AUTOMATED ENZYME IMMUNOASSAY SYSTEM

AIA-360

Operator's Manual

Revision. 17

Thank you for purchasing the AUTOMATED ENZYME IMMUNOASSAY SYSTEM AIA-360.
You are recommended to read carefully and familiarize yourselves with the information provided in this manual to ensure safe and correct operation of the system.

TOSOH CORPORATION
BIOSCIENCE DIVISION

Safety Precautions

Preface

It is recommended that you read carefully and familiarize yourselves with the following safety precautions in order to ensure safe and correct operation of the AIA-360 analyzer. The information displayed with the "Warning" and "Caution" signs in this manual is provided for the purposes defined below.

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

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

Precautions for Installation

Warning

- Connect System to Suitable Power Source
  - Make sure to connect the AIA-360 analyzer to a power source that has ample capacity and is free of significant voltage fluctuations.
  - Power sources with insufficient capacity or significant fluctuations in voltage pose a potential fire hazard.

- Carefully Check Ground Connections
  - Failure to properly ground the system is a potential source of electrical shock.
  - Make sure to connect the system to a three-pronged power socket.
  - Grounding the system helps to prevent system malfunctions due to noise as well as prevent electrical shock.
  - Do not connect the system ground line to gas pipes, water pipes, lightning rod lines or the telephone system ground line.
    - Gas pipes can ignite fires and cause explosions
    - Water pipes are not an effective ground
    - Lightning rods and telephone lines are a potential source of danger when lightning strikes

Safety Precautions

⚠ Caution

- Select Installation Site with Care
  - Refer to section “System Installation” in this manual and select a suitable site for installation of the AIA-360 system. Always contact Tosoh local representatives whenever installing or moving the AIA-360 system.

- Avoid Altering Power Cables, Using Under-Capacity Extensions and Branch Connecting from Power Outlets
  - These are potential sources of electrical shock or even fire.
  - Always select extension cables that have sufficient capacity and a ground line.

- Confirm Plug is Free of Dust or Dirt and Insert Firmly Into Socket
  - Make sure to remove and inspect the power plug several times a year.
  - Contamination from dust or foreign matter, failure to fully insert into socket or a loose socket may result in electrical shock or even fire.

Precautions for Use

⚠ Warning

- Handling Biohazards With Care

  - Only personnel with sufficient knowledge of immunological assay techniques and the procedures for handling infectious waste materials should be allowed to operate the AIA-360 system.
  - There is always the possibility that human sera have been contaminated with infectious agents. Mistakes in system operation and handling of such materials can transmit infectious agents to personnel in the general vicinity, as well as to the system operator. It is recommended that all specimens be handled with the utmost care and that the proper protective gear (goggles, gloves, masks etc.) be used at all times during maintenance procedures.
  - All specimen containers, including used reagent cups, reagent bottles, sample tips, reagent bottles, sample cups and waste fluids, have been exposed to human sera. It is recommended that proper protective gear (goggles, gloves, masks etc.) be worn at all times and that waste materials be disposed of in accordance with your area’s directive and the relevant laws and regulations in order to protect all personnel in the general operating vicinity and the surrounding environment.

  Opening covers or panels during operation may result in personal injury, such as lacerations or even the severing of fingers or hands if they are caught in such moving parts such as the dispense arm.

- Avoid Opening Covers or Panels During Assay Operations
  - Opening covers or panels during operation may result in personal injury, such as lacerations or even the severing of fingers or hands if they are caught in such moving parts such as the dispense arm.

⚠ Caution

- Operate Only in Accordance with Procedures Described in the Manual
  - Attempts to operate the AIA-360 using procedures not specified in this manual may affect the integrity of assay results and cause system malfunction.

- Preventing Leakage of Fluids
  - Leakages of assay solutions and wash solutions are potential sources of corrosion, electrical shock or even fire.
  - When fluid leakage is discovered, immediately shut down system operation and remove the power plug. It is recommended that proper protective wear (goggles, gloves, masks etc.) be worn at all times when cleaning up the leakage and inspecting and repairing the tubing connections that may be the source of the leak.
  - Should the system continue to leak, contact Tosoh local representatives.

- Immediately Shut Down System and Remove Power Plug When Signs of Malfunction (Burnt Odors, Etc.) Appear. Contact Tosoh Local Representatives.
  - Continuing to operate the system while it is malfunctioning may result in electrical shock and even fire.

- Avoid Opening Covers or Panels and Inserting Fingers or Rods into Operating Mechanisms.
  - The interior of the system is comprised of motor driven components operating at high speeds. Foreign objects or fingers and hands can easily be caught in the mechanisms, resulting in personal injury.

- Keep Covers and Doors Closed During Operation
  - Keep all covers and doors firmly closed during operation. The interior of the AIA-360 contains various moving parts, high-temperature components and high-voltage circuitry. Fingers and hands can easily get pinched or tangled in the mechanisms, resulting in lacerations, burns and electrical shock.
  - Special precautions must be taken when opening doors to replenish supplies of reagents and sample cups during system operation.

- Avoid Stopping and Starting System by Simply Inserting and Removing the Power Plug
  - This may cause electrical shocks or even fires.
  - Whenever shutting down the system, press the power supply switch located at the rear left of the system.

- Avoid Damaging the Power Supply Cable
  - Excessive pulling and bending or anchoring the cable into place may damage it, resulting in electrical shock or even fire.
  - Always take firm hold of the plug when removing the power cable.

- Do Not Replace Fuses Yourself
  - Always contact the nearest Tosoh local representatives when replacing the fuses installed on the various system circuit boards. Do not attempt to replace fuses yourself.
  - Burnt out fuses can indicate failures in electrical circuits caused by fluid leakage. Thus it is important to contact the Tosoh local representatives.

Safety Precautions

⚠ Caution

- Avoid Touching System Parts with Wet Hands
  - Touching certain system components may result in electrical shock.

- Used Only Trained Maintenance Personnel
  - Maintenance work must be performed by personnel with proper knowledge of system maintenance procedures and equipped with the proper protective gear (goggles, gloves, masks etc.). Physical injury incurred during maintenance can result in infection from specimens. Therefore, it is important that maintenance personnel perform their work in accordance with procedures outlined in this manual and only after they have received sufficient training in maintenance procedures.
  - Feel free to contact the Tosoh local representatives for information on maintenance procedures.

- Properly Disposing of Waste Materials
  - Take appropriate steps to separate all used materials from assay operations, including reagent cups, sample tips, reagent bottles, sample cups, specimen containers and waste fluids, according to the type of waste, and dispose of them in accordance with designated procedure. Always wear protective gloves to avoid direct contact with such materials. Waste materials must be disposed of in accordance with your area's directive and the relevant laws and regulations in order to protect all personnel in the general system vicinity and the surrounding environment.

- Always Wear Protective Gear
  - Make sure to wear the required protective gear (goggles, gloves, masks etc.) to prevent infection when working with specimens, waste fluids and the accessories used for system calibration.

- Place Fluid Containers in Their Designated Locations
  - Placing solution containers randomly in the main unit may result in spillage causing short-circuits that will damage electrical insulation and result in electrical shock.

- Inspect all specimens for air bubbles and foaming. Remove any air bubbles prior to analysis.
  - The liquid surface detection automatically performed on every specimen by the instrument is susceptible to bubbles or foaming. The instrument may detect the bubble as the liquid surface.
    Do not run samples which contain bubbles or foam. Make sure to remove any air bubbles prior to analysis regardless of their size.

- Use Only Tosoh Designated Components
  - Use only those accessories and expendables (supplies) listed in the Maintenance Accessories and Expendables section.

⚠ Warning

- At system shutdown, replace the substrate solution remaining in the substrate line with substrate replacement solution (70 % ethanol or 70 % isopropyl alcohol)
  - If the substrate solution remains in the substrate line for a long time, it may precipitate. Precipitation in the substrate line may clog the substrate line. Replacement of the substrate solution with distilled water may cause contamination of the substrate line and raise the substrate background.
    Make sure to use the substrate replacement solution (70 % ethanol or 70 % isopropyl alcohol) at system shutdown.

- Avoid Placing any Source of Flame Near the Substrate Compartment
  - It is important not to place any sources of flame near the Substrate compartment, as the Substrate line contains 70 % ethanol or 70 % isopropyl alcohol at the end of an assay operation.

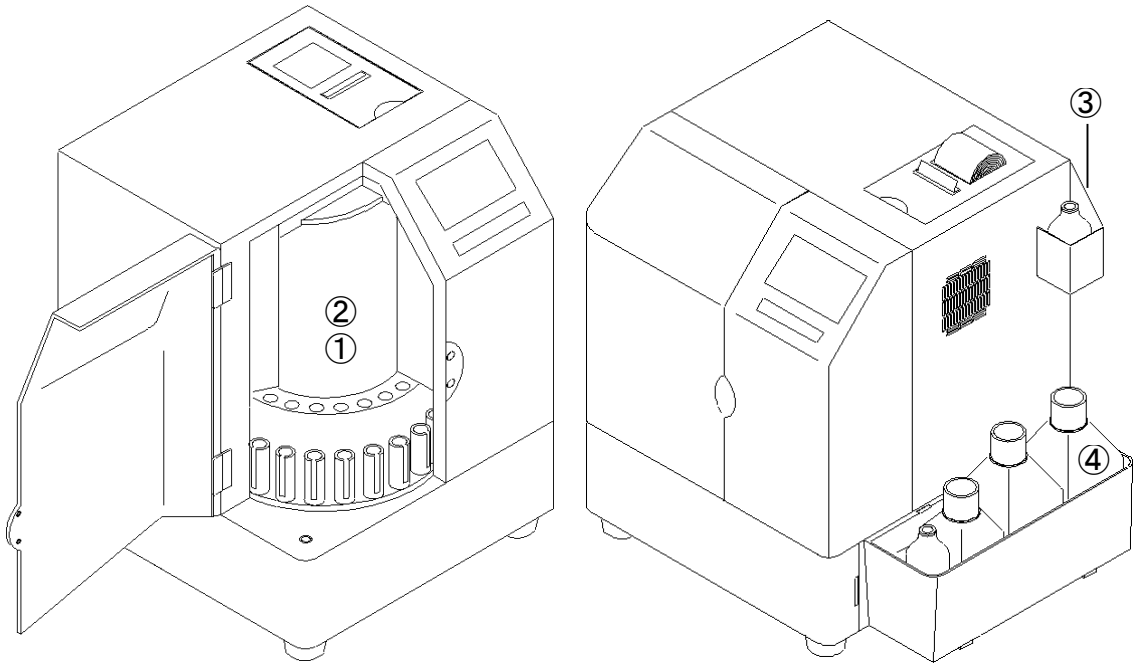
- Avoid Opening the Specimen Door During STAT (Priority) Sampling
  - When the STAT door lamp is red it indicates a sampling operation is in progress. Forcing the door open will damage the sampling nozzle and affect the integrity of assay results.

Removal of equipment from use for repair or disposal

- Contact the authorized representative
  - Blood to be tested might have been infected by pathogens. Misconduct on repair or disposal may bring infection to the operator or others working together. In the case of repairing and disposing, please contact the authorized representative.

Additional Precautions

- Locations of "Warning" and "Caution" Labels
  - Warning labels are provided at various locations on the AIA-360 system. Read these carefully to ensure safe system operation.



① Specimen Loading Location Warning Label

A red lamp comes on 10 seconds prior to start of rotation. Avoid adding or removing specimens or reagents when lamp is flashing, as hands or fingers may get caught in the mechanisms.

Safety Precautions

② Uncap Primary Tubes Warning Label

Please be sure to remove the cap of the primary tubes prior to placing on the carousel.
Operation will damage the parts in the AIA-360 when caps are not removed from the primary tubes.

③ Substrate Bottle Compartment Warning Label

It is important not to place any sources of flame near the substrate compartment, as the substrate line is composed of 70 % ethanol or 70 % isopropyl alcohol at the end of an assay operation and there is danger it may catch fire.

④ Waste Bottle and Contaminated Sera Caution Label

Note that the waste bottles are contaminated from sampled specimen. It is recommended that proper protective gear (gloves, etc.) be worn at all times when handling waste materials in an effort prevent contamination.

- Contact a Tosoh local representatives if the Warning or Caution labels become difficult to read due to peeling or becoming dirty. Replacement labels will be sent.
- Always store this manual in a safe and convenient place and make sure that it is passed on to any new person in charge.

Always Have Servicing Done by Tosoh Personnel

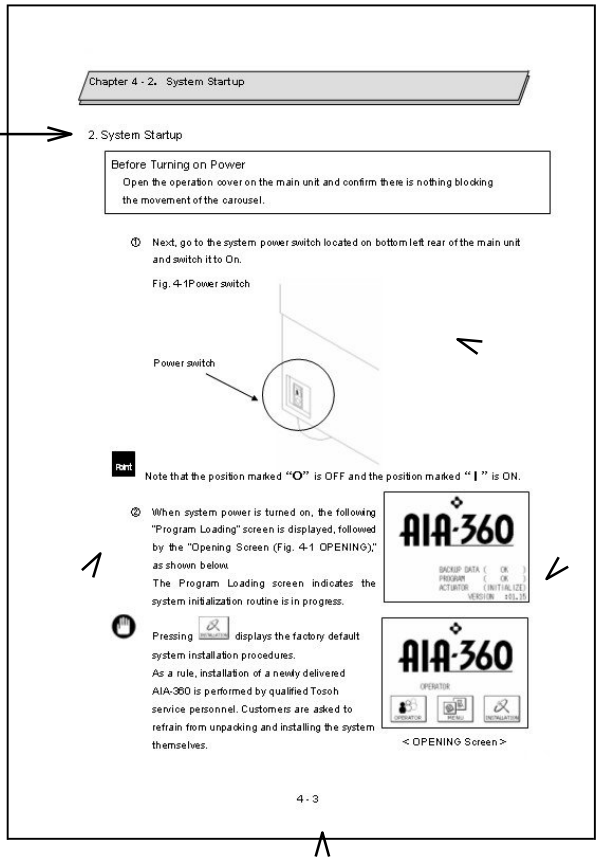
・ Attempts to disassemble, repair or modify the AIA-360 yourself may result in electrical shocks and even fires.

TOSOH CORPORATION
BIOSCIENCE DIVISION

How to Use This Manual

This system Operator's Manual is designed to ensure you will have the information you need to use and operate the AIA-360 system safely and correctly.
The AIA-360 manual is organized according to the layout shown below. Use this as a reference when reading this manual.

Section Headings
Sections are divided into to 3 subsections.


Chapter 4 - 2. System Startup

2. System Startup

Before Turning on Power
Open the operation cover on the main unit and confirm there is nothing blocking the movement of the carousel.

① Next, go to the system power switch located on bottom left rear of the main unit and switch it to On.

Fig. 4-1Power switch

Power switch

Point Note that the position marked "O" is OFF and the position marked "|" is ON.

② When system power is turned on, the following "Program Loading" screen is displayed, followed by the "Opening Screen (Fig. 4-1 OPENING)," as shown below.
The Program Loading screen indicates the system initialization routine is in progress.

Pressing displays the factory default system installation procedures.
As a rule, installation of a newly delivered AIA-360 is performed by qualified Tosoh service personnel. Customers are asked to refrain from unpacking and installing the system themselves.

< OPENING Screen >

4 - 3

Illustrations and Menu Screens
Combine with text to provide precise explanations.

Page
numbering is organized by chapter

Point Key Points provide helpful hints for mastering system operation.

Stop signs warn the potential operational mistakes.

Contents

Chapter 1: Introduction

Chapter 2: Installation

Chapter 3: Name of Parts and Functions on Main Unit

Chapter 4: Preparing System for Assay Operations

Chapter 5: Calibration

Chapter 6: Assay Procedures

Chapter 7: Error Messages and Flags

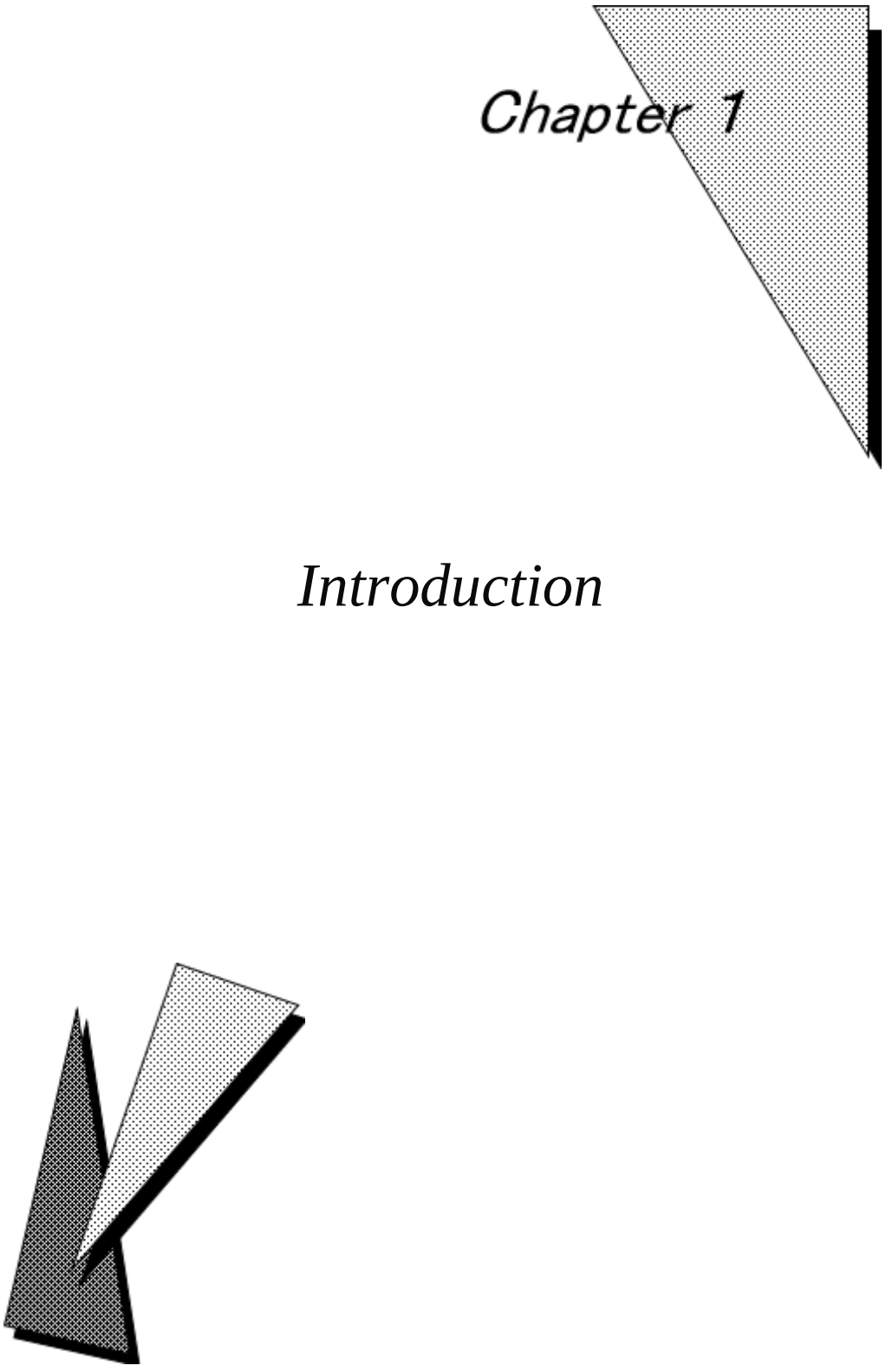
Chapter 8: Shut Down Operation (Shut Down Menu)

Chapter 9: Other Functions in SPECIAL MENU

Chapter 10: Daily Maintenance Procedures

Chapter 11: Consumable Supplies/Optional Parts

Chapter 12: Appendix



Introduction

Chapter 1: Introduction

Thank you for purchasing the AUTOMATED ENZYME IMMUNOASSAY SYSTEM AIA-360. This operator's manual provides a detailed description of the system configuration and operating procedures for the AIA-360. You are recommended to read carefully and familiarize yourselves with the information provided in this manual before commencing operation of the system.

Intended Use

The AUTOMATED ENZYME IMMUNOASSAY SYSTEM AIA-360 is an automated analyzer that measures a variety of substances in serum, plasma, and urine using the AIA-PACK reagent series.

Assay Principles

The AIA-360 is capable of performing two methods of immunoassay: an immunoenzymetric (IEMA) or sandwich immunoassay and a competitive binding (EIA) immunoassay.

An antigen-antibody reaction begins by combining a patient sample, control, or calibrator with a diluent in an immunoreaction test cup from the AIA-PACK reagent series. In the IEMA assay, during the incubation period, the antibodies attach to two distinct epitopes on the antigen being measured forming a sandwich. In the EIA assay, during incubation, antigen in the patient sample competes with enzyme labeled antigen for a limited number of antibody binding sites. In all methods, specimens are incubated at 37 °C with antibody bound to the surface of magnetic beads. Separation of the bound antibody from the free antibody is achieved by washing the beads with a wash solution that removes any unbound conjugates. After washing, a substrate, 4-methylumbelliferyl phosphate (4- MUP), is added to the test cup. The remaining enzyme activity on the solid phase (magnetic beads) is then measured using fluorescent rate method. Figure 1.1a illustrates the reaction scheme used on the AIA-360. Figure 1.1b illustrates the Assay Principles used on the AIA-360.

Chapter 1: Introduction

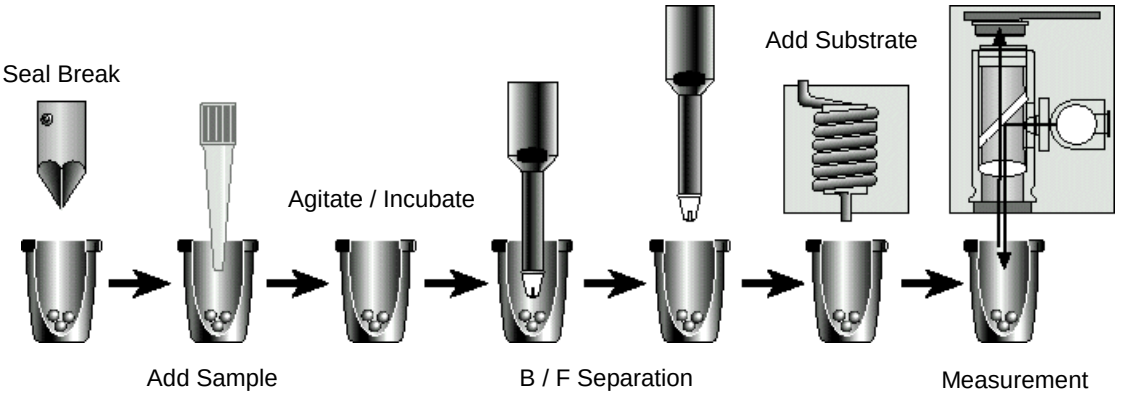


Figure 1.1a AIA-Systems Reaction Scheme

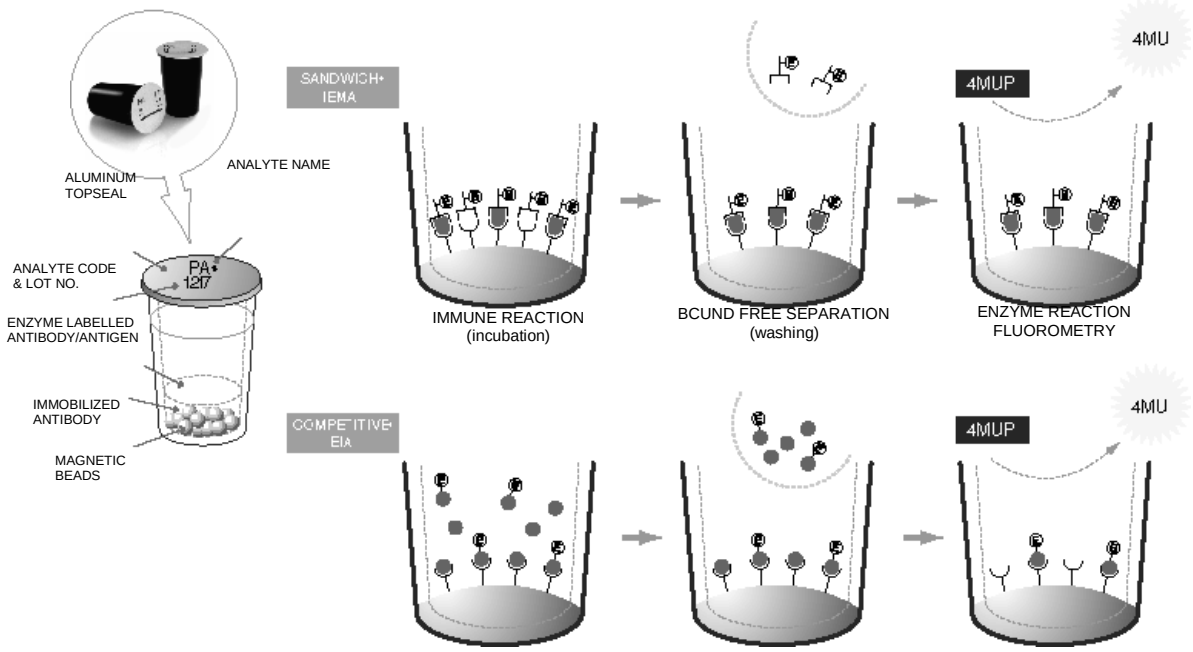


Figure 1.1b AIA-Systems Assay

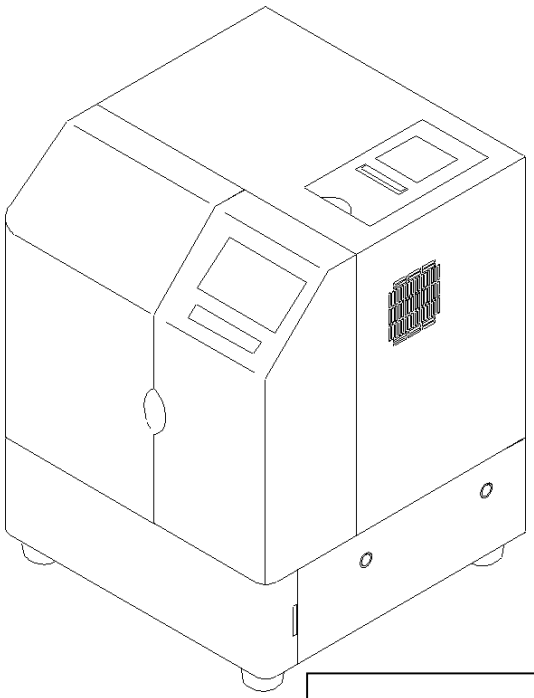
Chapter 1－1. System Outline

1. System Outline

The AIA-360 is designed with a very compact footprint, enabling it to serve as a desktop unit.

While the specimens and reagents used with the AIA-360 must be manually prepared, after sample loading, all processes prior to the assay results and system output are fully automated. The system is capable of performing up to 36 tests per hour. The first test results appear approximately 20 minutes after the assay operation commences. New assay operations can be added, even after assaying has begun. Up to four assay operations can be performed for each specimen.

Fig. 1-1 Overview of Main Unit

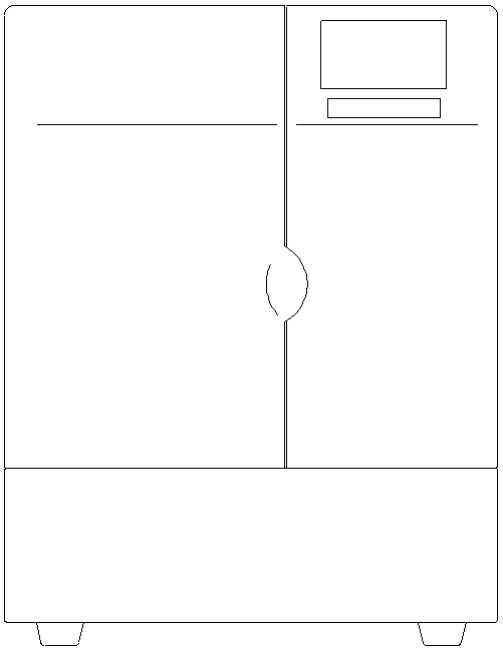


AUTOMATED ENZYME IMMUNOASSAY SYSTEM
AIA-360（For in vitro diagnostic use）

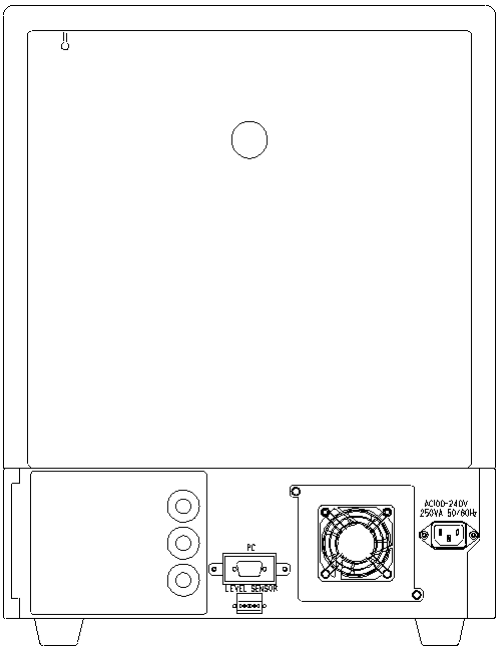
Chapter 1－1. System Outline

Fig. 1－2 Exterior View of AIA-360

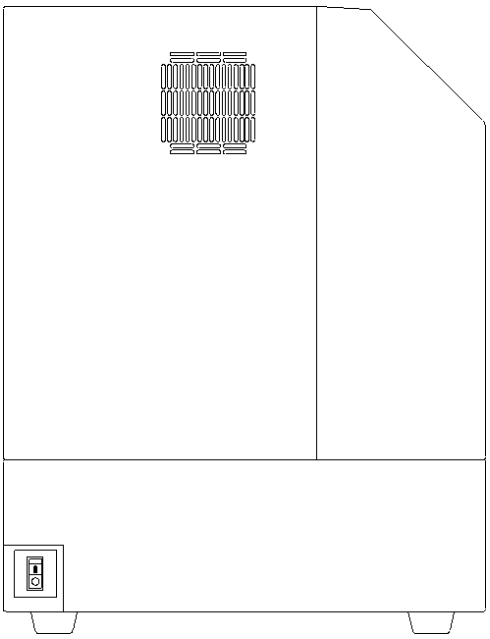
Front View



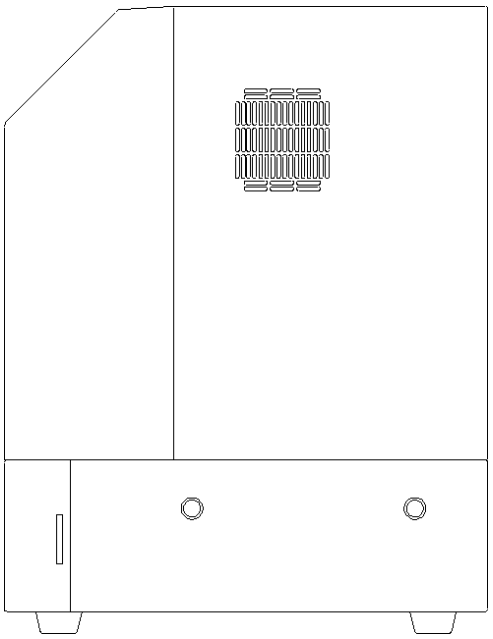
Rear View



Left Side



Right Side



Chapter 1－2. Specifications

2. Specifications

Main Specifications

Assay principal	Fluorometric enzyme immunoassay (FEIA)
Processing method	Automated continuance random access
Processing capacity	Max. 36 tests / hr. (ST reagents)
In vitro diagnostic reagent (medical)	ST AIA-PACK Series
Sample volumes	10 to 100μL
Sample clog detection	Pressure detection
Measuring conditions	Reaction temperature: 37°C Antigen-antibody reaction time ： 10 min.
Detection method	Fluorescent detection (top-to-top system)

Carousel

Reagent set count	Max. 25
Specimen set count	Max. 25
Sample containers	Test tubes (ϕ13×75, ϕ13×100, ϕ16×75, ϕ16×100) Combinable with dedicated sample cups
Specimen barcodes	CODE39, CODE128, ITF, NW-7 compatible (compliant with ASTM14466-92 and CLA guideline compliant barcodes) Min. element width (narrow) : 0.191 (0.254 or over recommended)
External output	RS-232C
Power supply/consumption	100 to 240 V AC, 50/60 Hz, 250 VA
External Dimensions/Weight	Main unit: 400 (W) × 400 (D) ×520 (H) mm, 29 kg

Operating Environment

Temperature	15°C to 30°C
Humidity	40 % to 80 % (no condensation)
Best	Average office level

Conformance Status

EMC standard	IEC61326-2-6: 2012
CISPR class and group categories	Class A, Group 1
FCC	Part 15 Sub, Part B Class A
EMC standard	Class 1: IEC60825-1: 1994

Chapter 1－3. Checking Packing Box Content

3. Checking Packing Box Content

As a rule, Tosoh service personnel always set-up the system. You are requested to refrain from opening the packing box and attempting to install the system yourselves.
You are requested to confirm, in the presence of the Tosoh serviceperson, that all accessories in the following list are included with the system when it is unpacked.

