AUTOMATED ENZYMATIC IMMUNOASSAY ANALYZER

AIA-2000

Operator manual

Review E

TOSOH CORPORATION
DIVISION OF BIOSCIENCE

About this manual

This operator manual is designed to ensure that users can operate the Immunoassay analyzer AIA-2000 safely and correctly.

This manual is provided to operators who have completed all required technical training. Working with the AIA-2000.

It is advisable for users to read carefully and familiarize themselves with the information in this manual. and make the AIA-2000 operate in strict accordance with the provided instructions.

Keep this manual in an easily accessible location for reference purposes.

Users must strictly adhere to all safety precautions highlighted in this manual.

This material presented is subject to change without prior notice due to progressive adjustments for system performance and its functionality.

Be sure to include this manual whenever you sell or transfer the AIA-2000.

Take note of all discrepancies, errors or omissions in the provided information, if you have issues. immediately notify the local services representative.

The copying, in whole or in part, of the information contained in this manual is strictly prohibited.

Pre-installation and notifications

It is recommended that both parties, coaches and operators carefully read and familiarize themselves with the following safety precautions to ensure proper functioning and correctness operation of the AIA-2000.
The information displayed using 'Warning' and 'Caution' are signs in this manual that are provided for the purposes defined below.

Warning	Indicate a risk with a medium damage level that, if not avoided, can turn out to be harmful oh serious.
Attention	Indicates a low level risk that, if it cannot be avoided, it can result in minor or moderate damage

Installation precautions

Warning

- **A analyzer with the right energy**

  Make sure to connect the AIA2000 to a voltage source with a sufficiently rated power. high to free it from voltage fluctuations.
  The energy sources that have insufficient nominal power or significant fluctuations In voltage, they present a potential fire risk.

- **Installation of grounding connections and verification**

  Make sure to properly ground the analyzer to avoid a potential electric shock.
  - Make sure to connect the analyzer to a three-terminal power cable.
  - Ground the analyzer's guides in both modules to prevent malfunction. due to an electrical shock.
  - Do not ground the analyzer line to gas pipes, water pipes, lightning rods or Telephone lines.
    Gas pipes: can ignite and cause fire explosions
    Water pipes: it is not an effective land
    The lightning rod and telephone lines: it is considered a potential source of danger when it They produce thunderstorms with lightning.

Attention

The installation site of the analyzer must be chosen appropriately.

Refer to chapter 3: System Installation in this manual to choose a suitable site for installation of the AIA-2000. Always notify a local service representative when installing or moving the AIA-2000.

Avoid modifying connection cables, using extensions or power adapters.

These are potential sources of electric shock.
As long as the selected extensions have a sufficiently rated power high and aligned to a ground connection.

Make sure the plug is free of dust or dirt and insert it firmly into the socket.

Make sure to remove and inspect the cable as it can get stuck several times a year.
The pollution from dusting off foreign matter from and/or, stop inserting entirely
The plug in the socket or a loose connection can result in electric shocks or fire.

Precautions for use

Warning

- **Manage biosecurity risks with caution.**

  Only personnel with sufficient knowledge of immunological testing techniques and the procedures for handling infectious materials should be allowed to do them to operate the AIA-2000.
  There is a possibility that blood and bodily fluid may have been contaminated by infectious agents. Mistakes in system operation and handling of such materials can result in the transmission of infectious agents to and/or from the system operator for Search personnel. It is recommended that all specimens are handled with caution. Care and that appropriate protective clothing (safety glasses, gloves, masks, etc.) is worn. at all times during maintenance procedures.
  All specimen containers, including test cups, test tips, reagent bottles, test cups and dispose of the fluids that may have been contaminated by blood and body fluid. It is recommended that appropriate protective clothing (safety goggles, gloves, masks etc.) is worn out in any way the times and what waste materials are disposed in accordance with the following directives and all other laws and regulations relevant to protect all personnel in the general neighborhood of operation and the environment surrounding.

- **Avoid opening covers or panels during equipment operations**

  Opening covers or panels during operation exposes the moving parts, such as the dispensing. this can cause severe bodily injuries, including lacerations or the rupture of the fingers or even the hands.

Attention

- **Operate only in accordance with the procedures described in this manual.**

  - Attempts to operate the AIA-2000 using procedures not prescribed in this manual It may adversely affect the integrity of the results and cause a malfunction. of the system.

- **Prevent fluid leakage**

  The leakage of the test solutions and washing solutions are potential sources of corrosion.
  - When the fluid leak is found, immediately stop the work, the system, and remove the power outlet. It is recommended that protective clothing be appropriate (safety goggles, gloves, masks, etc.) everything must be completely dry when cleaning, and inspecting and check the pipes and connections that are possible sources of leaks.

  If the analyzer continues with the liquid flow, notify the nearest service center. or the local distributor.

Immediately unplug the power when the work system stops. this stopped working (smells like fire, etc.) contact local representatives.

Continuing to use a malfunctioning analyzer can lead to consequences. an electric shock or a fire.

Avoid opening covers or panels by inserting fingers or any foreign objects. in the movement mechanisms of the equipment.

The interior of the analyzer consists of components such as automatic motors that operate at high speeds. Strange objects or fingers and hands can easily end up trapped in the mechanisms and resulting in bodily injury.

Attention

- **Keep covers and doors closed during operation**

Keep all covers and doors tightly closed during operation. The interior of the analyzer contains several moving parts, high-temperature components, and system of high voltage circuits. Fingers and hands can easily get stuck or entangled in the mechanisms, resulting in lacerations as a consequence and electric shock.

- Special precautions should be taken when opening doors to fill reagents and samples. The tips are provided during system operation.

Avoid turning the system off and on by simply inserting and removing the Power plug

Operating the AIA-2000 in this manner can damage and corrupt data on the hard drive. Controller PC and is a potential cause of electric shock and fire.

Whenever the system is about to be turned off, make sure to exit the system program using the Shutdown button, then the Windows exit and turn off using the power supply switch. energy was established on the left in front of the analyzer.

- **Avoid damaging the power supply cord**

The power cord can be damaged by excessive stretching and bending or anchoring. power cord in an inappropriate place, resulting in an electrical knot when turning on.

Always unplug the power cord from an outlet using the plug.

- **Avoid using the system with wet hands**

Turning on the system with wet hands can result in electric shock.

Exclusive use only by trained personnel

Maintenance work must be carried out by personnel with the appropriate knowledge of the system, maintenance procedures, and be equipped with appropriate protective clothing (gloves, masks, etc.). The physical damages sustained during work of maintenance may result in infections from the specimens. Therefore, it is It's important that the behavior of maintenance personnel aligns with the highlighted procedures in this manual and only after they have received the training sufficient received in the maintenance procedures. Please do not hesitate to Notify the local service center for information on the maintenance process.

- **The proper arrangement of external materials**

Take the appropriate steps to separate all the materials used in the assay according to the the operations, including test cups, test tips, reagent bottles, they test cups, specimen containers, and spill fluids, and arrange them accordingly designated procedures. Always wear protective gloves to avoid contact directly with such materials.

External materials must be placed according to the following instructions and with Laws and regulations allowed to protect all personnel in the general system environment. and the surrounding environment.

Always wear protective clothing.

Always wear the appropriate protective clothing (safety glasses, gloves, masks) etc.) to prevent infection when working with specimens, external fluids, and accessories of system calibration.

Inspect all specimens to avoid air bubbles and foam.
Remove all air bubbles before the analysis.

the detection of the liquid on the surface automatically executed on each specimen by the the instrument is susceptible to bubbles or foaming. The instrument can detect the bubble like the liquid surface. Do not run samples that contain bubbles or foam. Ensure to remove all air bubbles before the analysis regardless of their size.

Place the fluid containers only in the designated locations

The casual placement solution containers within the main unit may result in in spillage, causing short circuits that can damage the insulation and result electric in the electric shock.

Attention

- **Use only components from the Tosoh brand**

  Use unique accessories and consumable items (supplies) listed in the accessories of maintenance and section of consumable items.

At the end of using the instrument, replace the remaining substrate solution in the substrate line with the substrate replacement solution (70% ethanol)

If the substrate solution remains on the substrate line for a long time, it may to rush. Precipitation in the substrate line can block the substrate line. Replacement the substrate solution with distilled water may cause contamination of the line substrate and raise the substrate base. Make sure to use the replacement solution of substrate (70% ethanol) after using the system.

- **Avoid placing any source of fire near the substrate compartment.**

  It is important not to place fire sources near the substrate compartment. As the substrate line, there is 70% ethanol at the end of a test operation.

- **Do not tilt the wash tank or the diluent tank while the analyzer is running.**

The precise volume residues in the wash or diluent tank will not be detected if the the tanks tilt. Furthermore, this can cause incorrect results due to aspiration from the air of the duct before the liquid from the tank. To avoid this problem, do not incline the tanks. Even if the shortage of 'Washer/Diluent' gives an error message. Operation in progress stopped." It can be shown during test operations, as long as the tanks are not tilted, a sufficient volume of the wash residues in the tank for the B/F operations for the specimens that have been processed up to that moment. The trial operations are they will pause with this error message, but it resumes as soon as the Wash/Diluent is refilled.

Removing the equipment in use for repair or disposal

Warning

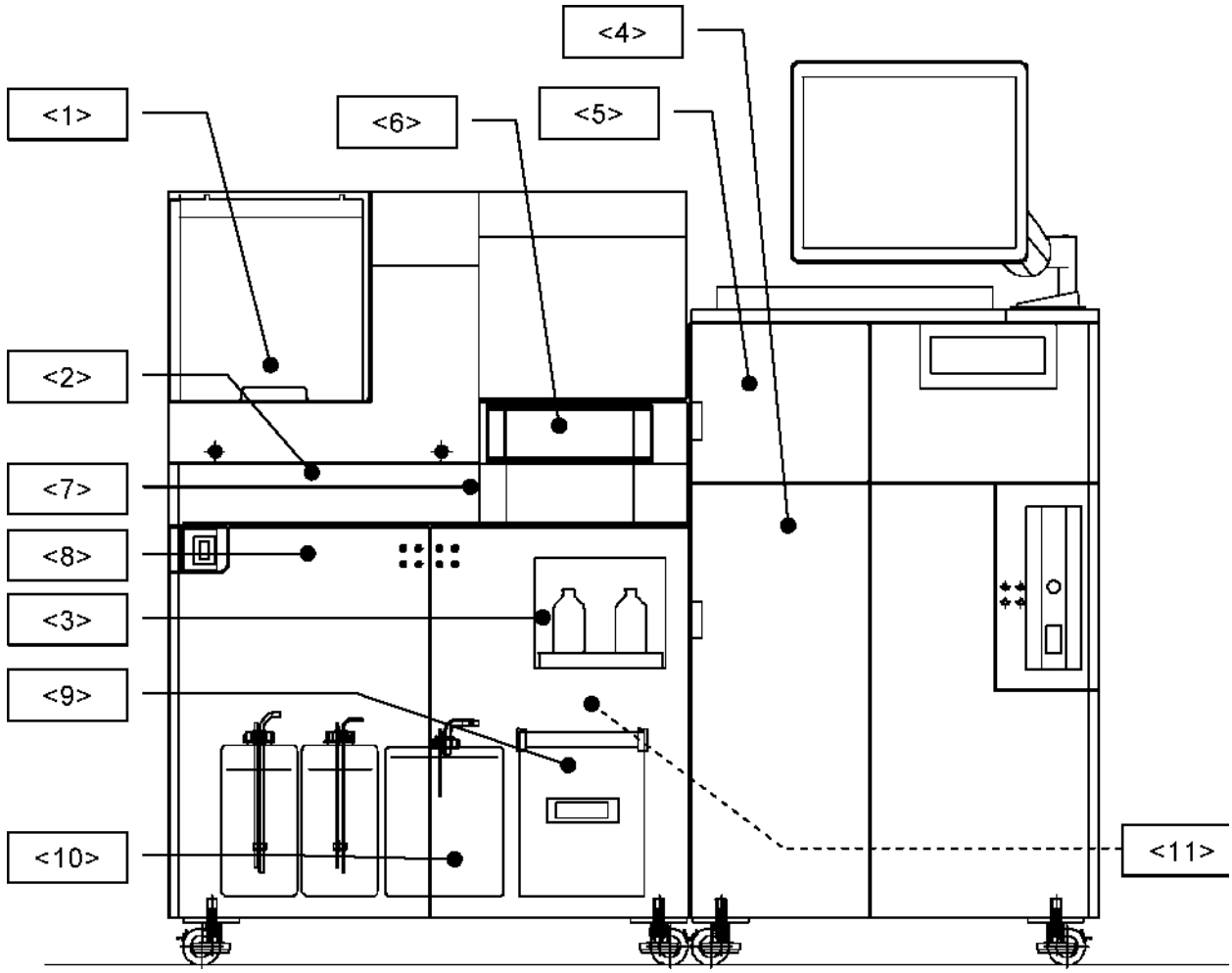
- **Notify an authorized representative**

There is a possibility that blood and bodily fluid may have been contaminated by agents. infectious. Errors in system repair or disposal may result in the transmission of infectious agents to and/or from the system operator to nearby personnel. Please notify an authorized representative for the analyzer repairs or information in the disposition.

Additional Precautions

Locations of labeled 'precautions'

Caution labels are set at various positions in the AIA-2000. Read these carefully for ensure the secure operation of the system.



the Wash Probe Biohazard label of (b / f)

Never touch the washing probes (b / f) while the system is in operation, this may affect the quality.
from the test results. The action may also result in bodily injury caused by contact with
the moving parts.
He (b / f) cleans the tips of the probes to prevent them from being contaminated by the specimen, so it must be handled.
with extreme care.

Safety precautions

Label for caution with the sample charger

Make sure to pause all current testing operations and
Stop the sample charger before trying to add a new one.
rack. Note that the sample racks should be located in
a convenient position in front of the line or the rack is not known
will be able to load correctly.

<3 > caution label for substrate compartment

It is important not to place sources of fire near the compartment of the
substrate, as the substrate lines are filled with 70% ethanol
At the end of a test operation, there is a fire hazard.

Caution label for the drawer of the classifier

Avoid inserting hands into the drawer of the classifier, as the moving parts
They can cause bodily injuries.
The action can also result in bodily injury caused by contact.
With moving parts.

caution label of the tip tray

Avoid inserting your hands into the tips drawer, like the moving parts.
they can cause bodily injuries.
The action can also result in bodily injury caused by contact.
With moving parts.

caution label of the reagent carousel

Avoid inserting hands into the reagent carousel, like the downward one,
The sample needle can cause bodily injury.

warning label for the suction area

Avoid inserting hands into the sample suction unit, like the one
Descend. The sample needle may cause bodily injury.

caution label of the diluent and washing solution

Note that the diluent and the washing solution tanks are the same. shape and size. Make sure to choose the color correctly.
Choosing the wrong tank will directly affect the results of the test.
Maximum Pressure: Atmospheric Pressure

biological waste container label

Make sure to wear appropriate protective clothing, such as gloves,
When handling the waste box, such as discarded cups and tips,
It was contaminated by potentially infectious specimens.

the label of the biological risk waste tank

Make sure to wear appropriate protective clothing, such as gloves,
When are you going to handle the waste tank, since this has been
Potentially contaminated by infectious specimens.

Waste Drain Biohazard Label (AIA-2000 LA Model ONLY)

Be sure to wear appropriate protective clothing, such as gloves,
When is the drainage going to be handled, as the waste liquid has been
Potentially contaminated by infectious specimens.

- If the Warning or Caution labels become difficult to read due to dirt or peeling, Call Tosoh service or the local representatives to change the labels.

- Keep this manual in a visible location, easily accessible for the reference purposes. Ensure that all new operators and administrators have access to this manual.

Notify Tosoh service center or local representatives.
When requesting repairs

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Introduction

Thank you for purchasing the AIA-2000 AUTOMATED ENZYME IMMUNOASSAY ANALYZER. The operator manual is designed to ensure that users can operate the AIA-2000 without danger and correctly. It is recommended that users carefully read and familiarize themselves with the information provided in this manual before operating the AIA-2000.

Overview of the manual

Chapter 1: General precautions for use

This chapter provides general precautions for the system used to ensure the The system operates at maximum performance capacity. Chapter 1 should be read before start all system operations.

Chapter 2: System Setup and Functionality

This chapter describes the AIA-2000 system configuration, features, and functionality. Included is an introduction to the AIA-2000 essay principles, and an overview of performance capabilities and limitations of the system.

Chapter 3: System Installation, Transportation, and Storage

Chapter 3 provides a detailed description of various installation requirements, including the environment and supply of operating energy.

Chapter 4: Overview of system operation

This chapter describes procedures and precautions that must be observed when loading. specimens and reagents. Be sure to follow the procedures in chapter 4 when doing make the system work.

Chapter 5: Operational Flow

Chapter 5 provides the operational flow, starting with system startup and finishing with the A description of a typical analysis operation.

Chapter 6: System Operation

Chapter 6 provides detailed descriptions of all aspects of the operation of system.

Chapter 7: Maintaining System Accuracy

Chapter 7 provides detailed descriptions of maintaining system accuracy.

Chapter 8: Other aspects of the operation

Chapter 8 provides detailed descriptions of other aspects of the operation of system.

Chapter 9: Maintenance

Chapter 9 describes the inspection and maintenance procedures required for keep the AIA - 2000 operating at its maximum capacity.

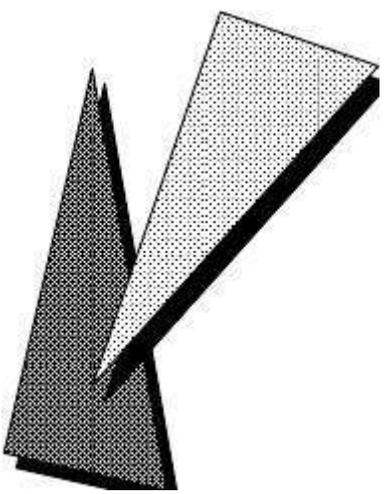
Representation of symbol

The AIA controller will display the output 'U' (lowercase u) instead of 'μ' (micro).

Contents

Chapter 1

General precautions for use



General precautions for the use of the AIA-2000 will be provided in the following sections.

Register operators and administrators while the actual testing tasks are executed automatically by the AIA-2000, the user is required to handle reagents, between the specimen request information, evaluate the results and execute maintenance tasks daily. Mistakes made at any stage can compromise the reliability of the test results.

AIA-2000 users are required to log into the system as operators or administrators. Both the operator and users at the administrator level are able to execute the routine testing operations, however, only users at the administrator level are authorized to change critical parameters and testing placements of the components in the system of individual systems.

The system parameters that are not accessible to operators can only be modified by cutting in as an administrator.

Make sure to register all system users as operators or preference administrators as the system is installed, and limit users to those who have received the appropriate training. Untrained staff is likely to make mistakes what can cause malfunction in the system.

Operational training

The trained service staff always inspects and provides detailed guidance.
during the installation of the AIA-2000. Tosoh or a local representative in each country also operates.
a teaching class for system operators. Do not hesitate to let me know.
a Tosoh service center or local representative for detailed information about the teaching programs.

Managing the system efficiently

Producing highly accurate test results requires good handling
Both the AIA-2000 and the reagent, as together they determine the precision of the patient results.
El desempeño del analizador y reactivos se puede verificar para encontrar que éstos
the performance standards driving the control measurement operations to regulate intervals. The AIA-2000 is equipped with self-diagnostic routines that show error messages whenever failures are detected. Corrective actions can be
In case of errors, refer to the appropriate section in this manual.

Handle reagents

The AIA-2000 is designed to handle random number reagents. Mix reagents with the different batch numbers will create confusion in the test results due to the inability to distinguish between large amounts. Carefully read the wrapped insert. in the reagent box to obtain information on how to handle large amounts of reactive.

Specimens

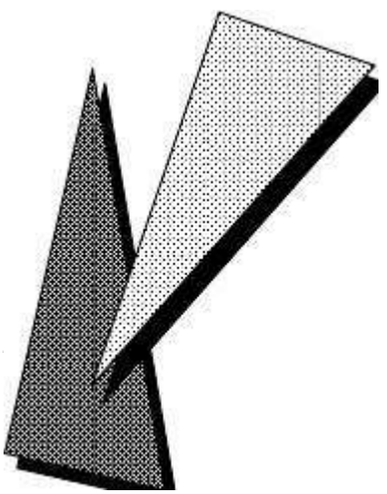
The type of specimen applicable for the AIA-2000 is indicated in the enclosed insert. the box of reagents for each analyte. All questions regarding the Specimen test operations must be directed to a Tosoh service center or local representative.

Users wonder how to avoid processing the following types of specimens, how they can affect system operation.

The specimens that have a tendency to coagulate during the process of essay.
(2) Specimens containing solid particles that tend to form occlusions during to dismiss.

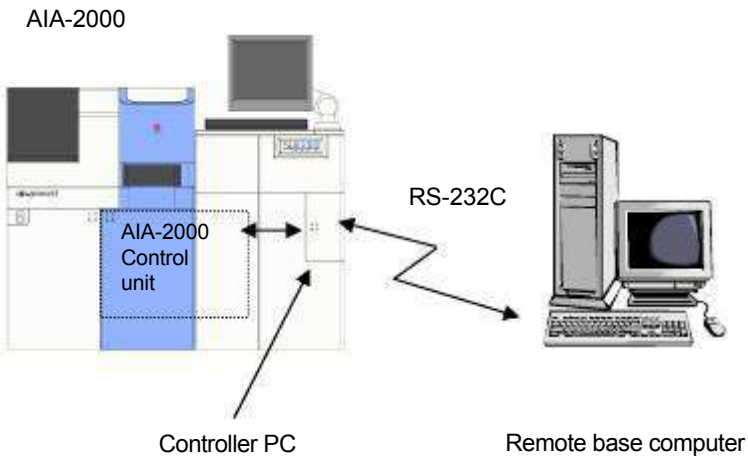
Chapter 2

System configuration and functionality



2.1 System configuration

The AIA-2000 AUTOMATED ENZYME IMMUNOASSAY ANALYZER consists of the AIA-2000 the analyzer unit (the main unit) and a personal computer (the controller PC) that is connects via a USB cable. The system is designed for the main unit to execute operations of essay in response to instructions sent from the controller PC unit.
The controller PC can, in turn, be connected by an RS-232C cable to the base computer that It receives requests and trial results trial results.



2.2 Controller PC Configuration

The controller PC is a system compatible with IBM PC/AT equipped with 1GB or more of memory. to run Microsoft Windows Vista Business or the Windows 7 Professional operating system.
It is strongly recommended that the controller PC be closed when the unit operations are taking place. main ones are completed and that the disk defragmentation is executed once every three months.

Be sure to observe the following precautions, which have been designed to prevent system instabilities.
Avoid using screensavers and power-saving features.
Do not use the controller PC for any applications other than it. AIA-2000 operations.
Do not start any other applications while the system control program is running. AIA-2000 is in operation.

2.2.1 File Configuration

The AIA-2000 system program is saved in the C:\Maxia folder in the c: guide of The controller PC. The folder of The C:\Maxia consists of the following directory structure.
(1) C:\ Maxia \ Documents\ Location of the electronic documentation (in PDF format).
(2) C:\ Maxia \ log \ Contains the trunk files to which the operational information of The system saves automatically. These log files will be compressed in the system. close it and save it in the folder C:\Maxia\registro\Soporte\ as the file "date.lzh", that represents the date when the system was closed.
(3) C:\ Maxia \ Mainte \ Contains the system maintenance program files.
(4) C:\ Maxia \ Resource\ Contains system and image resources.
C:\ Maxia \ System contains the database required for system operation and varies related files database.
(6) C:\ Maxia \ Placements\ Contains the system boot parameter files.

Do not edit or move any files located in the C:\Maxia folder. Controller PC, as this can make the system unstable.

2.2.2 System files

The files with system parameters of the AIA-2000 are described in the following sections.

Avoid editing system parameter files, as this may make the system unstable.

(1) C:\ Maxia \ Placements\ MaxiaConst.ini
It contains several parameters for the operation of the main unit.
(2) C:\ Maxia \ Collocations\ Maxia.ini
Contains system operation parameters (operating modes, RS-232C) takes shape etc.).
(3) C:\ Maxia \ Colocaciones\ Detector.ini
Contains unit parameters of the detector.
(4) C:\ Maxia \ System\ Master.mdb
Contains information about calibration data and test file.
(5) C:\ Maxia \ System \ SpecimenResult .mdb
Contains information about test requests and test results.
(6) C:\ Maxia \ Sistema\ QC.mdb
Contains test results of the control samples.

2.2.3 System Support

It is advisable to hold system files on a regular basis as a precaution against lack of system. This can be easily done using a DVD-RW guide on PC. controlador. Asegurese de que todas las operaciones de unidad principales hayan parado, y so I simply saved the entire C:\Maxia Folder to the supplementary media.

Refer to a DVD that provides software assistance for information on how to operate. a DVD-RW guide.

Wait until the system operation has finished before backing up the system with the download of the Maxia files for the backup.
DO NOT attempt to perform supplementary operations while the system is in operation as it can damage the files.

2.3 Specifications

Main specifications

Main Essay	Fluorescent Enzyme Immunoassay (FEIA)
Process method	Automated random access continuum
Process capability	Maximum 200 tests/h. (ST reagents)
In vitro diagnostic reagent	AIA-PACK series
Sample volumes	10 to 125 UL
Sample clot detection	Exert pressure on detection (Note 1)
Measuring conditions	Reaction temperature: 37 degrees
Reaction time of the test	10 min, 20 min, or 40 min. (depending on the) specification of the essay
Specimen dilution factors	2 per test specification in the ranges of 2 to 1000
Specimen pretreatment	The automatic pretreatment (minimum 10 at 37 degrees)
Detection method	The fluorescent measure (top system)
Precision control	Multirule (Levey-Jennings chart)

Test cup classifier

Number of cups available	Maximum 48 trays (960 tests) it can be added at any time upon request

Tip classifier

Tips	dedicated tips
Counting the set of tips	576 (96/rack, in 6 racks) Can be added or changed in any time upon request

Sample charger

Collection count of specimens	200 specimens, (add/change as required)
Sample containers	Test tubes: 13x75, 13x100, 16x75, 16x100 mm (length of x diameter) Can be used in the combination with the dedicated sample cups
Specimen barcodes	CODE39, CODE128, ITF, compatible with NW-7, JAN (docile with ASTM14466-92 and barcode standards of CLA) Minimum element width: 0.191mm (0.254mm)

Reagent carousel

Reagent set account	It has the capacity for 16 different types of reagents and They can be added at any time upon request.
External input/output	RS-232C (ASTM) or Ethernet (HL7 V2.4)
Power Supply/Power Consumption	AC100-240, 50/60 Hz, 700 VA (excluding controller PC and printer ( )) option On voltage category II
External Dimensions/Weight	(excluding controller PC and monitor)
2000 ST DE AIA	1500(w) 907 (d) 1260 (h) mm 400 kg
2000 LA DE AIA	1500(w) 1197 (d) 1260 (h) mm400 kg

Operating environment

Temperature	15 to 30 degrees Celsius
Humidity	40% at 80% R.H. (without condensation)
Degree of pollution	2
Octopus	Medium office level
Height	Up to 2000 m

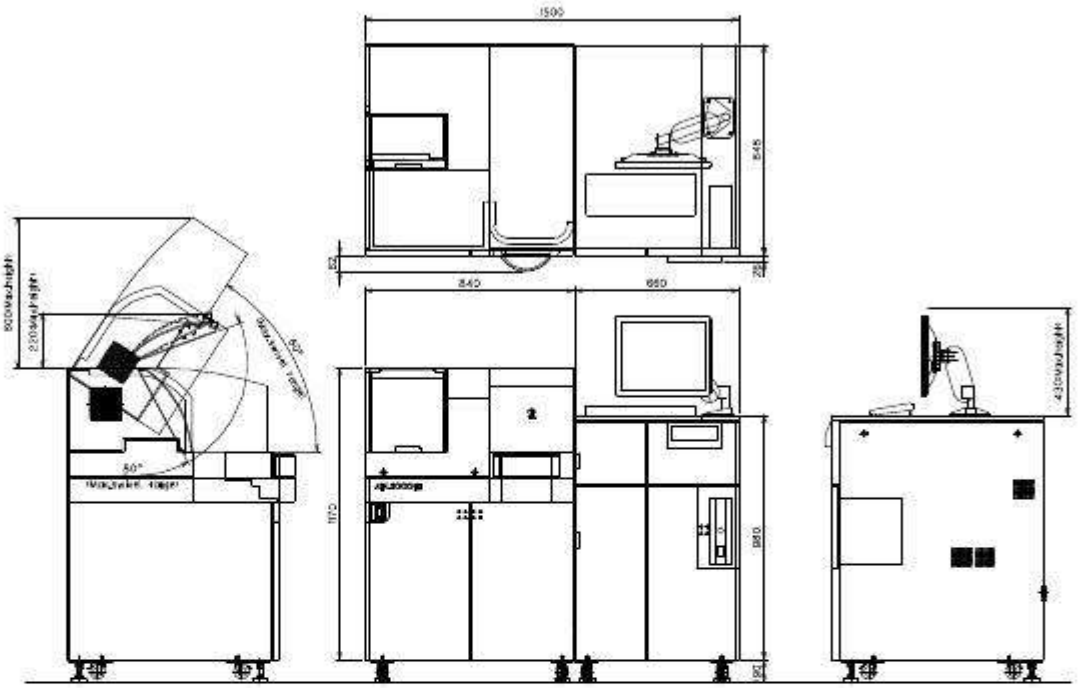
Standard of compliance

EMC standard	IEC61326 - 1: 2005 / EN61326 - 1: 2006 IEC61326 - 2 - 6: 2005 / EN61326 - 2 - 6: 2006
CISPR class and group categories	Class A, group 1
FCC	Part 15, Part B auxiliary, Class A

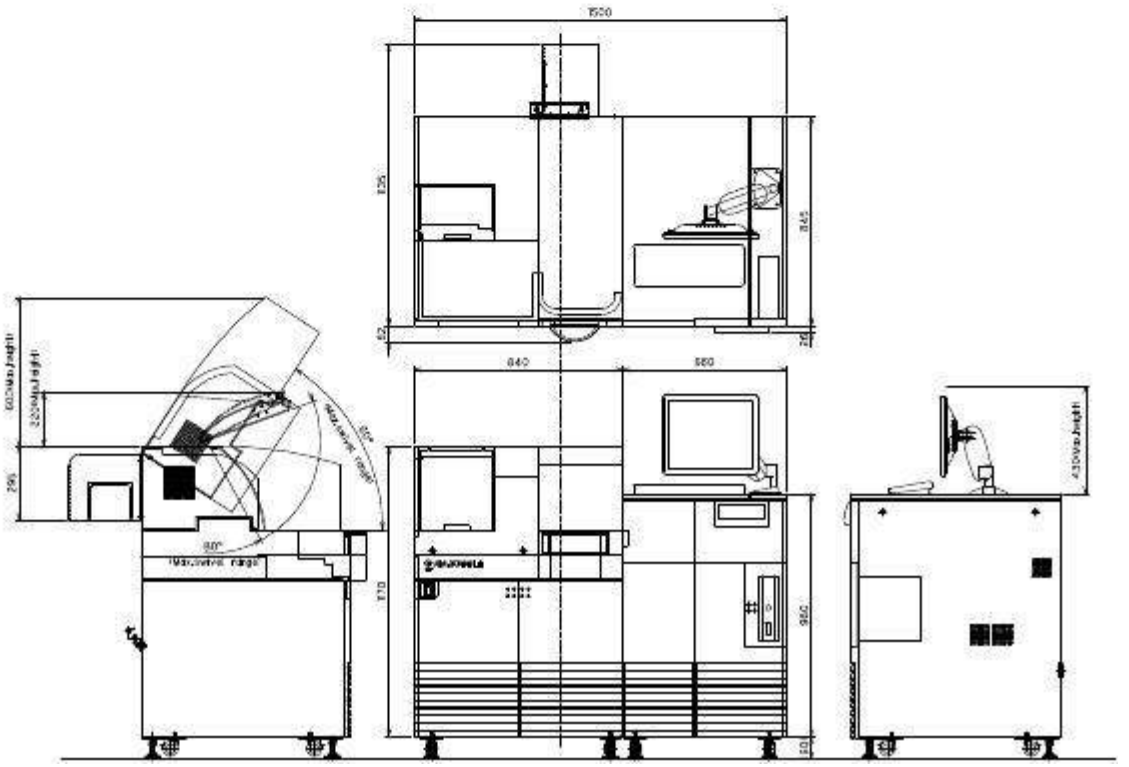
BARCODE READER Class 1: IEC60825 - 1: 2001

Note 1: Sample clot at the tip of the nozzle will be verified after suction of the specimen and announced by "SC" of the flag should vacuum clean the dust; the pressure exceeded approximately 10% or more of that. when it is completely stuck. Another banner UC that does not work in the implicit placement will be announced if The system detected an abnormal variation in vacuum pressure during the suction of the specimen.

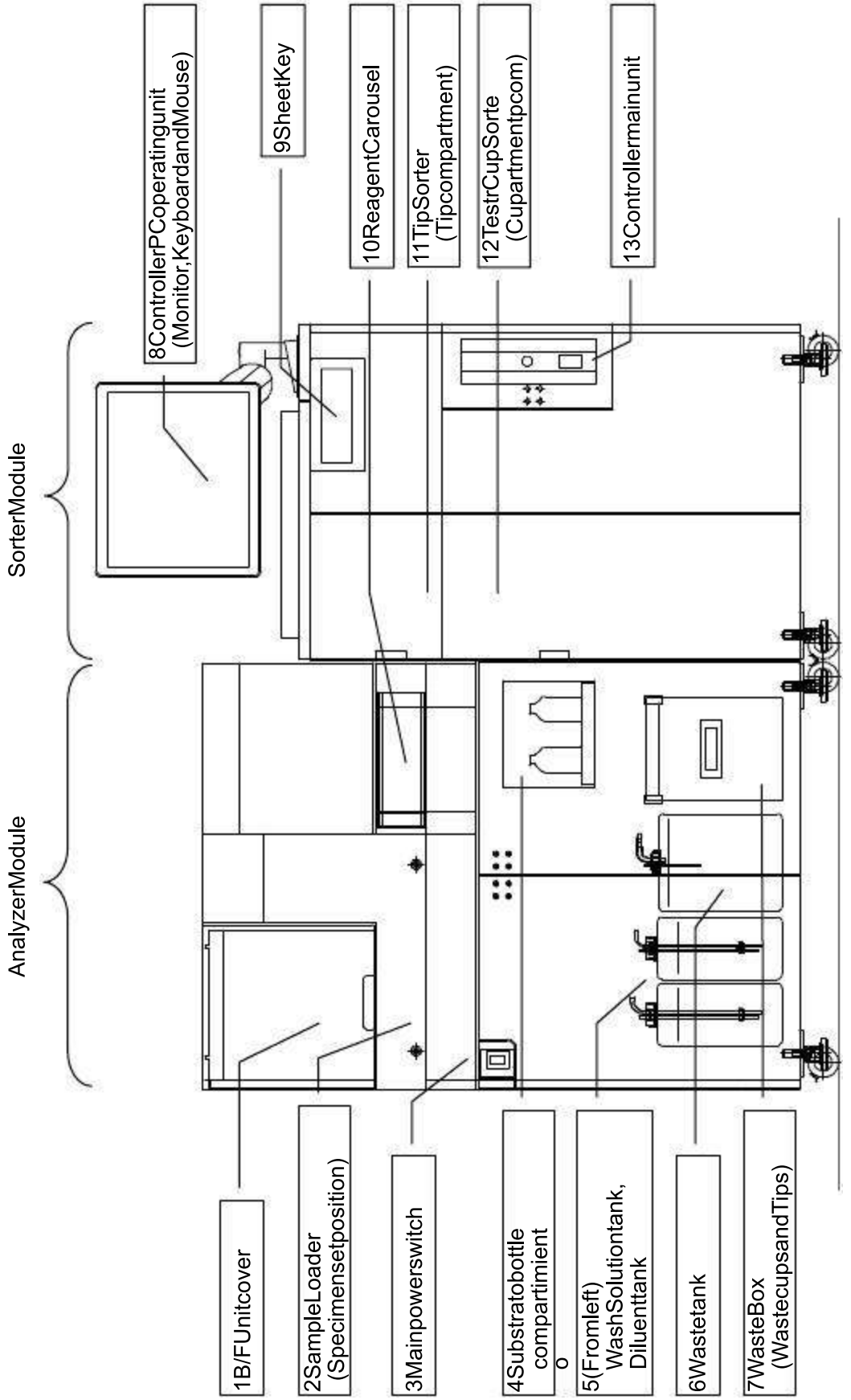
External dimensions of the AIA-2000 ST



External dimensions of the AIA-2000 LA



2.4 Part names



2.5 Functions of system units

2.5.1 Analyzer module

(1) Gate unit of the B/F: this opens when it is cleaned or when a change is needed. washing probes tips of the B/F.

(2) Cargador de muestra: los racks de muestra contienen copas de muestra y tubos de sample assays that are placed in the sample holder.

Substrate bottle compartment: The compartment where the substrate bottles are located They are installed with level sensors that indicate the amount of substrate remaining.

The washing solution and diluent compartment is located in a specific position and assigned to each one, on the left the WASH and on the right the diluent. Each tank has a capacity of 5L and come with an electrode sensor to indicate the remaining amount.

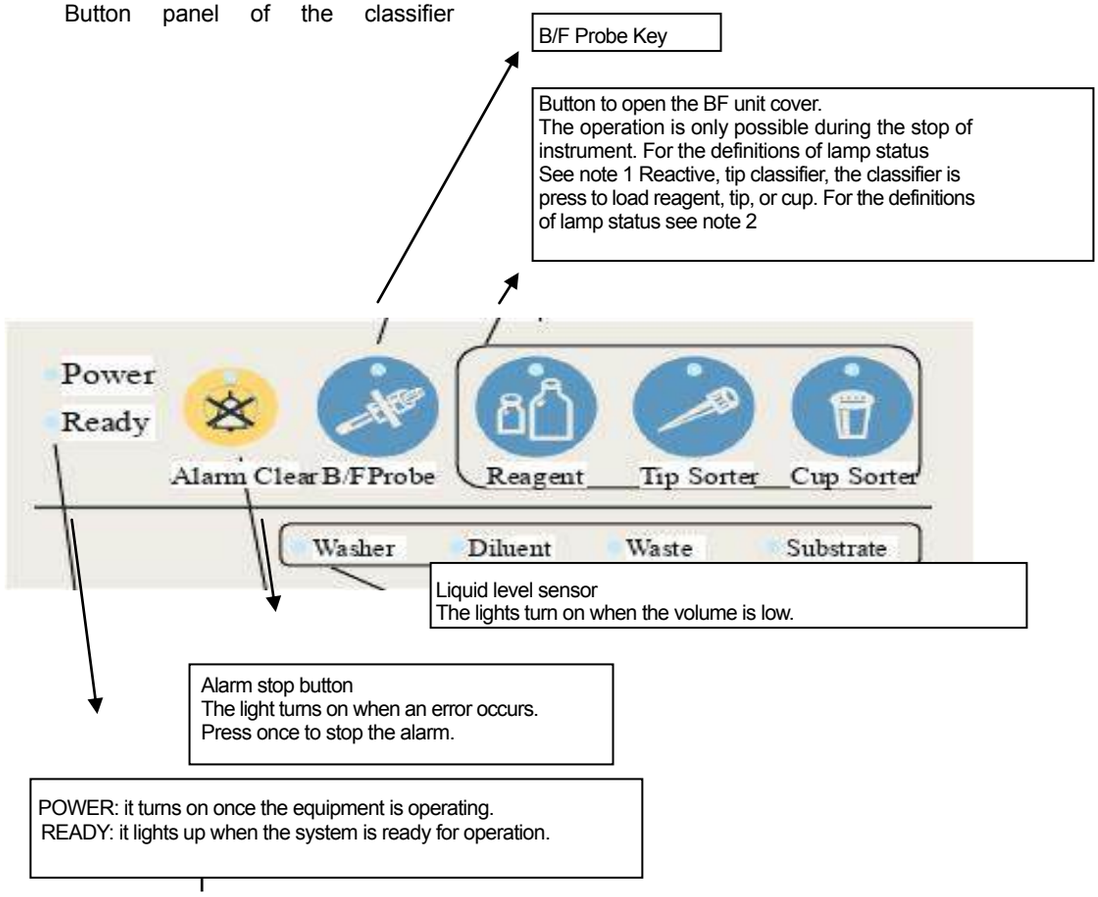
The waste tank is designed to retain the discarded fluids during the processing of samples, has a capacity of 10L and an electrode sensor for indicate when it is full.

The waste box is used to discard the used cups and tips in the test.

2.5.2 Classifier module

(8) The operating unit of the controller PC consists of a monitor of touch screen, keyboard, mouse, and barcode scanner, the console is designed for the controller operation.

Button panel of the classifier



Note 1: B/F Probe, definitions of warning statuses:

Outside: if the LED is flashing green, the instrument is preparing to open the B/F probe cover after it Press the key. In green: The drive cover of The B/F can be opened.

Nota 2: Reactivo, clasificador de tips, prueban el clasificador de copa, definicion de estatus de aviso:
Outside: if the red LED is flashing, the instrument is preparing to open the reagent carousel cover, the door of the tip classifier or the test cup classifier door after pressing the button, you must wait to be able to open.

In green: The reagent carousel cover, the tip sorter door, or the test cup The door of classifiers can be opened.

In red: 2-step reagents or pretreatment indicate that the operation is in process the button should not be pressed, this will cause the rehearsal to stop.

carousel of reagents
The reagent bottles or vials are loaded by opening this cover.

Tip classifier
The tip racks are loaded by opening this door.

Test cup classifier
The cup trays are loaded by opening this door.

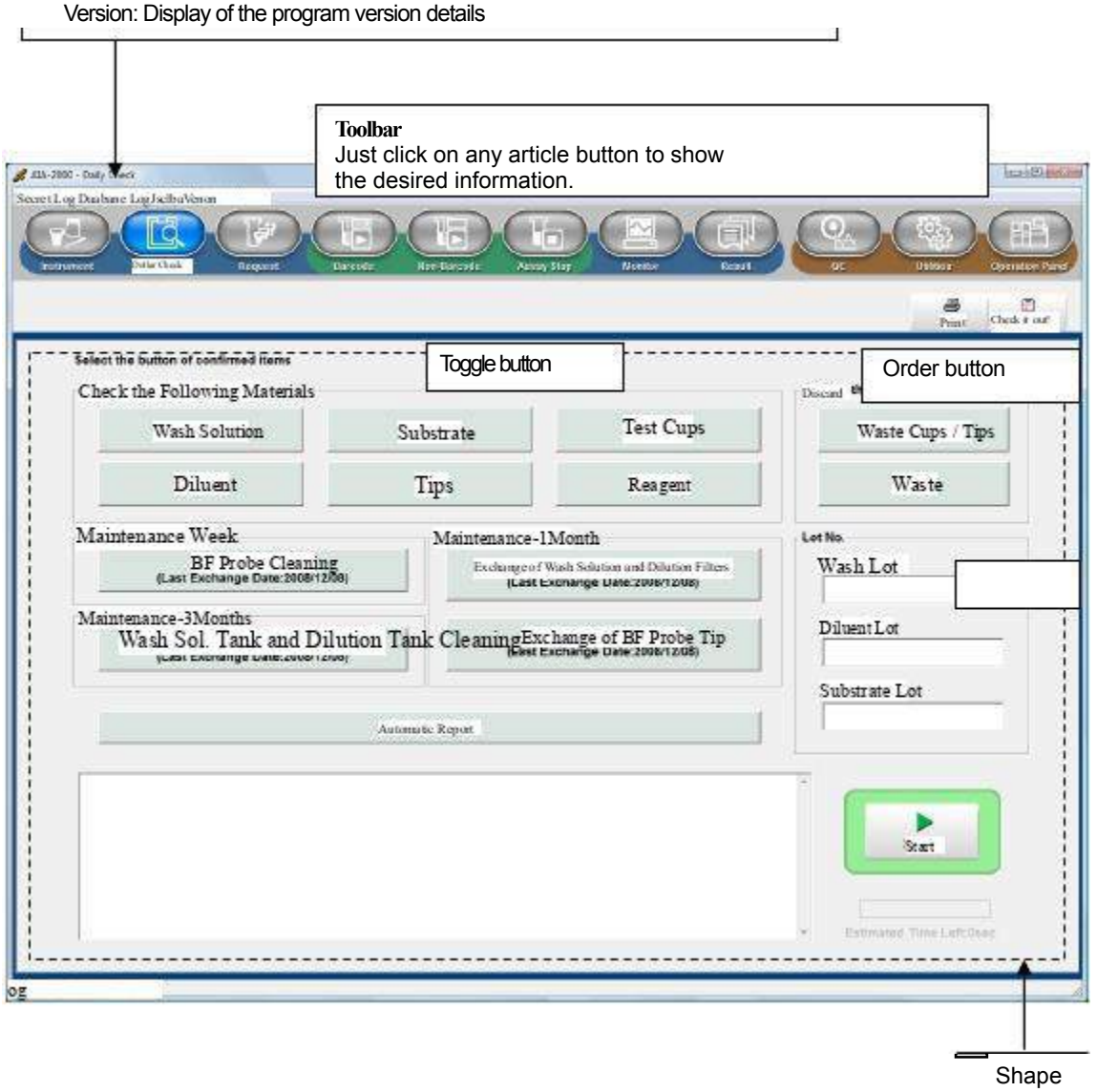
Controller PC unit
The controller PC is formed by turning on the power switch at the front.
case of controller PC.

