Kalstein

Horizontal Pulsating Vacuum Autoclave Automatic Vertical Sliding Door

Model YR053583-1

Instruction Manual

Thank you very much for purchasing our Horizontal Pulsating Vacuum Autoclave Automatic Vertical Sliding Door **YR053583-1**

Please read the “Operating Instructions” and “Warranty” before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the “Warranty” at a hand place for future reference.

 Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

Kalstein®

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With more than 25 years growing with our customers, Kalstein's multiformat and modern content, is now present in more than 10 countries and increasing.

CONTENT

NAME AND MODEL

YR053583-1 Horizontal Pulsating Vacuum Autoclave Automatic Vertical Sliding Door

USE

YR Horizontal Pulsating Vacuum Autoclave Automatic Vertical Sliding Door is Large pressure steam sterilizer is designed according to international standards and fully in line with CSSD, GMP. It is suitable for medical, pharmaceutical, scientific research and other organizations for sterilizing of surgical instruments, dressing, fabric, textile, rubber, liquid etc.

GENERAL VERSION

To bring the maximum performance into full play and ensure that the product operate safely, please read the manual carefully firstly and strictly comply with the requirements of installation, operation and maintenance mentioned in this manual. Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

Caution: The sterilizer can't be used for non-designed load, such as Vaseline, oil and powder.

● This series of equipment uses pulse mode to eliminate the air of the sterilization chamber so that the exclusion of chamber air is more than 99.99% and temperature uniformity degree up to 0.5℃, to ensure a reliable bactericidal effect.

● The material of main body is made of AISI 304/316L stainless steel, and the inner surface is mechanically polished and electrically polished, not only beautiful, but also greatly enhance the anticorrosion ability.

● The material of the inner door side is made of AISI 304/316L reinforcing ribs. Outside all coated insulation material, minimize heat radiation.

● Siemens touch screen dynamically displays the temperature, pressure, time and other parameters during the operation. Equipped with a printing system, to print and save operating data for future reference.

● Equipped with PLC controller, with features such as strong function, high reliability, flexible use and so on.

Ground signs		For this place to make the grounding.
Note flags		For drawing the attentions for the followed words.
Caution the electrical shock		With the danger of the electrical shock.
Caution hot Anti-scald mark		High temperature, don't touch.
AC flag		The power connect here is AC current.
Fragile		It is a fragile device, please handle with care.
Position up sign		Keep the arrows up during the transportation.
Keep dry sign		Don't get the packages wet during the transportation.
Lifting mark		It is the place for connecting the chain to lift the package.

TECHNICAL PARAMETER

1. Working pressure:0- 0.25MPa
2. Working temperature: 105-139 ℃
3. Pulse frequency setting range: 0-99 times
4. Sterilization time setting range: 0-999 minutes
5. Drying time setting range: 0-999 minutes
6. Safety valve settings: open at 0.28MPa
7. Pulse amplitude settings: positive 60KPa - 100KPa, negative -60KPa - -90KPa
8. Source of water: pressure 0.15-0.3MPa

9. Compressed air: 0.4MPa-0.8MPa
10. Power supply: Power is subject to the specific equipment order number
11. Compressed air pressure controller: lower limit 0.4MPa

HOW TO INSTALL AND COMMISSION

Notice: The correct installation plays an important role in its daily performance.

The equipment is usually shipped in wooden cases, and the packing cases should be inspected for damage before unpacking.

- Unpacking Inspection

- When unpacking, you should carefully check equipment components whether are intact and damaged. If yes, please make a record and contact with manufacturer in time.
- Carefully check the connection or fastener for looseness and fastening during

long distance transportation. If necessary, the M22 adjusting bolt should be fixed to the floor of the rack first.

- After unpacking the equipment, please refer to the equipment packing list to check and record whether the equipment and its random parts are complete. If you have any questions, please contact us.

- **Installation Conditions**

Equipment should be installed by professional staffs.

Notice: The equipment must be installed according to the requirements of our company, otherwise, we will not be responsible for the consequences caused by improper installation.

1. **Space requirements**

For the convenience of operation and maintenance, the height of the room should be at least 2.9 meters. The distance between the left and right sides of the sterilizer and the wall should not be less than 0.5m.

