Autoclave (MOST-T) Operation Manual

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Please read the Manual before using the equipment.

Before using the equipment for the first time, you should read through this Manual to familiarize yourself with the operation of the equipment and its safety instructions.

Please keep the Manual intact for the lifetime of the equipment.

Make sure that all updates received are saved in the Manual.

In the event of a change in the site or unit of use of the equipment, you must ensure that the Manual is transferred or handed over as part of the equipment as a whole.

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Safety precautions

This machine is equipped with some necessary safety guards.

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

Important matters

- Please read this Manual carefully before use.
- The machine must be operated by authorized personnel. Operators must receive relevant training.
- Since the machine uses steam, please take the necessary anti-scald measures before use.
- Please keep the machine clean for proper operation.
- Do not rinse or wash the machine with water.
- Installation and maintenance work must be performed by trained personnel.
- If the machine leaks due to a worn door seal, etc., be sure to repair it immediately.
- Machine related parts can only be obtained from SHINVA, otherwise normal operation of the equipment cannot be guaranteed.

Isolation switch

This machine must be equipped with a lockable power switch. The switch must be easily reachable on the wall near the machine. It must be installed and marked according to local regulations.

Emergencies

- Turn off the main power switch.
- Close the steam supply line stop valve (if any).
- Close the water supply line stop valve.

Product Responsibility

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

Warning Symbols

Special attention should be paid to the caution, warning and danger symbols in this Manual

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<u>1.</u>Preface

This Manual is applicable to the installation, operation and maintenance of **Shinva MOST-T Steam Sterilizer**.

Please read this Manual carefully before use to ensure that this equipment is safe and reliable for you! This Manual does not specifically indicate the actual configuration of the product, please refer to the product you have purchased and the accompanying packing list.

Product information

- Structure and composition: The product consists of the main body of the sterilizer, sealing door, piping system and control system.
- Product performance: Saturated steam is used as medium to achieve sterilization and disinfection under high temperature conditions, and the number of pulsations can be set as required.
- 3) Product application (use) range: for medical and health care, scientific research and other units for medical devices, laboratory vessels, culture media and non-closed liquid or preparation, and blood or body fluids may contact the sterilization of materials.
- 4) Contraindications: None
- 5) Main sterilization factor and intensity:

This equipment uses moist heat steam as the sterilization factor.

6) Sterilization principle

This equipment adopts a specific process to discharge the cold air from the sterilizer chamber and use saturated wet hot steam as the sterilization factor to achieve sterilization of items that can be penetrated by steam under high temperature, high pressure and high humidity, according to the combined effect of certain pressure and time.

- 7) Microbial killing category: killing bacteria and spores.
- 8) Special storage and transportation conditions and methods: None
- 9) production date: see the equipment nameplate
- 10) Use period / life: 8 years / 16000 cycles

1.1. Safety

Special attention should be paid to the cautions, warnings and dangers in this Manual.



Potential hazard to the equipment and should be given high priority.

Potential harm to personnel and must be strictly observed.

Damage to equipment or persons and must be strictly observed.

The replacement and repair of parts should be carried out by Shinva after-sales service company. shinva is not responsible for any damage to equipment, environment and person caused by private replacement of parts.

This sterilizer is only suitable for sterilizing medical instruments and items that are resistant to high temperature and high humidity, and cannot be used for sterilizing oils and powders such as petroleum jelly

It is strictly forbidden to use this equipment to sterilize liquids enclosed in glass bottles or glassware, because the operation or changes in temperature or pressure may cause the liquid bottles to burst and endanger the safety of people and equipment.

Before performing any operation, maintenance, or servicing of the equipment, please read and fully understand the contents of each section of the Manual, especially those marked with the above-mentioned symbols that should be noted. If the equipment is not used in the manner prescribed by the Company, the protection provided by the equipment may be impaired.

The Manual must be kept in a safe place to prevent loss or damage, and even

minor breakage should be avoided. The operator is obliged to repair and make up any part of the instruction manual that is lost, damaged or no longer applicable. No one, under any circumstances, may tear off or remove any part of the instruction manual from it. If you encounter a discrepancy with the instructions in the operating instructions or a situation not covered by the instructions, please contact the manufacturer for an upgrade or update.

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

This equipment is not suitable for sterilizing tightly sealed bottles of liquids. If you want to sterilize the above mentioned liquids, please contact us and we will choose a special sterilizer for you.

When using this equipment to sterilize tightly sealed bottles of liquid, it is easy for the operator's negligence or violation of operating procedures to explode the bottle, seriously endangering the safety of the person and equipment.

Chlorine ions are an important factor in the corrosion of stainless steel. Sterilizers are prohibited from sterilizing items containing chloride ions to avoid corrosion of internal stainless steel by deposited chloride ions and to extend the service life of the equipment.

If you see Anywhere on the equipment, consult the relevant documents, such as the Manual, in order to clarify the nature of the potential hazard and any countermeasures that must be taken.

When you see in any position of the equipment, it means that its surrounding temperature is high, please pay attention to avoid burns.



1) The unit using the product should carry out routine maintenance of the equipment during use and regular self-inspection.

2) The product unit should be in use at least once a month for self-inspection, and make records. The use of units in the use of products for self-inspection and routine maintenance of abnormalities found, should be dealt with in a timely manner.

3) The product unit should be used in the product safety accessories (safety valves, pressure gauges, etc.), safety protection devices, measurement and control devices and related subsidiary instruments for regular calibration, overhaul, and to make records.

4) The product operator and its related management personnel, in accordance with relevant state regulations by the special equipment safety supervision and management departments to pass the examination, obtain the national special operator certificate before engaging in the corresponding operations or management.

5) The use of units should be the operators of special equipment safety, energy saving education and training to ensure that special equipment operators have the necessary special equipment safety, energy saving knowledge. The product operators in the operation should strictly implement the operating procedures of special equipment and related safety regulations.

It is recommended to evaluate the electromagnetic environment before using the equipment. Prohibit the use of this equipment next to strong radiation sources (e.g., unshielded RF sources), as this may interfere with the proper operation of the equipment

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If there is an accident during the proper use of the product, if the device alerts or other malfunctions occur, please immediately cut off the power to the device and correct the malfunction according to the "Alarm Codes and Troubleshooting" the Manual, if the malfunction cannot be solved, please contact the manufacturer.

Before running the sterilization process, perform the necessary monitoring in accordance with national and regional regulations. Place the monitor (e.g. biological or chemical indicator) in the device, run the appropriate cycle to monitor the sterilization effect, and evaluate the results. If it passes, it can be used normally, if it fails, find the reason or contact the manufacturer.

When the equipment reaches the end of its service life or needs to be disposed of, please recycle it according to the relevant local recycling methods. Special attention should be paid to the batteries in the control system during the recycling process, which should not be discarded at will and should be put into the special recycling box set by the relevant organization.

When the sterilizer is in normal operation, the noise is measured with a sound level meter at 1m from the sterilizer and 1m from the ground height in 4 directions: left, right, front and back, and the noise is not more than 70Db (A weighting).

<u>1.2.</u> Symbol Description

<u>1.2.1.</u> Equipment Symbol

Table 1-1 List of Key Labels

	=		- /
No	Symbol	Function	Remarks

1	ESC	Return	
2	ОК	ОК	
3		Open	
4	▼	Down	
5		Up	Depends on different model

<u>1.2.2.</u>Label

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

Table 1-2 Table of safety signs

	0	Ţ	
On (power supply)	Off (power supply)	Ground (ground)	Protective
IEC417, No. 5007	IEC417, No. 5008	IEC417, No.5017	ground(ground)
			IEC417, No. 5019
	\sim 2	Λ	<u>^</u>
DC	AC	Refer to the attached	Pay attention to electric
			,
IEC417, No. 5031	IEC417, No. 5032	files	shock
IEC417, No. 5031	IEC417, No.5032	files ISO3864, No. B. 3. 1	shock ISO3864, No. B. 3. 6

Pay attention to the	Reference	Keep dry	Temperature limit			
surface overheating	instructions					
IEC417, No.5041						
	1					
X	4 4					
	*	and the second s				
Avoid sun exposure	Take care to prevent	Fuse				
	high voltage					
	IEC417, No.5036					
Safety symbol						

<u>1.3.</u> Technical Parameters

Table 1-	-3 моз	ST-T S	steri	lizer	parameters table	
				,		-

Product codo	Volumo	Chamber size /	Power supply	Input power /
Floader code	volume	mm (available)	Power suppry	KVA
T24	24L	Ф250×450	AC 120V 60 Hz	1.5
T45	45L	Ф316×618	AC 120V 60 Hz	3.0

- Design pressure: -0.1/0.30MPa
- Design temperature: 144°C
- Vacuum lower limit: -0.08MPa (B type)
- Temperature range: 105~138°C
- Temperature display accuracy: 0.1°C
- Pressure display accuracy: 1kPa

See equipment nameplate for details of specific equipment types.

2. Installation

Installation of sterilizers is usually performed by after-sales service personnel or official authorized engineer. The after-sales service personnel are trained in the installation, operation and maintenance of SHINVA sterilizers. These installation details are part of technical confidentiality and will not be repeated here. If you want to do the installation yourself, you can contact our local office sales staff and accept the guidance and supervision of SHINVA during the installation in order to ensure the quality assurance of the equipment during the warranty period.

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

2.1. Installation Requirements

2.1.1. Energy and facility demand

2.1.1.1. Water demand

The equipment itself comes with its own water tank, no need to connect water source, only need to manually add water to the equipment water tank. Equipment water must be used pure water, water quality to meet the following requirements:

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

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

After adding water to the tank, if prompt "Poor water quality", indicating that the water quality is not qualified, please replace the water quality to meet the requirements of the water source.

2.1.1.2. Power demand

1) 24L :

After placement, check whether the power supply meets the requirements: AC 120V 60Hz single-phase power supply, fluctuation range \pm 10%, power supply power \geq 1.5kVA. Plug will be plugged directly into the matching socket when the equipment is powered on.

2) 45L:

Power supply requirements AC 120V 60Hz single-phase power supply, fluctuation range \pm 10%, conventional equipment power cord without plug directly to the circuit breaker, power supply single-phase \geq 3.0kVA.

It is recommended to install a special wiring device (such as socket or circuit breaker) suitable for wiring at a height of 1 meter on the building near the equipment. Please do not place the equipment 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 the same size as the power plug of the power cord.

45L equipment about the circuit breaker "ON" is connected, "OFF" is disconnected.

When installing the equipment, please install the leakage protection device to prevent the safety problem caused by the damage of the parts.

<u>2.2.</u> Safety instructions

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

2.3. Equipment transportation

2.3.1. Dimensions and weight

Before the installation of the equipment and during the installation process, the professional construction personnel should be responsible for recording the name and model of the equipment under the guidance of the professional personnel so that the technical consultation can be made to shinva. Installation space requirements and equipment size are as follows (the following equipment size drawings are for reference only, the specific object shall prevail):



Do not install the equipment in a position where it is difficult to operate the equipment and the power switch of the equipment.



Front View

Right View



Item	Dimensions				
Volume	24L	45L			
L(mm)	659	855			
W(mm)	530	640			
H(mm)	390	500			
A(mm)	500	500			
B(mm)	410	537			
C(mm)	478	649			
D(mm)	50	52			

E(mm)	500	500
F(mm)	455-465	595-615
G(mm)	425	565
Weight (Kg)	65	115

2.3.2. Unpacking

1) Package disassembly

Open the top packaging cover , then remove the outer packaging of the equipment in turn, then take the equipment out of the packaging box, and finally remove the plastic film.

$\Delta_{\text{Handling precautions!}}$

- It is forbidden to lift the door when handling the equipment
- It is forbidden to lift the legs of the equipment when handling.
- It is forbidden to put the equipment on its side or upside down when handling.
- The diagram of the handling position when handling equipment is as follows:





Front end

Figure 2-2 Diagram of handling attention

Note: The above diagram is for reference only.

