TDR-X060 /TDR-X120/TDR-X120 II/ TDR-X240/TDR-X360

Automated Blood Culture Systems

Operator's Manual

Contents

For this Operator's Manual, the issue date is 2022-03.

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Responsibility on the Manufacturer Party

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- All installation operations, expansions, changes, modifications and repairs of this product are conducted by HNMR authorized personnel;
- The electrical installation of the relevant room complies with the applicable national and local requirements; and the product is used in accordance with the instructions for use.

WARNING:

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

NOTE: This equipment must be operated by skilled/trained clinical professionals.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

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HNMR's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by HNMR or repairs by people other than HNMR authorized personnel.

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- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Customer Service Department

Manufacturer:	**HUNAN MINDRAY Medical Technology Co., Ltd.**
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Preface

Before using the automated blood culture systems, please read this manual thoroughly and understand it for relevant operation instructions.
Please keep this manual properly for convenient use.

Who Should Read This Manual

This manual is written for technologist, supervisors and other personnel who operate and maintain the TDR-X instruments on a regular basis to:

- Perform daily operating tasks;
- Perform system maintenance and troubleshooting;
- Learn about the system hardware and software.

WARNING:

The device is to be operated only by clinical professionals, doctors or experimenters trained by Hunan Mindray or our authorized distributors.

What Can You Find in This Manual

This manual covers principles, operations, daily maintenance and troubleshooting of the system. Please operate and service the system strictly as instructed by this manual.

Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meanings in the text.

- Bold font indicates a chapter title, such as 5 Trouble shooting.
- Bold and Italic font indicates title on the screen, such as Bottle Info screen.
- <Buttons>: the angular bracket with bold font in it indicates buttons, knobs and other controls on control panel or on the keyboard.
- [Items in menu or buttons in dialog box]: the square bracket with bold font in it indicates items in menu, on the touch screen or buttons in dialog box.
- Click [Items or Buttons]: click item on the touch screen.
- [Items in Menu] → [Items in Submenu]: select a submenu item following the path.

Accompanying Files

Accompanying files including:

- Operator's Manual: describes the system functions, operation procedures, as well as safety information.
- Operation Guide: contains quick guide for basic operations of the system.
- Installation Guide: guide the service engineer to carry out instrument installation as well as software upgrading.
- HL7 Interface Operator's Manual

Software Interfaces in This Manual

Depending on the software version, preset settings and optional configuration, the actual interfaces may be different from those in this manual.

Safety Symbols, Labels and Silkscreen

Safety symbols, labels and silkscreen are used in this manual in order to remind you of the potential hazards and risks in operating this product. The symbols are used in combination with relevant texts.

1. Safety symbols	
	**WARNING:** Read the statement following the symbol. The statement is alerting you to an operating hazard that can cause personal injury.
	**CAUTION:** Read the statement following the symbol. The statement is alerting you to a possibility of system damage or unreliable results.
	**NOTE:** Read the statement following the symbol. The statement is alerting you to information that requires your attention.
	**BIOHAZARD:** Read the statement following the symbol. The statement is alerting you to a potentially biohazardous condition.
2. Labels and Silkscreen	
	Serial number

	Date of manufacture
	Manufacturer
	In Vitro diagnostic equipment
	Environment-friendly use period (20 years)
	CE marking.
	Authorized Representative in the European Community
	BIOHAZARD Read the statement following the symbol. The statement is alerting you to a potentially biohazardous condition.
	Electric Shock Alerting the user of electric shock. Do not remove the shell of the product; otherwise you may get electrically shocked.
	Personal injury or equipment damage may be caused.
	Watch your hands
	Electrical ground
	On (Main power)
	Off (Main power)

IOIOI	Serial Port
	USB Interface
	Ethernet port
100-240V~ 50/60Hz 500VA	Power supply specification, for combination module of 60 bottles or less.
100-240V~ 50/60Hz 1000VA	Power supply specification, for incubator or combination module of 120 bottles.
T 8AH 250V	Fuse model, for incubator or combination module of 120 bottles.
T 5AL 250V	Fuse model, for combination module of 60 bottles or less.
	Storage temperature
	Storage humidity
	Storage atmospheric Pressure

Summary of Hazards

To use the product safely and efficiently, pay attention to the following safety precautions. Ignoring any of these safety precautions may lead to personal injury or equipment damage.

WARNING:

1. **If the product is used in a manner not specified by our company, the protection provided by the product may be impaired.**
2. **If you want to relocate your system, contact our Customer Service Department or your local distributor.**

Electric Shock Hazards

Observe the following instructions to prevent electric shock.

WARNING:

1. **When the mains power is turned on, users other than the servicing personnel authorized by our company must not open the rear cover.**
2. **Spillage of solutions on the product may cause equipment failure and even electric shock. Do not place specimen and reagent on the product. In case of spillage, switch off the power immediately, remove the spillage and contact our Customer Service Department or your local distributor.**

Moving Parts Hazards

Observe the following instructions to prevent personal injury caused by moving parts.

WARNING:

1. **When the system is in operation, do not touch such moving parts.**
2. **Do not put your finger or hand into any open part when the system is in operation.**

Fire and Explosion Hazards

Observe the following instructions to prevent fire and explosion.

WARNING:

Ethanol is flammable substance. Please exercise caution while using ethanol.

Electromagnetic Noise Precautions

CAUTION:

1. **Electromagnetic noise may interfere with operations of the system. Do not install devices generating excessive electromagnetic noise around the system. Do not use such devices as radio transmitters in the room housing the system. Do not use other CRT displays around the system.**
2. **Do not use other medical instruments around the system that may generate electromagnetic noise to interfere with their operations.**
3. **Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. mobile phones or radio transmitters), as these may interfere with the proper operation.**
4. **The electromagnetic environment should be evaluated prior to operation of the device.**
5. **This device has been designed and tested to CISPR 11 Class A, and in a domestic environment may cause radio interference, in which case, you may need to take measures to mitigate the interference.**
6. **It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.**
7. **It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that it will perform as intended.**

Biohazards

Observe the following instructions to protect against the biohazardous infection by samples, calibrators and control samples.

BIOHAZARD:

Inappropriate handling of specimens may lead to biohazardous infection. Do not touch specimens directly with your hands. Wear gloves and lab coat, if necessary, goggles.

In case your skin contacts the specimens and mixtures, follow standard laboratory safety procedure and consult a doctor.

Waste Disposal

Observe the following instructions to prevent environmental pollution and personal injury caused by waste.

BIOHAZARD:

Dispose of waste parts or the whole unit in accordance with your local or national rule for waste disposal. Wear gloves and lab coat while handling them.

NOTE: The definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this system should not be treated as household waste. By ensuring that this system is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this system, please consult the distributor from whom you purchased the system.

1. Overview

1.1 Intended Scope

This device is intended for culture and detection of bacteria and Fungi in blood and other normally sterile body fluid in medical and health service, epidemic prevention institute and research institute.

1.2 Intend use

The instrument can be used in combination with an appropriate blood culture bottle. For clinical laboratories to qualitatively detect microorganisms in human blood or other sterile body fluids under normal conditions through in-vitro culture.

1.3 Performance and Technical Specifications

Item	Parameter
Bacteria type	Aerobic bacteria, anaerobic bacteria, facultative anaerobe, fastidious bacteria, Brucella, actinomycetes and fungi.
Sensitivity	Limitation of detection: 10 CFU.
Supported bottle	TDR Resin Aerobic, TDR Resin Peds, TDR Resin Anaerobic.
Capacity	The capacity varies with the product model, maximum cell number is 360.
Language	English.
Culture temperature	Temperature for each drawer can be set to 25℃-45℃ with the precondition that ambient temperature is lower than the set value.
Display	Touch screen.
Communication	RS232, Ethernet port, USB port.
Transport and storage condition	Temperature: -30℃～55℃; Relative humidity: 10% RH -93% RH, no condensation; Atmospheric pressure: 76kPa～106kPa.
Fuse	T 8AH 250V, for incubator or combination module of 120 bottles. T 5AL 250V, for combination module of 60 bottles.
Safety classification	Electric shock prevention: I; overvoltage category: II; pollution degree: 2.

Item	Parameter
Size & weight	● TDR-X060 600±10mm(W)，525±10mm(H,with foot)，755±10 mm(D,with handle) Weight：106±5Kg(unload)，112±5Kg (full load) ● TDR-X120 600±10mm(W)，1020±10mm(H,with foot)，755±10mm(D,with handle) Weight：180±5Kg(unload)，192±5Kg (full load) ● TDR-X120 II 475±10mm(W)，1020±10mm(H,with foot)，755±10mm(D,with handle) Weight：170±5Kg(unload)，182±5Kg (full load) ● TDR-X240 1085±20mm(W)，1020±10mm(H,with foot)，755±10mm(D,with handle) Weight：350±10Kg(unload)，374±10Kg (full load) ● TDR-X360 1570±30mm(W)，1020±10mm(H,with foot)，755±10mm(D,with handle) Weight：520±10Kg(unload)，556±10Kg (full load)

1.4 Principle of Detection

The system provide a suitable temperature for the recovery and growth of microorganism by heating and incubating culture bottles. Continuous mixing of sample and culture media is achieved through the mixing structure. Finally, by the detection the speed and amount change in the color of the base of culture bottle, the culture bottle would be determined to be positive.

1.5 Operating Precautions

Computer virus may destroy the operating software or test data. Do not use the computer for other purposes or connect it to the Internet. If the computer is infected by virus, please install anti-virus software to check for and clear virus.

Data should be transmitted in a closed network or virtual isolated network environment. The laboratory is responsible for the security of the virtual isolated network environment.

Make sure that the network authorization information (such as user information and password) is secure and not obtained by unauthorized persons.

Please use Microsoft firewall and kill the virus regularly.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

1.6 EMC Requirements

- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
- This equipment complies with the emission and immunity requirements of the EN61326-1:2013 and EN61326-2-6:2013.
- This equipment has been designed and tested to CISPR11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

NOTE:	It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user. It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

1.7 Contraindication

None.

2. Installation

2.1 Unpacking

Please remove the package with caution. Check the package and device, which are supposed to be intact. Check the packing list. If you find any damage or omission, please contact the transporter or the distributor.

2.2 Working Condition

The automated blood culture systems should be installed and worked in the following ambient environment:

- Temperature: 10℃-30℃;
- Humidity: 10%RH～90%RH;
- Atmospheric pressure: 76kPa～106kPa;
- Power supply: 100-240V～, 50/60Hz; three-wire power cord;
- Away from dust, direct sunlight, splash liquid, Corrosive gas, vibration, and strong electromagnetic interference.
- Power consumption:

Model	Power
TDR-X060	500VA
TDR-X120/ TDR-X120 Ⅱ	1000VA
TDR-X240	2000VA
TDR-X360	3000VA

NOTE:	Ambient temperature should not be higher than the preset incubation temperature.

WARNING:

1. **To ensure personal safety and normal operation of the device, the earthing wire of the power socket must be well grounded. Using a two-wire plug board is forbidden.**
2. **The device is for intended use and must not be opened without permission. The power switch, main control board, connecting wire, and incubation module can be checked and supplied only by the manufacturer.**
3. **The instrument should be placed in a contained environment with controlled access which has a tuberculosis exposure control plan. The locations should have surfaces which can be easily decontaminated using an appropriate topical disinfectant. The instrument must not be placed in an open corridor or hallway that is accessible to the general public or the patient population.**

Position

Space Requirement

Enough clearance should be left for good heat dissipation, otherwise instrument malfunction may be resulted in due to temperature raise. Space layout is shown as figure below (here takes TDR-X120 as an example):

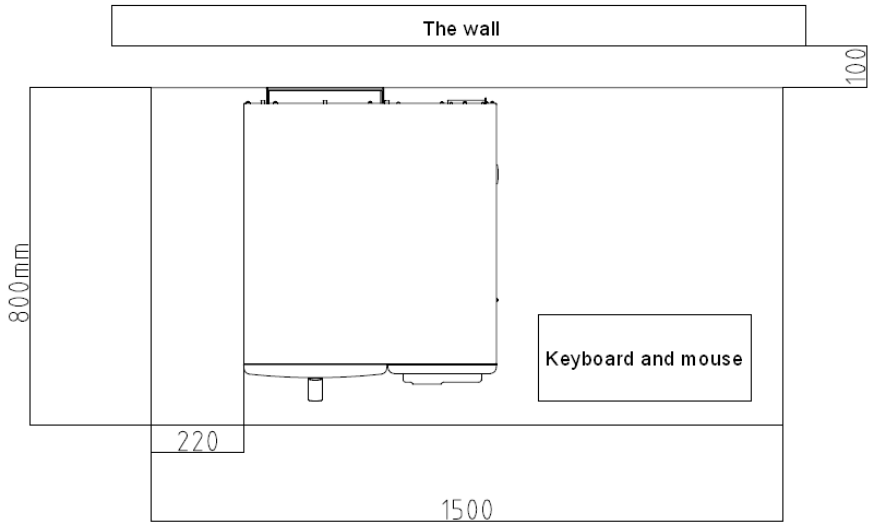


Fig 2-1 Space layout

Table requirement

The instrument is heavy, so the table is required to be dedicatedly designed to meet the load-bearing requirement. For load-bearing requirement of each model, please refer to table below:

Model	Min load-bearing	Remarks
TDR-X060	≥200Kg	For blood culture systems of 120 cells or more, please posit them on dedicatedly designed table.
TDR-X120	≥300 Kg	
TDR-X120 Ⅱ	≥300 Kg	

TDR-X240	⩾500 Kg	
TDR-X360	⩾700 Kg	

Table 2-1 Load-bearing requirement for each model

WARNING:

The table bearing capacity should meet the requirement as listed in table above.

Displacement

If you want to relocate your system, contact our Customer Service Department or your local distributor.

2.3 Installation Procedure

1. Install the printer (if applicable): follow the operation manual to connect the signal line to the combination module;
2. Connect barcode scanner cable to the available USB port;
3. Insert the USB receiver of the wireless keyboard & mouse set to the available USB port;
4. Connect the serial port cable (if applicable) and power supply cord respectively.

■ Power supply check:

Before powering on, check if the lines are properly connected, then power on the device. If the touch screen displays Function screen, it indicates that the instrument has been installed successfully.

NOTE: Before powering on the system, make sure all signal lines and power cord are properly connected.

