FISON

Automated Blood Culture System FM-ABCS-A100

Operational Manual

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1. Safety Measures

Before using the system, ensure every user has read and comprehended the user handbook and safety instructions.

To avoid coming into contact with potentially infectious materials, always handle blood culture bottles while wearing gloves, a lab coat, and face protection.

Check all culture bottles for cracks, contamination, or expiration before use. Do not load damaged bottles.

To avoid contamination, use rigorous aseptic technique when collecting samples and administering inoculation.

Aerosols may be released if bottles are removed or opened after being loaded into the system unless specifically directed by procedure.

In the event of a blood leak or broken bottle, use disinfectants and adhere to the proper biohazard cleanup procedures.

Use 70% isopropyl alcohol to clean bottle caps before adding them to the system.

To prevent pressure buildup, ensure the right amount of blood is put into each bottle in accordance with the instructions.

The system's loading area should be cleaned and disinfected both inside and out under the suggested maintenance schedule.

Prevent unauthorized repairs or alterations. The only people who should service the device are qualified technicians.

Ensure the equipment is grounded and linked to a reliable power supply. If necessary, disconnect the system while doing maintenance or cleaning.

2. Introduction

Automated Blood Culture System FM-ABCS-A100 keeps a steady temperature of 35°C ± 1.5°C for accurate microbial growth and detection. It has a bottle handling capacity of 60 units allowing multiple samples to be processed at the same time. It uses advanced integrated circuit technology to enhance system performance with reliable and efficient data processing. It uses smart intuitive software to provide an easy-to-use interface for seamless operation and monitoring.

3. Features

- ✓ Positive & Negative Algorithm
- ✓ New Temperature-Controlled Technology
- ✓ Powerful Data Management
- ✓ Constant Temperature Stability
- ✓ Smart Fault Processing
- ✓ HIS Compatibility
- ✓ Multi-Module Design
- ✓ Data Tracking & Customizable Software

4. Specifications

Model No.	FM-ABCS-A100
Incubation Temperature	35°C ± 1.5°C
Bottle Handling Capacity	60 units
Agitation Feature	Required
Positive Result Detection Time	Within 24 hours (most bacteria), at least 2 days for fungi like Candida albicans and Candida parapsilosis
Detection Technology	Fluorescence / Colorimetric / Pressure / Optical-based
Antibiotic Recovery Mechanism	Resin media or Adsorbent polymers technology
Barcode Reading Feature	Required
Bottle Types	Standard aerobic, anaerobic, pediatric
Interface	Touch / Keyboard
External Communication	USB / RS232
Supplied with the Instrument	License, latest upgradable software, appropriate PC (CPU ≥ 4GB RAM, 500GB HDD), LCD/LED/OLED Monitor (≥ 17''), printer, Windows XP or latest licensed version
Power Supply	220 to 240 V, 50 to 60 Hz, European plug, Single-phase main supply
Standard Accessories, Software, and Reagents	All standard accessories, software, and startup kits/reagents required for full functionality
Power Consumption	220 to 240 V, 50 to 60 Hz, European plug, Single-phase main supply
Dimensions (L×W×H)	650 cm × 470 cm × 520 cm
Weight	79 g

5. Applications

Automated Blood Culture System is used for Clinical Diagnosis of Sepsis, Monitoring of Immunocompromised Patients, Identification of Antimicrobial Resistance, Neonatal and Pediatric Infections, Pharmaceutical and Biopharmaceutical Testing, Veterinary Medicine.

6. Operations

6.1 Product performance

1) **System function**
   Continuous incubation function; Automatically evaluates culture findings. Hints at a variety of favourable and negative outcomes Alarm for temperature that is out of control.
2) **Culture Temperature**
   The set temperature should be accurate within ±1.5°C and fluctuate no more than 3.0°C.
3) **Appearance**
   Clear text and branding, no visible scratches, and a tight, dependable fastener connection are all necessary.
4) **Product main structure composition**
   The product is composed of an incubation module, a computer control module, control software, a detection module, and a power module.