2.5.3 Operation Control Screens

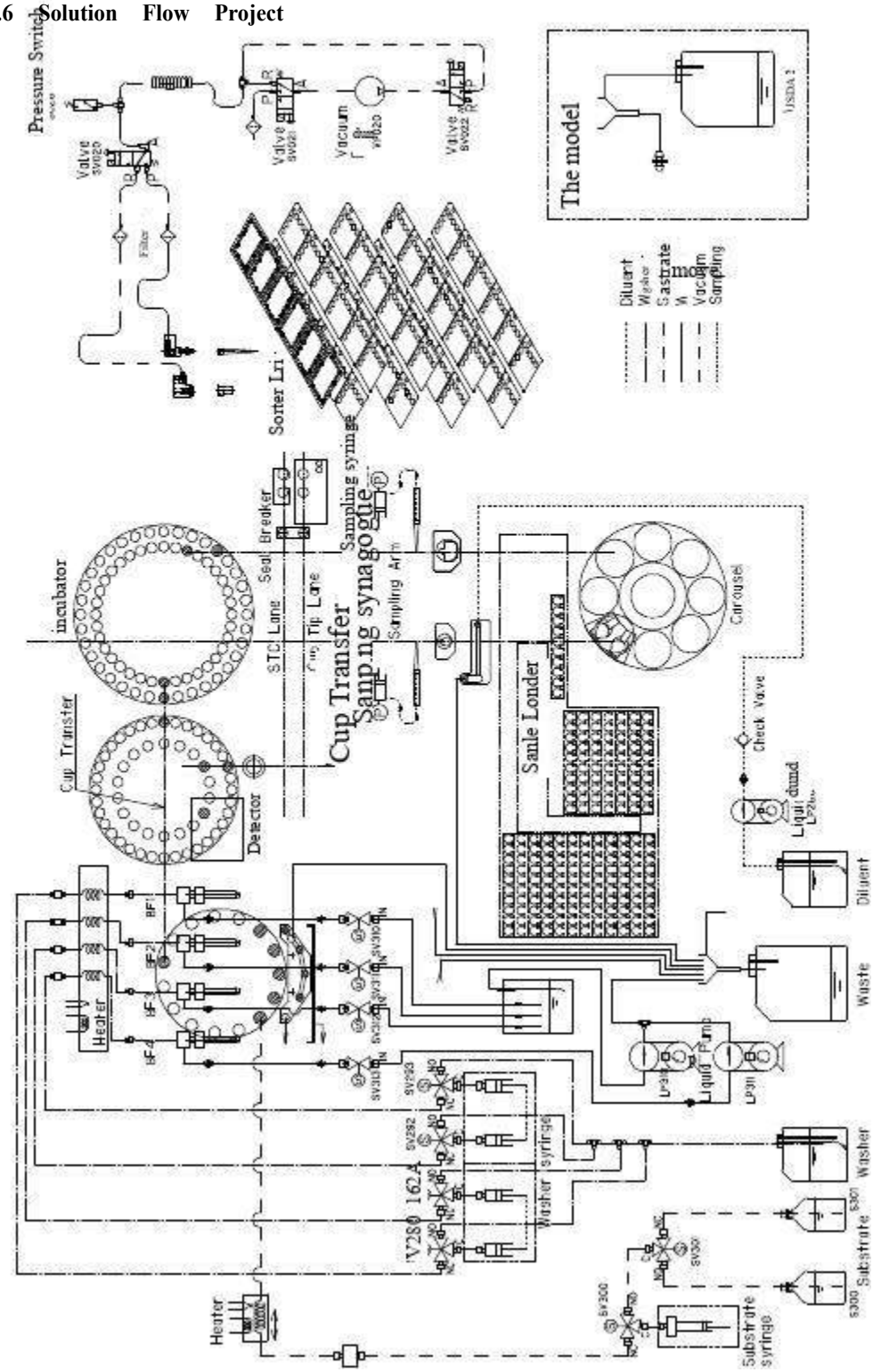
The various menu screens and menu keys that appear in the controller display are described below.

Menus

Solicitud: Nuevo, abrir, guardar como y salir
Record: The recorded errors are presented
Database: Closures, the system's database and backups that store the main data
System entry: The system can change the instrument operator.
Toolbar: The toolbar can be located at the top or bottom of the screen.
Version: Display of the program version details



2.6 Solution Flow Project



System functionality

2.7.1 Authorization level control

The AIA-2000 system separates users into two categories, operator and administrator, with access to all system functions based on these categories. Users without
Without appropriate authorization, they will not be allowed to edit the placements of various parameters.

2.7.2 Automatic dilution function

The measurable concentration range for each analyte is determined by range of
High concentrations of the specimens exceeding the test range are diluted.
first with the sample diluent (SDS) before being processed. Users choose the
dilution factor of the analyte from the assay request menu screen. The specimens are
they are diluted automatically according to the selected factor results and the test
they multiply by the same factor. (certain exceptional analytes do not multiply by the factor)

2.7.3 Automatic pretreatment function

The automatic pretreatment process executes a pretreatment reaction for 10 minutes at 37g. Pretreatment 1 (reaction solution) and pretreatment 2 (stop solution) is supplied to be used as pretreatment reagents. The parameters of Pretreatment is entered in advance in the Test File.

2.7.4 STAT (emergency samples)

The STAT sample can be processed using a specific sample rack as the priority.
The sample on the rack is specified as the priority for the carriers to handle it.
process as a STAT emergency sample.

2.7.5 Automatic Rephrase Function

The essay request can be automatically reformulated if the initial results have have been modified according to the user's defined condition.

2.8 Operating modes

The AIA-2000 system provides three basic operating modes. These are no-code bars, barcode and host question modes. The system operation format differs depending on whether the specimens are supplied using the built-in sample loader unit or an external rotation unit.

Note that the rotation operation is only available for the AIA-200LA model.
Note that the barcode-free mode is not available for the rotation operation.

2.8.1 No-barcode mode

As the name suggests, the specimens are processed without the use of the barcode. In the essay request, the information is entered manually into the controller's PC or downloaded from the base computer before testing operations. Once a specimen container is detected, the testing operation begins by checking in order the racks are placed according to how they are arranged (note that the non-barcode mode cannot be used) with the rotation operation.)

2.8.2 Barcode mode

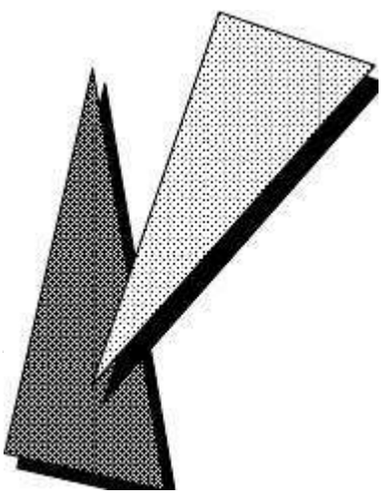
In barcode mode, the trial information request is entered manually into the PC of the instrument or is downloaded from the base computer before the operations of essay. When a specimen container's barcode is read, the system extracts the information for that barcode of the instrument request the PC can execute the specified test operation.

2.8.3 User Question Mode

In user question mode, the system reads the barcode of the specimen container and search in the instrument's PC for the information corresponding to that barcode, otherwise, the system sends the question to the base computer and downloads the necessary information. The test operation is carried out as specified and the results are sent to the base computer.

Chapter 3

System installation, Transportation and Storage



3: System installation, transportation and storage

This chapter provides specific guidelines to be followed both before and after the installation of the AIA-2000. The AIA-2000 is a high-precision analyzer that requires careful adjustment according to standards. specific to ensure stable and reliable operation. Tosoh or local representatives attend to the staff in the installation and maintenance procedure to inspect the delivery and installation of system. It is recommended that the AIA-2000 be installed in accordance with the instructions provided by the service staff.

3.1 Transportation and storage environment

Temperatura:	5 to 50 degrees Celsius
Humidity:	80% R.H. or less (not condenser)
Others:	Keep in a dry place Store indoors

3.2 Usage Environment

Install the AIA-2000 main unit on a level floor in an environment where it is not exposed to dust. toxic fumes, vibration, and direct sunlight.

Temperatura:	15 to 30 degrees Celsius
Humidity:	40 to 80% R.H. (no condenser)
Octopus:	Equivalent levels to the middle office
Height	Up to 2000 m

Do not allow the AIA-2000 to operate in an environment characterized by fluctuations in temperature. The resulting condensation can cause a leak and this can affect adversely affecting the normal operation of the system.

3.3 Power supply

Connect the AIA-2000 to a stable power supply outlet. Use a power outlet. independent and never share power outputs with other teams that consume the highs power quantities. The power supply requirements of the AIA-2000 are explained. next.

Voltage:	100-240 V
Frequency:	50/60 Hz
MaximumPower:	1 KVA for the main part unit and controller PC (excluding printer)

The operation of the AIA-2000 in an environment characterized by fluctuations does not hinder. voltage spikes, these are a potential source of errors in the system.

3.4 Installation space

Install the AIA-2000 in a location with ample peripheral space and a solid floor foundation. capable of supporting a weight of 400 kg. Space is an important consideration for the AIA-2000.

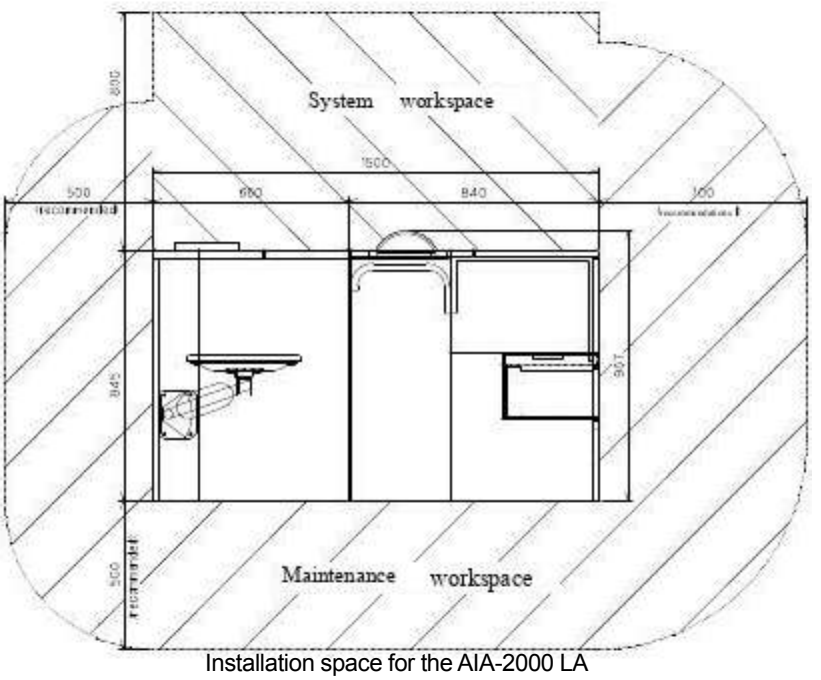
Dimensions of The AIA-2000

model ST:1500MM (W) * 907MM (D) * 1260MM (H)

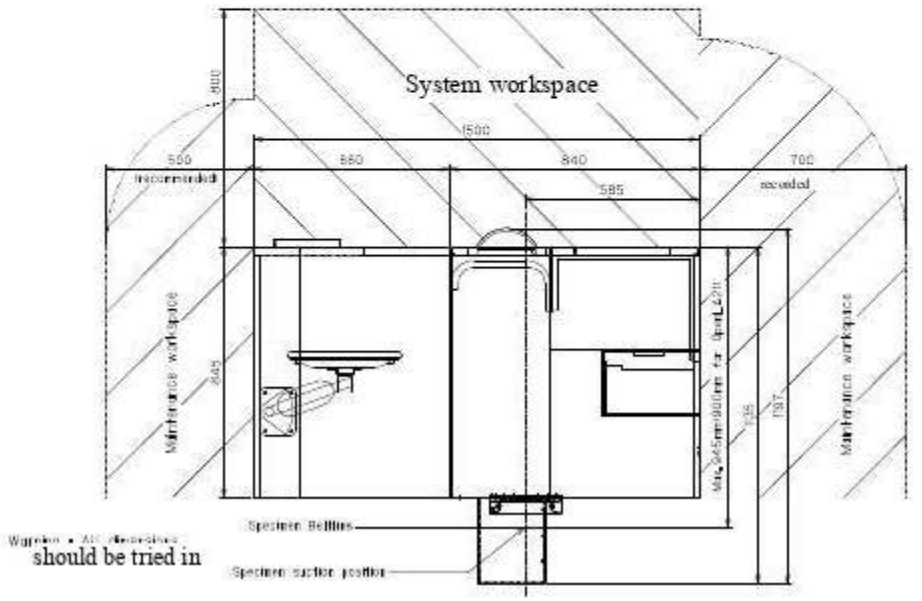
Model of LA: 1500MM (W) * 1197MM (D) * 1260MM (H)

For both the ST and LA models, a height of 1770 mm is necessary when the cover is open. It is important to ensure sufficient peripheral space that exists to accommodate the airflow. The refreshing indoor fans. Avoid exposing the system to closed spaces.

Installation space for the AIA-2000 ST



Installation space for the AIA-2000 LA



3.5 Standard accessories

Upon unpacking the AIA-2000 in the presence of service personnel, check the list of accessories. provided in the accessory box to ensure that all standard accessories are included in the package, immediately notify service personnel or the sales agent if the components are they are found incomplete.

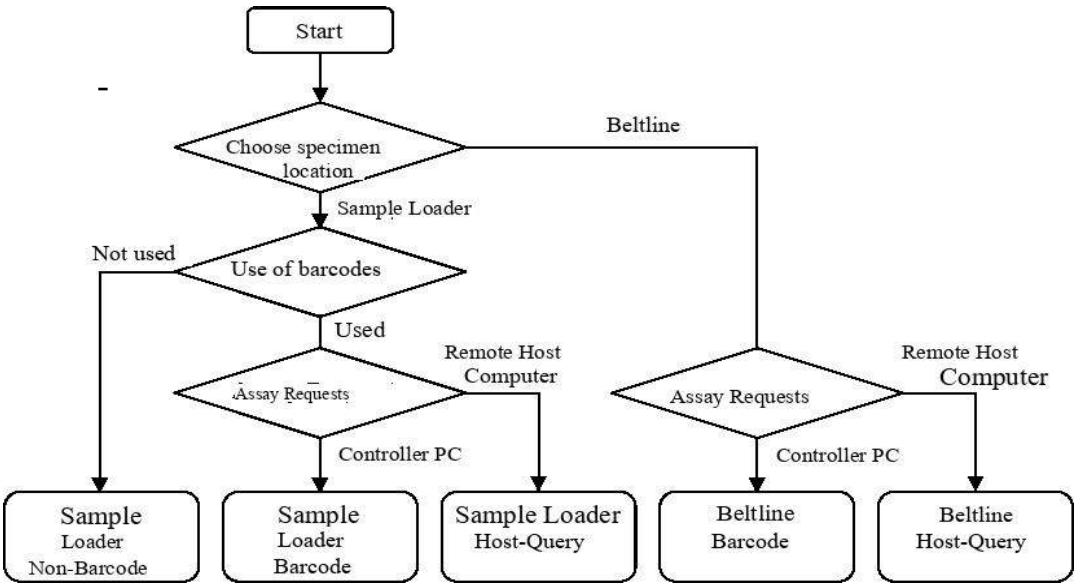
3.6 Register a system administrator

It is necessary to register a system administrator during the installation process. Make sure to have the appropriate operator, name, and password ready when asked to execute the service registration The system will not operate until the system administrator has been registered.

3.7 Mode of operation

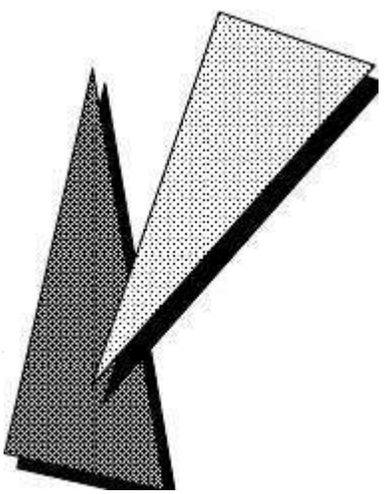
There are several operating modes as illustrated below. Refer to 'Chapter 6: Operation' of the system. for a detailed description of the system's operating modes.
Selection procedure mode

Note that the rotation mode is not available with the AIA-2000 ST model.



CH 4

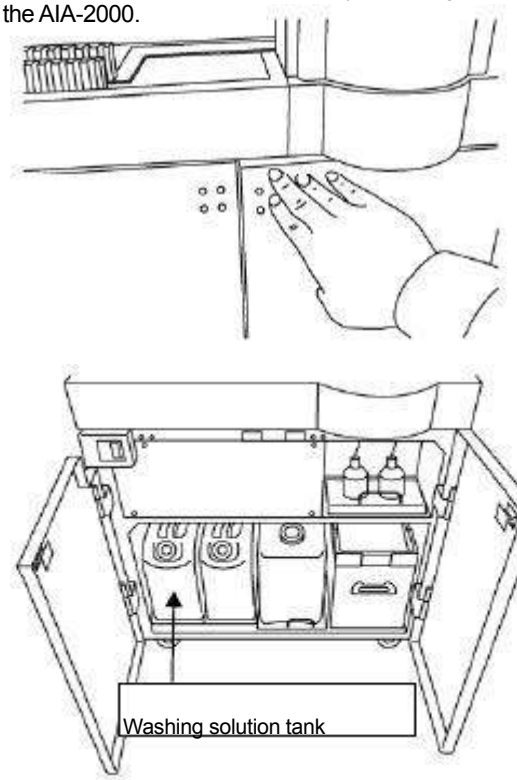
Overview of System operation



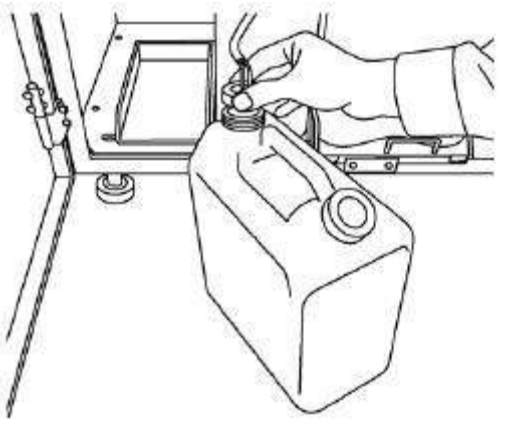
The procedures for loading specimens are described in the following sections. Be sure to follow. these procedures when operating the AIA-2000.

4.1 Install the washing solution

Gently open the wash solution compartment by pushing the doors of lower entries of the AIA-2000.



Remove the wash solution tank, then after storing the solution, place it back in its location.



Note that the washing solution tank has the same shape and size as the diluent tank. There is to be sure to choose the correct color of the washing solution tank for reference is orange color. Choosing the incorrect tank will directly affect the results of the test.

Acauti

Keep the sensor next to the solution hoses in the compartment when transferring the tube to another washing solution tank. The fluid leak is a potential source of electric shock.

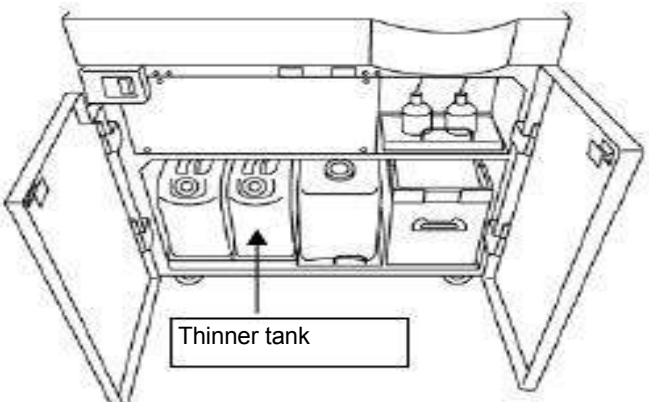
Refer to the insertion sheet of concentrated WASH when mixing the washing solution.

It is important to mix the concentrated WASH in water in the correct proportions.
If the dilution turns out to be significantly uneven, this can directly affect
The result of the tests.

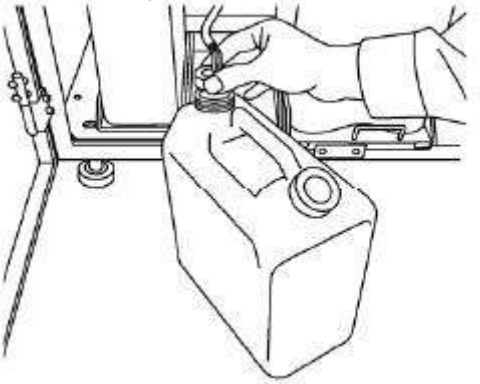
Close the tank lid.
Return the tank to the compartment.
Close the lower entrance doors of the AIA-2000.

4.2 Install the thinner tank

Open the diluent compartment by gently pushing the lower entrance doors. from AIA-2000.



Take the thinner outside, store it in your tank, and put the lid on when finished.



Note that the thinner tank has the same shape and size as the washing solution tank.
You must make sure to choose the correct color of the tank; for reference, the color is green.
Choosing the wrong tank will directly affect the results of the test.

caution

Keep the sensor next to the solution hoses in the compartment when transferring the tube to the thinner tank. The fluid leakage is a potential cause of electric shock.

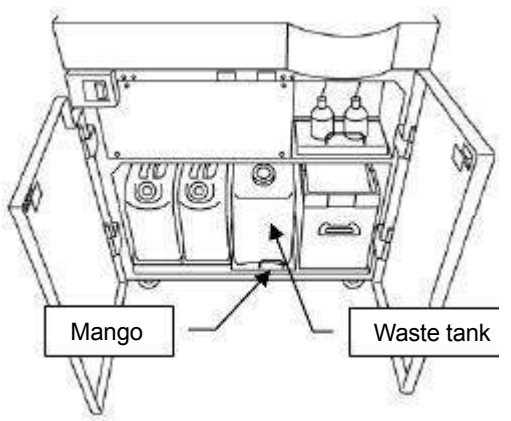
(3) Refer to the insertion sheet of the concentrated Diluent before mixing it.

It is important to mix the concentrated DILUENT in water in the correct proportions.
If the dilution turns out to be significantly uneven, this can directly affect
The result of the tests

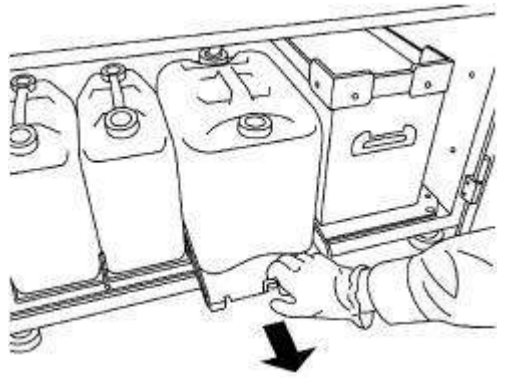
Close the tank lid.
Return the tank to the compartment.
(6) Close the lower entrance doors in the AIA-2000.

4.3 Dispose of the waste container

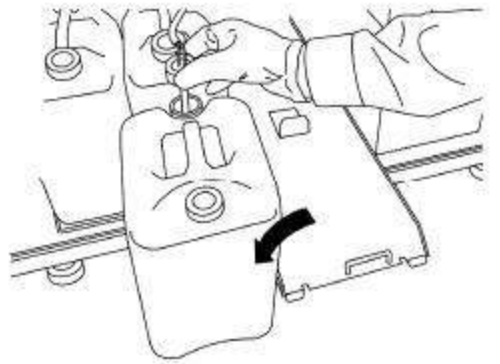
Gently press the doors to open the waste container compartment. lower entries of the AIA-2000.



Hold the handle and gently pull the tray to remove the waste container.



(3) Place the container on the floor and make sure that no liquid remains in the pipes. tank.



(4) Remove the lid from the waste container.

Acauti

Avoid removing the lid of the waste container before placing the tank on the floor, as this can cause liquid leakage.

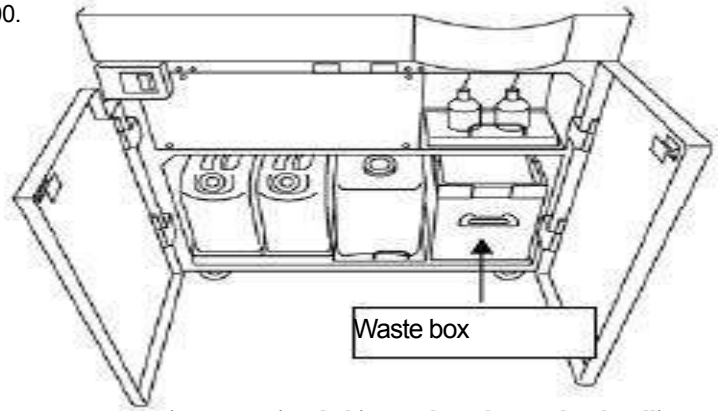
Be sure to wear the appropriate protection, such as gloves, when handling. the waste, since the fluid has been contaminated by specimens already analyzed.

Keep the sensor next to the solution hoses in the compartment during transfer tube to the waste container tank. Fluid leakage is a potential cause of electric shock.

Dispose of the waste fluid in the designated location.
Place the lid on the empty waste tank.
Place the stored waste in a tank at the back of your location.
Close the lower entrance doors in the AIA-2000.

4.4 Waste box for cups and tips

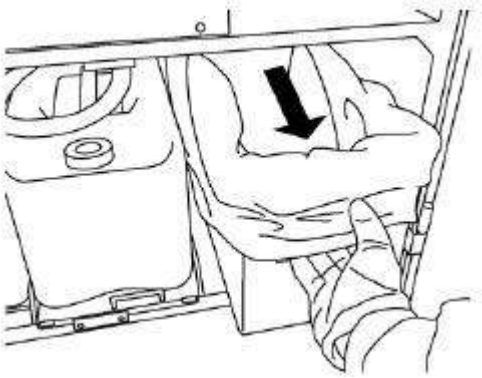
Gently open the waste compartment by pushing the lower entrance doors. from AIA-2000.



caution

Make sure to wear appropriate protective clothing, such as gloves, when handling. The waste box, like the cups and discarded tips, has been contaminated by potentially infectious specimens.

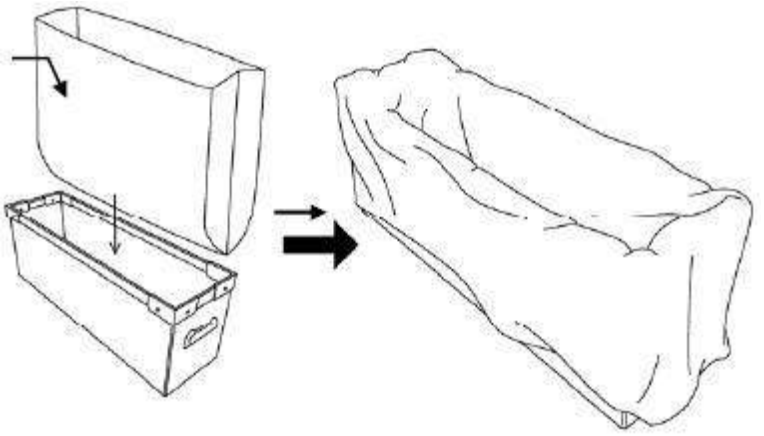
(2) extract the box for solid waste.



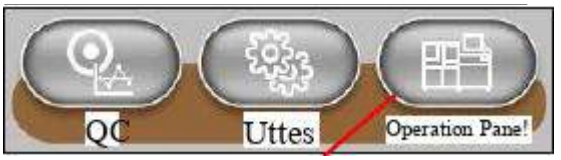
Remove the garbage bag that contains the solid waste.

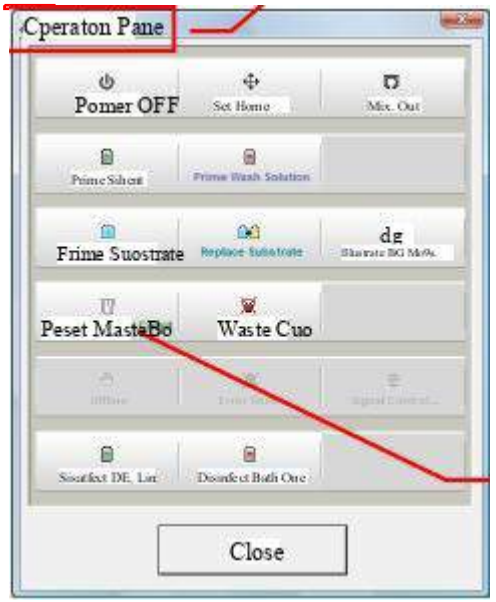
Put a new bag in the waste box and return it to its original position.

Trash bag
Part No. 0022201



Close the lower entrance doors of the AIA-2000.
(6) After placing the waste box, click on the Waste Box Count button. to restart the count.





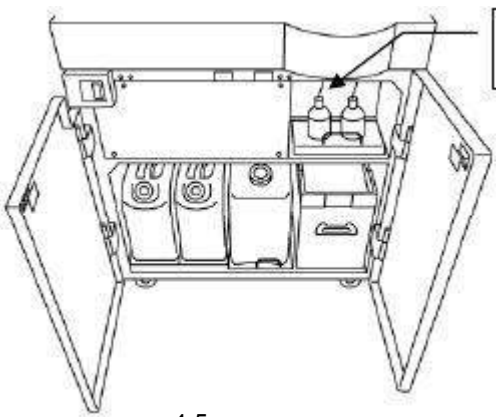
▪

Point **The discarded cups and tips are counted as they are discarded. The status of the waste box is displayed in the request part of the instrument (toolbar). When the account reaches 3600 trials, the base color of the waste box bar changes from gray to orange. When the residual amount is reset, the base colors (the waste cash status) returns to its original color) resets the count to 0 (the count is restarted).**

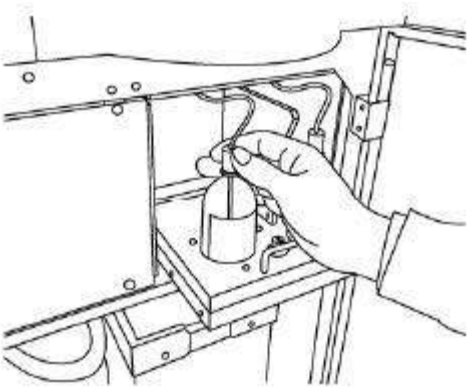
The contents of the waste box are not monitored by sensors, always check the level of the waste before starting the system operation.

4.5 Change of substrate and replacement solution bottles for substrate

Open the substrate compartment by gently pressing the entrance doors. lower in the AIA-2000.



Remove the bottle substrate tube.



Take out the bottle.

When changing from the replacement substrate solution (70% ethanol) to the substrate:
Put on the lid, remove the replacement substrate solution (70% ethanol) from the bottle, and store it until the testing operation has finished. After this, reinstall the substrate replacement, the solution of (70% ethanol).

When changing from the substrate to the substrate replacement solution (70% ethanol):
Put the lid on, remove the substrate bottle and place it in the refrigerator.

Install the bottle in its designated location.

Always install the substrate bottle with the label facing forward. The substrate level It has an optical sensor positioned at the back of the substrate container, which is why it has The label facing the back will cause detection errors.

Insert the tube into the bottle.
Close the lower entrance doors of the AIA-2000.

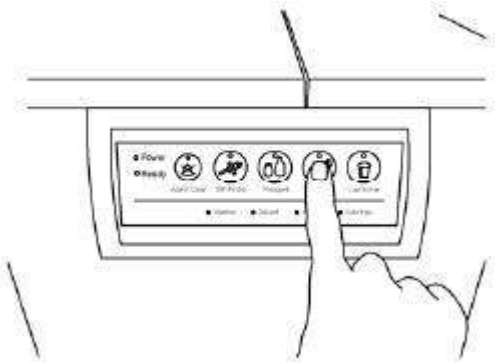
In case of single bottle mode, place the substrate bottle in the left position and the substrate the replacement solution (70% ethanol) the bottle on the right. In case of 2 bottles mode, Place the bottle substrate in both positions.

caution

Avoid placing potential spark sources near the substrate lines. Since the substrate replacement solution is 70% ethanol and could cause a fire.

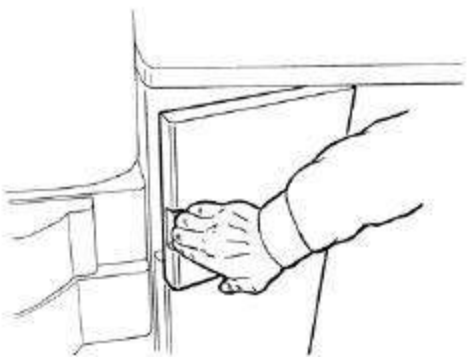
4.6 Install sample tips

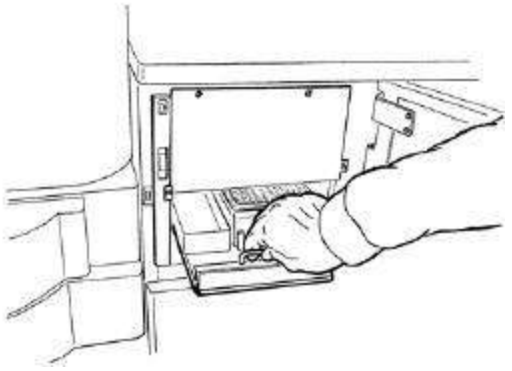
Press the tip classifier key on the AIA-2000 loader panel.



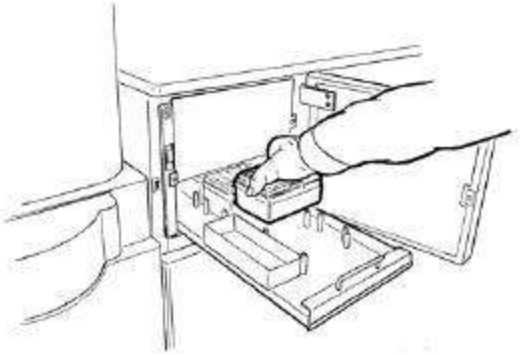
If the LED on the tip classifier panel is continuously red, or a 2-step reagent is In operation or pretreatment is in process, we have to wait for it to finish. The classifier key. the tip must not be pressed, as this can cause the testing process to be aborted causing the loss of the results.

The red LED flashes for a few seconds.
The LED changes from red to green, the lock has been released and the tip classifier door. can be opened.
Open the tip classifier door and take out the tip classifier drawer.





Take the tip rack and fill it in the correct order. Each rack contains 96 sample tips.

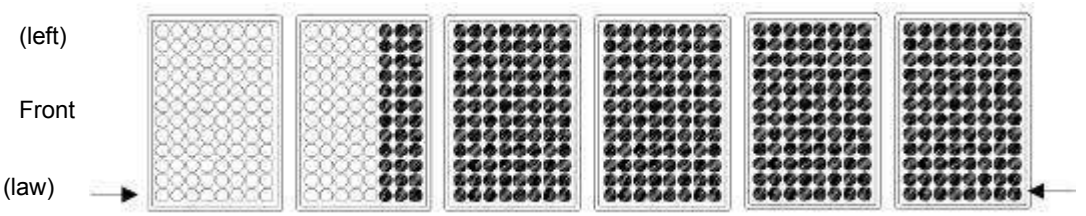


Replace tips that do not look good or are poorly placed. The drawer of The tip classifier has a maximum of six trays for onboard tips (a total of 576 tips).
(7) The AIA-2000 automatically detects the current number of tips when the drawer of the the tips classifier is completely closed and the tips classifier door is closed. (check the tips)

Avoid opening the tips classifier door for long periods of time when working with reagents of 2. steps or pre-treatment reagents. Record jumping and loss of results may occur when
- **the times of dispensing are coinciding or if pre-treatment operations are being carried out.**

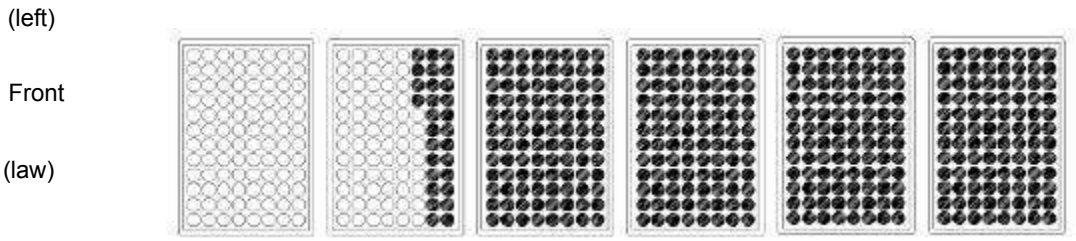
The team reads the tip lines starting from the right side, therefore, it is important to fill each row without leave empty positions.

Note: the inventory is not updated if there are tip positions outside the straight line on the right. and the classifier door has not been closed. Therefore, it is important not to remove the tips from the row since the First, since this is included in the inventory at the time of counting.



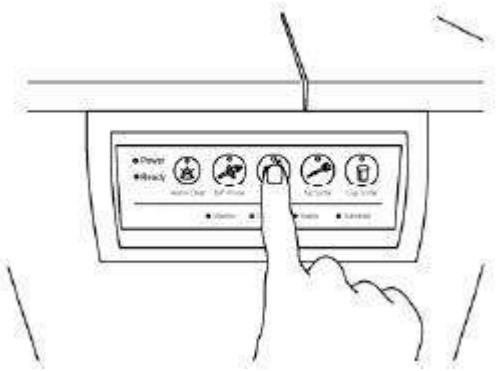
Line straight controlled by sensor.
The system detects the presence of 35 rows by 12 tips each = 420.

In the following example, the tips are consumed up to 412.
In this case, if there are no changes in the right row of tips, when pulling out and putting back the drawer, the system
Assume that no tips were consumed (the same account remains). The account is not updated to 408.



4.7 Notice for loading elements, shows that dilute the reagent of solution and pretreatment

Press the reagent key on the AIA-2000 loader panel.

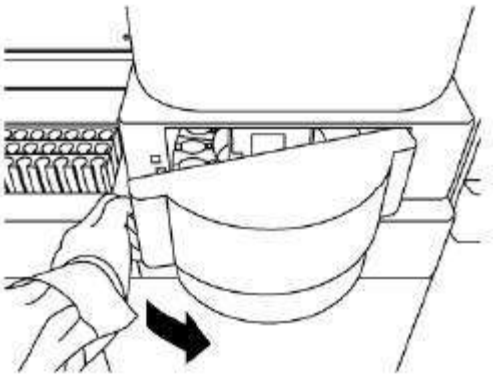


If the LED on the reagent panel is continuously red, or the 2-step reagent shows operation or pre-treatment in process. The reagent key should not be pressed, as this may cause the abort of the trial with the loss of results.

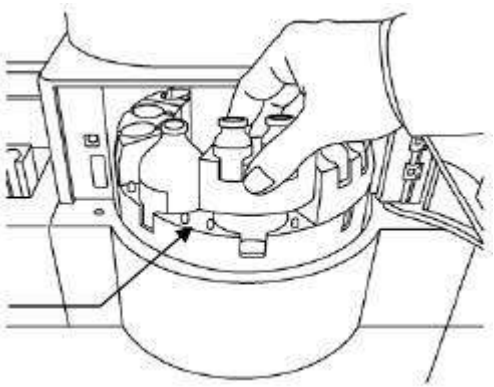
The red LED flashes for a few seconds.

The LED changes from red to green, the lock has been released and the reagent carousel cover it can be opened.

Open the gate that covers the reagent carousel.



Load 100ml bottles into the reagent carousel.
In the case of 5ml vials, use the reagent adapter.
In both cases, return the barcode to the front.



Positioning pin

Replace the reagent adapter aligned with the positioning pin.
Close the reagent carousel lid. The batch and reagent are read automatically.
when the cover closes. (through the barcode)
The reagent key shows the LED in red during the examination of the reagent.

Avoid opening the reagent carousel cover for long periods while working with two-step reagents or pre-treatment reagents. Record skipping and loss of results can occur when the times of dispensing are matched or if operations are being executed pretreatment

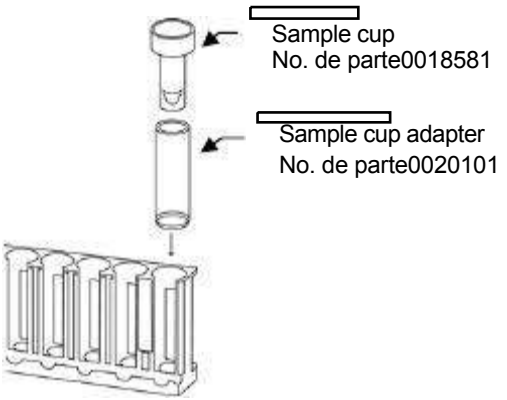
- **The system uses the previous level values when a record is read by barcode. When the level value is detected, that value is updated for the next operation.**

Pre-treatment reagent 2 must be placed in the left lateral position of the reagent. pretreatment 1. Solution 2 that does not have any barcode label is registered from Automatically form on the left side when solution 1 is registered with the barcode.

4.8 Load specimens, calibrators, and controls to test the charger

Specimens can be loaded into their tubes or dispensed in the required amounts. in the cups shown and loaded on the sample racks.

Note: the sample cup adapters must be installed in the sample rack when sample cups are used.

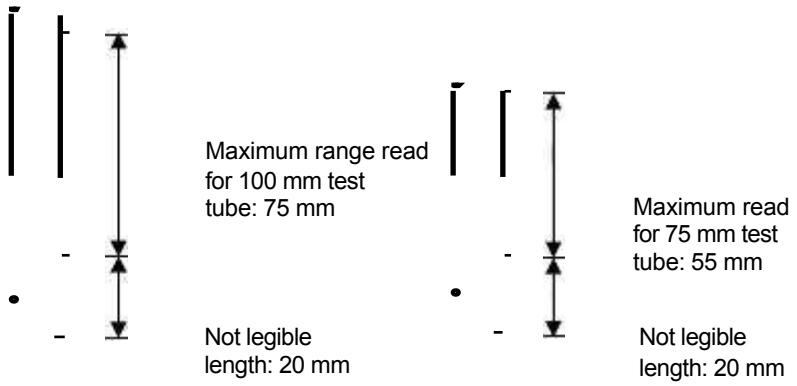


- **The minimum volume of the specification must be 100 µL for the sample cups and 500 µL for the test tubes.**

Note: the results of the samples cannot be validated for the conical test tubes. No have doubts in communicating with a Tosoh service center or local representatives for the Information on which types of test tubes can be used. In barcode mode.

Install test tubes with the barcode label facing the opening in the rack.

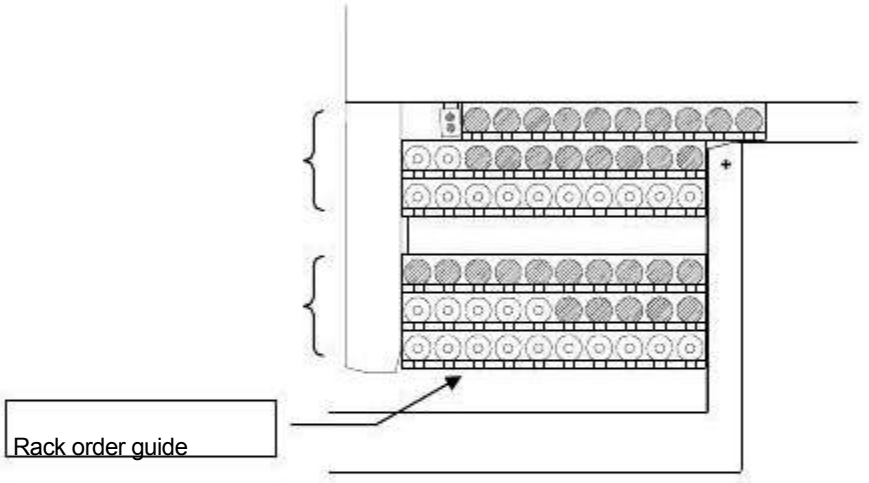
Make sure the barcode labels are within the valid reading range of barcode, as illustrated in the figure below. Dirty, wrinkled, poorly labeled or Curved surfaces will affect the reading of barcode.



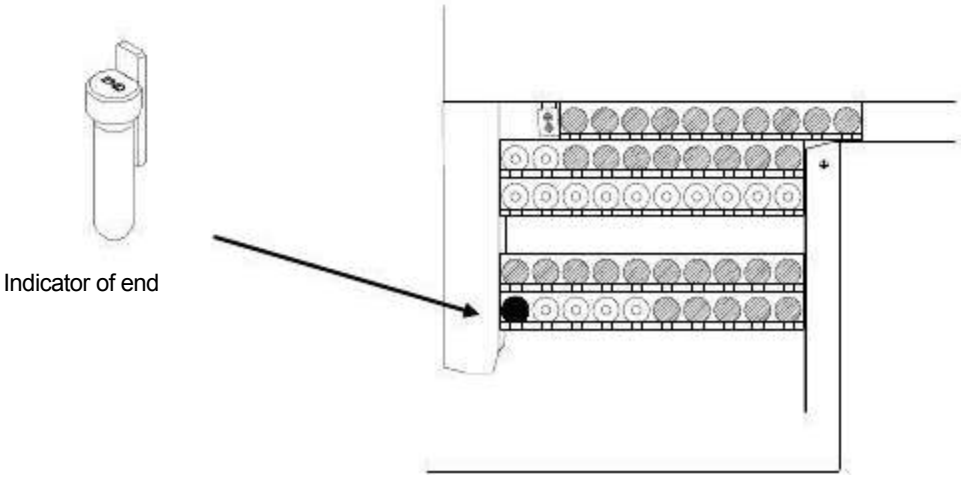
Note: Reading the range includes the barcode margin (blind spot).

- **It is important to apply barcode labels near the top of 75 mm primary tubes. to ensure effective label reading in cases where IDs with many digits are used.**

The sample loader feeds the sample in the format illustrated below.
the rotation order of the charger goes from the bottom right to the limit where it passes
to the right of the instrument where after processing it continues to move until it exits through the
Left where the route ends.