2.4 Instrument Structure

The blood culture system consists of one combination module, or a combination module and one or more incubator (vary with the product model).

The combination module is composed of incubating module, measurement module, agitating module, control module, as well as IPC; the incubator is composed of incubating module, measurement module, agitating module, and control module.

2.4.1 TDR-X060

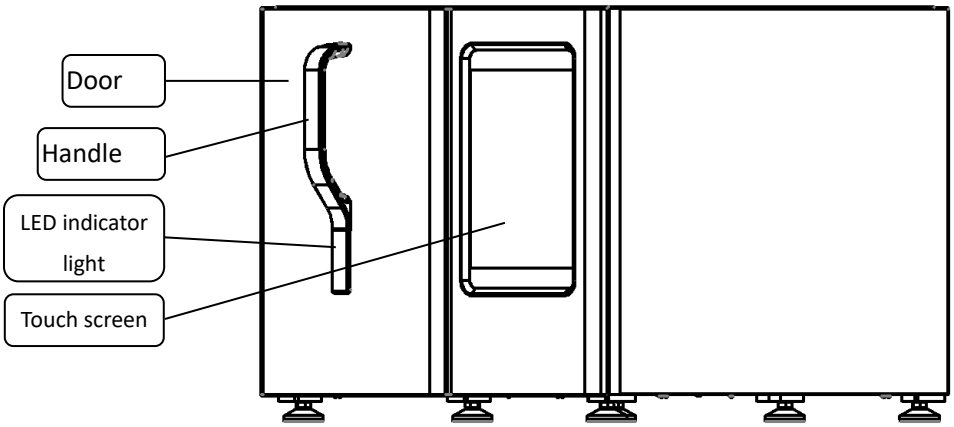


Fig 2-2 TDR-X060 front view

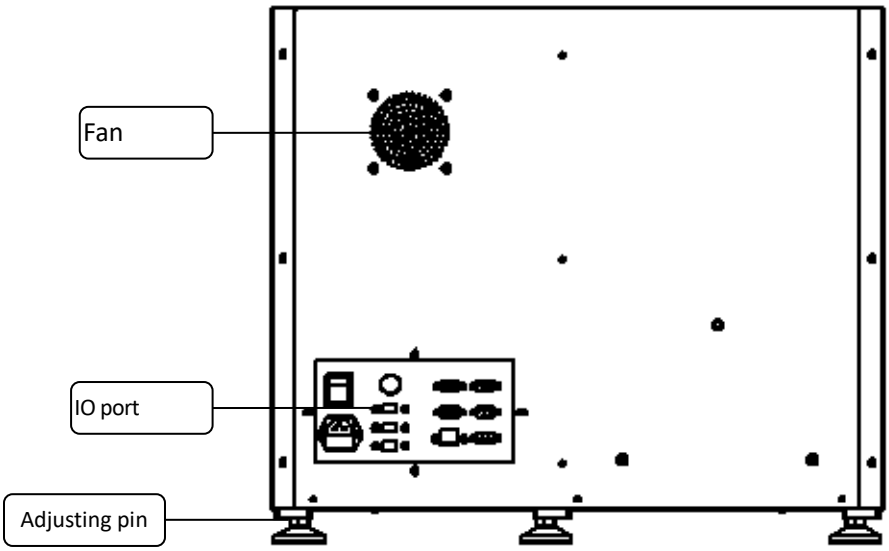


Fig 2-3 TDR-X060 rear view

No	Name	Function
1	Door	Heat preservation.
2	Handle	To open or close the drawer door.

No	Name	Function
3	LED indicator light	Three LED digital combinations below the handle; which represent the bottle counts in the drawer: The top combination: lights in white, shows the number of idle cells in real time; The middle combination: lights in red, shows the number of positive bottles in real time; The bottom combination: lights in green, shows the number of negative bottles in real time; LED indicator light at the inner side of the handle, which indicating the system status: Lights in red, indicating that there is positive bottle detected; Flashes in red, indicating that there is system malfunction detected; Flashes in yellow, indicating that the drawer door is opened.
4	Touch screen	Provides a way to display information. The operator may input selections and data by touching the screen.
5	Hand holding groove	Convenient for moving the instrument.
6	Fan	For instrument heat dissipation.
7	IO port	Including IPC power switch, power switch, power input socket, USB port (3), Ethernet port (1), and serial port (3).
8	Adjusting pin	To support and protect the device.

Table 2-2 Structure of TDR-X060

2.4.2 TDR-X240

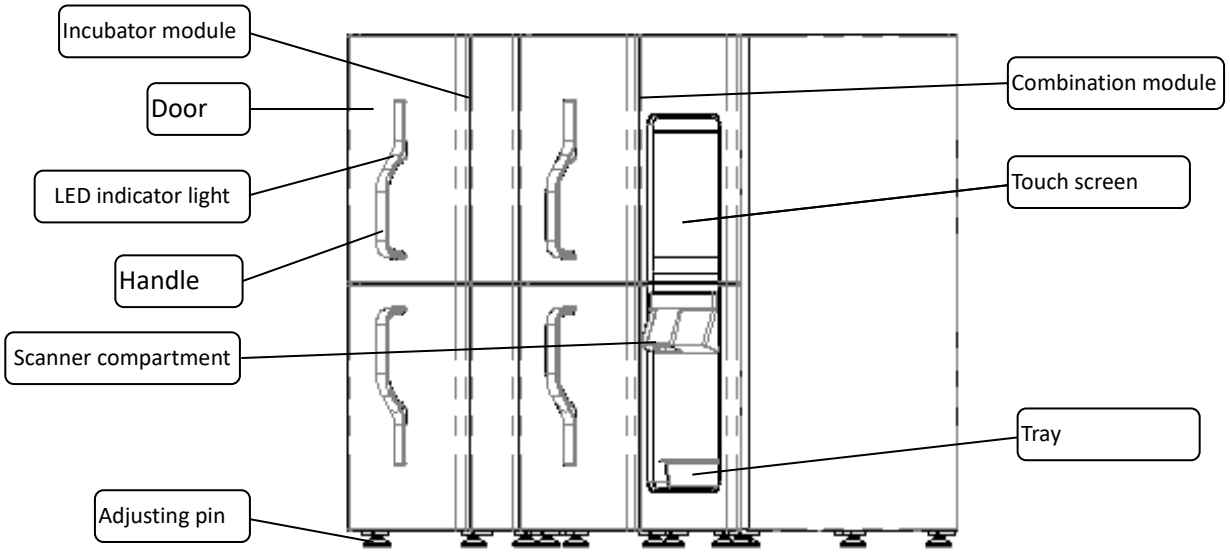


Fig 2-4 TDR-X240 front view

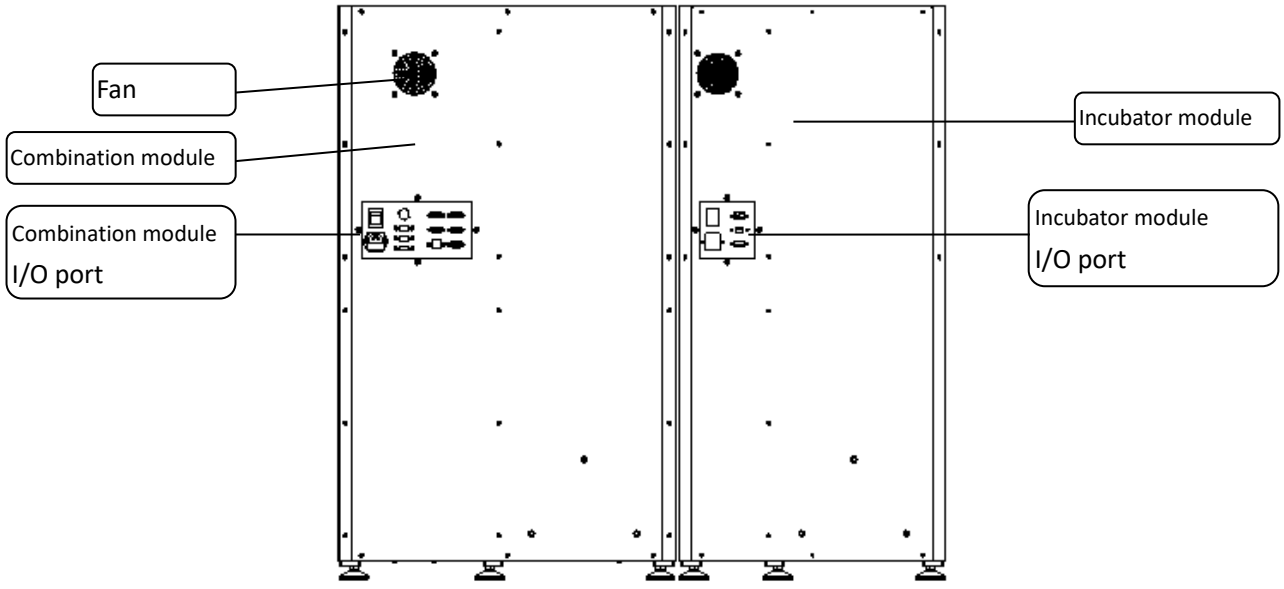


Fig 2-5 TDR-X240 rear view

No	Name	Function
1	Door	Heat preservation.
2	Handle	To open or close the drawer door.

No	Name	Function
3	LED indicator light	Three LED digital combinations above/below the handle; which show the bottle counts in the drawer: The top combination: lights in white, shows the number of idle cells in real time; The middle combination: lights in red, shows the number of positive bottles in real time; The bottom combination: lights in green, shows the number of negative bottles in real time; LED indicator light at the inner side of the handle, which indicating the system status: Lights in red, indicating that there is positive bottle detected; Flashes in red, indicating that there is system malfunction detected; Flashes in yellow, indicating that the drawer door is opened.
4	Scanner compartment	Provides a compartment to holding the barcode scanner. The compartment position can be adjusted by lifting it up or pushing down.
5	Tray	Provides a tray to temporarily place the bottle and reagent.
6	Touch screen	Provides a way to display information. The operator may input selections and data by touching the screen.
7	Hand holding groove	Convenient for moving the instrument.
8	Fan	For instrument heat dissipation.
9	Combination module I/O port	Including IPC power switch ,power switch, power input socket, USB port (3), Ethernet port (1), and serial port (3).
10	Incubator module I/O port	Power switch, 1 Ethernet port (for software remote upgrading and fault diagnosis), 1 serial port (to communicate with the combination module), and 1 USB port (to connect with USB device).
11	Adjusting pin	To support and protect the device.

Table 2-3 Structure of TDR-X240

2.4.3 TDR-X120

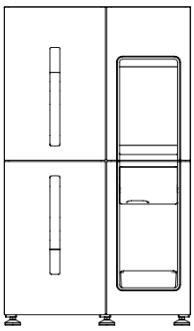


Fig 2-6 TDR-X120 Diagram

2.4.4 TDR- X360

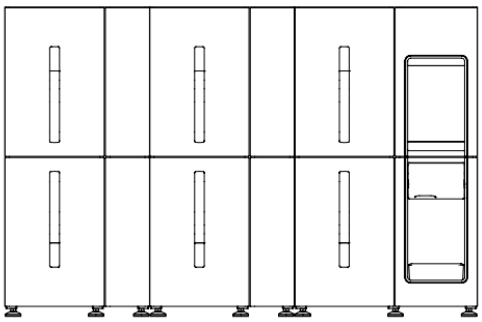


Fig 2-7 TDR-X360Diagram

2.4.5 TDR-120II

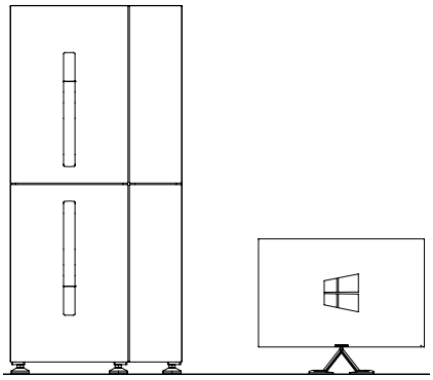


Fig 2-9TDR-120II Diagram

Tips:

- The structure of TDR-X120 is the combination module of TDR-X240; The structure of TDR-120II is the incubator module of TDR-X240; The differences of structures between TDR-X360 are: the incubator module number for TDR-X360 is 2.
- Position of combination module and incubator can be adjusted as your preference.

2.4.6 Incubator

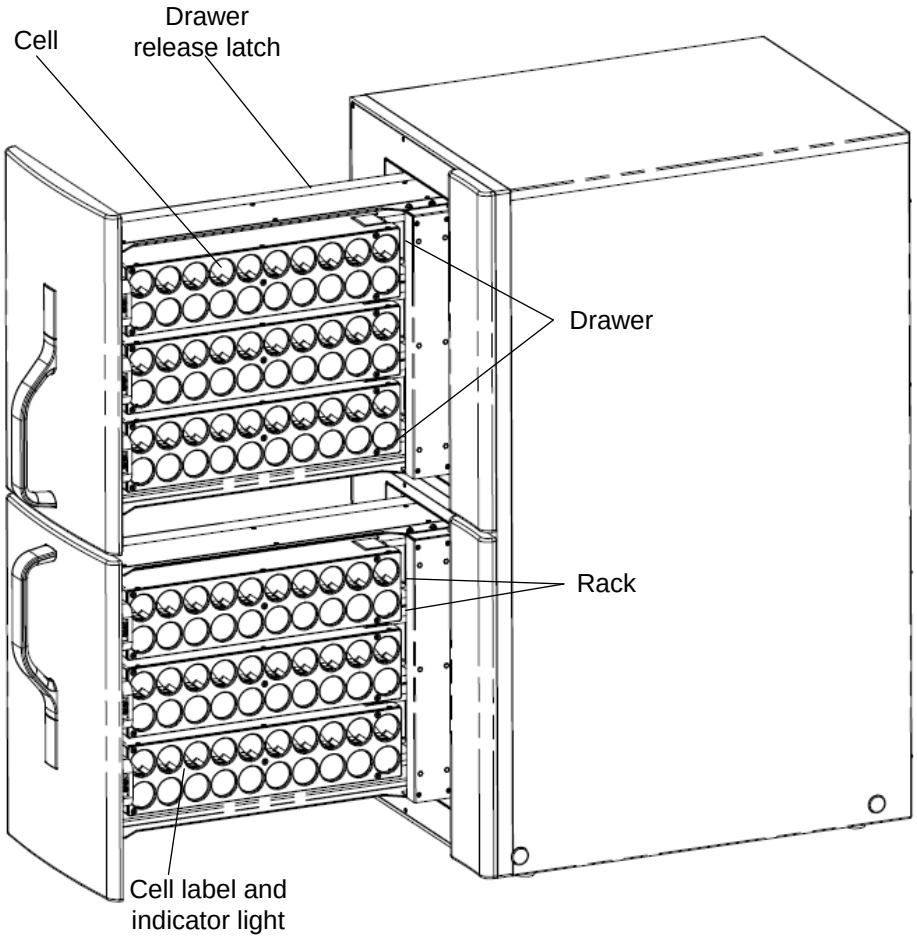


Fig 2-10 Incubator

No	Name	Function
1	Drawer	Labeled A or B in each incubation module. Each drawer contains 3 racks, with a capacity of 60 culture bottles.
2	Rack	Each rack contains 20 cells.
3	Cell	Designated with a number from 1 to 60. Each cell holds and monitors one culture bottle.
4	Drawer release latch	Supports the drawer to move back and forward.

