



华粤行医疗
HARIOMED

Harioculture HI-2 Benchtop Incubator User Manual

Caution: US Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Read the instructions

Copyright © 2024by

Hua Yue Medical Technology Co., Ltd.

All rights reserved.

This manual contains information that is subject to copyright. All rights reserved. The information in this manual has been carefully reviewed, but no liability is assumed for possible inaccuracies. Statement of this manual does not have any express or implied warranty. The specifications and performance characteristics of the hardware and software in the manual are subject to change without further notice. Hua Yue has the right to change the product to ensure greater reliability. Hua Yue would not be responsible for any liability arising from the use of any application, product usage or circuit problem.

All trademarks are the property of their owners, please do not infringe.

User Notice

Thank you very much for choosing Benchtop Incubator from Hua Yue Medical Technology Co., Ltd. Please read this manual carefully before operating the product. This manual covers all important information and data about operating the product. Users must strictly abide by its provisions to ensure the normal operation of the incubator. At the same time, attention and warning messages can help users use the instrument correctly and obtain accurate results.

Overview

To ensure the quality of the Benchtop Incubator, these products are strictly inspected before shipping. In order to ensure its safe and reliable operation and obtain correct analysis results, users must strictly follow the operation method described in this manual. In addition, proper transportation, storage and installation as well as reasonable operation and maintenance are conducive to the safe and normal operation

of the system.

This manual provides the information of routine operation, the composition and maintenance of the Benchtop Incubator, along with the parameters and performance characteristics. It provides an accurate reference for technicians who have been specially trained or have knowledge of the instrument. Operators must correctly understand the safety and warning information mentioned in this manual before operation.

Cybersecurity

This manual provides the initial password of the user account. Please change it after the first login and keep it securely to prevent unauthorized access. It is recommended and expected that users conduct appropriate network security awareness training to reduce cybersecurity risks to ensure that the device will work as designed in the intended user environment. If there is a network security breach or any suspicious security incident, you must notify the company immediately.

Notifications

This manual describes the specific application of the incubator, and how to start, operate and maintain the equipment. Note, tips and warnings in this manual are crucial to avoid incorrect operations.

Safety first principle was carried out during the whole process of development, manufacture, test and documentary. Keep these instructions manual close to the device which ensure you have easy access to the safety instructions and important information.

Please note these tips and warning information in the manual which can help you avoid being at risk and equipment damage. This type of information is displayed in a specific icon with the corresponding explanatory text. The ICONS used in this manual are shown in the following table:

ICONS	DISCRIPTION
-------	-------------

	Notice info: general information that reminds the user during the use of the product, or parts of this manual that require general attention.
	Caution info: important information to be paid attention to during the use of the product, or parts of this manual that require special attention.
	Warning info: if the product is not used in accordance with the correct safety measures, it will lead to the equipment damage, there will be a potential risk of serious injury or even death.

Supply and Transport

The specific shipping requirements shall be in accordance with the corresponding clauses in the order contract.

When unpacking, please carefully read the relevant information on the packaging materials, to ensure the integrity and undamaged of unpacking goods. Please try to keep all product packaging for use in case the equipment is needed to be returned.

Abuse Statement

If the equipment is not used in the manner specified by the company, the protection provided by the equipment itself may be compromised. The company is not responsible for any misuse of equipment or neglect of the safety guidelines outlined in the manual.

Warranty and Maintenance

Specific warranty and maintenance requirements shall be in accordance with the corresponding terms of the purchase contract.

Within the warranty period and the warranty scope, free maintenance service will be provided, mainly including spare parts maintenance, replacement, technical support and regular on-site services within warranty.

Any of the following faults that exceed the warranty period or occur within the warranty period shall be subject to out-of-warranty maintenance, and no free warranty service shall be provided, including but not limited:

- Incorrect use—water ingress, corrosion, fire, strong electric inrush, etc.
- Damage caused by the user who opens or disassembles the equipment without authorization
- Damage caused by force majeure (earthquake, lightning, flood, etc.).
- Interior part of equipment can't be changed without permission.
- Damage caused by failure use of product in accordance with the instruction manual and training.
- Regarding the products developed and manufactured by the company, the company strictly abides by the relevant national regulations in the disposal of waste products.

Confidentiality

All names and treatment data presented in this manual are purely fictional.

Technical Support

Please contact the manufacturer or local authorized representative.

Version Statement

In no event does Hua Yue assume the liability for any technical or editorial errors of commission, or omission; nor is liable for direct, indirect, incidental, or consequential damages arising out of the use or inability to use this manual.

The information in this manual is current at the time of publication. Our commitment to product improvement requires that we reserve the right to change equipment, procedures and specifications at any time.

This manual is protected by copyright, all rights reserved, and no part hereof may be copied or reproduced in any form without the prior written consent of Hua Yue.

Catalogue

User Notice	I
Overview	I
Cybersecurity	II
Notifications	II
Supply and Transport	III
Abuse Statement	III
Warranty and Maintenance	III
Technical Support	IV
Version Statement	IV
Catalogue	V
1 Device Overview	1
1.1 Device Synopsis	1
1.2 Product Performance	2
1.3 Device Features	3
2 Structural Composition	4
2.1 Culture Chamber	4
2.2 Display Interactive Device	5
2.3 Internal Control Part	6
3 Prepared by Users	8
4 Installation Requirements	9
5 Preparation before Use	11
6 Instruction for Use	12
6.1 Startup	12
6.2 Chamber Operation	13
6.3 User Login	15
6.4 Setting	17

6.5 Curve	18
6.6 Calibration	19
6.7 Log	20
6.8 Service	21
6.9 Alarm	22
6.10 Power off	24
7 Precautions and warnings	26
7.1 Precautions	26
7.2 Warnings	27
8 Maintenance and Upkeep	28
8.1 Device Cleaning	28
8.2 Device Disinfection	28
8.3 Device Maintenance	29
8.4 Device Unkeep	30
8.5 Service Life	30
9 Storage, Transport and Disposal	31
9.1 Storage	31
9.2 Transportation	31
9.3 Disposal	31
10 EMC Requirements	32
10.1 Electromagnetic Emissions	32
10.2 Electromagnetic Immunity	32
11 Listing of Accessories and package	34
12 Conform to Standard	35
13 Symbol glossary	36
14 Manufacturer Information	38

1 Device Overview

1.1 Device Synopsis

1.1.1 Product Name: Benchtop Incubator

1.1.2 Model: Harioculture HI-2

1.1.3 Indications for use

The Benchtop Incubator is intended to be used to provide an environment with controlled temperature at or near body temperature and gas concentrations (CO₂ and O₂) or mixed gas (CO₂ and other gases) and humidification for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproduction technology (ART) treatments.

1.1.4 Contraindications

None

1.1.5 Operating principle

This Benchtop Incubator is mainly constituted of culture chambers, temperature control system, humidity control system, gas control system and display interactive device. The outer surface of the Benchtop Incubator is covered with a heater to provide a suitable temperature environment for cell culture. The gas control mode inside the Benchtop Incubator is premixed gas mode. The Benchtop Incubator through the solenoid valve to adjust the gas flow and supply the gas to the chamber to maintain the gas concentration inside the Benchtop Incubator to the desired set point.

1.1.6 Intended user

Embryologists, other laboratory personnel and clinic staff at IVF clinics trained by Hua Yue Medical Technology Co., Ltd.



Figure 1.1 Appearance of the Benchtop Incubator.

1.2 Product Performance

Table 1.1 Specification of Benchtop Incubator.

Items	Parameters
Power supply	AC100-240 V, 50/60Hz, 400VA MAX
Weight	25Kg
Exterior dimension	500×377×220mm (Length × Width × Height)
Work pattern	Continuous running
Shell and chamber materials	ABS engineering plastics, aluminum
Number of culture chambers	2
Types of petri dishes	φ35mm(8x)/φ50mm(4x)/66×66mm(4x)
Working environment	Temperature 18 - 30°C, Relative humidity≤80%
Premixed gas supply pressure	1 bar
Temperature control range and accuracy	25°C- 42.0°C(Above room temperature 7°C), ± 0.1°C
Start-up time	At least 30 minutes, 1 hour is recommended

1.3 Device Features

Benchtop Incubator is a device designed to provide a controlled temperature and suitable gas environment for the culture of human samples. Its precise control for stable temperature and gas concentration provides a reliable environment for the growth and development of biological cells. For specific performance is as follows:

- ♦ Homogeneous and stable temperature: heated chamber from top to bottom could prevent condensation effectively; accurate temperature control, temperature accuracy is less than $\pm 0.1^{\circ}\text{C}$, uniformity is less than 0.2°C ; Fast heating speed, temperature can be stabilized in 30 minutes after startup of the Benchtop Incubator.
- ♦ Human-computer interaction module: Android touch screen can monitor the parameters of the device in real time, draw curves, and set various parameters; Comprehensive and reliable alarm management system can provide visual and auditory alarm when opening the chamber cover and exceeding the limited values of temperature and gas concentration, and record detailed alarm information.