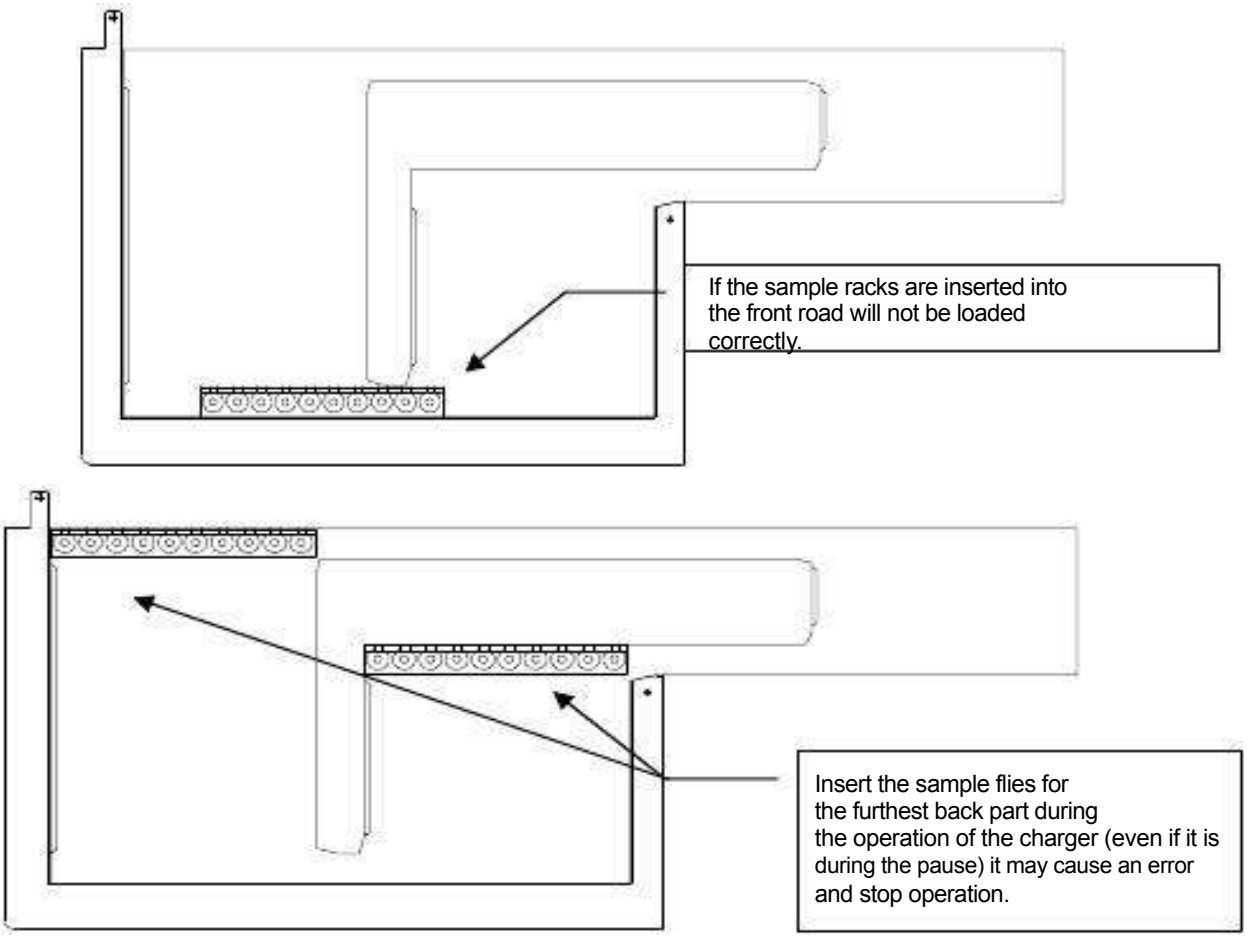


To conclude an essay, the team uses a finish indicator typically placed at the end.
Position of a rack, to prevent the equipment from repeating the reading cycle, it is necessary to use it once.
that we place all the samples that are going to be processed.



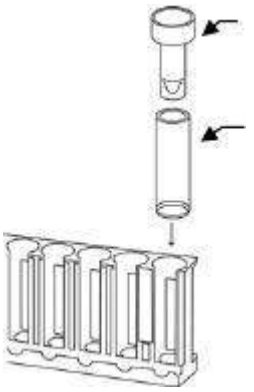
Load the sample racks for testing and insert the end indicator or an empty rack (empty rack)
in the end.

Make sure that the sample charger has stopped before loading the new sample racks.
This is because an error can occur during the rack movement process if we try to place a new one while the others are in motion
The end indicator or the empty rack must be inserted at the end, otherwise the loader You can continue your circulating movement. The locations where the sample racks do not can be placed as shown below.



4.9 Load STAT specimens (priority rack) to test loader

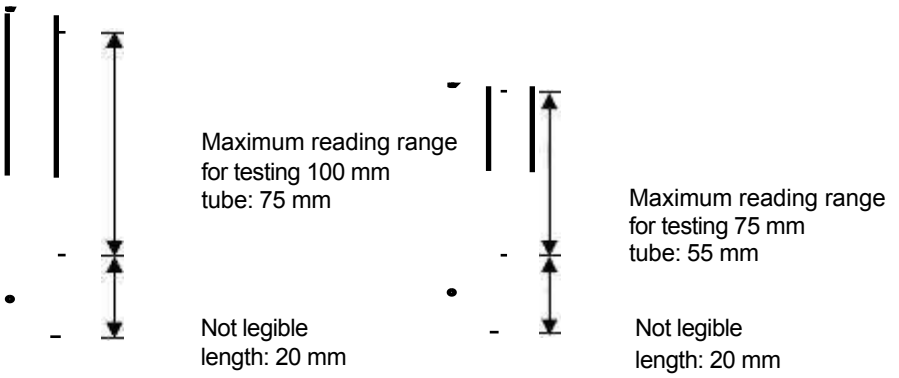
Specimens can be loaded into their tubes or dispensed in the required amounts. in the sample cups and loaded onto the sample racks.
Note: sample cup adapters must be installed in the sample rack when the sample cups are being used.



- **The dead volume of the specification is 100 µL for the sample cups and 500 µL for the tubes. of the essay around the background.**

Please note that sample results cannot be validated for conical tubes. Do not have inconvenience in communicating with a Tosoh service center or local representatives for the information about the type of test tubes that can be used.

In barcode mode, install test tubes with the barcode label facing the opening in the sample rack (towards the front).
Make sure that the barcode labels are within the reading range of the code bars, as illustrated in the figure below. Dirty, wrinkled or incomplete labels can affect the recognition of the code.



Note: Read the range including the barcode margin (quiet zone).

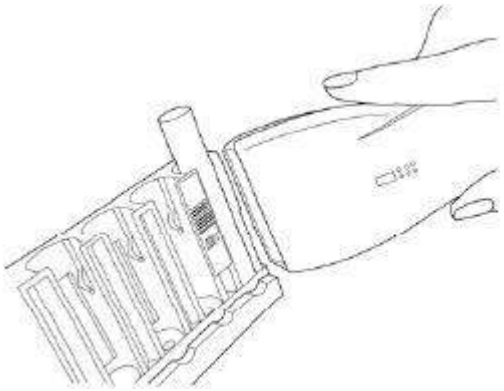
The barcode reader cannot read the 20 mm at the bottom of the tube. It is important to apply labels to Barcode near the top of 75 mm primary tubes to ensure label reading is effective in cases where IDs that use large numbers and labels are utilized.

If an additional trial request is prepared after an operation has started, charge the new sample and after dispensing it on the rack, when the one currently in progress is finished we proceed to insert the new rack.

(5) In cases where the sample charger requires more time than normal to stop, stop the operation choosing the pause option in the stop menu of the toolbar, then proceed to load the new rack and finally turn off the pause mode of the instrument.

For a description of pause procedures, refer to Chapter 6: Section 6.6.8 Test Pause/

(6) Register the rack IDs that use the electronic agenda barcode scanner or keyboard (manual).

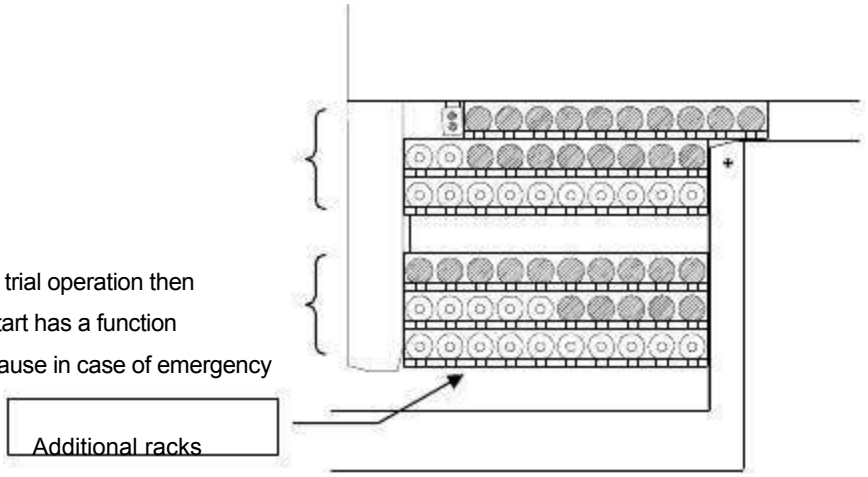


For a detailed description of the registration of rack ID, refer to chapter 6: STAT section 6.7

Essay requests (priority rack).

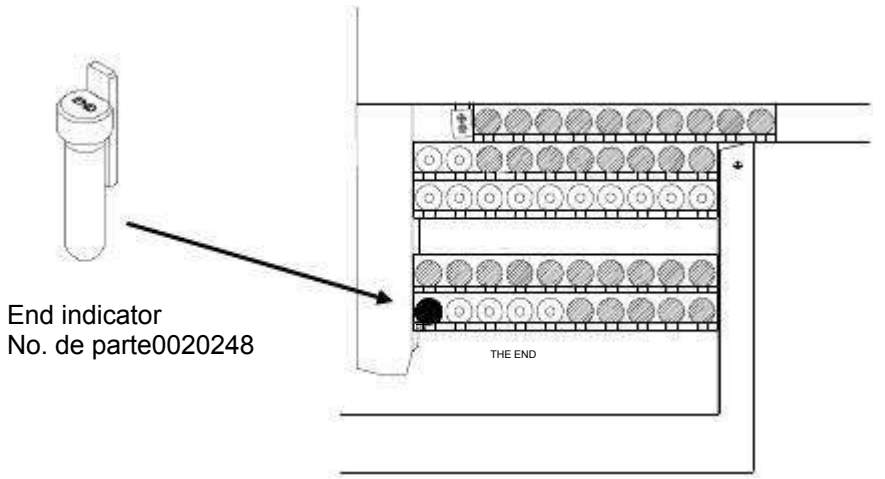
Load the additional sample racks after the sample loader has paused.

The end indicator or the empty rack should also be inserted at the end as an additional rack. of sample.

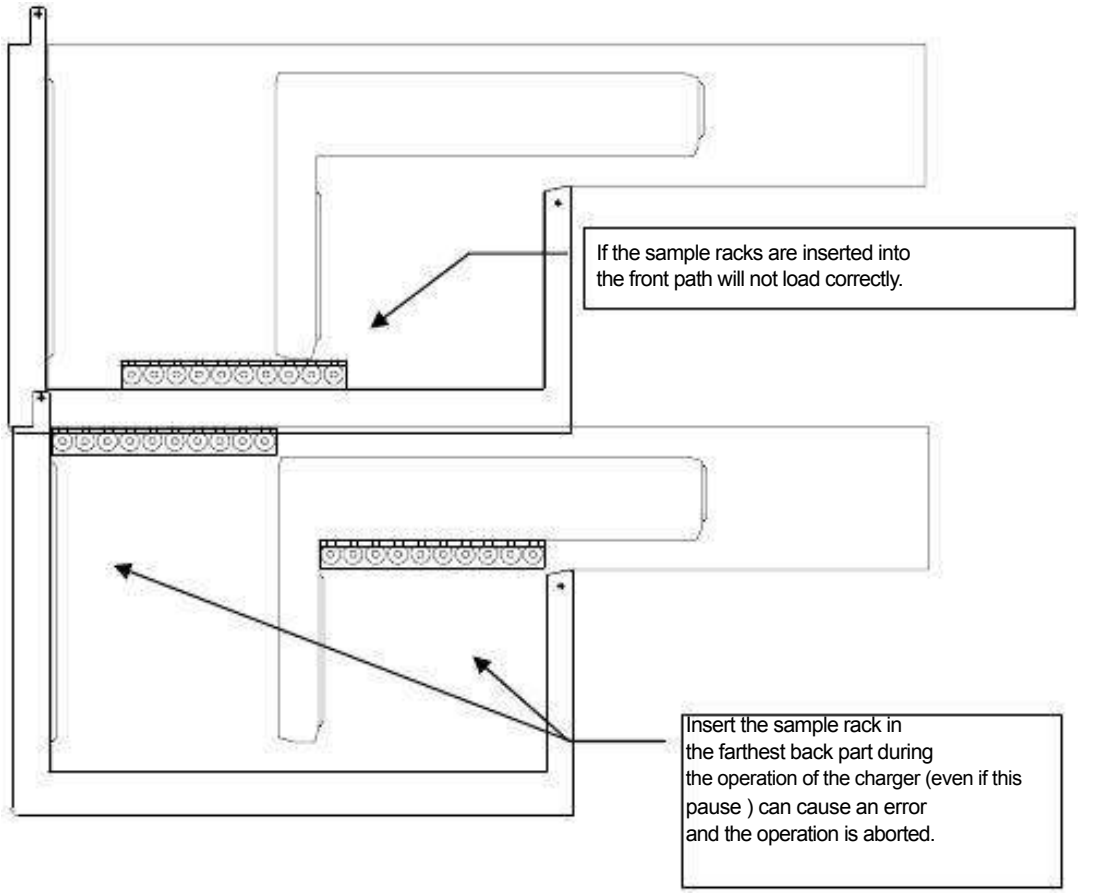


- **Often sharpen representatives, the defined indicator can be used to hone the fine.**

  this added point is easily shown.



Make sure that the sample charger has stopped before loading the new sample racks.
The end indicator or the empty rack must be inserted at the end; otherwise, the loader may continue their circular movement. The locations where the sample racks cannot be the placed ones are shown in the following images.

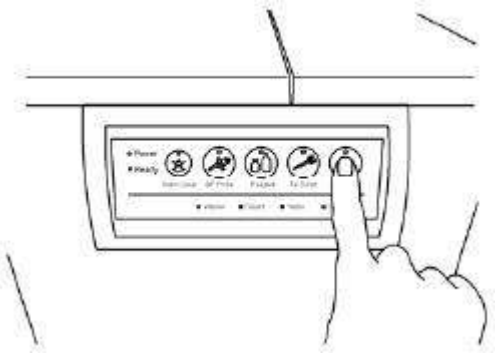


Point

- **For a detailed description of the STAT essay request, refer to chapter 6: STAT section 6.7 Trial and requests (the priority of the trial).**

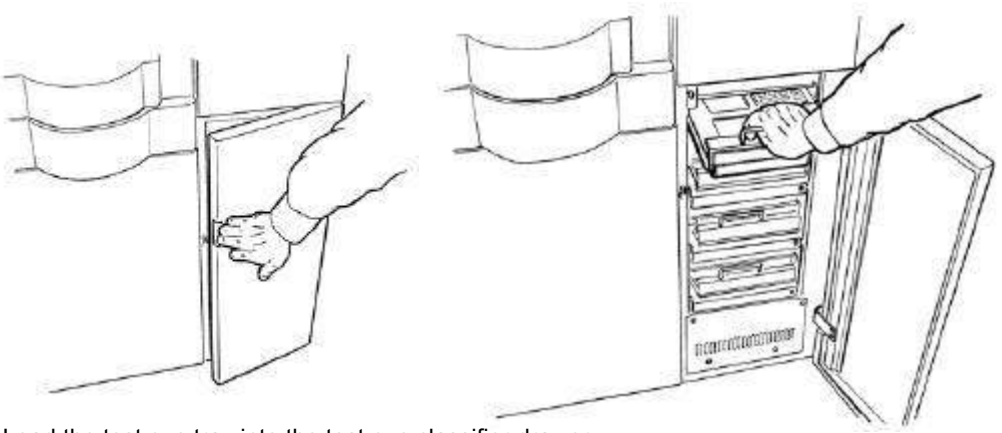
4.10 The test cups that you load

(1) Press the cup charger button located on the AIA-2000 classifier panel.



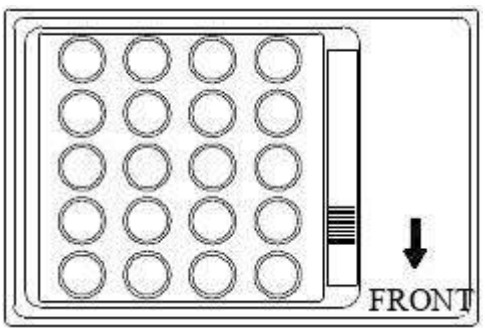
The LED on the cup classifier panel is continuously red if a 2-step reagent or Pretreatment is in process. The cup classifier panel should not be opened, as this may cause the abortion of the test procedure resulting in the loss of results.

The red LED flashes for a few seconds.
The LED changes from red to green, the lock has been released and the gate can be opened.
Open the classifier gate and check the drawer shown in the test cup classifier.



Load the test cup tray into the test cup classifier drawer.

- **The reagent tray must be placed on the right side, otherwise they cannot be read by the unit.**



Avoid opening the test cup classifier door for long periods of time while working with two-step reagents or pretreatment reagents. Skip a test record and loss of the results may occur when pretreatment operations are interrupted.

(7) After loading the trays, apply pressure on the classifier gate and close it. test cup classifier door.

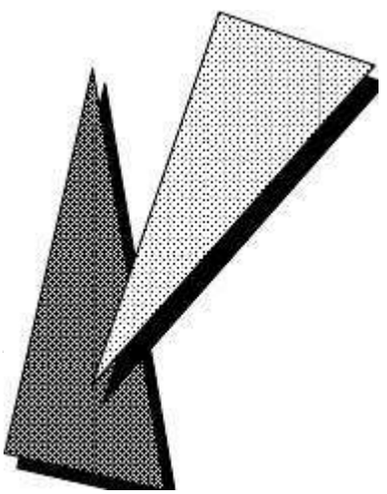
Specifications: a large number of test cups are analyzed in a way automatic while the classifier shows the red LED on.

If the classifier detects an error when examining the cups, it must open the drawer, remove it, and insert it. nuevamente para que el analizador realice nuevamente el inventario de las copas, de otra manera el test cup inventory recorded will be equivalent to zero.

The tests of different analytes should not be mixed within the same tray. The AIA-2000 read the information about the total number of analytes associated with the code label of bars attached to the tray. It does not read the information from the test cups, if there are cups of a number from a different lot or from a different analyte within a tray, the AIA-2000 will not detect the cup correct

CH 6

System operation

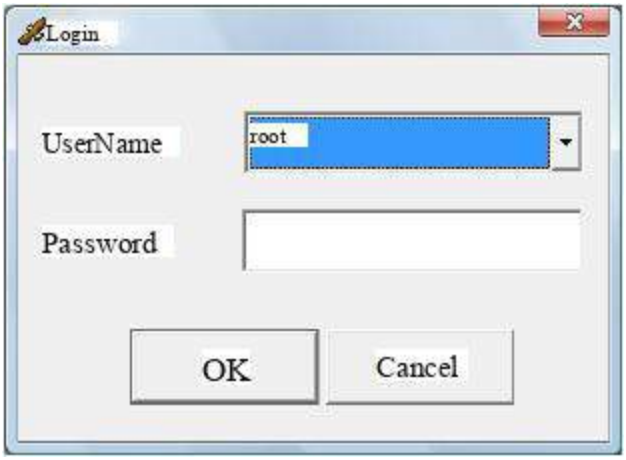


6.1 System startup

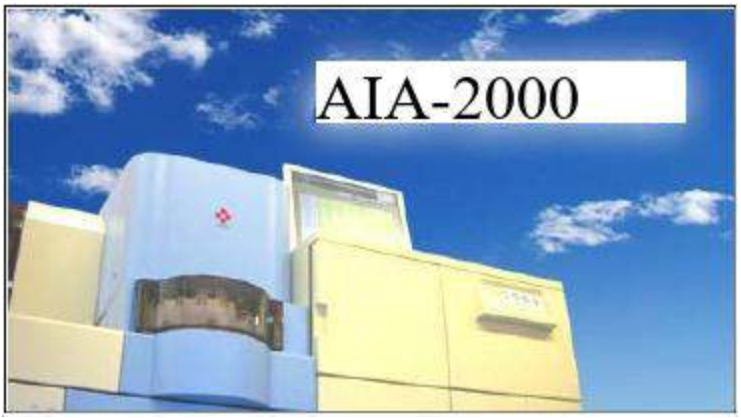
Turn on the main unit.
Turn on the PC controller.
Wait for Windows to load. (no password requirement)
Double click with the mouse on the AIA-2000 icon on the desktop to start the AIA-2000 program as shown in the following figure.
Between your username and password.

Point **You can choose the user 'root' as your username to have administrator authority without need for a password, not entering a password for the user "root" is used as a security method.**
For a description of username and password registration procedures, please refer to chapter 8: Registration of Administrator/Operator of section 8.6.1.

Click on the OK button.



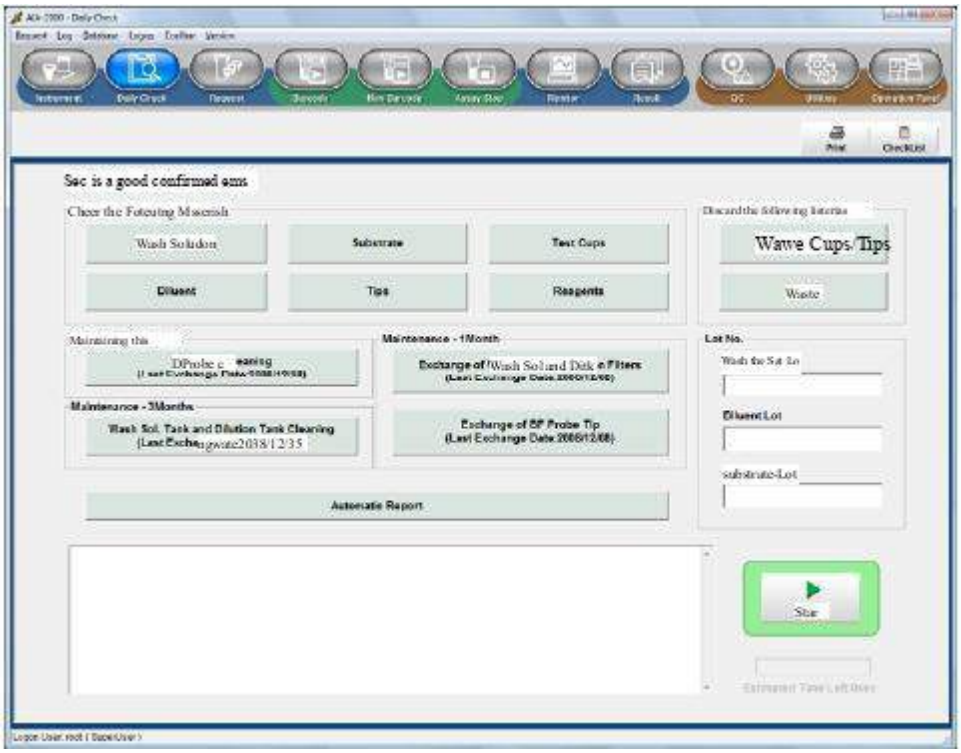
(8) This starts the system initialization and as shown in the image below is the loading screen of all parameters.



6.2 Daily verification

The daily verification procedure must be carried out before processing the samples. It begins inspecting the system, filling reagents and checking for any waste. It concludes with the substrate placed at the base. Always perform the daily check before starting to work.

Click on the daily check button in the toolbar as shown in the next screen.



If only the substrate base measurement is needed, click on the Substrate BG Meas.

6.2.1 Check the verification panel list daily.

Check the wash solution and fill if necessary, then click on the button
Panel that shows the Wash box.

(2) Check the Thinner and fill if necessary, then click on the panel that shows the checkbox of the Thinner.

(3) Waste (fluid level): Check the waste, store it in a tank, and empty if necessary.
then click on the discard button in the verification panel.

(4) Waste cups and tips: Check the waste and if necessary discard the bag and replace it with a new one.
new and then press the Waste Box button on the daily verification panel.

Install the substrate by replacing the bottle with a solution of alcohol (70% ethanol), then click.
about the substrate button on the daily verification panel.

Remove the substrate bottle from the refrigerator and wait for it to reach room temperature of 15 to 30 minutes. Rubbing the bottle remove any condensation before installing it in the compartment of substrate. The air tends to enter the supply lines when the substrate is cold, causing the resultados del ensayo sean inconsistentes. Condensación en la botella puede causar también que el sensor de functioning level is bad. In addition, it is necessary to ensure that the bottle is labeled and placed facing forward to prevent it from interfering with the bottle's sensor.

(6) Place the sample standardization cups (STD) and the test cups in the equipment.
required by the analytics used in the testing operation in the classifier unit

The standardization cup (when using a substrate bottle, usually an STD is used) is mandatory, the equipment automatically performs the daily substrate base measurement.
For a description of the procedure to verify the inventory, please refer to chapter 6.

6.3 Instrument

(7) Install the sample diluent solution (SDS) in the reagent carousel, and other reagents if necessary. required, then click on the reagent verification button.

Fill the racks in the tips classifier with Tips if necessary, then click on the button.
verification of tips in the daily verification panel.

(9) inspect the probes of the (B/F) Wash, perform the wash maintenance of the B/F if necessary,
Then click on the cleaning option of the (B/F). Clean the wash probes of the B/F.
once a week replace the probe tips once a month. For a description of the
cleaning procedure, refer to chapter 9: Washing of Cleaning B/F in section 9.2.1 is done
Refer to Chapter 9: Section 9.3.2 replacing B/F wash probe tips.

Distribute the entry number for the common reagents. The batch includes the washing solution,
the diluent, and the substrate in the correct text on the daily verification screen. This enables these numbers
To register on the online maintenance checklist.

Click the Start button after all items on the checklist have been completed.
maintenance has been verified.

At the time of daily verification, the number of substrate bottles to be used can To be modified. For placement, refer to chapter 8: Placement of substrates.
As the maintenance routine progresses, the reports are displayed in text form in the lower half of the screen.
Once the START button is clicked, the process begins, the Start button changes to red in case of aborting by pressing the button again.
- Note: other menu screens cannot be loaded while the daily verification routine is running. is in progress.

6.2.2 Maintenance Routine

Prepare the substrate line by placing the substrate bottle in the compartment.

(2) Clean the washing solution and remove any remaining washing solution in the Wash lines. The following errors may occur if the cleaning is not done. execute correctly.

2239:B/F failure in cleaning of probe 1.
"2240: B/F failure in cleaning probe 2."
2241:B/Failure in cleaning probe 3.
2242: B/Fall error in cleaning probe 4.

These messages indicate that the air was not completely removed from the solution line. of washing. If errors occur, press the B/F probe key on the classifier panel from AIA-2000, open the gate and check in the B/F unit what may be the causes of the problem. After this, click on the Wash Solution button in the operation panel (toolbar) to repeat the filling procedure until that the lines are completely error-free. Notify Tosoh service or representatives Check if the error messages still appear after washing 5 times or more.

The washing probes of the B/F are designed to draw the washing solution that the following error messages appear when a problem occurs.

2235:B/F suction failure in probe 1 appears when the suction of probe 1 fails.
2236:B/F suction failure in probe 2 appears when the suction of probe 2 fails.
2237:B/F suction failure in probe 3 appears when the suction of probe 3 fails.
2238:B/F suction failure in probe 4 appears when the suction of probe 4 fails.

If these errors appear, check the washing probe tips of the B/F.
If there are clots, refer to the procedure for flushing the tips of the B/F probes. described in chapter 9: Section 9.2.1 Clean washing probes of B/F.
Notify a Tosoh service center or local representatives if the messages are still They appear after the cleaning of the B/F probes has been done.

Clean the solvent
Eliminate any residue in the lines of the thinner.

Substrate base measurement

Dispense the substrate into the detector normalization cup (STD), measure the intensity of fluorescence in the detector and verification for the following results.

The substrate is correctly prepared.
The substrate base level is within specifications.
The light source is within specifications.

Base measurement of the substrate in progress
when the measurement operation starts. Note that if the temperature of the Incubator, of the B/F, of the PD, of the detector, of the washing solution or of the substrate heater has not stabilized, the measurement will not be taken and The message "3020: waiting for temperature stabilization" will appear on the screen. as an error. The system will then enter Standby. If the baseline measurement does not It starts in 30 minutes, the message 'The daily verification routine was not completed.' appears, indicating a possible lack of temperature control. It is recommended that alerts a Tosoh service center or local representatives.

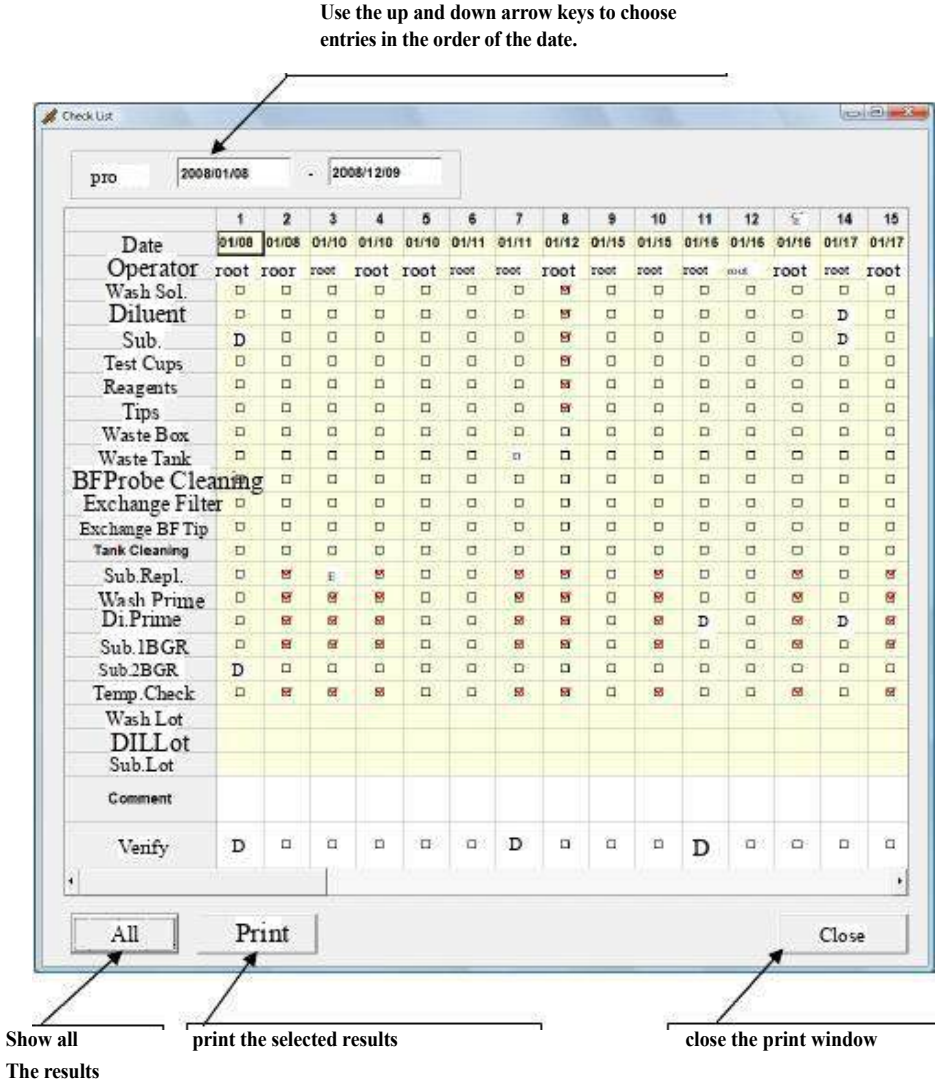
The measurement results are displayed as soon as the operation is completed.
The following results are shown.

Substrate purging is necessary in case the first attempt fails, make sure there is substrate present. compartment and the bottle was loaded in the AIA-2000 unit. If the error 'lack of substrate' still appears when the substrate is present, it is likely that the substrate needs an adjustment in the parameters of the sistema. En ese caso se recomienda avisar al servicio deTosoh o los representantes locales.

-4MU measurement level.
Ok: The measurement level of the substrate must be below 1500 nM
BH: 4MU the measurement level of the substrate is above 1500 nM
(This situation occurs if the substrate is contaminated or the lines were not filled correctly)
Lamp: intensity of illumination in the instrument
The intensity of the lighting is sufficient
LL: the intensity of the lighting is incorrect or the substrate did not load properly.

6.2.3 Checklist

The daily verification results are recorded in the online maintenance checklist.
by clicking the checklist button on the daily verification screen. The list entries can reach up to 1,100.



Entries can be made in the calendar format as shown in the figure.

Check the items on the list and their descriptions:

Date:	Date and time of the daily inspection
Operator:	Name of the operator performing the daily check
Washing sun.	The article is selected on the daily verification screen.
Thinner:	The article enters by selecting it on the daily verification screen.
Substrate:	The item is selected on the daily verification screen.
Test cups:	The article enters by selecting it on the daily verification screen.
Reagents:	The article is selected on the daily verification screen.
Tips:	The article is entered by selecting it on the daily verification screen.
Waste box:	The article is accessed by selecting it on the daily verification screen.
Waste tank:	The article is entered by selecting it on the daily verification screen.
BF Probe cleaning:	The article is selected on the daily verification screen.
filter change:	The article is selected on the daily verification screen.
BF tip change:	The item enters by selecting it on the daily verification screen.
Tank cleaning:	The item enters by selecting it on the daily verification screen.
Substrate Change:	The replacement of substrate or not
Ground premium. washing:	The replacement of washing solution or not
Thinner Prime:	El reemplazo diluente o no
Substrate 1 BGR:	Substrate 1 is measured and verified.
Substrate 2 BGR:	Substrate 2 is measured and verified.
Temperature check:	Temperature verification
Sun batch. washing:	Batch number entered during the daily verification
Thinner Batch:	Batch number entered during the daily verification
Substrate batch:	Batch number entered during the daily verification
Comentario:	Comment entry
Verify:	Button for verification.

The number of characters that can be placed in the comments is a maximum of 48, but only the first 26 characters can be printed.

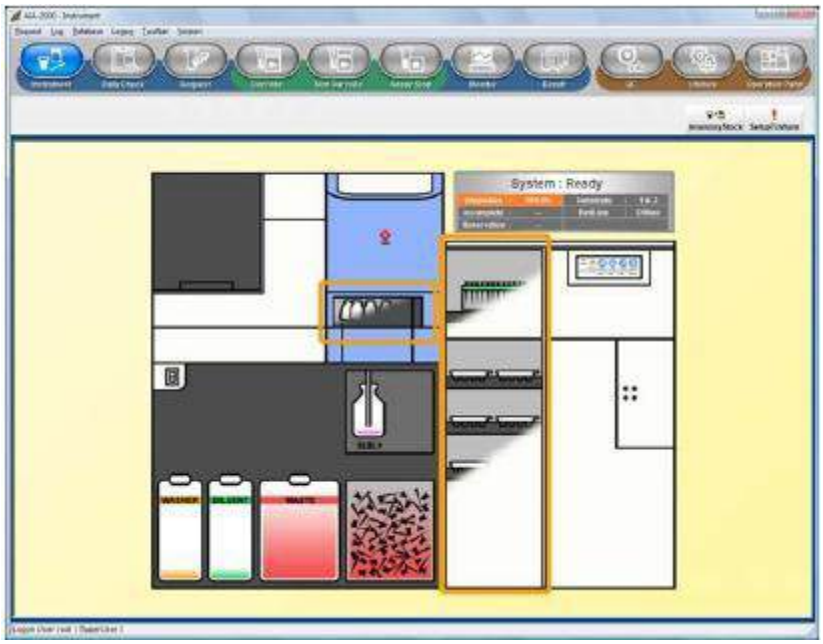
6.3 Instrument

6.3.1 Confirmation of the common reagent

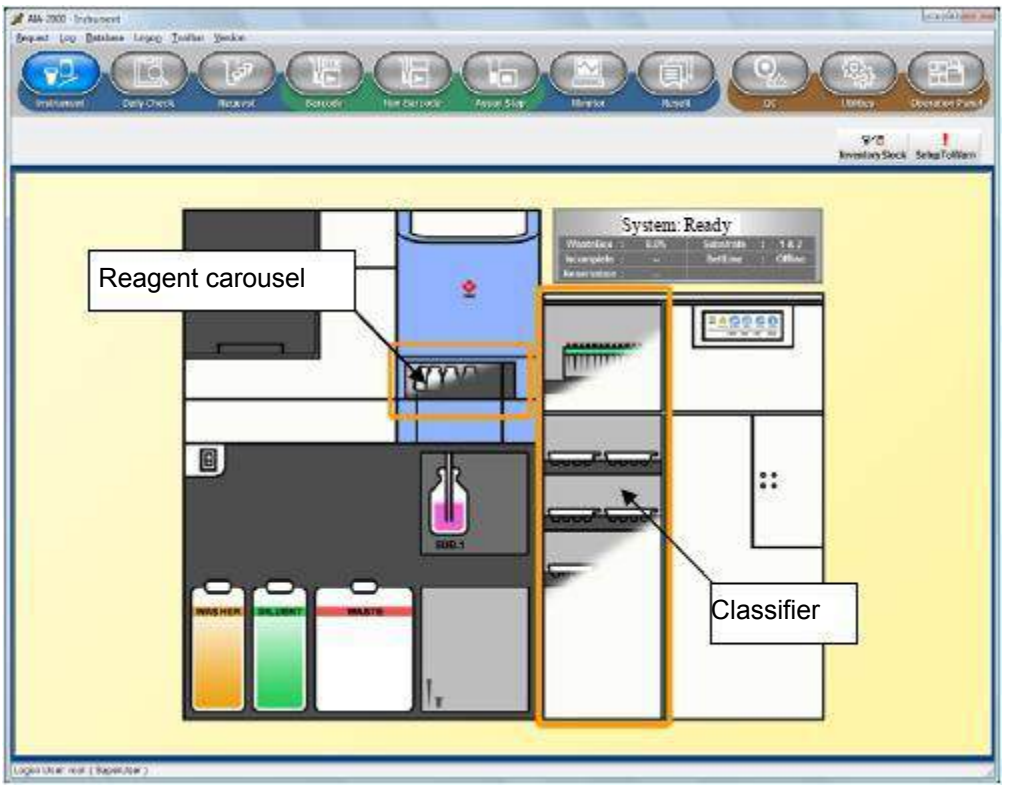
Click on the button in the toolbar. The next screen is shown and the condition of the tank etc. can be confirmed.

WASHING SOAP	(sufficient)	The tank shown is orange.
	insufficient	The tank shown is white.
DILUENT	sufficient	The tank shown is green.
	insufficient	The tank shown is white.
WASTE	The tank is shown white.	
	(complete)	The tank shown is red.
SUB.1 SUB.2		The used bottle is displayed.
	sufficient	The bottle shown is pink.
	insufficient	The bottle shown is white.

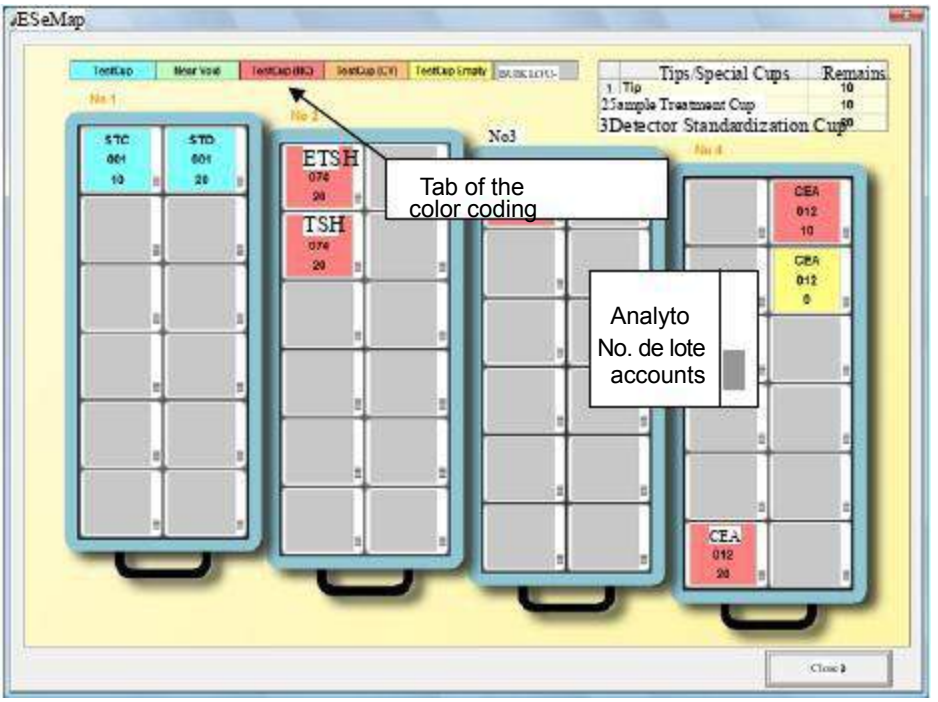
WASTE BOX (not complete): A tip and a cup are shown.
(complete): a large number of tips and cups are shown.



6.3.2 Confirmation of cups, test tips, and reagents carousel.

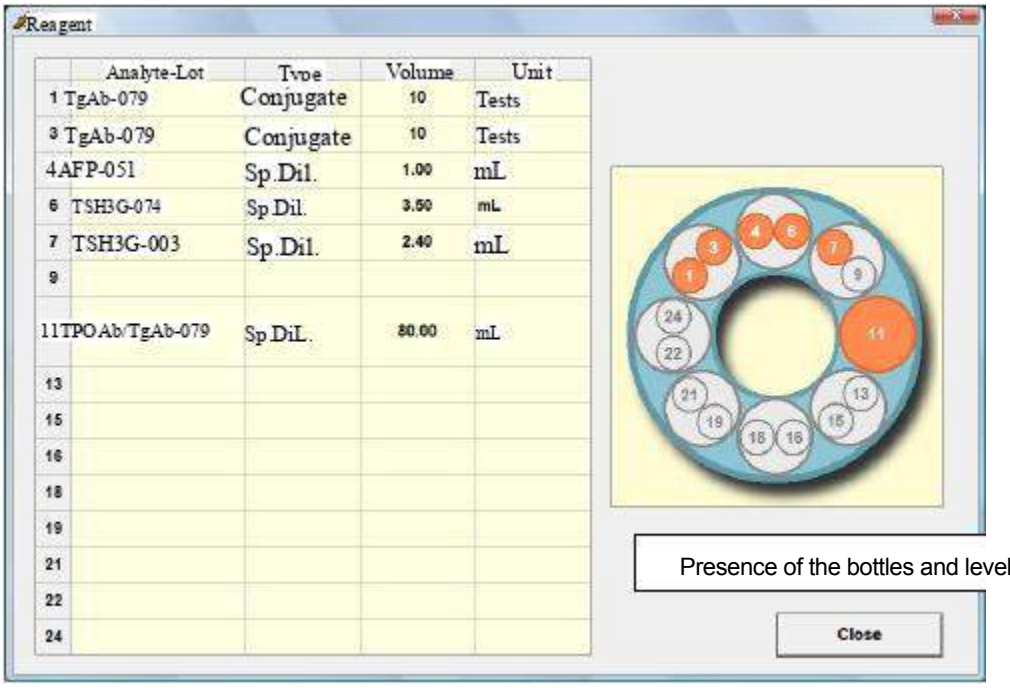


Classifier map: If you click on the classifier, an inventory is created (analyte, batch, accounts) of the different types of cups and tips that can be confirmed on this screen. The color coding Indicate if the calibration curve is available and if the calibration curve is valid.



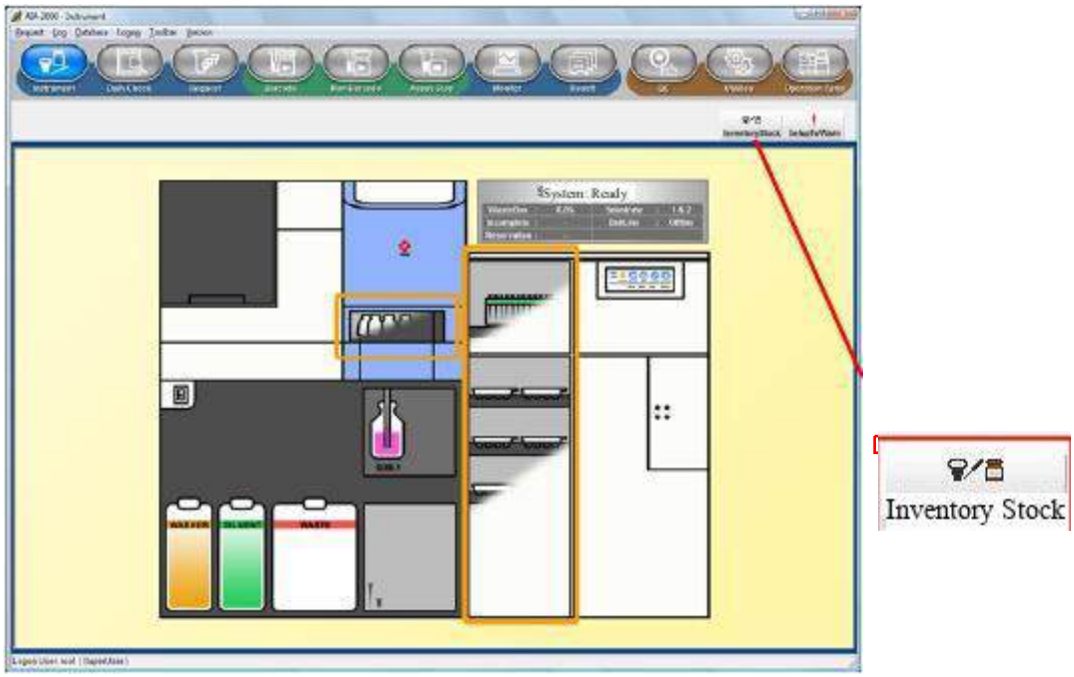
Reactive carousel

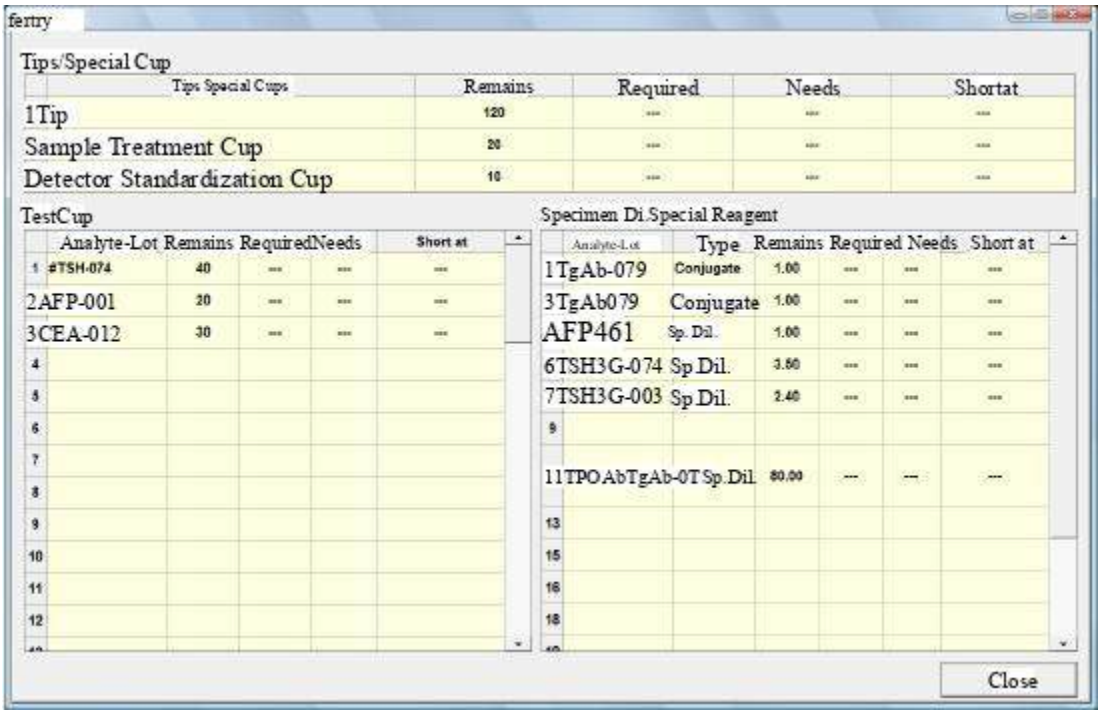
If you click on (part of) the reagent carousel, an inventory (reagent, lot, volume) is made of examined reagents in order to confirm them.