No	Name	Function
5	Cell label and indicator light	Label: designated with a number from 1 to 60. Indicator light: Illuminates in red to indicate which culture bottle can be unloaded when the operator selected to unload the positive bottle. Illuminates in green to indicate which culture bottle can be unloaded when the operator selected to unload the negative bottle. In bottle loading mode, light illuminates in yellow to indicate which cells are available. In bottle checking mode, light illuminates in yellow to indicate which cells are incubating. In anonymous bottle handling mode, light illuminates in yellow to indicate which cells are loaded with anonymous bottle. In lost bottle handling mode, light illuminates in yellow to indicate on which cell the bottle is lost. Light illuminates in yellow to indicate bottle load or unload was performed correctly.

Table 2-4 Structure of incubator

2.5 Power On

Connect the power cord between the system (both combination module and incubator) and mains power, then toggle the power switch to “ON”.

2.6 Power Off

Shutdown the system as steps described as below:

1. On the ***Function*** screen, click  to exit the operation software;
2. Exit the operation system;
3. Press the IPC power button  at the right side of the instrument to shut down the IPC;
4. Turn the power switch of both combination module and incubation module (if applicable) to off;
5. Shut down UPS (if applicable);
6. Disconnect the power cord of both combination module and incubation module.

NOTE: The blood culture system is a continuous operation device, restart the system only when necessary (first-time use or after power interruption).
System shutdown is not suggested except when system translocation is required or in case of predicted power interruption.

3. Software Basic Functions

The basic functions are those tasks that may be performed during daily workflow. They include:

- System status view and monitor
- Daily workflow operation
- Result automatic detection and report, growth curve checking
- Patient information, specimen, bottle information management, viewing and printing
- LIS sending and request
- Result statistics
- System setting and maintenance

3.1 Function Screen

Fig 3-1 Function screen

Title bar displays the screen name as well as software shut down icon.

Status bar displays the user name, system time, and if there is any system malfunction or warning, it will be shown on the status bar.

There provides access to status checking, specimens, result, statistics, system setup and maintenance.

- Status: shows the system status, provides access to bottle loading/unloading, etc.
- Specimens: to manage the patient or specimen information, provides access to information entering, editing, deleting, printing and LIS request.
- Results: provides viewing, inquiry, editing to both current test result and history result.
- Statistics: carries out statistics for specimen count, positive rate, duration before positive test result is detected, etc., according to the selected combinations.
- Setup: to set parameters for the system.
- Maintenance: individual control to all sub-modules, designated for service man only.

3.1.1 Status Main Screen

From the ***Function*** screen, click [**Status**] to access ***Status*** main screen, as shown in figure below:

Fig 3-2 Status main screen (take TDR-X120 as an example)

Status main screen indicates the number of bottles of each type currently loaded in the instrument as well as system status, which include counts of positive bottle, negative bottle and idle cell, door status, working status of incubator, and incubating temperature.

Idle: the currently available cell in the instrument, which can be loaded with the culture bottle.

Positive: identified bottle detected as positive.

Negative: identified bottle detected as negative.

Testing: the bottle still undergoing testing in the instrument, no test result is available up to now.

Anon: bottles that not associated bottle ID.

If instrument is configured with more than one incubator, please click  or  to view the

next or preview incubator status.

Click [**Load Bottle**] to access the ***Load Bottle*** screen, for details of bottle loading procedures, please refer to “4.3.1 Loading Bottles”.

Click [**Unload Bottle**] to access the ***Unload Bottle*** screen, for details of bottle unloading procedures, please refer to “4.3.2 Unloading Bottle”.

Click [**Solve Anon**] to access ***Solve Anon*** screen, for details of handling anonymous bottle, please refer to “4.4.1 Handling Anonymous Bottles”.

Click [**Status**] to access the ***Bottle Status*** screen, for details, please refer to “3.1.6 Viewing Bottle Status”.

Click  to return to the previous screen.

3.1.2 Loading Bottles

From the ***Function*** screen, click [**Status**] → [**Load Bottle**] to access the ***Load Bottle*** screen, as shown in the figure below:

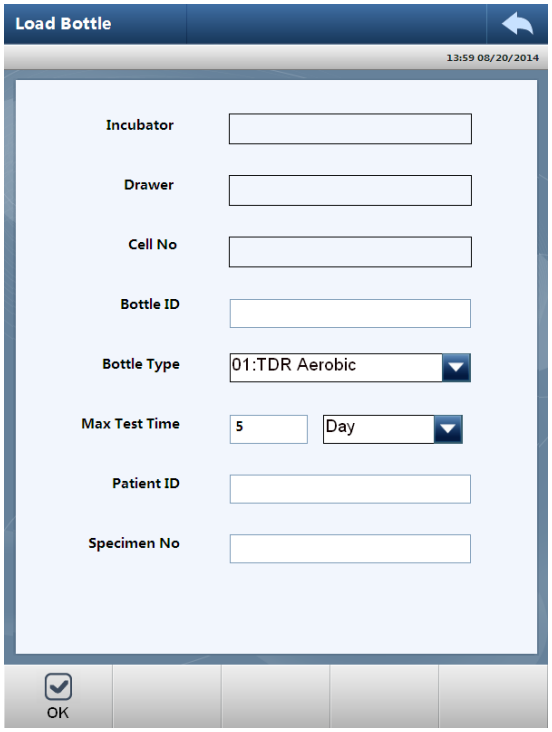


Fig 3-3 Load Bottle screen

For details of loading bottle, please refer to “4.3.1 Loading Bottles”.

Fields are defined as below:

Incubator: the incubator in which the bottle is loaded. The number will be filled automatically after the bottle is properly loaded.

Drawer: the drawer in which the bottle is loaded. The number will be filled automatically after the bottle is properly loaded.

Cell: the cell in which the bottle is loaded. The number will be filled automatically after the bottle is properly loaded.

Bottle ID: bottle ID of the loaded bottle, which can be automatically obtained by barcode scanning,

or manually entered through keyboard or touch screen.
Bottle type: automatically identified according to the bottle ID.
Max test time: the maximum time duration to detect a negative result, the default time is 5 days.
Patient ID: directly scan the ID on the ordering sheet (if any); or manually enter the ID into the text field. After patient ID is filled, the bottle is successfully associated with the specimen.
Specimen ID: the specimen ID can be selected from the drop-down list or entered manually through keyboard or soft key.

NOTE:	1. Before loading the bottle, please associate the bottle information with the patient. 2. If the bottle is directly inserted without bottle ID scanning, the bottle will be identified as anonymous.

3.1.3 Unloading Bottles

From the ***Function*** screen, click [**Status**] → [**Unload Bottle**] to access the ***Unload Bottle*** screen.
For details of unloading bottle, please refer to "4.3.2 Unloading Bottle".

3.1.4 Handling Anonymous Bottles

Anonymous bottles should be removed and identified as procedures described in "4.4.1 Handling Anonymous Bottles".

3.1.5 Handling Exceptional Bottles

Special bottle handling including bottle reloading, handling the lost bottle, or clearing out the lost bottles, etc., for details, please refer to "4.4 Handling Abnormal Bottles".

3.1.6 Viewing Bottle Status

From the ***Status*** main screen, click [**Status**] to access the ***Bottle Status*** screen, as shown in the figure below:

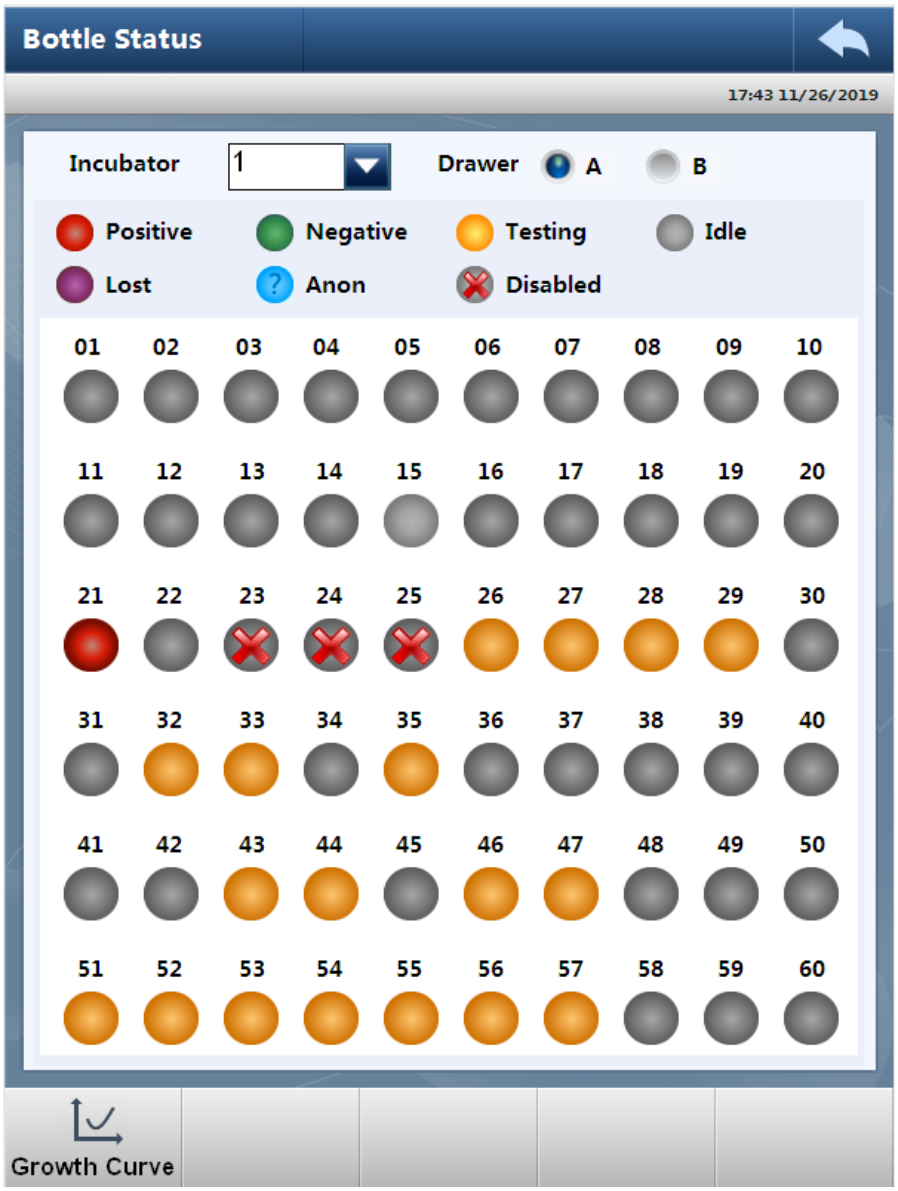


Fig 3-4 Bottle Status screen

For each cell, the cell ID appears at the top of the circle.

The color in the circle indicates the bottle status, of which:

: Circle in red, represents positive bottle;

: Circle in green, represents negative bottle;

: circle in orange, represents the bottle undergoing test, or negative-to-date bottle;

: Circle contains a “?” in blue, represents anonymous bottle that undergoing test;

: Circle in gray, represents idle cell;

: Circle in purple, it means the bottle on the cell is lost;

 : Circle contains a × in gray, it means the cell is disabled.

Bottle Status screen only displays the bottle status for the 60 cells in one drawer. To view the bottle status of a certain drawer, please select the incubator number first, and then click the radio button to select the drawer.

3.1.7 Viewing the Growth Curve

From the ***Bottle Status*** screen, click the cell icon to access the growth curve of the bottle, as shown in figure below:

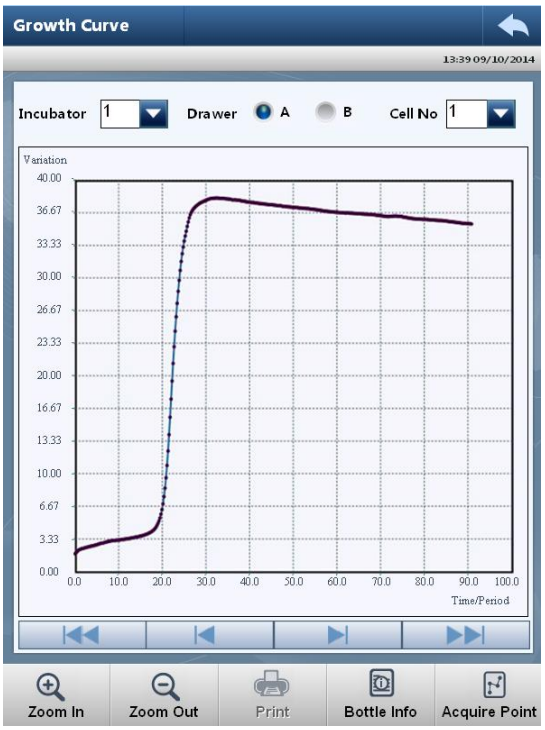


Fig 3-5 Growth Curve

Growth curve is generated according to sampling data of the culture period of each bottle, of which, horizontal axis represents sampling time, while vertical axis represents the reflectance variation. Besides, you can select the number of incubators, the drawer and the cell respectively to display the growth curve of the desired bottle.

