

SHINVA 新华医疗

Autoclave
(MOST-MK)
User manual

山东新华医疗器械股份有限公司
SHINVA MEDICAL INSTRUMENT CO.,LTD.



Please read the contents of this manual before

Before using the equipment for the first time, the user should read through this manual to familiarise himself with the operation of the equipment and its safety instructions.

Keep the instruction manual intact for the life of the equipment.

Make sure that all updates received can be saved in the instruction manual.

In the event of a change of site or organisation where the equipment is used, it must be ensured that the instruction manual is transferred or handed over as part of the equipment as a whole.

Safety Notes

This machine is equipped with a number of necessary safety guards.

In order to avoid injury, it is strictly forbidden to terminate or break these safety devices.

Notes

Please read this manual carefully before use.

This machine must be operated by authorised personnel. The operator must receive relevant training.

As this machine uses steam, please take the necessary anti-scald measures before use.

For proper operation, keep the machine clean.

Do not rinse or pour water over the machine.

Installation and maintenance work must be carried out by trained personnel.

In the event of leakage from the machine due to worn door seals, etc., be sure to have it repaired immediately.

Machine related accessories can only be obtained from New China Medical, otherwise the normal operation of the equipment cannot be guaranteed.

To ensure that operators receive sufficient training to use the equipment safely, all personnel regarding the operation and maintenance

of the equipment need to undergo regular training, training records and proof of understanding of the training content should be kept.

Disconnect switch

The machine must be equipped with a lockable power switch. The switch must be easily accessible on a wall near the machine. It must be installed and marked in accordance with local codes.

Urgent situation

Close the main power switch.

Close the steam supply line shut-off valve (if have).

Close the supply line shut-off valve.

Product Liability

Do not modify the equipment or operate it improperly without the permission of New China Medical, and New China Medical will not be responsible for any damages caused as a result.

Warning symbol

The CAUTION, WARNING and DANGER symbols in this instruction manual require special attention.

1. Preface

This manual applies to the installation, operation and maintenance of the Xinhua MOST-MK steam steriliser.

Please read this manual carefully before use to ensure that this equipment serves you safely and reliably! This manual does not specifically indicate the actual configuration of the product, please refer to the product you purchased and the accompanying packing list.

The relevant standards and product information that our steam sterilisers follow are listed below:

(A) medical device registration certificate number: Lu Meizhi quasi 20162110226

(B) Product Technical Requirements No.: Lu Meizhiquan 20162110226

(C) Executive standard number:

Product standard number: Q/0303SXH193

Pressure vessel standard number: GB/T 150.1 ~ 150.4-2011

(D) Structure and composition: by the main body of the steriliser, sealing door, piping system, control system.

(E) Product performance: for different types of sterilizers according to 3.14 of the specified method of testing, according to the provisions of the bio-indicator manufacturer of culture, sterilization cycle should ensure that the exposed bio-indicator is no longer biologically active. Untreated bioindicators shall be biologically active when incubated under the same conditions.

Note: "3.14" in (E) above is clause 3.14 of the technical requirements for steam sterilisers.

- 1.1. (A) product application (use) scope: for medical and health care, scientific research and other units for medical devices, laboratory equipment, culture media and non-enclosed liquids or preparations, and blood or body fluids may come into contact with the material of the Sterilization.
- 1.2. (B) product contraindications: no
- 1.3. (C) The main bactericidal factor and its intensity:
- 1.4. Main sterilising factor: moist hot steam.
- 1.5. The intensity of the main bactericidal factor: 121 °C Sterilization, Sterilization time \geq 20min; 134 °C Sterilization, Sterilization time \geq 4min;
- 1.6. (D) Sterilization principle (mechanism of action):
- 1.7. This equipment adopts a specific process to discharge the cold air inside the steriliser room, with saturated hot and humid steam as the sterilising factor, under the environment of high temperature, high pressure and high humidity, and under the combined effect of a certain temperature and time, it realises the Sterilization of the items that can be penetrated by the steam.
- 1.8. (E) Kill microorganisms category: kill bacteria and spores.
- 1.9. (VI) Special storage and transport conditions and methods: none
- 1.10. (VII) Packaging and transport: in line with GB/T 191-2008
- 1.11. (viii) Production date: see the nameplate of the equipment
- 1.12. (ix) Use term/life: 8 years/16000 cycles

Safety taboos

Particular attention should be paid to the notes, warnings and dangers in these instructions.



注意

Indicates a potential hazard to the equipment and should be given high priority.



警告

Indicates potential harm to personnel and must be strictly adhered to.



危险

Indicates damage to equipment or persons and must be strictly adhered to.



警告

Replacement and maintenance of spare parts should be carried out by Xinhua after-sales service unit, our company is not responsible for any equipment, environment and personal damage caused by private replacement of spare parts.



警告

This steriliser is only suitable for sterilising medical instruments and articles that are resistant to high temperatures and humidity, and cannot be used for sterilising oils and powders such as petroleum jelly!



危险

It is strictly prohibited to use this equipment for Sterilization of liquids encapsulated in glass bottles or glassware, because the operation or changes in temperature and pressure may cause the liquid bottles to burst, endangering the safety of persons and equipment.



注意

Before performing any operation, maintenance, or servicing of the equipment, please read and fully understand the contents of each section of the instruction manual, especially those marked with the above symbols that should be noted. Failure to use the equipment in the manner prescribed by us may impair the protection provided by the equipment.

The instruction manual must be kept in a safe place to prevent loss or damage, even minor breakages should be avoided. The operator is obliged to repair and complete any parts of the instruction manual that are lost, damaged or no longer applicable. No one, under any circumstances, may tear off or remove anything from the instruction

manual. In the event of any discrepancy with the instructions in the instruction manual or in cases not covered by the instruction manual, please contact the manufacturer for upgrading or updating.



注意

The storage place of the instruction manual should be ventilated and dry, avoiding humidity and high temperature.



警告

This equipment is not suitable for sterilising liquids in tightly sealed bottles. If you want to sterilise the above liquids, please contact us and we will select a special steriliser for you.



警告

Sterilization of tightly sealed bottles of liquid with this equipment, easy due to operator negligence or violation of operating procedures occurred in the bottle explosion accident, a serious threat to the safety of people and equipment.



注意

Chlorine ions are an important factor in the corrosion of stainless steel. Sterilisers are prohibited from sterilising items containing chlorine ions to avoid corrosion of internal stainless steel caused by deposited chlorine ions and to prolong the service life of the equipment.



注意

Whenever this symbols are seen anywhere on the equipment, it is necessary to consult the relevant documentation, such as instruction manuals, in order to ascertain the nature of the potential hazard and any countermeasures that must be taken.



注意



See symbols anywhere on the device, Indicates that the temperature around it is high, please take care to avoid burns.



- 1) The product use unit should be in use in the process of routine maintenance of equipment, and regular self-inspection.
- 2) The product should be used in the product at least once a month to carry out self-inspection, and make a record. The use of the product in use in the unit of self-inspection and routine maintenance of abnormalities found, should be dealt with in a timely manner.
- 3) The product should be used in the product safety accessories (safety valves, pressure gauges, etc.), safety protection devices, measurement and control devices and related ancillary instrumentation for regular calibration, overhaul, and make records.
- 4) the product operators and their related management personnel, should be in accordance with relevant state regulations by the special equipment safety supervision and management department qualified to obtain a national special operator certificate before engaging in the corresponding operations or management.
- 5) The use of units should be operating personnel for special equipment safety, energy conservation education and training to ensure that special equipment operators have the necessary knowledge of special equipment safety, energy conservation. The product operators in the operation should strictly implement the operating procedures of special equipment and related safety regulations.



- 1) This equipment meets the emission and immunity requirements specified in GB/T 18268.
- 2) This equipment is designed and tested according to Class A equipment in GB 4824. In a home environment, this equipment may cause radio interference and requires protective measures.
- 3) It is recommended to evaluate the electromagnetic environment before using the equipment. It is prohibited to use this equipment next to a strong radiation source (e.g.

unshielded RF source), otherwise it may interfere with the normal operation of the equipment.



Products in the correct use of the process of accidents, equipment for the alarm prompts or other faults, please immediately cut off the power supply of the equipment, and against the instruction manual "alarm code and measures to deal with" part of the fault rectification, such as failure to solve the problem, please contact the manufacturer.



Before running the Sterilization procedure in the equipment, the necessary monitoring is carried out in accordance with national and regional regulations. Put the monitoring substances (e.g. biological or chemical indicators) into the equipment, run the corresponding procedure to monitor the Sterilization effect, and evaluate according to the results. If the pass passes, it can be used normally, if not, find the reason or contact the manufacturer.



When the equipment reaches the use term or needs to be scrapped, please recycle according to the relevant local waste product recycling methods, the battery in the control system needs special attention in the recycling process, it should not be thrown away arbitrarily, and it should be put into the special recycling box set by the relevant organisations.




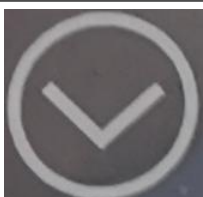



In the normal operation of the steriliser, the noise is measured with a sound level meter at 1m away from the steriliser and 1m above the ground, in four directions: left, right, front and back, and the noise is not greater than 70dB (A weighting). The sound pressure level generated by the equipment does not reach the threshold value of sound pressure level that may cause harm, and the operator does not need to take protective measures against sound pressure during normal use.

1.13. Equipment labelling instructions





1.13.1. Equipment labelling











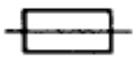
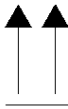
1-1 List of device key labels

序号	图标	作用	备注
1		return key	
2		Confirm key	
3		door opener	
4		down arrow key (on keyboard)	
5		up arrow key (on keyboard)	

Label: The specific definitions of the safety signs applied in the equipment are as follows:

1-2 List of safety signs

			
Switch on (power supply) IEC 417, No. 5007	Off (power supply) IEC 417, No. 5008	Grounding (ground) IEC 417, No. 5017	Protective earthing (ground) IEC 417, No. 5019

			
Direct Current IEC 417, No. 5031	Alternating current IEC 417, No. 5032	Note reference to accompanying information ISO 3864, No. B.3.1	Protection against electric shocks ISO 3864, No. B.3.6
			
Protect the surface from overheating IEC 417, No. 5041	Reference to the instructions for use YY0466, No. 3.3	Keep dry YY0466, No. 3.8	Temperature limitation YY0466, No. 3.11
			
Avoid sunlight YY0466, No. 3.6	Caution against high voltage IEC 417, No. 5036	Fuses IEC 417, No. 5016	Placement upwards GB/T171 No.3
security symbol			

Equipment Parameters

1-3 Equipment Parameter List

Equipment Model	Volume	Chamber Size/mm (Available)	Power supply	Input wattage /kVA
MOST-MK	24L	Φ 245*450	AC 220V 50 Hz	1.8

Design pressure: -0.1/0.30MPa

Design temperature: 144℃

Vacuum lower limit: -0.08MPa (B type)

Temperature selection range: 105~138℃

Temperature display accuracy: 0.1℃

Pressure display accuracy: 1kPa

For details of specific equipment types, see the nameplate of the equipment.

Installation

Installation of sterilisers is generally carried out by Xinhua Medical's after-sales service personnel. After-sales service personnel are trained in the installation, operation and maintenance of Xinhua Medical sterilisers. These installation details are part of the technical confidentiality and will not be repeated here. If the user wants to do the installation by himself, he can contact the sales staff of our local office and accept the guidance and supervision of Xinhua Medical during the installation, in order to ensure the quality assurance of the equipment during the warranty period.



The installation of the equipment must comply with the requirements of the relevant fire regulations.

1.14. Installation Requirements

1.14.1. Energy Needs

1.14.1.1. Water Requirements

The equipment itself comes with a water tank, no need to connect the water source, only need to manually add water to the equipment tank. The water used for the equipment must be pure water, and the water quality meets the following requirements:

- a) Conductivity: $\leq 15 \mu\text{s/cm}$ (room temperature)
- b) Bleach content: $\leq 2\text{mg / L}$
- c) PH value: 5-7
- d) Hardness: $\leq 0.02\text{mmol/L}$

The water tank is filled at least above the low water level line and at the same time below the high water level.

Order number for the J-type equipment requires external water source, pure water source requirements and water tank water quality requirements are the same, the cycle of external water source requirements are as follows:

Pressurised water source requirements are as follows:

Water static pressure: $\geq 0.3\text{MPa}$

Water pipe diameter: $\geq \text{DN}20$



If there is a poor water quality tip after adding water in the tank, it means that the water quality is not qualified for use, please replace the water quality to meet the requirements of the water source.

1.14.1.2. Power Requirements

Equipment power supply:

After placing, check whether the power supply meets the requirements: AC 220V 50Hz single-phase power supply, fluctuation range $\pm 10\%$, power supply power $\geq 1.8\text{kVA}$. 10A plug will be inserted directly into the matching socket when the equipment is energised.

It is recommended that a special wiring device (e.g. socket or circuit breaker) suitable for wiring be installed at a height of 1 metre on the building near the equipment. Do not place the appliance in a place where it is difficult to disconnect the power supply to ensure that it can be disconnected in case of emergency. For equipment with a power plug, make sure that the fixed socket is of the same size as the power plug of the power cord.



When installing the equipment, please install an earth leakage protection device to prevent safety problems caused by damaged parts.

1.15. Safety Instructions

When installing this equipment, you must carefully read the safety precautions in the "Safety Precautions" section of the "Preface".

