Tabletop Steam Sterilizer

Installation & Users' Manual

Q102B, Q82B, Q92B

Revision：**07**
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CE
2460

Preface

Thank you for purchasing this HäTmed table-top steam sterilizer. This User Manual describes usage guidelines for the autoclaves Q102B, Q82B and Q92B (referred to as “autoclave” throughout the manual). These guidelines cover installation, initial commissioning, standard operation, safety precautions and maintenance requirements. For your safety and sterilization quality, please read this User Manual carefully before you start operation of the autoclave.

Intended Use

HäTmed Q102B, Q82B and Q92B are suitable for use in medical facilities, such as general medical institutions or dental clinics. HäTmed sterilizers are designed and manufactured in strict compliance with EN 13060-2014. Q102B, Q82B and Q92B are B-class autoclaves that are designed for high standard sterilization of hollow instruments, packed instruments, geared instruments and textiles.

Symbols

Symbols and their meaning in this Manual:

Symbol	Indication	Explanation
	Risk to Health	Indicates a dangerous situation, such as high voltage or current, if not avoided, could cause life-threatening injuries.
	Danger of Burns	Indicates danger of burns, such as hot steam or surfaces.
	Critical Instructions	Indicates a critical instruction which, if not strictly followed, may lead to damage to the instruments or this autoclave.
	Important Information	Indicates important information.
	Protective earthing	Indicates protective earthing conductors.

Symbols on the device:

Symbol	Description
	Danger of Burns
	Manufacturer of this medical device
	Date of manufacture of the medical device
	Serial number of the medical device by the manufacturer
	EU Representative of the manufacturer of the medical device
	This User Manual contains important safety information. Failure to comply with the safety instructions could cause human injuries or material damage.
	Please read this User Manual carefully before using the device. The manual contains important safety information. The performance and life-span of this autoclave depends on the care accorded to it. Please store this User Manual carefully and in close proximity to the autoclave. It is a component of the product.
	In affixing this CE mark, the manufacturer declares that this medical device fulfills the requirements of the medical device directive. The 4-digit number confirms that this is monitored by an approved certification body.
	This symbol reminds the users to refer to the User Manual for important information.

Safety Instructions:

Only use this device for its intended use as described in this User Manual. While operating this autoclave, please make sure the safety instructions given below and in the individual chapters of this User Manual are strictly followed.

Qualified Personnel	➢ The sterilization of instruments and textiles using this autoclave may only be carried out by trained personnel.

Power cable and power plug	➢ Never change the main cable or power plug. Never use a damaged power cable or plug. ➢ Never operate the device if the plug or power cable is damaged. The power cable and plug should only be replaced by authorized personnel. ➢ Never unplug by pulling on the power cable. Always take hold of the power plug itself. ➢ Ensure that the power cable is not jammed or knotted. ➢ Never place the cable close to a source of heat. ➢ Never fix the power cable with sharp objects.
Setting up and installation	➢ Only have the autoclave setup, installed and started up by people authorized by the manufacturer. ➢ Never operate the autoclave in explosive atmospheres. ➢ The connections for electrical provision and water supply and draining must be set-up by trained personnel. ➢ The device is designed for use outside patient surroundings. It should be located at least 1.5 m away (radius) from the treatment area. ➢ If the device comes with a printer, the printer must be placed in such a way that it will not contact with liquids.
Emergency Door Open	➢ Do not use this emergency device under normal circumstance.
Decontamination and sterilization	➢ Follow the manufacturer instructions of instrument and textiles regarding their decontamination and sterilization. ➢ Observe the relevant standards and directives for the decontamination and sterilization of instruments and textile, e.g., RKI and DGSV. ➢ Only use packaging material and holders which have been approved by their manufacturer for steam sterilization.
Program termination	➢ Please observe that depending on the time of the program abort, opening the door following a program abort can lead to hot steam leaving the chamber. ➢ Depending on the time of the program abort, it is possible that the load is unsterile. If necessary, rewrapping and sterilize the affected objects.
Removal of the items sterilized	➢ Never use force to open the door. ➢ Use a tray holder to remove the tray. Never touch the sterilized items, the chamber or the door with bare hands. ➢ Check the wrapping of the sterilized objects for damage when removing them from the autoclave. If a wrapping is broken, re-pack the objects and re-sterilize it.

Transport and storage	➢ The device should always be carried by 4 people. ➢ Use suitable carrying straps to carry the device. ➢ Install and operate the device in a frost-free environment.
Maintenance	➢ Have the maintenance done only by authorized personnel. ➢ Comply with the predetermined maintenance intervals. ➢ Only original HäTmed spare parts may be used.
Errors	➢ Should the device issue the same malfunction message repeatedly, turn off the device. ➢ Only have the device repaired by authorized personnel.

Sterilization Programs:

Program Name	GEN 134	GEN 121	Quick B	Quick S	134+	Prion	Fabric
Dynamic pressure test of the sterilization chamber	✓	✓	✓	✓	✓	✓	✓
Air leak	✓	✓	✓	✓	✓	✓	✓
Empty chamber	✓	✓	✓	✓	✓	✓	✓
Solid load	✓	✓	✓	✓	✓	✓	
Solid and porous load	✓	✓			✓	✓	
Porous partial load	✓	✓			✓	✓	✓
Porous full load	✓	✓			✓	✓	✓
Hollow body B	✓	✓	✓	✓	✓	✓	
Hollow body A	✓	✓	✓		✓	✓	
Simple wrapping	✓	✓	✓	✓	✓	✓	✓
Multiple wrapping	✓	✓	✓		✓	✓	✓
Drying, solid load	✓	✓	✓	✓	✓	✓	
Drying, porous load	✓	✓			✓	✓	✓
Sterilization temperature	134 °C	121 °C	134 °C	134 °C	134 °C	134 °C	121 °C
Sterilization pressure	2.1 bar	1.1 bar	2.1 bar	2.1 bar	2.1 bar	2.1 bar	1.1 bar
Sterilization time	5.5min	16min	3.5min	3.5min	5.5min	20min	20min
Note: ✓= Conformity with all applicable sections of the standard EN 13060							

Contents

1 Device Description

1.1 Views of the device

1.1.1 Front view

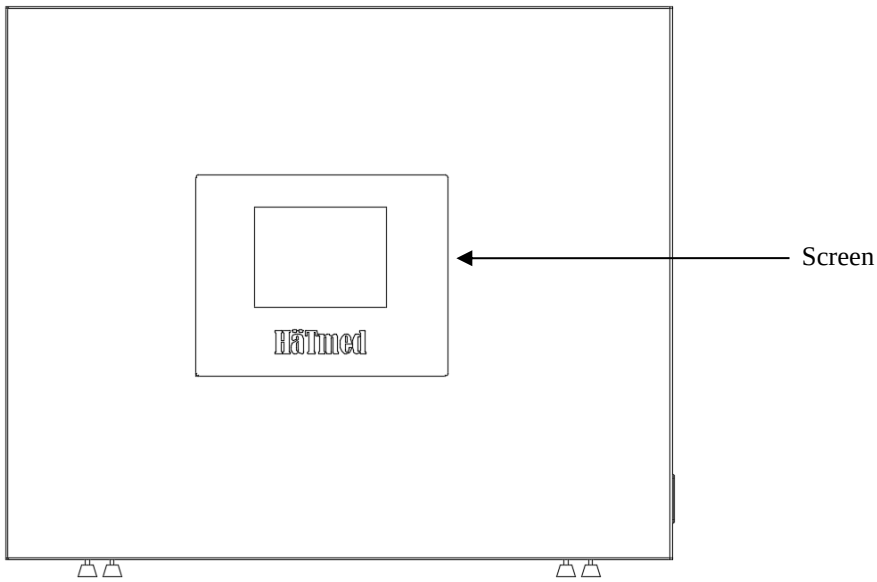


Figure 1.1 Front view

1.1.2 Side view

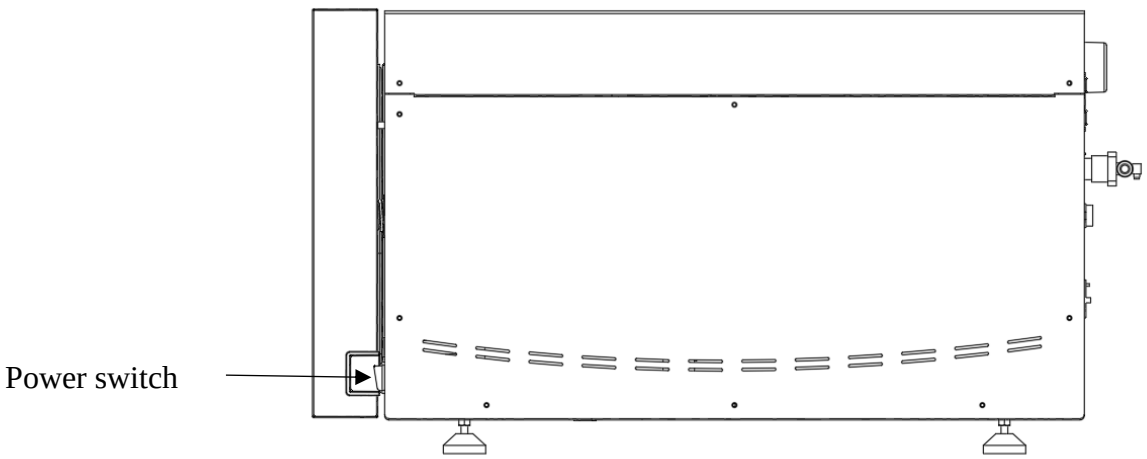


Figure 1.2 Side view

1.1.3 Rear view

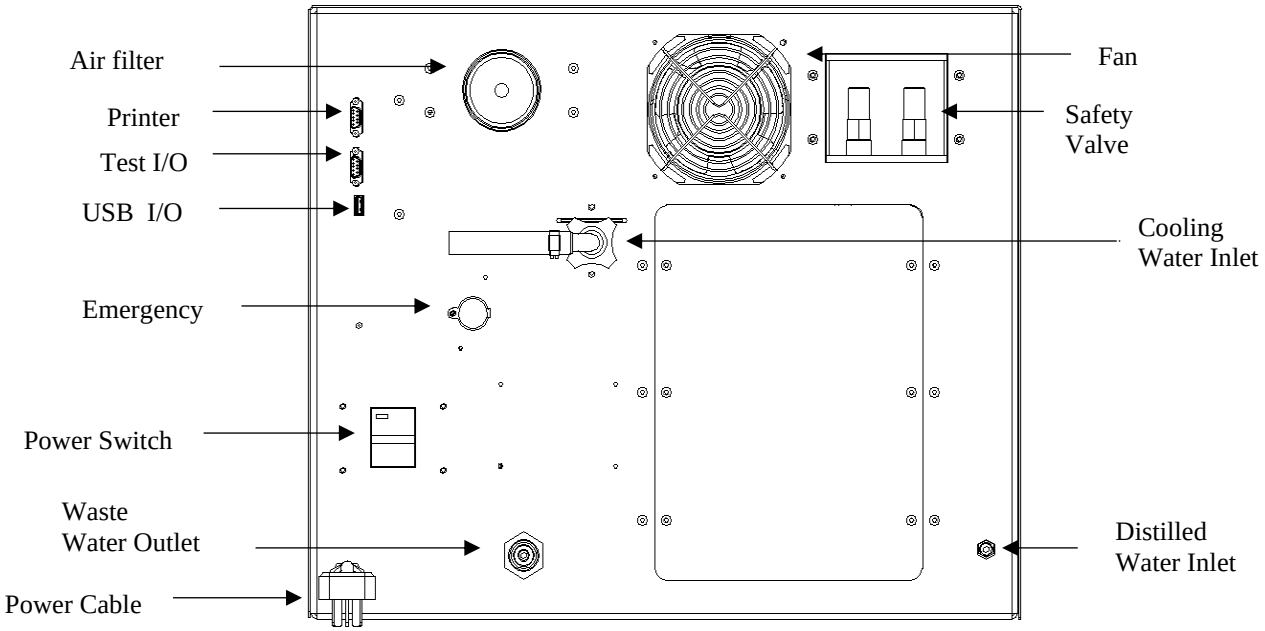


Figure 1.3 Rear view

1.1.4 Interior view

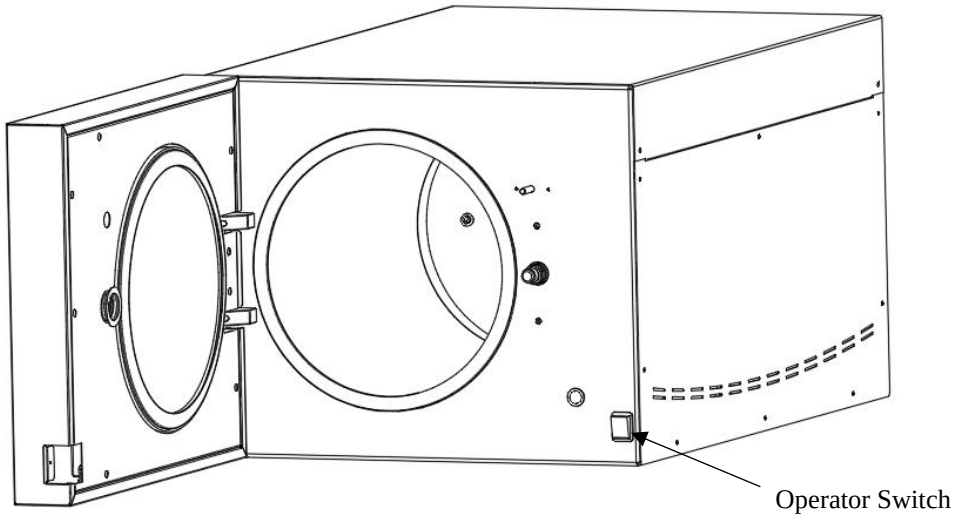


Figure 1.4 Interior view

1.1.5 Optional accessory

Mini thermosensitive printer

- Only use original HäTmed accessories. Consult manufacturer before using other accessories. Use of unauthorized accessories may cause unsuccessful sterilization or failure to function.
- Accessory equipment connected to analog and digital interfaces must be certified according to the respective EN/IEC standards.

