
Installation and User Manual Q21B



HaeTmed(Wuxi) Co., Ltd.

FOREWORD

Thank you for using the Q21B small steam sterilizer. This manual describes in detail the installation process, use preparation, standard operation, safety precautions, and maintenance of the Q21B small steam sterilizer . In order to enable you to use this product efficiently and safely, please read the installation and operation manual carefully before use.

Scope of application

The HäTmed small steam sterilizer is suitable for sterilizing medical instruments and laboratory utensils. The product design complies with the EN 13060-2014 standard and is a Class B sterilizer. As a universal sterilizer, it is suitable for various high-demand sterilization tasks .



- Do not sterilize any liquid, and use of this product to sterilize liquids in violation of regulations will damage the product and the sterilized load.

Structure and composition










Small steam sterilizer consists of sterilizer pressure vessel, safety valve, solenoid valve, sterilizer control, display device and recording system, air filter, vacuum pump and door lock mechanism.

Symbol Description

Notations in this manual:

| logo | significance | illustrate |
|------|-------------------|---|
| | safety alert | This symbol indicates a hazardous situation, such as high pressure, high current. If not avoided, life may be endangered. |
| | burn hazard | This symbol indicates a burn hazard, such as hot steam or hot surfaces. |
| | be sure to follow | This symbol draws the attention of the user, failure to follow will damage the product or the sterile load. |
| | Precautions | This symbol draws the user's attention to important matters. |

Logo on the product:

| logo | illustrate |
|---|--|
|  | Be careful of burns |
|  | the manufacturer of this medical device . |
|  | the medical device was manufactured. |
|  | The unique serial number assigned to this medical device by the manufacturer . |
|  | The name and address of the authorized agent of this product in the European Union. |
|  | Important information is contained in the Installation and Operation Manual. Failure to follow may damage the equipment or endanger personal safety. |
|  | Please read the installation and user manual carefully before operating this product. Important information is contained in the Installation and Operation Manual. The function and life of this product are directly related to whether the user follows the operating specifications and maintenance requirements in the installation and use manual. The installation and user manual is a part of this product, please keep it near the product. |
|  | The CE mark on the label of this product indicates that the manufacturer confirms that this product complies with the EU Medical Device Directive. The meaning of the following 4 digits means that the conformity of this product to the EU norms is supervised by the certification body licensed by the EU. |
|  | This mark draws the user's attention to the important matters in the installation and operation manual. |

Safety instructions



Use this product only for the purpose specified in this manual. Follow the safety instructions below and the safety precautions described in other chapters of this manual when operating this product. Failure to follow could endanger personal safety and / or damage the product .

| | |
|-----------------------------|--|
| liquid sterilization | ➤ Do not use this product to sterilize any liquid. |
| professional | ➤ Operators who use this product to sterilize instruments and fabrics must be trained professionals. |

| | |
|---|---|
| <p>Power cord and power plug</p> | <ul style="list-style-type: none"> ➤ Do not replace the power cord or power plug. Do not use a damaged power cord or power plug. ➤ Do not use this product if the power cord or plug is damaged. The power cord or power plug must be replaced by professionals authorized by the manufacturer of this product. ➤ Do not tug on the power cord, and be sure to handle the plug itself when plugging or unplugging it. ➤ Make sure the power cord is not kinked. ➤ Do not place the power cord near heat sources. ➤ Do not touch the power cord with sharp objects. |
| <p>Installation, setup and commissioning</p> | <ul style="list-style-type: none"> ➤ Installation, setup and commissioning should be performed by professionals authorized by the manufacturer of this product. ➤ Do not use or operate this product in areas where there is a risk of explosion. ➤ The electrical connection of this product and the connection of water inlet and outlet pipes should be performed by professionals. ➤ This product should not come into direct contact with patients. Please place this product at least 1.5 meters (radius) outside the diagnosis and treatment area. ➤ If an external printer is configured for this product, the printer must not be placed in a location where there is a risk of contact with liquids. |
| <p>emergency door opener</p> | <ul style="list-style-type: none"> ➤ Do not use this device to open the door under normal conditions. |
| <p>Dirt pretreatment and sterilization</p> | <ul style="list-style-type: none"> ➤ The pretreatment and sterilization of instruments and fabrics should follow the regulations of the instrument and fabric manufacturers. ➤ Relevant standards for disinfection and sterilization should be strictly followed, such as WS506-2016, WS310-2016 , etc. ➤ Use packaging or containers approved by the manufacturer for steam sterilization . |
| <p>program terminated</p> | <ul style="list-style-type: none"> ➤ Please note that when the product terminates abnormally at certain stages of the program, high temperature steam will emerge from the cavity after opening the door. ➤ The load may not have been sterilized when the program was terminated abnormally. Note the status shown on the display when the program was terminated. Loaded items should be repacked for sterilization if necessary. |
| <p>take out the load</p> | <ul style="list-style-type: none"> ➤ Do not use force to open the door. ➤ Use the tray handle to remove the tray. Do not touch the sterilized loaded items, cavity and door cover with bare hands to avoid burns. |

| | |
|--------------------------------|---|
| | <ul style="list-style-type: none"> ➤ Check the integrity of the packaging of the post-sterilized load, and if the packaging is found to be damaged, the instrument or fabric should be repacked for sterilization. |
| Moving and Transporting | <ul style="list-style-type: none"> ➤ Moving or carrying this product requires at least 2 people. ➤ Use a suitable harness. ➤ The packing box provided by the manufacturer of this product must be used for transportation . |
| Sterilization load | <ul style="list-style-type: none"> ➤ The sterilized load can only be sterilized using this product under the premise that the manufacturer allows steam sterilization. |
| maintenance | <ul style="list-style-type: none"> ➤ The maintenance and maintenance of this product must be carried out by professionals authorized by the manufacturer . ➤ Please perform maintenance on this product at the intervals specified in this manual. ➤ accessories supplied by the manufacturer of this product must be used . |
| Fault | <ul style="list-style-type: none"> ➤ If the product repeatedly displays the same failure prompt, please turn off the power. ➤ Fault repairs must be performed by professionals authorized by the product manufacturer . |

Principles of Sterilization and Types of Microorganisms Killed

H ä Tmed small steam sterilizer generates steam through electric heating. In the closed cavity, the steam pressure increases continuously, which makes the boiling point of water continuously increase, so that the temperature in the cavity increases accordingly. After the temperature reaches the standard and maintains for the time specified in the standard, it can kill various microorganisms including spores.

Program Introduction

| program name | Standar d 134 | Standar d 121 | Fast B | fast | 134+ | Nguyen Virus | the fabric |
|---|---------------|---------------|--------|------|------|--------------|------------|
| program type | B | B | B | S | B | B | B |
| Sterilization chamber dynamic pressure monitoring | √ | √ | √ | √ | √ | √ | √ |
| air leak | √ | √ | √ | √ | √ | √ | √ |
| no load | √ | √ | √ | √ | √ | √ | √ |
| solid load | √ | √ | √ | √ | √ | √ | |
| A small amount of porous and permeable mixed load | √ | √ | | | √ | √ | |
| small amount of porous permeability load | √ | √ | | | √ | √ | √ |
| Fully loaded porous permeability load | √ | √ | | | √ | √ | √ |
| B cavity load | √ | √ | √ | √ | √ | √ | |

| | | | | | | | |
|--|---|---|---|---|---|---|---|
| A cavity load | √ | √ | √ | | √ | √ | |
| simple packaging | √ | √ | √ | √ | √ | √ | √ |
| Composite packaging | √ | √ | √ | | √ | √ | √ |
| dry, solid load | √ | √ | √ | √ | √ | √ | |
| Dry, Porous Permeable Loads | √ | √ | | | √ | √ | √ |
| Note: √ Complies with the corresponding clauses in the EN 13060-2014 standard | | | | | | | |

DIRECTORY

| | | |
|------------|--|---------------|
| 1 | Device Description | - 1 - |
| 1.1 | product view | - 1 - |
| 1.1.1 | Front view | - 1 - |
| 1.1.2 | side view | - 1 - |
| 1.1.3 | Rear view | - 2 - |
| 1.1.4 | inner view | - 2 - |
| 1.2 | Technical Parameters | - 3 - |
| 1.3 | loading method | - 3 - |
| 1.4 | Smart Controller and Control Panel | - 3 - |
| 1.4.1 | Operation buttons and menu introduction | - 4 - |
| 1.5 | Emergency door opener | - 5 - |
| 1.6 | Device Workflow | - 5 - |
| 1.6.1 | Sterilization procedure | - 5 - |
| 1.6.2 | Vacuum test | - 6 - |
| 2 | Installation and Handling Instructions | - 7 - |
| 2.1 | Precautions for unpacking | - 7 - |
| 2.2 | Installation site requirements | - 7 - |
| 2.3 | Equipment height adjustment | - 7 - |
| 2.4 | connection requirements | - 8 - |
| 2.4.1 | Electrical connections | - 8 - |
| 2.4.2 | Distilled water connection | - 8 - |
| 2.4.3 | waste water connection | - 9 - |
| 2.5 | Installation service sheet | - 9 - |
| 2.6 | Handling instructions | - 9 - |
| 3 | first time using | - 11 - |
| 3.1 | start up | - 11 - |
| 3.2 | after booting | - 11 - |
| 3.3 | switch door | - 13 - |
| 3.4 | Feed water | - 14 - |
| 3.5 | Verification of sterilization effect | - 14 - |
| 4 | Sterilization procedure | - 15 - |
| 4.1 | Loading items to be sterilized | - 15 - |
| 4.2 | Select a sterilization program | - 15 - |
| 4.3 | Accessibility options | - 17 - |
| 4.3.1 | preheat setting | - 17 - |
| 4.3.2 | print automatically | - 17 - |
| 4.3.3 | extra dry | - 17 - |
| 4.4 | run a sterilization program | - 17 - |
| 4.4.1 | Start to sterilize | - 17 - |
| 4.4.2 | Program running process | - 17 - |
| 4.5 | manual stop | - 19 - |
| 4.6 | Sterilization program complete | - 21 - |
| 4.7 | Storage of sterile items | - 22 - |
| 5 | Functional testing and other procedures | - 23 - |
| 5.1 | vacuum test | - 23 - |
| 5.2 | B & D testing | - 25 - |
| 5.3 | Helix test | - 25 - |
| 5.4 | Drainage procedure | - 26 - |
| 6 | device settings | - 27 - |
| 6.1 | Date and Time Settings | - 27 - |
| 6.2 | language settings | - 29 - |
| 6.3 | running information | - 30 - |
| 7 | user settings | - 31 - |
| 7.1 | automatic setting | - 32 - |
| 7.1.1 | Automatic preheat setting | - 32 - |
| 7.1.2 | Automatic print settings | - 33 - |

| | | |
|-------------------|---|---------------|
| 7.1.3 | Water quality testing settings | - 33 - |
| 7.1.4 | extra dry setting..... | - 33 - |
| 7.2 | system settings..... | - 35 - |
| 7.2.1 | Modify user password..... | - 35 - |
| 7.2.2 | system reset | - 37 - |
| 7.3 | Maintenance | - 39 - |
| 8 | Sterilization records..... | - 40 - |
| 8.1 | View history..... | - 40 - |
| 8.2 | Export history..... | - 41 - |
| 8.3 | Print history | - 42 - |
| 8.4 | Query history..... | - 42 - |
| 8.5 | Automatic record printing | - 44 - |
| 8.6 | Record interpretation..... | - 44 - |
| 9 | Maintenance of small steam sterilizer..... | - 46 - |
| 9.1 | Cleaning of Loaded Items before Sterilization | - 46 - |
| 9.2 | Maintenance of small steam sterilizer..... | - 46 - |
| 9.2.1 | Cleaning and maintenance | - 46 - |
| 9.2.2 | Regular maintenance..... | - 47 - |
| 10 | Troubleshooting and common problem handling..... | - 48 - |
| 10.1 | Display shows nothing | - 48 - |
| 10.2 | High consumption of distilled water | - 48 - |
| 10.3 | drying effect is not good | - 48 - |
| 10.4 | no distilled water..... | - 48 - |
| 10.5 | unable to open the door | - 48 - |
| 10.6 | Leakage at the door or water dripping from below..... | - 49 - |
| 11 | Precautions..... | - 50 - |
| 11.1 | In order to ensure the safe use of the equipment, please be sure to cut off the power and water source before leaving work or for a long time (more than 8 hours) when it is unattended | - 50 - |
| 11.2 | Only designated distributors are qualified to provide you with spare parts and after-sales service. H à Tmed is not responsible for any consequences caused by unauthorized repairs by other personnel or the use of spare parts not produced by our company..... | - 50 - |
| 11.3 | Do not open the machine cover or place any objects inside the machine, otherwise it will damage the machine and endanger the safety of the operator..... | - 50 - |
| 11.4 | Once the machine is used, it means that the user agrees to all the above terms and promises to operate in accordance with the instructions for use..... | - 50 - |
| 11.5 | For the power supply line of the sterilizer, there should be a leakage protection device to prevent the leakage current of 30mA, and a reliable grounding wire should be connected..... | - 50 - |
| Appendix 1 | Safety device description | - 51 - |
| Appendix 2 | Piping System Schematic..... | - 52 - |
| Appendix 3 | Electrical Schematic..... | - 53 - |

