

# **Automated Blood Coagulation Analyzer**

# CS-2000i/CS-2100i **Instructions for Use**

CHAPTER 1 Introduction CHAPTER 2 Safety Information CHAPTER 3 Design and Function CHAPTER 4 Operation CHAPTER 5 Sample Preparation CHAPTER 6 Analysis CHAPTER 7 Maintenance and Supplies Replacement CHAPTER 8 Troubleshooting CHAPTER 9 Technical Information Index

# **Sysmex Corporation**

KOBE, JAPAN

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## 1. Introduction

Thank you for purchasing this Sysmex CS-2000*i*/CS-2100*i* fully automated blood coagulation analyzer.

The CS-2000*i*/CS-2100*i* is a fully automated blood coagulation analyzer for In Vitro Diagnostic use that can quickly analyze a large volume of samples with a high degree of accuracy.

This instrument can analyze samples using coagulation, chromogenic and immunoassay methods. The analyzed data can be retained in the stored joblist, displayed and printed. (Printing is only possible if the optional printer is connected.) The instrument also has a number of built-in functions, including automatic setting of reagent by a barcode, priority processing of STAT samples and quality control. A cap piercer unit can be installed as a factory option.

\* CS-2000*i*: without cap piercer unit CS-2100*i*: with cap piercer unit

The contents of screens illustrated in this manual are as displayed under Windows XP.

#### **Contact Address**

#### Manufacturer



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#### **Ordering of Supplies and Replacement Parts**

If you need to order supplies or replacement parts, please contact your local representative.

#### **Service and Maintenance**

Please contact the Service Department of your local representative.

## 1.1 Manual composition

The CS-2000*i*/CS-2100*i* manual comprises the following two sections. Read it carefully so that you can use the equipment correctly. After reading the manual, store it carefully where it will be available any time you need it.

- (1) CS-2000*i*/CS-2100*i* Instructions for Use (Volume 1) This manual gives a summary of the CS-2000*i*/CS-2100*i* and explains its basic operation and analysis procedures.
- (2) CS-2000*i*/CS-2100*i* Software Guide (Volume 2) This manual explains the operation procedure for each screen.

Table 1-01: Composition of the Instructions for Use

CHAPTER 1 Introduction	Manual composition, meanings of symbols used in this document, trademarks, system overview
CHAPTER 2 Safety Information	Safety information for usage
CHAPTER 3 Design and Function	Nomenclature and function summary
CHAPTER 4 Operation	Screen composition and basic operations
CHAPTER 5 Sample Preparation	Procedure from switching the power ON until the start of analysis  * The screen explanations give reference destinations in the Software Guide. For details on the operation procedures for each screen, see the Software Guide.
CHAPTER 6 Analysis	Procedure from the start of analysis until shutdown     The screen explanations give reference destinations in the Software Guide. For details on the operation procedures for each screen, see the Software Guide.
CHAPTER 7 Maintenance and Supplies Replacement	Maintenance items, replacement of supplies, supplies list
CHAPTER 8 Troubleshooting	Error log, error handling methods, error messages
CHAPTER 9 Technical Information	Device specifications, functional descriptions, packing, checkpoints for before and after installation

The provided instructions, reagents, instrument, software and customizable features have been validated for this system to optimize product performance and meet product specifications. User defined modifications are not supported as they may affect performance of the system and test results. It is responsibility of the user to validate any modifications made to these instructions, reagents, instrument or software.

Table 1-02: Composition of the Software Guide

CHAPTER 1 Introduction	Manual composition, meanings of symbols used in this document, trademarks
CHAPTER 2 Order Registration	Order related screens, functions and operation procedures
CHAPTER 3 Joblist	Joblist related screens, functions and operation procedures
CHAPTER 4 Browser	Browser related screens, functions and operation procedures
CHAPTER 5 Reagent Screen	Reagent related screens, functions and operation procedures
CHAPTER 6 Quality Control	Quality control related screens, functions and operation procedures
CHAPTER 7 Calibration Curve	Calibration curve related screens, functions and operation procedures
CHAPTER 8 System Setup	Setup related screens, functions and operation procedures
CHAPTER 9 Utility Tools	Utility tool related screens, functions and operation procedures
CHAPTER 10 GNU General Public License	GNU General Public License explanation

#### 1.2 Hazard information in this manual

Note, Information, Caution and Warning statements are presented throughout this manual to call attention to important safety and operational information. Non-compliance with this information compromises the safety features incorporated in the analyzer.



#### Risk of infection

This symbol indicates a possible hazardous situation which, if not avoided, may result in infection by pathogens and others.



## Warning!

High risk. Ignoring this warning could result in personal injury to the operator.



#### Caution!

Average risk. Ignoring this warning could result in property damage or incorrect measurement results.



## Information

Minor risk. Observe these considerations when operating this instrument.



#### Note:

Background information and practical tips.

#### 1.3 Protected names

- Sysmex is a registered trademark of SYSMEX CORPORATION.
- CA CLEAN I and CA CLEAN II are trademarks of SYSMEX CORPORATION.
- VENOJECT, Venosafe and VENOJECT II are registered trademarks of TERUMO Corporation.
- VACUTAINER is a registered trademark of Becton, Dickinson and Company.
- HEMOGARD is a trademark of Becton, Dickinson and Company.
- VACUETTE is a registered trademark of C.A. GREINER und Söhne GmbH.
- MONOVETTE is a registered trademark of SARSTEDT.
- Windows is a registered trademark of Microsoft Corporation in the United States and other countries.
- Linux is a registered trademark or trademark of Linus Torvalds in the United States of America and other nations.
- Other registered trademarks or trademarks referenced are property of their respective owners.

The fact that a trademark is not explicitly mentioned in this manual does not authorize its use.

## 1.4 Assay parameters (analysis parameters and calculated parameters)

The CS-2000*i*/CS-2100*i* can perform analyses and calculations of the following parameters. Additional analysis and calculation parameters can be registered as well.

Table 1-03: Analysis parameters and calculated parameters of CS-2000i/CS-2100i

Method	Analysis parameters	Calculated Parameters
Coagulation	Prothrombin Time (PT)	Prothrombin Ratio INR Derived Fbg
	Activated Partial Thromboplastin Time (APTT)	
	Fibrinogen clotting time (Fbg)	Fibrinogen concentration
	Extrinsic Factor Activity Assay (II, V, VII, X)	Factor II Activity Percent
		Factor V Activity Percent
		Factor VII Activity Percent
		Factor X Activity Percent
	Intrinsic Factor Activity Assay (VIII, IX, XI, XII)	Factor VIII Activity Percent
		Factor IX Activity Percent
		Factor XI Activity Percent
		Factor XII Activity Percent
Chromogenic	Antithrombin III (AT III)	Antithrombin III Activity Percent
	α2-Antiplasmin (α2PI)	α2-Antiplasmin Activity Percent
	Plasminogen (Plg)	Plasminogen Activity Percent
	Protein C (PC)	Protein C Activity Percent
Immunoassay	D-Dimer	D-Dimer concentration

## 1.5 System overview

The CS-2000*i*/CS-2100*i* is a fully automated blood coagulation analyzer for in vitro diagnostic use that can quickly analyze a large volume of samples with a high degree of accuracy.

This instrument can analyze samples using coagulation, chromogenic and immunoassay methods. The CS-2000*i*/CS-2100*i* comprises the following main devices.

- CS-2000*i*/CS-2100*i* Main Unit: Performs sample analysis.
- Information Processing Unit (IPU): Processes data generated by the Main Unit.



#### Caution!

- Results should always be evaluated in conjunction with clinical conditions and other laboratory findings.
- Independently of the concentration of the sample, non-specific reactions may occur in some cases and the dilution ratio and analysis result may not show the linearity in this case.
- It may not be possible to obtain correct analysis results if the test protocol is changed. The operator is personally responsible for any such changes. Furthermore, the warranty for this product only covers the use in the factory default settings.

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# 2. Safety Information

This chapter will present safety information for using this product safely and correctly. Read this chapter carefully before use.

## 2.1 Specified conditions of use

The CS-2000*i*/CS-2100*i* is intended solely for In Vitro diagnostic use. The primary sample for analysis is the plasma component of human blood with added anti-coagulant (sodium citrate). Any other use is regarded as non-specified. Only reagents and cleaning solutions mentioned in this manual are permitted for use. The specified conditions of use also entail the observance of the cleaning and maintenance procedures described in these instructions.

#### 2.2 General information

Read the manual before operating the CS-2000*i*/CS-2100*i*. Keep this manual for future reference.



#### Warning!

- The unpacking, setup and confirmation of correct initial operation is performed by your local technical representative.
- Take care to keep long hair, fingers and clothing away from rotating parts.
- Should the instrument emit any unusual odors or smoke, turn the main switch OFF immediately and unplug the power cable. Contact your local technical representative.
  - Failure to do so could result in fire, electrical shock or injury.
- Take care not to spill blood or reagent, or drop wire staples or paper clips into
  the instrument as this might cause a short or smoke. Should the instrument
  malfunction, turn the main switch OFF immediately and unplug the power cable.
  Contact your local technical representative.
- The operator should not touch any electrical circuitry inside the cover. The danger of electrical shock is particularly high when one's hands are wet.
- This instrument must not be connected to a power outlet rated at anything other than specified in the rating plate. Please note that the instrument must be grounded, or fire or electrical shock may result.
- Do not damage the power cable, place heavy objects on it or pull it with excessive force. Doing so may cause a fire or shock due to an electrical short or broken wiring.
- Switch OFF the power supply before connecting any peripheral devices (host computer, printer), or electrical shock or instrument failure may result.

#### 2.3 Installation



#### Caution!

- Install in a place which is not subject to water splash.
- Install in a place which is not subject to adverse effects of high temperature, high humidity, dust, direct sunlight, etc.
- Make sure the instrument is not exposed to strong vibration or impact.
- · Install in a well-ventilated area.
- Avoid installation of the instrument near devices that emit electrical interference, such as a centrifuge.
- Do not install the instrument close to stores of chemical substances or other sources of gas emissions.
- Do not use this instrument in any operating environment which has electroconductive or flammable gases, including oxygen, hydrogen and anesthesia.
- This instrument was designed for indoor use only.

# 2.4 Electromagnetic compatibility (EMC)

This instrument complies to the following IEC (EN) standards:

- IEC61326-2-6:2005 (EN61326-2-6:2006)
   Equipment for measurement, control and laboratory use EMC-Requirements.
- EME (Electro magnetic Emission)
   For this standard the requirements of class A are fulfilled.
- EMI (Electro magnetic Immunity)
   For this standard the minimum requirements with regards to immunity are fulfilled.

## 2.5 Avoidance of infection



#### Risk of infection

- In principle, all parts and surfaces of the instrument must be regarded as Bio-hazardous.
- Waste fluid and parts which have come into contact with it, should never be touched with bare hands.
- Should you inadvertently come in contact with potentially hazardous materials or surfaces, immediately rinse skin thoroughly with water, then follow your laboratory's prescribed cleaning and decontamination procedures.
- Take appropriate care in handling samples. Use of protective garments and gloves is strongly recommended when operating, maintaining, servicing or repairing the instrument. If something should get in your eyes or an open wound, rinse thoroughly with water and then contact your physician immediately.
- Control must be regarded as potentially hazardous. When performing quality controls, use protective garments and gloves. If something should get in your eyes or an open wound, rinse thoroughly with water and then contact your physician immediately.
- Take appropriate care in handling waste fluids. If you get them on your skin or clothes, wash them.

## 2.6 Handling of reagents



## Warning!

- Do not directly touch the reagents. Reagents can cause irritation of the eyes, skin and mucous membranes.
- Should you inadvertently come in contact with reagent, immediately rinse skin thoroughly with water.
- If a reagent should get in your eyes, rinse thoroughly with water and contact your physician immediately.
- If a reagent is accidentally swallowed, vomit or induce vomiting by drinking copious amounts of warm, salty water and contact your physician immediately.
- CA CLEAN II is an acidic cleaning agent. It should not come in contact with skin or clothing. If it happens rinse skin or clothing with plenty of water to avoid injury or damage.
- The CA CLEAN I detergent contains sodium hypochlorite. If CA CLEAN I comes in contact with the instrument's surfaces, it will affect the surface finish and there is danger of corrosion. Immediately wipe up CA CLEAN I with a damp cloth.
- Extra care should be taken to make sure CA CLEAN I is not mixed and used
  with acidic solutions such as CA CLEAN II. Direct mixing of CA CLEAN I and an
  acidic solution will result in the highly hazardous release of poisonous chlorine
  gas.
- When handling samples or reagents, always wear latex or non-latex gloves.
   After completion of work, wash hands with disinfectant to avoid the risk of infection with pathogens etc.



#### Caution!

- Follow directions on reagent labelings.
- Avoid letting the reagent come in contact with dust, dirt or bacteria.
- Reagents must not be used after their expiration date.
- · Handle reagents gently to avoid bubbling.
- Take care not to spill reagents.
- Handle and store reagents according to the instructions provided with each reagent.

Reagent can also be stored cooled inside the instrument overnight. For the sake of the storage stability of the reagents, however, they should be stored cooled with their lids closed, or taken out of the instrument and stored in a refrigerator with lids closed, if no analyses will be conducted for a long period.

Leaving reagents for long periods with open caps could affect data.

## 2.7 Quality control materials



## Caution!

- Do not inject or swallow.
- Follow directions on reagent labelings.
- Avoid letting the reagent come in contact with dust, dirt or bacteria.
- Reagents must not be used after their expiration date.
- · Handle reagents gently to avoid bubbling.
- Take care not to spill reagents.

#### 2.8 Laser



#### Warning!

A semiconductor laser barcode reader is used in the CS-2000*i*/CS-2100*i* reagent table. The laser barcode reader has a mechanism that prevents laser oscillation when the cover of the reagent table has been removed. Never look into the laser light source. There is a danger of causing eye pain or damage if one looks into the laser beam.

## 2.9 Maintenance



#### **Risk of infection**

Always wear protective garments and gloves when processing with the instrument and during maintenance. After completion of work, wash hands with disinfectant, or infection by bacteria could result.



#### Caution!

Do not leave the probe with aspirated reagent or sample inside it. The probe can get blocked as a result, so perform "Rinse Probe".



#### Information

When performing maintenance, use only the tools specially provided for such work.

## 2.10 Disposal of materials



## Warning!

- Waste fluids, instrument consumables and other waste materials must be disposed of appropriately in accordance with local laws, with due consideration of medical, infectious and industrial wastes.
- A battery is incorporated in the circuit board located in the right side interior of the instrument in order to keep the stored data. When disposing of the instrument, remove and dispose of the battery properly for recycling. Do not throw the battery into a fire, otherwise bursting can result.

#### Waste disposal



#### Risk of infection

After becoming waste at end-of-life, this instrument and its accessories are regarded as infectious. They are therefore exempted from EU directive 2012/19/EU (Waste Electrical and Electronic Equipment Directive) and may not be collected by public recycling to prevent possible risk of infection of personnel working at those recycling facilities.



## Warning!

- Do not dispose the instrument, accessories and consumables via public recycling!
- Incineration of contaminated parts is recommended!
- Contact your local Sysmex service representative and receive further instructions for disposal! Follow local legal requirements at all times.



#### Caution!

Waste effluents from the instrument may contain dangerous substances in it and decision about disposal only has to be made by local water authority.

#### Decontamination



## Warning!

Before decontaminating the instrument, be sure to turn off the power supply and unplug the power cord. This is necessary to avoid the risk of electric shock. When cleaning the instrument, always wear protective gloves and gown. Also, wash hands after decontamination carefully with antiseptic solution first and with soap afterwards. Do not open the instrument for decontamination inside. This is executed only by Service Technician.



#### Information

- To ensure decontamination of the instrument outer surfaces, clean the instrument surface at the end of the daily work. This has to be executed in the following three situations;
  - Regularly, at the end of a daily work,
  - Immediately, during contamination with potentially infectious material, and
  - In advance of repair or maintenance by the field technical service representative
- Wipe off the instrument surfaces using a cloth soaked with a suitable decontamination solution. Please use one-way cloths, e.g. made of paper or cellulose. The cloth may be moistened in a way only that no wetness may reach the inside of the instrument.
- The indicated residence time of the decontamination solution shall be observed.
- If required, you may afterwards remove normal contaminations with commercial neutral detergent, in case these could not be removed by the decontaminant.
- As a last step the instrument shall be dried with a dry one-way cloth.

#### 2.11 Instrument labels

#### Front of the Main Unit



## **WARNING**

Do not place your fingers and hands inside when analyzing. Doing so may result in injury.



## RISK OF INFECTION

In principle, all parts and surfaces of the instrument must be regarded as Bio-hazardous.



#### <u>CAUTION</u>

Use the buffer solution after equilibrating to the room temperature.



## CAUTION

When you open the cuvette hopper cover for removing the jammed cuvettes, check that the status of the instrument is "Ready". Otherwise, measurement results could be affected.

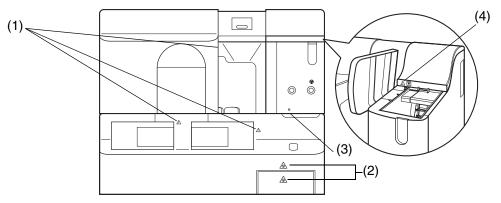


Figure 2-01: Front of the Main Unit

# Right of the Main Unit



# **WARNING**

Do not place your fingers and hands inside when analyzing. Doing so may result in injury.

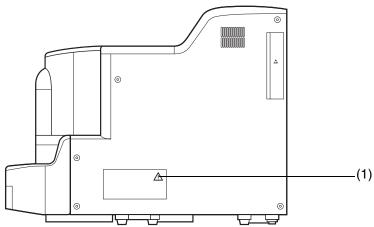


Figure 2-02: Right of the Main Unit

#### **Left of the Main Unit**



# **WARNING**

- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

Fuse rating

10A 250V

time lag



## **RISK OF INFECTION**

In principle, all parts and surfaces of the instrument must be regarded as Bio-hazardous.

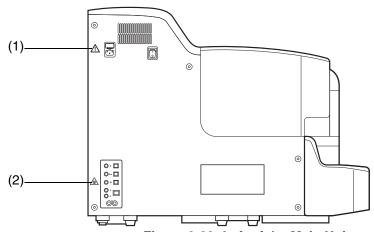


Figure 2-03: Left of the Main Unit

#### Interior left side of the Main Unit



# **RISK OF INFECTION**

In principle, all parts and surfaces of the instrument must be regarded as Bio-hazardous.

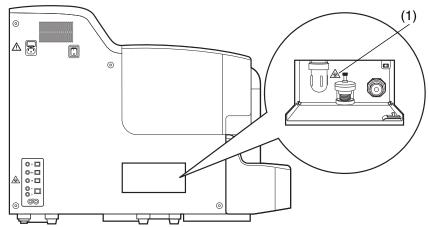


Figure 2-04: Interior left side of the Main Unit

## Front of the Pneumatic Unit



# RISK OF INFECTION

In principle, all parts and surfaces of the instrument must be regarded as Bio-hazardous.

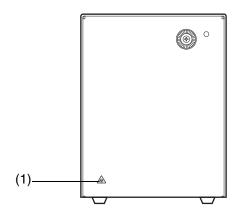


Figure 2-05: Front of the Pneumatic Unit

#### **Rear of the Pneumatic Unit**



# **WARNING**

- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.



# **WARNING**

Do not block the exhaust openings on the rear of the pneumatic unit.

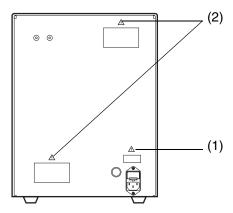


Figure 2-06: Rear of the Pneumatic Unit

#### Rinse tank

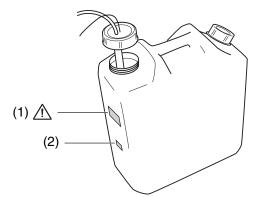


Figure 2-07: Rinse tank



## **CAUTION**

- Fill with distilled water only.
- Thoroughly clean the inside once a week.
- (2) The meaning of this abbreviations is:

Rns: Rinse

## Waste tank (Option)

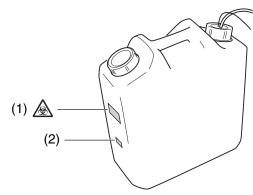


Figure 2-08: Waste tank (Option)



# **RISK OF INFECTION**

The waste tank and contents should be considered potentially biohazardous. Do not handle the waste tank without proper protective equipment. Wear gloves when handling. Wash your hands with disinfectant after completing the procedure.

- (2) The meaning of this abbreviations is:
  - W: Waste

## 2.12 Personnel



## Caution!

- Personnel with no or limited experience in using this instrument must be instructed by and receive training from fully experienced personnel.
- In the event that a malfunction of the instrument occurs, the person responsible for the instrument may take the measures indicated in the Instructions for Use, but any further steps that need to be taken must be referred to your local technical representative.
- The unpacking, setup and confirmation of correct initial operation is performed by your local technical representative.
- In case relocation becomes necessary after installation, contact your technical representative.
  - Problems resulting from the relocation of the instrument by anyone other than a technical representative are not covered by the Warranty even if it is in the warranty period.

## 2.13 Computer virus



## Warning!

Although our software has already been checked for computer viruses, the configuration of a specific user environment may make it prone to computer virus infections via the Internet or a network.

We recommend that our customers consider computer virus countermeasures that suit their computer operating environment. Customers that use antivirus software in their operating environment should take the following precautions.

- 1. Use the antivirus software to periodically check for viruses.
  - (1) Use antivirus software designed for your operating system to periodically check for viruses.
  - (2) Disable the antivirus software during instrument software operation as it may adversely affect instrument operation.
  - (3) Disable functions that check file access.
  - (4) Disable firewalls and any other functions that protect or control data transfers.
- 2. Do not install any software other than the antivirus software.
- 3. USB memory sticks, CD-Rs and other external memory devices should be checked for viruses before use.
- 4. Do not open files attached to email or files of unknown origin without first performing a virus check.
- 5. Do not download files from the Internet or other sources that are not required for instrument operation. However, the virus definition files used by the antivirus software are not subject to this restriction.
- 6. Always check for viruses before accessing files in a folder shared with other computers.
- 7. Check effectiveness of computer virus countermeasures used on other computer systems in your laboratory, and select the most effective for use on this instrument.
- 8. The customer must take sole responsibility when connecting to an external network (for example, the Internet).

#### 2.14 Use of other software



## Warning!

- Do not install any software other than that preinstalled on the instrument. And do not run any other software on the instrument. However, this restriction does not include the installation of antivirus software.
- Note that we will accept no liability whatsoever for any malfunctions arising from use of other software.

## 2.15 Operating System



#### Caution!

• Keep the Windows settings as stated below.

## **Regional and Language Options**

Standards and formats : English (United States)

#### **Customize Regional Options**

**Numbers** 

Decimal symbol as point : "."

Digit grouping symbol : ","

**Time** 

Time format : HH:mm:ss

Time separator : ":"

AM symbol : AM

PM symbol : PM

Date

Short date format : yyyy/MM/dd

If you use the IPU with the settings other than the above, you may not correctly input numeric values, dates, etc.

• The "," can not be used as decimal separator.

If you use the "," as decimal separator, you may not correctly input numeric values, etc.

# 3. Design and Function

This chapter explains the design and function of this instrument and of optional equipment that can be connected to it.

## 3.1 Overview

This instrument comprises the Main Unit (including the sampler), the Information Processing Unit (including the touch panel display) and the Pneumatic Unit. An optional printer can also be connected.

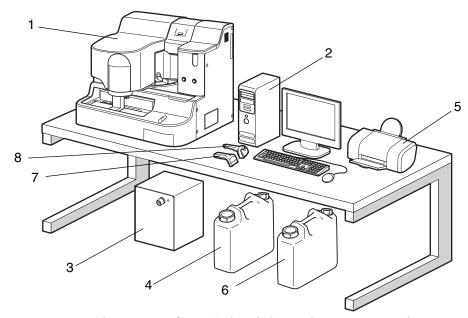


Figure 3-01: Overall view (with options connected)

#### 1 Main Unit

Performs sample analysis. It includes the sampler, which automatically supplies samples to the Main Unit.

#### 2 Information Processing Unit (IPU)

Processes data generated by the Main Unit. It is operated using the touch panel display, the keyboard and the mouse.

#### 3 Pneumatic Unit

Supplies compressed air to the Main Unit.

#### 4 Rinse tank

Fill with rinse solution.

#### 5 Printer (Optional)

Prints out analysis information, analysis results and a hard copy of the screen.

#### 6 Waste tank (Optional)

Stores waste fluid in the tank, if sewer system is not available.

#### 7 Handy barcode reader (Optional)

The Handy barcode reader can be used to input sample numbers, rack numbers and reagent IDs.

#### 8 2D barcode reader (Optional)

Reads barcodes to input calibrator's or reagent's assay sheet values, normal values and ISI values, and control's targets/limits.

#### 3.2 Main Unit

The Main Unit performs sample analysis. The sampler, which is installed at the front of the Main Unit, automatically supplies samples to the Main Unit.



## Warning!

- Do not reach into the inside of the instrument during analysis.
   Doing so may result in injury.
  - If the light shield lid is opened during analysis, an alarm will sound and operation will stop.
- Before replacing the fuse, turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electrical shock.



#### Caution!

- Do not open the STAT/buffer table cover if the STAT/buffer table cover LED is red.
  - This will cause an instrument fault.
- Do not open the reagent table cover during analysis, while the table cover LED is red. This will cause an instrument fault.
- Do not turn the power ON and OFF repeatedly in a short interval.
- · Use distilled water for the rinse.
- · Clean the rinse tank once a week.
- For continued protection against risk of fire, replace only with fuse of the specified type and current ratings.
  - Otherwise a malfunction or smoke emission may occur.

#### Left of the Main Unit

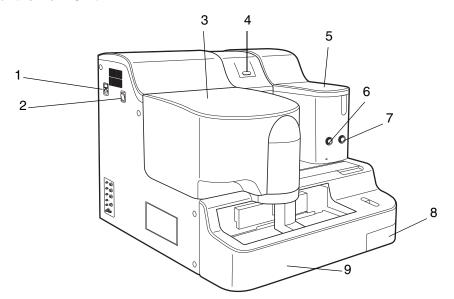


Figure 3-02: Left of the Main Unit

#### 1 Power connector

Connected to the power cable.

#### 2 Power Switch

Turns the power ON and OFF.

#### 3 Light shield lid

Open this cover to set reagents, to maintain the instrument, and perform similar tasks.



## Warning!

- When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked. If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.
- When closing the light shield lid, take care to avoid pinching your fingers.



#### Caution!

Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.

#### 4 Alarm indicator LED

This displays alarms affecting the instrument.

Green: State of readiness to begin analysis

Flashing green: State of readiness to begin sampler analysis, Interrupted

Flashing orange: Warming up, Analyzing

Red: Stopped due to error

#### 5 Cuvette hopper

Holds cuvettes and automatically supplies them to the instrument.

#### 6 Start button

This is the same as the Start button on the IPU screen.

#### 7 Mechanical stop switch

Press this switch to immediately stop the instrument's mechanical movement. Please remember that some of the samples in analysis could be discarded, and you have to re-run those samples.

#### 8 Cuvette trash tray

Used cuvettes are discarded here.

The Trash Box Liner CS2 can be set in the tray.

## 9 Sampler

The sampler automatically transports samples that are set in the sample rack to the aspiration position.

#### **Right of the Main Unit**

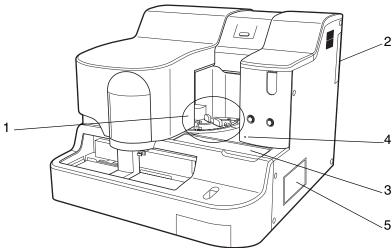


Figure 3-03: Right of the Main Unit

#### 1 Reagent table cover

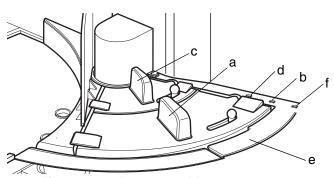


Figure 3-04: Reagent table cover

#### a Reagent table A cover

This is the cover for the reagent table A. Open it to replenish or replace reagents inside the reagent table A.

#### b Reagent table A cover LED

This LED indicates whether it is permissible to open the reagent table A cover.

Green: Ready to open Red: Not ready to open

#### c Reagent table B cover

This is the cover for the reagent table B. Open it to replenish or replace reagents inside the reagent table B.

## d Reagent table B cover LED

This LED indicates whether it is permissible to open the reagent table B cover.

Green: Ready to open Red: Not ready to open

## e Dispensing table cover

Can be opened for placing the cuvette containing a stir bar on the dispensing table.

#### f Dispensing table cover LED

This LED indicates whether it is permissible to open the dispensing table cover.

Green: Ready to open Red: Not ready to open

## 2 IPU connector

Connects the IPU.

## 3 STAT/buffer table cover

To set diluent, open this cover. STAT samples can also be set.

#### 4 STAT/buffer table cover LED

This LED indicates whether it is permissible to open the STAT/buffer table cover.

Green: Ready to open Red: Not ready to open

## 5 Exterior lamp cover

Open this cover to replace the lamp.



#### Caution!

Do not slide the lock levers of the table covers when the reagent table A cover LED and the reagent table B cover LED are red. If the lock handles are removed from their lock positions, the alarm will sound. Replace the lock levers to their original positions. Otherwise, the instrument will stop analysis.

#### Interior of the Main Unit (Left side)

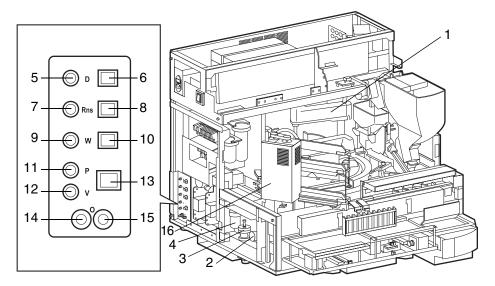


Figure 3-05: Interior of the Main Unit (Left side)

#### 1 Reagent arm

Aspirates reagent and adds it to the sample.

#### 2 0.10 MPa adjustment knob

Adjusts the pressure to 0.10 MPa.

#### 3 -0.067 MPa adjustment knob

Adjusts the vacuum to -0.067 MPa.

#### 4 Trap Chamber

This chamber prevents backflow.

## 5 Nipple (D)

**Spares** 

## 6 Connector (D)

**Spares** 

#### 7 Rinse aspiration nipple (Rns)

For aspirating the rinse water from the Rinse Tank. Connected to the rinse tank.

#### 8 Float Sensor Connector for Rinse Tank (Rns)

Connected to the float switch for rinse.

#### 9 Waste outlet nipple (W)

Waste fluid is discharged via this nipple. Connected to the drain sewer system or the optional waste container.

#### 10 Float Sensor Connector for Waste Tank (W)

Connected to the float switch (option) for waste fluid.

#### 11 Pressure inlet nipple (P)

Connected to the pressure outlet nipple of the Pneumatic Unit.

#### 12 Vacuum inlet nipple (V)

Connected to the vacuum outlet nipple of the Pneumatic Unit.

#### 13 Pneumatic Unit control cable

Connected to the cable which is used to turn the Pneumatic Unit ON/OFF.

## 14 Overflow waste line nipple (reagent) (O)

Waste fluid overflowing during reagent probe cleaning, for example due to hydraulic system error, is discharged via this nipple. Connected to the waste container.

#### 15 Overflow waste line nipple (sample) (O)

Waste fluid overflowing during sample probe cleaning, for example due to hydraulic system error, is discharged via this nipple. Connected to the waste container.

#### 16 CP mechanism (CS-2100*i*)

This is the mechanism for the cap piercer.

#### Interior of the Main Unit (Right side)

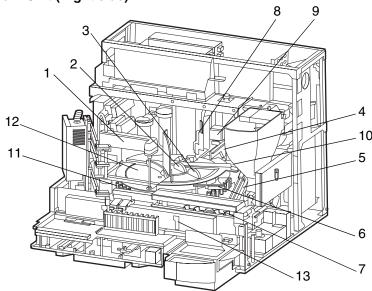


Figure 3-06: Interior of the Main Unit (Right side)

#### 1 Sample arm

Aspirates and dispenses samples, control plasma, calibrators and buffers (diluents).

## 2 Reagent table B

Set reagents here.

## 3 Reagent table A

Set reagents here.

#### 4 Detector catcher

Transfers cuvettes to the incubator well, to the detector well and to the dispensing table.

#### 5 Cuvette feeder

Aligns cuvettes from the hopper and supplies them.

#### 6 Supply catcher

Transfers a cuvette to the dispensing table.

## 7 STAT/buffer table

Set diluent/STAT samples here.

#### 8 Incubator

Incubates a sample in the cuvette.

#### 9 Detector

Analyzes a sample in a cuvette.

#### 10 HIL detector

Checks the aspirated sample for interfering substances.

#### 11 Dispensing table

This is the table for setting cuvettes and dispensing samples.

#### 12 Reagent table cover C

This is the cover for the reagent tables A and B. Open it to replenish or replace reagents while the status of the instrument is "Ready".

## 13 Barcode reader (sampler)

Reads the barcode of samples set on the sampler.

## 3.3 Information Processing Unit (IPU)

Processes data generated by the Main Unit. It is operated using the touch panel display, the keyboard and the mouse.

#### Front elevation

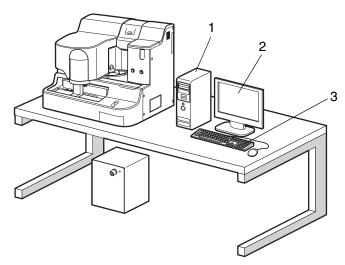


Figure 3-07: Information Processing Unit (IPU)

#### 1 IPU Main Unit

Main Unit of IPU.



#### Information

The IPU illustration shown is for reference only. Refer to the manual included with the computer for the layout of connection ports and other details. For further details, contact your local technical representative.

#### 2 Touch panel display

The IPU screen will appear. It can also be used as a touch panel.

## 3 Mouse, keyboard

Used to input data to the IPU. They can be used together with the touch panel for input.

## 3.4 Pneumatic Unit

Supplies compressed air to the Main Unit.



## Warning!

- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

#### Front of the Pneumatic Unit

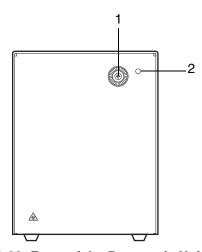


Figure 3-08: Front of the Pneumatic Unit

- 1 0.22 MPa regulator
  - Adjusts the 0.22 MPa pressure supplied to the Main Unit.
- 2 Pilot lamp
  - It lights when the Pneumatic Unit power supply is ON.

#### **Rear of the Pneumatic Unit**

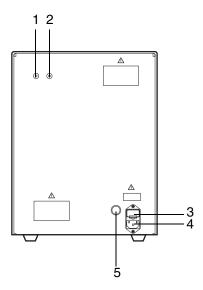


Figure 3-09: Rear of the Pneumatic Unit

## 1 Pressure outlet nipple

Used to supply pressure to the Main Unit. Connected to the pressure inlet nipple of the Main Unit.

#### 2 Vacuum outlet nipple

Vacuum is supplied to the Main Unit through this nipple. Connected to the vacuum inlet nipple of the Main Unit.

#### 3 Fuse

This is a time-lag fuse for 250V 4A (117V), 250V 3.15A (220-240V). Do not insert any fuse that does not match this rating.



#### Warning!

- To avoid electrical shock, disconnect the power supply before servicing.
- For the continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

#### 4 Power connector

Supplies power via power cable provided.

## 5 Pneumatic Unit control connector

Used as the input connector for turning ON/OFF of Pneumatic Unit power. Connected to the Pneumatic Unit control output connector of the Main Unit.

## 3.5 Options

This section explains optional devices which may be connected.

#### 1 Printer

Analysis data stored in memory can be output to a printer.

Conditions can be specified for printout of analysis results.

Windows-compatible printers (including USB and network printers) can be used.

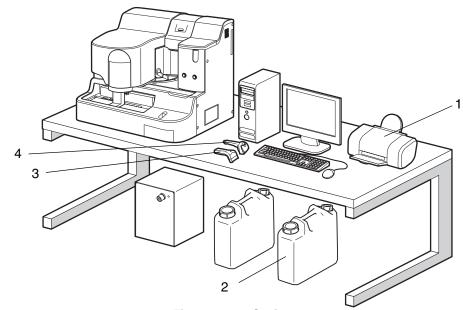


Figure 3-10: Options

## 2 Waste Tank (Optional)

Stores waste fluid in the tank, if sewer system is not available.

## 3 Handy barcode reader (Optional)

The Handy barcode reader can be used to input sample numbers, rack numbers and reagent IDs.



### Information

Set your Handy barcode reader to match the bar codes you use. Refer to the Handy barcode reader manual for the setting method.

## 4 2D barcode reader (Optional)

Reads barcodes to input calibrator's or reagent's assay sheet values, normal values and ISI values, and control's targets/limits.

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# 4. Operation

This chapter explains the overall operation and function of this device and composition of the IPU menu screen.

#### 4.1 Overview

The major contents of this chapter are:

## Overall operation

This explains details related to overall operation.

### **Composition of the IPU Menu Screen**

This gives the names of the parts of the IPU menu screen and explains their functions and the help dialogs.

## 4.2 Overview of operation

## 1. Analysis order (sample ID numbers, analysis parameters) registration method

Analysis starts with registering an analysis order. The order information (consisting of sample ID numbers and analysis parameters) can be registered in one of the two ways described below.

- On-line Registration (Auto Inquiry)
   The analysis parameters are received from the host computer, based on the sample ID numbers that are read by the sample ID barcode reader.
- Manual Order Registration
   The order information is registered (entered) manually in the screen.

For details of the analysis order registration method, see "Chapter 2 Order Registration" in the Software Guide.

### 2. Analysis mode

There are two analysis modes, as described below. Use the right mode for the situation.

Normal mode

In this mode, sample aliquots from all samples set on the sampler or in the STAT sample holder, including the volume required for retests, are taken into the instrument at the same time. Each test is then performed separately inside the instrument.

• Micro-sample mode

In this mode, the sample volume for each test is directly aspirated and analyzed from samples set on the sampler or in the STAT sample holder.

## 3. Analysis parameters and calculated parameters

For details on the analysis parameters and calculated parameters handled by the CS-2000*i*/CS-2100*i*, see "Chapter 1: 1.4 Assay parameters (analysis parameters and calculated parameters)".

#### 4. Passwords

This instrument is protected by a password so that the instrument can be operated under the control of a supervisor. User names (logon names) and passwords can be set.

Setting passwords allows limitation of the people able to use the instrument and enables safe handling of internally stored data.

For details on how to set and change the user password, see "Chapter 8: 8.4: 3. Changing password" in the Software Guide.

# 4.3 Composition of the IPU menu screen

The IPU menu screen is composed as follows.



Figure 4-01: IPU menu screen

The shortcut buttons for the main functions are displayed.

	Refer to "Chapter 4: 4.3: 1 Toolbar" for details.
2: View	The content displayed in this area will differ depending on the function that is in progress. Refer to "Chapter 4: 4.3: 2 View" for details.
3: Status bar	The status of the IPU and the instrument are displayed.

Refer to "Chapter 4: 4.3: 3 Status bar" for details.

4: Operation panel Operation buttons are displayed. Operation buttons are arranged according to the content of the View area.

1: Toolbar

## 1 Toolbar

The toolbar contains shortcut buttons to display screens for main functions.

Table 4-01: Toolbar shortcut buttons

Button	Name	Function	
He lp	Help	Displays the Error dialog box. See "Chapter 8: 8.3 Display of errors" for details.	
STAT	STAT	Displays the STAT sample Order screen. For details see "Chapter 2 Order Registration" in the Software Guide.	
Jobnst	Joblist	Displays the Joblist screen. For details see "Chapter 6 Analysis".	
Order	Order	Displays the Order screen. For details see "Chapter 2 Order Registration" in the Software Guide.	
Reagent	Reagent	Displays the Reagent screen. For details see "Chapter 5: 5.4 Analysis reagent preparation".	
QC Chart	QC Chart	Displays the Quality Control screen. For details see "Chapter 6 Quality Control" in the Software Guide.	
Calib. Curve	Calib. Curve	Displays the Calibration Curve screen. For details see "Chapter 7 Calibration Curve" in the Software Guide.	
Maint.	Maint.	Displays the Maintenance screen. For details see "Chapter 7 Maintenance and Supplies Replacement".	
Menu	Menu	Displays the Menu screen.	
Status	Status	Displays the Status Display screen.	
Shutdown	Shutdown	Displays the Shutdown dialog box. This button is masked during analysis and interrupted analysis. For details see "Chapter 6: 6.8 Shutdown".	

