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Operating Manual

BC120

Automated Blood Culture System

Version: V1.1

Autobio Labtec Instruments Co., Ltd.

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BC120

Automated Blood Culture System
Operating Manual

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This document can not be regarded as substitution of official trainings supported by Autobio. Automated Blood Culture system may only be used by personnel who has been authorized and trained by Autobio.

Contact

If you have any questions related to Automated Blood Culture system, please contact us by email with a short description of your question to the address below. Any suggestions for improving our products and services are gladly acceptable.

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Operating Manual

In Vitro Diagnostic Medical Device

IVD

This product is used for In Vitro Diagnostic Purpose.

Waste Electrical and Electronic Equipment (WEEE)

In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), the presence of the left symbol on the product or on its packaging indicates that this item must not be disposed of in the normal unsorted municipal waste stream. Instead, it is the user's responsibility to dispose of this product by returning it to a collection point designated for the recycling of electrical and electronic equipment waste. Separate collection of this waste helps to optimize the recovery and recycling of any reclaimable materials and also reduces the impact on human health and the environment.
For more information concerning the correct disposal of this product, please contact your local authority or the dealer who supplied this product.

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Operating Manual

1 INTRODUCTION

This manual is prepared for assisting the operators in taking full advantage of BC120, including specific definitions as well as handling and maintenance of the instrument.

1.1 General Description

BC120 is launched by Autobio to meet the requirements of growing automation of blood culture in microbiological laboratories. Combined with blood culture bottle of Autobio, the system can provide users with fast and accurate blood culture results. Thus, it can supply etiology diagnostic basis of bacteremia, septicaemia and septicemia and provide users with guideline on how to use antibiotic, which plays an important role in saving critically ill patients.

Figure 1 Automated Blood Culture System

1.2 System Description and Intended Purpose

Blood Culture is an artificial cultivation method. After inoculating the acquired blood from venipuncture to one or more culture bottle or culture tube, the bacteria in the bottle or tube can grow fastly and rapidly in a higher nutrient environment under certain conditions of temperature and humidity, then the pathogen can be determined. It is mainly used for diagnosis of the etiology of bacteremia, sepsis and septicemia in terms of clinic.

A full set of blood culture system contains blood culture instrument and blood culture bottle(also called blood culture medium). The blood culture bottle is consisted of substances such as bottle body, nutrition solution, indicator, adsorbent.The nutrient solution provides the bacteria with the nutrients they need to grow. The indicator indicates the changes in the growth of the bacteria. Adsorbent can absorb antibiotics in the blood to help bacteria grow.

BC120 Automated Blood Culture System is an automated equipment carrying out continuous incubation, concussion culture and automatic detection for Autobio blood culture bottle of Autobio company.

Figure 2 Blood Culture Bottle

1.3 Automated Blood Culture System

Figure 3 Automated Blood Culture System

Product component
This product is mainly composed of blood culture host, computer, bar code scanner and control software.The main technical indicators are stated as follow:

Item	Demand
Power supply requirement	100-120VAC,50/60Hz /200-240VACV,50Hz, 800VA
Accuracy of the temperature deviation	< +1.5℃
Temperature fluctuations	< 3.0℃
Voltage fluctuation	Not more than 10% per cycle
Maximum resistance between the instrument ground wire and the safety grounding of the laboratory	Less than 0.1 Ω
Transient overvoltage	Class Ⅱ
Sound pressure level	Less than 85dB

Precaution
The blood culture host contains two independent temperature control areas, and each temperature control area contains 60 independent test holes.
It is recommended to use the matching computer and bar code scanner. If users have their own computers and bar coder scanners, please consult with the manufacturer or installation engineer prior to using to ensure that the configuration of the computer and bar code scanner is not lower than requirements in the following table.

Computer configuration requirements:

Item	Requirements
CPU	Pentium processor 4 1.8 G
RAM	1G
Hard Disk	80G
Display	Resolution 800 × 600

Precaution
The computer and display should conform to the specification of current version of IEC/EN 60950 -1.

Bar code scanner specifications:

Item	Requirement
Bar code scanner dimension	One-dimensional bar code that supports english letters and arabic numerals.
Bar code type	Support code 128 and code 93 bar code type
Safety certificate	CE

Performance/Function Description
• Reliability
Automatic calibration and adjustment of the function of optical detection system, high precision temperature control system to ensure the stable and reliable operation of the instrument.
• Drawer-Type Structure
BC120 is drawer- type, convenient and quick to operate. There are 60 bottles in each drawer, 120 bottles in total.
• Independent Probe Unit
Each measurement hole has an independent optical detection device. There is no interference between each other, which can improve the stability of the system.
• Real-time Display of Information
BC120 attached information display screen shows the information of culture bottle in the box in real time and improves the convenience of user operation.
• Integrated Modular System
BC120 Supports multiple instruments cascade mode, and a set of control system can manage up to 5 blood culture hosts (600 bottles) to meet the requirements of future workload expansion of customers.
• Multiple Alarm Mode
Three kinds of alarm mode are in sound, light, color.
• Function of Putting the Bottles Lingeringly
A variety of mathematical operation models, support putting the bottles lingeringly for 48-hour at the most.
• Independent State Display
Each measuring hole has an independent status indicator.
• Continuous Concussion Incubation Function
Adopting continuous oscillating system with adjustable amplitude and frequency to make the blood and reagent thoroughly mixed to ensure the accuracy of blood culture result.
• Monitoring and Judging the Culture Results Automatically
The system reads and records the measurements every 10 minutes and forms a measurement curve. Moreover, it can automatically determine the culture positive and culture negative according to the measured value.
• Definite Alarm Way of the Culture Positive
When the system determines the positive result, then it alarms. Specifically, the color of test hole in the software interface is changed from blue to yellow, meanwhile the yellow indicator on the box lights.(please refer to Section 3.4 Positive Judgment).

• Temperature out of Control Alarm Function
The software can set the alarm range of temperature out of control. When the range is exceeded, the instrument will carry out a sound alarm, and the software indicates that the temperature is out of control.
• Repeatability of the Positive Results of Culture
BC120 automated blood culture system and blood culture bottle are tested according to the industry standard and enterprise standard. The test results of the standard strain are all positive, which can meet the relevant requirements. During the process of actual use, the contamination of the specimen and other substances in the specimen, such as white blood cells, may have an impact on the culture result, which will lead to false positive or false negative results . Please operate according to the specimen collection standard (please refer to Chapter 4 Specimen Collection). It is recommended to carry out blood sampling and experiment on the two sides or three bottles of the two bottles to ensure the accuracy of the experimental results.
• Powerful control and data analysis management software
Based on Windows®operating system software, the software improves customer ' s convenience.

- The real-time growth curve can be displayed. Customer can judge the result according to their experience and reduce the probability of false positive .
- Graphical display. The blood culture bottles with different culture state have different colors. The culture state can be seen clearly.
- Reliable positive alarm condition is created by using multiple mathematical models. The detection time of positive results is shortened and the detection rate of positive results is improved.
- Humanized management of database .
- Quick and convenient data query.
- Multi-models statistics.

2 Installation

2.1 Cautions

Please read the manual before operating the instrument. It is safe to use this instrument in accordance with the product manual. Do not attempt to make any modifications to this product.

Intended use

This product is only for the professional use of conventional laboratory and research institute. If the product is used for other purposes rather than intended use or is not repaired by engineer or authorized agent of Autobio, any damage caused by such reason above shall not be born by Autobio.

Service Life

The service life of instrument is 6 years. Equipment operation environment and use frequency are associated with the service life. Regular maintenance can prolong service life. If you have any questions, please contact after-sales service provider.

Carry/Installation

• It must be carried out by the manufacturer if the installation position of the instrument be moved after the installation. Four engineers hold the four corners of the instrument with their hands and force them at the same time to keep the obliquity as small as possible. The obliquity of the instrument must not exceed 30 degrees in the process of movement.
• Don't handle the instrument roughly. The instrument contains sensitive electronic components and precise mechanical vibration systems, therefore, much more attention must be paid during carriage. Two people hold the four corners of the instrument with their hands and force them at the same time to keep the obliquity as small as possible. The obliquity of the instrument must not exceed 30 degrees in the process of movement.
• For in door use only.
• The instrument should be put on a stable bench without being put together with other equipment which may cause vibration (e.g. a centrifuge).
• This instrument will produce continuous vibration during operation, therefore the workbench can not be shared with other medical devices, so as to avoid resonance and influence to other medical devices.
• The instrument should avoid direct sunlight.

Power supply

The power supply voltage must be consistent with the instrument's nameplate.
The instrument works continuously and has been running for 24 hours a day. Power interruption will affect the judgment of the reagent results and cause a lot of damages to the equipment, even can destroy the instrument. It is highly recommended that the instrument should be equipped with UPS (uninterrupted power supply) to ensure the normal operation.

Protective earthing

WARNING:To avoid electric shock, the instrument can only be connected to a supply mains with a protective earth.

Scope of application

This product is used in the clinical laboratory, via in vitro culture, detecting the microorganism in human body's blood or sterile body fluid of other normal conditions.