2 Structural Composition

The Benchtop Incubator is mainly composed of culture chambers, temperature control system, humidity control system, gas control system and display interactive device. The appearance of the device is shown in Figure 2.1.



Figure 2.1 Appearance of Harioculture HI-2 .

2.1 Culture Chamber

Culture chambers consists of chamber modules , petri dish trays and humidification chamber module.

Within each chamber, two petri dish trays are positioned, featuring a variety of shaped grooves to accommodate petri dishes of different models. There are two handle columns on the left and right sides of the petri dish tray with which users could pick and place the tray.

The chamber is arranged symmetrically, and the humidification chamber is middle of the two chambers. The Benchtop Incubator employs premixed gas to supply gas to itself. The premixed gas enters the Benchtop Incubator via the humidification chamber, thus achieving gas replacement and maintaining humidity inside the Benchtop Incubator. The chamber cover is designed with an electromagnetic lock, which enables effective management of the Benchtop Incubator's usage. It also supports a forced opening function to deal with emergencies.



Figure 2.2 Harioculture HI-2 Benchtop Incubator.

2.2 Display Interactive Device

The display interactive device is a 7-inch LCD screen which is used to display Benchtop Incubator running information such as the chamber temperature, gas concentration or gas flow and chamber status. At the same time, it also allowing for setting the chamber temperature, gas concentration control, gas flow rate control and patient information and so on. In the event of a device abnormality, the display screen will alert the user with an alarm prompt.



Figure 2.3 Display interactive device.

There is an Android system reset button under the display device, and while this

rarely happens, can be pressed to restart the Android system when the screen crashes, freezes, or system death. Please assured that the restart of the Android system will not affect the temperature and gas control of the device.

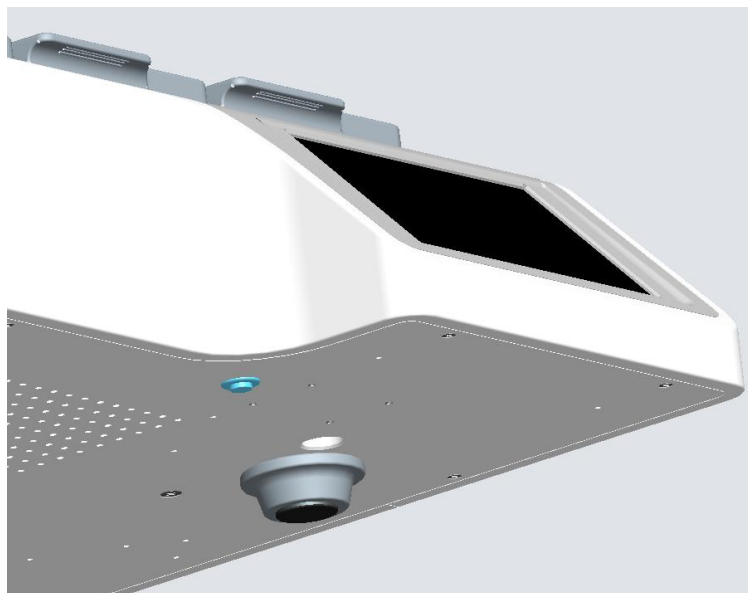


Figure 2.4 Screen reset button.

2.3 Internal Control Part

Internal Control Part includes temperature control system, humidity control system, gas control system.

Temperature control system composes of temperature sensor, heating unit, over temperature protector, micro-processor control unit, etc. Heating temperature of each chamber was controlled by fuzzy PID control method and dynamically adjusting each chamber heating power according to setpoint by the user.

The gas control system is a premixed gas control system. The premixed gas control system controls and adjusts the flow of premixed gas and supports the monitoring of the concentration of premixed gas.

The humidity control system allows water vapor from the heating and humidification chamber to flow through the pipeline and reach the culture chamber. The humidity control system can stably maintain the humidity percentage in the chamber and simulate specific environmental conditions to contribute to the success of the experiment.

The oxygen sensor is located inside the device and the device needs to be in a maintenance state for replacement. In order to ensure the embryo culture effect, the Benchtop Incubator should replace the new component in time before the O₂ sensor reaches the maximum service life. The specific replacement steps are as follows.

Replacement of O₂ sensor:

1. All petri dishes should be removed from the Benchtop Incubator and the power of the Benchtop Incubator should be turned off before replacing the O₂ sensor.
2. Open the right-side cover and unplug the connector of the sensor.
3. Rotate O₂ sensor counterclockwise and remove the O₂ sensor.
4. Rotate a new O₂ sensor clockwise into the threaded hole.
5. Plug in the O₂ sensor and arrange the wires.
6. Turn on the Benchtop Incubator power, calibrate O₂ sensor at two-point calibration mode according to section 6.6.
7. Refer to Section 6.8 to reset the sensor service life, the life shall be the nominal life of the sensor minus its time from the factory date to the current time.
8. Set temperature and gas concentration to the setpoint, and put the petri dish into the Benchtop Incubator after it is stabilized.

NOTICE

When the O₂ sensor reaches the end of its service life, its accuracy and stability will be worse, which will seriously affect the gas control of the device.

3 Prepared by Users

In order to ensure the normal operation of the Benchtop Incubator, users should provide the following items:

1. Medical mixed gas source.
2. Gas pressure reducing valve: Gas pressure reducing valve, measuring range of 1-2 bar (1bar is equal to about 0.1MPa), optional.
3. Power supply: Voltage AC100-240V, power frequency 50/60Hz, power not less than 450VA.

4 Installation Requirements

To ensure successful installation and normal running of the Benchtop Incubator, please install the Benchtop Incubator according to the following requirements:

1. Confirm the installation space of the Benchtop Incubator.

- The width of the installation table should be greater than 20cm in the direction of the device, which is convenient for the maintenance of the gas high efficiency filter and oxygen sensor.
- The length of the installation table be greater than 10cm in the direction of the device.
- Check whether the reserved installation positions meet the requirements. 20cm gap should be reserved at the rear of the Benchtop Incubator for connecting power cables and gas tubes and for later maintenance.
- The height of the installation table should meet the height and size of the chamber cover to open normally, so as to achieve the smooth taking of the petri dishes in the chamber.

2. The installation site of the equipment should be far away from the vibration center.

3. The installation environment should be Class 10,000 cleanliness, with ambient temperature ranging from 18°C-30°C, humidity no more than 80%, environmental pressure ranging from 80kPa - 101.3kPa.

4. External gas source mixture gas concentration is determined according to customer demand.

5. When the Benchtop Incubator is connected to the external gas supply, it must be confirmed that the gas pressure is between 1-1.5bar. Recommended gas pressure is 1bar.

6. Power supply confirmation: voltage is AC100-240V, power frequency is 50/60Hz, output power is not less than 450VA.

7. Handle the device with caution to avoid damage caused by impact.

8. In order to ensure safety, 2 adults are required to carry the Benchtop Incubator during installation.

9. After installation, it is necessary to clean the inside and surrounding environment of the Benchtop Incubator with ultra-clean vacuum cleaner or tools that do not produce fiber.

5 Preparation before Use

1. Put the Benchtop Incubator on a flat tabletop and place the dish trays in the chambers.
2. Operation environment confirmation: Class 10000 cleanliness, ambient temperature ranging from 18°C-30°C, humidity does not exceed 80%, environmental pressure ranging from 80kPa-101.3kPa.
3. The gas inlet on the rear panel of the Benchtop Incubator is connected to the mixed gas source with a CPC Quick connect coupling and a gas tube with an outer diameter of 6mm and an inner diameter of 4mm. The inlet gas pressure is 1bar.
4. Connect the power cable to the Power inlet on the rear panel of the device.
5. The Alarm Interface is the connection interface of the external alarm device, which can transmit the alarm information inside the device to the external alarm device.