When installing the single-door sterilizer, the distance between the rear end and the wall should be not less than 0.5m. The distance between front and rear side of the sterilizer and the opposite wall should be left at least 1.5 times of the total length of the device so that the sterilization trolley can turn freely, easy to push and pull.

2. **Ground requirements**

The surface should be smooth. If installed in the upstairs, the floor should be

strengthened according to the load-bearing condition.

- Ventilation and heat dissipation

In order to control the temperature of working environment, it is better to install ventilation device in the room.

- Drainage

The size of drain pipe outlet should be larger than that of sterilizer to reduce back pressure.

Drain pipe should be separately led to the trench to discharge outdoor, the trench should be at least 200 mm wide and 200 mm deep.

Caution: Drain pipe should be able to prevent back pressure generation of the drainage, otherwise, it will affect the sterilization or drying effect due to the poor discharge of condensed water.

Drainage pipe materials should be metal tube or PPR tube, which is high temperature resistant (85℃) and antiaging

3. Requirements For Steam, Water, Compressed Air and Power Supply

- Steam resource

Pressure of steam is 0.30-0.50Mpa.

For non-built-in steam generator equipment:

If external steam connected required, it is better to install a water steam separator on the steam pipeline, which can remove solid particles and condensed in the process of steam transportation so as to obtain high quality steam source for the sterilizer.

If the pressure of steam is too high (>0.5Mpa), a pressure relief valve should be added to the pipeline to ensure that the fluctuation does not exceed 10%.

The pipeline of industrial steam source is connected by DN25 internal thread. If sterilizer is far away from steam source, the diameter of steam transmission pipe should be increased to reduce pipe resistance.

For two-way steam inlet, the pipeline of pure steam is connected by a DN25-inch joint. Thermal insulation measures should be taken to reduce steam loss.

In order to observe the steam supply situation in time, it is better to install steam source valves and a pressure gauge with a range of 0-1Mpa on the steam source pipeline connected with jacket or chamber.

- Water resource

Water for steam generator: It must be soft water or pure water. The inlet pipe should be DN20 internal thread pipe.

Note: It is recommended that a pressure gauge with a range of 0-0.6Mpa and a valve be connected to the pipe so as to observe and control the water pressure.

Water for vacuum pump: soft water is recommended to improve the efficiency of vacuum pumping, protect the service life of vacuum pump, reducing the noise and drainage temperature.

Tap water also can be used for vacuum pump.

The inlet pipe is DN20 internal thread pipe.

Note: It is recommended that a pressure gauge with a range of 0-0.6Mpa and a valve be connected to the pipe so as to observe and control the water pressure.

Water for condenser: Tap water is to provide water for condenser. The inlet pipe is DN20 internal thread pipe.

Note: It is recommended that a pressure gauge with a range of 0-0.6Mpa and a valve be connected to the pipe so as to observe and control the water pressure.

Attention: The pipeline should be cleaned regularly.

If tap water is used for water supply, clean once a month, if soft water is used for water supply, clean it once a year.

Cleaning method: Add disincrustant to the bucket, connect the water inlet pipe to the bucket, start the vacuum pump for 10 seconds, the vacuum pump and the condenser will be filled with water of dissolving disincrustant, stop pumping and keep it for half an hour, and then connect the water source.

- Compressed air source

Air source pressure is *0.4-0.8MP*, compressed air connection pipe is soft pipe. (φ8 orφ6).

If no compressed air source: Please select 60L/min medical oil-free compressor for single equipment.

If compressed air source provided: compressed air should be piped to the vicinity of the sterilizer and installed a stop valve, a pressure relief valve, a pressure gauge and a φ8 (or φ6) plug-in through terminal quick change pipe joint.

- Power supply

The power supply shall be three-phase system.

A power switch box shall be installed on the rear wall of the sterilizer and near the equipment. A circuit breaker and a single phase circuit breaker shall be installed in the switch box.

A ground wire must be laid, and a line marked with ground number in the control cable must be reliably connected with the ground wire.

4. Installation

- Horizontal adjustment

Place the equipment directly on the horizontal ground.