1 Device Description

1.1 product view

1.1.1 Front view

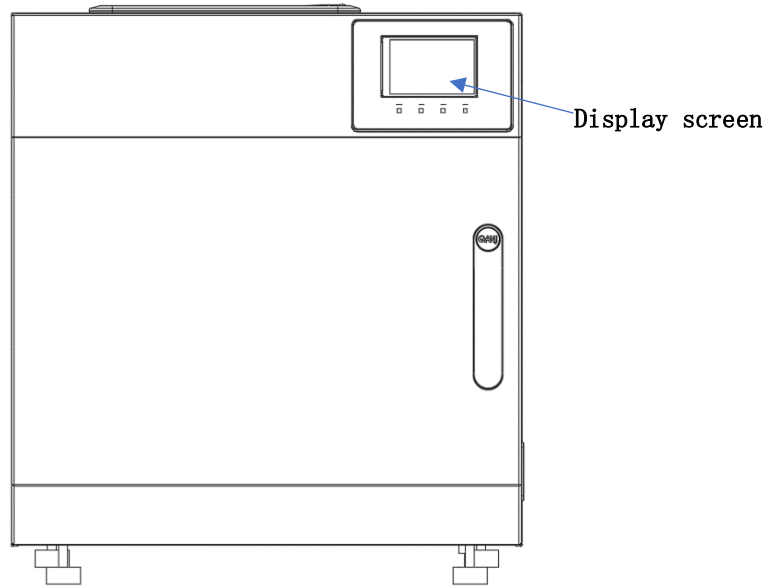


Figure 1.1 Front view

1.1.2 side view

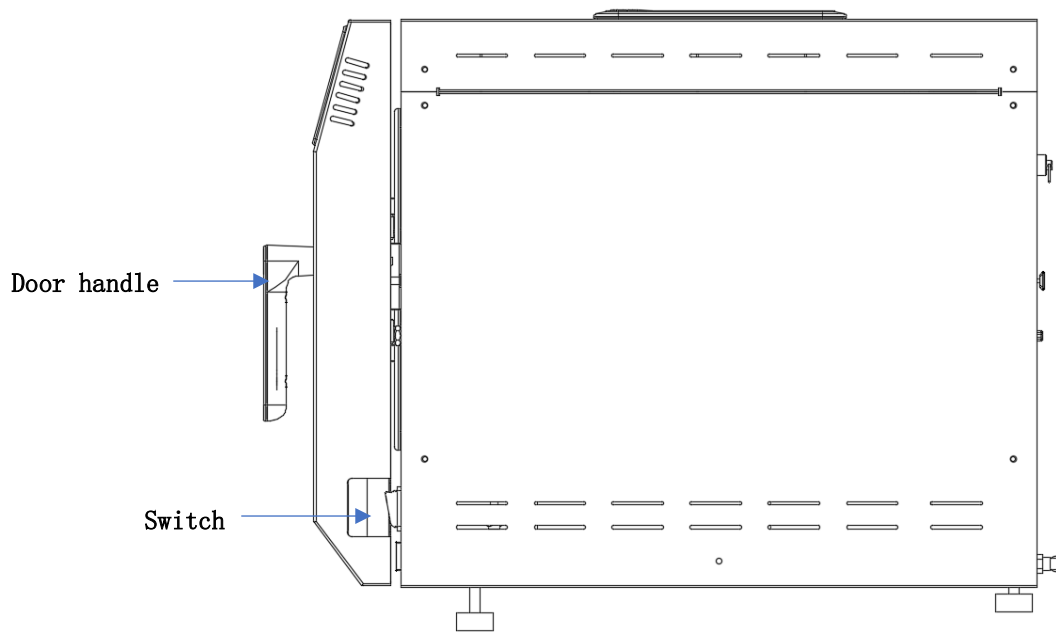


Figure 1.2 Side view

1.1.3 Rear view

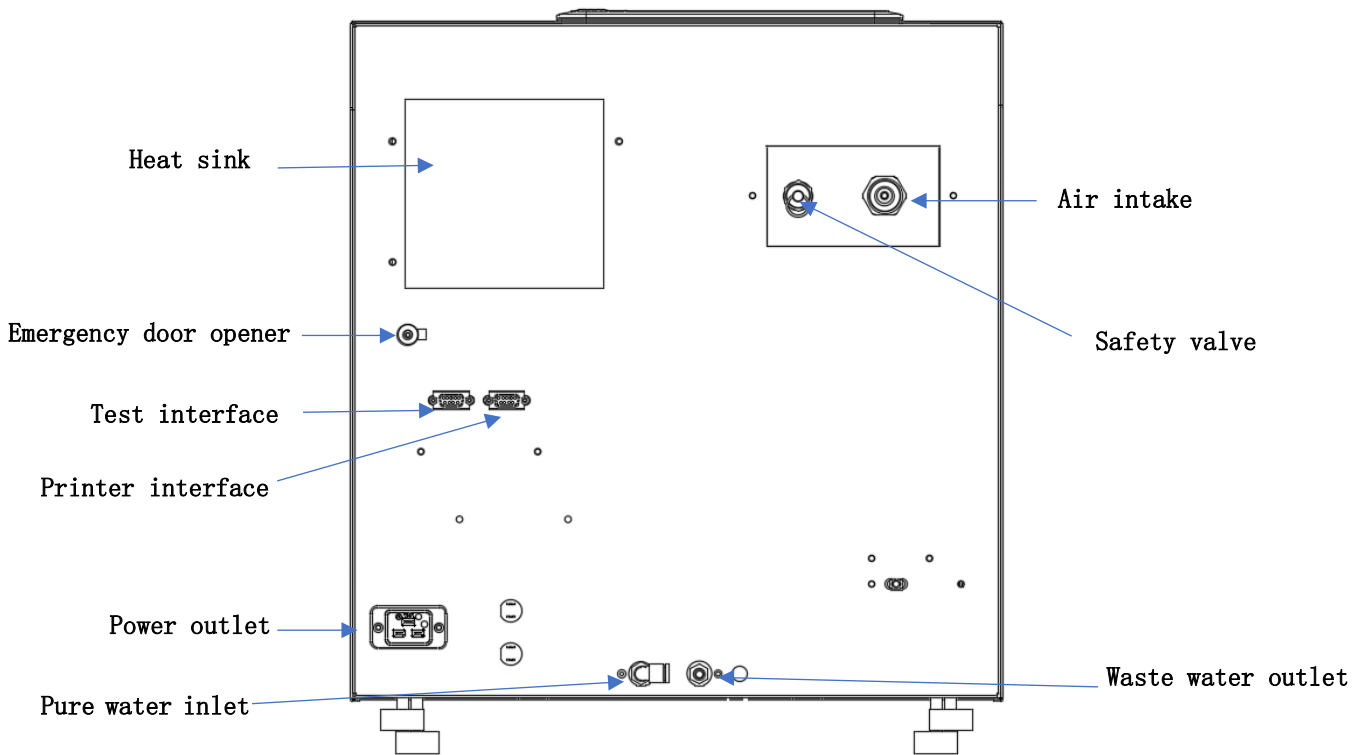


Figure 1.3 rear view

1.1.4 inner view

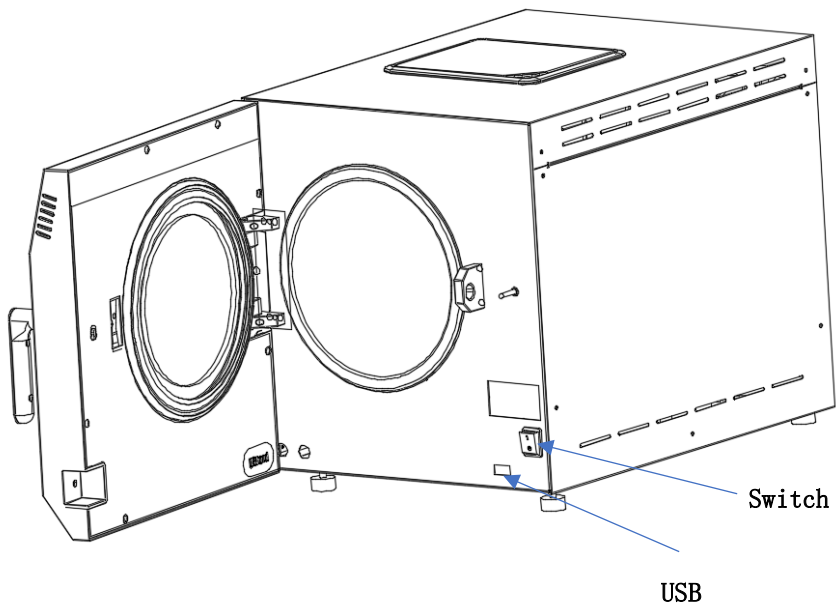


Figure 1.4 Internal view

1.2 Technical Parameters

| parameter name | Q21B |
|--|---|
| physical dimension | 656mm*452mm*500mm |
| Package Size | 690mm*580mm*700mm |
| Cavity size | Φ253mm*355mm |
| Sterilization chamber volume | 18L |
| Pressure Vessel Weight | 5.2kg |
| equipment weight | 48kg |
| Software version | V00 |
| Pressure Vessel Specifications | Working pressure is less than 0.25Mpa Working temperature: 115°C-138°C |
| Operating Voltage | AC 220V±22V, 50Hz±1Hz |
| Maximum power | 2000VA |
| fuse | 16A |
| work environment pressure | 70Kpa _ ~ 106Kpa _ |
| Working temperature | 5 °C ~ 40 °C |
| Storage and transportation ambient temperature | -20 °C ~ 55 °C |
| environment humidity | ≤ 85% |
| Maximum Wastewater Temperature | 100 °C |
| maximum noise | 70dB(A) |
| <p>Note 1: The maximum working voltage range is 198V ~ 242V Note 2: Anti-electromagnetic interference is the ability of the product to work normally in the presence of electromagnetic interference.</p> | |

1.3 loading method

The tray rack is included in the accessories of this product. The space inside the tray rack is a space that can be effectively sterilized. Please use the tray rack when loading items to be sterilized. The tray rack included in the standard accessories can hold 5 trays. or rotate 90 ° After C adapt to different load or container thickness.





1.4 Smart Controller and Control Panel

The intelligent controller is the core of the small steam sterilizer. In addition to completing the rapid collection, processing, fault detection and control of the sterilization process of the real-time parameters of the system, the controller also intuitively draws the temperature and pressure in the cavity time-varying curve. The controller also undertakes the evaluation and monitoring of the program control process. During the program operation, the current operating parameters are compared with the standard parameters. Once the parameters deviate from the standard parameters, a fault message will be generated immediately to ensure safety and sterilization during the sterilization process. bacteria quality.

realizes simple and efficient operation through an LCD screen and 4 buttons.

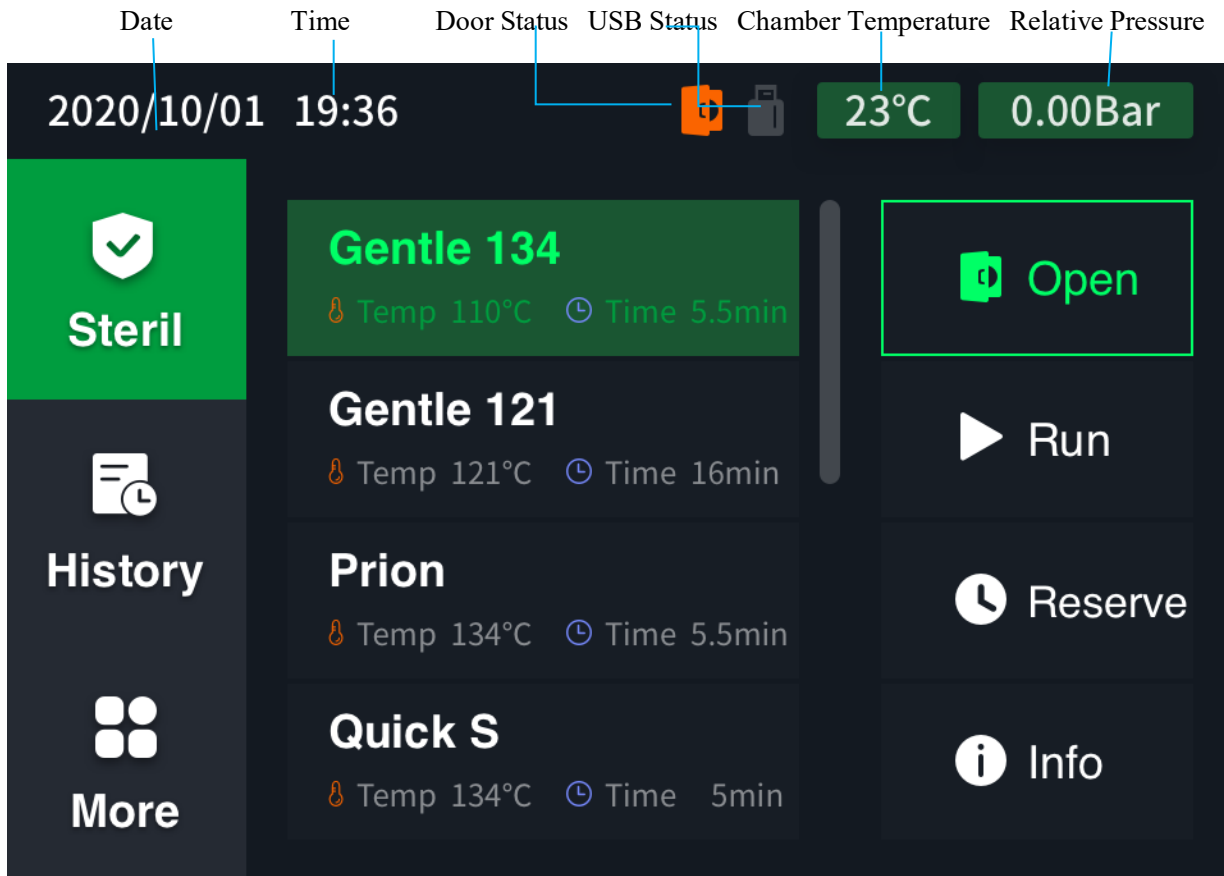
1.4.1 Operation buttons and menu introduction

4 buttons in different situations is as follows.

| | | | | |
|---|---|---|---|---|
| button position (face up from left to right) | 1 | 2 | 3 | 4 |
| |  |  |  |  |
| During program selection | return | previous option | next option | choose |
| standby mode | | | | start up |
| program runtime | | | | stop |
| when setting | | | | Sure |

interface introduction

Date Time Door Status USB Status Chamber Temperature Relative Pressure Chamber





Chamber



A menu

Secondary menu



Level 3 menu

(The main page  can be switched between the three-level menus by pressing the button )

There is also a USB disk insertion mark in the interface to display the USB access status.

| status flag | illustrate |
|---|--|
|  U disk status | Indicates the state of the U disk : inserted |
|  U disk status | Indicates the state of the U disk : not inserted |

There is also a door lock mark on the interface to display the door lock status.

| status flag | illustrate |
|---|---------------------------------------|
|  lock status | Indicates door lock status: open |
|  lock status | Indicates the door lock status: close |

1.5 Emergency door opener

Unconventional door opening method used when the machine cannot be powered on or the safety door lock is faulty due to other reasons . Under normal circumstances, do not use this method to open the door. The specific operation method: unscrew the emergency device on the back of the product Open the protective cover with the screw on the protective cover, then grasp the white plastic disc inside the protective cover with your right hand , pull it gently (the stroke is about 1CM), and at the same time, lift the door handle up with your left hand to open the door .

1.6 Device Workflow

1.6.1 Sterilization procedure

The sterilization process includes three stages, namely pre-vacuum, sterilization, and drying. After the program starts, the user can see the stage indication of the program running on the sterilization interface. The interface also displays the real-time temperature and pressure in the cavity , and the estimated remaining program running time.

| Process stage name | illustrate |
|------------------------------|--|
| 1. Pre-vacuum | In the pre-vacuum stage, the process of evacuating and injecting steam is repeated, and the air content in the cavity is reduced to a minimum as the mixture of air and steam is continuously pumped out. The number of repetitions of this process varies according to the selected program, the standard sterilization program is repeated 3 times, the Helix program and the 134+ program are repeated 4 times. |
| 2. Heating | The pre-vacuum is followed by a heating phase. Steam is continuously injected into the chamber, and the temperature and pressure in the chamber are continuously increased until reaching the specified values of the selected program. |
| 3. Sterilization maintenance | After the temperature and pressure reach the set value of the selected program, the sterilization holding stage starts and maintains a stable temperature and pressure for a period of time to ensure that the sterilization effect meets the specification requirements. |
| 4. Pressure relief | After the sterilization hold is over, the pressure in the cavity is released, and the steam in the steam generator is discharged at the same time. |
| 5. Dry | Items are vacuum-dried after sterilization. Drying begins after the pressure is released. The air in the chamber is always sterile during the drying process thanks to the high-efficiency air filter. |

| | |
|---------------|--|
| 6. Air intake | The drying process is also an air intake process, ensuring that the pressure in the chamber returns to ambient pressure at the end of the program. |
|---------------|--|






1.6.2 Vacuum test

The purpose of the vacuum test is to test the leak rate of the equipment. During the process, the items in the cavity were not sterilized. Please run the vacuum test with a cold machine, dry chamber, and no load.

| Process stage name | illustrate |
|---------------------------|--|
| 1. Vacuuming | The air in the chamber is pumped out until the pressure in the chamber reaches the pressure setting value for the vacuum test. |
| 2. Balance time | Then wait for 5 minutes to make the vacuum level in the cavity uniform. |
| 3. Test hold time | The test hold time is 10 minutes. During this time the device continuously monitors the pressure in the chamber. |
| 4. End of test | After the test, the screen displays the test results: vacuum degree and leak rate. |

2 Installation and Handling Instructions

2.1 Precautions for unpacking

| | |
|---|--|
|  | Installation, setup and commissioning should be performed by professionals authorized by the manufacturer of this product. |
|  | If the product is stored in different places before unpacking, it will take a while before it can be installed and turned on for use. During the process of moving from a place with low temperature to a place with high temperature, the electronic components inside the device will contain water vapor. Turning on the power immediately may affect the normal operation of the device and the safety of users. |
|  | The process of taking out and moving this product from the packing box must be operated by 2 people. |
|  | Please check the packing box and the unpacked device carefully. If you find that the packing box is damaged or the equipment is damaged, please contact the authorized dealer or logistics company immediately. |
|  | Please check and count the packing box and the random accessories inside the device. |

2.2 Installation site requirements

This product should be placed in a dust-free and dry environment. The ambient humidity is less than 85% , and the temperature is at 5 °C to 40 between °C.



- Do not use or operate this product in areas where there is a risk of explosion.



- The work surface must be able to support the weight of this product:
- After installation, each surface (except the bottom) of this product must leave a gap of more than 10 cm outward. Too small air gaps can lead to heat build-up, which can shorten the life of the device, degrade device performance, and prolong program run time.

2.3 Equipment height adjustment

Take out the spirit level from the accessory bag and place it at the horizontal position on the top of the product . Adjust the two front pads so that the front of the product is slightly higher than the rear , and the bottom and the table are clamped at 5°-10° . This facilitates drying of the sterile load and saves distilled water.

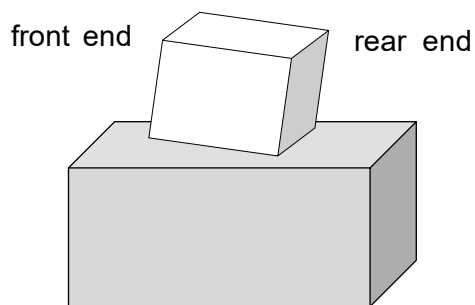


Figure 2.1 Equipment height adjustment

2.4 connection requirements

2.4.1 Electrical connections

- 220V/50Hz power supply. The maximum power fluctuation range is 198V ~ 242V.
- Use a separate 16A power loop. Provide 30 mA leakage protection.
- Make sure the power cord is not kinked or pinched (such as by a window or door).
- Do not tug on the power cord, and be sure to handle the plug itself when plugging or unplugging it.
- Do not place the power cord near heat sources.
- Do not touch the power cord with sharp objects.
- Do not replace the power cord or power plug. Do not use a damaged power cord or power plug.
- Do not use this product if the power cord or plug is damaged. The power cord or power plug must be replaced by professionals authorized by the manufacturer of this product.
- Protective grounding: Please ensure that the equipment is reliably connected to the ground during equipment installation.
- Do not place the equipment in a position where it is difficult to access the main power switch.



2.4.2 Distilled water connection

A small steam sterilizer without a built-in water tank needs to be equipped with an independent distilled water bucket. Take out the distilled water pipe from the accessory bag, pass one end of the distilled water pipe through the reserved through hole on the lid of the distilled water bucket and insert it into the bottom of the bucket, and connect the other end to the distilled water interface on the back of the product , and tighten it. Fill the distilled water tank or bucket with fresh distilled water before using this product . Distilled water is generally stored in the standard distilled water tank with a capacity of 12L, and the whole tank of distilled water can be sterilized up to 20 times. Please pay attention to observe the amount of distilled water remaining in the water tank, and replenish it in time so as not to affect the normal operation of the product .

- High quality distilled or demineralized water according to EN 13060-2014 Annex B. Because the formation of instrument rust depends on whether the quality of distilled water is up to standard;
- Conductivity \leq 20 μ s /cm ;
- In order to prevent the distilled water from being polluted, the lid of the distilled water tank must be tightened or tightly closed at all times;
- For small steam sterilizers with a built-in water tank, empty the waste water tank every time you add water;
- Clean the distilled water tank regularly, at least once a month;
- This product has a water quality monitoring device. When substandard distilled water is used for sterilization, this product will not work normally and will generate a prompt message that the water quality cannot meet the standard. When you see this message, please replace it with high-quality distilled water in time;
- If you need to use the water purification device, please consult the manufacturer of this product first ;
- All the water pipes connected to the back of this product should be inclined downwards and fixed firmly to ensure that there are no bends or knots.