6.3.3 Inventory holdings

If you click on the Inventory Stock button (order button), the inventory of tips, pre cups treatment (STC), standardization cups (STD), reagent cups, tray placement, the They can confirm according to the team's count.





Top list:

Tips: Present the current amount, and keep a count of the amount. remaining.

Sample treatment cup: Present the current amount, and keep a count of the amount. remaining pre-treatment cups (STC)

Standardization cup of the detector: Present the current amount, and keep a count of the amount remaining standardization cups (STD)

Left (background) of the list:
Display the current amount and keep a count of the remaining cups in the instrument.

Right (background) of the list:
Present the current amount, and notify of having an extra requirement for the sample diluent (SDS), conjugated or pre-treatment reagent.

If the conjugate inventory is not verified, the current count is designated as "unknown."
- **Inventory levels are updated through the verification at the level executed during the operation to to dismiss.**

6.4 Setting the system parameters

The procedure for entering the placement of required parameters is described below. Once registered, the parameter takes shape and rarely needs any changes. Refer to the section of the list below if necessary. modify any existing parameter. Otherwise, proceed to the next section.

- Capítulo 7: 7.2 materiales de Registro de QC
- Capítulo 8: 8.1 utilidades–la ventana de especificaciones

Chapter 8: 8.2 utilities – the Test Files window

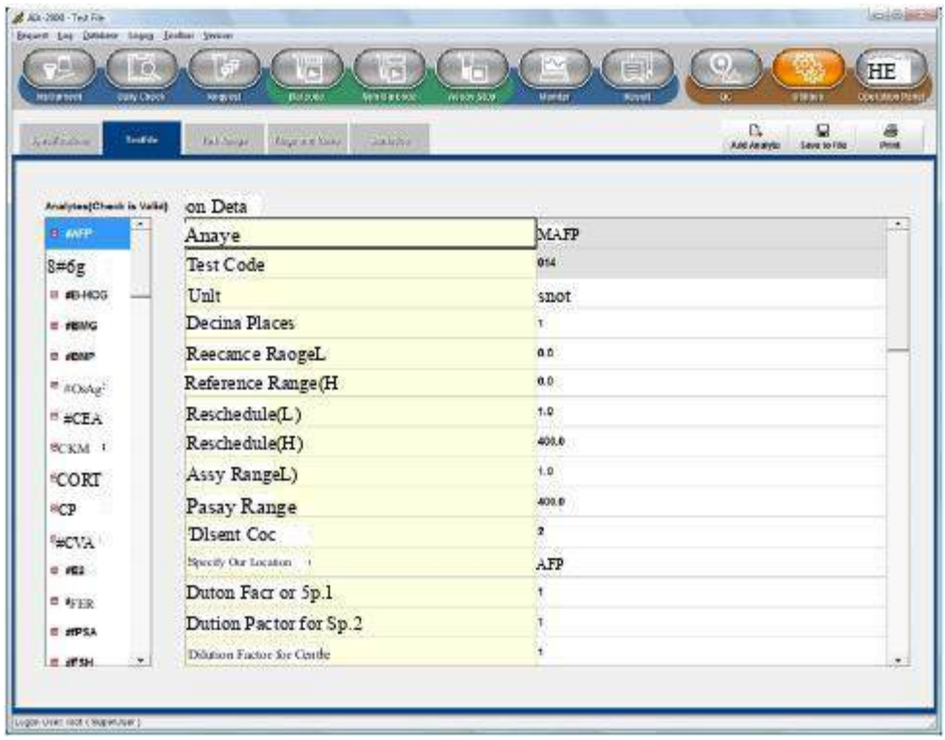
- Capítulo 8: 8.3 utilidades–referencia de la ventana de rangos
- Capítulo 8: 8.4 utilidades–las alertas y reglamentos que proveen los indicadores

Chapter 8: 8.6 changing operators

6.4.1 Files for test parameters

The Test Files contain the required parameters to set test conditions for each analyte. If the parameter placements have been completed, proceed to the next one. section.

Click on the utilities button in the toolbar to display the tab. delTest file.



When selecting an analyte, the parameters that can be modified are displayed on the screen. The placements of the parameter list shown in the center of the screen show What modifications can be made to the following articles?

Decimal places
Low range reference (L)
High range reference (h)
Low observation (L)
High observation (h)

The changes (L) and (h) the placements and verifications must be made when placing the alerts of low and high ranks.

Certain parameters cannot be edited depending on the authority assigned to a user. For the detailed description of the Test File parameters, refer to A1:Test Files from appendix 1.

6.5 The generated calibration curves

Users who have completed the calibration of a curve can continue to the Next section.

6.5.1 Load test cups, and pre-treatment reagent

Load the test cups for the Analytos as the calibration curves are being generating in the test cup classifier. For 2-step reagents, load the reactive carousel. Analytes that need pretreatment, load the reagent of pre-treatment in the reagent carousel

- **read for or the hollow proof classifier or the carousel of reactive. This means that the**
- **The immunoassay reagents (test cups and conjugate) must be loaded beforehand.**
- **from the curved generation step.**

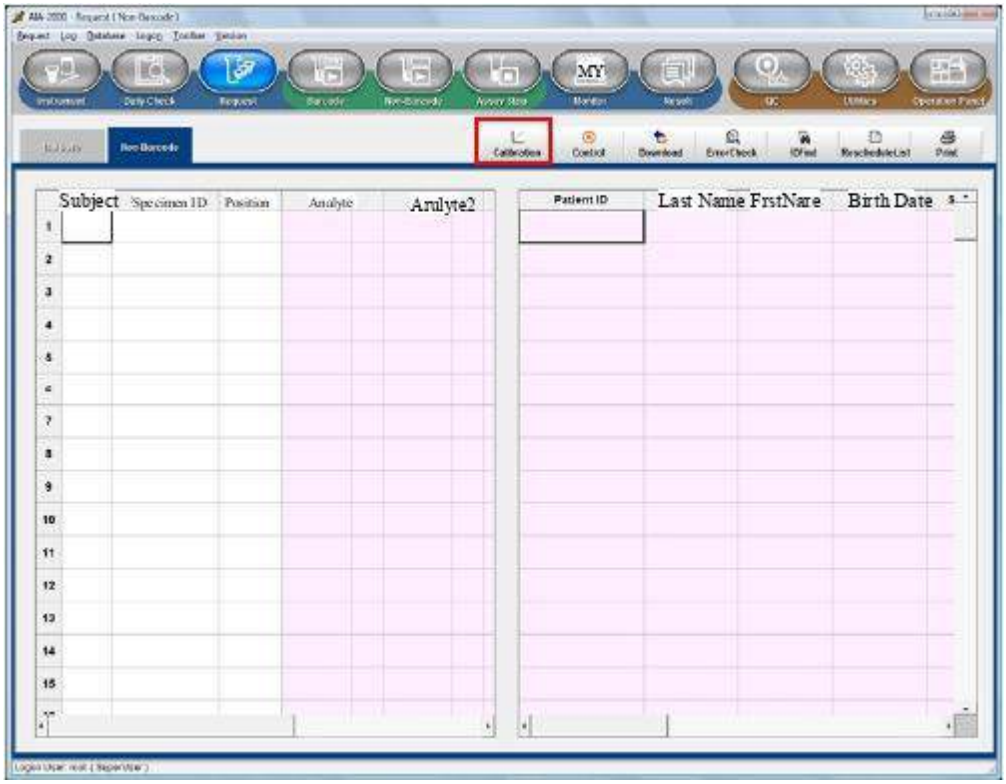
6.5.2 Reagent control batch number

The total number and count for the loaded reagents should be displayed on the screen. inventory. Verification to confirm batch numbers for test cups to be used in generating calibration curves.

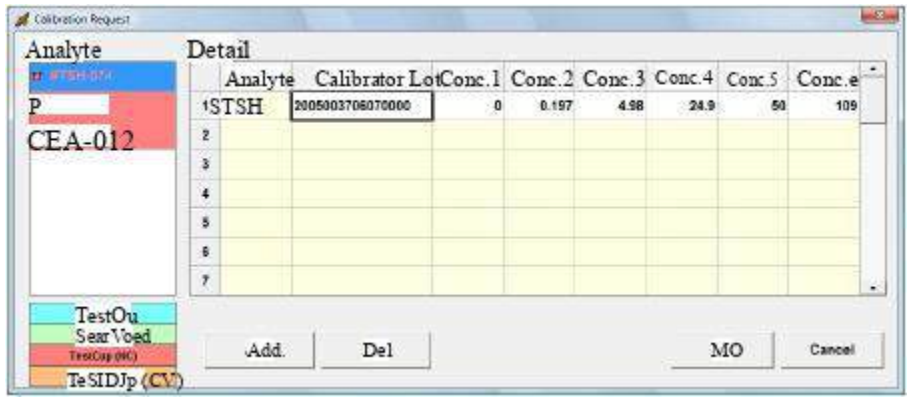
(1) Click on request by legal instrument button in the toolbar and then click on the Stock Inventory button (order button).
(2) Confirm that the reagents required to generate calibration curves are in the Inventory list.
(3) When using 2-step reagents, confirm that the analyte is named and draw lots for the numbers. listed in the section and section party of test cup reactive.

6.5.3 Calibration request

(1) Note that calibrators are not normally assigned barcode codes of specimen. However, requests can be generated in both ways from no barcode and barcode mode. Click Request Button on the bar of tools to display the no-barcode window or the barcode window bars.



Click on the Calibration button, as shown in the following image.

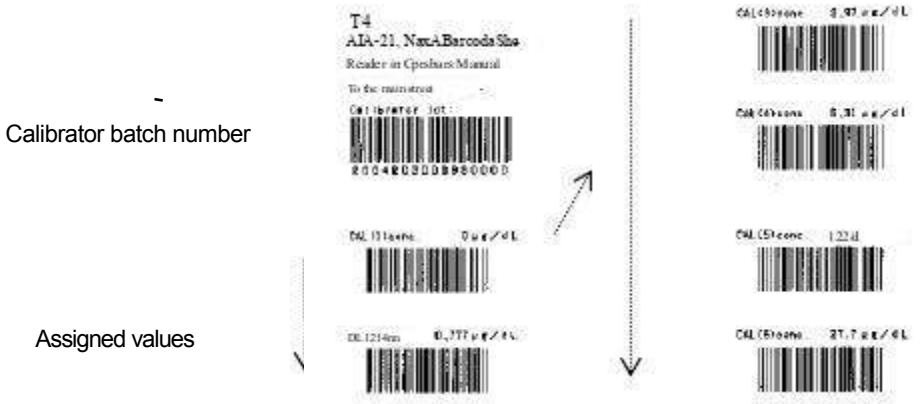


(4) Check the checkbox next to the desired analyte in the Validate Analyte list.
left and click on the added button. Then confirm selection and click on the
OK button to generate the calibration request.

The test hollows analyte and batch numbers in the test cup classifier are shown later
to the checkboxes in the list. Blue in the 'Analyte' box shows that the analytes with valid calibration, Green shows the calibration expiration date is Close, Red without calibration (NC) and orange spiraled calibration (CV).
- La nota que pide para las verificaciones de calibración se generen de forma automática
When the calibration verifications have been validated on the registration screen QC materials. For a detailed description, refer to chapter 7: Registering QC section 7.2 Materials

(4) Registrar draws lots numbers and assigns values. Distribute numbers and assign the values for the calibrators you can enter by simply clicking on the desired cell to enable editing and using the scanner provided to read the barcode of the caliper.

Examples of caliper barcode codes



Use the file window of archivoTest to enter the calibrator draw numbers and assign them.
values for the analytes not included in the classifier unit inventory.

Click on the practical use button in the toolbar to display the window
from fileTest.
Select the analyte to be calibrated.
Click on the calibrator cell lot number.
Use the electronic agenda barcode scanner to scan the barcode.
from the barcode calibrator the included sheet with the calibrator states.
Click on the Conc.cell for the CAL (1).
use the electronic agenda barcode scanner to examine the CAL (1)
barcode of the barcode the sheet included with the caliper says

Cauti **The recording gauges always assigned values in the incremental order. starting with the calibrator with the lowest value (CAL 1, CAL 2,...) to ensure the correct essay results.**

6.5.4 Work List

The work list can be submitted in advance as soon as the calibration request is complete by clicking on the Print request button (no-code window of bars or barcode window) the screen. The work list can also be the printed exterior.

6.5.5 Load cell

The calibrators and controls are dispensed in the sample cups using the pipette. volumes consist of the workload volume of the list plus dead volume and located on the rack of show positions specified in the job list

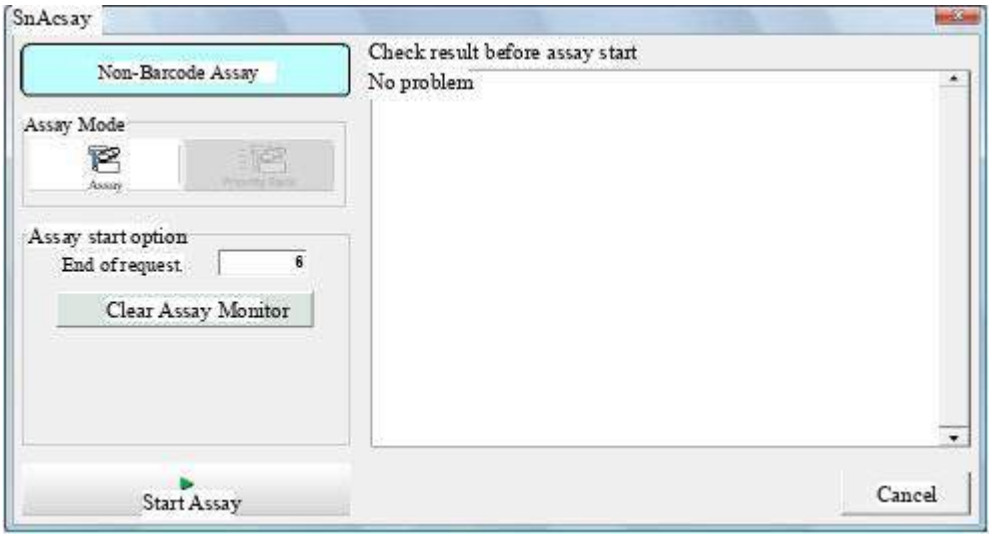
Point **The dead volume cup has 100 UL.**

6.5.6 Programming Calibration

Click on the no-barcode button or the Barcode button in the toolbar.

Click on the test button (test Mode button).

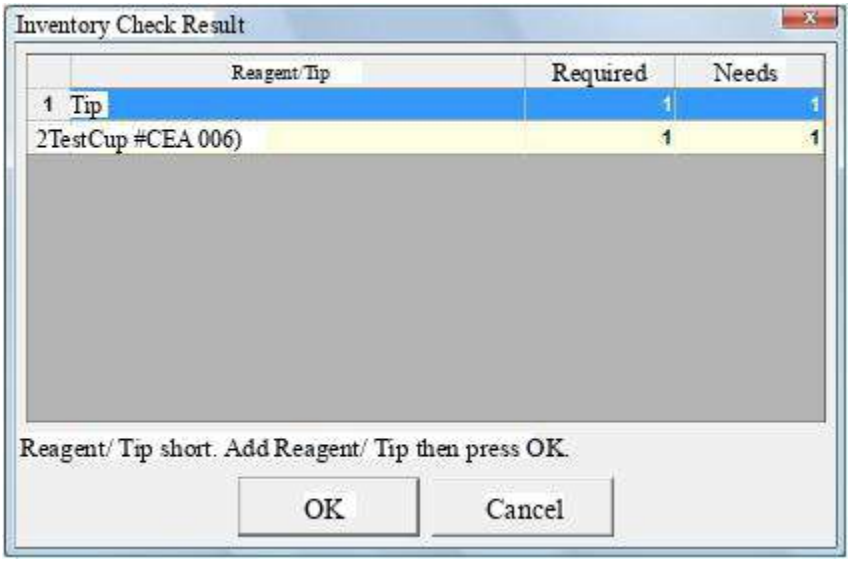
Calibration cannot be performed on priority rack testing.
The gauges and/or materials registered in the testing request will be tested in House series. They cannot be rehearsed at different times by dividing into parts. No Make a record and/or of calibrators control the materials that should not be tested.



Between the end of the application number for each request.
Click on the Start Assay button. The calibration process begins.

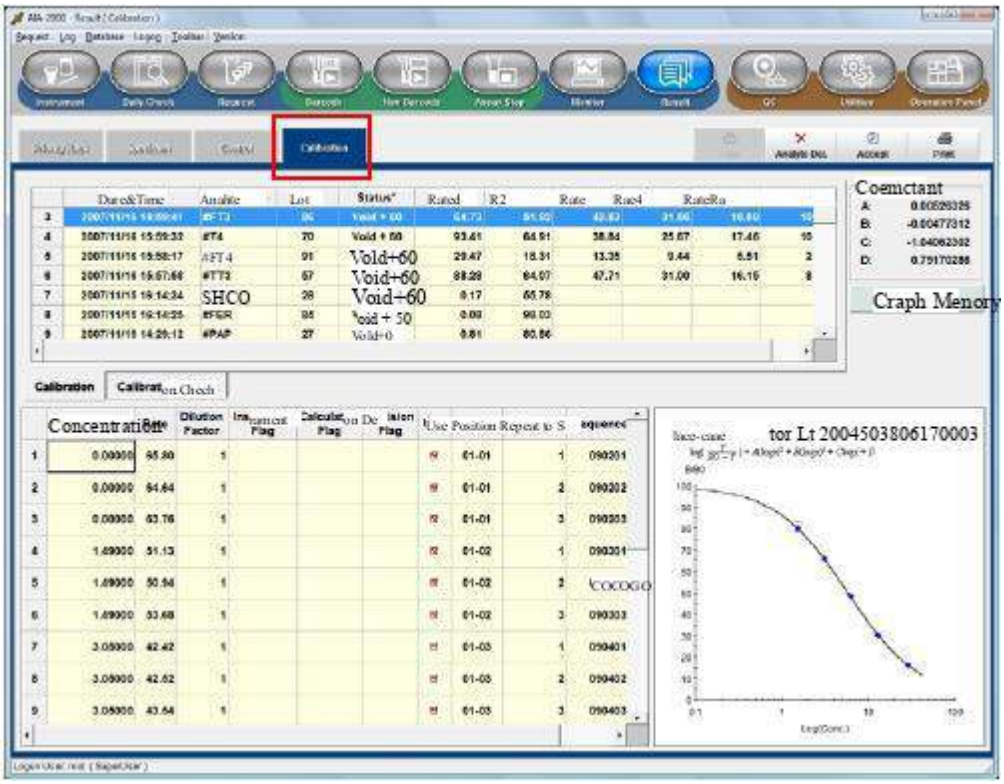
If the Clear Monitor button is clicked before clicking the Start Assay button, the measured data is removed from the test monitor.

The following screen is displayed if a reagent shortage or scarcity is detected. Please operate. Trial begins again after clicking the Cancel button and filling out the items. Note that affects the tests will be skipped if the OK button is clicked without filling in the reagents.



6.5.7 Review calibration results

When the full calibration is complete, click on the result button in the bar tools. Show the calibration window to confirm calibration results and check calibration curves. Selecting a line from the calibration list displays the data corresponding calibration and calibration curve graph.



Definitions of cell

Date and time	The date and time calibration curve was generated
Analyte	Analyte Name
Batch	Try the cup distributes No.
Status	The void (spiral) the concentration with the CV flag for the reference The calibration period of Void+ (spire) the NC flag (fixed) Accepted Depend (not fixed) Essay in process
Evaluate 1 to 6	The average values (index value) of results for each calibrator
Concentration	The calibrator assigned values
Index	Calibrator index value

Dilution factor: Calibrator dilution factor

Instrument flag: Instrument flag

Bandera calculada : Bandera calculada

Flag of decision	Decision flag
Use	Selection of the data used for the calibration curve
Position	Calibrator set position

No. of repetition: Measurement order for calibrators of identical concentration

No. de secuencia : No. de secuencia

Editing data

Unnecessary data can be eliminated by simply unchecking the boxes of verification in the usage column under pending status. When the calibrator is not placed It is in the work list service, new data arrangement requires it to calculate a curve. analytics correctly. You can rearrange data by clicking on the title of Analyte of an index and a sequence number with an asterisk (*).

Pun **The major calibrations, the longer access times and processing times required by curved data. The maximum calibrations should be limited to 300 and the unnecessary data regularly deleted.**

Button functions

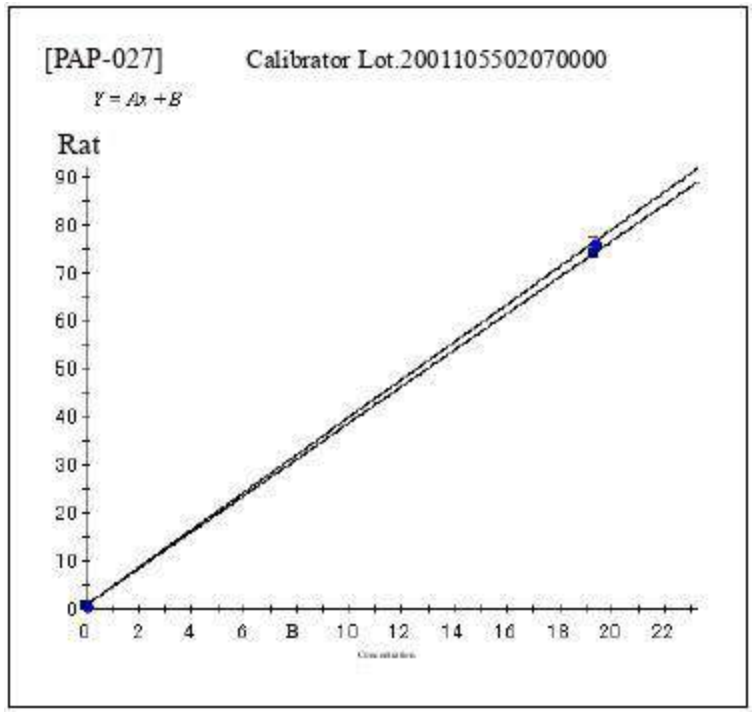
Analyte of	Delete the currently displayed calibration curve.

Note that deleted calibration curves cannot be restored.

Accept	Accept that the currently displayed calibration is curved.
Printing	Exhibitions the calibration report of the current calibration shown curve. The calibration report can also be printed on paper.

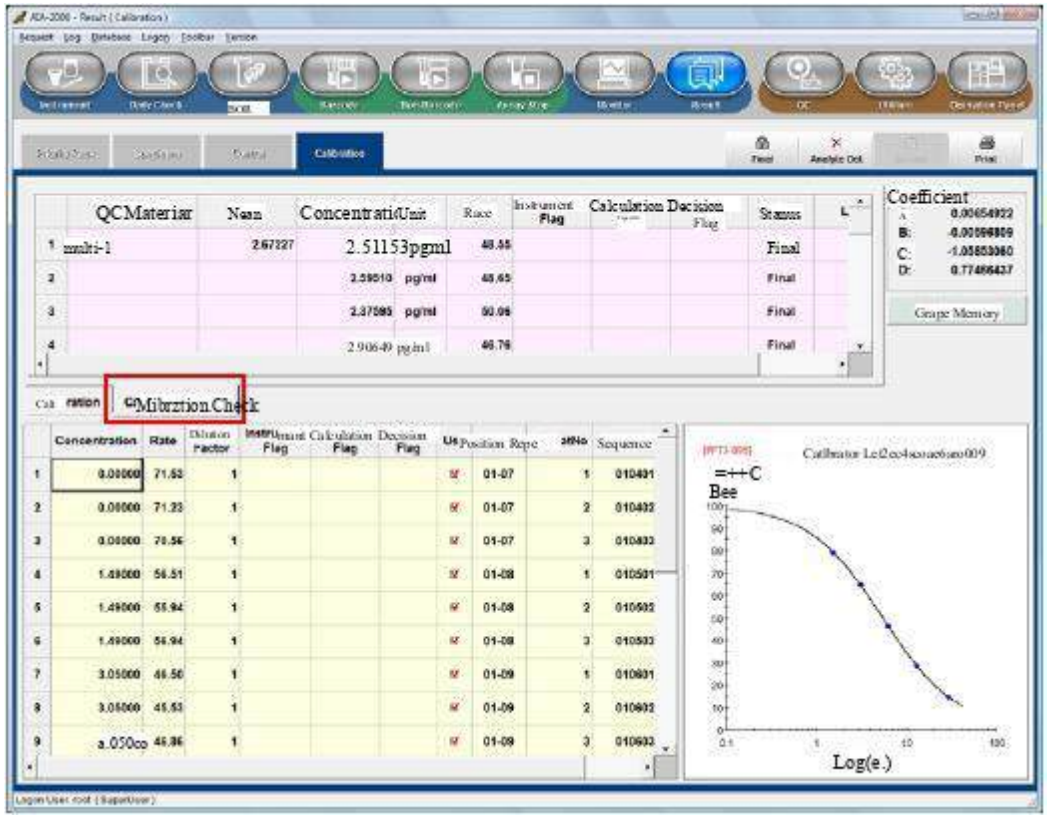
Graphics memory

Selecting the Memory button on the graph stores the graph to be overlaid, enabling coverage. From the result of subsequent calibration, draw the graph of. Unchecking the button removes the graph function layer. The graph can be overlaid only when the data is from same analyte and the same lot.



Calibration check window

This window shows test results of the control calculated with the curve of calibration. The control result is calculated using the calibration curve of simultaneously tested calibrator. Control results accepted as the final be used as QC data and displayed on the QC screen. The controls used for the Calibration verifications are entered in the QC materials Record screen. For the detailed description of the QC materials log, refer to chapter 7: Materials of Registering QC of section 7.2.



Cell definitions

QC material Control material name

Average	The average values (index value) of results for simple control
Concentration	The concentration of assigned value
Unit	Unit of measurement

Instrument flag: Instrument flag

Calculated flag: Calculated flag

Bandera de decisión: Bandera de decisión

Status	Status (Pending/Final/Reject) of test result
Depression	Lower the limit entered in the QC materials registration screen
High	The upper limit entered the QC materials registration screen.

6.6 Specimen and control testing

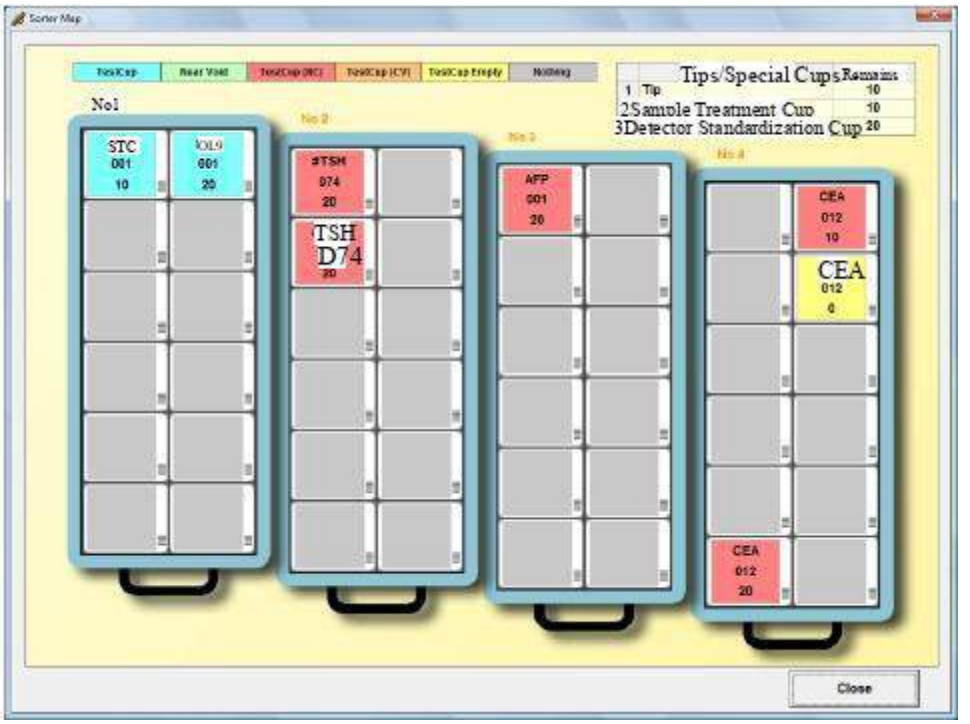
6.6.1 Load test cups, conjugate and pre-treatment reagent

Load the test cups into the test cup classifier. For 2-step trials, Load the word congener into the reagent carousel. For assays that need pretreatment, load the pretreatment reagent into the reagent carousel.

6.6.2 No. of the reagent control lot

Click on the request for legal instrument button in the toolbar and then click on inventory the Stock button (send button).

Confirm that all necessary reagents are listed on the inventory screen.



Confirm the hollow test lot numbers, as required to confirm the presence. of calibration curves.

When using 2-step reagents, click on the Inventory Stock button (order button) and confirm that the analyte names and draws the numbers listed in the cells of inventory in the test Section of cup and reagent (congener word) the section does game. Confirm that the sample is diluted by Reacting with the solution or pretreatment for each analyte is listed in the reagent section of the inventory window when it requires dilution or pretreatment.

6.6.3 Request for incoming essay

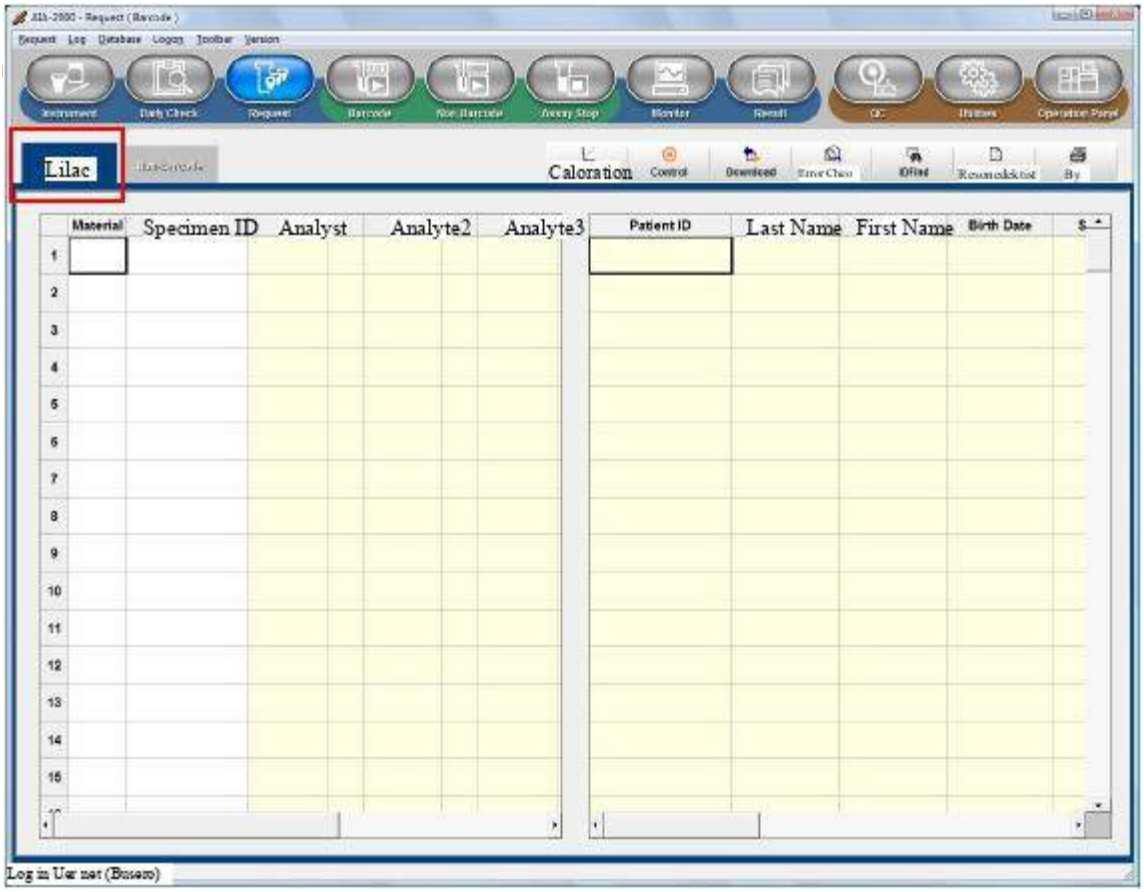
- Two types of entry sheets are available upon essay request: for the mode of barcode and the non-barcode mode.

Point **The following features may be familiar to you when viewing each request, please protect as below,**

F1: Jump to the main line. F2: Jump to the line until the end
F5: Roll of paper to the left supports F6: Paper roll to the right supports

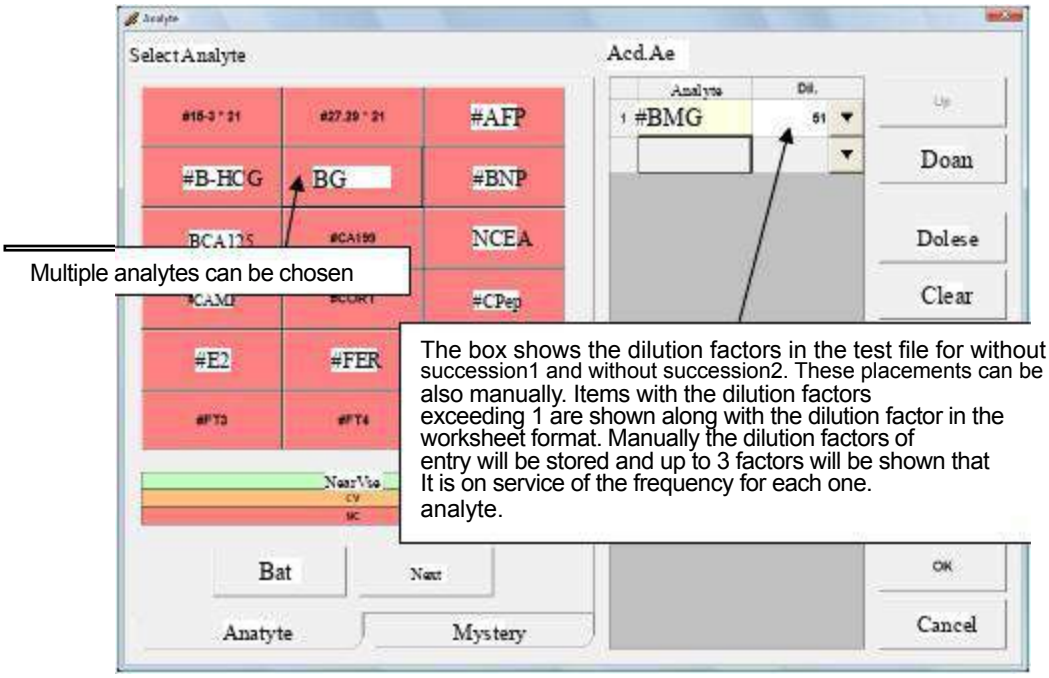
6.6.3.1 Use bar codes

Click on the request button in the toolbar to display the code window.
bars when generating requests for barcode specimens.



Request
Go to the material cell and select the specimen type from the dropdown text box.
choose specimen ID, then enter the barcode IDs either manually or
using the electronic agenda barcode scanner.
<3 > double click Analyte 1 shows a dialog box of valid analytes. Choose the
desired analyte or analytes and click on OK.

Choose the Analyte to request and click the OK button. Multiple selection is possible.
Simultaneously analyze.

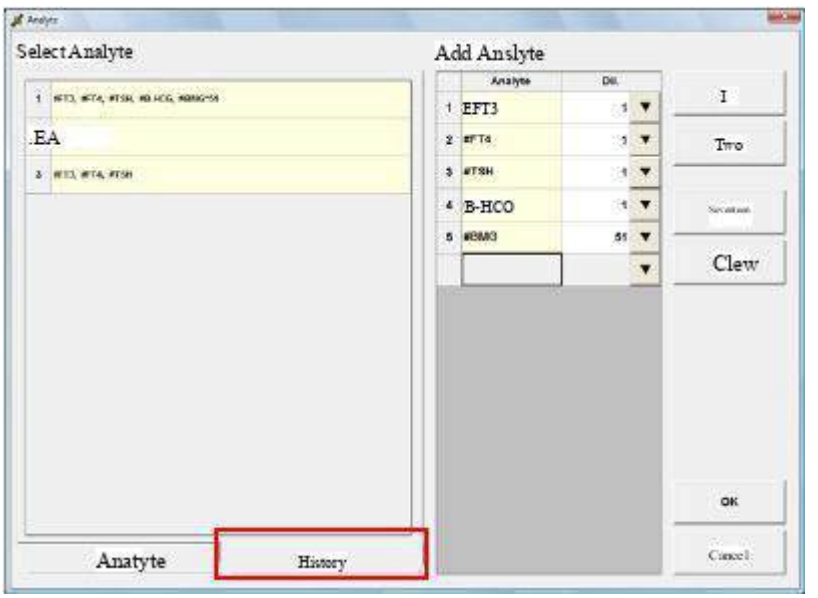


Button functions

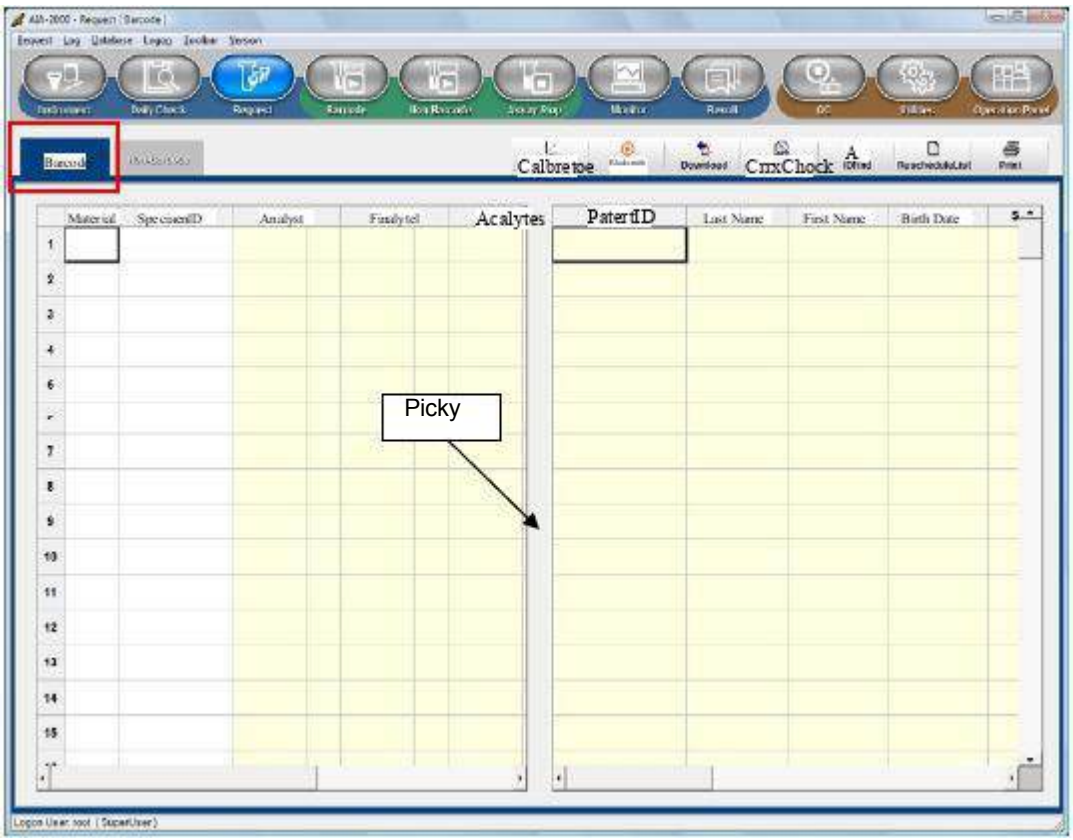
After (back part): Exhibitions in alphabetical order.

Ascent	Advance the selected analyte.
Down	The movements below the selected analyte.
Delete	Delete the selected analyte.
Of course	Clear the analyte in the Add.Analyte List.
APPROVAL	Request for Add. The list of Analyte is decided.
Cancellation	Request for Add. The list of Analyte is suppressed.

<5> select the history window to display the list of previously combined Analytes. order. In case of the same combination requests, it can be selected from the list at instant.



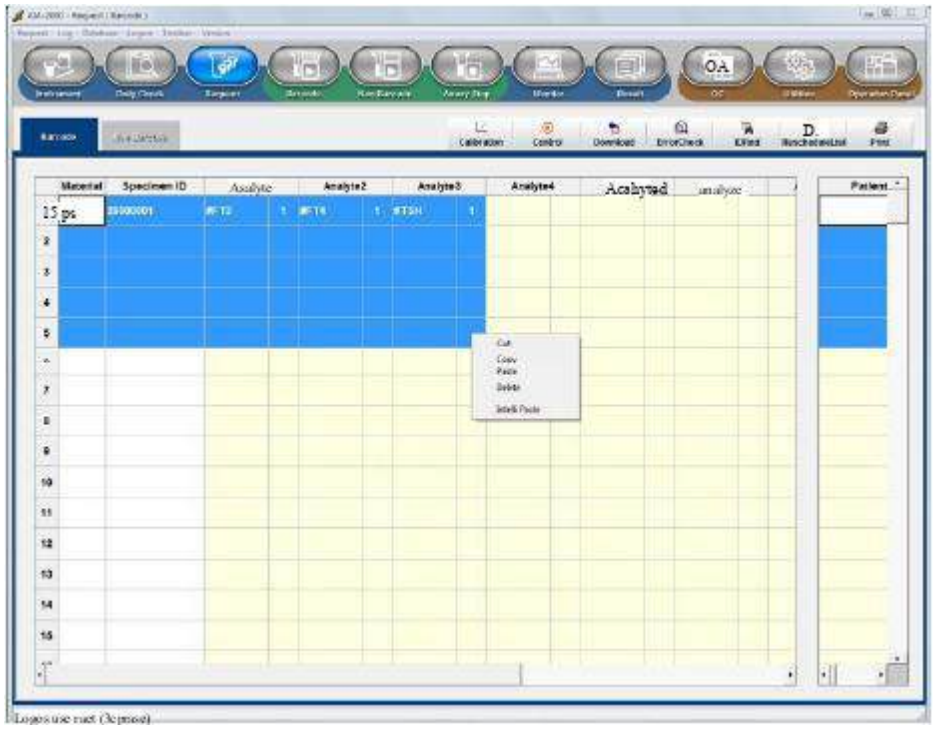
Move a picky one to leave and enter the sample information in the side area.
right. (not necessary to enter everything.) Request area of area and information
patients can be changed by moving a picky one to the right and left.



Definitions of cell

ID paciente 14 or the lowercase alphanumeric characters
Last name The patient surname entered using 16 or fewer alphanumeric characters
First name The patient's first name entered using 16 or fewer alphanumeric characters.
minors
Date of birth: The patient's date of birth was entered using 'YYYY/MM/DD' format
Sex Patient gender, chosen from Male/Female/Unknown
Smoker Indicate if the patient smokes tobacco.
Comment Comment among using 32 or the lower alphanumeric characters
Record date The record date and time are entered automatically.

- button when moving) of the desired sections
  A click on the secondary button of the mouse shows the pop-up menu.
  súbita entonces escoja pasta de Intelli.



Automatic application submission

- **The automatic request generation function simplifies the copying procedure. The first (top) cell of the selected range can be copied to the second and further down cells. Note that copying is only possible when the first cell is not in white.**

Information in the leftmost cell is copied when a single row is selected. This the feature is accustomed to generating multiple copies of the same request in a sample.

If the specimen type has already been entered, the automatic generation process you copy the dilution factors for individual items as well. Copy of the individual the specimen represents the information that can be avoided by pressing CTRL down during the generation process.

- The specimen IDs are copied to increase. The number of digits is not increased automatically.

(example)
9 followed by 0.
"09" followed by "10."

- **Point**

Save and open request:

Generated trial requests can be saved by choosing from the menu. and choose save like Saved requests can also be read by clicking about clear and choose the desired request.

- Note that all remaining requests are saved as a work program stop, even if not previously saved.

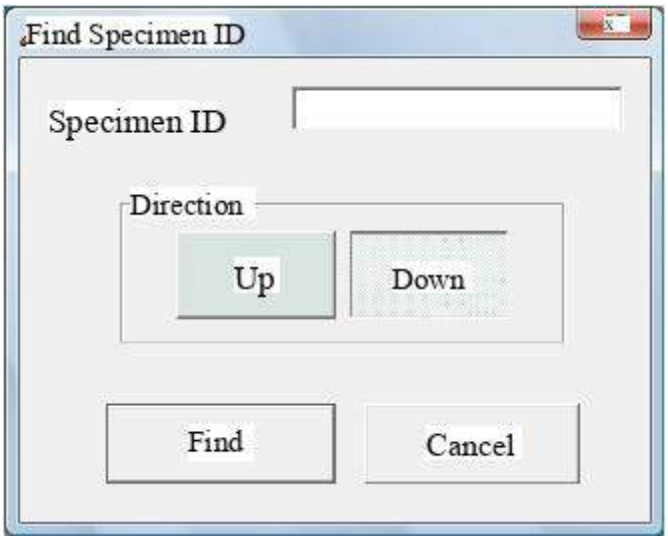
Button functions

Error verification: Clicking on the error shows the button that displays all the lines that contains errors, enable the operator to check the request error essay. While automatic checks are run when try operation principles, checking in advance if it is convenient when there is a lot of rehearsal they ask what is performed.

Click on the error and the button also changes automatically. Information for the left to fill gaps if the analytes were erased. any point. The verification process also checks inventory reagent. and issue warning messages if a shortage is detected.

