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Tosoh Automated Glycohemoglobin Analyzer

**HLC-723GR01**

# Operator's Manual

Rev. B

**REF**

0024750 Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01

**TOSOH CORPORATION**

BIOSCIENCE DIVISION

# Introduction

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This product is intended for in vitro diagnostic use only for the quantitative measurement of HbA1c in venous whole blood and diluted blood (hemolysate) specimens by healthcare professionals.

Rx - For Prescription Use Only

## About this manual

- This Operator's Manual is designed to ensure that you can operate the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 safely and correctly.
- The HLC-723GR01 must be operated only by personnel who have expertise in laboratory testing. Users must carefully read and familiarize themselves with the information in this manual and operate the HLC-723GR01 in strict accordance with the instructions provided.
- Keep this manual in an easily accessible location for reference purposes.
- Users must strictly adhere to all safety precautions outlined in this manual.
- Should you notice any discrepancies, errors or omissions in the information provided, you are requested to immediately notify Tosoh local representatives.
- The copyright of this manual belongs to Tosoh Corporation. This manual may not be copied, modified, or disclosed to third parties, in whole or in part. However, this does not apply to copying a part only for personal use other than commercial transactions.
- This manual is subject to change without prior notification.
- This manual is intended for the United States. If you need a manual for other countries or regions, please contact your local Tosoh representatives.

## Contacting us

- To request system inspection, repair, or other services, or if you have any questions about the operating procedures or other matters, please contact Tosoh local representatives.

## Readers of this manual

- Facility manager: personnel responsible for the management of clinical laboratories or the HLC-723GR01
- Quality control manager: personnel who perform regular quality control
- Operator: personnel who perform maintenance or daily check, and analysis using the HLC-723GR01

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- Trademark symbols such as (R) and TM may be omitted from system names and product names in this manual.

# Indications in This Manual

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## Safety notes

The information displayed using “DANGER”, “WARNING”, “CAUTION” and “NOTICE” signs in this manual are provided for the purposes defined below.

### **DANGER**

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

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### **WARNING**

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

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### **CAUTION**

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

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### **NOTICE**

Indicates no risk of injury, but a hazard with a medium level of risk which, if not avoided, could result in damage or malfunction to the system or equipment.

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Supplementary explanations and references are described as shown below.

**Note**

- Describes useful things to know when using the analyzer.

**Reference**

- Describes the items to be referred to.

# Use Period, Supply Period, and Warranty

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## Design-based standard use period of the HLC-723GR01

7 years after installation (self-certification based on in-house data)

- The design-based standard use period means an expected period during which the product can be used safely under normal conditions (with regular replacement of consumables and regular maintenance), in strict accordance with the Operator's Manual.
- The analyzer may deteriorate over time, earlier than the expected standard use period depending on the frequency and operating environment.
- If signs of malfunction appear, immediately shut down the analyzer, and contact Tosoh local representatives even before the standard use period has not passed.

## Regular Preventive Maintenance (PM)

Every 20,000 tests or every year

## Supply period of service parts

7 years after the end of sales

## Warranty

Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact Tosoh local representatives or refer to your warranty contract partner.

## Operating system support

This system is equipped with Windows OS. Although the end-of-support date of the Windows OS is announced by Microsoft Corporation, you can continue to use the system with the installed whitelist-based security software even after the Windows OS is no longer supported. For more information about the security software, please contact Tosoh local representatives.

# Applicable Instruments

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## **Analyzer**

- Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 (0024750)

## **Sample loader**

- 90 sample loader GR-90SL (0024752)
- 290 sample loader GR-290SL (0024753)

You must only use the analyzer, sample loader, column, elution buffers, and Hemolysis & Wash solution, filter element, suction filters, optional accessories, consumables and other service parts [Refer to 2.6.4 Consumables and optional accessories (sold separately)] dedicated to the HLC-723GR01.

When installing, relocating, and disposing of the system, contact Tosoh local representatives.

Tosoh cannot be held liable for any consequences arising from the use of non-specified reagents, components, and accessories or deviations from the descriptions in this manual.

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# 1

## Safety Precaution

### 1.1 Precautions

#### 1.1.1 Installation

#### WARNING

**Connect the power cable to the 2-pin socket with a ground terminal.**

- Failure to properly ground the analyzer is a potential source of electric shock.

**Firmly insert the power plug seated in the socket.**

**Use power cable that can support 250 VA.**

**If dust or dirt is attached to the blades or blade mounting part, unplug the power cable, and remove dust or dirt.**

**Observe the following precautions when handling the power cable:**

- Do not stretch the power cable.
- Do not bend the power cable by force.

**When unplugging the power cable, be sure to hold the plug.**

**When using an extension cable, select an extension cable with sufficient capacity and a ground terminal.**

- Mishandling may cause fire or electric shock.

**Do not install the system in the following locations:**

<b>Temperature</b>	Do not install the instrument in temperature outside the range of 15°C - 30°C
<b>Humidity</b>	Do not install the instrument in humid places outside the range of 20% ~ 80% (no condensation)
<b>Overvoltage Category: II</b>	Power voltage fluctuation must not exceed overvoltage II specifications
<b>Pollution degree: 2</b>	Install the instrument in location with no more than typical office level and dust
<b>Vibration: Reference: Electrical Safety Testing: IEC 61010-1:2017 Edition 3.1</b>	Install the instrument on a vibration-free and on a level platform
<b>Maximum Altitude</b>	Do not install an instrument at an altitude higher than 2,000 m or 6,600 feet
<b>Air currents or direct sunlight</b>	Install the instrument in a place where direct sunlight or wind can be avoided
<b>Other</b>	Avoid locations with poor ventilation and locations that store chemicals or near equipment that generates corrosive gas or electrical noise or near a flame. The unit must be at least one foot away from any sink.
<b>Power supply</b>	Do not install the instrument in other power supply conditions outside of the specifications: AC100 to 240 V, 50 / 60 Hz, 250 VA.

**⚠ WARNING**

**Do not connect the analyzer ground line to gas pipes, water pipes, lightning rods, or telephone system ground line.**

- Gas pipes can ignite fires and cause explosions.
- Water pipes are not effective grounds.
- Lightning rod and telephone lines are potential sources of danger when lightning strikes.

**Do not modify the power cable, or do not use a power distribution adapter.**

**Do not plug or unplug the power cable with wet hands.**

- This may cause fire and electric shock.

**NOTICE**

**Be sure to connect the analyzer to a power supply with the specifications indicated on the previous table.**

- Significant fluctuations in voltage may cause fire.

**1.2 Precautions for use****1.2.1 Handling of specimens****⚠ WARNING**

**When handling infectious materials such as biological specimens, be sure to wear Personal Protective Equipment (PPE) – protective clothing, goggles, gloves, mask, etc.).**

- When handling infectious materials such as biological specimens, waste liquid, and calibrators, or when replacing the column, filter element, or sampling needle, be sure to wear PPE to prevent infection.
- The used columns, filter elements, sampling needles, sample cups, and waste tank are contaminated by blood. When handling them, be sure to wear PPE.
- Dispose these as medical waste in accordance with the local laws and regulations to protect the surrounding environment.

**1.2.2 General handling****⚠ WARNING**

**Keep the covers and doors closed during operation.**

- The interior of the analyzer contains high-speed moving parts, high-temperature components, and high-voltage circuits. Foreign objects or fingers and hands can easily get pinched or caught in the mechanisms, or can cause burns or electric shock, resulting in injury.

**Do not shut down or start the analyzer by simply unplugging or inserting the power plug.**

- This may cause fire and electric shock.
- Always use the main power switch located on the left side of the analyzer.

**Do not touch the analyzer with wet hands.**

- This may cause electric shock.

## **WARNING**

### **Place reagent containers only in designated locations.**

- If the reagents are spilled out into the analyzer, it may cause a short-circuit or electric shock.

### **Do not disassemble or modify the analyzer.**

- This may cause fire and electric shock.

## **CAUTION**

### **Be sure to turn off the analyzer before replacing the sampling needle.**

- If the analyzer is operated with its main power turned on, it may damage the analyzer or result in injury.

### **Avoid opening covers and inserting fingers or any foreign object into the operating mechanism.**

- The interior of the analyzer is comprised of motor-driven components that operate at high-speeds. Foreign objects or fingers and hands can easily get pinched or caught in the mechanisms, resulting in personal injury.

## **NOTICE**

### **Connecting through the USB or RS-232 ports can introduce malware.**

- It is the laboratory's responsibility to establish proper security and controls. Please ensure USBs used are free from viruses or malicious software.

### **The HLC-723GR01 LAN port is disabled and cannot and should not be connected directly to the internet.**

**Connection to internal network for Laboratory Information System (LAS/LIS) can be achieved via RS-232C connection.**

**If integrating the Analyzer with another system such as LIS, it is the customer's responsibility to assure fields are mapped correctly between systems.**

### **Cybersecurity Precautions**

- It is the customer's responsibility to establish proper cybersecurity controls, policies, and training.

## 1.3 Maintenance

For daily maintenance, refer to section 6.2 "Daily ". For regular maintenance, contact Tosoh personnel.

## 1.4 Electromagnetic waves

This analyzer complies with the following EMC standards, (both are the standards for emission (CISPR 11 Class A) and immunity (professional healthcare facility environment)).

- IEC61326-2-6:2020

- IEC60601-1-2:2014 + A1:2020 (including IEC61000-3-2 Class A and IEC61000-3-3)

Since CISPR 11 Class A is an EMC standard for instruments intended for use in industrial environments or hospitals, this analyzer is not intended for use in residential environments and may not provide adequate protection against radio frequency communication services. Moreover, compliance with the above EMC standards does not guarantee that harmful electromagnetic waves are not generated in any installation environment.

Electromagnetic interference is generated under certain conditions, such as when the analyzer is not installed or used in accordance with the Operator's Manual or when a non EMC-compliant device is used, possibly causing malfunction (false analysis reports, etc.) of the analyzer or other peripheral instruments. This may cause misdiagnosis of patients, so it is recommended to install and use this analyzer in dedicated medical facilities. If the analyzer causes harmful electromagnetic interference to another instrument or is affected by harmful electromagnetic interference caused by another instrument, take the following measures.

- Change the direction or installation location of the analyzer.
- Move the device causing electromagnetic interference away from the analyzer.
- If the analyzer shares its power source with the device causing electromagnetic interference, connect the power cable to a separate power source.

### **WARNING**

**Do not use any RF communication devices, including cell phones, antenna cables, or external antennas, within an area of 30 cm of all parts of the analyzer or any other connected peripheral instruments, possibly causing malfunction the analyzer.**

**Do not use the analyzer near other instruments, or do not stack the analyzer and other instruments on each other. Doing so may cause malfunction. If such a situation is avoidable, make sure that the analyzer or any other instruments can operate properly.**

**It is recommended to use multimedia instruments that comply with CISPR32 (or CISPR32-equivalent) standard.**

**Do not use anything other than the specified or provided accessories, transducers, or cables. Doing so may increase electromagnetic interference emissions or reduce electromagnetic immunity. If such a situation is avoidable, make sure that the analyzer or any other instruments can operate properly.**

## 1.5 Batteries

The European Battery Directive requires separate collection of spent batteries to facilitate recycling and protect the environment.

The system contains batteries that are not intended for the operator to service or remove. Only a Tosoh representative or a qualified individual may remove the batteries in the system at the end of the life of the analyzer and may dispose of them in accordance with local regulations for separate collection of spent batteries.

### WARNING

**Improper handling of batteries can cause explosions or fire.**


- Do not remove, disassemble, or dispose of batteries.

## 1.6 Caution labels



Caution labels are applied in locations on the analyzer which require particular attention during operation or handling. Check the contents of the caution labels to use the system safely.

If the caution labels become difficult to read due to stain or tears, contact Tosoh local representatives for replacement labels.

### WARNING

Biohazard label	Description
	<p><b>Biohazard label (column oven, line filter, sampling needle, waste port, waste tank)</b></p> <ul style="list-style-type: none"> <li>• Take the utmost care to prevent exposure to biohazard materials.</li> <li>• Improper handling may cause infection.</li> <li>• The column, the line filter and the sampling needle, the waste port and the waste tank can be contaminated by samples. Do not touch the column, line filter, sampling needle, and waste tank with unprotected hands. Wear the proper protective clothing (gloves).</li> <li>• Empty the waste container regularly to avoid spill-over.</li> </ul>

### CAUTION

Caution label	Description
	<p><b>General hazards (sampling needle)</b></p> <ul style="list-style-type: none"> <li>• Take care to avoid general hazards</li> <li>• Make sure to turn the main power off prior to replacing the sampling needle.</li> <li>• When the autosampler is operating, contact with the needle tip can result in equipment damage or injury.</li> </ul>
	<p><b>Caution for high temperature (inside printer)</b></p> <ul style="list-style-type: none"> <li>• Take the utmost care when touching the inside of the printer</li> <li>• Do not touch the thermal head of the internal printer when changing the roll paper of the internal printer.</li> </ul>

## 1.7 What to do in case of an emergency

### 1.7.1 If a failure occurs

#### **WARNING**

**Immediately shut down the analyzer and unplug the power plug when problems such as burning smell, malfunction, or severe degradation of the analyzer occurs.**

- Continuing to operate an analyzer that is malfunctioning may cause electric shock, or fire.

**Contact Tosoh local representatives.**

**If eluent leaks, stop the operation, and unplug the power plug.**

- Wear the proper protective clothing (goggles, gloves, mask, etc.), wipe off the eluent and stop the leakage after making sure of no leakage in tube connections.
- Contact Tosoh local representatives when the leakage cannot be stopped.
- Elution buffer or Hemolysis & Wash solution leakage may cause fire, electric shock, or corrosion.

### 1.7.2 If an earthquake, a power outage, or a fire occurs

#### **WARNING**

**Immediately shutdown the analyzer and unplug the power plug.**

- Before restarting the analyzer, check for exterior damage, connect the power plug to the appropriate power source, and turn on the analyzer.

### 1.7.3 If a serious incident occurs and incident reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authority (e.g., EU competent authorities) in the country where the user and/or patient is established.

#### **WARNING**

**Immediately shutdown the analyzer and unplug the power plug.**

**Contact Tosoh local representatives and the regulatory authority.**

## 1.8 Relocation of the analyzer

#### **WARNING**

**Contact Tosoh local representatives.**

- This product uses human-derived specimens, so it may have been contaminated by infectious substances.

## 1.9 Disposal of the analyzer

### **WARNING**

**Contact Tosoh local representatives.**

- This product uses human-derived specimens, so it may have been contaminated by infectious substances.
  - Please ask authorized Tosoh Service Engineer to sanitize software and proprietary data for safe disposal of the device.
-

# 2 Overview

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## 2.1 Intended Use

The Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 is intended for in vitro diagnostic use for the quantitative measurement of % hemoglobin A1c (HbA1c) (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in human venous whole blood and hemolysate specimens using ion-exchange high performance liquid chromatography (HPLC).

This test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes, and for monitoring long-term blood glucose control in individuals with diabetes mellitus.

## 2.2 General Description

The Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 can perform a hemoglobin A1c test in just 50 seconds, to address the need for high throughput HbA1c analyzers in high volume laboratories. Hemoglobins elute in a specific order, and the chromatogram, along with the percentage of hemoglobin, is recorded. HbA1c results, including chromatograms, are automatically generated in just 50 seconds per sample.

This analyzer's small footprint and user-friendly operation makes it an ideal fit for any laboratory. The entire system requires less than 24 inches of counter space, and the touch screen LCD display has a flexible angle to enhance usability. The user-friendly interface offers broad options of functionalities and the main Menu screen, serves as the central hub for navigating through the user interface. From this point, users can seamlessly access various parts of the screen menu, allowing for easy and intuitive navigation.

The installation of the column and filter is user-friendly. Daily startup is quick, and the HLC-723GR01 can be programmed to power on automatically at specified times and days of the week. This automation is a built-in labor-saving feature.

The HLC-723GR01 system delivers A1c results with precision, accuracy, and reproducibility as recommended by the NGSP. After a brief warm-up, the system is ready to process samples and the operator simply places closed primary tubes or sample cups directly onto the system. Cap piercing and barcode identification are handled automatically, eliminating the need for sample pretreatment. Once the samples are loaded, the operator can initiate the process by pressing the "Start button" on the touch screen and step away. Each sample is diluted by the analyzer and then, through a proprietary step gradient procedure, is injected into the column for hemoglobin separation based on charge.

For user convenience, whole blood can be placed in the system using closed primary sample tubes or sample cups. The minimum whole blood sample volume in a primary sample tube is 1.0 mL, and 100 µL for a sample cup. The system's sample rack accommodates sample tubes as well as sample cups placed randomly in the sample rack. Continuous sample processing allows the operator to load additional samples at any time without interrupting the ongoing run. STAT capability is readily available, and loading a STAT specimen is a simple process.

Mechanical enhancements, such as the incorporated tube rotate function, eliminate the need for manual alignment of sample tubes when using barcodes.

Data can be stored on a USB device or transferred to a Laboratory Information System (LIS) via unidirectional or bidirectional interfaces for seamless data management and integration (see notice in this manual when connecting to a network).

## 2.3 Principle of HbA1c Assay

Based on the principle of high-performance liquid chromatography (HPLC) using a cation exchange column, the HLC-723GR01 analyzer separates hemoglobin components in a whole blood sample into 6 identifiable fractions in 50 seconds.

The detector continuously monitors the eluent absorbance of the hemoglobin fractions separated in the column. The HbA1c (% or mmol/mol) value can be reported along with the chromatogram. In addition, The GR01 analyzer also calculates and can report HbA1c levels in IFCC units (mmol/mol) converted using the master equation:

$$\text{IFCC (mmol/mol)} = 10.93 \times \text{NGSP(\%)} - 23.50 \quad ^1$$

## 2.4 Limitation of the Procedure

**The HbA1c test is not suitable for use in the following:**

- Samples collected from newborns should not be used.
- Diagnosing gestational diabetes.
- Diagnosing diabetes in patients with any condition where the lifespan of red blood cells is compromised, including recent significant or chronic blood loss, transfusions, significant iron deficiency, hemolytic diseases, hereditary spherocytosis, patients with hemoglobinopathies, with heterozygous sickle cell trait, or thalassemias.
- Diagnosing diabetes in patients with malignancies or severe chronic liver or kidney disease.
- In cases of rapidly evolving type 1 diabetes the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms.
- Hemoglobin A1c testing should not replace glucose testing for type 1 diabetes, in pediatric patients and pregnant women.

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<sup>1</sup> Geistanger A, Arends S, Berding C, Hoshino T, Jeppsson J-O, Little R, Siebelder C and Weykamp C, Statistical Methods for Monitoring the Relationship between the IFCC Reference Measurement Procedure for Hemoglobin A1c and the Designated Comparison Methods in the United States, Japan, and Sweden. Clin Chem 2008; 54(8) :1379-1385.

## 2.5 Hemoglobin Variants

Human hemoglobin (Hb) is a tetramer protein consisting of 2  $\alpha$ -chain globin molecules (141 amino acids) and 2 non- $\alpha$ -chain ( $\beta$ -chain,  $\gamma$ -chain, and  $\delta$ -chain) globin molecules (146 amino acids), each subunit containing a single heme molecule, constituting a stable structure.

Hemoglobin variant (abnormal hemoglobin) is a collective name for hemoglobins with an abnormal amino acid sequence, in which DNA base substitutions, deletion(s), or insertion(s) occurs in genes coding  $\alpha$ -chain and  $\beta$ -chain globins consisting of hemoglobin molecules. Generally, hemoglobin variants are inherited genetically, and more than 1,400 types of variants have been reported so far. (Refer to <https://globin.bx.psu.edu/>). Of those hemoglobin variants, HbD, HbS, HbC, and HbE are common. These commonly occurring variants elute in the peak windows designated as H-V0, H-V1, H-V2, or H-V3, respectively. Other abnormal hemoglobin variants have not been evaluated and for the confirmation of any particular hemoglobin variant, alternative methods are required.

The most commonly occurring variants mentioned above can be detected and presumptively identified by the HLC-723GR01. Refer to Instructions For Use for more information. Also refer to Section 7 of the Operator's Manual for information on Flag settings and reportability of HbA1c in the presence of variants.

### Note

Only the HbA1c values measured by this device should be reported to the health care provider. The test report displays %HbF and other detected hemoglobin variants; however, the performance characteristics of the hemoglobin variants detected by this device have not been reviewed or cleared by the FDA and therefore should not be reported to the healthcare provider. The hemoglobin variants detected by this device are only to ensure the validity of the HbA1c results because increased levels of hemoglobin variants may interfere with the percent HbA1c measurement. If a hemoglobinopathy is suspected, an FDA cleared test system for their measurement should be used.

## 2.6 Inspecting parts

The system components are packaged separately in 3 boxes: main unit, provided accessories, and sample loader. The items provided in each packaging box are listed below. Check that all the items are included.

The following 2 models of the sample loader are available: GR-90SL which can load up to 9 sample racks and GR-290SL which can load up to 29 sample racks.

The Sysmex Line Automation does not require a sample loader.

### 2.6.1 Main unit

<input type="checkbox"/> Operator's Manual (CD-R).....	1
<input type="checkbox"/> Power cable for the main unit (2 m or 79 inches) .....	1
<input type="checkbox"/> Waste tank (10 L) .....	1
<input type="checkbox"/> Waste tube (silicone, 9 mm ×1.6 m or 63 inches) .....	1
<input type="checkbox"/> Cable tie CV-150 .....	5
<input type="checkbox"/> Phillips screwdriver.....	1
<input type="checkbox"/> Sample Cup.....	20

<input type="checkbox"/> Printer paper roll .....	1 roll
<input type="checkbox"/> System USB memory stick .....	1
<input type="checkbox"/> Elution buffer holder .....	1
<input type="checkbox"/> Bottle cap (4 L) .....	1
<input type="checkbox"/> Barcode label for controls .....	6 sheets (2 sheets x 3 levels)
<input type="checkbox"/> Adapter for controls .....	6
<input type="checkbox"/> Accessory box .....	1
<input type="checkbox"/> Security software End User License Agreement (EULA).....	1
(included in the packaging box only when the software has already been installed at the shipment)	

### 2.6.2 90 sample loader (GR-90SL)

<input type="checkbox"/> Sample rack (SYSMEX).....	5
<input type="checkbox"/> Adapter for SYSMEX sample rack (13 mm) .....	50
<input type="checkbox"/> End marker .....	2
<input type="checkbox"/> Mounting screw .....	4

### 2.6.3 290 sample loader (GR-290SL)

<input type="checkbox"/> Sample rack (SYSMEX).....	10
<input type="checkbox"/> Adapter for SYSMEX sample rack (13 mm) .....	100
<input type="checkbox"/> End marker .....	2
<input type="checkbox"/> Mounting screw .....	4

## NOTICE

**All the provided items can be used only for HLC-723GR01. Do not use these items for other instruments.**

- If not, the system may not operate properly or may be damaged.

### 2.6.4 Consumables and optional accessories (sold separately)

- Column, reagents

Part No.	Product Name	Description
0024759	TSKgel GR01 HbA1c Column	Column: 1 piece
0024760	GR01 HbA1c Elution Buffer No. 1	800 mL (bag) × 10
0024761	GR01 HbA1c Elution Buffer No. 2	800 mL (bag) × 10
0024762	GR01 HbA1c Elution Buffer No. 3	800 mL (bag) × 10
018431US	HSi Hemolysis & Wash Solution (L)	2000 mL (bottle) × 5
0023502	HbA1c Calibrator Set (S)	1 mL × 4 × 2 levels
0023503	HbA1c Diluting Solution	100 mL × 2
0021974	Hemoglobin A1c Control Set	0.5 mL × 4 × 2 levels

Consumables

Part No.	Product Name	Description
0024781	Filter element with flange (11 mm)	5
0023862	Printer paper (W: 58 mm)	10 rolls
0019508	Sample Cup (500 pcs)	500
0018723	Suction filter	1
0024785	Sampling needle*	1
0024786	Sampling needle w/o groove *	1

\* Only personnel who have received the training can replace the sampling needle.

 Optional accessories

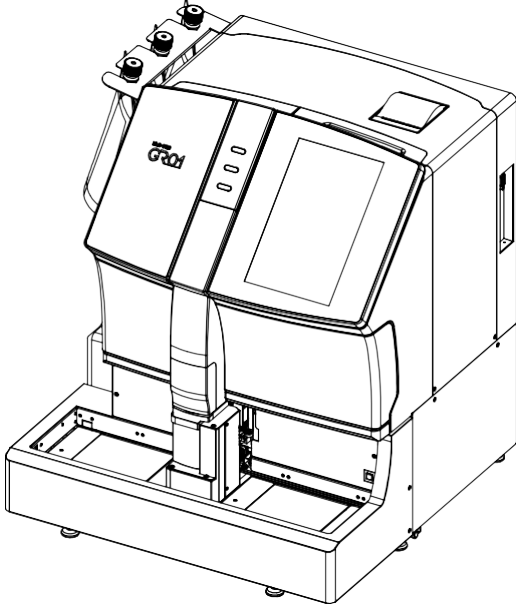
Part No.	Product Name	Description
0016320	Waste tank	10 L
0023274	SYSMEX sample rack (without adapter)	1
0018433	Adapter for SYSMEX sample rack (13 mm)	10
0018496	Adapter for SYSMEX sample rack (12 mm)	10
0018497	Adapter for SYSMEX sample rack (14 mm)	10
0024848	Adapter for control	2
0024847	Handheld barcode scanner (USB)	1
0024846	Laser BCR with attachment	1
0023932	LED signal tower kit	1 set
0024772	Buffer Switching Unit for GR	1 set
0024337	Printer (3 m USB cable)	1 set
0024852	Handheld barcode scanner holder	1

**Note**

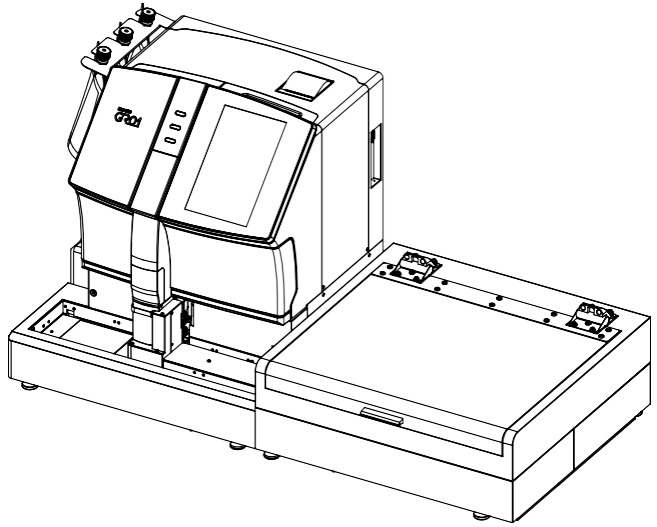
- Some optional accessories are not available or some of their specifications may be different in some countries and areas.

## 2.7 System configuration

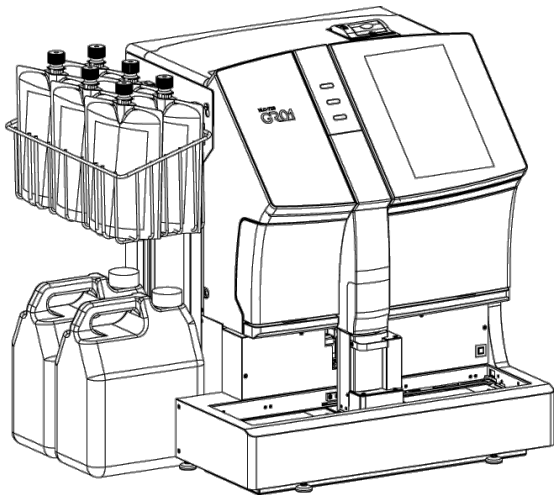
**When the GR-90SL is connected**



**When the GR-290SL is connected**

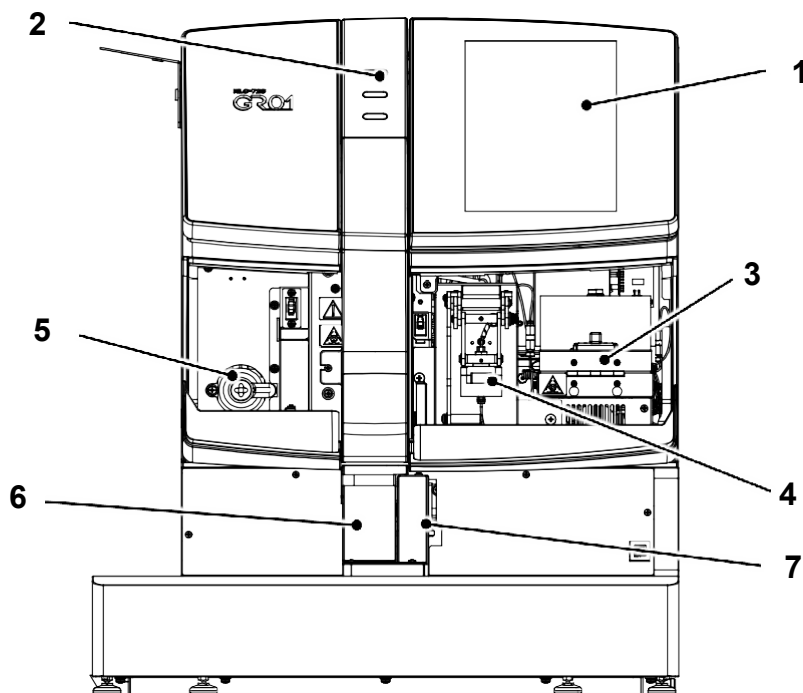


**When the buffer switching unit is connected**



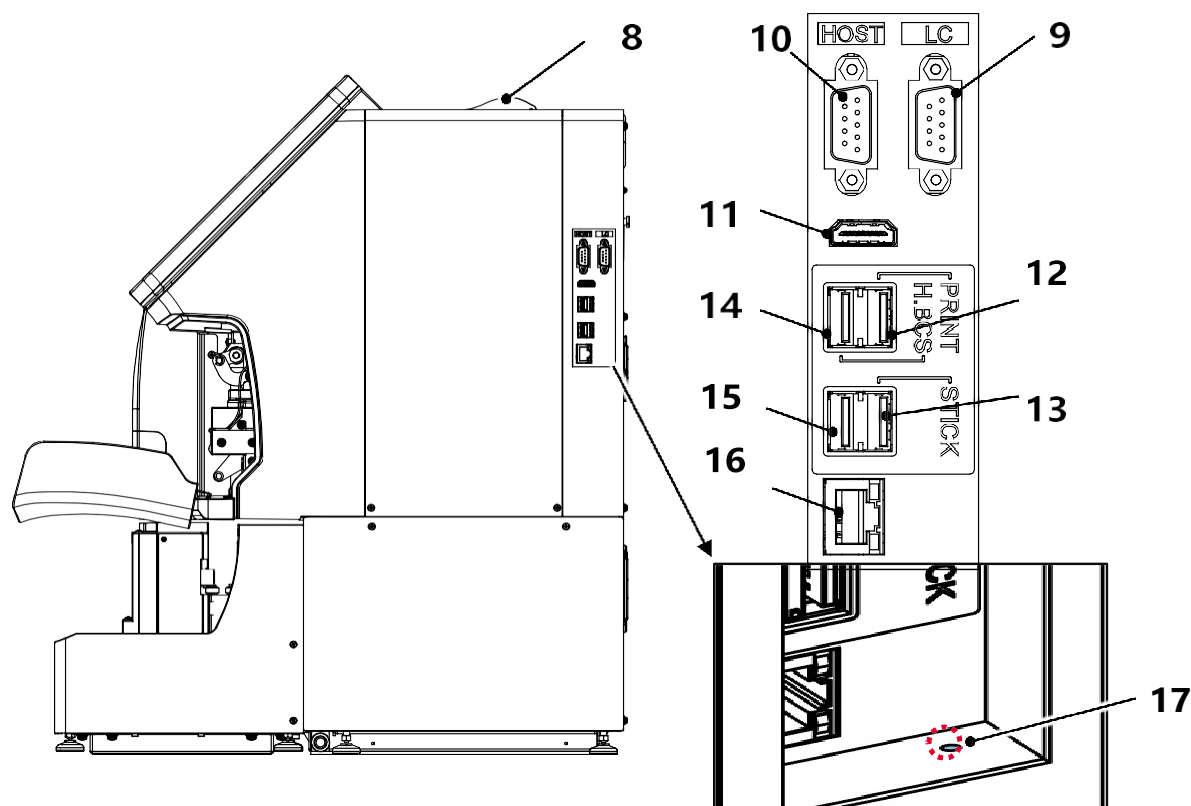
## 2.8 Units and functions

Front view



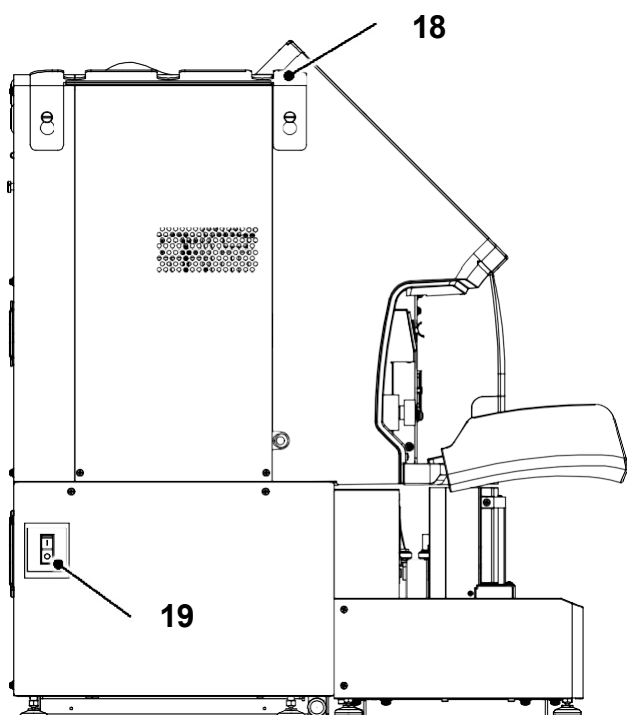
No.	Name	Function
1	Operation panel	The operation panel is a color LCD with touch keys. The angle of the operation panel can be adjusted. To adjust the angle, refer to “3.3 Adjusting the Angle of the Operation Panel (p.35)”. For more details on the operation panel, refer to “4 Operation Screen (p.37)”.
2	LED panel	The LED panel shows the analyzer status with 3 colors of LEDs. POWER (green): lights up when the instrument is turned on. RUN (blue): lights up when analysis is in progress. ERROR (red): lights up when an error occurs; turns off when the error is reset.
3	Column oven	The column oven contains the column, an essential component for analysis. The column oven is controlled at about 25°C. To replace the column, refer to “6.4.4 Replacing the column (p.146)”.
4	Line filter	The line filter contains the filter element. To replace the filter element, refer to “6.4.3 Replacing the filter element (p144)”.
5	Drain valve	If air bubbles enter the pump, open the drain valve to expel the bubbles. To remove air from the pump, refer to “6.2.7 Air removal from the pump (p.139)”.
6	STAT port	A priority sample is set at the STAT port, in a sample cup or a sample tube. For details of STAT analysis, refer to “5.8 STAT analysis (p.123)”.
7	BC Reader	The BC reader unit is built in the sample loader to read IDs on the barcode labels. For details of barcode labels, refer to “5.6.3 Checking the barcode label (p.118)”.

## Right side view

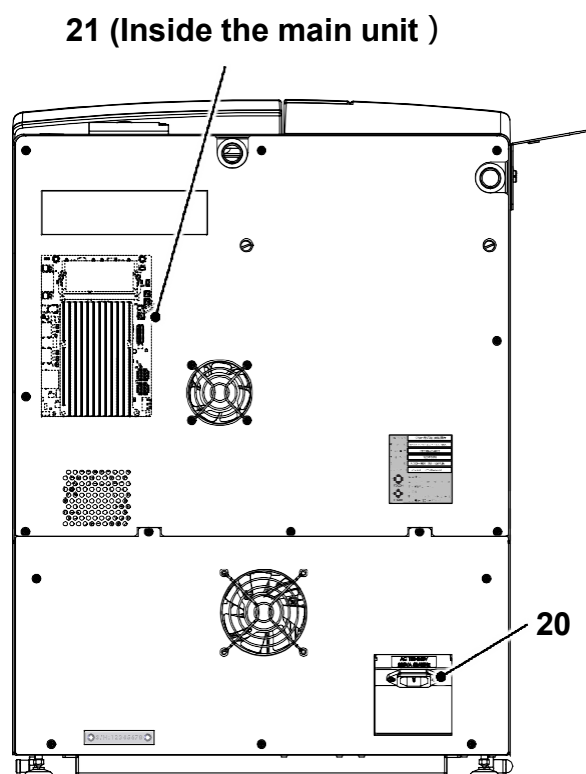


No.	Name	Function
8	Printer	This is a thermal printer, used to print analysis results, etc. To replace the printer paper roll, refer to “6.4.1 Replacing a paper roll (p.140)”.
9	LC port	This port is used when connecting to the SYSMEX laboratory automation system.
10	HOST port	This port is used to connect a data communication cable.
11	HDMI port	Not used.
12	USB printer port (PRINT)	This port is used to connect the external printer.
13	USB memory stick port (STICK)	This port is used to connect the system USB memory stick or a USB memory stick for storing analysis results. An encrypted USB memory stick or a password-protected USB memory stick cannot be used with this instrument. An exFAT-format USB memory stick is recommended to store analysis results.
14	Handheld barcode scanner port (H.BCS)	This port is used to connect the handheld barcode scanner.
15	USB port	Blocked by manufacturer-not usable.
16	LAN port	Blocked by manufacturer-not usable.
17	Reset switch	Press the RESET button only upon the recommendation of Tosoh personnel

Left side view



Rear view



No.	Name	Function
18	<b>Elution buffer holder</b>	This holder is used to hang elution buffer aluminum bags. It can be attached also to the back of the instrument.
19	<b>Main power switch</b>	This main power switch serves as a breaker for overcurrent protection.
20	<b>AC inlet</b>	This inlet is used to connect the provided power cable.
21	<b>PC unit</b>	A Windows PC is built into the instrument. The PC is equipped with an uninterruptible power supply (UPS) system for data protection.

# 3

## Installation and Management

### 3.1 Installation

#### 3.1.1 Installation

Only a Tosoh service engineer or personnel who have received maintenance training will install and deliver the instrument.

#### 3.1.2 Installation Environment

Install the instrument on a flat bench in an environment free from harmful gas, dust, and vibration, and not exposed to water, direct sunlight, or wind.

Operate the instrument under the conditions indicated below:

<b>Temperature</b>	Do not install the instrument in temperature outside the range of 15°C - 30°C
<b>Humidity</b>	Do not install the instrument in humid places outside the range of 20% ~ 80% (no condensation)
<b>Overvoltage Category: II</b>	Power voltage fluctuation must not exceed overvoltage II specifications
<b>Pollution degree: 2</b>	Install the instrument in a location with no more than typical office level and dust
<b>Vibration: Reference: Electrical Safety Testing: IEC 61010-1:2017 Edition 3.1</b>	Install the instrument on a vibration-free and on a level platform
<b>Maximum Altitude</b>	Do not install an instrument at an altitude higher than 2,000m or 6,600 feet
<b>Air currents or direct sunlight</b>	Install the instrument in a place where direct sunlight or wind can be avoided
<b>Other</b>	Avoid locations with poor ventilation and locations that store chemicals or near equipment that generates corrosive gas or electrical noise or near a flame. The unit must be at least one foot away from any sink.
<b>Power supply</b>	Do not install the instrument in power supply conditions outside of the specifications: AC 100 to 240 V, 50/60 Hz, 250 VA.

### CAUTION

**Use a power cable with sufficient capacity.**

- The power consumption of the HLC-723GR01 is 250 VA.

### NOTICE

**Do not use the instrument in an environment subject to rapid temperature changes.**

- Rapid temperature changes may result in condensation, causing electrical leakage or operation failure of the instrument.

### 3.1.3 Storage and Transportation Environment

Store or transport the instrument under the conditions indicated below.

#### Storage and transportation environment

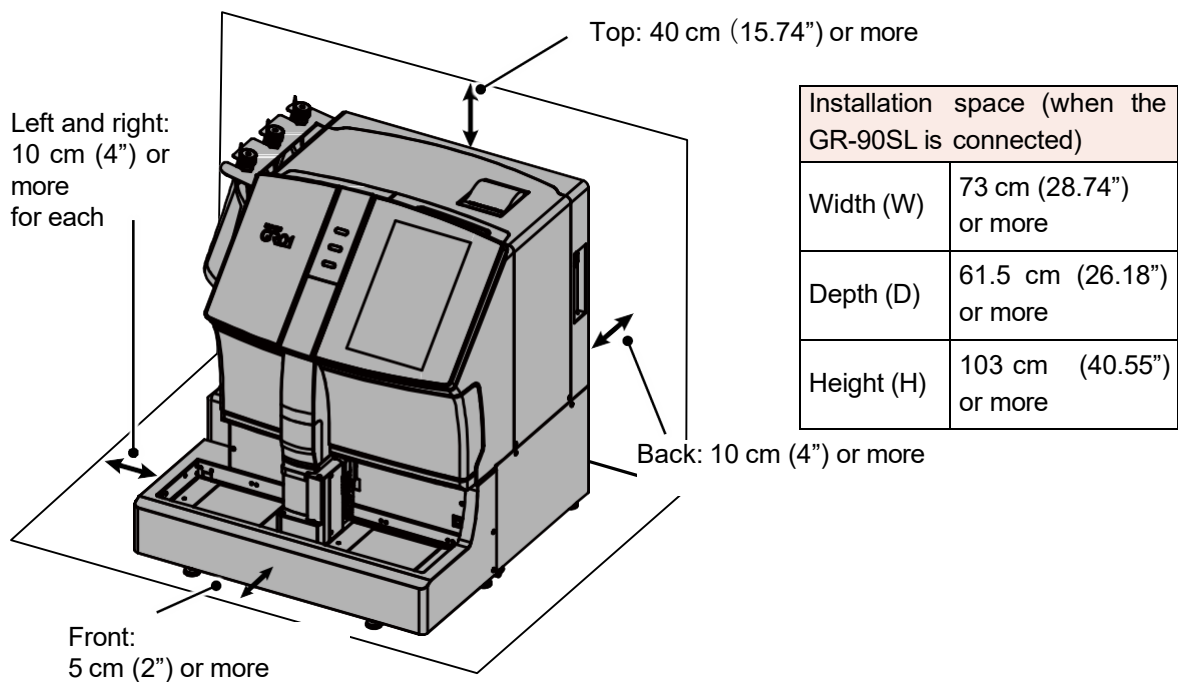
<b>Temperature</b>	0 to 50°C
<b>Humidity</b>	80% or less (No condensation)
<b>Other</b>	Keep dry. Store indoors.

### 3.1.4 Installation Space

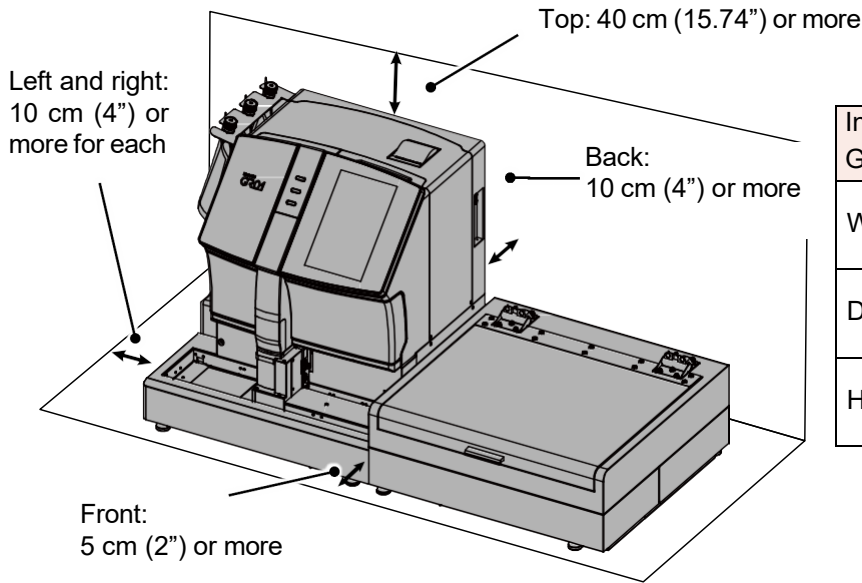
Do not place any other instruments or objects around the system, or inside the installation space indicated below.

Do not block the fans on the back of the instrument. Ensure operation space for turning off the main power switch or disconnecting the power cable.

#### Installation space (when the GR-90SL is connected)

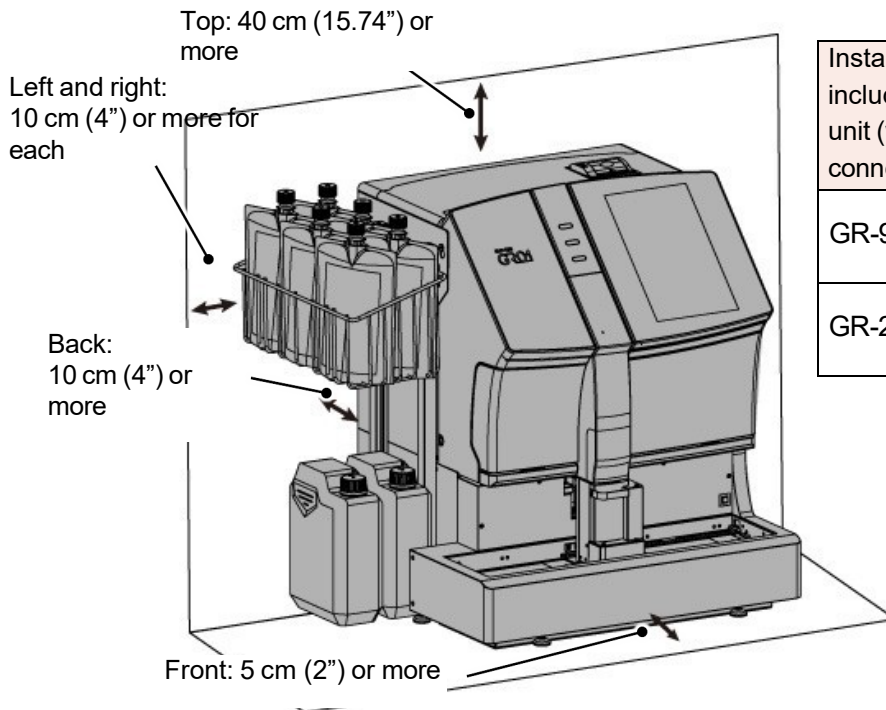


**Installation space (when the GR-290SL is connected)**



Installation space (when the GR-290SL is connected)	
Width (W)	132 cm (51.96") or more
Depth (D)	66.5 cm (26.18") or more
Height (H)	103 cm (40.55") or more

**Installation space (when the buffer switching unit is connected)**



Installation space (width) including the buffer switching unit (when the sample loader is connected)	
GR-90SL	80 cm (31.50") or more
GR-290SL	139 cm (54.72") or more

## 3.2 Connection

### 3.2.1 Waste Tube/Waste Tank

Adjust (or cut) the waste tube to an appropriate length (5 m (197") or less) and insert the waste tube fully into the waste tank so that it will not be bent.

Do not place any objects on the waste tube.

Place the waste tank at a position equal to or lower than the installation surface of the instrument.

## ⚠ CAUTION

**Place the waste tank on a flat and stable surface.**

- If the waste tank falls over, the waste liquid may spill out.
- Use a container such as a liquid receiving tray together with the waste tank.

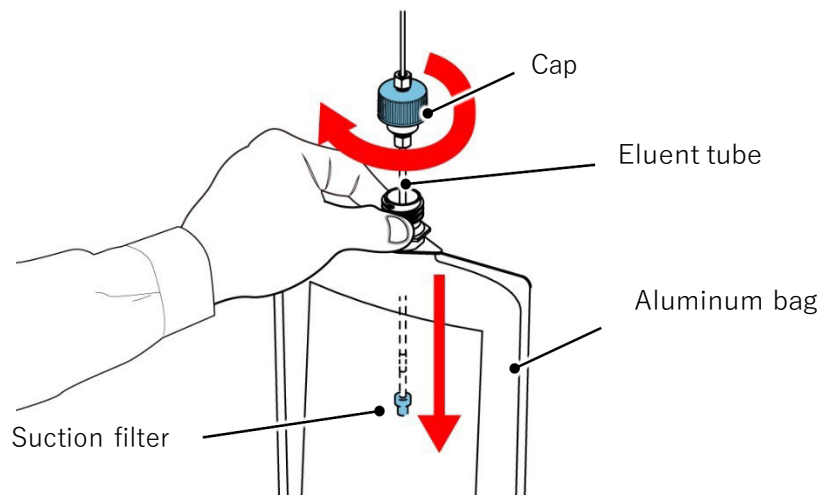
### Note

- If the waste tube is bent, the waste liquid may not drain out smoothly. If the waste tube is lifted to facilitate draining, it may trigger the waste liquid sensor, which will stop the analysis.
- The waste liquid is forced to be drained out by the pump, possibly causing bubbles in the waste liquid.