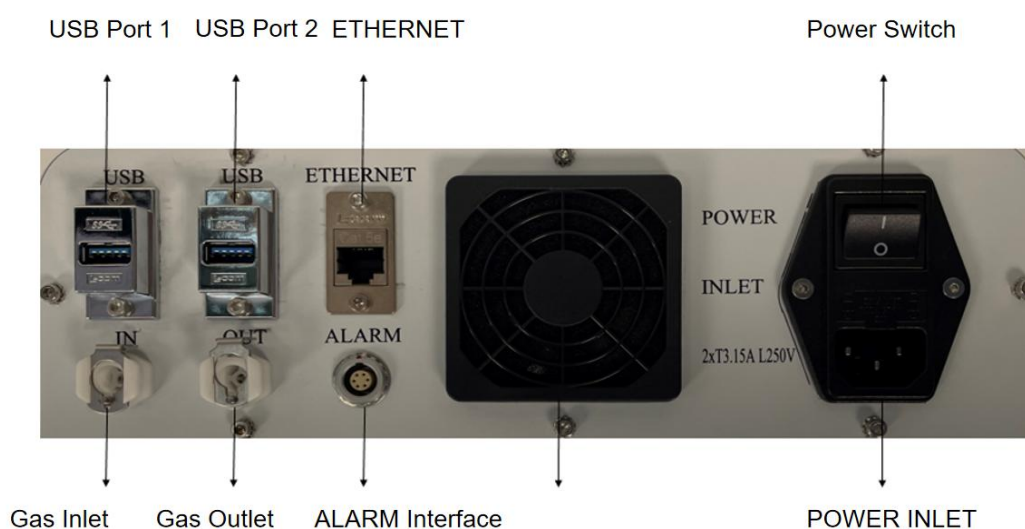


Figure 5.1 Interface on the Benchtop Incubator rear panel.

CAUTION

Ensure that the power supply and gas supply meet the requirements in the instructions above when power supply and gas supply are connected, otherwise, the Benchtop Incubator may not work or be damaged.

6 Instruction for Use

6.1 Startup

1. Please check and prepare the Benchtop Incubator basic working conditions according to Chapter 4 before starting the Benchtop Incubator.
2. Turn on the power switch on the rear panel of the Benchtop Incubator, and the touch screen on the right front of the device will light up, displaying the following picture.

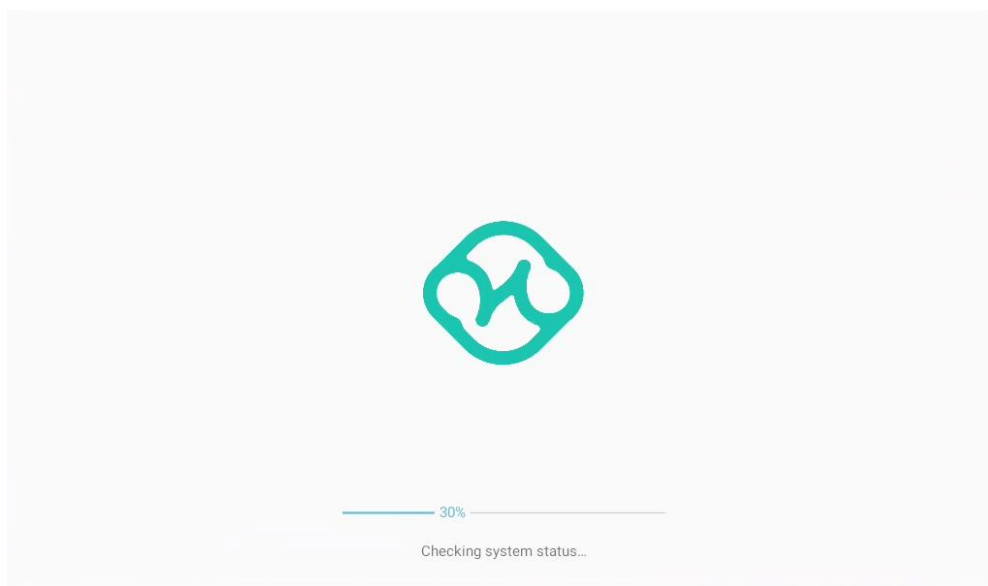


Figure 6.1 Loading page of the screen.

3. After starting the device, the user interface will be displayed as shown in Figure 6.2. The main interface can be divided into three parts: upper, middle and lower. At the top of the main interface, the current time information and navigation bar are displayed. Clicking on the icons on the navigation bar can jump to other interactive interfaces to access corresponding information and realize corresponding functions. The middle part of the main interface contains the status information of two chamber of the Benchtop Incubator and the status information of the humidification chambers corresponding to the two chambers. The information of each chamber includes real-time temperature and humidity of the chamber, chamber number, on/off status of

the chamber's electromagnetic lock, and patient information, etc. In the middle area between the two chambers, the real-time temperature of the humidification chamber and the real-time gas flow rate passing through the humidification chamber are displayed. The status bar at the lower part of the main interface also contains alarm information and gas concentration information. The left area shows the current alarm information. At the same time, clicking on the icon can choose whether to mute the alarm sound. If there are multiple alarm messages, all the alarm messages will be displayed in a scrolling manner one by one. And clicking on the alarm message can jump to the alarm page to view all the current alarm information in detail and understand the alarm reasons and take corresponding measures according to Section 6.9. The lower right part of the main interface also shows the real-time values of the concentrations of CO₂ and O₂ currently being introduced.



Figure 6.2 Main screen

4. After starting, the instrument will automatically control the temperature of each chamber, usually this process takes about half an hour, but it is recommended to start for cell culture after one hour. To change the temperature or flow rate, please refer to section 6.4.

6.2 Chamber Operation

Chamber operations are usually performed 30 minutes after the device is turned on and when the temperature inside the chamber reaches the set value. Chamber

operations of the Benchtop Incubator include opening the chamber, binding the labeled petri dish to the corresponding chamber, and unbinding. For opening the chamber, the user only needs to click on the lock icon“”. After it changes  and a "click" sound is heard, the chamber cover of the corresponding chamber number is unlocked. The chamber cover can be opened within 5 seconds after unlocking. Otherwise, the chamber cover will be automatically locked. The chamber cover should not be opened for too long. It is recommended to close it within 10 seconds because opening the chamber cover will affect the temperature and gas concentration in the chamber. If the chamber cover is not closed after 10 seconds, the horn will emit a door closing prompt tone for notification.

After opening the chamber cover, the user can place the labeled petri dish into the target chamber and close the chamber cover. If the petri dish has entered the database before this, that is, the patient's name and ID number are bound, the label on the petri dish will be recognized and displayed in the chamber with the corresponding number. If the label has not entered the database, the screen will show the picture as shown in Figure 6.3 at this time. The figure shows the number of the petri dish label, but the patient name, ID number and chamber number are not bound, indicating that the information of the petri dish has not been established in the database. At this time, it is necessary to bind the information of the petri dish. The corresponding operation is as follows. Click . The picture as shown in Figure 6.4 below appears. Enter the patient's name and ID number, check the petri dish with the corresponding number, and click "Determine" to complete the operation of binding the labeled petri dish to the corresponding chamber. If you want to unbind, just click  again, uncheck, and click "Determine" to complete the unbinding operation.

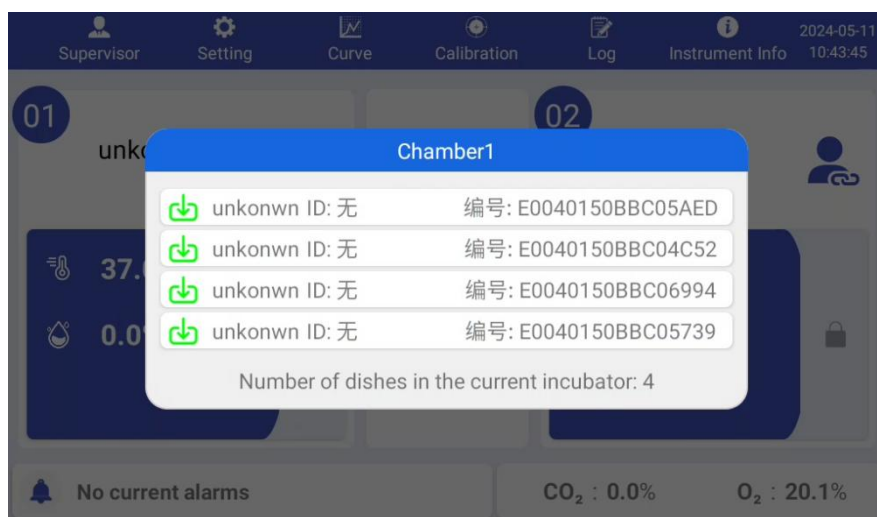


Figure 6.3 After the petri dish label is identified.

