

Automated Blood Culture System

Operating Manual

(Version 1.0)

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1. Name and Model

【Name】 Automated Blood Culture System

【Model】 BC64, BC128, BC256

2. Performance and Application

【Normal Working Conditions】

Environmental temperature: 5-40 °C

Relative humidity: ≤80%

Atmospheric pressure: 76KPa-106KPa

Power supply voltage: AC220V±22V, 50Hz±1Hz

Illumination: avoid direct sunlight.

【Performance Indicators】

Authentication capacity: able to detect 64~512 blood culture bottles simultaneously, and get positive result within 72 hours.

Scan frequency: automatic scanning once every 10 minutes.

Temperature deviation: less than ±1.5 °C

Rated power: 250W~2000W

【Application】 This product is used for automatic culture and detection of microbes in clinical human blood or other sterile body fluid.

3. Structure

【BC64 structure】

BC64 is composed of a main controller and a 64-hole unit.

Volume: 350mm×650mm×780mm

Weight: 51Kg

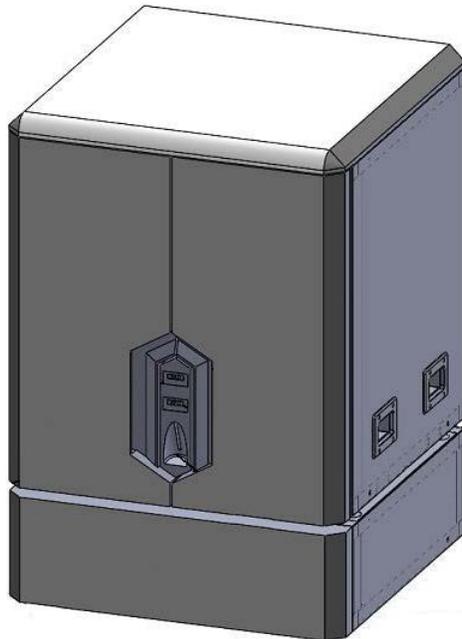


【BC128 structure】

BC128 is composed of a main controller and two 64-hole units.

Volume: 660mm×650mm×975mm

Weight: 128Kg



【BC256 structure】

BC256 is composed of a main controller and four 64-hole units.

4. Configuration Conditions of Computer

Requirements on hardware system: mainstream x86-model computer, including RS232 serial port.

Requirements on software system: Windows series (full installation version), Microsoft Office (2003 version or above).

5. Operating Conditions

In order to guarantee the normal operation of the instrument, it should be used under the following conditions with corresponding environment being maintained:

- 1) Environment with less dust and good ventilation. There is no corrosive, flammable or explosive gas or steam in room.
- 2) Avoid direct sunlight or heat radiation.
- 3) Level table (slope<1/200).
- 4) The table shall be strong enough to withstand the weight of 100kg.
- 5) Indoor temperature should be kept ranging from 5~40 °C.
- 6) Indoor relative humidity should be kept ranging from 10~90% without condensed water.
- 7) Necessary heat dissipation space around the instrument shall be 76cm to the left, 38cm to the right, 11cm for the back, 61cm for the upside. It is recommended to place the instrument on a table with height of 77~92cm.
- 8) The instrument can only be used at altitude ranging from 0 to 3km.
- 9) There should not have vibration that can be felt.
- 10) Variation of power supply voltage: AC220V (±22V); power of supply: 250W.
- 11) There is no machine emitting high frequency wave near the instrument.
- 12) Considerations about electromagnetic wave: No mobile phone, intercom or other electrical appliance emitting electromagnetic wave is allowed to carry into the room where the instrument is placed.
- 13) Protective grounding (grounding impedance should be less than 10 ohm).
- 14) Externally connected computer.

6. Safety Provisions

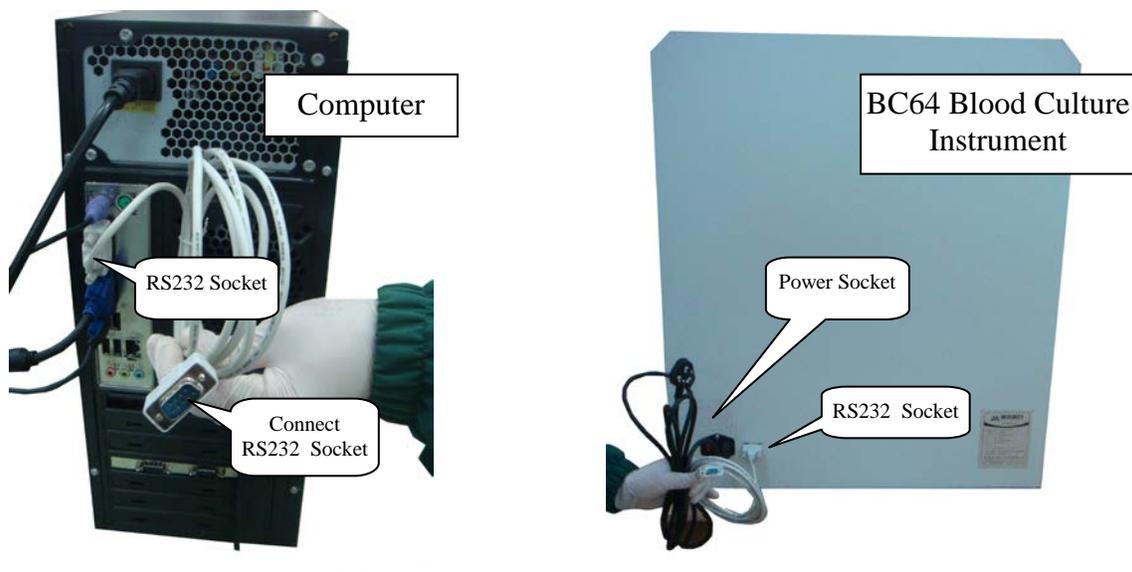
Below are the precautions about the automatic blood culture system. A user will possibly have the risks of death or serious injury if the user fails to abide by them. The severity of risks is unrelated to the following order.

