Document No. : PTF-UML Edt.9
Date of publication: 2024-09-09

# Total Thrombus formation Analysis System

## T-TAS®01

**for professional use**

# User's Manual

# - Instruction Manual -


This instruction manual contains operating instructions for the T-TAS® 01 Total Thrombus formation Analysis System. Please read this instruction manual thoroughly before using the system, and operate it appropriately.

Furthermore, please store the manual in a readily accessible location for reference.

## Intended Use

- The T-TAS 01 Instrument is intended for use with T-TAS reagent chips in the clinical laboratory.

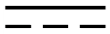
## Foreword

- The T-TAS®01 Total Thrombus formation Analysis System is an in vitro diagnostic medical device.
- Unauthorized reproduction of the content of this manual, either in part or in whole, is strictly prohibited.
- The content of this manual and system specifications may be subject to change without prior notice in the future.
- Images contained in this manual may be different from the actual product and screen in terms of version, design, etc.
- Use of the system in a manner that is inconsistent with the descriptions in this manual may cause damage, personal injury or invalidate the product warranty.
- This system should be used only by suitably trained operators.
- Equipment protection may be lost if this system is handled improperly by the customer, or from using the system without following the content of the manual.
- The manufacturer does not accept any responsibility for damages resulting from improper operation of the system by the customer, or from using the system without following the content of the manual.
- The system comes with a personal computer (dedicated computer) and touch panel monitor (dedicated monitor) to control the instrument. Do not use the dedicated computer and dedicated monitor with applications other than this system.
- A comprehensive clinical diagnosis must be made by the doctor in charge based not only on measurement results, but also on other information such as clinical presentation and other test results.
- 

## Software Cybersecurity

- The T-TAS 01 Instrument should not be connected to a wired or wireless network.
- The T-TAS 01 instrument is intended for use in the professional clinical laboratory.
- Only authorized personnel of the facility should have access to the device.
- In the event that this condition cannot be assured, additional cybersecurity measures are available to assist in limiting this sort of risk.
- Please contact ZACROS Corporation at ttas-info@zacros.co.jp for more information.

## Symbol Lexicon

| | | | |
|---|---|---|---|
| CE<br>European Conformity | c UL us LISTED<br>Electrical Safety Certification | IVD<br>In vitro diagnostic medical device | Rx only<br>This device is restricted to sale by or on the order of a licensed healthcare practitioner. |
| EC REP<br>Authorized Representative in the European Union |  <br>Importer |  <br>Manufacturer |  <br>JP<br>Country of Manufacture Japan |
| SN<br>Serial Number | #<br>Model Number | REF<br>Catalogue number |  <br>Direct current |
|  <br>Waste from Electrical and Electronic Equipment |  <br>Consult Instructions for Use |  <br>Consult Accompanying Documents |  <br>Biological Risks |
|  <br>Power Code Color Guide |  <br>Standby /Power On |  <br>LR Color Code (L: Left path, R: Right path) |  <br>DC IN |
|  <br>Keep Dry |  <br>Storage Temperature Limit |  <br>Storage Humidity limitation |  <br>Fragile |
|  <br>Handle with Care |  <br>Stacking Limit |  <br>This Side Up | ZACROS<br>Brand Logo |

Contents

# 1. Important Considerations

## 1.1. When Reading This Manual

This instruction manual contains instructions for correct and complete operation of the T-TAS 01 Total Thrombus formation Analysis System. Please read this manual thoroughly, and use the system in an appropriate manner.

## 1.2. Warnings and Precautions

Any serious incident that has occurred in relation to the T-TAS 01 Instrument shall be reported to the manufacturer or their authorized representative and the competent authority of the European Union Member State in which the user and/or the patient is established

In addition to describing the system operation, this instruction manual contains items that should be observed to prevent injury or harm to those using the system. These items are classified as follows.

Safety related precautions

| | |
|---|---|
| ⚠ WARNING | The WARNING symbol indicates danger. There is a risk of injury or death if the operating procedures and rules indicated here are not implemented properly or not observed. Please review the specified conditions thoroughly and ensure that they are met. |
| ⚠ CAUTION | The CAUTION symbol indicates danger. There is a risk of system damage, or suffering a major loss if the operating procedures and rules indicated here are not implemented properly or not observed. Please review the specified conditions thoroughly and ensure that they are met. |

Meaning of symbols

| | |
|---|---|
|  | Prohibited (content which is not permitted under any circumstances) |
|  | Instruction (content which must be observed) |
|  | Risk of fire or burns, cause of failure. |
|  | Risk of burns. |
|  | Risk of electric shock, cause of failure. |
|  | Risk of explosion. |
|  | Biohazard (risk of skin damage or infection). |
|  | Other instructions, advice |

## 1.3. To Ensure Safe Use

### 1.3.1. System Installation Precautions

(1) Please ask qualified personnel to install the system.
(2) Install in a location where the system will not be exposed to water.
(3) Install in a location where there are no adverse effects from atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, or air containing salt or sulfur.
(4) Pay attention to inclination, vibrations, shocks (including knocks and bumps during transportation), and other safety conditions.
(5) Pay attention to the frequency and voltage of the power supply, as well as power consumption.
(6) Connect this system to an easily accessible AC outlet.
(7) This system complies with the essential requirements for immunity and emissions set out in EN IEC 61326-2-6:2021 and IEC60601-1-2:2014 +AMD1:2020 (For 120 V).

| ⚠ WARNING | | |
|---|---|---|
|  | Do not install the system in a location where it may be exposed to water, or in locations used to store chemicals. |  |
| | Do not install the system in locations where gas is present, or near fire. |  |
| | Do not install the system on an uneven surface.<br>System failure or injury may occur if the instrument topples or falls. | |
| | Do not operate the system with other than the specified power supply voltage. |  |
| | Do not use an adapter other than the AC adapter provided with the system.<br>Furthermore, do not use the provided AC adapter for other equipment. |  |
| | Follow the precautions indicated when using the AC adapter.<br>Do not disassemble, modify, or damage the instrument. |  |
| | Do not connect a power cable other than that provided with the system to the instrument. |  |
|  | Ensure a reliable ground connection for both the instrument and dedicated computer. |  |
| | This system is designed and tested in accordance with CISPR 11 Class A (Environment suitable for hospitals, etc.).<br>Therefore, this system may cause radio disturbance when used in the home. If you use this system in the home, a radio interference mitigation should be taken. | |

| | | |
|---|---|---|
| | This system may not operate properly when it is interfered by electromagnetic wave. Do not use this system near the strong electromagnetic wave source (such as intended RF source without barriers) .<br>Electromagnetic interference can be detected by the interruption of measurement operation, error display, or loss of screen display. | |
| | To prevent the adverse effects of electromagnetic interference, use the system in accordance with the following information.<br>・Do not use this system in close contact with or on top of or under other devices.<br>・Do not connect anything other than the specified device or cable.<br>・Do not use portable RF communication devices such as smartphones within 30 cm of this system. | |
| ⚠ CAUTION | | |
| | Do not connect a USB hub to the dedicated computer USB port. | |
| | It is recommended to assess the electromagnetic environment before using this system.<br>Also see 11.3. EMD (Electromagnetic interference) Technical documentation. | |

### 1.3.2. Precautions Prior to Using the System

(1) Inspect the power supply connection, and ensure that the system is running properly.
(2) Ensure that all cords are connected properly and safely.
(3) Beware that using more than one piece of equipment with the same power supply simultaneously may hinder the acquisition of accurate measurement results, or cause danger.

| | | |
|---|---|---|
| ⚠ CAUTION | | |
| | Do not connect or disconnect the power plug with wet hands. | |
| | Run a virus check on USB flash drives connected to the dedicated computer to verify safety before use. | |

### 1.3.3. Precautions Prior to Using the System After Long Periods of Inactivity

When using the system again after a long period of inactivity, be sure to verify that the devices are functioning normally and safely before use.

### 1.3.4. Precautions to Prevent Fire or Failure During Use

(1) Monitor the entire system constantly to ensure that there are no abnormalities.

(2) If system abnormalities or malfunctions are discovered, turn OFF the power switch on the side of the instrument (see Figure: 1.3-2 below), and disconnect the AC adapter from the AC outlet. Next, contact Technical Support immediately.

*Figure: 1.3-1*

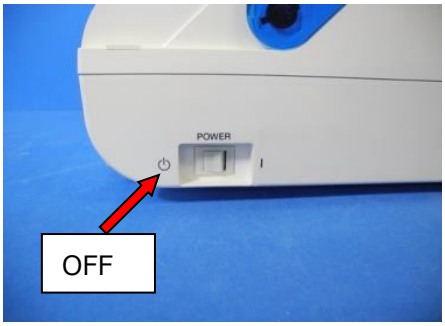



*Figure: 1.3-2*

(3) If fluid is spilled on the instrument, turn OFF the power, disconnect the AC adapter from the AC outlet, and wipe off the fluid.

(4) Take care to ensure that no one other than the intended users touch the devices.

| ⚠ WARNING | | |
|---|---|---|
| | Do not use in an environment where flammable gas is present.<br>Do not use combustible or explosive gases near the system.<br>This system does not have an explosion-proof construction. | |
| ⚠ CAUTION | | |
| | Do not use the system with the AC adapter covered by another object. | |
| | Turn OFF the power immediately to stop the system in any of the following situations.<br>• If water, reagents, or foreign material gets inside the instrument<br>• If abnormal noises or vibrations are observed while the instrument is running<br>• At times of abnormal system operation | |
| | Do not use consumable parts other than those specified in “11.1. List of Consumable Parts”. | |
| | Use consumable parts such as chips that have not exceeded their expiration date.<br>The validity period is indicated in “11.1. List of Consumable Parts”. | |
| | Do not pull nozzles or tubing with force. Furthermore, do not pull nozzles out more than 165 mm (6.5 in). There is a risk of damage to tubing and connections. | |

### 1.3.5. Precautions to Prevent Injury During Use

(1) Ensure that the instrument handling precautions described in this manual are strictly observed to prevent electric shock or burns.

(2) If using test solutions, mineral oil, disinfectant, or detergent, always wear personal protective equipment and wear protective clothing such as gloves, safety glasses, or masks, and follow the instructions given in this manual.

(3) There is a risk of injury when touching pointed objects directly by hand. Be sure to wear rubber gloves, and handle with care.

| ⚠ WARNING | | |
|---|---|---|
|  | Do not touch the hot parts of the AC adapter for long periods of time. Doing so can cause low-temperature burns. |  |
|  | Do not open Pump Cover unnecessarily. The internal solenoid valves may become hot and cause burns. |  |
|  | Do not use any barcode scanner other than the one specified as optional accessory. | |
|  | When handling reagents and specimens, wear personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats). |  |

### 1.3.6. Precautions to Prevent Biohazards

(1) When handling specimens, carrying out maintenance, or when conducting waste management, be mindful that the work involves the handling of biological hazards, and wear protective clothing (protective clothing, gloves, safety glasses, masks, etc.) according to local, state, and national requirements.

(2) If mineral oil or infectious substances comes into contact with the skin, wash or decontaminate the affected area accordance with the facility's work standards, and seek medical attention if necessary.

(3) Wipe up any fluids immediately that have overflowed from containers onto the instrument.

(4) If mineral oil or specimens are mistakenly ingested, seek medical attention.

| ⚠ WARNING | | |
|---|---|---|
|  | Wear personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) if touching parts of the instrument that might be contaminated with mineral oil or infectious specimens. |  |

### 1.3.7. Waste Fluid and Solid Waste Handling Precautions

(1) Handle waste fluid and solid waste (chip, reservoir, over-cap, etc.) as potentially infectious substances.

(2) If disposing of waste fluid or solid waste, do so as medical waste in accordance with local, state, and national requirements.

| ⚠ WARNING | | |
|---|---|---|
|  | If disposing of waste fluid or solid waste, wear personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats). |  |

### 1.3.8. Precautions Following System Use

(1) Turn OFF the power using the stipulated procedure.
(2) When unplugging cords, do not use excessive force such as holding and pulling the cords.
(3) Pay attention to the following concerning the storage location.
    ① Store in a location where the system will not be exposed to water.
    ② Store in an area where there are no adverse effects from atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, or air containing salt or sulfur content.
    ③ Pay attention to inclination, vibrations, shocks (including knocks and bumps during transportation), and other safety conditions.
    ④ Do not store in areas where chemical agents are stored or gas is present.
(4) After cleaning, arrange accessories and cords neatly, and keep them together.
(5) The instrument should be inspected and cleaned, if necessary, after each use to maintain optimal performance.

| ⚠ CAUTION | | |
|---|---|---|
|  | Disconnect the power plug if the system will not be in use for a while. |  |
| | Observe storage conditions when storing or transporting consumable parts or separately sold parts. Storage conditions are indicated in “11.1. List of Consumable Parts” and “11.2. List of Separately Sold Items”. | |

### 1.3.9. Maintenance and Inspection Precautions

Be sure to carry out periodic system and component inspections. Refer to Section 9 of this manual.

### 1.3.10. Precautions When Failures Occur

Do not try to repair the instrument when failures occur. Follow correct procedures and contact Technical Support for repairs. Attempts to repair the instrument could invalidate the warranty.

| ⚠ WARNING | | |
|---|---|---|
|  | Never disassemble or modify any of the system's component devices. |  |

### 1.3.11. System Transportation and Movement Precautions

| ⚠ WARNING | | |
|---|---|---|
|  | This system may be contaminated by infectious specimens. If transporting or moving the system, wear personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats). |  |
| ⚠ CAUTION | | |
|  | Do not apply shocks to, or drop the system when transporting or moving it. This may cause system failure or injury. | |
| | Do not transport or move the system while it is running.<br>Do not transport or move the system while it is connected to the AC adapter or external machinery.<br>This may cause system failure or injury. | |

### 1.3.12. System Transportation Precautions

| ⚠ WARNING | | |
|---|---|---|
|  | This system may be contaminated by infectious specimens. If transporting the system, wear personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats). |  |
| ⚠ CAUTION | | |
|  | Do not dispose of the packing boxes from which the system is removed at the time of delivery.<br>Use these packing boxes when transportation is necessary. | |
|  | Use the dedicated packing boxes for transportation. Furthermore, observe the storage conditions indicated in “2.9. Specifications.” when transporting the system. | |
| | Empty the oil bottle of mineral oil before transporting the system. | |

### 1.3.13. System Disposal Precautions

The T-TAS 01 instrument is designed to have a useful life of 5 years, assuming 30,000 cycles of assays in total. Components of the T-TAS 01 System (such as the instrument, dedicated PC, and monitor) 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 01 System, please contact your city office, waste disposal service or your local representative.

## 1.4. Caution Labels

The caution labels shown below (Figure: 1.4-1) are affixed to this instrument. Verify the content and location of the labels, and observe the precautions.

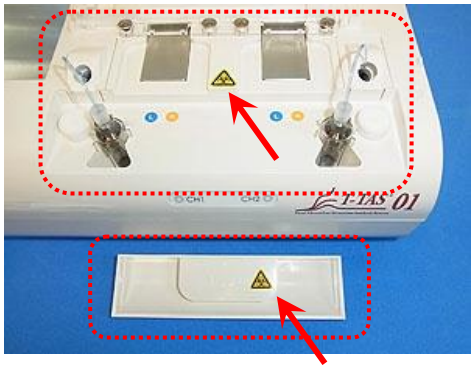


*Figure: 1.4-1*

| ⚠ WARNING | | |
|---|---|---|
|  | A potentially infectious specimen is handled inside the dotted line in the image above.<br>If touching this instrument, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn to prevent biohazards.<br><br>There is also a possibility of infectious specimens coming into contact with the dedicated monitor or dedicated computer. Protective clothing must also be worn even if operating the dedicated monitor or dedicated computer only. |  |

Although not shown here, the high-temperature caution labels are attached to the internal solenoid valves.

| ⚠ WARNING | | |
|---|---|---|
|  | Do not open Pump Cover unnecessarily. The internal solenoid valves may become hot and cause burns. |  |

# 2. System Overview

## 2.1. Definition of Terms, Conventions Used in This Manual

### 2.1.1. Definitions

Terms used in this system are defined below (Table: 2.1-1).

*Table: 2.1-1*

| Term | Definitions |
|---|---|
| System | Refers to both the hardware and software. |
| Instrument | Refers to the hardware used to move the specimen through the chip and perform the measurement. |
| Dedicated computer | Refers to the dedicated personal computer used to control the instrument. |
| Measurement software | Refers to the dedicated software used to run the system. |
| CH1 | Channel 1. Refers to side 1 (left side) of the dual system measurement system. |
| CH2 | Channel 2. Refers to side 2 (right side) of the dual system measurement system. |
| Chip | Refers to the disposable flow chamber microchips used with the T-TAS 01 System. |
| SC | System Check. This function is used to diagnose pressure leaks inside paths. The three types of system check are as follows.<br>Auto SC: Checks for pressure leaks inside the pumps.<br>Simple SC: Performs a simple check for pressure leaks inside the pumps.<br>Manual SC: Checks for pressure leaks up to the nozzle tips. |
| Bubble vent | Refers to the mechanism where mineral oil is aspirated from a Oil-bottle and discharged to the nozzles to eliminate air bubbles. |

### 2.1.2. Conventions Used in This Manual

This manual uses the following conventions.

*Table: 2.1-2*

| Convention | Usage purpose |
|---|---|
| “*.*. ****” | Indicates locations in the manual to be referenced.<br>Example) "2.1.2. Conventions Used in This Manual" |
| “***” account | Indicates an account used to sign in to the dedicated computer OS.<br>Example) "Operator" account |
| “***” screen | Indicates a screen displayed on the dedicated monitor.<br>Example) ”HOME” screen, "Sign-in" screen |
| [***]*** | Indicates locations that can be operated that are displayed on the dedicated monitor.<br>Example) [HOME] button, [Backup] tab |

| | |
|---|---|
| *** | Indicates locations in which characters can be entered that are displayed on the dedicated monitor.<br>Example) Operator ID (Operator ID entry field) |
| Figure: *.*-* | Displays an image. |
| Table: *.*-* | Displays a table. |

## 2.2. What is T-TAS?

T-TAS (Total Thrombus formation Analysis System) is a system that creates and analyzes thrombus formation under blood flow conditions using a disposable microchip (hereafter referred to as "chip") with micro-level paths.
When performing analysis using T-TAS, whole blood is passed through the chip, allowing the rigidity of the formed thrombus to be measured in the form of pressure. A chronological pressure waveform graph can be obtained from the T-TAS measurement results, allowing comprehensive total thrombus formation to be evaluated by analyzing the graph and comparing the calculated parameters.

■ PL chip for analysis of platelet thrombus formation (primary hemostatic ability)
Specific analysis of primary hemostatic ability is possible using collagen-coated microcapillary paths.
Refer to the PL chip package insert for additional details about the PL chip.

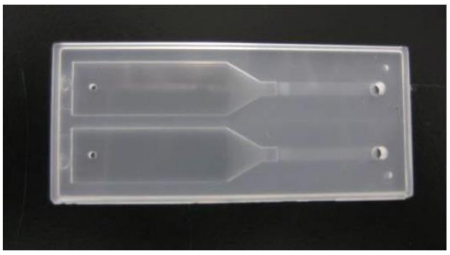


*Figure: 2.2-1*

## 2.3. Hardware Overview

The system hardware comprises the T-TAS 01 instrument, dedicated computer, and dedicated monitor.

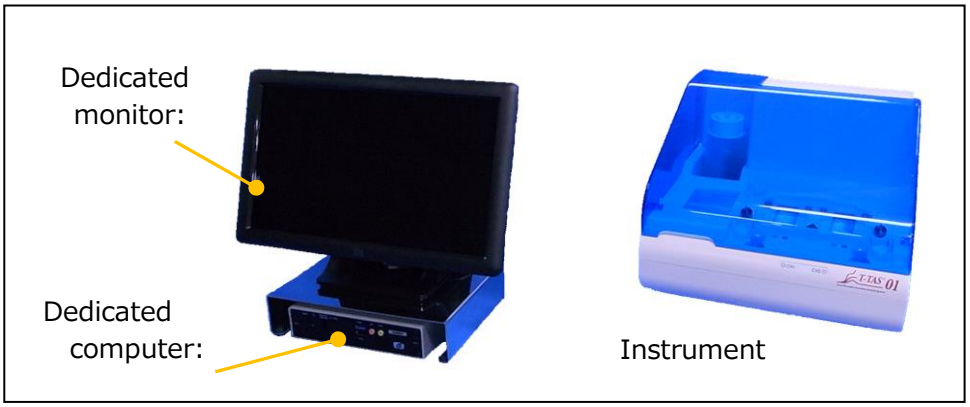



*Figure: 2.3-1*

■ Instrument:
Controls flow of the blood sample through the chip and measures the flow pressure. Pressure data inside the flow path is sent to the dedicated computer.

■ Dedicated computer:
This is a dedicated personal computer used to run the "measurement software" which operates this system. A separately sold barcode scanner can also be connected.

■ Dedicated monitor:
Serves as an interface between the user and this system using a touch panel monitor.

## 2.4. Instrument Overview

### 2.4.1. Instrument Operation Overview

This instrument measures changes in pressure when blood inside the chip coagulates while feeding blood specimens to the chip. The instrument has dual measurement systems (pump unit, stages), and is capable of performing measurements on 2 chips simultaneously.

The pre-heater temperature is controlled at 36°C while the instrument power is ON. Assay chips may be placed on the pre-heater for at least 1 min before the assay, to allow stabilization of the temperature. This step is optional, but can reduce the time required to heat the chip to the operating temperature.

The user places the chip on the stage of the channel for which the measurement is being performed. The CH1 stage and CH2 stage are controlled at the optimum temperature for measurement while chips are placed.