6.2 Software clinical function

6.2.1 Home Page

The interface can display the number of positive culture bottles, the number of negative culture bottles, the number of anonymous culture bottles, the current time, date, week, set temperature, instrument self-test error code, and the number of available and used holes. Can be used with a barcode scanning gun to load culture bottles; simply click the **"bottle"** or **"batch bottle"** button, and the user can scan the code to load the culture bottle.

6.2.2 State Page

The status of every culture bottle in the incubator can be seen in real time on the page. No positive or negative results have been obtained, and the culture bottle is being cultured, as shown by the blue ring hole mark. The hole's positive culture result is indicated by the orange ring hole mark. A negative culture result is shown by the green ring hole mark. It is clear from the white ring hole mark that the hole is empty and has not been put in an anonymous bottle. By selecting the ring hole identifier of the hole position in the culture bottle, the user can inspect the curve, make changes to the bottle, and adjust the hole level.

6.2.3 Query Page

In addition to querying the data by ID number, type, loading time, positive detection time, test result, and bar code value, the interface may show the culture bottle's culture curve.

6.2.4 Configuration Page

Statistics, parameter setting, instrument information, backup, upgrade, registration activation, calibration test, and more are all included in the interface.

6.3 Software interface introduction

The system consists of a home page interface, status interface, query interface, and setting interface.

6.3.1 Home Page

The following is a description of the main page interface **(Figure 1)**:

1) **Bottle:** The culture bottle is loaded using this.
2) **Bottle taking-positive bottle:** Display the number of positive culture bottles in the present culture instrument after unloading them.
3) **Bottle taking-negative bottle:** Display how many negative culture bottles are in the current culture instrument after unloading them.
4) **Take the bottle inside the bottle:** Display the number of culture bottles without culture results in the present culture instrument, then unload into the culture bottle.
5) Display the current time, date, and week.
6) Display the culture instrument to adjust the desired temperature.
7) Display the fault code for the cultural instrument. When the system fails, the associated fault code turns red. When the user clicks the red code, it displays the corresponding description and information.
8) Displays the number of available holes as well as the number of used holes.

Figure-1 Home Page

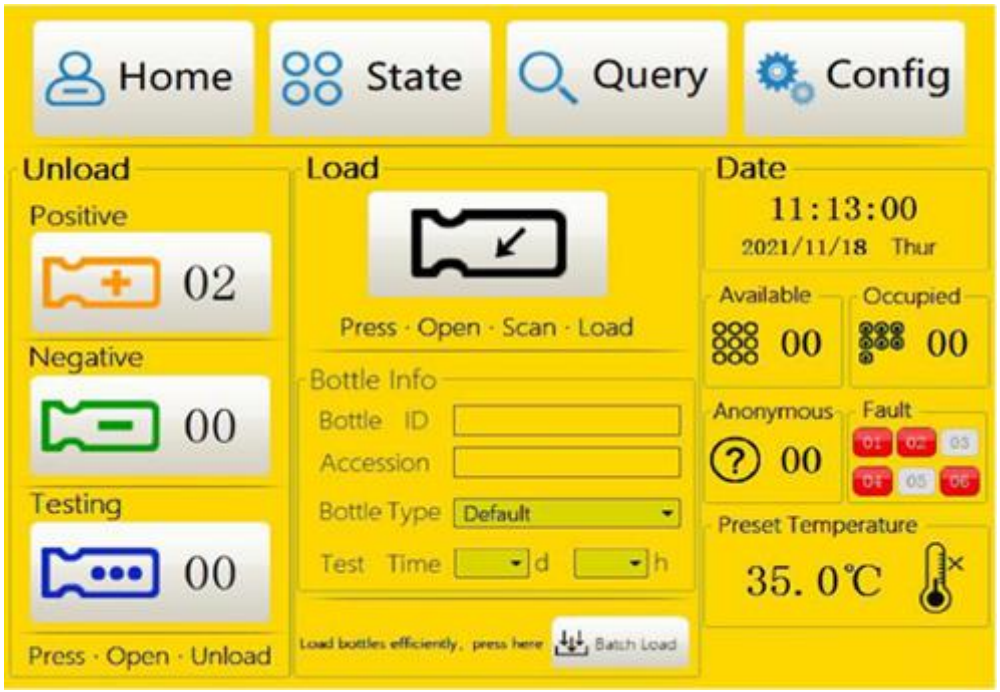

Figure-2 Home Page (With detection result status)