- 1) A pair of rubber gloves shall be used and direct contact is prohibited when applying a specimen that potentially does harm to human body or leads to infection. Rinse with plenty of water and conduct disinfection and see a doctor when necessary in case of contact with the specimen. The instrument should be disinfected after being stained.
- 2) No combustible or hazardous article may be used above or around the instrument; otherwise, fire or explosion will be caused.
- 3) The operation and maintenance shall follow the prescribed procedure. Do not touch any place other than the designated part. Do not open the back or side panel of the instrument when electrifying. Touching the cooling fan will cause injury.
- 4) The power switch should be OFF when opening the back panel and operation is only allowed on the designated part. There is danger of electric shock when touching circuit board when the power switch is ON.

- 5) Do not open the front top panel and back panel of the instrument; otherwise, touching the circuit board will damage IC.
- 6) Do not look at the light with the naked eye; otherwise, your eyes will be injured. Please wear protective glasses when you look at the light.
- 7) Rinse with plenty of water and see a doctor when necessary in case of contact with blood, etc. in the culture bottle.
- 8) The instrument is only used for clinical microbe detection of specimens of blood and sterile body fluid. It will fail possibly in other applications.
- 9) The specified conditions shall be met for instrument installation; otherwise, it is possible to affect the reliability of the determination results or damage the instrument. An operator shall thoroughly read the manual before use, and conduct operations according to relevant requirements.

7. Installation

The instrument may be used after placed on stable and fixed table and connected with power, communication wire, mouse and keyboard wire.