Table 4-01: Toolbar shortcut buttons

Button	Name	Function	
Stop	Stop	Stops analysis.	
Start	Start	Starts analysis.	

## 2 View

The View area displays icons, lists, tabs and dialog boxes, with the specific content varying according to the functions in use. The following dialog boxes are displayed on the IPU Menu screen.

Table 4-02: IPU menu screen icon list

Icon	Name	Function	
Help	Help	Displays the Error dialog box. For details see "Chapter 8: 8.3 Display of errors".	
STAT	STAT	Displays the STAT sample Order screen. For details see "Chapter 2 Order Registration" in the Software Guide.	
Joblist	Joblist	Displays the Joblist screen. For details see "Chapter 6 Analysis".	
Order	Order	Displays the Order screen. For details see "Chapter 2 Order Registration" in the Software Guide.	
Reagent	Reagent	Displays the Reagent screen. For details see "Chapter 5: 5.4 Analysis reagent preparation".	
QC Chart	QC Chart	Displays the Quality Control screen. For details see "Chapter 6 Quality Control" in the Software Guide.	
Cath Curve	Calib. Curve	Displays the Calibration Curve screen. For details see "Chapter 7 Calibration Curve" in the Software Guide.	
Mirt	Maint.	Displays the Maintenance screen. For details see "Chapter 7 Maintenance and Supplies Replacement".	

Table 4-02: IPU menu screen icon list

Icon	Name	Function		
Shutdown	Shutdown	Displays the Shutdown dialog box. For details see "Chapter 6: 6.8 Shutdown".		
Logoff	Logoff	Displays the log off confirmation dialog box. For details see "Chapter 6: 6.10 Logging off".		
Settings	Settings	Displays the Setting screen. For details see "Chapter 8 System setup" in the Software Guide.		
Controller	Controller	Displays the Controller screen.		
Test Operation	Test Operation	Displays the Test Operation screen.		
Version Information	Version Information	Displays the Version Information screen.		
Status	Status	Displays the Status Display screen.		

## 3 Status bar

The Status bar shows the state of the instrument (status and error messages). The composition of the Status bar is as shown below.



Figure 4-02: Status bar

Table 4-03: Composition of the Status bar

Parameters	Contents	
(1) Status of the Main Unit	Displays the current state of the Main Unit.  Main Unit nickname Instrument status message (Color)	
	Display the nickname of the main unit <sup>*1</sup> at the t default nickname is CS-2000 <i>i</i> or CS-2100 <i>i</i> .	op of the icon. The
	(*1 Nickname: The text string for "Device Nickna Settings, System Settings, Instrument Settings, Information). Status is indicated by the color as well as by the	Instrument
	Contents Color	
	Ready: State of readiness to begin analysis Green	
	Warming Up: Now warming up.  Gray – orange flashing	
	Processing: Analyzing (working). Orange	
	Asp. Ready: State of readiness to begin sampler analysis Gray-green flashing	
	Not Ready: When an error has occurred (Analysis cannot start).	
	Interrupted: Instrument has shifted to analysis orange – yellow interruption.	
	Int. Ready: Interrupted Gray-green flashing	
	OFF: Main Unit not connected. Gray	
(2) Message	An error or warning message is displayed. This area consists of buttons and when pressed, the Error dialog box appears. See "Chapter 8 Troubleshooting" for information on the Error dialog box and messages.	

Table 4-03: Composition of the Status bar

Parameters Contents		Contents			
(3) Indicators					
	a) Temperature	Indicates the temperature of the constant-temperature section of the Main Unit.  The constant-temperature section contains the reagent cooling unit, reagent probe and sensor/ sample incubation section. If any of these is outside normal status, it is set outside normal range.			
		Color	Contents		
		Backlight Color	Temperature in normal range.		
		Red	Temperature outside normal range.		
		Gray	Instrument not connected.		
	b) Reagent	Color	Contents		
	á	Yellow	One or more reagents are low.		
		Red	One or more reagents are running out.		
		Gray	Other than the above, including instrument not connected.		
	c) Cuvette	The remaining volu trash tray is display	me in the cuvette and the status of the cuvette ed.		
		Color	Contents		
		Backlight Color	There are enough cuvettes in the hopper and enough space in the cuvette trash tray.		
		Yellow	There are not enough cuvettes in the hopper, or enough space in the cuvette trash tray.		
		Red	The hopper has run out of cuvettes, or there is no space in the cuvette trash tray.		
		Gray	Instrument not connected.		
	d) Rinse	Displays the remain	ning volume of rinse.		
	$\boxtimes$	Color	Contents		
		Backlight Color	Rinse fluid volume is sufficient.		
		Yellow	Rinse fluid is running low.		
		Red	There is no rinse fluid.		
		Gray	Instrument not connected.		
(4	l)Status of host computer	This area displays the status of connections with the host computer.			
		Color	Contents		
		Green	Connecting		
		Orange	Connection established The status will change to "Connection established" when any packet is sent or received.		
_		Red	Connection impossible The status will change to "Connection impossible" if physically disconnected or connection has been attempted but no response is available.		
		(space)	No connection The setting on the device indicates that the host computer will not be used.		

## 4 Operation panel

Operation buttons are displayed. Operation buttons are arranged according to the content of the View area.

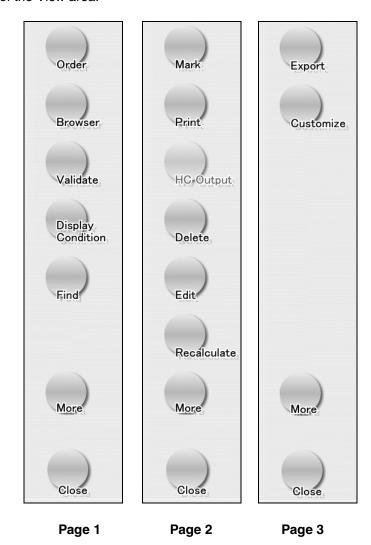


Figure 4-03: Operation panel (example of Joblist main screen)

# 5. Sample Preparation

This chapter describes the necessary preparations of instrument, reagents and samples before starting analysis.

## 5.1 Overview

Before beginning analysis, it is necessary to prepare the instrument, reagents and samples.

Prepare for analysis by following the steps described below.

Inspection before turning power ON 5-2 Turning ON the power 5-2 Analysis reagent preparation 5-6 Replenishing cuvettes 5-26 Explained in this chapter. Placing a SB Cuvette (cuvette containing a stir bar) 5-27 Setting Trash Box Liner CS2 (optional) 5-36 Confirm calibration curve 5-38 **Running Quality Control** 5-40 **Preparing Samples** 5-46 Analysis Order registration Order registration is explained in "Chapter 2 Order Order confirmation Registration" in the Software Guide. Analysis STAT Sample analysis Explained in "Chapter 6 Analysis". Checking the amount of remaining reagent **Emergency Stop** 

Table 5-01: Analysis flow chart

Shutdown

## 5.2 Inspection before turning power ON

Before turning ON the power to the instrument, check the following items:

### 1 Inspection of the rinse tank and waste tank

If the level of the rinse is low, fill the rinse tank with distilled water or deionized water

If a waste tank is connected, check the waste fluid volume in the tank. Empty the tank if it is almost full.

#### 2 Instrument inspection

Check the tubing and cord connections. Make sure that no tubes are disconnected or kinked and that the power cord is securely plugged into the AC outlet.

## 3 Checking the printer paper

If a printer is provided, make sure that it contains the amount of paper necessary for the number of samples to be processed in a day.

#### 4 Cuvette trash tray

Throw away any used cuvettes that are left in the cuvette trash tray.

## 5 Replenishing cuvettes

Add more cuvettes if there are not enough.

## 5.3 Turning ON the power

Follow the procedure below to turn ON the power.

- Turn ON the IPU personal computer power
- Start the IPU
- Main Unit power supply ON
- IPU logon



### Caution!

Check if a rinse tank and/or waste tank is connected before turning ON the Main Unit power.



#### Note:

- The power supply of the Pneumatic Unit is controlled from the Main Unit.
- After the power is turned ON, it will take a maximum of 30 minutes for the incubation table, detector block, reagent probe and reagent table to reach the prescribed temperature.

- Turn ON the IPU personal computer.
   Turn ON the printer power as well, if one is connected.
- 2. The IPU boots up and performs an automatic self check. During the self check, a splash screen appears.

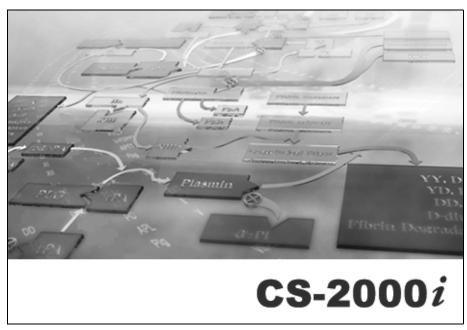


Figure 5-01: Splash screen (CS-2000i)

3. The splash screen closes automatically, then the IPU logon user selection dialog box appears.

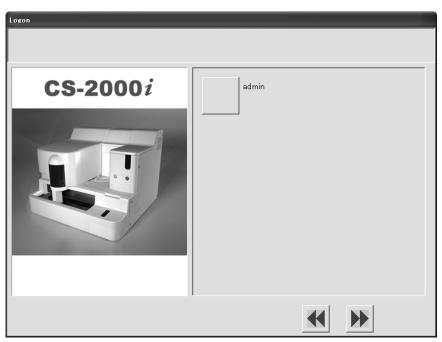


Figure 5-02: IPU logon user selection dialog box (CS-2000*i*)

4. Turn ON the power to the main unit.

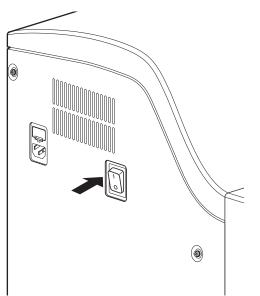


Figure 5-03: Main Unit power supply ON

5. Press a registered user button. The Logon dialog box will appear.

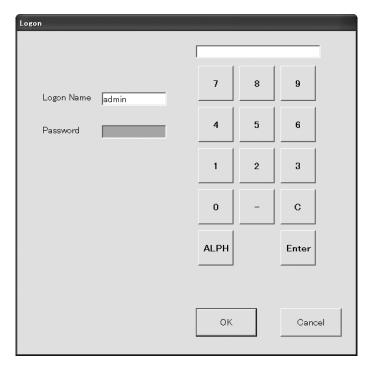


Figure 5-04: Logon dialog box

6. Input the registered logon name and password, then press **OK**. The IPU menu screen appears.

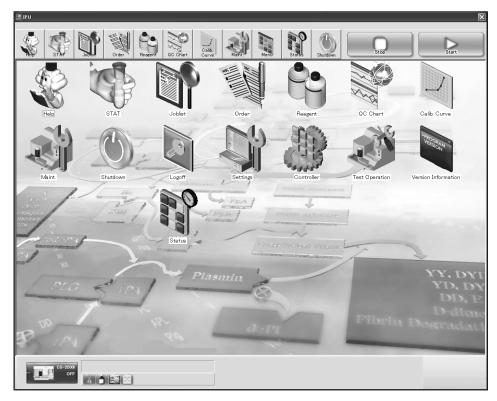


Figure 5-05: IPU Menu screen

## 5.4 Analysis reagent preparation

## 1. Reagent preparation

Prepare the required volume of reagents, Owren's Veronal buffer and reagent detergent for the anticipated work load.



#### Caution!

- For a test parameter which needs CA CLEAN I to rinse the sample probe, additional rinse step using rinse should be followed after the rinse step using CA CLEAN I.
- Otherwise, it may cause carryover of CA CLEAN I and a correct result may not be obtained.

Whenever analysis starts, approx. 500  $\mu$ L of CA CLEAN I is used to rinse the probe. The volume of Owren's Veronal buffer that is used per test includes the amount of diluent that is used for each analysis parameter.

Prepare each reagent, taking into consideration the number of samples for each parameter to be analyzed. Since not all of the reagent in a vial can be used, prepare an extra amount for each vial as shown below.

In case the extra volume is large, it is necessary to either pool two or more vials, or transfer to a Sample cup conical 4 mL.

## Reagent table

The reagent vials used and their extra volumes, are stated below.

Table 5-02: Reagent vials used and their extra volumes (reagent tables)

Vial and capacity	Extra volume required <sup>-</sup>	
Siemens reagent vial 5 mL (GW5)	0.3 mL (1.1 mL)**	
Siemens reagent vial 15 mL (GW15)	0.4 mL	
Siemens reagent vial 25 mL (GW25)	0.4 mL	
Sample Cup 4 mL (Cup 4 mL)	0.2 mL (0.5 mL)**	
SLD mini cup 1mL (SLDmini)***	0.10 mL (0.15 mL)**	

There may be variation in the stated extra volume due to differences in fluid viscosity and slight vial to vial variation.

## When a stir bar is used

Table 5-02: Reagent vials used and their extra volumes (reagent tables)

Vial and capacity	Extra volume required <sup></sup>	
Siemens reagent vial 5 mL (GW5)	1.3 mL	
Siemens reagent vial 15 mL (GW15)	2.1 mL	
Siemens reagent vial 25 mL (GW25)	2.1 mL	

- When using the stir bar, make the necessary settings with reference to "Chapter 8: 8.5 Reagent master registration" of the Software Guide. If the stir bar has been used, it may cause some inconsistency in the number of tests remaining.
- " There may be variation in the stated extra volume due to differences in fluid viscosity and slight vial to vial variation.

Additional CA CLEAN I or II sufficient to fill the vial to a depth of 10 mm is necessary to clean the tip and interior of the probe completely. The extra volumes shown below are the maximum which may be required.

Table 5-03: Amount of extra detergent to be prepared

Vial and capacity	Extra volume required	
CA CLEAN I 50 mL	7 mL	

<sup>&</sup>quot; The extra volume of the sample probe for the CS-2100i is stated in ().

<sup>&</sup>quot;These cannot be used for anything other than control and calibrator.

#### **Buffer table**

The reagent vials used and their extra volumes, are stated below.

Table 5-04: Reagent vials used and their extra volumes (buffer table)

Vial and capacity	Extra volume required	
Siemens reagent vial 5 mL (GW5)	1.2 mL (2.3 mL)**	
Siemens reagent vial 15 mL (GW15)	2.0 mL (3.9 mL)**	
Siemens reagent vial 25 mL (GW25)	2.0 mL (3.9 mL)**	
Sample Cup 4 mL (Cup 4 mL)	0.2 mL (0.5 mL)**	

There may be variation in the stated extra volume due to differences in fluid viscosity and slight vial to vial variation.

The extra volume stated for a sample cup is the value when a Conical 4 mL (code No. 424-1160-8) is used.



- Prepare a sufficient volume of reagent which takes into consideration the extra volume required.
  - When the volume of the reagent is insufficient, the sample may not be analyzed accurately.
- Use a Conical 4mL sample cup (code No.424-1160-8). If a different sample cup is used, the reagent may not be aspirated correctly, which would influence the analysis results.

<sup>\*\* ( )</sup> is the extra volume used in the CS-2100*i*.

## 2. Attaching the reagent cap and cover ring

Attach a reagent cap and cover ring to the reagent vial.

## Preparing the reagent cap and cover ring

Prepare a compatible reagent cap and cover ring for the reagent vial. No caps and cover rings can be used in reagent vials other than described in the table below.



## Caution!

Use the correct cap for reagent vials.

If the correct cap is not used, a probe crash or sampling error may occur and the reagent may not be aspirated correctly, which would influence the analysis results.

Table 5-05: Reagent vials and compatible caps/cover rings

Reagent vial	Compatible reagent cap	Compatible cover ring
Siemens reagent vial 5 mL (GW5)	Reagent cap S	Cap NO. 528
40mm 22mm	A slit is provided.	22mm
Siemens reagent vial 15 mL (GW15)	Reagent cap L	Cap NO. 527
50mm 30mm	No slit is provided.	26mm



#### Note:

Reagent caps are used to inhibit the reagent from being evaporated.

## Attaching the reagent cap and cover ring

Attach a reagent cap and then attach a cover ring to the reagent vial.

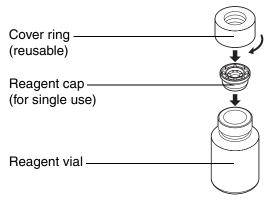


Figure 5-06: Attaching the reagent cap and cover ring



## Warning!

- When attaching or detaching the reagent cap and cover ring, always wear latex or non-latex gloves. Take care not to spill reagents. After completion of work, wash hands with disinfectant.
- Handle reagents according to the instructions provided with each reagent.
- Waste reagent caps must be disposed of appropriately in accordance with local laws, with due consideration of medical and infectious wastes.



- Reagent caps are for single use.
   Repeated use of the caps may result in an incorrect analysis result.
- When using a reagent cap, always attach a cover ring.
   If the cover ring is not used, the cap may rise up from the vial causing a probe crash or sampling error to occur. As a result, the reagent may not be aspirated correctly, which would influence the analysis results.
- Impurities such as reagent, condensation and dirt can adhere to a reagent cap that has been used, so do not reuse it.
  - Impurities may get mixed with reagents, which could affect data.
- If there are impurities such as reagent, condensation and dirt adhered to a cover ring, use it after removing them completely.
   Impurities may get mixed with reagents, which could affect data.
- In some cases, the cap may not be easily removed from the reagent vial. Take care not to spill the reagent or tear the gloves when removing the reagent cap.

## Caution!

- Reagent vial lids that have a flat inner surface can be closed with the reagent cap attached. For the sake of the storage stability, the reagents should be stored cooled with their cover rings removed and lids closed, or taken out of the instrument and stored in a refrigerator with their cover rings removed and reagent vial lids closed, if no analyses will be performed for a long period.
- Reagent vial lids that have a protrusion inside cannot be closed with the reagent cap attached.

If the reagent cap becomes deformed, the expected evaporation inhibitory effect may not be obtained. For reagent vial lids that have a protrusion inside, close the lid after removing the reagent cap.

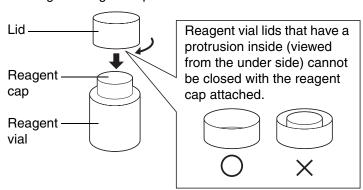


Figure 5-07: Attaching the lid to the reagent vial

- Do not mix reagents too strong to put them up near the mouth of the reagent vial, or do not mix them by inverting the vial with the reagent cap attached.
   Otherwise, reagents could get stuck to the reagent cap, thus affecting the data.
   When mixing reagents strongly or by inverting the vial, make sure to remove the reagent cap.
- Do not use a reagent cap other than specified (CSS-400A, CSL-400A).

Table 5-06: Reagent caps and cover rings

Part No.	Description	Min. lot
AS143226	Reagent cap S CSS-400A	200 pcs.
AF504574	Reagent cap L CSL-400A	100 pcs.
CC907148	Cap NO.528 (Kit NO.105)	10 pcs.
BB564291	Cap NO.527 (Kit NO.106)	10 pcs.

## Information of the mark in reagent cap

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## 3. Attaching SLD mini cups

### Preparing the SLD mini cups and reagent rack

Only use SLD mini cups in combination with the reagent vial and reagent rack stated in the table below.

Table 5-07: Applicable reagent vials and reagent racks

Reagent vial	Reagent rack"
Siemens reagent vial 5 mL (GW5)	Reagent rack C-1 (Container_Assy_No. 34) Reagent rack C-2 (Container_Assy_No. 35)

- \* This cannot be used for anything other than control and calibrator.
- \*\* The reagent rack with the yellow handle.



## Caution!

Always use SLD mini cups with the specialized reagent racks (Reagent rack C-1, C-2) for SLD mini cups. If you place the wrong reagent rack, it can cause probe crash or sampling errors, so the control and calibrator may not be aspirated correctly, which would influence the analysis results.



#### Note:

SLD mini cups are used to reduce the extra volume for control and calibrator.

## Attaching SLD mini cups

1. Transfer dissolved control and calibrator into SLD mini cups.

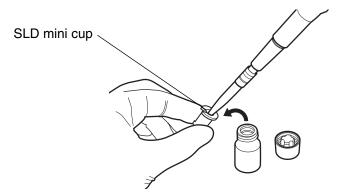


Figure 5-08: Transfer into SLD mini cups

 Attach an SLD mini cup to the reagent vial after transferring control and calibrator. Insert the SLD mini cup securely to the top of the reagent vial. SLD mini cups are for single use.

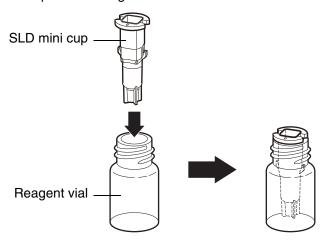


Figure 5-09: Attaching SLD mini cups

\* Set reagent vials with attached SLD mini cups so their barcode labels face the same way as the barcode label on the reagent rack.



## Warning!

- Wear rubber gloves when attaching and removing SLD mini cups, and take care to avoid splashing control and calibrator.
- Handle control and calibrator according to the instruction manuals provided with them.
- When disposing of SLD mini cups, process them according to local laws, as appropriate for medical and infectious waste.



## Caution!

- SLD mini cups are for single use.
   With repeated use it may not be possible to get correct analysis results.
- Do not use SLD mini cups that have reagents, condensed water, dust or other impurities on them. Analysis results could be affected by the presence of impurities.
- Handle the control and calibrator gently to avoid making bubbles when transferring it to SLD mini cups. Analysis results could be affected by the presence of bubbles.
- Insert the SLD mini cup securely to the top of the reagent vial. If the SLD mini cup is too high up, it can cause probe crash or sampling errors, so the control and calibrator may not be aspirated correctly, which would influence the analysis results.
- It can be difficult to remove the SLD mini cup from the reagent vial, so take care to avoid splashing control and calibrator, or breaking the gloves.
- Use only the specified SLD mini cup.
   If the SLD mini cup is not of the specified type, it can cause probe crash or sampling errors, so the control and calibrator may not be aspirated correctly, which would influence the analysis results.

Table 5-08: SLD mini cup

Part No.	Description	Min. lot
AX008688	SLD mini cup	500 pcs.

• Use the specified reagent racks.

Table 5-09: Specialized reagent rack for SLD mini cups

Part No.	Description	Min. lot
AX801638	Reagent rack C-1 (Container_Assy_No. 34)	1 pc.
BV995710	Reagent rack C-2 (Container_Assy_No. 35)	1 pc.

#### Information of the mark in SLD mini cup



In vitro diagnostic medical device



Consult instructions for use



Do not Reuse



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## 4. Adapter preparation

Prepare a compatible adapter for the reagent vials to be used in analysis.



#### Caution!

There are two types of adapter for the reagent table and three types for the buffer table. Use a correct adapter.

If the correct adapter is not used, the reagent may not be correctly aspirated and a probe crash or aspiration error may occur.

Table 5-10: Reagent vials and compatible adapters (reagent table)

Reagent vial	Compatible adapter	
Siemens reagent vial 5 mL (GW5)	Reagent holder No.19 (GW5) (Part No.424-3263-1)	Holder_ASSY NO.19 (Part No.AC833285)
40mm 22mm		
Sample Cup 4 mL (Cup 4 mL)	Reagent holder No.21 (Cup) (Part No. 424-3265-9)	Holder_ASSY NO.21 (Part No.CX073106)
16.6mm 38mm		

<sup>\*</sup> Siemens reagent vial 15 mL (GW15) and Siemens reagent vial 25 mL (GW25) do not require adapters. Place them directly into the reagent rack.

Table 5-11: Reagent vials and compatible adapters (buffer table)

Reagent vial	Compatible adapter	
Siemens reagent vial 5 mL (GW5)	Holder_ASSY NO.126 (Part No. CW084217)	
40mm		
Siemens reagent Siemens reagent vial 15 mL (GW15) vial 25 mL (GW25)	S/B Adapter (GW15) (Part No.442-3098-7)	
50mm 65mm		
Sample Cup 4 mL (Cup 4 mL)	S/B Adapter (SC) (Part No.442-3096-0)	
16.6mm 38mm		

## 5. Setting the reagents



## Warning!

- Extra care should be taken to make sure CA CLEAN I is not mixed and used with acidic solutions such as CA CLEAN II. Direct mixing of CA CLEAN I and an acidic solution will result in the highly hazardous release of poisonous chlorine gas.
- When handling samples or reagents, always wear latex or non-latex gloves.
   After completion of work, wash hands with disinfectant, or there is the risk of infection with pathogens etc.
- When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked.
  - If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.
- When closing the light shield lid, take care to avoid pinching your fingers.

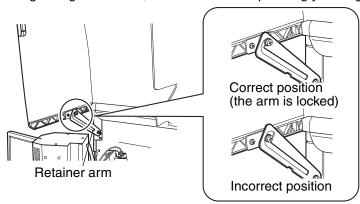


Figure 5-10: How to open the light shield lid



- Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.
  - How to close the light shield lid
    - (1) Lift the light shield lid up slightly.
    - (2) Lift the retainer arm in the arrowed direction to unlock it.
    - (3) Close the light shield lid slowly.

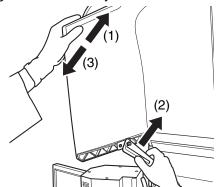


Figure 5-11: How to close the light shield lid



- Set the reagent vial at the position where the barcode label is seen clearly through the slit of the reagent rack and the adapter.
   If the position shifts, the barcode might not be able to be read.
- CA CLEAN I is used for rinsing the probe, so analysis is not possible if it is not set.
  - Always check the setting of CA CLEAN I before starting analysis.
- CA CLEAN I must be set in at least one position on reagent table A or B.
- After analysis has been completed, cap the CA CLEAN I, CA CLEAN II vials on the reagent racks.
- When analyzing analysis parameters that require rinsing with CA CLEAN II, set the CA CLEAN II on either reagent table A or B.
- Set the correct vial, or you cannot aspirate a reagent correctly.
- Handle and store reagents according to the instructions provide with each reagent.
  - Reagent can also be stored cooled inside the instrument overnight. For the sake of the storage stability of the reagents, however, they should be stored cooled with their lids closed, or taken out of the instrument and stored in a refrigerator with lids closed, if no analyses will be conducted for a long period. Leaving reagents for long periods with open caps could affect data.
- Do not place more than the regulation volume of reagent in the vial. If there is too much reagent, the error "The liquid level of vial is too high" may be issued.
- Opening and closing the reagent table covers in an environment with high humidity may cause condensation on the covers.
  - Use a dry cloth to wipe off any condensation which appears on the reagent table covers.
  - If condensation is left on the covers for long periods, it can drip into the reagents, which could influence results.

## Reagent screen display

1. Press Reagent on the toolbar.

The Reagent screen will appear.

The positions where the reagents are set and the status of each can be checked. For details see "Chapter 5 Reagent Screen" in the Software Guide.

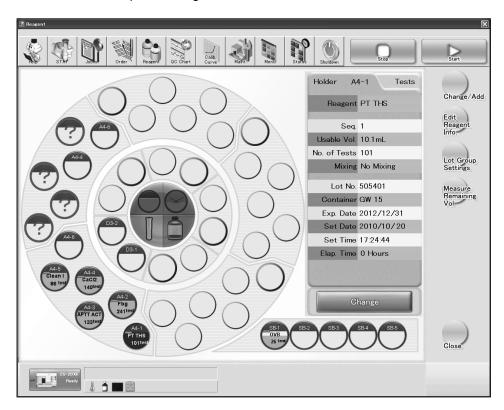


Figure 5-12: Reagent screen

## Replacement or addition of reagents and washing solution

- Press Reagent on the IPU menu screen toolbar.
   The Reagent screen will appear.
- Select the holder to be added or replaced from the reagent table status indicator area, then press **Change/Add** on the operation panel.
   The rack with the selected reagent holder moves to the replace/add position.



#### Note

- A confirmation dialog box is displayed if "Change/Add" is pressed during analysis.
  - It takes some time for the reagent rack to move to the replace/add position, so wait until the reagent table cover LED is lit green.
  - The status of the instrument is "Ready" until the reagent is actually replaced. Once the reagent table cover has been opened and closed again, it recognizes replacement as complete.
- The reagents cannot be replaced while the pressure is being adjusted.

3. Check that the cover LED for the reagent table concerned is green (cover ready to open), then release the lock and open the cover.

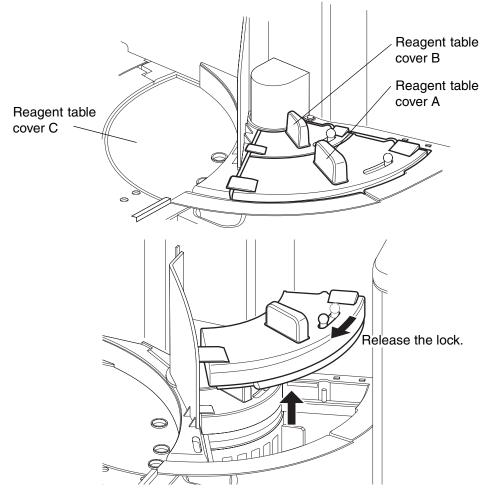


Figure 5-13: Reagent table cover



## Caution!

Remove reagent table covers A and B before removing reagent table cover C. Reagent table covers A and B could be damaged if they are still in place when reagent table cover C is removed.



## Note:

When the status of the instrument is "Ready", and the reagent table cover LED is green, you can open all the reagent table covers (A, B, C) and place reagents inside after opening the light shield lid.

4. Set the reagents and detergent in the reagent rack. If there is a gap between the reagent vial and rack, or if you use the provided containers (sample cup or other) for setting the reagent in the reagent rack, insert the applicable adapter provided. Set the reagent vial so that the barcode label is in the same direction as the barcode label of the rack. Set the reagent rack on the reagent table. Push the reagent rack all the way in.

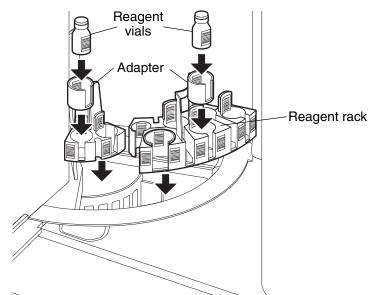


Figure 5-14: Setting the reagent vials (reagents and detergent)



- Do not set more than one reagent rack with the same number in one instrument. Reagent information will not be correctly read.
- Do not insert the accessory adapter in the wrong orientation. It would get stuck in the reagent rack. If you have inserted the accessory adapter in the reverse orientation and it is stuck in the reagent rack, refer to "Chapter 8: 8.2 When you suspect an error".
- Set reagent table cover C, then reagent table covers A and B. Reagent table covers A and B could be damaged if they are still in place when an attempt is made to attach reagent table cover C.
- Push the reagent rack, adapter and reagent vial all the way in.
   Otherwise, the reagent table cover or reagent rack may be damaged. As a result, the sample may not be aspirated correctly, which would influence the analysis results.

5. After setting the reagents and detergents, close the reagent table covers and slide the lock levers to their lock positions.

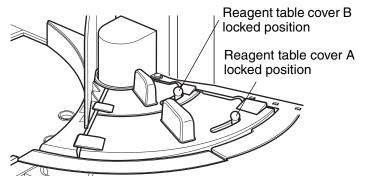


Figure 5-15: Reagent table cover

The barcode read dialog box is displayed. Press OK.
 The reagent table cover LED turns red (cover not ready to open).



#### Note:

Add a check mark to **Measure remaining reagent volumes after barcodes have been read.** and press OK to measure the remaining volumes of the reagents placed on reagent tables A and B and on the buffer table.



Figure 5-16: Barcode Read dialog box

When you select and press the reagent holder where the reagent was set from the reagent table status indicator area, the settings are displayed in the reagent holder information display area.

When reading fails

The reagent holder status changes to barcode reading error. Check the orientation of the reagent vial and repeat the barcode reading operation. The reagent holder affected by the error can be selected from the reagent table status indicator area, then press **Edit Reagent Info.** on the operation panel to use manual input.

When you press **Edit Reagent Info.**, the edit reagent information dialog box is displayed. Use it to set the reagent type, lot number, expiry date and vial type. For details see "Chapter 5: 5.3 Editing Reagent Information" in the Software Guide.

## Replacement or addition of diluents

- 1. Press **Reagent** in the toolbar on the IPU menu screen. The Reagent screen will appear.
- 2. Select the holder to be added or replaced from the reagent table status indicator area, then press **Change/Add** on the operation panel.
- 3. Check that the STAT/buffer table cover LED is green (cover ready to open), then open the cover.



#### Caution!

- Use the buffer solution after equilibrating to the room temperature.
   Otherwise, Coagulation Curve Error or prolonged clotting time might be obtained due to the occurrence of bubbles during the detection.
- When changing the diluent, change the reagent vial after removing the adapter from the buffer table. If the adapter is not removed, it becomes impossible, with some adapters, to recognize that the reagent has been changed.
- Push the adapter and reagent vial all the way in.
   Otherwise, the reagent table cover may be damaged or the sample may not be aspirated correctly, which would influence the analysis results.
- 4. Set diluent on the buffer table.

If there is a gap between the reagent vial and table, or if you use the provided containers (sample cup or other) for setting the reagent, insert the applicable adapter provided.

Set the reagent vial so that the barcode label is in the same direction as the barcode label of the rack.

When setting Owren's Veronal buffer into the buffer table, use the provided vials.

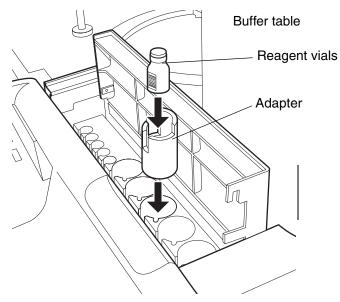


Figure 5-17: Setting the reagent vials (diluent)

5. Close the buffer table cover after setting the buffer.

6. The barcode read dialog box is displayed. Press **OK**.



#### Note:

Add a check mark to **Measure remaining reagent volumes after barcodes have been read.** and press OK to measure the remaining volumes of the reagents placed on reagent tables A and B and on the buffer table.

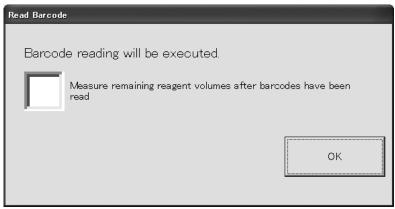


Figure 5-18: Barcode Read dialog box

When you select and press the reagent holder where the reagent was set from the reagent table status indicator area, the settings are displayed in the reagent holder information display area.

- When reading fails
  - A barcode reading error occurs, so select the reagent holder for which the error occurs from the reagent table status indicator area, then press **Edit Reagent Info.** on the operation panel.

The edit reagent information dialog box is displayed. Use it to set the reagent type, lot number, expiry date and vial type. For details see "Chapter 5: 5.3 Editing Reagent Information" in the Software Guide.



- When you use a barcode label for the reagent holder, use the appropriate reagent, vial and adapter corresponding to it.
  - The type of the reagent and information of the vial are coded in this barcode label.
- · Use a correct adapter.
  - If the correct adapter is not used, the reagent may not be correctly aspirated and a probe crash or aspiration error may occur. For details see "Chapter 5. 5.4: 4. Adapter preparation".
- When measuring the remaining reagent volume, remove the lid of the reagent vial. Measuring remaining reagent volume without removing the lid could cause a breakdown.
- When measuring the remaining reagent volume, also set the detergent necessary for measurement, such as CA CLEAN I. If there is not enough detergent, the measurement of remaining reagent volume will be interrupted.



#### Note:

 When the transfer vials are used, because the barcode label for a reagent holder provided in the supply part is affixed to the adapter for each vial, the automatic setting of reagent information by barcode reading becomes possible. (However, the lot number must be input manually.)

When using a S/B adapter, affix the barcode label to the flat area on the side. When using a reagent holder, affix the barcode label to the gently curved area on the side.

Put the adapter so that the barcode side may become the same direction as the barcode side of the reagent rack and set the reagent.

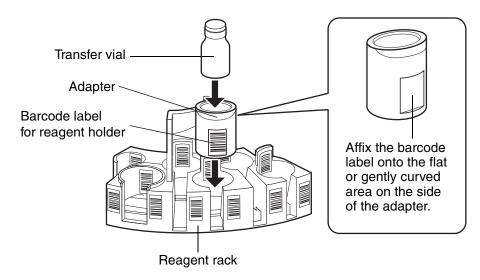


Figure 5-19: Reagent transfer

• The reagent rack (2 wells) for reagent table B is used when it is necessary to add a reagent vial, usually the racks are left outside the device.

## 5.5 Replenishing cuvettes

Replenish the number of cuvettes that are needed for your analysis.

The number of cuvettes required can be calculated as below for Normal mode and Micro-sample mode.

Necessary no. of cuvettes =

(No. of parameters)  $\times$  (No. of samples) + (No. of samples) : (in normal mode) (No. of parameters)  $\times$  (No. of samples) : (in micro-sample mode)



- As for the parameter such as AT III which requires multiple sample dilutions, additional cuvettes will be required.
   Supply extra cuvettes.
- Use the specified cuvettes only (SUC-400A).
- Cuvettes are intended for single use only.
   If used more than once, rewashed, or recycled, inaccurate measuring results may be obtained due to the effect of possible contamination. Inaccurate results could lead to inappropriate patient diagnosis or treatment.
- There may be a number of cuvettes left in the cuvette hopper.
- Do not replenish cuvettes above the limitation line. This will cause jamming.
- 1. Open the cuvette hopper lid.

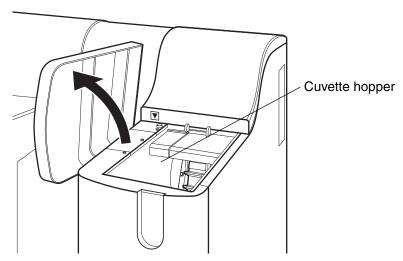


Figure 5-20: Cuvette hopper

- Replenish cuvettes. The cuvette hopper will hold approximately 500 tubes.
- 3. Close the cuvette hopper lid.

# 5.6 Placing a SB Cuvette (cuvette containing a stir bar)

When measuring parameters that require mixing during measurement, use the SB Set tool to place the SB Cuvette on the dispensing table, when the status of the instrument is "Ready".

## 1. IPU operation method

1. Press **Status** in the toolbar on the IPU menu screen. The Status Display screen is displayed.

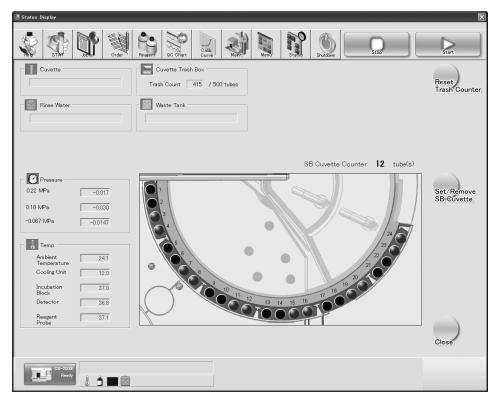


Figure 5-21: Status Display screen

The table below shows the relationship between the color of the dispensing table and its setting status.

Table 5-12: Dispensing table color and setting status

Color	Setting status					
Blue	An unused SB Cuvette is set.					
Black	Nothing is set.					
Gray	Setting status is unclear.					

Press Set/Remove SB Cuvette on the Status Display screen. The Confirmation dialog box appears.

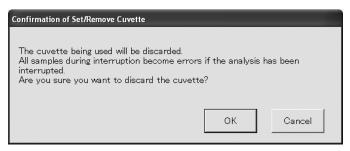


Figure 5-22: Confirmation dialog box

Press **OK** on the Confirmation dialog box.
 The cuvettes remaining on the dispensing table are discarded.
 The Confirmation dialog box appears after they are discarded.

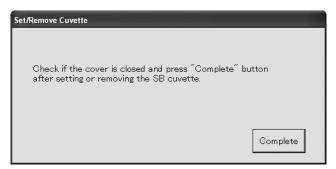


Figure 5-23: Confirmation dialog box



#### Note:

- All samples being analyzed will give errors if the analysis is interrupted.
- The cuvettes for which the setting status is unclear (Gray on the Status Display screen) are discarded.
- Unused SB Cuvettes that have already been set (with blue status on the Status Display screen) are not discarded.
- At this time, do not press Complete on the Confirmation dialog box. If you press Complete before placement, the instrument checks the setting status. Please repeat according to Step 2, after the status of the instrument turns to "Ready".

4. Check that the dispensing table cover LED is green. Open the light shield lid and dispensing table cover. Then set the SB Cuvette.

See "Chapter 5: 5.6: 2. Setting method of the SB Cuvette" when using the SB Set tool.

