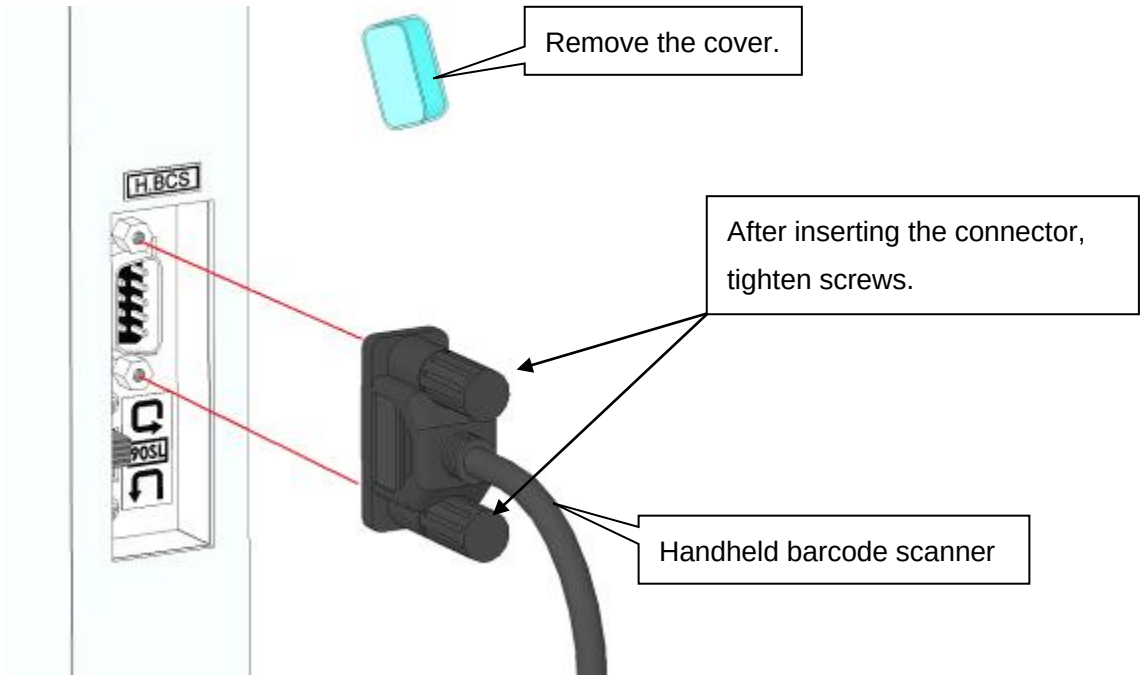
Connect a handheld barcode scanner to the dedicated connector on the right side of the analyzer.

Caution **Turn the main power off prior to connecting a handheld barcode scanner.**

Procedure

1. Turn the main power off.
2. Remove the protective cover of the dedicated connector (H.BCS) on the right side of the analyzer.
3. Connect the connector of the handheld barcode scanner to the H.BCS.

Fig. 3-24 Handheld barcode scanner connection



4. Turn the main power on.
5. Press the POWER key to warm the analyzer up.

Only the optional handheld barcode scanner specified by us (P/N: 0022944) can be connected to the analyzer.

1. **The power source for a handheld barcode scanner is supplied by HLC-723G11 main unit.**
2. **Refer to the user's manual (Operator's Manual or Instructions For Use) attached to the handheld barcode scanner for detail handling methods.**

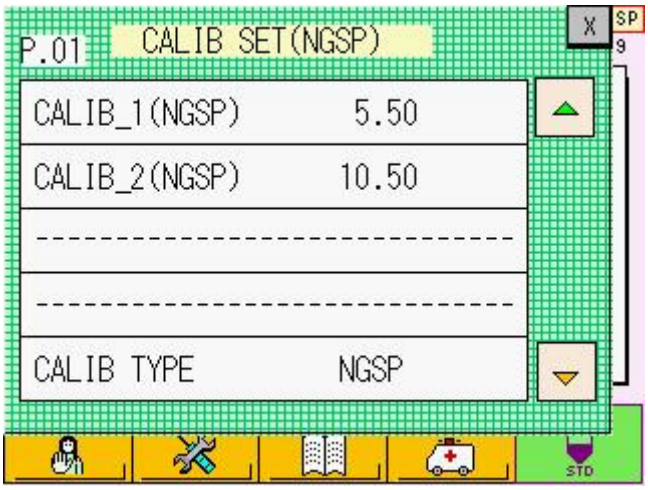
Calibration Aligned Values

When a handheld barcode scanner is connected to the analyzer, you can automatically input the calibrator's aligned value by reading the barcode sheets provided with the "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)".

Procedure

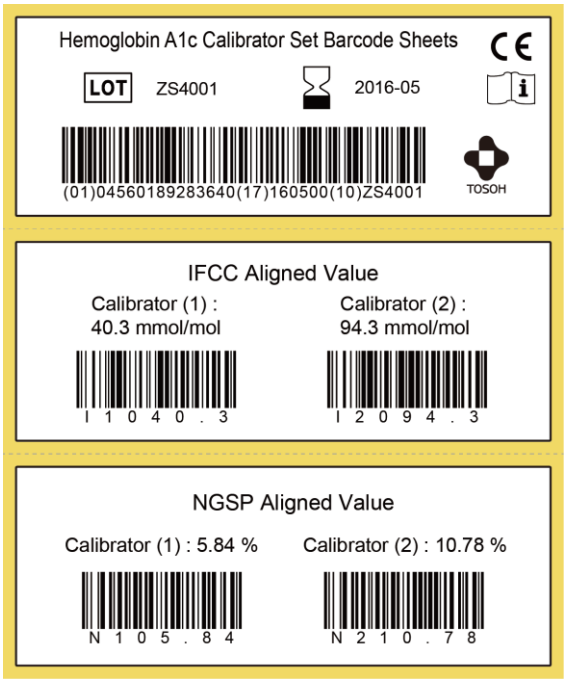
1. Press the CALIB STD key located at the bottom right of the main screen. The key will be displayed in green and the CALIB SET screen will be opened (Screen 3-28).

Screen 3-28 CALIB SET screen (first page)



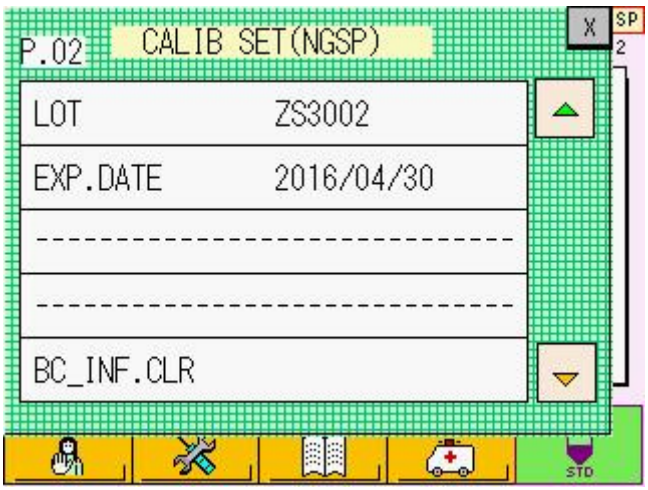
2. Read the barcode sheet provided with the "Hemoglobin A1c Calibrator Set" or "HbA1c Calibrator Set (S)" with a handheld barcode scanner. The calibrator lot number and aligned values will be input automatically.

Fig. 3-25 HbA1c Calibrator Barcode Sheets (sample)



3. The aligned values are automatically displayed on the first page of CALIB SET Screen. When the reagent information is read, its lot number and expiration date are displayed on the second page.

Screen 3-29 CALIB SET screen (second page)



4. Confirm the aligned values and the lot number. Press [X] key to close the CALIB SET screen and execute calibration.

Point **If the calibrator lot is incorrect, press the "BC_INF.CLR" key to delete the lot number and the expiration date.**

Reagent Lot Number

Users can register the reagent lot number and the expiration date by barcodes pasted on the boxes of TSKgel G11 Variant, G11 Variant Elution Buffer No.1, No.2 No.3 and Hemolysis & Wash Solution

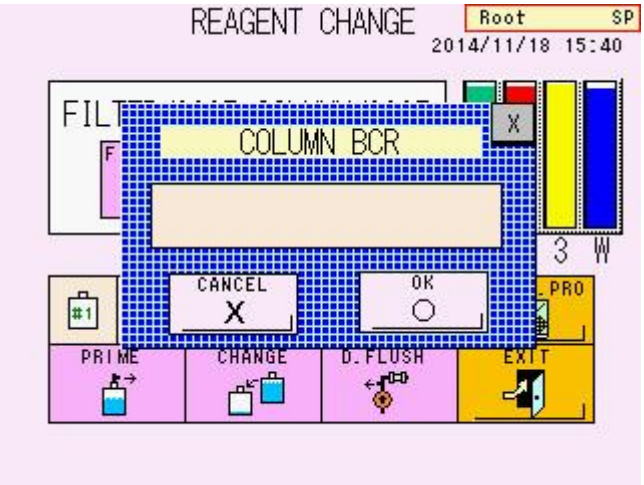
When replacing column or Elution Buffers, use the barcode on the label to input new information. Refer to the Chapter 5 for details about the column or Elution Buffers replacement.

Procedure

■ Registration of the column information

1. After placing new column, press the MAINTE key on the main screen, the REAGENT key on the MAINTE screen and the COL. RESET key on the REAGENT CHANGE screen successively. The COLUMN BCR pop-up screen will be opened (Screen 3-30).

Screen 3-30 COLUMN BCR screen

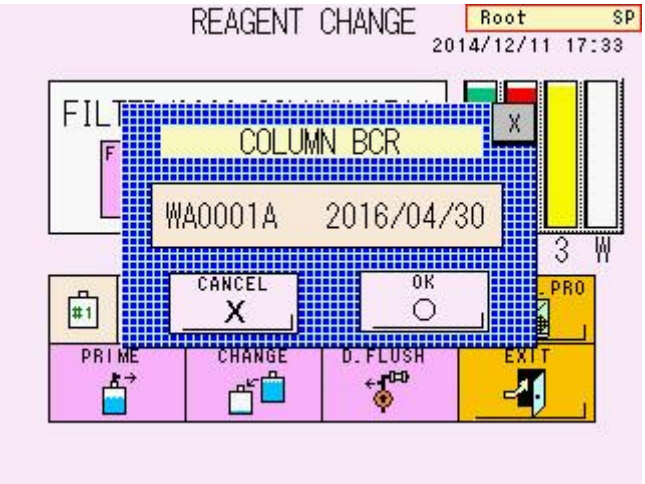


2. Read the barcode pasted on the box with a handheld barcode scanner.

Fig. 3-26 Column box (sample)

3. Confirm the lot number and expiration date on the screen and press the OK key.

Screen 3-31 COLUMN BCR screen (after reading barcode)

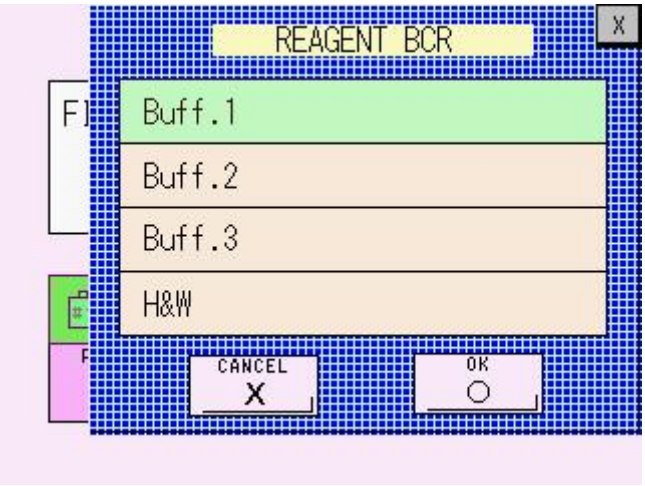


Procedure

■ Registration of Elution Buffers and Hemolysis & Wash Solution information

1. After placing new reagents, press the MAINTE key on the main screen, the REAGENT key on the MAINTE screen successively. The REAGENT CHANGE screen will be opened.
2. On the REAGENT CHANGE screen, press the line of the reagent you want to update information and confirm that the line is displayed in green. Then press the CHANGE key to open the REAGENT BCR screen. The line of the reagent you select on the REAGENT CHANGE screen has been displayed in green on the REAGENT BCR screen (Screen 3-32).

Screen 3-32 REAGENT BCR screen (ex.Elution Buffer No.1)



3. Read the barcode on the Elution Buffer box or on Hemolysis & Wash Solution bottle with a handheld barcode scanner.

Fig. 3-27 Elution Buffer Box

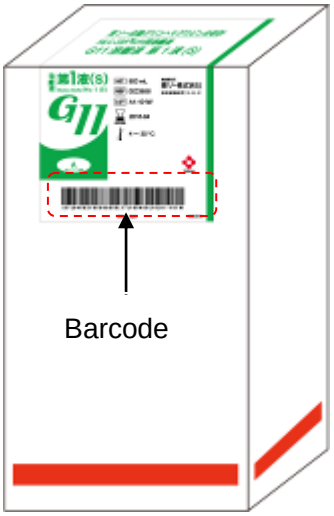
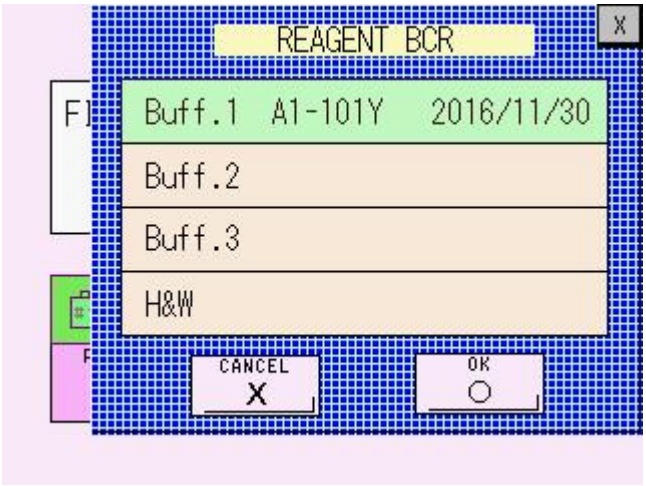


Fig. 3-28 Hemolysis & Wash Solution Bottle

4. Confirm the lot number and the expiration date on the screen and press the OK key. The PRIME is executed and the reagent information will be registered on the analyzer.

Screen 3-33 REAGENT BCR screen
(after reading barcode)



Point **When some reagents are replaced at the same time, you can read their barcodes in random order. The analyzer can recognize products and input information automatically.**

Confirmation

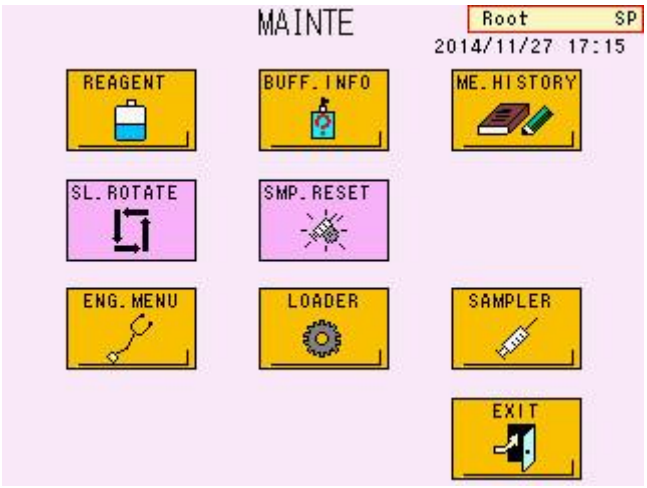
On the REAGENT INFO screen, you can confirm the information about the column and reagents input by handheld barcode scanner.

Procedure

1. Press the 

key to open the MAINTE screen.

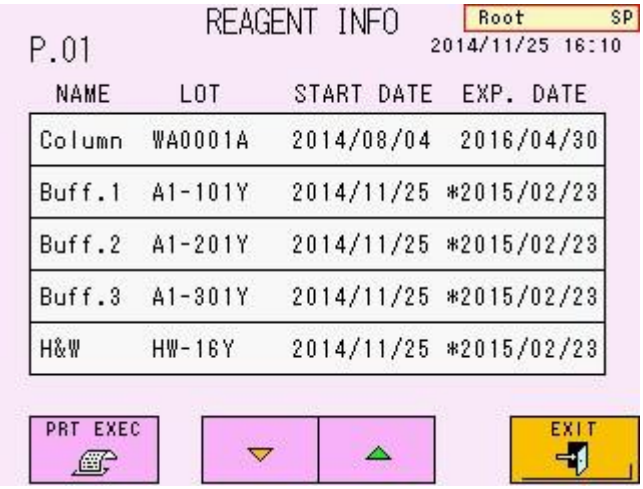
Screen 3-34 MAINTE screen



2. Press the 

key to open the REAGENT INFO screen. The lot number, the start date being used and the expiration date of the column, Elution Buffers, Hemolysis & Wash Solution and calibrators are displayed.

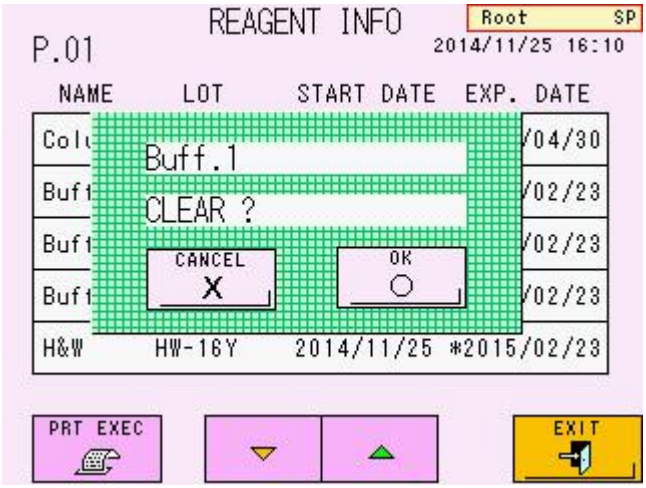
Screen 3-35 REAGENT INFO screen (P.01)



3. To clear the reagent information, select the reagent name. Confirm the reagent name on the pop-up window and press the [OK ○] key.

Point **Only Super Users can clear the reagent information.**

Screen 3-36 Pop-up window for clearing reagent information (sample)



Point

1. **The expiration date of Elution Buffers and Hemolysis & Wash Solution displayed on the REAGENT INFO screen is either 90th day after opening, or the expiration date printed on the label, whichever comes first. When there is the " * " mark in the front of the expiration date this indicates that the 90th date after opening has been reached.**
2. **The expiration date of the column is printed on the label.**
3. **The start/opening dates of the column, Elution Buffers and Hemolysis & Wash Solution are dates that their barcode information is registered.**
4. **When the expiration date has exceeded, an error will occur and the assay will stop. Replace the expired reagent to a new one.**
5. **Press the** 

key to print out the reagent information.

STAT Sample ID

The STAT sample ID can be registered by handheld barcode scanner. Refer to "**3.11 Priority Sample Assay**" for details about the STAT assay.

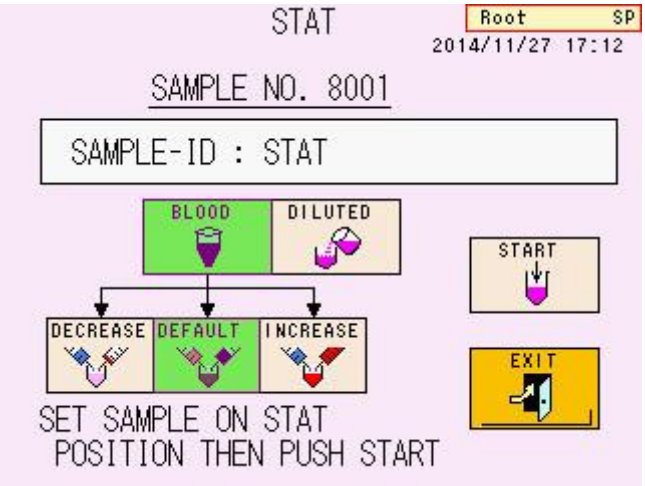
Procedure

1. Press the 

key to open the STAT screen.
2. Read the sample barcode with a handheld barcode scanner. The barcode information is automatically registered as the sample ID. Check the sample ID and press the 

key to schedule the STAT assay.

Screen 3-37 STAT screen



Control Barcode

If the control barcode is registered before an assay, the sample having that barcode is assayed as the control.

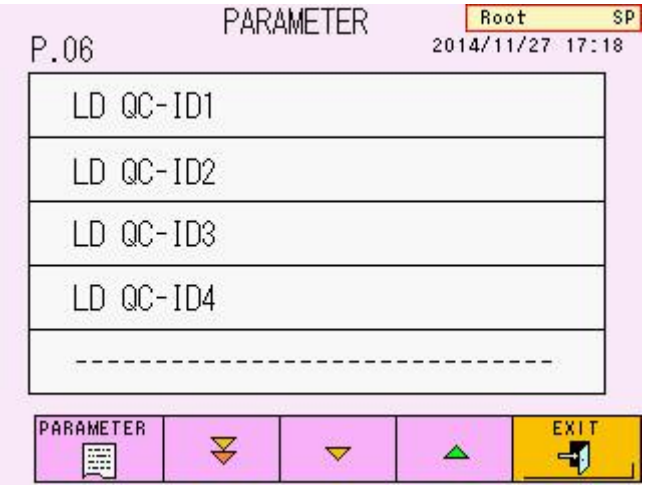
Procedure

1. Press the 

key to open the MENU screen.
2. Select the 

key. The PARAMETER screen will be displayed.
3. Press the  key and open P.06.

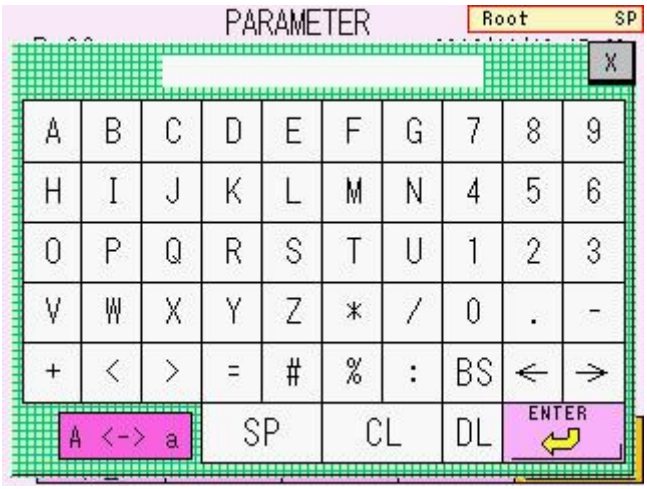
Screen 3-38 PARAMETER screen (P.06)



4. Select the ID that you want to register. The input screen will be opened.

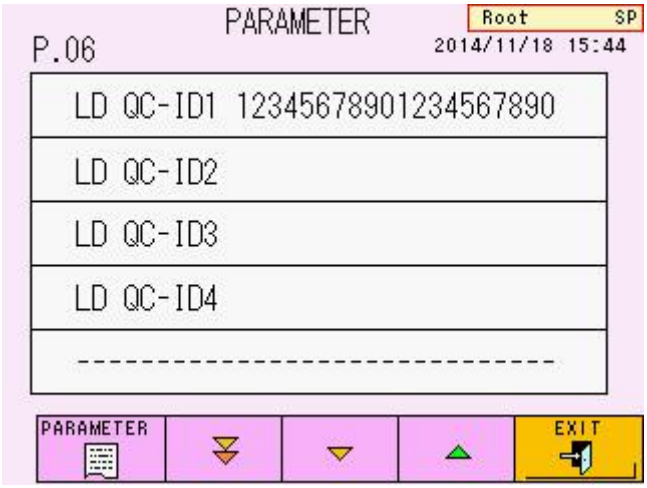
Point **The control ID can be input manually after selecting the "LC QC- ID" key.**

Screen 3-39 Input screen



5. Read the barcode. The ID is registered automatically and the input screen will be closed. Confirm the ID on the PARAMETER screen and return to the main screen.

Screen 3-40 PARAMETER screen after reading barcode (ex. 12345678901234567890)



Point

The assay result of controls can be searched by the search function on the LIST screen. Refer to "3.15 List Data" for searching list data.

How to log on

When a handheld barcode scanner is connected, you can change the users by reading an account barcode which is prepared on the following conditions.

[User account barcode conditions]

Barcode standard: CODE128

Composition: Refer to following example;

Composition	User name	Delimiter ($)	Password
Example	User1	$	1234

User name is number of letters up to 10.

Acceptable range of the password is 1 to 4-digit number.

Fig. 3-29 User account barcode (example)

Procedure

1. Press the 

key on the main screen to open the USER ACCOUNT screen.
2. Check that the 

key is displayed in green, read the user account barcode. When the barcode information (user name and password) corresponds to the user information registered in the analyzer, the user has changed.

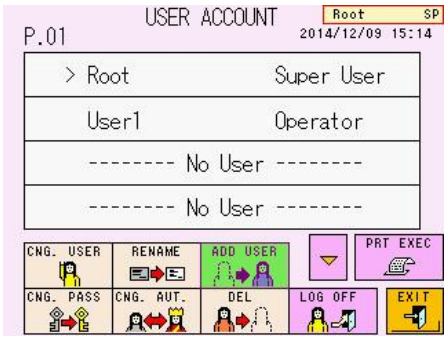
Addition a new user

When a handheld barcode scanner is connected, you can add a new user by reading the above-mentioned user account barcode. Refer to "**4.2 User Account**" for adding a new user..

Procedure

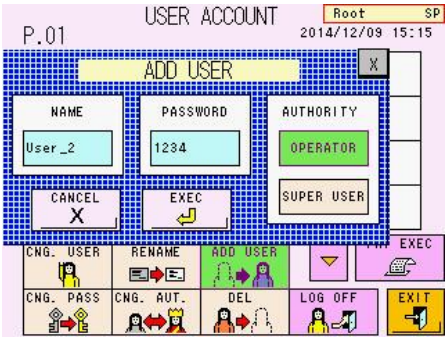
1. Press the ADD USER key. The ADD USER key will be displayed in green.
2. Press No User to open the ADD USER screen.

Screen 3- 41 USER ACCOUNT screen



3. When the USER ACCOUNT screen is displayed, read the user account barcode. If the user name printed on the barcode does not correspond to the user information registered on the analyzer, the user name and password will be input automatically on the ADD USER screen.

Screen 3- 42 ADD USER screen

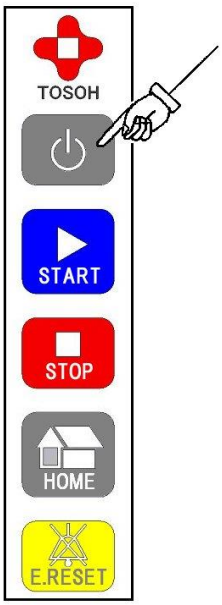


3.13 Power Off

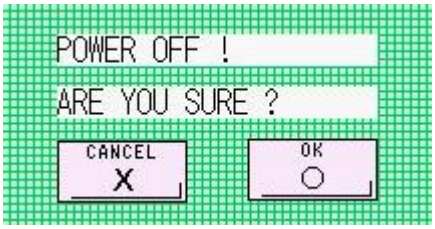
To shutdown the analyzer, press the POWER key. The message (Screen 3-43) will be displayed. Press the [OK ○] key on the screen or press the POWER key again to confirm the shutdown process. To cancel the shutdown process, press the [CANCEL X] key

The column oven and the degassing unit will keep on working after shutdown. To stop these units turn off the Main power switch (refer to Fig. 3-1).

Fig. 3-30 POWER off key



Screen 3-43 The message displayed by POWER off key



3.14 Interpretation of Results

Printout Format

The following printout formats are available with this system. To change the format, select (0) STD FORM, (1) SIMPLE FORM, (9) MAINTE FORM, (3) STD + R FORM or (8) MNT + R FORM on FORMAT of the PARAMETER screen. (0) STD FORM is the default factory setting.

- **(0) STD FORM**

  The assay values for HbA1c (s-A1c) and HbF will be output together with a chromatogram and all peak information.

- **(1) SIMPLE FORM**

  This is the most simply used format. The assay values for HbA1c (s-A1c) and HbF will be output together with a chromatogram.

- **(9) MAINTE FORM**

  This is the most detailed format and is the same format as (0) STD FORM but with the number of theoretical plate (indicated as TP) for HbA1c (s-A1c).

- **(3) STD + R FORM**

  This is the same format as (0) STD FORM but with the reagent information of the result.

  The reagent information is the following.

  - Lot number and start date of column
  - Lot number and start date of Elution Buffer No.1.
  - Lot number and start date of Elution Buffer No.2.
  - Lot number and start date of Elution Buffer No.3.
  - Lot number and start date of Hemolysis & Wash Solution
  - Lot number of calibrator and calibration date

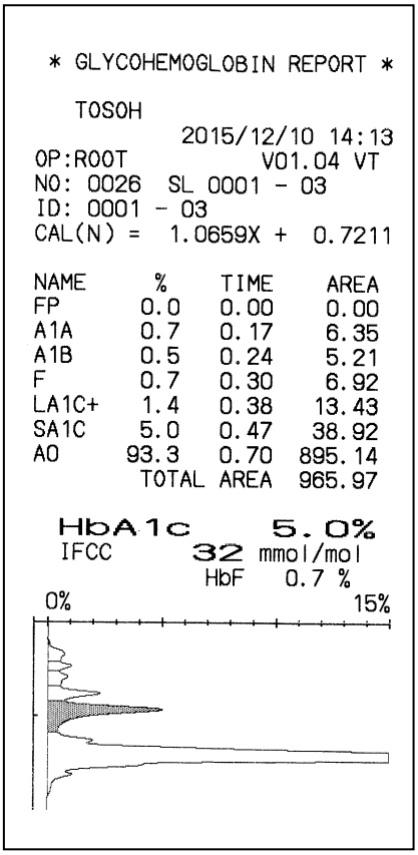
  When the results do not have the reagent information, these pieces of information are not output.

- **(8) MNT + R FORM**

  This is the same format as (9) MAINTE FORM but with the reagent information used in the assay.

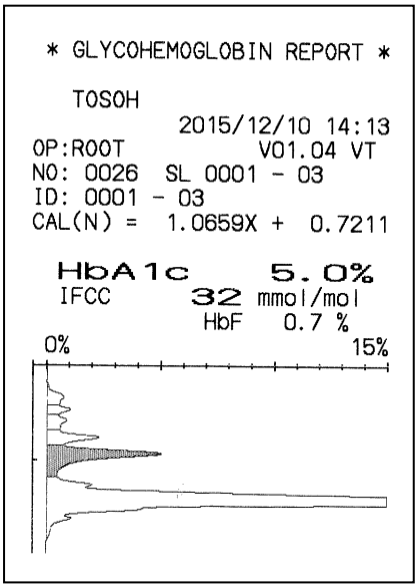
For detailed information on printout format, refer to "**4.9 Parameter Setting**".
You can print out the assay results saved in the analyzer's RESULT memory or to a USB stick by changing the FORMAT and running a RECALC operation.
(See "**4.12 Confirmation, Retransmission to Host, Reprint and Recalculation of Saved Results**")

Fig. 3-31 (0) STD FORM example



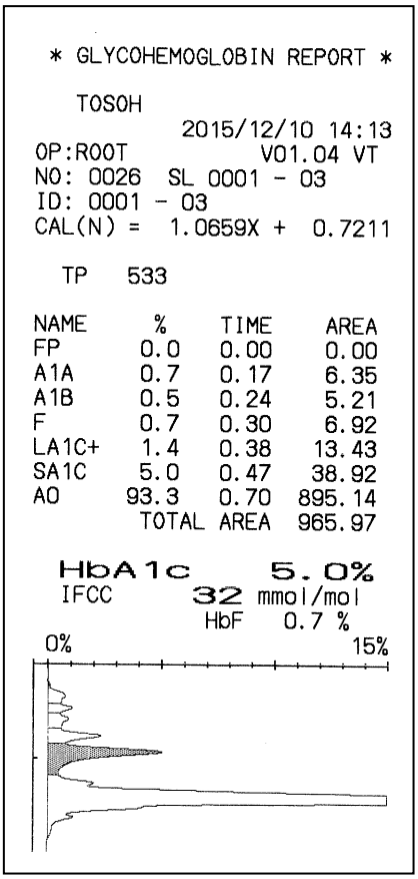
```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/10 14:13
OP:ROOT              V01.04 VT
NO: 0026  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0659X +  0.7211

NAME      %     TIME     AREA
FP       0.0   0.00     0.00
A1A      0.7   0.17     6.35
A1B      0.5   0.24     5.21
F        0.7   0.30     6.92
LA1C+    1.4   0.38    13.43
SA1C     5.0   0.47    38.92
A0      93.3   0.70   895.14
        TOTAL AREA     965.97

HbA1c      5.0%
IFCC        32 mmol/mol
             HbF   0.7 %
0%                    15%
```

Fig. 3-32 (1) SIMPLE FORM example



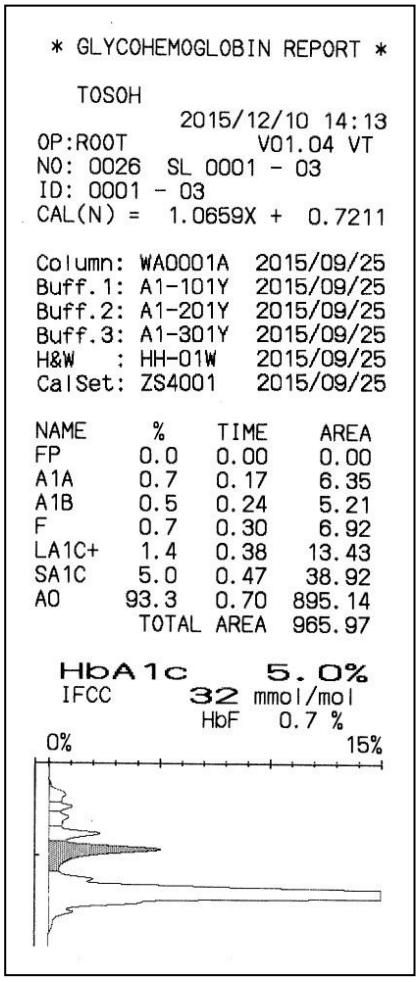
```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/10 14:13
OP:ROOT              V01.04 VT
NO: 0026  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0659X +  0.7211

HbA1c      5.0%
IFCC        32 mmol/mol
             HbF   0.7 %
0%                    15%
```

Fig. 3-33 (9) MAINTE FORM example



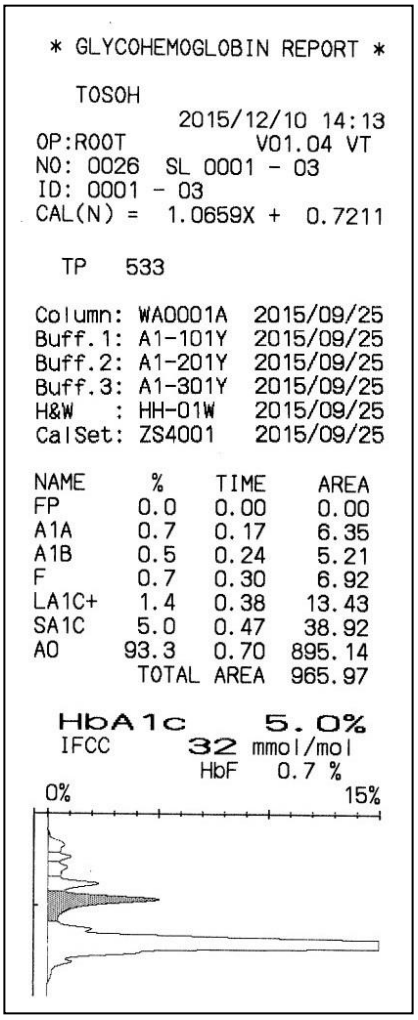
```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/10 14:13
OP:ROOT              V01.04 VT
NO: 0026  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0659X +  0.7211

  TP   533

NAME      %     TIME     AREA
FP       0.0   0.00     0.00
A1A      0.7   0.17     6.35
A1B      0.5   0.24     5.21
F        0.7   0.30     6.92
LA1C+    1.4   0.38    13.43
SA1C     5.0   0.47    38.92
A0      93.3   0.70   895.14
        TOTAL AREA     965.97

HbA1c      5.0%
IFCC        32 mmol/mol
             HbF   0.7 %
0%                    15%
```

Fig. 3-34 (3) STD + R
FORM example



```
 * GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/10 14:13
OP:ROOT              V01.04 VT
NO: 0026  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0659X +  0.7211

Column: WA0001A  2015/09/25
Buff.1: A1-101Y  2015/09/25
Buff.2: A1-201Y  2015/09/25
Buff.3: A1-301Y  2015/09/25
H&W   : HH-01W   2015/09/25
CalSet: ZS4001   2015/09/25

NAME      %    TIME     AREA
FP      0.0    0.00     0.00
A1A     0.7    0.17     6.35
A1B     0.5    0.24     5.21
F       0.7    0.30     6.92
LA1C+   1.4    0.38    13.43
SA1C    5.0    0.47    38.92
A0     93.3    0.70   895.14
        TOTAL AREA    965.97

HbA1c      5.0%
IFCC        32 mmol/mol
          HbF   0.7 %
0%              15%
```


Fig. 3-35 (8) MNT + R
FORM example



```
 * GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/10 14:13
OP:ROOT              V01.04 VT
NO: 0026  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0659X +  0.7211

  TP   533

Column: WA0001A  2015/09/25
Buff.1: A1-101Y  2015/09/25
Buff.2: A1-201Y  2015/09/25
Buff.3: A1-301Y  2015/09/25
H&W   : HH-01W   2015/09/25
CalSet: ZS4001   2015/09/25

NAME      %    TIME     AREA
FP      0.0    0.00     0.00
A1A     0.7    0.17     6.35
A1B     0.5    0.24     5.21
F       0.7    0.30     6.92
LA1C+   1.4    0.38    13.43
SA1C    5.0    0.47    38.92
A0     93.3    0.70   895.14
        TOTAL AREA    965.97

HbA1c      5.0%
IFCC        32 mmol/mol
          HbF   0.7 %
0%              15%
```

Test Report Interpretation

- **OP**

  Indicate the user name logged on during the assay.

- **NO**

  Indicate the sample numbers (4 digits). The 0001 is automatically given to the first sample of the day and the sample numbers are incremented by 1 after that. When the start day is changed, the numbers return to 0001.

  Numbers starting from 9001 are automatically assigned to the calibrator.

  Numbers starting from 8001 are automatically assigned to the STAT sample.

- **SL**

  Indicate the sample location number (rack number and sample position).

- **ID**

  When a barcode is used, the barcode number is given in the ID field.

  When a barcode is not used, the sample location number is given (rack number and sample position).

- **CAL**

  Show the calibration factors with which the assay result was calculated.

  This indication "CALIB" is changed as "CAL(IN)" or "CAL(N)" depending on FORMAT set value (in which units the calibration was done).

- **HbA1c**

  Show HbA1c (%) assigned by the calibration factors.

- **Chromatogram**

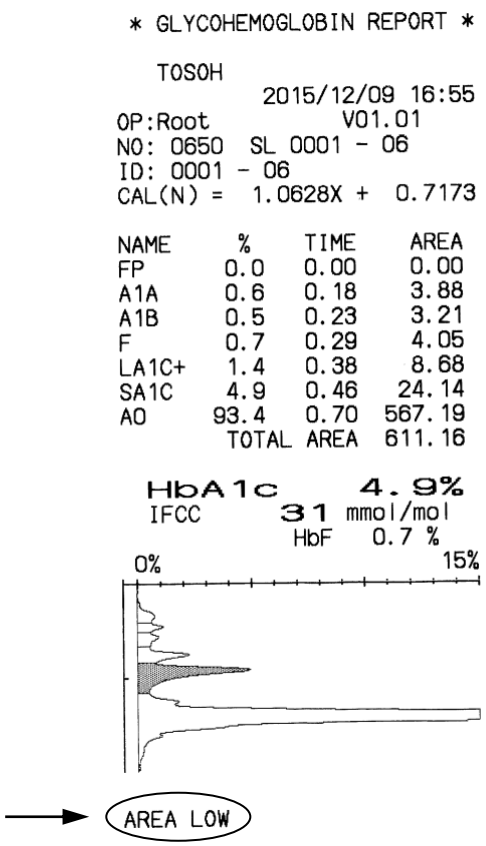
  The fractions separated by the column are shown as they are detected. The horizontal axis is adjusted as the 15 % in s-A1c concentration comes to the full scale. The vertical axis is the retention time from the instant the sample is injected into the column.

  The peak identified as HbA1c (s-A1c) is shaded.

- **FLAG**

If you input the flag parameters on the FLAG screen beforehand, messages are printed out when the assay result meets the flag conditions (Fig 3-36). Refer to "**4.21 FLAG Parameter Setting**" for further details.

Fig. 3-36 Printout example with FLAG



Detailed Peak Information

If the result is output in (0) STD FORM, the information for each hemoglobin fraction separated by the column is printed.

1) Name
   Indicate name of hemoglobin fraction identified corresponding to each peak. P00, P01, P02, etc. are assigned to unidentified peaks and are printed below the chromatogram

2) % (each peak area to the TOTAL AREA)
   This is the ratio of each peak area to the total peak area.
   The front peak (FP), which is normally not detected, is 0 %. If detected, FP is not included in the total peak area since it is not related to hemoglobin; however, it is shown in percentage (%) of its area in the total area for convenience.

3) TIME (elution time, retention time)
   Indicate the time of each peak top. The unit is minute.

4) AREA
   The peak area corresponds to the volume of each fraction. This is the value calculated by integrating the detector output by time. The unit is mV·s.

5) TOTAL AREA
   Indicate the sum of all peaks except for FP. This depends upon the sample concentration. The unit is mV·s. The acceptable range of TOTAL AREA is from 500 to 3500. However, highly reliable results can only be obtained in the TOTAL AREA range from 600 to 3000.

   When sampling whole blood directly from the primary tube, the analyzer automatically dilutes the sample by a fixed ratio of about 201. Samples will normally not be outside of the range indicated above, but in the case of a very low hemoglobin concentration (dialysis patients, anemia

patients, etc.), the TOTAL AREA may drop below 500.

If this happens, transfer the blood cells to a sample cup and run the STAT assay. When you want to use a diluted sample, dilute a whole blood sample manually with Hemolysis & Wash Solution by 100 times and select the "DILUTED" key. In case of automatic dilution, select the "Blood" key and the "INCREASE" key then run the STAT assay. Refer to "**3.8 Samples**" or "**3.11 Priority Sample Assay (STAT)**" for further details.

6) Chromatogram

Some fractions may be eluted out with different peak shapes or not be detectable depending upon the sample.

If you observe the same phenomena with several different samples, the assay conditions may not be optimal or the reagent or column may have been deteriorated. If there are shoulders or splits around the s-A1c or A0 peak, the column may have deteriorated. Replace the Elution Buffers or column and run the assay again.

If an abnormal shape of chromatogram is observed with a single specific sample, the sample may have been deteriorated (it may have been stored for a long time at room temperature after collection), or hemoglobin variants may be present.