1.2 Technical data

Device type	Q102B	Q82B	Q92B
Device dimensions	755mm*583mm*480mm	955mm*583mm*480mm	1100mm*583mm*480mm
Packaging dimensions	855mm*683mm*580mm	1055mm*683mm*580mm	1200mm*683mm*580mm
Chamber size	Φ319mm*411mm	Φ319mm*621mm	Φ319mm*711mm
Chamber volume	29 L	46 L	55 L
Pressure vessel weight	13.7 kg	19 kg	21.5 kg
Device empty weight	82 kg	112.2 kg	119.8 kg
Electricity supply	230V/50Hz		
Power consumption	4600VA		
Ambient pressure	70 Kpa ~ 106 Kpa		
Ambient temperature	5 °C ~ 40 °C		
Temperature for transport and storage	-20 °C ~ 55 °C		
Humidity	≤ 85%		
Max. instrument load	9 kg	16 kg	20 kg
Max. textile load	2.8 kg	4.5 kg	5.4 kg
Memory size	16M Byte		
Distilled water quality	Distilled or demineralized water according to EN 13060 Appendix C		
Distilled water pressure	≤ 30 Kpa		
Max. distilled water consumption	1450 ml	1600 ml	1750 ml
Cooling water pressure	≥ 2 bar		
Max. waste water temperature	95 °C		
Noise emission	70 dB(A)		

Length of power cable	1.8 m
IO input voltage	5V
Transient Over-Voltage	Category II
Pollution Degree Rating	II
Electromagnetic Compatibility	Comply with IEC61326-1-2005; No interference is caused by this device to its environment while it can continue to function in the presence of electromagnetic disturbances of specified level.
Conformity	EN13060-2014; EN61010-1; EN61010-2-040
Note 1: The maximum voltage range is 200V ~ 250V	

1.3 Optional trays for load

The autoclave is delivered with a mounting rack. The space inside the mounting rack is the space that can be sterilized effectively. Hence the rack must be used while loading the autoclave. The mounting rack can hold 5 trays.

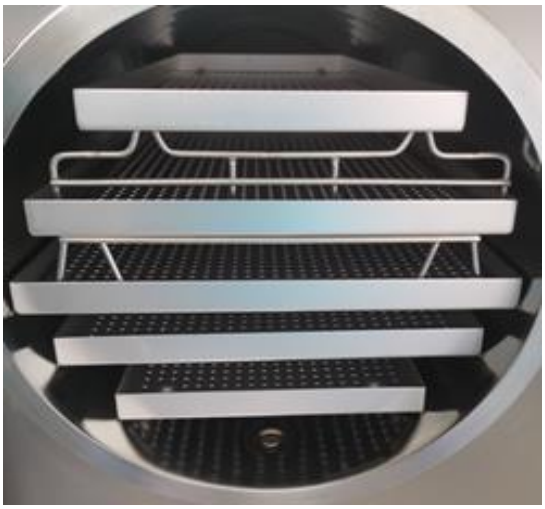


Figure 1.5 Mountings of load

1.4 Intelligent controller and the control panels

The controller is the core of the autoclave. It not only accomplishes real-time parameters acquisition, processing, fault detection and control of a sterilization process, but also accurately depicts the graph of temperature and pressure that change over time. The controller is also responsible for the assessment and monitoring of the program control process. During the sterilization period, it will compare the running parameter with the standard parameter, once the running parameter deviates from the standard, it will generate fault messages immediately, and ensure the safety and quality of the sterilization.

The control panels consist of a colored 5.6-inch touch display. The user interface is designed to follow users' intuition, thus offering convenient and simple operation.

1.4.1 Main interface

Upon power up, the screen displays HäTmed LOGO before entering main interface, through which users can access all operations: sterilization, test, log, setting and other advanced options.

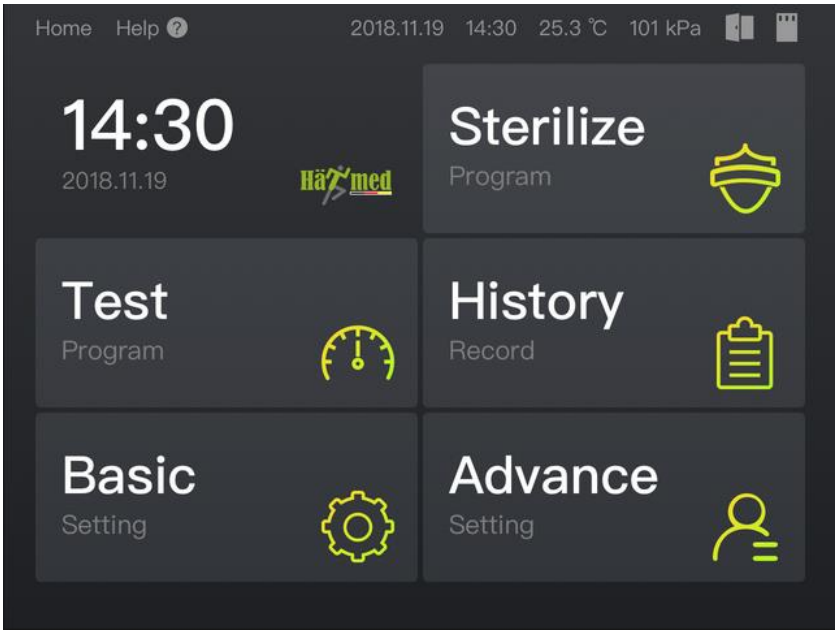


Figure 1.6 Main interface

1.4.2 Program selection interface

In program selection interface, the top portion displays system status bar, while the middle portion is the main menu and the bottom portion contains command keys for various operations.

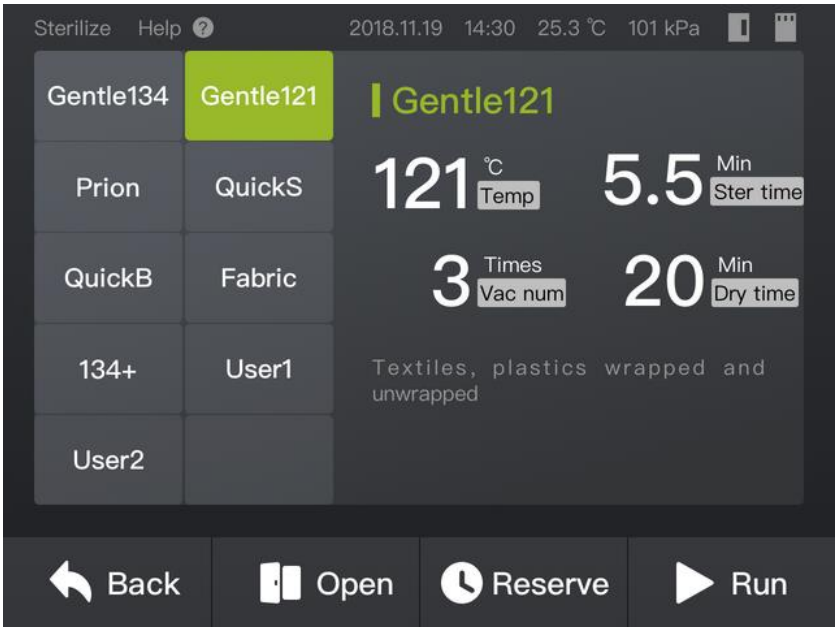


Figure 1.7 Program selection interface

1.4.3 Program running interface

In program running interface, system status bar is still in the top portion. The middle portion is separated into two. Left side shows the real-time temperature and pressure reading curves in the chamber. Right side displays program status bar. Command key “Stop” is located at the bottom right corner.

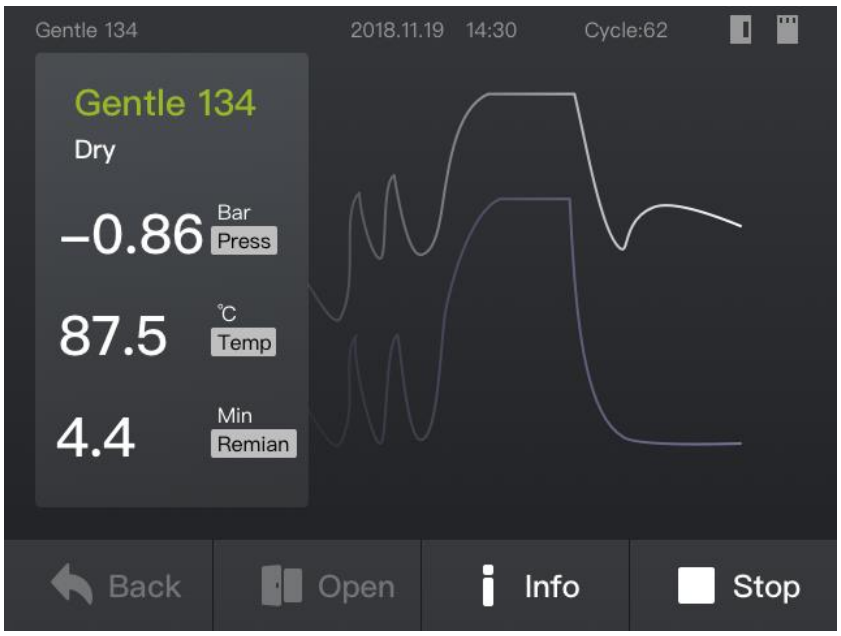


Figure 1.8 Program running interface

1.4.4 Program complete interfaces

After program completes, the screen shows program running results. In most circumstances, the message is "Program Run Succeed!". If the program did not succeed, the screen will show an error message. Temperature and pressure inside the chamber are shown for reference. Command keys are at the bottom for further process.

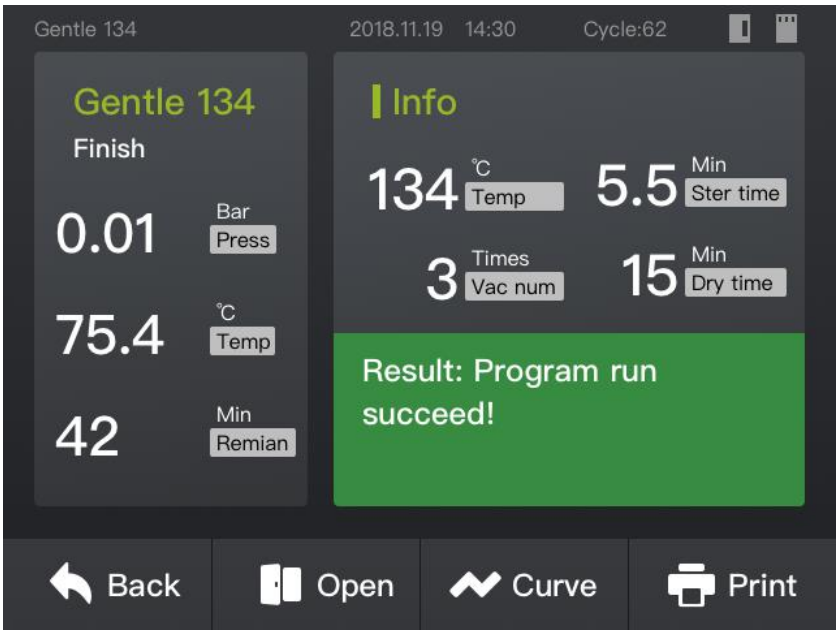


Figure 1.9 Program complete interface

1.4.5 Status symbols and command keys in the user interface

Status Symbol	Function
Door lock	Door lock status: open or closed
External storage	External storage status: connected or not
Warning info	Remind users to pay attention
Switch off	Switch is off
Switch on	Switch in on

Command key	Function
Back	Go back to upper-level menu
Next	Go next to upper-level menu

Open	Unlock and open the door
Reserve	Program reservation function
Start	Start current selected program
Info	Program information
Curve	Program curve
Stop	Stop current selected program
Print	Print record
Export	Export records to external storage
Confirm	Confirm previous input
Previous page	Go to previous page of current menu
Next page	Go to next page of current menu
Edit	Change the data
Page close	Close current page
Keyboard close	Close Keyboard
Page enter	Enter the page
Delete	Delete the data
Page up	Page scrolling up
Page down	Page scrolling down
Plus	Increase in number

	Minus	Decrease in number
	Cross	For click center

1.5 Emergency door handler

The emergency door handler at the rear of the device can be used when there is an electrical power failure or an issue with the safety door lock system. Do not use this handler under normal circumstances. Care must be taken to ensure there is no pressure in the chamber before using the emergency door handler.

Operation method: uninstall the screw on the Emergency cap, fit the emergency door open T-wrench on the shaft and turn counter clockwise until the door is open.

1.6 Program sequences

1.6.1 Regular sterilization program

A program runs in 3 phases, air removal, sterilization and drying phase. After program starts, the user can follow the program running status on the display. It shows the chamber temperature and pressure as well as time elapsed for the current running program.

Program Phase	Description
1.Air removal	The air removal phase comprises the conditioning and the evacuation. During conditioning, steam is repeatedly injected into the sterilization chamber to generate over-pressure. During evacuation, the mixture of air and steam is then removed repeatedly. This procedure is also called the fractionated pre-vacuum procedure. Number of pre-vacuum fraction varies from program to program. GEN134 is set for 3 times of pre-vacuum fraction and Helix or 134+ is set for 4 times.
2.Heating	The heating phase follows the air removal phase. Steam continuously entering into the chamber leads to an increase in pressure and temperature until the program-specific sterilization parameters are reached.
3.Sterilization	Sterilization phase begins when pressure and temperature match the pre-set nominal values. Sterilization phase ends when pressure and temperature are maintained for a period of time that is program-specific.
4.Pressure release	After sterilization phase, pressure releases by evacuating steam from chamber.