2.4.3 waste water connection

For small steam sterilizers without a built-in water tank, take out the drain hose from the accessory bag and insert it into the waste water port on the back of the product .

- All the water pipes connected to the back of the small steam sterilizer should be inclined downwards and fixed firmly to ensure that there are no bends or knots.



2.5 Installation service sheet



- After installation, please carefully fill in the installation service sheet in the product service manual as useful information for maintenance and proof of quality assurance.

2.6 Handling instructions

This product should be kept at a humidity of less than 85% and a temperature of -20 ° C ~ 55 ° Store and transport under C.

this product , perform the drainage procedure first, remove all the pipes on the back (distilled water pipes and drain pipes), and if a printer is connected, remove the printer data cable.

If the tray rack and trays are placed in the sterilization chamber during transportation, place a foam pad between the door and the tray rack before closing the door to prevent the tray rack from being damaged due to shaking during transportation.

the product must be put back into the packing box in the order when it was unpacked, and the packing box must be sealed.



- Use the drain procedure before handling this product.

3 first time using

3.1 start up

Toggle the power switch to turn it on. The power switch position is in the lower right corner of the internal view of the product.

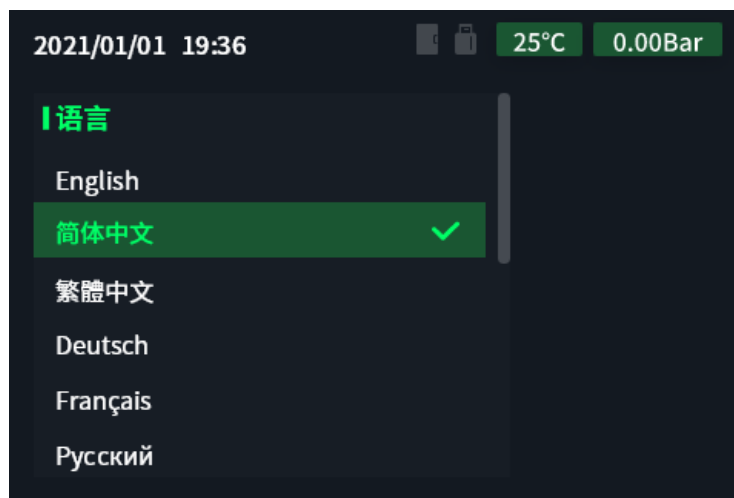


- Before using for the first time, please be sure to remove the latex plug at the air filter installation hole on the back of the product, and install the air filter included in the accessories.

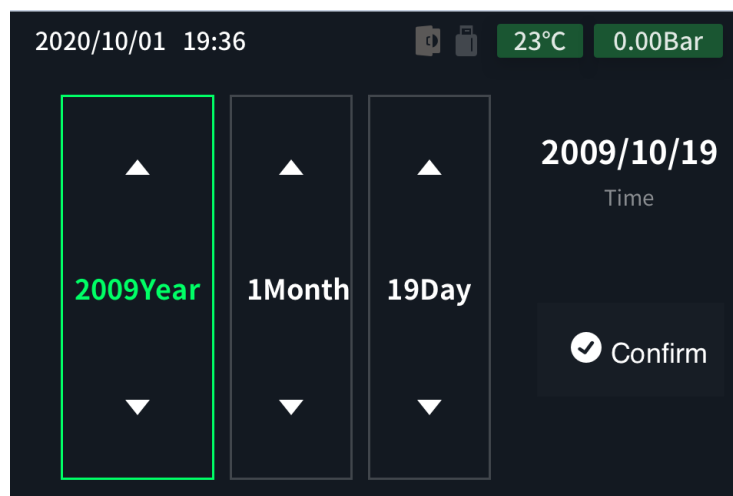
3.2 after booting

After turning on the device for the first time, please follow the automatic prompts of the system to set the language and time .

The first operation process is as follows:

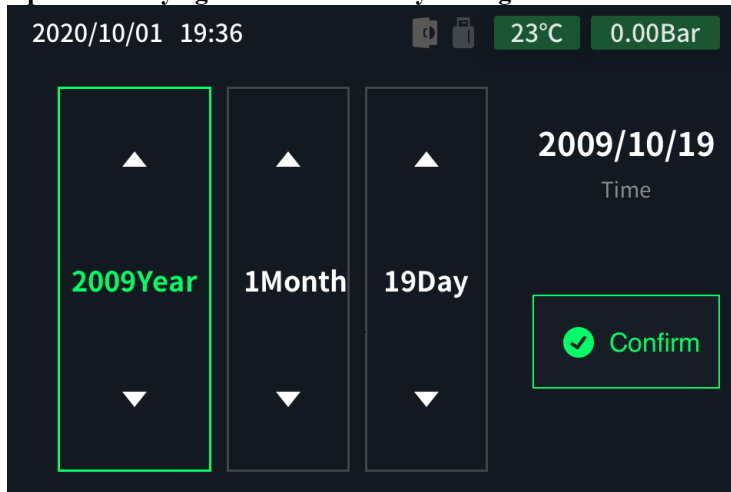



- Press  the or  key to select the language, and press the key to confirm. 

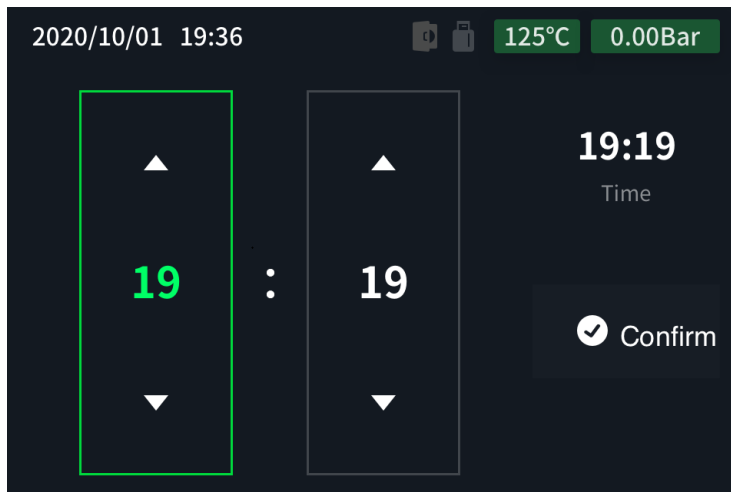





- Press  the or  key to adjust the year, press the key to confirm, and enter the month setting,

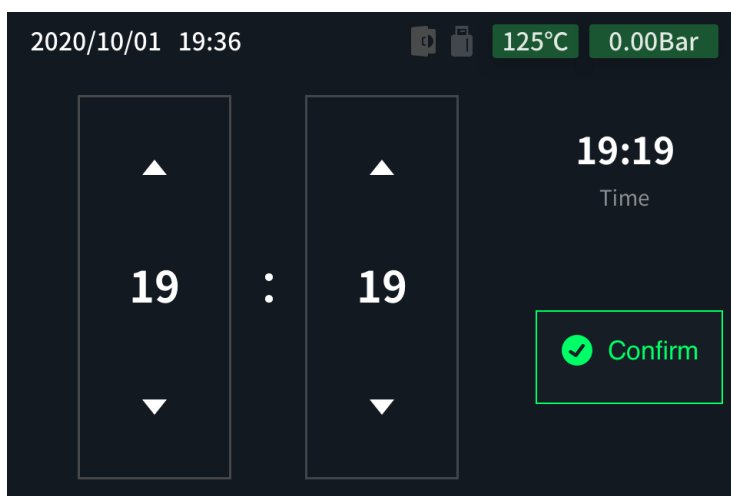
and   press the key again to enter the day setting.



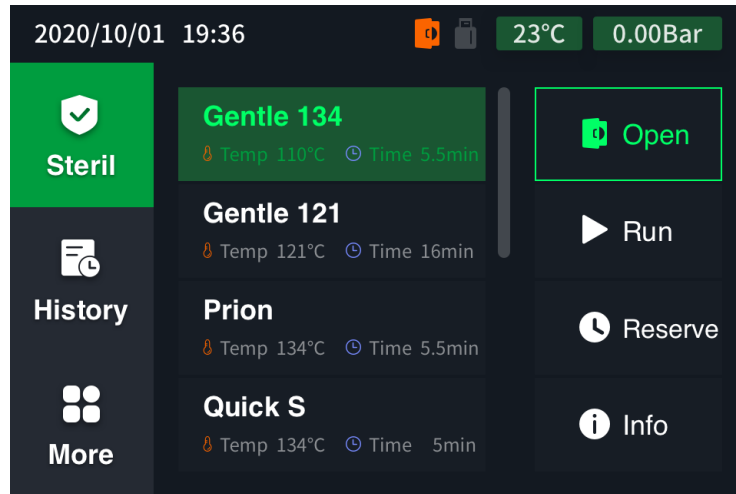
- After the date setting is completed, select the confirmation menu and press the key to enter the time setting. 




- Press  the or  key to adjust the time, and press the key to confirm. 



- Time setting complete
- After the time setting is saved, enter the system home page.



3.3 switch door

Door opening operation: select the door opening menu in standby mode, click  the button to open the door, the door lock mark in the system status bar will change status, indicating that the door lock has been opened, at this time, open the door handle on the right side of the front door panel of the product upwards 90° left and right, then pull the door outward.

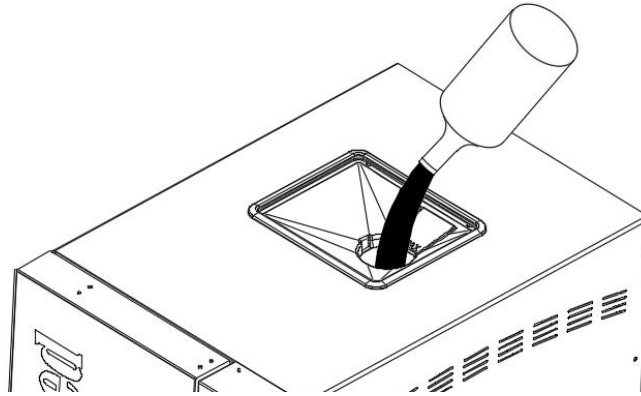
Door closing operation: close the small steam sterilizer door, and turn the door handle down to the end.



- When closing the door, please press the door handle down to the bottom at one time, the required force may increase after a period of use.
- Do not slam the door hard at any time.
- Failure to comply with the above requirements may affect the function and reliability of the door locking device.
- Only open the door when loading and unloading, and keep the door closed at other times to save energy.

3.4 Feed water

If the autoclave comes with internal water reservoirs, fill the distilled water tank from time to time. Make sure the water level in the distilled water tank is between the MIN and MAX marks. Close the lid as soon as refill is done to ensure cleanness.



Feed distilled water



- Use distilled or demineralized water that meets the requirements listed in EN 13060 Appendix C. Unqualified feed water may cause corrosion of instruments.



- For device with internal water tanks, please drain the waste water tank every time you feed water to the distilled water tank.

3.5 Verification of sterilization effect

a small steam sterilizer is newly installed or used for 12 months or repaired, BD test should be carried out without load and physical monitoring, chemical monitoring and biological monitoring should be carried out at full load. It can be used normally only after the monitoring is qualified. The verification of sterilization effect should follow the requirements of Appendix E of WS506-2016.

4 Sterilization procedure

4.1 Loading items to be sterilized

The random accessories of this product include tray rack and tray. The space inside the tray rack is a space that can be effectively sterilized, and the excess part is too close to the barrel wall to easily produce wet packages or burn the package. Always use tray racks and trays with holes in the bottom when loading items to be sterilized.

Correct loading is a key factor for effective sterilization and drying, and the following must also be observed during loading:

- The sterilized load must be sterilized under the premise that the manufacturer allows steam sterilization;
- Packaging materials for packaged sterilized products should meet the GB/T 19974 standard;
- the paper must be placed on top of the surface;
- When sterilizing mixed loads, fabrics are on top and metal objects are on the bottom;
- between the sterilization packs ;
- The metal pack and the dressing pack cannot fit together tightly;
- 90% of the cavity capacity .






4.2 Select a sterilization program

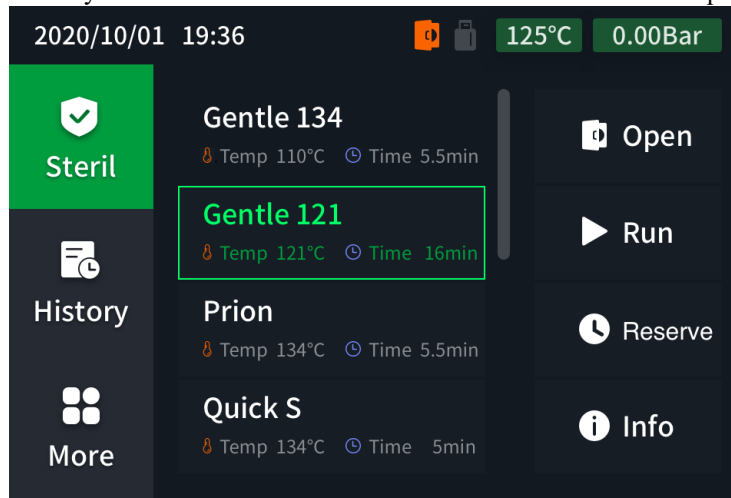
This product has 7 preset sterilization programs. Please select the appropriate sterilization program according to the load type and packaging material. The parameter setting and typical load description of the sterilization program are shown in the table below. The maximum load of Q21B is 7kg of instruments or 2.5 kg of fabric .

Table 3 -1 Sterilization program and parameter settings

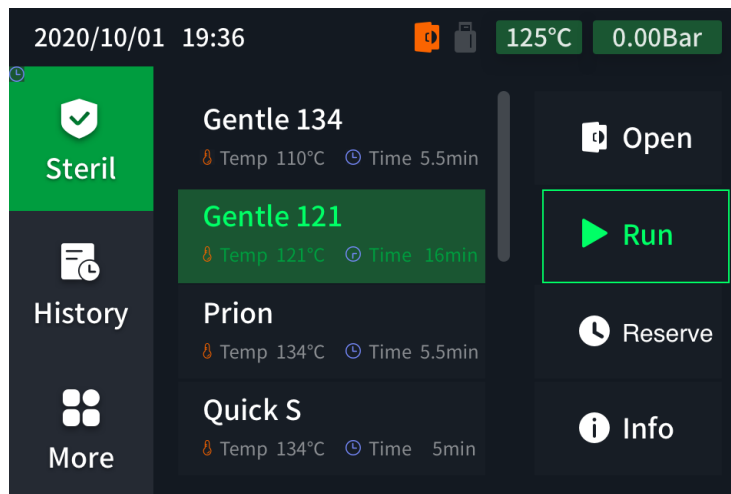
| program name | temperature (°C) | hold time (minutes) | drying time (minutes) | Sterilization load |
|------------------------|-------------------|-----------------------|------------------------|---|
| Standard 121 Procedure | 121 | > 15 | 1-99 | Small amounts of fabric, heat-labile appliances |
| Standard 134 Procedure | 134 | > 3 | 1-99 | Mixed loading, long-body hollow instruments and other complex instruments |
| 134+ programs | 134 | > 3 | 1-99 | Mixed loading, long-body hollow instruments and other complex instruments |
| quick procedure S | 134 | > 3 | 1-99 | Simple solid instruments, transmission instruments, hollow instruments. |
| Express Procedure B | 134 | > 3 | 1-99 | Packed instruments or unpacked simple solid instruments. |
| prions _ program | 134 | >20 | 1-99 | Heat-resistant instruments suspected of being infected by prions |
| fabric program | 121 | > 15 | 1-99 | the fabric |

Select the sterilization program as follows:

Enter the second-level menu of sterilization on the home page, press  or  to select the desired sterilization program,  and press the key to enter the third-level menu of the selected sterilization program.



- Press  the or  key to select the sterilization program, press the key to enter the submenu .



4.3 Accessibility options

4.3.1 preheat setting

The automatic preheating function can make the product reach the set temperature before the program starts, greatly reducing the time required for each sterilization.



After turning on the automatic preheat setting, the chamber will automatically heat up to 110°C. Please be careful of burns!

4.3.2 print automatically


After the automatic printing function is turned on and the product is correctly connected to the printer, the product can automatically print the sterilization record after the program ends.

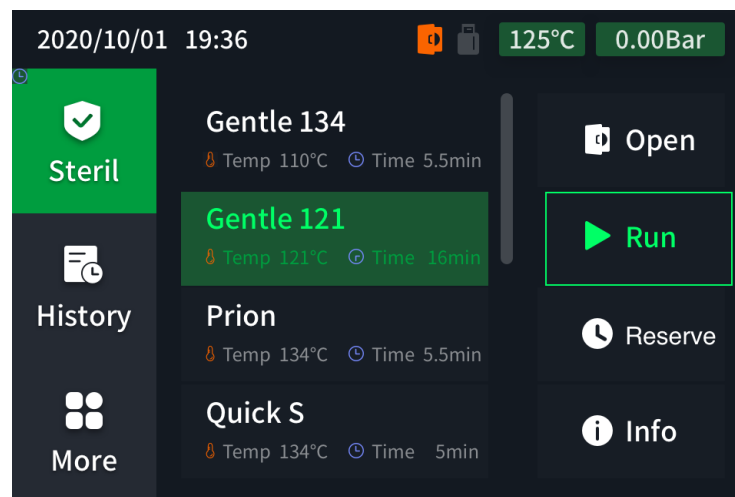
4.3.3 extra dry


Additional drying settings can be made according to user preferences. On the basis of the drying time in Table 3-1 , the drying time of the preset sterilization program can be extended to achieve a good drying effect for the load, especially cotton fabrics.