The instrument keeps the nozzle filled with mineral oil. The user attaches a reservoir to the tip of the nozzle, and transfers blood specimens into the reservoir using a pipette (not provided). The user also attaches the reservoir cap, and connects the reservoir to the temperature-controlled chip. The instrument controls the mineral oil feed and measures the pressure while feeding blood inside the reservoir to the chip, and displays the results on the dedicated monitor screen.

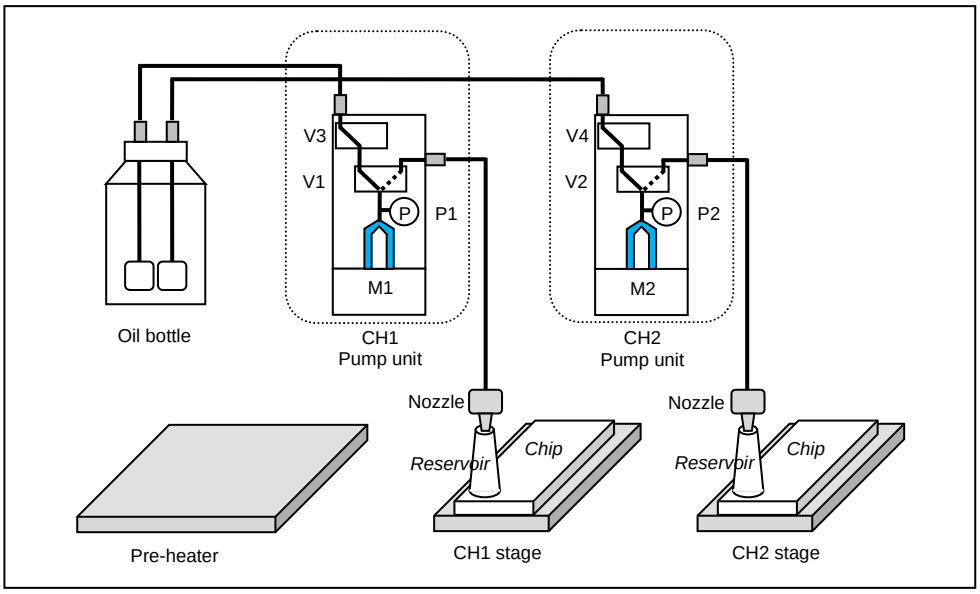



*Figure: 2.4-1*

*Table: 2.4-1*

| Legend | Name | Description |
|---|---|---|
| P1,P2 | Pressure sensor | Measures the pressure inside the paths. |
| V1,V2 | 3-way valve | Switches between path intake and discharge. |
| V3,V4 | 2-way valve | Closes the input side path when checking for pressure leaks. |
| M1,M2 | Motor | Drives the pumps. |

## 2.4.2. Names of Instrument Parts

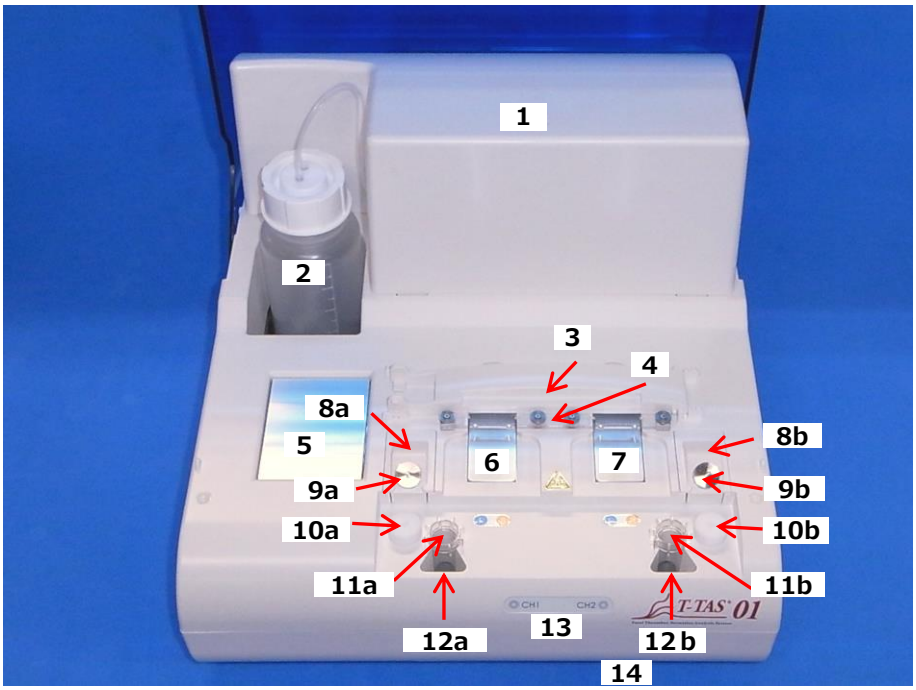



*Figure: 2.4-2*

*Table: 2.4-2*

| No. | Name | Description |
|---|---|---|
| 1 | Pump Cover | There are 2 pump units inside the cover.<br>The cover must not be opened by anyone other than service personnel. |
| 2 | Oil bottle | This is a container used to fill mineral oil. It is equipped with a filter to prevent the tubing becoming contaminated with foreign material.<br>The capacity is 250 ml.<br>Be sure to prepare the mineral oil indicated in ”11.1. List of Consumable Parts”. Use of a different mineral oil may affect the measurement; therefore, caution is advised. |
| 3 | Chip-code Reader | Identifies the chip type.<br>The reader can be opened and closed by gripping the handle on the left for cleaning. Please use closed at times other than cleaning. |
| 4 | Chip Holder | Holds the inserted chip. |
| 5 | Pre-heater | This can be used to pre-heat the chip.<br>Heats the chip to 36°C while the instrument power is ON. |
| 6 | CH1 Stage | The chip is inserted here when performing CH1 measurement. When the chip is inserted, the stage is heated to a temperature appropriate for the measurement. |

| | | |
|---|---|---|
| 7 | CH2 Stage | The chip is inserted here when performing CH2 measurement. When the chip is inserted, the stage is heated to a temperature appropriate for the measurement. |
| 8a | CH1 Nozzle Holder | When dispensing blood specimens into reservoirs, nozzles are placed here so that disposable reservoirs can be attached. |
| 8b | CH2 Nozzle Holder | |
| 9a | CH1 Nozzle | The nozzles discharge mineral oil, and are connected to tubing. The nozzles can be extended up to 165 mm (6.5 in). However, it is not possible to use the CH1 nozzle with the CH2 stage and vice versa.<br>Reservoirs and the SC bar are attached to the nozzle tip when performing a measurement or manual SC.<br>When not in use, place the nozzle on top of the waste tube to collect discharged fluid. |
| 9b | CH2 Nozzle | |
| 10a | CH1 SC Bar | When performing manual SC, insert nozzles into the SC bars.<br>The SC bars can be removed from the instrument but must be returned to their original positions. |
| 10b | CH2 SC Bar | |
| 11a | CH1 Waste tube | These are containers for collecting waste fluid from nozzles.<br>If removed from the instrument for emptying, they must be returned to their original position. |
| 11b | CH2 Waste tube | |
| 12a | CH1 Waste tube Holder | Waste tubes are set here. Be sure to use these with waste tubes in their set condition. |
| 12b | CH2 Waste tube Holder | |
| 13 | Status Indicator | Displays the instrument status. The respective statuses of CH1 and CH2 are displayed with red and green LEDs. |
| 14 | Waste Tray | This container is used to collect and store waste fluid that has overflowed from waste tubes. |

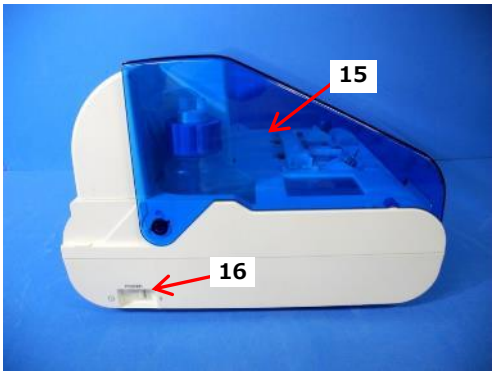



*Figure: 2.4-3*


*Figure: 2.4-4*

*Table: 2.4-3*

| No. | Name | Description |
|---|---|---|
| 15 | Cover | Protects the instrument from dust and debris. Use with the cover open when performing measurements. Close the cover when the instrument is not in use. |
| 16 | Power Switch | This switch is used to turn the instrument power ON and OFF. |
| 17 | DIP Switch | There are DIP switches used to determine instrument operation on the inside of the switch cover. The switch cover must not be opened by anyone other than service personnel. |
| 18 | USB Port | Connection point for a USB cable to communicate with the dedicated computer. |
| 19 | Power Port | Connect the power adapter for the instrument. |

### 2.4.3. Status Indicators

The status indicators shown in the box in the lower left image (Figure: 2.4-5) are divided into CH1 and CH2, each of which indicates the status of the relevant channel. Furthermore, the table in the lower right (Table: 2.4-4) shows the relationship between the LED indicators and status.


*Figure: 2.4-5*

*Table: 2.4-4*

| LED indicator | Channel status |
|---|---|
| OFF | Instrument power supply OFF |
| Red ON | Preparing for measurement |
| Red flashing | Error |
| Green ON | Measurement standby |
| Green flashing | Performing measurement |

* CH1 and CH2 on the instrument are divided up as shown in the following image (Figure: 2.4-6).

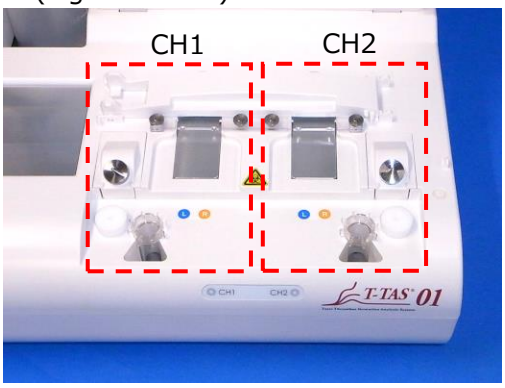



*Figure: 2.4-6*

### 2.4.4. USB Flash Drive Connection Location

If connecting a USB flash drive to the dedicated computer, connect to the top front USB port (see image below Figure: 2.4-7). The bottom front USB port is used for the separately sold barcode scanner.

*Figure: 2.4-7*

## 2.5. Entry with Barcode Scanner (Sold Separately)

The separately sold (see ”11.2. List of Separately Sold Items”) barcode scanner can be used to enter specimen information such as patient ID and chip lot numbers.

| ⚠ WARNING | |
|---|---|
| 🚫 | Do not use any barcode scanner other than the one specified as optional accessory. |

### 2.5.1. Using the Barcode Scanner

Connect the barcode scanner USB terminal to the USB port on the bottom front of the dedicated computer.
After tapping items to be entered on the touchscreen to activate the dialog box, press the barcode scanner switch and then scan barcodes. Barcode values are entered as is.

Character limit

Max. number of characters: Up to 100 characters for comments, 30 characters for other entries.
Prohibited characters: "," (commas) and pictographs
If ","(comma) is entered, it is converted into " "(space).

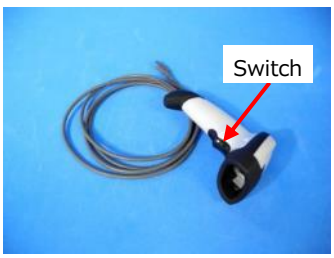



*Figure: 2.5-1*

### 2.5.2. Compatible Barcode Symbols

Code128, Code39, ITF, Codabar

## 2.6. Measurement Software Overview

> Information
> Measurement software is used to perform measurement, display data, and carry out maintenance by tapping the touchscreen. But if you tap it quickly, unintended behavior may occur. Slow touching can prevent malfunctions.

(Figure: 2.6 1) below shows the main screens and provides an overview of the measurement software.

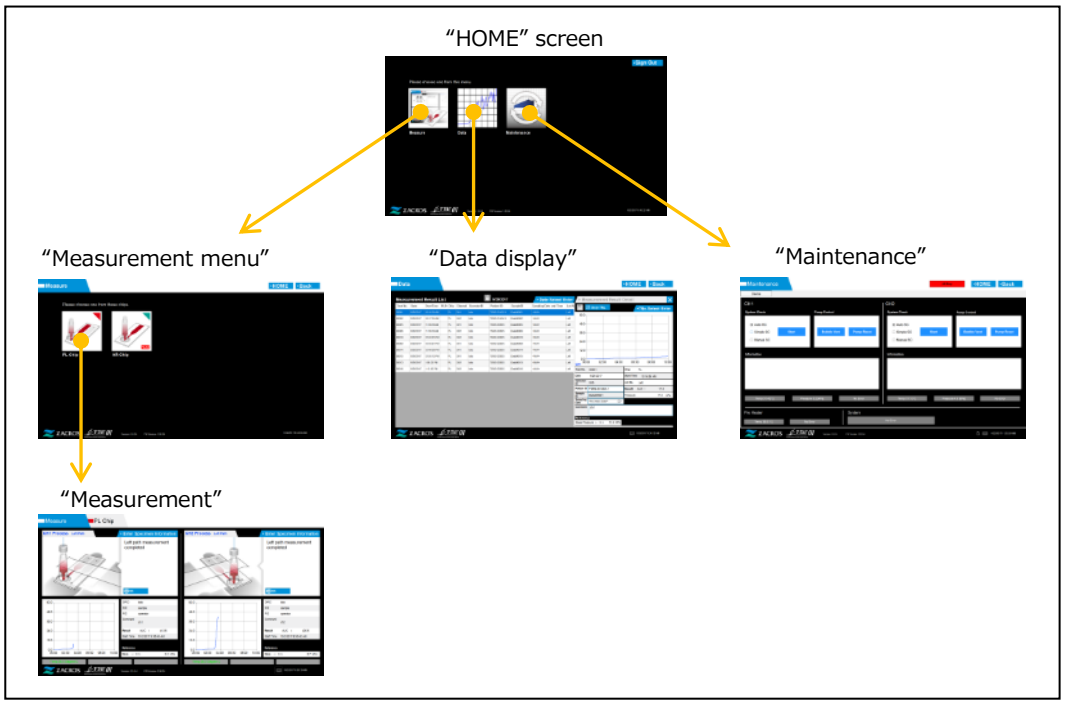



*Figure: 2.6-1*

- “HOME” screen

  This is the measurement software main screen.
  This screen is used to display the "Measurement menu" screen, "Data display" screen, and "Maintenance" screen, as well as to exit the measurement software.

- “Measurement menu” screen

  Select the measurement item (assay chip name) at this screen.

- “Measurement” screen

  This screen displays measurement procedure guidance, pressure graphs, and measurement results.
  An Operator ID registered by the "Supervisor" is required to perform measurement operation.

- “Data display” screen

  This screen displays a list of measurement results saved to the dedicated computer, and pressure data graphs.

- “Maintenance” screen

  This screen is used to perform system maintenance and register the Operator ID.

The displayed content and functions that can be used will differ depending on the user account used to sign in to the dedicated computer.

The following four accounts (Table: 2.6-1) can be used to sign into the dedicated computer OS.

*Table: 2.6-1*

| Account | Description | Password |
|---|---|---|
| Operator | This is the standard user account.<br>It is used to perform measurement operation and carry out daily maintenance. | No |
| Supervisor | This is the user administrator account. It is used to register the Operator ID and perform a data backup. | Yes |
| T-TAS Service | This is the account for service personnel. | Yes |
| Zacros | This is the manufacturer's account. | Yes |

### 2.6.1. Screen Transition

Screen transition buttons such as those shown below (Figure: 2.6-2) are located in each of the upper right screens of the measurement software. The content and active/inactive status of these buttons changes depending on the instrument status.


*Figure: 2.6-2*

a) Button displayed in position [A]

[HOME]: Displays the ”HOME” screen.
No display: Transition to the ”HOME” screen is disabled.
If chips have been inserted, the [HOME] button appears when they are removed in accordance with the on-screen guidance.

b) Button displayed in position [B]

[Back]: Displays the previously displayed screen.
[Data]: Displays the "Data display" screen.
No display: Screen transition is disabled. Screen transition is disabled while performing measurement.

Information

When USB communication between the device and the dedicated PC is interrupted while the "Measurement" screen is displayed, the [HOME] button becomes active.
When USB communication between the device and the dedicated PC is interrupted while the [Device] tab on the "Maintenance" screen is displayed and the letters of the control button become gray, the [HOME] and [Back] buttons becomes active.
* Normally, display transition buttons are disabled while the instrument is in operation.

## 2.7. Analyzing Pressure Waveform Graphs

The T-TAS system calculates parameters with the following method from pressure waveform graphs obtained when performing measurement. The calculated parameters are displayed as measurement results, and saved to the dedicated computer.

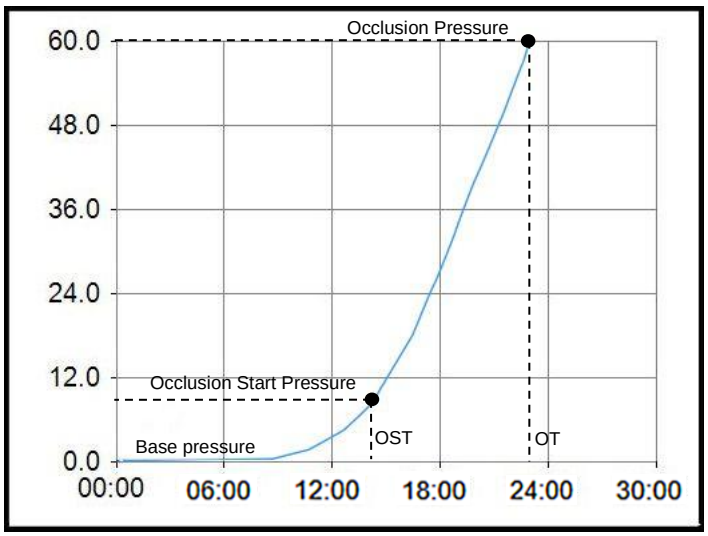



*Figure: 2.7-1*

■ PL chip

・Occlusion Start Pressure = Base pressure +10kPa
・Occlusion Pressure = Base pressure +60kPa

The terms in the above graph are defined as follows.
• The time at which the Occlusion Start Pressure is reached is known as the Occlusion Start Time (OST).
• The time at which the Occlusion Pressure is reached is known as the Occlusion Time (OT).
• The area below the response curve for the 10 minute period is known as AUC.

If the pressure waveform reaches the Occlusion Pressure within 10 minutes, the area below the response curve up to the point of arrival is added to the area for the remaining time with upper limit as the Occlusion Pressure, and the combined area is calculated as AUC.

## 2.8. List of Contents

The T-TAS 01 system contains the following (Table: 2.8-1).
Consumable parts and separately sold parts are not included. Refer to “11.1. List of Consumable Parts” and ”11.2. List of Separately Sold Items” and prepare separately.

*Table: 2.8-1*

| No. | Name | Quantity |
|---|---|---|
| 1 | Instrument | 1 |
| 2 | Oil-bottle (250 mL) (It is installed inside the instrument.) | 1 |
| 3 | Instrument AC adapter Identification mark: Green (incl. instrument AC adapter power cable) | 1 |
| 4 | Instrument USB cable | 1 |
| 5 | Dedicated computer | 1 |
| 6 | Computer AC adapter Identification mark: White (incl. computer AC adapter power cable) | 1 |
| 7 | Dedicated monitor | 1 |
| 8 | Monitor bottom plate | 1 |
| 9 | Monitor AC adapter Identification mark: Yellow | 1 |
| 10 | Monitor USB cable | 1 |
| 11 | VGA cable | 1 |
| 12 | Monitor rack | 1 |
| 13 | Knurled screw | 2 |
| 14 | Waste tube | 2 |
| 15 | SC Bar | 2 |
| 16 | Funnel | 1 |
| 17 | User's Manual | 1 |

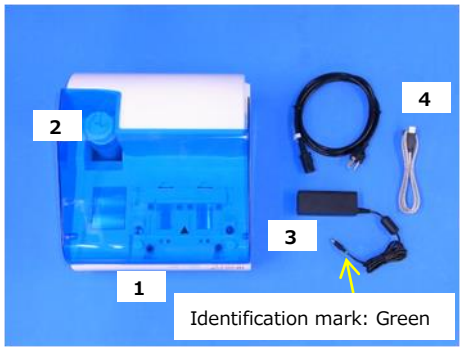



*Figure: 2.8-1*

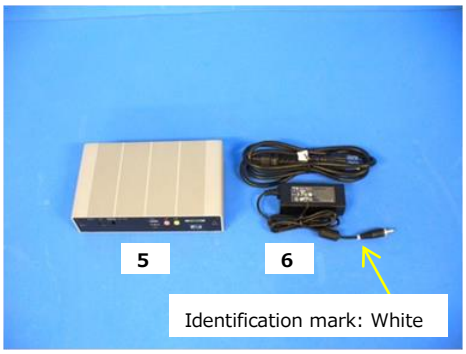



*Figure: 2.8-2*

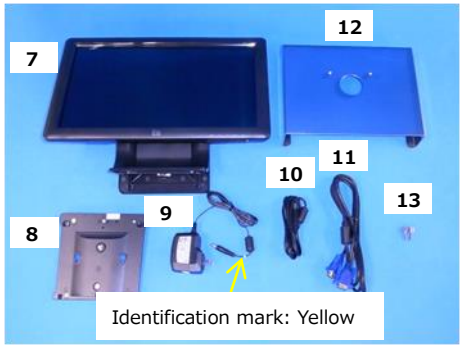



*Figure: 2.8-3*

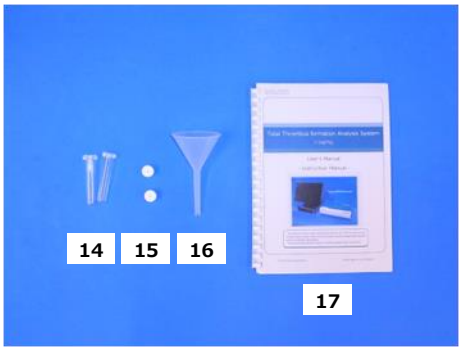



*Figure: 2.8-4*

## 2.9. Specifications

| ⚠ CAUTION | |
|---|---|
| | If the temperature at which the system has been installed is within the storage temperature range but outside the operating temperature limits, leave the system for a while, and allow it to adapt to the operating temperature (20℃ to 30℃) before use.<br>For reference: If the system is stored at 15℃, the approximate time that the system becomes stable is 30 minutes. |
| | The storage temperature condition varies between the instrument and the mineral oil.<br>Refer to "11.1. List of Consumable Parts"(Table: 11.1-1) for details on the storage temperature condition for the mineral oil. |

The instrument specifications are as follows (Table: 2.9-1).