### 3.2.2 Eluent Tube

While matching the color of the cap (with the eluent tube) with the label color of the Elution Buffer No. 1, 2, or 3 for GR01, insert each eluent tube into the aluminum bag of the corresponding elution buffer, and tightly close the cap. A suction filter is connected to the end of each eluent tube to prevent foreign matter from entering the instrument flow path. When opening/closing the cap, hold the plastic part as shown below.

<b>Elution Buffer No. 1</b>	Light green
<b>Elution Buffer No. 2</b>	Pink
<b>Elution Buffer No. 3</b>	Orange



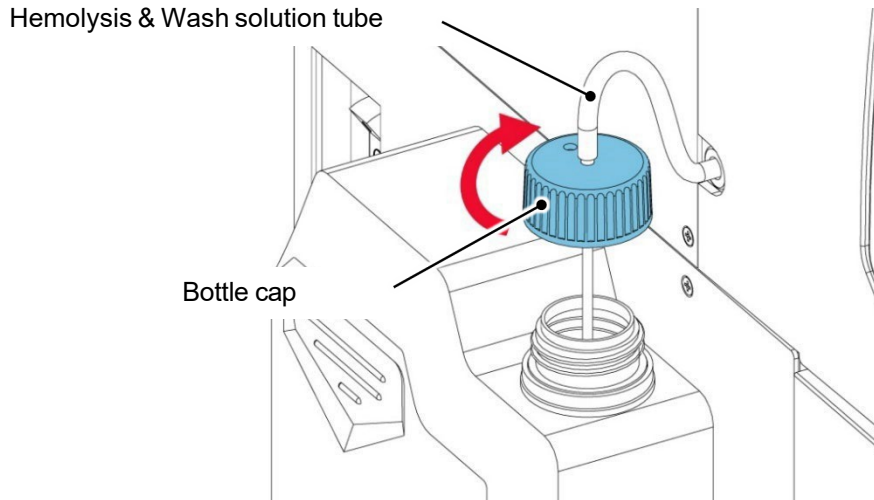
### Note

- If the tube is bent, the tube end may not reach the bottom of the aluminum bag. Be sure to connect the tube after straightening any bends manually.
- Before closing the cap, squeeze the aluminum bag to remove as much air as possible from the upper part of the aluminum bag.
- If the cap is not firmly closed, the eluent may degrade, and the operator may not be able to visually recognize the remaining volume of eluent because the aluminum bag will not deflate as the eluent decreases.

### 3.2.3 Hemolysis & Wash Solution Tube

Open the bottle cap of the Hemolysis & Wash solution bottle, insert the Hemolysis & Wash solution tube (with the anchor and the bottle cap) coming from the left side of the instrument, and then close the bottle cap. Check that the anchor reaches the bottom of the bottle.

(For more details, refer to “1.1.1 Installation (p.14)”.)

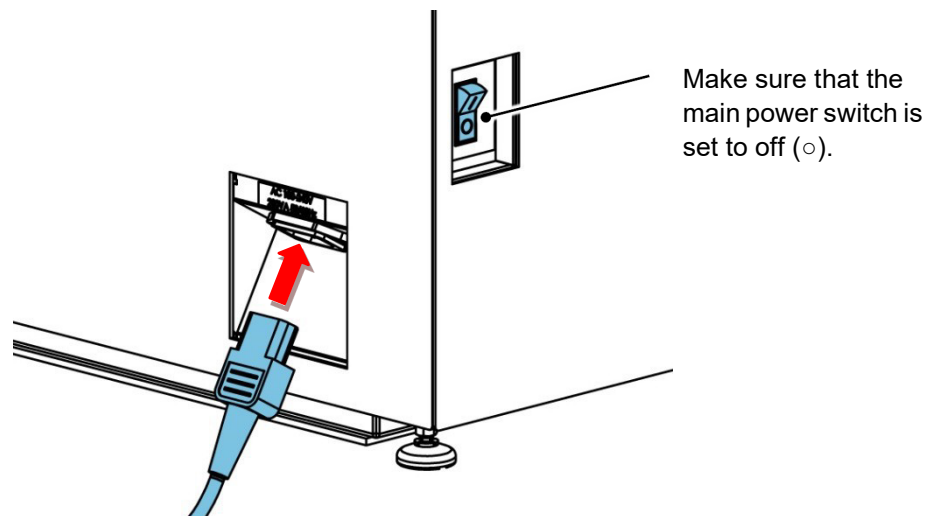


### 3.2.4 Power Supply

Connect the power cable provided securely to the AC inlet of the main unit.

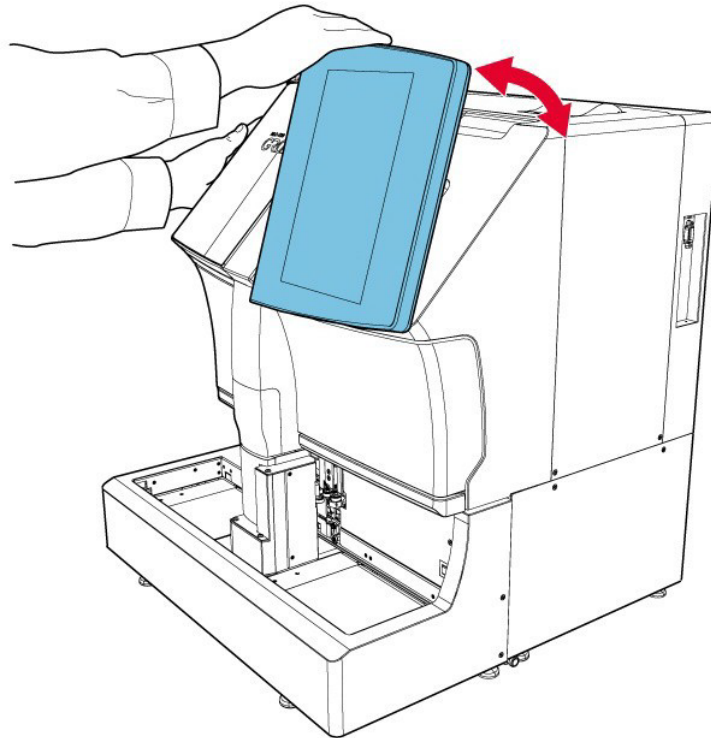
Make sure that the main power switch is set to off (○), and then connect the power plug into the socket.

A power source requires a capacity of over 10 A and a 2-pin socket with a grounding terminal.



### 3.3 Adjusting the Angle of the Operation Panel

The angle of the operation panel can be adjusted to an easily viewable angle, as necessary. To adjust the angle, hold the instrument with your left hand, grab the upper part of the operation panel with your right hand, and then move the operation panel slowly.



## 3.4 Column

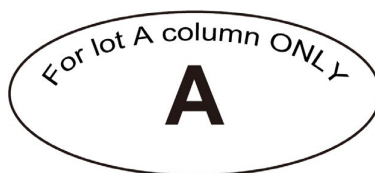
The dedicated column for HLC-723GR01 is the **TSKgel GR01 HbA1c** Column. To replace the column, refer to "6.4.4 Replacing the column (p.146)".

**Note**

- The column oven is controlled at 25°C so that potential fluctuating room temperature does not affect analysis results. The temperature of the column oven is always controlled, unless the main power switch is turned off, making it possible to start analysis without waiting for the column to reach the right temperature.

### 3.4.1 Precautions for Use of the Column

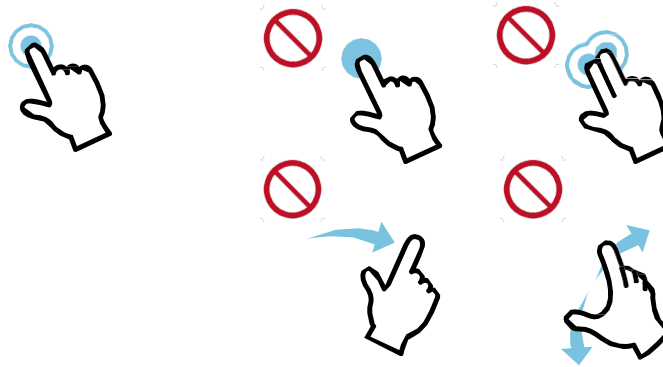
- Read the Instruction For Use (IFU) of the column carefully before use.
- If the column is stored in a refrigerator, be sure to let it return to room temperature before use.
- Always use the TSKgel GR01 HbA1c Column in combination with the GR01 HbA1c Elution Buffers No. 1 and No. 2 of the identical lot number. The column lot number is indicated by a single uppercase alphabetical character (A, B, etc.) on the label of the column packaging box. The Elution Buffer label displays an alphabetic character corresponding to the column lot number as shown below for Elution Buffers No. 1 and 2.



# 4 Operation Screen

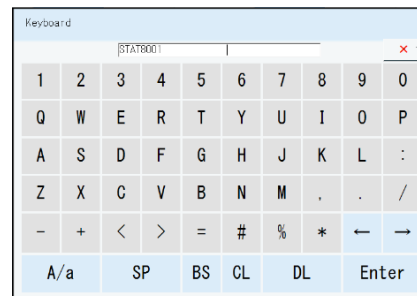
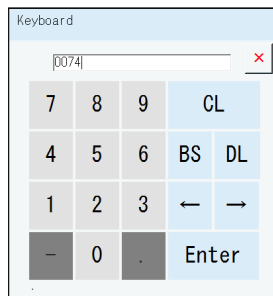
## 4.1 Operating the screen

To operate the screen of the operation panel, touch (single-tap) the screen with your finger. Double-tapping, swiping, long-tapping, multi-tapping, and pinching are not supported. The screen can be operated with vinyl-gloved hands; however, it may not operate properly depending on the material or thickness of the gloves.



## 4.2 Entering characters and numbers

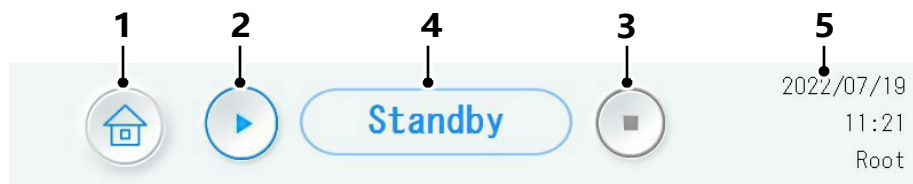
To enter characters and numbers, use a screen keyboard. The screen keyboard appears automatically when necessary. There are 2 types of screen keyboards:






Button	Description	Button	Description
CL	Clears the content of the field.	BS	Deletes one character before the cursor.
DL	Deletes one character after the cursor.	←/→	Moves the cursor back and forth.
A/a	Switches between uppercase and lower case.	SP	Inserts a space (blank).
Enter	Saves the entered text.	✕	Closes the screen keyboard. The entered text is not saved.

### 4.3 Common display (Top part of the screen)

The buttons and the analyzer status are displayed at the top part of the screen. The common display is not displayed depending on the screen.



No.	Button/Display	Description
1	Home button 	Tap to move to the main screen.
2	Analysis start button 	Tap to start an analysis from the current screen, without moving to the main screen.
3	Analysis stop button 	Tap to stop the analysis immediately, or to stop warming up and wash. When the analysis is stopped, the analysis results of the sample for which sampling or suction is in progress cannot be obtained.
4	Analyzer status	Shows the analyzer status. For details of the analyzer status, refer to “4.3.1 Analyzer status (p.38)”.
5	Date and time/logon user	Shows date at the top row, time at the middle row, and logon username at the bottom row. When no user is logged on, “No User” is displayed.

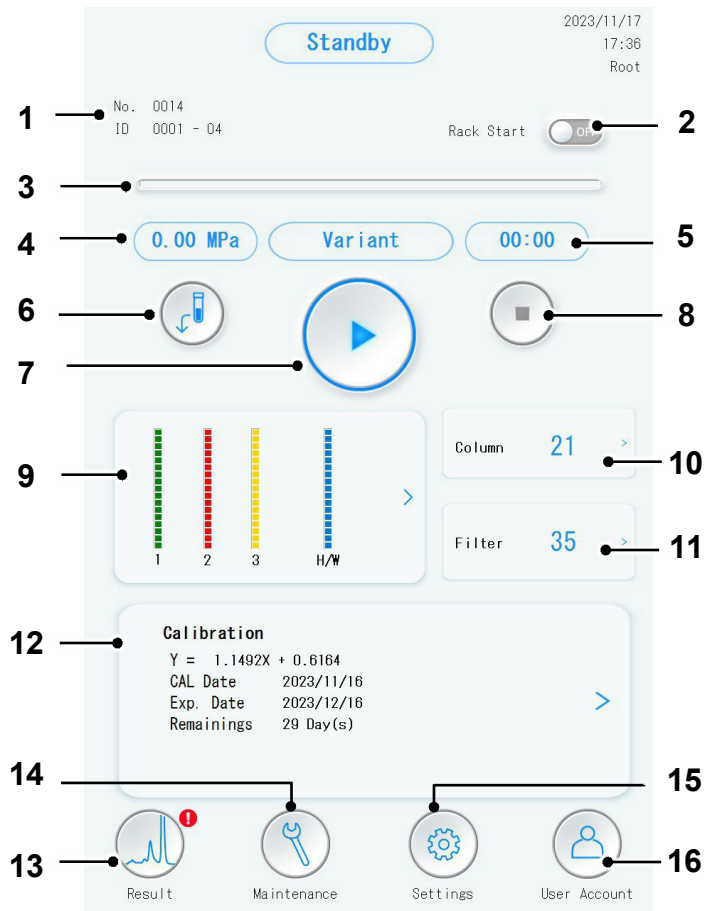
#### 4.3.1 Analyzer status

The analyzer status is displayed. Some operations such as checking the analysis results and changing settings are not available when the analyzer status is other than “Standby”.











Status display	Description
Warming up	Appears when the instrument is turned on. Initialization (warming up) is performed.
Standby	Appears when the instrument is ready for any operations including analysis.
Analysis	Appears when analysis is in progress or when the instrument is preparing for analysis.
Wash	Appears during wash operation after analysis is completed.
Priming	Appears during priming operation.
Air Removal	Appears during air removal operation.
Line Wash	Appears during line wash.

## 4.4 Main screen

The main screen is the initial screen that appears first after the instrument is turned on and a user is logged on.




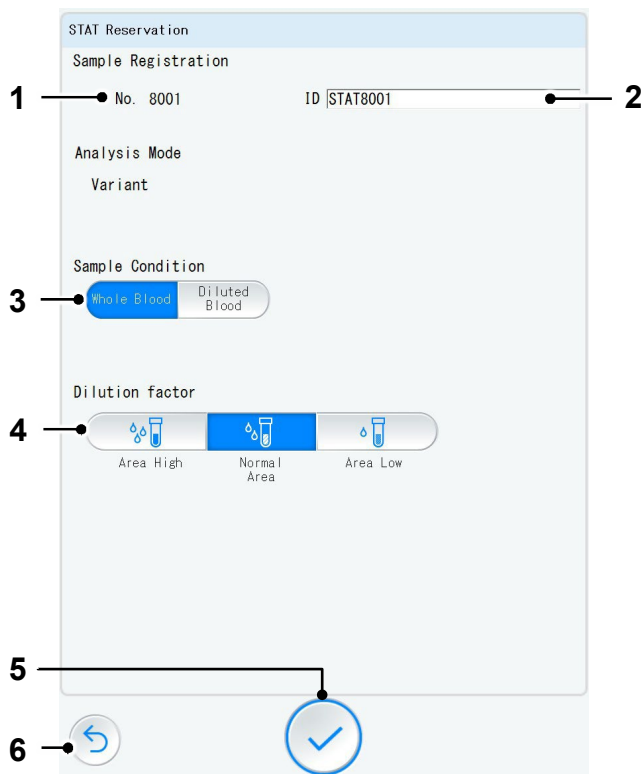
No.	Button/Display	Description
1	Sample information	Shows the information of the sample for which analysis is in progress or for the last completed sample. "No." indicates the analysis No. (sample No.), and "ID" indicates the sample tube barcode information or the sample rack and sample position information.
2	Rack Start switch	Select whether to enable/disable automatic rack start. With the [Rack Start] switch set to [ON], when a sample rack is loaded at the front right of the sample loader, the sample rack is detected and analysis is started automatically. Be sure to turn the setting [OFF] when performing maintenance operations (manual operations such as replacing various consumables, priming, etc.). (This button is not displayed when the GR-290SL is connected or when the [Rack Rotation] switch is set to [ON].)
3	Progress bar	Shows the progress of operation or analysis. The progress bar is reset each time an analysis is completed.



No.	Button/Display	Description
4	Pressure	Shows the current system pressure.
5	Remaining time	Shows the remaining time until an operation such as warming up or current analysis is completed.
6	STAT reserve button 	Tap to move to the STAT reservation screen. Refer to "4.5 STAT reservation screen (p.41)".
7	Analysis start button 	Tap to start an analysis.
8	Analysis stop button 	Tap to stop the analysis immediately, or to stop warming up and wash. When the analysis is stopped, the analysis results of the sample for which sampling or suction is in progress cannot be obtained.
9	Remaining reagent volume information/ Reagent replace button	Shows the remaining volumes of elution buffers and Hemolysis & Wash solution. When the button is tapped, the reagent replacement screen appears. Refer to "4.8.2 Reagent replacement screen (p.64)".
10	Column count/ Column replace button	Shows the usage count of the column that is currently in use. When the button is tapped, the column replacement screen appears. Refer to "4.8.3 Column replacement screen (p.66)". When the column count exceeds the specified count, the  mark appears.
11	Filter element count/ Filter element replace button	Shows the usage count of the filter element that is currently in use. When the button is tapped, the filter element replacement screen appears. Refer to "4.8.4 Filter element replacement screen (p.67)". When the filter element count exceeds the specified count, the  mark appears.
12	Calibration information/ Calibration reserve button	Shows the current calibration information. When the button is tapped, the calibration reservation screen appears. Refer to "4.6 Calibration reservation screen (p.42)".
13	Result button 	Tap to move to the result screen. Refer to "4.7 Result screen (p.43)". When a flag is attached to the analysis result, or when the QC data is out of the control range, the  mark appears.
14	Maintenance button 	Tap to move to the maintenance screen. Refer to "4.8 Maintenance screen (p.63)".
15	Settings button 	Tap to move to the settings screen. Refer to "4.9 Settings screen (p.81)".
16	User Account button 	Tap to move to the user account screen. Refer to "4.10 User switching screen (p.98)".

## 4.5 STAT reservation screen

To reserve STAT analysis, set the STAT conditions.

Tap the STAT reserve button  on the main screen, and the STAT reservation screen appears. For additional “Sample Condition” information refer to the Appendix section 11.4.



No.	Button/Display	Description
1	No.	Shows the sample No. for STAT analysis. A number in the 8000s is assigned to a STAT sample.
2	ID	Shows the sample ID. The ID is automatically entered, but it can also be entered manually using the keyboard or handheld barcode scanner, up to 20 characters.
3	Sample Condition buttons	Select the desired sample condition from [Whole Blood] or [Diluted Blood]. Diluted Blood refers to manually prepared hemolysate.
4	Dilution factor buttons	These buttons can be selected only when the [Whole Blood] button is selected for [Sample Condition]. Select the desired dilution factor from [Area High], [Normal Area], or [Area Low]. When sample condition is “Diluted Blood”, the analyzer does not perform any additional sample dilution.
5	Confirm button 	Tap to reserve STAT analysis with the specified conditions. When the analyzer status is “Standby”, STAT analysis starts immediately.
6	Return button 	Tap to return to the main screen without reserving STAT analysis.

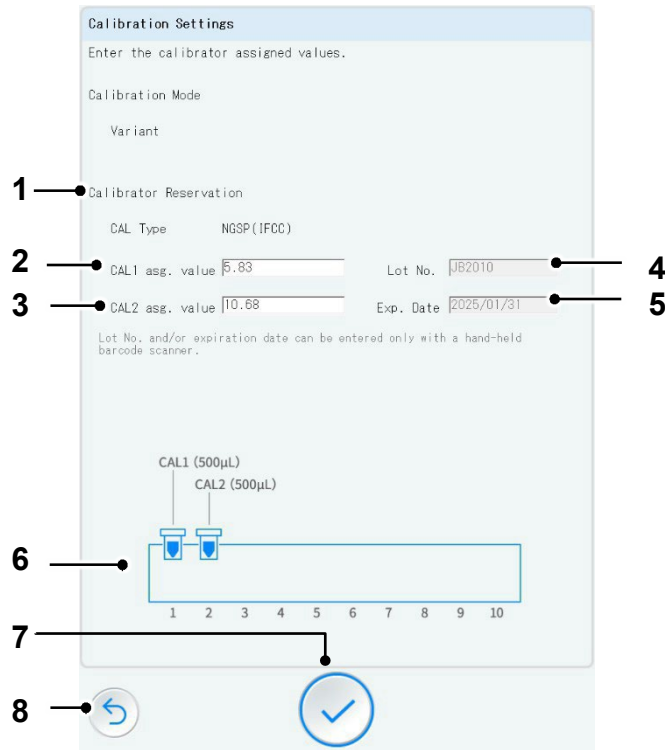
### Reference

- For STAT analysis, refer to “5.8 STAT analysis (p.123)”.

## 4.6 Calibration reservation screen

To reserve calibration, set the calibration conditions.

Tap the calibration reserve button on the main screen, and the calibration reservation screen appears.



No.	Button/Display/Entry	Description
1	Calibrator reservation field	Shows the assigned values of CAL1 and CAL2, lot No. and expiration date. The assigned values of CAL1 and CAL2 can be entered manually. The lot No. and expiration date can be entered only through the handheld barcode scanner.
2	CAL1 asg. value	Enter the assigned value of CAL1.
3	CAL2 asg. value	Enter the assigned value of CAL2.
4	Lot No.	Shows the lot No.
5	Exp. Date	Shows the expiration date.
6	Calibrator diagram	Shows which positions of the sample rack the calibrators should be set at. Set calibrators according to the order and volume indicated in the diagram.
7	Confirm button	Tap to reserve calibration.
8	Return button	Tap to return to the main screen without reserving calibration.

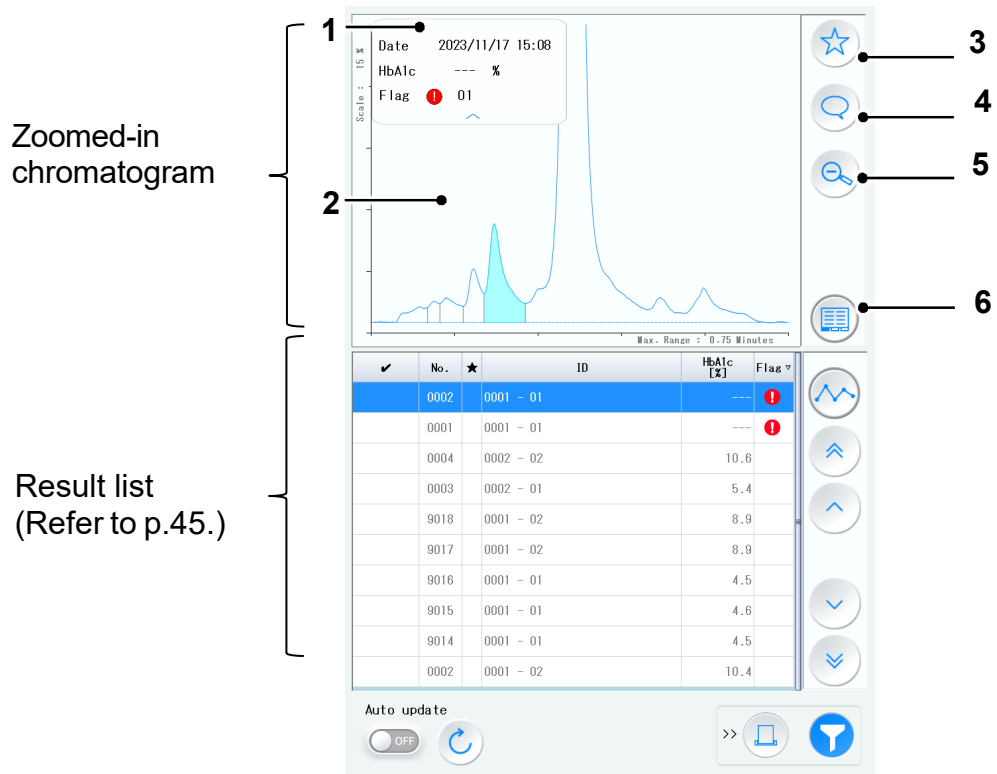
### Reference

- For details of calibration, refer to “5.4 Calibration (p.104)”.

## 4.7 Result screen

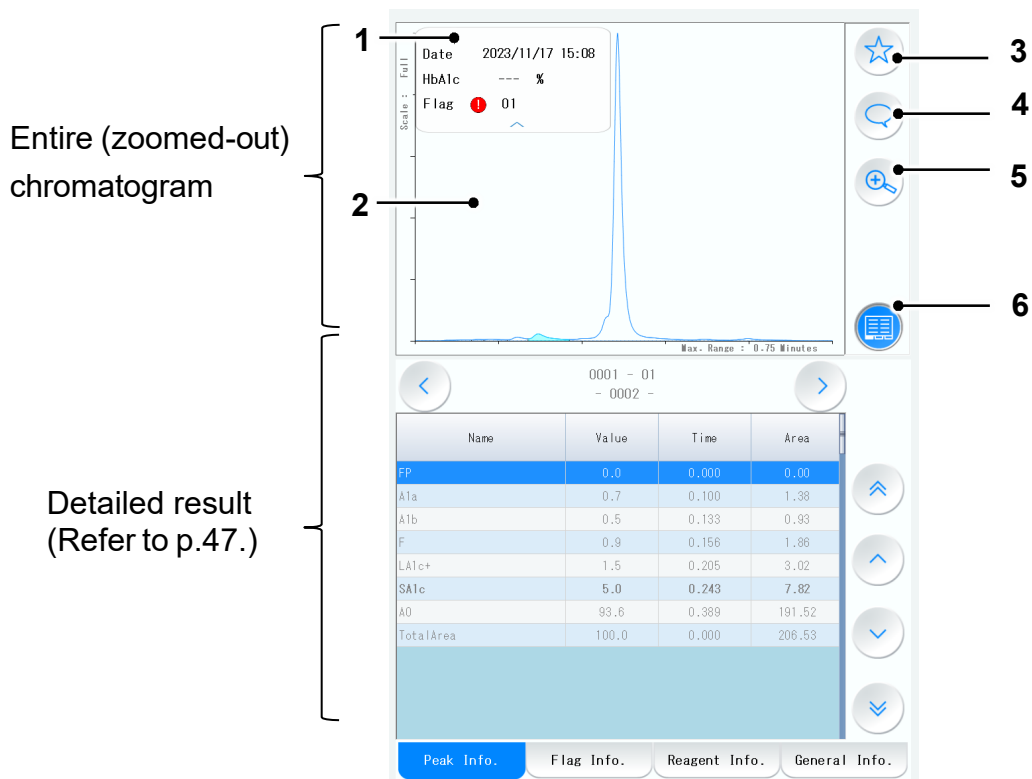
### 4.7.1 Result screen (outline)








Analysis results can be viewed and checked on the result screen.



5 (🔍/🔍): Zooms in/zooms out the chromatogram.

6 (📄): Switches the result screen between the list display and the detailed display.



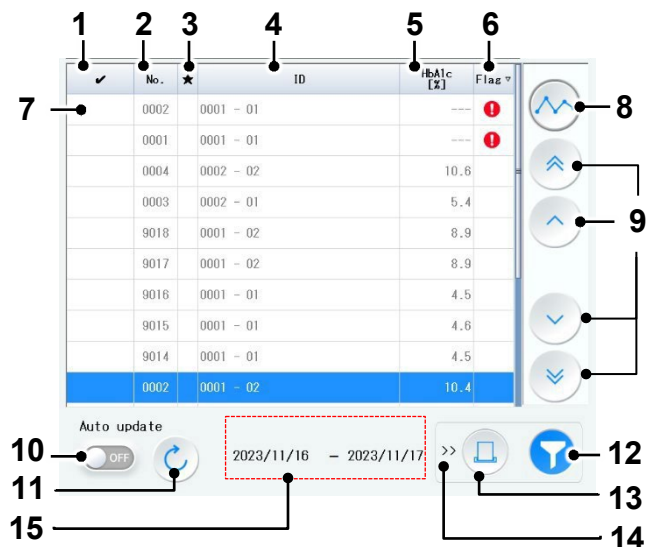
No.	Button/Display	Description
1	Results	Shows HbA1c (%) [HbA1c (mmol/mol)], and the attached flag. By tapping $\wedge$ or $\vee$ , the display can be hidden/shown.
2	Chromatogram	Shows the result in chromatogram. A peak in light blue is the SA1c peak.
3	Favorite button 	Tap to register the result as a favorite. If the result has already been registered, the  button is highlighted. Up to 500 results can be registered as favorites.
4	Comment button 	Tap to open the comment dialog. If a comment is added to the result, the  button is highlighted. For entering a comment, refer to "4.7.4 Comment dialog (p.50)".
5	Zoom-in/Zoom-out button 	Tap to zoom in/zoom out the chromatogram.
6	Switch result display button 	Tap to switch the result screen between the list display and the detailed display. When the detailed result is displayed, the  button is highlighted.




**Note**









Only the HbA1c values measured by this device should be reported to the health care provider. The test report displays %HbF and other detected hemoglobin variants; however, the performance characteristics of the hemoglobin variants detected by this device have not been reviewed or cleared by the FDA and therefore should not be reported to the healthcare provider. The hemoglobin variants detected by this device are only to ensure the validity of the HbA1c results because increased levels of hemoglobin variants may interfere with the percent HbA1c measurement. If a hemoglobinopathy is suspected, an FDA cleared test system for their measurement should be used.

### 4.7.2 Result screen (list display)

The result screen (list display) shows the analysis results in the list at the bottom of the screen.



No.	Button/Display	Description
1	Check mark	Results can be selected by putting a check mark on the leftmost column when printing the results or saving the results in PDF.
2	No.	Shows the analysis No.
3	Favorite	Shows whether the result has been registered as a favorite. "★" appears on the favorite result.
4	ID	Shows the sample ID.
5	HbA1c	Shows HbA1c (%).
6	Flag	Shows the attached flag. If a flag is attached, the  mark appears. By tapping the title part, results can be sorted by flag.
7	Result list	Up to 10 results can be listed. The information, including chromatogram, of the result highlighted in blue is displayed at the upper part of the result screen. When another result is selected, the result is highlighted in blue, and the information of the highlighted result is displayed at the upper part of the result screen.
8	QC button 	Tap to move to the QC screen. Refer to "4.7.5 QC screen (with [Trend] selected) (p.51)" and "4.7.6 QC screen (with [Settings] selected) (p.55)". When the QC data is out of the control range, the  mark appears.

No.	Button/Display	Description
9	Result selection buttons	<p>Tap to move up or down the selection (highlight).</p> <p>: Moves the highlight to 10 lines up. If the listed results are less than 10, the highlight is moved to the top result.</p> <p>: Moves the highlight one line up.</p> <p>: Moves the highlight one line down.</p> <p>: Moves the highlight to 10 lines down. If the listed results are less than 10, the highlight is moved to the bottom result.</p>
10	Auto update switch	<p>Select whether to enable/disable automatic update of analysis results.</p> <p>ON: Automatic update is enabled.</p> <p>OFF: Automatic update is disabled.</p>
11	Update button 	Tap to update the results.
12	Search button 	<p>Tap to move to the search screen. When the results are displayed by search conditions, the  button is highlighted.</p> <p>Refer to “4.7.7 Search screen (p.60)”.</p>
13	Output button 	<p>Tap to move to the output screen.</p> <p>Refer to “4.7.8 Result output screen (p.62)”.</p>
14	Pop-up button	Tap to show/hide the output button.
15	Specified time period	Shows the time period specified as a search condition.

**Note**

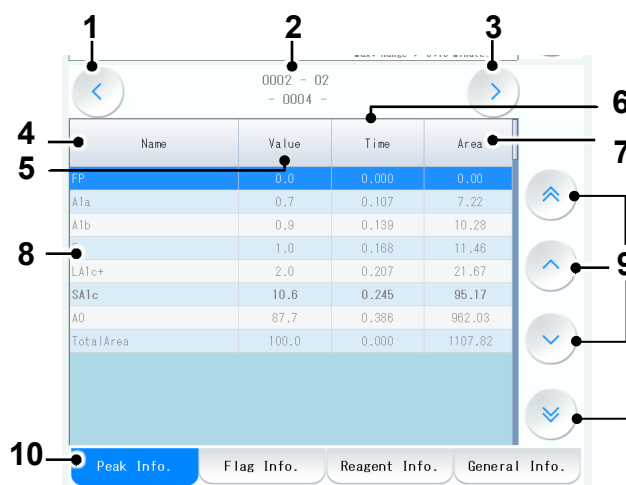
- When checking the past analysis results, be sure to set the [Auto update] switch to [OFF].
- When performing the analysis of many samples, do not leave the [Auto update] switch set to [OFF]. When the [Auto update] switch is returned to [ON], it takes a long time to load the results, possibly causing slower operation.
- Up to 150,000 results can be stored. If the number of stored results exceeds 150,000, results will be overwritten, replacing the oldest result first.
- Refer to section 4.7.8 for backup procedures to avoid any data loss.

### 4.7.3 Result screen (detailed display)

The result screen (detailed display) shows the detailed information (peak information, flag information, reagent information, and general information) at the bottom part of the screen depending on the selected tab.

#### Peak Information

When the [Peak Info.] tab is selected, the peak information of each separated hemoglobin fraction is displayed.

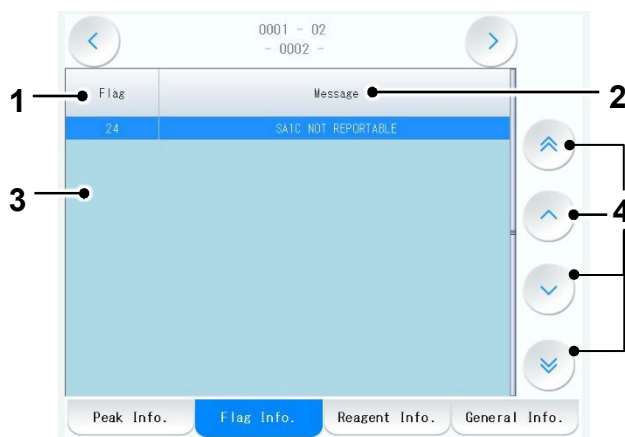


No.	Button/Display	Description
1	Next result button	Tap to move to the next result.
2	Sample Information	Shows the sample ID on the upper row, and the analysis No. on the lower row.
3	Previous result button	Tap to move to the previous result.
4	Name	Shows the peak name.
5	Value	Shows the peak area %.
6	Time	Shows the retention time.
7	Area	Shows the area.
8	Peak information area	Shows the peak information.
9	Peak selection buttons	<p>These buttons are available only when all the peak information is not displayed within 1 page of the screen.</p> <p>: Moves the highlight to 10 lines up. If the listed peaks are less than 10, the highlight is moved to the top peak.</p> <p>: Moves the highlight one line up.</p> <p>: Moves the highlight one line down.</p> <p>: Moves the highlight to 10 lines down. If the listed peaks are less than 10, the highlight is moved to the bottom peak.</p>

No.	Button/Display	Description
10	Information selection tabs	Select a tab from [Peak Info.], [Flag Info.], [Reagent Info.], and [General Info.] to show the desired information of the result.

### Flag information

When the [Flag Info.] tab is selected, the flag information of the analysis result is displayed.



No.	Button/Display	Description
1	Flag	Shows the flag No.
2	Message	Shows the flag message.
3	Flag information area	Shows the flag No. and flag message when a flag is attached.
4	Flag selection buttons	<p>These buttons are enabled only when all the flag information is not displayed within 1 page of the screen.</p> <p>⏶: Moves the highlight to 10 lines up. If the listed flags are less than 10, the highlight is moved to the top flag.</p> <p>⏴: Moves the highlight one line up.</p> <p>⏵: Moves the highlight one line down.</p> <p>⏷: Moves the highlight to 10 lines down. If the listed flags are less than 10, the highlight is moved to the bottom flag.</p>

## Reagent information

When the [Reagent Info.] tab is selected, the reagent information of the analysis result is displayed.

Reagents		
	Lot No.	Replacement Date
Elution Buff. No.1	XR-101X	2023/11/16
Elution Buff. No.2	XR-201X	2023/11/16
Elution Buff. No.3	XR-301X	2023/11/16
H/W	HW-04K	2023/11/15

	Serial No.	Count
Column	XC0001X	7
Filter element	-	21

Calibration	
Lot No.	ZB2010
CAL Imple. Date	2023/11/16

Navigation tabs: Peak Info., Flag Info., **Reagent Info.**, General Info.

No.	Display	Description
1	Reagent information	Shows the information of the Buffers and Hemolysis & Wash solution that were used for analysis: reagent type, lot No., and replacement date from the left.
2	Column/Filter element information	Shows the information of the column and filter element that were used for analysis: consumables name, serial No., usage count from the left.
3	Calibration information	Shows the information of the calibration at the time of analysis: lot No., calibration date from the top.

## General information

When the [General Info.] tab is selected, the general information of the analysis result is displayed.


Date	2023/11/16 11:42
No.	0004
ID	0002 - 02
Rack/Position	0002 - 02
Analysis Mode	Variant Mode
User ID	F.ENGINEER
CAL(N)	$Y = 1.1492X + 0.6164$
Pressure	8.480
Comment	

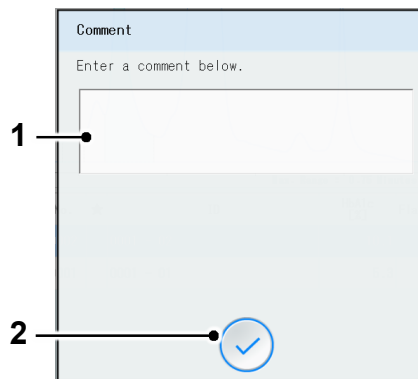
Navigation tabs: Peak Info., Flag Info., Reagent Info., **General Info.**


Display	Description
Date	Shows the analysis date and time.
No.	Shows the sample No.
ID	Shows the sample ID.
Rack/Position	Shows the sample rack No. and the sample position No.

Display	Description
Analysis Mode	Shows the analysis mode at the time of analysis.
User ID	Shows the name of the user that is logged on at the start of analysis.
CAL(N)	Shows the calibration factor used for the calculation of HbA1c.
Pressure	Shows the pressure value during the analysis.
Comment	Shows the comment added on the result screen.

#### 4.7.4 Comment dialog

When the comment button  is tapped, the comment dialog appears. Enter the desired comment for the selected result (up to 20 characters).




No.	Button/Display	Description
1	Comment field	Enter a comment using the screen keyboard.
2	Comment register button 	Tap to register the entered comment.

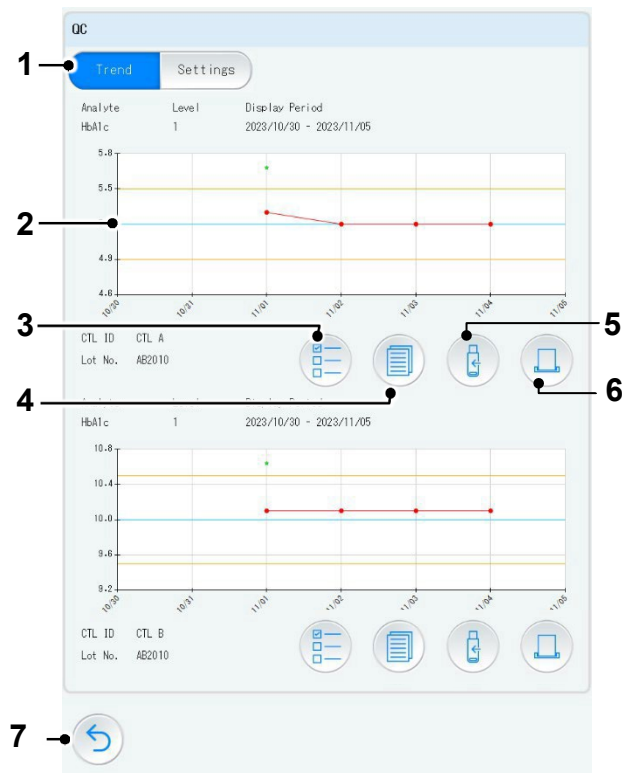
**Note**



- To add a comment to the selected result, access the analysis settings screen.
- Refer to “4.9.2 Analysis settings screen (p.83)”.




### 4.7.5 QC screen (with [Trend] selected)

When the QC button  is selected on the result screen, the QC (trend) screen appears. Check the trend graph(s) of the control result.

Up to 2 trend graphs with different conditions can be displayed at the upper part and lower part of a single screen.




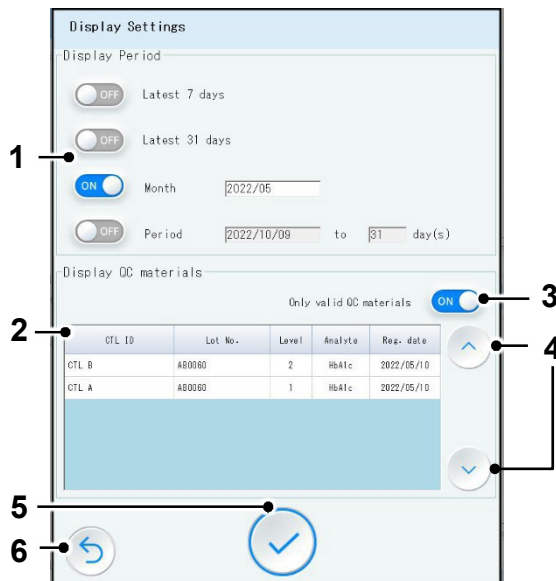
No.	Button/Display	Description
1	Display selection buttons	Tap to switch the display between the QC (trend) screen and the QC (settings) screen. By tapping [Trend], trend graphs are displayed, and by tapping [Settings], the QC materials can be registered or edited.
2	Trend graph	Shows the trend graph of the selected QC material within the selected period. The vertical axis is HbA1c (%), the horizontal axis is the date (up to 31 days can be displayed). The upper left part of the trend graph shows the analyte name, control level, display period, and the bottom part of the trend graph shows the control ID (CTL ID) and lot No.
3	Display period/QC material selection button 	Tap to open the display period/QC material selection dialog. Refer to " <a href="#">Display period/QC material selection dialog (p.52)</a> ".
4	QC trend result list button 	Shows the QC trend result list dialog within the selected display period. Refer to " <a href="#">QC trend result list dialog (p.53)</a> ".



No.	Button/Display	Description
5	USB output button 	Tap to output as PDF the QC data to a USB stick. This button is available only when the USB stick is connected.
6	Print button 	Tap to print the QC data. This button is available only when the external printer (optional) is connected.
7	Return button 	Tap to return to the result screen.



**Note** • Trend graphs with different QC materials or different display periods can be displayed on the upper and lower of the screen.

### Display period/QC material selection dialog

By tapping the display period/QC material selection button  on the QC screen, the desired display period and QC materials can be selected.

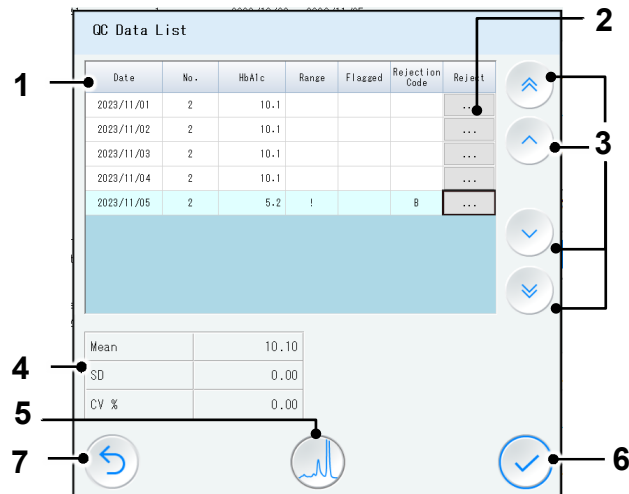






No.	Button/Display	Description
1	Display period selection switches	Select the display period. Set either one of [Latest 7 days], [Latest 31 days], [Month], or [Period] to [ON]. For [Month], specify the year and month, for [Period], specify the year and month and period. Up to 31 days can be specified.
2	QC material to be displayed on the trend graph	Shows selectable QC materials. The CTL ID, lot No., level, analyte, and registration date of each QC material are displayed.
3	Only valid QC materials switch	When the [Only valid QC materials] switch is set to [ON], only register valid QC materials are listed.
4	QC material selection buttons	 : Moves the highlight one line up.  : Moves the highlight one line down.




No.	Button/Display	Description
5	Set button 	Tap to set the display period and QC material for trend graph with the entered and selected contents.
6	Return button 	Tap to discard the entered and selected contents and to return to QC trend screen.

### QC trend result list dialog

The QC trend result list dialog shows the list of the results (QC data) used to display the QC trends.

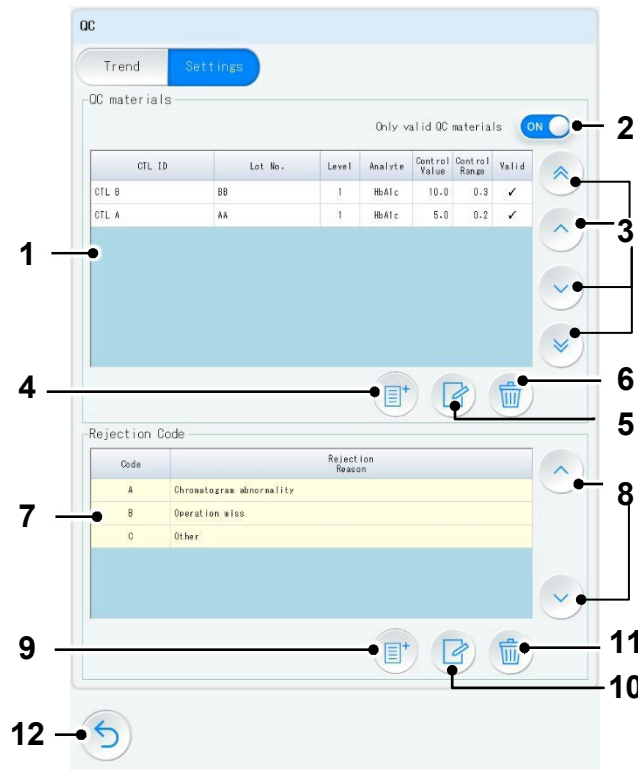









No.	Button/Display	Description
1	QC data list	Shows, in the list, QC materials specified to be displayed for the trend graph, within the selected display period. Shows the analysis date (Date) and sample No. (No.), and HbA1c value. When a value deviates from the control value or is out of the control range, the "!" mark appears. When a flag is attached to the result the "!" mark appears. When the reject button is selected and a rejection reason is selected, the corresponding rejection code is displayed in the [Rejection Code] cell.
2	Reject button	Tap to open the rejection reason dialog. By tapping the reject button, a specific result is excluded from the QC trend graph and calculation of QC data.
3	QC result selection buttons	 : Moves the highlight to 10 lines up. If the listed QC results are less than 10, the highlight is moved to the top QC result.  : Moves the highlight one line up.  : Moves the highlight one line down.  : Moves the highlight to 10 lines down. If the listed QC results are less than 10, the highlight is moved to the bottom QC result.







No.	Button/Display	Description
4	QC data (statistical values)	Shows the mean value (Mean), standard deviation (SD), and coefficient of variation (CV%) as QC data (statistical values). Listed items are QC materials specified to be displayed on the trend graph and the results within the selected display period. Rejected results are excluded.
5	Chromatogram display button 	Tap to display the chromatogram of the selected QC result.
6	Apply button 	Tap this button to apply the result to the QC data and trend graph. When the reject reason is specified on a result, the result is not reflected in the QC data and trend graph.
7	Return button 	Tap to return to the QC trend screen. If the screen is returned to the QC trend screen before changes are applied, the changed contents will be discarded.

#### 4.7.6 QC screen (with [Settings] selected)

When the display selection button [Settings] is selected on the QC screen, the QC (settings) screen appears. On this screen, a QC material can be newly registered, modified, and deleted, and a rejection reason can be newly registered, edited, or deleted.





No.	Button/Display	Description
1	QC material list	Shows registered QC materials. The selected QC material is highlighted in blue.
2	Only valid QC materials switch	When the [Only valid QC materials] switch is set to [ON], only registered valid QC materials are listed.
3	QC material selection buttons	<ul style="list-style-type: none"> <li>: Moves the highlight to 10 lines up. If the listed QC materials are less than 10, the highlight is moved to the top QC material.</li> <li>: Moves the highlight one line up.</li> <li>: Moves the highlight one line down.</li> <li>: Moves the highlight to 10 lines down. If the listed QC materials are less than 10, the highlight is moved to the bottom QC material.</li> </ul>
4	QC material register button 	Tap to open the QC material registration dialog for the selected QC material.
5	QC material edit button 	Tap to open the QC material editing dialog for the selected QC material.
6	QC material delete button 	Tap to delete the selected QC material.

No.	Button/Display	Description
7	Rejection reason list	Shows the combinations of rejection codes and rejection reasons. Up to 5 reasons can be registered. The selected rejection reason is highlighted in blue.
8	Rejection reason selection buttons	 : Moves the highlight one line up.  : Moves the highlight one line down.
9	Rejection reason register button 	Tap to open the rejection reason registration dialog.
10	Rejection reason edit button 	Tap to open the rejection reason editing dialog for the selected rejection reason.
11	Rejection reason delete button 	Tap to delete the selected rejection reason.
12	Return button 	Tap to return to the result screen.