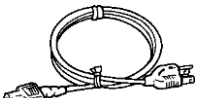
The components of seven parts, diluent, wash solution, and waste fluid bottles and caps, and the level sensor lead wire, are different depending on the date of manufacture, and either sets of parts “before change” or “after change” are provided with the instrument. For details of each item, see P. 1-8 “before change” and P. 1-9 “after change”. Note that the applicable seven parts cannot be used in combination with the parts “before change” and “after change”.

Packing List

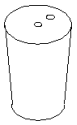
Main Unit（AIA-360）

[Accessories]

☐Power cable: 1.....
（Part No. 0008272）

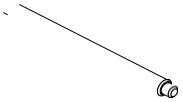


☐Substrate bottle rubber stopper: 1 .....
（Part No. 0021207）



☐Bottle cap: 10 .....
（Part No. 0021002）

☐Printer paper core: 1 .....
（Part No. 0019510）

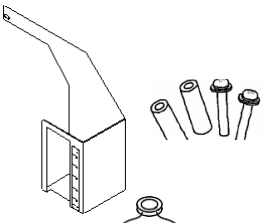


Chapter 1－3. Checking Packing Box Content

☐ Substrate holder: 1

screw and spacer: 2 pcs (each)

（Part No. 0021066）



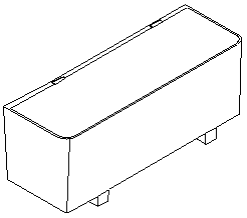
Bottle 30 mL : 2

（Part no. ：0018619）

☐Bottle 100 mL with a cap : 1

☐Bottle tray: 1

（Part No. 0021076）

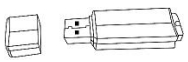


☐Smart media card: 1

or

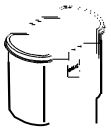
USB stick: 1

(with the initial parameters)



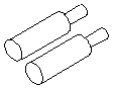
☐Waste Box: 1

（Part No. ：0019398）



☐Tank filter: 2

（Part No. 0018585）



Chapter 1－3. Checking Packing Box Content

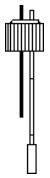
[Components of the seven parts before change (level sensor lead terminal: plug socket type)]

☐Diluent bottle 500 mL（DILUENT）: 1 .....
（Part no. ：0021067）

☐Wash solution bottle 1000 mL（WASH）: 1 .....
（Part no. ：0021068）

☐Waste fluid bottle 1000 mL（WASTE）： 1 .....
（Part no. ：0021069）

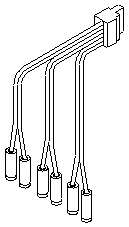
☐Diluent bottle cap: 1 .....
（Part no. ：0021103）



☐Wash solution bottle cap: 1 .....
（Part no. ：0021140）

Waste fluid bottle cap: 1 .....
（Part no. ：0021141）

Level sensor lead: 1 set .....
（Part no. ：0021138）

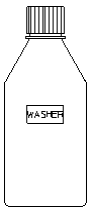


Chapter 1－3. Checking Packing Box Content

[Components of the seven parts after change (level sensor lead terminal: screw type)]

☐Diluent bottle 500 mL（DILUENT）: 1 .....
"Optional Parts: Part No.: 0024686
Part Name: DILUENT BOTTLE-2 WITH LABEL"

☐Wash solution bottle 1000 mL（WASH）: 1 .....
"Optional Parts: Part No.: 0024687
Part Name: WASHER BOTTLE-2 WITH LABEL"



☐Waste fluid bottle 1000 mL（WASTE）: 1 .....
"Optional Parts: Part No.:0024688
Part Name: WASTE BOTTLE-2 WITH LABEL"

☐Diluent bottle cap: 1 .....
"Part No.: 0024318, Part Name: DILUENT CAP ASSY-2"

☐Wash solution bottle cap: 1 .....
"Part No.:0024684, Part Name: WASH SOLUTION CAP ASSY-2"

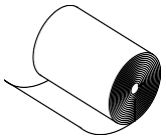
Waste fluid bottle cap: 1 .....
"Part No.: 0024685, Part Name: WASTE BOTTLE CAP-2"

Level sensor lead: 1 set .....
"Optional Parts: Part No.: 0024317,
Part Name: LEAD WIRE OF LEVEL SENSOR-2"'
*with screws

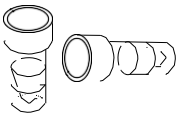
Chapter 1－3. Checking Packing Box Content

[Consumables]

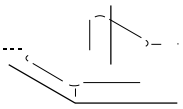
☐Printer paper (thermal paper roll): 1
（Part No. ：0019563）



☐Sample cups: 100



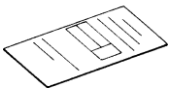
☐Detector Standardization test cups (STD cups): 1



[Others]

☐Operator's Manual CD : 1

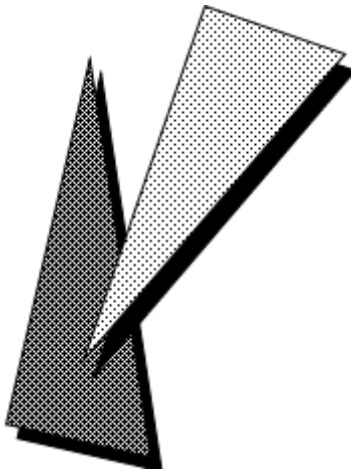
☐Inspection Certificate: 1



☐Warranty: 1

The items listed above should be included in this package.
If any items are missing, immediately contact Tosoh local representatives.

MEMO



Chapter 2

Installation

Chapter 2: Installation

As a rule, installation and set-up of a newly delivered AIA-360 analyzer is performed by a qualified Tosoh service personnel. You are asked to refrain from unpacking and installing the system yourselves.

1. Operating Environment

Make sure to install the system on a level table in an environment free from toxic fumes, dust, vibrations and exposure to direct sunlight.

Operate the AIA-360 within the range of conditions specified below.

Table 2-1 Operating Environment Conditions

Temperature	15 to 30 °C
Humidity	40 to 80 %
Power supply/consumption	100 to 240 V AC, 50/60 Hz, 250 VA
Overvoltage	Category II
Contamination level	2
Dust: level	equivalent to average office environment
Max. altitude	2000 m

Make sure to operate the AIA-360 within the range of conditions specified in the table above in an environment free of moisture from condensation.

2. Environment of transportation and storage

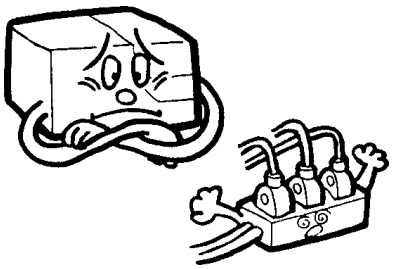
Transport and store the instrument under the following conditions if it is moved to another place and re-installed.

Temperature	5 to 50 °C
Humidity	80 % or less
Dust level	Keep dry, store indoors

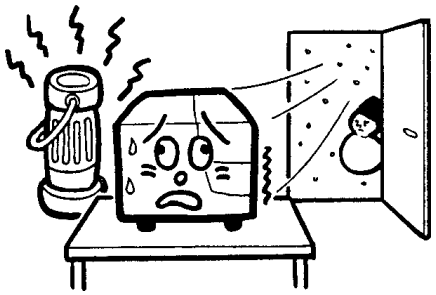
3. Installation Environment

Avoid installing the AIA-360 in locations subject to the following types of conditions

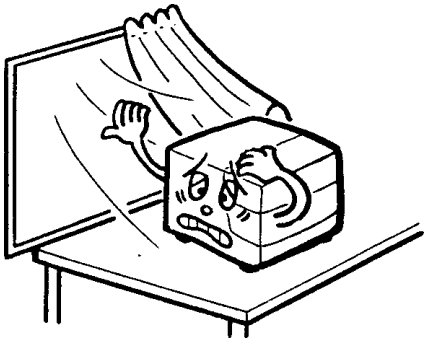
・Sharp fluctuations in power supply voltage



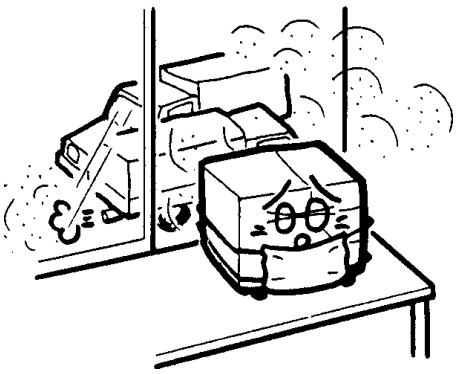
・Sharp fluctuations in temperature



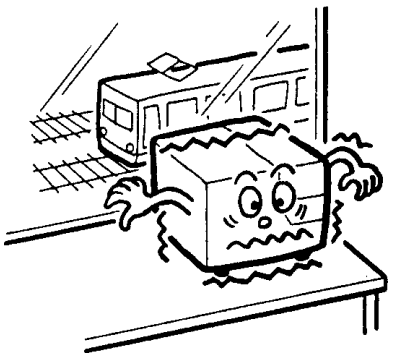
・Powerful air currents



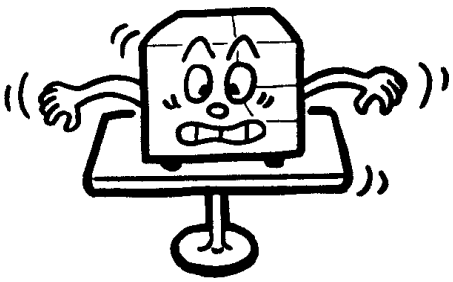
・ Excessive dust



・Excessive vibrations

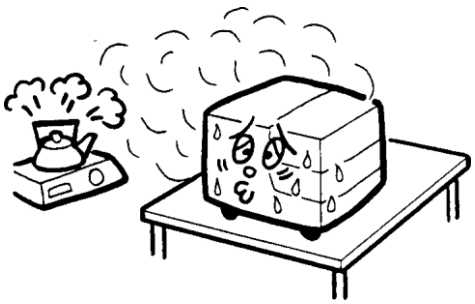


・ Unstable foundations

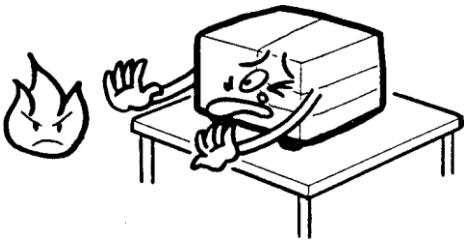


Chapter 2 - 3. Installation Environment

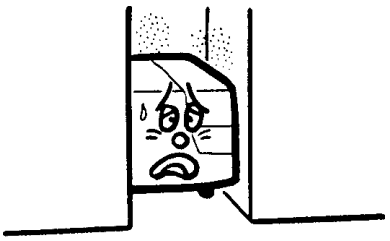
- **Location with High humidity (> 80%) or direct contact with water.**



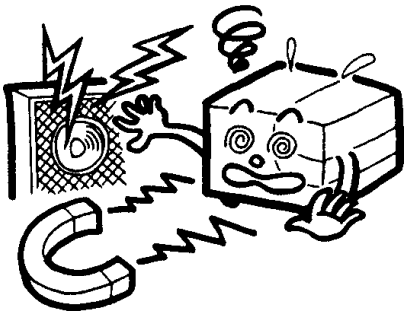
- **Open flames**



- **Narrow spaces with poor ventilation**



- **Strong electromagnetic fields and high frequencies**



4. Space Required for Installation

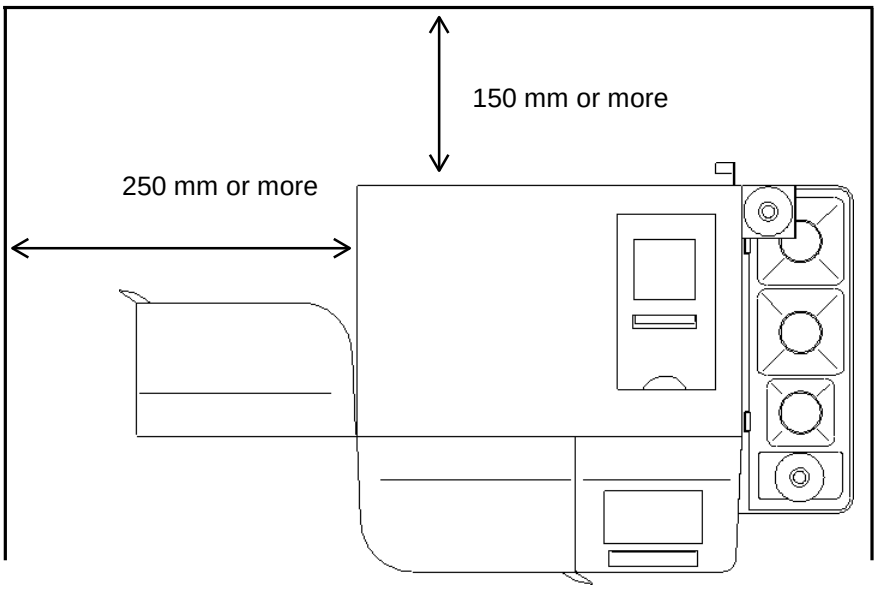
The dimensions of the AIA-360 are 400 mm (W) x 400 mm (D) x 520 mm (H). In addition to these dimensions, the AIA-360 requires extra space on the right side for the external attachment of the bottle tray for the diluent, wash solution and waste fluid bottles.

For ventilation purposes an electric fan is installed on the rear of the unit. Provide a extra margin of at least 150 mm at the back to allow the fan to function properly.

Also allow a margin of at least 250 mm on the left side to open the carousel door when loading samples and reagent cups.

The standard system weight of 29 kg increases to about 35 kg when the reagents are loaded. Make sure that the base on which the AIA-360 is installed is sufficiently strong to withstand this weight without vibrating.

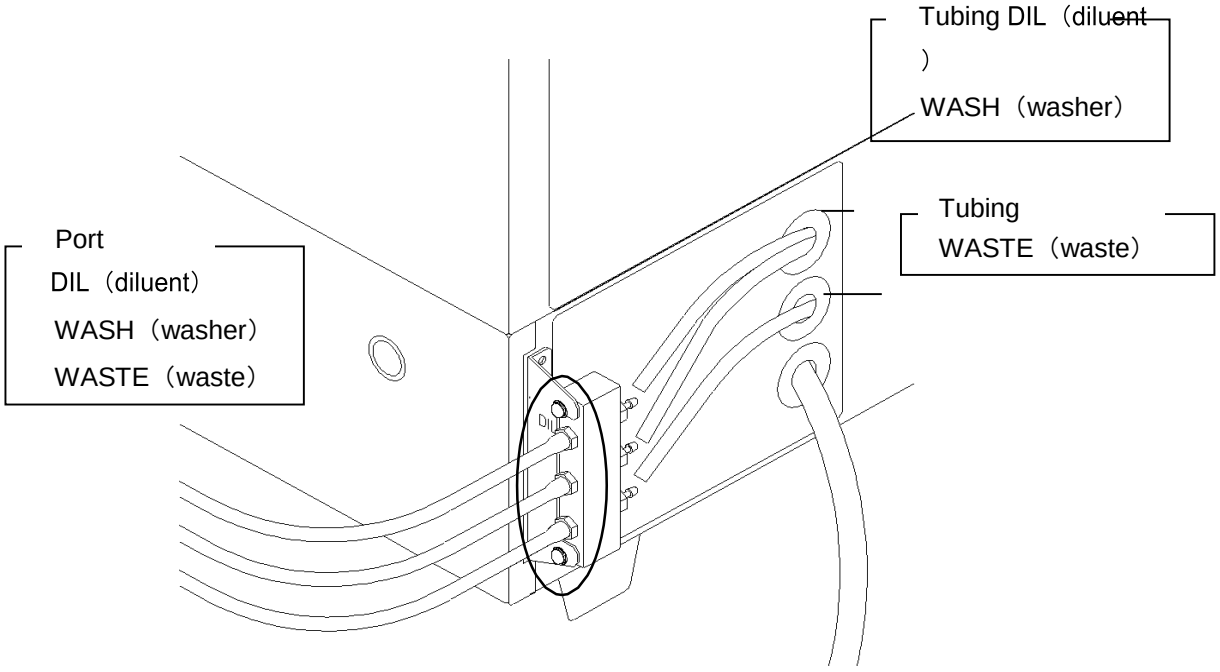
Fig. 2-1 Space Required for Installation



5. Installation Procedure

Connecting Tubing

Fig. 2-2 Port Branching Assembly



① Connect the tubes extending from the rear of the AIA-360 to the port branching assembly as shown below.

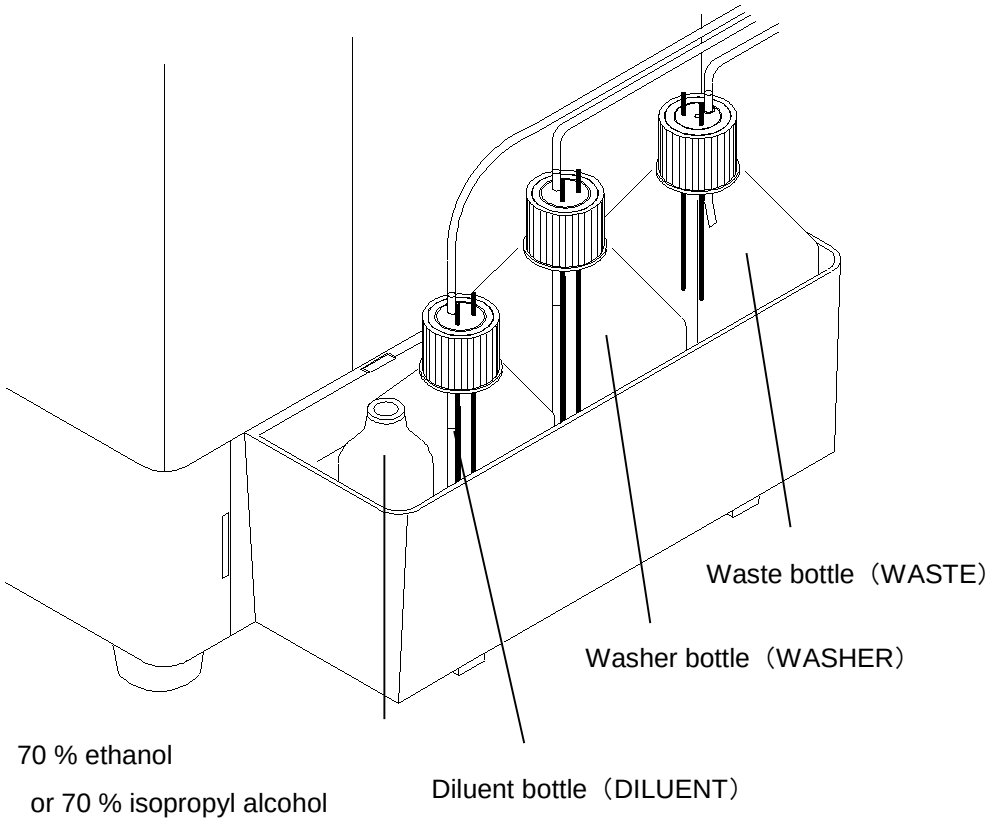
Diluent（DIL） tube	→	Port branch DIL
Wash solution（WASH） tube	→	Port branch WASH
Waste fluid（WASTE） tube	→	Port branch WASTE

Identification seals are attached to each tube. Use these to ensure tubes are connected to the correct port. Errors will result in incorrect assay results.

② Connect the tubes linked to the port branching assembly to the caps on each of the bottles.

Chapter 2 - 5. Installation Procedures

Fig. 2-3 Bottle Installation Order



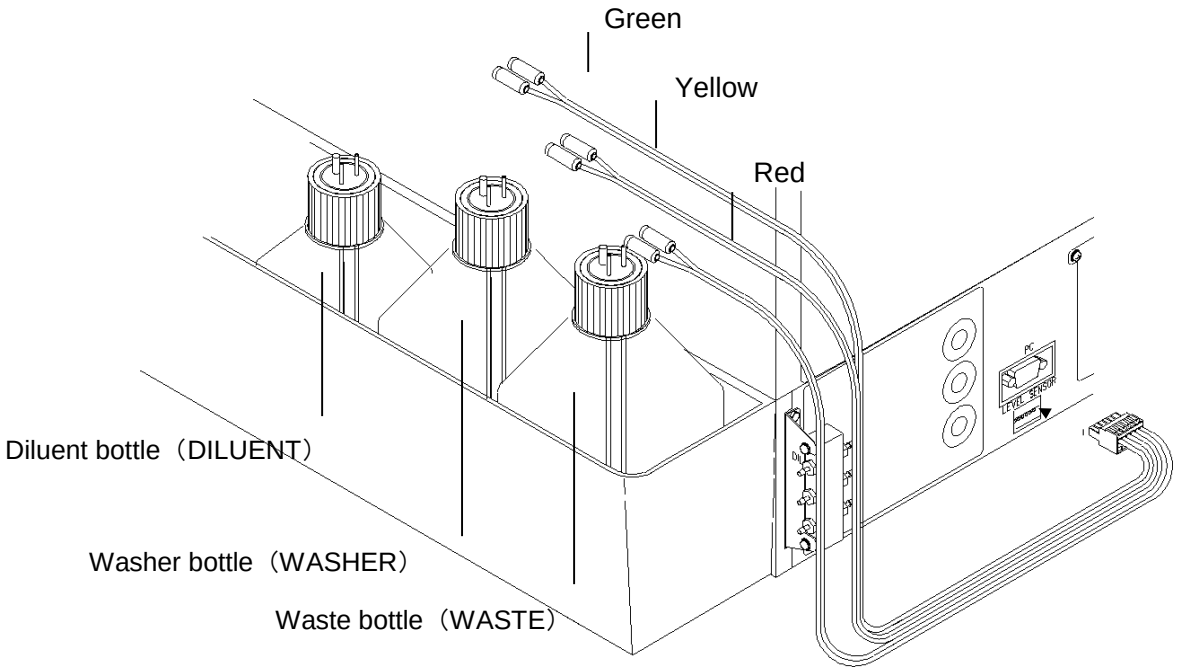
③ Tighten the bottle caps and arrange them in the order shown in Fig. 2-3, starting from the front with the diluent bottle, wash solution bottle, and waste fluid bottle.

The wash solution and waste fluid bottles are identical in shape, so be sure to check the identification seals to prevent any mixups.
Mistakes will result in incorrect assay results.

Chapter 2 - 5. Installation Procedures

Connecting Level Sensor Lead Wires

Fig. 2-4-1 Level Sensor Lead Wires (Plug Socket Type)



① Connect the connectors on the ends of the level sensor lead wire in the direction of the arrows shown in the figure above.

② Use the color coding on the terminals of the level sensor lead wires to ensure that they are correctly connected to the electrodes for each bottle.

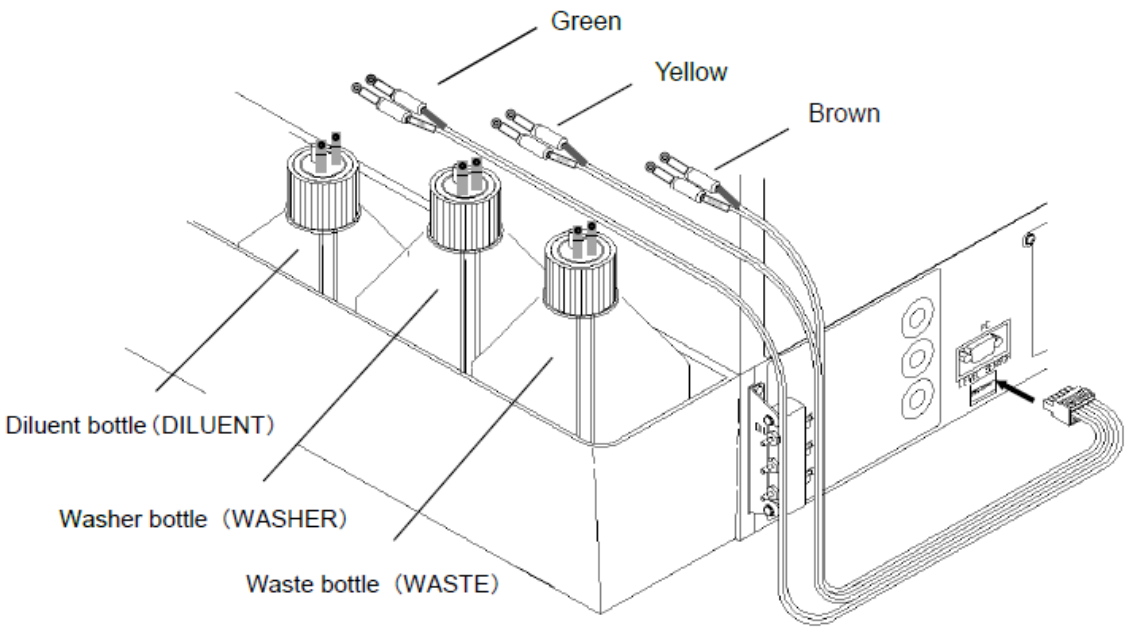
Waste fluid bottle（WASTE） → red
Wash solution bottle（WASHER） → yellow
Diluent bottle（DILUENT） → green

Make sure that level sensor lead wire connectors are correctly matched. Incorrectly connecting the lead wire will result in failure to issue warnings when the diluent and washer levels are low or when the waste tank is full.

Chapter 2 - 5. Installation Procedures

Connecting Level Sensor Lead Wires

Fig. 2-4-2 Level Sensor Lead Wires (Screw Type)



① Connect the connectors at the end of the level sensor lead wire 2 in the direction of the arrows shown in the figure above.

② Use the color coding and identification names on the terminals of the level sensor lead wire 2 to ensure that they are connected properly and firmly to the electrodes for each bottle 2 using the provided screws, and then cover the terminals with the rubber protection caps.

Waste fluid bottle（WASTE） → brown
Wash solution bottle（WASHER） → yellow
Diluent bottle（DILUENT） → green

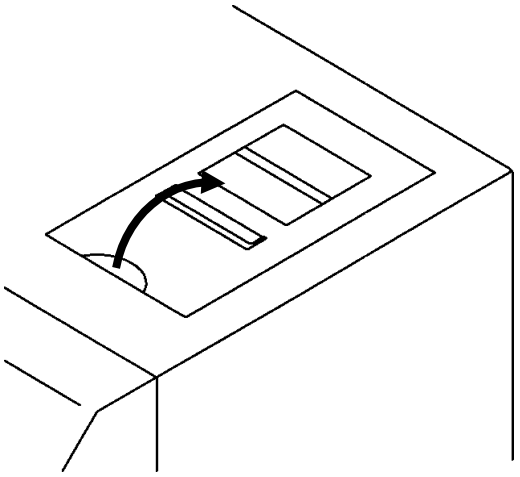
Make sure that level sensor lead wire 2 connectors are correctly matched. Incorrectly connecting the level sensor lead wire 2 will result in failure to issue warnings when the diluent and washer levels are low or when the waste bottle is full.

Chapter 2 - 5. Installation Procedures

Installing the Printer Paper

① Open the printer cover (top) by lifting upward.