Reagent

This instrument is used in combination with blood culture bottle. In the process of usage, please follow the instructions and safety regulations provided by the reagent manufacturer.

Biological contamination

Liquid waste is a potentially biological pollutant. Please wear gloves before contacting with such substances. The biological pollutants should be disposed in accordance with relevant laboratory procedures.
Blood bottle leakage may cause infection to personnel. Please wear protective glove when dealing with.

Power port

When installing the instrument, it should be considered whether there is enough space in the back side of the instrument to connect the instrument and the power adapter.

Drawer

Too much force can not be given during pulling and pushing the drawer. Open and close the drawer at a constant speed, otherwise it is possible to damage the drawer module.

Storage and transportation condition

During transportation and storage, temperature and humidity should meet the following requirements:

Temperature:	-40 ° C - +50 ° C
Humidity:	5% - 95% RH No condensation

Work environment

The instrument should be put on a stable bench, and should not be put together with other equipment that may cause vibration and exposed to direct sunlight.
Environment temperature: 10C ~ 30C
Relative humidity: ≤80%
Atmospheric pressure: 80kPa ~ 106kPa

2.2 Instrument Installation

2.2.1 Instrument connection

Number	Name	Number	Name
1	LCD	2	Input device
3	Power cord	4	PC
5	Communication line between PC and LCD	6	Terminal resistance
7	DB9 CAN cord	8	Instrument
9	Mains supply outlet with protective earth		

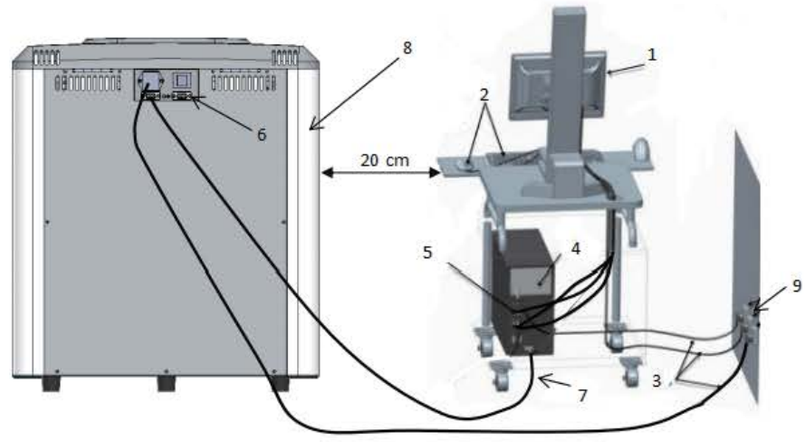


Figure 4 Connected instruction

Please connect the power cable according to the following:

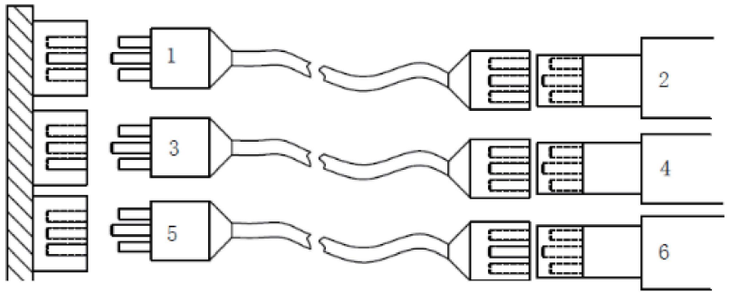


Figure 5 Power cable connect instruction

1 Instrument power plug
2 Instrument
3 Workstation power plug
4 Workstation
5 Display plug
6 Display

2.2.2 Instrument Installation

BC120 Automated Blood Culture System needs to be installed by the professional service engineer of Autobio. Any personnel without training or permission, please do not open the packaging and install instrument. Please contact installation engineer before installing the instrument. The installation space should be enough. Please see the instrument's dimension as follows:

Length	510mm
Width	685mm
Height	590mm
Weight	90kg

Space requirement:

Item	Size
instrument	width 685 mm, length 510 mm, height 590 mm
Ventilation space	Min 340 mm rear Min 490 mm top Min 220 mm both sides

Packing list:

Name	Number	Technical data
BC120	1	-
Packing box	1	-
Protective bubble	1	-
Packing bag	1	-
Accessory box	1	-
Power cord	1	3G 1.0mm2,max.2m
DB9-CAN cord	1	-
DB9-Impedance matching plug	1	-
Electric current fuse（T5AH 250V for 100-120VAC/T10AH250V for 200-240VAC）	2	50×20mm
CD	1	-
Aerobic culture bottle FA	1	-
Anaerobic culture bottle FN	1	-
Aerobic culture bottle SP	1	-
Accessory case	1	-
Bar-code scanner	1	-
Mini voice box	1	-
Calibration bar	2	-
Packing list	1	-

Precaution

1.The above contents shall be subject to the actual packing list.
2.Please replacing detachable mains supply cords by adequately rated cords.
3.Please replace fuse link with rating described in the above table.
4.The accessories of packing list must be supplied by manufacturer.

Precaution

1.The instrument is transported by mail. Please check whether the outer packing box is damaged. In case of damage, please contact us immediately.
2.Please confirm the laboratory environment. The instrument can be unpacked only when the environment reaches to the work standard of the blood culture instrument.
3.Please check the appearance of the instrument before installation. The graphic symbol and text on the main panel should be accurate, clear, uniform and without scratches.
4.The instrument needs to be placed on a stable working platform. Please confirm that the platform can bear the corresponding weight (>500kg).
5.There is an outlet in the back of the instrument in order to ventilate. Please confirm that the working platform is at least 10cm away from the wall.
6.The front support leg of the instrument needs to be more than 10cm away from the desktop, otherwise the instrument is easy to be tipped over when the drawer is opened.
7.The sudden power failure and large voltage fluctuation have a great damage to the instrument. In order to ensure the normal operation of the instrument, it is recommended to equip with a UPS power supply. For specific power parameters, please contact the engineer of Autobio.
8.Please do not put the equipment in the place where it is difficult to operate the disconnection device.
9.Please inspect and make sure the removable shell in place and screws and fasteners well fixed on the shell during operation.

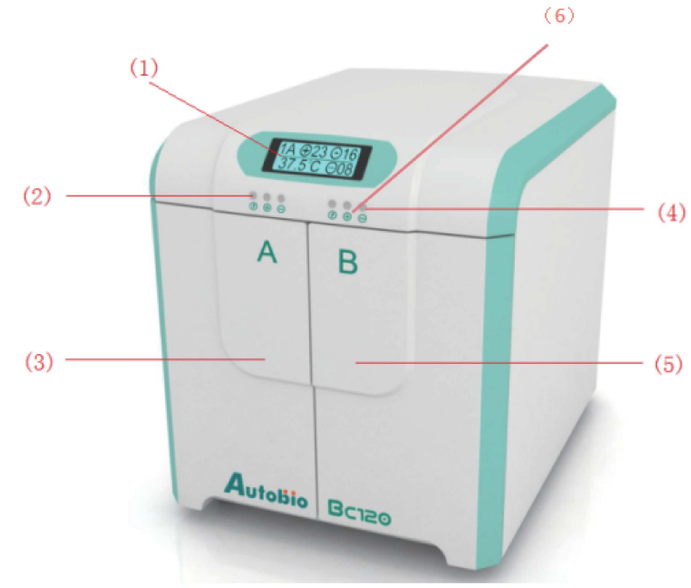
2.3 Biohazard

Materials derived from human or animal or tissue culture or in vitro culture must be treated in accordance with the principles of potential infection. When dealing with biological hazards, appropriate protective measures should always be worn, such as approved disposable gloves, waterproof lab coats and safety goggles. To deal with biological hazards material and waste according to the biological hazard process and local regulation.

If the instrument is to be scrapped, please contact the manufacturer.

3 System Function

3.1 Hardware structure



(1)	Information display	Display the information of the culture bottle in the box real-time , including the temperature inside the box, the positive culture bottle, the negative culture bottle and the quantity of the bottle body in the culture, and the AB drawer rolls to display.
(2)	A drawer power status indicator light	Indicate the state of A drawer, representing the power status of the drawer.When the blue indicator light is on, the power supply is normal.
(3)	A drawer	It can be pulled from the lower handle and contains 60 independent slots of detection holes.
(4)	B drawer status indicator light	Indicate the state of B drawer.When the green indicator light is on, in order,that is , some negative bottles in sequence . Please find the detail information from the monitor display.

(5)	B drawer	It can be pulled from the lower handle and contains 60 independent slots of detection holes.
(6)	B drawer status indicator light	Indicate the state of B drawer.When the yellow indicator light is on,in order,that is some positive bottles in sequence.Please find the detail information from the monitor display.

