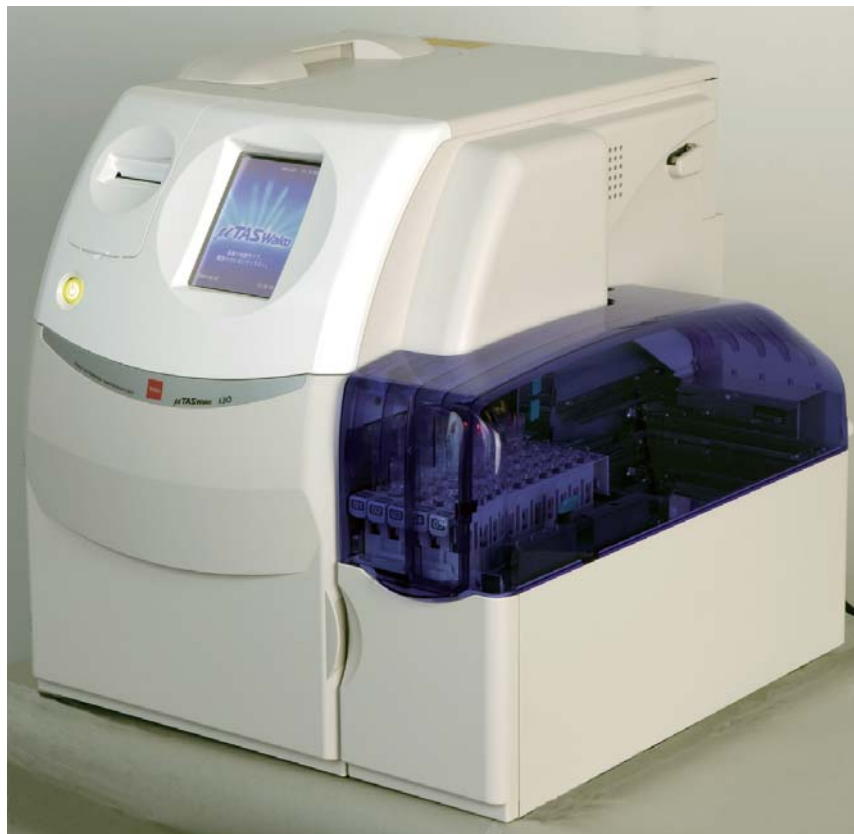

Instruction Manual

FULLY AUTOMATED IMMUNOANALYZER

μTAS Wako ***i30***



Wako Pure Chemical Industries, Ltd.

First Edition

December 2009

Thank you for purchasing the μ TASWako i30.

The μ TASWako i30 is an in vitro diagnostic medical device to analyze blood etc. using the specified reagents.

Before using this equipment, please read this manual carefully to follow the safety information and the usage precautions described in the manual.

Keep the manual near the μ TASWako i30, so that you can refer to it whenever necessary.

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Safe Usage and Handling Precautions	1
Component Names and Functions	2
Description of the Assay Principle	3
Operations	4
Inventory and Maintenance	5
Troubleshooting	6
Parameter Setup	7
Other Functions	8
Specifications/Consumables	9

1. Safe Usage and Handling Precautions	1-1
1.1 Definition of Specific Safety Precautions	1-1
1.2 Precautions before Operating This Equipment	1-1
1.3 Biohazards and Disposal	1-3
1.4 Laser Warning	1-4
1.5 High Voltage	1-4
1.6 Explosive Hazards	1-4
1.7 Electrical Hazards	1-5
1.8 Electromagnetic Compatibility (EMC)	1-6
1.9 Radio Specification	1-7
1.10 Waste Fluid	1-8
1.11 Installation Site Requirements	1-8
1.12 Action for Malfunction	1-10
1.13 Test Results for Diagnosis	1-10
1.14 Quality Control	1-11
1.15 Reagents	1-11
1.16 Handling Calibrators and Controls	1-11
1.17 Handling Samples	1-12
1.18 Detergent	1-12
1.19 Chip and Chip Cassette	1-12
1.20 Recording Paper	1-13
1.21 Labels	1-14
1.22 Periodic Maintenance	1-20
1.23 Product Warranty	1-20
2. Component Names and Functions	2-1
2.1 Component Names	2-1
2.1.1 External View	2-1
2.1.2 Bottle Storage and Chip Station (The front door opened.)	2-1
2.1.3 Sample Rack	2-2
2.1.4 Rear Panel	2-2
2.1.5 Chip, Reagent, Detergent	2-3
2.2 Stand-by Switch	2-4
2.2.1 Stand-by Switch and Power Monitor Function	2-4
2.2.2 Emergency Stop and Action for Recovery	2-4
2.3 Pipetting and Measuring	2-5
2.4 Operation / Display Panel	2-6
2.4.1 MAIN Dialog	2-6
2.4.2 Numeric Keyboard	2-11
2.4.3 PID Keyboard	2-12
2.5 SID Details	2-13
2.6 PID Details	2-13
3. Description of the Assay Principle	3-1

4. Operations	4-1
4.1 Startup Inspection.....	4-1
4.1.1 Preparation before Turning the Stand-by Switch On.....	4-2
4.1.2 Turning the Stand-by Switch ON.....	4-4
4.1.3 When the [Operator ID Function] Is Active.....	4-6
4.1.4 Turning off the Analyzer (Shut Down).....	4-7
4.1.5 Check List for Daily Checks before Use.....	4-9
4.1.6 Check List of Daily Checks after Use.....	4-9
4.1.7 Preparation of Sample Rack.....	4-10
4.1.8 Blood Collection Tube for μ TASWako i30.....	4-12
4.1.9 Placing Area for Barcode Label.....	4-13
4.1.10 Amount of Sample.....	4-14
4.2 Calibration Operation.....	4-15
4.2.1 Calibration Operation Using Barcode Labeled Holder.....	4-17
4.2.2 Calibration Operation with No Barcode Labeled.....	4-21
4.2.3 How to Check the Past Calibration Results.....	4-24
4.2.4 How to Calibrate by Selecting Reagent Bottle.....	4-25
4.2.5 Calibration Copy.....	4-26
4.3 Quality Control Operation.....	4-27
4.3.1 QC Operation Performed Automatically with Barcode Reading.....	4-27
4.3.2 QC Operation by Selecting Reagent Bottle.....	4-30
4.3.3 QC Operation for Old and New Reagent Bottles.....	4-33
4.3.4 How to Browse Results of QC Operation (Quality Control Chart).....	4-34
4.4 Standard Operation.....	4-35
4.4.1 Order List Dialog and Sample Rack.....	4-36
4.4.2 Manual Order Operation (Individual).....	4-37
4.4.3 Manual Order Operation (Batch).....	4-38
4.4.4 Auto Request Operation (with Barcode).....	4-39
4.4.5 Worksheet Request Operation (with Barcode).....	4-40
4.4.6 Worksheet Request Operation (without Barcode).....	4-41
4.5 Operation Methods.....	4-42
4.5.1 Details of Manual Order Operation (Individual).....	4-42
4.5.2 Details of Manual Order Operation (Batch).....	4-46
4.5.3 Editing Batch Order.....	4-47
4.5.4 Deleting Orders in Batch.....	4-48
4.5.5 Details of Auto Request Operation (with Barcode).....	4-49
4.5.6 Details of Worksheet Request Operation (with Barcode).....	4-50
4.5.7 Details of Worksheet Request Operation (without Barcode).....	4-52
4.6 Start Operation.....	4-55
4.6.1 Sample Loading When Continuously Performing Operation.....	4-58
4.7 Completion of Operations.....	4-59
4.8 Emergency (STAT) Sample Operation.....	4-61
4.8.1 STAT Operation Order.....	4-61
4.9 Additional Sample Loading during Operation.....	4-63
4.10 Checking Operation Status.....	4-64
4.11 Checking Test Results.....	4-65
4.11.1 Flow of Checking Results.....	4-65
4.11.2 Result Dialog.....	4-66

4.11.3	How to Check Printed Test Results	4-68
4.11.4	Recalculation Function	4-70
4.11.5	Retransmission and Reprint	4-72
4.12	Re-run Operation	4-73
4.12.1	Re-run Range	4-74
4.12.2	How to Order Re-run Operation	4-75
4.13	Power Outage and the Recovery.....	4-79
5.	Inventory and Maintenance	5-1
5.1	About Inventory Key	5-1
5.2	Consumables Dialog.....	5-2
5.2.1	Inventory Dialog.....	5-3
5.3	How to Set Reagents and Consumables.....	5-4
5.3.1	Reagents	5-4
5.3.2	Chips	5-8
5.3.3	Detergent.....	5-12
5.3.4	Purified Water and Waste Fluid.....	5-14
5.4	Periodic Maintenance	5-18
5.5	Items of User Maintenance.....	5-19
5.5.1	Weekly Inspection	5-19
5.5.2	Monthly Inspection.....	5-20
5.5.3	Quarterly Inspection (once every 3 months).....	5-24
5.5.4	Replacing Recording Paper.....	5-25
5.5.5	Cleaning Outer Covers	5-26
5.5.6	Liquid Leak Check around Bottles (Purified Water and Waste Fluid) and inside of the Maintenance Cover	5-27
5.5.7	Liquid Leak Check When External Water Supply and Drainage Kit (optional parts) Installed	5-28
5.6	Maintenance Function	5-29
5.6.1	Error Log.....	5-30
5.6.2	Condition Monitor	5-31
5.6.3	Washing Pipetting Probe	5-32
5.6.4	Washing Electrodes.....	5-33
5.7	Contrast Adjustment of Operation/Display Panel	5-34
5.8	Procedures before and after Long-term Disuse.....	5-35
5.8.1	Storage	5-35
5.8.2	Re-Start	5-35
6.	Troubleshooting	6-1
6.1	Error Indications.....	6-1
6.1.1	Error Indication Format.....	6-1
6.1.2	Error Level	6-1
6.2	Error List	6-2

Contents

6.3	Corrective Action	6-8
6.3.1	How to Recover from Chip Jamming.....	6-8
6.3.2	How to Recover from Sample Rack Transfer Error	6-12
6.3.3	When Waste Fluid Filled Detected	6-13
6.3.4	No Purified Water Supplied	6-14
6.3.5	When Reagent Surface Is Not Detected	6-15
7.	Parameter Setup.....	7-1
7.1	Parameter Setup List.....	7-1
7.2	Administrator Password and Parameter Setup Dialog	7-2
7.3	Parameter Setup Methods.....	7-3
7.3.1	Reference Interval Setup.....	7-3
7.3.2	Re-run Range Setup.....	7-5
7.3.3	Correlation Formula Setup	7-8
7.3.4	Date and Time Setup.....	7-11
7.3.5	Buzzer Setup	7-12
7.3.6	Printer Setup.....	7-13
7.3.7	Cal/QC Repeat Number	7-14
7.3.8	Inventory Warning Level Setup	7-15
7.3.9	Operator ID Setup	7-16
7.3.10	Accumulative Test Counts.....	7-18
7.3.11	Data Communication & Barcode Setup.....	7-19
7.3.12	Data Export.....	7-26
7.3.13	Software Version	7-28
7.3.14	Program Update	7-29
7.3.15	Maximum Rack Number Setup.....	7-31
7.3.16	Repeat Number for CV Setup.....	7-31
7.3.17	Pump Priming	7-32
7.3.18	Options Setup.....	7-33
7.3.19	AFP Peak Setting	7-34
8.	Other Functions	8-1
8.1	External Water Supply and Drainage Kit	8-1
9.	Specifications/Consumables.....	9-1
9.1	Specifications.....	9-1
9.2	Standard Accessory List	9-2
9.3	Consumables.....	9-2
9.4	Periodical Replacement Parts	9-3
9.5	Optional Parts	9-3

1 Safe Usage and Handling Precautions

1 Safe Usage and Handling Precautions

This section contains safety precautions which must be followed for the safe operation of the μ TASWako i30. Before using this equipment, please read this chapter carefully and follow the precautions given, so that you can operate it correctly.

