

Total Thrombus formation Analysis System

User's Manual

Model: T-TAS[®]wS

Ver. 1.0



This instruction manual describes the handling procedures for the T-TAS wS.
Before using this instrument, please read this instruction manual carefully to ensure proper operation.
Please also store the manual safely so that it can be viewed at any time.

Intended Use

The T-TAS wS Instrument is an in vitro diagnostic medical device intended for professional use with T-TAS reagent chips in the clinical laboratory.

Introduction

- T-TAS wS is an in vitro diagnostic medical instrument.
- Reproduction of the contents of this manual, in whole or in part, without permission is strictly prohibited.
- The contents of this manual and system specifications are subject to change without notice for improvement.
- While every effort has been made to ensure the accuracy of the contents of this manual, if you have any questions or notice any errors or omissions, please contact ZACROS Corporation.
- This instrument should be used only by properly trained operators.
- Improper handling of this instrument by the customer or use of this instrument in a manner not in accordance with the contents of this manual may impair the performance of this instrument.
- We are not liable for any damage caused by improper handling of this instrument by the customer or use of this instrument in a manner not in accordance with the contents of this manual.
- Clinical diagnosis based on the measurement results should be judged comprehensively by the physician in charge in conjunction with clinical symptoms and other test results.
- This manual is copyrighted by ZACROS Corporation. T-TAS® is a registered trademark of ZACROS Corporation.
- QR Code is a registered trademark of DENSO WAVE INCORPORATED.

Software Cyber Security

- T-TAS wS is intended for use in clinical laboratories.
- Only authorized personnel of the facility should have access to the device.
If this condition cannot be guaranteed, additional cybersecurity measures are available to limit this type of risk.
- For more information, please contact ZACROS Corporation.

Symbol Glossary

Symbol	Description
	CE marking
	Authorized Representative in the European Community
	Importer
	Manufacturer
	Consult Instruction Manual for Information
	In Vitro Diagnostic Medical Device
	Prescription Use Only
	Catalog Number
	Serial Number
	Caution; Consult Instruction Manual
	Waste Electrical and Electronic Equipment's Graphic Symbol
	Warning; Biological Hazard
	Center-positive DC plug
	SGS Marking for Electrical Safety Certification
	Standby/Power On
	Temperature Limit
	This Way Up
	Fragile, Handle With Care

Symbol	Description
	Handle with care
	Stacking Limit By Number
	Keep Dry
	Corporate Logo

Inquiries

For any questions regarding use, repairs, change of use location, transportation or disposal of this instrument, please contact ZACROS Corporation or your local distributor.

Manufacturer



Address: 1-1-1 Koishikawa, Bunkyo-ku, Tokyo 112-0002 Japan

Email: ttas-info@zacros.co.jp

URL: <https://www.zacros.co.jp/>

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1 For Safe Use

1.1 Before Reading this Manual

This manual describes the proper use and precautions for using the Total Thrombus formation Analysis System T-TAS wS. Please read this manual carefully and use the product correctly.

In addition, please keep this manual in a readily accessible location so that it is not lost.

1.2 Description of Warnings and Precautions

Serious incidents occurring with respect to T-TAS wS should be reported to the manufacturer or to the distributor and regulatory authorities of the country in which the user or patient resides.

This instrument is designed with operator safety as a top priority. However, due to the nature of the system, there are risks that cannot be removed. In this manual, the severity of those risks and the level of danger are indicated in four levels: "DANGER," "WARNING," "CAUTION," and "ATTENTION". Please read and fully understand the displayed items before operating and performing maintenance on this instrument.

The four levels are in order of severity regarding hazards (DANGER > WARNING > CAUTION > ATTENTION).

Safety Precautions



DANGER

"DANGER" describes situations in which there is an imminent danger of death or serious injury to the operator during operation of this instrument.



WARNING

"WARNING" describes situations that may result in death or serious injury to the operator during operation of this instrument.



CAUTION

"CAUTION" describes situations that may result in minor injury to the operator during operation of this instrument.

ATTENTION

"ATTENTION" describes situations that are not likely to cause injury to the operator, but may cause damage or malfunction to this instrument, facility, or equipment.

Meaning of Graphic Symbols and Symbols

In this manual, the terms "DANGER," "WARNING," "CAUTION," and "Attention" are accompanied by graphic symbols to make the warnings easier to understand.

Graphic Symbol		This graphic symbol indicates prohibited practices.
		This graphic symbol indicates mandatory items that must be performed.
		This graphic symbol indicates that the user should carefully read and understand the instruction manual.
		This symbol indicates the possibility of contact with infectious materials such as specimens, solid waste or waste fluid, and other hazards such as skin damage.
Symbol		This symbol describes matters that must be observed during the work and information that may affect the measurement results.
		This symbol describes additional explanations that could not be provided in the text, or information that is useful to know.
		This symbol describes references where relevant content and common steps are described.

1.3 For Safe Use

1.3.1 Precautions When Installing This Instrument

When installing this instrument, the following items should be noted:

- Ask the distributor to install this instrument.
- Install in a location where it will not be exposed to water.
- Install in a location where air pressure, temperature, humidity, ventilation, sunlight, dust, or air containing salt or sulfur will not adversely affect the product.
- Pay attention to stability status such as tilt, vibration, and shock (including during transportation).
- Note the frequency and voltage of the power supply and its power consumption.
- This instrument should be connected to an AC outlet or power strip that is easily accessible.
- This instrument complies with the emission and immunity requirements specified in EN/IEC 61326-2-6:2020 and IEC60601-1-2:2014+A1:2020 (for power supply voltage of 120 V).
- Allow at least 15 cm of space so as not to block the back of this instrument.



WARNING



- Do not install in areas subject to water or where chemicals are stored.
- Do not expose to organic solvents such as ketones, esters and ethers, or halogenated hydrocarbons.
- Do not install in areas where gas is generated or near fire.
- Do not install this instrument in an unstable location.
It may cause the instrument to fall or drop, resulting in malfunction or injury.
- Do not use the instrument with a voltage other than the specified power supply voltage.



Electromagnetic radiation may interfere with the normal operation of this instrument. Do not use near sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources). The presence of electromagnetic interference is indicated by the occurrence of interruption of measurement operation, display of errors, or loss of screen display.



The operation of this instrument or other equipment may be affected. Use according to the information provided below.

- Do not use this instrument in close contact with or stacked on top of other equipment.
- Do not connect any equipment or cables other than those specified.
- Do not use portable RF communication devices such as smartphones within 30 cm (12 in) of this instrument.



CAUTION



- Evaluate the electromagnetic environment before operating this instrument.
- The weight of this instrument is approximately 12 kg (26 lb). When transporting or installing this instrument, be careful not to drop it and injure your feet, etc.

ATTENTION



- Do not use a power cable other than the one supplied with this instrument.
This may cause malfunction or failure.
- Do not connect a USB hub to the USB port of this instrument.

1.3.2 Precautions Before Using This Instrument



WARNING



Do not plug or unplug the power plug with hands wet with water or other liquids. Failure to do so may cause electric shock.

ATTENTION



Use only USB flash drives that have been checked for viruses and other safety issues prior to connection to this instrument.

- Inspect the power supply connections to ensure that the instrument operates correctly.
- Ensure that all cord connections are correct and secure, and that the instrument is in good and safe working order before use.

1.3.3 Precautions to Prevent Ignition or Malfunction During Use



WARNING



- Do not use in an atmosphere with flammable gas.
- Do not use flammable and explosive gases near this instrument.
- This instrument is not explosion-proof.



CAUTION



In the following cases, immediately turn off the power and shut down the system.

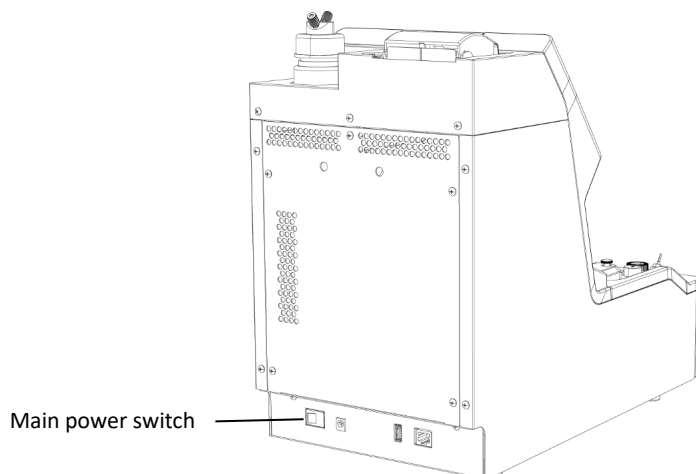
- If water, reagents, or foreign objects enter the instrument
- If abnormal sounds or vibrations occur during operation of this instrument
- Abnormal operation of this instrument

ATTENTION



- Do not use consumables other than those specified.
- Chips and other consumables should be used within their expiry dates.
- Do not pull hard on the nozzle or tubing. Do not pull the nozzle out more than 165 mm (6.5 in). Tubing and joints may be damaged.

- Always monitor the entire instrument for any abnormalities.
- If you find any abnormality or malfunction in the instrument, turn off the main power switch on the back of the instrument and disconnect the power plug from the AC outlet. Then immediately contact your distributor.



- If liquid is spilled on the instrument, turn off the instrument, disconnect the power plug from the AC outlet, and wipe up the spill.
- Take care that the equipment is not used by anyone other than the intended user.

1.3.4 Precautions to Prevent Injury During Use

 WARNING	
	• When handling reagents or samples, wear protective equipment such as protective gloves and eye protectors, and protective clothing such as a lab coat. • Direct hand contact with the nozzle or tubing may cause injury. Always wear protective gloves and handle with care.
ATTENTION	
	Do not use barcode readers other than the one specified.

- Strictly follow the instrument handling precautions described in this manual to prevent electric shock and burns.
- When using test solutions, mineral oils, disinfectants or detergents, wear protective clothing, protective gloves, eye protectors, masks, etc. and follow the instructions in this manual.

1.3.5 Precautions to Prevent Biohazards



WARNING



When touching areas that may be contaminated with mineral oil or infectious samples, wear protective equipment such as protective gloves and eye protectors, and protective clothing such as a lab coat.

- When handling specimens, performing maintenance, or managing waste, be aware that you are working with biological hazards and wear protective gear (protective clothing, protective gloves, eye protectors, masks, etc.) as prescribed by an expert who can judge the hazards.
- In the event of contact with mineral oil or infectious materials on skin, etc., treat it in accordance with the facility's standard of practice and seek medical attention where necessary.
- Immediately wipe up any liquids that overflow from the container to the instrument.
- If mineral oil or specimen is accidentally swallowed, seek medical attention.

1.3.6 Precautions for Handling Waste Fluid or Solid Waste



WARNING



When disposing of waste fluid or solid waste, wear protective equipment such as protective gloves and eye protectors, and protective clothing such as a lab coat.

- Waste fluid or solid waste (chips, Reservoirs, Over-caps, etc.) should be treated as infectious.
- When disposing of waste fluid or solid waste, dispose of it as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

1.3.7 Precautions After Using the System

ATTENTION



- Unplug the power plug when this instrument will not be used for an extended period of time.
- Please observe storage conditions when storing and transporting consumables and separately sold accessories.
- When removing cords, do not use excessive force such as holding and pulling cords. Instead, unplug cords by holding close to the connector.

- (1) Turn off the power according to the specified steps.
- (2) For storage, the following items should be noted.
 - Store in a location where it will not be exposed to water.
 - Store in a location where air pressure, temperature, humidity, ventilation, sunlight, dust, or air containing salt or sulfur will not adversely affect the product.
 - Pay attention to stability status such as tilt, vibration, and shock (including during transportation).
 - Do not store in areas where chemicals are stored or gases are generated.

- (3) Accessories and cords should be cleaned and then sorted and grouped together.
- (4) Be sure to keep the instrument clean for the next use.

1.3.8 Maintenance and Inspection Precautions

Be sure to perform periodic inspections of the instrument and its components.

1.3.9 Precautions in the Event of Malfunction

 WARNING	
	Never disassemble or modify the equipment comprising this instrument.

Contact the distributor if the instrument malfunctions, and do not repair it on your own.

1.3.10 Precautions for Transporting and Moving the System

 WARNING	
	This instrument may be contaminated by infectious samples. When transporting or moving the instrument, wear protective equipment such as protective gloves and eye protectors, and protective clothing such as a lab coat.

 CAUTION	
	• Do not apply impact or drop the system when transporting or moving it. Failure to prevent this may cause malfunction or injury. • Do not transport or move the system while it is in operation. Failure to prevent this may cause malfunction or injury. • Do not transport or move the system with external devices, etc. still connected. Failure to prevent this may cause malfunction or injury.

1.3.11 Precautions for Transporting the System

 WARNING	
	This instrument may be contaminated by infectious samples. When transporting instrument, wear protective equipment such as protective gloves and eye protectors, and protective clothing such as a lab coat.

 CAUTION	
	Empty the mineral oil in the oil bottle during transportation.

ATTENTION



- Please keep the packing box that this instrument came in during delivery. It will be used when transportation is required.
- Use the dedicated packing box for transportation. Please also transport the instrument in accordance with the storage conditions listed in "2.9 Specifications".

1.3.12 System Disposal Precautions



WARNING



When disposing of this instrument, wear protective equipment such as protective gloves and eye protectors, and protective clothing such as a lab coat.

Components of the T-TAS wS are covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE, 2012/19/EU) and must be disposed of in a safe and compliant manner. These items must be disposed of via designated collection facilities appointed by government or local authorities to ensure that the components are not disposed of as municipal waste. For more information about disposal of the T-TAS wS, please contact your city office, waste disposal service or your local representative.

1.3.13 Instrument Life

The life of this instrument is set at 5 years of self-certification. In addition, this manual becomes invalid with the life of the instrument.

Contact the distributor if the instrument has exceeded its life.

1.4 About Warning Labels

This instrument has warning labels attached to areas of potential hazard during operation and maintenance work.

Warning labels are displayed in an appropriate size and color scheme to catch the operator's eye, and include the symbols for the danger classification.



WARNING



- The operator must check in advance the positions of all warning labels attached to this instrument and fully understand their contents before performing any work.
- Never remove or alter the warning labels.

1.4.1 Types of Warning Labels

The warning labels used on this instrument are as follows.

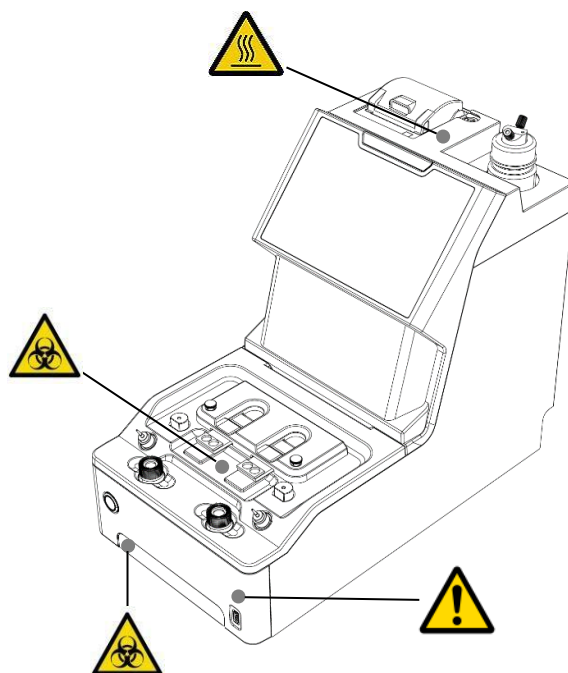
Warning label	Description
	The location where this label is affixed may cause instrument failure if mishandled.

	The location where this label is affixed is at risk of becoming infectious. Please operate wearing protective equipment (eye protectors, protective gloves, lab coat, etc.).
	The location where this label is affixed may be subject to high temperatures. Do not touch it unnecessarily as it may cause burns.

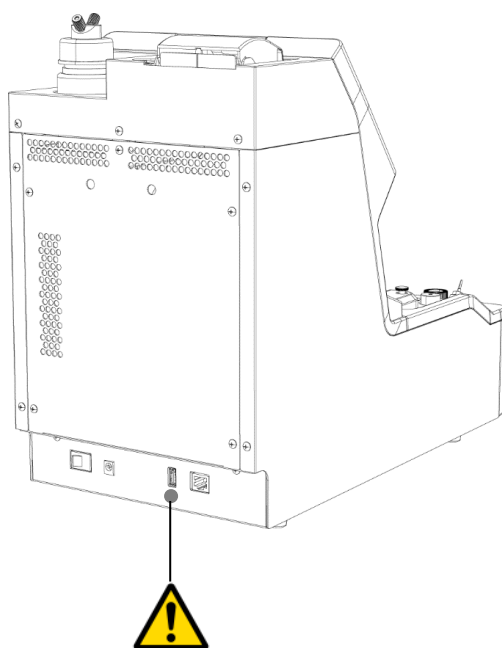
1.4.2 Attachment Position of Warning Labels

The position of the warning labels on this instrument are as follows.

Front



Back



1.5 When Moving This Instrument

When relocating this instrument, it is recommended to perform quality control and/or validation to ensure that instrument function has not been affected.



2 System Overview

2.1 Definition of Terms and Notation Rules

2.1.1 Definition

This section explains the definitions of terms used in this manual.

Terms	Definition
Instrument	Hardware that allows blood to flow through the chip to perform measurements.
Measurement Software	Dedicated software for operating the instrument.
Channel 1	This is the left side of the two measurement systems on the T-TAS wS instrument.
Channel 2	This is the right side of the two measurement systems on the T-TAS wS instrument.
Chips	Disposable chips with micro-level feed channels. Feed channels and coatings vary depending on the analysis application.
Auto SC	Abbreviation for Automatic System Check. This function automatically detects pressure leaks in the feed channel at the start of instrument operation and other times.
Manual SC	Abbreviation for Manual System Check. This function detects pressure leaks in the feed channel and can be performed by the following three operation modes: Perform Channel 1 Manual SC - Checks for pressure leaks in the tubing of Channel 1. Perform Channel 2 Manual SC - Checks for pressure leaks in the tubing of Channel 2. Perform Channels 1 & 2 Manual SC - Simultaneously checks for pressure leaks in the tubing of both Channels 1 and 2.
Simple SC	This function checks the opening and closing of valves in the feed channel before each measurement.

Bubble Vent	To remove air bubbles in the fluid feed channel, mineral oil is suctioned from the oil bottle and discharged from the nozzle into the waste bottle. The following three operation modes are available. Start Channel 1 Bubble Vent - Removes air bubbles from the fluid feed in Channel 1. Start Channel 2 Bubble Vent - Removes air bubbles from the fluid feed in Channel 2. Start Channels 1 & 2 Bubble Vent 1 & 2 - Simultaneously removes air bubbles from the fluid feed in Channels 1 and 2.
LIS	Abbreviation for Laboratory Information System.

2.1.2 Notation Rules

This manual is written in accordance with the following notation rules.

Terms	Definition
"***" account	Indicates the account used to sign in to the instrument. Example: "Administrator" account
"***" screen	Indicates the screen displayed on the touch panel of the instrument. Example: "Menu" screen, "Maintenance" screen
[***]	Indicates the operation buttons displayed on the touch panel of the instrument. Example: [HOME], [Backup]

ATTENTION



In this manual, the PL chip is shown as an example as a representative assay. Always refer to the individual instruction manuals for details, as each assay may differ.

2.2 What is T-TAS®?

T-TAS (Total Thrombus formation Analysis System) is a system for observing and analyzing thrombus formation under physiological blood flow conditions using a disposable chip with micro-level feed channels (hereinafter referred to as the "chip").

T-TAS measurements produce a waveform graph of pressure over time, which can be analyzed and the calculated parameters compared to evaluate the overall thrombus formation capability.

It is an in vitro diagnostic testing instrument used in combination with chips, kits and related consumables for T-TAS.

For the regulatory status, handling, and use of chips and kits with the T-TAS instrument, please refer to the respective instruction manuals.

2.3 Hardware Overview

This instrument is controlled via a built-in computer and a touch-screen monitor. The main components are a pump unit for mineral oil, a pressure sensor, and a temperature control unit.

2.4 Instrument Overview

This instrument is intended to quantitatively measure the hemostatic function of human whole blood. Please refer to the instruction manual for each chip and kit for details on the intended use.

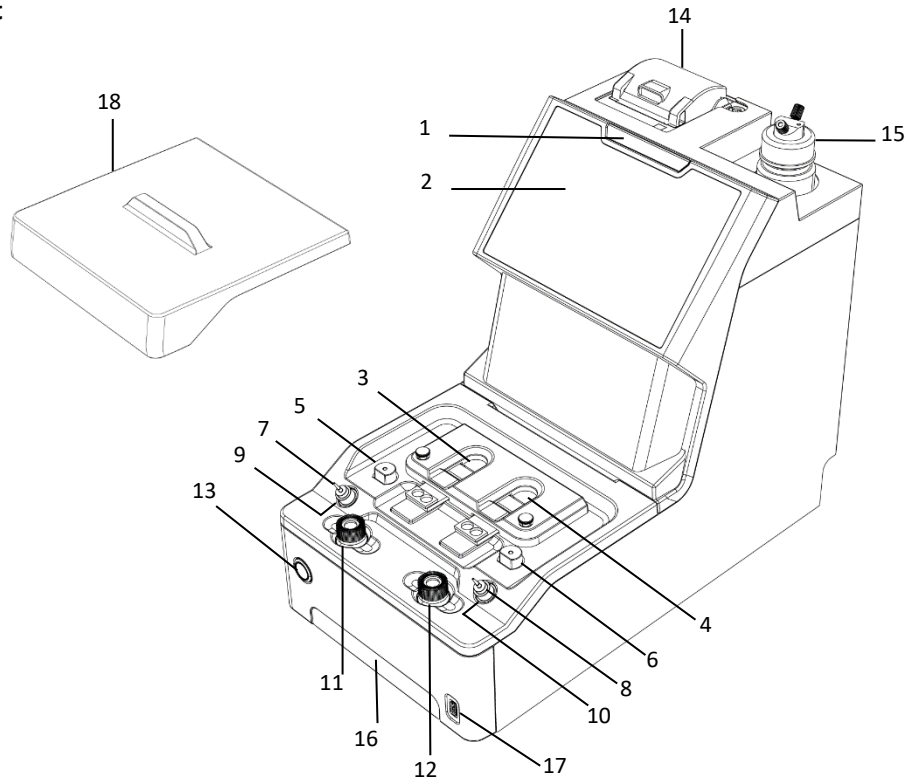
2.4.1 Overview of Instrument Operation

This instrument is controlled to feed mineral oil at a constant flow rate, and blood specimens flow from the Reservoir (specimen container) into the chip in conjunction with the mineral oil feed.

When the blood specimen interacts with the reagent in the chip under physiological flow conditions, a hemostatic reaction begins and the inside of the chip becomes occluded in proportion to the hemostatic ability of the blood sample. The pressure in the chip increases with the occlusion, which is detected by the pressure sensor. The thrombus formation ability of a blood specimen is displayed as a pressure vs. time waveform, and a dedicated calculation algorithm automatically displays the result on the touch-screen monitor following the conclusion of the measurement.

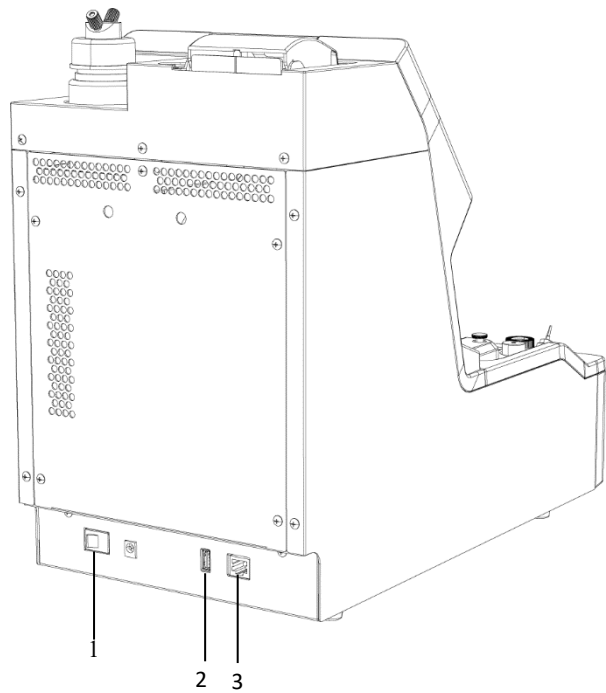
2.4.2 Name of Instrument Components

Front



Number	Name	Description
1	Indicator Light	Displays instrument status, such as measurement status or warning. See "2.4.3 Instrument Status Display" for more information about the indicator lights.
2	Touch-screen Monitor	Displays operation items and measurement results.
3	Channel 1 Chip Measurement Section	This is where the chip is inserted for Channel 1 measurements. When the chip is inserted, it heats up to a temperature suitable for measurement.
4	Channel 2 Chip Measurement Section	This is where the chip is inserted for Channel 2 measurements. When the chip is inserted, it heats up to a temperature suitable for measurement.
5	Channel 1 SC Bar	The SC bar is a physical barrier used to perform quality control. When the Channel 1 nozzle is inserted into the Channel 1 SC bar during manual SC, a leak check of the Channel 1 feed system can be performed.
6	Channel 2 SC Bar	The SC bar is a physical barrier used to perform quality control. When the Channel 2 nozzle is inserted into the Channel 2 SC bar during manual SC, a leak check of the Channel 2 feed system can be performed.

Number	Name	Description
7	Channel 1 Nozzle	The Channel 1 nozzle is the metal part at the end of the tubing for Channel 1, from which mineral oil is discharged. The nozzle is connected to the SC Bar during Manual SC and is connected to the reservoir during T-TAS assays. Cross use between Channel 1 and Channel 2 is not allowed.
8	Channel 2 Nozzle	The Channel 2 nozzle is the metal part at the end of the tubing for Channel 2, from which mineral oil is discharged. The nozzle is connected to the SC Bar during Manual SC and is connected to the reservoir during T-TAS assays. Cross use between Channel 1 and Channel 2 is not allowed.
9	Channel 1 Nozzle Holder	This is where the Channel 1 nozzle is placed to insert the Reservoir and a blood specimen is dispensed into the Reservoir prior to running a T-TAS assay.
10	Channel 2 Nozzle Holder	This is where the Channel 2 nozzle is placed to insert the Reservoir and a blood specimen is dispensed into the Reservoir prior to running a T-TAS assay.
11	Channel 1 Waste bottle	This container is used to catch the excess mineral oil that comes out of the Channel 1 nozzle.
12	Channel 2 Waste bottle	This container is used to catch the excess mineral oil that comes out of the Channel 2 nozzle.
13	Power Switch	Turns the power of the instrument on and off.
14	Printer	Prints measurement results and maintenance information.
15	Oil Bottle	Container for mineral oil. A filter is installed to prevent foreign matter from entering the tubing. Be sure to use only the mineral oil listed in "13.1 Consumables List". Please note that the use of different mineral oils may affect the measurement or damage the instrument.
16	Waste Tray	This is a container that receives and collects excess mineral oil waste overflowing from the Channel 1 and Channel 2 waste bottles.
17	USB Port	Connects a USB flash drive.
18	Cover	Protects the measurement section of the instrument from dust and other contaminants. Remove the cover from the measurement section when measuring. When the instrument is not in use, place the cover over the measurement section.



Number	Name	Description
1	Main Power Switch	Turns the main power of the instrument on and off.
2	USB Port	Connects the supplied barcode reader.
3	LAN Port	Connects a LAN cable for communication with an external PC or network.

2.4.3 Instrument Status Display

The status of the instrument can be checked by the indicator light at the top of the touch-screen monitor. Details are as follows.

Channel 1 \ Channel 2	Channel 2	Standby	Measuring	Measurement Completed	Error
	Channel 1	Standby	Measuring	Measurement Completed	Error
	Standby	Off/no light	Solid green	Solid orange	Flashing Red
	Measuring	Solid green	Solid green	Solid orange	Flashing Red
	Measurement Completed	Solid orange	Solid orange	Solid orange	Flashing Red
	Error	Flashing Red	Flashing Red	Flashing Red	Flashing Red



When bubble vent or manual SC is being performed, the indicator light is lit in "green".

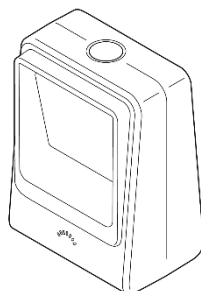
2.5 Barcode Reader

ATTENTION



Do not use a barcode reader other than the one supplied.

The barcode reader supplied is used to input specimen information such as patient identification number and chip lot number.



Barcode reader

2.6 Measurement Software Overview

In the measurement software, tapping on the "Menu" screen allows measurement, display of measurement data, lot management, and maintenance.

**CAUTION**



Do not operate with objects that have sharp tips.
Do not operate with more force than necessary.



A quick tap operation may cause unintended action.
Malfunctions can be prevented by performing the tap operation relatively slowly.

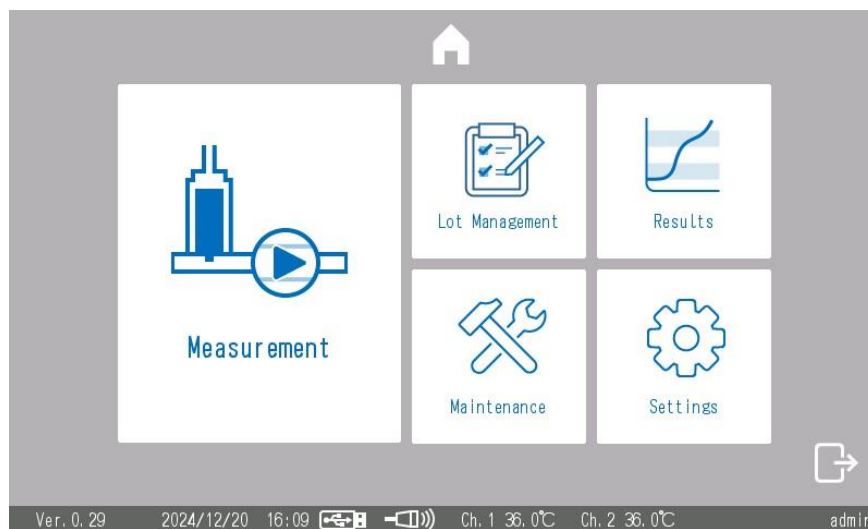


Measurement software updates can only be performed by authorized personnel specified by the manufacturer.



The measurement software uses Ricoh RT Font designed and produced by RICOH Industrial Solutions Inc.

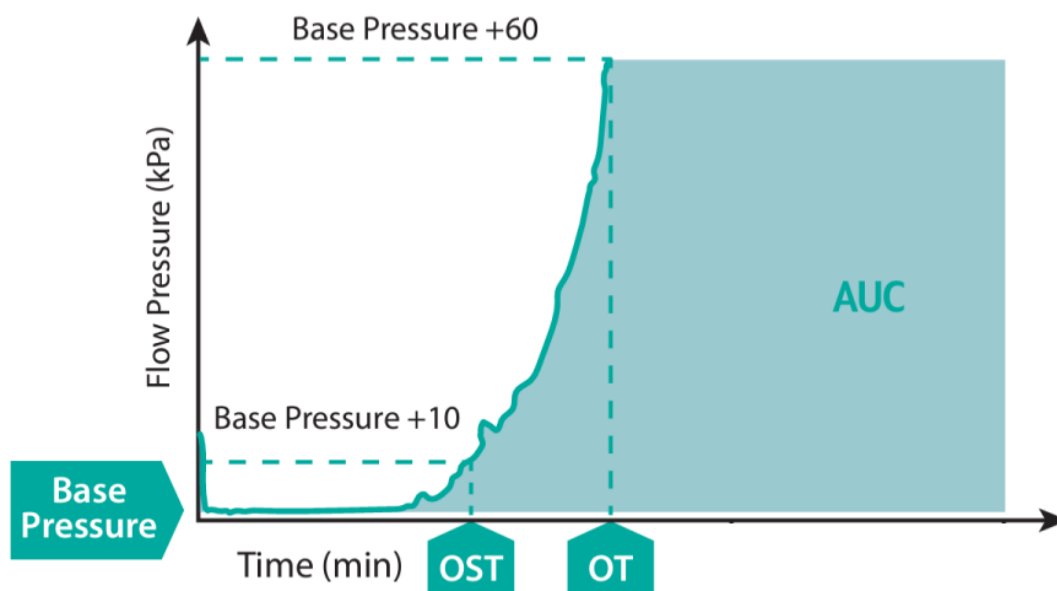
The "Menu" screen of the measurement software consists of the following.



For more information on the "Menu" screen, see "5.6 About the "Menu" Screen".

2.7 Pressure Waveform Graph Analysis

The T-TAS[®] system calculates parameters from the pressure waveform graph obtained from the measurement using the following method. The calculated parameters are displayed as measurement results and saved in the instrument.



The instrument is able to provide the following parameters.

- Base Pressure: Pressure at start of measurement
- OST (Occlusion Start Time): Time when pressure rises 10 kPa above baseline
- OT (Occlusion Time): Time when pressure rises 60 kPa above baseline
- AUC (Area Under the Curve): Area of the lower part of the graph plotted by pressure and time.

If Base Pressure+60 kPa is reached by the end of the measurement time specified for each assay, the AUC is calculated by adding the area under the reaction curve up to the point of reaching this pressure, and the area for the remaining time when the upper limit is set at Base Pressure+60 kPa.

It is not possible to draw conclusions about the diagnosis by this instrument alone.



The physician in charge should make a comprehensive judgment in conjunction with clinical symptoms and other test results.

Some assay parameters are not available to be viewed on the screen by default for certain assays. Please refer to the instruction manual of each assay for interpretation of assay-specific measurement results.

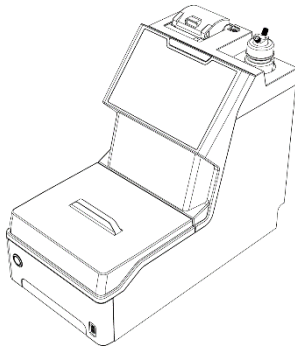
2.8 List of Contents

Before use, please make sure that all of the following items are present.
Consumables and separately sold accessories are not included.



For consumables and separately sold accessories, see "13.1 Consumables List" and "13.2 Assay-Related Products List".

Instrument main unit: 1 unit (set includes 1 x 100 mL oil bottle)



Power cord
(A type for US): 1 cord



Power cord
(C type for EU): 1 cord



AC adapter: 1 piece



Thermal paper roll:
1 box (5 rolls)



Barcode reader: 1 piece



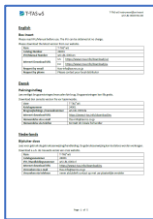
Waste bottles: 2 pieces



SC bars: 2 pieces



Box insert: 1 part



2.9 Specifications



CAUTION



If the instrument has been installed in an environment with storage temperatures outside the ambient operating temperature range, allow it to acclimatize by leaving it in the ambient operating temperature range (20 °C to 30 °C) for at least half an hour before use.

In addition, the storage temperature environment for the instrument and mineral oil is different.



For more information on the storage temperature environment for mineral oil, see "13.1 Consumables List".

The specifications of this instrument are as follows.