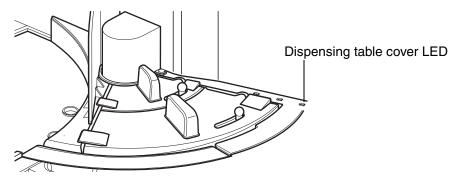


Figure 5-24: Dispensing table cover LED



# Warning!

When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked.

If it is not, the light shield lid could fall down and injure the user's head or elsewhere.

5. After placement, close the dispensing table cover and light shield lid, then press **Complete**.

The instrument checks the position of the SB Cuvettes.

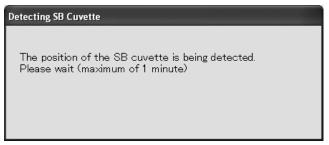


Figure 5-25: Detecting SB Cuvettes dialog box

 The SB Cuvette Counter information on the Status Display screen is updated, and the positions of the SB Cuvettes turn blue.
 Check that the number of set SB Cuvettes equals or exceeds the number required.

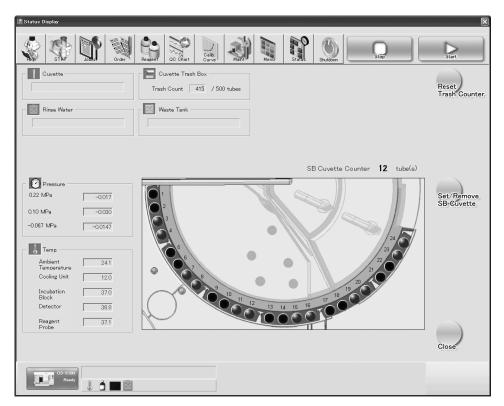


Figure 5-26: Status Display screen

Adding SB cuvettes to the dispensing table
 Repeat steps 2 through 5 on the Status Display screen.



#### Caution!

If you open the dispensing table cover without pressing **Set/Remove SB Cuvette**, the status of the SB Cuvetts turns to unclear (Gray on the Status Display screen). In that case, without pressing **Set/Remove SB Cuvette**, then take out the SB Cuvettes.

If you press Set/Remove SB Cuvette, all of the SB Cuvettes will be discarded.

Removing unused SB cuvettes from the dispensing table
 Take out the unused SB Cuvettes (Blue on the Status Display screen) by using the
 SB Set tool in reverse order as installation.

 Store them in empty positions on the second or third tray in the tray stack.

## 2. Setting method of the SB Cuvette

1. Prepare the SB Cuvette and SB Set tool.

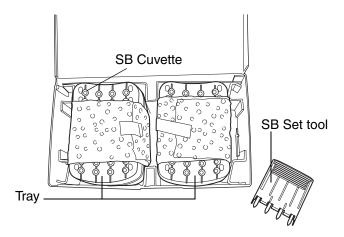


Figure 5-27: Preparing the SB Cuvette



# Caution!

• Do not use SB Cuvette other than specified.

Table 5-13: SB Cuvette

Part No.	Description	Min. lot
064-1041-9	SB Cuvette	144 pcs.

• SB Cuvettes are for one-time use only. Repeated use of the SB Cuvettes gives an incorrect analysis result.



## ∆ Note:

Please use the following SB Set tool, when you place the SB Cuvette.

Table 5-14: SB Set tool

Part No.	Description	Min. lot
063-4151-5	SB Set tool	1 pcs.

#### 2. Remove the tape and the upper tray.

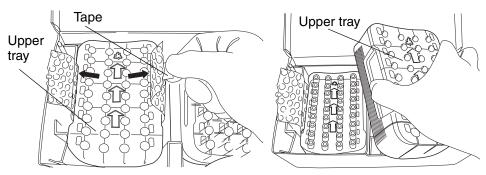


Figure 5-28: Removing the upper tray



#### Note:

There are no SB Cuvettes on the upper tray. 36 SB Cuvettes are on each tray (the second and third layers).

- 3. Remove the tray containing the cuvettes (the tray on the second or third layer) and place it on a stable bench top surface.
- 4. Make sure the upper surface of sliding plate and that of the fixed part are even. Then press the fair tapered projections of the SB Set tool into the 4 SB Cuvettes on the tray.

Use the SB Set tool after matching the direction of arrows on the set tool and the SB tray.

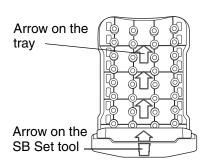


Figure 5-29: Orientation for using the Set tool

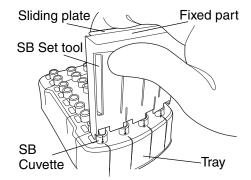


Figure 5-30: Inserting the SB Set tool 1



#### Caution!

If the tips of the SB Set tool become contaminated or dusty, wash with running water and wipe off any remaining fluid.

If they are contaminated, an incorrect analysis result may be generated.

5. Press the sliding plate down with fingers while pushing the SB Set tool in until it clicks.

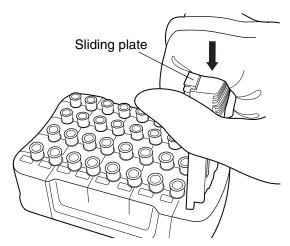


Figure 5-31: Inserting the SB Set tool 2

6. Hold up the SB Set tool, and confirm that there is one stir bar in each SB Cuvette to be set.

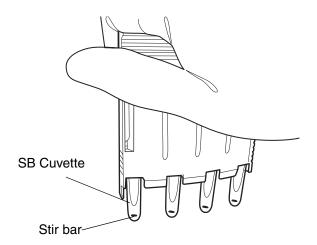


Figure 5-32: Confirming the stir bars



## Caution!

If there is more than one stir bar or no stir bar in the SB Cuvette, an incorrect analysis result may be generated.

7. Set the SB Cuvette in the instrument.

Make the arrow of SB Set tool point to the center of instrument, then set the SB Set tool in the dispensing table.

Set the SB Set tool in the dispensing table between the guides.

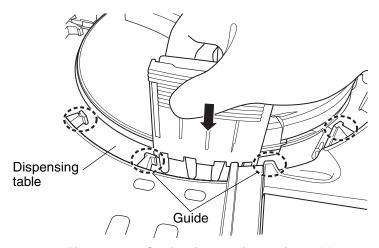


Figure 5-33: Setting in the dispensing table



#### Caution!

- Do not set the SB Cuvette in a position where there is already one set.

  The dispensing table may become damaged. The cuvettes or stir bars may fall into the instrument, and the instrument may become damaged.
- If you cannot insert the SB Cuvettes using the Set tool, contact your local technical representative.



#### Note:

You can set the SB Cuvette in any position where the status is black on the Status Display screen.

8. Hold the SB Set tool down while moving the sliding plate upwards. The SB cuvette are now set.

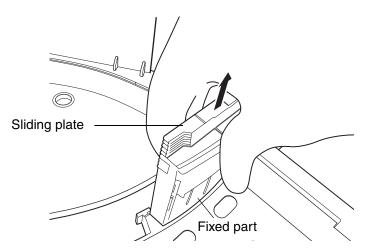


Figure 5-34: Setting in the dispensing table



#### Note:

Up to 24 SB Cuvettes can be set at one time.

- 9. Close the dispensing table cover.
- 10. Close the light shield lid.



#### Warning!

When closing the light shield lid, take care not to pinch your fingers.



#### Caution!

Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.

11. If there are unused SB Cuvettes in the tray, place them back into an empty SB Cuvette tray position and cover with the upper tray for protection.



## Caution!

- If the SB Cuvettes are not covered with the tray, dust could accumulate, and may result in an incorrect result.
- Store the SB Cuvette trays in a stable surface so that they do not fall. If the trash box falls down, the stir bars may fall out of the SB Cuvettes and become contaminated.

# 5.7 Setting Trash Box Liner CS2 (optional)

The optional Trash Box Liner CS2 can be set in the cuvette trash tray. The procedure for setting the liner is as follows:

1. Prepare one Trash Box Liner CS2 and form it into box shape.

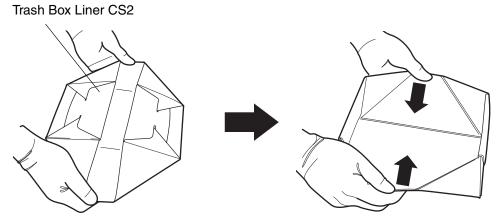


Figure 5-35: Preparing Trash Box Liner CS2

2. Insert Trash Box Liner CS2 into the cuvette trash tray.

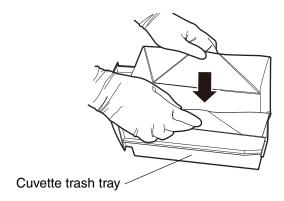


Figure 5-36: Setting Trash Box Liner CS2



## Caution!

If the Trash Box Liner CS2 is not inserted properly into the cuvette trash tray, it will not be possible to remove the tray from the instrument. Insert Trash Box Liner CS2 into the tray so that its bottom is flush with the tray.



#### Note:

Trash Box Liner CS2 can be inserted in either orientation.

# 3. Set the cuvette trash tray in place.

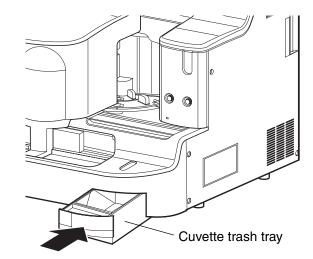


Figure 5-37: Setting the cuvette trash tray in place

#### 5.8 Confirm calibration curve

Confirm before performing analysis if the calibration curve is correctly set.



#### Caution!

If the calibration curve is not set correctly, the activity percent and other calculated parameters will not be calculated.

1. Press **Calib. Curve** on the IPU menu screen toolbar. The Calibration Curve screen will be displayed.

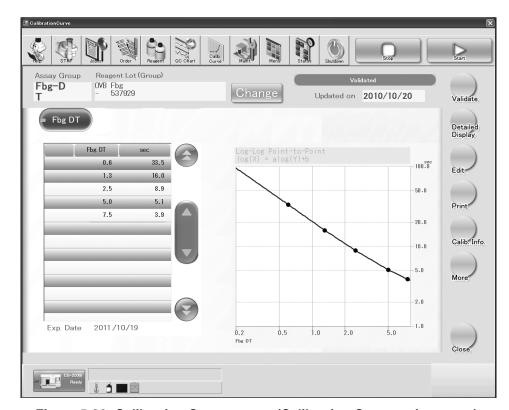


Figure 5-38: Calibration Curve screen (Calibration Curve main screen)

- 2. Check the calibration curve.
- 3. Press **Change** to check the calibration curves for other parameters. The Assay Group Selection dialog box will appear.

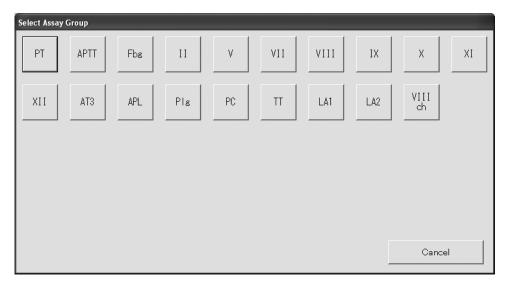


Figure 5-39: Assay Group Selection dialog box

- 4. Press the calibration curve parameter to check.
- 5. The calibration curve for the selected parameter will appear. Check the status of the calibration curves, with reference to "Chapter 7: 7.3 Displaying calibration curves" in the Software Guide. If there is a problem, remeasure the calibration curves, with reference to "Chapter 7: 7.2 Calibration curve order registration" in the Software Guide. In the same way, check the calibration curve for each analysis parameter.

# 5.9 Running quality control

To maintain the reliability of analyzed data, quality control has to be performed. With the CS-2000*i*/CS-2100*i*, when a QC sample is registered by order, and the control material (control plasma) is analyzed, the analysis data is stored in a QC file. By processing this analysis data with the QC program, you can monitor the instrument and reagent stability that vary from time to time.

QC analysis can be performed by manually registering an order, or by analyzing automatically at fixed intervals.

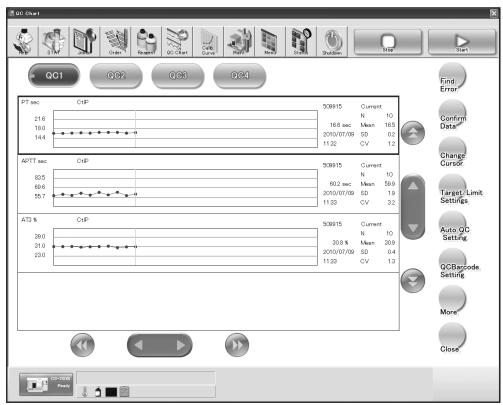


Figure 5-40: QC chart Display screen (QC main screen)

For details see "Chapter 6 Quality Control" in the Software Guide.

## How to make inquiries to the host computer

Use the sample number (QC01–QC20) for the quality control as the key to make an inquiry to the host computer about the order.

Use the QC Barcode Settings dialog box to make QC barcode ID (QC01–QC20) settings.

For details see "Chapter 6: 6.8. QC Barcode Setting" in the Software Guide.

## Manual analysis registration

The following explanation will apply to those cases in which the control material is set into a sample rack.



#### Note:

QC analysis is performed according to the same procedures as routine sample analysis. For details on how to register sample ID numbers and analysis parameters, see "Chapter 2 Order Registration" in the Software Guide. For details on analysis procedures, see "Chapter 6 Analysis".

1. Select **Order** on the IPU menu screen. The Order screen appears.

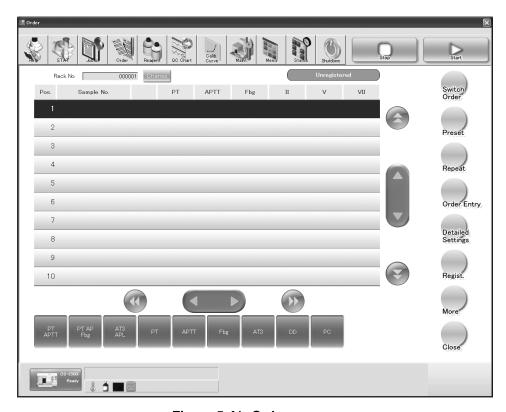


Figure 5-41: Order screen



#### Note:

The preset function can be used when orders are frequently registered with the same content.

Refer to "Chapter 2 : 2.2 : 7. Saving presets" in the Software Guide for saving presents, and to "Chapter 2 : 2.2 : 6. Loading Presets" in the Software Guide for loading presents.

#### 2. Press Order Entry.

The Order Entry dialog box will appear.

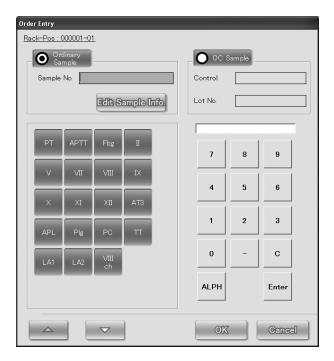


Figure 5-42: Order Entry dialog box

3. Add a check to **QC Sample**, and click the control to use from **Control**.

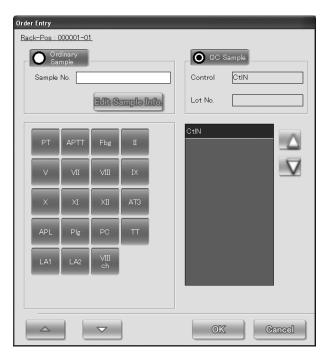


Figure 5-43: Order Entry dialog box

Order Entry

Rack-Pos : 000001-01

Ordinary
Sample
Sample No.

Edit Sample Info

Control CtlN
Lot No. 502701

FT APTT Fbg II

V VII VIII DX

X XI XII AT3

APL Plg PC TT

LA1 LA2 VIII ch

OK Cancel

4. Click a lot within the expiry date from Lot No.

Figure 5-44: Order Entry dialog box

- 5. Check the parameters to measure under Analysis Group.
- Press **OK**.Close the Order Entry dialog box and go back to the Order screen.
- 7. Press Regist.
- 8. Check that jobs subject to quality control have registered on the Joblist screen.
- 9. Set the control material into the sample rack and place the rack in the right rack pool.
- 10. Press the Start button on the Main Unit, or **Start** on the IPU menu screen toolbar. Analysis is performed and analysis data is automatically kept in the QC File.
- 11. Display the Quality Control screen and check the QC chart.
  For details see "Chapter 6: 6.2 QC charts display screen" in the Software Guide.



#### △ Note:

If sample numbers (QC01–QC20) for quality control are used, refer to "Chapter 2: 2.3: 4. Order input (registering quality control analysis orders manually)" in the Software Guide.

#### Auto QC analysis at fixed intervals

1. Set quality control reagents on the reagent table.



#### Note:

Refer to "Chapter 8: 8.11 Quality control settings" in the Software Guide for how to set the automatic interval for QC analysis.

2. Check that the status of the main unit is "Ready" or "Asp. Ready", then press the Start button on the main unit, or **Start** on the IPU toolbar.

Jobs are automatically registered for the parameters which are set as being subject to automatic QC analysis. Analysis begins and the analysis results are automatically saved to the QC file.

Subsequent QC analyses are performed automatically at the interval set under the QC settings, starting from the end of the first analysis.



#### Note:

- Registering controls under the QC barcode settings makes it possible to output QC data to the host computer under QC sample numbers (QC01~QC20).
   For details, refer to "Chapter 6: 6.8 QC Barcode Setting" in the Software Guide.
- Automatic analysis can be cancelled and resumed from the Auto QC Setting dialog box.

For details, refer to "Chapter 6: 6.7 Auto QC Setting" in the Software Guide.

Display the QC chart display screen, and check the QC chart.
 For details, refer to "Chapter 6: 6.2 QC charts display screen" in the Software Guide.

#### Auto QC analysis before aspiration of reagent from a new reagent vial (Vial QC)

1. Set control materials on the reagent table.



#### Caution!

Only "Current" in the current lot is analyzed for vial QC. Note that "New" for the new lot is not analyzed for vial QC.



#### Note:

Vial QC must be set to ON in order to perform QC Analysis automatically before aspiration of reagent from a new reagent vial.

See "Chapter 8: 8.11 Quality control settings" in the Software Guide for the vial QC setting method.

2. Check that the status indicated on the main unit is "Ready" or "Asp. Ready", then start analysis by pressing the Start button on the main unit, or **Start** on the IPU toolbar.

During analysis, QC analysis is performed automatically before reagent is aspirated from a new reagent vial, and the result is saved in a QC file. Vial QC analysis results are plotted on the QC chart, and analysis from the sampler resumes if the result is normal. Analysis is interrupted if the result is abnormal. When analysis starts on an assay group which is set for vial QC, the following Start Measurement Confirmation dialog box is displayed if QC has not been performed for the reagent for which sequence is "1".

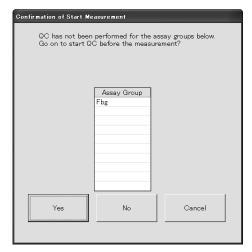


Figure 5-45: The Start Measurement Confirmation dialog box

3. Press Yes.

The Start Measurement Confirmation dialog box for Vial QC is displayed when reagent is aspirated from a new reagent vial, so press **OK**. The sampler stops until vial QC analysis is complete.

Press **No** to begin analysis without performing QC analysis. In that case, an assessment flag (\*) is attached to the analysis results, and, when the analysis result is displayed on the browser screen, the details dialog box states "Vial QC has not performed."

Press Cancel to avoid starting analysis.



#### Note:

QC analysis is not performed for STAT sample analysis and calibration curve analysis, even if reagent is aspirated from a new reagent vial.

# 5.10 Preparing samples

Set sample tubes or sample cups on the sample rack.



#### Caution!

For the CS-2000*i*, remove the sample tube cap and set on the device. Setting a sample tube with its cap on may result in a permanent damage.



#### Note:

- STAT samples in a sample tube or sample cup can also be set in the STAT/buffer table, as well as in the sample racks.
- For the CS-2100*i*, you can measure with the cap on. (Sampler analysis only) Analysis without a cap is also possible.

Follow the procedure below to prepare samples.

- 1. Preparation of samples (plasma)
- 2. Affixing Barcode Labels
- 3. Setting the Sample Rack into the Sampler

#### 1. Preparation of samples



#### Caution!

Precautions when handling plasma.

- As its container, use a plastic or silicone-coated glass tube.
- As anticoagulant, use 3.8%, 3.2% or 3.13% sodium citrate solution.
   When any other anticoagulant is used, it will cause a white precipitation and lead to incorrect analysis results.
- Mix blood and sodium citrate solution in an accurate ratio of 9 parts to 1 part, respectively. As the mixing ratio varies, coagulation time also varies, occasionally leading to incorrect analysis results.
- Analyze samples stored in the refrigerator within 4 hours of collection. Those samples that have had more than 4 hours pass after collecting and those kept in improper storage conditions may not give correct analysis results.
- If there are clots in the sample, they can cause the probe (piercer) and the rinse cup blocked, so remove the clots before analyzing. Buildup of clots in the probe (piercer) or the rinse cup would influence the analysis results.
- Samples of abnormal color may have an impact on analysis values, so they should be handled with care.

- 1. Add 1 part of 3.8%, 3.2% or 3.13% sodium citrate solution as anticoagulant to 9 parts of venous blood and mix the contents thoroughly.
- 2. For processing of the specimen, please follow the laboratory procedure or the guidance that applies according to your local regulatory agencies.
- 3. Set the centrifuged primary tube or separated plasma in another test tube in the sample rack.
  - Insert the test tube securely to the bottom of the rack.

Table 5-15: Sample tubes that can be used and their extra volumes

Useable (For the CS-2100 <i>i</i> , see "Table 5-20: Usable types of evacuated blood collection tubes and test tube adapters".)	Inner diameter 8 mm or more Outer diameter 10-15 mm, Length up to 75 mm (without cap) (Tubes of which inner diameter is 9.4 mm or less cannot be mixed on a rack.)
Extra volume required	<ul> <li>Sample cup 4 mL (Conical 4 mL) In the case of CS-2000i, 0.1 mL In the case of CS-2100i, 0.3 mL</li> <li>For a centrifuged sample See "Figure 5-47: Extra volume for a centrifuged sample (Sample tube type: standard sample tube)".</li> <li>For plasma only See "Figure 5-46: Extra volume for plasma only (Sample tube type: standard sample tube)".</li> </ul>

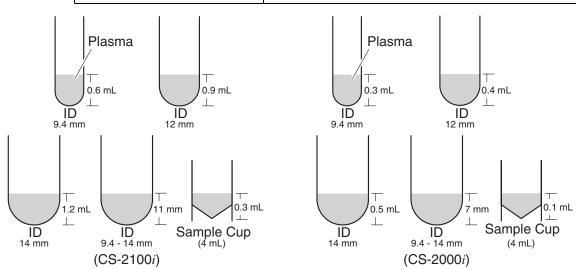


Figure 5-46: Extra volume for plasma only (Sample tube type: standard sample tube)

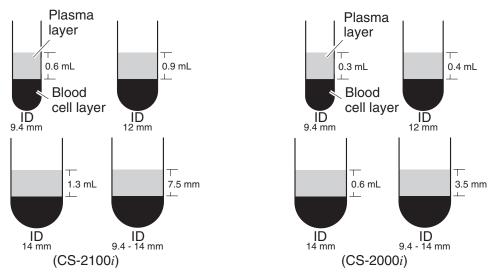


Figure 5-47: Extra volume for a centrifuged sample (Sample tube type: standard sample tube)

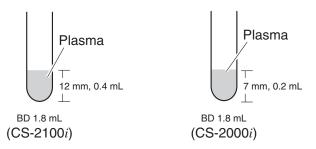


Figure 5-48: Extra volume for plasma only (Sample tube type: BD 1.8 mL)

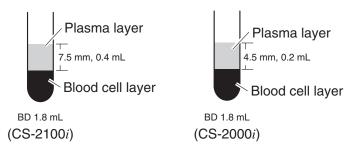


Figure 5-49: Extra volume for a centrifuged sample (Sample tube type: BD 1.8 mL)

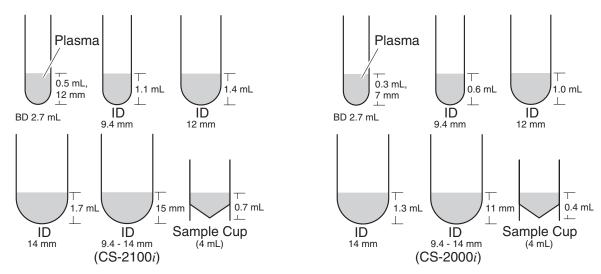


Figure 5-50: Extra volume for plasma only (Sample tube type: BD 2.7 mL)

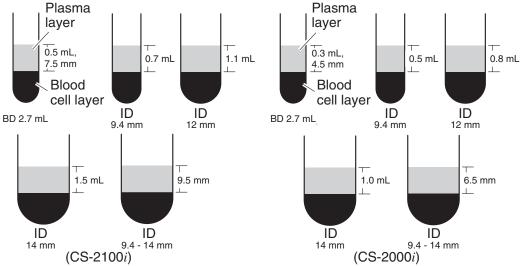


Figure 5-51: Extra volume for a centrifuged sample (Sample tube type: BD 2.7 mL)

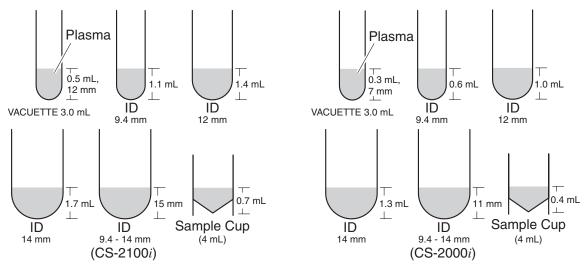


Figure 5-52: Extra volume for plasma only (Sample tube type: VACUETTE 3.0 mL)

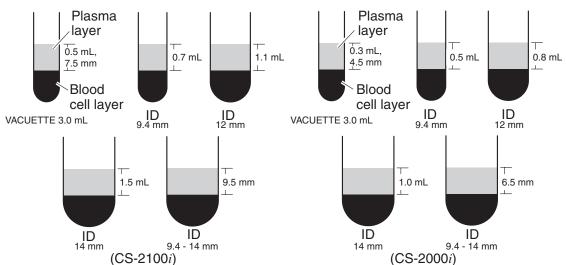


Figure 5-53: Extra volume for a centrifuged sample (Sample tube type: VACUETTE 3.0 mL)

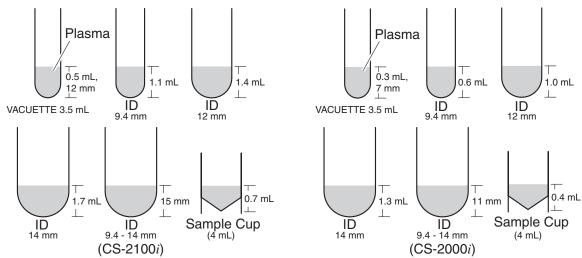


Figure 5-54: Extra volume for plasma only (Sample tube type: VACUETTE 3.5 mL)

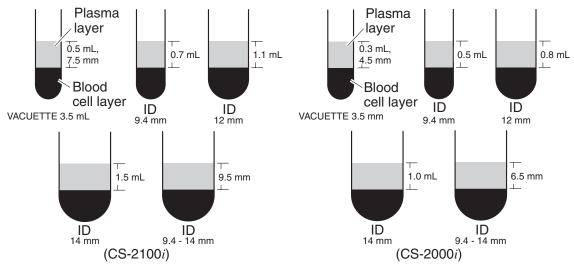


Figure 5-55: Extra volume for a centrifuged sample (Sample tube type: VACUETTE 3.5 mL)

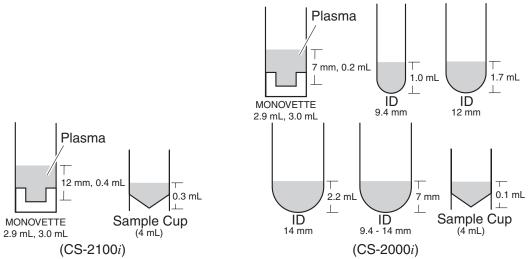


Figure 5-56: Extra volume for plasma only (Sample tube type: MONOVETTE)

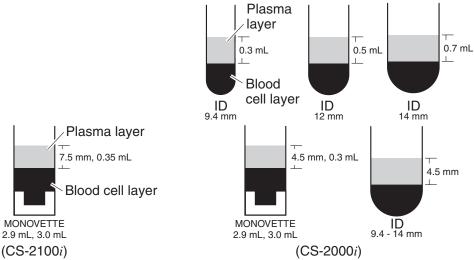


Figure 5-57: Extra volume for a centrifuged sample (Sample tube type: MONOVETTE)



#### Caution!

The sample volume which is actually required is the total required sample volume for the analysis parameters plus the extra volume.

Twice the required sample volume is necessary for performing replication analyses. The required sample volume corresponds to all the pre-set re-analysis conditions. In normal mode, samples are first taken into the instrument, so an extra  $130 \text{ (MAX)} \mu \text{L}$  is required in the CS-2000i.

As to the CS-2100i, an extra volume of 220 (MAX) µL is required.

If the specified test tube is not used or if the sample volume is insufficient, air and/ or blood cells may get aspirated and correct analysis results may not be obtained.

Table 5-16: List of extra volumes in normal mode

		CS-2100i	CS-2100i
	CS-2000 <i>i</i>	Standard Sample Tube     MONOVETTE     VENOSAFE	· BD · VACUETTE
When the sample is aspirated once	90 μL	170 μL (165 μL)	175 μL (165 μL)
When the sample is aspirated twice	130 μL	210 μL (200 μL)	220 μL (200 μL)

Figures in ( ) are extra volumes when analysis is performed by the CS-2100i in the sample tube, with no cap.

The maximum sample volume which may be aspirated at one time is 370  $\mu$ L (in the CS-2000i) or 320  $\mu$ L (in the CS-2100i). Simultaneous analyses are not possible if the total required blood volume exceeds this value.

(For repeat analyses and/or automatic re-analyses, approximately twice the normal volume will be required. Carefully calculate the sample volume when preparing the sample.)

Table 5-17: Maximum sample volume that can be aspirated at one time

			CS-2100i
	CS-2000 <i>i</i>	Standard Sample Tube     MONOVETTE     VENOSAFE	· BD · VACUETTE
When the sample is aspirated once	160 μL	100 μL (105 μL)	95 μL (105 μL)
When the sample is aspirated twice	370 μL	330 μL (340 μL)	320 μL (340 μL)

Figures in ( ) are maximum aspiration volumes when analysis is performed by the CS-2100i in the sample tube, with no cap.

Table 5-18: Examples of necessary sample volumes corresponding to measurement conditions

Example 1: Capped sample tubes: When analyzing samples centrifuged in standard sample tubes (inner diameter 9.4 mm)

• Analyze the two parameters PT and APTT in normal mode

	CS-2000i	CS-2100i
Volume necessary for PT	50 μL	50 μL
Volume necessary for APTT	50 μL	50 μL
Extra volume in normal mode	90 μL (one aspiration)	170 μL (one aspiration)
Extra volume to prevent incorrect blood cell aspiration	300 μL	600 μL
Total	490 μL	870 μL

Example 2: Capped sample tubes: When analyzing samples centrifuged with BD 1.8mL.

 Analyze the three parameters PT, APTT and Fbg in normal mode (set for automatic re-analysis)

	CS-2000i	CS-2100i
Volume necessary for PT	50 μL	50 μL
Volume necessary for APTT	50 μL	50 μL
Volume necessary for Fbg	10 μL (normal analysis) + 20 μL (automatic re-analysis) = 30 μL	10 μL (normal analysis) + 20 μL (automatic re-analysis) = 30 μL
Extra volume in normal mode	90 μL (one aspiration)	220 μL (two aspirations)
Extra volume to prevent incorrect blood cell aspiration	300 μL	600 μL
Total	520 μL	950 μL

Example 3: When analyzing samples transferred to sample tubes (when standard sample tube is selected as the sample tube type)

• Analyze the two parameters PT and APTT in micro-sample mode

	CS-2000i	CS-2100i
Volume necessary for PT	50 μL	50 μL
Volume necessary for APTT	50 μL	50 μL
Extra volume to prevent aspiration of air	100 μL	300 μL
Total	200 μL	400 μL

## Caution!

 The test tube adapter (tube holder No. 59) of 11-13 mm outer diameter is installed in the sample rack at the time of shipment from the factory. When you use test tubes with outer diameter 10-11 mm or 13-14 mm, remove this adapter and install an optional test tube adapter referring to the following.

Table 5-19: Separately sold test tube adapter

Part No.	Outer diameter	Test tube adapter
366-1793-6	10–11 mm OD	Tube holder No. 113 (WHITE)
366-1789-1	13–14 mm OD	Tube holder No. 58 (WHITE)
	14–15 mm OD	Not necessary

- Use a Conical 4mL sample cup (code No.424-1160-8), and set a sample of adequate volume. If a different sample cup is used and the sample volume is inadequate, the sample may not be aspirated correctly, which would influence the analysis results.
- If Sample cup conical 4mL (Part No.424-1160-8) is used, do not fill it with more than 3mL when measuring from the sampler. If the sample is too large, the error "The liquid level of sample tube is too high" may be issued.

Table 5-20: Usable types of evacuated blood collection tubes and test tube adapters

Sample tube	OD × Length	Test tube	Blood												
		adapter	volume	Det	fault		SD mL <sup>*7</sup>	2.7	D mL		JETTE	(San Coag Tu	IETTE dwich ulation be)		VETTE
				СР	OP*8	СР	OP*9	СР	OP*10	СР	OP*11	СР	OP*12	СР	OP
Terumo (VENOSAFE)	13 mm × 75 mm	Tube holder No. 59	1.8 mL	0*14	0	×	×	*6, *14	0*6	*6, *14	O*6	*6, *14	0*6	×	0
			2.7 mL	O <sup>*14</sup>	0	×	×	*6, *14	O*6	*6, *14	O*6	*6, *14	O*6	×	0
			3.6 mL	0*14	0	×	×	*6, *14	O*6	*6, <sup>*</sup> 14	O*6	*6, <sup>*</sup> 14	O*6	×	0
(Hemogard convention stopper typ 10.25 mm > (convention stopper typ 10.25 mm > (convention stopper typ (convention stopper typ 10.25 mm > (convention stopper typ )	13 mm × 75 mm (Hemogard, conventional stopper type)	Tube holder No. 59	4.5mL	O*2	0	×	×	*2, *6	o*6	*2,*6	O*6	*2,*6	O*6	×	0
	10.25 mm × 64 mm (conventional stopper type)	Tube holder No. 113	2.7 mL	×	O*3	×	×	×	*3, *6	×	*3,*6	×	*3,*6	×	O*3
	10.25 mm × 47 mm (conventional stopper type)	Tube holder No. 59 + BD rack adapter	1.8 mL	×	O*3	×	×	×	*3,*6	×	*3,*6	×	*3,*6	×	O*3
VACUTAINER Plus Plastic	13 mm × 75 mm	Tube holder	1.8 mL	×	×	0*14	0	×	×	×	×	×	×	×	×
Citrate Tube	(Hemogard)	No. 59	2.7 mL	×	×	×	×	0*14	0	×	×	*6, *14	0*6	×	×
VACUETTE	13 mm × 75 mm	Tube holder No. 59	3.0 mL	0*14	0	×	×	*6, *14	0*6	0*14	0	*6, *14	O*6	×	×
			4.0 mL	0*14	0	×	×	*6, *14	O*6	0*14	0	*6, <sup>*</sup> 14	O*6	×	×
	13 mm × 75 mm	Tube holder	2.0 mL	×	×	×	×	×	×	×	×	0*14	0	×	×
Sandwich Coagulation Tube		No. 59	3.0 mL	×	×	×	×	×	×	×	×	0*14	0	×	×
lube			3.5 mL	×	×	×	×	×	×	×	×	0*14	0	×	×

Table 5-20: Usable types of evacuated blood collection tubes and test tube adapters

Sample tube	OD × Length	Test tube					Т	ube Ty	/pe Se	lection	Settin	g			
		adapter	volume	Default			D mL <sup>*7</sup>	_	ID mL	VACL	JETTE	(San Coag	JETTE dwich ulation be)	MONO	VETTE
				СР	OP*8	СР	OP*9	СР	OP*10	СР	OP*11	СР	OP*12	СР	OP
MONOVETTE	13 mm × 65 mm	Tube holder No. 58	2.9 mL	×	0	×	×	×	O*6	×	O*6	×	O*6	*5, *14	0
	11.5 mm × 66 mm	Tube holder No. 59	3.0 mL	×	0	×	×	×	O*6	×	O*6	×	O*6	*5, <sup>Q</sup> 14	0

# $\triangle$

#### Caution!

O(CP): Sample tubes indicated by O can be used as capped tubes in the CS-2100*i* 

Sample tubes which are not described in the table are not validated by Sysmex.

O(OP): Sample tubes indicated by O can be used as open (uncapped) tubes in the CS-2000*i* or the CS-2100*i*.

If a cap is not set, open tubes which are described in the table of "Chapter 5: 5.10: 1. Preparation of samples" in both the CS-2000*i* and the CS-2100*i*.

- ×: Cannot be used.
- <sup>1</sup>: Tube holders No.58 and No. 113 are optional supply parts. Please contact your local representative for further information.
- <sup>2</sup>: Before the fourth consecutive piercing, equalize the pressure in the tube by releasing and refitting the cap.
- \*3: Micro-sample mode only.
- <sup>\*4</sup>: Please contact your local BD Preanalytical Solutions representative to order. When using BD rack adapter ensure correct attachment of barcode labels to avoid barcode read error.
- \*5: When using MONOVETTE sample tubes, ask the Sysmex branch or sales office about special handling conditions.
- <sup>\*6</sup>: If the minimum necessary sample is larger than the "default" setting for the sample tube type selected, see "Chapter 5: 5.10: 1. Preparation of samples".
- <sup>\*7</sup>: Sample cups (4 mL) can not be used.
- 8: All sample tubes must have an inner diameter larger than 9.4 mm.
- <sup>19</sup>: Only 1.8 mL (Hemogard) VACUTAINER Plus Plastic Citrate tubes can be used.
- \*10: 2.7 mL (Hemogard) VACUTAINER Plus Plastic Citrate tubes and sample tubes with an inner diameter larger than 9.4 mm can be used.
- \*\*\*\*\* VACUETTE tubes and sample tubes with an inner diameter larger than 9.4 mm can be used.
- <sup>112</sup>: VACUETTE Sandwich Coagulation tubes and sample tubes with an inner diameter larger than 9.4 mm can be used.
- \*13: Only 2.9 mL and 3.0 mL MONOVETTE can be used.
- <sup>\*14</sup>: Do not perform consecutive piercing operations more than third.

#### 2. Affixing barcode labels



#### Warning!

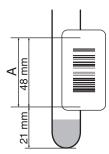
- If the sample barcode is used, use a check digit whenever possible.
   If no check digit is used, there is an increased risk of incorrect barcode reading.
- Observe the following precautions about affixing barcode labels.
   If the barcode label is not affixed correctly, the barcode could be misread, causing sample handling errors.
  - Affix labels so that the bars on the label are arranged horizontally when the tubes are placed in the rack.
  - Affix the label correctly, in the required position.
  - Do not affix multiple labels.
  - Affix labels so that they are free of surface wrinkles.
  - The barcode label must not peel off the tube (do not use labels that peel easily).
  - The sample tubes with affixed barcode labels must slide smoothly in and out of the rack.

When you use the sample ID barcode, a barcode label has to be affixed at the proper position and the tube has to be set in the rack correctly.

When setting the sample rack on the sampler, place the tube in the sample rack so that the barcode labels on the tubes correctly face the barcode reader.

Refer to the figure below in affixing a barcode label.

A rack number barcode is required for analysis. Affix the rack barcode label provided by referring to "Chapter 9. 9.4: 12. Preparing racks".



Attach so that the barcode is within the area indicated by A.

Figure 5-58: Affixing barcode labels

#### 3. Setting the sample rack into the sampler



#### Caution!

- If the sample rack is not correctly set, an instrument failure may result.
- If samples are left at room temperature for a long time, they may deteriorate. Place samples on the sampler immediately before the analysis starts. If there are many analysis parameters, or if there are parameters which take a long time to analyze, it may take time before the samples set in the sampler are aspirated. Take care to ensure that samples are not degraded by room temperature in that time.