5.Drying	Drying phase begins after pressure release. The load is dried using a vacuum. During drying the air filter ensures sterile environment in the autoclave.
6.Ventilation	Ventilation happens during drying phase. Upon program end, the chamber pressure is adapted to the ambient pressure.

1.6.2 Vacuum test

The purpose of vacuum test is to measure the leakage rate of the autoclave. No sterilization is performed during vacuum test. Please run vacuum test with a cold, dry and empty autoclave.

Program phase	Description
1.Air removal	Air is evacuated until the pressure in the chamber reaches the pre-set value.
2.Equilibration	An equilibration time of 5 minutes.
3.Measurement	Measurement time of 10 minutes during which pressure in the chamber is monitored and displayed.
4.Test end	The screen shows the test result: leakage rate

2 Installation and Transportation

2.1 Unpacking the device

	Only have the autoclave setup, installed and started up by people authorized by the manufacturer.
	If this autoclave had been kept in a different location from the installation site, wait for an appropriate time before installing and switching ON the autoclave. Autoclaves arriving from cold locations could contain moisture that affects the electrical parts and it could lead to unsafe operation for user and the device.
	The autoclave must be removed from the box and transported by 4 people. **Total weight : Q102B 82 kg; Q82B 112.2 kg; Q92B 119.8 kg**
	Check the external condition of the package and the autoclave. In case of any damage, contact the distributor or the transporter immediately.
	Please check all accessories in the box and the chamber of the autoclave according to the accessary table in Section 1.1 of this User Manual.

2.2 Set-up location requirements

Set up the autoclave in a dry and dustproof location. The air humidity should be lower than 85% and the ambient temperature 5 ºC to 40 ºC.

- Never setup or operate the autoclave in explosive atmospheres.

- The autoclave is designed for indoor use only.
- The position of the autoclave should be easy to access for disconnection or termination of operation.
- The workbench must be able to support the device weight:

  Q102B 82 kg; Q82B 112.2 kg; Q92B 119.8 kg
- The distance from each side of the autoclave to the surrounding surfaces must be at least 10 cm. Failure to follow these guidelines may lead to heat accumulation and adversely affect the function of the autoclave and could shorten the lifetime of the vacuum pump and increase cycle time.

2.3 Adjust height for the device

Find the gradient in the accessary bag and place it on top of the device. Observe the gradient while adjusting the two-foot pads in front. Ensure that the front of the device is higher than the rear. A proper position is while the angle between the bottom of the device and table is about 5°-10° which is beneficial for drying of sterilization load and minimizing distilled water consumption.

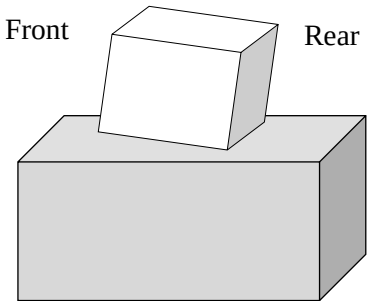


Figure 2.1 Adjust height for the device

2.4 Connections required

2.4.1 Power connection

- Power supply of 230V/50Hz. Max. voltage range of 200V ~ 250V
- Dedicated 25A power outlet. Protection from leakage current 30mA.

- Make sure the power cable is not knotted or jammed (e.g., between the doors or windows)
- Never unplug by pulling on the power cable. Always take hold of the power plug itself.
- Never lead the cable along a source of heat.
- Never use sharp objects to fix the cable.
- Never change the main cable or power plug. Never use a damaged power cable or plug.
- Never operate the device if the plug or power cable is damaged. The power cable and plug should only be replaced by authorized personnel.

2.4.2 Feed water supply

The autoclave does not come with internal water reservoirs. An external water container is needed. Take out the distilled water pipe from the accessary bag. Put the end with filter inside the distilled water container and connect the other end to the distilled water inlet at the rear of this autoclave (Fig. 1.3). Fill the contained with fresh distilled water before operating the autoclave.

- Use distilled or demineralized water that meets the requirements listed in EN 13060 Appendix C. Unqualified feed water may cause corrosion of instruments;
- Conductivity ≤20μs/cm;
- Feed water pressure ≤ 30 Kpa ;
- A 12L container can supply distilled water to the autoclave for more than 10 cycles. Please pay attention to the water level in the container and fill it in time to avoid program abort due to no distilled water;
- The cap of the distilled water contained must always be screwed tight to ensure cleanness of the feed water;
- Please clean the container at least once in a month;
- This device has water quality monitor. When fed with unqualified water, the autoclave will not work properly and but give warnings about water quality. Please change high quality distilled water immediately upon seeing the warning message;
- Please consult the manufacturer before using a water treatment unit.
- All water pipes connected at the rear of the autoclave are recommended to face downward and fixed firmly without bend or knot.

2.4.3 Cooling water connection

Take out the cooling water pipe from the accessory bag. Connect the female thread end to the cooling water inlet at the rear of the autoclave (Fig.1.3) and screw it tightly. Connect the other end to the tap water.

- All water pipes connected at the rear of the autoclave are recommended to face downward and fixed firmly without bend or knot.

2.4.4 Waste water draining

Take out the drain pipe from the accessory bag. Connect the female thread end to the waste water outlet at the rear of the autoclave (Fig.1.3) and screw it tightly. Fix the other end to the waste water sink.

- All water pipes connected at the rear of the autoclave are recommended to face downward and fixed firmly without bend or knot.

2.4.5 Printer connection (Optional)

Take out the power cable and data line from the printer package. Connect the data line from the printer to the DB9 connector at the rear of the autoclave (Fig. 1.3) and screw it tightly. Connect the original power cable that comes with the printer to supply power. Load paper roll before switch on the printer. The power switch of the printer is at the rear side of the printer.

- Please use the original power cable that comes with the printer;
- Status light (Red) ON indicates lack of paper;

- The autoclave has built-in memory that can store up to 4000 sterilization records. Sterilization records can be exported to external portable storage device any time through USB I/O (Fig. 1.3)

2.5 Record of Installation

- As documentation of proper installation as well as for warranty claim, the record of installation must be filled by person responsible.

2.6 Transportation

This device must be stored and transported in an environment that has air humidity level lower than 85% and ambient temperature -20 ºC ~ 55 ºC.

Before moving the autoclave, please run the drain program first. Then switch off the cooling water tap, take off all pipes at the rear of the device (cooling water pipe, distilled water pipe and waste water pipe). If a printer is connected, please disconnect the printer data line as well.

If the mounting rack and trays are placed in the chamber during the move, please put foam between the rack and chamber door to avoid abrasion or damage.

If the autoclave needs to be transported for long distance, it must be put back to its original package. Please make sure the box is sealed carefully after loading the autoclave.

- Please run drain program to drain residue water in it before moving or transporting the device.

3 Getting started

3.1 Switching on the device

To power on the autoclave press the power switch located at the back of the device (Fig. 1.3) and then press the operator switch at the bottom right corner of the device (Fig.1.4)

- Please remove the latex plug inside the air filter opening at the rear of the autoclave (Fig. 1.3) before switching on the device and install the air filter in the accessory bag.

3.2 After switching on

After switching on, please follow the system prompts to setup language, time, date and calibrate ambient pressure. After successfully calibrate ambient pressure, the control panel will prompt operation to enter the main menu. For setting up language, time and date during normal use, please refer to Chapter 6 of this User Manual.

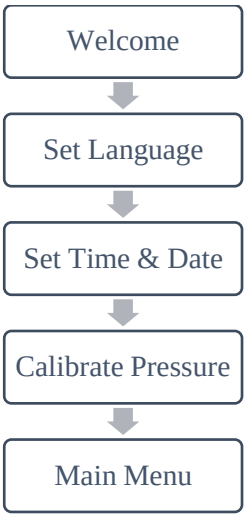


Figure 3.1 Flow for initial setup

3.2.1 Pressure calibration

During initial setup, the autoclave will prompt pressure calibration to set the pressure baseline according to ambient pressure at the location of installation. Door must be open during pressure calibration. Please follow the system prompt to open the door before pressure calibration. Initial setup is complete when pressure calibration succeeds. After a period of time, particularly if the autoclave is moved to somewhere else, pressure calibration must be performed again. For pressure calibration during normal use, please refer to Section 6.5.6 in this User Manual.

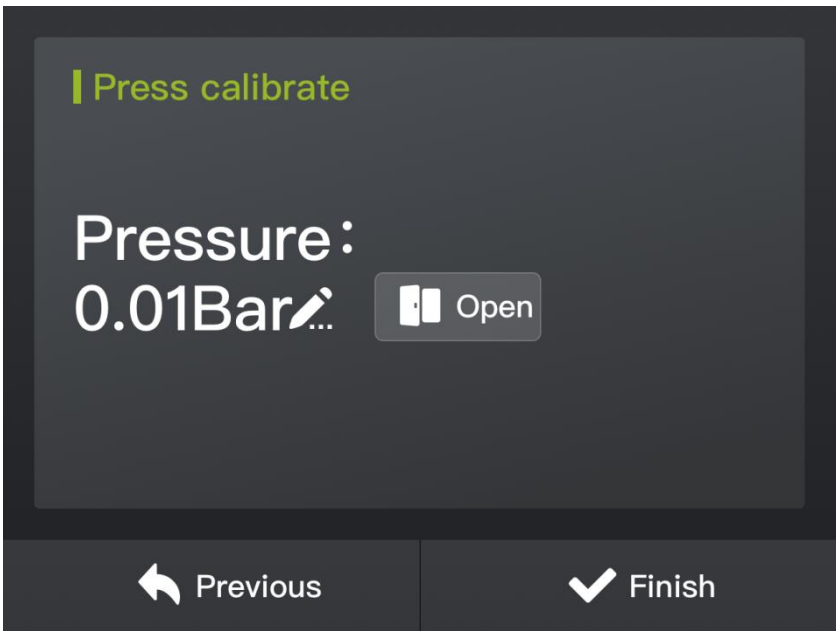


Figure 3.2 Pressure Calibration

3.3 Door operation

Opening the door: In program selection interface (Fig. 3.4) or program complete interface (Fig. 1.9), press **【Open】**icon (Fig. 3.4), the door will open automatically. The door lock status icon in system status bar will change to unlock indicating door unlocked.

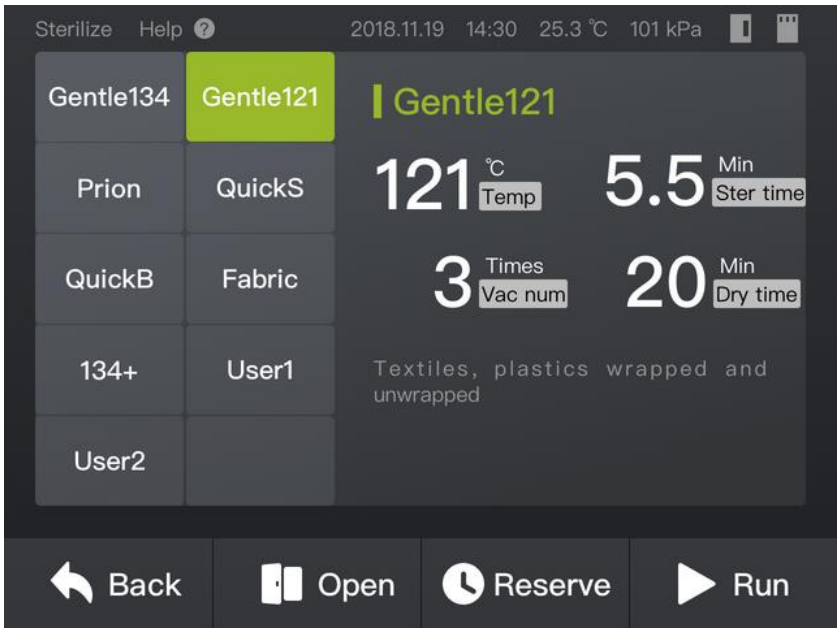


Figure 3.4 Door open icon

Closing the door: Move the door toward the chamber, when it is close enough, the motor-driven spindle automatically close the door. The door locks pressure-proof once a program starts.

- Under no circumstance should you slam the door shut.
- Failure to follow the above instructions may impair the functional reliability of the door lock mechanism.

- Leave the door open only for loading and unloading the autoclave. Keeping the door close helps energy saving.

4 Sterilization

4.1 Load the autoclave

Mounting rack and trays are standard accessories that come with the autoclave. Only the space framed by the rack is effective sterilization space. The outer rim of the chamber is too close to the chamber wall; hence loads may get wet or scorched. Please use the original mounting rack and trays that have ventilation holes at the base.

Proper loading is the key to effective sterilization and good drying results. The below instructions must be followed carefully to load the autoclave properly:

- Only use packaging materials and systems which meet EN 868 standard;
- While sterilizing instruments wrapped in plastic paper pouches, the paper side must be facing upward;
- While sterilizing mixed loads, always place textiles at the top;
- Leave sufficient room between pouches;
- The total loaded space should not exceed 90% of the chamber space.

4.2 Select program

The autoclave offers 7 pre-defined sterilization programs and 2 user-defined programs. Please select the sterilization program accordingly depending on whether and how the sterilization loads are wrapped. Furthermore, consider the resistance to high temperature of the items to be sterilized. The following table show which program to choose for what items to be sterilized in Q92B. Q82B and Q102B only varies in max. load weight from Q92B. The max. load weight for Q82B is 16 kg instruments or 4.5 kg textiles. The max. load weight for Q102B is 9 kg instruments or 2.8 kg textiles. Select program through program selection interface.