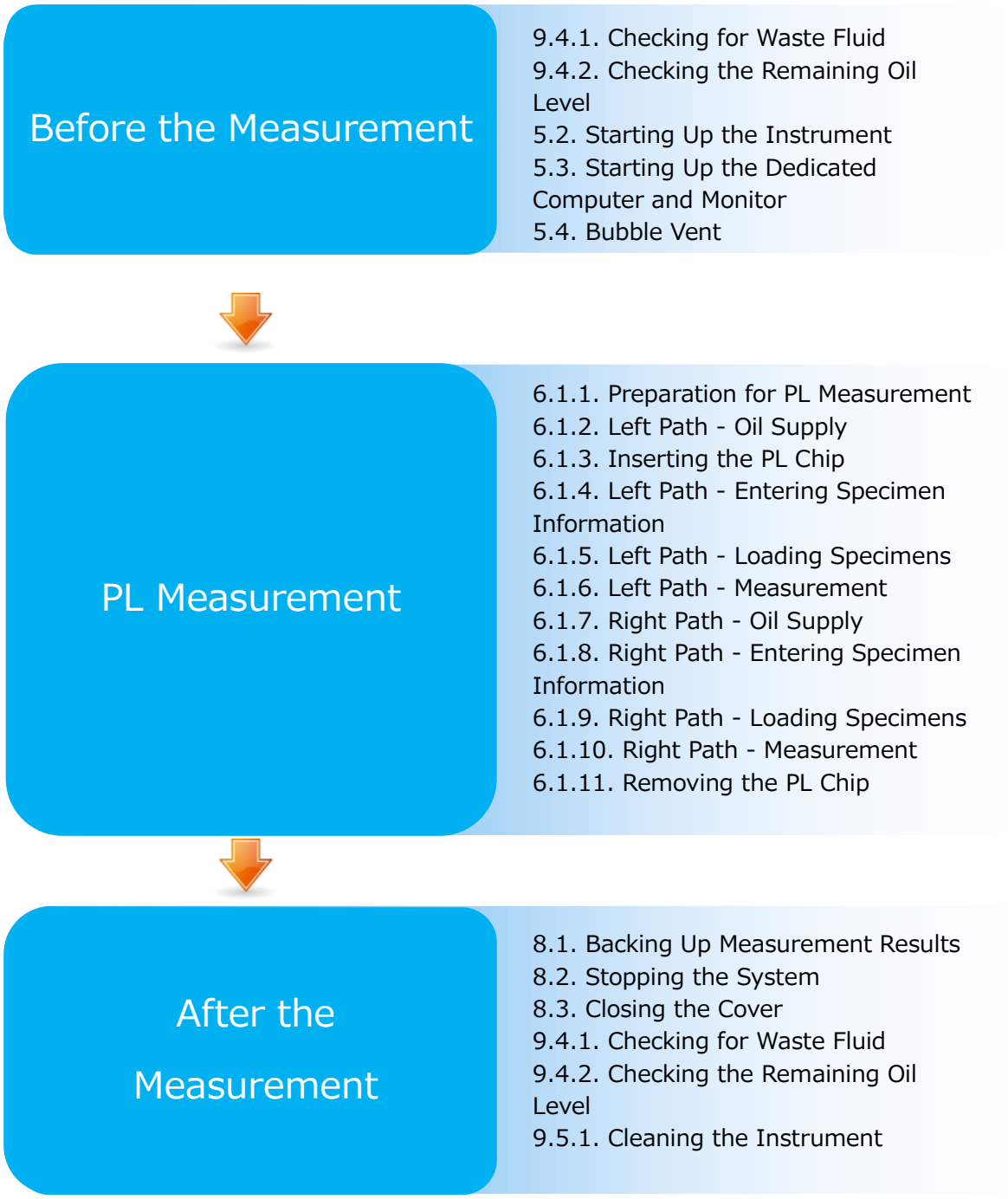
*Table: 2.9-1*

| No. | Item | Description |
|---|---|---|
| 1 | Product name | T-TAS®01 Total Thrombus formation Analysis System |
| 2 | Model name | T-TAS 01-1 |
| 3 | Rated voltage | AC Adaptor: 100 to 240 VAC 50/60Hz<br>Instrument: DC 12V (3.5A) |
| 4 | Power supply voltage variation | ±10% |
| 5 | Power supply transient overvoltage | Category II |
| 6 | Rated power consumption | 42W or less * |
| 7 | Dimensions | 320(W)×247(H)×360(D)mm |
| 8 | Weight | 6.0kg |
| 9 | Pressure detection range | -60kPa to 200 kPa |
| 10 | Storage temperature | 5°C to 50°C<br>Packing condition |
| 11 | Storage humidity | 10% to 90%. There should be no condensation.<br>Packing condition |
| 12 | Operating temperature | 20°C to 30°C |
| 13 | Operating humidity | 20% to 80%. There should be no condensation. |
| 14 | Operating altitude | Below 2,000 m |
| 15 | Rated contamination level | Contamination level II |
| 16 | Product safety standards | EN61010-1 A1:2019, IEC61010-1 A1:2016,<br>EN61010-2-101:2017, IEC61010-2-101:2018 |
| 17 | Electromagnetic compatibility standards | EN IEC61326-1: 2021 Class A,<br>EN IEC61326-2-6: 2021 Class A,<br>IEC 60601-1-2: 2014+AMD1:2020 (for120V) |
| 18 | Periodic replacement parts | None |
| 19 | Other | Restricted to indoor use |

* The rated power consumption for the entire system is 60W.

# 3. Operation Flow

The operation flow for performing measurement with this system is shown in the following diagrams. Ensure an overall understanding of this flow.
This flow involves measurement using a PL chip as an example.



# 4. Installation

Please ask qualified personnel to install the system.
Please contact Technical Support with any questions.

| ⚠ CAUTION | |
|---|---|
|  | Do not dispose of the packing boxes from which the system is removed at the time of delivery.<br>Use these packing boxes when transportation is necessary. |

## 4.1. Operating Environment

The system comprises the instrument, dedicated computer, and dedicated monitor. The total weight of this system is approximately 12 kg.
For installation of this system, prepare a workbench or a table which can support this weight and has a horizontal level with less vibration. In addition, to install this system and perform measurements, it requires a minimum benchtop space of 90 x 50 x 50 cm (width x depth x height). Please refer to chapter "1.3.1" for cautions and warnings for installation.

Use this system under the following (Table: 4.1-1) environmental conditions.

*Table: 4.1-1*

| Item | Condition |
|---|---|
| Place of use | Indoors |
| Operating temperature and humidity | Temperature: 20°C to 30°C<br>Relative humidity: 20% to 80% (there should be no condensation) |
| Altitude | Below 2,000 m |
| Power requirements | 100 to 240 VAC, 50/60Hz |
| Other | • The location should be free from powder or dust.<br>• The location should not be exposed to direct sunlight.<br>• The location should not be directly exposed to the air drafts from air conditioners or fans.<br>• There should be no chemicals, gas, or open flames nearby. |

## 4.2. "Supervisor" Account Password Setting

| ⚠ CAUTION | |
|---|---|
|  | Ensure that the user administrator manages the password for the "Supervisor" account. |

It is necessary to set a password for the "Supervisor" account that is used by the user administrator to sign in to the dedicated computer. When installing the system, ask qualified personnel to set a password. Furthermore, ask qualified personnel to reset the password if you forget it.

## 4.3. Wiring

Ask qualified personnel to perform electrical connections.
This system consists of the electrical equipment shown in the following diagram (Figure: 4.3-1).

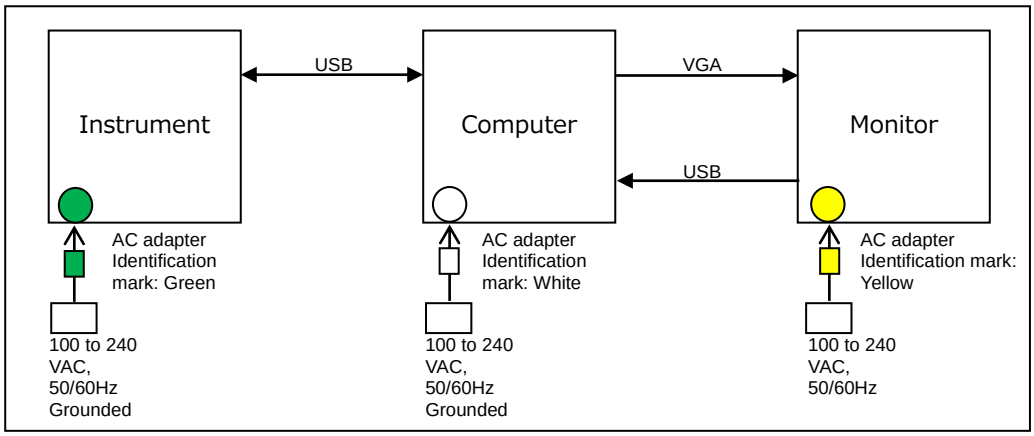



*Figure: 4.3-1*

| ⚠ WARNING | | |
|---|---|---|
| ❗ | Ensure a reliable ground connection for both the instrument and dedicated computer.<br><br>There is a risk of fire, electric shock, or burns. | |
| | Connect this system to an easily accessible AC outlet. | |
| 🚫 | Do not connect a power cable or AC adapter other than those provided with the system to the instrument. | |
| **⚠ CAUTION** | | |
| 🚫 | Do not connect other than the specified devices or cables to the dedicated computer.<br>There is a risk of malfunction. | |
| | Do not connect a USB hub to the dedicated computer USB port.<br>There is a risk of malfunction. | |
| ❗ | Run a virus check on USB flash drives connected to the dedicated computer to verify safety before use. | |

# 5. Before the Measurement

## 5.1. Registering the Operator ID

The measurement software checks the registered Operator ID, as well as the Operator ID entered when performing measurement. It will not be possible to perform measurement operations if the IDs fail to match.
The ID registration procedure is shown in “9.3.3. [Operator ID] Tab”. It is necessary to sign in with the "Supervisor" account to perform this procedure.

## 5.2. Starting Up the Instrument

Open the cover, and turn ON (Figure: 5.2-2) the power switch on the left side of the instrument.

*Figure: 5.2-1*

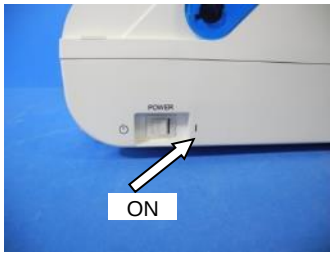



*Figure: 5.2-2*

## 5.3. Starting Up the Dedicated Computer and Monitor

a) Press the dedicated monitor and computer power switches once to turn them ON.

*Figure: 5.3-1*

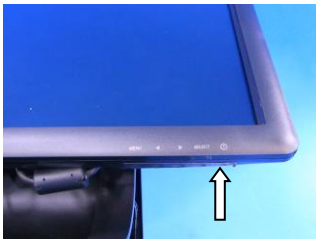


*Figure: 5.3-2*

b) The standby screen is displayed when the dedicated computer starts up.


*Figure: 5.3-3*

The dedicated computer date and time are adjusted by qualified personnel.
Contact Technical Support if the displayed date and time are incorrect.
If the measurement software was previously exited with the "Operator" account, sign-in will automatically be performed with the same account, and the measurement software startup screen will immediately be displayed.

c) Sign-in

Swipe up on the standby screen (Figure: 5.3-4 Standby screen) to display the "Sign-in" screen (Figure: 5.3-5 "Sign-in" screen).

When you swipe, please touch the lower part of the screen with one finger for about two seconds, then quickly sweep it up on the screen.

The order in which accounts are displayed will change based on the previous sign-out order.


*Figure: 5.3-4 Standby screen*


*Figure: 5.3-5 "Sign-in" screen*

If the measurement software was previously exited with an account other than "Operator", or the user signs in again after signing out, it will be necessary to select the "Operator" account at the "Sign-in" screen to sign in.

Even if signed in with the "Supervisor" account, select the "Supervisor" account at the "Sign-in" screen to sign in.

When signing in with the "Supervisor" account.

1. If the touch keyboard for password entry does not appear.

・Power off the dedicated monitor, and power on after waiting a couple of seconds.

・After the "Sign-in" screen appears, tap the password entry field to display the touch keyboard.


*Figure: 5.3-6*

2. If the [Password Reveal] button does not appear.

・Clear all of the password you entered. When you start entering password again, the [Password Reveal] button appears.


*Figure: 5.3-7*

d) T-TAS 01 measurement software startup

By signing in, the T-TAS 01 measurement software starts up, and the "HOME" screen is displayed.


*Figure: 5.3-8 Startup screen*

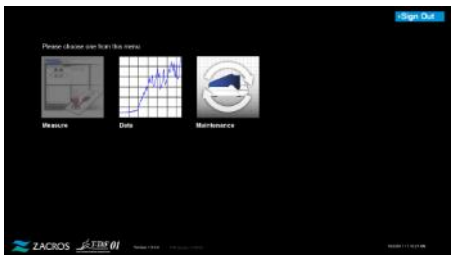



*Figure: 5.3-9 "HOME" screen*

e) T-TAS 01 instrument initialization

When the "HOME" screen is displayed, the instrument initializes automatically when the instrument power is ON.
When initialization is complete, the [Measure] button lights up, enabling the measurement option.

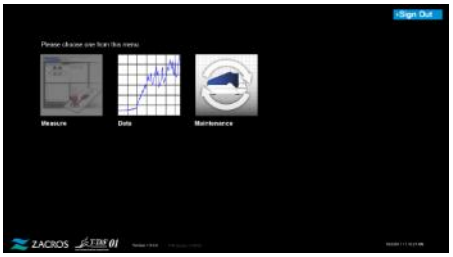



*Figure: 5.3-10*

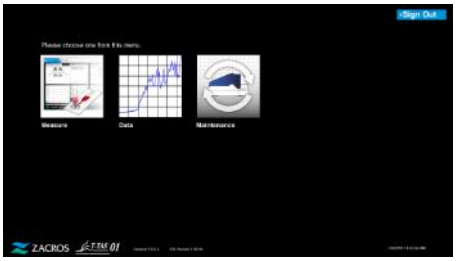



*Figure: 5.3-11*

When starting up for the first time each day, perform bubble vent after initialization is complete. (See next page.)

## 5.4. Bubble Vent

| ⚠ CAUTION | |
|---|---|
| | After starting up the system, perform bubble vent prior to the first measurement.<br>There is a risk of an error occurring if there are air bubbles in the tubing. |
| | Do not pull nozzles or tubing with force. Furthermore, do not pull nozzles out more than 165 mm (6.5 in). There is a risk of damage to tubing and connections. |

Perform the following operations to ensure that the mineral oil reaches the tips of the nozzles and eliminate any bubbles inside the tubing.

Prior to the bubble vent, perform "9.4.1. Checking for Waste Fluid" and "9.4.2. Checking the Remaining Oil Level ".

a) Place the CH1 and CH2 nozzles in the waste tubes.

*Figure: 5.4-1*

*Figure: 5.4-2*

b) Tap the [Maintenance] button to display the "Maintenance" screen.
If the [Measure] button or the name of the buttons on the "Maintenance "screen is grayed out, the measurement software does not recognize the instrument. Refer to "10. Troubleshooting".

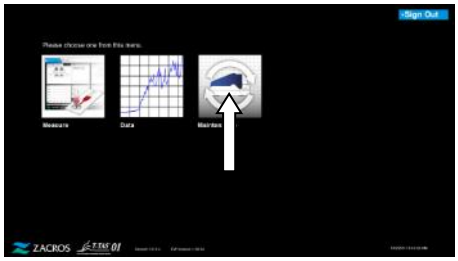


*Figure: 5.4-3*

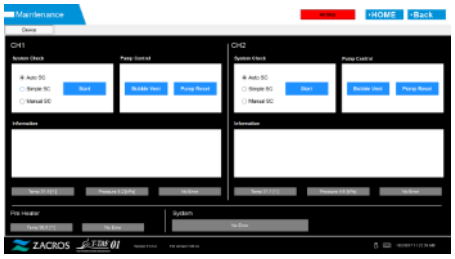


*Figure: 5.4-4*

c) Tap the CH1 and CH2 [Bubble Vent] buttons.

*Figure: 5.4-5*

*Figure: 5.4-6*

Ensure that the nozzles have been set in their waste tubes and tap the [OK] button. The Bubble vent procedure will begin. By performing the bubble vent procedure, air is expelled, and the inside of the tubing is filled with mineral oil.

# 6. Measurement

Prior to the measurement, perform "9.4.1. Checking for Waste Fluid" and "9.4.2. Checking the Remaining Oil Level ".

| ⚠ CAUTION | |
|---|---|
|  | Make sure the translucent connector and the nozzle are tightly connected. If they are loosely connected, hold the translucent connector and turn it clockwise to close tightly. |

a) Tap the [Measure] button on the “HOME” screen.

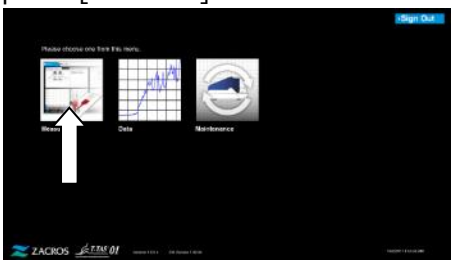


*Figure: 6-1*

b) The "Measurement menu" screen is displayed. Tap the [Chip] button for the type of measurement to be performed.

This menu displays only the buttons of items for which measurement is possible, and there are times when only a single button is displayed. There are 2 buttons in the following example (Figure: 6-2).

*Figure: 6-2*

| ⚠ WARNING | | |
|---|---|---|
|  | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. |  |
| | There is a risk of waste fluid, chip, reservoir, or Over-cap contamination. Dispose of as medical waste in accordance with local, state, and Federal regulations. |  |
| ⚠ CAUTION | | |
|  | Do not pull nozzles or tubing with force. Furthermore, do not pull nozzles out more than 165 mm (6.5 in). There is a risk of damage to tubing and connections. | |
| | Do not use consumable parts other than those specified in “11.1. List of Consumable Parts”. | |

| | |
|---|---|
| | Use consumable parts such as chips that have not exceeded their expiration dating. |

## 6.1. PL Measurement

| ⚠ CAUTION | |
|---|---|
| | Details on blood sample handling precautions and measurement results for PL measurement can be found in the instruction manual provided with the PL chip.<br><br>Read the chip instruction manual thoroughly before performing measurements. |

The chip for the PL measurement has left and right paths, which allows two blood samples to be measured. **The left path must be used first, followed by the right path.** It is not necessary to use both paths on a PL chip, but the order of the measurement cannot be reversed. (i.e. the left path cannot be used after the right path).
Before performing a PL chip measurement, ensure that the PL chip has reached room temperature.

### 6.1.1. Preparation for PL Measurement

By tapping the [PL Chip] button, the PL chip "Measurement" screen is displayed, and an auto SC starts if the system has just been started up. Mineral oil will be discharged from the nozzle tips. Set the nozzles in their waste tubes as instructed on the screen.

At times other than following startup, proceed to the next step.

The information on the left half of the "Measurement" screen is for CH1, and the information on the right half is for CH2.

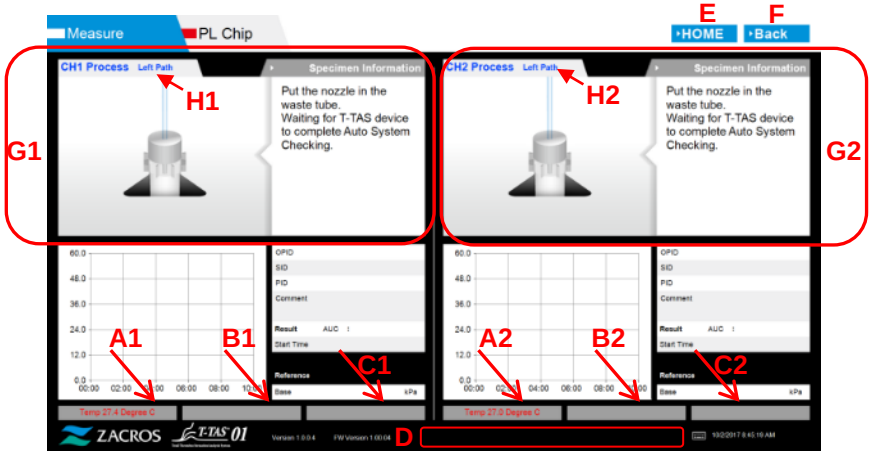



*Figure: 6.1-1*

*Table: 6.1-1*

| Symbol | Description |
|---|---|
| A1,A2 | Displays the CH1 and CH2 stage temperatures. |
| B1,B2 | Displays the CH1 and CH2 pressure when performing measurement. |
| C1,C2 | Displays the CH1 and CH2 error status. |
| D | Displays the pre-heater error status. |
| E | Displays the "HOME" screen. |
| F | Returns to the previous screen. |
| G1,G2 | Displays operation guidance for CH1 and CH2. |
| H1,H2 | Displays the channel and path during guidance.<br>* The character color for this section will be the same (blue, orange) as that of the path mark (L, R) on the instrument.<br>Use when performing a path check. |

### 6.1.2. Left Path - Oil Supply

Begin CH1 and CH2 oil supply. Mineral oil is discharged from the nozzle tips. Set the nozzles in their waste tubes as instructed on the screen.