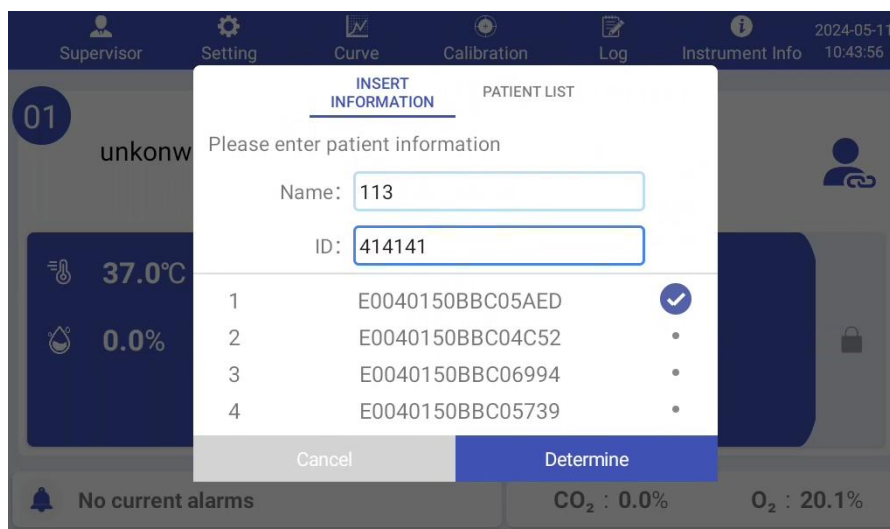


Figure 6.4 Picture of Petri dish label binding to the chamber

6.3 User Login

When the device is delivered, the “Supervisor” account is provided with administrator rights by default. The initial password of the account is “huayueadmin”. After the Benchtop Incubator is enabled, it is not logged in by default. User accounts are divided into Supervisor user, HighOperator user, and Operator user. "No login status" only has the lowest permission (chamber unlock, user login, view alarm information); Operator users can view Settings, Curves, Calibration, Logs, and Service interface information based on the permission of Not logged In Status. HighOperator user based on the rights of the Operator user, the HighOperator can set set points, calibrate,

export, and create Operator users. Supervisor user based on the HighOperator's rights, Supervisor can set upper and lower limits, create HighOperator users, and Operator users, and perform some system settings.

Click the leftmost icon of the navigation bar to display the login interface, as shown in Figure 6.5 below. In the login interface, the user can choose the account password login or the bracelet bound to the account to log in. When using the account password, enter the corresponding account and password on the touch screen and click "Login" to complete the login. If you use the bracelet to log in, you need to ensure that the bracelet binding has been completed when creating an account, as shown in Figure 6.5 below. Under this premise, just click "One click login with a wristband" and place the bracelet on the blue "RFID" pattern on the left side of the front of the Benchtop Incubator to complete the login.

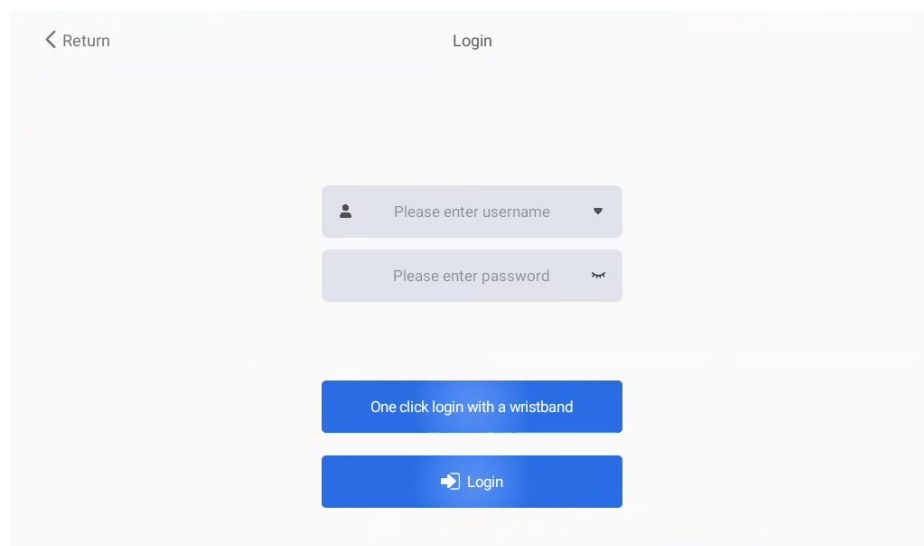


Figure 6.5 User login interface

When creating accounts, the system allows users with Supervisor to create accounts. The created users are classified into HighOperator users and Operator users. To create a new user, just fill in the box marked by the red star in Figure 6.6, that is, select the account type, account number and password, and the wristband can be bound later. HighOperator users can also create Operator users and manage the users they create, including changing passwords, deleting accounts and binding wristbands, as shown in Figure 6.7.

The interface is titled "User Management Interface" with a "< Return" button. It contains the following fields and buttons:

- Account category: Text input with "Supervisor" and a red asterisk.
- Username: Text input with "Supervisor" and a red asterisk.
- Password: Password input with "*****" and a red asterisk.
- Confirm password: Password input with "*****" and a red asterisk.
- Band number: Text input with "E0040150BBC0660A" and a "Reset" button.
- A large blue "Determine" button at the bottom.

Figure 6.6 User account creation interface.

The interface is titled "User Management Interface" with "< Return" and "Logout" buttons. It features a table of users and a bottom navigation bar.

Number	User Group	Username	Password	Band number	Control
1	Operator	hy	qwe	E0040150BBC06994	Modify Delete

Bottom navigation bar:

- Quit app
- Add a new account
- Change password

Figure 6.7 User Management page

6.4 Setting

In the navigation bar of the main interface, clicking the "Setting" icon will jump to the settings interface. On this interface, corresponding parameters can be set. As shown in Figure 6.8, in the setting interface, users can set the temperature of two chambers and the chamber cover, gas purging and maintenance flow, and purging duration. For gas concentration, this Benchtop Incubator can only use the upper and lower limits of gas concentration and humidity to control the chamber culture conditions, and an alarm will be triggered if the limit value is exceeded. Specifically, the upper and lower limit values can be set in the setting interface, while the high and low limit values are set

according to the values set in Section 6.8. After writing new values, the data will be updated only after clicking the "Save" button in the upper right corner. For the temperature item, the desired set points for the temperatures of the two chambers can be written in the "Target" column and saved by pressing the "Save" icon. The corresponding temperature in the chamber will be controlled near the set set point. In addition, according to needs, the magnitudes of maintain flow rate and purge flow rate and the purge duration can be set to quickly control the internal gas concentration and humidity to reach the system's set set point. In addition, it is also possible to set how long after opening the chamber cover a reminder for closing the cover will be given. The recommended setting duration is 5 seconds.

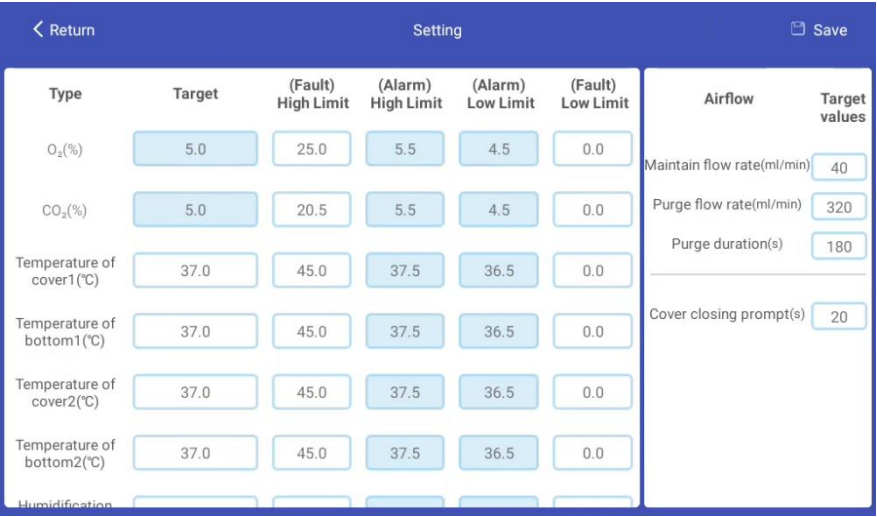


Figure 6.8 Setting screen.