Product name	T-TAS wS
Common name	T-TAS wS
Rated voltage	AC adapter: AC100 V to 240 V 50/60 Hz Instrument: 24 V DC $\pm 5\%$ (2.0 A)
Power supply voltage fluctuation	$\pm 10\%$
Power supply transient overvoltage	Category II
Rated power consumption	48 W or less
Dimensions	240 (W) x 410 (H) x 450 (D) mm [9.6 (W) x 16.1 (H) x 17.7 (D) in]
Weight	Approx. 12 kg (26 lb)
Pressure detection range	- 60 kPa to 200 kPa
Storage temperature	5 °C to 50 °C Packing condition
Storage humidity	10 % to 85 % RH, No condensation Packing condition
Ambient operating temperature	20 °C to 30 °C (68 °F to 86 °F)
Ambient operating temperature	20 % to 80 %, No condensation
Usage altitude	Less than 2,000 m (6,500 ft)
Rated pollution	Pollution Level II
Product safety standards	IEC 61010-1:2010, EN 61010-1:2010, UL 61010-1:2023, CAN/CSA C22.2 No.61010-1:2016, JIS C 1010-1:2019 IEC 61010-2-010:2019 IEC 61010-2-081:2019 IEC 61010-2-101:2018, CSA C22.2 No.61010-2-101:19, EN IEC 61010-2-101:2022
Electromagnetic Compatibility Standards	EN IEC 61326-1:2021 Class B, IEC 61326-1:2020 Class B EN IEC 61326-2-6:2021 Class B, IEC 61326-2-6:2020 Class B, IEC 60601-1-2:2014+A1:2020 (for power supply voltage of 120 V)
Periodic replacement components	N/A
Other	Indoor use only



3 Operation Flow

The flow of measurement with this instrument is as follows.

1	Preparation for measurement	1) Remove the cover → "5.1 Remove the Cover" 2) Start up the instrument → "5.2 Start Up the Instrument" 3) Connect the barcode reader → "5.3 Connect the Barcode Reader" 4) Measurement User login → "5.4 Measurement User Login" 5) Check waste fluid → "5.5 Dispose of Waste Fluid and Check Remaining Oil Level" 6) Check residual quantity of mineral oil → "5.5 Dispose of Waste Fluid and Check Remaining Oil Level" 7) Bubble vent → "5.7 Perform Bubble Vent" 8) Perform Manual SC → "11.1.2 Manual SC"
2	Measurement	1) Input order (Enter specimen information) → "6.2 Input Order" 2) Install the chip → "6.3 Chip Insertion" 3) Inject the specimen → "6.4 Specimen Injection" 4) Measure the specimen → "6.5 Start of Measurement" 5) Complete measurement of the specimen → "6.7 Measurement Completed" 6) Output measurement results → "6.7 Measurement Completed"

3	Exit operation	1) Shut down the instrument → "10.1 System Shutdown" 2) Clean the instrument → "11.4.4 Touch Panel Cleaning" 3) Close the cover → "10.2 Replace the Cover"
---	----------------	--



4 Installation

Contact the distributor for installation of this instrument.

ATTENTION



Please do not dispose of the packing box that this instrument came in during delivery, as it will be used if transportation is needed in the future.

4.1 Operating Environment

The total weight of this instrument is approximately 12 kg (26 lb). For installation, please provide a sturdy, level, low-vibration workbench or table that can support this weight. It also requires a minimum benchtop space of 500 x 650 x 550 mm (20 x 26 x 22 in) (W x D x H) to install the instrument and perform measurements.



See "1.3.1 Precautions When Installing This Instrument" for installation warnings and precautions.

Item	Conditions
Location of use	Indoor
Operating temperature & humidity	Temperature: 20 °C to 30 °C (68 °F to 86 °F) Relative humidity: 20 % to 80 % (no condensation)
Altitude	Less than 2,000 m (6,500 ft)
Power supply conditions	AC100 V to 240 V, 50/60 Hz
Other	• The area must be free of dust or dirt. • The location must be out of direct sunlight. • Location where it is not directly exposed to air blasts from air-conditioners, etc. • No chemical storage, gas generating area, or open flames nearby.



WARNING



Do not use any power cable other than the supplied one connected to the instrument.

4.2 Create "Administrator" Account



CAUTION

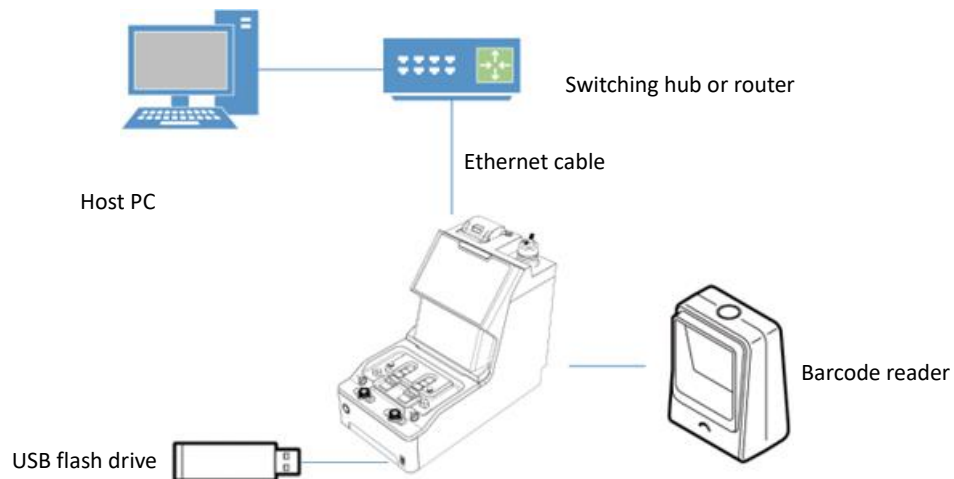


The password for the "Administrator" account must be kept in a secure location managed by the user administrator.

A new "Administrator" account should be created for the user administrator when this instrument is being installed for the first time. Ask the distributor to set up the user "Administrator" account and password when the instrument is installed. If you lose your password, refer to "9.2 Administrator Settings" to reset the password.

4.3 Data Connections

This instrument consists of the electrical device shown in the figure below.



Connect the USB flash drive only when necessary. Do not leave a USB drive connected to the instrument when not in use.

ATTENTION



- Do not connect any equipment or cables other than those provided with the instrument. Failure to do so may result in malfunction.
- Do not connect a USB hub to the USB port. Doing so may result in malfunction.
- External HDDs cannot be used.



- Use only USB flash drives that have been checked for viruses and other safety issues prior to connection to this instrument.
- Use a USB flash drive that does not have a password function.



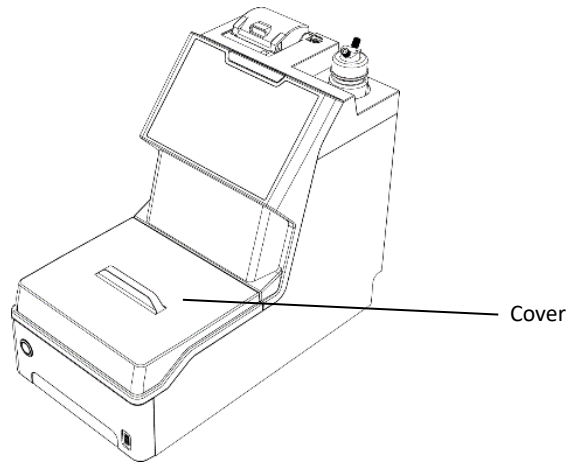
- The Ethernet cable should be of the following standard.
 - 10/100BASE-T



5 Preparation for Measurement

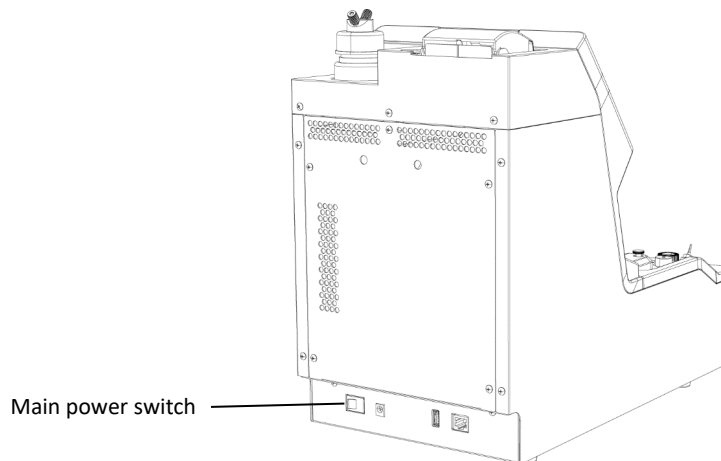
5.1 Remove the Cover

To use the instrument, lift up the cover and remove it. Place the removed cover on a flat surface for storage.



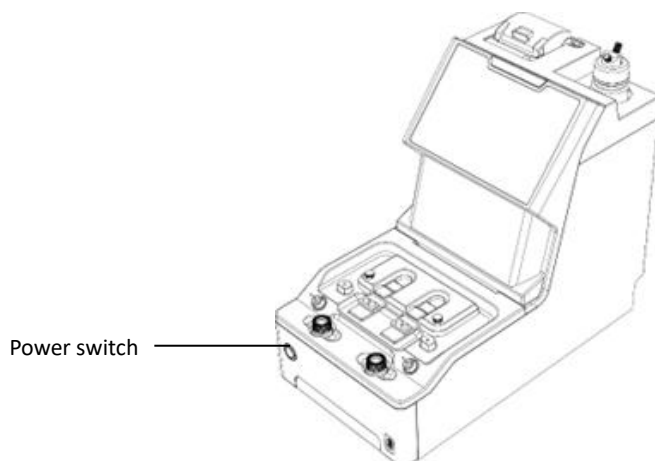
5.2 Start Up the Instrument

- 1 Press the main power switch on the back of the instrument.



If the main power is on, this operation is not necessary.

- 2 Press and hold the power switch on the front of the instrument for approximately 1 second.



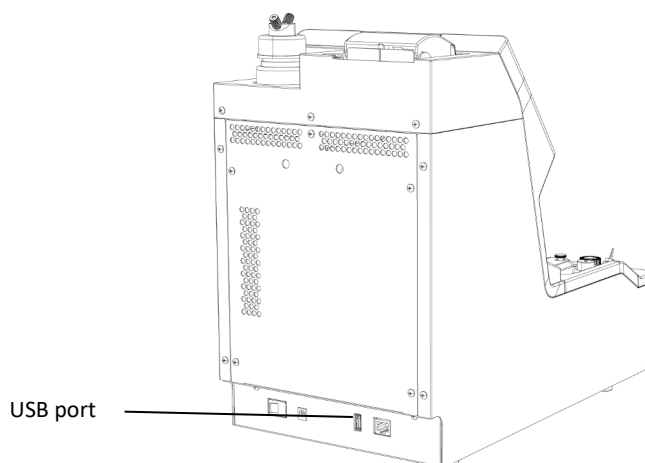
- 3 The instrument starts and the "Login" screen appears.

⚠ CAUTION	
	Heating of the chip measurement section begins as soon as the instrument is activated. Avoid prolonged contact with the chip measurement section.

5.3 Connect the Barcode Reader

ATTENTION	
	Do not use a barcode reader other than those provided.

- 4 Connect the barcode reader cable to the USB port on the back of the instrument.



Do not connect the barcode reader cable to the USB port on the front of the instrument.

- 5 When the barcode reader is recognized, the barcode reader icon appears in the lower center of the operation screen.



- 6 After selecting the items you wish to enter on the instrument monitor, read the QR code. The value of the barcode is entered as is.



Refer to the barcode reader user's manual for barcode reader handling and standards for codes that can be read.

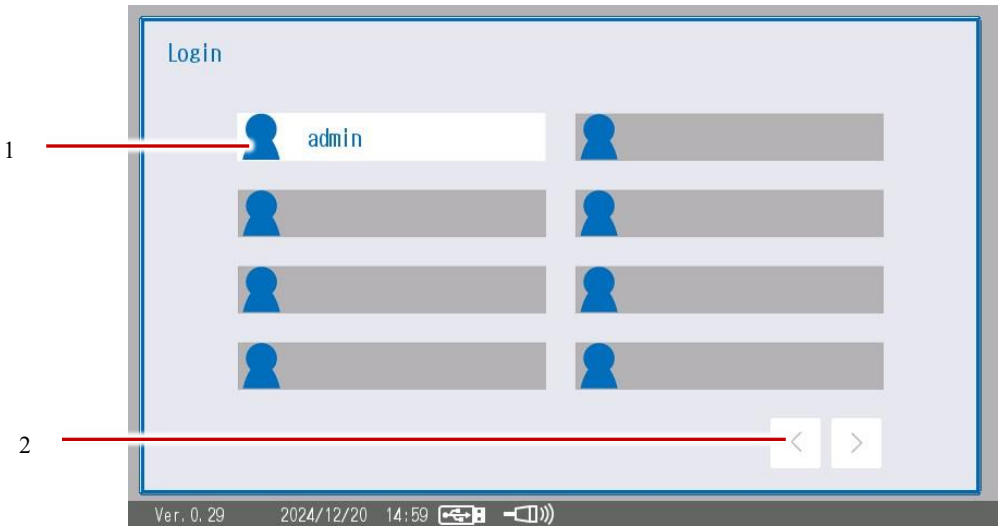


Install the barcode reader on a flat, stable surface.

5.4 Measurement User Login

Select the user that would perform the measurement and log in according to the following steps.

- 1 Tap to select a user name to log in. Tap the user name, and a screen prompting to enter the password appears.



Number	Item name	Description
1	User Name	Registered user.
2	[<] button [>] button	Tap to switch pages displaying user names.



If there is no user you wish to select, please register a new user. For information on registering users, see "9.2.1 User Registration".

- 2 Tap [Enter] for the password.



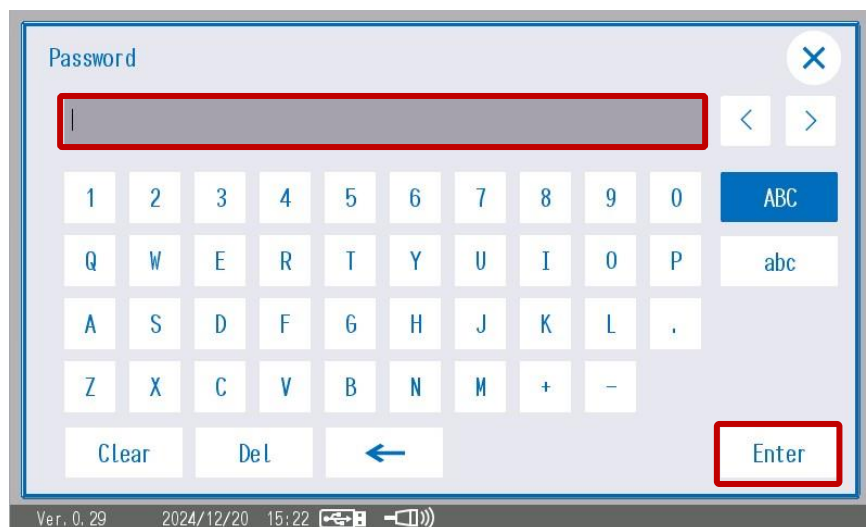
Ver. 0.29 2024/12/20 15:17

Tap [Enter] to display the "Keyboard" screen.



To select a different user, tap [Select User].

- 3 On the "Keyboard" screen, enter the password and tap [Enter].



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- 4 Tap [Login].

Login

User Name admin

Password *****

Enter

Select User

Login

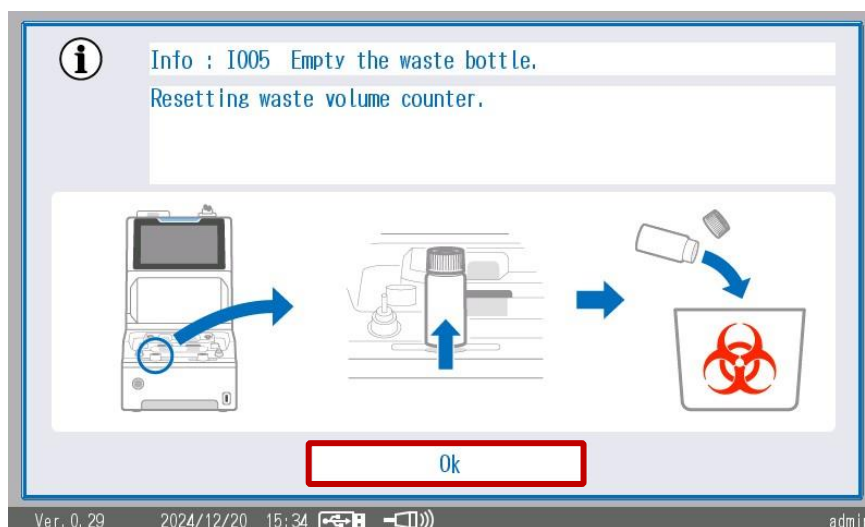
Ver. 0.29 2024/12/20 15:26

- 5 If the password is entered correctly, the login is complete.

5.5 Dispose of Waste Fluid and Check Remaining Oil Level

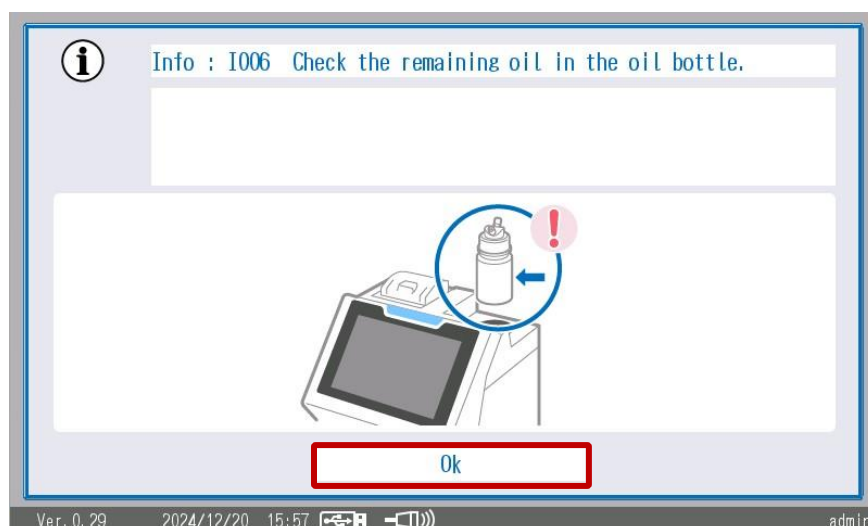
After logging in, follow the steps below to dispose of the waste fluid and check the remaining oil level.

- 1 Follow the instructions on the "Information" screen to dispose of the waste fluid in the waste bottle. When the waste bottle is empty, return the waste bottle to the instrument and tap [Ok].



See "11.2.2 Disposal of Waste Fluid" for how to check the waste fluid.

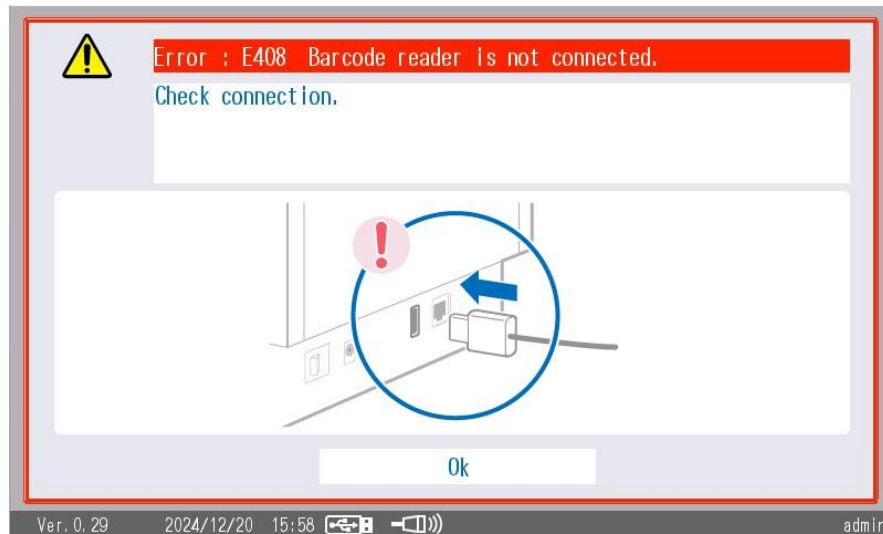
- 2 Follow the on-screen instructions to check the residual quantity of oil in the oil bottle. If the mineral oil level is less than one scale mark from the bottom of the oil bottle, refill the oil. After confirmation, return the oil bottle to the instrument and tap [Ok].



See "11.2.3 Check Remaining Oil Level" and "11.2.4 Oil Refilling Procedure" for how to check the remaining oil level and how to change the oil bottle.



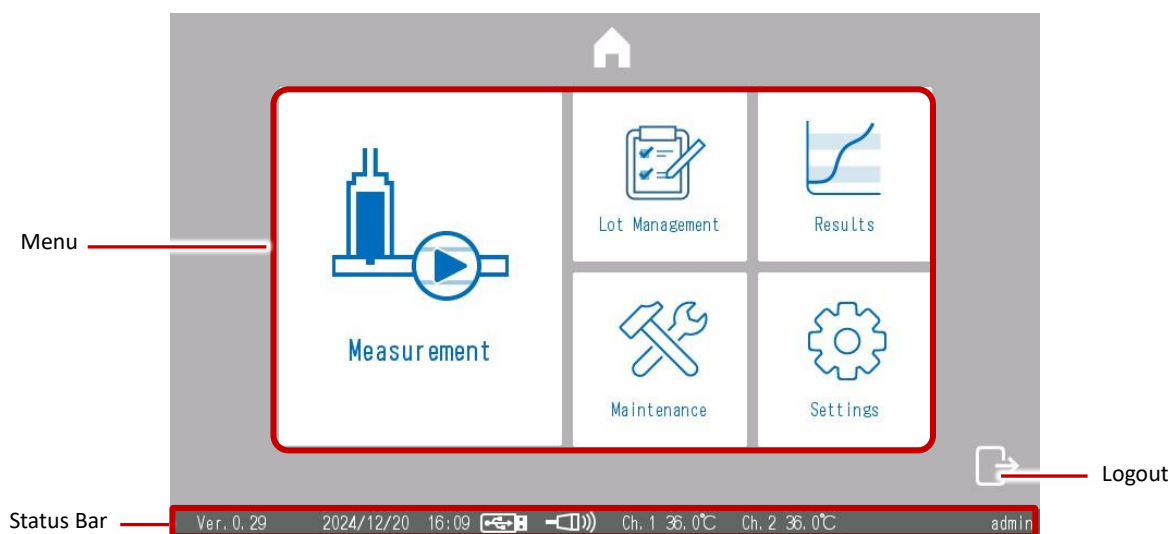
- If the barcode reader is not connected, the warning message “Barcode reader is not connected.” appears. Confirm that the supplied barcode reader is connected.



- If a barcode reader is connected, the barcode reader icon appears at the bottom of the screen.
- For barcode reader connections, see “5.3 Connect the Barcode Reader”.

5.6 About the “Menu” Screen

After logging in, the “Menu” screen will appear after the waste fluid is disposed of and the remaining oil level is checked. Tap the menu to select and execute. In addition to the menu, [Logout] can be used to re-select users, and [Shutdown] can be used to shut down the system.



5.6.1 Menu

Perform measurement and maintenance.

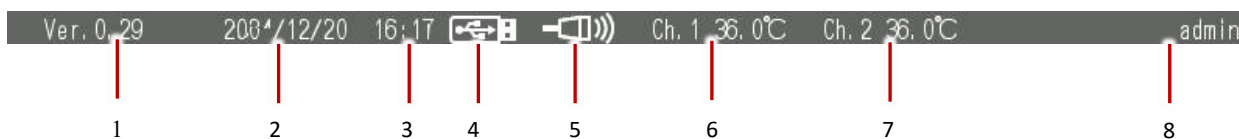
Menu name	Description
Measurement	Enter the measurement conditions and perform the measurement.
Lot Management	Register lot information for consumables by reading barcodes.
Results	You can check the stored measurement results.
Maintenance	Perform maintenance, such as bubble vent and manual SC, and check information about maintenance.
Settings	You can change settings on the clock and other relevant configurations, as well as other instrument settings.

5.6.2 Logout

You can logout and re-select a user or exit and shut down the system.

5.6.3 Status Bar

You can check the software version information of the unit, the clock, and the connection status of equipment.



Number	Name	Description
1	Software Version	Indicates the current software version.
2	Date	The current date is displayed.
3	Clock	The current time is displayed.
4	USB Connection Status	Indicates that a USB flash drive is connected. If no USB flash drive is connected, it will not be displayed.
5	Barcode Reader Connection Status	Indicates that the supplied barcode reader is connected. If the barcode reader is not connected, it will not be displayed.
6	Channel 1 Chip Measurement Section Temperature	The temperature of the chip measurement section of Channel 1 is displayed.
7	Channel 2 Chip Measurement Section Temperature	The temperature of the chip measurement section of Channel 2 is displayed.
8	User Name	The name of the currently logged-in user is displayed.

5.7 Perform Bubble Vent

After starting up the instrument, perform a bubble vent before taking measurements.

 **CAUTION**

 After starting up the instrument, always perform a bubble vent before taking the first measurement. Failure to perform a bubble vent may result in errors due to air bubbles generated in the tubing.



For bubble vent steps, see “11.2.1 Bubble Vent”.

5.8 Perform manual SC

After starting up the instrument, perform a manual SC before taking measurements.



CAUTION



After starting up the instrument, always perform a manual SC before taking the first measurement. Failure to perform manual SC may result in a lost measurement if there is an undetected blockage or leaks that has occurred in the tubing.



See “11.2.5
Manual SC” for manual SC steps.



6 Measurement

Tap [Measurement] on the “Menu” screen to display the “Measurement” screen. Enter the required information and perform the measurement. This instrument has two channels (measurement systems), each of which can be operated and measured independently.

ATTENTION

Perform the following operations in preparation for measurement.



- Bubble vent
- Manual SC
- Disposal of waste fluid
- Check remaining oil level



See “11.1.1
Bubble Vent”, “11.1.2
Manual SC”, “11.2.2 Disposal of Waste Fluid” and “11.2.3
Check Remaining Oil Level” for details.



WARNING



- This operation may pose a risk of infection. To prevent biohazards, always wear personal protective equipment such as gloves and eye protection, and protective clothing such as a lab coat.
- Waste fluid and used chips, Reservoirs, and Over-caps may pose a risk of infection if touched directly. Dispose of them as medical waste in accordance with the laws and regulations of the country in which the waste is generated.
- Do not reuse chips, Reservoirs, or Over-caps that have already been used once.



WARNING

Check that the nozzle and connector are not loose. If it is loose, hold the connector and turn it clockwise to tighten.



Connector

Nozzle

6.1 “Measurement” screen

Enter the order information about the measurement and perform the measurement.

Channel 1 Channel 2

Input Order

No. 0001
Specimen ID
Patient ID
Assay

Comment

Lot Management

Chip:

Results

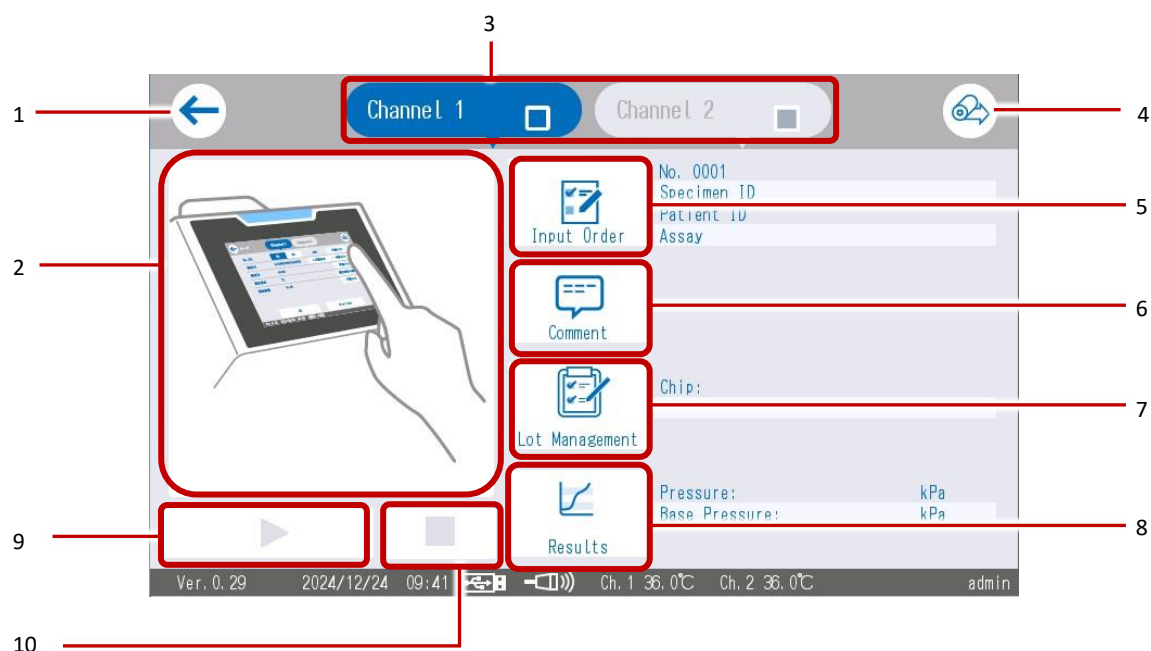
Pressure: kPa
Base Pressure: kPa

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When the “Measurement” screen is launched, auto SC is performed for the first time only.

How to Read the “Measurement” Screen



Number	Name	Description
1	[←] Button	Returns to the previous screen.
2	Operation Guide	Visual display of the next operation to be performed.
3	[Channel 1] Button [Channel 2] Button	Tap to switch between [Channel 1] or [Channel 2] to perform a measurement.
4	Paper Feed Button	Advance the paper from the printer for adjustment. When the paper runs out, it will appear in gray.
5	[Input Order] Button	Tap the “Input Order” button to display the “Input Order” screen, where the patient ID and other information is entered. To the right of the button, the information that has been entered will be displayed.
6	[Comment] Button	Tap to display the “Keyboard” screen, where a comment of up to 100 characters can be entered. To the right of the button, the comment that has been entered will be displayed.
7	[Lot Management] Button	Tap to display the “Lot Management” screen, where the consumables used for each assay are registered (see “7 Lot Management” for details). The expiry date of the assay chip is displayed on the right side of the button.
8	[Results] Button	Tap to go to the “Measurement Results” screen (see “8 Measurement Results” for details). To the right of the button, the result of the measurement is displayed.
9	[▶ (Start measurement)] Button	Tap to start the measurement. The button is active only after the preparation for measurement is completed.
10	[□ (Emergency stop)] Button	Tap to stop measurement.

6.2 Input Order

This section describes the steps to input order. Select the Channel to be measured and perform the input.

ATTENTION



Do not open two types of chips at the same time when inputting the order, as this may result in a mix-up in the chip used.

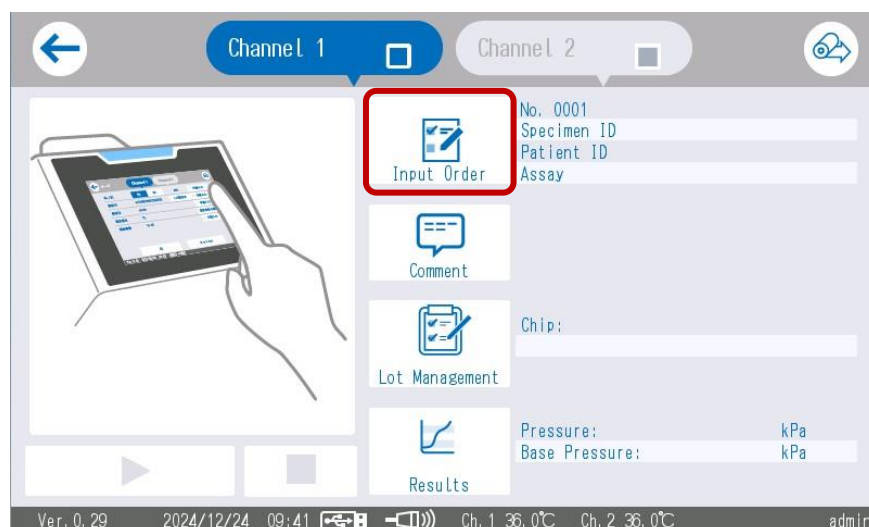
6.2.1 Channel Selection

- 1 Tap [Channel 1] or [Channel 2] to select the Channel to be used for the measurement.



Once the order input is started, the Channel cannot be switched until the measurement is started.

- 2 Tap [Input Order].



The “Order” screen appears.



If [Preauthentication] is set to [Enable] in the Administrator Settings, the user must be selected before the “Order” screen. For more information on [Preauthentication], see “9.2 Administrator Settings”.

6.2.2 Input Order

- Enter information about the measurement. Items marked with an asterisk (*) are required.

- 1 Use [No.] or [QC.] to register the type of measurement to be completed, then tap [Enter].



- [No.] or [QC.] numbers are automatically assigned in advance. Enter when changes are needed.
- [No.] indicates the patient specimen and [QC.] indicates the QC specimen.

“No.” screen or “QC.” Input screen appears.

- 2 Enter the number on the “No.” screen or “QC.” Input screen and tap [Enter].

- 3 Enter the specimen ID. Tap [LIS] or [Enter] to select the input method.

Order Channel 1 Channel 2

No./QC. No. QC. 0001 Enter

*Specimen ID LIS Enter

Patient ID Enter

*Assay Select Assay

Blood Collection Time Enter

Ok Cancel

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[LIS] can be used when the [LIS Order] item is set to [Enable] in the “LIS Settings” section of the “Settings” screen. See “9.4 LIS Settings” for more information.

If [LIS Inquiry] is Tapped

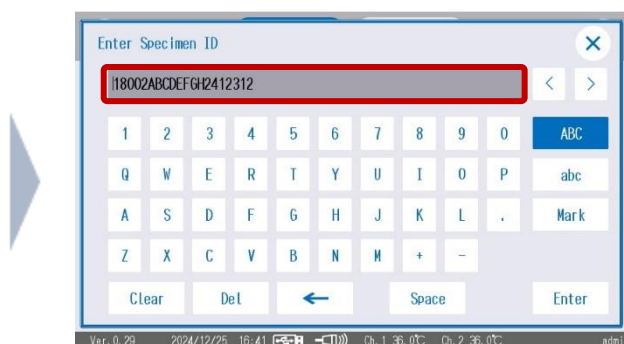
- 1) When the “LIS Inquiry” screen appears, tap [LIS].



The “Specimen ID” screen appears.



- 2) Scan the QR code of the specimen to be measured and enter the specimen ID.





If the QR code is too dirty to read, use the “Keyboard” screen to enter the code manually.

- 3) After the specimen ID is entered, tap [Enter].

- 4) The specimen ID, patient ID, and assay registered in the host are reflected. Tap [Ok] if there are no problems.



- If the LIS inquiry fails, tap [LIS Inquiry] and re-enter the specimen ID again.
- If no patient ID is registered for the host, the [Patient ID] field will be left blank.

If [Enter] is tapped

The “Specimen ID” screen appears. Enter the specimen ID and tap [Enter].

Enter Specimen ID

1 2 3 4 5 6 7 8 9 0 ABC

Q W E R T Y U I O P abc

A S D F G H J K L . Mark

Z X C V B N M + -

Clear Del ← Space Enter

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- 4 To enter the patient ID, tap [Enter] in the [Patient ID] field.



If a patient ID is not available or not used, this operation is not required.

Order Channel 1 Channel 2

No./QC. No. QC. 0001 Enter

*Specimen ID LIS Enter

Patient ID Enter

*Assay Select Assay

Blood Collection Time Enter

Ok Cancel

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- 1) The “Patient ID” screen appears.