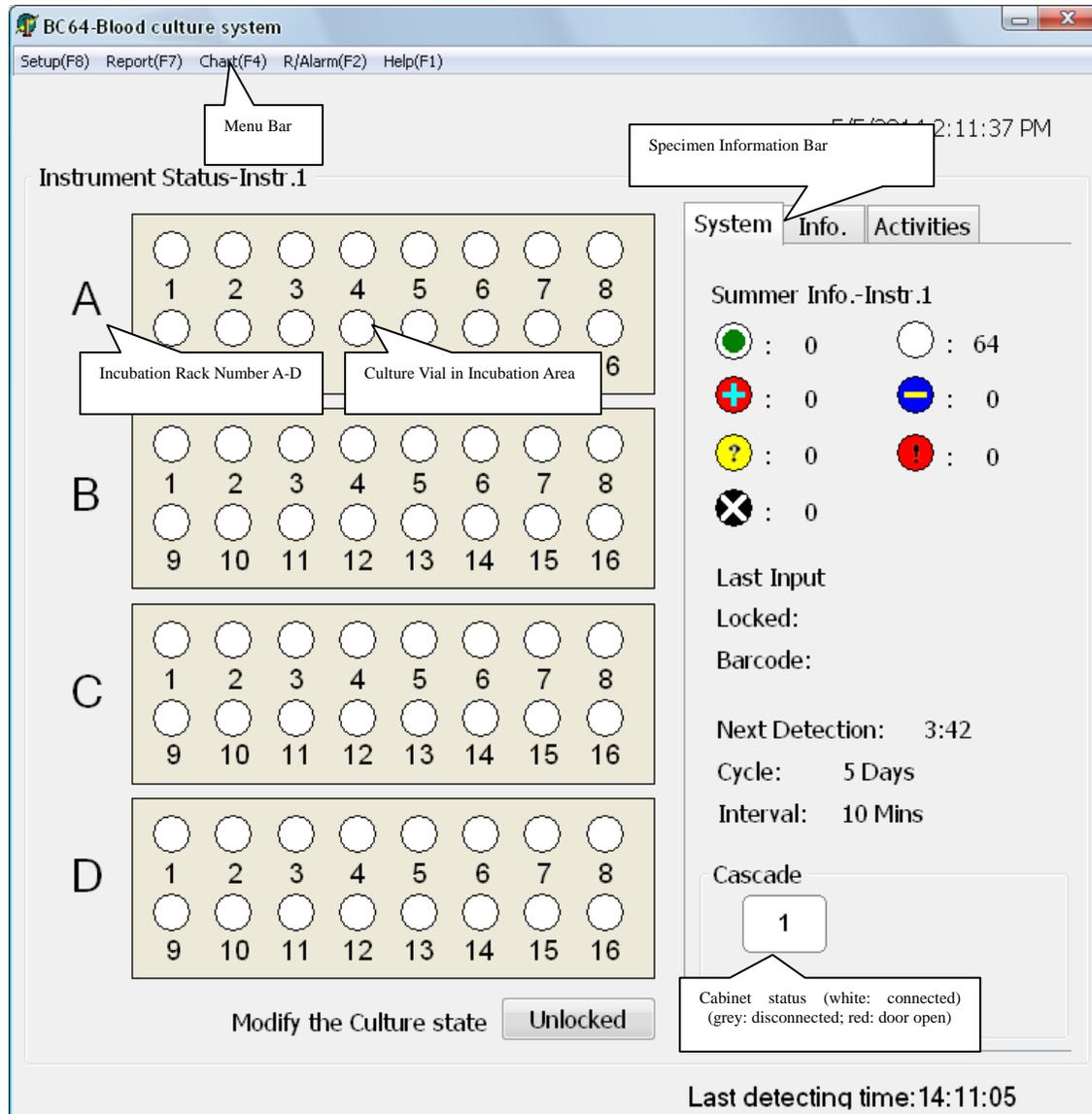


Connection between the instrument and computer: connect one end of the RS232 connection, which is delivered with the instrument, with serial port of computer, and the other end with RS232 port of the instrument. When multiple units are used with parallel connection, computer shall have multiple RS232 serial ports, and each unit shall be connected to a serial port.

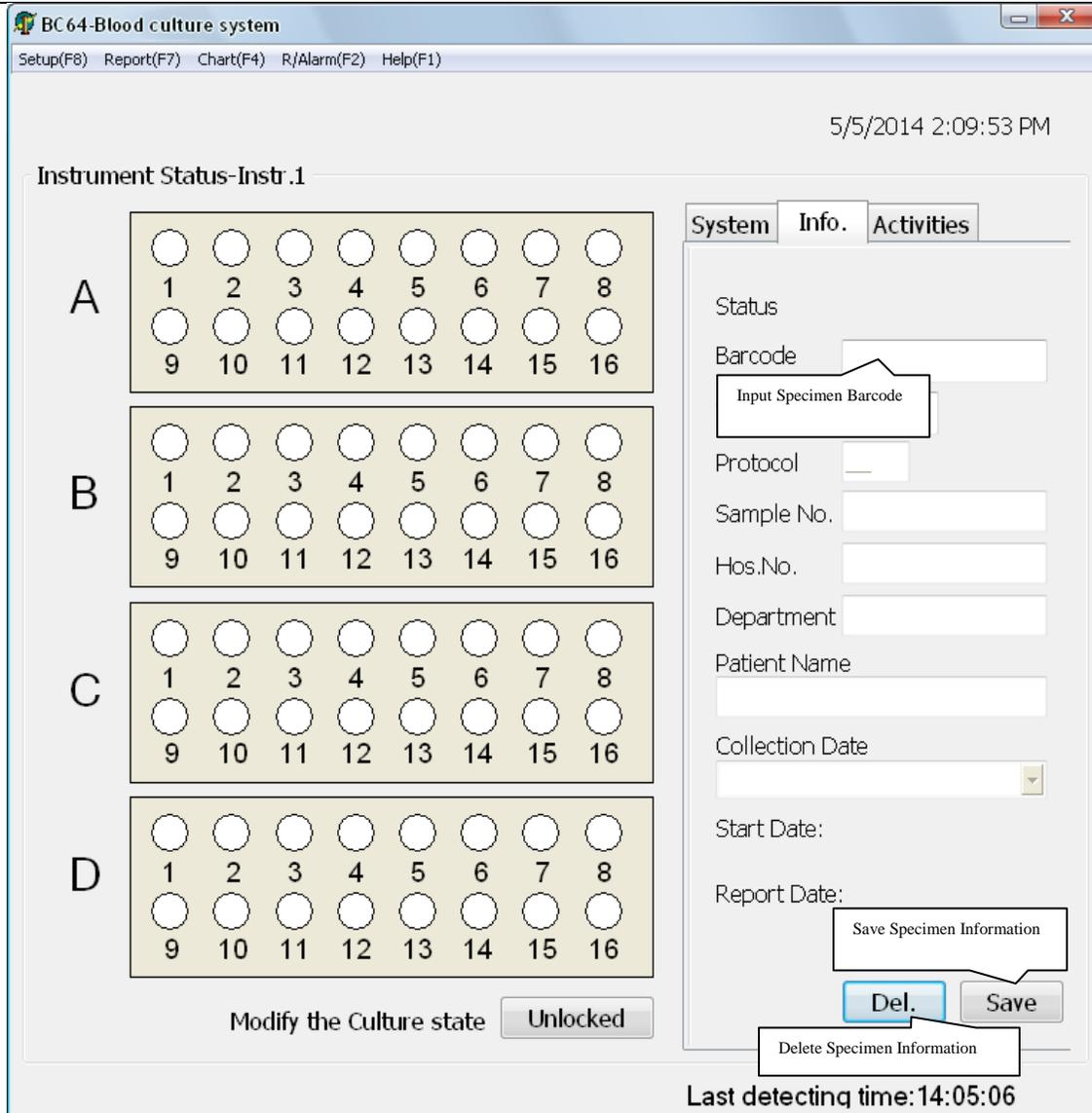
8. Uninstallation of Software

Double-click the uninstall program in program package to completely uninstall the software from the computer system.