The G11 Variant Analysis Mode can separate major hemoglobin variants (e.g., HbD, HbS, HbC and HbE derivative) from A0 derivatives. See **"6.4 Abnormal Chromatograms"** for typical chromatograms. But some hemoglobin variants may not be separated from A0 derivatives and they may interfere with the assay.

The chromatogram pattern for hemoglobin variants differs from that of typical sample, and it is difficult to have an accurate HbA1c % with the analyzer.

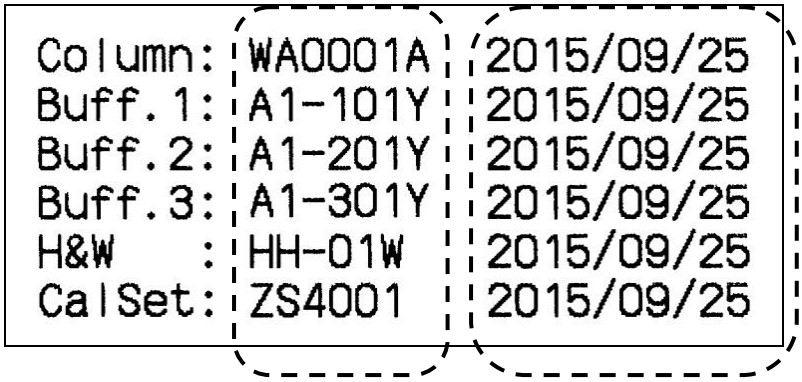
Reagent Information

If the result is output in (3) STD + R FORM or (8) MNT + R FORM, the reagent lot number used in the assay and its start/opening date can be printed for each sample in addition to information printed in (0) STD FORM.

1) Lot number
   Indicate the lot number of the column, Elution Buffer No. 1, 2, and 3 and Hemolysis & Wash Solution used in the assay and that of calibrator used in the latest calibration at the time of the assay.

2) Start date
   Indicate the start date being used of the column, Elution Buffer No. 1, 2, and 3 and Hemolysis & Wash Solution used in the assay and the latest calibration date at the time of the assay.

Fig. 3-37 Reagent Information printout example



How to Read Numbers and IDs

Sample numbers and IDs are automatically given to assay results. When the barcode on the primary tube is read, the barcode ID will be displayed in the sample ID column.

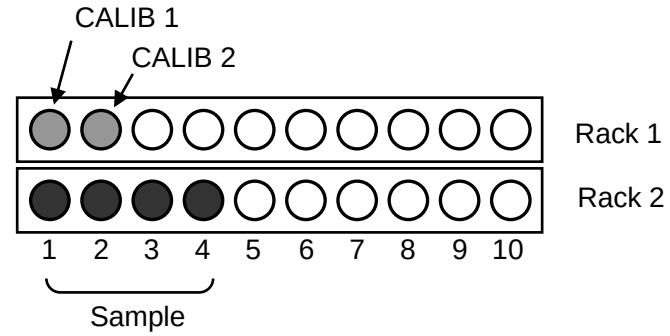
Example: CALIB. YES

The calibrator No. 1 is placed in the rack position 1-1

The calibrator No. 2 is placed in the rack position 1-2

The samples are placed in the rack positions 2-1 to 2-4

Fig. 3-38 Example



Sample NO.	Sample ID	
9001	0001-01	
9002	0001-01	····· CALIB 1
9003	0001-01	
9004	0001-02	
9005	0001-02	····· CALIB 2
0001	0002-01	····· Sample 1
0002	0002-02	····· Sample 2
0003	0002-03	····· Sample 3
0004	0002-04	····· Sample 4

Sample number: Numbers 9001- for the calibrator, numbers 8001- for the STAT sample, the others for the assay samples on the rack.

The first measurement of the day is No. 0001. The sample number automatically returns to 0001 whenever the date of the START changes.
If a specific sample number is desired, a 4-digit number can be entered under "SAMPLE NO." on the "PARAMETER" screen. Please note, however, that if the same number as the given number already exists in the RESULT memory or USB stick, the assay results in the RESULT memory or USB stick will be overwritten.

Sample numbers for calibration start from 9001 and automatically return to 9001 whenever the date changes.
Sample numbers for STAT assay start from 8001 and automatically return to 8001 whenever the date changes.

Point **If a specific sample number is desired, the acceptable range of sample number is from 0001 to 7999.**

3.15 List Data

List data is a table of assay result values that include the sample number (NO), sample location number (SL) and sample ID (ID).

The analyzer can save up to 800 assay results in the RESULT memory and displays the list data referring to the RESULT memory.

You can print and transmit data of the specified range.

Press the SEARCH key to seek the data meeting the search conditions. All that data or the part of them can be collectively printed and transmitted

In addition, IDs can be edited on the LIST screen by individually selecting assay results (refer to "**4.14 List Data Display and Barcode Editing**").

If the data meets the conditions specified in the FLAG (Refer to "**4.21 FLAG Parameter Setting**"), the flag code is listed on the LIST screen and printed out to the MK field (Fig. 3-39).

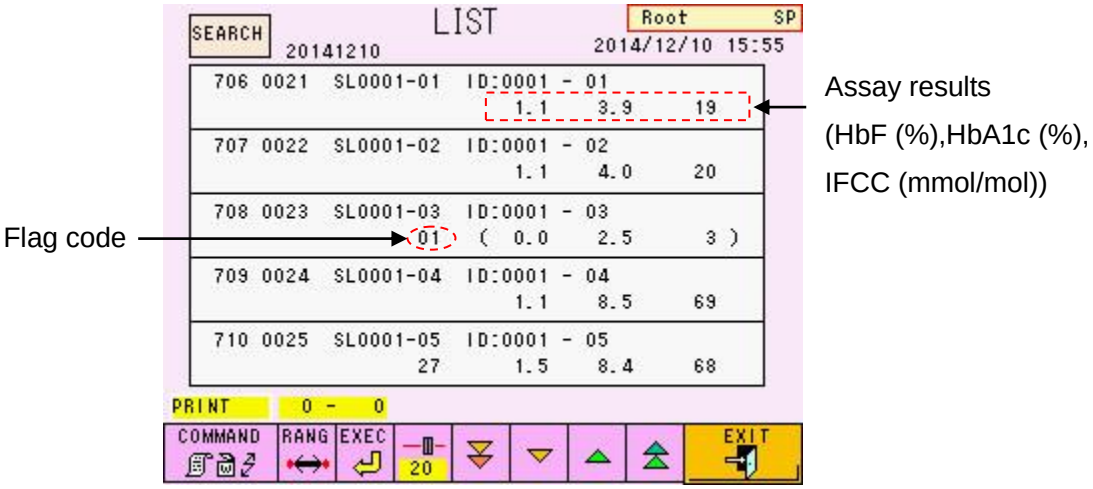
If LIST AUTO SAVE is set to YES on the PARAMETER screen, the list data is automatically saved to a USB stick for each batch data (apart from the data saved to the analyzer's RESULT memory). This data is saved to the USB stick in CSV format.

You must execute list data operations when the analyzer is in STAND-BY state.

Assay results obtained in the units other than the units currently set will not be listed on the LIST screen but listed shown on as Screen 3-45. And the command on the LIST screeen can not be applied to those data. To display those data and make the command applicable to them, set the same value to the CALIB TYPE on the PARAMETER screen as the value with which those data were obtained.

See "4.9 Parameter Setting" for set value to the FORMAT.

Screen 3-44 LIST screen



Screen 3-45 LIST screen

(an example assay results were obtained in IFCC units but LIST data were displayed after set value to the CALIB TYPE was changed to NGSP.)

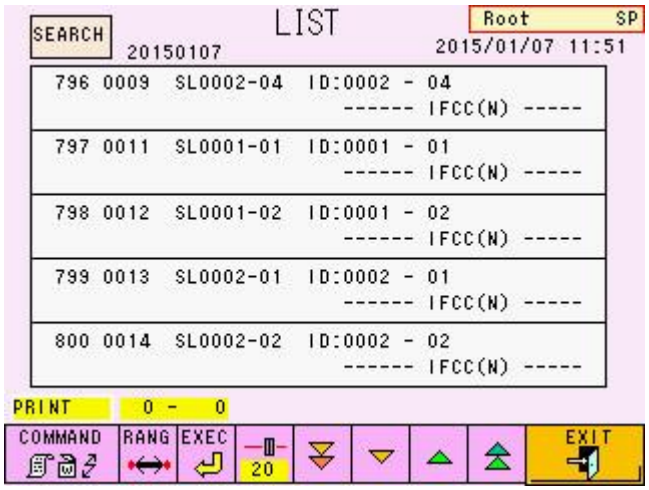
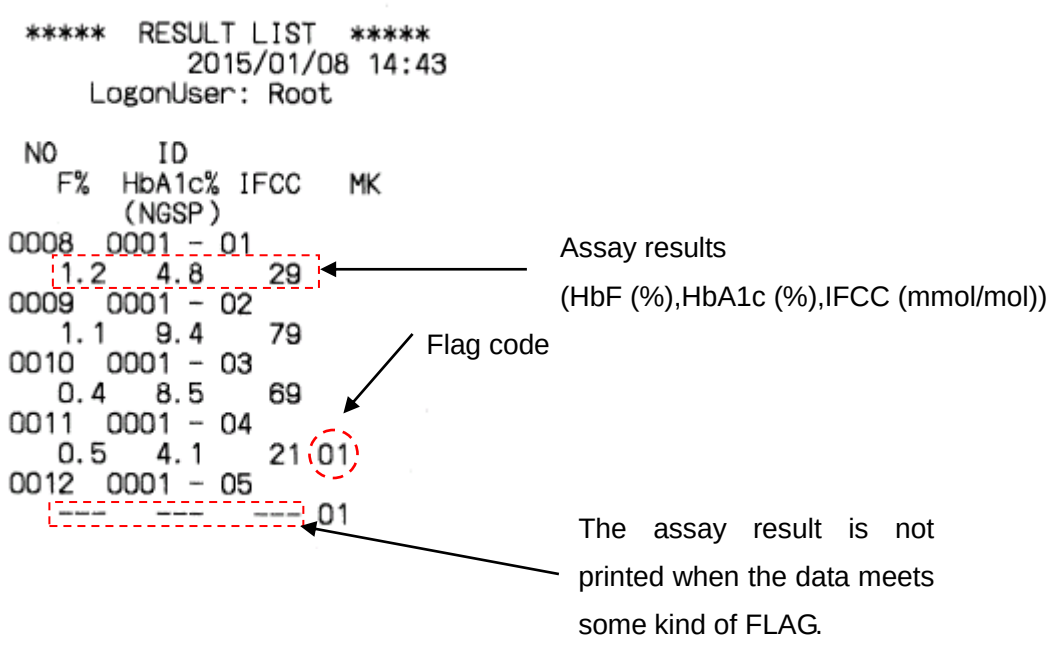


Fig. 3-39 List Print Out Example



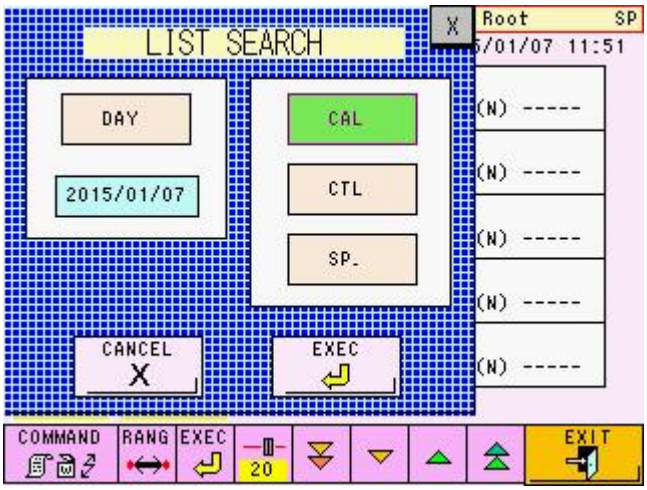
Procedure

■ How to search list data

ex. How to search the list data assayed on 10th December 2014

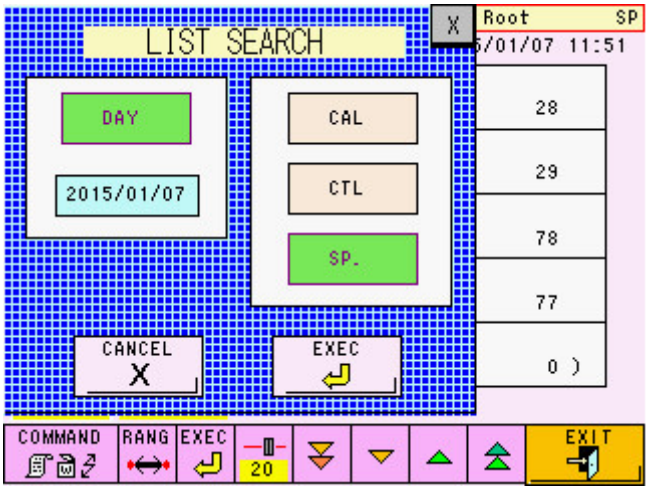
1. Press the SEARCH key to open the LIST SEARCH screen.

Screen 3-46 LIST SEARCH screen



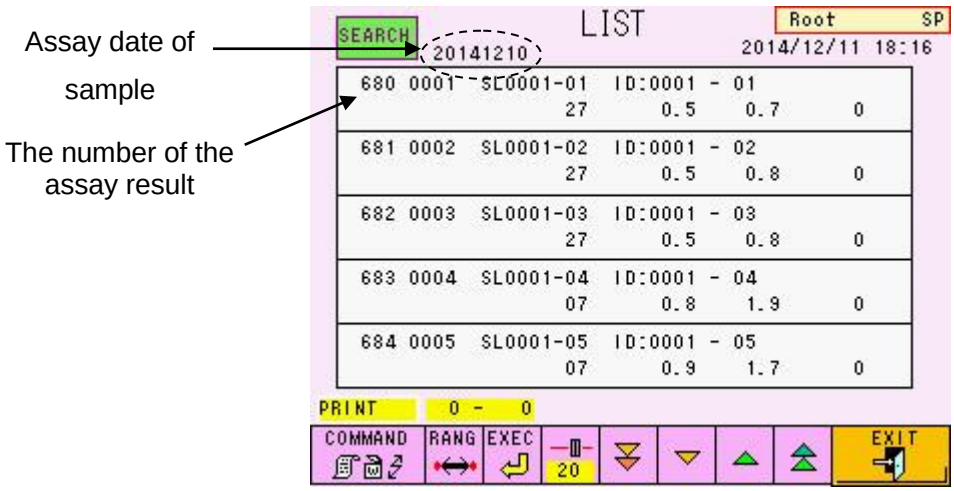
2. Press the DAY key and the SP. key. They are selected and the key color of them turns green. Then, press the CAL key. The selection is canceled and the key color turns white.

Screen 3-47 LIST SEARCH screen (example)



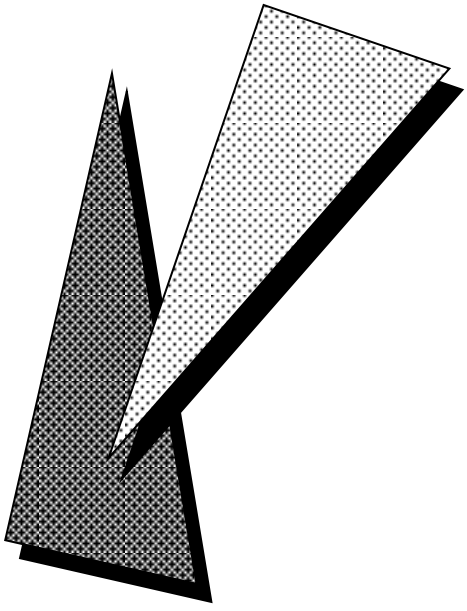
3. Press the 2015/01/07 key to open numeric keypad and input "2014/12/10" then press the EXEC key.
   YYYY/MM/DD. (YYYY: Year, MM: Month, DD: Day)
4. After confirming that "2014/12/10" is displayed on the LIST SEARCH screen, press the EXEC key to start search. Check the list data by using key.

Screen 3-48 List search results screen (example)



Chapter 4

Screen Operations

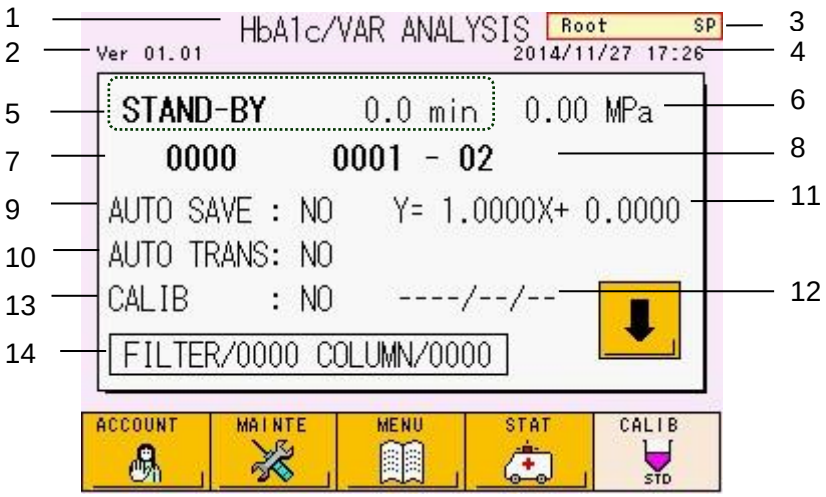


4 Screen Operations

4.1 Main Screen

The main screen (first screen) is the first screen displayed after the analyzer is turned on.

Screen 4- 1 Main screen (first screen)



Display content

1. Title
2. Program version number
3. Current user name and authority (SP or OP)
4. Current date and time
5. Status and remaining processing time or elapsed time

   PUMP CLEAN: During pump cleaning
   WARMING-UP: During warming up operation
   STAND-BY: In ready state
   ANALYSIS: During assay
   WASH: During wash operation
   COL.WASH: During column wash operation
   BUFF PRIME: During buffer replacement
   PURGE: During air purging
6. Pump flow pressure: Displayed in MPa (megapascal) units
7. Sample number currently under assay

8. Sample ID or rack position number currently under assay
9. Setting to auto save assay results on a USB stick
10. Setting for automatic transmissions to a host
11. Calibration factor currently in use
12. Calibration date
13. Calibration setting
14. Number of injections for the filter and column

Key Functions

: Displays the USER ACCOUNT screen

: Displays the MAINTE screen

: Displays the MENU screen

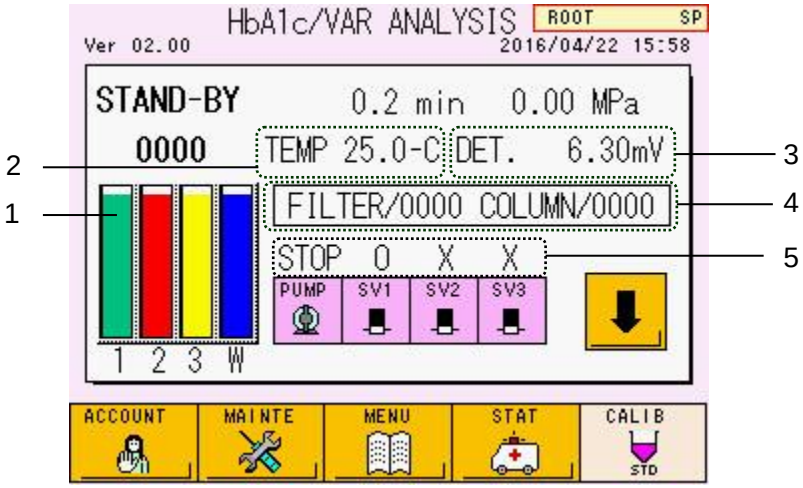
: Displays the STAT screen

: Sets whether or not to execute automatic calibration.
To set automatic calibration, press to change the key color from white to green () before assay start.


: Displays the second screen

The following information and operation keys are displayed on the second screen.

Screen 4- 2 Main screen (second screen)



Display content

1. The remaining volume of the eluents (G11 Variant Elution Buffer No. 1, 2, and 3 and the Hemolysis & Wash Solution are shown in sequence from the left)
2. Current temperature of the column oven
3. Detector output
4. Number of injections for the filter and column
5. The current operation status of the pump and solenoid valves

Key Functions

: Starts or stops pump run (STOP: stop pump FLOW: run pump)

: Opens or closes the valve for G11 Variant Elution Buffer No. 1
(o: opened x: closed)

: Opens or closes the valve for G11 Variant Elution Buffer No. 2
(o: opened x: closed)

: Opens or closes the valve for G11 Variant Elution Buffer No. 3
(o: opened x: closed)

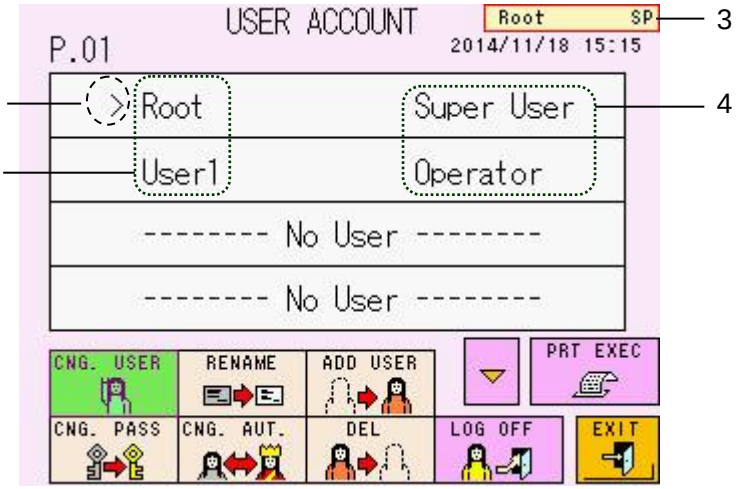

: Displays the first screen

Other display contents and key functions are identical to the first screen. After the MENU and other screens have been displayed, the analyzer display returns to the first screen.

4.2 User Account [Main screen] – [ACCOUNT]

Before starting assays, log on the analyzer. Press the ACCOUNT key to open the USER ACCOUNT screen.

Screen 4- 3 USER ACCOUNT screen



Display content

1. The arrow shows the active field.
2. User name
3. Current user name and authority (SP or OP)
4. User authority (Super User or Operator)

Key Functions

: Changes a user

: Renames a user (Super User only)

: Adds a new user (Super User only)

: Changes the password (Super User only)

: Changes user authority (Super User only)

: Deletes a user (Super User only)

: Executes log off

: Displays next page

: Prints out information about user

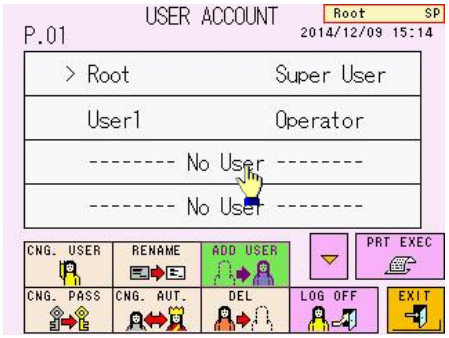
: Returns to the previous page

Operation Ex.　Addition of a new user (only Super User)

New user's name is "Tosoh" having Operator authority

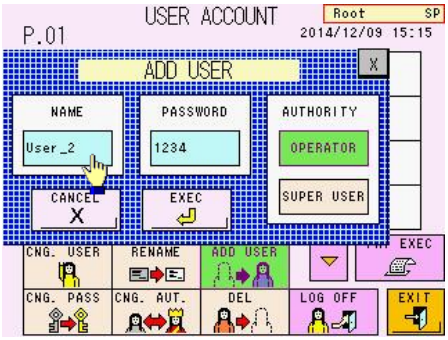
1. Press the ADD USER key. The ADD USER key will be displayed in green.
2. Press No User under the User1 to open the ADD USER screen.

Screen 4- 4 USER ACCOUNT screen

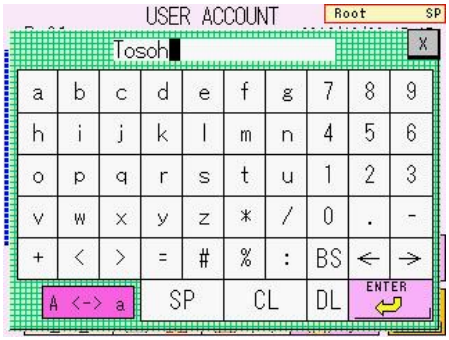


3. Press the NAME key, change "User_2" to "Tosoh" then push the ENTER key. Maximum acceptable number of letters is 10.

Screen 4- 5 ADD USER screen



Screen 4- 6 Input user name (example)

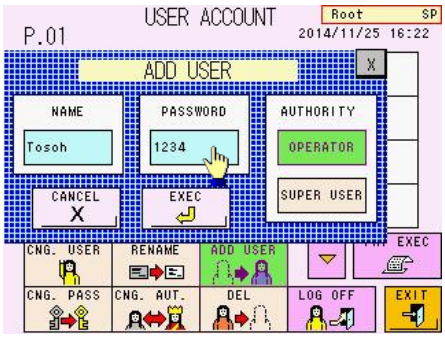


Point

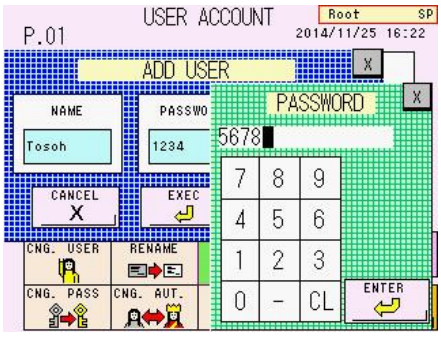
A name that is already present in the analyzer cannot be used and registered again.

4. Press the PASSWORD key and enter a new password "5678" (example). Acceptable range of the password is 1 to 4-digit number.

Screen 4- 7 ADD USER screen



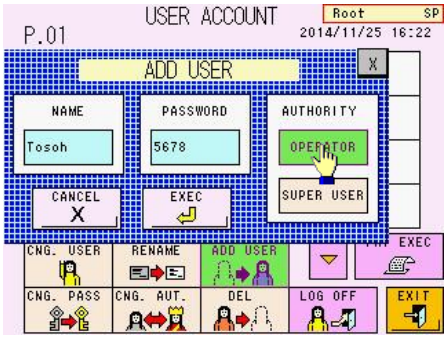
Screen 4- 8 Input passwords (example)



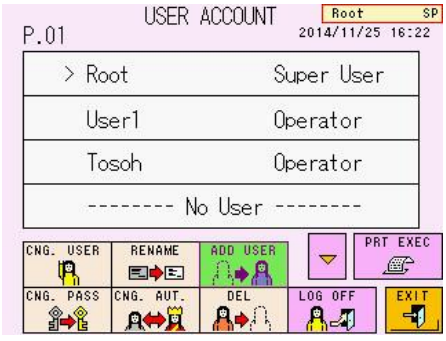
Point **You can input the user name and password with an optional handheld barcode scanner. Refer to "3.12 How to Use Handheld Barcode Scanner" for the details.**

5. Press the OPERATOR key. Confirm the user by pressing the EXEC key.

Screen 4- 9 ADD USER screen



Screen 4- 10 After adding user (example)

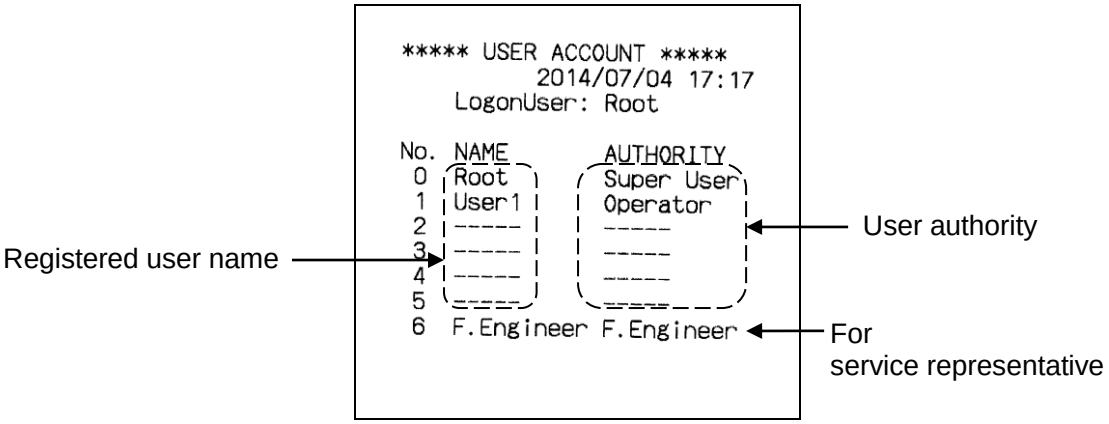


Point **User name "Root" and "F.Engineer" can not be deleted. Except for them, the maximum number of new users is 5.**

User Information Printout

User information registered in the main unit can be printed out by pressing the PRT EXEC key.

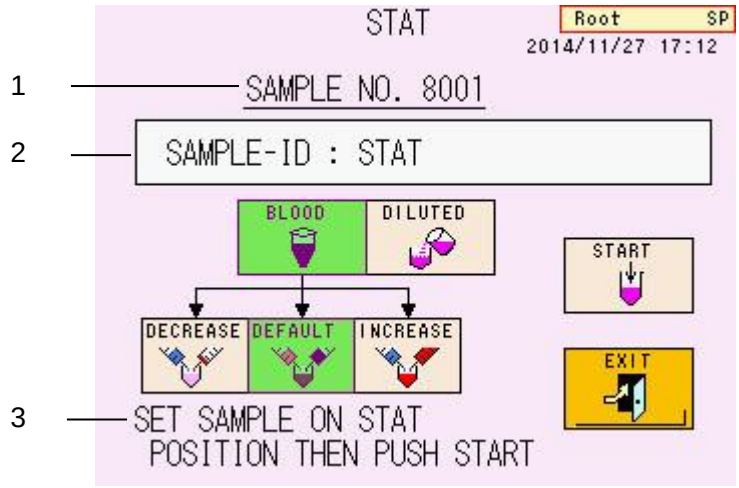
Fig. 4- 1 User information printout example



4.3 STAT [Main screen] – []

Press the  key on the main screen to display the STAT screen.
A sample requiring an immediate assay can be processed by placing it in the STAT position.
After acceptance of the STAT operation, confirm the execution key is displayed in green (). Press the  key to return the main screen. The  key will be also displayed in green (), showing that the STAT operation has been scheduled.
If you press the  key on the STAT screen without pressing the  key to return to the main screen, the STAT operation will not be scheduled. After the STAT sample is assayed, the  key will go back to be normal state ().

Screen 4- 11 STAT Screen



Display content

1. Number given to sample (STAT sample numbers are given sequentially starting from 8001)
2. ID given to sample
3. Message

Key Functions

: Assays a diluted sample

: Assays a whole blood sample

: Dilutes a whole blood sample at a default dilution rate
(A blood sample will be diluted by 201 times)

: Dilutes a whole blood sample at half time of the default dilution rate
(A blood sample will be diluted by 401 times)

: Dilutes a whole blood sample at twice of the default dilution rate
(A blood sample will be diluted by 101 times)

: Schedules a STAT assay

: Returns to the previous screen

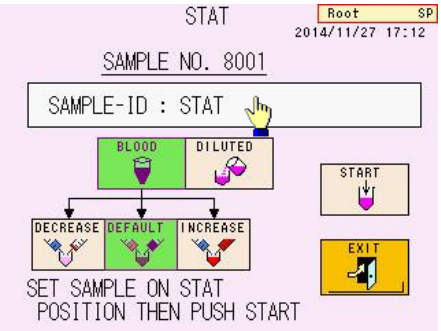
Operation Ex. STAT assay of a Total Area low sample

1. Check the 

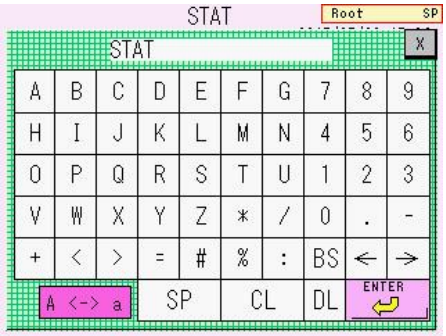
key on the main screen and make sure that a STAT operation is not being scheduled or the STAT sample assay is not in process.
2. Press the 

key to display the STAT screen.
3. Place a sample requiring an immediate assay into the STAT position.
4. Press the SAMPLE-ID to display the ID EDIT screen. Input an ID.

Screen 4- 12 STAT screen

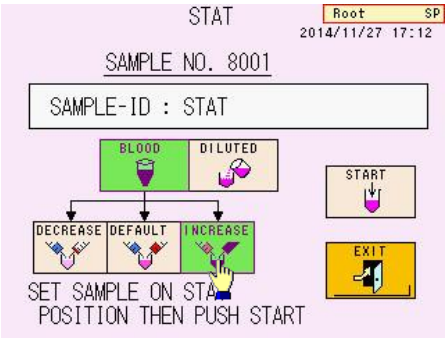


Screen 4- 13 ID EDIT Screen



5. When the sample shows low Total Area, select INCREASE key

Screen 4- 14 STAT screen



6. Press the  key and return to the main screen.

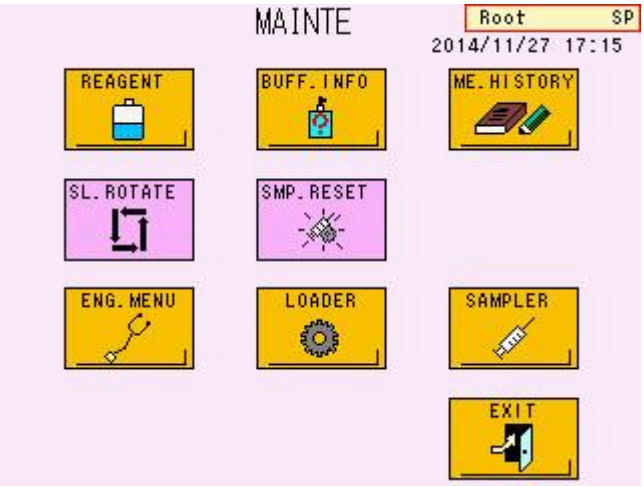
Point

When you have an optional handheld barcode scanner, the barcode ID can be input using the handheld barcode scanner.

4.4 Maintenance [Main screen] – [MAINTE]

Press the MAINTE key on the main screen to display the MAINTE screen.

Screen 4- 15 MAINTE screen



Key Functions

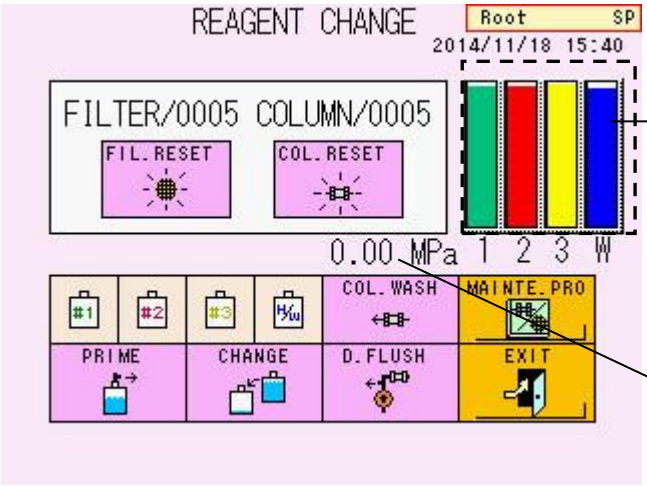
- REAGENT : Displays REAGENT CHANGE screen to reset the column counter and filter counter or to replace the reagents
- BUFF. INFO : Displays the information about the liquid reagents and column read with a handheld barcode scanner.
- ME. HISTORY : Displays maintenance history

  (only written by service representative)
- ENG. MENU : Used by only service representative (error occurs, if pressed)
- LOADER : Used by only service representative (error occurs, if pressed)
- SAMPLER : Used by only service representative (error occurs, if pressed)
- SL. ROTATE : Continuously rotates the sample loader (stops the loader when pressed again)
- SMP. RESET : Initializes (washes) the sampling unit
- EXIT : Returns to the previous screen

4.5 Reagent Change [Main screen] – [MAINTE] – [REAGENT]

This screen is used to reset the counter when the column or filter has been replaced, and to prime in order to purge air after replacing elution buffers, and to remove air from the pump valves.

Screen 4- 16 REAGENT CHANGE screen



Indicates the remaining volume of eluents.
(In sequence from left:
G11 Variant Elution Buffer No.1,
G11 Variant Elution Buffer No.2,
G11 Variant Elution Buffer No.3
and Hemolysis & Wash Solution)

Used to check the pressure during column washing.

Key Functions

- FIL.RESET : Resets the filter counter
- COL.RESET : Resets the column counter
- #1 : Selects Elution Buffer No.1 for PRIME or CHANGE Selected
- #2 : Selects Elution Buffer No. 2 for PRIME or CHANGE Selected
- #3 : Selects Elution Buffer No. 3 for PRIME or CHANGE Selected
- Hw : Selects the Hemolysis & Wash Solution for PRIME or CHANGE Selected
- COL.WASH : Washes the column by Elution Buffer
- PRIME : Replaces the reagent in the flow paths selected with the above key
- CHANGE : Replaces the reagent in the flow paths selected with the above key and resets the display for the remaining volume.
- D.FLUSH : Purges the air from the drain valve when air has entered into the pump

: Returns to the previous screen

: Displays the help screen for the maintenance.

Press the desired item. Maintenance method will be illustrated.

- Column Replacement
- Filter Replacement
- Buffer and Wash Replacement
- Printer Paper Replacement
- Open Drain Valve
- Close Drain Valve

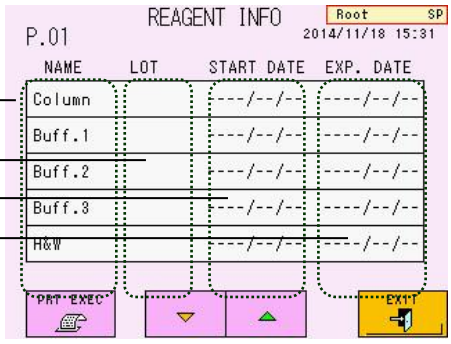
4.6 Reagent Information [Main screen] – [MAINTE] – [BUFF. INFO]

This screen is used to check the calibration date and the expiration date of calibration factors.

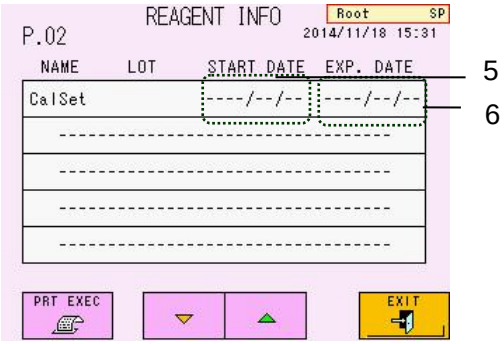
Point

When the barcode information on the liquid reagents/column box was read by handheld barcode scanner, the REAGENT INFO screen displays lot number, start date being used and expiration date of the liquid reagents/column. Refer to "3.12 How to Use Handheld Barcode Scanner" for details.

Screen 4- 17 REAGENT INFO screen (P.01)



Screen 4- 18 REAGENT INFO screen (P.02)



Display content

1. Reagent name
2. Reagent lot number
3. Date barcode is read
4. Expiration date of reagents
   (Refer to "3.12 How to Use Handheld Barcode Scanner" for the expiration date.)
5. Calibration date
6. Expiration date of calibration factors (The 30th date after calibration)

Point

Refer to "3.12 How to Use Handheld Barcode Scanner" for method of clearing reagents information. Only Super User can clear the expiration date.

Key Functions

PRT EXEC : Prints out current reagents information

: Displays the next page

: Displays the previous page

EXIT : Returns to the previous screen

Reagent Information Printout

Reagent information stored in analyzer can be printed out by pressing the PRT EXEC key.

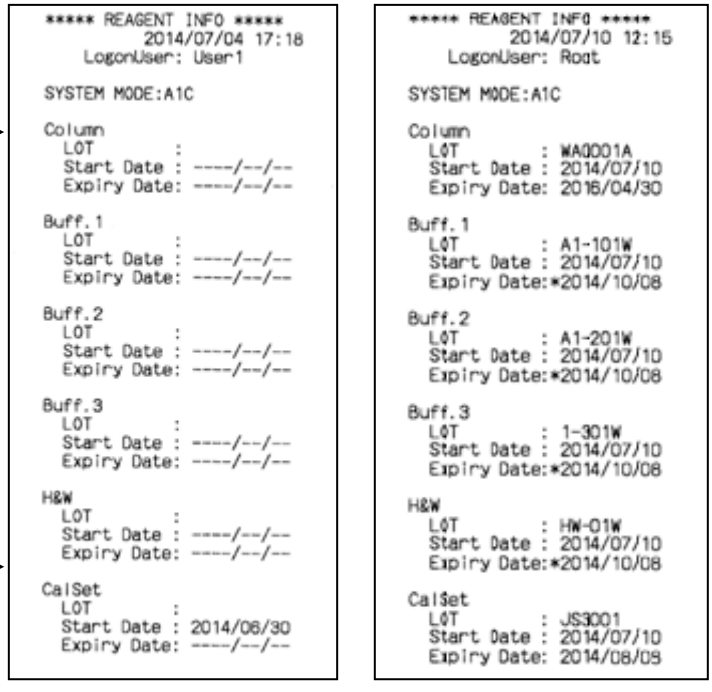
If you use a handheld barcode scanner, liquid reagents/column information will be printed out in addition to calibration information.

Fig. 4- 2 Reagent information printout example

(Left: without a handheld barcode scanner,
Right: with a handheld barcode scanner)

In sequence from top:
Reagent name
Reagent lot number
Start date being used
Expiration date

Calibration date
If calibration has not been performed, ----/--/-- will appear.