3.1.8 Viewing Bottle Information

From the ***Status*** main screen, click [**Status**] → [**Bottle Info**] to view the bottle information.

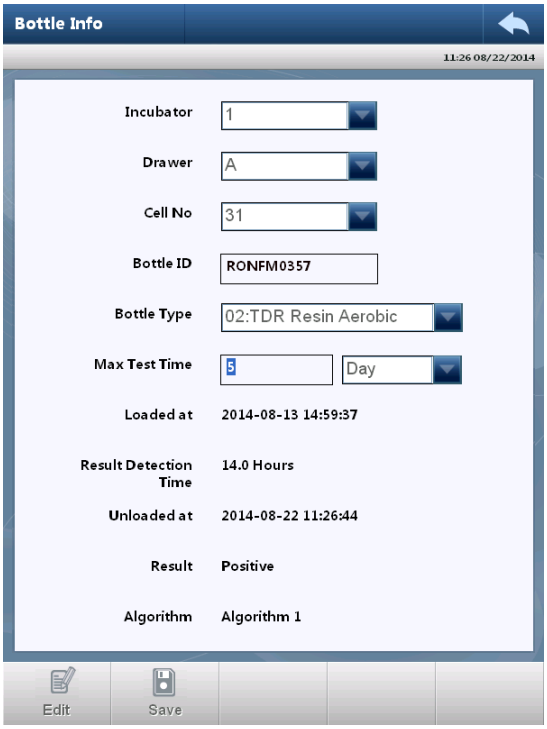


Fig 3-6 Bottle Info screen

Fields are defined as below:

Incubator: the incubator where the bottle is located;

Drawer: the drawer where the bottle is located;

Cell No: the cell where the bottle is loaded;

Bottle ID: can be read with barcode scanner and bottle type can be recognized from the ID;

Bottle type: available types are TDR Aerobic, TDR Resin Aerobic, TDR Peds, TDR Resin Peds, TDR Anaerobic, TDR Resin Anaerobic;

Max test time: the preset time to report negative result;

Load at: the time when the bottle was loaded, that is the time when bottle is detected;

Detection time: time duration before culture result is detected;

Unload at: the time when the bottle was unloaded;

Result: detected result will be either positive or negative or not available;

Algorithm: the algorithm adopted to determine the culture result.

3.1.9 Editing the Result

From the ***Bottle Info*** screen, click [**Edit**] to access ***Edit*** screen, as shown in figure below:

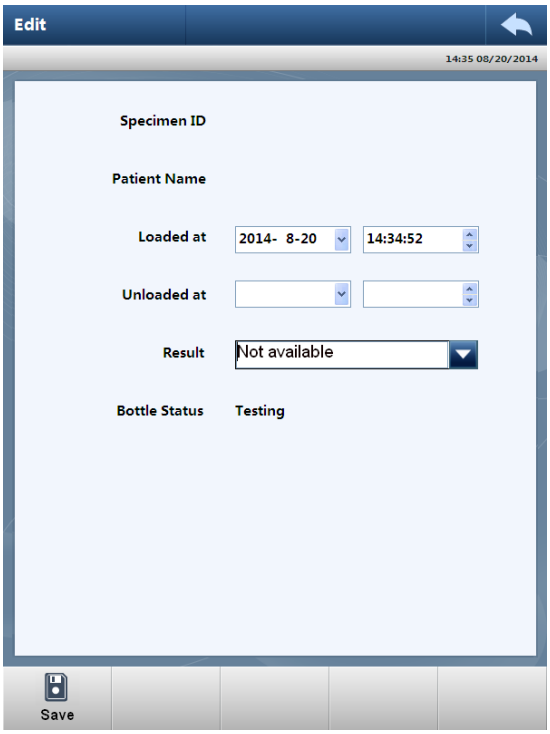


Fig 3-7 Edit screen

Culture result can be manually edited, for details, please refer to “4.4.6 Manually Assign the Result”.

3.2 Specimen

From the ***Function*** screen, click [**Specimens**] to access the ***Specimen*** screen, as shown in the figure below:

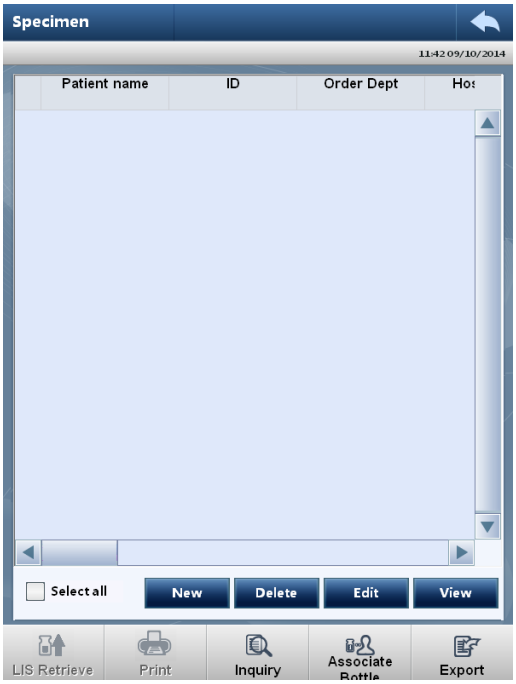


Fig 3-8 Specimen screen

On the ***Specimen*** screen, there displays specimen information, providing access to manage

specimen information, functions including add new specimen, delete specimen, edit, view, print and inquiry specimen information, printing and LIS request. Besides, you can perform LIS request or bottle-to-patient association from this screen.

3.2.1 Add New Specimen

Click [**New**] to access the ***New*** (Specimen) screen, as shown in the figure below:

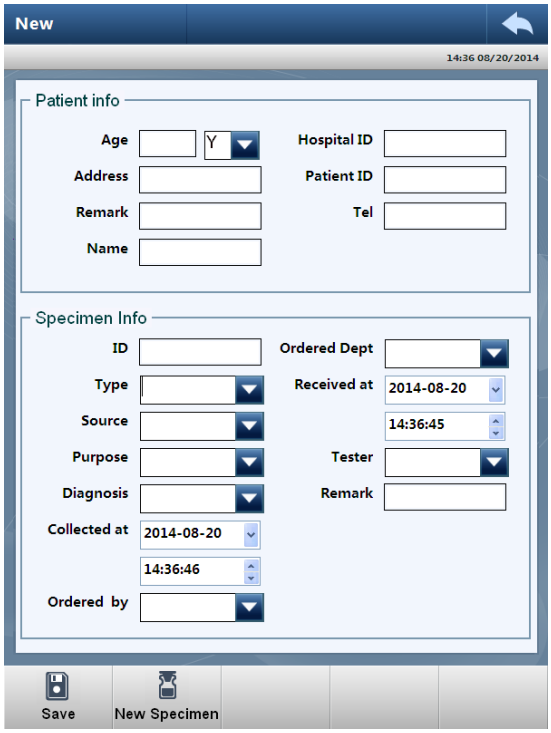


Fig 3-9 Add new specimen screen

Both patient information and specimen information are displayed on the screen; enter the correct data, and click [**Save**] to save the patient and specimen information.

Name, Hospital ID, and Specimen ID are mandatory fields.

3.2.1.1 New Specimen

From the ***New*** (Specimen) screen, click [**New Specimen**] to add a new specimen for the patent.

3.2.2 LIS Retrieve

Click [**LIS Retrieve**] to access ***LIS Retrieve*** screen.

Patient information can be retrieved from the LIS server according to query conditions, which include specimen ID range, patient ID and hospital ID.

1. Click the radio button to select the condition type.
2. Input content in the text field.
3. Click [**Retrieve**].
4. When patient information is obtained, sample list will be refreshed automatically.

3.2.3 Printing

Microorganism test report and specimen summary report can be reported if the system is properly connected with a printer.

- To print the microorganism test report: on the ***Specimen*** screen, select a record on the patient list, click [**Print**].
- To print the specimen summary report: on the ***Specimen*** screen, select more than one record on the patient list, click [**Print**].

3.2.4 History Specimen

From the ***Specimen*** screen, click [**Inquiry**] to access the ***Specimen-Inquiry*** screen, as shown in the figure below:

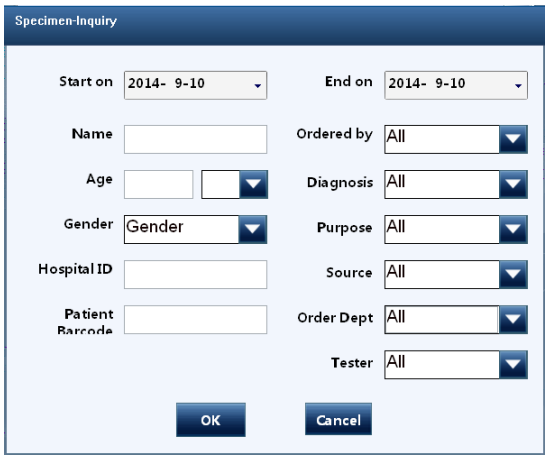


Fig 3-10 Specimen Inquiry screen

Enter or select the inquiry condition, click [**OK**], sample information that meets the preset conditions will be listed out.

3.2.5 Associating Bottles

From the ***Specimen*** screen, click [**Associate Bottle**] to access the ***Associate Bottle*** screen, as shown in the figure below:

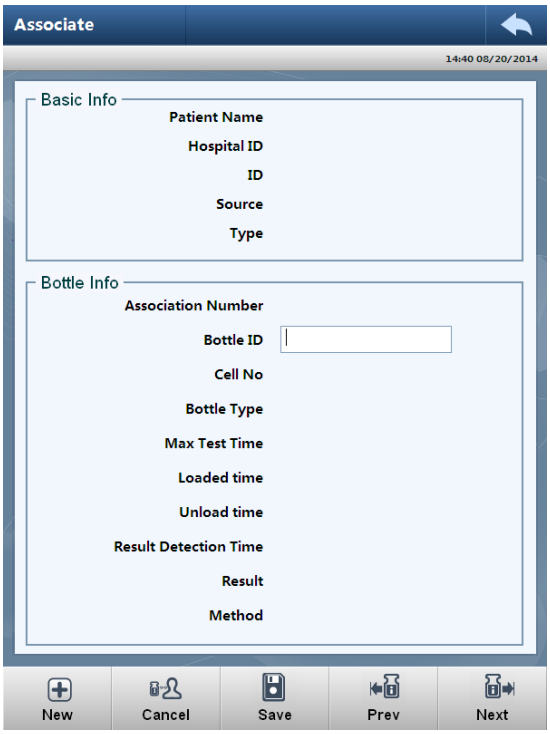


Fig 3-11 Associate Bottle screen

To associate a bottle with the specimen:

1. Anchor the cursor into the text filed beside Bottle ID;
2. Scan the bottle ID with the barcode scanner, or manually enter the bottle ID;
3. Click **[Save]**, the system asks “Are you sure to save the modified information?”, click [**Yes**];
4. If the same sample is needed to be associated with more than one bottle, just click [**New**], then repeat steps 2-3;

To view the previous or next associated bottle for the sample, please click [**<<**] or [**>>**] to navigate to the other bottle information.

3.2.6 Exporting Patient Information

From ***Specimen*** screen, select the sample information, click [**Export**] to export the sample associated patient information, sample information, bottle information and the test result.

The exported data are stored to the home directory of installation disk by name of TDR120PatientInfo.csv.

3.3 Results

3.3.1 Current Result

From the ***Function*** screen, click [**Results**] to access ***Result*** screen (default page is the current result), as shown in figure below:

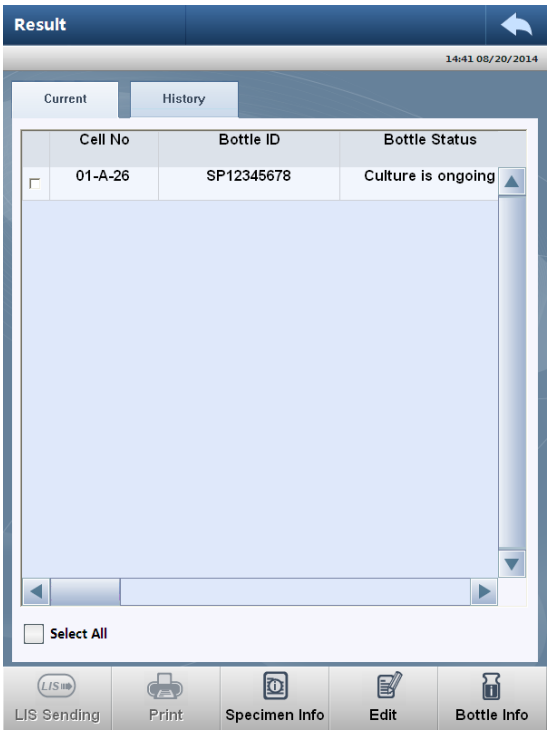


Fig 3-12 Current Result screen

On the ***Current*** page, there displays all bottle related information in the instrument. Also there provides access for LIS sending, result printing, specimen viewing, resulting editing and bottle information viewing.

3.3.1.1 LIS Sending

From ***Result*** screen, click [**LIS Send**] to access the ***Select Result Type*** page.

Select the result type (All, not sent, already sent) by clicking the corresponding radio button, click [**OK**].

3.3.1.2 Printing

When properly connected with a printer, report for bottles status and test result summary report can be printed through the ***Current*** screen by selecting the bottle record.

3.3.1.3 Viewing Specimen Information

On the ***Specimen*** screen, click [**View**] to view the specimen information.

3.3.2 History Result

From ***Function*** screen, click [**Result**] to open the ***Result*** screen, and then click [**History**] to open the ***History*** screen.

Select or enter the inquiry condition, then click [**Inquiry**] to search the result according to preset conditions.

Also there provides access for LIS sending, result printing, specimen viewing, resulting editing and bottle information viewing.

3.4 Statistics

The system provides statistics for positive detection results and positive detection rate.