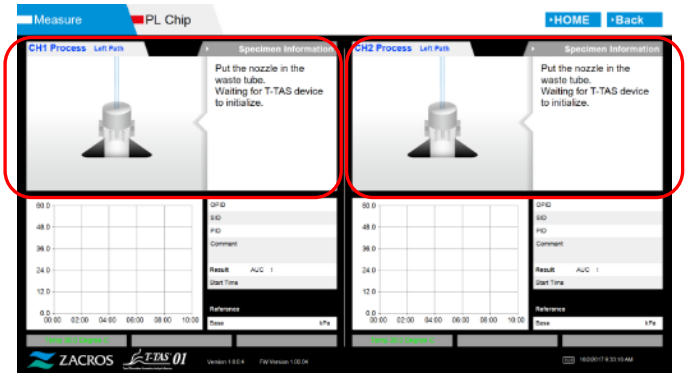



*Figure: 6.1-2*

### 6.1.3. Inserting the PL Chip

a) When oil supply is complete, a guidance screen requesting chip insertion is displayed.

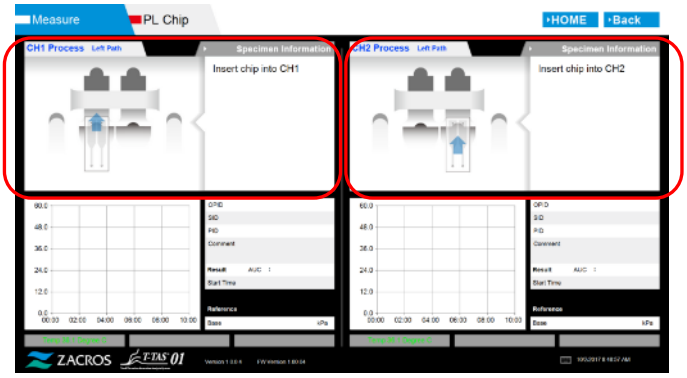



*Figure: 6.1-3*

b) Insert the PL chip to the back (see position indicated by broken line in lower right image (Figure: 6.1-6)) of the stage for the channel to be measured.

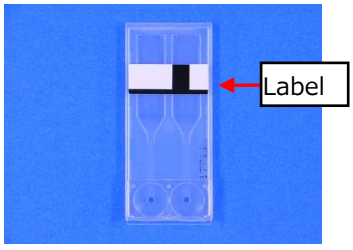



*Figure: 6.1-4*

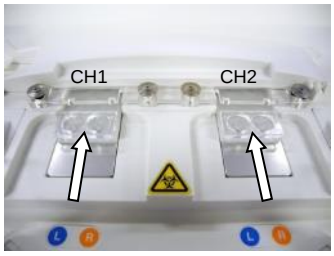



*Figure: 6.1-5*

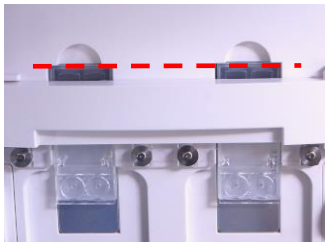


*Figure: 6.1-6*

*If the "Heating" screen or "Specimen information" entry screen is not displayed, this means the chip is not detected properly.
Please use the following procedure to recover the system.
(1) Remove the chip.
(2) Check the chip label condition. Wipe out smudge from the label if possible, and if it is unable to improve the label condition due to wear or other causes, replace the chip with another one.
(3) Clean the chip-code reader.
Refer to “9.5.1. Cleaning the Instrument” for the procedure.

(4) In accordance with the instructions on the screen, insert the chip straight to the back.
(5) Contact Technical Support if the same error occurs repeatedly.

> **Tips!**
>
> Placing the chip on the pre-heater to heat it up beforehand reduces the heating time required following chip insertion.
> The pre-heater is kept at 36°C constantly while the instrument power is ON.

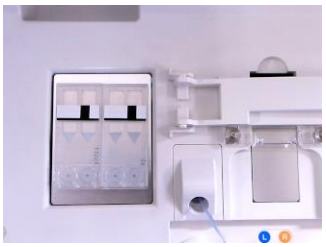


*Figure: 6.1-7 Pre-heater*

c) Heating begins when the PL chip is inserted. It takes several minutes for the temperature to stabilize.

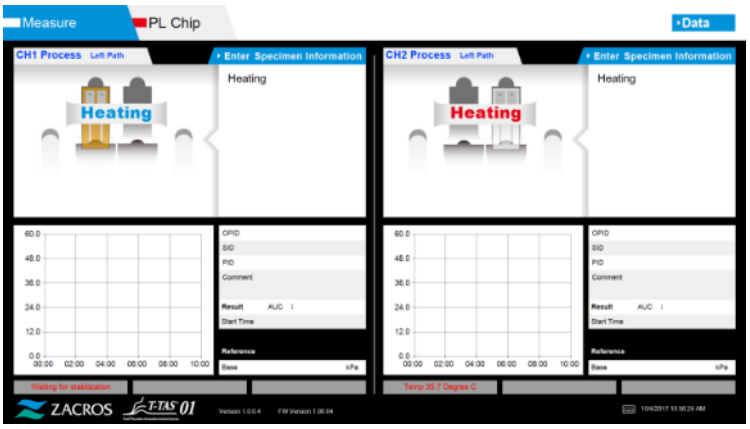


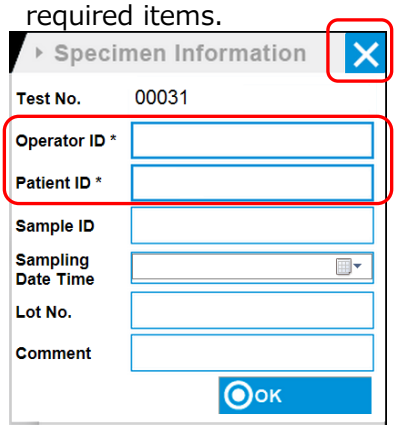

*Figure: 6.1-8*

### 6.1.4. Left Path - Entering Specimen Information

a) When heating is complete, "Specimen Information" for the left path is automatically displayed.
Also, by tapping the [Enter Specimen Information] button for the applicable channel during heating, "Specimen Information" can be also displayed.
If not using the left path, tap the [X] button (see Figure: 6.1-10) on the right of the "Specimen Information". Tap the [Yes] button at the exit confirmation screen to proceed to "6.1.7. Right Path - Oil Supply".


*Figure: 6.1-9*

b) "Specimen information" screen is displayed. Items with an asterisk (*) are required items.




Character limit

Max. number of characters: Up to 100 characters for comments, 30 characters for other
Prohibited characters: "," (commas) and pictographs.
If ","(comma) is entered, it is converted into " "(space).

*Figure: 6.1-10*

Test No. is automatically assigned.
A test result identification number is displayed in the Test No. box. When the date changes, numbers starting from 00001 are automatically assigned (Up to 999999).
This number cannot be changed.

*Table: 6.1-2*

| Specimen Info. Item | Description | Entry |
|---|---|---|
| Test No. | Numbers used by the instrument to identify test results. | Automatic |
| Operator ID | Operator ID number | Required |
| Patient ID | Patient ID number | Required |
| Sample ID | Specimen ID number | Optional |
| Sampling Date Time | Blood sampling date and time | Optional |
| Lot No. | Chip lot number | Optional |
| Comment | Remarks field | Optional |

c) Tap the items to be entered. If the keyboard is not displayed, it can be displayed by tapping the [Keyboard] icon in the lower right of the screen.

- Enter a number for the Operator ID that has been registered by the Supervisor. Measurement will not be possible if no Operator ID has been registered.

- The date for the Sampling Date Time is selected using the calendar icon, however, the current time is displayed for the time. Correct the current value to the correct time of blood sampling.

- If the chip is removed after entering specimen information, the system treats the chip as a new one even if the same chip is reinserted. Re-enter by entering specimen information again. However, as there is a risk of confusing chips or of contaminating specimens, reinserting chips that have already been inserted is not recommended.

d) After information entry is complete, tap the [OK] button to decide the specimen information. When you tap the [OK] button, a guidance about the specimen loading appears at the upper side of the screen. (Loading of specimens is explained in 6.1.5).At the lower part of the screen, the specimen information is displayed. But if the number of characters describing the specimen information is large, characters exceeded the limit are not displayed.

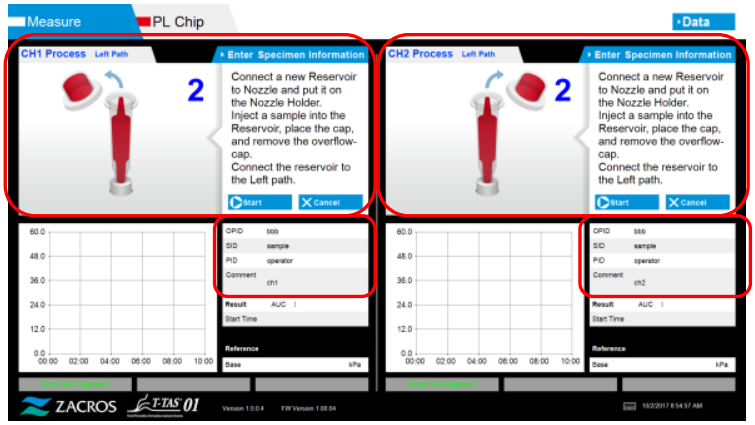



*Figure: 6.1-11*

## 6.1.5. Left Path - Loading Specimens

a) After entry of specimen information is complete, the description of specimen loading is displayed.

* "Over-cap removal" and "Reservoir insertion" pictures are displayed repeatedly at the guidance screen (Figure: 6.1-12 below), however, the numbers 1, 2, 3 and 4 are displayed in the upper right of the images, and therefore operation guidance should be viewed in order from 1.

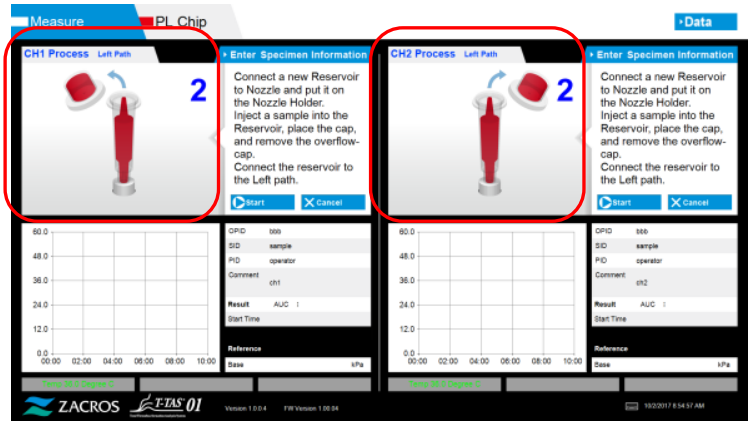



*Figure: 6.1-12*

b) Wipe up only the mineral oil adhering to the area around the nozzle while taking care not to soak up any of the mineral oil filled up to the nozzle tip.

Place the nozzle in the nozzle holder for the applicable channel. Store the tube inside the nozzle holder. Insert the reservoir into the nozzle.

*Figure: 6.1-13*

c) Gently fill the reservoir with 300 to 330 µL of anticoagulated whole blood (see PL chip package insert for suitable anticoagulants) while ensuring that the blood does not contain any air bubbles.

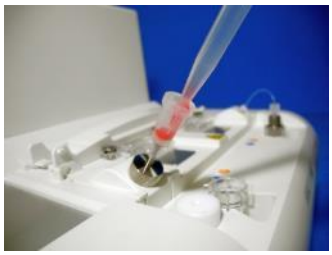


*Figure: 6.1-14*

*Figure: 6.1-15*

d) Close the reservoir with the reservoir cap with Over-cap. Push in firmly from above, and allow any excess blood to spill over into the Over-cap. When doing so, ensure that there are no gaps between the reservoir and the reservoir cap and Over-cap.

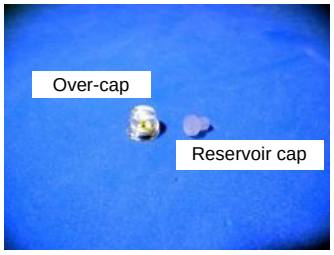



*Figure: 6.1-16*

*Figure: 6.1-17*

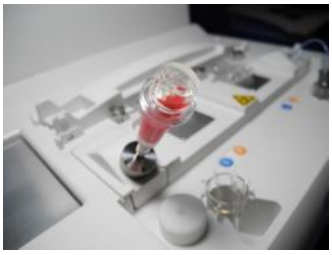


*Figure: 6.1-18*

| ⚠ WARNING | | |
|---|---|---|
| | If the amount of the blood in the reservoir is too much, the blood may spill out when you close the cap. | |

e) Remove the Over-cap only. Dispose of the removed Over-cap appropriately as infectious waste.

*Figure: 6.1-19*

f) Insert the reservoir into the **left side** of the chip insertion slot (with support ring) until you feel resistance. Ensure that the chip and reservoir have been set with no gaps.

*Figure: 6.1-20*

*Figure: 6.1-21*

g) Tap the [Start] button to begin left path measurement.

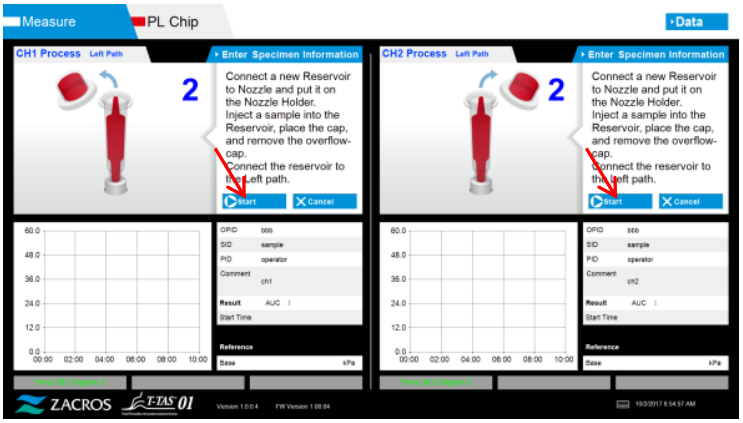



*Figure: 6.1-22*

### 6.1.6. Left Path - Measurement

a) A smoothed pressure graph is displayed on the screen during measurement.

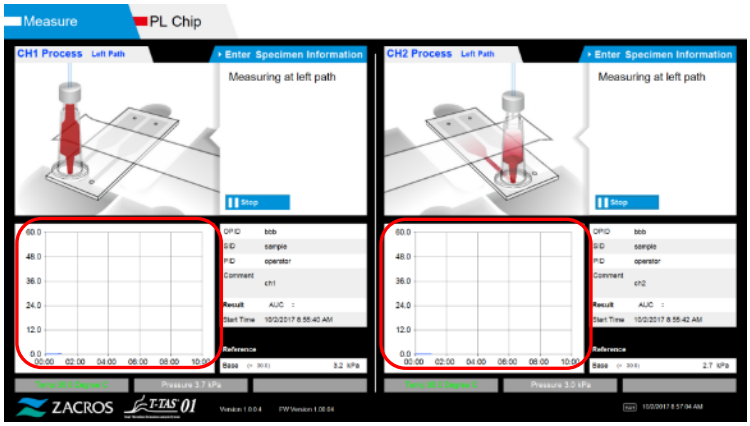



*Figure: 6.1-23*

b) Measurement is completed when either of the following conditions are met:

- If the pressure value prior to smoothing reaches the stipulated value (60kPa when performing PL measurement)

  * The graph shows smoothed values, and therefore it may appear as if the value has not reached 60kPa.

- If the stipulated time (10 minutes for PL measurement) has elapsed since the start of measurement

c) A message and results are displayed when measurement is complete. Tap the [OK] button. Measurement results are saved in the dedicated computer.

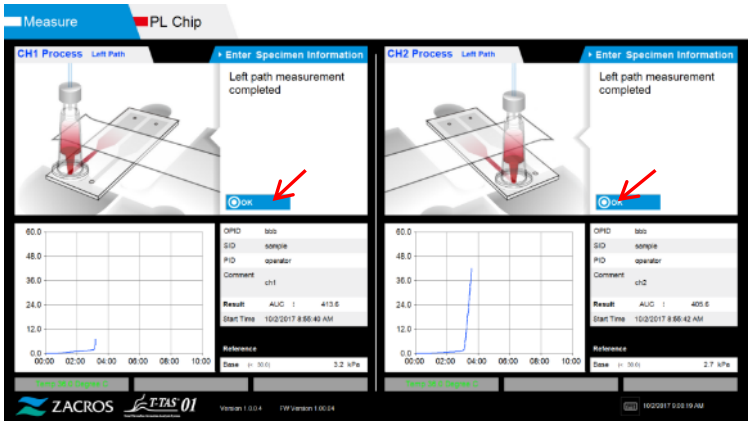



*Figure: 6.1-24*

d) When "Remove the reservoir from the chip..." is displayed on the screen, remove the reservoir from the chip. Ensure that the chip does not fall from the instrument when doing so.

| ⚠ WARNING | | |
|---|---|---|
| | Remove the reservoir from the chip with care.<br>There is a possibility that blood remaining inside the reservoir may leak out. | |

* "Reservoir removal" and "Nozzle insertion" pictures are displayed repeatedly, however, the numbers 1, 2, 3 and 4 are displayed in the upper right of the images, and therefore operation guidance should be viewed in order from 1.

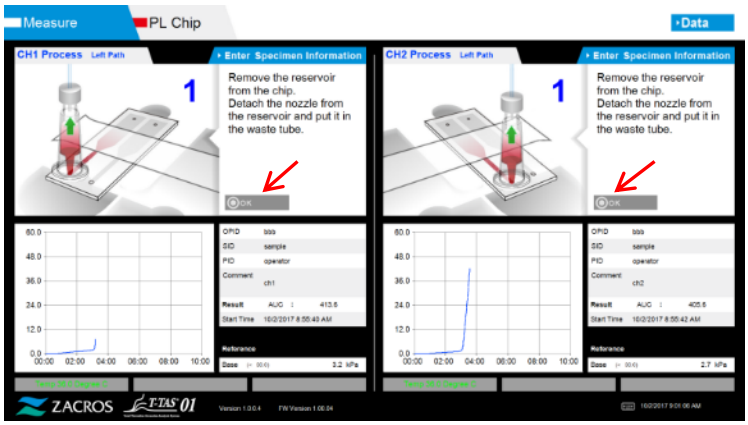



*Figure: 6.1-25*

Next, turn the reservoir horizontally and then remove it from the nozzle (Figure: 6.1-26, Figure: 6.1-27). Insert the nozzle in the waste tube. Dispose of the removed reservoir appropriately as infectious waste.

Figure: 6.1-26

Figure: 6.1-27

| WARNING | | |
|---|---|---|
| | Remove the reservoir from the nozzle with care.<br>There is a possibility that blood remaining inside the reservoir may leak out. | |

* Record the on-screen results from the time left path measurement is complete until this point.
  The results display is cleared when the next operation is performed. Next, carry out a check at the "Data display" screen.

Tap the [OK] button. Exit the results display and prepare for right path measurement.

Refer to “6.1.8. Right Path - Entering Specimen Information” for details on the procedure for completing measurement for the left path only.

### 6.1.7. Right Path - Oil Supply

Begin CH1 and CH2 oil supply. Mineral oil is discharged from the nozzle tips. Set the nozzles in their waste tubes as instructed on the screen.

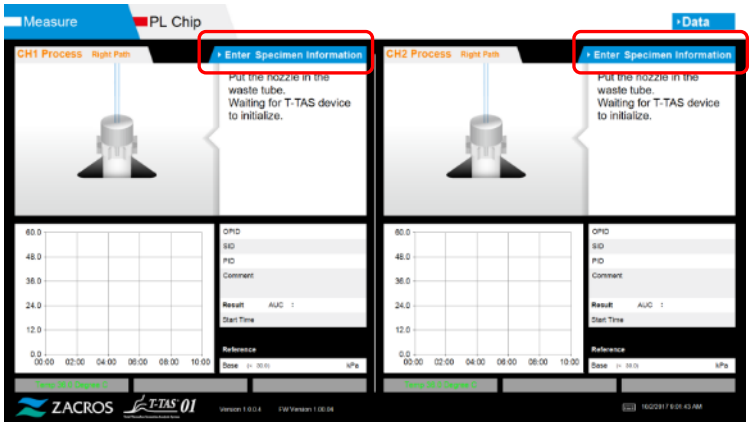
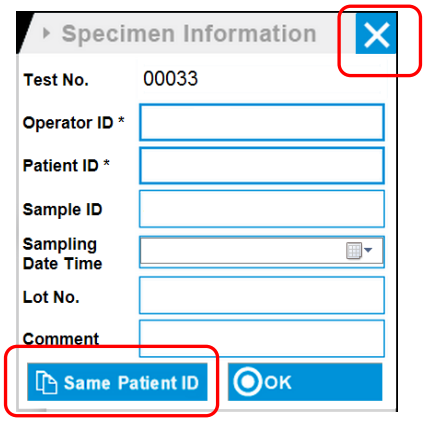



Figure: 6.1-28

### 6.1.8. Right Path - Entering Specimen Information

a) When oil supply is complete, "Specimen Information" screen for the right path is automatically displayed.
"Specimen Information" is also displayed by tapping the [Enter Specimen Information] button for the applicable channel.
If not using the right path, tap the [X] button (see Figure: 6.1-29) on the right of the "Specimen Information". Tap the [Yes] button at the exit confirmation screen to proceed to "6.1.11. Removing the PL Chip".

b) "Specimen information" screen is displayed. Items with an asterisk (*) are required items.