#### Precautions for the CS-2100i

- Micro-sample mode, calibration curve, quality control and STAT sample holder analysis cannot be performed while the cap is on.
- Do not perform four or more piercing operations using the same cap for each sample tube and do not perform piercing operations if the total volume aspirated exceeds 1.3 mL for three operations.
- Use the specified holder for the sample tubes. Failure to do so can cause the piercer or other equipment to fail or get damaged.
- Sometimes when caps are placed back on tubes, the tube interior gets pressurized and/or sample adheres on top of the cap. There is no data-related problem, but you may get infected with pathogens.
- Be sure that sample does not adhere to the cap of a centrifuged collection tube.
   If it adheres, proper sample aspiration may not be performed due to malfunction
   of the liquid surface sensor and correct analysis results may not be obtained.
   After a sample tube is centrifuged, take care to make sure that sample does not
   adhere to the back of the sample tube cap.

Precautions regarding sample volume in the CS-2100i

- Use only the specified sample tube according to the tube type selection setting
  when performing an analysis with the cap on. If the sample volume is low, the
  sample tube may be broken. Air may also get aspirated, preventing correct
  analysis results from being obtained.
- If the specified amount of sample is not collected into the sample tube, rinse solution from the piercer may enter the tube, due to vacuum, preventing correct analysis results from being obtained.
  - Use only tubes that contain the specified volume of sample.
- If performing an analysis with the cap on, make sure that the surface of the sample is less than 3 mm above the upper surface of the rack. If it is higher, the level cannot be monitored.
- When using sample cups, avoid setting samples which are low in plasma volume to avoid a "Probe Crash".

Precautions regarding use of 4.5 mL VACUTAINER (Hemogard Closure) in the CS- 2100i

 If 4.5 mL VACUTAINER sampling tubes (Hemogard) from BD are used, do not perform four or more piercing operations. Pressure errors can prevent the predetermined volume from being aspirated, leading to incorrect results.



#### Caution!

Precautions regarding use of 1.8 - or 2.7 - mL VACUTAINER (Conventional Stopper) tubes in the CS-2100i

- 1.8 or 2.7 mL BD VACUTAINER (Conventional Stopper) tubes can be used in micro-sample mode, but cannot be used in normal mode. Air may also get aspirated, preventing correct analysis results from being obtained.
   An "Abnormal Sample Volume" or "Insufficient Sample" error may occur.
- Set the sample rack onto the sampler.
   To set, align the sampler guide and sample rack groove.
   Up to 5 racks can be set at a time.

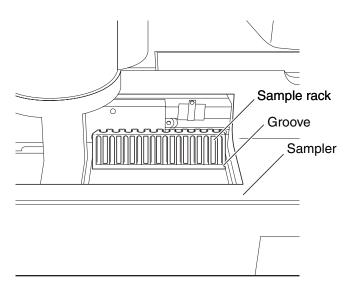


Figure 5-59: Setting sample racks

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# 6. Analysis

This chapter will explain the operating procedure from the start of analysis to shutdown.

#### 6.1 Overview

The operating procedure for analysis is as stated below. Analyze in accordance with analysis orders.

Inspection before turning power ON Turning ON the power Analysis reagent preparation Replenishing cuvettes Explained in "Chapter 5 Sample Preparation". Placing a SB Cuvette (cuvette containing a stir bar) Setting Trash Box Liner CS2 (optional) Confirm calibration curve **Running Quality Control Preparing Samples** Analysis Order registration Order registration 6-2 is explained in "Chapter 2 Order Order confirmation 6-4 Registration" in the Software Guide. **Analysis** 6-5 Explained in this 6-10 STAT Sample analysis chapter. Checking the amount of remaining reagent 6-12) **Emergency stop** 6-14 Shutdown 6-14

Table 6-01: Analysis Flow Chart

# 6.2 Order registration

This explains the method for registering analysis orders.

## How to register orders manually

When you press **Order** on the toolbar, the order screen below is displayed. For details see "Chapter 2 Order Registration" in the Software Guide.

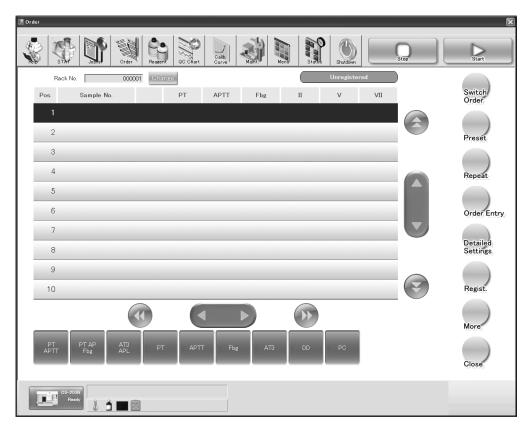


Figure 6-01: Order screen (rack order screen)

### How to register orders by sending an inquiry to the host computer

If there is a bidirectional connection between the host computer and the IPU, the sample number read by the barcode reader can be used to make an inquiry to the host computer for the analysis parameters and perform analysis accordingly. In that case, there is no need for analysis registration.

For details, refer to "Chapter 8:8.3:10 Order inquiry" in the Software Guide.



### Caution!

- If the sample number has already been registered manually, the registered sample number is used to make the inquiry, without reading the barcode.
- If the analysis parameters have already been registered manually, the registered analysis parameters are analyzed.
- When placing the cuvettes in the rack, arrange them so that barcode labels will face the front of the barcode reader when the rack is set in the sampler.
- Refer to "Chapter 5: 5.10 Preparing samples" for where to affix barcode labels.



### Note:

- If a read error occurred in during pre-reading of the sample barcodes, the sample numbers are assigned serial numbers, beginning when the power was switched on and prefixed with "ERR". (E.g.: ERR000000001) In that case, the barcode cannot be read at the aspiration position. The analysis order is either analyzed following an inquiry to the host computer, or following fixed parameters settings, as specified under "System settings → Operational Settings → Order inquiry → Automatic Order Inquiry → In the case of sample barcode reading error".
  - The setting under "System settings  $\rightarrow$  Operational Settings  $\rightarrow$  Automatic Output  $\rightarrow$  HC Output  $\rightarrow$  Barcode Reading Error" determines whether the result is automatically output to the host computer.
- If a read error occurs at the aspiration position, a Sample Barcode Error is issued, analysis is omitted, and an error is returned as the analysis result.
   The setting under "System settings → Operational Settings → Automatic Output → HC Output → Error Sample" determines whether the result is automatically output to the host computer.

### 6.3 Order confirmation

The use of the joblist is explained below as a method for confirming orders.

When you press Joblist on the toolbar, the Joblist screen below is displayed.

The joblist can display all registered orders (samples/QC/calibration curve), their state of progress and analysis results.

For details see "Chapter 3 Joblist" in the Software Guide.



Figure 6-02: Result Display screen (Joblist main screen)

### 6.4 Analysis

### 1. Start of analysis

Perform analysis.



### Warning!

Do not reach into the inside of the instrument during analysis.

Doing so may result in injury.

If the light shield lid is opened during analysis operation, an alarm will sound and the operation will stop.



### Caution!

- Switching the power OFF during analysis operation could result in permanent damage to the instrument.
  - To turn OFF the power, wait until the analysis is completed and the message "Ready" appears in the status display area.
- Check that the right and left rack pools of the sampler and the analysis line are free of dirt and foreign bodies.
- Check that no dirt or foreign bodies are stuck to the bottom of the rack, and that the rack is not damaged or deformed.
- During sampler analysis operation, do not push racks in as far as the analysis line by hand.
- Take care to avoid touching racks on the analysis line during sampler analysis operation.



### △ Note:

- When an analysis has started, the joblist cannot be changed. If an analysis is interrupted, however, those samples that have not yet started analysis can be changed or canceled.
- Analyses of samples in the STAT table are executed in order, starting from the holder with the lowest number.
  - In order to analyze additional new samples during analysis, register the order in the joblist.

 Check the instrument status display.
 Analysis can start if "Ready" (green) is indicated in the status display area at the bottom of the IPU menu screen.

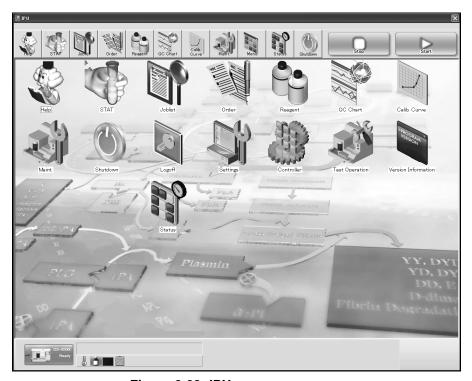
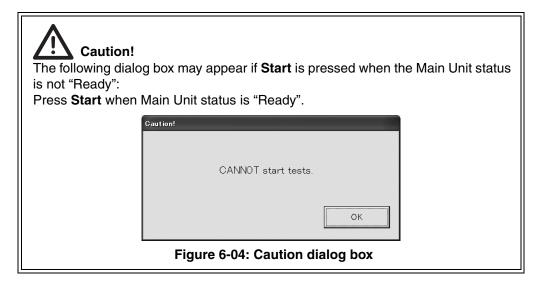


Figure 6-03: IPU menu screen

2. Press **Start** at the top of the IPU menu screen.

If the setting on the System Settings dialog box (Barcodes) is to not use rack barcodes, the Rack Number Input dialog box is displayed, so input the rack number and press **Start Measurement**.

The analysis will start and the message "Dispensing" will appear in the status display area.





### Note

When analysis is started without pressing **Regist.** on the Order screen, orders entered on the screen are automatically registered. For details of order registration, see "Chapter 2: Order Registration" in the Software Guide.

### 2. Displaying the analysis status

The Joblist screen can be used to check the status of each sample's analysis. The analysis status of each parameter to be analyzed is indicated in the Status column on the left of the list, using the symbols stated below.

"Pending"	Indicates a job that has been ordered but which has not started analysis.
"Processing"	Indicates that at least one of the analysis parameters is being analyzed.
"On Hold"	Indicates that all analysis parameters have been completed but the calibration curve has not been confirmed, so calculation parameters cannot be calculated.
" " (space)	This indicates that analysis has been completed normally.
"Review"	This indicates that analysis has been completed but a issue that requires confirmation by the user has occurred in one or more parameters.
"Error"	This indicates that analysis has been completed but an error has occurred in one or more parameters.

The backlight color changes according to the analysis status and results.

Table 6-02: Sample analysis status and backlight color

Backlight Color	Analysis Status
Blue	Not yet analyzed "Pending"
Green	Analysis is being processed "Processing"
No color	Analysis has been completed " " (space)
Yellow	Analysis complete, review required "Review", "On Hold"
Red	Analysis completed with error "Error"



Figure 6-05: Joblist main screen

### 3. Displaying sample information

The Joblist screen can be used to check sample information on samples.

The analysis status of each parameter to be analyzed is indicated in the Sample Info. column of the list, using the symbols stated below.

"Hem"	Indicates that the hemolytic check exceeded the acceptance limit.
"H*"	Indicates that the influence of turbidity or other inhibitor in the sample prevented an accurate hemolytic check.
"Ict"	Indicates that the icteric check exceeded the acceptance limit.
"[* "	Indicates that the influence of turbidity or other inhibitor in the sample prevented an accurate icteric check.
"Lip"	Indicates that the lipemic check exceeded the acceptance limit.
"L*"	Indicates that strong turbidity in the sample prevented an accurate lipemic check.
"Vol"	Indicates that the sample volume check exceeded the preset range.
<b>"_"</b>	Indicates that no sample volume check was carried out.
" "(space)	Indicates that hemolytic, icteric and lipemic checks were all below the acceptance limits and the sample volume check fell within the preset range.

### 4. Interrupt analysis

Interrupt analysis when you need to change the joblist or to replenish a reagent.



### Note:

The procedure for interrupting analysis of a routine sample in order to analyze a STAT sample differs from the procedure below. For details see "Chapter 6: 6.5 STAT sample analysis".

Press **Stop** on the toolbar.
 The Interrupt Analysis window will appear.

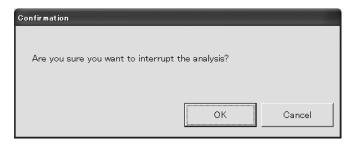


Figure 6-06: Confirmation dialog box

- Press **OK**.If you do not wish to interrupt analysis, press **Cancel**.
- 3. Press **Order** on the toolbar to change the registered order information. The Order screen appears. Alter the order.
- 4. Press **Reagent** on the toolbar to replenish reagents and other consumables. The Reagent screen will appear. Replenish reagents or consumables.
- Once you have finished changing the orders or replacing reagents or consumables, Press **Menu** on the toolbar.
   The Menu screen will appear.
- 6. Re-set the rack in the right pool and press **Start**. Analysis restarts.

### 6.5 STAT sample analysis

Analysis of STAT samples can be given priority over analysis of other samples. To analyze a STAT sample during other analysis, use the following procedure.



### Caution!

- If the STAT/buffer table cover LED is red, the cover will not open.

  If you try to open it by force, permanent damage to the instrument could result.
- Correct analysis results will not be obtained if serum samples and plasma samples have been interchanged.
- Capped sample tubes cannot be analyzed on the STAT sample holder, even on the CS-2100*i*. Manually remove the cap.
- 1. Press **STAT** on the toolbar.

The STAT Sample Order screen appears.

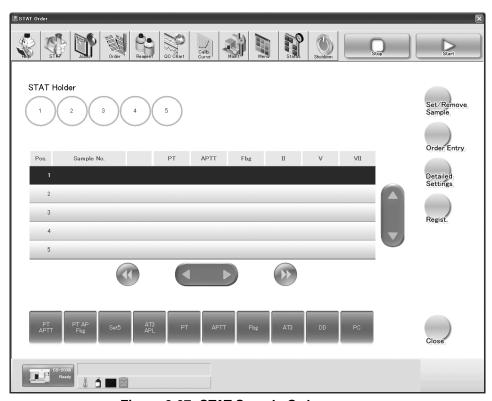


Figure 6-07: STAT Sample Order screen

- 2. Press **Set/Remove Sample** on the operation panel. The Confirmation dialog box will appear.
- 3. Press **OK** on the Confirmation dialog box to interrupt analysis and move the STAT holder to an accessible position.

The Executing dialog box appears until the movement is complete.

- 4. When STAT holder movement is complete, the Executing dialog box closes automatically.
  - At that stage, the STAT/buffer table cover LED turns green, indicating that the cover can be opened.
  - Open the STAT/buffer table cover and set the sample in the STAT holder.
- 5. Input the order for the samples set in the STAT sample holder, then press Regist.
- 6. Close the STAT/buffer table cover and press **OK** on the barcode read dialog box. The barcode reading will start.



### Note:

Add a check mark to **Measure remaining reagent volumes after barcodes have been read.** and press OK to measure the remaining volumes of the reagents placed on reagent tables A and B and on the buffer table.

- 7. Press the Start button on the Main Unit, or **Start** on the IPU menu screen toolbar. STAT sample analysis starts.
- 8. After STAT sample analysis, press **Set/Remove Sample**. Take the analyzed sample out of the STAT holder.

### 6.6 Checking the amount of remaining reagent

Check the amounts of remaining reagents from the IPU Menu screen or from the Reagent screen.

### 1. Checking remaining reagent volumes from the IPU menu screen

1. The IPU menu screen appears.

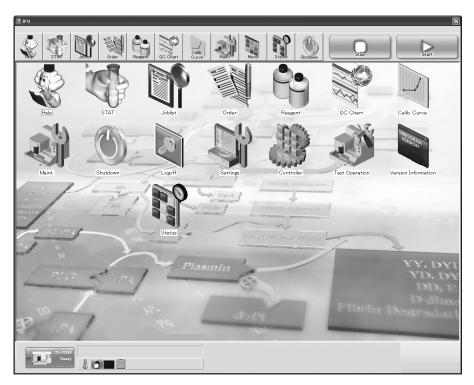


Figure 6-08: IPU menu screen

2. Check the status of the reagents on the bottom right of the menu screen.

Table 6-03: Reagent status

Reagents	Color	Contents
Ó	Yellow	One or more reagents are low.
	Red	One or more reagents are running out.
	Gray	Other than the above, including instrument not connected.

### 2. Checking remaining reagent volumes from the reagent screen

Press Reagent on the toolbar.
 The Reagent screen will appear.

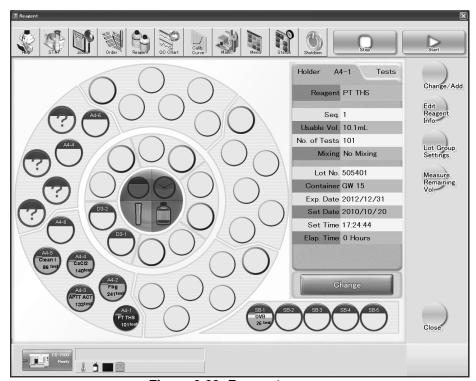


Figure 6-09: Reagent screen

2. Check the status of the reagents on the reagent tables, with reference to the following.

Table 6-04: Reagent holder background color and remaining reagent volume

Reagent holder display examples	Reagent holder background color	Remaining volume color	Remaining reagent
A4-6 PT THS	Gray	1	Remaining volume unknown
A4-6 PT THS PT THS	White	Pale blue	Reagent remaining (remaining volume is displayed visually in four levels)
A4-6 PT THS	Cream	Pale blue	Remaining volume warning

Table 6-04: Reagent holder background color and remaining reagent volume

Reagent holder display examples	Reagent holder background color	Remaining volume color	Remaining reagent
A4-6 PT THS	Pink	-	Reagent empty

### 6.7 Emergency stop

If the instrument suffers an emergency shutdown due to a sudden malfunction etc., press the Mechanical Stop switch on the Main Unit.

Please remember that some of the samples in analysis could be discarded, and you have to re-run those samples.

### 6.8 Shutdown

This is the procedure for shutting down the entire system.

The Shutdown cannot be executed during analysis or during an analysis interruption. To ensure secure operation, shut the system down and switch the PC off at least once every 24 hours.



### Caution!

- Be sure to turn OFF the power to the Main Unit after executing the shutdown. If the power is turned OFF without executing the shutdown, "S3I/O Communication Error" may occur.
- Handle and store reagents according to the instructions provide with each reagent.

Reagent can also be stored cooled inside the instrument overnight. For the sake of the storage stability of the reagents, however, they should be stored cooled with their lids closed, or taken out of the instrument and stored in a refrigerator with lids closed, if no analyses will be conducted for a long period.

Leaving reagents for long periods with open caps could affect data.

- 1. Set the CA CLEAN I on reagent table A. For details of the setting method, see "Chapter 5: 5.4: 5. Setting the reagents"
- Press **Shutdown** on the toolbar. The Shutdown dialog box will appear.



Figure 6-10: Shutdown dialog box

- 3. To continue cooling the reagent while it is stored inside the instrument, press **Continue reagent cooling**.
- 4. When you press **Turn off the Main Unit power**, the shutdown is executed according to the shutdown settings.
  - When the shutdown process is completed, the Shutdown Completion dialog box will appear.
  - If you press **Cancel** on the Shutdown dialogbox, the shutdown is cancelled and the Shutdown dialog box is closed.
- 5. Press **OK** on the Shutdown Completion dialogbox.
- 6. Press X on the right top of the IPU screen to exit the IPU software.
- 7. Shutdown Windows and turn OFF the power of the computer.
- 8. If the reagent is not to be kept cooled, turn the Main Unit power off. Do not turn off the Main Unit power if reagent cooling is to continue.

### 6.9 Sleep mode

If **Continue reagent cooling** is pressed before shutdown, the reagent can be stored cooled while the PC is turned off.



### Caution!

When the instrument is shut down with **Continue reagent cooling** selected, the waste tank cannot be removed after shutdown.

This is because waste fluids are regularly discarded, concurrently with the condensation removal that is carried out while the reagent is cooled.

When continuing reagent cooling, discard waste fluids before shutdown.

For details on discarding waste fluids, see "Chapter 7: 7.4: 3. Disposing of waste".

Follow the procedure below to ready the instrument for analysis.

- 1. Turn OFF the power to the Main Unit.
- 2. Start the PC.
- 3. Wait until the logon user selection dialog box appears.
- 4. Turn ON the power to the Main Unit.

### 1. Operation of the reagent table covers while in Sleep mode

If any of the reagent table covers, A, B or C, is opened while the instrument is in Sleep mode, an alarm sounds every three seconds.

### 2. Error handling while in Sleep mode

The method for handling errors which occur while the instrument is in Sleep mode is explained below.

 When the Main Unit detects a malfunction while in Sleep mode, the Alarm Indicator LED on the Main Unit changes from green flashing to red flashing, and an alarm sounds. The alarm stops when the Mechanical stop switch on the Main Unit is pressed. 2. Start the PC immediately and check the nature of the error.



### Caution!

- If a malfunction occurred during Sleep mode, it is possible that the quality of the reagent may have been adversely affected while cooled. Run quality control to confirm the quality of the reagent.
- Sleep mode is a function which allows the reagents to be stored cooled inside
  the instrument even when the PC has been switched off. The storage stability of
  reagents varies with the cooling temperature, whether or not the reagent vials
  have lids, the types of reagents, and their fluid volumes. Quality control at
  appropriate intervals is necessary to maintain the reliability of analyzed data.
- Follow directions on reagent labelings.
- Avoid letting the reagent come in contact with dust, dirt or bacteria.
- Reagents must not be used after their expiration date.
- Handle reagents gently to avoid bubbling.
- Take care not to spill reagents.
- Handle and store reagents according to the instructions provide with each reagent.

Reagent can also be stored cooled inside the instrument overnight. For the sake of the storage stability of the reagents, however, they should be stored cooled with their lids closed, or taken out of the instrument and stored in a refrigerator with lids closed, if no analyses will be conducted for a long period.

Leaving reagents for long periods with open caps could affect data.

### 6.10 Logging off

 Select **Logoff** on the IPU menu screen toolbar. The Log off Confirmation screen is displayed.

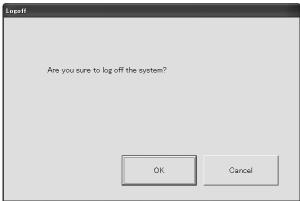


Figure 6-11: Logoff dialog box

2. Press OK.

The Logon dialog box will appear.

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### 7. Maintenance and Supplies Replacement

This chapter describes periodical maintenance and replacement of supplies.

### 7.1 Overview

Ensuring that the instrument will serve you in better operating condition requires periodic maintenance.

Carry out maintenance below according to the schedule.

### **Daily maintenance**

Cleaning probes

Discarding used cuvettes

Disposing of waste

Removing condensation from the reagent table and the reagent table cover

Checking and discarding trap chamber fluid in the Pneumatic Unit

Shutdown

### Weekly maintenance

Removing water from the tray

Cleaning instrument

Cleaning the rinse tank

Replacing Trash Box Liner CS2 (optional)

### **Monthly maintenance**

Cleaning the filter

### As-needed maintenance

Air pressure adjustment (when a pressure-related error occured)

Prime

Removing cuvettes from the cuvette disposal section

Removing cuvette blockages from the cuvette hopper

Wiping the piercer clean (CS-2100*i*)

### Confirming the cycle counts

Confirming the unit and parts cycle counts.

### Replacement of supplies

Replenishing reagents

Replenishing cuvettes

Replenishing rinse

Lamp replacement and calibration

Replacing the fuses of the Main Unit and the Pneumatic Unit



### Warning!

- When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked.
- If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.
- When closing the light shield lid, take care to avoid pinching your fingers.

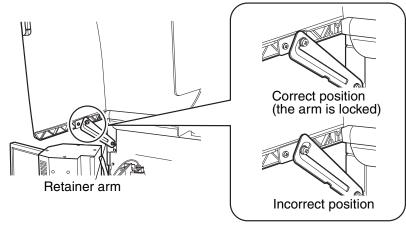


Figure 7-01: How to open the light shield lid



### Caution!

Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.

- How to close the light shield lid
  - (1) Lift the light shield lid up slightly.
  - (2) Lift the retainer arm in the arrowed direction to unlock it.
  - (3) Close the light shield lid slowly.

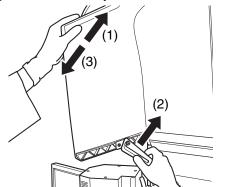


Figure 7-02: How to close the light shield lid

### Revised April 2013

DAILY MAINTENANCE:

## 7.2 Maintenance checklist

27

25

Year:

C/I							
24							
23							
22							
21							
20							
19							
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Day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 2	Clean probes	Discard used cuvettes	Dispose of waste	Remove condensation from the reagent table and the reagent table cover	Check and discard trap chamber fluid in the Pneumatic Unit	Shutdown	Signature
Item	Clea	Disc	Disp	Rem table	Chec the F	Shut	Sign

## WEEKLY MAINTENANCE:

ltem	m/d, signature					
Remove water from tray						
Clean the instrument						
Clean the rinse tank						
Replace Trash Box Liner CS2 (optional)						

# MONTHLY MAINTENANCE:

Item	m/d, signature					
Clean the filter						

# AS-NEEDED MAINTENANCE, REPLACEMENT OF SUPPLIES:

ltem	m/d, signature	m/d, signature m/d, signature	ltem	m/d, signature	m/d, signatu
Air pressure adjustment (when a pressure-related error occurred)			Replenish reagents		
Prime			Replenish cuvettes		
Remove cuvettes from the cuvette disposal section			Replenish rinse		
Remove cuvette blockages from the cuvette hopper			Lamp replacement and calibration		
Wiping the piercer clean (CS-2100;)			Replace the fuses of the Main Unit and the Pneumatic Unit		

### 7.3 Checking and performing maintenance

Checking maintenance tasks can be performed and maintenance history displayed on the Maintenance screen.

Press Maint. on the toolbar.

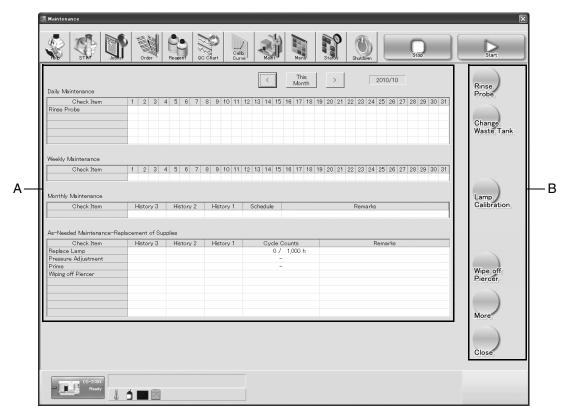


Figure 7-03: Maintenance screen

### A Maintenance schedule and history display area

This area displays the user maintenance and inspection schedule and history. If the scheduled date expires, the background turns yellow.

<	Display histor	v for the month	preceding the currently	,

displayed month of history.

**This Month** Display history for the current month.

Display history for the month following the currently

displayed month of history.

**Year/Month** Indicates the year and month for which history is displayed.

After the system boots up, the initial display on the Maintenance screen is of the current year and month.

**Daily Maintenance** The history of daily maintenance is displayed in one-month

units. The last three months can be displayed.

**Check Item** The names of daily maintenance items are displayed.

**Date** Implementation status marks are displayed for each date. O

appears next to all daily maintenance and inspection items

for every day. When the maintenance work has been

completed, the mark changes to ●.

Weekly Maintenance The history of weekly maintenance is displayed in one-

month units. The last three months can be displayed.

**Check Item** The names of weekly maintenance items are displayed.

Date Implementation status marks are displayed for each date.

For weekly maintenance and inspection items, O appears on the seventh date from the previous implementation of that item. When the maintenance work has been completed, the

mark changes to lacktriangle.

Monthly Maintenance History of monthly maintenance items is displayed for the

last three times, together with the scheduled date for the next time. Click the **Remarks** column to enter your

comments.

**As-Needed Maintenance** History of as-needed maintenance items is displayed for the

**Replacement of Supplies** last three times, together with the number of operations. Click the **Remarks** column to enter your comments.

### **B** Operation panel area

Operation buttons used on the maintenance screen are displayed.

1st page

**Rinse Probe** Executes probe rinse operation, a daily maintenance item.

**Change Waste Tank** Replaces the waste tank.

**Lamp Calibration** Performs lamp calibration after lamp replacement.

**Wipe off Piercer** Performs piercer cleaning.

This button is displayed for the CS-2100*i* only.

2nd page

**Pressure Adjustment** Displays the Pneumatic Adjustment screen.

**Prime** Supplies water.

**Print** If there is a connected printer, the history content for the

displayed history month can be printed out.

**Cycle Counter** Displays the unit and parts cycle counts.

Common to the 1st and 2nd page

**More** Switches the operation panel to the next page.

**Close** Closes the Maintenance screen.

### 7.4 Daily maintenance

### 1. Cleaning probes

Clean all sample probes and reagent probes.

- 1. Set the CA CLEAN I on reagent table A. For details of the setting method, see "Chapter 5: 5.4: 5. Setting the reagents"
- 2. Press **Rinse Probe** on the Maintenance screen. The Confirmation dialog box will appear.

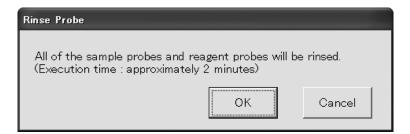


Figure 7-04: Confirmation dialog box

### 3. Press OK.

Probe rinsing begins and the Rinsing dialog box appears.

Press Cancel on the Rinsing dialog box to cancel rinse action.



### Risk of infection

Never touch the piercer tip of the CS-2100*i*. The tip of the piercer is sharply pointed and extremely dangerous. Handle it with care.

Accidentally touching the piercer tip could cause injury and infection with pathogens.



### Caution!

Take precautions to avoid touching the probes when your hand could be charged with static electricity.

This could cause instrument failure.

Turn OFF the power when you intend to touch the probes.



### Note:

Probe rinsing can also be performed at shutdown. For details see "Chapter 6: 6.8 Shutdown".

### 2. Discarding used cuvettes

### When using Trash Box Liner CS2 (optional)

The used cuvettes automatically fall into the trash drawer. After completion of the day's analysis or at least once every 24 hours, discard the used cuvettes from the Trash Box Liner CS2 and clean the cuvette trash tray with tap water.



### Risk of infection

Wear latex or non-latex examination gloves when discarding used cuvettes. After completion of work, wash hands with disinfectant. Handle all instrument parts as biologically hazardous. There is a risk of infection with pathogens etc. Also, discard the used cuvettes appropriately in consideration of the medical waste and the infectious waste procedures.

1. Take out the cuvette trash tray with the instrument power supply turned ON.

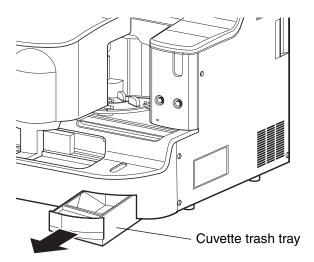


Figure 7-05: Discarding cuvettes

- 2. Remove the Trash Box Liner CS2 from the cuvette trash tray and discard used cuvettes.
- 3. Rinse the cuvette trash tray with tap water, then thoroughly wipe it dry.
- Set Trash Box Liner CS2 into the cuvette trash tray.
   Replace Trash Box Liner CS2 with a new one if it has been in use for a week or more.
- 5. Put the cuvette trash tray back in its original position.



### Caution!

- When a large number of used cuvettes accumulate, the cuvette trash tray and the Trash Box Liner CS2 get heavy. Take care not to drop cuvettes when taking out the tray or liner.
- If Trash Box Liner CS2 is used for a week or more, it can cause blockages in the cuvette disposal section, and might break when removed.
- Use the specified Trash Box Liner CS2.

Table 7-01: Trash Box Liner CS2

Part No.	Description	Min. lot
AM197840	Trash Box Liner CS2	20 pcs.

 The Reset Trash Counter dialog box is displayed if Monitor number of cuvettes in the trash box is set under Monitoring in the System Settings dialog box.
 For the details of settings, see "Chapter 8: 8.3 System settings" in the Software Guide.



Figure 7-06: The Reset Trash Counter dialog box

7. Press Yes.

The discard number is reset.



### Caution!

If **Monitor number of cuvettes in the trash box** is selected, the alarm will sound, in cases where the waste counts approach 500, then the analysis operations will discontinue. Wait for a while until the operations are completed. After the completion, dispose of the cuvettes by the above procedure.

### When not using Trash Box Liner CS2 (optional)

The used cuvettes automatically fall into the trash drawer. After completion of the day's analysis or at least once every 24 hours, discard the used cuvettes from the trash box and clean it with tap water.



### Risk of infection

Wear latex or non-latex examination gloves when discarding used cuvettes. After completion of work, wash hands with disinfectant. Handle all instrument parts as biologically hazardous. There is a risk of infection with pathogens etc. Also, discard the used cuvettes appropriately in consideration of the medical waste and the infectious waste procedures.

1. Take out the cuvette trash tray with the instrument power supply turned ON.

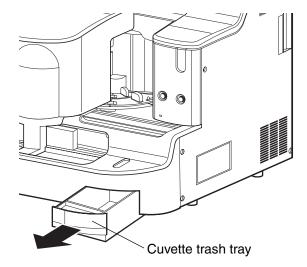


Figure 7-07: Discarding cuvettes

- 2. Discard used cuvettes.
- Clean the cuvette trash tray.
   Use tap water to clean the cuvette trash tray.
- 4. Dry the cuvette trash tray and restore it in place.



### Caution!

When a large number of used cuvettes accumulate, the cuvette trash tray gets heavy. Take care not to drop cuvettes when drawing out the box.

 The Reset Trash Counter dialog box is displayed if Monitor number of cuvettes in the trash box is set under Monitoring in the System Settings dialog box.
 For the details of settings, see "Chapter 8: 8.3 System settings" in the Software Guide.



Figure 7-08: The Reset Trash Counter dialog box

6. Press **Yes**. The discard number is reset.



### Caution!

If **Monitor number of cuvettes in the trash box** is selected, the alarm will sound, in cases where the waste counts approach 500, then the analysis operations will discontinue. Wait for a while until the operations are completed. After the completion, dispose of the cuvettes by the above procedure.

### 3. Disposing of waste

At completion of the day's analysis, discard the waste fluid that has collected in the waste tank, if provided.



### Risk of infection

When disposing of waste, always wear latex or non-latex examination gloves. After completion of operation, wash your hands with disinfectant.

Handle all instrument parts as biologically hazardous. There is a risk of infection with pathogens etc.

Also, discard the used cuvettes appropriately in consideration of the medical waste and the infectious waste.



### Caution!

- When the instrument is shut down with **Continue reagent cooling** selected, the waste tank cannot be removed after shutdown.
  - This is because waste fluids are regularly discarded, concurrently with the condensation removal that is carried out while the reagent is cooled. When continuing reagent cooling, discard waste fluids before shutdown.
- To replace the waste tank while the instrument is switched on, remove condensation regularly from the reagent table, by following steps 1 to 6, to prevent waste fluid draining from the tubes during replacement.
- To replace the waste tank with the instrument switched on, click on Change Waste Tank in the Maintenance screen. (This operation is not necessary if the instrument is switched off).

The Waste tank replacement confirmation dialog box is displayed.



Figure 7-09: Waste tank replacement confirmation dialog box



### Note

Removing condensation from the reagent table regularly prevents waste fluid from draining from tubes during the replacement process, so condensation removal is not performed while the waste tank replacement confirmation dialog box is displayed.

Open the waste tank cap.
 Turn the cap counterclockwise and take out the float switch, carefully avoiding splashing or dripping.

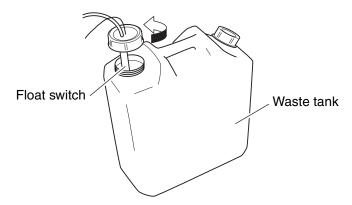


Figure 7-10: Removing the float switch

- Discard the waste fluid.Discard the waste fluid and empty the waste tank.
- 4. Attach the float switch to the waste tank and tighten the cap clockwise to close. Attach the float switch to the upper horizontal surface of the waste tank.
- 5. Check for any kinks, etc. in the tube.
- To replace the waste tank with the instrument switched on, click on **OK** in the waste tank replacement confirmation dialog box.
   The dialog box closes.



### Caution!

- When the tank becomes full with waste during analysis, an alarm will sound and the analysis operation will be interrupted. Wait for a while until the analysis operation is completed.
  - Discard waste in accordance with the above-mentioned procedure after completing the analysis operation.
  - After discarding, close the waste tank and press Start Analysis.
- When the tank becomes full after all samples have been dispensed, the Analysis Start Confirmation screen will not appear.

### 4. Removing condensation from the reagent table and the reagent table cover

After completion of the day's analysis or at least once every 24 hours, check to see if condensation has formed on the reagent table and the reagent table cover. Remove any if found.



### Warning!

Be sure to put on latex or non-latex examination gloves before starting work. After completion of work, wash your hands with disinfectant.

Handle all instrument parts as biologically hazardous.

There is a risk of infection with pathogens etc.



### Caution!

- Opening and closing the reagent table covers in an environment with high humidity may cause condensation on the covers.
  - Use a dry cloth to wipe off any condensation which appears on the reagent table covers.
  - If condensation is left on the covers for long periods, it can drip into the reagents, which could influence results.
- Remove reagent table covers A and B before removing reagent table cover C.
   Reagent table covers A and B could be damaged if they are still in place when reagent table cover C is removed.
- 1. Open the light shield lid and remove all reagent table covers.

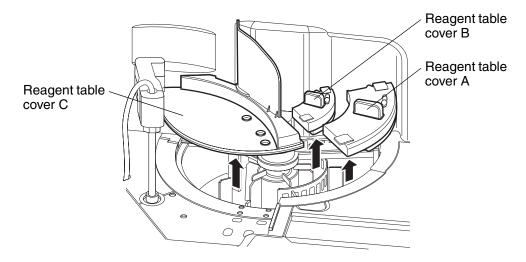


Figure 7-11: Removing reagent table covers



### Warning!

When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked.

If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.

2. Pull out all the reagent racks.

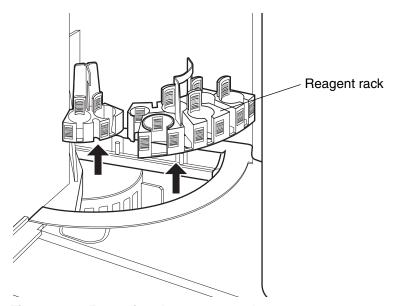


Figure 7-12: Removing the reagent racks

Remove the condensation from the reagent table.
 Using tweezers and paper towel, remove the condensation from the inside of the reagent table. Wipe off the condensation from the removed reagent racks as well.

4. Remove condensation from the reagent table covers.

Use a cloth or similar material to wipe any water off reagent table covers A, B and C.

Also wipe any water off the side of the reagent dispensing table cover (the shaded part).

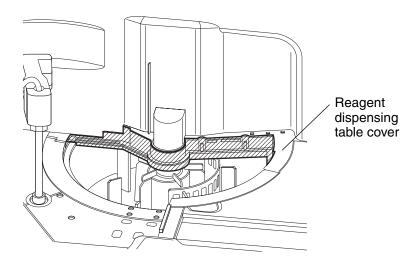


Figure 7-13: Reagent dispensing table cover

- 5. Fit the reagent racks in place.
- 6. Fit the reagent table covers and close the light shield lid.



### Warning!

When closing the light shield lid, take care to avoid pinching your fingers.



### Caution!

- Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.
- Set reagent table cover C, then reagent table covers A and B. Reagent table covers A and B could be damaged if they are still in place when an attempt is made to attach reagent table cover C.

### 5. Checking and discarding trap chamber fluid

After completion of the day's analysis, check the trap chamber fluid level and discard any fluid that has collected.



### **Risk of infection**

When draining the trap chamber, always wear latex or non-latex examination gloves. After completion of operation, wash hands with disinfectant. Handle all instrument parts as biologically hazardous.

There is a risk of infection with pathogens etc.



### Caution!

If fluid collects daily, the hydraulic system may have failed. Contact your local technical representative.

- 1. Turn OFF the power and wait approximately 30 seconds.
- 2. Turn the trap chamber on the left side of the Main Unit in the direction shown in the figure below and remove it.

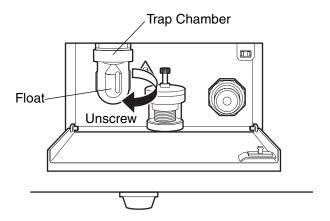


Figure 7-14: Removing the trap chamber

- 3. Discard the collected fluid. Do not discard the float.
- 4. Re-attach the trap chamber so that there is no leakage of air. Make sure the float is inside in the correct direction.

### 7.5 Weekly maintenance

### 1. Checking tray No.48 and removing water

Depending on the operating environment, condensed water may build up in tray No.48 under the Main Unit. Check it regularly, and remove any water that has accumulated.

Pull tray No.48 out from under the Main Unit.
 Pull it out horizontally, so that the water does not spill.