4.4 run a sterilization program

4.4.1 Start to sterilize

After selecting the sterilization program, select the run menu and click  the button to start the sterilization. The product will ensure the door is locked and monitor the distilled water quality after the program starts .

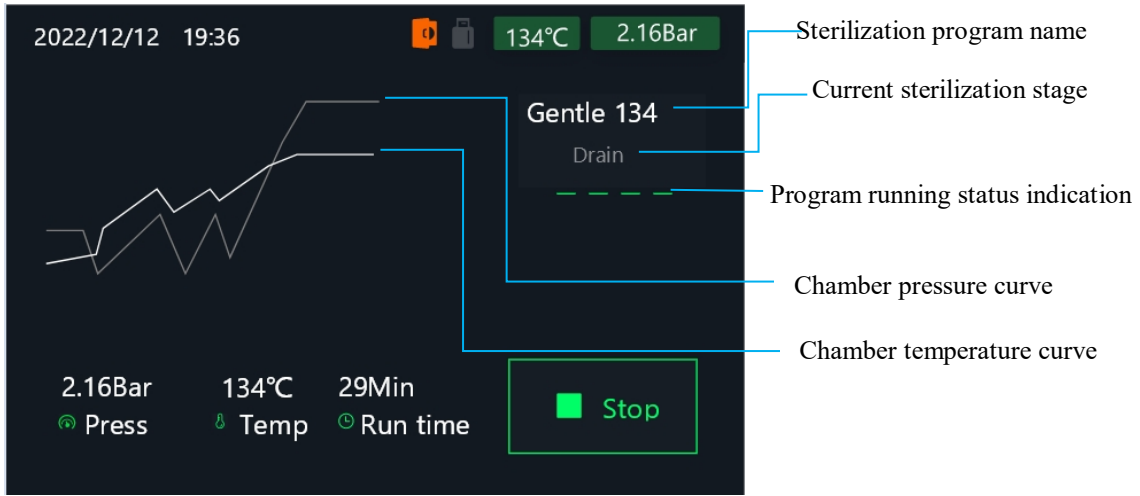


- Select the run menu and press the key to start  the sterilization.

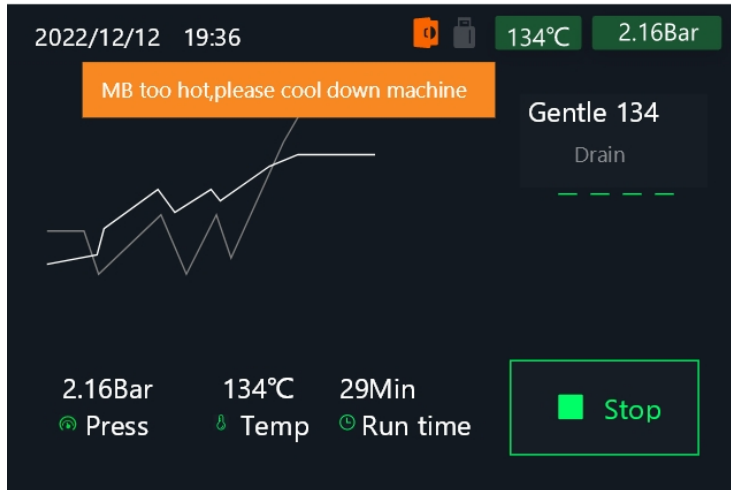
4.4.2 Program running process

The sterilization program operation process includes 3 stages, pre-vacuum, sterilization and drying. The controller monitors the operation of the equipment and the temperature and pressure in the cavity in real time, and displays relevant information on the screen.

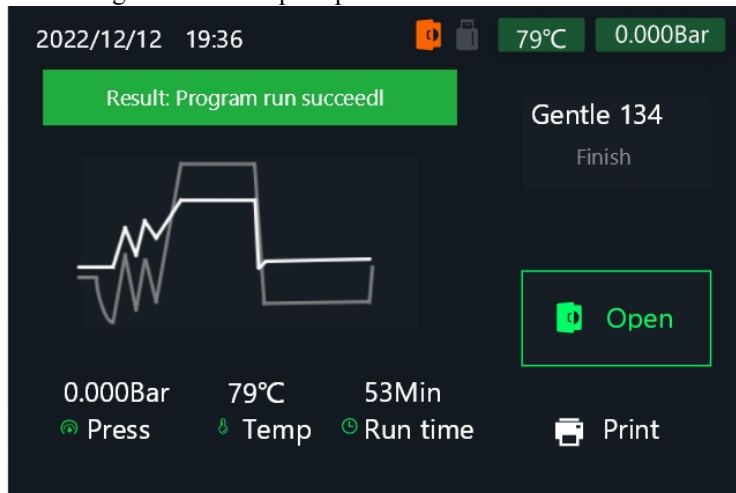
When the water quality is poor during the running of the program, the running interface will prompt the poor water quality



When the temperature of the main board is higher than 80° during program running, the running interface will display a high temperature prompt



After the program runs, the running result will be prompted



4.5 manual stop

A running program can be stopped manually at any stage. If the sterilization process is stopped before drying begins, the load is not sterilized. If the sterilization process is stopped manually after drying has started, the load has been effectively sterilized but not sufficiently dried. For the case of full packaged items, the possibility of wet packs is very high, and these items will not be able to be stored, because aseptic storage requires high dryness of packaged items.

After the program has been manually stopped, hot steam may come out when the door is opened and cause burns!




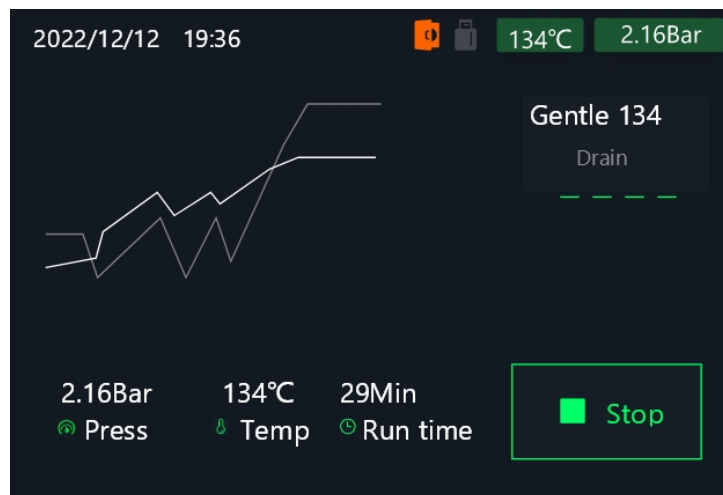
- Do not touch the product, contents, cavity or door cover with bare hands;
- Always use the tray handles to grab loads.

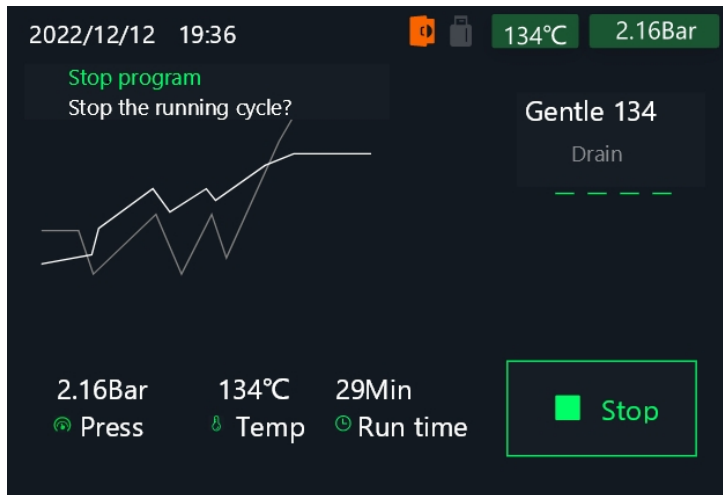
Stopping the sterilization process manually at an early stage may lead to infection!



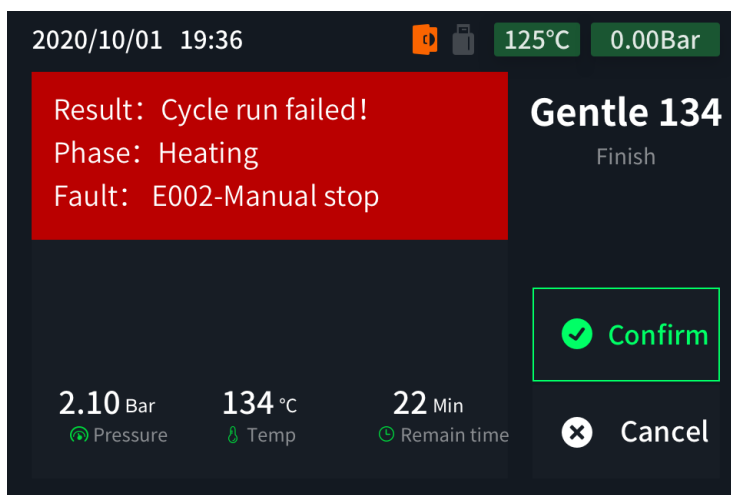
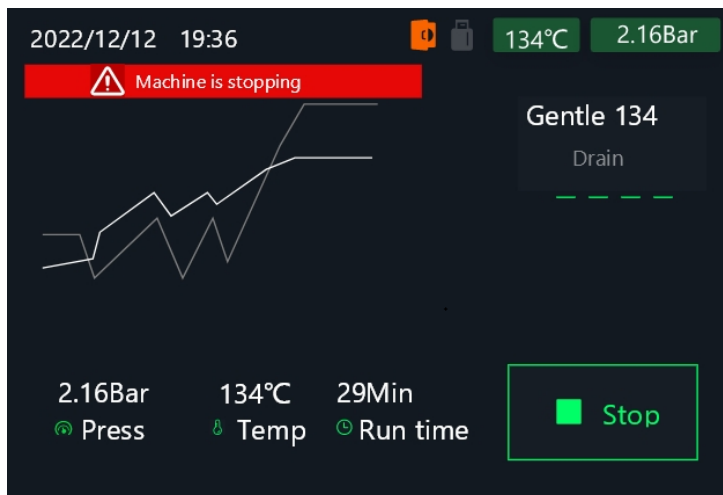
- When the sterilization process is manually stopped before drying begins, the load is not effectively sterilized and the use of these items may endanger the health of the operator and the patient;
- If necessary, the load should be repacked for sterilization.

If it is determined that the current program needs to be stopped manually, in the sterilization interface, please click  the key. After the manual stop, the screen displays the program end interface and manual stop fault information, and the intelligent controller immediately handles it according to the current situation, so that the inside of the cavity reaches a safe pressure, and other parts of the equipment also ensure a safe state. After the equipment reaches the safe state, the controller allows the operation of the door open button. The time required and the program running state when the machine is manually stopped usually take a few minutes.






- ▲
 Select the confirmation menu and press the button to stop the sterilization
 ↩



4.6 Sterilization program complete

the sterilization program ends normally, the screen displays the program end interface and the message of successful program operation. If the automatic printing function is set and a printer is connected, the product will

automatically print the sterilization record. Click  the key to open the door.

Be careful of burns!



- Do not force the door open. Failure to do so could result in damage to the product and/or hot steam rushing out of the cavity.
- After the sterilization, wait for a period of time until the product is fully cooled before opening the door;
- Do not touch any metal surface;
- Do not touch the sterilized loaded items, cavity and door cover with bare hands to avoid burns;
- Always use the tray handles to remove loads;
- Balance the tray when removing it to prevent the contents from slipping off.

Instruments or items with damaged packaging may not have been effectively sterilized and contact with these items could endanger the health of the operator or patient.



- If damaged packaging is found, please repackage and sterilize the item.
- Waiting for 5 minutes after the sterilization is finished before taking out the loaded items is conducive to the drying of sterile items;
- 11th edition (2017) of the correct method of cleaning and disinfection of medical devices issued by the international authoritative organization AKI Germany recommends that the criterion for judging the wet package is that there are still residual water droplets on or in the package 15 minutes after the end of sterilization.
- Physical parameters should be monitored and process variables recorded and checked for each sterilization cycle. When the sterilization temperature set for this cycle is 121°C, the maintenance time should not be less than 15 minutes; when the sterilization temperature set for this cycle is 134°C, the maintenance time should not be less than 3 minutes.
- Chemical monitoring should be carried out for each sterilization cycle. By observing the color change of the chemical indicator, follow the information and requirements provided by the indicator manufacturer to determine whether the sterilization requirements are met.



-
- Sterilization monitoring should comply with the requirements of Appendix E of WS 506-2016 .



- **The national standards for disinfection and sterilization WS310-2016 and WS506-2016 both stipulate that the operating cycle parameters of the sterilizer should be fully recorded and kept for 3 years.**

4.7 Storage of sterile items

The storage time of sterile packs after sterilization varies with the packaging material and storage conditions. It can be stored for up to 6 months under the conditions of full compliance with specifications, such as WS310-2016 . Please follow WS310-2016 for packaging requirements and storage conditions .

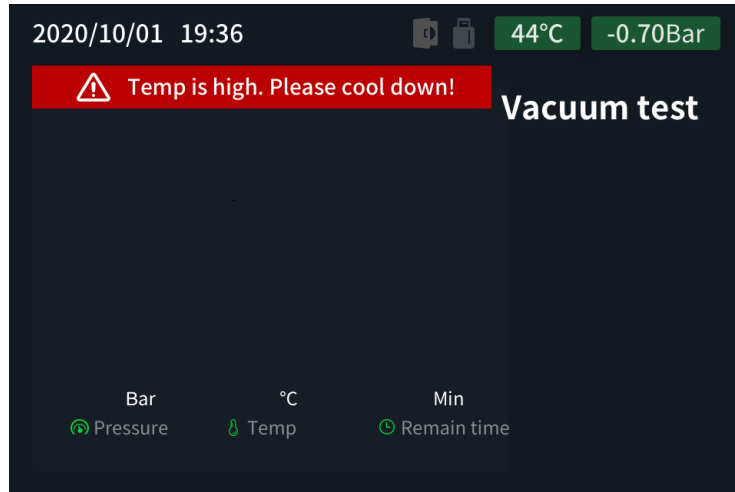


- Please follow the packaging material manufacturer 's recommendations or regulations for the storage time of the sterile pack;
- Do not store sterile items in contaminated areas;
- Sterile items must be stored in a dust-free, dry environment (except water , other liquids such as alcohol, disinfectants, etc. should also be avoided), and a suitable temperature environment.

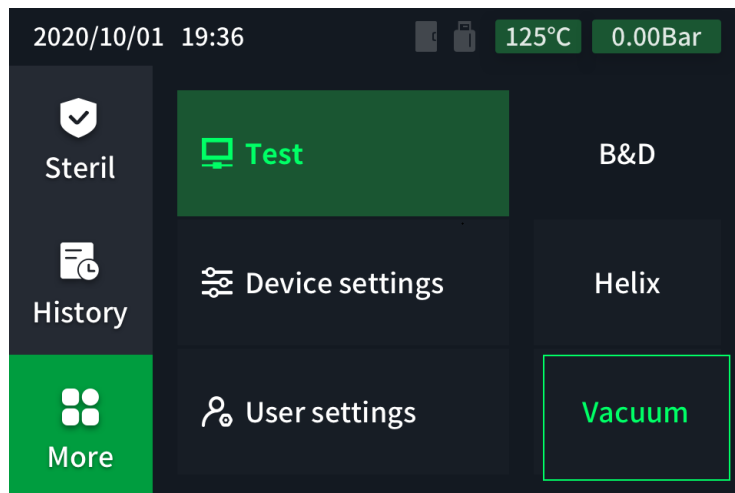
5 Functional testing and other procedures




5.1 vacuum test

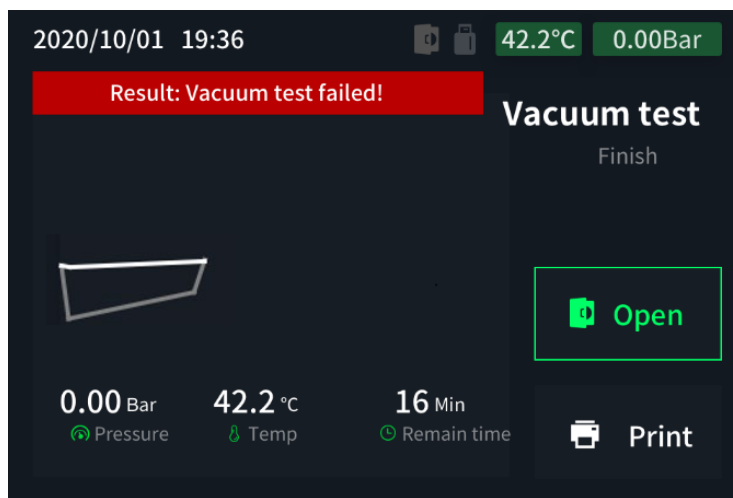
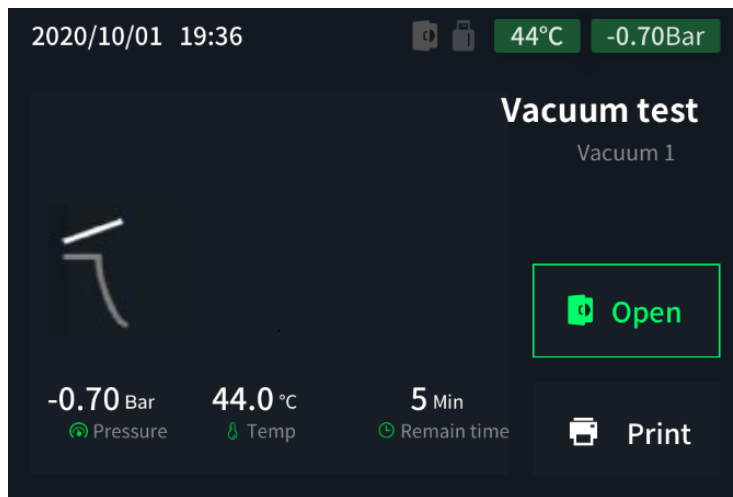
When installing for the first time, after a long period of non-use, after moving, or during regular inspections, it is recommended to perform a vacuum test to detect the degree of leakage of the product system. The Tester menu is located under the More menu. Before the vacuum test, make sure that the temperature in the cavity is lower than 45°, and if the temperature is too high, a relevant high temperature prompt will be given on the running interface.