Character limit

Max. number of characters: Up to 100 characters for comments, 30 characters for other
Prohibited characters: "," (commas) and pictographs.
If ","(comma) is entered, it is converted into " "(space).

*Figure: 6.1-29*

Test No. is automatically assigned.
A test result identification number is displayed in the Test No. box. When the date changes, numbers starting from 00001 are automatically assigned (Up to 999999).
This number cannot be changed.

*Table: 6.1-3*

| Specimen Info. Item | Description | Entry |
|---|---|---|
| Test No. | Numbers used by the instrument to identify test results. | Automatic |
| Operator ID | Operator ID number | Required |
| Patient ID | Patient ID number | Required |
| Sample ID | Specimen ID number | Optional |
| Sampling Date Time | Blood sampling date and time | Optional |
| Lot No. | Chip lot number | Optional |
| Comment | Remarks field | Optional |

c) Tap the items to be entered. If the keyboard is not displayed, it can be displayed by tapping the [Keyboard] icon in the lower right of the screen. By tapping the [Same patient ID] button, the Patient ID and Lot No. entered in the left path are copied.

- Enter a number for the Operator ID that has been registered by the Supervisor. Measurement will not be possible if no Operator ID has been registered.
- The date for the Sampling Date Time is selected using the calendar icon, however, the current time is displayed for the time. Correct the current value to the correct time of blood sampling.

- If the chip is removed after entering specimen information, the system treats the chip as a new one even if the same chip is reinserted. Re-enter by entering specimen information again. However, as there is a risk of confusing chips or of contaminating specimens, reinserting chips that have already been inserted is not recommended.

d) After information entry is complete, tap the [OK] button to decide the specimen information. When you tap the [OK] button, a guidance about the specimen loading appears at the upper side of the screen. (Loading of specimens is explained in 6.1.9).
At the lower part of the screen, the specimen information is displayed. But if the number of characters describing the specimen information is large, characters exceeded the limit are not displayed.

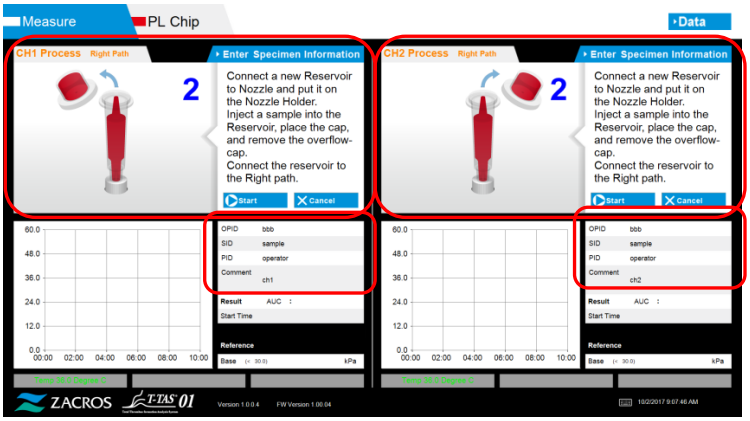



*Figure: 6.1-30*

### 6.1.9. Right Path - Loading Specimens

a) After entry is complete, the description of specimen loading is displayed.

* "Over-cap removal" and "Reservoir insertion" pictures are displayed repeatedly at the guidance screen (Figure: 6.1-31 below), however, the numbers 1, 2, 3 and 4 are displayed in the upper right of the images, and therefore operation guidance should be viewed in order from 1.

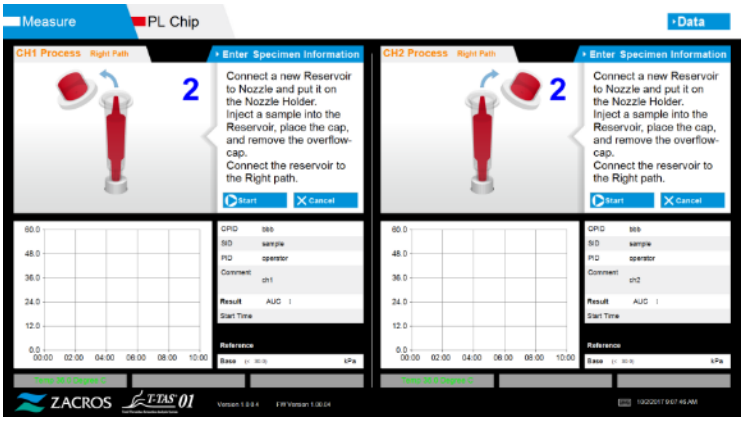



*Figure: 6.1-31*

b) Wipe up only the mineral oil adhering to the area around the nozzle while taking care not to soak up any of the mineral oil filled up to the nozzle tip.

Place the nozzle in the nozzle holder for the applicable channel. Store the tube inside the nozzle holder. Insert the reservoir into the nozzle.

*Figure: 6.1-32*

c) fill the reservoir with 300 to 330 µL of anticoagulated whole blood (see PL chip package insert for suitable anticoagulants) while ensuring that the blood does not contain any air bubbles.

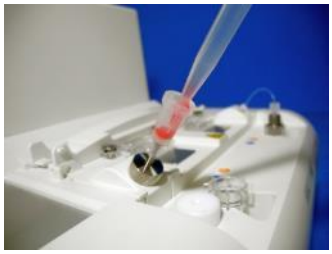


*Figure: 6.1-33*

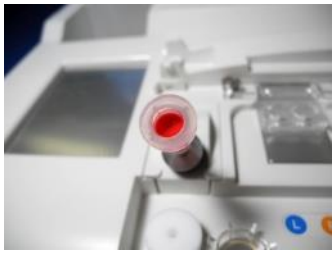


*Figure: 6.1-34*

d) Close the reservoir with the reservoir cap with Over-cap. Push in firmly from above, and allow any excess blood to spill over into the Over-cap. When doing so, ensure that there are no gaps between the reservoir and the reservoir cap and Over-cap.

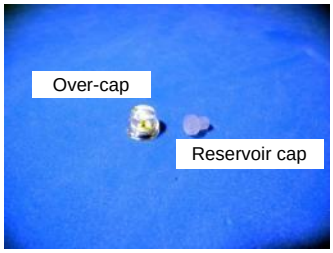



*Figure: 6.1-35*

*Figure: 6.1-36*

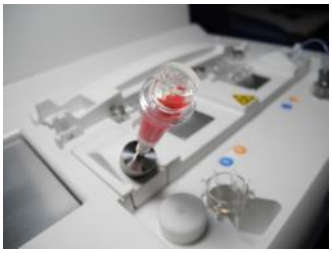


*Figure: 6.1-37*

| ⚠ WARNING | | |
|---|---|---|
| | If the amount of the blood in the reservoir is too much, the blood may spill out when you close the cap. | |

e) Remove the Over-cap only. Dispose of the removed Over-cap appropriately as infectious waste.

*Figure: 6.1-38*

f) Push the reservoir into the **right side** of the chip insertion slot (with support ring) until you feel resistance. Ensure that the chip and reservoir have been set with no gaps.

*Figure: 6.1-39*

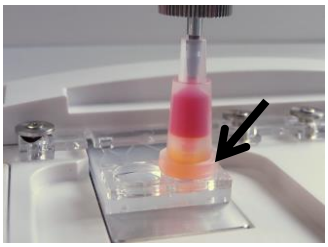


*Figure: 6.1-40*

g) Tap the [Start] button to begin right path measurement.

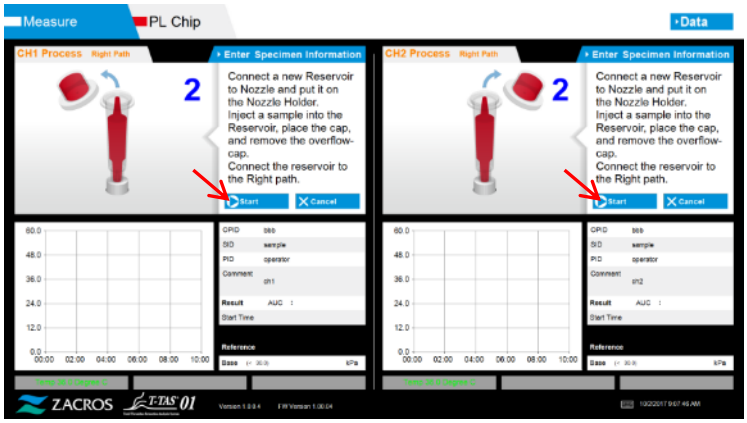



*Figure: 6.1-41*

## 6.1.10. Right Path - Measurement

a) A smoothed pressure graph is displayed on the screen during measurement.

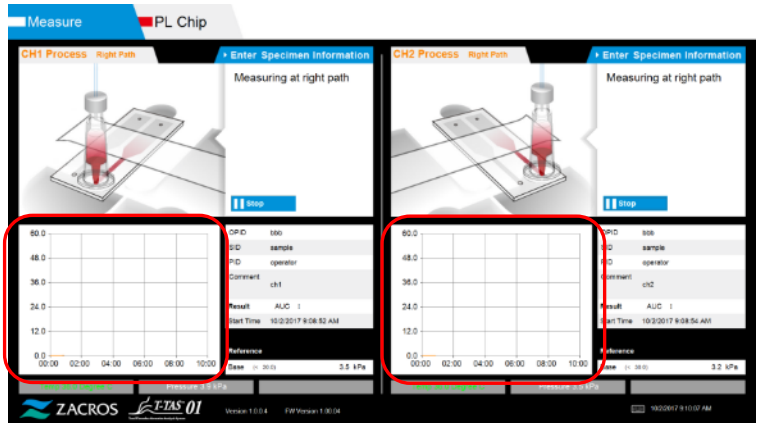



*Figure: 6.1-42*

b) Measurement is completed when either of the following conditions are met:

- If the pressure value prior to smoothing reaches the stipulated value (60kPa when performing PL measurement)
  * The graph shows smoothed values, and therefore it may appear as if the value has not reached 60kPa.
- If the stipulated time (10 minutes for PL measurement) has elapsed since the start of measurement

c) A message and results are displayed when measurement is complete.
Tap the [OK] button. Measurement results are saved in the dedicated computer.

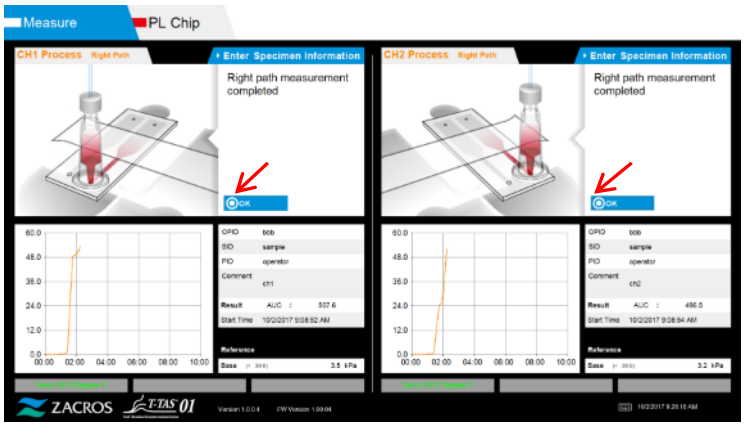



*Figure: 6.1-43*

d) When "Remove the reservoir from the chip..." is displayed on the screen, remove the reservoir from the chip. Ensure that the chip does not fall from the instrument when doing so.

| WARNING | | |
|---|---|---|
| | Remove the reservoir from the chip with care.<br>There is a possibility that blood remaining inside the reservoir may leak out. | |

* "Reservoir removal" and "Nozzle insertion" pictures are displayed repeatedly, however, the numbers 1, 2, 3 and 4 are displayed in the upper right of the images, and therefore operation guidance should be viewed in order from 1.

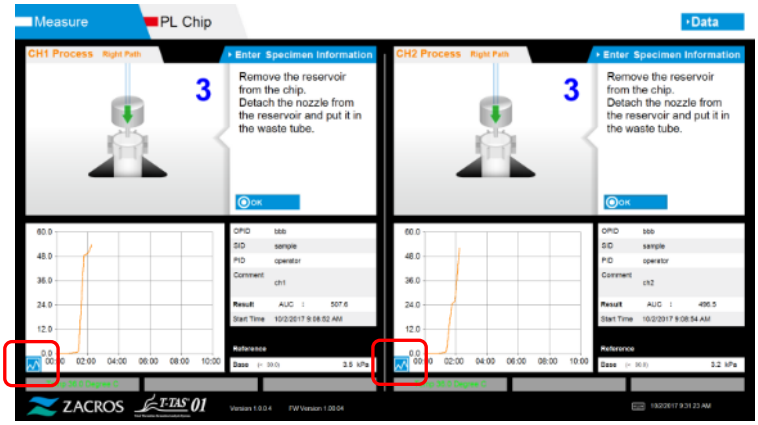



*Figure: 6.1-44*

* By tapping the graph display change button (see Figure: 6.1-45 below) displayed in the lower left corner of the graph following right path measurement, the graph display can be changed between "1 path" and a "superimposed graph of the left and right paths".

*Figure: 6.1-45*

Next, turn the reservoir horizontally and then remove it from the nozzle (Figure: 6.1-46, Figure: 6.1-47). Insert the nozzle in the waste tube. Dispose of the removed reservoir appropriately as infectious waste.

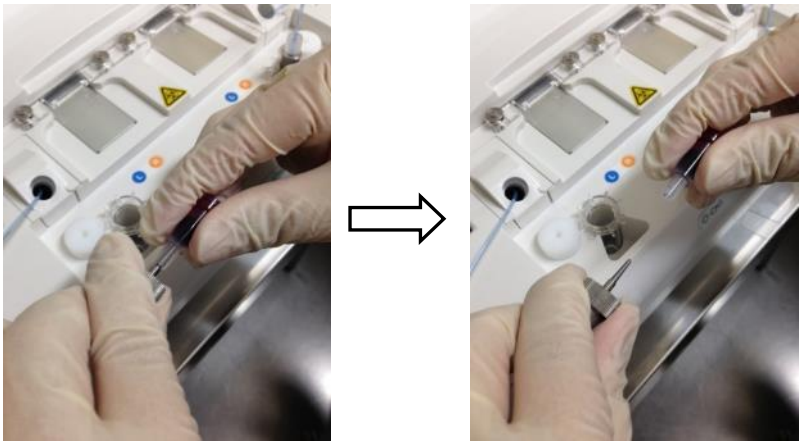


*Figure: 6.1-46*

*Figure: 6.1-47*

| ⚠ WARNING | | |
|---|---|---|
| | Remove the reservoir from the nozzle with care.<br>There is a possibility that blood remaining inside the reservoir may leak out. | |

Next, tap the [OK] button.

### 6.1.11. Removing the PL Chip

a) Remove the chip from the applicable stage as instructed in "Remove chip from CH*".
Dispose of the used chip appropriately as infectious waste.

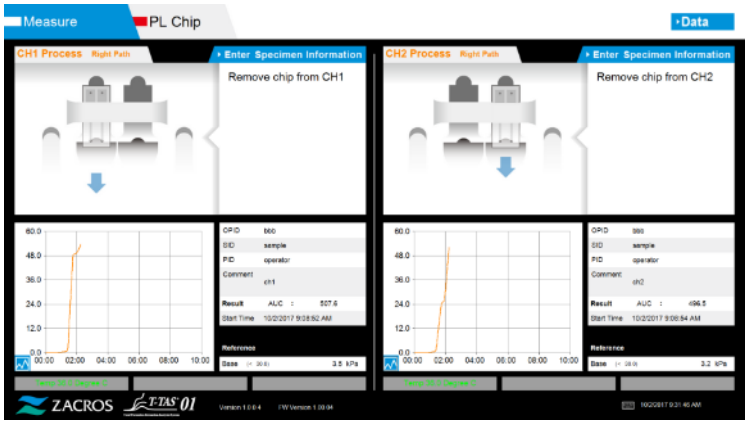



*Figure: 6.1-48*

b) Chip measurement is now complete.

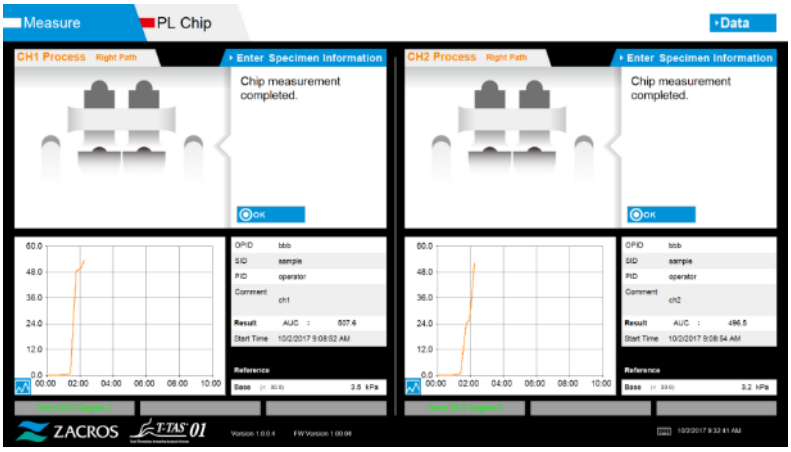



*Figure: 6.1-49*

* Record the screen results in the inspection report from the time right path measurement is complete until this point.
  The results display is cleared when the next operation is performed. Next, carry out a check at the "Data display" screen.

Tap the [OK] button to exit the results display and prepare for the next measurement.

# 7. “Data display” Screen

The measurement results saved to the dedicated computer can be displayed at the "Data display" screen.
Tap the [Data] button on the "HOME" screen to display the "Data display" screen.

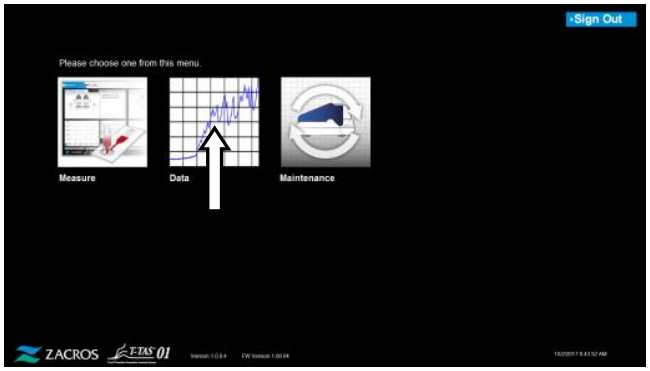



*Figure: 7-1*

## 7.1. Data List Display

Data saved to the dedicated computer is displayed at the "Data display" screen.

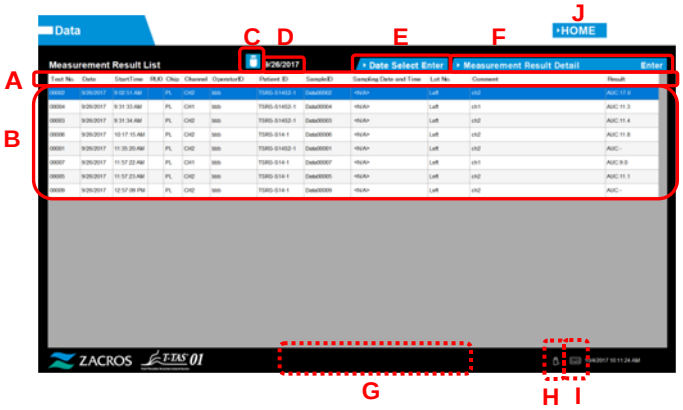



*Figure: 7.1-1*

*Table: 7.1-1*

| Symbol | Item | Description |
|---|---|---|
| A | Display item | Displays items displayed in the data list.<br>By tapping a display item, items are sorted with that item as the reference.<br>*In is not possible to sort by the RUO column.<br>Refer to the following table(Table: 7.1 2) for details on each display item. |

| Symbol | Item | Description |
|---|---|---|
| B | Data list | Displays a list of data measured on the same day.<br>The measurement date of the shown data is displayed in "D".<br>When a large number of characters is entered for specimen information, it is not possible for the data list to show all the characters entered.<br>To display the rest part of the specimen information which is not shown, tap any data to select, and tap the [Measurement Result Detail Enter] button to display the details. |
| C | [Backup] button  | By tapping the [Backup] button when it is blue, the backup begins.<br>Blue: Backup preparation complete<br>Gray: Backup not possible (no USB flash drive has been inserted, or data has not been selected during the backup) |
| D | Data display date | Displays the measurement date in the data display. |
| E | [Date Select Enter] button | The date for which the data list is displayed can be selected.<br>By tapping this button, a list of dates on which data has been saved appears. By tapping a date in the list, measurement data for that date is displayed in a list. |
| F | [Measurement Result Detail Enter] button | After tapping the data to be displayed in detail in the data list to select it, tap the [Measurement Result Detail Enter] button to display detailed results. |
| G | Message display area | Messages relating to the backup of measurement results are displayed. |
| H | [USB] icon  | When the measurement software recognizes the USB flash drive, an icon appears.<br>By tapping this icon before removing the USB flash drive, the drive can be safely removed. |
| I | [Keyboard] icon  | By tapping the icon, a keyboard is displayed on the screen. |
| J | [HOME] button | Displays the "HOME" screen. |

*Table: 7.1-2*

| Display item | Display item description | Modification possible/not possible |
|---|---|---|
| Test No. | Numbers used by the instrument to identify test results. | Not possible |
| Date | Measurement date | Not possible |
| Start Time | Measurement start time | Not possible |
| RUO | Research application measurement (measurement for other than medical application) mark field | Not possible |
| Chip | Measured chip | Not possible |
| Channel | Measurement channel | Not possible |
| Operator ID | Operator ID number (entered as specimen information) | Not possible |
| Patient ID | Patient ID number (entered as specimen information) | **Possible** |
| Sample ID | Specimen ID number (entered as specimen information) | **Possible** |
| Sampling Date and Time | Blood sampling date and time (entered as specimen information) | **Possible** |
| Lot No. | Chip lot number (entered as specimen information) | Not possible |
| Comment | Remarks (entered as specimen information) | **Possible** |
| Result | Measurement results<br>If the warning mark appears next to the data, it means "Pressure decreasing [501]" was detected during the measurement.<br>For more details on "Pressure decreasing [501]", please refer to "10.2 Table: 10.2 1". | Not possible |

### 7.1.1. Backing Up Measurement Results

Only measurement results are backed up with this procedure. Pressure data is not saved.
To back up measurement results and pressure data, it is necessary to sign in with the "Supervisor" account and perform the backup procedure from the "Maintenance" screen.

a) By connecting a USB flash drive to the dedicated computer, the [Backup] button turns blue, and a [USB] icon appears in the lower right of the screen.

b) By tapping the [Backup] button in the top of the screen, measurement results for the displayed date can be saved to the USB flash drive.
The [Backup] button turns gray while the USB flash drive is being accessed.

c) When the [Backup] button turns back to blue, and “Backup to USB flash drive completed.” appears in the lower middle of the screen, successful backup is complete.
Tap the [USB] icon in the lower right of the screen and remove the USB flash drive from the dedicated computer after ensuring that the [USB] icon has disappeared.

