

Tosoh Automated Glycohemoglobin Analyzer

**HLC-723<sup>®</sup>G8**  
**Operator's Manual**  
**(Variant Analysis Mode)**  
**Revision J**

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**

## Introductions

Read these safety precautions before use and handle the analyzer properly and be sure to follow the instructions stated here for safe operation.

The meanings of WARNING and CAUTION are as follows:



### 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.

## During installation



### WARNING

- **Connect an appropriate power source**
  - Connect to the power supply which gives sufficient power capacity and little voltage variation.
  - Fire may occur if the power capacity is insufficient or if the voltage exceeds the specifications.
- **Check the grounding connection**
  - Electrical shocks may result if the grounding is incomplete.
  - Be sure to connect the system to a three-pin power socket.
  - In addition to preventing electrical shocks, the grounding also prevents loss of sensitivity because of noise and analyzer malfunctions.
  - Do not connect the grounding line to gas pipes, water pipes, lightning rods, or telephone grounding lines.

Gas pipes: May cause explosions or fires

Water pipes: Do not sufficiently work as grounds

Lightning rods and telephone grounding lines:

Dangerous when struck by lightning

**CAUTION**

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- **Carefully select the installation location**
  - Refer to "Chapter 2, Section 2.4 Installation locations" in this manual and select an appropriate location for installation.
- **Do not change the power cord, nor use an extension cord, nor plug many cords into the same socket.**
  - The above use may cause fires or electrical shocks.
  - Make sure to remove dust clung to the plug and firmly insert the plug down to the bottom with no looseness.
  - Dust clung to the plug or looseness between plug and socket may cause fires or electrical shocks.

During use

**WARNING**

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- **Take great care to prevent infections**
  - We strongly recommend that the operation be executed only by those persons with full knowledge of clinical tests and how to handle potentially infectious materials.
  - Blood to be tested might have been infected by pathogens. Misconduct on operation may cause infection in the operator or others working together. During operation take great care in handling test samples and use protection such as glasses, gloves, mask to prevent infection.
  - Used column, filter, sampling needle and vial may have been contaminated with infectious materials. To dispose of these units and samples, follow the instructed procedure in compliance with regulations on medical wastes.



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**CAUTION**

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- **Do not operate in any other way than instructed in this manual.**
  - This may cause troubles such as disorder or injury or inaccurate result.
- **Check for eluent leakage**
  - Leakage of Elution Buffer or Hemolysis and Wash solution may cause fires, electrical shocks or corrosion.
  - When an eluent leakage is found, stop the operation and unplug the power cord. Then, put on appropriate protection, wipe off the eluent and take measures to stop the leakage by checking the tube connections.
  - Contact your local Tosoh service when a leakage cannot be stopped.
- **When a problem occurs '(burning smell, etc.), immediately stop operation, disconnect the power plug and contact a local service.**
  - Fires and electrical shocks may occur if operation is continued under such a condition.
- **Do not place fingers, rods, or other objects into moving or driving units during operation.**
  - The motor is running inside the unit. Fingers or other objects may get caught and get injured.
- **Close the cover and door during operation.**
  - Keep the cover and front door closed during operation. The interior of the analyzer contains various moving parts, high-temperature units and high-voltage circuitry, which may cause the operator to get caught, burned, shocked or otherwise injured.
  - Moreover, do not try to place any additional sample rack or sample during operation except for STAT port.
- **Do not operate and stop assay by plugging and unplugging the power cord.**
  - This may cause fires or electrical shocks.
  - Never fail to use the POWER KEY located on the front face or the main power switch on the left side of the analyzer.

**CAUTION**

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- **Do not damage the power cord.**
  - If the power cord is forcefully pulled, bent or fixed, it may cause fires or electrical shocks.
  - When unplugging the power cord, be sure to do so holding the plug itself.
  
- **Do not touch the analyzer with wet hands.**
  - It may cause electrical shocks.
  
- **Those who are not trained with this analyzer must not perform any operation required to maintain the unit.**
  - It may cause infection by injury or blood samples infected by pathogens unless he/she understands what procedure is required such as putting on protection (glasses, gloves, mask) during the daily maintenance.
  - When replacing the sampling needle, it may damage the unit if the needle is moved forcefully without unplugging the power cord. Unplug the power cord before conducting any maintenance.
  - If you have any question about maintenance, contact your local service.
  
- **Dispose properly of the waste**
  - The waste such as used sample vials, filters, columns and buffers accompanied with assay should be properly handled. When handling these, put on protection like gloves and do not touch them directly. Dispose of these properly in accordance with laws or regulations of medical waste not to damage the environment or health.
  
- **Put on protection**
  - When handling samples, waste, calibrators and so on, put on protection such as glasses, gloves and mask to prevent infection.
  
- **In the case of assaying centrifuged samples, please centrifuge them at less than 500 G/ 5 min.**

**CAUTION**

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- **Do not place any reagents outside the designated place for the unit.**
  - If the reagent leaks into the unit, it may cause short circuit or poor electrical insulation or electrical shocks.
- **Use the designated parts mentioned in this operator's manual.**
  - For the consumables and spare parts, use the parts listed in this operator's manual.
- **For diagnostic purposes, the results obtained from this assay should be used in conjunction with other data (e.g. symptoms, results of other tests, clinical impressions, therapy, etc.)**

**Removal of analyzer from use for repair or disposal**

**WARNING**

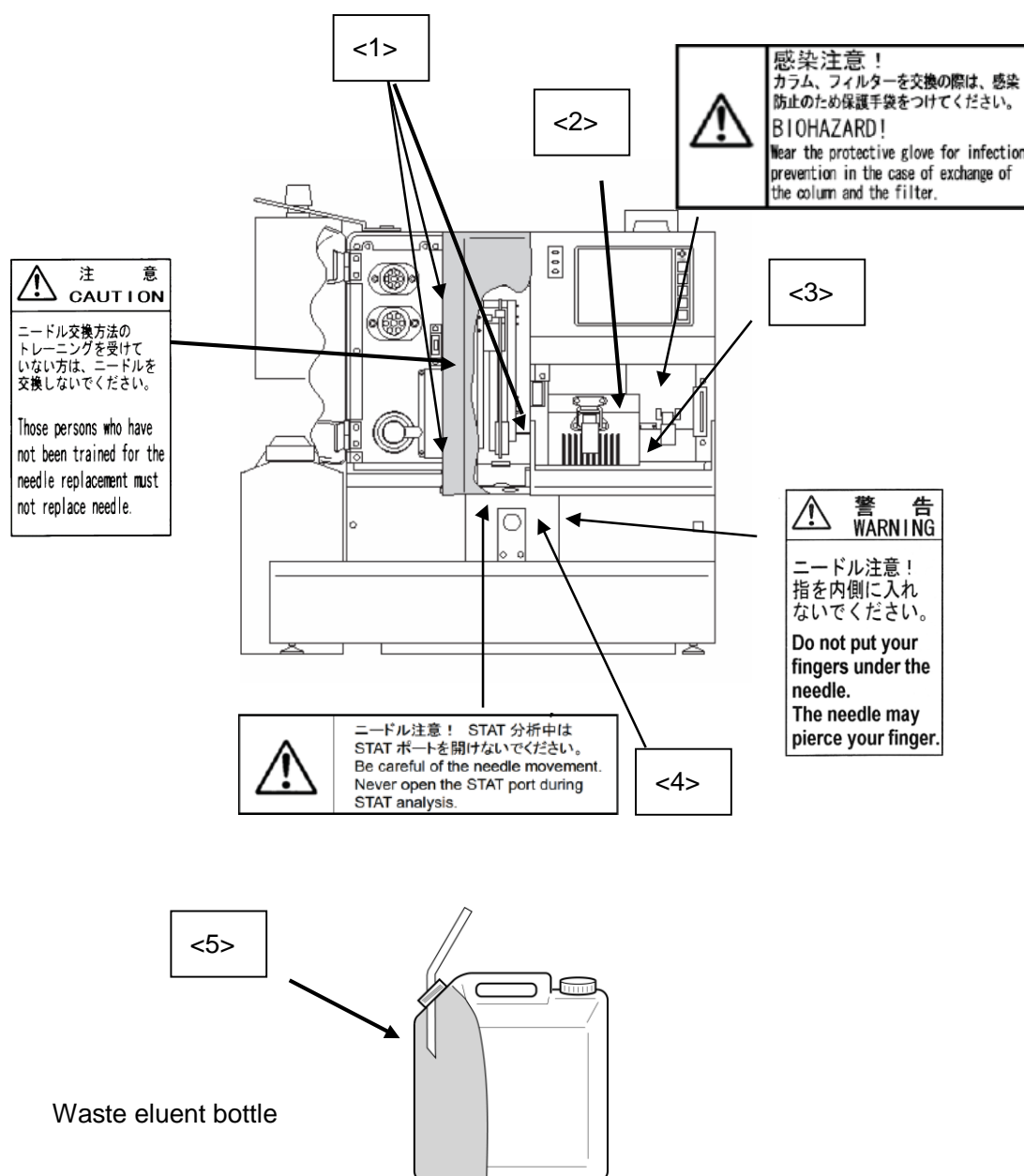
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- **Contact the authorized representative**
  - Blood to be tested might have been infected by (a) pathogen(s). Misconduct on repair or disposal of the analyzer may cause infection in you or others working together. In the case of repairing or disposing of the analyzer, please contact the authorized representative.

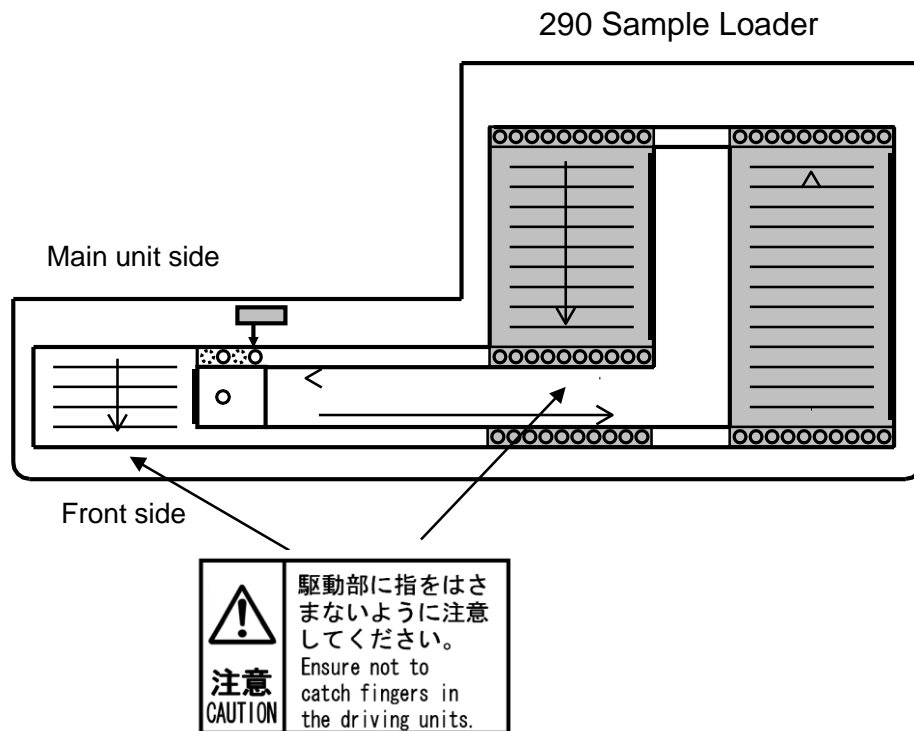
## Other precautions

- The warning labels are attached to the analyzer. Read the instruction thoroughly and follow them.

### Warning and caution labels attached



Caution labels attached



<1> Needle Cover Caution Label



Sampler mechanism.  
 Don't open this cover except maintenance.  
 Turn off the main power before opening the instrument.

<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> 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.

## &lt;4&gt; 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.

## &lt;5&gt; Waste Eluent Bottle Biohazard Label



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

- If the warning or caution labels have become faded, have dropped off or become illegible, contact your local Tosoh representative.
- Keep this manual with the instrument so that you can read it when necessary.

Symbols on the product labels

European Conformity



Manufacturer

Authorized  
representative in the  
European CommunityCatalogue number  
/ Part numberIn Vitro diagnostic  
medical device

Supplied by

Serial number /  
Column number**— Copyrights —**

- Copying or reprinting all or a part of this manual without the manufacturer's written approval is prohibited.
- The content of this manual is subject to change without notice.

**For repair, contact your local authorized Tosoh representative**

- Fires, electrical shocks and other problems may occur if the instrument is disassembled, repaired or remodeled by yourself.

TOSOH CORPORATION

# BIOSCIENCE DIVISION

## How to Use This Manual

This HLC-723G8 Operator's Manual is designed to ensure you will have the information you need to use and operate the HLC-723G8 system safely and correctly. This manual is organized according to the layout shown below. Use this as a reference when reading this manual.

**Section Heading**

Sections are divided into 3 subsections.

**Illustration**

Provided for your clear and precise understanding of the text.

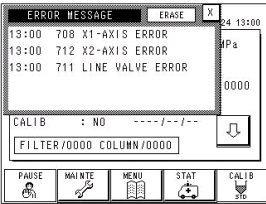
Rev. C CHAPTER 3 ASSAY OPERATIONS

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**3.9 Clearing Errors**

If an error occurs, a buzzer will sound and an error message will be displayed on the screen. The error LED (red) will illuminate on the left side of the screen.

**Screen 3-13 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 and the error LED will turn off.
2. Close the error message screen.

Make sure to confirm the cause of the error before clearing it. See **"Chapter 6: Troubleshooting"** for further details.

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**Page**  
numbered by chapter



Stop sign warns potential operational mistakes.



Key Point provides helpful hints for mastering system operations.

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# NOTE

## 1.1 Overview

The HLC-723G8 is intended to assay  $A_{1c}$  (% 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  $A_{1c}$  every 1.6 minutes with sampling and dilution. In addition to  $A_{1c}$  ( $HbA_{1c}$ ), both  $HbA_1$  and hemoglobin F ( $HbF$ ) can be measured.

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 G8.

You must use the specialized column, elution buffer, and Hemolysis and Wash solution dedicated to this system. No other column or reagents will work. Let us remind you that it's not our responsibility if you use any other column or reagent than ours on this system.

Dedicated column for the Tosoh Automated Glycohemoglobin Analyzer

HLC-723G8:

TSKgel G8 Variant HSi

Dedicated reagents for the Tosoh Automated Glycohemoglobin Analyzer

HLC-723G8:

G8 Variant Elution Buffer HSi No.1 (S)

G8 Variant Elution Buffer HSi No.2 (S)

G8 Variant Elution Buffer HSi No.3 (S)

HSi Hemolysis & Wash Solution (L) and (LL)

## NOTE

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

The service person 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 person 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 sample loaders are available, 90SL with 9 racks and 290SL with 29 racks. Each component comes with the accessories indicated below. Verify that all accessories are present.

1) Main Unit (HLC-723G8)	
- Power Cord for the Main Unit 2 m.....	1
- Waste Bottle 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
- Screw Driver (+) 100 mm.....	1
- Hex Wrench 9/64".....	1
- Hex Wrench 3 mm.....	1
- Hex Wrench 2.5 mm.....	1
- Sample Vial.....	20
- Printer Paper (Thermal paper roll).....	1
- System external storage device.....	1
(Smart Media card or USB stick)	
- Holder for reagent pack.....	1
- 4 L Bottle Cap.....	1
- Accessory box.....	1
- Handy connector.....	1
- Adaptor for $\phi 12$ .....	1

<b>1) 90 Sample Loader (G8-90SL)</b>	
- Sample Rack (TOSOH).....	9
- Vial Adapter.....	10
- End Marker for 90SL.....	2
- Mounting Screw.....	4
<b>2) 290 Sample Loader (G8-290SL)</b>	
- Sample Rack (TOSOH).....	30
- Vial Adapter.....	10
- End Marker for 290SL.....	2
- Mounting Screw.....	4

### 3) Optional and Separately Sold Products

#### - Column, Reagents

Part Number	Part Name	Description	Unit
0021848	TSKgel G8 Variant HSi	1 piece	1 box
0021849	G8 Variant Elution Buffer HSi No. 1 (S)	800 mL x 10 packs	1 box
0021850	G8 Variant Elution Buffer HSi No. 2 (S)	800 mL x 10 packs	1 box
0021851	G8 Variant Elution Buffer HSi No. 3 (S)	800 mL x 10 packs	1 box
0018431	HSi Hemolysis & Wash Solution (L)	2000 mL x 5 bottles	1 box
0019550	HSi Hemolysis & Wash Solution (LL)	4000 mL x 2 bottles	1 box
0018767	Hemoglobin A1c Calibrator Set	CAL(1), (2) (4 mL) x 5 each	1 box
0021974	Hemoglobin A1c Control Set	Level 1, 2 (0.5 mL) x 4 each	1 box
0023528	G8 HbA1c Calibrator Set (S)	CAL(1), (2) (1 mL) x 4 each	1 box
0023503	HbA1c Diluting Solution	100 mL x 2 bottles	1 box

- There is no expiration date set for the column (part number: 0021848)
- The expiration dates for other reagents are noted on their product labels.

#### - Consumables

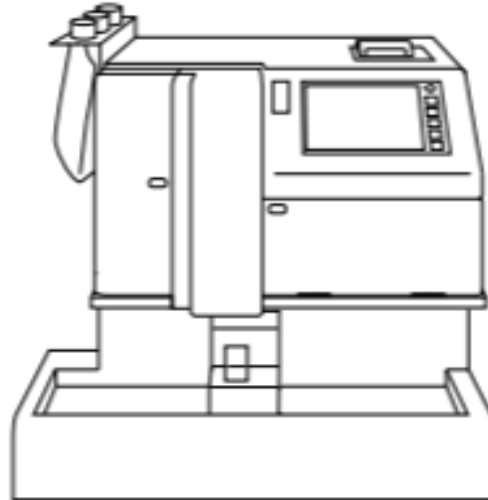
Part Number	Part Name	Description	Unit
0021600	Filter Element	5 pieces	1 bag
0019508	Sample Vial	500 vials	1 bag
0019563	Printer Paper	10 rolls	1 box
0017092	Needle Wash Block O-ring	5 pieces	1 bag
0018517	Plunger Seal	1 piece	1 bag
0018723	Suction Filter	1 piece	1 bag
0019500	Sample Needle Assembly	1 piece	1 box
0005952	Injection Valve Rotor Seal	1 piece	1 bag
0018718	Teflon® Tip (for 250 µL syringe)	2 pieces	1 bag
0019515	Teflon® Tip (for 5 mL syringe)	2 pieces	1 bag
0019495	AS Valve Rotor Seal	1 piece	1 bag
0021601	Sample Loop	1 piece	1 bag

#### - Optional Products

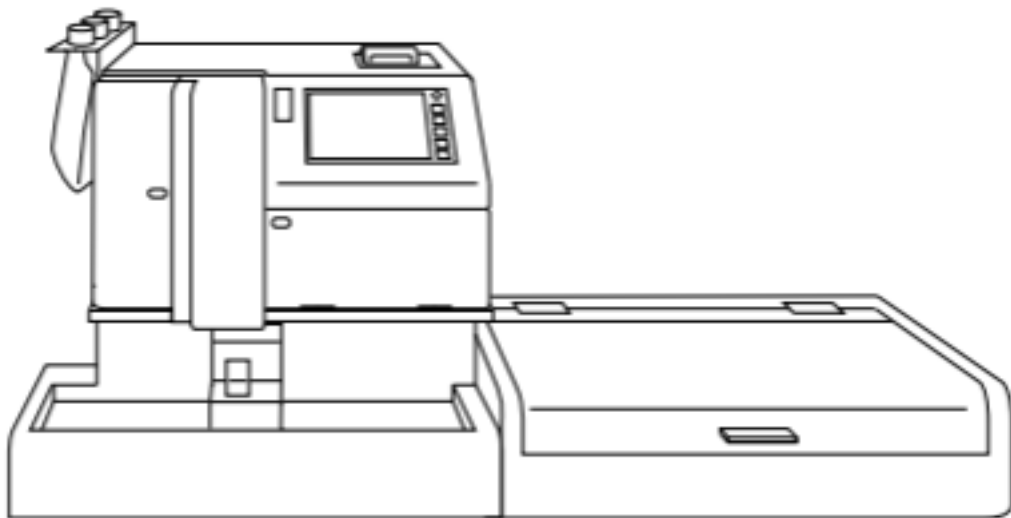
Part Number	Part Name	Description	Unit
0016320	Waste Eluent Bottle	10 L	1 bottle
0021641	Silicone Tube	15 m for waste fluid	1 piece
0021639	TOSOH Sample Rack	1 piece	1 bag
0018432	Sample Rack (without adapter) SYSMEX® 424-3303-3	1 piece	1 bag
0018433	φ13 adapter for SYSMEX® sample rack	10 pieces	1 bag
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
0018806	Elution Buffer Cap O-ring	5 pieces	1 bag
0019509	Vial adapter for SYSMEX® sample rack	10 pieces	1 bag
0020101	Vial adapter for TOSOH sample rack	10 pieces	1 bag

## 2.2 Analyzer Configuration

**Fig. 2-1 External Appearance (G8 90SL model)**

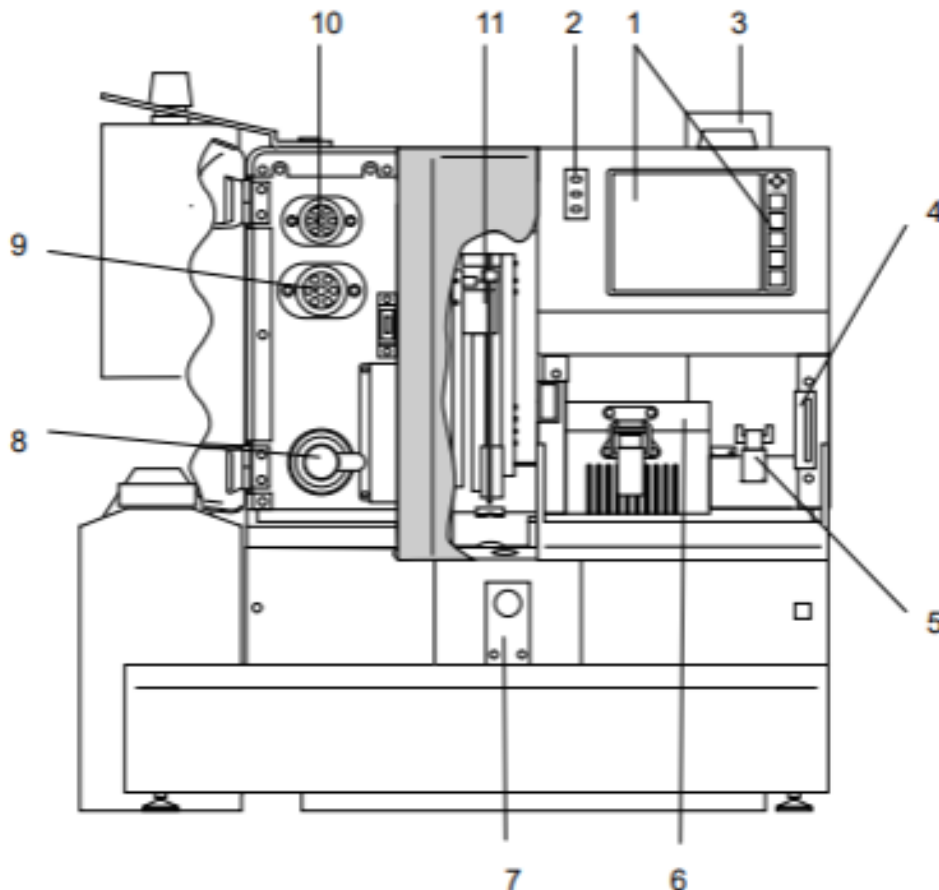


**Fig. 2-2 External Appearance (G8 290SL model)**



## 2.3 Units and Functions

Fig. 2-3 Front View (unit location)



1. Operation panel

The operation panel is a monochrome LCD with touch keys. The operation is controlled through the touch keys on the screen. 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 paper roll is thermal-sensitive. It prints out assay results, error messages and parameter status. The assay results can be printed out in three different formats. A roll can handle about 350 sample results depending upon the format.

### 4. Storage device

The analyzer is equipped with an internal Smart Media socket or an internal USB Socket. Use an external storage device corresponding to each socket.

It is used to store assay results, update and backup program versions.

When a USB Stick is used, the format usable in the analyzer is FAT32.

The number of sets of assay results that can be stored in the formatted external storage device is as follows.

Smart Media card (32MB, FAT): A maximum of 12,000 sets of assay results (but up to 500 days, even though less than 12,000 assay results)

USB stick (1GB, FAT32): A maximum of 240,000 sets of assay results (but up to 500 days, even though less than 240,000 assay results)

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



1. Only insert an external storage device corresponding to the internal Smart Media socket or the internal USB socket.
2. The capacity of a Smart Media card that can be used is 128 MB or less.
3. A USB stick that has a security function cannot be used.
4. The number of assay results that can be saved differs depending on the formatting method and the type of files saved together. The format of data used by other applications or the format of brand new external storage device may differ, thus reducing the number of assay results that can be saved. Prior to use, we recommend formatting the external storage device with the analyzer or a Windows-based PC. External storage Devices formatted by the analyzer can also be used on a PC.

### 5. Line filter

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

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6. Column oven

The column oven contains the column, a critical component in assaying. The column must be kept at a constant temperature at all times to prevent temperature fluctuations that affect the test results. The column oven maintains a constant temperature so that no wait time is required prior to starting an assay, unless the main power switch (side breaker) is turned off. The column can be manually connected. This allows the column to be easily replaced without using any special tools.

7. STAT port

Place priority samples here. The port can handle dedicated sample vials and primary tubes (75 mm).



100 mm primary tubes cannot be used.

8. Drain valve

If an air bubble enters the pump, open this valve to expel the bubble with a drain flush. Do not open this valve during an assay.

9. Injection valve

This valve is used to inject a sample into the assay line after sample dilution. The sample loop volume is 4  $\mu$ L.

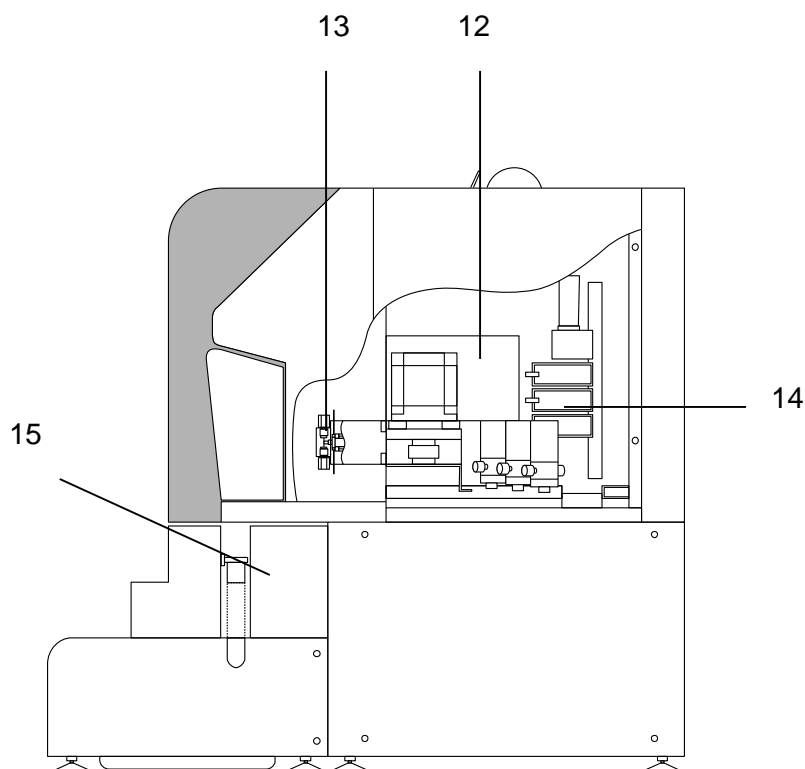
10. Rotary valve

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

11. Sampling mechanism

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

When a query is requested from the host computer, (hereinafter, "host"), you can select and assay only the sample for which a query has been requested, skipping the others.

**Fig. 2-4 Right Side View (unit location)****12. 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 detector and column temperatures are both controlled by the column oven.

**13. 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 different concentration elution buffers in 1.6-minute cycles by switching the solenoid valves. It also forms a gradient (concentration control), and the hemoglobin fractions are separated by the column.

**14. Degassing unit**

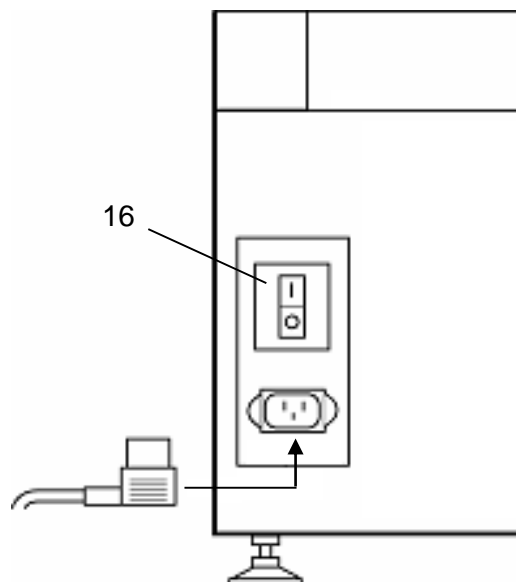
The degassing unit removes air bubbles in the pumped elution buffer. The vacuum pump runs intermittently to keep a constant vacuum pressure in the chamber.

**15. Bar code reader**

The bar code reader reads the bar code 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 bar code. When you are using a sample vial, attach a bar code label on a vial adapter, set the adapter in the rack, and place the sample vial in the adapter.

**16. Main power switch**

The main power switch is located above the AC inlet, on the left side rear of the main unit. 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.

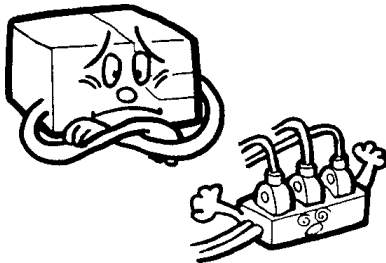
**Fig. 2-5 Left Side Rear**

## 2.4 Installation Locations

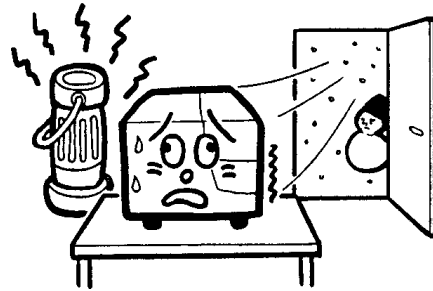
### Installation Location

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

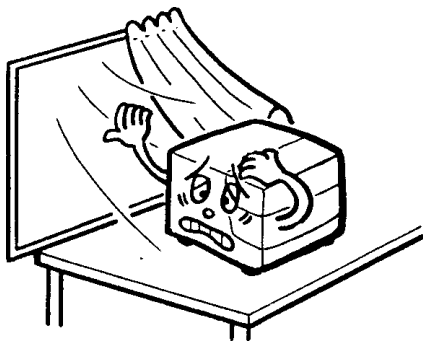
- Locations with large fluctuations in the power source



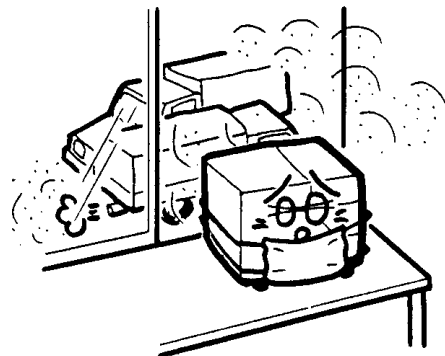
- Locations with rapid temperature changes



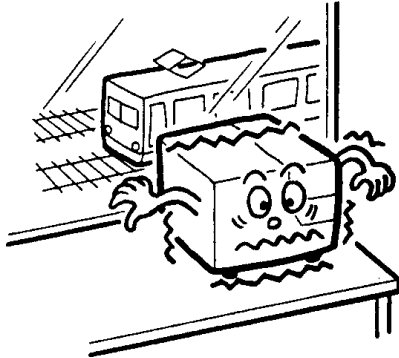
- Locations in the path of direct air currents



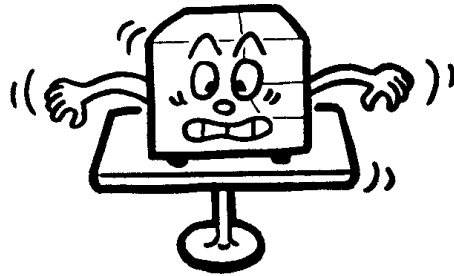
- Locations with large amounts of dust or dirt



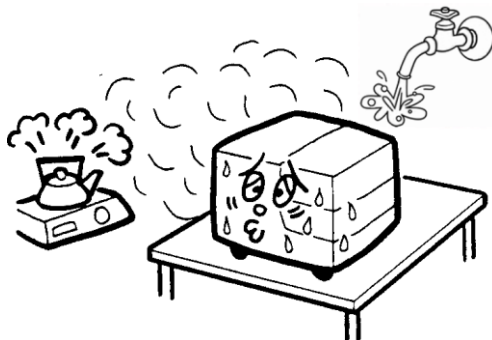
- Locations with excessive vibration



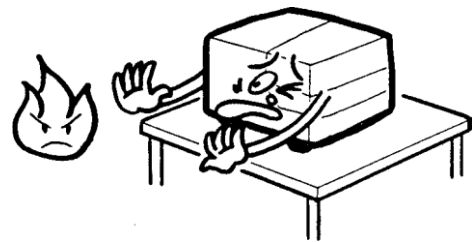
- Unstable locations



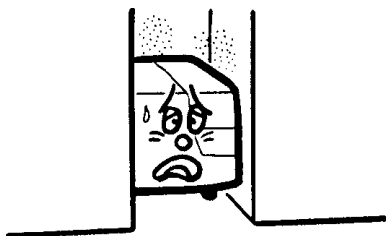
- Locations with high humidity (> 80 %)
- Locations near water sources, such as a sink



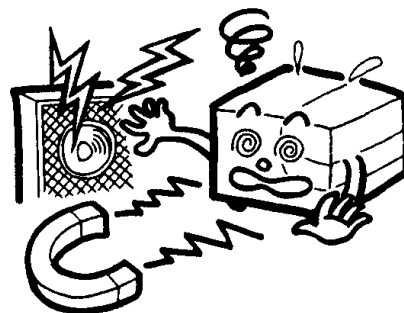
- Locations with a flame nearby



- 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 ~ 30 °C
Humidity:	20 % ~ 80 % (no condensation)
Dust:	About the quality in an office
Maximum Altitude:	2,000 m



Caution

**Do not use in an environment with drastic temperature differences. Such an environment can cause condensation to form, resulting in short circuits or improper functioning.**

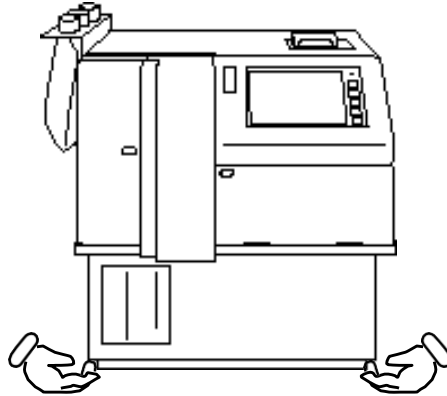
### Environment of Transportation and Storage

Transport and store the instrument under the following conditions if it is to be moved.