6.5 Curve

When users want to view the changes in various state parameters in the Benchtop Incubator (such as chamber cover temperature or CO₂ concentration), clicking the "Curve" icon in the navigation bar can jump to the curve manage interface. As shown in Figure 6.9, in the curve manage interface, users can view the change curves of monitoring data in the device. This interface mainly can realize curve management and find past parameter curves. In curve management, users can view the curve changes of the target parameter. Click "Curve Manage", check or uncheck the target parameter, and then click "Confirm" to control the displayed parameter curve. If you

want to find the curve changes in a past time period, click , select the target time period, and the curve manage interface will display the curve changes in the target time period, as shown in Figure 6.10. If you want to return to the current curve, just click . If changing the scale or position of the curve display, users can put two fingers together or apart to change the scale of the curve or slide the curve horizontally to change the position on the horizontal and vertical axes of the curve.

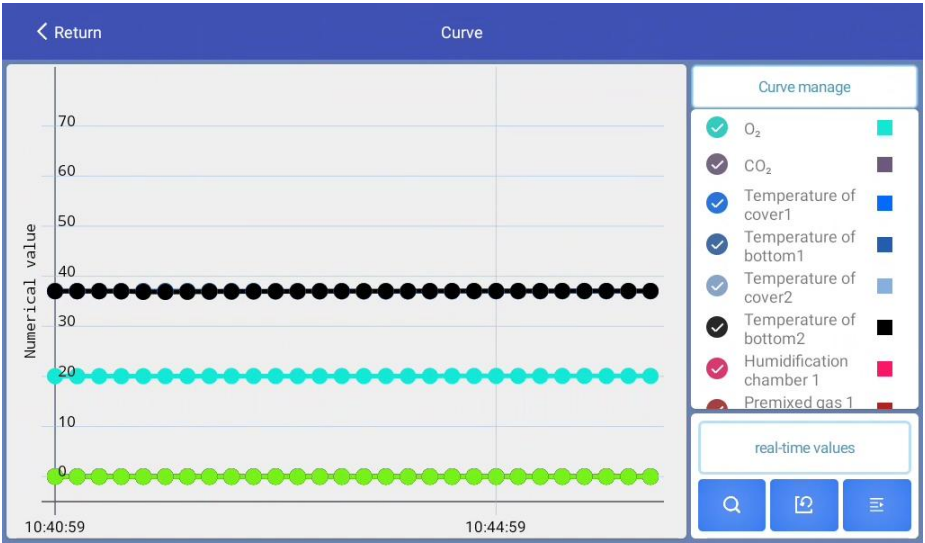


Figure 6.9 Curve manage interface.

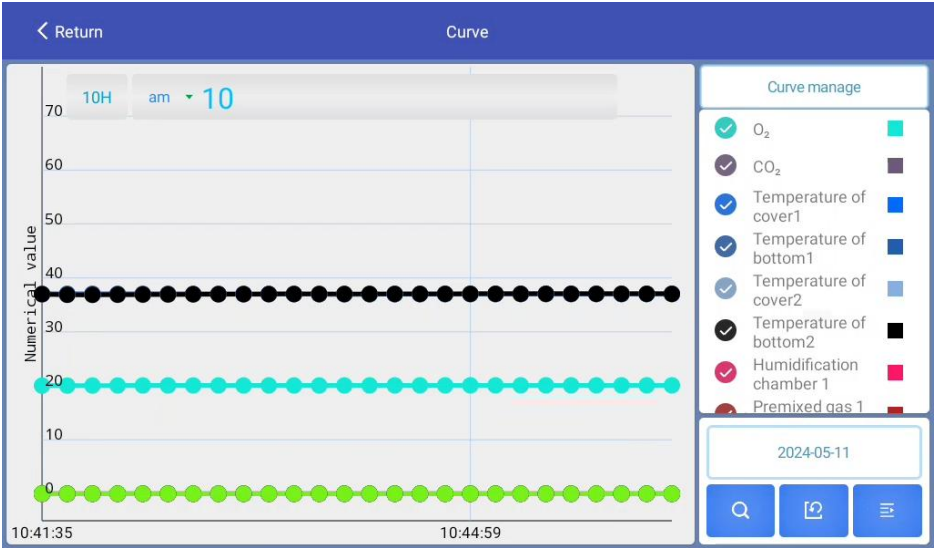


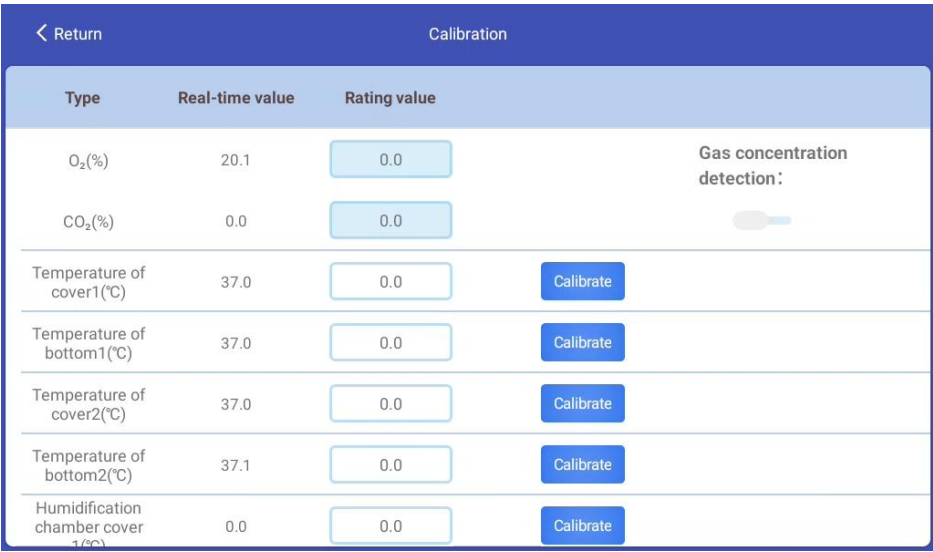
Figure 6.10 History curve manage interface.

6.6 Calibration

When the Benchtop Incubator is used for a period of time, the sensor may produce

small deviations due to natural attenuation, environmental changes, or other reasons. Therefore it requires a third party testing instrument (calibrated) to calibrate. Click the "Calibration" icon in the navigation bar, and the display screen will jump to the calibration interface as shown in Figure 6.11, so that the user can accurately calibrate the corresponding sensor. The Benchtop Incubator provides a single point calibration method for the user to calibrate the oxygen concentration, carbon dioxide concentration, chamber temperature, tube chamber temperature, premixed gas flow. The specific calibration steps are:

1. Use a third-party detection instrument to measure the parameters corresponding to the sensor, and wait until the value is stable.
2. Enter the value displayed by the third-party sensor in Calibration Value in the name row of the sensor parameter.
3. Click "Calibrate". If the real-time value in the Real-time value column changes to the written calibration value, the calibration succeeds.



< Return		Calibration	
Type	Real-time value	Rating value	
O ₂ (%)	20.1	0.0	Gas concentration detection: 
CO ₂ (%)	0.0	0.0	
Temperature of cover1(°C)	37.0	0.0	Calibrate
Temperature of bottom1(°C)	37.0	0.0	Calibrate
Temperature of cover2(°C)	37.0	0.0	Calibrate
Temperature of bottom2(°C)	37.1	0.0	Calibrate
Humidification chamber cover 1(°C)	0.0	0.0	Calibrate

Figure 6.11 Calibration interface

6.7 Log

During daily maintenance and management of the Benchtop Incubator, you can view the operation history of the device in logs. Click "Log" to switch to the log interface. On the log screen, you can scroll up and down to view system changes, the

corresponding time, and operation users. Click  to select the target time period or view the previous system modification information, as shown in Figure 6.12.