1.15.1. Equipment Transport

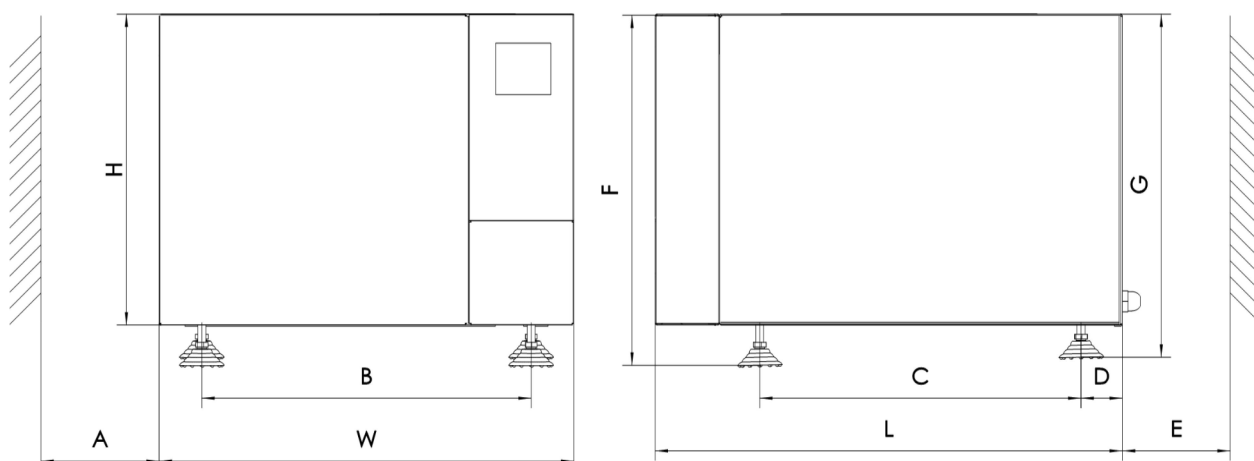
Dimensions and weight

Before the installation of the equipment, the installation process, should be under the guidance of

professionals by the professional construction personnel is responsible for recording the name and model of the equipment in order to our company for technical advice. Installation space requirements and equipment dimensions are as follows (the following equipment size chart is for reference only, specific in kind shall prevail):



Do not install the equipment in a location where it is difficult to operate the equipment or the power switch. When installing the equipment, the ground weighing requirement is that the ground should be able to withstand 120% of the total weight of the equipment.



2-1 Equipment external dimensions and installation distance diagram

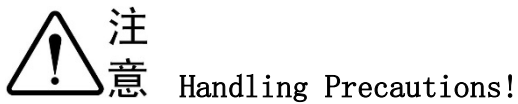
Item	Data
Volume	24L
Order Code	MK24
L(mm)	660
W(mm)	530
H(mm)	475
A(mm)	500
B(mm)	410
C(mm)	478
D(mm)	50
E(mm)	500

F(mm)	455-465
G(mm)	425
Total weight(Kg)	65
Chamber weight (kg)	7

1. 15. 2. Unpack

1) Packaging disassembly

Open the top packaging cover of the device, and then remove the outer packaging of the device in turn, and then remove the device from the packaging box, and finally remove the plastic film can be.

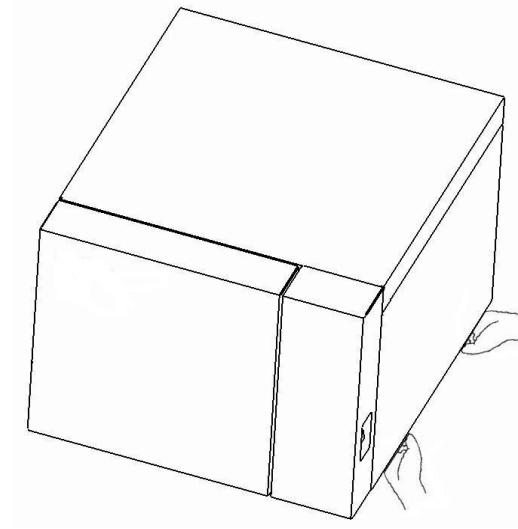
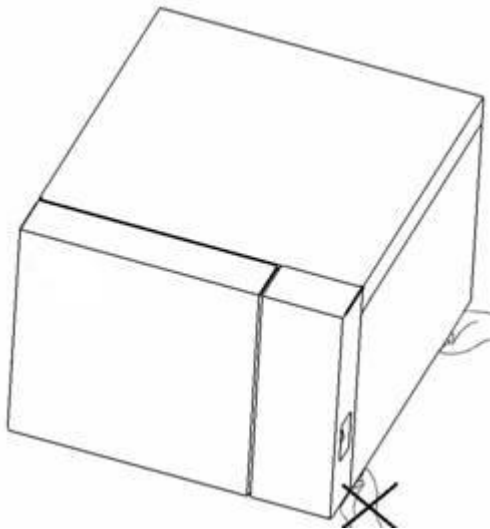


Lifting of doors is prohibited when handling equipment

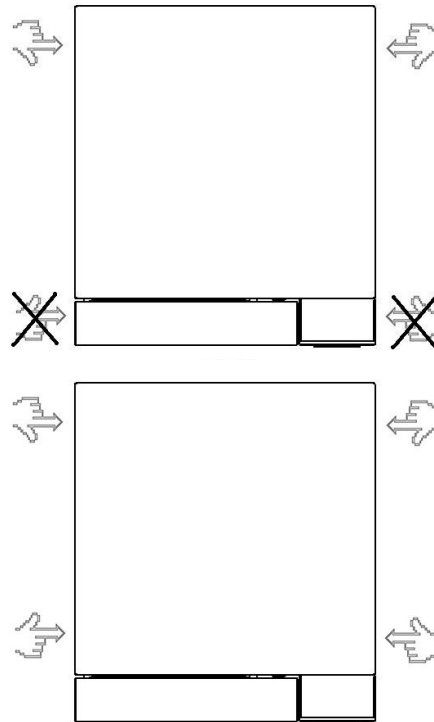
It is prohibited to lift the legs of the equipment when handling it.

It is prohibited to place the equipment on its side or upside down when handling the equipment.

The following is a diagram of the handling positions when handling



equipment:



2-2 Careful handling diagram

1) Equipment Inspection

- After the equipment is unpacked, first check whether the model number and name on the product nameplate match the order form. (The product nameplate is generally on the rear cover of the equipment)
- According to the detailed packing list of the equipment, carefully check whether the parts of the equipment are intact, whether there is any damage or loss, if so, you need to make a record and get in touch with our company in time.
- Carefully check whether each connection or fixed parts are loose due to long-distance transport, and tighten them if any.
- Inventory, record the equipment randomly carried accessories, the supporting relevant documents for safekeeping.

Do not tear off the protective film of the equipment before commissioning.

Storage environment

After the steriliser is boxed, it should be stored in a dry, ventilated room without corrosive gases or in a sheltered place

Normal operating condition

The equipment is required to be installed in a clean, dry, light-proof, smoothly ventilated environment with a small temperature difference.

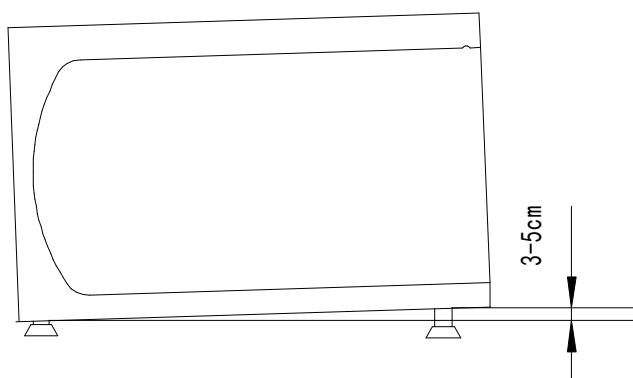
- Ambient temperature 5°C---40°C
- Relative humidity not more than 85%
- Atmospheric pressure 70kPa ---- 106kPa



Note: When the equipment is used in an environment where the temperature is lower than the normal working conditions, or there is a possibility of icing, it should be noted that after the use of the equipment, all the water in the tank should be discharged and the water stored in the pipelines of the equipment should be blown out with compressed air to ensure that there is no water stored in the equipment. This situation generally occurs in the winter equipment in the outdoor handling, or in the winter night equipment in the environment below 0 °C, equipment, if there is water, icing may damage the pipeline. In winter, you can turn on the preheating mode of the equipment, and preheat it before use.

1. 15. 3. Place and levelling

When the equipment is installed, it can be placed on a horizontal table, and then the front and rear height of the equipment should be adjusted according to the requirements of the following diagram to prevent the equipment from retaining too much water (the equipment drainage and vapour discharge ports are at the rear end).



2-3 Equipment in place levelling plan

Electrical installations

1. 15. 4 Cable connections

A cable is supplied with the unit for connection between the unit and the user's junction box. The

electrical installation must be operated by specialised personnel on site, see section "Power Requirements" for external wiring current-carrying conditions. In order to ensure the safety of persons and equipment, an earth wire must be laid, and the earth wire in the equipment casing and control cable must be reliably connected to the external ground.

Translated with DeepL.com (free version)



The equipment must be reliably earthed!

1.15.5 Phase sequence checking For single-phase electrical equipment power supply for the fire wire, zero wire, ground, with a plug equipment power cord into the socket that matches, without a plug power cord red for the fire wire, blue for the zero wire, yellow / green wire for the ground.

1.15.6 Power-on commissioning

The commissioning of the equipment is usually carried out by the manufacturer's after-sales service personnel.



Turn the power on before the unit opens the door! For specific operation of opening and closing the door see Opening and Closing the Door Operation.

1) After the energy conditions, pipework installation and electrical installation are complete, switch on and check that the water and electricity supply to the equipment is normal;

2) Switch on the power switch of the equipment and feed power to the equipment.

3) Check each control element. Enter the manual operation interface and click each valve and pump button one by one to confirm that the pump is running correctly and each valve can be opened normally;

4) Check the switching door. Click on the switching door button to confirm that the sealing door can run smoothly without abnormal noise.

5) Check the printer (if any), the printer self-test is normal and the print is clear;

1.16 Commissioning equipment

1.16.1 Water filling operation

1) Prepare pure water and a container for water to easily fill the tank.

2) Be careful not to let the water splash outside the water tank.

3) Add pure water to the water tank, add water to reach the position between the lowest water level line and the high water level line, cover the water tank lid (if any) to prevent some debris from falling into the water tank.



The water used in the equipment must be pure water, add water at least above the low water mark, to the high water level when about 4L of water.

Warm tips: equipment in continuous uninterrupted operation after 4 pots, the temperature in the water tank will rise, if the equipment at this time the pumping performance has decreased, it is recommended to replace the water in the water tank.



If there is a "poor tank water quality" screen prompt during the first operation of the equipment, it means that the water quality of the tank does not meet the requirements and the tank water needs to be replaced.



If there is no water in the water tank of the equipment but there is no hint of water shortage alarm, please contact our engineers and technicians to deal with the problem.



When the water level is lower than the low water level line (Min), you need to manually add pure water, when the water level is higher than the low water level there will be a buzzer beep, continue to add water to ensure that the water level is in the high and low water level between. When the water level is higher than the high water level (Max) will affect the pumping performance of the device, and easy to splash water outside the tank!

1.16.2 Atmospheric pressure setting

For the first commissioning of the equipment installation, it is necessary to set the atmospheric pressure value, otherwise the door will not open. Set the value of atmospheric pressure according to the method of atmospheric pressure setting in Chapter 8 "Administrator's Manual" - "Common

Functions of Control System" - "Atmospheric Pressure Setting" of this manual. Set the atmospheric pressure value according to the method in Chapter 8 "Administrator's Manual" - "Common Functions of the Control System" - "Atmospheric Pressure Setting".

1.16.3 Preheat mode setting

Equipment installation for the first time, you can turn on the preheating mode (not mandatory), open the preheating mode after part of the heating element standby heating can be appropriate to shorten the running time of the programme. According to the manual in Chapter 8 "Administrator's Manual" - "Control System Common Functions" - "Preheat Mode Setting" in the method to set the preheat mode. Set the preheat mode as described in Chapter 8 of this manual.

1.16.4 Safety Valve and Instrumentation Calibration

The safety valves and pressure gauges should be calibrated according to local policies and regulations before the equipment is put into operation.

During the normal use cycle, safety valves and pressure gauges should be calibrated regularly according to local regulations.

1.16.5 Other Tests

The choice of whether or not to perform a leak test is based on the type of equipment and is not necessary if the equipment does not have pulsating vacuum capability. The leak test is performed to check the sealing integrity of the tubes connecting the device to the inner chamber to ensure that there is no air in the cold air removal phase of the steriliser. Run the leak test programme that comes with the equipment and the results will be shown in the printout when the test is completed. The leakage rate should not exceed 0.13kPa/min.

Choose whether or not to perform the B-D test according to the type of equipment and relevant policies and regulations. Small pressure steam sterilizer generally do not have to carry out B-D test, such as B-D test, can be carried out in accordance with the following method: in the unloaded conditions, the B-D test object will be placed in the sterilizer in front of the bottom, near the cabinet door and the exhaust port, there is no object in the cabinet in addition to the test object, after the B-D test

cycle, take out the B-D test paper to observe the colour change. B-D test paper uniform uniformly (completely homogeneous) discoloration, then it is qualified; B-D test paper should be printed on the printout. B-D test paper uniform (completely uniform) discolouration, is qualified; B-D test paper discolouration is not uniform, is unqualified, should check the B-D test failure reasons, until the B-D test passed, the sterilizer can be used again.



The BD test is not a test of Sterilization effectiveness, but a functional test of the steriliser. It is not a substitute for routine monitoring of the Sterilization process.

1.16.7 Biological monitoring

Biological monitoring is used to test the Sterilization process and Sterilization effectiveness of Sterilization equipment.

Biomonitoring should be performed for newly installed equipment and during the normal life cycle of the equipment in accordance with relevant policies and regulations.