If an error occurs during the backup, ”Backup to USB flash drive failed. [632]” appears in the lower middle of the screen.

d) Files to be backed up

- The destination folder for the measurement result:
  [ USB flash drive ] ¥T-TAS01¥MeasuredResult¥YYYYMMDD
- The name of the measurement result file:
  "YYYYMMDDHHMMSS"_"Chip type"_MeasuredResult"TestNumber".csv
  e.g.) PL measurement: 20181205143217_PL_MeasuredResult00001.csv
- Format of the measurement result file: The number of columns is six. Delimited by commas.
- Content of the measurement result file: Refer to the Table: 7.1-3.

*Table: 7.1-3*

| Row | Column [ 1 ] Item identification name | Column [ 2 ] to Column [ 6 ] |
|---|---|---|
| 1 | T-TAS, | CONDITION & RESULT,,,, |
| 2 | Blank | ,,,,, |
| 3 | CONDITION, | Blank or RUO,App Version,*.*.*.*,FW Version,*.**.** |
| 4 | Test No., | Test number,,,, |
| 5 | Start, Date, | Start date,,, |
| 6 | Start, Time, | Start time,,, |
| 7 | OperatorID, | ,Operator ID,,, |
| 8 | SampleID, | , Sample ID,,,*(Number of editing) |
| 9 | PatientID, | , Patient ID,,,*(Number of editing) |
| 10 | Lot No., | , Chip Lot number,,, |
| 11 | Sampling Date and Time, | Date and time of sample creation,,,*(Number of editing) |

| | | |
|---|---|---|
| 12 | Comment, | , Comment,,,*(Number of editing) |
| 13 | Abnormal Wave Form, | Abnormal waveform determination flag,,,, |
| 14 | RESULT, | ,,,, |
| 15 | Chip, | Type of Chip,,,, |
| 16 | Channel, | Measurement channel,,,, |
| 17 *1 | AUC(Area Under the Curve), | AUC (Area Under the Curve),,,, |
| | Occlusion Time, | Occlusion time, (hh:mm:ss),,, |
| 18 | Pressure, | Pressure at the end of the measurement, (kPa) ,,,, |

*1: Either is saved depending on the index of the qualitative judgment.

## 7.2. Displaying Data Details

By selecting the data and tapping the [Measurement Result Detail Enter] button, detailed results are displayed.

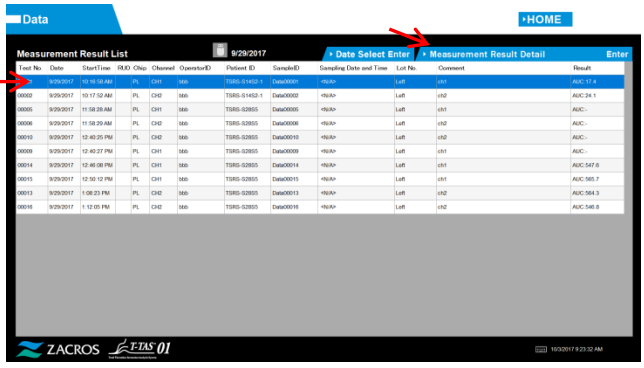



*Figure: 7.2-1*

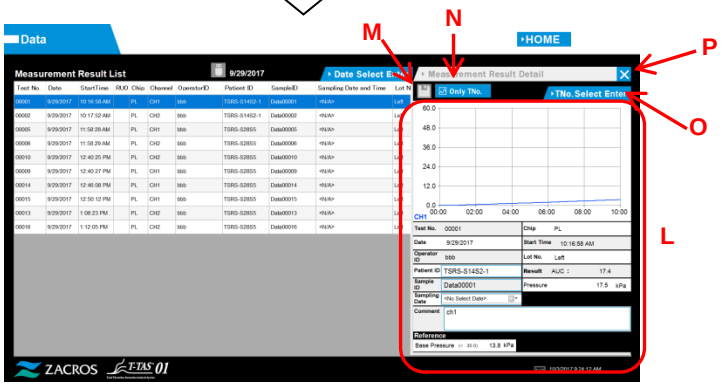
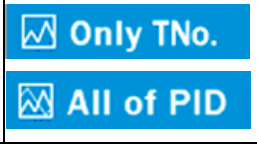



*Figure: 7.2-2*

*Table: 7.2-1*

| Symbol | Item | Description |
|---|---|---|
| L | Detailed results | Displays detailed results for the data selected from the data list. |
| M | [Save] button  | By tapping the blue [Save] button, the changed data is saved to the computer over the existing data.<br>Blue: Saving possible (data changes)<br>Gray: Saving not possible (no data changes) |
| N | [Superimposed graph display selection] buttons     | It is possible to superimpose and display measurement result graphs for the same Patient ID within the same measurement date (All of PID) or display individual measurement result graphs (Only TNo.).<br>The buttons displayed here show the selected condition. |

| Symbol | Item | Description |
|---|---|---|
| O | [TNo. Select Enter] button | Other Test Nos. for the same Patient ID within the same measurement date as that of the selected data are displayed in a list. Test Nos. for which detailed results are to be displayed can be selected from the list. |
| P | [X] | Close the detailed results. |

Of the detailed results displayed, Patient ID, Sample ID, Sampling Date, and Comment can be corrected. Tap the [Save] button following corrections to save.

When "Saving to Data drive completed." appears in the message display area, saving has been completed successfully. Corrected locations are displayed in slanted text. If an error occurs while saving, ”Saving to Data drive failed. [622]” appears.

Character limit
Max. number of characters: Up to 100 characters for comments, 30 characters for other
If ","(comma) is entered, it is converted into " "(space).
Prohibited characters: "," (commas) and pictographs

## 7.3. Superimposed Display of Measurement Results for the Same Patient

By selecting a single patient for which measurement results are to be displayed, tapping the [Only TNo.] button, and then changing to [All of PID], it is possible to superimpose and display measurement result graphs for the same Patient ID within the same measurement date.


*Figure: 7.3-1*

By tapping the [TNo. Select Enter] button, other Test Nos. for the same Patient ID within the same measurement date are displayed in a list. Test Nos. for which detailed results are to be displayed can be selected from the list.

# 8. After the Measurement

Stop the T-TAS 01 system using the following procedure after measurement is complete.

## 8.1. Backing Up Measurement Results

Back up measurement results to a USB flash drive.
Refer to “7.1.1. Backing Up Measurement Results” for details on the procedure.

* With the measurement results backup procedure above, pressure data is not saved. It is strongly recommended that measurement results and pressure data be backed up to ensure that data is retained in the event of a dedicated computer failure. To save pressure data, it is necessary to sign in with the "Supervisor" account and perform the procedure from the "Maintenance" screen. Refer to the "9.3.2. [Backup] Tab" on the "Maintenance" screen for Supervisors for details on the procedure.

## 8.2. Stopping the System

a) Stopping the dedicated computer

By tapping the [Sign Out] button in the upper right of the "HOME" screen, the OS "Standby screen" is displayed. (Figure: 8.2 2)
Swipe up the "Standby screen" to display the "Sign-in screen".

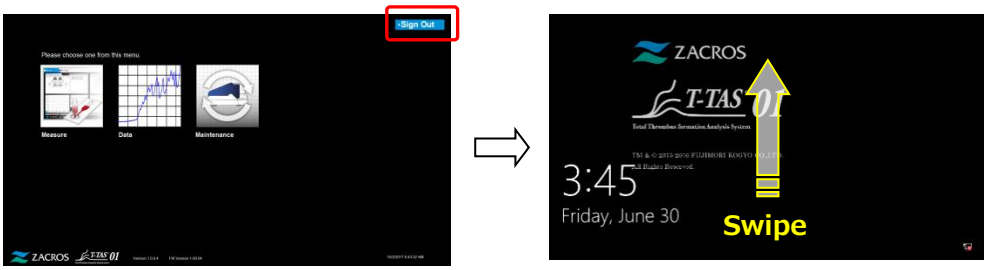



*Figure: 8.2-1*

*Figure: 8.2-2*

By tapping the [Power] button in the lower right of the "Sign-in" screen and then tapping "Shut down" on the menu that appears, the dedicated computer power turns OFF.

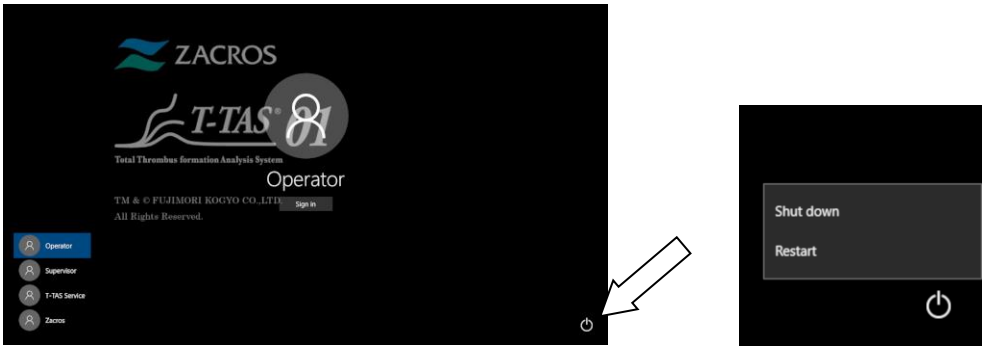



*Figure: 8.2-3*

*Figure: 8.2-4*

b) Turn OFF the instrument power.

*Figure: 8.2-5*

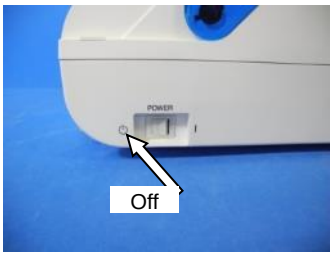



*Figure: 8.2-6*

## 8.3. Closing the Cover

Close the cover by gently pulling the cover down, over the instrument.

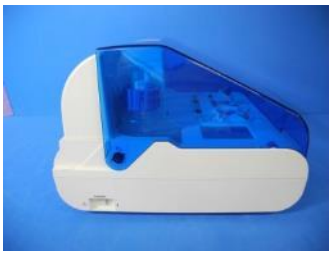


*Figure: 8.3-1*

# 9. Maintenance

| ⚠ CAUTION | |
|---|---|
|  | Do not pull nozzles or tubing with force. Furthermore, do not pull nozzles out more than 165 mm (6.5 in). There is a risk of damage to tubing and connections. |

## 9.1. “Maintenance” Screen

The "Maintenance" screen is equipped with a range of features for maintaining the instrument.
The displayed content and functions that can be used will differ depending on the account used to sign in to the dedicated computer.

Tap the [Maintenance] button on the "HOME" screen to display the "Maintenance" screen.

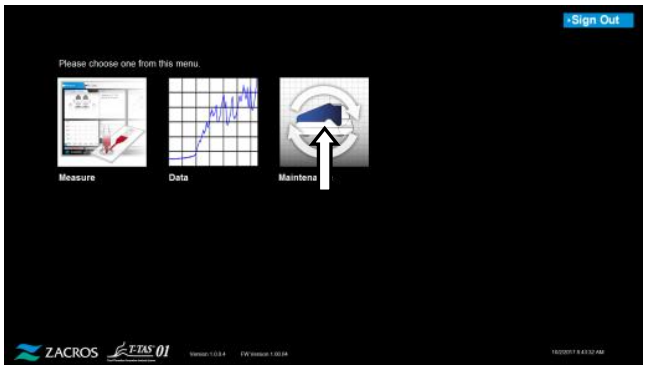



*Figure: 9.1-1*

## 9.2. Operator “Maintenance” Screen

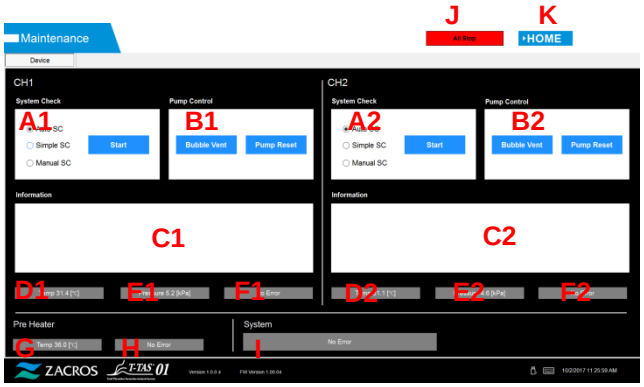



*Figure: 9.2-1*

*Table: 9.2-1*

| Symbol | Description |
|---|---|
| A1,A2 | System Check: Performs self-diagnosis of the tube system.<br>1. Select [Auto SC], [Simple SC], or [Manual SC].<br>2. Tap the [Start] button.<br>Refer to " 9.6.1. Manual SC" for details on the manual SC procedure.<br>Auto SC: This is a standard system check carried out automatically when the instrument starts up.<br>Simple SC: This is a simple system check carried out each time measurement is performed.<br>Manual SC: The above simple checks involve a check of the pumps only, however, this is a system check of the entire blood feed system, including the nozzles. |
| B1,B2 | Pump Control: Pumps and solenoid valves are interlinked to run the pumps.<br>By tapping the [Bubble Vent] button, mineral oil is discharged repeatedly 3 times from the nozzles after supplying oil from the oil bottle.<br>Refer to "9.7.1 Bubble Vent "for details on the procedure.<br>To ensure accurate measurement, the path from the pumps to the nozzle tips must be filled with mineral oil. If air bubble contamination is suspected inside the tubing, perform bubble vent to eliminate any air bubbles.<br>By tapping the [Pump Reset] button, the pumps are reset to their original positions.<br>Depending on the error type, it may not be possible to clear errors without performing pump reset. |
| C1,C2 | Information: The instrument status and instructions to the operator are displayed. |
| D1,D2 | Displays the CH1 and CH2 heater temperatures. |
| E1,E2 | Displays the CH1 and CH2 pressure. |
| F1,F2 | Displays the CH1 and CH2 error status. |
| G | Displays the pre-heater temperature. |
| H | Displays the pre-heater error status. |
| I | Displays the error status for the entire instrument. |
| J | Forcibly stops instrument operation. |
| K | Displays the "HOME" screen. |

## 9.3. “Maintenance” Screen for Supervisors

### 9.3.1. [Device] Tab

The [Device] tab content is the same as "9.2. Operator “Maintenance” Screen".

### 9.3.2. [Backup] Tab

At the [Backup] tab, measurement results and pressure data can be compiled in a range specified by date, and this data can be backed up to a USB flash drive.
* It takes approximately 2 minutes to back up one week of measurement results and pressure data.

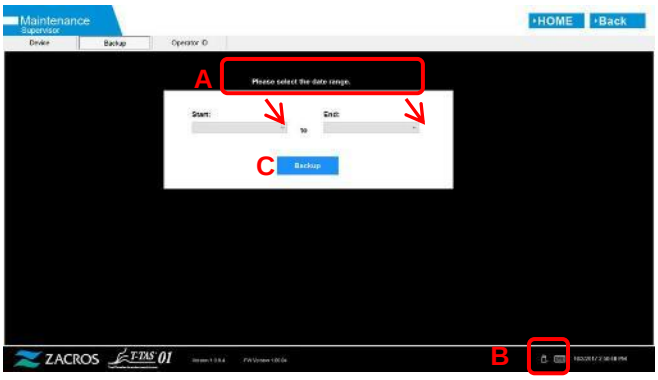



*Figure: 9.3-1*

*Table: 9.3-1*

| | |
|---|---|
| A | Message display area |
| B | [USB] icon display area |
| C | [Backup] button |

a) Connect the USB flash drive to the dedicated computer.
When the measurement software recognizes the USB flash drive, a [USB] icon appears in the lower right of the screen.
b) Specify the backup start date from the [Start:] list.
c) Specify the backup end date from the [End:] list.
d) Tap the [Backup] button to begin copying measurement results and pressure data to the USB flash drive.
The following message appears while copying.
”Please wait for a while. Copy Folder:*** (name of copy destination folder)"
e) When “Backup to USB flash drive completed.” appears, backup is complete.
Tap the [USB] icon in the lower right of the screen and remove the USB flash drive from the dedicated computer after ensuring that the [USB] icon has disappeared.

If an error occurs during the backup, the following message appears in message area A.
” Backup to USB flash drive failed. [633]”

f) Files to be backed up

- The destination folder for the measurement result :
  [ USB flash drive ] ¥T-TAS01¥Result¥YYYYMMDD
- The file name of the measurement result: YYYYMMDDHHMMSS_Result TestNumber.csv
- Format of the measurement result file: The number of columns is six. Delimited by commas.
- Content of the measurement result file: Refer to the Table: 9.3-2.

*Table: 9.3-2*

| Row | Column [ 1 ] Item identification name | Column [ 2 ] to Column [ 6 ] |
|---|---|---|
| 1 | T-TAS, | CONDITION & RESULT,,,, |
| 2 | Blank | ,,,,, |
| 3 | CONDITION, | Blank or RUO,App Version,*.*.*.*,FW Version,*.**.** |
| 4 | Test No., | Test number,,,, |
| 5 | Start, Date, | Start date,,, |
| 6 | Start, Time, | Start time,,, |
| 7 | OperatorID, | ,Operator ID,,, |
| 8 | SampleID, | , Sample ID,,,*(The number of editing data) |
| 9 | PatientID, | , Patient ID,,,*(The number of editing data) |
| 10 | Lot No., | , Chip Lot number,,, |
| 11 | Sampling Date and Time, | Date and time of sample creation,,,*(The number of editing data) |
| 12 | Comment, | , Comment,,,*(The number of editing data) |
| 13 | Abnormal Wave Form, | Abnormal waveform determination flag,,,, |
| 14 | RESULT, | ,,,, |
| 15 | Chip, | Type of Chip,,,, |
| 16 | Channel, | Measurement channel,,,, |
| 17 | Base Pressure, | Base pressure,(kPa),,, |
| 18 | Occlusion Start Time, | Occlusion start time, (hh:mm:ss),,, |
| 19 | Pressure, | Pressure at the end of the measurement, (kPa) ,,,, |
| 20 | OST, | Elapsed time before the pressure reaches 10 kPa after starting the measurement, (hh:mm:ss),,, |
| 21 | Occlusion Time, | Occlusion time, (hh:mm:ss),,, |
| 22 | AUC(Area Under the Curve), | AUC (Area Under the Curve),,,, |
| 23 | Judgement Result Kind, | Index of the qualitative judgment (AUC or OT),,,, |
| 24 | Before Measure Pressure, | Pressure at the start time of the measurement, (kPa),,,, |
| 25 | Stop Measure Pressure, | Pressure at the end of the measurement, (kPa),,,, |
| 26 | High Flow Time, | Duration of the high speed operation,(sec),,, |
| 27 | Measurement Time, | Duration of the measurement,(sec),,, |
| 28 | Base Pressure End Time, | End time of the base pressure calculation,(sec),,, |
| 29 | Base Pressure Upper Limit, | Upper limit of the base pressure threshold,(kPa),,, |

g) Pressure data files to be backed up

- The destination folder of the pressure data :
  [ USB flash drive ] ¥T-TAS01¥Data¥YYYYMMDD
- The file name of the pressure data:
  YYYYMMDDHHMMSS_DataTestNumber.csv
- Content of the pressure data file :
  The first row: "T-TAS,MEASURED DATA,Count =", the number of data
  The second and subsequent rows: Pressure data

### 9.3.3. [Operator ID] Tab

Register operators authorized to perform measurement operations at the [Operator ID] tab.
It will not be possible to perform measurement operations if the Operator ID used to enter specimen information at the "Measurement" screen does not match the ID registered here.

a) Enter the Operator ID to be registered in the Operator ID field.
The Remark field is optional.
A maximum of 30 Operator IDs can be registered.

b) By tapping the [Save ID] button, the currently displayed content is saved.

By tapping the [Cancel] button, entry is canceled, and the currently saved Operator ID is displayed.