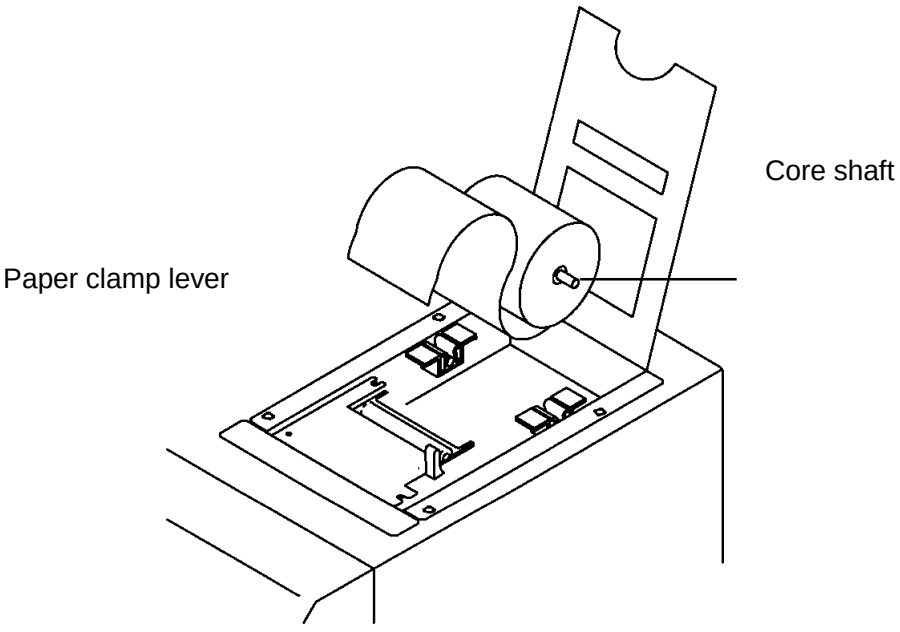
Fig. 2-5 Printer



② Pull the paper clamp lever to the full forward position and remove the paper core shaft by pulling upward.

③ Insert the core shaft into the paper roll and install it in the printer so it faces the correct direction.

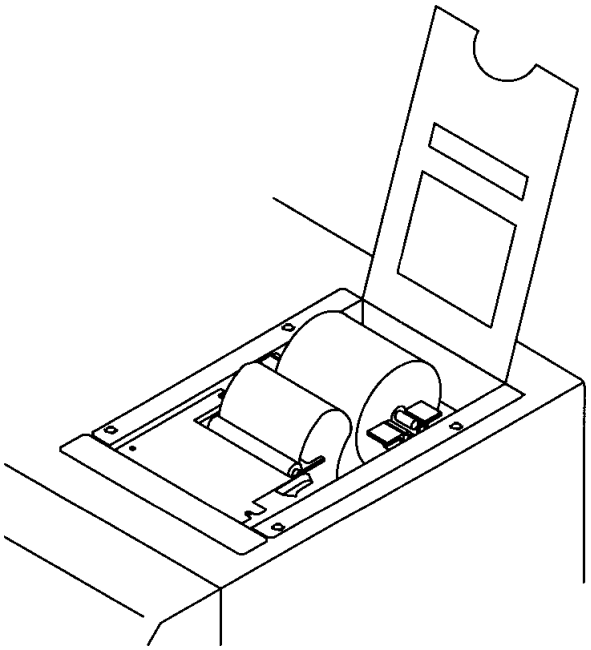
Fig. 2-6 Installing Printer Paper



Chapter 2 - 5. Installation Procedures

④ Return the paper clamp lever to its full back position and insert the tip of the paper into the printer mechanism.

Fig. 2-7 Installing Printer Paper



Note that the lever has two settings, so make sure to set to the full back position.

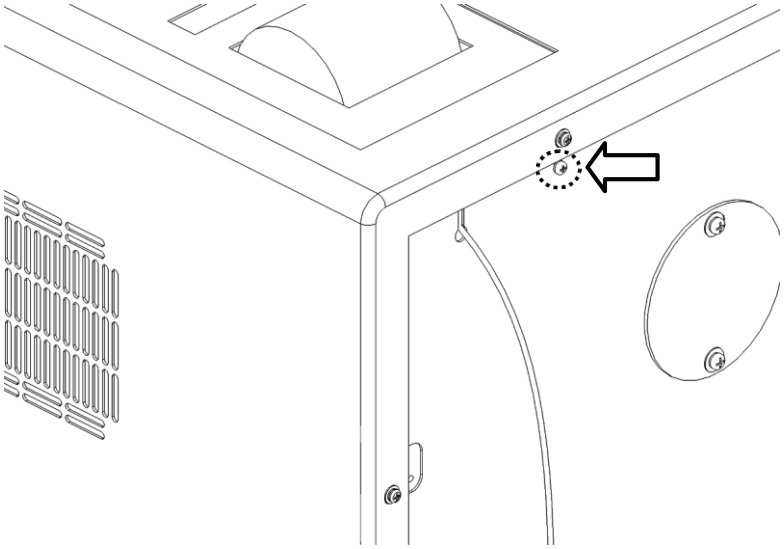
⑤ Close the printer cover (top), while remembering to pass the end of the printer paper through the cover's paper opening.

If paper is not positioned correctly, pull the paper clamp lever to the forward position and adjust, then return lever to full back position.

Chapter 2 - 5. Installation Procedures

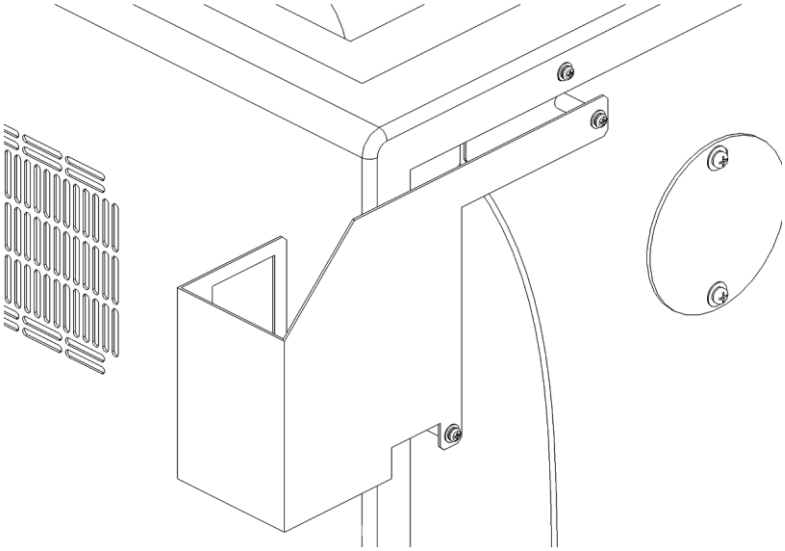
Installing Enzyme Substrate Fluid

Fig. 2-8 Attachment of the Substrate Solution Holder (1)



(1) Remove the screw shown in Fig. 2-8 (The removed screw will be of no use).

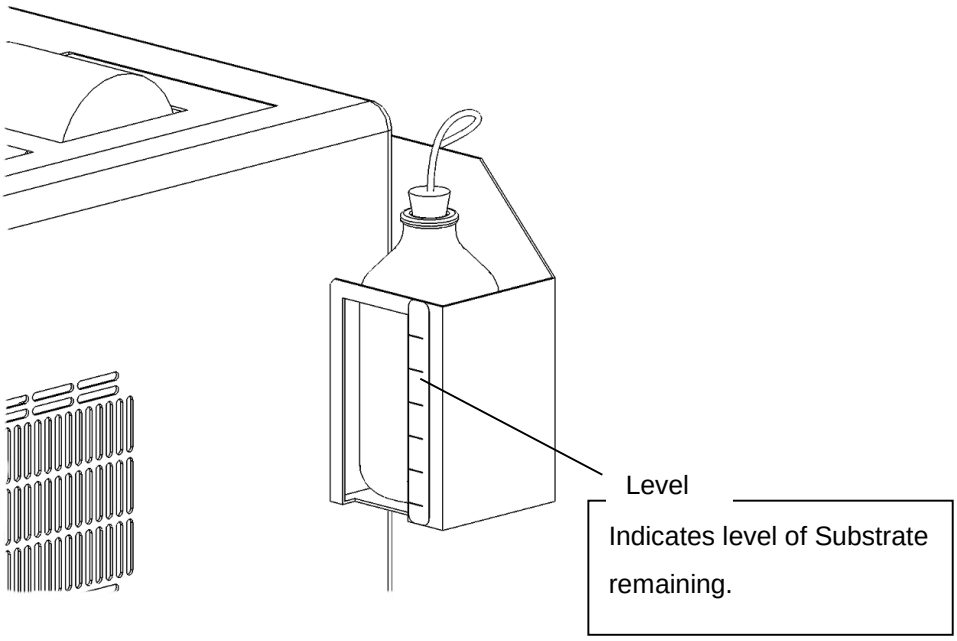
Fig. 2-9 Attachment of the Substrate Solution Holder (2)



(2) Using the screws and spacers included in the accessory fix kit, attach the substrate holder as shown in Fig. 2-9.

The substrate solution tube passes through and beneath the holder.

Fig. 2-10 Substrate Solution Holder and Enzyme Substrate Bottle



(3) Set the substrate bottle on the holder (See Fig. 2-10).

(4) Put the substrate solution tube deeply into the substrate bottle and plug the bottle with the rubber cap.

Put the tube into the bottle until the tube end touches to the bottom of the bottle.

Chapter 2 - 6. Power Supply

6. Power Supply

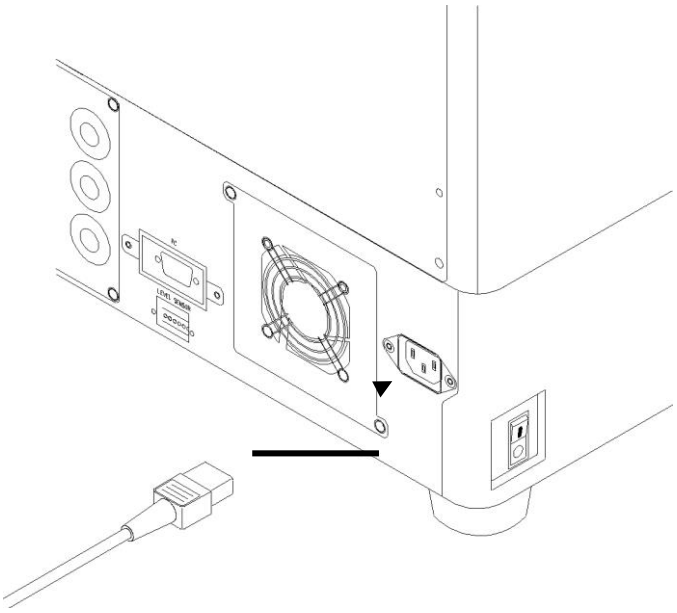
① Confirm the following system power supply specifications.

Power specifications ： 100/120V AC and 220/230V AC ±10 V
250 VA
50/60 Hz

- Connect the AIA-360 using the accessory power cable grounded to the power supply socket (10 A).
- Avoid connecting the AIA-360 to the same power socket as other equipment, such as refrigerators and compressors, that consume large volumes of power.
- Use only a power supply line equipped with circuit protector.

② After confirming that the power supply switch located on the left rear of the system is set to the OFF position, insert the power supply cable into the socket.

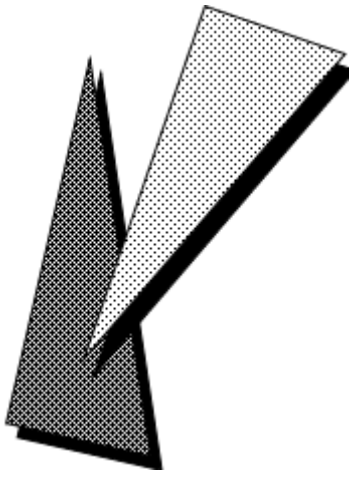
Fig. 2-9 Power Supply Socket



Point Note that the position marked "○" is OFF and the position marked "｜" is ON. Wait **at least 10 seconds** before turning on the instrument again after having turned it off.

Chapter 3

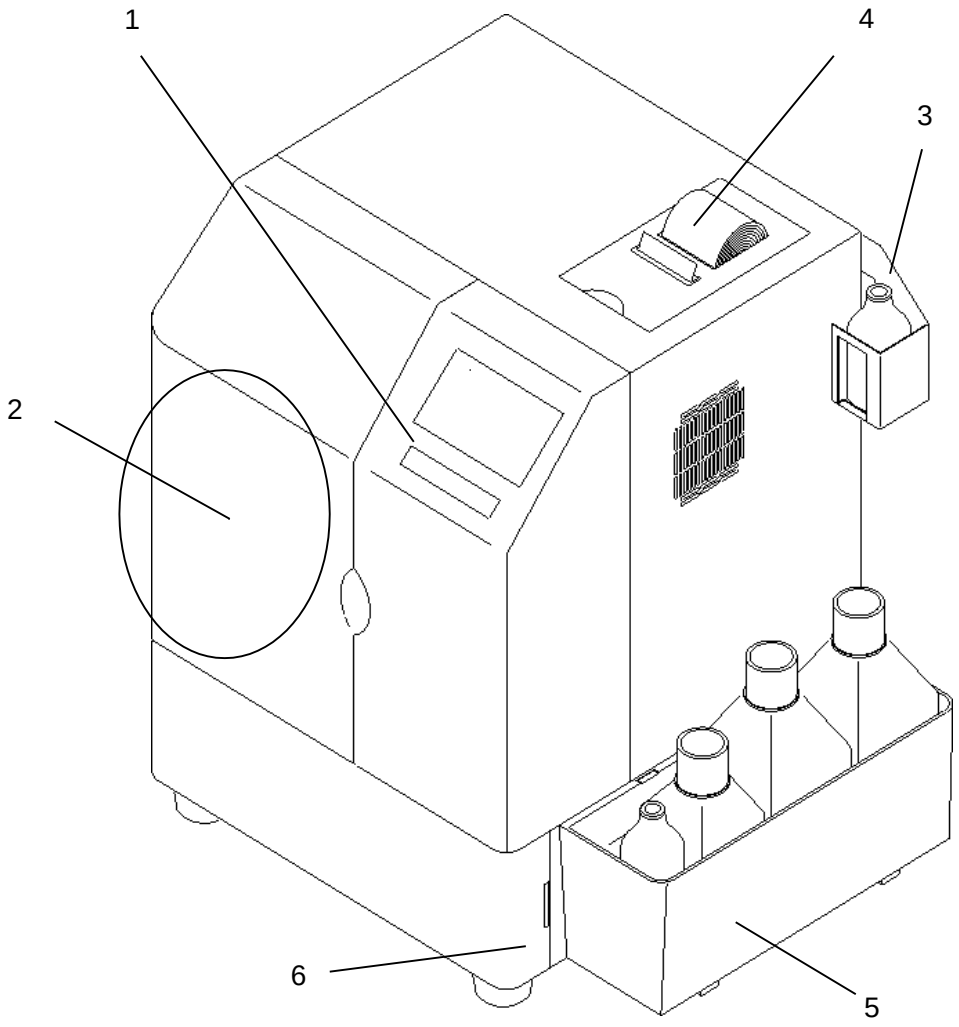
Name of Parts and Functions



Chapter 3: Name of Parts and Functions on Main Unit

The AIA-360 is comprised of the modules illustrated below.

Fig. 3-1 Overview of Main Unit



1. Display and operation panel 2
. Carousel (located inside door)
3. Substrate compartment 4.
Printer unit
5. Bottle tray
6. External recording media slot

Chapter 3: Name of Parts and Functions on Main Unit

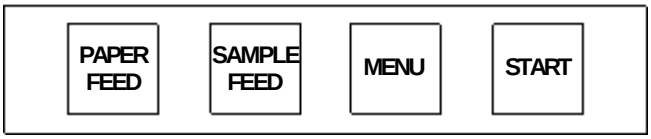
1. Display and Operation Panel

A LCD touch-panel equipped with sheet keys serves as both the display and key entry device for the AIA-360.

The LCD display is located on the front right side (when facing front) of the main unit.

The display shows the operating status of the current system and the assay results.

Fig. 3-2 Display and Sheet Keys (Sample)



Paper Feed Key

Used to feed printer paper.

Sample Feed Key

Moves the sample carousel forward by 1 cup.

Menu Key

Displays the menu screen.

Start Key

Starts the assay operation.

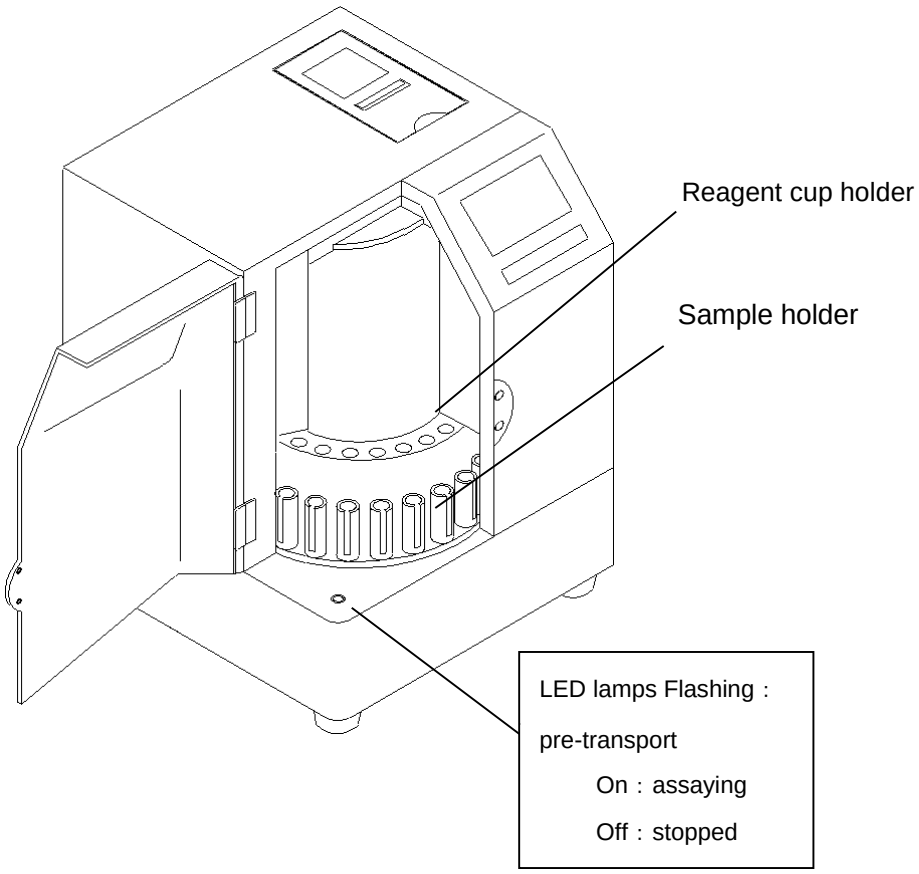
Do not depress the START key for a long time.

Depressing the START key for a long time (about two seconds or longer) sends an abort request for an emergency stop, and prints a warning message.

2. Carousel

The main carousel is the unit that serves as both the reagent cup holder and the sample holder. The carousel is designed to rotate the specimen and reagent cups. Seven reagent cup holder slots and seven sample holder slots are visible when the carousel door is opened.

Fig. 3-3 View With Carousel Door Open



Point

- When the SAMPLE FEED key is depressed for two seconds or longer, the carousel rotates automatically and returns to its home position.
- To stop the carousel from automatically rotating, press the SAMPLE FEED key once again.

Caution Be careful not to get your fingers caught when the carousel moves.

3. Substrate Compartment

This compartment is used for the enzyme substrate bottle and the 70 % ethanol or 70 % isopropyl alcohol solution bottle.

4. Printer Unit

The printer is designed to the print assay results, error information and system parameters onto a roll of thermal printer paper. Depending on the font selected, the printer can print the assay results for up to 2000 test cups on one roll of paper.

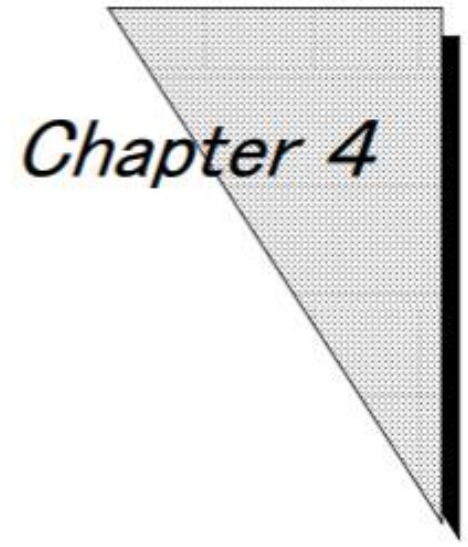
5. Bottle Tray

Note that the diluent, wash solution and waste fluid bottles and the 70 % ethanol or 70 % isopropyl alcohol solution bottle are stored outside rather than inside the main unit.

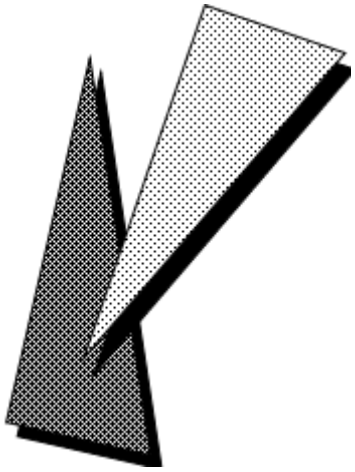
6. External Recording Media Slot

The system program is updated using external recording media.

MEMO

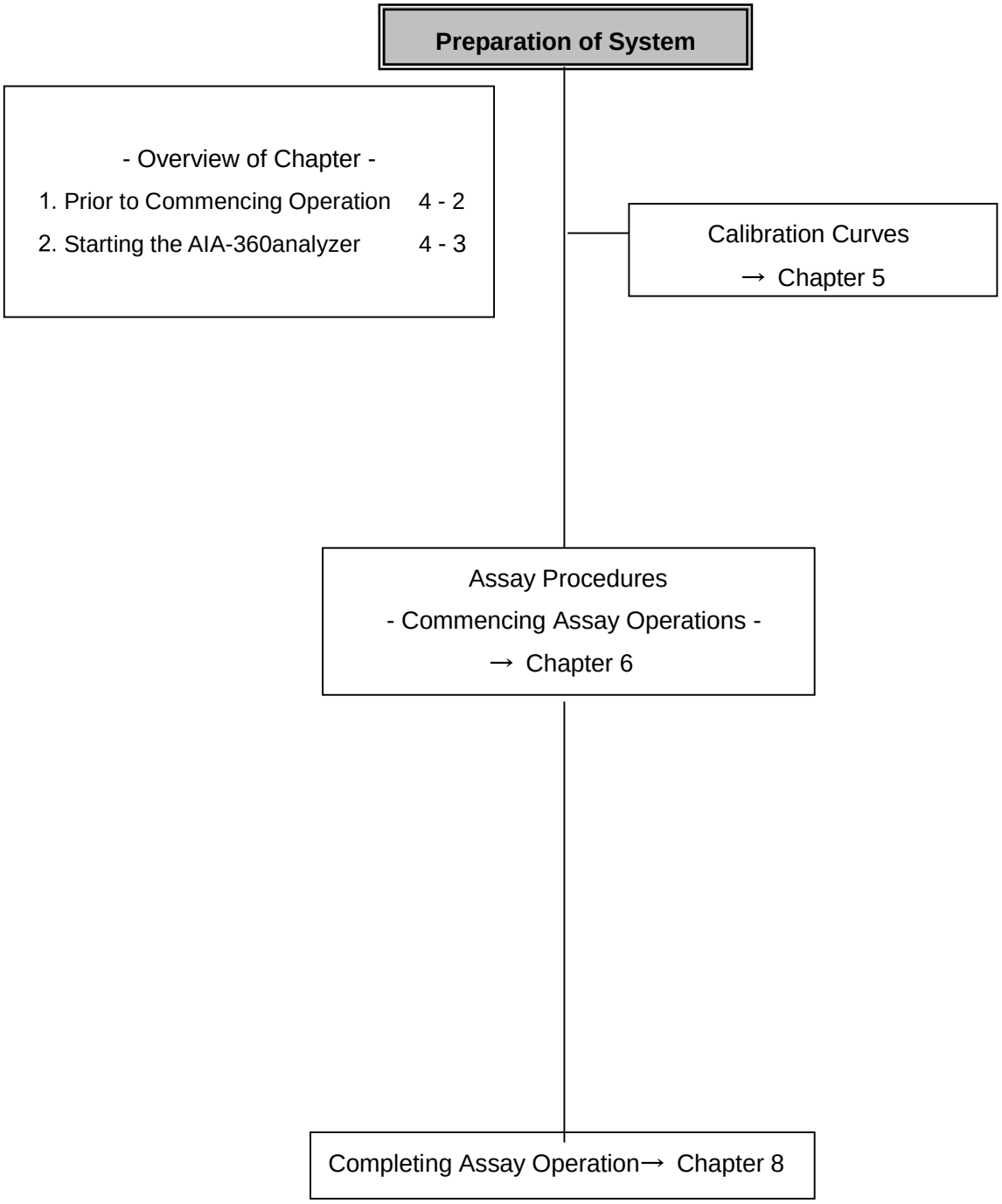


Preparing System



Chapter 4: Preparing System for Assay Operations

Introduction



1. Prior to Commencing Operation

The following items are required for performing assay operations.

- Reagent cup
- Enzyme substrate solution
- Detector standardization cup （STD cup）
- Diluent and wash solution
- 70 % ethanol or 70 % isopropyl alcohol
- Samples （patient specimens and calibrators）

Make sure to properly mix the substrate, diluent and wash solutions in accordance with the instructions provided in the manual.

The following two types of samples are used for assay operations in the AIA-360.

1. Patient specimens 2.
Calibrators（standards）

1. Assaying Patient Specimens

Prepare the specimens and reagent cups. Dispense the required volume of specimen into the sample cup or primary tube. The required specimen volume is defined as the sum of all dispensed analyte volumes, plus the dead volume.

Dead volume: 100µL for sample cups. Approximately 500 µL for the straight type OD 11 mm primary tube but varies depending on tube bore and shape.

Point

Up to four analytes can be assayed from a single specimen. However, the specimen must be divided into two portions whenever assaying five or more analytes from a single specimen.

Applicable specimen type for the AIA-360 is indicated on the insert sheet provided with reagents for each analyte. Users are asked to avoid assaying the following types of specimens, as they can affect system operation.

- Specimens that have a tendency to clot during the assay process.
- Specimens containing solid particles that tend to form occlusions during dispense operations.

2. Generating Calibration Curves

Prepare calibrator and reagent cups. Measuring calibrators is necessary when generating calibration curves. Begin by compiling an appropriate calibration program, then prepare calibrators and reagent cups and perform measuring operations accordingly.

Chapter 4 - 2. System Startup

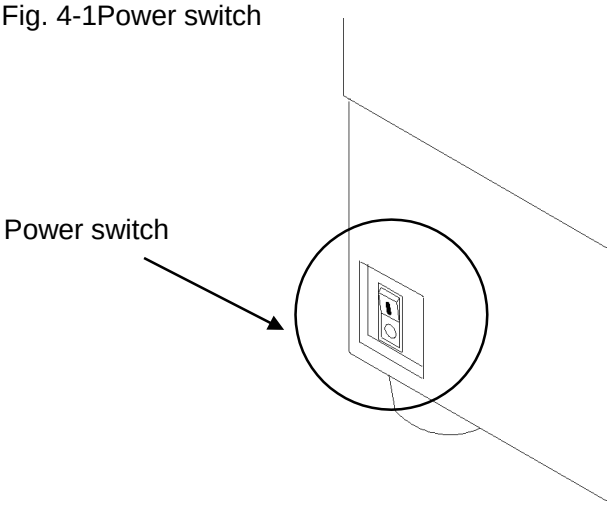
2. System Startup

Before Turning on Power

Open the operation cover on the main unit and confirm there is nothing blocking the movement of the carousel.

① Next, go to the system power switch located on bottom left rear of the main unit and switch it to On.

Fig. 4-1Power switch

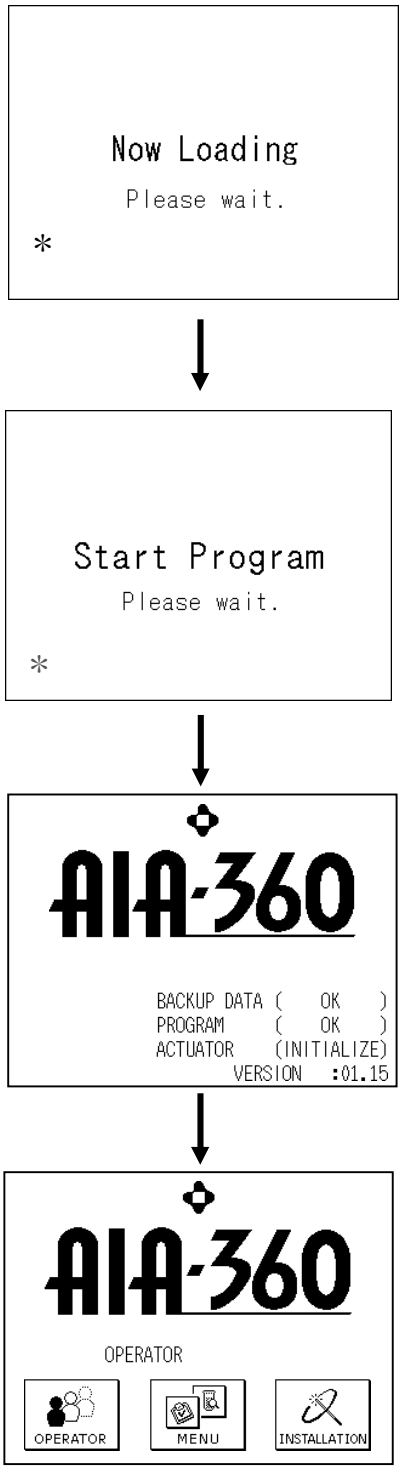


Point Note that the position marked "○" is OFF and the position marked "｜" is ON.

Chapter 4 - 2. System Startup

② When system power is turned on, the Now Loading Screen, the Start Program Screen and the OPENING Screen of the AIA-360 are displayed in order on the display.

＊ There is a display type in which the Now Loading Screen and the Start Program Screen are not displayed.



＜OPENING Screen＞

Pressing [INSTALLATION] displays the factory default system installation procedures.
As a rule, installation of a newly delivered AIA-360 is performed by qualified Tosoh service personnel. Customers are asked to refrain from unpacking and installing the system themselves.

Chapter 4 - 2. System Startup

2.1 Confirming/Selecting Operator Name

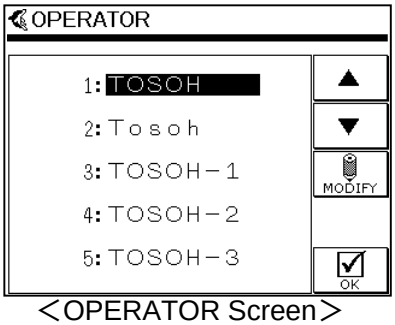
① Confirm the current operator name displayed in the OPENING screen.