From the ***Function*** screen, click [**Statistics**] to access the statistics screen, as shown in figure below:

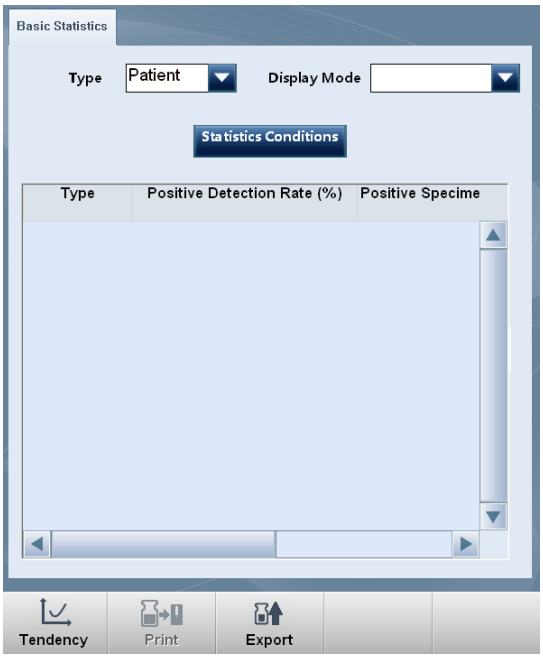


Fig 3-13 Statistics Main screen

Select the statistics type: patient or bottle, then select the display mode.

If statistics type is Patient, available display modes are Ordering Department, Specimen Source, Tester, and Ordered Time; when Bottle is selected as the statistics type, display mode can be Bottle Type only

3.4.1 Select the Statistics Combination

From the ***Statistics*** screen, select [**Statistics Conditions**] to access the following screen:

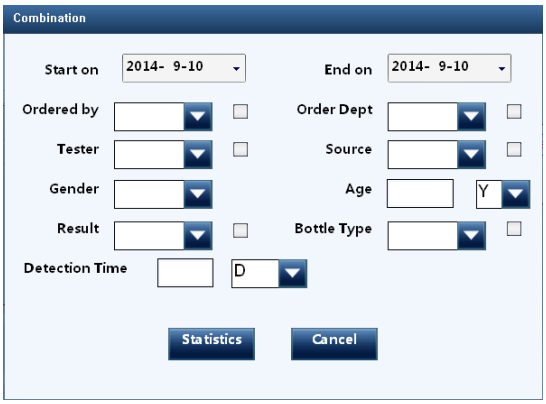


Fig 3-14 Select Statistics Conditions

Fill in the conditions, click [**Statistics**], and then statistics result will be shown.

Or, select the check box beside the condition to select more than one item, click [**OK**].

3.4.2 Tendency Chart

From ***Statistics*** screen, click [**Tendency Chart**], then select the chart type, and click [**OK**] to view the tendency chart as selected.

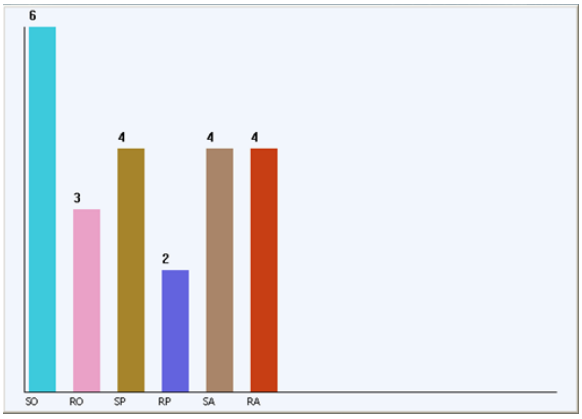


Fig 3-15 Tendency chart-bar

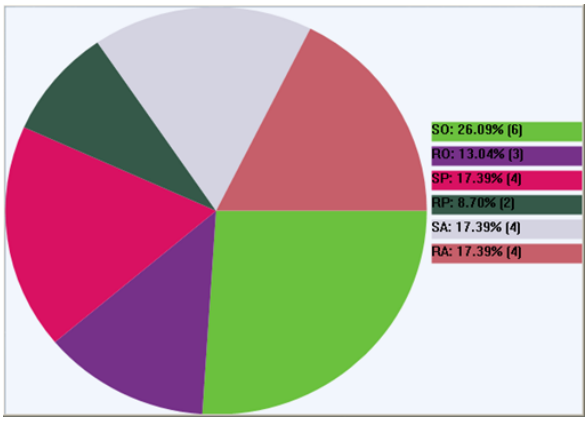


Fig 3-16 Tendency chart-pie

3.4.3 Print Statistical Result

On the ***Statistics*** screen, click [**Print**] to print the statistical result.

3.4.4 Export Statistical Result

On the ***Statistics*** screen, click [**Export**] to export the statistical result.

3.5 Setup

From the ***Function*** screen, click [**Setup**] to access the ***Setup*** screen, as shown in the figure below:

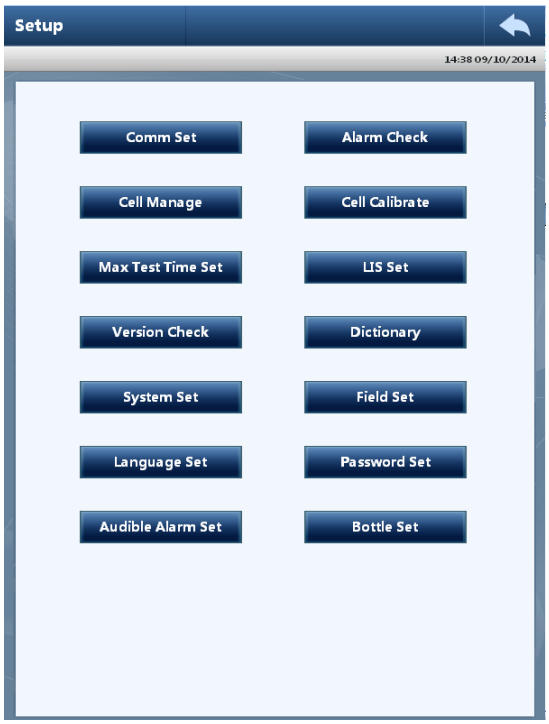


Fig 3-17 Setup screen

3.5.1 Communication Setting

Through communication setting, barcode scanner port (for serial port communication type only) and incubator port can be set.

Make sure that the preset port for both scanner and incubator are consistent with the actual connection, otherwise, communication failure may be resulted in.

Select the port number in the drop-down list respectively according to actually connection, then click [**OK**] to confirm the setting.

3.5.2 Cell Management

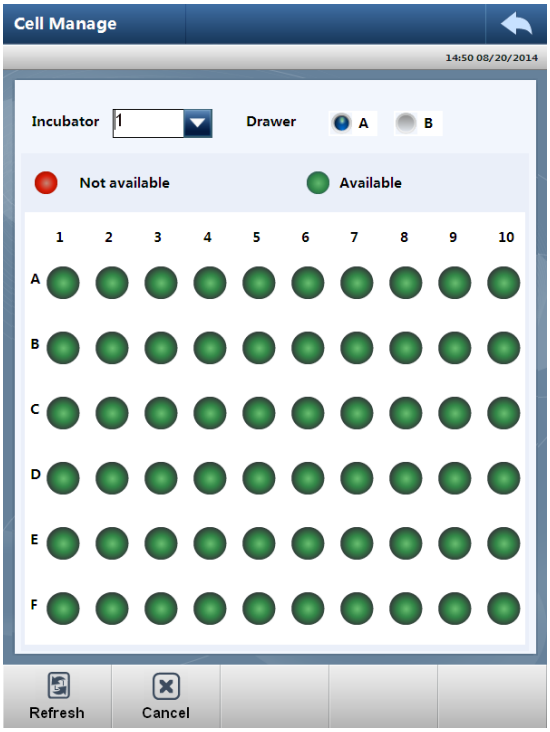


Fig 3-18 Cell Manage screen

If any cell in the incubator is detected to be damaged or abnormal data is found for the cell, please disable the cell through ***Cell Manage*** screen.

1. From the ***Setup*** screen, click [**Cell Manage**] to access the ***Cell Manage*** screen;
2. Select the incubator and drawer respectively, the 60 cells in the selected drawer will be shown;
3. Click the target cell icon, the icon changes into red, which means the cell is disabled; click the icon again, the icon changes into green, and the cell is enabled;
4. Click the return previous icon to exit bottle management.

3.5.3 Maximum Test Time Setting

Fig 3-19 Max Test Time set screen

■ Set maximum test time

The maximum test time can be set according to bottle type.

1) Select bottle type in the drop-down list;
2) Enter the time length as well as time unit;
3) Click [**OK**].

■ Set negative prediction time

The user can set 3 time points to enable the system predict negative result, and the result prediction can be viewed on the ***Result*** screen.

Enter the time as well as time unit, click [**OK**].

3.5.4 Version Checking

On the ***Version Check*** screen, there display version of all modules.

3.5.5 System Setting

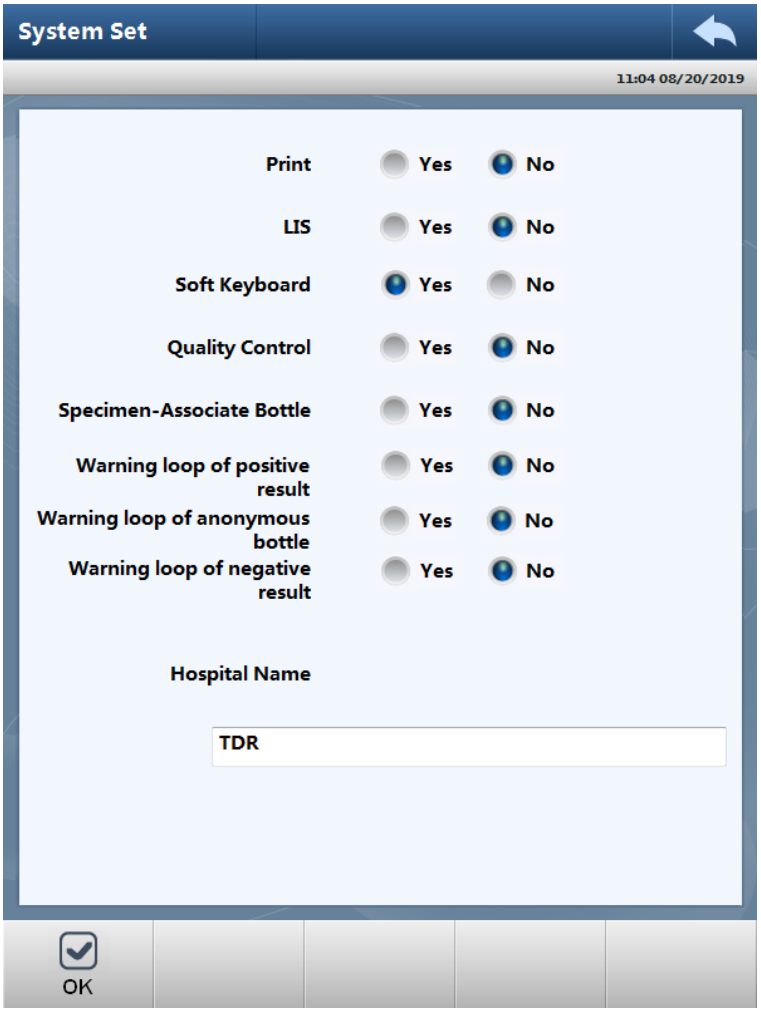


Fig 3-20 System Set screen

Part of system functions can be enabled or disabled through system setting. Those functions include print, LIS, Soft Keyboard, Quality Control, Specimen-Associate Bottle, Warning loop of positive result, Warning loop of anonymous bottle and Warning loop of negative result.

To enable or disable the system function:

1. Click the radio button beside the function module, “Yes” means to enable the function, while “No” means to disable the function.
2. Click [**OK**] to save the setting.

3.5.6 Language Setting

System language can be set through ***Language Set*** screen.

Select the language from the drop-down list; click [**OK**] to save the setting.

After language setting, please restart the software to enable the system language to take effective.

3.5.7 Audio Alarm Setting

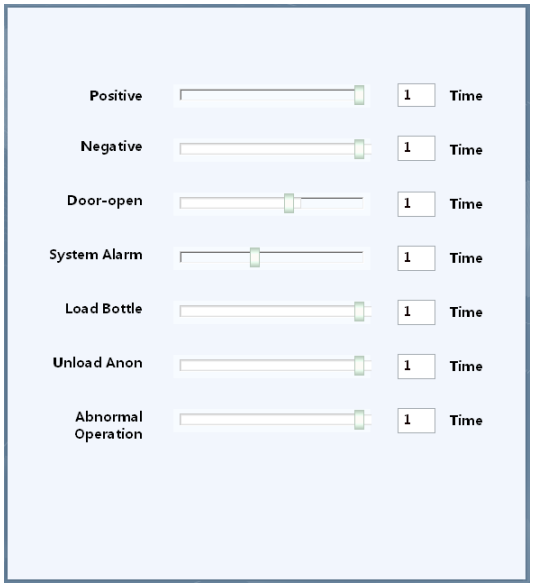


Fig 3-21 Audible Alarm Set screen

Both the volume and repeat count for all the audio alarms can be set through ***Audio Alarm Set*** screen.

- Set the volume

Drag the slider left or right to change the volume, to the left, the volume decreases, while to the right, the volume increases. Click [**OK**] to save the setting.

- Set the repeat counts

Directly enter the repeat count through keyboard or soft keyboard, click [**OK**] to save the setting.

3.5.8 Alarm Checking

To better understand the instrument status, all system alarms and malfunctions can be checked through ***Alarm Check*** screen.

Alarm/malfunction source and occurrence time are listed in the table. Besides, alarms/malfunctions can be searched according to query conditions as the operator set.

3.5.9 Cell Calibration

All cells in the instrument have been calibrated before delivery. However, calibrations are required at a fixed period (about 3 months); this is the duty of the operator.

For details of cell calibration, please refer to “6.4.2 Cell Calibration”.