Temperature:	5 °C ~ 50 °C
Humidity:	80 % or less (no condensation)
Other:	Keep dry and store indoors

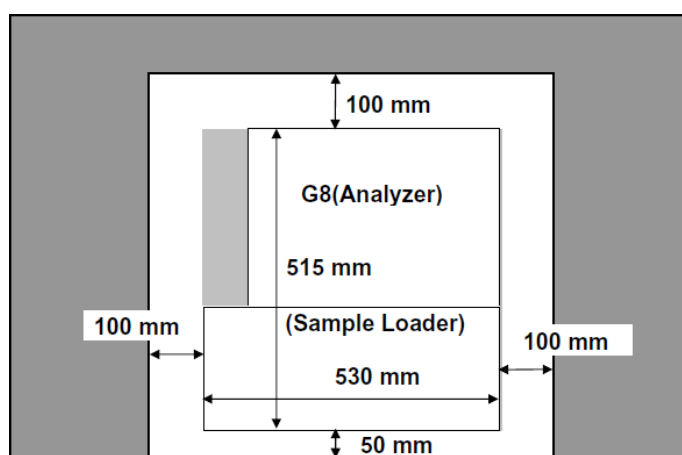
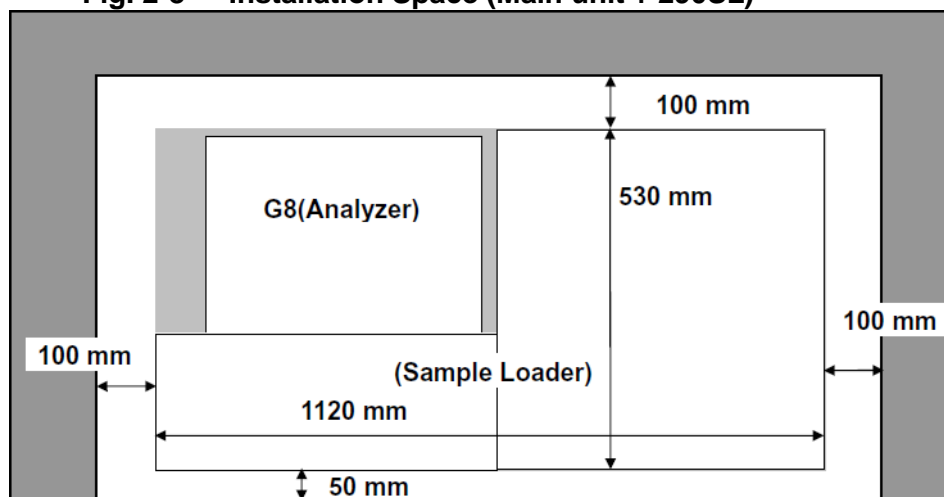
The analyzer should only be moved by two or more people using both hands to grasp the bottom section of the analyzer (**Fig. 2-6**).

**Fig. 2-6 Where 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.

**Fig. 2-7 Installation Space (Main unit + 90SL)****Fig. 2-8 Installation Space (Main unit + 290SL)**

## 2.5 Connections

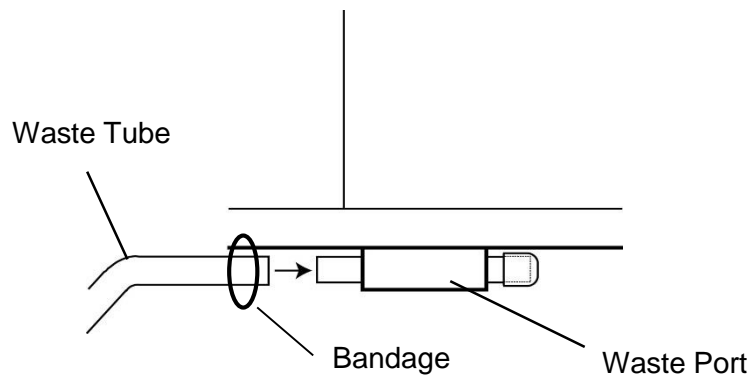
### Waste Tube

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.

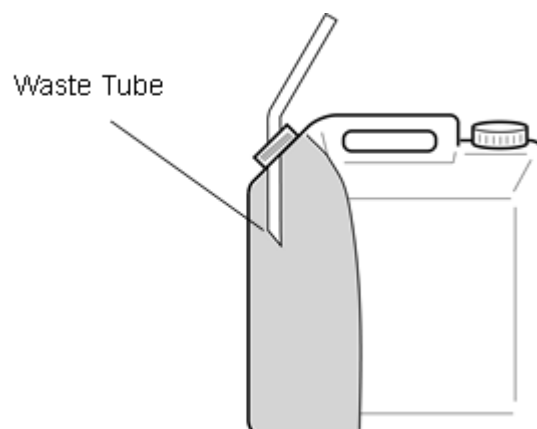
Insert the other end of the tube into the waste bottle. (Refer to **Fig. 2-10**)

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

**Fig. 2-9 Waste Tube Connection**



**Fig. 2-10 Tube Insertion into Waste Eluent Bottle**



When changing the analyzer location, make sure that the tube is not loose, broken or bent and that the waste eluent drains out smoothly.

The sample loader must also be temporarily disconnected when changing the analyzer location. Please contact the authorized representatives first.



1. If the waste tube is bent and waste eluent cannot smoothly drain, the sample dilution may not be accurately executed during the assay.
2. Keep the waste tube end above the top of the waste eluent.

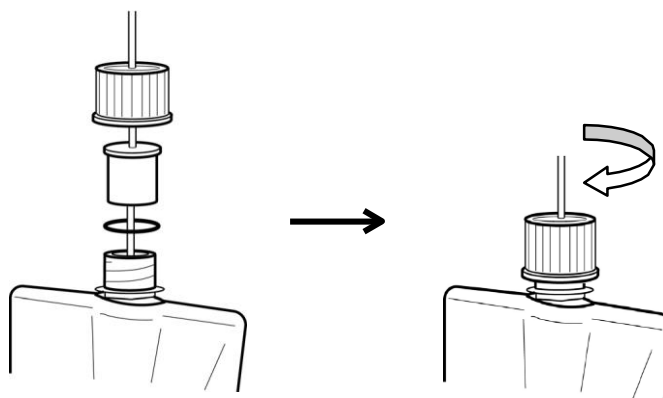
**Elution Buffer Tube (Suction Tube)**

Match the color marks of the elution buffer tube with the same color on elution buffer pack No. 1, 2, and 3, and then insert the tube into the aluminum pack and seal by closing the bottle cap squeezing all air out of the pack.

Elution Buffer No. 1: **green**  
Elution Buffer No. 2: **red**  
Elution Buffer No. 3: **yellow**

The suction filter is attached to the end of each elution buffer tube. If the tube is bent, straighten it out before connecting it and make sure it reaches the bottom of the aluminum pack.

**Fig. 2-11 Suction Tube Connection (Aluminum Pack)**



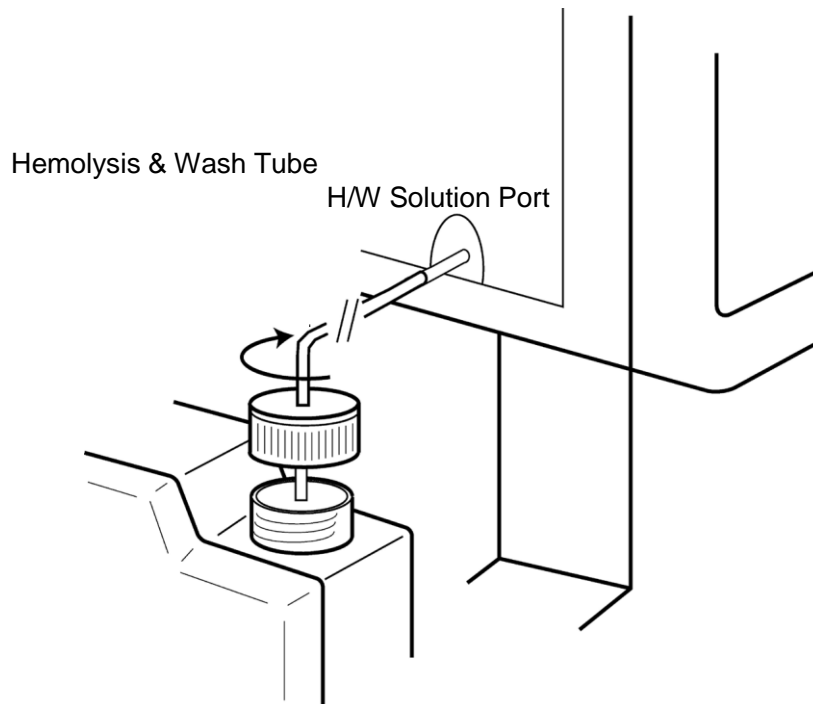
For aluminum pack reagents, squeeze the pack manually to remove as much air space as possible, and then firmly close the bottle cap. If the cap is loose, the elution buffer may deteriorate. It will also become difficult to check the remaining volume visually.

### Hemolysis & Wash Solution Tube

Open the Hemolysis & Wash (H/W) solution cap and insert the Hemolysis & Wash solution tube (with anchor and bottle cap) into it and tighten the bottle cap. The Hemolysis & Wash tube is sticking out of the H/W Solution port on the left side of the main unit. Make sure that the anchor has reached the bottom of the bottle.

If you are using a 4-L bottle of Hemolysis & Wash solution (LL), use the specialized bottle cap for LL provided as a standard accessory.

**Fig. 2-12 Hemolysis & Wash Solution Tube Connection  
(main unit and bottle connections)**



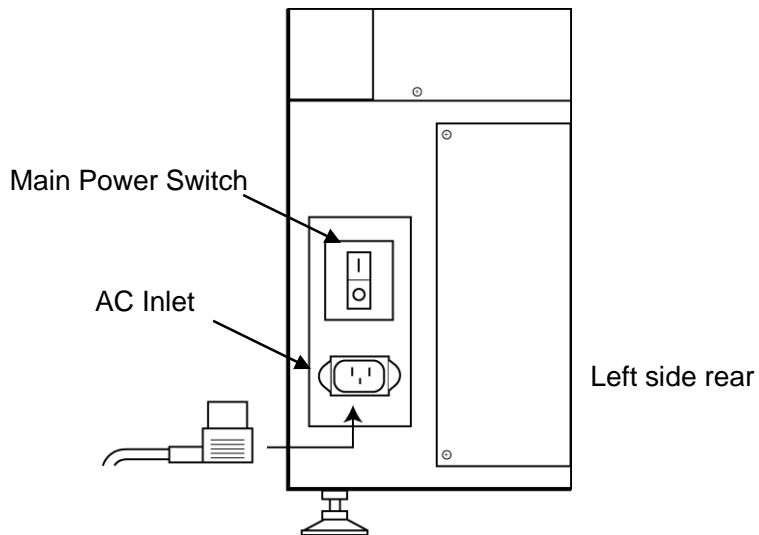
**Power Source**

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

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

The socket's power capacity must be 10 A and above. Be sure to connect the unit to three-pin power socket

**Fig. 2-13 Power Cord Connection**



- 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 during an emergency, do not place anything in front of the switch.
  5. Leave enough space to allow the power cord connector to be unplugged from the AC inlet.
  6. Never insert too many power cords into the same socket. Never use with an extension cord.

## 2.6 Column

The dedicated column for HLC-723G8 is the TSKgel G8 Variant HSi.

Never use the column with any other instrument than G8.

Refer to the instruction manual included with the column, and to "**Chapter 5, Section 5.6 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 your local representative.

Next, confirm that the following inserts are included with the column.

- Instructions For Use 1
- Inspection Report 1

### Column Connection

#### Procedure

- 1) Take the column out of the box and remove the protective plugs on both ends. Do not throw away these plugs, as they are needed for storage.
- 2) 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.
- 3) Press the arrow key located on the lower right side of the screen. The key for manual eluent delivery is displayed. Use the key to run the pump and confirm that eluent is being delivered from the column flow line end. Use 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.
- 4) Verify the proper column flow direction (which is stated on the label, (➡) direction) and connect the flow line to the inlet side of the column. Use the screen key to run the pump and verify 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.

- 5) Use the screen key to start the pump again, verify that the pressure is rising quickly and that there is no leakage at the flow line connection. After that, stop the pump and close the column oven.
- 6) Select the REAGENT key from the MAINT screen, press the COL.RESET key, and reset the column counter to zero.

### Column Use Cautions

- 1) Be sure to carefully read the instructions contained in this manual and related instructions provided in the G8, G8 Variant Elution Buffer HSi and HSi Hemolysis & Wash Solution manuals.
- 2) The TSKgel G8 Variant HSi is designed exclusively for use in combination with the analyzer system, elution buffers and hemolysis wash solutions listed below, never in any other combinations.
  - Tosoh Automated Glycohemoglobin Analyzer HLC-723G8
  - G8 Variant Elution Buffer HSi (No. 1, 2 and 3 (S))
  - HSi Hemolysis and Wash Solutions (L), (LL)
- 3) When changing column, be sure to assay dummy samples several times and check the chromatogram results.
- 4) Always use the TSKgel G8 Variant HSi in combination with the G8 Variant Elution Buffer HSi of the identical lot number. The column lot number is indicated by a single uppercase alphabetical character (A, B, etc.) on the label of column box.

The elution buffer label displays an alphabetic character corresponding to column lot number, as shown below.



- 5) Care must be taken to ensure that the solutions are delivered only in the direction indicated by the arrow on the name plate on the column being used.
- 6) In cases in which the column is not used for more than one week, remove the column from the analyzer unit, reattach its protective plugs to protect it from drying out and store in cool dark place at 4 to

15 °C.

- 7) Please do not bump or shake the column.
- 8) If the pressure is more than the pressure (which is indicated on the column inspection report) +4 MPa, first replace the line filter. If the pressure still does not drop, replace the column.

**NOTES**

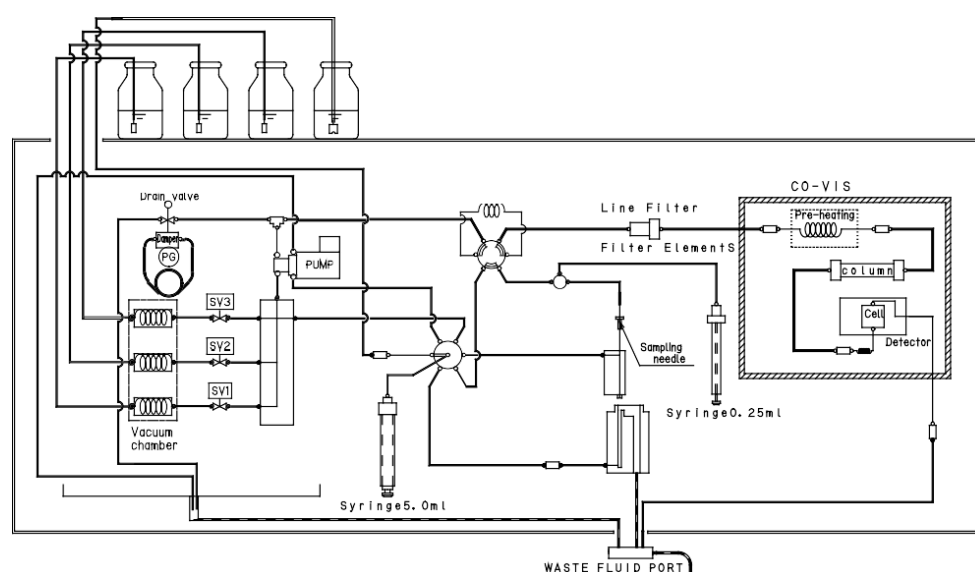
### 3.1 Assay Principles

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 components of hemoglobin, including hemoglobin A<sub>1c</sub> are quickly (1.6 min per sample) separated into 6 fractions and assayed. A step gradient with three different salt concentrations (G8 Variant Elution Buffer HSi No. 1, No. 2 and No. 3) is used for separation.

**Fig. 3-1** shows the flow path of the main unit. 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  $\mu$ L 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.

**Fig. 3-1 Flow Path Diagram**



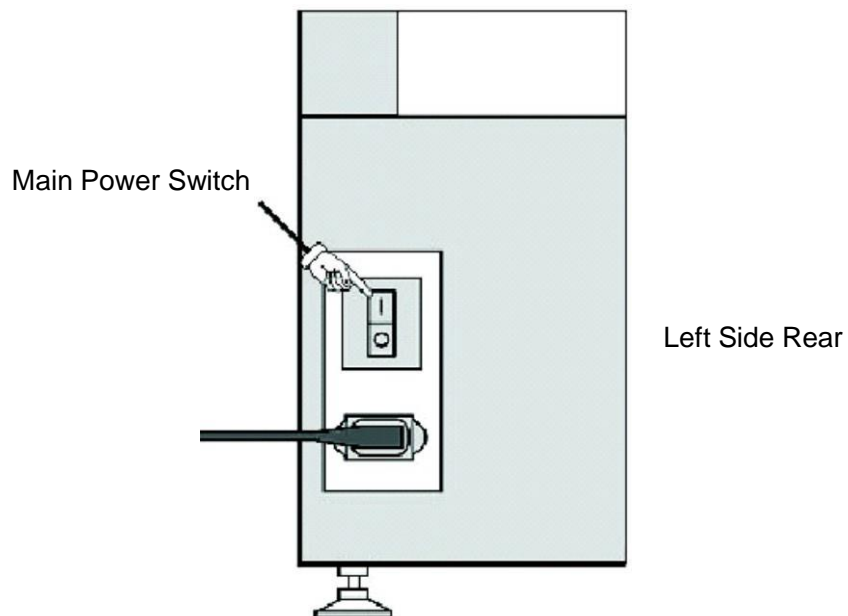
## 3.2 Power On

### Turning Main Power On

The main power switch of the analyzer is located at the back of the left side, just above the AC inlet.

The side marked “I” indicates power on, and the side marked “O” indicates power off.

**Fig. 3-2 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 cord from the power socket and contact a service representative.



**Caution** Do not touch the power source, sheet 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 external storage device in advance in order to read the system program.

If the system has been already installed, please make sure that there is no external storage device in the storage device socket or a storage device 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



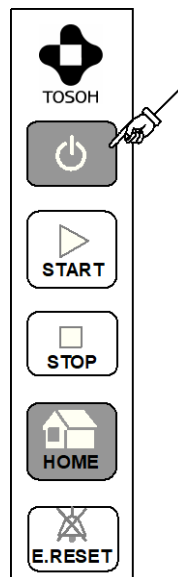
**Screen 3-2 Display after main power is turned on,  
before the Power Key is pressed (normal operation)**

```
##### SYSTEM LOADER #####  
                                BOOT 01.00  
Memory Test ..... OK  Printer Test ..... OK  
MJ Trans Test ... OK  EXB Trans Test ... OK  
LCD Trans Test ... OK  AS Trans Test ... OK  
HST Trans Test ... OK  LC Trans Test ... OK  
  
Waiting for Power Key...
```

2. Please make sure that there is no external storage device in the storage device socket or a storage device for saving the results is installed in the socket before startup. If a system external storage device 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 key sheet on the right side of the control panel.  
The POWER LED on the left side of the control panel will illuminate when the key is pressed.