Enter Patient ID

1 2 3 4 5 6 7 8 9 0 ABC

Q W E R T Y U I O P abc

A S D F G H J K L . Mark

Z X C V B N M + -

Clear Del ← Space Enter

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- 2) Enter the ID on the “Patient ID” screen and tap [Enter].

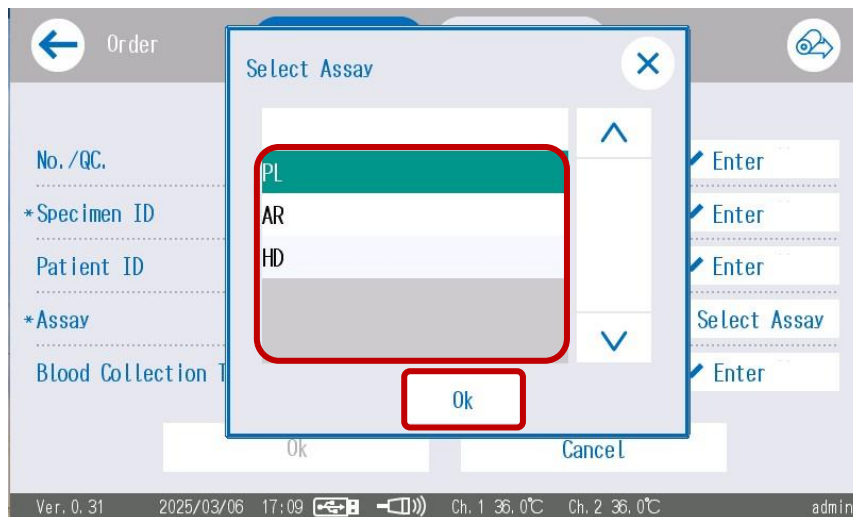
- 5 Tap [Select Assay] in the Assay field.



If you entered the specimen ID using [LIS Inquiry], the assay has already been changed. This operation is not required

- 1) The [Select Assay] list appears.

2) Tap the assay and tap [Ok].



6 To change the blood collection time, tap [Enter] in the blood collection time field.



The blood collection time is automatically entered (see below). If the blood collection time is not recorded, this operation is not necessary.



The time automatically entered for the blood collection time is the time when the specimen ID was entered. If you wish to change the time that is automatically entered using a fixed offset, you can do so from the "Settings" screen under [Administrator Settings]. See "9.2 Administrator Settings" for more information.

- 7 When the required information has been entered, the [Ok] button will be enabled.

Order

Channel 1 Channel 2

No. /QC. No. QC. 0001 Enter

*Specimen ID SAMPLE-ID_1234567890 LIS Enter

Patient ID PATIENT-ID1234567890 Enter

*Assay PL Select Assay

Blood Collection Time 09:30 Enter

Ok Cancel

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Tap [Ok] to complete order input and return to the “Measurement” screen.

Channel 1 Channel 2

No. 0001
Specimen ID SAMPLE-ID_1234567890
Patient ID PATIENT-ID1234567890
Assay PL

Input Order

Comment

Lot Management

Results

Chip:

Pressure: kPa
Base Pressure: kPa

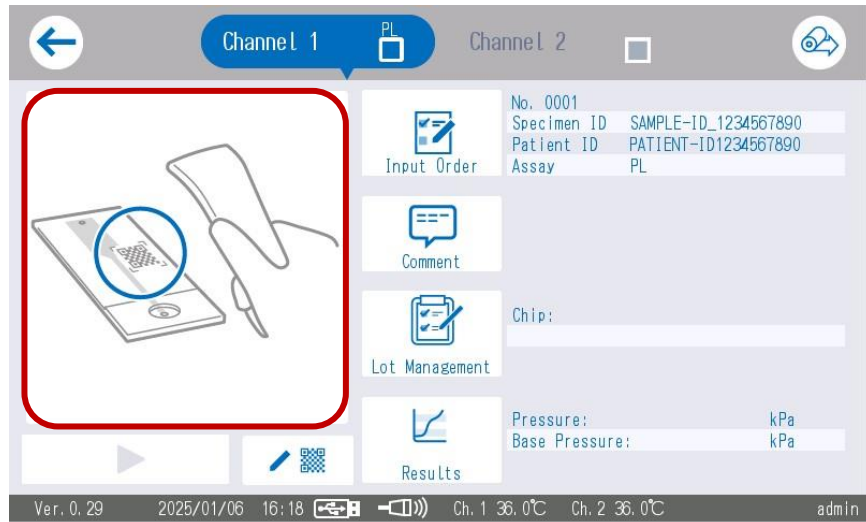
Ver. 0.29 2024/12/25 16:49 Ch. 1 36.0°C Ch. 2 36.0°C admin

6.3 Chip Insertion

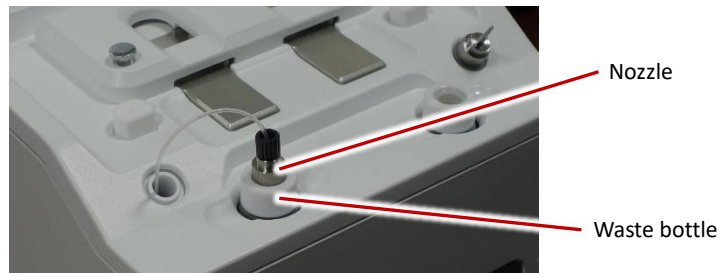
After order input is complete, insert the chip into the instrument according to the following steps.



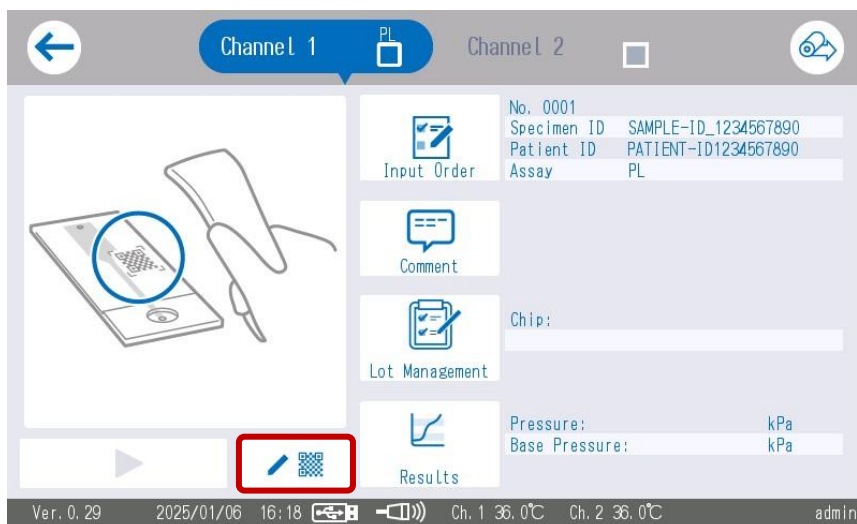
If you are unsure of the steps, please refer to the instructions displayed on the left side of the screen.



- 1 Set the nozzle of the Channel to be measured into the waste bottle.



- 2 Tap [QR Code] to verify that the chip to be used matches the information in the input order.



Tap [QR Code] to display the “Enter Chip ID” screen.



- 3 Read the QR code on the chip with the barcode reader and enter the chip ID.

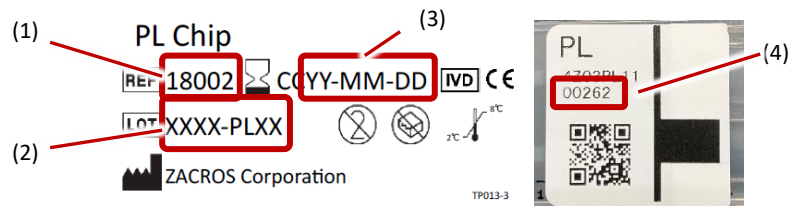


If the QR code is too dirty to read, tap the “Keyboard” screen and enter the chip ID.

When entering the chip ID using the keyboard, enter the following information in the following order without using spaces or hyphens.

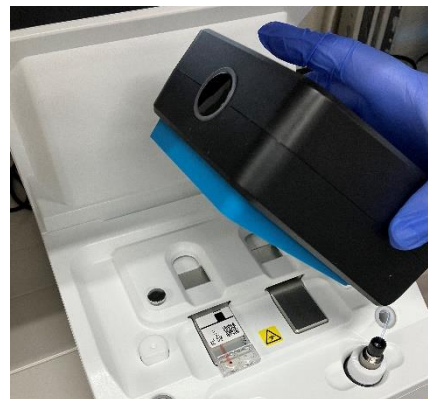
From the package label: (1) REF No. of the chip [5-digit], (2) Lot number [8-digit], (3) Expiry date in YYMMDD format [6-digit]

From the label attached to the chip body: (4) Serial number [5-digit]. In the example below, the chip ID would be 18002XXXXPLXXYYMMDD00262.



How to Read a Chip When Using a Chip with Two Feed Channels Consecutively

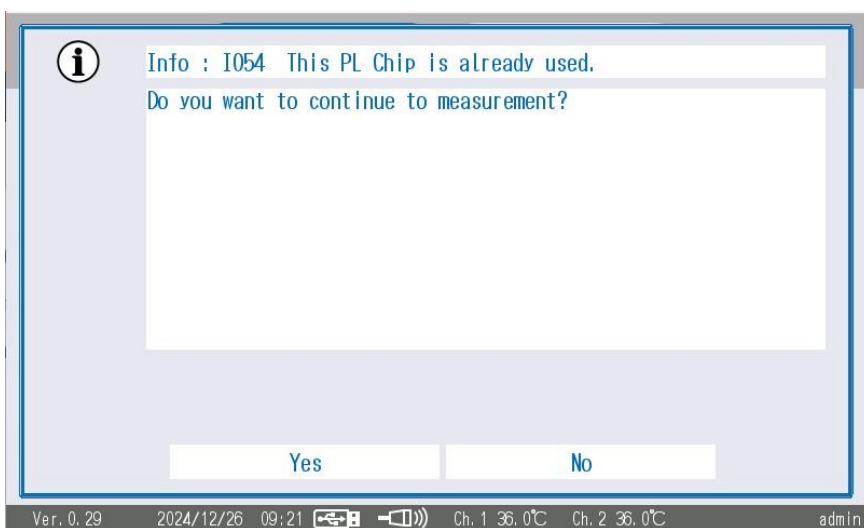
If you are using a chip with two feed channels consecutively, read the QR code without pulling the chip out of the instrument completely. Pull the chip out of the instrument slightly to expose the QR code, hold the barcode reader over the top, and read it.



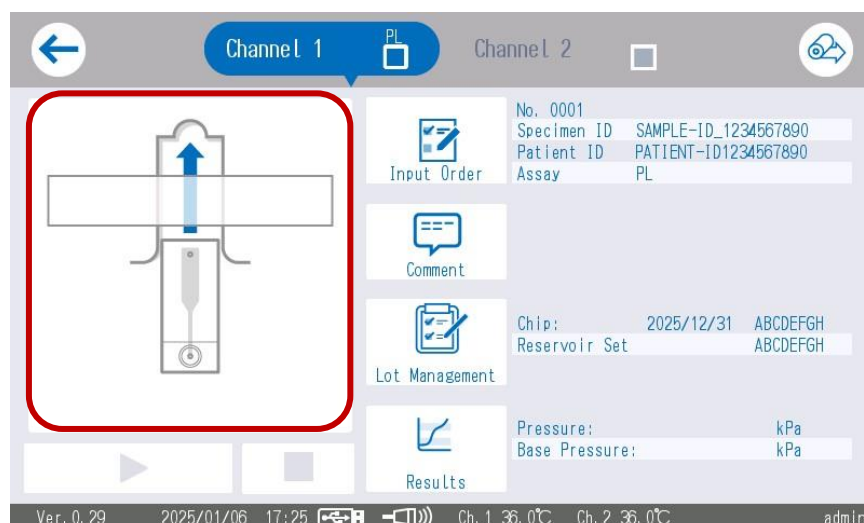
- 4 Enter the chip ID, then tap [Enter] to match the chip ID to the order.



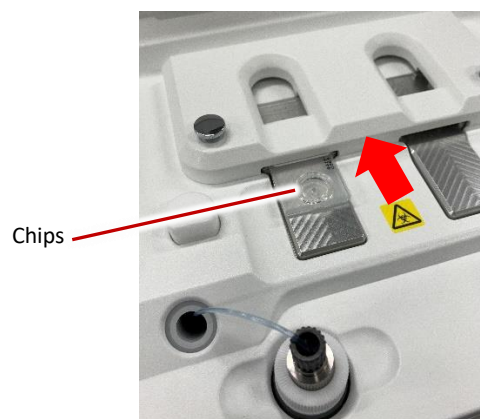
If the ID of an already measured chip is matched, you will get the message “This PL chip is already used. Do you want to continue to measurement?” Tap [Yes] only if you want to use the unused channel of a PL chip.



- 5 Once the chip ID is matched, the the following screen is displayed.

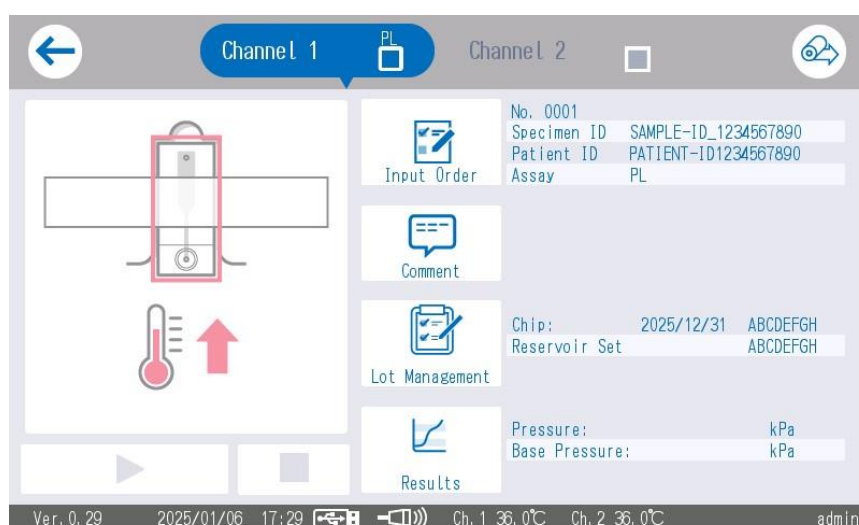


- 6 Insert the chip into the stage of the Channel where the measurement is to be made, inserting it straight to the back until it stops.



Allow the chip to acclimatize at room temperature for at least 30 minutes before performing an assay.

- 7 When the chip is detected, heating begins and the screen below is displayed to indicate that heating is in progress. Wait for some time until the temperature stabilizes. When the heating is completed, the chip preparation is complete. Heating may take several minutes to complete.



If No Chips are Detected

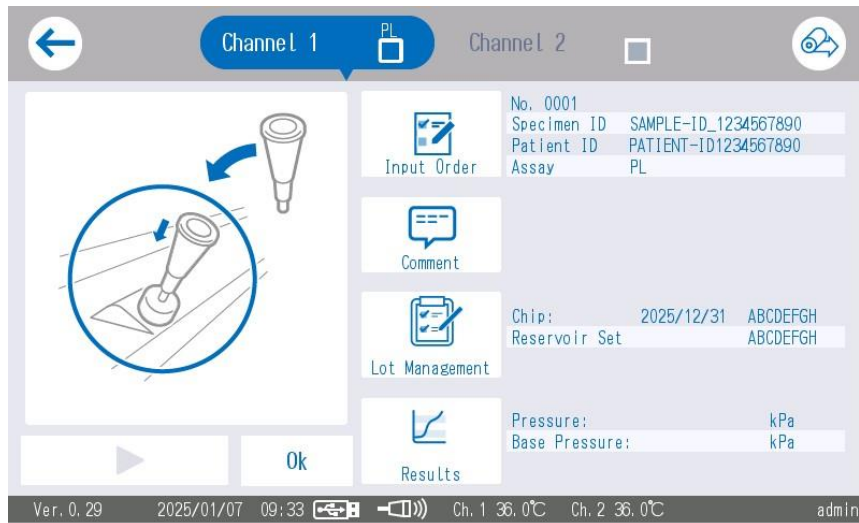
If the display does not change to show that heating is in progress after the chip is inserted, the chip has not been detected correctly. Remove the chip and insert again.



- If the chip is not detected after re-insertion, replace the chip with a new one.
- Check the label on the chip and if there is no abnormality, clean the chip measurement section. See “11.4.2 Chip Measurement Section Cleaning”.
- If detection failure is repeated after replacing the chip and cleaning the chip measurement section, please contact your local distributor.

6.4 Specimen Injection

After heating of the chip is finished and the screen shown below appears, inject the specimen according to the following steps.



WARNING



- This operation may pose a risk of infection. To prevent biohazard contamination, always wear personal protective equipment such as gloves and eye protection, and protective clothing such as a lab coat.
- Waste fluid and used chips, Reservoirs, and Over-caps may pose a risk of infection if touched directly. Dispose of them as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

CAUTION



- Do not use consumables not listed in "13.1 Consumables List" and "13.2 Assay-Related Products List".
- Chips and other consumables should be used within their expiry dates. The expiry dates can be found on the label of the consumables.
- Please refer to the instructions provided with the chip for handling precautions and measurement results of blood samples related to the measurement.
- Please read and understand the instruction manual of the chip before taking measurements.



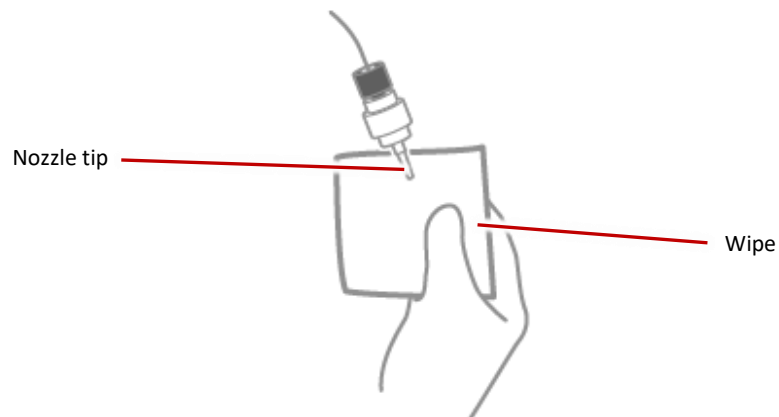
If you are unsure of the steps, please refer to the instructions displayed on the left side of the screen.

- 1 Pull the nozzle of the applicable Channel out of the waste bottle and wipe off the mineral oil with a dust-free lab wipe etc.

 WARNING



Mineral oil should be treated as an infectious material and disposed of as medical waste in accordance with the laws and regulations of the country in which the waste is generated.



- 2 Return the nozzle to the nozzle holder of the applicable Channel.

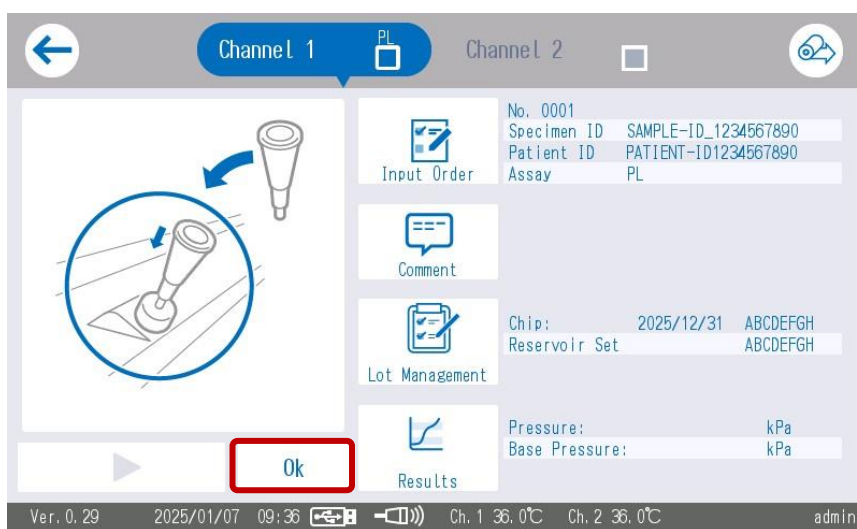


The tubing should be completely housed inside the nozzle holder.

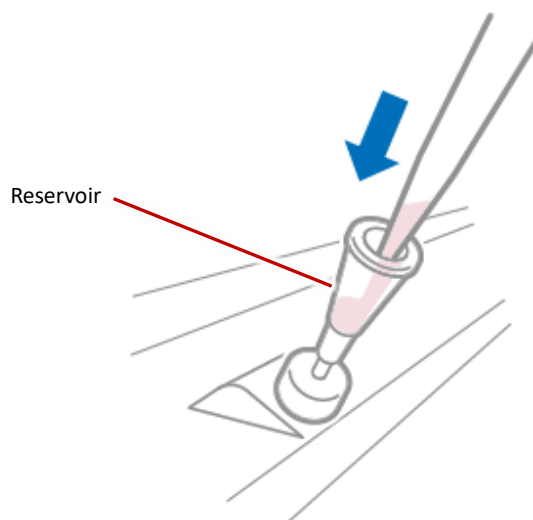
- 3 Set the Reservoir at the tip of the nozzle as shown in the picture.



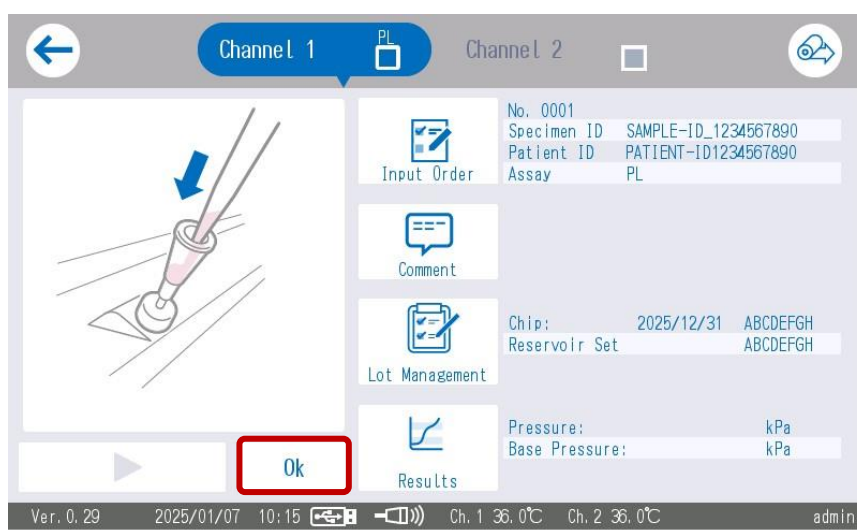
- 4 After attaching the Reservoir to the nozzle, tap [Ok].



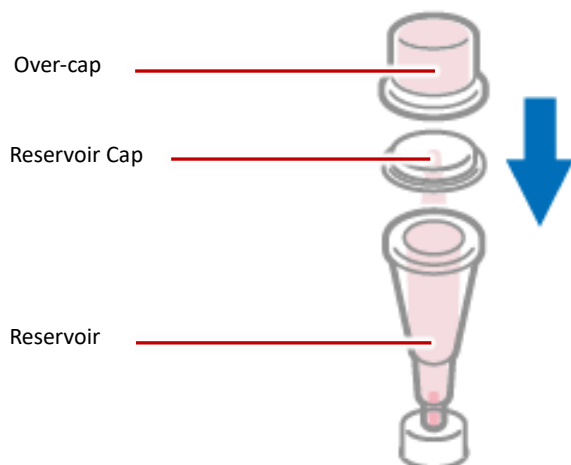
- 5 Inject the specimen into the Reservoir of the Channel used for performing the measurement. Gently inject the specimen (refer to the instructions for use of each chip for specimen type, preparation method, and injection volume) into the Reservoir along the side wall, making sure that there are no air bubbles in the blood as it enters the reservoir.



- 6 After injecting the specimen into the Reservoir, tap [Ok].



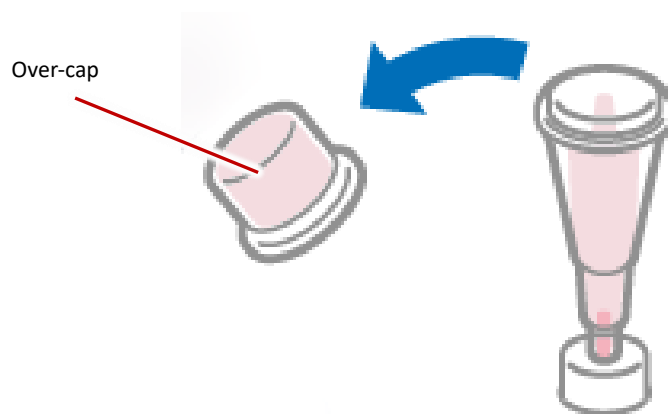
- 7 Attach the Reservoir Cap with Over-cap to the Reservoir into which the blood was injected. Press in firmly from directly above and allow excess blood to overflow into the Over-cap.



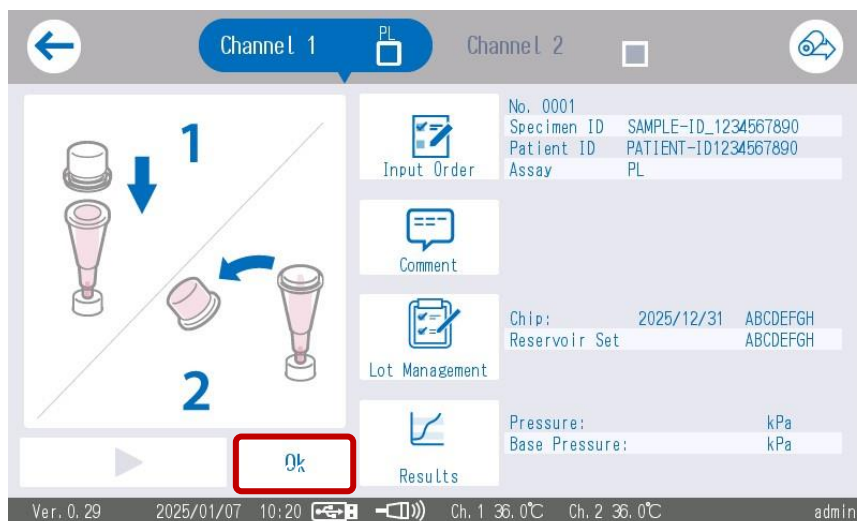
- 8 Ensure that there is no gap between the Reservoir, Reservoir Cap, and Over-cap.

 WARNING	
	If there is too much blood in the Reservoir, blood may be ejected when the lid is closed. Observe the specified injection volume.

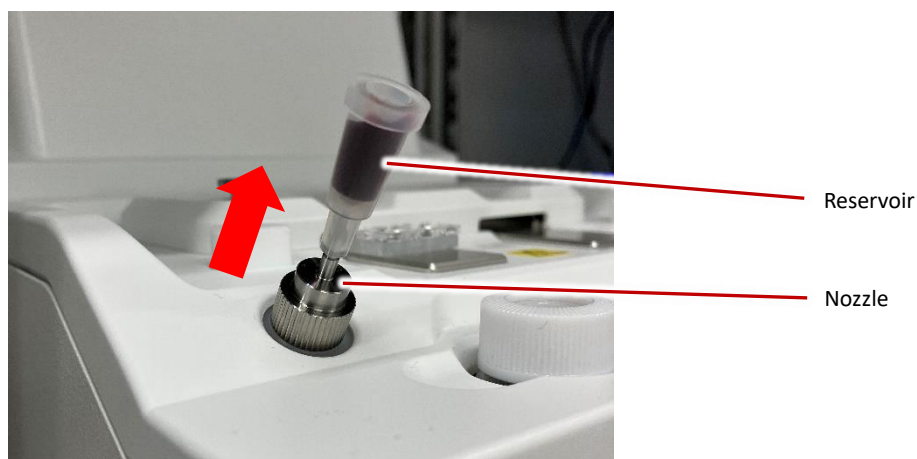
- 9 Remove only the Over-cap. The removed Over-cap should be disposed of appropriately as infectious waste.



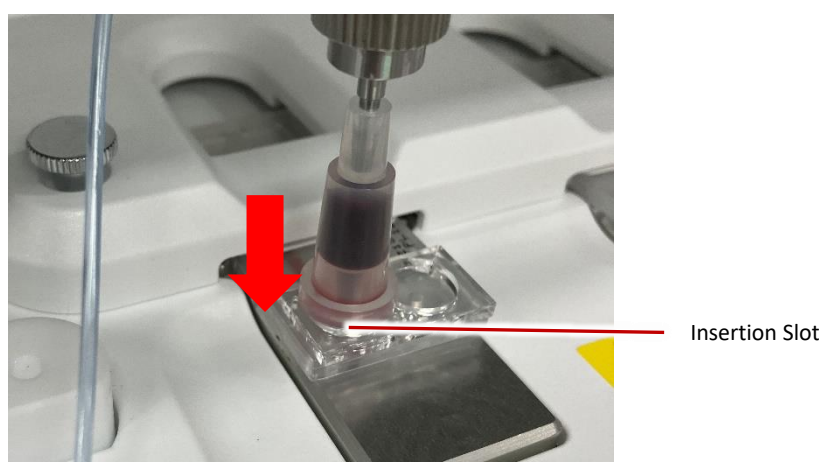
- 10 Tap [Ok] when the Over-cap has been removed and disposed of.



- 11 Grasp the plastic reservoir (not the metal nozzle) and lift up the entire reservoir-nozzle assembly.

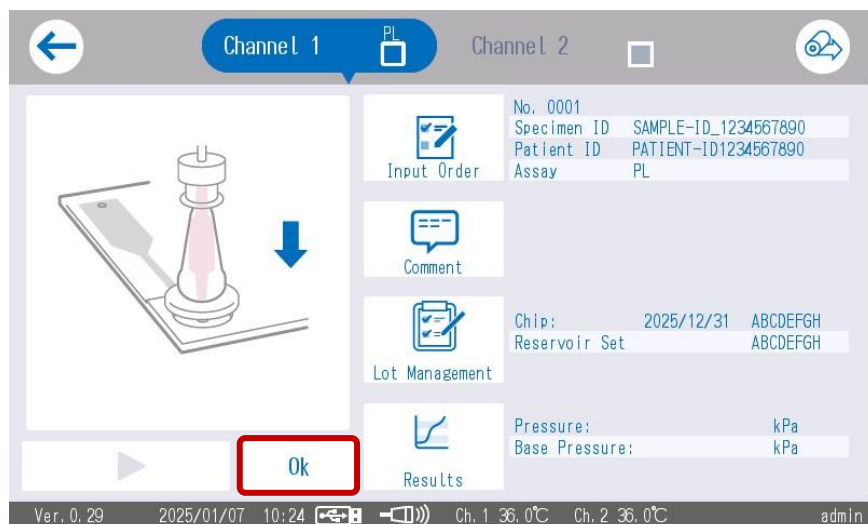


- 12 Gently push the Reservoir with a slight twisting motion into the insertion slot of the chip (with the auxiliary ring) until it feels secure.

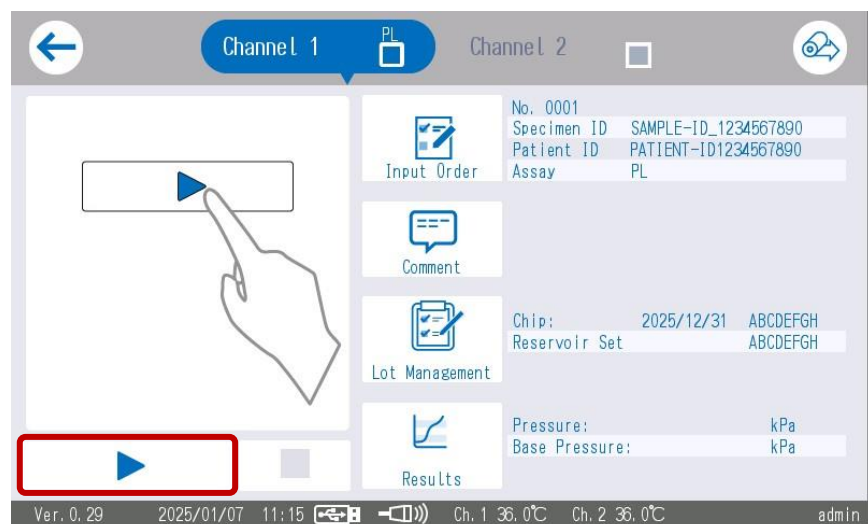


If the chip has two feed channels and one of the insertion slots has already been used, use the other slot.

- 13 Check that the chip and Reservoir are set without gaps, and that no blood has entered the chip before starting the assay. If they are set properly, tap [Ok].



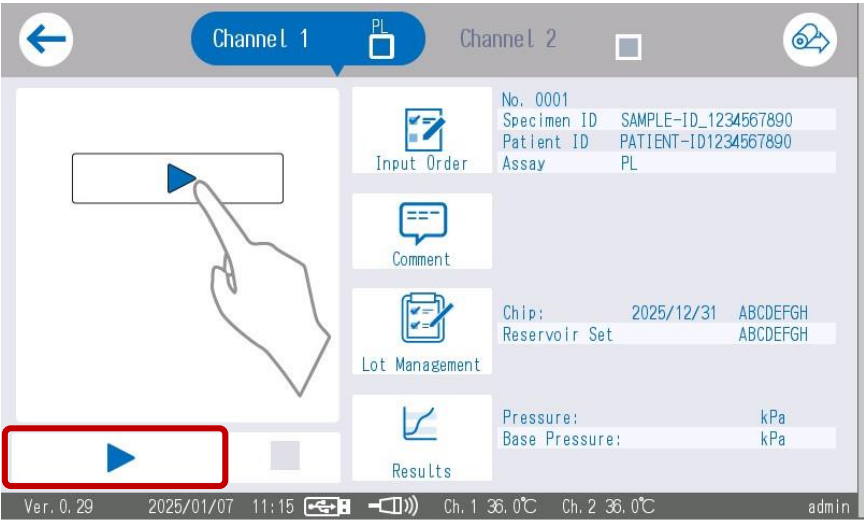
- 14 The display of [▷] will change to [▶] and can be pressed to start the measurement.



Assay preparation is complete.

6.5 Start of Measurement

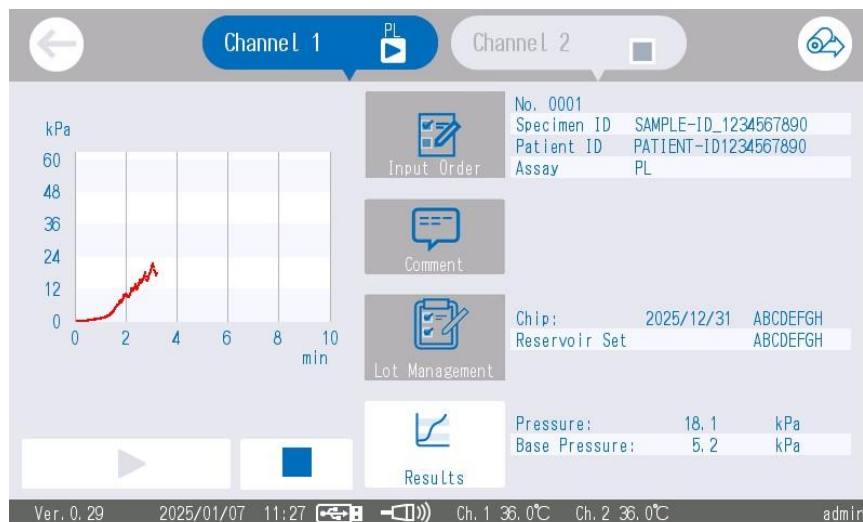
Tap [▶] to perform measurement.