## QC material registration dialog

New QC material can be registered by setting the CTL ID, lot No., level, analyte, control value, control range, and valid switch setting of the QC material.

Once the QC material is enabled (the [Valid] switch is set to [ON]), when a sample barcode with the registered CTL ID is read, the sample can be recognized as the QC sample. To display the trend of the obtained result, set the [Valid] switch to [ON]. Even when the QC material used in the past is disabled (the [Valid] switch is set to [OFF]), the results obtained so far are maintained.

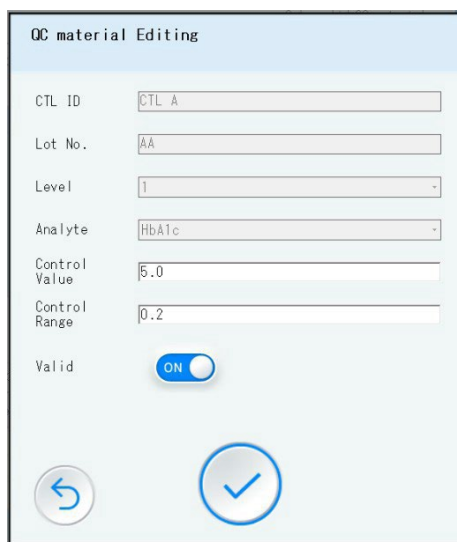
Button/Display	Description
CTL ID	Enter the control ID (CTL ID).
Lot No.	Enter the control lot No.
Level	Select the control level from 1, 2, or 3.
Analyte	Only HbA1c can be selected.
Control Value	Enter the assigned value to control.
Control Range	Enter the control range (acceptable range of the control value).
Valid switch	Select whether to enable/disable the QC material. ON: The QC material is enabled. OFF: The QC material is disabled.
Register button 	Tap to register the QC material with the entered and selected contents.
Return button 	Tap to discard the entered and selected contents and to return to QC trend screen.



### Note

- Up to 6 QC materials can be enabled (the [Valid] switch is set to [ON]). To register more QC materials, it is necessary to disable the already registered QC materials.
- When a QC material is deleted, the QC results obtained from the QC material will be deleted.
- By reading the barcode sheet provided with the Hemoglobin A1c Control Set (manufactured by Tosoh) using the optional handheld barcode scanner, the assigned values can be entered automatically.
- Refer to “5.5.2 Registering QC material (p.110)”.

## QC material editing dialog



The following QC material settings can be edited, control value (assigned value to control), control range and valid switch setting; the CTL ID, lot No., level, and analyte cannot be changed.



Button/Display	Description
CTL ID	Shows the CTL ID of the selected QC material.
Lot No.	Shows the lot No. of the selected QC material.
Level	Shows the level of the selected QC material.
Analyte	Shows the analyte of the selected QC material.
Control Value	Enter to edit the assigned value to control.
Control Range	Enter to edit the control range.
Valid switch	Select whether to enable/disable the QC material. ON: The QC material is enabled. OFF: The QC material is disabled.
Edit button 	Tap to apply changes to the QC material with the entered and selected contents.
Return button 	Tap to discard the entered and selected contents and to return to QC trend screen.



### Rejection reason registration dialog

A combination of the rejection code and rejection reason, which is to be selected when excluding the result from the QC trend graph, can be newly registered.

Button/Display	Description
Code	Select a rejection code from D to H.
Rejection Reason	Enter a comment for rejection reason (up to 32 characters).
Register button 	Tap to register the rejection reason with the entered and selected contents.
Return button 	Tap to discard the entered and selected contents and to return to QC trend screen.

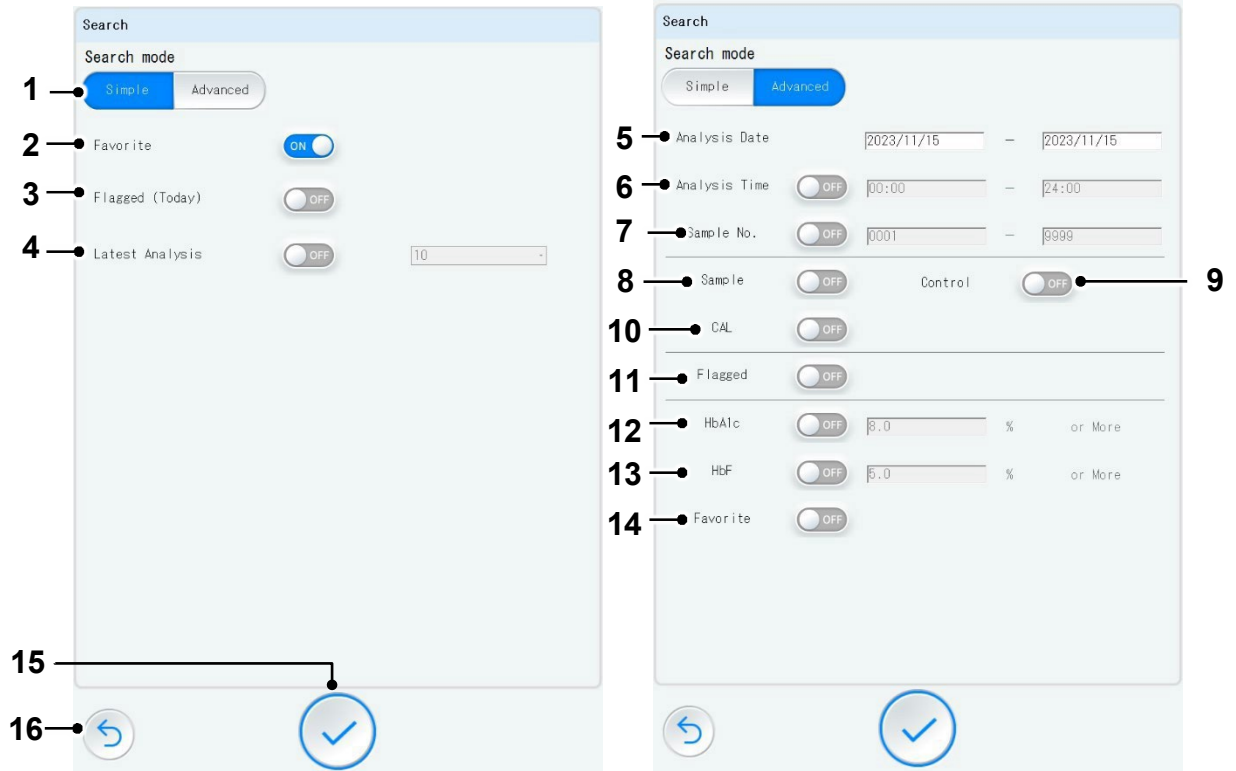
### Rejection reason editing dialog

The registered rejection reason can be edited.



Button/Display	Description
Code	Shows the rejection reason code. It cannot be edited.
Rejection Reason	Enter to edit the comment for rejection reason (up to 32 characters).
Edit button 	Tap to apply changes to the comment for rejection reason with the entered and selected contents.
Return button 	Tap to discard the entered and selected contents and to return to QC trend screen.

### 4.7.7 Search screen

Analysis results can be searched for using the Simple search or Advanced search mode. For the detailed procedure, refer to “5.9.4 Search procedure (p.127)”.



No.	Button/Display	Description
1	Search Mode buttons	Select the desired search mode from [Simple] or [Advanced].
2	Favorite switch	Select whether to search for only favorite results. ON: Search is performed from favorite results. OFF: Search is performed from all results.
3	Flagged (Today) switch	Select whether to search for only flagged results. ON: Search is performed from the flagged results on the current day. OFF: Search is performed from all results.
4	Latest Analysis switch	Select whether to search for the latest results with the specified number. ON: The number of search results can be specified. OFF: The number of search results cannot be specified. When the [Latest Analysis] switch is set to [ON], the number of search results can be specified from [10], [25], [50], [100], [250], and [500].
5	Analysis Date	Specify the desired year, month, and day. If not set, results for the current day are selected for search.

No.	Button/Display	Description
6	Analysis Time switch	Select whether to search for results by time. ON: The time can be specified. OFF: The time cannot be specified. When the [Analysis Time] switch is set to [ON], specify the time range (hour and minute).
7	Sample No. switch	Select whether to search for results by sample No. ON: The sample No. can be specified. OFF: The sample No. cannot be specified When the [Sample No.] switch is set to [ON], specify the sample No. range.
8	Sample switch	Select whether to search for sample results. ON: Search is performed from sample results. OFF: Search is not performed from sample results. (when either or both of the [Control] switch and/or [CAL] switch are/is set to [ON].)
9	Control switch	Select whether to search for control results. ON: Search is performed from control results. OFF: Search is not performed from control results. (when either or both of the [Sample] switch and/or [CAL] switch are/is set to [ON].)
10	CAL switch	Select whether to search for calibrator results. ON: Search is performed from calibrator results. OFF: Search is not performed from calibrator results. (when either or both of the [Sample] switch and/or [Control] switch are/is set to [ON].)
11	Flagged switch	Select whether to search for flagged results. ON: Search is performed from flagged results. OFF: Search is performed from all results.
12	HbA1c switch	Select whether to search for results by HbA1c (%). ON: Search is performed from results with the HbA1c (%) value larger than the specified value. OFF: Search is performed from all results. When the [HbA1c] switch is set to [ON], enter the HbA1c (%) value manually.
13	HbF switch	Select whether to search for results by HbF peak information. ON: Search is performed from results with the HbF (%) value larger than the specified value. Please note that this does not reflect a validated HbF (%) result. OFF: Search is performed from all results. When the [HbF] switch is set to [ON], enter the HbF (%) value manually. Please note that this does not reflect a validated HbF (%) result.
14	Favorite switch	Select whether to search for only favorite results. ON: Search is performed from favorite results. OFF: Search is performed from all results.
15	Search button 	Tap to start search.
16	Return button 	Tap to return to the result screen without starting a search.

**Note**

- When all of the [Sample], [Control], [CAL] switches are set to [OFF], search is performed from results of all sample types.

### 4.7.8 Result output screen

The results can be output (printed, uploaded to the host computer, saved as PDF, saved as list data) by selecting the output target from [Range] or [Selected].



When the [Range] button is chosen:

The screenshot shows the 'Result Output' screen. At the top, there are two buttons: 'Range' (highlighted in blue) and 'Selected'. Below this, there are input fields for 'Meas. Date' (2023/11/15 - 2023/11/15), 'Meas. Time' (00:00 - 24:00), and 'Sample No.' (0001 - 9999). There are four toggle switches: 'Print' (OFF), 'Host Communication' (OFF), 'Save as PDF' (OFF), and 'List Data' (OFF). A dropdown menu next to the 'Print' switch shows the number '1'. At the bottom, there are two circular navigation buttons: a back arrow and a checkmark.

When the [Selected] button is chosen:

The screenshot shows the 'Result Output' screen. At the top, there are two buttons: 'Range' and 'Selected' (highlighted in blue). Below this, there are input fields for 'Meas. Date' (2023/11/15 - 2023/11/15), 'Meas. Time' (00:00 - 24:00), and 'Sample No.' (0001 - 9999). There are four toggle switches: 'Print' (OFF), 'Host Communication' (OFF), 'Save as PDF' (OFF), and 'List Data' (OFF). A dropdown menu next to the 'Print' switch shows the number '1'. At the bottom, there are two circular navigation buttons: a back arrow and a checkmark.

Button/Display	Description
Output target selection buttons	Select the desired output target from [Range] or [Selected]. When the [Selected] button is selected, the results selected on the result list screen (with ✓ marks) are output.
Analysis Date	Specify the date range of analysis (year, month, and day).
Analysis Time	Specify the time range of analysis.
Sample No.	Specify the sample No. range.
Print switch	Select whether to print the results using the specified printer. ON: Results are printed. OFF: Results are not printed. When the [Print] switch is set to [ON], also select the number of copies from [1] or [2].
Host Communication switch	Select whether to upload the results to the host computer. ON: Results are uploaded to the host computer. OFF: Results are not uploaded to the host computer.
Save as PDF switch	Select whether to save the results as PDF in the USB memory stick. ON: PDF is saved in the USB memory stick.

Button/Display	Description
	OFF: PDF is not saved in the USB memory stick.
Save as list data switch	Select whether to save the results as list data (.csv format) in the USB memory stick. ON: List data is saved in the USB memory stick. OFF: List data is not saved in the USB memory stick.
Output button 	Tap to output (print, send to the host computer, or save as PDF) the results as specified.
Return button 	Tap to return to the result screen without starting search.

**Note**




- When printing on the external printer, up to 4 results can be printed on a single sheet of paper.










## 4.8 Maintenance screen

### 4.8.1 Maintenance screen

The history of maintenance or various operations can be viewed from this screen.



No.	Button	Description
1	Reagent Replacement button 	Tap to move to the reagent replacement screen.
2	Column Replacement button 	Tap to move to the column replacement screen.
3	Filter Element Replacement button 	Tap to move to the filter element replacement screen.

No.	Button	Description
4	Suction Filter Replacement button 	Tap to move to the suction filter replacement screen.
5	Manual Operations button 	Tap to move to the manual operation screen.
6	Air Removal button 	Tap to move to the air removal screen.
7	Backup button 	Tap to move to the backup screen. * This button is enabled only for a user with Super User authority.
8	Version Information button 	Tap to move to the version screen.
9	Replacement History button 	Tap to move to the replacement history screen.
10	Maintenance History button 	Tap to move to the maintenance history screen.
11	Logon History button 	Tap to move to the logon history screen.
12	Error History button 	Tap to move to the error history screen.

#### 4.8.2 Reagent replacement screen

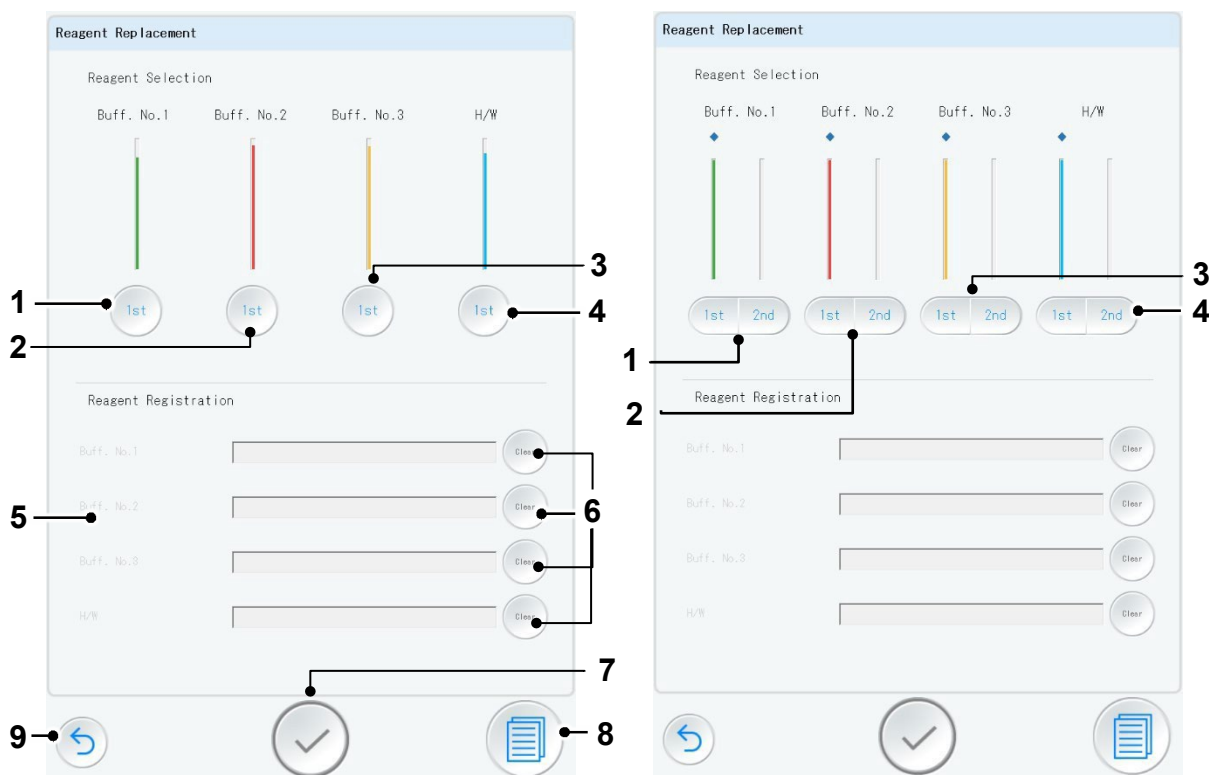
The elution buffers and Hemolysis & Wash solution to be replaced can be registered from this screen.




The reagent replacement screens are shown below:

Left: the screen displayed when the buffer switching unit is not connected

Right: the screen displayed when the buffer switching unit is connected.

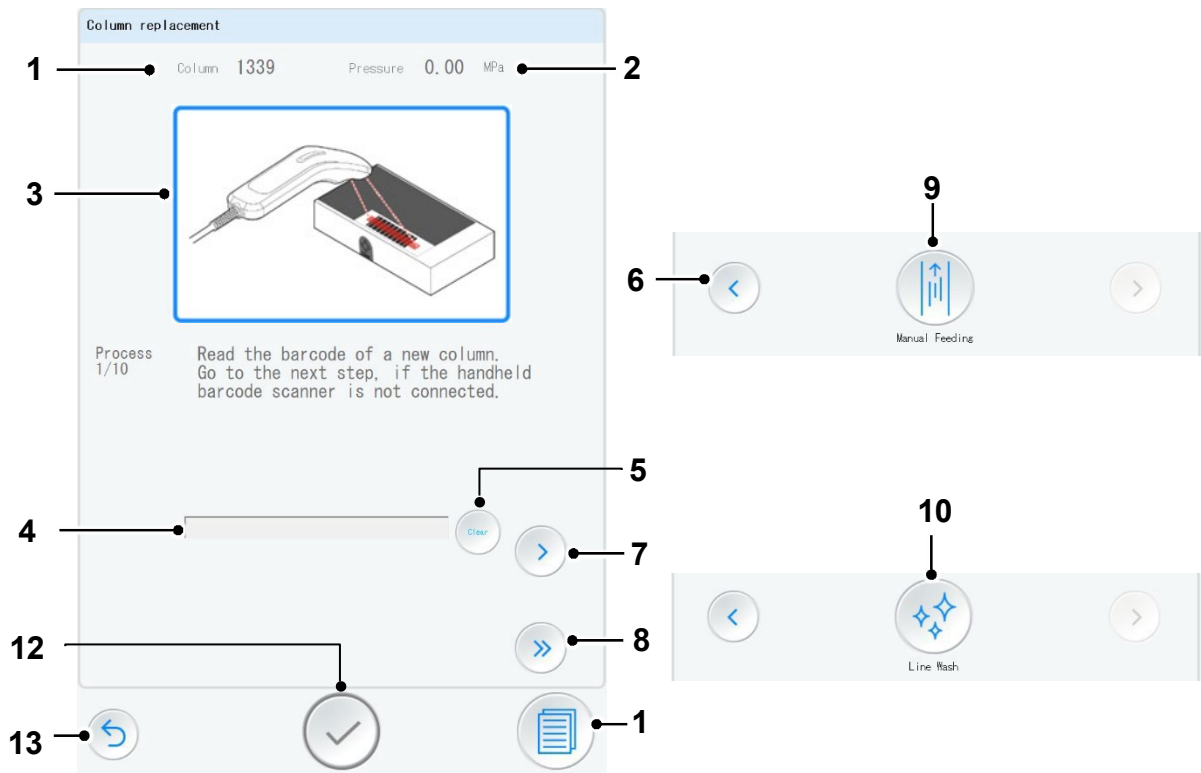
When the buffer switching unit is connected, “◆” is displayed above the color bar of each reagent.











No.	Button/entry field	Description
1	Buff. No.1 replacement button	Tap to replace the Elution Buffer No.1. (Tap [1st] or [2nd] when the buffer switching unit is connected.)
2	Buff. No.2 replacement button	Tap to replace the Elution Buffer No.2. (Tap [1st] or [2nd] when the buffer switching unit is connected.)
3	Buff. No.3 replacement button	Tap to replace the Elution Buffer No.3. (Tap [1st] or [2nd] when the buffer switching unit is connected.)
4	Hemolysis & Wash solution replacement button	Tap to replace the Hemolysis & Wash solution. (Tap [1st] or [2nd] when the buffer switching unit is connected.)
5	Reagents to be registered	The reagent information can be entered by reading the barcode on the packaging box of elution buffers and Hemolysis & Wash solution using the handheld barcode scanner. Only the information of the reagent for which the button is tapped can be registered. Manual entry is not available.
6	Clear button	Tap to delete the entered reagent information.
7	Register button 	Tap to register the entered reagent information.
8	Replacement history button 	Tap to move to the replacement history screen.
9	Return button 	Tap to return to the previous screen (main screen or maintenance screen).

### 4.8.3 Column replacement screen

The column can be replaced by following the steps indicated on the screen.

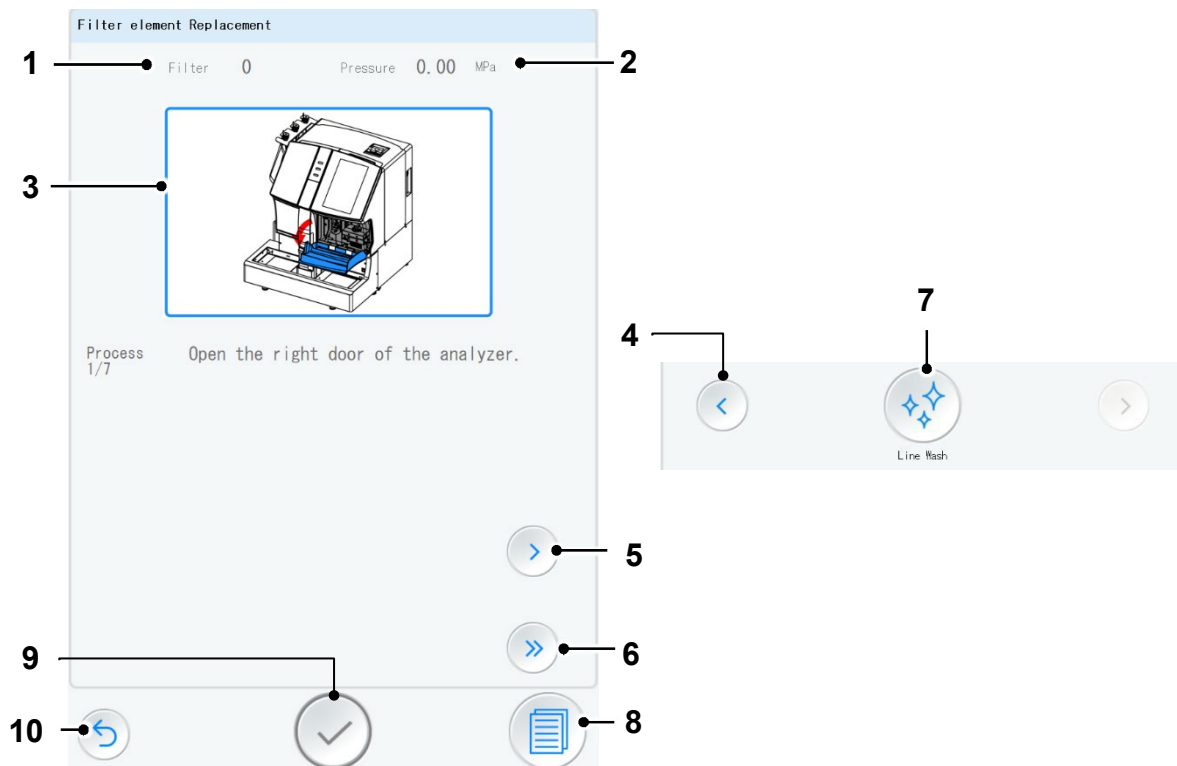







No.	Button/Display	Description
1	Column count	Shows the usage count of the column.
2	Pressure	Shows the system pressure.
3	Operation procedure	Shows operation steps with figures and text.
4	Information field for the column to be registered	The column information can be entered by reading the barcode on the packaging box of the column using the handheld barcode scanner. Manual entry is not available.
5	Clear button	Tap to delete the entered column information.
6	Previous button 	Tap to move to the previous page.
7	Next button 	Tap to move to the next page.
8	Skip button 	Tap to skip to the page showing the operation procedure such as eluent feeding.
9	Manual Feeding button 	Tap to perform manual feeding. The operation is indicated on Step 6.
10	Line Wash button 	Tap to perform line wash. The operation is indicated on Step 8.
11	Replacement history button 	Tap to move to the replacement history screen.
12	Finish button 	This button is enabled only on the final step of the procedure.



No.	Button/Display	Description
		Tap to close the column replacement screen, and to return to the previous screen (main screen or maintenance screen).
13	Return button 	Tap to return to the previous screen (main screen or maintenance screen).

#### 4.8.4 Filter element replacement screen

The filter element can be replaced by following the steps indicated on the screen.

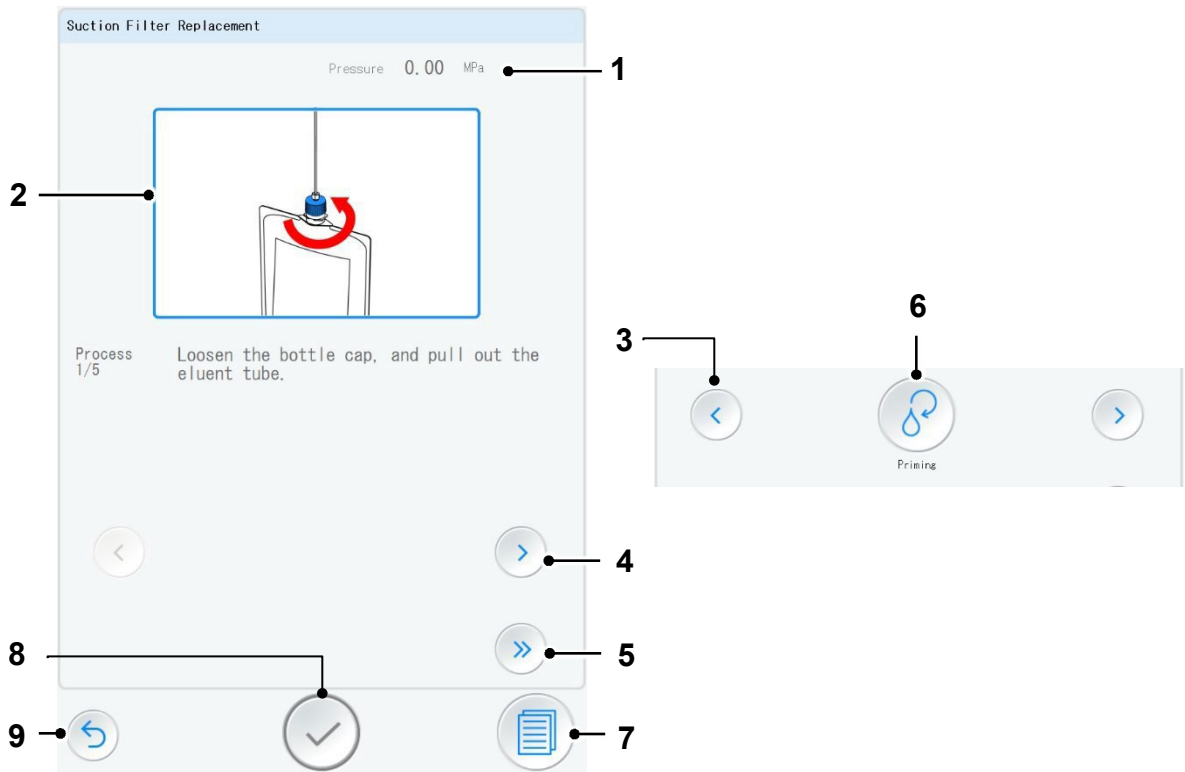







No.	Button/Display	Description
1	Filter count	Shows the usage count of the filter element.
2	Pressure	Shows the system pressure.
3	Operation procedure	Shows operation steps with figures and text.
4	Previous button 	Tap to move to the previous page.
5	Next button 	Tap to move to the next page.
6	Skip button 	Tap to skip to the page showing the operation procedures such as eluent feeding.
7	Line Wash button 	Tap to perform line wash. The operation is indicated on Step 7.
8	Replacement history button 	Tap to move to the replacement history screen.



No.	Button/Display	Description
9	Finish button 	This button is enabled only on the final step of the procedure. Tap to close the filter element replacement screen, and to return to the previous screen (main screen or maintenance screen).
10	Return button 	Tap to return to the previous screen (main screen or maintenance screen).

### 4.8.5 Suction filter replacement screen

The suction filters can be replaced by following the steps indicated on the screen.

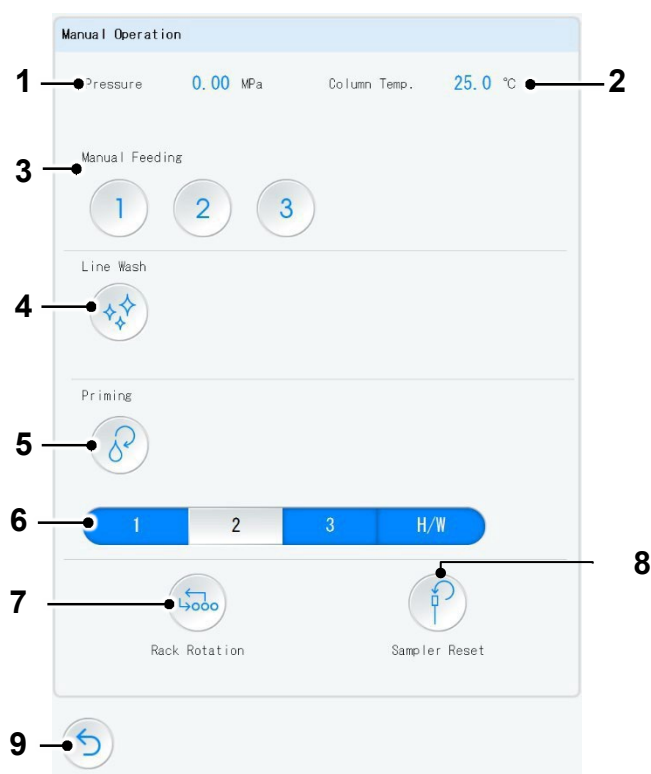







No.	Button/Display	Description
1	Pressure	Shows the system pressure.
2	Operation procedure	Shows operation steps with figures and text.
3	Previous button 	Tap to move to the previous page.
4	Next button 	Tap to move to the next page.
5	Skip button 	Tap to skip to the page showing the operation procedures such as eluent feeding.
6	Priming button 	Tap to perform priming. The operation is indicated on Step 4.
7	Replacement history button 	Tap to move to the replacement history screen.




No.	Button/Display	Description
8	Finish button 	This button is enabled on the final step of the procedure. Tap to close the suction filter replacement screen, and to return to the previous screen (main screen or maintenance screen).
9	Return button 	Tap to return to the previous screen (main screen or maintenance screen).

#### 4.8.6 Manual operation screen

Line wash and column wash, eluent feeding, sampler or sample loader operations can be performed from the manual operation screen.

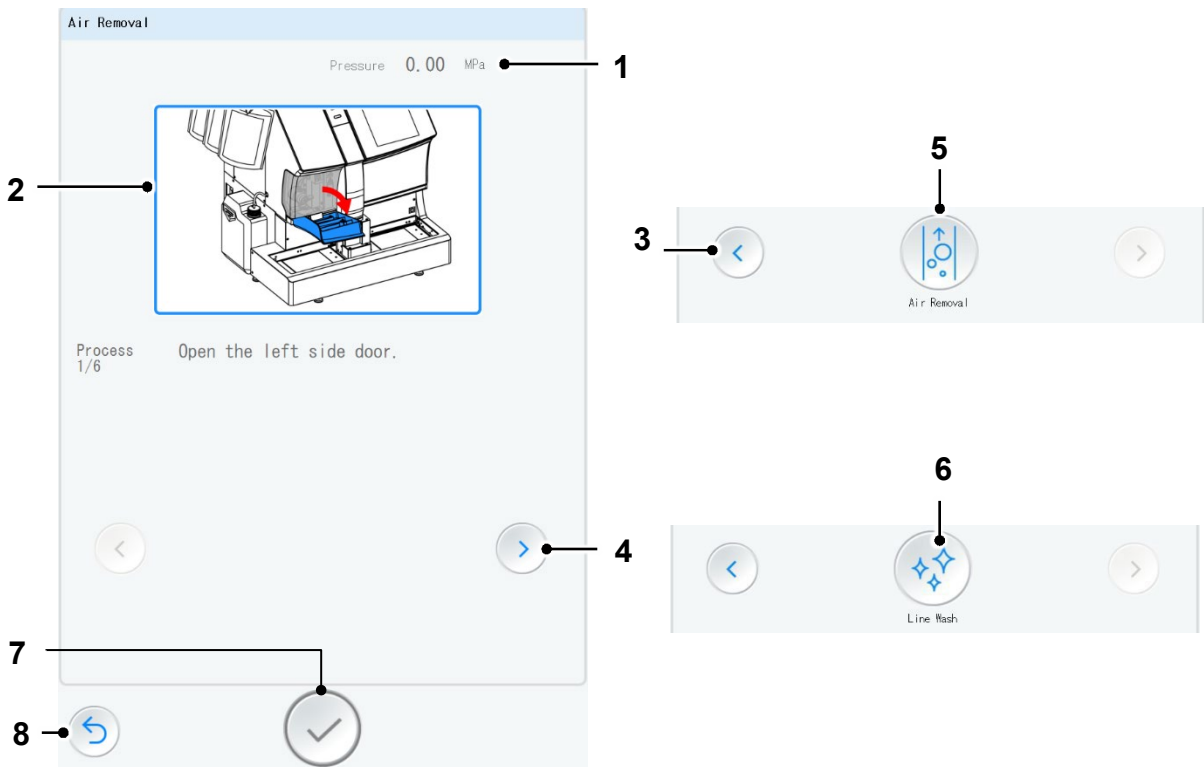







No.	Button/Display	Description
1	Pressure	Shows the system pressure.
2	Column Temp.	Shows the column temperature. The column oven is controlled at about 25°C.
3	Manual Feeding buttons	Tap to start feeding of the eluent selected with the following buttons:  for Elution Buffer No.1,  for Elution Buffer No.2,  for Elution Buffer No.3.
4	Line Wash button 	Tap to start eluent feeding to wash the lines and wash the column and filter.
5	Priming button 	Tap to perform priming of the reagent line selected with the elution buffers/Hemolysis & Wash solution selection button(s).


No.	Button/Display	Description
6	Elution buffers/Hemolysis & Wash solution selection buttons	Select the reagent button(s) to perform priming. Multiple selection is possible.
7	Rack Rotation button 	Tap to start rack rotation on the sample loader.
8	Sampler Reset button 	Tap to initialize (wash) the sampler unit.
9	Return button 	Tap to return to the maintenance screen.

### 4.8.7 Air removal screen

Air can be removed by following the steps indicated on the screen.

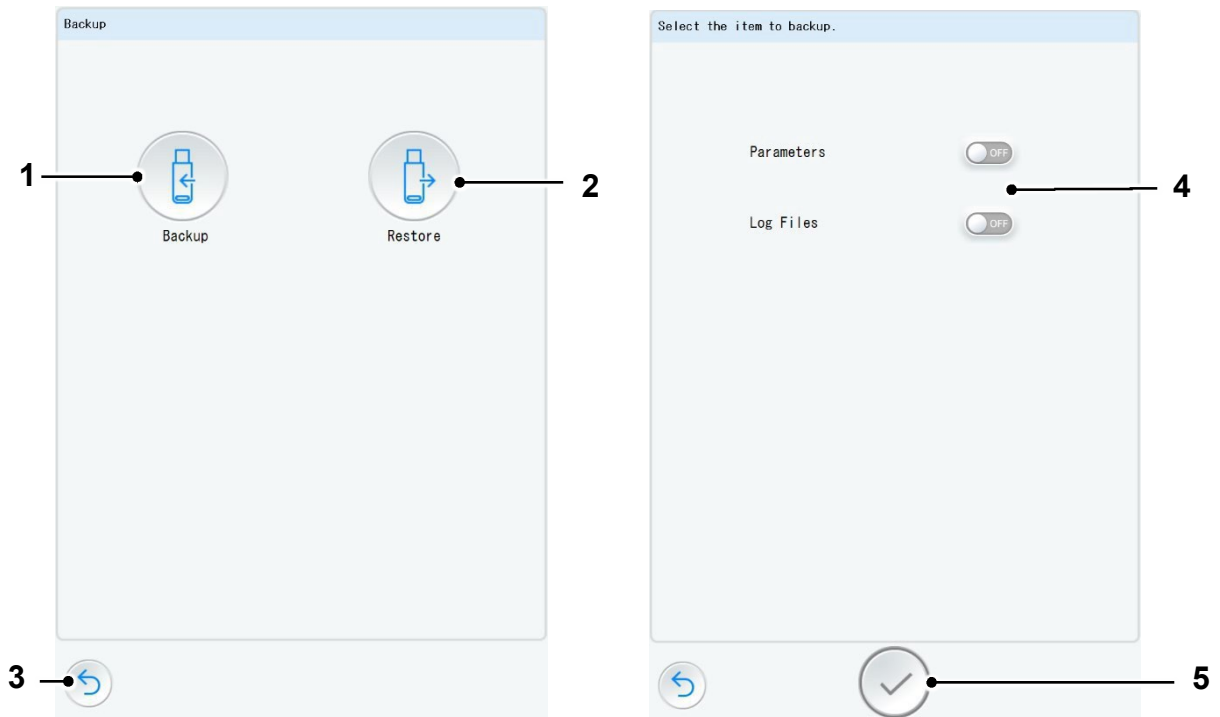






No.	Button/Display	Description
1	Pressure	Shows the system pressure.
2	Operation procedure	Shows operation steps with figures and text.
3	Previous button 	Tap to move to the previous page.
4	Next button 	Tap to move to the next page.
5	Air removal button 	Tap to open the drain valve and perform air removal. The operation is indicated in Step 3.
6	Line Wash button 	Tap to perform line wash. The operation is indicated in Step 5.
7	Finish button 	This button is enabled only on the final step of the procedure.

No.	Button/Display	Description
		Tap to close the air removal screen, and to return to the maintenance screen.
8	Return button 	Tap to return to the maintenance screen.

#### 4.8.8 Backup screen

The parameters can be backed up and restored. Only a user with Super User authority can access this screen.



No.	Button	Description
1	Backup button 	Tap to back up the parameters.
2	Restore button 	Tap to restore the parameters.
3	Return button 	Tap to return to the maintenance screen.
4	Backup/restore target selection switches	Select whether to back up for each item. The [Log Files] switch is not displayed when the [Restore] button is tapped.
5	Backup/restore button 	Tap to start backup or restoration of the selected item(s).

### NOTICE

**Use a designated format USB memory stick for backup.**

- Use an exFAT-format USB memory stick for backup.

## 4.8.9 Version screen

The versions of the system and software can be viewed and printed.

Version

System Version: Ver.01.01.000

Software	Version No.	Compare No.	Result
MAIN Boot	Ver.01.00.0000	Ver.01.00.0000	OK
Main System	Ver.01.01.0001	Ver.01.01.0001	OK
AS Boot	Ver.01.00.0000	Ver.01.00.0000	OK
AS System	Ver.01.01.0000	Ver.01.01.0000	OK
PC Controller	Ver.01.01.0000	Ver.01.01.0000	OK

Database	Version No.	Compare No.	Result
AnalysisData	Ver.01.00.007	Ver.01.00.007	OK
CalData	Ver.01.00.000	Ver.01.00.000	OK
EternalData	Ver.01.00.000	Ver.01.00.000	OK
Flg	Ver.01.01.000	Ver.01.01.000	OK
Log	Ver.01.01.000	Ver.01.01.000	OK
MainteData	Ver.01.01.000	Ver.01.01.000	OK
QCData	Ver.01.00.000	Ver.01.00.000	OK
ReagentData	Ver.01.01.000	Ver.01.01.000	OK
UserInfo	Ver.01.00.000	Ver.01.00.000	OK
AnalysisData2212	Ver.01.00.007	Ver.01.00.007	OK
AnalysisData2211	Ver.01.00.007	Ver.01.00.007	OK
AnalysisData2210	Ver.01.00.007	Ver.01.00.007	OK
AnalysisData2209	Ver.01.00.007	Ver.01.00.007	OK
AnalysisData2208	Ver.01.00.007	Ver.01.00.007	OK
AnalysisData2207	Ver.01.00.007	Ver.01.00.007	OK

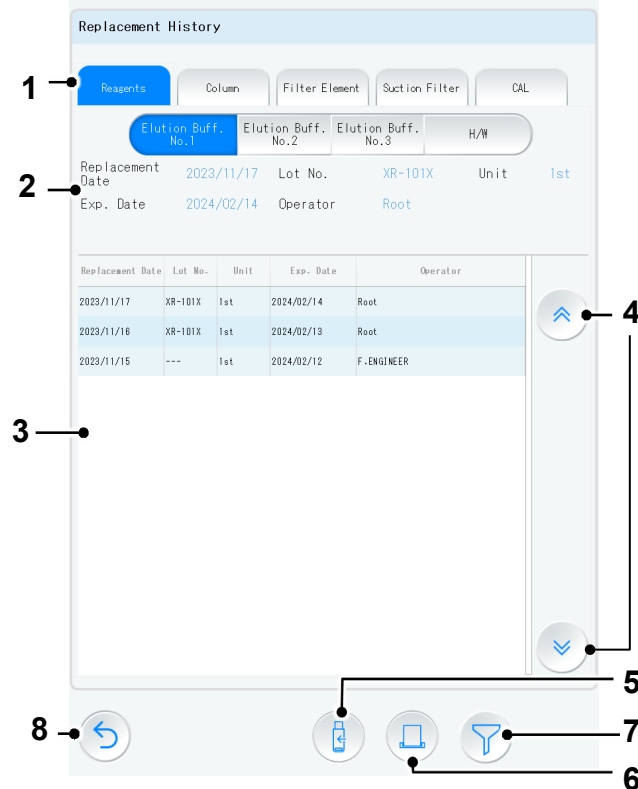
Navigation icons: Back, Print, Up, Down





**Note**



- You are requested to refer to this screen as necessary when consulting the Tosoh local representatives.

### 4.8.10 Replacement history screen

The replacement history of reagents (elution buffers, Hemolysis & Wash solution), column, filter element, and suction filters and the calibration history can be displayed on the screen.

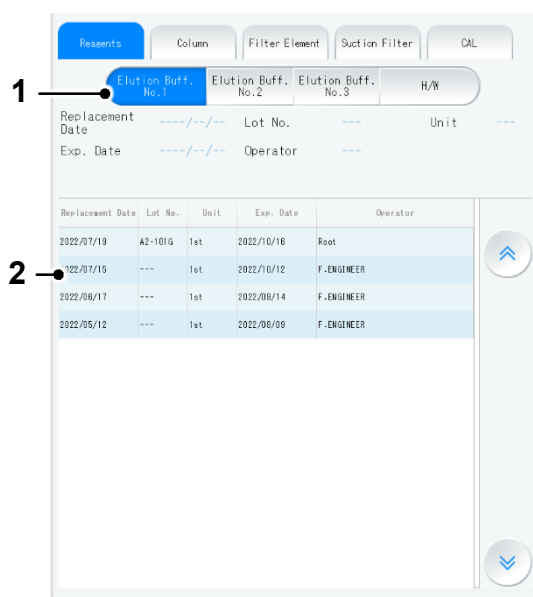


No.	Button/Display	Description
1	History selection tabs	Select the desired tab from [Reagents], [Column], [Filter Element], [Suction Filter], or [CAL] to show the replacement history of reagents (elution buffers, Hemolysis & Wash solution), column, filter element, or suction filters and the calibration history.
2	Current status	Shows the information of the consumables that are currently in use.
3	History	Shows the information of the consumables that were replaced in the past. An item with the older replacement date is displayed at the lower part of the screen.
4	History page selection buttons	 Moves to a newer history page.  Moves to an older history page.
5	USB output button 	Tap to output the replacement history data to a USB stick as a PDF. This button is available only when the USB stick is connected.
6	Print button 	Tap to print the replacement history data. This button is available only when the external printer (optional) is connected.

No.	Button/Display	Description
7	Display range button 	Show the display range settings dialog. Select the current year, the current month, or specific period of days to be displayed. The button will be highlighted when setting the display range.
8	Return button 	Tap to return to the maintenance screen.

## Reagent replacement history screen

The information and the replacement history of the reagents that are currently in use can be displayed.



No.	Button/Display	Description
1	Reagent selection buttons	Select the desired button from [Elution Buff. No.1], [Elution Buff. No.2], [Elution Buff. No.3], or [H/W].
2	Reagent information	<p>Replacement Date: Shows the replacement date of the reagent.</p> <p>Lot No.: Shows the lot No. of the reagent.</p> <p>Unit: Shows the unit of the reagent.</p> <p>When the buffer switching unit is connected, "1st" or "2nd" is displayed. When the buffer switching unit is not connected, only "1st" is displayed.</p> <p>Exp. Date: Shows the reagent expiration date or expiration date after opening, whichever comes first.</p> <p>Operator: Shows the ID of the logon user who replaced the reagent.</p>

### Column replacement history screen

The information and the replacement history of the column that is currently in use can be displayed.

Replacement Date	Exp. Date	Serial No.	Operator	Count
2022/07/19	---/--/--	---	Root	23
2022/07/19	2039/12/31	GF0001A	Root	30

Display	Description
Column information	<p>Replacement Date: Shows the replacement date of the column.</p> <p>Count: Shows the usage count of the column.</p> <p>Exp. Date: Shows the expiration date of the column.</p> <p>Operator: Shows the ID of the logon user who replaced the column.</p> <p>Serial No.: Shows the serial No. of the column.</p>

### Filter element replacement history screen

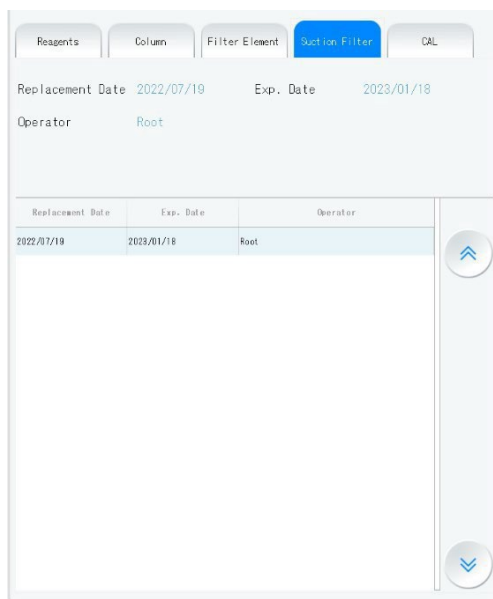
The information and the replacement history of the filter element that is currently in use can be displayed.

Replacement Date	Operator	Count
2022/07/19	Root	53
2022/07/12	Root	187
2022/05/13	F-ENGINEER	1430

Display	Description
Filter element information	<p>Replacement Date: Shows the replacement date of the filter element.</p> <p>Count: Shows the usage count of the filter element.</p> <p>Operator: Shows the ID of the logon user who replaced the filter element.</p>

### Suction filter replacement history screen

The information and the replacement history of the suction filters that are currently in use can be displayed.



Display	Description
Suction filter information	<p>Replacement Date: Shows the replacement date of the suction filters.</p> <p>Expiration Date: Shows the expiration date of the suction filters.</p> <p>Operator: Shows the ID of the logon user who replaced the suction filters.</p>

## Calibration history screen

The current calibration information and the calibration history can be displayed.

The screenshot shows a 'Replacement History' screen with a top navigation bar containing buttons for 'Reagents', 'Column', 'Filter Element', 'Suction Filter', and 'CAL'. Below this, there are two main sections:

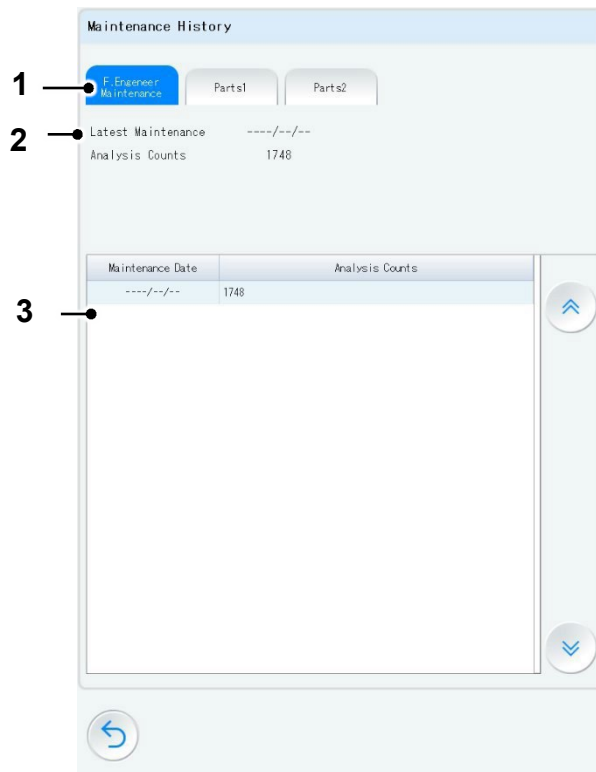
- Section 1 (Current Calibration Information):** This section displays key details for the current calibration:
  - Calib. date: 2023/11/16
  - Exp. Date: 2023/12/16
  - Lot No.: ZB2010
  - Rem. Days: 29
  - Formula:  $Y = 1.1492X + 0.6164$
  - Operator: F.ENGINEER
- Section 2 (Calibration History Table):** This section displays a table of past calibrations:
 

Calib. date	Formula	Operator	Lot No.	Exp. Date
2023/11/16	$Y = 1.1492X + 0.6164$	F.ENGINEER	ZB2010	2023/12/16
2023/11/16	$Y = 1.1418X + 0.6308$	Root	---	2023/12/16
2023/11/15	$Y = 1.1088X + 0.7893$	F.ENGINEER	---	2023/12/15

No.	Button/Display	Description
1	Calibrator information	<p>Calib. Date: Shows the date at which the calibration was performed.</p> <p>Exp. Date: Shows the expiration date of the calibration factor.</p> <p>Lot No.: Shows the lot No. of the calibrator.</p> <p>Rem. Days: Shows the remaining valid days of the calibration.</p> <p>Formula: Shows the calibration formula.</p> <p>Operator: Shows the ID of the logon user who performed calibration.</p>
2	Calibration history	<p>Shows calibrations that were performed in the past.</p> <p>An item with the older calibration date is displayed at the lower part of the screen.</p>

### 4.8.11 Maintenance history screen

The maintenance history can be displayed on this screen.