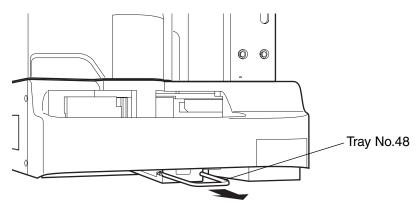


Figure 7-15: Removing tray No.48

2. Remove any water that has accumulated in the tray.

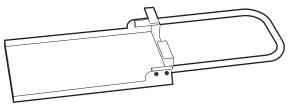


Figure 7-16: Tray No.48

3. Fit tray No.48 back in place, in the reverse order of removal. Refer to "Chapter 9: 9.4: 8. Setting tray No.48" for details of setting the tray in place.

### 2. Cleaning instrument

Clean the instrument surface at periodic intervals.



### Risk of infection

- Before cleaning the instrument, be sure to turn OFF the power supply and unplug the power cord. This is necessary to avoid the risk of electrical shock.
- Be sure to put on latex or non-latex examination gloves before starting work.
   After completion of work, wash hands with disinfectant.
   Handle all instrument parts as biologically hazardous.
   There is a risk of infection with pathogens etc.

### Cleaning the instrument exterior

- Turn OFF the power to the Main Unit.
   Unplug the power cord to the Main Unit.
- 2. Using a paper towel that has been moistened with water and a neutral detergent, wipe over the interior; then wipe again with a soft, dry paper towel.

### Cleaning the instrument interior

- Turn OFF the power to the Main Unit.
   Unplug the power cord to the Main Unit.
- 2. Open the light shield lid.



### Warning!

When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked.

If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.

- 3. Using a paper towel that has been moistened with water and a neutral detergent, wipe off the impurity of the buffer table circumference; then wipe again with a soft, dry paper towel.
- 4. Close the light shield lid.



### Warning!

When closing the light shield lid, take care to avoid pinching your fingers.



### Caution!

- Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.
- Never use any other cleaning solution than water and neutral detergent. Otherwise, the surface coating may be damaged.

### 3. Cleaning the rinse tank

Clean the rinse tank periodically.



### Caution!

Do not touch the float switch with your hand.

If dust or foreign matter adheres to the float switch, the tank interior will get contaminated. If the interior gets contaminated, correct analysis results may not be obtained.

If your hand or other object touches the float switch, wash off the float switch with rinse (or distilled water) and then attach it to the tank.

- 1. Turn the cap of the rinse tank with which the tube is connected in a counterclockwise direction and take out the float switch.
- 2. Use mains water to wash the inside of the tank and the float switch, then rinse them with distilled water.
- Replenish rinse (distilled water).
   Fill the rinse tank with rinse (distilled water).
- 4. Attach the float switch to the rinse tank and tighten the cap clockwise to close.
- 5. Check for any kink etc. in the tube.

### 4. Replacing Trash Box Liner CS2 (optional)

Please replace Trash Box Liner CS2 once a week, as a guideline. Refer to "Chapter 7: 7.4: 2.: When using Trash Box Liner CS2 (optional)" for the replacement method for Trash Box Liner CS2.



### Caution!

If Trash Box Liner CS2 is used for a week or more, it can cause blockages in the cuvette disposal section, and might break when removed.

### 7.6 Monthly maintenance

### 1. Filter inspection and cleaning

The main unit includes a filter to block the entry of dust. The filter should be cleaned regularly.



### Caution!

- The filter should be cleaned regularly.

  If the filter gets clogged, it prevents the intake of air from outside to the interior of the instrument through the rear panel, potentially causing abnormal temperature errors. It also encourages infiltration of air through the reagent table cover, so that if the reagents are left for long periods with their lids not closed, condensation, or evaporation of the reagents, could have an influence on data.
- Do not use water to wash the filter.
- 1. Remove filter NO.16A, filter NO.513 and filter NO.514 as shown below.

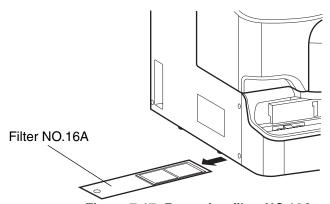


Figure 7-17: Removing filter NO.16A

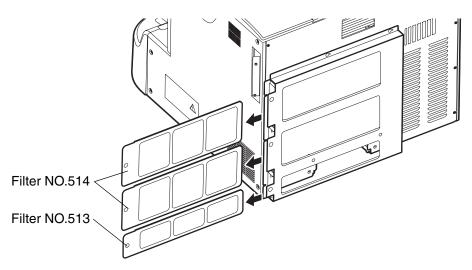


Figure 7-18: Removing filter NO.513 and filter NO.514

- 2. Use a vacuum cleaner or similar tool to remove dust from the filter.
- 3. After cleaning, push filter NO.16A, filter NO.513 and filter NO.514 fully back into place, in the reverse order of removal.



#### Note

Replace the filters with new ones if they are very dirty.

#### 7.7 As-needed maintenances

#### 1. Pressure and vacuum adjustments

Compressed air from the Pneumatic Unit is adjusted to -0.067 MPa, 0.22 MPa and 0.10 MPa. These pressures are constantly monitored by pressure sensors and if abnormality is detected, an error message will be displayed.

If any pressure related error message is displayed, check the tubing connections for leaks. If nothing abnormal is found, adjust the pressures.

To adjust the pressure, turn the adjustment knobs (located on the pressure adjustment area on the left side of the Main Unit and on the Pneumatic Unit front) as you check the current pressure readings on the Pressure Adjustment dialog box.

## Left Side (Main Unit)

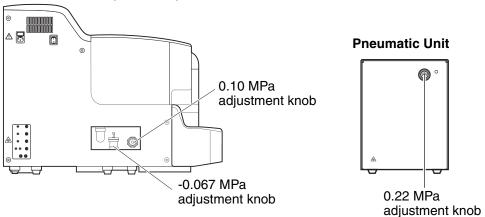


Figure 7-19: Pressure and vacuum adjustments



#### Note:

The reagents cannot be replaced while the pressure is being adjusted.

#### Displaying the Pressure Adjustment dialog box

1. Press **Pressure Adjustment** on the Maintenance screen. The Pressure Adjustment dialog box will appear.

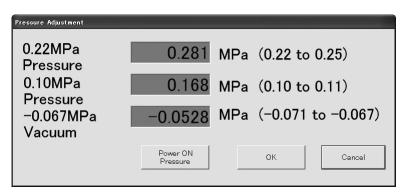


Figure 7-20: Pressure Adjustment dialog box

- 2. Press the Power ON Pressure.
- 3. Once adjustment is complete, press the **Power OFF Pressure**.
- 4. Press OK.

#### Adjusting the 0.22 MPa Pressure (adjustment range: 0.22 to 0.25 MPa)

1. Loosen the fixing screw on the 0.22 MPa adjustment knob by turning a screwdriver counterclockwise while the adjustment knob is held to prevent from rotating.

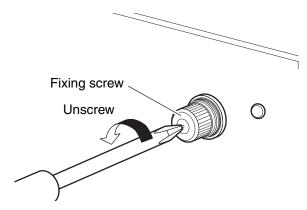


Figure 7-21: Adjusting 0.22 MPa pressure 1

 Adjust the pressure by turning the adjustment knob as you check the current value for the 0.22 MPa pressure on the Pressure Adjustment dialog box.
 The pressure will rise as you turn the adjustment knob clockwise.

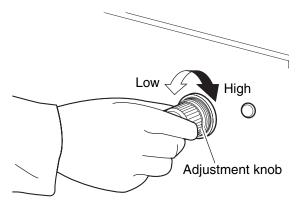


Figure 7-22: Adjusting 0.22 MPa pressure 2



## Caution!

- Always adjust pressure so as to increase to the predetermined level. If the
  pressure is too high, lower it to a value that is below the specified pressure; then
  slowly raise the pressure.
  - Failure to do so can prevent correct pressure adjustment.
- After adjusting 0.22 MPa pressure, also adjust 0.10 MPa pressure.
- 3. After adjustment, tighten the fixing screw while taking care not to allow the adjustment knob to rotate.

#### Adjusting the 0.10 MPa Pressure (adjustment range: 0.100 to 0.110 MPa)

- 1. Open the cover on the left side of the Main Unit and pull the 0.10 MPa adjustment knob toward you to unlock.
- Adjust the pressure by turning the adjustment knob as you check the current value for the 0.10 MPa pressure on the Pressure Adjustment dialog box. The pressure will rise as you turn the adjustment knob clockwise.

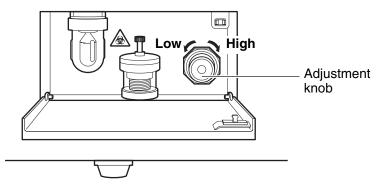


Figure 7-23: 0.10 MPa pressure adjustment



#### Caution!

Always adjust pressure so as to increase to the predetermined level. If the pressure is too high, lower it to a value that is below the specified pressure; then slowly raise the pressure.

Failure to do so can prevent correct pressure adjustment.

3. After adjustment, prevent the adjustment knob from turning by pressing it in until it locks.

#### Adjusting -0.067 MPa Vacuum (-0.071 to -0.067 MPa)

- 1. Loosen the fixing nut of the bellows unit located on the left side of the Main Unit.
- 2. Adjust the pressure by turning the adjustment knob as you check the current value for the -0.067 MPa pressure on the Pressure Adjustment dialog box.

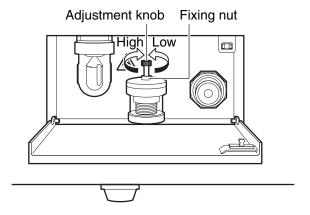


Figure 7-24: Vacuum adjustments



#### Caution!

- The pressure will rise as you turn the adjustment knob clockwise.
- Always adjust pressure so as to increase to the predetermined level.
   If the pressure is too high, lower it to a value that is below the specified pressure;
   then slowly raise the pressure.
- 3. After adjustment, tighten the fixing nut while taking care not to allow the adjustment knob to rotate.

#### 2. Prime

Whenever the instrument has been left without operation for a long period of time (more than one week), refill the hydraulic line with rinse (distilled water) before restarting analysis.

- 1. Prepare the rinse and the waste tank.
- Press **Prime** on the Maintenance screen. The Confirmation dialog box will appear.



Figure 7-25: Prime Confirmation dialog box

## 3. Press **OK**.

Water supply begins and the Executing dialog box appears.

## 3. Removing cuvettes from the cuvette disposal section



#### Risk of infection

Always wear Latex or non Latex examination gloves when removing cuvettes from the cuvette disposal section.

After completion of operation, wash hands with disinfectant.

Handle all instrument parts as biologically hazardous. There is the risk of infection with pathogens etc.

If cuvettes have accumulated in the cuvette disposal section, remove the jammed cuvettes by using the provided Cuvette removal rod (trash).

- 1. Turn OFF the power to the Main Unit.
- Remove the cuvette trash tray.
   If cuvettes get caught and make it difficult to remove the cuvette trash tray, shake it back and forth first.

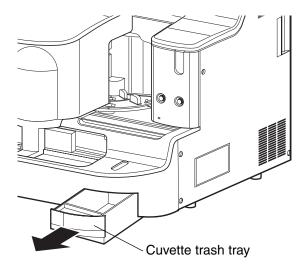


Figure 7-26: Removing the cuvette trash tray

3. Jammed cuvettes drop out of the cuvette chute, so use Tray No.48 or a similar container to catch them.

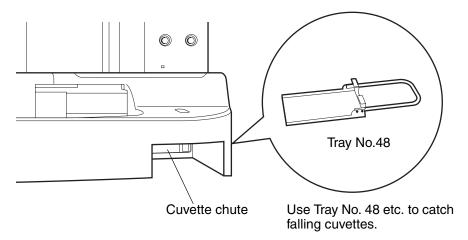


Figure 7-27: Cuvette Chute

4. Push the tip of the accessory cuvette removal rod (trash) into the chute and move it back and forth and around to dislodge jammed cuvettes from the chute. Tray No.48 should also be used at that stage to catch dislodged cuvettes which fall out of the chute.

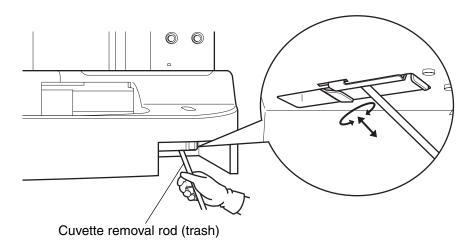


Figure 7-28: Inserting the cuvette removal rod (trash)

5. If the tray is dirty, wipe it with an alcohol-soaked gauze etc.

## 4. Removing cuvette blockages from the cuvette hopper

A void may form within the pile of cuvettes in the cuvette hopper, blocking the supply of cuvettes. If that happens, use the accessory cuvette removal rod (hopper) to stir the cuvettes so that they pack down evenly inside the cuvette hopper.

1. Open the cuvette hopper lid. Loosen the cover fastening screw and open the cuvette hopper cover.



#### Caution!

The status of the instrument must be "Ready" when you perform this operation. Otherwise, measurement results could be affected.

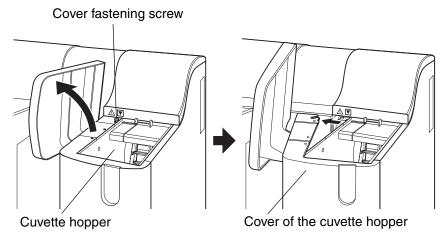


Figure 7-29: Cuvette hopper

 Insert the cuvette removal rod (hopper) at the position marked ▼, while looking inside. When doing so, hold near the curved part of the cuvette removal rod (hopper).

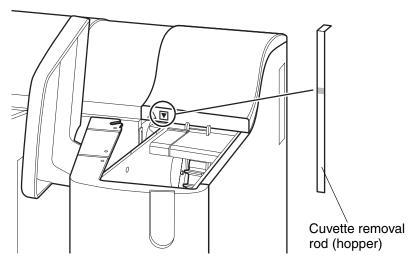


Figure 7-30: Inserting the cuvette removal rod (hopper) 1

3. Insert the rod until it touches the cuvettes, then move it vertically and to all sides while looking into the hopper, to stir to the interior.

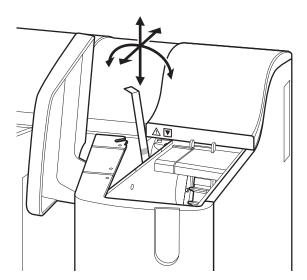


Figure 7-31: Inserting the cuvette removal rod (hopper) 2

4. Take the cuvette removal rod (hopper) out, then close the cuvette hopper cover and screw in the cover fastening screw.

#### 5. Wiping the piercer clean (CS-2100*i*)

If the piercer is soiled, wipe it clean.



#### Risk of infection

Never touch the piercer tip.

The tip of the piercer is very sharp and extremely dangerous. Handle it with care and make sure to use the jig for wiping off when cleaning the piercer. Accidentally touching the piercer tip could cause injury and infection with pathogens.

• Use protective gloves when cleaning piercers. After completion of work, wash hands with disinfectant.

Handle the piercer as biologically hazardous.

There is a risk of infection with pathogens.



#### Caution!

Avoid touching the piercers when your hand could be charged with static electricity. It could cause instrument failure.

- 1. Make sure that the light shield lid is closed.
- 2. Display the Maintenance screen. For details of the Maintenance screen, see "Chapter 7: 7.3 Checking and performing maintenance".
- Press Wipe off Piercer on the operation panel.
   If Wipe off Piercer is not displayed, press More to switch the page.

The Wipe off Piercer dialog box appears.

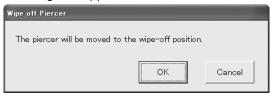


Figure 7-32: Wipe off piercer dialog box

#### 4. Press OK.

The piercer starts moving to the wipe-off position for cleaning. When the movement is complete, the Turn off the power confirmation dialog box appears.



Figure 7-33: Turn off the power confirmation dialog box

- 5. Turn OFF the Main Unit power.
- 6. Open the light shield lid.

#### 7. Set the jig for wiping off.

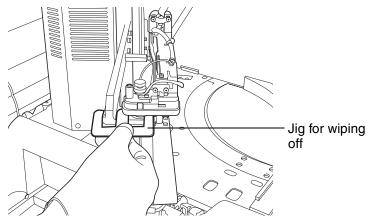


Figure 7-34: Setting the jig for wiping off

8. Wipe the piercer clean.

While holding the sample arm with one hand, wipe the piercer up and down with a gauze soaked with purified water, etc. To prevent the instrument from being contaminated, lay a gauze, etc. on the covers of surrounding parts.

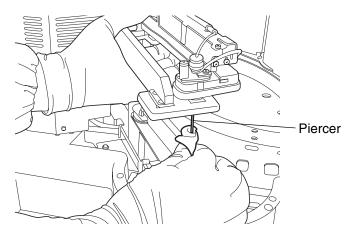


Figure 7-35: Wiping the piercer clean

- 9. When cleaning is complete, remove the gauze, etc. on the covers of surrounding parts and the jig for wiping off.
- 10. Close the light shield lid.
- 11. Turn ON the Main Unit power.
  For details, see "Chapter 5: 5.3 Turning ON the power".

## 7.8 Confirming the cycle counts

The unit and parts cycle counts can be displayed on the Cycle Counter dialog box.

1. Press **More** on the Maintenance screen to switch to the next operation panel page, then press **Cycle Counter**.

The Cycle Counter dialog box is displayed.

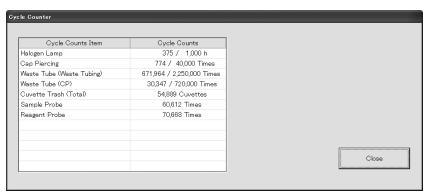


Figure 7-36: Cycle Counter dialog box

The unit and parts cycle counts are displayed as described below. If the cycle counts exceed the supported counts, the background color turns yellow.

**Halogen Lamp** The lamp lighting time is displayed.

Cap PiercingCap piercing cycle counts are displayed.Waste Tube (Waste Tubing)Pinch valve cycle counts are displayed.Waste Tube (CP)Pinch valve cycle counts are displayed.



#### Caution!

- If the cycle counts exceed the supported counts, the unit and parts must be replaced.
- For details on replacing the halogen lamp, refer to "Chapter 7: 7.9: 4. Lamp replacement and calibration".
- For piercer and pinch valve replacement, contact your service representative.

The following cycle counts are displayed as reference information.

**Cuvette Trash (Total)** The total number of waste cuvettes is displayed.

Sample Probe Sample probe dispensing cycle counts are

displayed.

**Reagent Probe**Reagent probe dispensing cycle counts are

displayed.

## 7.9 Replacement of supplies

#### 1. Replenishing reagents

If a reagent runs out during analysis, an error message "Insufficient Reagent (Reagent Name)" will appear.



#### Caution!

- If a reagent runs out for a sample which has already started incubation, analysis error will occur. Reanalyze after replenishing the reagent.
- Do not tilt the reagent table covers when removing them. If there is condensation on a reagent table cover, tilting it can cause the condensation to drip into the reagent, which could influence results.
- Remove reagent table covers A and B before removing reagent table cover C.
   Reagent table covers A and B could be damaged if they are still in place when reagent table cover C is removed.
- 1. On the Reagent screen, select the reagent holder position to replenish from the reagent table status indicator area.
- 2. Press the Change/Add on the Reagent screen.
- Press **OK**.
   After a slight delay, the color of the table cover indicator will change to green.
- 4. Move the lock lever to the open position and open the reagent table cover.

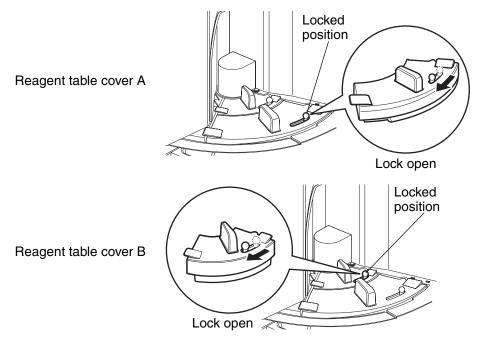


Figure 7-37: Reagent table cover

5. After setting the reagents in the reagent holders, close the reagent table covers and turn the lock levers to their lock positions.



#### Risk of infection

When handling factor-deficient plasma, always wear latex or non-latex gloves. After completion of work, wash hands with disinfectant.

There is a risk of infection with pathogens etc.



#### Caution!

· Setup each reagent correctly.

Failure to do so will cause incorrect analysis results.

If a reagent is accidentally setup incorrectly and analysis is performed, thoroughly clean the probe with detergent. For details on how to clean the probe, see "Chapter 7: 7.4: 1. Cleaning probes".

- Take steps to prevent contaminants and dust from getting inside reagent vials and detergent containers. If contaminated, correct analysis results may not be obtained.
- Use the correct adapter.
  - If the right adapter is not used, the reagent may not be aspirated correctly, which would influence the analysis results.
  - For details on the adapter to use, see "Chapter 5: 5.4: 4. Adapter preparation".
- Please take special care not to tilt the vial when placing it on the buffer table.
- Opening and closing the reagent table covers in an environment with high humidity may cause condensation on the covers.
  - Use a dry cloth to wipe off any condensation which appears on the reagent table covers.
  - If condensation is left on the covers for long periods, it can drip into the reagents, which could influence results.
- Set reagent table cover C, then reagent table covers A and B. Reagent table covers A and B could be damaged if they are still in place when an attempt is made to attach reagent table cover C.

When you close the cover after replenishing reagents, Barcode Read dialog box appears.

6. Press OK.

The reagent barcode is read.

7. Press Start.

Analysis restarts.

## 2. Replenishing cuvettes

If the cuvettes run short during analysis, the message "Cuvette will be used up soon." will be displayed. If you supply the instrument with cuvettes while this message is displayed, analysis will continue without interruption.

If there are no more cuvettes, analysis will be interrupted and the message "The analyses are suspended because cuvettes are used up." will appear. Replenish cuvettes; then press **Start Analysis**. Analysis will continue.

- 1. Open the cuvette hopper lid.
- Replenish cuvettes.The cuvette hopper will hold approximately 500 cuvettes.



#### Caution!

Do not replenish cuvettes above the limitation line. This will cause jamming.

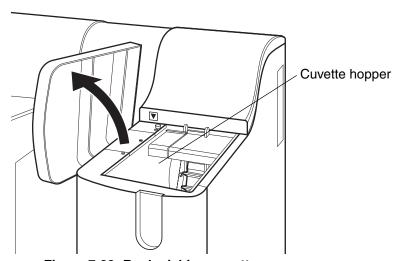


Figure 7-38: Replenishing cuvettes

3. Close the cuvette hopper lid.



#### Caution!

- Use the specified cuvettes only (SUC-400A).
- Cuvettes are intended for single use only.
   If used more than once, rewashed, or recycled, inaccurate measuring results may be obtained due to the effect of possible contamination. Inaccurate results could lead to inappropriate patient diagnosis or treatment.
- There may be a number of cuvettes left in the cuvette hopper.



#### Note:

For cuvette part numbers, see "Chapter 7: 7.10 Supply parts list".

#### 3. Replenishing rinse

If the rinse runs out during analysis, the message "No rinse (Rinse Tank)" will appear and analysis will be interrupted. After finishing the analysis operation, replenish with rinse as described in the procedure below.



#### Caution!

Do not touch the float switch with your hand.

If dust or foreign matter adheres to the float switch, the tank interior will get contaminated. If the interior gets contaminated, correct analysis results may not be obtained.

If your hand or other object touches the float switch, wash off the float switch with rinse (or distilled water) and then attach it to the tank.

1. Turn the cap of the rinse tank with which the tube is connected in a counterclockwise direction and take out the float switch.

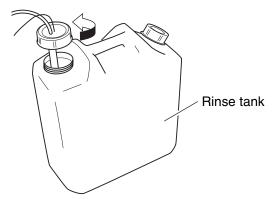


Figure 7-39: Replenishing rinse

- 2. Check by eye for any dirt, impurities, floating material or similar substances inside the tank.
  - If there exists any substance, use tap water to wash the inside of the tank and the float switch, then rinse them with rinse water.
- Replenish rinse (distilled water).Fill the rinse tank with rinse (distilled water).
- 4. Attach the float switch to the rinse tank and tighten the cap clockwise to close. Attach the float switch to the upper horizontal surface of the rinse tank.
- 5. Check for any kink etc. in the tube.
- 6. Press **Start**. Analysis restarts.

#### 4. Lamp replacement and calibration

Keep a spare lamp available at all times, in case the lamp blows suddenly. We recommend replacing the lamp after a guideline period of 1,000 hours in use. Perform lamp calibration after replacing the lamp.

## Replacing the lamp



## Warning!

Before replacing the lamp, turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electrical shock.

After turning the power OFF, wait 30 minutes to allow the lamp to become cool.



#### Caution!

Always perform lamp calibration after replacing the lamp.

If you do not perform lamp calibration correctly, it may not be possible to obtain accurate analysis results.

- 1. Turn OFF the power of the Main Unit and unplug the power cord to the Main unit. Then wait for about 30 minutes until the lamp gets cold.
- 2. Open the lamp cover located on the right side of the Main Unit by pushing the top once, so that it pops up.

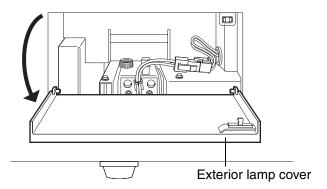


Figure 7-40: Opening the exterior lamp cover



## Note:

For the lamp part number, see "Chapter 7: 7.10 Supply parts list".

3. Press the clamp of the connector and disconnect the connectors.

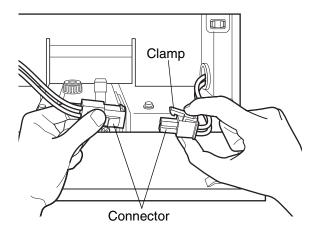


Figure 7-41: Disconnecting lamp connectors

4. Loosen the thumb screw.

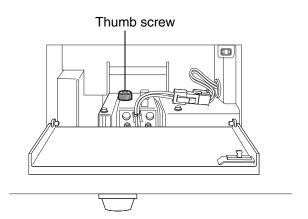


Figure 7-42: Thumb screw

5. Remove the lamp holder from the lamp unit.

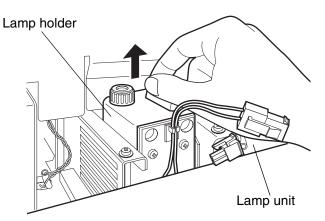


Figure 7-43: Removing the lamp holder

Lift the lamp retainer part of the lamp holder, then remove the lamp from the lamp holder.

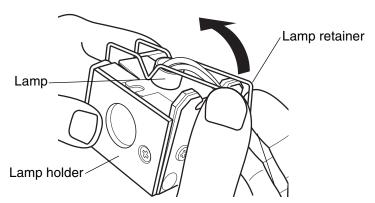


Figure 7-44: Removing the lamp

7. Install a new lamp in the reverse order of removal.



#### Caution!

- Do not touch the lamp surface with your fingers, or lamp performance could be affected.
  - If you transfer oil or protein from your fingers, the lamp may be damaged when the temperature rises.
- Do not jar the lamp when changing it. In particular, momentary shocks, such as when the lamp is dropped, may shorten lamp lifetime, so handle the lamps carefully during replacement.
- If the glass surface is touched during replacement, leaving fingerprints or other
  marks, and the lamp is turned on before the marks have been removed,
  abnormal burning can occur while the lamp is alight, potentially shortening its
  life or cracking it. Any dirt on the glass should be wiped away with alcohol etc.
  before fitting the lamp.
- 8. After installing the lamp and replacing the covers, reconnect the power cord and turn ON the power switch of the Main Unit. Wait for 30 minutes before starting the lamp calibration.

#### Lamp calibration



#### Caution!

- Before starting lamp calibration, wait 30 minutes after the Main Unit is powered ON until the intensity of the lamp has stabilized. If you start lamp calibration while the light intensity is unstable, the analysis results may be incorrect.
- If the message "Calibrate the lamp" appears, calling for lamp calibration, during analysis, suspend dispensing of new samples.
- After performing the lamp calibration, we recommend you to perform QC analysis and check the analysis data, then perform calibration curve analysis as necessary.
- 1. Press **Lamp Calibration** on the Maintenance screen. The confirmation dialog box will appear.



Figure 7-45: Confirmation dialog box

- Press OK.
   Lamp calibration begins and the Executing dialog box appears.
   Press Cancel on the Executing dialog box to cancel lamp calibration action.
- 3. After calibrating the lamp, the confirmation dialog box will appear. Select **Reset lamp counter.**, then press **OK**.

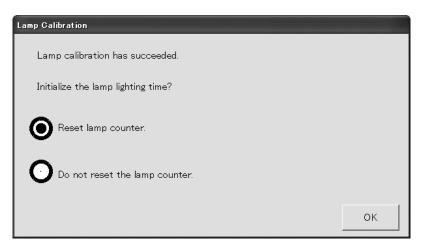


Figure 7-46: Confirmation dialog box

#### 5. Replacing fuses

Over-current protection fuses are used in the Main Unit and Pneumatic Unit. When a fuse is blown, replace it with the following procedure.



## Warning!

To avoid electrical shock, disconnect power supply before servicing.

- 1. Turn OFF the power of the Main Unit and disconnect the power cords for the Main Unit and the pneumatic unit.
- 2. With a screwdriver, remove the fuse cap holder.

## Main Unit (left side), Pneumatic Unit (rear)

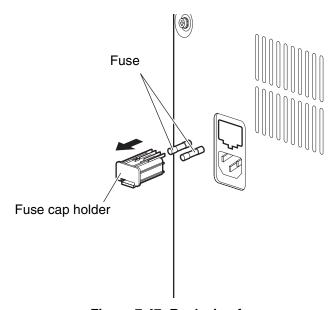


Figure 7-47: Replacing fuses

3. Replace the fuse and attach the fuse holder cap to the instrument.



## Warning!

For continued protection against the risk of fire, replace only with a fuse of the specified type and current ratings.

Table 7-02: Fuse

## **Main Unit**

Specification	Part No.	Description	Fuse Type	Quantity
100 - 240 VAC	266-7768-1	Fuse 250V 10A 50T100H	Time Lag	2

## **Pneumatic Unit**

Specification	Part No.	Description	Fuse Type	Quantity
100 - 117 VAC	266-5011-3	Fuse 250V 4A ST4-4A-N1	Time Lag	2
220 - 240 VAC	266-5293-0	Fuse 250V 3.15A No. 19195	Time Lag	2

# 7.10 Supply parts list

## 1. Consumable supplies

Table 7-03: Consumable supplies

Part No.	Description	Min. lot
064-1481-0	Cuvette SUC-400A	3,000 pcs.
CR323182	Halogen lamp JB12V24WF6/SSM	1 pc.
266-7768-1	Fuse 50T100H (250V 10A)	1 pc.
266-5011-3	Fuse 250V-4A-N1	1 pc.
424-1160-8	Sample cup conical 4 mL	100 pcs.
061-0611-4	Piercer No. 20 package	1 pc.
AS143226	Reagent cap S CSS-400A	200 pcs.
AF504574	Reagent cap L CSL-400A	100 pcs.
CC907148	Cap NO.528 (Kit NO.105)	10 pcs.
BB564291	Cap NO.527 (Kit NO.106)	10 pcs.
064-1041-9	SB Cuvette	144 pcs.
AM197840	Trash Box Liner CS2	20 pcs.
AX008688	SLD mini cup SLD-400A	500 pcs.

# 2. Spares

Table 7-04: Spares

Part No.	Description	Min. lot
367-9228-2	Teflon mixer (micro rotor I 12.7×φ3.0) (for reagent mixing)	1 pc.
424-3334-9	Sampler rack No.3 (WHITE) (sampler rack assembly without tube holder No.58)	1 pc.
424-2400-4	20L Container M20 container	1 pc.
963-2001-9	Float switch assembly No.19 (for waste tank 20L S20)	1 pc.
442-3096-0	S/B Adapter (SC)	5 pc.
CW084217	Holder_ASSY NO.126 (GW5)	1 pc.
442-3098-7	S/B Adapter (GW15)	1 pc.
AC833285	Holder_ASSY NO.19	1 pc.
CX073106	Holder_ASSY NO.21	1 pc.
443-1369-5	Filter NO. 16A	1 pc.
366-1793-6	Tube holder No.113 (WHITE) (11 mm diameter collection tube adapter, for sample rack)	1 pc.
366-1789-1	Tube holder No. 58 (WHITE) (14 mm diameter collection tube adapter, for sample rack)	1 pc.
366-1791-9	Tube holder No. 59 (WHITE) (13 mm diameter collection tube adapter, for sample rack)	10 pc.
BU985293	Barcode label for reagent holder (CA CLEAN II) on CS2	5 pcs.
CU813644	Barcode label for Owren's Veronal Buffer on CS2	5 pcs.
462-3010-1	Cuvette removal rod (hopper)	1 pc.
442-5430-3	Teflon 4.2×3.2 (L=330) (Cuvette removal rod (trash))	1 pc.
CL038559	Reagent rack barcode label A-6 (Label_No. 336)	1 pc.
CM352781	Reagent rack barcode label A-7 (Label_No. 337)	1 pc.
BS611780	Reagent rack barcode label A-8 (Label_No. 338)	1 pc.
CV282522	Reagent rack barcode label A-9 (Label_No. 339)	1 pc.
AC128466	Reagent rack barcode label A-10 (Label_No. 330)	1 pc.
AU178017	Reagent rack barcode label D-6	1 pc.
BA897328	Reagent rack barcode label D-7	1 pc.
AB847846	Reagent rack barcode label D-8	1 pc.
CF457900	Reagent rack barcode label D-9	1 pc.
BR856255	Reagent rack barcode label D-10	1 pc.
AD738522	Reagent rack A seal	1 pc.
CG369313	Reagent rack D seal	1 pc.
CM095265	Filter NO.513	1 pc.
AU666611	Filter NO.514	1 pc.
063-4151-5	SB Set tool	1 pc.
AX801638	Reagent rack C-1 (Container_Assy_No. 34)	1 pc.
BV995710	Reagent rack C-2 (Container_Assy_No. 35)	1 pc.
CF468084	Jig for wiping off (Jig No. 1104)	1 pc.
CT904571	2D barcode reader (1900GSR-1)	1 pc.

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# 8. Troubleshooting

This chapter explains the error messages that are displayed by the CS-2000*i*/CS-2100*i*, as well as failures that can occur and the corrective action if a failure occurs.

#### 8.1 Overview

The major contents of this chapter are:

#### When you suspect an error

This explains the symptoms of breakdown and how to solve them.

## How to display errors

Recent errors can be displayed and checked.

#### How to display the error log

Errors are recorded in the error log. The error contents can be checked by displaying the error log.

#### Troubleshooting by error messages

This section provides a list of the error messages that can appear on the screen when a problem occurs. It also explains the corrective action to take.

#### **System confirmation**

This section explains how to perform test operations to confirm that the system operates correctly.

If the instrument does not return to the normal operating condition even after you have taken the action described in this chapter, contact your local technical representative for assistance of this page.



# Warning!

- When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked.
- If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.
- When closing the light shield lid, take care to avoid pinching your fingers.

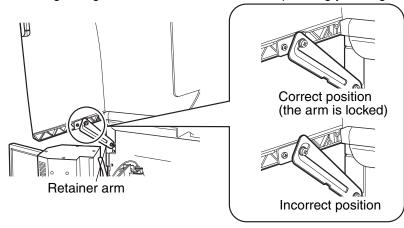


Figure 8-01: How to open the light shield lid



#### Caution!

Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.

- How to close the light shield lid
  - (1) Lift the light shield lid up slightly.
  - (2) Lift the retainer arm in the arrowed direction to unlock it.
  - (3) Close the light shield lid slowly.

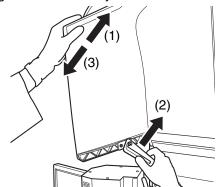


Figure 8-02: How to close the light shield lid

# 8.2 When you suspect an error

1.	Turning the power ON does not start the instrument.	<ul><li> Is the power cord connected properly?</li><li> Is the power supplied to AC outlet?</li></ul>
2.	When the power of the Main Unit is ON, nothing is displayed and a "beep" keeps sounding.	<ul> <li>There is a possibility that memory error has occurred. Turn OFF the power of the Main Unit and turn it ON again 1 - 2 minutes later.</li> </ul>
3.	The screen displays nothing.	Is the screen switched ON?     See "Chapter 3: 3.5 Options".
4.	Fluid leaks from the instrument.	Turn OFF the power and wipe off leaked fluid.     If fluid leakage persists after turning ON the power, contact your local technical representative.



## **Risk of infection**

Be sure to put on latex or non latex examination gloves before starting work. After completion of work, wash your hands with disinfectant. If your hands should be contaminated with blood, there is a hazard of infection by pathogenic bacteria.

5.	An error occurs.	Search the following message lists for the error in question and refer to the corresponding pages in Troubleshooting "Chapter 8: 8.5: 3. Corrective action":  • Message List  The error messages are listed in "Alphabetical" and "Functional" order, to search for the pages corresponding to the displayed message list.  • Troubleshooting  Probable causes and corrective action for each error message are described.			
6.	An abnormality was found in the instrument during analysis.	<ul> <li>Stop the analysis operation by pressing the Mechanical Stop switch.</li> <li>Refer to "Chapter 6: 6.7 Emergency stop".</li> </ul>			
7.	The accessory adapter jammed in the reagent rack.	Is the adapter inserted backwards?  The stopper to prevent vial rotation can catch and prevent removal. Hold the stopper down while removing the adapter.			
	vial rota				
	Figure 8-03: Removing the adapter				

# 8.3 Display of errors

Recent errors can be displayed, and details such as the recovery method can be checked.

1. Press the **Message Area** on the status bar. The Error Help dialog box will appear.

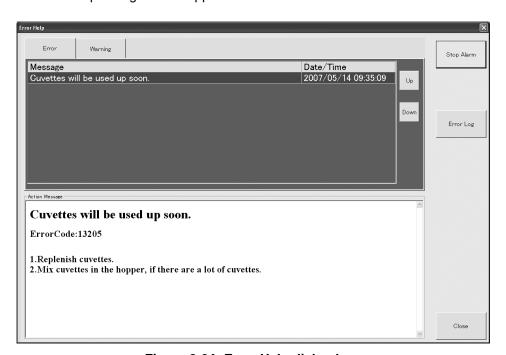


Figure 8-04: Error Help dialog box

Error tabs	
Message	The message for the error that occurred will appear.
Date/Time	This displays the date and time when the error occurred. The format of display is determined by the system setting.
Action Message	This displays details (recovery method) for the error selected in the list.
Warning tab	
Message	The message for the warning generated will appear.
Date/Time	This displays the date and time when the warning was generated. The format of display is determined by the system setting.
Action Message	This displays details (recovery method) for the warning selected in the list.
Up	Moves the list selection cursor up one line.
Down	Moves the list selection cursor down one line.
	Moved the net delection during down one into.

The ErrorLog screen will appear. For details see

"Chapter 8: 8.4 How to display the error log".

**Error Log** 

- 2. Press Stop Alarm if an alarm sounds.
- 3. Next, perform error recovery with reference to the Action Message and troubleshooting information.
- Press Close.
   Closes the Error Help dialog box.



#### Note:

The alarm can be stopped by clicking on the Error Help dialog box.

# 8.4 How to display the error log

The message for the error that occurred is stored in the error log. By displaying the error log, you can check past error history, including resolved errors.

## 1. Error log display

1. Press **Error Log** in the Error Help dialog box. The ErrorLog screen will appear.

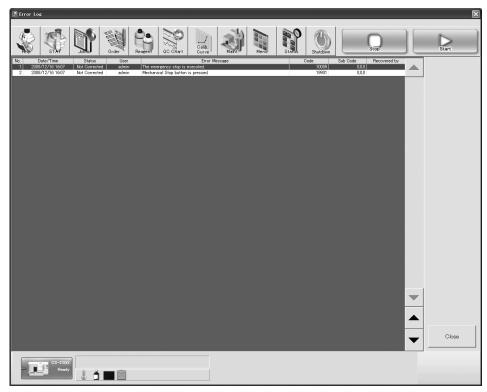


Figure 8-05: ErrorLog screen

**Date/Time** This displays the date and time when the error occurred.

The format of display is determined by the system setting.

**User** This displays the name of the user logged on when the

error occurred.

Error Message The error message is displayed.
 Code The error code is displayed.
 ▲ Displays the next list page up.
 ▼ Displays the next list page down.

2. Press Close.

The ErrorLog screen will close.