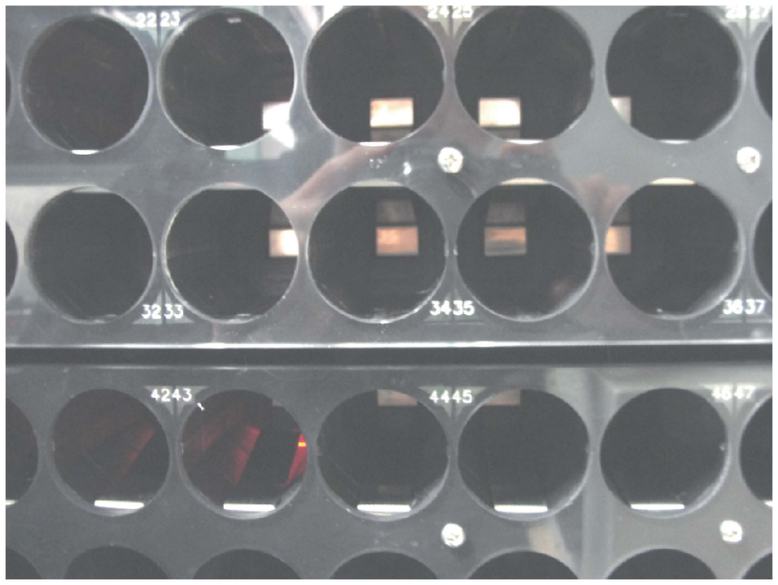


Figure 6 Measuring holes

There are 120 independent slots measuring holes in the instrument, each of which is marked with numbers. An elastic reed is installed in the hole to hold the bottle in place to prevent the bottle from moving or dropping down during vibration.

Precaution

When the blood culture bottle is inserted, the bottle body needs to be inserted into the bottom and rotated 90 degree, otherwise the measurement value may be unstable and invalid.

Figure 7 Bottle situation status indication

There is a status indicator above the side of each measuring hole to indicate the different states of the hole.

Figure 8 Instrument

Precaution

1.Please open the drawer of the instrument with the handle, and it is forbidden to pull away from other positions of the drawer, such as upward and right side. Otherwise, it is very easy to damage the instrument.
2.It is forbidden to open the two drawers at the same time. When one is closed, the other one can be opened. Otherwise, the center of gravity will be easily changed and the instrument will be overturned.
3.Slowly pull the drawer out about 5 cm before the drawer is totally opened and stop when it sounds "click", then continue to open the drawer to the required position, and close the drawer in reverse order.
4.If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

3.2 Instrument turn on /turn off

3.2.1 Turn on

1. Turn on the computer and monitor.
2. Ensure the terminal resistance of BC120 and DB9 CAN cord between instrument and computer connected normally.
3. Press the back switch of the BC120 to the position shown as below:

Figure 9 Switch of the BC120

3.2.2 Turn off

Press the back switch of the BC120 to the another position shown as “0”.

3.3 Software installation

Software installation steps:
1. Ensure that the computer runs on the Windows XP/Windows 7 operating system;
2. Open the USB CAN Driver file in the CD-ROM to install USB - Can driver;
3. Download .NET framework environment clicking here: http://www.microsoft.com/zh-cn/download/details.aspx?id=21;
4. Install SQLEXPR32_CHS.EXE from CD-ROM;
5. Confirm whether the SQL Server (SQLEXPRESS) service is starting.
If not, start the service following these steps: "computer" -- "management" -- "service" -- "SQL Server (SQLEXPRESS)".
6. Open the “Automated Blood Culture Control System Installation Package.msi” to install the software of blood culture system.
7. This software can run on the computer after restarting the computer.

3.4 User interface

Figure 10 Login interface

The blood culture analyzer should be started for 5 minutes before running the software. Double click the “Automated Blood Culture Control System” icon to login to the admin user with password: admin.
Only the administrator user has these permissions such as creating users, deleting users, restoring passwords, and so on. New password should be filled into the box and confirmed when restoring it and will be saved after clicking “Enter” button, and the main interface of software will appear at the same time. Users can login with the new password after restarting the software. After creating a new user name in the new user box, the new user which has been authorized the common permissions or system permissions will be added to database list after. New users can login when software is restarted.

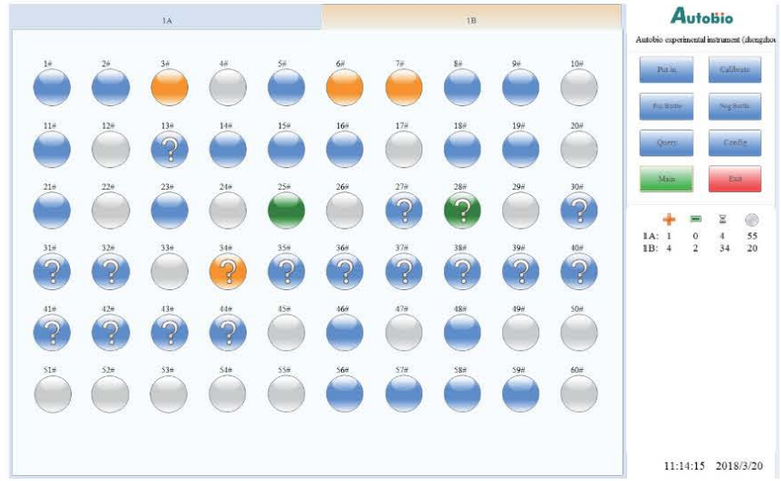


Figure 11 Main interface

The main interface shows the current blood culture status of the host with a graphical interface. 1A or 1B is corresponding to different box connected to the software (it can be extensible to 5A/5B) and the different color spheres show the different status of the tests.

Sphere	Color	Means
60#	Gray	The test position has no blood culture bottle. The number above the sphere signifies the test position in the box.
50#	Blue	The blood culture bottle is being cultivated. The number above the sphere signifies the test position in the box.
36#	Yellow	Positive bottle; The number above the sphere signifies the test position in the box.

30# 	Green	Negative bottle; The number above the sphere signifies the test position in the box.

Figure 12 Box information

The information of the box is located at the bottom right of the main interface including the number of positive bottles, negative bottles, being cultivated bottles and the available positions.

Figure 13 Statistics data

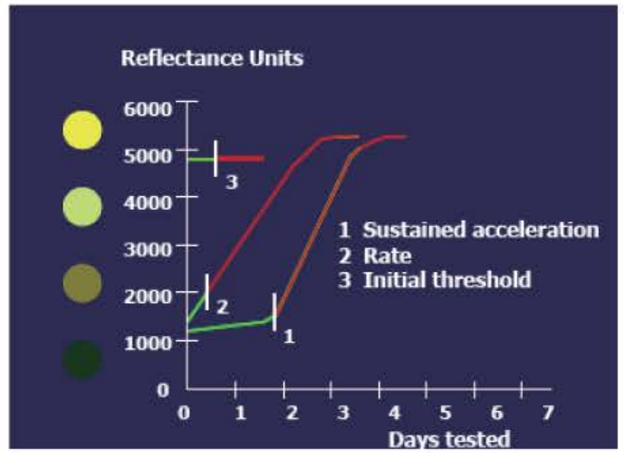
The overall information of all the blood culture boxes on-line is shown at the bottom right of the main interface as follows:

1A: 1B:	Name of the boxes online; (It can be extensible to 5A/5B.)
 4 3	Total of positive bottles of the corresponding box
 50 4	Total of negative bottles of the corresponding box
 0 47	Total of being cultivated bottles of the corresponding box
 6 6	Total of available positions without culture bottles of all boxes.

11:14:15 2018/3/20	The current system time; Do not modify it or the software will throw some exceptions.

3.5 Judgment of positive results

Automated blood culture analyzer can be able to continually monitor the color of bottom of the blood culture bottles applying noninvasive technique and determine positive according to the curve of bacteria reproduction. There are three judgement factors: sustained acceleration, rate and initial threshold.



Initial threshold: When the blood culture bottles are placed into BC120, bacteria has been reproduced enough to make color of the sphere change through sensors and instrument alarm until the sphere turns to yellow by calculating the initial threshold. (The time of on-the-fly of the blood culture bottles can be delayed by this way.)

Rate: It is an available calculation method that when the blood culture bottles are placed into instrument, bacteria in the bottles has been in the growing period by multiply reproduction but the sphere's colors not changing.

Sustained acceleration: It is a method similar to curve of bacteria reproduction used under such a condition that the bacteria is starting to reproduce after an adaptation period and the sphere's color has not changed when the blood culture bottle are placed into instrument.

The three rules of positive in the software explained are as follows: 1—sustained acceleration; 2—rate; 3—initial threshold.

The blood culture bottle will turn yellow as long as satisfying one of the three conditions and the indicator light comes on with sound alarm while the indicator light of positive on the panel of instrument is on.

3.6 Operation of placing bottles

Precaution

1. Please only use consumables within their expiration date.

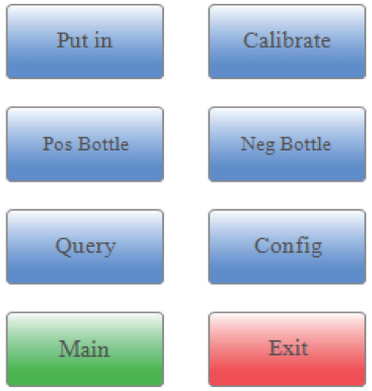


Figure 14 Command button

It will appear this interface after clicking the “Put in” button.