No.	Button/Display	Description
1	Maintenance selection tabs	Select the desired tab for maintenance from [F. Engineer Maintenance], [Parts1], or [Parts2]. F. Engineer Maintenance: The latest maintenance by Field engineer. Parts1: Injection valve rotor seal (I.V.Seal) Rotor vale rotor seal (R.V.Seal) Sample loop (S.Loop) Plunger seal (P.Seal) Parts2: Needle O-ring (O-ring) Pump check valve (C.Valve) Waste filter (D.Filter)
2	Maintenance information	The latest maintenance/replacement information is displayed. Latest Maintenance: Shows the date of the latest maintenance by Field engineer. Latest Replacement: Shows the date of the latest replacement by Field engineer. Analysis Counts: Shows the usage count after the latest maintenance/replacement.
3	Maintenance history	Shows the history of maintenance performed in the past.

### 4.8.12 Logon history screen

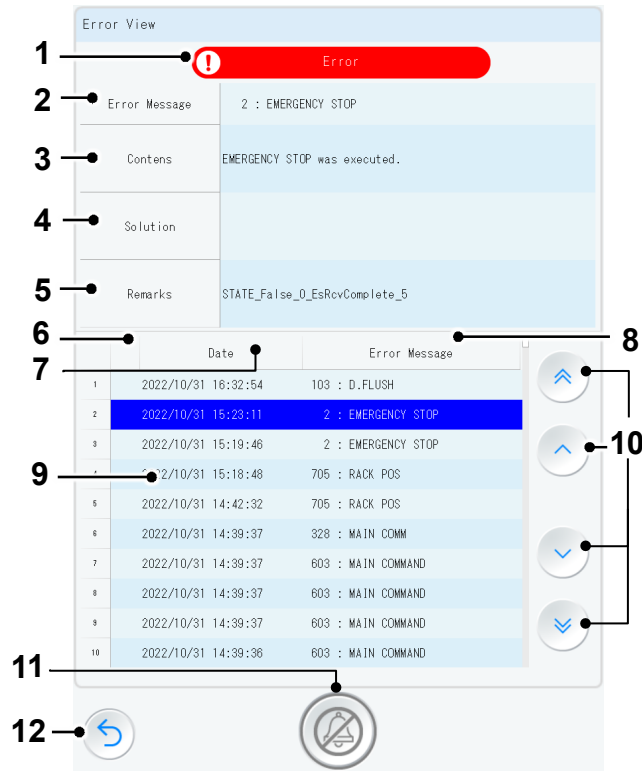
The logon/logoff history can be displayed on this screen.



Logon/Logoff	User ID	Date/Time
Logon	Root	2022/07/22 10:00
Logoff	F.ENGINEER	2022/07/22 10:00
Logon	F.ENGINEER	2022/07/22 09:59
Logoff	Root	2022/07/22 09:59
Logon	Root	2022/07/22 09:22
Logoff	Root	2022/07/21 18:38
Logon	Root	2022/07/21 16:08
Logoff	Root	2022/07/21 13:52
Logon	Root	2022/07/21 11:50
Logoff	Root	2022/07/20 19:23
Logon	Root	2022/07/20 14:06
Logoff	Root	2022/07/20 11:44
Logon	Root	2022/07/20 09:54
Logoff	Root	2022/07/20 09:52
Logon	Root	2022/07/20 09:48
Logoff	F.ENGINEER	2022/07/19 19:47
Logon	F.ENGINEER	2022/07/19 19:46
Logoff	Root	2022/07/19 19:05
Logon	Root	2022/07/19 16:48
Logoff	F.ENGINEER	2022/07/19 16:48
Logon	F.ENGINEER	2022/07/19 16:48
Logoff	Root	2022/07/19 16:48
Logon	Root	2022/07/19 16:47
Logoff	F.ENGINEER	2022/07/19 16:47
Logon	F.ENGINEER	2022/07/19 16:47
Logoff	Root	2022/07/19 16:47








Display	Description
Logon/Logoff	Shows [Logon] or [Logoff] for each item.
User ID	Shows the ID of the logon or logoff user.
Date/Time	Shows the date and time at which the application is logged on or off.

### 4.8.13 Error history screen



The error history can be displayed on this screen.



No.	Button/Display	Description
1	Event type	[Error] or [Warning] is displayed for each event.
2	Error Message	Shows the Error No. and the message of the event that occurred.
3	Content	Shows the content of the event that occurred.
4	Solution	Shows the solution of the event that occurred.
5	Remarks	Shows the detailed information, if any.
6	Bell mark 	Shows whether the user has checked the event or not. When the  mark is displayed, the event has not been checked yet.
7	Date	Shows the date and time at which the event occurred.
8	Error Message	Shows the Error No. and message for the date the event occurred.
9	Event history	Shows the history of the events that occurred. The selected event is highlighted in blue.

No.	Button/Display	Description
10	Event selection buttons	Tap to move up or down the selection (highlight).  : Moves the highlight to 10 lines up. If the listed events are less than 10, the highlight is moved to the top event.  : Moves the highlight one line up.  : Moves the highlight one line down.  : Moves the highlight to 10 lines down. If the listed events are less than 10, the highlight is moved to the bottom event.
11	Check button 	Tap the button after checking an event that occurred. When the check button is tapped, the  disappears.
12	Return button 	Tap to return to the previous screen (main screen or event screen).

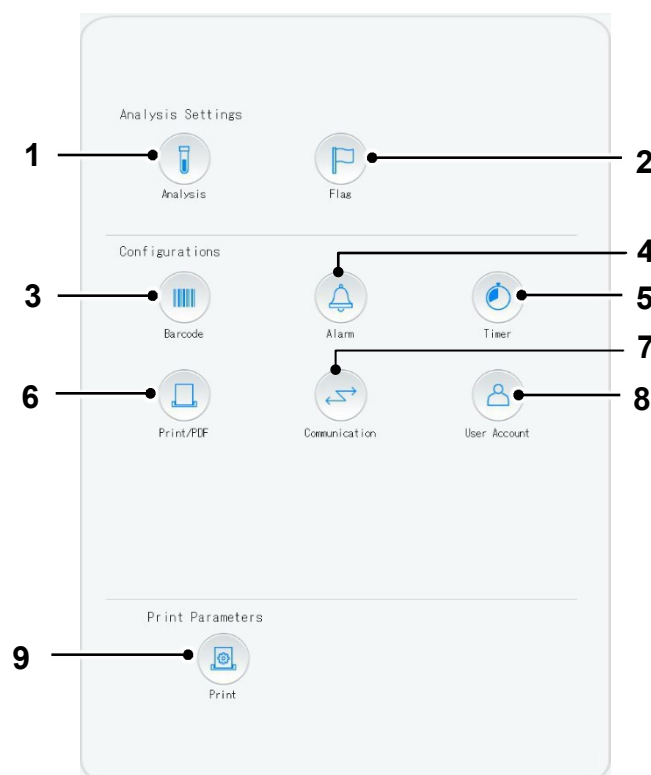
**Note**










- To return to the previous screen, tap the check button  to clear all  marks.

## 4.9 Settings screen

### 4.9.1 Settings screen

Analysis- or configurations-related settings can be performed or printed from this screen.




No.	Button	Description
1	Analysis settings button 	Tap to move to the analysis settings screen. Refer to "4.9.2 Analysis settings screen (p.83)".
2	Flag check button 	Tap to move to the flag screen. Refer to "4.9.3 Flag settings screen (p.85)".
3	Barcode button 	Tap to move to the barcode settings screen. Refer to "4.9.4 Barcode Settings Screen (p.86)".
4	Alarm button 	Tap to move to the alarm settings screen. Refer to "4.9.5 Alarm Settings screen (p.87)".
5	Timer button 	Tap to move to the timer settings screen. Refer to "4.9.6 Timer settings screen (p.88)".
6	Print/PDF button 	Tap to move to the print/PDF settings screen. Refer to "4.9.7 Print/PDF settings screen (p.90)".
7	Communication button 	Tap to move to the communication settings screen. Refer to "4.9.8 Communication settings screen (p.92)".
8	User Account button 	Tap to move to the user account settings screen. Refer to "4.9.9 User account settings screen (p.94)".
9	Print Parameters button 	Tap to move to the parameter print screen. Refer to "4.9.10 Parameter print screen (p.98)".


### Changing and saving the parameter settings

The parameter settings can be changed and saved (modified) on the corresponding setting screen.

The parameter settings can be changed only when the analyzer status is on "Standby".

The parameter settings can be saved by tapping the save button  after changing the parameter settings.

The save button is enabled only when the parameter settings are changed.

When the return button  is tapped, the changed contents are discarded and then the screen is returned to the settings screen.

#### Note

- When the analyzer status is other than "Standby", the setting can only be viewed.

## 4.9.2 Analysis settings screen

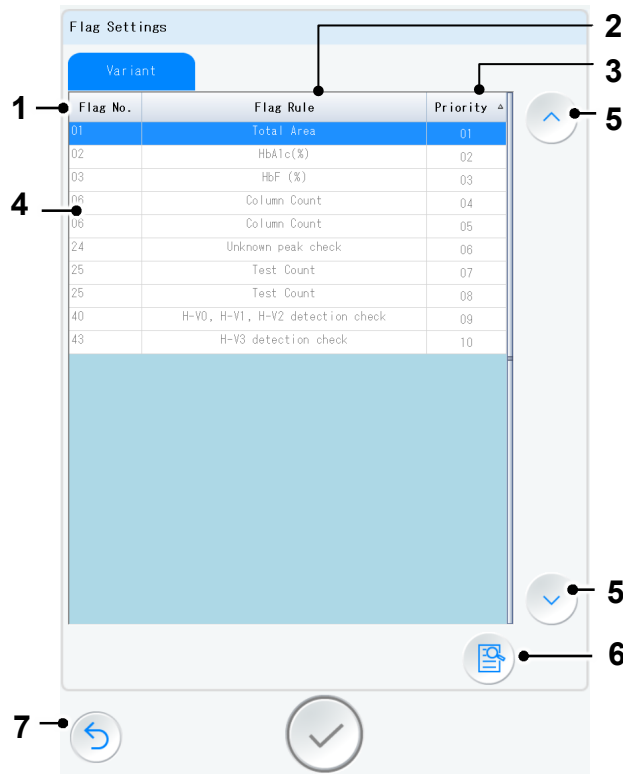
Analysis-related settings can be performed from this screen.





Button/Display	Description
Start Sample No.	Enter the sample No. for sample analysis.
Rack Rotation switch	Select whether to enable/disable sample rack rotation on the sample loader. ON: Rack rotation is enabled. OFF: Rack rotation is disabled. This setting is applied only to the GR-90SL.
Rack Start switch	Select whether to enable/disable automatic rack start. With the automatic rack start enabled, when a sample rack is loaded at the front right of the sample loader, the sample rack is detected and then analysis is started automatically. ON: Automatic rack start is enabled. OFF: Automatic rack start is disabled. This setting is applied to the GR-90SL.
Sample Condition buttons	Select the sample condition. Standard: When [Standard] is selected, the sample in the sample tube is recognized as whole blood, the sample in the sample cup as manually prepared hemolysate. Whole Blood: When [Whole Blood] is selected, both samples in the sample tube and sample cup are recognized as whole blood. Diluted Blood: When [Diluted Blood] is selected, both samples in the sample tube and sample cup are recognized as manually prepared hemolysate. Host Query: Samples are recognized according to the order from

<b>Button/Display</b>	<b>Description</b>
	the host computer. * When the [Query] switch is set to [OFF] or when a query cannot be sent due to failure including the barcode reading error, the [Standard] setting is applied.
Optional Comment	Enter a comment such as the analyzer name or other information.
Flow Factor	Enter the flow factor, around 1.000 normally. Only a user with Super User authority can specify the flow factor. * Do not change the value unless otherwise indicated.

### 4.9.3 Flag settings screen

Attached flags can be viewed. For the details of the flag settings and how the flags are used, refer to “7.2 Flag settings (p.155)”.

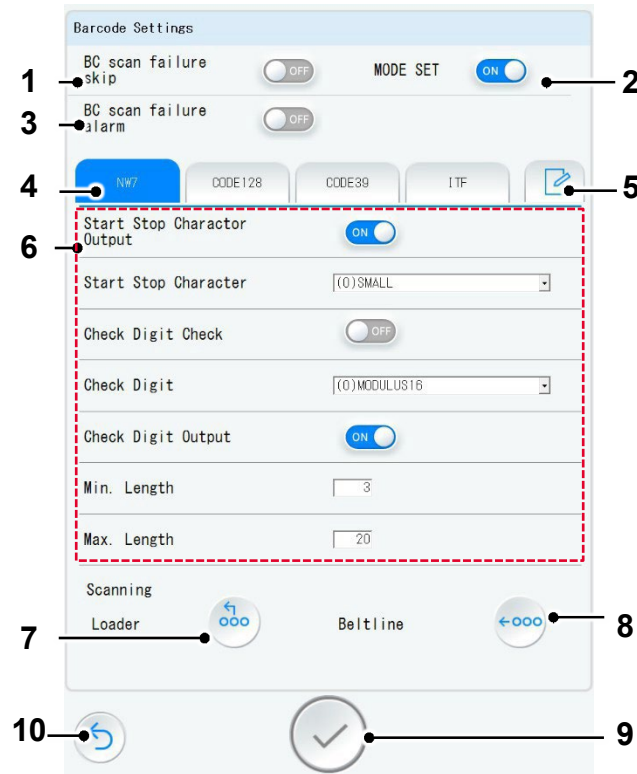


No.	Button/Display	Description
1	Flag No.	Shows the flag No.
2	Flag Rule	Shows the flag rules.
3	Priority	Shows the flag priority.
4	Flag information	Shows the flag information. The selected flag information is highlighted in blue.
5	Flag selection buttons	 : Moves the highlight one line up.  : Moves the highlight one line down.
6	Flag information button 	Tap to open the flag setting dialog for the selected flag.
7	Return button 	Tap to return to the previous screen (settings screen).




#### 4.9.4 Barcode Settings Screen

The settings for the barcode type, reading operation, and action in case of reading failure can be specified.

Up to 4 barcode types can be selected.

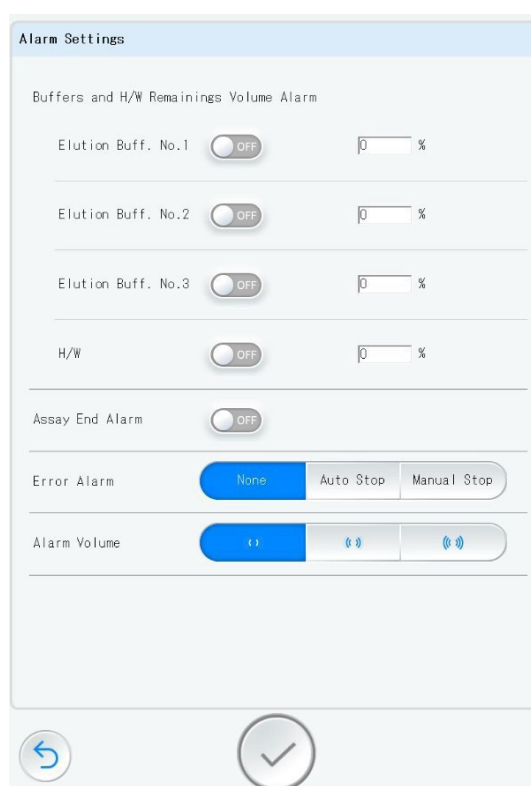


No.	Button/Display	Description
1	BC scan failure skip switch	Select whether to skip analysis if the barcode cannot be read properly during analysis. ON: A warning (Code: 670) is triggered, and then the sample analysis is skipped. OFF: The sample analysis is not skipped. A warning (Code: 670) is not triggered.
2	MODE SET switch	Select whether to write the parameter settings in the barcode reader. ON: The parameter settings are written. OFF: The parameter settings are not written. Only a user with Super User authority can change the switch setting.
3	BC scan failure alarm switch	Select whether to be notified with a warning (alarm) if the barcode cannot be read properly during analysis. ON: A warning (Code: 671) is triggered. OFF: A warning (Code: 671) is not triggered.
4	Barcode type tabs	Select the barcode type to check the settings for.
5	Barcode type selection button	Tap to move to the barcode type selection screen. This button is enabled only for a user with Super User authority.

No.	Button/Display	Description
6	Barcode settings	Shows the settings of the selected barcode type. Only a user with Super User authority can change the settings.
7	Scanning Loader button 	Tap to read the barcode with the barcode reader on the sample loader.
8	Scanning Beltline button 	Tap to read the barcode with the barcode reader on the laboratory automation system.
9	Set button	Tap to set the barcode type and barcode settings with the entered and selected contents.
10	Return button 	Tap to return to the previous screen (settings screen).

#### 4.9.5 Alarm Settings screen

The alarm settings can be viewed or changed on this screen.

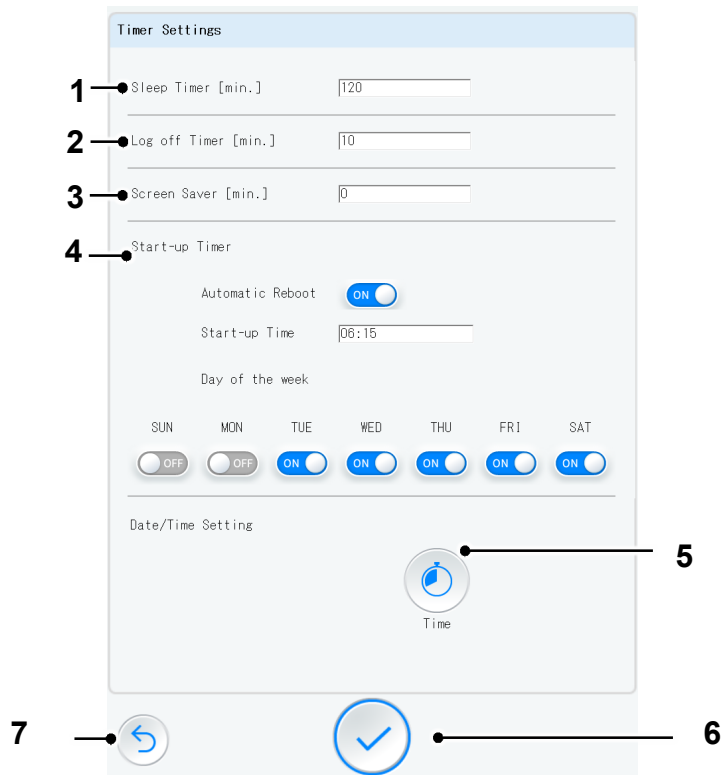


Button/Display	Description
Buffers and H/W Remaining Volume Alarm switches	When the switch of the desired reagent is set to [ON] and then the threshold value for remaining volume (%) is entered, an alarm buzzer sounds if the remaining volume reaches the specified volume. The analysis is continued even when an alarm buzzer sounds. The remaining volume (%) is just an estimate.
Assay End Alarm switch	When the [Assay End Alarm] switch is set to [ON], an alarm can sound when analysis (batch analysis) is completed. The buzzer stops automatically.



Button/Display	Description
Error Alarm buttons	Select the desired alarm setting when an error occurs. None: No buzzer sounds. Auto Stop: A buzzer sounds and stops automatically. Manual Stop: A buzzer continues to sound until the buzzer is stopped manually. The buzzer can be stopped by tapping the bell mark on the error dialog.
Alarm Volume buttons	Select the desired volume of the alarm buzzer.

### 4.9.6 Timer settings screen

The time settings can be viewed, and the current time can be changed on this screen.



No.	Button/Display	Description
1	Sleep Timer [min.]	Set the time (minutes) when the analyzer enters the sleep state after the last screen operation is performed. The initial value is "120". The value can be set between "0" to "300". When "0" is entered, the analyzer does not enter the sleep state.
2	Log off Timer [min.]	Set the time (minutes) when the application is automatically logged off after the last screen operation is performed. The initial value is "10". The value can be set between "0" to "300". When "0" is entered, the application is not logged off automatically.

No.	Button/Display	Description
3	Screen Saver [min.]	<p>Set the time (minutes) when the screen saver starts after the last screen operation is performed. (The screen saver starts even during analysis when no screen operation is performed after the specified time.) The initial value is "0". The value can be specified between "0" to "300". When "0" is entered, the screen saver does not start.</p>
4	Start-up Timer Automatic Reboot switch Start-up Time field Day of the week switches	<p>Set the time and the day of the week at which the analyzer is to wake up from sleep mode or reboot automatically.</p> <p><b>Automatic Reboot [ON]</b> If the analyzer is in sleep status, the analyzer reboots automatically at the specified time and day of the week and begins warming up.</p> <p><b>Automatic Reboot [OFF]</b> If the analyzer is in sleep status, the analyzer begins warming up automatically at the specified time and day of the week.</p> <p>The start-up time can be specified from the timer keyboard dialog, and the day of the week can be selected by tapping the corresponding switch to change to [ON] or [OFF].</p>
5	Date/Time Setting Time button 	<p>Tap to open the timer keyboard dialog. The current time can be changed. This button is enabled only for a user with Super User authority.</p>
6	Set button	Tap to set the timer.
7	Return button 	Tap to return to the previous screen (settings screen).

**Reference**

For the sleep and screen saver functions, refer to “5.10 Turning off the analyzer and screen display (p.132)”.

**Note**

- If Automatic Reboot is set [ON] and Start-up Timer is set at least once a week, it is not necessary to turn off the main power at least once every 7 days.
- The start-up function is only valid in sleep status (screen off) and not in Standby status.

## **NOTICE**

**Be sure to verify the current time setting before starting analysis or replacing consumables.**

**If the current time is incorrect (for example due to daylight saving time), the time must be changed prior to starting analysis or replacing consumables for the day. If the time is changed after analysis or consumable replacement, the following problems may occur.**

- The display order of results may be changed.
  - The various histories may not be displayed properly on the history screen.
  - Results may not be sent to the host computer during communication.
-

## NOTICE

- The expiration date of calibrator, consumables, and calibration factor may not be managed properly.
- Results displayed on the QC screen may be changed.

### Timer keyboard dialog

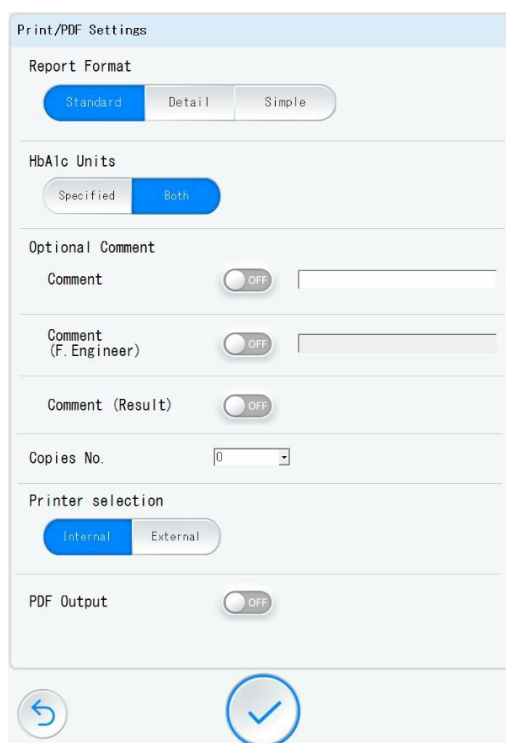
This dialog box is used to set the start-up timer and to set the current time.



1	Set time	Shows the set time (hour: minute).
2	Change target selection buttons	Select the [Hour] or [Minute].
3	+ button	Tap to increase the number of the selected item.
4	— button	Tap to reduce the number of the selected item.
5	Set button	Tap to set the time.

### 4.9.7 Print/PDF settings screen

The Print/PDF settings can be specified on this screen. These settings are necessary to print or save results as PDF for each analysis.



Button/Display	Description
Report Format selection buttons	<p>Select the desired report form for printing and PDF. Standard: The HbA1c (%) value, chromatogram, and information of all peaks for each result are displayed. Detail: The reagent information (the lot No. and usage start date of the column, elution buffers, and Hemolysis &amp; Wash solution, the lot No. of the calibrator, and the calibration date) is displayed in addition to the information displayed when [Standard] is selected.</p> <p>Simple: The HbA1c (%) value, and chromatogram for each result are displayed.</p> <p>For report form examples, refer to “7.3.2 Report formats (p.159)”.</p>
HbA1c Units buttons	<p>Select whether to print the results including IFCC unit.</p> <p>Specified: The result is printed in the NGSP unit.</p> <p>Both: The result is printed in the NGSP and IFCC units.</p>
Optional Comment	<p>Set each comment switch to [ON] to add the comment in the printed report or PDF.</p> <p>The comment can be manually entered. The procedure of entering comment is the same as [Optional Comment] in “4.9.2 Analysis settings screen (p.83)”.</p>
Comment (F.Engineer) switch	<p>Set this switch to [ON] to add the Field engineer comment in the printed report or PDF. Only the Tosoh Field engineer can edit this comment.</p>
Comment (Result) switch	<p>Set this switch to [ON] to add the comment added on the result screen in the printed report or PDF.</p>
Copies No.	<p>Select the number of copies for printer from [0], [1], or [2].</p> <p>The initial value is “1”.</p>
Printer selection buttons	<p>Select the printer from [Internal] or [External].</p>
PDF Output switch	<p>Select whether to save the result as PDF in the USB memory stick.</p> <p>ON: The result is saved as PDF.</p> <p>OFF: The result is not saved.</p>

**Note**

- When [External] is selected for [Printer selection], it is necessary to connect the external printer to the instrument and turn on the external printer. To save PDFs, it is necessary to insert the USB memory stick to the designated USB port of the instrument.

### 4.9.8 Communication settings screen

The communication settings can be specified on this screen.

Button/Display	Description
Query switch	Select whether to send a query to the host computer. The initial setting is [OFF]. ON: A query is sent to the host computer. OFF: A query is not sent to the host computer.
Auto Upload switch	Select whether to upload the results to the host computer automatically. The initial setting is [OFF]. ON: Results are uploaded to the host computer automatically. OFF: Results are not uploaded to the host computer automatically.
BC scan failure skip switch	Select whether to skip analysis if the barcode cannot be read properly. The initial setting is [OFF]. ON: The sample analysis is skipped. OFF: The sample analysis is not skipped.
BC scan failure alarm switch	Select whether to be notified with an alarm if the barcode cannot be read properly during analysis. The initial setting is [OFF]. ON: An alarm sounds. OFF: An alarm does not sound.
Baud rate	Select the desired baud rate (bps) from [1200], [2400], [4800], [9600], [19200], or [38400]. The initial setting is [9600].
Parity	Select the desired parity from [NONE], [ODD], or [EVEN]. The initial setting is [NONE].

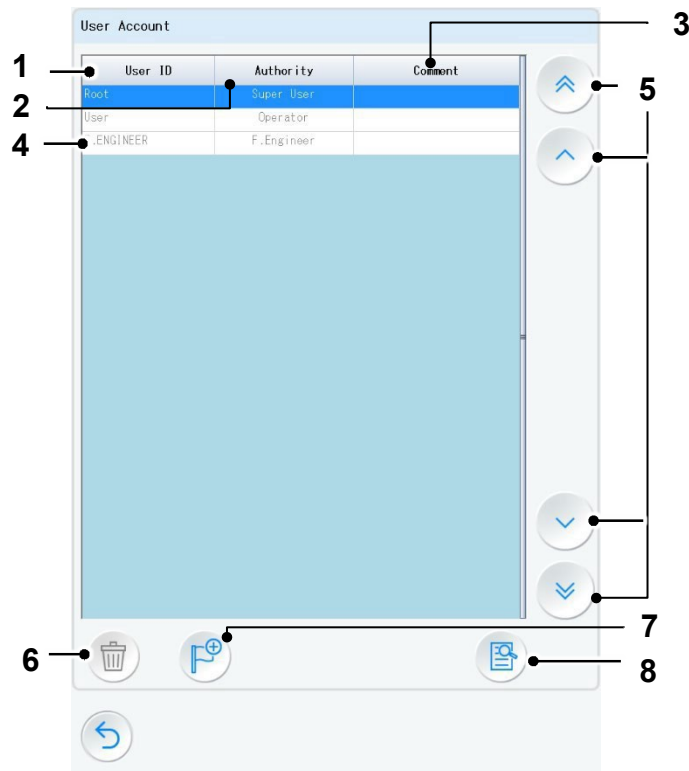
Button/Display	Description
Data Length	Select the desired data length from [7BIT] or [8BIT]. The initial setting is [8BIT].
Stop bit	Select the desired stop bit from [1BIT] or [2BIT]. The initial setting is [1BIT].
RTS-CTS control	Select whether to control hardware flow from [ON] or [OFF]. The initial setting is [OFF].
Comm. Mode	Select the desired communication mode from the following: STD FORM, CLASS FORM A, CLASS FORM B, CLASS FORM C, RP FORM, CDS FORM, NP FORM A, NP FORM B, NP FORM C, NP FORM D. The initial setting is [STD FORM].
Comm. Component	Select the desired sending order of components. The initial setting is [12345687ABC-].
Barcode Digits	Select the desired number of digits for the barcode from [BC13], [BC18], [BC20], or [BCNO] (not send). The initial setting is [BC20].
Sample No. Digits	Select the desired number of digits for the sample No. from [3 digit] (last 3-digit), [5 digit 2], [5 digit 1], [8 digit time], or [8 digit day]. The initial setting is [8 digit time].
Flag Communication Form	Select the desired error communication form for the HbA1c (%) value with unreportable flag from [ZERO] (0), or [SPACE] (blank). The initial setting is [ZERO].




**Note**

- The following settings cannot be changed (can be only viewed): Baud rate, Parity, Data Length, Stop bit, RTS-CTS control, Comm. Mode, Comm. Component, Barcode Digits, Sample No. Digits, Error Communication Form.
- For the settings of communication with the host computer, refer to “7.5 Host communication settings (p.162)”.
- If you have any questions about the communication settings, contact Tosoh local representatives.

### 4.9.9 User account settings screen

A user account can be added, deleted, or viewed on this screen.



No.	Button/Display	Description
1	User ID	Shows the user ID.
2	Authority	Shows the authority of the user. (Super User, Operator, F.Engineer) [F.Engineer] is only for the Tosoh service engineer.
3	Comment	Shows the comment attached to the user.
4	User list	Shows the registered users. The selected user is highlighted in blue.
5	User selection buttons	<ul style="list-style-type: none"> <li>⏪: Moves the highlight to the previous page.</li> <li>⏩: Moves the highlight one line up.</li> <li>⏴: Moves the highlight one line down.</li> <li>⏭: Moves the highlight to the next page.</li> </ul>
6	User delete button 	Tap to delete the selected user account. This button is enabled only for a user with Super User authority.
7	User register button 	Tap to open the user account registration dialog. A new user account can be created. This button is enabled only for a user with Super User authority.
8	User edit button 	Tap to open the user account editing dialog. The selected user account can be edited on this screen.

**Note**

- The [F.Engineer] and [Root] users cannot be edited or deleted even by a user with Super User authority.
- Up to 100 users (including [F.Engineer] and [Root]) can be registered.
- The username and password are case-sensitive.
- A user with the same name as a registered user cannot be registered under the same name.

**User account registration dialog**

A user account can be newly registered on this dialog screen.



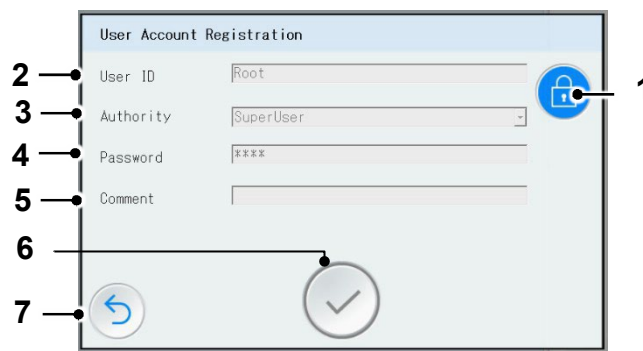
Button/Display	Description
User ID	Enter the username to be registered, up to 10 characters. (Required)
Authority	Select [Super User] or [Operator].
Password	Enter the password, from 12 to 32 digits. (Required)
Comment	Enter the user comment, up to 20 characters. (Optional)


**Note**

- The Password must contain at least one lowercase letter, one uppercase letter, one number, and one symbol.
- The Password expires in 90 days.

## User account editing dialog

The password and comment can be changed on this dialog.



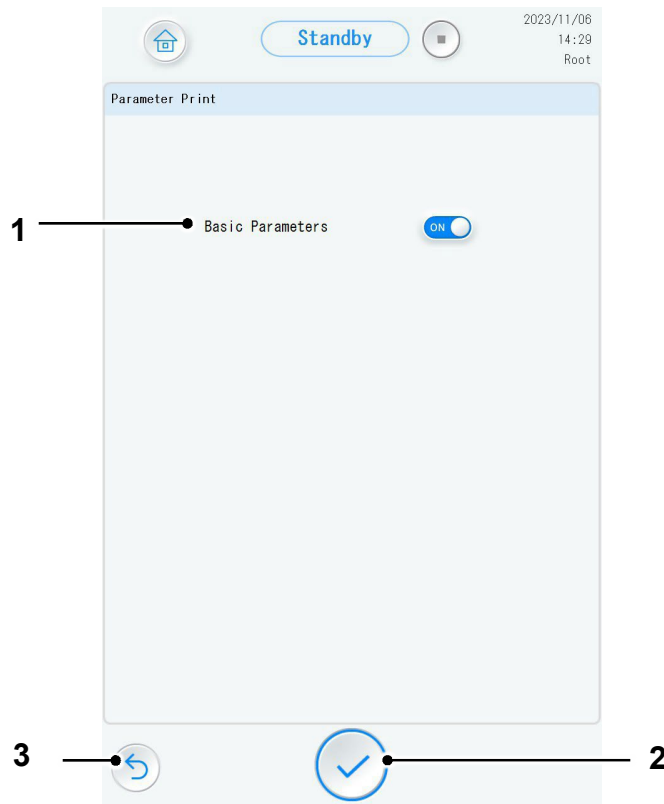
No.	Button/Display	Description
1	Editing lock release button	Tap to release the lock for the password and comment.
2	User ID	Shows the user ID.
3	Authority	Shows the authority of the user.
4	Password	Enter the password, from 12 to 32 digits. (Required)
5	Comment	Enter the user comment, up to 20 characters.
6	Set button 	Tap to complete editing with the entered contents.
7	Return button	Tap to return to the user settings screen.


### Note

- The Super User has the authority to edit the users (excluding Root and field service).

### 4.9.10 Parameter print screen

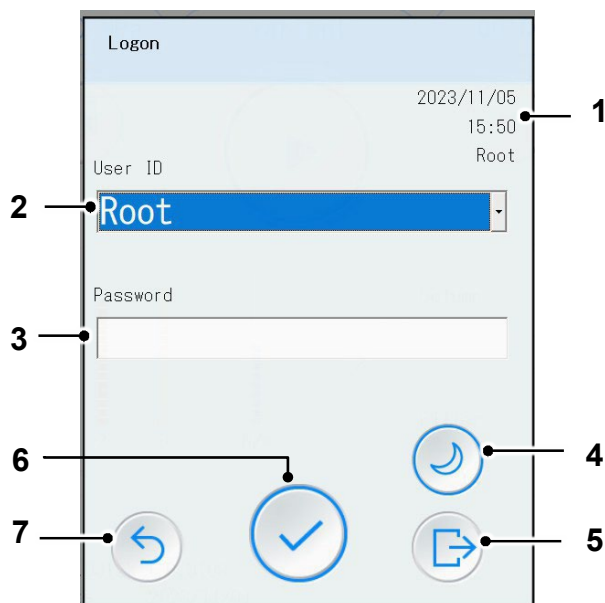
The selected parameters can be printed using the internal or external printer.




No.	Button	Description
1	Basic Parameters	Select whether to print analysis settings, flag settings, barcode settings, alarm settings, timer settings, print/PDF settings, and communication parameters. ON: These items are printed. OFF: These items are not printed.
2	Print button 	Tap to print the item. The button is enabled only when there are any switches set to [ON].
3	Return button	Tap to return to the settings screen.

## 4.10 User switching screen

A user can be switched to another user or can be logged off from the application, or the analyzer can be switched to the sleep state on this screen.



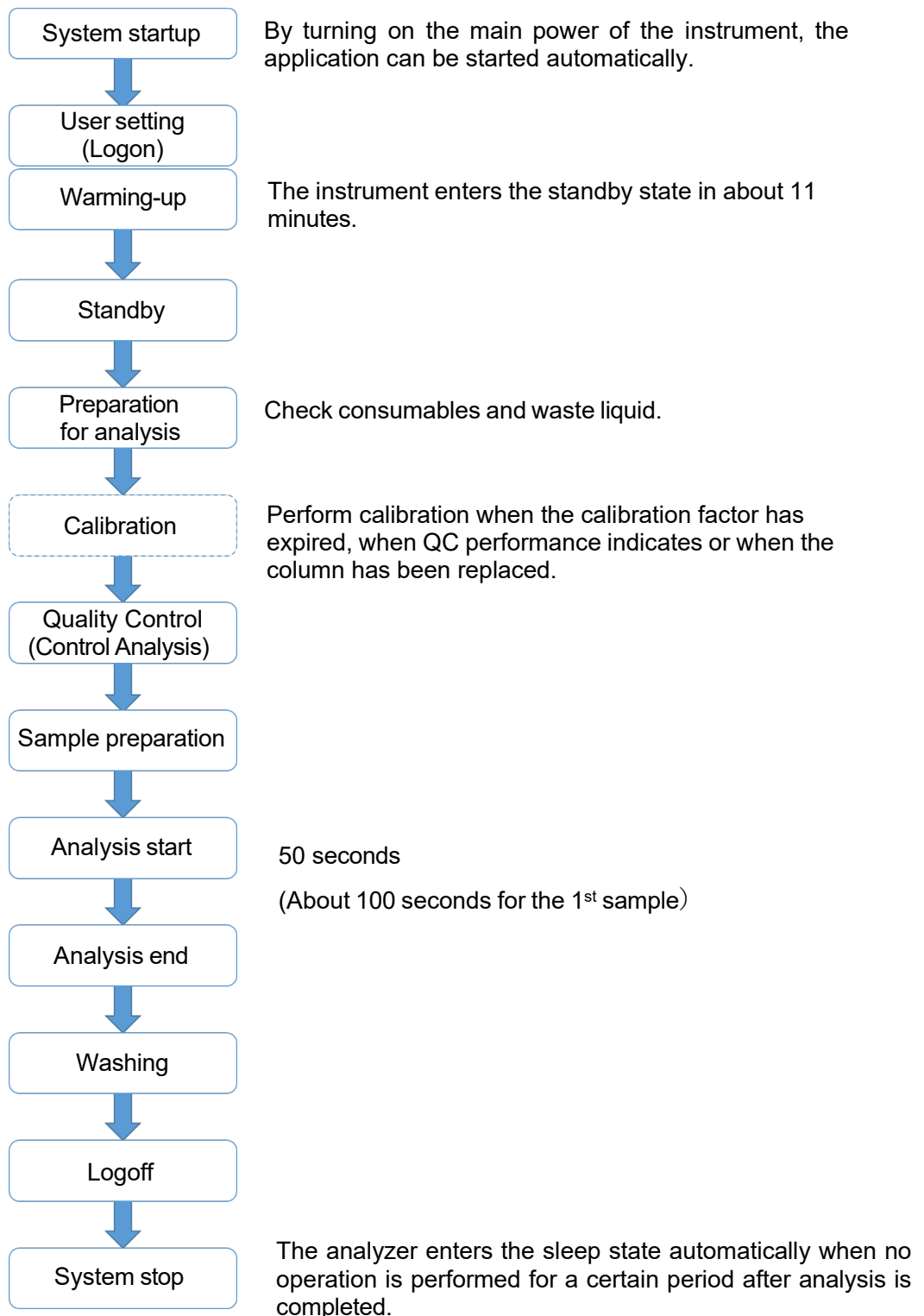
No.	Button/Display	Description
1	Date and time/logon user	Shows date at the top row, time at the middle row, and logon username at the bottom row.
2	User ID selection drop-down list	Select the desired user from the drop-down list of the registered users. The comment attached to the user is displayed below the drop-down list.
3	Password entry field	Enter the password of the selected user.
4	Sleep button	Tap to open the sleep confirmation screen.
5	Log off button	Tap to log off.
6	Log on button 	Tap to log on as the selected user.
7	Return button	Tap to return to the main screen.

# 5

## Analysis operation

### 5.1 Analysis Flow

The following chart shows the analysis flow.



## 5.2 System Startup

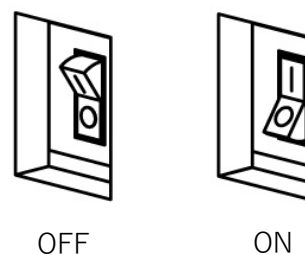
### NOTICE

**Do not turn off the main power switch of the instrument during startup except in case of emergency.**

- The screen may not be started properly. If no display appears on the screen after the main power switch is turned on, refer to “9 Troubleshooting (p.166)”.

### 5.2.1 System startup procedure

- 1 Turn on the main power switch.  
The main power switch is located on the left back of the instrument, viewed from the front.  
When the “|” side is pushed in, the main power switch is turned on. When the “○” side is pushed in, the main power switch is turned off.




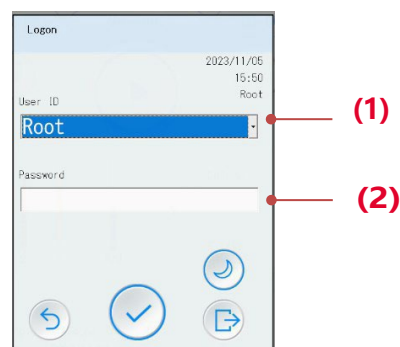
- **Note** • This main power switch serves as a breaker for overcurrent protection. If the main power switch is turned off immediately after it is turned on, there may be a current leakage.

- 2 Start the application.  
When the main power switch is turned on, the application starts up automatically.

- **Note** • If no display appears on the screen, the screen is not updated, or an error occurs during startup, an internal failure may have occurred on the instrument. Turn off the main power switch once and start from **Step 1** again.



- 3 Log on to the application and warming up starts.  
A logon screen appears.  
The instrument starts warming up (analyzer status: Warming up).  
Select a logon username (1), enter the password (2), and tap the log on button .



**Reference**

- To add or edit a user, or change the password, refer to “7.4 User account settings (p.160)”. A logon is necessary.

- 4** The analyzer enters the “Standby” state.  
After warming up is completed, the analyzer status changes to “Standby”, and the instrument is ready for analysis.

The analyzer enters the sleep state automatically when no operation is performed for a defined period.

- **Reference** • For setting the time period until the analyzer enters the sleep state, refer to “4.9.6 Timer settings screen (p.88)”.

## 5.3 Preparation for Analysis

Before starting analysis, check consumables and waste liquid.

**Note**

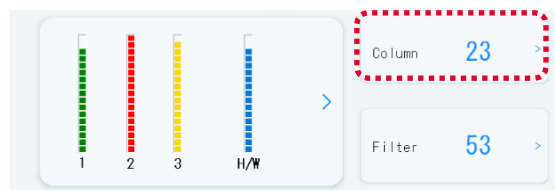
- In daily check, check necessary supplies in addition to the items in this section.

### 5.3.1 Checking the column

#### Injection count of the column

Check the injection count of the column and that no warning mark has appeared on the Column count/Column replace button.

When the warning mark appears, replace the column with a new one (Section 6.4.4 Replacing the column). The TSKgel GR01 HbA1c Column injection lifetime is 5,000 injections (column count).



#### Expiration date of the column

Check the expiration date of the column indicated on its label.  
An expired column cannot be used for analysis.

**Note**

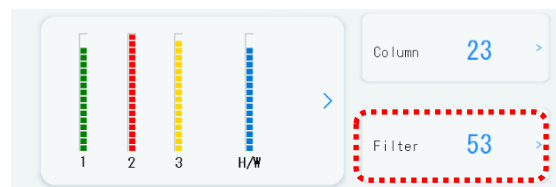
- The injection count of the column is managed based on serial number.
- If the column is replaced with a column previously used, the column count starts from the previously counted number.

### 5.3.2 Checking the filter element

#### Injection count of the filter element

Check the injection count for the filter element and that no warning mark has appeared on the Filter element count/Filter element replace button.

When the warning mark appears, replace the filter element with a new one (Section 6.4.3 Replacing the filter element). The filter element injection lifetime is 600 injections.

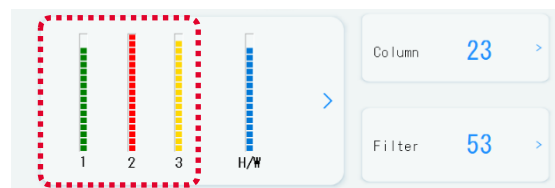


### 5.3.3 Checking the elution buffers

#### Remaining volume of each elution buffer

Check the remaining volume of each elution buffer on the main screen.

If the volume is insufficient for the number of samples expected for analysis, replace the elution buffer.



#### Expiration date of each elution buffer

Check the expiration date of each elution buffer indicated on its aluminum bag label.

An expired elution buffer cannot be used for analysis.

#### Expiration date of each elution buffer (after opening)

The expiration date of each elution buffer after opening is 90 days unless its expiration date is shorter.

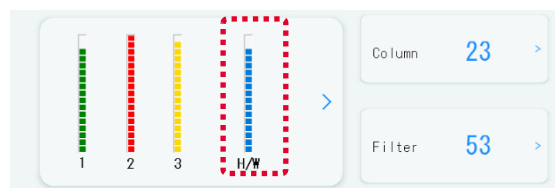
An elution buffer for which more than 90 days have passed after opening or the expiration date after manufacturing has passed cannot be used for analysis.

### 5.3.4 Checking the Hemolysis & Wash solution

#### Remaining volume of the Hemolysis & Wash solution

Check the remaining volume of the Hemolysis & Wash solution on the main screen.

If the volume is insufficient for the number of samples expected for analysis, replace the Hemolysis & Wash solution.



#### Expiration date of the Hemolysis & Wash solution

Check the expiration date of the Hemolysis & Wash solution indicated on its bottle label.

An expired Hemolysis & Wash solution cannot be used for analysis.

#### Expiration date of the Hemolysis & Wash solution (after opening)

The expiration date of the Hemolysis & Wash solution after opening is 90 days unless its expiration date is shorter.

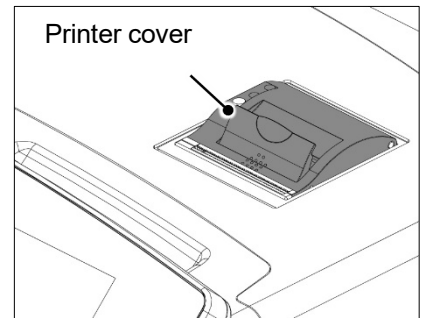
A Hemolysis & Wash solution for which more than 90 days have passed after opening or the expiration date after manufacturing has passed cannot be used for analysis.

### 5.3.5 Checking the remaining quantity of the printer paper roll (for the internal printer)

#### Remaining quantity of the printer paper roll

When [Internal] is selected for [Printer selection] on the Print/PDF settings screen, check the remaining printer paper roll through the printer cover.

When a red line appears on both sides of the paper, replace the roll with a new one. (Only about 8 sample results can be printed in the standard format on the remaining paper.)



For printer settings, refer to “7.3 Print/PDF settings (p.158)”.

#### Note

Even if the printer paper roll runs out during analysis, the result can be printed after all sample analyses are completed because the results are stored in the memory of the instrument.

About 230 sample results can be printed with one roll. (It depends on the print format.)

To refill the printer paper roll for the external printer, refer to the operator's manual of the external printer.

### 5.3.6 Checking the waste liquid

#### Waste tank

Visually check that the waste tank has sufficient capacity.