6.3.2 State Page

The 60-hole indication lights on the status screen (as shown in **Figure 3**) correspond to 60 holes. The hole's condition is indicated by the colour of the hole indication light. The following is a description of each colour hole indicator on the status screen:

1) The positive nature of the hole is shown by its orange ring marking.
2) An anonymous positive vial is indicated by the orange hole ring + "?" mark on the culture vial with the hole position.
3) The hole culture bottle is negative, as indicated by the green ring marking on the hole.
4) Green hole ring + "?" The symbol signifies that the culture vial at the hole location is a negative, anonymous vial.
5) The hole culture bottle is being cultured and evaluated, and no positive or negative results have been found, according to the blue hole ring identification.
6) The well culture vial is an anonymous vial being cultured for testing, and no positive or negative findings have been acquired, according to the identifier, which is blue hole + ring "?"
7) The absence of a culture bottle indicates that the hole is empty, as indicated by the white hole ring.

To view the bottle's culture curve, change the hole position information, and activate or disable the hole position, click the ring identifier.

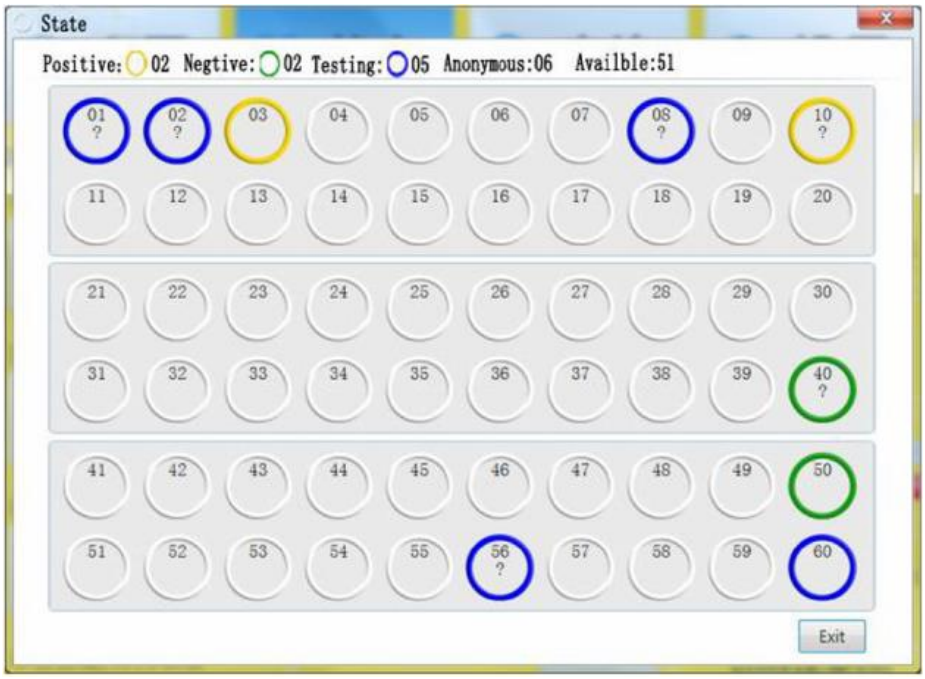

Figure-3 State Page

6.3.3 Query Page

The query interface **(Figure 4)** can query the historical data information of the unloaded culture bottle.