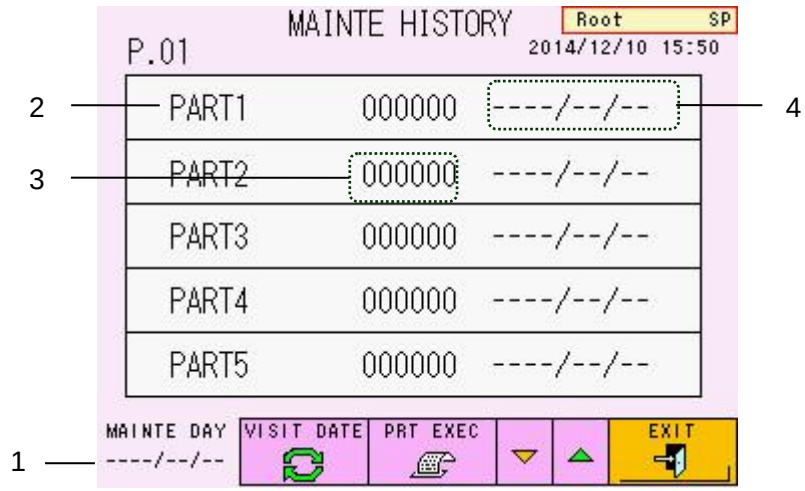
```
***** REAGENT INFO *****
          2014/07/04 17:18
    LogonUser: User1

SYSTEM MODE:A1C

Column
  LOT          :
  Start Date   : ----/--/--
  Expiry Date: ----/--/--

Buff.1
  LOT          :
  Start Date   : ----/--/--
  Expiry Date: ----/--/--

Buff.2
  LOT          :
  Start Date   : ----/--/--
  Expiry Date: ----/--/--

Buff.3
  LOT          :
  Start Date   : ----/--/--
  Expiry Date: ----/--/--

H&W
  LOT          :
  Start Date   : ----/--/--
  Expiry Date: ----/--/--

CalSet
  LOT          :
  Start Date   : 2014/06/30
  Expiry Date: ----/--/--
```

```
***** REAGENT INFO *****
          2014/07/10 12:15
    LogonUser: Root

SYSTEM MODE:A1C

Column
  LOT          : WA0001A
  Start Date   : 2014/07/10
  Expiry Date: 2016/04/30

Buff.1
  LOT          : A1-101W
  Start Date   : 2014/07/10
  Expiry Date:*2014/10/08

Buff.2
  LOT          : A1-201W
  Start Date   : 2014/07/10
  Expiry Date:*2014/10/08

Buff.3
  LOT          : 1-301W
  Start Date   : 2014/07/10
  Expiry Date:*2014/10/08

H&W
  LOT          : HW-01W
  Start Date   : 2014/07/10
  Expiry Date:*2014/10/08

CalSet
  LOT          : JS3001
  Start Date   : 2014/07/10
  Expiry Date: 2014/08/05
```

4.7 Maintenance History [Main screen] – [MAINTE] – [ME. HISTORY]

You can check the date that maintenance is executed.

Screen 4- 19 MAINTE HISTORY screen



Display content

1. The latest maintenance date
2. Part name (10 parts)
3. Each part count
4. The latest maintenance date of each part

Key Functions

VISIT DATE : Used only by service representative (error occurs, if pressed)

PRT EXEC : Prints out the maintenance history

: Displays the next page

: Displays the previous page

EXIT : Return to the previous screen

4.8 Menu [Main screen] – [MENU]

Press the MENU key on the main screen to display the MENU screen.

Screen 4- 20 MENU screen

Key Functions

Reference page

- USB STICK : Displays the USB STICK screen .....P. 4 - 31
- UTILITY : Displays the UTILITY screen (used only by Super User)..P. 4 - 51
- LIST : Displays the LIST screen.....P. 4 - 42
- RESULT : Displays the RESULT screen .....P. 4 - 34
- PARAMETER : Displays the PARAMETER screen.....P. 4 - 19
- TIMER : Displays the WEEKLY TIMER screen .....P. 4 - 39
- RECALC : Displays the RECALC screen.....P. 4 - 36
- BELT LINE : Only used when the analyzer is connected to specimen transport system
  (refer to "**Specimen Transport System Operator's Manual**" for details)
- LOG VIEW : Displays the LOG VIEW screen .....P. 4 - 47

: Confirms settings of communication, flag and barcode ....P. 4 - 50

: Used only by service representative

: Sets the characters printed in the comment line of the assay results .....P. 4 - 46

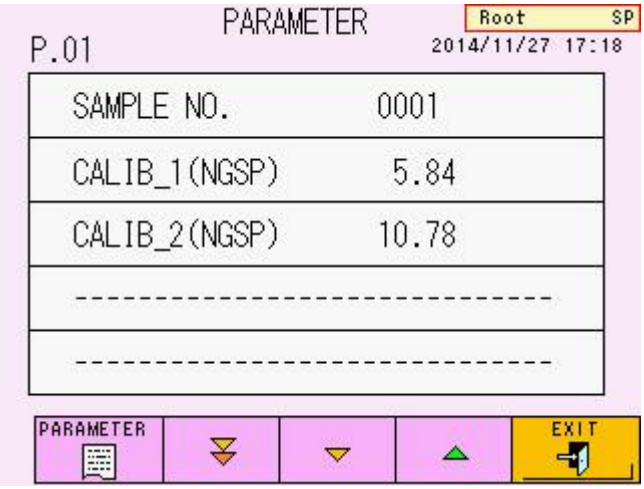
: Returns to the previous page

Detailed explanations for each key are given on the pages listed above.

4.9 Parameter Setting [Main screen] – [MENU] – [PARAMETER]

Press the PARAMETER key on the MENU screen to open the PARAMETER screen. In addition to Super User, Operator can change parameters on this screen.
Select the various parameters to change their setting.

Screen 4- 21 PARAMETER screen (P.01 / P.07)



Key Functions

- PARAMETER : Prints out a list of parameters
- : Displays the page after the next page
- : Displays the next page
- : Displays the previous page
- EXIT : Returns to the previous screen

Point **There are a total of seven PARAMETER screens. The key functions are the same for all of the screens.**

Parameter (P.01 / P.07)

SAMPLE NO.: The first sample number on the next assay (normally set automatically)

CALIB_1: Aligned value of calibrator 1

CALIB_2: Aligned value of calibrator 2

Point

Aligned values to be entered will be prompted with NGSP/IFCC indication as below.

For entering in NGSP units:

CALIB_1(NGSP)

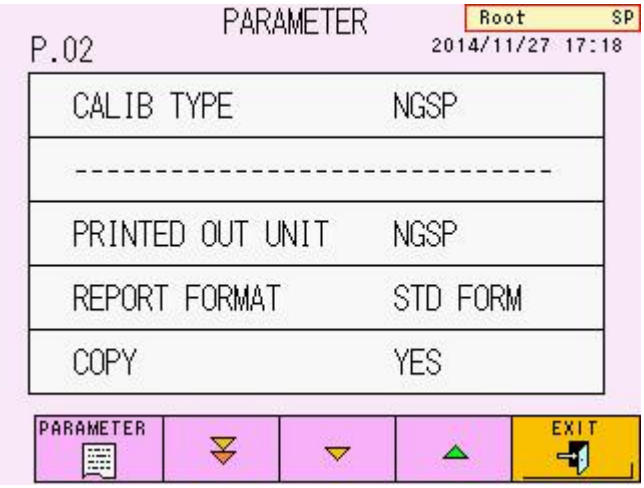
CALIB_2(NGSP)

For entering in IFCC units:

CALIB_1(IFCC)

CALIB_2(IFCC)

Screen 4- 22 PARAMETER screen (P.02 / P.07)



Parameters (P.02 / P.07)

CALIB TYPE: Changes the units of the aligned values of calibrator to be input, corresponding to the units of assay results
(1) NGSP (3) IFCC

PRINTED OUT UNIT: Setting for printing the assay results
(0) in the specified units by CALIB TYPE
(1) in both units of NGSP and IFCC, but the units specified by CALIB TYPE comes first.

Example

If CALIB TYPE was set to "NGSP," assay results will be printed in the order of NGSP and IFCC.
In the case of the above setting, "(0) NGSP" and "(1) NGSP + IFCC" will appear on the selection screen.

REPORT FORMAT: Sets the print format
(Refer to "**3.14 Interpretation of Results**")
(0) STD FORM:
Detailed peak information with the chromatogram
(1) SIMPLE FORM:
Basic peak information with the chromatogram
(9) MAINTE FORM:
STD FORM with the number of theoretical plate
(3) STD+R FORM:
STD FORM with the reagent information
(8) MNT+R FORM:
MAINTE FORM with the reagent information

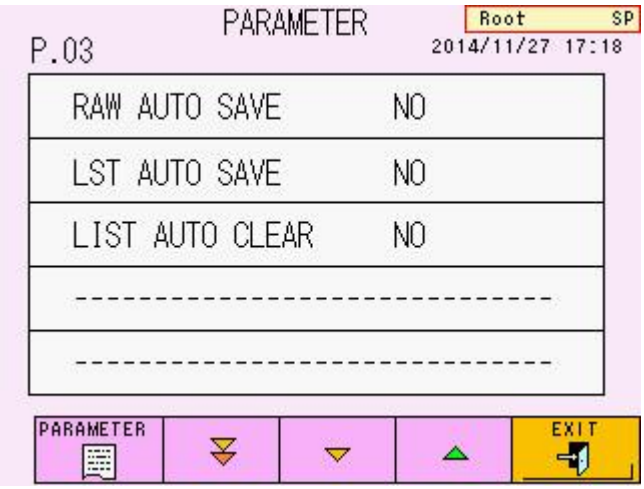
COPY: Determines print setting
(0) NO: do not print, (1) YES: print

Point **PRINTED OUT UNIT, REPORT FORMAT and COPY parameters can be reflected to the recalculation.**

Point **You can also check the units of set calibrator value by the following calibration equation to be printed on the assay result report.**

CALIB TYPE	Calibration equation
NGSP	CAL(N) = AX + B
IFCC	CAL(IN) = AX + B

Screen 4- 23 PARAMETER screen (P.03 / P.07)



Parameters (P.03 / P.07)

RAW AUTO SAVE: Automatically saves the assay results to the USB stick
(0) NO: no save, (1) YES: save

Point

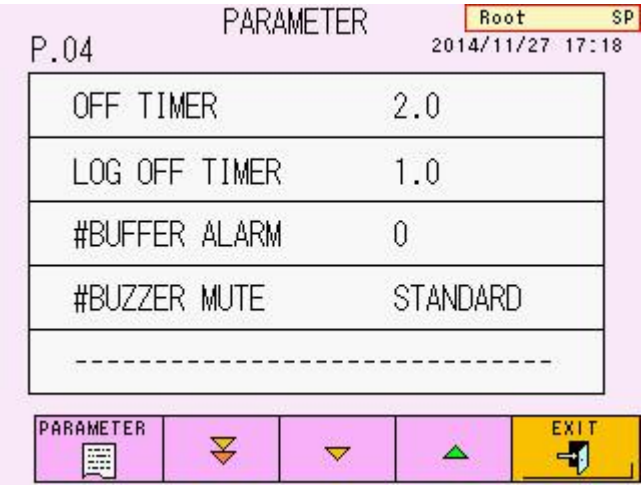
If the USB STICK FULL error occurs during assays, you can resave the results to a USB stick by using the SAVE key on the RECALC screen after the assay has completed. (Refer to "4.12 Confirmation, Retransmission to Host, Reprint, Recalculation of Saved Results")

LST AUTO SAV: Automatically saves the list data to the USB stick
(0) NO: no save, (1) YES: save

LIST AUTO CLEAR: Clears results each time START is pressed
(0) NO: no clear, (1) YES: clear

If the LIST AUTO CLEAR setting is (1) YES, previously measured assay data saved to the RESULT DB will also be deleted.

Screen 4- 24 PARAMETER screen (P.04 / P.07)



Parameters (P.04 / P.07)

OFF TIMER: Time from STAND-BY state to power shut off. The unit is in hour.
(0.0 to 3.0: 0.0 indicates no automatic power shut-off)

LOG OFF TIMER: Time from STAND-BY state to log off.
The unit is in hour.
(0.0 to 3.0: 0.0 indicates no automatic log off)

#BUFFER ALARM: Beeps when the remaining volume of elution buffer or Hemolysis & Wash Solution is less than volume %
(0 to 99: 0 indicates no alarm)

Use the BUFFER ALARM function only as a rough guide.

#BUZZER MUTE: Sets the buzzer to mute

(0) STANDARD: The buzzer not muted.

(1) ERR BUZZER: Mutes the error buzzer tone. (The end-of-assay buzzer tone sounds.)

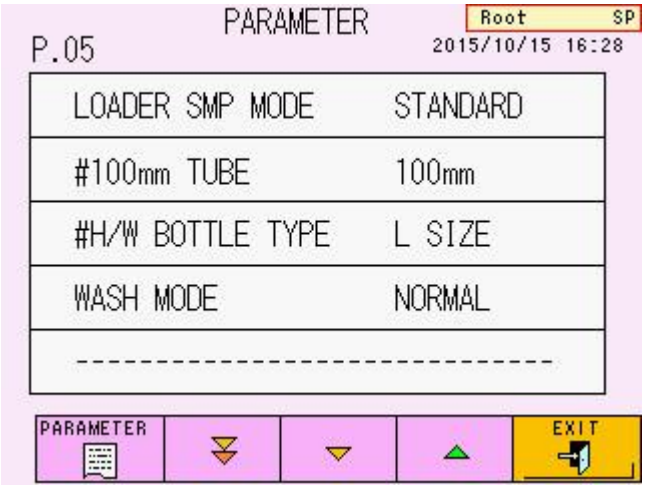
(2) END BUZZER: Mutes the end-of-assay buzzer tone. (The error buzzer tone sounds.)

(3) ALL BUZZER: Mutes all buzzer tones.

(4) NONE (SP): The buzzer not muted.
The error buzzer tone can be stopped by pressing the E.RESET key.

(5) END BZ (SP): Mutes the end-of-assay buzzer tone.
(The error buzzer tone sounds.) The error buzzer tone can be muted by pressing the E.RESET key.

Screen 4- 25 PARAMETER screen (P.05 / P.07)



Parameters (P.05 / P.07)

LOADER SMP MODE: Designates the sample container type

Container	Primary tube	Sample cup
(0) STANDARD	Whole blood	Diluted sample
(1) WHOLE BLD	Whole blood	Whole blood
(2) DILUTED	Diluted sample	Diluted sample
(3) HOST	Specified by host	

Point **Regardless of the LOADER SMP MODE setting, calibrators will be recognized as diluted samples.**

Never assay a whole blood as a diluted sample. Filter and column must be replaced. After LOADER SMP MODE is changed to (2) DILUTED, pay attention to the assay.

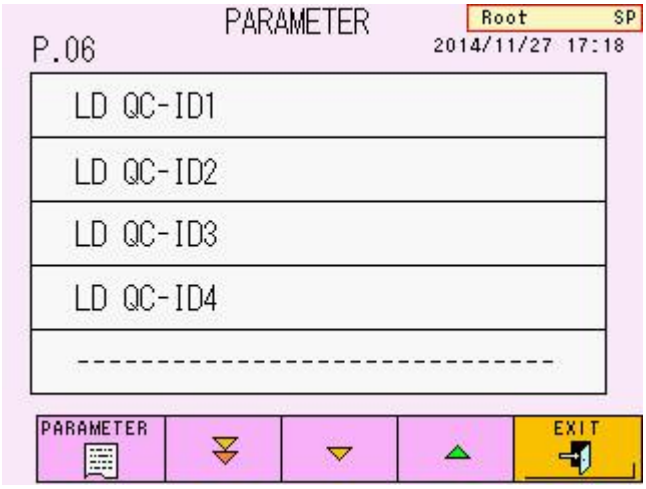
#100mm TUBE: Settting for the primary tube length
(0) 75 mm: Tube length is 75 mm
(1) 100 mm: Tube length is 100 mm

Caution **If you use a combination of 75 mm and 100 mm tubes, set to (1) 100 mm. When 75 mm and 100 mm primary tubes are set together, the 75 mm tubes will be pulled up after being sampled and will be forwarded as they are. If these tubes are forwarded to the sampling position, the sampling needle could be bent due to misalignment.**

#H/W BOTTLE TYPE: Setting for the Hemolysis & Wash Solution bottle size.
(0) L SIZE, (1) LL SIZE

WASH MODE: Setting for the WASH mode
(0) NORMAL, (1) SIMPLE

Screen 4- 26 PARAMETER screen (P.06 / P.07)

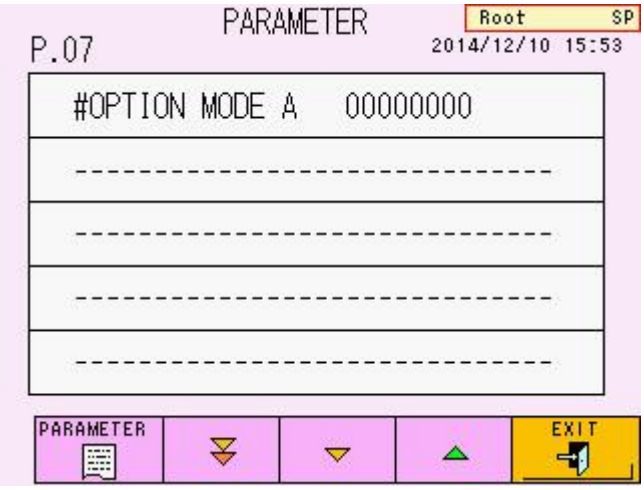


Parameters (P.06 / P.07)

LD QC-ID (1 to 4): Registers control ID (maximum 4) for quality control

Point **LD QC-ID can be input using the optional handheld barcode scanner connected to the analyzer.**

Screen 4- 27 PARAMETER screen (P.07 / P.07)



Parameters (P.07 / P.07)

#OPTION MODE A: Sets an optional function

1 bit: Sets to mute the buzzer

Setting 0: does not beep when result meets Flag condition.

Setting 1: beeps when result meets Flag condition.

2 – 8 bit: Used only by service representative

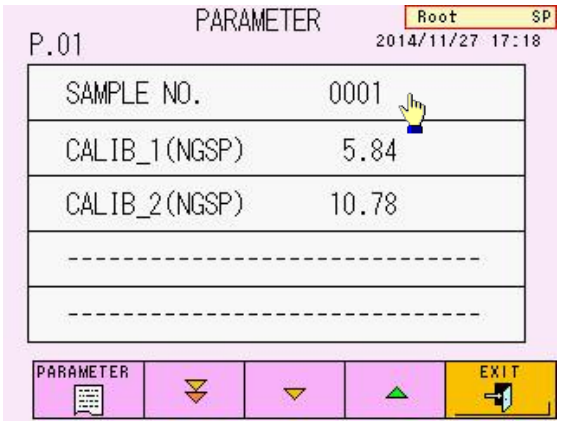
Operation Ex. **Example of changing a parameter**

-- Entering a value from the numeric keypad

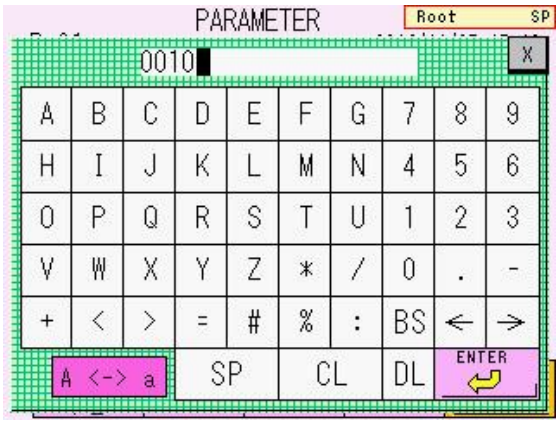
Change the setting of the "Sample No." Press the keys in sequence.

1. Press the "SAMPLE NO." line to open the "PARAMETER" input screen.
2. Press the "CL" key to clear the numerical value, then enter "0010" using the numeric keypad.
3. Confirm that "0010" appears at the top of the input screen, then press the ENTER key. The input screen will close.
4. Confirm that "SAMPLE NO." has changed to "0010." This completes setting work.

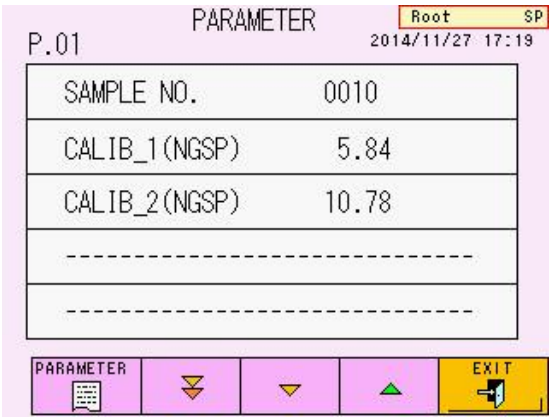
Screen 4- 28 PARAMETER screen



Screen 4- 29 Input example



Screen 4- 30 After entering the parameter

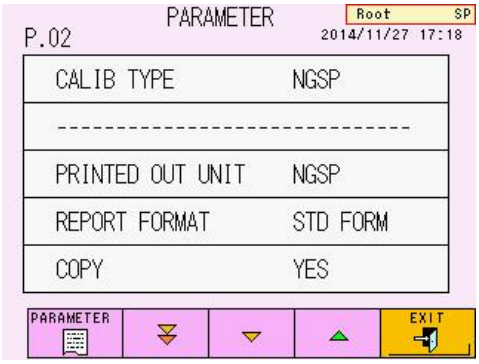


Operation Ex. **Example of changing a parameter -- Selection type**

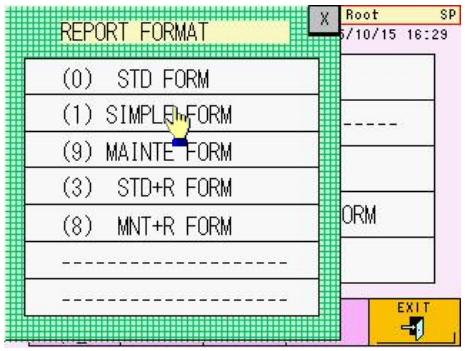
Change the setting of "REPORT FORMAT". Press the keys in sequence.

1. Press the "REPORT FORMAT" line to open the selection screen.
2. Select the desired setting. Here, select "(1) SIMPLE FORM."
3. The parameter will change to "SIMPLE FORM."

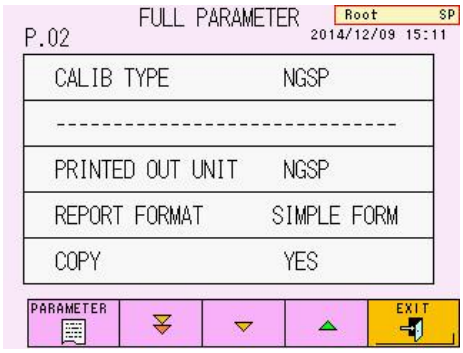
Screen 4- 31 PARAMETER screen



Screen 4- 32 Input example



Screen 4- 33 After entering the parameter

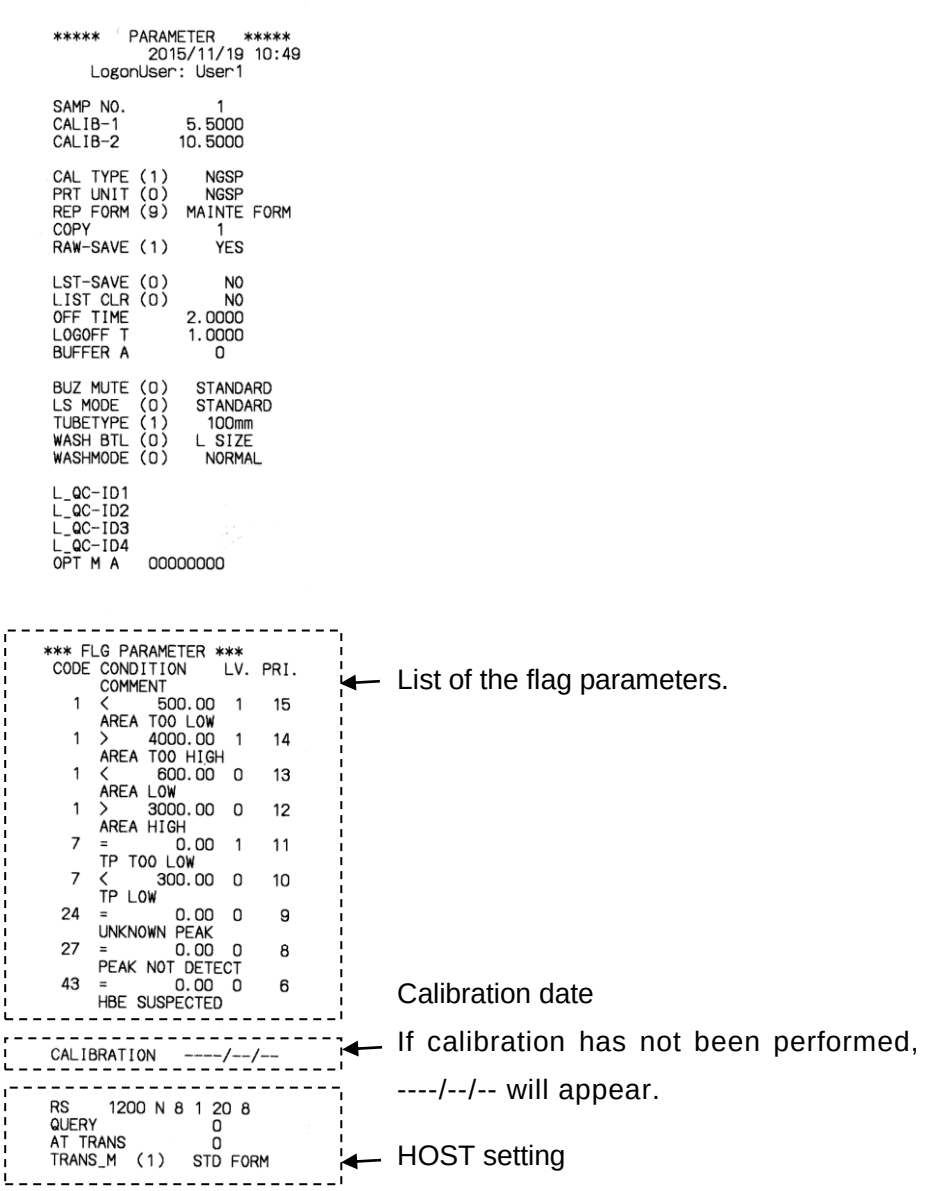


Parameter Printout

Press the PARAMETER key on the PARAMETER screen to print out a list of parameters.

In addition to the parameters, a list of the flag parameters, calibration date and external communication settings will be printed.

Fig. 4- 3 Parameter printout example



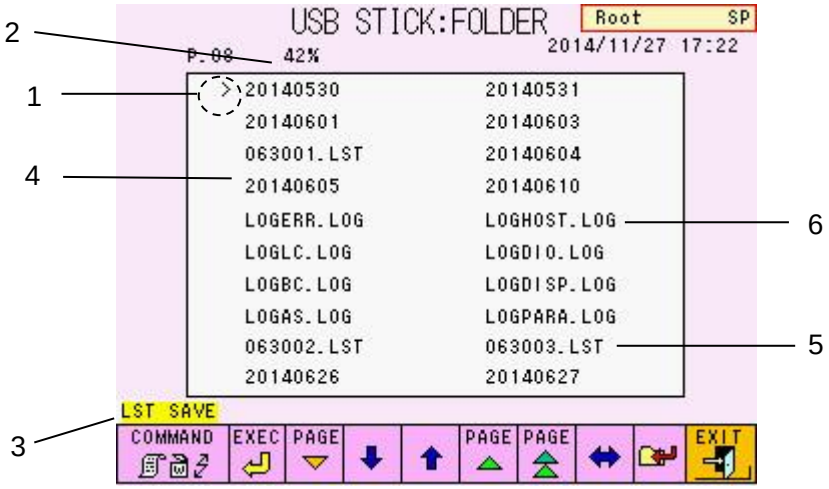
4.10 USB Stick [Main screen] – [MENU] – [USB STICK]

Press the USB STICK key on the MENU screen to display the USB STICK: FOLDER screen.

Use the ↓ ↑ ↔ keys on that screen to select a folder (move the >). Press the key and the list of the file will be displayed on the USB STICK: FILE screen.

Saving list data and parameters to a USB stick, formatting a USB stick, and printing/deletion of files and folders on a USB stick are performed here.

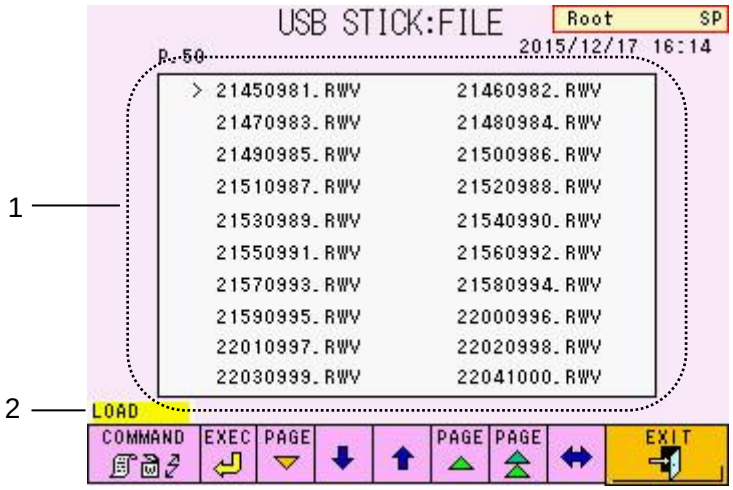
Screen 4- 34 USB STICK: FOLDER screen



Display content

1. The arrow shows the active field
2. Percentage of USB stick in use
3. Selected command
4. Folder (Data is stored in a folder of the assay date)
   Folder name is decided on the assay date (YYYYMMDD).
   YYYY: Year, MM: Month, DD: Day
5. List data (MMDDNN.LST)
   MM: Month, DD: Day, NN: Serial number (No.)
6. Log data (. LOG) (For maintenance)

Screen 4- 35 USB STICK: FILE screen



Display content

1. Assay data for each sample (HHMMNNNN.RWV)
   HH: Hour, MM: Minute, NNNN: Sample No.
2. Selected command

Key functions (USB STICK: FOLDER / USB STICK: FILE screens)

: Command key (Commands change when pressed)

Command Descriptions and Executable Statuses

Command types		STAND-BY	ANALYSIS	WASH
Command	Content			
LST SAVE	List data save (Valid only in USB STICK: FOLDER screen) File will be saved as MMDDNN.LST (MM: Month, DD: Day, NN: Serial No.)	O	×	×
PRM SAVE	Parameter save (Valid only in USB STICK: FOLDER screen) File will be saved as SYSTEM.PRM.	O	×	×
LOAD	File loading Parameters and list data can be loaded	O	×	×
FORMAT	Format USB stick	O	×	×
PRINT	List of files or folders can be printed	O	×	×
DELETE	Selected files or folders can be deleted	O	×	×

O: Can be executed x: Cannot be executed

: Execution key for the selected command

: Displays the next page

: Displays the previous page

: Displays 4 pages prior


: Moves the active field (arrow: >) down


: Moves the active field (arrow: >) up


: Moves the active field (arrow: >) right or left


: Selects folder

: Returns to the previous screen

Operation Ex. **List data deletion operation**

The operation for deleting list data is indicated below.

1. Use the    keys to move the ">" mark to the list filename that you want to delete from the USB STICK: FOLDER screen.
2. Press the 

key until DELETE is displayed.
3. Press the 

key to delete the selected list.

Folders and the data stored in that folder, as well as individual data items, can be deleted by following the same procedure.

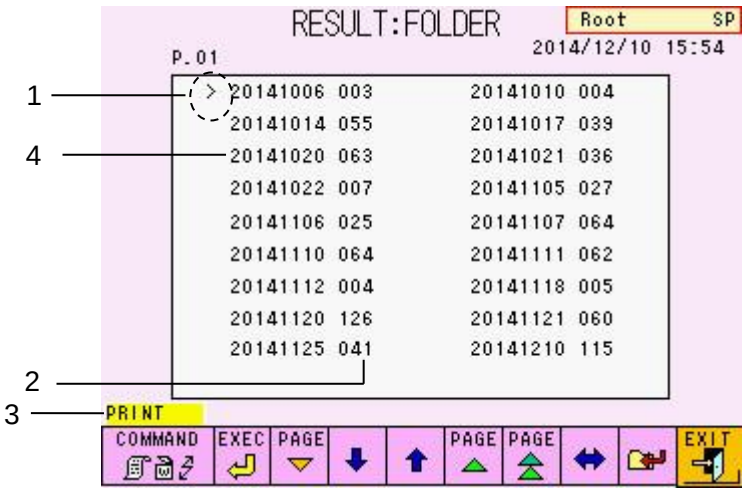
1. **The commands you can execute may be depending on the analyzer's operational states.**
2. **The analyzer can not display folder names and filenames that exceed 12 characters. The analyzer may have an error with the USB sticks that have folder names and filenames that exceed 12 characters.**

4.11 List of Saved Data [Main screen] – [MENU] – [RESULT]

Press the RESULT key on the MENU screen to display the RESULT: FOLDER screen. Use the ↓ ↑ ↔ keys on this screen to select a folder (move the ">" mark). Press the ↵ key to display the files saved in that folder on the RESULT: FILE screen.

The file/folder lists on the RESULT screen can be printed or deleted.

Screen 4- 36 RESULT: FOLDER screen



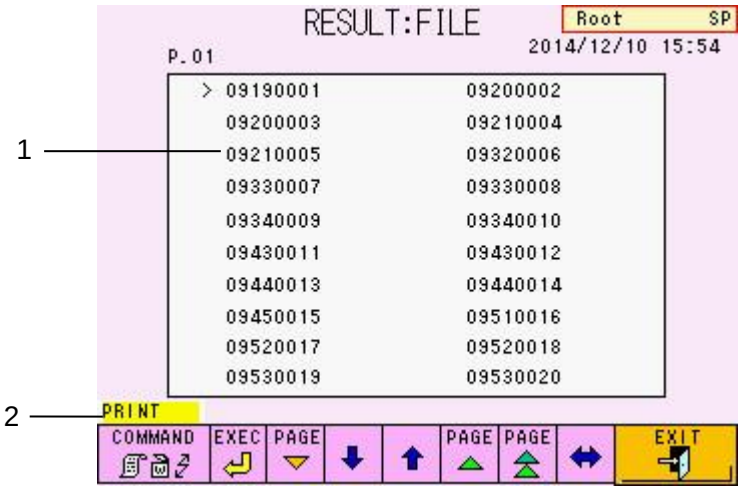
Display content

1. The arrow shows the active field
2. Number of saved results
3. Selected command
4. Folder (Data are stored in a folder whose name corresponds to the assay date)

   Folder name is decided by the assay date (YYYYMMDD).

   YYYY: Year, MM: Month, DD: Day

Screen 4- 37 RESULT: FILE screen



Display content

1. Assay data for each sample
   File name is decided by the assay time and the sample number.
   (HHMMNNNN) HH: Hour, MM: Minute, NNNN: Sample No.
2. Selected command

Key Functions

: Command key (Commands change when pressed)

: Execution key for the selected command

: Displays the next page

: Displays the previous page

: Displays 4 pages prior


: Moves the active field (arrow: >) down


: Moves the active field (arrow: >) up


: Moves the active field (arrow: >) right or left

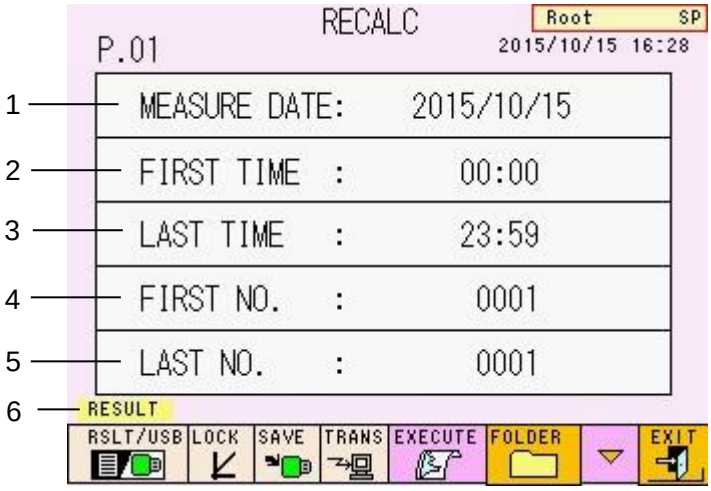

: Selects the folder

: Returns to the previous screen

4.12 Confirmation, Retransmission to Host, Reprint and Recalculation of Saved Results [Main screen] – [MENU] – [RECALC]

Press the RECALC key on the MENU screen to display the RECALC screen.
The assayed results, which are stored in the analyzer's memory (RESULT) or in a USB stick, can be reprinted, retransmitted to a host, and recalculated with different calibration factors. Up to 800 results can be stored in RESULT.

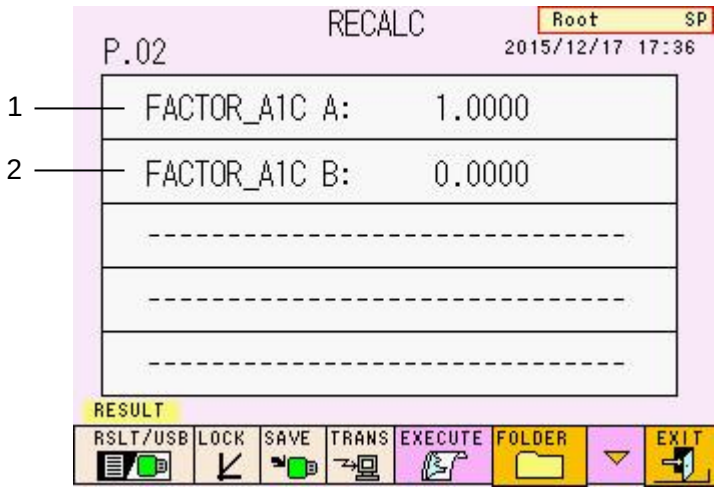
Screen 4- 38 RECALC screen (P.01)



Display content

1. Measure date of sample (YYYY/MM/DD)
   YYYY: Year, MM: Month, DD: Day
2. First data time of the results (HH: MM)
   HH: Hour, MM: Minute
3. Last data time of the results (HH: MM)
   HH: Hour, MM: Minute
4. First data number (Sample No.) of the results
5. Last data number (Sample No.) of the results
6. Current selected media (RESULT memory or USB stick)

Screen 4- 39 RECALC screen (P.02)



Display content

1. FACTOR_A1C A
   (Valid when recalculating results after changing the calibration factor)
2. FACTOR_A1C B
   (Valid when recalculating results after changing the calibration factor)

Key Functions

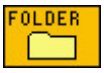
RSLT/USB : Selects whether the data to be processed is stored in the analyzer's memory (RESULT) or on a USB stick (USB)
(RESULT : RSLT/USB , USB: RSLT/USB)

LOCK : When selected (displayed in green), executes recalculation using the calibration factors set in the RECALC screen
(Used by only Super User)

SAVE : When selected (displayed in green), saves the recalculated results to a USB stick

TRANS : When selected (displayed in green), automatically transmits the recalculated results

EXECUTE : Starts printing and recalculation operations



: Displays the data folders
(Main unit memory (RESULT) or a USB stick (USB))

: Displays the next page (Used by only Super User)

: Returns to the previous screen

Point

1. **Recalculated data will be printed, saved (overwriting previous results) and transmitted (when the TRANS key is selected). If RESULT is selected, the data will be overwritten onto the RESULT area. If USB is selected, the data will not be overwritten and saved onto the USB stick.**
   If the SAVE key is selected (displayed in green) on the RECALC screen, the data will be saved to the USB stick, regardless of whether RESULT or USB stick is specified.
2. **The heading will change to the heading currently set at the RECALC execution.**
   (Refer to "4.15 Entering a COMMENT")
3. **Automatically the current date and calibration factors are input whenever the RECALC screen is opened. Then the LOCK key will be cancelled.**

Recalculation should be executed in the STAND-BY state.

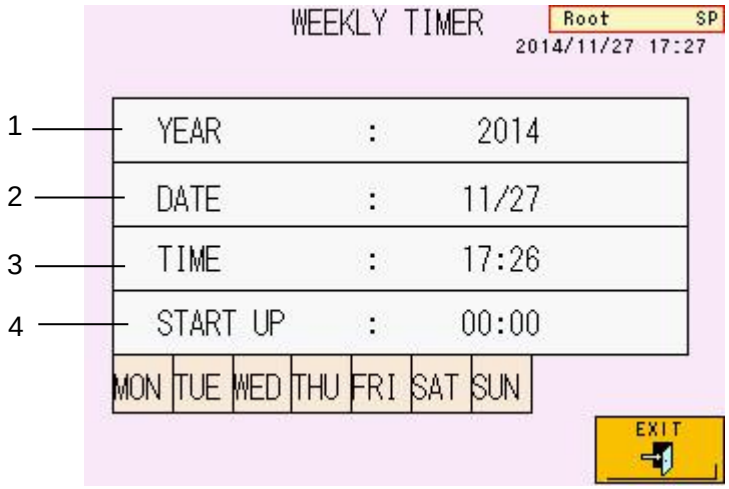
4.13 Date/Time and Weekly Timer Setting

[Main screen] – [MENU] – [TIMER]

Press the TIMER key on the MENU screen to display the WEEKLY TIMER screen. When the timer is selected, the analyzer goes in the STAND-BY mode with the startup operation completed automatically on a specified input day every week.

When the timer startup is activated, the power is automatically turned on and WARMING UP is executed at the designated START UP time. The analyzer goes in STAND-BY state after PUMP CLEAN is complete. Normally, when nothing is input from the operation panel for 2 hours, the power is automatically turned off.

Screen 4- 40 WEEKLY TIMER screen



Display content

1. Year
2. Date
3. Time
4. START UP time (default value is "00:00")

Key Functions

MON TUE WED THU FRI SAT SUN : Input the analyzer startup day of the week

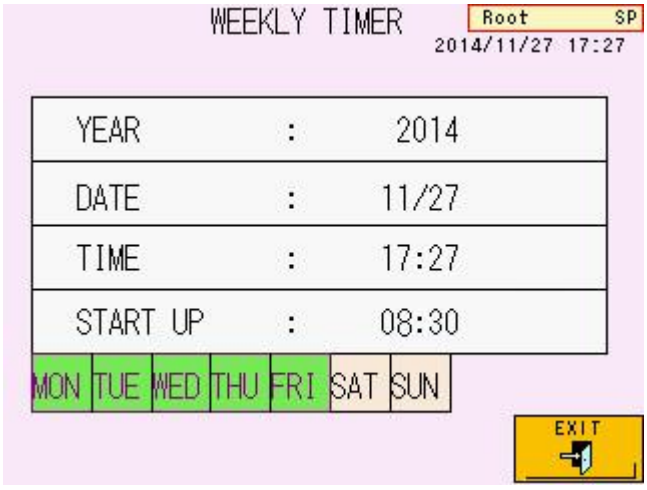
EXIT : Returns to the previous screen

Operation Ex. **Example of setting for a weekly timer**

The scheduled analyzer's startup day/time is set at 8:30 on every Mondays to Fridays.

1. Check that the current date/time shown is correct.
2. If the values are incorrect, select the value to be corrected and display the input screen.
3. Input the correct date/time and return to the WEEKLY TIMER screen.
4. Use the MON TUE WED THU FRI SAT SUN key to select the day of the week on which you want the analyzer to start up. Selected day's key will be displayed in green.
5. Select START UP, display the input screen, and input the time "08:30".
6. Check the specified day and START UP time on the WEEKLY TIMER screen.