ID finding: The specimen ID is entered in the specimen ID column. Choose the direction of the finding (click on the Direction button) and do click

about the button finding then the cursor moves to the line of the Specimen ID. corresponding

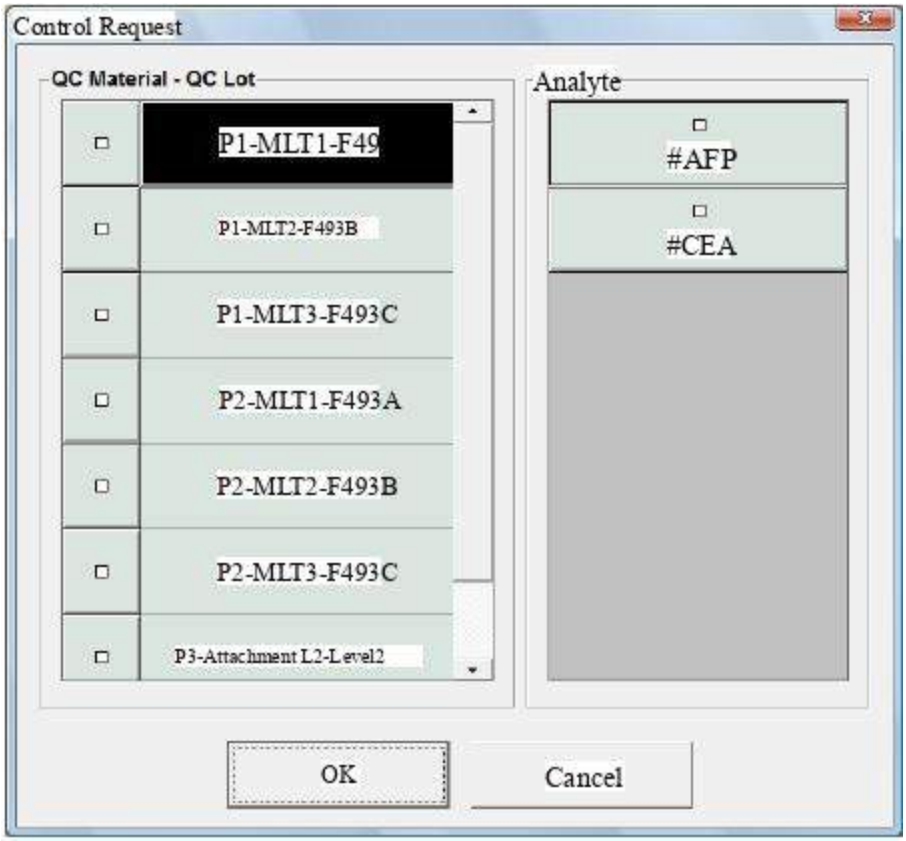


Printing paper. Exhibitions the work list The work list can also be printed on

Control essay requests

Click the Control button. The following dialog box is displayed.

Select the desired QC material by clicking on the toggle button. For a detailed description of the QC material registration procedure, refer to chapter 7: Section 7.2 Registrar QC materials.



Select for each material and click the QC button OK.

Dilution factors can only be changed by editing the dilution factor information. home control the Test file

Requests can be made from the barcode request screen while operating. with the A beltline unit

Point **Only the test will result in obtaining the QC material name for the specimen. The ID is used for quality control. The control data will be compared to the range. of the test (L, H) but I did not verify with the reference range (L, H) nor the Reschedule fixes (RL,RH).**

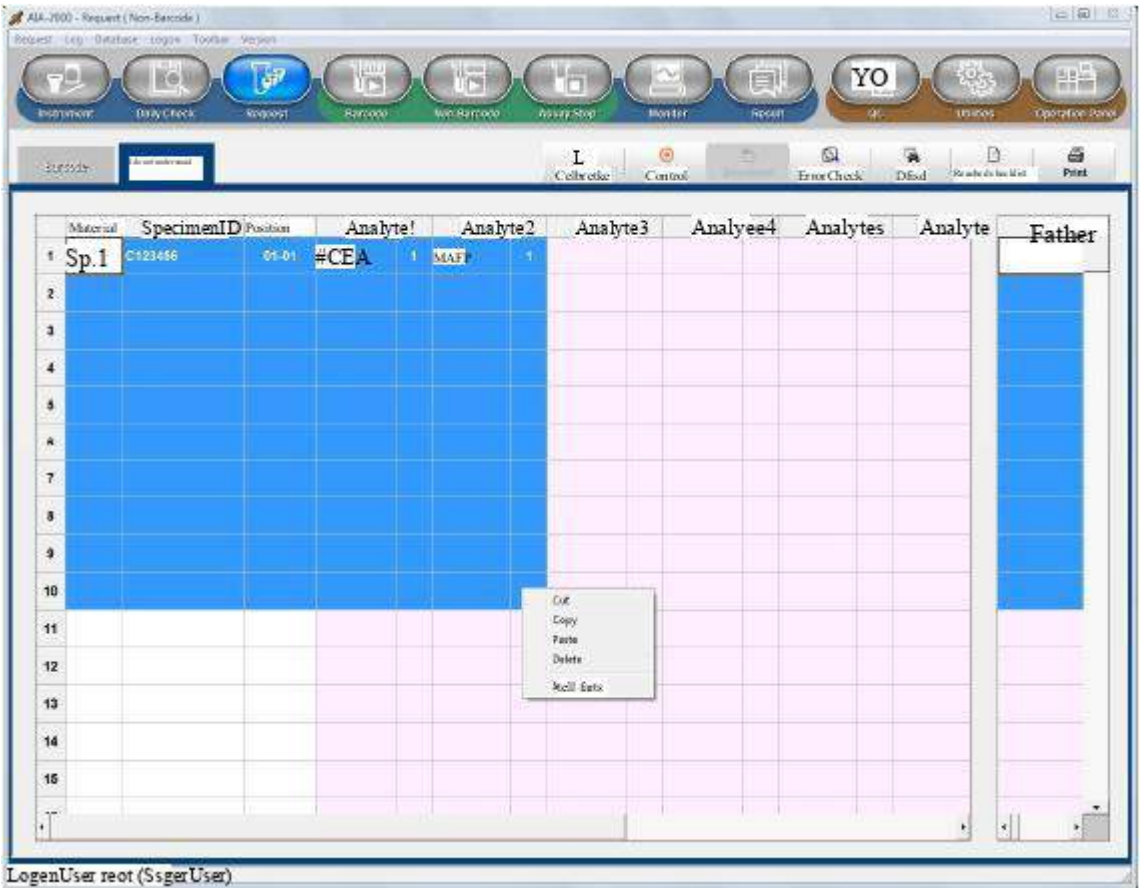
Calibration verification requests

Control the testing requests for calibration verifications will be generated automatically. automatic as long as the calibration requests are entered if the calibration verification It has been enabled in the QC materials Registration Screen. For a detailed description of the QC material registration procedure, refer to chapter 7: Registering Materials QC of section 7.2.

6.6.3.2 Operate without barcodes

Click on the Request button in the toolbar to display the window for
no barcode. This is basically the same as the barcode request procedure.
bars with the differentiate only to be That the information for the specimen positions in the essay requests must be entered in the position cells in advance.
The number usually used to indicate the specimen's position is a combination of the sample of two digits the rack places (rack) the number indicating the test that starts order and a specimen of two digits place (in the rack) the number. The rack counts for each batch of essay go out of 01, with the position numbers running around
01 to 10. (sample entry) Rack number position number

01-01	(put 1 in the tormenting sample 1)
01-02	(put 2 in the sample torments 1)
02-01	(put 1 in the sample torment 2)

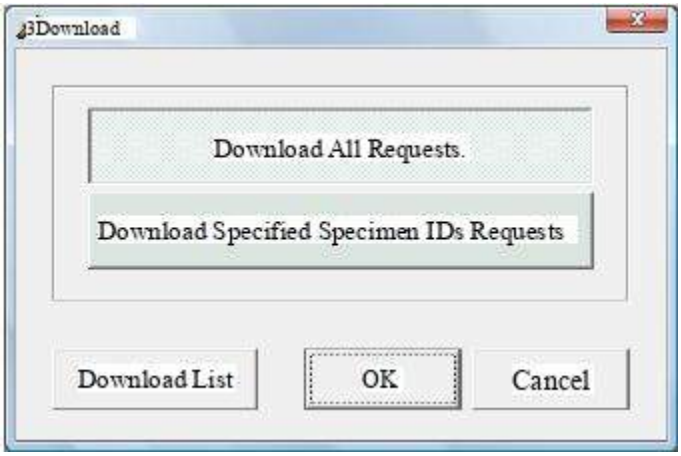


Point

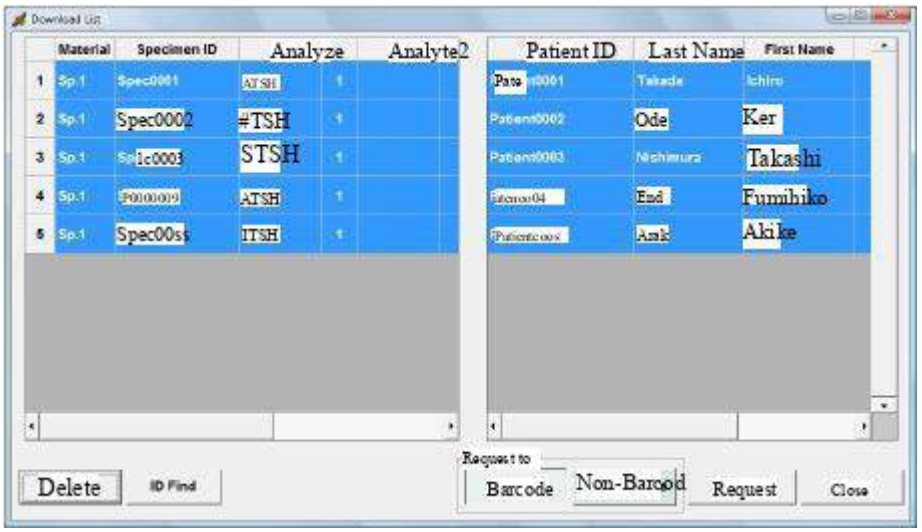
- **Las solicitudes pueden generarse de forma automática simplemente entrando la primera position and drag and drop the required lines of the application.**
Note that non-barcode essay requests are not valid for the
Beltline operation. - Specimens without barcodes cannot be rescheduled.
form
automatic.

6.6.3.3 Download essay requests from a base computer

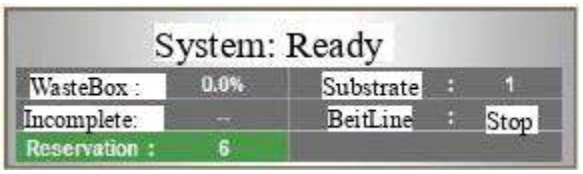
Essay requests can be obtained from a base computer by performing an operation. download. Click on the Download button on the trial request screen. The box of The following dialogue is displayed. Choose or download all requests or download. they specified the specimen ID requests



The downloaded request is displayed in the download list dialog box. Choose the data. to practice, then choose the mode and copy to practice the request screen. Any Unnecessary, the lines can be deleted this way.



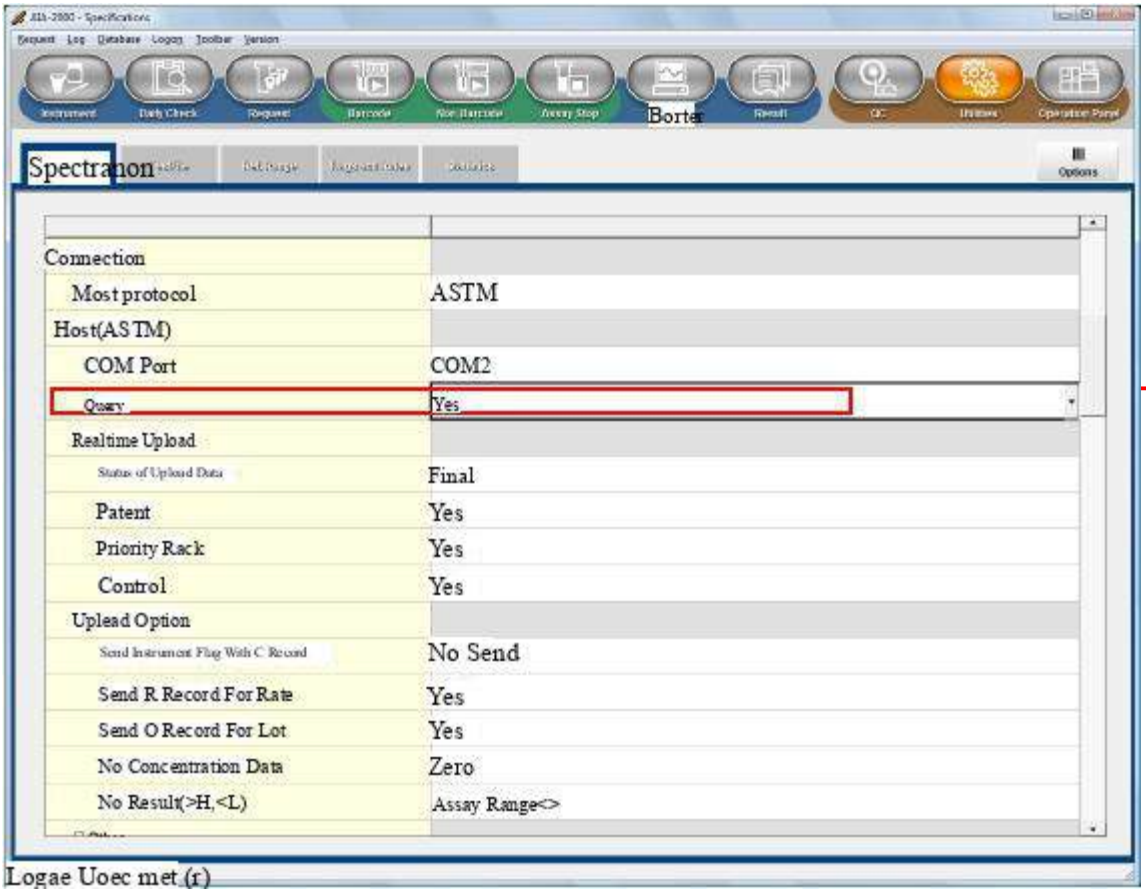
When a request was downloaded from a base computer, the status color reservation shows the part of the instrument screen changes from gray to green.



Although requests for controls can be derived from the base computer, they manage results. cannot be used as quality control data unless the QC material name is used as the specimen ID.

6.6.3.4 The essay requests in the host question mode

Requests issued to the base computer are referred to as "questions of "Host" in the AIA-2000 system. Test requests do not need to be generated when the mode the host question is used. The placement of the host question mode is due to log in to enable the system to inquire the host computer for the requests of essay based on examined barcode information. Click the button to Utilities in the toolbar to display the specification window. This is done by choosing yes in the status of the question.



When the AIA-2000 reads the specimen ID barcode, it searches the database for a request for existing essay. Otherwise found, inquire the base computer. If a specimen ID request not found, the specimen is skipped.

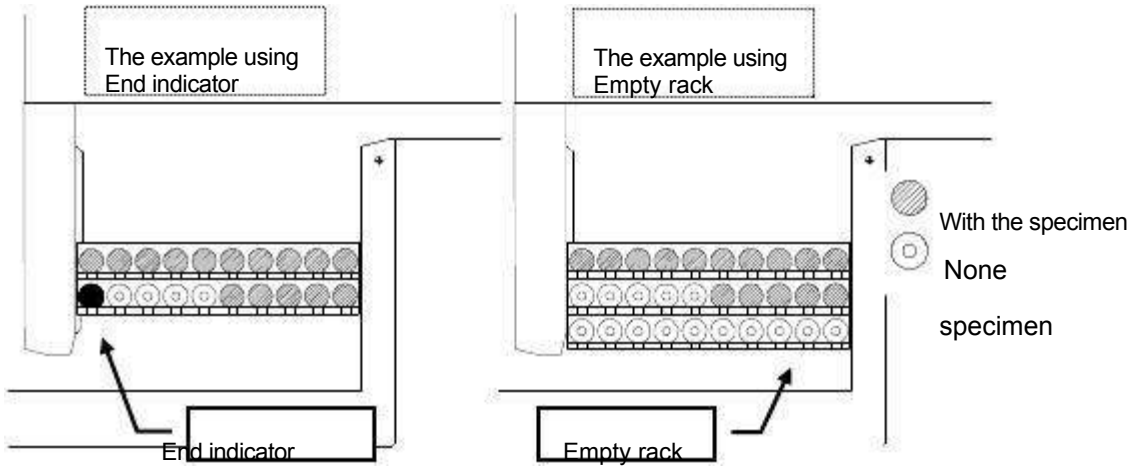
6.6.4 Specimen Sets

The description given in this section is limited to the sample built-in charger. Refer to it. beltline unit documentation for a beltline system operation description.
If barcodes are used, specimen order can be casual, as they will be elaborated.
in the request order essay. Otherwise used, however, they must be loaded that is in position number service.

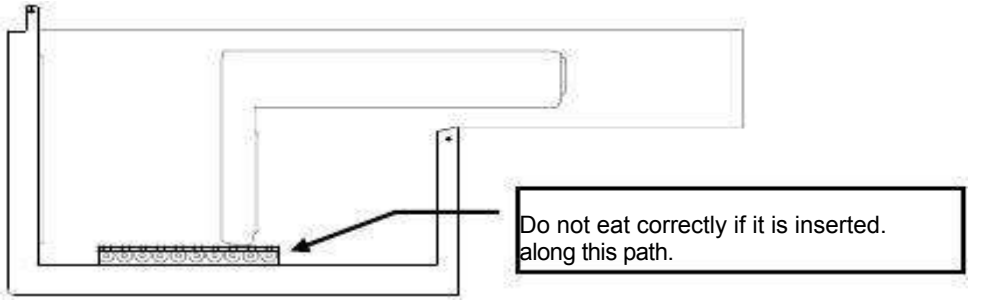
screen. The specimen volumes, on the other hand, are verified by clicking on the printing

button in the essay asks for screen and display the work list

Load the sample flight containing specimens with the end indicator (or empty the rack) inserted at the final position. Note that the sample charger will continue operating simply unless it detects the end indicator.



Make sure that the sample charger has stopped before loading a new sample. Action while the sample charger is operating may result in interruptions caused by rack power errors. Locations where the racks are located they cannot be loaded show below.



The sampling operation usually ends when the sample loader detects the indicator of

end and stops. If planning additional rehearsal tasks, be sure to load the sample rack.

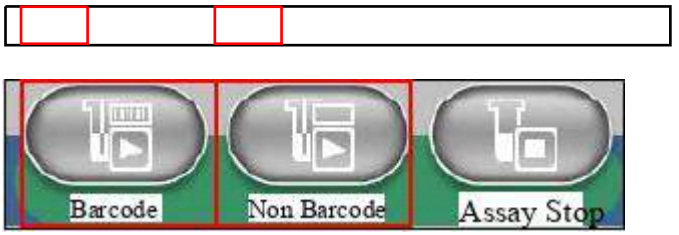
containing specimens and insert a rack that contains an end indicator before starting.

youcanreplaceitforthedefinedindicator.

A simple test unit is referred to as a 'batch' operation in the loader. Sample loader. The sample loader detects the end indicator at the end of the sample racks or the rack empty like the end of the batch operation and finished operation.

6.6.5 Principle of testing

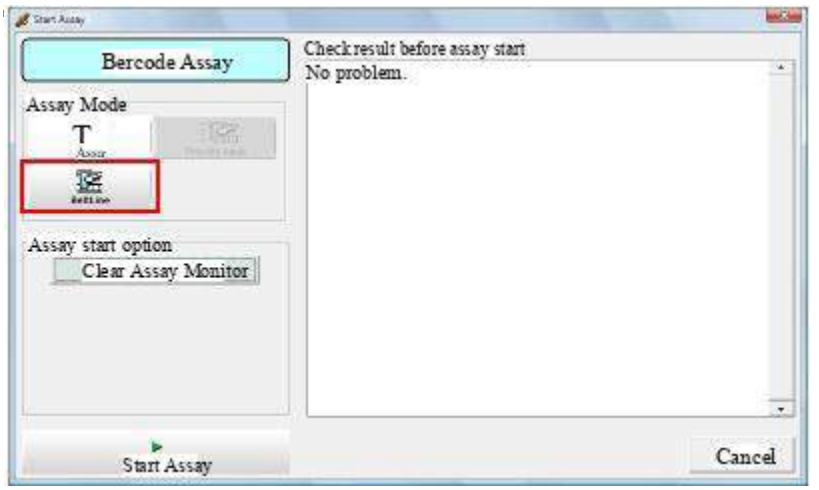
Click on the desired test mode button (barcode or no-barcode) bars) in the toolbar.



Point o **The operating modes can be switched between the units of batch process.**

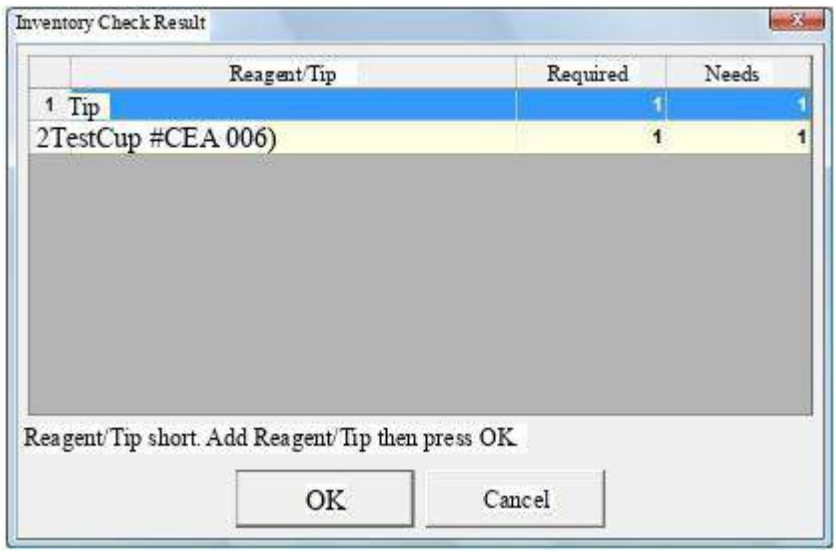
Make sure to enter the number of the last line (last sequence) of the essay request. when to operate in barcode-free mode.

(2) The Beltline option is included in the mode list in the LA model. Choose mode from the Beltline to operate from the Beltline.



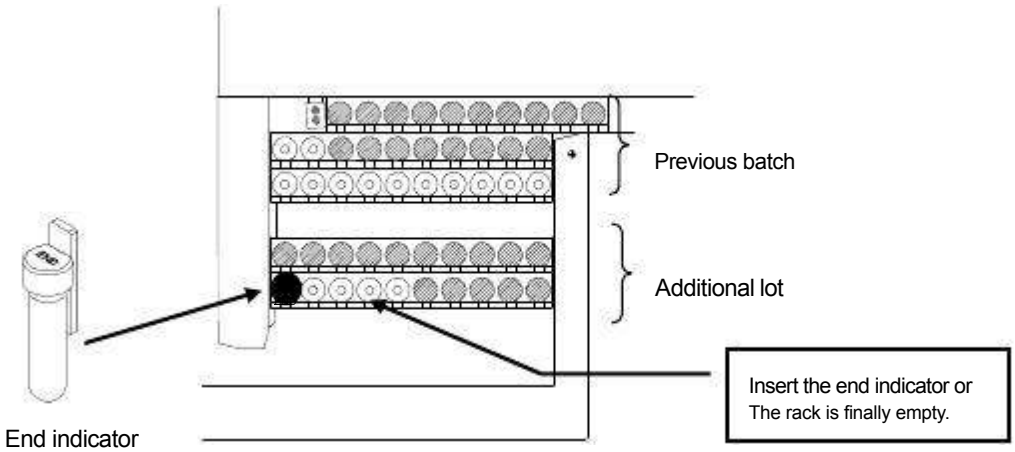
(4) Click on the Assay button to begin. The assay operation starts. verified, marked on the test monitor.

The following screen is displayed if a shortage of tips or reagents is detected.
Run the test principle again after clicking the Cancel button and
Filling reagents. Note that tested effects skip if the OK button is clicked.
without filling out reagents.



6.6.6 The additional testing operations

Wait until the previous batch dispensing operation has completed and the sample loader get tall. Then load the next batch of specimens behind the end indicator (or empty la rack) insertado al final del lote previo. Esté seguro de incluir el indicador de fin (o vacie Fly) at the end of the new batch. The end indicator (or empty the rack) must be inserted at the end of each batch. After the specimens have been loaded, generate a new test request and the operation essay begins. By frequently adding specimens, the end indicator can to be used to sharpen the end so that this added point is easily shown.



Point In cases where the sample charger requires significant time to stop, make a stop
operation by first choosing the pause in the stop dialog box trial,
then I loaded a new rack. For a description of pause procedures, refer to
Chapter 6: Section 6.6.8 Test the pause/continue.

Note that additional essay requests cannot be added to the batch once the the operation has begun.
Upon entering the additional trial operations before the sample operation for the current batch has completed, the selective pause of the first to stop the loader Show, then load the new sample racks. Without pausing the loader of Show the load before it may result in interruptions caused by rack feeding errors.
Note that additional tests cannot be entered automatically in the test operations.

When adding new racks while the sample charger pauses, you are sure to place the sample flight in front of the designated line to secure racks load correctly (see the appropriate warning labels).

The placement torments the one himself.
posterior part during the operation (still
If pause) mistakes trigger the trigger and
stop the sample charger.

6.7 STAT Assay (emergency tests)

Emergencies are practiced using the priority rack. The emergency specimens
They can be ordered in both barcode mode and non-barcode mode. The
Emergency specimens are placed on a rack, so the rack ID is recorded.
like the priority rack at the moment the operation begins. When the operation starts
Test, the rack ID is read by the AIA-2000 and the rack ID is compared with the rack ID
registered as a priority. It is recommended to register the emergency rack ID before
perform the analysis of it. After the priority rack test is conducted.
The process of the interrupted specimen samples will continue.

**If the sample charger placement is not in rotation mode, the rack testing of
Priority cannot be executed. If the priority rack test is started, the testing of the
Other specimens cannot be executed until the specimens from the rack are processed.
priority is completed.**

6.7.1 Access the STAT test operation (emergency/priority)

The emergency test request is made on the REQUEST screen (barcode or
(no barcode). For a detailed description of the desired test request, please
refer to chapter 6: section 6.6.3 Request for admission of evidence

Calibrators and controls cannot be processed as emergency samples.

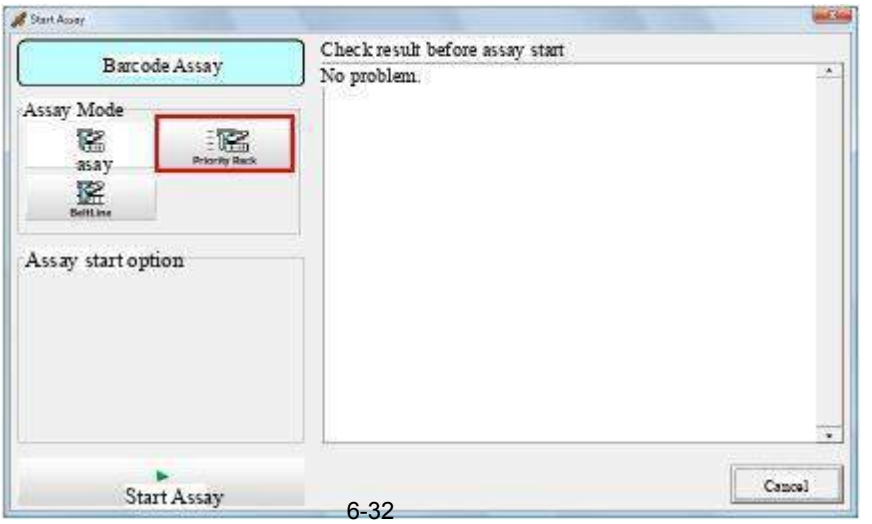
6.7.2 STAT specimen configuration (emergency/priority)

The priority rack is placed after the end indicator (or the empty rack) of the last test.
added. For a detailed description of the essay entry request, refer to the chapter
6: section 6.6.4 positioning of specimens and chapter 6: section 6.6.6. Operations of
additional essays

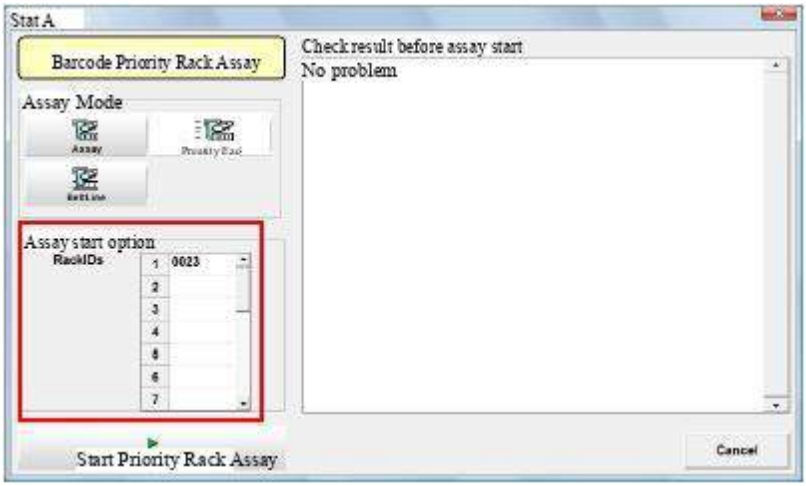
6.7.3 Start of STAT test (priority/emergency test)

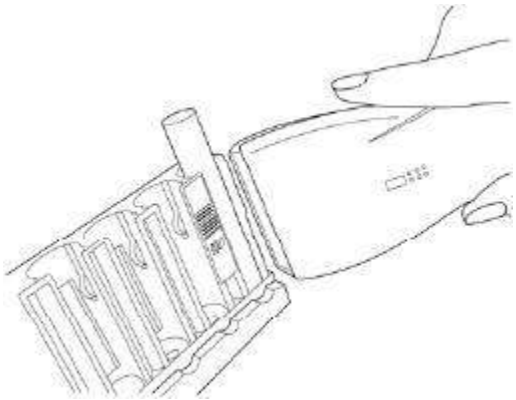
Click on the barcode button or the no-barcode button in the bar.
of tools according to the testing mode.

Click on the Priority Rack button of the desired test mode (barcode / no-barcode.

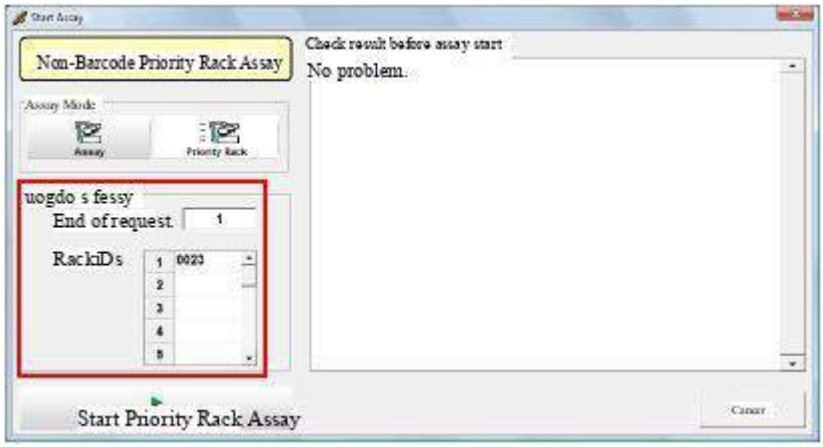


The priority rack ID is placed in the rack ID box (start of testing operation). using the barcode scanner or keyboard (manual).

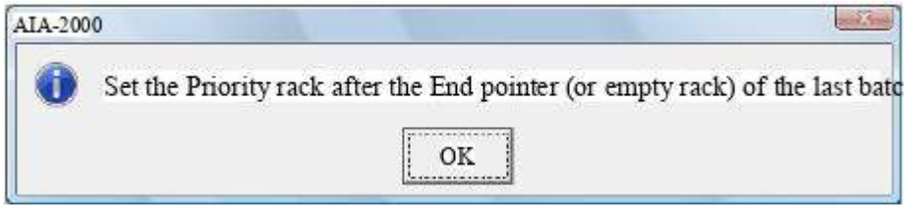




Make sure to enter the number of the last line (last sequence) of the essay request. when operating in non-barcode mode.



Click on the button .START PRIORITY RACK ASSAY
(6) the following dialogue box will be displayed. Click on the OK button. the rack operation priority will be initiated.



6.7.4 Display of priority rack analysis

Once the essay has started, essay requests made on the request screen tests are displayed on the test monitor screen and the operator will be able to monitor the progress of the tests using the test monitor. The background color of the corresponding cells is indicated in yellow (priority specimens)

If the 'test status' exists, the analytes (blue) are in the test monitor. same time when the priority tests begin, the priority rack analysis will start afterwards that the status of the analyte is converted to "dispensed status" (orange). During the priority rack test, the base color of the toolbar will be green.
The priority rack is displayed in yellow in the patient window (the monitoring window of rack). Only the priority rack is displayed in the priority rack window (the window of rack monitor.

Point

If the priority rack analysis is initiated, the other tests cannot be analyzed. until the priority rack analysis is completed.
if a priority rack is not placed at the end of the standard sample rack when starting the analysis From the priority rack, the following error message will appear: 'THE PRIORITY RACK SER ' POSITION IS WRONG
If the priority rack is unable to connect, the following error message will be displayed. THERE IS NO PRIORITY RACK. The rack analysis will not be performed. of priority and the team will return to the usual rehearsal mode.

6.7.5 End of priority rack testing

When the priority rack test is finished, the following dialogue is displayed. Remove the priority rack and click on the OK button.

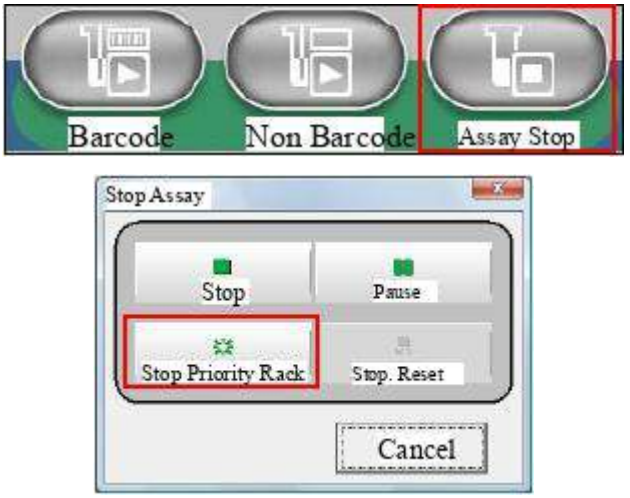
▪

Poin

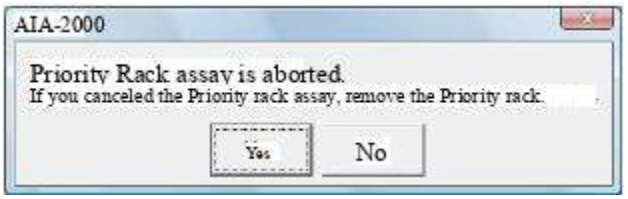
If it is not able to return to the sample position it was in just before the test
After the priority rack analysis is completed, the following error message will be displayed.
THERE IS NO SPECIMEN THAT THERE JUST BEFORE THE PRIORITY RACK ASSAYSTART
(no specimens were found in testing before starting the priority rack test).

6.7.6 Priority rack test stop

Click the Stop button in the toolbar. The trial dialog box of
The stop will be displayed, click on the button 'STOP PRIORITY RACK' (stop the rack of priority)



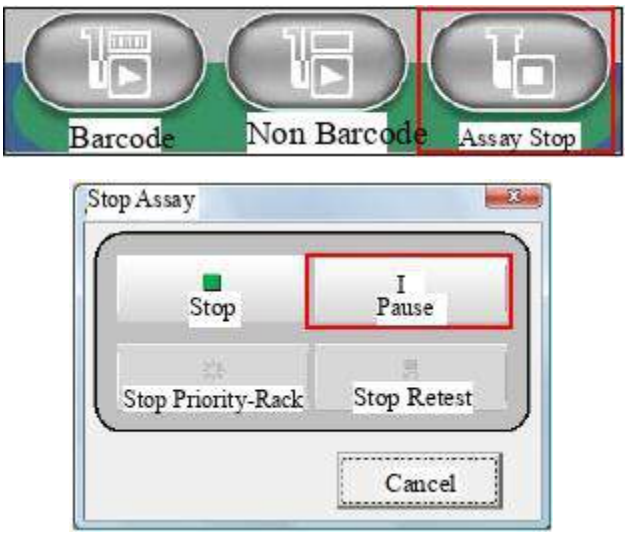
(2) The following dialogue box is displayed. Remove the priority rack and click on the OK button in the dialog box.



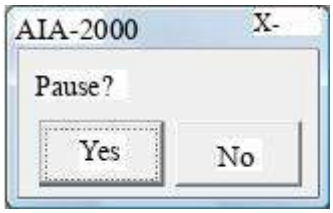
6.8 Pause/Continue the trial

The Pause/Continue feature in the trial may be used to temporarily pause the current specimen so that new specimens can be uploaded in time for processing during an activity or when specimen jump occurs due to a reagent shortage. the analysis of the specimens already dispensed will continue.

Click on the 'ASSAY STOP' button in the toolbar.
it will show the rehearsal stop dialog box, then click on the Pause button the dialog box.



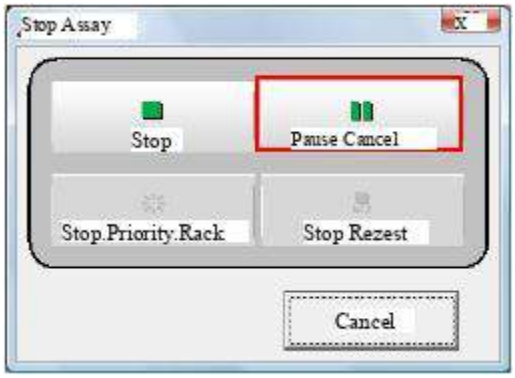
When the following dialog box is displayed, click the yes button.



Try pauses when the next scheduled sample will start. During the pause, the the base color of the toolbar will be pink as shown below.

(4) To continue the operation, complete the task manually, then click on the Cancel button.

pause(dialogbox StopAssay) to display the following dialog box.



Click the yes button.
The paused sample is being analyzed again.

6.9 Supervision of testing

The status of the AIA-2000 is indicated by colors as shown below.

During a STOP, the base color of the toolbar is gray.

During the rehearsal, the base color of the toolbar is blue.

<Pause> During the break, the base color of the toolbar is pink.

Abort the pause. During aborting the pause, the base color of the toolbar is yellow.

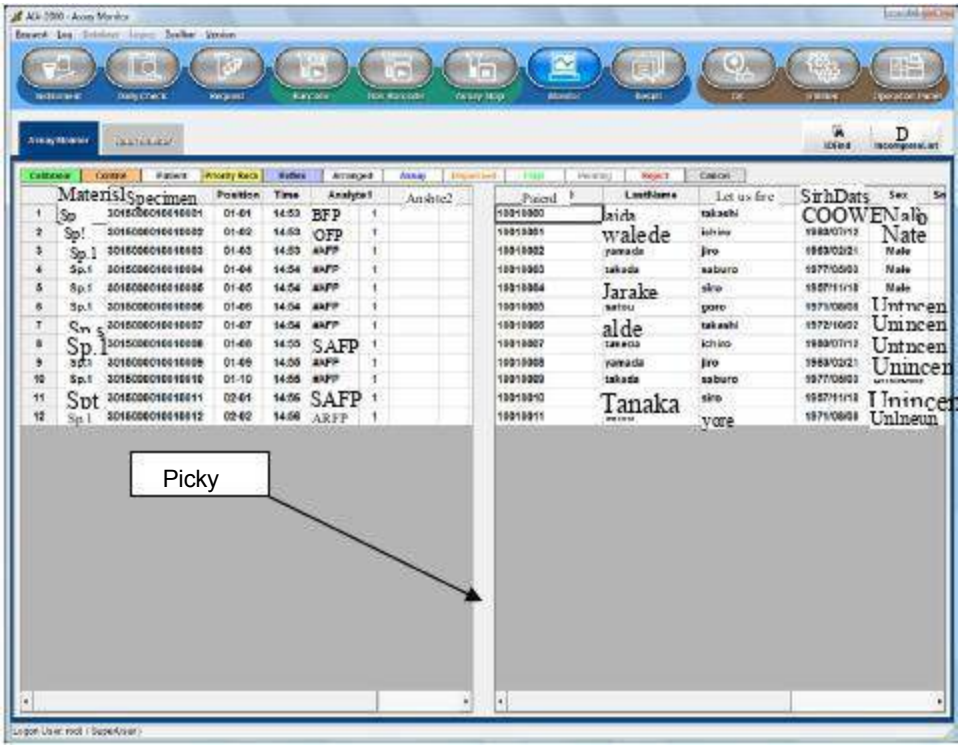
The rehearsal cannot be performed during a break.

<priority show> During the emergency trial, the base color of the toolbar it is green.

The rehearsal cannot be conducted during an emergency response.

6.9.1 Test Monitor

Once the trial has started, the trial requests made on the request screen tests are displayed on the test monitor screen and the operator will be able to monitor the progress of the tests using the test monitor.



The base colors of the status cells and characters indicate the status of each cell.

Base color of the cell

CAL Orange (calibrator)
QC ..... Green (control)
Sp1, Sp2 ..... Blanco (patient)
Yellow (priority rack; STAT Assay)
Purpura (reflex)

Character color of Analito 1 (-24)

The status of the Analyte is shown as the following colors.

Black Willing
Blue Essay
Orange ..... Dispensated

Character color of Analyte 1 (-24) that test completed

Green ..... Final
Gray Pending
Red ..... Discarded

If the request is canceled, the line's base color turns gray.

Simply hover the mouse pointer over the analytes with completed analysis to see the results. Any untested analyte is returned to the test request screen at the end from the operation of the test. All the lines show the estimated completion times until the final result of the line (specimen) is obtained. The order of the resource list is as the tests progress. Once finished, the samples will be placed at the top, the samples arranged in the center and the scheduled samples at the back. Result area and area of Patient information can be changed by moving a stubborn one to the right and left.

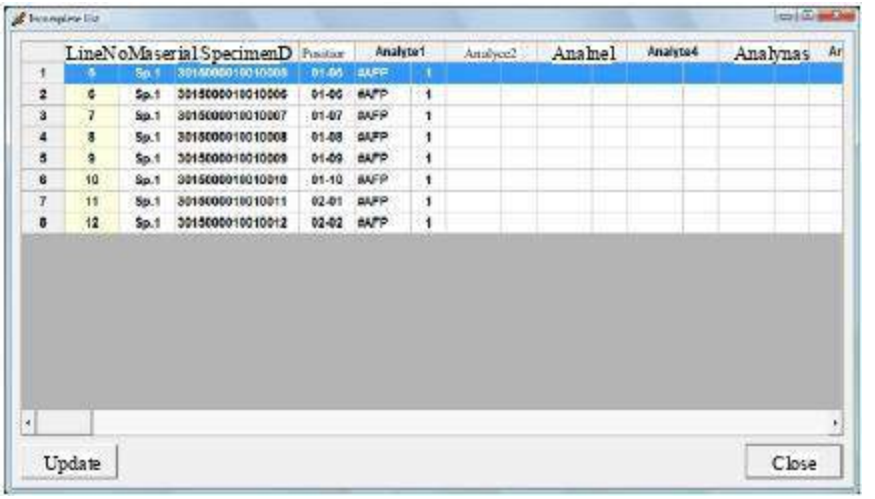
■ The dialog box may be moved to bring the cursor

F1: Jump to the main line **F2: Jump to the end of the line**
F5: Move to the left **F6: Move to the right**
F7: Jump to patient information

Button functions

ID finding The specimen ID is entered in the specimen ID column. Choose the address of the finding (click on the button address) and click About the Find button, then the cursor moves to the Specimen ID line. corresponding

Incomplete list: The incomplete analyte (black character) in the control screen essay is shown in the dialog box (incomplete list). The dialog box for the The incomplete sample list cannot be edited. The list does not update. automatically but by clicking on the Update button.

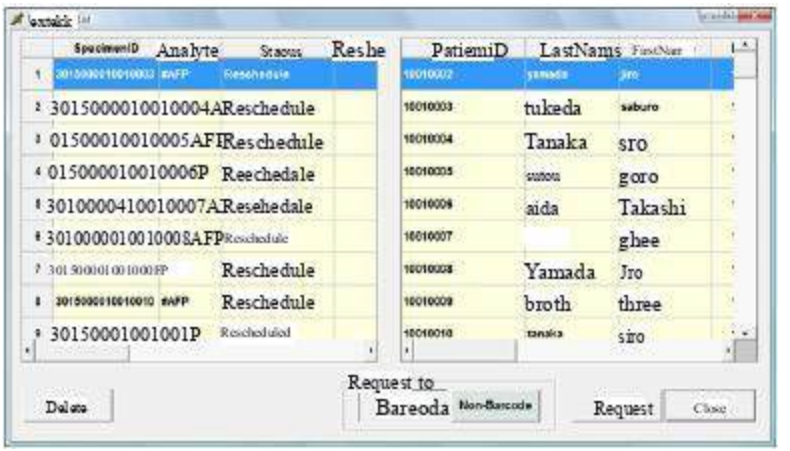


■

Point with the finger - the dialog box of the Reschedule list automatically appears when a result is judged. how

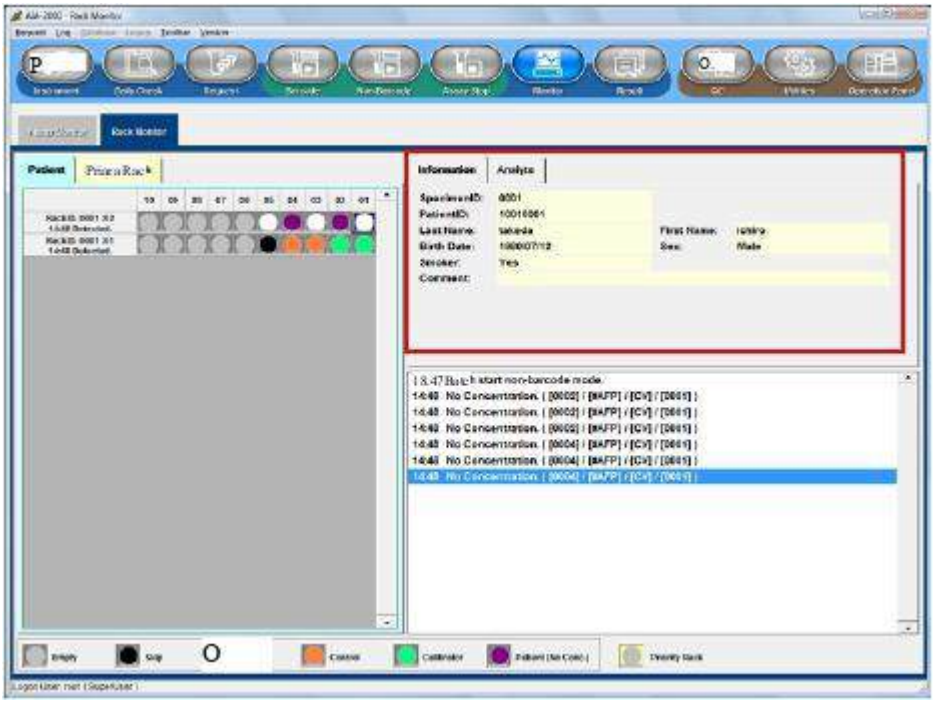
reschedule.