### 5.3.7 Checking the suction filters

#### Expiration date of the suction filters

The expiration date of the suction filters is 6 months after replacement.

Suction filters for which more than 6 months have passed after replacement cannot be used for analysis.

To check the suction filters' expiration date, refer to “**1** Suction filter replacement history screen (p.76)”.

### 5.3.8 Checking the calibration

#### Expiration date of the calibration factor

The expiration date of the calibration factor is 30 days after the latest calibration.

To perform calibration when the calibration factor has expired or when calibration is necessary, such as when the column has been replaced or other reasons, refer to “5.4.4 Calibration Procedure (p.105)”.



## 5.4 Calibration

### 5.4.1 About calibration

The analyzer requires calibration using 2 levels of calibrators with different values of HbA1c (%).

As calibrators, only the "HbA1c Calibrator Set (S)" (Part No.: 0023502) can be used with the HLC-723GR01. No other calibrators can be used.

### 5.4.2 When is calibration necessary?

Be sure to perform calibration when:

#### **The column has been installed**

Be sure to perform calibration when a new column has been installed.

#### **The control analysis value is out of the reference range**

Be sure to perform calibration when the analysis value of one or more QC control(s) is/are out of the reference range.

#### **The expiration date of the calibration factor has expired**

The expiration date of the calibration factor is 30 days after the latest calibration.

When the expiration date has been reached, a warning appears. Perform calibration.

#### **The flow factor setting has been changed**

Be sure to perform calibration after performing a flow factor adjustment following "7.1.5 Flow factor (p.154)".

### 5.4.3 Reconstituting the Calibrator

Refer to the Instructions For Use provided with the calibrator set for details of the proper handling of "HbA1c Calibrator Set (S)" (Part No.: 0023502).

- Lyophilized human hemoglobin component is sealed in the vials in the calibrator set. Store unsealed vials in a refrigerator at 2 to 8°C and use them before the expiration date.
- When using the calibrator, open the vial, and dissolve the component according to the Instructions For Use of the calibrator set.
- The expiration date after reconstitution is indicated in the Instructions For Use of the calibrator set.



## NOTICE

**Never use an expired calibrator.**

### 5.4.4 Calibration Procedure

- 1 Tap the calibration reserve button on the main screen.  
When entering the information using the handheld barcode scanner, go to **Step 2**.  
When entering the information manually, go to **Step 4**.

Calibration

$Y = 1.1492X + 0.6164$

CAL Date 2023/11/16

Exp. Date 2023/12/16

Remainings 29 Day(s)

- 2 Register the calibrator.  
(When entering the information using the handheld barcode scanner)  
Read the barcodes (1) and (2), and (3) [The reading position is different depending on the CAL Type ([NGSP]).] on the barcode sheet provided with the HbA1c calibrator set.

HbA1c Calibrator Set (S) Barcode Sheets

LOT ZB2010 2024-06

(1) (2) (3)

IFCC Aligned Value

HbA1c Calibrator (1): 40.1 mmol/mol

HbA1c Calibrator (2): 94.8 mmol/mol

NGSP Aligned Value

HbA1c Calibrator (1): 5.82 %

HbA1c Calibrator (2): 10.82 %

- 3 Make sure that the calibrator information is entered properly in the [CAL1 asg. value], [CAL2 asg. value], [Lot No.], and [Exp. Date] fields on the calibration settings screen.  
Go to **Step 5**.

Calibrator Reservation

CAL Type NGSP (IFCC)

CAL1 asg. value 5.83 Lot No. J082010

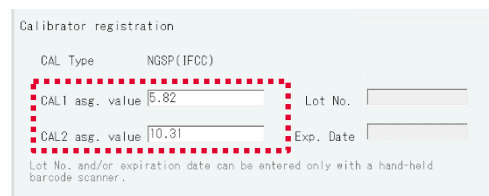
CAL2 asg. value 10.68 Exp. Date 2025/01/31

Lot No. and/or expiration date can be entered only with a hand-held barcode scanner.

**Note**

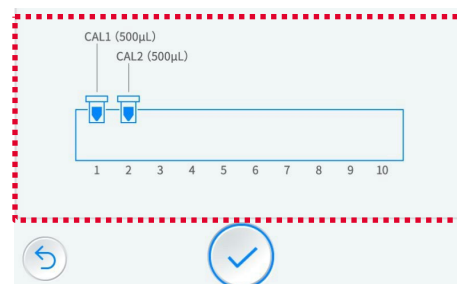
- If a wrong barcode is read, read the correct barcode again.
- To clear the information in the [Lot No.] and [Exp. Date] fields, return to the main screen, and open the calibration settings screen again.

- 4** Register the calibrator.  
(When entering the information manually)  
Tap the blank [CAL1 asg. value] field.  
Enter the assigned value of the Calibrator (1) correctly using a screen keyboard.  
Also tap the blank [CAL2 asg. value] field and enter the assigned value of the Calibrator (2) correctly.


**Note**

- The information cannot be entered manually in the [Lot No.] and [Exp. Date] fields.


- 5** Set the reconstituted calibrators on the sample rack as indicated in the diagram on the screen.  
Be sure to use the 1<sup>st</sup> sample rack.

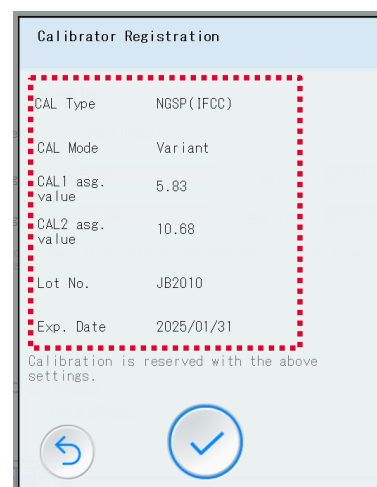


- 6** Make sure that the correct assigned values are displayed in the [CAL1 asg. value] and [CAL2 asg. value] fields and that the calibrators are set properly as indicated in the diagram.

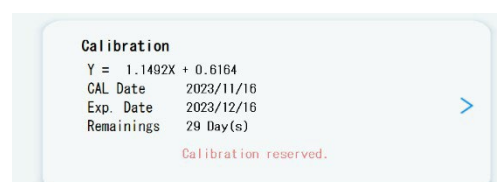
Then, tap the calibration register button .

- 7** Check the reserved calibration contents on the calibration reservation confirmation dialog.

Then, tap the set button .



- 8** “Calibration reserved.” appears at the lower part of the analysis start button.  
Tap the analysis start button to start calibration.



## NOTICE

**Make sure that the assigned values of the calibrators displayed on the screen match the assigned values indicated on the Instructions For Use of the calibrator set or the values provided on the calibrator vials.**

If a wrong value is entered, the obtained calibration factor is not correct, and reliable results cannot be obtained.

### Note

- By setting controls or samples at other positions of the sample rack on which the calibrators are set, analysis can be continued sequentially.

### 5.4.5 Sample No. of calibration results

A sample number in the 9000s (9001 to 9999) is automatically assigned to a calibration result.

Consecutive numbers are assigned from 9001 and restart from 9001 when the calibration date changes.

### 5.4.6 Calculation method of the calibration factor

The Calibrator (1) with the low value (about 6.0 %) is analyzed 3 times, and the Calibrator (2) with the high value (about 11.0 %) is analyzed twice, for a total of 5 times to calculate the calibration factor.

The first analysis result for the Calibrator (1) is discarded, and the average HbA1c (%) of the 2<sup>nd</sup> and 3<sup>rd</sup> analysis results is calculated as the analysis value of Calibrator (1). The average HbA1c (%) of the 4<sup>th</sup> and 5<sup>th</sup> analysis results is calculated as the analysis value of Calibrator (2). From those analysis values and the assigned values of the calibrators, the calibration factor is calculated using the following linear equation.

<b>Object of correction</b>	HbA1c (%)
<b>Calibration formula</b>	$(\text{HbA1c (\%)} \text{ after calibration}) = A \times (\text{HbA1c (\%)} \text{ before calibration}) + B$ $A = (\text{CAL2 assigned value} - \text{CAL1 assigned value}) / (\text{CAL2 analysis value} - \text{CAL1 analysis value})$ $B = \text{CAL2 assigned value} - \text{CAL2 analysis value} \times A$

### 5.4.7 Calibration error

A calibration error occurs when the calibrator analysis results meet the following conditions:

#### Error conditions

- The difference in the HbA1c (%) value between the 2<sup>nd</sup> and 3<sup>rd</sup> analysis results is 0.3 % or more.
- The difference in the HbA1c (%) value between the 4<sup>th</sup> and 5<sup>th</sup> analysis results is 0.3 % or more.
- The average HbA1c (%) value of the 2<sup>nd</sup> and 3<sup>rd</sup> analysis results is  $\pm 30$  % or more than the assigned value.
- The average HbA1c (%) value of the 4<sup>th</sup> and 5<sup>th</sup> analysis results is  $\pm 30$  % or more than the assigned value.

A calibration error also occurs when the analyzer recognizes sample tubes instead of sample cups during calibration.

When an error occurs, the analysis is automatically stopped. Samples set at other positions of the same sample rack will not be analyzed and the calibration reservation will be canceled. Since calibration has not been completed, it is necessary to reserve calibration again before sample analysis can start.

Possible causes of calibration errors are as follows:

- The Calibrators (1) and (2) are set in the wrong positions of the sample rack.
- The entered assigned values of the calibrators are incorrect.
- The calibrators were not reconstituted properly.
- The expiration date of the calibrator has passed.
- Samples other than the calibrators were analyzed.
- The column lot No. does not match the Elution Buffer No. 1 and/or No. 2 lot number.
- The expiration date of the column or an elution buffer has passed.
- The calibrators are in sample tubes, not in sample cups.

If a calibration error occurs, troubleshoot the cause of the error by referring to the above, and perform calibration again.

## 5.5 QC (Quality control)

### 5.5.1 QC material and control barcode label

Prepare a control and barcode label to register the QC material.

This section describes the procedure for registering QC material using the Hemoglobin A1c Control Set (manufactured by Tosoh) (Part No.: 0021974) and the provided control barcode labels in the Accessory Kit (barcode standard: CODE39).

The end user can create their own control labels using the barcode standard previously registered in the instrument.

There is no limit to the number of QC materials that can be registered. Up to 6 QC materials can be enabled (the [Valid] switch is set to [ON]).

Once the QC material is enabled (the [Valid] switch is set to [ON]), when a sample barcode with the registered CTL ID is read, the sample will be recognized as a QC sample. To obtain the QC data, it is necessary to enable the corresponding QC material.

For reconstituting the Hemoglobin A1c Control Set (manufactured by Tosoh) refer to the Instructions For Use of the control set.

### NOTICE

#### The QC materials analysis uses the diluted samples setting.

- When the information on the control barcode label matches the registered CTL ID, the sample is measured as a diluted sample regardless of the sample container.
- Attaching a registered control barcode label to a whole blood sample will result in an AREA TOO HIGH flag.

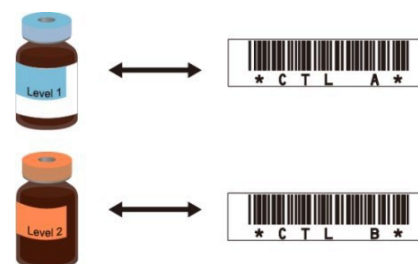
#### Note

- To use the provided barcode label, register the barcode settings for CODE39. If the CODE39 settings are changed from the initial settings, the Control barcode label may not be read properly.
- Multiple QC materials can be registered for one CTL ID. However, only one of those QC materials can be enabled.
- When a QC material is deleted, the QC data previously obtained with the deleted QC material will also be deleted.
- To allow viewing past trend graphs in the future, it is recommended to disable the QC material (set the [Valid] switch to [OFF]), instead of deleting the QC material.

## 5.5.2 Registering QC materials

### 1 Registering new QC materials


- 1 Prepare barcode labels allocated to each control.  
For example, a control level 1 is assigned to the “CTL A” barcode, and control level 2 to the “CTL B” barcode.



- 2 Tap the QC button  on the result screen to open the QC screen.

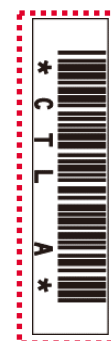
No.	ID	IBAtc (T)	Flac #	Mode
9010	0001 - 04		9.2	S
9009	0001 - 04		9.2	S
9008	0001 - 03		4.6	S
9007	0001 - 03		4.6	S
9006	0001 - 03		4.6	S
9005	0001 - 02		9.8	L
9004	0001 - 02		9.8	L
9003	0001 - 01		4.5	L
9002	0001 - 01		4.5	L
9001	0001 - 01		4.5	L

- 3 Tap the [Settings] button to switch to the QC screen.

Tap the QC material register button . Register the CTL ID one by one as the QC material.

CTL ID	Lot No.	Level	Tex	General Tolerance	General Range	Valid
CTL C	ABERE	2	IBAtc	9.5	9.5	✓
CTL B	ABERE	1	IBAtc	5.6	9.3	✓

- 4 Read the barcode specified in **Step 1** using the handheld barcode scanner as a CTL ID. If the handheld barcode scanner is not connected, or the barcode standard of the label is COOP 2 of 5, enter the CTL ID manually.



#### Note

- The analyzer recognizes a sample with the sample barcode matched with the registered ID as QC material. If the manually entered CTL ID is incorrect, the analyzer cannot recognize the sample as QC material.
- Do not enter the start/stop characters “\*\*”.
- The handheld barcode scanner does not support the barcode standard of COOP 2 of 5.

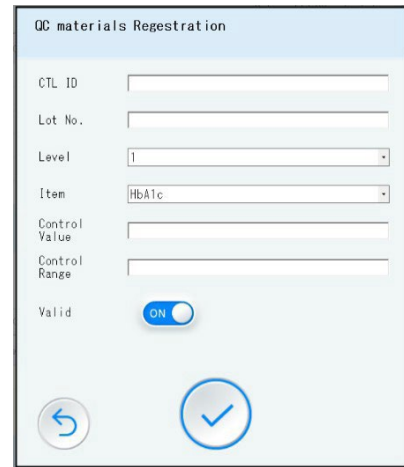
- 5 Register the lot No., control value [%], and control range [%] of the QC material.  
Prepare the Hemoglobin A1c Control Set 2D Barcode Sheet.



Read the 2D barcode sheet using the handheld barcode scanner.

When the handheld barcode scanner is not connected, manually enter the information described in the Instructions For Use of the control set.

- 6 Make sure that the displayed contents match the information described in the Instructions For Use of the control set.  
To enable this control as a QC material for QC trend graphs, set the [Valid] switch to [ON].  
Then, tap the register button .  
To register another control, repeat the steps from **Step 5**.



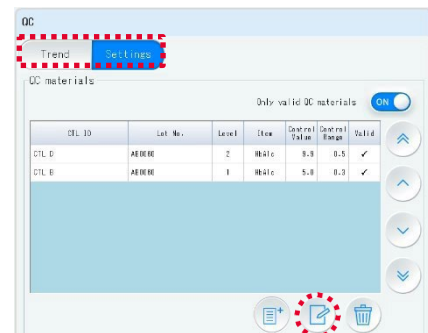
## Editing QC material information

- 1 Tap the QC button on the result screen to open the QC screen.

✓	No.	★	ID	HbA1c [%]	Flan <sup>o</sup>	Mode
	9010		0001 - 04	9.2		S
	9008		0001 - 04	9.2		S
	9008		0001 - 03	4.6		S
	9007		0001 - 03	4.6		S
	9006		0001 - 03	4.6		S
	9005		0001 - 02	8.8		L
	9004		0001 - 02	8.8		L
	9003		0001 - 01	4.5		L
	9002		0001 - 01	4.5		L
	9001		0001 - 01	4.5		L

- 2 Tap the [Settings] button to switch to the QC screen.

Tap the QC material edit button .  
Edit a QC material information separately.

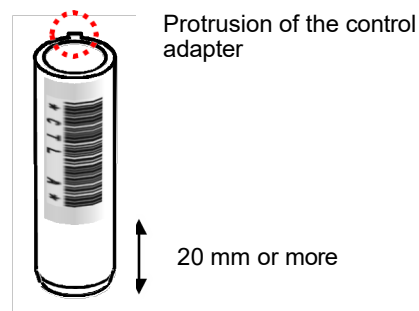


- 3 Edit the QC material information.  
The following items can be edited:
  - Control value (assigned value to control)
  - Control range
  - [ON] or [OFF] of the [Valid] switch

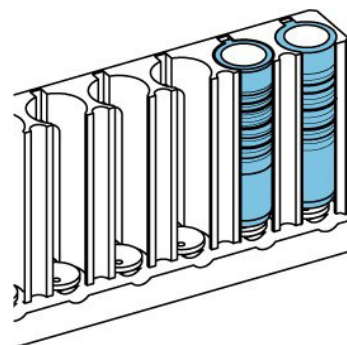
### 5.5.3 Analyzing QC materials

Since controls are recognized automatically as QC materials from the barcode labels attached to the control adapters, controls can be set on the sample rack together with other samples.

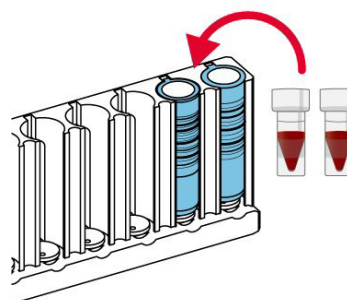
- 1** Attach the barcode label to the control adapter according to the following conditions:
  - When attaching the barcode label, leave at least 20 mm of space from the bottom of the control adapter.
  - Attach the barcode label to the label reading surface (opposite side of the protrusion of the control adapter).
  - Attach the barcode label vertically.
  - Attach the barcode label to the surface of the control adapter.



- 2** Set control adapters with the barcode label facing the front, on the sample rack, according to the type or number of QC materials.



- 3** Dispense a minimum of 0.5 mL of prepared QC material into each sample cup. Set each sample cup into the control adapter with the corresponding barcode label.



- 4** Set other samples on the sample rack that will be analyzed in the same batch. After the QC material is analyzed, the analysis result will be displayed automatically on the QC screen.

## 5.5.4 Checking QC results

QC results can be checked even when the analyzer status is "Analysis".

However, the results of QC materials analyzed while the QC screen is opened will not be displayed on the QC screen. Close the QC screen, and open it again to update the QC screen.

QC materials cannot be registered, edited, or deleted when the analyzer status is "Analysis".

### Note


- It is recommended that at least two levels of controls be run at least once per day. If one or more control samples are out of the established ranges, it is necessary to investigate the cause.  
Rerun the controls / Reconstitute and run new controls / Recalibrate and run controls / Contact Tosoh Technical Support

- Tap the QC button  on the result screen to open the QC screen.

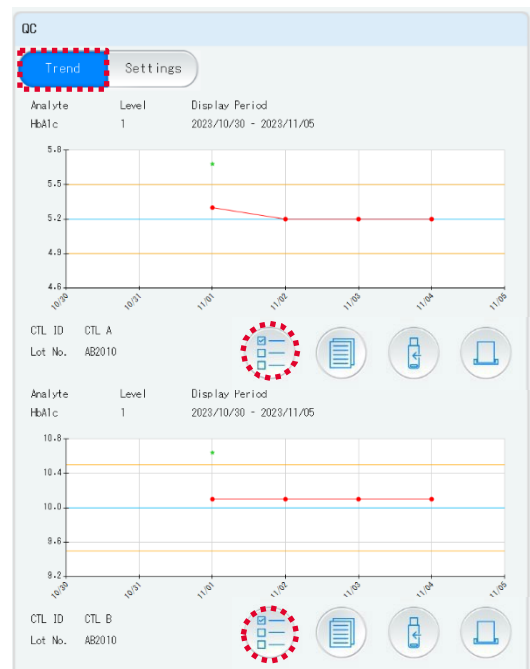
✓	No.	★	ID	HbA1c [文]	Flag
	0004		0002 - 02	10.6	
	0003		0002 - 01	5.4	
	9018		0001 - 02	8.9	
	9017		0001 - 02	8.9	
	9016		0001 - 01	4.5	
	9015		0001 - 01	4.6	
	9014		0001 - 01	4.5	
	0002		0001 - 02	10.4	
	0001		0001 - 01	5.4	
	9013		0001 - 02	9.0	




- Tap the [Trend] button to switch to the QC trend screen.

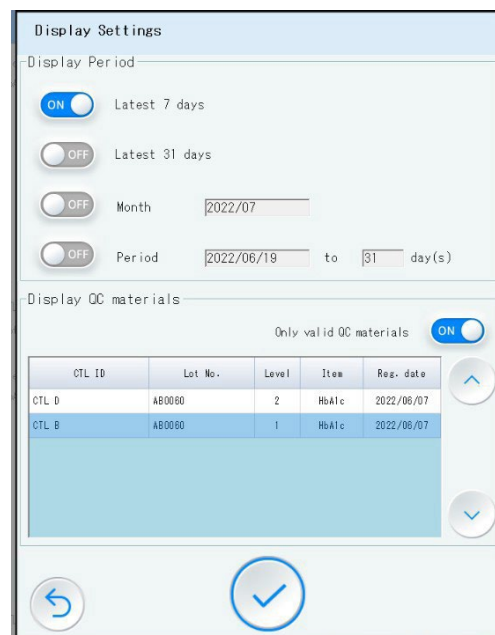
Tap the display period/QC material selection

button  to select the display content. If this step is not necessary, skip to **Step 4**.

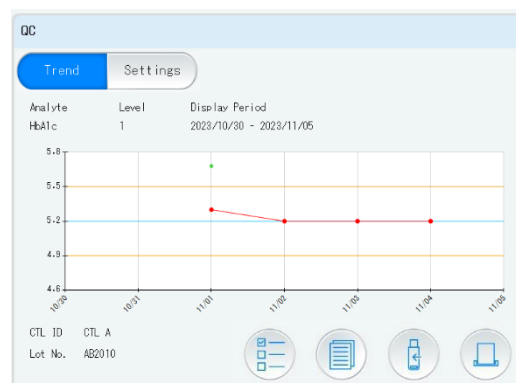
The trend graphs of different QC materials or during different time periods can be displayed at the upper part and lower part of the screen.



- 3 Tap  and  to select the desired display period from [Latest 7 days], [Latest 31 days], [Month], or [Period]. Tap the set button .



- 4 Check the trend graphs.  
 Blue line: control value (assigned value)  
 Yellow line: control range for the control value  
 • : average value of a day  
 ▲ : maximum or minimum value of a day  
 ★ : date at which the calibration was performed



- 5 Check the detailed data.  
 The analysis results of the QC materials during the period specified in **Step 3** are displayed in the list.

- ① The chromatogram of the selected result can be displayed.
- ② The selected result can be deleted. The deleted result will be excluded from the trend graph.
- ③ The mean value (Mean), standard deviation (SD), and coefficient of variation (CV%) are shown as QC data (statistical values) based on the analysis results included during the specified period (excluding the deleted results).

Date	No.	HbA1c	Range	Flagged	Reject Code	Reject
2022/07/19	3	5.2				...
2022/07/20	9	5.3				...
2022/07/20	10	5.3				...
2022/07/20	12	5.3	!		C	...
2022/07/21	1	5.3	!		C	...

Mean	5.27
SD	0.06
CV %	1.10

If using Control material from another vendor, contact Tosoh Technical Support.

## 5.6 Preparing a sample

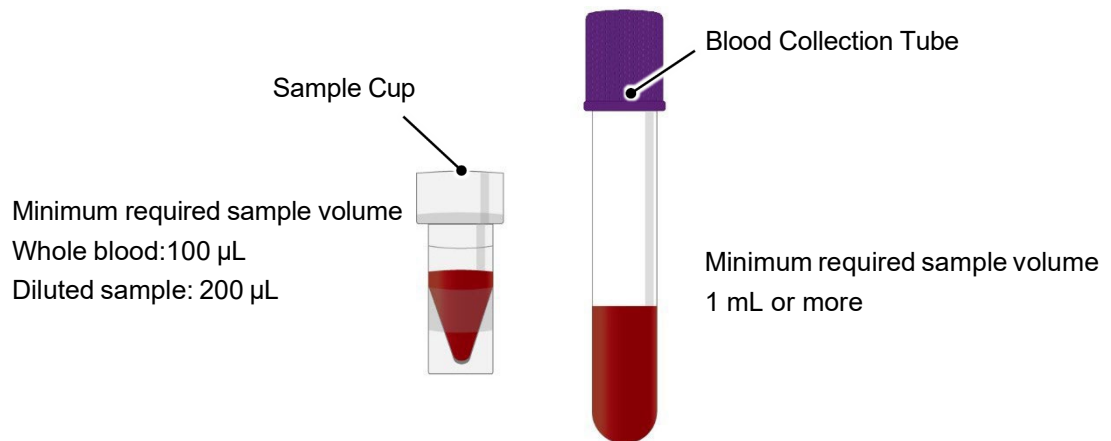
### 5.6.1 Samples

Venous whole blood and manually diluted whole blood/hemolysate samples can be used with this analyzer.

Blood collection tubes (K2 EDTA and/or K3 EDTA tubes) can be used for the HbA1c assay (refer to the column Instructions For Use). Manually diluted whole blood/hemolysate samples can be tested using sample cups.

### 5.6.2 Sample containers

Blood collection tubes (sample tubes) and dedicated sample cups can be used with this analyzer.



#### Sample tubes

Sample tubes with rubber caps can be directly set on the sample rack. Before setting the sample tubes on the sample rack, invert the sample tubes repeatedly to fully mix the contents. The sizes of sample tubes that can be directly set are 12 to 15 mm in diameter, 75mm to 100 mm in length.

The minimum required sample volume is 1 mL for whole blood. If there is only a small amount of whole blood, it is recommended to transfer it to a sample cup manually and analyze it as a STAT sample (see Section 5.8.1).

#### Note

- To obtain more accurate analysis results, it is recommended to invert the whole blood sample tubes repeatedly to fully mix the contents.
- If AREA TOO LOW or AREA TOO HIGH flag occurs, perform the STAT measurement.

### Sample tube diameter and appropriate adapter

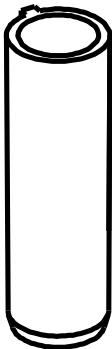

As shown in the following table, select the appropriate adapter depending on the diameter of the sample tube used or the sample type to be analyzed.

When using a sample tube that is 12 to 14 mm diameter, place the adapter in the sample rack, and then place the sample tube in the adapter. With GR-90SL or GR-290SL, an adapter for 13 mm is included as an accessory.

Adapters for 12 mm and 14 mm tubes can be purchased separately (Part No.: 0018496 or Part No.: 0018497, respectively).

For a sample tube of 15 mm, directly place the sample tubes in the sample rack.

When using sample tubes with barcode labels attached, make sure that the sample tubes are well placed on the sample rack, the sample tubes are rotated and that the label is not stuck to the sample rack or adapter.

Adapter name	Control adapter	Adapter for 12 mm Adapter for 13 mm Adapter for 14 mm
Corresponding sample loader	GR-90SL GR-290SL	GR-90SL GR-290SL
Sample tube	N/A	12 mm for 12 mm 13 mm for 13 mm 14 mm for 14 mm
Sample cup	Available (A barcode label can be attached)	Available only for 13 mm (A barcode label cannot be attached)
Shape		
Note	To use QC function, attach the barcode label to the adapter.	This adapter is manufactured by SYSMEX.

## NOTICE

**Insert the sample tubes straight into the sample rack.**

- If the sample tube is not inserted straight or not well-seated, the sampling needle could be bent as a result.

## NOTICE

**Use an adapter of the appropriate size depending on the diameter of the sample tube used.**

- If a larger adapter is used, the sampling needle could be bent or damaged.
- If a smaller adapter is used, the sample tube cannot be rotated, and then the barcode label cannot be read properly.

---

**Use control adapters only with the HLC-723GR01.**

- Sample cups may be misidentified as sample tubes.

---

**Do not use Tosoh sample racks previously used on models such as HLC-723G8.**

- Only SYSMEX racks can be used with the HLC-723GR01, regardless of the connected sample loader.

### Note

- For information on SYSMEX racks, contact Tosoh Technical Support.

### **Sample cups (diluted samples/hemolysates, calibrators, controls)**

Use a sample cup for diluted samples, calibrators, and controls.

When using a sample cup, use the appropriate cup adapter for the sample rack. For the appropriate adapter, refer to “**Sample tube diameter and appropriate adapter (p.116)**”. For calibrators and controls, refer to their IFUs.

### **Diluting a whole blood sample manually/Hemolysate preparation**

- 1** Add 5  $\mu\text{L}$  of a whole blood sample into a sample cup.
- 2** Add 750  $\mu\text{L}$  of Hemolysis & Wash solution, and mix thoroughly (dilution rate: 151 fold).

### Note

- If the manually diluted/hemolysate sample results are flagged with “AREA TOO LOW” or “AREA TOO HIGH”, reanalyze the sample by the manual dilution procedures described below.

“AREA TOO LOW”: Manually dilute 5  $\mu\text{L}$  of a whole blood sample with 500  $\mu\text{L}$  of Hemolysis & Wash solution and run in the “Diluted Blood” setting in the “Sample Condition” setting (Section 5.8 STAT Analysis)

“AREA TOO HIGH”: Manually dilute 5  $\mu\text{L}$  of a whole blood sample with 1000  $\mu\text{L}$  of Hemolysis & Wash solution and run in the “Diluted Blood” setting in the “Sample Condition” setting (Section 5.8 STAT Analysis)

## NOTICE

- **The maximum sample volume for a sample cup is 1 mL. If sample volume is larger, the sample may spill, possibly causing infection, contamination of other containers, or damage to the analyzer.**

- Biohazard materials may spill.

### **Sample cups (whole blood samples)**

Use a sample cup with whole blood if the sample volume is limited.

Set the sample cup at the STAT port to perform analysis as a STAT sample. For more details of STAT analysis, refer to “5.8 STAT analysis (p.123)”.

### (Reference) Sample cups (whole blood samples) using the sample rack

By specifying the sample condition setting, a whole blood sample in a sample cup can also be analyzed using the sample rack. This is done by setting the [Sample Condition] to [Whole Blood].

However, note that the analyzer will analyze a whole blood sample in a sample cup without automatic dilution if the [Standard] or [Diluted Blood] setting under [Sample Condition] is selected. In this scenario, the column and filter element will be saturated with a sample, and they must be replaced or washed, otherwise analysis cannot be performed after that.

For changing the sample condition setting, refer to “4.9.2 Analysis settings screen (p.83)”.

### 5.6.3 Checking the barcode label

The barcode reader in the analyzer reads the IDs on the barcode labels attached to the sample tubes and attaches the read IDs to the analysis results. The analyzer also compares the ID on the queries with the attached read IDs and sends the result with the attached read IDs to the host computer.

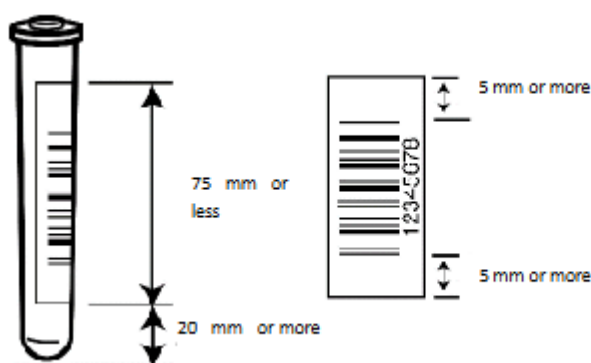
When using a sample cup, attach the barcode label to the optional control adapter.

When a barcode cannot be read properly or when a sample container without a barcode label is used, a sample rack number starting from 0001 (for the 1<sup>st</sup> sample rack after starting the analysis) and a position number (1 to 10) are assigned automatically. (e.g.: 0001-03 or 0008-01)

Be sure to attach the barcode label vertically. If the label is not attached vertically or is wrinkled, a reading error may occur.

#### Note

- When the [BC scan failure alarm] switch is set to [ON] on the barcode settings screen, a warning (Code: 671) is notified when the barcode cannot be read properly.
- When the [BC scan failure skip] switch is set to [ON] on the barcode settings screen, a warning (Code: 670) is notified when the barcode cannot be read properly, and analysis of the sample is not performed.
- For details of these settings, refer to “4.9.4 Barcode Settings Screen (p.86)”.



#### Note

- A 5-mm or larger margin space (quiet zone) should be left at the upper and lower part of the barcode label.
- The tilt angle of the barcode label should be within 5°.

- Do not attach the barcode label to the sample rack. Otherwise, the analyzer might read the barcode not of the sample but of the sample rack.

There are strict printing specifications for each barcode standard. Labels that do not conform to specifications (lines too thin, etc.) will result in a poor reading rate or may be completely unreadable. Contact your label printer manufacturer for printing specifications.

If the barcode is created following other standards than those of the initial setting, the barcode setting should be changed.

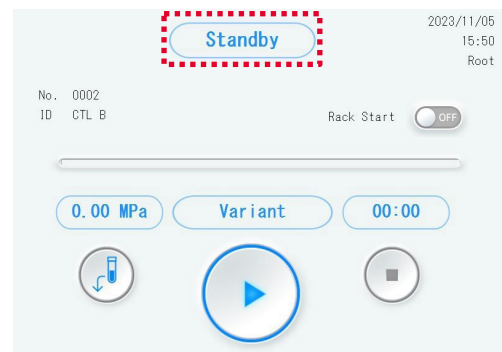
For readable barcode standards, refer to “11.1 Specifications of the HLC-723GR01 (p.197)”.

For changing the barcode settings, refer to “4.9.4 Barcode Settings Screen (p.86)”.

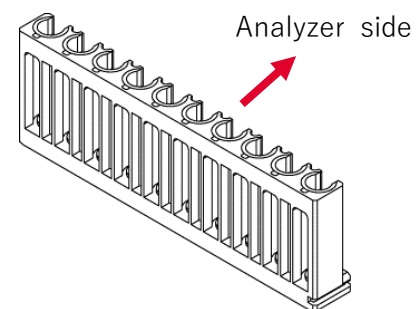
## 5.7 Analysis


### 5.7.1 Starting an analysis

- 1 Check the analyzer status.  
When the analyzer status is in “Standby” mode, analysis is started immediately after the analysis start button is tapped.  
When the analyzer status is “Warming up”, analysis is started when warming up is completed after the analysis start button is tapped.



- 2 Place samples in the sample rack and then load the sample rack on the sample loader.  
Be careful with the direction the sample rack is facing.  
For loading a sample rack, refer to “5.7.2 Loading a sample rack (p.120)”.



- 3 Tap the analysis start button  on the main screen.  
The analysis start button is also located on the common display (“4.3 Common display (Top part of the screen) (p.38)”).

#### Note

- When the [Rack Start] switch on the main screen is set to [ON], analysis is automatically started even when the analysis start button is not tapped.
- For details of the rack start function, refer to “7.1.2 Sample loader settings (p.154)”.

## 5.7.2 Loading a sample rack

### CAUTION

**Do not move the sample rack with your hands, or do not add a sample while the sample loader is in operation.**

- Users might catch their fingers in the moving parts.

### NOTICE

**When loading sample racks on the sample loader, be sure to engage the slit on the lower right side of the sample rack to the rail for overturn prevention on the sample loader.**

- Otherwise, the sample rack might be overturned.

#### **Loading sample racks on the GR-90SL**

With the GR-90SL, rack rotation is either enabled or disabled (the [Rack Rotation] switch on the analysis settings screen is set to [ON] or [OFF]). For changing the rack rotation setting, refer to “4.9.2 Analysis settings screen (p.83)”.

#### **Loading sample racks when rack rotation is disabled**

Load the 1<sup>st</sup> sample rack in area (A) as shown in the Top view of the GR-90SL on the next page and load subsequent sample racks from the back (analyzer side) in order. Up to 5 sample racks can be loaded in area (A).

#### **Loading sample racks when rack rotation is enabled**

Four (4) sample racks can be loaded in area (B) in addition to 5 sample racks in area (A). Therefore, a total of 9 sample racks can be loaded.

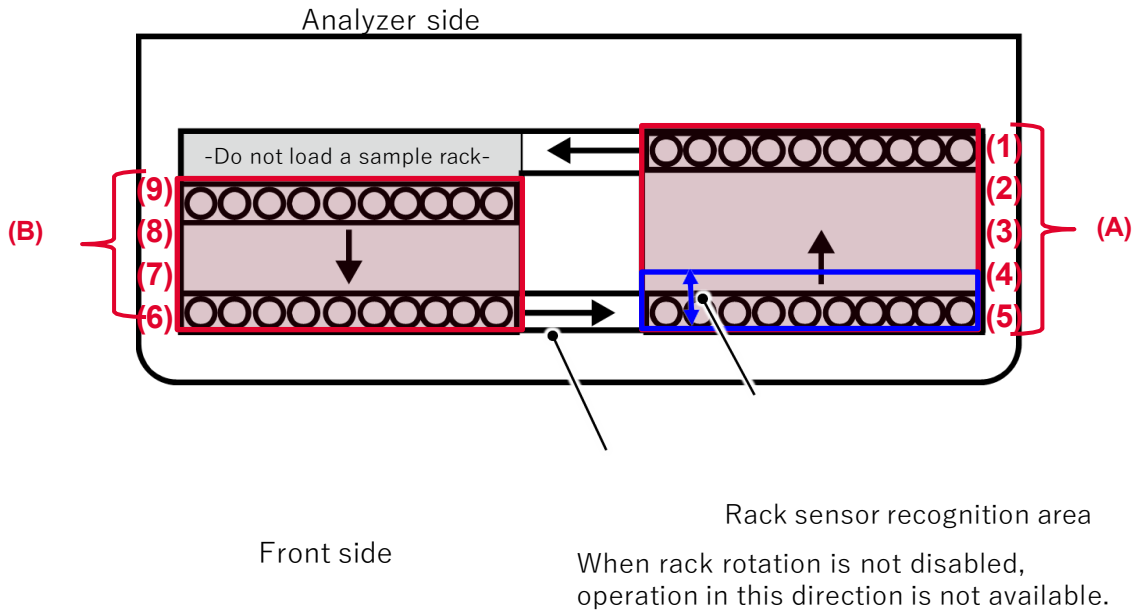
Then, load sample racks in area (B) from the front side in order, and leave a space for one sample rack on the analyzer side.

Insert an end marker to the last sample rack. An empty rack with no samples may also be loaded as the last sample rack.

#### Note

- When the rack start function is enabled (the [Rack Start] switch on the main screen is set to [ON]), analysis is automatically started when the rack sensor detects a sample rack.
- When the error LED is lit, such as when an error occurred or when analysis was aborted, analysis is not started automatically even when the rack start function is enabled.

**Top view of the GR-90SL**



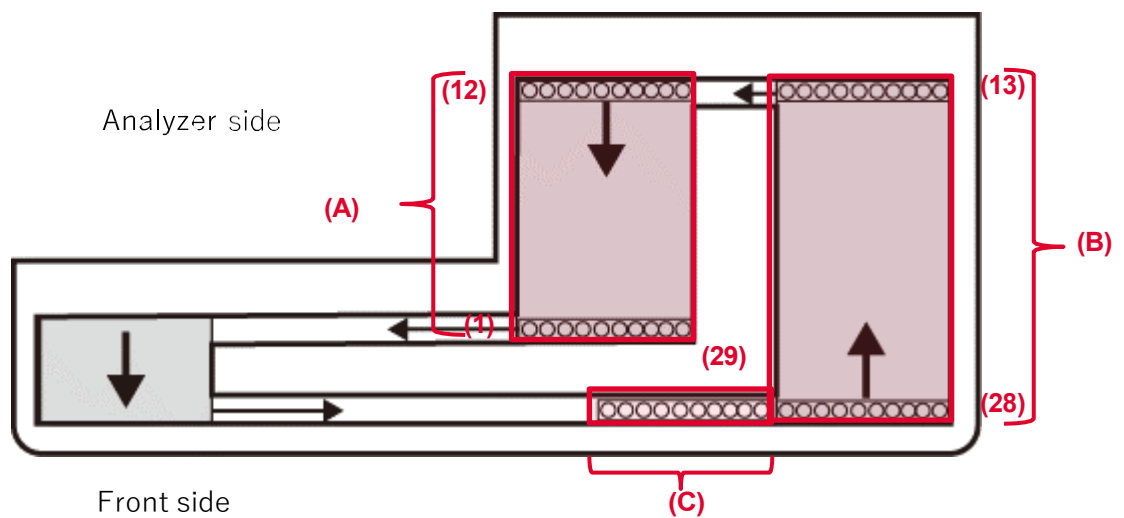
**Loading sample racks on the GR-290SL**

Load the 1<sup>st</sup> sample rack in area (A) as shown in the Top view of the GR-290SL below and load subsequent sample racks from the front side in order. Up to 12 sample racks can be loaded in area (A).

Then, load sample racks in area (B) from the analyzer side in order. Up to 16 sample racks can be loaded in area (B). Finally, load one sample rack in area (C), immediately next to the sample rack loaded in area (B). A total of 29 sample racks can be loaded.

The last sample rack needs to be with an end marker. An empty rack with no samples may also be loaded as the last sample rack.

**Top view of the GR-290SL**



### 5.7.3 Completing the run

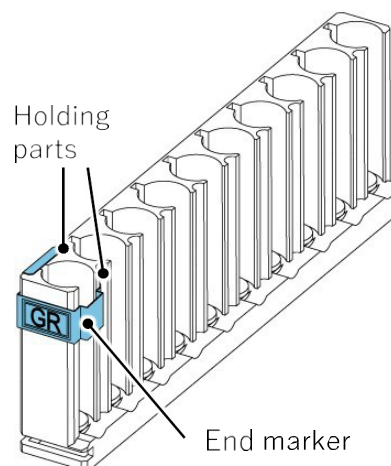
When using the GR-90SL or GR-290SL as a sample loader, attach an end marker to the last sample rack .

When the end marker is attached to the last rack (end rack), analysis automatically ends after analysis of all samples set on the sample rack is completed.

As an alternative to the end marker, an empty sample rack can also be used.

#### Attaching an end marker


- 1 Squeeze the end marker with your fingers until the opening is 6 to 8 mm wide.
- 2 Attach the end marker at the No.10 position of the last sample rack. Set its flat surface on the opposite side of the slit.
- 3 Make sure that the 2 holding parts are tightly fit to the sample rack.
- 4 Samples can be set at any position including the No. 10 position of the end rack (the sample rack to which the end marker is attached).



#### Note

- When using an end marker:
- Attach the end marker properly.
  - Use only an end marker with “GR”.

### 5.7.4 Stopping analysis for an emergency

To stop analysis in case of an emergency, tap the analysis stop button  on the main screen. The analysis stop button is also located on the common display (Refer to “4.3 Common display (Top part of the screen) (p.38)”).

When analysis is stopped, the analysis results of the sample for which analysis or data processing was in progress at that time will be discarded. The analysis results of the sample being sampled will also be discarded.

## NOTICE


**In case of emergency that might cause damage to the instrument or injury to users, be sure to turn off the main power or unplug the power cable.**

## 5.8 STAT analysis

### 5.8.1 STAT analysis procedure

#### When the analyzer status is in "Analysis"

If there is only a small amount of whole blood, it is recommended to manually transfer it to a sample cup and analyze it as a STAT sample. In addition, samples that were flagged with AREA TOO HIGH or AREA TOO LOW can be retested at different dilution settings using the STAT function.

- 1 Tap the STAT reserve button  on the main screen to open the STAT reservation screen.
- 2 Enter the ID for the sample to be analyzed.  
The ID can be read using the handheld barcode scanner (excluding the COOP 2 of 5 standard). Make sure that the ID is entered properly.  
When no ID is specified, a consecutive number starting from STAT8001 is assigned automatically.
- 3 Open the STAT port cover of the sample loader and place a STAT sample.  
Make sure that the sample tube or sample cup is fully inserted and close the STAT port cover.
- 4 Select Sample Condition from [Whole Blood] or [Diluted Blood]. For an illustration of STAT function sample processing, see Section 11.4.

#### Note

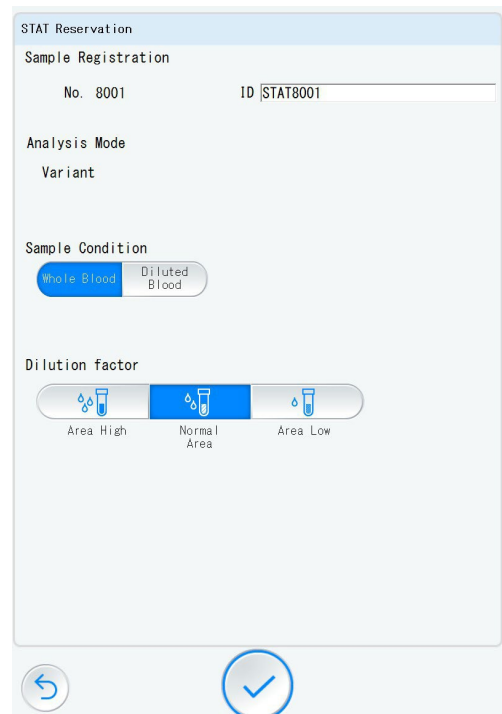
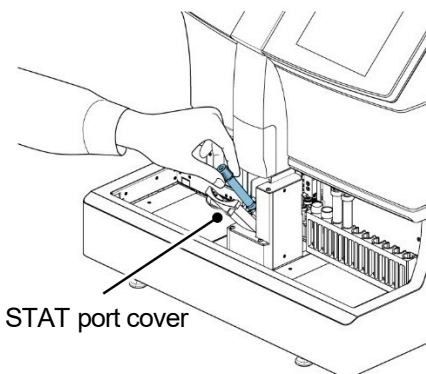
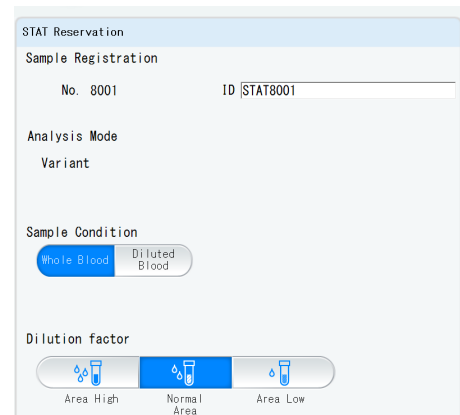
- Sample Condition is not the choice of sample container (sample tube or sample cup).
- The sample container type is automatically recognized by the analyzer.



When selecting [Whole Blood], also select the dilution factor.

Select [Area Low] for a sample previously flagged with an AREA TOO LOW flag.

Select [Area High] for a sample previously flagged with an AREA TOO HIGH flag.

Select [Normal Area] for a sample not previously flagged with an AREA TOO HIGH or AREA TOO LOW flag



- 5 Confirm that the specified information is correct and tap the confirm button . Following the sample for which analysis or sampling is in progress at that time, the STAT analysis is started.
- 6 The STAT reserve button  will be highlighted in blue. After the button color is returned to normal, the next STAT reservation can be accepted. STAT analysis can be reserved during calibration, the reserved STAT analysis will start after calibration is completed.

### **When the analyzer status is in “Standby”**

When the analyzer status is in “Standby”, not “Analysis”, STAT analysis can be immediately started with the sample set in the STAT port by tapping the confirm button: (analysis using a sample rack is not performed).

When the STAT confirm button is tapped in **Step 6**, STAT analysis is immediately started.

## CAUTION

**Never open the STAT port cover during STAT analysis or sampling from the STAT sample.**

- Otherwise, the sampling needle and analyzer may be damaged, or a user may get injured.
- STAT analysis may be stopped due to an error.

### **5.8.2 Sample No. assigned to a STAT sample**

A Sample number in the 8000s (8001 to 8999) is automatically assigned to a STAT result. Consecutive numbers are assigned from 8001 and are restarted from 8001 when a date changes.

## **5.9 Checking analysis results**

### **5.9.1 Checking analysis results**

With this analyzer, analysis results including chromatograms can be checked on the result screen or on the paper report printed by the internal printer.

Analysis results can also be checked using an optional external printer.

For details of the result screen, refer to “4.7.1 Result screen (outline) (p.43)”.

#### **Note**

- It is recommended to check chromatograms as well as the HbA1c values for all samples.
- When checking results sent to a testing system at each facility, refer to the host communication specifications at each facility.

## 5.9.2 Checking analysis results during analysis



Even when the analyzer status is in “Analysis”, results for completed samples can be checked on the result screen. Operations on the search screen and output screen are not allowed during analysis.