9. Specimen Determination Procedure



In the main interface of program, the status (e.g. culture, negative/positive) of culture bottles in incubation rack is displayed on the left; the specimen information, culture duration and detection interval of the last input may be seen on the right (including the specimen with finished culture).



9.1 Culture Data Input

After preparation of culture bottle:

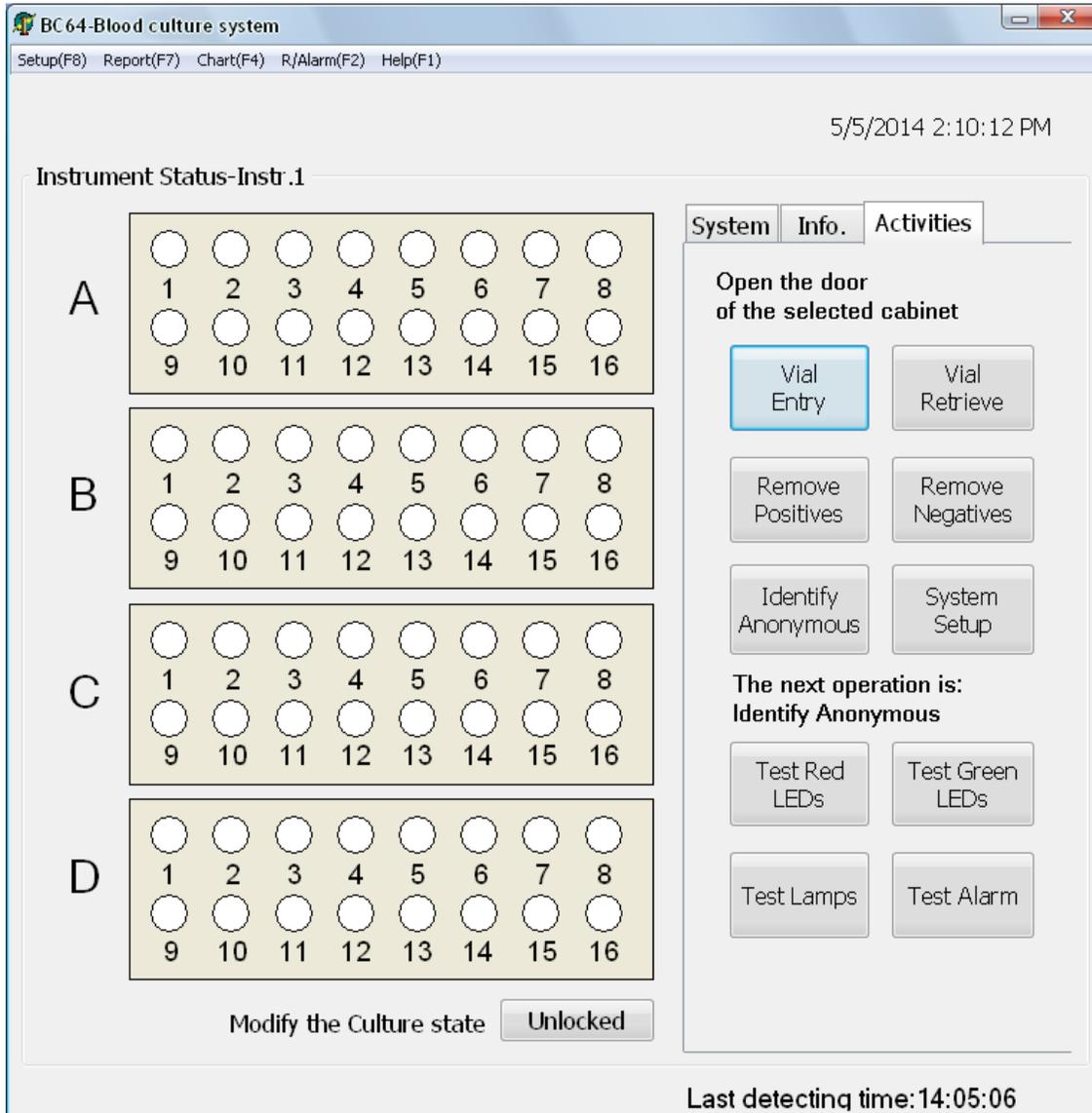
- 1) Tear off one of the two barcodes on culture bottle, and paste it on the report of submitting for inspection for future query;
- 2) Press the Specimen Information Bar (Bottle) in the left of interface, press the Input field after the “Barcode” label (Input Specimen Barcode) and scan the barcode of culture bottle with an external scanner;
- 3) After input of specimen barcode, click Enter; specimen information may be entered or modified in sequence;
- 4) Press “Save” key below or F10 to save information as prompted.

9.2 Entry Procedure of Culture Bottle

After culture bottle information is entered into computer:

- 1) In the Activities area of the figure above, click “Bottle Entry” button;

- 2) Open the instrument door;
- 3) A prompt of bottle entry will appear;
- 4) Align the barcode on bottle with the scanning groove below the instrument door; prompt tone will be given off. In the Activities area, a prompt of putting the bottle into the instrument will appear, and the indicating light of the corresponding vacant space on incubation rack will be ON;



- 5) Put the culture bottle at the prompted bottle position;
- 6) After hearing the prompt tone, which indicates completion of operations, repeat steps 4)~5) until all the culture bottles have entered;
- 7) Close the door.