Point The operator name is also printed on the printouts.

② If the correct operator name is displayed, simply press the MENU icon.

（Proceed to section “2.2 Confirming Enzyme Substrate Solution Level.”）

③ To change the operator name, simply press the OPERATOR icon. Use ▲ ▼ to move the cursor to the desired operator name then press the OK icon to select.



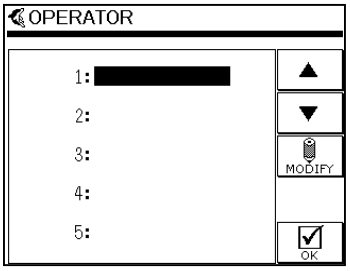
＜OPERATOR Screen＞

Registering New Operator Name

The AIA-360 analyzer allows registration of up to 5 operators, retained even when the power is turned off.

1) Press the OPERATOR icon.

This displays the OPERATOR Screen.

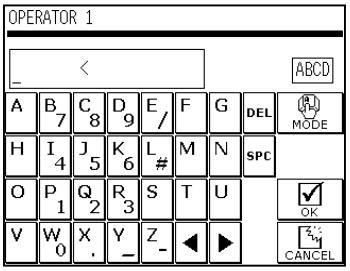


＜OPERATOR Screen＞

2) Use ▲ ▼ to move the cursor to the new operator number to be registered.

Then press the MODIFY icon.

This displays the KEYBOARD INPUT screen.



＜KEYBOARD INPUT Screen＞

Point Pressing the MODE icon displays the following content.

ABCD Alphabet (uppercase) abcd Alphabet (lower case)

1234 Numerals

Chapter 4 - 2. System Startup

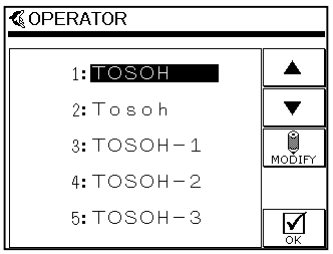
3) Register operator name (using up to eight characters).

4) Press the OK icon after entering the name and return to the Operator Screen.

Changing/Deleting Operator Names

1) Press the OPERATOR icon to display Operator Screen.

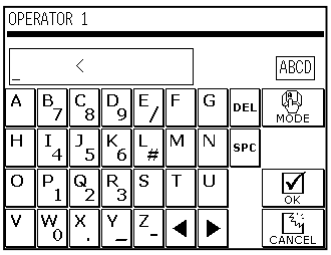
2) Use ▲ ▼ to move cursor to operator number to be deleted and press the MODIFY icon.
This displays the KEYBOARD INPUT Screen.



＜OPERATOR Screen＞

1) Press the DEL to delete when changing or deleting the operator name.

2) When name change is successful, press the OK icon.



＜KEYBOARD INPUT Screen＞

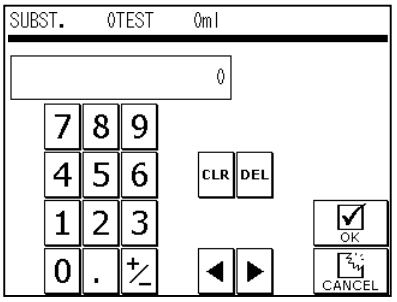
Chapter 4 - 2. System Startup

2.2 Confirming Enzyme Substrate Solution Level

① The SUBSTRATE Screen is displayed.

② Enter the enzyme substrate solution level indicated on the solution level scale.

③ Next, press the  icon.



＜SUBSTRATE INPUT Screen＞

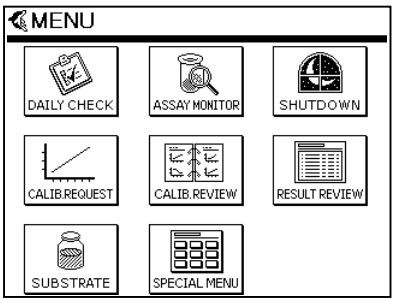
- Note that the correct enzyme substrate solution level must always be entered. Failure to do so will result in DAILY CHECK errors.
- Also be sure to enter the new substrate level in the SUBSTRATE screen whenever installing a new enzyme substrate solution.

Point The current level of enzyme substrate solution can be checked by going to the START UP screen and pressing  or by going to the ASSAY MONITOR screen and pressing the  icon.
This displays the SUBSTRATE screen, which indicates the current level of solution and number of assay tests possible with this solution.

Chapter 4 - 2. System Startup

2.3 DAILY CHECK

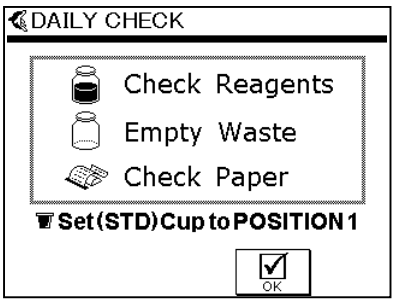
① The MENU screen is displayed.



＜MENU Screen＞

② Press the 

icon in the MENU screen to display the DAILY START CHECK screen.
Then check the following items.



＜DAILY START CHECK Screen＞

∗ Check Reagents

Make sure there is sufficient WASHER（Wash Solution）and DILUENT（diluent）.

∗ Empty Waste

Discard waste fluid and empty the waste tank (WASTE).

∗ Check Paper

Check to see that there is sufficient printer paper.

③ In accordance with the “Set（STD）Cup to POSITION 1” instructions, place one detector standardization cup (STD cup) in position No. 1 in the Reagent Cup table.

④ Then press the 

icon.

∗ After the 

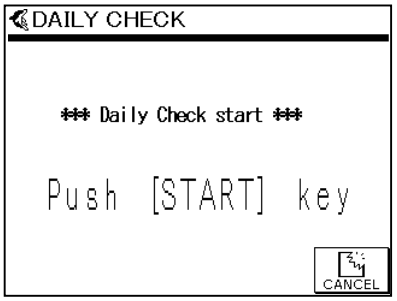
icon is pressed, the following errors may occur.

- Error No.3023 PM DUE : Periodic Maintenance due.
- Error No.3024 PM REQUIRED : Periodic Maintenance is required. If the errors occur, contact the service department for maintenance.

Chapter 4 - 2. System Startup

⑤ When DAILY CHECK screen appears, press the START key.

Fluid supply lines automatically fill and performs a substrate background measurement (enzyme substrate fluorescent intensity check).

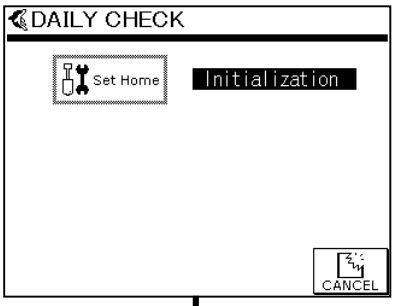


＜DAILY CHECK Screen＞

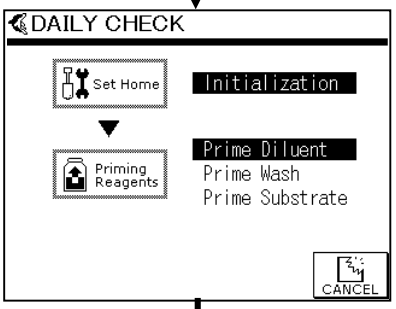
The DAILY CHECK requires approximately seven minutes.

【Screens that appear during the DAILY CHECK

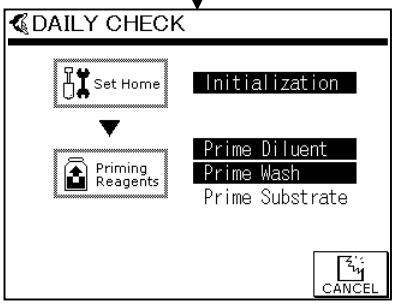
】 Confirmation of initialization sequence



Priming of diluent



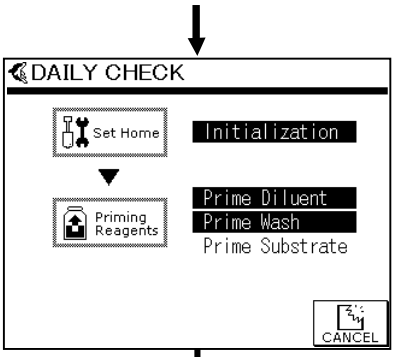
Priming of wash solution



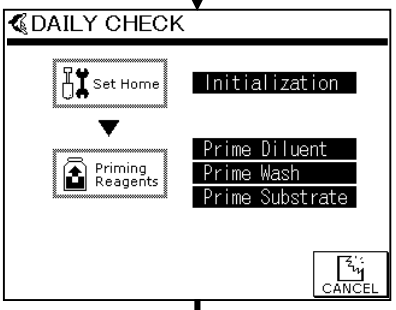
When errors occur during priming of diluent or wash solution, check bottle level and confirm tube reaches down to the fluid.

Chapter 4 - 2. System Startup

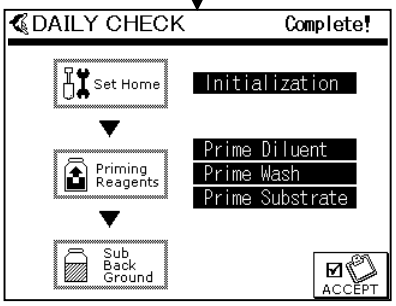
Priming of substrate



Measuring substrate background



When errors occur during substrate background measurement, check substrate level and whether substrate has been replaced with 70 % ethanol or 70 % isopropyl alcohol.

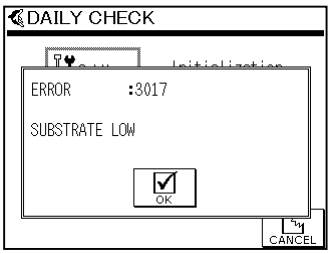


In the Event of Errors

An error message is displayed at the top right of the DAILY CHECK screen whenever an item deviates from the normal operating range.

Press the CANCEL icon to return to the START UP screen.

Redo the DAILY CHECK once corrective measures have been taken.

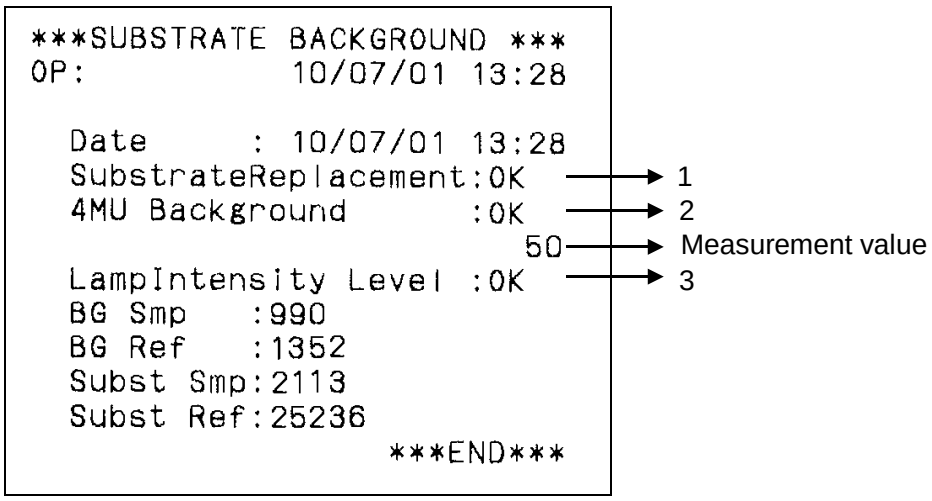


＜ERROR Screen (Example)＞

Chapter 4 - 2. System Startup

⑥ Sample lines are initialized and the results output to the printer when the substrate background measurement operation is complete.

Fig. 4-2 Sample Printout



1. Indicates whether the enzyme substrates solution priming operation was successful by 'OK' or 'ERR'. When the lamp intensity of the detector decreases, an 'ERR' appears, too.

   OK: When successful

   ERR: When unsuccessful or the lamp intensity of the detector decreases

   →Check substrate level and perform DAILY CHECK again.

   When 'ERR' appears again, please ask a Tosoh local representative.

2. Performs fluorescent intensity (background intensity) measurement of enzyme substrate solution to check for possible problems. This measurement result is reported by 'OK' or 'HB' with measurement value in nmol/L.

   OK: When lower than 1500 nmol/L (No problem)

   HB: When equal to or higher than 1500 nmol/L (Background was too high)

   → Replace the enzyme substrate and perform DAILY CHECK again.

3. Indicates intensity of Detector lamp by ‘OK’ or ‘LL’.
   OK: If sufficient
   LL: If insufficient
   →Please ask a Tosoh local representative.

⑦ Press the ACCEPT icon.

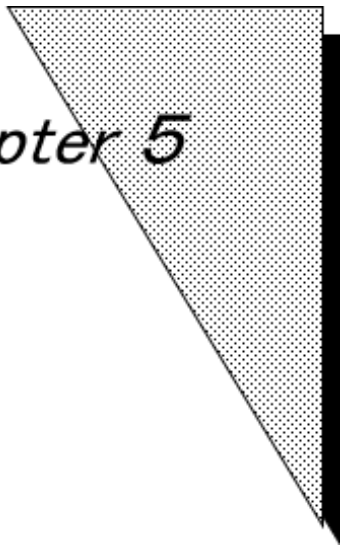
When Starting Assay Before Daily Check is Completed Successfully

In any of the following cases, a warning message will appear indicating that daily check has not been completed successfully.

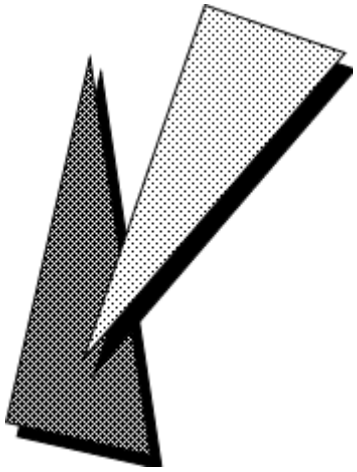
- When starting a specimen assay or calibration after turning on the instrument, without performing daily check.
- When starting specimen assay or calibration after shutting down the instrument, without performing daily check.
- When starting specimen assay or calibration after daily check has been terminated abnormally.

Pressing OK cancels the start of specimen assay and calibration. Perform daily check if necessary.

The warning message appears only once. Regardless of whether daily check has been performed or not, the warning message will not appear at the next assay start.

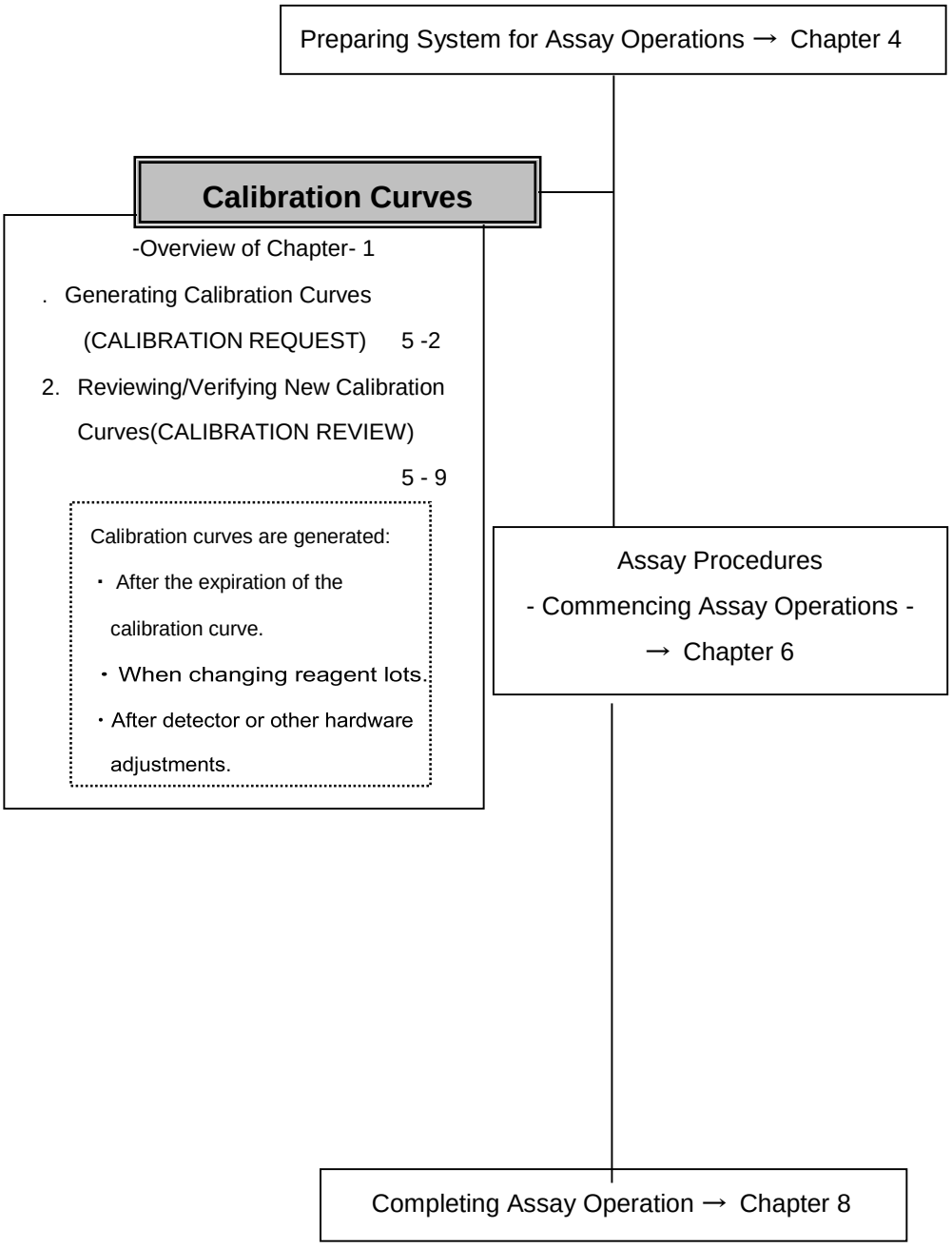


Calibration



Chapter 5: Calibration

Introduction



Chapter 5- 1. Generating Calibration

1. Generating Calibration Curves

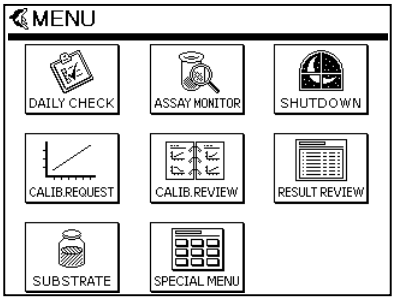
1.1 Calibration Requests

Procedures for generating calibration requests are described in the following sections.

Note that calibration curves cannot be generated during assay operations.
Sample measurement cannot be performed during calibration.

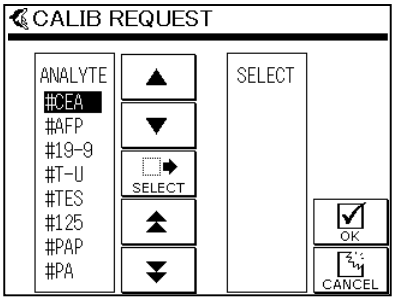
Procedures

① Press the MENU key to display the MENU Screen.

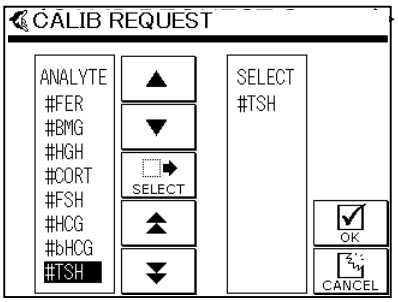


＜MENU Screen＞

② Press CALIB.REQUEST to display the CALIB REQUEST screen.



③ Press ▲ ▼ to move the cursor to desired item and press SELECT to select.



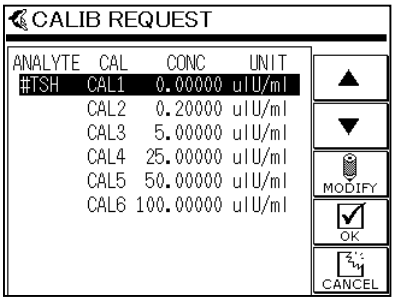
Point Pressing ⏫ ⏬ moves the display to the next page.

Note that the number of analytes that can be calibrated is four for a two-point calibration, one for a 6-point calibration and one for a combined two-point and six-point calibration

Chapter 5- 1. Generating Calibration Curves

④ Pressing [OK] displays the CALIB REQUEST (Conc. Set) screen.

⑤ Confirm that the concentration matches the concentration listed on the calibrator label.

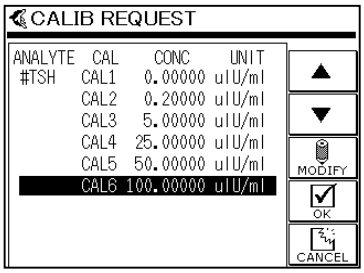


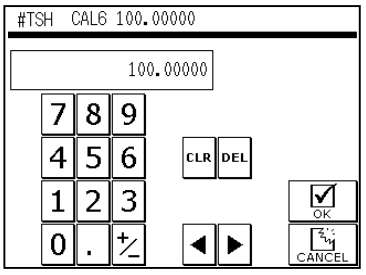
＜CALIB REQUEST（Conc. Set） Screen＞

⑥ Press [OK] if the correct concentration is displayed.
Otherwise, change the concentration.

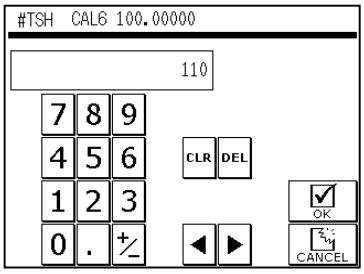
Changing Concentration

1) Use [▲] [▼] to move the cursor to CAL and press [MODIFY].
This displays the Conc Input screen.





2) Press [CLR] to clear the concentration and enter the new concentration (shown on calibrator bottle).



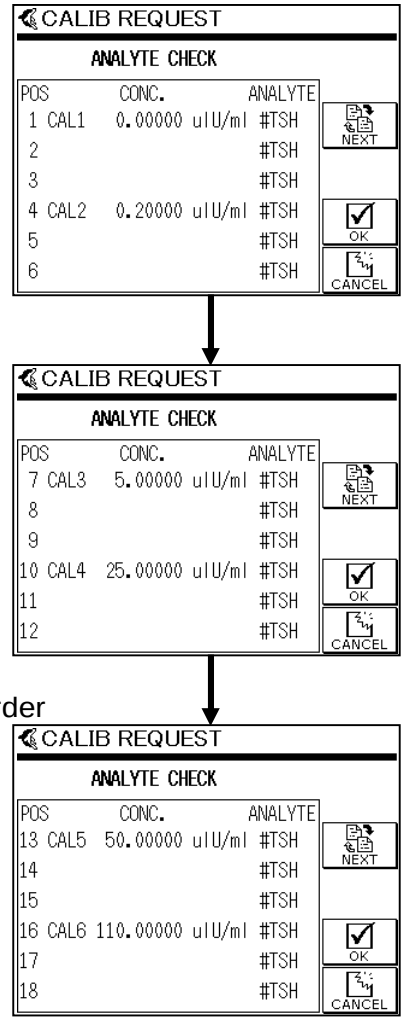
＜Conc. INPUT Screen＞

3) Press [OK] to redisplay the CALIB REQUEST (Conc. Set) screen.

4) Confirm that the concentration has changed in the CALIB REQUEST (Conc. Set) screen then press [OK].

Chapter 5- 1. Generating Calibration Curves

⑦ This displays the CALIB REQUEST (Analyte set) screen. Install the calibrator and reagent cup while confirming progress on the screen.



＜CALIB REQUEST(Analyte set) Screen＞

Point Press NEXT to display the next screen and move the carousel to the next position.

- Calibration measures each concentration three times.
- Calibrators must be positioned in order of concentration, from the lowest one.
- Reagent cups are positioned in sequence without empty slots in between.

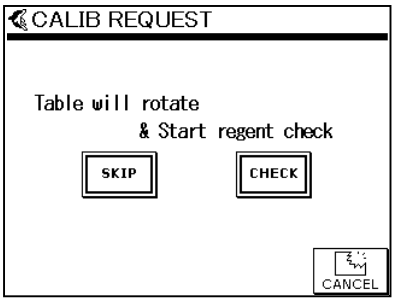
Chapter 5- 1. Generating Calibration Curves

1. 2 Performing Calibration

① Load the calibrator and reagent cup and press [OK].

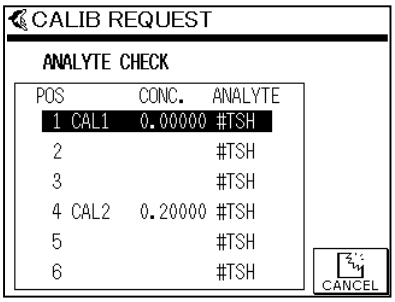
If Diluent, Wash, or Substrate ran short at a calibration, the calibration should be redone to obtain an accurate result.
Please be sure to check the residual quantity of Diluent, Wash, or Substrate before requesting calibration.

② This displays the CALIB REQUEST (Check Start) screen.



＜CALIB REQUEST(Check Start) Screen＞

③ Press [CHECK] to rotate the carousel and check the positioning of calibrators and reagent cups. This displays the “Calibrator & Analyte Check 1” screen.



＜CALIB REQUEST(Analyte Check 1) Screen＞

Point

- Move the cursor to the CAL being checked.
- This highlights the selected CAL.
- Checking takes approximately 2 minutes for a two-point calibration, five minutes for a six-point calibration and seven minutes for a combined two-point and six-point calibration.
- Press [SKIP] to skip the calibrator and reagent cup check and go on to the CALIB REQUEST (Analyte Check 2) screen.

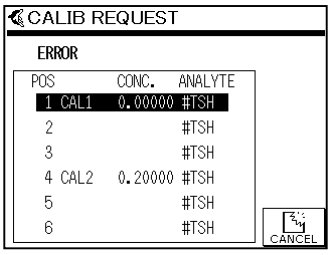
Chapter 5- 1. Generating Calibration Curves

Errors

Errors occur when the calibrator position is wrong, the calibrator is missing or when the reagent cup analyte or lot numbers are wrong.

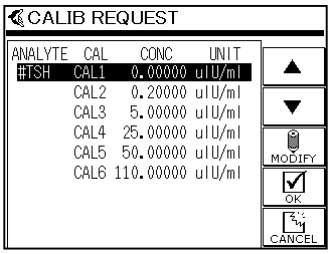
1) Errors are displayed on the CALIB REQUEST (Analyte Check 1) screen.

Point The cursor stops at the location of the error.



＜ERROR Screen（Sample）＞

2) Pressing CANCEL redisplays the CALIB REQUEST (Conc. Set) screen.



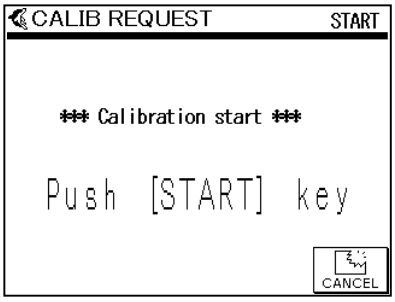
＜CALIB REQUEST(Conc. Set) Screen＞

3) Reload the calibrator and reagent cups correctly and check again.

Misplacing the calibrator concentrations orders will not result in errors. Position calibrations in order of concentration, from the lowest to the highest.

④ When loaded correctly, the CALIB REQUEST (Analyte Check 2) screen appears.

⑤ Press the START key to start the calibration.



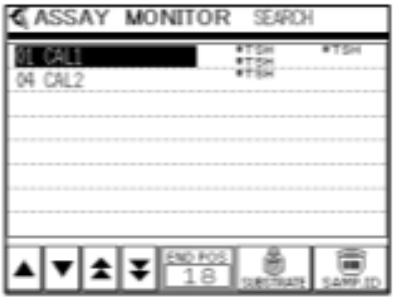
＜CALIB REQUEST (Analyte Check 2) Screen＞

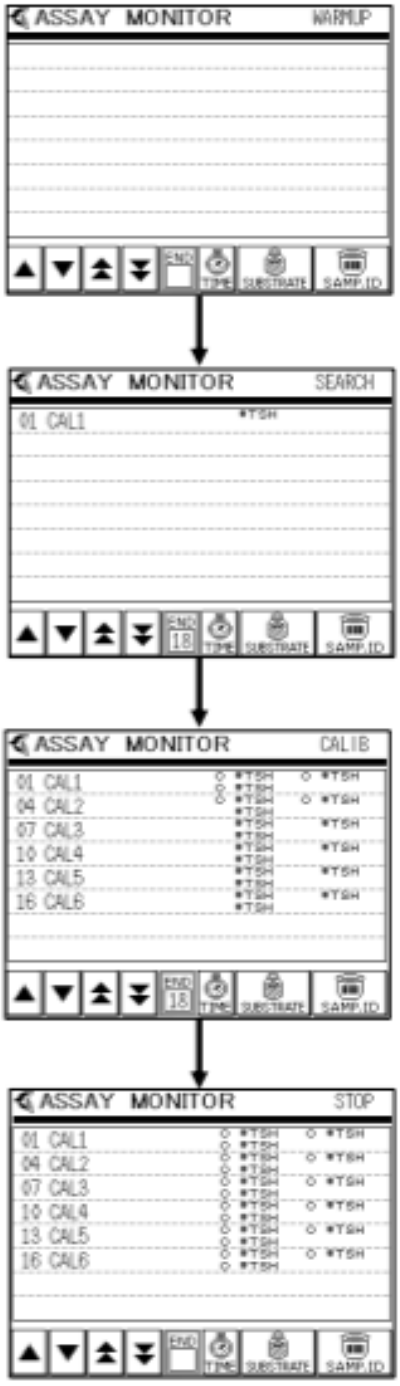
Do not depress the START key for a long time. Depressing the START key for a long time (about two seconds or longer) sends an abort request for an emergency stop and prints a warning message.

Chapter 5- 1. Generating Calibration Curves

If a warning message indicating that daily check has not been performed, refer to “Chapter 4-2. System startup”, and follow the procedure.

【Screens Displayed During Calibration】





Sample measurement cannot be performed during calibration.

⑥ When the calibration is complete, the CALB displayed at the top right of the screen changes to STOP.