- 2) Equipment inspection
- After unpacking the equipment, first check whether the model number and name on the product nameplate match with the order form. (The product nameplate is usually on the rear cover of the equipment)
- Check carefully whether the equipment parts are intact, damaged or missing according to the equipment packing list, if so, make a record and contact shinva in time.
- Check carefully whether the connection or fixed parts are loose due to long-distance transportation, and tighten them if there are.
- Inventory and record the accessories carried with the equipment, and the relevant documents matched for proper storage.
- Do not tear off the protective film of the equipment before commissioning.

2.3.3. Storage environment

After the sterilizer is packed, it should be stored in a dry, ventilated, non-corrosive indoor or sheltered place.

2.3.4. Normal working conditions

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

➤ Ambient temperature 5°C---40°C

- ⊳ Relative humidity not more than 85%
- Atmospheric pressure 70kPa ---- 106kPa \triangleright

Note: When the ambient temperature of the equipment is lower than the normal working condition temperature, or there is a possibility of icing, it is necessary to drain all the water in the water tank after the use of the equipment, and use compressed air to blow out the water stored in each pipeline of the equipment 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 is lower than 0 $^{\circ}$, if there is stored water in the equipment, icing may damage the pipeline. In winter, you can turn on the warm up mode to preheat it before use.

2.3.5. Positioning and leveling

The equipment can be placed on a horizontal table when it is installed. After that, the front and rear height of the equipment should be adjusted according to the requirements of the following diagram to prevent the equipment from storing too much water (the equipment drainage and vapor discharge port is at the back end).





2.4. Electrical installation

2.4.1. Cable connection

The equipment comes with a cable for the connection between SHINVA equipment and user junction box. The electrical installation must be operated by professional personnel on site, and the external wiring current carrying condition is described in the "Power Requirements" section. In order to ensure the safety of the person and equipment, a ground wire must be laid, and the ground wire in the equipment shell and control cable must be reliably connected to the external ground wire.

The equipment must be reliably grounded!

2.4.2. Phase sequence check

For single-phase electrical equipment power supply for the fire line, zero line, ground, with a plug device power cord into a matching socket, without the plug power cord red for the fire line, blue for the zero line, yellow / green line for the ground.

2.4.3. Power on commissioning

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

Please turn the power on before opening the door of the equipment! The specific door operations see the Door Operation.

- After the energy conditions, piping installation and electrical installation are completed, open and check whether the water and electricity supply of the equipment is normal.
- 2) Turn on the power switch of the equipment and supply 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 that each valve can be opened normally.
- Check the switch door. Click on the switch door button to confirm that the sealed door can run smoothly without any noise.
- 5) Check the printer (if any), the printer self-test is normal and printing is clear.

2.5. Commissioning

2.5.1. Add water

- 1) Prepare pure water, and prepare a container of water, easy to add water to the tank.
- 2) Be careful not to let the water splash outside the tank.
- 3) Add pure water to the tank, add water to reach the position between the lowest water level line and the high water level line, cover the tank lid (if any) to prevent some debris from falling into the tank.

Equipment water must be pure water, add water at least above the low water mark, to the high water level when about 4L water (24L equipment), 14L water (45L equipment).

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

If there is "Poor water quality in the tank" screen when the equipment is running for the first time, it means that the water quality in the tank does not meet the requirements and the tank water needs to be replaced.

If there is no water in the equipment tank but there is no water shortage alarm prompt, 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 beeping, continue to add water to ensure that the water level is between the high and low water level. When the water level is higher than the high water level (Max) will affect the evacuation performance of the equipment, and easy to splash water outside the tank!

2.5.2. Atmospheric pressure setting

When the equipment is installed for the first time, it is necessary to set the atmospheric pressure value, otherwise the door will not open. In accordance with Chapter 8 of this Manual, "Manager's Manual" - "Common functions of the control system" - "Atmospheric pressure setting" to set the atmospheric pressure value.

2.5.3. Warm-up setting

When the equipment is installed for the first time, the warm-up mode can be turned on (not compulsory), and some heating elements can be heated in standby mode after the preheat mode is turned on to shorten the cycle running time appropriately. Set the preheat mode according to the method in Chapter 8, "Manager's Manual" - "Common Functions of Control System" - "Preheat Mode Setting" in this manual. 2.5.4.

2.5.4. Safety valve and instrument calibration

Before starting the equipment, the safety valve and pressure gauge should be calibrated according to the relevant local policies and regulations.

In the normal use cycle, the safety valve and pressure gauge should be regularly calibrated according to local regulations.

2.5.5. Other tests

According to the type of equipment, choose whether to carry out the leakage test or not, if the equipment does not have the function of pulsating vacuum, the leakage test is not necessary. The leak test is to check the sealing integrity of the pipes connected to the inner chamber of the equipment to ensure that there is no air in the cold air removal phase of the sterilizer. Run the leak test cycle that comes with the device, and the test results will be shown in the printed record after the test is completed. The leak rate should not exceed 0.13 kPa/min.

Choose whether to perform the B-D test according to the type of equipment and relevant policies and regulations. if B-D test is performed, it can be performed as follows: under no-load conditions, put the B-D test object in the front bottom layer inside the sterilizer, near the cabinet door and exhaust port, with no objects inside the cabinet except the test object, after the B-D test cycle, take out the B-D test paper and observe the color change; the B-D test paper changes color evenly and uniformly (completely and evenly). If the B-D test paper changes color unevenly, the sterilizer is qualified; if the B-D test paper changes color unevenly, the sterilizer is unqualified and the reason for the failure of the B-D test should be checked until the B-D test is passed, then the sterilizer can be used again.

BD test is not a sterilization effect test, but a functional test of the sterilizer. It is not a substitute for routine monitoring of the sterilization process.

2.5.6. Biological monitoring

Bio-monitoring is used to test the sterilization process and the sterilization effectiveness of the sterilization equipment.

Biological monitoring should be performed for new installations and during the normal use cycle of the equipment according to relevant policies and regulations.

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2.5.7. Delivery

The equipment can be delivered to users only after the relevant performance test is completed and qualified after installation.

3. Function

<u>3.1.</u> Overview

Note: The following in this section is a schematic diagram of the appearance of the equipment, for reference only, the details of the actual appearance of the equipment shall prevail.

24L/45L equipment as follows:



Figure 3-1 Equipment appearance diagram I

Table 3-1	Part	name	list
-----------	------	------	------

SN	Name	SN	Name
1	Water tank	10	Door Cover
2	Side cover	11	Door gasket
3	Display screen	12	Equipment top cover
4	Keypad area (see 3.2 for	13	Power Cord
	details)		

5	Switch and print area	14	Door lock hook
6	Drain port	15	Pressure gauge* (see
			Note 3 below)
7	Door close position micro		
	switch		
8	Carrier rack*		
9	Equipment foot		

Notes:

(1) Carrier rack *: different volumes of equipment are slightly different, the picture for reference only, subject to the actual equipment configuration.

(2) Pressure gauge; because of different volume equipment configuration, the pressure gauge configuration is slightly different, depending on the actual equipment.45L equipment has a pressure gauge to indicate the chamber pressure.

Other visible parts of the equipment are as follows:

Table 3-2	2 Diagram	of	other	visible	parts
-----------	-----------	----	-------	---------	-------

Picture	Name	Picture	Name
	Power switch		Safety Valves
	Printer (Optional)		Chamber filters
	U disk interface (Configured when U disk reading function is optional)		Air filter

	Filter (Inside water tank)	Fuse (18L/24L, on the rear cover of the equipment)
	Water Level Probe (Inside water tank)	Circuit breaker (29L/45L, on the rear hood of the equipment)
Max Min	Water level indicator line (Inside water tank)	Circuit breaker (60L/80L)
	Water circulation outlet (Inside water tank)	Heat sink (on the rear cover of the equipment)
	Water tank drainage port (below the right side of the main body after opening the door)	Evaporator water release switch (60L/80L)
	Pressure gauge (45L and above volume)	Evaporator water discharge port (60L/80L)
00	External water connection (Order No. T18-J/ T24-J)	

3.2. Working Principle

This sterilizer removes the cold air from the chamber and then uses saturated hot and humid steam as the sterilization factor to achieve sterilization of items that can be penetrated by steam under the combined effect of a certain temperature and time. All preset process parameters of this equipment are set with thermophilic fatty liver bacilli budding at specific resistance or microorganisms of equivalent performance (see relevant national standards for details) as representatives of sterilizable microorganisms under the load described in this cycle.

Note 1: When the sterilization load may be infected with microbial resistance 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 microorganism, and only after the corresponding process confirmation can be used.

Note 2: The killing ability of the sterilization factor for the agreed microorganisms can only be effectively guaranteed when the equipment and related facilities are in normal working condition. Equipment failure, external connection system failure, and irregular loading of the sterilized load may affect the killing effect of the sterilization factor.

Note 3: When the load to be sterilized changes, the operator should verify whether the load to be sterilized is suitable for sterilization in this equipment before carrying out the relevant operation, otherwise it may cause unpredictable damage to the equipment or the load!

Note 4: The temperature sensor be positioned so as to measure the temperature of the steam at a location as close as is practical to the coldest point within the chamber.

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3.3. Structure and function

The product consists of sterilizer body, sealing door, piping system and control system. With saturated steam as the medium, it achieves sterilization and disinfection under high temperature conditions.

The piping structure of the product is as follows.

Steam inlet pipeline: Steam enters the main body of the equipment from the evaporator through the steam inlet pipeline. (24, 45L): Injection pump, water inlet valve, cast evaporator.

Return air pipeline: air enters the inner chamber through the return air pipeline to balance the negative pressure of the inner chamber, the main components: return air filter, return air solenoid valve, one-way valve.

Evacuation (exhaust) pipeline: exclude the inner chamber steam as well as through the vacuum system to complete the function of evacuation (for equipment with vacuum function), the main components: filter, one-way valve, evacuation (exhaust) valve, F5 slow discharge valve (if any), condenser.

Vacuum system (if any): through a specific structure to complete the function of evacuation, the main components: water tank, filter, circulation pump, condenser, ejector.

Inlet pipeline: inject water into the evaporator through the pump. Main components: water tank, filter, pump, water injection solenoid valve.

3.3.1. Operation panel

Key Introduction:

SN	ICON	Function	Remarks
1	ESC	Return	
2	ОК	Confirm	

Table 3-3 Key Introduction Table

3		Door open	
4	▼	Down	
5		Up	Some equipment are not configured

Note: The specific icon has been subject to the actual machine

1) Return

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

- 2) OK
- Press this key to select the icon where the cursor is located
- When setting parameters, used as the moving cursor
- 3) Open

Open the door by pressing the key

- 4) Down
- Press this key to move the cursor down or to the right
- When setting parameters used as a minus key (long press for continuous minus)
- Page turning function
- 5) Up
- Press this key to move the cursor up or to the left
- Use as the plus key when setting parameters (long press for continuous plus)
- Page turning function

Icon displaying description:

The display is normal, without flicker, garbled code, no display and other abnormalities, and can be operated normally according to the operation manual. When the cursor moves to the selected icon or parameter name, the color of this part will be reversed: for example, when the cursor is not on the icon



When the cursor moves to the icon:

III 🐜 🌣 🗙 📐

Table 3-4 Meaning of each icon

SN	Icon	Function
4		The cursor moves to this icon, press OK and jump to the
		SELECT CYCLE screen.
2	*	The cursor moves to this icon, press OK and jump to the
2	*	SYSTEM SETTINGS screen
2		The cursor moves to this icon, press OK and jump to the
3		SERVICE and screen
4		The cursor moves to this icon, press OK and jump to the
4		ALARM screen
F		The cursor moves to this icon, press OK, the cycle starts,
5		the screen jumps to the cycle running screen
C		The cursor moves to this icon, press OK and jump to
	PARAMETER VIEW screen	
-	- ta=	The cursor moves to this icon, press OK and jump to the
	لگا	parameter settings for running cycle
0	L.	The cursor moves to this icon, press OK and jump to the
0	m	I/O information view screen
		The cursor moves to this icon, press OK and jump to the
9		process data viewing screen (running time of each
		stage).
10	a	The cursor moves to this icon, press OK and jump to the
10	\square	ABORT CYCLE confirmation screen.