Indicator bacteria for bio-verification are thermophilic fatty liver bacteria spores. Biological test substance kits are prepared separately according to different Sterilization loads and are prepared as follows:

- 1) When sterilising unpackaged bare articles, put the bio-indicator into the special paper-plastic bag for pressure steam Sterilization, i.e. the bio-test kit;
- 2) When sterilising packaged articles, select the most difficult to sterilise article packages under the Sterilization procedure, and put the bio-indicator into the centre of the packages, i.e. the bio-test packages;
- 3) When sterilising lumen type articles, select the corresponding lumen type PCD and prepare it as biological PCD, i.e. biological test kit;
- 4) When sterilising special articles, select the corresponding loads according to different load types to prepare biological test kits.

Inactivation of biological verification methods: the middle of each layer of the sterilizer, the exhaust

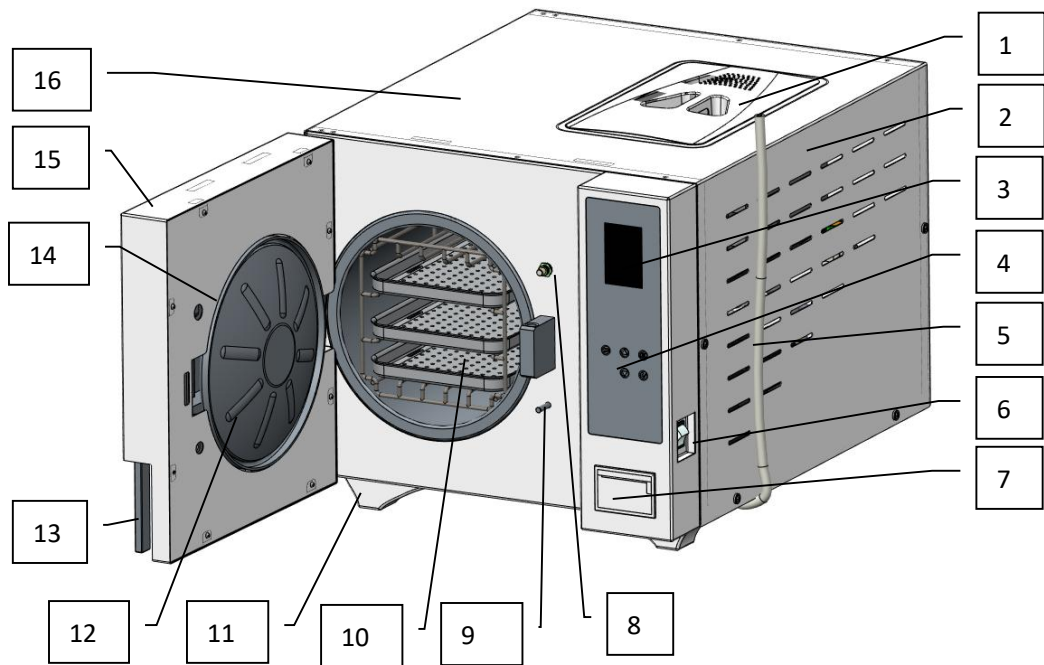
port and near the door of the sterilizer are placed in a biological test kit, put the simulated conventional treatment of goods in the sterilizer to full capacity, after a sterilization cycle, take out the biological indicator in the biological test kit, incubated at $56\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ for 7d (time can also be based on the time specified by the indicator manufacturer incubation), to observe the colour change of the incubation, and at the same time, set up a positive control and negative control; self-contained biological indicator is carried out according to the instructions and set up a positive control. Control and negative control; self-contained bio-indicator according to the instructions, and set up a positive control.

Biological evaluation index: self-contained bio-indicator is evaluated according to the requirements of the product specification. If the colour change of the experimental group, the positive control group and the negative control group meets the requirements of the product specification after being cultured for a specified period of time according to the requirements, the sterilization is qualified, and the opposite is not qualified. After 7d incubation of the slices, if the positive control group turns from purple to yellow, and the experimental group and the negative control group do not change the colour, then the sterilization is qualified; otherwise, it is unqualified.

1.16.8 Delivery and use

After the installation of the equipment to complete the relevant performance tests and qualified, the equipment can be delivered to the user.

2. Functions Introduction



3-1 Spare parts list

No.	Name	No.	Name
1	Water Tank	10	Loading rack and trays
2	Side Cover	11	Equipment Foot
3	Display Screen	12	Sealing Door
4	Button	13	Door Handle
5	Water tank drainage pipe	14	Door Sealing Gasket
6	Equipment Switch	15	Door Cover
7	Printer	16	Top Cover
8	Door Switch		
9	Electromagnetic locking lever		

Note:

(1)Loading Rack*: Different volume equipment loading rack slightly different, the picture for reference, to the actual equipment configuration shall prevail.

2.1. Working Principle

This steriliser removes the cold air from the inner stainless steel chamber and then uses saturated hot and humid steam as the sterilising factor to achieve the Sterilization of items that can be penetrated by the steam under a certain combination of temperature and time. All preset process parameters of this equipment are set with the thermophilic fatty liver bacteria spores or microorganisms with equivalent properties (see the relevant national standards for details) as the representative of sterilisable microorganisms under the load conditions described in this procedure.

Note 1: When the resistance of microorganisms that may be infected by the sterilised load is greater than the standard agreed resistance (e.g. prions), it is necessary to adjust the Sterilization temperature, Sterilization time and other relevant process parameters according to the characteristics of the specific microorganisms, and to pass the corresponding process confirmation before use.

Note 2: Sterilization factor on the agreed micro-organism killing ability only in the equipment and related facilities are in normal working condition can be effectively guaranteed, equipment failure, external connection system failure, the loading of the load to be sterilised is not standardised, etc. may affect the killing effect of the Sterilization factor.

Note 3: Due to changes in the load to be sterilised, the operator should verify that the load to be sterilised is suitable for Sterilization in this equipment before proceeding with the operation, otherwise unpredictable damage may be caused to the equipment or load!

2.2. Structure and Function



The product consists of steriliser body, sealing door, piping system and control system. Saturated steam is used as the medium to achieve the effect of disinfection and Sterilization under high temperature.




The piping structure of the product is as follows:

- 2.2.1. Steam inlet piping: steam enters into the main body of the equipment from the evaporator through the steam inlet piping, the main components are water injection pump, water inlet valve, casting evaporator.
- 2.2.2. Back to the air pipeline: air through the back to the air pipeline into the inner chamber, balance the negative pressure of the inner chamber, the main components: back to the air filter, back to the air solenoid valve, check valve.
- 2.2.3. Evacuation (exhaust) pipeline: exclude the inner chamber steam and vacuum system to complete the function of vacuum (applicable to equipment with vacuum function), the main components: filter, check valve, evacuation (exhaust) valve, condenser.
- 2.2.4. Vacuum system (if any): complete the function of evacuation through specific structure, main components: water tank, filter, circulating pump, condenser, ejector.
- 2.2.5. Water inlet pipeline: inject water into the evaporator through the pump.
Main components: water tank, filter, pump, water injection solenoid valve.

Operation Panel

Button introduction:

Code	Icon	Function	
1		Return	
2		Confirm	

3		Open the door	
4		Down button	
5		Up button	

1) Return

Press this button to return the screen to the previous screen.

2) Confirm (OK)

Press this button to select the icon where the cursor is located and is used to move the cursor when setting parameters.

3) Open the door (Open)

The device can be opened by pressing the door open button

4) Down button (Down)

Press this key to move the cursor down or right and is used as a minus key when setting parameters (press and hold for continuous minus) and is used to turn the page

5) Up button (Up)

Press this key to move the cursor up or left.

is used as a plus key when setting parameters (press and hold to add consecutively).

is used to turn the page

Display Icons Introduction:

The main interface icon of the display when the device is powered on:

Start
Cycle

Cycle
Setting

Auxiliary
Function

System
Setting

No	Icon	Function
1	Start Cycle	Move the cursor to this icon, press the OK button and then the screen jumps to the selection of the programme running screen
2	Cycle Setting	Move the cursor to this icon, press the OK button and then the screen jumps to the password authority screen, enter the authority password and then enter the parameter setting screen;
3	Auxiliary Function	Move the cursor to this icon, press the OK button and the screen will jump to the auxiliary function setting screen.
4	System Setting	Move the cursor to this icon, press the OK button and the screen will jump to the system parameter setting screen.

Display

The device display shows information about the pressure and temperature of the device.

Sealing Door

The cabinet door of this steriliser is mainly composed of door plate, door cover, door rubber ring, door lock structure and other components.



Do not place your hands and other objects on the inside of the cabinet door cover or in the direction the door runs when closed!!!!

1) Open the door and Close the door

For details on opening and closing the door, see the "Door Operation" section.

2) Safety interlock

The equipment is equipped with a safety interlock structure, when the door is

closed in place, the electromagnetic lock is released to lock the door to ensure that the door will not be opened by mistake, to ensure the safety of the operation process.

3) Door Gasket

Structure: the seal is a specially processed annular silicone rubber ring, is an important part of the sealing of the inner chamber environment, it is in a constant state of extrusion and force, the correct installation and maintenance of its normal work as well as the service life is critical, my company uses a specially formulated silicone rubber sealing ring, effectively ensuring its stability and reliability in the high temperature working environment.

Principle: The sealing ring is installed in a ring-shaped groove on the end surface of the cabinet door frame. After closing the door, it is tightly pressed with the door panel to achieve the sealing of the door;

Use: During installation, press the door rubber ring evenly into the groove of the door panel, and be careful not to reverse the installation. For the installation of the door rubber ring, see section "Replacing the door rubber ring".



警告

Make sure that the pressure in the inner chamber is reduced to equilibrium with the outside atmospheric pressure and that the temperature of the liquid is reduced below the boiling point before opening the door automatically or manually!

2.2.6. Description of safety devices

The autoclave is equipped with the following safety devices:

- Over-temperature automatic protection device: double over-temperature automatic protection is provided inside the evaporator and pot wall.
- Door safety interlocking device: automatic door lock is adopted, only when the door is closed in place, the steriliser can start the working procedure; the door can not be opened when there is pressure in the inner chamber or when the power supply is not connected.
- Safety valve for automatic pressure relief: exceeding the set pressure, the safety valve opens to release the pressure.
- Electronic circuit safety device: DC control circuit over-voltage overload protection, AC

main circuit short circuit protection.

2.2.7. Printer

Please refer to the actual equipment for the exact availability of printers. Printer Information:

- 1) Printing method: line thermal printing
- 2) Printing paper width: 57mm
- 3) Thermal printing paper specifications: 57mm wide, 30mm ϕ

See section 5 for printer structure and paper replacement.

Note: The specific printer is subject to the actual equipment configuration.

3. Cycle

This device is equipped with several programs in the default state, of which 134 Universal, 121 Universal, B134 Rapid, N134 Rapid, Prion, Custom, and Liquid programs belong to the Sterilization category, BD&Helix and Vacuum Test belong to the Testing category, and Preheating, Drying, and Cleaning programs belong to the Auxiliary category.

Depending on the configuration of the device, some devices are not able to start certain types of programmes; Type B devices are able to start vacuum programmes (B134 Rapid, BD&Helix, Vacuum Test, etc.), while Class S and Class N devices are not able to start vacuum programmes. Additional specific information can be found on the equipment nameplate.

4. Preparation for Use

4.1. Daily Inspections

- 1) Check that the printer paper (if configured) has been properly seated and is not out of paper;
- 2) Check that the pressure gauge (if configured) is at zero (at standard atmospheric pressure) in standby mode;
- 3) Check whether there is any obvious vapour leakage or other irregularities in the equipment;

4.2. Equipment Power-on

Water Supply

Check whether the water level in the tank between the high water level and low water level, if the water tank lack of water, please add water to the high and low water level, the water tank water level over the high water level, please drain the water tank to the high and low water level, the specific method to participate in the water tank drainage section

Power-on

Press the "ON" end of the boat switch to power up the device, if the device is configured with a circuit breaker, please power up the circuit breaker switch first. Power switch on, steriliser without alarm equipment can be used normally, without preparation time.

4.3. Operation Instructions

Door Operation

Closing operation:

As shown in the figure below, when the door is in the open state, first pull up the door handle, then close the door in place, and finally press the door handle down to the vertical state to complete the closing action. The door status on the display changes from "door open" to "door locked", indicating that the door is locked.



Open the door operation: the door in the closed state, click on the open button, the display door status from the "door has been locked" "change to" door has been unlocked "in the door has been unlocked state, with a hand pull the door handle can open the door.



注意

When the equipment is installed at the atmospheric pressure of 1 atmospheric pressure (i.e., open the door state, the pressure of the inner chamber is displayed as 0), can be opened and closed the door pressure conditions $\pm 5\text{kPa}$, when the equipment is located in areas with high altitude, open the door pressure will drop accordingly.

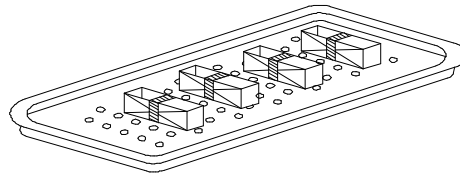


注意

When the chamber pressure is detected to be out of range, pressing the open button will indicate that the door cannot be opened, "Do not meet the conditions for opening the door, cannot open the door". At this time it is necessary to check the equipment chamber pressure, atmospheric pressure and operating conditions.

4.4. Loading loads

- 1) The loading items are prohibited from touching the wall of the steriliser chamber, and gaps should be left between the Sterilization packs to facilitate the penetration of the sterilising medium.
- 2) Catheters should be placed in such a way that both ends are in an open state and there are no sharp elbows or twists.
- 3) Instruments should be placed with the opening down or sideways to prevent water storage.
- 4) Instruments should be evenly placed and spaced without overlapping, as this may cause inadequate Sterilization and drying.



- 5) It is appropriate to place instruments, apparatus and articles of the same material in the same batch for Sterilization. When the materials are not the same, textile items should be placed on the upper vertical, metal instruments placed on the lower level.
- 6) It is prohibited to place trays of packaged items and trays of instruments on textiles or softer items to avoid the formation of condensation and wetting of the items below.