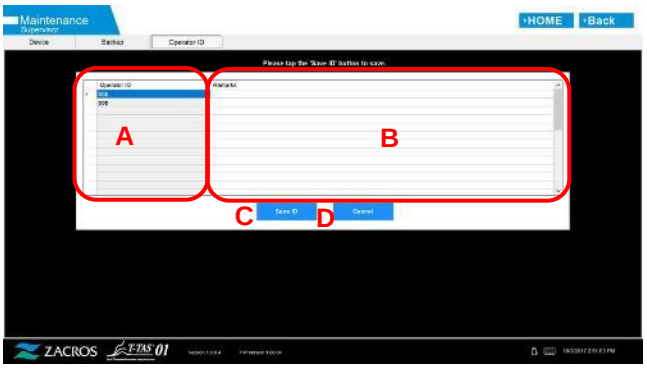



*Figure: 9.3-2*

*Table: 9.3-3*

| | |
|---|---|
| A | Operator ID field |
| B | Remark field |
| C | [Save ID] button |
| D | [Cancel] button |

Character limit

Max. number of characters: Operator IDs are limited to 30 characters, and Remarks are limited to 100 characters.
Prohibited characters: "," (commas) and pictographs
If ","(comma) is entered, it is converted into " "(space).

## 9.4. Daily Maintenance (Before and After Use)

Carry out the following maintenance every day before and after using the system.

| ⚠ WARNING | | |
|---|---|---|
| | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. | |
| | Waste fluid carries a risk of infection. Dispose of as medical waste in accordance with local, state, and Federal regulations. | |

### 9.4.1. Checking for Waste Fluid

a) **Waste tubes**

Move the nozzles to their nozzle holders.

*Figure: 9.4-1*

*Figure: 9.4-2*

Dispose of the mineral oil inside the waste tubes.

Handle mineral oil as an infectious substance, and dispose of as medical waste in accordance with local, state, and Federal regulations.

Next, set the nozzles in their original waste tubes.

*Figure: 9.4-3*

*Figure: 9.4-4*

b) **Waste tray**

Dispose of any mineral oil that has accumulated in the waste tray.

Handle mineral oil as a potentially infectious substance, and dispose of as medical waste in accordance with local, state, and Federal regulations.

Next, set the waste tray in its original location.

*Figure: 9.4-5*

### 9.4.2. Checking the Remaining Oil Level

Ensure that the mineral oil level in the oil bottle is above the Min level (75 ml). If the oil level falls below the Min mark shown in the image below, use the funnel provided to add mineral oil until the Max level (250 ml mark) is reached.

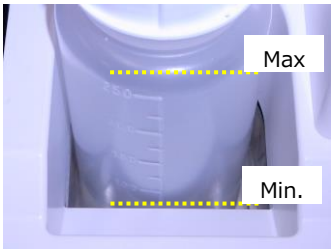



*Figure: 9.4-6*

> **Tips**
> The Min (75 ml) level is the quantity at which the fluid level is no longer visible with the oil bottle placed on the instrument.

**Oil Replenishment Procedure**

a) Opening oil-bottle cap

When you open the oil-bottle cap, do not turn the cap but turn the oil-bottle to prevent the connected tube from twisting.

*Figure: 9.4-7*

b) Filling with oil

Open the oil-bottle cap slightly, then fill with the specified mineral oil using the funnel provided until Max level (250 ml mark) is reached.

*Figure: 9.4-8*

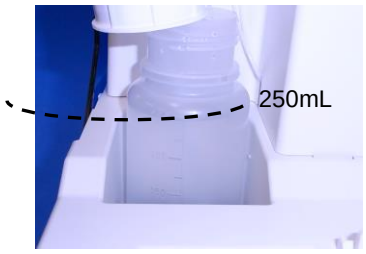



*Figure: 9.4-9*

c) Closing oil-bottle cap

When you close the oil-bottle cap, do not turn the cap, but turn the oil-bottle to prevent the connected tube from twisting.

*Figure: 9.4-10*

## 9.5. Daily Maintenance (After Use)

### 9.5.1. Cleaning the Instrument

| | | |
|---|---|---|
| | ⚠ WARNING | |
| | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. |  |
|  | If using ethanol for cleaning, do so in a well-ventilated location with no open flames present.<br><br>There is a risk of fire if the instrument is exposed to heat or sparks. If the location is equipped with a ventilation system, run it before carrying out work. |  |
| | If using sodium hypochlorite for cleaning, do so in a well-ventilated location. If the location is equipped with a ventilation system, activate it before carrying out work. |  |
|  | Do not mix chemicals used for cleaning with other chemicals.<br>There is a risk of toxic gases being produced, or of explosion. |  |
| | ⚠ CAUTION | |
|  | Soak fluids used for cleaning in a disposable paper towel, and wipe after giving the towel a thorough squeeze. If water gets inside the instrument, there is a risk of electric shock or instrument failure. |  |
|  | Do not use liquid other than that specified for cleaning.<br>There is a risk of surface degradation or instrument failure. | |

**Instrument exterior**

Eliminate any oil or dirt from specimens or mineral oil from the surface of the instrument (Figure: 9.5-1, all visible locations), waste tubes, chip reader window (Figure: 9.5-2), and waste tray with a disposable paper towel lightly soaked in diluted neutral detergent, and then wipe with a disposable paper towel soaked in ethanol (80%) or sodium hypochlorite (0.5%). After using sodium hypochlorite solution, wipe off the chemical with a disposable paper towel soaked in water. Failure to do so could lead to the corrosion of metal parts.

*Figure: 9.5-1*

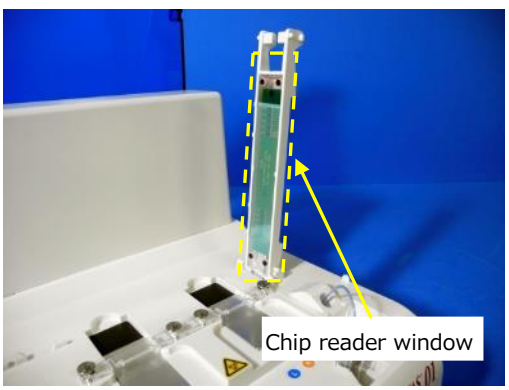



*Figure: 9.5-2*

## 9.6. Monthly Maintenance

### 9.6.1. Quality Control: Manual SC

| ⚠ WARNING | | |
|---|---|---|
| | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. | |

To ensure accurate measurement, perform manual SC in intervals of at least once each month. With manual SC, the entire blood feed system, from the pumps to the nozzle tips, can be checked.

a) Select [Manual SC] on the "Maintenance" screen and tap the [Start] button.

*Figure: 9.6-1*

b) Insert the nozzles firmly in the SC bars and tap the [OK] button to begin manual SC.

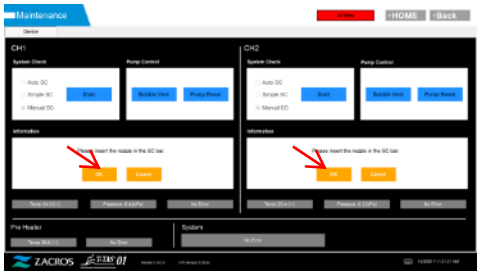


*Figure: 9.6-2*

*Figure: 9.6-3*

*Figure: 9.6-4*

c) When manual SC is completed successfully, "System Check is completed" appears. Set the nozzles in the waste tubes. If an error is displayed, refer to " 10.2. Error Messages".

*Figure: 9.6-5*

*Figure: 9.6-6*

## 9.7. Maintenance as Needed

### 9.7.1. Bubble Vent

Perform bubble vent when a system check error occurs, or if air bubble contamination is suspected inside the tubing.

a) Set the nozzle for the applicable channel for which bubble vent is to be performed in its waste tube.

*Figure: 9.7-1*

*Figure: 9.7-2*

b) Tap the [Maintenance] button on the "HOME" screen to display a "Maintenance" screen.

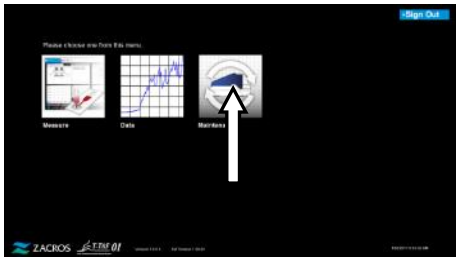


*Figure: 9.7-3*

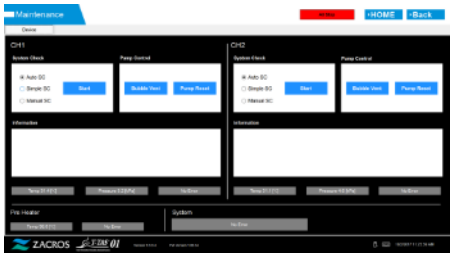


*Figure: 9.7-4*

c) Tap the [Bubble Vent] button for the applicable channel.

*Figure: 9.7-5*

*Figure: 9.7-6*

Ensure that the nozzles have been set in their waste tubes, and tap the [OK] button. Bubble vent begins. By performing bubble vent, the inside of the tubing is filled with mineral oil.

### 9.7.2. Cleaning the Dedicated Monitor

| ⚠ WARNING | | |
|---|---|---|
|  | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. |  |
| | If using ethanol for cleaning, do so in a well-ventilated location with no fire present.<br>There is a risk of fire if the dedicated monitor is exposed to heat or sparks. If the location is equipped with a ventilation system, run it before carrying out work. |  |
|  | Do not mix chemicals used for cleaning with other chemicals.<br>There is a risk of toxic gases being produced, or of explosion. |  |
| ⚠ CAUTION | | |
|  | Soak fluids used for cleaning in a disposable paper towel, and wipe after giving the towel a thorough squeeze. If water gets inside the instrument, there is a risk of electric shock or dedicated monitor failure. |  |
|  | Do not use liquid other than that specified for cleaning.<br>There is a risk of surface degradation or instrument failure. | |

When cleaning the dedicated monitor, disconnect the monitor AC adapter beforehand.

Use a disposable paper towel lightly soaked in diluted neutral detergent to clean the monitor exterior.

Apply window glass detergent, glass polishing spray, or ethanol (80%) to a disposable paper towel to clean the touch screen. Furthermore, please be aware that using ethanol may leave white traces on the screen.

Do not use organic solvents such as thinner or benzene, or polishing detergent.

If chemicals get inside the dedicated monitor, do not turn ON the power until an inspection has been performed.

### 9.7.3. Cleaning the Dedicated Computer

| ⚠ WARNING | | |
|---|---|---|
| | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. |  |
|  | If using ethanol for cleaning, do so in a well-ventilated location with no fire present.<br>There is a risk of fire if the dedicated monitor is exposed to heat or sparks. If the location is equipped with a ventilation system, run it before carrying out work. |  |
|  | Do not mix chemicals used for cleaning with other chemicals.<br>There is a risk of toxic gases being produced, or of explosion. |  |
| ⚠ CAUTION | | |
|  | Soak fluids used for cleaning in a disposable paper towel, and wipe after giving the towel a thorough squeeze. If water gets inside the instrument, there is a risk of electric shock or dedicated monitor failure. |  |
|  | Do not use liquid other than that specified for cleaning.<br>There is a risk of surface degradation or instrument failure. | |

When cleaning the dedicated computer, disconnect the AC adapter.

Eliminate any oil or dirt with a disposable paper towel lightly soaked in diluted neutral detergent, and then wipe with a disposable paper towel soaked in ethanol (80%).

If chemicals get inside the dedicated computer, do not turn ON the power until an inspection has been performed.

### 9.7.4. Cleaning the Barcode scanner (Sold Separately)

| ⚠ WARNING | | |
|---|---|---|
|  | This work carries a risk of infection.<br>To prevent biohazards, ensure that personal protective equipment (such as gloves and safety glasses) and protective wear (such as lab coats) are worn. |  |
| | If using ethanol for cleaning, do so in a well-ventilated location with no fire present.<br>There is a risk of fire if the dedicated monitor is exposed to heat or sparks. If the location is equipped with a ventilation system, run it before carrying out work. |  |
|  | Do not mix chemicals used for cleaning with other chemicals.<br>There is a risk of toxic gases being produced, or of explosion. |  |
| ⚠ CAUTION | | |
|  | Soak fluids used for cleaning in a disposable paper towel, and wipe after giving the towel a thorough squeeze. If water gets inside the instrument, there is a risk of electric shock or dedicated monitor failure. |  |
|  | Do not use liquid other than that specified for cleaning.<br>There is a risk of surface degradation or instrument failure. | |

When cleaning the barcode scanner, disconnect the USB cable beforehand.

Eliminate any oil or dirt with a disposable paper towel lightly soaked in diluted neutral detergent, and then wipe with a disposable paper towel soaked in ethanol (80%).

If chemicals get inside the barcode scanner, do not turn ON the power until an inspection has been performed.

# 10. Troubleshooting

## 10.1. When Experiencing Trouble

If the following trouble occurs and the system has still not recovered to its normal condition even after taking measures to remedy the problem, contact Technical Support.

### 10.1.1. The instrument power does not turn ON.

If the status indicator on the front of the instrument does not light up even when the power switch is turned ON, refer to "4.3. Wiring", and ensure that the instrument AC adapter is connected correctly.

### 10.1.2. The dedicated computer power does not turn ON.

Refer to "4.3. Wiring", and check the following.

- Is the dedicated computer AC adapter connected correctly?

### 10.1.3. Nothing displays on the dedicated monitor.

Refer to "4.3. Wiring", and check the following.

- Are the dedicated computer and monitor AC adapters connected correctly?
- Is the dedicated computer and monitor wiring connected correctly?
- Is the dedicated computer and monitor power ON?

### 10.1.4. The measurement software does not recognize the instrument.

If the measurement software recognizes the instrument, and the [Measure] button on the "HOME" screen does not become active, refer to "4.3. Wiring", and check whether the USB cable between the dedicated computer and instrument is connected correctly.

## 10.2. Error Messages

Error messages are displayed on the monitor screen when the system is potentially experiencing trouble.

A list of error messages can be seen in the following table. If the following error messages are displayed, follow proper procedure to recover the system to its normal operating condition.
Of recovery steps (1), (2) ..., if the system is recovered to its normal condition with step (1), no further action will be required.
Contact Technical Support if the instrument does recover after action is taken.

*Table: 10.2-1*

| Code | Error Description | Recovery procedure |
|---|---|---|
| 001 | Invalid communication [001]<br>Please refer to the operation manual. | (1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System |

<table>
<tr><td>002</td><td>Invalid communication [002]<br>Please refer to the operation manual.</td><td rowspan="2">When an Error Occurs”, and exit the system.</td></tr>
<tr><td>003</td><td>Invalid communication [003]<br>Please refer to the operation manual.</td></tr>
<tr><td>004</td><td>T-TAS device CPU board failure [004]<br>Please refer to the operation manual.</td><td>(1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.</td></tr>
<tr><td>005</td><td>T-TAS device memory failure [005]</td><td>(1) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>(2) Wait for at least 1 minute, and then restart the system.<br>(3) Contact Technical Support if the same error occurs repeatedly.</td></tr>
<tr><td>031</td><td>Pre-heater temperature error [031]<br>Please refer to the operation manual.</td><td>Measurement can still be continued even if a pre-heater error is displayed. In this case, however, do not place the chip on the pre-heater. The temperature of the chip placed on the pre-heater may rise too much to prevent it being used.<br><br>(1) Check and take measures to improve the operating temperature. Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen. The current pre-heater temperature and error status can be checked at the "Maintenance" screen.<br><br>The error will still be displayed on the "Measurement" screen even if the error display has disappeared from the "Maintenance" screen. Use the following procedure to recover the system.<br><br>(2) Next, exit the T-TAS system when no chips have been inserted in either of the channels.<br>(3) Wait for at least 10 minutes, and then restart the system.<br>(4) Contact Technical Support if the same error occurs repeatedly.<br><br>The error status will be cleared after exiting and then restarting the system, however, the same error will be detected again if the cause has not been resolved.</td></tr>
</table>

| | | |
|---|---|---|
| 033 | Pre-heater failure [033]<br>Please refer to the operation manual. | Measurement can still be continued even if a pre-heater error is displayed. In this case, however, do not place the chip on the pre-heater. The temperature of the chip placed on the pre-heater may rise too much to prevent it being used.<br>(1) Contact Technical Support if the same error occurs repeatedly.<br>Pre-heater temperature control is stopped while errors are occurring. The error status will be cleared after exiting and then restarting the system, however, the same error will be detected again if the cause has not been resolved. |
| 111<br>211 | Invalid communication [*11]<br>Please refer to the operation manual.<br>* [111] is a CH1 error.<br>[211] is a CH2 error. | (1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>Stop use of the instrument even if one of the channels is normal. |
| 112<br>113<br>114<br>212<br>213<br>214 | Pump failure [***]<br>Please refer to the operation manual.<br>* [112], [113], and [114] are CH1 errors.<br>[212], [213], and [214] are CH2 errors. | (1) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen.<br>(2) Perform a reset, bubble vent, and manual SC for the applicable channel at the "Maintenance" screen, and ensure that there are no abnormalities.<br>(3) Return to the "Measurement" screen, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(4) Contact Technical Support if the same error occurs repeatedly.<br>(5) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |

| | | |
|---|---|---|
| 116<br>216 | Pump out of range error [*16]<br>Please refer to the operation manual.<br><br>* [116] is a CH1 error.<br>[216] is a CH2 error. | (1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br><br>Stop use of the instrument even if one of the channels is normal. |
| 121<br>221 | Pressure sampling error [*21]<br>Please refer to the operation manual.<br><br>* [121] is a CH1 error.<br>[221] is a CH2 error. | (1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br><br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |
| 122<br>222 | Pressure error [*22]<br>Please refer to the operation manual.<br><br>* [122] is a CH1 error.<br>[222] is a CH2 error. | (1) Check and take measures to improve the operating temperature.<br>(2) Clean the nozzle tips.<br>(3) Inspect the operation method for chip and reservoir handling to ensure that there is no tube bending.<br>(4) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen.<br>(5) Perform a reset, bubble vent, and manual SC for the applicable channel at the "Maintenance" screen, and ensure that there are no abnormalities.<br>(6) Return to the "Measurement" screen, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(7) Contact Technical Support if the same error occurs repeatedly.<br>(8) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br><br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |

<table>
<tr><td>123</td><td rowspan="2">System check error [*23]<br>Please refer to the operation manual.<br><br>* [123] is a CH1 error.<br>[223] is a CH2 error.</td><td rowspan="2">(1) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen.<br>(2) Perform a reset, bubble vent, and manual SC for the applicable channel at the "Maintenance" screen, and ensure that there are no abnormalities.<br>(3) Return to the "Measurement" screen, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(4) Contact Technical Support if the same error occurs repeatedly.<br>(5) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br><br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel.</td></tr>
<tr><td>223</td></tr>
<tr><td>131</td><td rowspan="2">Heater failure [*31]<br>Please refer to the operation manual.<br><br>* [131] is a CH1 error.<br>[231] is a CH2 error.</td><td rowspan="2">(1) Check and take measures to improve the operating temperature, and leave the system at room temperature following improvements.<br>(2) Wait for at least 10 minutes, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(3) Contact Technical Support if the same error occurs repeatedly.<br>(4) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br><br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel.</td></tr>
<tr><td>231</td></tr>
<tr><td>133</td><td>Heater failure [133]<br>CH1 inoperable.<br>Please refer to the operation manual.</td><td>(1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.</td></tr>
</table>