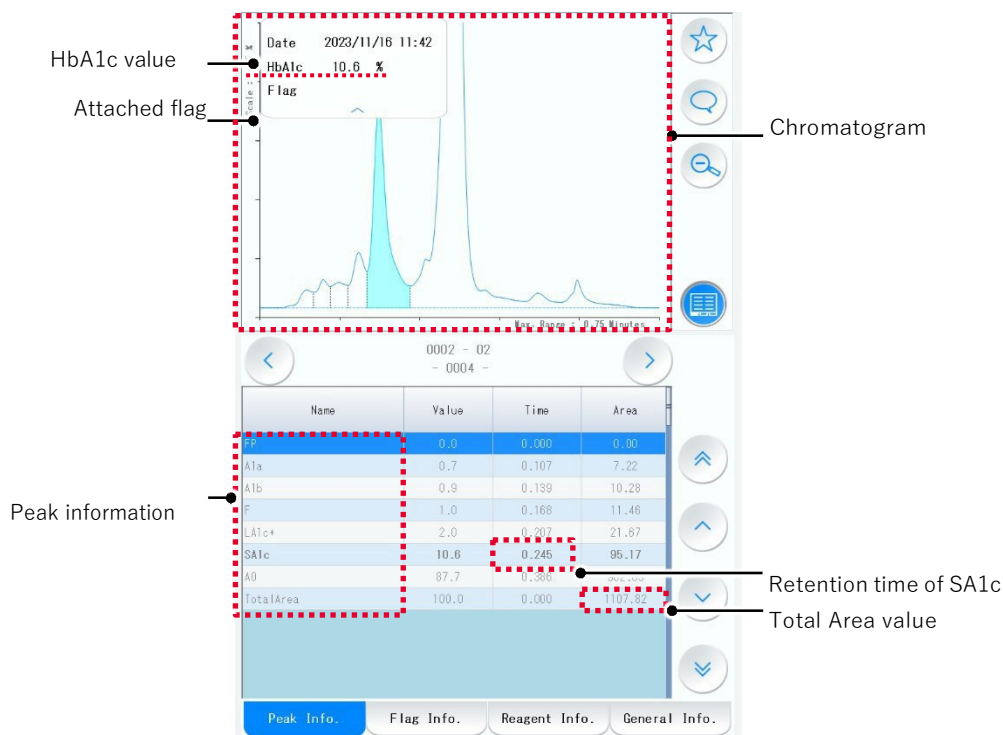
Real-time printing is available, and results can be printed using the internal printer or the external printer each time results are reported.

### Note

- When checking past analysis results, be sure to set the [Auto update] switch to [OFF].
- When analyzing a large number of samples, do not leave the [Auto update] switch set to [OFF] for a long time. When the [Auto update] switch is left to [OFF] for a long time, tap the update button after analysis is completed.

## 5.9.3 Results checking procedure

Tap the result button  on the main screen to move to the result screen. Tap the switch result display button  and the following screen appears.



Please note that the %HbA1c is calculated using the SA1c peak area and other peak area information. Only the reported %HbA1c value is validated and can be reported to the healthcare provider. These values can be used for troubleshooting purposes. Check the following items for each result.

### Attached flag

Check if a flag is attached or not.

When a flag is attached to the result, tap the [Flag Info.] tab to display the detailed flag information.

### HbA1c value

The value shows the HbA1c (%) value calculated with the calibration factors.

“SA1c” information shows the calculated HbA1c (%) value.

**Note**

- Since the HbA1c value is a calculated value, the total sum of the values (%) of all peaks may not be 100.0 %.

**Chromatogram**

The chromatogram shows the hemoglobin fractions separated by the column as they are detected. The vertical axis is adjusted so that 15 % of the SA1c value will be the full scale. The horizontal axis is the retention time from sample injection into the column. The peak identified as SA1c is highlighted in light blue.

**Note**

- By tapping the zoom-out button , the vertical axis is displayed in full scale.

**Peak information**

The Peak Names in the table below describe the peaks for the six expected hemoglobin fractions (A1A, A1B, F, LA1c+, SA1c, and A0). The other Peak Names are associated with hemoglobin variants and unknown peaks that may be detected.

Please note that the %HbA1c is calculated using the SA1c peak area and other peak area information. Only the reported %HbA1c value is validated and can be reported to the healthcare provider.

Peak name	Content
<b>FP</b>	Non-hemoglobin-derived peak called a front peak. Normally, this peak is not detected. For samples with a large volume of plasma, a large peak may be detected as FP.
<b>A1A</b>	Hemoglobin A1a peak, one of the hemoglobins detected in normal samples.
<b>A1B</b>	Hemoglobin A1b peak, one of the hemoglobins detected in normal samples.
<b>F</b>	Hemoglobin F peak, one of the hemoglobins detected in normal samples. This is also called fetal hemoglobin.
<b>LA1c+</b>	Labile hemoglobin A1c peak.
<b>SA1c</b>	Stable hemoglobin A1c peak. The calculated value is reported as HbA1c (%).
<b>A0</b>	Hemoglobin A0 peak, one of the non-glycated hemoglobins detected in normal samples. Normally, it has the largest area of the hemoglobin fractions.
<b>H-V0</b>	The presence of a peak in this window may indicate the presence of the hemoglobin D variant in the sample.
<b>H-V1</b>	The presence of a peak in this window may indicate the presence of the hemoglobin S variant in the sample.
<b>H-V2</b>	The presence of a peak in this window may indicate the presence of the hemoglobin C variant in the sample.
<b>H-V3</b>	The presence of a peak in this window may indicate the presence of the hemoglobin E variant in the sample.
<b>P00, etc.</b>	Unknown peaks. A number (e.g.: P00 and P01...) is assigned depending on the number of detected unknown peaks. The HbA1c (%) value is non-reportable when these peak are detected, and the result will have a Flag.

**Reference**

For more information about Variant peaks, refer to “2.5 Hemoglobin Variants (p.23)”. Please also see page 157 for more information related to Flag No. 40 and Flag No. 43 that are triggered when a peak is detected in a variant elution window.

### Checking the Total Area value

The Total Area value shows the sum of all peaks except for FP (unit: mV·s). This value depends on the hemoglobin concentration. The acceptable range of the Total Area value is 300 to 1800. When sampling whole blood directly from the sample tube, the analyzer automatically dilutes the sample at a fixed ratio (1:200). Normally, the Total Area value for samples will not be out of the range indicated above. Please follow the instructions below in case the "AREA TOO HIGH" or "AREA TOO LOW" flag is triggered.

"AREA TOO LOW" - For whole blood samples with a very low hemoglobin concentration, the Total Area may be below 300 in rare cases.

For such a sample, transfer it to a sample cup, and perform a STAT assay with the following.

- When manually preparing a hemolysate sample, dilute a larger volume of whole blood with Hemolysis & Wash solution manually (1:100), and select [Diluted Blood] for "Sample Condition" before analysis.
- When using automatic dilution in the analyzer, select [Whole Blood] for "Sample Condition", and [Area Low] for [Dilution Factor] for a 1:100 automatic dilution. For more details, refer to "5.8 STAT analysis".

"AREA TOO HIGH" - For whole blood samples with a very high hemoglobin concentration, the Total Area may be above 1800 in rare cases.

- When manually preparing a hemolysate sample, add a larger volume of Hemolysis & Wash solution manually (1:400), and select [Diluted Blood] for "Sample Condition" before analysis.
- When using automatic dilution in the analyzer, select [Whole Blood] for "Sample Condition", and [Area High] for [Dilution Factor] for a 1:400 automatic dilution. For more details, refer to "5.8 STAT analysis".



### Retention time of SA1c

[Time] shows the retention time of each peak.

The [Time] value (retention time) of SA1c is normally within the range of 0.240 to 0.255 (minutes). However, the value may be out of the range depending on the sample used.

If the [Time] (SA1c retention time) value is frequently out of the range indicated above, with the QC control and normal samples, contact Tosoh local representatives.

## 5.9.4 Search procedure


The search screen can be displayed by tapping the result button  on the main screen, and then tapping the search button  on the result screen.

### Simple search

Only with simple selection options, the following searches are available


- Search for favorite results
- Search for flagged results for the current day
- Search for the latest results using the specified sample number

### Search for favorite results

Only favorite results (for which the favorite button  is tapped) are listed on the result screen.

The search is performed on all past results stored in the instrument.

Select [Simple] for [Search Mode] on the search screen.

Set the [Favorite] switch to [ON] and tap the search button .



### Search for flagged results

Only flagged results on the same day are listed on the result screen.

Select [Simple] for [Search Mode] on the search screen.

Set the [Flagged (Today)] switch to [ON]

and tap the search button .




### Search for the latest results with a specified number

The latest results are listed on the result screen by specifying the number of results.

Search is performed from all past results stored into the instrument starting with the most recent ones.

Select [Simple] for [Search Mode] on the search screen.

Set the [Latest Analysis] switch to [ON], specify the number of search results from the drop-down list ([10], [25], [50], [100], [250], or [500]), and tap the search button .



## Advanced search

With more detailed settings than the simple search options, search results can be further narrowed down.

### Advance search procedure

- 1 [Analysis Date] (Required)  
To specify a specific date, enter the same date in both fields.
- 2 [Analysis Time] (Optional)  
Once entered, the specified time period is set as a search condition together with the setting specified in **Step 1**.
- 3 [Sample No.] (Optional)  
To specify the sample No. range, set the switch to [ON].  
  
The specified sample No. range is set as a search condition together with the setting specified in **Step 1**.  
  
When the time period is specified in **Step 2**, only results with a sample No. within the specified time period are listed.
- 4 Other items (Optional)  
In addition to settings specified in **Steps 1** to **3**, more detailed search conditions can be specified.

The screenshot shows a 'Search' screen with a 'Search mode' selector set to 'Advanced'. The interface includes several search criteria:

- Analysis Date:** Two date input fields, both set to 2023/11/15.
- Analysis Time:** A toggle switch (OFF), a time range from 00:00 to 24:00.
- Sample No.:** A toggle switch (OFF), a range from 0001 to 9999.
- Sample:** A toggle switch (OFF).
- Control:** A toggle switch (OFF).
- CAL:** A toggle switch (OFF).
- Flagged:** A toggle switch (OFF).
- HbA1c:** A toggle switch (OFF), a value of 8.0, a percentage sign, and 'or More'.
- HbF:** A toggle switch (OFF), a value of 5.0, a percentage sign, and 'or More'.
- Favorite:** A toggle switch (OFF).

At the bottom, there are two circular navigation buttons: a back arrow and a checkmark.

#### Note

- The maximum number of available search results is 4,000.
- If the number of search results exceeds 4,000, add search conditions by performing **Steps 2** to **4**.

## 5.9.5 Printing results / Saving results as PDF

### Real-time printing / saving as PDF

Each time analysis results are obtained, they can be printed or saved as a PDF on a USB memory stick.

- Real-time printing  
Real-time printing is available on either the internal or the external printer. Select [Internal] or [External] for [Printer selection] on the Print/PDF settings screen. Select [1] (1 copy for each result) or [2] (2 copies for each result) for [Copies No.]. Select [0] when not using real-time printing.
- Real-time saving as PDF  
Set the [PDF Output] switch to [ON] on the Print/PDF settings screen. Real-time saving can be used together with real-time printing.

A PDF file is saved for each analysis in the “GR01” folder and “ResultPDF” folder included in the “GR01” folder. When those folders do not exist, they will be automatically created.

The PDF data is created in the following format (about 5 KB):

“analysis year, date, and time (11-digit)\_Sample No. (4-digit)\_PDF creation year, date, and time (11-digit)”.

**Note**

- When a USB memory stick is not connected, PDF files are not stored.
- Prepare another USB memory stick for storing analysis results in addition to the system USB memory.
- An exFAT-format USB memory stick is recommended to store analysis results. With USB memory sticks in other formats, sufficient capacity is not secured and PDFs may not be stored. The USB memory sticks with a format that is not supported on Windows cannot be used with this instrument.
- An encrypted USB memory stick or a password-protected USB memory stick cannot be used with this instrument.
- For the location of the USB memory port, refer to “2.8 Units and functions (p.27)”.

### Reprinting saved results / resaving saved results as PDF

Analysis results saved in the instrument can be printed or saved as PDF on the USB memory stick. They can also be saved as a list file (.csv format) on the USB memory stick. Reprinting and resaving are not available during analysis.

#### Specifying the desired results

- 1 On the result screen, check the box of the analysis results to be printed, saved as PDF, or saved as a list file.  
Multiple selection is possible.
- 2 Tap the output button to open the output screen.
- 3 Select [Selected] for [Output Target].
- 4 When reprinting the saved results, set the [Print] switch to [ON], and select the number of copies from [1] (1 copy for each result) or [2] (2 copies for each result).
- 5 When resaving saved results as PDF, set the [Save as PDF] switch to [ON].
- 6 When saving results as list data, set the [Save as list data] switch to [ON].
- 7 Tap the output button.

#### Specifying the desired range

- 1 Tap the output button on the result screen to open the output screen.
- 2 Select [Range] for [Output Target].  
Specify the date range of analysis (year, month, and day) for [Analysis Date] (required).  
Specify the time range of analysis for [Analysis Time] (optional).  
Specify the sample No. range for [Sample No.] (optional).  
Only results within the specified date and time range and with the specified sample No.

can be reprinted or resaved as PDF.

- 3** When reprinting the saved results, set the [Print] switch to [ON], and select the number of copies from [1] (1 copy for each result) or [2] (2 copies for each result).
- 4** When storing saved results in PDF format, set the [Save as PDF] switch to [ON].
- 5** When saved results as list data, set the [Save as list data] switch to [ON].
- 6** Tap the output button.

### 5.9.6 Sending results to the host computer

Analysis results can be sent to the host computer via RS-232C communication.

Real-time transfer (results are sent to the host computer each time they are obtained) and batch transfer (results are sent to the host computer by selecting the desired results or specifying the desired range on the output screen after analysis) are available.

For host communication settings, refer to "7.5 Host communication settings (p.162)".

#### Real-time transfer

- 1** Make sure that the analyzer status is on "Standby".
- 2** Tap the communication button to open the communication settings screen ("4.9.8 Communication settings screen (p.92)").
- 3** Set the [Auto Upload] switch to [ON].
- 4** Once the setting is completed, the obtained results are automatically sent to the host computer.

#### Note

- It may take about 1 minute until communication is completed after analysis is completed.
- If an error occurs, the settings of the instrument or host computer may not be set properly.

#### Batch transfer (by selecting the desired results)

- 1** Make sure that the analyzer status is on "Standby".
- 2** On the result screen, check the box of the analysis results to be sent to the host computer.  
Multiple selection is possible.
- 3** Tap the output button to open the output screen.
- 4** Select [Selected] for [Output Target].
- 5** Set the [Host Communication] switch to [ON].
- 6** Tap the output button.

### **Batch transfer (by specifying the desired range)**

- 1** Tap the output button on the result screen to open the output screen.
- 2** Select [Range] for [Output Target].  
Specify the date range of analysis (year, month, and day) for [Analysis Date] (required).  
Specify the time range of analysis for [Analysis Time] (optional).  
Specify the sample No. range for [Sample No.] (optional).  
Only results within the specified date and time range and with the specified sample No. can be sent to the host computer.
- 3** Set the [Host Communication] switch to [ON].
- 4** Tap the output button.



## **5.10 Turning off the analyzer and screen display**

When analysis is completed, the analyzer automatically starts a wash operation. When the wash operation is completed, the analyzer status turns to “Standby”.

Analysis can be started even during a wash operation. When there is no additional analysis, turn off the screen display (sleep state).

The screen saver function to decrease the screen brightness during analysis is also available.

### **Sleep function**

The Sleep function can be started manually by tapping the user account button  on the main screen to open the user account screen, and then tap the sleep button .

Or the analyzer will enter the sleep state automatically when 60 minutes (initial setting) have passed without no touch operation during the “Standby” state or when 60 minutes (initial setting) have passed after analysis or manual operation is completed. For checking or changing the Sleep function settings, refer to “4.9.5 Alarm Settings screen (p.87)”.

To return from the sleep state, touch the screen.

The analyzer will start warming up, and a user is required to log on to the application.

### **Screen saver function**

When a specified time has passed after the last screen operation, the screen saver starts, and the screen brightness will decrease. Analysis will continue while the screen saver is running.

The log on status is maintained. However, once a specified time for the Log off timer has passed, a user is logged off.

By touching the screen, screen saver is canceled and then the screen is returned to the normal screen.

For checking or changing the settings, refer to “4.9.5 Alarm Settings screen (p.87)”.

### **Main Power off**

Turn off the main power of the analyzer if analysis is or will not performed for one week or longer.

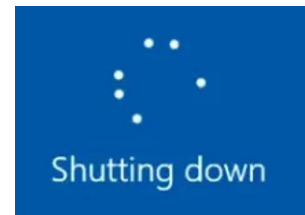
Also turn off the main power at least once a week.

**Note**

- If the main power is turned on for more than 10 days continuously, analysis cannot be performed from the 10th day on.
- Turn the main power off and on, and then analysis can start again.
- If Automatic Reboot is set [ON] and the Start-up Timer is set for at least once a week, it is not necessary to turn off the main power at least once every 7 days manually. Refer to “4.9.6 Timer settings screen (p.88)”

**Turning off the main power of the analyzer**

- 1** Make sure that the analyzer status is on “Standby”.
- 2** Turn off the main power of the analyzer.
- 3** The shutting down screen appears.
- 4** The screen becomes darker, and then the main power of the analyzer is turned off.



Shutting down screen

**Note**

- The PC is equipped with a small uninterruptible power supply (UPS) system. After the main power of the analyzer is turned off, the screen display and the PC are turned off.

**NOTICE**

**To restart the analyzer, make sure that the screen display was turned off and dark, wait for about 5 seconds, and then turn the main power on.**

- If the analyzer is not shut down properly or if the main power is turned on immediately after shutdown, no display may appear on the screen.
- If no display appears on the screen even after the main power of the analyzer is turned on, refer to “9.8 When no display appears on the screen (p.173)” in “9. Troubleshooting”.

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**In case of an emergency that may cause damage to the instrument or injury to users, be sure to turn off the main power or unplug the power cable regardless of the analyzer status.**

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# 6 Maintenance

## 6.1 About maintenance

Consumables and service life-limited parts are used with the analyzer.

Daily maintenance, regular replacement of consumables, and periodic maintenance must be performed to maintain stable performance and to obtain correct analysis results.

### 6.1.1 Manual Maintenance Procedures

Item to check	Frequency	Reference
Cleaning of the analyzer	When dirt is noticeable When necessary	"6.2.1 Cleaning of the analyzer (p.136)"
Preparation for analysis	Before every analysis	"5.3 Preparation for Analysis (p.101)"
Manual eluent feeding	When checking the pressure	"6.2.2 Manual eluent feeding (p.137)"
Line wash	Analysis results are unstable. When a Total Area value is too high.	"6.2.3 Line wash (p.137)"
Eluent priming	Analysis results are unstable.	"6.2.4 Eluent priming (p.138)"
Sample rack rotation	When checking operation	"6.2.5 Sample rack rotation (p.138)"
Sampler reset	When checking operation	"6.2.6 Sampler reset (p.139)"
Air removal from the pump	When the pressure does not rise during eluent feeding	"6.2.7 Air removal from the pump (p.139)"

### 6.1.2 Regular replacement of consumables (replacement by the customer)

Item to check	Frequency	Reference
Printer paper roll	When remaining paper is insufficient or paper has run out	"6.4.1 Replacing a paper roll (p.140)"
Hemolysis & Wash solution	When remaining volume is insufficient	"6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)"
Elution Buffer	When remaining volume is insufficient	"6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)"

Item to check	Frequency	Reference
Filter element	When the warning mark appears.	"6.4.3 Replacing the filter element (p.144)"
Column	When the warning mark appears.	"6.4.4 Replacing the column (p.146)"
Suction filters	Every 6 months	"6.4.5 Replacing the suction filters (p.149)"
Sampling needle*	When the needle is clogged or bent	"6.4.6 Replacing the sampling needle (p.150)"

\* Only personnel who have received the training can replace the sampling needle.

### 6.1.3 Periodic Maintenance (replacement by the service engineer )

Item to check	Frequency
Check the barcode scanner.	Every 20,000 tests or every year
Check the end marker sensor.	
Check the sample rack holder and the sample holder.	
Check the sample sensor.	
Check the needle descent position.	
Check the dilution port and wash block.	
Check the actuator of the sampling unit.	
Check the column oven temperature.	
Check the operation of the solenoid valves (4 locations).	
Check the operation of the vacuum pump.	
Check the operation of the waste pump.	
Replace the rotor seal of the injection valve.	
Replace the rotor seal of the rotary valve.	
Replace the sample loop.	
Wash or replace the pump check valve.	
Replace the plunger seal.	As determined by Tosoh personnel
Replace the needle O-ring.	
Replace or clean the waste filter.	
Replace the valve stator face.	
Replace the syringe L-tip.	As determined by Tosoh personnel
Replace the syringe (0.1 mL)	
Replace the drain valve O-ring	

**Note**

- For replacement of consumables or regular maintenance, contact Tosoh local representatives.

## 6.2 Daily maintenance

### 6.2.1 Cleaning of the analyzer

#### CAUTION

**Be sure to turn off the main power of the analyzer before cleaning.**

**If not turned off,**

- Users might catch their fingers in moving parts.
- Foreign objects, including clothes, might get caught in the moving parts, causing damage to the analyzer.

**Never remove a cover to clean the inner parts of the analyzer.**

- When dirt inside the analyzer, such as the waste port, is noticeable, contact Tosoh local representatives.

When blood or eluent adheres to the analyzer, immediately wipe it off with a wipe.

Otherwise, it may stick and cause corrosion.

If liquid may have leaked extensively, contact Tosoh local representatives.

For dirt stuck to the analyzer cover, wipe it off with a tightly wrung wipe moistened with a neutral detergent.

#### NOTICE

**Wipe off the plastic covers with a tightly wrung wipe moistened with sodium hypochlorite.**

- If cleaned using organic solvent such as ethanol, the covers may discolor.

For dirty metal parts, wipe the dirt off with a tightly wrung wipe moistened with a neutral detergent. If contaminated, wipe it off with a wipe moistened with 70% ethanol or isopropyl alcohol.

Moisture left on the surface may cause corrosion.


For dirt on the belt of the sample loader or the display, wipe it off with a wipe moistened with 70% ethanol or isopropyl alcohol.




## 6.2.2 Manual eluent feeding

To check eluent feeding pressure or that eluent is fed properly, perform manual eluent feeding for a specified time.

### Manual eluent feeding procedure

1 Make sure that the analyzer status is on “Standby”.

2 Open the maintenance screen and tap the manual operation button .

3 Tap the desired manual feeding button to start eluent feeding:  for Elution Buffer No.1,  for Elution Buffer No.2,  for Elution Buffer No.3.

4 Check the eluent feeding pressure from the [Pressure] value at the upper part of the screen. To stop eluent feeding, tap the manual feeding button again. Make sure that the [Pressure] value is 0 MPa.





## 6.2.3 Line wash

To wash the column and analyzer lines with eluent, perform a line wash. If analysis results are unstable or after a sample with a high hemoglobin concentration is analyzed, analysis results may be stabilized by performing a line wash. The line wash stops automatically.

### Line wash procedure

1 Make sure that the analyzer status is on “Standby”.

2 Open the maintenance screen and tap the manual operation button .



3 Tap the line wash button .

### 6.2.4 Eluent priming

The analyzer automatically performs a priming or purging cycle with eluent to replace eluent in the flow lines with fresh eluent before analysis, when the analyzer is turned on and when the analyzer status has been on “Standby” for more than 70 minutes.

When analysis results are unstable such as when the analyzer has not been used for a long time, analysis results may be stabilized by performing an eluent priming.

#### Eluent priming procedure



- 1 Make sure that the analyzer status is on “Standby”.
- 2 Open the maintenance screen and tap the manual operation button .
- 3 Tap the desired elution buffer or select Hemolysis & Wash solution (H/W) for priming. Selection of multiple options is possible. Tap the priming button  to start priming.

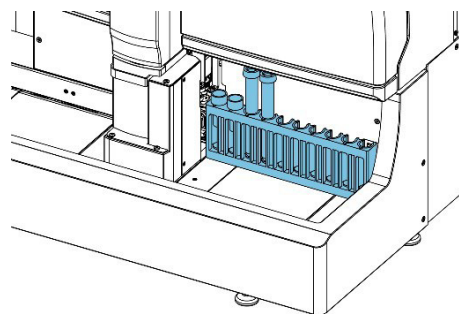


### 6.2.5 Sample rack rotation

To check the operation of the sample loader such as after the sample loader recovers from an error, perform a sample rack rotation.

#### Sample rack rotation procedure



- 1 Make sure that the analyzer status is on “Standby”.
- 2 Open the maintenance screen and tap the manual operation button .
- 3 Load a sample rack on the sample loader. To check the sample rack rotation, set a sample cup or sample tube on the sample rack. (If no sample is set on the sample rack, the analyzer recognizes the sample rack as an empty rack, and sample rack rotation will not be performed.)
- 4 Tap the rack rotation button  to check the operation of the sample loader. To stop rack rotation, tap the rack rotation button again.




## 6.2.6 Sampler reset

To check the operation of the sampling unit after recovery from a sampler related error, or to wash the sampling unit including the sampling needle, perform a sampler reset.

### Sampler reset procedure

- 1 Make sure that the analyzer status is on "Standby".
- 2 Open the maintenance screen and tap the manual operation button .
- 3 Tap the sampler reset button .  
Sample reset stops automatically after completion.

## 6.2.7 Air removal from the pump

- 1 Make sure that the analyzer status is on "Standby".
- 2 Open the maintenance screen and tap the air removal button .
- 3 The air removal wizard screen appears.  
Perform air removal by following the procedure indicated on the screen.

### NOTICE

**For opening/closing the drain valve, be sure to follow the procedure indicated on the screen.**

- If the drain valve is not opened, an error "D.FLUSH ERROR (103)" occurs, and air removal is stopped.

#### Note

- When air removal is performed, 15 mL of Elution Buffer No.1, and 5 mL each of Elution Buffer No.2 and No.3 are consumed.

## 6.3 Checking the replacement history of consumables

The replacement history of consumables (column, filter element, suction filters, elution buffers, Hemolysis & Wash solution) can be checked on the replacement history screen. For more details, refer to "4.8.10 Replacement history screen (p.73)".

## 6.4 Replacing consumables

### NOTICE

#### Use only Tosoh designated consumables.

- Consumables other than the designated ones are not covered by the warranty. Tosoh cannot be held liable for any consequences arising from the use of non-designated consumables.

### 6.4.1 Replacing a paper roll

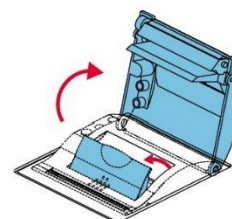
Use the Tosoh designated printer paper roll (Part No: 0023862).

Each roll is 30 meter long. About 230 sample results can be printed in the standard format.

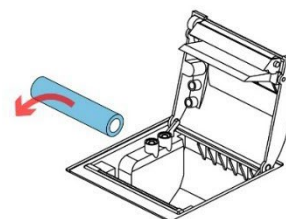
The length of content may differ depending on the detected peaks and attached flags.

#### Replacement procedure of a paper roll

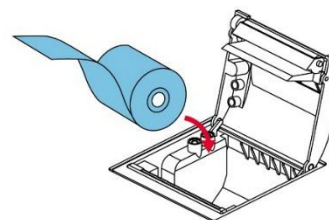
- 1 Pull up the open/close lever located at the top of the analyzer) to open the printer cover.



- 2 Remove the remaining paper and the empty mandrel.

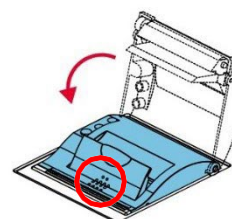


- 3 Place a new roll in the empty mandrel in the correct direction.



- 4 Leave a tail of paper sticking out of the printer, and push the part with "o" to close the printer cover.

If the printer cover is not closed properly, an error will occur.



## 6.4.2 Replacing elution buffers and Hemolysis & Wash solution

Before starting analysis, make sure that the remaining volumes of elution buffers and Hemolysis & Wash solution are sufficient.

Replace elution buffers and Hemolysis & Wash solution as early as possible when the remaining volume is insufficient.

If an elution buffer or Hemolysis & Wash solution is added to the remaining volume, correct analysis results cannot be obtained.

### Note

- The graph displayed on the main screen is the estimated volume of each reagent. There may be discrepancy between the displayed volume and the actual volume.
- To use the remaining volume efficiently, it is recommended to use the optional buffer switching unit.
- If elution buffers are used in a wrong combination, there may be a case where only one peak is detected. In such a case, use elution buffers in the correct combination.

## Replacement procedure of an elution buffer or Hemolysis & Wash solution

### Replacing an elution buffer

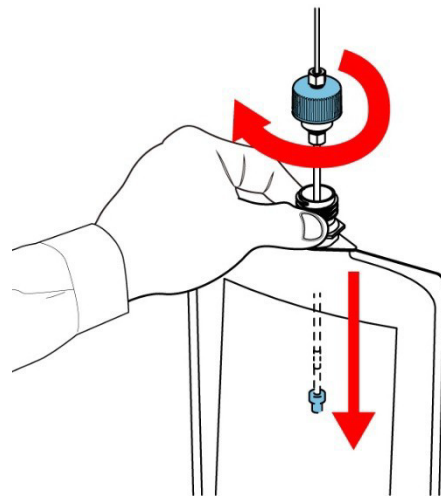
- 1 Make sure that the analyzer status is on "Standby".
- 2 Remove the old elution buffer aluminum bag from the elution buffer holder, and hang the new elution buffer aluminum bag instead. Uncap the new aluminum bag.
- 3 Loosen the cap of the old elution buffer aluminum bag and pull out the suction tube.
- 4 Insert the suction tube into the new elution buffer aluminum bag.

Confirm that the end of the tube (suction filter) reaches the bottom of the aluminum bag.

- 5 Before tightening the cap make sure no air remains inside the aluminum bag by purging the bag.

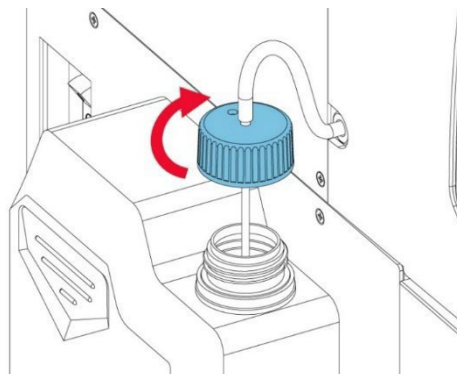
When replacing multiple elution buffer aluminum bags, repeat **Steps 2 to 5**.

After bag replacement and tube connection is completed, go to **Step 6**.




### Replacing Hemolysis & Wash solution

- 1** Make sure that the analyzer status is on “Standby”.
- 2** Remove the cap of the new Hemolysis & Wash solution bottle.
- 3** Loosen the cap of the old Hemolysis & Wash solution bottle and pull out the Hemolysis & Wash solution tube.
- 4** Insert the Hemolysis & Wash solution tube into the new Hemolysis & Wash solution bottle.  
Confirm that the end of the tube (anchor) reaches the bottom of the bottle.
- 5** Tighten the cap.  
After replacement and tube connection is completed, go to **Step 6**.



### Registering the elution buffer and Hemolysis & Wash solution

- 6** Tap the desired reagent replacement button  to open the reagent replacement screen.  
The reagent replacement screen can be displayed by tapping the remaining reagent volume information/reagent replace button.
- 7** Select all the newly replaced elution buffers and Hemolysis & Wash solution.

When the optional handheld barcode scanner is not connected, go to **Step 10**.



**Registering the reagent information (optional)**

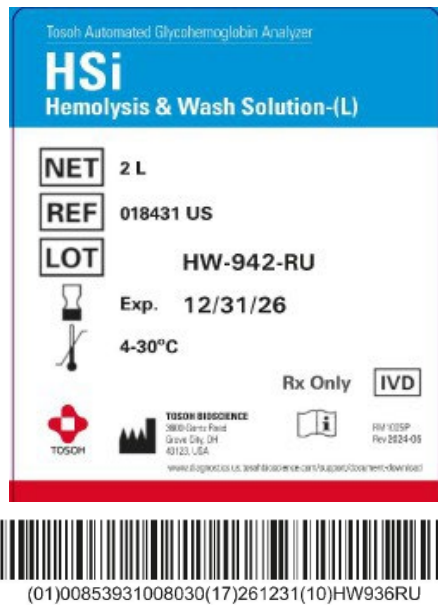
**8** Register the reagent information.

Using the handheld barcode scanner, scan the barcode on the newly installed elution buffer label (or elution buffer box label) or Hemolysis & Wash solution label.

Elution buffer label/elution buffer box label



Hemolysis & Wash solution label



**9** Confirm that the lot No. of the new reagent has been read correctly.

**Apply the changes and perform priming**

- 10** Tap the register button to apply the changes.
- 11** The eluent inside the analyzer flow lines will be replaced with the newly installed buffers (eluent priming will be performed.)
- 12** The graph display of the new reagent volumes will be updated. Some reagent volume is consumed during priming, so the remaining volume of each reagent decreases slightly.

### 6.4.3 Replacing the filter element

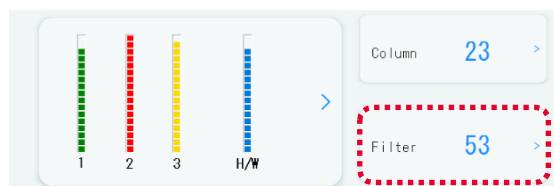
Replace the filter element in the following cases:


- When the filter element count is expected to reach 600 (injections) before analysis is finished.
- When the feeding pressure is 4 MPa higher than the pressure indicated on the Inspection Report of the column.

#### Replacement procedure of the filter element

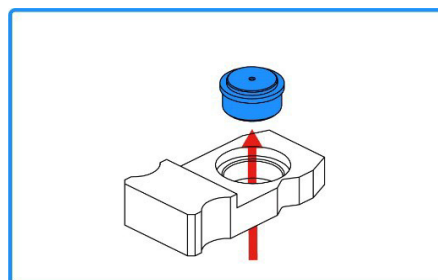
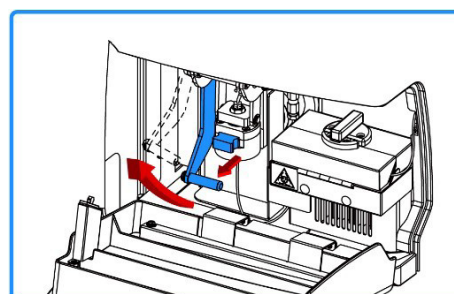
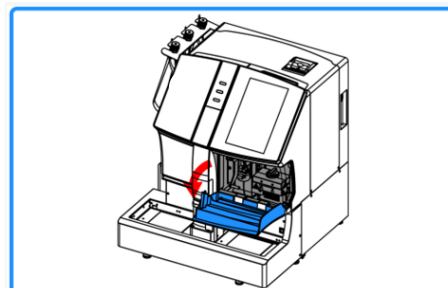
- 1 Tap the filter element count/filter element replace button on the main screen to open the filter element replacement screen.

(The filter element replacement screen can be displayed by tapping the filter element replace button on the maintenance screen.)

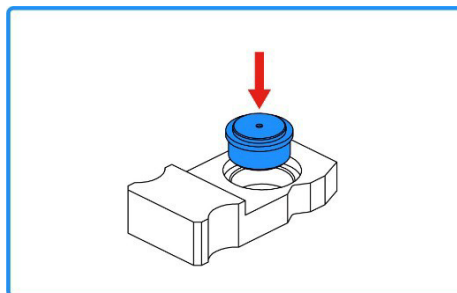


Follow the procedure indicated on the screen to replace the filter element. The procedure includes line wash. This step cannot be skipped. The other steps can be skipped to the next manual operation by tapping the skip button .

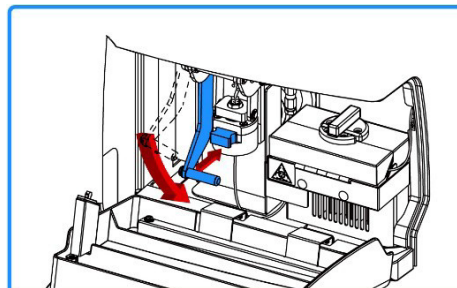
- 2 (Step 1/7) Open the right door of the analyzer.
- 3 (Step 2/7) Pull up the filter handle and pull out the filter holder.
- 4 (Step 3/7) Remove the old filter element by pushing it with a finger from the bottom.



- 5** (Step 4/7) Insert a new filter element into the filter holder.



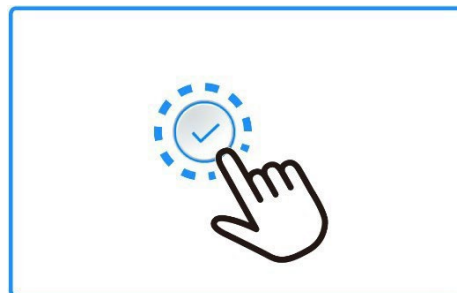
- 6** (Step 5/7) Insert the filter holder and pull down the filter handle.



- 7** (Step 6/7) Tap the line wash button. Confirm there is no liquid leak from the line filter.



- 8** (Step 7/7) Tap the ✓ button to complete the replacement of the filter element.



**Note**

- Never reuse the removed filter element because it has been deformed.
- If air enters the flow lines at the time of replacing the filter element, the chromatogram baseline may be abnormal (noise may appear). After the replacement, check that no abnormal baseline appears in the chromatogram. If an abnormal baseline appears, perform an additional column wash, analyze dummy samples again, and then check the chromatogram.

#### 6.4.4 Replacing the column

Replace the column in the following cases:

- When the feeding pressure is 4 MPa higher than the pressure indicated on the Inspection Report of the column and when the feeding pressure is not reduced even after replacement of the filter element
- When multiple peaks on multiple chromatograms have split into 2 fractions
- When analysis results of QC samples are consistently out of the assigned range (indicated on the Hemoglobin A1c Control Set) even after recalibration
- When a calibration error occurs frequently
- When the column expires
- When the warning mark appears
- When the column count reaches 5,000 injections.

Contact Tosoh Technical Support if the above problems cannot be resolved even after column replacement.

### **NOTICE**

**Check the column lot number of both the column and the elution buffers (No.1 and No.2).**

- When replacing the column, be sure to check that the column lot number of the new column is the same as that of the elution buffers No.1 and No.2.
- If the lot number is different, replace elution buffers No.1 and No.2 with the same lot number as the column.
- If the column and elution buffers No.1 and No.2 have different lot numbers, correct analysis results cannot be obtained.

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**Be sure to let the column reach room temperature before use.**

- If a column stored in a refrigerator is immediately used, correct analysis results cannot be obtained.
-

## Replacement procedure of the column

- 1 Tap the column count/column replace button on the main screen to open the column replacement screen.

(The column replacement screen can be displayed by tapping the column replace button on the maintenance screen.)

Follow the procedure indicated on the screen to replace the column. The procedure includes manual feeding  and line wash . These steps cannot be skipped. The other steps can be skipped to the next manual operation by tapping the skip button .

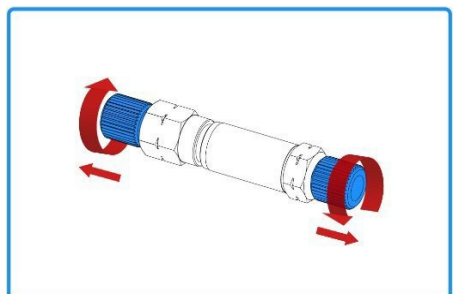
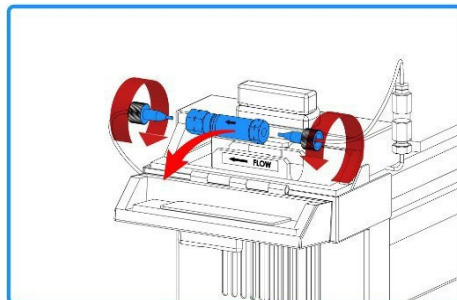
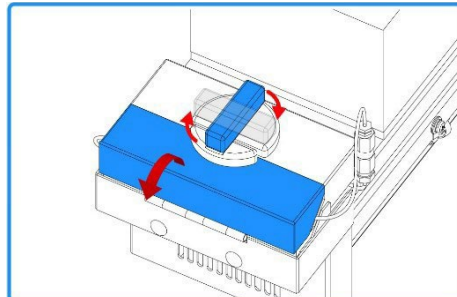
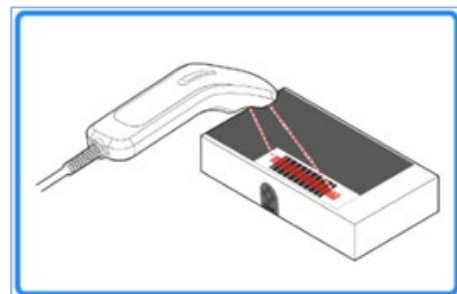
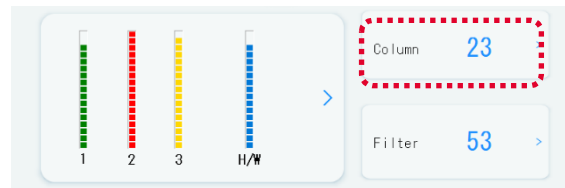
- 2 (Step 1/10) Read the barcode of a new column.

If the handheld barcode scanner is not connected, go to the next step.

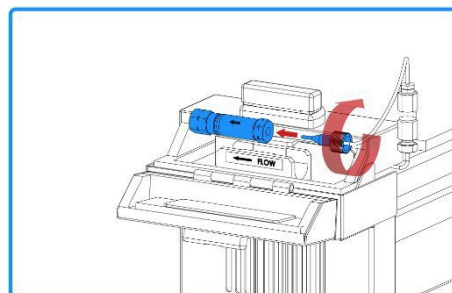
- 3 (Step 2/10) Open the column oven.


- 4 (Step 3/10) Remove the old column.

- 5 (Step 4/10) Remove the end fittings of the new column.



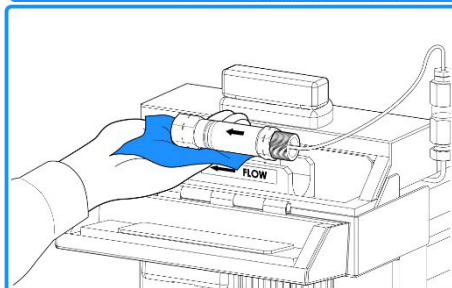
**6** (Step 5/10) Connect the inlet side of the column (right side).



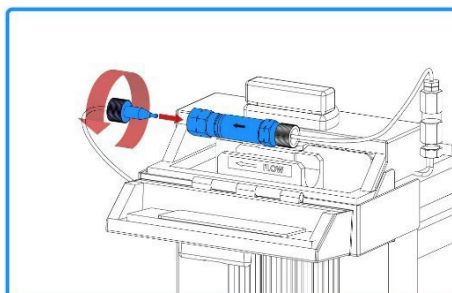
**7** (Step 6/10) Tap the manual feeding button .

When the eluent comes out from the outlet (left) side of the column, tap the manual feeding button to stop eluent feeding.

Hold a wipe on the outlet (left) side of the column to receive the eluent.



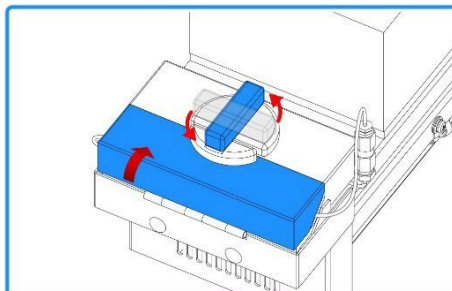
**8** (Step 7/10) Connect the outlet (left) side of the column.




**9** (Step 8/10) Tap the line wash button. Check the column pressure and confirm that no liquid leaks from the column.



**10** (Step 9/10) Place the column in the column compartment and close the column oven.



**11** (Step 10/10) Tap the  button to complete the column replacement. After replacing the column, it is recommended to prime with whole blood until chromatography without flags is observed. Perform calibration.



**Reference**

For calibration, refer to "5.4.4 Calibration Procedure (p.105)".


## 6.4.5 Replacing the suction filters



### NOTICE

**When replacing the suction filters, be sure to replace all 3 suction filters.**

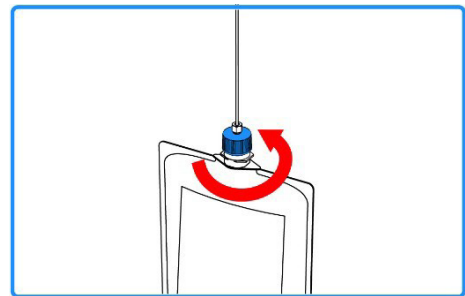
- Never replace only one suction filter for a specific elution buffer.

#### Replacement procedure of the suction filters

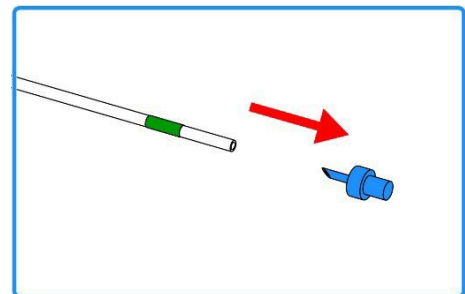
- 1 Tap the suction filter replacement button  on the maintenance screen to open the suction filter replacement screen.

Follow the procedure indicated on the screen to replace the suction filter. The procedure includes an eluent priming operation . This step cannot be skipped. The other steps can be skipped to the next manual operation by tapping the skip button .

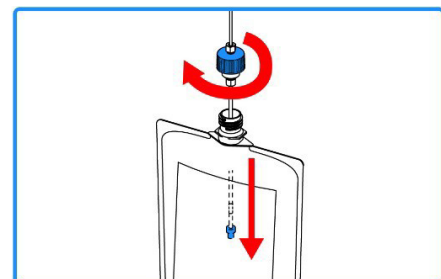
- 2 (Step 1/5) Loosen the cap and pull out the eluent tube.



- 3 (Step 2/5) Remove the old suction filter.




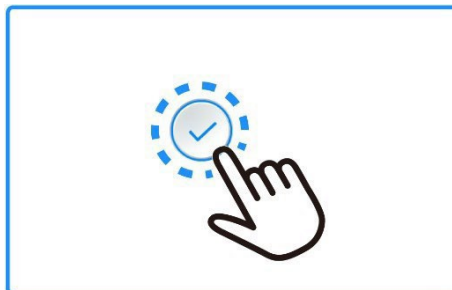
- 4 (Step 3/5) Insert a new suction filter.  
Insert the eluent tube into the corresponding elution buffer aluminum bag. Purge the bag and tighten the cap.



- 5** (Step 4/5) Replace the suction filters of all 3 elution buffers. After replacement of each filter is completed, tap the priming button.



- 6** (Step 5/5) Tap the  button to complete the replacement of the suction filters.



### 6.4.6 Replacing the sampling needle

#### CAUTION

**Only personnel who have received training can replace the sampling needle.**

**Otherwise,**

- The sampling needle and analyzer may be damaged, or a user may get injured.
- If the replacement procedure is unclear, contact Tosoh Technical Support.

**Wear the proper protective clothing (goggles, gloves, mask, etc.) when replacing the sampling needle.**

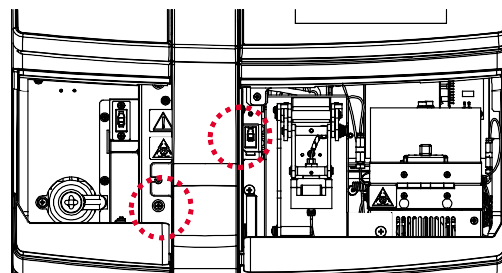
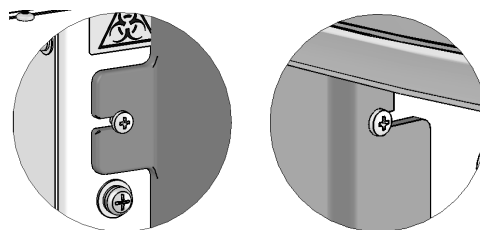
- The sampling needle and wash assembly are contaminated with blood samples.
- A user may get injured.

**Never replace the sampling needle when the main power of the analyzer is turned on.**

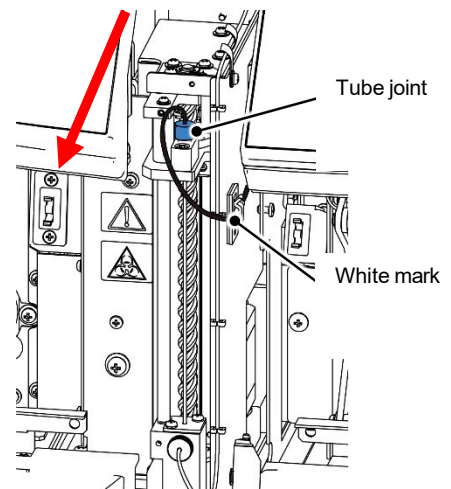
- The analyzer may get damaged, or a user may get injured.

#### **Replacement procedure of the sampling needle**

- 1** Turn off the main power of the analyzer.  
Open the left and right doors.  
Remove the 2 screws of the needle cover using the provided Phillips screwdriver.  
Grasp the needle cover, and carefully pull it out to the front.

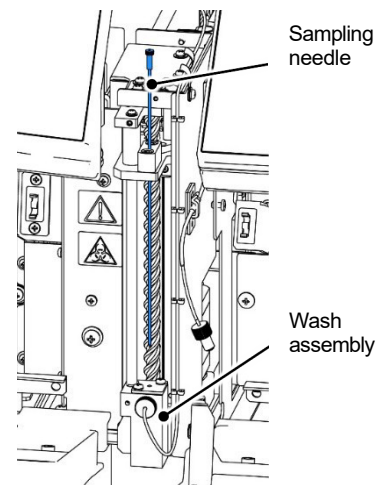


- 2 Grasp the upper part of the sampling unit by hand and pull the unit out to the front. Loosen and remove the tube joint at the upper part of the sampling unit by hand.

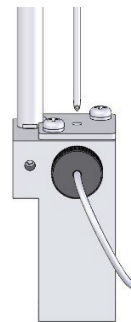


- 3 Pull up the sampling needle slowly. If the sampling needle cannot be pulled up straight (such as when the sampling needle was damaged or bent), cut the sampling needle using cutting pliers.