**Fig. 3-3 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 On and Before System Startup**

(Normal operating status when system external storage device is not read)

```

##### SYSTEM LOADER #####
                                BOOT 01.00
Memory Test ..... OK  Printer Test ..... OK
MJ Trans Test ... OK  EXB 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

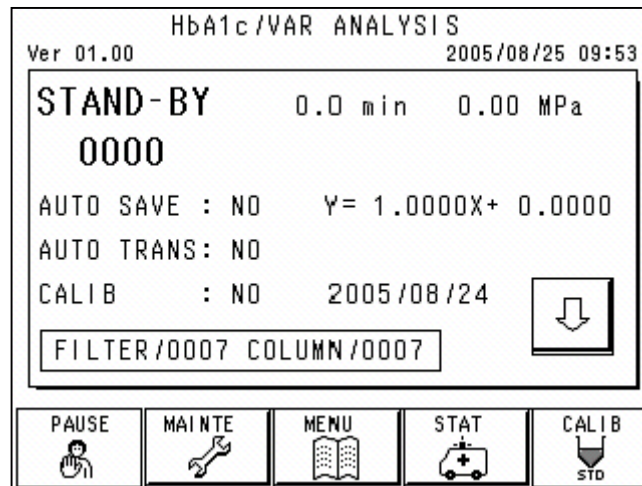
Checking Data ..... Alive

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)



6. The startup sequence continues. The sampling mechanism is checked, the pump is washed, the Elution Buffers are primed, the sampling and dilution flow lines are initially washed, and WARMING UP starts.



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, or some other event prevents the analyzer from activating the WARMING UP sequence, the analyzer may have a problem inside. Turn off the main power switch and then follow the procedures from [Step 1](#) above. If the analyzer still doesn't start, contact a service representative.

### 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 instrument)
- AS Program  
(program for operating the sampling and the loading unit)
- Assay Parameters  
(parameter files related to analyzer operating conditions)
- Assay results (result data)  
(assay results stored in the main unit memory)

Therefore, there is no need to load system information from the system external storage device, 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 storage device socket.

Refer to **“Chapter 7: Appendix”** for details regarding how to download programs and data from external storage device. 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 a service representative for battery replacement.

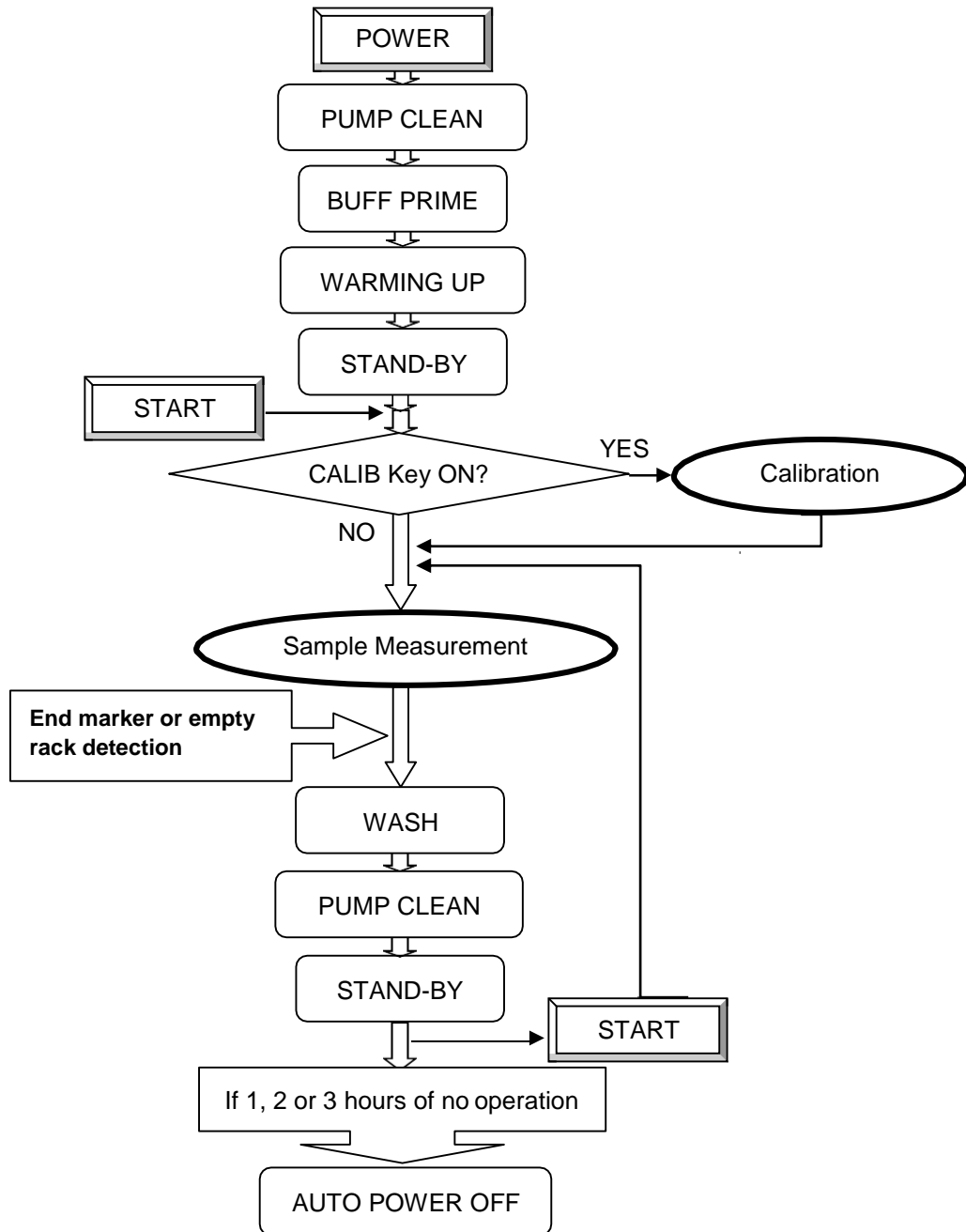
To return the backup parameters to their default factory values, input "CLR" in the password screen. Turn the main power switch off and then on again to restart the analyzer. All parameters are returned to their default factory settings.

See **“Chapter 4 Section 4.7 Card (External storage device)”** and **“Chapter 4 Section 4.14 Password Input”** for further details.

### 3.3 Assay Flow

The flow of standard assay operations is shown below.

**Fig.3-4 Assay Flow Chart**



The current condition of the analyzer and the current operation in progress are shown in the status of the **MAIN** screen.

Assay operations are stopped and the instrument goes in STAND-BY state when the STOP key is pressed once during operation. Press the STOP key twice in order to execute an EMERGENCY STOP.



1. When the STOP key is pressed during an assay, the results of the sample currently being assayed are printed and the wash operation is executed. When the STOP key is pressed twice during an analysis, an emergency stop is executed, and the wash operation is immediately started. The assay is cancelled and results of the current assay are not printed. If the STOP key is pressed twice during the wash operation, the analyzer will go in STAND-BY status and eluent delivery will stop.
2. In the same way, the PUMP CLEAN, BUFF PRIME, and WARMING UP operations, which are executed automatically after the power is turned on, can also be cancelled by pressing the STOP key. However, when the warming up cycle is interrupted, unreliable assay results can be obtained. When an operation has been cancelled, switch the POWER OFF then ON to automatically execute the operations again.



Make sure to execute the BUFF PRIME and WARMING UP operations prior to the first assay of the day (do not cancel these operations).

### 3.4 Operation Status

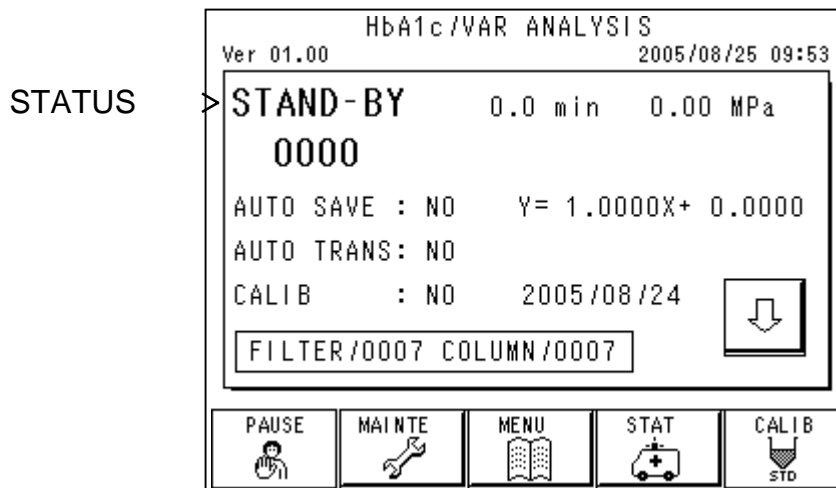
After the POWER key is pressed, the first screen displayed is the main screen (first screen). HbA1c/VAR ANALYSIS is displayed at the top of the screen. During analysis, the main screen should remain displayed. The current operation status is displayed in the upper left of the screen. The following status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

#### Status

- WARMING UP
- STAND-BY
- ANALYSIS
- WASH
- BUFF PRIME
- PUMP CLEAN

See the following pages for further details.

#### Screen 3-5 Main Screen (first screen)

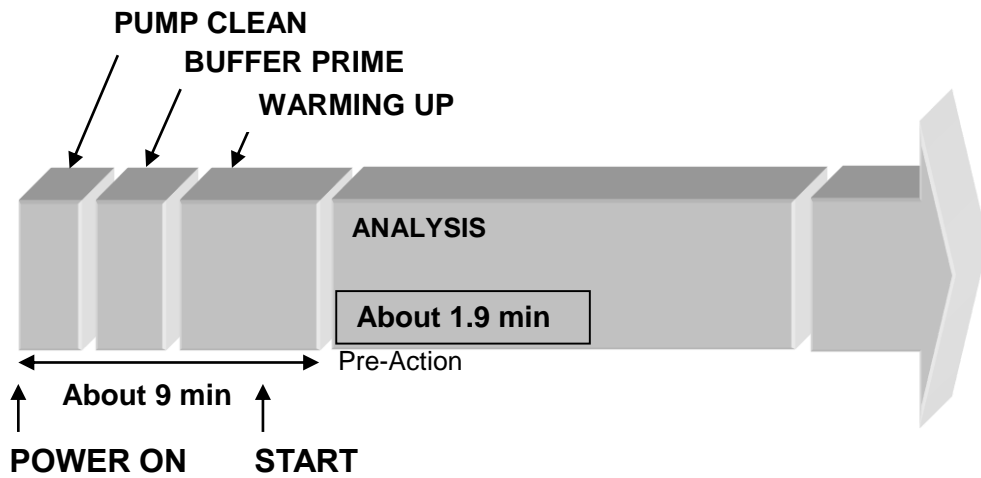


**Status**

- **WARMING UP**

Press the POWER key. After PUMP CLEAN and BUFF PRIME, the pump will run the reagent and automatically equilibrate the assay lines and column. After pumping each Elution Buffer sequentially for 9 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 accurate results. During the WARMING UP operation, set the samples and calibrators to be assayed and press the START key. The system will go into the ANALYSIS state automatically and start the assays after completing the WARMING UP operation.

**Fig. 3-5 Start Command during the WARMING UP Operation**

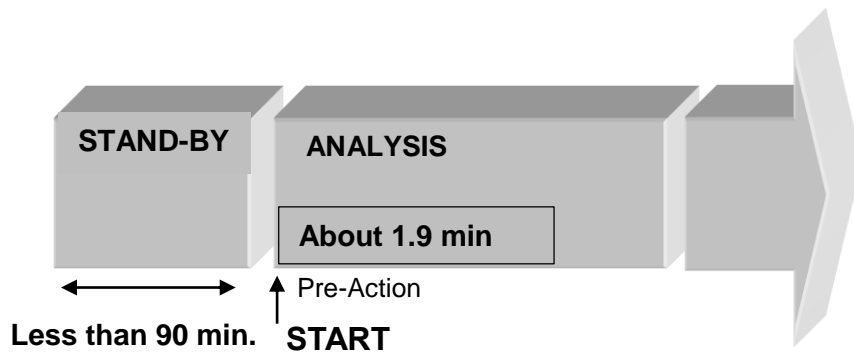


- **STAND-BY**

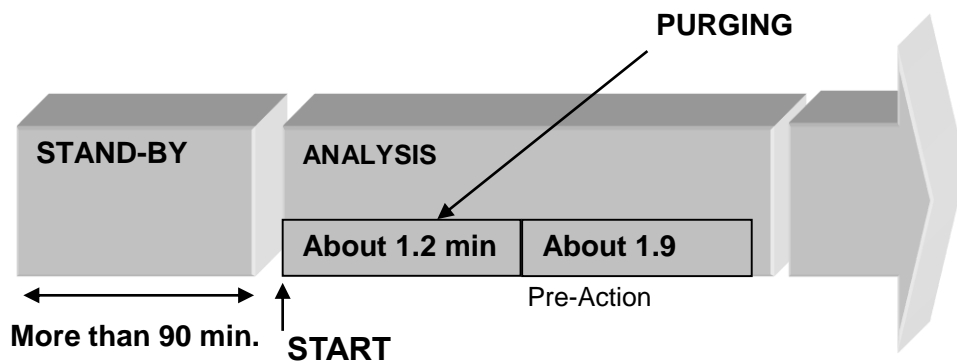
When the WARMING UP or WASH operations are complete, the analyzer goes in STAND-BY. In this state, the pump stops flow and Elution Buffer is not consumed. If two hours elapse without pressing any sheet key or touch panel, the power will be automatically turned off. The waiting time before power-off can be changed with the OFF TIMER setting on the PARAMETER screen.

**Fig. 3-6 Start Command during STAND-BY**

a) If STAND-BY time is less than 90 minutes



b) If STAND-BY time continues for 90 minutes or more



- **ANALYSIS**

Set the calibrators, controls and samples and press the START key. The assay will start and the analyzer will go in ANALYSIS state. When the system starts from the STAND-BY state, the analyzer transfers the rack and begins pumping/sampling when the sample containers are detected. If the sample is whole blood, it is diluted with the Hemolysis & Wash Solution 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 1.9 minutes) and the assay of the first sample then begins (sample injection). Next, subsequent samples are processed in a 1.6-minute cycle. The result, including the assay value (HbA<sub>1c</sub> % or mmol/mol) is output with the printer.

It takes approximately 3.5 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 90 minutes or more, a PURGING operation is done to replace all elution buffers and to clean the line. Since the PURGING operation takes about 1.2 minutes, it will take a total of approximately 4.7 minutes until the first assay result is printed in this case.

The STOP key can be pressed at any time during ANALYSIS to abort the assay. If this is done, the sample currently being assayed is completed, the results for that assay are printed, and the WASH operation is executed. If the STOP key is pressed twice, an emergency stop is executed, the assay is immediately aborted, and the WASH operation executed. If the STOP key is again pressed twice, the WASH process is cancelled; the analyzer goes in STAND-BY state, and the flow is stopped.

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



**Caution** Make sure to place an end marker or empty rack at the end of the samples to stop the assay process. If this is not done, the assayed samples will be assayed again due to the rotating structure of the sample loader. Primary tubes could also stay pulled up due to the piercing action after assay. If the tube is assayed 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 in position 1 of the rack if possible. However, the rack placement position is limited to the range indicated in **Fig. 3-15** and **Fig. 3-16**.
2. The assay ends by placing an end marker or an empty rack, or pressing the STOP key.

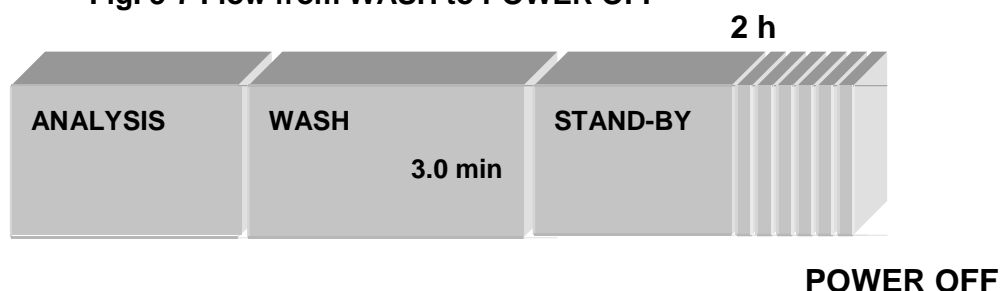
### • WASH

The analyzer goes in WASH state when the assay is complete. In this state, Elution Buffer No. 3 is automatically pumped for 1.0 minute, then No. 1 is pumped for 2.0 minutes to wash the column. Once this is complete the analyzer goes in STAND-BY state.

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

Always execute a WASH operation when 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. This can shorten the column life. For executing a WASH operation, please assay a dummy sample and execute a Wash operation completely.

**Fig. 3-7 Flow from WASH to POWER OFF**





If the sample's ID is queried to the host computer (query mode), release the query mode and assay a dummy sample. Please make sure that the WASH operation has been executed.

- **BUFFER PRIME**

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

In addition, when an eluent PRIME or CHANGE is executed on the MAINTENANCE - 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 (5 mL/wash) after the power is turned on and the WASH is complete.

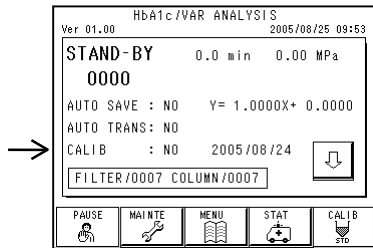
- **PURGING (does not display as a status on the screen)**

If the analyzer has been in the STAND-BY state for 90 minutes or more, all elution buffers in the flow line are automatically replaced with a new buffer just before starting assays. (1 mL, each buffer) At the same time, the sample line is automatically washed (5 mL of the Hemolysis & Wash Solution is used). This process takes about 1.2 minutes. The ANALYSIS state is displayed during this time. Once the PURGING operation is complete, pump delivery and sampling automatically starts.

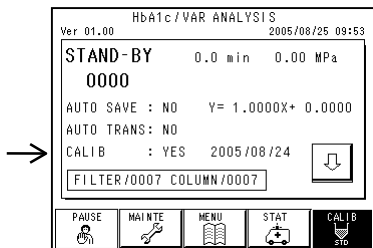
### 3.5 Checks before Assay

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

#### 1. Check the calibration setting





- Main Screen - Not Highlighted



- Main Screen - Highlighted

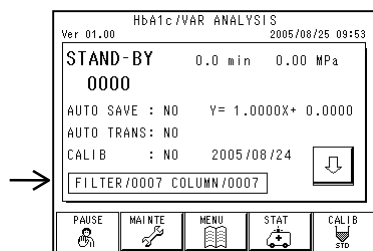
On the main screen (first screen), check the status of the calibration and the CALIB key display.

(  : process calibrator assays before actual sample assay,  : assay starts with first sample) Use the "Hemoglobin A<sub>1c</sub> Calibrator Set" or "G8 HbA<sub>1c</sub> Calibrator Set (S)" to calibrate the analyzer. Other calibrators cannot be used.

The assigned values for calibrators differ for each lot. Input the new assigned value when you change lots. See **“Chapter 3 Section 3.6: Calibration”** for information about the input method.

The lot number is printed on the calibrator box, Instructions for Use, and vial; the assigned values in NGSP units are printed in the Instructions for Use and on the vial; the assigned values in IFCC units are printed only in the Instructions for Use.

#### 2. Check the column and filter count numbers



- Main Screen -

##### [Column]

The number shown on the main screen is the number of shots since the last replacement.

- Replacement period: as needed

Refer to **“Chapter 5 Section 5.6: Column Replacement”** for the cases to replace the column.

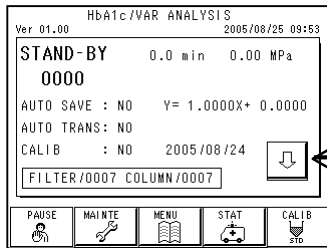
##### [Filter]

The number shown on the main screen is the number of shots since the last replacement.


- Replacement period: 400 counts

Refer to **“Chapter 5 Section 5.7: Filter Replacement”** for the cases to replace the filter.

**3. Check the remaining volumes of Elution Buffers and Hemolysis & Wash Solution**



- Main Screen (first screen)

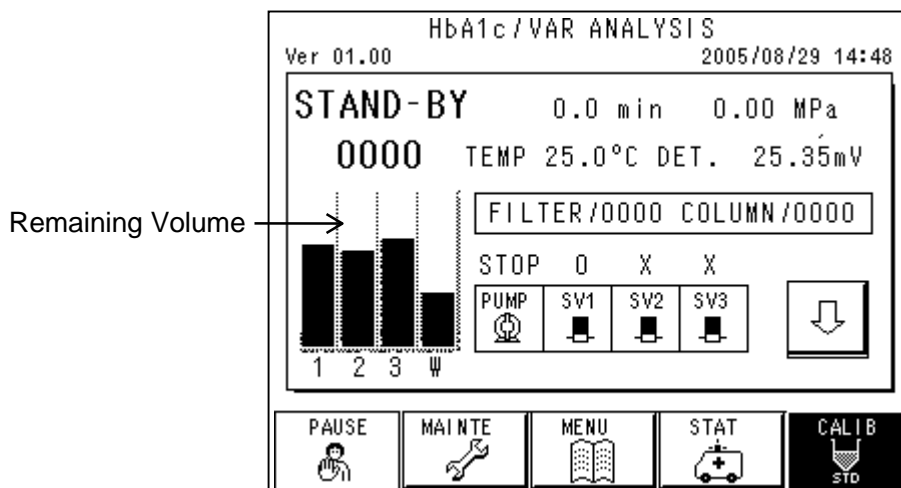
Press the  key on the right bottom of the main screen (first screen). The screen (second screen) will appear and bar graphs will show the remaining "volumes of each buffer.

Approximate consumption volumes are shown below for each buffer.

In addition, be aware that some reagents are used in the PUMP CLEAN, BUFF PRIME, WARMING UP, and WASH operations. Confirm that the remaining volumes are sufficient.

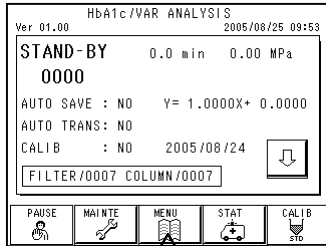
<b>Elution Buffer 1:</b>	<b>0.80 mL/test</b>
<b>Elution Buffer 2:</b>	<b>0.88 mL/test</b>
<b>Elution Buffer 3:</b>	<b>0.72 mL/test</b>
<b>Hemolysis &amp; Wash Solution:</b>	<b>3.95 mL/test</b>

**Screen 3-6 Main Screen (second screen)**

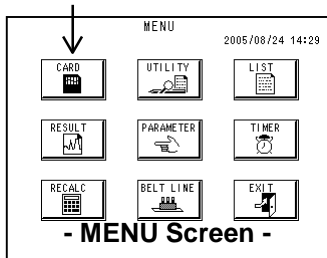



Remaining Volume →

**4. External storage device space for assay result storage**



- Main Screen -



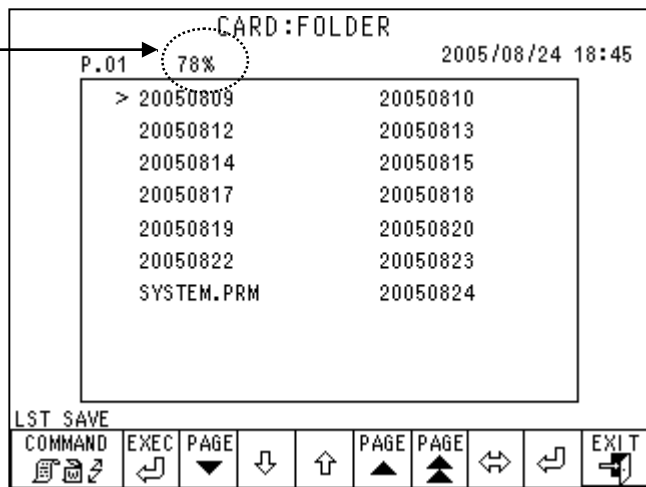
Insert an external storage device into the socket and select  key from the MENU screen. A list of assay result folders stored in the external storage device will appear and the percentage of used storage device space will be displayed on the upper left of the screen. The number of sets of assay results that can be stored differs depending upon the type of the external storage device. Refer to **“Chapter 2. Section 2.3: Units and Functions, 4. Storage device”**.

If the list data is stored together, this number will be reduced.

Use the PARAMETER screen to set the type of data to be stored. Since assay results are also stored in the RESULT memory in the main unit, saving the results on an external storage device 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.

**Screen 3-7 CARD: FOLDER Screen**

External storage device space in use



**Point**

1. If data other than RAW data assay results are stored in the external storage device (system files, etc.), the space available for storing results is reduced. In addition, the storage device cannot be formatted during an assay. Check the remaining volume prior to giving the start command and load a formatted external storage device prior to starting the assay.
2. The number of results which can be stored in an external storage device may depend on how the storage device is formatted. Prior to use, we recommend formatting the storage device with the analyzer or a Windows-based PC. External storage devices formatted by the analyzer can also be used on a PC.

### 5. Remaining Printer Paper (Thermal Paper Roll)

Check the remaining volume of printer paper (thermal paper roll).

A red bar indicates a small volume remaining. Replace the roll with a new roll when this bar appears.

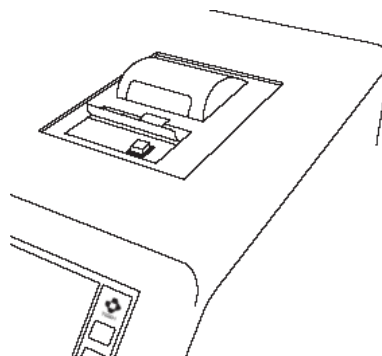
If the paper looks like it will run out during an assay, press the PAUSE key in the MAIN screen to temporarily pause the analysis. Wait until the results of the sample currently being processed are printed, and then replace the paper. After replacement, press the PAUSE key to restart the assay. The assay will restart automatically once the PAUSE key is pressed or if no further input is received for approximately 16 minutes.

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.

About 350 results can be printed with one roll (when using format 0).

(See "[Chapter 3 Section 3.12: Interpretation of Results](#)")

**Fig. 3-8 Printer Unit**



## 6. Waste Eluent Bottle

Be sure to empty the waste eluent bottle before starting an assay.



Caution

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

## 7. Other Items to Check

Check the flow line connections (particularly the filter and the column inlet and outlet) for leaks during WARMING UP operations. Tighten the connection if a leak is found.



The Elution Buffers, Hemolysis & Wash Solution, column, and filter cannot be replaced during an assay. When replacement is required, press the STOP key to make a temporary stop and wait for the analyzer to go in STAND-BY state. Make the replacement while in the STAND-BY state.

### 3.6 Calibration

Each laboratory must monitor QC results according to good laboratory practices to determine when to recalibrate. Calibration frequency should be based upon QC results and chromatogram quality.

The analyzer is calibrated using CAL(1) and CAL(2) calibrators with different HbA<sub>1c</sub> assigned values. Use the "Hemoglobin A1c Calibrator Set" or "G8 HbA1c Calibrator Set (S)" for calibration (P/N: 0018767 or 0023528).

We recommend calibrating the analyzer once a week, as a guide. 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.

Use the "Hemoglobin A1c Control Set" (P/N: 0021974) together with the calibrators for the control of daily test results.



Caution

**Each laboratory must carry out the daily test result control and check the results for good laboratory practices.**

## 1. 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.

- **CALIB.: COMPLETED**

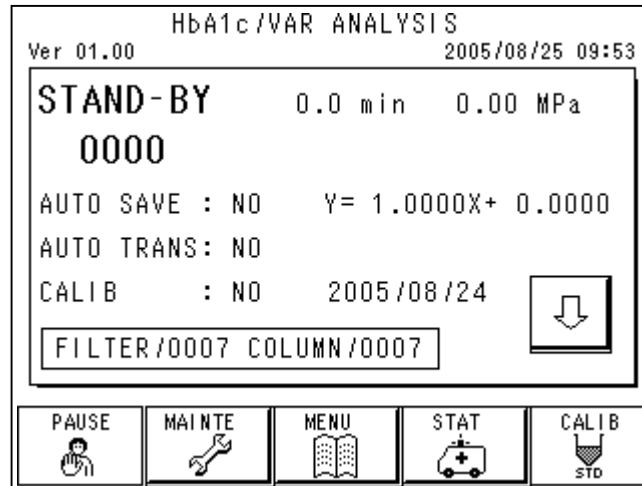
This indicates that automatic calibration is complete. Subsequently, automatic calibration will not be executed even if the START key is pressed. Set the real samples to start the assay. They will be tested in accordance with the factors displayed on the screen.

When the CALIB 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 CALIB key is not selected. Automatic calibration will not be executed. The test result will be corrected by the factors displayed on the screen. To use values not corrected by the calibration factors, input FACTOR A = 1 and FACTOR B = 0 on the PARAMETER screen, then start the assay. 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 in an external storage device.

### Screen 3-8 Screen is CALIB.: NO

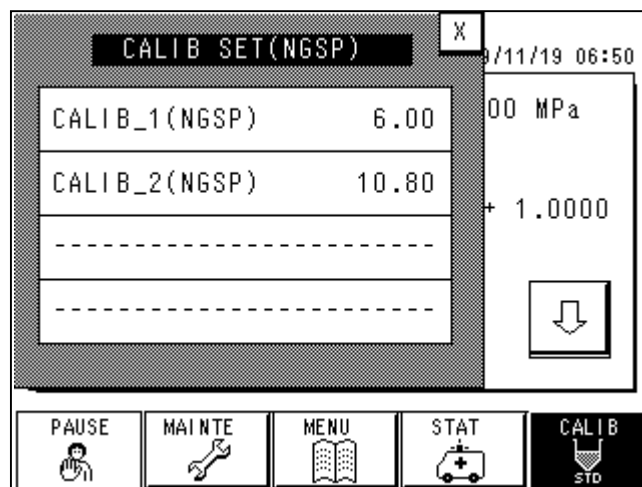


### Scheduled Automatic Calibration

Press the CALIB key located at the bottom right of the main screen.

The key is highlighted and the calibrator's assigned value input screen is displayed. Confirm the assigned value. If the calibrator's lot has been changed or if the assigned value is incorrect, input the correct value. Close the input screen.

### Screen 3-9 Assigned Value Input Screen (for NGSP unit)





The analyzer accepts assigned values of calibrator in NGSP (National Glycohemoglobin Standardization Program) units (%), Mono S units (%) and IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) units (mmol/mol). Assigned values in each unit are printed on the Instructions for Use of "Hemoglobin A1c Calibrator Set" or "G8 HbA1c Calibrator Set (S)".

The title line of the Assigned Value Input Screen displays the unit of assigned values which should be entered.

For entering in NGSP units



For entering in Mono S units



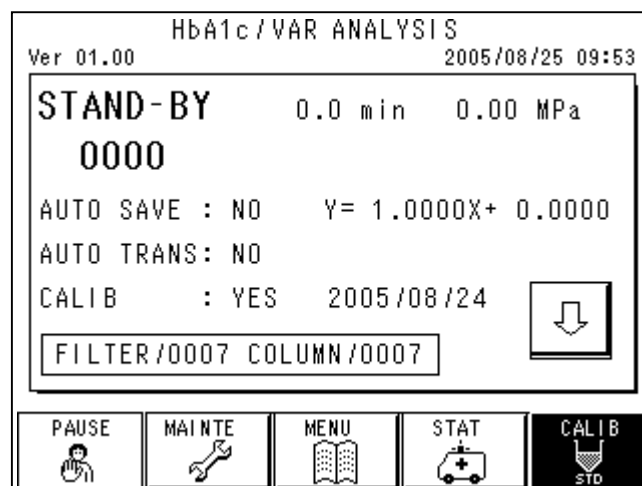
For entering in IFCC units



To switch the units in which assay results are reported, change the Printout format on the PARAMETER screen (page 2 of 4). Refer to **Chapter 4 Section 4.6: Parameter Setting** for specific procedures.

After entering assigned values, close the Assigned Value Input Screen by pressing the  mark at the top right of the Screen. Verify that the CALIB key on the main screen is highlighted and that the CALIB message is YES.

### Screen 3-10 Screen is CALIB.: YES

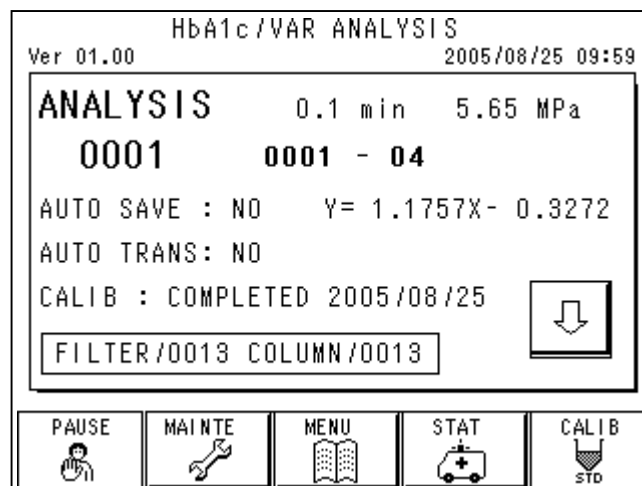


First set the CAL(1) and CAL(2) calibrators in the sample cups at the No.1 and No.2 positions of the first rack. Press the START key. The calibration will be processed automatically before real samples are assayed.

Once the automatic calibration is complete, the CALIB message will change to COMPLETED and the CALIB key will no longer be highlighted.

In addition, the calibration factors determined will be displayed on the screen. Behind the calibrators in the rack, place patient samples that will be assayed and their values will be corrected using the newly calculated calibration factors.

### Screen 3-11 Screen is CALIB.: COMPLETED



## 2. Calibrator Reconstitution

Read the calibrator set Instructions for Use for details regarding the proper handling of the "Hemoglobin A<sub>1c</sub> Calibrator Set" or "G8 HbA<sub>1c</sub> 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 A<sub>1c</sub> Calibrator Set" or "G8 HbA<sub>1c</sub> Calibrator Set (S)".  
After the material has sufficiently dissolved, dispense the required volume (500 µL or more per use) 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 A<sub>1c</sub> Calibrator Set" or "G8 HbA<sub>1c</sub> Calibrator Set (S)". Never use the reagent whose expiration date has passed.

### 3. Calculation procedure to determine the factor after calibration

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

The No. 1 and No. 2 samples on the first sample rack are treated as CALIB-1 and CALIB-2.

CALIB-1 is the low value calibrator (approximately 6.0 %) and CALIB-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 for a total of 5 times.

The first assay result for CALIB-1 is discarded and the average HbA<sub>1c</sub> % of the 2nd and 3rd assay is calculated as the result for CALIB-1. The average HbA<sub>1c</sub> % of the 4th and 5th assay is calculated as the result for CALIB-2. Based on the assay results and the assigned values, the following linear equation is used to calculate the calibration factors.

---

**Object of correction:** HbA<sub>1c</sub> %

**Correction formula:** (HbA<sub>1c</sub> % after correction) = A × (HbA<sub>1c</sub> % before correction) + B

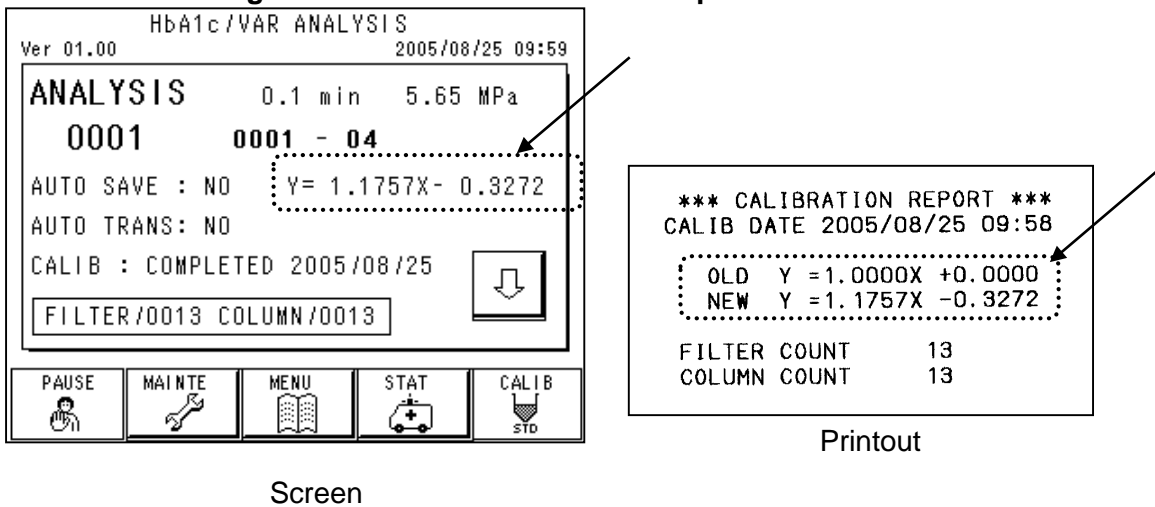
$$A = (\text{CALIB-2 assigned value} - \text{CALIB-1 assigned value}) / (\text{CALIB-2 assayed value} - \text{CALIB-1 assayed value})$$

$$B = \text{CALIB-2 assigned value} - (\text{CALIB-2 assayed value} \times A)$$

---

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.

**Fig. 3-9 Screen and Printout Examples**



After the FORMAT set value is entered in the PARAMETER screen (refer to **“Chapter 4 Section 4.6: Parameter setting”**), the indication for the calibration factors to be printed on assay results will be printed as like “CAL(IN) = AX + B” or “CAL(N) = AX +B”, to show in which units the calibration was done and is currently applied. If the FORMAT set value is changed, the indication for the calibration factors will be changed accordingly.

See “Point” on P4-13 for details.

#### 4. Calibration error

A calibration error occurs when the calibrator assay results meet the following conditions. When an error occurs, the assay automatically stops, and after washing, the analyzer goes in the STAND-BY state. If a calibration error occurs, samples placed behind the calibrator will not be assayed. The main screen display changes to NO and the CALIB key is not highlighted. When the operation is again started, calibration is executed again because it has not been completed.

##### - Error conditions

1. **The difference in the s-A<sub>1c</sub> % value between the 2nd and 3rd assay result is 0.3 % or more.**
2. **The difference in the s-A<sub>1c</sub> % value between the 4th and 5th assay result is 0.3 % or more.**
3. **One or some of the s-A<sub>1c</sub> % of the 2nd through the 5th assay results differ(s) more than 30 % from the assigned value.**



When assigned values in IFCC units (mmol/mol) were entered, the calibration error will be checked after automatically converting the entered values into NGSP units (%) or Mono S units (%) using the following Master equation or the equation recommended by EQUALIS (External quality assurance in laboratory medicine in Sweden) on “Algorithms recommended by EQUALIS for conversion of HbA<sub>1c</sub>-results with different standardisations” dated November 2, 2009, respectively:

$$\text{NGSP (\%)} = 0.09148 \times \text{IFCC (mmol/mol)} + 2.152.$$

$$\text{Mono S (\%)} = 0.0957 \times \text{IFCC (mmol/mol)} + 1.016.$$

These errors could be caused by the following.

1. **The calibrator has been left for more than 1 week after reconstitution or has been left at room temperature for a long period of time.**
2. **The filter or column is clogged and the pressure is high.**
3. **There is a leak.**
4. **Samples other than the calibrator were assayed.**

Execute calibration again after replacing the filter and column, preparing a new calibrator and tightening the tubing line joints.



Use 500  $\mu$ L or more of both CALIB-1 and CALIB-2 (LOW and HIGH). An assay may not start with an insufficient volume of less than 500  $\mu$ L. While in the automatic calibration mode, if a sample other than the calibrator sample is placed in the first and second positions and assayed, a calibration error will occur or the calibration factors may be falsely calculated based on the values obtained with the samples.

### 3.7 Samples

#### Samples Containers

Primary tubes and special sample vials 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 primary tubes higher than 75 mm.