The vacuum test operation is as follows,



- Press  the or  key to select the vacuum test program, press the key to start 

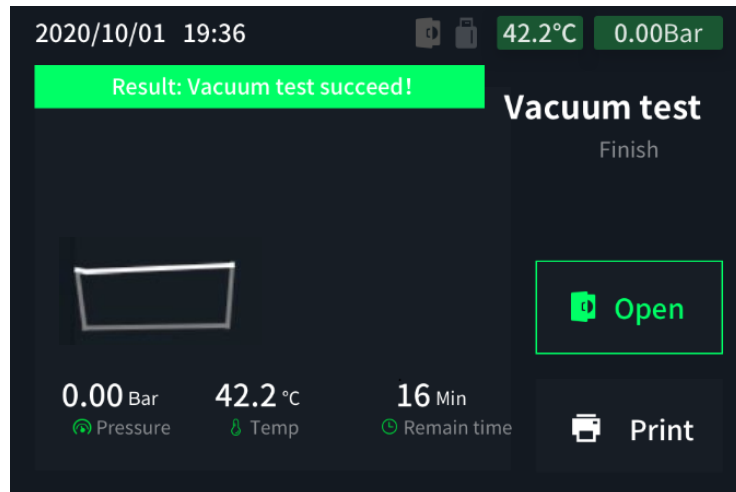


- The vacuum test should be carried out when the system is cooled and the cavity is kept dry;
- In order for you to successfully complete the vacuum test procedure, please check that the product door is closed and the cooling water valve is open before starting the procedure.

After the vacuum test program is started, when the pressure in the sterilization container reaches the relative vacuum value specified in the standard, the vacuum system stops and a 5-minute balance time is started. After the balance time is over, a 10-minute vacuum test is started. After the test is completed, the system returns to normal pressure.

After the vacuum test is over, the system will prompt the result on the program end interface and save the record in the memory. If the automatic printing function is set and a printer is connected, the test result will be printed at the same time.

When the vacuum test is passed, the prompt message on the interface is "Result: Vacuum test successful". It shows that the leakage rate of the system meets the requirements.



The print information is as follows:

Temperature: 37.0 +1.0/-0.9 °C
 Leakage rate : 0.00 kPa/min Leakage rate : <0.13Kpa/min
 Leak Test: (0.13 max)-Pass!

When the vacuum test fails, the interface prompts the message " Result: Vacuum test failed". Indicates that the leakage rate of the system does not meet the requirements.

The print information is as follows:

Temperature: 37.0 +1.0/-0.9 °C
 Leakage rate : 0.15 kPa/min Leakage rate : >0.13Kpa/min
 Leak Test: (0.13 max)-Pass!



- If the vacuum test fails, do not continue to use the product and contact the manufacturer or authorized dealer immediately.

5.2 B &D testing

B &D test is used to check the steam permeability of this product to porous porous loads, such as cotton fabrics. Select B &D test in the test program interface .



- Please follow the information and requirements provided by the test kit manufacturer for the test method and test result judgment ;
- WS310-2016 stipulates that weekly B &D testing must be monitored and records kept.

5.3 Helix test

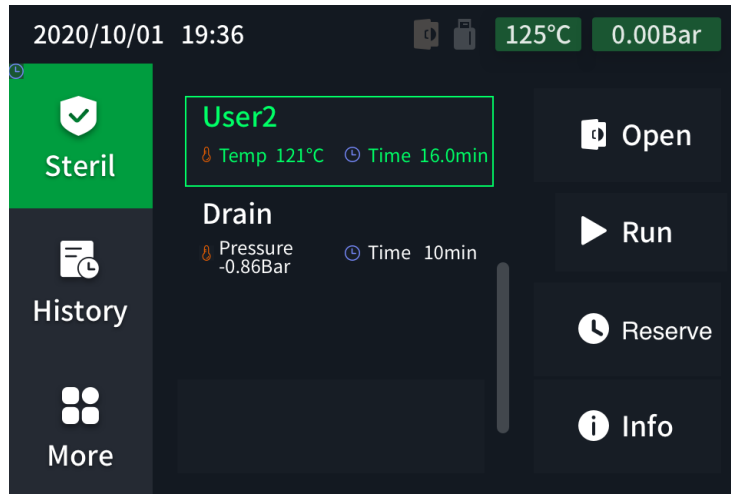
The Helix test is used to verify the steam penetration and saturation of this product for Class A lumen devices, such as dental handpieces. Select the Helix test in the test program interface .



- Please follow the information and requirements provided by the test kit manufacturer for the test method and test result judgment .

5.4 Drainage procedure

This product supports the user in performing the drain procedure when required. This program is used to drain residual water from small steam sterilizers. The Drain program menu is the last one in the Sterilization menu .

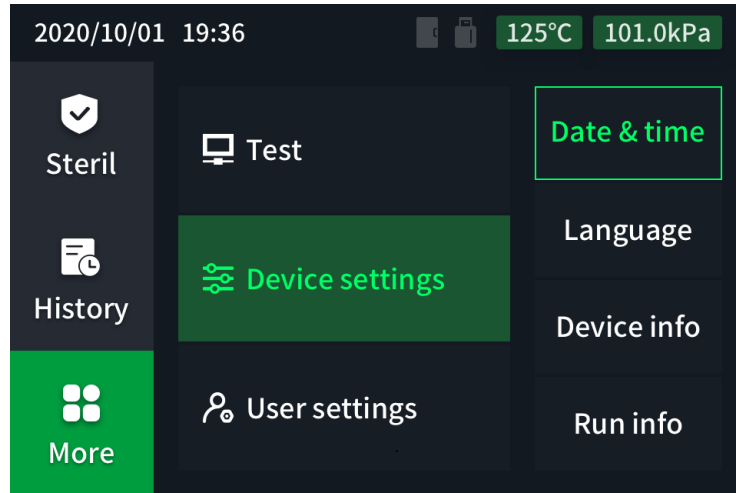


- When there is obviously water in the bucket after opening the door, it is recommended to use the drainage program before loading the items for sterilization, especially when the program is abnormally terminated, this situation is likely to occur, please open the door to check;
- Use the drain procedure before handling this product.

6 device settings

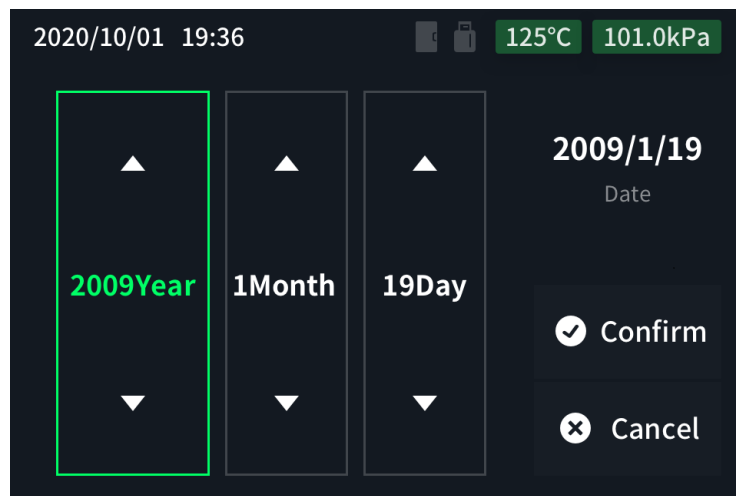
Enter the device setting interface to set the date and time , language setting , view device information and view machine operation information .





Entering the user setting menu needs to enter the user password.

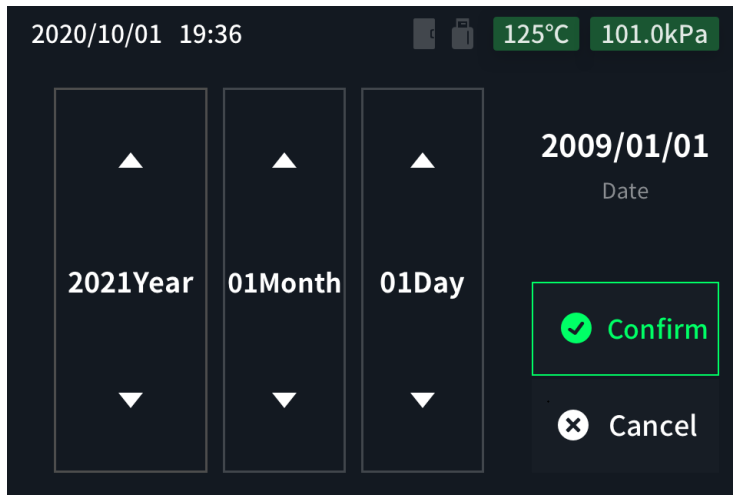


6.1 Date and Time Settings

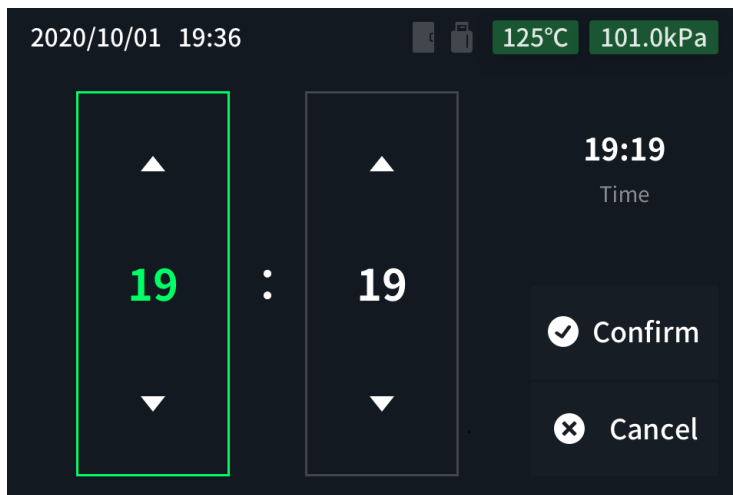
Enter the date setting menu, the date setting operation is as follows:







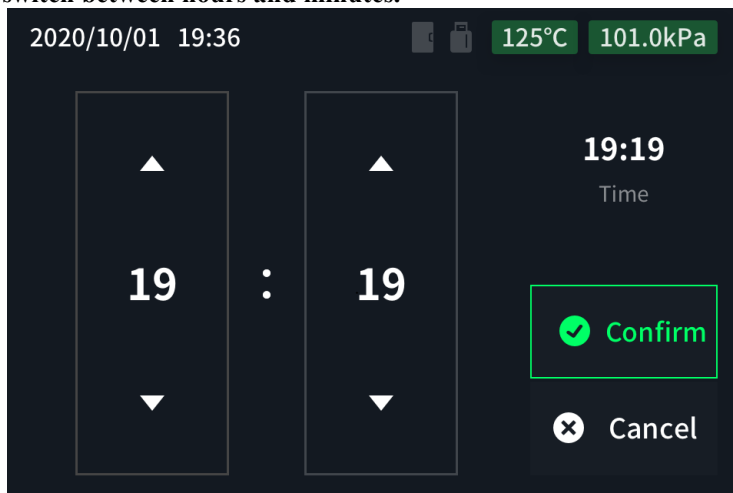
- At this time, press the  and  keys to add and subtract the date information, and press the  and  keys to switch between the year, month, and day.



- After the setting is completed, select the confirmation menu, press  the save date setting, and automatically enter the time setting.






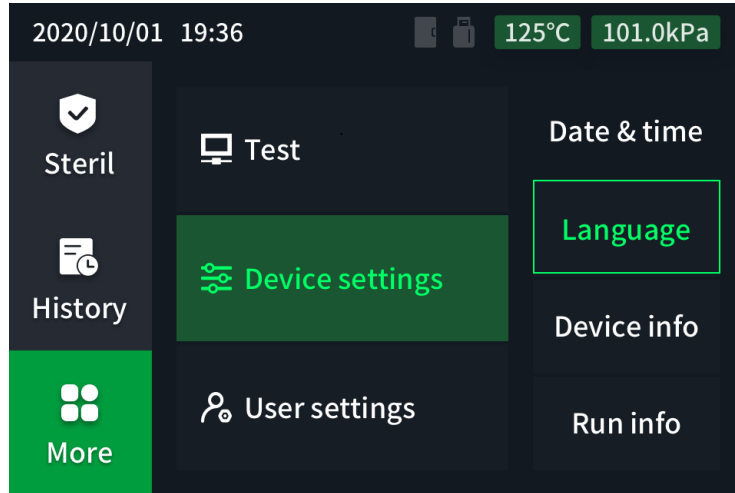
- At this time, press  and  keys to add and subtract time information, and press  and  keys to switch between hours and minutes.




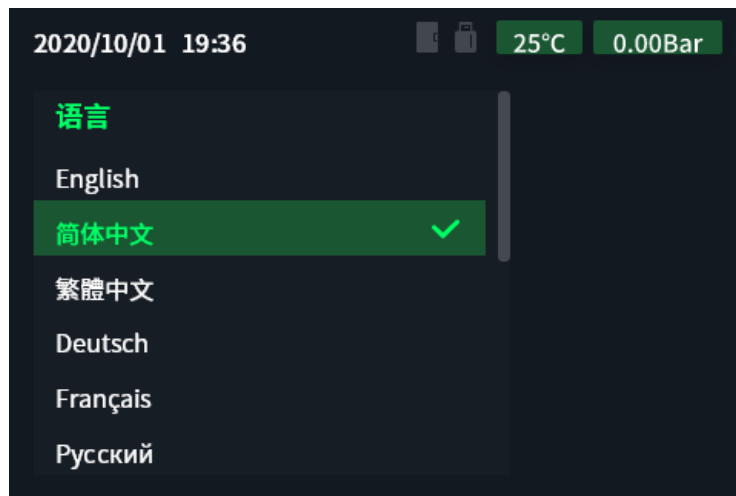
- After the setting is completed, select the confirmation menu and press  Save Time Setting.




6.2 language settings

Click the [**Language**] menu to enter the language setting interface, select the language  through 
the and  keys , and click to complete the setting.

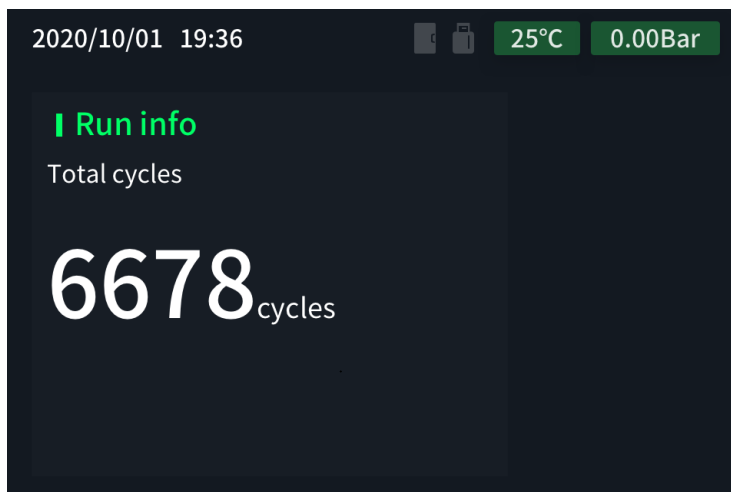


Select the language menu, press the key to enter the language setting. 



- At this time, press the  and  keys to select the language, and press to  exit the language setting after the setting is completed .