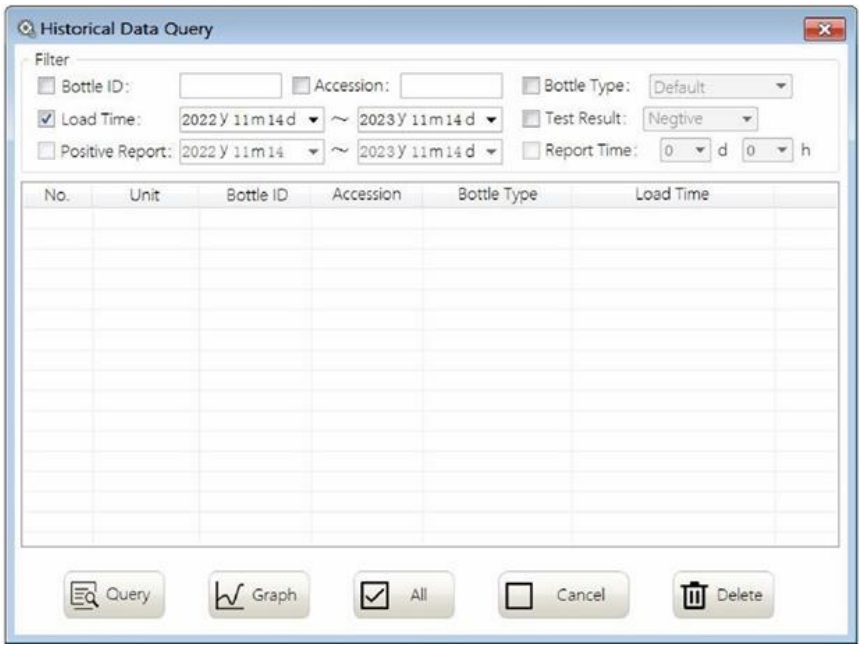

Figure-4 Query Page

6.3.4 Configuration Page

When maintaining the instrument, technical and professional staff use this page **(Figure 7)**. The incubator's system parameters can be changed and configured via the configuration interface.

To utilize each function button normally, first input the top-level operation password. After that, you can adjust the culture temperature, alarm sound, system registration/activation, incubation oscillation, and other system parameters.