3.5.10 LIS Setting

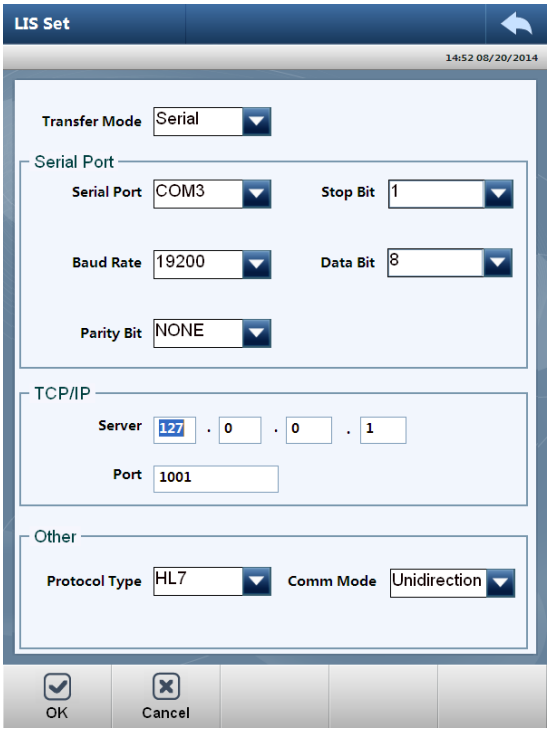


Fig 3-22 LIS Set screen

Before first LIS request or sending, please preset the LIS parameters on the automated blood culture systems according to parameters on the LIS server and actual connection.

- Select transfer mode

Select the transfer mode (serial port or TCP/IP) in the drop-down list according to actual communication between the blood culture system and LIS server.

- Set the serial port parameter

Parameters to be set include port number, stop bit, baud rate, data bit, and parity bit. Please set the parameters according to those set on the LIS server.

- Set TCP/IP parameter

Parameters to be set include IP address of the LIS server and port, please set the parameters according to those set on the LIS server.

- Set others parameter

Set protocol type and communication mode according to actual condition.

3.5.11 Dictionary Setting

In the dictionary, there stores options available for part of the text fields. Take gender as an example, you can preset Male, Female and Unknown through dictionary setting, so when to fill the gender on the Sample Info page, you do not need to enter the text through keyboard, just select the available item from the drop-down list beside Gender.

Items can be set include Laboratory Physician, Specimen Type, Ordering Dept, Ordering Physician, Gender, Age, Specimen Source, Culture Purpose, and Diagnosis.

3.5.12 Field Setting

Items can be displayed on the header field of patient info, specimen info and result can be set as required.

To set the text:

1. Select the category by clicking the radio button;
2. Select an item from the available item in the right side, click 

to move it to the selected item in the left side;
3. Select an item from the selected item in the left side, click 

to move it to the available item in the right side;
4. Click 

to move all available items to the selected area.
5. Click 

to remove all selected items to the available item area in the right side.
6. Click [**OK**] to save the setting.

3.5.13 Bottle Setting

New bottle information, which including bottle name, name abbreviation, and maximum test time, can be added to the system through bottle setting.

The currently available types are listed in the table, to add new bottle type:

1. Click [**New**] to access the ***Setup-Bottle Type*** screen;
2. Enter bottle name, name abbreviation, and maximum test time respectively;
3. Click [**OK**] to save the setting, and click the return previous button to exit.

3.5.14 Cell Automatic QC Function

■ Enable the automatic QC function:

1. From the ***Main*** screen, click **[*Setup*]**->***System Set*** to access the ***System Set*** screen, check the **[*Yes*]** option of ***Quality Control*** to enable the automatic QC function.
2. Restart the machine.

■ QC work-flow

1. The system performs the automatic QC for idle cells monthly;

2.If the cell QC failed, it will give alarm info on the top of the screen, perform the following procedures:

- Identify the disabled cell: from the ***Main*** screen, click **[*Status*]**->***[Status]*** to access the cell status screen, the status of QC failed cells will display as disabled.
- Inspect the cell for debris and remove or clean, if necessary.
- Calibrate (Refer to the Section 5.3.1 of service manual to do cell calibration)

Connect your local distributor if cell calibration failed.

3.5.15 Warning loop of positive result, anonymous bottle and negative result

■ Enable the warning loop function:

1. From the ***Main*** screen, click ***[Setup]***->***System Set*** to access the System Set screen, check the corresponding ***[Yes]*** option to enable the ***warning loop*** of positive result, anonymous bottle and negative result function.
2. Restart the software.

■ Set the warning loop period for positive result and anonymous bottle

1. From the ***Main*** screen, click ***[Setup]***->***Warning loop setting*** to access the ***Warning loop period setting*** screen.
2. Tap the ***[Add],*** click the drop-down list of ***Warning Type*** option to choose the corresponding type.
3. Click the drop-down list of ***Time Interval*** to set the cycle time.
4. Set the warning time period: Check the check boxes of days and set the time period.

■ Warning loop of negative result

If the negative bottles have been reported the result for more than 2 days, when you open the corresponding drawer, it will prompt “There are negative bottles in the system, please handle them in time!”

4. Blood Culture Work-flow

4.1 Blood Culture Workflow Chart

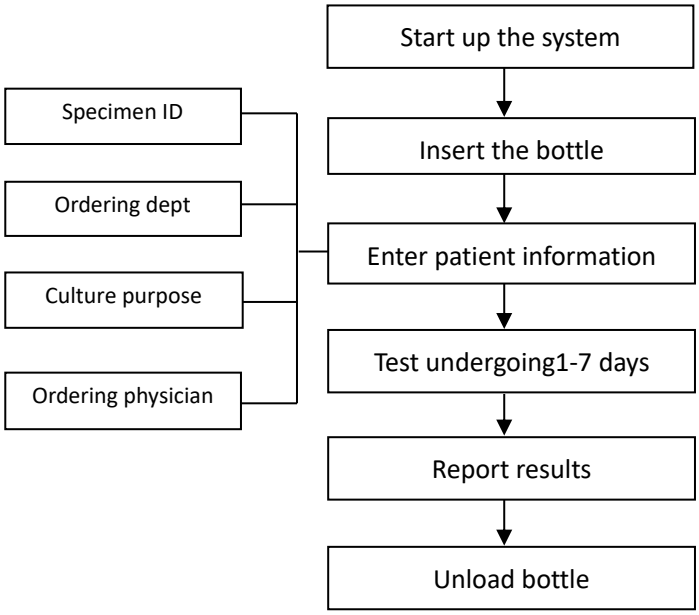


Fig 4-1 Blood Culture Workflow Chart

4.2 Start-up the System

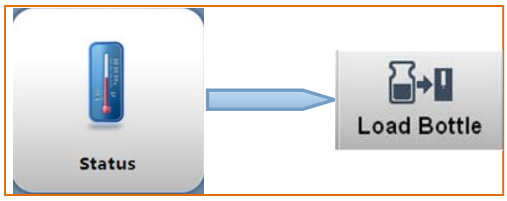
For details, please refer to “2.5 Power On”.

4.3 Culture Workflow

4.3.1 Loading Bottles

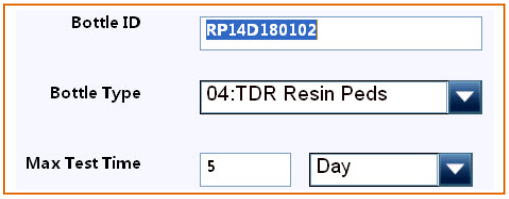
NOTE:	Inspect each bottle and sensor before loading: if the sensor is yellow, treat the bottle as positive culture. If the bottle is cracked, do not load the bottle. Make sure to associate the bottle with patient in the following three ways: Stick the same specimen ID to both the bottle and order sheet; or stick a patient ID onto the bottle; or peel off one of the bottle ID and stick it on the order sheet.

1. Enter into loading bottle mode



- Method 1: on the main screen, click [**Status**] → [**Load Bottle**] to enter into ***Load Bottle*** screen.
- Method 2: Scan the barcode on the bottle with barcode scanner, ***Load Bottle*** screen pops up.

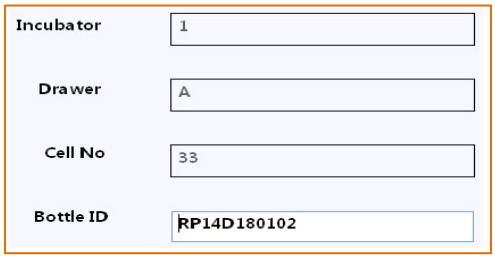
2. Load bottle information



- Scan the barcode on the bottle, and verify that both bottle type and maximum test time are correct.

3. Insert the bottle

- Open the drawer, cell indicators for all empty cell illuminate as orange.
- Insert the bottle, sensor first, to any of the available cell (make sure the bottle is fully seated into the cell), the cell indicator light blinks slowly and there will be one short beep to acknowledge the bottle is successfully loaded.



- Cell information will be shown on the screen, confirm the information, and the bottle is successfully loaded.
- Repeat bottle ID scanning and bottle inserting for each remaining bottle.

NOTE:	When inserting a bottle, ensure that the bottle is fully seated into the cell; visually check that the top of all bottles are at the same level. When bottles are loaded in batch, ensure to load a new bottle only after you hear a short beep which acknowledges that the bottle ID is successfully identified.

4. Exit bottle loading

When all bottles are loaded, close all drawers to exit bottle loading.

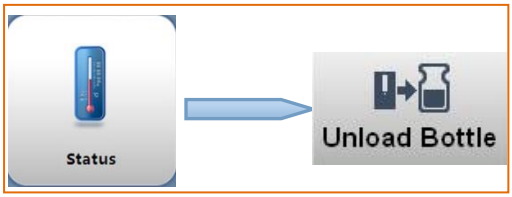
5. Load patient information
   a) From ***Function*** screen, click "[**Specimen**]→[**New**]" to access the ***New Specimen*** screen;
   b) Enter the correct patient information, click [**Save**].
6. Associate bottle with the specimen
   a) From ***Function*** screen, click [**Specimen**] to access the ***Specimen*** screen;
   b) Select patient information;
   c) Click [**Associate Bottle**] to access ***Associate Bottle*** screen;
   d) Scan the bottle ID on the order sheet, ensure the bottle ID is correct;
   e) Click [**Save**] to finish the association.

NOTE:	When all bottles are loaded, ensure that all drawers are completely closed. If the door is opened longer than a limited duration, LED indicator light at the inner side of the handle will flash in yellow, please avoid this situation.

4.3.2 Unloading Bottle

To unload the bottle with detection result already available, please follow the procedures as below.

1. Enter into unloading bottle mode



◆ On the ***Function*** screen, click [**Status**] →[**Unload Bottle**] to enter into ***Unload Bottle*** screen.

2. Remove the bottle

◆ On the ***Unload Bottle*** screen, click the appropriate unload button (**Unload Positive, Unload Negative**).

◆ System prompts the user to unload the selected bottle type.

Negative

Positive

◆ Open the indicated drawer, cell indicator light up to all bottles in the selected category.

Tips:

If **Unload Positive** is selected, the positive cell indicator lights illuminate as red.

If **Unload Negative** is selected, the negative cell indicator lights illuminate as green.

◆ Remove one target bottle, the cell indicator light blinks slowly, the bottle information is shown on the corresponding text field.

◆ Confirm the bottle information.

◆ Repeat the operation above for each remaining bottle to be removed.

3. Exit bottle unloading

When all target bottles are unloaded, close the drawer to exit bottle unloading.

4.3.3 Viewing Bottle Culture Status

To check bottle status during the culture, please follow the procedures as below:

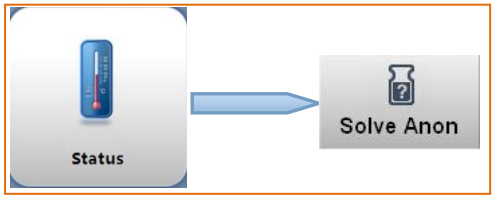
1. From ***Status*** screen, click [**Status**] to access Bottle Status screen;
2. Select the incubator and drawer where the target cell located, there displays the 60 bottle (cell) status, click the target bottle icon to open the growth curve;
3. Click [**Bottle Info**] at the bottom of the screen to view the bottle related information.

4.4 Handling Abnormal Bottles

4.4.1 Handling Anonymous Bottles

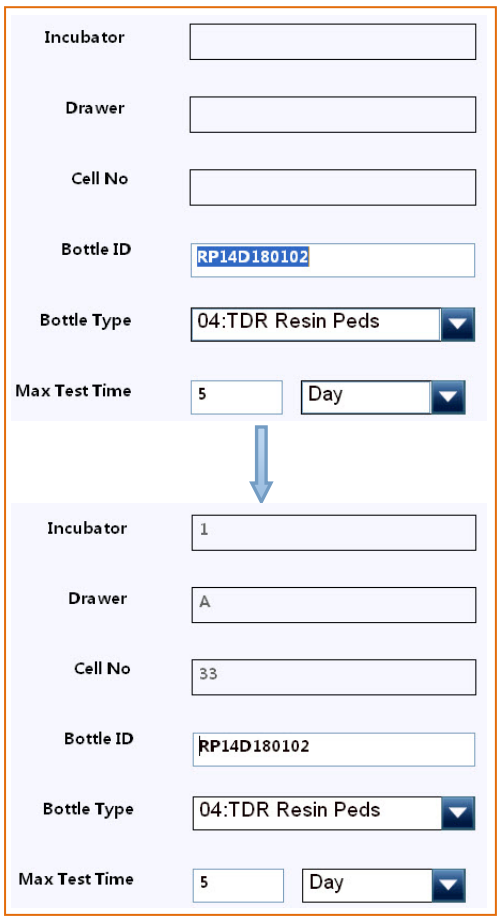
NOTE:	When handling the anonymous bottle, the bottle must be reloaded into the cell from where it has been removed after bottle ID is identified.

1. Enter into anonymous bottle handling mode



◆ From ***Function*** screen, click "[**Status**] →[**Solve Anon**]" to enter into ***Solve Anon*** screen.

2. Handle anonymous bottles



- Pull out the drawer, all the anonymous cell LED indicators light orange;
- Draw out a bottle, scan the bottle ID, the bottle information is shown on the screen;
- Insert the bottle to the cell from where the bottle has been removed (make sure the bottle is fully seated into the cell), the cell indicator light blinks slowly and there will be one short beep to acknowledge the bottle is successfully loaded.

- Cell information is shown on the screen, confirm it, and the anonymous bottle is handled;
- If any other anonymous bottle is needed to be handled, just remove the bottle, scan the ID and reload the bottle as procedures described as above.

Handling the Anonymous Bottle that Flags with Culture Result

The methods applied for handling the anonymous bottle that flags with culture result is the same as those for the anonymous bottle that has no resulted reported.

3. Exit anonymous bottle handling

When all anonymous bottles are handled, close the drawer to exit handling the anonymous bottle mode.