Chapter 5 - 2. Reviewing/Updating New Calibration Curves

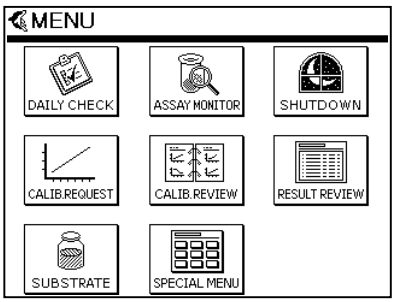
2. Reviewing/Updating New Calibration Curves（CALIBRATION REVIEW）

2.1 Calibration Review

The first assay result is output approximately 20 minutes after the assay operation begins, result reports appear every 100 sec thereafter.
Review and calculations using the calibration data should be conducted when calibration is complete.
Calibration data can be reviewed using the CALIB REVIEW screen.

Procedures

① Press the MENU key to display the MENU screen.

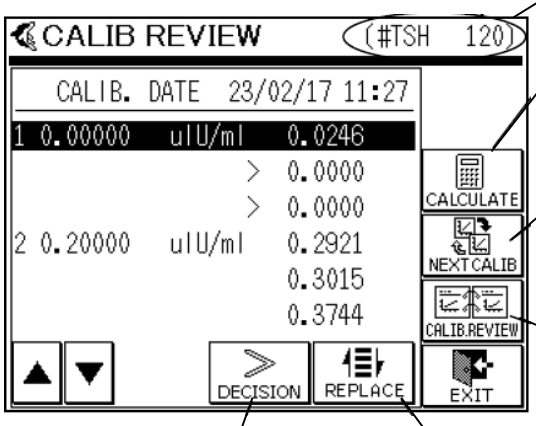


＜MENU Screen＞

② Press 

to display the CALIB REVIEW screen.

<CALIB REVIEW Screen>



Item and Lot

Calculates Calibration Curve
Moves to <CALIB ACCEPT Screen>.

Displays unreviewed calibration data in sequence.

Displays list of
reviewed calibrations.
Moves to <CALIB REVIEW LIST Screen>.

Assigns accept and do not accept flags to each value.

Sort RATE values in
ascending/descending order.
Moves to <CALIB REPLACE Screen>.

Chapter 5 - 2. Reviewing/Updating New Calibration Curves

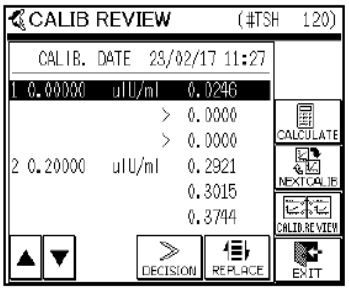
③ The system is designed so that all unflagged assay results that appear when the screen is displayed are accepted. In order to delete data inappropriate for the calibration calculations, use ▲ ▼ to move the cursor to the inappropriate value and press DECISION to reject.

Point To accept the rejected data item, simply press DECISION to toggle.

Point If the calibrators are positioned in a wrong order and assays are performed the RATE values can be sorted in ascending/descending order.

To Sort the RATE Values

1) Press REPLACE on the CALIB REVIEW screen.
The CALIB REPLACE screen appears.



<CALIB REVIEW Screen>

2) Press to select the sort order.
Ascending order : INCREASE RATE ORDER
Descending order : DECREASE RATE ORDER

<CALIB REPLACE Screen>

The initial cursor position on the CALIB REPLACE screen is different depending on the calibration curve type of each analyte.

3) Press OK to sort the order and return to the CALIB REVIEW screen.

4) Press CANCEL to return to the CALIB REVIEW screen without sorting the order.

If the RATE values cannot be sorted, a warning message appears.

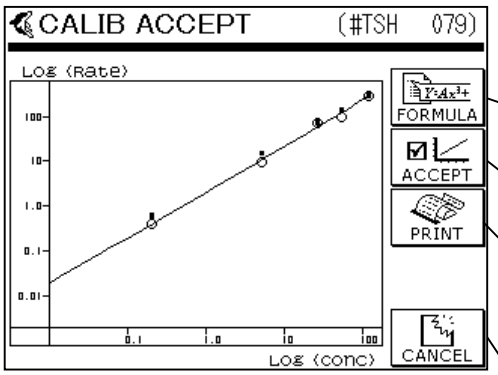
Chapter 5 - 2. Reviewing/Updating New Calibration Curves

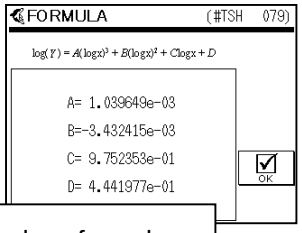
④ Once assay results have been reviewed, press 

.

This displays the CALIB ACCEPT screen.

＜CALIB ACCEPT Screen＞





Displays formula

Accepts the calibration curve

Prints out the CALIBRATION REPORT.

Redisplays the CALIB REVIEW screen.

Horizontal axis flags indicate concentrations and vertical flags the rates.

Point

Calibrations displayed in the CALIBRATION ACCEPT screen can be recalculated repeatedly until 

（calibration verify）is pressed.

Chapter 5 - 2. Reviewing/Updating New Calibration Curves

2.2 Verifying Calibration Curves

The calibration curves are verified once calibration results have been reviewed.

Note that assay data cannot be changed or recalculated once verification has been performed.

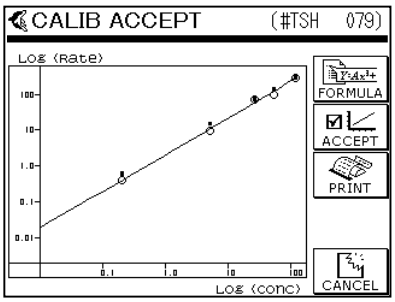
Point

- The maximum number of lots verifiable per analyte is two.
- The same lot cannot be verified.

Procedures

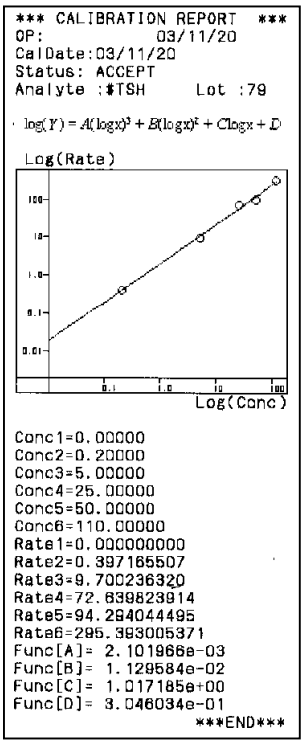
Go to the CALIB ACCEPT screen

① Press ACCEPT to review the calibration curves.



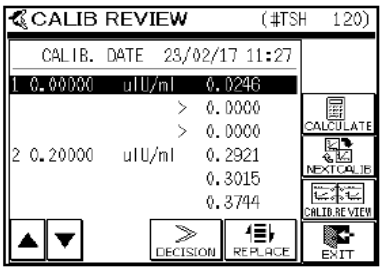
② A CALIBRATION REPORT will be printed out.

Fig. 5 - 1 Sample Printout



Chapter 5 - 2. Reviewing/Updating New Calibration Curves

③ Any unverified calibration curves can be displayed by calling up the CALIB REVIEW screen.

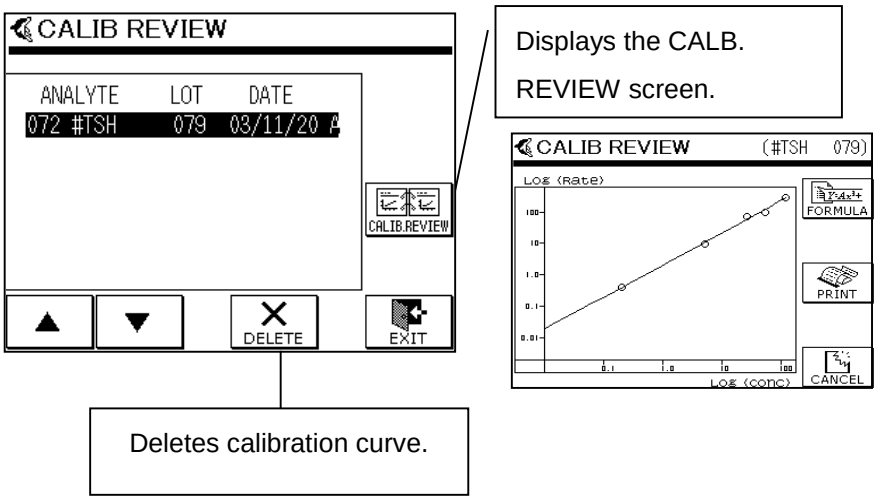


<CALIB REVIEW Screen>

Point To delete unverified calibration results, press CALIB.REVIEW , select the Calibration curve on the CALIB REVIEW LIST screen, and press DELETE .

④ The CALIBRATION REVIEW LIST screen is displayed when all calibration curves have been verified.

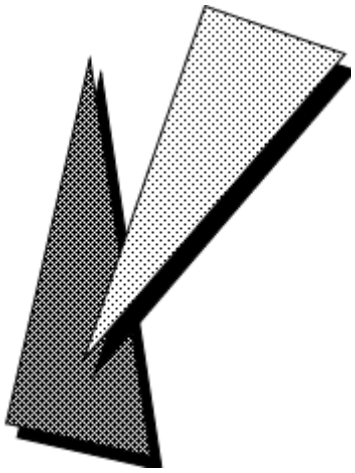
＜CALIB REVIEW LIST Screen＞



MEMO

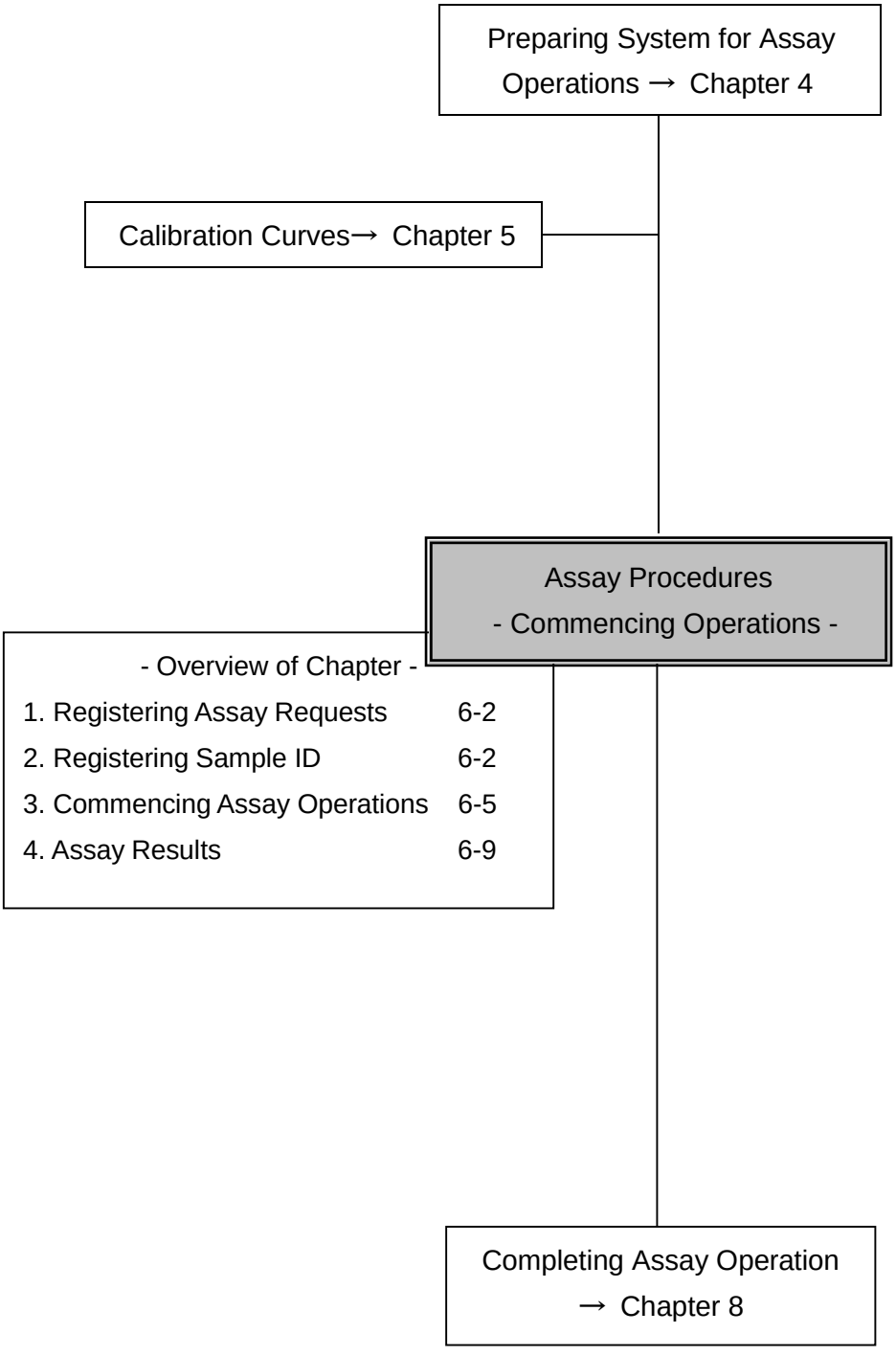
Chapter 6

Assay Procedures



Chapter 6: Assay Procedures

Introduction



Chapter 6 - 1.Registering Assay Requests

1. Registering Assay Requests

Assay requests are registered automatically using the combination of an internal barcode reader and a cup reader.
The AIA-360 is equipped with a camera capable of reading analyte names and lot numbers, enabling it to automatically distinguish between specimen types and select the appropriate assay operations, as soon as specimens and reagent cups are loaded in the carousel.

Point

- Note that up to four tests can be performed per specimen. This means that the fifth and all subsequent reagent cups per specimen will be skipped.
- In cases where tests are performed using designated sample cups, sample IDs will be assigned in the order SMPL1, SMPL2, SMPL3, etc.

2. Registering Sample ID

AIA-360 automatically registers a sample's ID using the built-in barcode reader.
The ID of an arbitrary sample can be registered by entering a sample ID before starting an assay.
The sample ID registration conditions are as follows:

Sample Container	Arbitrary Sample ID	
	Input	No Input
Sample cup	Entered ID is registered.	Auto registration (SMPL1, SMPL2, SMPL3, …)
Blood tube with no barcode label	Entered ID is registered.	Auto registration (SMPL1, SMPL2, SMPL3, …)
Blood tube with barcode label	Entered ID is registered if it matches the sample ID read by the built-in barcode reader. If they do not match, an IM flag is attached with no assay.	Auto registration (Sample ID on barcode label)

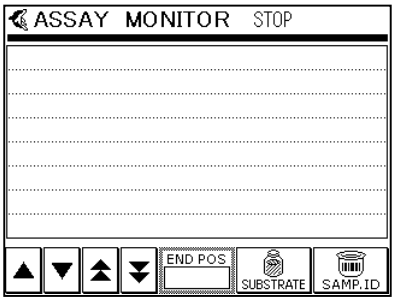
For the settings of the built-in barcode reader, see Chapter 9 "OTHER FUNCTIONS - SPECIAL, MENU - 6.BCR PARAM (DETAILED SETTINGS OF BARCODE)".

Chapter 6 - 2.Registering Sample ID

2.1 Entering a sample ID

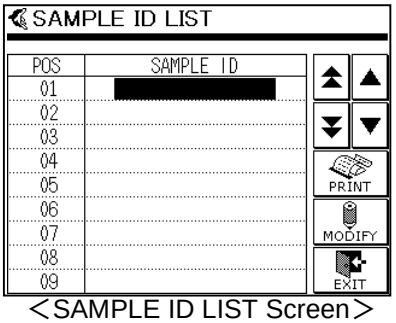
Enter a sample ID before the sample passes the built-in barcode reader.
Once a sample has passed the barcode reader, its ID cannot be entered.

① Press SAMP.ID on the ASSAY MONITOR screen.
The SAMPLE ID LIST screen is displayed.



＜ASSAY MONITOR Screen

② Move the cursor to the sample ID to be inputted by using ▲ ▼ and then press MODIFY.
The SAMPLE ID screen is then displayed.



＜SAMPLE ID LIST Screen＞

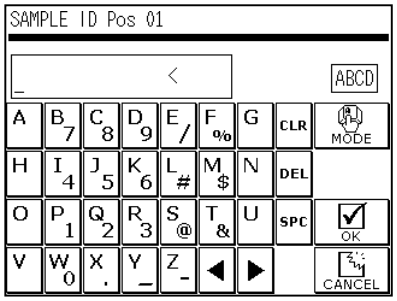
③ Enter a sample ID (16 digits max.).

Pressing MODE changes the mode as follows:

ABCD Alphabetic characters (uppercase)

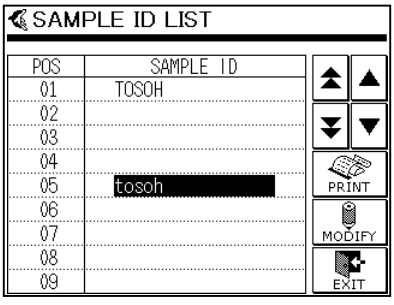
abcd Alphabetic characters (lowercase)

1234 Numerals and/or symbols



＜SAMPLE ID Screen＞

④ After inputting, press OK to return to the SAMPLE ID LIST screen.

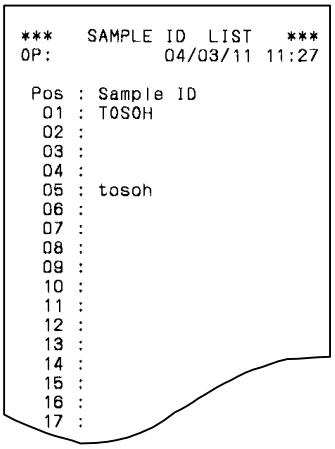


＜SAMPLE ID LIST Screen＞

Section 6 - 2. Registering a Sample ID

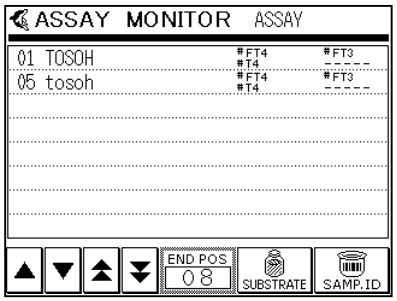
Point

Pressing PRINT prints a sample ID list. To prevent mistakes occurring, check the sample ID list when loading samples.



⑤ After checking that a sample ID has been entered, press EXIT.

⑥ When the ASSAY MONITOR screen is displayed, start inspection according to Section 3. “Commencing Assay Operations”.



<ASSAY MONITOR screen>

The built-in barcode reader reads a sample and the entered sample ID is registered.

Point

- After a sample has been read by the built-in barcode reader, the entered sample ID disappears from the SAMPLE ID LIST screen.
- An arbitrary sample ID can also be entered for additional assay.

3. Commencing Assay Operations

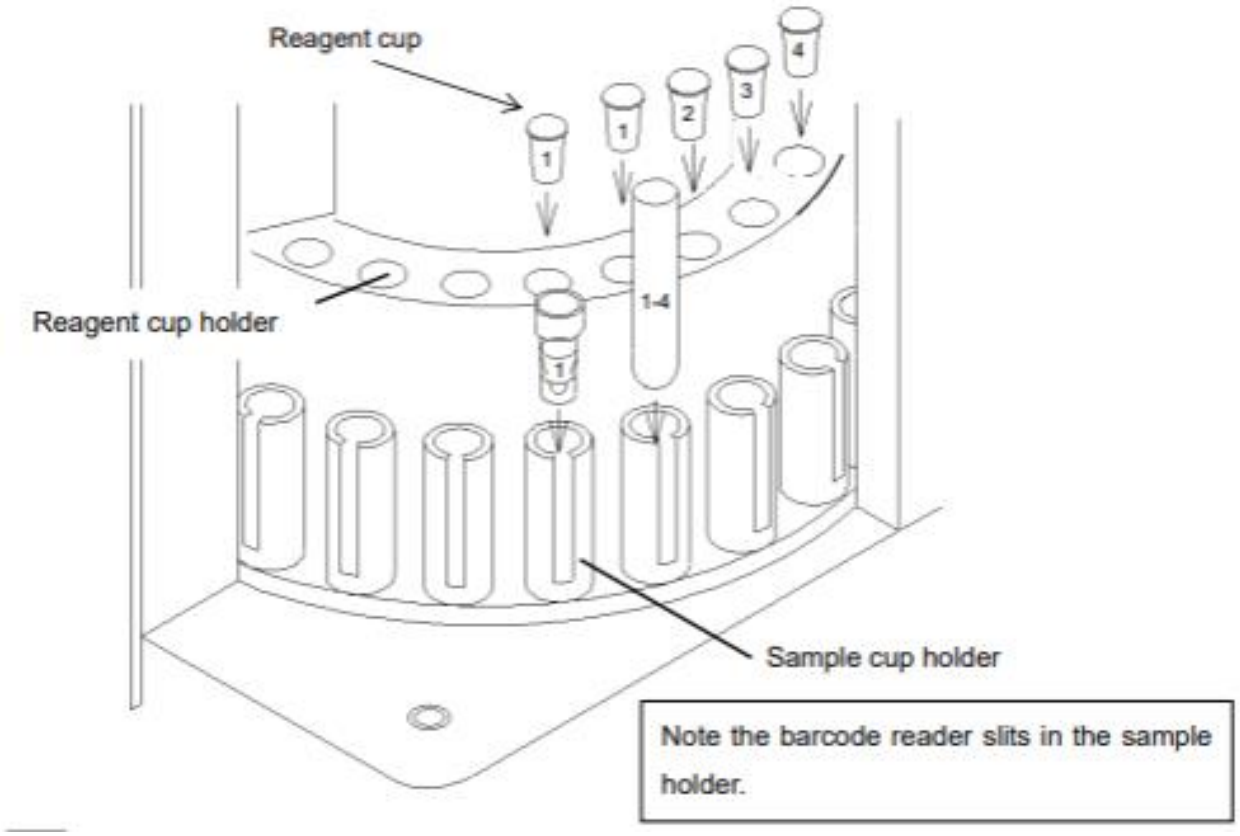
3.1 Commencing Assay Operations

① Assay operations begin with the loading of specimens and reagent cups into the carousel.

Test Tube (sample cup) and Reagent Cup Loading Procedure

Begin by loading test tubes (or designated sample cups) into the sample holder and reagent cups (numbers correspond to analytes) into the reagent cup holder.

Fig. 6-1 Test Tube and Reagent Cup Loading Procedure

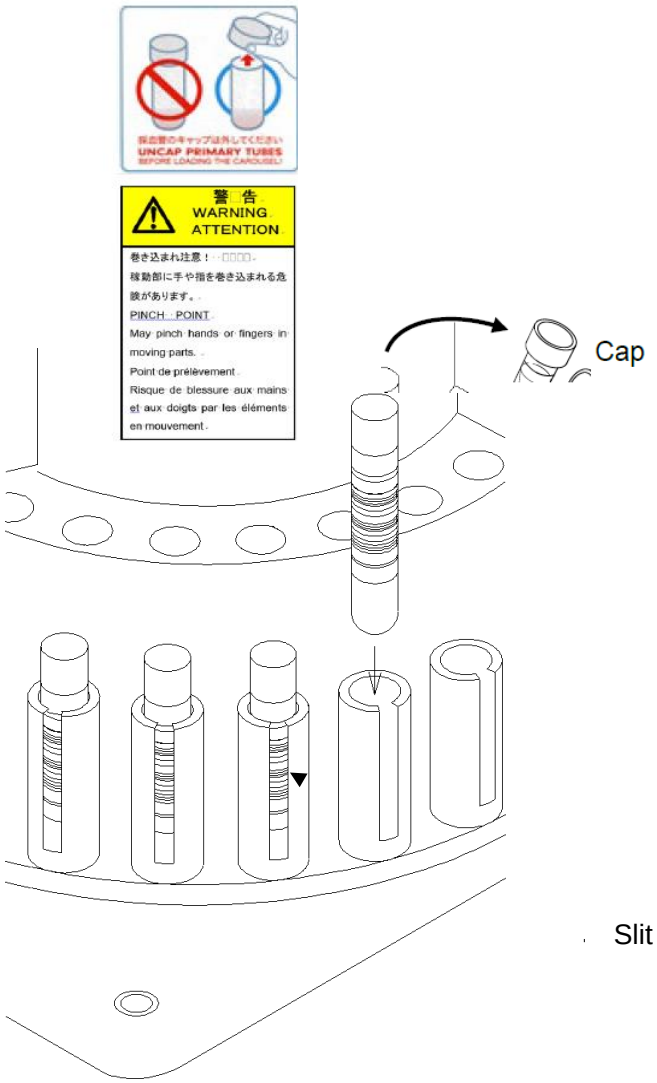


Point

- Up to four reagree cups can be assayed per specimen.
- To analyze multiple analytes per specimen, load the reagent cups at the consecutive positions of the reagent cup holder, and load the specimen only at the first position of the corresponding sample cup holder.
- The carousel can be moved one position at a time by pressing the SAMPLE FEED key.

Chapter 6 - 3.Commencing Assay Operations

- Before loading test tubes or other containers into the sample cup holder be sure to remove their caps.
  If not, accurate results may not be obtained, and the instrument may be damaged.
- Be sure to firmly insert the test tubes (sample cups) and reagent cups into their holders. Loosely inserted cups can get caught when the carousel rotates and stops the assay operation.
- Be sure to position the bar codes at the sample holder slits when using test tubes with barcodes attached, so that they can be easily read.



Chapter 6 - 3.Commencing Assay Operations

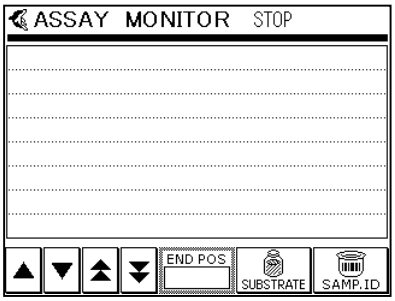
② Once the samples and reagent cups have been loaded, press 

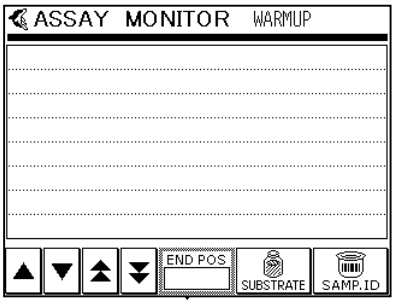
on the MENU screen to display the ASSAY MONITOR screen.

③ Press START to start the assay operation.

＜ASSAY MONITOR Screen>

The carousel moves in clockwise direction when the assay begins.

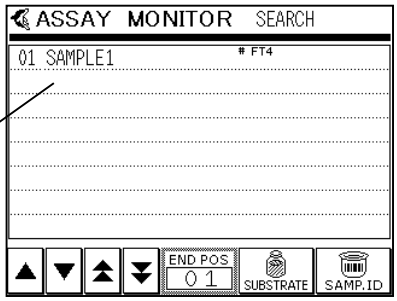




Do not depress the START key for a long time. Depressing the START key for a long time (about two seconds or longer) sends an abort request for an emergency stop and prints a warning message.

If a warning appears indicating that daily check has not been performed, refer to “Chapter 4-2 System Startup”, and follow the procedure.

Note that pressing SAMPLE FEED during the assay operation will not move the carousel forward.

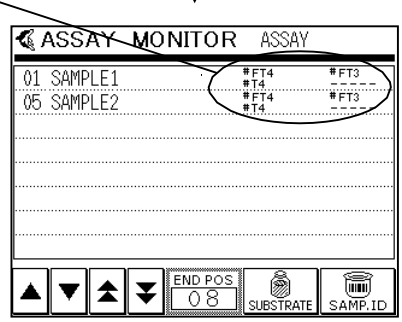


SAMPLE ID

Sample ID (up to 16 characters) can be displayed on the screen when the specimen is read.

ANALYTE

Analytes in the reagent cups read from the camera are displayed for each sample. (Maximum 4 tests)



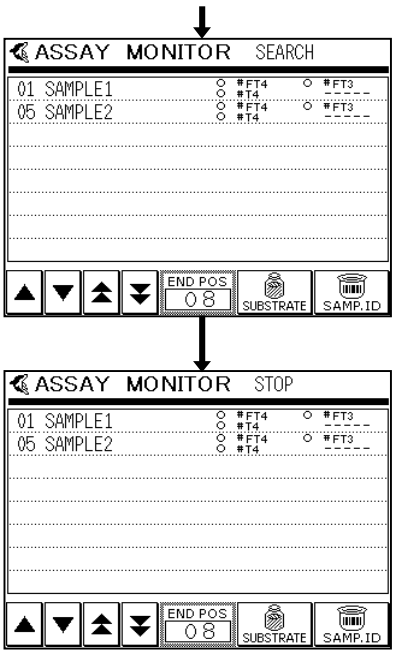
If a problem happened while assaying, press the START key for a long time (about two seconds or longer) to send an abort request for an emergency stop. Then a warning message will be printed.

Chapter 6 - 3.Commencing Assay Operations

④ The carousel makes one more rotation after the reagent cup in the final position has been assayed.

⑤ Once it has confirmed that all reagent cups have been assayed, 'CLOSING' will be displayed on the upper right of a screen and it will go into end process.
After end process, 'STOP' is displayed and measurement is suspended.

⑥ Collect the test tubes and sample cups all after the assays are completed.



- The carousel can be moved one position at a time by pressing the SAMPLE FEED key.

If there is any test tube with its cap still attached when collecting sample containers, perform the assay again.

Additional

Additional assays can be added while assay operations are in progress by inserting them in the visible section of the carousel.

Point Additional assays may be added only while either “ASSAY” or “SEARCH” are displayed at the top right of the ASSAY MONITOR screen.