3.3.2. Gauges

Some equipment is equipped with pressure gauges for indicating the pressure of the equipment. Among them, 45L is equipped with one pressure gauge to indicate the chamber pressure.

3.3.3. Door

The door is mainly composed of door plate, door cover, door gasket, door lock structure and other components.

Do not put your hands and other objects on the inside of the door hood of the cabinet door or on the direction of door operation when closing the door!!

1) Door lock mechanism

60L (excluding) below the volume of equipment using the door motor work to drive the door lock hook rotation, the door lock hook directly pull the door tightly locked structure.



Figure 3-4 Below 60L door open and close schematic

2) Door open and close

Open and close the door operation see "Door Operation" section.

3) Safety interlock
60L and above volume equipment is equipped with safety interlock structure, when the door motor work drive ring rotation to a predetermined position, the electromagnetic lock release will drive the ring lock system can not be turned to ensure that the door will not be opened by mistake, to ensure the safety of the operation process.

4) Gasket

Structure: The seal ring is a specially processed annular silicone rubber ring, is an important part of the sealed interior environment, it is in a constant state of extrusion and stress, correct installation and maintenance of its normal work and service life is essential, shinva uses a special formula of silicone rubber material to effectively ensure its stability and reliability in high temperature working environment.

Principle: The sealing ring is installed in an annular groove on the end face of the cabinet door frame. After closing the door and the door plate closely pressed together to achieve the door seal.

Use: The installation process will be evenly pressed into the groove of the door plate, be careful not to install it backwards. For installation of the door rubber ring, see the section "Replacing the door rubber ring".

Please make sure that the chamber pressure is balanced with the external atmospheric pressure and the liquid temperature is below the boiling point before opening the door automatically or manually!

<u>3.3.4.</u> Description of safety devices

The sterilizer is equipped with the following safety devices:

- Over-temperature automatic protection device: The evaporator and the wall of the pot are equipped with double over-temperature automatic protection.
- Door safety interlock device: with automatic door lock, the sterilizer can start the working procedure only when the door is closed in place; the door cannot be opened when the inner chamber is under pressure or the power is not connected.
- > Safety valve with automatic pressure relief: when the set pressure is exceeded, the

safety valve opens to release the pressure.

Electronic circuit safety device: DC control circuit over-voltage and overload protection, AC main circuit short-circuit protection.

3.3.5. Printer(Optional)

Printer is optional, please refer to the actual equipment for the specific availability of printer. Printer information:



Figure 3-5 Printer

Printer parameters:

- 1) Print method: line thermal printing
- 2) Print paper width: 57mm
- 3) Effective printing width: 48mm
- 4) Print head life: 6000000 lines
- Thermal paper specifications: 57mm wide, 30mmφ
 Printer structure and print paper replacement see section 5

<u>3.4.</u> Cycle

The equipment is equipped with 10 sets of cycles by default, among which the "B134UNIV.", "B121UNIV.", "USER", "N-Quick", "B-Quick" are all sterilization cycles, "BD Test" and "Leak Test" are testing cycles, and "Preheat", "Drying" and "Cleaning" are auxiliary cycles.

Depending on the equipment configuration, some equipment cannot start certain class cycles; Class B type equipment can start vacuum class cycles ("B-Quick", BD Test, "Leak Test", etc.), Class S type and class N-type equipment cannot start vacuum class cycles, and Class S type N-type equipment cannot sterilize cavity class loads. Other specific information can be

found on the equipment nameplate information.

4. Preparation

4.1. Daily check

- Check whether the printer's print paper (if configured) has been properly placed and whether it is out of paper.
- Check whether the pressure gauge (if configured) is at zero (at standard atmospheric pressure) in standby mode.
- Check whether the equipment has obvious steam leakage or other abnormal phenomena.

4.2. Equipment start-up

4.2.1. Water supply

Check whether the water level of the water tank is between the high and low water level, if the water tank is short of water, please add water to the high and low water level, the water tank level exceeds the high water level, please drain to the high and low water level, please refer to the water tank drainage section for the specific method.

4.2.2. Power-on

Press the "ON" end of the switch to power on the equipment, if the equipment is equipped with circuit breaker, please power on the circuit breaker switch first. If the power switch is turned on, the sterilizer without alarm can be used normally without preparation time.

5. Operation description

5.1. Door operation

24L/45L:

Door close: push the right side of the door cover by hand or hold the door clasp to push the sealing door, the device detects the door closed, then automatically closes door, the screen prompts "closing", when the closing action is completed, the screen prompts "door closed", you can start the cycle and other operations as needed.

Door open: When the temperature and pressure of the equipment are normal and the cycle is not running, just press the door open button, the equipment will start to automatically execute the door open action, the screen will prompt "opening the door", when the door open action is completed, the screen will prompt the door open or please open the door, at this time the door has been unlocked, pull the buckle position to open the door.

Close operation:

When close the door in the door open state, pull the door handle with your hand to turn outward at a certain angle, the other hand press the door plate, press the door to the close state position, the right hand to pull the door handle to turn inward to restore the original position, so that the door safety lock press the door closed position micro switch. After pressing the door closed, you can let go of the hand and wait for a while, after the pressure balanced in the chamber, the door motor automatically starts to work, drive the drive ring and door lock hook rotation. After the rotation in place, the door motor stops rotating, the electromagnetic lock locking, closing the door operation is over. Door close process display door state change in order to "door open", "door closing", "door closed".

Open operation:

Under the condition of opening the door, press the "door open" key, the display screen prompts "door opening", the electromagnetic lock is powered back, the door motor works, driving the drive ring and the door lock hook rotation. Rotate in place, the door motor stops rotating, then rotate the door handle outward at a certain angle and pull the door handle to open the door. In the standby state, in line with the conditions of the door, if the door handle is pulled directly outward rotation, it can also trigger the door motor to work to complete the door opening action. Open the door process display door state change in order to "door closed", "door opening", "door open".

When the atmospheric pressure at the installation of the equipment is 1 (i.e., in door open state, the chamber pressure display is 0), the pressure condition of the door can be opened and closed for \pm 5 kPa; when the equipment is located in high altitude areas, the door pressure will drop accordingly.

When the detection of the chamber pressure is not within the range, press the door button, it will not open the door and prompt "does not meet the conditions to open the door, can not open the door". At this time, you need to check the equipment chamber pressure, atmospheric pressure and operating status.

A method to safely access the chamber and load in the event of a power failure:

1) Remove the screws using a screwdriver and open the side cover of the device.



Remove the screws in the red boxes by a screwdriver to uninstall side cover of the device.

2) How to open the door by manual



After removing the side cover, the structure in "Figure A" can be seen. Then please press the electromagnetic lock with one hand as shown in "Figure B". Next step, please pull the metal column of the motor hook with force as shown in "Figure C", the purpose is to pull the door motor hook from the closed position. Please note that it requires certain strength to pull the motor hook. After the door motor is pulled apart, the position changes as follows, from the state in "Figure D" to the state in "Figure E".





3) After the motor is pulled, the door can be opened directly



After pulling the door motor hook in step (2), the door is unlocked, and the door can be opened directly in front of the device.

<u>5.2.</u>Load

- Loaded items should not touch the sterilizer chamber wall, and gaps should be left between sterilization packages to facilitate the penetration of sterilization media.
- The catheter should be placed in such a way that both ends are open and without sharp bends or twists.
- Instruments should be placed with openings down or on their sides to prevent water storage.
- 4) Instruments should be placed evenly and spaced apart without overlap, as this may cause inadequate sterilization and drying.
- 5) It is advisable to sterilize instruments, appliances and articles of the same material in the same batch. If the materials are not the same, textile items should be placed vertically on the upper layer and metal instruments on the lower layer.



- 6) It is forbidden to place pallets of packaged items and instrument pallets on textiles or softer items to avoid the formation of condensation and wetting of the items below.
- It is forbidden to place pallets of packed items and trays of instruments on textiles or softer items to prevent condensation from forming and wetting the items below.

5.3. Select cycle

Refer to the following steps:

Select the "I" on the main screen and press the "ok" key to enter the select cycle screen, select the cycle type (sterilize cycle, test cycle or auxiliary cycle). Select the sterilize cycle to enter the select cycle screen, and move the cursor to select a specific cycle.



P1: 0kPa T1: 32.1℃ T3: 32.1℃ T2: 32.1℃ Cycles: 0000 Serial No: 000000 Fast-start:XXXX Sterilize program Test program Auxiliary program SELECT CYCLE B134UNIV. B121UNIV. USER N-Quick B-Quick

Figure 5-2 Select cycle flow chart

Click Quickstart to run is the same as the one you ran last time. You can click here to quickly start the last selected cycle directly from memory.

The default parameters of the cycles and the applicable load types are shown in the following table.

Cycle	Sterilize Temp./°C	Time/s	Dry time/s	Applicable load type
				Type B: High temperature resistant packaged
				or unpackaged solid or hollow instruments,
B134UNIV.	134	240	1200	fabrics, etc.
				Type S: High temperature resistant packaged
				or unpackaged solid instruments, fabrics, etc.
	121	1200	1200	Items such as rubber and fabric instruments
BIZIONIV.				that are not resistant to high temperature
USER	134	240	1200	User parameters are available upon demands
	134	240	60	Single-handled or a small amount of
N-QUICK				unwrapped solid instruments
	134	240		Single-handled or a small amount of
B-Quick			60	unwrapped lumen instruments (applicable to
				Class B type)
BD Test	134	210	900	Test the penetration effect of equipment

Table 5-1 cycle default parameters and applicable load type

				steam, cold air removal effect (applicable to
				Class B type)
Leak Test	Evacuate: 30	Os,		Detection of equipment leakage (for Class B
	Test: 600s			type)
Preheat	134	240	30	Warm up the equipment
Drying			1200	Dry items
Cleaning	Time 600e	•		Washing device with its own evaporator (for
	Time: 600s			24/45L)

Note: The maximum running time of the machine is obtained by testing with a standard load.

For exotic medical instruments, the medical institution should require the instrument company to provide the instrument cleaning, packaging, sterilization method and sterilization cycle parameters and follow them.

For implants, the medical institution shall require the instrument company to provide the material, cleaning, packaging, sterilization method and sterilization cycle parameters of the implant, and follow the requirements for sterilization; the sterilization of implants shall be released after the biological monitoring results are qualified.

5.4. Start cycle

After selecting a specific cycle, press "ok" to enter the cycle start screen, move the cursor to ", press "ok" to start, the screen jumps to the running screen, the cycle starts to run.

P1:	0kPa	T1: 32.1℃
т3:	32.1℃	T2: 32.1℃
NO.:	02	
TYPE	: B134UNI	V.
PARA	A: 134℃	C/ 240 S
	DOOR	: CLOSED
\Diamond		٥

Figure 5-3 Start cycle screen

Please note that there is a "Quickstart" function in the select cycle type in the previous

section "Select Cycle". It is the same as the last cycle you ran. You can click here to start the last selected cycle directly and quickly. The equipment has no requirement for intermittent operation, but when the single tank internal circulation equipment is in continuous operation, the temperature inside the tank may rise after 4 pots of continuous uninterrupted operation, and if the evacuation performance of the equipment decreases at this time (specifically, the vacuum time of the equipment is extended), it is recommended to replace the water inside the tank.

5.5. Cycle running view

After the cycle starts, it jumps to the screen :



Figure 5-4 Cycle running screen

The information in this cycle running view screen is described as follows:

You can view the cycle, chamber pressure P1, chamber temperature T1, cycle stage (e.g.

"purge" stage in the figure above), running time, and door status directly in the screen.

Icon:

1) You can view the parameters of the currently running cycle, such as "sterilize temperature", "sterilize time", etc. after selecting the cycle.