Table 4-1 Sterilization programs and load description

Program	Temp (℃)	Sterilization (min)	Drying (min)	Max. cycle time (min)	Typical load	Max. load weight
GEN121	121	16	20	60	Textile load up to 5.4 kg or thermo-unstable instruments up to 20 kg.	5.4 kg / 20 kg
GEN134	134	5.5	15	56	Mixed load. Hollow instruments etc.	20 kg
134+	134	5.5	15	61	Mixed load. Hollow instruments etc.	20 kg
Quick S	134	3.5	2	50	Solid instruments, simple geared or hollow instruments.	20 kg
Quick B	134	3.5	6	52	Wrapped instruments up to 12 kg or 20 kg unwrapped solid instruments.	12 kg / 20 kg
Prion	134	20	15	60	Materials that are suspicious to Prion disease.	20 kg
Fabric	121	20	20	65	Textile loads of up to 5.4kg.	5.4kg

4.3 Additional program options

4.3.1 Automatic pre-heat

The automatic pre-heating function heats the autoclave chamber to a program-specific pre-heated temperature before the program start, or holds this temperature between two program runs. This will shorten the cycle times. For setting automatic pre-heating, please refer to Section 6.5.1.

After switching on the automatic pre-heating function, the autoclave will heat up the chamber automatically to 110℃. Please take caution to avoid burns!

4.3.2 Automatic printing

If automatic printing is switched on and printer is connected to the device correctly, the system will print record automatically after the program completes. For setting automatic printing, please refer to Section 6.5.2 in this User Manual.

4.3.3 Additional drying

The autoclave offers additional drying function for users that prefer better drying results at the cost of longer drying time. If additional drying is set, the drying time listed in Table 4-1 will be extended. This function is particularly useful for drying large amount of textile loads. For setting additional drying, please refer to Section 6.5.7 in this User Manual.

4.3.4 Start time pre-set

The autoclave allows users to select any program and start it at a pre-set time. After setting pre-set start time for a selected program, an alarm clock icon will be shown in grey area in the top of the main interface. The autoclave must be switched on at the pre-set time, otherwise the pre-set start time expires. If the autoclave is powered on, the selected program will start automatically at the pre-set time. Pre-set start time is configured in sterilization program interface. For example, if GEN134 is the selected program, first select GEN134 in the program selection interface (Fig. 1.7). The screen displays program introduction interface and click the alarm clock in this interface (Fig. 4.2). In the pre-set start time configuration interface (Fig. 4.1), set the start time and confirm the settings by clicking 【Confirm】

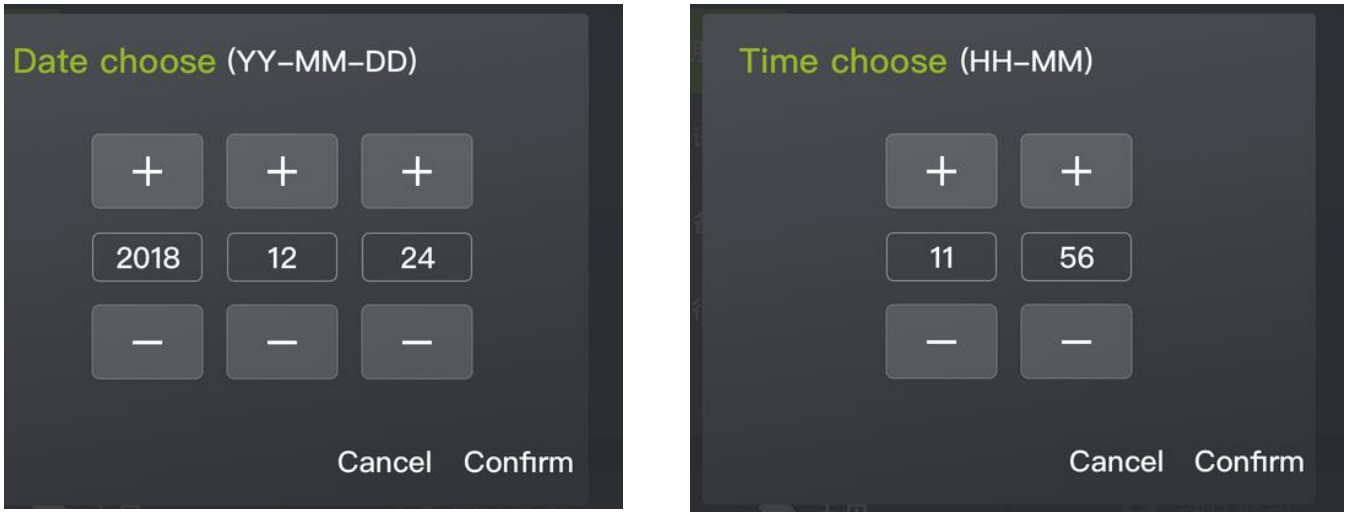


Figure 4.1 Pre-set start time setting

- Unsupervised operation of this autoclave is at the operator's risk. HäTmed accepts no liability what so ever for any damage resulting from unsupervised operation.

Please take caution of the following notes after pre-set start time:

- The autoclave should be powered on;
- Distilled water pipe is properly connected and distilled water container has sufficient water;
- Cooling water pipe and waste water pipe are connected properly.
- Items to be sterilized are properly loaded and autoclave door closed.

4.5 Running the cycle

4.5.1 Start the cycle

In the program introduction interface, click 【**Start**】. The autoclave will check the door lock status and water quality before running the selected program.

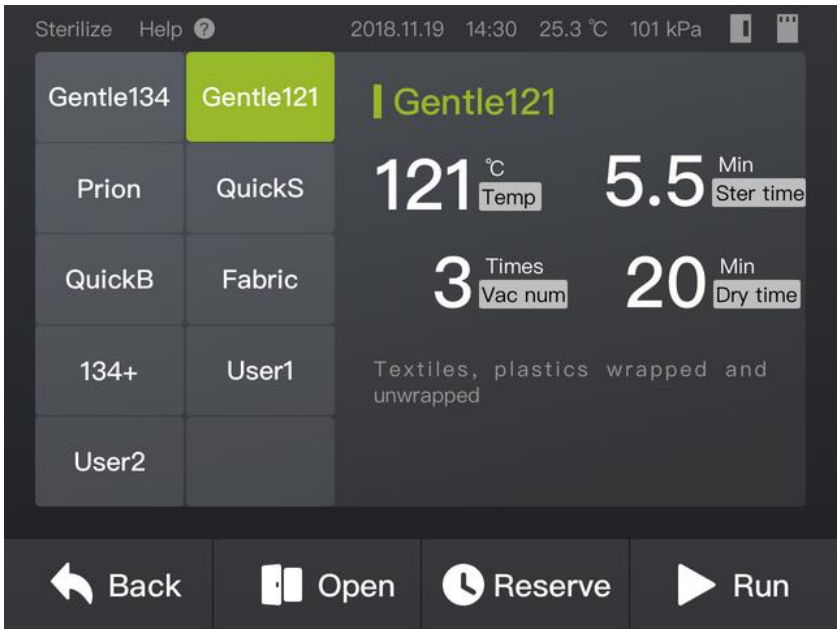


Figure 4.2 Program introduction interface

4.5.2 Program execution

A program runs in 3 phases, the air removal phase, sterilization and drying. Please refer to Section 1.6.1 of this User Manual for explanation of each phase. The screen displays real-time chamber temperature and pressure as well as time information of the cycle, as shown in Fig. 4.3.

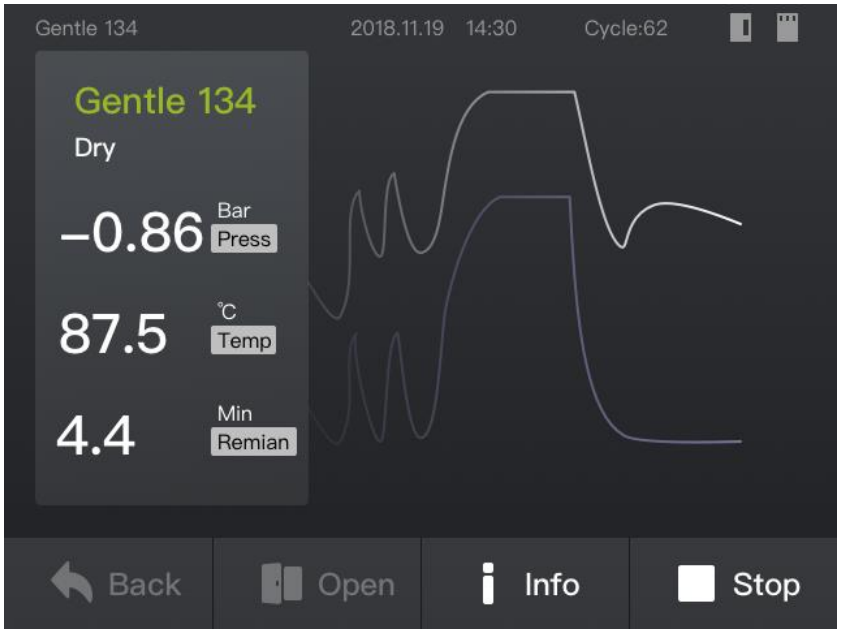


Figure 4.3 Manual stop button

4.6 Manual program abort

A program can be aborted in all phases. If program ends before drying begins, the sterilization load is unsterile. Otherwise, the items have been sterilized but not sufficiently dried. In full load case, it is highly possible for wet pack to occur. These wet packs cannot be stored because sterile storage set high requirements on the level of dryness.

Hot steam can be released from the autoclave when opening the door after a program abort. This could result in burns!

- Never touch the sterilized instruments, the chamber or the door with bare hands. These components are hot!
- Always use a tray handle or proximity gloves to remove the trays.

Danger of infection from early program abort!

- Aborting a program before the drying phase begins means that the load is unsterile. This endangers the health of your patients and the operator;
- If necessary, repack the load and repeat the sterilization.

If manual abort is necessary, please click 【**Stop**】in the screen. After the program is manually aborted, the screen prompts error messages and displays program ending interface. The intelligent controller keeps monitoring temperature and pressure in the chamber and status of other components of the device. The controller will only allow the user to open the door when it is safe to do so. Usually, it takes a few minutes for the device to reach the stage.

Figure 4.4 Manual abort message

4.7 Program complete

After a program runs successfully to the end, the screen displays program complete interface and program success message. If automatic printing is set and the printer is connected correctly, the autoclave will print the sterilization record automatically. Click 【**Open**】to open the door.

Danger of burns from hot surfaces and hot steam!

- Never use force to open the door. This could damage the device and /or result in the emission of hot steam;
- Allow the autoclave to cool sufficiently before opening;
- Do no touch any hot metal parts;
- Never touch the sterilized instruments, the chamber or the door with bare hands.
- Always use a tray handle or proximity gloves to remove the trays.
- Hold the mount level when removing it from the chamber. Otherwise, the load could slide off.

Damaged or burst packaging lead to unsterile instruments. This endangers the health of patients and operators.

- Should the packaging be damaged or have burst, re-pack and re-sterilize the items.

- Leaving the sterilized items in the chamber for 5 min after the program completes is beneficial for dryness of the sterile packs;
- According to the AKI (red brochure 10. Edition; S.57), residual moisture in the form of a few drops of water capable of evaporating within 15 min is tolerated, but actual pools of water are not acceptable.

- **It is recommended to keep records of every cycle for further reference. In some countries, it is mandatory to do so.**

4.8 Storing sterile instruments

The maximum storage time is dependent on the packaging and the storage conditions. For standard-conform packaged sterilized instruments, if protected from dust, it can amount to up to six months. Comply with the provisions of DIN 58953, part 8 and the criteria specified below for the storage of sterilized instruments.

- Comply with the maximum storage duration in accordance with the packaging type;
- Do not store the sterilized instruments in the decontamination area;
- Store the sterilized instruments in dustproof, dry (free from moisture, alcohol, disinfectant etc.), temperature-controlled environment.

5 Function tests and other programs

5.1 Vacuum test

Please run a vacuum test to check leakage rate at first time use, after long idle time or moving to a new location and during regular maintenance check. Choose 【Test】 in the main interface (Fig. 1.6) to enter test program interface. Click 【Vacuum】 and the screen displays vacuum test introduction interface. Click 【Run】 to run vacuum test.

Figure 5.1 Test program interface

- Please run the vacuum test with cold, dry and empty chamber;
- Please ensure the autoclave door is locked tightly and cooling water tap is on;
- It is recommended to run Vacuum test once weekly in routing operations.

At the beginning of the vacuum test, air is extracted out from the chamber and pressure inside the chamber drops. When the pressure in the chamber reaches program-specified value, vacuuming stops. This is followed by 5-min balance time and 10-min vacuum test. During the test, the screen displays real-time pressure in the chamber. The autoclave returns to ambient pressure after the vacuum test. Test record is stored in the built-in memory. If automatic printing is set and a printer is installed, the test record will be printed automatically too.

If test passed, the screen prompts “Vacuum test succeed”, which means that leakage rate of the system meets design requirement. The printed message is as below:

```
- - - - - - - - - - - - - - - -
  PROGRAM PROPERLY EXECUTED!          Test passed!
  Leakage rate: <0.13Kpa/min     Leakage: <0.13Kpa/min
```

Your system is steady!
- - - - - - - - - - - - - - - -

If test failed, the screen prompts “Vacuum test fail”. The printed message is as below:

- - - - - - - - - - - - - - - -
PROGRAM PROPERLY EXECUTED! Test failed!
Vacuum Test Fail!
- - - - - - - - - - - - - - - -

- If vacuum test failed, please stop using this autoclave and contact distributor or manufacturer immediately.

5.2 Bowie &Dick Test

The Bowie & Dick test serves as the proof of steam penetration for porous materials such as textiles. Choose **【B&D Test】** in test program interface (Fig. 5.1).

- Conduct the test and interpret test results according to the manufacturer’s instruction of the test pack;
- It is recommended to run B&D once weekly in routing operations.

5.3 Helix test

Helix test serves as the proof of steam quality (saturation) and penetration for hollow A instrument, such as dental hand-piece. Choose **【Helix Test】** in test program interface (Fig. 5.2).