6.6 Measuring

While measuring, an elapsed time-pressure graph is displayed on the screen. The measurement continues until the following status is reached.

- When the measured pressure reaches the occlusion pressure
- When the maximum assay time has elapsed from the start of measurement
- If an emergency stop is performed



If any of the following errors occur, an emergency stop is automatically performed. After the emergency stop, follow the resolution method on the screen and at "12.2 About Error Messages".

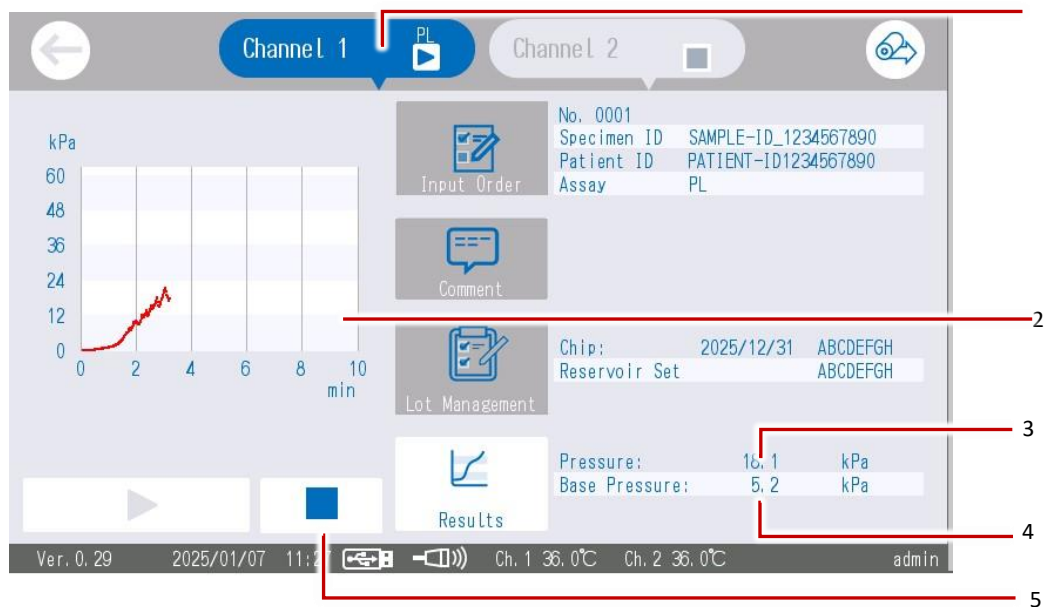
- E011 Atmospheric pressure error
- E012 Baseline pressure error
- E013 Pressure above limit
- E014 Pressure below lower limit
- E015 Abnormal pressure drop
- E020 Pump volume below threshold
- E022 Hardware error (Pressure sensor)
- E023 Hardware error (Chip heater)

ATTENTION



Do not touch the nozzle or Reservoir during the measurement.
Do not remove the chip from the measurement section during the measurement.

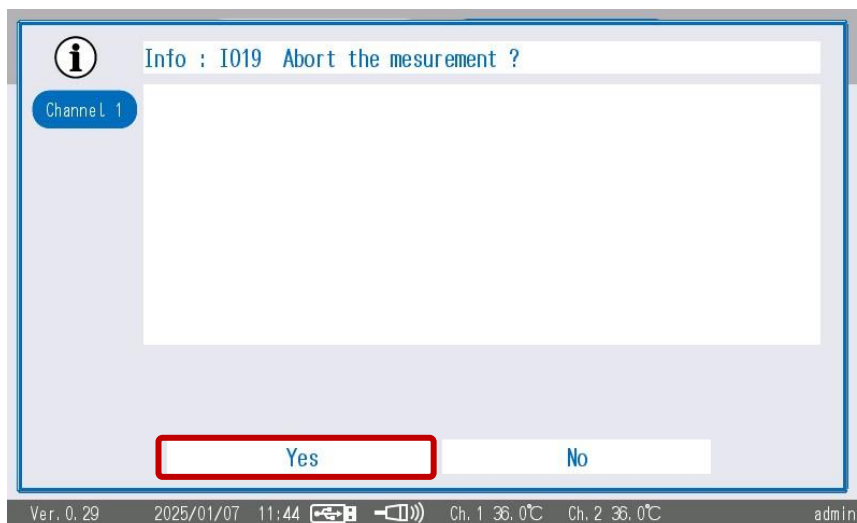
How to Read the "Measurement" Screen



Number	Name	Description
1	[Channel 1] Button [Channel 2] Button	Tap while measuring to switch to the other Channel to input order. [▶] is displayed for the channel that is measuring, and [■] is displayed for the channel that is not in operation.
2	Graph	The horizontal axis displays the elapsed time and the vertical axis displays the pressure.
3	Pressure	Displays the current channel pressure value.
4	Base Pressure	Displays the pressure value at the start of measurement.
5	[■] Button	Emergency stop, performed by tapping.

About Emergency Stop

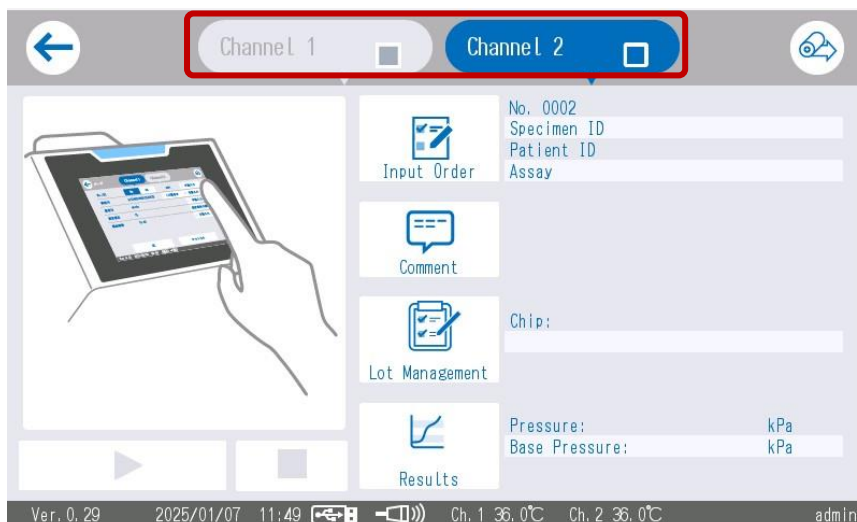
Tapping the  button while measuring will stop the measurement. Tap [Yes] when the confirmation message appears.



It is not possible to resume the measurement after an emergency stop has been performed. The results of an emergency stop measurement are saved up to the point at which it is stopped. However, the measurement results (OT, OST, AUC) are not calculated.

About Order Input While Measuring

While measuring using one channel, you can input orders for the other channel that is not in use. Tap [Channel 1] or [Channel 2] on the screen to display the order input screen for the channel that is not in use.

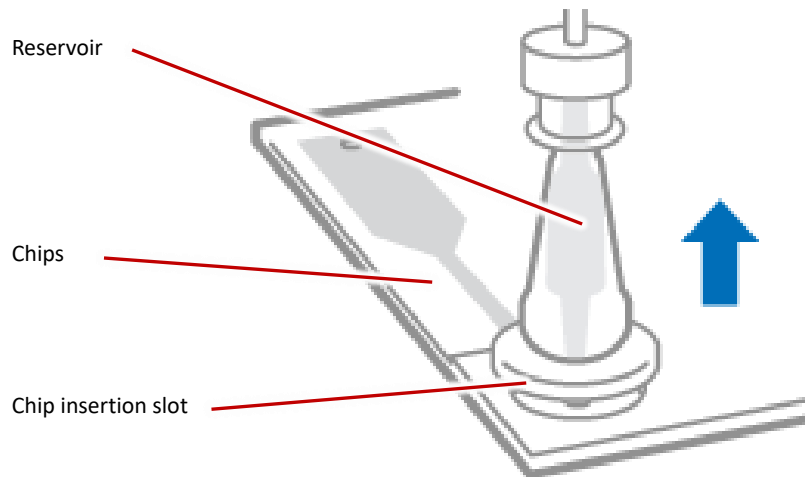


6.7 Measurement Completed

6.7.1 Disposal of Used Chips and Reservoirs

Once the measurement is complete, dispose of the chips and Reservoirs used as follows.

- 1 Remove the Reservoir from the chip. Use caution to ensure that the chip does not fall out of the instrument.



WARNING



Remove the Reservoir from the chip with care.
Blood remaining in the Reservoir may leak out.

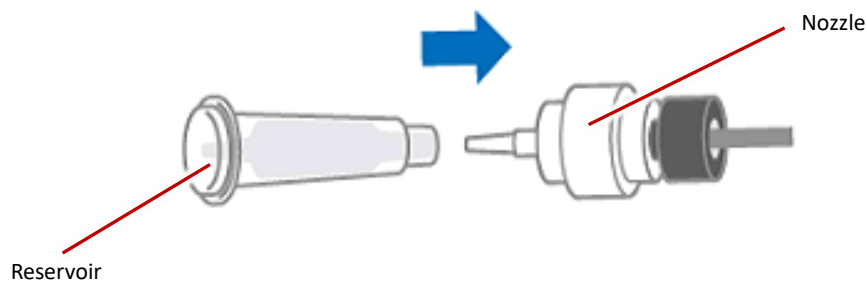


If the chip has two feed channels and you wish to continue to use the other feed channel for measurement, do not pull out the chip but leave it inserted.



If you wish to continue to use the other channel of the chip that has two feed channels, please input the order again. If you wish to authenticate the chip, please refer to "How to Read a Chip When Using a Chip with Two Feed Channels Consecutively" at "6.3 Chip Insertion".

- 2 Turn the Reservoir on its side (horizontally) and remove it from the nozzle using a twisting motion.



WARNING



Remove the Reservoir from the nozzle with care. Take care not to loosen the connection between the tubing and nozzle.

Blood remaining in the Reservoir may leak out, especially if the reservoir is not held horizontally when removed from the nozzle.

- 3 Dispose of the removed Reservoir properly as infectious waste.
- 4 Insert the nozzle into the waste bottle.



- 5 Remove the chip from the measurement section and dispose of it properly as infectious waste.

WARNING



- Waste fluid and used chips, Reservoirs, and Over-caps may pose a risk of infection if touched directly. Dispose of them as medical waste in accordance with the laws and regulations of the country in which the waste is generated.
- Do not reuse chips, Reservoirs, or Over-caps that have already been used once.

- 6 Once the chip and Reservoir have been processed, tap [Ok].

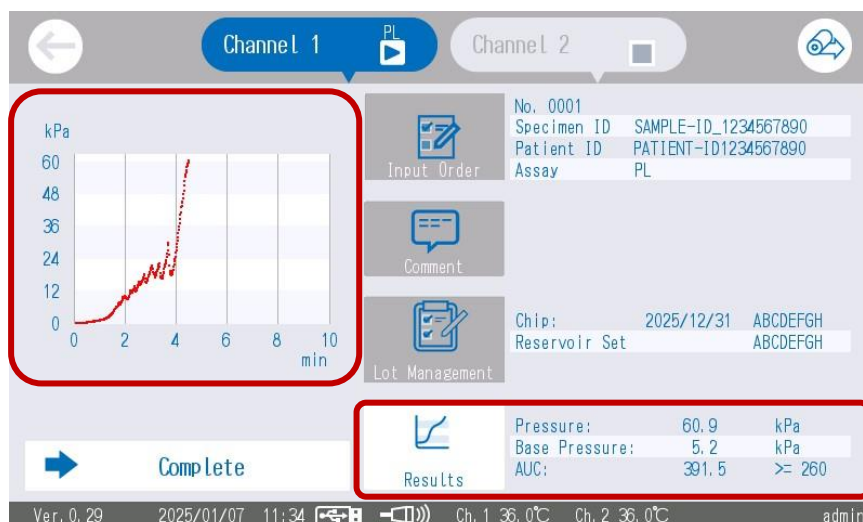


Tap [Ok] to display the "Measurement" screen.

This completes the processing of the used chip and Reservoir.

6.7.2 Confirmation of Measurement Results

The measurement results are displayed on the "Measurement" screen, where the details can be confirmed. Measurement results are saved in the instrument and may also be printed by the printer, if enabled.



If you do not want to use the printer for real-time output, you can set the printer not to print in the "Printer Settings" section of the "Settings" screen. See "9.3 Printer Settings" for more information.



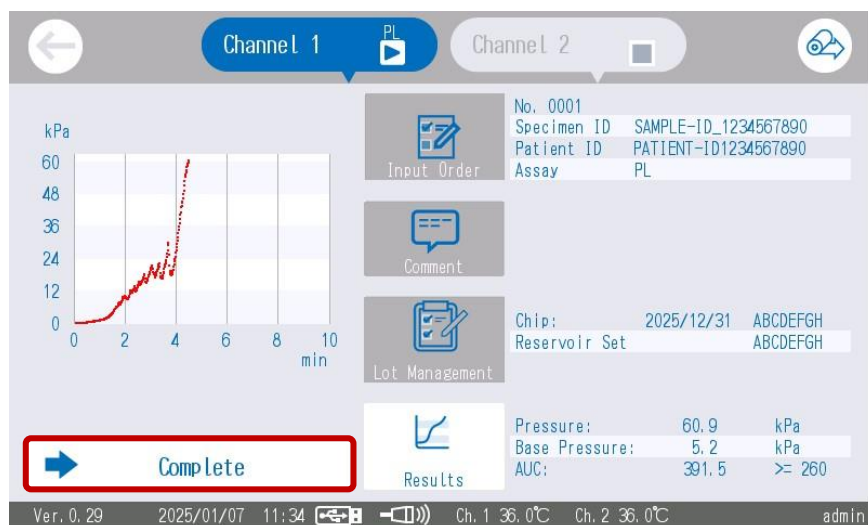
CAUTION



Do not touch the blade inside the printer when tearing off the printer paper. Doing so may cause injury.

6.7.3 Measurement Completed

After confirmation, tap [Complete].



This completes the measurement procedure.

A simple SC is performed, and the "Input Order" screen is displayed.

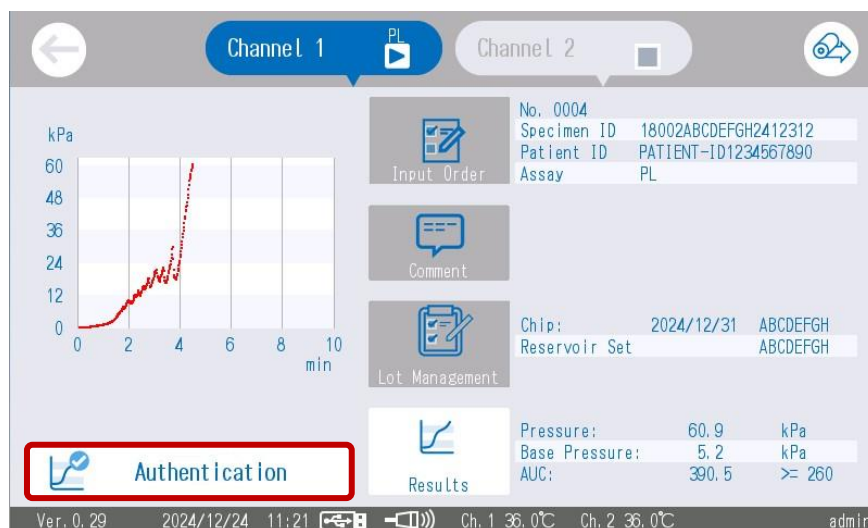
Authentication of Measurement Results

If both "Authenticate" and "Realtime Output" are set to [Enable] on the "LIS Settings" screen, the [Authentication] button will be displayed instead of the [Complete] button. After confirming the results, follow the procedure below for the administrator to perform authentication and output the measurement results to LIS before completing the measurement.



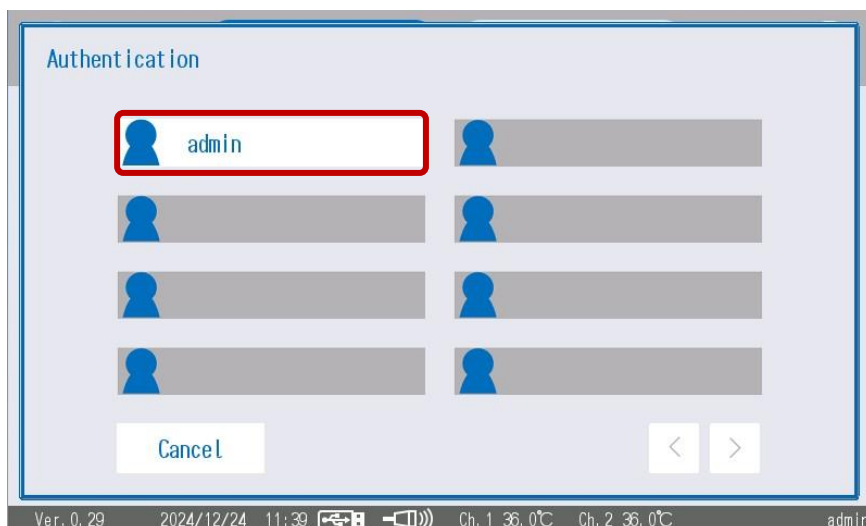
By default, the "Authenticate" setting is set to [Disable]. To change the setting, see "9.4 LIS Settings".

- 1 Tap [Authenticate].



Tap [Authenticate] to display the "Authentication" screen.

- 2 On the "Authentication" screen, select and tap the administrator you wish to receive authentication from.

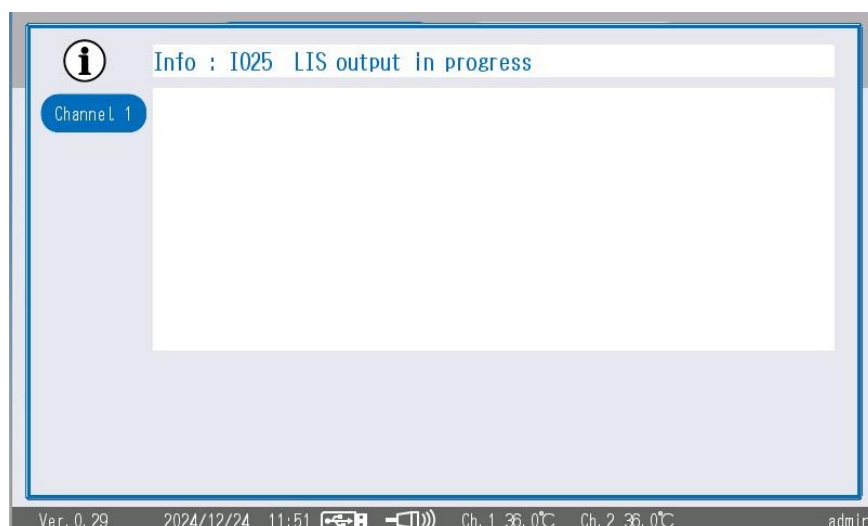


Only user names with administrator privileges are displayed.

- 3 Tap [Enter] and have the administrator enter their password, then select and tap [Authentication] or [Unapprove].



- 4 When the administrator taps [Authentication], the data is output to the LIS, and then the "Measurement Results" screen is displayed.



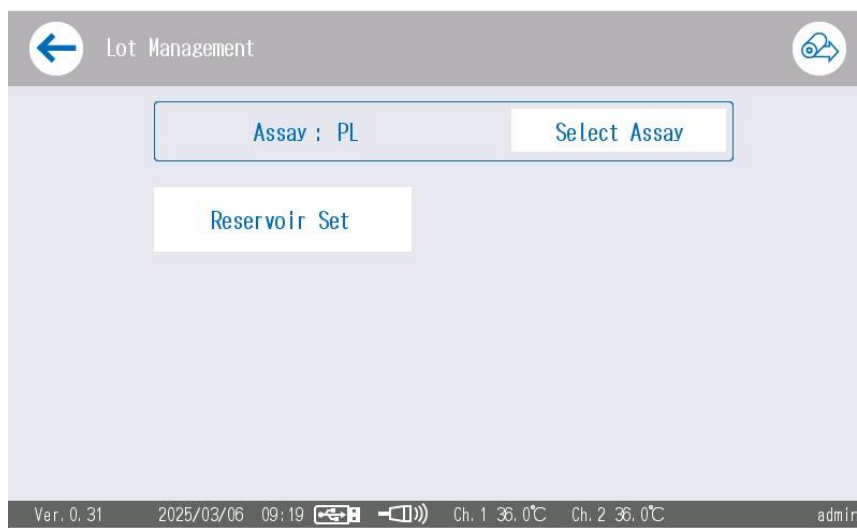
If [Unapprove] is tapped, the "Measurement Results" screen will be displayed without output to LIS.

This completes the measurement results authentication procedure.



7 Lot Management

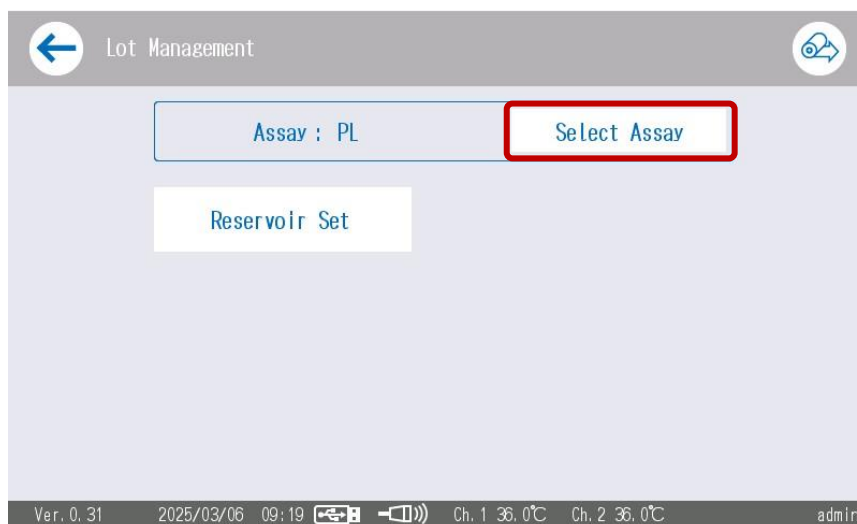
Tap [Lot Management] on the "Menu" screen to display the "Lot Management" screen, where information about consumables used for each assay can be registered. Once registered, the barcode ID and lot number can be confirmed. Register lot information when the lot of the consumables to be used is switched.



7.1 Registration Method

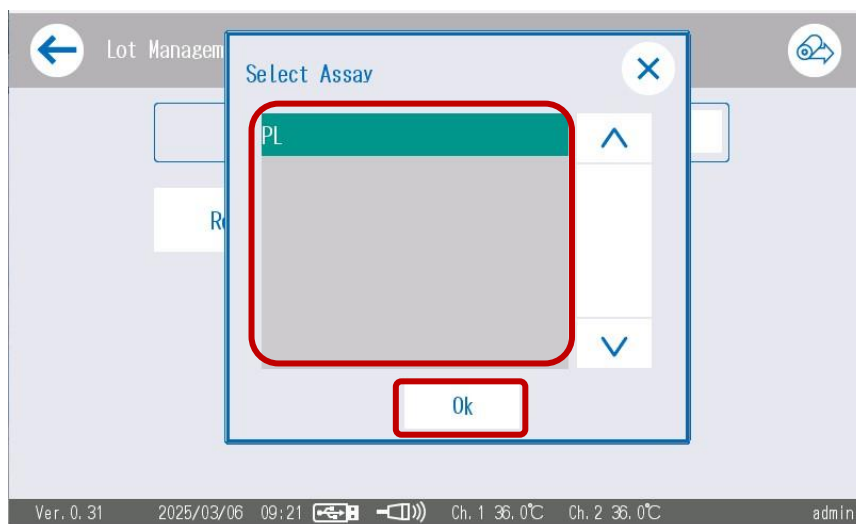
Registration is performed via the following method.

- 1 Tap [Select Assay].

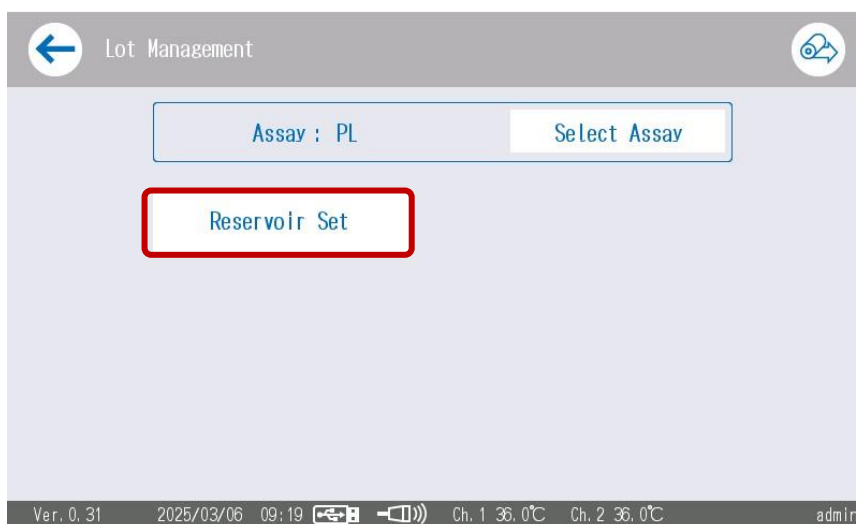


The "Select Assay" screen is displayed.

- 2 Select the assay and tap [Ok].



- 3 Tap [Reservoir Set].



Details of the Reservoir Set are displayed.



- 4 Register the ID of the consumables. Tap [Enter].

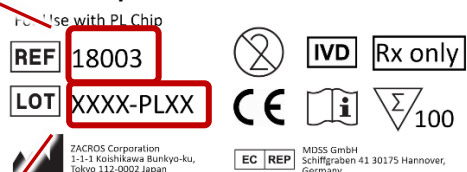


The "Enter ID" screen is displayed.



- 5 Scan the QR code on the box of the Reservoir set with the barcode reader. Once scanned, the QR code number will be entered on the "Enter ID" screen.

(1) PL Chip Reservoir set



(2)





The ID can also be entered on the "Keyboard" screen. When entering on the "Keyboard" screen, hyphens should be omitted.

To enter the ID of the Reservoir using the keyboard, enter the following information in the following order, without spaces or hyphens.

(1) REF No. of the Reservoir set [5-digit], (2) Lot number of the Reservoir set [8-digit]. In the above example, the ID would be 18003XXXXPLXX.

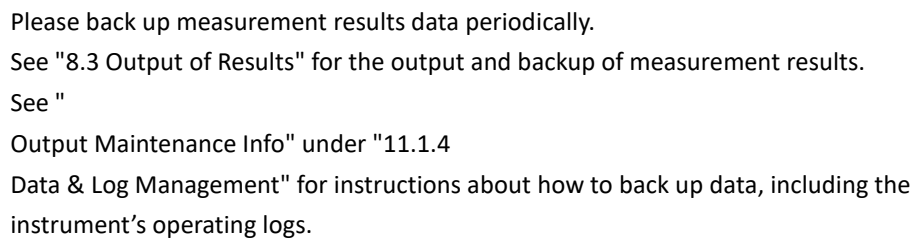
This information can be confirmed on the label of the Reservoir set.

- 6 The lot number will be registered.

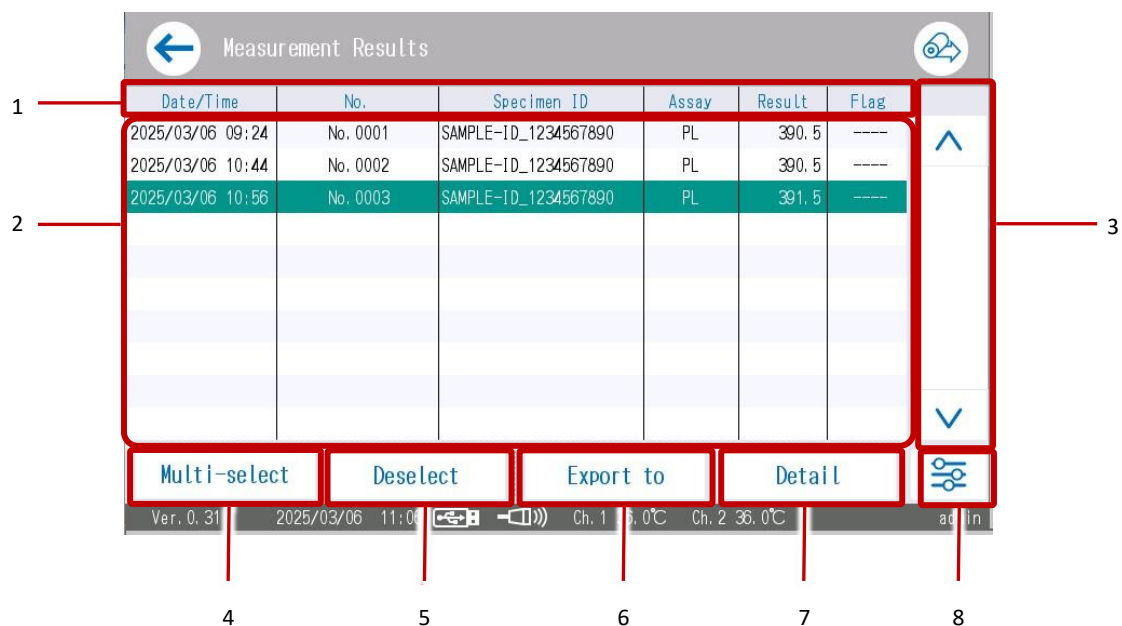
The screenshot shows a screen titled "PL Chip Reservoir Set". It has a back arrow icon on the top left and a user icon on the top right. The main area contains two input fields. The first field is labeled "ID" and contains the text "18003ABCDEFGH". To its right is a button with a pencil icon, a grid icon, and the text "Enter". The second field is labeled "Lot Number" and contains the text "ABCDEFGH". This second field is highlighted with a red rectangular border. At the bottom of the screen, there is a status bar with the following information: "Ver. 0.29", "2024/12/24 15:16", a battery icon, a signal icon, "Ch. 1 36.0°C", "Ch. 2 36.0°C", and the username "admin".

Measurement Results						
Date/Time	No.	Specimen ID	Assay	Result	Flag	
2025/03/06 09:24	No. 0001	SAMPLE-ID_1234567890	PL	390.5	----	▲
2025/03/06 10:44	No. 0002	SAMPLE-ID_1234567890	PL	390.5	----	
2025/03/06 10:56	No. 0003	SAMPLE-ID_1234567890	PL	391.5	----	
						▼
Multi-select		Deselect	Export to		Detail	⚙️
Ver. 0.31		2025/03/06 11:11	🔋 🔊	Ch. 1 36.0°C Ch. 2 36.0°C		admin

When new measurement results are obtained and the number of saved measurement results exceeds 5,000, the oldest data will be deleted first.



8.1 How to Read the "Measurement Results" Screen



Number	Name	Description
1	Column titles	Indicates the items displayed in the data list. "Date/Time": The date and time the measurement was performed "No.": The measurement number of the patient or QC specimen "Specimen ID": The specimen ID entered at the time of measurement "Assay": The assay measured "Result": The measurement results of the assay "Flag": Error information that occurred during the measurement
2	Measurement Results	A list of measurement results is displayed. A measurement result can be selected by tapping it, and the selected measurement result is displayed in green.
3	Scroll bar	Tap [↑] to select the measurement result one line above, and tap [↓] to select the measurement result one line below. Tap and hold [↑] and [↓] to scroll continuously. Tap the scroll box in the center to select the measurement results in the tapped location.
4	[Multi-select] button / [Deselect] button	Tap the [Multi-select] and [Deselect] buttons to specify the range to be selected.
5	[Deselect] button	Releases the range selected with the [Multi-select] and [Deselect] buttons.
6	[Export to] button	Outputs the measurement results of the range selected using the [Multi-select] and [Deselect] buttons to the printer, USB flash drive, or LIS. It is disabled while a selection is being made (while the [Deselect] button is displayed).
7	[Detail] button	The details of the selected measurement result can be viewed.
8	[Filter] button	The measurement results can be filtered and displayed by [Type], [Status], [Period], and [ID].

8.2 Details of Measurement Results

The details of measurement results can be viewed by tapping [Detail] while data is selected. After completing the review, tap [←] in the upper left corner to return to the "Measurement Results" screen.



- Tap [→] or [←] above the graph to switch to the details of the previous or next measurement results.
- The full text of comments can be viewed by tapping the [...] in the Comment column.

8.3 Output of Results

The measurement results of the selected range can be output to the printer, USB flash drive, or LIS. Select and output measurement results using the following method.

- 1 Tap to select the measurement result that will be the starting point of the selected range.

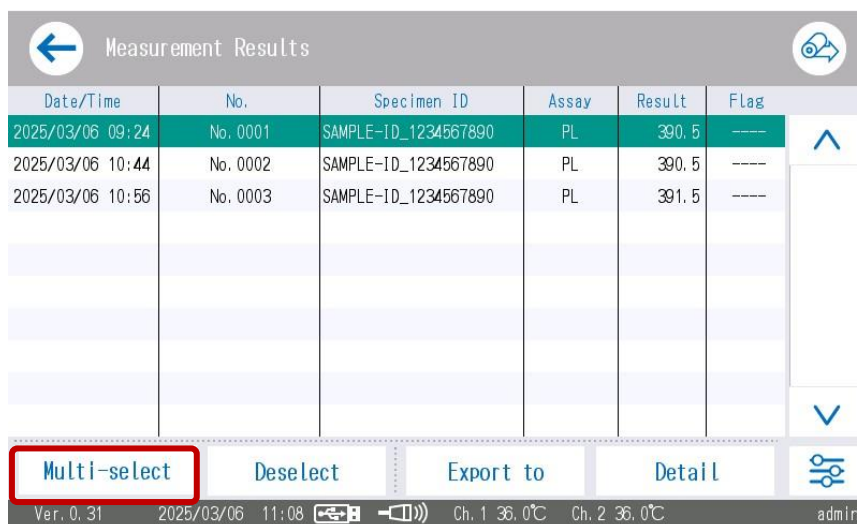
The 'Measurement Results' screen displays a table with the following data:

Date/Time	No.	Specimen ID	Assay	Result	Flag
2025/03/06 09:24	No. 0001	SAMPLE-ID_1234567890	PL	390.5	----
2025/03/06 10:44	No. 0002	SAMPLE-ID_1234567890	PL	390.5	----
2025/03/06 10:56	No. 0003	SAMPLE-ID_1234567890	PL	391.5	----

At the bottom of the table are buttons: Multi-select, Deselect, Export to, and Detail. On the right side, there are up and down arrows (↑ and ↓) and a settings icon (gear).

Status Bar: Ver. 0.31, 2025/03/06 11:08, Ch. 1 36.0°C, Ch. 2 36.0°C, admin.