Note: If barcode is not entered and saved in advance, the steps of bottle entry may also be completed; in case of duplicate barcodes, position indicating light will not be ON and alarm will flash in software interface.

9.3 Remove Negatives

The default culture duration of common bacteria is 5 days. If bacteria growth is not detected within 5 days, the bottle will be deemed as negative. Negative mark () will appear at corresponding position of software interface; green negative alarm will be shown at the indicating light position below the instrument door with alarm sound on.

- 1) You can press “F2” or “R/Alarm” button on the menu bar to temporarily eliminate the alarm sound;
- 2) Open the instrument door, wait until the incubation rack stops shaking and software prompts that the door is opening;
- 3) In the Activities area, click “Remove Negatives” button;
- 4) Continue the operations below after hearing prompt tone; otherwise, repeat step 2);
- 5) Position indicating light of the negative bottle is green;
- 6) Remove all the negative bottles;
- 7) Close the door (the instrument will submit result after several seconds after the door is closed).
- 8) If the door is opened without any bottle removal operation, the alarm sound will stop temporarily until the next specimen that conforms to negative/positive judgment appears.

9.4 Remove Positives

After the host discovers positive bottle, positive mark () will appear at corresponding position of software interface; red positive alarm will be shown at the indicating light position below the instrument door with alarm sound on. The priority level of positive indicating light is higher than that of negative indicating light, i.e. when both negative and positive specimens exist in the instrument, the red indicating light will be ON, and the green indicating light (for negative) will be ON after all the positive specimens are removed.

- 1) Press “F2” or “R/Alarm” button on the menu bar to temporarily eliminate the alarm sound;
- 2) Open the instrument door, wait until the incubation rack stops shaking and software prompts that the door is opening;
- 3) In the Activities area, click “Remove Positives” button;
- 4) Continue the operations below after hearing prompt tone; otherwise, repeat step 3);
- 5) Position indicating light of the positive bottle is red;
- 6) Remove all the positive bottles;
- 7) Close the door (the instrument will submit result after several seconds after the door is closed).
- 8) If the door is opened without any bottle removal operation, the alarm sound will stop temporarily until the next specimen that conforms to negative/positive judgment appears.

9.5 Procedure for Handling Anonymous bottle

If a culture bottle enters the instrument without scanning of barcode on the bottle, the instrument will be unable to find data of the bottle and will report error with error type of anonymous bottle. Then, anonymous mark () will appear at corresponding position of software interface; yellow error alarm will be shown at the indicating light

position below the instrument door with alarm sound on.

- 1) Press “F2” or “R/Alarm” button on the menu bar to temporarily eliminate the alarm sound;
- 2) Open the instrument door, wait until the incubation rack stops shaking and software prompts that the door is opening;
- 3) In the Activities area, click “Identify Anonymous” button;
- 4) The position indicating light of anonymous bottle on incubation rack will be ON;
- 5) Remove the anonymous bottle from the designated position, and scan the barcode on the bottle;
- 6) Continue the operations below after prompt tone is heard and corresponding position of software is changed from anonymous status into culture/positive/negative status, and the previous position indicating light is OFF, and the position indicating light of the next anonymous bottle is ON; otherwise, repeat step 5);
- 7) Put the culture bottle at the previously designated position (from which the anonymous bottle was removed);
- 8) Repeat steps 5)~7) until all the anonymous bottles have been handled (upon completion, a prompt that anonymous bottles have been handled will appear in the Activities area);
- 9) Close the door.

9.6 Procedure for Handling Lost Bottle

In case of any loss of culture bottle at the position of “culture status” or any failure of detectors, the system will report the error status, and mark of lost bottle () will appear at corresponding position of software interface; yellow error alarm will be shown at the indicating light position below the instrument door with alarm sound on.

- 1) Press “F2” or “R/Alarm” button on the menu bar to temporarily eliminate the alarm sound;
- 2) Open the mainframe door, wait until the incubation rack stops shaking and software prompts that the door is opening;
- 3) In the Activities area, click “Bottle Retrieve” button;
- 4) Align the barcode on the found culture bottle with the scanning groove below the instrument door; prompt tone will be given off, and the indicating light of vacant position of the lost bottle on incubation rack will be ON;
- 5) When the position indicating light of the lost bottle on incubation rack is ON, insert the bottle into the vacant position. After hearing the prompt tone, which indicates completion of operations, repeat steps 4) ~5) until all the lost bottles are retrieved and the door is closed.
- 6) If the culture bottle is not at the designated position and can not be found, click the bottle position, and then select “Delete” below the specimen information bar to vacate the bottle position;
- 7) If the culture bottle is already at the designated position and has been inserted properly, but still shows “!” after detection, it shall be judged that the culture hole has problem. In this case, click the bottle position, select “Delete” to vacate the bottle position, and then select “Delete” to prompt closing of the bottle position.

9.7 Manual Setup of Culture Bottle Status

The Culture Bottle Status in the process of culture may be set manually:

- 1) Press “F9” key or “Unlock”, and input the unlocking password in the pop-up window of Input Password (default password: 1).