**Note** • If the sampling needle cannot be pulled up from the wash assembly, stop replacement, and contact local Tosoh representatives.



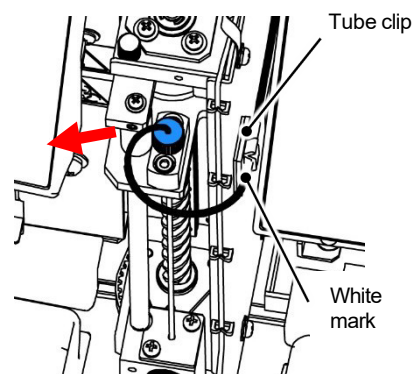
- 4 Insert the new sampling needle through the hole of the wash assembly. Make sure that the sampling needle is fully inserted.



- 5** Connect the tube joint temporarily, and tighten it securely by hand while rotating the tube to the left.

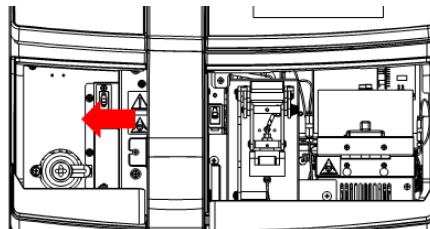
Confirm that the tube joint is secured with the tube clip at the white mark position.

Move the sampling unit forward and backward several times to confirm the sampling unit does not get stuck with the tube.



- 6** Attach the needle cover in the reverse order of **Step 2**. Tighten the screws while pulling the needle cover to the left and confirm that the needle cover is securely fixed.

Turn on the main power of the analyzer and confirm that the analyzer operates properly.



## 6.5 Checking the replacement history of regular replacement parts

The replacement history of regular replacement parts can be checked on the maintenance screen.




For more details, refer to “4.8.11 Maintenance history screen (p.78)”.

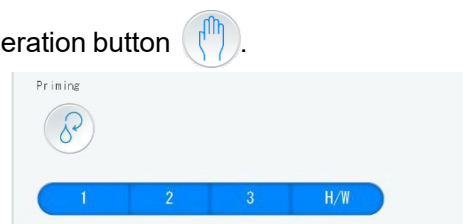
### Note

- Only a service engineer can update the maintenance history. Users cannot edit the maintenance history.

## 6.6 When the analyzer is not used for a long time

If the analyzer will not be used for more than 1 week, it is necessary to replace eluent in the analyzer lines with reagent grade water.

- 1 Make sure that the analyzer status is on “Standby”.
- 2 Remove the column. Securely attach the end fittings at both ends of the column and store the column in a cool place (2 to 15° C).
- 3 Connect an old column. (It is not necessary to perform the column replacement procedure.)
- 4 Insert the ends of the tubes for all elution buffers and Hemolysis & Wash solution into a container containing 500 mL of reagent grade water. (They can be inserted in a separate container for each type of tubes.)
- 5 Open the maintenance screen and tap the manual operation button .
- 6 Select all the reagents (elution buffers and Hemolysis & Wash solution (H/W)) for priming.  
Tap the priming button  to start priming.
- 7 Tap the line wash button .
- 8 Turn off the main power of the analyzer.



## NOTICE

**When it is anticipated that the analyzer will not be used for more than seven days, replace eluent with reagent grade water in the lines.**

- Never store the lines with Hemolysis & Wash solution or organic solvents.

**When ready to use the analyzer again, use new elution buffers and Hemolysis & Wash solution.**

- There will be a large discrepancy between the displayed volume and the actual volume.

**When starting the analyzer again, first calibrate and analyze controls or known samples to confirm that there are no problems with the chromatogram and analysis values before starting sample analysis.**

# 7

## Various settings

---

This chapter describes the major setting (analysis settings, flag settings printing/saving PDF settings, user account settings, host communication settings).

For other settings, refer to “4.9 Settings screen (p.81)”.

### 7.1 Analysis settings

#### 7.1.1 Start sample No. setting

The first sample No. for the next analysis can be specified. Consecutive numbers after the specified number are assigned to subsequent samples. The sample numbers are automatically assigned and reset when the testing date changes.

#### 7.1.2 Sample loader settings

##### Sample rack rotation

When using the GR-90SL, it is possible to select whether to enable/disable sample rack rotation on the sample loader.

##### Rack start

When using the GR-90SL, it is possible to enable the rack start function.

With this function enabled, when a sample rack is detected at the rack set position, analysis is started automatically even without the analysis start button tapped.

This function is available only when sample rack rotation is disabled.

#### 7.1.3 Sample condition setting

The desired sample condition setting can be selected. Default setting is whole blood in tubes and diluted blood/hemolysate in sample cups.

**Note**

- Be sure to return the sample condition setting when temporarily changing it. The analyzer may analyze a whole blood sample without dilution or may dilute a hemolysate, an already manually diluted sample.

#### 7.1.4 Optional comment

A comment such as the analyzer name or account name can be entered.

The entered comment is printed in the printed results or saved PDF results.

Up to 20 characters can be entered as a comment.

#### 7.1.5 Flow factor

The pump flow factor can be changed only when SA1c Retention Time is outside specifications.

Only a user with Super User authority can change the flow factor.

## NOTICE

**Do not change the flow factor unless otherwise indicated.**

- The pump flow factor must be set with respect to the retention time of the SA1c peak, etc. Contact Tosoh local representatives.
  - If an incorrect value is entered, correct analysis results cannot be obtained.
- 

## 7.2 Flag settings (Set by Tosoh personnel during installation)

### 7.2.1 Flag function

The GR01 software is equipped with a set of Flags that determine if an HbA1c result is reportable. The reportability depends on a combination of flag priority settings, flag levels and reference ranges.

Threshold value(s), of each flag item, including the Total Area and HbA1c (%), are pre-set. The Flag number (Flag No.) and the message corresponding to the flag will be displayed on the result screen and printed on the chromatograms. Each Flag has a priority level.

The report priority level [Report Level] of a flag is assigned as:

[0: Reportable] or

[1: Non reportable].

[0: Reportable] - the HbA1c (% , mmol/mol) value is calculated, and a flag is displayed. The chromatograms must be appropriately evaluated.

[1: Non-reportable] - the HbA1c (% , mmol/mol) value is not reported, and a flag is displayed.

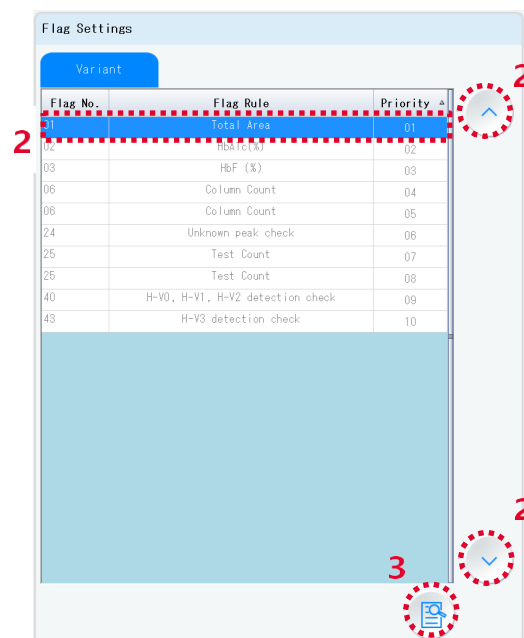
It is recommended to perform reanalysis after addressing the underlying reason for the flag(s). If flag persists, testing with an alternate method should be considered.

If flag(s) "HB-VAR DETECT", "PEAK NOT DETECT", and/or "UNKNOWN PEAK" is (are) detected, a hemoglobin variant may be present.

For details on variant hemoglobins, refer to "2.5 Hemoglobin Variants (p.23)". The Flag settings for hemoglobin variants are described in the section below.

## 7.2.2 Viewing the flag settings

- 1 Tap the flag settings button on the settings screen to open the flag settings screen.
- 2 The flag conditions are listed. Tap the flag selection buttons (▲ or ▼) to select (highlight) the desired flag.
- 3 Tap the flag information button to access the detailed flag information.



## 7.2.3 List of flag rules

For items with a specified threshold value, a flag is displayed when the obtained value is less than (<) or greater than (>) the specified value. The following tables show the flags used by the GR01 analyzer. The flags are set at the time of analyzer installation by Tosoh personnel, and the flags can only be changed by Tosoh personnel, not the user. Information for each flag shows the flag number, the flag item, a short description of the flag, the criteria the flag is used for, the message displayed when the flag is triggered, and whether the HbA1c value is reported when the flag is triggered (“reportable”) or not reported (“non-reportable”). Refer to Section 9 *Troubleshooting* to resolve flags as applicable.

### Fixed registered flags

Flag No. 01	Flag item: Total Area	
Description	Upper cutoff Total Area for AREA TOO LOW	Lower cutoff Total Area for AREA TOO HIGH
Criteria (Initial)	300	1800
Message	01 AREA TOO LOW	01 AREA TOO HIGH
Report level	Non-reportable	Non-reportable

Flag No. 02	Flag item: HbA1c (%)	
Description	Lower cutoff value for HbA1c (%)	Upper cutoff value for HbA1c (%)
Criteria (Initial)	3.9	16.9
Message	02 SA1C TOO LOW	02 SA1C TOO HIGH
Report level	Non-reportable	Non-reportable

Flag No. 03	Flag item: HbF (%)
Description	Upper cutoff value for HbF (%)
Criteria (Initial)	32.2
Message	03 SA1C NOT REPORTABLE
Report level	Non-reportable

Flag No. 06	Column Count
Description	Upper cutoff value for Column count
Criteria (Initial)	5000
Message	06 COLUMN COUNT > 5000
Report level	Non-reportable

Flag No. 24	Flag item: Unknown peak
Description	Set "1" if flagging unknown peak
Criteria (Initial)	1
Message	24 SA1C NOT REPORTABLE
Report level	Non-reportable

Flag No. 25	Test Count
Description	Upper cutoff value for Test count
Criteria (Initial)	20,000
Message	25 PM OVERDUE
Report level	Non-reportable

Flag No. 40	Flag item: HB-VAR Detect Check (H-V0, H-V1, H-V2) *
Description	Set "1" if peak is detected in the H-V0, H-V1, or H-V2 elution window
Criteria (Initial)	1
Message	40 HB-VAR DETECT
Report level	Reportable

Flag No. 43	Flag item: HB-VAR Detect Check (H-V3) *
Description	Set "1" if flagged Detect H-V3
Criteria (Initial)	1
Message	43 HB-VAR DETECT
Report level	Reportable

\* Common variant peaks often elute in these windows. Uncommon variants can also elute in these windows and caution needs to be exercised by the user as the accuracy of the HbA1c result might be impacted.

## 7.3 Print/PDF settings

### 7.3.1 Printer type

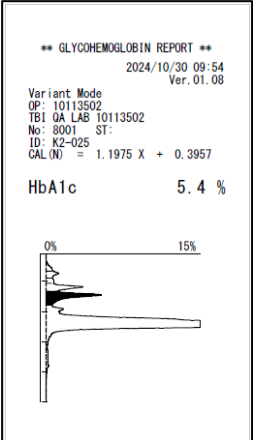
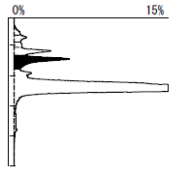
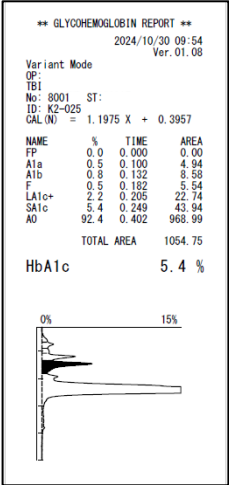
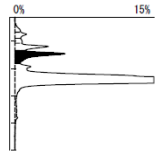
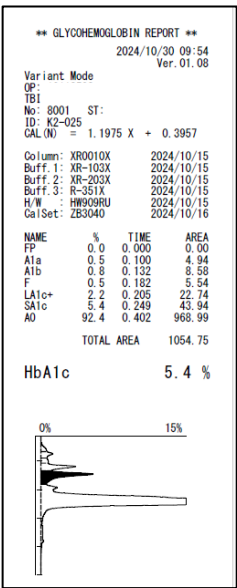
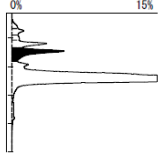
With this analyzer, the internal thermal printer and a Tosoh-designated external monochrome laser printer can be used.

#### **Items that can be printed from the internal printer or the external printer**

- Analysis results (real-time printing)
- Analysis results (reprinting)
- Version information (printed from the version screen)
- Calibration results (when calibration is completed)
- Parameters (printed from the print parameters button on the settings screen)

### 7.3.2 Report formats

The following 3 printing formats are available with this analyzer when printing or saving as PDF: Standard, Detail, or Simple.

Report Format	Simple	Standard	Detail																																																																
Printed contents	<ul style="list-style-type: none"> <li>- Analysis date</li> <li>- Program version (Ver.)</li> <li>- Analysis mode</li> <li>- User ID (operator)</li> <li>- Sample No.</li> <li>- Sample location (SL)</li> <li>- ID</li> <li>- Calibration information (CAL)</li> <li>- HbA1c (%)</li> <li>- Chromatogram</li> <li>- Flag message</li> </ul>	<p>In addition to the items printed in the Simple format,</p> <ul style="list-style-type: none"> <li>- Obtained value of each peak</li> <li>- TOTAL AREA</li> </ul>	<p>In addition to the items printed in the Standard format,</p> <ul style="list-style-type: none"> <li>- Reagent information</li> </ul>																																																																
Standard printing length	About 9.2 cm (3.62") (Without any flag, NGSP unit only)	About 13.0 cm (5.12") (Without any flag, NGSP unit only)	About 15.2 cm (5.98") (Without any flag, NGSP unit only)																																																																
Example	 <p> <b>** GLYCOHEMOGLOBIN REPORT **</b>            2024/10/30 09:54            Ver. 01.08            Variant Mode            OP: TBI            No: 8001 ST:            ID: K2-025            CAL(N) = 1.1975 X + 0.3957            HbA1c 5.4 %            0% 15%   </p>	 <p> <b>** GLYCOHEMOGLOBIN REPORT **</b>            2024/10/30 09:54            Ver. 01.08            Variant Mode            OP: TBI            No: 8001 ST:            ID: K2-025            CAL(N) = 1.1975 X + 0.3957  <table border="1"> <thead> <tr> <th>NAME</th> <th>%</th> <th>TIME</th> <th>AREA</th> </tr> </thead> <tbody> <tr><td>FP</td><td>0.0</td><td>0.000</td><td>0.00</td></tr> <tr><td>Ala</td><td>0.5</td><td>0.100</td><td>4.94</td></tr> <tr><td>Alb</td><td>0.8</td><td>0.132</td><td>8.58</td></tr> <tr><td>F</td><td>0.5</td><td>0.182</td><td>5.54</td></tr> <tr><td>LA1c+</td><td>2.2</td><td>0.205</td><td>22.74</td></tr> <tr><td>SA1c</td><td>5.4</td><td>0.249</td><td>43.94</td></tr> <tr><td>AO</td><td>92.4</td><td>0.402</td><td>968.99</td></tr> </tbody> </table>           TOTAL AREA 1054.75            HbA1c 5.4 %            0% 15%   </p>	NAME	%	TIME	AREA	FP	0.0	0.000	0.00	Ala	0.5	0.100	4.94	Alb	0.8	0.132	8.58	F	0.5	0.182	5.54	LA1c+	2.2	0.205	22.74	SA1c	5.4	0.249	43.94	AO	92.4	0.402	968.99	 <p> <b>** GLYCOHEMOGLOBIN REPORT **</b>            2024/10/30 09:54            Ver. 01.08            Variant Mode            OP: TBI            No: 8001 ST:            ID: K2-025            CAL(N) = 1.1975 X + 0.3957            Column: XR0010X 2024/10/15            Buff: 1: XR-103X 2024/10/15            Buff: 2: XR-203X 2024/10/15            Buff: 3: R-351X 2024/10/15            H/W: HB090RU 2024/10/15            CalSet: ZB3040 2024/10/16  <table border="1"> <thead> <tr> <th>NAME</th> <th>%</th> <th>TIME</th> <th>AREA</th> </tr> </thead> <tbody> <tr><td>FP</td><td>0.0</td><td>0.000</td><td>0.00</td></tr> <tr><td>Ala</td><td>0.5</td><td>0.100</td><td>4.94</td></tr> <tr><td>Alb</td><td>0.8</td><td>0.132</td><td>8.58</td></tr> <tr><td>F</td><td>0.5</td><td>0.182</td><td>5.54</td></tr> <tr><td>LA1c+</td><td>2.2</td><td>0.205</td><td>22.74</td></tr> <tr><td>SA1c</td><td>5.4</td><td>0.249</td><td>43.94</td></tr> <tr><td>AO</td><td>92.4</td><td>0.402</td><td>968.99</td></tr> </tbody> </table>           TOTAL AREA 1054.75            HbA1c 5.4 %            0% 15%   </p>	NAME	%	TIME	AREA	FP	0.0	0.000	0.00	Ala	0.5	0.100	4.94	Alb	0.8	0.132	8.58	F	0.5	0.182	5.54	LA1c+	2.2	0.205	22.74	SA1c	5.4	0.249	43.94	AO	92.4	0.402	968.99
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**Note**

- Calibrator and control analysis results cannot be printed in the Simple format. They are printed in the Standard format even when [Simple] is selected for [Report Format].

## 7.4 User account settings

### 7.4.1 User authority

There are three types of logon user authorities and one logoff user authority.

Super User: user authority for the administrator

Operator: user authority for operators.

F.Engineer: user authority for Tosoh service engineer (logon is not permitted)

No User: user authority for a logoff user.

For users with Operator authority, some operations are limited as shown in the table below. For users with No User authority, only emergency stopping, canceling the error, checking the main screen, and operating the logon screen are permitted.

User Authority	Super User	Operator
Backup	Possible	Not possible
Analysis settings	Possible	Changing the flow factor is impossible.
Flag settings	Viewing is possible.	Viewing is possible.
Barcode settings	Possible	Viewing is possible. Barcode reading check is possible.
Time setting	Possible	Not possible
User account settings	Possible	Creating and deleting a user is impossible. Changing user information is possible only when it is the user's own information.

### NOTICE

#### The logon password is the responsibility of the user.

- If the password of a user with Operator authority is unknown, a user with Super User authority can log on, change the password from the user account editing dialog. If the password of a user with Super User authority is unknown, contact the Tosoh local representatives.

#### User must not log on as F.Engineer by themselves.

- Logging on as F.Engineer without permission from Tosoh is considered unauthorized access. Tosoh cannot be held liable for any consequences arising from this misuse.

## 7.4.2 Creating/deleting a user/Editing user information

### Creating a user

- 1** Log on as a user with Super User authority.  
At the time of analyzer installation, at least one user with Super User authority is created.
- 2** Tap the user register button on the user account settings screen.
- 3** Enter the username.  
A user with the same name as an already registered user cannot be registered.
- 4** Select [Super User] or [Operator] from the [Authority] pull-down menu.  
For limitations depending on the user authority, refer to "7.4.1 User authority (p.160)".
- 5** Enter the password.
- 6** Enter a comment if necessary.
- 7** Tap the set button to register the user account.

### Deleting a user

- 1** Log on as a user with Super User authority.
- 2** Select a user to delete from the list on the user account settings screen.
- 3** Tap the user delete button.

### Changing user information

- 1** Log on as a user with Super User authority. Or log on as a user to edit that user's information.
- 2** Super User: select a user to edit from the list on the user account settings screen.
- 3** Tap the user edit button.
- 4** Tap the editing lock release button to release the lock for editing.
- 5** Edit the username, user authority, password, or comment as necessary, and tap the set button.

## 7.5 Host communication settings

Analysis results can be sent to the host computer via RS-232C communication.

Real-time transfer (results are sent to the host computer each time they are obtained) and batch transfer (results are sent to the host computer by selecting the desired results or specifying the desired range on the output screen after analysis) are available.

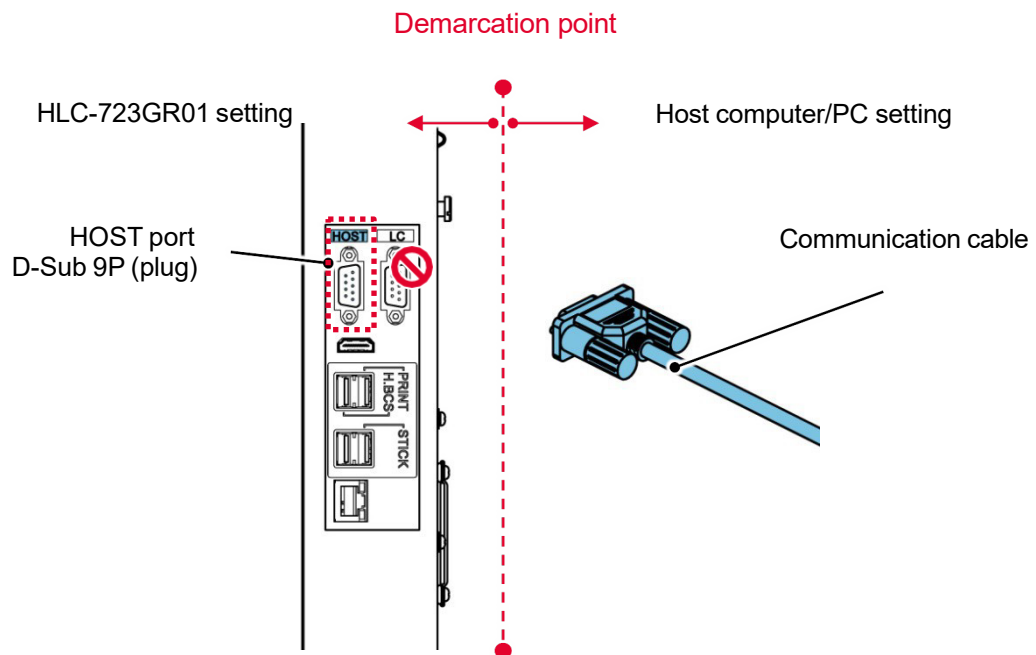
For detailed communication specifications and various settings, refer to the separate “HLC-723GR01 Host Computer Specification Manual”, which can be obtained from the Tosoh local representatives.

### 7.5.1 Communication specifications

Item	Specifications
Transmission method	RS-232C, start-stop transmission
Rate	1,200, 2,400, 4,800, 9,600, 19,200, 38,400 bps
Transmitted code	ASCII
Data length	7,8 bit
Parity	Even, odd, none
Stop bits	1 bit, 2 bit

### 7.5.2 Connection

Connect the RS232c serial cable to the HOST port on the right side of the analyzer. Do not connect the communication cable to the LC port.



# 8

## Optional accessories

---

The following optional accessories are provided with the HLC-723GR01.

These accessories can be added either at installation or after installation. They may be used according to the needs of the facility. For more information regarding optional accessories, contact Tosoh Technical Support.

### 8.1 Handheld barcode scanner

#### 8.1.1 Using the handheld barcode scanner

With the optional handheld barcode scanner, the following operations are available.

- **Reading a barcode sheet of the calibrator set**

Refer to "5.4.4 Calibration Procedure (p.105)".

- **Reading a barcode sheet of the control set**

Refer to "5.5.2 Registering QC materials (p.110)".

- **Reading a column barcode**

Read a column barcode in the procedure indicated on the column replacement screen.  
Refer to "4.8.3 Column replacement screen (p.66)".

- **Reading barcodes of elution buffers and Hemolysis & Wash solution**

Replacing elution buffers and Hemolysis & Wash solution (p.141)".

- **Reading a sample ID for STAT analysis**

Refer to "5.8 STAT analysis (p.123)".

### NOTICE

**The handheld barcode scanner does not support the barcode standard of COOP 2 of 5.**

- Sample ID information from labels with a COOP 2 of 5 standard must be entered manually.
- 

#### 8.1.2 Connecting the handheld barcode scanner

Connect the handheld barcode scanner to the USB (H.BCS) port.

### NOTICE

**Before connecting or removing the handheld barcode scanner, turn off the main power of the analyzer.**

---

**NOTICE**

**Be sure to connect the handheld barcode scanner to the designated USB (H.BCS) port.**

- If connected to a port other than the USB (H.BCS) port, the handheld barcode scanner may not be recognized properly.

**8.2 Buffer switching unit**

This unit allows additional bags of elution buffers and Hemolysis & Wash solution for uninterrupted analysis.

When the remaining volume of each reagent is low, the reagent automatically switches to a new bag or bottle of the reagent that is low in volume.

**⚠ WARNING**

**When using the buffer switching unit, ensure that the waste tank is not full. Empty the waste tank if at capacity.**

- Failure to do so will result in spilling of waste liquid containing biological material.

**NOTICE**

**Before analysis, make sure that the filter element and column injection counts have not reached their limits, 600 and 5,000 respectively.**

**8.3 External printer**

The Tosoh-designated external printer can be connected to the analyzer.

It is required to install a printer driver to operate the external printer.

If adding an external printer after analyzer installation, contact Tosoh Technical Support.

For items that can be printed using the external printer, refer to “7.3.1 Printer type (p.158)”.

**8.3.1 Connecting the external printer**

Connect the external printer to the USB printer (PRINT) port.

**NOTICE**

**Before connecting or removing the external printer, turn off the main power of the analyzer.**

**Be sure to connect the external printer to the designated USB (PRINT) port.**

- If connected to a port other than the USB (PRINT) port, the external printer may not be recognized properly.

## 8.4 LED signal tower kit

LED signal tower kit P/N 0023932 can only be set up by Tosoh personnel.

By connecting this kit, the analyzer status and the error status are easily recognizable.

The signal light colors are as follows:

- Green: The signal light is lit up during analysis and wash.
- Red: The signal light is lit up when an error occurs. The light goes off when the error is reset.

## 8.5 Laser barcode reader

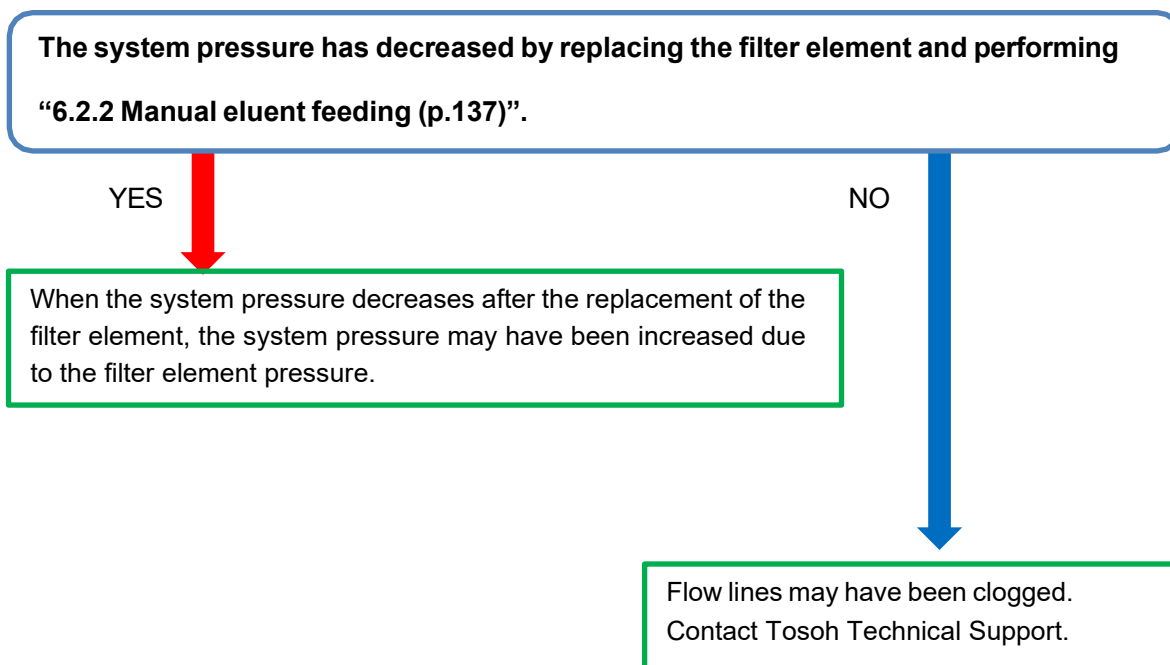
The standard barcode reader does not support the CODE93 barcode standard, so when this standard barcode is used for sample labels, the optional laser barcode reader is required.

If the reading failure occurs frequently, such as when the barcode print quality is low, the barcode reading rate may be improved by replacing the barcode reader with the laser barcode reader.

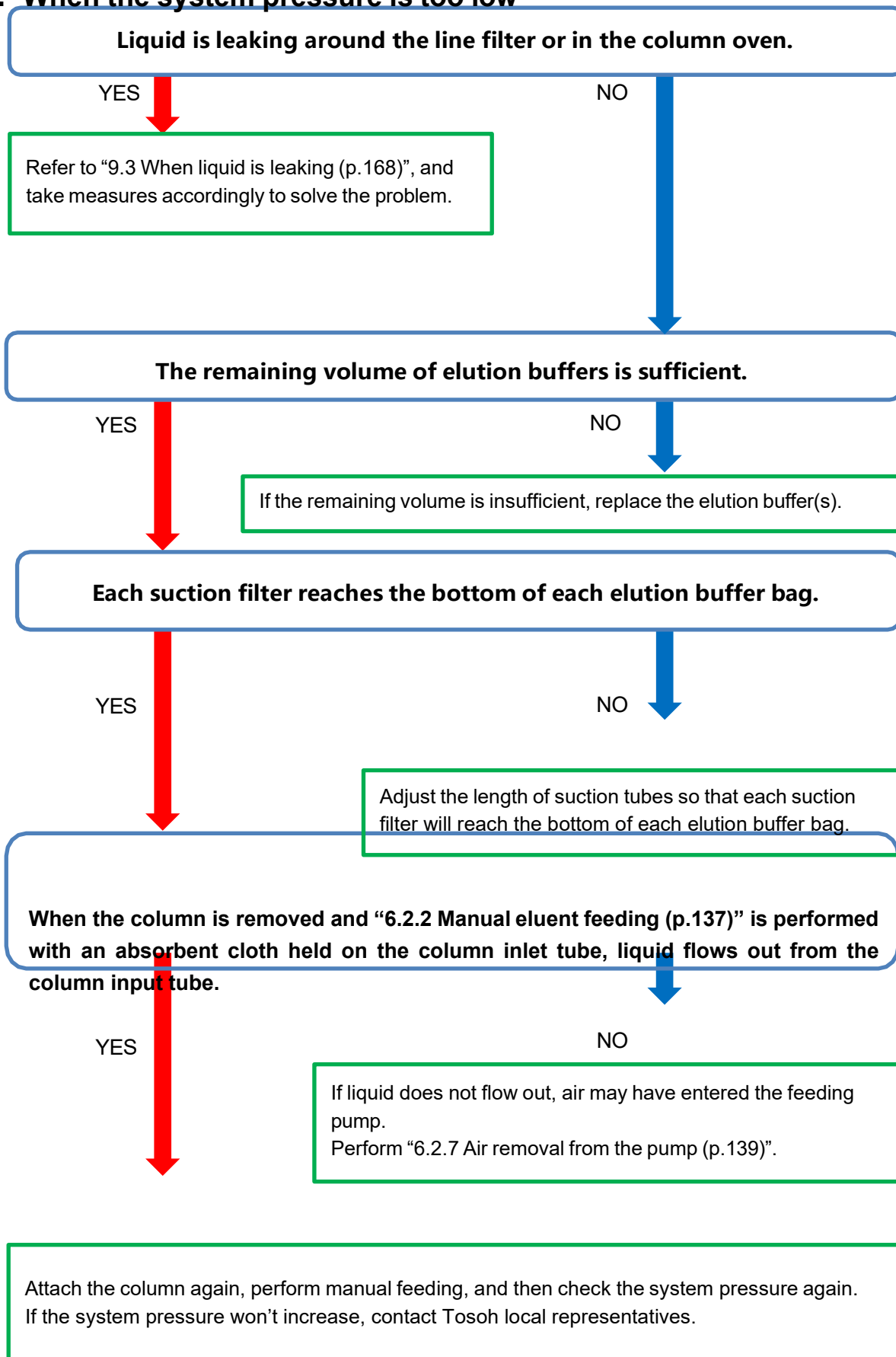
# 9 Troubleshooting

When a problem persists even after the measures described in this chapter are taken, contact Tosoh local representatives.

## 9.1 When the system pressure is too high



## 9.2 When the system pressure is too low



### 9.3 When liquid is leaking

If a leakage is found, stop analysis immediately, turn off the main power, and disconnect the power plug. The waste liquid containing blood may leak. To prevent infection, be sure to wear the proper protective clothing (goggles, gloves, mask, etc.) before wiping off the liquid.

**Liquid is leaking from the bottom of the analyzer.**

YES

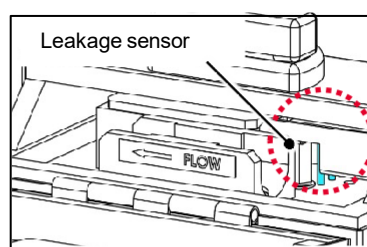
Contact Tosoh Technical Support.

NO

**A "COLUMN LEAK ERROR" occurred.**

YES

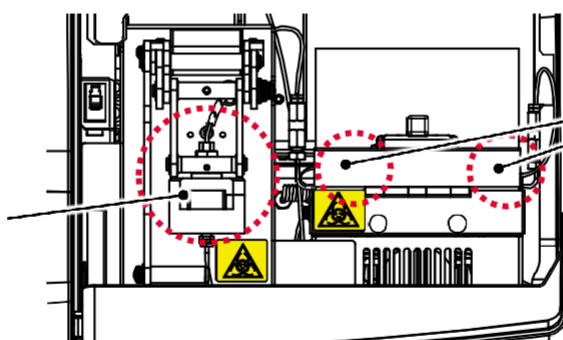
- If liquid leaks from a column joint part and the leakage sensor comes into contact with the liquid, a "COLUMN LEAK ERROR" occurs, and analysis is aborted.
- ⇒ Remove the column, wipe off the liquid from the column holder and sensor, and reconnect the column.



NO

**Liquid is leaking from the filter holder, before/after the column joint parts.**

Filter holder



Column joints

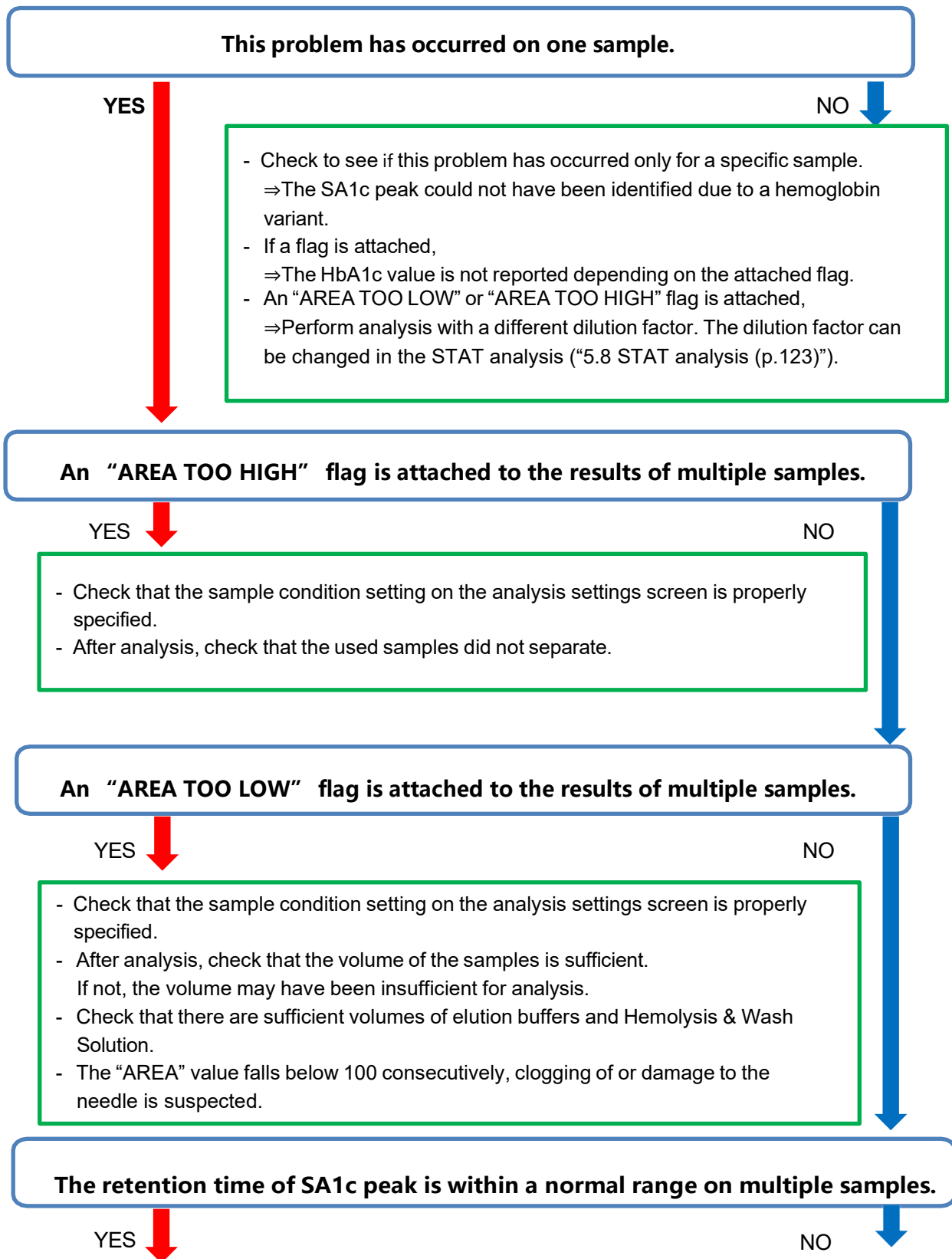
YES

- If liquid leaks from the filter holder  
⇒ Tighten the handle tightly.
- If liquid leaks from a column joint  
⇒ Remove the column, wipe off the liquid from the column holder and sensor, and reconnect the column.

NO

When a leakage point cannot be found or when the leakage cannot be stopped, contact Tosoh Technical Support.

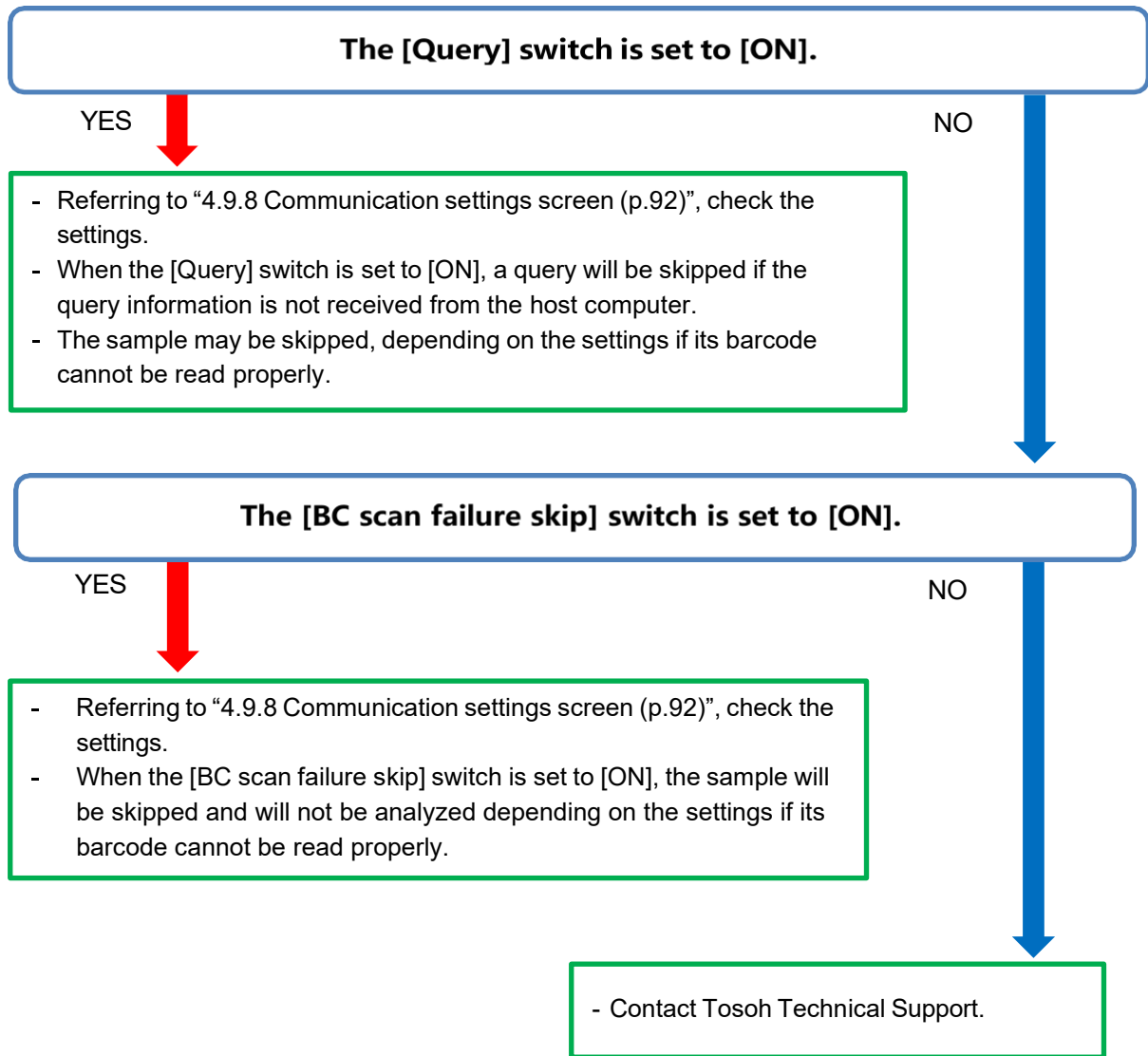
## 9.4 When the HbA1c value is not reported



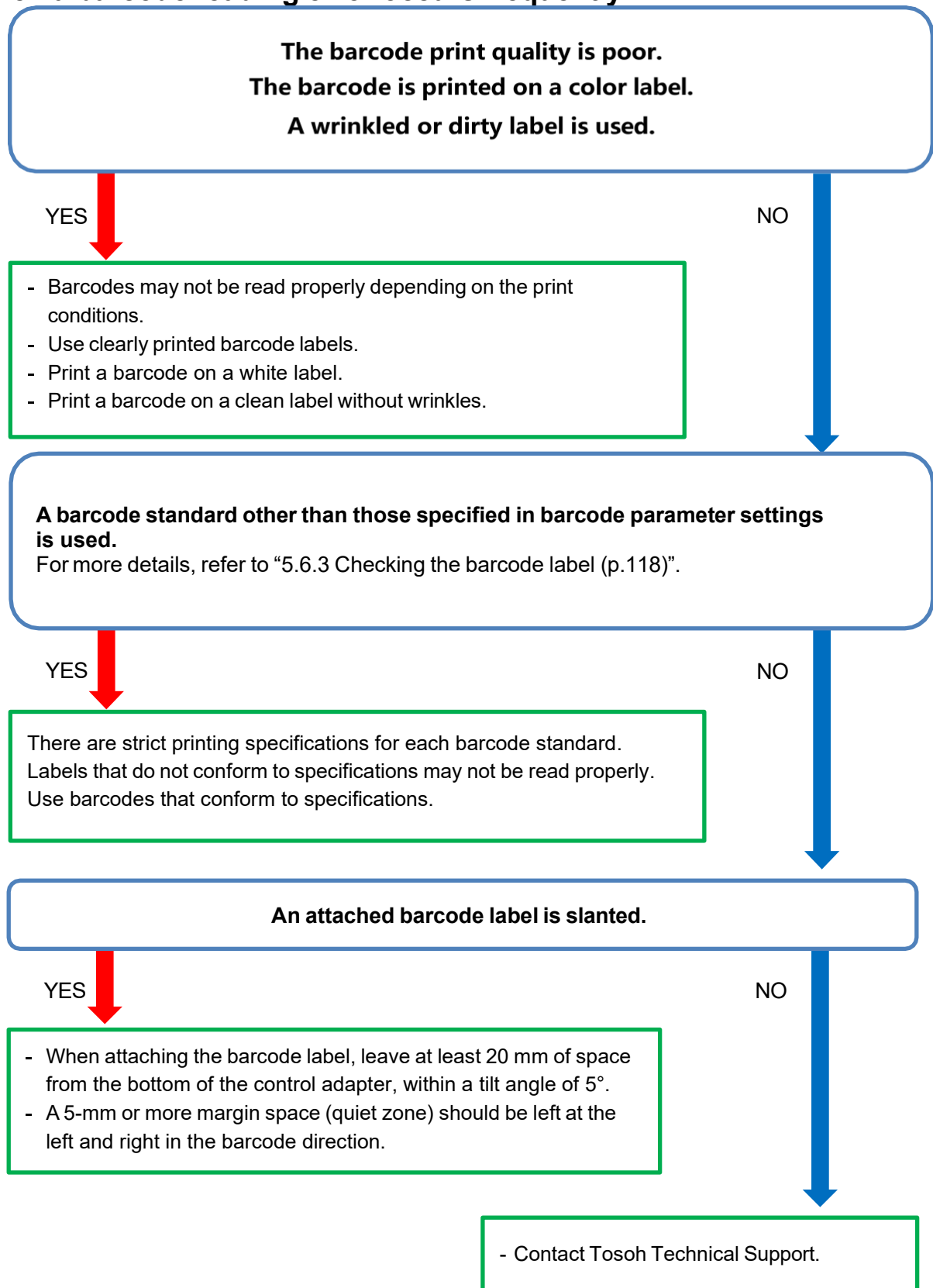
Contact Tosoh  
Technical Support.

- Confirm that elution buffers and elution tubes are used in the correct combination.
- Confirm that the lot number of the column and elution buffers are identical.
- Check the filter holder or column joints for any leakage.
- If error persists, contact Tosoh Technical Support.

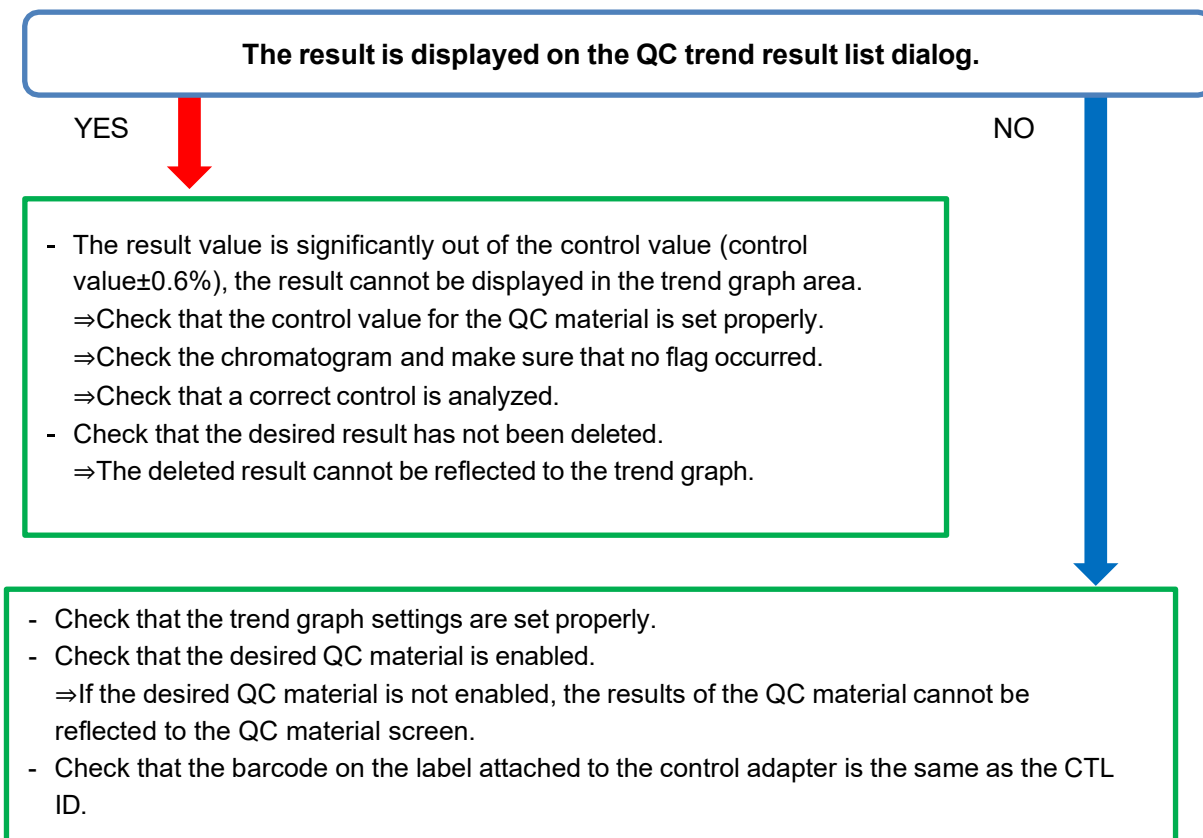
## 9.5 When a sample was skipped.