1.1 Definition of Specific Safety Precautions

Specific safety precautions are noted by the terms WARNING, CAUTION, IMPORTANT, and additional information by NOTE. The respective meanings are as follows:

WARNING

Indicates hazardous situations that may lead to serious injury, even death or the transmission of infectious agents if the precaution is not followed.

CAUTION

Indicates hazardous situations that may lead to minor or moderate injury or physical damage if the caution is not followed.

IMPORTANT

Indicates improper handling that could have an adverse effect on the accuracy of the measurement values if the precaution is not followed.

NOTE: Indicates procedures requiring special attention, instructions that must be followed, supplementary explanations, etc.

1.2 Precautions before Operating This Equipment

CAUTION

Before using this equipment, please read this Instruction Manual carefully so that you can operate the equipment correctly.

CAUTION

Whenever you operate this equipment, be sure to observe the precautions described in this manual. Failure to do so may subject you to injuries, cause property damage, or produce incorrect test results.

CAUTION

This equipment is an in vitro diagnostic medical device using in vitro diagnostic agents. Do not use the equipment for other purposes. This equipment is classified as an in vitro diagnostic medical device under DIRECTIVE 98/79/EC.

CAUTION

This equipment is only to be operated by personnel appropriately trained for its intended use and correct operation. Patients do not come into direct contact with the equipment.

1 Safe Usage and Handling Precautions

CAUTION

Wako Pure Chemical Industries, Ltd. shall not be liable for malfunction and damage resulting from connection with other devices or use of software not supplied by Wako Pure Chemical Industries, Ltd.

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CAUTION

The accessories (for example, AC power cable, etc.) are specified only for this equipment. Do not use the specified accessories for other equipment.

CAUTION

Do not place cups or containers with liquids on the equipment. If liquids spill over the equipment, fire or electrical shock may occur.

CAUTION

Do not place heavy objects on the equipment, and do not apply force on the equipment. This may result in damage and/or malfunction on the equipment.

CAUTION

Do not have an impact shock on the equipment. Otherwise, malfunction and/or damage on the equipment may occur.

CAUTION

Do not strike or scratch the operation/display panel using a sharp-pointed instrument (mechanical pencil or ballpoint pen, etc.). This may result in damage and/or malfunction on the equipment.

CAUTION

The settings described in Chapter 7 include important settings, which affect test results such as correlation formula. The settings must be operated only by the administrators who have the responsibility for the use of the equipment. Inputting a password allows the administrators to operate the administrator tools.

CAUTION

Do not remodel the μ TASWako i30.

CAUTION

The durability period for this equipment is 6 years after installation at your site.
(This period is valid as long as the precautions for use are followed and regular periodic maintenance is performed correctly.)
As the concerns for safety or performance will increase when this period of 6 years expires, please consult your customer support for advice.

! CAUTION

Whenever you operate or touch the parts  labeled, be sure to observe the precautions described in Sec. 1.21 (P1-14) "Labels".

! CAUTION

Keep ethanol away from fire as it is highly flammable, when using it for disinfection or cleaning.

1

1.3 Biohazards and Disposal

! WARNING

As used (contaminated) consumables (e.g., used chips, sample tubes, blood collection tubes, reagents, calibrators, Controls, or detergent's cups) and contaminated swabs or cloths used for cleaning the equipment are infectious waste, process the waste correctly in compliance with any applicable regulations in your country, such as by incineration, melting, sterilization or disinfection. Even if you entrust a dealer with the disposal, ensure to process the waste correctly in compliance with any applicable regulations.

! WARNING

When discarding the equipment that may be contaminated with blood samples, be sure to process it correctly in compliance with any applicable regulations in your country because it is infectious waste.

! WARNING

When handling blood samples and performing maintenance (cleaning the analyzer), always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles), referring to the sample handling rules of your facility. If any part of the body comes in contact with samples, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

! WARNING

Do not touch used chips and sample tubes with bare hands as these are contaminated with blood sample. If any part of the body comes in contact with contaminated consumables, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

! WARNING

When samples come in contact with the equipment's components, immediately clean and disinfect the components using soft cloth moistened with ethanol for disinfection.

! CAUTION

The LCD display lamps in this product contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws.

1 Safe Usage and Handling Precautions

1.4 Laser Warning

<Embedded laser>

The μ TASWako i30 has a built-in laser [class 3B, 638nm, maximum 45 mW (CW)].

<Safety standard>

This equipment complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No.50, dated (June 24, 2007).

This equipment is a Class 1 laser product (designed according to IEC60825-1:2001).

<Laser safety>

As above, this equipment conforms to the FDA performance standards (Laser Notice No.50), so the laser radiation is designed to be safety. As long as the users operate the equipment correctly, so that the safety is fully guaranteed.

<Covers of the equipment>

The covers of the equipment are secured using screws.

If the screws are loosened or the covers are removed, the laser beam may be leaked.

Be sure not to loosen the screws and not to remove the covers, except for by technicians specially trained.

WARNING

Do not remove the covers secured by screws.

As the equipment has a built-in laser source, the laser radiation may expose to users to harm their eyes. If the equipment is possible to be abnormal, please contact your customer support for assistance.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

1.5 High Voltage

This equipment uses high voltage.

As long as the users operate the equipment correctly (including user maintenance), there are no risks to touch the high voltage at all.

WARNING

Do not remove the covers secured by screws.

Otherwise, electrical shock may occur as the equipment includes high voltage inside.

1.6 Explosive Hazards

WARNING

As this equipment is not explosion-proof, be sure not to use flammable and explosive gas around the equipment.

1.7 Electrical Hazards

WARNING

The power supply voltage applied to the equipment is AC100 - 240V.

To avoid electrical shock, follow the precautions as bellow:

- Avoid installation sites where water may splash, etc., on the equipment.
- Make sure that the equipment is properly grounded to a protective earth lead for indoor wiring.
- Make sure that all cables have been properly connected.

WARNING

Plug the power cable of the equipment into an outlet with a grounding receptacle. If the equipment is not grounded to a protective earth, this may cause electrical shock.

WARNING

When plugging the power cable in or removing it from an outlet, be sure to hold onto the plug body, not just the cable. Otherwise, the power cable will have physical damage, so that electrical shock or danger of fire may result.

WARNING

Do not remove covers secured by screws from the equipment. Otherwise, contacting exposed hazardous voltage may cause electrical shock, or touching moving parts may cause injury.

1.8 Electromagnetic Compatibility (EMC)

CAUTION

This equipment conforms to the following EMC requirements:

- EN61326-1:2006 (Class A)
- FCC Part 15 Subpart B:2009, Class A
- ICES-003 Issue No.4, Class A

This is a class A product. In a domestic environment, this product may cause radio interference in which case the user may be required to take adequate measures.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area may cause harmful interference in which case the user will be required to correct the interference at his own expense.

This Class A digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la class A est conforme a la norme NMB-003 du Canada.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

Consult your customer support for help.

CAUTION

Do not use other devices (such as mobile phone) which generate and can radiate radio frequency energy near the equipment. Otherwise, physical damage or malfunction on the equipment may occur.

<Statements for EN61326-2-6>

NOTE: It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

On the other hand, it is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

This equipment complies with the emission and immunity requirements described in EN61326-2-6.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The electromagnetic environment should be evaluated prior to operation of the device.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources, mobile phone), as these may interfere with the proper operation.

1.9 Radio Specification

CAUTION

This equipment conforms to the following Radio requirements:

- EN301 489-17 V1.3.2
- EN301 489-1 V1.8.1
- EN300 330-2 V1.3.1
- FCC Part 15 Subpart C 15.225
- RSS210 Issue 7

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment.

This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. The antenna used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

1 Safe Usage and Handling Precautions

1.10 Waste Fluid

WARNING

When discarding waste fluid, be sure to process it correctly in compliance with any applicable regulations in your country, such as laws for preventing water pollution and for sewerage system. Otherwise, this may cause environmental pollution or go against the laws.

WARNING

The waste fluid may contain infectious substances. When handling the waste fluid, always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles), referring to the sample handling rules of your facility. Do not touch the waste fluid directly with bare hands.

If any part of the body comes in contact with waste fluid, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

WARNING

When waste fluid is spilled over the equipment, always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles) to wipe out the spilled fluid and disinfect the part using ethanol for disinfection.

CAUTION

For the information about the concentrations of toxic or harmful substances which the reagents contain, refer to the instructions for use accompanied with the reagents.

1.11 Installation Site Requirements

WARNING

Plug the power cable of the equipment into an outlet with a grounding receptacle. If the equipment is not grounded to a protective earth, this may cause electrical shock.

CAUTION

Avoid the following installation sites:

- Places where spills or water leakage may occur.
- Places where the equipment is exposed to direct sunlight.
- Places near sources of heat such as heaters.
- Places where the temperature may drastically change.
- Places where the equipment is subject to vibration or its support table is unstable.
- Slope places.
- Dusty area.
- Windy places such as the wind from air conditioner directly blows.
- Places where electromagnetic radiation exists.