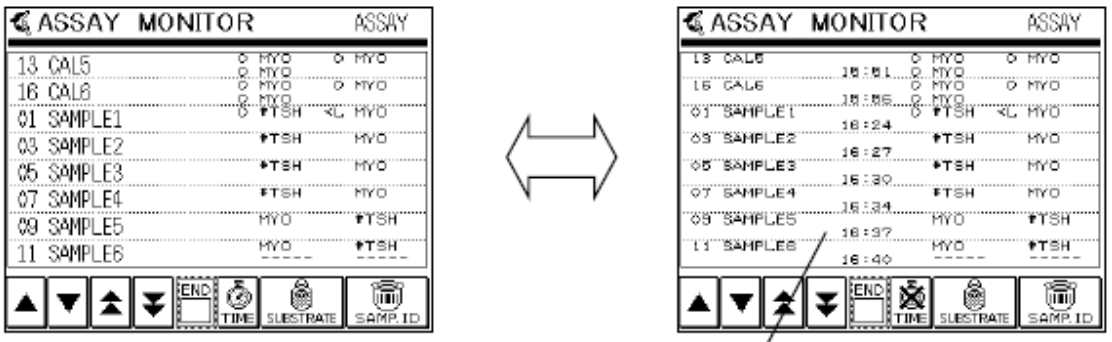
1) Make sure to remove any samples and reagent cups that have already been assayed at this time.
2) Then insert the additional samples and reagent cups in the visible section of the carousel.

The LED lamp begins flashing 10 seconds before the carousel begins to rotate.
Take care not to get fingers caught in the carousel when inserting additional samples and reagent cups.

3) The new assays will be added automatically.

Display of estimated end time of assay

When TIME on the ASSAY MONITOR screen is pressed during measurement, the screen is changed and the estimated end time of assay is displayed.



Estimated end time of assay
Displays the estimated assay end time of the specimen.

Point

Press TIME to return to the previous display (to hide the time display on the screen).

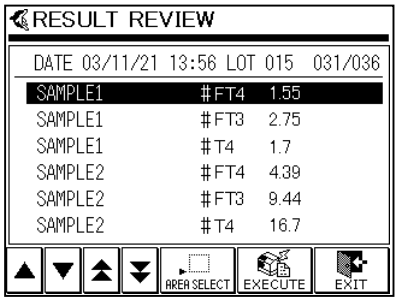
Press TIME to show the time display on the screen.

4. Assay Results

4.1 External Output of Assay Results

① Press 

on the MENU screen to display the RESULT REVIEW screen.

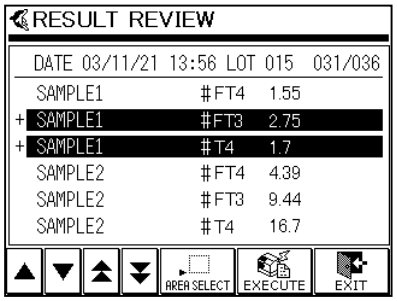


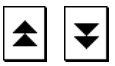
＜RESULT REVIEW Screen>

② Press 

and use  to select the range of detailed Assay Results to output externally.

（Selected range is flagged by the + sign）

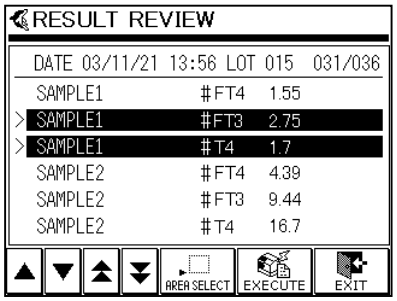


Point Press  to proceed to the next screen.

③ Press 

to confirm the selected range.

（This changes the + signs to the > sign）



Point To delete the specified range the specified range, press 

.

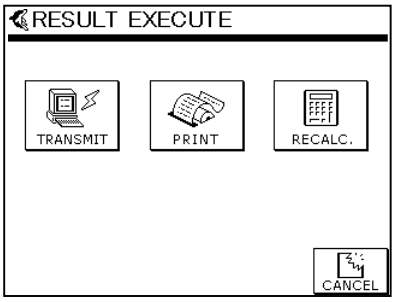
④ Next, press 

.

⑤ This displays the RESULT EXECUTE screen.

⑥ Pressing the 

displays the RESULT REVIEW screen and the selected range of Assay Results is output externally.

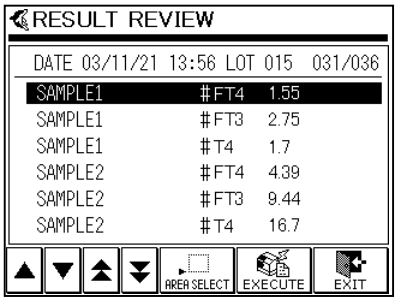


＜RESULT EXECUTE Screen>

4.2 Printing Assay Results

① Press 

on the MENU screen to display the RESULT REVIEW screen.

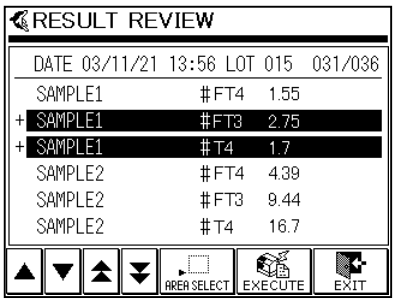


＜RESULT REVIEW Screen>

② Press 

and use  to select the range of detailed Assay Results to output externally.

（Selected range is flagged by the + sign）

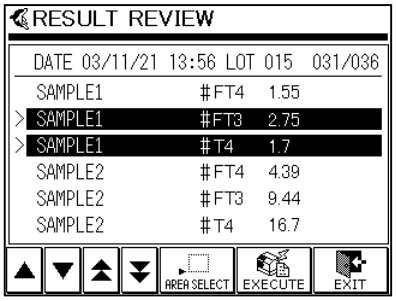


Point Press  to proceed to the next screen.

③ Press 

to confirm the selected range.

（This changes the + signs to the > sign)



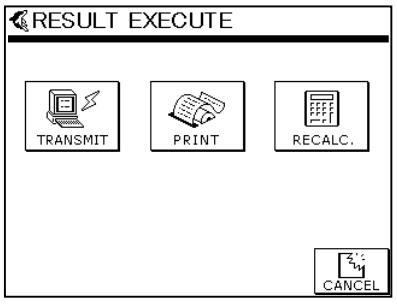
Point To delete the specified range the specified the specified range, press 

.

④ Next, press 

.

⑤ This displays the RESULT EXECUTE screen.



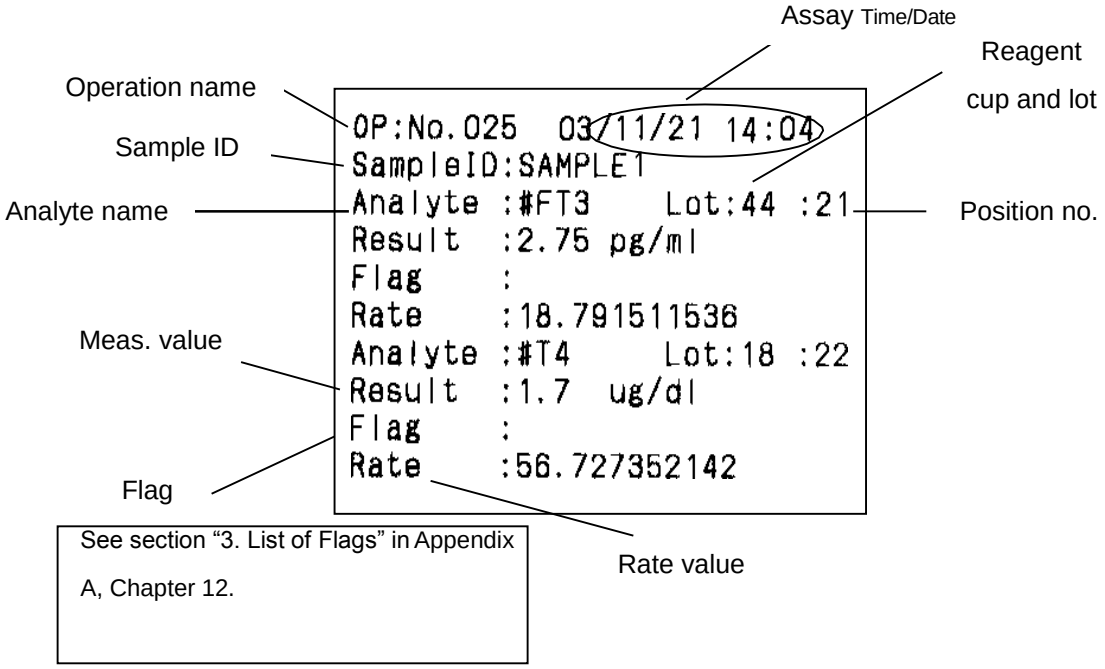
⑥ Press 

to print out the selected range of Assay Results.

＜RESULT EXECUTE Screen＞

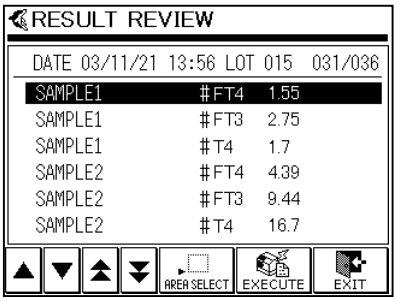
Chapter 6 - 4.Assay Results

Fig. 6-2 Sample Assay Result Printout



4.3 Recalculating Assay Results

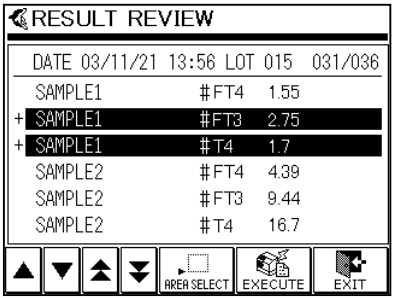
① Press  on the MENU screen to display the RESULT REVIEW screen.

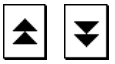


＜RESULT REVIEW Screen>

② Press  and use  to select the range of detailed Assay Results to output externally.

（Selected range is flagged by the + sign）



Point Press  to proceed to the next screen.

Chapter 6 - 4.Assay Results

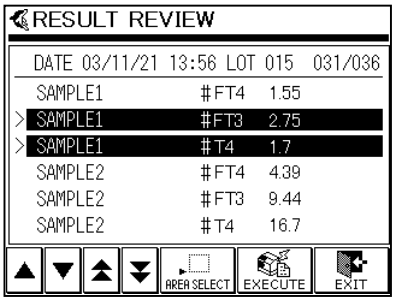
③ Press AREA SELECT to confirm the selected range.
（This changes the + signs to the > sign）

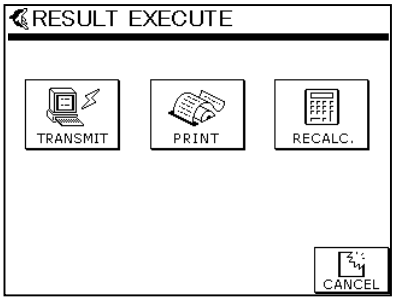
Point To unselect the specified range, press AREA SELECT.

④ Next, press EXECUTE.

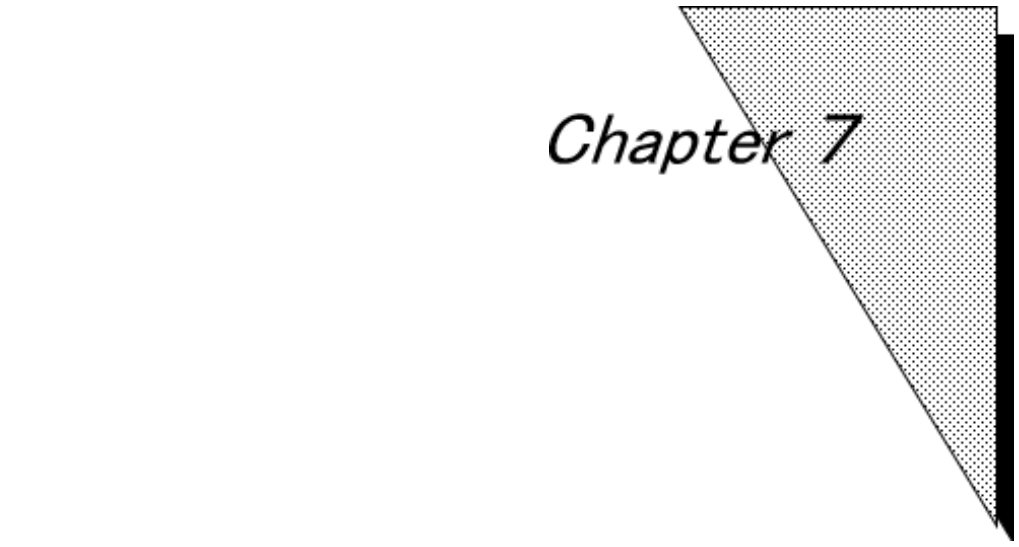
⑤ This displays the RESULT EXECUTE screen.

⑥ Pressing RECALC. recalculates the selected range of Assay Results.

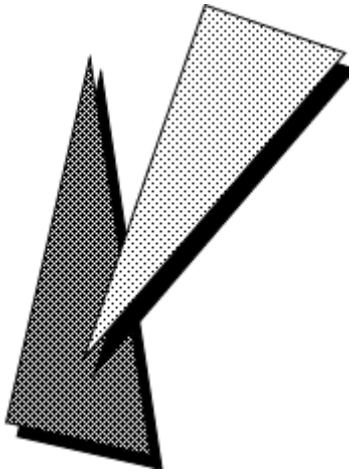




＜RESULT EXECUTE Screen>



Error Messages and Flags



Chapter 7: Error Messages and Flags

1. List of Error Messages

If a problem occurs during assay or it is difficult to continue an assay, an error message is displayed.

Together with the error message, a buzzer sounds to alert the operator to the error.

At the same time, the printer also prints the error message.

If an assay is not completed normally due to an error, an error flag may be attached to the assay value.

1.1 Error Message Lists

When an assay is started soon after turning the power switch on, if the incubator has not reached the appropriate temperature, Error Message No. 3003 is displayed and the assay may not be started.

No.	Error Message	Meaning	Troubleshooting
3003	WAITING FOR TEMPERATURE	Waiting for the temperature to rise.	Wait until the temperature rises to correct temperature.

If one of Error Messages No. 3017 to 3020 is displayed, the assay is suspended. If a reaction is in progress, however, the assay continues. Take the appropriate action in accordance with the displayed message and restart the assay. After all the ongoing assays end, perform the corresponding troubleshooting and press the START key to restart assays.

No.	Error Message	Meaning	Troubleshooting
3017	SUBSTRATE LOW	Insufficient substrate.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', replace the enzyme substrate with new one and press the START key to restart assay operation.
3018	WASTE TANK FULL	The waste tank is full.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', empty the waste tank and press the START key to restart assay operation.
3019	WASHER LOW	Insufficient wash solution.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', replace the wash solution with new one and press the START key to restart assay operation.
3020	DILUENT LOW	Insufficient diluent.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', replace the diluent with new one and press the START key to restart assay operation

Section 7-1: List of Error Messages

If an error occurs, the device stops and the message shown below is displayed.
If an error message is displayed during an assay, you may not be able to continue the assay.

Operating Errors

No.	Error message	Description	Troubleshooting
0001	FILE SYSTEM ERROR	The external recording medium could not be initialized.	Use other media or contact Tosoh local representative.
0002	MAIN PROGRAM OPEN ERROR	The main program cannot be read.	Use other media or contact Tosoh local representative.
0003	MAIN PROGRAM FORMAT ERROR	The file format of the main program is incorrect.	Use other media or contact Tosoh local representative.
0004	SLAVE PROGRAM OPEN ERROR	The slave program cannot be read.	Use other media or contact Tosoh local representative.
0005	SLAVE PROGRAM FORMAT ERROR	The file format of the slave program is incorrect.	Use other media or contact Tosoh local representative.
0006	TOUCH PANEL PROGRAM OPEN ERROR	The touch panel program cannot be read.	Use other media or contact Tosoh local representative.
0007	INSTALLATION OPEN ERROR	The image data cannot be read.	Use other media or contact Tosoh local representative.
0008	INSTALLATION FORMAT ERROR	The format of the image data file is incorrect.	Use other media or contact Tosoh local representative.
0009	INSUFFICIENT STANDARD CUP	No standard cup is loaded for the daily check.	Load a standard cup on reagent cup holder No.1 and repeat.
0010	TWO CALIBRATION CURVES CONFIRMED	Calibration curves of two lots have already been confirmed.	Delete a calibration curve before accept a new one.
0011	SAME LOT CALIBRATION CURVE	Calibration curves have already been confirmed for the same lot.	Delete the old calibration curve before accept a new one.
0012	CALIBRATION NOT ENOUGH	There is insufficient data to calculate calibration curves.	Repeat the calibration.
0013	CALCULATION ERROR	Calculation error of the calibration curve.	Repeat the calibration.
0014	CALIBRATION DATA ZIGZAG	The calibration curve rates are not in ascending order.	Repeat the calibration.
0015	TOO MANY CALIBRATION DATA	The calibration curve data is abnormal.	Repeat the calibration.
0016	CALIBRATION DATA MINUS RATE	Logarithm calculation of calibration curve failed.	Repeat the calibration.
0017	TOMAS DATA WRITE ERROR	Unable to write external recording medium.	Use other media or contact Tosoh local representative.

Section 7-1: List of Error Messages

Communication-related errors

No.	Error message	Description	Troubleshooting
1001	UNABLE TO SEND TO SLAVE	FIFO has become full during transmission to the slave.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1002	UNABLE TO RECEIVE FROM SLAVE	A communication error occurred during transmission to the slave.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1003	RECEIVE DATA ERROR FROM T.PANEL	A communication error occurred during reception from the touch panel.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1004	TRANSMISSION TO T.PANEL TIMED OUT	A timeout error occurred during reception from the touch panel.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1005	BARCODE ERROR	A barcode communication error occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1006	ASTM PARITY ERROR	A parity error occurred in ASTM communication.	Check the communication settings and cable.
1007	ASTM FRAME ERROR	An ASTM communication frame error occurred.	Check the communication settings and cable.
1008	ASTM OVERRUN ERROR	ASTM communication overrun error	Check the communication settings and cable.
1009	ASTM BUFFER FULL	The ASTM communication buffer has become full.	Check the communication settings and cable.
1011	ASTM RETRY ERROR	An ASTM communication retry error occurred.	Check the communication settings and cable.
1012	ASTM SEND TIMEOUT	A send timeout event occurred in ASTM communication.	Check the communication settings and cable.
1013	ASTM RECEIVE TIMEOUT	A receive timeout error occurred in ASTM communication.	Check the communication settings and cable.
1014	ASTM NO RESPONSE	No response was received in ASTM communication.	Check the communication settings and cable.

Control related errors

No.	Error message	Description	Troubleshooting
2001	RTC POWER ON CLEAR	An internal clock backup error occurred.	Reset the date and time. If this problem reoccurs, contact Tosoh local representative.
2002	TESTCUP READ ERROR	The test cup read error occurred.	If this problem reoccurs frequently, contact Tosoh local representative
2003	TESTCUP READ ERROR	The test cup position error occurred at the detector calibration.	Set the test cup to a right position.
2004	DET CALIB. TESTCUP READ ERROR	The test cup read error at the detector calibration.	Set the STD cup to a right position.
2005	DET CALIB. DIVIDE BY ZERO	Data error at the detector calibration.	Check the conditions, Repeat the detector calibration.

Section 7-1: List of Error Messages

Control related errors

No.	Error message	Description	Troubleshooting
2006	DET CALIB. DATA VARIANCE ERROR	Data variance error at the detector calibration.	Check the conditions, Repeat the detector calibration.
2007	DET CALIB. ABNORMAL DATA	Data abnormal error at the detector calibration.	Check the conditions, Repeat the detector calibration.
2008	DET CALIB. SUBSTRATE HB	The background intensity of substrate is high.	Replace the new substrate
2009	BF PROBE LIQUID SENSOR ERROR	Liquid detection error in BF probe.	Contact Tosoh local representative.
2010	SAMPLE LEVEL FAILURE	A liquid detection open-circuit error occurred at the sample nozzle.	Contact Tosoh local representative.
2011	AIR DETECTED [SAMPLE]	There is no contact with the liquid surface after sample suction.	Contact Tosoh local representative.
2012	AIR DETECTED [DILUENT]	There is no contact with the liquid after diluent suction.	Contact Tosoh local representative.
2013	SAMPLE LEVEL DETECTION ERROR	The liquid surface cannot be detected even at the bottom of the sample cup or the blood sample tube.	Contact Tosoh local representative.
2014	SAMPLE SHORTAGE DETECTED	Insufficient sample.	Prepare enough volume of specimen.
2015	BF PROBE PURGE FAILURE	Purging by the BF probe is abnormal.	Clean up the wash probe tip or replace it. Contact Tosoh local representative.
2016	BFPROBE SUCTION FAILURE	Suction by the BF probe is abnormal.	Contact Tosoh local representative.
2017	SUBSTRATE PURGE FAILURE	The substrate was not purged normally.	Check for insufficient substrate.

Monitor-related errors

No.	Error message	Description	Troubleshooting
3001	PRINTER PAPER END	No paper is loaded in the printer.	Load paper in the printer.
3002	PRINTER HEADUP	The printer head has gone up.	Lower the printer head.
3003	WAITINGFOR TEMPERATURE	Waiting for the temperature to rise.	Wait until the temperature rises to correct temperature.
3004	TEMPERATURE TIMEOUTED	A timeout error occurred while waiting for the temperature to rise.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3005	TURN TABLE TEMPERATURE LOW	The turntable temperature is below the lower limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3006	WASHER TEMPERATURE LOW	The wash solution temperature is below the lower limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3007	SUBSTRATE TEMPERATURE LOW	The substrate temperature is below the lower limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

Monitor-related errors

No.	Error message	Description	Troubleshooting
3008	TURN TABLE TEMPERATURE HIGH	The turntable temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3009	WASHER TEMPERATURE HIGH	The wash solution temperature is above the target temp.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3010	SUBSTRATE TEMPERATURE HIGH	The substrate temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3011	TURN TABLE TEMP. MALFUNCTION	The turntable temperature sensor disconnection occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3012	WASHER TEMP. MALFUNCTION	The wash solution temperature sensor disconnection occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3013	SUBSTRATE TEMP. MALFUNCTION	The substrate temperature disconnection error occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3014	TURN TABLE TEMP. LIMIT	The turntable temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3015	WASHER TEMP. LIMIT	The wash solution temperature reach the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3016	SUBSTRATE TEMP. LIMIT	The substrate temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3017	SUBSTRATE LOW	Insufficient substrate.	Replace the enzyme substrate.
3018	WASTE TANK FULL	The waste tank is full.	Empty the waste tank.
3019	WASHER LOW	Insufficient wash solution.	Replenish the wash solution.
3020	DILUENT LOW	Insufficient diluent.	Replenish the diluent.
3021	LEAK SENSOR S701 DETECTED	Leakage sensor S701 activated.	Contact Tosoh local representative.
3022	LEAK SENSOR S702 DETECTED	Leakage sensor S702 activated.	Contact Tosoh local representative.
3023	PM DUE	Periodic Maintenance due.	Contact Tosoh local representative.
3024	PM REQUIRED	Periodic Maintenance is required.	Contact Tosoh local representative.

Actuator-related errors

No.	Error message	Description	Troubleshooting
4001	TURN TABLE HOME SENSOR	The turntable motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4002	TURN TABLE HOME NOT FOUND	The home position of the turntable motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4003	TURN TABLE HOME OVERRUN	The turntable motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

Actuator-related errors

No.	Error message	Description	Troubleshooting
4004	TURN TABLE SLIP	The turntable motor slipped.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4005	TURN TABLE ACCELL	The acceleration/deceleration table of the turntable motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4006	TURN TABLE S106	The turntable anti-rotation sensor is activated.	Check that the blood sample tube is in contact with the sensor.
4007	MIXER HOME SENSOR	The mixer motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4008	MIXER HOME NOT FOUND	The home position of the mixer motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4009	MIXER HOME OVERRUN	The mixer motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4010	MIXER SLIP	The mixer motor slipped.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4011	MIXER ACCELL	The acceleration/deceleration table of the mixer motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4012	SPEC.SY HOME SENSOR	The specimen syringe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4013	SPEC.SY HOME NOT FOUND	The home position of the specimen syringe motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4014	SPEC.SY HOME OVERRUN	The specimen syringe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4016	SPEC.SY ACCELL	The acceleration/deceleration table of specimen syringe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4017	SPEC.SY CLOG DETECTED	Specimen clog was detected.	The item is not assayed. Repeat assay.
4018	SPEC.Z-AXIS HOME SENSOR	The specimen Z-axis motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4019	SPEC.Z-AXIS HOME NOT FOUND	The home position of the specimen Z-axis motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4020	SPEC.Z-AXIS HOME OVERRUN	The specimen Z-axis motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

Actuator-related errors

No.	Error message	Description	Troubleshooting
4022	SPEC.Z-AXIS ACCELL	The acceleration/deceleration table of the specimen Z-axis motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4023	SPEC.R-AXIS HOME SENSOR	The specimen R-axis motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4024	SPEC.R-AXIS HOME NOT FOUND	The home position of the specimen R-axis motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4025	SPEC.R-AXIS HOME OVERRUN	The specimen R-axis motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4027	SPEC.R-AXIS ACCELL	The acceleration/deceleration table of the specimen R-axis motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4028	SPEC.T-AXIS HOME SENSOR	The specimen θ-axis motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4029	SPEC.T-AXIS HOME NOT FOUND	The home position of the specimen θ-axis motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4030	SPEC.T-AXIS HOME OVERRUN	The specimen θ-axis motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4032	SPEC.T-AXIS ACCELL	The acceleration/deceleration table of the specimen θ-axis motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4033	SEAL BREAK HOME SENSOR	The seal breaker motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4034	SEAL BREAK HOME NOT FOUND	The home position of the seal breaker motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4035	SEAL BREAK HOME OVERRUN	The seal breaker motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4037	SEAL BREAK ACCELL	The acceleration/deceleration table of the seal breaker motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4038	WASH.PROBE HOME SENSOR	The BF probe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4039	WASH.PROBE HOME NOT FOUND	The home position of the BF probe motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4040	WASH.PROBE HOME OVERRUN	The BF probe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

Actuator-related errors

No.	Error message	Description	Troubleshooting
4042	WASH.PROBE ACCELL	The acceleration/deceleration table of the BF probe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4043	WASH.SY HOME SENSOR	The BF syringe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4044	WASH.SY HOME NOT FOUND	The BF syringe motor home position cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4045	WASH.SY HOME OVERRUN	The BF syringe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4047	WASH.SY ACCELL	The acceleration/deceleration table of the BF syringe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4048	SUBST.SY HOME SENSOR	The substrate syringe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4049	SUBST.SY HOME NOT FOUND	The substrate syringe motor home position cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4050	SUBST.SY HOME OVERRUN	The substrate syringe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4052	SUBST.SY ACCELL	The acceleration/deceleration table of the substrate syringe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4053	SEAL BREAK POS. SENSOR	The seal breaking position sensor is faulty.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

System-related errors

No.	Error message	Description	Troubleshooting
5001	INTERNAL ERROR	Internal program error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5002	NO RESPONSE FROM SLAVE	Slave response not detected error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5003	SLAVE COMMAND ERROR	Slave command error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5004	SLAVE FIFO ERROR	Slave FIFO error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5005	MAIN PROGRAM ERASE TIMED OUT	Main program erase timeout.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5006	MAIN PROGRAM WRITE ERROR	Main program write error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5007	MAIN PROGRAM COMPARE ERROR	Main program compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5008	MAIN PROGRAM NOT INSTALLED	Main program not found.	Contact Tosoh local representative.
5009	SLAVE PROGRAM ERASE TIMED OUT	Slave program erase timeout.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5010	SLAVE PROGRAM WRITE ERROR	Slave program write error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5011	SLAVE PROGRAM COMPARE ERROR	Slave program compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5012	SLAVE PROGRAM NOT INSTALLED	Slave program not found.	Contact Tosoh local representative.
5013	INSTALLATION ERASE TIMED OUT	Image data erase timeout.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5014	INSTALLATION WRITE ERROR	Image data write error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5015	INSTALLATION COMPARE ERROR	Image data compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5016	INSTALLATION NOT INSTALLED	Image data not found.	Contact Tosoh local representative.
5017	PRINTER HARD ERROR	Printer hardware error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

System-related errors

No.	Error message	Description	Troubleshooting
5018	ASSAY ABORTED	Measurement terminated.	Repeat assay.
5019	DETECTOR CALIB. ABORTED	Detector calibration aborted.	Check the conditions, Repeat the detector calibration.
5020	DETECTOR TASK ERROR	Detector calibration task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5021	TURNTABLE TASK ERROR	Turntable task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5022	SPECIMEN TASK ERROR	Specimen arm task execution error.	Turn the power off and on again. Send the printed error report to Tosoh local representative.
5023	SEALBREAK TASK ERROR	Seal break task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5024	CCD TASK ERROR	Cup read task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5025	SUBTRATE TASK ERROR	Substrate task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5026	WASHER TASK ERROR	BF washing task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5027	DRAIN TASK ERROR	Drain task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5029	CSUM ERROR (PARAM)	Control parameter checksum error.	Turn the power off and on again and check the parameters. If this problem reoccurs, contact Tosoh local representative.
5030	CSUM ERROR (REAGENT)	Test file checksum error.	Turn the power off and on again and check the test file and calibration curve. If this problem reoccurs, contact Tosoh local representative.
5031	CSUM ERROR (RESULT)	Assay result checksum error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5032	CSUM ERROR (ERRLOG)	Error log checksum error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5033	CSUM ERROR (OPERATION LIST)	Operation log checksum error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Section 7-1: List of Error Messages

System-related errors

No.	Error message	Description	Troubleshooting
5034	TESTFILE FLASH COMPARE ERROR	Test file data write compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5035	MUTEX LOCK UNLOCK ERROR	Control variable acquisition error for sample dispensing task.	Send the printed error report to Tosoh local representative.

Section 7-2: List of Flags

2. List of Flags

A flag is attached to an assay result as appropriate: an error flag if an assay does not complete normally because of a problem or a user flag (normal or abnormal value) to enable the user to discriminate an assay result.

When an error flag is attached, the assay result may or may not be available depending on the error. When an error flag is not attached, the result of a normally finished assay is available. If no assay result is available due to an error, take the appropriate action according to Section 2.1 “Flag Lists” and Section 2.2 “Detailed Meanings of Flags and Action”.