The registrations were judged as ineligible and will not be shown in the Reschedule list.
A request for an essay can be created using this list. After choosing the request mode,
Also. Barcode or no barcode, choose the inscriptions for reference.
a-tried, and then click on the Create Request Button. The chosen registrations will
They will be removed from the list and a new request can be created in accordance with the request screen.
of essay. Certain requests in the application the screen can be cleared if they are not necessary.



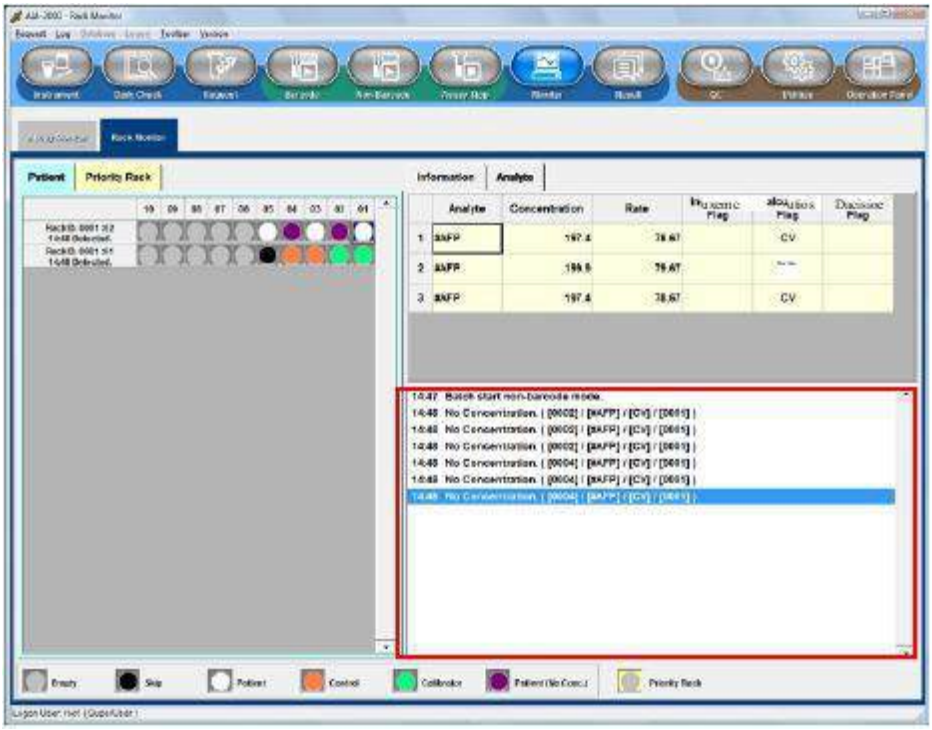
6.9.2 Rack Monitor

The rack monitor displays the current status of the sample racks that have been completed. sample operations. The status information includes sample torment ID, test the rack position and specimen status.



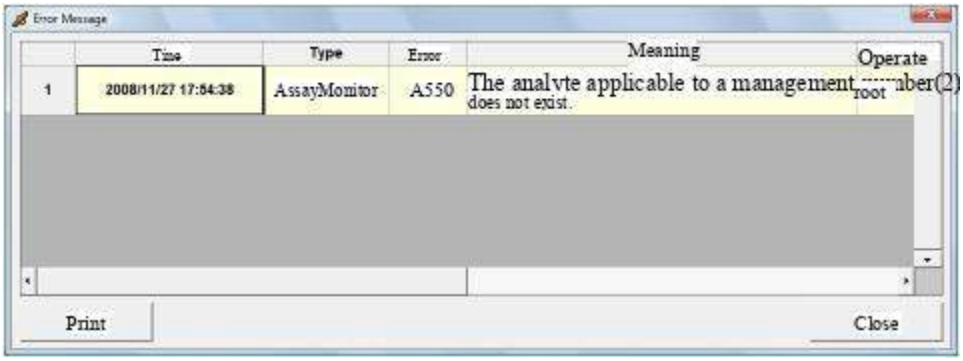
Patient information can be displayed at the top right of the screen by clicking on individual cells. Specimens whose assay results could not be obtained should be shown On the right side of the screen, making it easy to classify and confirm. specimen positions when rescheduling a test operation.

Point **This function is available for trial operations execute using the sample. Built-in Charger**



6.9.3 Mensajes de error

Error messages during system operation should be logged in the file
error trunk. The following error dialog box always appears whenever an error occurs. The
the operator can continue other operations while the box is displayed. Each message
The error has a checkbox that can be selected to indicate the error.
confirm if.



The previous errors can be displayed by selecting records from the menus.

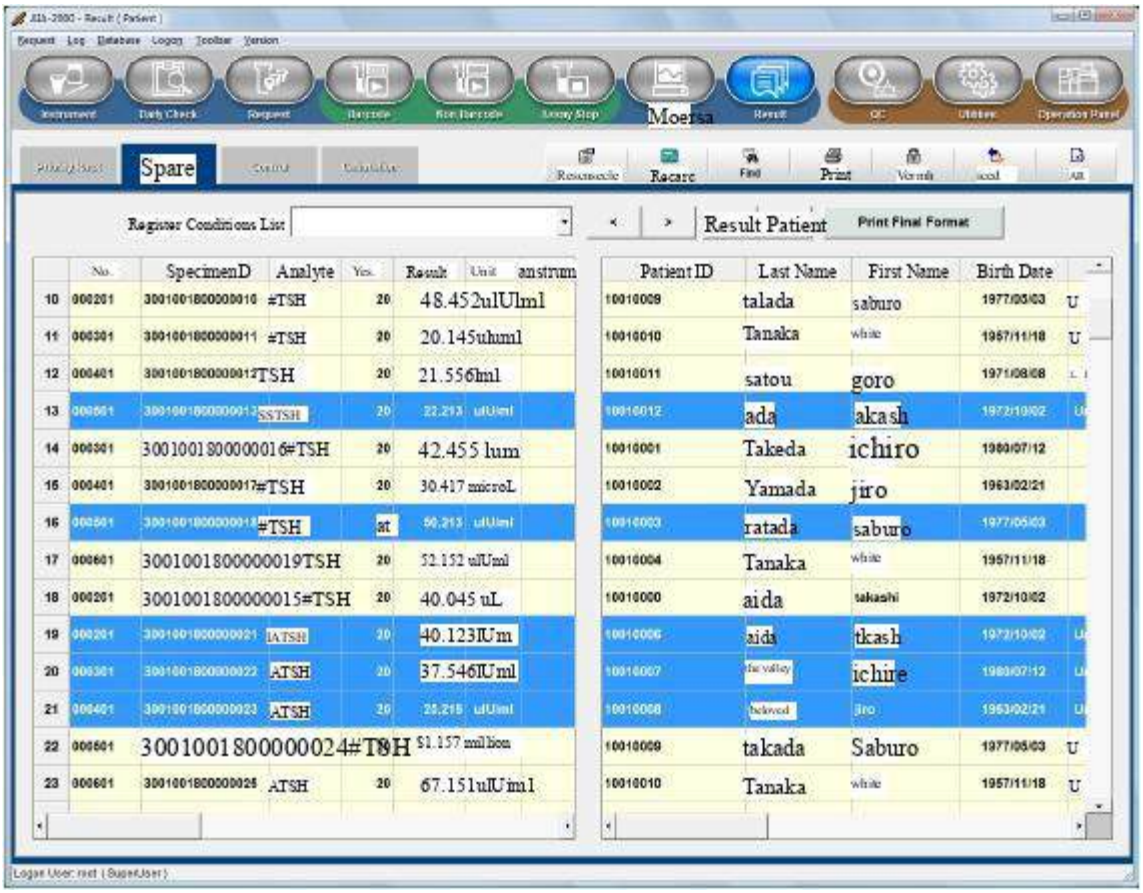
When the text in the error message cannot be seen, click twice on the cell to expand it.
the size of the cell. Double-click the mouse button a second time to restore the cell to its original dimensions. Error logs can be deleted by choosing the area, clicking the secondary key of the mouse on and then choosing "delete". Note that they will not be recovered if deleted.

6.10 Review of results

6.10.1 The specimen (patient)

To view the results of routine specimen tests, click on the Results button in the bar.
tobtoshowthespecimenwindow

- Point with your finger - the latest data is shown in the first line of the table.



Definitions of cell

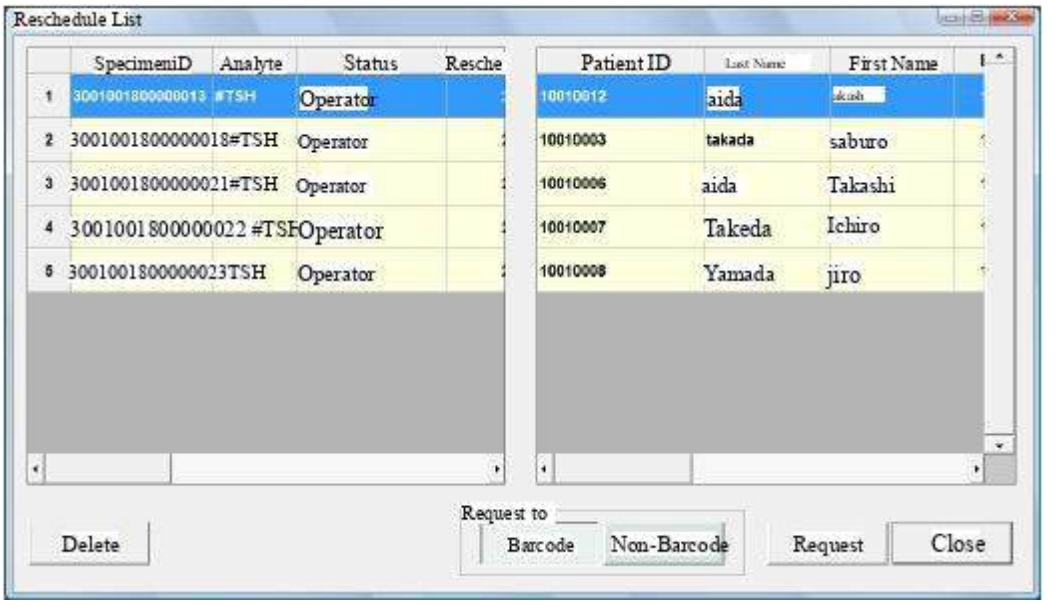
No.	Sequence number
Specimen ID	Specimen ID
Analyte	: Analyte Name
Heart	dilution factor of the test
Result	Calculated concentration
Unit	Unit of measurement
Instrument flag: Request for legal instrument flag, refer to A3: Appendix 3: Types of Banderas	
Calculated flag	Calculated flag
Decision flag	Decision flag
Date time	The majority of the recent date and time of the result calculation of essay
Status	Status of test result dependent defective product final
XMit	Status of the result transmission to the base computer I unsent X sent
Operator	Name of the operator performing the test operation
Index	Index value
Batch	Distribute the number of the test cup used in the operation of essay

POS	Specimen position number
Date of rehearsal	Date and time of the trial operation was executed
Comment	The data that were entered at the time of the request
Patient ID	The data that has been entered at the time of the request
Last name	The data that has been entered at the time of the request
First name	The data that have been entered at the time of the request
Date of birth	The data that have been entered at the time of the request
Sex	The data that have been entered at the time of the request
Smoker	The data that has been entered at the time of the request
Comment	The data that was entered at the time of the request
Record date	The date and time recorded for the first patient ID

Button functions

Reschedule Button:

To reschedule an essay request. Choose the results for reference.
If rehearsed, then click on the Reschedule Button and the Reschedule list dialog
they will appear. After selecting the application mode, whether barcode or no-barcode,
Choose registrations to request, then click on the Request button.



Recalc Button:

I am accustomed to executing the recalculation of the test results that uses calibration.
validate the curve. Select the target data, then click on the Recalc button.

■ [illegible]

Data selection procedure identical to that of the Windows operation.

(Example 1)
When selecting lines 1 to 10 for recalculation:
Use the mouse to select line 1.
Hold down the shift key on the keyboard and select article 10 with the mouse.
With lines 1 to 10 highlighted, click on the Recalculate button.

(Example 2)
When selecting lines 1 and 5 for the recalculation:
Use mouse to select line 1.
Hold down CTRL and click on the selected item 5 with the mouse.
With lines 1 and 5 highlighted, click on the Recalculate button.

Find Button:

Clicking on the button found displays the dialog box found that allows
usuarios para entrar múltiple condiciones de búsqueda. Hacer click sobre el botón encontrado
in the dialog box retrieves information matches the search conditions and displays it in a
worksheet.

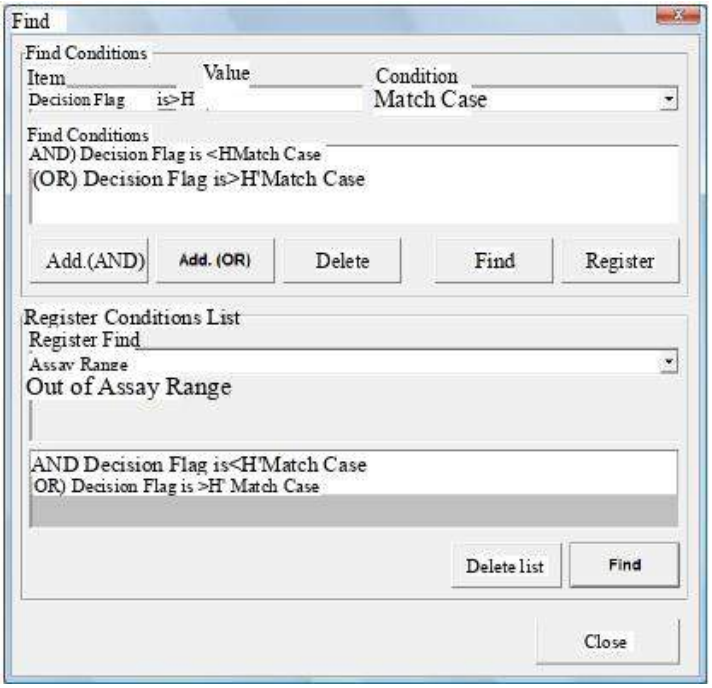
The first seeks the condition that it can be entered by clicking on the Add (AND) button.

y

additional search conditions can be added by clicking on the Add that
(AND) or the Add that (OR) buttons.

For example, to search results whose decision flags are < L or > H.

Select 'Decision Flag' in the boxee properties, between '<L' in the value box and select
Check the party in the boxed condition, and then click on the Add that (AND) the
button. The search condition will appear in the blank box accordingly. To add
a search condition, between '>H' in the value box and click on the Add that (OR)
the button.



Clicking on the top button shows the results it finds.
set of search conditions. Frequently use search condition sets
They can be registered in the boxee registration condition list using the button
Register. By clicking on the lower button, it shows the results.
find the registered condition set. Use the Delete list button to delete conditions
search of the registered list.

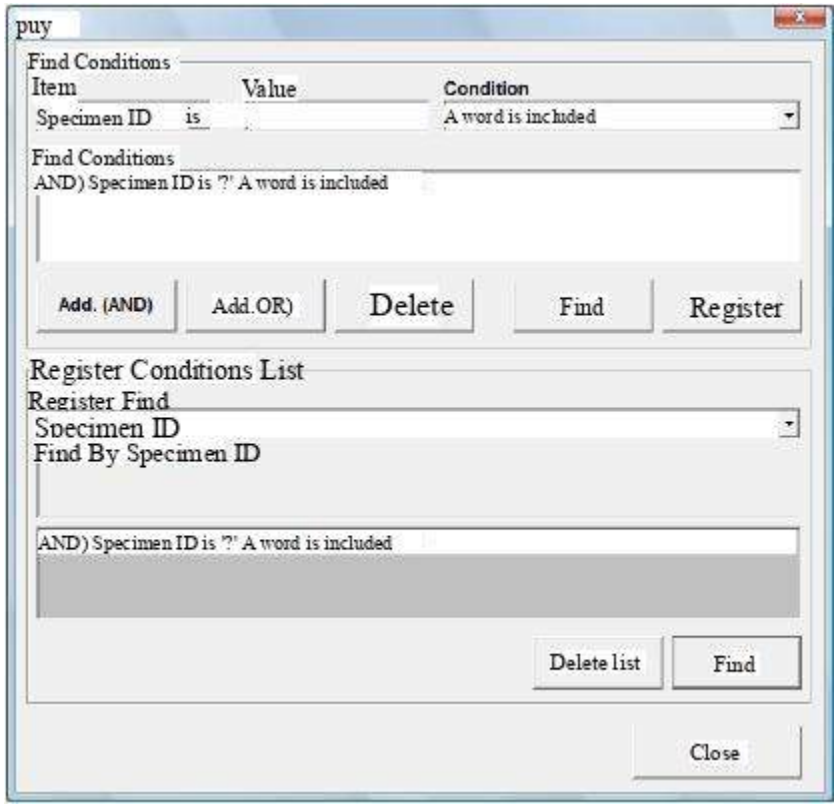
■

Point

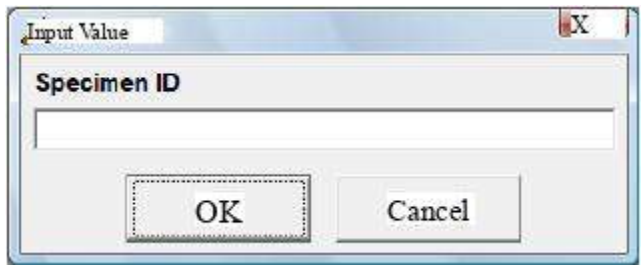
**Even if the found button is not clicked, it may search if the condition of
Search is registered. Selection of the search condition was recorded from the condition.
next from registration The list will show search results.**

in value box jobs as a variable when searching.

For example, select 'Specimen ID' in the boxee properties, between '.' in the value box and choose the word from "A is included" in the condition box.



When clicking on the upper Find button, the input value dialog will appear as down. After entering specimen ID, click on OK. Then the results with the the same specimen ID will be searched and displayed on the screen.



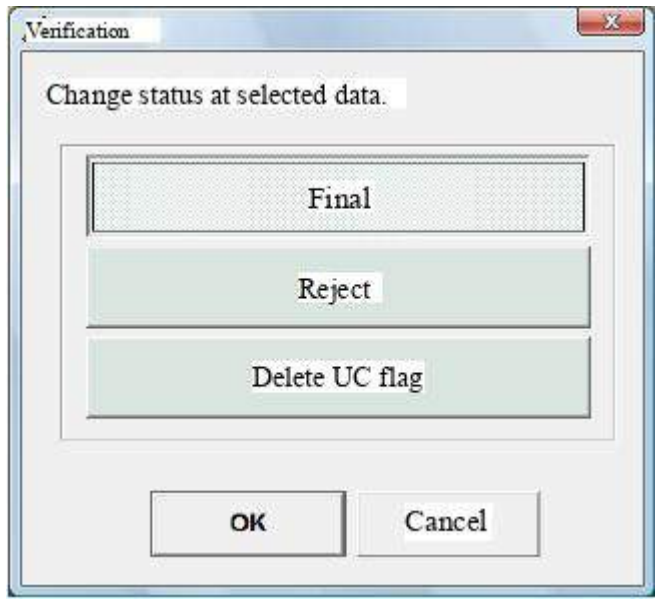
Print Button:

The printing feature allows for a printout of the current screen with or without the patient. added information. If the final print format button (toggle button) on the screen of the result is clicking on, printing data with patient information. Choose the data

To target, then click on the print button. Refer to the illustrated examples. up for the data selection procedure.

Check button:

I usually verify the integrity of results, 'Pending' the test results will be or accept as The final or rejected. The data selection procedure is identical for that for Windows. Refer to the examples illustrated in the Recalculate button description.



About the Delete UC flag (the UC flag function is not marked as working)
the implicit placement) When abnormal pressure is detected during suction of specimen, the UC flag will be attached to the result. Possible causes are the suction of clot, air or the high viscosity of the sample. If the same flag was attached to the result retested even after the removal of clots or bubbles from the specimen, the viscosity Then high of the sample can be more likely. If a result is reproduced and thus the result may not be any concern, then the UC flag could be deleted from result choosing 'Delete UC flag' in the verification dialog.

Load button:

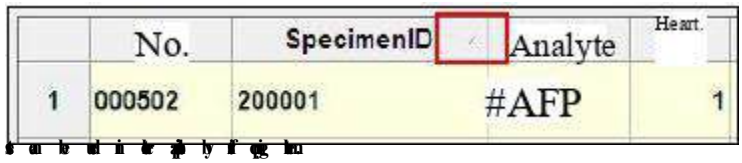
I usually transmit test results to the main computer. Choose the target data, then click the Upload button. The data selection procedure is identical to that of the Windows operation. Refer to the examples above.

All the button:

Click on all the discards, search for conditions, and show all results.

[illegible]

- **Puede cambiar en un ascendente o una orden descendente haciendo click sobre la subida o el Mark below. If the entire button is clicked, clarify the order of change.**



[illegible]

- **the clipboard.**
  - **Double-clicking the mouse changes the selection from line selection to selection cell.**
  - **Drag the mouse to select the data section to copy.**
  - **Press the c of CTRL (continue in CTRL while pressing c) to transfer the data for the Clipboard**
  - **Click twice on the mouse again to return to strikethrough mode. selection.**

■ [illegible]

F1 (or press CTRL PageUp) **Jump to the top of the list**

F2 (or press CTRL PageDown) Jump to the end of the list

F5 **Scroll to the left**

F6 **Move to the right**

These functions are only available when the worksheet is active.

Examine the previous data The results of previous tests are stored in the database. Data. Choosing the past is the database of the menus that switch operation to that database. data. Note that new test operations cannot be started while the past the database is chosen. The system automatically switches back to the current database when a trial operation begins.

Loading of past data

It is possible to load the past data. Note that, however, from the current fileTest. Parameters such as test range will be used at the time of loading the test file. The parameters used during tests in the past need to be the same as the current parameters.

Note that the previous data cannot be recalculated, so it is important to confirm them. Data before closing the system.

< & > button

The screen cursor left (results list) can be moved without using a mouse. Cursor can move in a transverse direction without moving a line. The cursor cannot to exceed the fussy.

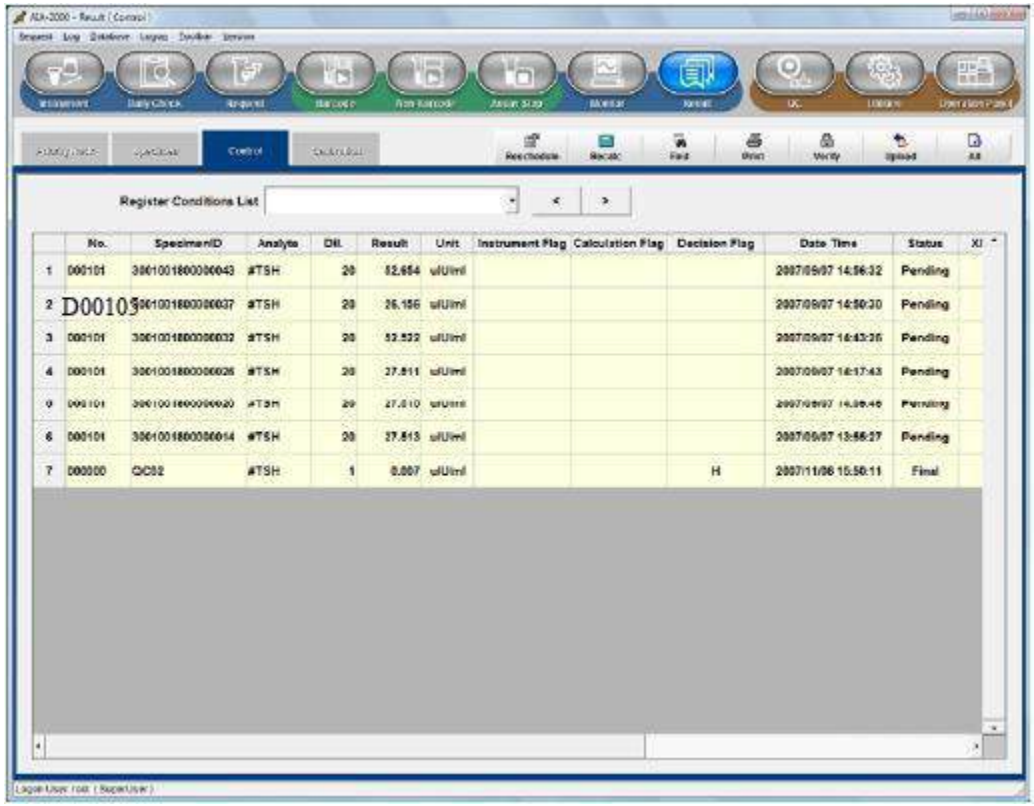
Result and the patient button

The display area (or patient information) can be changed without using a mouse. If you click the Result button, the result area expands. Similarly, the button Patient click on then patient information area expands. The area displayed The screen can be changed by moving the picky one.

6.10.2 Controls

To parameterize the control specimen and analyze results, click on the Results button in the bar.
tools to show the control window. The items and button functions are identical
for those provided in the essay Results of the specimen (patient). For a description
detailed description of the items and button functions, refer to chapter 6: The specimen of section
- 6.10.1 (patient).

[illegible]



Button functions

Reschedule	Reschedule a request on the request screen
Recalc	Calculate the concentration used in the last calibration curve
Finding	Findings and show results that match the conditions of search entered in the search dialog box
Printing	Preview of screen print display images
Verify	Choose whether to accept as final or defective product test result.
Load	Transmit the final test results to the base computer
All	Remove the conditional search and display all data

6.10.3 the STAT specimens (the priority torments the trial)

To test the results of the STAT (priority queue), click on the Result button.
toolbar to display the priority rack window. The items and functions of
the buttons are identical to those provided in the patient's test results
(specimen). For a detailed description of the items
And regarding functions, refer to chapter 6: The specimen in section 6.10.1 (patient).

6.11 To wrap

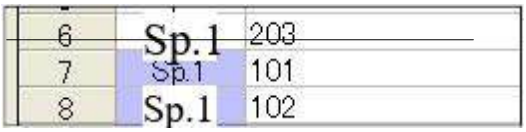
Enhancing the condition is defined in the flag and regulations, it is protected as follows, refer to chapter Section 8.4 Utilities - Flag and regulations provide indicators.

Enrich

Enrich the specimen in the same analytes under the same condition.

2. Enrie (TestFileDil.)
   Dilute the specimen with the dilution breakdown into factors defined in fileTest and do it in the same analytes.
3. Enrie (panel)
   Enter the specimen in defined analytes in the panel
   It is possible to apply another dilution factor that is not defined in the Test file.

When I tested the results, they find the retest condition, send principles of mode. The cell color the turns blue.



After testing the process in all sample requests, the sample racks are rotated. quickly look for specimens to be tested again. The sample flies loaded as high as the corresponding barcode label is found. The specimen position it must be identical to the original position. The specimens sought are tested under the condition of retest defined above.

Order point specimens in the barcode code can be retested.

Make Enrie available once and for all for the specimen.
The request is rescheduled if the test has been requested.
The no-barcode asks for a screen and the result flag has been set as retest

Additional essay requests are not available during enrich mode. It is it is recommended that the reschedule function is used when additional requests are frequently need.
No sample flies out during the drying mode, or the specimens cannot. to meet.

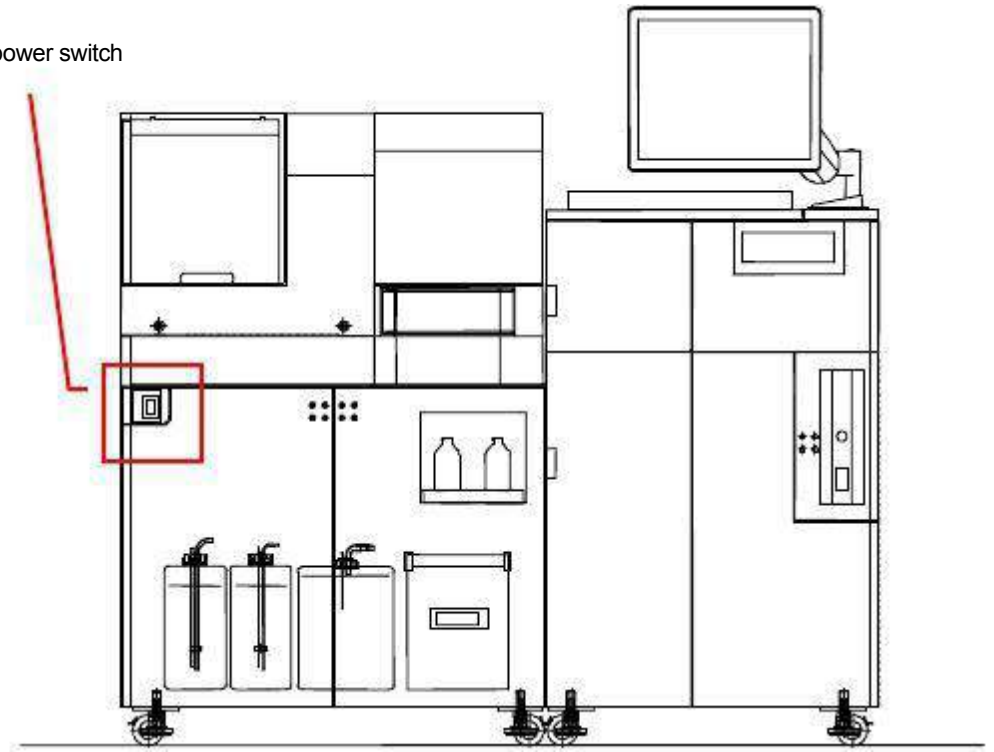
6.12 Emergency stop

It is recommended that operators execute an emergency shutdown of the system during the test. the operations when the possibility of the system that causes bodily harm and/or fire arises.

Turning the main power off disconnects the left side of the main unit.
Take first aid measures as necessary to limit each injury or damage.
Report all details of the incident to the nearest or local Tosoh service center. representatives and follow the instructions provided by the service staff.

Note that normal work shutdown routines will not be executed when the power The supply switch is used to end operation.
If the main power is disconnected during a tips transport, the tips It will be loose at that time as the tip transportation bomb will be power of a the same time.
Before disconnecting, abort the AIA-2000 application software by pressing the Try the Stop button on the toolbar and press the Stop button additionally on the appeared unexpectedly for the dialogue box essay except in the emergency.

Main power switch



6.13 Close

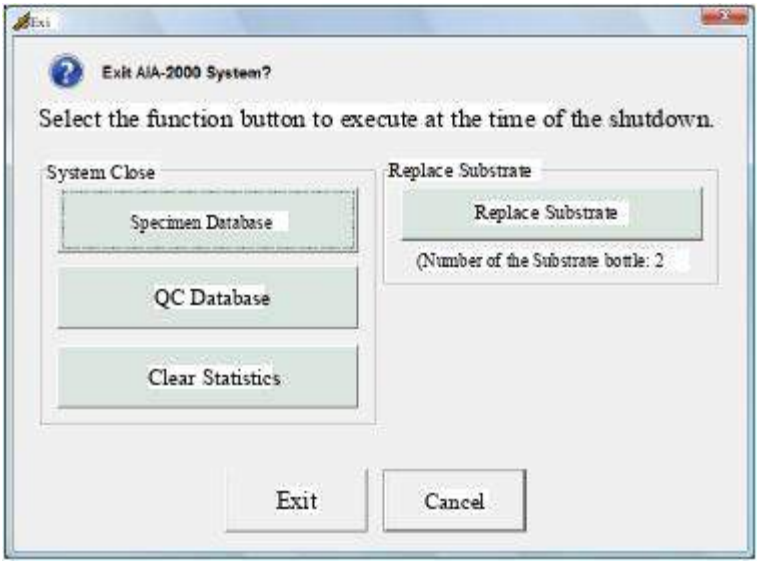
When they finish testing operations, they refrigerate the specimens, test cups, and others. Materials that deteriorate at room temperature. Prepare the substrate lines with the Substrate the replacement solution (70% ethanol).

Quite specimens of the sample charger and reagents (conjugate, the sample Dilute the reagent for solution and pretreatment from the reagent carousel and transfer. to the refrigerator. Cover the top parts of the reagent bottles that use parafilm. etc.

They test all the cups of the classifier and transfer the test cup to the refrigerator.

Transfer the substrate bottles to the refrigerator and replace with the substrate. the replacement solution (70% ethanol) bottles.

(4) Click on it. The button was located at the upper right of the screen.

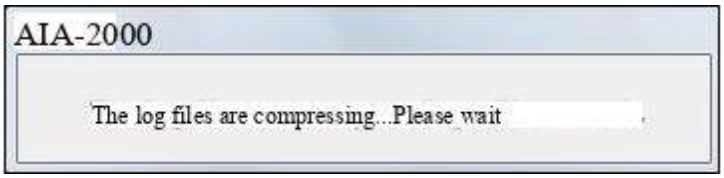


Click on the Database button to execute the system shutdown.
Click on the Replace Substrate button and click the Exit button.

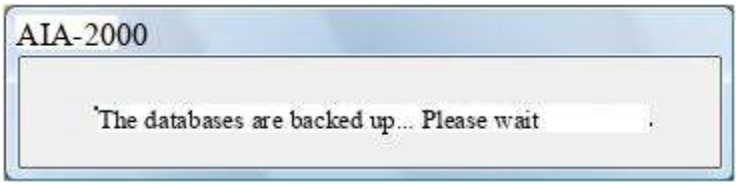
The specimen contains data from the testing of STAT specimens (the priority

Torture the essay), the specimens and routine control specimens. Base of data from The QC contains QC data.

It is recommended that the specimen database is closed daily.
Files and databases will be automatically uploaded supported by closure.
the system shows the following message. (trunk files are compressed and) saved.

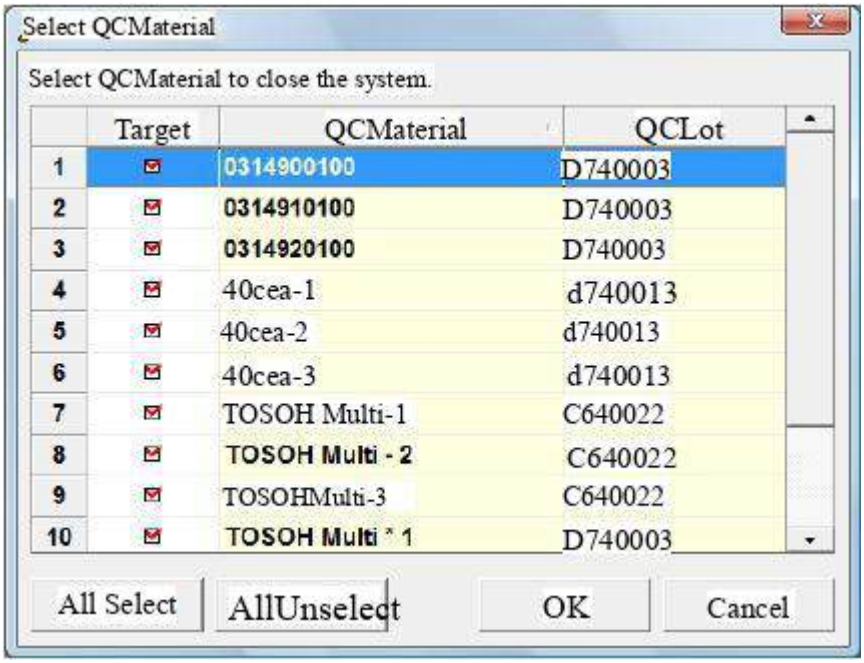


Databases are uniformly supported upwards when the system closure does not the following message is displayed.



Point it out with your finger - it is recommended that the QC database be closed according to the terms of Quality control.

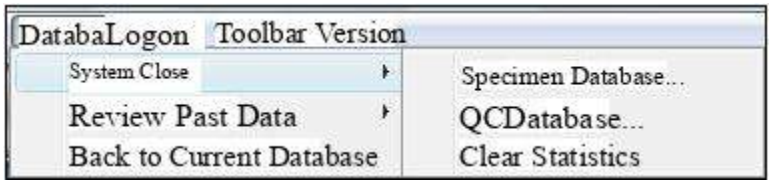
Database system closure of QC selects the QC material for closure target of the system after entering the filename to save, and clicking on OK button.



Point with your finger - the species database can be saved by clicking on 'database' in the menu bar:

and choose the database to close. If the database is saved, a new database data will be opened.

The QC database is the same process as the database of specimen. It was recommended that the QC database is closed according to the terms Quality control.



- Note that new test operations cannot be executed until the system is closed in cases where the current number of trial results exceeds 10,000.
All specimen results must be confirmed before the database.
The specimen is closed, or recalculation cannot be executed.
Please note that when the QC database is closed, the base switches...
data for a new one and data in the previous database is not recoverable.

Please check and change the bottle for the replacement substrate solution (the 70%) The ethanol) before execution.

The program closures when this procedure has been completed. Turn off the main power.

Close Windows Vista.

6.14 Measures at the time of the hourly power failure (the power failure at the moment of the no-rehearsal)

6.14.1 Request for legal instrument (AIA-2000) for method

I changed the substrate bottles for the substrate replacement solution (70% ethanol) bottles.Lleve a cabo de trabajo escriba en el capítulo 6: 6.13 cierran

6.14.2 Restoration process

Ensure that the power has been restored.

(2) Carry out the work write in chapter 6: 6.1 system startup and chapter 6: 6.2 Daily verification after switching the power supply of the AIA-2000.

The essay can be started.

6.14.3 Reagents

Handle the test cups and other reagents, closing the operation as usual.

written at home Chapter 6: 6.13 they close

Diluent and wash solution can remain in the AIA-2000.

Change the Substrate line to the substrate replacement solution (70% ethanol) and refrigerate the remaining substrate.

Refrigerate cups, test calibrators, and other reagents (conjugate it, the sample diluting Solution reagent and pretreatment.

6.15 Measures at the moment of sudden power failure (the power failure at the time of the rehearsal)

6.15.1 At the time of power failure

Return the power supply of the AIA-2000 and keep it off until the power is restored.

When a power failure occurs during testing, the AIA-2000 is shut down in mid. From the operation. Do not take sample racks drawn in less than the AIA-2000 when the The power supply is going out. There is a possibility that components of the AIA-2000 They can be damaged by taking samples flying in this way.

When it is expected that a power failure will continue for a long time, change the The substrate bottles to the substrate replacement solution (70% ethanol) bottles. (the Substrate in the Substrate line is not replaced with replacement solution } Substrate.) It is recommended that the substrate be refrigerated.

6.15.2 Restoration method

Ensure that the power is restored.

(2) Carry out work write in chapter 6: 6.1 system start-up after turning in the power supply of the AIA-2000.

(3) Because the AIA-2000 was closed mid-operation, click on the ready house. button in the operation panel (toolbar).

Ensure that the ready house is completed without any errors. In case of error, refer to A4: Appendix4–the error messages.

(5) Because there is the case that the specimen is in the AIA-2000 rack, click outside. button on the operation panel (toolbar).

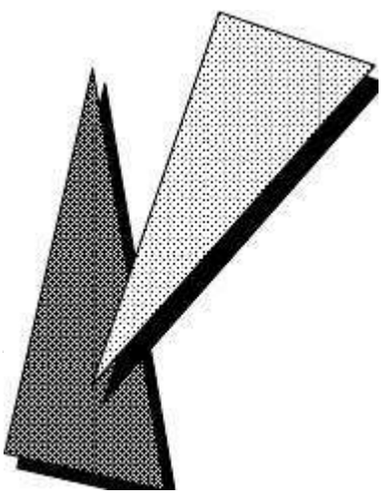
Carry out work write in chapter 6: 6.2 check daily.

The control is tested and the result is verified to be within the limits.

If there is no problem, start the usual essay.

CH 7

Maintain System precision

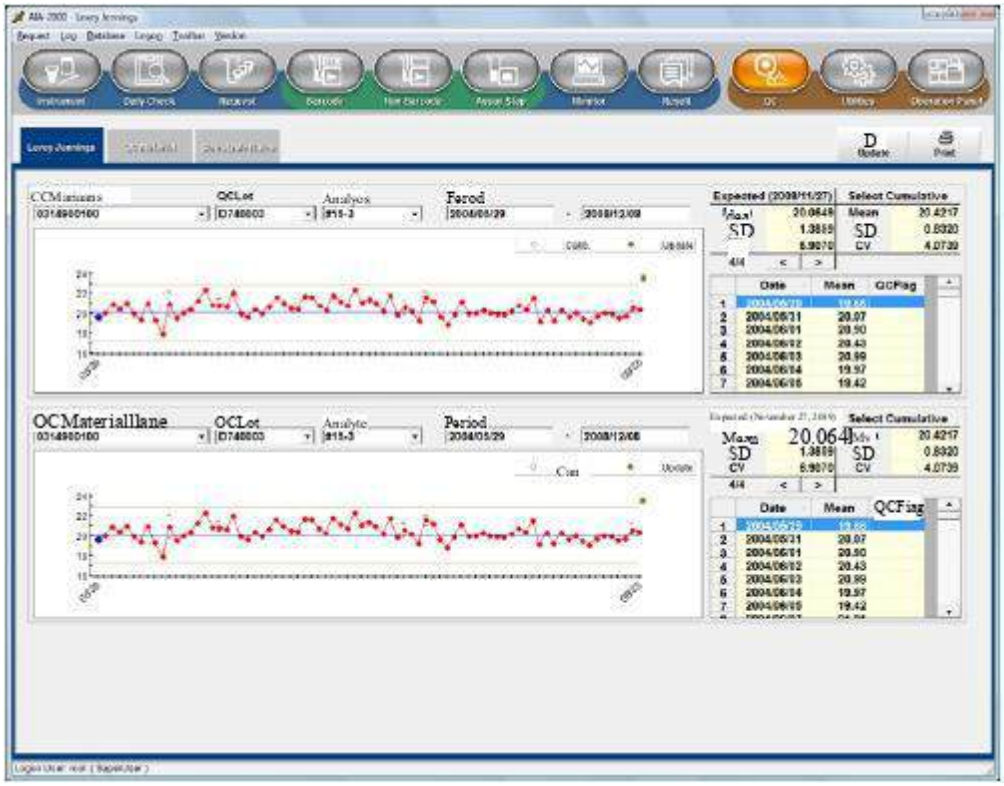


7.1 Levey - the map of Jenning

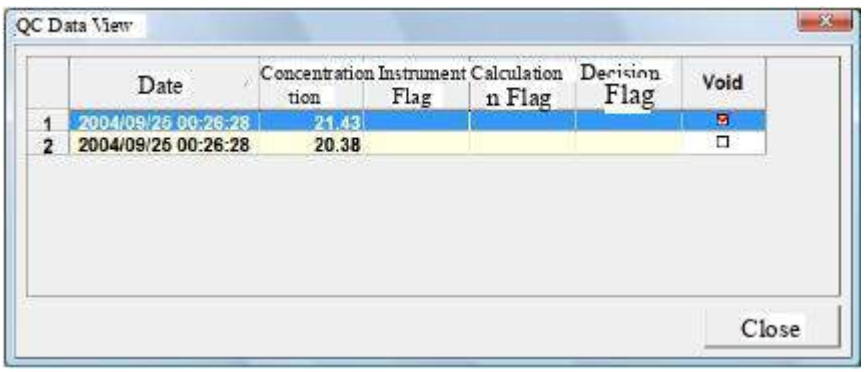
Shown on the screen below is the Levey-Jennings chart, which shows control of the assay resulting co-determined by the combination of 'Analyte-QC lot material No.' as well as related statistical information.

- **The data shown in the Levey-Jennings chart corresponds to the finalized data.**

  The essay is required for the controls requested as the QC materials. This includes also finalized the data file as the calibration verifies.



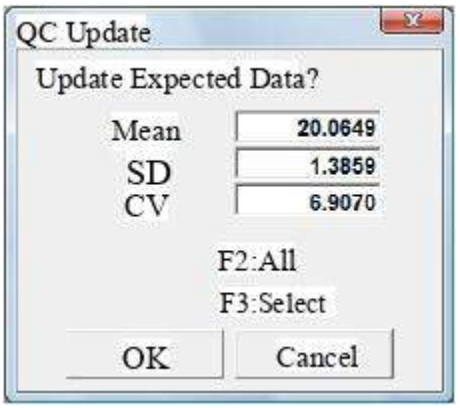
The previous screen is the Levey-Jennings chart that can be displayed by selecting material. of 'QC Name, QC Lot and Analyte'. The daily Levey-Jennings map data is shown on the right of the screen. Double-clicking the mouse button on a cell shows a dialog box that contains detailed data, which may be accustomed to deleting the data unnecessary. The administrator's authority is required to delete unnecessary data. The R1 to the Evaluation of the R6 flag results, that it is entered using the regulations of select QC provide. indicators should be displayed in the form of a chart and a worksheet. Also shown in the chart it is the calibration record.



The period is used to set the date range for the displayed Levey-Jennings map.

The Update button (QC update) is used to update the average, SD, and CV values.

(expected values), as well as the Levey-Jennings chart.



Point **Pressing the F2 key enables 'expected' values (which means, SD and CV) to appear in the Entry method. Pressing the F3 key enables 'Select Cumulative' values (meaning, SD and CV) to appear in the entry form.**

Statistical information

Control range (estimated)

Date: The updated date

Average: The estimated average value (corresponds to the meaningful value of the draw the graph of). If the value is not updated, it is determined by it the following formula that uses the values of low and high depression of that range

I have entered the QC material in the register.

Signifies = (go through the + highest fix below) / 2

SD: The estimated standard deviation value (corresponding to the SD value of the graph). If the value is not updated, it is determined by it.

the following formula that uses the values of range and high depression of that rank

CV: I have entered the QC material into the register.

SD = (average height array) / 2

Estimated CV%. If the value is not updated, it is determined by it

the following formula that uses the values of low and high range depression from range that has entered into the registration of QC material.

CV = (SD/means). 100

Show from the period (choose cumulative)

This is a statistical value for the graphical display period (date range). The Meaning data for a simple day is calculated as a simple article.