(1) Install the equipment in the following environmental conditions:

Location:	Indoor use (No direct sunlight exposed)
Illumination:	Below 6,000 cd/m ² (lux)

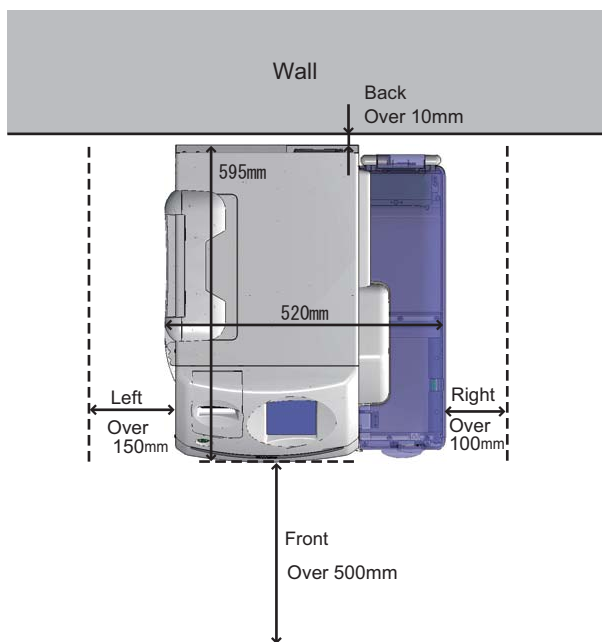
Altitude:	Up to 2,000m
Transient overvoltage category:	II
Pollution degree:	2
Ingress protection rating:	IPX0 (No Protection)
Operating temperature:	15 to 30°C (59 to 86°F) [Temperature shift during operation must be within 2 degrees.]
Operating humidity:	30 to 80% RH (no vapor condensation)

(2) Use the equipment under the following electrical requirements:

Input voltage:	100 - 240V ~
Voltage fluctuation range:	±10%
Frequency:	50 - 60 Hz
Phase:	Single
Rated current:	4 - 1.7 A
Type of protection against electrical shock:	CLASS 1 EQUIPMENT

(3) Plug the equipment into an independent AC outlet separate from other devices.

(4) For the installation site, empty space is necessary as follows: at least 10 cm on the right-hand side; at least 15 cm on the left-hand side; at least 0.5 cm on the back; at least 50 cm on the front; at least 15 cm on the upper side of the equipment.



! IMPORTANT

Keep the required empty space around the equipment for the installation work. Otherwise, exhaust heat will not work properly to cause adverse effects on test results.

1 Safe Usage and Handling Precautions

- (5) The load on a rubber foot of the equipment is approx. 8 kg. Make sure that the strength of the floor at the installation site is acceptable.

CAUTION

Do not move the equipment to another installation site.
This may result in injury or damage on the equipment.
Even if moving within the same facility, please contact your customer support.

1

1.12 Action for Malfunction

CAUTION

When the equipment generates unusual noise, smell, or smoke, immediately unplug the power cable, and contact your customer support.

CAUTION

Do not place any objects near the wall socket so that the power cable's plug of the equipment can be easily pulled out from the wall.

CAUTION

For emergency, empty space on the back is necessary to unplug the power cable connector from the appliance inlet of the analyzer.

1.13 Test Results for Diagnosis

IMPORTANT

Make a diagnosis in a comprehensive manner, considering other relative test results or clinical situation.

IMPORTANT

In case that malfunction (errors) of the equipment are displayed (printed) before/during test processing, or warning indications are printed out along with test results, the test results may NOT be accurate. Refer to Chapter 6: "Troubleshooting" and rerun the tests.

IMPORTANT

To maintain the accuracy of your test results, daily quality control is necessary. Perform quality control using Controls.

IMPORTANT

The equipment has a function to compensate test results using predetermined coefficients. However, when reviewing the performance and the results, use measurement values before the compensation.

1.14 Quality Control

IMPORTANT

When using the equipment, run Controls to monitor the equipment maintains its performance properly.
Incorrect test results will cause wrong diagnosis and may lead the patient to danger.

1.15 Reagents

WARNING

As used (remaining) reagent bottles and the adapters for opening are infectious waste, process the waste correctly in compliance with any applicable regulations in your country, such as by incineration, melting, sterilization or disinfection. Even if you entrust a dealer with the disposal, ensure to process the waste correctly in compliance with any applicable regulations.

IMPORTANT

Please read the instructions for use of the reagents carefully to follow the instructions and use them correctly.

IMPORTANT

Do not use reagents other than specified on “ μ TASWako i30 Reagent Consumable Supply List”.

IMPORTANT

In case that the power has not been supplied for a period of time, load reagents into the storage after the temperature reaches below 10°C (50°F). When the reagents are stored beyond the required storage temperature described in the reagent package or the instructions for use, the reagents may deteriorate.

1.16 Handling Calibrators and Controls

WARNING

As used (remaining) calibrators and Controls in cup are infectious waste, process the waste correctly in compliance with any applicable regulations in your country, such as by incineration, melting, sterilization or disinfection. Even if you entrust a dealer with the disposal, ensure to process the waste correctly in compliance with any applicable regulations.

IMPORTANT

To obtain test results, it is necessary to perform calibration; more specifically, measuring calibrator for each reagent bottle.
Be sure to perform calibration each time a reagent bottle is set.

IMPORTANT

To maintain the system accuracy and observe the calibration condition, we recommend measuring Controls for quality control.

1.17 Handling Samples

WARNING

When handling samples, always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles), referring to the sample handling rules of your facility. If any part of the body comes in contact with samples, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

IMPORTANT

Make sure that there are no foreign matter in the sample. If there are fibrin deposit in the sample, remove them before the measurement. The foreign matter or fibrin may clog in the pipetting probe to cause malfunction of the equipment.

IMPORTANT

Thick samples sometimes clog in the pipetting probe and decrease the pipetting volume to cause adverse effects on test results.

IMPORTANT

When sample is left in a sample cup for a long time, the sample may concentrate. Particularly, in case that the amount of the sample is small, pay attention to the concentration. The evaporation of the sample may increase the error of the measurement accuracy.

1.18 Detergent

WARNING

As used (remaining) detergent bottles are infectious waste, process the waste correctly in compliance with any applicable regulations in your country, such as by incineration, melting, sterilization or disinfection. Even if you entrust a dealer with the disposal, ensure to process the waste correctly in compliance with any applicable regulations.

IMPORTANT

The equipment performs pipetting samples and reagents using a pipetting probe. To wash the probe thoroughly, the equipment uses the detergent for μ TASWako. If the detergent is not used properly, the pipetting probe may not be washed thoroughly.

Be sure to use the specified detergent and follow the number of times for use. Do not refill detergent into the bottle.

1.19 Chip and Chip Cassette

WARNING

Do not touch used chips with bare hands. This may cause infection. If any part of the body comes in contact with contaminated consumables, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

! WARNING

As used chips are infectious waste, process the waste correctly in compliance with any applicable regulations in your country, such as by incineration, melting, sterilization or disinfection. Even if you entrust a dealer with the disposal, ensure to process the waste correctly in compliance with any applicable regulations.

! WARNING

Do not use a defective or cracked sample cup. The defective sample cup or scattering sample may cause contamination, infection, and injury.

! IMPORTANT

When loading a chip cassette, be sure to remove the chip tie beforehand and then set it correctly. If the chip cassette is not loaded correctly, the trouble, such as the equipment does not work or is broken, will occur.

! IMPORTANT

Do not use a chip that has been dropped out once from the chip cassette accidentally. Otherwise, the accurate test result may not be obtained.

! IMPORTANT

Do not handle a chip and a chip cassette by wet hands.
The chip is contaminated, so that the accurate test result may not be obtained.

! IMPORTANT

Used chips and sample cups cannot be reused. If used ones are reused, the accurate test results may not be obtained.

! IMPORTANT

Do not use chips other than specified for the equipment. Otherwise, the accurate test results may not be obtained.

! IMPORTANT

Use chips after warming up to the room temperature. Otherwise, the accurate test results may not be obtained.

1.20 Recording Paper

- (1) Use the specified recording paper for the μ TASWako i30.
- (2) Do not use paper other than the type specified. Otherwise, the printer head may be damaged.

1 Safe Usage and Handling Precautions

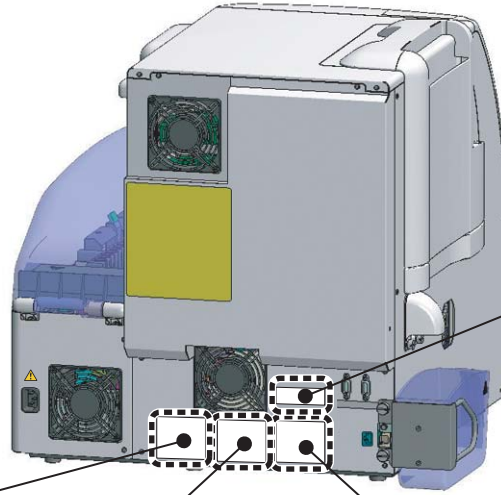
1.21 Labels

WARNING


Do NOT peel off the labels on the equipment.

If the labels are unclear to read, or have been peeled off, it is necessary to replace them with new ones. Please contact your customer support for assistance.

- Name-plate/HHS label/FCC label/US mercury label



US mercury label

 LCD display lamps contain mercury.
Dispose of properly.



FCC label


FCC ID X2IUTASWAKOI30 IC ID 8779A-UTASWAKOI30
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
This Class B digital apparatus complies with Canadian ICES-003. Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

HHS label

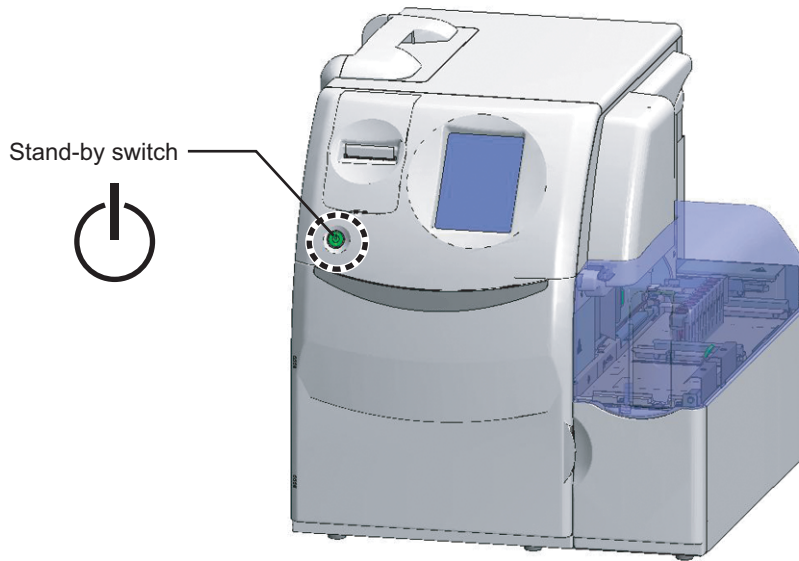
Wako Pure Chemical Industries, Ltd. 1-2, Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan	
IMMUNO ANALYZER	
MODEL	μTASWako i30
SERIAL No.	
MANUFACTURED	FFTPT
Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No.50, dated (June 24, 2007).	
405N101414	

Name-plate

Manufacturer Wako Pure Chemical Industries, Ltd. 1-2, Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan	
Fluorometer for Clinical Use IMMUNO ANALYZER μ T A S W a k o i 3 0	
100-240V~ 4-1.7A 50-60Hz	
FOR IN VITRO DIAGNOSTIC USE	
 	
SN	LABORATORY EQUIPMENT 19NS 405N101413

 : This symbol shows the alternating current.