Choose the cycle

Refer to the following steps for programme selection:

The device automatically enters the main interface after switching on the power supply, select the programme type "Run Programme" icon in the main interface screen, press the "ok" key to enter the programme type selection screen, select the programme class, and then move the cursor to select the specific programme in the "Programme Selection" screen. Move the cursor in the "Programme Selection" screen to select a specific programme.

The "One-Click Run" section remembers the last selected programme, and the programme

you want to run is the same as the one you last ran. You can click here to quickly start the last selected programme directly from memory.

The default parameters of the programme and the applicable load types are shown in the section "Programme parameter settings".



For exotic medical devices, the medical institution should require the device company to provide the device cleaning, packaging, Sterilization method and Sterilization cycle parameters, and follow the requirements of its Sterilization method and Sterilization cycle parameters for Sterilization.



For implants, the healthcare facility should require the device company to provide the material, cleaning, packaging, Sterilization method and Sterilization cycle parameters of the implant and follow the requirements of its Sterilization method and Sterilization cycle parameters for the Sterilization; implant Sterilization should be released after the biomonitoring results have been passed; and the Sterilization of implants in emergency situations should follow the requirements of WS 310.3.

Start the cycle

After selecting a specific programme, press the "ok" key to enter the programme start screen, move the cursor to select the programme start icon "Run Programme", press the "ok" key to start the programme, the screen jumps to the The screen will jump to the "Run" screen, and the programme will start to run.

Please note that there is a function of "one-key run" in the program type selection screen of "Select Program" in the previous section, the "one-key run" remembers the last selected program, and the program you want to run is the same as the one you ran last time. For the programme you want to run, it is the same as the programme you ran last time. You can click here to quickly start the last selected programme directly from memory. The equipment does not require intermittent operation, but the single-tank internal circulation equipment in continuous operation, continuous

uninterrupted operation of 4 pots, the temperature in the tank may rise, if the equipment pumping performance has decreased (specifically manifested in the equipment to extend the vacuum time), it is recommended to replace the water in the tank.

Cycle run view

When the programme starts, it jumps to the programme running screen:

You can check the programme type, chamber pressure P1, chamber temperature T1, programme stage (e.g., the "replacement" stage in the above diagram), running time, and door status directly on the screen.

Icon meaning:

- 1) Parameter View: After selecting the entry, you can view the program parameters set by the currently running program, such as "Sterilization Temperature", "Sterilization Time" and so on;
- 2) Inputs and outputs: select enter to view the input and output status of each component and the pot wall temperature T2 (if any), evaporator temperature (or pressure); the following table lists the explanations of the symbol names contained in the display.

P1: 0kPa	T1: 32.1℃
T3: 32.1℃	T2: 32.1℃
F6 OFF	I1 ON
F3 OFF	I2 ON
F4 OFF	I3 OFF
B1 OFF	
B2 OFF	
H1 OFF	
H2 OFF	
DS OFF	

Code	Name		Code	Name		Code	Name
			B1	Circulation pump		I1	Door Closed Position
F3	Evacuation valve		B2	Water injection pump		I2	Solenoid lock off position
F4	Back air valve		H1	Condenser1		I3	
F6	Water injection valve		H2	Heating Film			
			DS	Solenoid lock			

Error infos: Select Enter to view the current alarm information of the programme; Select the alarm information icon to enter the alarm information screen. If there is a corresponding alarm, the display will pop up the corresponding alarm dialogue box: for example, E16 water shortage alarm message prompt.

See "Alarm Information" section for alarm information comparison table.

1) Stage Information: Select to view the time of each stage of the programme; On the Run screen, select the Stage Information icon to enter the Stage Information screen.

Replacement time: actual running time of the replacement phase

Pulsating vapour discharge 1 time: the actual running time from the upper limit to the lower limit of the 1st pulsation

Pulsating vapour inlet 1 time: the actual running time from the lower limit to the upper limit of the 1st pulsation

Pulsating vapour discharge 2 time: the actual running time from the upper limit to the lower limit of the 2nd pulsation

Pulsating vapour inlet 2 time: the actual running time from the lower limit to the upper limit of the 2nd pulsation

Pulsating vapour discharge 3 time: the actual running time from the upper limit to the lower limit of the 3rd pulsation

Temperature rise time: actual running time of temperature rise

Sterilization time: Sterilization time running value

Sterilization Tmax: maximum value of temperature in Sterilization phase (the highest temperature that may occur in the Sterilization cycle is the set Sterilization temperature +4° C, which does not occur under normal circumstances)

Sterilization Tmin: minimum value of the temperature in the Sterilization phase

Exiting the programme: After selecting Enter, you can enter the programme's "Exit in

the middle" selection screen and choose whether to exit the programme or not, see "Exiting the programme section" below;

Exiting the program

On the programme running screen, select the exit icon to enter the exit confirmation screen. If you need to exit, press the "OK" button, and the programme will perform the exit operation. If you don't need to exit, please press "Back" to go back to the programme running screen.

After exiting, please wait until the display prompts you to go back, then press the back button; then you can open the door or run the programme again.

End of the program

If you are starting a leak programme, the display will show Leak Green Pass or Fail and the leak rate value.

If the programme ends abnormally, the programme displays an alarm message and prompts "Please return" after the alarm is automatically processed.

You can click on the "open key" to open the door to unload the sterilised items, or click on the "return key" to return to the programme start-up interface.

Unload the loadings

When the Sterilization is finished open the door by pressing the door open button as prompted by the device. Open the door and wait for more than 5min to dissipate most of the heat in the inner stainless steel chamber. Operators wear gloves or other protective tools to remove the sterilised items to prevent burns.



注意

If the sterilised items are removed immediately after the end of the programme, a small amount of condensation may appear on the sterilised items! In this case, it is recommended to open the door and wait for more than 5 min before removing the sterilised articles.



注意

After opening the door, the inner cavity of the equipment, the inner side

of the door, the sterilised items and the tray shelves are all in a high temperature state, in order to prevent scalding necessary protective measures must be taken to protect the safety of the operator!

Storage of sterile items

A dust-free, airtight, dry storage environment with little fluctuation in ambient temperature should be selected.

Storage expiry time: the storage time of sterile goods is related to the packaging material and the type of packaging, unpackaged goods should be used immediately after Sterilization.

Packing Material	Expiry date of sterile items	Mark
Plain cotton packing	14 days	When sterile articles are stored and environmental standards are not met (storage conditions: ambient temperature <24 ° C, ambient humidity <70%), the expiry date of sterile articles packed in ordinary cotton materials should not exceed 7 days.
Medical disposable paper bags	30 days	
Disposable medical crepe paper	180 days	
Medical Nonwoven Fabrics	180 days	
Disposable paper-plastic bags (Tyek)	180 days	
Rigid containers	180 days	

4.4.1. Printer

Replacement of printing paper



注

意

When the paper added to the printer is about to run out, a red mark will appear on the paper to prompt the user to replace the paper (the printer is optional, some devices are not configured with a printer).

As shown in the figure, gently snap the rotary spanner from the lower hair, you can open the printer cover.

load the print paper, and pull out a section (beyond a little tear paper teeth), pay attention to the paper put neatly, the direction of the paper for the liquid side (smooth surface) up (if the reverse will not be able to complete the print), with a fingernail scratching the print paper, black traces of the side of the upward.

Close the paper compartment cover, the print head to go to the paper shaft pressure flush print paper after a little force to the print head to go to the paper shaft pressure back to the print head, and push the rotary spanner into the reset.

Turn on the printer's power supply, so that the head rotation, this time to see if the paper is going askew, if going askew need to adjust the print paper, until the print paper out of the paper when perpendicular to the outlet.

Cleaning and maintenance

After a long time of using the thermal printer, the thermal strips and rollers will leave some dirt, if not cleaned in time will affect the use and life of the printer. We recommend that you do not regularly clean. Paper bin cover open, with a cotton swab dipped in a little alcohol, gently wipe the printer thermal head, and the paper bin on the roller.

Print Record Viewing

Note: The printer is optional, the following printout is a schematic illustration, the content and data are for reference only. Different volumes of equipment, different procedures between the printouts are slightly different, please take the actual printout of the equipment shall prevail.

Sign:				
Sterilie finish				
Start	12:35:40	80.0	0	
Balance	12:35:00	70.0	-93	
	12:34:00	73.0	-93	
	12:33:00	74.0	-91	
	12:32:00	75.0	-80	
	12:31:00	80.0	208	
Dry	12:30:00	90.0	-20	
Exhaust	12:29:00	134.5	210	
	12:28:00	134.5	210	
	12:27:00	134.4	209	
	12:26:00	134.5	210	
Sterile	12:25:00	134.3	208	
	12:24:55	126.9	170	
	12:23:55	120.2	120	
	12:22:55	115.4	70	
Heat	12:21:55	83.7	-80	
	12:19:40	113.4	60	
	12:18:30	84.7	-80	
	12:17:00	112.9	60	
	12:16:00	85.2	-80	
Pulse	12:14:30	110.0	50	
	12:13:00	100.3	0	
	12:12:00	95.8	0	
	12:11:00	75.4	0	
Displace	12:10:00	50.1	0	
Situation	Time	Tem.	Press	

Dry time: 0300s				
Sterile Tem. : 134.0 Sterile Time: 240s				
Program-01: ***** Pulse time: 3				

Cycle times: 000001 Operator No. :				
Indicate tape: <input type="checkbox"/> Success <input type="checkbox"/> Fail				
Indicator: <input type="checkbox"/> Success <input type="checkbox"/> Fail				
Date: 2017-01-01				
Equipment No. : 20170001				

Perform load drying

Sterilization stage, maintaining temperature and pressure for a certain period of time for Sterilization

Heat-up phase for steam penetration and load temperature increase

This stage is used to remove cold air from the inner chamber

Programme parameter setting information

Equipment Information and Operation Information

4.4.2 Performance Testing

Biological monitoring

Biomonitoring is used to test the effectiveness of the Sterilization process and Sterilization equipment. For details, see the "Biomonitoring" section in the preceding chapter.

B-D testing

The B-D test is a test of the ability of a high vacuum steriliser sterilising porous load healthcare products to successfully remove air.

The B-D test is selected according to the type of equipment and relevant policies and regulations. According to GB/T 30690 small pressure steam steriliser generally do not need to carry out B-D test, if B-D test, the test method can be referred to Chapter 2. B-D test before starting the cold pot preheating procedure to preheat the equipment.



The BD test is not a test of Sterilization effectiveness, but a functional test of the steriliser. It is not a substitute for routine monitoring of the Sterilization process.

Vacuum Leakage Testing

The choice of whether or not to perform a leak test is based on the type of equipment and is not necessary if the equipment does not have pulsating vacuum capability. The leak test is performed to check the sealing integrity of the tubes connecting the device to the inner chamber to ensure that there is no air in the cold air removal phase of the steriliser. Run the leak test programme that comes with the equipment and the results will be shown in the printout when the test is completed. The leakage rate should not exceed 0.13kPa/min.

4.5 Equipment Power on.

When the appliance has been used, leave the door open. Disconnect the unit by pressing the boat switch "OFF". If the unit is equipped with a circuit breaker, disconnect the unit circuit breaker.

5. Notes on the handling of special cases

5.1. Manual exit programme

See Chapter 5, "Exit Procedures".

5.2. Exit in the middle of the programme

In order to ensure the safety of the equipment and the validity of the results of the Sterilization, if there are some faults or unreasonable states during the operation of the program, the program will alarm and exit automatically.

The following is a list of common alarm messages that will cause the programme to exit in the middle:

Error code and meaning	Error code and meaning
E00 Program interruption	E16 Water shortage in the water tank
E01 Door Closed Position Disconnect	E17 Lack of water in the circulating water tank
E02 Chamber Overheat	E18 Circulating water tank full
E03 Chamber wall overheat	E20 Door unlocked
E04 Sterile temperature too low	E21 Evaporator water level error
E05 Vacuum overtime	E22 Evaporator over-temperature
E06 Heat-up overtime	E23 Motor position disconnect
E07 Water injection overtime	E24 Evaporator 1 sensing fault
E09 Motor operation overtime	E26 Door unlocked.
E10Chamber Overpressure	E27 Evaporator pressure failure
E11 Evaporator overpressure	E28 Configuration code error
E12 Chamber sensor failure	E50 Communication Failure Alarm
E13 Chamber wall sensor failure	
E14 Evaporator sensor failure	

Error code and meaning	Error code and meaning
E15 Pressure sensor failure	

When the programme exits automatically, the screen will display the alarm or prompt message that triggered the programme exit, and then the programme will go to the exit processing stage, and the reason for the programme exit will be recorded on the printout record (if any).

Waiting for the end of the programme exit processing flow, the programme ends and the following screen (example) will be displayed:

02# 134 common (use)
P1: 0kPa T1: 32.1°C
E05 Vacuum timeout
Return
Door status: locked

At this time, press the return key or open the door key to exit to the startup interface of the programme, after the alarm appears, please contact professional our authorised technical maintenance personnel to find out the cause of the problem.

5.1. Tank water shortage alarm

There is a "water tank water shortage" alarm, check whether there is water in the water tank, no water, please add water to the high water level, low water level. After adding water, it still prompts "water shortage in water tank" alarm, then you need to reset the lower limit of water quality value according to the method of "water quality test" in "process parameters" in Chapter 9.

5.1. Poor water quality tips

If the equipment is equipped with a water tank, when the water quality of the tank is lower than the standard requirements, a poor water quality prompt appears. Please replace it with pure water that meets the requirements. If the use of water quality to meet the requirements of the

water quality is still prompted by poor water quality, this time you need to contact the equipment supplier to deal with the problem.



注意

Prolonged use of substandard water quality can lead to clogging of lines and evaporators!