6.3 running information

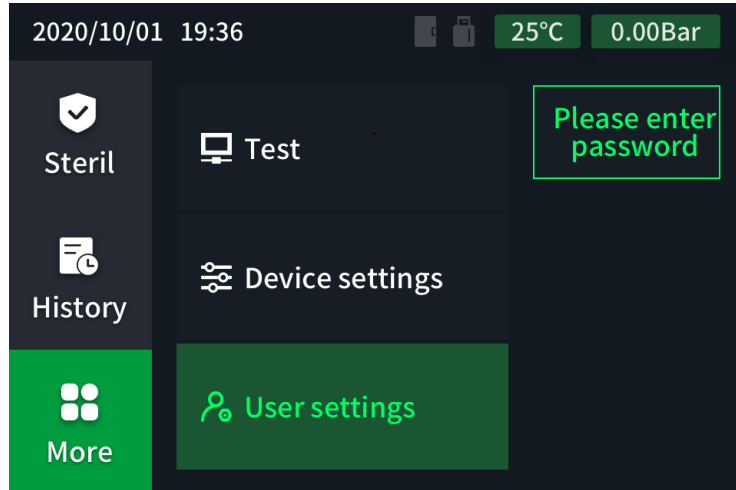



Running information can view the number of sterilizations that the equipment has currently run

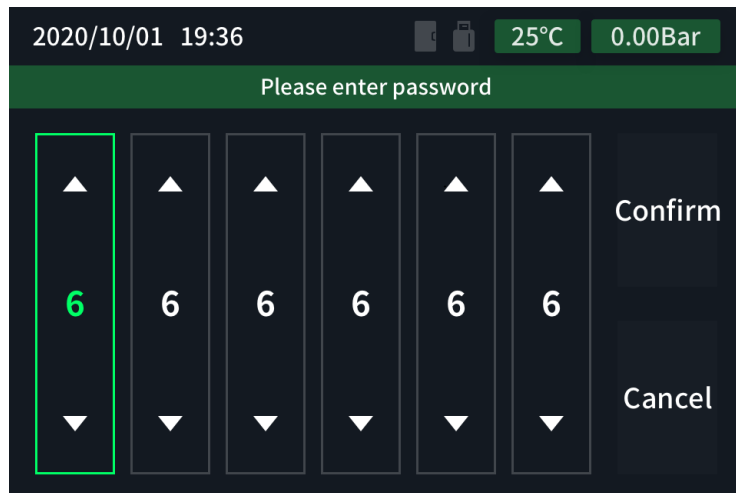
7 user settings





Enter the user setting interface to perform automatic preheating, automatic printing, water quality testing, additional drying settings and password settings, system reset, pressure calibration, maintenance information viewing, and custom program parameter settings .

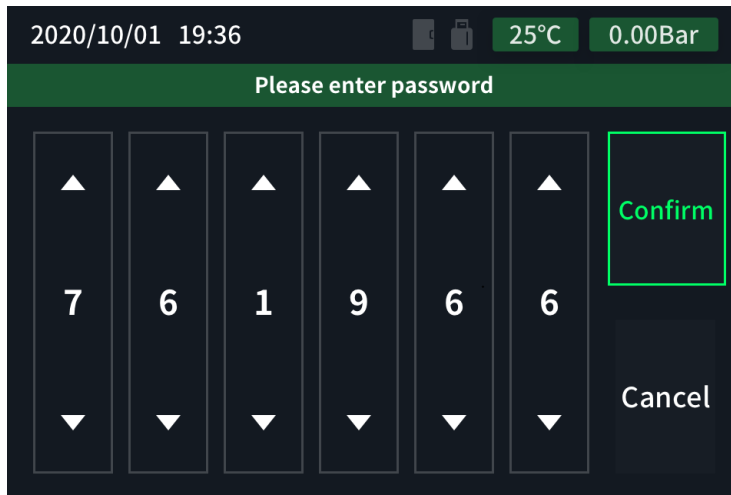
Entering the user setting menu needs to enter the user password.




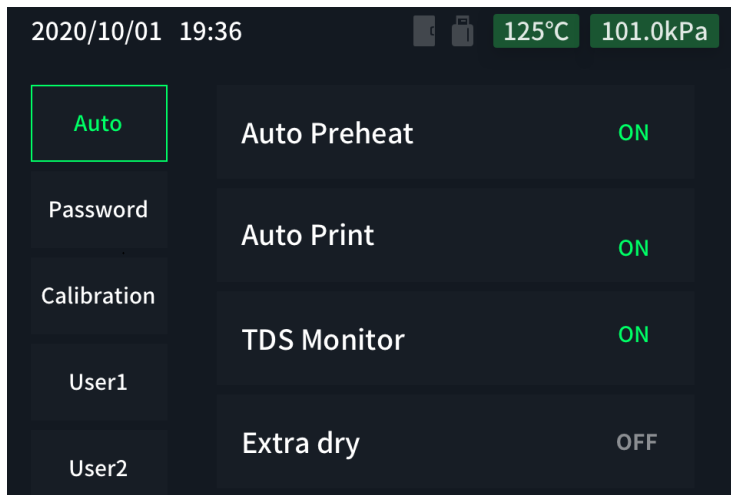
-  Press the key to enter the password input.



- Press  the or  key to adjust the password, press the key to enter the next one, and 
 press the key to return to the previous one.



- After entering the password, press the key to enter the user setting. 

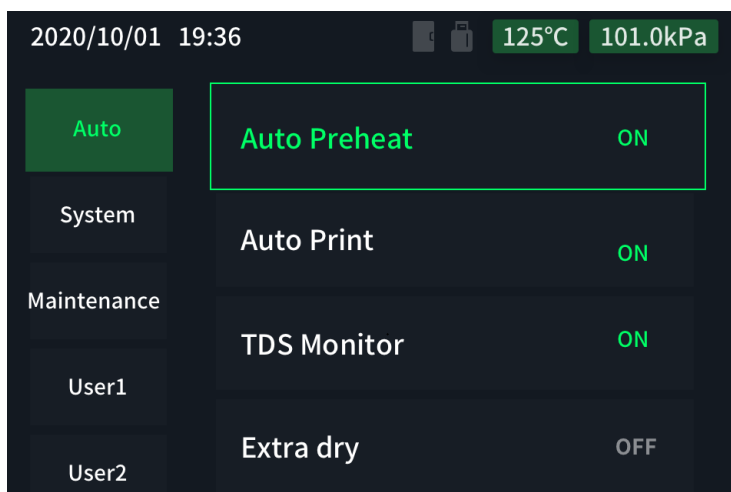


7.1 automatic setting

Automatic settings can configure some common control options of the device.

7.1.1 Automatic preheat setting

The automatic preheating setting operation is as follows:



- Select the automatic preheating menu, and press the button to turn on and off.

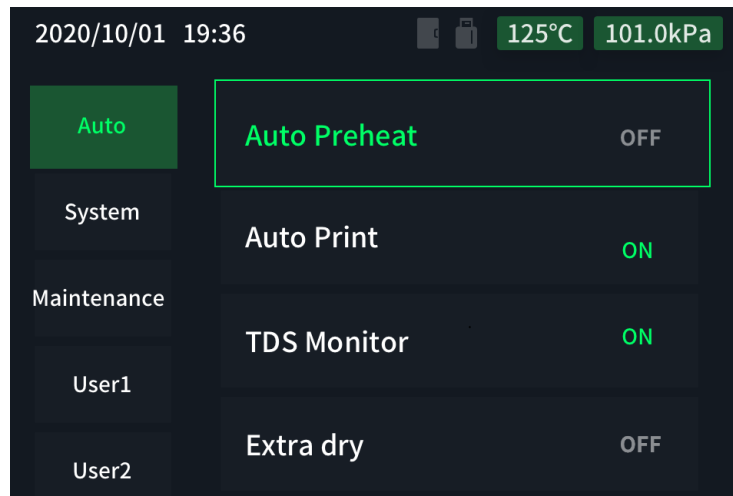


Figure 6.2 Automatic preheating setting



After turning on the automatic preheat setting, the chamber will automatically heat up to 110°C. Please be careful of burns!

7.1.2 Automatic print settings

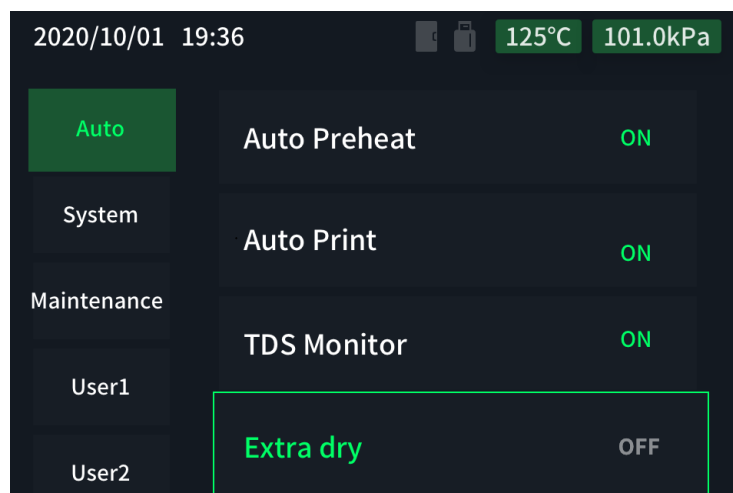
The automatic print setting operation is the same as the automatic preheating setting

7.1.3 Water quality testing settings

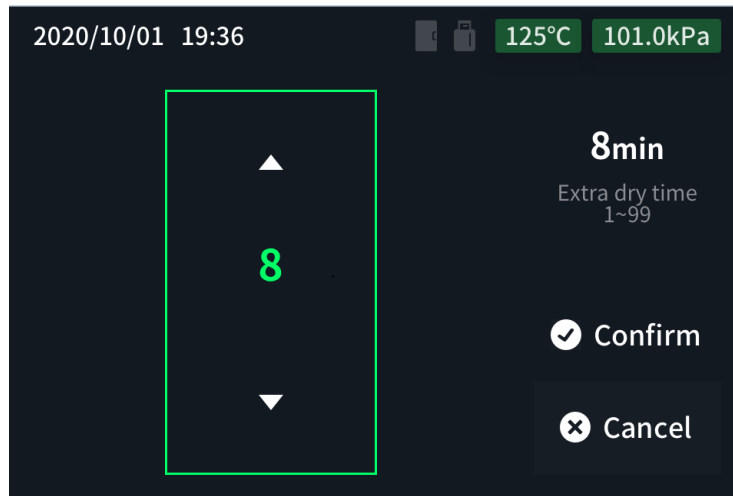
Water quality detection setting operation is the same as automatic preheating setting

7.1.4 extra dry setting




The Extra Dry setting operates as follows:

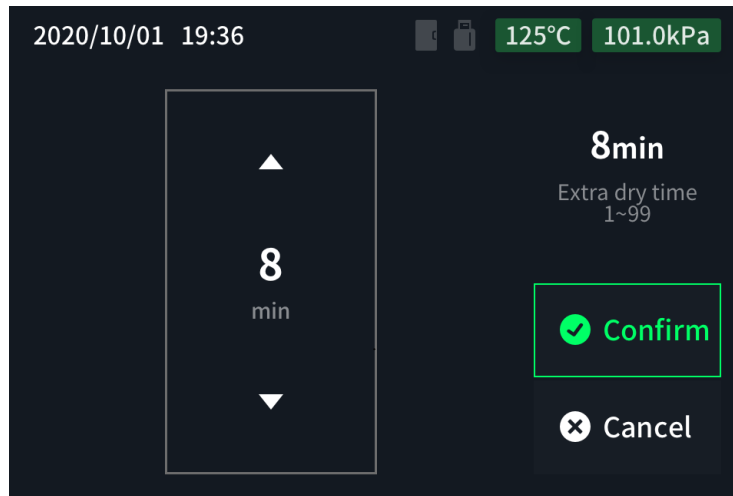


- Select the extra drying menu, press the button to start the operation, and automatically enter the

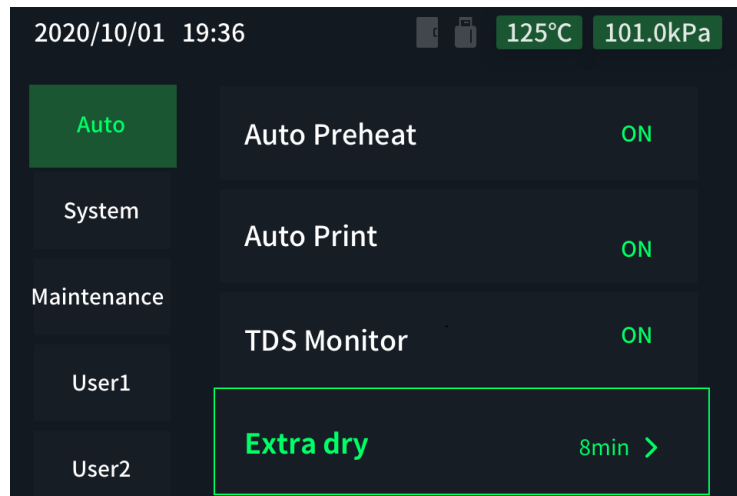


extra drying time setting after turning on.

- Press  the or  key to adjust the time, and press the key to return, which means the default value is 8 minutes. 

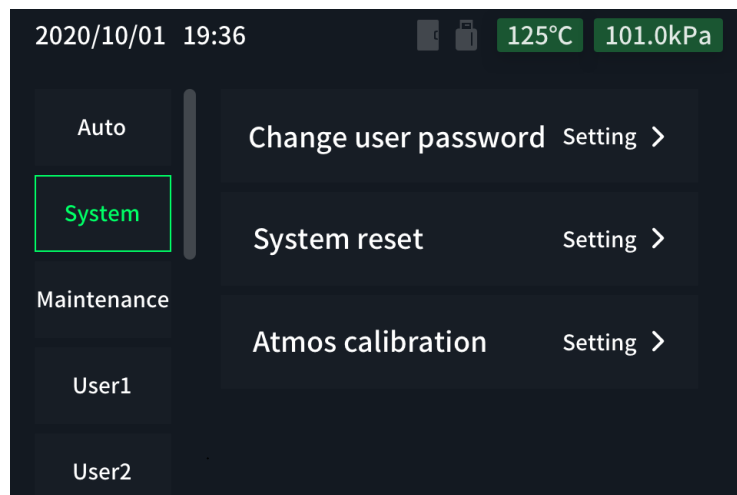


- After the setting is completed, select the confirmation menu and press Set .



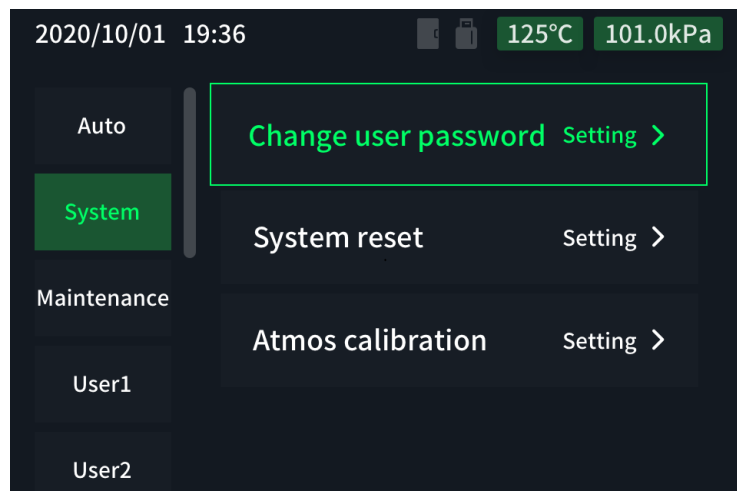
7.2 system settings

Enter the system setting interface to modify the user password , reset the system , and calibrate at normal pressure .

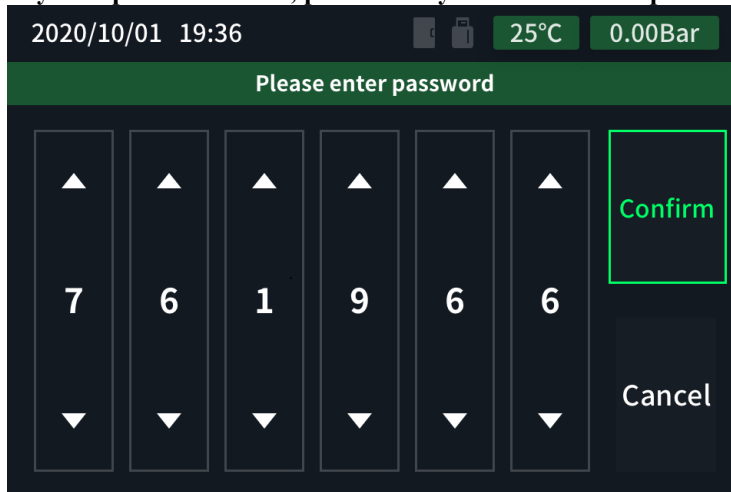




7.2.1 Modify user password




Modify the user password as follows:

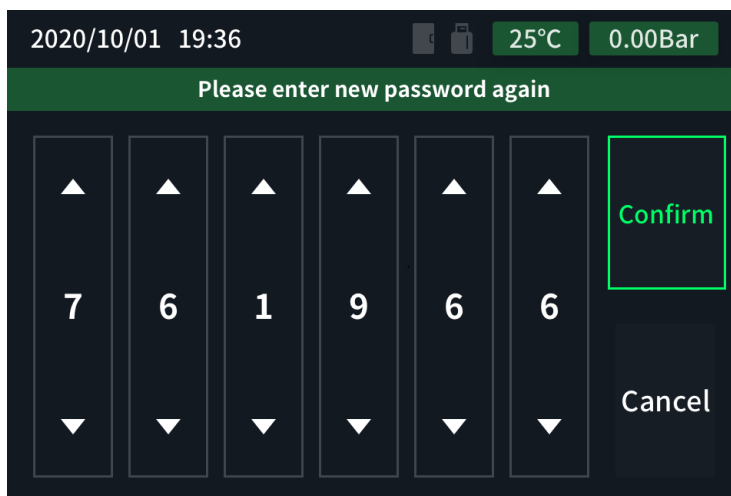



- Select the modify user password menu, press the key to enter the user password setting. 