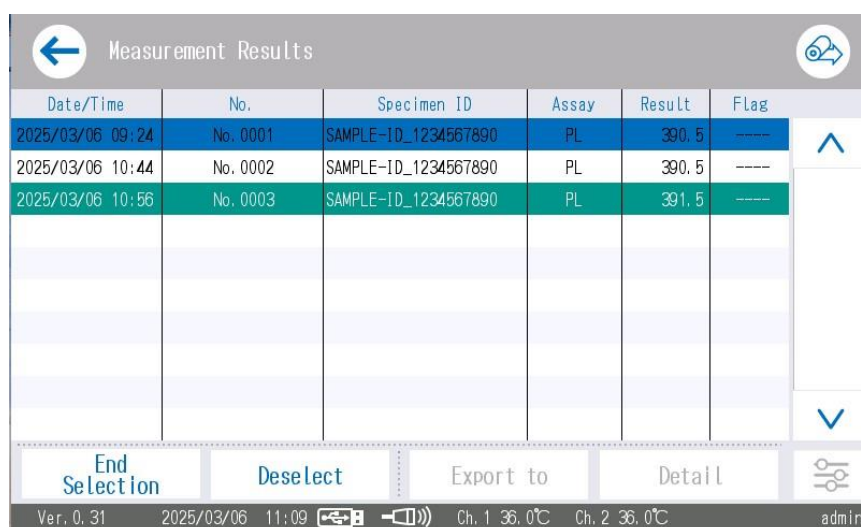
- 2 Tap [Multi-select] to set the starting point of the selected range.



Date/Time	No.	Specimen ID	Assay	Result	Flag
2025/03/06 09:24	No. 0001	SAMPLE-ID_1234567890	PL	390.5	----
2025/03/06 10:44	No. 0002	SAMPLE-ID_1234567890	PL	390.5	----
2025/03/06 10:56	No. 0003	SAMPLE-ID_1234567890	PL	391.5	----

Ver. 0.31 2025/03/06 11:08 Ch. 1 36.0°C Ch. 2 36.0°C admin

- 3 Tap the measurement result that will be the end point of the selected range.



Date/Time	No.	Specimen ID	Assay	Result	Flag
2025/03/06 09:24	No. 0001	SAMPLE-ID_1234567890	PL	390.5	----
2025/03/06 10:44	No. 0002	SAMPLE-ID_1234567890	PL	390.5	----
2025/03/06 10:56	No. 0003	SAMPLE-ID_1234567890	PL	391.5	----

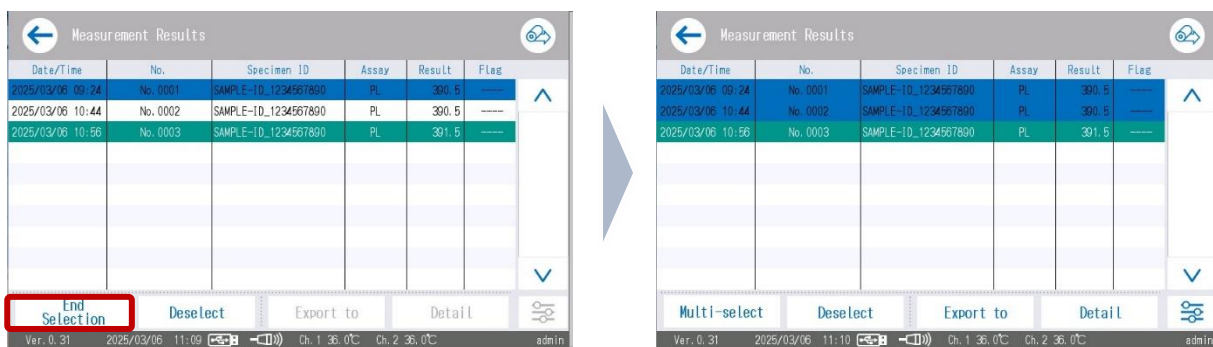
Ver. 0.31 2025/03/06 11:09 Ch. 1 36.0°C Ch. 2 36.0°C admin

The starting point will turn blue and the end point will turn green.

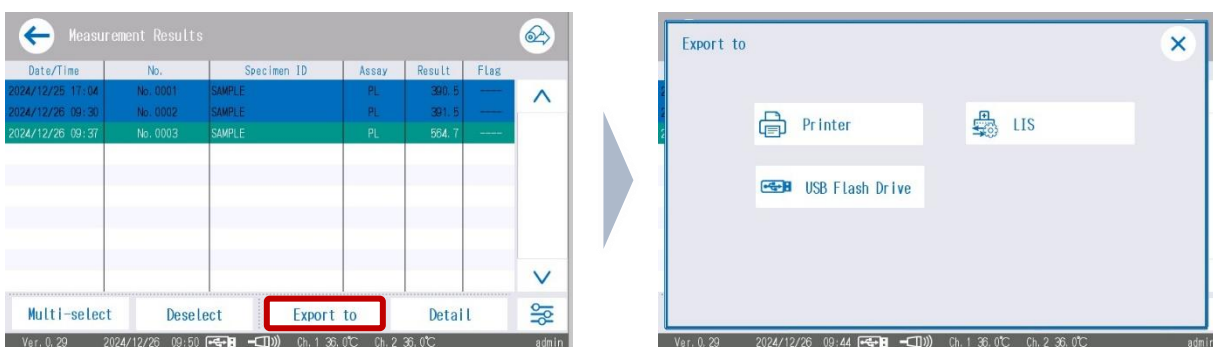


- To release the selection, tap [Deselect].

- 4 Tap [End Selection] to select the range from the starting point to the end point. The measurement results displayed in blue and green are the selected range.



- 5 Tap [Export to], then tap to select an output destination.



Select an output destination to commence the output.



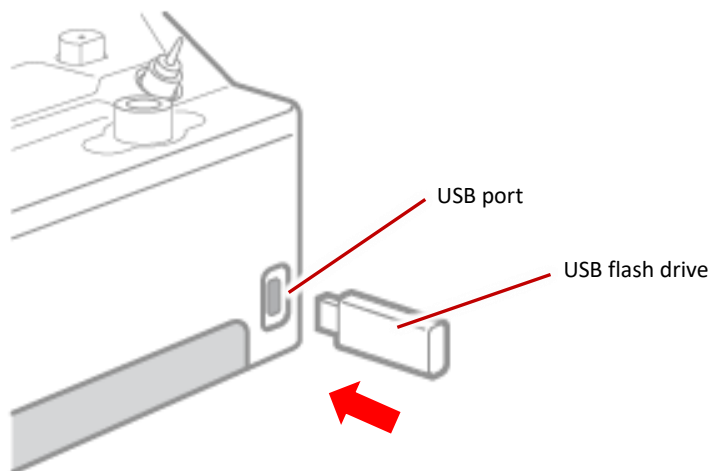
The selected range is retained until either the "Menu" screen is returned to, or [Deselect] is tapped.



To output a single result rather than a range, it is not necessary to select a starting point and end point. Tap to select the result to be output, and then tap [Export to].

When Outputting to a USB Flash Drive

Insert a USB flash drive into the instrument's USB port, then follow the instructions at "8.3 Output of Results" to output to the USB flash drive. In this case, a file in comma-separated value (CSV) format will be output to the USB flash drive.



Insert a USB flash drive into the USB port on the front of the instrument.

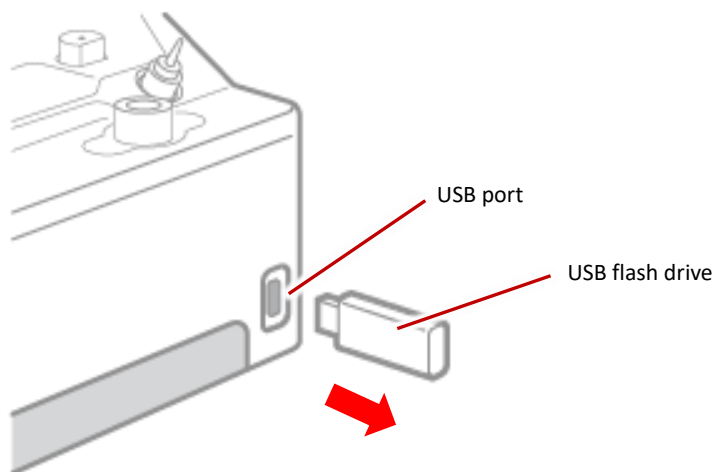


If multiple outputs are made to the same USB flash drive on the same day, the new outputs will be added to the CSV file which was saved first.



If the results that were output on a previous day are still remaining on the USB flash drive, they will be saved as separate data, not overwritten.

After the output to the USB flash drive is complete, remove the USB flash drive from the instrument's USB port.



ATTENTION



External HDDs cannot be used.



Use a USB flash drive that does not have a password function.

8.4 Filtered Display

Measurement results can be filtered and displayed by period, ID, etc. Select the criteria to be filtered and tap [Ok].

Filter

Type

No.

☒

QC.

☒

Status

Normal

☒

Error

☒

Period

Select

All Period

ID

All ID

Select

Patient ID

☐

Specimen ID

☒

Ok

Cancel

Ver. 0.29

2024/12/26 11:17

Ch. 1 36.0℃

Ch. 2 36.0℃

admin



9 Settings

By tapping [Settings] on the "Menu" screen to display the "Settings" screen, the instrument's system settings can be changed and the settings for the printer, LIS, etc. can be set. Tap to select the item for which you want to change the setting. The settings that can be changed vary by account type. Accounts with user privileges can change the [System Settings] and [Password Settings], and accounts with administrator privileges can change all items.



Examples of Frequently Used Settings

Settings	Item name
Volume	System Settings
Change password	Change Password
User registration and deletion (account settings)	Administrator Settings
Language selection	Administrator Settings
Blood Collection Time Settings	Administrator Settings

9.1 System Settings

You can change settings related to the instrument's display and operating sounds. They can be changed by an account with user or administrator privileges.



Item name	Description
Date Format	You can change the date display method. Tap to select the display format.
Date/Time	Tap the item you wish to change to change the date or time.
Volume	Tap [-] or [+] to change the volume in steps from 0 to 3.
Screen Brightness	Change the screen brightness in steps from 20 to 100. Tap [+] or [-] to adjust the brightness by increments of five. Tap [Enter] to enter the brightness value directly on the "keyboard" screen.

9.2 Administrator Settings

You can set the blood collection time offset, add or delete accounts, enable preauthentication, enable RUO assays, and change the display language. Only accounts with administrator privileges can make these changes.



Item name	Description																																
Blood Collection Time	Set the automatic entry of the blood collection time at the time of inputting an order. Can be set in the range of 0 to 99 minutes ago from the [Change Time]. The default is set to [0 minutes ago], in which case it is not automatically entered. If automatic entry is not used, the operator can manually enter the blood collection time.																																
Accounts	Tap [Register] to register a new user. Tap [Delete] to select and delete a user.																																
Preauthentication	Can be set to select a user with administrator privileges prior to inputting an order.																																
RUO Assay	Can be set to enable RUO (Research Use Only) assays.																																
Language	You can switch the screen language by selecting it from the list. <table><tr><th>Number</th><th>Language</th><th>Number</th><th>Language</th></tr><tr><td>01</td><td>English</td><td>08</td><td>Swedish</td></tr><tr><td>02</td><td>Japanese</td><td>09</td><td>Danish</td></tr><tr><td>03</td><td>German</td><td>10</td><td>Finnish</td></tr><tr><td>04</td><td>Italian</td><td>11</td><td>Norwegian</td></tr><tr><td>05</td><td>Dutch</td><td>12</td><td>Spanish</td></tr><tr><td>06</td><td>Polish</td><td>13</td><td>Portuguese</td></tr><tr><td>07</td><td>French</td><td>14</td><td>Greek</td></tr></table>	Number	Language	Number	Language	01	English	08	Swedish	02	Japanese	09	Danish	03	German	10	Finnish	04	Italian	11	Norwegian	05	Dutch	12	Spanish	06	Polish	13	Portuguese	07	French	14	Greek
Number	Language	Number	Language																														
01	English	08	Swedish																														
02	Japanese	09	Danish																														
03	German	10	Finnish																														
04	Italian	11	Norwegian																														
05	Dutch	12	Spanish																														
06	Polish	13	Portuguese																														
07	French	14	Greek																														

9.2.1 User Registration

- 1 Tap [Register] on the "Administrator Settings" screen.



The "Account Registration" screen is displayed.

- 2 Tap [Enter] and enter the user name and password for the new account you wish to register.

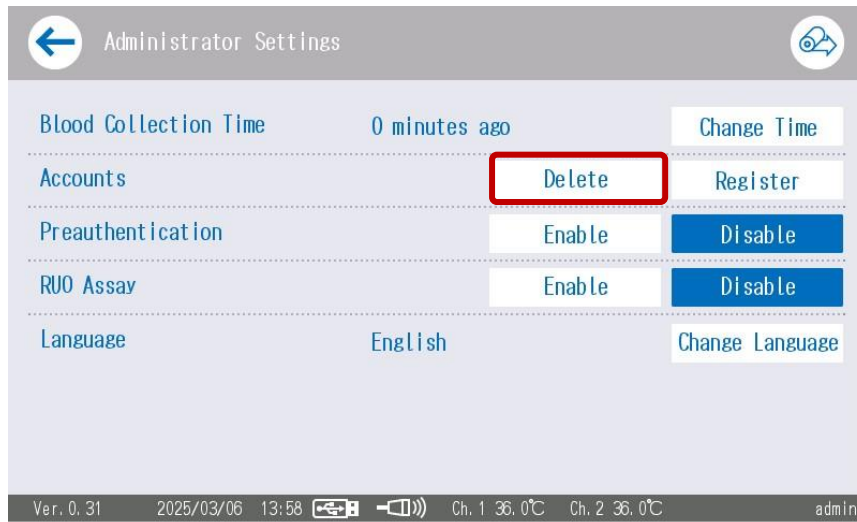


- The user name must be at least 2 characters and the password must be at least 4 characters.
- Letters are case-sensitive.
- A user name that already exist cannot be used.

3 Tap [Register].

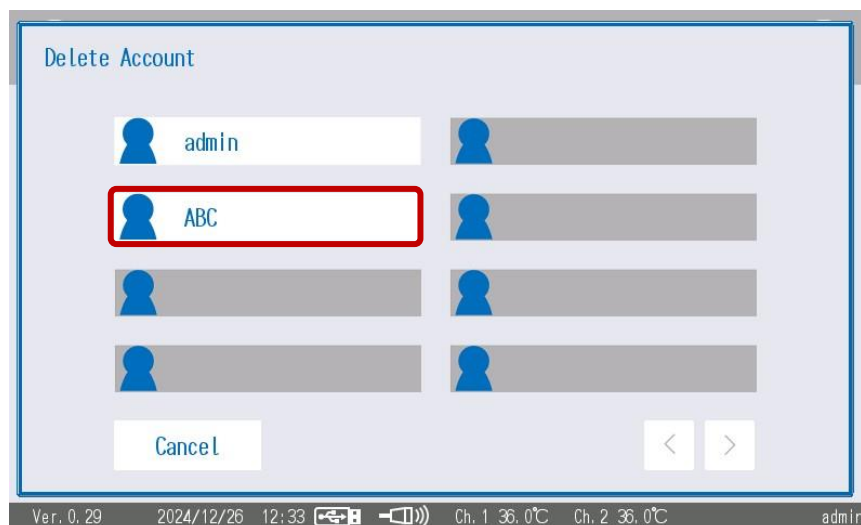
The image shows a mobile application screen titled "Account Registration". It contains three input fields: "User Name" with the text "TTAS", "Password" with masked characters "****", and "Account Type" with two buttons: "User" (highlighted in blue) and "Administrator". Each input field has an "Enter" button to its right. At the bottom of the form, there are two buttons: "Register" (which is enclosed in a red rectangular box) and "Cancel". The bottom status bar of the device shows "Ver. 0.29", the date "2024/12/26", the time "11:36", and temperature readings "Ch. 1 36.0°C" and "Ch. 2 36.0°C". The username "admin" is visible in the bottom right corner of the status bar.

- 1 Tap [Delete] on the "Administrator Settings" screen.



The "Delete Account" screen is displayed.

- 2 Tap the user name of the account you wish to delete.



ATTENTION



Deleted accounts cannot be restored. Please be very careful when deleting.

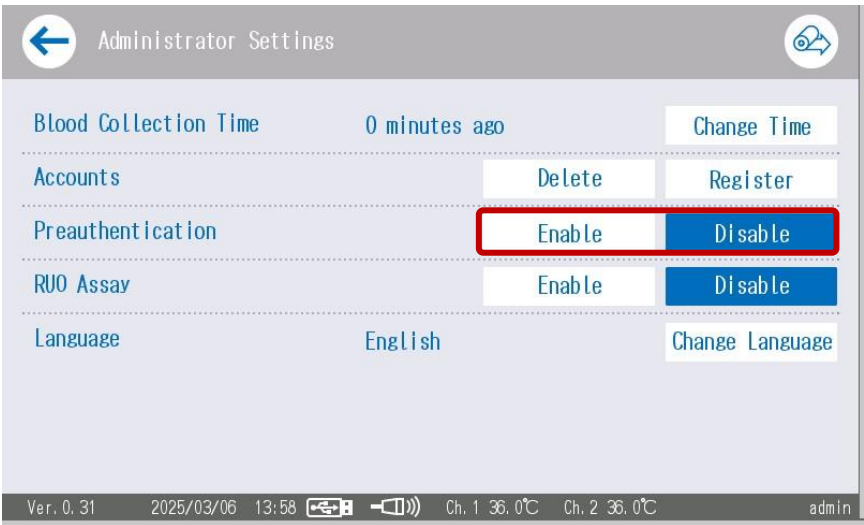


Please understand that, in order to prevent the accidental deletion of all accounts, the "admin" account, which is registered by default, cannot be deleted.

Please receive the password for the "admin" account from the distributor at the time of installation and retain it.

9.2.3 About Preauthentication

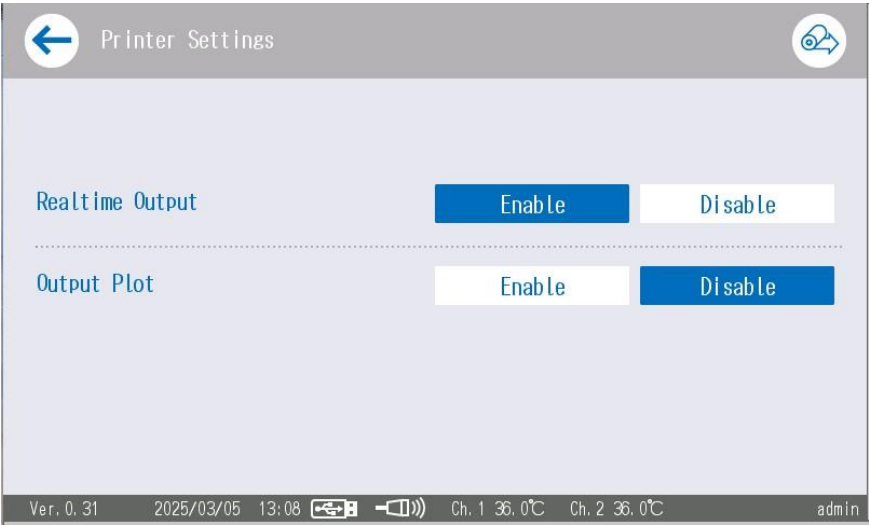
Can be set to select a user with administrator privileges prior to inputting an order.



Item name	Description
Enable	Before the Order screen is displayed, a user with administrator privileges must be selected and its password entered.
Disable	Order input is performed without selecting a user with administrator privileges.

9.3 Printer Settings

You can change settings related to the printer. Only accounts with administrator privileges can make these changes.

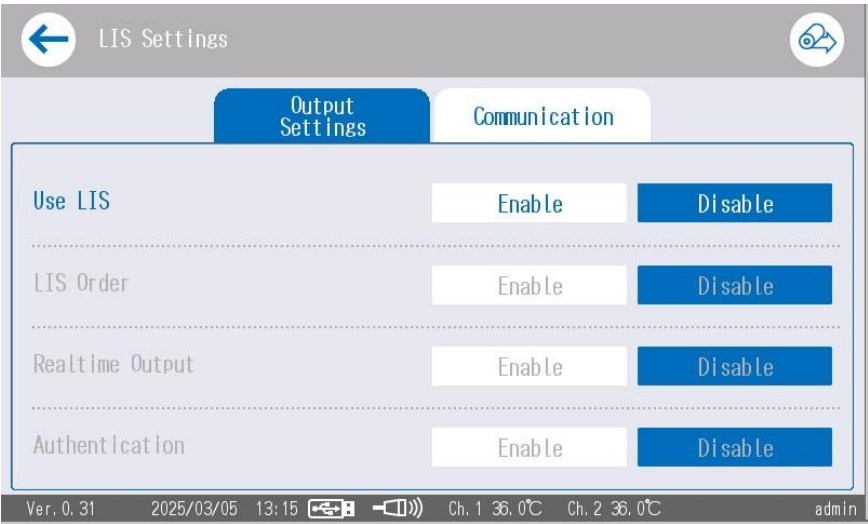


Item name	Description
Realtime Output	You can set whether the results are automatically printed after the measurement is completed.
Output Plot	You can set whether the graph displayed on the "Measurement Results" screen is also printed when measurement results are printed.

9.4 LIS Settings

You can change settings related to LIS. Tap the [Output Settings] and [Communication] buttons to switch between the details being set. Only accounts with administrator privileges can change the LIS settings.

9.4.1 Output Settings



Tap the [Output Settings] button to change the following details.

Item name	Description	
Use LIS	Selects whether or not LIS is used.	
LIS Order	Selects whether or not the LIS inquiry function is used for order information.	
Realtime Output	Selects whether or not the measurement results are output to LIS at the same time as the measurement is completed.	
Authentication	Selects whether or not authentication confirmation by an administrator is performed when outputting to LIS.	
	Enable	Once the measurement is complete, an authentication operation by a user with administrator privileges is required before the measurement results can be output to the LIS.
	Disable	Measurement results are output to LIS immediately upon completion of the measurement.

9.4.2 Communication

Tap the [Communication] button to configure the LIS "IP Address" and "Subnet Mask" settings. Tap [Enter] to enter the information.

← LIS Settings

Output Settings

Communication

IP Address	127. 0. 0. 1	↗ Enter
Subnet Mask	255. 255. 255. 0	↗ Enter
Default Gateway	0. 0. 0. 0	↗ Enter
MAC Address	12-34-56-78-90-12	
Host IP Address	127. 0. 0. 1	↗ Enter
Host Port Number	2575	↗ Enter

Ver. 0. 312025/03/05 17:14Ch. 1 36. 0℃Ch. 2 36. 0℃admin

9.5 Change a password

If logged in with user privileges, the user's own password can be changed; if logged in with administrator privileges, the passwords of all users registered on the instrument can be changed.

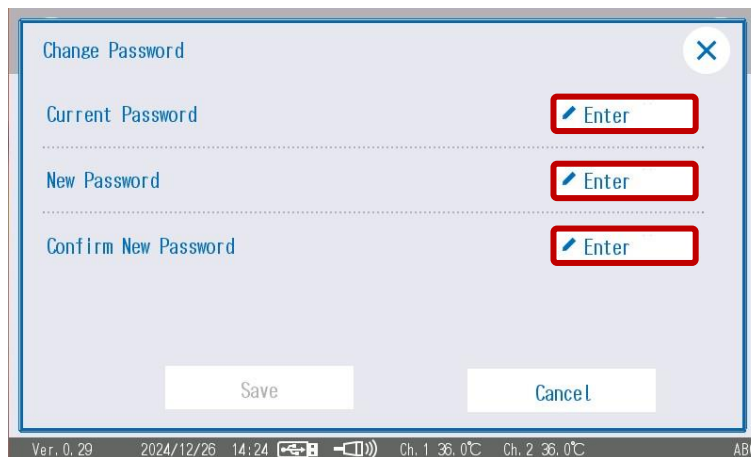
9.5.1 If logged in with user privileges

- 1 Tap [Change Password] on the "Settings" screen.



The "Change Password" screen is displayed.

- 2 Tap [Enter] to enter the current and new passwords.



- The password must be at least 4 characters long.
- Letters are case-sensitive.

- 3 Tap [Save].



The "Change Password" screen is displayed. It features three input fields: "Current Password", "New Password", and "Confirm New Password". Each field has a masked password "****" and an "Enter" button with a pencil icon. At the bottom, there are "Save" and "Cancel" buttons. The "Save" button is highlighted with a red rectangle. The status bar at the bottom shows "Ver. 0.29", "2024/12/26 14:32", and temperature readings "Ch. 1 36.0°C" and "Ch. 2 36.0°C".

9.5.2 If logged in with administrator privileges

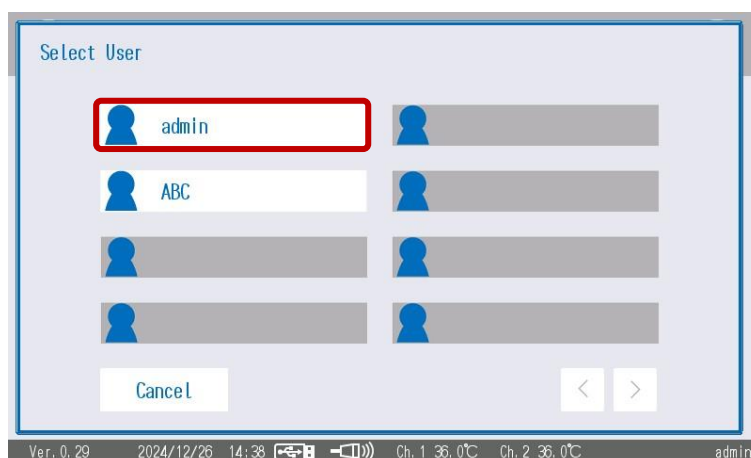
- 1 Tap [Change Password] on the "Settings" screen.



The "Settings" screen is displayed. It contains several menu items: "System", "Administrator", "Printer", "LIS", and "Change Password". The "Change Password" button is highlighted with a red rectangle. The status bar at the bottom shows "Ver. 0.31", "2025/03/06 17:25", and temperature readings "Ch. 1 36.0°C" and "Ch. 2 36.0°C". The user "admin" is logged in.

The "Select User" screen is displayed.

- 2 Tap the user name of the account you wish to change the password for.



The "Select User" screen is displayed. It shows a list of users: "admin", "ABC", and several empty slots. The "admin" user is highlighted with a red rectangle. At the bottom, there is a "Cancel" button and navigation arrows. The status bar at the bottom shows "Ver. 0.29", "2024/12/26 14:38", and temperature readings "Ch. 1 36.0°C" and "Ch. 2 36.0°C". The user "admin" is logged in.

The "Change Password" screen is displayed.

- 3 Tap [Enter] to enter the new password.

Change Password

New Password Enter

Confirm New Password Enter

Save Cancel

Ver. 0.29 2024/12/26 14:38 Ch. 1 36.0°C Ch. 2 36.0°C admin



- The password must be at least 4 characters long.
- Letters are case-sensitive.

- 4 Tap [Save].

Change Password

New Password **** Enter

Confirm New Password **** Enter

Save Cancel

Ver. 0.29 2024/12/26 14:49 Ch. 1 36.0°C Ch. 2 36.0°C admin



10 Exit Operation

10.1 System Shutdown

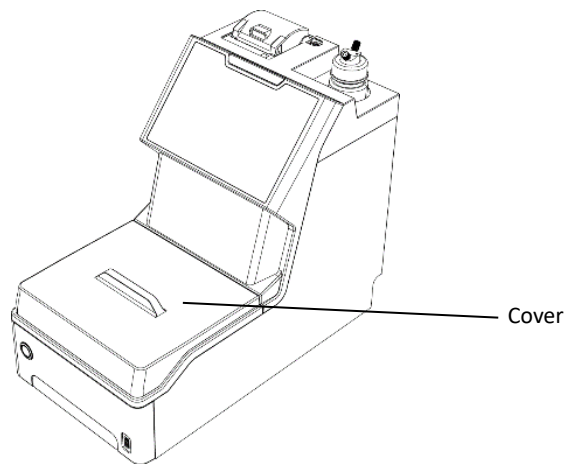
Follow the steps below to shut down the system.

- 1 Tap [Logout] on the "Menu" screen to display the "Logout" screen.
- 2 Tap [Shutdown].



10.2 Replace the Cover

Replace the cover when the instrument is not in use.



ATTENTION



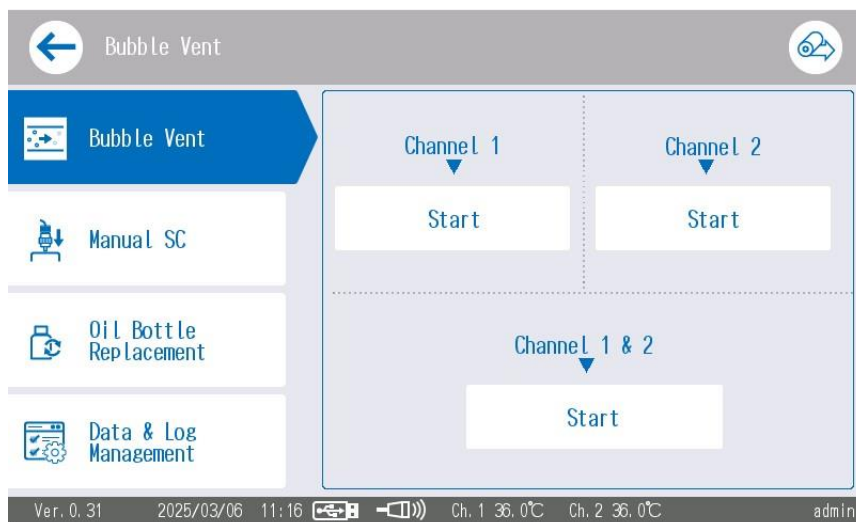
Do not use a cover other than the specified item.



11 Maintenance

11.1 About the Maintenance Screen

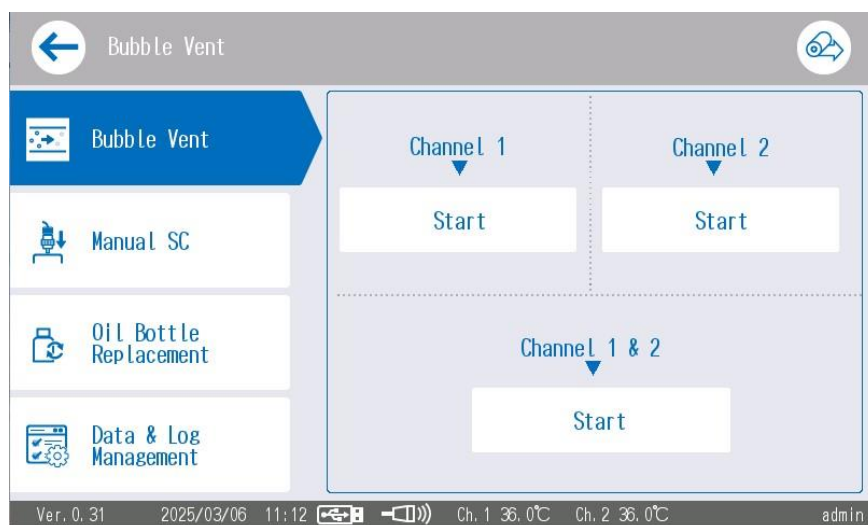
The "Maintenance" screen is where maintenance and data management operations are performed. Tap [Maintenance] on the "Menu" screen to open the "Bubble Vent" screen.



Item name	Description
Bubble Vent	Displays the item for performing Bubble Vent of the fluid feed channel as maintenance after starting up the instrument or when performing oil bottle replacement.
Manual SC	Displays the item for checking for leaks in the fluid feed channel.
Oil Bottle Replacement	Reset the residual quantity in the oil bottle when the oil is refilled.
Data & Log Management	Select the following items from the screen to save communication logs and print setting values. • Save Communication Log • Print Parameter Setting • Error History • Output Maintenance Info

11.1.1 Bubble Vent

Displays the item for performing Bubble Vent of the fluid feed channel as maintenance immediately after starting up the instrument each day or when performing oil bottle replacement. Tap [Maintenance] on the "Menu" screen to display the "Bubble Vent" screen.



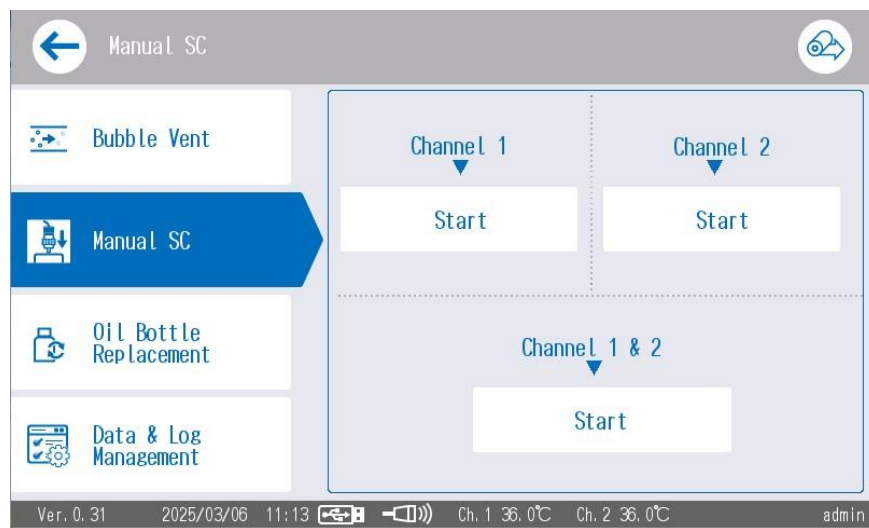
Item name	Description
Channel 1 Start	Tap to perform Bubble Vent of the fluid feed for Channel 1.
Channel 2 Start	Tap to perform Bubble Vent of the fluid feed for Channel 2.
Channel 1 & 2 Start	Tap to simultaneously perform Bubble Vent of the fluid feed for Channels 1 and 2.



For performing the bubble vent operation, see "11.2.1 Bubble Vent".

11.1.2 Manual SC

Displays the item for checking for leaks in the fluid feed channel. Tap [Manual SC] on the "Bubble Vent" screen to open the "Manual SC" screen.



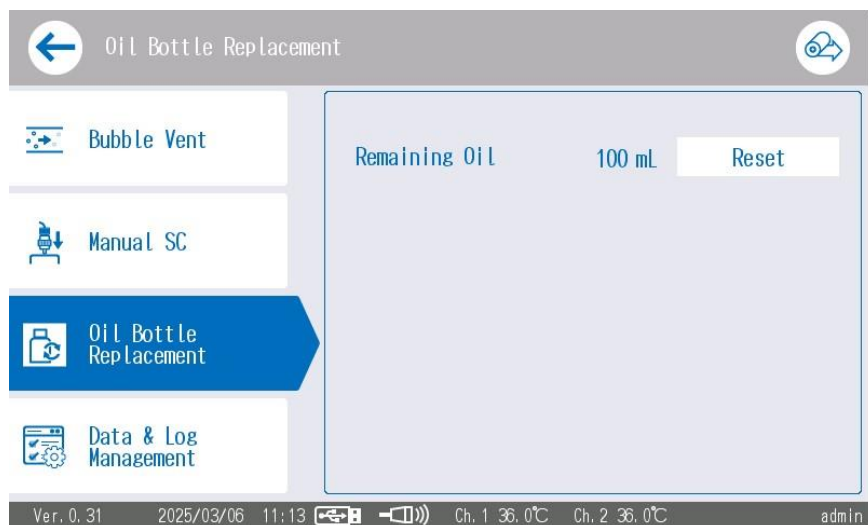
Item name	Description
Channel 1 Start	Tap to perform a leak check of the fluid feed for Channel 1.
Channel 2 Start	Tap to perform a leak check of the fluid feed for Channel 2.
Channel 1 & 2 Start	Tap to simultaneously perform a leak check of the fluid feed for Channels 1 and 2.



For performing the Manual SC operation, see "11.2.5 Manual SC".

11.1.3 Oil Refilling

Displays the screen for resetting the residual quantity when the oil is refilled. Tap [Oil Bottle Replacement] on the "Bubble Vent" screen to open the "Oil Bottle Replacement" screen.