5.1. Cannot open the door prompt

When the equipment is installed at a high altitude, it is necessary to adjust the atmospheric pressure value of the equipment when the pressure deviates from one atmosphere, otherwise the door will not open. Set the atmospheric pressure in accordance with chapter 8 "Administrator's Manual" - "Control System Common Functions" - "Atmospheric Pressure Setting" in this manual. Reset the atmospheric pressure value.

6. Sterilization techniques

6.1. Load packing and loading guidelines

6.1.1. Packing materials

The selection and use of packaging materials should follow the following principles:

- 1) Sterilization packaging materials include rigid containers, disposable medical crumpled paper, paper-plastic bags, paper bags, textiles, non-woven fabrics and so on.
- 2) Sterilization packaging materials should meet the requirements of GB/T 19633.
- 3) Open tanks should not be used for packaging of sterilised items.
- 4) Textile packaging materials should be cleaned once used, no stains, and no breakage in light inspection. Textiles should be non-bleached fabrics; wrapping cloth in addition to the four edges should not be stitched, should not be sewn; before the initial use should be washed at high temperatures, degreasing de-sizing, de-colouring; there should be a record of the number of times it is used.
- 5) The use and operation of rigid containers should follow the manufacturer's instructions or guidebook.

6.1.2. Packing of fabrics

- 1) The packaging material and the sterilised article being packed should be dry before packing.
- 2) Packaging materials should be placed at a temperature of $18^{\circ}\text{C} \sim 22^{\circ}\text{C}$ and a relative humidity of $35\% \sim 70\%$ for 2h before use, and carefully inspected for mutilation and breakage.
- 3) Cotton dressings can be packaged in cotton in accordance with the requirements of YY/T 0698.2; cotton gauze dressings can be used in accordance with the requirements of YY/T 0698.2, YY/T 0698.4, YY/T 0698.5 medical paper bags, non-woven fabrics, crumpled paper or composite bags, using a small package or a single package.

- 4) The weight of the dressing package should not exceed 5kg.

6.1.3. Packaging of instruments

- 1) The items should be thoroughly cleaned before Sterilization, and after the items are washed, they should be dried and packed in time.
- 2) Surgical instruments should be placed in basket frames or perforated trays for matching

packaging.

3) Surgical instruments should be packed by 2 layers of packing materials in 2 times by using closed packing method.

4) The weight of the instrument package should not exceed 7kg.

6.1.4. Packaging of utensils

1) Items should be thoroughly cleaned before Sterilization, and after items are washed, they should be dried and packed in time.

2) Plates, pots, bowls and other utensils, should be packaged separately.

3) Sealed packaging such as the use of paper bags, paper-plastic bags and other materials, a layer can be used, applicable to individually packaged instruments.

6.1.5. Loading

Sterilised items are loaded according to the following requirements:

1) Special Sterilization racks or baskets should be used to load sterilised items. There should be a gap between the Sterilization packages to facilitate the penetration of the sterilising medium.

2) It is appropriate to place instruments, apparatus and articles of the same material in the same batch for Sterilization.

3) When the material is not the same, textile items should be placed in the upper layer, vertical, metal instruments placed in the lower layer.

4) Surgical instrument packages, hard containers should be placed flat; pots, plates, bowls should be placed diagonally, glass bottles and other bottom non-porous utensils should be inverted or placed on the side; paper bags, paper-plastic packaging items should be placed on the side; to facilitate the entry of steam and cold air discharge.

5) Select the lower exhaust pressure steam Sterilization procedure, large packages should be placed in the upper layer, small packages should be placed in the lower layer.

6) The loading capacity of the lower exhaust pressure steam steriliser should not exceed 80% of the cabinet volume. The loading capacity of pre-vacuum pressure steam steriliser should not exceed 90% of the cabinet volume. At the same time it should not be less than 10% of the cabinet volume.

Maximum load of the equipment:

Volume	Maximum load for instruments	Maximum load for fabrics	Maximum weight per bag
24L	5.5 kg	2.5 kg	1.5 kg

The maximum total amount to be carried by a single pallet is the maximum weight of a single package, and the maximum weight to be carried by a shelf is the maximum load of the instrument class.

6.2 Sterilization procedures

Procedure description: This device is equipped with several sets of procedures under default status, among which 134 general, 121 general, B134 rapid, N134 rapid, prion, custom, liquid procedures are all Sterilization procedures, BD&Helix, vacuum test are test procedures, preheating procedures, drying procedures, cleaning procedures are auxiliary procedures.

The differences in the Sterilization procedures for different order numbers are described in the "3.4 Procedures" section of this manual.

The default parameters of the programme and the applicable load types are shown in the "Programme parameter settings" section.

6.3 Suitable items for Sterilization

1) Principle

Pressure steam Sterilization should be preferred for moisture- and heat-resistant instruments, apparatus and articles.

Select the Sterilization method according to the instrument manual.

Tube lumen instruments should not be sterilised by under-vented pressure steam Sterilization.

Rigid containers and oversized and overweight packages should follow the Sterilization parameters provided by the manufacturer.

Foreign instruments should follow the packaging and Sterilization methods and parameters provided by the supplier for foreign instruments and implants.

For cases where it is not possible to check the instructions for use of the device, you can consult the Sterilization information of the same type of device in the same hospital to choose the Sterilization method.

2) Sterilization of prohibited items

Fibre-optic instruments: fibre-optic cables, medical cables, flexible mirror cables, etc.

electronic instruments: non-metallic drills, gynaecological motors, electric knife, etc.

Soft scopes : gastroscope, enteroscope, tracheoscope, bronchoscope, choledochoscope, cystoscope, ureteroscope, etc.

oils and fats : paraffin oil

hermetic glass bottles

Powder : talcum powder, traditional Chinese medicine, powder injection medicine, etc.



警告

This equipment is not suitable for sterilising liquids in tightly sealed bottles. If this equipment is used to sterilise tightly sealed bottles of liquid, it is easy for the operator to negligence or violation of operating procedures occurred in the bottle explosion accident, a serious danger to the safety of people and equipment.

7.Manager's Handbook

7.1 Common functions of the control system

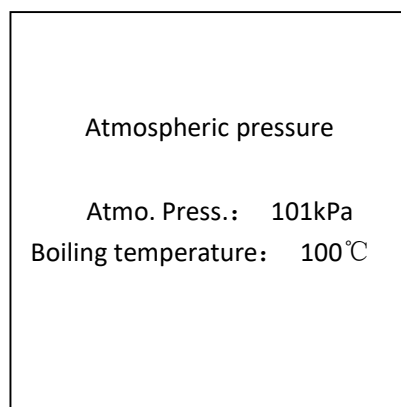
In the main interface of the device display (as shown in the left figure below), move the cursor to select the cursor "auxiliary functions", after confirmation, you can enter the system parameter screen (as shown in the right figure below), in the system parameter setting screen can have been part of the parameters and functions of the settings.

System Setting: Atmospheric pressure Preheat mode Print Settings Time setting Language Selection USB status Water quality testing	System Setting: FO value Print Overflow pipes
--	---

7.1.1 Atmospheric pressure setting

If the equipment is used in a location with high altitude, it is necessary to adjust the "atmospheric pressure" in order to open and close the door normally. If the atmospheric pressure is not matched correctly, the display may indicate "Do not meet the conditions for opening the door, can not open the door, please go back" during the process of opening and closing the door. Only when the "inner room pressure-P1" is in the range of "atmospheric pressure $\pm 5\text{kPa}$ " can the door open/close operation be executed.

Select the "Atmospheric Pressure" option in Figure 8-1, and then enter the atmospheric pressure setting screen as Figure 8-2. Press OK to move the cursor to the "Atmospheric Pressure: 101kPa" option, and then press "Down" to move the cursor to "Atmospheric Pressure: 101kPa". Press OK to move the cursor to the "Atmospheric Pressure: 101kPa" option, and then adjust the value with the "Down" key to match the local atmospheric pressure. The default value here is 1 standard atmospheric pressure 101kPa when the device is shipped.



Setting method is as follows: Under normal standby condition, check the pressure parameter shown in the display "Pressure of inner room - P1", and it is recorded as "A (with symbol)", then set the atmospheric pressure as "101+A". A", then set the atmospheric pressure to "101+A". For example, if the "Pressure-P1" is "-6 kPa", then the atmospheric pressure is approximately 95 kPa (101 kPa-6 kPa) according to "101+A".

Note: The value of atmospheric pressure is set according to the value of atmospheric pressure at the place where the equipment is installed, and the boiling point temperature is automatically calculated with the change of the value of atmospheric pressure, so there is no need to adjust it separately! Standard atmospheric pressure: that is, the atmospheric pressure at sea level, which is what we usually call 1 atmosphere (101 kPa). The value is about 0.1MPa = 101kPa. The atmospheric pressure decreases with increasing altitude, below 3km, for every 1km increase in altitude, the atmospheric pressure decreases by about 10kPa.

7.1.2 Preheat mode setting

Select the "Preheat Mode" option on the System Parameters screen in Figure 8-1, and then enter the Preheat Mode Setting screen. You can adjust the mode of "Warm-up Mode" on or off by pressing the down key. The factory default is Off.

When the preheat mode is on, the device will preheat the heating film or evaporator in standby mode. When the preheat mode is on, the running time of the programme can be shortened appropriately.


7.1.3 Print Setting

Select the "Print Setup" option on the System Parameters screen in Figure 8-1, and then enter the Print Setup screen. You can adjust the mode of "Print Setting" on or off by pressing the down key. The factory default is On.

When the print mode is on, if your device is matched with a printer, it can print data, but when it is off, it will not print any more.

7.1.4 Time Setting

Select the "Time Setting" option in Figure 8-1, and then enter the warm-up time setting screen as Figure 8-3. Press the "OK" key to move the cursor to select the date and time items in turn, and adjust the selection items through the "Down" key. Press "Down Key" to adjust the selected items, and press "Down Key" to adjust the size of the data cyclically. Adjustment is complete, press the return key to return to the meeting can be.



Time Setting
Date: 2001-01-01
Time: 12:01:01

7.1.5 Language Selection

In Figure 8-1, select the "Language Selection" option on the System Parameters screen, and then enter the Language Selection screen. In this screen, you can display and print the language selection of Chinese and English switch.

7.1.6 Water quality testing

In Figure 8-1, select the "Water Quality Test" option on the System Parameters screen, and then enter the Water Quality Test screen.

Water Quality Testing
Testing water quality values :
1537
Upper limit of water quality
value: 3500
Lower limit of water quality
value: 1567

Confirm Back

Set the upper and lower limits of the water quality value in this interface, here you need to set correctly, otherwise there will be false alarms such as "water shortage in the tank" and "poor water quality in the tank".

Detected water quality value: the actual value detected by the device, cannot be modified.

Upper limit of water quality value: the default is 3500, generally do not need to modify.

Lower limit of water quality value: Setting method: In the case of no water in the tank (water quality probe is exposed to the air) to see the "detection of water quality value" is "B", then set the "lower limit of water quality value" to "B + 30". B+30", for example, in the figure below, if the "Detected water quality value" is 1537, then the "Lower limit of water quality value" is set to 1567.

After setting, select "Confirm" and return to complete the setting.

7.1.7 USB Status

Select the "USB Status" option on the System Parameters screen in Figure 8-1, and then enter the USB Status screen. In this screen, you can check the USB status information.

Note: This USB reading function is optional.

7.1.8 F0 value print

In Figure 8-1, select the "F0 Value Printing" option on the System Parameters screen, and then enter the F0 Value Printing Setting screen. In this screen, you can set whether F0 value printing is on or off.

7.1.9 Overflow pipes

This mode is only available for dual tank configured units. If the unit is configured with dual tanks, there will be an "Overflow Piping" option on this screen, after confirming, you will enter the overflow piping setup screen, and you can select "Connected" or "Not Connected". After connecting the sewage tank (circulating water tank) drain line and sewage collection device of the equipment, select this mode as "connected", the equipment sewage tank will automatically overflow to the sewage collection device when it is full of water, and will not report the alarm of "circulating water tank full". If you do not connect the tank drain line and sewage collection device, please select this mode as "not connected", in this mode the circulating water tank will trigger the "circulating water tank full" alarm when the tank is full, and you need to manually remove the water from the tank.

7.2 Detailed explanation of the process of running the programme

The screen displays the name of each programme stage and status data such as the temperature and pressure of the equipment's inner chamber. A Sterilization cycle of the equipment mainly consists of the following stages:

- 1) Preparation stage: In the preparation stage, the equipment preheats the evaporator and the wall of the pot to reach the set preheating temperature, and if the printing function is turned on, the printing of the table header is also completed in the preparation stage.
- 2) Replacement stage: start to the inner chamber into the steam at the same time open the exhaust valve, remove the cold air from the inner chamber.
- 3) Pulsing stage: Pulsing to remove cold air, first exhaust steam or vacuum to the set lower limit of pulsation, then start to exhaust steam to raise the pressure to the upper limit of pulsation, and then continue to exhaust steam or vacuum and so on until the number of pulsation reaches. Play the role of as far as possible to completely exclude the role of cold air.
- 4) temperature stage: the inner chamber temperature and pressure, when the Sterilization temperature is reached after a delay into the Sterilization stage.
- 5) Sterilization stage: In the Sterilization stage, the temperature and pressure of the inner chamber are controlled to be maintained in a certain control range until the end of Sterilization.
- 6) Vapour removal stage: remove the steam from the inner chamber and reduce the pressure in the inner chamber.

7) Drying stage: After the pressure in the inner chamber is removed, the items in the Sterilization chamber are dried.

8) Equalisation stage: If the pressure in the inner chamber is not within the range of opening and closing pressure, it will automatically equalise the pressure until it reaches the opening condition.

9) End stage : The buzzer sounds and the display indicates the end at the same time.

Corresponding relationship between pressure and time in the work cycle, different order numbers of equipment, different procedures slightly different.