# 8.5 Troubleshooting by error messages

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### 3. Corrective action

#### 1. Pressure and vacuum errors

Error message	Pressure Error (0.22MPa) (Start) Pressure Error (0.1MPa) (Start) Vacuum Error (-0.067MPa) (Start)
Probable cause	<ol> <li>The pressure adjustment is incorrect.</li> <li>The pneumatic or hydraulic system has failed.</li> <li>The pneumatic unit power supply is suspended.</li> <li>The tube is kinked or blocked.</li> </ol>
Solution	<ol> <li>Check the Pneumatic Unit power cord connection and the tube connection and nipple looseness.</li> <li>If they are securely connected, adjust the pressure in the "Maintenance" screen.</li> </ol>

Error message	Pressure Error (0.22MPa) (Rinse) Pressure Error (0.1MPa) (Rinse)
Probable cause	<ol> <li>The pressure adjustment is incorrect.</li> <li>The pneumatic or hydraulic system has failed.</li> <li>The pneumatic unit power supply is suspended.</li> <li>The tube is kinked or blocked.</li> </ol>
Solution	Contact your service representative.

Error message	Vacuum Error (-0.067MPa) (Rinse)
Probable cause	<ol> <li>The pressure adjustment is incorrect.</li> <li>The pneumatic or hydraulic system has failed.</li> <li>The pneumatic unit power supply is suspended.</li> <li>The tube is kinked or blocked.</li> </ol>
Solution	<ol> <li>Operate the "Prime" in the "Maintenance" screen.</li> <li>If error persists, contact your service representative.</li> </ol>

# 2. Temperature errors

Error message	Temperature Error (Ambient temperature) (Low) Temperature Error (Detector Block) (High) Temperature Error (Reagent Probe) (High) Temperature Error (Reagent Probe) (Low) Temperature Error (Cooling Unit) (Low) Temperature Error (Incubation Block)(High)
Probable cause	<ol> <li>The ambient temperature is unsuitable. (The temperature range: 15 to 30 degrees centigrade.)</li> <li>The thermistor has failed.</li> <li>The temperature control unit has failed.</li> </ol>
Solution	<ol> <li>Set the ambient temperature between 15 and 30 degrees C.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Temperature Error (Ambient temperature) (High)
Probable cause	<ol> <li>The ambient temperature is unsuitable. (The temperature range: 15 to 30 degrees centigrade.)</li> <li>The thermistor has failed.</li> <li>The temperature control unit has failed.</li> <li>There is an object on the left of the instrument.</li> </ol>
Solution	<ol> <li>Set the ambient temperature between 15 and 30 degrees C.</li> <li>Remove the object if it exists within the range of 30cm from the left of the instrument.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Temperature Error (Detector Block) (Low) Temperature Error (Incubation Block)(Low)
Probable cause	<ol> <li>The ambient temperature is unsuitable. (The temperature range: 15 to 30 degrees centigrade.)</li> <li>The thermistor has failed.</li> <li>The temperature control unit has failed.</li> </ol>
Solution	<ol> <li>Wait until the temperature in the detector becomes 37 degrees C.</li> <li>Set the ambient temperature between 15 and 30 degrees C.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Temperature Error (Cooling Unit) (High)
Probable cause	<ol> <li>The ambient temperature is unsuitable. (The temperature range: 15 to 30 degrees centigrade.)</li> <li>The thermistor has failed.</li> <li>The temperature control unit has failed.</li> </ol>
Solution	<ol> <li>Wait until the temperature in the cooling unit becomes below 15 degrees C.</li> <li>Set the ambient temperature between 15 and 30 degrees C.</li> <li>If the temperature in the cooling unit is 36 degrees C or higher, the cooling function does not work.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Thermistor Error (Ambient temperature)
Probable cause	<ol> <li>The thermistor has failed.</li> <li>The temperature control unit has failed.</li> </ol>
Solution	Contact your service representative.

Error message	Temperature error of the cooling unit occurred during sleep mode
Probable cause	<ol> <li>The ambient temperature is unsuitable. (The temperature range: 15 to 30 degrees centigrade.)</li> <li>The thermistor has failed.</li> <li>The temperature control unit has failed.</li> </ol>
Solution	The issue of the reagent quality might occur during cooling. Contact your service representative.

Error message	Temperature control unit Error
Probable cause	The temperature control unit has failed.
Solution	Contact your service representative.

Error message	Temperature control unit error occurred during sleep mode
Probable cause	The temperature control unit has failed.
Solution	The issue of the reagent quality might occur during cooling. Contact your service representative.

### 3. Chamber errors

Error message	Check Waste Tubing
Probable cause	<ol> <li>The waste tube is kinked or blocked.</li> <li>The float switch in the internal waste chamber has failed.</li> </ol>
Solution	<ol> <li>Check the waste tube connection securely.</li> <li>Check the waste tube for kink and block.</li> <li>Check the trap chamber and discard any fluid that has collected.</li> </ol>

Error message	No rinse of the rinse chamber
Probable cause	1) The rinse fluid tube is withdrawn or blocked. 2) The hydraulic system has failed. 3) The float switch in the rinse chamber has failed.
Solution	<ol> <li>Check the connection of external-rinse-tank tube securely.</li> <li>Check the external-rinse-tank tube for kink and block.</li> </ol>

Error message	Discard waste. (Waste Tank)
Probable cause	<ol> <li>The external waste tank has filled with waste.</li> <li>The float switch connector for the external waste tank is disconnected.</li> <li>The float switch in the external waste tank has failed.</li> </ol>
Solution	<ol> <li>Discard the waste fluid.</li> <li>Check the float switch connector connection in the external waste tank securely.</li> </ol>

Error message	The analyses are suspended because the waste tank is full with waste.
Probable cause	<ol> <li>The external waste tank has filled with waste.</li> <li>The float switch connector for the external waste tank is disconnected.</li> <li>The float switch in the external waste tank has failed.</li> </ol>
Solution	<ol> <li>Discard the waste fluid, after the analyses are completed.</li> <li>Check the float switch connector connection in the external waste tank securely.</li> </ol>

Error message	Insufficient rinse (Rinse Tank) No rinse (Rinse Tank)
Probable cause	<ol> <li>The rinse fluid is running low in the external rinse tank.</li> <li>The float switch is disconnected in the external rinse tank.</li> <li>The float switch in the external rinse tank has failed.</li> </ol>
Solution	Replenish the rinse.     Check the float switch connector connection in the external rinse tank securely.

Error message	Rinse will be short. (Rinse Tank) The analyses are suspended because rinse is used up. (Rinse Tank)
Probable cause	<ol> <li>The rinse fluid is running low in the external rinse tank.</li> <li>The float switch is disconnected in the external rinse tank.</li> <li>The float switch in the external rinse tank has failed.</li> </ol>
Solution	<ol> <li>Replenish the rinse, after analyses are completed.</li> <li>Check the accurate float switch connector connection in the external rinse tank.</li> </ol>

Error message	Waste tube error occurred during sleep mode.
Probable cause	<ol> <li>The waste tube is kinked or blocked.</li> <li>The float switch in the internal waste chamber has failed.</li> <li>The pressure adjustment is incorrect.</li> <li>The pneumatic or hydraulic system has failed.</li> <li>The pneumatic unit power supply is suspended.</li> <li>The tube is kinked or blocked.</li> </ol>
Solution	<ol> <li>Check the waste tube connection securely.</li> <li>Check the waste tube for kink and block.</li> <li>Check the trap chamber and discard any fluid that has collected.</li> </ol>

# 4. Hydraulic line errors

Error message	Error in the hydraulic line for internal rinse in the sample probe Error in the hydraulic line for external rinse in the sample probe Error in the hydraulic line for rinse cup ejection in the sample probe Error in the hydraulic line for internal rinse in the reagent probe Error in the hydraulic line for external rinse in the reagent probe Error in the hydraulic line for rinse cup ejection in the reagent probe Error in the hydraulic line for rinse cup bottom ejection in the reagent probe Error in the hydraulic line for CP rinse cup ejection
Probable cause	1) The tube is kinked or blocked.
Solution	<ol> <li>Operate the "Prime" in the "Maintenance" screen.</li> <li>If error persists, contact your service representative.</li> </ol>

### 5. Mechanical errors

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Error message	Mechanical Error (Piercer Unit) (Initialization)
	Mechanical Error (Piercer Unit) (Operation Pulse)
	Mechanical Error (Cap-Holding Unit)
	Mechanical Error (Supply Catcher Z) (Initialization)
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	Mechanical Error (Sample Arm Z) (Operation Pulse)
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	Mechanical Error (Sample Arm Rotation) (Operation Pulse)
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	Mechanical Error (Sample Syringe) (Operation Pulse)
	Mechanical Error (Sample Table) (Initialization)
	Mechanical Error (Sample Table) (Operation Pulse)
	Mechanical Error (Reagent Arm Z) (Initialization)
	Mechanical Error (Reagent Arm Z) (Operation Pulse)
	Mechanical Error (Reagent Arm Rotation) (Initialization)
	Mechanical Error (Reagent Arm Rotation) (Operation Pulse)
	Mechanical Error (Reagent Syringe) (Initialization)
	Mechanical Error (Reagent Syringe) (Operation Pulse)
	Mechanical Error (Reagent Table A) (Initialization)
	Mechanical Error (Reagent Table A) (Operation Pulse)
	Mechanical Error (Reagent Table B) (Initialization)
	Mechanical Error (Reagent Table B) (Operation Pulse)
Probable cause	1) The origin sensor or the mechanism has failed.
	2) Something is obstructing movement of the unit.
Solution	1) Remove obstructing object or matter, if present.
	2) If error persists, contact your service representative.
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Error message	Mechanical Error (Lamp Filter)
Probable cause	<ol> <li>The origin sensor or the mechanism has failed.</li> <li>Something is obstructing movement of the unit.</li> </ol>
Solution	Restart the main unit.     If error persists, contact your service representative.

Error message	Mechanical Error (Detector Unit Catcher Mixing Motor)
Probable cause	The wire of the mixing motor is broken or deteriorated.
Solution	Contact your service representative.

Error message	Mechanical Error (Detector Block Mixing Motor) (Channel No.) Mechanical Error (Reagent Mixing Motor) (Reagent Table A) Mechanical Error (Reagent Mixing Motor) (Reagent Table B)
Probable cause	The mixing motor has failed.
Solution	Contact your service representative.

Error message	Mechanical Error occurred during sleep mode. (Sample Arm Z) (Initialization) Mechanical Error occurred during sleep mode. (Reagent Arm Z) (Initialization) Mechanical Error occurred during sleep mode. (Reagent Table A) (Initialization) Mechanical Error occurred during sleep mode. (Reagent Table B) (Initialization)
Probable cause	The origin sensor or the mechanism has failed.     Something is obstructing movement of the unit.
Solution	<ol> <li>The issue of the reagent quality might occur during cooling.</li> <li>Remove obstructing object or matter, if present.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Mechanical Error occurred during sleep mode. (Reagent Table A) (Operation Pulse) Mechanical Error occurred during sleep mode. (Reagent Table B) (Operation Pulse)
Probable cause	<ol> <li>The mechanism has failed.</li> <li>Something is obstructing movement of the unit.</li> </ol>
Solution	<ol> <li>The issue of the reagent quality might occur during cooling.</li> <li>Remove obstructing object or matter, if present.</li> <li>If error persists, contact your service representative.</li> </ol>

# 6. Dispensing and spares errors

Error message	Probe Crash (Sample Arm) (CP Rinse Cup) Probe Crash (Sample Arm) (Sample Table) Probe Crash (Sample Arm) (Rinse Cup)
Probable cause	<ol> <li>Something is obstructing to move down.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The probe crash sensor has failed.</li> </ol>
Solution	Contact your service representative.

Error message	Probe Crash (Reagent Arm) (Eject Position)
Probable cause	<ol> <li>Something is obstructing to move down.</li> <li>The failure or incorrect positioning of the reagent dispensing mechanism.</li> <li>The probe crash sensor has failed.</li> <li>The failure or incorrect positioning of the detector catcher.</li> </ol>
Solution	Contact your service representative.

Error message	Probe Crash (Reagent Arm) (Rinse Cup)
Probable cause	<ol> <li>Something is obstructing to move down.</li> <li>The failure or incorrect positioning of the reagent dispensing mechanism.</li> <li>The probe crash sensor has failed.</li> </ol>
Solution	Contact your service representative.

Error message	The liquid level of vial is too high. (sample arm) (Reagent)
Probable cause	<ol> <li>Dew condensation water adheres to the reagent cap.</li> <li>Reagent adheres to the reagent cap.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>Incorrect positioning of the sample probe and reagent table</li> <li>Too much reagent in the vial</li> </ol>
Solution	<ol> <li>When the reagent cap gets wet, use the new cap.</li> <li>Reduce the reagent when too much reagent is in the vial.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	The liquid level of vial is too high. (sample arm) (Detergent)
Probable cause	1) Dew condensation water adheres to the reagent cap. 2) Detergent adheres to the reagent cap. 3) The reagent vial type differs from the reagent information settings. 4) The adapter for the reagent vial is improper. 5) Incorrect positioning of the sample probe and reagent table 6) Too much detergent in the vial
Solution	<ol> <li>When the reagent cap gets wet, use the new cap.</li> <li>Reduce the detergent when too much detergent is in the vial.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	The liquid level of vial is too high. (reagent arm) (Reagent)
Probable cause	<ol> <li>Dew condensation water adheres to the reagent cap.</li> <li>Reagent adheres to the reagent cap.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>Incorrect positioning of the reagent probe and reagent table</li> <li>Too much reagent in the vial</li> </ol>
Solution	<ol> <li>When the reagent cap gets wet, use the new cap.</li> <li>Reduce the reagent when too much reagent is in the vial.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	The liquid level of vial is too high. (reagent arm) (Detergent)
Probable cause	<ol> <li>Dew condensation water adheres to the reagent cap.</li> <li>Detergent adheres to the reagent cap.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>Incorrect positioning of the reagent probe and reagent table</li> <li>Too much detergent in the vial</li> </ol>
Solution	<ol> <li>When the reagent cap gets wet, use the new cap.</li> <li>Reduce the detergent when too much detergent is in the vial.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Cuvette Jammed (Conveyor)
Probable cause	<ol> <li>The cuvette is jammed in conveyer.</li> <li>The conveyor sensor has failed.</li> <li>The conveyor mechanism has failed.</li> </ol>
Solution	<ol> <li>Remove any cuvettes that have jammed inside the cuvette hopper.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Cuvette Jammed (Small Hopper)
Probable cause	<ol> <li>The cuvette is jammed in the small hopper.</li> <li>The operation of the guide is defective.</li> <li>The small hopper sensor has failed. (The sensor status is always ON.)</li> <li>The rail sensor has failed. (The sensor status is always OFF.)</li> </ol>
Solution	<ol> <li>Remove the jammed cuvettes by using Cuvette removal rod (hopper).</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Cuvette Jammed (Rail Rotor)
Probable cause	<ol> <li>The cuvette is jammed on the rail.</li> <li>The cuvette is jammed in the rotary feeder.</li> <li>The motor for the rotary feeder is defective</li> <li>The rail sensor has failed. (The sensor status is always ON.)</li> <li>The rotary feeder sensor has failed. (The sensor status is always OFF.)</li> </ol>
Solution	Contact your service representative.

Error message	Rotary Feeder Unit Sensor Error
Probable cause	The rotary feeder sensor has failed. (The sensor status is always ON.)     The cuvette catcher error of the supply catcher occurs in the supply catcher.
Solution	Contact your service representative.

Error message	Cuvette Detection Sensor Error
Probable cause	The cuvette detection sensor has failed.
Solution	Contact your service representative.

Error message	Cuvette Trash Hole Mechanical Error
Probable cause	<ol> <li>The cuvette removal mechanism has failed.</li> <li>The hole into the trash box is jammed.</li> </ol>
Solution	<ol> <li>Remove the jammed cuvettes by using Cuvette removal rod (trash).</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Insufficient Sample (Liquid Surface Not Detected) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The sample volume is insufficient.</li> <li>The sample is not set.</li> <li>The liquid surface sensor has failed.</li> <li>The error in sample aspiration occurs due to bubbles or clotting.</li> </ol>
Solution	<ol> <li>Set the sample with required volume and analyze again.</li> <li>Check the sample.</li> </ol>

Error message	Insufficient Sample (Reverse Liquid Surface Not Detected) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The sample volume is insufficient.</li> <li>The sample tube type differ from the sample tube type settings.</li> <li>The liquid surface sensor has failed.</li> <li>The error in sample aspiration occurs due to bubbles.</li> </ol>
Solution	<ol> <li>Set the sample with required volume and analyze again.</li> <li>Check the sample.</li> <li>Check the vial setting.</li> </ol>

Error message	Insufficient Sample (Probe Crash) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The sample volume is insufficient.</li> <li>The sample tube is with cap closed. (Except CS-2100i Normal Mode)</li> <li>The sample tube type differ from the sample tube type settings.</li> <li>The adapter for the sample tube is improper.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The probe crash sensor has failed.</li> </ol>
Solution	<ol> <li>Set the sample with required volume and analyze again.</li> <li>Take the cap off. (Except CS-2100i Normal mode)</li> <li>Check the vial setting.</li> <li>Check if the correct adapter which is suitable for the sample tube.</li> </ol>

Error message	Abnormal Sample Volume (Sample Table Primary Dispensing) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The error in primary dispensing and aspiration occurs due to bubbles or clotting.</li> <li>The liquid surface sensor has failed.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The failure or incorrect positioning of the sample aspiration table.</li> </ol>
Solution	Check the sample.

Error message	The liquid level of sample tube is too high. (sample arm) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>Too much sample in the sample tube</li> <li>The sample tube type differs from the sample tube type settings.</li> <li>The liquid surface sensor has failed.</li> </ol>
Solution	<ol> <li>Please decrease the amount of the sample in the sample tube when too much sample is in the sample tube. In CS-2100i, wipe off the piercer by pressing the Wipe Piercer Button.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Abnormal Aspiration Sample Volume (Sample Table Secondary Dispensing) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The liquid surface sensor has failed.</li> <li>The error in sample aspiration occurs due to bubbles.</li> </ol>
Solution	Check the sample.     Slippage has formed in position of sample pipette. Contact your local service representative.

Error message	Sample Volume is short (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The sample volume is insufficient.</li> <li>The sample is not set.</li> <li>The liquid surface sensor has failed.</li> </ol>
Solution	<ol> <li>Set the sample with required volume and analyze again.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Insufficient Reagent (Sample Arm Liquid Surface Not Detected) (Reagent) Insufficient Reagent (Sample Arm Reverse Liquid Surface Not Detected) (Reagent)
Probable cause	<ol> <li>The reagent volume is insufficient.</li> <li>The sample tube type and reagent vial type differ from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The liquid surface sensor has failed.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The failure or incorrect positioning of the buffer table and the reagent table.</li> <li>The error in reagent aspiration occurs due to bubbles or clotting.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the reagent.</li> <li>Check the vial setting.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the sample probe may be incorrect. Check the reagent left in the container, the remaining volumes of control, calibrator, factor-deficient plasma and detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Reagent (Sample Arm Probe Crash) (Reagent)
Probable cause	<ol> <li>The reagent volume is insufficient.</li> <li>The vial is with cap closed.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The probe crash sensor has failed.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The failure or incorrect positioning of the buffer table and the reagent table.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Uncap the vial.</li> <li>Check the vial setting.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the sample probe may be incorrect. Check the reagent left in the container, the remaining volumes of control, calibrator, factor-deficient plasma and detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Detergent (Sample Arm Liquid Surface Not Detected) (Detergent) Insufficient Detergent (Sample Arm Reverse Liquid Surface Not Detected) (Detergent)
Probable cause	<ol> <li>The rinse volume is insufficient.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The liquid surface sensor has failed.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The failure or incorrect positioning of the reagent table.</li> <li>The error in detergent aspiration occurs due to bubbles.</li> </ol>
Solution	<ol> <li>Replenish the detergent.</li> <li>Check the detergent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the detergent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the sample probe may be incorrect. Check the reagent left in the container, the remaining volumes of control, calibrator, factor-deficient plasma and detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Detergent (Sample Arm Probe Crash) (Detergent)
Probable cause	<ol> <li>The rinse volume is insufficient.</li> <li>The vial is with cap closed.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The probe crash sensor has failed.</li> <li>The failure or incorrect positioning of the sample dispensing mechanism.</li> <li>The failure or incorrect positioning of the reagent table.</li> </ol>
Solution	<ol> <li>Replenish the detergent.</li> <li>Uncap the vial.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the detergent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the sample probe may be incorrect. Check the reagent left in the container, the remaining volumes of control, calibrator, factor-deficient plasma and detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Reagent (Reagent Arm Liquid Surface Not Detected) (Reagent) Insufficient Reagent (Reagent Arm Reverse Liquid Surface Not Detected) (Reagent)
Probable cause	<ol> <li>The reagent volume is insufficient.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The liquid surface sensor has failed.</li> <li>The failure or incorrect positioning of the reagent dispensing mechanism.</li> <li>The failure or incorrect positioning of the reagent table.</li> <li>The error in reagent aspiration occurs due to bubbles.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the reagent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the reagent probe may be incorrect. Check the reagent left in the container, the remaining volumes of detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Reagent (Reagent Arm Probe Crash) (Reagent)
Probable cause	<ol> <li>The reagent volume is insufficient.</li> <li>There is a cap with the vial.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The probe crash sensor has failed.</li> <li>The failure or incorrect positioning of the reagent dispensing mechanism.</li> <li>The failure or incorrect positioning of the reagent table.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Uncap the vial.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the reagent probe may be incorrect. Check the reagent left in the container, the remaining volumes of detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Detergent (Reagent Arm Liquid Surface Not Detected) (Detergent) Insufficient Detergent (Reagent Arm Reverse Liquid Surface Not Detected) (Detergent)
Probable cause	<ol> <li>The rinse volume is insufficient.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The liquid surface sensor has failed.</li> <li>The failure or incorrect positioning of the reagent dispensing mechanism.</li> <li>The failure or incorrect positioning of the reagent table.</li> <li>The error in detergent aspiration occurs due to bubbles.</li> </ol>
Solution	<ol> <li>Replenish the detergent.</li> <li>Check the detergent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the detergent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the reagent probe may be incorrect. Check the reagent left in the container, the remaining volumes of detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Insufficient Detergent (Reagent Arm Probe Crash) (Detergent)
Probable cause	<ol> <li>The rinse volume is insufficient.</li> <li>The vial is with cap closed.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> <li>The probe crash sensor has failed.</li> <li>The failure or incorrect positioning of the reagent dispensing mechanism.</li> <li>The failure or incorrect positioning of the reagent table.</li> </ol>
Solution	<ol> <li>Replenish the detergent.</li> <li>Uncap the vial.</li> <li>Check the vial settings.</li> <li>Check if the correct adapter which is suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the detergent replenishment.</li> <li>If the error still occurs despite correct container settings and use of the correct reagent vial adapter, the position of the reagent probe may be incorrect. Check the reagent left in the container, the remaining volumes of detergent, and the analysis results for several tests preceding the start of the error. If you find anything abnormal, contact your service representative.</li> </ol>

Error message	Reagent volume will be short (Reagent)
Probable cause	<ol> <li>The reagent volume is below the number of the reagent warning.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Ready the reagent replenishment.</li> <li>Check the vial settings.</li> <li>Check if the correct adapter which is suitable for the reagent vial.</li> </ol>

Error message	Reagent volume will be short (Buffer)
Probable cause	<ol> <li>The reagent volume is below the number of the reagent warning.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Ready the reagent replenishment.</li> <li>Check the vial settings.</li> <li>Check if the correct adapter which is suitable for the reagent vial.</li> </ol>

Error message	The analyses are skipped because the reagent is used up (Reagent)
Probable cause	<ol> <li>The reagent volume is below the number of the reagent suspend.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

Error message	The analyses are skipped because the reagent is used up (Buffer)
Probable cause	<ol> <li>The buffer volume is below the number of the reagent suspend.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

Error message	The analyses are suspended because the reagent is used up. (Reagent)
Probable cause	<ol> <li>The reagent volume is below the number of the reagent suspend.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

Error message	The analyses are suspended because the reagent is used up. (Buffer)
Probable cause	<ol> <li>The reagent volume is below the number of the reagent suspend.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

Error message	Detergent volume will be short
Probable cause	<ol> <li>The rinse volume is below the number of the reagent warning.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Ready the detergent replenishment.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> </ol>

Error message	The analyses are suspended because the detergent is used up.
Probable cause	<ol> <li>The rinse volume is below the number of the reagent suspend.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the detergent</li> <li>Check the vial settings</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

Error message	The analyses are skipped because the required reagent is not set. (Assay Group)
Probable cause	<ol> <li>The required volume of the reagent, rinse and buffer is short.</li> <li>The required reagent is not set on the reagent table.</li> <li>The required detergent is not set on the reagent table.</li> <li>The required buffer is not set on the STAT/buffer table.</li> <li>The reagent vial types of the required reagent, detergent, or buffer differ from the reagent information settings.</li> <li>The barcode of the required reagent, detergent or buffer cannot be read.</li> <li>The registration of the required reagent, detergent or buffer is not accurate in the "Reagent Master" and "Reagent Lot Master".</li> <li>Some required reagent do not have the check for "Used In Sample Analysis" in the "Lot Group Settings".</li> </ol>
Solution	<ol> <li>Replenish the required reagent, detergent and buffer.</li> <li>Check the required reagent on the reagent table.</li> <li>Check the required detergent on the reagent table.</li> <li>Check the required buffer on the STAT/buffer table.</li> <li>Check the registration of the required reagent, detergent and buffer in the "Reagent" screen.</li> <li>Check the barcode aspect of the required reagent, detergent and buffer.</li> <li>Check the registration of the reagent, detergent and buffer in the "Reagent Master" and "Reagent Lot Master".</li> <li>Check if "Used In Sample Analysis" in the "Reagent" screen.</li> </ol>

Error message	The analyses are suspended because the required reagent is not set. (Assay Group)
Probable cause	<ol> <li>The required volume of the reagent, rinse and buffer is short.</li> <li>The required reagent is not set on the reagent table.</li> <li>The required detergent is not set on the reagent table.</li> <li>The required buffer is not set on the STAT/buffer table.</li> <li>The reagent vial types of the required reagent, detergent, or buffer differ from the reagent information settings.</li> <li>The barcode of the required reagent, detergent or buffer cannot be read.</li> <li>The registration of the required reagent, detergent or buffer is not accurate in the "Reagent Master" and "Reagent Lot Master"</li> <li>Some required reagent do not have the check for "Used In Sample Analysis" in the "Lot Group Settings".</li> </ol>
Solution	<ol> <li>Replenish the required reagent, detergent and buffer.</li> <li>Check the required reagent on the reagent table.</li> <li>Check the required detergent on the reagent table.</li> <li>Check the required buffer on the STAT/buffer table.</li> <li>Check the registration of the required reagent, detergent and buffer in the "Reagent" screen.</li> <li>Check the barcode aspect of the required reagent, detergent and buffer.</li> <li>Check the registration of the reagent, detergent and buffer in the "Reagent Master" and "Reagent Lot Master".</li> <li>Check if "Used In Sample Analysis" in the "Reagent" screen.</li> </ol>

Error message	Cuvettes will be used up soon.
Probable cause	<ol> <li>The cuvette is short.</li> <li>The detection of remaining quantity of cuvettes is failure.</li> </ol>
Solution	<ol> <li>Replenish cuvettes.</li> <li>Mix cuvettes in the hopper, if there are a lot of cuvettes.</li> </ol>

Error message	The analyses are suspended because cuvettes are used up.
	<ol> <li>The cuvette runs out.</li> <li>The rotary feeder sensor has failed.</li> <li>The rail sensor has failed.</li> </ol>
Solution	Replenish cuvettes and analyze again.

Error message	The required reagent volume cannot be assigned. (Assay Group)
Probable cause	<ol> <li>The required volume of the reagent, rinse and buffer is short.</li> <li>The required reagent is not set on the reagent table.</li> <li>The required detergent is not set on the reagent table.</li> <li>The required buffer is not set on the STAT/buffer table.</li> <li>The reagent vial types of the required reagent, detergent, or buffer differ from the reagent information settings.</li> <li>The barcode of the required reagent, detergent or buffer cannot be read.</li> <li>The registration of the required reagent, detergent or buffer is not accurate in the "Reagent Master" and "Reagent Lot Master".</li> <li>Some required reagent do not have the check for "Used In Sample Analysis" in the "Lot Group Settings".</li> </ol>
Solution	<ol> <li>Replenish the required reagent, detergent and buffer.</li> <li>Check the required reagent on the reagent table.</li> <li>Check the required detergent on the reagent table.</li> <li>Check the required buffer on the STAT/buffer table.</li> <li>Check the registration of the required reagent, detergent and buffer in the "Reagent" screen.</li> <li>Check the barcode aspect of the required reagent, detergent and buffer.</li> <li>Check the registration of the reagent, detergent and buffer in the "Reagent Master" and "Reagent Lot Master".</li> <li>Check if "Used In Sample Analysis" in the "Reagent" screen.</li> </ol>

Error message	The required reagent volume cannot be assigned. (Reagent)
Probable cause	<ol> <li>The reagent volume is below the number of the reagent suspend.</li> <li>The reagent volume is below the required quantity for the test.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the reagent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

Error message	The required reagent volume cannot be assigned. (Buffer)
Probable cause	<ol> <li>The buffer volume is below the number of the reagent suspend.</li> <li>The reagent volume is below the required quantity for the test.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	Replenish the reagent.     Check the vial settings.     Check the adapter suitable for the reagent vial.     Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.

Error message	The required detergent volume cannot be assigned. (Detergent)
Probable cause	<ol> <li>The rinse volume is below the number of the reagent suspend.</li> <li>The reagent volume is below the required quantity for the test.</li> <li>The reagent vial type differs from the reagent information settings.</li> <li>The adapter for the reagent vial is improper.</li> </ol>
Solution	<ol> <li>Replenish the detergent.</li> <li>Check the vial settings.</li> <li>Check the adapter suitable for the reagent vial.</li> <li>Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.</li> </ol>

### 7. Sampler and barcode reader errors

Error message	Mechanical Error (Sampler) (Feed-In) Mechanical Error (Sampler) (Shift)
Probable cause	<ol> <li>The origin sensor or the mechanism has failed.</li> <li>Something is obstructing movement of the unit.</li> </ol>
Solution	Remove the obstructing object, if present.     Reset the rack.

Error message	Mechanical Error (Sampler) (Feed-Out)
Probable cause	<ol> <li>The origin sensor or the mechanism has failed.</li> <li>Something is obstructing movement of the unit.</li> </ol>
Solution	Remove obstructing object, if present.

Error message	Reset Sample Rack (Rack position error) Reset Sample Rack (Cap Sensor)
Probable cause	<ol> <li>The rack is left on the measurement line when the analysis begins.</li> <li>The cap sensor has failed.</li> </ol>
Solution	<ol> <li>Remove the rack on the measurement line and reset the rack.</li> <li>If error persists, contact your service representative.</li> </ol>

Error message	Reset Sample Rack (Feed-In motion error)
Probable cause	<ol> <li>The rack is not correctly set.</li> <li>The rack remains on the analysis line.</li> <li>Something is obstructing the rack feed-in operation.</li> <li>The rack feed-in mechanism is defective.</li> </ol>
Solution	<ol> <li>Remove the obstructing object, if present.</li> <li>Reset the rack.</li> </ol>

Error message	Reset Sample Rack (Shift motion error)
	<ol> <li>The rack remains on the measurement line in the left rack pool.</li> <li>Something is obstructing the rack shift operation.</li> <li>The rack shift mechanism is defective.</li> </ol>
Solution	Remove the rack on the measurement line and reset the rack.

Error message	Reset Sample Rack (Unexpected Shift)
Probable cause	The rack moves during aspiration.     The rack shift sensor has failed.
Solution	Remove the rack on the measurement line and reset the rack.

Error message	Remove Sample Rack (Left Rack Pool)
Probable cause	<ol> <li>The left rack pool has filled with analyzed racks.</li> <li>The sensor of the left rack pool has failed.</li> <li>The obstructing object exists in front of the sensor of the left rack pool.</li> </ol>
Solution	<ol> <li>Check the left rack pool for the obstructing object. Remove the object if present.</li> <li>Remove the analyzed racks from the left rack pool and reset the required rack.</li> </ol>

Error message	Mechanical Error (Sample Barcode Scanner) (Initialization)
Probable cause	<ol> <li>The origin sensor or the mechanism has failed.</li> <li>Something is obstructing movement of the unit.</li> </ol>
Solution	Contact your service representative.

Error message	Mechanical Error (Sample Barcode Scanner) (Operation Pulse)
Probable cause	The mechanical has failed.     Something is obstructing movement of the unit.
Solution	Contact your service representative.

Error message	Sample Barcode Error (Aspiration Position)
Probable cause	<ol> <li>The aspect of the sample ID label is wrong in the rack.</li> <li>The barcode label is dirty.</li> <li>The barcode label does not match the specification.</li> <li>The sample tube sensor has failed.</li> </ol>
Solution	<ol> <li>Check the aspect of the sample ID label correctly in the rack.</li> <li>Check the barcode label.</li> </ol>

Error message	The sample tube does not exist (Aspiration Position) (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The sample tube does not exist on the aspiration position.</li> <li>The sample tube sensor has failed.</li> </ol>
Solution	Check the sample tube in the rack.

Error message	The measurement is skipped by the sample ID error.
Probable cause	<ol> <li>The sample tube does not exist on the aspiration position.</li> <li>The aspect of the sample ID label is wrong in the rack.</li> <li>The barcode label is dirty.</li> <li>The barcode label does not match the specification.</li> <li>The sample tube sensor has failed.</li> </ol>
Solution	<ol> <li>Check the aspect of the sample ID label correctly in the rack.</li> <li>Check the barcode label.</li> </ol>

Error message	Could Not Read the Rack Barcode
Probable cause	<ol> <li>The aspect of the rack ID label is wrong.</li> <li>The rack barcode label is dirty.</li> <li>The rack barcode label does not match the specification.</li> </ol>
Solution	Check the sample rack barcode label.

Error message	Sample ID Mismatch (Order and Reading Position)
Probable cause	The registered sample ID differs from the sample ID which is read by the barcode scanner.
Solution	Check the barcode label on the sample tube.

# 8. Analysis and order errors

Error message	Set SB Cuvette
Probable cause	<ol> <li>The required cuvette with stir bar is not set in the sample aspiration table.</li> <li>The setting is not performed with "Set SB cuvette".</li> </ol>
Solution	Select the "Set/Remove SB Cuvette" in the "Status" screen and set the SB cuvettes. Then analyze again.

Error message	Two or more reagent racks of the same rack ID are set on the reagent table.
Probable cause	Two or more reagent racks of the same rack ID are set on the reagent table.
Solution	Open the reagent cover C. And check the reagent racks if two or more reagent racks of same rack ID are set on the reagent table.

Error message	Set Detergent (Detergent)
Probable cause	<ol> <li>The required detergent is not set on the reagent table.</li> <li>The reagent vial type of the required detergent differs from the reagent information settings.</li> <li>The required detergent barcode is not read.</li> <li>The registration of the required detergent is not accurate in the "Reagent Master" and "Reagent Lot Master".</li> </ol>
Solution	<ol> <li>1) Check the required detergent on the reagent table.</li> <li>2) Check the registration of the detergent in the "Reagent" screen.</li> <li>3) Check the reagent barcode aspect of the detergent.</li> <li>4) Check the registration of the detergent in the "Reagent Master" and "Reagent Lot Master".</li> </ol>

Error message	Set Reagent (Reagent)
Probable cause	<ol> <li>The required reagent is not set on the reagent table.</li> <li>The reagent vial type of the required reagent differs from the reagent information settings.</li> <li>The required reagent barcode is not read.</li> <li>The registration of the required reagent is not accurate in the "Reagent Master" and "Reagent Lot Master".</li> </ol>
Solution	<ol> <li>Check the required reagent on the reagent table.</li> <li>Check the registration of the reagent in the "Reagent" screen.</li> <li>Check the reagent barcode aspect of the reagent.</li> <li>Check the registration of the reagent in the "Reagent Master" and "Reagent Lot Master".</li> </ol>

Error message	The reagent expires. (Reagent)
Probable cause	<ol> <li>The reagent expires.</li> <li>The registration of the "Exp.Date" is not accurate in the "Reagent Lot Master".</li> </ol>
Solution	<ol> <li>Check the reagent Exp.Date.</li> <li>If the reagent expires, replace with a new reagent.</li> <li>Check the Exp.Date in the "Reagent Lot Master" screen.</li> </ol>

Error message	Set Buffer (Buffer)
Probable cause	<ol> <li>The required buffer is not set on the STAT/buffer table.</li> <li>The reagent vial type of the required buffer differs from the reagent information settings.</li> <li>The required buffer barcode is not read.</li> <li>The registration of the required buffer is not accurate in the "Reagent Master" and "Reagent Lot Master".</li> </ol>
Solution	<ol> <li>1) Check the required buffer on the STAT/buffer table.</li> <li>2) Check the registration of the buffer in the "Reagent" screen.</li> <li>3) Check the reagent barcode aspect of the buffer.</li> <li>4) Check the registration of the buffer in the "Reagent Master" and "Reagent Lot Master".</li> </ol>

Error message	Reduce the orders.
Probable cause	The required sample volume for orders exceeds the maximum volume (500 $\mu$ L) of the sample aspiration.
Solution	The total of sample volume exceed the maximum aspiration volume. Reduce the orders.  One assay group which needs multiple analyses may exceed the maximum aspiration volume.  In that case, reduce the multiple analyses in "Assay Group Settings"
	Caution! The required sample volume depends on combinations of orders. Part of aspiration volume becomes extra volume.

Error message	It is an order that cannot be measured (Rack No. – Tube Pos.)
Probable cause	<ol> <li>The test protocol or dilution ratio is wrong.</li> <li>The total number of aspiration buffer, factor-deficient plasma, reagent and detergent for each aspiration exceeds 10 in the test protocol.</li> </ol>
Solution	Problem in the combination of Dilution Ratio for Measurements and Test Protocol in Assay Group Settings. Please select another Dilution Ratio.

Error message	Could not find the order of the rack No. (Rack No.)
Probable cause	The order of specified rack number is not registered.
Solution	Check the analysis order.

Error message	The sample tube does not exist
Probable cause	<ol> <li>The sample tube is not set in the ordered rack position.</li> <li>The sample tube sensor has failed.</li> </ol>
Solution	Set the sample tube in the ordered rack position, and analyze again.

Error message	Take off the cap from sample tube. (Micro Mode) (Rack No. – Tube Pos.)
Probable cause	The sample tube is with the cap closed. (Micro Mode cannot be performed while the cap is on. Only CS-2100 <i>i</i> can detect it with the cap in micro-sample mode.)
Solution	Take off the cap from sample tube, and analyze again.     Measurement for normal-mode.

### 9. External I/O errors

Error message	The order received from the host computer is invalid.
Probable cause	<ol> <li>The parameter ID received from the host computer differs from the host ID defined in the Assay Group Setup screen.</li> <li>Reagents to analyze the parameter received from the host computer do not exist or not available.</li> </ol>
Solution	Check the order from the host computer.

Error message	Can not analyze with the dilution ratio ordered from the Host Computer. (Rack No Tube Pos.)
Probable cause	The order whose dilution ration is not registered "Dilution Ration Master" is ordered from the Host Computer.
Solution	<ol> <li>The analysis performed with the default dilution ration in the assay group settings.</li> <li>Contact your service representative.</li> </ol>

Error message	HC Off-line HC CTS Time Out
Probable cause	The host computer program does not start up.     The connection cable is disconnected from the host computer.
Solution	Check the connection with the host computer and its connector.

Error message	HC ACK Code Error HC Transmission Count Error HC Communication Error The port to connect with the HC can not be opened.
Probable cause	<ol> <li>The connection setting is not suitable for the host computer.</li> <li>The connection cable is disconnected from the host computer.</li> </ol>
Solution	Check the connection with the host computer and its connector.

Error message	HC ACK Time Out HC ETX Time Out HC STX Time Out
Probable cause	<ol> <li>The connection cable is disconnected from the host computer.</li> <li>The host computer do not respond within the prescribed time-out time.</li> </ol>
Solution	Check the connection with the host computer and its connector.

Error message	There is no order in Host Computer (Rack No Tube Pos.)
Probable cause	Order inquiry is sent to the host computer, but "No order" is returned.
Solution	Check the its registration in the host computer.

Error message	HC Order is wrong (Rack No Tube Pos.)
Probable cause	The order is false when the order inquiry is run on the host computer.
Solution	Check the order in the host computer.