Item name	Description
Remaining Oil	Displays the amount of remaining oil in the oil bottle. Tap [Reset] to reset the residual quantity to 100 mL.

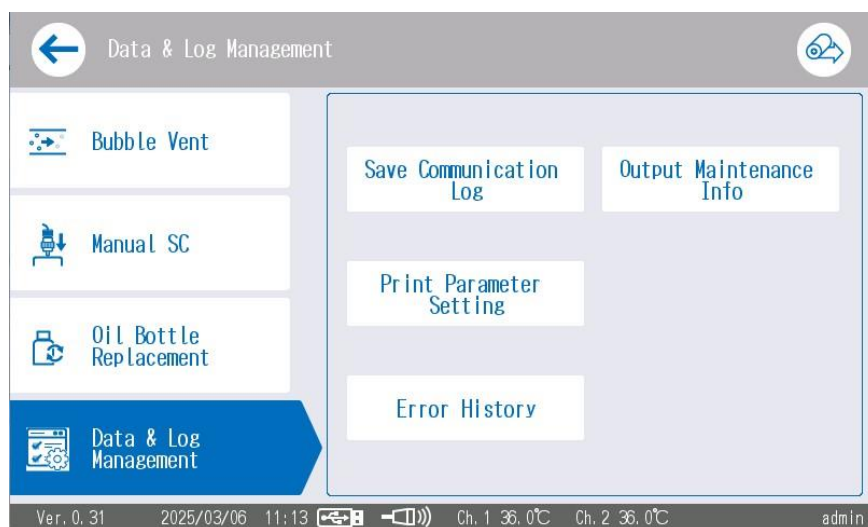


For information on oil refilling, see “11.2.4 Oil Refilling Procedure”.

11.1.4 Data & Log Management

Various maintenance information can be output from the "Data & Log Management" screen.

Tap [Data & Log Management] on the "Bubble Vent" screen to open the "Data & Log Management" screen.

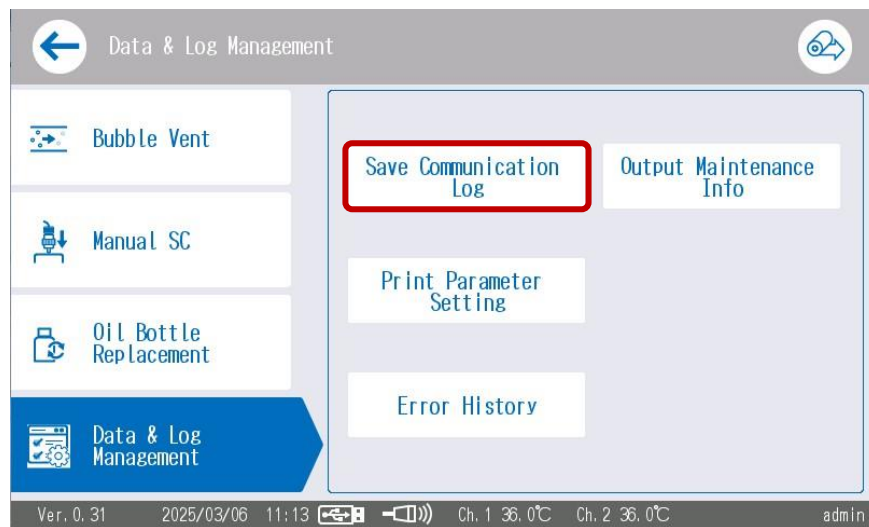


Item name	Description
Save Communication Log	Communication logs with the LIS are saved on the SD card inside the instrument.
Output Maintenance Info	Saves the maintenance information stored in the instrument to a USB flash drive. An administrator can select whether to keep or delete measurement results.
Print Parameter Setting	Outputs the parameter setting values to the printer.
Error History	Tap to display the "Error History" screen.

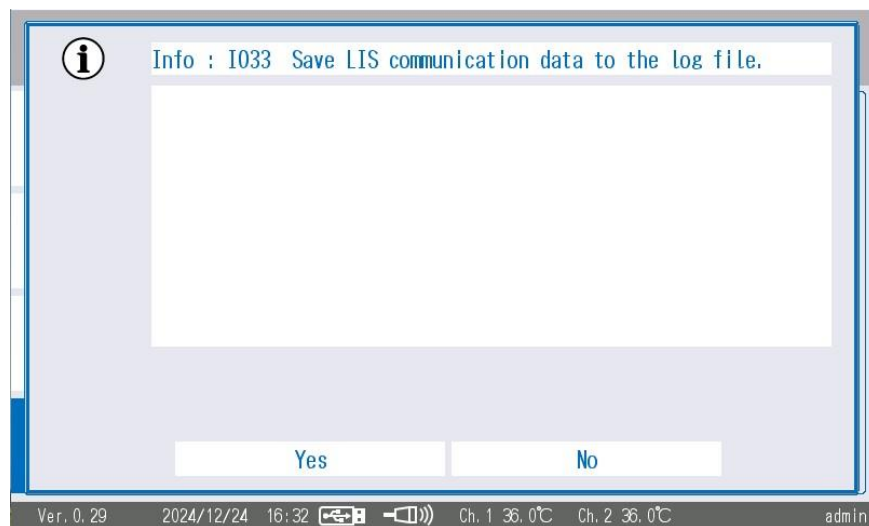
Save Communication Log

Save the communication log with the LIS inside the instrument according to the following procedure.

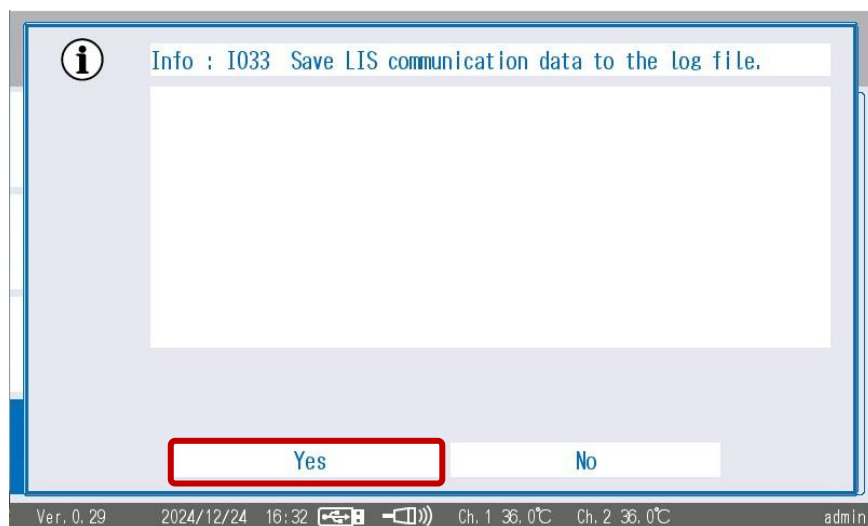
- 1 Tap [Save Communication Log] on the "Data & Log Management" screen.



The "Information" screen is displayed.

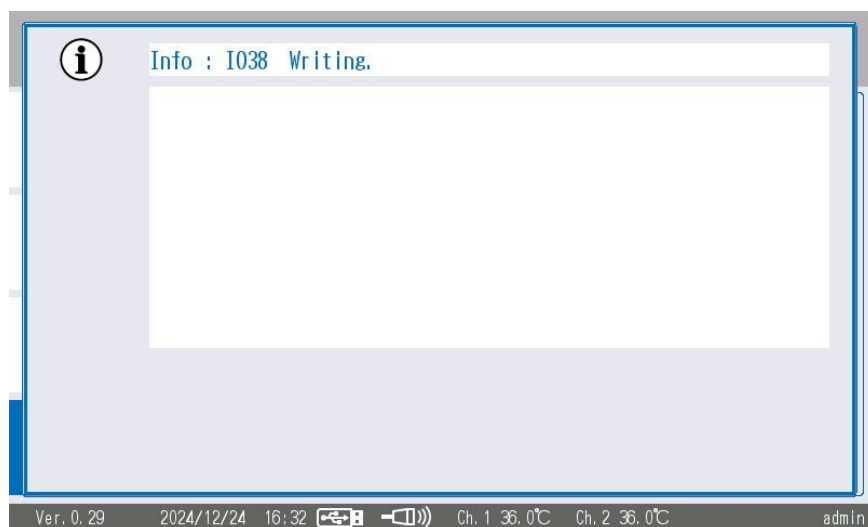


- 2 Tap [Yes] on the "Information" screen to commence saving.



If "Error: E302 Communication log is empty" is displayed, please perform the operation after communication with the LIS.

- 3 When the saving of the communication log commences, an "Information" screen is displayed to indicate that the data writing is in process.

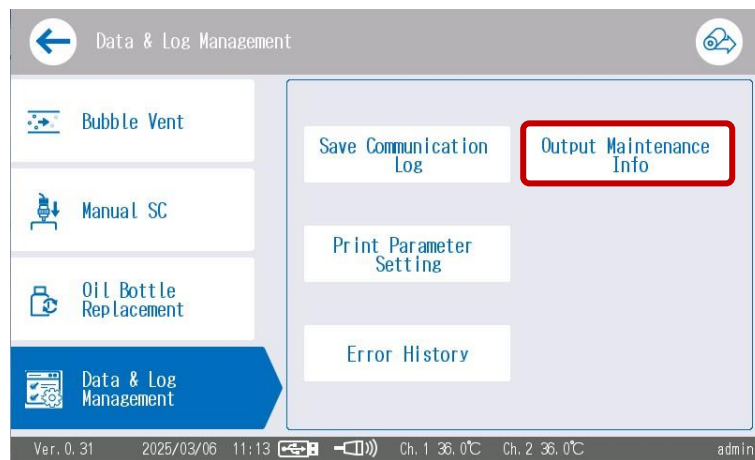


When writing is complete, a completion message is displayed.

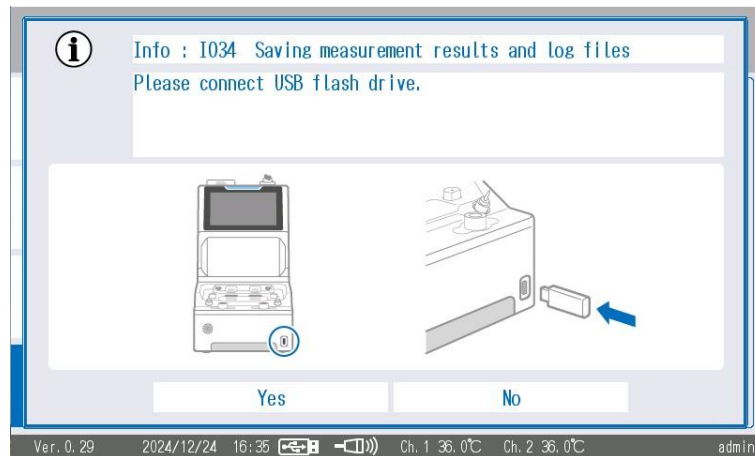
Output Maintenance Info

Save the information in the instrument to a USB flash drive in accordance with the following procedure.

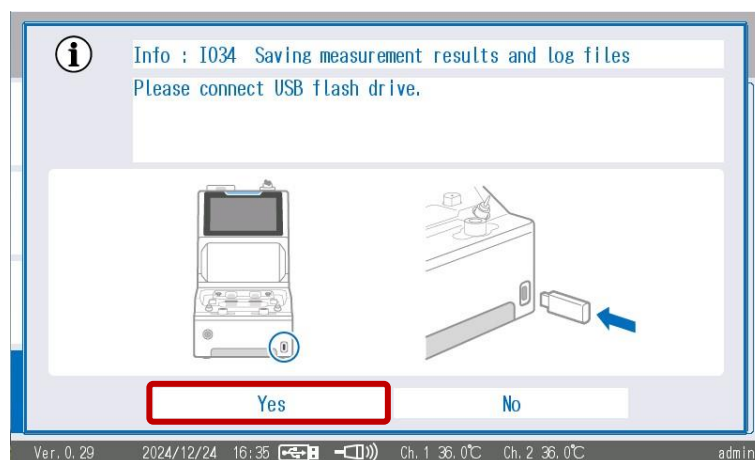
- 1 Tap [Output Maintenance Info] on the "Data & Log Management" screen.



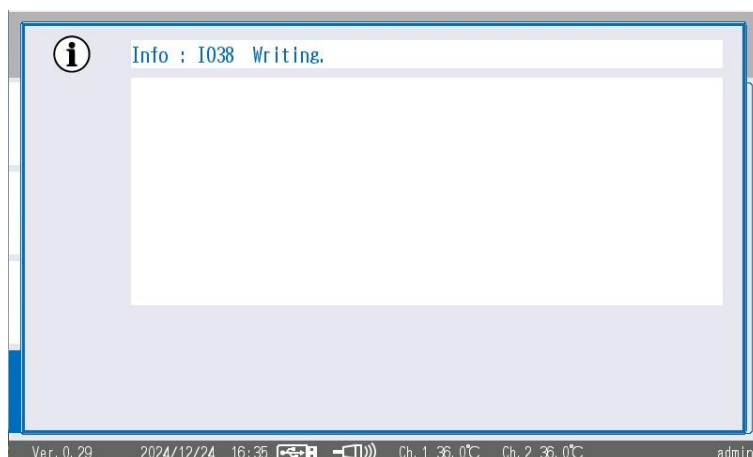
The "Information" screen is displayed.



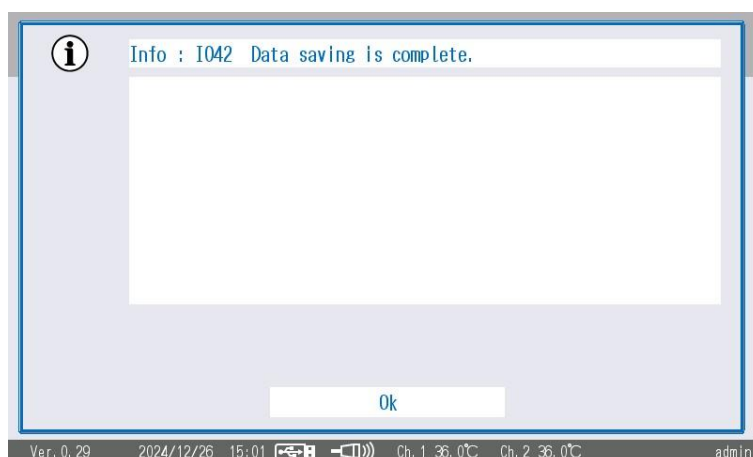
- 2 Tap [Yes] on the "Information" screen to commence saving.



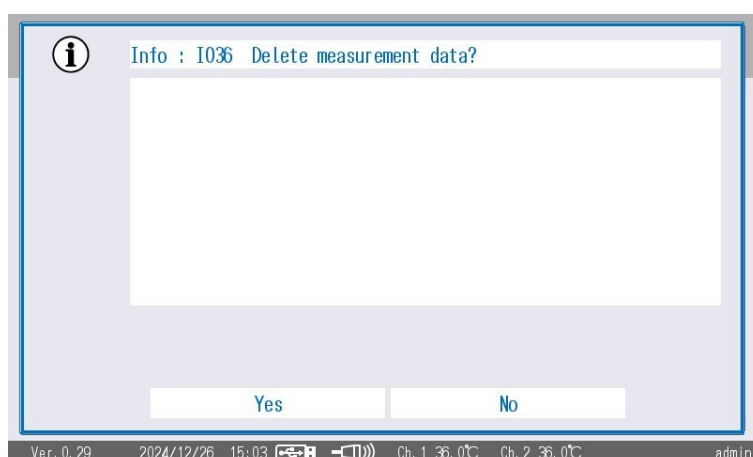
- 3 When the output commences, an "Information" screen is displayed to indicate that the data writing is in process.



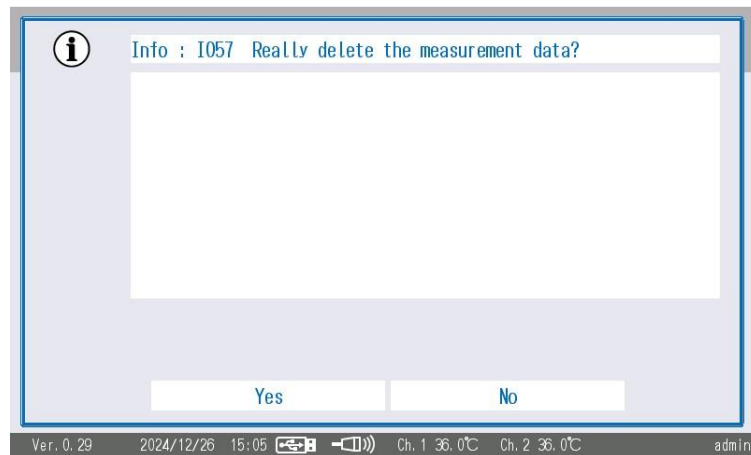
When writing is complete, a completion message is displayed.



- 4 When an administrator taps [Ok], the "Information" screen will be displayed asking if the measurement results data should be deleted.



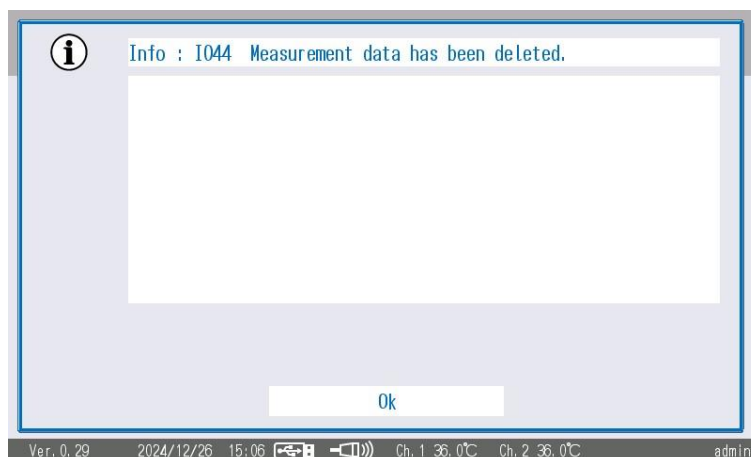
- 5 Tap [Yes] on the "Information" screen to display the following "Information" screen for reconfirmation.



- 6 By tapping [Yes] on the "Information" screen, the deletion of the measurement results will begin and the "Information" screen is displayed to indicate that the deletion is in process.



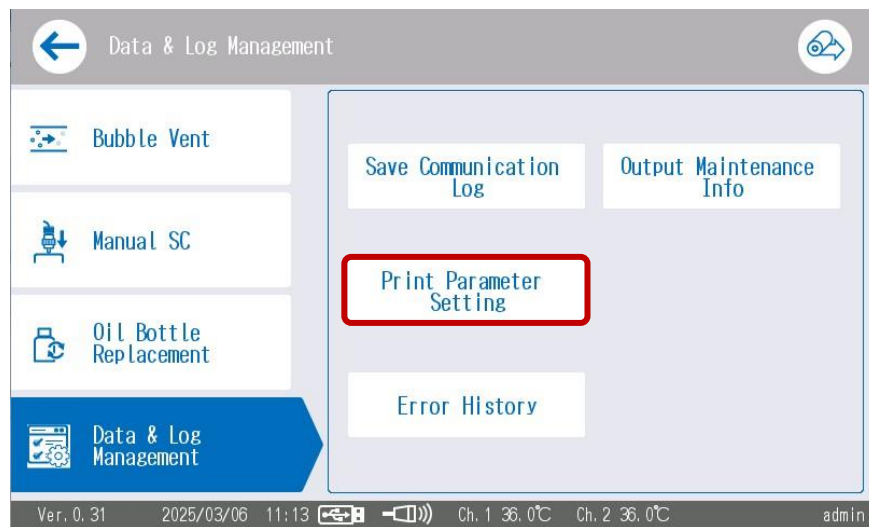
When deletion is complete, a completion message is displayed.



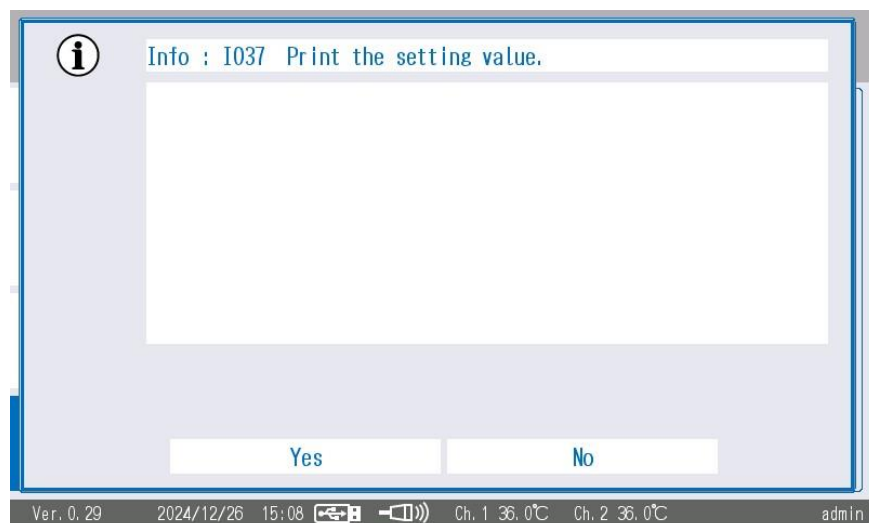
Print Parameter Setting

Print the setting values to the printer in accordance with the following procedure.

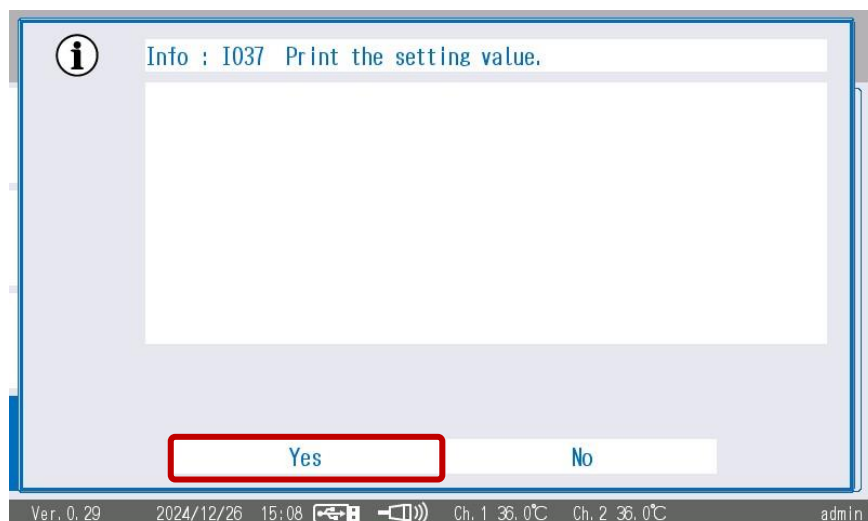
- 1 Tap [Print Parameter Setting] on the "Data & Log Management" screen.



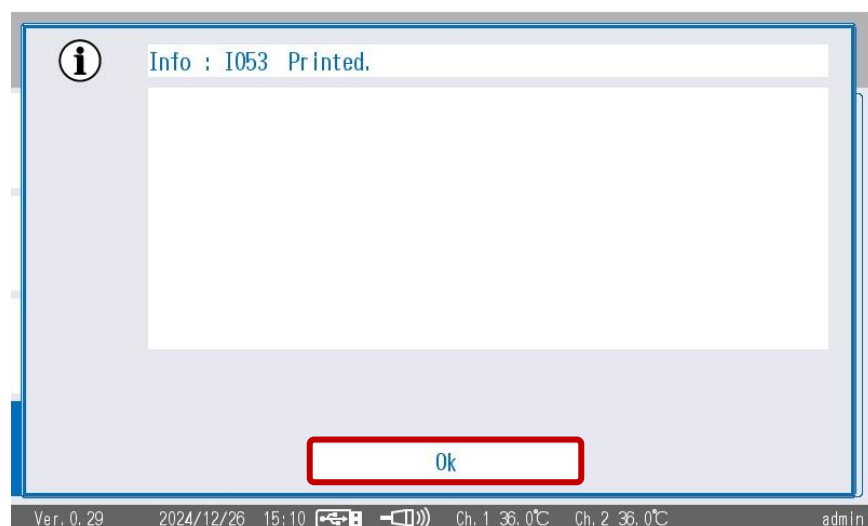
The "Information" screen is displayed.



- 2 Tap [Yes] on the "Information" screen to commence printing.



- 3 When the printing is finished, the "Information" screen is displayed to indicate that printing is complete.
Tap [Ok].

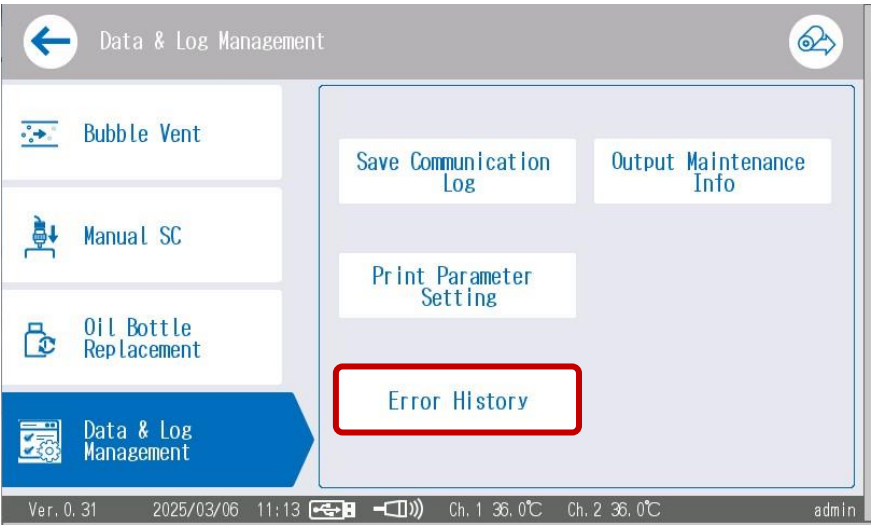


If the printer runs out of paper or the printer cover is open and the printer cannot print, a print failure error message is displayed.

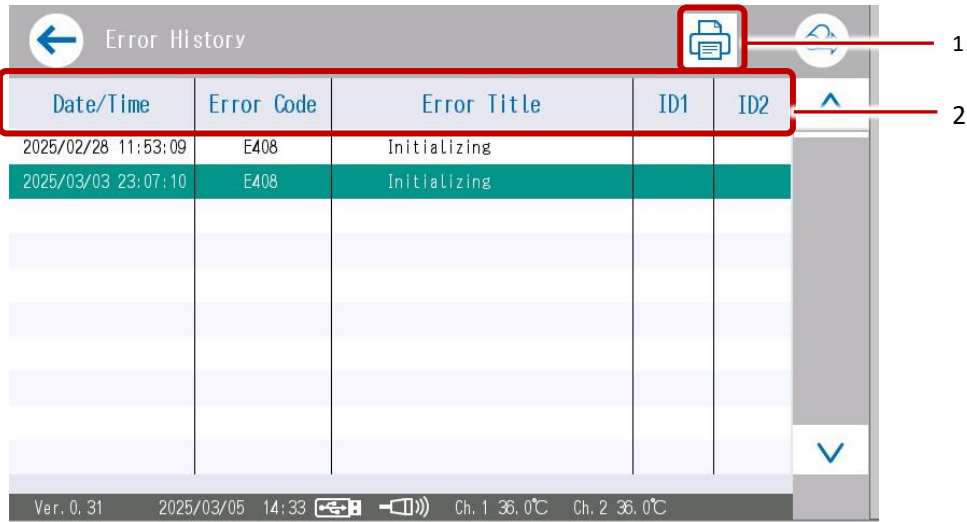
Error History

Follow the procedure below to view the error history.

- 1 Tap [Error History] on the "Data & Log Management" screen.



The "Error History" screen is displayed.



Number	Name	Description
1	[Print] button	Tap to print a list of errors that have occurred during the current day. If no errors have occurred, nothing will be printed.
2	Column titles	"Date/Time": Error occurrence date "Error Code": Identifier of the error "Error Title": Name of the location where the error occurred "ID 1": Troubleshooting identifier #1 for the manufacturer "ID 2": Troubleshooting identifier #2 for the manufacturer

11.2 Pre-use inspection

Perform the following maintenance before operating this instrument.

 **WARNING**

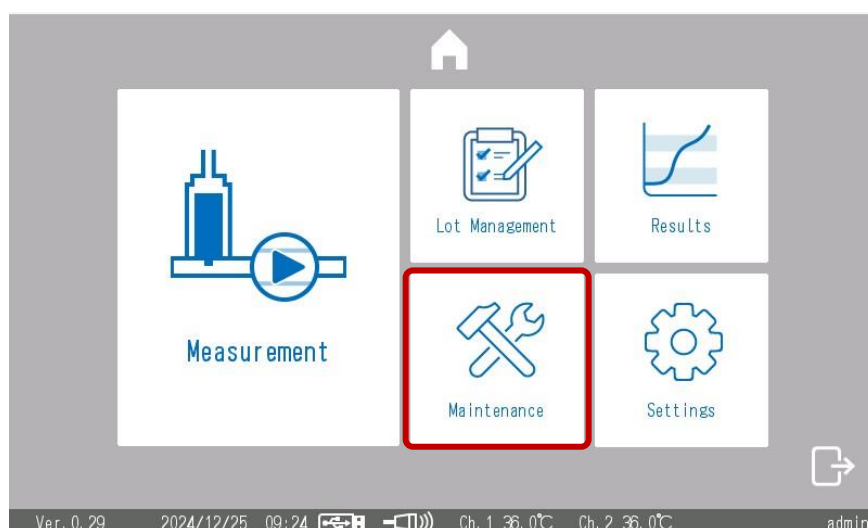


- This operation may pose a risk of infection. To prevent biohazards, always wear personal protective equipment such as gloves and eye protection, and protective clothing such as a lab coat.
- Mineral oil and waste bottles pose a risk of infection. Dispose of them as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

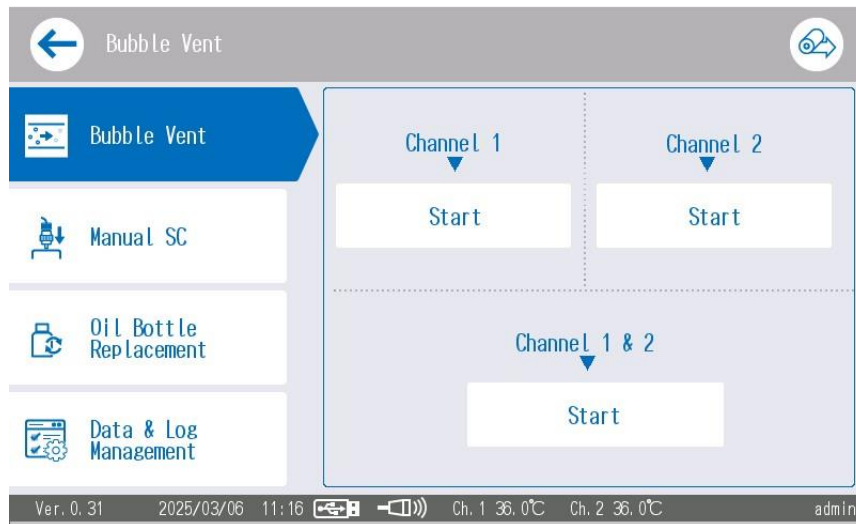
11.2.1 Bubble Vent

Bubble Vent is an operation to flush out air bubbles in the tubing. Bubble Vent must be performed after starting up the instrument, when an error occurs, and when replacing the oil bottle.

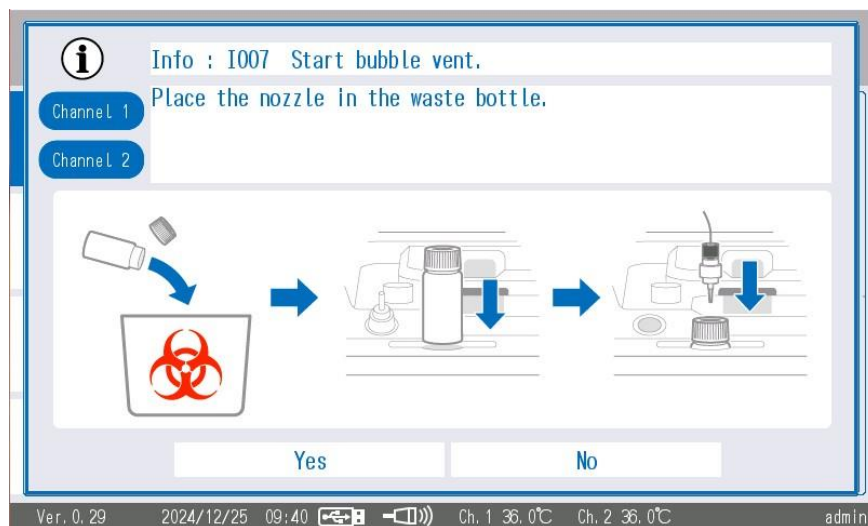
- 1 Tap [Maintenance] on the "Menu" screen.



The "Bubble Vent" screen is displayed.



- 2 Tap [Start] for Channel 1 & 2.
The "Information" screen is displayed.

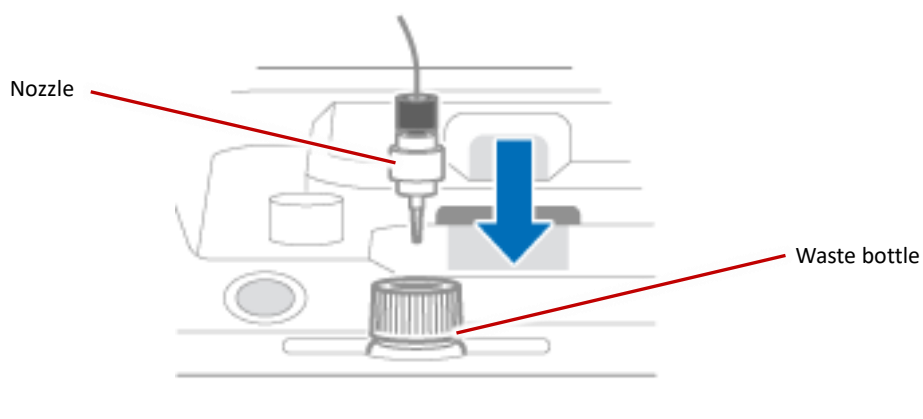


If you select [Start] for Channel 1 or Channel 2, you can perform Bubble Vent for each channel.

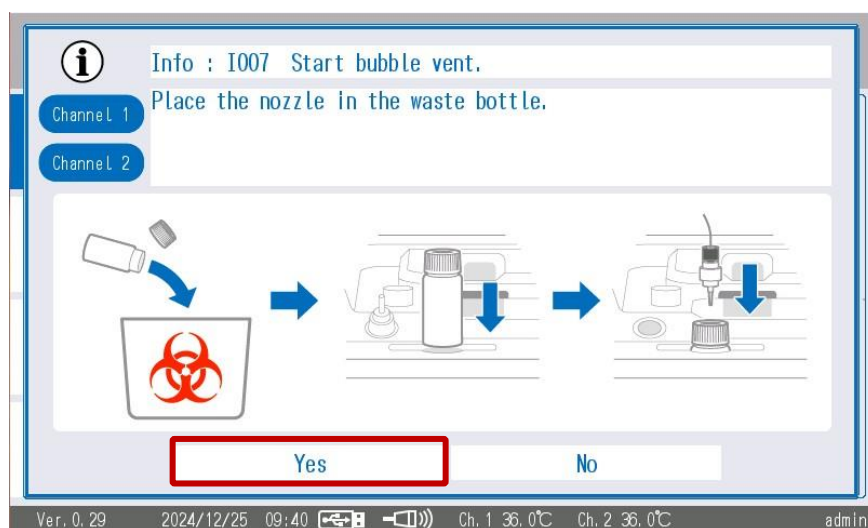
- 3 Confirm that empty waste bottles are inserted for Channel 1 and Channel 2.