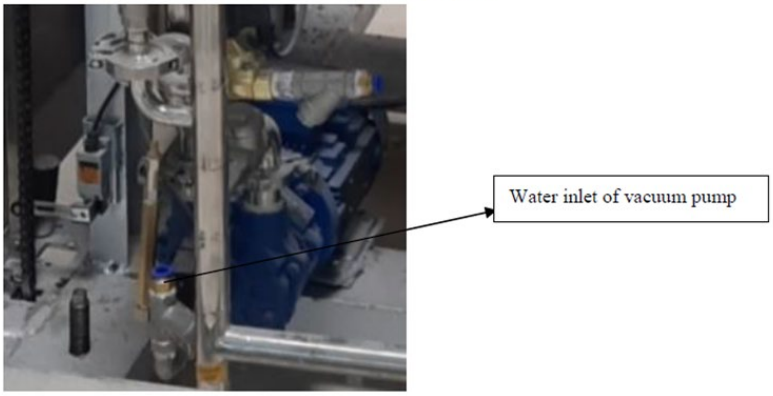
After the equipment in place, lift the holder with the adjusting bolt on the bottom of the equipment, to make the four wheels suspended, and put the level meter on the chamber guide rail, then adjust the bolt on the bottom, to make the sterilizer horizontal in the left and right directions.

Then adjust the four bolts of the outside trolley wheel to make the height of the rail consistent with the height of the guide rail in the chamber, and lock the fixing nut (the direction of the two front directional wheels should be consistent with the direction of the guide rail of the outside trolley).

Push the sterilization trolley into or out of the chamber from the outside trolley, and ensure that the sterilization trolley is convenient to enter and exit, and the outside trolley is flexible to push and pull.

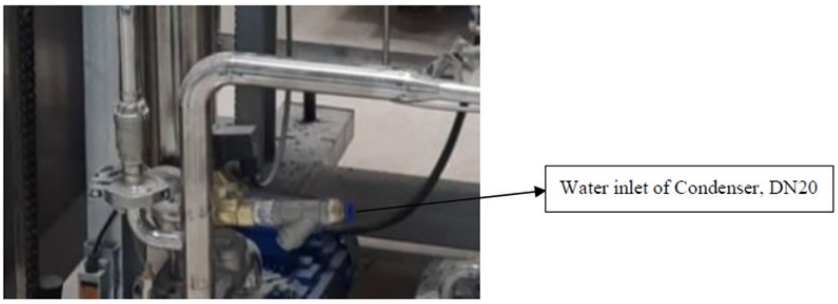
- Water, electric, steam and pipeline connection

Step 1 Connect the water supply pipeline for vacuum pump



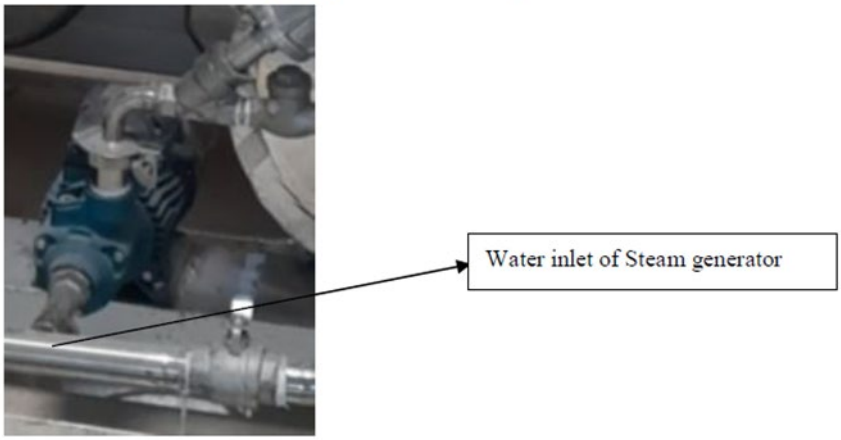
0.15—0.3MPa tap water or soften water, the soften water is better. The pipeline is DN20.

Step 2 Connect the water supply pipeline for condenser



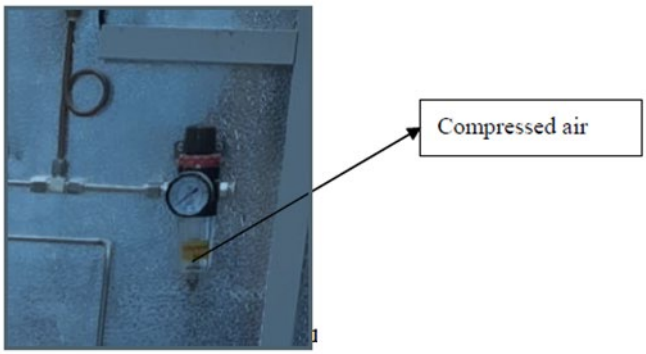
0.15—0.3MPa tap water or soften water, the soften water is better. The pipeline is DN20.