PARA:				
2 # B134UNIV				
STER TIME:	4min			
STER TEMP:	134 ℃			
DRY TIME:	10min			
PULSE: 3				
PULSE MAX:	60kPa			
PULSE MIN:	-80kPa			
PURG.TIME:	240s			

Figure 5-5 Cycle parameters view screen

2) After entering, you can view the input and output status of each component and the temperature of the pot wall T2 (if any) and the evaporator temperature (or pressure); the table below shows the explanation of the symbols included in the display.

P1:	0kPa	T1:	32.1℃
T3: 32	2.1 ℃	т2:	32.1℃
F2	OFF	Н2	OFF
F3	OFF	10	OFF
F4	OFF	11	OFF
F5	OFF	12	OFF
F6	OFF	13	OFF
B1	OFF	14	OFF
B2	OFF	15	OFF
H1	OFF	16	OFF

Figure 5-6 Input and output status view screen

The following table shows the explanation of the display screen code introduction (some individual codes are not used and are reserved as reserved items)

Table 5-2 List of Codenames

Code	Name		Code	Name	Code	Name
F2	Inlet valve		B2	Solenoid pump	I2	Motor ON
						position
						detection
F3	Evacuation		H1	Evaporator 1	I3	Reserved
	valve					
F4	Return air		H2	Heating	I4	Evaporator
	valve			membrane		high water
						level

F5	Тгар	H3	Evaporat	tor 2	I5	Evapora	tor low
			(45L)			water le	vel
F6	Water	10	Door	close	I6	Door	locked
	injection		position			position	
	valve		detection				
B1	Circulation	I1	Motor	OFF			
	pump		position				
			detection				

3) A select to enter to view the current alarm information of the cycle:

Select the Ito enter the alarm information screen. If there is a corresponding alarm, the display will pop up the corresponding alarm dialog box: for example, E16 NEED MORE WATER.

P1: 0kPa T1: 32.1℃
T3: 32.1 ℃ T2: 32.1℃
NO.: 02 PHASE: 02
ALARM: 02
E05 VACUUM FAIL
OCCUR:2011-11-11 11:11:11
ACK : 2011-11-11 11:12:11

E16! Water Lack

Figure 5-7 Alarm Information View Screen

See the "Alarm Information" section for the details.

4) **I**: You can view the time of each stage.

In the running screen, select **I** to enter the process data screen.

	PH	ASE INFO
PUR:	4:00	STE: 6:00
PV1:	2:00	MAX: 134.5
PP1:	1:00	MIN: 134.7
PV2:	2:00	
PP2:	2:00	156.0℃
PV3:	2:00	
PP3:	3:00	

Figure 5-8 Process Information View Screen

Pur: Actual running time of the purge stage phase

- Pv1: The actual running time of the 1st pulsation upper limit to lower limit
- Pp1: The actual running time from the 1st pulsation lower limit to the upper limit
- Pv2: Actual running time of the 2nd pulsation upper limit to lower limit
- Pp2: The actual running time from the 2nd pulsation lower limit to the upper limit
- Pv3: The actual running time of the 3rd pulsation upper limit to lower limit
- Pp3: Actual running time of temperature rise
- Ste: Sterilization time running value

Max: Maximum value of sterilize stage temperature (the highest temperature that may occur in the sterilization cycle is the set sterilization temperature +4°C, which does not occur under normal circumstances)

Min: Minimum value of temperature in sterilize stage

5) Step 2: After entering, you can enter the selection screen of "Cycle aborted" and choose whether to abort the cycle, see "Cycle aborted" below.

5.6. Cycle aborted

In the cycle running screen, select the will abort. If you don't need to, please press "ESC" to go back to the cycle running screen.



Figure 5-9 Abort cycle Screen

After aborting, please wait, and then press the Back button; then you can open the door or run the cycle again.

5.7. Cycle end

After the cycle ends normally, the screen will be as follows:

02# B134UNIV.	
P1: 0kPa T1: 32.1℃	
END	
ELAPSED: 30:00	
***** OPEN DOOR *****	

Figure 5-10 End of cycle

If you start the leak cycle, the display will show the leak qualified or unqualified, and show the leakage rate value.

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

You can click the "Open" button to open the door and unload the sterilized items, or click the "Return" button to return to the cycle startup interface.

5.8. Unload

After the sterilization is finished, press the "Open" button to open the door according to the prompt. Wait for 5 min to dissipate most of the heat in the chamber. The operator should have gloves or other protective tools to remove the sterilized items to prevent burns.

If the sterilized items are removed immediately, a small amount of condensation may be found on the sterilized items!

For 45L equipment, if the next sterilization process is started five minutes

after opening the door after one cycle is finished, the difficulty of closing the door can be avoided!

After opening the door, the chamber, the inside of the door, the sterilized articles and the tray shelves are in a high temperature state, so in order to prevent burns, the necessary protective measures must be taken to protect the operator's safety!

5.9. Storage of sterile items

Choose a dust-free and airtight storage environment that is dry and does not fluctuate in ambient temperature.

Storage validity time: The storage time of sterile articles is related to the packaging material and the type of packaging, and the unpackaged articles should be used immediately after sterilization.

Package material	Validity	Remarks
Ordinary cotton packaging	14 days	When sterile articles are stored and the environmental standards are not met (storage conditions: ambient temperature <24 $^{\circ}$ C, ambient humidity <70%), the validity period of sterile articles packed with ordinary cotton materials should not exceed 7 days.
Medical disposable paper bag	30 days	
Disposable medical crumpled paper	180 days	
Medical non-woven fabric	180 days	
Disposable paper-plastic bags Pouch	180 days	
Rigid containers	180 days	

5.10. Printer (Optional)

5.10.1. Structure



Figure 5-11 Printer structure

1. paper outlet 2. LF button/indicator 3. thermal print head 4. paper roll 5. paper bin switch 6. data interface 7. fixed frame

Button switch operation and indicator light:

After the printer is powered on, the indicator light flashes, and when the light flashes slowly indicates a lack of paper. After normal power-on, press the LF key for paper. Self-test mode: press the LF key does not release, while powering up the printer, that is, print out the self-test paper.

5.10.2. Installation



Figure 5-12 Printer installation

Installation method: the printer embedded part into the installation holes of the device panel, as shown in the figure to install the card on both sides of the printer on the fixed frame, and tighten the screws, left and right symmetrical each set, the same installation method. For the panel to be installed thickness of 0.5-8mm thick metal or plastic plate; thickness will not affect the solidity of the printer installation.

5.10.3. Printer paper



1) Replace paper

When the paper is about to run out, the red appear on the paper to prompt the user to replace the print paper (printer is optional, some equipment is not equipped with a printer).

- As shown in Figure 1, gently snap out the rotary wrench at the arrow position, and snap out as shown in Figure 2.
- Continue to rotate the wrench, when the print head paper axis and print head separated, open the paper bin cover.
- Add paper, and pull out a cut (beyond a little tear teeth), pay attention to the paper put neatly, the direction of the paper for the liquid side (smooth side) up (if installed in reverse will not be able to complete the print), as shown in Figure 4.
- Close the paper bin cover, the print head paper axis pressed flush with the print paper after a little force to the print head paper axis back to the print head, and the rotary wrench to push into the reset.
- Turn on the printer's power, so that the head rotation, this time to see if the paper goes crooked, if you need to adjust the print paper, until the print paper vertical in the paper outlet.

2) Cleaning and maintenance

After using thermal printer for a long time, 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 a good job of cleaning from time to time. After the paper bin cover is opened, use a cotton swab with a little alcohol to gently wipe the thermal head of the printer, and the rollers on the paper bin.

5.10.4. Print Record View

Note: The printer is optional and the following is the print record explanation. The content and data are for reference only. Different volumes of equipment, different procedures between the print record are slightly different, please take the actual equipment print record shall prevail.

SIGN:				
CYCLE C	OMPLETE			
END	12:35:40	80.0	0	
VENT	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	
EXHA	12:29:00	134.5	210	Sterilize stage, maintain
	12:28:00	134.5	210	certain time temperatu
	12:27:00	134.4	209	and pressure for
	12:26:00	134.5	210	sterilization
STER	12:25:00	134.3	208	
	12:24:55	126.9	170	
	12:23:55	120.2	120	Warm-up stage for ste
	12:22:55	115.4	70	penetration and I
HEAT	12:21:55	83.7	-80	temperature increase
	12:19:40	113.4	60	
	12:18:30	84.7	-80	
	12:17:00	112.9	60	<u> </u>
	12:16:00	85.2	-80	This stage is used to
PULS	12:14:30	110.0	50	remove cold air from the
	12:13:00	100.3	0	chamber
	12:12:00	95.8	0	
	12:11:00	75.4	0	
PURG	12:10:00	50.1	0	
STAG	TIME	TEMP	PRES	
*****	********	*******	*****	
DRY TIN	/E: 0300s	STERTEMP	: 134.0	
PURGTI	ME: 0240s	STERTIME	E: 240s	
PROG -0	02: B134Un	iv. PULSE	: 3	
*****	*******	*******	*****	
CYCL CN	NT: 000001	OPER ID:		
INDITAF	PE: 🗆 PASS	D FAIL		
INDICA	INDICARD: PASS FAIL			Equipment information
DATE: 2017-01-01			and operation informat	
DATE:	2017-01-01			

Figure 5-14 Schematic diagram of printing records

5.11. Performance test

5.11.1. Bio-monitoring

Bio-monitoring is used to test the sterilization process and the sterilization effect of the sterilization equipment. See the "Bio-monitoring" section in the previous section for details.

5.11.2. B-D Test

The B-D test is a test of the successful removal of air from a high vacuum sterilizer used to sterilize porous loaded healthcare products.

The BD Test is not a sterilize effect test, but a functional test of the sterilizer. It is not a substitute for routine monitoring of the sterilization process.

5.11.3. Vacuum leak test

The leak test is selected according to the type of equipment, but is not necessary if the equipment does not have a pulse vacuum function. The leak test is performed to check the sealing integrity of the piping connecting the equipment to the chamber to ensure that the cold air removal phase of the sterilizer is free of air. Run the leak test cycle that comes with the device, and the test results will be shown in the printed record after the test is completed. The leak rate should not exceed 0.13 kPa/min.

5.12. Equipment OFF

After the equipment is used, put the door in the open state. Press the switch "OFF" to disconnect the equipment. If the equipment is equipped with circuit breaker, please disconnect the equipment circuit breaker.

<u>6.</u> Special situation handling instructions

6.1. Manual abort cycle

See Chapter 5 "Abort cycle"

6.2. Cycle aborted

In order to ensure the safety of the equipment and the validity of the sterilization results, the cycle will alarm and abort automatically if some malfunction or unreasonable condition occurs during the cycle operation.

The following is a list of common alarms that can cause the cycle to abort during cycle running:

Alarm code and content	Alarm code and content
E00 Interrupted	E16 Water1 Lack
E01 Door SW close	E17 Water2 Lack
E02 Chamber-T1 high	E18 Water2 Full
E03 Ch-out-T2 high	E20 Door Unlock
E04 Temp. Low	E21 Water SW Error
E05 Vacuum failed	E22 Generat.T3 high
E06 Heat failed	E23 MoterSW unclose
E07 Water time Out	E24 Genera1.T3 Error
E09 Motor Overtime	E26 Door locked
E10 Over Pressure	E50 Communic. Err
E11 Generat.P2 high	
E12 ChamberT1 Error	
E13 Ch-out-T2 Error	

Table 6-1 Alarm message list

Alarm code and content	Alarm code and content
E14 Generat.P2 high	
E15 Genera.P1 Error	

When the cycle abort automatically, the screen will display the alarm or prompt message that triggered, and then the cycle will turn to the abort stage, and the reason will be recorded on the print record (if any).