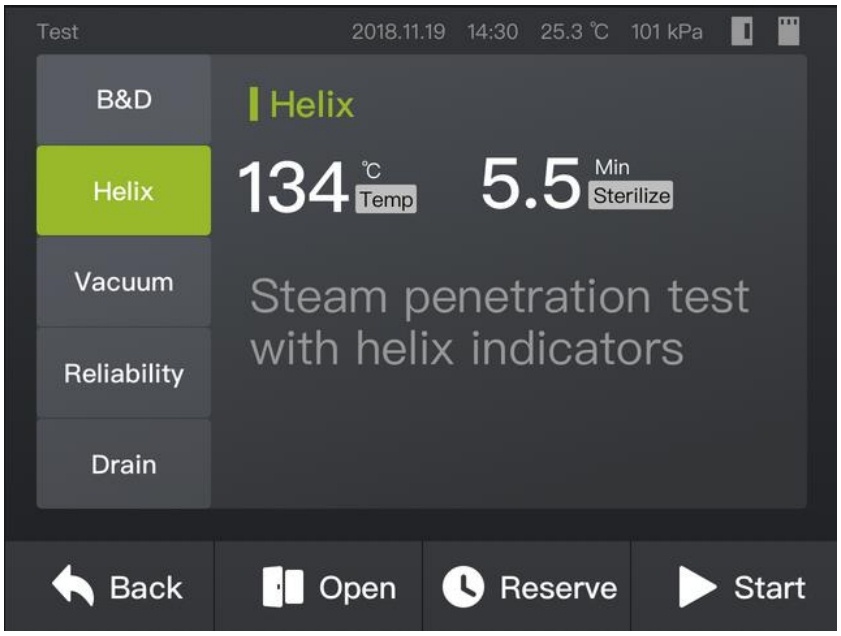


Figure 5.2 Test program interface

- Conduct the test and interpret test results according to the manufacturer's instruction of the test pack.

5.4 Reliability test

The autoclave features with reliability test for safety check of the system during regular maintenance or routing operation. Choose **【Reliability】** in test program interface (Fig. 5.1).

5.5 Drain program

Drain program serves to discharge residual water inside the autoclave. Choose **【Drain】** in test program interface (Fig. 5.1).

- If water is ponding in the chamber when you open the door, please run drain program before loading items to be sterilized. If last program was aborted in the middle way, it is possible that significant amount of water is left in the chamber. Please open the door to check after program abort;
- Please run drain program before moving or transporting the device.

5.6 User defined program

The autoclave offers 2 user defined programs – User-1 & User-2. Users can configure these programs based on particular need or personal preference. Configurable parameters include sterilization temperature, number of times of pre-vacuum, sterilization time and drying time.

Configure the user defined programs following Section 6.5.8 of this User Manual. After configuration, choose **【Sterilize】** in main interface to access program selection interface (Fig. 5.2) . Click **【User-1】** or **【User-2】** to choose specific program. Operations to run these programs are same as to run pre-set sterilization programs, as described in Section 4.4 of this User Manual.

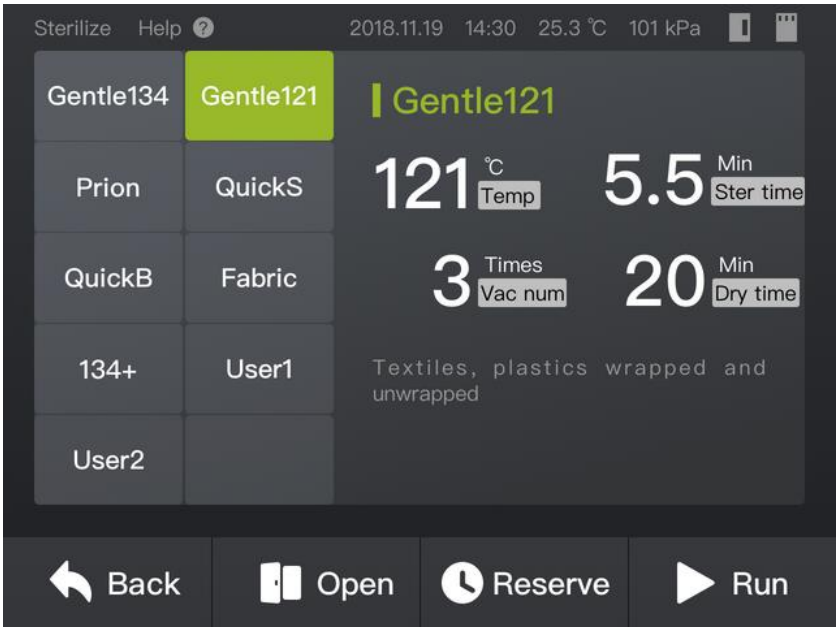


Figure 5.3 Program selection interface

6 Settings

Click 【**Setting**】in main interface (Fig. 1.6) to enter system settings interface (Fig. 6.1). Users can set date, time and language or check device information and cycle information.

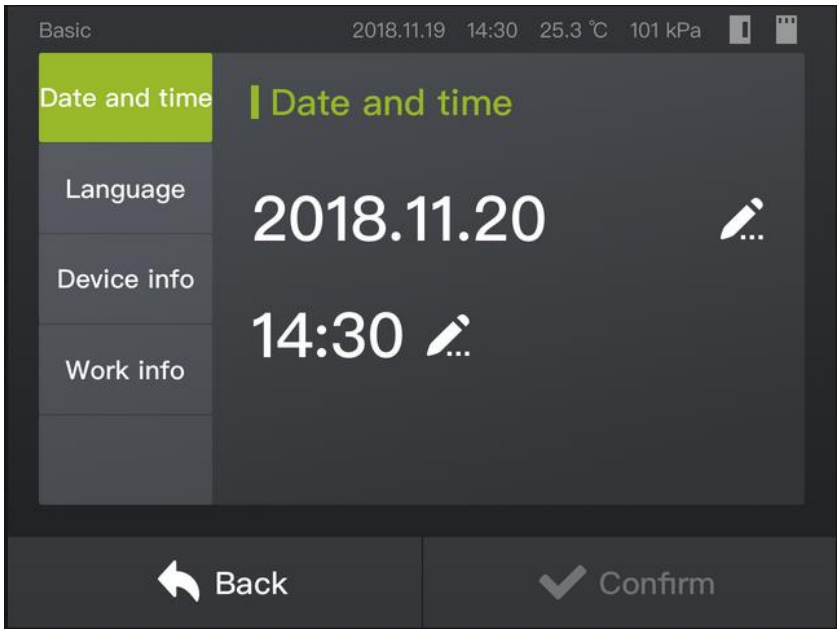


Figure 6.1 System settings

6.1 Date and time

Click 【**Time Set**】in system settings interface (Fig. 6.1) to enter date and time setting interface. Click 【+】or 【-】to set the correct year, month, date, hour and minute, then click 【✓】to confirm.

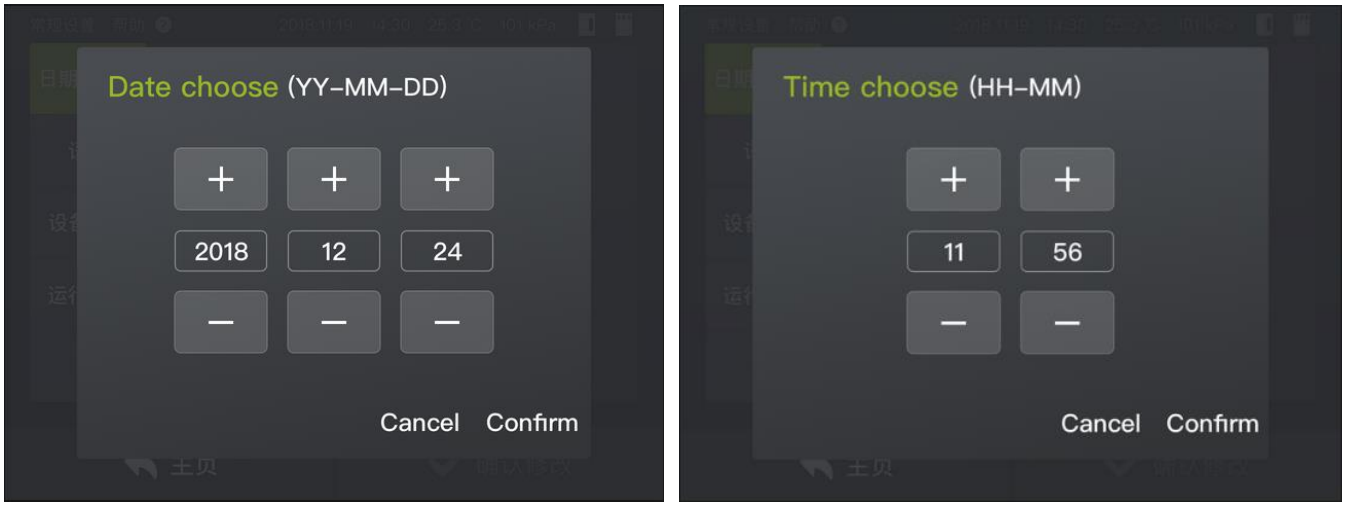


Figure 6.2 Date and time setting

6.2 Language

Click 【**Language**】in system settings interface (Fig. 6.1) to enter language setting interface. Choose language, then click 【✓】to confirm.

Figure 6.3 Language setting

6.3 Device information

Device information page displays serial number of the device and its hardware and software versions. Click 【**Device info**】in system settings interface (Fig. 6.1) to enter device information interface. When finish reading, click 【✓】to confirm and the screen will return to system settings interface.

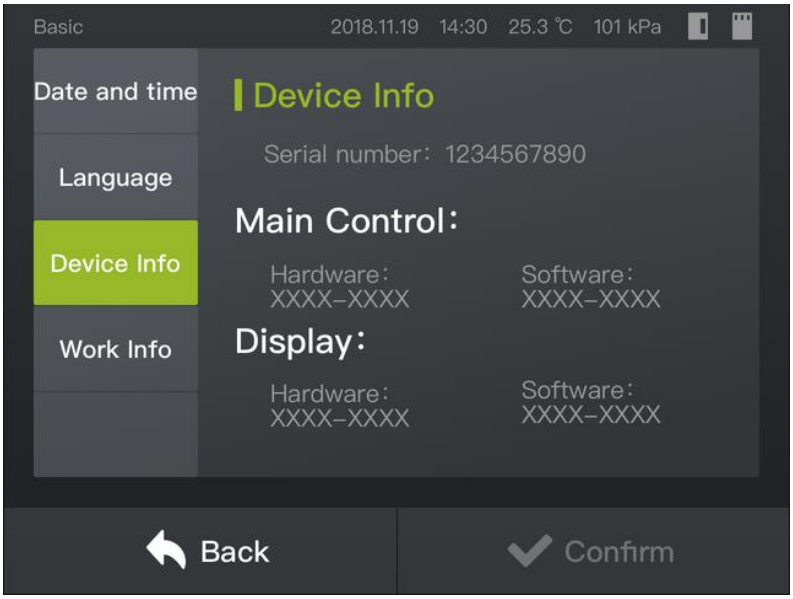


Figure 6.4 Device information

6.4 Cycle information

Cycle information displays the total number of cycles the autoclave has run. Click 【**Cycle info**】in system settings interface (Fig. 6.1) to enter cycle information interface. When finish reading, click 【✓】to confirm and the screen will return to system settings interface.

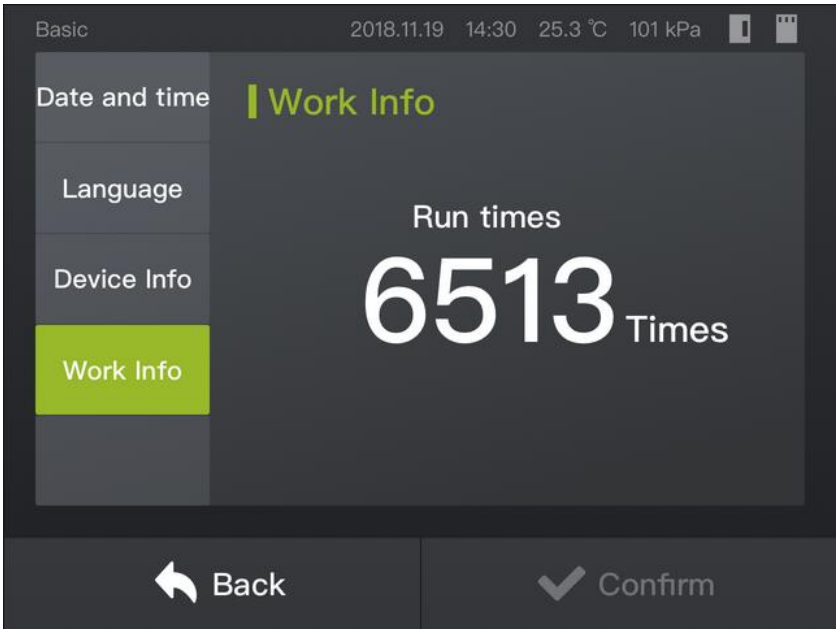


Figure 6.5 Cycle information

6.5 Advanced settings

Advanced settings include automatic pre-heat, automatic printing, touch screen calibration, user password reset, water quality check, system reset, additional drying, user defined program configuration. To ensure sterilization quality and safe operation of the autoclave, settings and configurations of sterilization parameters or special features are protected by password. User must enter password to access the advanced settings.