- 4 Insert the Channel 1 and Channel 2 nozzles into the waste bottles.

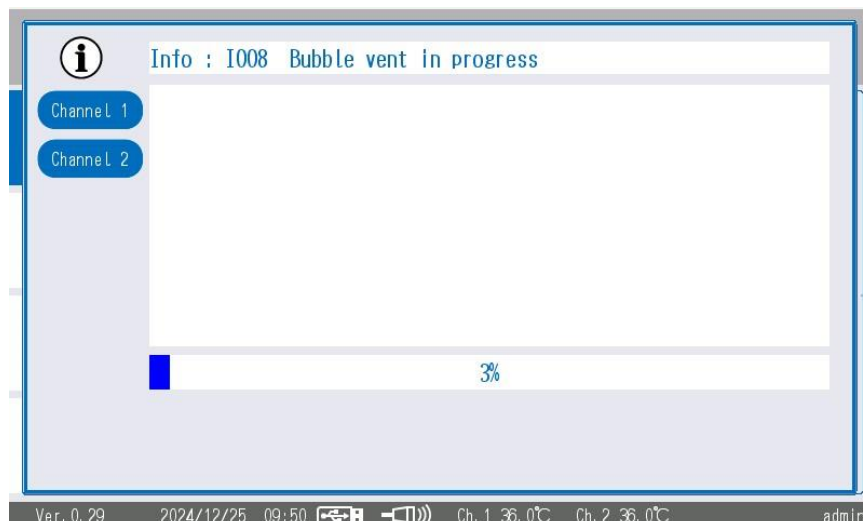


- 5 Tap [Yes] on the "Information" screen.



To cancel the Bubble Vent, tap [No] on the "Information" screen.

- 6 The Bubble Vent is performed.
A buzzer will sound when the Bubble Vent is successfully completed, unless sound has been turned off.



11.2.2 Disposal of Waste Fluid

This section describes the waste bottle for Channel 1. Perform the process in the same manner for the waste bottle for Channel 2.

- 1 Remove the Channel 1 nozzle from the Channel 1 waste bottle.



- 2 Wipe the nozzle tip of Channel 1 with a dust-free lab wipe etc. to remove any mineral oil, then return it to the Channel 1 nozzle holder.

 **WARNING**

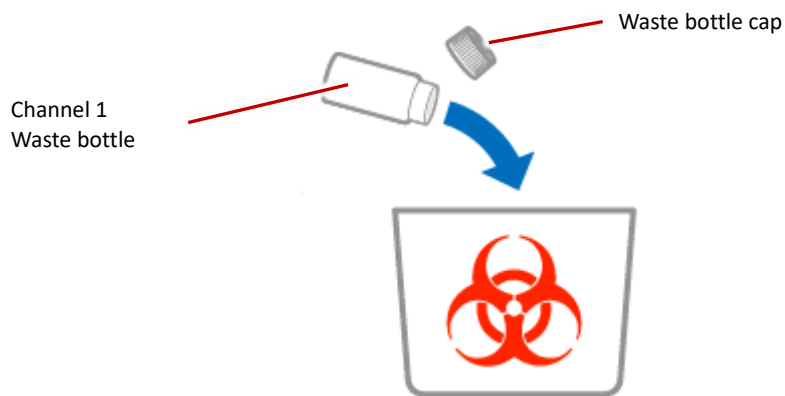


Mineral oil should be treated as an infectious material and disposed of as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

- 3 Remove the Channel 1 waste bottle from the instrument.



- 4 Remove the waste bottle cap from the Channel 1 waste bottle.
- 5 Discard the mineral oil that has accumulated in the Channel 1 waste bottle.
Wipe off any mineral oil on the Channel 1 waste bottle with a disposable paper towel.



 WARNING	
	Mineral oil should be treated as an infectious material and disposed of as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

- 6 Attach the waste bottle cap to the Channel 1 waste bottle.

- 7 Insert the Channel 1 waste bottle into the instrument.



11.2.3 Check Remaining Oil Level

Please confirm that the residual quantity of mineral oil in the oil bottle is at least one scale mark from the bottom of the oil bottle.

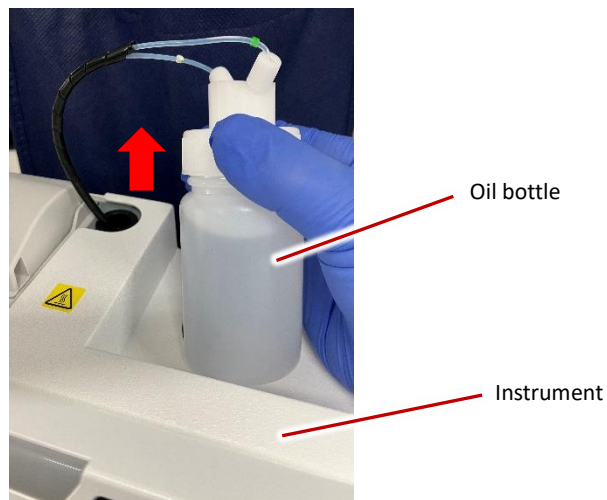
If the mineral oil level is less than one scale mark from the bottom of the oil bottle, please refill the oil.

ATTENTION

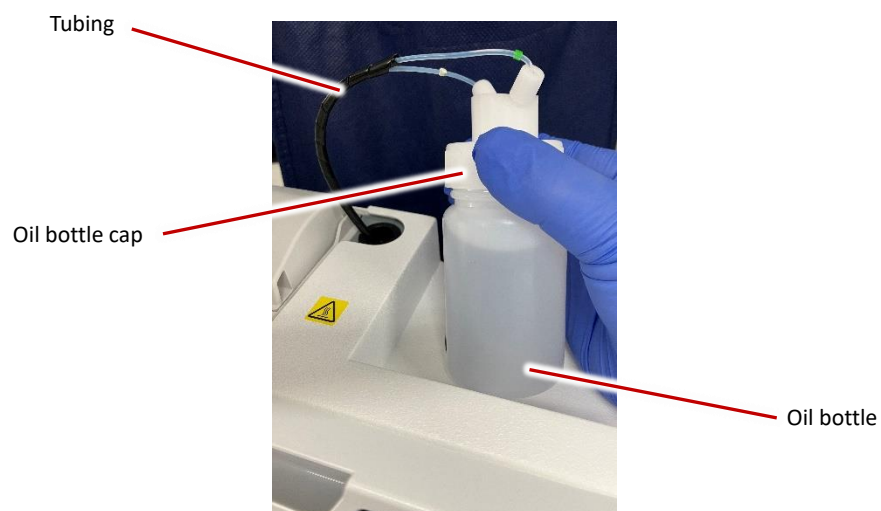


Please ensure that only the designated mineral oil is used. Failure to do so may result in instrument failure or incorrect measurement.

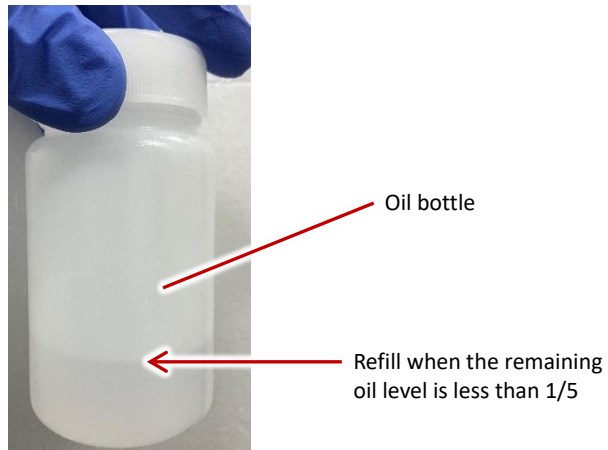
- 1 Lift the oil bottle from the instrument.



Lift the oil bottle just enough to prevent the base of the tubing from bending at the oil bottle cap.

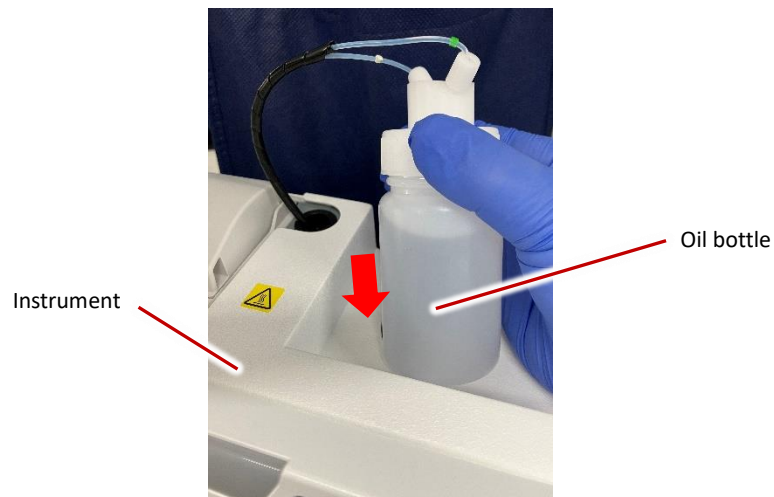


- 2 Use the following picture as a guide to confirm that there is enough oil remaining.
Refill the bottle when the residual quantity is approximately 1/5 of the bottle's capacity or less.



For information on oil refilling, see “11.2.4 Oil Refilling Procedure”.

- 3 If the residual quantity of oil is more than 1/5 of the oil bottle's capacity, return the oil bottle to the instrument.

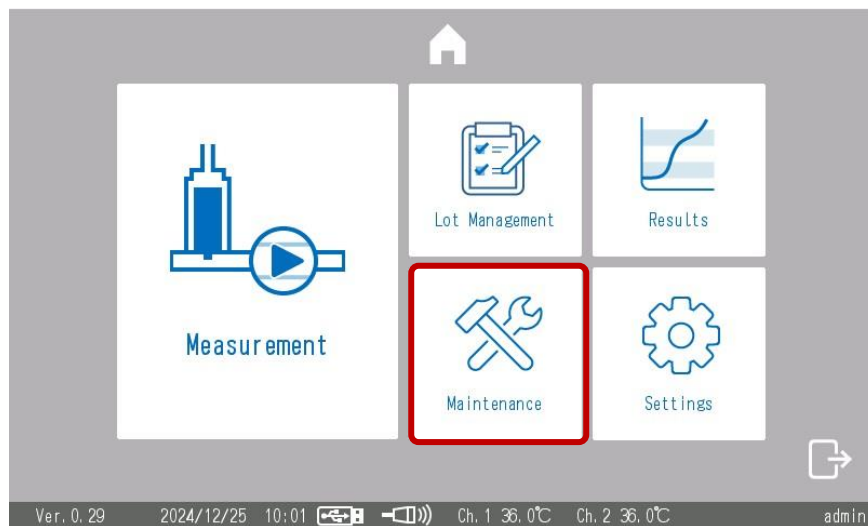


ATTENTION

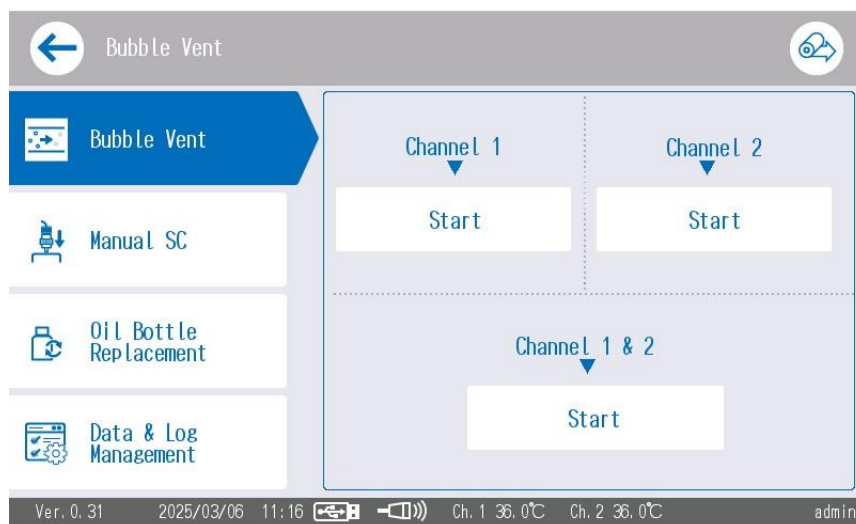


Please ensure that only the designated mineral oil is used. Failure to do so may result in instrument failure or incorrect measurement.

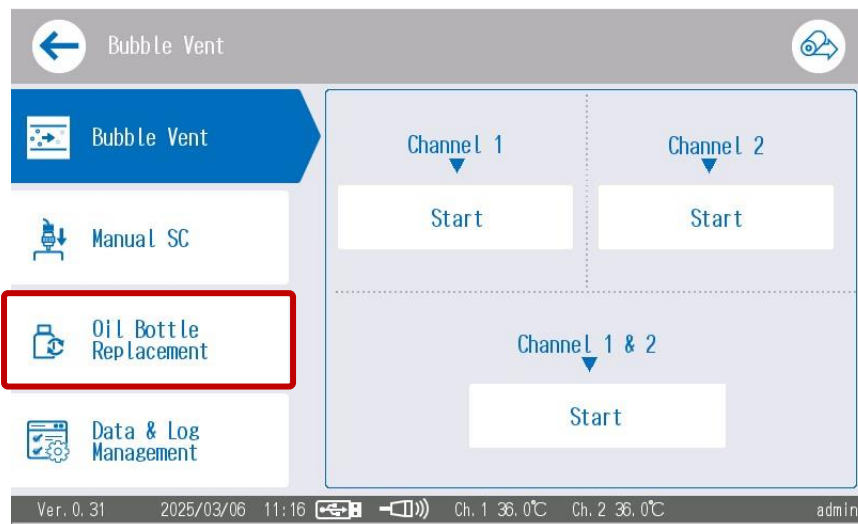
- 1 Prepare the designated mineral oil.
- 2 Tap [Maintenance] on the "Menu" screen.



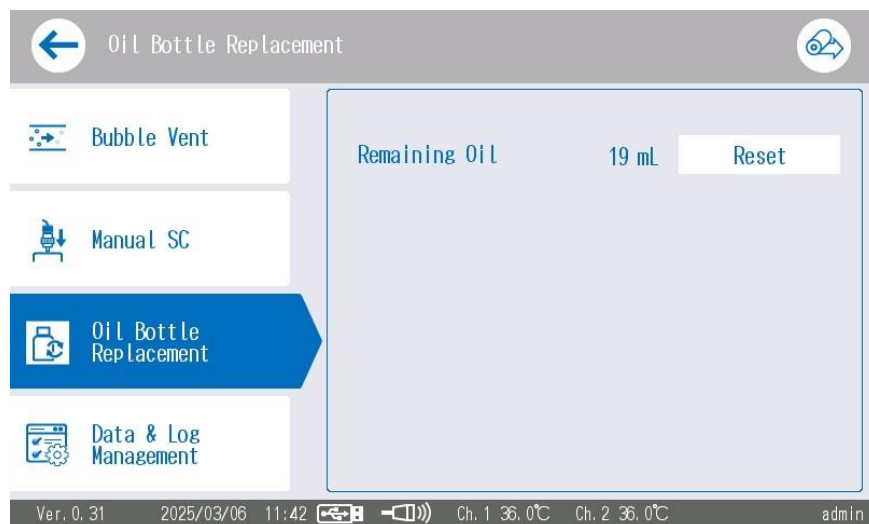
The "Bubble Vent" screen is displayed.



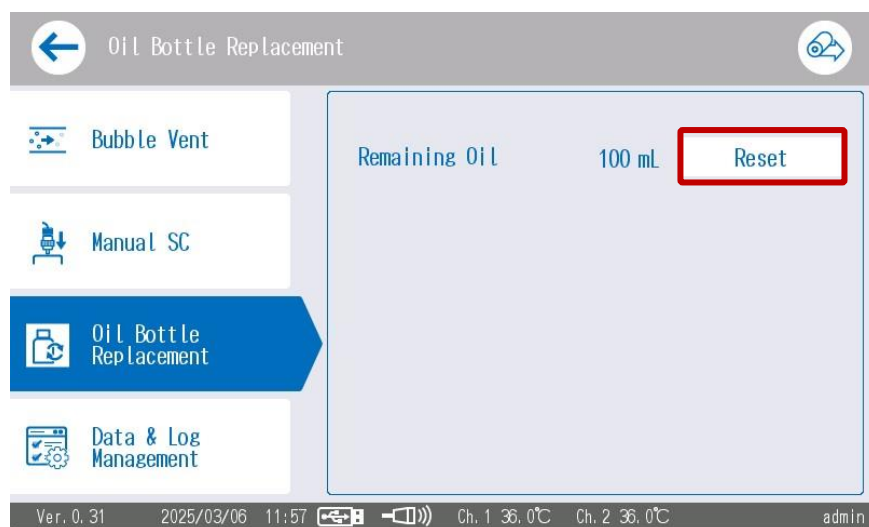
- 3 Tap [Oil Bottle Replacement] on the "Bubble Vent" screen.



The "Oil Bottle Replacement" screen is displayed.

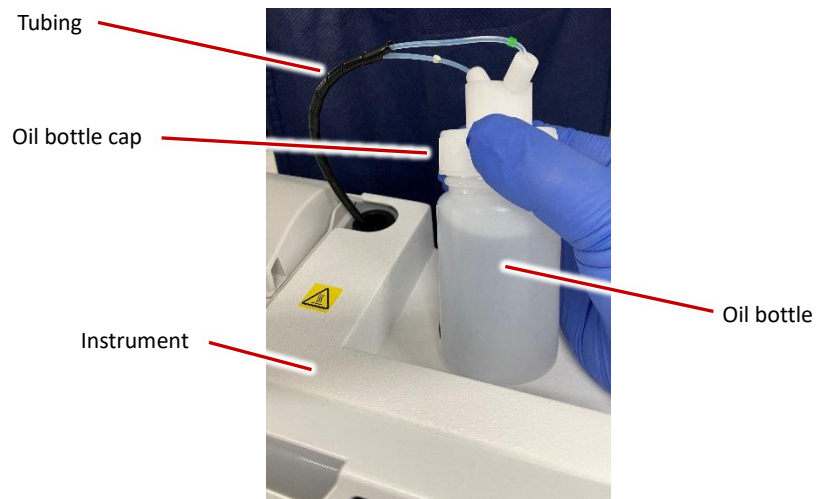


- 4 Tap [Reset].



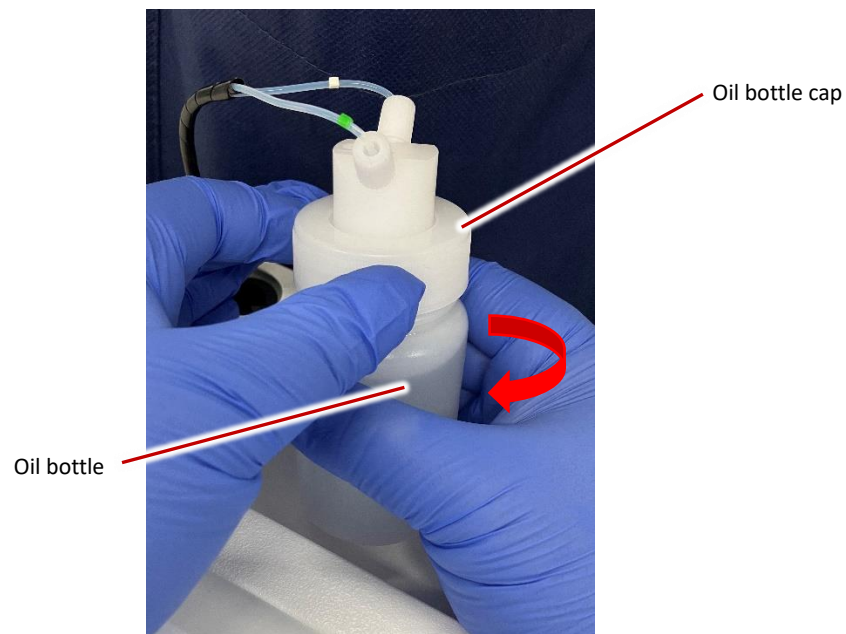
A new [Remaining Oil] value of 100 mL will appear on the "Oil Bottle Replacement" screen.

- 5 Lift the oil bottle from the instrument.

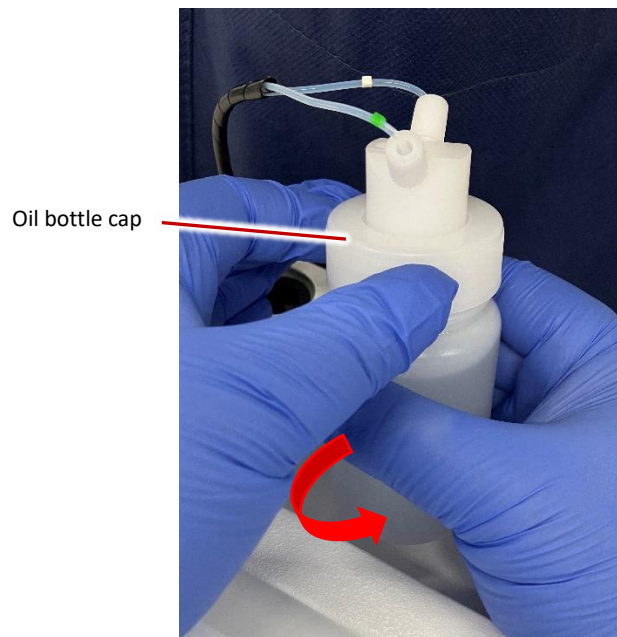


Lift the oil bottle just enough to prevent the base of the tubing from bending at the oil bottle cap.

- 6 Remove the oil bottle from the oil bottle cap.
In order to prevent twisting of the connected tubing, open the oil bottle cap by rotating the oil bottle without rotating the oil bottle cap.

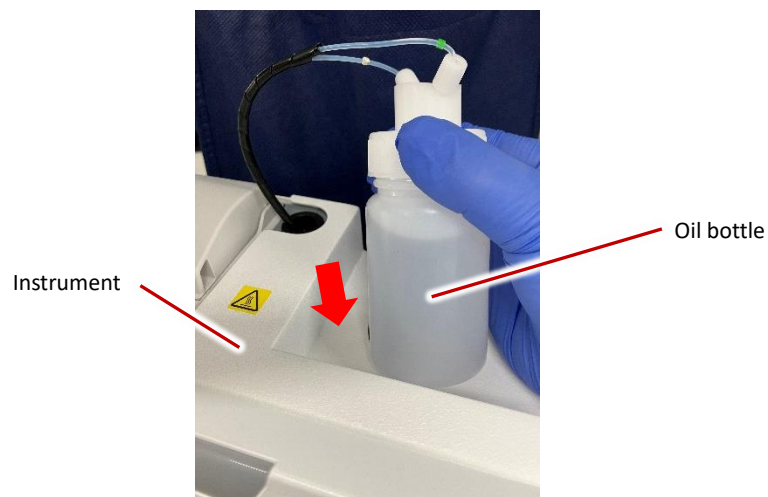


- 7 Refill the oil bottle provided with the instrument with oil.
In order to prevent twisting of the connected tubing, close the oil bottle cap by rotating the oil bottle without rotating the oil bottle cap.



When refilling oil, do not pour the oil above the instrument, but place the bottle on a level workbench or table etc. before pouring the oil.

- 8 Set the oil bottle in the instrument.



- 9 After filling the oil, perform Bubble Vent and Manual SC.



See "11.2.1 Bubble Vent" for the bubble vent operation and "11.2.5 Manual SC" for the manual SC procedure.

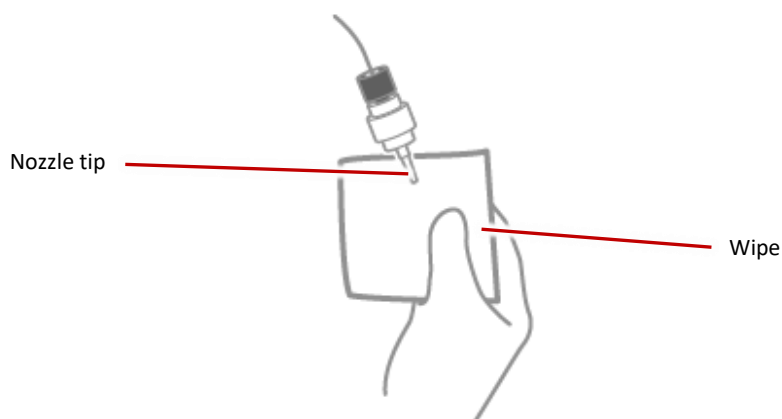
11.2.5 Manual SC

Manual SC confirms there are no leaks or blockages in the entire feed system, from the pump to the nozzle tip. This section describes the Manual SC for Channel 1.

Perform Manual SC for "Channel 2" or simultaneously for "Channel 1 & Channel 2" in the same manner.

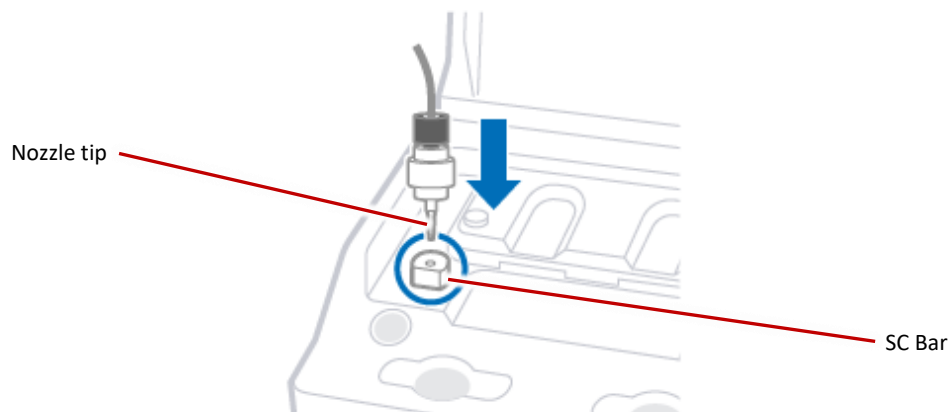
ATTENTION	
	Use only the genuine SC Bar that is supplied with the product.
	Before performing the Manual SC, check that the SC Bar is not dirty or damaged. For information on how to clean the SC Bar, see "11.4.1 SC Bar Cleaning".
	If the SC Bar is damaged, please contact the distributor.

- 1 Wipe the nozzle tip of Channel 1 with a dust-free lab wipe etc. to remove any mineral oil.



 WARNING	
	Mineral oil should be treated as an infectious material and disposed of as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

- 2 Insert the Channel 1 nozzle tip firmly into the Channel 1 SC Bar.



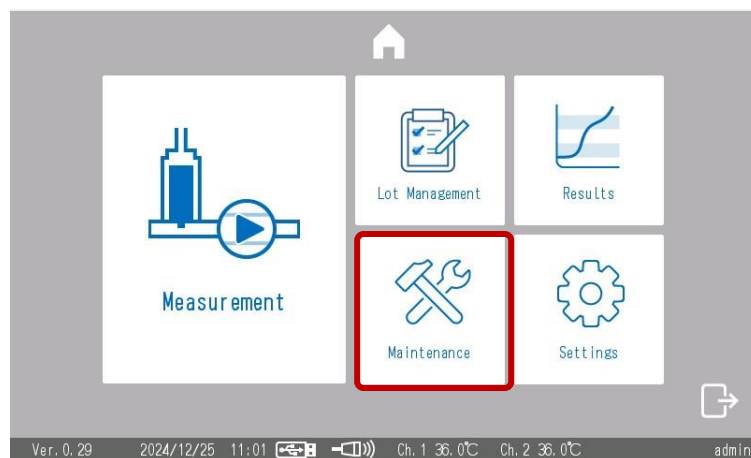
Insert the Channel 1 nozzle all the way into the Channel 1 SC Bar.

ATTENTION

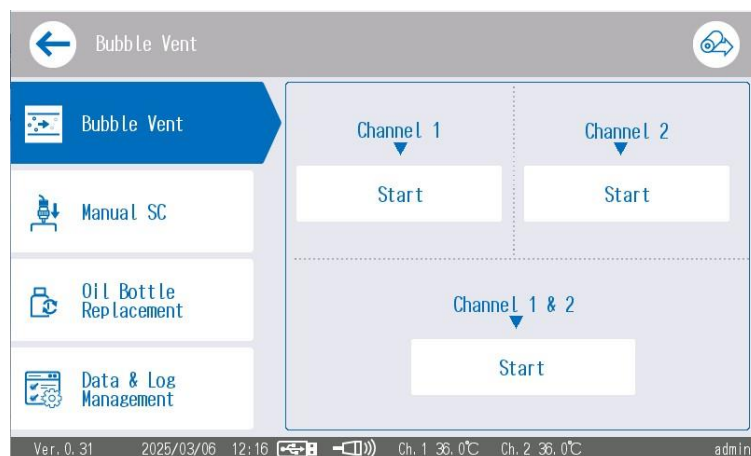


Applying a stronger force than necessary when inserting the nozzle into the SC bar may damage the SC bar and prevent the system check being performed correctly.

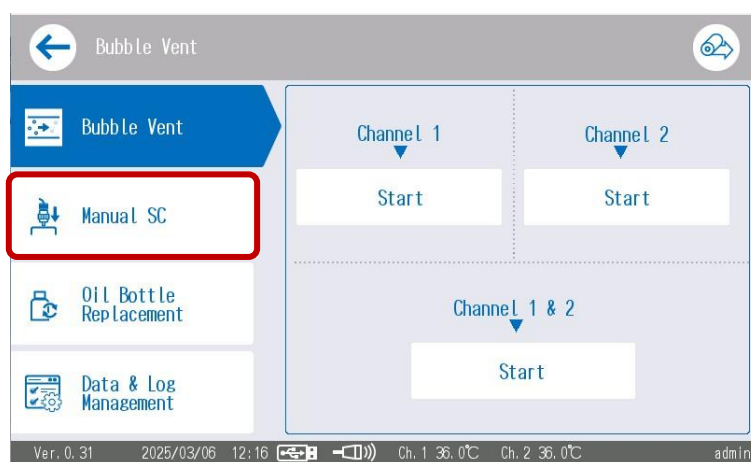
- 3 Tap [Maintenance] on the "Menu" screen.



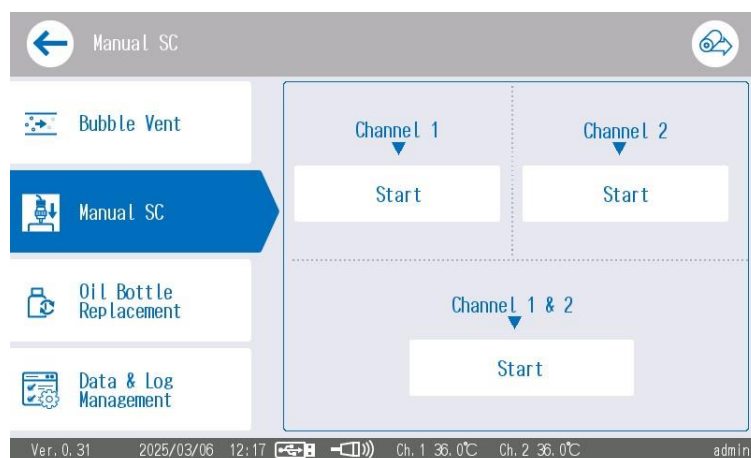
The "Bubble Vent" screen is displayed.



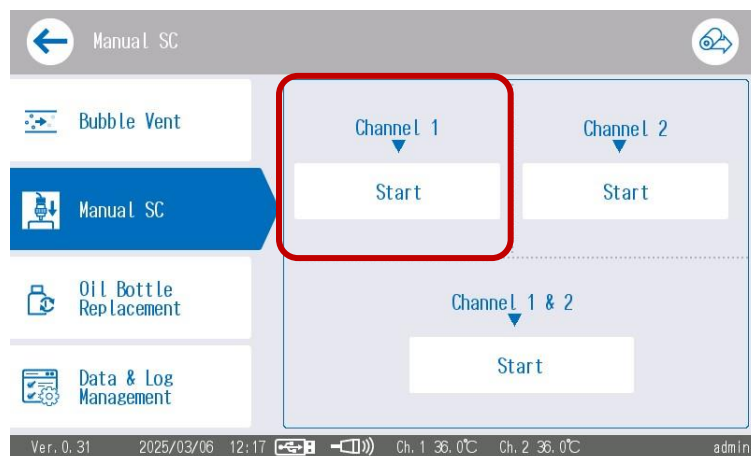
- 4 Tap [Manual SC] on the "Bubble Vent" screen.



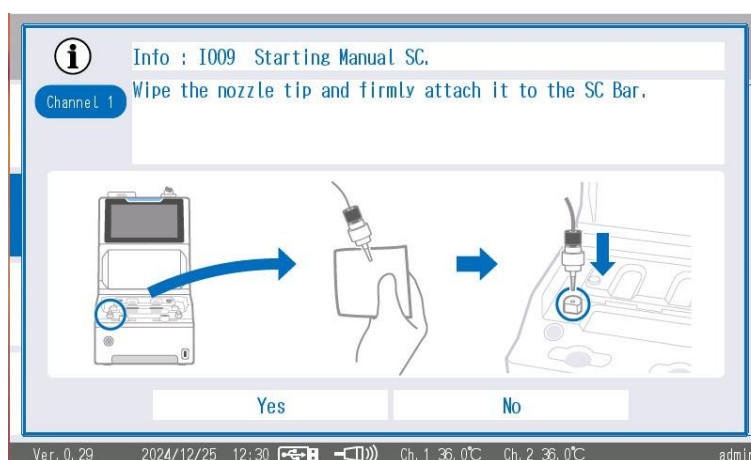
The "Manual SC" screen is displayed.



- 5 Tap [Start] for Channel 1.

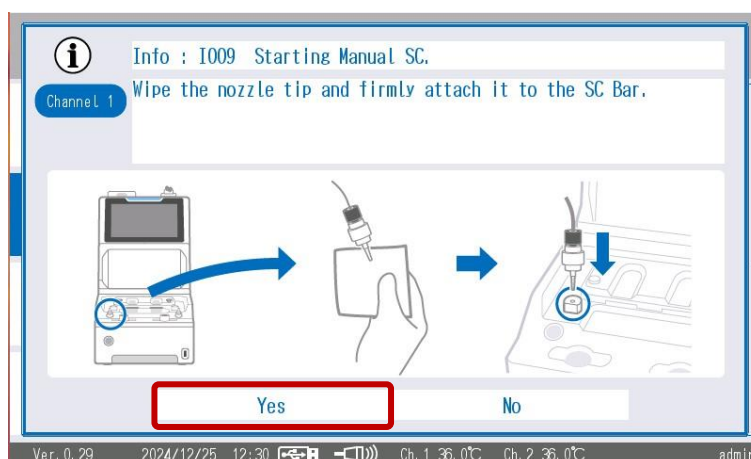


The "Information" screen is displayed.