After waiting for the cycle aborted finish, the cycle ends and the following screen will be displayed (example) :



Figure 6-1 Example of the cycle non-normal end

At this time, press the Back key or Open key to exit to the cycle start-up interface, after the alarm, please contact our authorized technical maintenance personnel to find the cause of the problem.

6.3. Alarm -- Need more water

There is a "Need more water" alarm, check whether there is water in the tank, if not, please add water between the high water level and low water level. After adding water, it is still prompted "Need more water", you need to follow the "Water quality test" of "Process parameters" in Chapter 9 to reset the lower limit of the water quality value.

6.4. Unqualified water

If the equipment is configured with a water tank, when the water quality of the tank is lower than the standard requirements, it will prompt. Please replace the pure water to meet the requirements. If the water quality has met the requirements, it still prompt "Unqualified water", then you need to contact the equipment supplier to deal with the problem.

Use of unqualified water quality for a long time will lead to pipeline and evaporator blockage!

6.5. Alarm-Can't open door

When the equipment installation site is located in high altitude areas, when the pressure deviates from an atmosphere, you need to adjust the equipment atmospheric pressure value, otherwise the door will not open the situation. Follow the setting of atmospheric pressure in Chapter 8 "Manager's Manual" - "Common Functions of Control System" - "Atmospheric Pressure Setting" in this Manual.

7. Sterilize Techniques

7.1. Packing and loading guide

7.1.1. Package material

Principles for selection and use of packaging materials:

- Materials include rigid containers, disposable medical crepe paper, paper-plastic bags, paper bags, textiles, non-woven fabrics, etc.
- 2) Open-storage tanks should not be used for packing.
- 3) Textile packaging materials should be cleaned as soon as they are used, without stains and without breakage during light inspection. Textiles should be non-bleached fabrics; wrapping cloth should not have stitching except for the four edges and should not be sewn; high temperature washing, degreasing and decoloring should be done before the first use; records of using should be kept.
- 4) The use and operation of rigid containers should follow the manufacturer's Manual or Guide Manual.

7.1.2. Packaging of fabrics

- 1) Before packaging, the packaging material and the sterilized articles shall be dry.
- 2) Before use, the packaging materials should be placed at a temperature of $18^{\circ}C \sim 22^{\circ}C$ and relative humidity of $35^{\circ}\% \sim 70^{\circ}\%$ for 2h and carefully checked for defects and damages.
- 3) The weight of the bedding package should not exceed 5 kg.

7.1.3. Packaging of instruments

- 1) Items should be thoroughly cleaned before sterilization. After washing, the items should be dried and packed in time.
- Surgical instruments should be placed in basket frames or trays with holes for matching packaging.
- Surgical instruments should be packed in 2 layers of packaging material in 2 packages by using closed packaging method.
- 4) The weight of the instrument package should not exceed 7 kg.

<u>7.1.4.</u> Packaging of utensils

- The items should be thoroughly cleaned before sterilization. After washing, the items should be dried and packed in time.
- 2) Dishes, pots, bowls and other utensils should be packaged separately.
- 3) Sealed packaging such as paper bags, paper-plastic bags and other materials can be used in one layer and is suitable for individually packaged instruments.

<u>7.1.5.</u> Load

Sterilized items are loaded according to the following requirements:

1) Specific sterilization racks or baskets should be used for loading sterilized items. Gaps should be left between packages to facilitate the penetration of sterilization media.

2) It is advisable to sterilize instruments, apparatus and articles of the same material in the same batch.

3) When the materials are different, textile items should be placed on the upper layer and placed vertically, and metal instruments should be placed on the lower layer.

4) Surgical instrument packages and hard containers should be placed flat; pots, trays and bowls should be placed sideways; glass bottles and other vessels without holes at the bottom should be placed upside down or sideways; paper bags and paper-plastic packaging should be placed sideways to facilitate steam entry and cold air discharge. 5) When choosing the lower exhaust steam sterilization cycle, large packages should be placed on the upper layer and small packages should be placed on the lower layer.

The maximum loading volume of the steam sterilizer is 80% of the available space of the sterilization chamber volume.

Volume	Maximum weight of	Maximum weight of textile
	instrument	
24L	5.5 kg	0.8 kg
45L	10.5 kg	1.3 kg

Table 7-1 List of load weights of equipment

The maximum weight of the load and the maximum volume of the load, the one which up to the limit firstly, is the maximum load of the equipment.

7.2. Sterilize cycle

The equipment is equipped with 10 sets of cycles by default, among which the "B134UNIV.", "B121UNIV.", "USER", "N-Quick", "B-Quick" are all sterilization cycles, "BD Test" and "Leak Test" are testing cycles, and "Preheat", "Drying" and "Cleaning" are auxiliary cycles.

Depending on the equipment configuration, some equipment cannot start certain class cycles; Class B type equipment can start vacuum class cycles ("B-Quick", BD Test, "Leak Test", etc.), Class S type N-type equipment cannot start vacuum class cycles, and Class S type N-type equipment cannot sterilize cavity class loads. Other specific information can be found on the equipment nameplate information.

The default parameters of the cycle and the applicable load types are as 5.3.

7.3. Suitable for sterilized items

1) Principle

- steam sterilization should be preferred for instruments, appliances and articles that are resistant to moisture and heat.
- Select the sterilization method according to the Manual
- Lumen should not be sterilized by gravity steam sterilization

- For rigid containers, oversized and overweight packages, should follow the sterilization parameters provided by the manufacturer
- Foreign instruments should follow the packaging, sterilization methods and parameters provided by the supplier
- If you cannot check the instructions for use of the instruments, you can consult the sterilization information of the same type of instruments in the same hospital to choose the sterilization method.

2) Contraindicated sterilization items

- Fiber optic instruments: fiber optic connection cables, medical cables, flexible endoscope connection cables, etc.
- Electronic instruments: non-metallic electric drills, gynecological motors, electric knives, etc.
- Flexible endoscope: gastroscope, enteroscope, tracheoscope, bronchoscope, biliary scopes, cystoscope, ureteroscope, etc.
- Grease : Paraffin oil
- Sealed glass bottles
- Powder : Talcum powder, Chinese medicine, powder injection medicine, etc.

This equipment is not suitable for sterilizing tightly sealed bottles of liquids. If this equipment is used to sterilize tightly sealed bottles of liquid, it is easy to burst due to negligence or violation of the operation rules, which will seriously endanger the safety of the person and the equipment.

8. Manager manual

8.1. Common functions

In the main interface of the equipment display (the following left figure), move the cursor to select, after that, you can enter the system parameters screen (the following right figure), in the system parameters setting screen can set the parameters and functions.

	SYSTEM SETTINGS:
ChamberP1: XXXX kPa	Pressure point
chamberT1: XXXX°C	Preheat
Chbr-outT2: XXXX°C	Print mode
Generator – T3: XXXX °C	Time/Date
Door state: closed	Language
	USB State
	F0 printer

Figure 8-1 Main interface and the system parameters

8.1.1. Pressure point setting

If the equipment is used in a high altitude location, you need to adjust the "Pressure point " to open and close the door normally. If the atmospheric pressure is not matched correctly, the display may prompt "Do not meet the door opening conditions, can not open the door, please return" during the opening and closing process. Only when the "inner chamber pressure-P1" is within the range of "atmospheric pressure ± 5 kPa" can the door be opened and closed.

Select "Atmospheric pressure" option in the system parameter screen in Figure 8-1, and enter the atmospheric pressure setting screen in Figure 8-2. Press OK to move the cursor to the "Atmospheric pressure: 101kPa" option, and adjust the value by Press "Down" to adjust the value to match the local atmospheric pressure. The factory default here is 1 standard atmospheric pressure of 101kPa.



Figure 8-2 Atmospheric pressure setting

Setting method: When the equipment is in normal standby mode, check the pressure parameter shown in the display "Chamber pressure-P1", and record it as "A (with symbol)", then set the atmospheric pressure as "101+A". For example, when "chamber pressure-P1" is "-6kPa", according to "101+A", the atmospheric pressure is about 95kPa (101 kPa-6 kPa).).

Note: The atmospheric pressure value is set according to the atmospheric pressure value of the equipment installation site, and the boiling point temperature is calculated automatically with the change of the atmospheric pressure value, no separate adjustment is needed! Standard atmospheric pressure: that is, the atmospheric pressure at sea level, which is what we usually call 1 atmosphere (101 kPa). Its value is about 0.1MPa = 101kPa. Atmospheric pressure decreases with the increase of altitude, below 3km, the atmospheric pressure decreases about 10kPa for every 1km increase in altitude.

8.1.2. Preheat mode

Select " Preheat" in the system parameter screen in Figure 8-1, and then enter the setting screen. You can adjust the ON/OFF by clicking Down button. The normal factory default is OFF.

When the warm-up is ON, the equipment will preheat the heating film or evaporator in standby. The Warm-up can shorten the running time of the cycle.

8.1.3. Print mode setting

In Figure 8-1, select the "Print Settings" and enter the print settings screen. You can adjust the "Print setting" ON/OFF by pressing the Down button. The normal factory default is ON.

When the print mode is ON, you can print data if the equipment matched with a printer, but when it is OFF, no more printing will be done.

8.1.4. Time/date setting

In Figure 8-1, select the "Time Setting" and then enter the warm-up time setting screen in Figure 8-3. Press the "OK" key to move the cursor to select the date and time items in turn, and use the Down key to select items. Press the Back button to return after the adjustment is finished.



Figure 8-3 Time setting screen

8.1.5. Language

In Figure 8-1, select the "Language" and then enter the language selection screen. In this screen, you can choose Chinese and English.

8.1.6. USB state

Select the "USB State" in Figure 8-1, and then enter the USB State screen. In this screen, you can check the data reading process after inserting an external storage device (U disk or SD card). The "**" in front of "Flash Storage **/40" is the actual number of storage, the equipment can store about 40 pots of data, and it will be overwritten automatically when it is full. The "U disk storage number 0000" is the process of inserting U disk or SD card to store inside.

Note: This USB reading function is optional.



Figure 8-4 USB state screen

8.1.7. F0 value print

In Figure 8-1, select the "F0 value print" and then enter the F0 value printing setting screen. In this screen, you can set F0 value printing ON/OFF.

8.1.8. Overflow pipe

This mode is only applicable to double tank configuration equipment. If the equipment is configured as double tanks, there will be "Overflow pipeline" option in this screen, and you can select "Connected" or "Not connected". After connecting the sewage tank (circulating water tank) drainage pipeline and sewage collection device of the equipment, select this mode as "connected", the sewage tank of the equipment will automatically overflow to the sewage collection device after the water is full, and will not report "Tank 2 full" alarm. If you do not connect the sewage tank drainage pipe and sewage collection device, please select this mode as "not connected", in this mode the circulating water tank will trigger the "Tank 2 full" alarm when the water is full, you need to manually remove the water from the tank.

8.2. Process of cycle working flow

The screen shows the name of each cycle stage and the status data of the temperature and pressure of the chamber of the equipment. One sterilization cycle of the equipment mainly contains the following stages:

1) Warm-up stage: In the preparation stage, the equipment preheats the evaporator and the

pot wall to reach the set temperature. If the printing function is turned on, the printing of the table head is also completed in the preparation stage.

- Purge stage: Start fill steam into the chamber while opening the exhaust valve to exclude cold air from the chamber.
- 3) Pulse stage: Pulse to remove cold air, first exhaust steam or vacuum to set the lower limit of pulsation, and then begin 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 pulsations reached. This is to exclude the cold air as completely as possible.
- 4) Heat up stage: Heat up and pressurize the chamber, and when the sterilization temperature is reached, delay to the sterilization stage.
- 5) Sterilize stage: Control the temperature and pressure of the chamber in the sterilization stage to maintain a certain control range until the end of sterilization.
- 6) Exhaust stage: Exhaust the chamber steam and reduce the chamber pressure.
- Dry stage: Dry the items in the sterilization chamber after the chamber pressure is removed.
- 8) Ventilation stage: If the chamber pressure is not within the opening and closing pressure range, then the pressure will be automatically balanced until the opening condition is reached.
- 9) End stage: The buzzer sounds and the display indicates the end.