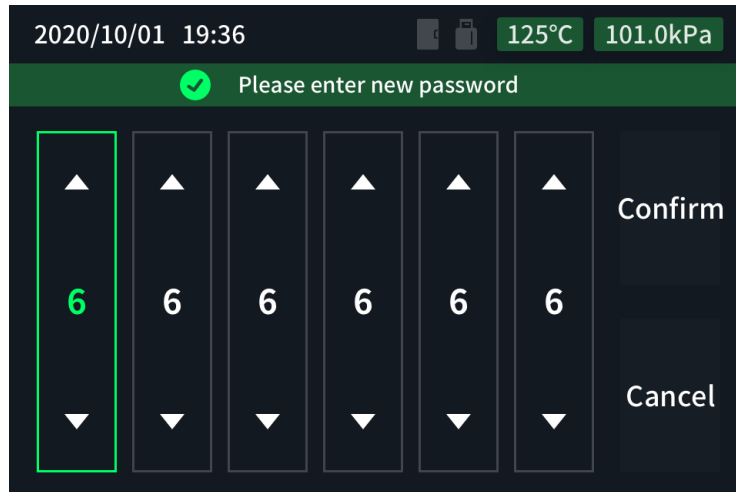


- At this time, press the  and  keys to set the password, and press to  enter the next password setting after the setting is completed.

- At this time, press the  and  keys to set the password. After the setting is complete, select the confirmation menu and press the key  again to enter the new password.

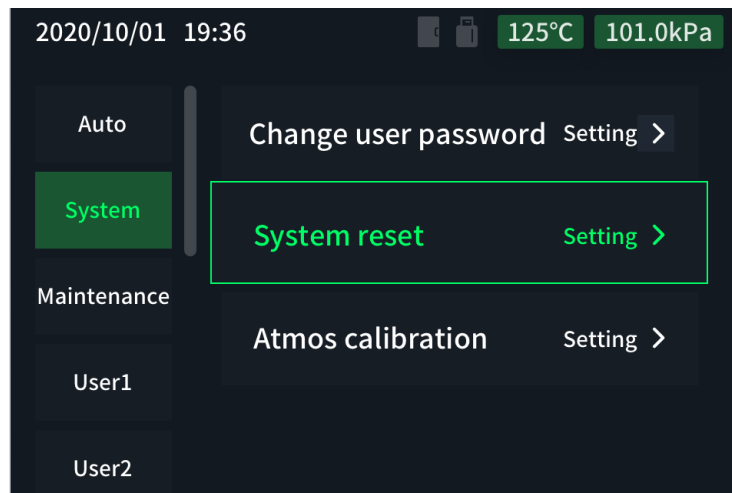


- After entering the new password again, select the confirmation menu and press  to complete the password setting.

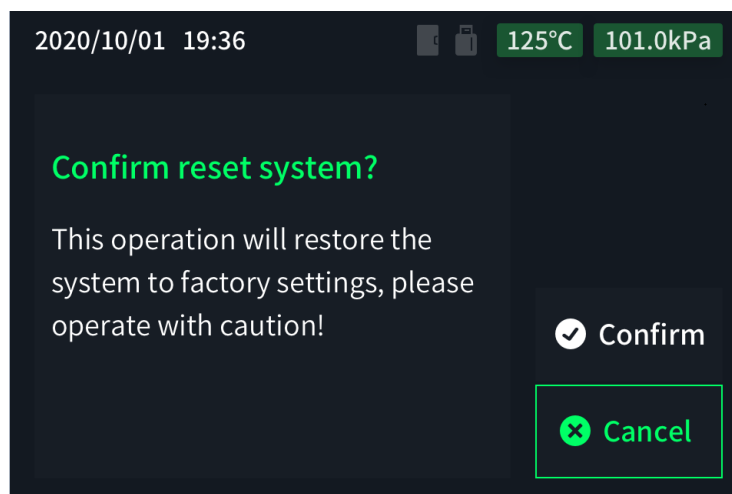


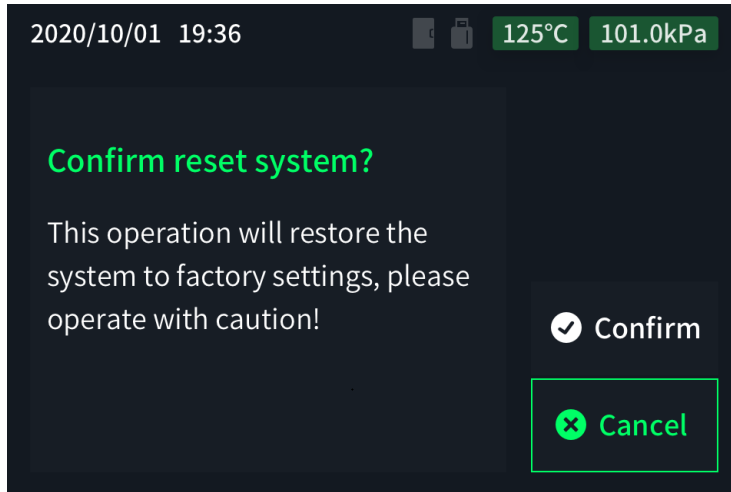
7.2.2 system reset



The system reset operation is as follows:

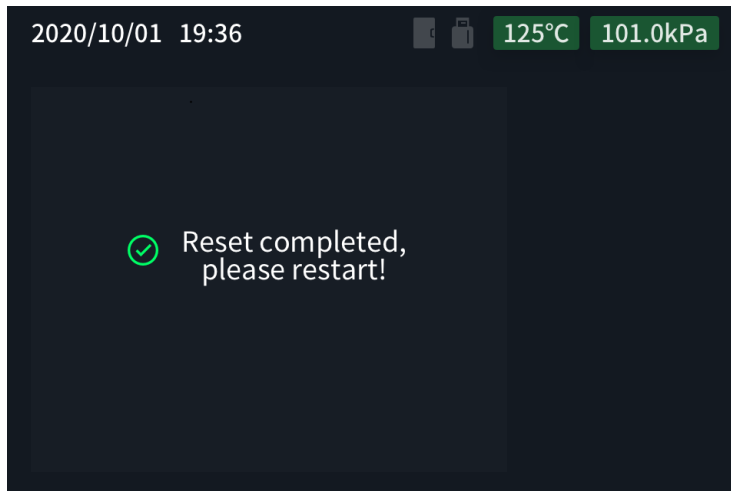


- Select the system reset menu and press the key to enter the system reset. 



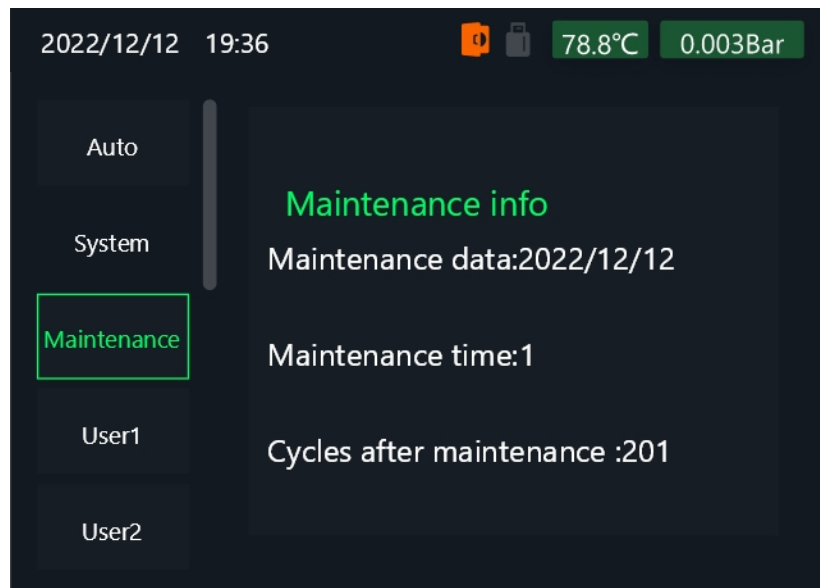


- At this time , press   to reset the system.



7.3 Maintenance

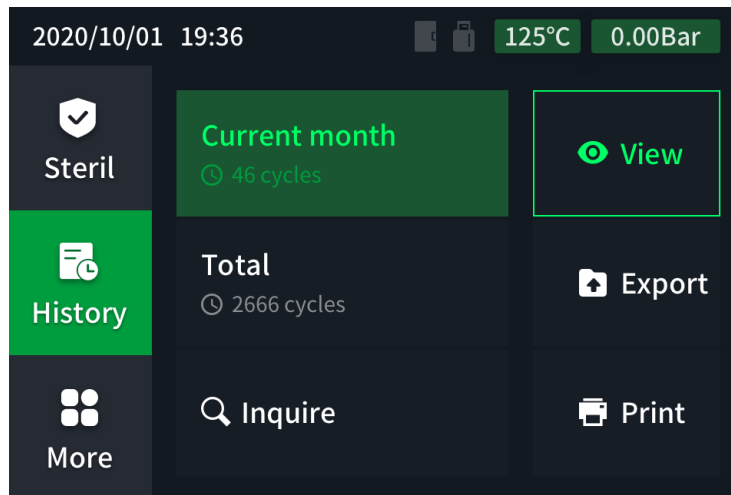
In the maintenance menu, you can check the date of the latest maintenance of the machine, the number of maintenance times, and the number of sterilization operations after maintenance



8 Sterilization records

Sterilization records document and store real-time data at each stage of the sterilization process. The memory of this product can store up to two years of sterilization records. Sterilization records are named with serial numbers, such as: 0001.TXT , which can be exported through the USB interface or printed out through a micro-printer.

The historical records can operate the records of the current month, all records, or view the historical records within a certain period of time.






8.1 View history





- Select the View menu press  to enter the history list.

The screenshot shows a list of sterilization records with the following data:

| Number | Date | Program | Result | 666cycles |
|--------|------------|---------|-------------|-----------|
| 1 | 2020/10/01 | Vacuum | Manual stop | |
| 2 | 2020/10/02 | Vacuum | Manual stop | |
| 3 | 2020/10/02 | Vacuum | Manual stop | |
| 4 | 2020/10/02 | Vacuum | Manual stop | |
| 5 | 2020/10/02 | Vacuum | Manual stop | |
| 6 | 2020/10/02 | Vacuum | Manual stop | |
| 7 | 2020/10/02 | Vacuum | Manual stop | |

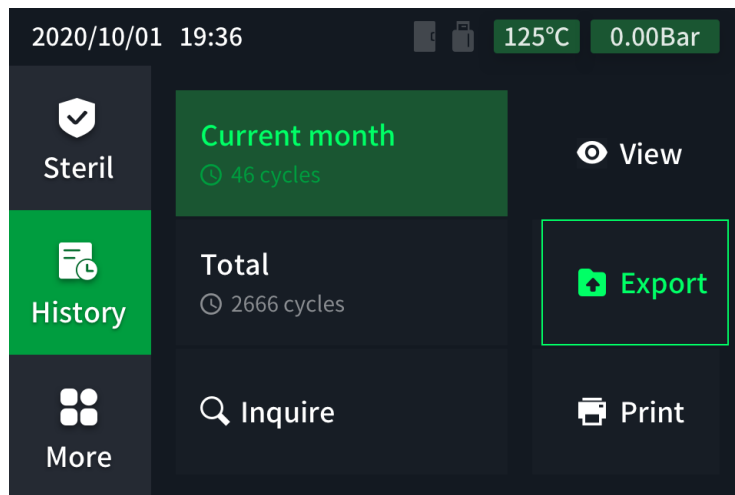
- At this time, press  and  keys to select the historical record to be viewed, and press  to view the detailed information of the record.



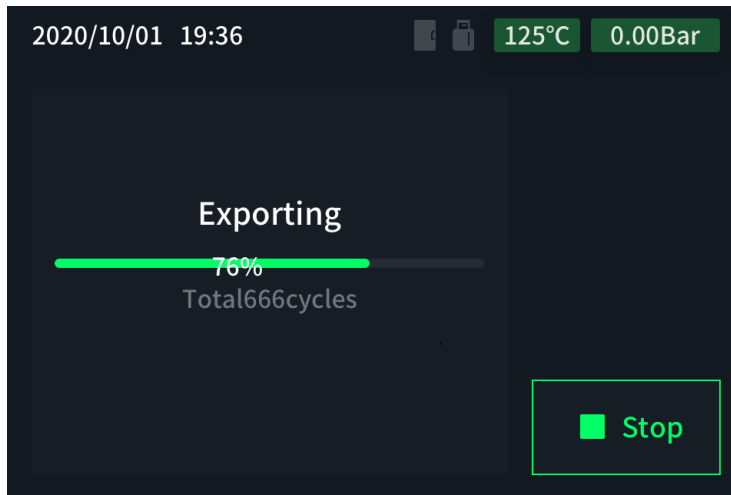
- Press  and to turn up and  down records, press  to select the export and print menu, press  to print and export a current historical record.

8.2 Export history

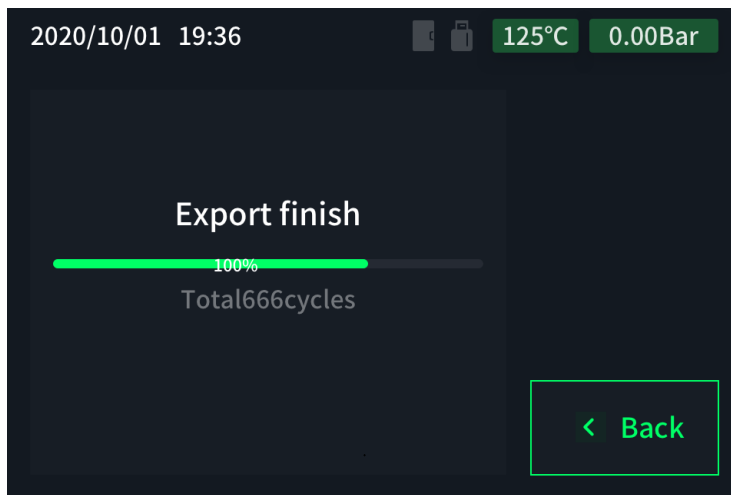
In order to keep the sterilization records for a long time, the sterilization records can be exported to the computer or portable storage device through the USB interface. Specific operation: Insert the U disk into the USB interface, export the records according to the following process, after the export is completed, the interface will display the prompt of export completion, and you can remove the U disk at this time.



- Select the Export menu button to export the records. 



- Press the key during the export process to stop the export.

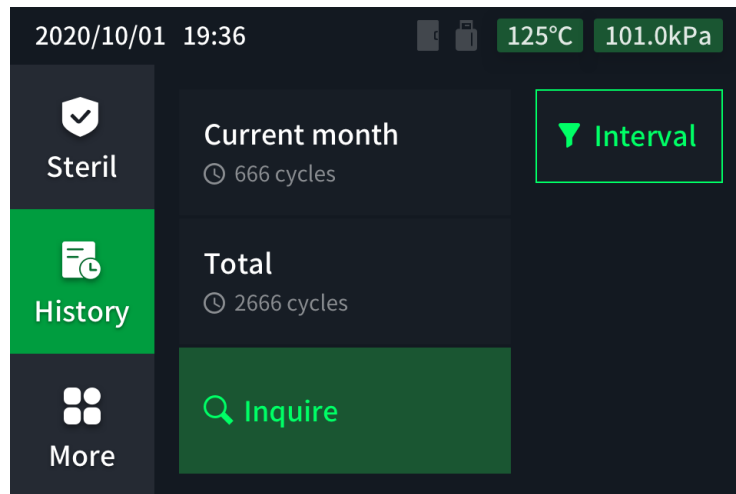






8.3 Print history

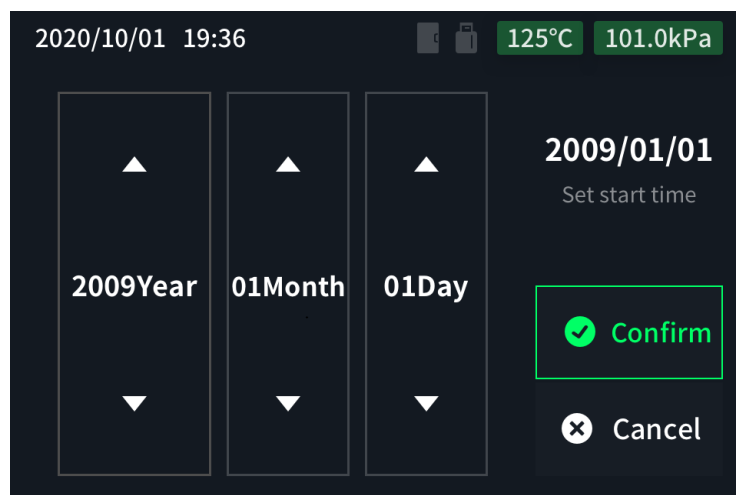
The operation of printing records is the same as exporting history records.

8.4 Query history

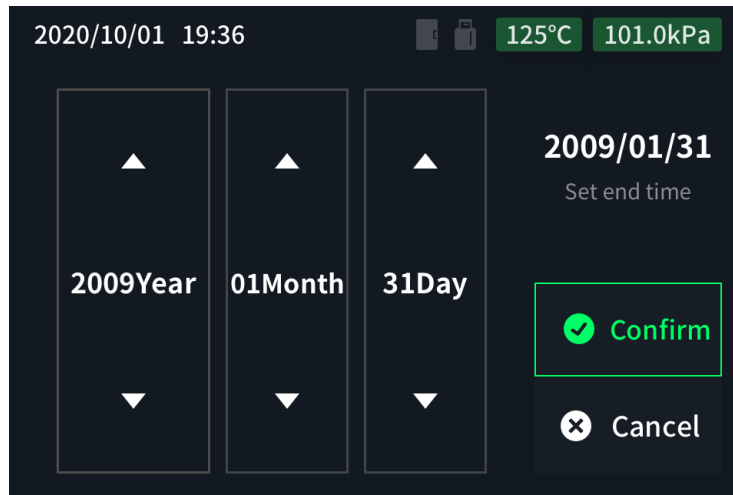
A time interval can be set to query historical data within this time period.