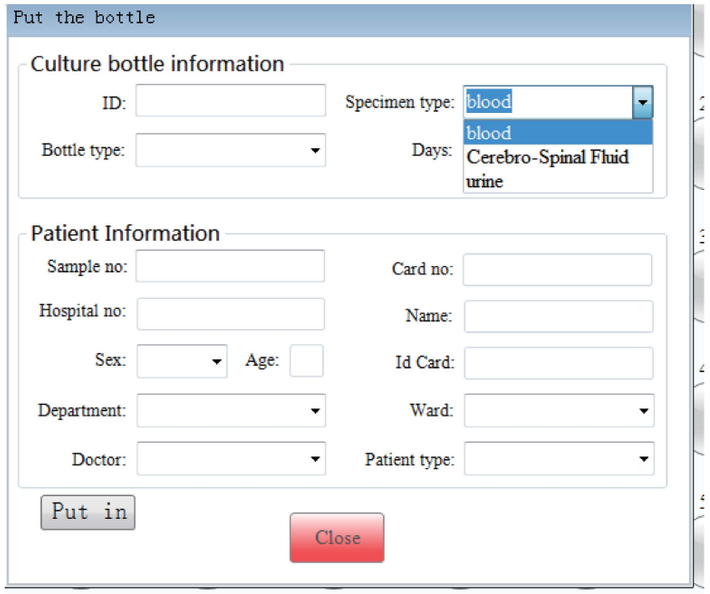


Figure 15 Interface of placing bottle

The blood culture bottle can be placed into box after the interface same as picture 15 appearing and filling the ID of the bottle into the ID box. The ID can be input manually or by bar-code scanner (notice: it is necessary to fill it in, or the bottle will be regarded as anonymous). Patient information can be input manually (supporting LIS system) as an optional item.

Steps of placing bottles are as follows:

1.Click the “Put in” command button.

2.Input the ID of culture bottle (bar-code scanner or manually).

3.Input the information of patient.

4.The indicator lights will flash with sounds ringing out after placing the culture bottle into the any available position with indicator lights on of the box.

5.Then it will appear the initial interface of placing bottles again and can place the bottles following the steps 1 to 3.

6.Click the “End” button after all of the operations of placing bottles.

3.7 Regulations of taking out the bottles

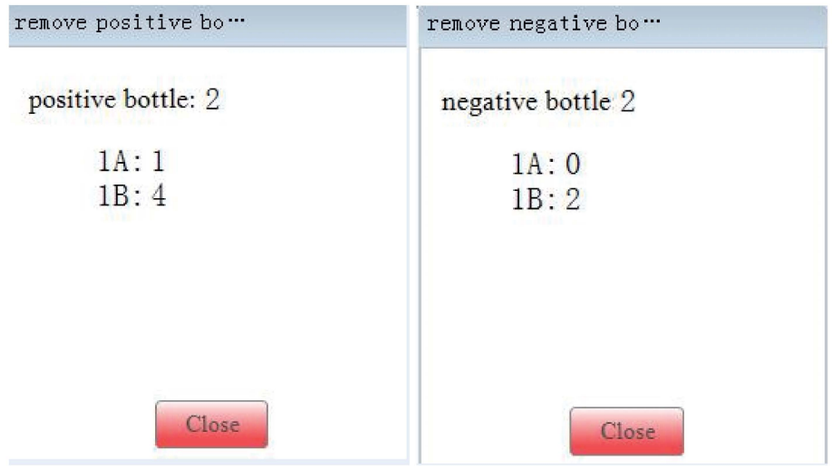


Figure 16 Regulations of taking out the bottles

When results of the positive or negative bottles come out, the bottles can be taken out as follows:

1.Click the “Taking out N/P bottles” command button;

2.There will be a interface displaying the counts of N/P bottles on-the-fly in the each box;

3.The indicators corresponding of the N/P bottles will light on when the blood culture host drawers are opened;

4.Take out the blood culture bottles and the software will calculate and save the counts of bottles taken out automatically which are displayed on the interface same as figure 16.

3.8 Information of blood culture bottles

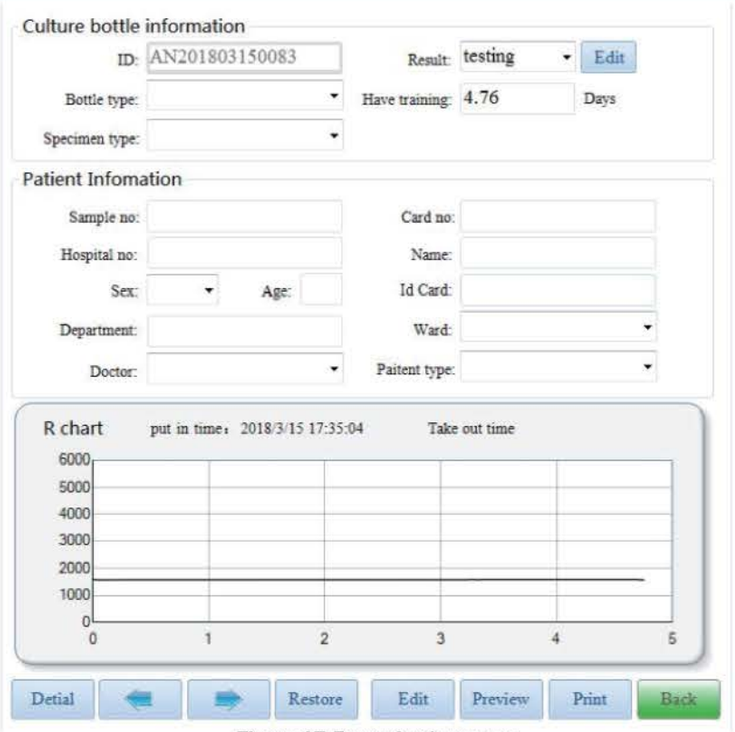


Figure 17 Reproduction curve

The information of corresponding bottles will be displayed on the right of the interface shown as figure 18 after clicking the bottles appeared on the main interface.

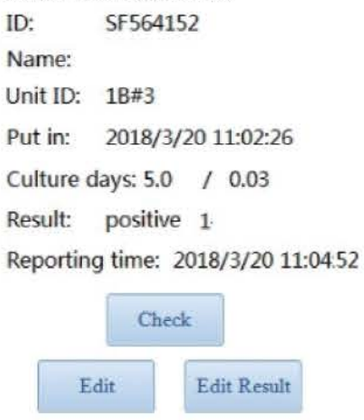


Figure 18 Bottles information

ID: SF564152 Name: Unit ID: 1B#3 Put in: 2018/3/20 11:02:26 Culture days: 5.0 / 0.03 Result: positive 1 Reporting time: 2018/3/20 11:04:52	Bottle information is as follows: ID: Manufacturing No. (unalterable) Culture days: 5.0/0.03 The first number indicates the maximum training days of the blood culture bottle, and the number behind indicates the actual culture days. Result: Positive 2 The blood culture bottle result is judged by software and the number is the calculation method.
Edit	Modify the patient information.
Edit Result	Modify the N/P results of the blood culture bottles (under the administrator permission).
Check	View the reproduction curve information of blood culture bottle (trend line with R value).
Edit Result Result: testing Ok Close	Modify the results of blood culture bottle manually (testing, positive and negative)

The reproduction curve of the bottle can be viewed by double clicking the icon which indicates existing bottles on main interface shown as figure 19.

The information interface of culture bottle is divided to two parts of which one is culture bottle information showed at the top of the screen including bottle ID, culture result, culture type and culturing days and the other is reproduction curve at the bottom of screen with x-axis indicating culturing days and y-axis indicating R value by which the N/P culture bottle can be confirmed.

The patient information interface shows patient essential information by blood culturing(optional).

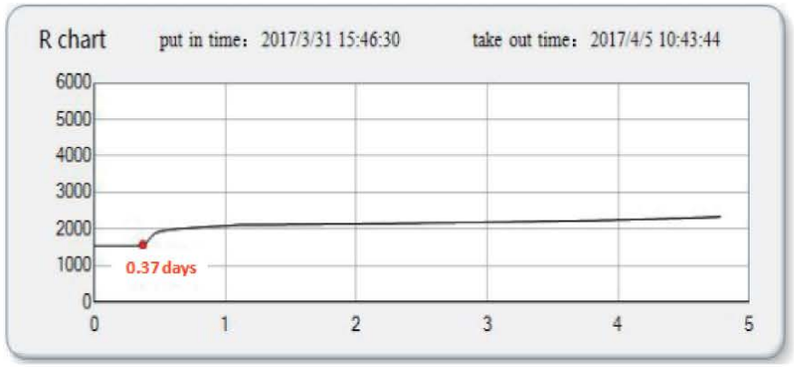


Figure 19 Reproduction curve of positive bottle

Reproduction curve of the positive bottle is shown as figure above. Software will calculate the days of culture bottle being positive and display it on the graph according to the three judgment rules. The curve will be recorded continually if the bottles are kept on culturing.

3.9 Query and Statistics data

All of the results measured by this instrument are saved into the blood culture system which can be searched by clicking the "Query" command button shown as figure 10 and interface appeared as figure 20 below.