Step 3 Connect the water supply pipeline for steam generator



0.15—0.3MPa soften water or pure water. The pipeline is DN20.

Step4 Connect compressed air, Pressure range: 0.4MPa—0.8MPa



Step 5 Connect power supply: three-phase 380±10%V/50Hz

Step 6 Connect drainage pipeline: the diameter of drain pipe selected should be bigger than the drain outlet of the sterilizer, in order to reduce the back pressure.

The drainage pipeline should be separately led to the trench and discharge to the outdoor.

Drain water, DN 25

5. Commissioning

Please check the electrical wiring, socket, etc. whether off, loose, water, drainage, steam and compressed air connection is correct.

- Observe the pressure values

Open the water source valve, steam valve (external steam generator) and compressed air as well as power supply.

Please check the pressure value as below whether is correct:

Water for vacuum pump: 0.15—0.3MPa soften water or tap water.

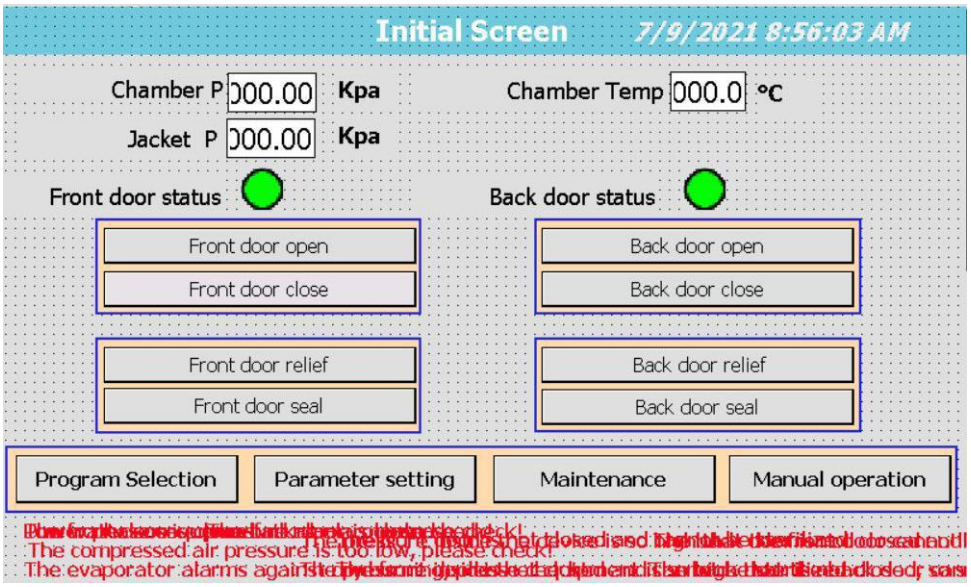
——Water for steam generator: 0.15—0.3MPa soften water or pure water.

——Steam for steam generator: 0.30— 0.50MPa, only for connecting external steam source.