Correspondence between pressure and time in the work cycle is different due to order number. and cycle flow. Take the "B134Univ." as an example.



Note: When the equipment is not equipped with vacuum function, the pulse stage is positive pressure; the above is a schematic diagram for reference only, the actual cycle running is subject to the actual equipment.

9. Display screen operation guide

9.1. Main menu

If there is no alarm after the machine is powered on, it will enter the main menu screen directly.

ChamberP1: XXXX kPa		
chamberT1: XXXX°C		
Chbr-outT2: XXXX°C		
Generator –T3: XXXX °C		
Door state: closed		

Figure 9-1 Main menu screen

Chamber pressure-P1: Pressure of the sterilizer chamber and is denoted by P1.

Chamber temperature-T1: Temperature of the sterilizer chamber and is denoted by T1.

Jacket temperature - T2: Temperature of the sterilizer pot wall chamber and is denoted by

T2.

Boiler T-T3: Temperature of the evaporator directly connected to the main body of the equipment and is denoted by T3 (for 45L equipment).

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

9.2. Alarm screen

The alarm screens of the equipment in standby state and operation stage are as follows:

	02# B134UNIV. P1: 0kPa T1: 32.1℃
E16 Water Lack	E05 VACUUM FAIL
	PRESS RETURN
	DOOR: CLOSED
	ht 🖪 🕅 🗖

Figure 9-2 Alarm screen in standby state and operation stage

After the alarm occurs, please contact our professional maintenance personnel to find the cause of the problem.

<u>9.3.</u>Cycle running

9.3.1. Select cycle

Please refer to the "Select cycle" in Chapter 5 "Operation instructions".

9.3.2. Cycle running

Please refer to the "Start cycle" in Chapter 5 "Operation instructions".

<u>9.3.3.</u> Value display

Please refer to the "Cycle running view" in Chapter 5 "Operation instructions".

<u>9.4.</u> System parameters

"Atmospheric pressure", "warm up mode", "Print setting", "Time setting", "Language", "USB state", "F0 print", and "Overflow mode" in the system parameters, please Refer to the "Common Functions of Control System" in Chapter 8 "Manager Manual".

9.5. Cycle value setting

9.5.1. Select editing cycle

The editing of the cycle parameters must be performed by a trained technician.

The key parameters of the sterilization process are described as follows:

Sterilize temperature and sterilize 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 chamber as the set sterilization temperature.

Note: The setting of each cycle parameter should be amended in use according to the specific situation or your own sterilization process. After the completion of the amendment, it needs to be verified and qualified, and the final biological test should be conducted after all qualified before use.

Non-authorized cycles will not be available for use and editing.

In the cycle start-up screen (see Chapter 5 "Start cycle" for the steps to enter this screen),

select the is to set the cycle parameters.

- After selecting the parameter setting icon, enter the password and move the cursor to "OK" and enter the parameter setting.
- In the parameter setting screen, move the cursor by the "OK" key to select the parameter to be modified.
- The cursor stays on the parameter name and the value is modified by pressing the Down button.
- When the setting is completed, press the Back key to return.
| P1: 0kPa T1: 32.1℃
T3: 32.1℃ T2: 32.1℃ | | PARA:
2 # B134UNIV. |
|---|--------------------------|-------------------------|
| | ****** ACCESS CODE****** | STER TIME: 4 min |
| NO.: 02 | 0000 | STER TEMP: 134 ℃ |
| TYPE: B134UNIV. | | DRY TIME: 10min |
| PARA: 134°C/240 S | ОК ВАСК | PULSE: 3 |
| DOOR: CLOSED | | PULSE MAX: 60kPa |
| | HMI: xxxxxxxxx | PULSE MIN: -80kPa |
| | PLC: xxxxxxxxxx | PURG.TIME: 240s |

Figure 9-3 Select editing cycle

9.5.2. Cycle parameter setting

Program parameters are listed in 5.3

Note: The maximum running time of the machine is tested with the standard load. The above is the default data of the cycle, the actual equipment shall prevail.

Sterilize time: running time of sterilize stage, range [0,99] min

Sterilize temperature: maintain temperature of sterilize stage, range [105 ,138]°C

Dry time: running time of the dry stage, range [0,99] min

Pulse time: number of pulse, range [0,6]

Pulse upper limit: pulse stage pressure upper limit, range [0,150] kPa

Pulse lower limit: pulse stage pressure lower limit, range [-99,50] kPa (Class S type range [0,50] kPa)

Purge time: purge time fixed setting value 4min.

"B-Quick", "BD Test", "Leak Test" are only available for Class B type equipment, not for Class S type equipment. "Clean" are only available for 24/45L equipment.

Type B sterilizers are used to sterilize all packaged and unpackaged solid loads, Class A lumen loads and porous permeable loads for testing as required by the standard.

Type S sterilizers are used for sterilizing special sterilized items specified by the manufacturer, including unpackaged solid loads and at least one of the following:

porous permeable items, small porous permeable strips, Class A cavity loads, Class B cavity loads, single-packaged items, and multi-packaged items.

Type N sterilizer is used for sterilization of unpackaged solid loads.

Cycle:the equipment is equipped with 10 sets of cycles by default, among which the "B134UNIV.", "B121UNIV.", "USER", "N-Quick", "B-Quick" are all sterilization cycles, "BD Test" and "Leak Test" are testing cycles, and "Preheat", "Drying" and "Cleaning" are auxiliary cycles.

Depending on the equipment configuration, some equipment cannot start certain class cycles; Class B type equipment can start vacuum class cycles ("B-Quick", BD Test, "Leak Test", etc.), Class S type N-type equipment cannot start vacuum class cycles, and Class S type N-type equipment cannot sterilize cavity class loads. Other specific information can be found on the equipment nameplate information.

The default process parameters of the system are all set under the standard load conditions specified in the product standard after testing. If the load used by the user changes or the loading method changes, it is necessary to go through the relevant process verification before use (the user must first make sure that the load to be sterilized can run on the process corresponding to the specified cycle). After the user modifies the parameters of the sterilization cycle, the sterilization quality needs to be monitored and confirmed to be qualified before use.

✓ "B134UNIV.","B121UNIV.","USER",,"B-Quick"are all pulse vacuum sterilization cycles and have the same process flow, with the values of the relevant parameters adjusted to the characteristics of the different loads.

B134UNIV." is mainly suitable for sterilization of packaged high temperature resistant items, e.g. standard simulated loads are metal screws with paper-plastic packaging, fabric loads with wrapped cloth.

B121UNIV." is mainly suitable for rubber-like loads with relatively low temperature resistance.

■ "B-Quick" is only suitable for sterilization of a single Class A cavity item in a hot pot condition for user emergencies, while the sterilization must be completed and used within 4 hours, and the instrument needs to be shipped to the place of use

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in such a way as to prevent secondary contamination by environmental and other factors.

Note: When running N-or B-Quick cycles, the shelves and extra trays need to be removed if the shortest run time is to be achieved.

N-Quick" is only suitable for sterilization of a single bare instrument in a hot pot condition, in case of user emergency, while the sterilization must be completed and used within 4 hours, and it is necessary to prevent secondary contamination of the instrument by environmental and other factors when transporting it to the place of use.

■ BD Test is used to test the effect of cold air removal and steam penetration with special devices, such as standard BD packs, disposable BD packs, etc. The parameter values of this cycle are set according to the parameters required by the most commonly used BD test paper manufacturers, and if they are different from the equipment or test paper used by the hospital, the specific parameters should be modified with reference to the requirements of the equipment or test paper used parameters. This procedure is set according to the parameters required by the manufacturers of the most commonly used PCD devices (134°C sterilization for 3.5 minutes), and if different from those used in hospitals, the specific parameters should be modified with reference to the requirements of the adopted equipment. ✓ Leak Test is used to test the sealing of the pipeline or device connected to the chamber under negative pressure.

You can choose this cycle for testing during the commissioning process or routine testing of the equipment, especially after long-distance transportation, when there is a possibility of loose pipes and other phenomena (or when the B-D test fails). It is mainly used to test the vacuum leakage of the sterilization equipment in order to check the sealing condition of the piping. This test is performed with the chamber of the sterilizer empty. When the cycle runs to the test stage and the pressure change does not exceed 1.3 kPa within 600 seconds, the vacuum leak test passes. If the test is not normal then it must be serviced. Check the door seal and the connection part of piping system and inner chamber, etc. to find out the leakage point, and

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after eliminating, re-test until the test is normal. This procedure is for testing only and is not to be used as a verification that the sterilization is qualified and reliable.

✓ "Preheat", "DRY" and "Cleaning" are auxiliary cycles, which must be used in strict accordance with the applicable conditions of the cycle.

"Preheat", when running the cycle in the first pot of the equipment, you can first run the "Preheat" with no load to preheat the equipment to achieve better and faster sterilization and drying effect.

"DRY", the items can be dried individually, and the corresponding drying time can be set according to different requirements to achieve the requirements of drying items.

Cleaning", clean the evaporator, the user can run the "Cleaning" once every month to prevent the pipeline from scaling or attaching other impurities to affect the heating efficiency.

9.6. System maintenance

In the main interface (the following left figure), move the cursor to select \square , enter the password, select to "OK" to confirm to enter the system maintenance screen (the following right figure), in the system maintenance screen can set the parameters and functions.

		SERVICE:
ChamberP1: XXXX kPa		EQUIP CONFIG.
chamberT1: XXXX°C	ACCESS CODE	CALIBRATE
Chbr-outT2: XXXX°C	0000	MANUAL
Generator –T3: XXXX °C		ACCESS CODE
Door state: closed	ОК ВАСК	MODE SETTINGS
		ADVANCED SETTINGS
	HMI: xxxxxxxxx	RESET
	PLC: xxxxxxxxxxx	



9.6.1. Equipment information

Equip. ID: This is the set number when it is shipped from the factory, and it is not necessary to modify here after it is shipped.

CONF.CODE: The configuration code of the hardware and cycle, which cannot be modified after leaving the factory, and may cause it not to operate normally.

CYCLES: The cycle times of the equipment.

BRIGHT: Adjust the brightness of the display

EQUIP TYPE: The configuration code of the equipment hardware and cycle, which can adjust B or S level. After the factory here can not be modified, the modification may cause the equipment can not operate normally.

If you need to modify the relevant parameters, select "OK" after the modification completed.



Figure 9-5 Equipment information screen

9.6.2. Calibrate

- DEV P1: Chamber pressure
- DEV T1: Chamber temperature
- DEV T2: Jacket temperature
- DEV T3: Evaporator temperature
- DEV P2: Evaporator pressure

When it is determined that there is a deviation in the actual detection value of the pressure or temperature of the equipment, calibration of the detection can be performed by

"Calibrate". If the detection is low, add a certain value to the corresponding calibration, and if the detection is high, subtract a certain value from the corresponding calibration.

> P1: 0 kPa T1: 32.1℃ T3: 32.1℃ T2: 32.1℃ CALIBRATE P1: 0 kPa T1: 0 ℃ T2: 0 ℃ T3: 0 ℃

Figure 9-6 Calibrate

9.6.3. Manual operation

In the Manual operation screen, move the cursor to the corresponding option by using the "Down" key, and adjust the corresponding component ON or OFF with OK key is confirmed.

The following table is the introduction of the display screen code description (there are individual codes are not used, as a reserve item)

Code	Name	Code	Name	Code	Name
E2	Stoom inlot volvo	רם	Electromagnetic	10	Motor ON position
12			pump	12	detection
F3	Evacuation valve	H1	Evaporator 1	I3	Reserved
EA	Doturn Air Valvo	<u>ц</u> р	Heating membrane	тл	Evaporator high water
F4	Return All Valve			14	level
F5	Тгар	H3	Evaporator 2 (45L)	15	Evaporator low water level
EC	Water injection	10	Door close position	τc	Deer lecked level
го	valve	10	detection	10	
D1	Circulation Dump	T1	Electric OFF position		
DI			detection		

MANUAL:						
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°C						
T3: XXX.X℃ T2: XXX.X℃						

Figure9-7 Manual operation

9.6.4. Password setting

Reset the password in this screen, enter "password", "new password", "confirm", and then select "OK" to complete the modification.