Figure 20 Query interface

Time range can be queried (default one year) as shown in figure above. Information can be acquired by clicking the "Query" command button after they are input to the box. It is suitable that filling items into the fuzzy query box if the information demanded is uncertain (0001 is unsure belong to ID, case number or sample number) to obtain the corresponding information with clicking the "Fuzzy query" button.

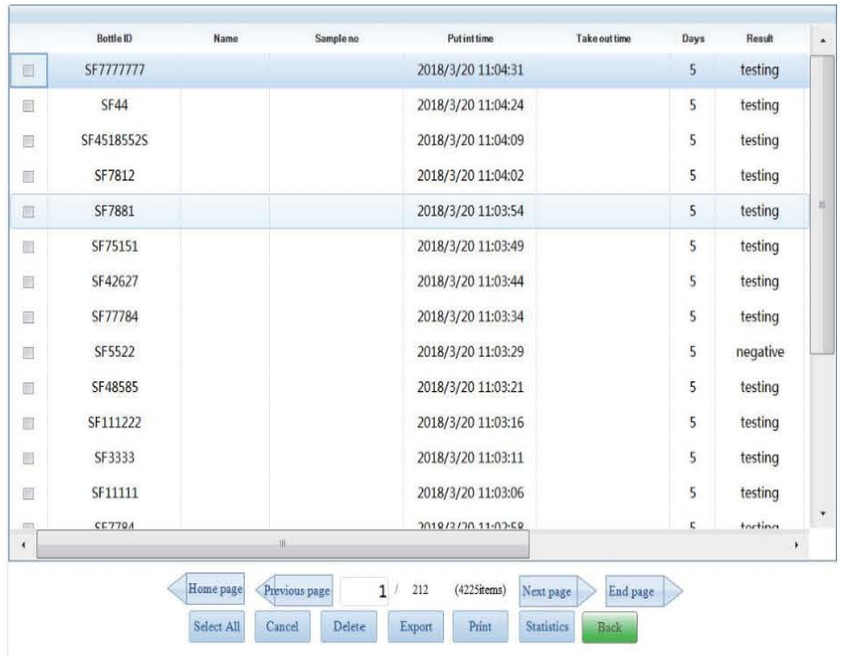
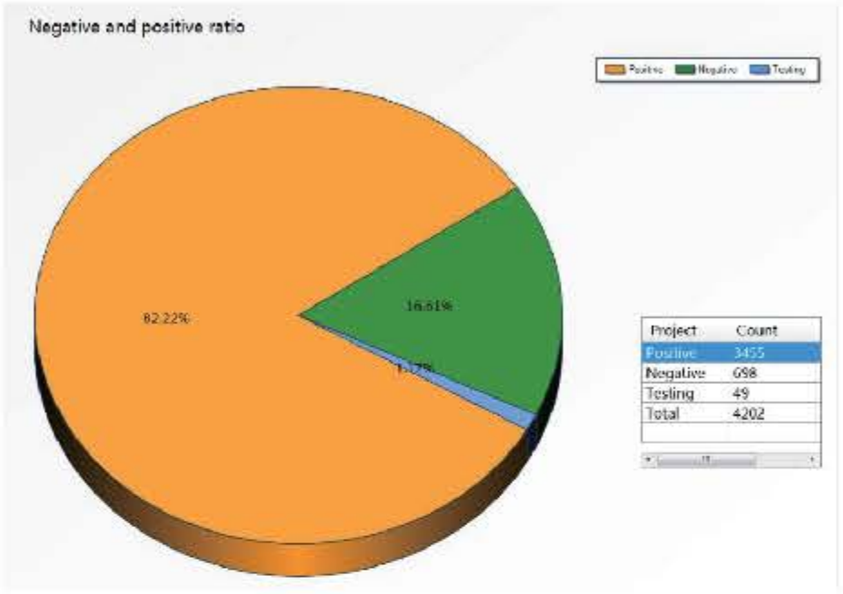


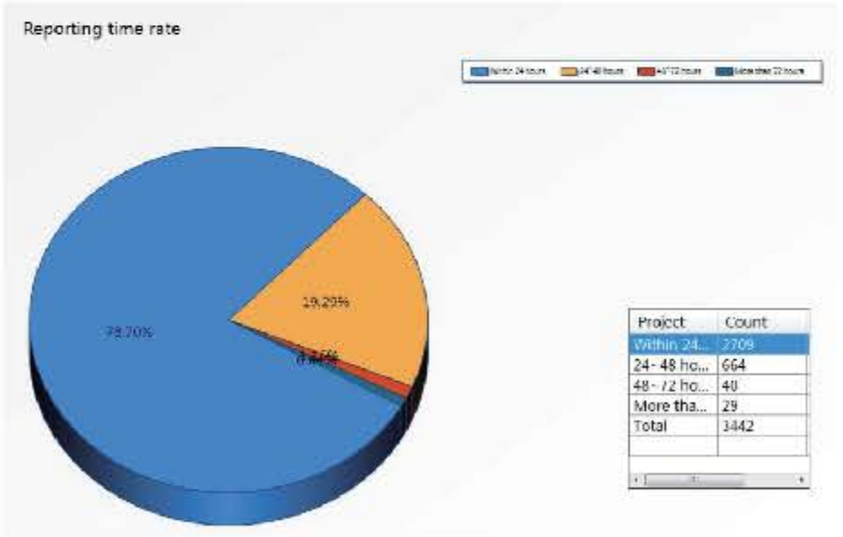
Figure 21 Query information

Click "Query" button in figure 16, and all completed test will be shown as figure 17 and click "Statistics" button and all sample information will be reported after statistics by software. There are three kinds of statistic pattern:

1. N/P ratio: Make a statistic for the quantity of positive, negative bottles and culturing bottles, and their occupancy rate, over a period of time.
2. Occupancy rate of culture medium: Make a statistic for the quantity of different blood culture bottles used and their occupancy rate over a period of time.
3. The ratio of reporting positive: Make a statistic for the counts of blood culture bottles according to the time of reporting positive result for 0-24h, 24-48h, 48-72h and more than 72h and occupancy over a period of time.



Occupancy of N/P blood culture bottles



Statistics data according to hours of reporting positive

3.10 Configure

Figure 22 will appear after clicking the "Query" command button in figure 14.

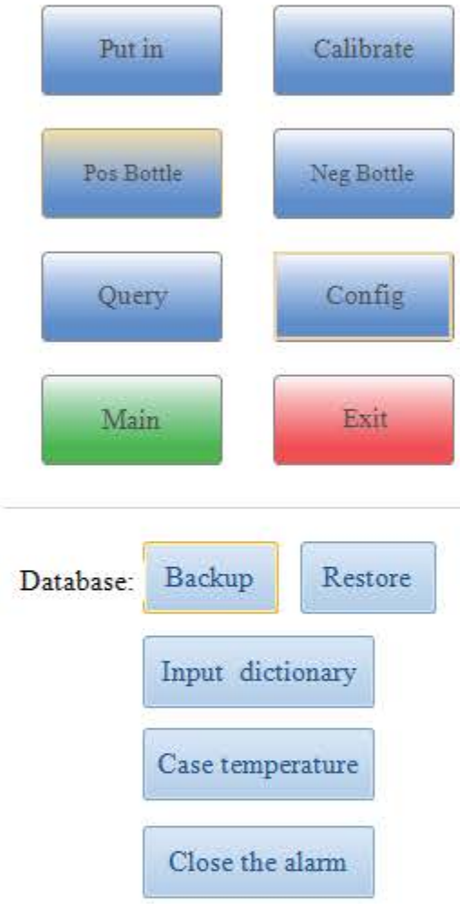


Figure 22 Configure command

Backup	Software database (including all of the historical data) will be saved to the selected path after clicking "Save". It is suggested that the database should be saved once a month.
Restore	This function can restore database when there are problems about it or setup software again by clicking this button, then select the previous backup database and open it.

Input dictionary This function supports editing the common information to see figure below:

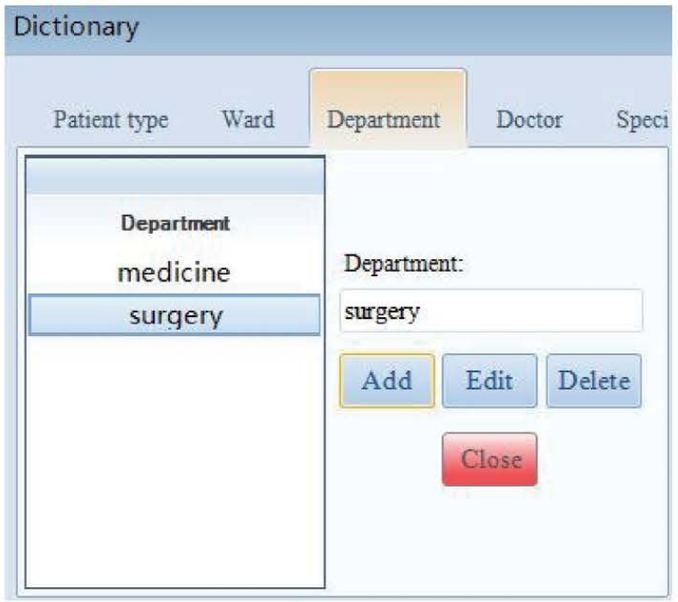
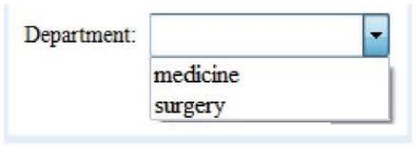


Figure 23 Input dictionaries

The edited information is available in the combobox during executing other operations such as inputting patient information after editing the dictionaries.