**Caution Do not put your finger under the needle. The needle may pierce your finger.**

The minimum required sample volume is approximately 1 mL for whole blood. If the volume of the sample is insufficient, dilute 5 uL of the sample with 1 mL of the Hemolysis & Wash Solution in a sample vial. This dilution rate is just a guideline. Please see "SAMPLE VIALS" on next page for specific procedures. For samples with a low hematocrit, blood cells may not be sampled. It is advisable to collect a sample of a sufficient quantity (1 mL or more) and mix by turning the primary tubes upside down prior to setting the primary tubes on the sample rack.



**Caution 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 500 G/5 min.**

**- When using a SYSMEX® Rack**

If you are using 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.

( $\phi$ 12 adapter: P/N 0018496,  $\phi$ 14 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 VIALS**

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

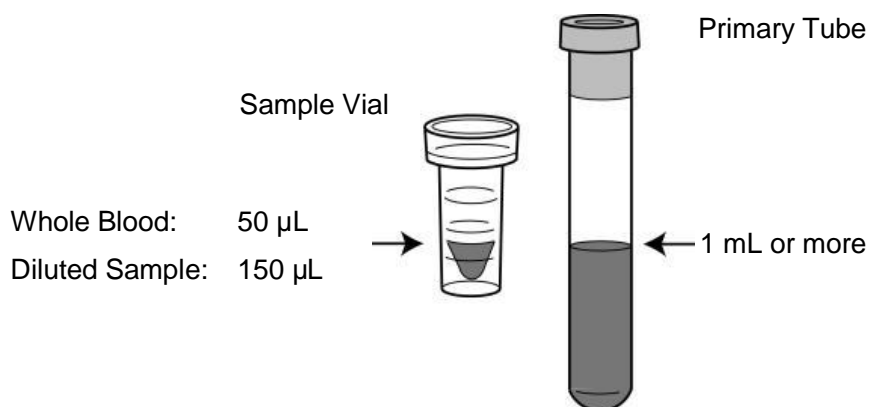
When you use a sample vial, make sure to attach a vial adapter (P/N: 0020101).

If you are using a SYSMEX® rack, make sure to put on a rack adapter or attach a vial adapter (P/N: 0019509) before setting the sample vial.

After dissolving the calibrator, dispense the necessary volume into the sample vial. A minimum of 500  $\mu\text{L}$  of each calibrator is required.

If the sample volume is low and no red blood cells can be suctioned from the primary tube, or when the hematocrit is low, the TOTAL AREA of the assay results may drop below 500. If this happens, test results may be unreliable. Assay the sample again using the following procedure.

**Fig. 3-10 Minimum Sample Volume**



**Procedure**

1. Let the sample stand for a while, then dispense 50  $\mu$ L or more of the sedimented blood cells (refer to **Fig. 3-10**) into a sample vial.
2. Confirm that the LOADER SMP MODE in the PARAMETER screen (refer to **“Chapter 4 Section 4.6: Parameter Setting”**) is set to 1 (initial value is set to 0).
3. Place the vial in the sample rack and run the assay.

When the analyzer status is in the ANALYSIS, set a sample in the same way to the STAT position, select CUP, and execute a STAT sample assay. In this case, do not need to follow the PARAMETER change mentioned above in Step 2.

Please refer to the Instructions for Use of the buffers about usable types of primary tubes.

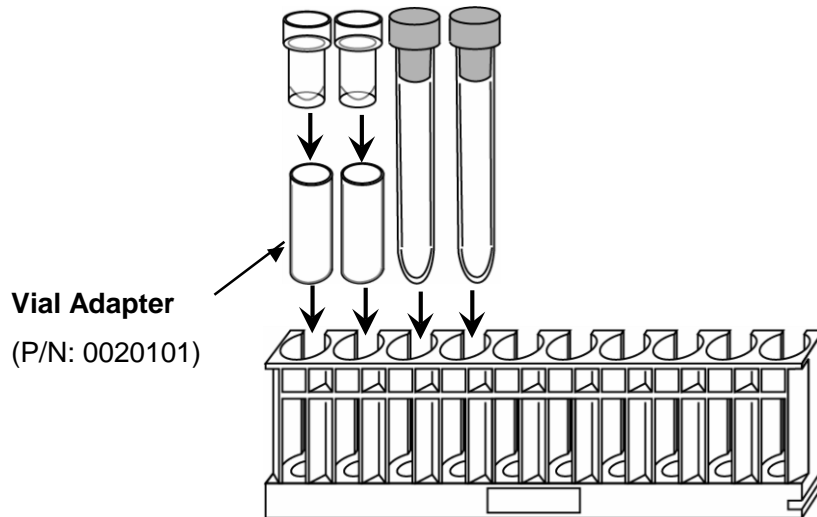
**Caution**

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. If you are using 12 - 14 mm diameter primary tubes on a SYSMEX® rack, make sure to attach a rack adapter to avoid looseness, otherwise the sampling needle could be bent.

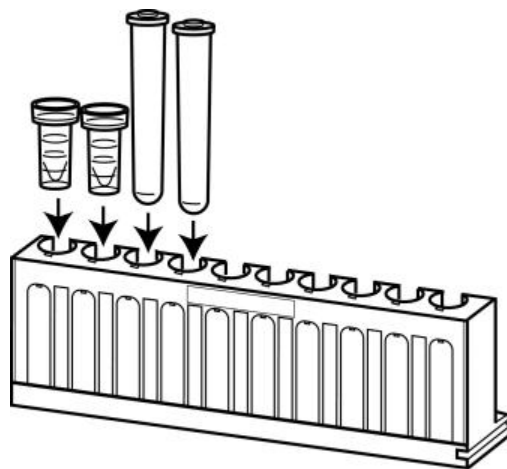
If primary tubes with labels and those without labels are mixed together on the same rack, or when different types of primary tubes from different manufacturers are mixed on the same rack, make sure all the tubes are firmly held in place. If the tubes are excessively loose, prepare racks with different adapter diameters for each primary tube type.

**Fig. 3-11 Loading Method for Primary Tubes and Sample Vials  
(Example)**

**(For TOSOH rack)**



**(For SYSMEX® rack with Rack Adapter)**

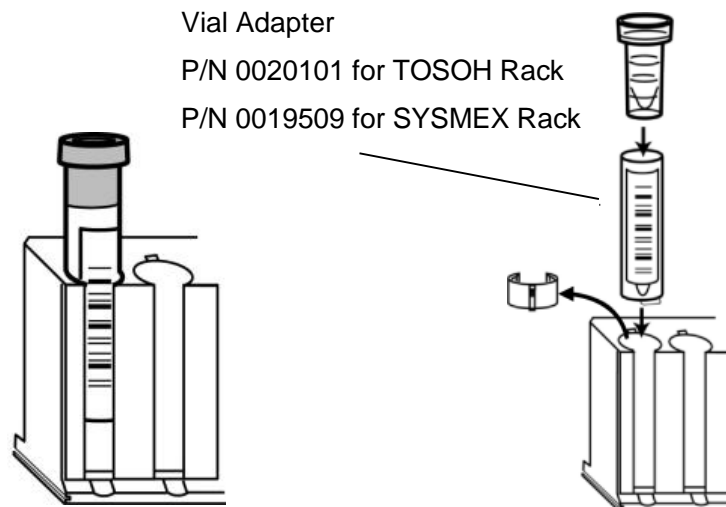


**Bar Code Label Confirmation**

The analyzer reads the bar code ID on the labels affixed to primary tubes and can transfer test information inquiries and assay results with IDs to the host. ID information can also be printed on the test report from the internal printer of the main unit. If a sample container with no bar code is processed, the rack ID will be sent or printed with the test results instead of the sample ID.

When processing primary tubes on the sample rack, the bar code label must be oriented toward the slit (the bar code will therefore face the main unit when the rack is placed in the analyzer). When attaching bar code labels to sample vials, use the optional vial adapter.

**Fig. 3-12 Label Direction and Vial Adapter Setting Position in a Rack**

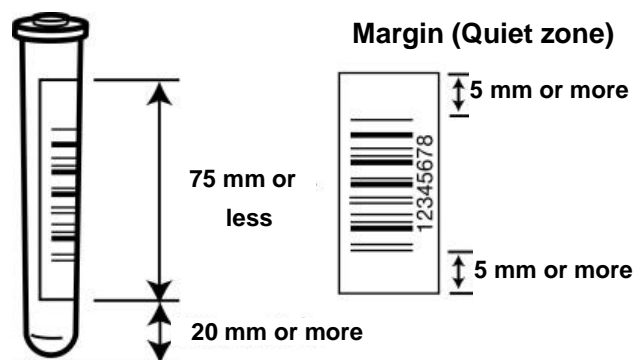


In addition, a 5-mm margin (blank space) is required on the top and bottom of the printed bar code.

If a bar code cannot be read or a sample container has no bar code, the rack number and the position on the rack (1 ~ 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. 3-13**. A reading error will occur if the label is set at an angle or if it is wrinkled.

**Fig. 3-13 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 bar code specifications do not specify an initial setting, and a reset may be required.

Refer to **“Chapter 7, Section 7.3: Specifications”** for code specifications. Refer to **“Chapter 4, Section 4.19: Bar Code Reader Setting and Reading Check”** for details on how to change the settings.



The bar code 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 bar code, as indicated in **Fig. 3-13**.

### 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.

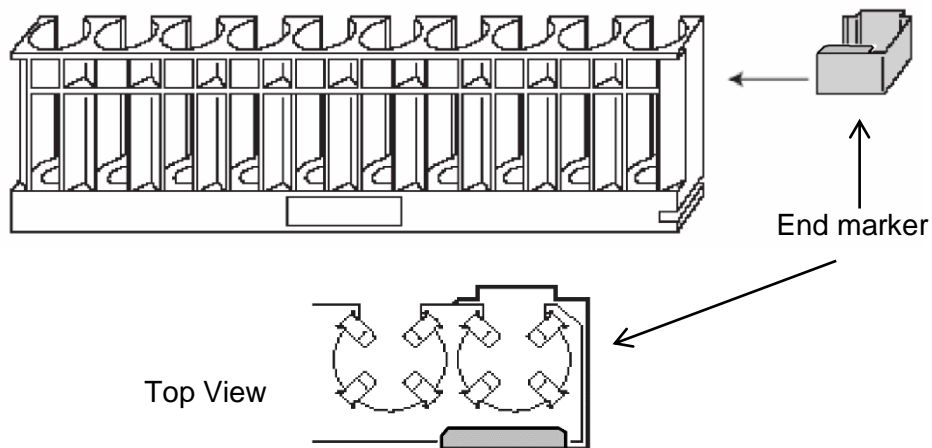
#### Procedure

1. Squeeze the end marker with fingers until the opening is 6 ~ 8 mm wide.
2. Set the end marker in the position shown in **Fig. 3-14**.

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 final rack.

**Fig. 3-14 End Marker Attachment**



There are two types of end markers: for the 90SL (P/N: 0021640) and for the 290SL (P/N: 0021668). These two markers have different shapes. Verify which sample loader you are using and select the correct end marker accordingly. Selection of an improper end marker could result in improper operation and damage to the machine and its components.

### Sample Rack Loading



**Caution** Take care not to catch your fingers in the driving units when placing the racks, manually changing positions, or adding samples during an assay.

### Procedure

1. Sample racks can be loaded in the rack positions (shaded) shown in **Fig. 3-15** and **Fig. 3-16**. 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 from the inside out. 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 thereafter. 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. 3-15 Top View of 90 Sample Loader**

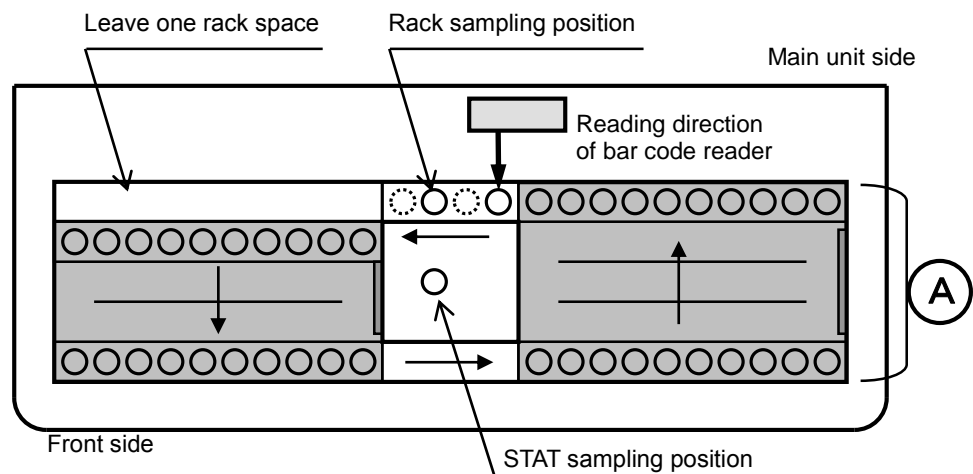
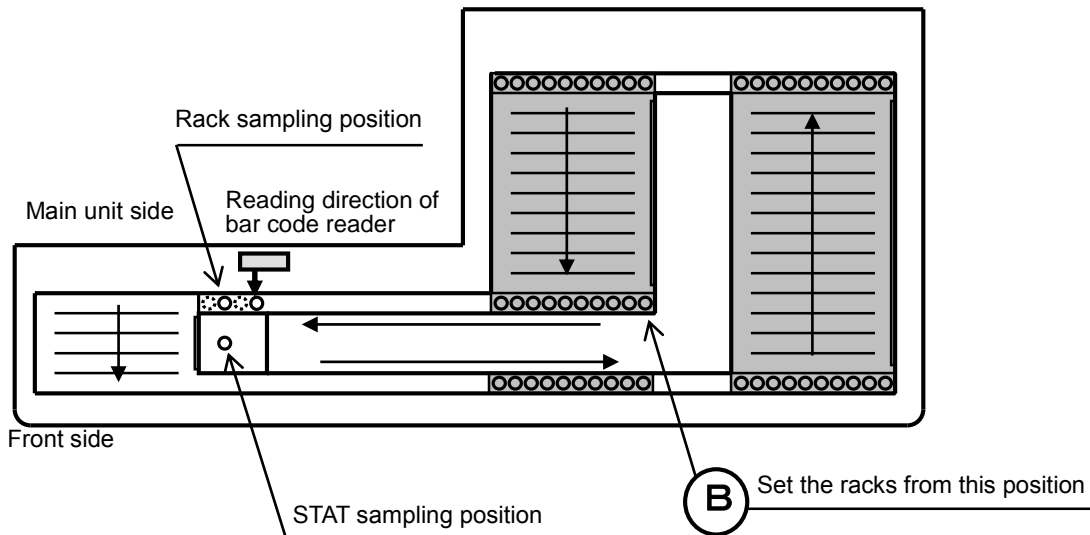


Fig. 3-16 Top View of 290 Sample Loader



1. Load the rack when the analyzer is in WARMING UP or STAND-BY state. During ANALYSIS, if the sensor is activated, RACK POS ERROR comes out and the assay will be aborted. Never load 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 is left empty. However, there must be a rack in the A position, as indicated in **Fig. 3-15**.

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. 3-16**.

2. When loading racks on the sample loader, be sure to engage the slit on the right rear side of the rack to the chuck on the sample loader for preventing its overturn. 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.

### Units for reporting and calibration

Assay results are calibrated and reported using the calibration factors determined with the entered assigned 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 **“Chapter 4 Section 4.6: Parameter Setting”**), correct results will not be reported.

When the units for reporting assay results are changed by the FORMAT on the PARAMETER screen, therefore, calibration should be re-performed before assaying.

See **“Chapter 3 Section 3.6: Calibration”** for calibration procedures.

See **“Chapter 4 Section 4.6: Parameter Setting”** for setting of Printout format.



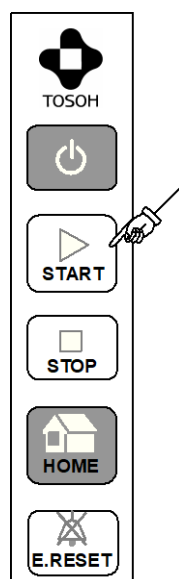
**Caution** Assuming the current calibration factors were determined in NGSP units (or in Mono S units), if assays are performed under a setting to report in IFCC units, a calibration error will occur, and vice versa.

### 3.8 Assay Start and End

#### Starting an Assay

After placing samples on the loader correctly, press the START key on the operation panel 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. 3-17 START Command



If the START command is input during WARMING UP, the assay will start immediately after WARMING UP is complete.

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



**Caution** Take care not to catch your fingers in the driving units when placing the racks, manually changing sample positions, or adding samples when assay is in process.



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

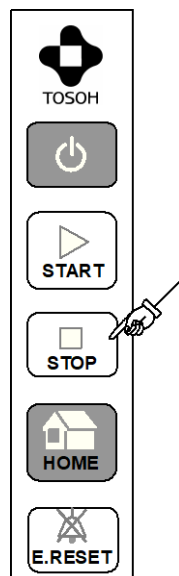
### Ending an Assay

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.

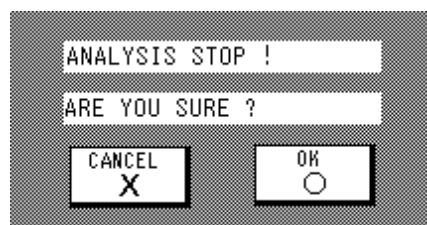
To stop the assays while the assays are in process, press the STOP key. The message below (**Screen 3-12**) will be displayed. Press "OK" on the screen or press the STOP key again to confirm the stop process. Press "CANCEL" to cancel the stop process.

After the assay currently processed is completed, the result will be output, and the analyzer will go in WASH state.

**Fig. 3-18 STOP Command**



**Screen 3-12 The message to stop an assay**



If the STOP key is pressed again after initially being pressed, operation will immediately stop and a WASH operation will be executed. Assay results of the sample currently being processed will not be reported. If the STOP key is pressed during the WASH process, the PUMP CLEAN process will be executed. If the STOP key is pressed again, the analyzer will go in STAND-BY state.

Be sure to execute WASH when the assay is complete. If the WASH operation is insufficiently executed, some sample may remain in the column, the column lifespan may be shortened, and the next sample results may be affected.



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.**



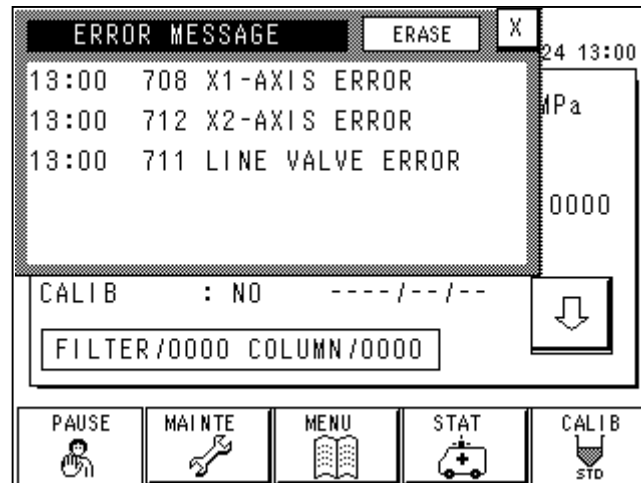
If you terminate an assay by pressing the STOP key, do not immediately remove the samples and racks. The final sample may still be in the assay after the STOP key has been pressed. If the rack or samples are immediately removed, the sensor will be activated and a RACK POS ERROR will occur, and the assay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

Check that all the assay results have been printed out and that the analyzer has entered into the WASH state. Once it has, remove the samples and racks.

### 3.9 Clearing Errors

If an error occurs, a buzzer will sound and an error message will be displayed on the screen. The error LED (red) will illuminate on the left side of the screen.

**Screen 3-13 Error Message Screen**



Follow the procedure below to clear the error.

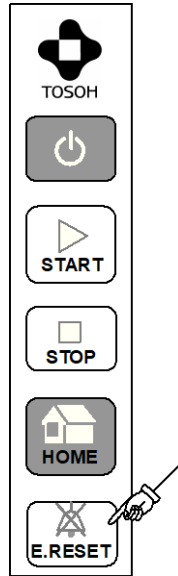
#### Procedure

1. Press the E.RESET key on the sheet key. The buzzer will stop and the error LED will turn off.
2. Close the error message screen.



Make sure to confirm the cause of the error before clearing it. See **“Chapter 6: Troubleshooting”** for further details.

Fig. 3-19 E.RESET Command



### 3.10 Priority Sample Assay (STAT)

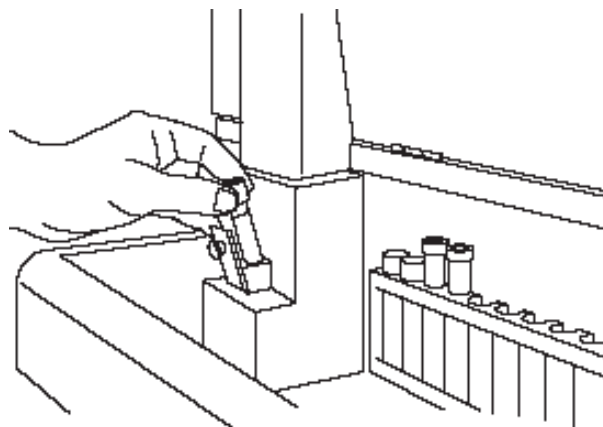
If a priority sample needs to be assayed, set the sample in the STAT port located in the middle of the sample loader.

The sample can be processed either with a primary tube or a sample vial. Both diluted and whole blood samples can be processed.

#### Procedure

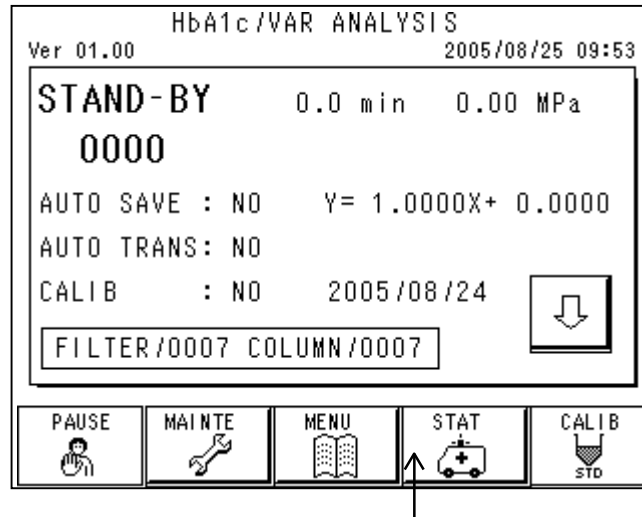
1. Verify that the STAT key on the main screen is not highlighted (i.e., not in scheduling or analyzing stat) and manually open the analyzer's STAT port.
2. Remove any sample container already in the port and set in the sample to be assayed.

**Fig. 3-20 Priority Sample Loading**



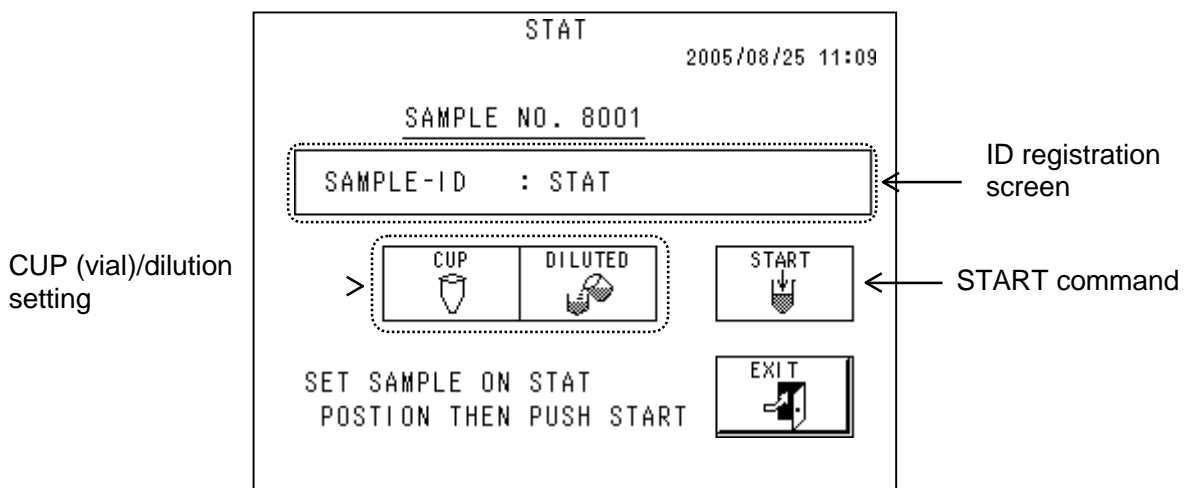
3. Press the STAT key on the main screen.

### Screen 3-14 Main Screen (first screen)



4. The STAT screen will be displayed.  
Register a sample ID as required. Select the type of container (highlighted specifies cup) and dilution (highlighted indicates diluted sample) then securely close the STAT port.

### Screen 3-15 STAT Screen



5. Press the START key.

Registration is complete when SCHEDULED is displayed at the bottom of the STAT screen. Press the EXIT key. The STAT key will be highlighted when the main screen is displayed.

When the assay currently being processed is completed, the STAT sample is immediately processed.

When the sampling is complete, the STAT key display will return to normal (not highlighted). Open the front door and remove the sample.



Caution

**Never open the STAT port door during sampling (while the STAT key is highlighted). The needle can be bent or can cause injury.**



Before you open or close the STAT port door, check that no STAT assay is indicated on the screen (STAT key unhighlighted), and that no STAT sample is being assayed.

### 3.11 Power OFF

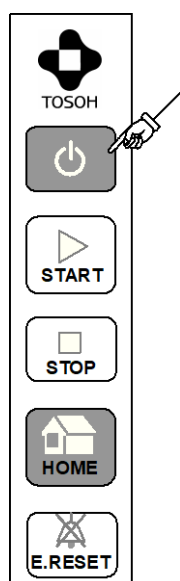
To shutdown the analyzer, press the POWER key (refer to **Fig.3-21**).

The message (**Screen 3-16**) will be displayed.

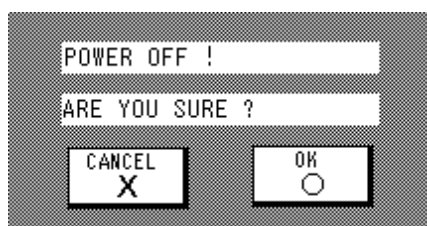
Press “OK” on the screen or press the POWER key again to confirm the shutdown process. To cancel the shutdown process, press the “CANCEL”.

The column oven and the degassing unit keep on working after the shutdown. To stop units turn off the Main power switch (refer to **Fig.3-2**).

**Fig. 3-21 Power OFF Key**



**Screen 3-16 The message displayed by Power OFF Key**



### 3.12 Interpretation of Results

#### Printout Format

The following three printout formats are available with this system. To change the format, select 0, 1 or 9 on FORMAT of the PARAMETER screen. FORMAT 0 is the default factory setting.

- **FORMAT 0**

This is the most detailed format. The assay values for HbA<sub>1c</sub> (s-A<sub>1c</sub>), HbF, and HbA<sub>1</sub> will be output together with a chromatogram and all peak information.

To select this printout format, set 0 to the last digit for FORMAT on the PARAMETER screen.

- **FORMAT 1**

The assay values for HbA<sub>1c</sub> (s-A<sub>1c</sub>), HbF, and HbA<sub>1</sub> will be output together with a chromatogram.

To select this printout format, set 1 to the last digit for FORMAT on the PARAMETER screen.

- **FORMAT 9**

The same format as Format 0 but with the number of theoretical plate (indicated as TP) for HbA<sub>1c</sub> (s-A<sub>1c</sub>).

For detailed information on Printout format, see **“Chapter 4 Section 4.6: Parameter Setting”**.

You can print out the assay results saved to the analyzer’s RESULT memory or to an external storage device by changing the FORMAT and running a RECALC operation.

(See **“Chapter 4. Section 4.9: Confirmation. Transmission to Host. and Recalculation of Saved Results”**)



**Test Report Interpretation**

- **NO.**

Indicates the sample numbers (4 digits). The 0001 is automatically given to the first sample of the day and the sample numbers are assigned in succession. When the START day is changed, the numbers return to 0001. Numbers starting from 9001 are automatically assigned to the calibrator and numbers starting from 8001 are automatically assigned to the STAT samples.

- **ID**

When a bar code is used, the bar code number is given in the ID field. When a bar code is not used, the sample position number is given (position and rack number).

- **CALIB**

Shows the calibration factors with which the assay result was calibrated. This indication "CALIB" is changed as "CAL(IN)", "CAL(N)" or "CAL(J)", depending on FORMAT set value (in which units the calibration was done). See "**Point**" on P4-13 for details.

- **NAME**

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

H-V0, H-V1 and H-V2 are assigned to hemoglobin variants. These peaks are reported when hemoglobin variants are detected. HbS is reported as H-V1. HbD and HbC are reported as H-V0 and H-V2 respectively.

- **TOTAL AREA**

The total of each area except for the FP peak is printed.

This corresponds to the hemoglobin concentration (The value is calculated by integrating the detector output by time. The unit is mV·s.)

- **HbA<sub>1</sub> (Total A<sub>1</sub>)**

Shows the total value of A<sub>1a</sub>, A<sub>1b</sub> and s-A<sub>1c</sub>.

- **Chromatogram**

The fractions separated by column are shown as they are detected. The horizontal axis is adjusted as the 15 % in s-A<sub>1c</sub> concentration comes to the full scale. The vertical axis is the retention time from the instant the sample is injected into the column. The unit is in minutes.

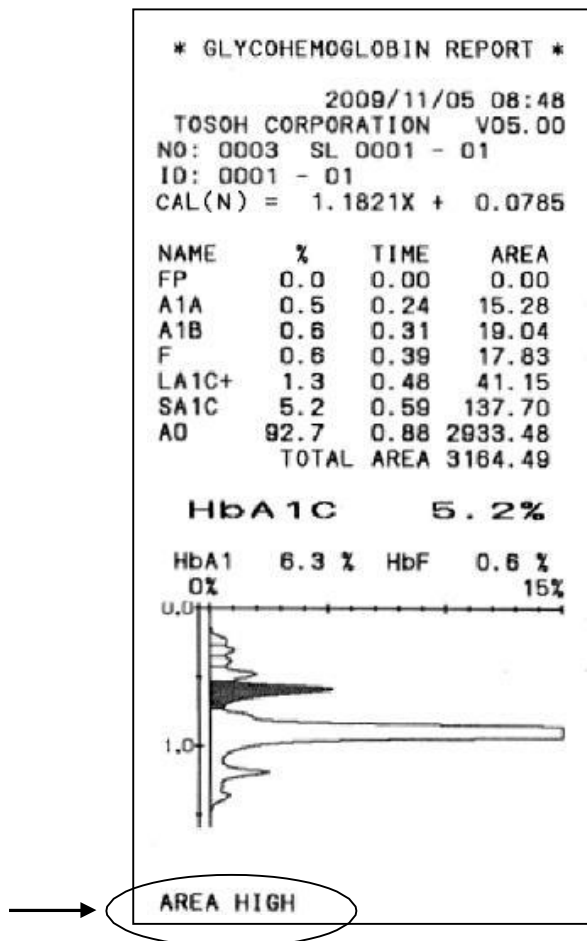
The peak identified as HbA<sub>1c</sub> (s-A<sub>1c</sub>) is shaded.

- **FLAG**

If you input the flag parameters on the FLAG screen beforehand, messages are printed out when the test result meets the flag parameters.

See "[Chapter 4, Section 4.18: FLAG Parameter Setting](#)" for further details.

**Fig. 3-23 Printout Example with FLAG**



### Detailed Peak Information

If the result is output in FORMAT 0, the information for each hemoglobin fraction separated by the column is printed.

- 1) % (each peak area against the TOTALAREA)  
This is the ratio of each peak against the total peak area (excluding FP). The front peak, FP, is always 0.0 %, since it is not related to hemoglobin.
- 2) TIME (elution time, retention time)  
Indicates the time of each peak top.
- 3) 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. The TOTAL AREA, which is the sum of all peaks, changes depending upon the sample concentration. The acceptable range of TOTAL AREA is from 500 to 4000. However, highly reliable results can only be obtained in the TOTAL AREA range from 700 to 3000.

When sampling whole blood directly from the primary tube, the analyzer automatically dilutes the sample by a fixed ratio of about 200. 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 vial and run the assay again.

See **“Chapter 3 Section 3.7: Samples”** for further details.

## 4) Chromatogram

The  $A_{1a}$ ,  $A_{1c}$  and HbF may be eluted out with different peak shapes or not be detectable depending upon the sample.

If you observe this phenomena, shoulders or splits around the s- $A_{1c}$  or A0 peak with several different samples in series, the assay condition may not be optimal or the Elution Buffers or the column may have been deteriorated. Review the chromatograms to determine the cause of the problem and replace the Elution Buffers or column if necessary, 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 G8 Variant Analysis Mode can separate major hemoglobin variants (HbD, HbS and HbC). See **“Chapter 6 section 6.4: Abnormal Chromatograms”** for typical chromatograms. Some hemoglobin variants like HbE may not be separated 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 s- $A_{1c}$  % with the analyzer.

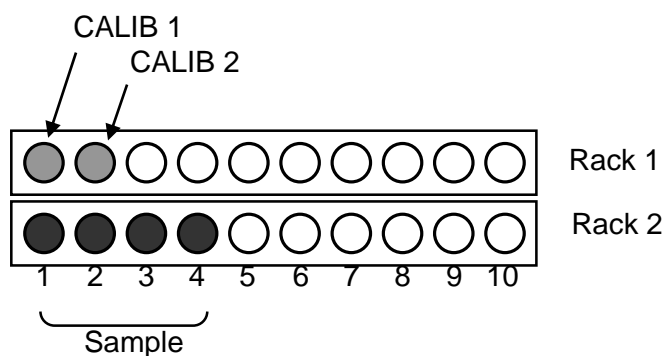
**NO. and ID Interpretation**

The sample number (NO.) and sample ID (ID) are automatically given but when the barcode on primary tube is read, the barcode ID is printed in the ID field.

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. 3-24 Example**



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

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

The sample numbers start from 0001 for the first assay tested on the day. When the START day is changed, the numbers return to 0001.

Specific numbers can be assigned to the sample numbers by inputting four-digit number to the PARAMETER. Take note if a sample number is overlapped with a number already assayed, the older result in RESULT or an external storage device will be overwritten.

### 3.13 List Data

List data is a table of assay results values that include the sample NO. and ID.

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

You can print and transmit data of the range specified.

Press the TODAY key to specify today's data obtained on the same day as the last assay data in the RESULT memory. Those data can be collectively printed and transmitted.

In addition, IDs can be edited on the LIST screen by individually selecting test results.

If the data meet the conditions specified in the FLAG, the flag code is listed on the LIST screen and printed out to the MK field.

If LIST AUTO SAVE is set to 1 on the PARAMETER screen, the list data is automatically saved to an external storage device for each batch data (apart from the data saved to the analyzer's RESULT memory). This data is saved to the external storage device in CSV format.



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

#### Point

Press the TODAY key on the LIST screen to extract and display only the data obtained on the same day as the last measured assay results.



Assay results obtained in the units other than the units currently set will not be listed on the LIST screen but listed as **Screen 3-19**. To display those data, set the same value to the FORMAT on the PARAMETER screen as the value with which those data were obtained.

See **“Chapter 4 Section 4.6: Parameter Setting”** for set value to the FORMAT.

Screen 3-17 LIST Screen

TODAY		LIST		2009/11/17 09:36		
1	20091113	676 9026 0001 - 02	1.0	9.1	10.5	5
2	677 0022 0002 - 01	1.1	5.1	6.3		
3	678 0023 0002 - 02	0.5	01	8.4	8.0	6
4	679 0024 0002 - 03	0.5	7.5	9.1		
	680 0025 0002 - 04	0.7	8.5	9.8		
PRINT 0 - 0						
COMMAND	RANG	EXEC	20	↓	↑	EXIT

#### Display content

1. Assay date of sample  
YYYYMMDD. (YYYY : Year, MM : Month, DD : Day)  
If assays were done in a certain time period, this will be displayed as:  
Ex. 20091104—20091105
2. The number of the assay result
3. Sample number
4. Sample ID or rack position number
5. Assay results ( HbF(%), HbA1c(%), HbA1(%))
6. Flag code  
See **Chapter 4 Section 4.18: FLAG Parameter Setting** for details.

Assay results obtained in IFCC units are listed on the LIST screen in the format defined by "TRANS G5/7 MODE" in the PARAMETER screen. The set parameters are not normally displayed on the screen. Contact the service personnel to change it.

See **Chapter 7 Section 7.2: Communication with a Host Computer** for details.

**Screen 3-18 LIST Screen** (examples assay results were obtained in IFCC units)

TODAY		LIST			
20091113				(2009/11/17 09:35	
676 9026 0001 - 02	1.0	77	10.5		
677 0022 0002 - 01	1.1	36	6.3		
678 0023 0002 - 02	0.5	49	8.0		
679 0024 0002 - 03	0.5	61	9.1		
680 0025 0002 - 04	0.7	71	9.8		
PRINT	0 - 0				
COMMAND	RANG	EXEC	20	EXIT	

TODAY		LIST			
20091113				2009/11/17 09:34	
676 9026 0001 - 02	1.0	9.1	77		
677 0022 0002 - 01	1.1	5.1	36		
678 0023 0002 - 02	0.5	6.4	49		
679 0024 0002 - 03	0.5	7.5	61		
680 0025 0002 - 04	0.7	8.5	71		
PRINT	0 - 0				
COMMAND	RANG	EXEC	20	EXIT	

Assay results (in IFCC units)

TRANS G5/7 MODE : 18

Assay results (in IFCC units)

TRANS G5/7 MODE : 28

**Screen 3-19 LIST Screen** (an example assay results were obtained in IFCC units but LIST data were displayed after set value to FORMAT was changed to that for reporting in NGSP units.)

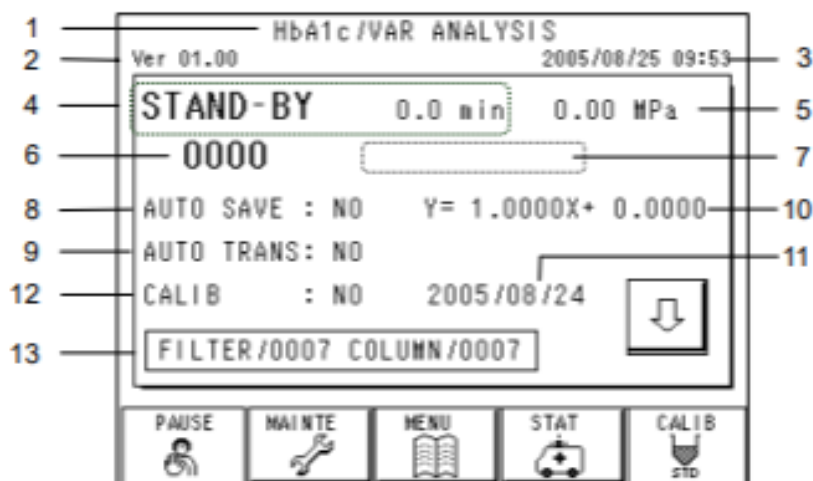
TODAY		LIST			
20091109 - 20091110				2009/11/19 07:29	
581 0002 0001 - 02		-----	IFCC(N)	-----	
582 0003 0001 - 03		-----	IFCC(N)	-----	
583 9001 0001 - 01		-----	IFCC(N)	-----	
584 9002 0001 - 01		-----	IFCC(N)	-----	
585 9003 0001 - 01		-----	IFCC(N)	-----	
PRINT	0 - 0				
COMMAND	RANG	EXEC	20	EXIT	

**NOTES**

## 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 (Displays the assay mode currently in operation)
2. Program version number
3. Current date and time
4. Status and remaining processing time or elapsed time
 

PUMP CLEAN:	Displayed during pump cleaning	}	(about 4.2 min.)
BUFF PRIME:	Displayed during buffer replacement		
WARMING UP:	Displayed during warm-up (about 4.8 minutes)		
STAND-BY:	In ready state (pump stopped)		
ANALYSIS:	Displayed during assay		
WASH:	Displayed during wash operation (about 3.0 minutes)		
5. Pump flow pressure: Displayed in MPa (Mega Pascals) units
6. Sample number currently under assay
7. Sample ID or rack position number currently under assay
8. Setting to auto save assay results on an external storage device

9. Setting for automatic transmissions to a host
10. Calibration factor currently in use
11. Date calibrated
12. Calibration setting