Error message	TCP/IP Connection Error
Probable cause	<ol> <li>The connection setting is not suitable for the host computer.</li> <li>The connection cable is disconnected from the host computer.</li> <li>The network card has failed.</li> </ol>
Solution	Check the connection with the host computer and its connector.

Error message	TCP/IP Receive Error
Probable cause	<ol> <li>The connection setting is not suitable for the host computer.</li> <li>The connection cable is disconnected from the host computer.</li> <li>The NIC has failed.</li> </ol>
Solution	Check the connection with the host computer and its connector.

Error message	S3I/O Communication Error (Board ID – Function No.)
Probable cause	The board has failed.     The wiring cable has failed.
Solution	Contact your service representative.

Error message	Barcode Scanner Error (Reagent)
Probable cause	<ol> <li>The barcode reader has failed.</li> <li>The connection cable is disconnected.</li> </ol>
Solution	Contact your service representative.

Error message	Logger AD Conversion Error
Probable cause	<ol> <li>The board has failed.</li> <li>The wiring cable has failed.</li> </ol>
Solution	Contact your service representative.

### 10.QC and Calibration curve errors

Error message	QC Flag Limit (Assay Parameter)
Probable cause	The results of quality control analysis exceed the upper or the lower flag limit.
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Stop Limit (Assay Parameter)
Probable cause	The results of quality control analysis exceeded the upper or the lower stop limit.
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (1-2s) (Assay Parameter) QC Stop Limit (1-2s) (Assay Parameter)
Probable cause	The results of QC analysis exceed limit (mean ±2SD).
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (1-3s) (Assay Parameter) QC Stop Limit (1-3s) (Assay Parameter)
Probable cause	The results of QC analysis exceed limit (mean ±3SD).
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (2-2s) (Assay Parameter) QC Stop Limit (2-2s) (Assay Parameter)
Probable cause	The results of consecutive QC analysis exceed limit (mean ±2SD).
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (4-1s) (Assay Parameter) QC Stop Limit (4-1s) (Assay Parameter)
Probable cause	The results of 4 consecutive QC analysis exceed limit (mean ± 1SD).
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (R-4s) (Assay Parameter) QC Stop Limit (R-4s) (Assay Parameter)
Probable cause	The difference between this result and the previous QC analysis result exceeds 4SD.
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (5-0.5s) (Assay Parameter) QC Stop Limit (5-0.5s) (Assay Parameter)
Probable cause	The results of 5 consecutive QC analysis exceed limit (mean $\pm$ 0.5SD).
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (7T) (Assay Parameter) QC Stop Limit (7T) (Assay Parameter)
Probable cause	All results of 7 consecutive QC analysis increase or all decrease.
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	QC Flag Limit (10X) (Assay Parameter) QC Stop Limit (10X) (Assay Parameter)
Probable cause	The results of 10 consecutive QC analysis all deviate to the same side.
Solution	<ol> <li>Check the expiration date of control plasma which is displayed.</li> <li>Check the expiration date of the reagents which are used.</li> <li>Check that they are stored correctly.</li> </ol>

Error message	The QC analysis could not be performed. (Assay Group)
Probable cause	The control for the assay group target for the vial QC is not placed on the reagent table.
Solution	Check the reagents on the reagent table. Check that the control plasma is stored correctly.

Error message	The automatic QC analysis with fixed interval can not be performed.
Probable cause	<ol> <li>The main unit is in the status other than "Ready" or "Asp.Ready".</li> <li>The main unit is being maintained.</li> <li>The reagent is being changed.</li> <li>The test was suspended.</li> </ol>
Solution	<ol> <li>Check if the instrument is measurable.</li> <li>Press the Start switch on IPU or Start button of the main unit when the automatic QC analysis with fixed interval is restarted.</li> </ol>

# 11.Operation errors

Error message	Close the cover (Light Shield Lid)
Probable cause	<ol> <li>The light shield lid is opened</li> <li>The sensor of the light shield lid has failed.</li> </ol>
Solution	Close the Light Shield Lid.

Error message	The cover is opened. (Light Shield Lid)
Probable cause	<ol> <li>The light shield lid is opened</li> <li>The sensor of the light shield lid has failed.</li> </ol>
Solution	Emergency stop is executed due to opening of the Light Shield Lid. Close the Light Shield Lid.

Error message	Close the cover (Reagent Rack Cover A)
Probable cause	<ol> <li>The reagent rack cover A is opened.</li> <li>The sensor of the reagent rack cover A has failed.</li> </ol>
Solution	Close the reagent rack cover A and turn the lock lever to lock the cover.

Error message	The cover is opened. (Reagent Rack Cover A)
Probable cause	<ol> <li>The reagent rack cover A is opened during analysis.</li> <li>The sensor of the reagent rack cover A has failed.</li> </ol>
Solution	Emergency stop is executed due to opening of the reagent rack cover A. Close the reagent rack cover A and turn the lock lever to lock the cover.

Error message	Close the cover (Reagent Rack Cover B)
Probable cause	<ol> <li>The reagent rack cover B is opened.</li> <li>The sensor of the reagent rack cover B has failed.</li> </ol>
Solution	Close the reagent rack cover B and turn the lock lever to lock the cover.

Error message	The cover is opened. (Reagent Rack Cover B)
Probable cause	<ol> <li>The reagent rack cover B is opened during analysis.</li> <li>The sensor of the reagent rack cover B has failed.</li> </ol>
Solution	Emergency stop is executed due to opening of the reagent rack cover B. Close the reagent rack cover B and turn the lock lever to lock the cover.

Error message	Close the cover (Reagent Rack Cover C)
Probable cause	<ol> <li>The reagent rack cover C is opened.</li> <li>The sensor of the reagent rack cover C has failed.</li> </ol>
Solution	Close the reagent rack cover C.

Error message	The cover is opened. (Reagent Rack Cover C)
Probable cause	<ol> <li>The reagent rack cover C is opened during analysis.</li> <li>The sensor of the reagent rack cover C has failed.</li> </ol>
Solution	Emergency stop is executed due to opening of the reagent rack cover C. Close the reagent rack cover C.

Error message	Close the cover (Sample Table)
Probable cause	<ol> <li>The sample table cover is opened.</li> <li>The sensor of the sample table cover has failed.</li> </ol>
Solution	Close the sample table cover.

Error message	The cover is opened. (Sample Table)
Probable cause	<ol> <li>The sample table cover is opened.</li> <li>The sensor of the sample table cover has failed.</li> </ol>
Solution	Emergency stop was executed due to opening of the sample table cover.  Close the sample table cover.

Error message	Close the cover (STAT/Buffer Table Cover)
Probable cause	<ol> <li>The STAT/buffer table cover is opened.</li> <li>The sensor of the STAT/buffer table cover has failed.</li> </ol>
Solution	Close the STAT/buffer table cover.

Error message	The cover is opened. (STAT/Buffer Table Cover)
Probable cause	<ol> <li>The STAT/buffer table cover is opened during analysis.</li> <li>The sensor of the STAT/buffer table cover has failed.</li> </ol>
Solution	Emergency stop was executed due to opening of the STAT/buffer table cover. Close the STAT/buffer table cover.

Error message	Power turned Off during operation
Probable cause	The power is turned off during operation.
Solution	The analysis might be not completed. Check the stored data and analyze again if it is not completed.

Error message	Mechanical Stop button is pressed
Probable cause	The mechanical stop switch is pressed.
Solution	Check the results of analysis in the Joblist. Analyze the error sample again.

Error message	The sample tube is removed from STAT Holder. (Pos. No.)
Probable cause	<ol> <li>The sample whose analyses are not completed is removed from the STAT holder.</li> <li>The sample tube sensor of the STAT holder has failed.</li> </ol>
Solution	Reset the sample in the STAT holder.

Error message	Reagent rack cover A was opened during sleep mode.
Probable cause	<ol> <li>The reagent rack cover A is opened.</li> <li>The sensor of the reagent rack cover A has failed.</li> </ol>
Solution	Close the reagent rack cover A and slide the lock lever to lock the cover.     The issue of the reagent quality might occur during cooling.

Error message	Reagent rack cover B was opened during sleep mode.
Probable cause	<ol> <li>The reagent rack cover B is opened.</li> <li>The sensor of the reagent rack cover B has failed.</li> </ol>
Solution	<ol> <li>Close the reagent rack cover B and slide the lock lever to lock the cover.</li> <li>The issue of the reagent quality might occur during cooling.</li> </ol>

Error message	Reagent rack cover C was opened during sleep mode.
Probable cause	<ol> <li>The reagent rack cover C is opened.</li> <li>The sensor of the reagent rack cover C has failed.</li> </ol>
Solution	<ol> <li>Close the reagent rack cover C.</li> <li>The issue of the reagent quality might occur during cooling.</li> </ol>

### 12.Other errors

Error message	Detector Block Error (Channel No.)
Probable cause	<ol> <li>The detector wells have contamination.</li> <li>The optical fiber malfunctions.</li> <li>The pre-amp has failed.</li> </ol>
Solution	Contact your service representative.

Error message	Replace the lamp
Probable cause	The lamp intensity significantly declines.     The lamp has failed.
Solution	Replace the lamp. Select the " <b>Lamp calibration</b> " button in the Maintenance screen.

Probable cause The lamp intensity exceeds the upper or lower limit of the set range.  Calibrate the lamp.  Note:  If you perform analysis while lamp intensity exceeds the upper or	Error message	Calibrate the lamp.
Note:  If you perform analysis while lamp intensity exceeds the upper or	Probable cause	The lamp intensity exceeds the upper or lower limit of the set range.
lower limit of the set range, detection of abnormal transmitted light and other analysis errors are more likely to occur.	Solution	Note:  If you perform analysis while lamp intensity exceeds the upper or lower limit of the set range, detection of abnormal transmitted

Error message	Set the cuvette trash box
Probable cause	<ol> <li>The cuvette trash tray is removed.</li> <li>The cuvette trash tray has failed.</li> </ol>
Solution	Set the cuvette trash box.

Error message	The cuvette trash box will be full soon.
Probable cause	The cuvette trash tray exceeds the warning level.
Solution	Discard the cuvettes in the trash box after analyses are completed.

Error message	The analyses are suspended, because cuvette trash box becomes full.	
Probable cause	The cuvette trash has filled with the cuvettes.	
Solution	Discard the cuvettes in the trash box after analyses are completed.	

Error message	It's time to replace (Waste Line Pinch Valve)			
Probable cause	The waste line pinch valve counts exceed 2,250,000 times.			
Solution	Replacement of the waste line pinch valve is required. Contact your local service representative for replacement.			

Error message	It's time to replace (Piercer Needle)		
Probable cause	The piercer counts exceed 40,000 times.		
Solution	Replacement of the piercer needle is required. Contact your service representative.		

Error message	Adjustment Error	
Probable cause	The memory of BBU has failed.	
Solution	Contact your service representative.	

Error message	The cooling fan is not rotating.			
Probable cause	The cooling fan has failed.			
Solution	<ol> <li>Reagents are not enough cooled. Put them back in the refrigerator.</li> <li>If the error persists, contact your service representative.</li> </ol>			

Error message	The cooling fan stopped during sleep mode.		
Probable cause	The cooling fan has failed.		
Solution	<ol> <li>The issue of the reagent quality might occur during cooling. Perform the QC analysis.</li> <li>If the error persists, contact your service representative.</li> </ol>		

Contact your local technical representative for more information on any error messages that are not mentioned in this manual.

# 4. Analysis data error

Code	Message	Cause	Countermeasures
0000.0000.0000	Dilution Ratio was Changed	Change the dilution ratios for parameters which cannot be calculated because of their dilution ratio, such as coagulation time and ratio, and INR.	_
0000.0000.0340	Wave Changed 340nm	The analysis wavelength was changed to 340nm to reduce the impact of inhibitors.	Check whether the coagulation curve is abnormal, and repeat the analysis if necessary.
0000.0000.0405	Wave Changed 405nm	The analysis wavelength was changed to 405nm to reduce the impact of inhibitors.	Check whether the coagulation curve is abnormal, and repeat the analysis if necessary.
0000.0000.0575	Wave Changed 575nm	The analysis wavelength was changed to 575nm to reduce the impact of inhibitors.	Check whether the coagulation curve is abnormal, and repeat the analysis if necessary.
0000.0000.0660	Wave Changed 660nm	The analysis wavelength was changed to 660nm to reduce the impact of inhibitors.	Check whether the coagulation curve is abnormal, and repeat the analysis if necessary.
0000.0000.0800	Wave Changed 800nm	The analysis wavelength was changed to 800nm to reduce the impact of inhibitors.	Check whether the coagulation curve is abnormal, and repeat the analysis if necessary.
0000.0000.1100	Vial QC has not performed.	Analysis was performed using a reagent that had not received QC analysis.	Follow the judgment criteria for the institution.
0000.4000.0010	Display Digit Overflow	Calculated results from the calibration curve exceeded the number of display digits.	Take action such as diluting the sample, then repeat the analysis.
0000.4000.0020	Calculation Failure	Calculation based on the calibration curve was impossible due to an analysis error or other cause.	Repeat the analysis.
0000.4000.0030	Validated Calibration Curve is not found	There was no validated calibration curve.	Check and validate the calibration curve on the calibration curve screen. After that, repeat the analysis if necessary.
0000.4000.0041	Extrapolation Boundary Over (Upper)	The analysis results exceeded the calibration curve extrapolation range.	Change the dilution ratio, then repeat the analysis.
0000.4000.0042	Extrapolation Boundary Over (Lower)	The analysis results fell below the calibration curve extrapolation range.	
0000.4000.0050	Calculated later	The value has been recalculated.	_

Code	Message	Cause	Countermeasures	
0000.5000.0010	Formula Calculation Failure	Formula calculation failed.	_	
0000.5000.0020	Formula Calculation Failure	An analysis error prevented Formula calculation.	Repeat the analysis.	
0000.5000.0050	Problem in Calculating Formula	The Formula calculation expression, such as circular reference etc. was improper.	Check the Formula calculation expression under the Formula calculation settings.	
0000.6000.0100	Upper Report Limit Over	The upper limit value for report limit was exceeded.	Follow the judgment criteria for the institution.	
0000.6000.0200	Lower Report Limit Over	The lower limit value for report limit was exceeded.	Follow the judgment criteria for the institution.	
0000.6000.0300	Upper Mark Limit Over	The upper limit value for error judgment limit was exceeded.	Follow the judgment criteria for the institution.	
0000.6000.0400	Lower Mark Limit Over	The result was below the lower limit value for error judgment limit.	Follow the judgment criteria for the institution.	
0000.6000.0500	MDA Slope Ratio Over	The gradient between the MDA analysis results and the calibration curve exceeds the set range.	Check the calibration curve and the sample.	
0000.6000.0600	Difference between replicated results	Results of repeated analyses exceeded the permissible divergence range.	Follow the judgment criteria for the institution.	
0000.7000.0020	Mean Calculation Failure	The average value could not be calculated, due to an analysis error.	Repeat the analysis.	
0001.0000.0000	Detector Block Temperature Error	Detector block temperature was not in the range 36.5~37.5°C.	The detector block may have failed. Please contact your local technical representative.	
0002.0000.0000	Slight Coagulation	The detected coagulation reaction was extremely weak.  1) Coagulation activity of the sample is low.	Check the coagulation curve and follow the judgment criteria for your institution.	
		Fibrinogen concentration of the sample is low.	For fibrinogen analysis, change low as the dilution ratio and reanalyze.	
		The status of the sample and the reagent has some problem.	Check status of the sample and the reagent, and re-analyze.	

Code	Message	Cause	Countermeasures
0004.0000.0000	Analysis Time Over	The coagulation reaction did not finish within the detection time.	
		Coagulation activity of the sample is low.	Change a longer     maximum detection time     and re-analyze.
		Fibrinogen concentration of the sample is low.	For fibrinogen analysis, change low as the dilution ratio and reanalyze.
		3) The buffer is cool.	Equilibrate buffer to room temperature, and reanalyze.
		The status of the sample and the reagent has some problem.	Check status of the sample and the reagent, and re-analyze.
0008.0001.0000	Initial fluctuation drop	A major abnormal change was found in the initial portion of the coagulation curve.	
		Coagulation reaction has abnormalities.	Check the coagulation curve and follow the judgment criteria for your institution.
		2) The buffer is cool.	Equilibrate buffer to room temperature, and reanalyze.
		The status of the sample and the reagent has some problem.	Check status of the sample and the reagent, and re-analyze.
0008.0002.0000	Coagulation Curve Error: Sharp Drop	There was a sudden change in the curve.	
	Lifer. Sharp brop	Coagulation reaction has abnormalities.	Check the coagulation curve and follow the judgment criteria for your institution.
		2) The buffer is cool.	Equilibrate buffer to room temperature, and reanalyze.
		The status of the sample and the reagent has some problem.	Check status of the sample and the reagent, and re-analyze.
0008.0008.0000	Coagulation Curve Error: Jump Up	An excessively rapid change was detected in the coagulation curve.	
		Coagulation reaction has abnormalities.	Check the coagulation curve and follow the judgment criteria for your institution.
		2) The buffer is cool.	Equilibrate buffer to room temperature, and reanalyze.
		The status of the sample and the reagent has some problem.	Check status of the sample and the reagent, and re-analyze.

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Code	Message	Cause	Countermeasures
0008.0016.0000	Coagulation Curve Error: Stepping Curve	The coagulation reaction responded to multiple stages.  1) Coagulation reaction has abnormalities.	Check the coagulation curve and follow the judgment criteria for your institution.
		<ul><li>2) The buffer is cool.</li><li>3) The status of the sample</li></ul>	2) Equilibrate buffer to room temperature, and reanalyze. 3) Check status of the
		and the reagent has some problem.	sample and the reagent, and re-analyze.
0008.0032.0000	Coagulation Curve Error: Fbg Curve Error	The intensity of coagulation reaction is high, but the coagulation time is long. For only Fbg.  1) Fibrinogen concentration of the sample is high.	For fibrinogen analysis,     change high as the     dilution ratio and re-
		2) The buffer is cool.	analyze. 2) Equilibrate buffer to room temperature, and reanalyze.
0008.0064.0000	Coagulation Curve Error: Terrace	An abnormal plateau was detected at an intermediate stage of the coagulation reaction.	
		Coagulation reaction has abnormalities.  The buffer is cool.	Check the coagulation curve and follow the judgment criteria for your institution.     Equilibrate buffer to room temperature, and re-
		The status of the sample and the reagent has some problem.	analyze. 3) Check status of the sample and the reagent, and re-analyze.
0008.0128.0001	Early Reaction Error: Slow Reaction	An abnormal reaction was detected at an initial stage of the coagulation.	
0008.0128.0002	Early Reaction Error: Start Angle 1	Coagulation reaction has abnormalities.	Check the coagulation curve and follow the independent criteria for your contents.
0008.0128.0004	Early Reaction Error: Start Angle 2	2) The status of the sample	judgment criteria for your institution. 2) Check status of the
0008.0128.0016	Early Reaction Error: Early %	and the reagent has some problem.	sample and the reagent, and re-analyze.
0008.0256.0000	Noise	Coagulation curve abnormalities 1) The coagulation reaction may have been contaminated with some kind of noise.	Check the coagulation curve and follow the judgment criteria for your institution.

Code	Message	Cause	Countermeasures	
0016.0000.0000	Turbidity Level Over	Turbidity was too high to allow analysis.  1) The sample is too turbid.	Check status of the sample and re-analyze.	
0032.0000.0000	No Coagulation	The coagulation reaction was not detected.  1) Coagulation activity of the sample is low.  2) Fibrinogen concentration of the sample is low.	Change a longer maximum detection time and re-analyze.     For fibrinogen analysis, change low as the dilution ratio and re-	
		<ul><li>3) The buffer is cool.</li><li>4) The status of the sample and the reagent has some</li></ul>	<ul><li>analyze.</li><li>3) Equilibrate buffer to room temperature, and reanalyze.</li><li>4) Check status of the sample and the reagent,</li></ul>	
0032.0002.000	Flat Curve	problem.  Reaction curve is flat and the coagulation reaction did not finish within the detection time.  1) Coagulation activity of the sample is low.  2) Fibrinogen concentration of the sample is low.  3) The buffer is cool.	and re-analyze.  1) Change a longer maximum detection time and re-analyze. 2) For fibrinogen analysis, change low as the dilution ratio and reanalyze. 3) Equilibrate buffer to room temperature, and reanalyze. 4) Check status of the sample and the reagent,	
0064.0000.0000	Aged Sample	problem.  1 hour elapsed after the sample was taken into the instrument.	and re-analyze.  Re-analyze.	
0128.0000.0000	Range Over	Coagulation time was extremely short.  1) Fibrinogen concentration of the sample is high.  2) The status of the sample and the reagent has some problem.	<ol> <li>For fibrinogen analysis, change high as the dilution ratio and reanalyze.</li> <li>Check status of the sample and the reagent, and re-analyze</li> </ol>	

Code	Message	Cause	Countermeasures
0256.0000.0000	Trans Light High	Transmitted light is extremely high.  1) The status of the sample and the reagent has some problem.  2) The halogen lamp has a problem.	1) Check status of the sample and the reagent, and re-analyze. 2) Check status of the halogen lamp and calibrate it if need.
4001.0000.0000	Trans Light Low	Transmitted light is extremely low. 1) The sample is too turbid. 2) The halogen lamp has a problem.	1) Check status of the sample and re-analyze. 2) Check status of the halogen lamp and calibrate it if need.
4002.0000.0000	Trans Light High	Transmitted light is extremely high.  1) The status of the sample and the reagent has some problem.  2) The halogen lamp has a problem.	1) Check status of the sample and the reagent, and re-analyze. 2) Check status of the halogen lamp and calibrate it if need.
4004.0000.0000	No Linearity	Reaction curve lacks linearity.  1) The status of the sample and the reagent has some problem.	Check the reaction curve and follow the judgment criteria for your institution.
4008.0000.0000	Reaction Curve Error	Reaction curve switched to the opposite direction.  1) The status of the sample and the reagent has some problem.	Check the reaction curve and follow the judgment criteria for your institution.
4016.0000.0000	Antigen Excess	The reaction was extremely high.  1) The antigens in the sample were exceeding.	Change low as the dilution ratio and reanalyze.
4128.0000.0000	No Polynomial adjustment	Reaction curve could not be polynomially approximated.  1) The status of the sample and the reagent has some problem.	Check the reaction curve and follow the judgment criteria for your institution.
4256.0000.0000	Range in non-linear	Reaction curve is not linear or could not be linearly approximated.  1) The status of the sample and the reagent has some problem.	Check the reaction curve and follow the judgment criteria for your institution.

Code	Message	Cause	Countermeasures	
9999.0000.0000	Measurement Failure	An error in analysis action occurred in the instrument during analysis of the sample. Or analysis was stopped during aspiration in microsample mode.	Refer to the error log for the instrument, take corrective action, then repeat the analysis.	
9999.0000.9010	TEST_RECV_ELS E_ERROR	An unexpected error occurred in the calculation and storage	In most cases, such errors can be resolved by	
9999.0000.9020	ASSY_CALV_PAR A_ERROR	of analysis results.	repeating the analysis. If this kind of problem occurs frequently, please contact	
9999.0000.9030	ASSY_CALV_INF_ ERROR		your local technical representative.	
9999.0000.9040	ASSY_ANLY_CAL C_ERROR	-		
9999.0000.9050	ASSY_RECV_ELS E_ERROR			
9999.0000.9060	ASSY_ANLY_NOP RISET_ERROR	OR		
9999.0000.9070	ASSY_ANLY_NOR ESULT_ERROR			
9999.0000.9080	ASSY_ANLY_DILU TION_ERROR			
9999.0000.9090	ASSY_CALY_NOD ATA_ERROR			
9999.0000.9100	ASSY_AVER_IRIG ALRESULT_ERRO R			
9999.0000.9110	TEST_REAGENTL OT_ERROR			
Unknown9999	Unknown Message	The IPU was shut down abnormally during analysis.	Analysis was not completed and must be repeated.	

# 5. Displaying sample information

Code	Mes	sage	Cause	Countermeasures
Code	Job List Browser		Cause	Countermeasures
1000.1000.0000	Hem	Hemolytic Sample	Sample suspected of hemolysis.	Check the reaction curve and follow
1000.2000.0000	Ict	Icterous Sample	Sample suspected of icterus.	judgment criteria for the institution.
1000.3000.0000	Lip	Lipemic Sample	Sample turbid due to lipemia.	
1100.4000.0000	Vol	Defective Sample Volume	Sample suspected of inappropriate volume.	
-	H*	No message	Indicates that the influence of turbidity or other inhibitor in the sample prevented an accurate hemolytic check.	
-	*	No message	Indicates that the influence of turbidity or other inhibitor in the sample prevented an accurate icteric check.	
-	L*	No message	Indicates that strong turbidity in the sample prevented an accurate lipemic check.	

# 8.6 System confirmation

This section explains how to perform test operations to confirm that the system operates correctly.

#### 1. Reagent barcode reading test

This section explains how to perform test operations to confirm that reagent barcodes can be read

- Press **Test Operation** on the IPU menu screen.
   The Test Operation dialog box will appear.
- 2. Press **Reagent Barcode Reading Test** on the Test Operation dialog box. The Reagent Barcode Reading Test screen will appear.

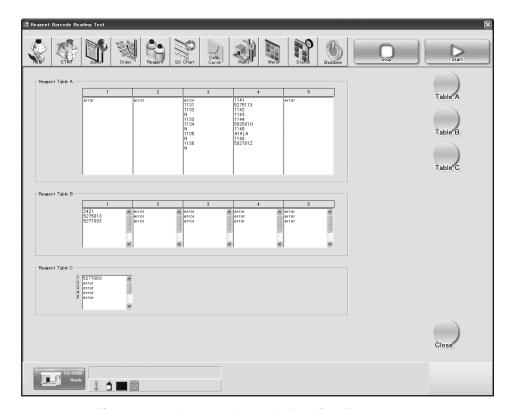


Figure 8-06: Reagent Barcode Reading Test screen

- 3. Set the reagent vial on the reagent rack on the reagent table that you want to conduct barcode reading tests, then close the reagent table cover.
- 4. Press the button for the reagent table tested.

The instrument will automatically read the barcode to display the scanned data on the screen.

The holder number and barcode are displayed in that order.

If the instrument fails to read the barcode, "error" will appear on the screen when no reagent rack is set.

"N" will appear next to the holder number when the rack is set but no reagent vial is placed in it.

#### 2. Sample barcode reading test

This section explains how to perform test operations to confirm that sample barcodes can be read.

- 1. Press **Test Operation** on the IPU menu screen. The Test Operation dialog box will appear.
- 2. Press Sample Barcode Reading Test on the Test Operation dialog box. The Sample Barcode Reading Test dialog box will appear.

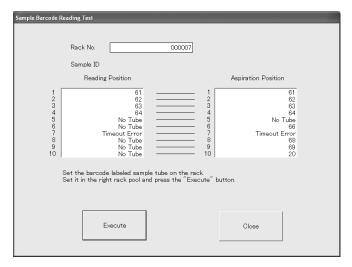


Figure 8-07: Sample Barcode Reading Test dialog box

- 3. Set the barcode labeled sample tube on the sample rack, and place it in the right rack pool.
- 4. Press Execute.

The instrument will automatically feed in the sample racks to read the barcodes. The scanned barcode data is displayed on the screen.

Sample IDs that have been read in the reading position and aspiration position will

Barcode read error messages are as described below.

Display Contents

Table 8-01: Barcode read error messages

Display	Contents
No Tube	No sample tube is placed.
Check-Digit Error	Check digits are incorrect.
Timeout Error	Unable to read because of unacceptable barcodes, etc.
Read Error	Scanned data is incorrect.

Blank page

# 9. Technical Information

This chapter explains the instrument specifications, basic principles, packing contents and installation.

#### 9.1 **Instrument specifications**

### 1. Analysis parameters/calculated parameters

See "Chapter 1: 1.4 Assay parameters (analysis parameters and calculated parameters)".

# 2. Number of simultaneous analysis parameters

Maximum 60 parameters

### 3. Analysis mode and sample processing speed

#### **Analysis mode**

Normal mode

In this mode, sample volumes from all samples set by the sampler or by the STAT sample holder, including retests, are taken into the instrument at the same time, then each test is performed separately inside the instrument.

 Micro-sample mode In this mode, the sample volume for each test is directly collected and analyzed from samples set by the sampler or by the STAT sample holder.

### 4. Operating principles

#### Sample dispensing

Plasma components obtained by centrifuging blood that has previously been treated with anti-coagulant are dispensed into cuvettes at fixed volumes for each analysis parameter or are diluted to be dispensed at fixed volumes.

#### **Analysis**

Coagulation

Light is applied to a mixture of blood plasma and reagent and the method analysis change in turbidity (when the fibrinogen is transformed into fibrin) is detected as the change in transmitted light.

Chromogenic method analysis of change in light absorbance is detected.

The reaction is started by mixing plasma and reagent and the rate

**Immunoassay** 

Plasma and latex reagent are mixed to start a reaction and the method analysis change in absorbance of the latex clumps generated is detected.

#### 5. Detection time

Up to 1,800 sec. for each parameter

#### 6. Analysis time (default)

PT 180 seconds **APTT** 180 seconds 100 seconds Fbg

#### 7. Time resolution

Sampling can be performed for up to 1,800 seconds, at intervals of 0.1 seconds.

#### 8. Display

Graphical display on the touch panel display

#### 9. Printout

Permits graphic printing through an optional graphic printer.

#### 10.Cooling of reagents

The reagent holders are cooled using Peltier elements to control temperature.

**Reagent holder** :40 wells ( $10^{\circ}$ C ± $2^{\circ}$ C, ambient temperature  $20^{\circ}$ C –  $28^{\circ}$ C, in operation) ( $4^{\circ}$ C –  $15^{\circ}$ C, ambient temperature  $15^{\circ}$ C –  $30^{\circ}$ C)

### 11.Reagent dispensing

The reagent probe detects the liquid surface of reagent and aspirates and dispenses reagent through a syringe.

### 12. Sample dispensing

The sample probe detects the liquid surface of the sample, pipettes sample from the tubes and dispenses it into cuvettes on the sample aspiration table. An additional sample probe aspirates this sample from the sample aspiration table and dispenses it into cuvettes on the sample aspiration table (when in normal mode).

When the sample amount is limited, the sample probe can pipette a sample directly from the sample tubes to cuvettes on the sample aspiration table. (when in micro-sample mode)

Automatic re-analyses cannot be executed when in micro-sample mode.

#### 13.Cuvette

**Cuvette** : Maximum approx. 500 tubes can be loaded in the hopper

and supplied automatically

#### 14.Detector

Photodetection unit : 10 wells (of which 4 wells have a mixing function using stir

bars)

Incubation unit : 10 well

#### 15.Temperature control

Detector $:37^{\circ}C\pm0.5^{\circ}C$ Sample heater $:37^{\circ}C\pm1.0^{\circ}C$ Reagent probe $:37^{\circ}C\pm0.5^{\circ}C$ 

#### 16. Time taken to reach set temperature

Within 30 minutes after power supply turn-ON (when room temperature is within the temperature range of usage conditions)

#### 17.STAT sample processing

The routine analysis can be interrupted for preferential processing of a specified sample contained in a sample collection tube.

STAT samples can be set in dedicated holders or sample racks.

#### 18. Automatic re-analysis function

When upper and lower limit values are set for re-analysis, the system will automatically execute re-analysis and dilution analysis as needed (when in normal mode).

# 19. Profile settings

Sets of multiple preset test parameters (profiles) can be prepared through one-time key input.

#### 20. Number of stored samples

Analysis data : 10,000 samples

### 21.Quality control

 $\overline{X}$  Control (L-J Control) :1,200 plots  $\times$  750 files, 40 parameters

#### 22. Calibration curve

12 points, 250 parameters

#### 23. Operating environmental range

Ambient temperature : 15 to 30°C

**Relative humidity**: 30 - 85% (No condensation anywhere other than the

reagent table)

Atmospheric pressure: Normal pressure

# 24. Electrical rating

**Voltage** : Main Unit 100 – 240V

Pneumatic Unit 100 – 117V

220 - 240V

Frequency : 50/60 Hz

Power consumption : Main Unit 800 VA or less.

Pneumatic Unit 100 - 117V 230VA or less 50Hz

280VA or less 60Hz

220 - 240V 220VA or less 50Hz

250VA or less 60Hz

Heat compensation

required

: Approx. 4,000 BTU/h (1,040 kcal/h)

Installation category (excess voltage

(CXCC33 VOI

: Category II

category)

Laser class category : Class I (IEC60825-1)

Protection type : Class I equipment

#### 25. Storage conditions

Ambient temperature :-10°C to 60°C

Relative humidity :30% to 95%

Atmospheric pressure :70 kPa to 106 kPa

# 26. Dimensions and weight

# **IPU Main Unit**

- : Approx. 280(W)  $\times$  approx. 355(D)  $\times$  approx. 400(H) mm, approx. 17kg
- \* The dimensions include the sampler and exclude projections. The IPU and other options are not included.

# 9.2 Principles

This chapter explains the analysis principles and analysis mechanism in the CS-2000*i*/CS-2100*i*.

Analysis principles

Describes the multi-wavelength transmitted light detection methods (coagulation, chromogenic and immunoassay methods).

Analysis mechanism

Describes the analysis mechanism for each unit in mechanical, hydraulic and electrical systems.

#### 1. Analysis principles

After a fixed quantity of sample has been warmed for a certain time period, reagent is added.

The system shines light onto the sample and reagent mixture and the changes in transmitted light are detected during the process of blood coagulation (coagulation method), the process of color emission by a chromogenic synthetic substrate (chromogenic method) and the process of latex aggregation by the antigen-antibody reaction (immunoassay method). The percentage detection method is used to find the coagulation time (coagulation method) and the rate method or the VLin Integral method is used to find the change in absorbance per minute ( $\triangle$ OD/min) (for the chromogenic and immunoassay methods).

#### Coagulation point detection method (percentage detection method)

To detect the coagulation time, the percentage detection method is employed. The level of transmitted light intensity that is present right after the reagent is added but before coagulation has started is defined as 0% and the level of transmitted light intensity that is present after coagulation is completed is defined as 100%. The time that it takes for the level of transmitted light intensity to reach the preset detection percentage is found from the reaction curve. This is defined as the coagulation time. (In the diagram below it is set to 50% of the coagulation end point.)

This method allows determination of the coagulation time even on those specimens demonstrating only a slight change in transmitted light intensity.

The coagulation time can thus be detected using samples that show small amounts of transmitted light intensity (low fibrinogen samples) or even samples whose speed of change is only slight (samples with an extended coagulation time).

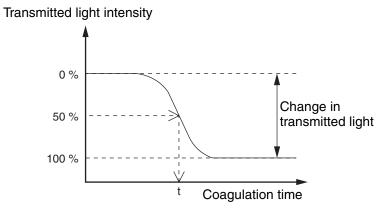


Figure 9-01: Percentage detection method

#### Rate method

Between the set start time and end time, the transmitted light data is analyzed and linear regression is used to find the amount of change in light absorbance per minute.

# **VLin Integral Method**

Under the set conditions, the start point and end point are set that will give the maximum change in absorbance and the best linear approximation for each sample. Between the start and end, transmitted light data is analyzed and linear regression is used to find the change in light absorbance per minute.

#### **Drifting Baseline Method**

This method means that the coagulation time is a time where the amount of change in light absorbance is greater than threshold.

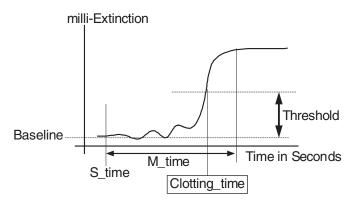


Figure 9-02: General diagram for Drifting Baseline Method

#### **Calibration Curve**

A linear relationship exists between the change in light absorbance and the concentration (or activity percent) when both parameters are plotted on a graph. The CS-2000*i*/CS-2100*i* can make use of the aforementioned relationship to prepare calibration curves.

The axes of the calibration curves can be set as shown below.

- (1) Log log linear approximation (or polygonal line)
- (2) Log real (real log) linear approximation (or polygonal line)
- (3) Log reciprocal (reciprocal log) linear approximation (or polygonal line)
- (4) Real real linear approximation (or polygonal line)
- (5) Reciprocal Reciprocal linear approximation (or polygonal line)
- (6) Real reciprocal (reciprocal real) linear approximation (or polygonal line)

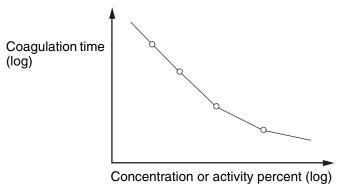


Figure 9-03: Calibration curve for the coagulation method

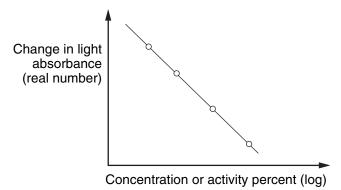


Figure 9-04: Calibration curves for the chromogenic, immunoassay and aggregation methods

# Calculation of PT ratio and INR value

Ratios can be calculated by entering normal values in the CS-2000*i*/CS-2100*i*. For reagents provided with an ISI (International Sensitivity Index), input the ISI to calculate the INR (International Nomalized Ratio).

If PT is used 
$$PT \text{ ratio} = \frac{ \text{Coagulation time for sample plasma PT} }{ PT \text{ normal value} }$$
 
$$INR= (PT \text{ ratio})^{ISI}$$



#### Caution!

ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling.

Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value.

Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.

### Multi-wavelength transmitted light detection

The configuration of the detector block is shown below. Light from the light source is separated into 340, 405, 575, 660 and 800 nm components by five filters. Separated light is directed to the detector wells by optical fibers. In each detector well, the light shines on a cuvette containing a sample in which the collected sample and reagents are mixed. Light which has been transmitted through the sample is detected. This transmitted light is converted into an electrical signal which is stored and processed by a microcomputer to find the coagulation time and the amount of change in light absorbance ( $\triangle$ OD/min).

The wavelengths used, the analytical methods (percentage method, rate method), whether or not to perform a prozone check, mixing conditions during analysis and other analysis conditions are set and performed in the same detector well for the three analysis methods (coagulation, chromogenic and immunochemical).

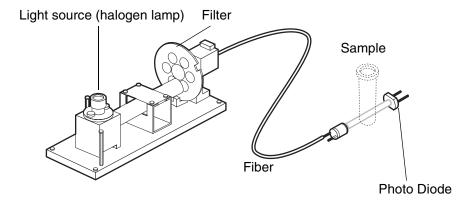


Figure 9-05: Multi-wavelength transmitted light detection method

#### 2. Analysis mechanism

The CS-2000*i*/CS-2100*i* employs mechanical, hydraulic and electrical systems and performs analysis according to the procedure described below.

- 1. Samples in the right rack pool are carried to the aspiration position by sampler operation.
- 2. The sample dispensing probe aspirates the required amount of sample plasma from the sample rack.
- The required amount is automatically calculated for each sample and depends on the preset analysis parameters and number of replications (repetitions). The aspirated sample plasma is used to carry out automatic re-analysis and redilution analysis.
  - Dilution and measurement can also be performed directly, without aspiration. (Micro-sample mode)
- 4. The sample dispensing probe dilutes and measures the aspirated sample and then dispenses it into the cuvettes.
- 5. The sample-containing cuvettes are warmed (incubated) for a certain time period.
- 6. The reagent probe aspirates a certain amount of the prescribed reagent from the reagent vial in the reagent racks.
  - The reagent is warmed within the reagent probe for a certain time period.
- 7. The sample that was warmed in the incubator is carried to the reagent dispensing position by the catcher and the reagent inside the reagent probe is added.
- 8. The sample tube to which the reagent has been added is mixed by the catcher and then carried to the detector block, where detection of analysis simultaneously starts.
- 9. In the detector block, the coagulation reaction is detected through the change in transmitted light.
- 10. The cuvettes of samples that have been analyzed are transported to the cuvette trash tray by the catcher.
- 11. The samples that have been aspirated and analyzed completely are also transported by the catcher to the cuvette trash tray for disposal.

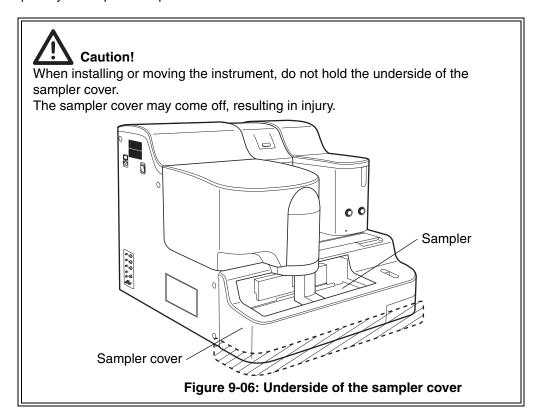
# 9.3 Package contents

- 1 Main Unit
- 2 Pneumatic Unit
- 3 Provided parts
- 4 IPU

# 9.4 Installation

#### 1. Check before installation

Make sure that the CS-2000*i*/CS-2100*i* is free from external flaws and check the quantity of the provided parts.