8. Display screen operation guide

8.1 Main Menu

If there are no alarms after powering up the unit, the display will go directly to the main menu screen.◦

Chamber Pressure-P1:	0 kPa		
Chamber Temperature-T1:	32.1 °C		
Chamber wall temperature -T2:	32.1 °C		
EvaporatorT--T3:	32.1 °C		
Door Status:	Door Closed		
Run	Program	Auxiliary	System
Program	Setting	Function	Setting

Inner chamber pressure - P1: indicates the pressure inside the inner chamber of the steriliser and is expressed as P1;

Inner chamber temperature - T1: indicates the temperature of the inner chamber of the steriliser and is expressed as T1;

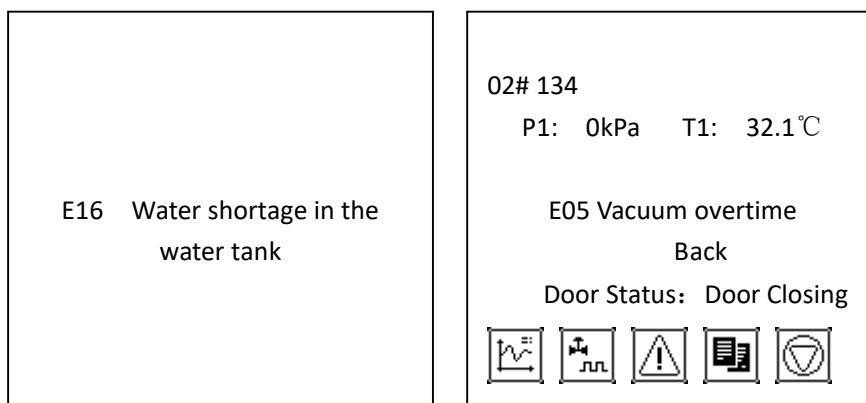
Inner chamber wall temperature - T2: indicates the temperature of the wall chamber of the steriliser and is expressed as T2;

Evaporator T-T3: indicates the temperature of the evaporator directly connected to the main body of the device and is indicated by T3 (applicable to 18L/24L/29L/45L devices);

Note: different configurations of the equipment display slightly different, the specific display has been the actual equipment display shall prevail.

8.2 Alarm Display

The alarm display for the unit in standby and operation phases are as follows, respectively:



8.3 Running the program

8.3.1 Select the program

Please refer to the "Selecting a programme" section in the "Operating instructions".

8.3.2 Program operation

Please refer to the "Start-up Procedures" section in the "Operating Instructions".

8.3.3 Value display

Please refer to the section "Checking the operation of the programme" in the "Operating instructions".

8.3.4 System parameter

System parameters "Atmospheric Pressure", "Preheat Mode", "Print Setting", "Time Setting", For the settings of "Atmospheric Pressure", "Preheat Mode", "Print Setting", "Time Setting", "Language Selection", "USB Status", "F0 Printing", and "Overflow Mode" in the System Parameters, refer to Chapter 8, "Administrator's Manual". Refer to the section "Common Control System Functions" in Chapter 8 "Administrator's Manual".

8.4 Program value setting

8.4.1 Select Edit Program



Editing of programme parameters must be carried out by trained professional technicians.


Sterilization process key parameters description:

Sterilization temperature and Sterilization time are the key parameters affecting the Sterilization process, during the Sterilization process, the control system controls the lower limit of the Sterilization temperature range in the Sterilization chamber to the set Sterilization temperature.

Note: The setting of the parameters of each procedure should be amended in use according to the specific circumstances or their own Sterilization process, and after the completion of the amendments need to be verified and qualified, and ultimately biological testing should be all qualified before use.



Non-authorized programs will not be allowed to use and edit.

On the programme start-up screen, select the parameter setting icon , programme parameter settings can be made.

Select the parameter setting icon to confirm and enter the password input interface, through the "OK", "down", "back" combination of password input, then Move the cursor to "Confirm" to enter the parameter setting.

In the parameter setting screen, move the cursor to "Confirm" to select the parameter you want to modify.

The cursor stops at the name of the parameter you want to modify, and then press the down key to modify the value.

Press the Return key to back to after the setting is completed.

8.4.2 Programming Parameter Setting

Program	Sterile Tem. /°C	Sterile Time. /s	Drying Time/s	Applicable load type or function
134°C	134	360	900	Type B equipment: high temperature resistant solid and hollow

				instruments with or without packaging, fabrics, etc. Type S equipment: high temperature resistant solid instruments with or without packaging, fabrics, etc.
121℃	121	1200	900	Rubber, fabric instruments, etc. that are not resistant to high temperatures
B134 Rapid	134	240	60	Single handle or small number of exposed cavity type instruments (for type B devices)
N134 Rapid	134	240	60	Single handle or small number of exposed solid instruments
Prion	134	1080	900	Loads containing bacteria that are more difficult to kill
Customize	134	360	900	Customize
BD&Helix	134	210	600	Testing the penetration effect of vapour and cold air removal from the equipment (applicable to B-type equipment)
Vacuum test	Test: 900s			Detection of equipment leakage (for type B equipment)
Preheat	134	240	30	Preheat
Drying	----	-----	600	Dry
Washing	Time: 600s			Cleaning equipment with its own evaporator

Note: The maximum running time of the device is tested under loading standard load. The above is the default data of the programme, the actual equipment shall prevail.

Sterilisation time: running time of the sterilisation phase, range [0 ,99]min

Sterilisation temperature: Sterilisation stage holding temperature, setting range [105 ,138]° C

Drying time: drying stage running time, setting range [0 ,99]min

Pulsation number: Pulsation number, setting range [0 ,6]

Upper pulsation limit: upper pressure limit value of pulsation stage, setting range [0 ,150]kPa

Lower pulsation limit: lower pressure limit value of pulsation stage, setting range [-99 ,50] kPa
(S-type range [0 ,50] kPa)

Displacement time: Displacement phase time fixed setting value 4min。



“B134 Quick”, “BD&Helix”, “Vacuum Test” are only available for B-type equipment, not for S-type equipment. The “Cleaning Programme” is only available for conventional 18/24/29L/45L units.

Type B steriliser is used for sterilisation of all packaged and unpackaged solid loads, Class A cavity loads and porous permeable loads for testing as required by the standard.

Type S sterilisers are used for special sterilisation of items specified by the manufacturer, including unpacked solid loads and at least one of the following: sterilisation of porous permeable items, small quantities of porous permeable strips, Class A cavity loads, Class B cavity loads, single-packed items and multi-layer packaged items.

The N-steriliser is used for the sterilisation of unpacked solid loads.

Programmes: The device is equipped with several programmes in the default state, of which 134 General, 121 General, B134 Rapid, N134 Rapid, Prion, Custom and Liquid programmes belong to the Sterilisation category, BD&Helix and Vacuum Test belong to the Testing category, and Preheating, Drying and Cleaning programmes belong to the Auxiliary category;

When the device is able to start the vacuum type procedures (BD&Helix, vacuum test, etc.) the device is a type B device, and when the device is unable to start the vacuum type procedures the device is a class S device, which is not able to sterilise cavity type loads. Check the nameplate for specific information.

■ The default process parameters of this equipment system are all the default parameters set after testing under the standard load conditions stipulated in the product standard, if the load used by the user is changed or the loading mode is changed, it is necessary to verify the relevant process before use (the user needs to make sure that the loads to be sterilised can be operated in the process corresponding to the specified procedure first). After the user modifies the parameters of the sterilisation procedure, it is necessary to carry out the monitoring of the sterilisation quality, and then use it after the monitoring is confirmed to be qualified.

■ 134General, 121General, Custom, B-Class and Prion are all pulsating vacuum sterilisation programs and have the same process flow, with the values of the relevant parameters adjusted according to the characteristics of the different loads.

■ The 134 general purpose is mainly suitable for the sterilisation of heat-resistant items with packaging, e.g. the standard analogue loads are metal screws with paper-plastic wrapping, fabric loads with wrapping cloth.

■ The 121 general purpose applies mainly to rubber loads with relatively low temperature resistance.

■ The B134 Rapid Procedure is only suitable for the sterilisation of individual Class A cavities in a hot pot, in case of user emergency, and must be used within 4 hours of completion of sterilisation, and to prevent secondary contamination of the environment and other factors when the instrument is transported to the place of use.。

WARNING: When running the N134 Rapid or B134 Rapid Rapid class programmes, the shelves and extra trays need to be removed if the shortest run times are to be achieved.

Prions are suitable for the sterilisation of bacteria viruses etc. that cannot be killed by normal sterilisation type procedures (shorter sterilisation times).

The N134 Rapid procedure is only suitable for sterilisation of single exposed instruments in hot pots, in case of emergency by the user, and the sterilised instruments must be used within 4 hours, and it is necessary to prevent secondary contamination of the environment and other factors when the instruments are transported to the place of use.

BD&Helix program is used to test the effect of cold air exclusion and steam penetration with special equipment, such as standard BD packs, disposable BD packs, etc. The parameter values of this program are set according to the parameters required by the manufacturers of the most commonly used BD test strips, and if they are different from those adopted by the hospitals, they should be modified with reference to the requirements of the adopted equipment or test strips. Parameters. Can also be used with a special lumen PCD test a certain length of the lumen of the cold air exclusion effect and steam penetration effect of the device, this procedure parameter values according to the most commonly used PCD device manufacturers require the parameters and set (134 °C sterilisation for 3.5 minutes), such as different from that used in hospitals, should be referred to using the requirements of the device to modify the specific parameters.

vacuum test programme is used to test the equipment in the negative pressure state and the inner chamber connected to the part of the pipeline or device sealing. In the process of commissioning or routine routine testing of equipment, especially after long-distance transport, there may be such phenomena as loose pipelines (or B-D test failed), at this time, you can choose this procedure for testing. It is mainly used to test the vacuum leakage of the sterilisation equipment in order to check the sealing condition of the lines. This test is carried out under the premise that the inner chamber of the steriliser is empty. After the programme has been run to the test stage, the vacuum leakage test passes if the pressure does not change by more than 1.3kPa within 600 seconds. If the test is not normal it must be serviced. Check the door seal and the connection part of the pipework system and the inner chamber, etc., to find out the leakage point, exclude it, and then re-test until the test is normal. This procedure is for testing only and is not intended to be used as a verification of whether the sterilisation is qualified and reliable.


preheating procedure, drying procedure, cleaning procedure as an auxiliary class of procedures, the use of such procedures must be strictly in accordance with the applicable conditions of the procedure to be used.

preheating procedure, in the first pot of equipment to run the programme can be the first no-load run preheating procedure to make the equipment for preheating, in order to achieve better and faster sterilisation and drying effect.

drying programme, the items can be individually dried, according to different requirements set the appropriate drying time, to achieve the drying requirements of the items.

cleaning programme can clean the evaporator, and the user can run the cleaning programme once every one month to prevent the pipeline from scaling or attaching other impurities to affect the heating efficiency.

8.4.3 System maintenance

In the main screen of the device display (below left), move the cursor to select the “”, After confirming, you can enter the password interface, and again after entering the password interface, select "Confirm" to determine to enter the system maintenance screen (the following right figure), in the system maintenance screen can have been part of the parameters and functions of the settings.

8.4.4 Equipment Infos

Device number: This is the set number of the equipment when the equipment is shipped from the factory, after the factory users do not have to modify this.

Configuration code: the configuration code for the hardware and programme of the device, after the factory users here can not be modified at will, the modification may cause the device can not run normally.

Cycle times: the number of cycles of the device.

LCD parameters: adjust the brightness of the display

Device Type: Configuration code for hardware and programme of the device, it can adjust the device to B class, S class or N class. After the factory here can not be modified, the modification may cause the device can not run normally.

Configuration Code Configuration Description: After selecting Enter, you can view the configuration data of the specific configuration code. Non-authorised

professionals cannot configure it.

If you need to modify the relevant parameters, select "Confirm" after modification to complete the modification.

Note: After the equipment is shipped from the factory, the content of this screen can not be changed at will by the user, if you need to adjust, you need to be authorised by the company's trained professionals to operate. In the equipment to replace the control board or display must be configured after the content of this screen, such as not configuring the equipment may cause the equipment can not run normally.

8.4.5 Deviation Calibration

DEV P1: Deviation calibration of inner chamber pressure

DEV T1: Deviation calibration of the inner chamber temperature

DEV T2: Deviation calibration of pot wall temperature

DEV T3: Deviation calibration of evaporator temperature

DEV P2: Deviation calibration of evaporator pressure

When it is determined that the actual measured value of the pressure or temperature of the device deviates, the detection can be calibrated by means of a deviation calibration. If the detection is low, add a certain value to the corresponding calibration, if the detection is high, subtract a certain value from the corresponding calibration.

P1:	0	kPa	T1:	32.1	°C
T3:	32.1	°C	T2:	32.1	°C
Deviation Calibration					
DEV	P1:	0	kPa		
DEV	T1:	0	°C		
DEV	T2:	0	°C		
DEV	T3:	0	°C		

8.4.6 Manual Operation

In the manual operation interface, move the cursor to the corresponding option by using the "down key", and then adjust the corresponding component to turn ON or OFF after the OK key is pressed.

The following table describes the display screen designations (some designations are not used and are reserved as reserved items).

Code	Name	Code	Name	Code	Name
F2	Steam inlet valve	B1	Circulation pump	I1	Motor closing position detection
F3	Evacuation valve	B2	Water injection pump	I2	Motor opening position detection
F4	Back air valve	H1	Evaporator1	I4	Evaporator high water level
F5	trap (for water delivery)	H2	Heating film		
F6	Water injection valve	I0	Door closing position detection	I5	Evaporator lowwater level
M1	Axial fan				

Manual Operation:

F2 :	OFF	B1:	OFF
F3 :	OFF	B2:	OFF
F4 :	OFF	H1:	OFF
F5 :	OFF	H2:	OFF
F6 :	OFF	LK:	OFF
M1:	OFF	H3:	OFF
P1:	XXXkPa	T1:	XXX.X℃
T3:	XXX.X℃	T2:	XXX.X℃

8.4.7 Password setting

To reset the device password on this screen, enter "Password", "New Password", "Confirm Password", and then select "Confirm". "Confirm" to complete the modification

8.4.8 Mode Setting

Mode setting
 USB Settings
 Evacuation Mode
 Water Tank mode
 Drying Mode
 Sterilization mode
 Electromagnetic lock mode

1) USB Setting

USB-related information can be set.