Click 【**Advance**】 in main interface (Fig. 1.6) and key in factory default user password "858369" to enter advanced settings interface

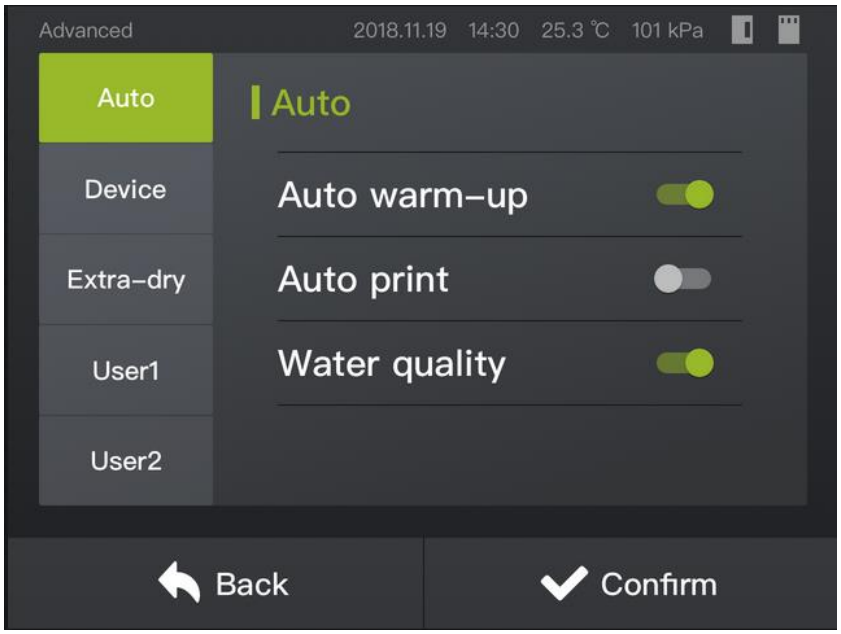


Figure 6.6 Advanced settings

6.5.1 Automatic pre-heat

Click 【Auto】in advanced settings interface (Fig. 6.7) to enter auto setting interface. Choose or , then click 【√】to confirm.

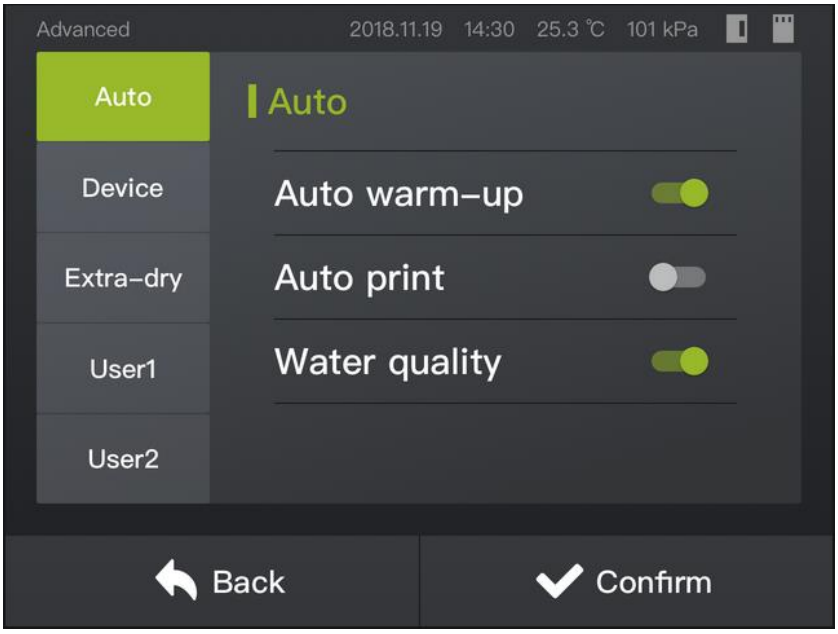


Figure 6.7 Automatic pre-heat setting

After switching on the automatic pre-heating function, the autoclave will heat up the chamber automatically to 110℃. Please take caution to avoid burns!

6.5.2 Touch screen calibration

If the point of touch to the point of response is unaligned after a period of time, touch screen calibration may be needed. Click 【Device】in advanced settings interface (Fig. 6.7) to enter device interface. Click 【Touch Calibration】to perform touch screen calibration. Click the 【+】following the screen prompts. After calibration is complete, the screen will return to advanced setting interface.

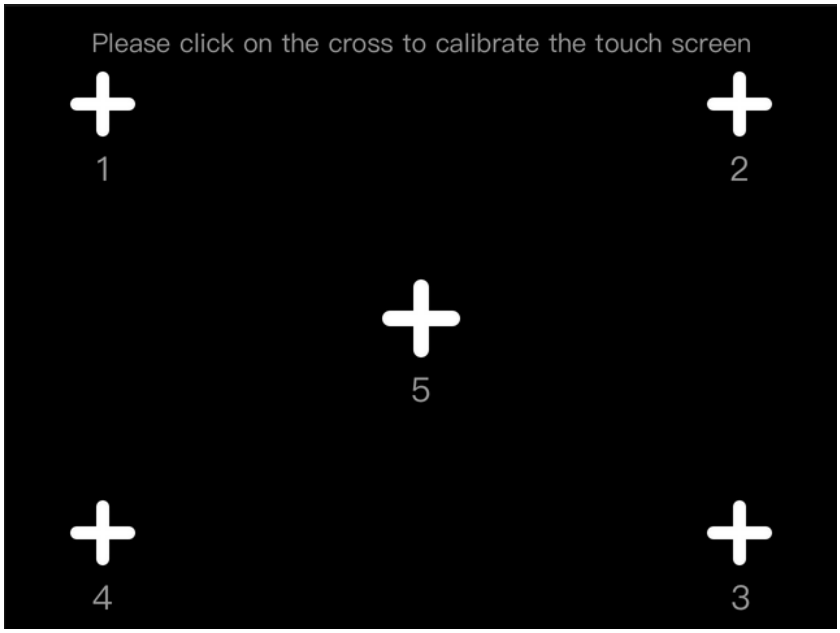


Figure 6.8 Automatic printing setting

6.5.3 Modify user password

Click 【Device】 in advanced settings interface (Fig. 6.7) to enter device interface. Click 【Modify user password】to perform modify user password. Click 【 】and【√】to proceed and system will prompt to confirm the new password.

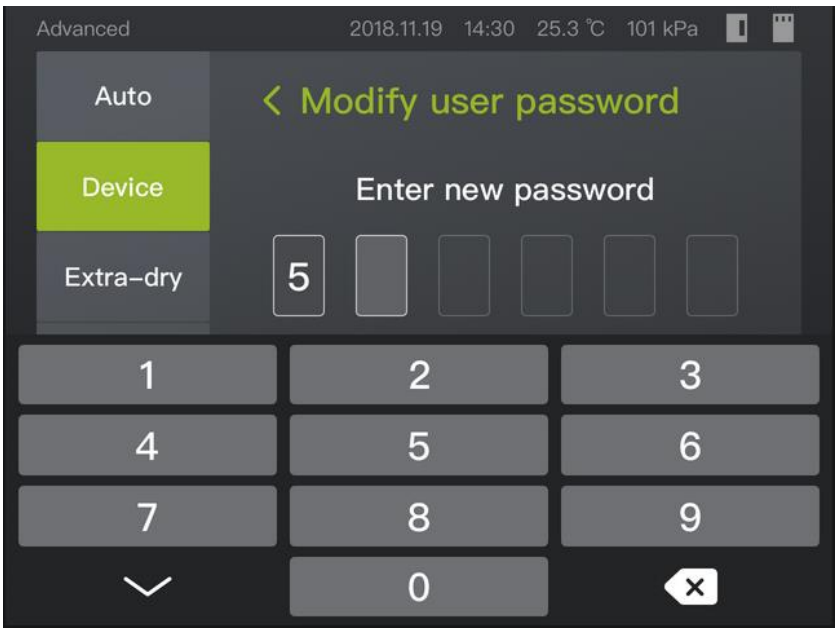


Figure 6.9 Touch screen calibration

6.5.4 Water quality check

Click **【Water Quality】** in advanced settings interface (Fig. 6.6) to enter water quality check setting interface (Fig. 6.10). Choose ○ or ●, then click 【✓】 to confirm.

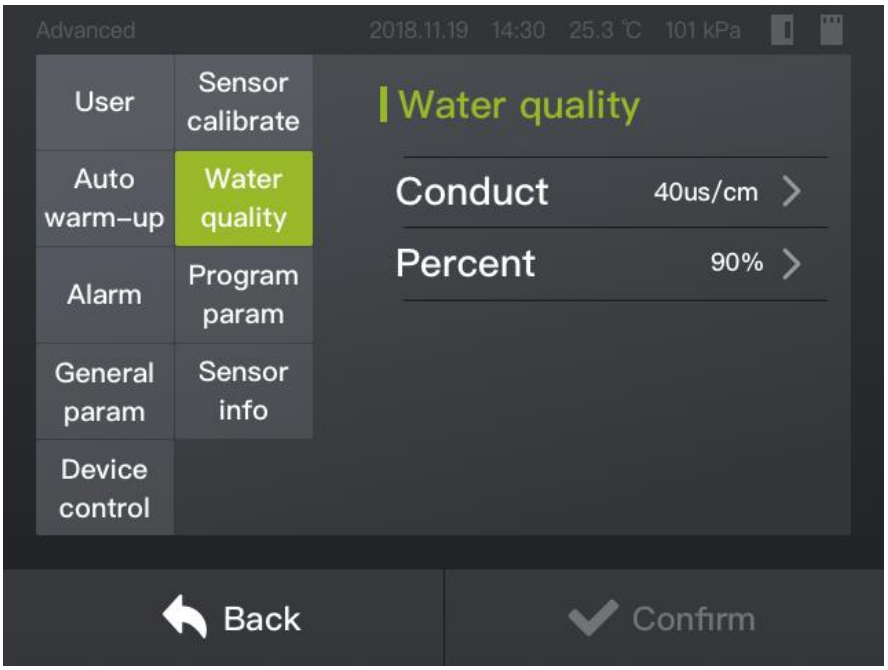


Figure 6.10 User password reset

6.5.5 System reset

Click 【Device】in advanced settings interface (Fig. 6.6) to enter device interface. Click 【System reset】to perform system reset. Click 【Confirm】, the autoclave will be restored to its factory default settings.

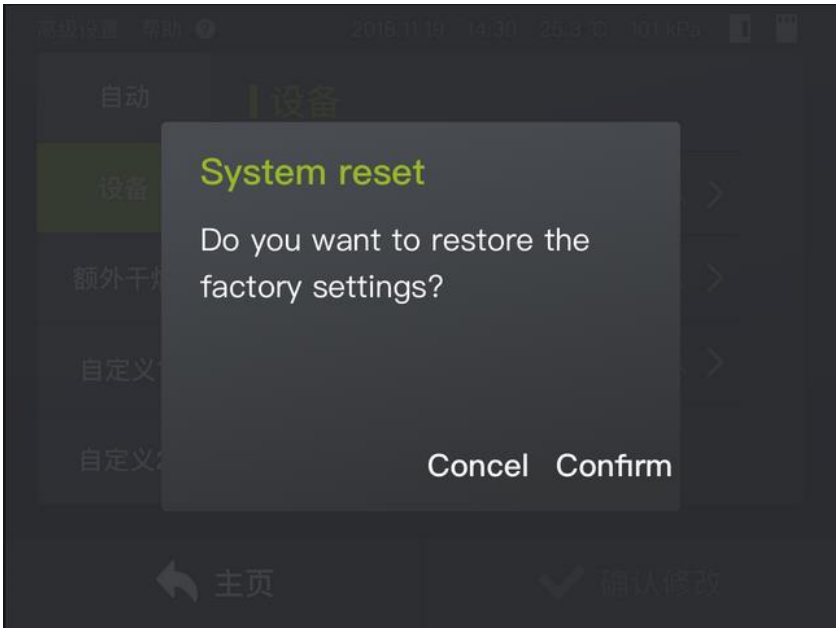


Figure 6.11 Water quality check setting

6.5.6 Additional drying

Click 【Extra-dry】in advanced settings interface (Fig. 6.7) to extra-dry setting interface. Choose or , then click to change time, click 【√】to confirm.

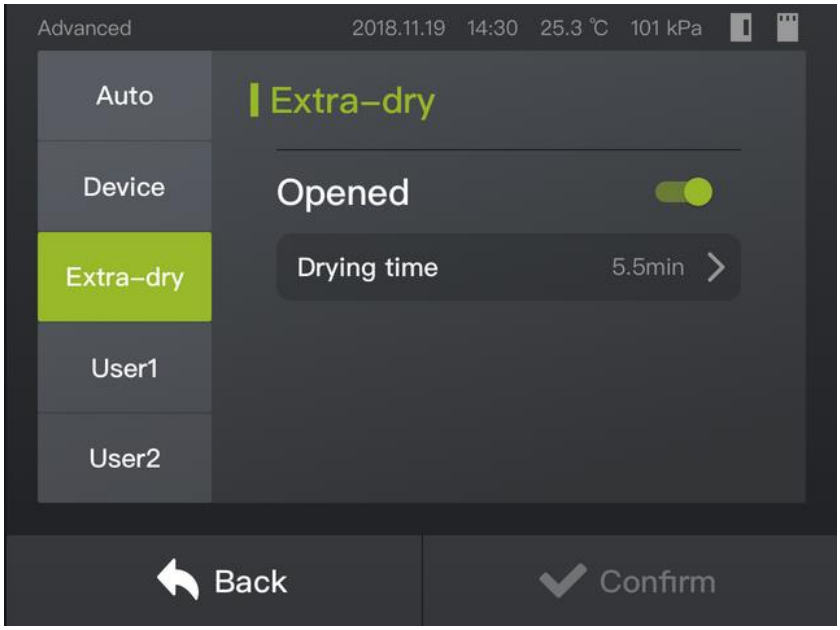


Figure 6.12 System reset

6.5.7 Additional drying

Click **【User1】**or **【User2】**in advanced settings interface (Fig. 6.6) to enter user defined program configuration interface (Fig. 6.14). Set sterilization temperature, number of times of pre-vacuum, sterilization time and drying time, then click 【✓】to confirm.