Screen 4- 41 WEEKLY TIMER screen (example)



Point

1. **The scheduled analyzer's startup day is displayed in green. Before starting the timer, make sure to set both START UP time and the analyzer startup day.**
2. **The timer period from STAND-BY to POWER OFF can be changed using the OFF TIMER parameter. (Refer to" 4.9 Parameter Setting".)**

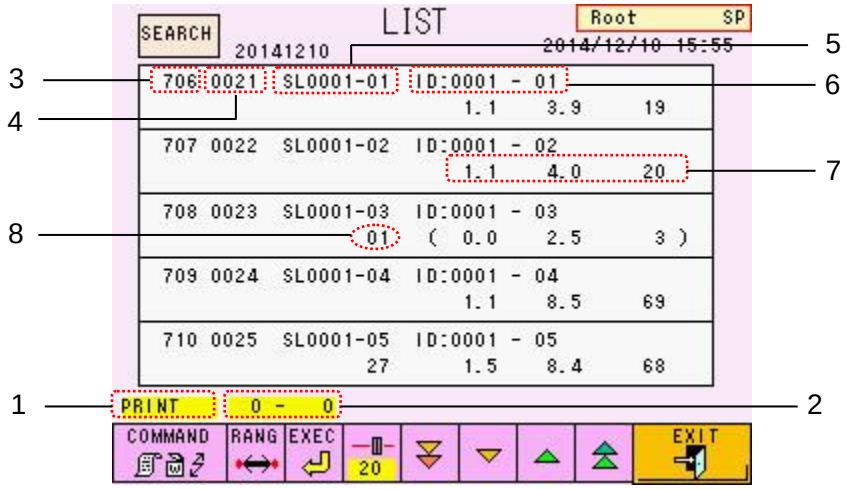
If the main power has been off, the scheduled analyzer startup is not activated. For a weekly timer, let the main power stay on and turn the power off by pressing the power button.

4.14 List Data Display and Barcode Editing

[Main screen] – [MENU] – [LIST]

Press the LIST key on the MENU screen to display the LIST screen.
A list of stored results can be displayed, printed, deleted, and transmitted to the host. The sample IDs can also be input or corrected on this screen after the assay. Only Super User can input or correct the sample IDs.

Screen 4- 42 LIST screen



Display content

1. Command
2. First and last number of the selected results to which the command is being applied (001 to 800)
3. Specified number which the command is being executed.
4. Sample number
5. Unit
   Unit is displayed as SLxxxx-yy in a normal assay (xxxx: rack number, yy: potion number on the rack). In a STAT assay, ST is displayed.
6. Sample ID
   Alphanumeric characters of the barcode (when read with a handheld barcode scanner) or xxxx-yy (xxxx: rack number, yy: position number on the rack).

7. Assayed values

   In the left sequence HbF (%), HbA1c (%) and HbA1c (% or mmol/mol).

   If assayed results are parenthesized, these results meet flag conditions which are set to level 1. These results are not reliable.

8. Flag code

   If a sample meets flag conditions, flag code is displayed. Refer to "**4.21 FLAG Parameter Setting**" for details.

Key Functions

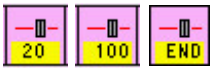
: Displays the LIST SEARCH screen

: Selects a command (Commands change when pressed)
("DELETE" command is used by only Super User)

Command types	
Command	**Function**
PRINT	Prints the selected results
DELETE	Deletes the selected results
TRANS	Transmits the selected results

: Changes the data to which commands are applied

: Executes the selected command



: Changes the scroll settings (can be set to 20, 100 and END)


: Scrolls down in STEP units

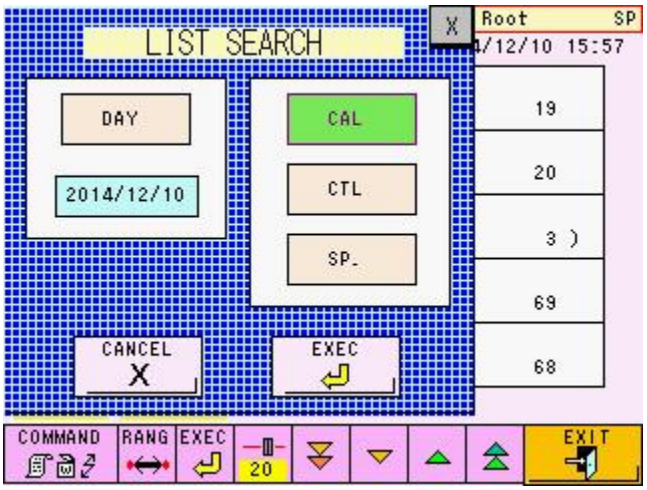

: Scrolls up in STEP units


: Scrolls down in single screen units


: Scrolls up in single screen units

: Returns to the previous screen

Screen 4- 43 LIST SEARCH screen



Key Functions

DAY : Adds the "assayed on the specified date" to the list search conditions

2014/12/10 : Enters the "specified date"

CAL : When selected (displayed in green), adds "calibrator" to the list search conditions.

CTL : When selected (displayed in green), adds "control" to the list search conditions.

SP. : When selected (displayed in green), adds "sample" to the list search conditions.

CANCEL : Cancels the list search and returns to the LIST screen.

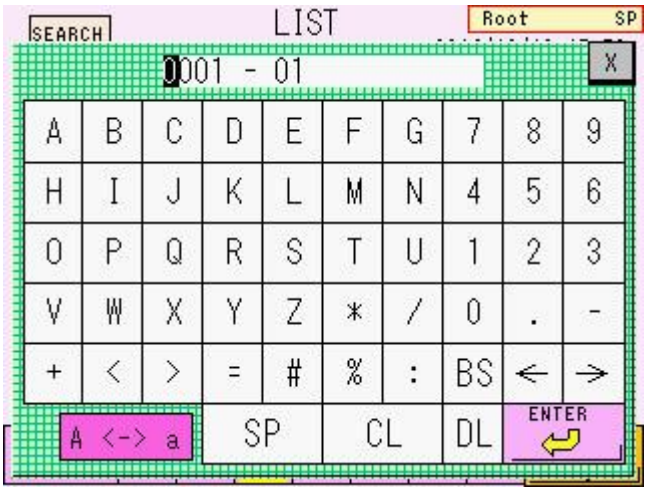
EXEC : Executes the list search

X : Closes the LIST SEARCH screen

Operation Ex. **Barcode ID Editing (Super User only)**

1. On the LIST screen, select the sample whose barcode ID you want to change, and then display the input screen.
2. Press CL to clear the ID. Input the correct ID, press the ENTER key, confirm the input and return to the LIST screen.
3. Confirm the new barcode ID on the LIST screen.

Screen 4- 44 Barcode ID input screen



4.15 Entering a COMMENT [Main screen] – [MENU] – [COMMENT]

Press the COMMENT key on the MENU screen to display the COMMENT screen.
The text input here will be printed at the top of the results printout (including RECALC) each time results are printed. Use this function to input the facility name, instrument serial number, etc., for assay results control.
Up to 20 characters can be input.
If you have edited the comment before RECALC is executed, the new comment will be printed.

Screen 4- 45 COMMENT screen

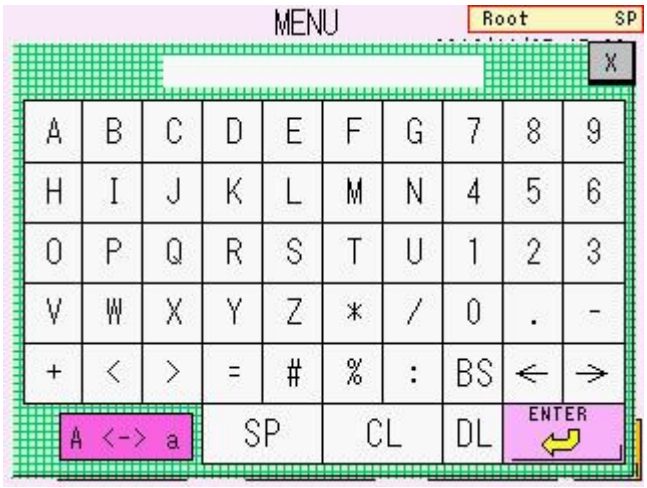
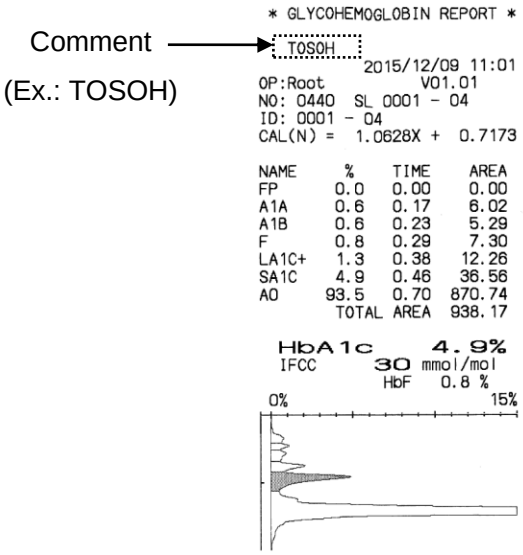


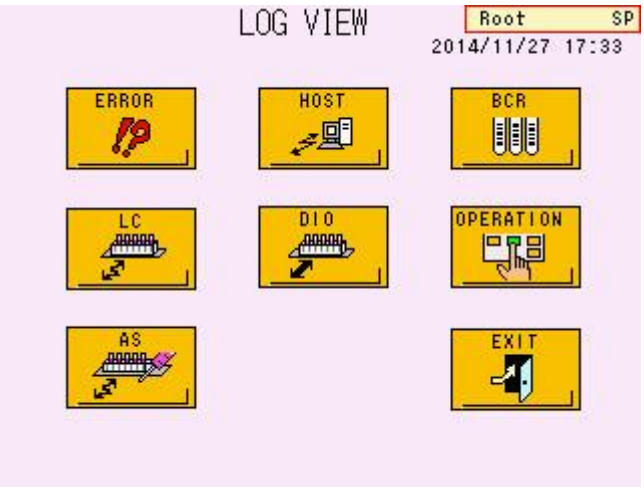
Fig. 4- 4 Heading printout example (TOSOH)



4.16 Log File Check [Main screen] – [MENU] – [LOG VIEW]

Press the LOG VIEW key on the MENU screen to display the LOG VIEW screen.

Screen 4- 46 LOG VIEW screen



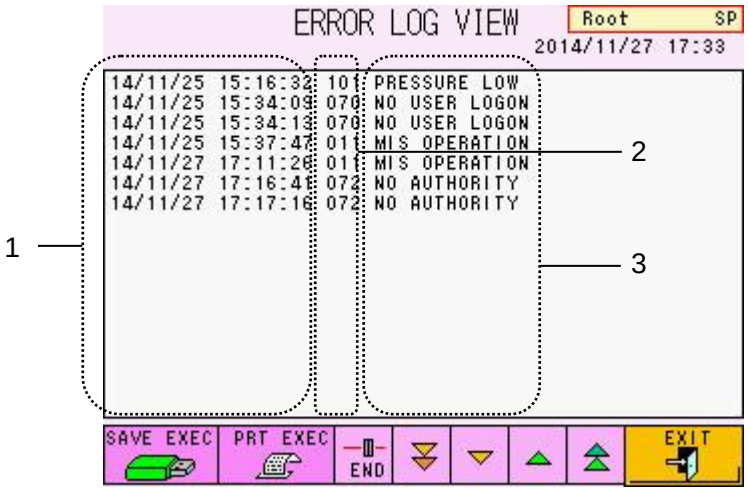
Key Functions

- ERROR : Displays the analyzer error log
- HOST : Displays a log of communications with the host
- BCR : Displays a log of scanned barcodes
- LC : Displays the communication log with the specimen transport system controller
- DIO : Displays a detailed log of communications with the host computer
- OPERATION : Displays a log of screen operation.
- AS : Displays a log of auto sampler operation
- EXIT : Returns to the previous screen

Operation Ex. **The error log**

Press the ERROR key. The next screen will be displayed.

Screen 4- 47 ERROR LOG VIEW screen



Display content

1. Date and time the error occurred
2. Error code number
3. Error message

   Refer to "**6.3 Error Messages**" for detailed error messages.

Key Functions

SAVE EXEC : Stores the log list on a USB stick
8 kinds of files (LOGERR.LOG, LOGHOST.LOG, LOGBC.LOG, LOGAS.LOG, LOGDIO.LOG, LOGLC.LOG, LOGDISP.LOG, LOGPARA.LOG) are stored.

PRT EXEC : Prints the log list on the printer

100 500 2000 END : Changes the scroll settings


: Scrolls down in STEP units


: Scrolls up in STEP units


: Scrolls down in single screen units


: Scrolls up in single screen units

: Returns to the previous screen

Point **When you want to get details about other log screens and their contents, contact Tosoh local representatives.**

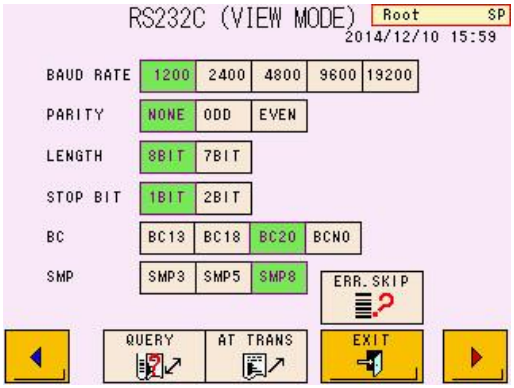
4.17 Transmission, Flag and Barcode Setting Check

[Main screen] – [MENU] – [VIEW CONF.]

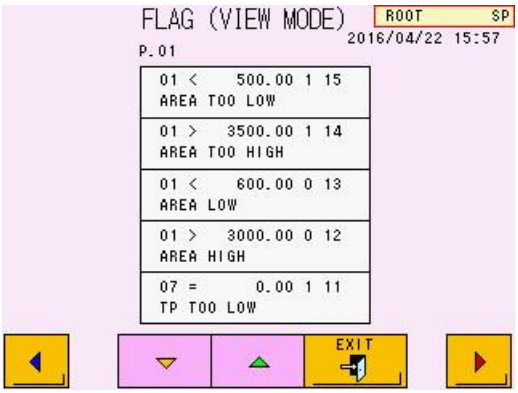
Press the VIEW CONF. key on the MENU screen to confirm the settings of data communication (RS232C), flag and barcode.

You can use the ERR.SKIP key, QUERY key and the AT TRANS key.

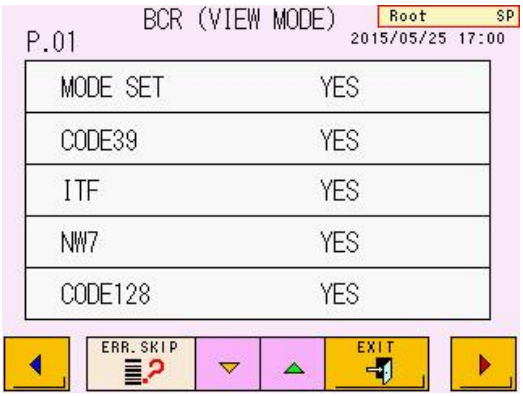
Screen 4- 48 RS232C (VIEW MODE) screen



Screen 4- 49 FLAG (VIEW MODE) screen



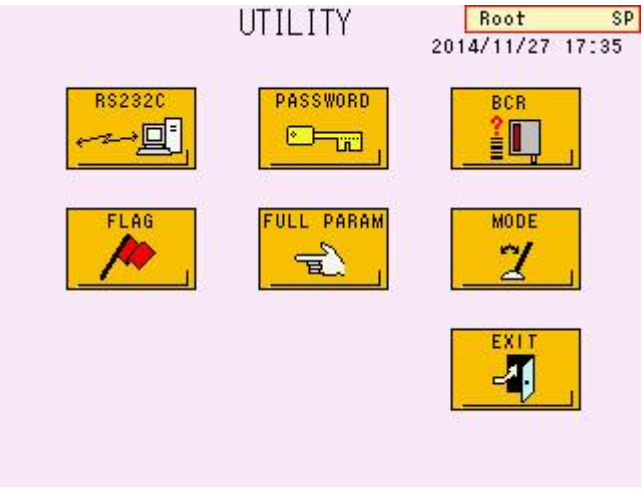
Screen 4- 50 BCR (VIEW MODE) screen



4.18 Utilities [Main screen] – [MENU] – [UTILITY]

Press the UTILITY key on the MENU screen to display the UTILITY screen. Only Super User can open the UTILITY screen.

Screen 4- 51 UTILITY screen



Key Functions

Reference page

RS232C : Displays RS232C (data communication) screen ..... P.4 - 55

PASSWORD : Password input (for service representative)

BCR : Displays the BCR screen ..... P.4 - 61

FLAG : Displays the FLAG screen ..... P.4 - 57

FULL PARAM : Displays the FULL PARAMETER screen. ..... P.4 - 52

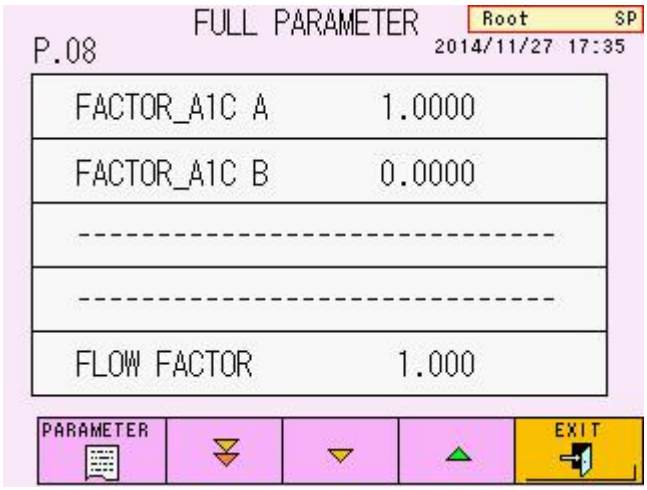
MODE : Can be used if multiple modes are activated. Please contact Tosoh local representatives for more details

EXIT : Returns to the previous screen

4.19 Full Parameter [Main screen] – [MENU] – [UTILITY] – [FULL PARAM]

Press the FULL PARAM key on the UTILITY screen to open the FULL PARAMETER screen. Super User can change parameters (flow-rate or calibration factor etc.) in addition to parameters which Operator can edit. P.01 to P.07 pages are same with the PARAMETER screen (Refer to "**4.9 Parameter Setting**").

Screen 4- 52 FULL PARAMETER screen (P.08 / P.09)



Key Functions

PARAMETER : Prints out a list of full parameters

: Displays the page after the next page

: Displays the next page

: Displays the previous page

EXIT : Returns to the previous screen

Point **There are a total of nine PARAMETER screens. The key functions are the same for all of the screens.**

Parameters (P.08 / P.09)

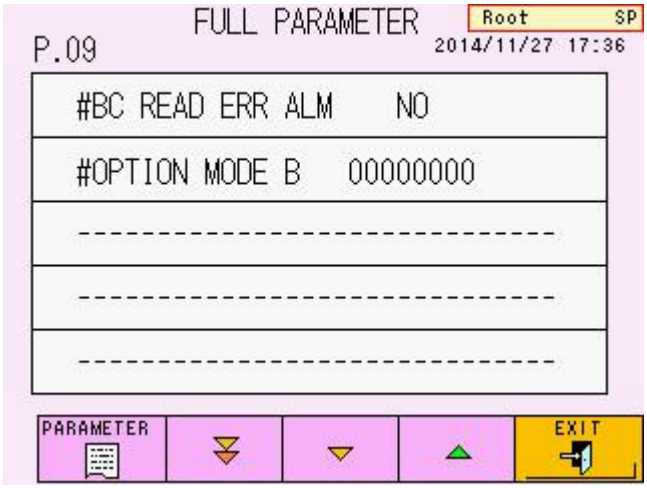
FACTOR_A1C A: Calibration factor A
(Automatically calculated in automatic calibration mode but may be changed by key input)

FACTOR_A1C B: Calibration factor B
(Automatically calculated in automatic calibration mode but may be changed by key input)

FLOW FACTOR: Pump flow factor

Never change the FLOW FACTOR without instructions from Tosoh local representatives. Accurate results may not be obtained if this parameter is changed.

Screen 4- 53 FULL PARAMETER screen (P.09 / P.09)



Parameters (P.09 / P.09)

#BC READ ERR ALM: Beeps when barcode can not be read correctly.
(1) YES
(0) NO
#OPTION MODE B: (for service representative)

Full Parameter Printout

Press the PARAMETER key on the FULL PARAMETER screen to print out a list of full parameters.

In addition to the normal parameters, calibration factors and flow factor will be printed.

```
*****   PARAMETER   *****
          2015/11/19 13:03
    LogonUser: Root

SAMP NO.          1
CALIB-1        5.5000
CALIB-2       10.5000

CAL TYPE (1)    NGSP
PRT UNIT (0)    NGSP
REP FORM (9)  MAINTE FORM
COPY              1
RAW-SAVE (1)     YES

LST-SAVE (0)      NO
LIST CLR (0)      NO
OFF TIME       2.0000
LOGOFF T       1.0000
BUFFER A          0

BUZ MUTE (0)   STANDARD
LS MODE  (0)   STANDARD
TUBETYPE (1)    100mm
WASH BTL (0)   L SIZE
WASHMODE (0)    NORMAL

L_QC-ID1
L_QC-ID2
L_QC-ID3
L_QC-ID4
OPT M A   00000000

FACTOR A       1.0000
FACTOR B       0.0000
FLOW           1.0000
BC ERR A (0)      NO
OPT M B   00000000

*** FLG PARAMETER ***
 CODE CONDITION    LV. PRI.
      COMMENT
   1  <     500.00  1   15
      AREA TOO LOW
   1  >    4000.00  1   14
      AREA TOO HIGH
   1  <     600.00  0   13
      AREA LOW
   1  >    3000.00  0   12
      AREA HIGH
   7  =       0.00  1   11
      TP TOO LOW
   7  <     300.00  0   10
      TP LOW
  24  =       0.00  0    9
      UNKNOWN PEAK
  27  =       0.00  0    8
      PEAK NOT DETECT
  43  =       0.00  0    6
      HBE SUSPECTED

CALIBRATION   ----/--/--

RS    1200 N 8 1 20 8
QUERY             0
AT TRANS          0
TRANS_M  (1)   STD FORM
```

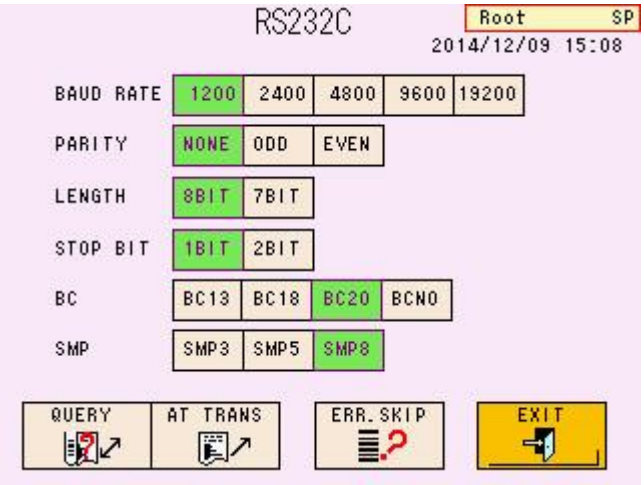
These parameters are printed out on the FULL PARAMETER screen.

4.20 Data Communication Setting

[Main screen] – [MENU] – [UTILITY] – [RS232C]

Press the RS232C key on the UTILITY screen to display the RS232C screen.
To transmit data in real time, press the AT TRANS key.

Screen 4- 54 RS232C screen



Key Functions

1200: Sets the baud rate to 1200 bps
2400: Sets the baud rate to 2400 bps
4800: Sets the baud rate to 4800 bps
9600: Sets the baud rate to 9600 bps
19200: Sets the baud rate to 19200 bps
NONE: Sets the parity to none
ODD: Sets the parity to odd numbers
EVEN: Sets the parity to even numbers
8 BIT: Sets the data length to 8 bits
7 BIT: Sets the data length to 7 bits
1 BIT: Sets the stop bit to 1
2 BIT: Sets the stop bit to 2
BC 13: Transmits the barcode using 13 digits
BC 18: Transmits the barcode using 18 digits

BC 20: Transmits the barcode using 20 digits

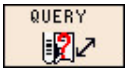
BC NO: Does not send the barcode ID

SMP 3: Handles the sample number with the last 3 digits

SMP 5: Uses 5 digits for the sample number

SMP 8: Uses 8 digits for the sample number

(ID number is added to the front of the number for a total of 8 digits)



: When this key is displayed in green (

), a query with ID is executed and only designated samples are processed.

: When this key is displayed in green (

), results are automatically transmitted.

: When this key is displayed in green (

), the sample assay with barcode reading error is skipped.

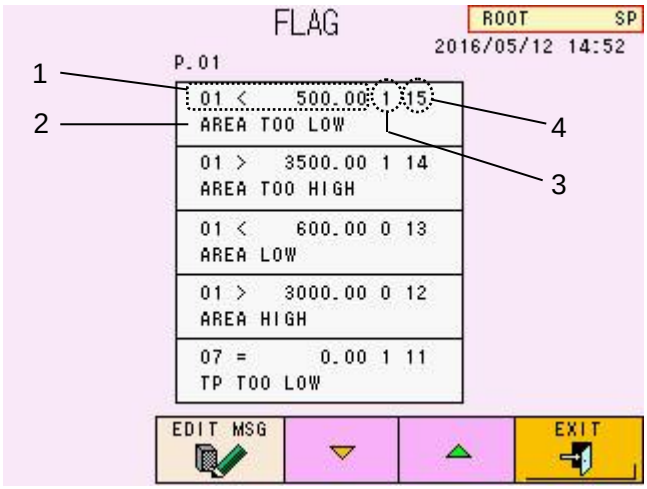
: Returns to the previous screen

4.21 FLAG Parameter Setting

[Main screen] – [MENU] – [UTILITY] – [FLAG]

Press the FLAG key on the UTILITY screen to display the FLAG screen.
The analyzer checks results according to the flag parameters set on this screen. Flags can be printed with the results. You can set the level for each flag. If the flag level is set to 0, the assay values are printed out with the flag message. If the level is set to 1, the assay value is not reported.
For RECALC, the determination is made in accordance with the current FLAG conditions. If you set new FLAG conditions or change them and execute a RECALC, make sure of the settings. Maximum of 20 flags can be input.

Screen 4- 55 FLAG screen



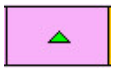
Display content

1. Criteria (code/condition/num. value)
2. Flag message output when result meets condition
   (maximum of 16 characters available to show message)
3. Flag Level
   (Level 0: The assay values are displayed/printed or transmitted to the host with Flag.)
   (Level 1: "---" is displayed or printed in the field of the assay result with Flag. But a blank or "0" is transmitted to the host computer with Flag.)
4. Flag superiority (1 to 20)
   (The larger figure, the more superior)

Key Functions

: Displays the message editing screen


: Scrolls down in single screen units


: Scrolls up in single screen units

: Returns to the previous screen

Operation Ex. Flag condition input

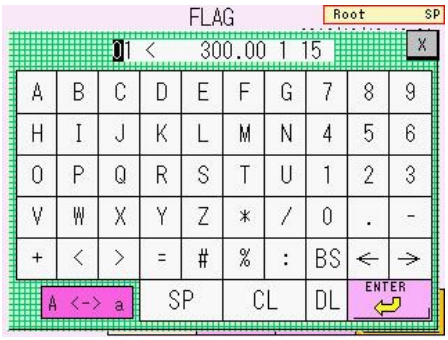
1. Press the input line on the screen to select. (The field is blank when the settings are new.) The flag condition input screen is displayed. Input the values for the "flag code", "flag condition", "flag values (number)", "flag level" and "flag superiority". Press the 

key to close the numerical value input screen.
2. Press the 

key and display it in green.
3. Press the input line on the screen and open the message input screen. Input the text that you want to display when the criteria conditions are met and press the 

key to return to the FLAG screen.
4. Check the content again on the FLAG screen. To modify the input message, input and correct from step 3.
5. RECALC the previously assayed data and make sure of the settings.
6. If you want to remove a set condition, select the line, enter 0 = 0.

Screen 4- 56 Flag condition input screen



Screen 4- 57 Message input screen

[Flag conditions]

>	Result is greater than the assigned cut-off value
<	Result is smaller than the assigned cut-off value
>=	Result is greater than or equal to the assigned cut-off value
<=	Result is smaller than or equal to the assigned cut-off value
=	Result is equal to the assigned cut-off value

[Flag codes (items)]

01	TOTAL AREA
02	HbA1c (%)
03	HbF (%)
05	FILTER COUNT
06	COLUMN COUNT
07	Number of theoretical plate
08	Unidentified peak between L-A1c+ and s-A1c when data =0 Unidentified peak between s-A1c and A0 when data =1
09	Number of peaks
10	Sample number
24	Report if more than one unknown peak was detected, to be used as "24 = 0".
27	Report if one or some of A1a, A1b, F, L-A1c+, s-A1c or A0 peaks were not detected, to be used as "27 = 0".
35	Retention time of s-A1c
36	Retention time of A0
40	Reports if H-VAR peak was detected. To enable, set as "40 = 0"
41	HbA1c (mmol / mol)
42	L-A1c+ (%)
43	Reports if P-HV3 peak was detected. To enable, set as "43 = 0"

Point

1. The initial setting is as follows.

01 < 500.00	1	AREA TOO LOW	15
01 > 3500.00	1	AREA TOO HIGH	14
01 < 600.00	0	AREA LOW	13
01 > 3000.00	0	AREA HIGH	12
07 = 0.00	1	TP TOO LOW	11
07 < 300.00	0	TP LOW	10
24 = 0.00	0	UNKNOWN PEAK	9
27 = 0.00	0	PEAK NOT DETECT	8
43 = 0.00	0	HBE SUSPECTED	6
07 > 850.00	0	TP HIGH	5

2. Set the levels under the conditions indicated below.
   Level 0: The value falls within an acceptable range, but the data should be handled with care.
   Level 1: The value is out of the acceptable range. Try assaying again.
3. When the code (11, 12, 13, …), added +10 to the code for 1 - 10, is used, the analyzer will perform the flag error check only when the calibrator is processed.
4. The theoretical plate number is an index related to column efficiency and is used for determining the column lifespan.
5. To delete a flag condition, select the line you want to delete and input 0 = 0.
6. If a sample meets two or more flag conditions, all relevant flag messages will be printed on the report. However, only one flag code is displayed on the LIST screen. The Level 1 flags will be given priority over the Level 0 flags.
7. The transmission to the host depends on the compatibility.
8. If a result meets flag conditions, the error occurs to inform that the result meets flag conditions.

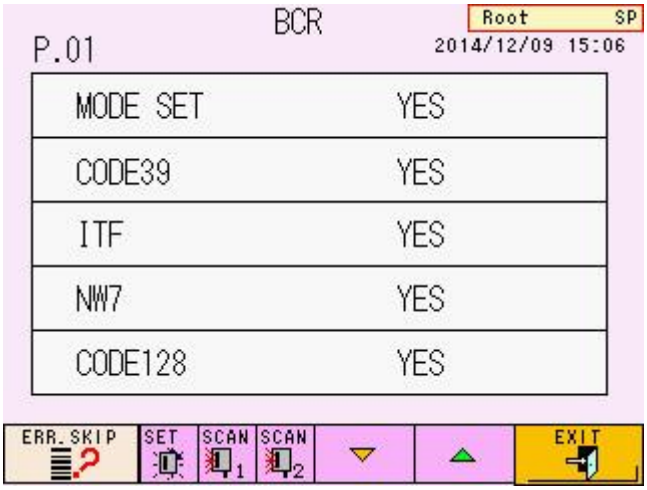
Do not give the same flag superiority to different flag codes.

4.22 Barcode Reader Setting and Reading Check

[Main screen] – [MENU] – [UTILITY] – [BCR]

Press the BCR key on the UTILITY screen to display the BCR screen.
You can make barcode settings and execute a reading check on this screen.

Screen 4- 58 BCR screen (P.01)



Key Functions

ERR.SKIP : Skips unreadable barcoded samples during an assay (displayed in green when pressed ERR.SKIP)

SET : Inputs conditions (barcode specifications you want to use) into the barcode reader.

SCAN1 : Checks reading capability of barcode reader (by scanning)

SCAN2 : Only used when connecting to specimen transport system (refer to the "**Specimen Transport System Operator's Manual**".)

▽ : Displays the next page

△ : Displays the previous page

EXIT : Returns to the previous screen

Parameters

MODE SET: Determines whether or not to set the barcode reader ((0) NO: do not set, (1) YES: set)

CODE39: Sets use of CODE 39 ((0) NO: do not use, (1) YES: use)

ITF: Sets use of ITF ((0) NO: do not use, (1) YES: use)

NW7: Sets use of NW-7 (Codabar) ((0) NO: do not use, (1) YES: use)

CODE128: Sets use of CODE128 ((0) NO: do not use, (1) YES: use)

JAN: Sets use of JAN (UPC/EAN) ((0) NO: do not use, (1) YES: use)

INDUST-2OF5: Sets use of INDUSTRIAL 2 of 5 ((0) NO: do not use, (1) YES: use)

COOP-2OF5: Sets use of COOP 2 of 5 ((0) NO: do not use, (1) YES: use)

Up to four types of codes can be used at once.

CODE39 STR&STP: Sets transmission of start/stop character (*) with code39 ((0) NO: do not transmit, (1) YES: transmit)

CODE39 CHK-DIG: Sets inspection for check digits (modulus43) with code39 ((0) NO: do not inspect, (1) YES: inspect)

CODE39 CD OUT: Sets transmission of check digits with code39 ((0) NO: do not transmit, (1) YES: transmit)

CODE39 MIN: Sets the minimum number of check digits with code39 (3 to 20)

CODE39 MAX: Sets the maximum number of check digits with code39 (3 to 20)

ITF CHK-DIG: Sets inspection for check digits (modulus10/weight3) with ITF ((0) NO: do not inspect, (1) YES: inspect)

ITF CD OUT: Sets transmission of check digits with ITF
((0) NO: do not transmit, (1) YES: transmit)

ITF MIN: Sets the minimum number of check digits with ITF
(2 to 20)

ITF MAX: Sets the maximum number of check digits with ITF
(2 to 20)

NW7 STR&STP: Sets transmission of start/stop character with NW-7
((0) NO: do not transmit, (1) YES: transmit)

NW7 S/L CHAR: Sets the type of start/stop character transmitted with NW-7
((0) SMALL: lower case, (1) LARGE: upper case)

NW7 CHK-DIG: Sets inspection for check digits (modulus10/weight2) with NW-7 ((0) NO: do not inspect; (1) YES: inspect)

NW7 CD TYPE: Sets the check-digit type for inspection with NW-7
(0) MODULUS16
(1) MODULUS11
(2) M10/W2: modulus10/weight2
(3) M10/W3: modulus10/weight3
(4) 7CHECK DR, (5) M11 -A: modulus11-A
(6) M10/W2 -A: modulus10/weight2-A

NW7 CD OUT: Sets transmission of check digits with NW-7
((0) NO: do not transmit, (1) YES: transmit)

NW7 MIN: Sets the minimum number of check digits with NW-7
(3 to 20)

NW7 MAX: Sets the maximum number of check digits with NW-7
(3 to 20)

CODE128 DBL CHAR: Sets check of double character start pattern for CODE128
((0) NO: do not inspect, (1) YES: inspect)

CODE128 MIN: Sets the minimum number of check digits with code 128
(1 to 20)

CODE128 MAX: Sets the maximum number of check digits with code 128
(1 to 20)

JAN UPC-E: Sets use of UPC-E with JAN
((0) NO: do not use, (1) YES: use)

JAN JAN8: Sets use of JAN8 with JAN
((0) NO: do not use, (1) YES: use)

JAN JAN13: Sets use of JAN13 with JAN
((0) NO: do not use, (1) YES: use)

JAN UPC-A OUT: Sets the number of output digits for UPC-A used with JAN
((0) 13 DIGITS, (1) 12 DIGITS)

JAN UPC-E ZERO: Sets addition of UPC-E system code "0" with JAN
((0) NO: do not add, (1) YES: add)

INDUST-2OF5 MIN: Sets the minimum number of check digits with INDUSTRIAL 2 of 5 (1 to 20)

INDUST-2OF5 MAX: Sets the maximum number of check digits with INDUSTRIAL 2 of 5 (1 to 20)

COOP-2OF5 MIN: Sets the minimum number of check digits with COOP 2 of 5(1 to 20)

COOP-2OF5 MAX: Sets the maximum number of check digits with COOP 2 of 5 (1 to 20)

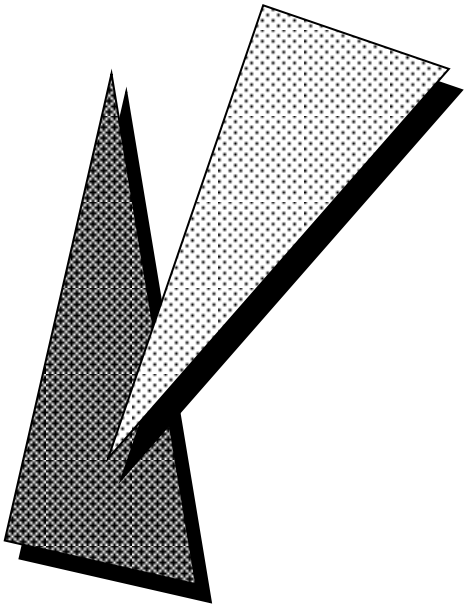
After changing the parameters, make sure to press the 

key.
If this is not done, the new settings will not work.

NOTE

Chapter 5

Maintenance Procedures



5 Maintenance Procedures

5.1 Daily Care

Wipe away dirt on the front side of the analyzer's plastic components (needle cover, etc.) with a soft cloth immersed in neutral detergent solution and squeezed tightly.

Caution **Do not use organic solvents such as ethanol to clean the plastic components. Such components may warp and discolor.**

Wipe away dirt on the metallic components with a soft cloth immersed in neutral detergent solution and squeezed tightly. If dirt is severe, wipe away using a cloth immersed in ethanol.
If moisture remains on the surface of the analyzer, the metal parts may rust.

Lightly wipe away blots and stains on the sample loader belt, display, and operation key with a cloth immersed in ethanol.

5.2 Checklist

- **Pre-assay Checklist**

The following table provides a checklist of procedures to be performed on a daily basis before starting assays (pressing START key)

No.	Items to Check	Content	Refer to
1	Calibration settings	Check the calibration factor and calibration date →execution	3.6 3.7
2	Column	Check counter and expiration date → replace	3.6 5.9
3	Filter	Check counter → replace	3.6 5.8
4	Elution Buffers	Check volume and expiration date → replace	3.6 5.4
5	Hemolysis & Wash Solution	Check volume and expiration date → replace	3.6 5.4
6	USB stick	Check remaining volume → replace or initialize	3.6 7.1
7	Printer paper	Check volume → replace	3.6 5.3
8	Waste tank	Check waste volume → treat waste	3.6

- **Be sure to check the following items before starting an assay**

No.	Items to check/replace	Maintenance schedule	Refer to
1	Printer paper	Out of paper (Every 270 tests)	5.3
2	Filter	Every 600 tests	5.8
3	Suction filter	Every 6 months	5.10
4	Sampling needle	When clogged or bent	5.11

- **The following items are checked by service representative.**

No.	Items to check / replace	Service frequency (guide or target)
1	Check the barcode reader	Every 15000 tests or Annually
2	Check the end marker sensor	
3	Check the rack holder and the sample holder	
4	Check the sample sensor	
5	Check needle descent position	
6	Clean dilution port and wash assembly	
7	Check the actuator of sampling unit	
8	Check the column oven temperature	
9	Check the solenoid valve's action (3 locations)	
10	Check vacuum pump's action	
11	Check waste pump's action	
12	Replace the rotor seal of the injection valve	
13	Replace the rotor seal of the rotary valve	
14	Replace the sample loop	
15	Wash or replace of the pump check valves	
16	Replace the plunger seal	
17	Replace the needle O-ring	
18	Replace or clean the waste filter	
19	Replace the valve stator face	When dirty or worn
20	Replace the Teflon® tip of syringe (5 mL)	When worn
21	Replace the syringe (0.1 mL)	When worn
22	Replace the drain valve O-ring	When worn

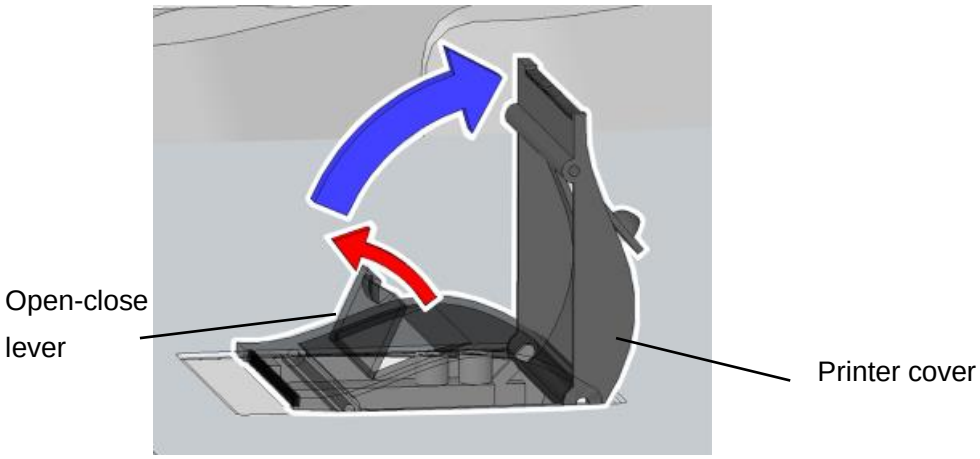
5.3 Printer Paper Replacement

Use printer paper dedicated to the G11 analyzer.
Each roll has a width of 58 mm and a length of 30 m. When STD FORM is used as the printout format, results for approximately 270 samples can be printed.

Procedure

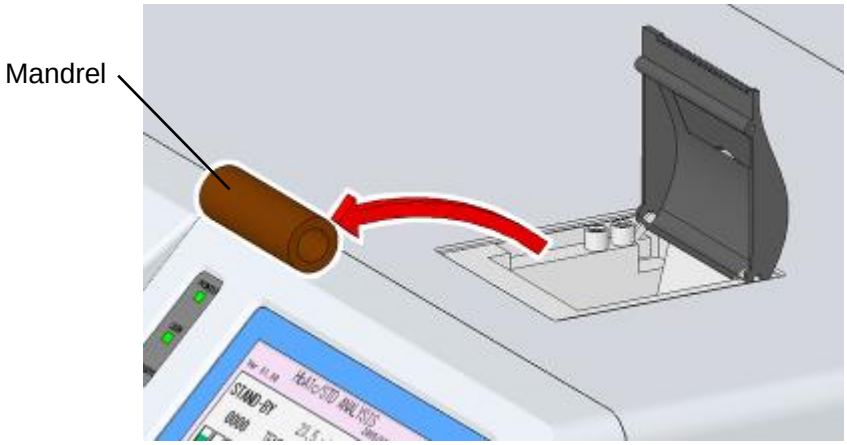
1. Pull the open–close lever and lift the printer cover (upper lid) to the back to open.