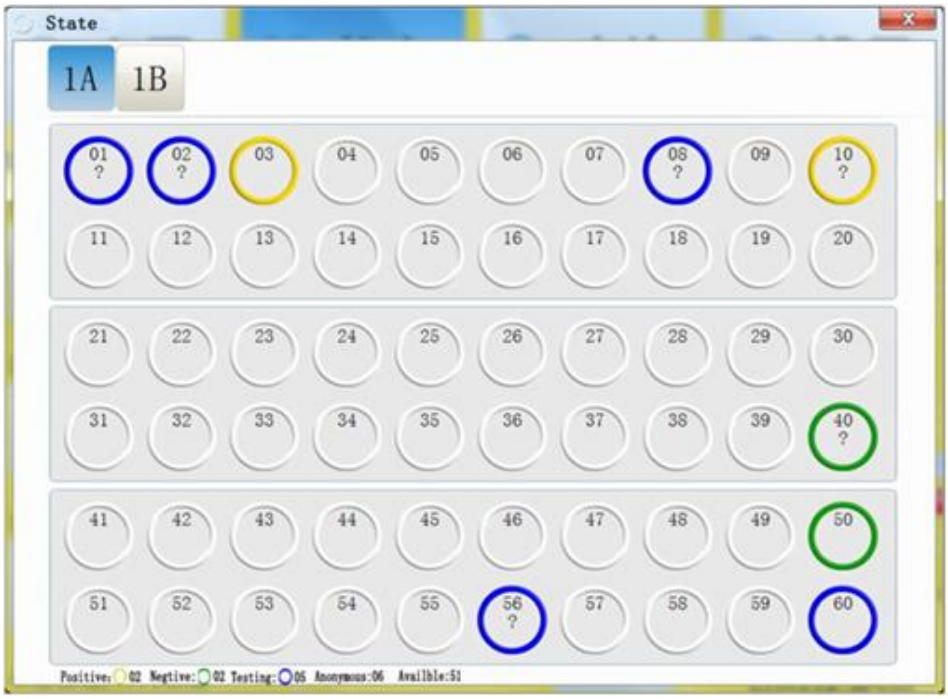

Figure-5 State Page

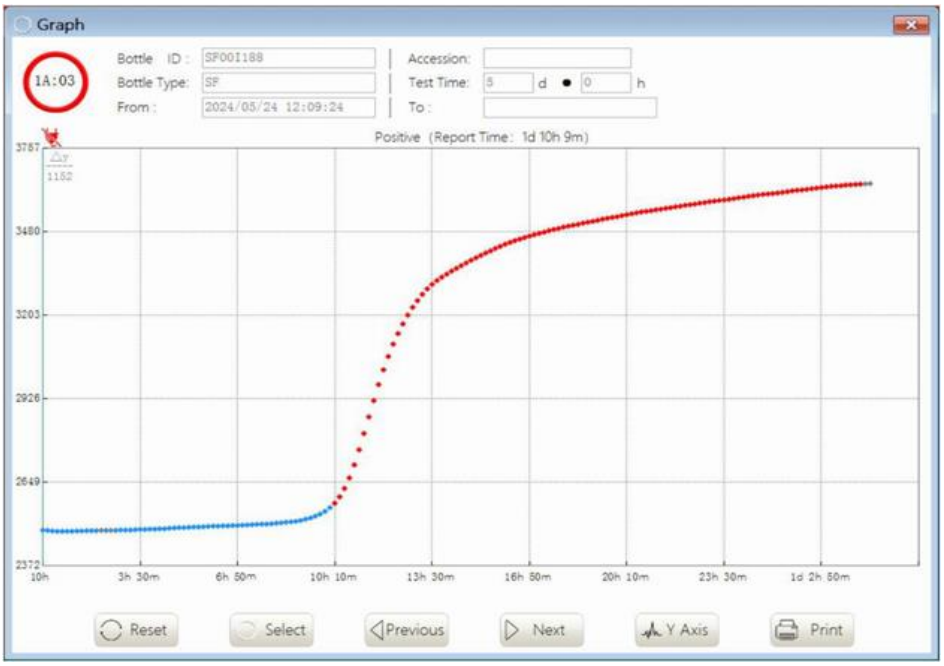

Figure-6 State Page (Positive Graph)

Figure-7 Configuration Page

6.4 Simple operation process and system tips

6.4.1 Load the Named Culture Bottle

1) Open the cabin door after clicking the bottle button on the main page.
2) Scan the cultural bottle's barcode. The beep indicates that the scan was successful.
3) Push the culture bottle to the bottom after inserting it into the empty hole. When the loading of the bottle is finished, a beep is played and the green indicator at the matching hole adjacent to the culture bottle hole turns from on to off.
4) Follow steps 2 and 3 to load the next named culture bottle.
5) After loading, close the hatch.

6.4.2 Unload the Positive Culture Bottle

1) After selecting the **"Positive bottle"** button from the main page interface's bottle taking area bar, open the hatch door.
2) After removing the bottle from the hole that corresponds to the green indication that is on, wait until the hole's green indicator beeps to indicate that the bottle removal is complete, changing from On to Off.
3) Follow step 2 to unload the next positive culture bottle.
4) Once the load is unloaded, close the hatch.

6.4.3 Unload the Negative Culture Bottle

1) After selecting the **"Negative bottle"** button from the main page interface's bottle taking area bar, open the hatch door.
2) After removing the bottle from the hole that corresponds to the green indication that is on, wait until the hole's green indicator beeps to indicate that the bottle removal is complete, changing from On to Off.
3) Follow step 2 to unload the next negative culture bottle.
4) Once the load is unloaded, close the hatch.

6.4.4 Unload in test Culture Bottle

1) After selecting the **"In the bottle retrieval area"** button on the main page interface, open the hatch door.
2) After removing the bottle from the hole that corresponds to the green indication that is on, wait until the hole's green indicator beeps to indicate that the bottle removal is complete, changing from On to Off.
3) Follow step 2 to unload the next culture bottle in the test.
4) Once the load is unloaded, close the hatch.