Case temperature The different body temperature can be read by clicking "Read" button in the dialog as figure below:

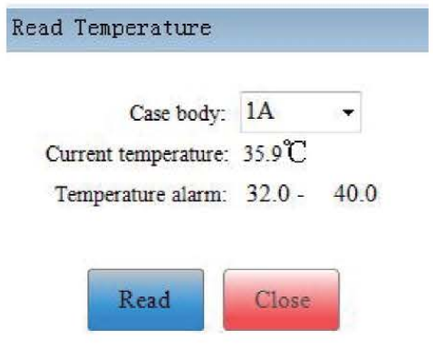


Figure 24 Box temperature

3.11 Calibration

The software will give prompt on the position of measuring holes where problems happened. The normal operation can not be continued to the measuring holes unless calibration will be executed with calibration bar. Please contact service engineer of Autobio before calibrating the instrument in case that the parameter of measuring unit will change after calibration.

Figure 25 Calibrate bar

Figure 25 will display after clicking the "Calibration" command button on figure 10.

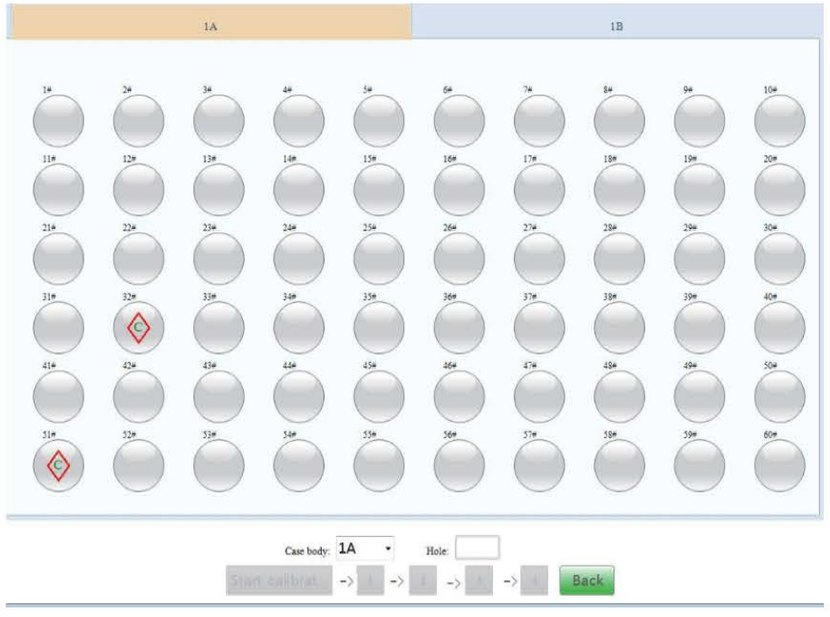
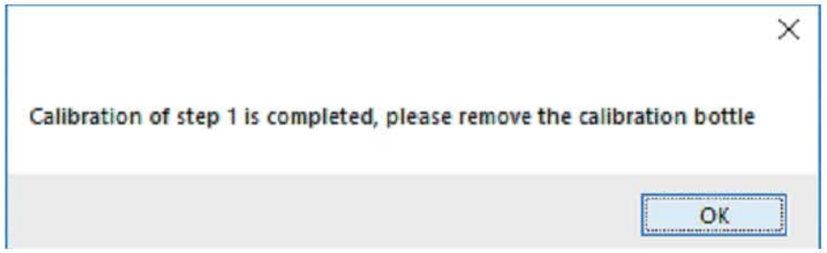


Figure 26 Calibration interface

The calibration steps are as follows:
1.Click the calibrating position and follow the next steps if the "Start calibrating" button turns black.
2.Click "Start calibration" command button and the "1" flag behind it turns to black from gray;
3.Insert the side of calibration bar marking "1" to the corresponding position to ensure the reaching to the bottom of the hole, otherwise the calibration failure may be caused.
4.Click the flag "1" in the picture above; there will be "tick" sound after about two seconds and the "1" flag changes to gray, "2" flag turns to black and dialog box pops up at the same time.



Click OK to finish the first step.
5. Calibrate the calibration bar "2" "3" and "4" in turn until the "4" is calibrated to prompt successfully and prompt "Calibrate successfully" following steps 3-4, which means finishing the calibration. It is suggested that the host and control software should be restarted. Then open the drawer and shut down after 3-5 seconds. The position returns to be available after ensuring that the initial flag of the position is disappeared.
Notice: Flag "1", "2", "3" and "4" of the calibration bar are distinguished by the colors. Please contact service engineer of Autobio if the position is still ineffective or the "calibration failure" is suggested after the calibrating.

3.12 Daily maintenance and considerations

3.12.1 For Manufacturer's service personnel before maintenance

No	Risk	Protect measures	Safe verify
1	Maintaining the instrument under the condition of power supply may lead to electric shock.	Disconnect the power supply before the instrument maintenance.	Make sure the neutral line and the live line are connected correctly and connect all the ground wires of the instrument. Make sure all the ground lead and screws are tight.
2	Blood bottle leakage may cause infection to service personnel	Wear protective glove when maintaining	Make sure there are no liquids in discharge groove and blood bottle in case of breakage.
3	Instrument incline or topple over may hurt maintenance personnel.	It is forbidden to open two drawers at the same time.	Make sure two drawers are not opened at the same time.

3.12.2 Instrument cleaning

Instrument cleaning once a week:
- Clean instrument surface and the testing frame of the box with tissue dipped with alcohol.
- Clean up the liquid spilling in the liquid leakage groove during the process in time.
- Do not sprinkle the liquid on the electronic components of the instrument.

Consideration:
- Put the bottle appropriately to ensure that the bottle is contact with the bottom of the hole completely.
- It is forbidden to adjust the time of the computer system during the operation of the instrument.
- Do not pull out the terminal resistance during the operation of the instrument.
- It is not recommended to take out the bottle during the culturing process. Please put the bottle back within 60 seconds so that the result of the cultivation can not be influenced if it has to be taken out.
- Do not open two drawers at the same time in case of the instrument losing its balance and falling off.
- Open and close the drawers slowly.
- Pull the bottom to open the drawer to guarantee equal force on the doors.
- Do not place the blood culture bottle in the invalid position after the failure shown on the software interface.
- Ensure that there are no obstructions in front of the control unit scanner in the range of 15 cm; Otherwise it will continue to trigger the scanner and affect the scan of the normal blood culture bottle.

3.12.3 Instrument safety verification

Safety verification will be performed by manufacturer during expected service life.

3.13 Common Malfunctions Settlement

Situation: The instrument cannot start normally.
Reasons:
1. The internal fuse of the instrument is burnt out;
2. The power line of the instrument is not well connected;
3. The power supply voltage of the instrument is unstable.
Suggestions:
1. Check the fuse and replace it with a new one if burnt out.
2. Check whether the power line of the instrument is in electrified state, the plug is not inserted firmly and the switch is open or not, if there is such a case, insert the plug firmly then turn on the socket power switch.
3. Open the instrument after the voltage turns stable.
4. Fit appropriate UPS power.

Situation: Failure of the connection between software and the instrument.
Reasons:
1. The data line of the computer is not well connected with the instrument;
2. The COM ports of the computer or instrument are damaged;
3. Data line is not conductive or there is breakdown in the internal line;
4. Software loading is error.

Suggestions:
1. Check whether the connection port of the data line is loose and the connection between the data line and the COM port is incorrectly connected;
2. Change the COM ports of computer and the instrument in turn to find the fault COM port and take a replacement;
3. Use the multimeters to check whether the data line is connected and change the data line if it is not conductive;
4. Check the version and model of the software whether it is not well installed. Re-setup the software if there are problems.

Situations: The lamp does not scan on the testing frame after opening the drawer
Reasons:
1. Flexible Flat Cable (FFC) between the testing frames is loose or damaged;
2. The dial-up is incorrect on the detection board in the testing frame;
3. The procedure in the testing board is error or detection board damage;
4. The power line on the test board is not connected.
Suggestions:
1. Check and reconnect the FFC between the testing frame or change it;
2. Take down detection board frame to switch the dial-up to the specified position;
3. Reload the procedure or replace the circuit board;
4. Check and reconnect the power line of the testing frame to ensure that it is in the state of electricity.