2) Evacuation Mode

The evacuation mode allows you to select "delay mode" and "pressure mode". The default is "delay mode".

Delay mode: In the pulsating evacuation process, after evacuating to a certain negative pressure value, the next stage will be injected automatically after a delay.

Pressure Mode: During the pulsation evacuation process, it will keep evacuating to the set lower pressure limit value before moving to the next stage.

3) Water tank mode

Water tank mode can be "single tank", "dual tank" mode selection. According to the hardware configuration to match the choice, the equipment does not allow modification after the factory.

4) Drying mode

The drying mode can be selected as "evacuation mode" and "back to empty mode".

Evacuation mode: the whole stage of drying keeps the evacuation state all the time, and the pressure of the inner chamber is in the state of high negative pressure in the drying stage.

Back to empty mode: keep the evacuation state in the first stage of drying, and carry out negative pressure back to empty in the late stage of drying to increase the gas flow in the inner chamber, and the pressure rises close to the standby zero level state.

5) Sterilization mode

Sterilisation mode can be selected as "temperature mode" or "pressure mode".

Temperature mode: In temperature mode, the sterilisation process is controlled by the pressure of the inner chamber recorded by the temperature of the inner chamber, and the value of "internal pressure limit" in the programme parameters is not involved in the control in this mode.

Pressure mode: In the pressure mode, the sterilisation process is controlled by the value of "internal pressure limit" set in the programme parameters during the sterilisation phase, and the value of "internal pressure limit" in the programme parameters is involved in the control in this mode.

6) electromagnetic lock mode

The solenoid lock mode can be configured as "with solenoid lock" or "without solenoid lock", and the mode is configured according to whether or not there is a solenoid lock in the structure of the opening and closing door for 45L or less volume equipment.

8.4.9 Process parameters

In the process parameter interface, you can set process parameters such as "water quality test", "printing interval", "P2 upper limit", "temperature rise interval", "evacuation delay", "delayed start", "drying delay" and so on. ", "pumping delay", "delayed start", "drying delay" and other process parameters can be set.

Process parameters

Water quality test

Printing interval

P2 upper limit

Tem. Rise interval

Evacuation delay

Dealyed start

Drying dealy

1) Water quality test

Set the upper and lower limits of the water quality value in this interface, here you need to set correctly, otherwise there will be false alarms such as "water shortage in the tank" and "poor water quality in the tank".

Detected water quality value: the actual value detected by the device, cannot be modified.

Upper limit of water quality value: the default is 3500, generally do not need to modify.

Lower limit of water quality value: Setting method: In the case of no water in the tank (water quality probe is exposed to the air) to see the "detection of water quality value" is "B", then set the "lower limit of water quality value" to "B + 30". B+30", for example, in the figure below, if the "Detected water quality value" is 1537, then the "Lower limit of water quality value" is set to 1567. After setting, select "Confirm" to complete the setting.

Water quality test

Detection water quality value: 1537

Upper limit of water quality value: 3500

Lower limit of water quality value: 1567

Confirm Back

2) Printing interval

You can set the printing interval of the printer, in the same phase of the default 60s to collect data to print once, you can take 5s as the interval unit, set the range [5,180]s.

3) P2 upper limit

Set the upper pressure limit for evaporator P2, default 240 kPa, setting range [50,280] kpa This parameter can be set if the evaporator pressure is too high or too low when running sterilisation at a temperature other than the default.

4) Temperature rise interval

In the screen of temperature rise and steam discharge, you can set parameters such as "temperature rise equilibrium time", "temperature rise equilibrium differential pressure", "post-step temperature rise differential pressure", "post-step temperature rise equilibrium time", "steam discharge stage slow discharge time", "steam discharge stage shutdown time", and so on. Equilibrium Time", "Slow Discharge Time in Steam Discharge Phase", "Shutdown Time in Steam Discharge Phase" and other parameters.

Temperature rise equilibrium time: when the temperature of the inner chamber is close to the sterilisation temperature during the temperature rise stage, the temperature of the inner chamber is controlled to maintain at a certain temperature value up and down during the stage known as temperature rise equilibrium, and the time of this equilibrium is called the temperature rise equilibrium time, with a setting range of [0,1800] s. When the load is liquid or a larger volume of the load, if there is a bad effect of the temperature penetration, this parameter can be adjusted to regulate the temperature of the load penetration and uniformity. Uniformity.

Temperature rise equilibrium differential pressure: During the temperature rise equilibrium stage, the reference value of the pressure equilibrium of the inner chamber is the pressure difference from the inner pressure limit;

Post-step temperature rise differential pressure: the difference in pressure for each rise in the post-step temperature rise phase in which the chamber pressure continues to rise after the end of the temperature rise equilibrium phase;

Post-step temperature rise equilibrium time: at the end of the temperature rise equilibrium stage, the chamber pressure continues to rise in the post-step temperature rise stage, the pressure

value after each rise in the corresponding chamber pressure value of the maintenance time.

Vapour exhaust phase slow exhaust time: at the end of the sterilisation phase after the exhaust phase, the exhaust valve opening time once;

Closing time of the vapour exhaust phase: the time when the vapour exhaust valve is closed once in the vapour exhaust phase after the end of the sterilisation phase;

5) Evacuation delay

During the pulsation pumping phase (if any) the pressure reaches the lower pumping limit and continues to delay pumping for a certain period of time, the default is 15 s. The range can be set to [0,300]s.

6) Delayed start

After selecting the device to start operation, it will start to enter the operation phase formally after a certain set time delay. Default 0s, can be set range [0,1800]s.

7) Drying delayed

At the end of the drying stage, continue the drying delay for a certain set value before ending the programme, default 0s, settable range [0,1800]s.

8.4.10 Restore Factory Settings

In the system maintenance interface, select "Restore Factory Settings", enter to restore factory settings to determine the screen prompts "OK to restore factory settings, otherwise please return", if you need to restore the OK button to determine, if you do not need to restore the return button to return. After restoring the factory settings, it is necessary to reset the "lower limit value of water quality detection", the setting method is shown in the "Process Parameters" section.

9. Maintenance technology


9.1 Safety Instructions

The following safety precautions must be read carefully when operating and maintaining this equipment.



- Burn hazard: If the ambient temperature is above 30° C, the surface

temperature of the sterilisation chamber door may be high.

- Risk of burns and electric shocks: Repairs or adjustments must only be carried out by trained personnel. Use of the appliance by untrained or unauthorised personnel or installation of unauthorised components will cause damage to personnel and the appliance.
- Observed labelled  (high voltage hazard), the main switch must be switched off before opening.

BURN HAZARD: Allow the steriliser, evaporator (if present) and other accessories to cool to room temperature before carrying out any cleaning or maintenance procedures.

Do not use the steriliser to treat flammable liquids or to sterilise liquids enclosed in glass bottles or glassware.

BURN HAZARD: The steriliser and grid shelves will be hot after the cycle process. Use protective gloves when removing loaded items.

Drop Hazard: Items should be prevented from falling. Sterile packs dropped on the floor or misplaced in an unclean place should be considered contaminated.

EXPLOSION HAZARD: This steriliser is not intended for use with any flammable liquids or any other liquids.

BURN HAZARD: When sterilising liquids, the following must be observed in order to avoid personal injury or property damage caused by bottle explosions and boiling hot liquids:

- 1) Healthcare instruments must not be sterilised for liquids that come into direct contact with patients;
- 2) Use only vented covers, not airtight screw caps or rubber stoppers;
- 3) use only borosilicate glass bottles – do not use plain bottles or bottles not intended for sterilisation;
- 4) avoid opening the door immediately at the end of the procedure. At the end of the procedure, wait for a period of time before opening the door and unloading the sterilised items;

5) Do not bump hot bottles; this may cause them to explode! Do not move the bottle if it appears to be boiling or bubbling;

6) Move bottles from the steriliser rack to the storage area only after they have cooled to the point where they can be touched.

BURN HAZARD: If the auto-complete cycle fails, wait until the programme has finished processing automatically before opening the door. Do not open the sterilisation chamber door if water is leaking through the door gasket.

Sterility Assurance Hazard: The sterility of the load will not be assured if there is a failure of the chemical indicator card, bio-indicator, BD test, etc. If these problems occur, contact a service professional for repairs before using the unit.

9.2 维护计划

Frequency and content of equipment cleaning and maintenance:

Code	Part name	Maintenance interval	Maintenance requirements	Mark
1	Chamber	Once a day	Keep clean and free of sewage	
2	Chamber filtration unit	Once a month	Keep clean and free of sewage	Located at the vapour outlet of the equipment
3	Tray(Rack)	Once a day	Keep trays (racks) clean and free of dirt	
4	Water tank	Once two weeks	Water tank walls free of dirt	
5	Door seal gasket	Once a week	Keep the surface of the door tape free of dirt	
6	Evaporator	Once a month	Tank water must meet requirements	Run the cleaning programme (if available) for cleaning
7	Water tank filter	Once a month	Filters cleaned and free of debris	

Code	Part name	Maintenance interval	Maintenance requirements	Mark
Note: The above maintenance cycle table should be flexibly adjusted in conjunction with the user's use of the equipment to ensure that the equipment is used to play a more excellent performance and better meet your needs.				



注意

Maintenance can be done with common general-purpose tools and no special tools are required.

List of spare parts maintained and replaced by specialists:

Code	Name	Use
1.	Door seal gasket	Door Seal Use
2.	Bellow	Door safety interlock use
3.	Solenoid valve	Use in piping
4.	Travel switch	Position detection

Note: For equipment accessories, please refer to the actual configuration of the equipment to find the corresponding accessory information.

Every year, check the door locking device, equipment wiring, temperature and pressure display, over-temperature temperature control protection, and internal piping connections. Check whether the door locking device is firmly pressed after closing the door, no screws loose, signal detection switch deformation and other abnormalities; check the wiring is firm, no shedding, aging, burning, damage and other abnormalities; check the temperature and pressure display and daily use of the display deviation is abnormally large; check the over-temperature and temperature-control protection is intact, there is no temperature-control protection of frequent action, wiring loosening, wire falling off, burned out, and other abnormalities occurring; Check whether the internal pipeline connection is normal, there is no leakage of steam, water and other circumstances. This kind of work needs to be carried out by professional maintenance personnel, after checking the above abnormalities found should

immediately stop using, and contact the manufacturer after-sales service to deal with.

9.3 Maintenance Guide

9.3.1 Equipment Cleaning

9.3.1.1 Water Tank cleaning

Firstly, after draining the water tank, then use a clean rag to wipe the inside of the tank and the water quality testing probe clean, and at the same time remove the dirt inside the tank.



注意

It is best not to remove the tank filter during the cleaning process to prevent dirt from falling into the drain line and the circulating water line.



注意

For sterilisation of dental handpieces the water tank should be changed after 5 procedures if there is a lot of grease in the tank and the tank should be cleaned with a rag and detergent. For other common loads and more frequent daily use, the water can be changed once every three days and the tank can be cleaned by wiping with a clean rag and water.

9.3.1.2 Door seal gasket cleaning

After removing the door seal, use a clean damp rag to wipe it down, if you can't wipe it down thoroughly you can use a cleaning agent, and finally just rinse it off with water, and at the same time wipe the seal groove with a clean damp rag. For the removal of the seal, refer to the section on replacing the seal.

9.3.1.3 Tray and rack cleaning

Use a clean, damp rag to wipe down the tray or shelves, etc., and then rinse with water.

9.3.1.4 Replacement of seal gasket

NOTE: It is recommended that the door seal be replaced when the seal appears to be yellowing, blackening, or softening, and when the unit has been in use for more than 2 years.

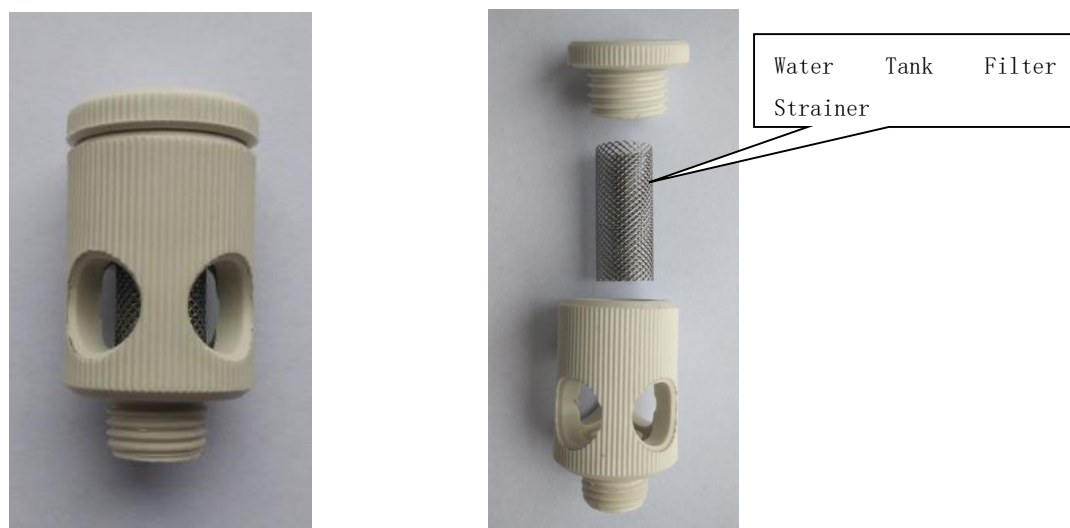
9.2 Filter cleaning and replacement

9.2.1 Inner Chamber Filter and Cleaning

The inner chamber filter is located at the vapour discharge port of the main body of the equipment, which needs to be cleaned after a period of use.