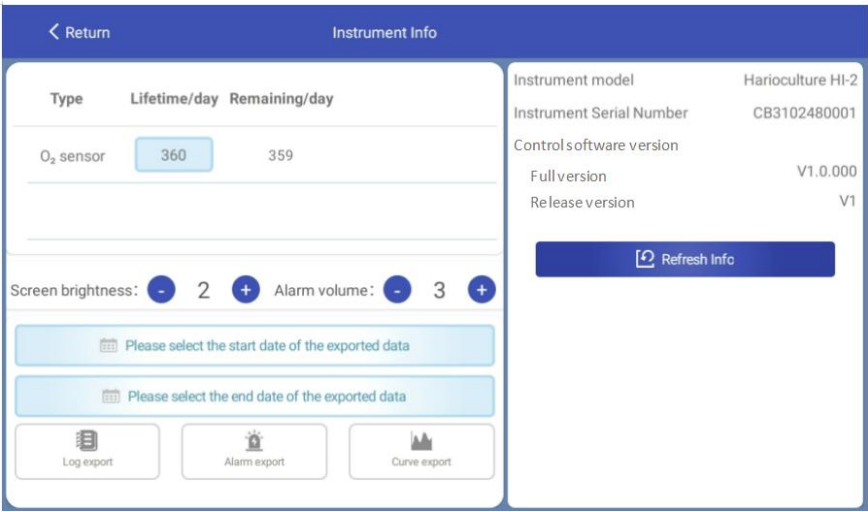
The screenshot shows a mobile application interface for log management. At the top, there is a blue header bar with a '< Return' button on the left and a 'Log' title in the center. Below the header, there is a date selection area with two date pickers, both set to '2024-05-11', and a magnifying glass icon on the right. The main content area is a table with three columns: 'Time', 'User', and 'Content'. The table contains eight rows of log entries, all with the user 'Supervisor'.

Time	User	Content
2024-05-11 10:45:46	Supervisor	Login success
2024-05-11 10:45:26	Supervisor	Exit success
2024-05-11 10:43:42	Supervisor	Chamber1 into the culture dish with, rfid is E0040150BBC05739
2024-05-11 10:43:42	Supervisor	Chamber1 into the culture dish with, rfid is E0040150BBC06994
2024-05-11 10:43:42	Supervisor	Chamber1 into the culture dish with, rfid is E0040150BBC04C52
2024-05-11 10:43:42	Supervisor	Chamber1 into the culture dish with, rfid is E0040150BBC05AED
2024-05-11 10:43:41	Supervisor	CloseChamber1

Figure 6.12 Log management interface

6.8 Service

Click the "Service" icon in the navigation bar, and the display screen will jump to the service interface as shown in Figure 6.13. The remaining life of the wearing parts is displayed on the upper left of this interface. In the middle left area, the user can choose whether to indicate the concentration of CO₂ and O₂, adjust the brightness of the screen, and the volume of the speaker. On the lower left, you can export logs, alarms, or curve data for a specific period of time. On the right of the interface, you can view the Instrument model, Instrument serial number, software version number.



The screenshot shows a mobile application interface for service information. At the top, there is a blue header bar with a '< Return' button on the left and an 'Instrument Info' title in the center. The interface is divided into two main sections. The left section contains a table for sensor information, a section for screen brightness and alarm volume controls, and three buttons for exporting data. The right section displays instrument details.

Type	Lifetime/day	Remaining/day
O ₂ sensor	360	359

Screen brightness: - 2 + Alarm volume: - 3 +

Please select the start date of the exported data

Please select the end date of the exported data

Log export Alarm export Curve export

Instrument model	Harioculture HI-2
Instrument Serial Number	CB3102480001
Control software version	
Full version	V1.0.000
Release version	V1

Refresh Info

Figure 6.13 Service interface

In the “Engineering Maintenance” icon in the upper right corner of the interface, users with advanced permissions can also realize the functions shown on the right of Figure 6.14, such as SETTING PARAMS, LANGUAGE SWITCHING, and LOGOUT DURATION.

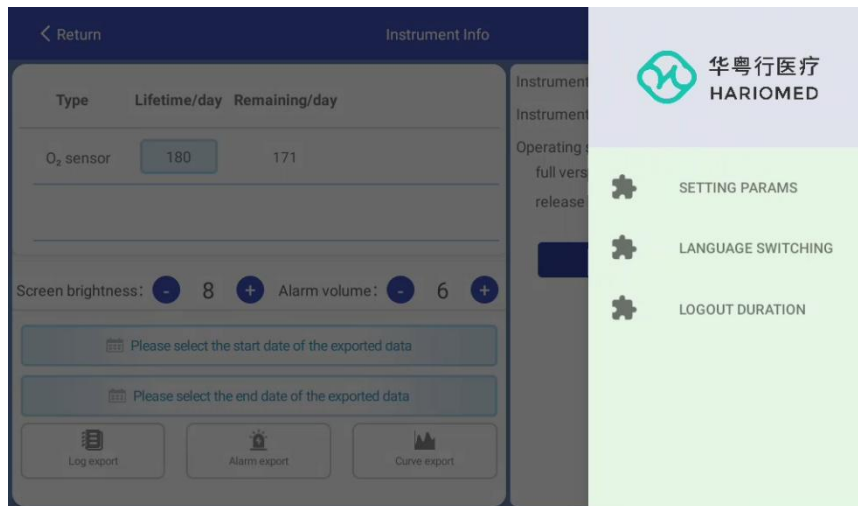


Figure 6.14 System setting interface

6.9 Alarm

When users want to know detailed alarm information, they can click the alarm center in the lower left corner of the main interface to enter the alarm information interface as shown in Figure 6.15. In this interface, you can view all the current alarm according to the Alarm level, including Alarm code, First alarming time, latest alarming time and alarm description. In addition, you can also swipe the screen or click "Alarm History" to view the previous alarm information. When viewing historical alarm information, you can also select a specific date to view it, as shown in Figure 6.16.