Fig. 5-1 Printer



2. Remove the empty mandrel.

Fig. 5-2 Remove the empty mandrel

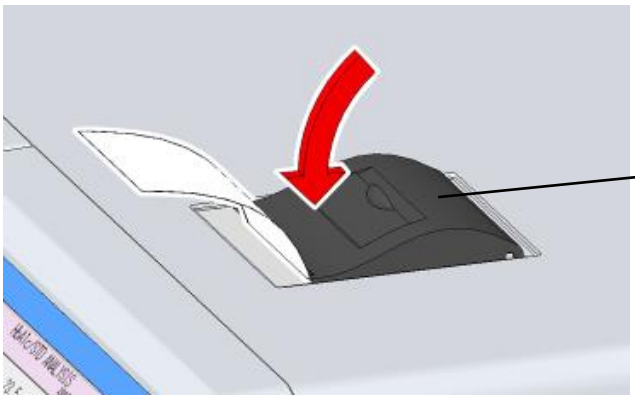


3. Set the new roll with great care for the direction.

Fig. 5-3 Setting a new roll

4. Close the printer cover.

Fig. 5-4 Printer cover



If you do not close the printer cover, "PRINTER OFF LINE" error will occur. In that case, the assay result cannot be printed

5.4 Elution Buffer and Hemolysis & Wash Solution Replacement

Replace Elution Buffers and Hemolysis & Wash Solution as early as possible when remaining volume is low.

The remaining volume of buffers is displayed in a graph on the main screen (second screen) by pressing the ⬇ key in the main screen (first screen).

Since the graphical display is only an indication, there may be some difference with the actual remaining volume depending on usages.

Procedure

1. If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also change the state to STAND-BY state by pressing the STOP key.
2. Replace the buffer or Hemolysis & Wash Solution.
3. Confirm that the end of the tube reaches the bottom of the pack.
   For buffers, be sure to securely fasten the cap to make a tight seal.
   Tightly seal the cap for the Hemolysis & Wash Solution as well. However, do not completely seal these packs with paraffin film or other seals. A complete seal may cause poor fluid pumping.

Fig.5-5 Elution Buffers Tube connection

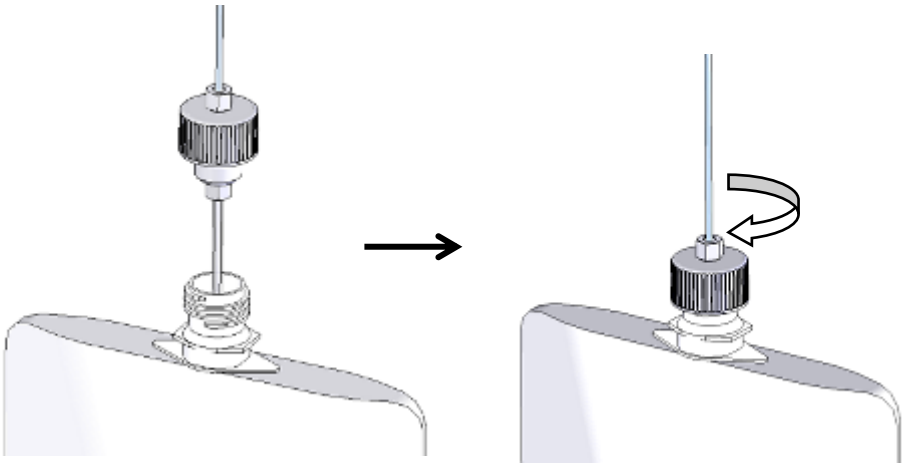
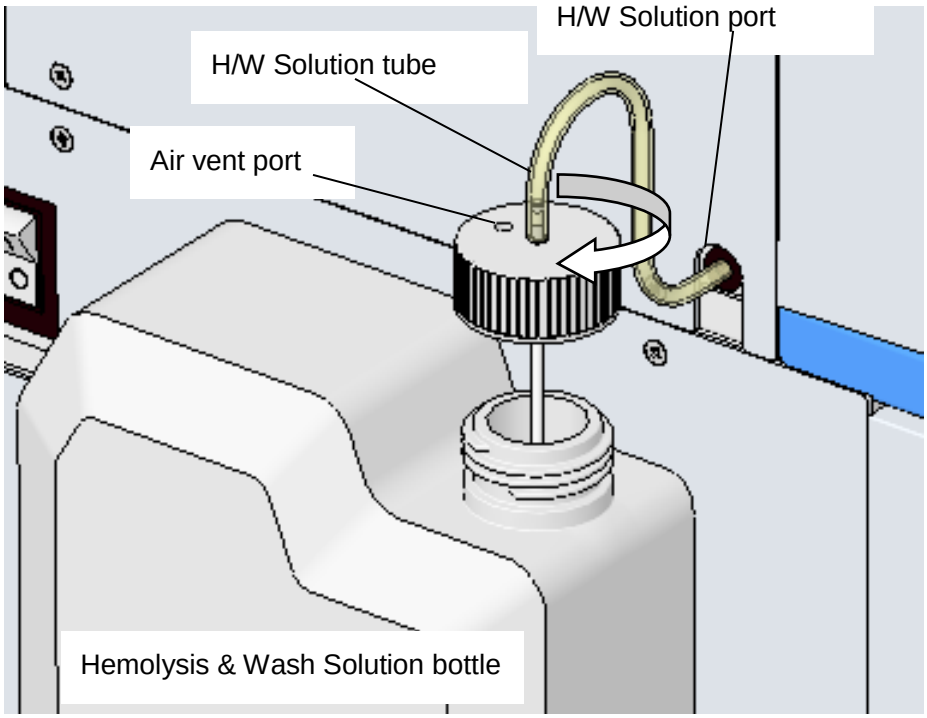
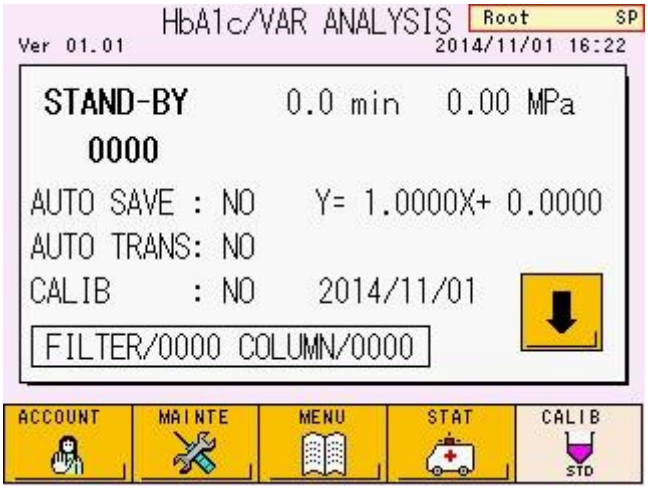


Fig. 5-6 Hemolysis & Wash Solution Tube Connection



4. Press the  key in the main screen.

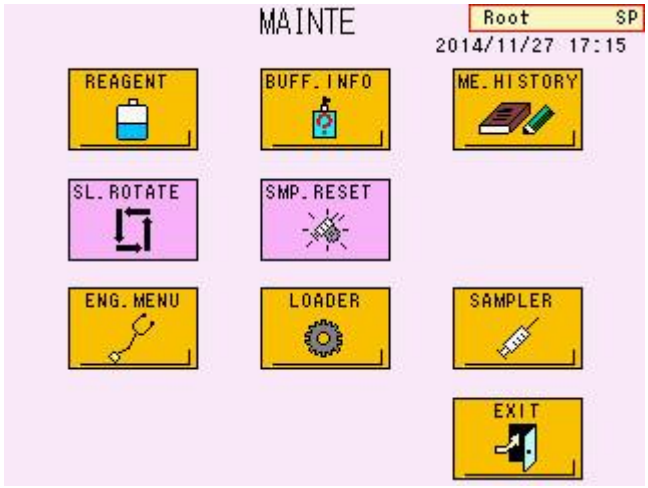
Screen 5-1 Main screen



5. Press the 

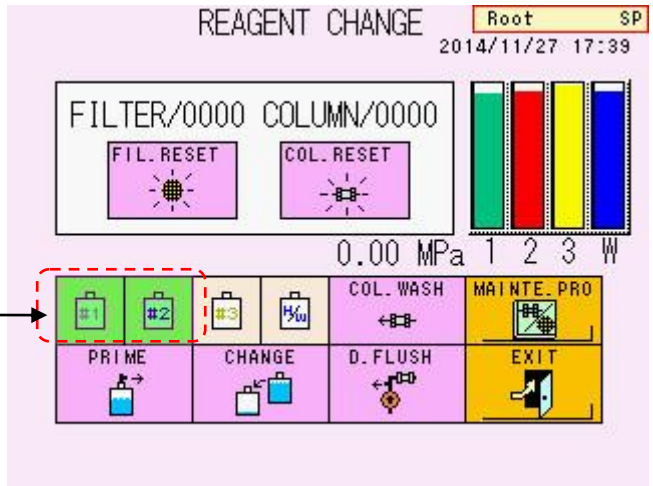
key in the MAINTE screen.

Screen 5-2 MAINTE screen



6. Select the keys of the reagents which you replaced. Pressed key will be displayed in green.

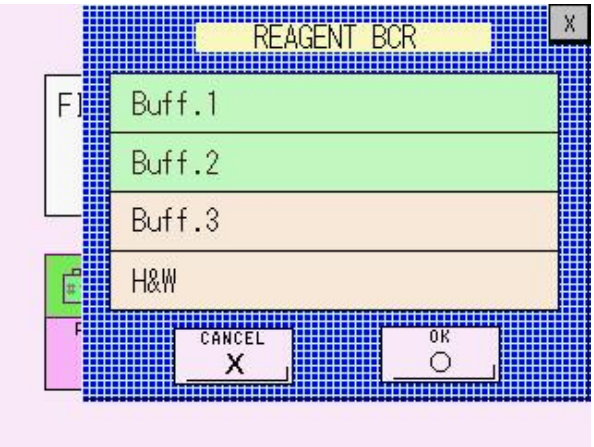
Screen 5-3 REAGENT CHANGE screen
(ex. Elution Buffer No.1 and 2 replacement)



Selected buffer keys are displayed in green.

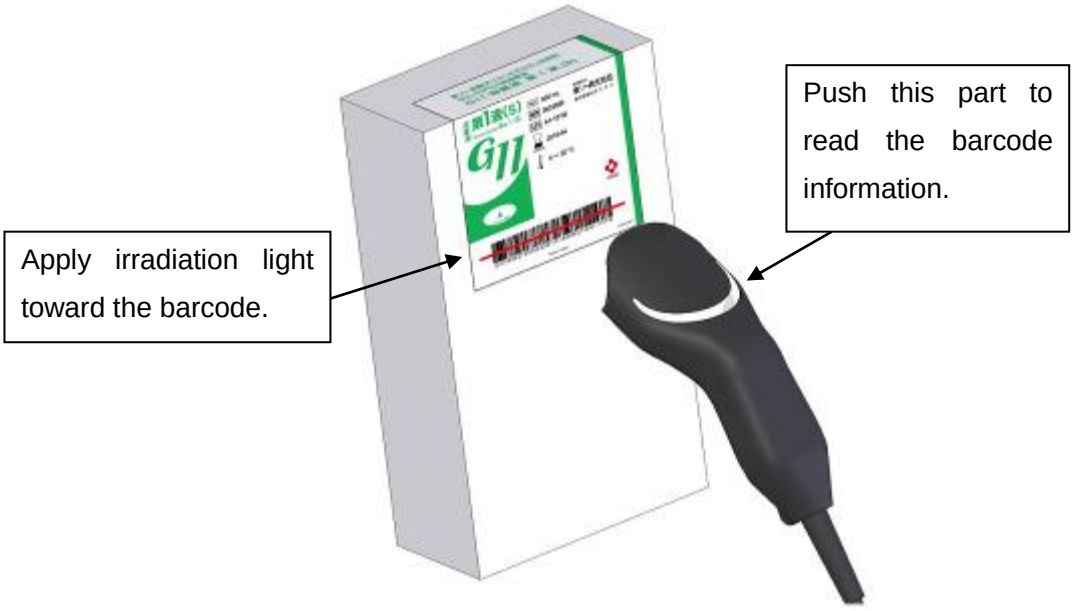
7. Press the CHANGE key. Screen 5-4 will be displayed.
   When you use an optional handheld barcode scanner, go to 8.
   With no barcode scanner, press the OK key and go to 11.

Screen 5-4 Reagent replacement screen-1



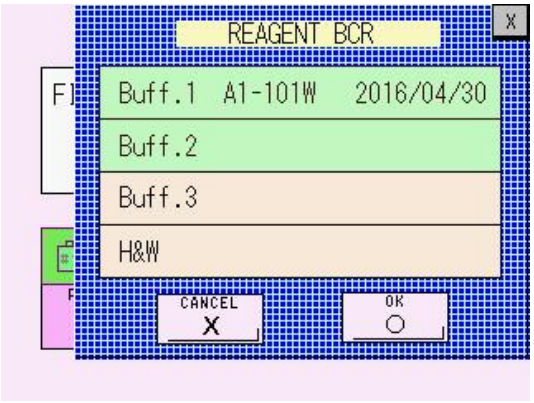
8. When Screen 5-4 displayed, read the barcode on the Elution Buffer box with a handheld barcode scanner

Fig. 5-7 Reagent information
read with a handheld barcode scanner (Elution Buffer No.1)



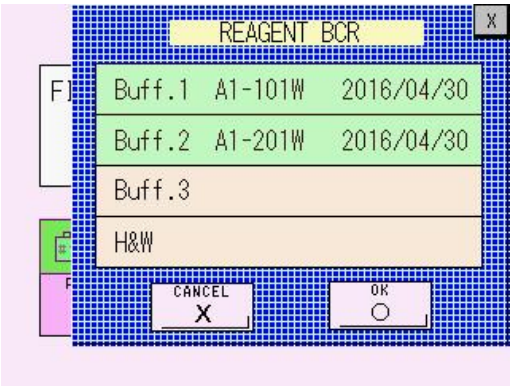
9. Confirm the barcode information on Screen 5-5 (ex. the lot number and expiration date of Elution Buffer No.1)

Screen 5-5 Reagent replacement screen-2



10. After inputting all reagents information you replace, press the [OK ○] key.

Screen 5-6 Reagent replacement screen-3



11. The reagents in the flow line of the analyzer will automatically be replaced with the new reagents.
12. Operations are complete when the "CHANGING..." message disappears. Confirm that the graph for the replaced reagent returns to 100 %.

    The remaining volumes of buffers displayed in a graph decrease slightly for changing.

Point

Approximately 5 mL of each eluent will be consumed when CHANGE is executed.

1. Only use reagents specified for the analyzer.
2. Never use reagents whose expiration date has passed.
3. Do not reuse remaining Elution Buffer or Hemolysis & Wash Solution or mix remaining reagent with a different or new one. Handle the remaining solutions as general waste fluid and dispose of them according to your facility's procedures. Elution Buffers and Hemolysis & Wash Solution contain sodium azide as a preservative. Dispose of the reagents using large volumes of water.
4. When using buffers in aluminum packs, tighten the cap until it is firmly shut. A loose cap could cause high concentrations and unreliable results. In addition, the remaining volume cannot be checked visually if the cap is loose.
5. The counter for the remaining volume of Hemolysis & Wash Solution is adjusted based on the packaging size when a service representative sets up the analyzer. When you want to change the size, use the cap fitting to the bottle and change "H/W BOTTLE TYPE" parameter setting.

5.5 Elution Buffer Priming

The analyzer automatically executes priming or purging with Elution Buffers when the power is turned on and when it has been in STAND-BY state for 70 minutes or more. It replaces the buffer in the flow lines.

However, if the analyzer has been shut down for a long period of time, air may have entered into the flow lines or the buffer concentration in the flow line may have increased. As a result, you may experience problems such as unstable pumping pressure, incorrect chromatograms (unidentified peak P00 may appear), and an abnormal assay value for the control.

If this happens, execute a manual priming of the buffers, and then execute the DRAIN FLUSH described in the next section. In addition, executing the COLUMN WASH will resolve the problem in most cases.

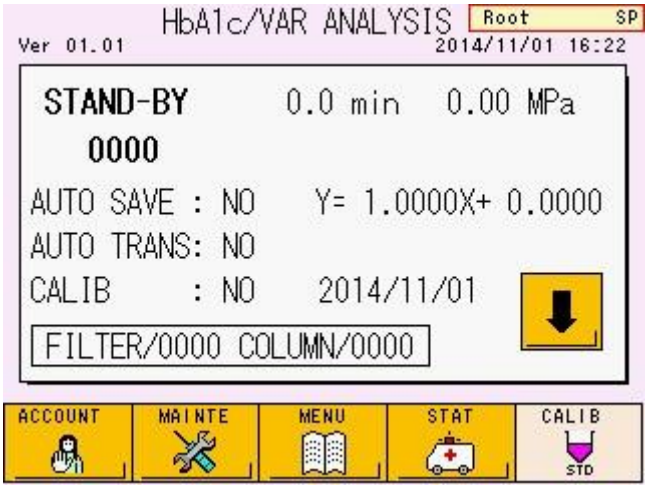
Perform manual priming using the following procedure.

Procedure

1. If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also press the STOP key to switch the analyzer into STAND-BY state.
2. On the main screen, press the 

key.

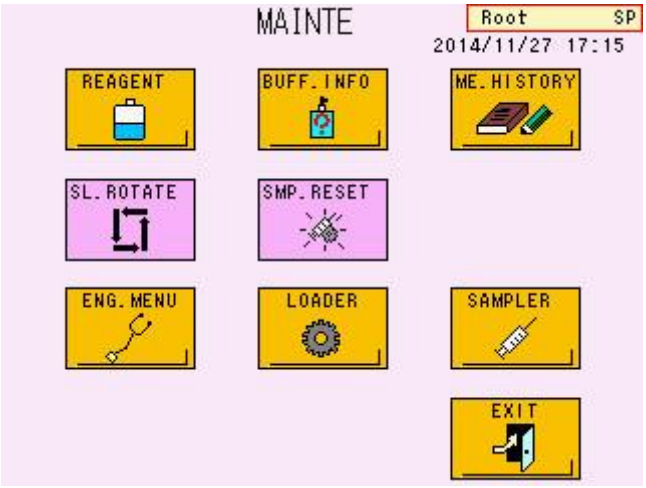
Screen 5-7 Main screen



3. On the MAINTE screen, press the 

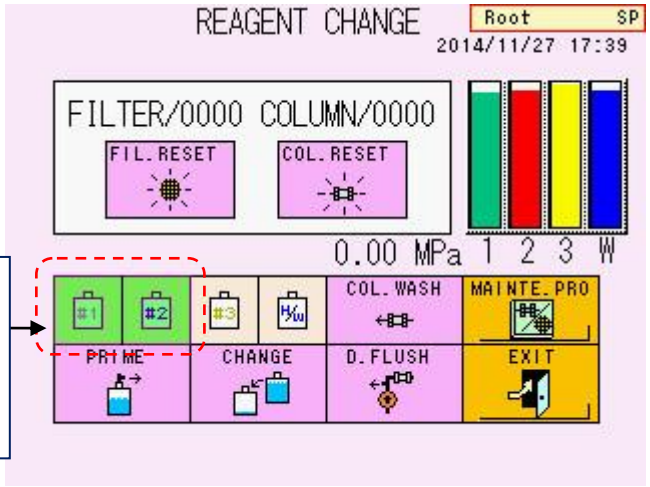
key.

Screen 5-8 MAINTE screen



4. Select the keys of the reagents which you want to prime. Pressed key will be displayed in green.

Screen 5-9 REAGENT CHANGE screen
(Example: Buffer No.1 and 2 priming)



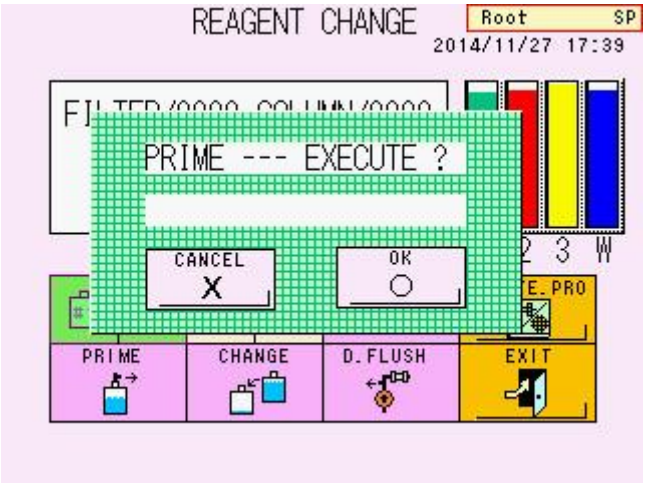
Selected buffer keys are displayed in green.

5. Press the 

key. A confirmation message (Screen5-10) will be displayed.
If everything is all right, press the 

key.

Screen 5-10 PRIME Message screen



6. The reagent in the flow lines of the analyzer will automatically be replaced.
7. The operation is complete when the "PRIMING..." display disappears.

Point

Approximately 5 mL of each eluent will be consumed when the PRIME is executed.

5.6 Pump Air Removal

If the pressure will not rise or stabilize even though the pump works and sufficient buffer is delivered, air may be trapped in the liquid end of the pump.
When this occurs, use the following procedure to remove the air from the pump.

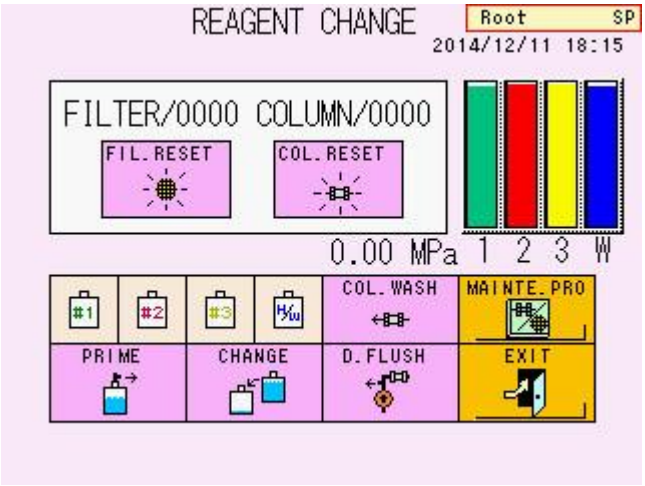
Procedure

1. If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also change the state to STAND-BY state by pressing the STOP key.
2. On the MAINTE screen, press the 

key.
3. Press the 

key.

Screen 5-11 REAGENT CHANGE screen



4. The following message will be displayed requesting that the drain valve be opened (Screen 5-12). Open the door on the left side of the analyzer and turn the drain valve 90 degrees in the counterclockwise direction to open the valve. Be careful not to turn the valve more than 90 degrees.

Screen 5-12 OPEN DRAIN VALVE message

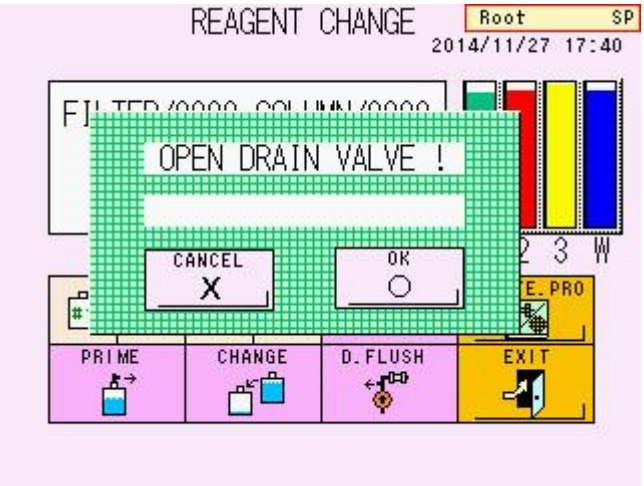
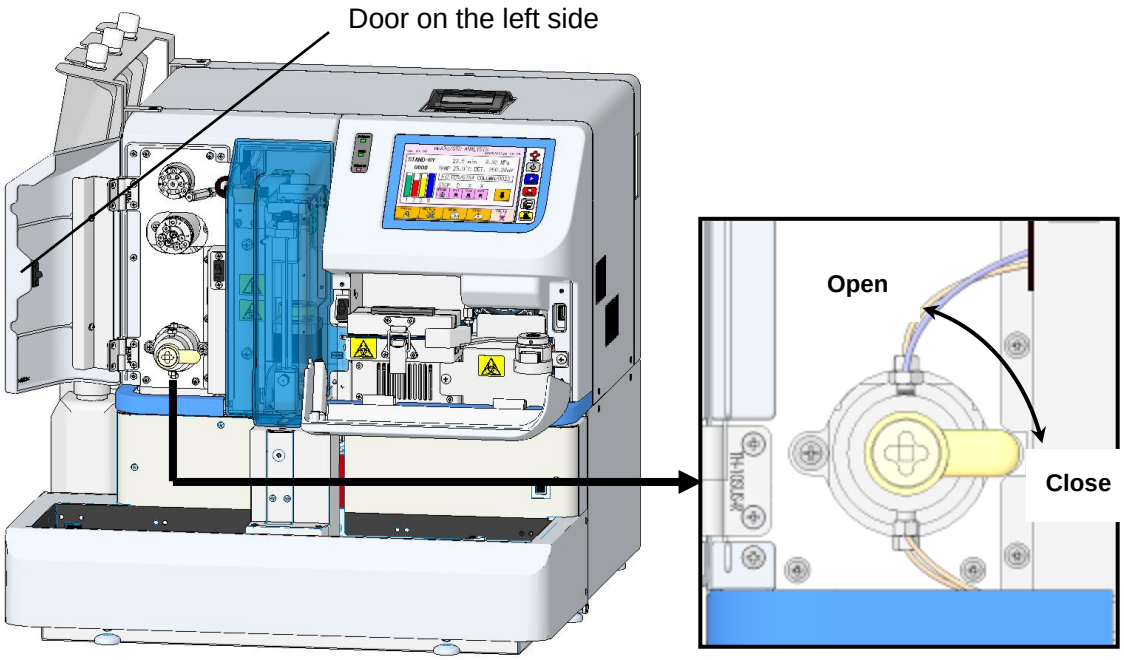
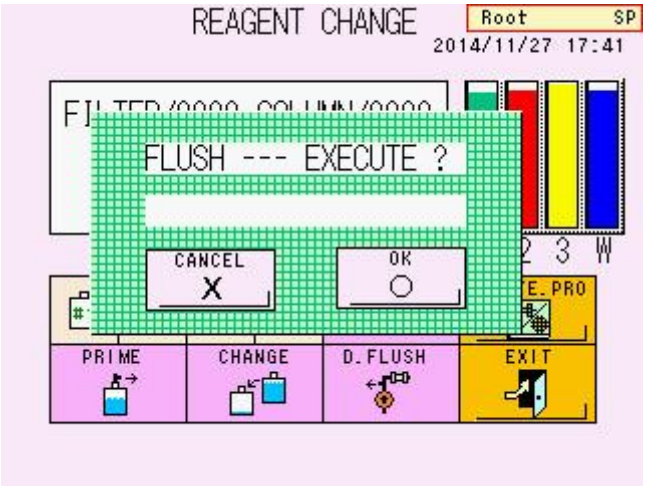


Fig. 5-8 Drain Valve



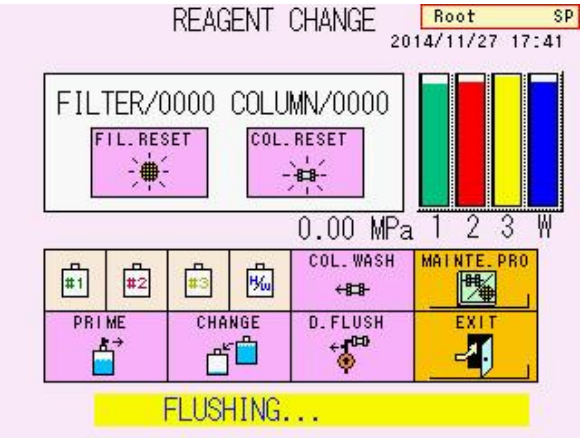
5. Press the [OK ○] key.
6. The confirmation message will be displayed (Screen 5-13). If everything is all right, press the [OK ○] key.

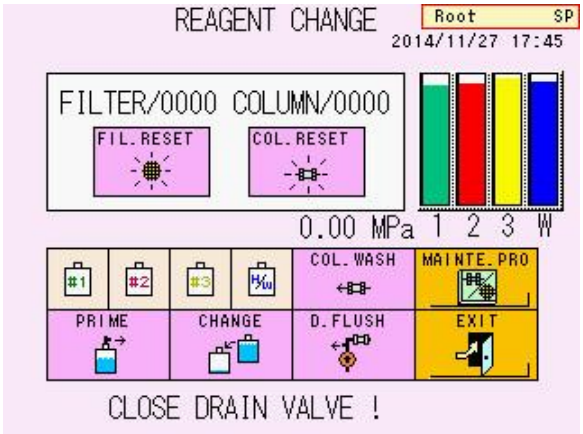
Screen 5-13 FLUSH message screen

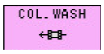


7. Since air trapped in the pump will be automatically removed, wait until the "FLUSHING..." message disappears.
8. A message will be displayed requesting that the drain valve be closed. Turn the valve back 90 degrees in the clockwise direction to securely close it.

Screen 5-14 Screens during flushing (left) and after flushing (right)





9. Press the 

on the REAGENT CHANGE screen to execute the "COLUMN WASH" (Refer to "**5.7 Column Wash**").
10. If the pressure was stabilized within a range less than the pressure (which is indicated on the column inspection report) +4 MPa, air removal is completed.
11. If the pressure does not rise or is unstable, stop the pump and follow the air removal procedure again.

Point

Approximately 15 mL of Elution Buffer No.1 and 5mL of No.2, No.3 will be consumed when DRAIN FLUSH is executed.

During the above procedure, always open the drain valve in accordance with the instructions on the screen message. If the valve is not opened,"DRAIN FLUSH ERROR" occurs and will stop the air flushing. Open the drain valve and follow the air removal procedure again.

5.7 Column Wash

When an emergency stop is executed during analysis, the sample currently under assay will remain in the column. This can shorten the column life. Make sure to execute the COLUMN WASH operation.

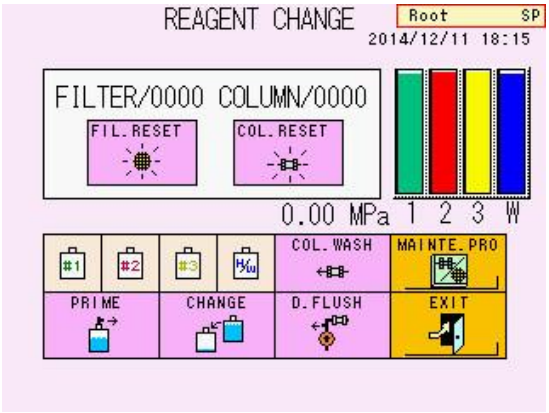
Procedure

1. After an emergency stop is executed, wait for the assay to end and STAND-BY to be displayed.
2. On the MAINTE screen, press the REAGENT key to open the REAGENT CHANGE screen.
3. Press the COL. WASH key.
4. A confirmation message (Screen5-16) is displayed. Press the OK key.
5. The analyzer automatically starts to flow reagents and wash the column (In order of Elution Buffer No.3: 30 seconds, No.2: 30 seconds, and No.1: 30 seconds).

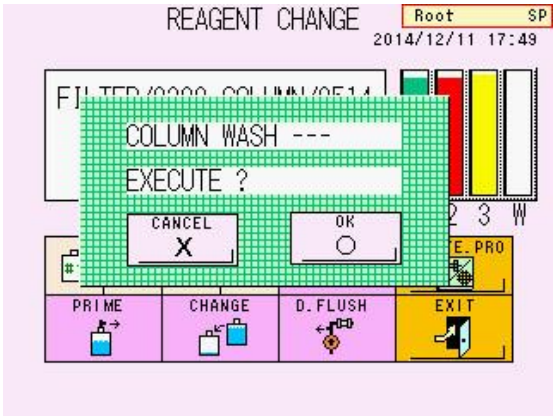
Point

Approximately 1.1 mL of each eluent will be consumed when the COLUMN WASH is executed.

Screen 5-15 REAGENT CHANGE screen



Screen 5-16 COLUMN WASH message screen



5.8 Filter Replacement

Replace the filter element in the following cases.

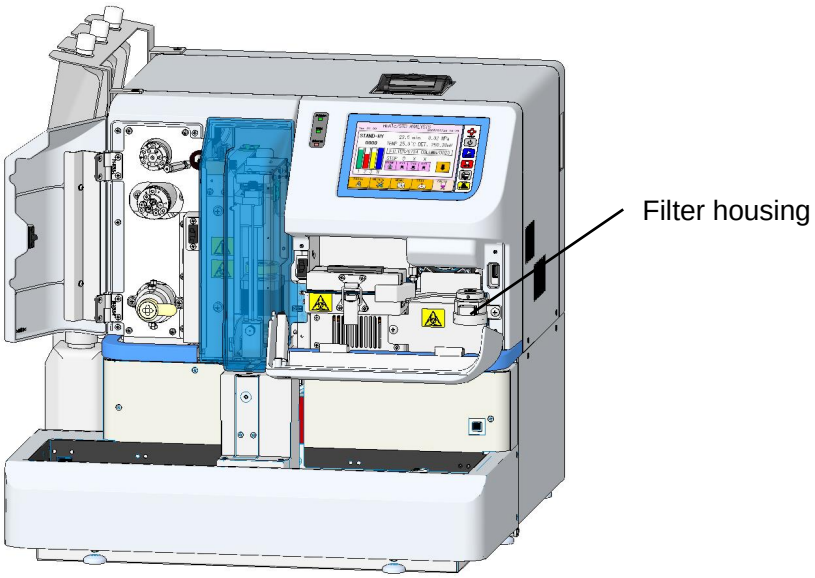
1. When the filter counter reaches 600 injections.
2. When the pressure is more than the pressure (which is indicated on the column inspection report) +4 MPa.

Caution **The filter has been in contact with blood samples. Wear protective clothing (goggles, gloves, masks, etc.) and take sufficient care to prevent infection during replacement and handling.**

Procedure

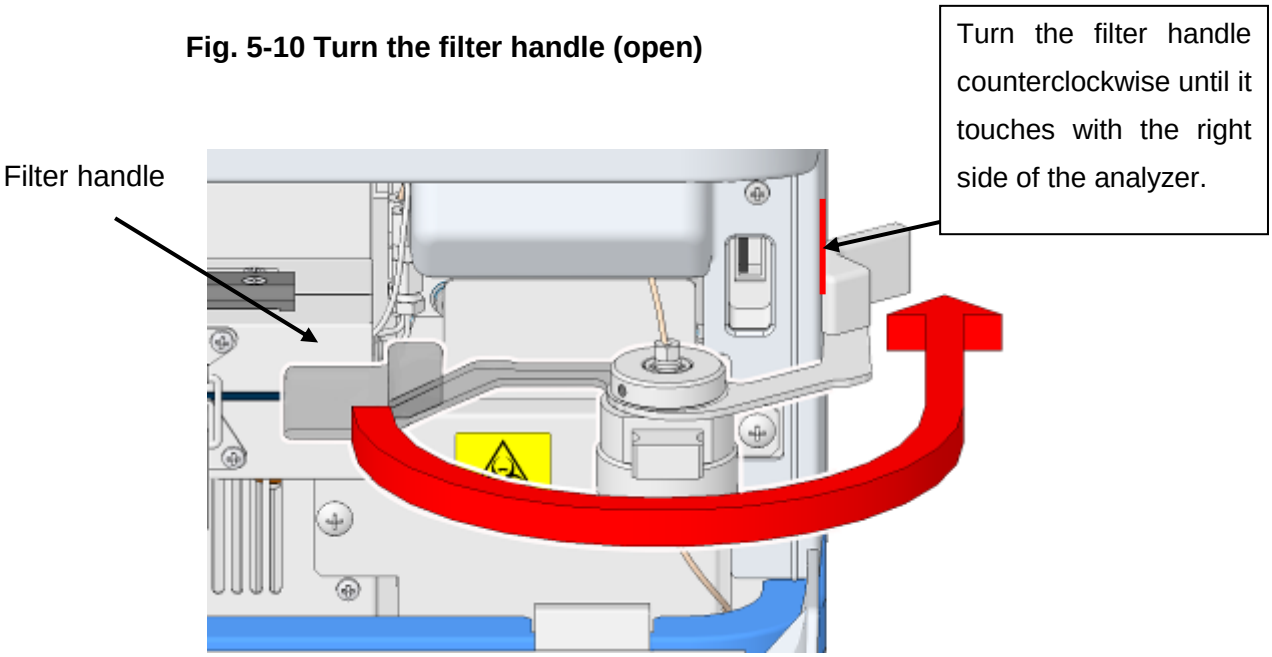
1. If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also change the state to STAND-BY state by pressing the STOP key.
2. Open the door below the display.

Fig. 5-9 Front View



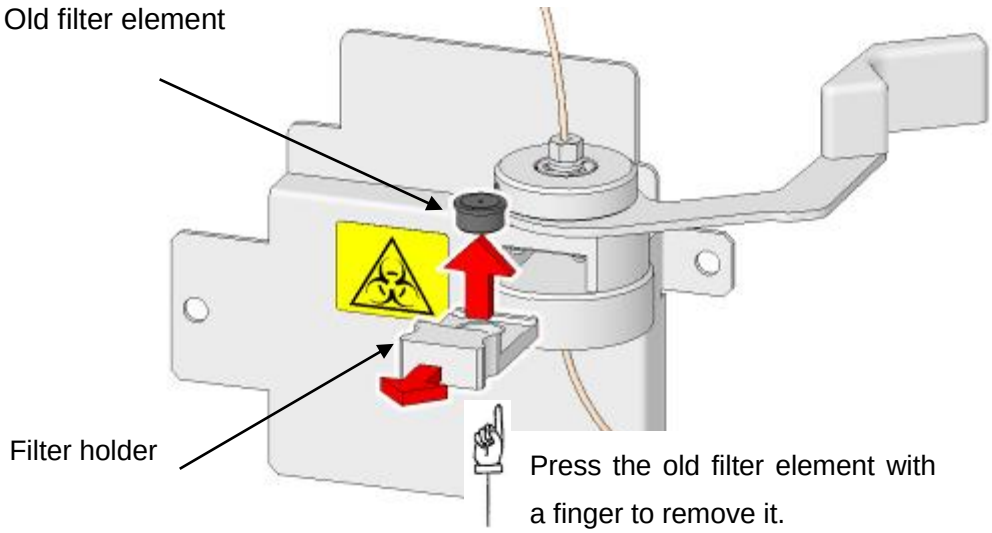
3. Turn the filter handle counterclockwise until it touches with the right side of the analyzer.

Fig. 5-10 Turn the filter handle (open)



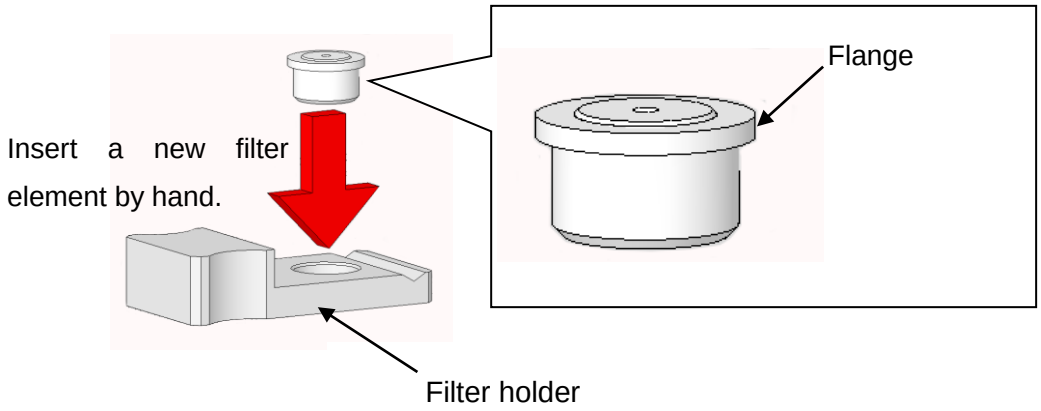
4. Pull out the filter holder to take out the old filter element.

Fig. 5-11 Remove the filter element



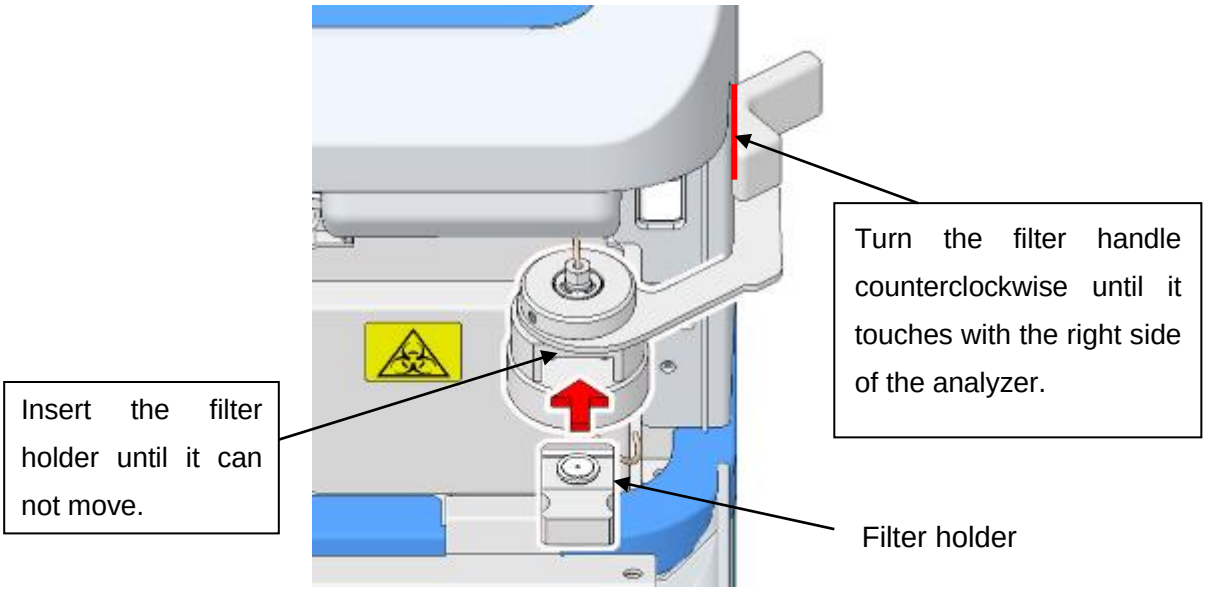
5. Insert the new filter element to the filter holder.

Fig. 5-12 Place a new filter element



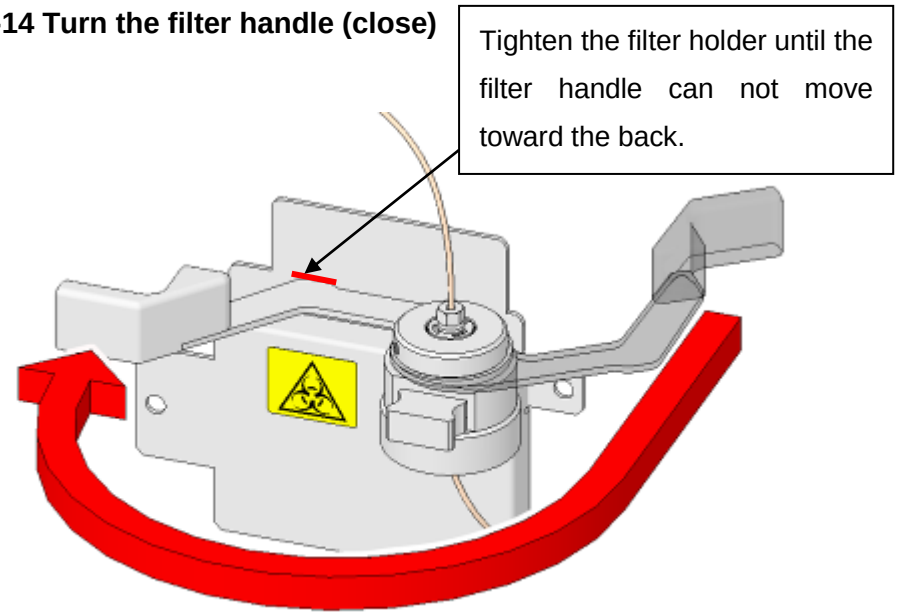
6. After checking the filter handle touches the right side of the analyzer, insert the filter holder to the filter housing until the filter holder can not move.