Remove the nut, take out the filter, and clean the impurities on the filter with water. Reinstall after cleaning.

9.2.2 Water Tank Filter

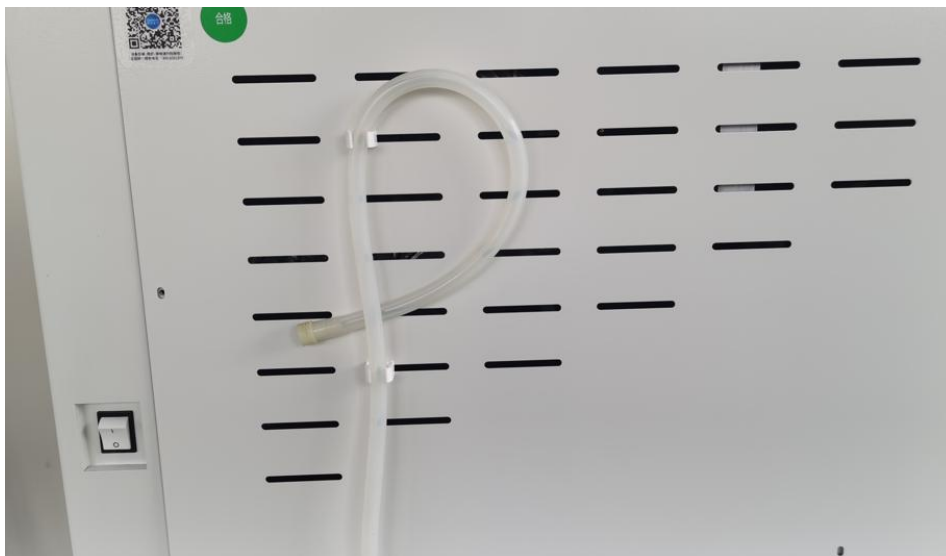


The tank filter is threaded and when cleaning or replacing it first remove the filter from the tank by rotating the filter anti-clockwise. Disassemble the filter as shown in the diagram above, then clean the filter using water and a brush. After cleaning, recover the filter and reinstall it back into the tank.

9.2.3 Solenoid valve cleaning

If the solenoid valve seal is not tight need to take out the solenoid valve parts for cleaning, cleaning is completed in accordance with the disassembly steps will be reassembled solenoid valve, this work for the solenoid valve failure sealing can not be cleaned, by professional maintenance personnel.

9.2.4 Water tank Drainage



Water tank drain is located in the equipment side cover, need to carry out drainage, the equipment side cover external fixed pipeline from the equipment side cover buckle removed, the pipeline of the pagoda plug can be unplugged to carry out drainage, after the end of the drainage, the pagoda plug again inserted into the pipeline to seal the drainage pipeline, and then the drainage pipeline will be fixed to the side cover fixed buckle can be.

9.3 Check and replace safety valves

9.3.1 Check safety valves

To prevent the safety valve from being in a blocked condition, under normal use, once a month, allow steam pressure to be released through it.

1) Run the sterilisation programme.

(2) When the pressure P1 in the sterilisation container reaches 100kPa, pull the pull ring on the safety valve so that it is in an open state for about 2 seconds, and there is a spray of steam, which indicates that the safety valve of the evaporator is working properly, otherwise the safety valve needs to be calibrated or replaced.



After pulling the pull ring on the safety valve, steam will be sprayed out, it is best to use a screwdriver and other tools when pulling the pull ring, do not use your fingers directly to pull, the operator should also try to stay away from, to prevent burns.

9.3.2 Replacing safety valves

This operation is restricted to specialised personnel only.

- 1) Remove the safety valve retaining screws and remove the safety valve from the safety valve base.
- 2) Replace it with a qualified safety valve. (Qualification criteria: Ensure that the safety valve opens when the pressure is between 0.29MPa and 0.3MPa).
- 3) Test a sterilisation process.

9.4 Replacement of printing paper

See "Printers" section for details

9.4.1 Fuse Replacement



注意

All fuses (or fuse) in this equipment need to be replaced by trained maintenance professionals, engineers and technicians. Always disconnect the power supply and check the fuse parameters when replacing the fuse!

9.4.1.1 Mainboard Fuses



First disconnect the power supply connected to the unit.

Knock out the fuse holder with a flat-bladed (one-pronged) screwdriver and pull out the cap containing the fuse.

Replace the fuse (fuse). When replacing the fuse, be sure to check whether the parameters of the new fuse are the same as the original specifications, here the parameters of the fuse are: 20A 6*32.

After replacing the fuse, insert the cover of the fuse holder containing the fuse into the fuse holder and align it with the guide groove of the fuse holder.

9.5 Battery Replacement

For equipment equipped with a battery control board and display, the battery model for the 3V CR2032 button battery, in the battery appears to run out of power, you can replace the corresponding type of battery.

9.6 Alarm information

Alarm Codes and Handling Measures

Code	Alarm code	Causes	Treatment measures
1.	E00 Program interruption	Option to stop and exit the programme while it is running	Wait for the device to prompt to return and then open the door or reselect the programme
2.	E01 Door Closed Position Disconnect	Door closure bit not detected during programme run.	Exit the programme and check that the door switch is mounted and wired correctly.
3.	E02 Chamber Overheat	Detection of inner chamber temperature exceeding the sterilisation temperature by +4° C	Check the temperature detection parts of the equipment or contact our engineers and technicians.
4.	E03 Chamber wall overheat	Cavity wall temperature over 160° C detected	Check the temperature detection parts of the equipment or contact our engineers and technicians.
5.	E04 Sterile temperature too low	During sterilisation the temperature of the inner chamber is below the sterilisation temperature for longer than the preset time.	Check the exhaust solenoid valve and clean it.
6.	E05 Vacuum overtime	The evacuation has not reached the predetermined lower limit	➤ Check for clogged inner chamber body filters and tank filters and clean them

Code	Alarm code	Causes	Treatment measures
		value within the specified time.	<ul style="list-style-type: none"> ➤ Check door rubber rings for dirt and clean them ➤ Check that the water tank is not filled with too much water to submerge the drain fitting on the inside of the tank
7.	E06 Heat-up overtime	Temperature rise phase time exceeds preset time	<ul style="list-style-type: none"> ➤ Check equipment for visible steam leaks ➤ check whether the exhaust steam solenoid valve is not sealed tightly and continue to clean ➤ Check whether the evaporator temperature is normal ($>130^{\circ}\text{C}$)
8.	E07 Water injection overtime	Filling time exceeds preset time	<p>Check equipment for visible steam leaks</p> <p>check whether the exhaust steam solenoid valve is not sealed tightly and continue to clean check whether the water injection pump, water injection valve and other components are working properly</p> <p>Check whether the evaporator temperature is normal ($>130^{\circ}\text{C}$)</p>
9.	E09 Motor operation overtime	During door opening and closing, the motor operates for more than a predetermined period of time	<ul style="list-style-type: none"> ➤ door rubber ring is installed incorrectly or not in place ➤ Loose or broken wiring inside the unit.
10.	E10 Chamber Overpressure	Inner chamber pressure exceeds preset pressure	Check pressure sensors, exhaust valves, traps, etc.
11.	E11 Evaporator overpressure	Evaporator pressure exceeds preset pressure	Check pressure sensors, heating control elements, etc.
12.	E12 Chamber sensor failure	Detection of temperature anomalies in the inner chamber, e.g. 0°C or 200°C	Check the inner chamber temperature sensor or the main board
13.	E13 Chamber wall sensor	Detection of chamber wall	Check chamber wall temperature

Code	Alarm code	Causes	Treatment measures
	failure	temperature anomalies, e.g. 0 ° C or 200 ° C	sensor or main board
14.	E14 Evaporator sensor failure	Detection of abnormal evaporator temperature, e.g. 0 ° C or 300 ° C	Check evaporator temperature sensor or main board
15.	E15 Pressure sensor failure	Detection of abnormal inner chamber pressure, e.g. -100kPa or 300kPa	Check the inner chamber pressure sensor or main board
16.	E16 Water shortage in the water tank	Tank not detecting water level	<ul style="list-style-type: none"> ➤ Water tank not adding pure water ➤ The parameters of the water quality testing device of the water tank are set incorrectly.
17.	E17 Lack of water in the circulating water tank	Circulating water tank low water level signal trigger	Fill circulating water tank to above low water line number
18.	E18 Circulating water tank full	Circulating water tank high water level signal trigger	Circulating water tank draining
19.	E20 Door unlocked	Door lock tight closing switch not detected during running programme	<ul style="list-style-type: none"> ➤ Check door locking closing switch wiring ➤ Check that the solenoid lock contacts are in place when locking the door locking switch.
20.	E21 Evaporator water level error	Storage evaporator detects low water level not detecting high water level	<ul style="list-style-type: none"> ➤ Check evaporator water level probe connection wire ➤ Check for proper ground connection ➤ Check probe PTFE insulation
21.	E22 Evaporator over-temperature	Cast evaporator temperatures over 230 ° C	<ul style="list-style-type: none"> ➤ check evaporator temperature sensor ➤ Check evaporator heating related control components
22.	E23 Motor position disconnect	Motor level switch signal not detected during programme operation	Check that the wiring and mounting of the motor position switch are secure.
23.	E24 Evaporator 1 sensing	Abnormal temperature detection, e.g. 0 ° C or 300 ° C,	Check evaporator temperature

Code	Alarm code	Causes	Treatment measures
	fault	of the first evaporator in a double-cast evaporator plant into which the injected water flows	sensor or main board
24.	E26 Door unlocked	Electromagnetic lock microswitch is not disconnected during the door opening process	Check that the electromagnetic lock is properly energised and retracted
25.	E27 Evaporator pressure failure	Faulty evaporator pressure detection	Check evaporator pressure sensor or control main board
26.	E28 Configuration code error	Configuration code configuration error	Reconfigure the configuration code according to the configuration code configuration instructions.
27.	E50 Communication Failure Alarm	Communication error between display and control board	Check the display and motherboard
28.			

Note: The above list is only an alarm query table, due to equipment differences, some alarm codes are not configured in different volume, order number equipment, please note that when querying. In winter, when the ambient temperature of the equipment is lower than 0 °C, there may be "E12", "E13", "E14" and other temperature sensor failure alarms, which can be waited for a while when the environment in which the equipment is located rises to 0 °C. If the ambient temperature of the equipment is higher than 0°C, the alarm will be cancelled when the equipment is powered off and then powered on again.

10. Accessories

The list of accessories that come with the regular equipment (the accessories that come with the special equipment may be different, subject to the actual accessories that come with the equipment, the following table is for reference only). The "(xxL)" in the specification list below indicates that the accessory is only available for that volume model.



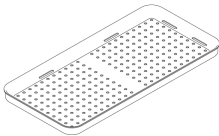
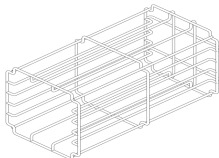


注意

1: Parts or spare parts used in this equipment can only be inspected or supplied by our company or our regular agents.



注意

2: If you have optional USB or SD card data reading function, there will be USB or SD card data reading software and other related accessories in the attachment. Regarding the USB or SD card data reading software, please refer to the software installation and use instructions.

Code	Name	Specification	Photo	Mark
1	Tray	24L		Contain sterilised items and place in tray racks when in use.
2	Rack	24L		Holding trays or sterilized items
3	Tray picker	18L/24L		Pick and place tray to prevent burns
4	Print paper (optional)	56*30		Device print paper, replace it when it runs out, see the section on replacing print paper for details on how to replace it.

- ✓ Appendix A Operating Procedures
- ✓ I. Pre-shift Preparation:
 - ✓ Water tank add pure water as required or equipment connect water source as required.
 - ✓ Turn on the power supply and place the steriliser power supply in the on state to prepare for the operation of the procedure.
 - ✓ Determine whether to perform a B-D test according to the specified requirements or load type;
 - ✓ Arrange the package to be sterilised, the bundle is not easy to be too tight, with chemical indication tape outside and chemical indication card inside.
- ✓ Second, the sterilisation operation:
 - ✓ According to the requirements of the regulations if the B-D test, to be qualified for the test or to complete the preheating, the items to be sterilised and disinfected into the sterilisation chamber, packages and packages should leave a gap between the four sides do not stick to the wall of the machine and the door.
 - ✓ Close the door of the steriliser, select the sterilisation procedure according to the sterilised articles, check whether the sterilisation parameters are correct and start the procedure.
 - ✓ During the process of sterilisation, the operator should not be far away from the equipment, and should closely observe the operating condition of the equipment, and if there is any abnormality, deal with it in time to prevent accidents from occurring.
 - ✓ Do a good job of monitoring the effect of sterilisation, record archives, to facilitate tracking and investigation.
 - ✓ After the end of the sterilisation, wait for the pressure in the room to return to zero before opening the door to take out the items.
 - ✓ After the sterilised items are removed from the steriliser, they should be carefully checked and placed to prevent secondary contamination.
- ✓ Third, the work after the shift:

- ✓ Open the cabinet door, put the power switch in the disconnected state, and cut off the total power supply outside the equipment.
- ✓ In the tip of poor water quality or continuous uninterrupted operation of five sterilisation processes must be replaced after the water.
- ✓ daily work is completed, the inside and outside of the steriliser should be kept clean, you should use a clean rag and water to clean the inner chamber of the dirt, once a week a small maintenance, once a month a large maintenance.
- ✓ Fourth, precautions:
 - ✓ Sterilised items shall not be mixed with unsterilised items.
 - ✓ qualified sterilised items, should indicate the date of sterilisation, qualified mark.