- Stand-by switch



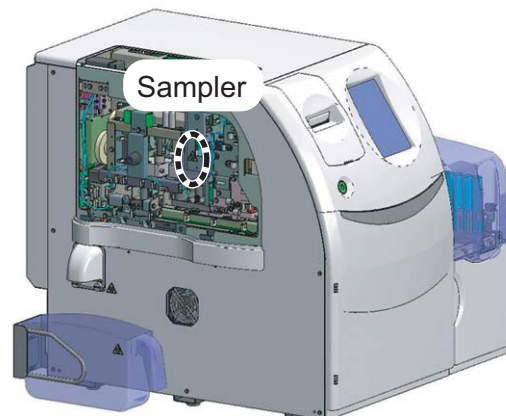
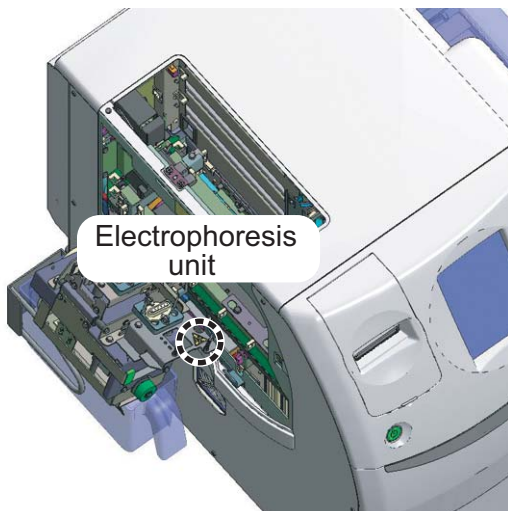
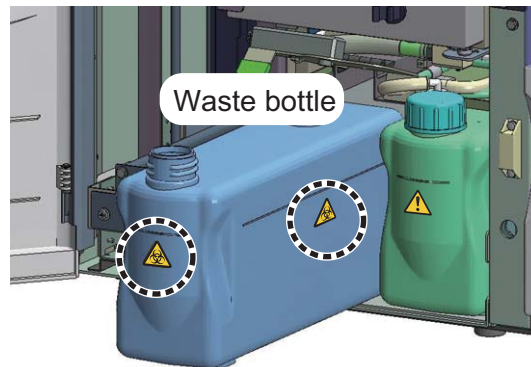
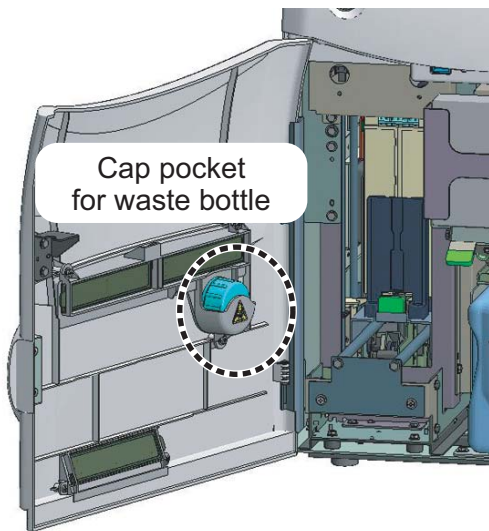
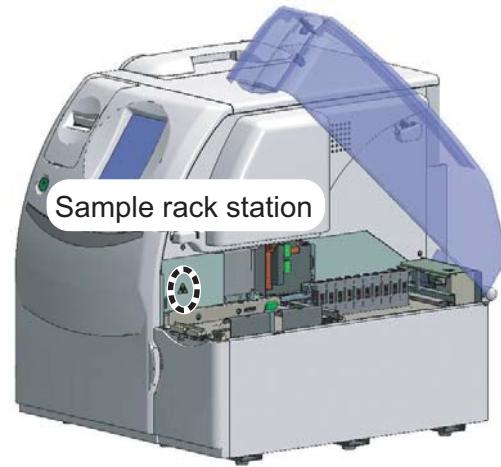
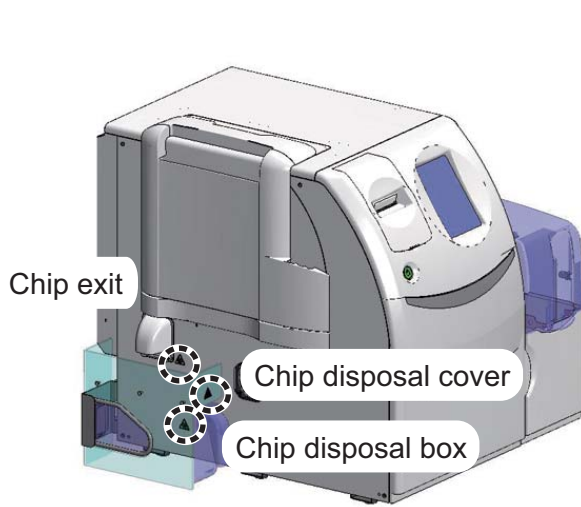
1 Safe Usage and Handling Precautions

- Biohazard label



<Biohazard label>
The label means biohazard (infections) warning.
Be sure to follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles). When discarding infectious waste, be sure to process it correctly in compliance with any applicable regulations in your country.

1



• Laser caution labels

注意 — ここを開くとクラス3Bのレーザー光が出ます。ビームの被ばくを避けてください。

CAUTION — CLASS 3B LASER RADIATION WHEN OPEN. AVOID EXPOSURE TO THE BEAM.

VORSICHT — KLASSE 3B LASERSTRAHLUNG WENN ABDECKUNG GEÖFFNET. NICHT DEM STRAHL AUSSETZEN.

ATTENTION — RAYONNEMENT LASER DE CLASSE 3B EN OUVRANT ICI. EVITER L'EXPOSITION AU FAISCEAU.

ATTENZIONE — RAGGIO LASER CLASSE 3B IN CASO DI APERTURA IN QUESTA POSIZIONE. NON ESPORSI AL RAGGIO.

ATENCIÓN — RADIACION LASER DE CLASE 3B EN CASO DE ABRIR AQUI. EVITAR LA EXPOSICIÓN A LOS RAYOS.

OBSERVERA — KLASSE 3B LASERSTRÅLNING OM ÖPPNAD HÄR. UNDVIK ATT UTSÄTTA DIG FÖR STRÅLEN.

FORSIGTIG — KLASSE 3B LASERUDSTRÅLING NÅR AFSKÆRMNING ER ÅBEN. UNDGÅ BESTRÅLING FRA LASERSTRÅLEN.

ADVARSEL — KLASSE 3B LASERSTRÅLING UTGÅR HER HVIS ENHETEN ÅPNES. UNNGÅ EKSPONERING AV STRÅLEN.

주의 — 이곳을 열면 등급 3B의 레이저 광선이 나옵니다. 빔에 피폭되지 않도록 주의하여 주십시오.

VOORZICHTIG — KLASSE 3B LASERSTRALLEN INDIEN HIER GEOPEND. VERMIJD BLOOTSTELLING AAN LASERSTRALLEN.

CUIDADO — EMITE RADIACÃO LASER DA CLASSE 3B QUANDO ABERTO AQUI. EVITE EXPOSIÇÃO AO RAIOS.

HUOMAUTUS — LUOKAN 3B LASERSÄTELYÄ LAITTEEN OLLESSA AUKI. VÄLTÄ ALTISTUMISTA LASERSÄTEELLE.

ΠΡΟΣΟΧΗ — ΥΠΑΡΧΕΙ ΑΚΤΙΝΟΒΟΛΙΑ ΛΕΙΖΕΡ ΤΑΣΕΩΣ 3B ΟΤΑΝ ΑΝΟΙΧΤΕΙ. ΑΠΟΦΥΓΕΤΕ ΤΗΝ ΕΚΘΕΣΗ ΣΤΗΝ ΑΚΤΙΝΑ ΤΟΥ ΛΕΙΖΕΡ.

注意 — 打开这里时，会发出3B级的激光。请务必避开以免受到激光扫描。

注意 — 打开时将发出3B级的激光。请避免激光束的照射。

<Laser caution label>

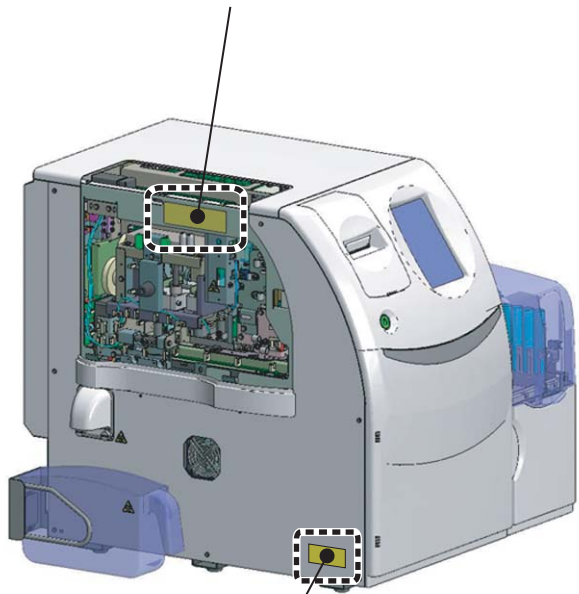
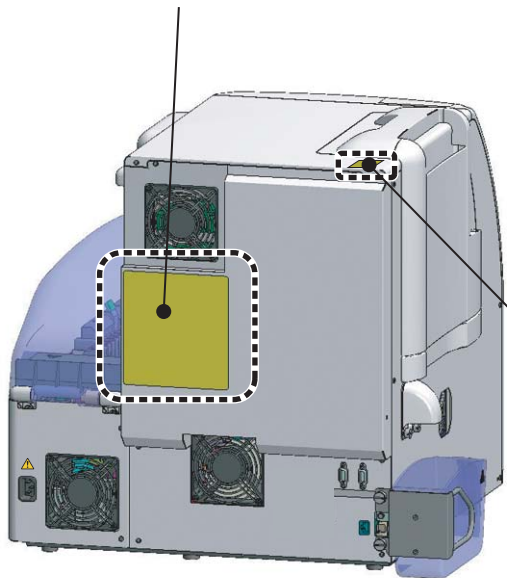
Leaked laser beam may cause blindness.
Do not remove covers secured by screws.