Point Average: Mean value

SD: Desviación estándar

CV: CV%

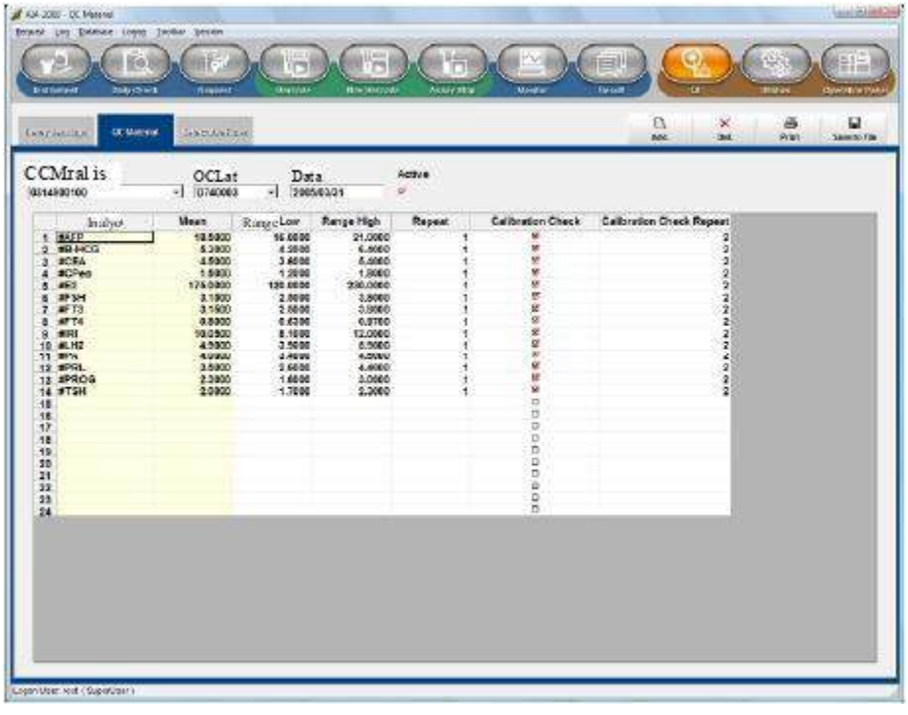
Specification window of the utilities in the toolbar may be accustomed to specifying the display of three items. For information on placements what enters, refer to chapter 8: Section 8.1.4 Other placements.

When an analyte is selected in an analyte box by pressing the CTRL key, the control data with the same analyte but with different large amounts of the QC material can be show in the other control maps.

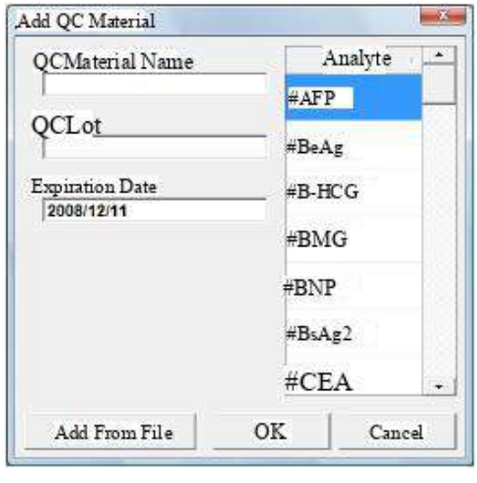
7.2 Register QC materials

The material record of QC must be carried out before any control test requests.
materials.

Click the QC button on the toolbar to display the material window.
QC.



(2) Click on the added button and the following dialog box will be displayed. To add materials, between the material name, distribute No. and the expiration date and choose the analytes checking the boxes, then click on the OK button.



The Add button File is used to enter material QC data previously.
saved files.

■ Point **The note that separates with a dash (-) cannot be used for the QC material they name or throw out.
lucky numbers.**

Between the upper limits and the more acceptable lower limits for each analyte in the range depression high-ranking cell.

(4) When measuring simultaneously, monitor the materials during calibration, check the
The calibration checks the cell and the repetition includes the calibration to check the cell.
repetition

If the button is clicked on the currently displayed material, name and distribute none
erase it.

7. Maintain system accuracy

[illegible]

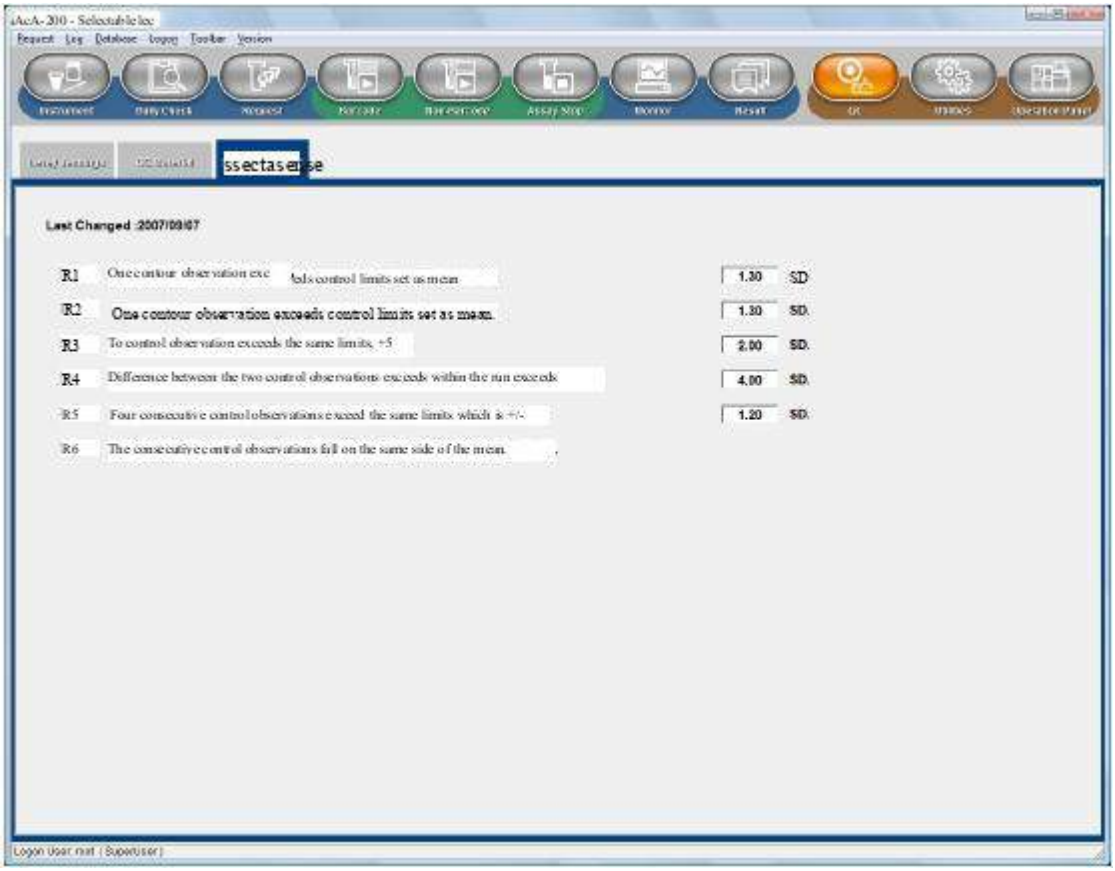
only one can be rehearsed at a time. In this case, the entirety of the number with the asset

- **The verified checkbox specifies the QC material that will be tested.**

The control material to be used for quality control operations must register first as a QC material. Note that control material results unregistered will not be used as QC data.

7.3 Selected Regulations

They are used to setting the control range and control governing for QC materials.



Regulations

The result is R1-flagged when a control observation exceeds the SD value. specified.

R2: The result is R2-flagged when a control observation exceeds the SD value. specified.

R3: The result is R3-flagged when two consecutive control observations exceed the specified value of SD.

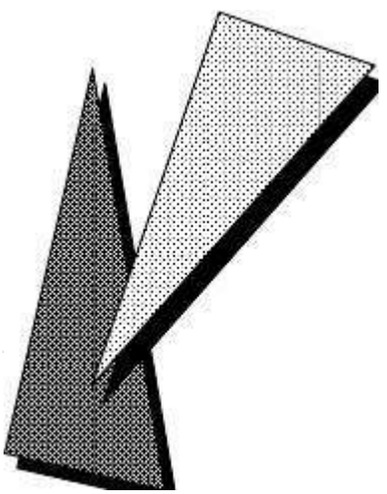
R4: The result is R4-flagged when the difference between the two consecutive controls the observations exceed the specified SD value.

R5: The result is R5-flagged when four consecutive control observations exceed the specified SD value.

R6: The result is R6-flagged when ten consecutive control observations touch the same side of the average.

CH 8

Other aspects of the operation

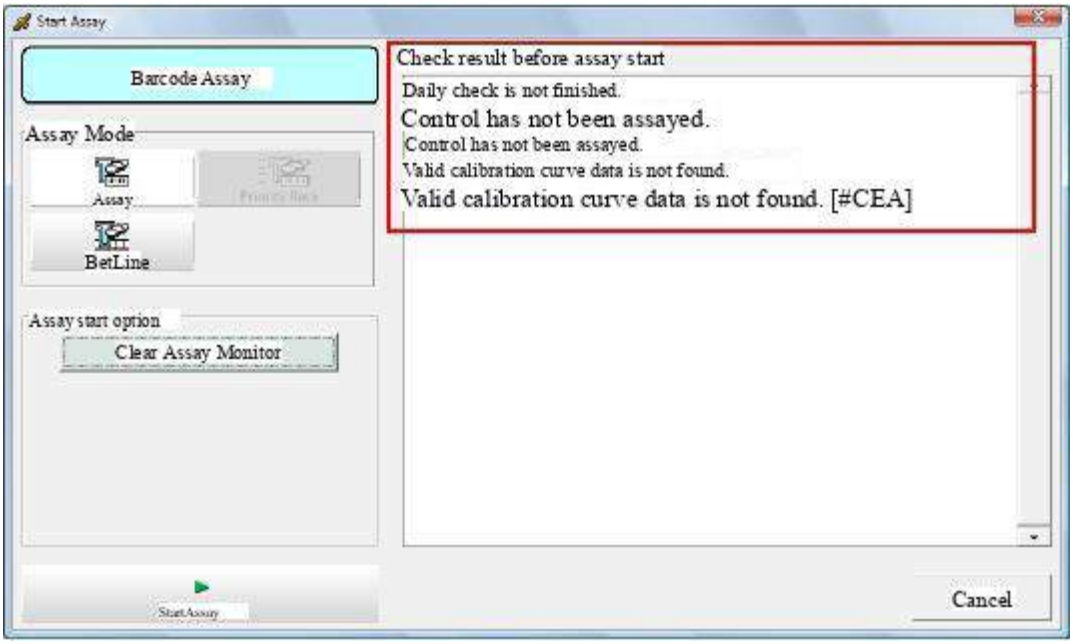


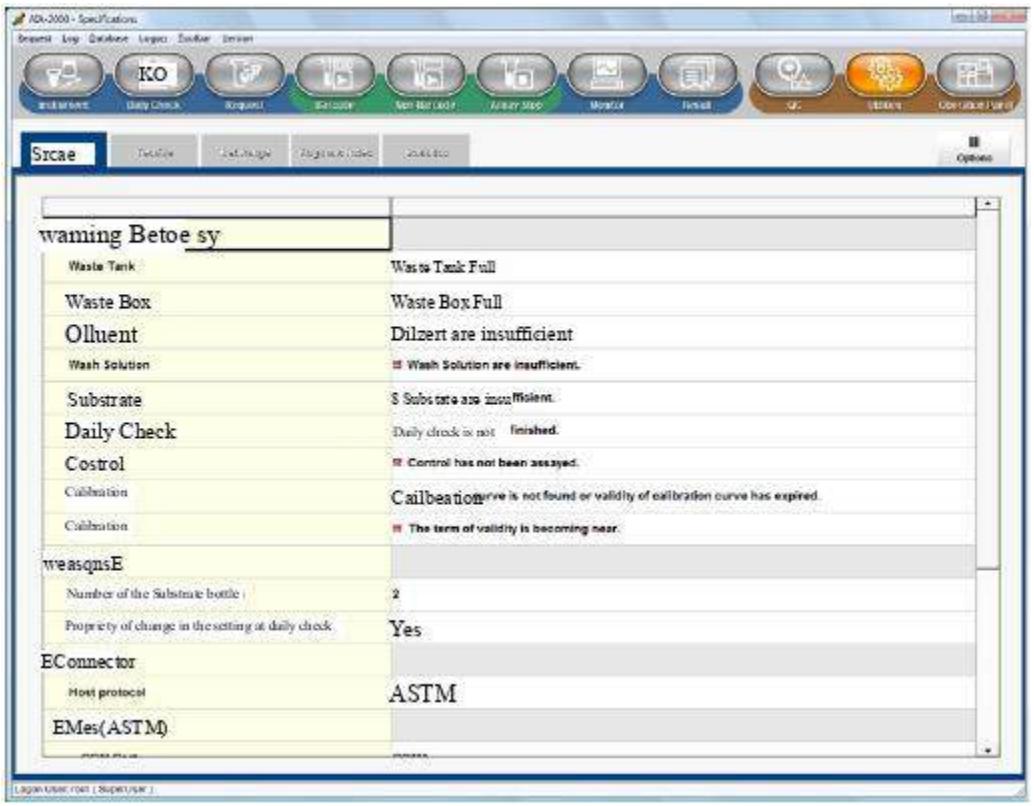
8.1 The utilities – the specifications window

The specification window is used to enter parameter placements on the AIA-2000.

8.1.1 Arrangements of the verification result before the test begins

The articles that will show warnings before the test principles can be choose. When an item corresponds to a warning, the warning is displayed in the dialogue of the verification result before the start of the test.



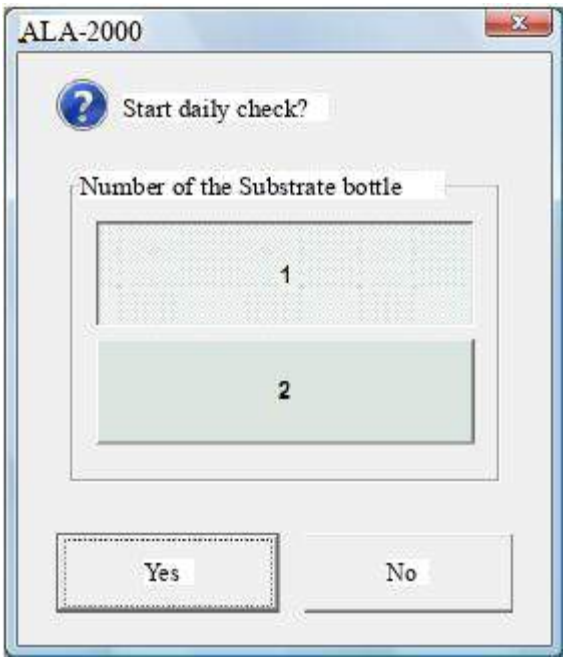


Desert tank The warning is displayed when the empty tank is full.
Empty box The warning is shown when the empty box is complete.
Thinner tank The warning is displayed when the thinner is insufficient.
Washing solution tank: The warning is displayed when the washing solution is insufficient.
Substrate The warning is displayed when the substrates are insufficient.
Daily verification The warning is displayed when the daily check was not complete.
normally.
Control The warning is displayed when the control is not tested.
Calibration curve: The warning is displayed when the calibration curve is not found or
the validity of the calibration curve has expired.
Calibration curve: The warning is displayed when the calibration curve is expired.
close.

8.1.2 Placement of substrates

Es posible preparar el número de las botellas de substrato para usar o el decoro del cambio from the placement at the time of the daily verification.

Number of substrate bottles One bottle or two bottles
Decoration of the change from placement to daily verification: None or yes



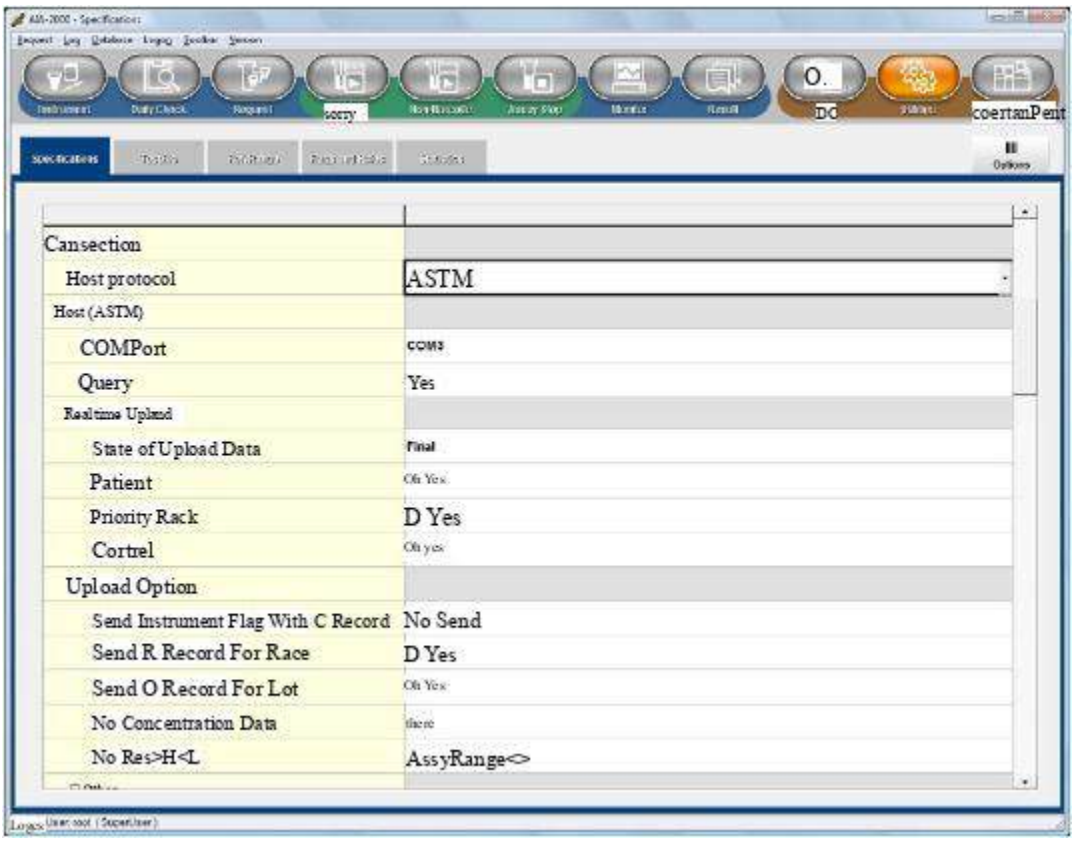
Cauti

If the mode changes from the 2 bottle mode to the 1 bottle mode, the base of the substrate-2 should be measured.
Please carry out the daily verification.
In case of 2 bottle mode, when testing operations has been completed, prepare the Substrate line with the substrate replacement solution (70% ethanol) not only the substrate-1 alignae is but also the substrate-2 alignae is.

8.1.3 Base computer connection

Communication with the base computer is conducted using an RS232C cable and ASTM. E1381-91 and E1394-91 compatible transmission interacts or uses Ethernet and The OpenLA21 standard (HL7 Ver2.4) compatible transmission interacts. Notify Tosoh service center or local representatives if the specifications are more Detailed communication between the AIA-2000 and the base computer is needed.

8.1.3.1 ASTM standard



Host question status

The AIA-2000 system starts by reading a specimen ID and issuing a question to PC controller that checks its inventory of generating samples is requested and returns the relevant one. information to the AIA-2000. If the equalization information is found, the controller's PC issues To ask the base computer.

Load in real time

Specify the types of specimens (whole or final) for which reports are issued to the host computer when the essay is complete.

Load option

Send the hanging instrument with C Record

This specifies whether or not to send instrument flags.

Send to the R registrar for the index

This specifies whether or not to send index values.

8. Other aspects of the operation

No data concentrations

This determines the way in which the date is announced instead of the concentration when none the concentration is obtained.

No result (> h, <L)

This determines the way in which the data is reported instead of the concentration when the The result is ">H" or "<L.".

The test range of fileTest (upper limit and lower limit) is included in reports.

when the essay The rank is chosen.

The symbols are added to the report when they test the range (<>). Choose one.

RS232C and protocol placements

The placements are entered here to configure the transmission link with the base computer.

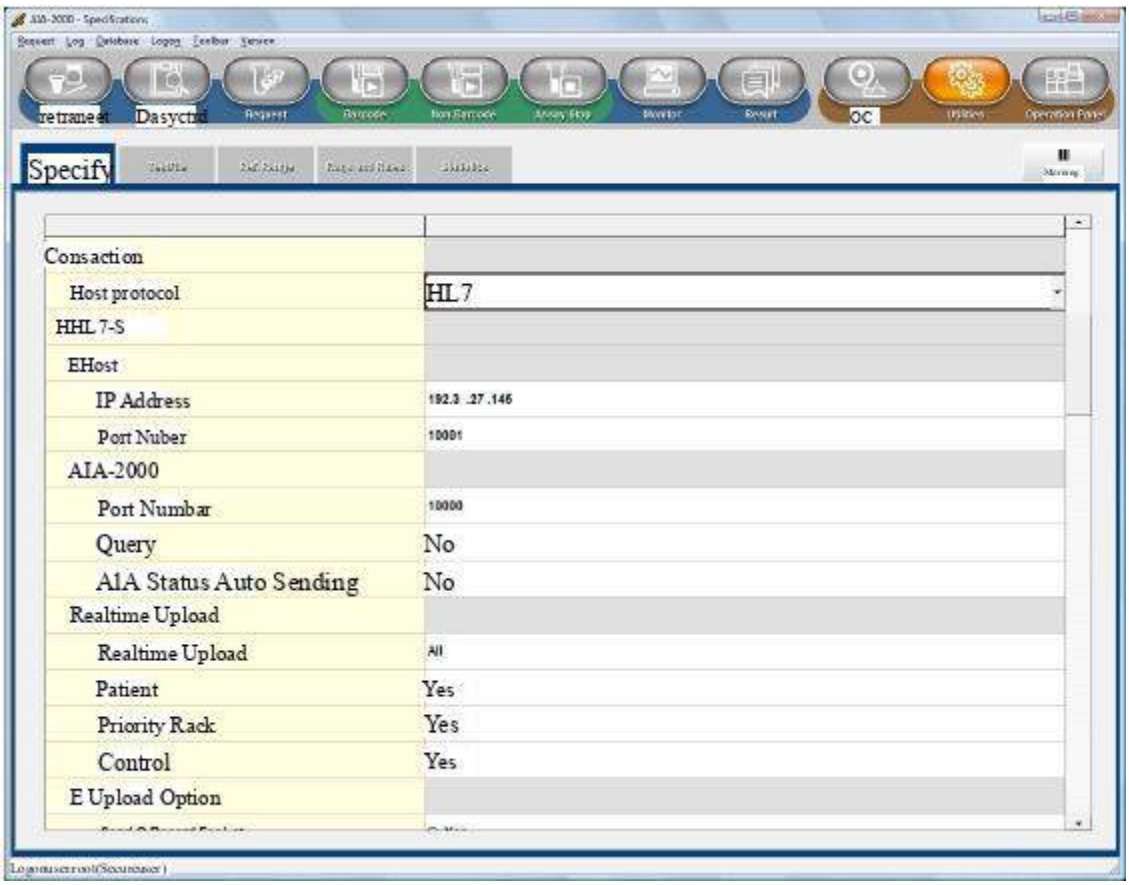
The placements entered here should not be changed once the connection is established.

Within parameters according to the specifications of the base computer.

[illegible]

parameter placements.

8.1.3.2 OpenLA21 Standard (HL7 Ver2.4)



Connection placement

Placement of the IP address of the base computer and the port number between the AIA-2000 and the base computer.

AIA-2000 Setting

Port number

Enter the port number.

Question

First, the AIA-2000 system reads a specimen ID and issues a question to the controller PC. Then the PC checks the essay they ask to generate and store it and returns the the relevant information regarding AIA-2000. If no similar information was found, the the PC controller sends a question to the main computer when the 'Yes' button has been pressed chosen.

AIA Status car transmission

Determine if the status of AIA-2000 is sent to the LIS periodically.

Load in real time

Specify the types of specimens (patient, priority flying or controlling) for which the reports They are sent to the base computer when their tests are completed.

Load option

Send to the registrar for the batch. This specifies whether or not to send the reagent batch.

No data concentrations

This determines the date on which it is announced instead of the concentration when none. the concentration is obtained.

No results (> h, <L)

This determines the way in which the data is reported instead of the concentration when the >H or <L.

The test range of fileTest (upper limit and lower limit) is included in reports. when the essay The range is chosen.

The symbols are added to the report when they test the range (< >) choose it.

■

Point **Exit the system program and restart the system in order to validate the new one. parameter placements.**

8.1.4 Other placements

Other placements can define the number of analytes that can be displayed, auto of Calibration accepted, the Levey-Jennings map number and paper size

Number of analytes that can be displayed: Maximum 24 analytes

It is possible to display up to 24 analytes.

The calibration car accepts Automatic or manual

This parameter chooses whether the calibration curves are accepted automatically or manually.

Choose 'Automatic' the media that the calibration curve generates should be used to do Concentration calculations for all controls processed in the same operation. The new calibration the curve is automatically accepted if it has been included in the higher ones and further down limit specify on the QC Material screen.

Select 'Manual' to enable the operator to view the calibration results in the calibration. protect and choose to accept the calibration curves.

Levey-Jenning's Chart 2 or 3 control view

The Levey-Jennings Chart showed on a screen that it can be switched to two or three displays for compare a control map.

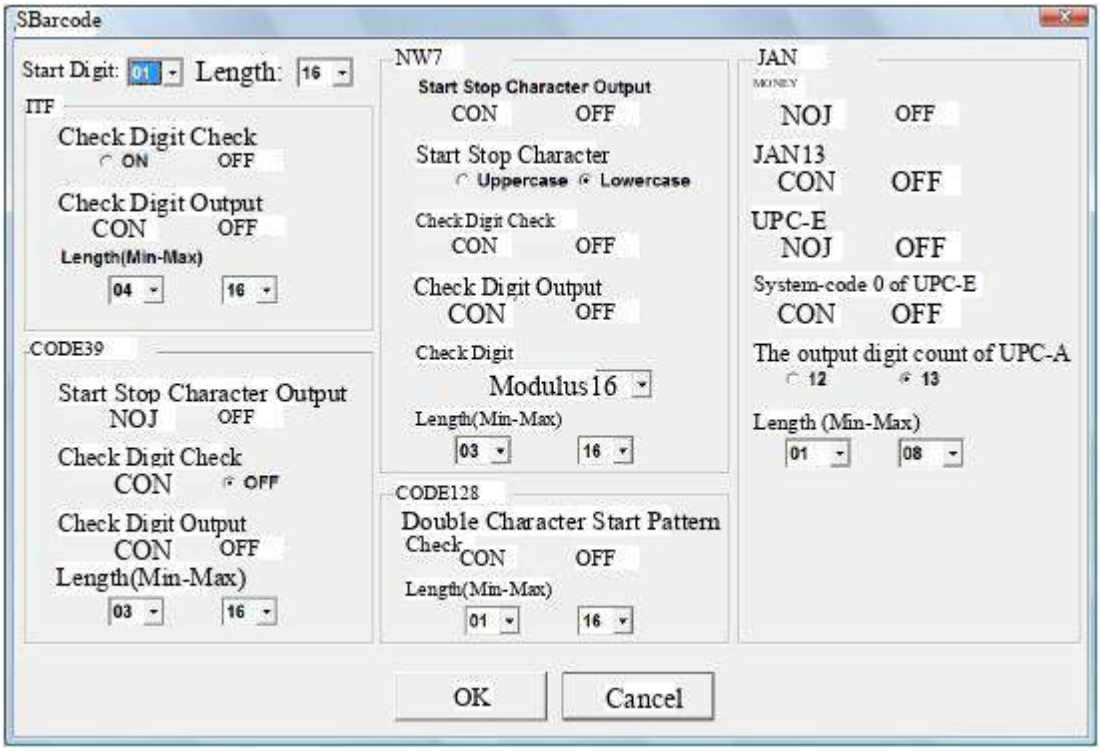
Paper size A4 or letter

A4 is the implicit page size for report prints.

8.1.5 Barcode placements

The AIA-2000 system is designed to operate with a maximum of four different types of barcodes in a time. Between parameter placements according to the type of barcode and specifications. Note that ITF conventions must be observed for all the Tosoh calibrators that use the ITF barcode format.

Click on the options button on the specification screen.
This shows the following screen.



Selected parameters for each barcode type.
Click on the OK button.

Starting digit

Indicate the first digit, use for the specimen IDs in barcodes in the Specimen containers.

Length

Indicate the valid digit length used for specimen IDs in barcodes. specimen containers.

Example: When the leading digit is 3 and the effective length is 10, the specimen ID for the barcode '123456789ABCDE' can be '3456789ABC'.

For a detailed description of the barcode parameters, refer to chapter 11: Appendix 2: Barcode Placements

8.2 File Window Utility Test

The fileTest window is used to enter the test parameter in the form for the individual analytes. For a detailed description of the fileTest parameters, refer to Chapter 10: Appendix 1 Test Files.

Because the test file directly affects the results of the trial, only users with the level The administrator is granted authority to view and edit all parameters of fileTest.

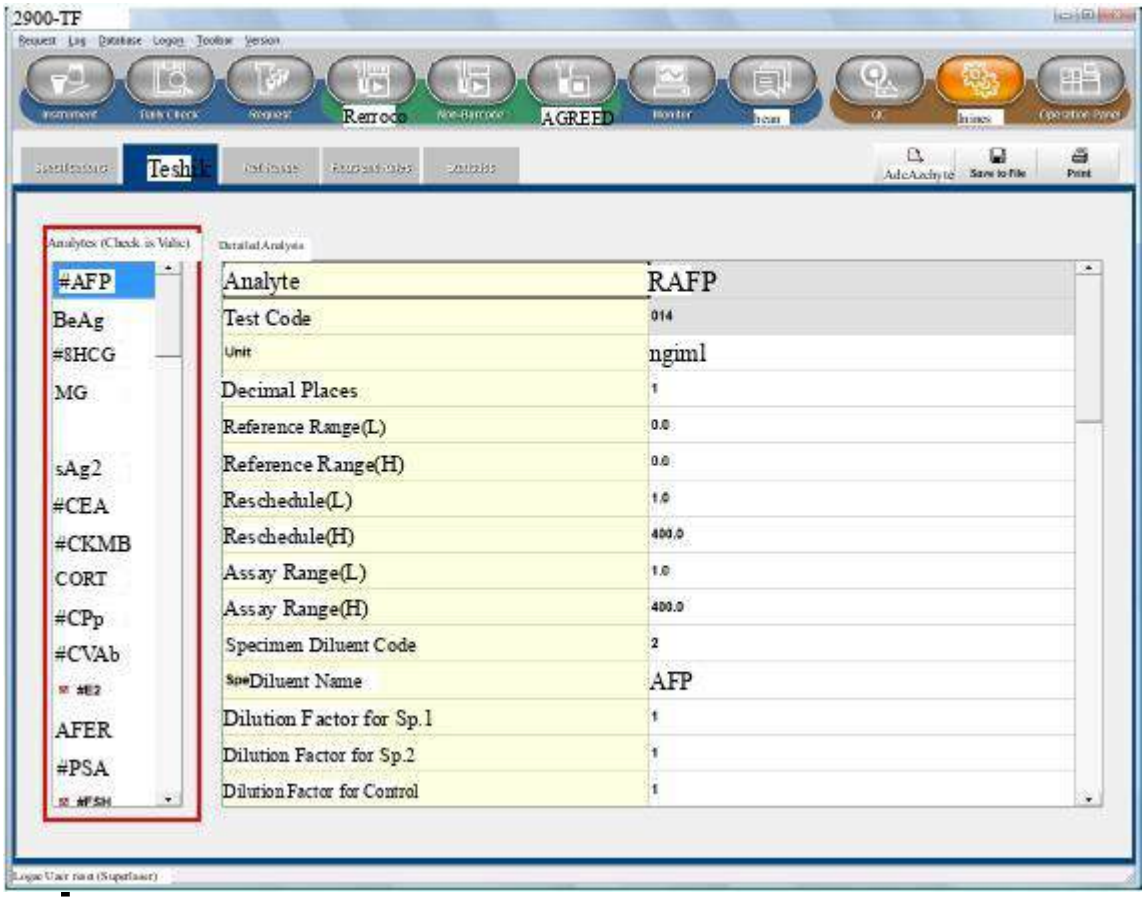
8.2.1 Test file

Before starting test operations, it is necessary to prepare the analytes used in the AIA-2000 as the valid system analytes. The analytes verified on the list of the Valid analytes are on the left side of the screen.

The valid analytes can be selected from the test request screen.

Click on the utilities in the toolbar to display the file window Test.

Go to the list on the left of the fileTest providing indicators and select the boxes of verification along with the desired analytes.



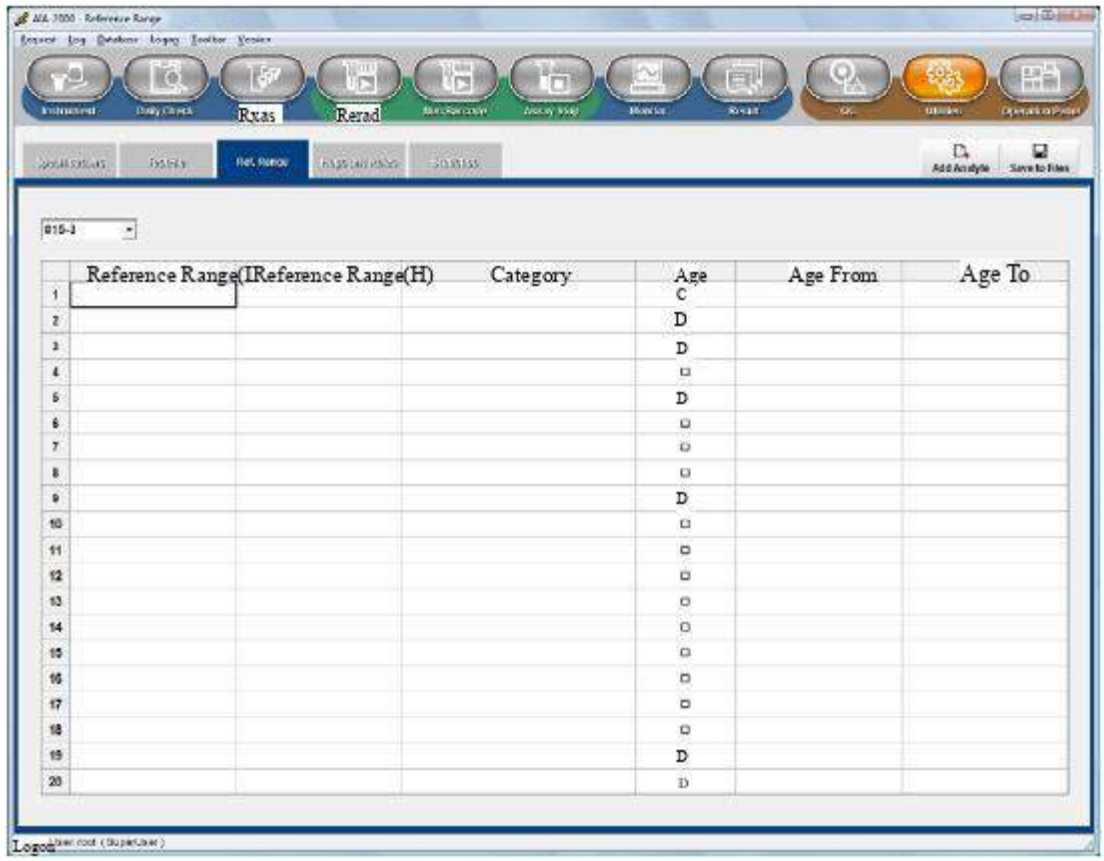
Click the Print button to display a print preview.

8.3 The utilities –refer to the range window

The reference range window is used to enter reference placements.
for the individual analytes.

8.3.1 Placement reference range

The AIA-2000 provides a function that enables users to define the reference range
Specific according to grouping by age and gender.
Flag verification is executed based on the 'reference range' entered in the files.
Test. However, please note if the 'reference range' cells shown are selected.
In the "Ref.Range" window, the entered values will replace those in the files.
Test. Therefore, users should be recommended to limit placements to only analytes that
demand yourself.



A caution

**Use this function in strict compliance with the instructions provided by Tosoh.
to ensure the exact verification of results.**

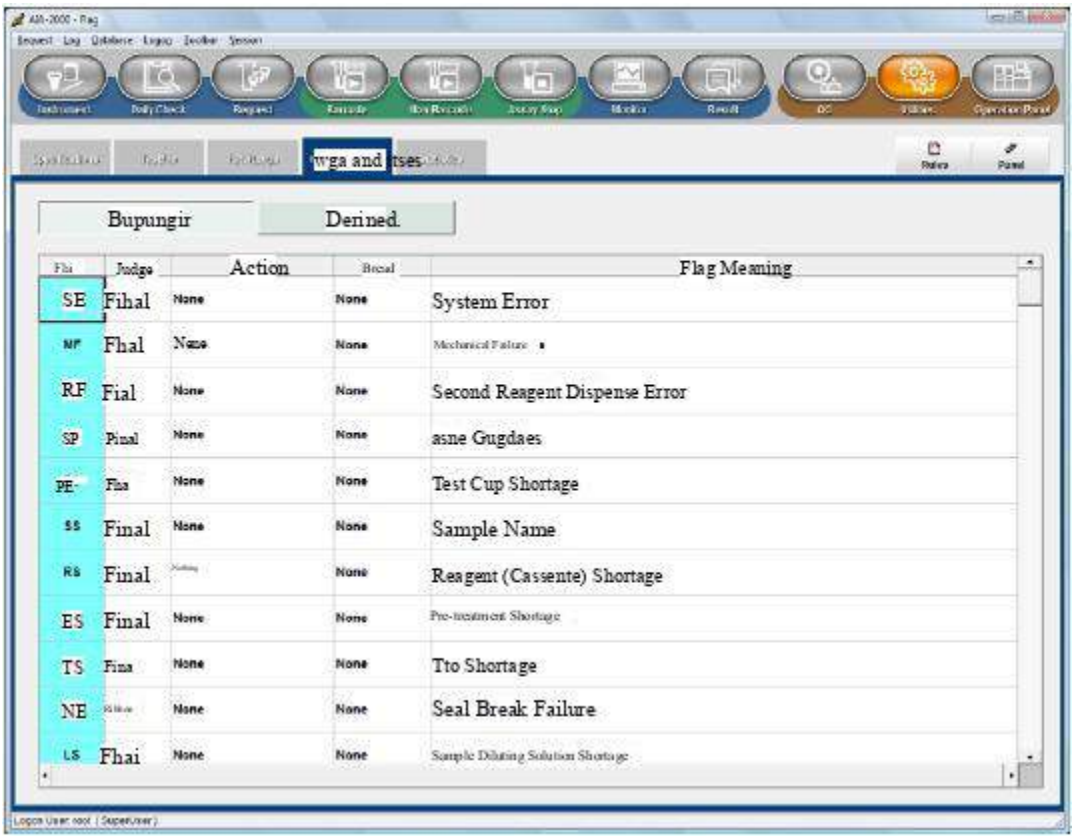
8.4 The utilities - the flags and regulations provide indicators

8.4.1 Flags

The flags and regulations provide indicators that are accustomed to entering the criteria. to determine if the test results are completed, they are automatically processed with the specified operations.

(1) Click on the utilities in the toolbar to display the flags and regulations provide indicators.

The status (judge) and specified operations (action) should be defined for each flag, such as shown below.



Choosing the pending all button assigns the "Pending" status to test all results.

Choosing the defined button activates the specified operational placements for each flag. Completed the trial, the results are either assigned a status or automatically issued a request the reschedule processing, depending on the placement of the flag.

Flag: (for a detailed description of flags, refer to chapter 12: Appendix 3: Flags) Judge: (status of test result)

Final
It indicates that test results are accepted and established as final.

Defective product
Indicate that test results (excluding those for calibrators) should be rejected. status when the test results are rejected on the results screen.

To depend
Indicate that trial results depend on the additional decision.

Action: (definable flag operations)

Enrich
Automatically generates the reassay request and starts the testing operation.

Enrie (heart of TestFile)
Automatically generate reassay requests based on the dilution factor in the file.
Test and start the trial operation.
When "Retest (dil deTestFile)" is determined for ">H" of the flag, a request for
reassay will be automatically created with the dilution factor used in the previous cycle of
multiply by the number that is placed in the 'Default for > H' multiplier
the file TestWhen will be determined for 'DO' of the flag, a reassay request
It will be automatically created using the dilution factor used in the previous test cycle.
multiplied by the number that is placed in the 'Default for DO' multiplier in the file
Test When to be determined for another hanging apart from above, a request for reassay
It will be automatically created with the dilution factor used in the previous test cycle.
Multiply by the number that is placed in the 'Dilution' factor for each specimen
(SP1 or SP2 or Control) in the Test file
The maximum dilution factor is 1000 times.

Enrie (panel)
Automatically generates reassay requests based on a reschedule panel and
They start the trial operation. The reschedule panel is registered in the button list.
panel can be selected in the list cell to the right supports. Reschedule Panel
Refer to '8.4.3 Dialog' in this chapter for rescheduling jury placement.

Reschedule
Automatically generate reassay requests for the tests with flags in the
previous cycle essay.

Reschedule (heart of TestFile)
Automatically generate a reassay request based on the dilution factor in the
TestWhen "Reschedule (dil deTestFile)" is set to ">H" of the
flag, a reassay request will be automatically created with the dilution factor
used in the previous testing cycle multiplied by the number placed in the
multiplier of 'Default for > H' in the Test file When being determined for 'DO' of
the flag, a reassay request will be automatically created with
the dilution factor used in the previous test cycle multiplied by the number set
in the multiplier of 'Default for DO' in the Test file
When being determined for another hang apart from above, a reassay request will be
automatically created with the dilution factor used in the previous testing cycle
multiply by the number that is placed in the 'Dilution' factor for each specimen
(SP1 or SP2 or Control) "in the Test file The maximum dilution factor is 1000 times.

Reschedule (panel)
Automatically generate a reassay request based on a reschedule, choose juror.
Register on the Panel button. The panel can be selected in the cell list to the right.
8.4.3 Reschedule Panel Dialog in this chapter for the reschedule choose jury placement.

Panel: (defined in the panel dialogue)

The priority flags are shown to be in service of the highest priority flag at the top of the list.

Flags 01 to 99 are all the definable user flags. The various criteria of flag verification has been entered using the regulations button.

8.4.2 The regulations converse (the regulations button up)

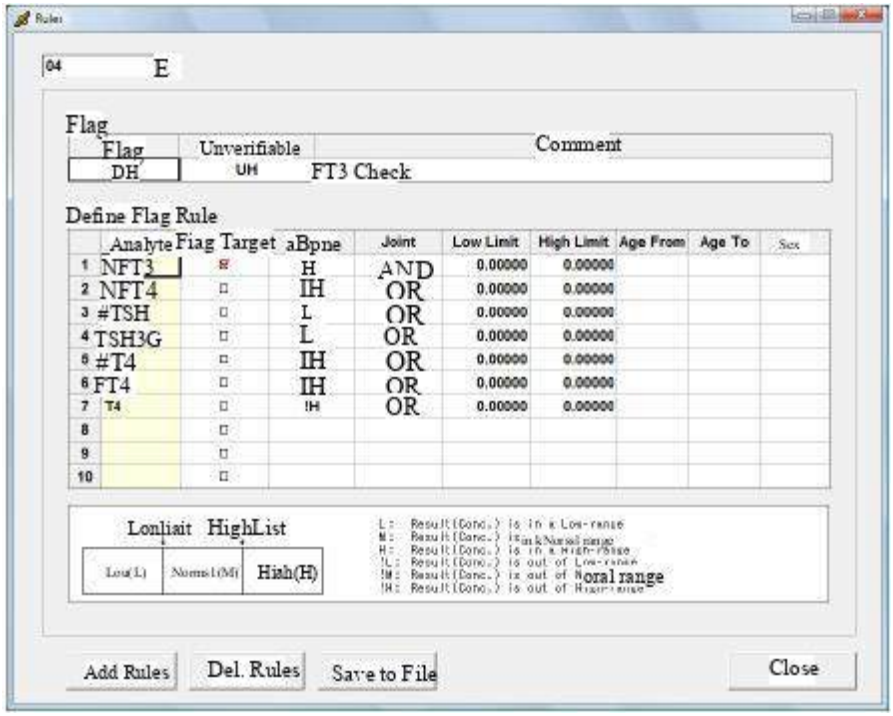
The regulations can define the final judgment governing a defined flag.
user.

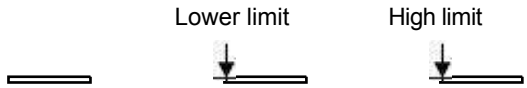
8.4.2.1 The verification governs for user-defined flags

The verification governs for the user-defined flags among the regulations.
dialogue (button). Flags can be assigned to test the results that satisfy the
specific verification criteria. Multiple individual criteria can be defined for
the tiling.

caution **Use this function in strict accordance with the instructions provided by Tosoh for ensure the accurate verification of results.**

Flags 01 to 99 are user definable and can be assigned a name (alphanumeric) of two characters. The flags can be assigned different names depending on whether they are close to their verification criteria or the verification criteria were not applicable.
The verification results for flags 01 to 99 should be displayed at the decision flag position in the Result screen.
The verification criteria can be defined according to the analytes that have been applied, the assigned analytes, the conditions, age, and gender.
As the verification screen guide illustrates, if the target is included in the depression (L), state Normal (M) or high (h) the range is determined by the use of the criteria. The low and high limit here This reference range (L, h) of the analyte and the values can be modified.





La depresión (L) El estado normal (m) el alto (h)

Types of criteria.

L The result (Conc.) is in a low range.
M The result (Conc.) is within normal range.
H The result (Conc.) is in a high-ranking one.
! L:Result (Conc.) is out of lower range
!M: Result (Conc.) is out of normal range
! H:Result (Conc.) is out of high range

8.4.2.2 The verification data that enters takes shape

(1) Place the analyte to be assigned the flag in the first row and click on it. checkbox flag objective.

(2) The reference range for the Test file is typically entered using the 'Low limit' and "Limit" altovalores (the values entered when the analyte was first entered use it by default.

(3) With verification criteria, the verifiers (L, m, h, !LA L, !LA M, !la h) shown in the the lower section of the screen is used to select the type of result values for to hang oneself.

Coupling (4) conditions 'Or' and 'And' to be provided and used as per the the following procedures.

when there is one or zero of the analyte to be verified, apart from those I assigned the hang (the combination conditions are not applied):
Analyte assigned the flags to be flagged when all the results of verification is 'True' (the articles are ignored if the target checkbox of the flag has not been chosen.