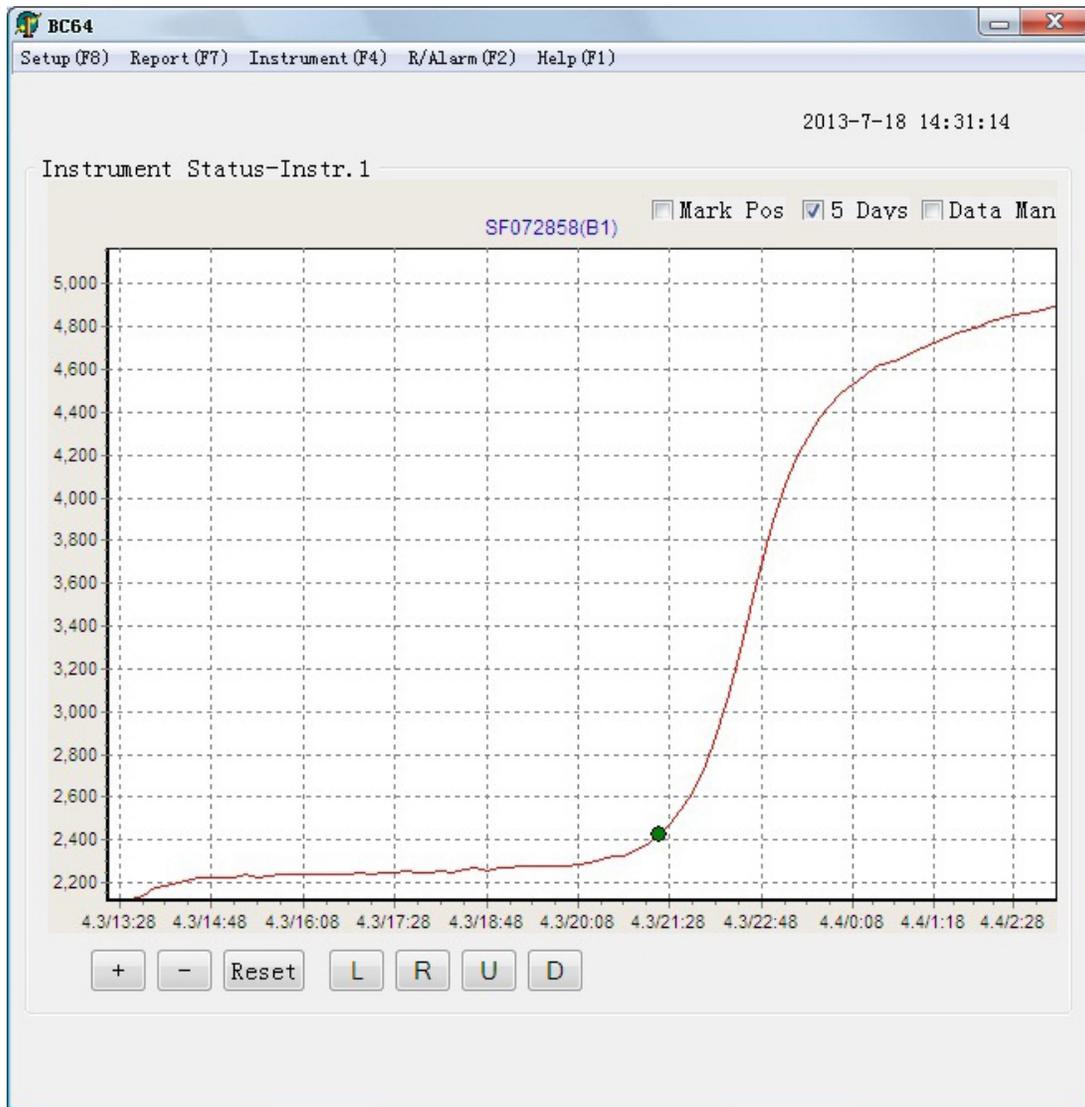
- 2) After unlocking, the incubation rack number A~D in the software will be blue;
- 3) Click with cursor the specimen in “Culture Bottle Status” to modify its negative/positive status (in unlocking status, error position and vacant position can not be selected);
- 4) After modification, press “F9” key or “Lock” to change the incubation rack number in the software into red; modification is impossible after locking;
- 5) If negative bottle is set, follow the procedure of Remove Negatives;
- 6) If positive bottle is set, follow the procedure of Remove Positives;
- 7) Unlocking password may be changed in “Password Setup” in Setup (F8).

9.8 Culture Bottle Status and Data Inquiry

Status and relevant data of the culture bottle in the process of culture may be directly searched in computer:

- 1) Press the corresponding specimen hole position, and relevant “Specimen Information (Bottle)” will appear on the right;
- 2) Or, move the cursor to “Barcode” in the specimen information bar, input the culture bottle barcode, and press Enter;
- 3) Or, move the cursor to “Position” to input the position information, and press Enter;
- 4) Relevant status and data will be displayed on screen;
- 5) If step 2) is implemented, the information bar will enter editable status, conduct modification operation, and then click “Save” button below.
- 6) For a specimen being cultured, if operation mistake occurs at a certain bottle position (for example, bottle is lost and can not be found; barcode of anonymous bottle can not be found) and it is necessary to vacate the hole position, just click the hole position and click “Delete” button below the specimen information bar; after a prompt that “Delete the bottle position status?” or “Delete the specimen?” is displayed, click “Yes” to delete wrong information of the hole position.
- 7) Culture duration of a specimen may be separately set in “Culture Days” in the specimen information bar; for some special specimens whose culture duration needs to be extended, or some retrieved bottles whose short-term culture needs to be separately set, make modification here and save.