1

注意 — ここを開いて、インターロックを解除するとクラス3Bのレーザー光が出ます。ビームの被ばくを避けて下さい。

CAUTION — CLASS 3B LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED. AVOID EXPOSURE TO THE BEAM

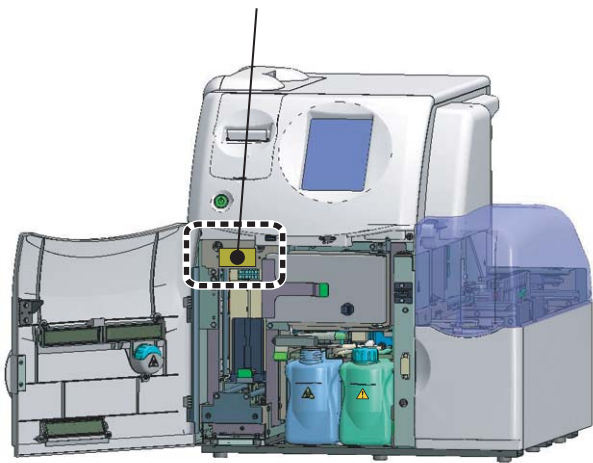
ATTENTION — RAYONNEMENT LASER DE CLASSE 3B A L'OUVERTURE ET QUAND LE VERROUILLAGE EST DEJOUÉ. EVITER L'EXPOSITION AU FAISCEAU



注意 — ここを開くとクラス3Bのレーザー光が出ます。ビームの被ばくを避けて下さい。

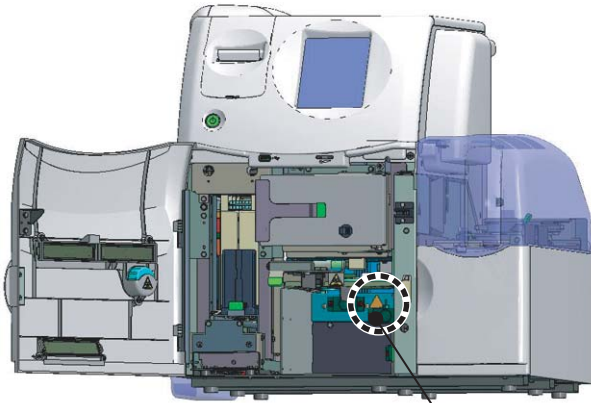
CAUTION — CLASS 3B LASER RADIATION WHEN OPEN. AVOID EXPOSURE TO THE BEAM.

ATTENTION — RAYONNEMENT LASER DE CLASSE 3B EN OUVRANT ICI. EVITER L'EXPOSITION AU FAISCEAU.



1 Safe Usage and Handling Precautions

- High temperature caution label

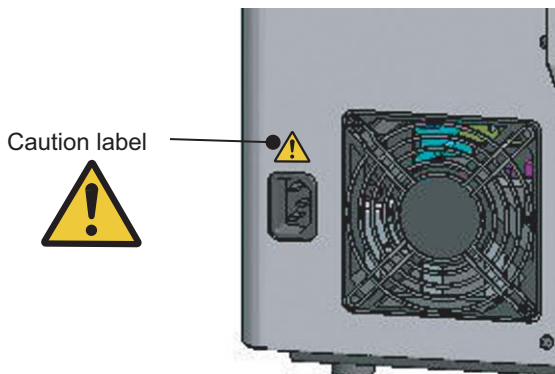


High temperature caution label



The high temperature part is the fin of the radiator above the label.

- Caution label



Caution label



⚠ CAUTION

When you lay a hand on the part during use or just after use, you may get burned. When performing the maintenance or the inspection, be sure to check that the part has completely cooled down.

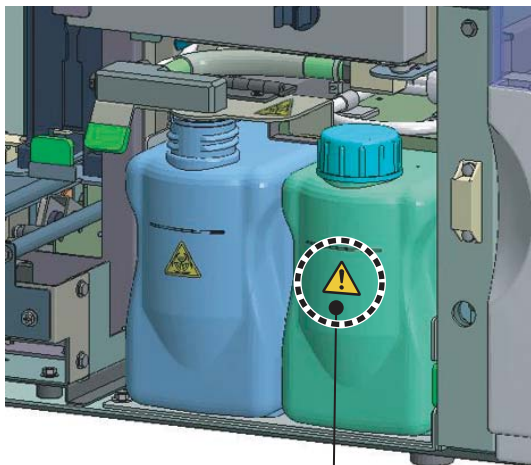
⚠ CAUTION

Be sure to use the specified power cable packed as an accessory.

⚠ CAUTION

Supply purified water into the purified water bottle.

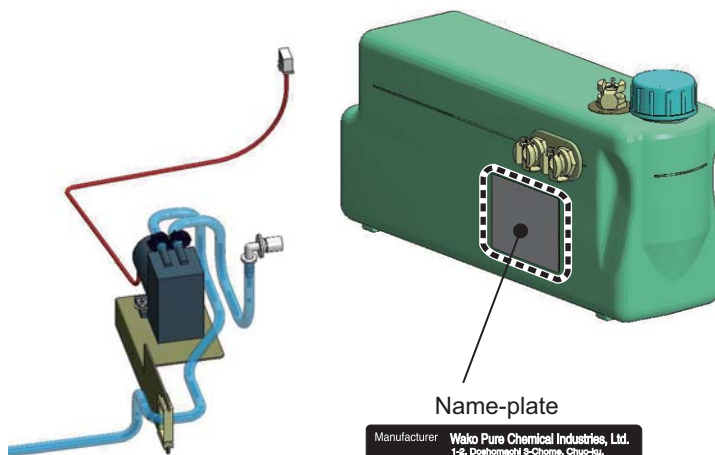
NOTE: The purified water must be either distilled water or ion-exchanged water (the electric conductance must be under $1\mu\text{S}/\text{cm}$.)



Caution label



- Name-plate of external water supply and drainage kit (option)



Name-plate



1.22 Periodic Maintenance

In order to maintain the safety and the performance of the equipment, the periodic maintenance and inspection are necessary.

The maintenance and inspection by the customer are described in the body of this manual in detail.

We recommend our maintenance support contract for the maintenance by the technicians trained for the equipment.

1.23 Product Warranty

Wako Pure Chemical Industries, Ltd. warrants this equipment for one year from the date of the initial installation.

If this equipment does not function during the warranty period only in the case of manufacturer's defect, your customer support will repair or replace the parts without charge.

However, we shall not liable for malfunction and damage of the following cases:

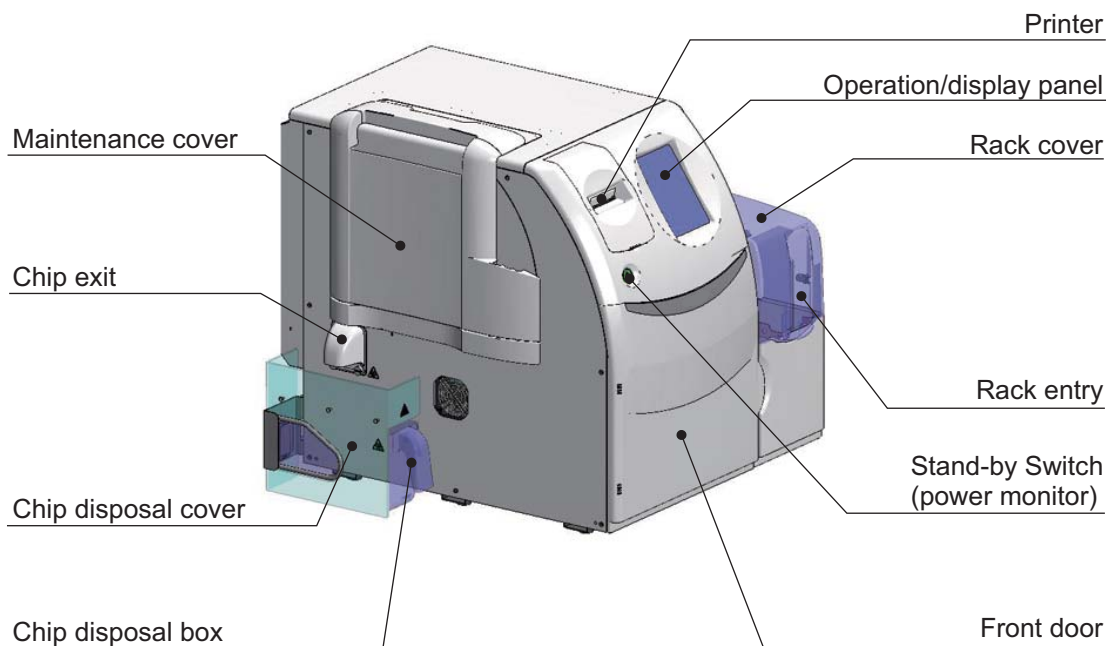
- (1) The equipment has been operated incorrectly.
- (2) The equipment has been repaired or remodeled by dealers other than specified by Wako Pure Chemical Industries, Ltd.
- (3) The parts or reagents not specified by Wako Pure Chemical Industries, Ltd. have been used for the equipment.
- (4) The malfunction or damage has been caused by reasons other than this equipment.
- (5) The equipment has been used in the severe condition, such as high temperature, high humidity, corrosive gas, or vibration.
- (6) The malfunction or damage is caused by fires, earthquakes, and other natural disasters.
- (7) After the first installation on the site, the customers have moved or transported the equipment only by themselves.
- (8) The malfunction or damage of the consumables or the equivalent parts.