# 2. Provided parts check list

Table 9-01: CS-2000i/CS-2100i provided parts check list

No.	Part No.	Description	Quantity
1	AP921512	CS-2000i/CS-2100i (S) IFU (EN)	1
2	AQ061411	CS-2000i/CS-2100i (S) Software Guide (EN)	1
3	CU625098	CDR_Assy No. 37 (CS-2000 <i>i</i> /CS-2100 <i>i</i> software for OUS use only CD-ROM)	1
4	CR098953	CDR_Assy No. 51 (CS-2000 <i>i</i> /CS-2100 <i>i</i> software for use in the USA CD-ROM)	1
5	AG864834	CDR_Assy No. 38 (CS-2000i/CS-2100i Data Base CD-ROM)	1
6	923-8092-8	Power Cord No. 15	1
7	073-2762-7	Sampler rack package assembly (WHITE) (6 racks) (with Holder No. 59)	1
8	BU985293	Barcode label for reagent holder (CA CLEAN II) on CS2 (5 labels)	1
9	CU813644	Barcode label for Owren's Veronal Buffer on CS2 (5 labels)	1
10	CW084217	Holder_ASSY NO.126 (GW5)	2
11	442-3098-7	S/B Adapter (GW15) (for GW15/GW25)	2
12	442-3096-0	S/B Adapter (SC)	2
13	AC833285	Holder_ASSY NO. 19 (GW5)	5
14	CX073106	Holder_ASSY NO. 21 (Cup)	6
15	CD466647	Reagent cap S (10) (Kit NO.109)	1
16	AH759521	Reagent cap L (10) (Kit NO.110)	1
17	CC907148	Cap NO.528 (10) (Kit NO.105)	1
18	BB564291	Cap NO.527 (10) (Kit NO.106)	1
19	AF252785	Trash Box Liner CS2 (5) (Kit NO.141)*	1
20	AX801638	Reagent rack C-1 (Container_Assy_No. 34)	1
21	BV995710	Reagent rack C-2 (Container_Assy_No. 35)	1
22	BA515007	SLD mini cup (100pcs) SLD-400A MAIN PREPARATION*	1

<sup>\*</sup> Not for sale (refer to "Chapter 7: 7.10: 1. Consumable supplies" when ordering).

Table 9-02: CS-2000i/CS-2100i Main Unit provided parts check list

No.	Part No.	Description	
1	953-1082-1	Float switch No. 17 (for rinse water tank)	1
2	424-2400-4	20 L container (for rinse water tank)	1
3	367-2187-1	CS2 Cuvette trash tray	1
4	BB274286	CS2 Reagent table A cover (Cover_Assy No. 57)	1
5	BX820077	CS2 Reagent table B cover (Cover_Assy No .58)	1
6	CA646494	CS2 Reagent table C cover (Cover_Assy No. 59)	1
7	265-9436-5	LAN cable NSEDT-PC-S-MP4P-2SB568B/AB	1
8	367-9228-2	Teflon mixer (micro rotor I 12.7 $\times$ $\phi$ 3.0) (for reagent mixing)	3
9	442-5338-7	Tubes 6 x 4: 20 m	1
10	BK603598	Tubes 6.5 × 3 (silicon): 5 m	1
11	443-1369-5	Filter NO. 16A	1
12	CD260744	Holder_Assy NO. 28	1
13	424-1160-8	Sample cup conical 4 mL	20
14	BR795472	Barcode label No. 1 Barcode label (1-60)	2
15	369-7856-7	Display mark No. 553	1
16	266-7768-1	Fuse 50T100H	2
17	BB033811	CS Reagent rack A-1 (Container_Assy_No. 11)	1
18	AC527658	CS Reagent rack A-2 (Container_Assy_No. 12)	1
19	BU496600	CS Reagent rack A-3 (Container_Assy_No. 13)	1
20	AS961141	CS Reagent rack A-4 (Container_Assy_No. 14)	1
21	AY539778	CS Reagent rack A-5 (Container_Assy_No. 15)	1
22	BR673198	CS Reagent rack D-1 (Container_Assy_No. 21)	1
23	BQ339135	CS Reagent rack D-2 (Container_Assy_No. 22)	1
24	BH045576	CS Reagent rack D-3 (Container_Assy_No. 23)	1
25	BF780266	CS Reagent rack D-4 (Container_Assy_No. 24)	1
26	AM260869	CS Reagent rack D-5 (Container_Assy_No. 25)	1
27	073-1621-5	Tray No. 48 assembly	1
28	462-3010-1	Cuvette removal rod (hopper)	1
29	442-5430-3	Teflon 4.2×3.2 (L=330) (Cuvette removal rod (trash))	1
30	CR323182	Halogen lamp JB12V24WF6/SSM	1
31	CM095265	Filter NO. 513	1
32	AU666611	Filter NO. 514	2
33	CQ314797	Chute NO. 140	1
34	CF468084	Jig for wiping off (Jig No. 1104)	1

#### 3. Installation space

To ensure optimal instrument performance, install it at an appropriate location.

- Select a place that is close to the power supply and a suitable drain.
- Secure enough space that in an emergency you can cut off the power by unplugging the power cable.
- Giving consideration to heat radiation by the instrument, secure at least a 5 cm clearance between the wall and the instrument's rear panel. (The minimum clearance between the rear filter and the wall is 2 cm.)
- Giving consideration to maintenance, servicing and heat radiation by the instrument, secure at least a 30 cm clearance between the two sides and the wall.
- If an optional graphic printer is provided, additional desktop space is required. The instrument dimensions are shown below. The power cord is 1.8 m long.

Table 9-03: Dimensions of instrument units

	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
IPU Main Unit	Approx. 775	Approx. 865	Approx. 675	Approx. 100
Pneumatic Unit	Approx. 280	Approx. 355	Approx. 400	Approx. 17



#### Caution!

- Warm air is vented from the left side of the instrument. If you place cuvettes etc.
  on the left side of the instrument, warm air will be made to circulate inside the
  instrument, raising its recognition temperature above room temperature, and
  potentially causing abnormal temperature errors.
- Secure at least a 5 cm clearance between the instrument's rear panel and the wall. (The minimum clearance between the rear filter and the wall is 2 cm.) If the clearance between the rear panel and the wall is less than 5 cm, the intake of air from outside to the interior of the instrument through the rear panel will be inadequate, potentially causing abnormal temperature errors. It also encourages infiltration of air through the reagent table cover, so that if the reagents are left for long periods with their lids not closed, condensation or evaporation in the reagents could have an influence on data.

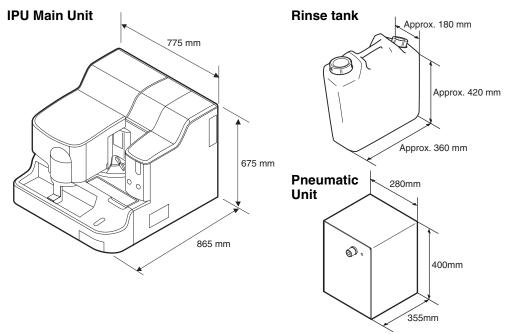


Figure 9-07: Dimensions of component units

# 4. Removing shipping clamps

Loosen the screws which fix the pneumatic unit.
 As shown in the figure, the Pneumatic Unit is fixed with two cross-slot head screws at the bottom.

Loosen the screws using a cross-slot screwdriver.

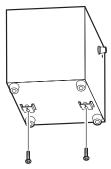


Figure 9-08: Removing the fixing materials for the Pneumatic Unit

2. Loosen the two screws and open the cuvette hopper cover.

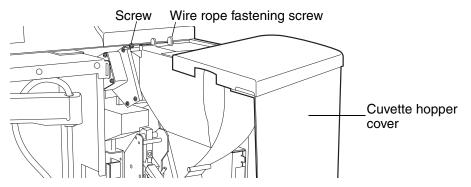


Figure 9-09: Removing the cuvette hopper cover

3. Open the light shield lid, loosen the two screws in the figure below, then remove Cover A.

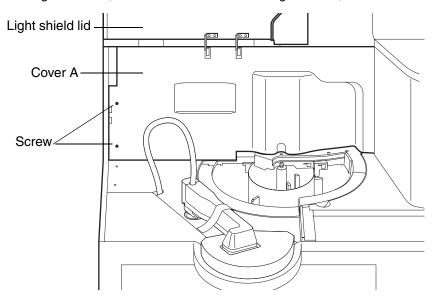


Figure 9-10: Removing the operating section internal cover



#### Warning!

- When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked. If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.
- When closing the light shield lid, take care to avoid pinching your fingers.



### Caution!

Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.

- 4. Remove the clamp first and then the fastener A (two pieces).
- 5. Peel off the two pieces of tape fastening the reagent arm, then lift up the reagent arm.
- 6. Remove the Fastener C.
- 7. Remove the tapes (from two places), then remove fasteners B (two places).

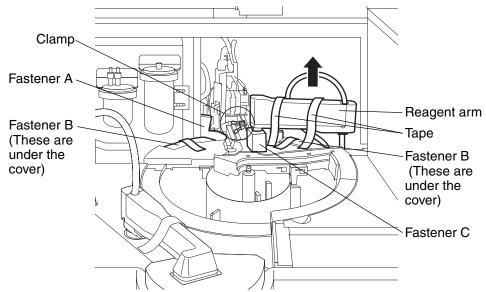


Figure 9-11: Removing Fasteners A, B and C

8. Open the dispensing table cover up, then remove Cover B.

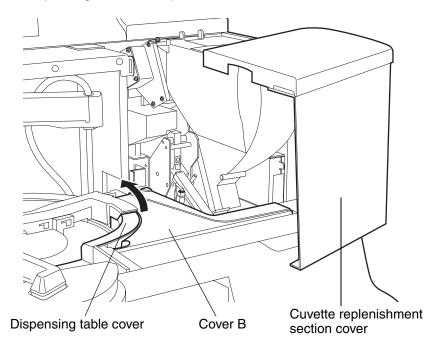


Figure 9-12: Removing Cover B

9. Remove the tape fastening the supply catcher section.

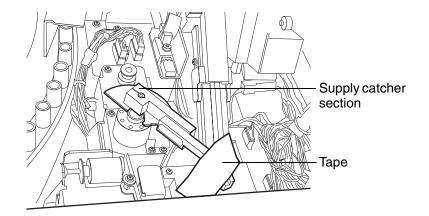


Figure 9-13: Removing the supply catcher section tape

10. Peel off the tape fastening the right side of the dispensing table.

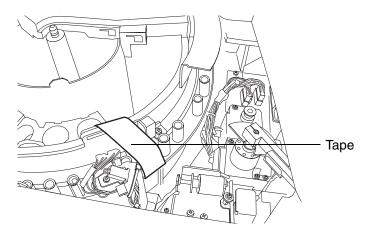


Figure 9-14: Removing the dispensing table section tape

11. Remove Fasteners D on the front of the dispensing table.

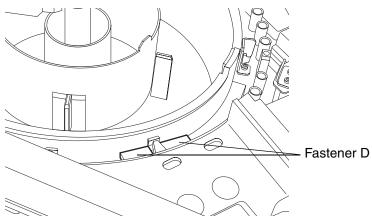


Figure 9-15: Removing Fastener D

- 12. Peel off the tape fastening the sample arm, then lift up the sample arm.
- 13. Remove Fastener E (at three points on the CS-2100i).

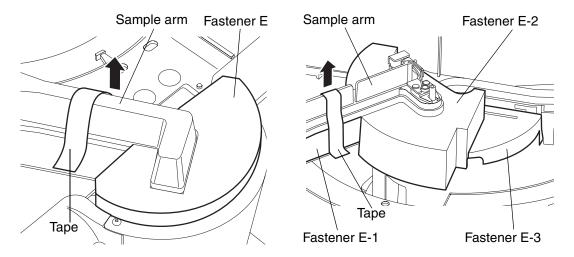


Figure 9-16: Removing Fastener E (CS-2000i) Figure 9-17: Removing Fastener E (CS-2100i)

14. Open the STAT/buffer table cover and remove Fastener F.

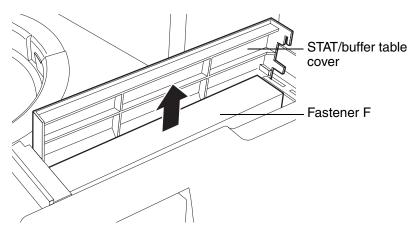


Figure 9-18: Removing Fastener F

15. Reversing Steps 15 through 2, install the removed covers to their original positions. When attaching the cuvette hopper cover, fasten the ends of the wire rope as shown in the diagram.

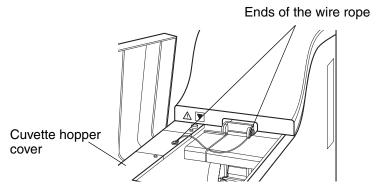


Figure 9-19: How to attach the wire rope

# 5. Attaching Chute NO.140

1. Place chute NO.140 on the guides of the cuvette trash tray, then push it all the way in.

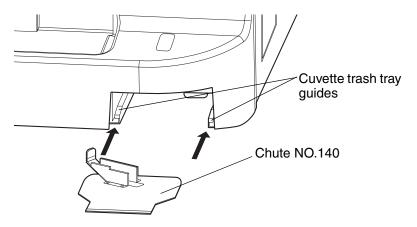


Figure 9-20: Inserting Chute NO.140

2. Lift the inner side of chute NO.140, so that it catches to the magnet above (It will be lifted up and make a "click" sound).

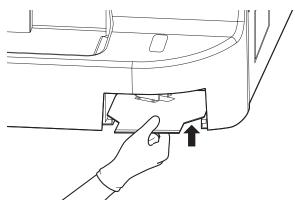


Figure 9-21: Attaching Chute NO.140

# 6. Setting the cuvette trash tray in place

Set the cuvette trash tray in place.

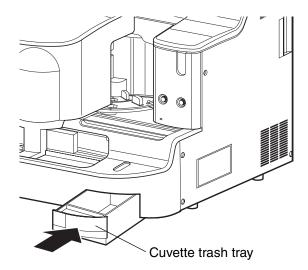


Figure 9-22: Setting the cuvette trash tray in place

# 7. Setting the filters and the holder

Set filter NO. 16A in place.
 Put between the instrument's bottom plate guides.

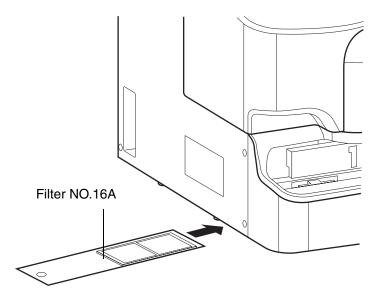


Figure 9-23: Setting filter NO.16A

2. Loosen the seven screws. Attach holder\_ASSY NO.28, then screw the screws back in to fasten it.

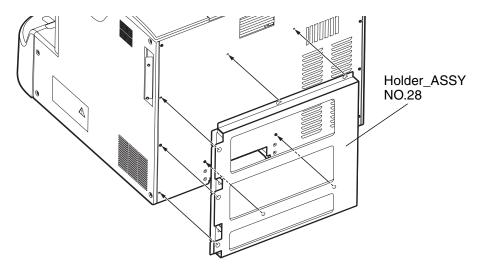


Figure 9-24: Setting Holder\_ASSY NO.28

3. Set filter NO.513 and filter NO.514.

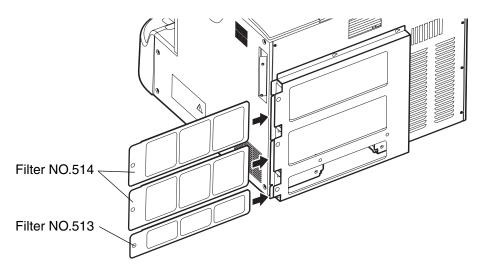


Figure 9-25: Setting filter NO.513 and filter NO.514

#### 8. Setting tray No.48

Set tray No.48 in the position shown in the diagram.

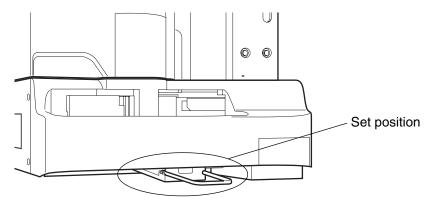


Figure 9-26: Tray No.48 set position

Align the position of the projection on the underside of the Main Unit and the notch on the tray to set the tray in place. Push the tray firmly all the way in.

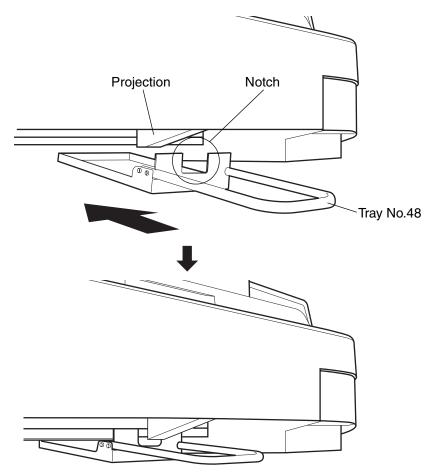


Figure 9-27: Setting tray No.48

# 9. Setting the reagent rack

Set the supplied reagent tracks.

1. Open the light shield and place the reagent rack (6 wells) between the table guides of reagent table A (outside). Place the racks to the inside of the device by turning the reagent table by hand to move it forward. Five racks can be installed.

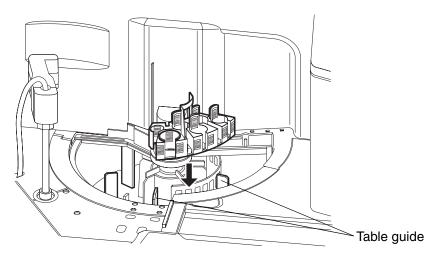


Figure 9-28: Setting the reagent rack (reagent table A)



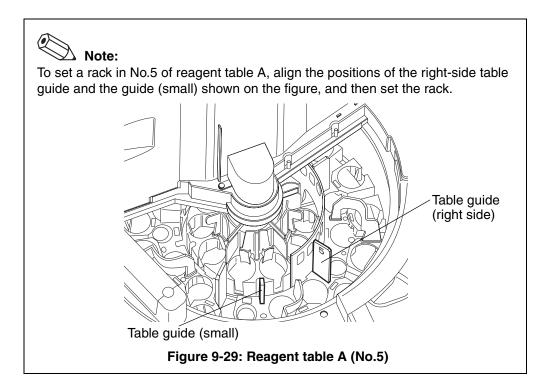
### Warning!

- When reaching into the inside of the instrument with the light shield lid open, always check that the retainer arm is locked. If it is not, the light shield lid could fall down, injuring the user's head or elsewhere.
- When closing the light shield lid, take care to avoid pinching your fingers.



### Caution!

Unlock the retainer arm before closing the light shield lid. If you try to close the light shield lid without unlocking it, the light shield lid could be damaged.



2. Place the reagent rack (2 wells) between the table guides of reagent table B (inside). Place the racks to the inside of the device by turning the reagent table by hand to move it forward. Five racks can be installed.

The reagent rack (2 wells) is used when it is necessary to add a reagent vial, usually the racks are left outside the device.

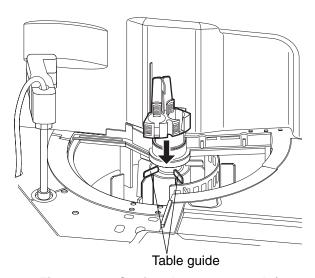


Figure 9-30: Setting the reagent rack (reagent table B)

3. Open the light shield lid and set the three reagent table covers in place.

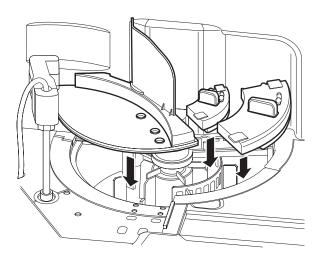


Figure 9-31: Setting the reagent table covers

Confirm that there is no space between the table and the rack after reagent rack placement.

#### 10. Connecting the rinse tank and waste tank

Connect the rinse tank and the waste tank.

The waste tank is optional. If no waste tank is attached, connect a suitable waste container or waste drainage equipment.

#### Connecting the rinse tank

- 1. Connect the rinse aspiration nipple to the rinse tank nipple with the polyurethane tube  $(6 \times 4)$  provided.
- 2. Connect the float switch cable to the float switch connector (Rns).

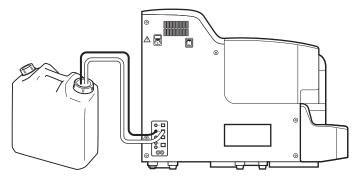


Figure 9-32: Connecting the rinse tank

# Connecting the drain tube

1. Connect the polyurethane tube provided  $(6 \times 4)$  to the waste outlet nipple and the silicon tube provided  $(6.5 \times 3)$  to the overflow waste line nipple. Connect these tubes to a drain or an optional waste tank.

#### Connecting the waste tank (Option)

1. Connect the float switch cable to the float switch connector (W).

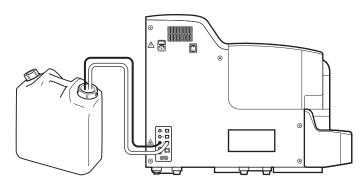


Figure 9-33: Connecting the waste tank



# Caution!

Make sure to connect a waste tank before turning ON the Main Unit power.

## 11. Connecting the power cord, IPU and connection cord

Connect the Pneumatic Unit to the Main Unit, then connect the power cord provided. When the output to the optional printers and host computer is desired, connect the instrument to each device with the connection cord.

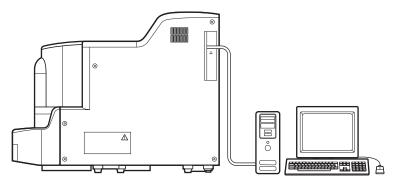


Figure 9-34: Connection with the IPU



#### Caution!

Use the power cord that comes with the instrument. Also, do not use it with any other instrument.

## Connecting the Main Unit, IPU and Pneumatic Unit

- 1. Make sure the power switches of the Main Unit and Power Unit are OFF. The power is OFF when the power switch "O" is pressed.
- 2. Use the cable provided to connect the IPU connector on the right side of the Main Unit and the connector on the back of the IPU.

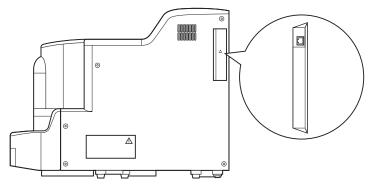


Figure 9-35: Connecting connectors

- 3. Connect the pressure outlet nipple marked "P" on the rear of the Pneumatic Unit and the nipple marked "P" on the left side of the Main Unit with a polyurethane tube (6x4).
- 4. Connect the pressure outlet nipple marked "V" on the rear of the Pneumatic Unit and the nipple marked "V" on the left side of the Main Unit with a polyurethane tube (6x4).

5. Connect the Pneumatic Unit control cord provided on the left side of the Pneumatic Unit to the connector on the left side of the Main Unit.

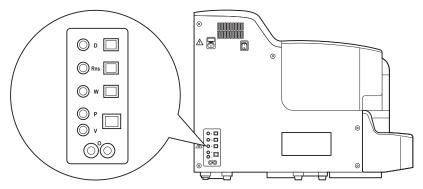


Figure 9-36: Connecting the Main Unit and Pneumatic Unit

## Connecting the power cord

Make sure the Main Unit power switch is OFF.
 The power is OFF when the power switch "O" is pressed.



## Caution!

Make sure the Main Unit power switch is OFF (in the "O" position), before connecting the power cord.

Otherwise, you could suffer an electric shock.

2. Connect the provided power cords to the power connector on the rear of the Pneumatic Unit and the left side of the Main Unit respectively.

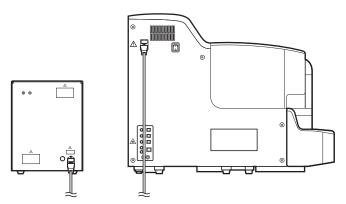


Figure 9-37: Connecting the power cord

3. Insert the provided power cord into a power supply outlet.

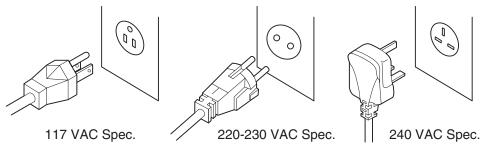


Figure 9-38: Connecting the power supply outlet



## Caution!

Always ground this instrument.

Inadequate grounding creates the danger of electrical shock.

## Connecting the host computer and printer

Make sure the power switch is OFF.
 The power is OFF when the power switch "O" is pressed.



## Caution!

Make sure the power switch is OFF ("O" is pressed), before routing the connection cord.

Otherwise, the unit may be damaged.

- 2. Connect with each device using connection cords.
- 3. Perform the necessary settings for the connected devices. See "Chapter 8 System Setup" in the Software Guide.

#### 12. Preparing racks

Affix the rack label marks and rack barcode labels on the sampler racks that come with this instrument.

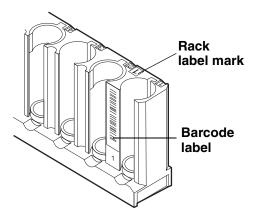


Figure 9-39: Affixing label marks and barcode labels



### Note:

In each rack, affix a label mark and

a rack barcode label with the same number (1-6).

Affix rack barcode labels aligned with the top edge of the rack.

Check that the correctly numbered label and mark are affixed to each rack.

## 13. Filling with rinse

Correct analysis is not possible unless the hydraulic line of the CS-2000*i*/CS-2100*i* has enough rinse. Prime the rinse inside the hydraulic line, as follows.

- 1. Replenish the rinse tank with rinse (distilled water).
- 2. Turn the power switch ON in the order IPU, then Main Unit.
  The power is ON when the power switch "|" is pressed.
  When the power is turned ON, the IPU screen displays the Login screen.
- 3. Enter the logon name and password and press OK.
- 4. The self check is performed and programs loaded, then the Menu screen appears.
- Select Maint. on the Menu screen. The Maintenance screen will be displayed.
- 6. Press **Prime** on the Maintenance screen. The Confirmation dialog box will appear.
- 7. Press OK.

Water supply begins and the Executing dialog box appears.

## 9.5 ID barcode specifications

## 1. Acceptable barcode

The types of barcode acceptable to the instrument and the check digit(s) are listed below.



## Warning!

Use the check digit as much as possible.

If the check digit cannot be used, the potential of the incorrect reading of the barcode label may be increased.

## (1) Sample ID No.

Table 9-04: Barcode and check digit

Type of barcode	Check digit	No. of digits		
ITF	Not Used	1-15 digits (Sample ID No.)		
	Modulus 10	1-15 digits (Sample ID No.) +1 digit (Check digit) =16 digits Max.		
NW-7	Not Used	1-15 digits (Sample ID No.)		
(CODABAR)*	Modulus 11	1-15 digits (Sample ID No.)		
	W.Modulus 11	+1 digit (Check digit) =16 digits Max.		
	Modulus 16			
CODE-39	Not Used	1-15 digits (Sample ID No.)		
	Modulus 43	1-15 digits (Sample ID No.) +1 digit (Check digit) =16 digits Max.		
JAN-13	Modulus 10	12 digits (Sample ID No.) +1 digit (Check digit) =13 digits		
JAN-8	Modulus 10	7 digits (Sample ID No.) +1 digit (Check digit) = 8 digits		
CODE-128	Modulus 103	1-15 digits (Sample ID No.) +1 digit (Check digit) = 16 digits Max.		
ISBT128	Modulus 103	"=" or "&" + 13 digits (Sample ID No.) +1 digit (Check digit) =15 digits		

<sup>\*</sup> As the Start and Stop codes, use one of the characters "A", "B", "C", "a", "b" and "c".

## (2) QC File No.

QC File No. can be read if printed with CODE-39 or CODE-128.

Table 9-05: Barcode and check digit

Type of barcode	Check digit	No. of digits (File No.)	No. of digits for check digit
CODE-39	Either of "Use" or "Not Use"	4 digits "QC01", "QC02", "QC20"	Not Used or 1 digit
CODE-128	"Use"	4 digits "QC01", "QC02", "QC20"	1 digit

## (3) Rack No.

Table 9-6: Barcode and check digit

Type of barcode	Check digit	No. of digits
NW-7 (CODABAR)*	Modulus 16	6 digits (Rack No.) +1 digit (Check digit) = 7 digits
CODE-39	Modulus 43	6 digits (Rack No.) +1 digit (Check digit) = 7 digits

<sup>\*</sup> As the Start and Stop codes, use one of the characters "D" and "d".

#### 2. Dimension of barcode elements

Narrow element  $\geq$  200  $\mu m$ 

Wide element ≤ 1.2 mm

Narrow element ≤ Gap between characters ≤ Wide element

#### 3. Narrow/wide ratio

For each character, the wide element to narrow element ratio must comply with the following:

Narrow (Max.): Wide (Min.) = 1: 2.2 or more Narrow (Min.): Narrow (Max.) = 1: 1.3 or less Wide (Min.): Wide (Max.) = 1: 1.4 or less

## 4. PCS (Print contrast signal)

Standard: PCS value ≥ 0.45

## 5. Reflection characteristics of label surface

A laminated label cannot be read.

#### 6. Irregularity and roughness of printing

When a bar element is magnified by a microscope, the following may be observed.

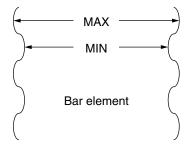


Figure 9-40: Magnified bar

When the variation coefficient (S) in the width of a bar is defined:

$$S = \frac{MAX - MIN}{MAX} \times 100\%$$

Then the variation coefficient (S) must be 20 % or less.

#### 7. Dimensions of barcode label

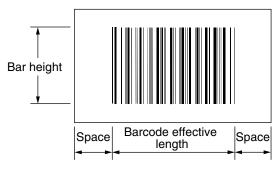


Figure 9-41: Barcode label

Space : 5 mm or more

Barcode effective length: 48 mm or less (Optimum: 40 mm or less)

Bar height : 20 mm or more (Rack label height: 6 mm or more)

## 8. Check digit

To improve the reliability of an ID No. read, check digit(s) can be added. This section explains how to calculate the check digit for modulus 10/weight 3, modulus 11, weighted modulus 11, modulus 16, modulus 43 and modulus 103.

#### (1) Modulus 10/Weight 3

This Modulus 10/Weight 3 method is used in the bar code symbology such as JAN, NW-7 and ITF (Interleaved 2 of 5). The check digit computation method is shown as follows;

- [1] The least significant digit (most right digit) and all digits that occur on the odd position from right to left within the data digits are defined as odd digits. All the digits are divided into two groups, odd digits and even digits.
- [2] Add all odd digits. Multiply the sum by 3.
- [3] Add all even digits.
- [4] Add the result of [2] and result of [3] above.
- [5] Subtract the foremost (least significant) digit from 10 to obtain the check digit. In case of the ITF, the total number of the digits must be an even number. In such case, add "0" to the most significant digit (most left digit).

## Example No. 1:

Calculation of the check digit for the JAN code 4912345 (7 digits) is shown below:

[1] Add odd digits (counted from the least significant digit):

$$5 + 3 + 1 + 4 = 13$$
.

Multiply the sum by 3, as: 
$$13 \times 3 = 39$$

- [2] Add even digits: 4 + 2 + 9 = 15
- [3] Add the results of [1] and [2] above, as: 39 + 15 = 54
- [4] Check digit is obtained by subtracting the most right digit of the sum of [3] above from

10 as: 
$$10 - 4 = 6$$

Hence the check digit is 6.

## Example No. 2:

Calculation of the check digit for the ITF code 524362 (6 digits) is shown below:

- [1] Add odd digits: 2 + 3 + 2 = 7. Multiply the sum by 3, as:  $7 \times 3 = 21$
- [2] Add even digits: 6 + 4 + 5 = 15
- [3] Add the results of [1] and [2] above, as: 21+15 = 36
- [4] Obtain the check digit as: 10 6 = 4

Hence the check digit is 4.

However, in Example No. 2, the sum of the total number of the data digits and the checkdigit gives an odd number 7 in this case. Therefore, "0" is added to the most significant digit (most left digit) and check digit is appended to the data, as 05243624.

## (2) Modulus 11

The following example uses the sample ID No. 258416.

[1] Each digit is weighted:

[2] Add up the multiplied results as given below:

$$S = 14 + 30 + 40 + 16 + 3 + 12 = 115$$

[3] When S is divided by 11, calculate the remainder and obtain the complement of the remainder. This complement will be the check digit.

$$115 \div 11 = 10$$
 with remainder 5

$$11 - 5 = 6$$
, thus the check digit is 6.

However, all English symbols except the numerals of 0 - 9 are regarded as 0 in making the calculation. Also, when S is divisible by 11 with remainder 0 and when calculation of the check digit results in 10, zero is entered as the check digit.

### (3) Weighted Modulus 11

Weighted modulus 11 has two sets of weight. When the check digit is computed to 10 as a result of applying the first weight set, the second weight set is applied. The result should always be between 0 and 9. The calculation method is exactly the same as modulus 11 except for the difference in weighting.

The following example uses the sample ID No. 258416.

[1] Weighing each digit.

Weight:	W12	W11	W10	W9	W8	W7	W6	W5	W4	W3	W2	W1
First Set:	6	3	5	9	10	7	8	4	5	3	6	2
Second Set:	5	8	6	2	10	4	3	7	6	8	5	9
	2	5	8	4	1	6						
	×	×	×	×	×	×						
Weight	8	4	5	3	6	2						
	16	20	40	12	6	12						

[2] Add up the multiplied results as given below:

$$S = 16 + 20 + 40 + 12 + 6 + 12 = 106$$

[3] When S is divided by 11, calculate the remainder and obtain the complement of the remainder. This complement will be the check digit.

 $106 \div 11 = 9$  with remainder 7

11 - 7 = 4, thus the check digit is 4.

However, all English symbols except the numerals of 0 - 9 are regarded as 0 in making the calculation. Also, when S is divisible by 11 with remainder 0 and when calculation of the check digit results in 10, zero is entered as the check digit.



#### Note:

Weight for the 13th to 15th digits is assumed to be 0.

#### (4) Modulus 16

Modulus 16 is the check-digit computation method used in the NW-7 and CODABAR symbologies. Since the NW-7 and CODABAR symbologies use 4 kinds of start/stop codes, these start/stop codes are computed from the data digits. The following example uses the ID number D998147D.

[1] Add the values of all the data characters including the start and stop codes. The numerical value of each of the data character is given below:

Character	Value	Character	Value	Character	Value
0	0	7	7	•	14
1	1	8	8	+	15
2	2	9	9	Α	16
3	3	-	10	В	17
4	4	\$	11	С	18
5	5	:	12	D	19
6	6	/	13		

Table 9-7: Numerical value assignments for computing the modulus 16 check character

Sum = 19 + 9 + 9 + 8 + 1 + 4 + 7 + 19 = 76

[2] Divide the sum by 16 and get the remainder. Then subtract the remainder from 16. The result is the check digit. When the remainder is 0, check digit becomes 16. In such a case set the check digit to "0".

 $76 \div 16 = 4$  with remainder 12,

16 - 12 = 4

Hence the check digit is 4.

- [3] This check digit is appended to the left of the stop code in the ID number; the bar code label is now D9981474D.
- [4] When the ID Reader reads this bar code label, the instrument computes the check digit and recognizes the read as a valid read if the remainder is 0.

## (5) Modulus 43

Modulus 43 is the check digit computation method used in CODE-39 symbology. A value is assigned to each of the 43 characters. All characters are converted into the value and computed. The following example uses the ID number 258-416.

[1] Add the values of all the data characters. The numerical value of each of the data characters is given below:

Table 9-8: Numerical value assignments for computing the modulus 43 check character

Character	Value	Character	Value	Character	Value
0	0	F	15	U	30
1	1	G	16	V	31
2	2	Н	17	W	32
3	3	1	18	Х	33
4	4	J	19	Y	34
5	5	К	20	Z	35
6	6	L	21	-	36
7	7	М	22		37
8	8	N	23	(Space)	38
9	9	0	24	\$	39
А	10	Р	25	/	40
В	11	Q	26	+	41
С	12	R	27	%	42
D	13	S	28		
Е	14	T	29		

Sum = 
$$2 + 5 + 8 + 36 + 4 + 1 + 6 = 62$$

- [2] Divide the sum by 43 and get the remainder.  $62 \div 43 = 1$  with remainder 19
- [3] Find the check-character. The check-character is that character whose value is equal to the remainder. In this example, the letter "J" has the value of 19 which is equal to the remainder. Therefore "J" is the check-character.
- [4] This check-character is appended to the ID number, after the least significant digit. The bar-code label is now "258-416J".

(6) Modulus 103

Modulus 103 is the check-digit computation method used in the CODE-128 symbology.

CODE-128 takes three different character table depending on the start code. Each of 128 characters is assigned a value as shown in the following table. All characters are then converted to their corresponding values and computed.

- [1] All characters except the stop code are converted to their corresponding values according to the table.
- [2] The first character, such as "Start (Code A)", indicates that the Code A set is used until other code set is specified. Multiply the most significant digit by 1, multiply the second digit by 2, multiply the third digit by 3, and so on.
- [3] Add all the products. Then, divide the sum by 103. To obtain a check digit, convert the remainder to the corresponding character in the table.

The following example uses the ID number Start (Code A) 123-4567.

[1] Convert each character into values using Code A set, and multiply by the weight.

```
Start (Code A) 103 = 103
```

- $1 \quad 17 \times 1 = 17$
- $218 \times 2 = 36$
- $3 19 \times 3 = 57$
- $-13 \times 4 = 52$
- $4 20 \times 5 = 100$
- $5 21 \times 6 = 126$
- $6 22 \times 7 = 154$
- $7 \quad 23 \times 8 = 184$
- [2] The sum of the products is 829.
- [3] This sum is divided by 103 as;  $829 \div 103 = 8$  with remainder 5.
- [4] The corresponding character for the value 5 is %. Hence the check digit is %.

Table 9-9: Numerical value assignments for computing the modulus 103 check character

Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
0	(space)	(space)	00	53	U	U	53
1	!	!	01	54	V	V	54
2	"	"	02	55	W	W	55
3	#	#	03	56	Х	Х	56
4	\$	\$	04	57	Y	Y	57
5	%	%	05	58	Z	Z	58
6	&	&	06	59	[	[	59
7	,	,	07	60	\	\	60
8	(	(	08	61	]	]	61
9	)	)	09	62	^	^	62
10	*	*	10	63	_	-	63
11	+	+	11	64	NUL	,	64
12	,	,	12	65	SOH	а	65
13	-	-	13	66	STX	b	66
14			14	67	ETX	С	67
15	/	/	15	68	EOT	d	68
16	0	0	16	69	ENQ	е	69
17	1	1	17	70	ACK	f	70
18	2	2	18	71	BEL	g	71
19	3	3	19	72	BS	h	72
20	4	4	20	73	HT	i	73
21	5	5	21	74	LF	j	74
22	6	6	22	75	VT	k	75
23	7	7	23	76	FF	ı	76
24	8	8	24	77	CR	m	77
25	9	9	25	78	SO	n	78
26	:	:	26	79	SI	0	79
27	;	;	27	80	DLE	р	80
28	<	<	28	81	DC1	q	81
29	=	=	29	82	DC2	r	82
30 31	> ?	> ?	30 31	83 84	DC3 DC4	s t	83 84
32	@	@	32	85	NAK		85
33	A	A	33	86	SYN	u v	86
34	В	В	34	87	ETB	W	87
35	С	С	35	88	CAN	X	88
36	D	D	36	89	EM		89
37	E	E	37	90	SUB	y z	90
38	F	F	38	91	ESC	{ -	91
39	G	G	39	92	FS		92
40	H	H	40	93	GS	}	93
41	I	1	41	94	RS	~	94
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44	L	L	44	97	FNC2	FNC2	97
45	М	М	45	98	SHIFT	SHIFT	98
46	N	N	46	99	CODE C	CODE C	99
47	0	0	47	100	CODE B	FNC4	CODE B
48	Р	Р	48	101	FNC4	CODE A	CODE A
49	Q	Q	49	102	FNC1	FNC1	FNC1
50	R	R	50	103	S	TART (Code	A)
51	S	S	51	104	START (Code B)		
52	Т	Т	52	105	S	TART (Code	C)
						STOP	

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