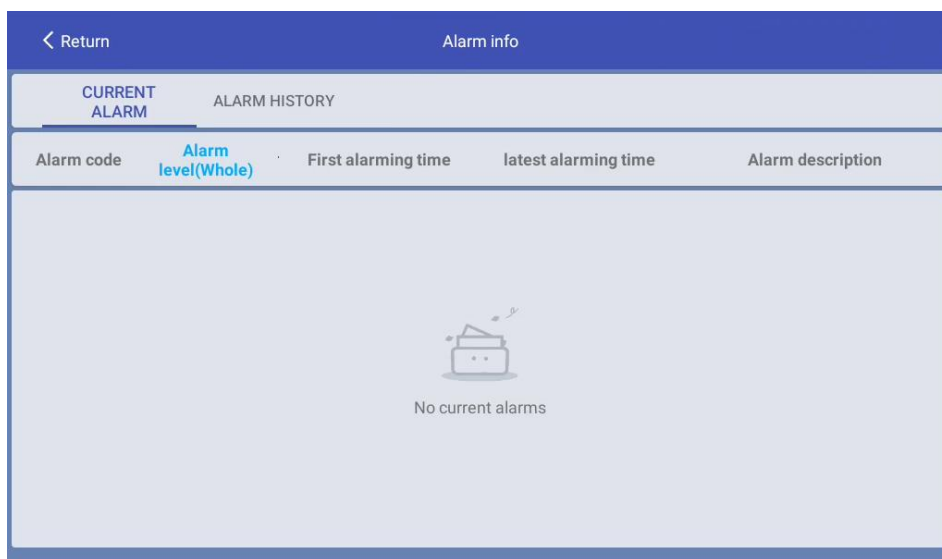


Figure 6.15 Alarm information interface

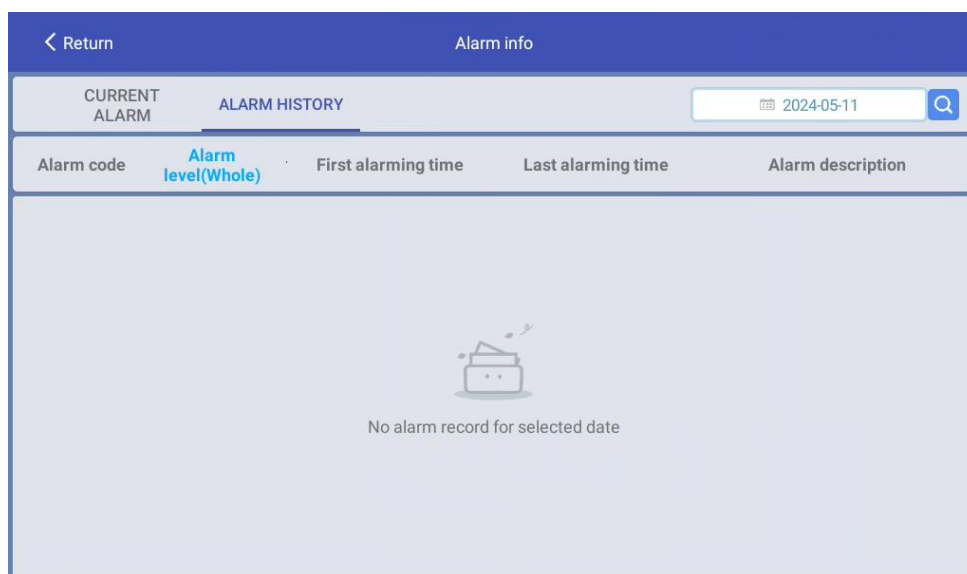


Figure 6.16 Interface of Alarm history information

Table 6-3 Main alarm display table of touch screen

Touch screen alarm	Alarm Description	Solution
Chamber temperature	Chamber temperature exceeds the upper limit	Verify that whether the setpoint has been changed for a short time and that the ambient temperature is between 18°C and 30°C.
Chamber temperature	Chamber temperature exceeds low limit	Verify that whether the setpoint has been changed for a short time or the Benchtop Incubator has just been turned on. Check that

		the ambient temperature is between 18°C and 30°C.
Humidification chamber water level	Humidification chamber water level exceeds the low limit	Check the water level in the humidification chamber. If the water is insufficient, fill the humidification chamber to the Max line
Gas pressure	Gas pressure exceeds the lower limit	Check whether the gas supply is abnormal, whether the gas pressure is near 1bar, and whether the gas tube is blocked or leaking.
Chamber temperature	Chamber temperature exceeds the upper limit	Verify that whether the setpoint has been changed for a short time and that the ambient temperature is between 18°C and 30°C.

NOTICE

If the fault still cannot be rectified and the device cannot work normally, cut off the power supply and contact the manufacturer or authorized representative for repair.
Do not repair the incubator by yourself.

6.10 Power off

1. Make sure all petri dishes are removed from the Benchtop Incubator before shutting down.
2. Turn off all gas sources.
3. Turn off the power switch and unplug the power cord.
4. If the device needs to be moved or transported after powering off. It is recommended to remove all trays in the Benchtop Incubator to avoid damage to the Benchtop Incubator due to friction.

NOTICE

If the fault still cannot be rectified and the device cannot work normally, cut off the power supply and contact the manufacturer or authorized representative for repair.

Do not repair the incubator by yourself.

7 Precautions and warnings

7.1 Precautions

- Read the user manual carefully before using the device. Place the user manual near the Benchtop Incubator.
- Read the user manual carefully before using the device. Place the user manual near the Benchtop Incubator.
- Do not use the device outdoors. If the device is exposed to rain, it may cause electric leakage or electric shock.
- Only qualified engineers and professional maintenance personnel can install the equipment. Unauthorized personnel may cause electric shock or fire.
- The device should be installed on a flat table. When the table is not stable or the site is not suitable for installation, the equipment may turn over and cause injury.
- Do not install the device in humid environment where water may spatter. It may cause the insulation measures of the device cannot achieve the expected effect, which may lead to electric leakage or electric shock.
- Do not install the device in the presence of combustible or volatile substances. It could cause an explosion or a fire.
- Do not install the Benchtop Incubator where there is acid or corrosive gas. This will lead to electric leakage or electric shock due to corrosion.
- Do not insert metal objects such as nails and cables into the holes, gaps, or sockets on the device. May cause electrical shock or accidental injury due to contacting with moving parts.
- To avoid electric shock or injuries, turn off the power supply before repairing or maintaining the equipment.
- Do not touch electrical components or operate switches with wet hands. It could cause an electric shock.
- Do not bind, handle or trample the electric wires. Do not damage or destroy the

power plug. Damaged power cables may cause fire or electric shock

- Do not dismantle, repair or alter the equipment without authorization. Unauthorized operations may cause a failure that could result in fire, electric shock, or injury.
- Unplug the Benchtop Incubator when it is not in use for a long time. If not removed, this power connection may cause electrical shock, leakage, or fire due to aging of the insulation.
- Do not replace the fuse in the power interface without authorization. It should be replaced by a professional. The fuse specifications are T3.15 A and H250V.
- The external power supply must be grounded for protection. Otherwise, the internal components may be damaged if there is instrument failure.
- If hazardous substances leak on the surface of the equipment or into the equipment, appropriate disinfection and cleaning should be carried out.
- Do not use cleaning agents or disinfectants that may cause chemical reactions with equipment components or materials contained in the equipment.
- If there is doubt about the compatibility of disinfectants or cleaning agents with equipment components or materials contained in equipment, consult the manufacturer or authorized representative.

7.2 Warnings

- Do not use the Benchtop Incubator in a manner not mentioned in the manual that may endanger the operator's life and cause equipment failure.
- Do not use Benchtop Incubators when the alarm system is faulty and not repaired.
- After turning off the power switch, check the settings before re-operating after a power failure. Improper settings may result in components damaged.

8 Maintenance and Upkeep

8.1 Device Cleaning

When cleaning the exterior of the Benchtop Incubator, clean and dry all exterior surfaces of the Benchtop Incubator with a lint-free wipe soaked in sterile distilled water. During the wiping process, the lint-free wipe must be wrung out to avoid the liquid entering the device during the wiping process. When cleaning the inside of the Benchtop Incubator, please refer to the following cleaning procedure.

Benchtop Incubator internal cleaning process:

- Remove the petri dish currently being cultured and place it in another Benchtop Incubator.
- Turn off the power supply of the Benchtop Incubator and power off the instrument.
- Open the culture chamber cover and remove the internal petri dish tray, then wipe the surface of the tray with a sterile distilled water-soaked lint-free wipe.
- Clean the interior of the culture chamber and the chamber cover with a lint-free wipe moistened with sterile distilled water.
- Visual inspect the cleanliness of the Benchtop Incubator, if it is visually clean, it can be ready for use. If the visual is still not clean, repeat the above steps to clean again, and leave it for 10 minutes to ensure the surface is completely dry.
- After the cleaning is complete, reconnect the power supply to the Benchtop Incubator to power it on. Before returning the removed petri dishes to the Benchtop Incubator, let the Benchtop Incubator run empty for 1 hour to ensure that the temperature and gas concentration are stable before transferring the culture dishes back.

8.2 Device Disinfection

- When disinfecting the exterior of the Benchtop Incubator, first wipe all external

surfaces with a lint-free wipe soaked in 75% medical alcohol. Then, clean and dry all external surfaces with a lint-free wipe moistened with sterile distilled water. During the wiping process, the wipe must be wrung out to avoid liquids entering the interior of the device. For disinfection of the interior of the Benchtop Incubator, please follow the disinfection procedure below.

- Remove the petri dish currently being cultivated and place it in another Benchtop Incubator.
- Turn off the Benchtop Incubator power and power off the device.
- Open the culture chamber cover and remove the internal petri dish tray. Wipe the surface of the tray with a lint-free wipe soaked in 75% medical alcohol, then wipe again with a lint-free wipe moistened with sterile distilled water and let it air dry.
- Clean the interior and chamber cover with a lint-free wipe soaked in 75% medical alcohol, ensuring that each chamber is properly disinfected. Then, wipe the aforementioned areas with a lint-free wipe moistened with sterile distilled water.
- Visual inspect the cleanliness of the Benchtop Incubator, if it is visually clean, it can be ready for use. If the visual is still not clean, repeat the above steps to clean again, and leave it for 10 minutes to ensure the surface is completely dry.
- After cleaning is complete, connect the Benchtop Incubator to the power supply and switch on the device. Before returning the removed petri dishes to the Benchtop Incubator, let the Benchtop Incubator run empty for 1 hour to ensure that the temperature and gas concentration are stable before transferring them back into the Benchtop Incubator.

8.3 Device Maintenance

Replacement cycle and method of accessories, inspection methods:

- Gas filter: Replaced every 3 months.
- O₂ sensor: Every 1 year. Authorized engineers are recommended to handle it.
- See Section 2.3 for replacement method.
- After replacement, relevant calibration should be carried out according to Section

6.6. After running for a period of time, observe whether the adjustment of gas concentration on the instrument has been stabilized.