2 Component Names and Functions

2 Component Names and Functions

2.1 Component Names

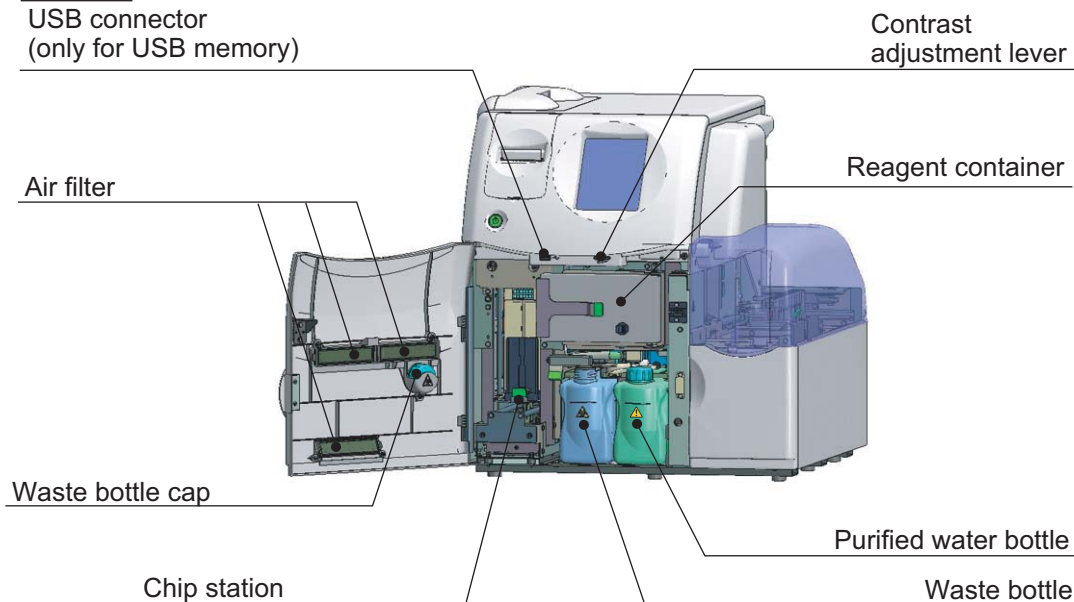
2.1.1 External View



2.1.2 Bottle Storage and Chip Station (The front door opened.)



USB connector
(only for USB memory)

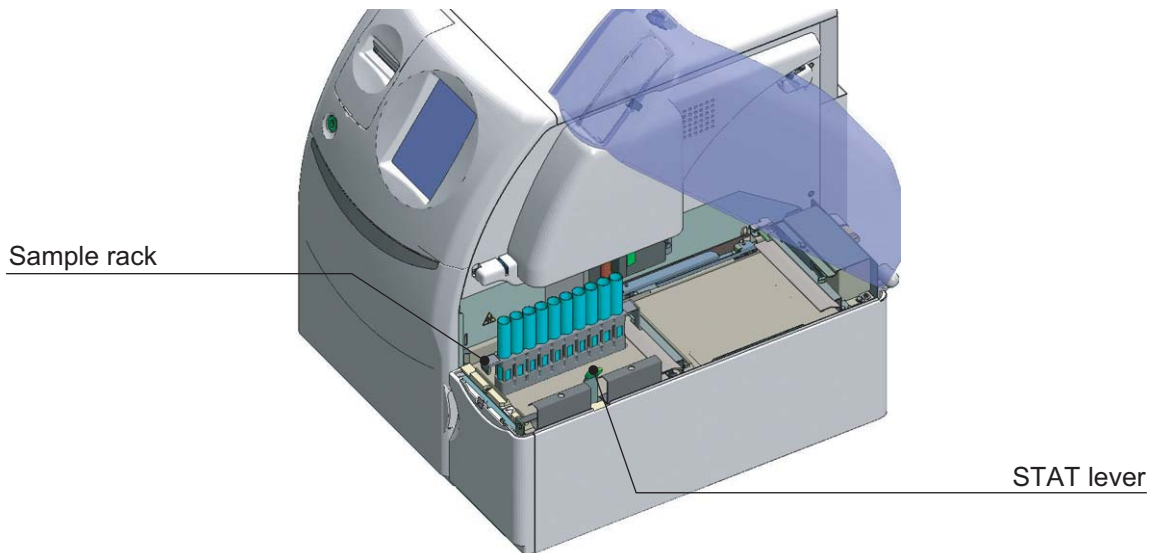


CAUTION

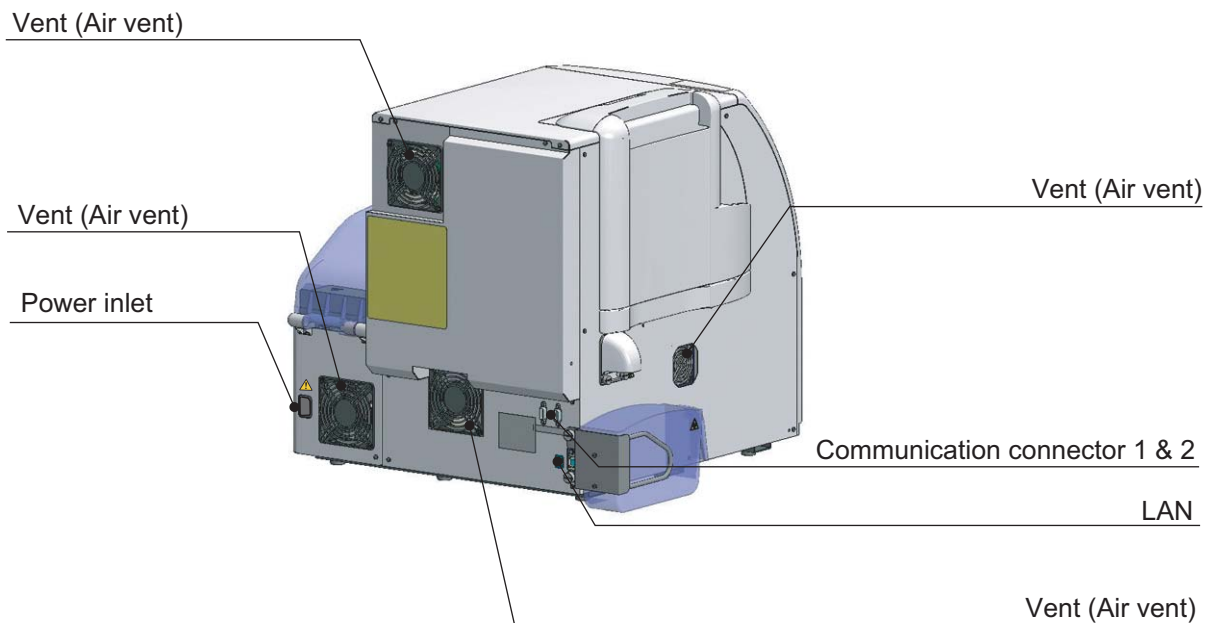
The USB connector of this analyzer is used only for USB memory. Do not use the USB connector for other purposes.

2 Component Names and Functions

2.1.3 Sample Rack



2.1.4 Rear Panel



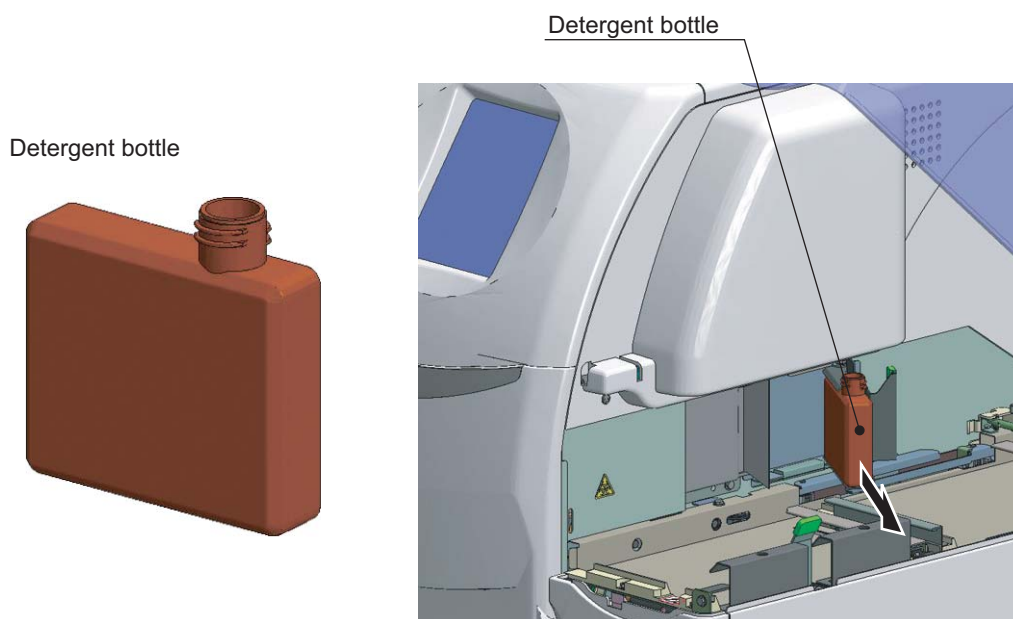
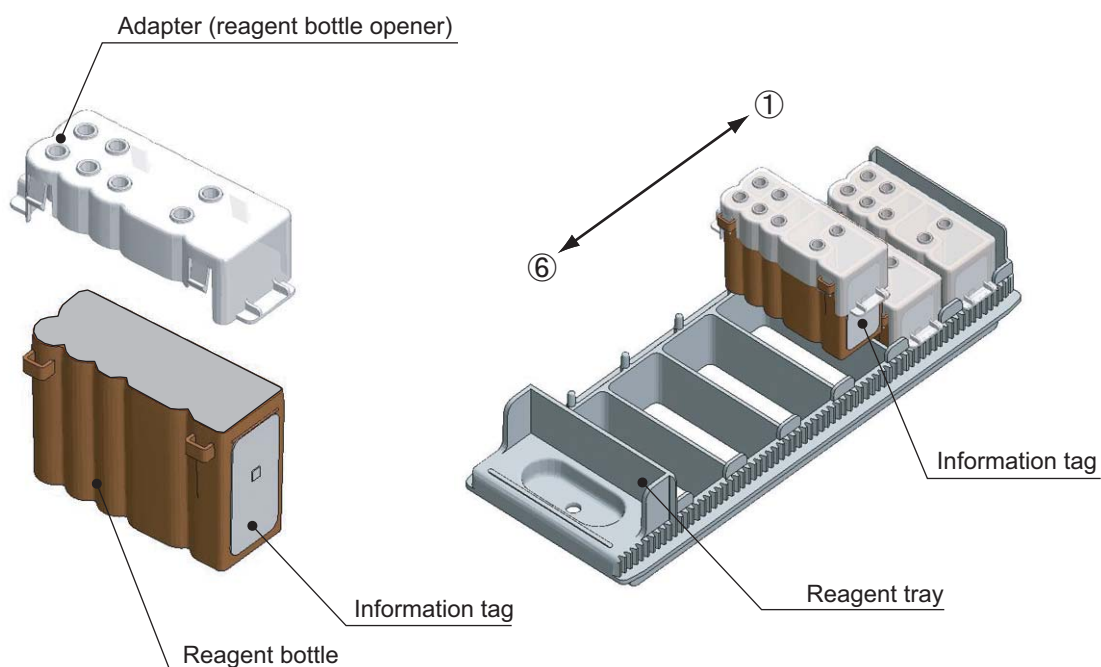
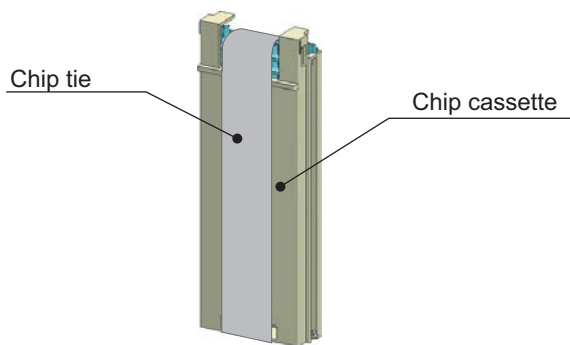
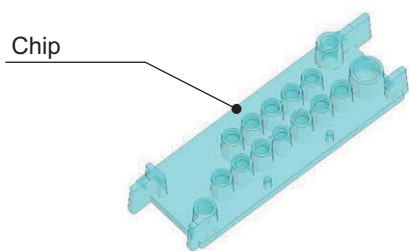
CAUTION

When the analyzer generates unusual noise, smell, or smoke, or other emergency situations that need emergency stop occur, immediately unplug the power cable, and contact your customer support.