Fig. 5-13 Insert the filter holder



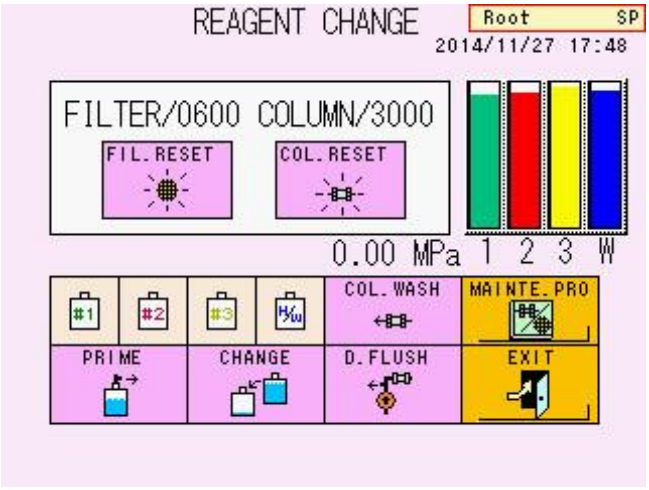
7. Turn the filter handle clockwise to the first place. Make sure to tighten the filter holder until the filter handle can not move toward the back.

Fig. 5-14 Turn the filter handle (close)

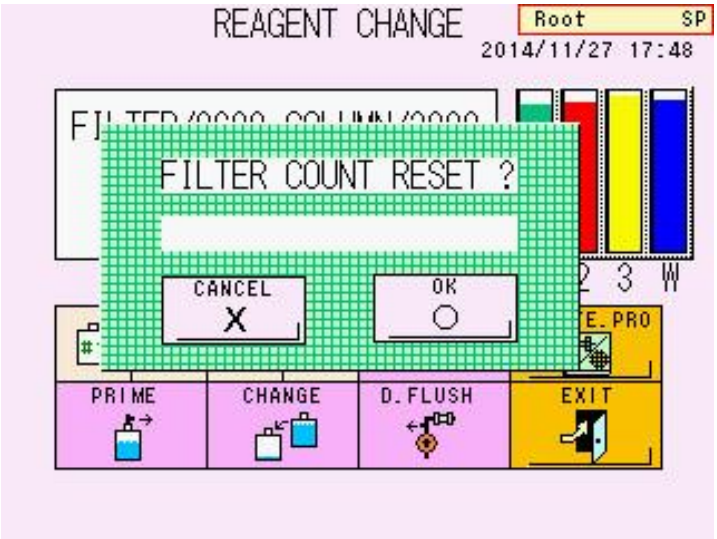


8. Press the COL. WASH key to execute the COLUMN WASH (Refer to "**5.7 Column Wash")**.
9. Check that the pressure falls within a range less than the pressure (which is indicated on the column inspection report) +4 MPa.
10. After installing a new filter, reset (zero) the filter counter.
    Press the FIL. RESET key on the REAGENT CHANGE screen.

Screen 5-17 REAGENT CHANGE screen



Screen 5-18 FILTER COUNT RESET message screen



11. The confirmation message (Screen5-18) is displayed.
    Press the [OK ○] key.

Caution

The used filter has been in contact with blood samples. Therefore, wear protective clothing (goggles, gloves, masks, etc.) and take sufficient care to prevent infection during filter replacement and handling. In addition, dispose of the used filter as infectious waste according to the procedures in your facility.

As a filter is tightened once, it becomes deformed, never use it again.

5.9 Column Replacement

We recommend column replacement on a regular basis.
Replace the column in the following cases.

1) When the pressure is more than the pressure (which is indicated on the column inspection report) +4 MPa and the pressure is not reduced by filter replacement.
2) When peaks on the chromatogram (particularly the s-A1c peak, shaded) have become broad or broken into two fractions (Caution: If this phenomenon is observed only with a specific sample, column deterioration may not be the cause. Other factors, such as a hemoglobin variant, could be the cause.)
3) When assay results for quality control samples are consistently out of the assigned ranges even after re-calibration.
4) When the CALIB ERROR persistently occurs.
5) The expiration date printed on the label has passed.

Please contact Tosoh local representatives if the above troubles are not resolved after column replacement.

Caution

The column has been in contact with blood samples. Wear protective clothing (glasses, gloves, masks, etc.) and take sufficient care to prevent infection during replacement and handling.

Procedure

1. If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also change the state to STAND-BY state by pressing the STOP key.
2. Open the door below the display, remove the latch, and open the column oven.
3. Next, remove the old column.

Fig. 5-15 Front View

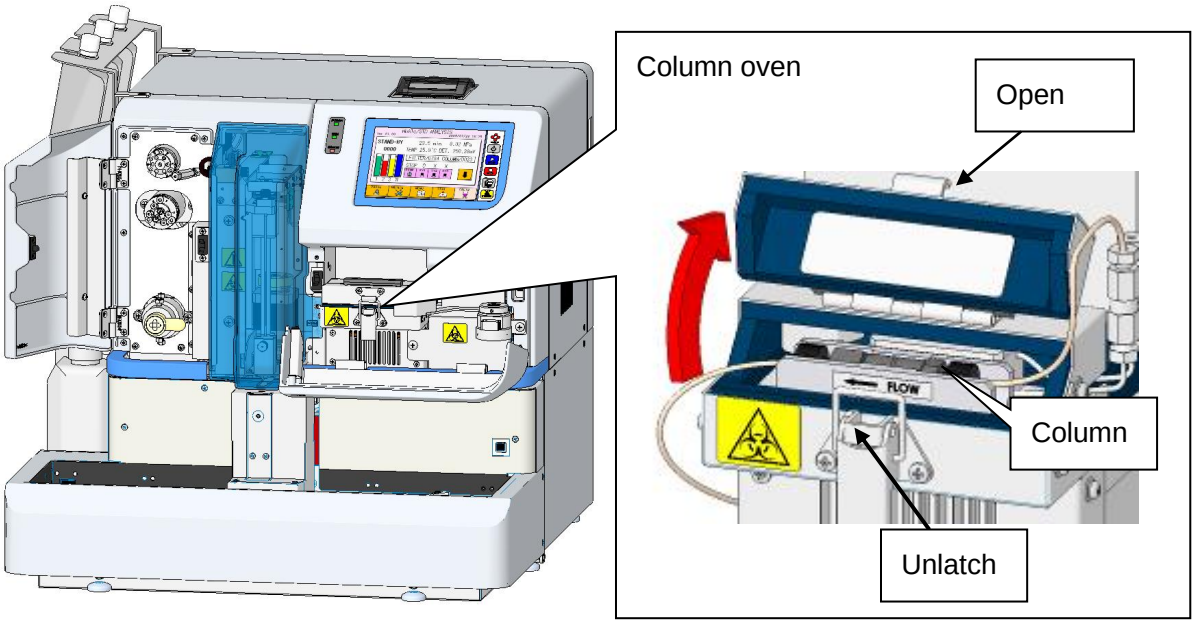
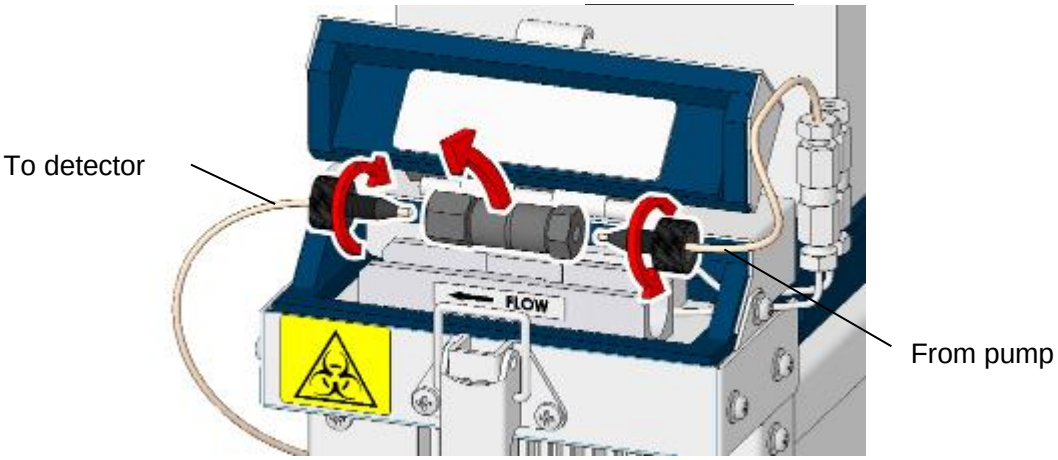
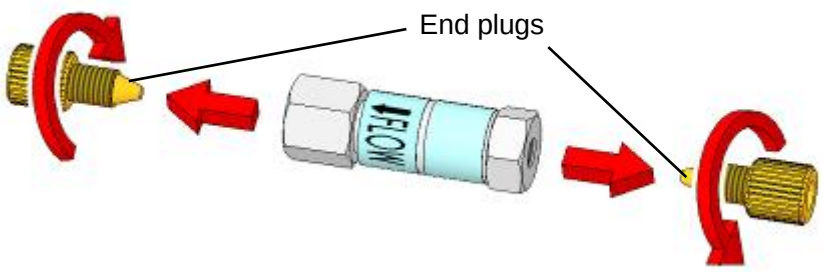


Fig. 5-16 Remove the old column



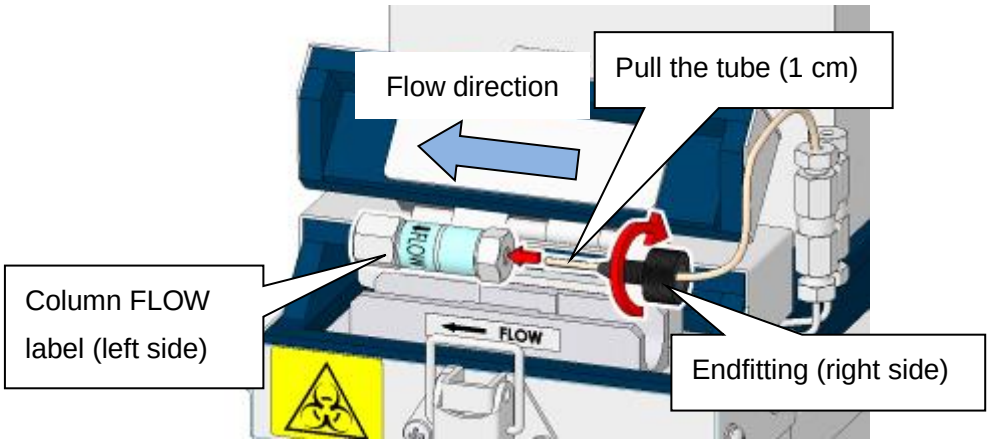
4. Remove the end plugs of a new column. Retain the end plugs because they are necessary for long-term storage of the column.

Fig. 5-17 Remove end plugs of a new column



5. Connect the new column to the pump (inlet) side only, taking care of the flow direction shown by the arrow on the label. Before connecting, pull the inlet tube (approximately 1 cm) from the end of the endfitting.

Fig. 5-18 Connecting a new column (right side)

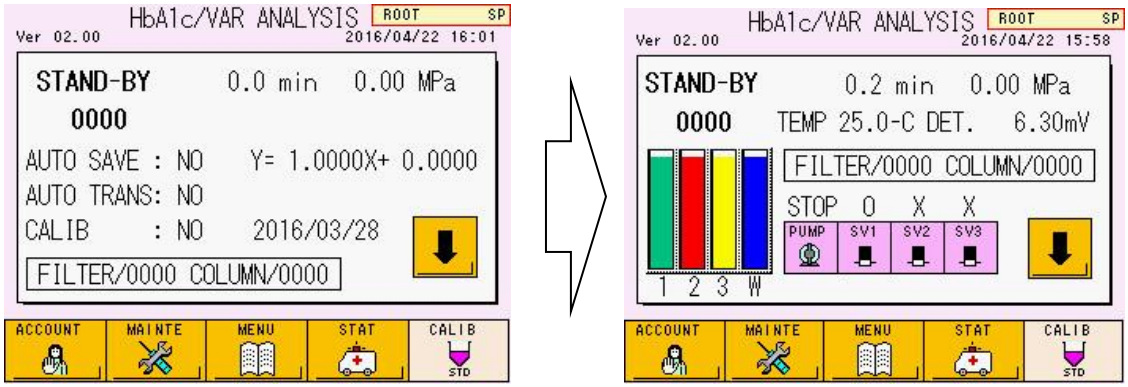


Point **Measurements will not be accurate if there is a gap between the tip of the tube and the column.**

6. Hold a lab wipe or another wipe to the left side of the column to prevent the solution from touching the analyzer.

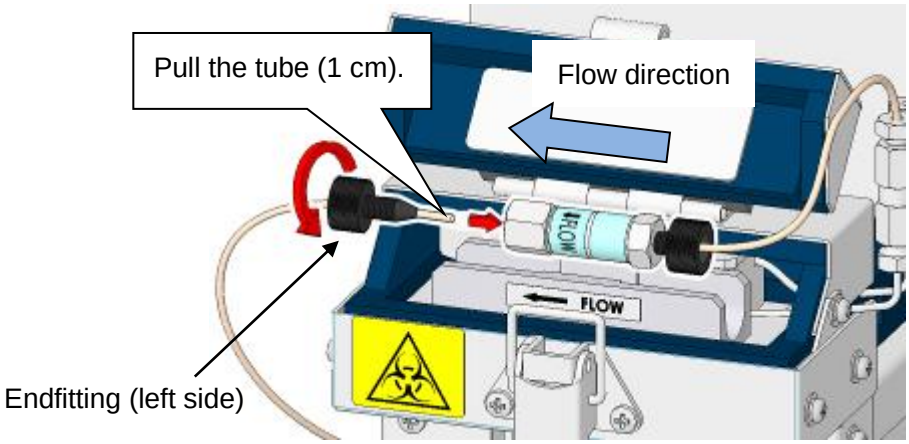
7. Open the main screen (second screen).

Screen 5-19 Main screen (left: first screen, right: second screen)



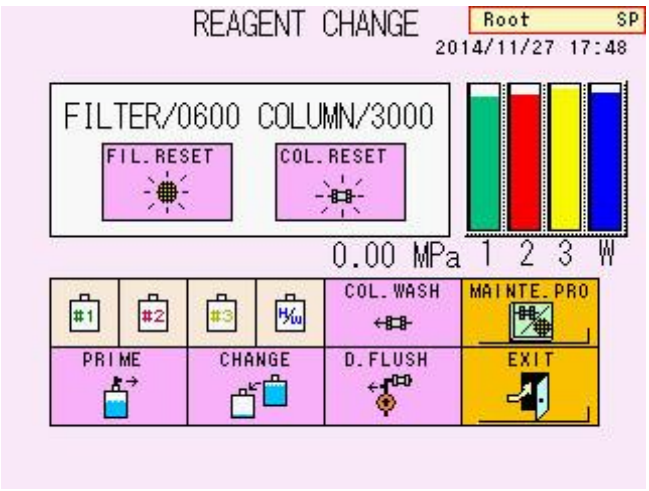
8. Confirm that the SV1 key is open (O) on the main screen and press the PUMP key to start the pump.
9. When buffer comes out of the open end of the column, press the PUMP key to stop the flow.
10. Connect the column outlet to the detector side (left side).

Fig. 5-19 Connecting a new column (left side)



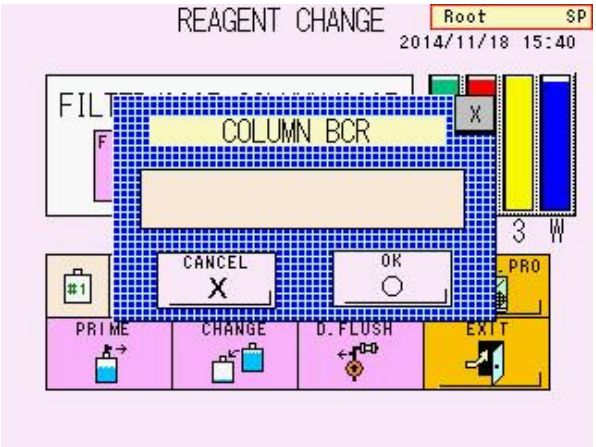
11. Press the MAINTE key on the main screen. Press the REAGENT key on the MAINTE screen to open the REAGENT CHANGE screen. Select the COL. WASH key to execute the "COLUMN WASH" (See "**5.7 Column Wash**")
12. Make sure that the pressure falls within a range less than the pressure (which is indicated on the column inspection report) +4 MPa and that there are no leaks from the column connections
13. Place the column in the aluminum block, close the column oven cover, and lock the latch.
14. After replacing the column, reset (zero) the column counter in the REAGENT CHANGE screen by pressing the COL. RESET key.

Screen 5-20 REAGENT CHANGE screen



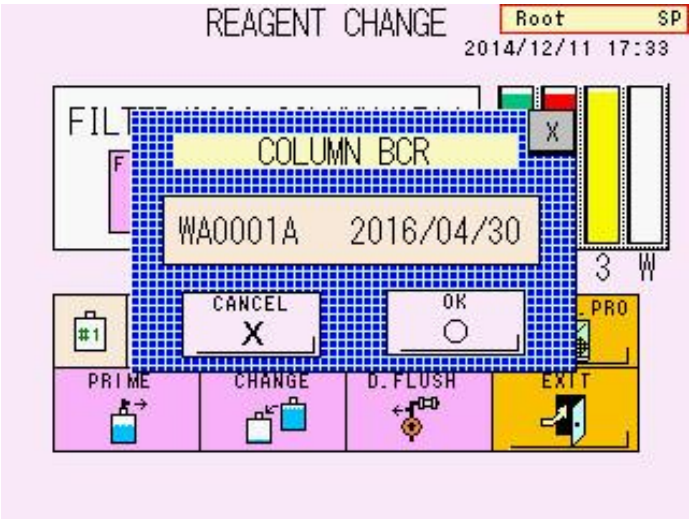
15. Screen 5-21 will be displayed.
    When you use an optional handheld barcode scanner, go to 16.
    With no barcode scanner, press the OK key to finish replacing and go to 18.

Screen 5-21 Column count reset message screen - 1



16. When screen 5-21 displayed, read the barcode on the column box with a handheld barcode scanner.
17. Confirm the column information on the screen (ex. Screen 5-22) and press the OK key.
18. Before calibrating the newly installed column, run at least three whole blood samples to prime the column. Calibrate the system and run controls.

Screen 5-22 Column count reset message screen - 2



Caution **The used column has been in contact with blood samples. Therefore, wear protective clothing (glasses, gloves, masks, etc.) when handling. Dispose of the column as infectious waste in accordance with your facility's waste disposal procedures.**

1. Be sure not to use any other column than the column for the HLC-723G11.
2. Securely insert the inlet tube to the end with no space at the connections.
3. Return the new column to a room temperature prior to replacing.

5.10 Suction Filter Replacement

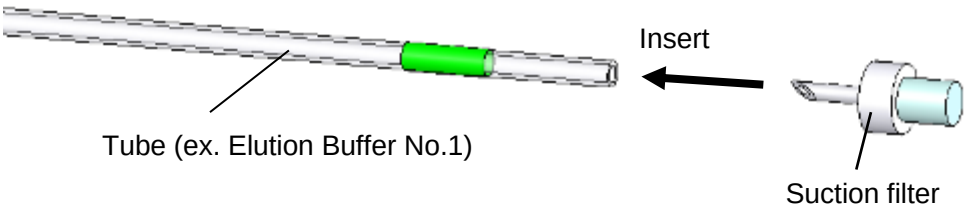
To remove foreign particles, the suction filter is attached to the inlet end of the Elution Buffer tube inserted in the Elution Buffer pack or bottle. If the suction filter is clogged, the pump will not operate normally and reliable results may not be obtained. Make sure to periodically replace the filter. Replace all three filters at the same time.

Foreign particles inside the filter can not be removed by cleaning. Replace the used filter with a new one.

Procedure

1. If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also change the state to STAND-BY state by pressing the STOP key.
2. Loosen the bottle caps for elution buffers.
3. Pull out the Elution Buffer tube and remove the old suction filters.
4. Securely attach the new suction filters, re-insert the tube into the pack, and close the caps.

Fig. 5-20 Suction Filter Attachment



5. After all three filters have been replaced, execute PRIME for Elution Buffer No. 1, 2, and 3 on the REAGENT CHANGE screen.
   Refer to "**5.5 Elution Buffer Priming"** for details about the PRIME operation.

Used suction filters can be disposed as general nonflammable waste according to the procedures at your facility.

5.11 Sampling Needle Replacement

Replace the sampling needle if it is bent or broken. Use the following procedure to replace the sampling needle.

Caution

Access to the inside of the analyzer is needed to replace the sampling needle. Be sure that only personnel who have been trained by Tosoh local representatives perform these operations. Be sure to wear protective clothing (goggles, gloves, masks, etc.) and take sufficient care to prevent infection during handling. Take care not to touch the end of the sampling needle during handling.

Procedure

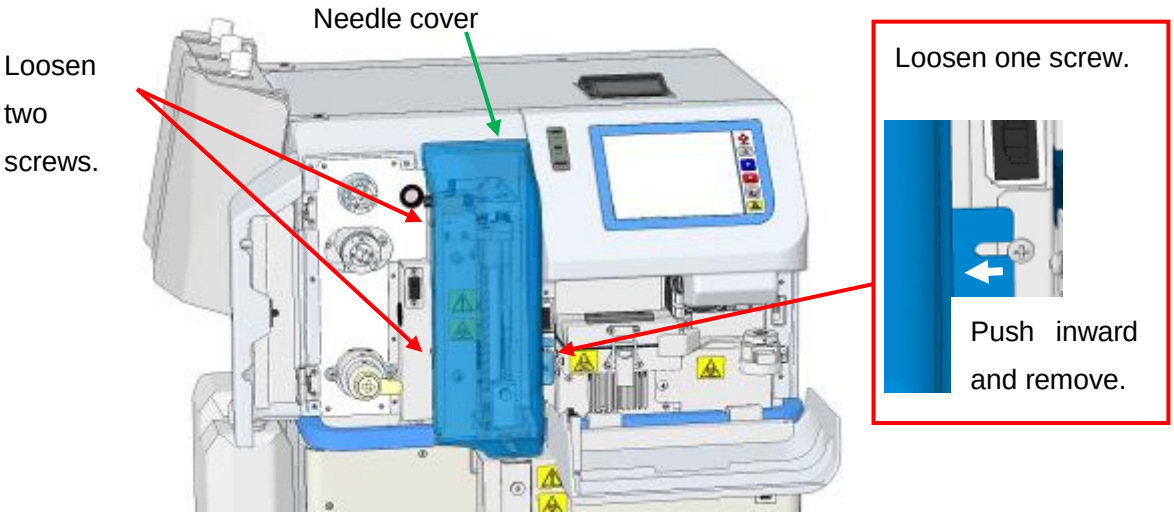
1. Turn the POWER key and main power switch off to stop the analyzer operations during needle replacement. The sampling needle unit cannot be drawn unless the POWER key is off.

Caution

The needle may be broken or cause injury if it's forcibly moved.

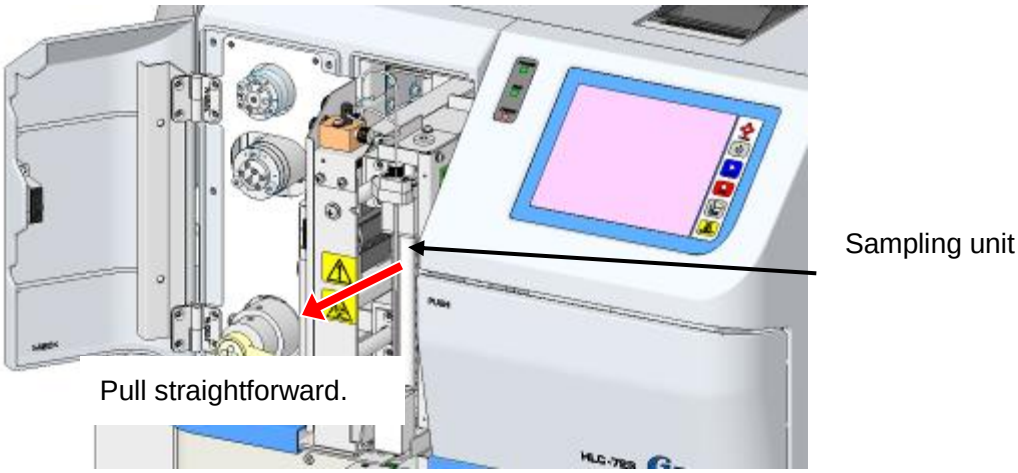
2. Open the left-side door and loosen two needle cover screws indicated in Fig. 5-21. You do not need to remove the screws.
3. Open the door below the display and loosen one needle cover screws indicated in Fig. 5-21.
4. Grasp the needle cover, push it inward while taking care not to break it, and remove it from the needle cover screw indicated in 3.

Fig. 5-21 Remove the needle cover



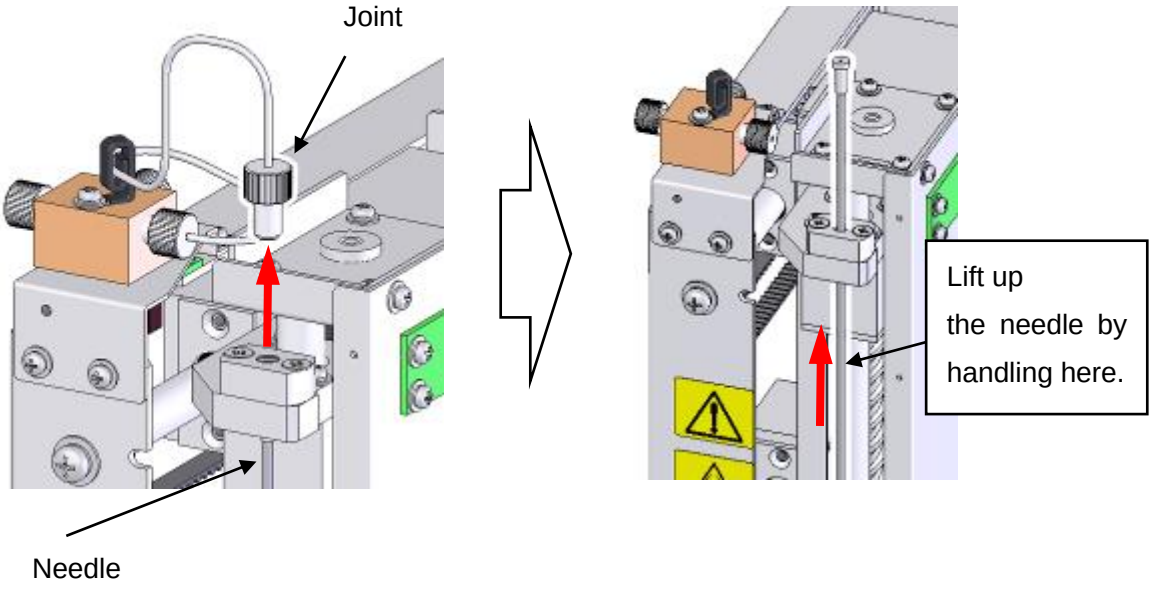
5. Check that the cover has been removed from the screws and remove the cover by pulling it straightforward.
6. You will see the sampling unit back in the middle. Grasp the upper part of the sampling needle unit by hand and slowly pull the unit forward as much as possible.

Fig. 5-22 Pull the sampling unit



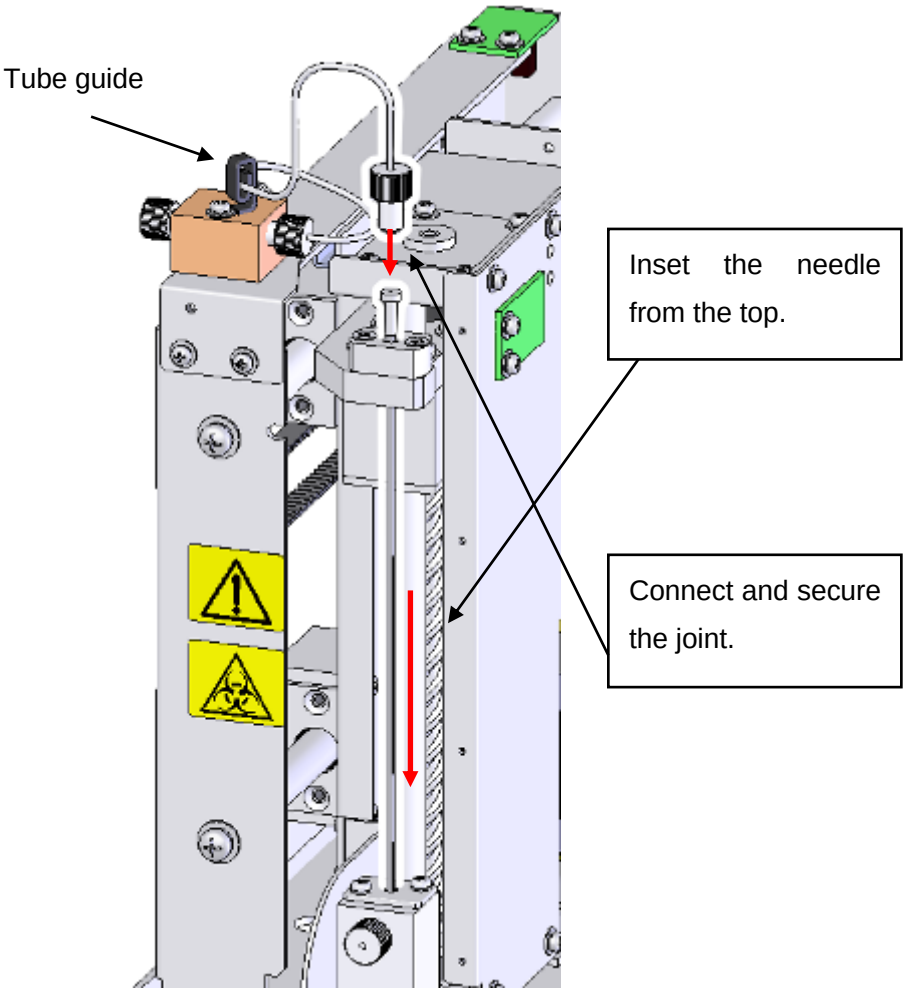
7. Since a small volume of reagent will spill during replacement, place a lab wipe under the sampling needle tip.
8. By hand, loosen and remove the joint on the upper section of the sampling needle.
9. Slowly lift up the sampling needle to remove.

Fig. 5-23 Remove the sampling needle



10. Insert the new sampling needle and connect the joint tightly.

Fig. 5-24 Sampling needle replacement



11. Move the sampling unit back and forth and confirm that the flow line does not catch on anything. If necessary, loosen the joint, turn the sampling needle, and change the stay direction to prevent the flow line from catching on anything.
12. Push the sampling unit back, close the sampling unit cover by following the procedure in reverse, and secure the screws.

13. Check that USB stick is not in the socket, turn on the main power.
14. Press the POWER key and wait for STAND-BY state to be displayed.
15. Assay a control or a dummy sample to confirm that the sample suction is processed correctly (check that the Total Area in the result is about the same as before the sampling needle was replaced).

If the needle becomes bent immediately after replacement, check that the primary tubes match the sample rack or sample rack adapter.
If the needle placement is clearly off center of the primary tube, it must be adjusted. Cancel the assay and contact Tosoh local representatives.

Caution **Dispose the used sampling needle as infectious waste according to the procedures at your facility.**

Chapter 6

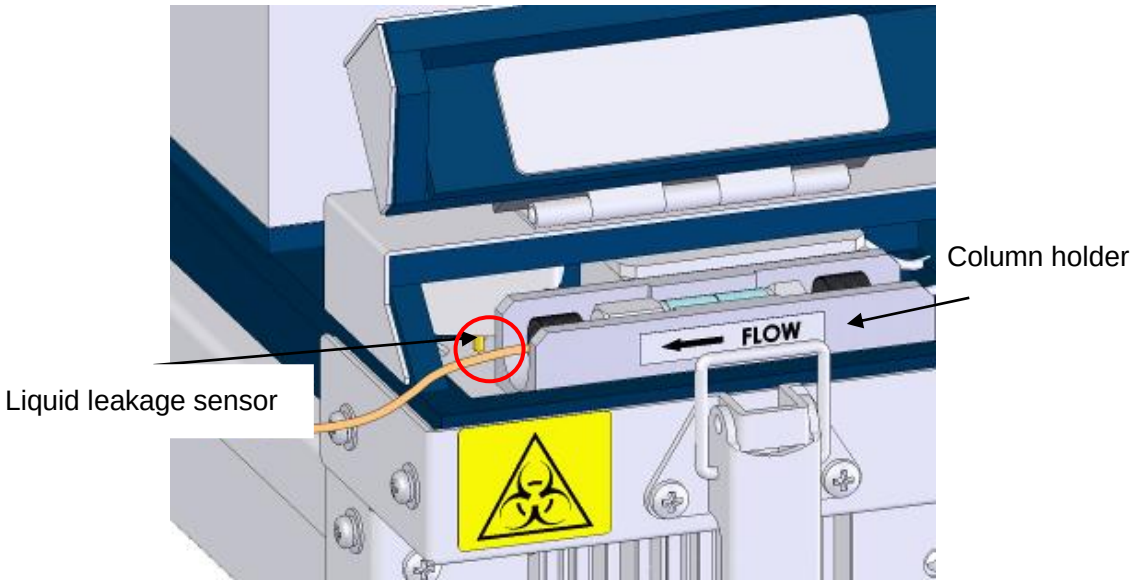
Troubleshooting

6 Troubleshooting

6.1 Assay Precautions

- **Liquid leakage**
  - If you discover liquid leakage, immediately switch OFF the analyzer and unplug the power cable.
  - Sometimes, leaking waste liquid contains blood. In order to prevent infection, wear appropriate protective gear (goggles, gloves, masks, etc.), and then wipe the liquid away.
  - Check the line filter handle. If there is liquid leakage, push the handle to the back completely.
  - If liquid is leaking from the connection between the tube and the column, the leaking sensor detects liquid leakage and "COLUMN LEAK ERROR" will occur to stop the assay. Remove the column, wipe liquid around the column holder and sensor, and connect the column again.

Fig. 6- 1 Liquid leakage sensor in the column holder



  - If liquid is leaking from the bottom of the analyzer, if you cannot find the source of leakage, or if you cannot stop leakage, contact Tosoh local representatives.

- **Column**
  - Be sure to read the Instructions For Use enclosed in the column box, as well as this manual.
  - Be sure not to use any other column than the column for the HLC-723G11.
  - Use the column before the expiration date indicated on the label.
  - Store columns with the end plugs in place, in a refrigerator when not in use.
  - Please handle the column with care. Do not drop or give a shock to the column.
  - Alphabetical lot ID, such as A and B, are shown on the box label of the column. Be sure to match this lot ID with the lot ID for the Elution Buffers.
  - Do not use tools to disassemble a column.

- **Elution Buffers**
  - Be sure to read the Instructions For Use enclosed in the Elution Buffer box, as well as this manual.
  - Be sure not to use any other buffer than the buffer for the HLC-723G11.
  - Use the Elution Buffers before the expiration date indicated on the label.
  - Use the Elution Buffers within 90 days after opening.
  - Be sure to match the lot ID for the Elution Buffers with that for the column.
  - Do not refill the Elution Buffer.

- **Hemolysis & Wash Solution**
  - Be sure to read the Instructions For Use enclosed in the Hemolysis & Wash Solution box, as well as this manual.
  - Be sure to use the Hemolysis & Wash solution designated for the HLC-723 Series by TOSOH.
  - Use the Hemolysis & Wash Solution before the expiration date indicated on the label.
  - Use the Hemolysis & Wash Solution within 90 days after opening.

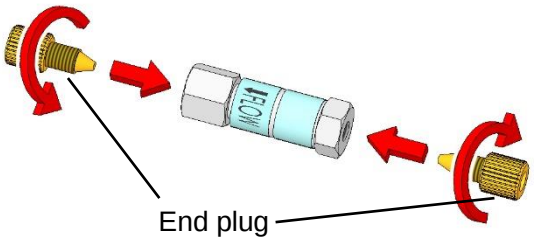
- Do not refill the Hemolysis & Wash Solution.
- There are no differences between lot IDs for the Hemolysis & Wash Solution.

- **Long-term shutdown**
  - If the analyzer is to be shut off for one week or more, remove and store the column, following the procedure below.

Procedure

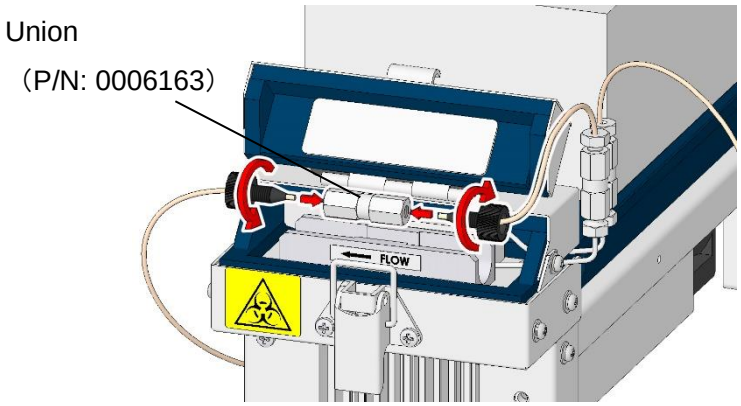
1. Remove the column following the procedure set out in "**5.9 Column Replacement**".
   Install the end plugs on the column, and then store the column in a cool place such as a refrigerator.

Fig. 6- 2 How to store the column



2. Connect the union provided in place of the column.

Fig. 6- 3 Connecting the union

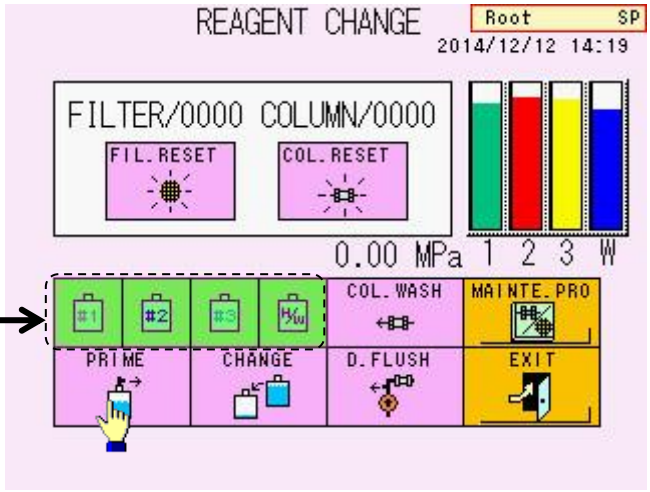


3. Remove all suction tubes from the Elution Buffers and Hemolysis & Wash solution and put them in a bottle containing purified water. Seal

the cap for the Elution Buffers and Hemolysis & Wash solution before the storage.

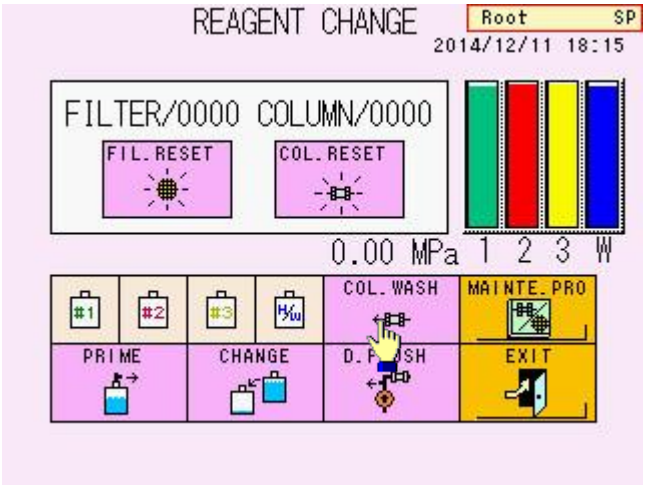
4. Prime all liquids on the REAGENT CHANGE screen following "**5.5 Elution Buffer Priming**".

Screen 6- 1 REAGENT CHANGE screen (PRIME)



5. Perform COL.WASH on the REAGENT CHANGE screen in "**5.7 Column Wash**" in order to replace all reagents in the tubes with purified water.

Screen 6- 2 REAGENT CHANGE screen (COL.WASH)



1. Do not wash the flow line for Hemolysis & Wash Solution with Elution Buffers.
2. Absolutely do not insert the suction tube for the Elution Buffer in Hemolysis & Wash Solution container to wash the tubes.
3. Attach the end plugs to the column ends and store the column in a cool place, such as a refrigerator, to prevent the inside of the column from drying out.

- **Operating Condition Changes**
  - Be aware that changes in assay parameters done during ANALYSIS state are invalid until the current assay is complete. Make changes when the analyzer is in STAND-BY state.

6.2 General System Failures

- **Power will not turn on**
  - Is the power cable properly connected?
  - Is the main power switched on?
  - Was the POWER key pressed?

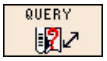
- **The USB stick cannot be read or written**
  - Is the USB stick correctly inserted in the USB socket?
  - Is the USB stick write-protected?
  - Are you using a USB stick with a security function?
  - Are you using a storage medium other than a USB stick?

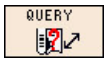
- **Analyzer will not start with timer startup**
  - Is the date (year, month, and day) properly set?
    Refer to "**4.13 Date/Time and Weekly Timer Setting**".

- **Only abnormal chromatograms appear**
  (Refer to "6.4 Abnormal Chromatograms")
  - Is the sample volume sufficient?
    1 mL or more is required with primary tubes and 200 µL or more is required with sample cups (diluted samples). Take special care with the calibrator volume since CALIB-1 is injected 3 times and CALIB-2 is injected 2 times. The required volume of each calibrator is described on the Instructions For Use of Calibrator Set.
  - Is the buffer being pumped properly?
    Check the pressure on the main screen.
    If the pressure is lower than the value indicated on the column inspection report or if the pressure appears unstable, refer to "**5.6 Pump Air Removal**" and remove the air from the pump.
  - Is there sufficient Hemolysis & Wash Solution?
  - Do the column and/or filter need replacement?
  - Does the column lot ID agree with the Elution Buffer lot ID?
  - Has the expiration date not passed?
  - Do the buffer label colors agree with the colors of the tube labels?