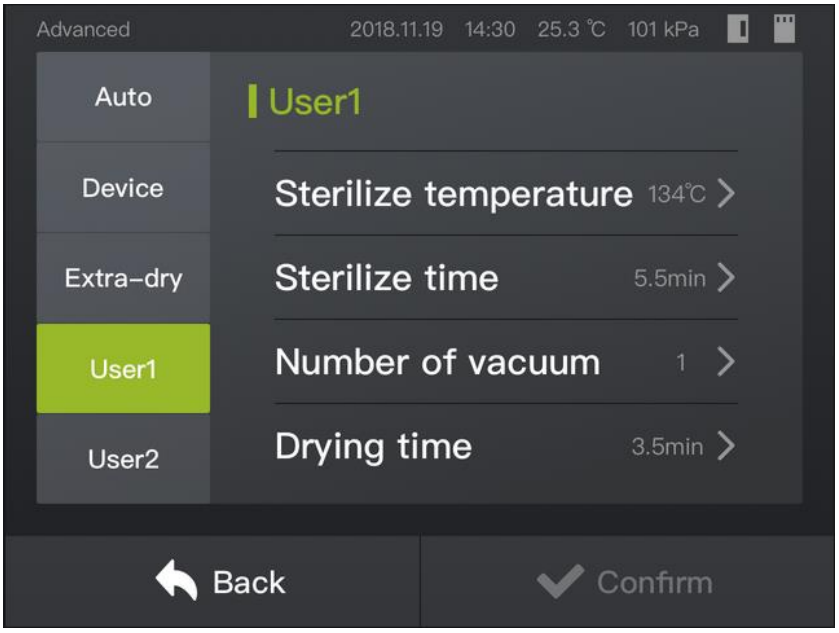


Figure 6.13 Additional drying setting

7 Logging

The autoclave records and stores real-time data of the sterilization process. The built-in memory of this device can store records up to 4000 cycles. Log file is named after cycle number, e.g., 00001.TXT. These logs can be exported to portable USB disk or printed via a mini printer.

7.1 Find logs

Click 【History】 in main interface (Fig. 1.6) to enter sterilization record interface (Fig.1.6). Choose a time period or 【Inquire】 to enter dates input interface (Fig. 7.1). After selecting a date, the screen will list all logs of those dates (Fig. 7.2).

.

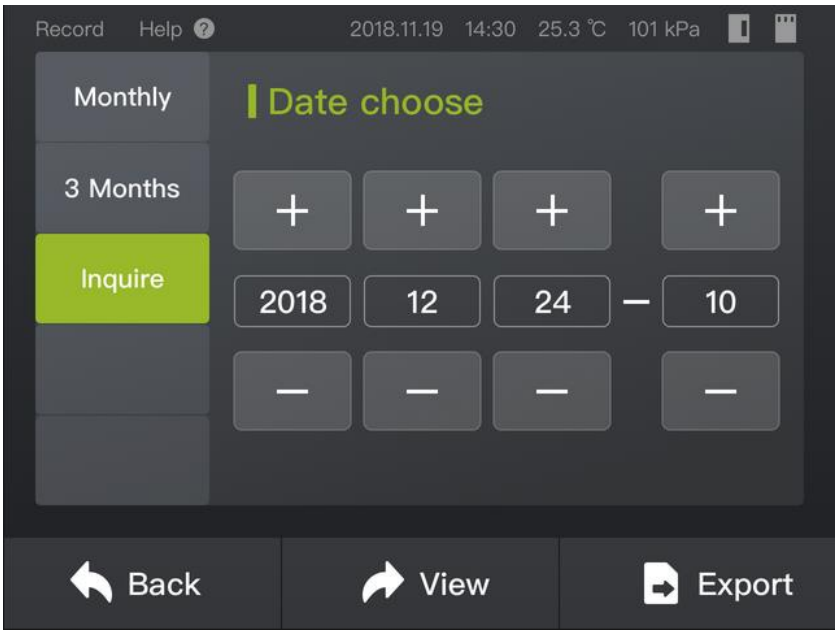


Figure 7.1 Sterilization record interface

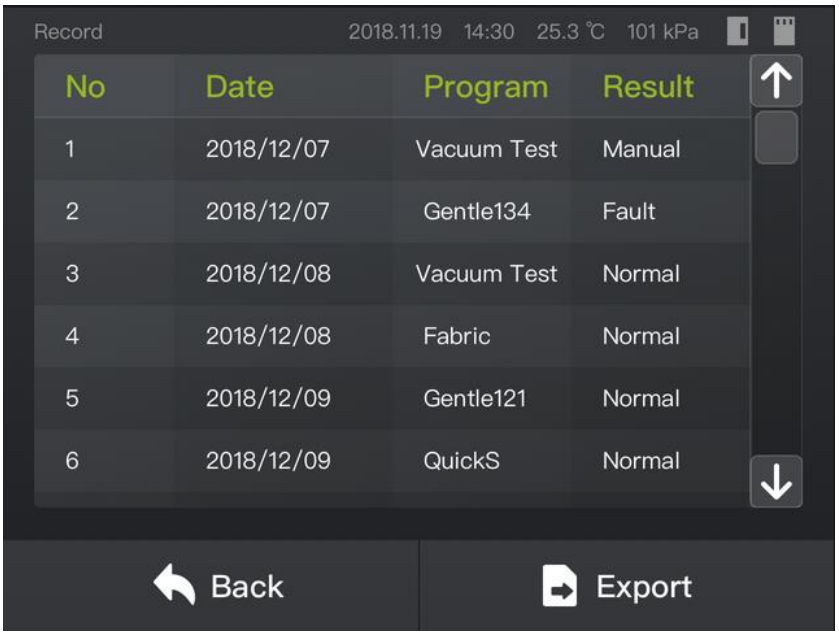


Figure 7.2 Date select interface

7.2 Export logs

For permanent storage of sterilization records, all logs can be exported through the USB interface to a computer or other portable storage device. To operate: Insert the USB disk into the USB interface. Select logs in log select interface (Fig. 7.2) and press【**Export**】. A progress bar appears to indicate the export process. When it reaches 100%, the screen will prompt “Export Succeed”. The USB disk can be removed.

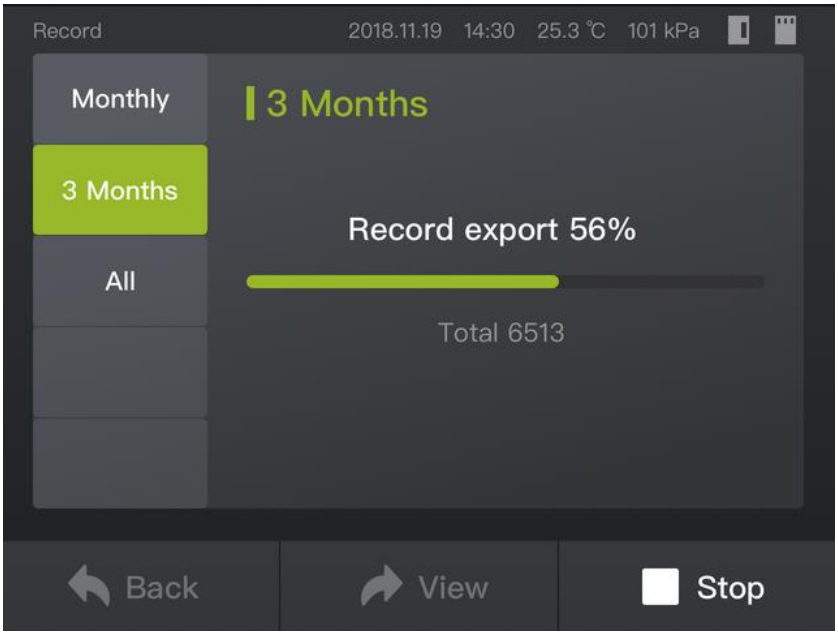


Figure 7.3 Log export progress

7.3 Print logs

Select log (Fig. 7.3) to enter the log display and print interface (Fig. 7.6) and click 【**Print**】. If a printer is connected to the autoclave, the selected log will be printed out.

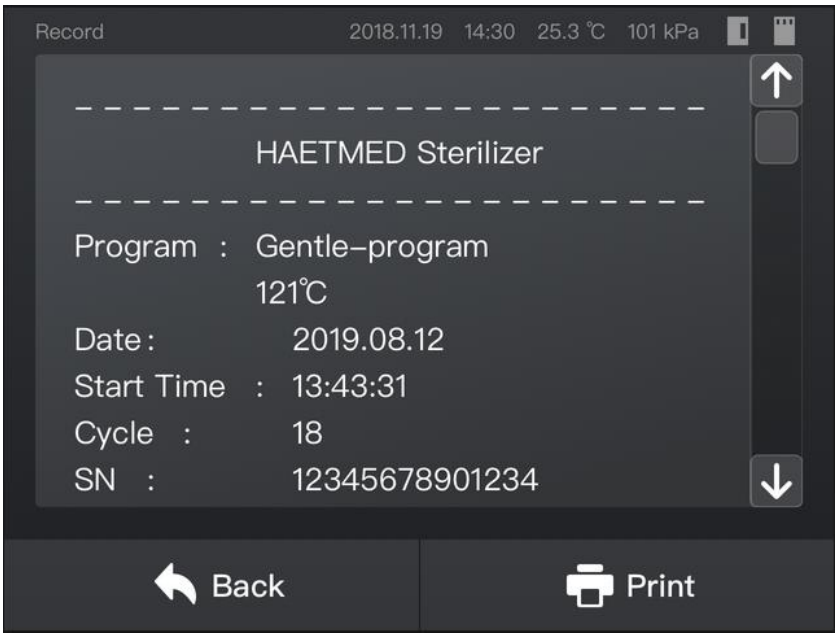


Figure 7.6 Log display and print interface

7.4 Read a log file

A typical sterilization log file is shown and explained below:

```
- - - - - - - - - - - - - - - - -
HAETMED Sterilizer
- - - - - - - - - - - - - - - - -
Cycle Date :     2021.02.03
Start Time :     17:50:24
Cycle No.  :     46
Program    :    Gentle program
                134°C 5min B
- - - - - - - - - - - - - - - - -
SN :          6A4611205210126AB
Hardware Version : Qx3_V1.4
Software Version : 00.01.00.19
- - - - - - - - - - - - - - - - -
Start Temp   :    99.0 °C
Conductivity :     7.1 us/cm
- - - - - - - - - - - - - - - - -
Stage      Press    C    Time
           (bar)  (°C) (H:M:S)
Start     :  0.00 101.1 0:00:00
1.Vacuum  : -0.95  88.4 0:04:51
1.Steam   :  0.29 109.1 0:06:07
2.Vacuum  : -0.85  86.9 0:09:17
2.Steam   :  0.30 111.0 0:10:25
3.Vacuum  : -0.85  89.9 0:13:43
Sterilize :  2.05 134.1 0:19:57
- - - - - - - - - - - - - - - - -
Hold Start:  2.13 134.9 0:20:37
End Hold  :  2.12 135.1 0:25:27
Release   :  0.14 106.0 0:27:23
Dry Start :  0.14 106.0 0:27:23
Dry End   : -0.93  84.9 0:42:23
Vent      : -0.05  94.1 0:43:06
Complete  : -0.02  93.8 0:43:11
- - - - - - - - - - - - - - - - -
Cycle End Time : 18:34:21
PROGRAM SUCCESSFUL!

Temperature:135.0 +0.1/-0.1 °C
Pressure : 2.13 +0.02/-0.02 bar
Sterilization  : 0:43:11
- - - - - - - - - - - - - - - - -
PK:1.000,PB:0.00
TK:1.000,TB:0.30
Vmin:212.3,Vmax:228.5
CS:0
- - - - - Record Ends - - - - -
```

Model Name

Program Date Start time
Cycle number Serial number
Pre-heat temperature Feed water conductivity

Temperature, pressure during 2-time pre-vacuum

Sterilization start
Sterilization end
Pressure release
Drying start
Drying end
Ventilation
Program finish

Final report including sterilization temperature; pressure; program run time; finish time;
Hardware version;
Software version.

8 Warnings and errors

8.1 Warnings and errors

The autoclave prompts warning messages whenever necessary to give notice and alert of an erroneous situation. When warning messages prompt, the autoclave also gives alarm sound. All warning messages are listed below:

Table 8-1 Warnings and errors message

Code	Warning Message	Causes	Checking or Maintenance Approaches
	Please close the door	The door is not closed correctly.	Close the door and push the door handle towards the end
	Please drain the tank	Water level in the waste water tank is too high	1、Drain water from the waste water tank.
	Cool the chamber	Temperature in chamber is higher than 45°during vacuum test	1、Open the door; start vacuum test after the chamber is cool.
	High Pressure	Pressure in chamber >1.04Bar	1、Wait until pressure in chamber becomes atmosphere pressure 2、Contact your distributor if pressure doesn't become normal
	Low Pressure	Pressure in chamber <-0.95Bar	1、Wait until pressure in chamber becomes atmosphere pressure 2、Contact your distributor if pressure doesn't become normal
	NO USB Disk	USB connection error	1、Check if USB cable is connected 2、Contact your distributor if the warning prompts repeatedly
	NO Record	No log is found. It means the autoclave has not run any program or just gone through system reset.	1、Run one sterilization cycle
02	Forced Stop	Stop button was pushed when during sterilization cycle	1、Re-run the sterilization cycle after checking the device
03	Door Sensor 1	Door sensor status is open during sterilization cycle	1、Check the door sensors and make sure door is closed tightly and door handle pushed to the end. 2、If same warning prompts repeatedly, contact your distributor.
04	Door Sensor 2	Door sensor status is open during sterilization cycle	1、Check the door sensors and make sure door is closed tightly and door handle pushed to the end. 2、If same warning prompts repeatedly, contact your distributor.
05	Door Sensor 1&2	Door sensor status is open during sterilization cycle	1、Check the door sensors and make sure door is closed tightly and door handle pushed to the end. 2、If same warning prompts repeatedly, contact your distributor.