<2 > cuando allí está los analytes múltiples para verificarse, aparte del un asignado la bandera (and the combination condition is 'Or'):
When the analyte assigned the flag as 'True,' other analytes are verified at home.
Sequence to determine if your status is True/False/No Result/Not examined.
(See Case A.)
When 'True', find the analyte hangs and verification ends.
When "False," the analyte is not flagged and verification ends.
If all analytes are 'No Result,' the analyte hangs with the 'Unverifiable' flag.
If all the analytes are 'Not Tested,' the verification ends without the analyte being hanging.

<3 > when there are multiple analytes to be verified, besides the assigned flag (and the combination condition is 'And'):
When the assigned analyte marks the flag as 'True,' other analytes are checked at home.
sequence to determine if your status is True/False/No Result/Not examined.
(See Case B.)
In this case, all the analytes are verified.
If all the analytes are 'True,' the analyte hangs.
If any analyte is 'False,' the analyte does not hang.
If any analyte is 'No Result,' the analyte is flagged with the 'Unverifiable' flag.
If any analyte is 'NotTested,' and there is no 'No Result,' the analyte is not flagged.

The verifications are carried out to the point where they test all required results by the specimen at home the question has been completed.
The test results include the following indicators

Normal state of result: Test result of the detected concentration. Results

DO, >H or <L
. In the case of DO, the concentrations are verified as either very high or very low, depending on the calibration factor.

No result: Indicates inability to determine the concentration.
This is for cases when the entire system hangs and the arithmetic flags (NC, CE, DL, BH) assign yourself.

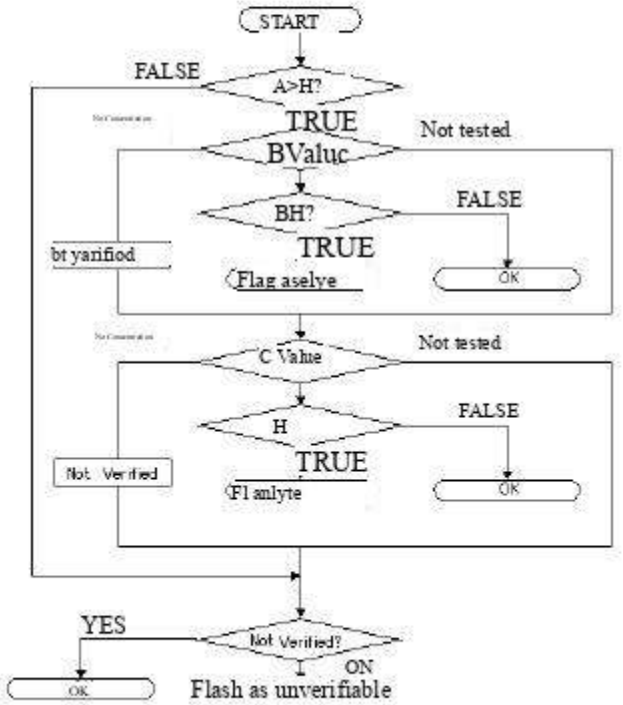
No examine: Indicate which analyte was skipped instead of being examined due to SS or PS. status.

Package A

Define Flag Rule

	Analyte	Flag Target	abpnr	Joint	Low Limit	High Limit	Age From	Age To	Sex
1A		☑	H	AND	0.00000	100.00000			
2B		□	H	OR	0.00000	100.00000			
3C		□	H	OR	0.00000	100.00000			
4		□							
5		□							
6		□							
7		□							
8		□							
9		□							
10		□							

A>HandB>HrA>HandC>H



When the values for A of analytes and b are high, or when the values for A of analytes and c are high, the analytes hang.
When no concentration is detected for analytes b and c, the analytes are not verified and the "Unverifiable" the flag is applied. In this case, the b of analyte takes priority over c of analyte and thus the c of analyte is not referenced when the concentration is detected in B. of analyte
If the 'Unverifiable' flag is not required, it can be disabled by not entering a placement for that name.

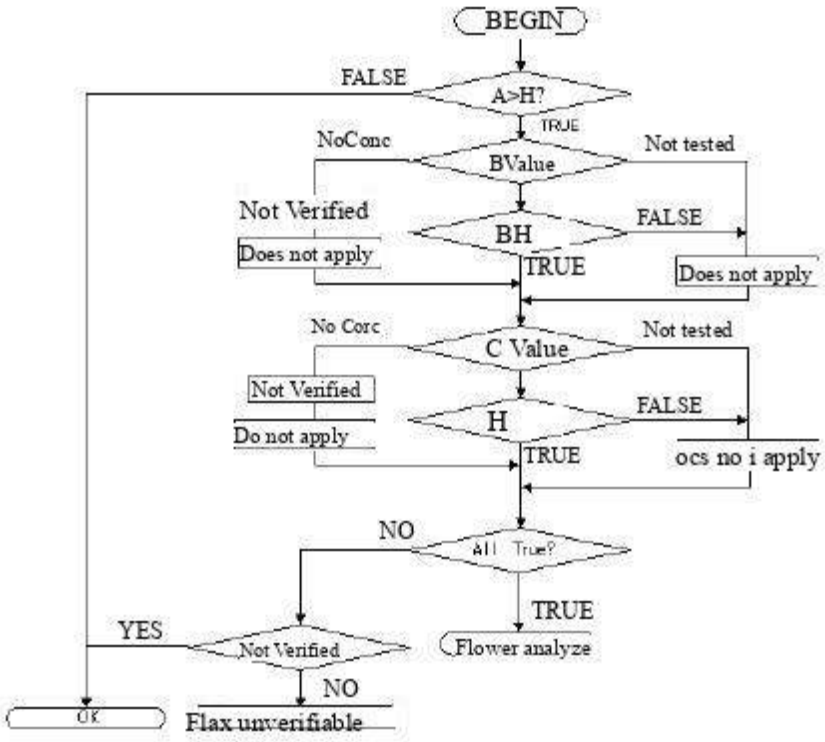
8. Other aspects of the operation

Case B

Define Flag Rule

	Analyte	Flag Target	Judge	Joint	Low Limit	High Limit	Age From	Age To	Sex
1	A	☑	H	AND	0.00000	100.00000			
2	B	☐	H	AND	0.00000	100.00000			
3	C	☐	H	AND	0.00000	100.00000			
4		☐							
5		☐							
6		☐							
7		☐							
8		☐							
9		☐							
10		D							

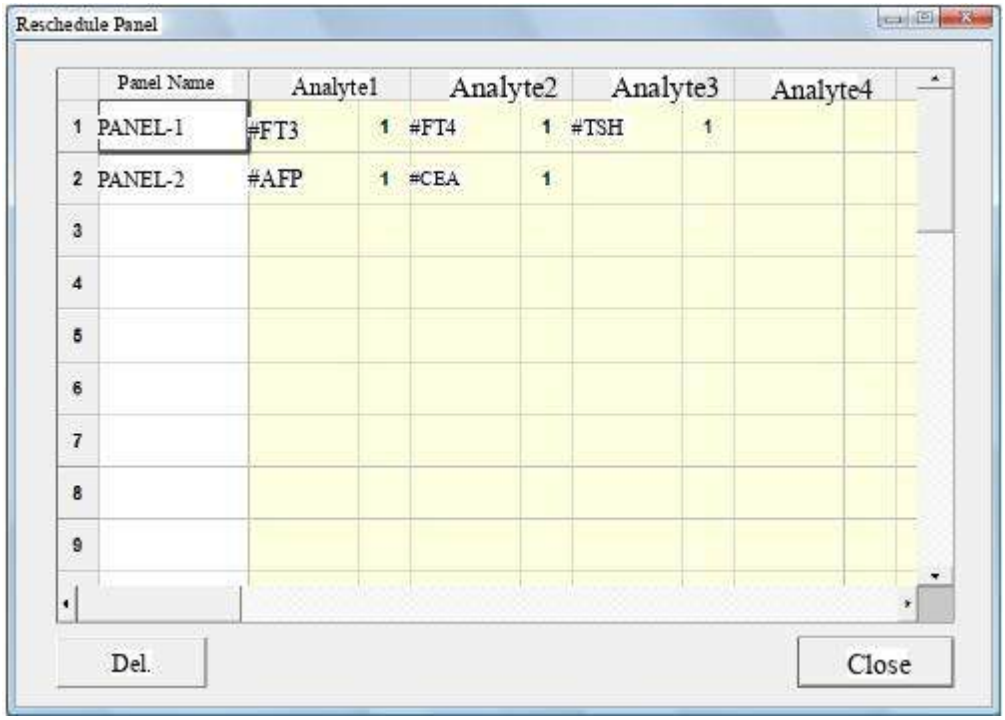
AHandB>HandCH



When the values for A of analytes, b, and c are high, analyte a hangs.
When no concentration is detected for b of analytes or c, analyte a not verified and the "Unverifiable" the flag is applied. If the "Unverifiable" flag is not required, it can be disabled. not entering a position for that name.

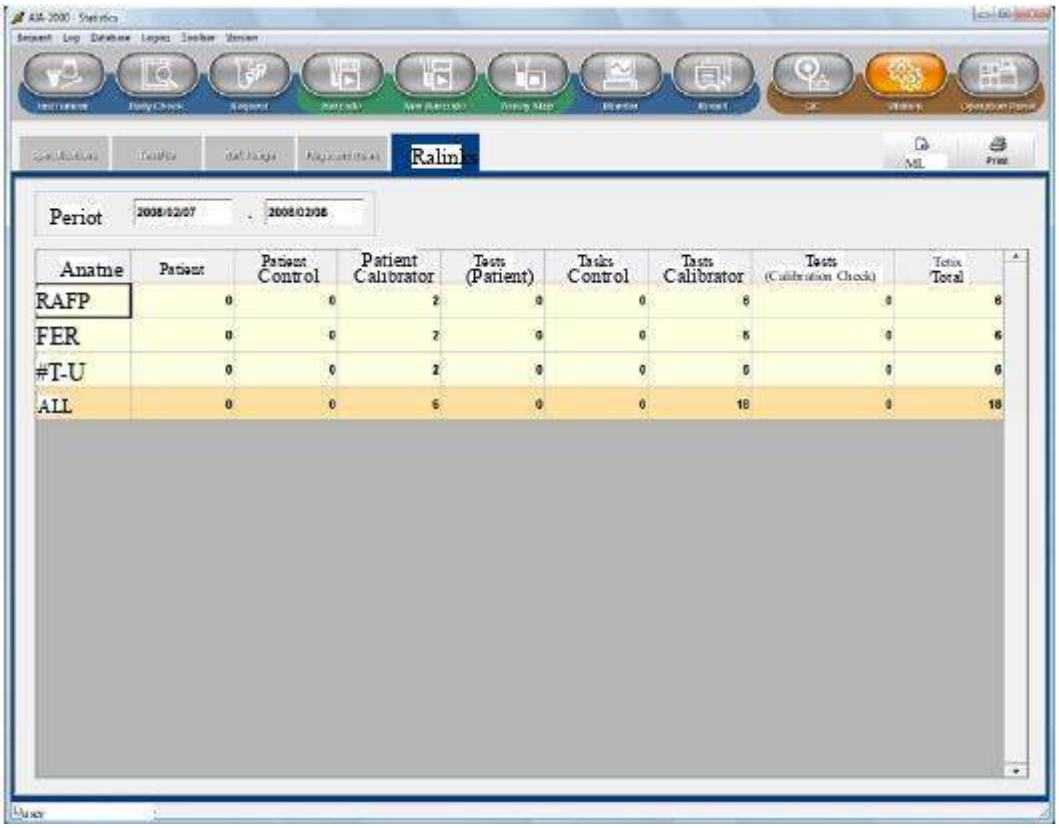
8.4.3 Reschedule the panel dialog (panel button)

The Reschedule panel dialog can define the rescheduling panel name. The Reschedule panel is used when rescheduling samples for new tests will be based on different dilution factors. The reassay operations for executed are defined in the flag and the regulations provide indicators. The operations that use panels should specify the name of the rescheduling panel.

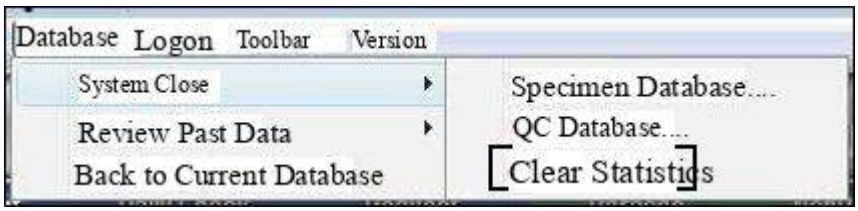


8.5 The Utilities - the statistics window

The statistics window is accustomed to collating the monthly totals for specimens and
Used test cups. The number of 'Patient Sample' does not signify the number of patients tested.
pero el número de todo ensaye las muestras que incluyen muestras, controles, calibradores pacientes y
calibration verification materials.



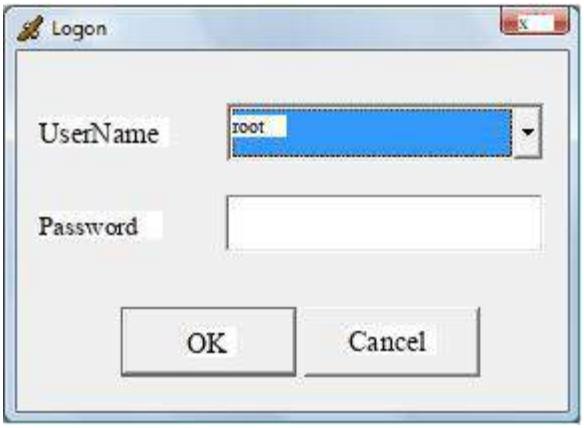
Statistical data can be clarified by going to the database menu and selecting the system.
close, followed by Clear statistics. Note that you cannot choose specific information
to clarify, but you must clarify all the information instantly.



8.6 Changing Operators

The login in the menu bar is used for the system entry. It is important for
log in to the system as the administrator in order to be able to access all the required menu
shield and execute the necessary actions. In addition to system boot, the input utility in the
The system can be used while changing operators as long as the system is in operation.

Choose the entry menu in the system from the menu bar. The following screen is displayed.



Choose the username and password entry.
Click on the OK button.

8.6.1 Administrator/Operator Registration

(1) Salir el sistema AIA-2000 programa y empieza el programa de gerente de usuario de el Windows starts menu. In case the system administrator password is lost.
Yes, notify the Tosoh service center or local representatives.

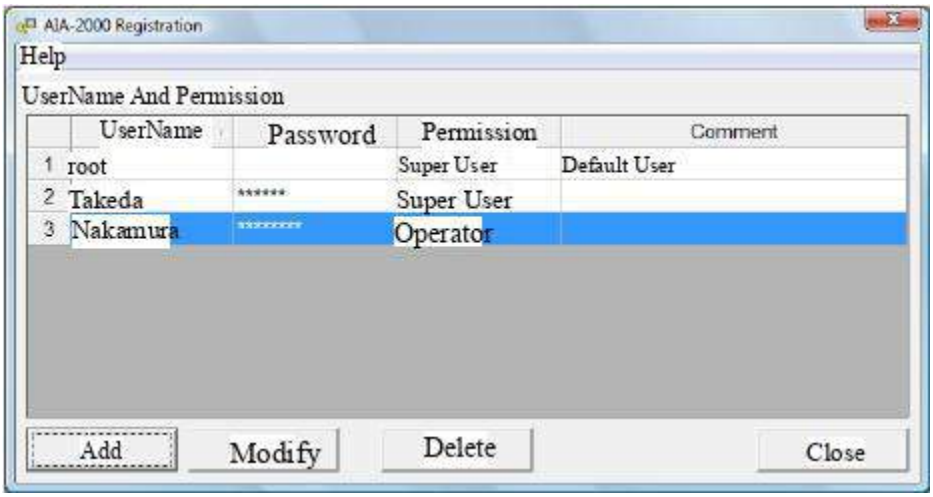
(2) Enter the necessary information by clicking on the corresponding cells displayed in the screen menu. User names can be entered consuming up to 32 characters alphanumeric.

Passwords are entered using up to 32 alphanumeric characters.
Administrators register as 'Super User' and test operators as 'Operator.'

- Register the required number of users (administrators and operators) for the AIA-2000
The factory default administrator username is 'root' without a password.

[illegible]

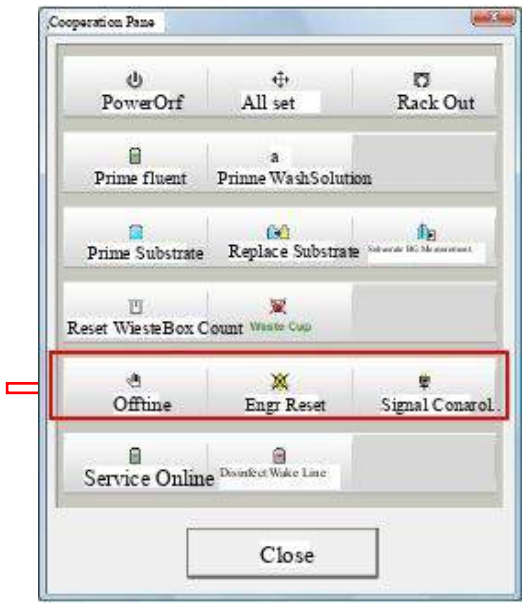
8. Other aspects of the operation



The user manager program is running.
Start the recently added user in the AIA-2000 system program. login screen in the system and enter the system.

8.7 Beltline Control

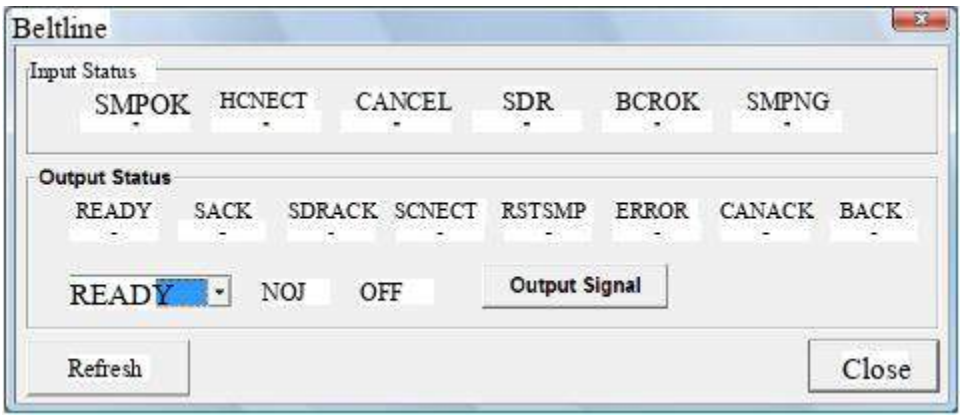
Three buttons on the operation panel (toolbar) are provided for only the model from the AIA-2000 System



Online/Offline	Enable the AIA-2000 to process specimens from the beltline I disabled the AIA-2000 process for specimens of the beltline.
Restart/Error Reset	Start again transmission specimens of the beltline Clear any errors that occurred during the operation with the beltlinea
Notable control	Exhibitions the following dialog box used to define the signal beltline configuration.

BeltLine Dialog (communicate the control dialogue)

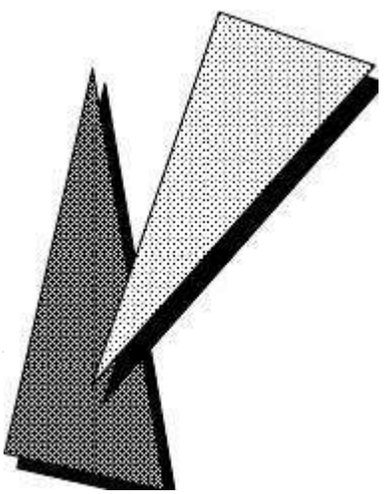
This exhibition communicates status, such as ON, OFF, or '-' in case of the unknown.



The BeltLinea dialogue is used for the maintenance of the beltline. It should not be used during normal operation. For detailed description, refer to the 'Beltline System manual.

CH 9

Maintenance



Implementing a regular maintenance program will ensure maximum optimal performance and safety. for the operation of the AIA-2000 system. Guidance on the correct maintenance procedures is provided during the installation process. Ensure that only properly authorized personnel are allowed trained, qualified to perform maintenance work.

9.1 Daily Verification

Always perform the daily check before starting the AIA-2000 system. On work stoppage of system, replace the substrate with the substrate replacement solution (70% ethanol) and use it to prepare the substrate lines.

Do not replace the substrate with distilled water. If it is left too long, this may Cause contamination of the substrate lines and increase the substrate base.

9.1.1 Clean the Substrate lines

If the white high (BH) the flag appears with the base of 4MU during daily verification, use The following procedures to clean the substrate lines.

(1) Replace the substrate bottle with the substrate replacement solution (ethanol of 70%).

Click on the Replace Substrate button in the operation panel (toolbar) tools) to start the substrate replacement sequence.

(3) Repeat the above procedure three times.

Prepare nitric acid with a concentration of 0.14 mol/L. (Concentrate mixed nitric acid) with distilled water at 1:100 they create an equivalent concentration.

Replace the substrate replacement solution (70% ethanol) the bottle with the acid. Nitric solution.

Click on the Substrate button of Replace in the operation panel (toolbar tools) to start the substrate replacement solution (70% ethanol) the replacement sequence.

Repeat the previous procedure three times.

Reinstall the replacement substrate solution (70% ethanol) the bottle.

Click on the Replace Substrate button in the operation panel (toolbar) tools) to start the nitric acid replacement solution sequence.

Repeat the previous procedure three times.

Replace the substrate replacement solution (70% ethanol) the bottle with the substrate bottle. Click on the Daily Check button in the toolbar and run the daily verification once more.

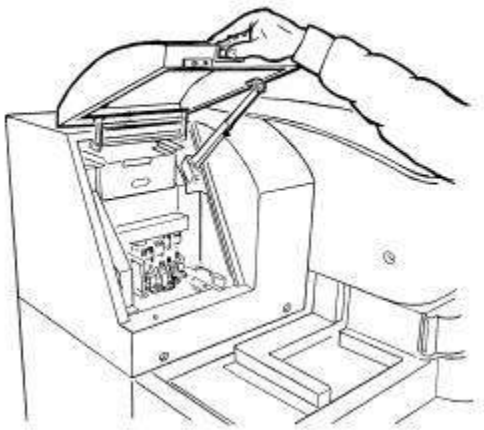
9.2 Weekly Maintenance

9.2.1 Clean B/F washing probes

9.2.1.1 Open the B/F cover unit

Ensure that the AIA-2000 is in stop operation, then press the Probe button. B/F (blade key).

After the lock is released, open the B/F cover unit.



(3) Close the AIA-2000 system program. (a dialog box prompting you to the substrate will appear. Simply ignore this (do not push any button) if planning to continue trial operations.

Turn off the main power.

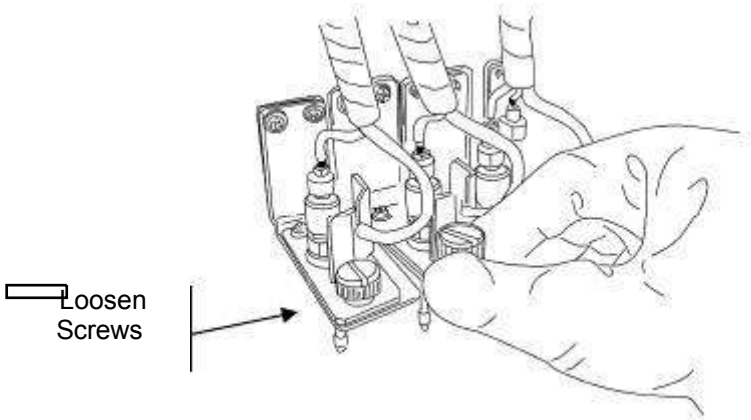
Caution

The tips of the B/F Wash probe are constantly in contact with specimens. that may contain infectious substances, they always wear gloves like this replace and clean probes.

Make sure to turn off the system power before carrying out the tasks. maintenance. Bodily injury can result from the gain caught while moving the parts mechanics of the system.

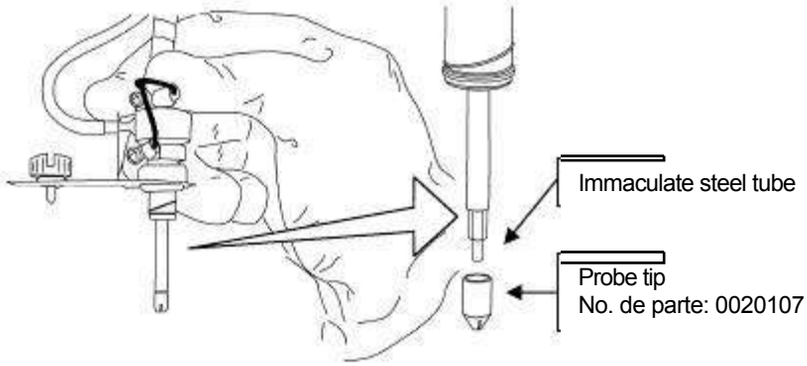
9.2.1.2 Remove washing probes from B/F

Loosen the securing screws for the B/F wash four, make adjustments and remove them. ascending upward.



9.2.1.3 Clean washing probes of B/F

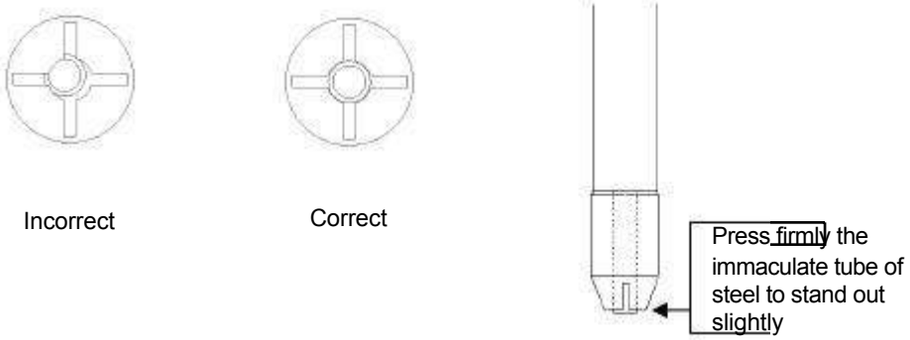
It is quite possible that the washing probe of B/F tilts from each of the washing probes of B/F.



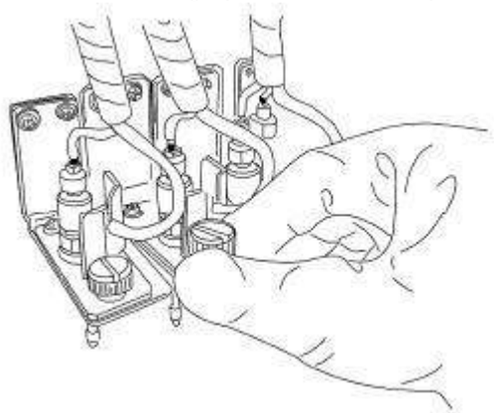
(2) Clean the withdrawn washing probe of B/F, it tilts for about 5 minutes in a neutral ultrasonic detergent bath, then rinsed with deionized water. If not yet I cleaned, replaced with a new probe they lean (separate No.: 0020107)

After cleaning, reattach the tipss to your probes.

The washing of The B/F is done by probing, the tips are firmly inserted with the pass. stainless steel tube through the center of the inclined probe the stainless steel tube the center should slightly extend past the probe tip when correctly positioned installed.



(5) Reinstall the B/F washing probes to their position and tighten the securing screws.



caution **The improper installation of the washing probe tips of B/F can cause the test. inexact results.**

9.2.1.4 Install B/F unit

Reinstall the B/F wash probes to their position and tighten the securing screws. Close the cover B/F unit.

9.2.2 Clean the substrate lines

If the substrate lines became test results dirty, inaccurate, it could cause,
execute the following procedures once a week to clean the substrate lines
after the end of the rehearsal.

Replace the substrate bottle with the substrate replacement solution (ethanol of 70%).

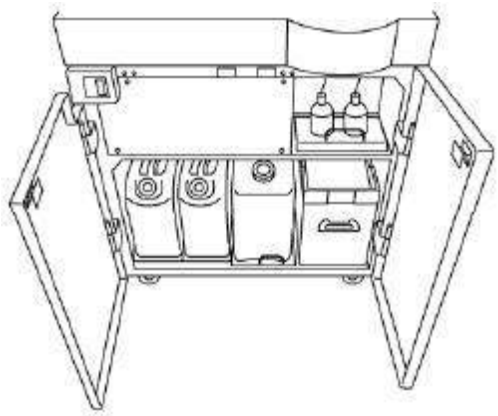
Click on the Replace Substrate button in the operation panel (bar of tools) to start the substrate replacement sequence.

Repeat the above procedure three times.

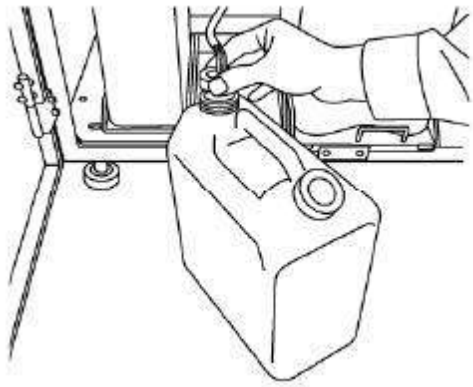
9.3 Mantenimiento mensual

9.3.1 Replace filters for washing solution and thinner

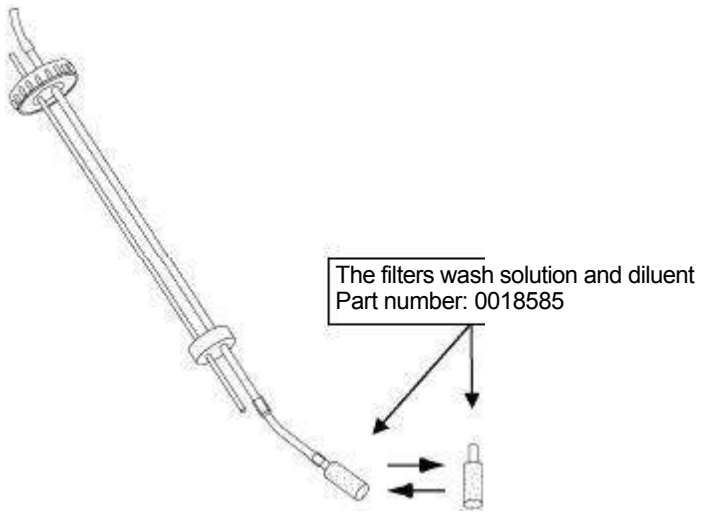
Open the wash solution and diluent compartment gently, hurrying in Inferior entrance doors of the AIA-2000.



Take out the 5-liter tank of washing solution or thinner and remove the lid from the side. where the tube is inserted.



(3) As shown in the figure below, remove the washing solution or attached diluent filter. at the end of the suction nozzle and replace with a new one. (separate No.: 0018585)

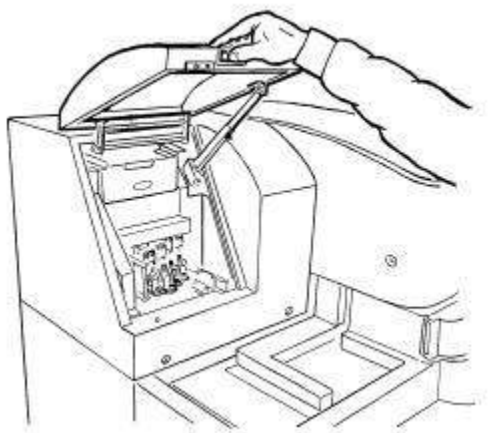


Screw the cover back onto the tank and return it to the compartment. Close the lower entry doors of the AIA-2000.

9.3.2 Replacing B/F washing probe tips requires trials.

(1) Ensure that the AIA-2000 is in stop operation, then press the Probe button. B/F (leaf key).

After the latch is released, open the B/F cover unit.

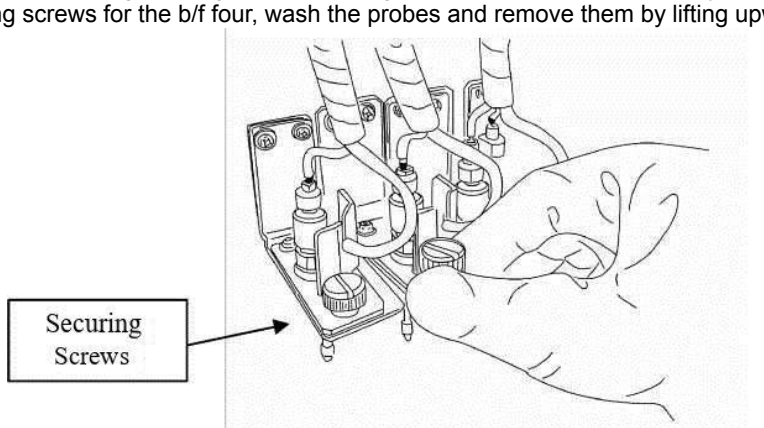


Close the AIA-2000 system program.

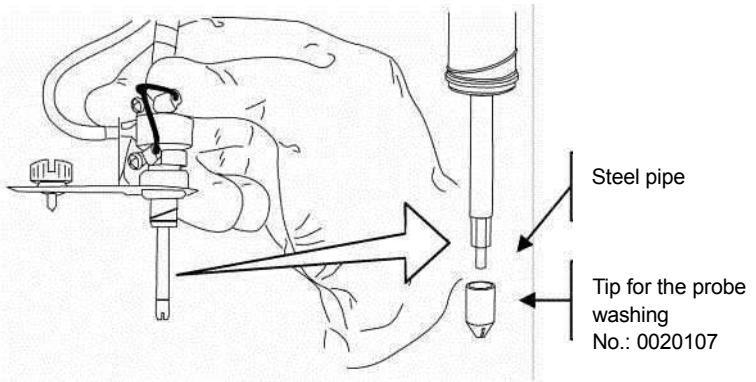
-el b / f washes the probe suggestions to be constantly in contact with specimens that may Contain infectious substances, they always wear gloves when replacing probes.

Be sure to turn off the system power before performing maintenance tasks. The injury Corporal can result from the gain caught when moving the mechanical parts of the system.

Loosen the securing screws for the b/f four, wash the probes and remove them by lifting upwards.

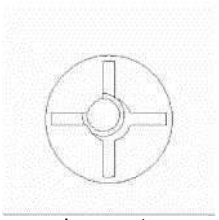


It is important if the washing probe of b / f tilts from each of the washing probes of b / f.



(7) Replace with new b / f key the probe is tilted (separate No.: 0020107)

The b / f washes the probe suggestions to be firmly inserted with the passage of steel tube. stainless steel through the center of the probe suggestion The stainless steel tube to the center must push outward slightly past the probe suggestion when properly installed.

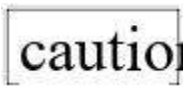


Incorrect

Tighten firmly until the steel tube protrudes slightly from the tip.

Reinstall the washing of b / f, adjustments are made to its position and the screws are tightened to secure.

Reinstall the wash probes of B/F to their position and tighten the securing screws.



The incorrect installation of the wash probe tips of B/F can cause the test results may not be accurate.

Close the B/F cover unit.

9.4 Quarterly maintenance

9.4.1 Clean wash solution and diluent tanks

Insist on the regularity that cleans the plastic tanks that the handle washes solution and thinner. After mixing, the two solutions will remain as stable for thirty days. room temperature. Simply cover the upward solution already in the tank afterwards this period can result in the progressive accumulation of mold and bacteria that can change the pH balance. Changes in the pH balance are a potential cause of the inaccuracy between runs of certain analytes. Clean the tanks thoroughly with water from a little tap, then rinse lightly with distilled water. If it molds or the bacteria they are located, disinfect the tank and the AIA-2000's washing solution and diluent lines using Hypochlorous acid (or commercial bleach) disinfects. Disinfection procedures are described. down.

9.4.1.1 Disinfect tanks

Completely wash the wash solution tank with distilled water.

(2) Add approximately two liters of water to the plastic tank, then mix in Approximately 20ml of hypochlorous acid.

Tape and secure the tank well and shake thoroughly to clean. In case the pollution is very deep, leave the tank's contents for at least 1 hour.

Rinse the tank with distilled water to remove any residue of hypochlorous acid.

9.4.1.2 Disinfect solution lines

Prepare a tank that contains one liter of distilled water. Pour this into Approximately 10ml hypochlorous acid.

(2) Insert the pipes of the diluent and the washing solution into the prepared tank.

Click on the disinfect line button for the diluent on the operation panel (bar of tools).

Click on the disinfect button for the washing solution line on the operation panel. (toolbar).

Remove the washing solution and diluent pipes from the tank.

Rinse the tank well with water to remove any residue of hypochlorous acid.

Add 1 liter of distilled water to the tank.

Insert the pipes of the diluent and the washing solution into the prepared tank.

Click on the disinfect line button for the thinner on the operation panel (toolbar tools).

Click on the disinfect button for the washing solution line on the operation panel. (toolbar).

(11) Insert the washing solution and its diluent suction touches the lid in your recently respective mixed washing solution tanks and diluent.

Click on the disinfect line button of the diluent on the operation panel (bar of tools).

Click the disinfect button on the washing solution line in the operation panel. (toolbar).

9.6 When the instrument is turned off for long periods of time

When the system is turned off for a long time, it is recommended that you wash the Wash solution and the Diluent of the solution lines is discarded and replaced with distilled water, make sure to empty the waste tank and the container for cup and tip waste. Prepare the substrate lines with the substrate the replacement solution (70% ethanol) and make sure the main switch of power has been turned off.

9.7 The startup after an extended period of hibernation.

When the system has been left idle for extended periods, the washing solution tends to solidify the probes, dispense and suction the washing solution into the B/F washing probe tips. This is important for cleaning the probes of the (B/F). For the description of procedures, refer to the Chapter 9: 9.2.1 cleaning B/F the washing probes.
if an error occurs when dispensing the wash solution and diluent or shows that it is below the level in The daily verification, although not accurate, is possibly caused by the presence of air in the line. reactive at the moment of aspirating the solution. Click on the Solution line button to disinfect wash and disinfect the thinner line in the same way on the operation panel (of the tool bar) and run the solution wash to dispense Wash and diluent,
execute before the daily verification. Clean the first line of Substrate with nitric acid, so with the substrate replacement solution (70% ethanol) before switching to the substrate. For the description of procedures, refer to 'Chapter 9: 9.1.1 Clean the lines of' Substrate.

9.8 External cleaning

Use a completely dry cloth and add a little neutral detergent for the outside.
If the pollution is strong, use a cloth that contains 70% alcohol.
The remaining liquid on the surface can cause corrosion.

Do not use organic solvents such as ethanol to clean the plastic.
This action may cause the decomposition of this component.

Gently rubbing, I removed the stains from the sample charger strap, then I used a cloth and repeat the procedure this time with 70% alcohol

9.9 Computer or PC Controller

9.9.1 Maintain optimal performance

Running the AIA-2000 for extended periods accumulates a large amount of results. that the saturation of information in the database can decrease the speed of the quick process and destabilize the system operation. If this happens, follow the following procedures.

Close system. (save the current databases and changes to the new database). For detailed description, refer to 'Chapter 6:6.13 closing operation.'

Close Windows Vista.

(3) Run a disk scan and defragment (refer to Windows support for execute this procedure.

- **The defragmentation process takes several hours, so it should be run overnight.**

9.9.2 System support

It is recommended that system files be saved on an external device such as a caution against system failures. This can be easily done using a DVD-RW in the PC controller. Make sure that all operations have finished, then save the full folder from: C/ Maxia for him.

Refer to the CD/DVD that indicates the help files of the software for its correct use. DVD-RW and the ability to create a backup.

- **Wait for the AIA-2000 system file support until the system operation has finished**
- **Try to perform the supplementary operation while the system is not in use. To avoid a malfunction of the files.**

9.10 Consumer goods (provisions)

No.	Pair number	Description	Specifications	Quantity
1	Tank for	Wash/Diluent	5L	1
2	0018624	Tank for waste	10 L	1
3	Sample	cup	1000/ bag	1 bag
4	0019215	Sample tips for the AIA-2000	1000/ box	1 box
5	0019216	Tip rack	Without tips	1
6	Sample	rack	with spring, 18/box	1 box
7	0020101	Sample Cup Adapter	10/ bag	1 bag
8	0020248	End indicator	-	1
9	0020107	Probe tips	6/ bag	1 bag
10	0022206	Reagent rack for 2 vials	-	1
11	0022200	The waste box AIA-2000	-	1
12	0022201	The AIA-2000 waste bag	10/ bag	1 bag
13	Standardization	cups (STD)	200/ box	1 box
14	0021207	Substrate bottle	-	1
15	0018585	The filters wash solution and diluent	10/ bag	1 bag

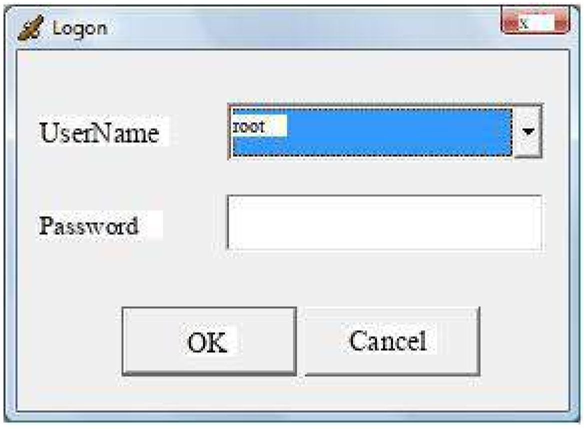
&KDQJLQJ 2SHUDWRUV

7KH IROORZLQJ PHQX EDU LV XVHG WR VHW WKH V\VWHP'V LPSRUWDQW

SRLQWV WR WKH V\VWHP DGPLQLVWUDWRU DFFRXQW WR EH DFFHVVLEOH

7KH V\VWHP EHFRPHV PRUH VHFXUH ZKLOH FKDQJLQJ RSHUDWRUV

&KRRVH WKH PHQX LWHP RQ WKH PHQX EDU 7KH IROORZLQJ ZLQGRZ LV GLVSOD\HG



&KRRVH WKH XVHU QDPH DQG SDVVZRUG HQWU\

&OLFN RQ WKH 2. EXWWRQ

$GPLQLVWUDWRU 5H 2SHUDWRU

6DIHW\ V\VWHP IRU

:LQGRZV DGPLQLVWUDWRU SDVVZRUG

<HV QRW WR EH UHSUHVHQWDWLYHV

(QWHU WKH SDVVZRUG LQ WKH ILHOG DQG VSHFLI\ WKH FKDUDFWHUV

DOSKDQXPHULF

3DVVZRUG FDQ FRQWDLQ DOSKDQXPHULF FKDUDFWHUV

$GPLQLVWUDWRU DFFRXQW SDVVZRUG

5HJLVWHU WKH XVHU QDPH DQG SDVVZRUG

7KH IDFWRU\ GHIDXOW DGPLQLVWUDWRU XVHUQDPH LV URRW

&HUWLILFDWH DGPLQLVWUDWRU

The testing conditions (testing volume, calibration double figure, and dilution breaks down into factors) for the individual analytes between them in the Test files. This chapter provides a detailed description of The various articles that examine the test archives. R of symbols, w or h under an article show that the editing permission to some systems designs, an excellent user, and an operator, respectively in that order. If no symbols are displayed, all users can edit the article. R means read-only, w means grabbable and h means hidden (do not show).

Reference

Article	Meaning
Unit	Unit of measurement for concentrations. Used when displaying, printing, and sending to the base computer test results.
Decimal places	Specify the degree of concentration in decimal terms. Used for displaying, printing, and sending to the base computer the results expressed in decimals.

Reference range

Referencing the range depression (	Specify the lower limit of the reference range. Under the trial range, the results are assigned the flag of L. Put the value of L afterwards
Reference the height of rank (h)	Specify the upper limit of the reference run. About the range, the results are assigned the flag of h. Put the value of h afterwards.
Reschedule Depression	Specify the lower limit for rescheduling range. Under the range, the results are assigned the flag of RL. Default values for
Height of Reschedule	Specify the upper limit for rescheduling range. Regarding the range, the results are assigned the flag of RH. Default values to Assay
Trial range depression	Specify the lower limit for the test range. Under the range, the results of the test are assigned to < the L hangs.
High range of trial	Specify the upper limit (linearity) for the test range. Regarding the range, the results are assigned > the hanging h.

Reschedule Range

Article	Meaning
Specimen diluent code Specify code used for the sample diluting solution (SDS).	
Specimen diluent name Specify the name used for the sample diluting solution (SDS).	
Dilution factor for Sp.1	Specify the implicit dilution factor for specimen material 1.
Dilution factor for Sp.2	Specify the implicit dilution factor for specimen material 2
Dilution factor for control Specify the implicit dilution factor for the control sample.	
The implicit multiplier for DO The implicit multiplier for generating the reschedule asks when the	essay the result hung with the flag of too high detector range
The implicit multiplier for > the h The implicit multiplier for generating the reschedule asks when the	essay the result hung with > the h hangs. The current dilution factor is

Test range

Article	Meaning
Factor A, b	Compensation breaks down into factors (concentrations). Cal. formula: y = b + de AX, where one is the slope and b is intersection of y
Calibration code ROFRWR	Specify the defining calibration of code doubles the constants of model (fix
The calibrator doubles (n)	Specify the number of times the same concentration calibrator. The measurements are retracted when generating curves.
Caliper batch RW RW H	16-the digit number usually specified the calibration batch.
Nombre de calibrador (1-12) RW RW H	Specify names of calibrators of various concentrations. The names of the calibrator are generated automatically when its lot the numbers are entered.
Calibrator conc. 1-12 RW RW H	Specify concentrations for the calibrators. Between 2 and 6, different concentrations can be used. depending
Dilation factor for calibration (Cal)	Specify the calibration dilution factor.
Calibration period RDERWH	Specify the valid period of the curve calibration.
Incubation time (10/40) ROFRWH	Represent specific parameters for individual measurements. No modifications.
Practice the protocol (1-7) ROFRWH	
Specimen volume ROFRWH	
Diluente volume ROFRWH	
Conjugate volume RDERWH	
Dilluted conjugate volume RDERWH	
Pretreatment ROFRWH	
Volume of specimen of pretreatment	
Pretreatment reagent code RW RW H	
Pretreatment reagent name RW RW H	
1 volume of reagent of pretreatment	
2 volumes of reagent of pretreatment	
System factor ROFRWH	
Calibration verification code RDERWH	Usually verify the calibration manually.
Virtual concentration RDERWH	Parameters in the cubic trunk logit format specifying the virtual concentration.
Origin of graph RDERWH	Parameters in the cubic logit format specifying the origin of graphic.
Calculation with Dilution Factor RDERWR	This factor is for the review of results.