2.1 Flag Lists

Error flags

FLAG	Meaning	Action	CAL.	Result
SE	System error	Terminate assay	REJECT	INCOMPLETE
ME	Item error (unable to assay)	Do not assay	REJECT	INCOMPLETE
AE	Test cup read error	Do not assay	REJECT	INCOMPLETE
NB	Seal breaking failure	Do not assay	REJECT	INCOMPLETE
IM	Sample ID mismatch	Do not assay	REJECT	INCOMPLETE
WU	B/F washing failure	Do not assay	REJECT	INCOMPLETE
DS	Insufficient diluent	Do not assay	REJECT	INCOMPLETE
WS	Insufficient wash solution	Do not assay	REJECT	INCOMPLETE
SS	Insufficient sample	Do not assay	REJECT	INCOMPLETE
SP	Waste liquid full	Do not assay	REJECT	INCOMPLETE
SC	Nozzle clogged	Do not assay	REJECT	INCOMPLETE
LE	Lot read error	Do not assay	REJECT	INCOMPLETE
DO	Over detector range	Perform assay	REJECT	INCOMPLETE
NC	No calibration curve	Perform assay	-	RATE
CE	Operation error	Perform assay	REJECT	INCOMPLETE
<L	Lower than the calibration area	Perform assay	-	RATE
>H	Higher than the calibration area	Perform assay	-	RATE
IO	Imperfect temperature control	Perform assay	REJECT	RATE
MF	Mechanical error in dispensing sample	Do not assay	REJECT	INCOMPLETE
BS	Insufficient enzyme substrate	Perform assay	REJECT	INCOMPLETE
HB	High substrate blank	Perform assay	REJECT	RATE
CV	Calibration curve expired If it passes 60 days or more since the expiration date, assay results will be reported in rate values with NC flags.	Perform assay	-	CONC
DL	Insufficient substrate dispensing volume or low detector light intensity	Perform assay	REJECT	RATE
MA	Mismatch between reading and order (CALIBRATION)	Use reader Info	REJECT	-

Section 7-2: List of Flags

User flags

L	Lower than (user) reference range	Perform assay	-	CONC
H	Higher than (user) reference range	Perform assay	-	CONC
	No flag indicates normal result	Perform assay	ACCEPT	CONC

Abbreviations

CAL. : ACCEPT … Calibrator data automatically accepted
REJECT … Calibrator data automatically rejected

Result : INCOMPLETE … Assay result incomplete
RATE … Only rate value obtained
CONC … Rate and concentration value obtained

2.2 Detailed Descriptions of Flags and Actions

SE: The assay could not be completed due to a problem (error) that does not disable the device.

ME: The assay item could not be read at calibration or it was an item which cannot be used in AIA-360. Check labeling on the test cup and repeat assay.
If this flag appears continuously, the cup reader may have been displaced. Contact Tosoh local representative.

Point This flag may be attached if the test cup is not checked by pressing SKIP in the CALB REQUEST (Check START) screen.

AE: The assay item could not be read by the cup reader.
In this case, no assay request is assumed and the assay is cancelled.
Check labeling on the test cup and repeat assay.
If this flag appears continuously, the cup reader may have been displaced. Contact Tosoh local representative.

NB: The seal of the test cup could not be broken. The assay is cancelled.
The seal breaker may have a dirty blade or be displaced.
Contact Tosoh local representative.

Section 7-2: List of Flags

IM: The sample was skipped because the input sample ID did not match the one read by the built-in barcode reader. Repeat assay after checking the barcode label position and quality and also the sample order.

WU: During B/F washing, the wash solution could not be drained.
If this flag appears continuously, the tip of the B/F washing probe may be dirty or clogged. Contact Tosoh local representative.

DS: Insufficient diluent has been detected. Replenish the diluent and repeat assay.

WS: Insufficient wash solution has been detected. Replenish the wash solution and repeat assay.

SS: The assay was cancelled because of insufficient sample. If this flag appears when there is an enough sample, either the sample nozzle or the sample detection sensor may be faulty. If this problem occurs frequently, contact Tosoh local representative.

SP: The waste bottle has become full. Discard the waste liquid and repeat assay.

SC: Dispensing was cancelled because clogging was detected during sample suction. Check that the sample is free of fibrin or other substances. If the sample is not clouded, the sample nozzle may be faulty or the tubing may be blocked. If this problem occurs frequently, contact Tosoh local representative.

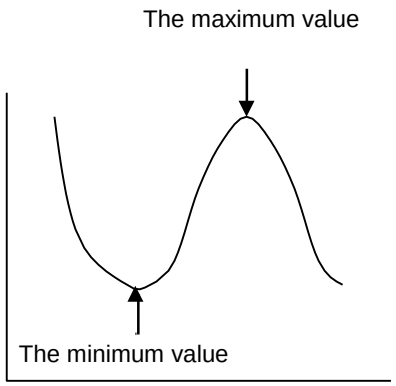
LE: The lot number of the assay item could not be read by the cup reader.
In this case, no assay request is assumed and the assay is cancelled.
Check labeling on the test cup and repeat assay.
If this flag appears continuously, the cup reader may have been displaced. Contact Tosoh local representative.

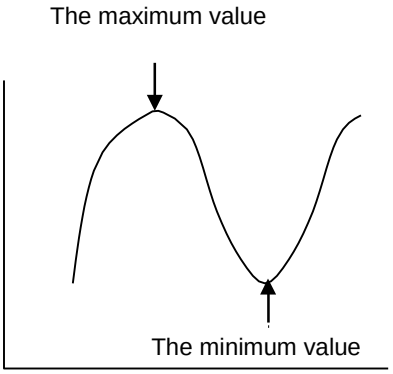
Section 7-2: List of Flags

DO: No result could be obtained because the measuring range of the detector was exceeded. Dilute the sample as required and repeat assay.

NC: No result was obtained because there was no calibration curve for the item or lot.
Alternatively, the concentration could not be calculated because the calibration curve has expired 60 days ago or earlier.
In these cases, create a calibration curve and recalculate to obtain a result.

CE: No result was obtained because an operation error occurred during the rate calculation or the conversion of concentration. An item using a multi-point calibration curve may result in an error for some relationship between the shape of the calibration curve and the conversion range of concentration. Check that the calibration curve does not have the minimum value or the maximum value in the calibration area (see the figure) and that the calibration area is in the range specified by the manufacturer.
For the range of calibration area, the minimum value is set to ASSAY L and the maximum value to ASSAY H in the TEST FILE screen.





<L: The assay result was not accepted because it lies below the calibration area.

>H: The assay result was not accepted because it lies above the calibration area. Dilute the sample as required and assay it again.

Section 7-2: List of Flags

IO: The temperature exceeded the controllable range.
If this flag appears frequently, contact Tosoh local representative.

MF: A flag is attached due to an abnormality occurring during sample dispensing.
Operation continues but a return failure disables the assay.

BS: There is insufficient enzyme substrate.
Replace the enzyme substrate.

HB: The substrate has decomposed and the blank is high.
If the substrate blank is high, dispersion in a low enzyme activity area will be large. Replace the substrate and repeat assay.
If the HB flag appears even after the substrate is replaced, the substrate line may be contaminated. In this case, contact Tosoh local representative.

CV: The calibration curve has expired.
Set up the calibration curve for the same lot and recalculate in the RESULT REVIEW screen.
If it passes 60 days or more since the expiration date, assay results will be reported in rate values with NC flags.

DL: The substrate dispensing amount is less than the specified amount or the lamp intensity of the fluorescence detector is low. If the DL flag is attached, replace the substrate (MAINTE screen → 6. REPLACE SUBSTRATE 

) and repeat assay. If the DL flag appears again, contact Tosoh local representative.

MA: The assay item read by the camera is different from the requested assay item. Check the read and requested items.

Point This flag may be attached if the test cup is not checked by pressing 

in the CALB REQUEST (Check START) screen.

2.3 Meanings of Daily Check Flags and Actions

After performing a daily check on the substrate background, the result is printed. The printed flags have the following meanings:

1. Substrate Replacement

OK: Liquid substitution with the enzyme substrate is sufficient.

ERR: Liquid substitution with the enzyme substrate is insufficient or the lamp intensity of the detector decreased.
Check the remaining amount of enzyme substrate and perform the daily check again.
If an 'ERR' appeared again, please contact Tosoh local representative.

2. 4MU Background

OK: The fluorescence intensity (background intensity) of the enzyme substrate is below 1500 nmol/L.

HB: The fluorescence intensity (background intensity) of the enzyme substrate is 1500 nmol/L or more.
Replace the enzyme substrate and perform daily check again.

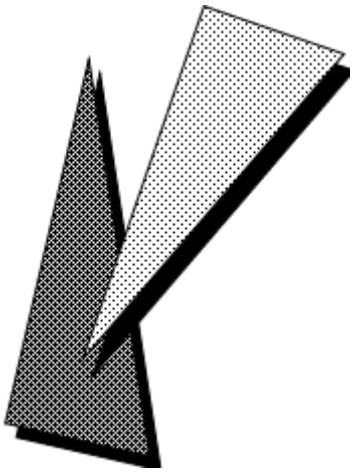
3. Lamp Intensity Level

OK: The lamp intensity of the detector is sufficient.

LL: The lamp doesn't light or the lamp intensity of the detector is not sufficient.
Please contact Tosoh local representative.

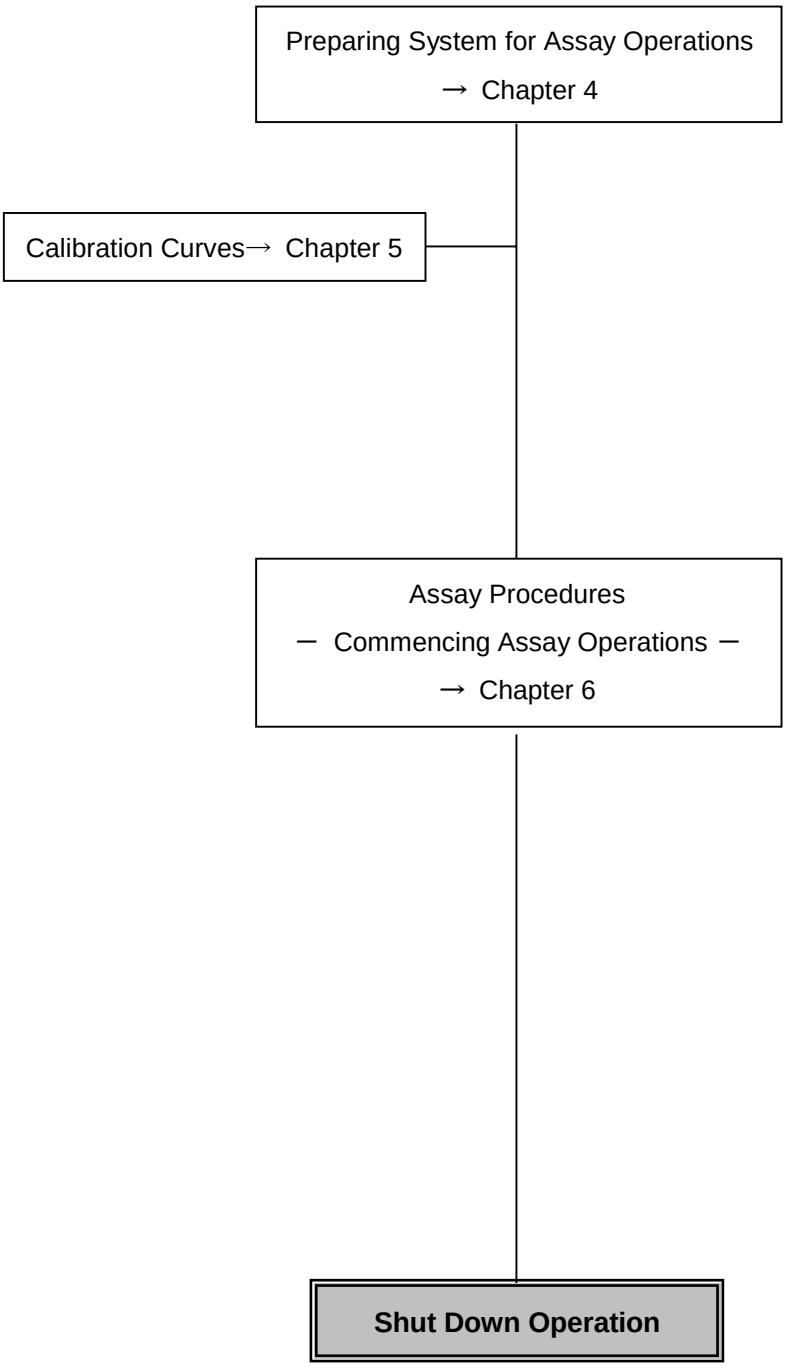
Chapter 8

Shutting Down Operation



Chapter 8：Shut Down Operation (Shut Down Menu)

Introduction



Chapter 8 - 1.Shut Down Operation (Shut Down Menu)

1. Shut Down Operation (Shut Down Menu)

Make sure to prime the substrate lines at the end of each day of operation. Leaving the substrate in the lines will result in fluid evaporation and precipitation of the reagent, which may clog the lines. Residual substrate in the lines may also cause a higher background measurement.

Replace the substrate in the lines by priming them with 70 % ethanol or 70 % isopropyl alcohol solution.
Also note that priming the lines with distilled water will contaminate the lines and cause higher background measurement results for the enzyme substrate.

Procedures

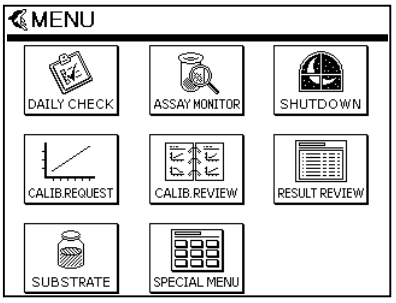
① Remove all sample cups, test tubes and reagent cups for which assays have been completed.

② Remove the enzyme substrate bottle and replace it with the 70 % ethanol or 70 % isopropyl alcohol solution bottle.

- Seal the enzyme substrate bottle with a clean rubber stopper or parafilm and place in refrigerator.
- Diluent and wash solution do not require refrigeration, so need not be removed.

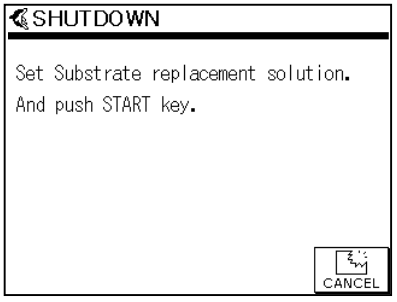
③ Press MENU to display the MENU screen.

④ Press SHUTDOWN.



<MENU Screen>

⑤ Message on the SHUT DOWN screen. This displays “Set substrate replacement solution and press START”.



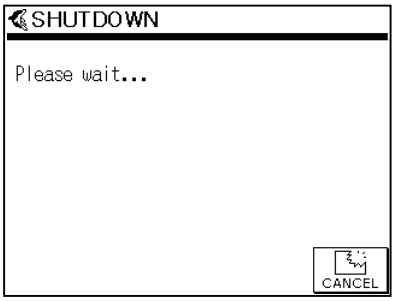
<SHUT DOWN Screen>

Point

Note that the SHUT DOWN screen is not displayed during the assay operations

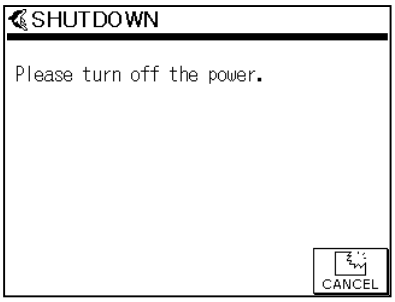
Chapter 8 - 1.Shut Down Operation (Shut Down Menu)

⑥ Press START to commence the substrate replacement operation.
The “Please Wait…” message is displayed while the priming operation is in progress.

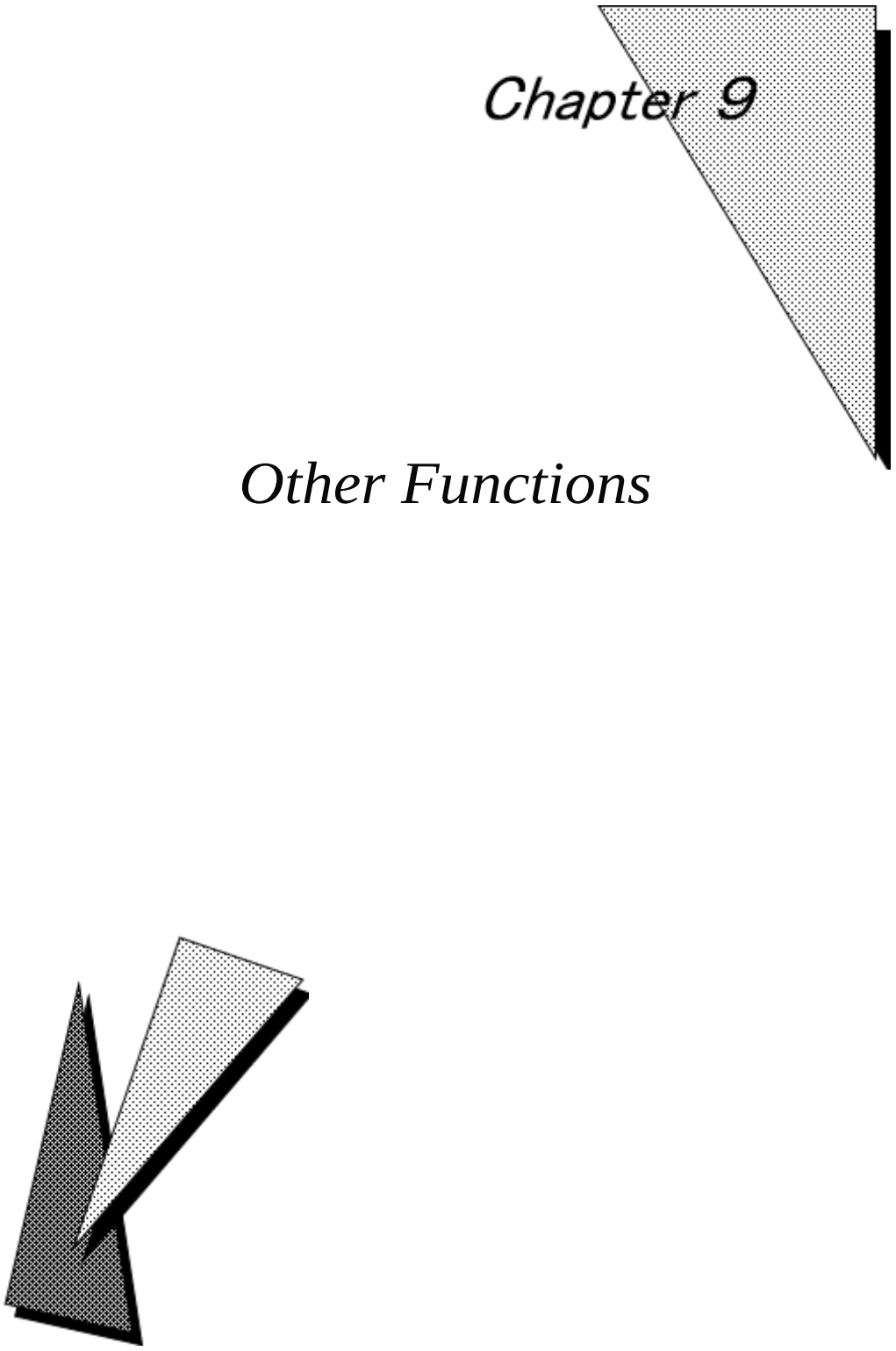


A shut down operation in progress can be terminated by pressing CANCEL.

⑦ “Please Turn off the Power” will appear on the screen, indicating that the priming operation is complete.
Turn off the system power supply.



Point Note that assay results are retained in the system memory after the power is turned off. System memory is capable of storing up to 800 assay results. Assay results are deleted in order starting from the oldest as new results are entered in the memory.



Chapter 9

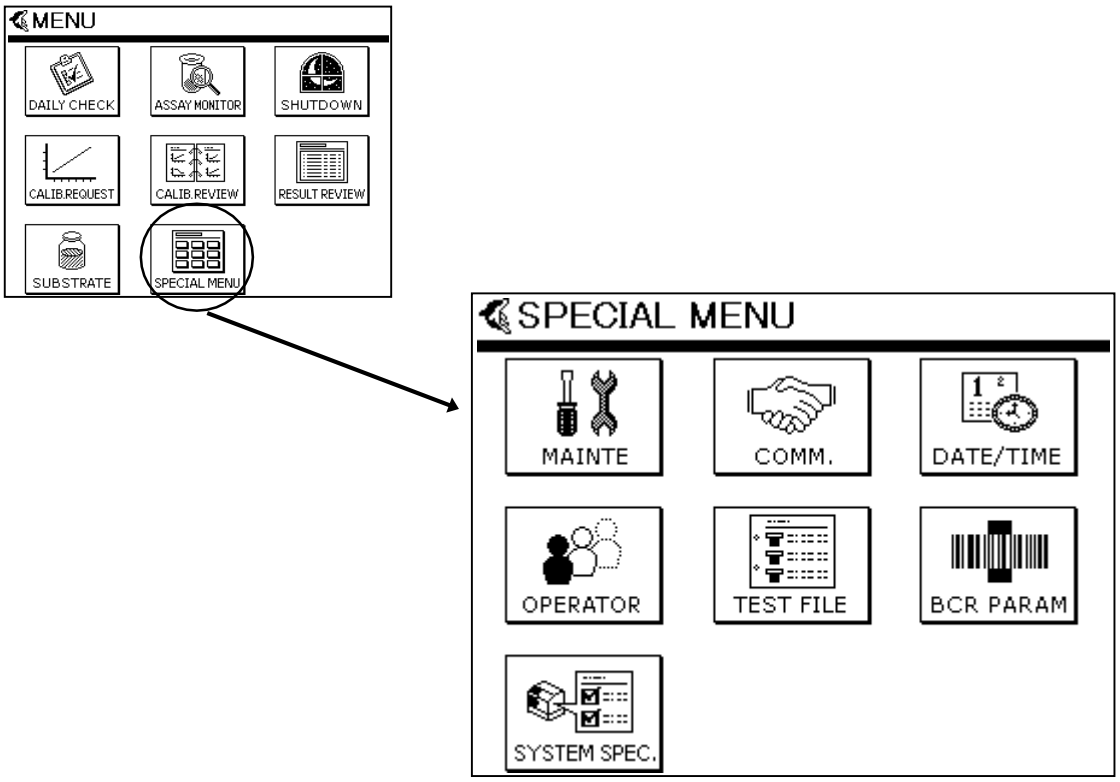
Other Functions

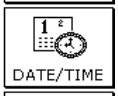
Chapter 9: Other Functions in SPECIAL MENU

The SPECIAL MENU provides the menus required for entering various system operation settings and maintenance utility functions.

Press 

in the MENU screen to display the SPECIAL MENU screen.



	MAINTE	: Used to monitor the status of various system components.
	COMM.	: RS232C transmission parameter settings
	DATE/TIME	: Used to set date and time.
	OPERATOR	: Used to register and change operator names.
	TEST FILE	: Used to enter parameters for individual test items (analytes).
	BCR PARAM	: Used to enter barcode parameters.
	SYSTEM SPEC.	: Used to enter system operating specifications.

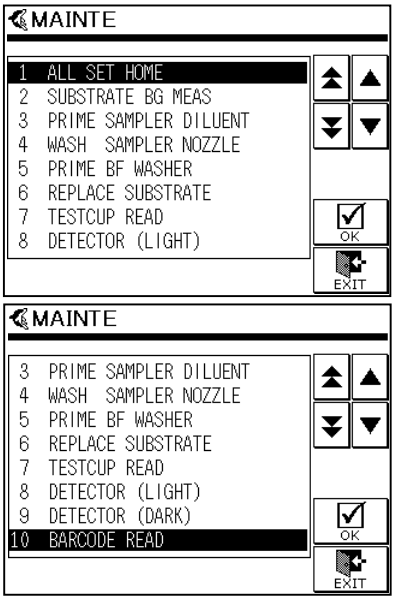
Chapter 9 – 1.MAINTE (Maintenance Tool)

1. MAINTE（Maintenance Tool）

This utility is used to check the operating status of the AIA-360 system's various operating components.

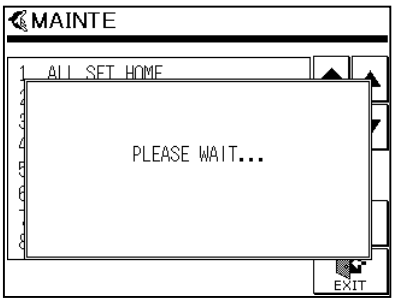
Basic Operating Procedures

① Go to MAINTE SCREEN, move cursor to the item to be checked and press [OK].



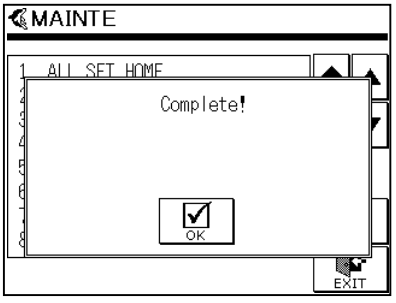
＜MAINTE Screen＞

② The WAIT screen (Please Wait…) appears while the selected item is being checked.



＜WAIT Screen＞

③ The status check is completed by pressing [OK] when "Complete!" appears on the screen.



＜Complete! Screen (Sample)＞

Please observe the operation checking procedures whenever they are provided for specific items.

Chapter 9 – 1.MAINTE (Maintenance Tool)

1：ALL SET HOME ：Moves the various system components back to their correct start positions.

2 ： SUBSTRATE BG MEAS ：Performs substrate background measurement.

Perform after installing a new substrate solution bottle, but first use "6：REPLACE SUBSTRATE" to prime the enzyme substrate lines.

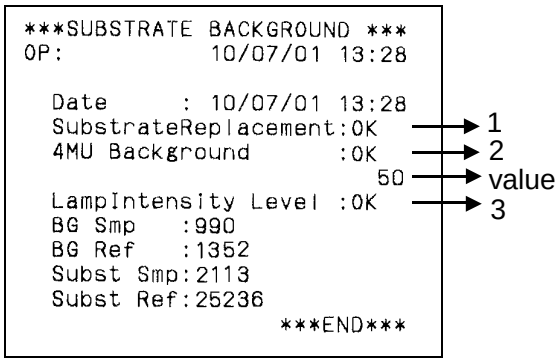
① Place 1 detector standardization cup (STD cup) in the No. 1 position (slot) in the reagent cup holder.

② Move cursor to "2 ： SUBSTRATE BG MEAS."

③ Press the OK button to activate the carousel and perform substrate background measurement.

④ The "Complete! Screen" is displayed and measured results are printed out when the measuring operation completes.

Fig 9-1 Sample Printout of Substrate Background Measurement Results



1. Indicates whether substrate replacement using the new substrate solution was successful.
   OK ： When successful
   ERR： When unsuccessful

2. Indicates whether the operation to measure fluorescent intensity (background intensity) of the enzyme substrate detected any problems. This is reported with value in nmol/L.
   OK ：When lower than 1500 nmol/L (No problem)
   HB ：When equal to or higher than 1500 nmol/L (Background was too high)

3. Indicates the status of detector lamp intensity.
   OK： When sufficient
   LL ： When insufficient → Contact a Tosoh local representatives.

Chapter 9 - 1.MAINTE (Maintenance Tool)

3 : PRIME SAMPLER DILUENT : Used when filling up diluent

This is used when priming system with diluent.

① Prime the system with diluent.

② Move cursor to “3 : PRIME SAMPLER DILUENT” and press OK.

This launches the diluent filling operation.

4 : WASH SAMPLER NOZZLE : Used for washing sampling nozzle 5

: PRIME BF WASH : Used when filling buffer with wash solution

This is used when priming system with wash solution.

① Prime the system with wash.

② Move cursor to “5 : PRIME BF WASH” and press OK to start the filling operation.

6 : REPLACE SUBSTRATE : Used when priming enzyme substrate lines

This is used when priming system with new substrate.

① Replace current substrate with a new bottle of substrate.

② Move cursor to “6 : REPLACE SUBSTRATE” and press OK to start the substrate priming operation.

When substrate priming is finished, use “2 : SUBSTRATE BG MEAS” to perform substrate background measurement.

7 : TESTCUP READ : Used when performing reagent cup read test

① Use the SAMPLE FEED key to move the cup reader into position when performing a read test on a reagent cup.

② Move cursor to “7 : TESTCUP READ” and press OK.

This reads the reagent cup analyte code and lot number located below the cup reader and displays them on the screen.

Chapter 9 - 1.MAINTE (Maintenance Tool)

8 ： DETECTOR （LIGHT） ： Used for Testing Fluorescent Detector

① Use the SAMPLE FEED key to move the reagent cup to a position below the fluorescent detector unit.

② Move cursor to “8 ： DETECTOR （LIGHT） and press OK.

This displays detector data. (While lamp is on.)

9 ： DETECTOR （DARK） ： Used to Test Fluorescent Detector Unit （Dark measurement）

① Use the SAMPLE FEED key to move the reagent cup to be tested to a position below the fluorescent detector unit.

② Move cursor to “9 ： DETECTOR （DARK） and press OK.

This displays detector data. (While lamp is off.)

10 ： BARCODE READ ： Used to Test Barcode Read Performance

① Used the SAMPLE FEED key to move the primary tube to be read beside the barcode reader.

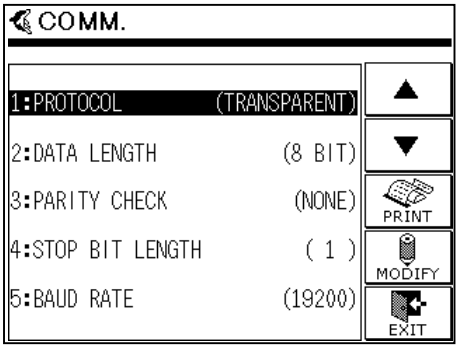
② Move cursor to “10 ： BARCODE READ” and press OK.

This performs the barcode read operation and displays the data.

Chapter 9 - 2.Communications（RS232C Transmission Parameter Settings）

2. COMM.（RS232C Transmission Parameter Settings）

The AIA-360 uses the RS232C serial interface for transmitting data with external devices. Enter the parameter settings required for transmitting with the selected external device. The settings in parentheses to the right are the ones currently selected for that parameter. Move cursor to the desired parameter and press MODIFY to select.



＜COMM. Screen＞

These settings must be entered or updated the first time the AIA-360 is started or when changes to the settings are required. Note that the new settings are stored in the system memory and retained, even when the power is turned off.
For detailed descriptions of transmission protocols and hardware settings, refer to "Appendix B: RS232C Transmission" in "Chapter 12."

Note that transmission settings cannot be modified while assay operations are in progress.

Point Pressing PRINT will print out the current screen.