13. Number of injections for the filter and column

### ● Key Functions



: PAUSE (temporary stop) command  
 When the PAUSE key on the main screen is pressed during ANALYSIS, the key is highlighted and sampling is temporarily stopped. Pumping into the assay line continues, so the sample results currently being assayed will be output. Use this function when replacing the printer paper or performing other operations during an assay.

The pause is automatically released 10 cycles (1 cycle is 1.6minutes) after the PAUSE key is pressed.

Release the pause by pressing the PAUSE key again.



: Displays the maintenance screen



: Displays the menu screen



: Used to set and process STAT (priority) samples



: Sets whether or not to execute automatic calibration.

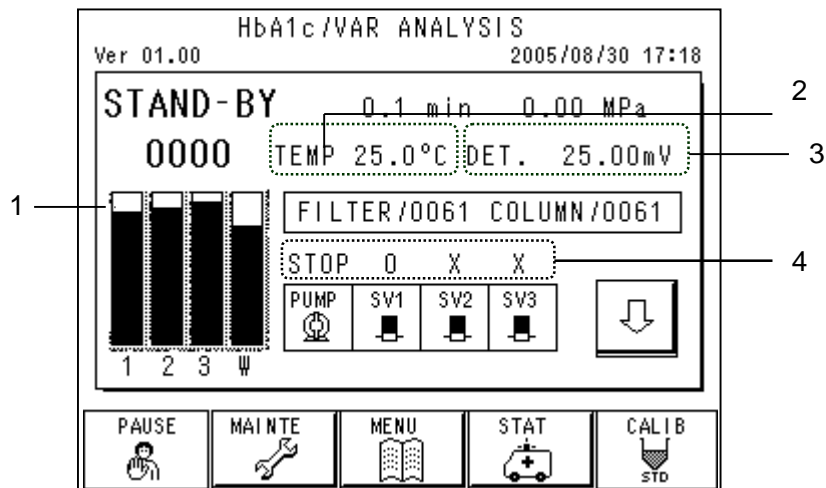
To set automatic calibration, press and highlight the key before giving the start command.



: Displays the second screen of the MAIN 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 (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. 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 Elution Buffer No. 1<br>(o: opened      x: closed      GE: Gradient elution) |
|  | : | Opens or closes the valve for Elution Buffer No. 2<br>(o: opened      x: closed      GE: Gradient elution) |
|  | : | Opens or closes the valve for Elution Buffer No. 3<br>(o: opened      x: closed      GE: Gradient elution) |
|  | : | Displays the first screen  |

Other display content 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.

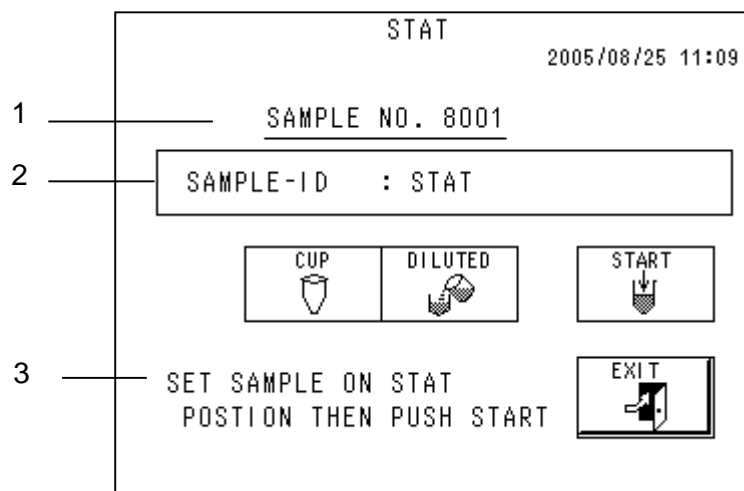
## 4.2 STAT [Main screen] – [ ]

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, press the  key to return to the main screen. The STAT key will be highlighted (  ), 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 unhighlighted.





### Screen 4-3 STAT Screen










#### Display content

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

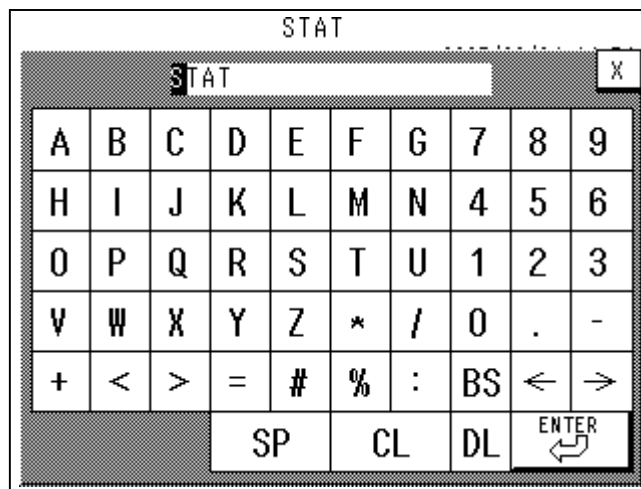
**Key Functions**

- : Changes the ID number
-  : Highlighted when a sample vial is set
-  : Highlighted when a diluted sample is set
-  : Registers the STAT sample
-  : Displays the previous screen


**Operation Ex.**

- 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  to display the ID EDIT screen. Input an ID.
- 5) Select a cup (vial)/tube (  ), and and diluted/undiluted sample (  ). Press the  key.
- 6) Press the  key to return to the main screen.
- 7) If the STAT sample assay is scheduled, the key on the main screen is highlighted (  ).

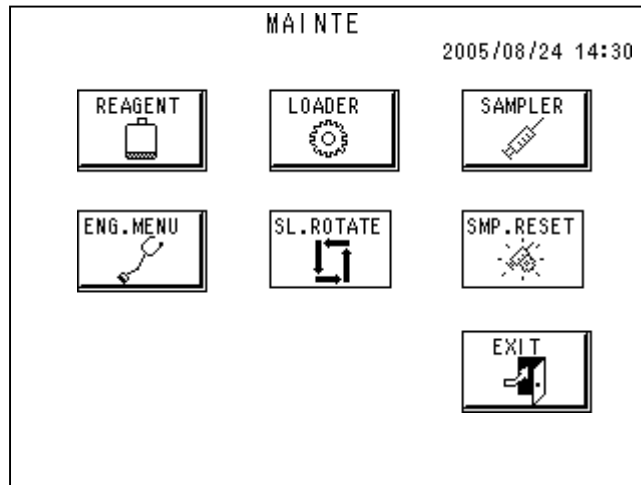
**Screen 4-4 ID EDIT Screen**










### 4.3 Maintenance [Main Screen] – [ ]

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

#### Screen 4-5 MAINTENANCE Screen



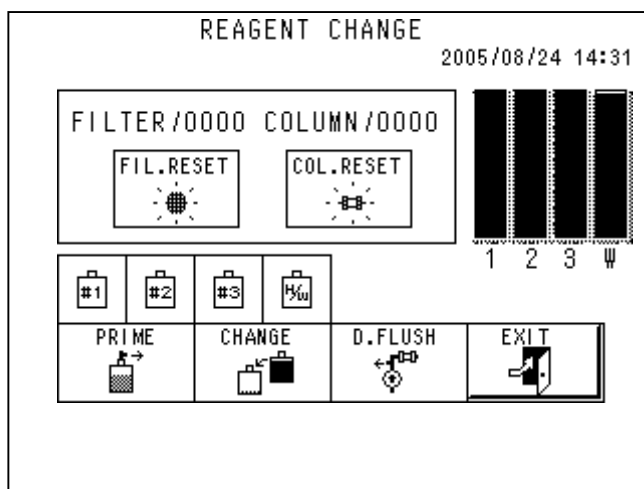
#### Key Functions

-  : Displays another screen to reset the column and filter counter or replaces the reagent
-  : Used by only service person (nothing executes, even if pressed)
-  : Used by only service person (nothing executes, even if pressed)
-  : Used by only service person (nothing executes, even if pressed)
-  : Continuously rotates the sample loader.  
Stops the loader when the key is pressed again.
-  : Initializes (washes) the sampling unit
-  : Returns to the previous screen











#### 4.4 Reagent Change [ - ]

This key 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 4-6 REAGENT CHANGE Screen



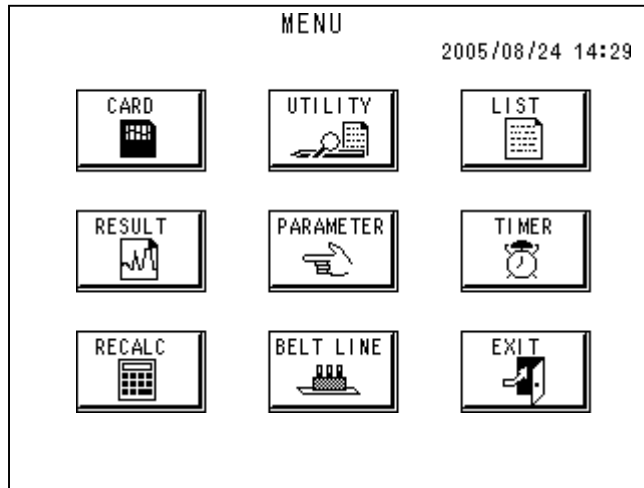
##### Key Functions

-  : Sets the filter counter to 0
-  : Sets the column counter to 0
-  : Selects Elution Buffer No.1 for PRIME and CHANGE
-  : Selects Elution Buffer No. 2 for PRIME and CHANGE
-  : Selects Elution Buffer No. 3 for PRIME and CHANGE
-  : Selects the Hemolysis & Wash solution for PRIME and CHANGE
-  : Replaces reagent in the flow paths selected with the above key
-  : Replaces the reagent in the flow paths selected with the above key. Resets the display for the remaining volume.
-  : Purges the air from the drain valve when air has entered into the pump
-  : Returns to the previous screen










**4.5 Menu [Main Screen] – [  ]**

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

**Screen 4-7 MENU Screen**




**● Key Functions**

	<u>Reference page</u>
 :	Displays the card (external storage device) screen.....P 4 – 19
 :	Displays the utility screen.....P 4 – 30
 :	Displays the list data editing screen.....P 4 – 28
 :	Displays the list of measurement results stored in analyzer.....P 4 – 22
 :	Displays the parameter settings screen.....P 4 – 9
 :	Displays the date and timer screen.....P 4 – 26
 :	Displays recalculation screen for test results (RESULT, CARD (External storage device)).....P 4 – 24
 :	Only used when LA connecting
 :	Returns to the previous screen





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

## 4.6 Parameter Setting [ ] - [ ]





Press the  key on the main screen to display the PARAMETER screen.  
Select the various parameters to change their setting.

### Screen 4-8 PARAMETER Screen (page 1 of 4)

PARAMETER	
P.01	2009/11/19 07:57
SAMPLE NO.	0001
CALIB_1(NGSP)	6.00
CALIB_2(NGSP)	10.80
-----	
-----	

#### ● Key Functions

-  : Displays the page after the next page
-  : Displays the next page
-  : Displays the previous page
-  : Returns to the previous screen

#### **Point**

There are four PARAMETER screens in total. The key functions are the same for all of the screens.

## Screen 4-9 PARAMETER Screen (page 1 of 4)

PARAMETER	
P.01	2009/11/19 07:57
SAMPLE NO.	0001
CALIB_1(NGSP)	6.00
CALIB_2(NGSP)	10.80
-----	
-----	

## Parameters (page 1 of 4)

SAMPLE NO.:	The first sample number on the next run (normally set automatically)
CALIB_1 :	Assigned value of calibrator 1
CALIB_2 :	Assigned value of calibrator 2

**Point**

Assigned values to be entered will be prompted with NGSP/Mono S/IFCC indication as below.

For entering in NGSP units:

CALIB\_1(NGSP)

CALIB\_2(NGSP)

For entering in Mono S units:

CALIB\_1(Mono S)

CALIB\_2(Mono S)

For entering in IFCC units:

CALIB\_1(IFCC)

CALIB\_2(IFCC)

## Screen 4-10 PARAMETER Screen (page 2 of 4)

PARAMETER	
P.02	2009/11/19 08:01
FACTOR_A1C A	1.0000
FACTOR_A1C B	0.0000
-----	
-----	
FORMAT(N+I)	110

## Parameters (page 2 of 4)

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)

FORMAT: Comprised of 3 digits as ABC.

The last digit (C): See also "**Chapter 3 Section 3.12: Interpretation of Results**"

0	FORMAT 0 (Detailed peak information with the chromatogram)
1	FORMAT 1 (Basic peak information with the chromatogram)
9	FORMAT 0 with the number of theoretical plate

Second digit from the last (B):

Specifies assay results are reported in NGSP (or Mono S) units (%) and/or IFCC units (mmol/mol)

0	Reported only in the units with which the calibration will be performed. Note this will be displayed as a blank when the third digit from the last was 0.
1	Reported in the both units. The units with which the calibration will be performed come first.

Third digit from the last (A): Specifies the units for calibration

0	JDS units. Shown as a blank on the screen.
1	NGSP units.
2	IFCC units. Assay results in JDS units are reported too.
3	IFCC units. Assay results in NGSP units are reported too.
4	Mono S units.
5	IFCC units. Assay results in Mono S units are reported too.

Indication of "FORMAT" on the PARAMETER screen will be replaced as e.g. "FORMAT(I+N)" depending on a combination of the three digits ABC (set value) above, to clarify the units for calibration as well as the units for reporting. This indication corresponds to the FORMAT set value.

Summary table for FORMAT set value

Units for calibration	Units reported together	Printout format	Set value	Indication after entering set value
JDS units	None	FORMAT 0	000	FORMAT(J)
		FORMAT 1	001	FORMAT(J)
	IFCC units	FORMAT 0	010	FORMAT(J+I)
		FORMAT 1	011	FORMAT(J+I)
NGSP units	None	FORMAT 0	100	FORMAT(N)
		FORMAT 1	101	FORMAT(N)
	IFCC units	FORMAT 0	110	FORMAT(N+I)
		FORMAT 1	111	FORMAT(N+I)
IFCC units (Assay results in JDS units are reported too.)	None	FORMAT 0	200	FORMAT(I)
		FORMAT 1	201	FORMAT(I)
	JDS units	FORMAT 0	210	FORMAT(I+J)
		FORMAT 1	211	FORMAT(I+J)
IFCC units (Assay results in NGSP units are reported too.)	None	FORMAT 0	300	FORMAT(I)
		FORMAT 1	301	FORMAT(I)
	NGSP units	FORMAT 0	310	FORMAT(I+N)
		FORMAT 1	311	FORMAT(I+N)
Mono S units	None	FORMAT 0	400	FORMAT(M)
		FORMAT 1	401	FORMAT(M)
	IFCC units	FORMAT 0	410	FORMAT(M+I)
		FORMAT 1	411	FORMAT(M+I)
IFCC units (Assay results in Mono S units are reported too.)	None	FORMAT 0	500	FORMAT(I)
		FORMAT 1	501	FORMAT(I)
	Mono S units	FORMAT 0	510	FORMAT(I+M)
		FORMAT 1	511	FORMAT(I+M)

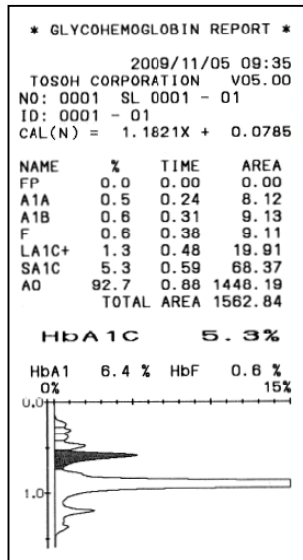
**Point**

The units for calibration applied are indicated as like "CAL(IN)" on assay results as below:

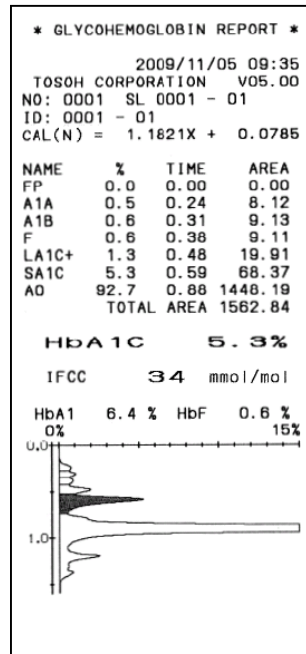
Units for calibration	Indication for calibration factors
JDS units	"CALIB Y = AX + B" or "CAL(J) = AX + B"
NGSP units	CAL(N) = AX + B
IFCC units (Assay results in JDS units are reported too.)	CAL(IJ) = AX + B
IFCC units (Assay results in NGSP units are reported too.)	CAL(IN) = AX + B
Mono S units	CAL(M) = AX + B
IFCC units (Assay results in Mono S units are reported too.)	CAL(IM) = AX + B

Fig. 4-1 Printout Example

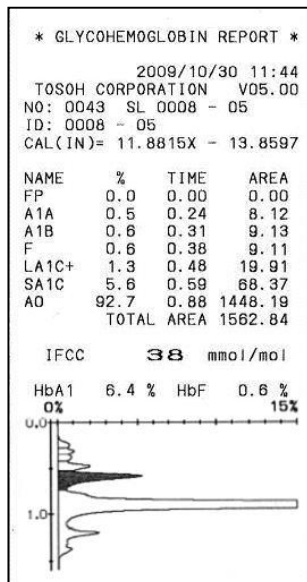
FORMAT set value : 100



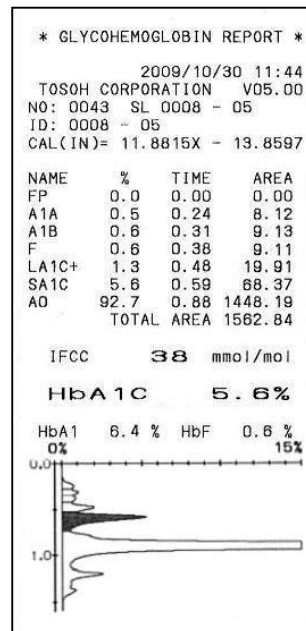
FORMAT set value : 110



FORMAT set value : 300




FORMAT set value : 310



## Screen 4-11 PARAMETER Screen (page 3 of 4)

PARAMETER	
P.03	2005/08/25 14:30
RAW AUTO SAVE	0
LST AUTO SAVE	0
LIST AUTO CLEAR	0
OFF TIMER	2.0
COPY	1



## Parameters (page 3 of 4)

- RAW AUTO SAVE: Automatically saves the assay results to the external storage device  
(0: no save, 1: save)
- LST AUTO SAVE: Automatically saves the list data to the external storage device  
(0: no save, 1: save)
- LIST AUTO CLEAR: Clears results each time START is pressed  
(0: do not clear, 1: clear)
- OFF TIMER: Time from STAND-BY mode entry until power shut-off.  
The unit is in hour.  
(0 ~ 3: 0 indicates no automatic power shut-off)
- COPY: Number of printout copies (0 ~ 3)

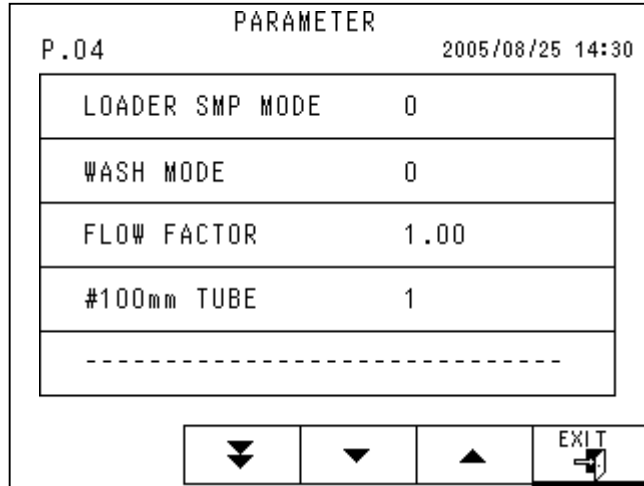


If the LIST AUTO CLEAR setting is 1, previously measured assay data saved to the RESULT section will also be deleted.

**Point**

If the CARD FULL error occurs during assays, you can resave the results to an external storage device by using the SAVE key on the RECALC screen after the assay has completed. (See “**Chapter 4. Section 4.9: Confirmation, Transmission to Host, Recalculation of Saved Results**”)

**Screen 4-12 PARAMETER Screen (page 4 of 4)**



● Parameters (page 4 of 4)

LOADER SMP MODE: Designates the sample container type

Container	Primary tube	Sample vial
0	Whole blood	Diluted sample
1	Whole blood	Whole blood
2	Diluted sample	Diluted sample
3	Specified by host	

**Point**

Regardless of the LOADER SMP MODE setting, calibrators will be recognized as diluted samples and the STAT sample will be processed using the settings on the STAT screen.

WASH MODE:	WASH mode settings This parameter is not alive in the Variant mode Never change this parameter The initial value is "0"
FLOW FACTOR:	Pump flow factor Never change this parameter without instruction from the service personnel
#100mm TUBE:	Setting for the primary tube length If you are using a combination of 75 mm and 100 mm tubes, set to 100 mm (0: 75 mm, 1: 100 mm)



1. Never change the FLOW FACTOR without instruction from the service personnel. Accurate results may not be obtained if this parameter is changed.




- Caution**
1. **Make sure the #100 mm TUBE is correctly set. Otherwise the analyzer can be damaged.**
  2. **If 75 mm and 100 mm primary tubes are set together, the 75 mm tubes will be pulled up after being assayed and will be forwarded as they are. If these tubes are forwarded to the sampling position, the sampling needle could be bent due to misarrangement.  
Make sure to place an end marker or an empty rack after the last sample so that assaying operations will stop.**

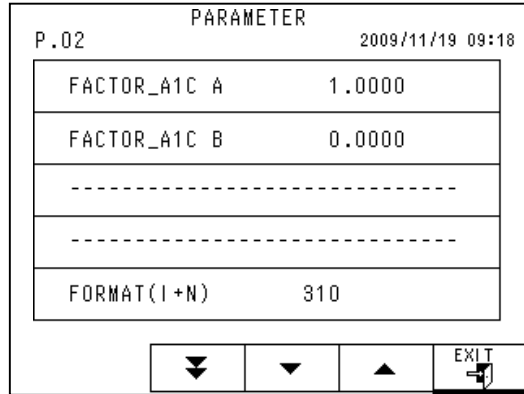
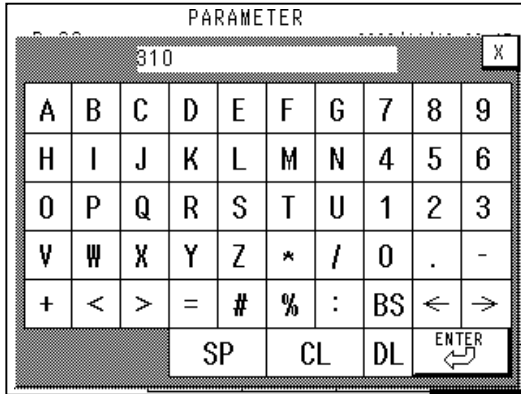
**Operation Ex.**

**- Parameter change procedure**

The procedure for changing the FORMAT to 310 (calibration in IFCC units and reporting in IFCC units together with in NGSP units) is shown below. Press the keys in the designated sequence.

- 1) Press the screen's FORMAT line and open the PARAMETER input screen.
- 2) Press the CL key to clear existing values and use the numerical keys to input "310".
- 3) Confirm that "310" is displayed in the input field, press the  key and close the input screen.
- 4) Confirm that FORMAT was set to 310 and the indication "FORMAT" was replaced with "FORMAT(I+N)". The parameter input is now complete.






**Screen 4-13 PARAMETER Input Screen      Screen 4-14 Change Example**



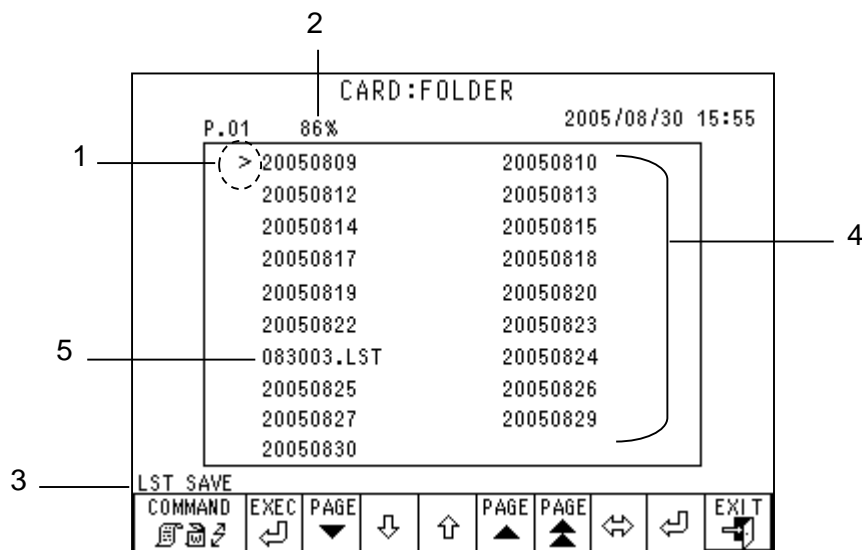
**Point**

All settings and analyzer parameter changes should be executed in the same way, as indicated above.

## 4.7 Card (External storage device) [ ] – [ ]

Press the  key on the MENU screen to display the CARD: FOLDER screen. Use the    keys on that screen to select a folder (move the arrow ">"). Press the  key and the list of the file will be displayed on the CARD: FILE screen. Saving list data and parameters to an external storage device, formatting an external storage device, and printing/deletion of files and folders on an external storage device are performed here.

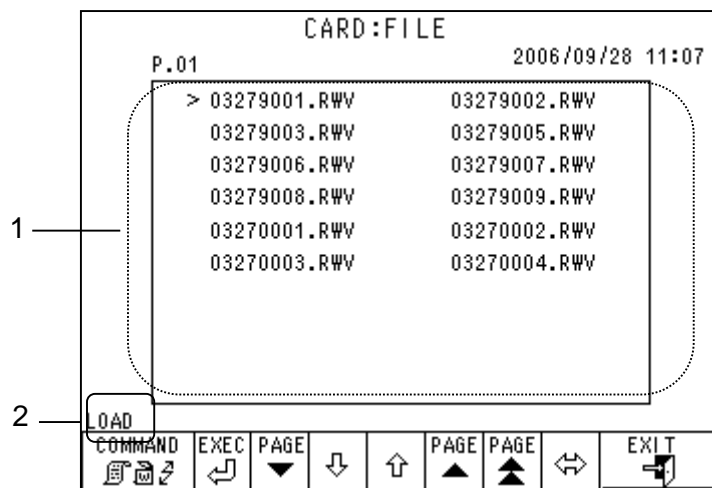
### Screen 4-15 CARD: FOLDER Screen



#### Display content

1. The arrow shows the active field
2. Percentage of external storage device in use
3. Selected command
4. Folder (Data is stored in a folder of the assay date)
5. List data (extension: LST)

**Screen 4-16 CARD: FILE Screen**



● Display content

1. Assay data for each sample (extension: RWV)
2. Selected command

● Key functions (CARD: FOLDER / CARD: FILE screens)












: Command key (Commands change when pressed)

Command Descriptions and Executable Statuses

Command types		WAMING-UP	STAND-BY	ANALYSIS	WASH
Command	Content				
LST SAVE	List data save (Valid only in CARD: FOLDER screen) Filename will automatically be assigned using the ID number and serial number	1	1	3	1
PRM SAVE	Parameter save (Valid only in CARD: FOLDER screen) File will be saved as SYSTEM.PRM.	3	1	3	3
LOAD	File loading Parameters and list data can be loaded	2	1	3	2
FORMAT	Format external storage device	1	1	3	1
PRINT	List of files or folders can be printed	1	1	1	1
DELETE	Selected files or folders can be deleted	1	1	3	1






1: Can be executed      2: Applied only for list data      3: 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
	:	Return 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 CARD: FOLDER screen.
- 2) Press the  key until DELETE is displayed.
- 3) Press the  key to delete the selected list.

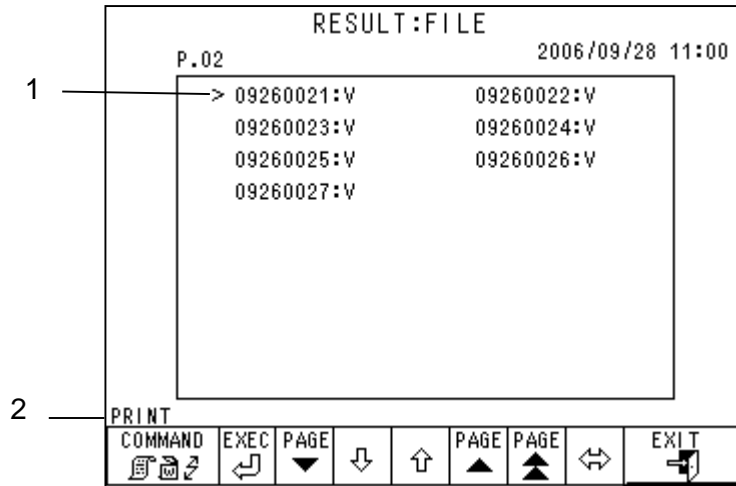
Folders and the data stored in that folder, as well as individual data items, can be deleted by following the same procedure.



1. The commands you can execute may be depending on the analyzer's operational states. When a Smart Media card is used, its usable capacity is 128 MB or less.
2. The analyzer cannot display folder names and filenames that include double-byte characters or that exceed 12 characters. The analyzer may have an error with the external storage devices that have folder name and filenames that include double-byte characters or that exceed 12 characters.













## Screen 4-18 RESULT: FILE Screen



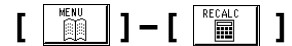
### Display content


1. Assay data for each sample
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
	:	Displays the previous screen

## 4.9 Confirmation, Transmission to Host, Recalculation of Saved Results



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

The assayed results, which are stored in the analyzer's memory (RESULT) or in an external storage device, can be printed, retransmitted to a host, and recalculated with different calibration factors. Up to 800 test results can be stored in RESULT.

### Screen 4-19 RECALC Screen









P.01		RECALC	2005/08/24 14:55
1	ID NO.	:	20050101
2	FIRST NO.	:	0001
3	LAST NO.	:	0001
4	FACTOR_A1C A:		1.0000
5	FACTOR_A1C B:		0.0000

RSLT/CARD	LOCK	SAVE	TRANS	EXECUTE	FOLDER	▼	EXIT
-----------	------	------	-------	---------	--------	---	------

#### Display content

1. Assay date of sample (same as the folder name)
2. First data number of the results
3. Last data number of the results
4. FACTOR\_A1C A  
(Valid when recalculating results after changing the calibration factor)
5. FACTOR\_A1C B  
(Valid when recalculating results after changing the calibration factor)


### Key Functions

-  : Selects whether the data to be processed is stored in the main unit memory (RESULT) or in an external storage device (CARD) (Highlighted item is selected)
-  : When highlighted, executes recalculation using the calibration factors set in the RECALC screen
-  : When highlighted, saves the recalculated results to a CARD
-  : When highlighted, automatically transmits the recalculated results
-  : Starts printing and recalculation operations
-  : Used to check the data folders
-  : Not used
-  : Return to the previous screen

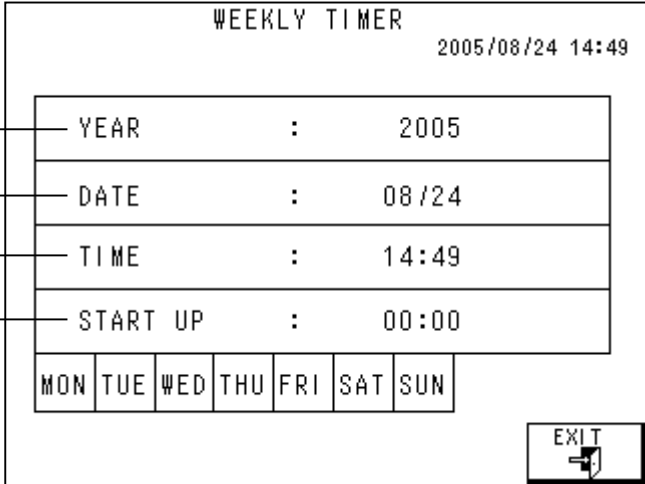
### Point

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 the SAVE key is selected on the RECALC screen, the data will be saved to the external storage device, regardless of whether RESULT or CARD is specified.
2. The heading will change to the heading currently set at the RECALC execution.  
(See "**Chapter 4. Section 4.16 Entering a Heading**")

#### 4.10 Date/Time and Weekly Timer Setting [ ] - [ ]

Press the  key on the main screen to display the WEEKLY TIMER screen. When the timer is selected, the analyzer goes in the STAND-BY mode with WARMING UP completed automatically on a specified input day every week. When the timer startup is activated, the power automatically comes on and WARMING UP is executed at the designated START UP time. The analyzer goes in STAND-BY state after WARMING UP is complete. Normally, when nothing is input from the operation panel for 2 hours, the power is automatically turned off.

#### Screen 4-20 WEEKLY TIMER Screen



The screenshot shows the WEEKLY TIMER screen with the following settings:

WEEKLY TIMER		2005/08/24 14:49
1	YEAR	: 2005
2	DATE	: 08/24
3	TIME	: 14:49
4	START UP	: 00:00

Below the settings is a weekly timer bar with the following days: MON, TUE, WED, THU, FRI, SAT, SUN. An EXIT button with a right arrow is located in the bottom right corner.

#### ● Display content

1. Year
2. Date
3. Time
4. START UP time

### Key Functions

MON	TUE	WED	THU	FRI	SAT	SUN	:	Input the analyzer startup day of the week
EXIT							:	Return to the previous screen

### Operation Ex.

#### - Example setting for a weekly timer

- 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 highlight and select the day of the week on which you want the analyzer to start up.
- 5) Select START UP, display the input screen, and input the time to start up.
- 6) Verify the specified day (highlighted) and START UP time on the WEEKLY TIMER screen.

### Point

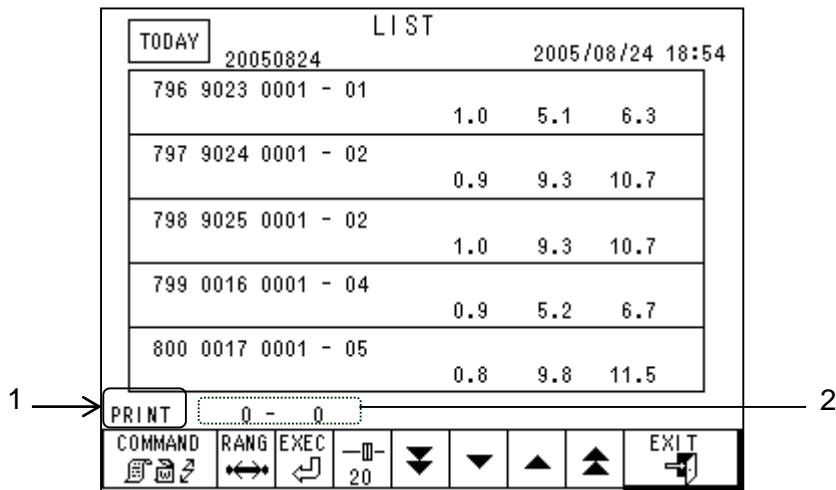
1. The scheduled analyzer's startup day is displayed highlighted. Before starting the timer, make sure to set both START UP time and the analyzer startup day.
2. The timer period from STAND-BY to POWER OFF can be changed using the OFF TIMER parameter. (See "**Chapter 4 Section 4.6 Parameter Setting**")

4.11 List Data Display and Bar Code Editing [  ] - [  ]

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

A list of stored results can be displayed, printed, deleted, and transmitted to the host. Unreadable bar code IDs can also be input or corrected on this screen after the assay.



Screen 4-21 LIST Screen











● Display content

1. Command
2. First and last number of the selected results to which the command is being applied

● Key Functions


-  : When highlighted, only assay results which have the same date of the latest operation are selected.
-  : Command key (Commands change when pressed)

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
	:	Execution key for 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
	:	Return to the previous screen

### **Operation Ex.**


#### **- Example of bar code editing**

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

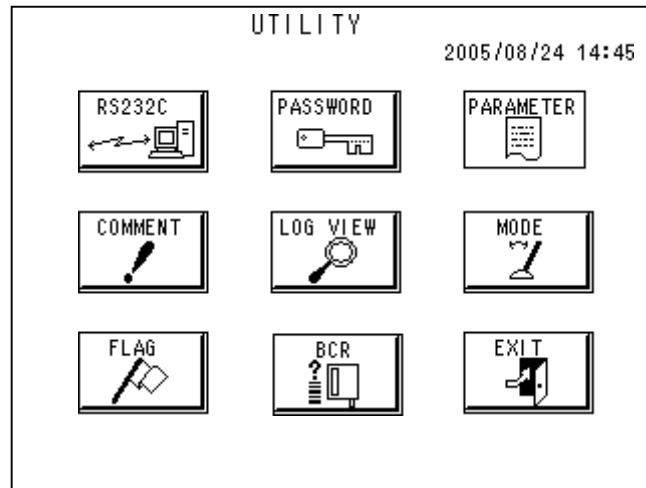
#### **Screen 4-22 Bar Code Input Screen**

TODAY		LIST								
015 - 01										X
A	B	C	D	E	F	G	7	8	9	
H	I	J	K	L	M	N	4	5	6	
O	P	Q	R	S	T	U	1	2	3	
V	W	X	Y	Z	*	/	0	.	-	
+	<	>	=	#	%	:	BS	←	→	
				SP	CL	DL	ENTER			










**4.12 Utilities** [  ] - [  ]

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


**Screen 4-23 UTILITY Screen**






● Key Functions

	<u>Reference page</u>
 : Displays RS232C settings screen.....	P.4 – 31
 : Password input (for service personnel).....	P.4 – 33
 : Parameter Printout.....	P.4 – 34
 : Sets text to print in comment space of assay results___	P.4 – 35
 : Displays a list of errors, communications log, etc.....	P.4 – 36
 : Change the analysis mode	
 : Sets and changes flag entry parameters (FLAG file)___	P.4 – 38
 : Sets and test the bar code reader.....	P.4 – 43
 : Return to the previous screen	

### 4.13 Data Communication Setting [ ] - [ ] - [ ]

Press the  key on the UTILITY screen to display the RS232C screen.  
To transmit data in real time, press the AT TRANS key (“auto transmit” at the bottom) to highlight.

**Screen 4-24 RS232C Screen**

RS232C							
2005/08/24 18:56							
SMP3	BC13	BM	8BIT	X-ON	1BIT	NONE	1200
SMP5	BC18	HM	7BIT	X-OF	2BIT	ODD	2400
SMP8	BC20	RAW				EVEN	4800
	BCNO						9600
QUERY 		AT TRANS 		EXIT 			

#### Key Functions

- 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)
- BC 13: Transmits the bar code using 13 digits
- BC 18: Transmits the bar code using 18 digits
- BC 20: Transmits the bar code using 20 digits
- BC NO: Does not send the bar code ID
- BM: Transmits in BASIC mode
- HM: Transmits in HI-LEVEL mode
- RAW: Transmits in RAW mode
- 8 BIT: Sets the data length to 8 bits

7 BIT: Sets the data length to 7 bits  
X-ON: Sets the X parameter on (flow control on)  
X-OFF: Sets the X parameter off (flow control off)  
STP 1: Sets the stop bit to 1  
STP 2: Sets the stop bit to 2  
NONE: Sets the parity to none  
ODD: Sets the parity to odd numbers  
EVEN: Sets the parity to even numbers  
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



: When this key is highlighted, a query with ID is executed and only designated samples are processed.




: When highlighted, results are automatically transmitted

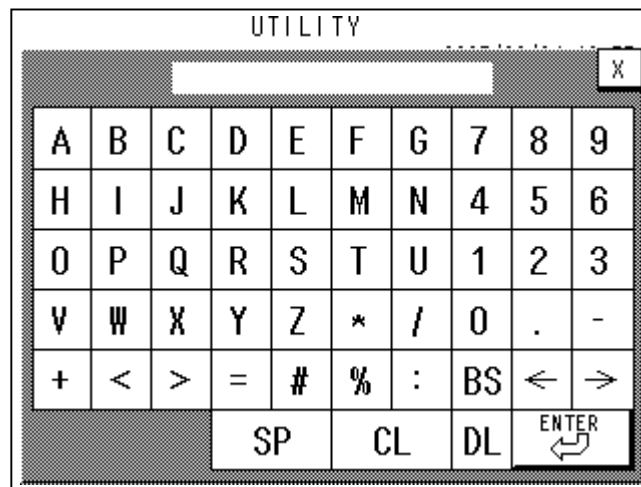


: Return to the previous screen


#### 4.14 Password Input (parameter initialization) - -

Press the  key on the UTILITY screen to display the PASSWORD screen.  
Input "CLR" on this screen to delete the parameters stored in the main unit.  
During daily operations, this space is blank.

#### Screen 4-25 PASSWORD Screen




#### Operation Ex.

- 1) From the UTILITY screen, press the  key to display the PASSWORD screen. Input "CLR".
- 2) Turn the POWER key off.
- 3) Turn the main power switch off.
- 4) Insert an external storage device containing a SYSTEM.PRM file into the storage device socket.
- 5) Turn on the main power. Then, after the startup message is displayed, turn the POWER key on.
- 6) Parameter initialization is complete when the main screen is displayed.



The PASSWORD screen is used to initialize the parameters.  
No operation except the input of "CLR" is guaranteed.  
Do not enter any text except "CLR".

#### 4.15 Parameter Printout [ ] - [ ] - [ ]

Press the  key on the UTILITY screen to print out a list of parameters, as shown below.

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

**Fig. 4-2 Parameter Printout Example**