4.4.2 Plug Out the Bottle before Result Obtained

If any bottle is need to be pluged out before result is obtained, please follow the procedures as below:

1. Open the drawer door;
2. Plug the target bottle, and keep the door open, the system will prompt “Improper bottle unloading, please insert the bottle into the same cell as before!”
3. Check the bottle, and then insert the bottle into the cell as before.

NOTE:	Limit the bottle checking duration to no more than 5 minutes. Plugging out the bottle undergoing the test may affect the detection result, so try to avoid this operation if not necessary.

If a bottle smearing is needed, please perform the operation strictly according to the procedures as below:

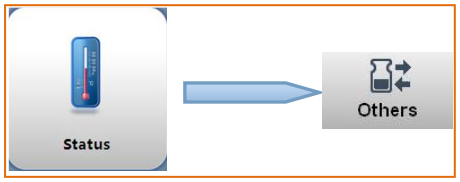
1. Open the drawer door;

2. Plug the target bottle, and keep the door open, the system will prompt “Improper bottle unloading, please insert the bottle into the same cell as before!”
3. Close the drawer door, the bottle status changes into missing bottle;
4. After the smearing is finished, please reload the bottle as procedures for a missing bottle, for details, please refer to “4.4.3 Handling the Lost Bottles”.

4.4.3 Handling the Lost Bottles

If a bottle is plugged out not follow unloading bottle procedures, the system will mark this bottle as a lost bottle.

1. Enter into handling lost bottles mode



◆ From the ***Function*** screen, click [**Status**] →[**Others**] to enter into ***Others*** screen.

2. Handle the lost bottles

◆ Click [**Lost Pro**], the system prompts “Scan the bottle ID and reload the bottle to the right cell”, click [**OK**].

◆ Scan the bottle ID, bottle information is shown on the Bottle Info screen;
◆ Pull out the drawer, all missing bottle cell indicator light up as orange;
◆ Insert the bottle to any of the available cell (make sure the bottle is fully seated into the cell), the cell indicator light blinks slowly and there will be one short beep to acknowledge the bottle is successfully loaded.
◆ Repeat bottle ID scanning and bottle inserting for each remaining missing bottle.

3. Exit lost bottle handling

When all lost bottles are handled, completely close the drawer to exit handling the lost bottles mode.

4.4.4 Clear Out the Lost

Precondition: all the resolvable missing bottles are handled. For those untraceable bottle (s) or the bottles that are meaningless for continue culture, they can be cleared out in order to release the cells.

1. Request for and clear out the lost bottle

- On the ***Function*** screen, click "[**Status**] → [**Others**]" to enter into ***Others*** screen.
- Select [**Clear Lost**]; the system prompts "Are you sure to clear out all lost bottles?" click [**Yes**].
- When all meaningless lost bottle are cleared out, the system prompts "No lost bottle to be handled!" click [**OK**], and the lost bottle cells are changed into idle cells.

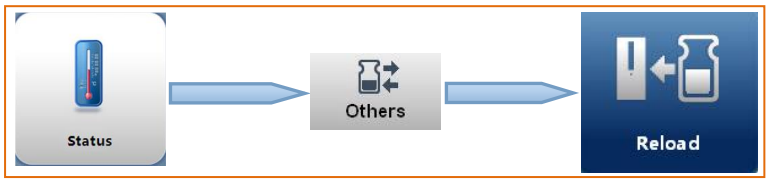
2. Exit lost bottle clearing

Click  to exit lost bottle clearing mode.

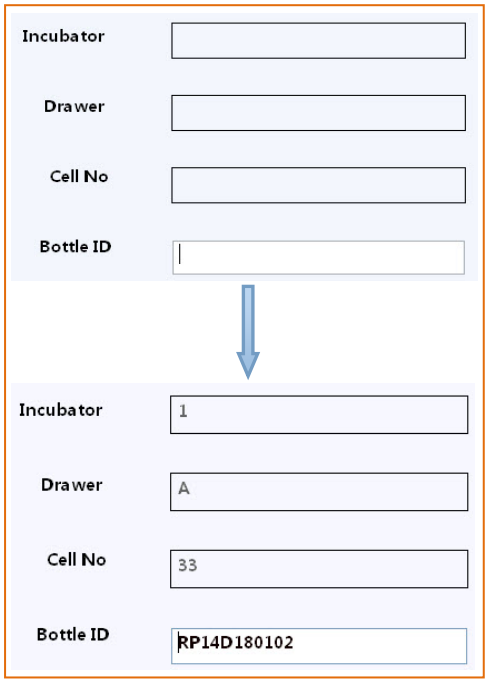
4.4.5 Reload the Bottle

For a finished bottle (result reported as positive or negative), if the doctor want it to be subcultured, please reload it as procedures described as below.

1. Request for and Reloading the Bottle



- On the main screen, click [**Status**]→[**Others**] to enter into ***Others*** screen.
- Select [**Reload**] to pops up the **Reload Bottle** screen.



- Pull out the drawer, all the available cell LED indicators light orange;
- Scan the bottle ID, the position where the bottle has been removed is shown on the screen;
- Insert the bottle to any idle cell (make sure the bottle is fully seated into the cell), the cell indicator light blinks slowly and there will be one short beep to acknowledge the bottle is successfully loaded;
- If any other bottle needs to be reloaded, scan the bottle ID and insert the bottle as procedures described as above.

2. Exit reload bottle mode

Close the drawer to exit reloading bottle mode.

4.4.6 Manually Assign the Result

If the reported result need to be modified as a result of physician's judgment, please do the modification as procedures described as below:

1. From ***Status*** screen, click [**Status**] to access ***Bottle Status*** screen;
2. Select the incubator and drawer where the target bottled is located respectively, click the bottle icon to display the growth curve of this bottle;
3. Click [**Bottle Info**] to access Bottle Info screen;
4. Click [**Edit**] to access the ***Edit*** screen, and select the option in the drop-down list beside Result;
5. Click [**Save**], the system asks if to save the modified information! Click [**OK**] to save the modified result.

NOTE:	Result modification is not recommended if not necessary; please take care before the operation.

4.5 Precautions during Culture

- Instrument power off longer than 30 minutes, test result may be not correct.
- Check the temperature on the Status main screen daily, ensure that the deviation should be no more than ±2°C, and otherwise contact the manufacturer.
- Avoid metal pieces like pins, falling into the instrument, especially in the cell, to avoid short circuit, or bottle bad contact.
- Make sure the bottle is fully seated into the cell, the top of all bottles are at the same level.
- If the system warms “QC failed, please calibrate the cell manually!” please handle it in time, for details, please refer to contents in 6.4.2.
- Make sure to closed the drawer door completely; otherwise detection result may be affected.
- If there is anonymous bottle in the incubator, handle the anonymous bottle first, otherwise detection result may be affected.
- This equipment must be operated by skilled/trained clinical professionals.

5. Troubleshooting

This chapter describes different types of instrument faults that may be encountered when using the instrument. Cause(s) and solution(s) for each type of fault problem are also listed.

> **CAUTION:**
>
> **Failure to follow the procedures in this operator's manual or failure to attend to fault conditions reported by the system within one hour may lead to invalid test results and the need to subculture bottles.**
>
> **Faults about incubator temperature out of control may adversely affect the test result and should be addressed immediately.**

If any instrument fault can't be corrected by solutions as described in this chapter, or fault encountered is not listed, please contact our Customer Service Department or your local distributor.

5.1 Common Faults and Corrective Actions

Fault type	Description	Measure
Temperature out of control	After the system being started for longer than 90 minutes, the temperature deviation between the actual and target are greater than 2℃.	Restart the incubator. If the faults still exist after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Sensor failure	After the system being started for longer than 120 minutes, temperature fluctuation is greater than 1℃.	Restart the incubator. If the faults still exist after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Abnormal fan speed	Rotating speed for some of the fan is abnormal.	Restart the incubator. If abnormal fan count is more than 3 after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Fan not stopped	Fan can't be stopped when the door is opened.	Close and then open the drawer. If the faults still exist after repeating the operation for 3 times, please contact our Customer Service Department or your local distributor.

Abnormal temperature	Temperature is less than 0℃ or greater than 60℃.	Close and then open the drawer. If the faults still exist after repeating the operation for 3 times, please contact our Customer Service Department or your local distributor.
Abnormal AD	When light is on, AD value is less than the fixed value; When light is off, AD value is greater than fixed value.	If the fault was detected for 3 times, please power off the instrument, check if power supply was stable. If the fault still exists, please contact our Customer Service Department or your local distributor.
Motor does not work	The motor does not work when door is closed.	Restart the incubator. If abnormal fan count is more than 3 after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Motor does not stop	The motor does not stop when door is closed.	Restart the incubator. If abnormal fan count is more than 3 after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Two drawers are opened.	Two drawers for the same incubator are opened.	Closed one of the drawer door.
Communication failure	Central Control Unit communication with lower computer failed.	Restart the incubator and IPC, if the faults still exist after repeating the operation for 3 times, please contact our Customer Service Department or your local distributor.
Drawer was opened for too long	The time that drawer keeps open is longer than the limit time.	Close the drawer.
Connection failure	Serial port cable not properly connected; combination module is powered off.	Check the serial port connection; plug out and connect the cable again; check if incubator power is on; restart the instrument.
	Serial port on PC is damaged, or serial port on the main board of combination module is damaged.	Contact our Customer Service Department or your local distributor to replace the serial port or main board.
Communication failure after system startup	Communication failed when software is started up.	Check if the incubator is working; Check if serial port connection is loose.
One-key uploading failed	One-key uploading failed.	Restart the industrial personal computer.
Printer connection failure	Printer has not been powered on; printer and instrument are not connected; printer driver has not been installed.	Do the following checking: if printer connection was proper; if printer was powered on if the driver has been installed

		if the printer was the default one.
	The printer is damaged, or printer port on the industrial personal computer is damaged.	Replace the main board of IPC or the printer.
Insufficient disk space	Hard disk space is not enough.	Contact our Customer Service Department or your local distributor to delete the log and data.
Insufficient memory	System runs out of memory	Restart the industrial personal computer.
LIS connection failure	Abnormal network connection, LIS server is not started up.	Do the following checking: If LIS setting was correct; if connection was correct; LIS server was properly started up.
Bottle ID already existed	There already exists the bottle ID in the database.	The bottle ID has been identified and memorized by the system. Scan a new bottle.

5.2 Mechanical Faults and Corrective Actions

Fault type	Description	Measure
Abnormal noise from the instrument	Abnormal noise during instrument working	Restart the instrument. If the faults still exist after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Door opening is hard	Door can't be opened smoothly	Restart the instrument. If the faults still exist after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Drawer door can't be closed	Door can't be closed smoothly	Restart the instrument. If the faults still exist after being restarted for 3 times, please contact our Customer Service Department or your local distributor.
Incubator module can't be vertically stopped	When door is opened, incubator module agitating can't be stopped.	Restart the instrument. If the faults still exist after being restarted for 3 times, please contact our Customer Service Department or your local distributor.

6. System Maintenance

6.1 Daily Maintenance and Precautions

- Place the blood culture system away from the direct sunlight otherwise the test precision may be affected.
- Check the temperature on the Status main screen daily, ensure that the deviation should be no more than ±2°C, and otherwise contact the manufacturer.
- Use soft dry cloth to clean the device and make it clean once a week. If the panel of the device is dirty, please wipe it with clean water. Organic solvent such as gasoline, diluted paint, benzene compounds, alcohol and so on are not allowed because they will deform and erode the instrument, make the paint off and affect the performance and appearance.
- Do not use the water to clean the liquid crystal monitor instead use the soft clean dry cloth or tissue to wipe it.
- Use the cotton swabs dipped with pure alcohol to clean the cell as well as light-transmitting plate every three months.
- Do not move or knock the instrument during the testing, to avoid bacteria solution spillage into the instrument.
- Hot-plug is forbidden; disconnect the power cord when the system is to be idle for a long period.
- The device must only be operated by skilled/trained doctors, nurses or clinical professionals.

6.2 Preventive Maintenance

Routine preventive maintenance is included in HNMR service program. There is no additional requirement for customer performed preventive maintenance. Contact our Customer Service Department or your local distributor to schedule periodic service.

6.2.1 Safety Precautions and Procedures

The design of the instrument provides several features in the interest of operator and laboratory safety.

- All blood culture bottles are manufactured of polycarbonate to limit the damage to bottle.
- All bottles are non-leaking to reduce the risk of liquid leakage.
- Each bottle cell is sealed to help contain and minimize effects of liquid leakage.
- Light-transmitting plate is incorporated at the bottom of each cell to separate little objects and liquid from PCB or other components.
- The circulating fans within the incubation and combination modules turn off whenever any drawer is open, minimizing airflow and the potential for aerosols.

- Any mention of bleach refers to the standard 5.25% sodium hypochlorite. A 10% bleach solution would indicate a 1:10 dilution of the standard 5.25% sodium hypochlorite.

WARNING:

Pathogenic microorganisms including Hepatitis B virus and Human Immunodeficiency Virus (HIV) may be present in specimens. Universal Precautions and Local Laboratory guidelines should be followed in handling all items contaminated with blood or body fluids. If an inoculated bottle is found to be leaking or is accidentally broken during collection or transport, use the established procedures in your facility for dealing with biohazardous material. As a minimum, Universal Precautions should be employed. Bottles should be discarded in an appropriate manner.

All liquid leakages should be handled in the way dealing with infectious disease.

6.2.2 General Precautions

The following precautions should be observed during maintenance and repair, even in situations where a spill is neither observed nor suspected.

- As a minimum requirement, the operator should wear gloves, eye protection and a lab coat.
- Any parts removed or tools used should be cleaned using a 10% bleach solution or EPA-registered tuberculocidal disinfectant before removal from the laboratory.
- Anything that can't be disinfected should be sealed in a plastic bag, labeled as biohazardous and handled accordingly. In addition, the laboratory's safety precautions should always be observed.

6.2.2.1 Spill Cleanup

In case of liquid spillage, follow your laboratory's spill cleaning up procedures.

WARNING:

For spills that might involve M.tuberculosis, proper protective equipment should be worn, including suitable respirator, gloves, eye protection, and a lab coat. In some cases, coveralls or shoe covers should be worn to avoid contaminating street clothing.