8.4 Device Unkeep

- It's necessary to contact the manufacturer or agent for maintenance inspection once a year. Check the function modules inside the instrument, calibrate the internal sensors, and verify the internal protection device and system to ensure the normal operation of the equipment.
- When the device is being repaired, maintained or out of use, the device needs to be emptied. Remove all the petri dishes being cultured in the Benchtop Incubator and take out the uniform temperature plates in the culture chambers. Perform external cleaning and disinfection on the inside of the culture chambers and the uniform temperature plates. The cleaning and disinfection methods are carried out as described above Section 8.1 and 8.2.

8.5 Service Life

The production date of the equipment can be found on the product label. Its service life is 10 years. In the course of use, the user shall carry out maintenance, maintenance and repair in accordance with the requirements of this manual. After maintenance, maintenance or repair, it is determined that the basic safety and effectiveness of the product can be maintained, can be used normally.

9 Storage, Transport and Disposal

9.1 Storage

The Benchtop Incubator should be stored in a warehouse where the relative humidity does not exceed 80%, the temperature is below 40 °C, the ventilation is good, and there is no acid, alkali and other corrosive gases.

The storage period of Benchtop Incubator shall not exceed one year. The incubator that exceeds the storage period shall be inspected during unpacking. Only the incubator that passes the inspection can be circulated and used.

9.2 Transportation

During transportation, the Benchtop Incubator shall be prevented from direct exposure of rain and snow, sun and strong vibration, and shall not roll or fall. The transportation shall be careful. Normal land, sea and air vehicles can be used for transportation in accordance with the contract.

9.3 Disposal

In order to minimize the waste of electrical and electronic equipment, please do not discard the Incubator and accessories at will. Waste must be disposed in accordance with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) as amended by Directive (EU) 2018/849. The disposal of waste and residues should be in accordance with relevant national laws and regulations. The user is responsible for disposal with observation of the local requirements.



Because the waste of electrical and electronic equipment vary from country to country. The user is responsible for disposal with observation of the local requirements.

10 EMC Requirements

10.1 Electromagnetic Emissions

Table 10.1 Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Benchtop Incubator is intended for use in the electromagnetic environment specified below. The user of the Benchtop Incubator should assure that it is used in such an environment.		
Emissions tests	Compliance	Electromagnetic environment--guidance
RF emissions CISPR 11	Group 1	The Benchtop Incubator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Benchtop Incubator is suitable for use in all establishments, including non-domestic establishments and those not directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuation (flicker emission) IEC 61000-3-3	Not applicable	

10.2 Electromagnetic Immunity

Table 10.2 Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity				
The Benchtop Incubator is intended for use in the electromagnetic environment specified below. The user of the Benchtop Incubator should assure that it is used in such an environment.				
Port	Phenomenon	Basic standard	Test value	Performance criterion
ENCLOSURE	ESD	IEC 61000-4-2	±4 kV contact discharge ±8 kV air discharge	B B
	Electromagnetic field	IEC 61000-4-3	10V/m (80 MHz to 1 GHz) 3V/m (1,4 GHz to 6 GHz) ^a	A A
	Power frequency magnetic field ^b	IEC 61000-4-8	30 A/m (50 Hz, 60 Hz)	A
AC power (including protective earth)	Burst	IEC 61000-4-4	±2 kV (5 kHz or 1 00 kHz)	B
	Surge	IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground	B B

	Conducted RF	IEC 61000-4-6	3 V(1 50 kHz to 80 MHz), see NOTE	A
	Voltage dip	IEC 61000-4-11	0 % during 1 cycle 40 % during 1 0/1 2 cycles ^c 70 % during 25/30 cycles ^c	B C C
	Short interruptions	IEC 61000-4-11	0 % during 250/300 cycles ^c	C
DC power ^{d, e} (including protective earth)	Burst	IEC 61000-4-4	±2 kV (5 kHz or 1 00 kHz)	B
	Surge	IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground	B B
	Conducted RF	IEC 61000-4-6	3 V(150 kHz to 80 MHz) see NOTE	A
I/O signal/control ^e (including functional earth)	Burst ^d	IEC 61000-4-4	±1 kV (5 kHz or 1 00 kHz)	B
	Surge ^f	IEC 61000-4-5	±1 kV line-to-ground	B
	Conducted RF ^d	IEC 61000-4-6	3 V (1 50 kHz to 80 MHz) see NOTE	A
I/O signal/control ^e (connected directly to mains supply)	Burst ^d	IEC 61000-4-4	±2 kV (5 kHz or 1 00 kHz)	B
	Surge ^f	IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground	B B
	Conducted RF ^d	IEC 61000-4-6	3 V(150 kHz to 80 MHz) see NOTE	A
NOTE Equipment considered in this table is typically used in industrial installations with the cabling arranged on metallic structures. This reduces coupling of electromagnetic fields into cables and hence justifies a lower immunity level compared to that given in the generic immunity standard IEC 61 000-6-2. The level of 3 V is used for more than 1 5 years without immunity issues and hence proved to be sufficient.				
a In case testing is performed also in the frequency range from 1 GHz to 1 ,4 GHz, the same test level as above 1 ,4 GHz is recommended. b Only to magnetically sensitive equipment. c For example, “25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test”. d Only in the case of lines > 3 m. e DC power PORTS intended to be connected to a low voltage DC supply (≤ 60 V), where secondary circuits (isolated from the AC mains supply) are not subject to transient overvoltages (i.e. reliably-grounded, capacitively-filtered DC secondary circuits) shall be regarded as I/O signal/control PORTS . f Only in the case of LONG - DISTANCE LINES				

11 Listing of Accessories and package

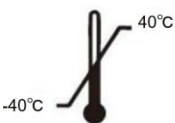
To ensure that you receive all the products you ordered, please check the contents of the packing boxes according to the Package list below. If something is missing or damaged, please contact the supplier immediately.

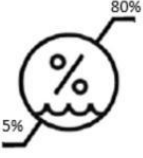
Name	Number	Name	Number
φ6mm air tube 3m	1	Quick connect male coupling	2
Cord Set	1	Petri dish tray	4
Humination box	2	Gas filter	2
6 to 8 quick connect coupling	1	Alarm cable	1
User Manual	1	Qualification certificate	1
Auxiliary material			
Hoop	3	Nylon ties	10
T shaped pagoda connector D8	1	Drying agent	5

12 Conform to Standard

Item	Standards
EMC requirements	■ IEC 61326-1:2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements ■ EN IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
Safety requirements	■ ANSI UL 61010-1:2012 Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements ■ IEC 61010-1:2010+AMD1:2016 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements ■ EN 61010-1:2010 + A1:2019 + AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements ■ ■ IEC 61010-2-010:2019 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials ■ EN IEC 61010-2-010:2020 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials

13 Symbol glossary

Symbol	Description
	Manufacturer Indicates the medical device manufacturer.
	Date of manufacture Indicates the date when the medical device was manufactured.
	Fragile, handle with care: Indicates a medical device that can be broken or damaged if not handled Carefully.
	This way up: To indicate correct upright position of the transport package.
	Keep dry: Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight: Indicates a medical device that needs protection from light sources
	Do not roll: Transport package shall not be rolled or turned over but shall remain in the upright position.
	Warning: Warns that non-professionals do not open.
	Biological risks: Indicates that there are potential biological risks associated with the medical device
	Temperature limit Minimum:-40°C ;Maximum:40°C Indicates the temperature limits to which the medical device can be safely exposed.

	Humidity limitation: Minimum:5% Maximum:80% Indicates the range of humidity to which the medical device can be safely exposed
	Caution when discarded: See section 9.3
	Medical device: Indicates the range of humidity to which the medical device can be safely exposed
	Serial number: Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Unique device identifier: Indicates a carrier that contains unique device identifier information (Applicable in countries with UDI requirements)
	Prescription Use: Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician

14 Manufacturer Information



Hua Yue Medical Technology Co., Ltd.

First Floor, C2 building, No.11 Kaiyuan Road, Huangpu District,

Guangzhou City, Guangdong

Province, 510530, P.R. China

Tel: +86-020-34821111

Fax: +86-020-34820098

【User Manual Information】

Issue date:

【Version】 : A-01