```

***** PARAMETER *****
                2010/08/17 14:54

PARAMETER
SAMP NO.          1
CALIB-1          5.5000
CALIB-2         10.5000
FACTOR A         1.0000
FACTOR B         0.0000

FORMAT           110
RAW-SAVE         0
LST-SAVE         0
LIST CLR         0
OFF TIME        2.0000

COPY             1
LS MODE          0
WASHMODE         0
FLOW             1.0000
TUBE100          1


*** FLG PARAMETER ***
CODE FLAG DATA LEVEL
COMMENT
  1 < 700.00 0
    AREA LOW
  1 > 3000.00 0
    AREA HIGH
 40 = 0.00 0
    HB-VAR DETECT
  1 < 500.00 1
    AREA TOO LOW
  1 > 4000.00 1
    AREA TOO HIGH

CALIBRATION      NO

RS  8 20 B 8 N 1 N 1200
QUERY          0
AT TRANS       0

```

#### 4.16 Entering a Heading [ ] - [ ] - [ ]

Press the  key on the UTILITY 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.

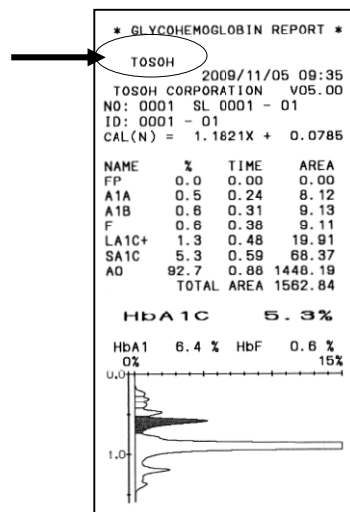
Up to 20 characters can be input.

If you edit the heading when RECALC is executed, the new heading will be printed.


#### Screen 4-26 COMMENT Screen

UTILITY									
TOSOH									X
A	B	C	D	E	F	G	7	8	9
H	I	J	K	L	M	N	4	5	6
O	P	Q	R	S	T	U	1	2	3
V	W	X	Y	Z	*	/	0	.	-
+	<	>	=	#	%	:	BS	←	→
			SP	CL		DL	ENTER		

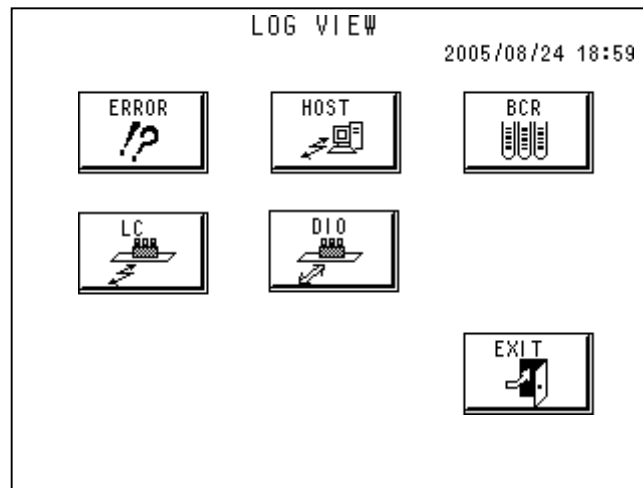
Fig. 4-3 Heading Printout Example (TOSOH)









#### 4.17 Log File Check [ ] - [ ] - [ ]

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

#### Screen 4-27 LOG VIEW Screen




#### ● Key Functions

-  : Displays the analyzer error log
-  : Displays a log of communications with the host computer
-  : Displays a log of scanned bar codes
-  : Displays the communication log with the line controller when LA is set. When it isn't, a log of auto sampler communications is displayed.
-  : Displays the DIO log when LA is set. When it isn't, a detailed log of communications with the host computer is displayed.
-  : Return to the previous screen

**Operation Ex.**

The example here uses the error log.

Press the  key. The next screen will be displayed.

**Screen 4-28 ERROR LOG VIEW Screen**

ERROR LOG VIEW				2005/08/24 18:59
05/08/24	11:35:22	001	STOP ACCEPTED	
05/08/24	11:35:24	002	EMERGENCY STOP	
05/08/24	12:03:10	001	STOP ACCEPTED	
05/08/24	12:03:13	002	EMERGENCY STOP	2
05/08/24	12:06:54	001	STOP ACCEPTED	
05/08/24	12:07:00	002	EMERGENCY STOP	
05/08/24	13:42:10	011	MIS OPERATION	
05/08/24	14:42:59	011	MIS OPERATION	
05/08/24	14:43:21	011	MIS OPERATION	
05/08/24	14:55:29	511	FILE NOT FOUND	3
05/08/24	14:59:02	511	FILE NOT FOUND	
05/08/24	17:46:18	002	EMERGENCY STOP	
05/08/24	17:46:46	001	STOP ACCEPTED	
05/08/24	17:49:14	001	STOP ACCEPTED	
05/08/24	17:49:18	002	EMERGENCY STOP	
05/08/24	18:26:15	001	STOP ACCEPTED	
05/08/24	18:26:15	002	EMERGENCY STOP	

1 — [ ]

2 — [ ]

3 — [ ]



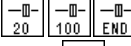





SAVE EXEC PRT EXEC — 20 — 100 — END ↓ ↑ ↓ ↑ EXIT

- Display content

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

See "**Chapter 6 Section 6.3: Error messages**" for detailed error messages.

- Key Functions

	:	Stores the log list on an external storage device
	:	Prints the log list on the printer
	:	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
	:	Return to the previous screen



#### 4.18 FLAG Parameter Setting [ ] - [ ] - [ ]

Press the  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. When you set new FLAG conditions or change them and execute a RECALC, make sure to confirm the settings.

Screen 4-29 FLAG Screen

FLAG		2006/09/28 10:50
P.01		
01 < 700.00	0	
AREA LOW		
01 > 3000.00	0	
AREA HIGH		
40 = 0.00	0	
HB-VAR DETECT		
01 < 500.00	1	
AREA TOO LOW		
01 > 4000.00	1	
AREA TOO HIGH		
EDIT MSG	▼	▲
		EXIT
		





#### ● 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 computer 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.)

### Key Functions

	:	Displays the message editing screen
	:	Scrolls down in single screen units
	:	Scrolls up in single screen units
	:	Return to the previous screen



### Input Ex.

- 1) Press the input line on the screen to select. (The field is blank when the settings are new.)
- 2) The numerical value input screen is displayed. Input the values for the “flag code”, “flag condition”, “flag values (number)” and “flag level” (in that order). Press the  key to close the numerical value input screen.
- 3) Press the  key to highlight.
- 4) Press the input line on the screen and open the message input screen.
- 5) Input the text that you want to display when the criteria conditions are met and press the  key to return to the FLAG screen.
- 6) Verify the content again on the FLAG screen. To modify an input message, input and correct from step 3).
- 7) RECALC the previously assayed data and verify settings.
- 8) If you want to remove a set condition, select the line, enter 0 = 0 and press the  key.

### Screen 4-30 Numerical Value Input Screen

FLAG									
01 > 2200.00 0									
A	B	C	D	E	F	G	7	8	9
H	I	J	K	L	M	N	4	5	6
O	P	Q	R	S	T	U	1	2	3
V	W	X	Y	Z	*	/	0	.	-
+	<	>	=	#	%	:	BS	←	→
				SP	CL	DL	ENTER		

**[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)]**

1	TOTAL AREA
2	s-A <sub>1c</sub> %
3	F %
4	HbA <sub>1</sub>
5	FILTER COUNT
6	COLUMN COUNT
7	Number of theoretical plate
8	Unidentified peak between LA <sub>1c</sub> and s-A <sub>1c</sub> when data =0 Unidentified peak between s-A <sub>1c</sub> and A <sub>0</sub> when data =1
9	Number of peaks
10	Sample number

Flag codes 11-20: When +10 is added to the above code (11, 12, 13, ...), the analyzer will perform the flag error check only when the calibrator is processed. In addition, the following flag codes are available.

24	Reports if only one unknown peak was detected
25	TEST counter
40	Reports if an H-V peak was detected. To enable, set as "40 = 0"
41	High s-A <sub>1c</sub> (mmol/mol)
42	High L-A <sub>1c</sub> %
43	Reports the presence of a peak (P-HV3) in a specific time range between s-A <sub>1c</sub> and A <sub>0</sub> when set as "43> 9999.99"
45	Detects a sample which had a higher P-HV3 value than or equal to the set value when set as "45 >= x.x"

## Screen 4-31 Message Input Screen

FLAG									
AREA HIGH									X
A	B	C	D	E	F	G	7	8	9
H	I	J	K	L	M	N	4	5	6
O	P	Q	R	S	T	U	1	2	3
V	W	X	Y	Z	*	/	0	.	-
+	<	>	=	#	%	:	BS	<	>
SP				CL		DL		ENTER	

**Point**

- In the Initial Entry,
 

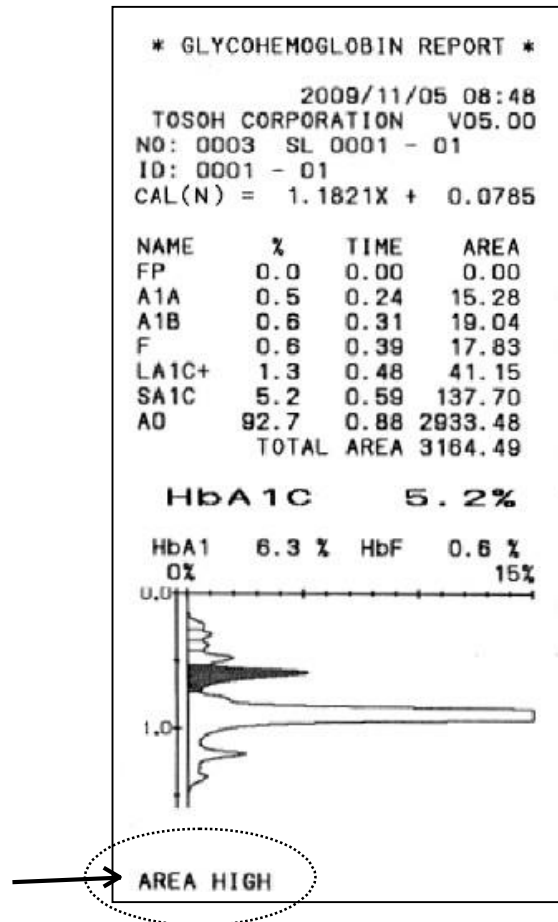
01 < 700	0	AREA LOW
01 > 3000	0	AREA HIGH
40 = 0	0	HB-VAR DETECT
01 < 500	1	AREA TOO LOW
01 > 4000	1	AREA TOO HIGH

 are set.
- 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.
- The theoretical plate number is an index related to column efficiency and is used for determining the column lifespan.
- To delete a flag condition, select the line you want to delete and input 0 = 0.
- If the same sample meets two or more flag conditions, all relevant flag messages will be printed on the report. However, only one flag code is transmitted to the host and is displayed on the LIST screen. The Level 1 flags will be given priority over the Level 0 flags. A flag set lower in the table has higher priority.

Fig. 4-4 Printout Example (AREA HIGH)



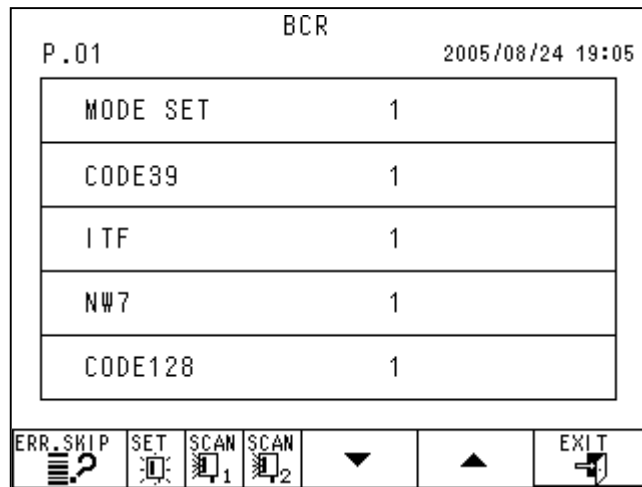
## 4.19 Bar Code Reader Setting and Reading Check










Press the  key on the UTILITY screen to display the BCR screen.

You can make bar code settings and execute a reading check on this screen.

### Screen 4-32 BCR Screen (P.01)



#### Key Functions

-  : Skips unreadable bar-coded samples during assays (highlighted when pressed)
-  : Inputs conditions (bar code specifications you want to use) into the bar code reader.
-  : Checks reading capability of bar code reader (by scanning)
-  : Checks reading capability of bar code reader for LA (by scanning)
-  : Displays the next page
-  : Displays the previous page
-  : Return to the previous screen

### Parameters

MODE SET:	Determines whether or not to set the bar code reader (0: do not set, 1: set)
CODE39:	Sets use of CODE 39 (0: do not use, 1: use)
ITF:	Sets use of ITF (0: do not use, 1: use)
NW-7:	Sets use of NW-7 ( <b>Codabar</b> ) (0: do not use, 1: use)
CODE128:	Sets use of CODE128 (0: do not use, 1: use)
JAN:	Sets use of JAN ( <b>UPC/EAN</b> ) (0: do not use, 1: use)
INDUST-2OF5:	Sets use of INDUSTRIAL 2 of 5 (0: do not use, 1: use)
COOP-2OF5:	Sets use of COOP 2 of 5 (0: do not use, 1: use)



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

CODE39 STR&STP:	Sets transmission of start/stop character (*) with code39 (0: do not transmit, 1: transmit)
CODE39 CHK-DIG:	Sets inspection for check digits (modulus43) with code39 (0: do not inspect, 1: inspect)
CODE39 CD OUT:	Sets transmission of check digits with code39 (0: do not transmit, 1: transmit)
CODE39 MIN:	Sets the minimum number of check digits with code39 (3 ~ 20)
CODE39 MAX:	Sets the maximum number of check digits with code39 (3 ~ 20)
ITF CHK-DGT:	Sets inspection for check digits (modulus10/weight 3) with ITF (0: does not inspect, 1: inspect)
ITF CD OUT:	Sets transmission of check digits with ITF (0: do not transmit, 1: transmit)
ITF MIN:	Sets the minimum number of check digits with IFT (2 ~ 20)
ITF MAX:	Sets the maximum number of check digits with IFT (2 ~ 20)
NW-7 STR&STP:	Sets transmission of start/stop character with NW-7 (0: do not transmit, 1: transmit)
NW-7 S/L CHAR:	Sets the type of start/stop character transmitted with NW-7 (0: lower case, 1: upper case)

---

---

NW-7 CHK-DIG:	Sets inspection for check digits (modulus10/weight2) with NW-7 (0: do not inspect; 1: inspect)
NW-7 CD TYPE:	Sets the check-digit type for inspection with NW-7 (0: modulus16, 1: modulus11, 2: modulus10/weight2, 3: modulus10/weight3, 4: 7 check DR, 5: modulus11-A, 6: modulus10/weight2-A)
NW-7 CD OUT:	Sets transmission of check digits with NW-7 (0: do not transmit, 1: transmit)
NW-7 MIN:	Sets the minimum number of check digits with NW-7 (3 ~ 20)
NW-7 MAX:	Sets the maximum number of check digits with NW-7 (3 ~ 20)
CODE128 DBL CHAR:	Sets check of double character start pattern for CODE128 (0: do not check; 1: check)
CODE128 MIN:	Sets the minimum number of check digits with code 128 (1~20)
CODE128 MAX:	Sets the maximum number of check digits with code 128 (1~20)
JAN UPC-E:	Sets use of UPC-E with JAN (0: do not use, 1: use)
JAN JAN8:	Sets use of JAN8 with JAN (0: do not use, 1: use)
JAN JAN13:	Sets use of JAN13 with JAN (0: do not use, 1: 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 addition, 1: add)
INDUST-2OF5 MIN:	Sets the minimum number of check digits with INDUSTRIAL 2 of 5 (1~20)
INDUST-2OF5 MAX:	Sets the maximum number of check digits with INDUSTRIAL 2 of 5 (1~20)
COOP-2OF5 MIN:	Sets the minimum number of check digits with COOP 2 of 5 (1~20)
COOP-2OF5 MAX:	Sets the maximum number of check digits with COOP 2 of 5 (1~20)

**NOTES**

## 5.1 Daily Care

Use a cloth dampened with neutral detergent to wipe stains from the analyzer's plastic components on the front side (needle cover, etc.).



**Caution** Do not use organic solvents such as ethanol to clean the plastic components. Doing so could warp or discolor such components.

Use a cloth dampened with neutral detergent to wipe blots and stains on metallic components as well. If contamination is severe, wipe using a cloth soaked in ethanol.

Water remaining on metallic surfaces will cause rust.

Lightly wipe away blots and stains on the sample loader belt, display, and key sheet with a cloth soaked 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 CALIB key display	3.6
2	Column	Check counter → replace	5.6
3	Filter	Check counter → replace	5.7
4	Elution buffers	Check volume → replace	5.3
5	Hemolysis & Wash Solution	Check volume → replace	5.3
6	Smart Media	Check remaining volume → replace or initialize	4.7
7	Printer paper	Check volume → replace	5.8
8	Waste eluent bottle	Check waste volume → treat waste	3.5.6
9	Tube leakage	Check flow path → Tighten	


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

No.	Items to check/replace	Maintenance schedule	Refer to
1	Column	After 1500 tests	5.6
2	Filter	After 400 tests	5.7
3	Suction filter	Every 6 months	5.9
4	Sampling needle	When bent or broken	5.10
5	Needle O-ring	Annually	5.11

- The following items are checked by service personnel.

No.	Items to check / replace	Service frequency (guide or target)
1	Check the bar code reader	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 screws of sampling unit	
8	Check the screw of the parts driving the valves	
9	Check the column oven temperature	
10	Check the solenoid valve's action (3 locations)	
11	Check vacuum pump's action	
12	Replace the rotor seal of the injection valve	
13	Replace the rotor seal of the AS valve	
14	Wash or replacement of the pump check valves	
15	Replace the plunger seal	
16	Lubrication of pump drive unit	
17	Replace the Teflon® tip of syringe	
18	Replace the sample loop	Annually or every 20,000 sample injections
19	Replace the valve stator face	When dirty or worn
20	Replace the drain valve packing	When worn

### 5.3 Elution Buffer and Hemolysis & Wash Solution Replacement

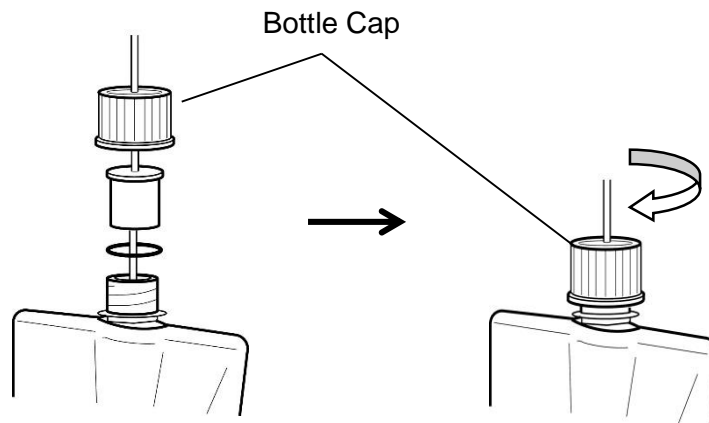
Replace elution buffers and Hemolysis & Wash solution as early as possible when remaining volumes are low. The remaining volumes of buffers are displayed in a graph on the main screen (second screen) by pressing the  key in the main screen (first screen).

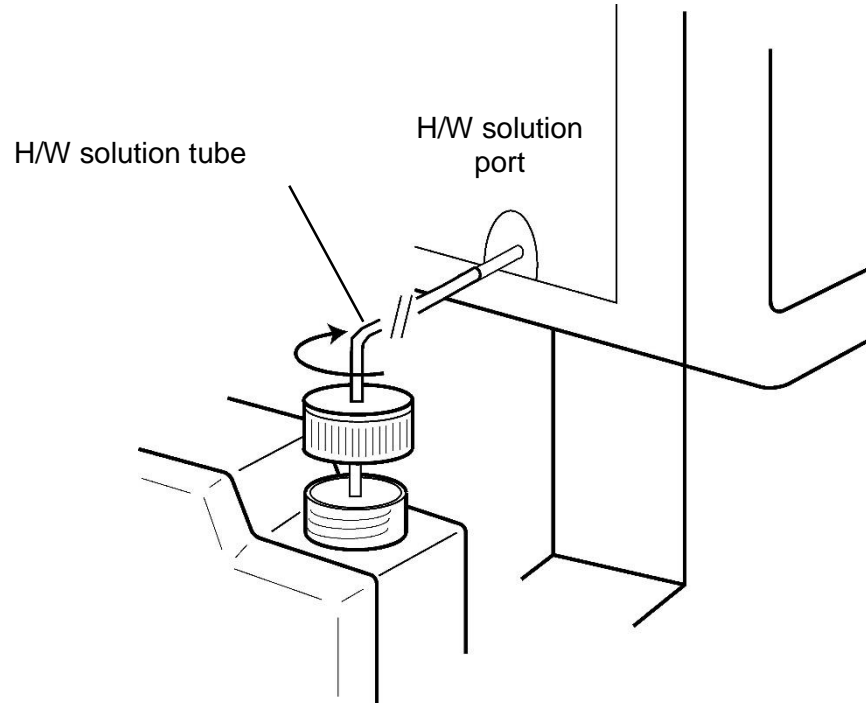
Since the graphical display is only an indication, there may be some difference with the actual remaining amount depending on usage conditions.


#### Procedure

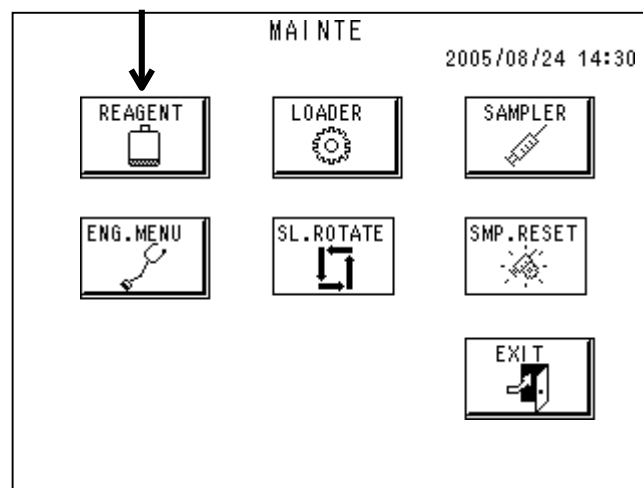
- 1) If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also change the state to STAND-BY state by pressing the STOP key.
- 2) Replace the buffer or Hemolysis & Wash solution.
- 3) Confirm that the end of the tube reaches the bottom of the container.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

**Fig.5-1 Elution Buffers**



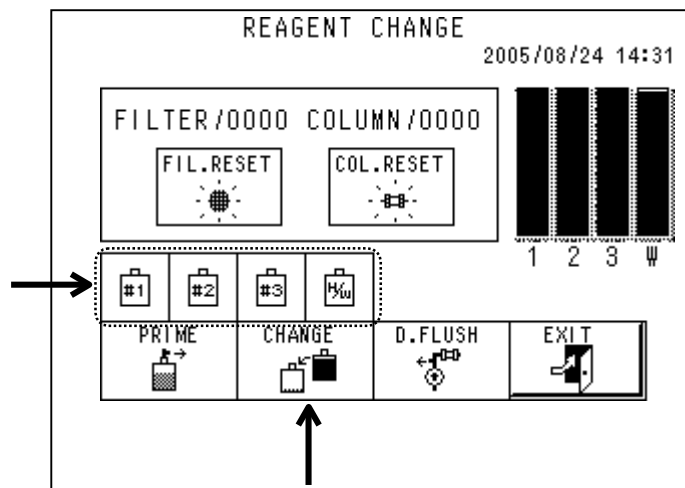
**Fig. 5-2 Hemolysis & Wash Solution Tube Connection**


- 6) Press the  key in the MAINT screen.

**Screen 5-1 MAINT Screen**

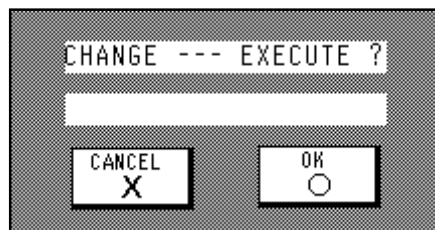
- 7) Highlight the keys of the reagents which you want to replace.  
(Example: Highlight key #1 and #2 when you want to replace buffer No.1 and 2.)

### Screen 5-2 REAGENT CHANGE Screen



- 8) Press the  key. A confirmation message will be displayed.  
If everything is all right, press the OK key.

### Screen 5-3 CHANGE Message



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

#### Point

Approximately 5 mL of each reagent 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. The 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 each buffer is adjusted based on the standard packaging size. Therefore, do not use any other container since no exact remaining volume can be displayed. To change the size, contact a service representative.

## 5.4 Elution Buffer Priming


The analyzer automatically executes priming or purging with all elution buffers when the power is turned on and when it has been in STAND-BY state for 90 minutes or more. It replaces the buffer in the flow lines, and then starts the pump run and assay.

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 path may have increased. As a result, you may experience problems such as unstable pumping pressure, inordinate chromatograms (unidentified peak P00 may appear), and an abnormal assay value for the control.

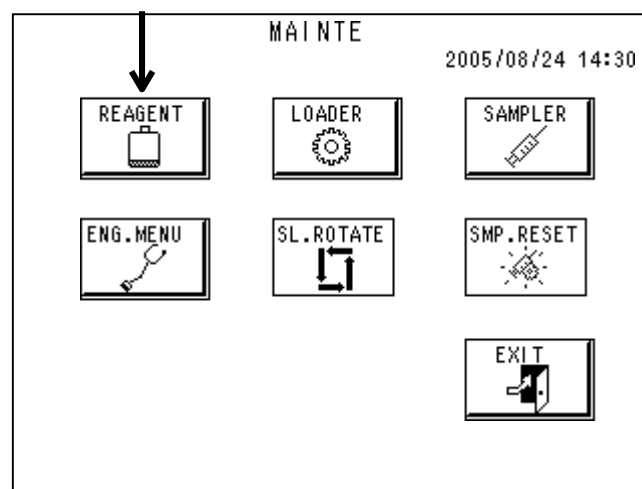
If this happens, execute a manual priming of the buffers, and then execute the DRAIN FLUSH described in the next section. Manual pumping of elution buffer No. 1 for approximately 20 minutes should resolve the problem in most cases.

Perform manual priming using the following procedure.

### Procedure

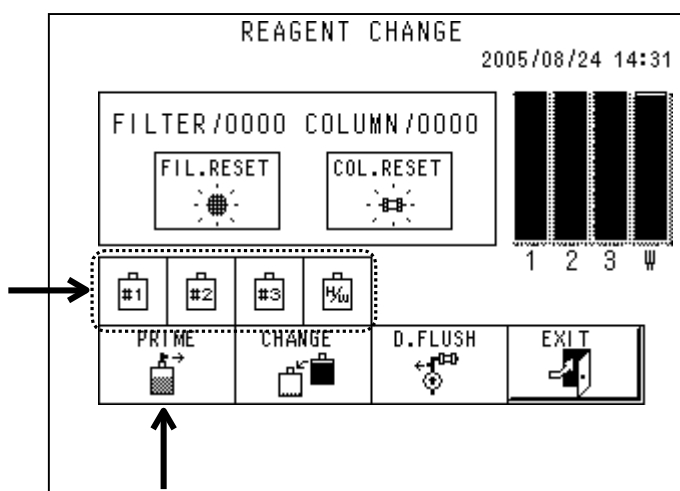
- 1) If the analyzer is not in STAND-BY state, wait for the assay to end and STAND-BY to be displayed. You can also press the STOP key to switch the analyzer into STAND-BY state.
- 2) On the MAINT screen, press the  key.


### Screen 5-4 MAINT Screen



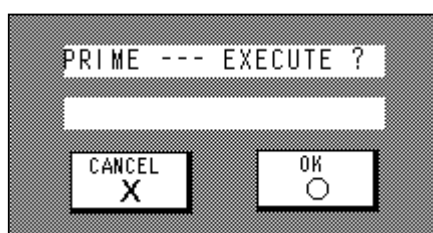
- 3) Highlight the key for the reagent to be primed.  
(Example: Highlight key #1 and #2 for buffer No. 1 and 2 to prime them.)

### Screen 5-5 REAGENT CHANGE Screen



- 4) Press the  key. A confirmation message will be displayed.  
If everything is all right, press the OK key.

### Screen 5-6 PRIME Message Screen



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

#### Point



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

## 5.5 Pump Air Removal

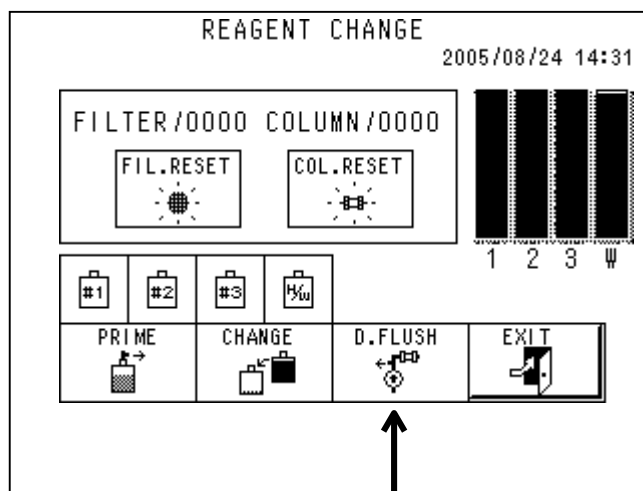
If the pump runs, but the pressure will not rise or stabilize even though sufficient buffer is delivered, air may be trapped in the liquid end of the pump.

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) From the MAINT screen, press the  key.
- 3) Press the  key.

### Screen 5-7 REAGENT CHANGE Screen



- 4) The following message will be displayed requesting that the drain valve be opened. 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 5-1 OPEN DRAIN VALVE Message

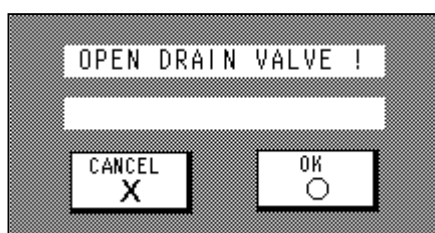
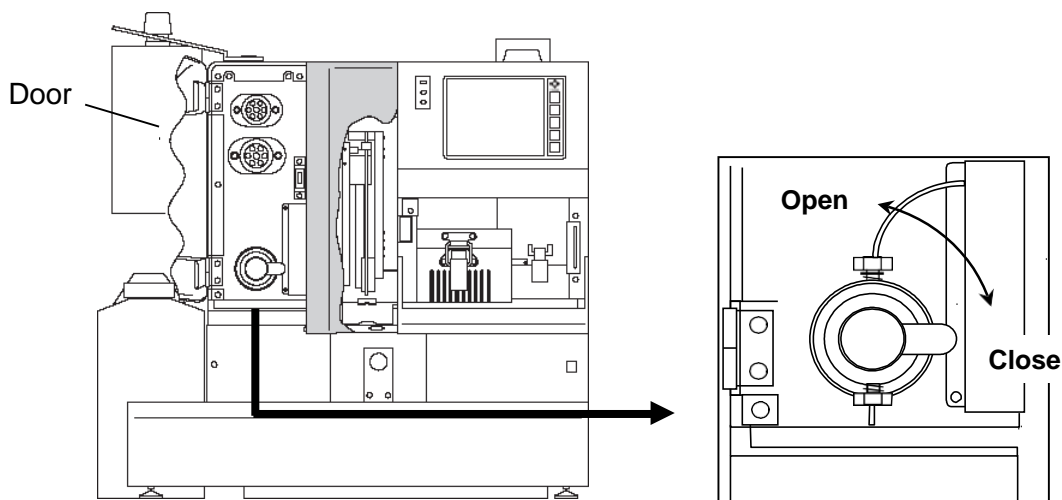
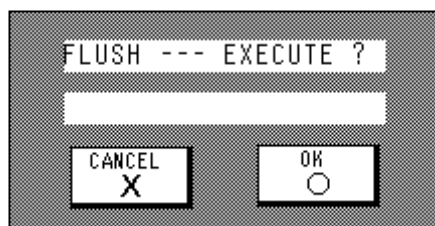




Fig. 5-3 Drain Valve



- 5) Press the OK key.
- 6) The confirmation message will be displayed. If everything is all right, press the OK key.

### Screen 5-9 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.
- 9) Return to the Main Screen (second screen), press the  key and operate the pump.
- 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. Press the  key again to stop.
- 11) If the pressure does not rise or is unstable, stop the pump and follow the air removal procedure again.

#### Point

Approximately 5 mL of each eluent 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, the flushing buffer to remove the air will flow backward into the buffer bottle and reliable results may not be obtained.

## 5.6 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-A<sub>1c</sub> 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.

Please contact a Tosoh representative if the above troubles are not resolved after column replacement.



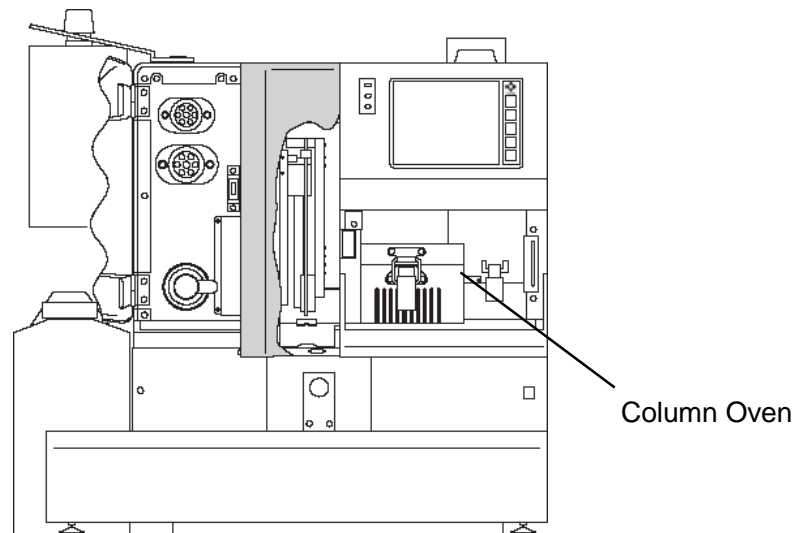
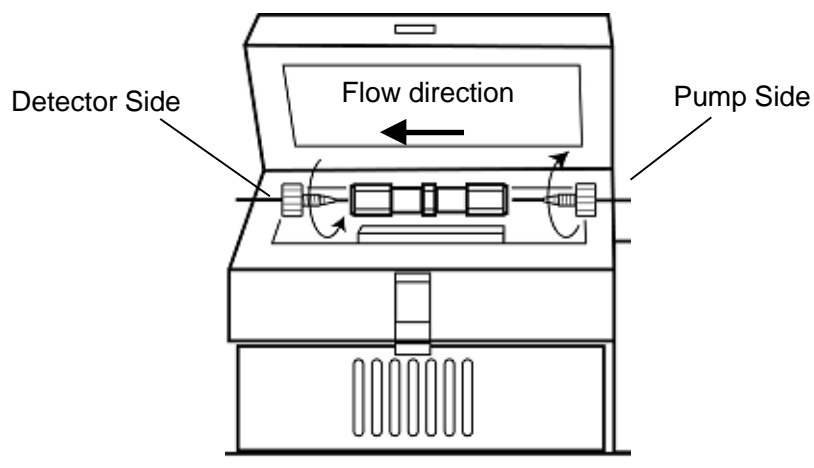
**Caution** The column has been in contact with blood samples. Wear protective clothing (glasses, gloves, mask, etc.) and take sufficient care to prevent infection during replacement and handling.

### Point





When Calibration error occurs or control results are not acceptable, it may be needed to replace the column.

### 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. 5-4 Front View****Fig. 5-5 Column Oven**

- 4) Confirm that the SV1 key is open (O) on the main screen (second screen).
- 5) Place lab wipes on the filter side (right side) of the column flow line.

- 6) Press the  key to start the pump.
- 7) Remove the protective plugs of the column. Retain the protective plugs because they are necessary for long-term storage of the column.
- 8) Connect the new column to the pump (inlet) side only, taking care of the flow direction shown by the arrow on the label, which should be right to left, and let the buffer flow into the column. When buffer comes out of the open end of the column, press the  key to stop the flow.
- 9) Connect the column outlet to the detector side (left side) and press the  key to start the pump. The fluid will begin flowing.
- 10) 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.
- 11) Place the column in the aluminum block, close the column oven cover, and lock the latch.
- 12) Press the  key to stop the pump.
- 13) Before calibrating the newly installed column, run at least three whole blood samples to make sure that all specifications are in line. If all specifications are in line, calibrate the system and run controls.



**Caution** The used column has been in contact with blood samples. Therefore, wear protective clothing (glasses, gloves, mask, 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-723G8.
2. After connecting a new column, reset (zero) the column counter in the REAGENT CHANGE screen.
3. Securely insert the inlet tube to the end with no space at the connections.

## 5.7 Filter Replacement

Replace the filter in the following cases.

1. When the filter counter reaches 400 injections.
2. When the pressure is more than the pressure (which is indicated on the column inspection report) +4 MPa.

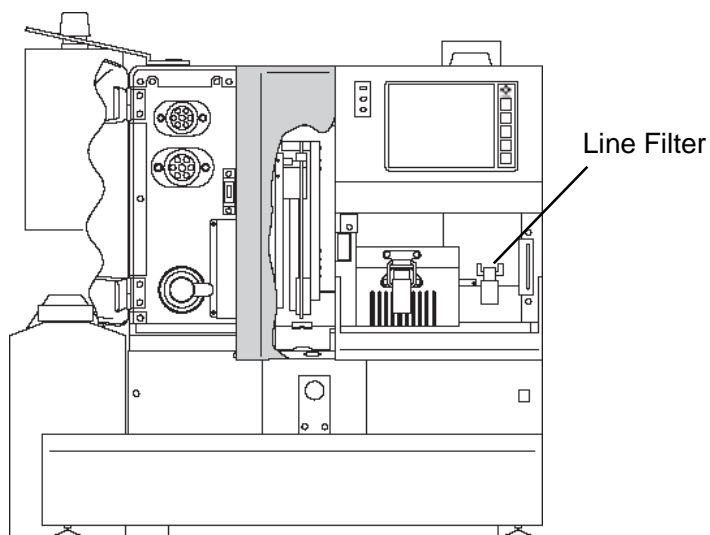


**Caution** The filter has been in contact with blood samples. Wear protective clothing (glasses, gloves, mask, etc.) and take sufficient care to prevent infection during replacement and handling.




### 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.

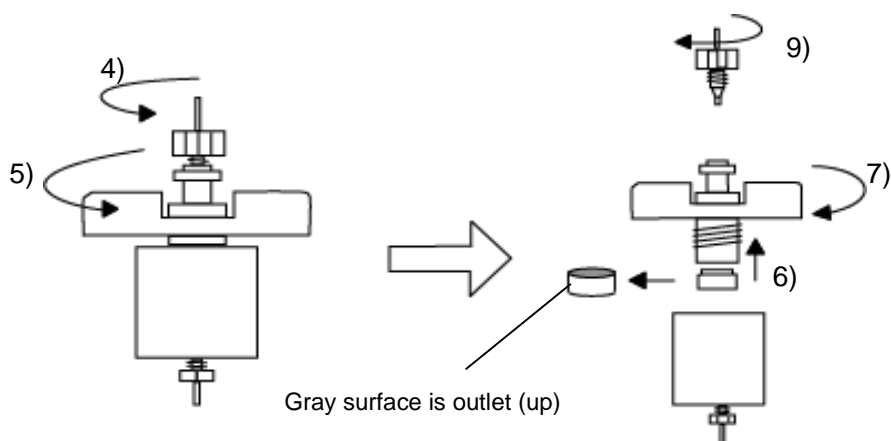
**Fig. 5-6 Front View**



- 3) Confirm on the main screen (the second screen) that the SV1 key is open (O).
- 4) Remove the filter outlet (top) flow line.

- 5) Turn the top of the filter holder assembly by turning it counterclockwise and remove the filter holder by pulling it straight out.
- 6) Lightly press the top of the holder to take out the old filter element. Place the new element with great care of surface of filter. The gray colored surface is the outlet (up) side.
- 7) Firmly tighten the top of the filter holder assembly by hand until no further tightening is possible.
- 8) Place a lab wipe at the filter holder outlet and run the pump by pressing the  key to remove the air inside the element. Check that no more bubbles come from the outlet side, and then press the  key to stop the pump.
- 9) Connect the outlet side flow tube.
- 10) Press the  key again to start the elution buffer delivery. 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 filter housing components and tube connections. If a leak is found, tighten the assembly further.

**Fig. 5-7 Filter Replacement**



**Caution**

The used filter has been in contact with blood samples. Therefore, wear protective clothing (goggles, gloves, mask, 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.



1. After installing a new filter, reset (zero) the filter counter on the REAGENT CHANGE screen.
2. As once a filter is tightened it is deformed, it cannot be used again.

## 5.8 Printer Paper Replacement

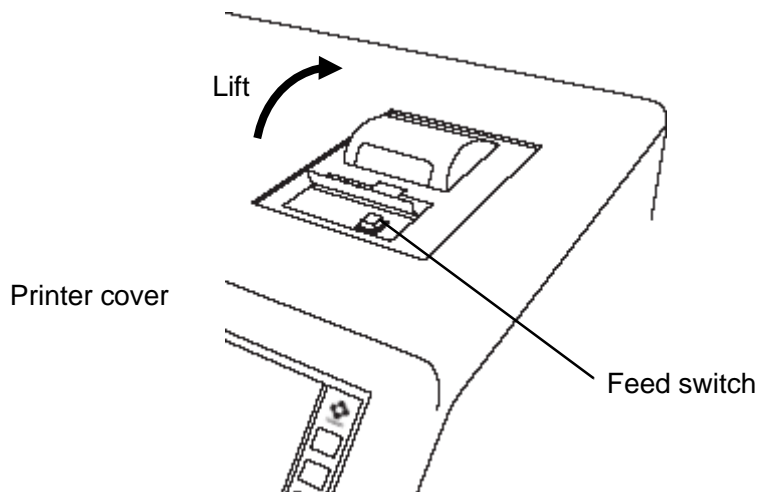
Use printer paper dedicated to the G8 analyzer.

Each roll has a width of 60 mm and a length of 42 m. When FORMAT 0 is used as the printout format, results for approximately 350 samples can be printed.

### Procedure

- 1) Lift the printer cover (upper lid) to the back to open.

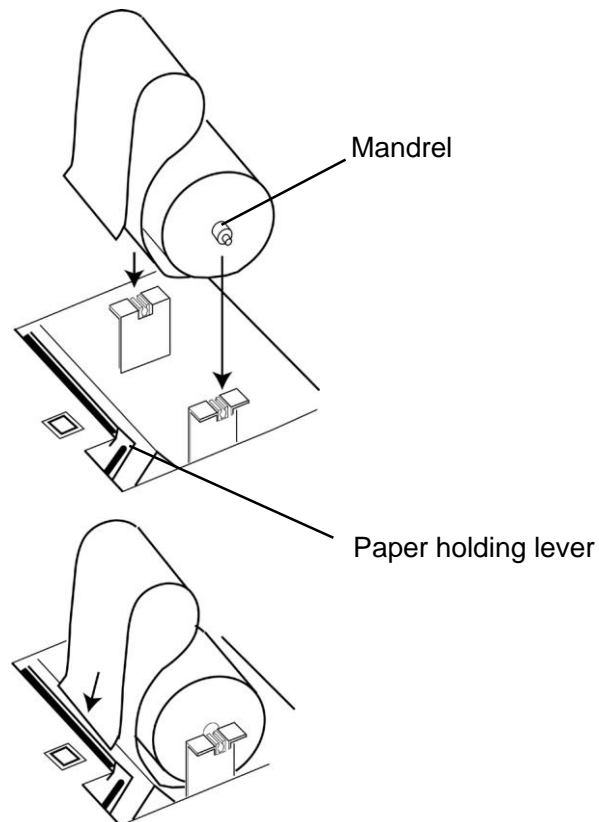
**Fig. 5-8 Printer**



- 2) Push the paper holding lever down to the very front and wrap the remaining paper onto the roll.
- 3) Lift the roll up and remove the mandrel.
- 4) Insert the mandrel into the new roll and set it with great care for the direction.

- 5) Return the paper holding lever to the very back and insert the paper into the printer as shown in **Fig. 5-9**. The paper will automatically be fed. Since the lever has a two-step stop, be sure to position it at the very back.

**Fig. 5-9 Printer Paper Placements**



- 6) Check for twisted paper. If the paper is twisted, push the paper holder lever to the front, adjust the paper, and return the lever to the back.



If you do not return the paper holding lever to its original position, a "PRINTER OFF LINE" error will occur.

## 5.9 Suction Filter Replacement

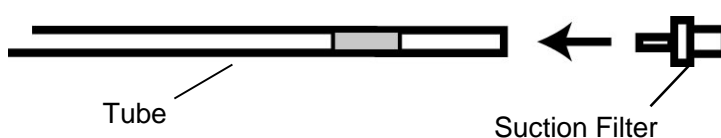
To remove foreign particles, the suction filter is attached to the inlet end of the elution buffer tube inserted in the elution buffer pack or bottle. If the suction filter is clogged, the pump will not operate normally and reliable results may not be obtained. Make sure to periodically replace the filter. 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. 5-10 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. See "[Chapter 5. Section 5.3 Elution Buffer and Hemolysis & Wash Solution Replacement](#)" for details about the PRIME operation.



Used suction filters can be disposed as general nonflammable waste according to the procedures at your facility.

## 5.10 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 or its representatives perform these operations. Be sure to wear protective clothing (goggles, gloves, mask, etc.) and take sufficient care to prevent infection during handling. Take care not to touch the end of the sampling needle during handling.

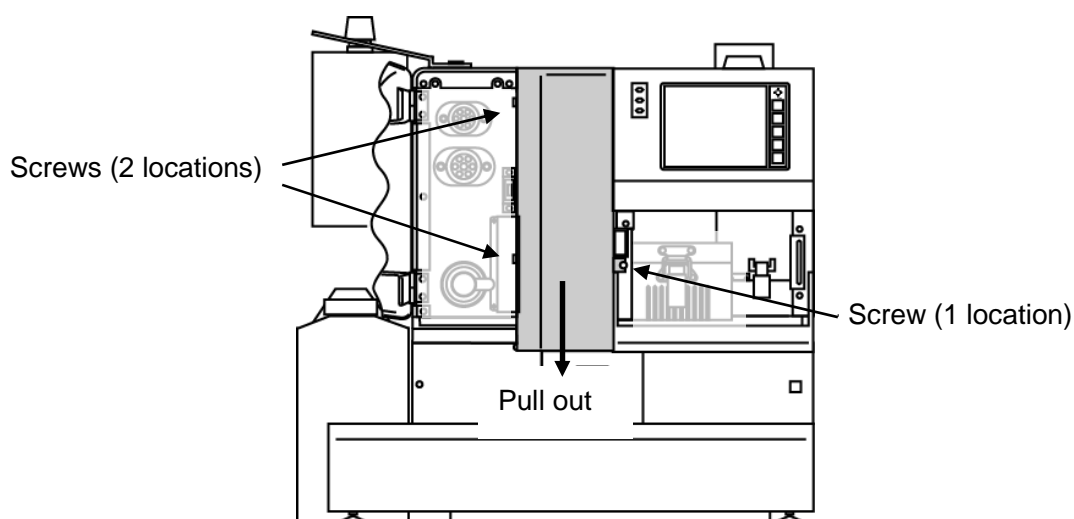
### Procedure

- 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.



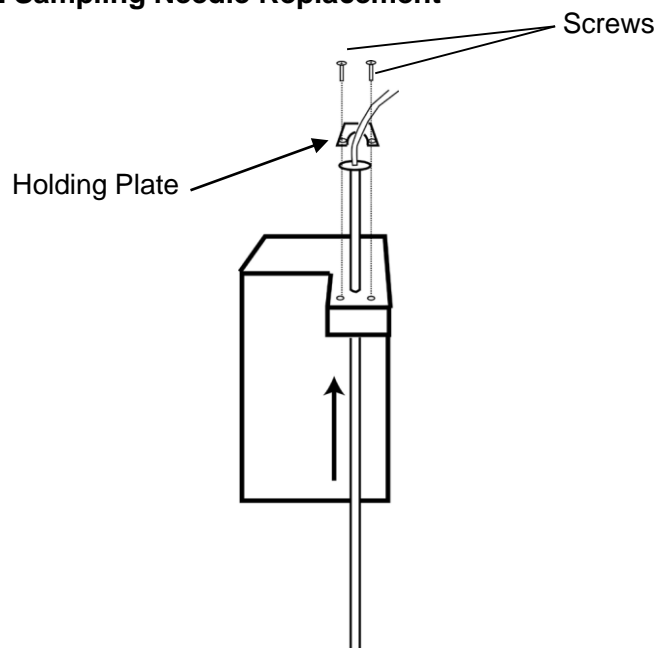
**Caution** The analyzer may be broken or cause injury if it's forcibly moved.

Fig. 5-11 Front View



- 2) Open the left-side door and loosen two needle cover screws indicated in **Fig. 5-11**. You do not need to remove the screws.
- 3) Open the door below the display and loosen one needle screw indicated in **Fig. 5-11**.
- 4) Grasp the needle cover, push it inward while taking care not to break it, and remove it from the needle screw indicated in 3) above.
- 5) Once you verify that the cover has been removed from the screws shown in **Fig.5-11**, remove the cover by pulling it straightforward.
- 6) You will see the sampling needle 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.
- 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 connected to the 3-way block of the sampling needle flow line.
- 9) Remove the screws on the upper section of the sampling needle. Be careful not to drop the screws or the holding plate inside the machine during this operation. (**Fig. 5-12**)
- 10) Remove the tube from the black clip.

**Fig. 5-12 Sampling Needle Replacement**



- 11) Slowly lift up the sampling needle to remove.
- 12) Insert the new sampling needle and secure the upper plate with the screws. When you do so, make sure that the needle tip hole is oriented forward.
- 13) Fix the flow line by the black clip so that it doesn't twist, and then securely connect the joint to the 3-way block.
- 14) Move the sampling needle unit back and forth and confirm that the flow line does not catch on anything. If necessary, loosen the screws, turn the sampling needle, and change the stay direction to prevent the flow line from catching on anything.
- 15) Push the sampling needle unit back, close the sampling unit cover by following the procedure in reverse, and secure the screws.
- 16) Turn on the main power and return the analyzer to STAND-BY state.
- 17) Assay a dummy sample or control to confirm that the sample aspiration is processed correctly (see the total area in the result should be about the same as before the sampling needle replacement).



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 your local representative.



**Caution** Dispose of the used sampling needle as infectious waste according to the procedures at your facility.

### 5.11 O-ring Replacement in Needle Wash Assembly

In order to prevent reagent leaks, an O-ring is located in the upper part of the needle wash assembly, through which the sampling needle passes. When the O-ring has worn down, Hemolysis & Wash solution may spill out of the top of the assembly or the sampling needle may be insufficiently washed, causing unreliable results. Periodically change the O-ring to avoid this problem.



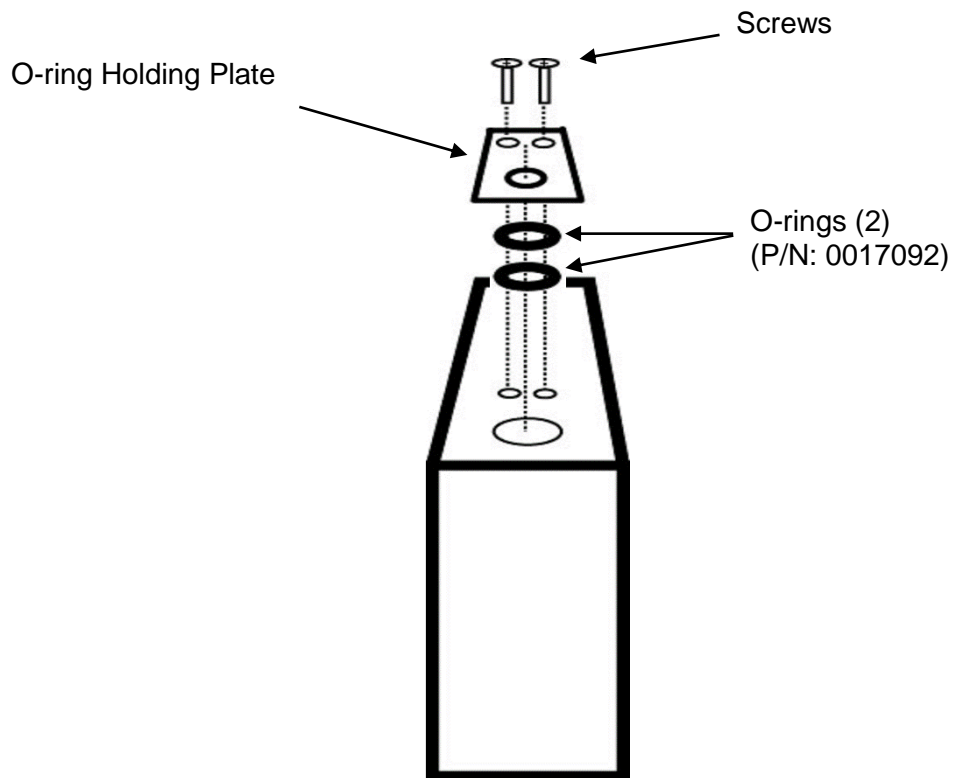
**Caution** Access to the inside of the analyzer is needed to replace the O-ring. Be sure that only personnel who have been trained by Tosoh or its representatives perform these operations. Be sure to wear protective clothing (goggles, gloves, mask, etc.) and take sufficient care to prevent infection during handling.



#### Procedure

- 1) Follow the procedure in "**Chapter 5. Section 5.10: Sampling Needle Replacement. Steps 1 to 11**" and remove the sampling needle from the washing assembly.
- 2) Remove the O-ring holding plate using a screwdriver. Be careful to prevent screws and other parts from falling into the machine at this time.
- 3) Remove the O-ring using a small screwdriver or other appropriate tool.
- 4) Set the new O-ring and re-install the holding plate.
- 5) Insert the needle slowly into the wash assembly and secure the upper side with the plate.
- 6) Follow the procedure described in "**Chapter 5. Section 5.10: Sampling Needle Replacement. Steps 12 to 14**" and reattach the flow line and cover.

Fig. 5-13 O-ring Replacement



**Caution** Dispose of the used O-ring as infectious waste according to the procedures at your facility.

## 6.1 Assay Precautions

- **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-723G8.
- Store columns in a refrigerator before use.
- Do not bump the column.
- Alphabetical lot number, such as A and B, are shown on the box label of the column. Be sure to match this number with the lot number for the elution buffer.
- 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-723G8. Use the elution buffers before the expiration date indicated on the label.
- For G8 Variant Elution Buffer No. 1, No. 2 and No. 3 be sure the lot number matches the column lot number.
- Do not refill the elution buffer or use it without ensuring that the lot numbers are the same.

- **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-723G8/HLC-723G7/HLC-723GHbV by TOSOH. Use the Hemolysis & Wash solution before the expiration date indicated on the label.
- There are no differences between lots for the Hemolysis & Wash solution.

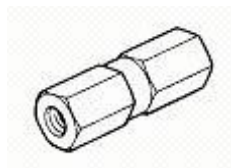
- **Long-term shutdown**

- If the analyzer is to be shut off for one week or more, replace the reagents in the analyzer flow line with purified water, using the procedure below.