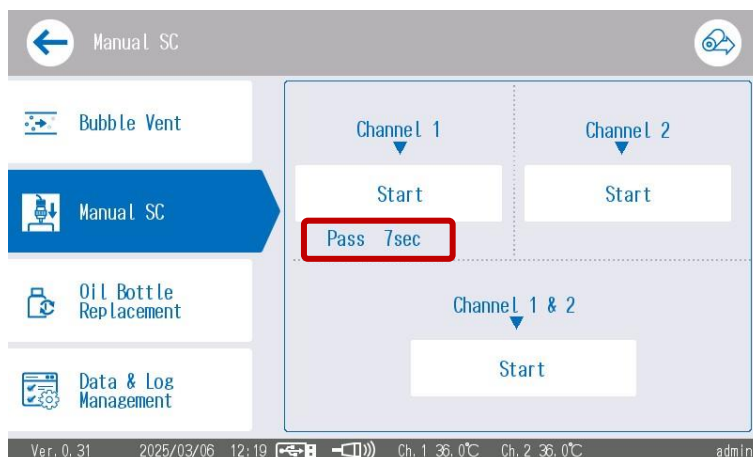
- 6 Confirm that the steps illustrated on the screen have been followed. Tap [Yes] on the "Information" screen.

The Manual SC will begin.



To cancel the Manual SC, tap [No] on the "Information" screen.

- 7 When the Manual SC is complete, a buzzer will sound (unless sound has been turned off) and the result will be displayed on the "Manual SC" screen and output to the printer.



If an error is displayed on the screen, confirm the error and remedy it.



See "12.2

About Error Messages" for information on how to resolve errors that are displayed.



The result of the Manual SC is displayed as Pass (success) or Fail (error), along with the time required for completing the Manual SC (SC Time).

- 8 Remove the Channel 1 nozzle tip from the SC Bar.
- 9 Wipe the nozzle tip of Channel 1 with a dust-free lab wipe etc. to remove any mineral oil, then set it into the Channel 1 waste tank.



WARNING



Mineral oil should be treated as an infectious material and disposed of as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

11.3 Monthly Maintenance

For measurements to be conducted safely, perform the following maintenance at intervals of at least once a month.



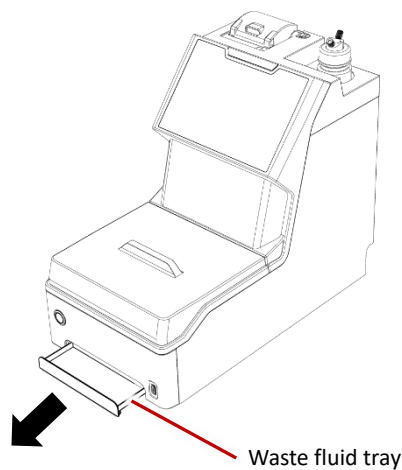
WARNING



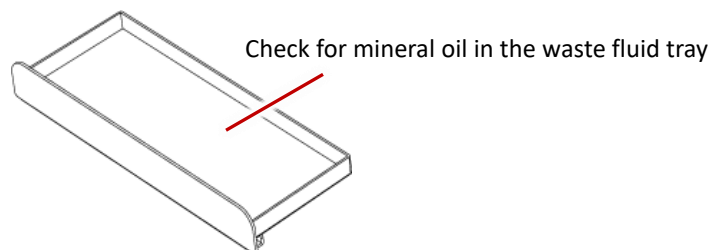
- This operation may pose a risk of infection. To prevent biohazards, always wear personal protective equipment such as gloves and eye protection, and protective clothing such as a lab coat.
- Mineral oil should be treated as an infectious material and disposed of as medical waste in accordance with the laws and regulations of the country in which the waste is generated.

11.3.1 Waste Fluid Tray Check

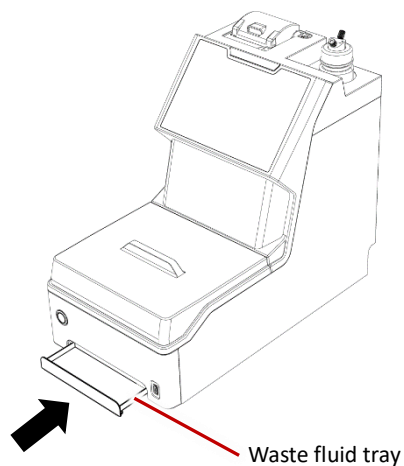
- 1 Remove the waste fluid tray from the instrument.



- 2 Check for mineral oil in the waste fluid tray.



- 3 If mineral oil has accumulated in the waste fluid tray, discard the mineral oil and wipe the tray.
- 4 Attach the waste fluid tray to the instrument.



11.3.2 Perform Manual SC

If Manual SC is not routinely performed as a pre-use inspection, please perform the Manual SC at least once a month in accordance with the procedure in "11.2.5

Manual SC".

11.3.3 Data Backup

Please back up the data in the instrument periodically.

See "

Output Maintenance Info" under "11.1.4

Data & Log Management" for data backup procedure.

11.4 Maintenance Performed when Needed

Perform the following maintenance when dirt is noticeable.

 WARNING	
	This operation may pose a risk of infection. To prevent biohazards, always wear personal protective equipment such as gloves and eye protection, and protective clothing such as a lab coat.
	- When ethanol is used for cleaning, perform the operation in a well-ventilated area free from fire. Exposure to heat or sparks may cause ignition. If a ventilation instrument is present, switch it on before performing the operation. - If sodium hypochlorite is used for cleaning, perform it in a well ventilated area. If a ventilation instrument is present, switch it on before performing the operation.
	Do not mix chemicals used for cleaning with other chemicals. There is a risk of harmful gas generation or explosion.

 CAUTION	
	Dampen a disposable paper towel etc. with the liquid to be used for cleaning and wring it firmly before using it for wiping. If liquid gets inside the instrument, it may cause electric shock or instrument failure.
	Do not use any liquid for cleaning other than those specified. It may result in surface deterioration or instrument failure.

11.4.1 SC Bar Cleaning

This section describes the SC Bar cleaning for Channel 1. Perform the cleaning in the same manner for Channel 2 SC Bar.

- 1 Remove the Channel 1 SC Bar from the instrument.

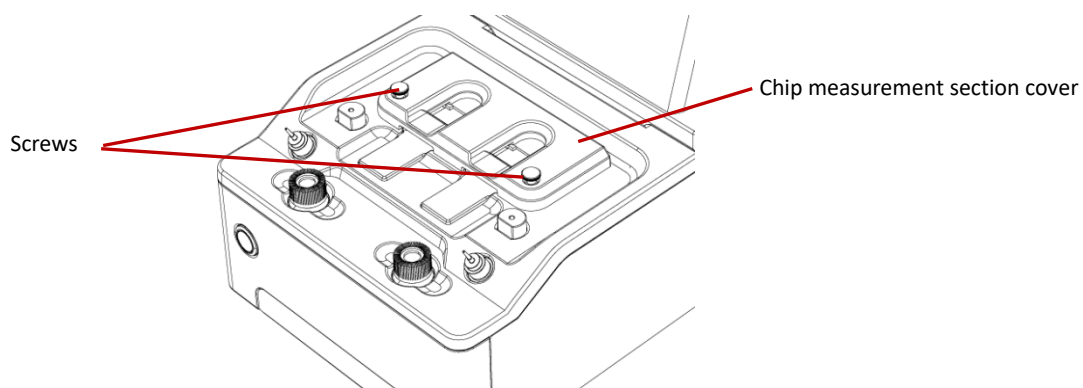


- 2 Wipe the Channel 1 SC Bar with a disposable paper towel dampened with a solution of ethanol (80 %) or sodium hypochlorite (0.5 %), or disinfecting wipes, if available.
- 3 Insert the Channel 1 SC Bar into the instrument.

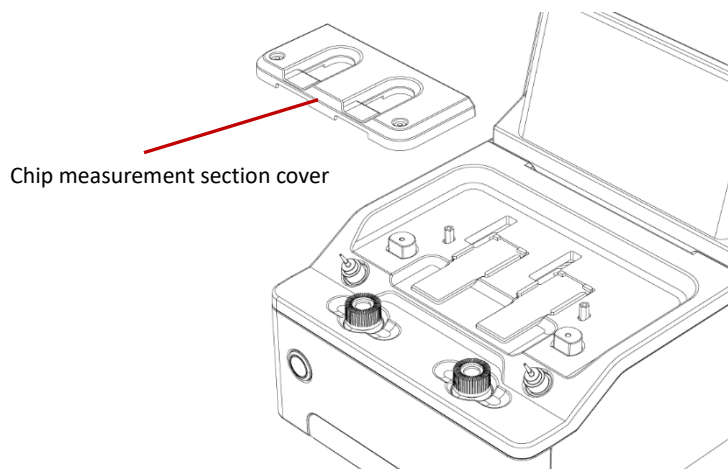


11.4.2 Chip Measurement Section Cleaning

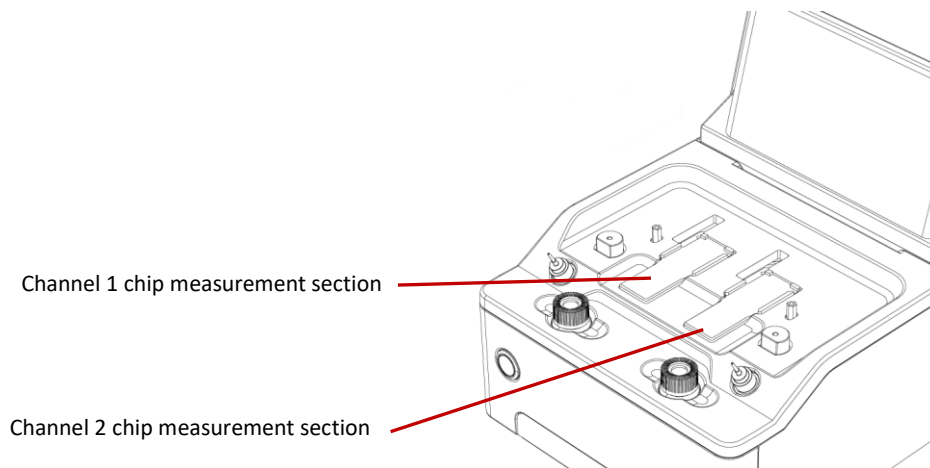
- 1 Remove the two screws securing the chip measurement section cover.



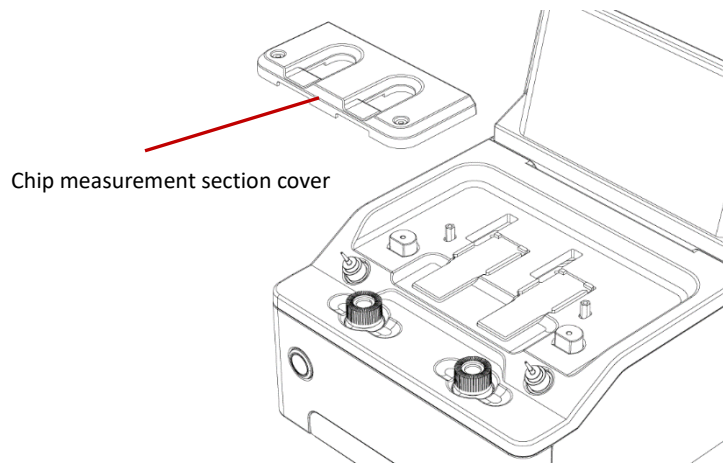
- 2 Remove the chip measurement section cover.



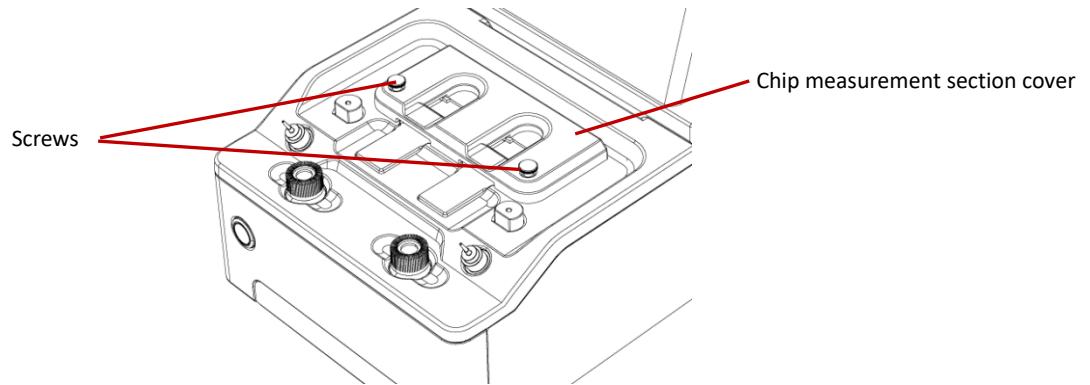
- 3 Dampen a disposable paper towel with diluted mild detergent.
- 4 Wipe any dirty areas of the Channel 1 or Channel 2 chip measurement section.



- 5 Dampen a disposable paper towel with a disinfecting ethanol (80 %) or sodium hypochlorite (0.5 %) solution.
- 6 Wipe the areas that were wiped in step 4.
- 7 Attach the chip measurement section cover.

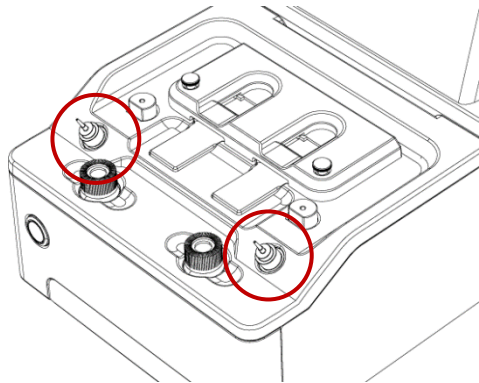


- 8 Secure the chip measurement section cover with the two screws.



11.4.3 Nozzle Area Cleaning

- 1 Dampen a disposable paper towel with diluted mild detergent.
- 2 Wipe the nozzles and surrounding areas that are dirty.



- 3 Dampen a disposable paper towel with a disinfecting ethanol (80 %) or sodium hypochlorite (0.5 %) solution.
- 4 Wipe the areas that were wiped in step 2.

11.4.4 Touch Panel Cleaning

ATTENTION



- When cleaning the touch panel, do not use a disinfecting ethanol (80 %) or sodium hypochlorite (0.5 %) solution.
- When cleaning the touch panel, wipe it with a soft, dry cloth without applying much force. (A commercially available eyeglass cloth etc. is suitable)

11.4.5 Instrument Exterior Cleaning

- 1 Dampen a disposable paper towel with diluted mild detergent.
- 2 Wipe any exterior areas that are dirty.
- 3 Dampen a disposable paper towel with a disinfecting ethanol (80 %) or sodium hypochlorite (0.5 %) solution.
- 4 Wipe the areas that were wiped in step 2.

11.4.6 Thermal Paper Roll Replacement

If the thermal paper roll runs out, replace the thermal paper roll according to the following procedure.



Thermal paper roll replacement should be performed when measuring is not being performed.



When the thermal paper roll runs out, the paper feed mark in the upper right corner of the screen will be crossed out.

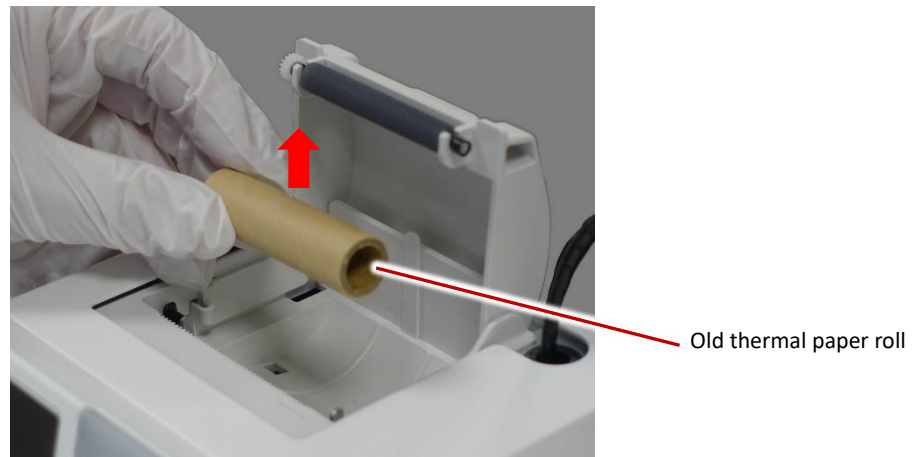


- 1 Open the printer cover.



Printer cover

- 2 Remove the old thermal paper roll from the printer.

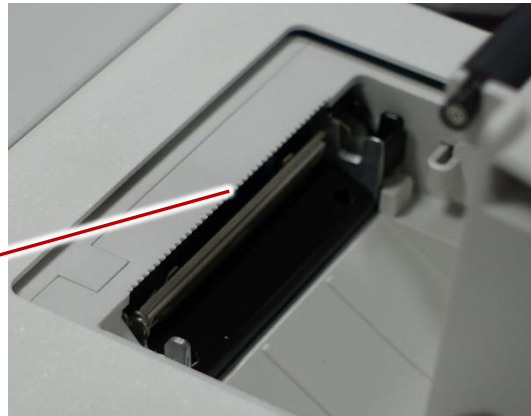


CAUTION

Do not touch the blade inside the printer when removing the old thermal paper roll. Doing so may cause injury.



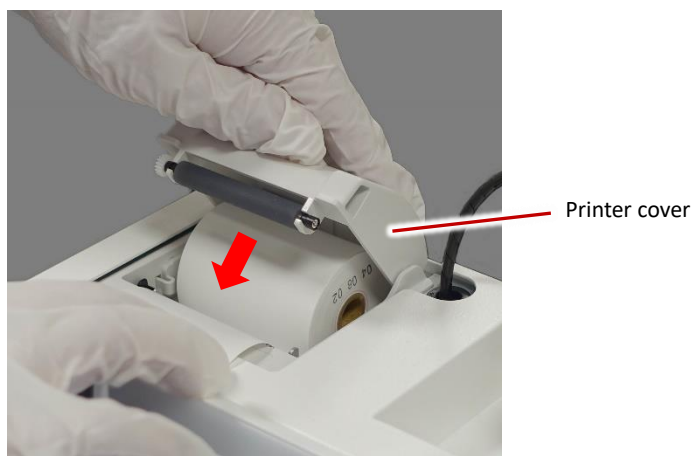
Blade



- 3 Install the new thermal paper roll in the printer as illustrated.



- 4 Close the printer cover.



- 5 Press and hold the paper feed mark in the upper right corner of the screen to feed the printer paper.





12 Troubleshooting

12.1 When a Problem Occurs

If any of the following problems occur and it is not resolved after performing the measures listed below, please contact the distributor.

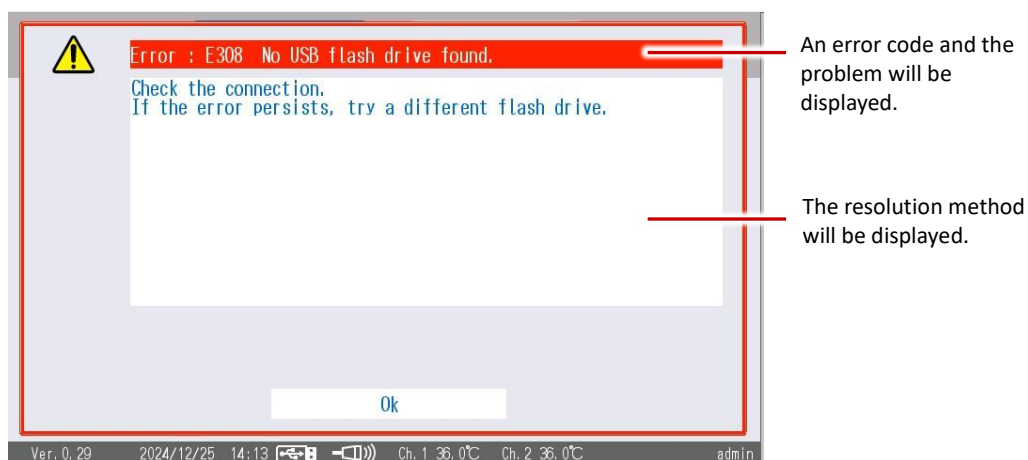


If the problem is not listed in the table below, please contact the distributor.

Problem	Resolution Method
The instrument does not turn on.	The power supply may be not supplying power. Confirm that the power cord is connected properly.
	Confirm that the main power switch on the back of the instrument is turned to "ON".
The screen is difficult to see.	Adjust the screen brightness in the "System Settings" screen.
The display does not change when a button is pressed.	Make sure that nothing is placed on the touch panel.
The temperature is not stable	If wind from an air conditioner is blowing directly on the chip measurement section, please block the wind.
	Make sure that the ambient operating temperature is in the range of 15°C to 30°C (68 °F to 86 °F).
Measurement results do not print.	Reload the thermal paper roll if the out-of-paper mark is displayed.
	Confirm the settings on the "Printer Settings" screen.
The printout is hard to read	Confirm that the proper thermal paper roll is being used. Using thermal paper roll other than the specified paper may result in poor print quality or printer malfunction. For the specified paper, please contact the distributor.
The instrument does not output to the LIS	Confirm the connection to the LIS and the output settings on the "LIS Settings" screen.

12.2 About Error Messages

An error message will be displayed on the screen when a problem may have occurred in the instrument's system.



The following is a list of error messages. If any of these are displayed, perform the action in accordance with the resolution method to restore the system to a normal state.

If the equipment is not restored after performing the action, please contact the distributor.

Error Code	Location of Problem	Problem	Resolution Method
E002	Bubble Vent	The waste bottle is full.	Empty the waste bottle.
E003	Bubble Vent	There is not enough oil.	Replace the oil bottle.
E004	Auto SC	Auto SC error	Perform Bubble Vent and Manual SC. If the problem occurs repeatedly, please contact the distributor.
E005	Simple SC	Simple SC error	Perform Bubble Vent and Manual SC. If the problem occurs repeatedly, please contact the distributor.
E006	Manual SC	Manual SC error	After confirming that nozzle and tube connections are not loose, perform Bubble Vent three times and re-perform the Manual SC.
E010	When measurement is complete or when measurement results are displayed	Past expiration	Use consumables that are within their expiration dates.

Error Code	Location of Problem	Problem	Resolution Method
E011	When measurement is complete or when measurement results are displayed	Atmospheric pressure error	Confirm there is no abnormality in the chip feed channel and re-measure after Bubble Vent. For the bubble vent operation, see "11.2.1 Bubble Vent".
E012	When measurement is complete or when measurement results are displayed	Baseline pressure error	Confirm there is no abnormality in the chip feed channel and re-measure after Bubble Vent. For the bubble vent operation, see "11.2.1 Bubble Vent".
E013	When measurement is complete or when measurement results are displayed	Pressure above limit	Confirm there is no abnormality in the chip feed channel and re-measure after Bubble Vent. For the bubble vent operation, see "11.2.1 Bubble Vent".
E014	When measurement is complete or when measurement results are displayed	Pressure below lower limit	Confirm there is no abnormality in the chip feed channel and re-measure after Bubble Vent. For the bubble vent operation, see "11.2.1 Bubble Vent".
E015	When measurement is complete or when measurement results are displayed	Abnormal pressure drop	Confirm that no blood has leaked.
E016	When measurement is complete or when measurement results are displayed	Pressure decreasing	Confirm that no blood has leaked.
E017	When measurement is complete or when measurement results are displayed	Chip temp. above limit	Confirm that the ambient operating temperature is within the range before performing the operation again.
E018	When measurement is complete or when measurement results are displayed	Chip temp. below limit	Confirm that the ambient operating temperature is within the range before performing the operation again.
E019	When measurement is complete or when measurement results are displayed	Chip removal abnormality	Re-perform the measurement. Do not remove the chip during measurement.
E020	When measurement is complete or when measurement results are displayed	Pump volume below threshold	If this error occurs, please contact the distributor.
E021	When measurement is complete or when measurement results are displayed	Pump return-to-origin error	If this error occurs, please contact the distributor.

Error Code	Location of Problem	Problem	Resolution Method
E022	When measurement is complete or when measurement results are displayed	Pressure sensor error	If this error occurs, please contact the distributor.
E023	When measurement is complete or when measurement results are displayed	Chip heater error	If this error occurs, please contact the distributor.
E100	When the [Measurement] button is pressed	The chip has been removed.	Prepare to perform the measurement again.
E101	When the [Measurement] button is pressed	The heater plate has not reached standby temperature.	Wait for a while before operating.
E102	Preparation for measurement	Register the consumables.	Refer to "7 Lot Management" to register the lot information of the PL Reservoir set.
E103	Preparation for measurement	The chip does not match the order.	Use the chip for the assay selected on the "Order" screen and perform the operation again.
E105	Preparation for measurement	The expiry date has passed.	Confirm the expiry date of the chip, replace it with an unexpired chip, and perform the operation again.
E106	LIS related	Response message abnormality	If this error occurs, please contact the distributor.
E107	LIS related	Negative response from LIS	Reconfirm the Specimen ID that was entered, and if the error is not resolved, please contact the distributor.
E108	LIS related	LIS connection failed.	Confirm that the LAN cable is connected. Confirm that the LIS is operating. If this error is not resolved, please contact the distributor.
E109	LIS related	LIS is not responding. (Response message)	Confirm that the LIS is operating. If this error is not resolved, please contact the distributor.
E110	When an order is completed	The pump suction volume has exceeded the upper limit.	If this error occurs, please contact the distributor.
E111	Preparation for measurement	The chip has already been used. Use a new chip.	Perform the operation again using a new chip.
E201	Password related	Password is incorrect.	Enter the password again.
E202	Password related	User name or password is incorrect.	Enter the user name and password again.

Error Code	Location of Problem	Problem	Resolution Method
E203	Password related	Confirmation password does not match.	Enter the password again so that it matches the password you entered the first time.
E204	Account related	This user name is in use.	Register a different user name.
E205	Account related	Unable to register the account.	20 accounts have already been registered. Please delete an unnecessary account and perform the operation again.
E206	Account related	Cannot register the user.	Perform the operation again, and if it fails repeatedly, restart the instrument and perform the operation again.
E207	Account related	Cannot delete the user.	Perform the operation again, and if it fails repeatedly, restart the instrument and perform the operation again. * Please understand that, in order to prevent the accidental deletion of all accounts, the "admin" account, which is registered by default, cannot be deleted.
E301	Date and time setting	The entered value is outside of the range.	Enter a value within the setting range.
E302	Maintenance Information	Communication log is empty.	Perform the operation after a communication has occurred.
E303	Maintenance Information	Failed to write to USB flash drive.	Confirm the USB flash drive connection, and if it fails repeatedly, use a different USB flash drive.
E304	Maintenance Information	Failed to read USB flash drive.	Confirm the USB flash drive connection, and if it fails repeatedly, use a different USB flash drive.
E305	Maintenance Information	Failed to write to internal memory.	Perform the operation again, and if it fails repeatedly, restart the instrument and perform the operation again.
E306	Maintenance Information	Failed to erase measurement data.	Perform the operation again, and if it fails repeatedly, restart the instrument and perform the operation again.
E307	Maintenance Information	Printing failed.	Confirm the condition of the printer's paper and cover.
E308	Maintenance Information	USB flash drive not found.	Confirm the USB flash drive connection, and if it is not found even though there is no problem with the connection, use a different USB flash drive.

Error Code	Location of Problem	Problem	Resolution Method
E401	Hardware error	Program error	Press the power button on the instrument to force shutdown. If this error recurs, please contact the distributor.
E402	Hardware error	Hardware error (Flash memory)	Press the power button on the instrument to force shutdown. If this error recurs, please contact the distributor.
E403	Hardware error	Hardware error (EEPROM)	Press the power button on the instrument to force shutdown. If this error recurs, please contact the distributor.
E404	Hardware error	Hardware error (Touch panel)	Press the power button on the instrument to force shutdown. Do not continue to touch the touch panel during startup. If this error recurs, please contact the distributor.
E405	Hardware error	Internal communication error (printer)	Press the power button on the instrument to force shutdown. If this error recurs, please contact the distributor.
E406	Hardware error	The Date IC has been reset.	Refer to "9.1 System Settings" to set the date and time.
E408	Preparation for measurement	Barcode reader is not connected.	Refer to "5.3 Connect the Barcode Reader" to connect the barcode reader. If the problem is not resolved after reconnecting, restart the instrument.

12.3 Operation When an Error Occurs

If an error message is displayed, please follow the resolution method in "12.2 About Error Messages".



WARNING



- When an error occurs, blood or mineral oil may be splashed or spilled during the removal of Reservoirs, etc.
- This operation may pose a risk of infection. To prevent biohazards, always wear personal protective equipment such as gloves and eye protection, and protective clothing such as a lab coat.



13 Appendix

13.1 Consumables List

The consumables for this instrument are as follows.

Please contact the distributor for purchasing information.

Catalog No. REF	Product name	Remarks
wS-SP-0006	Waste bottle	Set of 2
wS-SP-0007	SC Bar	Set of 2
wS-SP-0031	Thermal paper roll	Set of 5
330779	Mineral oil	Company name: Sigma-Aldrich CAS No.: 8042-47-5 EC No.: 232-455-8

ATTENTION



Consumables that can be replaced by the user are limited to those listed in the table above.



WARNING



When disposing of consumables, please dispose of them in accordance with laws and regulations related to waste.

13.2 Assay-Related Products List

The assay-related products for this instrument are as follows.
Please contact the distributor for purchasing information.

Catalog No. REF	Product name	Remarks
18002	PL Chip	
18003	PL Chip Reservoir set	
18004	BAPA Tube	



For instructions on how to use assay-related products, please refer to the relevant product's package insert.



WARNING



When disposing of assay-related products, please dispose of them in accordance with laws and regulations related to waste.

13.3 EMD (Electromagnetic Disturbance) Technical Data

This instrument complies with the EMD (Electromagnetic Disturbance) standard IEC60601-1-2:2014+A1:2020 (power supply voltage 120 V only). The EMD standard specifies that noise generated by equipment should be kept below a certain level so as not to affect other equipment or be affected by electromagnetic waves emitted by other equipment (such as smartphones). Because the EMD standard requires that detailed information about the EMD environment be provided to the user in order for the equipment to function safely, a technical description is provided below.

 **WARNING**

!

This instrument must be used in accordance with the information provided in the EMD Technical Document.

!

The operation of this instrument or other equipment may be affected. Use according to the information provided below.

- Do not use this instrument in close contact with or stacked on top of other equipment.
- Do not connect any equipment or cables other than those specified.
- Do not use portable RF communication devices such as smartphones within 30 cm (1 ft) of this instrument.

Electromagnetic emissions

Emission test items	Applicable Standards	Applicability
Conducted and radiated RF emissions	CISPR 11	Group 1 Class B

- This instrument uses RF energy for internal functions only. Thus, its RF emissions are very low and very unlikely to cause interference to nearby electronic equipment.
- This instrument is suitable for use in specialist medical facility environments that are not directly connected to commercial low-voltage distribution systems.

Electromagnetic Immunity / Exterior Ports

Immunity Test Items	Applicable Standards	Applicability
Electrostatic Discharge	IEC61000-4-2	±8 kV (contact) ±2, ±4, ±8, ±15 kV (in air)
Radiated RF electromagnetic field	IEC61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % amplitude modulation (1 kHz)
Nearby electromagnetic fields from RF wireless communication equipment	IEC61000-4-3	See "Immunity to Nearby Electromagnetic Fields from RF Wireless Communication Equipment"
Power supply frequency magnetic field	IEC61000-4-8	30 A/m 60 Hz

Immunity Test Items	Applicable Standards	Applicability
Proximate magnetic fields	IEC61000-4-39	See "Immunity to Proximate Magnetic Fields".

- The floor should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30 %.

This instrument is suitable for use in electromagnetic environments in specialist medical facilities.

Immunity to Nearby Electromagnetic Fields from RF Wireless Communication Equipment

Test Frequency (MHz)	Bandwidth (MHz)	Communication Service	Modulation	Maximum Power (W)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	28
614	614 – 698	5G Band	Pulse modulation 217 Hz	0.2	9
656					
698					
694	694 – 790	5G Band	Pulse modulation 217 Hz	0.2	9
742					
790					
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	28
870					
930					
1675	1675 – 1680	5G Band	Pulse modulation 217 Hz	0.2	9
1677.5					
1680					
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation 217 Hz	2	28
1845					

Test Frequency (MHz)	Bandwidth (MHz)	Communication Service	Modulation	Maximum Power (W)	Immunity Test Level (V/m)
1970		LTE Band 1, 3, 4, 25; UMTS			
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	28
3400	3400 – 4800	5G Band	Pulse modulation 217 Hz	0.2	9
3450					
3500					
3600					
3625					
3700					
3900					
3950					
4200					
4400					
4500					
4600					
4700					
4800					
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	9
5500					
5785					

- Do not use portable RF communication devices such as smartphones within 30 cm (1 ft) of this instrument.
- The field strengths from fixed transmitters such as wireless (cellular/cordless) telephones and land-based mobile radio base stations, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be theoretically predicted with accuracy. A field survey of electromagnetic fields should be considered to estimate the electromagnetic environment caused by fixed RF transmitters. If the field strength measured at the location where this instrument is used exceeds the applicable RF compliance levels listed above, please confirm that the instrument operates properly. If abnormal operation is observed, additional measures may be necessary, such as changing the orientation or installation location of the instrument.

Immunity to Proximate Magnetic Fields

Test Frequency	Modulation	Immunity Test Level (A/m)
134.2 kHz	Pulse modulation / 2.1 kHz 50 %	65
13.56 MHz	Pulse modulation / 50 kHz 50 %	7.5

Electromagnetic Immunity / AC Input Power Port

Immunity Test Items	Applicable Standards	Immunity Test Level
Electrical fast transient / burst	IEC61000-4-4	± 2 kV Repetition frequency: 100 kHz
Surge	IEC61000-4-5	Line-to-line: ± 0.5 kV and ± 1 kV Line-to-ground: Not applicable as there is no protective grounding
Conducted disturbance induced by RF electromagnetic fields	IEC61000-4-6	3 V between 0.15 MHz and 80 MHz 6 V between 0.15 MHz and 80 MHz in the ISM band 80 % amplitude modulation (1 kHz)
Voltage dip	IEC61000-4-11	0 % Ut 0.5 cycles: Phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315 0 % Ut 1 cycle: Phase Angle 0° 70 % Ut 30 cycles: Phase angle 0°
Momentary power outage	IEC61000-4-11	0 % Ut 300 cycles: Phase Angle 0°

- The power supply quality of the power supply used in this instrument should be that of a professional medical facility environment.
- If the use of the instrument is to be continued in the event of a power failure, an uninterruptible power supply (UPS) is recommended.

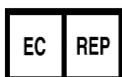
Electromagnetic Immunity / Signal I/O Ports

Immunity Test Items	Applicable Standards	Applicability
Electrostatic Discharge	IEC61000-4-2	±8 kV (contact) ±2, ±4, ±8, ±15 kV (in air)
Electrical fast transient / burst	IEC61000-4-4	± 1 kV Repetition frequency: 100 kHz
Conducted disturbance induced by RF electromagnetic fields	IEC61000-4-6	3 V between 0.15 MHz and 80 MHz 6 V between 0.15 MHz and 80 MHz in the ISM band 80 % amplitude modulation (1 kHz)

- The floor should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30 %.

Revision History

Version Number	Revision Date	Details
Ver. 1.0	March 6, 2025	First edition



MDSS GmbH
Schiffgraben 41 30175 Hannover, Germany



MedEnvoy Global BV
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands



ZACROS Corporation
1-1-1 Koishikawa, Bunkyo-ku, Tokyo
112-0002 Japan
e-mail: ttas-info@zacros.co.jp