9.6.5. Mode settings

1) USB

You can set the "USB CONNECT", "ALARM" and "ERASE" switch.

USB CONNECT: Set whether the USB icon is displayed at the top of the main interface after the external storage device is inserted.

ALARM: Set whether the alarm icon is displayed on the top of the main interface after the data storage area of the display is full.

ERASE: Set whether to clear the operation data stored in the storage area.

2) VACUUM MODE

The VACUUM MODE can select from "DELAY MODE" and "PRES. MODE". Default delay mode.

DELAY MODE: During Vacuum process, after to a certain negative pressure value, the next stage will be injected automatically after a time delay.

PRES. MODE: During Vacuum process, evacuate until the set pressure lower limit value before moving to the next stage.

3) WATER TANK QTY

WATER TANK QTY can select " SINGLE" and "DOUBLE". According to the hardware

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configuration to match, the equipment is not allowed to be modified after the factory.

MODE SETTINGS:
UDISK SETTINGS
VACUUM MODE
WATER TANK QTY
DRYING MODE
STER. CONTROL

Figure 9-8 Mode settings

<u>9.6.6.</u> Process parameters

In the process parameters interface can set "WATER QUALITY", "PRINT INTERVAL", "P2 MAX. LIMIT", "HEAT INTERVAL", "VACUUM DELAY", "DELAY START", "DELAY DRYING" and other process parameters.

ADVANCED SETTINGS:						
WATER QUALITY						
PRINT INTERVAL						
P2 MAX. LIMIT						
HEAT INTERVAL						
VACUUM DELAY						
DELAY START						
DELAY DRYING						

Figure 9-9. Process parameters

1) WATER QUALITY

In this interface to set the upper and lower limits of the water quality value, here you need to set correctly, otherwise there will be "NEED MORE WATER" "UNQUALIFIED WATER" and other alarms.

Water quality value: The actual value detected by the device, can not be modified.

MAX. VALUE: the default is 3500, generally do not need to modify.

MIN. VALUE: Setting method: under no water in tank (water quality probe exposed to the air) to view the "TEST VALUE" for "B", then the "MIN. VALUE" set to "B + 30", for example, the

following chart, "TEST VALUE" for 1537, then the "MIN. VALUE" set to 1567.

After the setting is complete, select "OK".



Figure 9-10 Water quality settings

2) PRINT INTERVAL

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

3) P2 MAX. LIMIT

The max. limit of evaporator P2 is set to 240 kPa by default, and the setting range is [50,280] kpa, which can be set if the evaporator pressure is too high or too low when running sterilization at non-default temperature.

4) HEAT INTERVAL

Set purge time during heating stage. The range is [0,1200]s. This parameter can be adjusted to increase the temperature uniformity of the load if the temperature penetration is not good when the load is a liquid or a large volume load.

5) VACUUM DELAY

In the pulse vacuum stage (if any), the pressure reaches the lower limit and continues to delay for a certain time, the default is 15s. The range is [0,300] s.

6) DELAY START

After starting the equipment, delay a certain set time to start the formal running. Default 0s, and range [0,1800]s.

7) DRY DELAY

After the drying stage is finished, continue drying delay for a certain set value before ending the cycle, default 0s, settable range[0,1800]s.

<u>9.6.7.</u> Reset factory settings

In the system maintenance interface select "Reset factory settings", it will prompt "Reset", if you need to reset, press OK button; if not, press BACK button. After the Reset factory settings, you need to reset MIN. VALUE, the method to see "Process parameters" section.

<u>9.7.</u> Display menu tree



10. Maintenance Techniques

<u>10.1.</u> Safety Precautions

When operating and maintaining this equipment, the following safety precautions must be read carefully.

(!)

- Burn hazard: If the surrounding temperature is higher than 30°C, the sterilization chamber door surface temperature may be higher.
- Burn and electric shock hazard: Repair or adjustment must be performed by trained professionals. Use of this equipment by untrained or unauthorized personnel or the installation of unpermitted parts will cause damage to personnel and equipment.
- Observe the labeled (high voltage) and the main switch must be turned off before opening.
- Burn hazard: Make the sterilizer, evaporator (if any) and other accessories to cool to room temperature before performing any cleaning or maintenance procedures.
- Do not use the sterilizer to treat flammable liquids or to sterilize liquids enclosed in glass vials or glassware for containment.
- Burn hazard: The sterilizer and grill shelves will be hot after the cycle. Use protective gloves when removing loaded items.
- Drop hazard: Prevent items from falling. Sterile packages dropped on the floor or misplaced in unclean places should be considered contaminated.
- Explosion hazard: This sterilizer is not intended for use with any flammable liquids or any other liquids.
- Burn hazard: When sterilizing for liquids, to avoid personal injury or property damage caused by exploding bottles and boiling hot liquids, the following rules must be

observed:

- 1) Health care instruments shall not be sterilized for liquids that come into direct contact with patients.
- 2) Use only liquid cycle to sterilize liquids; other cycles are not safe for liquids.
- 3) Use only ventilated covers, no airtight screw caps or rubber plugs
- Use only borosilicate glass bottles do not use ordinary bottles or bottles that are not intended for sterilization
- 5) Avoid opening the door immediately at the end of the cycle. Wait for a period of time after the end of the liquid cycle before opening the door and unloading the sterilized items.
- 6) Do not bump the hot bottles, this may cause them to explode! Do not move the bottle if it appears to be boiling or bubbling.
- Do not move the bottles from the sterilizer rack to the storage area until they have cooled enough to touch.
- Burn hazard: If the automatic completion cycle fails, wait until the automatic processing of the cycle is completed before opening the door. Do not open the sterilization chamber door if water is leaking from the door gasket.
- Sterility assurance hazard: If chemical indicator cards, biological indicators, BD tests, etc. fail, the sterility of the load will not be assured. If these problems occur, contact a maintenance professional for repair before using the equipment.

<u>10.2.</u> Maintenance Plan

Frequency and content of equipment cleaning and maintenance:

SN	Name	Frequency	Requirements	Remarks
1	Chamber	Every day	Keep clean and free of sewage	
2	Chamber filter	Even month	Keep clean and free of courses	Located at the sterilizer
2	device	Every month	Reep clean and free of sewage	discharge port
3	Tray (Shelf)	Every day	Keep clean and free of sewage	
4	Maton tople	Every two	No dirt on the wall of the water	
	water tank	weeks	tank	

Table 10-1 Maintenance list

SN	Name	Frequency	Requirements	Remarks
E Deservation		Every week	Keep the surface of the door	
5 Door gasket	gasket free of dirt			
c	Evaporator	E	Water quality must meet the	Run clean cycle (if any) to
6 Evaporator	Every month	requirements	clean	
-	Matan tapl filton	Even v meenth	The filter is clean and free of	
/ //	water tank filter	Vater tank filter Every month	debris	

Note: The above Maintenance List should be combined with the user's operation of the equipment for flexible adjustment to ensure that the equipment to play a more excellent performance to better meet your needs.

Maintenance can be done with common general-purpose tools, no special

tools.

List of parts to be maintained and replaced by professionals:

SN	Name	Code/Specification	Functions
		95604005 (18/24/29L)	
1.	Door gasket	956040060 (45L)	Seal the door
		13103-0800102R2	
2.	Bellows	13002-00301	Door safety interlock
	Colonaid	984050044 (2mm)	
3.	Solenoid	963410539 (4mm)	Used in pipeline
	valve	984050013 (8mm)	
	Miero ewit-h	984360649 (Long)	Leastion detection
4.	Micro switch	984170017 (Short)	Location detection

Table 10-2 Parts List

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

Check the door lock device, equipment wiring, temperature and pressure display, over-temperature control protection, internal piping connection, etc. every year. Check whether the door locking device is firmly pressed together after closing, no loose screws, signal detection switch deformation and other abnormalities; check the wiring firmly, no shedding, aging, burning, damage and other abnormalities; check whether the temperature and pressure display has abnormally large deviations from the daily use display; check whether the over-temperature temperature control protection is intact, whether there is frequent action of temperature control protection, loose wiring, line off, burned out and other abnormalities. Check whether the internal pipeline connection is normal, whether there is steam leakage, water leakage and other situations. Such work should be carried out by professional maintenance personnel, and the above abnormalities should be stopped immediately after inspection, and contact the manufacturer for after-sale treatment.

10.3. Maintenance guide

10.3.1. Equipment washing

10.3.1.1. Water tank washing

First of all, after draining the tank water, then use a clean rag to wipe the inside of the tank and the water quality detection probe, while removing the dirt from the tank.

During washing, it is best not to remove the tank filter first to prevent dirt from falling into the drainage and circulating water pipeline.

If you are sterilizing dental handpieces, and the water tank has a lot of oil in it, you need to replace the water after 5 cycles and clean the tank with a rag and detergent. For other common loads with a high number of uses per day, the water can be replaced once every three days and the tank can be washed with a clean rag and water.

10.3.1.2. Door gasket washing

After removing the door gasket, use a clean wet rag to wipe it, if you can't wipe it thoroughly, you can use cleaning agent, and finally rinse it with clean water, and wipe the sealing groove with a clean wet rag. For the removal of the gasket, refer to the introduction of the door gasket replacement section.

10.3.1.3. Tray/shelf washing

Use a clean wet rag to wipe the tray or shelf, etc., and then rinse with water.

10.3.2. Replace gasket

24L Gasket:



Figure 10-1 24L gasket

45L Gasket:



Figure 10-2 45L Gasket

SN	Name	SN	Name
1	Door cover	3	Door gasket
2	Sealing groove	4	Sealing door

When installing the door gasket, install it into the sealing groove as shown in the diagram, you can follow the installation diagram.

First of all, the four points of the gasket (evenly divided four points, indicated by circles in the above diagram) pressed into the sealing groove, and then the remaining part will be pressed into the sealing groove one by one, and finally the whole gasket will be installed flat.

Note: The gasket must be installed correctly in accordance with the instructions, the narrow side into the sealing groove, the wide side facing outward, which can not be installed in reverse, otherwise there will be air leakage, water leakage, vacuum difficulties and other problems.

10.3.3. Filter washing and replacement

10.3.3.1. Chamber filter and washing

The inner chamber filter (Y-type filter) is located between the discharge port of the main body of the equipment and the discharge solenoid valve F3, and the equipment needs to be washed after a period of use, the filter diagram as follows:



Figure 10-4 Filter Structure

After removing the cap nut, remove the filter and wash the impurities on the filter with water. Re-install it after washing.

10.3.3.2. Water tank filter



Figure 10-5 Filter Structure

Water tank filter has threads, so rotate the filter counterclockwise to remove it when washing or replacement. Disassemble the filter as shown in the figure above, and then wash the filter with water and brush. After that, restore the filter and re-install it back into the water tank.

10.3.4. Solenoid valve washing

Solenoid valve washing refer to the following steps: (Take SMC solenoid valve as an example, the specific configuration of the solenoid valve to the equipment shall prevail)



Figure 10-6 Filter washing diagram

The solenoid valve parts will be taken out and washed. The solenoid valve will be reassembled according to the previous disassembly steps.

10.3.5. Water tank drainage



Figure 10-7 Water tank drain port

If it is equipped with a water tank, the port is used to drain the water from the tank, and the port is located at the bottom right of the main body after opening the door. When drainage is needed, insert the special drainage pipe connector into the tank drainage port to drain the water normally. When the drainage is finished, pull out the drainage pipe by pressing the thin piece at the top of the drainage port and pulling out the drainage pipe.





After inserting the connector, press the thin piece to pull out the connector

Figure 10-8 Drain port connected diagram

10.3.6. Check and replace the safety valve

Check safety valve

To prevent the safety valve from being in a blocked state, under normal use, make the steam pressure to be released once a month.