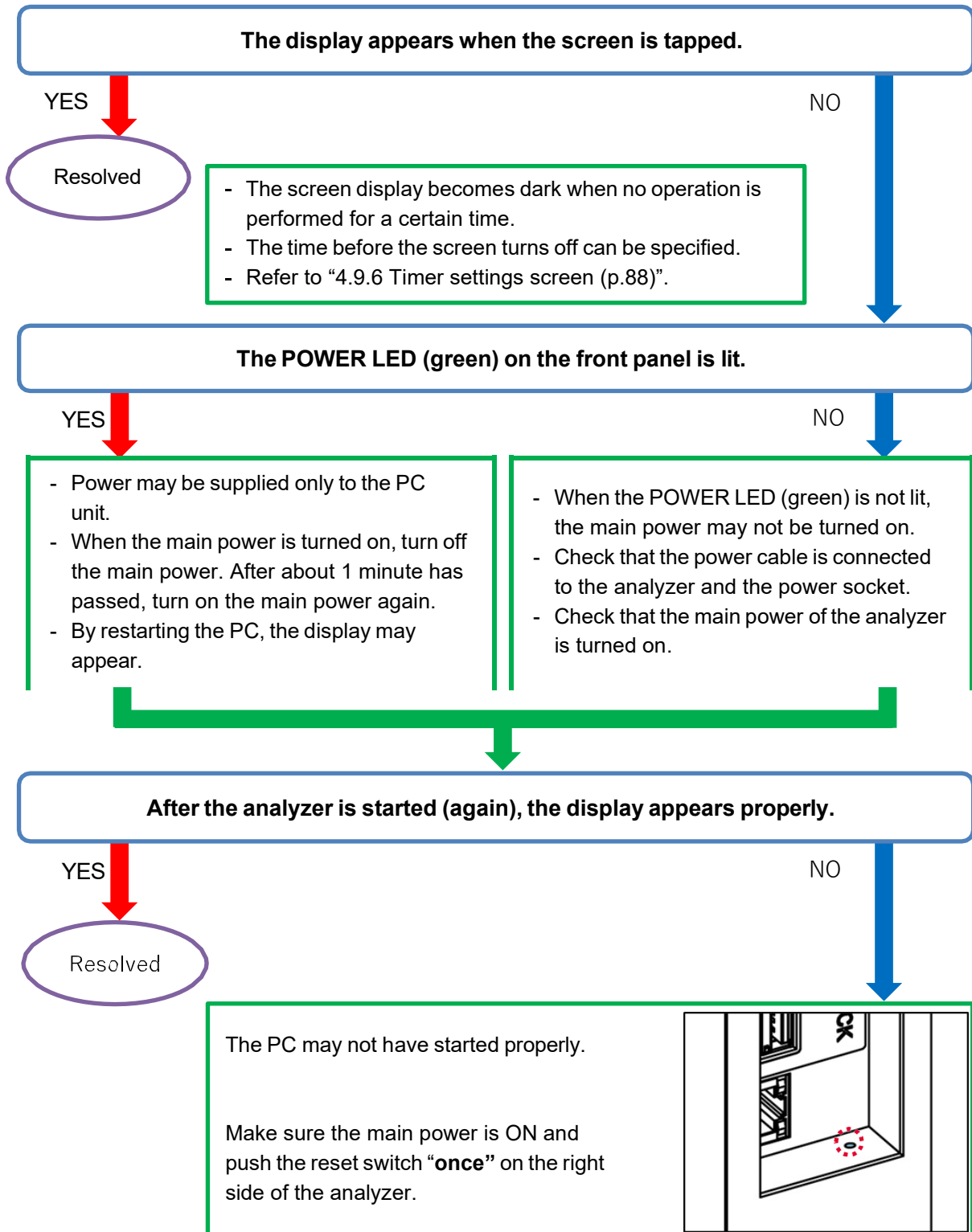
## 9.6 When a barcode reading error occurs frequently



## 9.7 When a control analysis result cannot be reflected to the QC trend



## 9.8 When no display appears on the screen

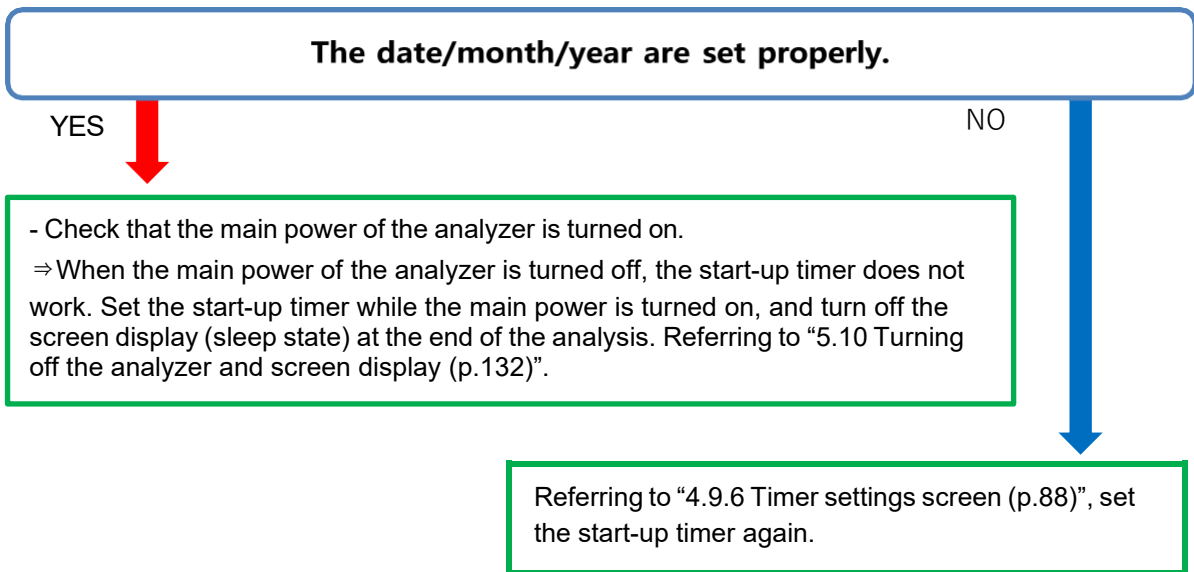


### NOTICE

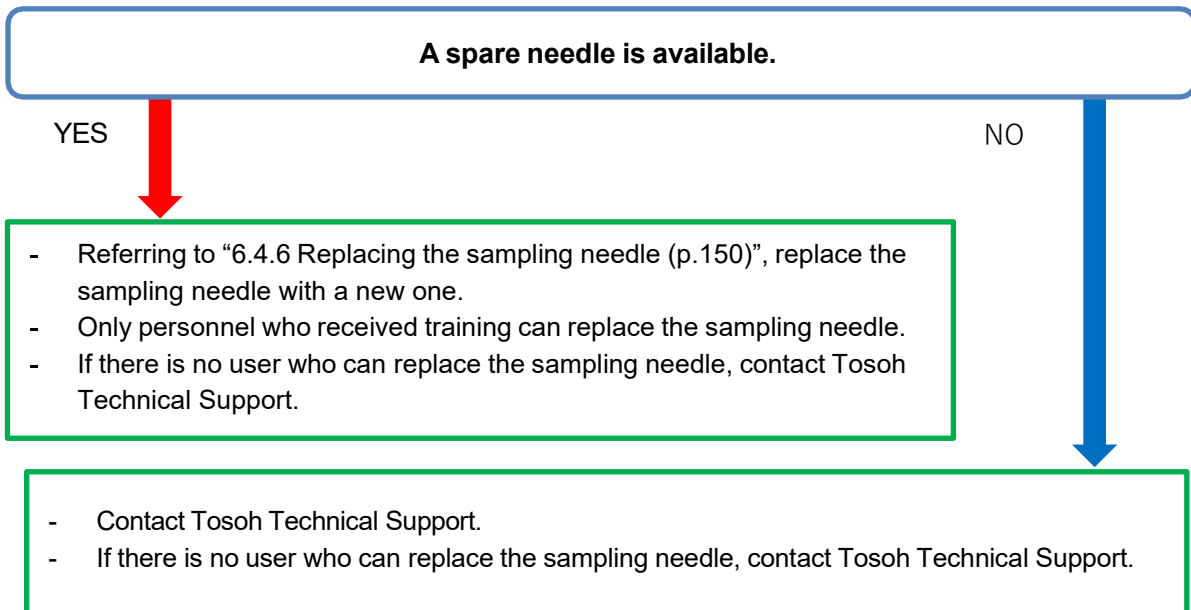
**Do not push the reset switch when the analyzer main power is OFF.**

- The application may not start properly. When the main power is turned off, power is supplied from the UPS, but if the power supply from the UPS is interrupted while restarting by pressing the reset button, it may cause abnormalities in the application or PC.

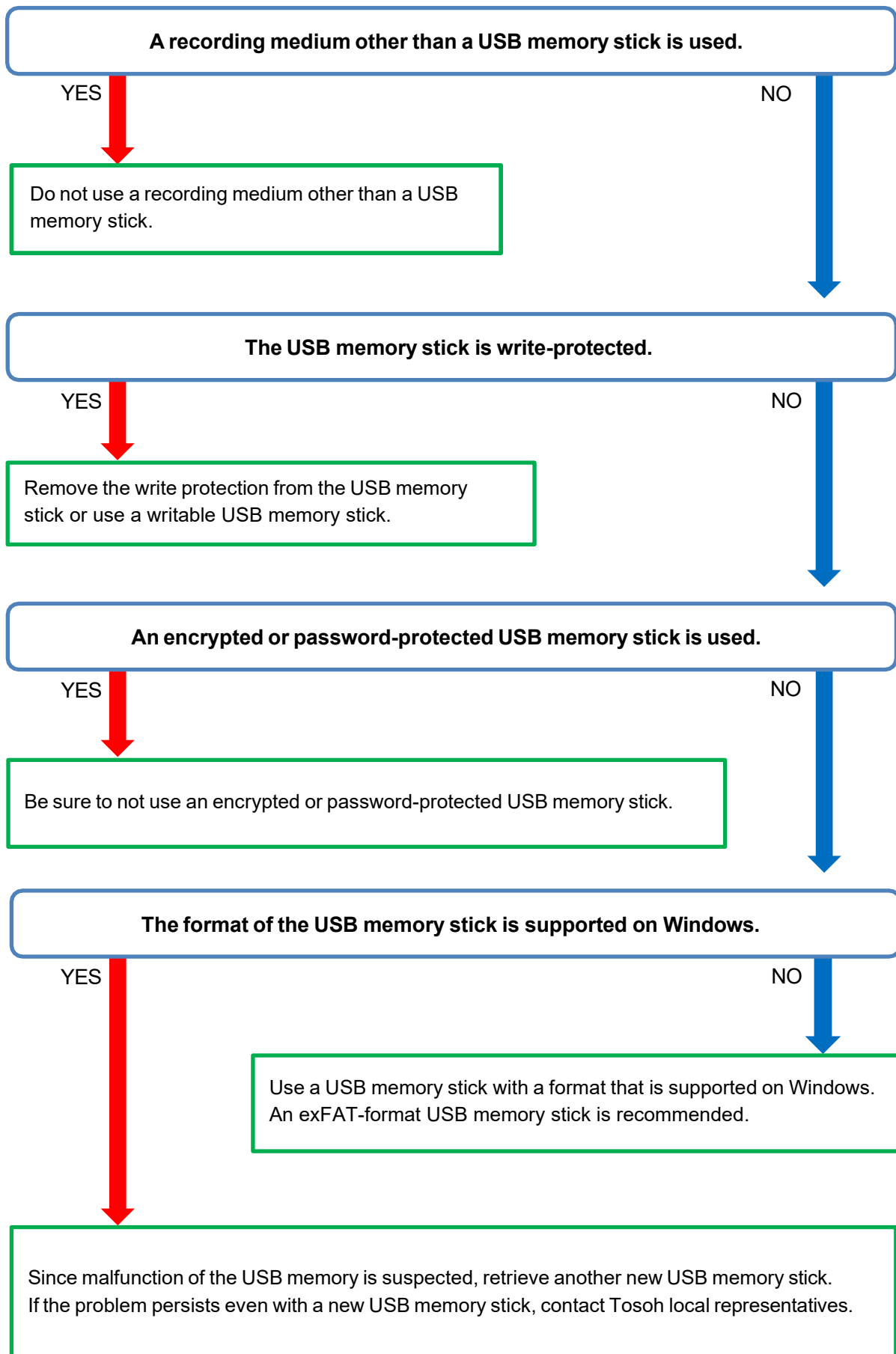
### 9.9 When the instrument did not start with a timer



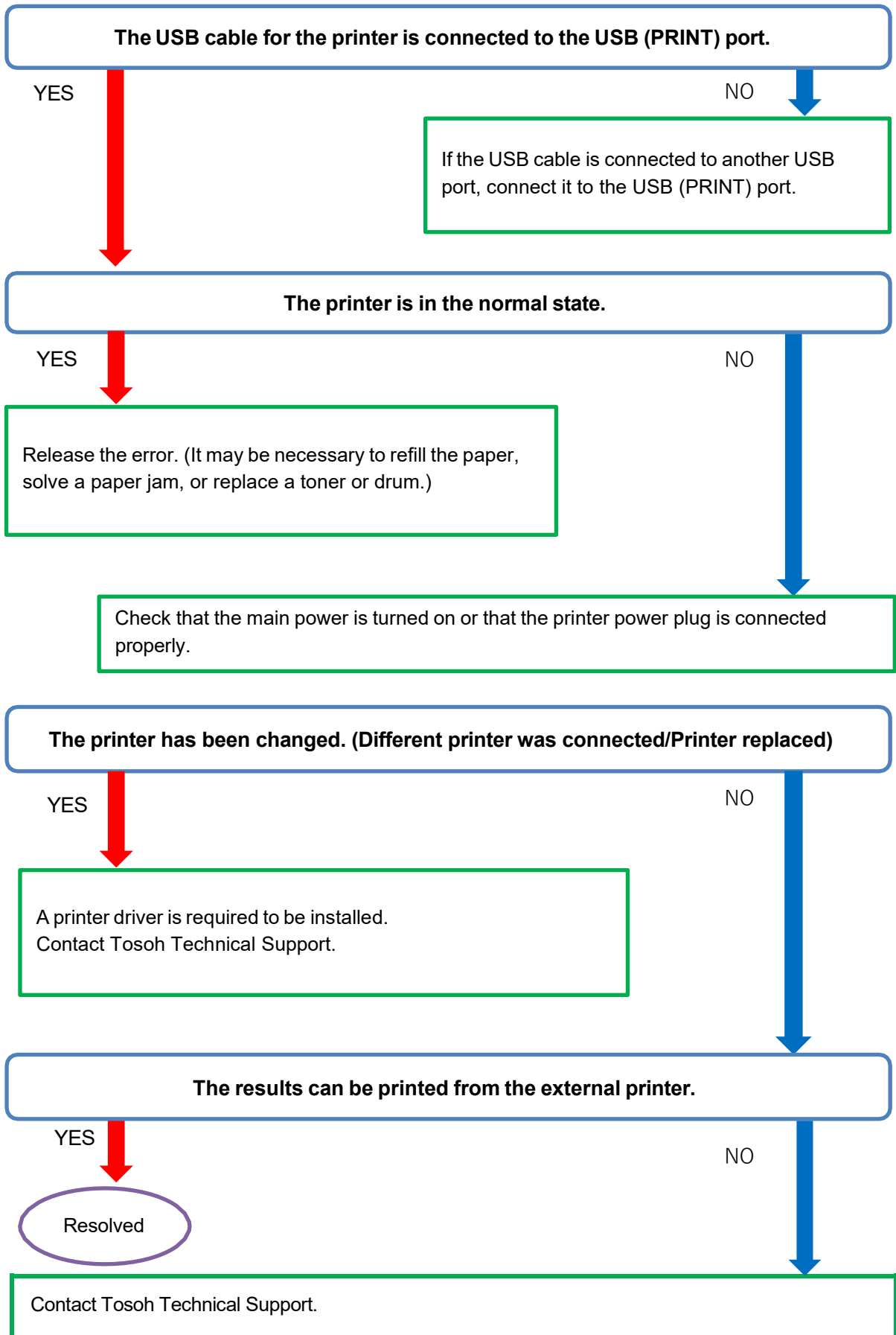
### 9.10 When the sampling needle is bent or broken



## 9.11 When data cannot be read from/written in the USB memory stick



### 9.12 When results cannot be printed using the external printer.



# 10 List of errors and warnings



An Error is a notification indicating that the performance of the analyzer cannot be guaranteed.

When an Error occurs, an analysis or operation in progress is stopped.

When the cause of an error is solved, the analysis or operation can be started again.

A warning is a notification indicating that analysis can be continued but that analysis results may be affected.

## Note

- To return to the previous screen from the error screen, tap the error reset button  to clear the  mark.
- If the cause is left unsolved, the error may occur continuously.

If the error persists even after taking the measures suggested in “Solution”, contact Tosoh local representatives. (Make a Note of the error code and include the message for Tosoh contact.)

### • Operation error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
002	EMERGENCY STOP	The analyzer has been stopped due to an emergency.	-	-	Error

### • Status monitoring error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
100	PRESSURE HIGH	The column or filter element is clogged.	Replace the filter element and check the pressure. If the pressure is still high, contact Technical Support.	9.1 When the system pressure is too high (p.166)	Error
101	PRESSURE LOW	Air has entered the pump, or a leakage has occurred.	Check the column joints for any leakage. If there is no leakage, perform air removal procedure.	9.2 When the system pressure is too low (p.167)	Error
102	PRES LIMIT OVER	A flow line is clogged, or an abnormal pressure has been detected.	Replace the filter element, and then turn off/on the main power of the analyzer.	9.1 When the system pressure is too high (p.166)	Error
103	D.FLUSH ERROR	The drain valve is closed.	Open the drain valve.	6.2.7 Air removal from the pump (p.139)	Error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
110	TEMP UNSTABLE	The column oven door is open.	Close the column oven door. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
111	TEMP LIMIT OVER	Noise has appeared in the signal from the temperature sensor, or a sensor failure has been detected.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
115	COLUMN LEAK ERROR	A leakage from the column has occurred.	Check the column joints for any leakage. If there is a leakage, wipe off the liquid, and connect the column tubes again.	9.3 When liquid is leaking (p.168)	Error
120	STAT DOOR OPEN	The STAT port door is open.	Close the STAT port door.	5.8 STAT analysis (p.123)	Warning
121	STAT DOOR ERROR	The STAT port door has been detected as open before the suction of a STAT sample.	Close the STAT port door and perform the STAT assay again.	5.8 STAT analysis (p.123)	Error
125	GRAD SENSOR ERROR	The GRAD sensor for monitoring the pump motor rotation has detected a failure.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
130	CHECK FILTER COUNT	The injection number (filter count) of the filter element has exceeded the upper limit.	Check the filter element.	6.4.3 Replacing the filter element (p.144)	Warning
131	CHECK COLUMN COUNT	The injection number (column count) of the column has exceeded the upper limit.	Check the column.	6.4.4 Replacing the column (p.146)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
140	BUFFER1 EMPTY	The remaining volume of Elution Buffer No.1 has fallen below a specified value.	Replace Elution Buffer No.1.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning
141	BUFFER2 EMPTY	The remaining volume of Elution Buffer No.2 has fallen below a specified value.	Replace Elution Buffer No.2.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning
142	BUFFER3 EMPTY	The remaining volume of Elution Buffer No.3 has fallen below a specified value.	Replace Elution Buffer No.3.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning
145	H/W EMPTY	The remaining volume of the Hemolysis & Wash solution has fallen below a specified value.	Replace the Hemolysis & Wash solution.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning
146	H/W BOTTLE EMPTY	The bottle of the Hemolysis & Wash solution is empty.	Replace the Hemolysis & Wash solution.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Error
148	DRAIN FULL ERROR	The waste chamber is filled with waste liquid.	Empty the waste tank and turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
150	BUFFER1 EXPIRED	Elution Buffer No.1 is expired.	Replace Elution Buffer No.1.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Error
151	BUFFER2 EXPIRED	Elution Buffer No.2 is expired.	Replace Elution Buffer No.2.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Error
152	BUFFER3 EXPIRED	Elution Buffer No.3 is expired.	Replace Elution Buffer No.3.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Error
155	H/W EXPIRED	The Hemolysis & Wash solution is expired.	Replace the Hemolysis & Wash solution.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
156	COLUMN EXPIRED	The column is expired.	Replace the column.	6.4.4 Replacing the column (p.146)	Error
157	CAL.CURVE EXPIRED	The calibration factor is expired.	Perform calibration.	5.4 Calibration (p.104)	Warning
158	LOT MISMATCH	The column lot No. does not match with that of the elution buffers.	Match the column lot No. between the column and elution buffers.	5.3.1 Checking the column (p.101) 5.3.3 Checking the elution buffers (p.102)	Error
159	R_INF. NOT SET	The information of the column, elution buffers, and Hemolysis & Wash solution has not been registered.	Read the barcodes of the column, elution buffers, and Hemolysis & Wash solution to register their information.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141) 6.4.4 Replacing the column (p.146)	Error
160	NOT CALIBRATED	Calibration has not been performed.	Perform calibration.	5.4 Calibration (p.104)	Warning
161	REAGENT NOT SET	The column, filter element, elution buffers, and Hemolysis & Wash solution have never been replaced.	Check the Reagent log and see which item needs to be registered. Replace the column, filter element, elution buffers, and Hemolysis & Wash solution.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141) 6.4.3 Replacing the filter element (p.144) 6.4.4 Replacing the column (p.146)	Error
170	RACK START CANCELLED	The rack start operation cannot be started.	Remove a sample rack.	-	Warning
180	BUFFER1 EXPIRED	Elution Buffer No.1 is expired. (Buffer switching unit)	Replace Elution Buffer No.1.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning
181	BUFFER2 EXPIRED	Elution Buffer No.2 is expired. (Buffer switching unit)	Replace Elution Buffer No.2.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
182	BUFFER3 EXPIRED	Elution Buffer No.3 is expired. (Buffer switching unit)	Replace Elution Buffer No.3.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning
183	H/W EXPIRED	The Hemolysis & Wash solution is expired. (Buffer switching unit)	Replace the Hemolysis & Wash solution.	6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Warning

• Data processing errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
200	AREA LOW ERROR	Samples for which the peak area falls below the lower limit have been detected several times in succession.	Check that there are sufficient volumes of samples, elution buffers, and Hemolysis & Wash solution.	5.6 Preparing a sample (p.115) 6.4.2 Replacing elution buffers and Hemolysis & Wash solution (p.141)	Error
201	CALIB ERROR	The calibration results are varied or out of the assigned value.	Check the setting order and entered assigned values of calibrators. If a mistake is found, correct the order or a value, and perform calibration again.	5.4 Calibration (p.104)	Error
202	TP LOW ERROR	Samples for which the theoretical plate falls below the lower limit have been detected several times in succession	If this error occurs for a different sample, contact Technical Support	Contact Technical Support	Error
203	AREA EX. HIGH	The peak area is too high.	Replace the filter element.	6.4.3 Replacing the filter element (p.144)	Error
232	NON REQUESTED DATA	Data other than requested has been received. (Internal communication error)	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132)	Error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
				5.2.1 System startup procedure (p.100)	
233	ANALY DATA RECEIVED ERROR	Analysis data could not be received. (Internal communication error)	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

• Communication errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
310 to 318	EXB COMM ERROR (**)	An error has occurred in BCR communication for LA line	Check the connection of the BCR for LA line. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
320 to 329	MAIN COMM ERROR (**)	An error has occurred in internal (MAIN) communication.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
330 to 339	AS COMM ERROR (**)	An error has occurred in internal (AS) communication.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
340	HOST COMM ERR(PE)	A parity error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
341	HOST COMM ERR(FE)	A framing error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
342	HOST COMM ERR(OR)	An overrun error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
343	HOST COMM ERR(BF)	A buffer full error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p/132) 5.2.1 System startup procedure (p.100)	Warning
344	HOST COMM ERR(OL)	A long data error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
345	HOST COMM ERR(RE)	A retry error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
346	HOST COMM ERR(ST)	A send timeout error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
347	HOST COMM ERR(RT)	A receive timeout error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
348	HOST COMM ERR(NR)	A no response error has occurred in host communication.	Check cable connection between analyzer and host computer. Check the host computer status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
350	LC COMM ERROR(PE)	A parity error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
351	LC COMM ERROR(FE)	A framing error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
352	LC COMM ERROR(OR)	An overrun error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
353	LC COMM ERROR(BF)	A buffer full error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
354	LC COMM ERROR(OL)	A long data error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
355	LC COMM ERROR(RE)	A retry error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
356	LC COMM ERROR(ST)	A send timeout error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
357	LC COMM ERROR(RT)	A receive timeout error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
358	LC COMM ERROR(NR)	A no response error has occurred in LA communication.	Check cable connection between analyzer and LA PC. Check the LA PC status. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

## • Printer errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
400	PAPER EMPTY	The internal printer is out of paper.	Replace the printer paper roll for the internal printer.	6.4.1 Replacing a paper roll (p.140) 8.3 External printer (p.164)	Warning
401	PRINTER OFF LINE	Communication with the printer cannot be established.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
402	PRINTER COVER OPEN	The cover of the internal printer is not closed.	Close the cover of the internal printer.	6.4.1 Replacing a paper roll (p.140)	Warning
420	PRINTER ERROR	The internal printer has malfunctioned.	Check the cover of the internal printer and close it. Turn off/on the main power of the analyzer.	6.4.1 Replacing a paper roll (p.140) 5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
421	PRINTER NOT FOUND	1. The internal printer has malfunctioned. 2. No external printer is connected.	1. Turn off/on the main power of the analyzer. 2. Connect an external printer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

## • USB memory stick errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
500	USB NOT READY	The USB memory stick is not inserted into the USB port.	Insert the USB memory stick to the USB port.	-	Warning
510	USB STICK FULL	The USB memory stick is full.	Replace the USB memory stick.	-	Warning
511	FILE NOT FOUND	The file could not be found.	Insert the proper USB memory stick.	-	Warning
530	USB HARD ERROR	The USB memory stick cannot be accessed.	Replace the USB memory stick. Turn off/on the main power of the analyzer.	-	Warning

## • Control and monitoring errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
603	MAIN COMMAND ERROR	An invalid command was sent in analyzer internal (PC) communication. (An analyzer internal communication failure has occurred.)	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
622	MAIN SOFT ERROR	Main software error has occurred.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
630	BELT BCR NO RESP	No response has been received from the BCR for LA line.	Check the connection of the BCR for LA line. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
631	BELT BCR SET ERROR	A setting error has occurred on the BCR for LA line.	Check the BCR setting for LA line and change the setting as necessary. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
632	BCR SET ERROR	A setting error has occurred on the BCR.	Check the BCR setting for LA line and change the setting as necessary. Turn off/on the main power of the analyzer.	4.9.4 Barcode Settings Screen (p.86) 5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
640	QUERY NO RESPONSE	No response to a query has been received from the host computer.	Check the host computer setting and change the setting as necessary. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
641	IRREGULAR QUERY	Invalid response to a query has been received from the host computer.	Check the host computer setting and change the setting as necessary. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
650	BELT ID UNMATCH	The IDs do not match between the samples sent from the LA line and read with BCR.	Check the LA system and change the setting as necessary. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
660	BELT LINE ABORT	An error occurred on the LA line or analyzer, so the processing of the sample sent from the LA line has been aborted.	Check the LA system and the analyzer and change their settings as necessary. Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
670	SKIP : #####	1. An error occurred in host communication, so an assay was not performed. 2. The barcode could not be read or the sample ID read with BCR does not match with the sample ID of the order from the host computer, so a sample assay was not performed.	1. Check connection with the host computer. Turn off/on the main power of the analyzer and the host computer. 2. Check the barcode label. If there is no problem with the barcode label, clean the BCR.	5.6 Preparing a sample (p.115)	Warning
671	BC ERR: RRRR - PP	The ID of the sample set at the PP position of rack No. RRRR has failed to be read.	Check the barcode label. If there is no problem with the barcode label, clean the barcode reader.	5.6 Preparing a sample (p.115)	Warning
680	CALIB POS ERROR	The calibrator positions are not correct.	Set calibrators in the correct order.	-	Error
690	MAIN BOOT ERROR	A failure has occurred on the boot program (MAIN).	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

## • AS errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
702	BC COMM ERROR	A communication error has occurred between the analyzer and the BCR.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
703	AS COMMAND ERROR	An invalid command (AS) has been detected in the analyzer.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
704	SAMPLE NOT FOUND	No sample was detected.	Place a sample in the sample rack.	-	Error
705	RACK POS ERROR	The rack transfer lever could not be returned because there was a subsequent sample rack.	Remove the sample rack and perform assay again.	-	Error
706	SYRINGE-L ERROR	An operation error has occurred on syringe-L.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
707	SYRINGE-S ERROR	An operation error has occurred on syringe-S.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
708	X1-AXIS ERROR	An operation error has occurred on the sample loader X1-axis.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
709	Y1-AXIS ERROR	An operation error has occurred on the sample needle Y1-axis.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
710	Z1-AXIS ERROR	An operation error has occurred on the sample needle Z1-axis.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
711	LINE VALVE ERROR	An operation error has occurred on the switch valve.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
712	X2-AXIS ERROR	An operation error has occurred on the sample loader X2-axis.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
713	X3-AXIS ERROR	An operation error has occurred on the sample loader X3-axis.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
714	Y2-AXIS ERROR	An operation error has occurred on the sample loader Y2-axis.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
718	INJ VALVE ERROR	An operation error has occurred for the injection valve.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
722	AS SOFT ERROR	An internal control error (AS) has occurred.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
723	SAMPLE MISMATCH M	The sample information does not match each other (MAIN).	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
724	SAMPLE MISMATCH A	The sample information does not match each other (AS).	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
726	LOADER LEFT FULL END	The rack-out position is full of sample racks, so analysis is stopped.	Remove sample racks from the rack-out position of the sample loader.	-	Warning
727	LOADER LEFT FULL	The rack-out position is full of sample racks.	Remove sample racks from the rack-out position of the sample loader.	-	Warning
728	LOADER RIGHT RACK JAM	Sample racks are stuck in the rack-in position, so the sample loader cannot operate.	Reposition sample racks to the front in the rack-in position on the sample loader.	-	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
731	CB1 BOARD ERROR	A failure has occurred on the internal board of the sample loader.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
733	BCR BF-AXIS ERROR	A BF-axis error has occurred on the barcode unit. (GR-90SL)	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
734	LOADER CAPACITY OVER	The sample loader is full of sample racks.	Remove sample racks.	-	Error
790	AS BOOT ERROR	A failure has occurred on the boot program (AS)	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

• LA control errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
800	BL BC UNMATCH	The ID sent from the LC line does not match the ID read with the BCR for LA line.	Check the barcode label. If there is no problem with the barcode label, clean the BCR for LA line.	-	Warning
801	BL BC READ ERROR	A barcode could not be read with the BCR for LA line.	Check the barcode label. If there is no problem with the barcode label, clean the BCR for LA line.	-	Warning
802	BELT LINE ERROR	An abnormal signal has been received from the LA line.	Check the LA line.	-	Warning
803	BL ID TRANS ERROR	An ID has been sent when the analyzer is not ready.	Check the LA line.	-	Warning

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
804	BL ID NOT ACCEPT	A sample has arrived even though the ID has not been received.	Check the LA line.	-	Warning
805	BELT LINE DOWN	A connection signal has been cut off Or communication with the LA line has been interrupted.	Check the LA line.	-	Warning
806	BL COMM ERROR	A communication error has occurred on the LA line.	Check the connection of the communication cable for the LA line.	-	Warning
810	BL SAMP SIG ERR	The SMPOK signal has been cut off during sampling.	Check the LA line.	-	Error

• Database errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
900	DB ACCESS ERROR	Connection to the database has failed.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
901	DB READ ERROR	The processing of obtaining values from the database has failed.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
902	DB WRITE ERROR	The processing of writing values to the database has failed.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

## • File access errors

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
1000	FILE READ ERROR	A file could not be read.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display p.132) 5.2.1 System startup procedure (p.100)	Error
1001	FILE WRITE ERROR	A file could not written.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error
1002	FILE NOT FOUND	No file is found.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

## • Elapsed days errors (after startup)

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
1100	ACTIVITY LIMIT (7)	7 or more days have passed since turning on the analyzer.	Turn off/on the main power of the analyzer within 3 days. 10 or more days have passed since turning on the analyzer, analysis cannot be performed or the analyzer cannot be operated.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Warning
1101	ACTIVITY LIMIT (MAX)	10 or more days have passed since the analyzer was turned on.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

## • Software version error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
1110	SOFTWARE MISMATCH ERROR	PC and device software versions are mismatched.	Contact Technical Support.	-	Error

## • Unexpected error

Error code	Message	Content / Cause	Solution	Reference	Error / Warning
9999	PROGRAM EXCEPTION	An unexpected error has occurred while the program is running.	Turn off/on the main power of the analyzer.	5.10 Turning off the analyzer and screen display (p.132) 5.2.1 System startup procedure (p.100)	Error

# 11 Appendix

## 11.1 Specifications of the HLC-723GR01

Analyte	HbA1c (% , mmol/mol)	
Applicable samples	Venous whole blood (K2 EDTA and/or K3 EDTA samples and diluted/hemolysate samples)	
Assay principle	Ion exchange high-performance liquid chromatography	
Processing throughput	50 seconds / sample	
Calibration	2-point calibration by calibrators	
Detection method	2-wavelength absorbance (Detection wavelength: 415 nm / 500 nm)	
Sampling volume	3 $\mu$ L for whole blood samples, 150 $\mu$ L for diluted/hemolysate samples	
Sample rack	10 sample tubes or cups per rack	
Sample loading capacity	90 samples (when the GR-90SL is connected) 290 samples (when the GR-290SL is connected)	
Sample suction	Nozzle	
Sample injection	Sample loop (5 $\mu$ L)	
Sample dilution	Automatic dilution with Hemolysis & Wash solution on the dilution port	
Sample container	Sample tubes (12 to 15 mm in diameter $\times$ 75 mm or 100 mm in length) Dedicated sample cup (with adapter)	
Sample barcode	Barcode with a maximum of 20 digits Barcode standards: 4 types of barcodes can be selected at a time from the following: NW-7 (Codabar), CODE39, ITF, CODE128, JAN (UPC/EAN), Industrial 2 of 5, COOP 2 of 5 (CODE39 is available only with the optional laser barcode reader.)	
Dimensions	Main unit and GR-90SL	530 (W) $\times$ 515 (D) $\times$ 615 (H) mm 20.9 (W) $\times$ 20.3 (D) $\times$ 24.2 (H) inches (excluding protrusions)
	Main unit and GR-290SL	1120 (W) $\times$ 530 (D) $\times$ 615 (H) mm 44.1 (W) $\times$ 20.9 (D) $\times$ 24.2 (H) inches (excluding protrusions)
Weight	Main unit	Approx. 34 kg or 75 lbs
	Sample loader (GR-90SL)	Approx. 9 kg or 20 lbs
	Sample loader (GR-290SL)	Approx. 26 kg or 57.3 lbs
Display	10.1-inch color LCD	
Input	Capacitive touch panel	
Storable number of samples	Internal memory: Max. 150,000 samples USB memory stick (optional): PDF report	

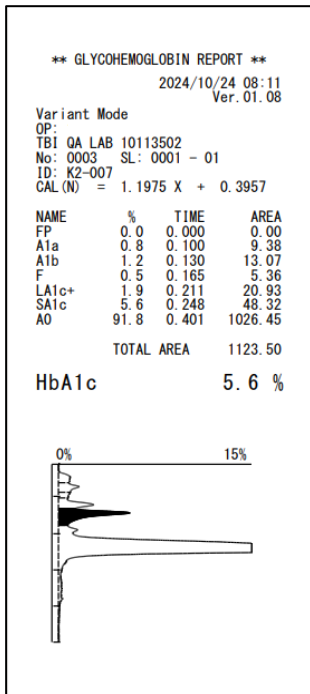
Printer	Internal printer: Thermal printer (paper width: 58 mm) External printer: Monochrome laser printer (optional)
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External output		Serial communication (RS-232C)
Quality control		Trend management function (Max. 31 days)
Eluent feeding		Single plunger pump (Maximum feeding pressure: 18 MPa)
Temperature control (column)		Approx. 25°C
Applicable sample rack		SYMEX rack (with plastic bottom)
Data processing unit		OS: Windows 10 IoT Enterprise LTSC
Power	Power supply	AC100 to 240 V ( $\pm 10\%$ ), 50 / 60 Hz
	Power consumption	250 VA
Operating environment	Temperature	15 to 30°C
	Humidity	20 to 80 % (No condensation)
	Over voltage category	II
	Pollution degree	2
	Dust	Ordinary office level
	Maximum Altitude	2,000 m or 6,600 feet
Standard conformity	EMC standard	IEC61326-2-6 :2020, IEC 60601-1-2:2014
	Barcode reader	IEC60825-1: 2014, Class 1 LED Product
	Handheld barcode scanner (optional)	IEC62471:2006, exempt group
	Laser barcode scanner (optional)	EN60825-1: 2014, Class 1 Laser Product

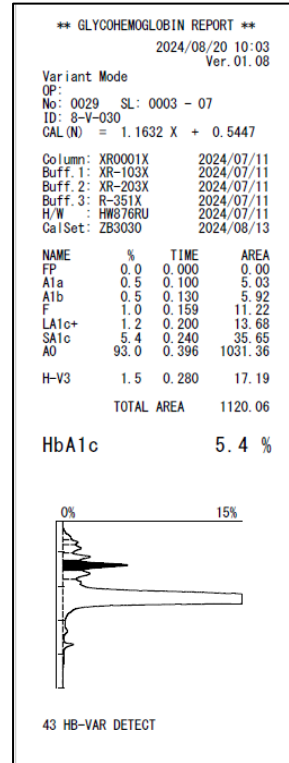
## 11.2 Chromatogram examples

The additional peak information provided in addition to %HbA1c on the chromatograms should only be used in troubleshooting and has not been validated. Only the %HbA1c value should be reported to the healthcare provider.

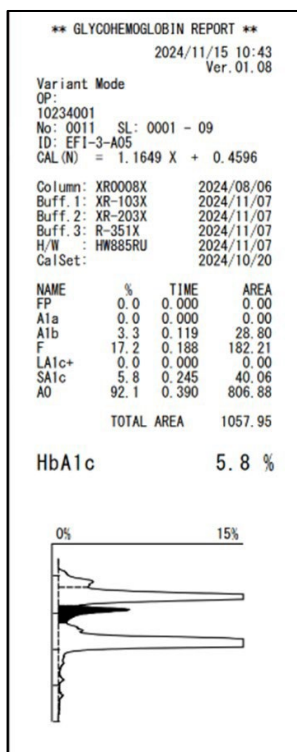
### 11.2.1 Normal sample



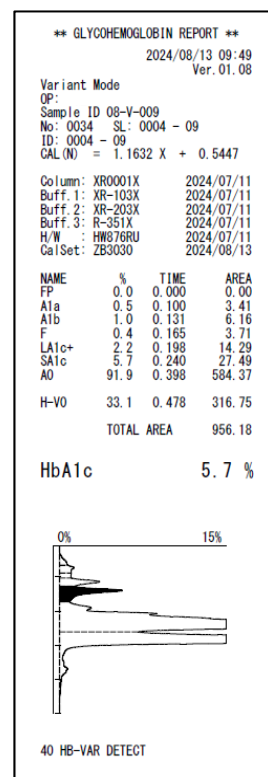
### 11.2.3 Sample with HbAE



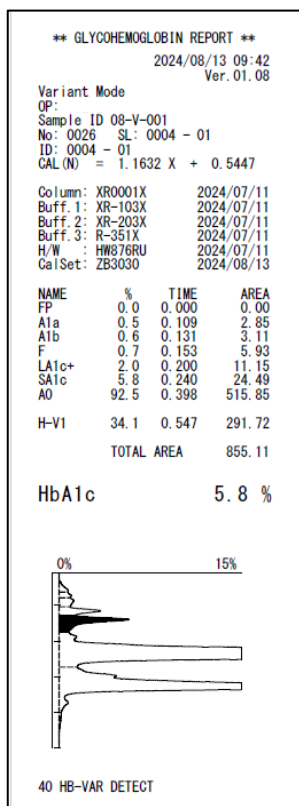
### 11.2.2 Sample with high HbF



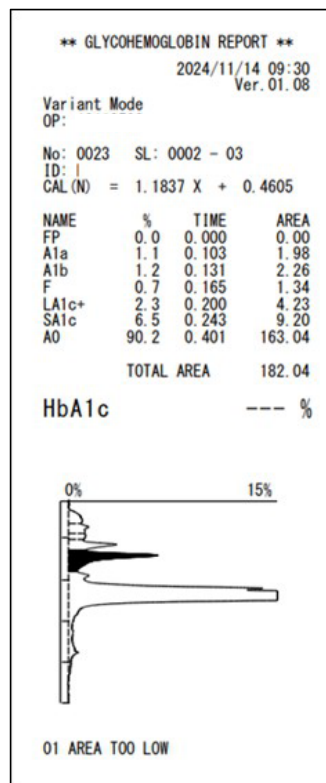
### 11.2.4 Sample with HbAD



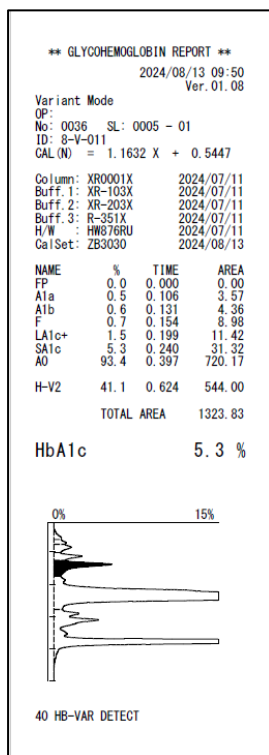
### 11.2.5 Sample with HbAS



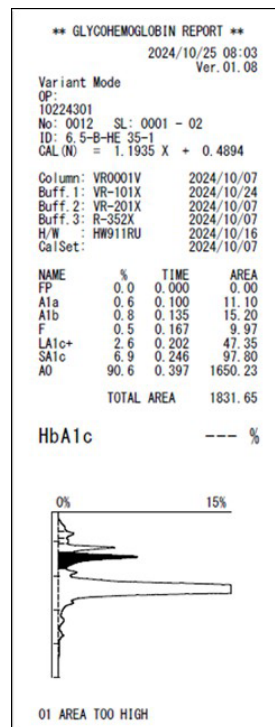
### 11.2.7 Sample flagged with Area Too Low



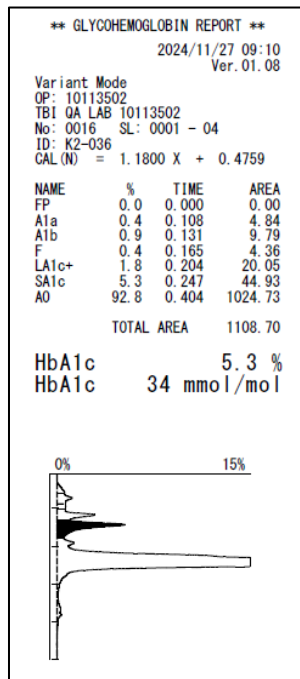
### 11.2.6 Sample with HbAC



### 11.2.8 Sample flagged with Area Too High



### 11.2.9 Chromatogram reporting both NGSP units and IFCC units



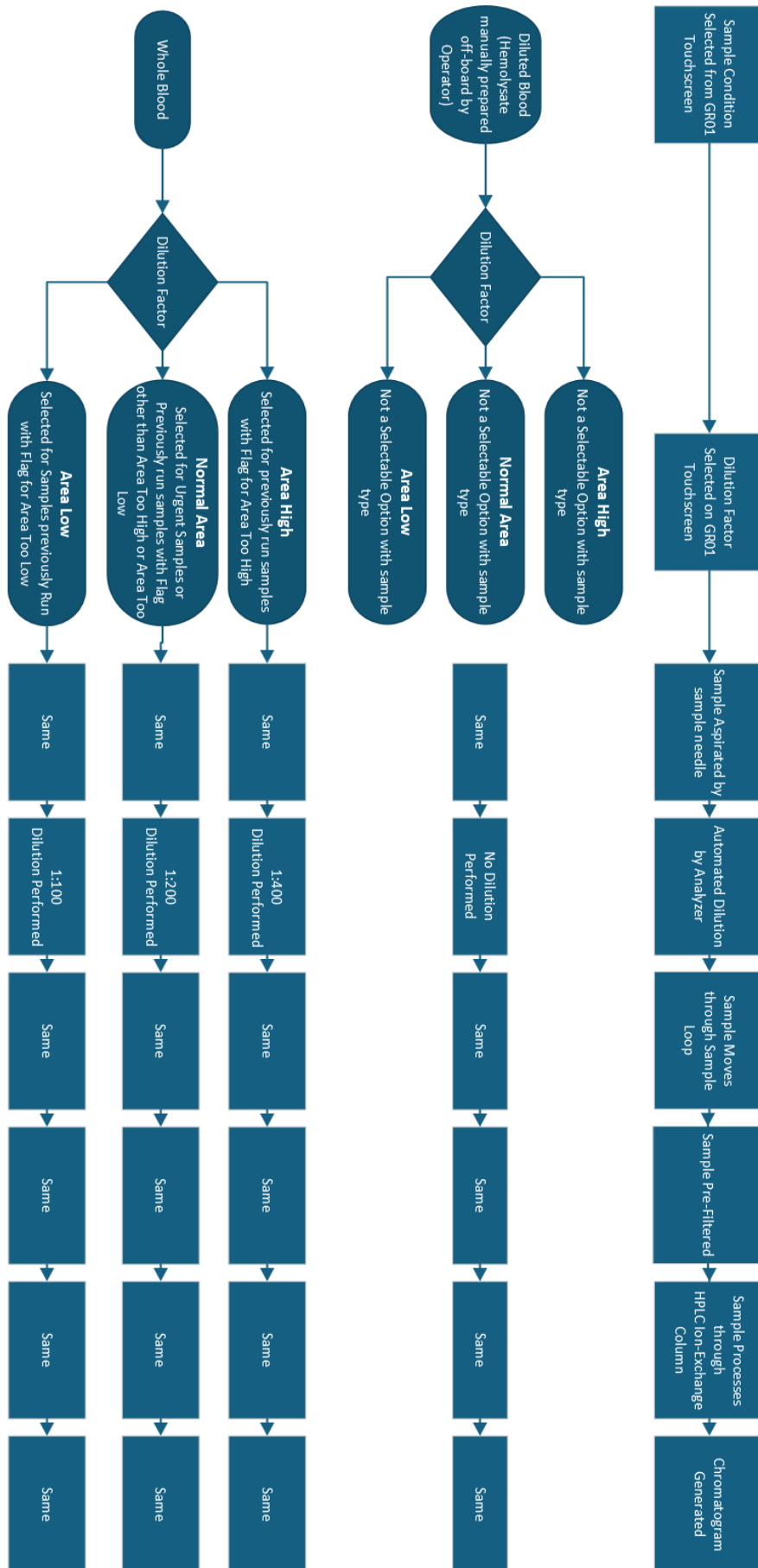
### 11.3 Compliance to IEC60601-1-2:2014+A1:2020

Emission test	Test levels
CISPR11 Conducted emission	Group 1 Class A
CISPR11 Radiated emission	
IEC61000-3-2 Harmonic current emissions	Class A
IEC61000-3-3 Voltage changes, voltage fluctuations and flicker	d-max Manual switching 24 times test applied Pst

Immunity test	Test levels		
IEC61000-4-2 Electrostatic discharge	Contact: $\pm 8$ kV Air: $\pm 2$ , $\pm 4$ , $\pm 8$ , $\pm 15$ kV		
IEC61000-4-3 Radiated electromagnetic field	80 MHz - 2.7 GHz: 3 V/m		
IEC61000-4-3 Proximity fields from RF wireless communications equipment	Test frequency (MHz)	Modulation	Immunity test level (V/m)
	385	Pulse modulation 18 Hz	27
	450	Pulse modulation 18 Hz	28
	710, 745, 780	Pulse modulation 217 Hz	9
	810, 870, 930	Pulse modulation 18 Hz	28
	1720, 1845, 1970	Pulse modulation 217Hz	28
	2450	Pulse modulation 217Hz	28
	5240, 5500, 5785	Pulse modulation 217Hz	9
IEC61000-4-4 Electrical fast transient/burst	Power port: $\pm 2$ kV I/O port: $\pm 1$ kV		
IEC61000-4-5 Surge	L-L: $\pm 0.5$ , $\pm 1$ kV L-PE: $\pm 0.5$ , $\pm 1$ , $\pm 2$ kV		
IEC61000-4-6 Immunity to conducted disturbances, induced by radio-frequency fields	0.15 MHz - 80 MHz: 3 V ISM frequency band: 6 V		
IEC61000-4-8 Power frequency magnetic field	30 A/m		

Immunity test	Test levels		
IEC61000-4-11 Voltage dips	0% during 0.5 cycle: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % during 1 cycle: 0° 70 % during 25 cycles: 0°		
IEC61000-4-11 Short interruptions and voltage variations	0 % during 250 cycles: 0		
IEC61000-4-39 Proximity magnetic fields	Test frequency	Modulation	Immunity test level (A/m)
	134.2 kHz:	Pulse modulation 2.1 Hz	65
	13.56 MHz	Pulse modulation 50 Hz	7.5

## 11.4 Illustration of the GR01 STAT Function Workflow for Hemolysate (Diluted Sample) and Whole Blood.







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