CAUTION

Do not connect the communication connectors or the LAN connector to a host computer or PC which has not been approved by IEC/UL60950-1.

2.1.5 Chip, Reagent, Detergent



2.2 Stand-by Switch

2.2.1 Stand-by Switch and Power Monitor Function

NOTE: The Stand-by switch is used only for starting up the analyzer.

To stop the analyzer, use the [Shut Down] key on the operation/display panel.

During operation process, the [Shut Down] key is not active.

The Stand-by switch has a lamp that indicates the power supplied condition.

The indicator of the Stand-by switch means as follows:

<Indicator lamp of the Stand-by switch and power supplied condition>

Indicator lamp of the Stand-by switch	Power supplied unit / condition
Slowly ON/OFF	The reagent container is only powered.
ON	The analyzer (all) is powered.
Quickly ON/OFF (within 1 sec.)	Temperature control error for the reagent container

2.2.2 Emergency Stop and Action for Recovery

CAUTION

When the analyzer generates unusual noise, smell, or smoke, or other emergency situations that need emergency stop occur, immediately unplug the power cable, and contact your customer support.

IMPORTANT

When carrying out emergency stop, press the Stand-by switch to initialize the analyzer after recovering the emergency stop condition. If the initialization is not carried out, the reagent container condition is not guaranteed, therefore, the reagents may not be stored properly.

IMPORTANT

When the power is not supplied for a certain period of time, the reagent's performance may degrade. After recovering from the emergency stop condition, run controls and make sure that the performances of the reagents and the analyzer are reliable before use.

When the power is supplied after the emergency stop, the reagent container is powered and the analyzer will be being powered OFF, but in the Stand-by condition.

By pressing the Stand-by switch, the orders just before the emergency stop will be cancelled, although the already obtained test results have been memorized. The test results during operation process will be errors.

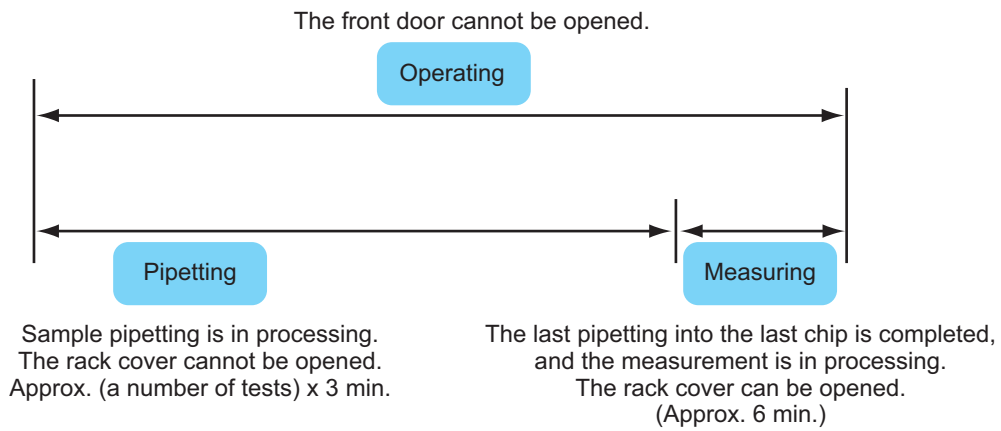
In case of two-way communication, simply select the [START] key to restart.

In case of using worksheet, receive the worksheet again.

2.3 Pipetting and Measuring

This manual describes a process during the “Operating” process as the “Pipetting” process or the “Measuring” process distinctly.

The “Pipetting” and the “Measuring” mean as follows:






2.4 Operation / Display Panel

2.4.1 MAIN Dialog

Analyzer status key Refer to Sec. 4.10 (P4-64)

The analyzer condition is indicated by the message and the color.

-  Sample loading available
-  Processing (Operating, etc.)
-  Action is necessary.

By pressing the analyzer status key, the display turns to the condition display dialog.

STAT / Re-run key



Refer to Sec. 4.8 (P4-61), 4.12 (P4-73)

During operation process, the [STAT] key will be displayed.

The key is used to operate STAT samples.

When re-run lists exist after operation, the Re-run key will be displayed.

Remaining sample display (indicator and number displayed)

For routine operation, the colored indicator means the remaining ordered samples.

The denominator indicates the ordered samples and the numerator indicates the completed samples

NOTE: Remaining samples for calibration and control tests will not be displayed (counted).

Refer to Sec. 2.4.1.1 (P2-7)



Results key

Refer to Sec. 4.11.1 (P4-65)

The key is used to browse test results.

Orders key

Refer to Sec. 2.4.1.2 (P2-8)

The key is used to order operations. The key name depends on the communication settings.

STOP / START /Auto Start / Auto Start Cancel keys



The key is used to start or stop operations. The key name depends on the analyzer condition.

Refer to Sec. 2.4.1.3 (P2-9)

Operator ID switching key

Refer to Sec. 4.1.3 (P4-6)

The key is used to switch operator ID.

When the setting is "The operator ID is not in use", the key will not be displayed.

MENU key

The key is used to switch to the MENU dialog.

FEED key

The FEED key is used to advance recording paper in the printer. Paper advances one line each time the key is selected.

Shut Down key Refer to Sec. 4.1.4 (P4-7)



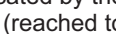
The key is used to stop (shut down) the analyzer.

NOTE: The Stand-by switch is used only for powering the analyzer on. It is impossible to stop the analyzer by the Stand-by switch.

Inventory key Refer to Sec. 5.1 (P5-1)

The key is used to check the inventory of reagents and consumables.

The condition is indicated by the color.

-  Full
-  Low (reached to the alarm point)
-  Empty exists.

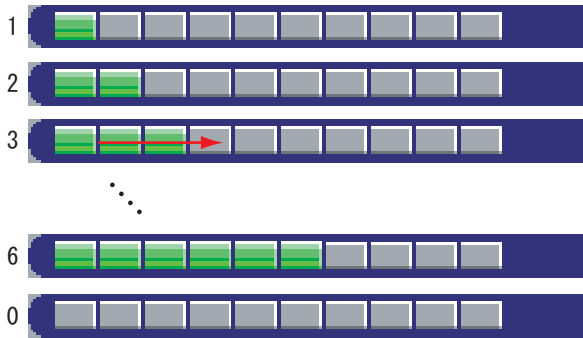
NOTE: Grayed key is not active now.

2.4.1.1 Remaining sample display (indicator and number displayed)



Completed samples

Ordered samples
(+STAT sample orders)



For routine operation, the colored indicator means the remaining ordered samples.

The denominator indicates the ordered samples and the numerator indicates the completed samples.

The remaining part (colored) of the indicator indicates the current operation status, such as expanding and shortening repeatedly on the left figure.

2

NOTE: Remaining samples for calibration and control tests will not be displayed (counted).

NOTE: When operating STAT samples after interruption, the STAT orders will be counted in the denominator.

NOTE: When the communication setting is "Bidirectional + Batch (+ Barcode or - Barcode)", the denominator is the order of the worksheet.






NOTE: When the communication setting is "Bidirectional + Individual", the number will not be displayed.

2 Component Names and Functions

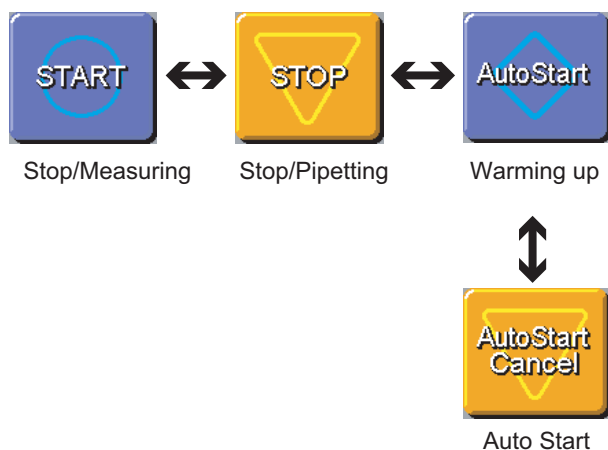
2.4.1.2 [Orders], [Host Order], [ONLINE], [OFF LINE] keys

The key name depends on the communication settings.

Refer to Section 7.3.11 (P7-19) for the communication settings.

Communication setting	Keys	Descriptions
Bidirectional + Individual	<p>ON LINE / OFF LINE</p> 	<p>When the communication is established, the [ON LINE] key will be displayed.</p> <p>When selecting the [ON LINE] key, the communication with the host computer is disconnected and the [OFF LINE] key will be displayed.</p> <p>When selecting the [START] key during the [ON LINE] status, the [OFF LINE] key will be automatically displayed if the response from the host computer is not received.</p> <p>NOTE: During operation process, the key cannot be switched.</p>
Bidirectional + Batch + Barcode	<p>Host Order / OFF LINE</p> 	<p>The key is used to receive worksheet in batch from the host computer.</p> <p>If the response from the host computer is not received, the [OFF LINE] key will be automatically displayed.</p>
Bidirectional + Batch - Barcode	<p>Host Order / OFF LINE</p> 	<p>The key is used to receive worksheet in batch from the host computer after designating a number of samples.</p> <p>If the response from the host computer is not received, the [OFF LINE] key will be automatically displayed.</p>
One-way: Results only	<p>Orders</p> 	<p>The key is used to switch to the order dialog.</p>
None	<p>Orders</p> 	<p>Orders can be browsed.</p>

2.4.1.3 [START], [STOP], [Auto Start], [Auto Start Cancel] keys

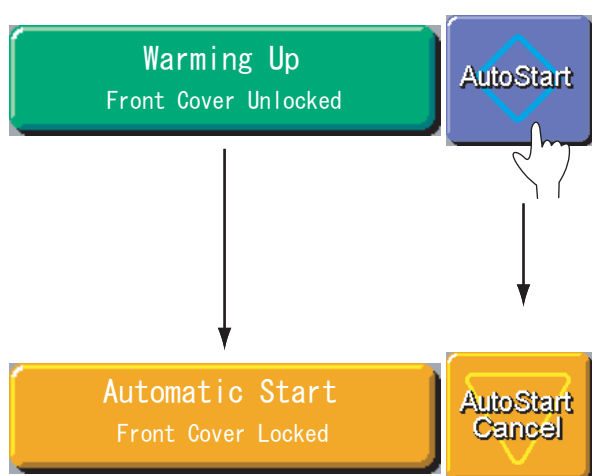


[START] key

The START key is used to start operation.