- 1) Run the sterilize cycles (instrument cycle or bedding cycle, etc.).
- 2) When the pressure P1 in the sterilize vessel reaches 100kPa, pull the upper ring on the safety valve so that it is in the open state for about 2 seconds and steam is ejected,

indicating that the evaporator safety valve is working properly, otherwise the safety valve needs to be calibrated or replaced.

Pull the upper ring on the safety valve will have steam emitted. When pulling the ring, it is best to use a screwdriver and other tools, do not directly use your fingers, the operator should also try to stay away to prevent burns.

> Replace the safety valve

This operation is limited to professional personnel.

1) Remove the safety valve set screw and remove the safety valve from the base.

2) Replace it with a qualified safety valve. (Qualification criteria: Make sure the safety valve opens at a pressure between 0.29MPa and 0.3MPa).

3) Test a sterilize cycle.

10.3.7. Replace print paper

For details, see the section "Functions" - "Structure and Functions" - "Printer".

10.3.8. Replace fuse

All fuses (or fuse) of this equipment need to be replaced by trained professional maintenance personnel, engineers and technicians. When replacing the fuse, be sure to cut off the power and check the fuse parameters!

10.3.8.1. Main board fuse

There is a corresponding fuse in the equipment accessories, if the fuse is burnt out, you can find the corresponding fuse and replace it.



Figure 10-12 Main board fuse diagram

10.3.8.2. Equipment main power fuse (only for 24L)



Figure 10-13 Main power fuse diagram

- > First cut off the power connected to the equipment.
- Turn the fuse holder counterclockwise with a flat (one-piece) screwdriver and pull out the cover holding the fuse.
- Replace the fuse . Be sure to check whether the parameters of the new fuse are the same as the original specifications when replacing it, here the fuse parameters are: 20A 6*32.
- After replacement, insert the fuse holder cover with the fuse into the holder and align it with the guide slot of the fuse base.
- > Rotate clockwise to tighten the fuse so that it will not spring back.

10.3.9. Door safety interlock bellows replacement

The door safety interlock device is a safety protection device to prevent the door motor circuit from opening automatically when the sterilization vessel is under pressure, and its installation position is as follows:



Figure 10-14 Schematic diagram of Door safety interlock structure 1 Door safety connector, 2 Silicone gasket, 3 Liner, 4 Bellows, 5 Bellows liner, 6 Safety pin 7 safety pin jacket

The principle of operation is as follows:

The pressure generated by the chamber of the sterilizer stretches the 4 Bellows and pushes the 6 Safety pin through the 7 Safety pin jacket and then presses the external micro switch to break the working circuit of the door opening motor and prevent the door motor from being powered to open the door by mistake. When the pressure is released, the fuse pin retracts and breaks the micro switch, the door motor circuit closes and the door can be opened and closed.

Replacement method is as follows:

- Remove the connection line in door insurance connector
- Rotate to remove the door insurance connector
- Slowly pull out parts 2-6.
- Remove the damaged bellows and replace it with a new one.
- Put the above components back into the safety pin jacket, re-tighten the door safety connector and connect the piping.
- Test the complete sterilization cycle.

Note: Normal bellows is usually replaced once every two years, and should be replaced immediately after damage and leakage, depending on the actual use of the equipment.

10.3.10. Battery replacement

For the control board and display of the equipment equipped with battery, the battery type is 3V CR2032 button battery. When the battery runs out of power, the corresponding type of battery can be replaced.

<u>10.4.</u> Alarm information

Alarm code and troubleshooting

Table 10-3 Alarm code and troubleshooting

SN	Alarm code and	Reasons	Troubleshooting
SIN	content		
		Select stop and abort the cycle	Wait for the prompt to return and
1.	E00 Interrupted	while it is running	then open the door or re-select the
			cycle
		Door closed position not	Exit the cycle and check if the door
2.	E01 Door SW close	detected during cycle running.	switch is installed and wired
			properly.
		The temperature of the	Check the equipment temperature
2	E02 Chamber T1 high	chamber is detected to exceed	our engineering technicians.
3.	E02 Chamber-11 high	the sterilization temperature	
		+4°C	
		The temperature of the	Check equipment temperature
4.	E03 Ch-out-T2 high	chamber wall is detected to	our engineering staff.
		exceed 160°C	
		Chamber temperature is below	Check the discharge solenoid valve
5.	E04 T L	the sterilization temperature for	and clean it.
	E04 Temp. Low	longer than the preset time	
		during the sterilization process	
6.	E05 Vacuum failed	Evacuation does not reach the	> Check whether the chamber

CN	Alarm code and	Reasons	Troubleshooting
SN	content		
		predetermined lower limit in the specified time	 body filter and water tank filter are clogged and cleaned Check whether the door gasket is dirty and clean it Check whether the water tank is filled with too much water and cannot submerge the drainage joint on the inner wall of the tank
7.	E06 Heat failed	Duration of the heating stage exceeds the preset time	 Check equipment for obvious steam leaks Check whether the steam discharge solenoid valve is not sealed tightly and continue to clean Check whether the evaporator temperature is normal (>130 °C)
8.	E07 Water time Out	Water injection time exceeds the preset time	Check whether the injection pump, injection valve and other components are working properly
9.	E10 Over Pressure	Motor working time during opening and closing the door exceeds the preset time	 Door gasket installation error or not installed in place Loose or broken wiring inside the equipment
10.	E11 Generat.P2 high	Chamber pressure exceeds preset pressure	Check pressure sensors, steam discharge valves, traps and other components
11.	E12 ChamberT1 Error	Evaporator pressure exceeds preset pressure	Check pressure sensors, heating control elements, etc.
12.	E13 Ch-out-T2 Error	Detect abnormal chamber temperature, e.g. 0°C or 200°C	Check chamber temperature sensor or main board
13.	E14 Generat.P2 high	Detect abnormal chamber wall temperature, such as 0° or 200°C	Check chamber wall temperature sensor or main board

CN	Alarm code and	Reasons	Troubleshooting
SN	content		
14.		Detect abnormal evaporator	Check evaporator temperature
	E15 Genera.P1 Error	temperature, such as 0° C or	sensor or main board
		300 °C	
		Detect abnormal chamber	Check chamber pressure sensor or
15.	E10 Over Pressure	pressure, such as -100kPa or	main board
		300kPa	
		The water tank can not detect	> Water tank is not added pure
16.	E16 Water1 Lack	the water level	waterThe water tank water quality
			testing device parameters are
			set incorrectly.
17.	E17 Water2 Lack	Circulating water tank low	above low water level line number
		water level signal triggered	
10	E18 Water2 Full	Circulating water tank high	Circulating water tank drain
10.		water level signal trigger	
	E20 Door Unlock	Door locking and closing switch	Check the door locking closure
		is not detected during cycle	> Check whether the
19.		running	electromagnetic lock contact
			locking action is in place when
			pressed closed
20.	E21 Water SW Error	Energy storage evaporator	> Check the evaporator water
		detects low water level but not	level probe connection line Check whether the around
		high water level	connection is normal
			> Check whether the probe
			polytetrafluoroethylene insulation is normal
21.	E22 Generat.T3 high	Cast evaporator temperature	 Check evaporator temperature
		exceeds 230°C	sensor
			related control components
		The motor level switch signal is	Check the wiring of the motor
22.	E23 MoterSW unclose	not detected in the cycle	off-position switch and whether the
		operation	installation is fixed firmly

SN	Alarm code and	Reasons	Troubleshooting
	content		
23.	E24 Genera1.T3 Error	Double casting evaporator equipment, injecting water into the first evaporator temperature detection abnormal, such as 0 $^{\circ}$ C or 300 $^{\circ}$ C	Check the evaporator temperature sensor or the main board
24.	E26 Door locked	Open the door process electromagnetic lock micro switch is not disconnected	Check whether the electromagnetic lock is normally powered to retrieve
25.	E50 Communic. Err	Display and control main board communication error	Check the display and motherboard

Note: The above list is only the alarm inquiry table, due to equipment differences, some alarm codes are not configured in different volumes and order numbers of equipment, please pay attention. In winter, when the ambient temperature of the equipment in normal use without fault is lower than 0° , there may be "E12", "E13", "E14" and other temperature sensor failure alarms. In this case, you can wait for a while when the environment in which the equipment is located rises above 0° , power off and then re-energize the alarm is eliminated.

<u>11.</u> Accessories

The list of accessories that come with the conventional equipment (the accessories that come with the special equipment may be different, and the actual accessories that come with the equipment shall prevail, and the table below is for reference only). The following specification list is marked with "(xxL)" to indicate that the accessory is only equipped in the product of that volume model.

Note 1: The parts or spare parts used in this equipment can only be checked or provided by shinva or our regular agency.

SN	Name	Specifications	Photos	Remarks
1	Тгау	13101-0230702(24L)		Hold sterilized items in tray shelves when in use
2	Net cover	13100-0450301 (45L)		Hold sterilized items and place them on the sterilization grid when in use
3	Shelf	13101-0230701(24L)		Holds trays or sterilized items
4	Grid shelf	13100-0450302(45L)		Lower shelf for sterilized items and top shelf for sterilization mesh
5	Tray picker	24L		Remove and place trays to prevent burns

6	Drain hose (with connector)	946010016 (964070918)	After opening the door, insert the water release connector for waterproofing the box water
7	Glass fuse	5A 5*20	The fuse of the main board power board is not required to be replaced normally, but needs to be replaced when it is burnt out, see the fuse replacement section for details.
8	Ceramic fuse	20A 6*32	The fuse at the power line of the equipment (24L), normal need not be replaced, need to be replaced after burnout, see the fuse replacement section for details of the replacement method.
9	Corrugated tube	13002-00301	Pressure switch parts door insurance accessories, damaged and leaky or replaced when used for about 2 years. Use a wrench to disassemble the door insurance assembly can be replaced.
10	Printing paper (optional)	901990159	Equipment printing paper (used with E26 printer), replace when used up, see the section on replacing printing paper for details of replacement method.

Appendix A Operation guide

- I. Pre-shift preparation:
- ✓ Add pure water to the water tank as required or connect the equipment to the water source as required.
- \checkmark Turn on the power supply and put the sterilizer power on to prepare for cycle operation.
- ✓ Determine whether to conduct the B-D test according to the specified requirements or load type.
- ✓ Organize the packages to be sterilized, bundle them not too tightly, put chemical indication tape outside and chemical indication card inside.
- II. Sterilization operations:
- ✓ if the B-D test is performed according to the specified requirements, after the test is passed or the preheating is completed, put the sterilized items into the sterilization chamber, leaving a gap between the packages and the bundles, and do not stick to the wall of the apparatus and the door plate all around.
- Close the sterilizer door, select the sterilization cycle according to the sterilized articles,
 check whether the sterilization parameters are correct and start the cycle.
- During the sterilization process, the operator should not be far away from the equipment and should closely observe the operation condition of the equipment and deal with any abnormalities in time to prevent accidents.
- ✓ Do a good job of monitoring the sterilization effect and record and archive to facilitate tracking and investigation.
- After the sterilization is finished, wait for the pressure in the room to return to zero before opening the door to take out the items.
- ✓ After taking out the sterilized items from the sterilizer, check and place them carefully to prevent secondary contamination.

III. Post-shift work:

- ✓ Open the door, put the power switch in the disconnected state, and cut off the external total power supply of the equipment.
- ✓ After prompting "water quality unqualified" or running five sterilize cycles continuously without interruption, the water must be replaced.

- After daily work, the sterilizer should be kept clean inside and outside, and the chamber should be cleaned of dirt with clean rags and water, with small maintenance once a week and major maintenance once a month.
- IV. Cautions:
- \checkmark Sterilized items should not be mixed with non-sterilized items.
- ✓ Qualified sterilized items should be marked with the sterilization date and qualified mark.

Appendix B Electrical wiring diagram (24L/45L)