Fig. 9-2 Sample printout of transmission parameters

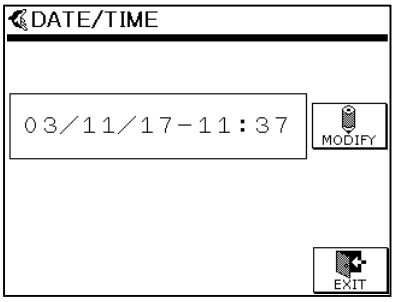
```
***  COMM     PARAMETER  ***
OP:NO.002     04/01/09 15:49

1:PROTOCOL     (TRANSPARENT)
2:DATA LENGTH        (8 BIT)
3:PARITY CHECK        (NONE)
4:STOP BIT LENGTH      ( 1 )
5:BAUD RATE          (19200)
                   ***END***
```

Chapter 9 – 3.DATE／TIME（Time and Date Settings）

3. DATE/TIME（Time and Date Settings）

① Press 

to display the DATE/TIME screen.



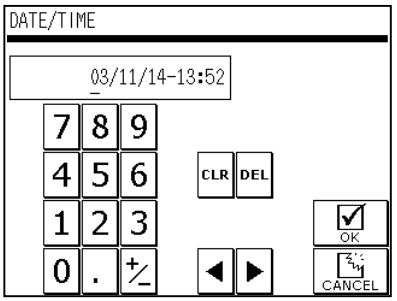
＜DATE/TIME Screen＞

② Press 

to display the DATE/TIME INPUT screen.

③ Enter the current time and date then press 

to redisplay the DATE/TIME screen.



＜DATE/TIME INPUT Screen＞

4. OPERATOR　(Registering and Changing)

The OPERATOR screen is used to register new operators, or change or delete currently registered operators.

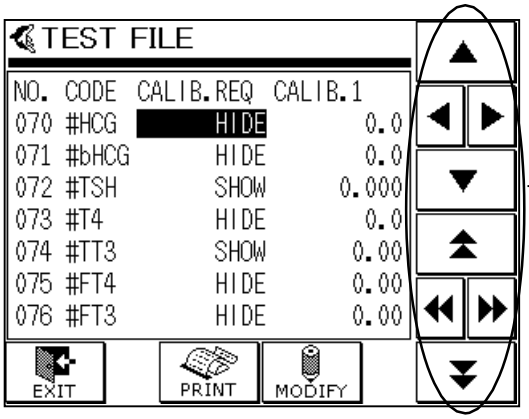
For a detailed description, refer to section “2.1 Confirming/Selecting Operator Name” in “Chapter 4.”

Point The operator name is included on system printouts.

Chapter 9 - 5.TEST FILE（of Analyte parameters）

5. TEST FILE（of analyte parameters）

The AIA-360 enables users to check and modify certain parameter settings for the individual analytes used in the assaying of reagents. Users are able to select the median range and decimal place settings for parameters as necessary.



The TEST FILE consists of multiple pages, which can be scrolled through using the arrow keys.

- TEST FILE settings cannot be modified while assay operations are in progress.
- Note that the new settings are stored in the system memory and retained even when the power is turned off.
- Changes made to parameter settings will be saved when the operator leaves the TEST FILE screen to go to another screen. It is important to note that parameter changes will be lost if system power is lost while still in the TEST FILE screen.

Point

Parameter information can be printed by pressing PRINT.

Fig. 9-3 Sample TEST FILE Printout

```
***  TEST FILE  REPORT  ***
OP:NO.002    04/01/09 16:02

Code          :004
Analyte       :BMG
Unit          :mg/l
Decimal       :4
Specimen Vol.:15
Diluent  Vol.:135
Referance(L) :0.0020
Referance(H) :0.4000
Assay    (L) :0.0020
Assay    (H) :0.4000
Factor1  (A) :1.000000
Factor1  (B) :0.000000
Factor2  (A) :1.000000
Factor2  (B) :0.000000
Calib Code   :4
Calib Reps   :3
Calib Conc(1):0.00000
Calib Conc(2):0.01250
Calib Conc(3):0.05000
Calib Conc(4):0.15000
Calib Conc(5):0.30000
Calib Conc(6):0.40000
Virtual Conc :0.00000
Graph Origin :0.00000
                ***END***
```

Chapter 9 – 5.TEST FILE（of Analyte parameters）

Column Name	Description	
NO.	Analyte code	Number from 0 to 127 unique to each analyte.
CODE	Analyte name	Abbreviated name consisting of five alphanumerics.
CALIB.REQ*	Specifies whether this Analyte code is displayed or not on the screen.	
CALIB.1 to 6	Calibration concentrations	
CAL LOT L CAL LOT R	Number of the lot for which calibration curves were selected. The AIA-360 allows for the creation of 2 lots of calibration curves per analyte. Lot numbers for current calibration curves are displayed under LOT. L and LOT. R.	
UNIT	Units of concentration	Unit of measurement for concentration.
SMPL. VOL	Sample volume	Sample volume (μ L).
DIL. VOL	Diluent volume	Volume of diluent dispensed together with sample (μ L).
ASSAY L	Assay range lower limit	Designates minimum effective assay concentration. Concentrations below this limit are not assayable.
ASSAY H	Assay range upper limit	Designates maximum effective assay concentration. Concentrations higher, even if mathematically viable, cannot be used as concentration values.
REF. L*	Median range lower limit	Users can specify as required.
REF. H*	Median range upper limit	Users can specify as required.
DECIMAL*	Decimal places	Designates the effective number of decimal places for expressing concentrations. Users can specify as required.

Procedures for Setting CALIB.REQ* Places

① Move cursor to “CALIB REQ*” column and press 

.

② Select “SHOW” and “HIDE”.

SHOW : Display

HIDE : Do not display

Procedures for Setting REF. L*, REF. H* and DECIMAL* Places

① Move cursor to desired column and press 

.

② Enter desired values when the INPUT screen is displayed.

③ Press 

to confirm setting.

Note that users cannot change settings other than those for CALIB REQ*, REF. L*, REF. H* and DECIMAL* Places.

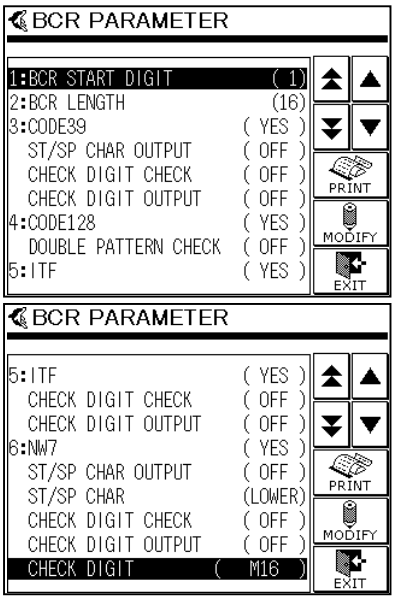
Chapter 9 – 6.BCR PARAM（Detailed Barcode Settings）

6. BCR PARAM（Detailed Barcode Settings）

These settings are used to specify various barcode parameters.

The settings in parentheses to the right are the ones currently selected for that parameter.

To change the setting, move the cursor to the design parameter and press MODIFY to change a value or a enter setting.



＜BCR PARAMETER Screen＞

1 ： BCR START DIGIT

Designates start digits (1 to 15) for reading the barcode IDs attached to specimens.

Default：1

2 ： BCR LENGTH

Designates the maximum double-digit length (1 to 16) for reading the barcode IDs attached to specimens.

Default：16

3 ： CODE39

Specifies whether or not to read the CODE39 barcode label.

Default value：YES（read）

ST/SP CHAR OUTPUT

Designates the start or stop character for reading CODE39 barcode labels.

Default value：OFF（unused）

CHECK DIGIT CHECK

Specifies the check setting for the CODE39 check digit.

Default value：OFF（do not check）

CHECK DIGIT OUTPUT

Specifies whether or not to send check digit for CODE39 barcode label.

Default value ON（used）

- When CHECK DIGIT CHECK is set to OFF, CHECK DIGIT OUTPUT automatically becomes ON and cannot be switched to OFF.
- When CHECK DIGIT CHECK is set to OFF, not all digits can be used as an ID without setting CHECK DIGIT OUTPUT to ON.

4 ： CODE128

Specifies whether or not to read the CODE128 barcode label.

Default value：YES（read）

DOUBLE PATTERN CHECK

Specifies whether or not to use double character start pattern for CODE39 barcode label.

Default value：OFF（unused）

5 ： ITF

Specifies whether or not to read the ITF barcode label.

Default value：YES（read）

CHECK DIGIT CHECK

Specifies the checks setting for the ITF check digit.

Default value：OFF（do not check）

CHECK DIGIT OUTPUT

Specifies whether or not to send check digit for ITF barcode label.

Default value：ON（used）

- When CHECK DIGIT CHECK is set to OFF, CHECK DIGIT OUTPUT automatically becomes ON and cannot be switched to OFF.
- When CHECK DIGIT CHECK is set to OFF, not all digits can be used as an ID without setting CHECK DIGIT OUTPUT to ON.

6 ： NW7

Specifies whether or not to read the NW7 barcode label.

Default value：YES（read）

ST/SP CHAR OUTPUT

Designates the start or stop character for reading NW7 barcode labels.

Default value：OFF（unused）

ST/SP CHAR

Designates the type of start or stop character for the NW7 barcode label.

Default value：LOWER（lowercase）

CHECK DIGIT CHECK

Specifies the checks setting for the NW7 check digit.

Default value：OFF（do not check）

Chapter 9 - 6.BCR PARAM（Detailed Barcode Settings）

CHECK DIGIT OUTPUT

Specifies whether or not to send check digit for NW7 barcode label.

Default value：ON（used）

- When CHECK DIGIT CHECK is set to OFF, CHECK DIGIT OUTPUT automatically becomes ON and cannot be switched to OFF.
- When CHECK DIGIT CHECK is set to OFF, not all digits can be used as an ID without setting CHECK DIGIT OUTPUT to ON.

CHECK DIGIT

Designates the type of check digit for the NW7 barcode label.

7 CHK-DR	：	7 check DR
M16	：	modulus 16 （Default value）
M11	：	modulus 11
M10/2W	：	modulus 10/2
wait M10/3W	：	modulus 10/3
wait		
M11-A	：	weighted modulus
11 M10/2W-A	：	runs

- BCR PARAM settings cannot be changed while assay operations are in progress
- Changes made to parameter settings will be saved when the operator leaves the BCR PARAM screen to go to another screen. Parameter changes are saved in system memory, and thus do not have to be reentered each time the system is restarted.

Chapter 9 - 6.BCR PARAM（Detailed Barcode Settings）

Point Parameter information can be printed by pressing PRINT.

```
***  BCR      PARAMETER  ***
OP:NO.002     04/01/09 16:14

1:BCR START DIGIT       ( 1)
2:BCR LENGTH            (16)
3:CODE39              ( YES )
  ST/SP CHAR OUTPUT   ( OFF )
  CHECK DIGIT CHECK   ( OFF )
  CHECK DIGIT OUTPUT  ( OFF )
4:CODE128             ( YES )
  DOUBLE PTN CHECK    ( OFF )
5:ITF                 ( YES )
  CHECK DIGIT CHECK   ( OFF )
  CHECK DIGIT OUTPUT  ( OFF )
6:NW7                 ( YES )
  ST/SP CHAR OUTPUT   ( OFF )
  ST/SP CHAR          (LOWER)
  CHECK DIGIT CHECK   ( OFF )
  CHECK DIGIT OUTPUT  ( OFF )
  CHECK DIGIT      (   M16  )
                   ***END***
```

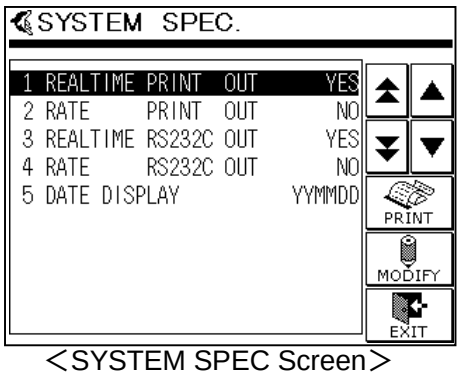
Fig. 9-4　Sample Barcode Parameter Printout

7. SYSTEM SPEC.（System Operation Settings）

The various operating conditions for the AIA-360 are entered from this screen.
The settings in parentheses to the right are the ones currently selected for that parameter.

To change setting, move cursor to design parameter and press 

to change value or enter setting.



＜SYSTEM SPEC Screen＞

1 ： REALTIME PRINT OUT

Specifies whether or not to print assay reports for each assay operation.
The factory default is “Yes.”

2 ： RATE PRINT OUT

Specifies whether or not to output rate when printing assay reports.
The factory default is “No.”

3 ： REALTIME RS232C OUT

Specifies whether or not to output assay reports via the RS232C port for each assay operation.
The factory default is “No.”

4 ： RATE RS232C OUT

Specifies whether or not to output rate when outputting assay reports via the RS232C port.
The factory default is “No.”

5 ： DATE DISPLAY

Specifies the format for displaying the date.

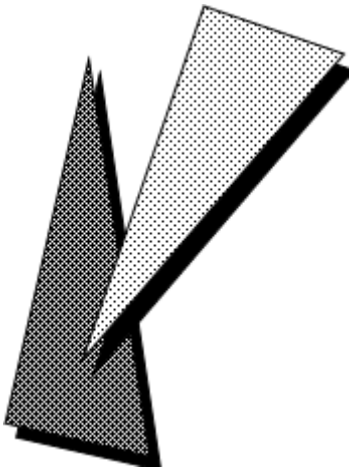
①YY/MM/DD
②MM/DD/YY
③DD/MM/YY

The factory default is ①.

MEMO

Chapter 10

Daily Maintenance Procedures



Chapter 10: Daily Maintenance Procedures

This chapter describes the daily inspection and maintenance procedures that users must perform in order to maintain the peak performance capability of AIA-360

1. Daily Maintenance Procedures

1.1 System Startup

For the description of system startup maintenance procedures, refer to section "2. System Startup" in "Chapter 4: Preparing System for Assay Operation."

1.2 System Shutdown

For description of system shutdown maintenance procedures, refer to section "1. System Shutdown (Shutdown menu)" in "Chapter 8: Terminating Assay Operations."

When shutting down the system the enzyme substrate solution in the mobile phase lines must be replaced with a 70 % ethanol or 70 % isopropyl alcohol solution. If mobile phase is not washed out with 70 % ethanol or 70 % isopropyl alcohol, the water content in the mobile phase will evaporate and the reagent/additive will precipitate and clog the lines.

Seal the substrate bottle with a clean rubber stopper or parafilm and refrigerate.

2. Weekly Maintenance Procedures

2.1 Substrate Line

If the substrate line is dirty, the substrate blank becomes higher. After assays, wash the substrate line following the procedures below every week.

1) Replace the substrate bottle with a bottle of 70 % ethanol or 70 % isopropyl alcohol.
2) Prime the substrate line by performing '6: REPLACE SUBSTRATE' on the MAINTE screen.
3) Perform step #2 a total of 3 times.

Chapter 10－3. Monthly Maintenance Procedures

3. Monthly Maintenance Procedures

3.1 Updating Calibration Curves

The length of validity of the calibration curve varies according to the item; however, most remain valid for 90 days. Assay results will be flagged with the CV flag when a calibration curve has expired. Update calibration curves as necessary.

4. Three-Month Cycle Maintenance Procedures

4.1 Diluent and Wash Solution Bottles

Make sure to clean the diluent and wash solution bottles with aqueous hypochlorite on a regular basis by following the procedures below.

1) Discard the solution out of the bottles and rinse them with tap water.
2) Pour about 300 mL of tap water and about 3 mL of aqueous hypochlorite into each bottle.
3) Tightly cap the bottles and wash them by rigorously shaking them. If the bottle is very dirty, leave it for an hour.
4) Rinse them thoroughly under running water not to leave hypochlorous acid.
5) Rinse them in purified water.

If you use extra tanks to reserve diluent or wash solution, wash the extra tanks in the same procedure.

5. Six-Month Cycle Maintenance Procedures

5.1 Diluent and Wash Lines

It is effective to clean the diluent and wash lines at the same time to clean the diluent and wash solution bottles. Note that it takes an hour.

1) Pour about a liter of purified water and 10 mL of aqueous hypochlorite into a clean reservoir.
2) Remove the tubes from the diluent and wash solution bottles and detach the filters from the tube ends. Put the tube ends into the reservoir prepared at the procedure 1). The procedures 3) – 6) should be performed as quickly as possible not to expose the metallic sensor portion to aqueous hypochlorite for a long time.

3) Perform '3: PRIME SAMPLER DILUENT' on the MAINTE screen five times to fill the diluent line with aqueous hypochlorite. Next perform '5: PRIME BF WASHER' on the same screen five times to fill the wash line with aqueous hypochlorite.
(Even when an error "2015 BF PROBE PURGE FAILURE" occurs, ignore the error, and continue the operation.)

4) Pour about a liter of purified water into another clean reservoir and put the tube ends into this reservoir. Make sure the metallic sensor portion exposed to aqueous hypochlorite is to be washed well in purified water not to leave hypochlorous acid.
5) Leave them for about five minutes.
6) Perform '3: PRIME SAMPLER DILUENT' and '5: PRIME BF WASHER' on the MAINTE screen five times each to remove hypochlorous acid from the diluent and wash line completely.
(Even when an error "2015 BF PROBE PURGE FAILURE" occurs, ignore the error, and continue the operation.)
7) Prepare the diluent and wash solution in the cleaned diluent and wash solution bottles respectively. Attach new filters to the diluent and wash line tube ends and put them into each bottle. Be sure not to put the tube ends into the wrong bottles.
8) Perform '3 PRIME SAMPLE DILUENT' and '5 PRIME BF WASHER' five times each.
(Even when an error "2015 BF PROBE PURGE FAILURE" occurs, ignore the error, and continue the operation.)

5.2 Replacing Filters for Diluent and Wash Solution Bottles

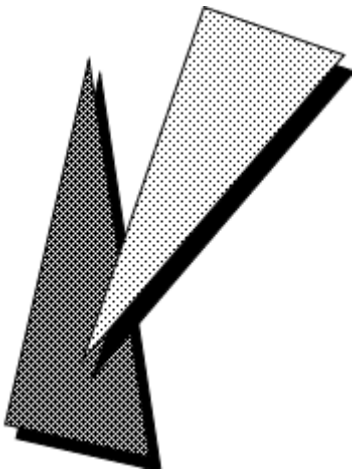
Make a point of replacing the in-line diluent and wash solution bottle filters on a regular basis. Do this by removing the tubes from the diluent and wash solution bottles, detaching the filters from the tube ends and replacing them with new ones.
(Part No. 0018585)

6. If AIA-360 Becomes Dirty

Wet a cloth with a neutral detergent; wring well, and wipe down the dirty area of the instrument. If the instrument is very dirty, use a cloth wetted with the 70 % ethanol or 70 % isopropyl alcohol solution. Avoid water or moisture build-up on the surface of the AIA-360 system, as it may cause the metal to rust.

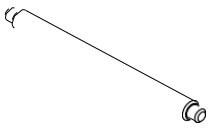
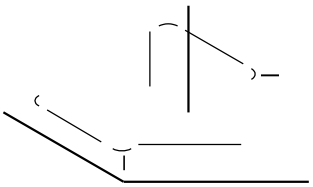
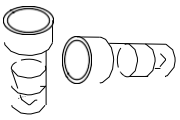
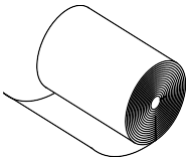
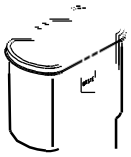
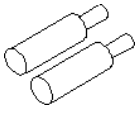
Chapter 11

Maintenance Parts



Chapter 11: Consumable Supplies/Optional Parts

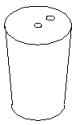
1. Consumable Supplies

Part no.	Part Name and Specifications	Schematic Diagram	No. Included
0019510	PRINTER PAPER CORE SHAFT For AIA-360		1
0020107	PROBE TIP		6/pack
0020970	DETECTOR STANDARDIZATION CUP （STD CUP）		200/box
0018581	SAMPLE CUPS		1000/pouch
0019563	PRINTER PAPER 60 mm×42 m		10 rolls/box
0019398	WASTE BOX		1
0018585	TANK FILTERS		10/pouch

Chapter 11 - 1. Supplies/Optional Parts

Part no.	Part Name and Specifications	Schematic Diagram	No. Included
0018619	BOTTLE 30 mL		1

2. Optional Parts

Part no.	Part Name and Specification	Schematic Diagram	No. Included
0021207	PLUG-2.SUBSTRATE		1

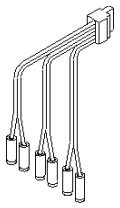
The components of the diluent, wash solution, and waste fluid bottles and the level sensor lead wire are different depending on the date of manufacture, and either sets of parts “before change” or “after change” are provided with the instrument. Note that the applicable parts cannot be used in combination with the parts “before change” and “after change”.

[Before Change] (plug socket type)

Diluent, Wash solution, waste liquid bottles, and level sensor lead wire

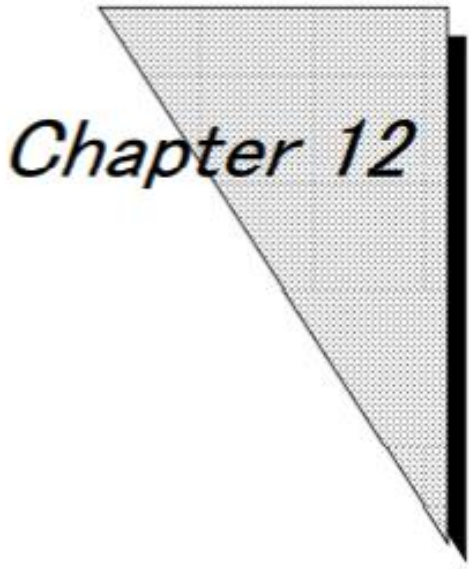
Part no.	Part Name and Specification	Schematic Diagram	No. Included
0021067	DILUENT BOTTLE: with label 500 mL		1
0021068	WASH SOLUTION BOTTLE: with label 1000 mL		1

Chapter 11 - 1. Supplies/Optional Parts

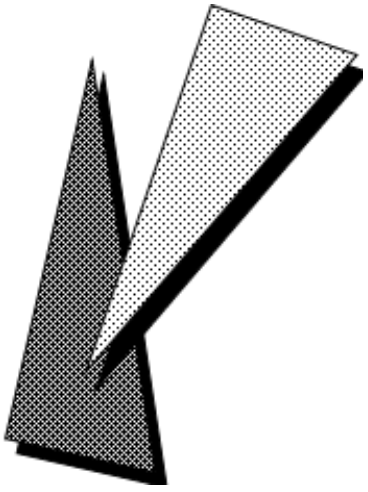
0021069	WASTE BOTTLE: with label 1000 mL		1
0021138	LEVEL SENSOR LEADS		1

[After change] (screw type)
Diluent, Wash solution, waste liquid bottle 2, level sensor lead wire 2

Part No.	Part Name and Specification	Schematic Diagram	No. Included
0024686	DILUENT BOTTLE: with label 500 mL Part Name: (DILUENT BOTTLE-2 WITH LABEL		1
0024687	WASH SOLUTION BOTTLE: with label 1000 mL Part Name: (WASTE BOTTLE-2 WITH LABEL)		1
0024688	WASTE BOTTLE: with label 1000 mL Part Name: (WASTE BOTTLE-2 WITH LABEL)		1
0024317	LEVEL SENSOR LEADS Part Name: (LEAD WIRE OF LEVEL SENSOR-2) * with screws		1



Appendix



Chapter 12: Appendix

Appendix A: Barcode Label Specifications and Precautions for Use

The following sections outline the specifications for barcode labels used when performing assay operations that utilize the internal barcode reader to read barcode labels applied to primary tubes. Precautions for use are also described.

1. Barcode Label Specifications

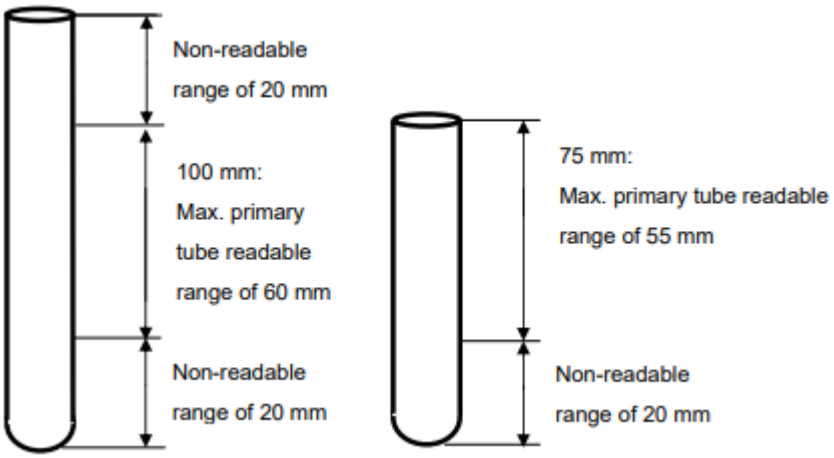
Applicable barcodes	: CODE128 ・ NW-7 ・ CODE39 ・ ITF
Minimum element width （Narrow width）	: 0.191（0.254 or higher recommended）
PCS	: 0.5 or higher（white reflectance 75 %）

2. Barcode Effective Read Range

The barcode effective read range is designated as shown below in corresponding to the sample holder slit position.

Point

The barcode reader is unable to read the bottom 20 mm portion. It is important to apply barcode labels near the top of 75 mm primary tubes to ensure effective label reading in cases where sample IDs use a large numbers of digits.



Note: Read range includes barcode margin (quiet zone).

3. Maximum Number of Readable Barcode Digits

The table below lists examples of the maximum readable number of barcode digits calculated according to the barcode effective read range.

	Code		Element width (narrow)	Max. no. readable digits	
				75 mm	100 mm
1	CODE128		0.191（min.）	16	16
2			0.254（norm.）		
3	NW-7	C/D: no (check digit)	0.191（min.）	16	
4			0.254（norm.）	14	
5		C/D: yes	0.191（min.）	16	
6			0.254（norm.）	13	
7	CODE39	C/D: no	0.191（min.）	16	
8			0.254（norm.）	10	
9		C/D: yes	0.191（min.）	16	
10			0.254（norm.）	9	
11	ITF	C/D: no	0.191（min.）	16	
12			0.254（norm.）		
13		C/D: yes	0.191（min.）		
14			0.254（norm.）		

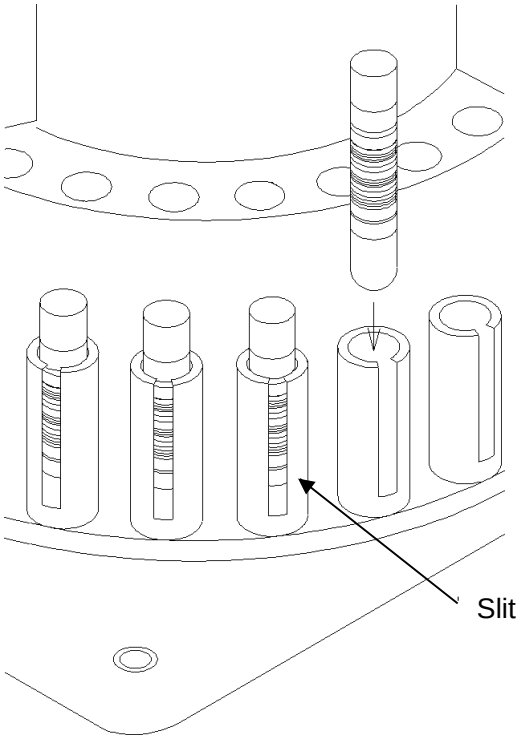
Note: Calculated with wide : narrow ratio of 2.5 and margin (quiet zone) of 2.54 mm per digit

- Note that the number of readable digits may be limited for CODE39 and NW7, depending on the conditions when using 75 mm test tubes.
- Effective barcode read range may decrease, depending on the quality of the barcode label used.

4. Loading Test Tubes with Barcode Labels

The sample holders used in the carousel are equipped with slits in order to read the barcodes.

Make sure to position the test tubes with the bar code label facing out of the slit.



Chapter 12 - Appendix B: RS232C Transmission

Appendix B: RS232C Transmission

The RS232C port provided in the AIA-360 is used for transmitting data to external systems using the following specifications.

1. Transmission Specifications

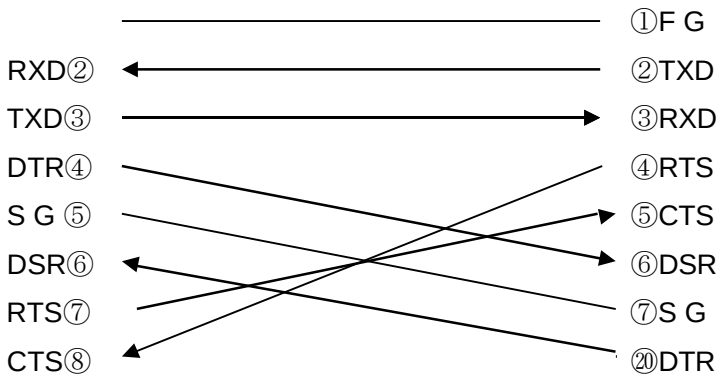
(1) Signal format	RS232C
(2) Transmission format	asynchronous, half duplex
(3) Transmission speed	9600
(4) Data length	8-bit ASCII
(5) Stop bits	1
(6) Parity	NONE
(7) Protocol mode	independent
(8) Check characters	none
(9) Connector	D-SUB（male 9-pin）

Chapter 12 - Appendix B: RS232C Transmission

2. Pin Assignment

Standard Configuration

AIA-360（9-pin Connector） Host unit（25-pin connector）



Signal Names

Signal name	Abbreviation	Direction	Description
Frame ground	FG	-	Used to ground frame.
Data send	TXD	output	Sends data from AIA-360. Off when data not present.
Data receive	RXD	input	Receives data coming to AIA-360. Off when data not present.
Request to send	RTS	output	On during request to send.
Clear to send	CTS	input	Transfers data when on.
Data set ready	DSR	input	Not used.
Signal ground	SG	-	Used to ground signal
Data terminal ready	DTR	output	Always on.

Signal Specifications

Signal status	Signal voltage
SPACE (ON)	+ 3 V or higher
MARK (OFF)	- 3 V or lower

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Rev.17 (Date of publication March, 2024)