**Procedure**

- 1) Remove the column and connect the open ends of the flow line with a union.

**Fig. 6-1 Union (P/N: 0006163)**



- 2) Move all suction tubes in the elution buffers and Hemolysis & Wash solution to a bottle containing purified water, and then prime all liquids on the REAGENT CHANGE screen.
- 3) Execute manual pumping for approximately 10 minutes by using the pump key in the main screen (the second screen) in order to replace all reagents in the tubes with purified water.



1. Do not wash the flow line for the Hemolysis & Wash solution with elution buffers.
2. Absolutely do not insert the suction tube for the elution buffer in the Hemolysis & Wash Solution container to wash the tubes.
3. Attach the protective plugs to the column ends and store 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 are invalid until the current assay (during ANALYSIS state) is complete. Make changes when the analyzer is in STAND-BY state.

## 6.2 General System Failures

- **Power will not come on**
  - Is the power cord properly connected?
  - Is the main power switched on?
  - Was the POWER key pressed?
  
- **The external storage device cannot be read or written**
  - Is the external storage device correctly inserted in the storage device socket?
  - Are you using an external storage device other than a Smart Media card or USB stick?
  - Does the external storage device have adequate free space available?
  - Is the external storage device write-protected?
  - Is a card up to 128 MB being used?
  - Are you using a USB stick with a security function?
  - Are you using a USB stick formatted to a format other than FAT32?
  
- **Analyzer will not start with timer startup**
  - Is the date (year, month, and day) properly set?  
See **“Chapter 4 Section 4.10: Date/Time and Weekly Timer Setting”**.
  
- **Only abnormal chromatograms appear**
  - Is the sample volume sufficient?

1 mL or more is required with primary tubes and 150  $\mu$ L or more is required with vials (diluted samples). Take special care with the calibrator volume since CALIB-1 is injected 3 times and CALIB-2 is injected 2 times. A volume of 500  $\mu$ L or more of each calibrator is therefore required.
  - Is the Buffer being pumped properly?

Verify the pressure on the main screen.

If the pressure is lower than the column pressure indicated on the column inspection report or if it looks unstable, refer to **“Chapter 5. Section 5.5: 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 number agree with the elution buffer lot number? Has the expiration date not passed?
  - Do the buffer label colors agree with the colors of the tube labels?

- **Frequent bar code reading errors**

- Is the printing quality sufficient?
- Is it printed on a white label?
- Are you using a bar code set in the bar code parameter? Are the labels clean and unwrinkled?

See **“Chapter 3 Section 3.7: Samples – Bar Code Label Confirmation”**.

- Are the samples set as the bar code labels oriented toward the bar code 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 rotation.

At least 5 mm of space (margin) is required to the left and right in the bar code.

- **Errors with sample vials (Z1 error)**

- Was the sample sensor not bent downward because the rack was moved forcibly?

**If a TOSOH rack is being used**

- Is a vial adapter attached to the rack onto which the vial has been placed?

**If a SYSMEX® rack is being used**

- Is a vial adapter attached to the sample rack onto which the vial has been placed?
- Is a SYSMEX® rack with a proper adapter attached (13 mm diameter, etc.) being used?

- **Sampling needle is bent or broken**

- Are the primary tubes properly installed in the rack to stand straight?
- Is the end marker properly attached?  
If the end marker is incorrectly installed, damage will occur when the analyzer moves the rack.
- Is the parameter for a #100 mm tube properly set?  
See **“Chapter 4, Section 4.6: Parameter Setting”** and check the settings.



**If a TOSOH rack is being used**

- Has the primary tube holder (spring) not become weak?  
Make sure the tubes are held in place so they don't rattle.

**If a SYSMEX® rack is being used**

- Is a vial adapter attached to the sample rack onto which the vial has been placed?
- Is a SYSMEX® rack with a proper adapter attached (13 mm diameter, etc.) being used?  
A sample rack adapter must be attached to the rack securely when using 12 ~ 14 mm diameter primary tubes.

- **Some samples cannot be assayed**

- Is the query mode set?  
Referring to **“Chapter 4 Section 4.13: Data Communication Setting”**, confirm  key status.  
Samples are skipped when using a query mode if the test request from the host computer is not directed.  
If the bar code affixed to the sample is not properly read, the sample will be skipped when  is set (highlighted) on the BCR screen.  
See **“Chapter 4 Section 4.19: Bar Code Reader Setting and Reading Check”**.  
Contact the service representative when successive samples are not detected.

## 6.3 Error Messages

When consulting with service representatives about a problem, please note the error message and error number. This will allow them to solve the problem faster. In addition, 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 a service personnel.

---

### General Error Messages

---

With these errors, the assay stops and the analyzer immediately goes in STAND-BY state.

#### 100 PRESSURE HIGH

The pump pressure exceeded the upper limit (15 MPa) set in the PRES HIGH parameters.

When the filter or column replacement period has been exceeded, first replace the filter or column. If the pressure is still high, remove the inlet and outlet flow line around the column and filter, and determine which part is the cause of the high pressure. Then, contact the service representative.

The target pressure is within a range less than the pressure (which is indicated on the column inspection report) +4 MPa.

#### 101 PRESSURE LOW

The pressure will not rise because the pump is unable to run due to air bubbles in the pump check valve. If the elution buffer is empty, place a new elution buffer and execute REAGENT CHANGE. Next, execute DRAIN FLUSH. See **“Chapter 5 Section 5.5: Pump Air Removal”**.

Execute manual pumping using the PUMP key in the main screen (second screen), and open and close the drain valve 2 or 3 times. If the pressure rises when the drain valve is closed, the operation is complete. If the pressure still does not rise or stabilize, execute DRAIN FLUSH again. In addition, confirm that the drain valve is securely closed.

**102 PRES LIMIT OVER**

The pump pressure has risen abnormally, then the shutdown circuit has been activated. Turn the main power switch off and remove the cause of the pressure increase.

(Refer to "**100 PRESSURE HIGH**")

**718 INJ.VALVE ERROR**

The injection valve is operating abnormally. The rotor seal of the valve requires replacement. If the error occurs many times, contact a service representative.

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**Errors resulting in STAND-BY status after stopping an assay and executing WASH**

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**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 rack, the problem may be caused by an empty reagent (Hemolysis & Wash solution). Check the remaining volume of Hemolysis & Wash solution and start the assay again.

**201 CALIB ERROR**

Assay results for the calibrators were unsatisfactory.

Refer to "**Chapter 3, Section 3.6: Calibration**". Check the dilution method, and the column and filters. Verify that the reagents have not expired.

Do the values for CALIB-1 and CALIB-2 in the PARAMETER screen agree with the assigned values (refer to the Instructions for Use or the label of the calibrator)?

Are the units for calibration appropriate (refer to "**Chapter 3 Section 3.7: Samples - Units for reporting and calibration**").

**680 CALIB POS ERROR**

The calibrator bar code was not able to be read or the placement order was incorrect.

**702 BC COMM ERROR**

This is an abnormality in communications with the bar code reader, possibly caused by poor contact at an internal cable or another such problem. Contact a service representative if the problem occurs repeatedly.

**703 AS COMMAND ERROR**

Communications with the sampling assembly is abnormal. Contact a service representative if the problem occurs repeatedly.

Errors resulting in STAND-BY status after stopping an assay and executing WASH

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#### **704 SAMPLE NOT FOUND**

This error occurs when an empty rack, with no sample, is set and the START command is input.

If this error occurs even when samples are in place, there could be a sensor problem. Contact a service representative.

#### **705 RACK POS ERROR**

(Rack position 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 an assay run, this error may occur. Do not touch racks or primary tubes during an assay run.

#### **710 Z1-AXIS ERROR**

An abnormality occurred in the up and down movement of the sampling needle.

If this occurs during a STAT assay, check that the container (CUP or TUBE) is correctly set.

The error also occurs when the sample vial was misrecognized as a primary tube, due to the disoriented sample sensor

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## Errors which do not interrupt assays

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When the following errors occur, 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)

### **220 NO PEAK DETECT**

No peaks could be detected. This problem could be caused by insufficient sample uptake because coagulated sample may have been processed or by an empty sample uptake.

### **221 ##### NOT DETECT (##### is the peak ID)**

A specific peak (hemoglobin fraction) could not be detected. When this occurs repeatedly with some samples, the elution buffer may have become concentrated, resulting in unidentified peak detection on chromatograms. Never mix the buffers.

When the error only occurs with specific samples, the hemoglobin variant may be present in the samples.

Errors which do not interrupt assays

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**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 bar code could not be read.  
Verify the bar code label.  
(An ID number exceeding initial 12 digits is abbreviated as "\_")

The following messages are displayed on the STATUS screen but not printed.

**01 STOP ACCEPTED**

Instruction to stop assay is received by pressing the STOP key once during an assay.

**02 EMERGENCY STOP**

Instruction to make an immediate stop is received by pressing the STOP key twice during an assay.

**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.

**400 PAPER EMPTY**

There is no printer paper. Install a new paper roll.

**401 PRINTER OFF LINE**

The printer paper holding lever is lifted up. Set the lever correctly.

**500 CARD NOT READY**

There is no external storage device. Insert a formatted external storage device into the socket.

**501 WRITE PROTECT**

The Smart Media card is write-protected.  
Peel off the write-protect sticker on the card.

**510 CARD FULL**

The external storage device is full. Prepare a new, formatted external storage device.

Errors which do not interrupt assays

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**511 FILE NOT FOUND**

A nonexistent file in the external storage device is attempted to be read.

**530 CARD HARD ERROR**

There is a problem with the socket or external storage device. This error also occurs when a USB stick cannot be written due to write protect. Replace with a new, formatted external storage device and try again. If the storage device cannot be formatted, there may be a problem with the socket itself. Contact a service representative.

### Error Messages and Their Meanings

**Error Level**    0: Warning            1: Go in STAND-BY state    2: Go in WASH state

**Alarm Level**    0: Beep for 1 sec    1: Beep for 30 sec

and turn on ERROR LED & Patolight® (optional)

**Print**            0: No                    1: Yes

Error Messages	Meanings	Countermeasure	Error Level	Alarm Level	Print
<b>Operation errors</b>					
001 STOP ACCEPTED	STOP was executed		0	0	0
002 EMERGENCY STOP	EMERGENCY STOP was executed		0	0	0
010 SYSTEM RUNNING	Command could not be executed during assay	Re-execute after assay is complete	0	0	0
011 MIS OPERATION	Command was not allowed	Feed correct command	0	0	0
020 #9999 PARAM ERROR	Parameters are not correct	Re-install the backup parameters stored in an external storage device	0	0	1
030 UNMATCH MODE DATA	Different mode data was attempted to be read	Set the proper 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 bar codes were input	Designate up to 4 bar codes types	0	0	0
<b>Status monitoring errors</b>					
100 PRESSURE HIGH	Pump pressure exceeded upper limit (PRES-HIGH)	Inspect for clogging at column and filter	1	1	1
101 PRESSURE LOW	Pump pressure fell below lower limit (PRES-LOW)	Execute air removal	1	1	1
102 PRES LIMIT OVER	Pump pressure abnormality was detected	Inspect for clogging at filter. Main power must be shut off then turned on again to re-start operations.	1	1	1
110 TEMP UNSTABLE	Column temperature will be not stabilized. (exceeds COL.T-RANGE)	Inspect temperature control. Check that TEMP parameters are correct.	2	1	1
111 TEMP LIMIT OVER	Temperature abnormality was detected	Inspect temperature control. Main power must be shut off then turned on again to re-start operations.	2	1	1

120 STAT DOOR OPEN	The STAT door is open	Close the door	0	1	1
<b>Error Messages</b>	<b>Meanings</b>	<b>Countermeasure</b>	<b>Error Level</b>	<b>Alarm Level</b>	<b>Print</b>
130 FILTER COUNT OVER	The injection limit for filter (input value) has been exceeded	Replace the filter	0	1	1
131 COLUMN COUNT OVER	The injection limit for column (input value) has been exceeded	Replace the column	0	1	1
140 BUFFER EMPTY	Buffer volume is low. (get below the limit input)	Replace eluent	0	1	1
150 GRAD SENSOR ERROR	The GRAD sensor on the pump malfunctioned.	Check the GRAD sensor.	0(STD) 2(other)	1	1
<b>Data processing errors</b>					
200 AREA LOW ERROR	The peak area which does not reach the minimum required area (50) occurred three times in series.	Check the samples, buffers, and Hemolysis & Wash Solution	2	1	1
201 CALIB ERROR	Calibration results were out of the acceptable range	Check the samples, buffers, and Hemolysis & Wash Solution	2	0	1
211 PEAK PATTERN ERROR	Peaks were not separated well	Check the samples, buffers, and Hemolysis & Wash Solution	0	0	1
220 NO PEAK DETECT	Peaks were not detected	Check the samples, buffers, and Hemolysis & Wash Solution	0	0	1
221 #####NOT DETECT	The ##### 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		0	0	1
231 NO RAW DATA	No raw data have been stored		0	0	1
<b>Communication errors</b>					
300 MJ COMM ERROR (PE)	Parity error occurred in displayed device data communication	Check connection	0	1	1
301 MJ COMM ERROR (FE)	Framing error occurred in displayed device data communication	Check connection	0	1	1
302 MJ COMM ERROR (OR)	Overrun error occurred in displayed device data communication	Check connection	0	1	1
303 MJ COMM ERROR (BF)	Buffer full error occurred in displayed device data communication	Check connection	0	1	1
304 MJ COMM ERROR (OL)	Overly long data error occurred in displayed device communication	Check connection	0	1	1
305 MJ COMM ERROR (RE)	Retry error occurred in displayed device data communication	Check connection	0	1	1
306 MJ COMM ERROR (ST)	Timeout error for sending occurred in displayed device data communication	Check connection	0	1	1
307 MJ COMM ERROR (RT)	Timeout error for receiving occurred in displayed device data communication	Check connection	0	1	1

Error Messages	Meanings	Countermeasure	Error Level	Alarm Level	Print
308 MJ COMM ERROR (NR)	A no response error occurred in displayed device data communication	Check connection	0	1	1
310 EXB COM ERROR (PE)	Parity error occurred in BCR communication for LA line	Check connection	0	1	1
311 EXB COM ERROR (FE)	Framing error occurred in BCR communication for LA line	Check connection	0	1	1
312 EXB COM ERROR (OR)	Overrun error occurred in BCR communication for LA line	Check connection	0	1	1
313 EXB COM ERROR (BF)	Buffer full error occurred in BCR communication for LA line	Check connection	0	1	1
314 EXB COM ERROR (OL)	Overly long data error occurred in BCR communication for LA line	Check connection	0	1	1
315 EXB COM ERROR (RE)	Retry error occurred in BCR communication for LA line.	Check connection	0	1	1
316 EXB COM ERROR (ST)	Timeout error for sending occurred in BCR communication for LA line	Check connection	0	1	1
317 EXB COM ERROR (RT)	Timeout error for receiving occurred in BCR communication for LA line	Check connection	0	1	1
318 EXB COM ERROR (NR)	No response error occurred in BCR communication for LA line	Check connection	0	1	1
320 LCD COM ERROR (PE)	Parity error occurred in LCD communication through KEY	Check connection	0	1	1
321 LCD COM ERROR (FE)	Framing error occurred in LCD communication through KEY	Check connection	0	1	1
322 LCD COM ERROR (OR)	Overrun error occurred in LCD communication through KEY	Check connection	0	1	1
323 LCD COM ERROR (BF)	Buffer full error occurred in LCD communication through KEY	Check connection	0	1	1
324 LCD COM ERROR (OL)	Overly long data error occurred in LCD communication through KEY	Check connection	0	1	1
325 LCD COM ERROR (RE)	Retry error occurred in LCD communication through KEY	Check connection	0	1	1
326 LCD COM ERROR (ST)	Timeout error for sending occurred in LCD communication through KEY	Check connection	0	1	1
327 LCD COM ERROR (RT)	Timeout error for receiving occurred in LCD communication through KEY	Check connection	0	1	1
328 LCD COM ERROR (NR)	No response error occurred in LCD communication through KEY	Check connection	0	1	1
330 AS COMM ERROR (PE)	Parity error occurred in AS communication	Check connection	0	1	1
331 AS COMM ERROR (FE)	Framing error occurred in AS communication	Check connection	0	1	1

<b>Error Messages</b>	<b>Meanings</b>	<b>Countermeasure</b>	<b>Error Level</b>	<b>Alarm Level</b>	<b>Print</b>
332 AS COMM ERROR (OR)	Overrun error occurred in AS communication	Check connection	0	1	1
333 AS COMM ERROR (BF)	Buffer full error occurred in AS communication	Check connection	0	1	1
334 AS COMM ERROR (OL)	Overly long data error occurred in AS communication	Check connection	0	1	1
335 AS COMM ERROR (RE)	Retry error occurred in AS communication	Check connection	0	1	1
336 AS COMM ERROR (ST)	Timeout error for sending occurred in AS communication	Check connection	0	1	1
337 AS COMM ERROR (RT)	Timeout error for receiving occurred in AS communication	Check connection	0	1	1
338 AS COMM ERROR (NR)	No response error occurred in AS communication	Check connection	0	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)	Overly 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	Meanings	Countermeasure	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)	Overly 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	Check connection	0	1	1
361 LCD COM ERROR (01)	An 01 error (display processing) occurred in LCD communication through KEY	Check connection	0	1	1
362 LCD COM ERROR (02)	An 02 error (overrun/framing error) occurred in LCD communication through KEY	Check connection	0	1	1
363 LCD COM ERROR (03)	An 03 error (parity error) occurred in LCD communication through KEY	Check connection	0	1	1
364 LCD COM ERROR (04)	An 04 error (sum check error) occurred in LCD communication through KEY	Check connection	0	1	1
365 LCD COM ERROR (05)	An 05 error (address error) occurred in LCD communication through KEY	Check connection	0	1	1
366 LCD COM ERROR (06)	An 06 error (count error) occurred in LCD communication through KEY	Check connection	0	1	1
367 LCD COM ERROR (07)	An 07 error (screen error) occurred in LCD communication through KEY	Check connection	0	1	1
368 LCD COM ERROR (08)	An 08 error (format error) occurred in LCD communication through KEY	Check connection	0	1	1
369 LCD COM ERROR (09)	An 09 error (received data over) occurred in LCD communication through KEY	Check connection	0	1	1
370 LCD COM ERROR (0B)	An 0B error (retry command error) occurred in LCD communication through KEY	Check connection	0	1	1

Error Messages	Meanings	Countermeasure	Error Level	Alarm Level	Print
371 LCD COM ERROR (0F)	An 0F error (ETX error) occurred in LCD communication through KEY	Check connection	0	1	1
372 LCD COM ERROR (10)	A 10 error (DLE error) occurred in LCD communication through KEY	Check connection	0	1	1
373 LCD COM ERROR (11)	An 11 error (character error) occurred in LCD communication through KEY	Check connection	0	1	1
374 LCD COM ERROR (12)	An 12 error (command error) occurred in LCD communication through KEY	Check connection	0	1	1
<b>Printer errors</b>					
400 PAPER EMPTY	Printer is out of paper	Replace the paper roll	0	0	0
401 PRINTER OFF LINE	Printer lever is not set	Set the printer lever	0	0	0
420 PRINTER ERROR	Printer is broken	Inspect the printer	0	0	0
<b>External storage device errors</b>					
500 CARD NOT READY	No external storage device is set	Set the external storage device	0	0	0
501 WRITE PROTECT	The Smart Media card is write-protected	Peel off the sticker on the Smart Media card.	0	0	0
510 CARD FULL	The external storage device is full	Insert a new, formatted external storage device	0	0	0
511 FILE NOT FOUND	The file could not be found	Insert the proper external storage device. Input the correct number.	0	0	0
520 CARD DATA ERROR	External storage device data is corrupted	Format the external storage device to re-use	0	0	0
530 CARD HARD ERROR	External storage device could not be accessed or the USB stick is write-protected	Inspect the external storage device and socket or remove write protection from the USB stick	0	0	0
<b>Control and monitoring errors</b>					
600 AS NO RESPONSE	Autosampler is not responding	Check connections. Turn the main power off then on to re-start.	2	1	1
610 SAMPLER BUSY	AS is currently operating and cannot accept any commands	Wait for operation to end	2	1	1
620 SAMPLE NOT INJECT	Assay of previous sample is not yet complete, so sample was not processed		0	0	1
630 BELT BCR NO RESP	BCR for LA line is not responding	Check connections	0	0	1
631 BELT BCR SET ERROR	Setting error occurred in the BCR for LA line	Check connections	0	0	1
632 BCR SET ERROR	BCR setting error occurred	Check connections	0	0	1
640 QUERY NO RESPONSE	No response is received for order query to host	Check the host	0	1	1

Error Messages	Meanings	Countermeasure	Error Level	Alarm Level	Print
650 BELT ID UNMATCH	Sample ID sent by HOST does not agree with the sample ID read by BCR	Check LA line	0	1	1
660 BELT LINE ABORT	Error occurred at LA line or analyzer during connecting to HOST. No sample processing was executed.	Remove the cause of the error	0	1	1
670 SKIP:#####	Assay was not done for the sample indicated by the ID because the bar code could not be read or some other problem occurred (ID number exceeding initial 12 digits will be abbrev. as "-")	Inspect bar code label etc.	0	0	1
680 CALIB POS ERROR	The calibrator position is wrong	Inspect the calibrator position, bar code label, etc.	2	1	1
<b>AS errors</b>					
701 PULSE ERROR	Pulse data was abnormal	Check the pulse parameters	2	1	1
702 BC COMM ERROR	A communication error occurred in the BCR with AS	Check the BCR connection	2	1	1
703 AS COMMAND ERROR	The AS received an invalid command	Check the AS connection	2	1	1
704 SAMPLE NOT FOUND	Sample could not be detected	Start assay after setting samples	2	1	1
705 RACK POS ERROR	The rack transfer lever cannot return due to the presence of an incoming rack	Remove the rack	2	1	1
706 SYRINGE-L ERROR	Operation error in syringe-L	Inspect syringe-L. Execute SMP.RESET.	2	1	1
707 SYRINGE-S ERROR	Operation error in syringe-S	Inspect syringe-S. Execute SMP.RESET.	2	1	1
708 X1-AXIS ERROR	Operation error in X1-axis	Inspect X1-axis. Execute SL.ROTATE.	2	1	1
709 Y1-AXIS ERROR	Operation error in Y1-axis	Inspect Y1-axis. Execute SMP.RESET.	2	1	1
710 Z1-AXIS ERROR	Operation error in Z1-axis	Inspect Z1-axis. Execute SMP.RESET.	2	1	1
711 LINE VALVE ERROR	Operation error in switching valve (AS valve)	Inspect valve on line. Execute SMP.RESET.	2	1	1
712 X2-AXIS ERROR	Operation error in X2-axis	Inspect X2-axis Execute SL.ROTATE	2	1	1
713 X3-AXIS ERROR	Operation error in X3-axis	Inspect X3-axis. Execute SL.ROTATE.	2	1	1
714 Y2-AXIS ERROR	Operation error in Y2-axis	Inspect Y2-axis. Execute SL.ROTATE.	2	1	1
715 Y3-AXIS ERROR	Operation error in Y3-axis	Inspect Y3-axis. Execute SL.ROTATE.	2	1	1
716 Y4-AXIS ERROR	Operation error in Y4-axis	Inspect Y4-axis. Execute SL.ROTATE.	2	1	1

Error Messages	Meanings	Countermeasure	Error Level	Alarm Level	Print
717 Y5-AXIS ERROR	Operation error in Y5-axis	Inspect Y5-axis. Execute SL.ROTATE.	2	1	1
718 INJ VALVE ERROR	Operation error in injection valve	Inspect injection valve. Execute SMP.RESET.	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 RACK FULL	The sample rack is full on the transport side	Remove rack	0	1	0
730 TUBE MIXING ERROR	The rack moved at mixing or bar code reading (100SL-GA)	Inspect the tube condition	2	1	1
<b>LA line control errors</b>					
800 BL BC UNMATCH	ID transmitted from LA does not match ID read by the BCR for LA line	Inspect BCR and bar code label	0	1	1
801 BL BC READ ERROR	Bar code could not be read by the BCR for LA line	Inspect BCR and bar code label	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
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
807 BL ANAL START	Assay start command was received from LA line		0	0	1
808 BL ANAL STOP	Assay stop command was received from LA line		0	0	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

## 6.4 Abnormal Chromatograms

Most whole blood samples will contain six fractions: A<sub>1a</sub>, A<sub>1b</sub>, F, L-A<sub>1c+</sub>, s-A<sub>1c</sub>, and A<sub>0</sub> but the percentage of each hemoglobin component may vary slightly from patient to patient. A normal chromatogram is shown below in Figure 6-2.

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<sub>1c</sub> % 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 6-3 through Figure 6-14 for examples of abnormal chromatograms.

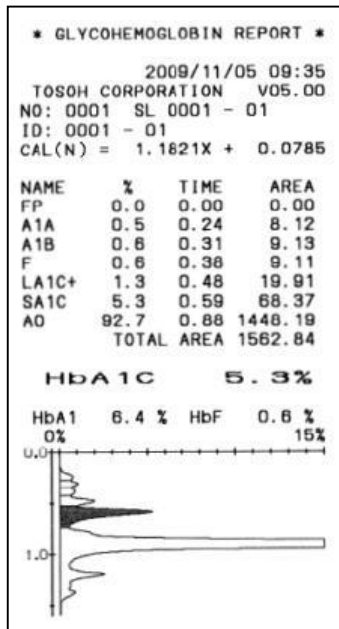
Mathematical algorithms used in the software exclude variant peaks eluting after the A<sub>0</sub> peak when calculating the Total Area. The s-A<sub>1c</sub> % is usually not affected in such situations, although chromatograms should be carefully reviewed. HbD, HbS and HbC elute after the A<sub>0</sub> peak. The s-A<sub>1c</sub> % is generally reportable on the HLC-723G8 when these hemoglobins are present in the heterozygous state with HbA.

If a hemoglobin variant peak elutes before the A<sub>0</sub> peak, the s-A<sub>1c</sub> % measured will be erroneous and should not be reported. If a hemoglobin variant peak elutes independently of the s-A<sub>1c</sub> peak, but before the A<sub>0</sub> peak, it will cause a false decrease in the s-A<sub>1c</sub> result. Flag code 43 can be used to detect the presence of a P-HV3 peak where the glycated form of HbE typically elutes. (See "Chapter 4 Section 4.18: FLAG Parameter Setting" for flag settings.)

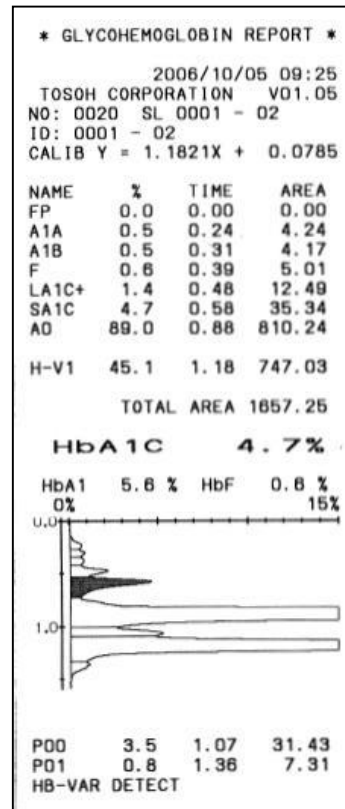
Glycemic monitoring for patients displaying any homozygous hemoglobin other

than HbAA such as HbSS, HbCC or the double heterozygous HbSC, cannot be performed using HbA<sub>1c</sub> because there is no HbA present. Alternative testing is mandatory for these types of patients.

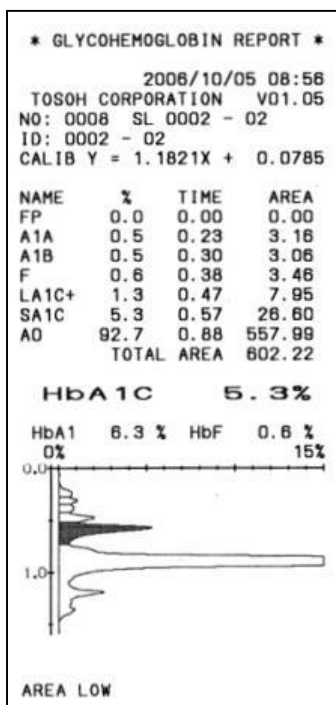
**Fig. 6-2 Normal Chromatogram  
HbA<sub>1c</sub> is reportable**



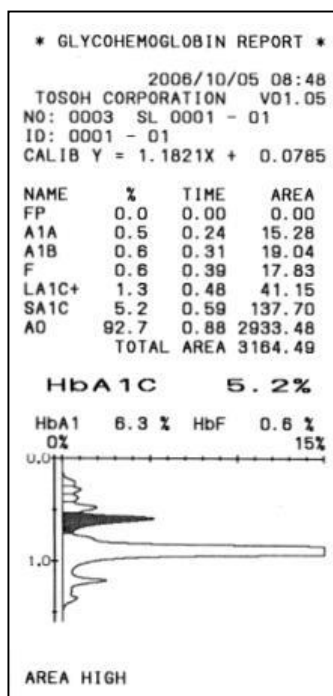
**Fig. 6-3 Hemoglobin Variant (AS)  
HbA<sub>1c</sub> is reportable**



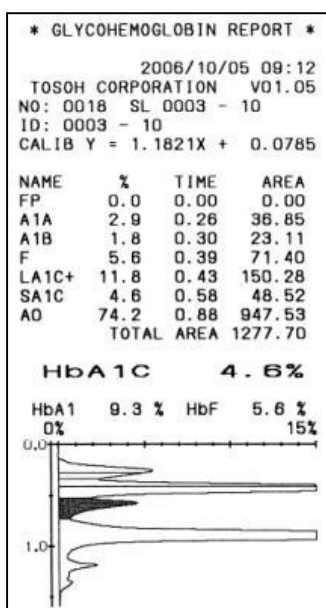
**Fig. 6-4 Total Area is low  
(500 < Total Area < 700)  
HbA<sub>1c</sub> is reportable**



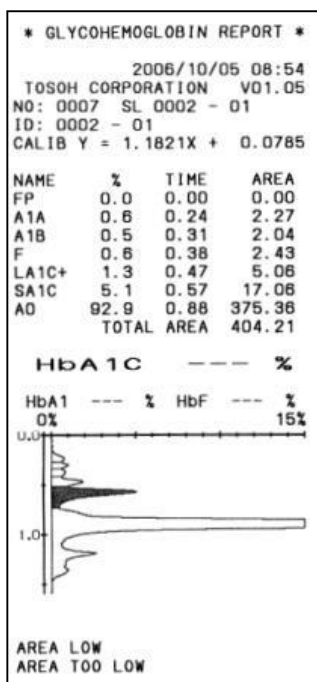
**Fig. 6-5 Total Area is high  
(3000 < Total Area < 4000)  
HbA<sub>1c</sub> is reportable**



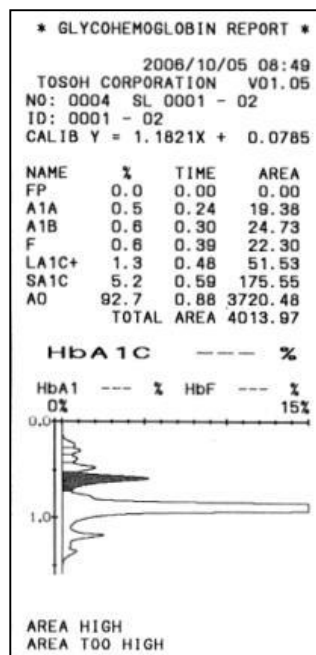
**Fig. 6-6 HbF is high  
HbA<sub>1c</sub> is not reportable**



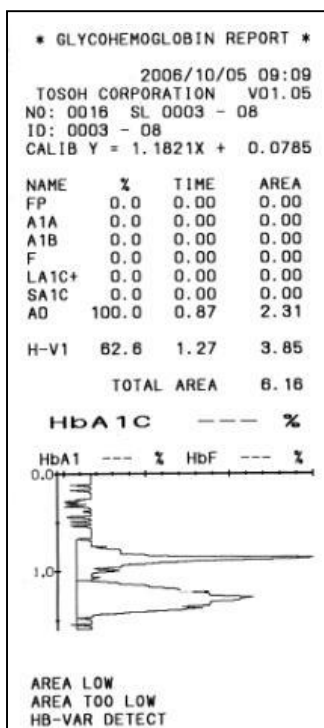
**Fig. 6-7 Total area (< 500) is too low  
HbA<sub>1c</sub> is not reportable**



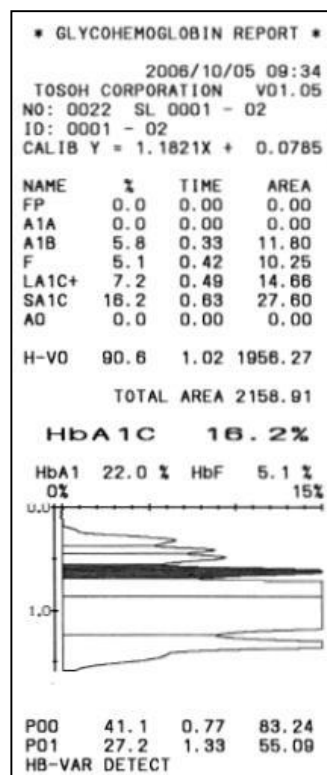
**Fig. 6-8 Total area (> 4000) is too high  
HbA<sub>1c</sub> is not reportable**



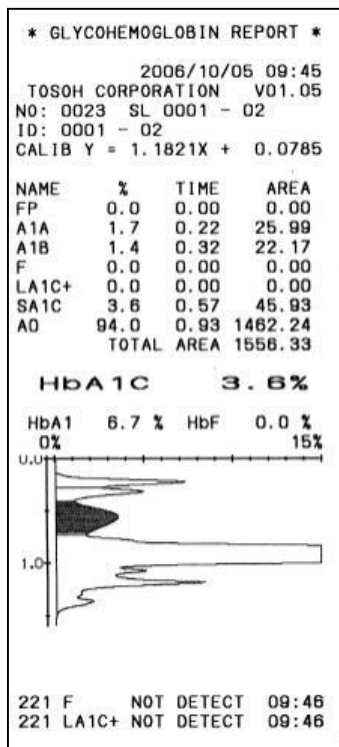
**Fig. 6-9 Insufficient sampling volume  
HbA<sub>1c</sub> is not reportable**



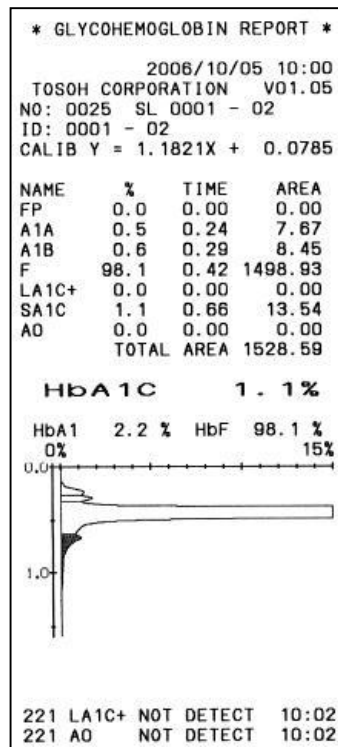
**Fig. 6-10 Defective pump delivery  
HbA<sub>1c</sub> is not reportable**



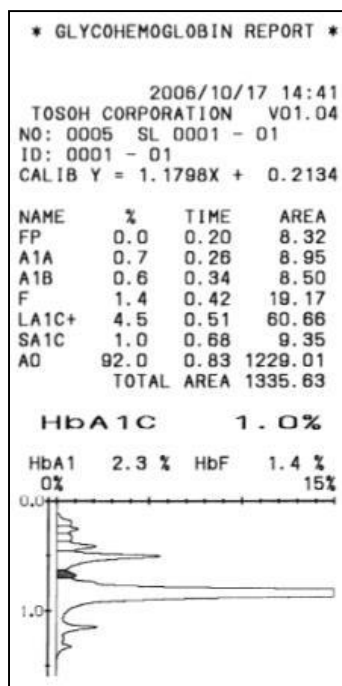
**Fig. 6-11 Elution Buffers No. 1 and 2 are Incorrectly Set  
HbA<sub>1c</sub> is not reportable**



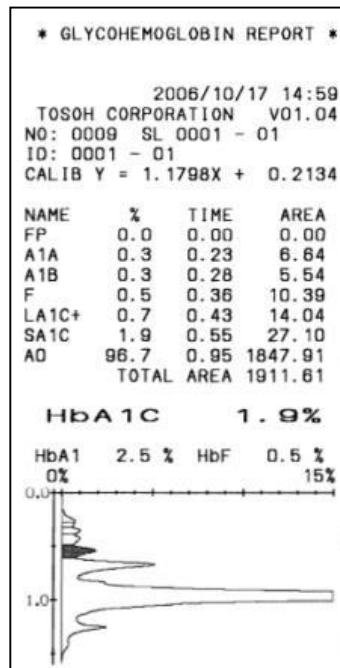
**Fig. 6-12 Elution Buffers No. 2 and 3 are Incorrectly Set  
HbA<sub>1c</sub> is not reportable**



**Fig. 6-13 Low flow rate  
HbA<sub>1c</sub> is not reportable**



**Fig. 6-14 High flow rate  
HbA<sub>1c</sub> is not reportable**



### 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.

**NOTES**

## 7.1 Downloading Files from the External Storage Device

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 storage device socket.

### System and AS program Downloading

#### Procedure

- 1) Turn off the main power switch of the analyzer.
- 2) Insert the system external storage device into the socket.
- 3) Turn on the main power switch.
- 4) **Screens 7-1** and **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