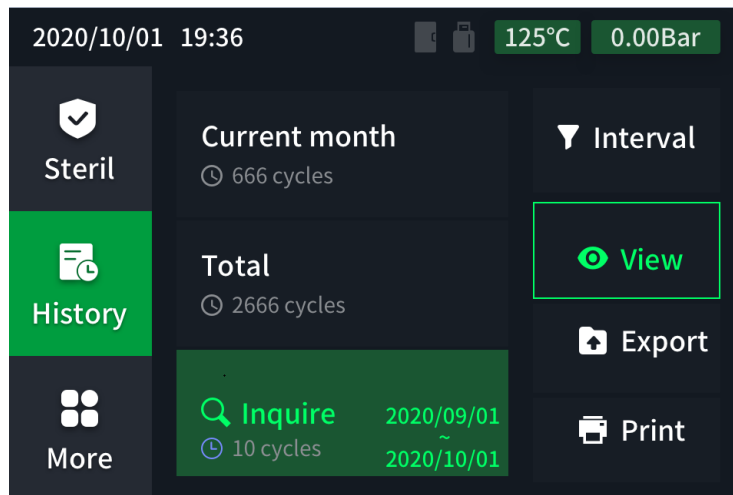
- Select the setting interval menu, press the key to enter and query the time setting. 
- Press  and  to adjust the time, press  to enter the next setting.



- After the start time is set, press  to enter the end time setting.



- After the end time is set, press  OK.



8.5 Automatic record printing

After the automatic printing function is turned on and the product is correctly connected to the printer, the sterilization record can be automatically printed after the program ends.

8.6 Record interpretation

The formats for printer output and sterilization records stored in internal memory are as follows

v

```

-----
                GANJ Sterilizer
-----
Cycle Date : 2023.04.17
Start Time : 12:57:27
Cycle No.  : 3
Program    : Gentle 134 program
-----
SN          : 632603105230317AT
Hardware Ver : GJx_V1.5
Software Ver : 01.00.03.31
Paramete Ver : PGJx_V01.3
-----
Extern Temp : 111.6°C
-----
Stage      Press   Temp   Time
          (bar)  (°C)  (H:M:S)
Start      : 0.004  78.6  0:00:00
1.Vacuum   :-0.848  71.7  0:02:34
1.Steam    : 0.304  104.3 0:04:57
2.Vacuum   :-0.706  76.0  0:07:37
2.Steam    : 0.314  106.3 0:09:45
3.Vacuum   :-0.506  82.3  0:11:17
3.Steam    : 1.545  127.0 0:15:15
-----
Steril Sta: 2.202 135.0 0:18:21
Steril End: 2.193 135.1 0:23:51
Drain End  : 0.019 102.3 0:25:22
Dry Start  : 0.019 102.3 0:25:22
Dry End    :-0.845  72.0  0:45:22
Vent End   :-0.100  80.7  0:46:01
Complete   :-0.022  80.7  0:46:11
-----
End Time   : 13:44:04

                PROGRAM SUCCESSFUL!

Temp       : 135.1 +0.0/-0.4°C
Press      : 2.194 +0.01/-0.04Bar
Time Cost  : 0:46:11
Cond       : 25.64us/cm
-----
STI:0.0,0.0,0.0,0.0,0
DEB:100.6,576,0,2,0
DIS:1,3,0,0
KB:1000,0,1000,0
Vmin:226.5,Vmax:236.1
-----
Operator:

----- Record Ends -----

```

Product number
Date
start time run
times program
Program

The serial number of the machine

The serial number of the machine

initial cavity temperature

3 times vacuuming, record pressure,
temperature and time information

Sterilization Hold Phase
Sterilization Hold
Complete
Pressure Release
Drying Start
Drying
Complete Inlet Sterilization Complete

Final report, record sterilization
temperature, pressure, time
consumption and water conductivity

REV . V01

9 Maintenance of small steam sterilizer

9.1 Cleaning of Loaded Items before Sterilization

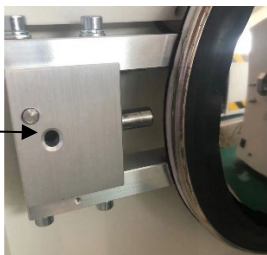


- Before sterilization, the sterilization load such as mobile phones must be thoroughly cleaned;
- The dust and pollutants separated in the sterilized load will cause blockage of filters, valves and pipelines, so the unwashed sterilized load is not allowed to enter the product for sterilization ;
- all product cleaning, disinfection, and sterilization protocols provided by the device manufacturer .

9.2 Maintenance of small steam sterilizer

9.2.1 Cleaning and maintenance

Regular cleaning and maintenance can effectively prolong the service life of this product and ensure a good working condition .

| Maintenance item | maintenance cycle | special tools | maintenance operations |
|--|----------------------|-----------------|---|
| Replace the seal | Sterilize 1000 times | | Open the door of this product and check whether the sealing ring is deformed or wrinkled. If it is deformed or wrinkled, it is recommended to replace it. |
| Seal maintenance | 2 weeks | | Take off the sealing ring, rinse it with clean water and wipe it dry with a soft cloth, then reinstall the lid. Note: Pay attention to the installation direction of the sealing ring (the narrow side is close to the lid, and the wide side is close to the barrel). |
| Door lock maintenance | Sterilize 100 times | lubricating oil | Spray a small amount of lubricating oil on A on the left side of the barrel cover, and wipe the outer surface with a paper towel.  |
| Cleaning the Distilled Water Tank | Sterilize 300 times | | wash with clean water |
| Clean the filters at both ends of the cooling water inlet pipe | Sterilize 100 times | | Unscrew the nuts at both ends of the water inlet pipe and rinse with clean water. |

| | | | |
|--|---------------------|--------|---|
| Clean the bottom filter of the sterilization chamber | Sterilize 200 times | wrench | Unscrew the filter with a wrench and wash it with clean water |
| cleaning tray | Sterilize 100 times | | Rinse with clean water and clean with toothpaste if stained |
| Sterilization chamber | weekly | | Wipe the sterilization cavity with a clean damp medical cotton cloth, then dry the cavity with a clean dry medical cotton cloth |

9.2.2 Regular maintenance



- A comprehensive maintenance of the small steam sterilizer should be carried out every year to ensure good equipment working condition and sterilization effect;
- The maintenance and maintenance of this product must be carried out by professionals authorized by the manufacturer .

10 Troubleshooting and common problem handling

10.1 Display shows nothing

Phenomenon: After turning on the power of this product , the display screen cannot be turned on normally.

Solution:

- ✧ Check whether the main power socket has electricity;
- ✧ Check whether the power plug of this product is plugged in;
- ✧ If the screen still does not display, please contact an authorized hatmed dealer.

10.2 High consumption of distilled water

Phenomenon: The distilled water consumption is much more than the specified amount.

Solution:

- ✧ Check whether the foot pads of this product are adjusted correctly. Under normal circumstances, the front is slightly higher than the back;
- ✧ Open the door of this product to check whether the filter at the bottom of the sterilization container is blocked;
- ✧ None of the above operations can help reduce the consumption of distilled water, please contact the authorized distributor of H ä Tmed .

10.3 drying effect is not good

Phenomenon: drying can not achieve satisfactory results.

Solution:

- ✧ Check whether the foot pads of this product are adjusted correctly, the front is slightly higher than the back;
- ✧ Open the product door to check whether the filter at the bottom of the sterilization container is blocked;
- ✧ Check that the maximum load is not exceeded (especially textiles), that the sterilized load is placed correctly (not in direct contact with the pressure vessel wall), and that the standard tray and tray rack are used for loading;
- ✧ Activate automatic preheating;
- ✧ Open the left cover and check if the filter is clogged;
- ✧ If none of the above operations can help dry well, please contact an authorized H ä Tmed dealer.

10.4 no distilled water

Phenomenon: No distilled water.

Solution:

- ✧ Check whether there is water in the distilled water tank;
- ✧ Check that the distilled water tube is not bent, kinked and inserted in place .

10.5 unable to open the door

Phenomenon: The door cannot be opened even through the emergency door opening button.

Solution:

-
- ✧ Check if the air filter installation hole on the back is blocked;
 - ✧ Disconnect the side panel, unplug the silicone tube connected to the air filter solenoid valve , and discharge the negative pressure in the cavity ;
 - ✧ When the exhaust sound gradually weakens until it disappears, the door can be opened ;
 - ✧ Connect the silicone tube back to the original place, and tighten the clamp, turn on the machine and do a vacuum test to check for leaks.

10.6 Leakage at the door or water dripping from below

Phenomenon: There is obvious air leakage or water dripping.

Solution:

- ✧ Check whether the sealing ring is installed correctly (the long side with " H " is exposed);
- ✧ Check the sealing ring for damage.

11 Precautions

- 11.1 In order to ensure the safe use of the equipment, please be sure to cut off the power and water source before leaving work or for a long time (more than 8 hours) when it is unattended .
- 11.2 Only designated distributors are qualified to provide you with spare parts and after-sales service. H ä Tmed is not responsible for any consequences caused by unauthorized repairs by other personnel or the use of spare parts not produced by our company.
- 11.3 Do not open the machine cover or place any objects inside the machine, otherwise it will damage the machine and endanger the safety of the operator.
- 11.4 Once the machine is used, it means that the user agrees to all the above terms and promises to operate in accordance with the instructions for use.
- 11.5 For the power supply line of the sterilizer, there should be a leakage protection device to prevent the leakage current of 30mA, and a reliable grounding wire should be connected.

Appendix 1 Safety device description

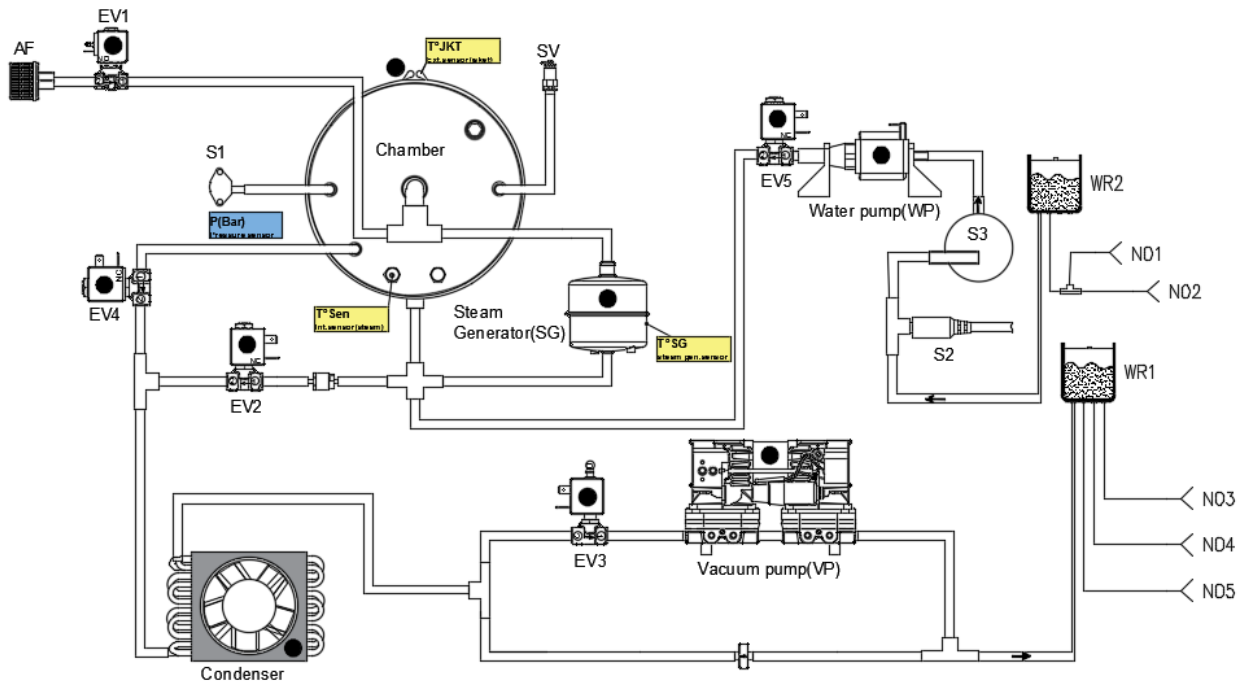
In order to ensure the safe and reliable use of the system, a series of protection devices are used to protect key equipment.

Preheating system over-temperature protection switch: The preheating system has an over-temperature protection switch. When the temperature exceeds the threshold temperature of the over-temperature protection switch, it will automatically disconnect the power circuit of the preheating system to realize the protection function of the preheating system.

Steam generator over-temperature protection switch: The steam generator has a three-way temperature switch. When the temperature of the steam generator exceeds the threshold temperature, it will automatically disconnect the power circuit of the steam generator to play a protective function.

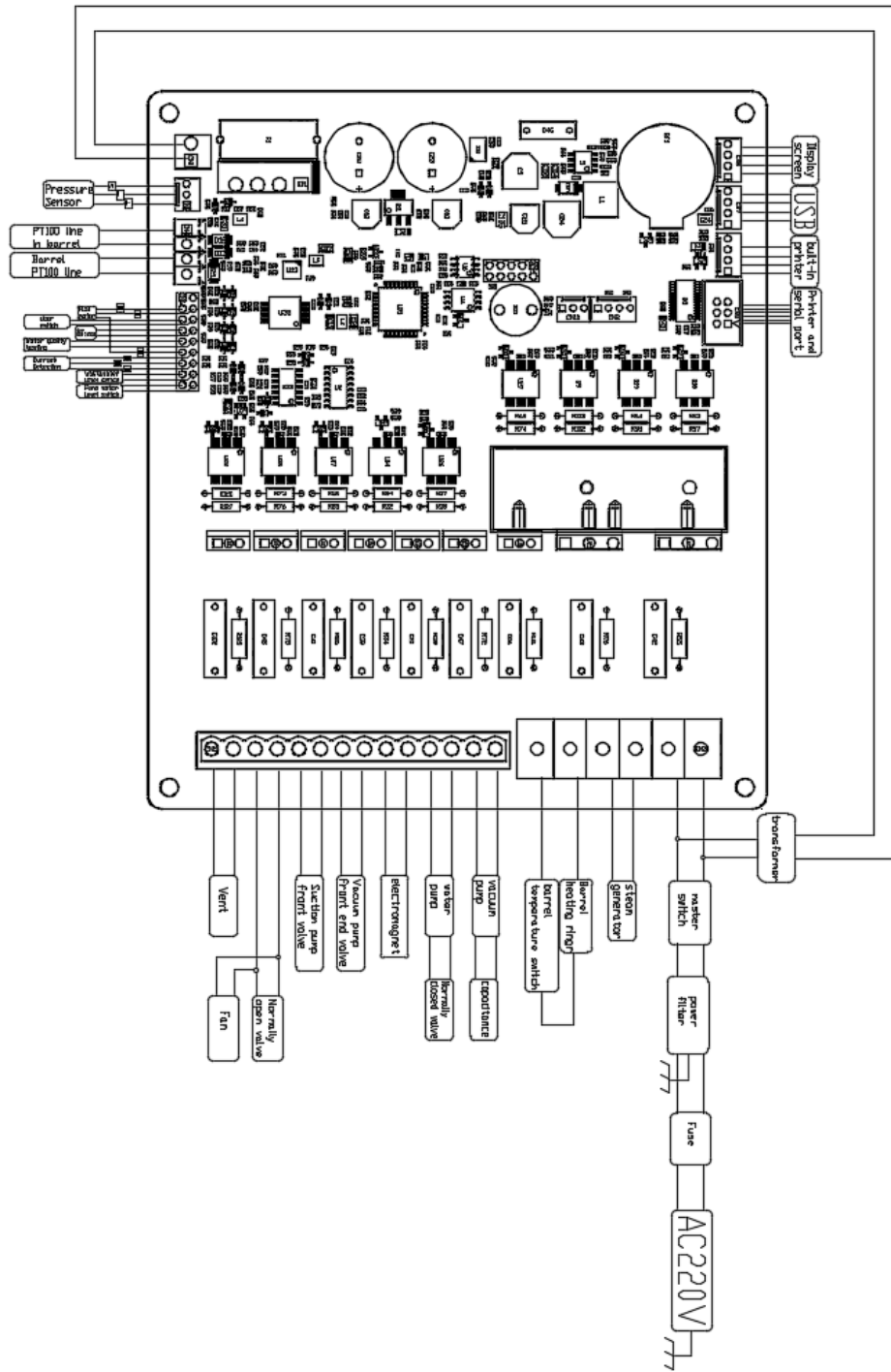
Pressure relief valve: When the pressure in the sterilization container is greater than 1.3 times the working pressure, the pressure relief valve will automatically open to keep the pressure in the sterilization container within a safe pressure range .

Appendix 2 Piping System Schematic



Piping System Schematic

Appendix 3 Electrical Schematic



Electrical schematic diagram of small steam sterilizer

Registrant/Manufacturer: **HaeTmed(Wuxi) Co., Ltd.**

Registrant/manufacturer address: Area A, 6th Floor, Building 7, No. 1699, Huishan Avenue, Huishan Economic Development Zone, Wuxi City, Jiangsu Province

Production address: Area A, 6th Floor, Building 7, No. 1699, Huishan Avenue, Huishan Economic Development Zone, Wuxi City, Jiangsu Province

Production date: see product label

Recommended lifespan: 8 years

Zip code: 214174

Tel: 0510-66682078 Fax: 0510-66682079

Email: info@haetmed.de Website: www.haetmed.de



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