9.9 Growth Curve Inquiry



For the culture bottles that are in the course of culture or have finished culture, growth curve can be inquired directly on computer:

- 1) Following the above step 9.8, press “F4” or the key of “Chart/Instrument” on the menu bar for direct entry into the interface of “culture curve”;
- 2) You can return to the “Instrument” interface by pressing “F4” or the key of “Chart/Instrument” again;
- 3) If the cultured specimen is positive, cue points will be marked on the curve. You can further check the time of positive reporting by clicking the “Mark Pos” above the curve interface.
- 4) If you click the “5 Days” above the curve interface, the curve axis will be changed according to the culture duration of 5 days, and show the culture progress of the current specimen during 5 days.
- 5) You can check the reading values of specimen at each detection time by clicking the “Data Man” above the curve interface.

- 6) If you want to check the curve trend in a certain range, you only need to use mouse to select the curve in the range from upper left to lower right, and then you can zoom in and check. If you want to return to the initial curve range, you only need to make reverse selection with mouse from lower right to upper left, or you can just click “+” or “-” to zoom in or zoom out the curve, and “R (Right), L (Left), U (Up), D (Down)” to move the curve, or press the “Reset” key or switch the “culture/curve” interface to return to the initial curve.

9.10 Retrieval of Positive Culture Bottles

The removed positive culture bottles can be put back for redetection:

- 1) Move the cursor to the “Barcode” position in the “Specimen Information” region, input the barcode of the removed positive culture bottle, and then press “Enter”;
- 2) Click the “Redetect” key, and select “Yes” on the pop-up window to continue to make detection.
- 3) Following the steps for entry of new bottle, put the culture bottle at the fixed position on the incubation rack. Then the specimen will be in culture state, and will have a continuous detection for 5 days (or a user-defined period) based on its historical curve.

Notes: 1. In order to prevent the difference in temperature and the time breakpoint from affecting positive judgment, it is not advisable to conduct retrieval operation of the specimen that has been removed for a long time;

2. The retrieval operation shall be made after the specimen has been removed according to normal removing procedure (follow the removing procedure for positive bottles after “positive” has been automatically reported).

9.11 System Setup

Press “F8” or the “Setup” key on the menu bar to enter the setup interface:

It is recommended that all the following functions are set up by manufacturer’s engineer or product specialist.

| Item | Functions |
|--------------------|--|
| Hospital name | After a hospital name is entered, the name will appear on the top of the main frame of the software. |
| Communication port | Numbering the communication ports between the host computer and the instrument; the default value is 1; the cascade may be set as 1; 2; 3...n (“1~n” is the port number; separated by a semicolon in between). |
| Positive alarm | Setting whether there will be alarm when detecting positive/negative bottles. |
| Culture duration | Setting culture duration for the culture bottles; the default value is 5 days; it may be set within the range of 5~30 days. |

| | |
|--------------------|---|
| Reporting time | Setting the time of reporting negatives; N (N>0) stands for the time N on the fifty day; the default value is 0 (according to the number of culture days * 24 hours). |
| Automatic deleting | It determines how long the historical information will be maintained in the system; it may be set within the range of 30 days ~ 1 year (default). |
| Backup path | Setting the backup path for database files by clicking [...] (automatic backup every day). |
| Password setup | Setting unlocking password to change culture state. |

9.12 Report Format

Press “F7” or the “Report” key on the menu bar to enter the report mode:

- (1) Place the cursor on the date necessary for statistics, and click;
- (2) Select the items for statistics in the “Statistical Items”;
- (3) Press “<” or “>” for page turning;
- (4) Press “Print” to print the statistical content;
- (5) Press “Back” to return to the interface of culture information;

| Report format | Print content |
|-------------------------|--|
| Bottle Inventory | Print all the relevant text data of the culture bottles in the current host; negatives/positives can be selected. |
| Culture Summary | Print the general information in the system on culture state within the time range that has been set; negatives/positives can be selected. |
| Culture History | Print the information of all the removed positive and negative bottles within the time range that has been set; negatives/positives can be selected. |

10. Quality Control

Do not use the culture bottle whose warranty period has expired.

Do not use any damaged or defective culture bottle; dispose of discarded culture bottles according to relevant regulations.

As required, within 72 hours, the blood culture bottles of strains under quality control shall be positive.