Situation: The temperature inside of the drawers is low after opening them.
Reasons:
1. The temperature detection sensor in the drawers can not work any more;
2. The part on the power board supplying voltage of the heating band is damaged;
3. Heating band failure results in its not working;
4. The position on the main board controlling the sensor in the drawer is damaged;
5. The set value of the drawer temperature is too low.
Suggestions:
1. Check whether the joint connecting the sensor and the main board is loose and the sensor is damaged. If the sensor is damaged, it should be replaced in time;
2. Check whether the voltage of the power plate supplied to the heating band is normal. If abnormal, it is necessary to change the sensor in time;
3. Check whether the resistance at both ends of the connecting line of the heating plate on the power board is about 3V or not. If not, it is necessary to replace the heating plate in time;
4. Replace CPU board with a new one;
5. Check the set value of the drawer in the software and change it in time if it is too low.

Situation: The gated sensor does not trigger after opening the drawer for a period of time
Reasons:
1.Turn off the alarm in the software;
2. Sensors are damaged;
3. The connection line between the gated control sensor and main board is loose or damaged;
4. The buzzer on the main board is damaged;
5. The connection lines of gated control sensor are out of order;
6. There is an external object triggering the gated control sensor.

Suggestions:
1. Turn on the alarm in the settings of the software;
2. Change the sensor;
3. Check whether the connection line between gated control sensor and the main board is loose. Replace the connection line if it is damaged;
4. Replace the main board;
5. Remove the drawer to take off the sensor, and reconnect the sensor;
6. Remove the drawers and clean the obstruction around the sensor to ensure that the sensor is not triggered.

Situation: The gated control sensor keeps alarm after the drawer is closed.
Reasons:
1.The drawers are not closed well and the sensor can not detect them. .
2. The sensor baffle on the drawer is damaged , which may cause the failure of sensor being triggered after the drawer is closed.
Suggestions:
1. Pull out the drawer and close it again to ensure the drawer gate is closed tightly;
2. Check whether there is any damage about the sensor of which position is changed due to looseness of screw. After the screw is fastened, mechanical position of the sensor baffle needs to be adjusted to contact with the gated control sensor so that the sensor can be ready for triggering.

4 Sample Collection

4.1 Sample Collection Timing

① Fever（≥38 ℃） or hypothermia（≤36 ℃）, More frequency with intermittent remittent fever, Gram-negative bacilli, such as Escherichia coli infection of which the manifestation is bimodal heat;
② Chills;
③ Leukocytosis,（>10.0×109/ L, Especially when there is a "nuclear left shift"）;
④ Granulocytopenia（<1.0 ×109/ L）;
⑤ Thrombocytopenia;
⑥ Skin and mucous membrane hemorrhage, commonly seen in haemolytic streptococcal infection bacteremia, and rose rashes may appear on the 4th to 10th days of typhoid fever, and dark red plaque hematomas may appear on the 4th to 6th days of typhus;
⑦ Coma;
⑧ Multiple organ failure;
⑨ Blood pressure decreasing;
⑩ Breathing rapidly(breathing rate> 20/min or CO2 partial pressure <32 mmHg); hepatosplenomegaly; arthralgia; C-reactive protein, endotoxin and procalcitonin etc increasing.

As long as the patient is suspected of having a bloodstream infection, blood culture specimens should be collected immediately before the usage of antibiotics. If the patient has been treated with antibacterial drugs, the flask containing the antibiotic drug adsorbent should be selected to blood cultured before the next antibacterial drug application. Bacteria usually enters the blood 1 hour before the chills and fever, which is the best time for the collection of blood culture specimens for pathogen culture.

4.2 Blood culturing period

For adult patients with suspected bacteremia and fungemia, it is recommended to collect 2 to 3 sets of blood culture specimens from different positions (like two arms) at the same time or within short time intervals (within 10 minutes) so that "two bottles of both sides" can be achieved. If necessary, a third set of bottles can be inoculated from the veins of the lower extremities at the same time or at short intervals. Within 2 to 5 days after blood culture is collected, blood cultures do not need to be repeated.
It is only necessary to collect blood at different time points in patients with suspected infective endocarditis or continuous bacteremia in catheter-related infections.
In infants and young children, it is necessary to collect blood culture specimens twice at different positions.

Description: One aerobic blood culture bottle and one anaerobic blood culture bottle combine as one set of conventional blood culturing. The so-called "double-bottle bilateral" refers to inoculating blood from one site to inoculate one culture bottles set, and then sampling blood from another site to inoculate another culture bottles set. One venous blood injection into multiple culture bottles should be considered as a single blood culturing.
Studies have shown that only one set of blood cultures whose detection rate of pathogenic bacteria was only 65%, two sets of blood cultures were 80%, and three sets of blood cultures were 96%. Single bottle or a single set of blood cultures not only has low detection rates, but it is difficult to distinguish between false positives caused by contamination. As a result, it is difficult to make clinical explanations and it should be resolutely repealed.
Within 2 to 5 days after the initiation of antimicrobial therapy, bacteria in the blood will not be immediately cleared. Patients with general bacteremia or fungemia can judge the efficacy by clinical performance without rechecking blood cultures or continuously monitoring blood cultures. However, there are two exceptions: Firstly, in patients with bacterial endocarditis, for the elimination of bacteremia or fungemia, continuous blood culture can be used to assess and guide treatment; secondly, with infective endocarditis Unrelated anaemia of Staphylococcus aureus, 48 to 96 hours follow-up of its positive blood cultures is a good predictor of complex S. aureusemia.
Requirements: Recommended blood volume for adult patients is 20 to 30 ml, with at least10 ml per set, not less than 5 ml per bottle. The recommended quantity of blood for infants and young children should be less than 1% of the total blood volume of the child and not less than 2 ml per bottle. For laboratories using finished blood culture bottles, sufficient blood specimens must be collected as recommended by the blood culture bottle manufacturer.
Explanation: Blood culture blood collection is the most important variable factor affecting the detection rate of pathogenic bacteria. Under normal circumstances, the bacterial concentration in the peripheral blood of adult bacteremia is 1 to 10 CFU/ml, and when the blood volume of adult blood culture is between 2 and 30 ml, the detection rate of pathogenic bacteria is positively proportional to the amount of blood collected. Children also have data indicating that the detection rate is positively correlated with the amount of blood collected from blood cultures. However, since the concentration of pathogenic bacteria in children's blood is high, it is generally about 10 times the concentration of pathogenic bacteria in adult bloodstream infections. The amount of blood culture specimens does not have to be equal to that of adults. However, children may also have low levels of bacteremia. The amount of blood culture will depend on the blood volume and age of the child.
Generally 7 days are required for incubation by traditionally manual blood culture methods. The standard blood culture period for the automated blood culture system is 5 days. After 5 days, negative blood culture specimens do not need to be changed.
Note: The standard blood culture cycle for automated blood culture systems is 5 days. Culture cycles for Brucella, Haemophilus influenzae, Actinobacillus, Cardiomyces, Echinococcus eroticum, Bacillus cereus, and Streptococcus mutans are 5 days. It is not necessary to extend the incubation time for blood cultures of patients who are suspected of having infective endocarditis. Studies have shown that automated blood culture systems typically detect between 95% and 97% of clinically valuable bacteria and fungi within 3 to 4 days. However, it is still recommended that culture period should be 5 days. Special circumstances can extend the culture time appropriately.

4.3 Blood culture results reporting method

Both negative and positive results of blood culture are very important for the diagnosis and treatment of patients. In particular, the positive results of blood culture should be included in the scope of the crisis report, and a special crisis value reporting system should be established. Detailed records include patient information and specimens sent. The time, type and quantity of the test, the time of the system's positive alarm, smear staining results, and the reporter's and informants' contents should also be recorded in the clinical department.

It is recommended that hospitals that have established a laboratory information management system (LIS) should send blood cultures information to the Internet in a timely manner so that clinicians can keep abreast of the progress of blood culture tests. At least the following information should be included:

a Laboratory has received application but not received specimen yet;

b Specimens have been received, but numbers of blood cultures and testing items have not been received yet;

c Being testing, result does not come out;

d 24 hours without growth;

e 48 hours without growth;

f System has positively alarmed, positive alarm time and direct smear staining microscopic examination results;

g Preliminary identification results after overnight culture;

h Final identification and drug sensitivity test results.

4.4 Blood culture pollution problem and identification

In order to minimize blood culture pollution, laboratory must take following measures:

a. Pay attention to the training of blood culture specimen collection techniques to reduce the occurrence of pollution;

b. Collect appropriate blood culture volume to effectively detect pathogenic microorganisms and correctly distinguish blood culture pollution;

c. Establish a standardized procedure that can objectively and accurately assess whether blood culture-positive strains are pathogens or pollution bacteria, in conjunction with the development status of hospital blood cultures.

Identification of blood culture pollution:

a. Only this bottle of blood is cultured within 48 hours. Laboratory personnel need to retrieve patient data and discuss possible clinical values with the clinician: pathogens/contaminants cannot be determined. No susceptibility testing unless it is clinically required.

b. There is another set or another bottle of blood culture within 48 hours, but if the result is negative, it will be notified as a pollution, no susceptibility testing unless clinical requirements.

c. There is another set or another bottle of blood culture within 48 hours and the result is positive. If the identification result is all Streptococcus viridans, it is considered as pathogenic bacteria. Do the susceptibility test and report the result to the clinic; if the identification result is the same type but other potentially pollution bacteria, their clinical significance cannot be determined and they need to be discussed with the clinician about their possible clinical value: pathogens/contaminants cannot be determined. No susceptibility testing unless clinical requirements.