- Gently cover the spill area with a paper towel. Apply a 10% bleach solution of other EPA registered tuberculocidal disinfectant.
- Use the bleach solution, wet down all surfaces with which the spill may have come in contact.
- Allow all surfaces adequate contact time (15 – 30 minutes) with the bleach solution before cleaning up.
- All materials used in the clean up should be treated as biohazardous waste.

6.2.2.2 Disinfection Procedures for Spills onto the Instrument

WARNING:

Handle specimens and inoculated culture bottles as though capable of transmitting infectious agents. All inoculated bottles, specimen collection needles, and blood drawing devices should be autoclaved before they are discarded.

Any blood or test specimen spilled on the instrument should be removed immediately using the following procedures.

- Wear protective gloves before handling the spill.
- Clean the spill from the instrument following your institution's recommended procedure for decontamination or the procedure described in the latest version of Clinical and Laboratory Standards Institute (CLSI) guideline "Protection of Laboratory Workers from instrument Biohazards and Infectious Disease Transmitted by blood ,Body fluids, and Tissue" CLSI Document M29-A.
- After decontamination, wipe with damp (water only) towel and thoroughly dry.

6.2.2.3 Disinfection Procedures for Spills within the Instrument

WARNING:

If a spill is detected that might involve M.tuberculosis, only persons wearing protective clothing and suitable respiratory protection should remain in the room.

Any test specimen spilled in the instrument should be removed immediately and the affected areas decontaminated using the following procedures.

1. Visually inspect the extent of the leakage or spill. Determine if one or more racks or the drawer itself is contaminated.
2. Remove the leaking bottle if possible.

NOTE: If a bottle is lodges in the cell, please contact our Customer Service Department or your local distributor. Do not try to dislodge bottle by pulling on the rack.

3. Unload positive and negative bottles in affected racks (s). Refer to "4.3.1 Loading Bottles" for details.
4. Relocate remaining bottles in affected racks in procedures for relocating lost bottles as described in "4.4.3 Handling the Lost Bottles".

NOTE: Bottles affected by the spill should not be reloaded until they have been decontaminated. Decontaminate the bottles following your institution's recommended procedures for decontamination or the procedures described in the latest version of Clinical and Laboratory Standards Institute (CLSI) guideline "Protection of Laboratory Workers from instrument Biohazards and Infectious Disease Transmitted by blood ,Body fluids, and Tissue" CLSI Document M29-A.
The contaminated cell, rack or drawer should never be used.

5. If an affected cell contains a large amount of liquid, carefully aspirate it using a pipette or similar device, and dispose of it in an appropriate biohazardous waste container.
6. If the spill is confined to one drawer or a few cell of a drawer, the affected cell may be cleaned in disinfected with a 10% bleach solutions, using the following procedures:

CAUTION:

Do not expose the cell or rack to the bleach solution for an extended period. 10% bleach is the ONLY disinfectant that has been validated for used with the cells. Do not use a different disinfectant or a bleach solution stronger than 10% or damage to cell components may occur.

a) Insert absorbent material, such as gauze, into the cell to absorb any remains fluid. Carefully remove and discard the gauze in a biohazardous waste container.
b) Wipe out the interior of the cell with gauze soaked with 10% bleach solution and discard the gauze in a biohazardous waste container.
c) Insert several layers of gauze saturated with a 10% bleach solution into the cell and let sit for 5-30 minutes to decontaminate. The gauze should be soaked to the point of saturation but not so wet that liquid drips out of the cell.
d) Remove and discard the gauze in a biohazardous waste container.
e) Wipe the interior of the cell with gauze soaked in distilled water to rinse.
f) Allow the cell to air dry.
g) Calibrate the cell. If the cell passes calibration, enable the cell (for details, please refer to "6.4.2 Cell Calibration").

7. If the cell fails calibration or there is visible blood stain residue still present in the cell, particularly on the bottom, clean as follows:
   a) Insert absorbent material, such as gauze, into the cell to absorb any remains fluid. Carefully remove and discard the gauze in a biohazardous waste container.
   b) Rinse with 10% bleach solution, then distilled water and let it air dry.
   c) Calibrate the cell. If the cell still can't be calibrated, disable the cell and mark it.
8. For more extensive spills, it may be necessary to remove one or more racks or an entire drawer. To remove the rack or drawer, please contact our Customer Service Department or your local distributor.

NOTE: Decontaminate bottles, cells, racks, and drawers following your institution's recommended procedures for decontamination or the procedure described in the latest version of Clinical and Laboratory Standards Institute (CLSI) guideline "Protection of Laboratory Workers from instrument Biohazards and Infectious Disease Transmitted by blood ,Body fluids, and Tissue" CLSI Document M29-A.

6.3 Fuse Replacement

In case of fuse burnout, unplug the power cord; use a flathead screwdriver to open the fuse box. Take out the fuse to see if it is burnt up. Replace it with two new fuses and close the fuse box. If the new fuses were burnt up in a short time, please contact our Customer Service Department or your local distributor in time.

6.4 Software Maintenance

From the ***Function*** screen, click [**Maintenance**] to access the ***Maintenance*** main screen.
Through software maintenance, parameter inquiry and configuration, data backup/deleting, software upgrading, system debugging and log viewing can be carried out.
Software maintenance only can be accessed by service engineer.

6.4.1 Temperature Calibration

When any of the following situations is encountered, please contact our Customer Service Department or your local distributor.

- System gives out temperature related fault;
- Abrupt temperature change (greater than 2℃);
- Obviously sensed that the displayed temperature is not consistent with the actual.

6.4.2 Cell Calibration

All cells in the instrument have been calibrated before delivery. However, calibrations are required at a fixed period (about 3 months), or if a cell fails its automatic internal diagnostic check.

NOTE:	A cell which has failed the automatic internal diagnostic check no longer records bottle readings and will not be indicated as available when loading bottles. The cell must be calibrated or disabled. If the cell to be calibrated contains a bottle, the bottle should be relocated into other cell.

Follow the procedures described as below when to calibrate a cell:

1. From the ***Function*** screen, click [**Setup**] to access the ***Setup*** screen;
2. Click [**Cell Calibrate**] to access ***Cell Calibrate*** screen.
3. Select the cell to be calibrated:
   a) Select the incubator (1-5);
   b) Select the drawer(A or B);
   c) Select cell (1-60).
4. Click [**C1 Calib**], insert Standard C1 (marked with one circle around the Standard) into the selected cell and press [**OK**] as the system prompts “Insert the Standard C1 into the yellow light cell then press [**OK**].”
5. Wait until system prompts “C1 calibration is finished, please perform C2 calibration with Standard C2.”, and [**C1 Calib**] button changes into [**C2 Calib**]. Click [**C2 Calib**], insert Standard C2 into the selected cell and press [**OK**] as the system prompts “Insert the Standard C2 (The other end of Standard C2 marked with two circles around the Standard) into the yellow light cell then press [**OK**].”
6. Wait until system prompts “C2 calibration is finished, please perform C3 calibration with Standard C3.”, and [**C2 Calib**] button changes into [**C3 Calib**]. Click [**C3 Calib**], insert Standard C3 (marked with three circles around the Standard) into the selected cell and press [**OK**] as the

system prompts “Insert the Standard C3 into the yellow light cell then press [**OK**].”

7. Wait until system prompts “Calibration succeeded!”, and then exit the calibration by clicking the Return Preview button. If the system prompts “Cell calibration failed!” please try the calibration again.

NOTE:	If the recalibration failed again, please contact our Customer Service Department or your local distributor.

Appendix A Blood Culture Bottles

A.1 Bottle Structure

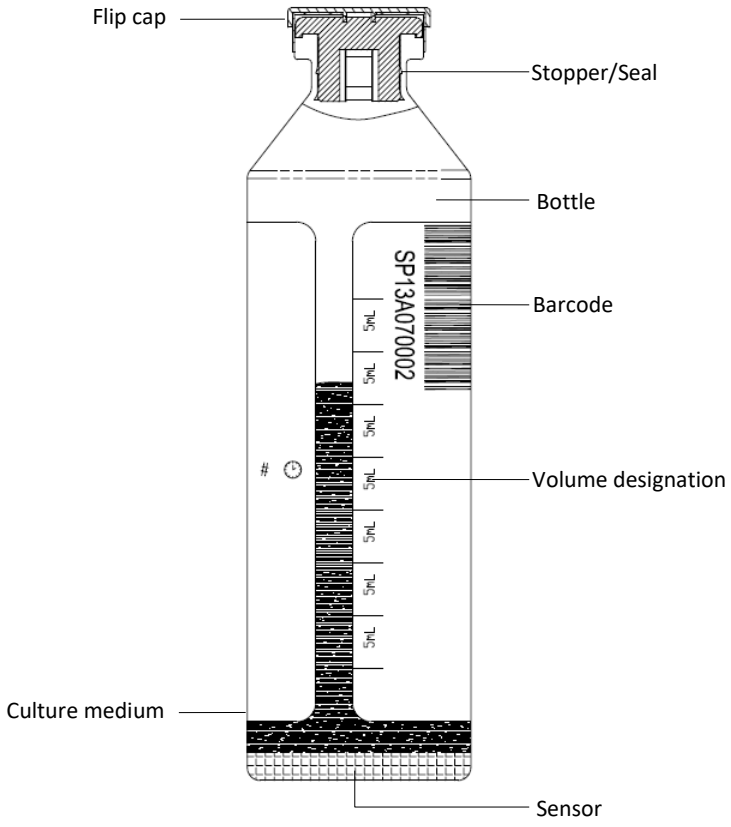


Fig A-1 Culture bottle

Flip Cap

Plastic flip cap that ensures septum seal cleanliness, but not sterilized.

Stopper/Seal

Butyl stopper secured with a color-coded aluminum seal. The stopper is not sterile and should be disinfected prior to sample inoculation.

Bottle

Plastic bottle manufactured of biological safe polycarbonate.

Volume designation

Markings which indicate approximate volume. These demarcations assist in approximating the volume of sample added to a bottle.

Barcode

The blood culture system adopts barcode system to load bottle information. Each bottle has a barcode on its label. For convenience, a portion of this barcode label may be peeled off and affixed to other records.

Entering the barcode commands the system to apply the proper algorithm to the bottle readings and to direct the bottle to the proper drawer type.

Sensor

Colorimetric carbon dioxide sensor attached internally to the bottom of each bottle.

A.1.1 Limitations of the Test

Refer to package insert enclosed with the TDR culture bottles for additional information.

Many variables involved in blood culture testing can't be practically controlled to provide total confidence that results obtained are due solely to proper or improper performance of any culture medium or detection system.

NOTE:	A Gram-stained smear from a negative bottle may sometimes contain a small number of non-viable organisms that were derived from culture medium components, staining reagents; immersion oil, or glass slides, therefore, false-positive results are indicated.

A.2 Classification of Culture Bottles

The following reagents, consumables, blood culture bottles are provided for use on the automated blood culture systems. For details, please refer to the corresponding package. For prices, please contact your local distributor.

NOTE:	All blood culture bottles are manufactured of biological safe polycarbonate to limit the damage to bottle.

- TDR Aerobic (Purple cap)

Used for culture and detection of aerobic microorganisms (bacteria or moulds) in blood and other normally sterile body fluid. Each bottle is filled with 40 ml nutrient broth, which is made up of compound amino acid, carbohydrate, and pure water. The gas filled in the bottle is a mixture of oxygen and carbon dioxide.

- TDR Anaerobic (Green cap)

Used for culture and detection of anaerobic microorganisms in blood and other normally sterile body fluid. Each bottle is filled with 40 ml nutrient broth, which is made up of nitration, compound amino acids, carbohydrate, and pure water. The gas filled in the bottle is a mixture of nitrogen and carbon dioxide.

- TDR Peds (Yellow cap)

Used for culture and detection of aerobic microorganisms (bacteria or moulds) in blood and other normally sterile body fluid. Each bottle is filled with 25 ml nutrient broth, which is made up of compound amino acid, carbohydrate, and pure water. The gas filled in the bottle is a mixture of oxygen and carbon dioxide.

- TDR Resin Aerobic (Blue cap)

Used for culture and detection of aerobic microorganisms (bacteria or moulds) and facultative anaerobe in blood and other normally sterile body fluid. Each bottle is filled with 35 ml nutrient broth, which is made up of compound amino acid, carbohydrate, and pure water. Ion exchange resin and polymeric adsorbent are added to adsorb antibiotics. The gas filled in the bottle is a mixture of oxygen and carbon dioxide.

- TDR Resin Anaerobic (Milk-white cap)

Used for culture and detection of anaerobic microorganisms in blood and other normally sterile body fluid. Each bottle is filled with 35 ml nutrient broth, which is made up of compound amino acids, carbohydrate, and pure water. Ion exchange resin and polymeric adsorbent are added to adsorb antibiotics. The gas filled in the bottle is a mixture of nitrogen and carbon dioxide.

- TDR Resin Peds (Red cap)

Used for culture and detection of aerobic microorganisms (bacteria or moulds) and facultative anaerobe in blood and other normally sterile body fluid. Each bottle is filled with 25 ml nutrient broth, which is made up of compound amino acid, carbohydrate, and pure water. Ion exchange resin and polymeric adsorbent are added to adsorb antibiotics. The gas filled in the bottle is a mixture of oxygen and carbon dioxi.

Appendix B Toxic and Harmful Substances/Elements

Part Name	Toxic and harmful substances or elements					
	Lead(Pb)	Mercury(Hg)	Cadmium(Cd)	Hexavalent Chromium(Cr((VI)	Polybrominated biphenyls(PBB)	Polybrominated diphenyl ethers (PBDE)
Drawer	○	○	○	○	○	○
Drawer door	○	○	○	○	○	○
Touch screen	○	○	○	○	○	○
Instrument frame	○	○	○	○	○	○
Boards	×	○	○	○	○	○
Ports	○	○	○	○	○	○
Barcode Scanner	○	○	○	○	○	○
Cable	○	○	○	○	○	○

○：shows that the content of the toxic and harmful substance contained in the part is below the required limit specified in SJ/T11363-2006 standards.

× : shows that the content of the toxic and harmful substance contained in the part is above the required limit specified in SJ/T11363-2006 standards.

Appendix C Automatic Data Backup Function

The system database is SQL Server 2005, it has automatic data backup function, when the software program is restarted, the database will be automatically backup to the path C:/ProgramFiles/BloodCulture/Database/Backup.

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