<table>
<tr><td>233</td><td>Heater failure [233]<br>CH2 inoperable.<br>Please refer to the operation manual.</td><td>Stop use of the instrument even if one of the channels is normal.</td></tr>
<tr><td>141</td><td>Chip code reading error[141]<br>Remove chip from CH1.<br>Please refer to the operation manual.</td><td rowspan="2">(1) Remove the chip.<br>(2) Check the chip label condition. Wipe dirt from the label if possible, and if unable to improve the situation due to fraying and so on, replace with another chip.<br>(3) Clean the chip-code reader. Refer to “9.5.1. Cleaning the Instrument” for details on the procedure.<br>(4) Refer to the screen guide, and insert the chip straight to the back.<br>(5) Contact Technical Support if the same error occurs repeatedly.<br>(6) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel.</td></tr>
<tr><td>241</td><td>Chip code reading error[241]<br>Remove chip from CH2.<br>Please refer to the operation manual.</td></tr>
</table>

| | | |
|---|---|---|
| 403 | Abnormal pressure drop [403]<br>Check leakage on the liquid line.<br>Please refer to the operation manual. | (1) Ensure that there is no blood or mineral oil leakage. Clean any dirty parts of the instrument.<br>(2) Inspect the operation method for parts at which leakage has occurred. (Example: Are the nozzles, reservoirs, or caps loose?)<br>(3) Refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(4) Contact Technical Support if the same error occurs repeatedly.<br>(5) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |

| | | |
|---|---|---|
| 404 | Pressure error [404]<br>Please refer to the operation manual. | (1) Check and take measures to improve the operating temperature.<br>(2) Clean the nozzle tips.<br>(3) Inspect the operation method for chip and reservoir handling to ensure that there is no tube bending.<br>(4) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen.<br>(5) Perform a reset, bubble vent, and manual SC for the applicable channel at the "Maintenance" screen, and ensure that there are no abnormalities.<br>(6) Return to the "Measurement" screen, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(7) Contact Technical Support if the same error occurs repeatedly.<br>(8) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |

| | | |
|---|---|---|
| 405 | Pressure baseline error [405]<br>Please refer to the operation manual. | (1) Clean the nozzle tips.<br>(2) Inspect the operation method for chip and reservoir handling to ensure that there is no tube bending.<br>(3) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen.<br>(4) Perform a reset, bubble vent, and manual SC for the applicable channel at the "Maintenance" screen, and ensure that there are no abnormalities.<br>(5) Return to the "Measurement" screen, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button to begin the recovery process.<br>(6) Contact Technical Support if the same error occurs repeatedly.<br>(7) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |
| 406 | Temperature stability timeout error [406]<br>Please refer to the operation manual. | (1) Check and take measures to improve the operating temperature, and leave the system at room temperature following improvements.<br>(2) Wait for at least 10 minutes, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button at the "Measurement" screen to begin the recovery process.<br>(3) Contact Technical Support if the same error occurs repeatedly.<br>(4) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |

| | | |
|---|---|---|
| 407 | Temperature out of range [407]<br>Please refer to the operation manual. | (1) Check and take measures to improve the operating temperature, and leave the system at room temperature following improvements.<br>(2) Wait for at least 10 minutes, refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button at the "Measurement" screen to begin the recovery process.<br>(3) Contact Technical Support if the same error occurs repeatedly.<br>(4) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>It will not be possible to use the channel for which an error is occurring, however, if this error is only occurring at one channel, use can be continued at the other unaffected channel. |
| 408 | Command process timeout error [408]<br>Please refer to the operation manual. | (1) Contact Technical Support.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>Stop use of the instrument even if one of the channels is normal. |
| 800 | T-TAS device reboot detection error [800]<br>Please refer to the operation manual. | (1) Check for a power failure, as well as whether electricity is being supplied by the socket.<br>(2) Check whether the instrument power plug has been properly inserted into the AC outlet (socket).<br>(3) Turn ON the instrument power switch properly.<br>(4) Auto recovery is performed if there is no chip.<br>(5) Refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button on the "Measurement" screen to begin the recovery process.<br>(6) Contact Technical Support if the same error occurs repeatedly.<br>(7) Use the normal procedure to exit the system. |

| | | |
|---|---|---|
| 999 | Communication disconnected [999]<br>Please check the USB connection. | (1) Ensure that the instrument power is ON.<br>(2) Ensure that the USB cable is connected correctly.<br>(3) Refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button on the "Measurement" screen to begin the recovery process.<br>(4) Contact Technical Support if the same error occurs repeatedly.<br>(5) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system. |
| 501 | WARNING: Pressure decreasing [501]<br>There may be leakage in the liquid line.<br>Please refer to the operation manual. | Measurement will continue even if a warning occurs. A warning mark will appear next to the data also, as there is a possibility that the measurement results are abnormal.<br>(1) Ensure that there is no blood or mineral oil leakage from the chips, reservoirs, caps, or nozzles.<br>• If any leakage is found, inspect the operation method and measure again.<br>• If there is no leakage, the waveform of the blood itself may also be considered. A comprehensive judgment should be made by someone capable of making a medical judgment taking other information into consideration. |
| 502 | T-TAS device is disconnected. [502] | (1) Ensure that the instrument power is ON.<br>(2) Ensure that the USB cable is connected correctly.<br>(3) Reboot the computer.<br>(4) Contact Technical Support if the same error occurs frequently.<br>(5) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>If the communication via USB is disconnected, some buttons become invalid because the operation to access the instrument becomes unable. |

| | | |
|---|---|---|
| 503 | Pre-heater temperature out of range [503] | Measurement can still be continued even if a pre-heater error is displayed. In this case, however, do not place the chip on the pre-heater. The temperature of the chip placed on the pre-heater may rise too much to prevent it being used.<br><br>(1) Check and take measures to improve the operating temperature. Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and tap the [Maintenance] button to display the "Maintenance" screen. The current pre-heater temperature and error status can be checked at the "Maintenance" screen.<br>(2) Contact Technical Support if the same error occurs repeatedly.<br>(3) Pre-heater temperature adjustment stops while an error is occurring. Heating starts again when the temperature drops, however, the error will occur repeatedly if the cause of the error has not been resolved. |

| | | |
|---|---|---|
| 601 | A different chip is inserted. [601]<br>Please remove the chip. | (1) Remove the chip. By removing the chip and tapping the [OK] button displayed on the "Measurement" screen, the error status will be resolved at the screen.<br>(2) Check whether the name of the measurement chip displayed on the screen matches the inserted chip type. If the chip displayed on the screen is wrong, return to the "Measurement menu" screen and select the correct chip name. If the wrong chip has been inserted, prepare the correct chip.<br>(3) Check the chip label condition. If abnormalities such as dirt or damage are visible on the label, replace with another chip.<br>(4) Check whether the chip-code reader has been set in the correct position. Furthermore, clean the chip-code reader if it is dirty. Refer to “9.5.1. Cleaning the Instrument” for details on the procedure.<br>(5) When inserting the chip, insert it straight into the back without stopping halfway.<br>(6) Contact Technical Support if the same error occurs repeatedly.<br>(7) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system. |

| | | |
|---|---|---|
| 602 | CH1:<br>Chip removed from CH1 [602]<br><br>CH2:<br>Chip removed from CH2 [602] | If the chip is removed during measurement, an error will occur and measurement will be terminated.<br><br>Try the following if an error is detected even though the chip is present.<br>(1) Remove the chip.<br>(2) Check the chip label condition. If abnormalities such as dirt or damage are visible on the label, replace with another chip.<br>(3) Check whether the chip-code reader has been set in the correct position. Furthermore, clean the chip-code reader if it is dirty. Refer to “9.5.1. Cleaning the Instrument” for details on the procedure.<br>(4) Refer to "10.3.1. Tapping the [OK] Button When an Error Occurs", and tap the [OK] button on the "Measurement" screen to begin the recovery process.<br>(5) When inserting the chip, insert it straight into the back without stopping halfway.<br>(6) Contact Technical Support if the same error occurs repeatedly.<br>(7) If the measurement software is exited with an error occurring, refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system. |
| 621 | Data drive is full. [621] | (1) Back up any necessary data, and contact Technical Support. |
| 622 | Saving to Data drive failed. [622] | (1) Wait for at least 1 minute, and try saving data again.<br>(2) If it appears as though saving will be unsuccessful again, back up any necessary data, and contact Technical Support. |
| 625 | Operator ID not found. [625] | (1) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs", return to the "HOME" screen, and then sign out.<br>(2) Sign in again with the "Supervisor" account, and register an Operator ID from the "Maintenance" screen.<br>(See "9.3.3. [Operator ID] Tab").<br>(3) Contact Technical Support if the error occurs even after registering the Operator ID. |

| | | |
|---|---|---|
| 631 | USB flash drive removal failure [631] | (1) Wait for at least 1 minute, and try the removal operation again.<br>(2) Refer to “10.3.3. Exiting the System When an Error Occurs”, and exit the system.<br>(3) Wait for at least 1 minute, and then restart the system.<br>(4) Contact Technical Support if the error occurs frequently. |
| 632 | Backup to USB flash drive failed. [632] | (1) Wait for at least 1 minute, and try saving data again.<br>(2) Check the available USB flash drive capacity, write permission settings, and consistency of the specifications, and take necessary measures.<br>(3) Replace the USB flash drive and try again.<br>(4) Contact Technical Support if unable to perform a simple backup. |
| 633 | Backup to USB flash drive failed. [633] | (1) Wait for at least 1 minute, and try saving data again.<br>(2) Check the available USB flash drive capacity, write permission settings, and consistency of the specifications, and take necessary measures.<br>(3) Replace the USB flash drive and try again.<br>(4) Contact Technical Support if unable to perform a backup from the "Maintenance" screen. |

## 10.3. Operation When Errors Occur

| ⚠ WARNING | | |
|---|---|---|
|  | When carrying out such work as reservoir removal when an error occurs, blood or mineral oil may be splattered or spilled.<br>Operators must take sufficient biohazard measures such as protecting their eyes, nose and mouth with safety glasses and a protective mask, wear protective gloves and protective wear, ensure that those in the vicinity are moved to a safe place, and work carefully while preventing splattering by covering the area around chips and reservoirs with paper towel. |  |
| ⚠ CAUTION | | |
| After exiting the system following an error, the error display will be reset when the power is turned ON again. Consequently, if the cause of the error has not been eliminated, the system will run until the error is detected again. | | |

If an error is displayed, remedy the problem by referring to the recovery procedure described in "10.2 Error Messages". Common operation methods in the recovery procedure are described below.

### 10.3.1. Tapping the [OK] Button When an Error Occurs

a) If the reservoir has been set on the chip, remove the reservoir from the chip remaining on the stage. Blood or mineral oil may be splattered or spilled when removing the reservoir. Be sure to take measures such as wearing protective equipment, and carry out work carefully.

b) If the nozzles have been set in the reservoirs, remove the nozzles from the reservoirs. Set the nozzles in their waste tubes, and dispose of the removed reservoirs and reservoir caps appropriately as infectious waste.

c) If a chip has been inserted, remove the chip from the stage. Dispose of the used chip appropriately as infectious waste.

d) By removing the chip, the [OK] button on the "Measurement" screen becomes active. Tap the [OK] button on the "Measurement" screen. The instrument then begins a series of operations in the order reset, following by mineral oil supply, and then Simple SC.
* If an abnormality is detected again, an error will reoccur.

### 10.3.2. Returning to the "HOME" Screen When an Error Occurs

a) If there is a channel that is functioning normally, wait until all measurement processes are complete.

* Continued use is possible at the channel that is functioning normally even if an error has occurred for the other channel. Despite this, it is recommended that Technical Support be contacted without delay.

b) If the reservoir has been set on the chip, remove the reservoir from the chip remaining on the stage. Blood or mineral oil may be splattered or spilled when removing the reservoir. Be sure to take measures such as wearing protective equipment, and carry out work carefully.

c) If the nozzles have been set in the reservoirs, remove the nozzles from the reservoirs. Set the nozzles in their waste tubes, and dispose of the removed reservoirs and reservoir caps appropriately as infectious waste.

d) If a chip has been inserted in the stage, remove the chip from the stage. Dispose of the used chip appropriately as infectious waste.

e) By removing the chip, the [HOME] button on the "Measurement" screen becomes active. It is possible to return to the "HOME" screen by tapping the "HOME" button in the upper right of the "Measurement" screen.

### 10.3.3. Exiting the System When an Error Occurs

| ⚠ CAUTION | | |
|---|---|---|
|  | In case of abnormal odor or smoke, turn OFF the power switch, then unplug the power cable. Stop using the instrument immediately. Contact Technical Support. |  |

a) Refer to "10.3.2. Returning to the "HOME" Screen When an Error Occurs" above, and return to the "HOME" screen.

b) The procedure thereafter is the same as the normal exit procedure. Dispose of any mineral oil that has accumulated in the waste tubes or waste tray, and set the nozzles on the waste tubes.

c) Replenish the oil bottle with mineral oil, if needed.

d) Back up measurement results.

e) Ensure that there are no chips on the stages, sign out from the "HOME" screen, and then shut down the computer.

f) Turn OFF the T-TAS 01 instrument body and monitor power switch.

**Precaution:**

The instrument is reset when the power is turned ON again, and therefore the error will disappear. However, if the cause of the error has not been eliminated, the system will run until the error is detected again, and the error will be displayed.

# 11. Appendix

## 11.1. List of Consumable Parts

*Table: 11.1-1*

| Catalog No. REF | Item name<br>Part No. (model No.) | Validity period<br>Storage conditions | Remarks |
|---|---|---|---|
| 18002 | PL Chip | *1 | |
| | PL Chip | *1 | |
| 18003 | PL Chip Reservoir set | None | |
| | PL Chip Reservoir set | None | |
| 18004 | BAPA tube | *2 | |
| | BAPA tube | *2 | |
| 330779 | Mineral oil | None | Sigma-Aldrich<br>CAS No. : 8042-47-5<br>EC No. : 232-455-8 |
| | MFCD00131611 | 5°C to 35°C | |

*1 Refer to the PL Chip package insert.

*2 Refer to the BAPA tube package insert.

## 11.2. List of Separately Sold Items

*Table: 11.2-1*

| Catalog No. REF | Item name<br>Part No. (model No.) | Validity period<br>Storage conditions | Remarks |
|---|---|---|---|
| PTF100 | Barcode scanner | None | Company name : ZEBRA |
| | LI2208-USBR | 5°C to 50°C | |

## 11.3. EMD (Electromagnetic interference) Technical documentation

This system complies with the EMD (electromagnetic interference) standard, IEC 60601-1-2: 2014+AMD1:2020(Power supply voltage of 120V only). The EMD standard specifies that noise generated by certified device should not affect other devices such as smartphones, and that electromagnetic waves emitted by other devices should not affect certified device to a certain level.
This chapter and "1.3.1. System Installation Precautions" contain all the instructions necessary to maintain basic safety and essential performance regarding electromagnetic interference. Please also check.
The technical descriptions related to EMD are described below.

| ⚠ WARNING | |
|---|---|
| | This system must be used based on the information provided in the EMD technical documentation. |
| | To prevent the adverse effects of electromagnetic interference, use the system in accordance with the following information.<br>・Do not use this system while it is in close contact with or on top of or under other devices.<br>・Do not connect anything other than the specified devices or cables to the system.<br>・Do not use portable RF communication devices such as smartphones within 30 cm of this system. |

**-Electromagnetic Emission-**

Table: 11.3-1

| Emission test item | Applicable standard | Conformity |
|---|---|---|
| Conduction and radiated RF emissions | CISPR 11 | Group1<br>ClassA |
| ・The system uses RF energy only for internal functions.<br>・This system is suitable for use in a medical facility environment that is not directly connected to a commercial low-voltage distribution system. | | |

**- Electromagnetic Immunity/Exterior Port –**

Table: 11.3-2

| Immunity test item | Applicable standard | Immunity test level |
|---|---|---|
| Electrostatic discharge | IEC61000-4-2 | ±8 kV(contact discharge)<br>±2,±4,±8,±15 kV(air discharge) |
| Radiated RF electromagnetic field | IEC61000-4-3 | 3 V/m<br>80 MHZ – 2.7 GHz<br>80% Amplitude modulation（1 kHz） |
| Near electromagnetic field from RF wireless communication device | IEC61000-4-3 | Refer to Table: 11.3-3 |
| Power frequency magnetic field | IEC61000-4-8 | 30 A/m　60 Hz |

| | | |
|---|---|---|
| Proximity magnetic fields | IEC61000-4-39 | 134.2kHz 50% 65A/m<br>13.56MHz 50% 7.5A/m |
| ・The floor is preferably made of wood, concrete or ceramic tile. If the floor is covered with synthetic material, the preferable relative humidity is at least 30%.<br>・This system is suitable for use in electromagnetic environments in specialized medical facilities. | | |

**- Immunity to Near Electromagnetic Fields from RF Wireless Communications Equipment –**

Table: 11.3-3

| Frequency (MHz) | Frequency band (MHz) | Communication service | Modulation | Maximum power (W) | Separation distance (m) | Immunity test level (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380 – 390 | TETRA 400 | Pulse modulation 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700 – 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400 – 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100 – 5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |
| Do not use RF communication devices such as smartphones within 30 cm of this system. | | | | | | |

**- Electromagnetic Immunity/AC Input Power Port –**

Table: 11.3-4

| Immunity test item | Applicable standard | Immunity test level |
|---|---|---|
| Electrical fast transient/burst | IEC61000-4-4 | ±2 kV<br>Repetition frequency : 100 kHz |
| Surge<br>Line to Line | IEC61000-4-5 | ±0.5 kV and ±1 kV |
| Surge<br>Line to Ground | IEC61000-4-5 | ±0.5 kV, ±1 kV and ±2 kV |
| Conducted interference induced by RF electromagnetic fields | IEC61000-4-6 | 3 V between 0.15 MHz and 80 MHz<br>6 V in ISM band between 0.15 MHz and 80 MHz 80% amplitude modulation (1 kHz) |
| Voltage dip | IEC61000-4-11 | 0 % Ut 0.5 circle<br>Phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° |
| | | 0% Ut 1 cycle and 70% Ut 25/30 cycle<br>Single phase angle of 0 ° |
| Short-time power outage | IEC61000-4-11 | 0 % Ut 250/300 cycle |
| ・The power source used in this system is suitable for the quality of power used in specialized medical facilities。<br>・To continue using this system when power is interrupted(power outage), use a power source that will not be interrupted. | | |

**- Electromagnetic immunity/signal input/output port –**

Table: 11.3-5

| Immunity test item | Applicable standard | Immunity test level |
|---|---|---|
| Electrostatic discharge | IEC61000-4-2 | ±8 kV(contact discharge)<br>±2,±4,±8,±15 kV(air discharge) |
| Conducted interference induced by RF electromagnetic fields | IEC61000-4-6 | 3 V between 0.15 MHz and 80 MHz<br>6 V in ISM band between 0.15 MHz and 80 MHz<br>80% amplitude modulation (1 kHz) |
| ・The floor is preferably made of wood, concrete or ceramic tile. If the floor is covered with synthetic material, the preferable relative humidity is at least 30%. | | |

## 11.4. Maintenance and Repair Records

Maintenance and Repair Records

[Maintenance, repair worker name]

[Maintenance, repair worker address]

[Point of contact for instrument failure]

[Business hours]

*Table: 11.4-1*

| Date of installation | Date | |
|---|---|---|
| Instrument serial No. | | |
| Date of maintenance, repair | Details of maintenance, repair | Carried out by |
| / / | | |
| / / | | |
| / / | | |
| / / | | |
| / / | | |
| / / | | |
| / / | | |
| / / | | |
| / / | | |
| / / | | |

Quality control: Manual SC Records

[Laboratory name]

[Responsible person]

[Approval date]

*Table: 11.4-2*

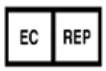
| Instrument serial No. | | | |
|---|---|---|---|
| Date of Manual SC | "System Check is completed" is displayed on the screen after Manual SC is implemented. | Pass / Fail | Carried out by |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |
| / / | Display: Yes / No | Pass / Fail | |

## 11.5. Instruction Manual Revision History

| Date of publication YYYY-MM-DD | Revision details | Revision No. |
|---|---|---|
| 2024/09/09 | 1. Reflected company name change from Fujimori Kogyo Co. Ltd. to ZACROS Corporation. (Header and Footer for all pages, “Forward”)<br>2. Changed Product name for PL Assay Consumables in Chapter 11. | 9 |
| 2023-03-31 | 1. Revised EMC Standard [Page No: 1-2]<br>2. Added Caution message "Also see 11.3..."[Page No: 1-3]<br>3. Chapter 2.9 Table: 2.9-1 Revised EMC Standard [Page No: 2-13]<br>4. Revised EMC Standard. Added description "This chapter and 1.3.1...also check" [Page No: 11-2]<br>5. Added the standard "Proximity magnetic fields" [Page 11-3] | 8 |
| 2022-03-31 | 1. Added ”for professional use” to the cover page. [Page No: Cover Page]<br>2. Added to Software Cybersecurity for connecting to the network. [Page No: Prolegomenon]<br>3. Change Symbol Lexicon. [Page No: Prolegomenon]<br>-Added ”Model Number”, “Direct current”, “Country of manufacture”, “Storage Humidity limitation” and ”Importer”.<br>-Change the symbol of "Stacking Limit".<br>-Changed "IVD" symbol from "For In Vitro Diagnostic Use" to "In vitro diagnostic medical device".<br>4. Added matters related to serious incidents to Section 1.2. [Page No: 1-1]<br>5. Clarified the relationship between system disposal and WEEE Directive and useful life in Section 1.3.13. [Page No: 1-7]<br>6. Chapter 2.9 Table: 2.9-1 Revised Product Safety Standard [Page No.: 2-13]<br>7. Revised the title of Section 9.6.1 regarding quality control. [Page No: 9-10]<br>8. Added record of manual SC to Section 11.5 [Page No: 11-5-1, 11-5-2]<br>9. Added the Importer in the last page. [Page No.: 11-7] | 7 |
| 2020-12-21 | 1. Manufacturer's address change due to relocation of headquarters.<br>2. Correction of errors. | 6 |
| 2020-05-20 | 1. Cybersecurity precautions have been added at the beginning. | 5 |

| | | |
|---|---|---|
| | 2. "Rx only" has been added to Symbols Lexicon.<br>3. The following corrections are made in response to comply with IEC60601-1-2: 2014.<br>- 1.3.1 Warning about EMC are added.<br>- 2.9 "IEC60601-1-2:2014" has been added to Electromagnetic compatibility standards.<br>- 11.3 EMD (Electromagnetic interference) Technical documentation are added. | |
| 2019-06-05 | 1. The following corrections are made in response to an update of the measurement software.<br>- 7.1 Explanation of [Back] button is removed.<br>- 9.2 Explanation of [Back] button is removed.<br>- 10.2 The method how to fix Code 121 and 221 errors is changed.<br>2. 2.7 The graph is corrected. | 4 |
| 2018-11-15 | 1. Explanations needed are added.<br>- 1.3.1. Warnings and Precautions on EMC<br>- 4.1. Information on installation space<br>- 2.6. Incorrect behavior due to quick taps<br>- 5.3. How to display the touch keyboard. How to swipe<br>- 6.1.3. How to fix when the device does not detect the assay chip<br>- 6.1.4. What is shown on the screen when the number of characters is large<br>- 6.1.8. What is shown on the screen when the number of characters is large<br>- 7.1. Warning symbol in the Result column, Sorting of RUO column, and what is shown on the screen when the number of character is large<br>- 9.3.3. The number of Operator ID users can register<br>- 10.2. How to fix Codes 033, 121, and 221<br>- Information on the prohibited characters in the text entry box<br>2. Applicable parts are edited due to the change in the monitor, the oil-bottle, and the tube guide.<br>3. “Specimen Information” screen is corrected. (6.1.4.)<br>4. Intended Use is added.<br>5. European Conformity symbol is added. | 3 |
| 2018-05-31 | Complete revision | 2 |
| 2017-08-30 | Newly issued | 1 |

CE

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