Explanation: False positive blood culture caused by pollution is a relatively common problem. Even if the best blood culture specimen collection method is used, it is difficult to reduce the pollution rate under 2%. False positive results in blood cultures will lead to unnecessary antibiotic treatment, prolonged hospital stay, increased patient burden and selective pressure on bacterial resistance. Accurately identifying pollution can greatly reduce the corresponding cost and subsequent pollution rate. However, at present, there is no golden standard for determining blood culture pollution. For example, coagulase-negative Staphylococci (CNS) is the most common contaminant and one of the most common bacteremia pathogens. It is a worldwide problem that requires clinicians and laboratory personnel to communicate with each other and analyze them comprehensively. The identification of blood culture pollution mainly depends on the following aspects: microbial identification, positive detection time, repeated culture results, and clinical characteristics.

Identification of microbial strains for determining blood culture pollution values: When isolated microorganisms are Staphylococcus aureus, Klebsiella pneumoniae, Escherichia coli, and other Enterobacteriaceae, Pseudomonas aeruginosa, Candida albicans In bacteria, more than 90% of the pathogens are bloodstream infected. The possibility of isolating these pathogens,,which are Streptococcus pyogenes, Streptococcus agalactiae, Listeria monocytogenes, Neisseria meningitidis, Neisseria gonorrhoeae, Haemophilus influenzae, Bacteroides fragilis, Other Candida and Cryptococcus neoformans , is even lower. In contrast, Corynebacterium, Micrococcus, Oxycoccus, Bacillus, Propionibacterium, Streptococcus viridans, and coagulase-negative staphylococci are rarely pathogens of bacteremia.

The value of number of blood culture positive bottles for determining blood culture pollution: All or most of the blood culture bottles of patients with endocarditis or bloodstream infections are positive. Conversely, blood culture pollution is often only positive in one bottle. This is a guideline for blood cultures. One important reason for recommending blood culture should be two sets of four bottles (two bottles of both sides). The following formula can be used to explain the clinical value of two or more blood cultures: If the pollution rate of a hospital blood culture is 3%, then a patient's two blood cultures (collecting blood from different sites) are positive and possibility of being polluted by the same bacteria is 0.09% (3% X 3%).

Another tool to identify pollution of blood cultures is Time To Detection (TTD), provided that pathogens are detected and grown earlier than pollution bacteria, but in fact there is a cross between them, especially with the application of automated blood system, the growth time of the detection of pollution bacteria is shortened, and difference between the pathogenic bacteria and the TTD of pollution bacteria becomes narrower, and the identification value becomes even more blurred.

In conclusion, the current judgment of blood culture pollution still lack an independent golden standard. Only through continuous communication between clinical staff and laboratories, chance of using pollution bacteria as pathogens can be reduced, on the other hand, correct blood culture collection and treatment methods can be promoted, only by that possibility of pollution can be reduced and a benign cycle can be sustained so that the interference can be minimized to clinical diagnosis and treatment by occurrence of blood culture contamination.

5 EMC Statement

a) A statement that our product BC120 complies with the requirements on transient emissions and interference resistance has been described in the part of the IEC 61326 series.
b) According to emission compliance, this device belongs to Class A, which has been designed and tested according to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case it may be required to take action to eliminate such interference.
c)The electromagnetic environment of your lab should be evaluated prior to operation and setup of the device.
EMC Warnings:
Do not use the device in the vicinity of sources with excessive electromagnetic radiation (e.g. unshielded, intentionally operated high frequency sources) with a reason that they could interfere with the proper operation of the instrument.

6 Warranty statement

Autobio guarantees that malfunctions of BC120 and its accessories could not occur under normal conditions of use and will provide a 12-month warranty on the product from the date of purchase, except:
a) Warranty label on the instrument housing is missing or damaged.
b) Instruments and accessories are not installed, powered, and operated in accordance with this instructions and accessories manual.
c) Damage during transit.
d) Damage caused by spillage of reagents, exposure to corrosive substances or gases.
e) Instrument has been repaired or altered by customers or any unauthorized technician.
f) Instrument is internally damaged by an unknown voltage.
g) Damage caused by natural disaster or force majeure.
Failure of the product during the warranty period, Autobio will give free repairing, or replace the corresponding accessories based on Autobio decision. The warranty period of replacement parts within the warranty period is based on instrument warranty period.
Warranty services are non-transferable and do not apply to products that have been damaged due to misuse, alteration, improper transport, or repaired by someone else other than the manufacturer and authorized service agent.
This statement does not include shipping fees. The manufacturer does not guarantee that this product fully meets your requirements and it is your responsibility to determine whether the product meets your requirements. The only responsibility and obligation of the manufacturer is to supply maintenance or repair damaged products by replacing accessories. Under no circumstances will the manufacturer be liable for direct or indirect damages (including but not limited to damages caused by service disruptions and business losses) of the purchaser or any third party, or civil liability related to the product.

6.1 Product return process

We make every effort to provide the best customer service and perfect product return process. To achieve this goal, please support our work by following the instructions below.
Any product returned by a laboratory must comply with the following steps:
1. Contact your dealer for a return authorization.
2. Fill in and sign the "Disinfection Statement" (which can refer to Appendix 2) to ensure that the disinfection process has been properly performed.
3. Properly package the instrument to be returned. It is recommended to use the original packaging and use the transport holder to secure the carrier.

Precaution
Please contact your distributor if you do not have suitable packing box.
It may cause serious damage to the instrument and have a negative impact on your quality warranty if the returned product is not properly packed.
4. Attach a complete “Disinfection Statement” on the surface of the packing box and other relative transportation documents .
5. Send the product back to the address stated in the “Backtracking Authorization”, which can refer to Annex 1.

Precaution
Delay could occur if it is not operated according to the above process.
The product will be temporarily stored until further investigation is completed if the returned product do not have a complete “Disinfection Statement”.
We have the right to send the product back if the customer does not provide the corresponding documents within one month. And the customer will pay for the delivery fee.
Please contact your local distributor if you need further helps in providing the corresponding documents such as “Disinfection Statement” or transportation documents.

6.2 Backtracking authorization and disinfection statement

Backtracking Authorization and ***Disinfection statement*** in annex should be filled if the product needs to be returned.

6.3 Remove from use

If the instrument removes from use for repair, disposal, transportation or will not be used temporarily, users should contact the manufacturer, and it cannot be handled as a regular item.

Annex

Annex 1 Backtracking Authorization

Company:				Company: Autobio Diagnostics Co., Ltd.	
Address:				Address:No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China	
Contact				Receipt: Customer service center	
Tel				Tel: [86]-400-056-9995	
Fax		Zip		Zip	450016

Fault description:

Annex should be sent back together with the instrument:

Precautions for the instrument packaging:
1. Please pack the instrument with the original packing box if it still exists.
2. Please pack the instrument with polystyrene foam layer if the original packing box does not exist.
a.Put the instrument in a box with foam in the bottom, and fill the side and top with foam, then seal the box to prevent damages caused by shocking during transportation.
b.After the first layer finished, put it in a larger packing box and fill its four side and top with foam.
c.Seal the outer packing box.

Note: 1. Please read the precautions of the instrument packaging carefully.
2. Please fill the blanks in this annex and put it in the box to be sent back together.

Operating Manual

Annex 2 Disinfection statement

Product name:	Serial No.:
Model:	Backtracking authorization:
Purchase date:	No. of warranty:

A Does the internal or external of the product have ever been exposed to the following environment? Please mark "yes" or "no" with X, then answer each of the questions below and give a detailed description in the B column.

	Yes	No		Yes	No
1 It has been exposed to pathological blood and body fluid			4 Chemical or material may endanger health		
2 Any other biohazardous substance			5 Radioactive material (inform detailed information below, including name, quantity and residual activity of the isotope)		
3 Substance that can be decomposed to dangerous substance			6 Other hazards		

B Inform detailed information about the harmful substances in the environment that the product has been exposed to, including the name, quantity and related safety analysis date:

*** If harmful substances have been used, disinfection treatment must be done***

C Your disinfectant method (Table can be attached):

D Whether the substances mentioned in part A or B are likely to remain contaminated?

I guarantee the truth and efficiency of the information provided above.

Sign:	Date:
Name:	Title:
Company:	
Address:	
Tel:	E-mail:

Annex 3 Manufacturer and product information

Manufacturer: AUTOBIO LABTEC INSTRUMENTS CO., LTD.
Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China
Contact: [86]-400-056-9995

After sales service provider:
Company: Autobio Diagnostics Co., Ltd.
Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China
Contact: [86]-400-056-9995

Product information:
Name: Automated Blood Culture System
Model: BC120
Date of manufacture: See nameplate on the instrument

Annex 4 Safety symbols

Safety Symbols	Interpretation
	Documentation must be consulted in all cases where this symbol is marked
	Dangerous voltage
	OFF (Power)

	ON (Power)
	Protective earth (ground)
	Consult instructions for use
	In vitro diagnostic medical device
	Biological risks