[STOP] key

The key is used to stop the current operation during operation process.



[Auto Start] key

[Auto Start Cancel] key

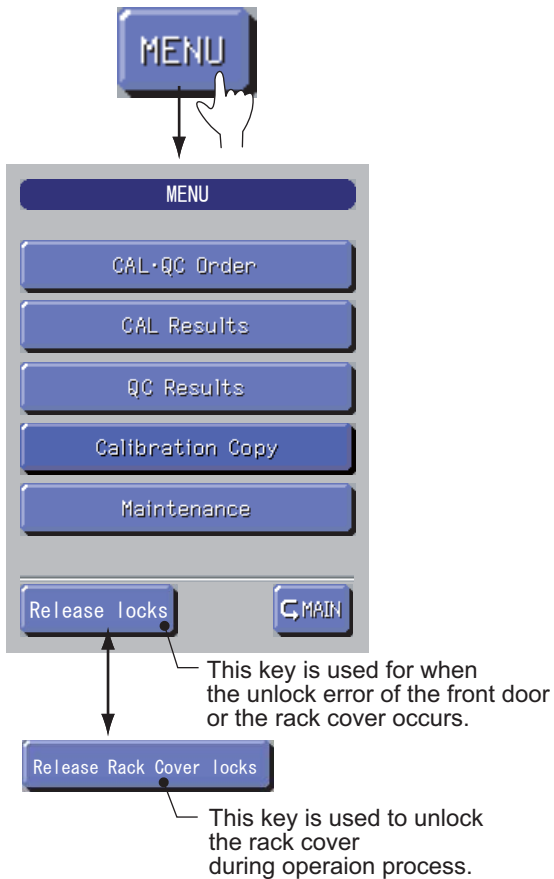
During warming up process, the left will be displayed.

The key is used to reserve automatic start that the operation automatically will start just after the analyzer has been warmed up.

When the automatic start is being reserved, [Auto Start] will be displayed on the analyzer status key.

When the automatic start is being reserved, the [Auto Start Cancel] key is displayed and the reservation can be canceled by the key.

2.4.1.4 [MENU] key

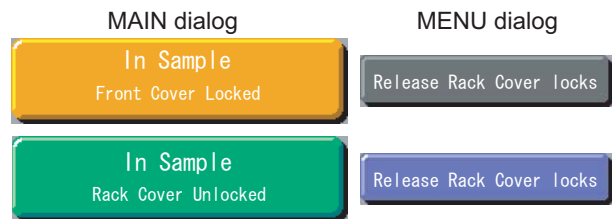


The key is used to switch to the MENU dialog.

The MENU dialog has the following menu:

- CAL/QC Order
- CAL Results
- QC Results
- Calibration Copy
- Maintenance

When the message "Rack Cover Unlocked" is displayed on the status indicator key, the [Release Rack Cover locks].key will be effective on the main menu.

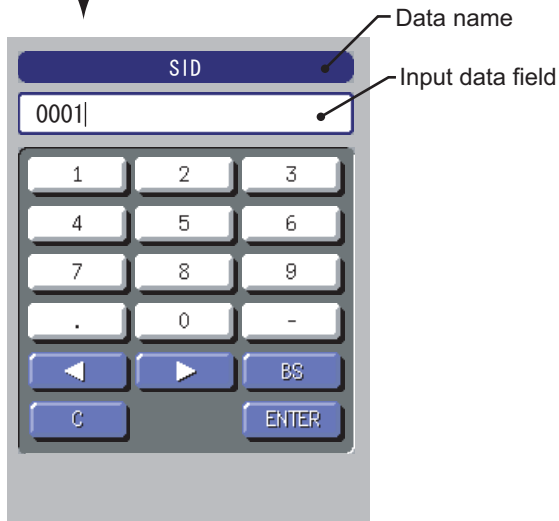
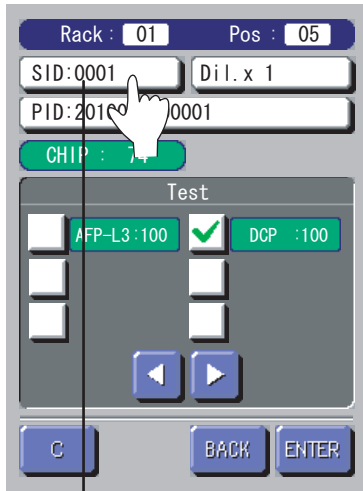


This key is used when loading the next sample at the end of the operation process or when loading STAT sample.

2.4.2 Numeric Keyboard

On numeric data input dialog, the common numerical keyboard will be displayed.

Each manual order dialog



By selecting a numeric data input field, the numeric keyboard will be displayed.

The left figure is an example for inputting SID.

SID details: Refer to Section 2.5 (P2-13)

PID details: Refer to Section 2.6 (P2-13)

Inputting data on the keyboard followed by the [ENTER] key enters the data into the field.

Key	Descriptions
[0] - [9]	Inputs Numeric character
[-]	Inputs Minus sign
[.]	Inputs Decimal point
[C]	Clears Current field at all.
[<] [>]	Moves the cursor.
[BS]	Back space Clears a figure each.
[ENTER]	The input data is accepted, and the previous dialog will appear.

2 Component Names and Functions

2.4.3 PID Keyboard

In PID input field on the order dialog, the common PID keyboard will be displayed.

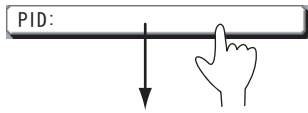
By selecting the PID key, the PID keyboard will appear.

Using the [123] key and the [ABC] key, the input mode can be switched between numerical and alphabetical.

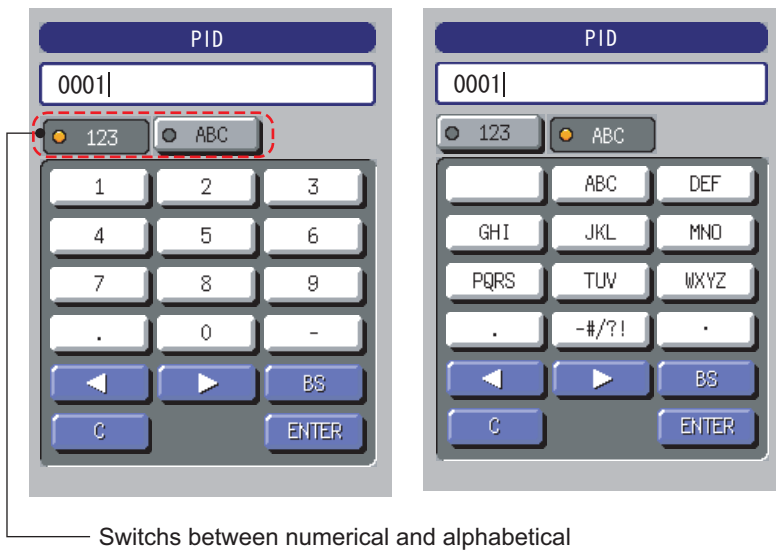
A maximum of 13 alphanumerical characters can be input for a PID.

Inputting alphanumerical characters on the PID keyboard followed by the [ENTER] key enters the PID data.

PID key on the order dialog



PID numerical keyboard ↔ PID alphabetical keyboard

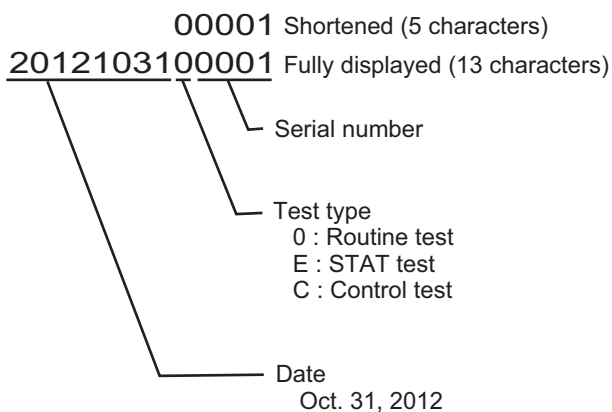


Available alphanumerical characters

Numerical input	Alphabetical input
1	
2	ABC abc
3	DEF def
4	GHI ghi
5	JKL jkl
6	MNO mno
7	PQRS pqrs
8	TUV tuv
9	WXYZ wxyz
0	- # / ? ! . , ; () %
.	.

2.5 SID Details

SID details



The SID is an ID number for a sample which given in sequence of tests everyday.

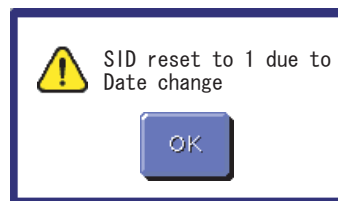
The SID is 13 numerical characters, consisting of year (4 characters), month (2 characters), day (2 characters), test type (1 character), and sequential number (4 characters). However, in the SID input dialog, the five characters are only displayed, eliminating data of year, month, and day. And, the characters to be input are 4.

2

NOTE: For calibration, the SID will not be given.

NOTE: Once inputting a SID, the next SID will be incremented by one for the previous SID.

NOTE: When the date changes, the SID's count will be reset, starting from "00001". At the timing of the reset, "SID reset to 1 due to Date change" will appear.



The message is displayed when the analyzer has been using at 0 o'clock. Also, when the SID has been reset after turning the Stand-by switch on, the message will be displayed. However, during operation process, the SID will not be reset.

NOTE: If the date does not change after the shutdown, the SID will not be reset to "00001".

2.6 PID Details

The PID is a number that distinguishes an individual patient.

When using a sample with a barcode, the read barcode data will be automatically input.