```

##### SYSTEM LOADER #####
                                BOOT 01.00
Memory Test ..... OK  Printer Test ..... OK
MJ Trans Test ... OK  EXB Trans Test ... OK
LCD Trans Test ... OK  AS Trans Test ... OK
HST Trans Test ... OK  LC Trans Test ... OK

Waiting for Power Key...

```

- 5) Press the POWER KEY.
- 6) **Screen 7-3** will be displayed and the AS program and system program are loaded one after the other.  
(This takes about 6 minutes.)


### Screen 7-3 System Loader Screen

```

##### SYSTEM LOADER #####
                                BOOT 01.00
Memory Test ..... OK  Printer Test ..... OK
MJ Trans Test ... OK  EXB 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

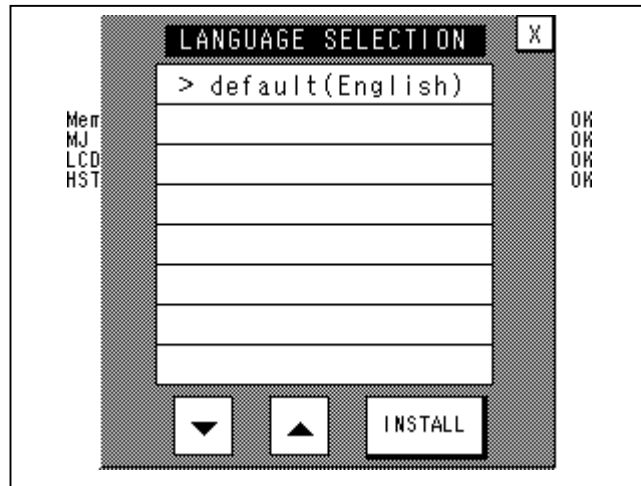
Searching System ... HLC-72368
System Version ..... 01.00
Loading System .....



```

- 7) Once the system has been loaded, the Language Selection screen will be displayed.

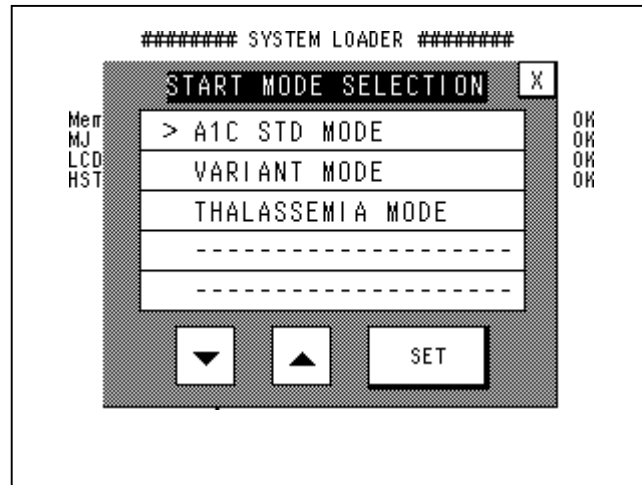
#### Screen 7-4 Language Selection Screen



- 8) Select “**default**” and press the **INSTALL** key.
- 9) When loading is complete, the analyzer automatically starts up and goes in WARMING UP state. After confirming that the analyzer has entered into the WARMING UP state, remove the system external storage device from the socket.

If you enter “CLR” as the password, **Screen 7-5** may be displayed, depending upon the version upgrade contents. If so, continue on to step 10.

- 10) After **Screen 7-4** has been displayed, **Screen 7-5** will automatically be displayed.

**Screen 7-5 Assay Mode Selection Screen**

- 11) Check that **VARIANT MODE** is selected and then press the **SET** key.
- 12) The system loader screen appears. When loading is complete, the analyzer automatically starts up and goes in WARNING UP state.
- 13) Remove the system external storage device.

The AS program (filename: **AS.MOT**) and system program (filename: **SYSTEM.MOT**) are required to operate the analyzer. Both of these programs are stored in the accessory system external storage device.

When the main power is turned on, the analyzer searches the files on the external storage device in the socket. If the AS and system program are found, they are automatically loaded in the internal memory of the analyzer. During a system upgrade, or when "CLR" is entered as the password (Refer to "**Chapter 4, Section 4.14: Password Input**"), the assay parameters are overwritten and returned to their initial values. If the assay parameters have been saved beforehand (filename: **SYSTEM.PRM**), by loading back the saved parameters from it the analyzer is ready to operate as it has been. To save the assay parameters on an external storage device, see next section.

## Assay Parameter Storage and Loading

### Procedure

#### [Storage]

- 1) Confirm that the analyzer is in STAND-BY state.
- 2) Insert a formatted external storage device into the socket.
- 3) Press the CARD key on the MENU screen.
- 4) Display PRM SAVE using the COMMAND key.
- 5) Press the EXEC 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 external storage device containing the assay parameters (**SYSTEM.PRM**) into the socket.
- 3) Press the CARD key on the MENU screen.
- 4) Display LOAD using the COMMAND key.
- 5) Press the EXEC key.
- 6) The assay parameters stored in the external storage device will be loaded and stored into the analyzer.

The filename valid for storing/loading the assay parameters is **SYSTEM.PRM** only. If there is already the **SYSTEM.PRM** file on the external storage device, it will be overwritten by 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 external storage device.

Refer to "**Chapter 4. Section 4.7: Card (External storage device)**" for details.

## 7.2 Communication with a Host Computer

Results can be sent to a host computer using the RS-232C port (EIA-232 / EIA-574). Real-time transfer of each data set (every 1.6 minutes) 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-723G8 Host connection specifications**" for detailed communication specifications and various settings. (This manual can be obtained from one of our sales representatives.)

### (1) Communication start

When communicating with a host computer, press to highlight AT TRANS 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 COMMAND key after designating a data range from the list screen. A specific result can also be designated and re-transmitted from the RECALC screen.

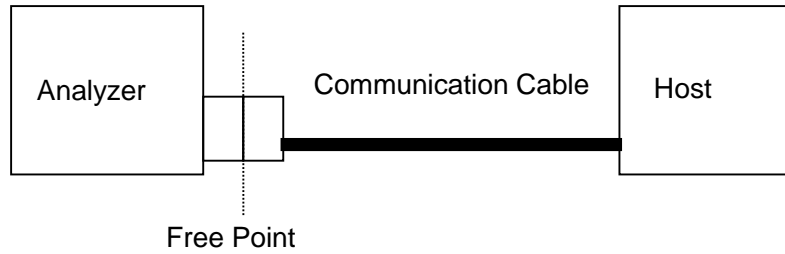
### (2) Communication specifications

Item	Specification
Transmission method	RS-232C, start-stop transmission, half-duplex
Rate	1200, 2400, 4800, 9600 bps
Transmitted code	ASCII
Data length	7 bit, 8 bit
Parity	Even, odd, none
Stop bits	1 bit, 2 bit



When the raw data transmission mode is selected (RAW mode), be sure to select 9600 bps due to a large volume of data.

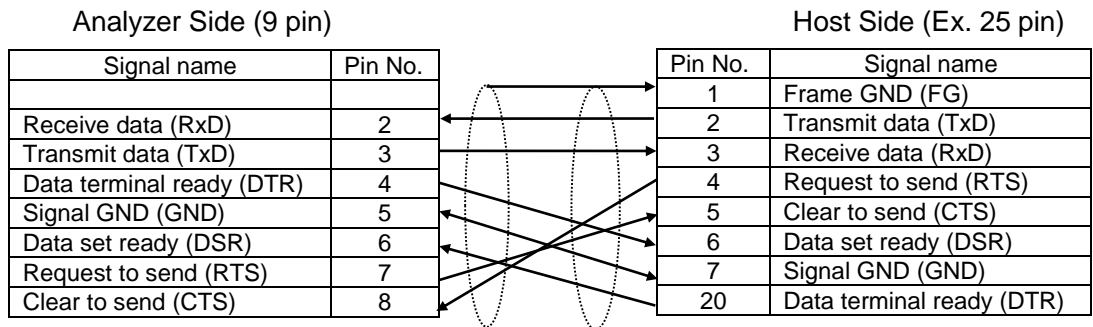
**(3) Connection**



**(4) Connector**

A **D-Sub 9P** (male) is installed on the analyzer side as the connector.  
 The connector of the communication cable which is connected to the analyzer should be **D-Sub 9S** (female).

**(5) Pin Assignment**



## (6) Communication Modes

There are two communication modes: the query mode, in which the analyzer queries a test order to the host using the sample ID after reading the bar code, and the result transmission mode, in which the analyzer transmits results to the host every time results are obtained. Various formats compatible with applications and the former models (GHbV and G7) are available for the result transmission mode. Non-handshake and handshake protocols are available as the basic transmission method. In addition, flow control is available as an option using X-ON/OFF code for the non-handshake protocol.

## (7) Communication Formats

There are three available communication formats: G8 format (standard), G7 format and GHbV (A1c2.2) compatible format. Select the desired format using **TRANS G5/7 MODE** on the PARAMETER screen of the analyzer. By this parameter, data format (in JDS units, NGSP units, Mono S units or IFCC units) for transmitting assay results to the host is also defined as below.

TRANS G5/7 MODE is comprised of two digits as AB.

The last digit (B) which defines communication format.

Setting value 8: G8 format (default setting)

Setting value 7: G7 model compatible format

Setting value 6: GHbV model compatible format (When 5 digits are selected for the sample number, except when the sample is STAT or CALIB, the sample number is extended by adding a 0 to the top digit of the sample #)

Setting value 5: GHbV model compatible format

The second digit from the last (A) which is used when assay results in IFCC units are transmitted to the host.

0 – 3 can be set to this, but refer to **“Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 Host connection specifications”** for details, which is provided from the Tosoh sales representative upon request.

When 1 – 3 is set to this digit, assay results in IFCC units are displayed on the LIST screen.



The parameter settings are made by the service personnel and the set parameters are not normally displayed on the screen.

**(8) BASIC mode, HI-LEVEL mode, and RAW mode**

There are two modes in all communication formats: BASIC and HI-LEVEL. The primary difference in these modes is the transmission protocol. The non-handshake protocol is used in BASIC mode and the handshake protocol is used in the HI-LEVEL mode. In addition, the RAW mode (chromatographic data transmission) is available in the G7 and G8 formats, and is used with the same protocol as the HI-LEVEL mode. The various modes correspond to the following selection keys in the RS-232C screen of the analyzer.

BM key: BASIC mode  
HM key: HI-LEVEL mode  
RAW key: RAW mode (the protocol is the same as the HI-LEVEL mode)

**(9) Query to host**

When executing a query to a host, set the QUERY key on the RS-232C settings screen to ON (highlighted).

When assaying all samples set on the loader without using the query mode, set the QUERY key to OFF (not highlighted).

## 7.3 Specifications

### Main Specifications

Analytes:	HbA <sub>1c</sub> (s-A <sub>1c</sub> ), HbF, HbA <sub>1</sub>
Applicable samples:	Whole blood and diluted samples
Assay principle:	Ion exchange high performance liquid chromatography
Processing throughput:	1.6 min/sample (Variant Analysis Mode)
Detection method:	2-wavelength absorbance (detection wavelength: 415 nm)
Sampling unit	
Sampling volume:	3 µL for whole blood and 80 µL for diluted samples
Sample rack:	10 primary tubes or vials per rack
Sample loading capacity:	90 samples or 290 samples
Sample suction:	Nozzle suction
Sample injection:	Sample loop (4 µL)
Sample dilution:	Dilution by Hemolysis & Wash solution in the dilution port
Sample tubes or vials:	12 ~ 15 mm diameter × 75 ~ 100 mm primary tubes Sample vials (using adapter)
Sample ID recognition:	Bar code with maximum of 20 digits
Bar code 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 monochromatic LCD
Input:	Pressure-sensitive touch panel / sheet keys
Output:	Thermal printer
Storage:	Smart Media card or USB stick
	For details about the usable external storage device and the number of sets of assay results that can be stored, refer to " <b><u>Chapter 2. Section2.3: Units and functions, 4. Storage device</u></b> ".
Pump unit:	Single plunger pump (Max transport pressure: 15 MPa)
Column Temperature control:	Electronic cooling (Temperature: approx. 25 °C)

Data processing unit: RS-232C serial communication port (bi-directional)  
Data storage by internal memory (for up to 800 samples)  
Recalculation (reprinting) of achieved result  
Automatic startup by timer  
Error flag function for abnormal results

Calibration: 2-point method for HbA<sub>1c</sub>

Dimensions (prongs not included)

Main unit and 90SL combination: 530 (W) × 515 (D) × 482 (H) mm

Main unit and 290SL combination: 1120 (W) × 530 (D) × 482 (H) mm

Weight

Main unit: approx. 26.5 kg

Sample Loader 90SL: approx. 7.5 kg

Sample Loader 290SL: approx. 25.0 kg

### **Operating Environment Conditions**

Power supply / consumption (common to 90SL model and 290SL model):

AC100 - 240 V, 50 / 60 Hz, 180 VA

- EU Area: AC230 V, 50 Hz, 180 VA

- USA and Canada Area: AC120 V, 60 Hz, 180 VA

Temperature: 15 °C ~ 30 °C

Humidity: 20 % ~ 80 % R.H. (without condensation)

Over voltage category: II

Pollution degree: 2

Altitude: up to 2,000 m

Electric power quality: Typical commercial or hospital environment

Dust: Typical office level

### **Environment of Transportation and Storage**

Temperature: 5 °C ~ 50 °C

Humidity: 80 % R.H. or less (without condensation)

Others: Keep dry and store indoors

**Standard Conformity**

EMC standard:	IEC60601-1-2: 2001
CISPR11 class and group categories:	Class A, Group 1
FCC:	Part 15, Sub Part B Class A
EN61010-1: 2001 (2nd Edition)	
EN61010 2-081:2002, +A1: 2003, EN61010-2-101: 2002	
UL610100-1, CAN/CSA c22.2 No. 61010-1-04	
Bar code reader:	Class 1: IEC60825-1: 1994

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