- **Frequent barcode reading errors**
  - Is the printing quality sufficient?
  - Is it printed on a white label?
  - Are you using a barcode set in the barcode parameter? Are the labels clean and unwrinkled?
    Refer to **"3.8 Samples - Barcode Label Confirmation"**.
  - Are the samples set as the barcode labels oriented toward the barcode reader?
  - Are the labels properly affixed?
    Attach the labels at least 20 mm from the bottom of primary tubes and with less than 5° of inclination. At least 5 mm of space (margin) is required to the left and right in the barcode.

- **Sampling needle is bent or broken**
  - Contact the service representative.

- **Some samples cannot be assayed**
  - Is the query mode set?
    Refer to "**4.20 Data Communication Setting**", confirm the 

    key status.
    Samples are skipped when using a query mode if the assay request is not directed from the host computer.
    If the barcode affixed to the sample is not properly read, the sample will be skipped under the certain circumstances (host computer setting etc.) when the 

    is set (displayed in green) on the BCR screen. Refer to "**4.22 Barcode Reader Setting and Reading Check**".
    Contact the service representative when successive samples are not detected.

- Is the error skip mode set?

  Refer to "**4.20 Data Communication Setting**", confirm the 

  key status.

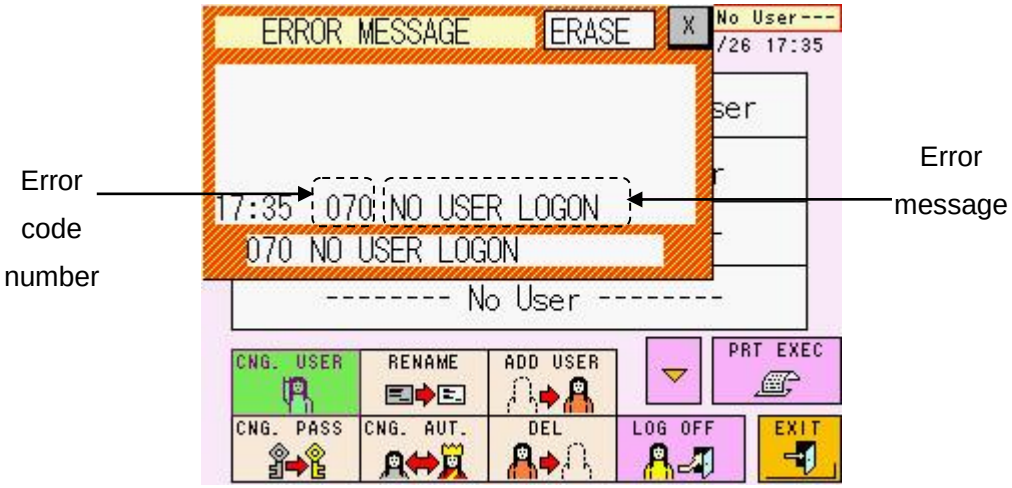
  In setting Error Skip mode, the assay will be skipped if the barcode affixed to the sample is not properly. If assays are skipped frequently, contact the service representative when successive samples are not detected.

6.3 Error Messages

When consulting with Tosoh local representatives about a problem, please note the error message and error number. This will allow them to solve the problem faster.

If you follow the suggested solutions in this section and are still unable to resolve the error, or if you encounter an error message that is not noted, contact Tosoh local representatives.

Screen 6- 3 ERROR MESSAGE screen



General Error Messages

With one of these errors, the assay stops and the analyzer immediately goes in STAND-BY state.

100 PRESSURE HIGH

The pump pressure exceeded the upper limit (20 MPa).

If the filter or column replacement period has been exceeded, first replace the filter or column. If the pressure is still high, contact Tosoh local representatives.

The target pressure is within a range less than the pressure (which is indicated on the column inspection report) +4 MPa.

101 PRESSURE LOW

Pump pressure fell below the lower limit (2.0 MPa).

Confirm the liquid leakage from the connection between the tube and the column.

The pressure will not rise because the pump is unable to run due to air bubbles in the pump or in the check valves. If the Elution Buffer is empty, place a new Elution Buffer. If the Elution Buffer is sufficient, check the tip of the suction tube reaches the bottom of the container. Execute REAGENT CHANGE and DRAIN FLUSH (See "**5.5 Elution Buffer Priming**" and "**5.6 Pump Air Removal**"). Next, execute COL.WASH on the REAGENT CHANGE screen (See "**5.7 Column Wash**"). If the pressure rises, the operation is complete.

If the pressure still does not rise or is not stabilized, execute DRAIN FLUSH again. In addition, confirm that the drain valve is securely closed.

718 INJ.VALVE ERROR

The injection valve is operating abnormally. If the error occurs many times, contact Tosoh local representatives.

Errors resulting in STAND-BY status after stopping an assay

200 AREA LOW ERROR

Three successive results below the lower limit of the Total Area (50) were output. If the error message still comes up even when sufficient volume of sample is set in the holder, the problem may be caused by an empty reagent or the tip position of the suction tube (Hemolysis & Wash Solution). Check the remaining volume and the tip of the suction tube of Hemolysis & Wash Solution, and start the assay again.

201 CALIB ERROR

Assay results for the calibrators were unsatisfactory.

Refer to "**3.7 Calibration**".

Check the dilution method. And check that the column and filters and the reagents have not expired.

Input the values for CALIB-1 and CALIB-2 in the PARAMETER screen confirm with the assigned values (refer to the Instructions For Use or the label of the calibrator)

Are the units for calibration appropriate (refer to "**3.7 Calibration - Scheduled Automatic Calibration**")?

702 BC COMM ERROR

This is an abnormality in communications with the barcode reader, possibly caused by poor contact at an internal cable or another problem. Contact Tosoh local representatives if the problem occurs repeatedly.

704 SAMPLE NOT FOUND

This error occurs when sample isn't set and the START command is input. If you use G11-90SL, check the rack circulation switch setting (see "**3.8 Samples - Sample Rack Rotation**")

If this error occurs even when samples are in place, there could be a sensor problem. Contact Tosoh local representatives.

705 RACK POS ERROR

The sample rack was not properly transferred.

Set the rack in the correct position and start again.

If you touch or move a rack during ANALYSIS state, this error may occur. Do not touch racks or primary tubes during ANALYSIS state.

710 Z1-AXIS ERROR

An abnormality occurred in the up and down movement of the sampling needle.

The error also occurs when the sample cup was misrecognized as a primary tube, due to the disoriented sample sensor

If you manage the reagents by handheld barcode scanner, following errors stop the assay.

150 BUFFER EXPIRED

The Elution Buffer has expired. Replace it with a new one.

151 H/W EXPIRED

The Hemolysis & Wash Solution has expired. Replace it with a new one.

152 COLUMN EXPIRED

The column has expired. Replace it with a new one.

154 LOT MISMATCH

The column lot ID does not match with lot of G11 Variant Elution Buffer. Make sure that the column is used with the same lot of G11 Variant Elution Buffer.

Errors which do not interrupt assays

When one of the following errors occurs, a message will be displayed, but the assay will continue.

120 STAT DOOR OPEN

The door on the STAT port is open. Close the door.

130 FILTER COUNT OVER

The filter count indicates the filter life has been reached.
(Only if the alarm is set)

131 COLUMN COUNT OVER

The column count indicates the column life has been reached.
(Only if the alarm is set)

140 BUFFER EMPTY

The remaining reagent is low.

(Only if the alarm is set)

145 H/W EMPTY

The remaining Hemolysis & Wash Solution is low.

(Only if the alarm is set)

153 CAL.CURVE EXPIRED

Calibration factors have expired. Execute calibration.

220 NO PEAK DETECT

No peaks have been detected. This problem could be caused by insufficient sample volume uptake because coagulated sample may have been processed or by an empty sample .

221 #### NOT DETECT (#### is the peak ID)

A specific peak (of hemoglobin components) could not be detected. When this occurs repeatedly with some samples, the Elution Buffer may have been concentrated or liquid may be leaking, resulting in unidentified peak detection on chromatograms.

When this error only occurs with specific samples, a hemoglobin variant may be present in the samples.

640 QUERY NO RESPONSE

No response was received from the host in the query mode.

Check the communication cable or the host computer settings.

670 SKIP: ############

The sample shown by ############ (ID) was not assayed because the barcode could not be read.

Check the barcode label.

(An ID number exceeding initial 12 digits is abbreviated as "_")

The following messages are displayed on the STATUS screen but not printed.

001 STOP ACCEPTED

During assays, press the STOP key once, and then either press OK on the pop-up screen, or press the STOP key once to issue an instruction to interrupt the assay.

002 EMERGENCY STOP

After issuing an assay interruption instruction, press the STOP key once to issue an emergency shutdown instruction.

003 CANCEL ACCEPTED

Operations were canceled by another operation. For example, this occurs when operations such as stop operation are requested during a transmission on the LIST screen.

010 SYSTEM RUNNING

Instruction that can't be processed during assay is received.

For example, this occurs when operations such as recalculation are requested during an assay.

070 NO USER LOGON

The key (ex. START key) was pressed before log on. Log on by an appropriate user account.

071 PASSWORD ERROR

Incorrect passwords were entered to log on. Input the correct passwords.

072 NO AUTHORITY

Current log on user has no authority to operate. Log on by an authorized Super User account.

190 ####FLAG**

Result shown by #### (sample number) meets Flag condition of code **.

400 PAPER EMPTY

There is no printer paper. Set a new paper roll.

401 PRINTER OFF LINE

The printer cover is open. Close the cover correctly.

500 USB NOT READY

There is no USB stick. Insert a formatted USB stick into the USB socket.

510 USB STICK FULL

The USB stick is full. Prepare a new, formatted USB stick.

511 FILE NOT FOUND

A nonexistent file in the USB stick is attempted to be read.

530 USB HARD ERROR

There is a problem with the USB socket or USB stick. Replace with a new, formatted USB stick and try again. If the USB stick cannot be formatted, there may be a problem with the socket itself. Contact Tosoh local representatives.

If you manage the reagents by a handheld barcode scanner, following errors will occur.

080 EXCEEDED EXP.DATE

The reagent has exceeded the expiration date read with a handheld barcode scanner. Replace it with a new one before the expiration date.

081 INVALID BARCODE

The information read with a handheld barcode scanner was invalid (ex. The barcode of Elution Buffer No.2 was read as the one of No.1). Read a valid barcode.

Error Messages and Their Meanings

Error Level 0: Warning
1: To STAND-BY state
2: To WASH state (To STAND-BY state except ANALYSIS state)

Alarm Level 0: Beep for 1 sec.
1: Beep for 30 sec. and turn on ERROR LED & Signal tower (optional)
4: Beep for 5 sec. (can not carry a rack out)
5: The barcode is not properly read

Print 0: No 1: Yes

Error Messages	Content	Measure	Error Level	Alarm Level	Print
Operation errors					
001 STOP ACCEPTED	STOP was executed		0	0	0
002 EMERGENCY STOP	EMERGENCY STOP was executed		0	0	0
003 CANCEL ACCEPTED	Operations were canceled by other operation.		0	0	0
010 SYSTEM RUNNING	Command could not be executed while another operation is running	Re-execute after operation stops	0	0	0
011 MIS OPERATION	Command was not allowed	Feed correct command	0	0	0
020 #9999 PARAM ERROR	Parameters are not correct	Turn the main power off then on	0	0	1
030 UNMATCH MODE DATA	Different mode data was attempted to be read	Set the proper data	0	0	0
031 UNMATCH CAL TYPE	Re-print or Re-calculation data is not match with CALIB TYPE	Set the CALIB TYPE of the data.	0	0	0
040 SAMPLING BUSY	ERROR RESET operation is not possible due to sample processing through LA line.	Execute ERROR RESET after sample processing through LA line is complete	0	0	0
050 EXCEEDED 4 KINDS	More than 4 types of barcodes were input	Designate up to 4 barcodes types	0	0	0
060 INVALID CHOICE	An invalid selection was done by the parameter setting	Choose the correct parameter	0	0	0
070 NO USER LOGON	No user logged on	Log on	0	0	0
071 PASSWORD ERROR	Incorrect passwords were entered	Input correct passwords	0	0	0
072 NO AUTHORITY	Unauthorized operation was done	Log on by an authorized user and operate	0	0	0
080 EXCEEDED EXP.DATE	The reagent read by handheld barcode scanner has exceeded its expiration date	Replace by a new reagent	0	0	0
081 INVALID BARCODE	Handheld barcode scanner attempted to read an invalid barcode	Read a valid barcode	0	0	0

Error Messages	Content	Measure	Error Level	Alarm Level	Print
082 TYPE MISMATCH	Handheld barcode scanner attempted to read different assigned values	Read a valid barcode	0	0	0
Status monitoring errors					
100 PRESSURE HIGH	Pump pressure exceeded upper limit (PRES-HIGH)	Inspect for clogging at column and filter (see "5.8 Filter Replacement")	1	1	1
101 PRESSURE LOW	Pump pressure fell below lower limit (PRES-LOW)	Execute air removal (see "5.6 Pump Air Removal")	1	1	1
102 PRES LIMIT OVER	Pump pressure abnormality was detected	Check clogging of filter Turn the main power off then on to re-start operations. (see "5.8 Filter Replacement")	1	1	1
103 D.FLUSH ERROR	Pump pressure abnormality was detected during drain flush	Confirm the drain valve is open (see "5.6 Pump Air Removal")	1	1	1
110 TEMP UNSTABLE	Column temperature is not stabilized.	Turn the main power off then on	2	1	1
111 TEMP LIMIT OVER	Temperature abnormality was detected	Turn the main power off then on	2	1	1
115 COLUMN LEAK ERROR	Leakage from the column was detected	Check leakage around the column oven If there is leakage, wipe it and re-connect the column (see "5.9 Column Replacement")	1	1	1
120 STAT DOOR OPEN	The STAT door is open	Close the door (See "3.11 Priority Sample Assay)	0	1	1
125 GRAD SENSOR ERROR	The GRAD sensor on the pump detected abnormality.	Perform the measure for the error100 or for the error102.	0	1	1
130 FILTER COUNT OVER	The injection limit for filter (input value) has been exceeded	Replace the filter (see "5.8 Filter Replacement")	0	1	1
131 COLUMN COUNT OVER	The injection limit for column (input value) has been exceeded	Replace the column (see "5.9 Column Replacement")	0	1	1
140 BUFFER EMPTY	Buffer volume is low. (fell below the setting)	Replace eluent (see "5.4 Elution Buffer and Hemolysis & Wash Solution Replacement")	0	1*	1
145 H/W EMPTY	Hemolysis & Wash Solution volume is low. (fell below the setting)	Replace Hemolysis & Wash Solution (see "5.4 Elution Buffer and Hemolysis & Wash Solution Replacement")	0	1*	1
146 H/W BOTTLE EMPTY	Hemolysis & Wash Solution volume is low. (detected air)	Replace Hemolysis & Wash Solution (see "5.4 Elution Buffer and Hemolysis & Wash Solution Replacement")	1	1	1

Error Messages	Content	Measure	Error Level	Alarm Level	Print
148 DRAIN FULL ERROR	The waste tank is full	Check the waste tank Turn the main power off then on	1	1	1
150 BUFFER EXPIRED	The Buffer has expired	Replace the buffer (see "5.4 Elution Buffer and Hemolysis & Wash Solution Replacement")	2	1	1
151 H/W EXPIRED	The Hemolysis & Wash Solution has expired	Replace Hemolysis & Wash Solution (see "5.4 Elution Buffer and Hemolysis & Wash Solution Replacement")	2	1	1
152 COLUMN EXPIRED	The column has expired	Replace the column (see "5.9 Column Replacement")	2	1	1
153 CAL. CURVE EXPIRED	Calibration factors have expired	Execute calibration (see "3.7 Calibration")	0	1	1
154 LOT MISMATCH	The column lot ID does not match with lot ID of G11 Variant Elution Buffer.	Check the column lot ID and lot of buffers(see "2.6 Column")	2	1	1
155 R_INF. NOT SET	The column information or Elution buffers information are not registered.	Register the column information and Elution buffers information.	2	1	1
190 #### FLAG**	Result #### meets Flag condition (#### is sample number and ** is Flag code)	Check the result	0	0	0
Data processing errors					
200 AREA LOW ERROR	The peak area which does not reach the minimum required area occurred several times in series (the minimum area and the number of times are set in parameters)	Check the samples, buffers, Hemolysis & Wash Solution and waste tank	2	1	1
201 CALIB ERROR	Calibration results were out of the acceptable range	Check calibrators and assigned values (See "3.7 Calibration")	2	1	1
211 PEAK PATTERN ERROR	Peaks were not separated well	Check the samples, buffers, Hemolysis & Wash Solution and liquid leakage.	0	0	1
220 NO PEAK DETECT	Peaks were not detected	Check the samples, buffers, Hemolysis & Wash Solution and liquid leakage.	0	0	1
221 #####NOT DETECT	##### peak could not be detected	Check the samples, buffers, and Hemolysis & Wash Solution	0	0	1
230 RAW DATA FULL	No more available space for data collection	Initialize parameters	0	0	1
231 NO RAW DATA	No raw data was attempted to recalculate or reprint.	None (Recalculation and reprinting is impossible)	0	0	1
Communication errors					

Error Messages	Content	Measure	Error Level	Alarm Level	Print
310 EXB COMM ERROR (PE)	Parity error occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
311 EXB COMM ERROR (FE)	Framing error occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
312 EXB COMM ERROR (OR)	Overrun error occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
313 EXB COMM ERROR (BF)	Buffer full error occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
314 EXB COMM ERROR (OL)	Long data error occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
315 EXB COMM ERROR (RE)	Retry error occurred in BCR communication for LA line.	Check connection Turn the main power off then on	0	1	1
316 EXB COMM ERROR (ST)	Timeout error for sending occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
317 EXB COMM ERROR (RT)	Timeout error for receiving occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
318 EXB COMM ERROR (NR)	No response error occurred in BCR communication for LA line	Check connection Turn the main power off then on	0	1	1
320 LCD COM ERROR (PE)	Parity error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
321 LCD COM ERROR (FE)	Framing error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
322 LCD COM ERROR (OR)	Overrun error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
323 LCD COM ERROR (BF)	Buffer full error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
324 LCD COM ERROR (OL)	Long data error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
325 LCD COM ERROR (RE)	Retry error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
326 LCD COM ERROR (ST)	Timeout error for sending occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
327 LCD COM ERROR (RT)	Timeout error for receiving occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
328 LCD COM ERROR (NR)	No response error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
330 AS COMM ERROR (PE)	Parity error occurred in AS communication	Turn the main power off then on	1	1	1
331 AS COMM ERROR (FE)	Framing error occurred in AS communication	Turn the main power off then on	1	1	1

Error Messages	Content	Measure	Error Level	Alarm Level	Print
332 AS COMM ERROR (OR)	Overrun error occurred in AS communication	Turn the main power off then on	1	1	1
333 AS COMM ERROR (BF)	Buffer full error occurred in AS communication	Turn the main power off then on	1	1	1
334 AS COMM ERROR (OL)	Long data error occurred in AS communication	Turn the main power off then on	1	1	1
335 AS COMM ERROR (RE)	Retry error occurred in AS communication	Turn the main power off then on	1	1	1
336 AS COMM ERROR (ST)	Timeout error for sending occurred in AS communication	Turn the main power off then on	1	1	1
337 AS COMM ERROR (RT)	Timeout error for receiving occurred in AS communication	Turn the main power off then on	1	1	1
338 AS COMM ERROR (NR)	No response error occurred in AS communication	Turn the main power off then on	1	1	1
340 HOST COMM ERR(PE)	Parity error occurred in HOST communication	Check the connections and communication specifications	0	1	1
341 HOST COMM ERR (FE)	Framing error occurred in HOST communication	Check the connections and communication specifications	0	1	1
342 HOST COMM ERR (OR)	Overrun error occurred in HOST communication	Check the connections and communication specifications	0	1	1
343 HOST COMM ERR (BF)	Buffer full error occurred in HOST communication	Check the connections and communication specifications	0	1	1
344 HOST COMM ERR (OL)	Long data error occurred in HOST communication	Check the connections and communication specifications	0	1	1
345 HOST COMM ERR (RE)	Retry error occurred in HOST communication	Check the connections and communication specifications	0	1	1
346 HOST COMM ERR (ST)	Timeout error for sending occurred in HOST communication	Check the connections and communication specifications	0	1	1
347 HOST COMM ERR (RT)	Timeout error for receiving occurred in HOST communication	Check the connections and communication specifications	0	1	1
348 HOST COMM ERR (NR)	No response error occurred in HOST communication	Check the connections and communication specifications	0	1	1
350 LC COMM ERROR (PE)	Parity error occurred in LA communication	Check the connections and communication specifications	0	1	1
351 LC COMM ERROR (FE)	Framing error occurred in LA communication	Check the connections and communication specifications	0	1	1
352 LC COMM ERROR (OR)	Overrun error occurred in LA communication	Check the connections and communication specifications	0	1	1

Error Messages	Content	Measure	Error Level	Alarm Level	Print
353 LC COMM ERROR (BF)	Buffer full error occurred in LA communication	Check the connections and communication specifications	0	1	1
354 LC COMM ERROR (OL)	Long data error occurred in LA communication	Check the connections and communication specifications	0	1	1
355 LC COMM ERROR (RE)	Retry error occurred in LA communication	Check the connections and communication specifications	0	1	1
356 LC COMM ERROR (ST)	Timeout error for sending occurred in LA communication	Check the connections and communication specifications	0	1	1
357 LC COMM ERROR (RT)	Timeout error for receiving occurred in LA communication	Check the connections and communication specifications	0	1	1
358 LC COMM ERROR (NR)	No response error occurred in LA communication	Check the connections and communication specifications	0	1	1
360 LCD COM ERROR (??)	An unknown error occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
361 LCD COM ERROR (01)	A 01 error (display processing) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
362 LCD COM ERROR (02)	A 02 error (overrun/framing error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
363 LCD COM ERROR (03)	A 03 error (parity error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
364 LCD COM ERROR (04)	A 04 error (sum check error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
365 LCD COM ERROR (05)	A 05 error (address error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
366 LCD COM ERROR (06)	A 06 error (count error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
367 LCD COM ERROR (07)	A 07 error (screen error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
368 LCD COM ERROR (08)	A 08 error (format error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
369 LCD COM ERROR (09)	A 09 error (received data over) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
370 LCD COM ERROR (0B)	A 0B error (retry command error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1

Error Messages	Content	Measure	Error Level	Alarm Level	Print
371 LCD COM ERROR (0F)	A 0F error (ETX error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
372 LCD COM ERROR (10)	A 10 error (DLE error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
373 LCD COM ERROR (11)	An 11 error (character error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
374 LCD COM ERROR (12)	A 12 error (command error) occurred in LCD communication through KEY	Turn the main power off then on	0	1	1
Printer errors					
400 PAPER EMPTY	Printer is out of paper	Replace the paper roll (see "5.3 Printer Paper Replacement")	0	0	0
401 PRINTER OFF LINE	Printer cover is open	Close the printer cover	0	0	0
420 PRINTER ERROR	Printer is in trouble	Turn the main power off then on	0	0	0
USB stick errors					
500 USB NOT READY	No USB stick is set	Set the USB stick	0	0	0
510 USB STICK FULL	The USB stick is full	Insert a new, formatted USB stick	0	0	0
511 FILE NOT FOUND	The file could not be found	Insert the proper USB stick. Input the correct number.	0	0	0
520 USB DATA ERROR	USB stick data is corrupted	Format the USB stick to re-use (See "4.10 USB Stick" or "7.1 Downloading Files from the USB Stick")	0	0	0
530 USB HARD ERROR	USB stick could not be accessed	Replace USB stick Turn the main power off then on	0	0	0
Control and monitoring errors					
620 SAMPLE NOT INJECT	Assay of previous sample is not yet complete, so sample was not injected	Turn the main power off then on	0	0	1
630 BELT BCR NO RESP	BCR for LA line is not responding	Check connections Turn the main power off then on	0	0	1
631 BELT BCR SET ERROR	Setting error occurred in the BCR for LA line	Check the BCR mode for LA line (see "4.22 Barcode Reader Setting and Reading Check") Turn the main power off then on	0	0	1

Error Messages	Content	Measure	Error Level	Alarm Level	Print
632 BCR SET ERROR	BCR setting error occurred	Check the BCR setting (see "4.22 Barcode Reader Setting and Reading Check") Turn the main power off then on	0	0	1
640 QUERY NO RESPONSE	No response is received for order query to host	Check the HOST Turn the main power off then on	0	1	1
650 BELT ID UNMATCH	Sample ID sent by HOST does not agree with the sample ID read by BCR	Check transport line Turn the main power off then on	0	1	1
660 BELT LINE ABORT	Error occurred at transport line or analyzer during connecting to HOST. No sample processing was executed.	Remove the cause of the error Turn the main power off then on	0	1	1
670 SKIP:############	Assay was not done for the sample indicated by the ID because the barcode could not be read or some other problem occurred (ID number exceeding initial 12 digits will be abbreviated. as "_")	1.Check the connections and communication specifications 2.Inspect barcode label (see "3.8 Samples") or clean the BCR	0	0	1
671 BC ERR:RRRR-PP	The sample barcode which indicates rack No.RRRR and sample position No.PP could not be read (occurs only for specific settings).	Inspect barcode label (see "3.8 Samples") Clean the BCR	0	5	1
675 RACK SKIP:XXXXXX	Assay was not done for the sample on the unusable rack	Check the rack type.	0	0	1
680 CALIB POS ERROR	The calibrator position is wrong	Inspect the calibrator position, barcode label, etc.	2	1	1
AS errors					
701 PULSE ERROR	Pulse data was abnormal	Turn the main power off then on	2	1	1
702 BC COMM ERROR	A communication error occurred in the BCR and AS	Turn the main power off then on	2	1	1
703 AS COMMAND ERROR	The AS received an invalid command	Turn the main power off then on	2	1	1
704 SAMPLE NOT FOUND	Sample could not be detected	Start assay after setting samples Inspect the sample recognition sensor	2	1	1
705 RACK POS ERROR	The rack transfer lever cannot return due to the presence of an incoming rack	Remove the rack and start assay	2	1	1
706 SYRINGE-L ERROR	Operation error in syringe-L	Turn the main power off then on	2	1	1
707 SYRINGE-S ERROR	Operation error in syringe-S	Turn the main power off then on	2	1	1

Error Messages	Content	Measure	Error Level	Alarm Level	Print
708 X1-AXIS ERROR	Operation error in X1-axis	Turn the main power off then on	2	1	1
709 Y1-AXIS ERROR	Operation error in Y1-axis	Turn the main power off then on	2	1	1
710 Z1-AXIS ERROR	Operation error in Z1-axis	Turn the main power off then on	2	1	1
711 LINE VALVE ERROR	Operation error in switching valve (AS valve)	Turn the main power off then on	2	1	1
712 X2-AXIS ERROR	Operation error in X2-axis	Turn the main power off then on	2	1	1
713 X3-AXIS ERROR	Operation error in X3-axis	Turn the main power off then on	2	1	1
714 Y2-AXIS ERROR	Operation error in Y2-axis	Turn the main power off then on	2	1	1
715 Y3-AXIS ERROR	Operation error in Y3-axis	Turn the main power off then on	2	1	1
716 Y4-AXIS ERROR	Operation error in Y4-axis	Turn the main power off then on	2	1	1
717 Y5-AXIS ERROR	Operation error in Y5-axis	Turn the main power off then on	2	1	1
718 INJ VALVE ERROR	Operation error in injection valve	Turn the main power off then on	1	1	1
722 SOFT ERROR	An AS control error occurred	Turn the main power off then on	2	1	1
723 SAMPLE MISMATCH M	Sample position transmitted from AS does not match position at main unit	Turn the main power off then on	2	1	1
724 SAMPLE MISMATCH A	Sample position transmitted from main unit does not match position at AS	Turn the main power off then on	2	1	1
725 SAMPLE MISMATCH H	Sample ID transmitted from HOST does not match information at main unit	Turn the main power off then on	2	1	1
727 RACK FULL LEFT	The sample rack is full on the left side	Remove the rack on the left side	0	4	0
728 RACK FULL RIGHT	The sample rack is full on the right side	Remove the rack on the right side	0	4	0
LA control errors					
800 BL BC UNMATCH	ID transmitted from LA does not match ID read by the BCR for LA line	Inspect barcode label Clean the BCR	0	1	1
801 BL BC READ ERROR	Barcode could not be read by the BCR for LA line	Inspect barcode label Clean the BCR	0	1	1
802 BELT LINE ERROR	Trouble signal was received from LA line	Inspect transport line	0	1	1
803 BL ID TRANS ERROR	ID was transmitted when assay was not accessible	Inspect transport line	0	1	1
804 BL ID NOT ACCEPT	Samples came in even though ID was not received	Inspect transport line	0	1	1

Error Messages	**Content**	Measure	Error Level	Alarm Level	Print
805 BELT LINE DOWN	LA line connection signal was off or communication from LA line was interrupted	Inspect transport line	0	1	1
806 BL COMM ERROR	LA communication error occurred	Check connection	0	1	1
809 BL MODE CHG ERR	There was an error to change command in the mode setting	Inspect transport line	0	0	1
810 BL SAMP SIG ERR	The SMPOK signal from LA line during sampling is off	Inspect transport line	2	1	1

* When only buffer volume falls below the setting or remaining buffer volume is 0, the alarm goes off.

Fig. 6- 4 Position of each axis and conveyor on 90 sample loader

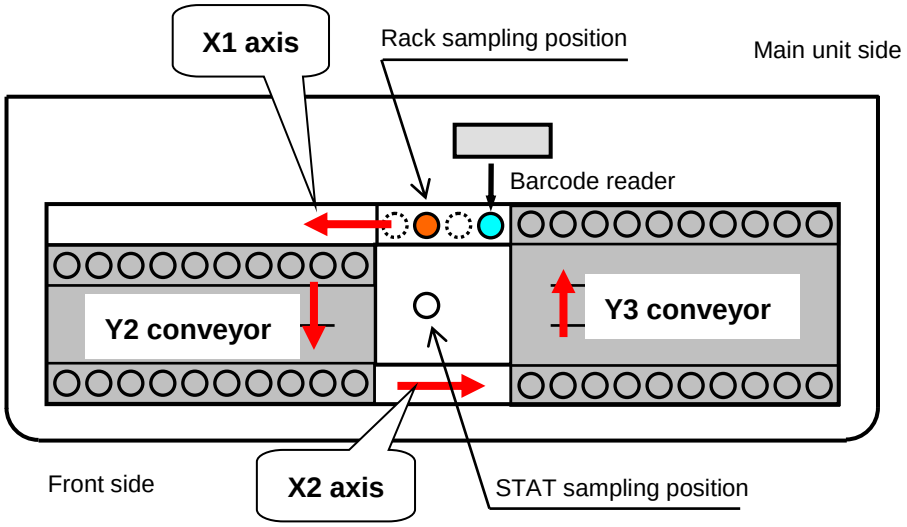
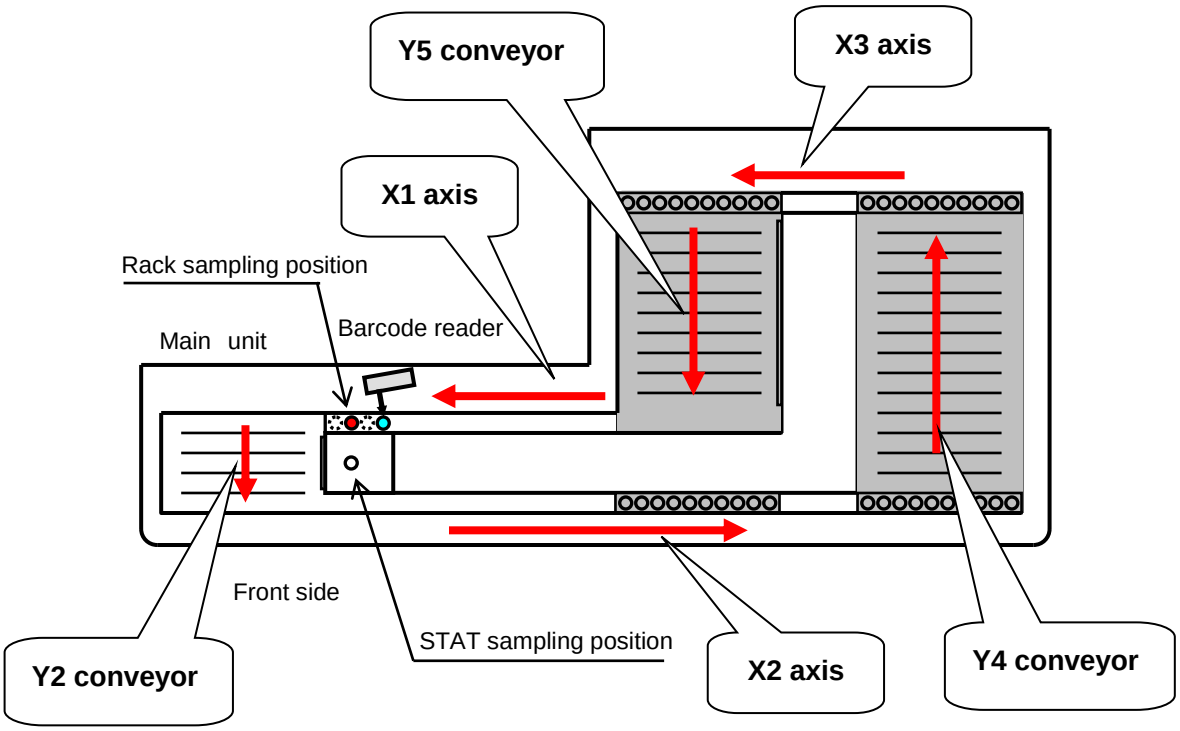


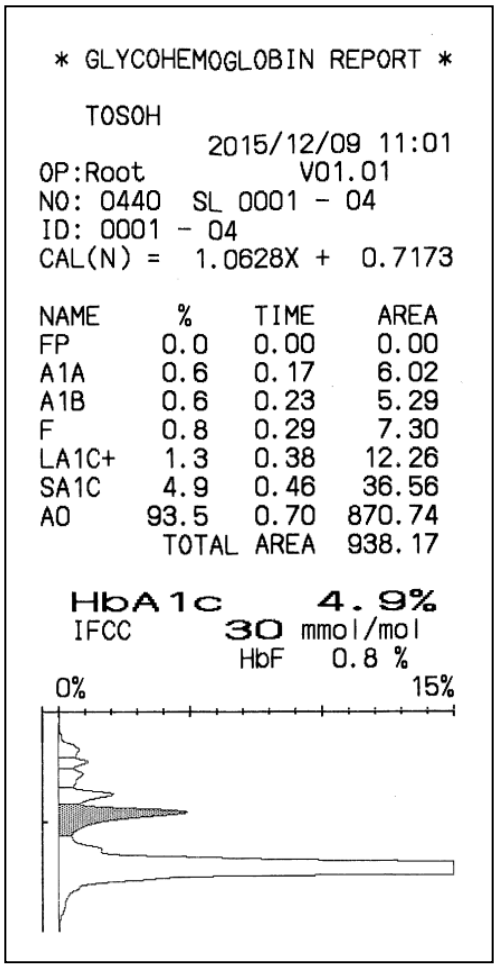
Fig. 6- 5 Position of each axis and conveyor on 290 sample loader



6.4 Abnormal Chromatograms

Although the percentage of each hemoglobin component may vary slightly from patient to patient, most whole blood samples will contain six fractions: A1a, A1b, F, LA1c+, s-A1c, and A0. A normal chromatogram is shown below in Fig.6-7.

Fig. 6- 7 Normal chromatogram



Abnormal chromatograms, which are typically characterized by the presence of an unknown peak, a misidentification of one or some of the above six fractions or a deformed shape of peak, may be occasionally seen during routine testing. The s-A_{1c}% may be invalid depending on the cause of the abnormal chromatogram, therefore it is important to review all chromatograms to determine whether the results are valid.
Analyzer problems such as a malfunction of the pump or sampling unit, a column that has been used for a long time and reagents that are incorrectly set or have been depleted can also cause abnormal chromatograms. In these cases, sequential chromatograms are usually all affected from the point that the problem began. If an abnormal chromatogram is only obtained with a single specific sample, the sample may have deteriorated or hemoglobin variants may be present.
See Figure 6-8 through Figure 6-23 for examples of abnormal chromatograms.

The software excludes peaks eluting after the A0 peak when calculating the Total Area. The HbA1c % is usually not affected in such situations though chromatograms should be carefully reviewed. HbD, HbS and HbC elute after the A0 peak as H-VAR peak. The HbA1c % is generally reportable on the HLC-723G11 when these hemoglobins are present in the heterozygous state with HbA.

If a hemoglobin variant peak elutes independently of the s-A_{1c} peak, but before the A_0 peak, it will cause a false decrease in the s-A_{1c} result. However the analyzer detects the presence of a P-HV3 peak where the glycated form of HbE typically elutes (See "Chapter 4 Section 4.21: FLAG Parameter Setting" for flag settings.)

If a hemoglobin variant peak elutes before the s-A1c peak, the HbA1c% measured will be erroneous and should not be reported.

Glycemic monitoring for patients displaying any homozygous hemoglobin other than HbAA such as HbSS, HbCC or the double heterozygous HbSC, cannot be accomplished using HbA1c because there is no HbA present. Alternative testing is mandatory for these types of patients.

Remember that all abnormal chromatograms are not necessarily the result of abnormalities in the patient sample. Analyzer problems such as a malfunctioning

pump or sampling unit, a column that should be replaced or reagents that are wrongly placed or have run short can also cause abnormal chromatograms. In these cases, chromatograms for a certain number of samples are usually all affected from the point that the problem began. See Figure 6-8 through Figure 6-23 for examples of these types of abnormalities.

Abnormal Chromatograms - Samples

Fig. 6- 8 Hemoglobin Variant (AD)
HbA1c is reportable

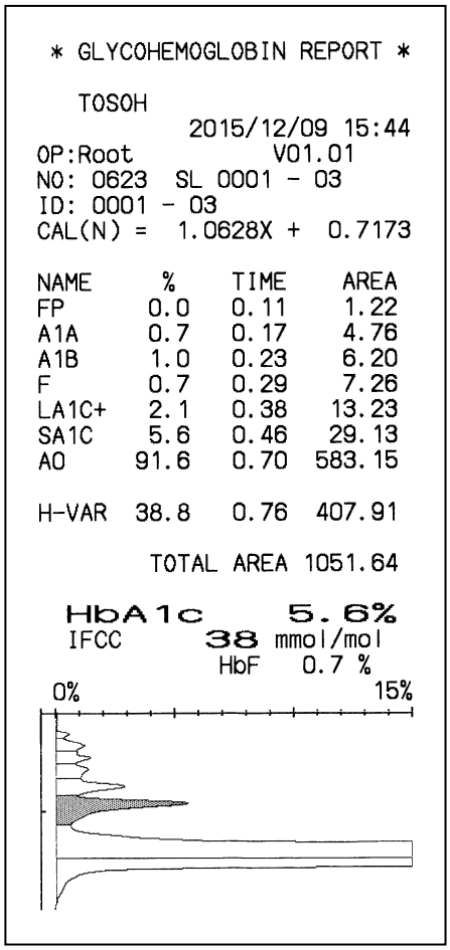


Fig. 6- 9 Hemoglobin Variant (AS)
HbA1c is reportable

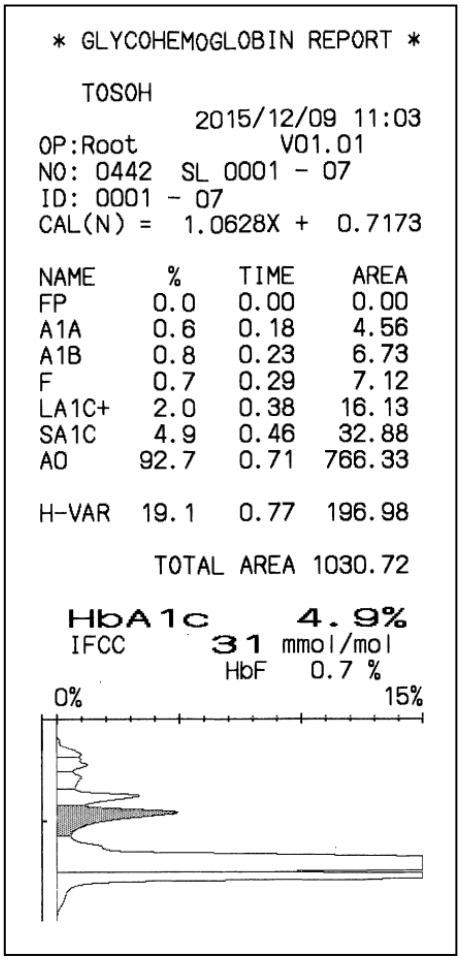


Fig. 6- 10 Hemoglobin Variant (AC)
HbA1c is reportable

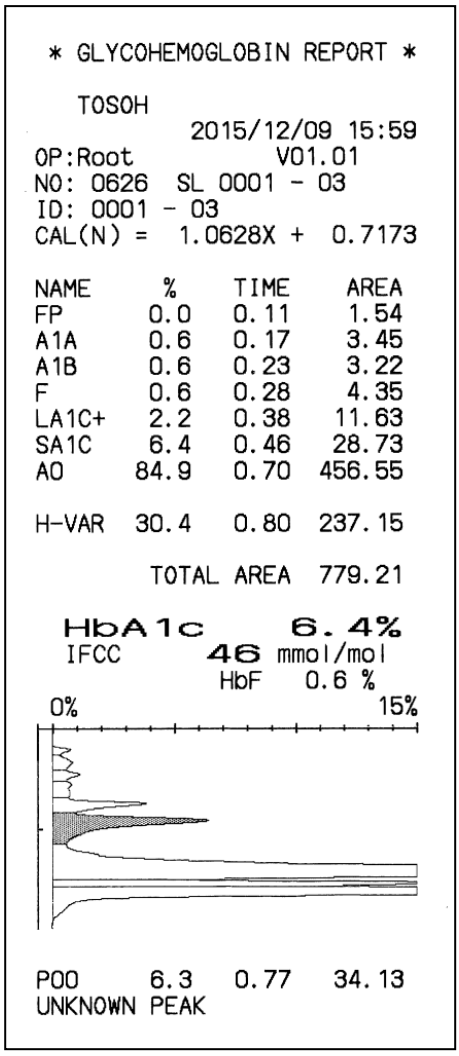


Fig. 6- 11 Hemoglobin Variant (AE)
HbA1c is reportable

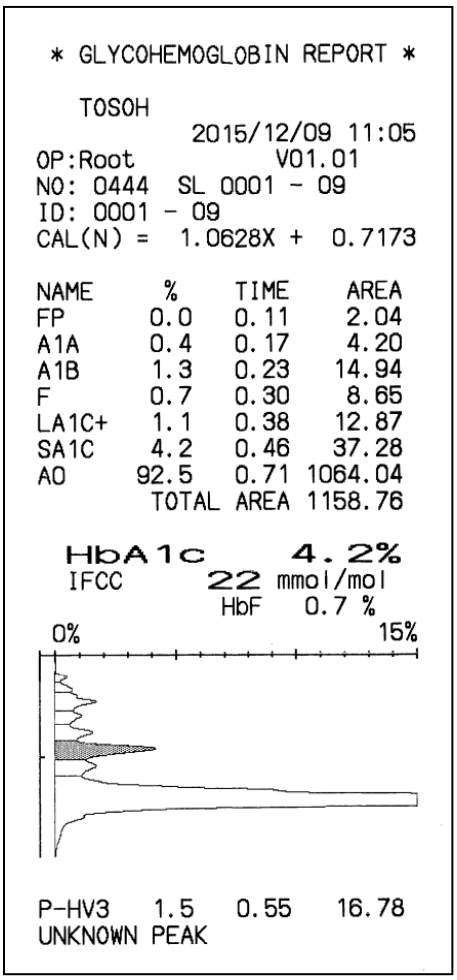


Fig. 6- 12 Area low sample
HbA1c is reportable

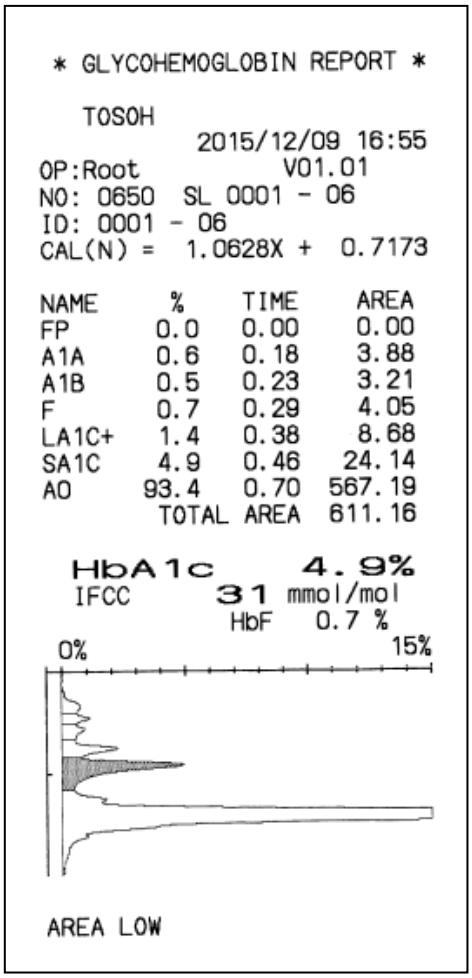
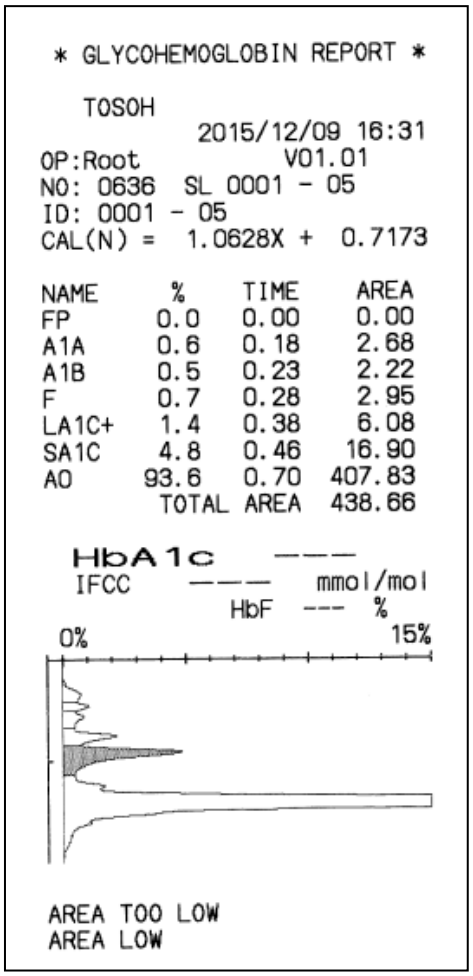


Fig. 6- 13 Area too low sample
HbA1c is not reportable



In the case of a very low hemoglobin concentration (dialysis patients, anemia patients, etc.), the TOTAL AREA of the assay results may drop below the minimum required area (flag: AREA LOW or AREA TOO LOW). If this happens, dilute a whole blood manually or select the dilution rate "INCREASED" on the STAT assay.