06	Preheat Timeout	Heater fault	1、Check the heater wrapped around the chamber 2、If same warning prompts repeatedly, contact your distributor.
08	No Dist. Water	Distilled water pipe is stuck/flow meter signal timeout	1、Check if distilled water pipe is twisted or knotted； 2、Check flow meter 3、If same warning prompts repeatedly, contact your distributor.
09	Water Quality	Unqualified distilled water	1、Use better quality distilled water 2、Clean water tank regularly
10	No Cooling Water	1、 Cooling water pipe is not connected properly 2、 Cooling water tap is not switched on 3、 Cooling water pressure does not meet device requirement	1、 Check if cooling water pipe is properly connected 2、 Check if cooling water tap is switched on 3、 Use cooling water supply that meets the device requirement or install additional water pump
11	Vacuum Timeout	Vacuum test failure	1. Check and clean seals; 2. Run vacuum test with cool and dried chamber 3. If the message appears repeatedly, please contact your distributor.  Please do not adjust the gate spacing without guide from qualified personnel. **Warning** When vacuum test fail, do not perform any operation using the autoclave, please contact your distributor.
13	Steam Timeout	Steam Generator Fault	1、Check the steam generator 2、If same warning prompts repeatedly, contact your distributor.
16	Temper SW Open	Temperature switches open	1、Check temperature switch and other cable connection 2、If same warning prompts repeatedly, contact your distributor.
17	Release Timeout	Exhaust valve fault	1、Check the exhaust valve 2、If same warning prompts repeatedly, contact your distributor.

20	System Error	System configuration error	1、Check system configuration 2、If same warning prompts repeatedly, contact your distributor.
22	Drain Timeout	Draining valve fault	1、Check draining valve 2、If same warning prompts repeatedly, contact your distributor.
23	Levelling Timeout	Air filter valve fault	1、Check air filter valve 2、If same warning prompts repeatedly, contact your distributor.
24	Press Max Limit	Pressure in chamber exceeds upper limit during operation	1、Stop the device, check the device thoroughly，if no other error，try again 2、If same warning prompts repeatedly, contact your distributor.
26	Press Min Limit	Pressure in chamber exceeds lower limit during operation	1、Stop the device, check the device thoroughly，if no other error，try again 2、If same warning prompts repeatedly, contact your distributor.
25	Temper Max Limit	Temperature in chamber exceeds upper limit during operation	1、Stop the device, check the device thoroughly，if no other error，try again 2、If same warning prompts repeatedly, contact your distributor.
27	Temper Min Limit	Temperature in chamber exceeds lower limit during operation	1、Stop the device, check the device thoroughly，if no other error，try again 2、If same warning prompts repeatedly, contact your distributor.
30	Balance Timeout	Leaking	1、Check pipelines, door sealing, chamber opening for leakage

9 Common issues and troubleshooting

If the solutions below do not work, please contact HäTmed distributor.

9.1 Screen No Display

Situation: No display or abnormal display after power on the autoclave.

Solution:

- ✧ Check whether the power outlet has power;
- ✧ Check whether the power plug of the autoclave is inserted.

9.2 Large Consumption of Distilled Water

Situation: The consumption of distilled water is larger than normal.

Solution:

- ✧ Check the foot pads, the front ones should be higher than the rear ones;
- ✧ Check whether the filter at the bottom of the chamber is stuck.

9.3 Load not dried sufficiently

Situation: Loads are not dried sufficiently.

Solution:

- ✧ Check the foot pads, the front ones should be higher than the rear ones;
- ✧ Check whether the filter net at the bottom of the chamber is stuck;
- ✧ Check whether the maximum load capacity is exceeded (especially textile), whether the sterilization load is placed correctly and allows easy dissipation of steam.
- ✧ Activate the preheating function;
- ✧ Open the left side panel, check if the filter is stuck.

9.4 No Distilled Water

Situation: No Distilled Water.

Solution:

- ✧ Check if the distilled water tank has sufficient water in it;
- ✧ Check if the distilled water pipe is twisted or knotted.

9.5 Leaking air or water at the door opening

Situation: Observable air leaking or water drops at the door opening.

Solution:

- ✧ Check if the sealing ring is placed corrected (Wider side with “H” mark towards the chamber);
- ✧ Check if the sealing ring is broken.

9.6 No cooling water

Situation: No cooling water.

Solution:

- ✧ Check if cooling water pressure is sufficient and stable;
- ✧ Check if cooling water tap is switched on;
- ✧ Check if cooling water pipe is knotted.

9.7 Cannot open the door

Situation: Cannot open the door even with emergency door open tool

Solution:

- ✧ Check air filter opening at the rear is covered or blocked;
- ✧ Open the outer case of the device, plug off the silicon tube connected on the air filter valve;
- ✧ Pressure will be released from the chamber and you can hear sound of leaking air;
- ✧ When the sound is diminishing, you can try to open the door;

- ✧ Connect the pipe to its original location and clip the clamping ring tight;
- ✧ Switch on the device and run vacuum test to check leakage.

10 Attention:

- ✧ In order to ensure the safe use of the devices, please be sure to cut off the power and water before off-work or when nobody is on duty for more than 8 hours. HeaTmed will not be responsible for any consequences caused by the water or power failure.
- ✧ Only the assigned dealers are qualified to provide you with spare parts and after-sales service. HaeTmed is not responsible for the consequences caused by the use of repairs provided by unqualified personnel or by the use of spare parts not produced by HaeTmed.
- ✧ Do not open the cover or put any objects inside the device, otherwise it will damage the device and endanger the safety of the operator.
- ✧ Once the device starts to use, it means that the user agrees to all the above terms and promises to operate the device in accordance with the instructions.
- ✧ Protection from leakage current 30 mA.

Appendix 1 Safety mechanism

To ensure that the device is safe and reliable, a series of protective mechanism are implemented.

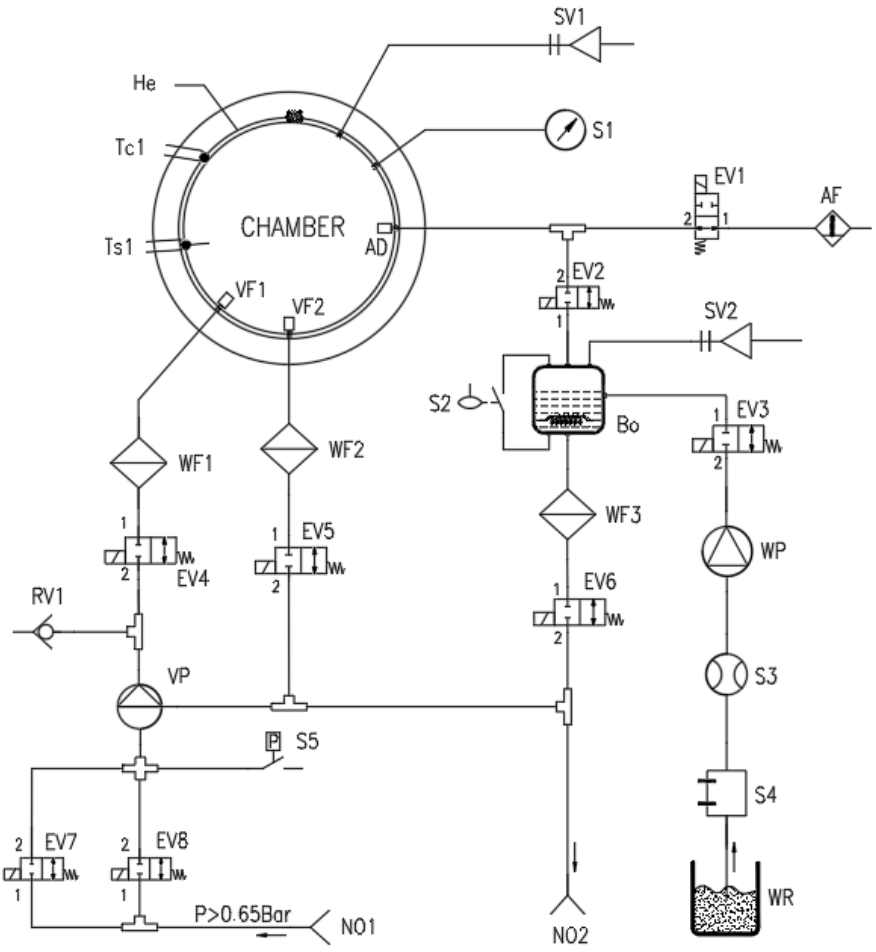
Preheating system over-temperature protection switch: There is an over-temperature protection switch in the preheating system. When the temperature exceeds the threshold of the over-temperature protection switch, the power supply circuit of the preheating system will be automatically cut off to protect the preheating system.

Steam generator over-temperature protection switch: There is an over-temperature protection switch under the steam generator. When the temperature of the steam generator exceeds the threshold of the over-temperature protection switch, the power supply circuit of the steam generator will be automatically cut off to protect the steam generator.

The safety valve for the chamber: When the pressure in the chamber reaches the safety threshold, the safety valve opens automatically to keep pressure in the chamber in safe range.

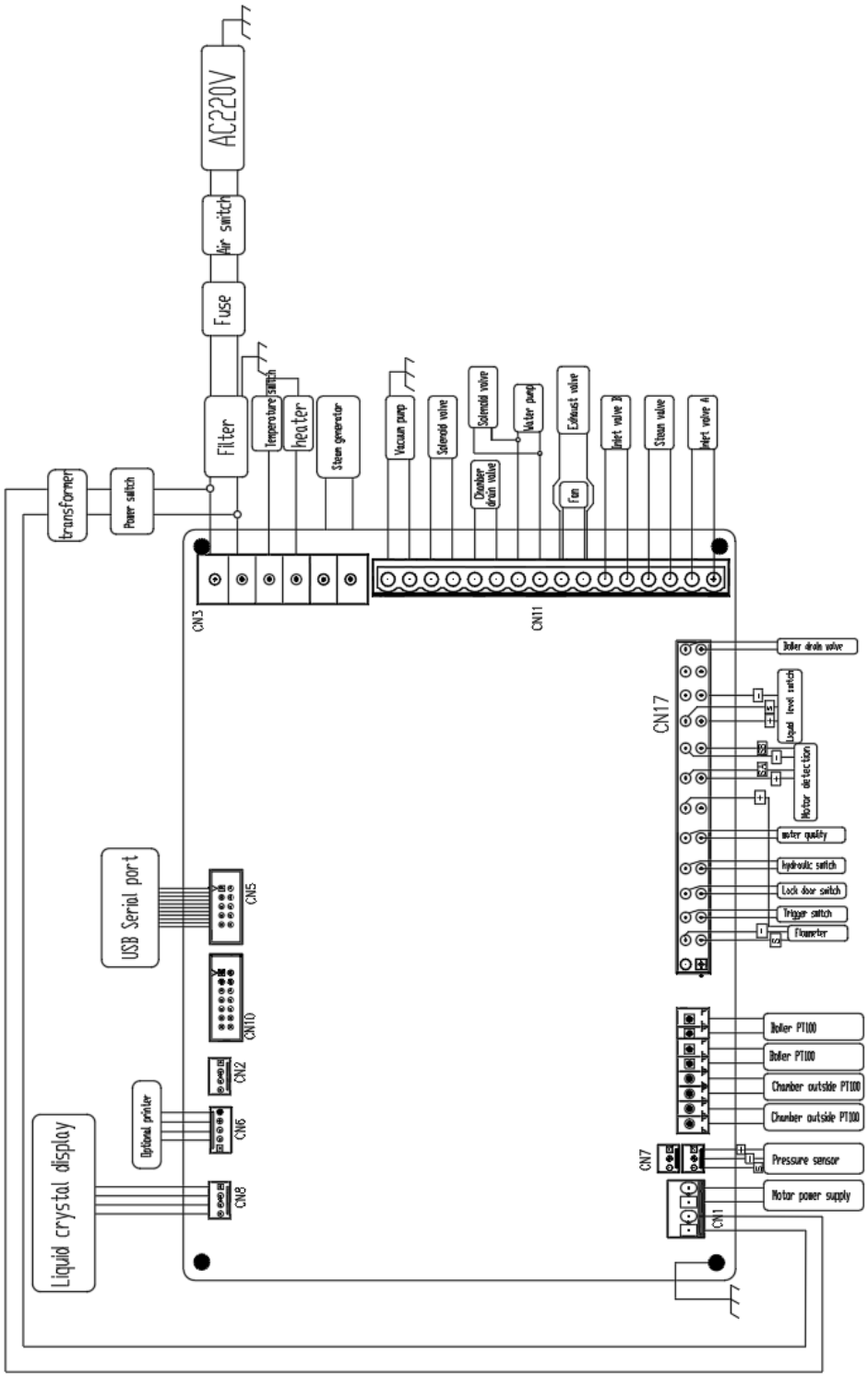
The safety valve for the steam generator: When the pressure in the steam generator reaches the safety threshold, the safety valve opens automatically to keep pressure in the steam generator in safe range.

Appendix 2 Block diagram



SV1	Chamber Safety Valve
SV2	Boiler Safety Valve
S1	Pressure Sensor
S2	Level Sensor
S3	Flow Sensor
S4	Conductivity Sensor
S5	Pressure Switch
EV1	Ventilation Valve
EV2	Steam Inlet Valve
EV3	Vibration Pump Valve
EV4	Exhaust Valve
EV5	Chamber Drain Valve
EV6	Boiler Drain Valve
EV7,EV8	Water Inlet Valve
RV1	Pressure-relief Valve
AF	Air Filter
WF1,WF2,WF3	Water Filter
VF1,VF2	Vapor Filter
AD	Air Diffuser
He	Heating Resistance
Bo	Steam Generator
VP	Vacuum Pump
WP	Vibration Pump
Tc1	Chamber Temperature Sensor
Ts1	Control Temperature Sensor
WR	Supply Water Reservoir
NO1	Cooling Water inlet Nozzle
NO2	Waster Water outlet Nozzle

Appendix 3 Electrical diagram



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