ATCC strains used for quality control are as follows:

Quality control strains of aerobic bottles

| | |
|--|--------------------------------------|
| Staphylococcus aureus ATCC 25923 | Candida krusei ATCC 6258 |
| Streptococcus pneumoniae ATCC 49619 | Escherichia coli ATCC 25922 |
| Streptococcus pyogenes ATCC 19615 | Pseudomonas aeruginosa ATCC 27853 |

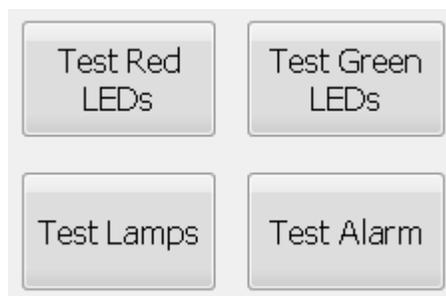
Quality control strains of anaerobic bottles

| | |
|------------------------------------|---------------------------------------|
| Bacteriodes fragilis CICC 10398 | Staphylococcus aureus ATCC 25923 |
| Escherichia coli ATCC 25922 | Clostridium perfringens ATCC 13124 |

It is advised to carry out tests of negative bottle and positive bottle on each batch of culture bottles. For positive tests, it is suggested to select the escherichia coli or staphylococcus aureus of 10ul 0.5 McFarland, put them into 10ml sterile saline solution, mix evenly, and add 100ul diluted bacteria liquid into 10ml sterile saline solution to make the bacteria liquid of 103CFU/ml. Inoculate 1ml of the bacteria liquid in a culture bottle, and put the bottle and another culture bottle of non-inoculated specimen into the instrument for detection at the same time. Positive bottle shall be detected within 72 hours, and non-inoculated bottle shall remain negative from beginning to end. Such result shows that the preservation and transportation of the culture bottles meet relevant requirements. Otherwise, please do not use the bottles, and contact the Technology Service Department.

11. Daily Maintenance

- 1) Check the status of all the indicating lights and alarm signals
 - (1) Open the door of the mainframe.
 - (2) Click the following buttons under the “Activities” bar in the following sequence (“Test Lamps” shall be clicked with door closed).



Light indicator Yellow:Missing/anonymous; Red: Positive; Green: Negative; Blue: Detecting

Light Priority Blue-Yellow-Red-Green (the light in highest priority will be on when aforesaid 4

status occur at same time)

- 2) Every other month, check whether the temperature inside the instrument's incubator is the same as that indicated on the display screen (deviation range $< \pm 1.5^{\circ}\text{C}$). It shall be guaranteed that the door closing period of the instrument is more than 2 hours.
- 3) Every three months, check whether the detectors in the instrument are clean. Dry cotton swabs may be used for cleaning if necessary.
- 4) Please keep the temperature in the room at $18-25^{\circ}\text{C}$; keep the lab dry and clean; do not open windows frequently; close the door after you.
- 5) In case of power failure, please switch off the power of the instrument and restart it after the power is back on.
- 6) In case of alarm of failure that can not be eliminated, you only need to power off the instrument and restart it after 3 minutes.



- 7)  is a sign of biological pollution, indicating that the discarded blood culture bottles after use shall be disposed of according to relevant regulations.
- 8) **IVD** is a sign of medical equipment for in vitro diagnosis.
- 9) In case of any accident or malfunction during use, please turn off the power immediately and contact the distributor or manufacturer. Do not dismantle the instrument and maintain it by yourself.
- 10) This equipment is a sophisticated precision instrument. If calibration is required in case of serious error during use, the calibrating work shall be carried out by professional engineers from the manufacturer. The instrument does not contain any accessories inside. For maintenance or replacement of components and parts, please contact the distributor or manufacturer.

12. After-Sales Service

【Warranty】

- 1) Our company is responsible for replacement and transportation costs in case of any failure of the instrument caused by defect in material or manufacturing within one month from the date of delivery.
- 2) Our company will provide maintenance free of charge in case of any failure of the instrument caused by defect in material or manufacturing within 12 months from the date of delivery. The transportation of the instrument to the maintenance department is at the customer's cost, and the return of the instrument to the customer is at our company's cost.
- 3) Our company will charge appropriate costs for maintenance of the instrument after the warranty period.

【Coverage】

Our company is not responsible for any damage caused by the customer's incorrect use, or use under unsatisfactory conditions, or unauthorized maintenance or refit.

13. Unpacking and Inspection

1. When opening the packing case of the instrument for the first time, the user should take out the instrument according to the marks on the packing case. Please do not pound or pry. Handle with care to avoid damage to the instrument.
2. Check the instrument and the accessories with the Packing List enclosed in the packing case. In case of any mistakes, please contact the supplier or the company in a timely manner.

14. Transportation and Storage

1. Before the instrument leaves the factory, it is packed in accordance with rain-proof, damp-proof and shock-proof requirements, and is fixed in the packing case. To avoid damage to the instrument or the accessories, violent collision is strictly prohibited in the course of handling.
2. If the instrument will not be used for a long time, it should be packed in accordance with rain-proof, damp-proof and shock-proof requirements, and stored in a well-ventilated room with temperature of $-10\sim 40^{\circ}\text{C}$ and relative humidity $\leq 90\%$ and free of corrosive gas.

Render Health Technology Limited



ZHUHAI MEIHUA MEDICAL TECHNOLOGY LIMITED

Unit A1 and B1, 1st floor, Unit 3B-3, 3rd floor, Annex building,

No.10, first Keji road, Gangwan avenue,

Tangjiawan, Zhuhai, 519085, China

Http://www.render-health.com **Email:** info@render-health.com

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| EC | REP | CMC Medical Devices & Drugs SL |
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C/ Horacio Lengo N 18
29006, Málaga-Spain