Fig. 6- 14 Area high sample
HbA1c is reportable

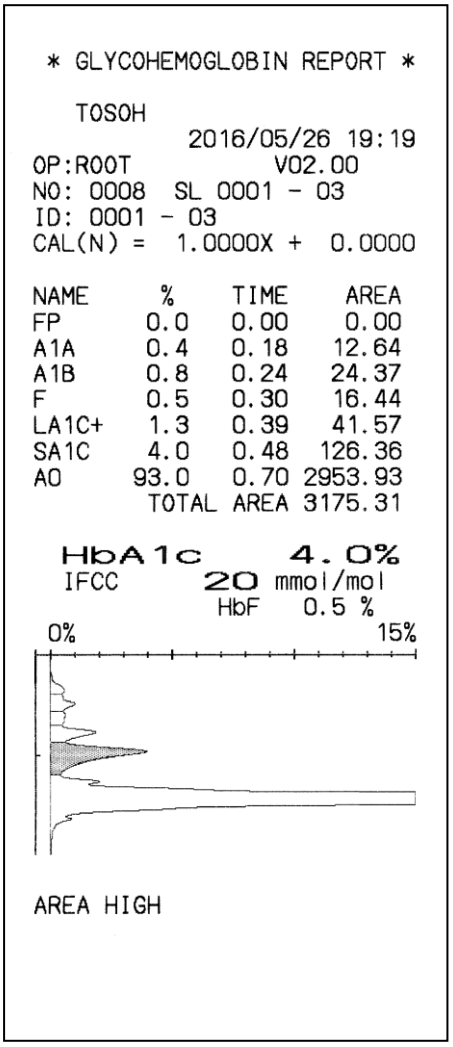
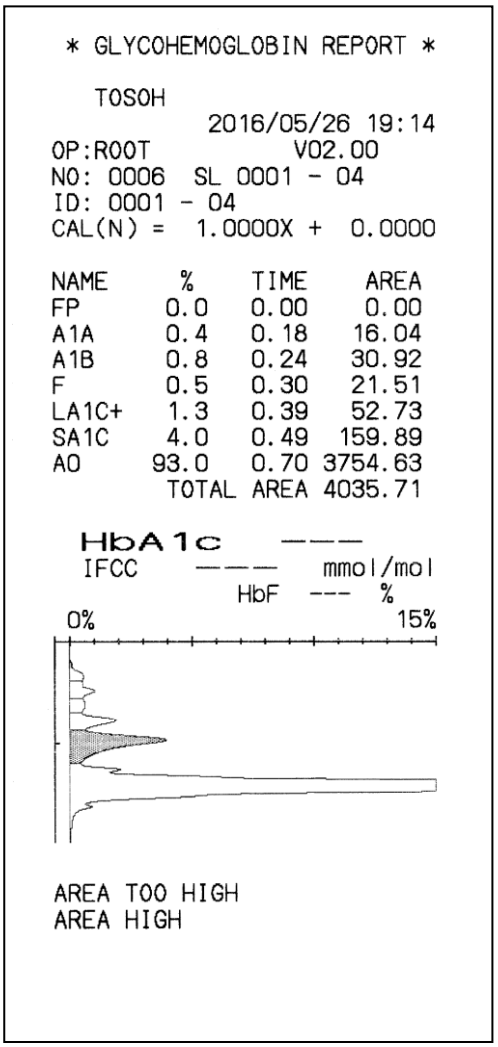


Fig. 6- 15 Area too high sample
HbA1c is not reportable



In the case of a very high hemoglobin concentration (centrifuged sample, aged sample etc.), the TOTAL AREA of the assay results may exceed the maximum required area (flag: AREA HIGH or AREA TOO HIGH).

If this happens, turn the primary tube upside down, dilute a whole blood manually or select the dilution rate "DECREASED" on the STAT assay.

Abnormal Chromatograms – Analyzer Problem

Fig. 6- 16 TP low column
HbA1c is not reportable

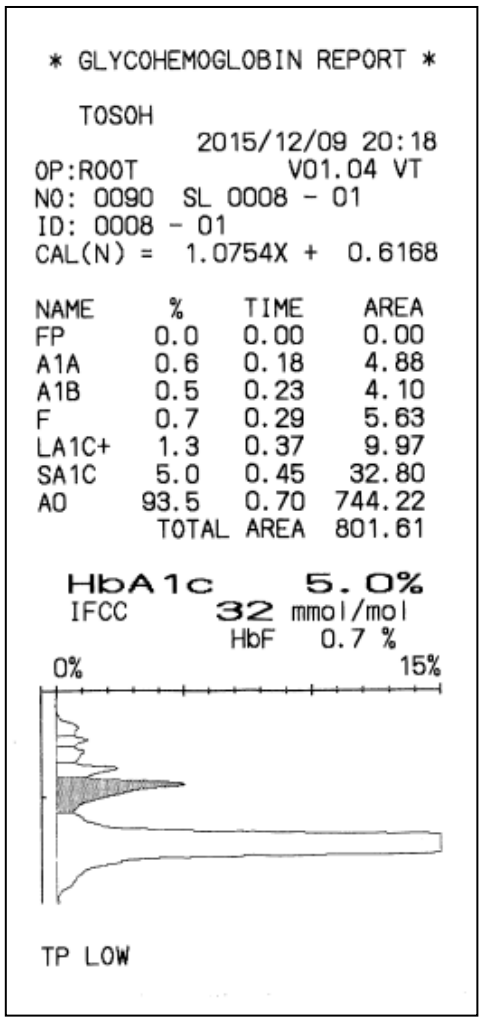


Fig. 6- 17 TP too low column
HbA1c is not reportable

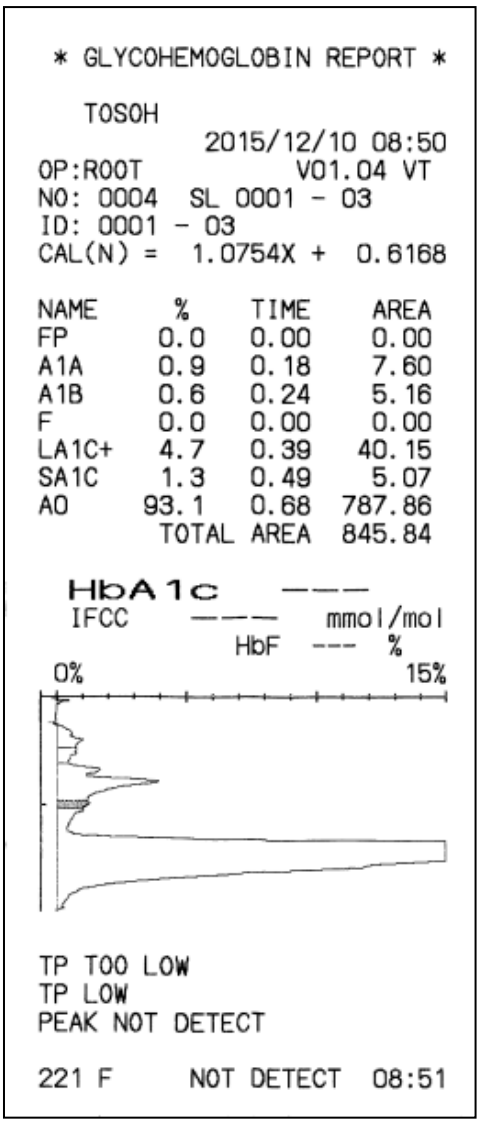
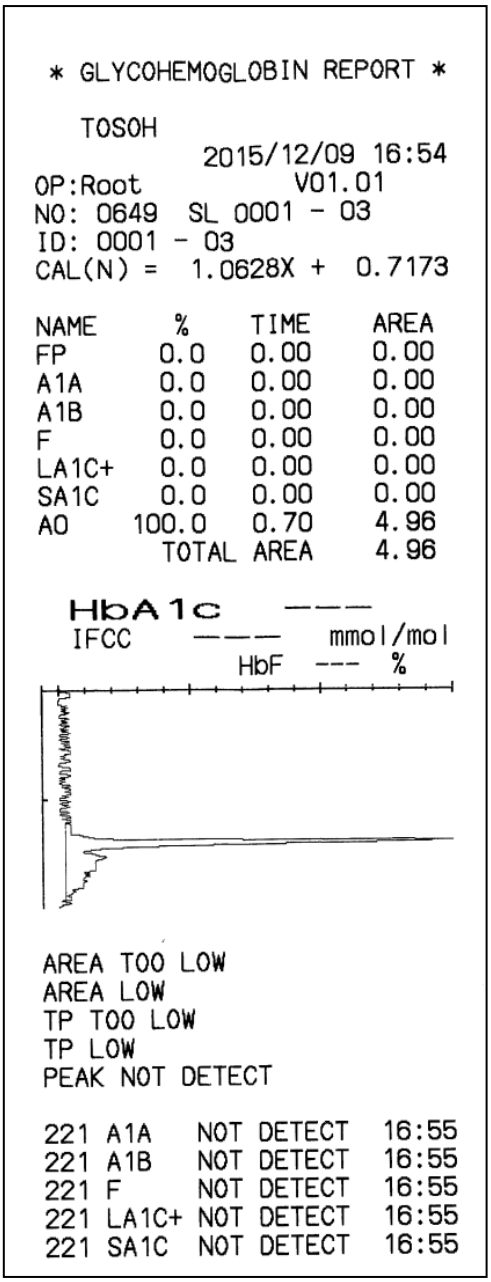


Fig. 6- 18 Insufficient sample suction
HbA1c is not reportable

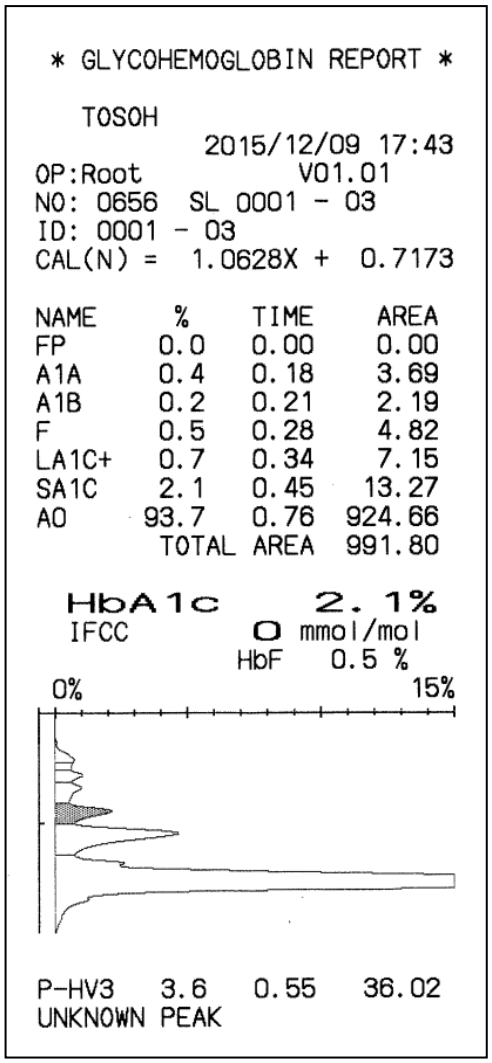


```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
            2015/12/09 16:54
OP:Root          V01.01
NO: 0649  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0628X +  0.7173

NAME      %     TIME     AREA
FP       0.0   0.00     0.00
A1A      0.0   0.00     0.00
A1B      0.0   0.00     0.00
F        0.0   0.00     0.00
LA1C+    0.0   0.00     0.00
SA1C     0.0   0.00     0.00
AO     100.0   0.70     4.96
         TOTAL AREA     4.96

HbA1c  ---
IFCC   ---   mmol/mol
          HbF  ---  %
```



```
AREA TOO LOW
AREA LOW
TP TOO LOW
TP LOW
PEAK NOT DETECT

221 A1A    NOT DETECT  16:55
221 A1B    NOT DETECT  16:55
221 F      NOT DETECT  16:55
221 LA1C+  NOT DETECT  16:55
221 SA1C   NOT DETECT  16:55
```

Fig. 6- 19 Insufficient pump delivery
HbA1c is not reportable



```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
            2015/12/09 17:43
OP:Root          V01.01
NO: 0656  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0628X +  0.7173

NAME      %     TIME     AREA
FP       0.0   0.00     0.00
A1A      0.4   0.18     3.69
A1B      0.2   0.21     2.19
F        0.5   0.28     4.82
LA1C+    0.7   0.34     7.15
SA1C     2.1   0.45    13.27
AO      93.7   0.76   924.66
         TOTAL AREA     991.80

HbA1c  2.1%
IFCC   0 mmol/mol
          HbF  0.5 %
0%              15%
```



```
P-HV3    3.6   0.55   36.02
UNKNOWN PEAK
```

Fig. 6- 20 Exceeded pump delivery
HbA1c is not reportable

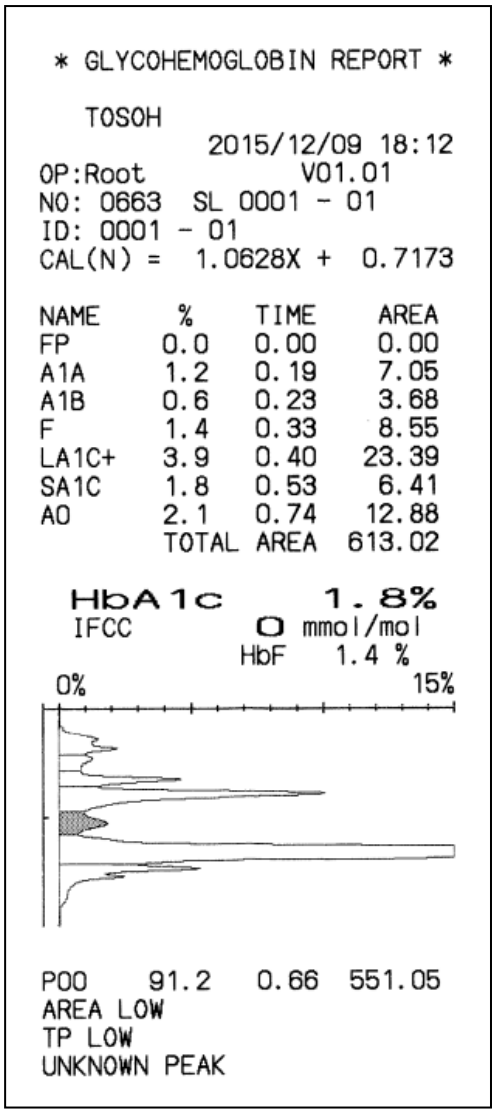


Fig. 6- 21 Elution Buffers No. 1 and 2 are incorrectly set
HbA1c is not reportable

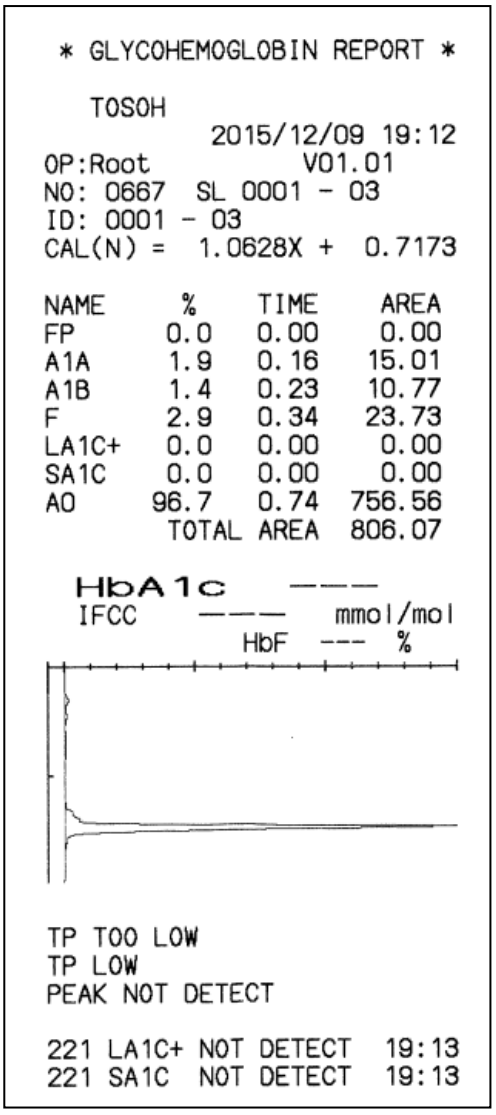
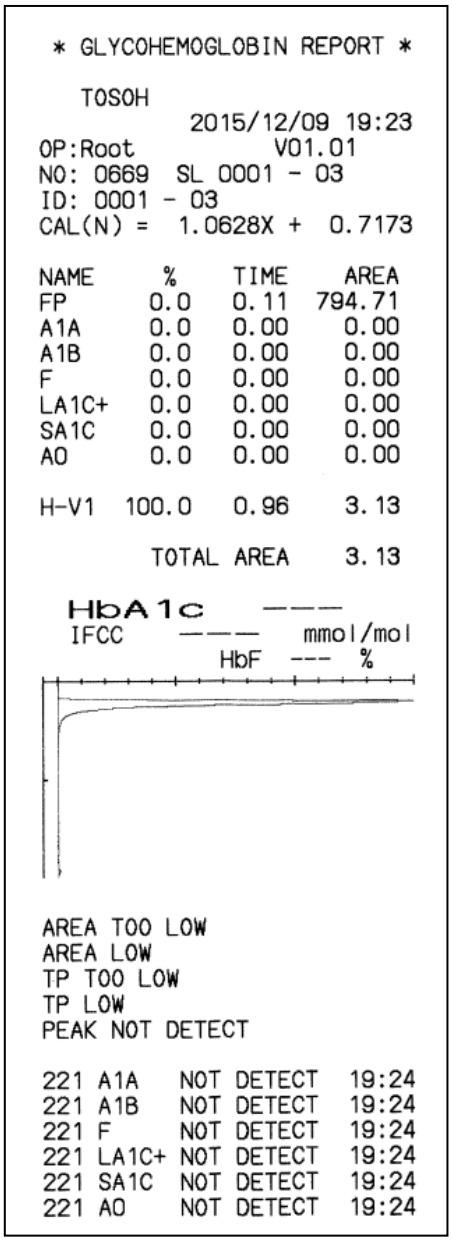


Fig. 6- 22 Elution Buffers No. 1 and 3 are incorrectly set HbA1c is not reportable

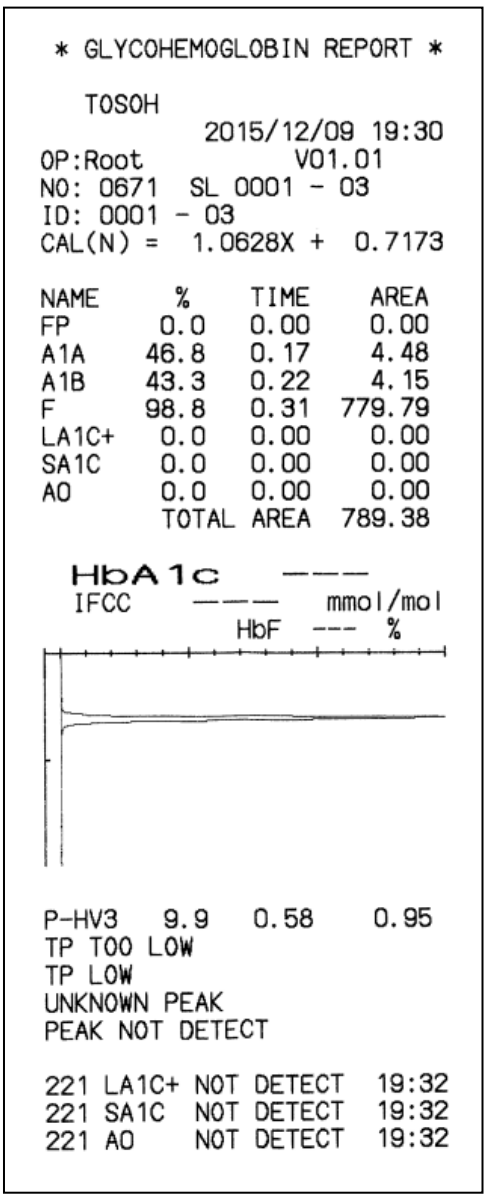


```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/09 19:23
OP:Root            V01.01
NO: 0669  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0628X +  0.7173

NAME      %     TIME     AREA
FP       0.0    0.11   794.71
A1A      0.0    0.00     0.00
A1B      0.0    0.00     0.00
F        0.0    0.00     0.00
LA1C+    0.0    0.00     0.00
SA1C     0.0    0.00     0.00
AO       0.0    0.00     0.00

H-V1   100.0    0.96     3.13

          TOTAL AREA      3.13

HbA1c  ---
IFCC   ---    mmol/mol
          HbF  ---  %
```



```
AREA TOO LOW
AREA LOW
TP TOO LOW
TP LOW
PEAK NOT DETECT

221 A1A    NOT DETECT   19:24
221 A1B    NOT DETECT   19:24
221 F      NOT DETECT   19:24
221 LA1C+  NOT DETECT   19:24
221 SA1C   NOT DETECT   19:24
221 AO     NOT DETECT   19:24
```

Fig. 6- 23 Elution Buffers No. 2 and 3 are incorrectly set HbA1c is not reportable



```
* GLYCOHEMOGLOBIN REPORT *

   TOSOH
              2015/12/09 19:30
OP:Root            V01.01
NO: 0671  SL 0001 - 03
ID: 0001 - 03
CAL(N) =  1.0628X +  0.7173

NAME      %     TIME     AREA
FP       0.0    0.00     0.00
A1A     46.8    0.17     4.48
A1B     43.3    0.22     4.15
F       98.8    0.31   779.79
LA1C+    0.0    0.00     0.00
SA1C     0.0    0.00     0.00
AO       0.0    0.00     0.00
         TOTAL AREA     789.38

HbA1c  ---
IFCC   ---    mmol/mol
          HbF  ---  %
```



```
P-HV3    9.9    0.58     0.95
TP TOO LOW
TP LOW
UNKNOWN PEAK
PEAK NOT DETECT

221 LA1C+ NOT DETECT   19:32
221 SA1C  NOT DETECT   19:32
221 AO    NOT DETECT   19:32
```

Analyzer problems such as a malfunctioning pump or sampling unit, a column that should be replaced or reagents that are wrongly placed or have run short can also cause abnormal chromatograms with flags or errors.

If it happens, specify the cause and take measures (confirming connections, executing air removal, etc).

6.5 Troubleshooting, too high total area

If a flag 01 "AREA TOO HIGH" was triggered, the sample result that triggered the flag is not reportable.

If an extremely high total area (> 10,000) is observed, the 10 consecutive sample results following the sample that triggered the flag must be discarded because of possible erroneous measurement results due to sample carryover. The samples including the one that triggered the flag should therefore be re-measured after taking the following measures:

(1) Replace the filter.

(2) Put 1 mL of purified water into 5 to 10 sample cups each and set them in a sample rack.

(3) Measure them until a "200 AREA LOW ERROR" is reported with three times of TOTAL AREA < 50. Then, the instrument will enter the WASH process. Remove the sample rack.

(4) Turn off the power of the instrument and turn it on again.

(5) Perform a calibration. Check if QC materials are measured without any problems in results.

6.6 Power Cut

- Planned power cut

—Preparation—

1. Saving parameters to a USB stick (See "**4.10 USB Stick**")
2. After saving, remove the USB stick.
3. Print out parameters stored in the main unit (See "**4.9 Parameter Setting**").
4. Turn the main power off.

—After power outage recovering—

1. Turn the main power on.
2. The analyzer beeps at startup and the backlight on the screen will temporarily dim. Press the POWER key located at the top of the operation key on the right side of the control panel.
3. Check the results of controls or dummy samples to confirm that the analyzer operates normally.

- Unexpected power failure

1. Turn the main power switch off and remove a USB stick. If a power failure occurs during assay, leave the sample rack as it is.
2. After power failure recovering, turn the main power on.
3. The analyzer beeps at startup and the backlight on the screen will temporarily dim. Press the POWER key located at the top of the key sheet on the right side of the control panel.
4. After WARMING-UP operation, confirm there is no sample rack on the sample loader. If there are sample racks, remove them.
5. Check the results of controls or dummy samples to confirm that the analyzer operates normally.

Chapter 7

Appendix

7 Appendix

7.1 Downloading Files from the USB Stick

The analyzer's system program and assay parameters are backed up by the internal battery.

When the system program version has been upgraded or some problem has corrupted the system program, use the following procedure to reload the program and other data from the USB socket.

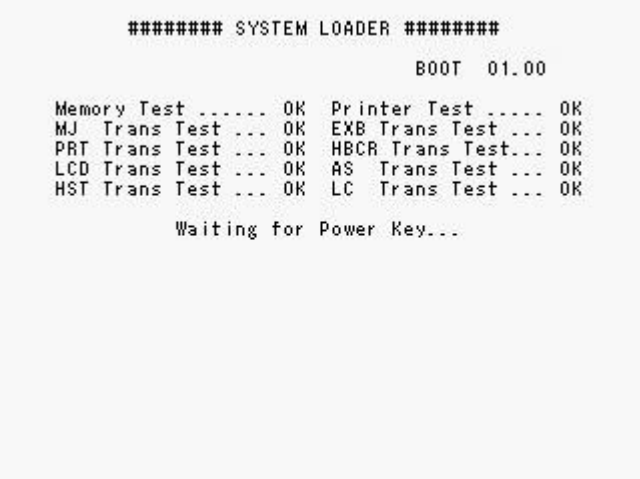
System Program Downloading

Procedure

1. Press the POWER key.
2. Turn off the main power switch of the analyzer.
3. Insert the system USB stick into the USB socket.
4. Turn on the main power switch.
5. Screen 7-1 and Screen 7-2 will be displayed and then the screen will go temporarily dark.

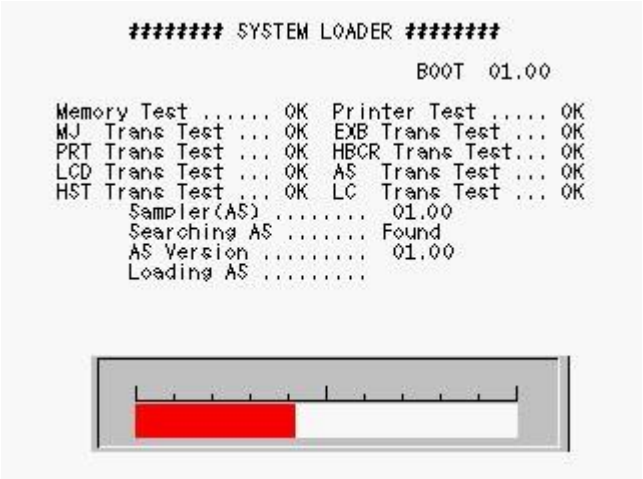
Screen 7- 1 Just after main power is turned on

Screen 7- 2 Just before power key is pressed



6. Press the POWER key.
7. Screen 7-3 will be displayed and the system program is loaded one after the other.
   (This takes about 6 minutes.)

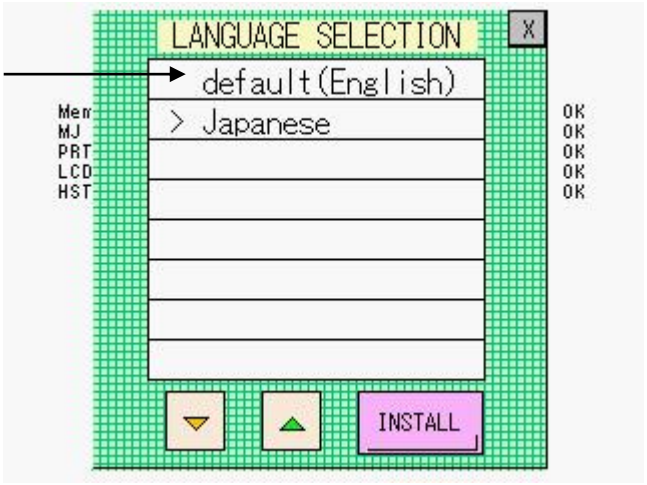
Screen 7- 3 SYSTEM LOADER screen



8. Once the system has been loaded, the LANGUAGE SELECTION screen will be displayed.

Screen 7- 4 LANGUAGE SELECTION screen

Select the "default (English)"

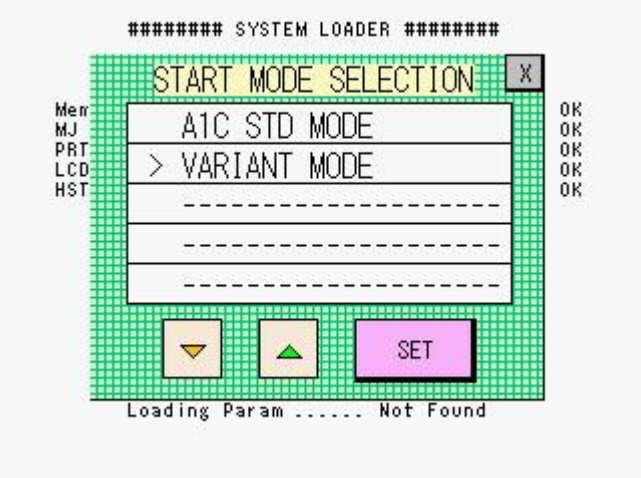


9. Select "default (English)" and press the INSTALL key.
10. When loading is complete, the analyzer automatically starts up and goes in PUMP CLEAN state. After confirming that the analyzer has entered into PUMP CLEAN state, remove the system USB stick from the USB socket.

If the settings of the analyzer have been removed accidentally, Screen 7-5 may be displayed, depending upon the version upgrade contents. If so, continue on to step 11.

11. After Screen 7-4 has been displayed, Screen 7-5 will automatically be displayed.

Screen7-5 START MODE SELECTION screen



12. Check that VARIANT MODE is selected and then press the SET key.
13. The system loader screen appears. When loading is complete, the analyzer automatically starts up and goes in WARMING UP state.

The AS program (filename: **AS.MOT**) and system program (filename: **SYSTEM.MOT**) are required to operate the analyzer. Both of these programs are stored on the accessory system USB stick.

When the main power is turned on, the analyzer searches the files on the USB stick inserted into the USB socket. If the system program is found, it is automatically loaded in the internal memory of the analyzer. During a system upgrade, the assay parameters are overwritten and returned to their initial values. If the assay parameters have been saved beforehand (filename: SYSTEM.PRM) by reloading the saved parameters from it, the analyzer is ready to operate as it has been. To save the assay parameters on a USB stick, see next section.

Assay Parameter Storage and Loading

Procedure

[Storage]

1. Confirm that the analyzer is in STAND-BY state.
2. Insert a formatted USB stick into the USB socket.
3. Press the 

key on the MENU screen.
4. Display PRM SAVE using the 

key.
5. Press the 

key.
6. Confirm that the stored assay parameter file (SYSTEM.PRM) is displayed.

[Loading]

1. Confirm that the analyzer is in STAND-BY state.
2. Insert the USB stick containing the assay parameters (SYSTEM.PRM) into the USB socket.
3. Press the 

key on the MENU screen.
4. Display LOAD using the 

key.
5. Press the 

key.
6. Press the 

key on the message screen.
7. The assay parameters stored in the USB stick will be loaded and stored into the analyzer.

The valid filename for storing/loading the assay parameters is SYSTEM.PRM only. If there already is a SYSTEM.PRM file on the USB stick, it will be overwritten by the new contents when performing assay parameters storage.

Point

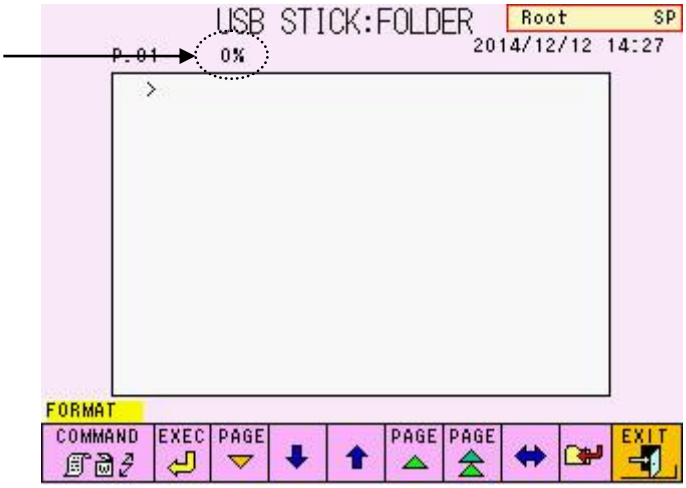
When the analyzer is installed and the assay parameters are set, store the parameter file (SYSTEM.PRM) on the USB stick.
Refer to "4.10 USB Stick" for details.

USB Stick Format

Procedure

1. Confirm that the analyzer is in STAND-BY state.
2. Insert a formatted USB stick into the USB socket.
3. Press the USB STICK key on the MENU screen.
4. Display FORMAT using the COMMAND key.
5. Press the EXEC key.
6. Press the OK key on the message screen.
7. The percentage of the USB stick in use will be 0%.

Screen 7- 6 Just after USB stick is formatted



7.2 Communication with a Host Computer

Results can be sent to a host computer using the RS-232C port. Real-time transfer of each data set (every 1 minute) or batch transfer of the transmitted list data using the recalculation function are both possible.

The outline of the host communications is shown below. Refer to the separate **"Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 Host Computer Connection Specification Manual"** for detailed communication specifications and various settings.
(This manual can be obtained from a Tosoh local representative.)

1. Communication start

When communicating with a host computer, press the 

key on the RS232C screen.

Each time results are output, they will be transmitted in the designated format (real-time transfer).

Batch transmission is possible by selecting TRANS using the 

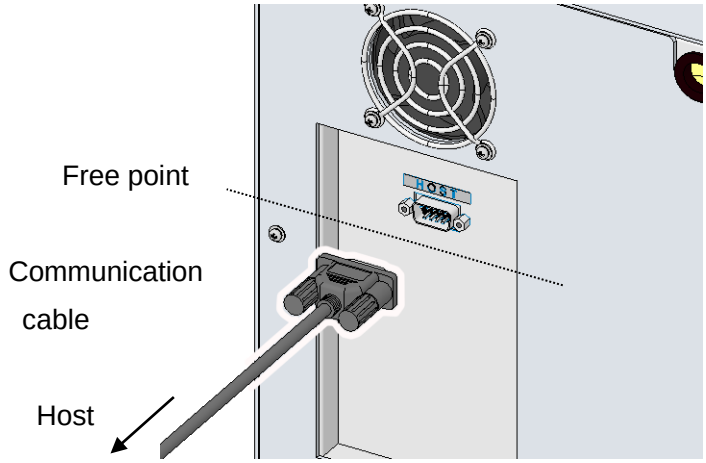
key after designating a data range from the list screen. A specific result can also be designated and re-transmitted from the RECALC screen.

2. Communication specifications

Item	Specification
Transmission method	RS-232C, start-stop transmission, half-duplex
Rate	1200, 2400, 4800, 9600, 19200 bps
Transmitted code	ASCII
Data length	7 bit, 8 bit
Parity	Even, odd, none
Stop bits	1 bit, 2 bit

3. Connection

Fig. 7- 1 Connection the cable



4. Connector

The connector of the communication cable which is connected to the analyzer should be D-Sub 9S (female).

5. Pin Assignment

Analyzer Side Host Side (Ex. 25 pin)

Signal name	Pin No.	Pin No.	Signal name
		1	Frame GND (FG)
Receive data (RxD)	2	2	Transmit data (TxD)
Transmit data (TxD)	3	3	Receive data (RxD)
Data terminal ready (DTR)	4	4	Request to send (RTS)
Signal GND (GND)	5	5	Clear to send (CTS)
Data set ready (DSR)	6	6	Data set ready (DSR)
Request to send (RTS)	7	7	Signal GND (GND)
Clear to send (CTS)	8	20	Data terminal ready (DTR)

6. Communication setting

Refer to the separate "**HLC-723G11 Host Computer Connection Specification Manual**".

7.3 Analyzer Specifications

Main Specifications

Analytes: HbA1c (s-A1c)
Applicable samples: Whole blood and diluted samples
Assay principle: Ion exchange high performance liquid chromatography
Processing throughput: 60 seconds/sample
Detection method: 2-wavelength absorbance
(detection wavelength: 415 nm/ 500 nm)
Sampling unit
Sampling volume: 3 µL for whole blood and 150 µL for diluted samples
Sample rack: 10 primary tubes or cups per rack
Sample loading capacity: 90 samples or 290 samples
Sample aspiration: by Nozzle
Sample injection: Sample loop (5 µL)
Sample dilution: Dilution by Hemolysis & Wash Solution in the dilution port
Sample tubes or cups: 12 to 15 mm diameter × 75 to 100 mm primary tubes
Sample cups
Sample ID recognition: Barcode with maximum of 20 digits
Barcode standards: NW-7 (Codabar), CODE39, ITF
and CODE128 (initial setting),
or JAN (UPC/EAN), Industrial 2 of 5
and COOP 2 of 5 (requires setting change)
Operation unit
Display: 320 × 240 dot matrix color LCD
Input: Pressure-sensitive touch panel / operation keys
Output: Thermal printer
Storage: USB stick
Pump unit: Single plunger pump (Max transport pressure: 20 MPa)
Column Temperature control: Electronic control (Temperature: approx. 25 °C)

Data processing unit

RS-232C serial communication port (bi-directional)

Data storage by internal memory (for up to 800 samples)

Data storage by eternal memory (5 kB/sample in case of FAT32 format)

Recalculation (reprinting) of achieved result

Automatic startup by timer

Error flag function for abnormal results

Calibration: 2-point calibration by calibrators

Power supply / consumption (common to 90SL model and 290SL model):

AC100 - 240 V, 50 / 60 Hz, 200 VA

- EU Area: AC230 V, 50 Hz, 200 VA
- USA and Canada Area: AC120 V, 60 Hz, 200 VA

Main supply voltage fluctuation: Up to ±10 % of the nominal voltage

Operating Environment Conditions

Temperature:	15 °C to 30 °C
Humidity:	40 % to 80 % R.H. (without condensation)
Over voltage category:	II
Pollution degree:	2
Altitude:	Up to 2,000 m
Mains power quality:	Typical commercial or hospital environment
Dust:	Typical office level
Others:	Indoor use

Dimensions (prongs not included)

Main unit and 90SL combination:	530 (W) × 515 (D) × 482 (H) mm
Main unit (LA type) and 90SL combination:	560 (W) × 725 (D) × 482 (H) mm
Main unit and 290SL combination:	1120 (W) × 530 (D) × 482 (H) mm

Weight

Main unit:	Approx. 29 kg
Main unit (LA type):	Approx. 31 kg
Sample Loader 90SL:	Approx. 8 kg
Sample Loader 290SL:	Approx. 25 kg

Standard Conformity

Safety standard: IEC61010-1: 2010 / EN61010-1: 2010
IEC61010-2-101: 2002 / EN61010-2-101: 2002
UL61010-1

EMC standard: IEC61326-2-6: 2012 / EN61326-2-6: 2013

Barcode Reader:

IEC60825-1: 1994 +A1: 2002 + A2: 2001, Class 1 LED Product

Barcode Scanner (an Optional component):

EN60825-1: 2007, Class 1 Laser Product

Laser barcode reader (an Optional component):

EN60825-1: 2007, Class 2 Laser Product

Note

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