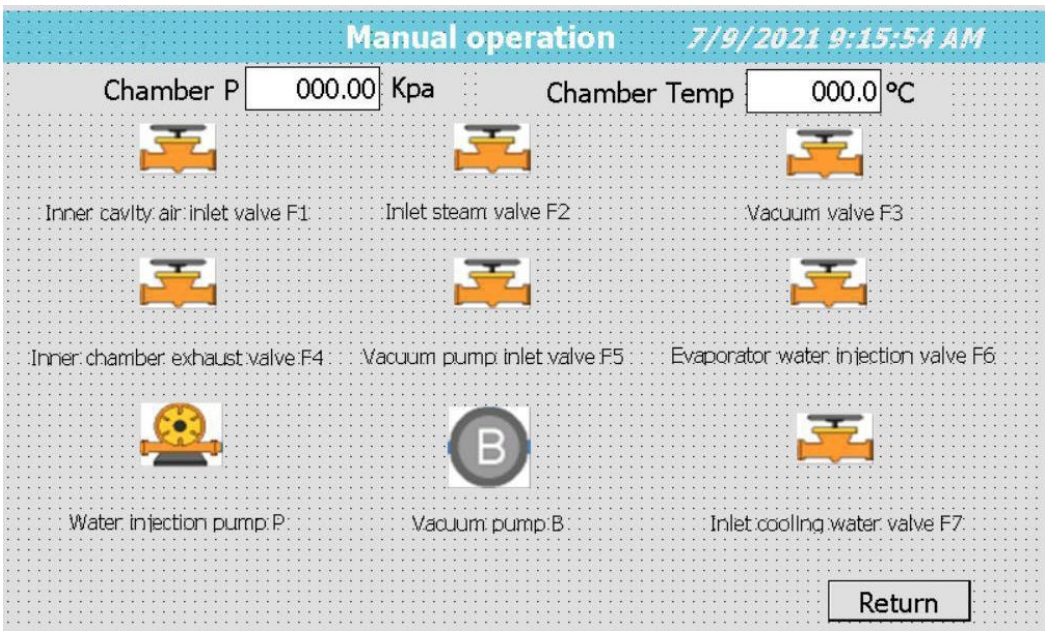
——Compressed air: 0.4MPa—0.8MPa

- Check the direction of rotation of vacuum pump

Turn on the power switch, the touch screen will automatically enter the initial screen



Press "Manual operation" button then enter into the "Manual operation" interface.



Click the " vacuum pump "  button to start the vacuum pump working and then close the "vacuum " in 10 seconds.

Meanwhile, observe the rotating direction of the motor fan of the vacuum pump whether is the same as the arrow direction marked on the pump body (that is clockwise rotation).

Otherwise, cut off the equipment immediately, adjust any two fire wires of the three-phase leakage circuit breaker in the distribution box.

Attention: *Long-time reversal working of vacuum pump will damage the vacuum pump. So it is a must to check the direction of vacuum pump before operation.*

- Check the operation status of each valve

Note1: Press water pump P and Generator water valve F6, if it is high level in the steam generator, the water pump doesn't work.

Note2: If the door is not closed properly, the steam inlet valve in the inner chamber is forbid to work in order to avoid risk.

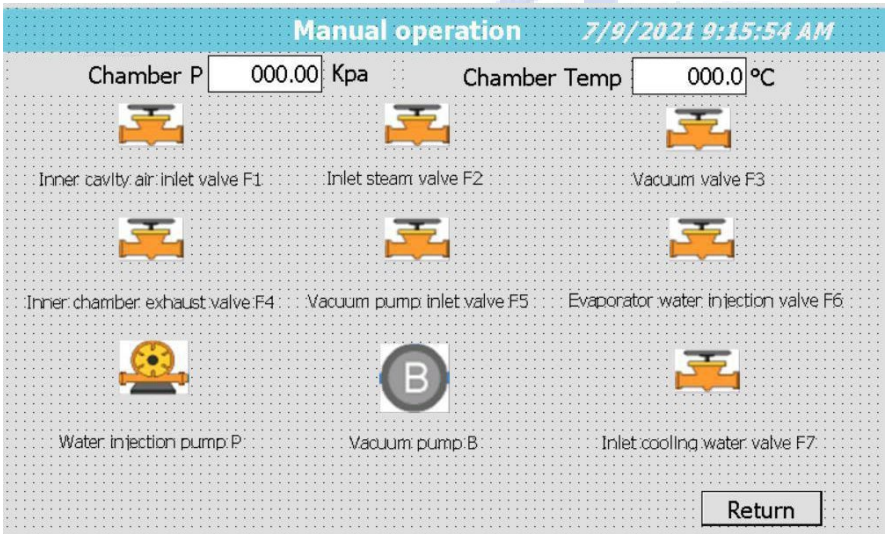
F1: Air Valve	F2: Chamber steam inlet valve	F3: Vacuum valve	F4: Chamber drain valve	F5: Vacuum pump inlet valve
F6: Generator water valve	F7: Cooling water valve	P: Water pump	B: Vacuum pump	

Pneumatic valve-- In the manual operation interface, click the pneumatic valve symbol one by one to see whether the red head is extended.

Magnetic valve-- In the manual operation interface, open the magnetic valves, and gently close to the top of the magnetic valve with a screwdriver, you should feel a strong magnetic attraction.

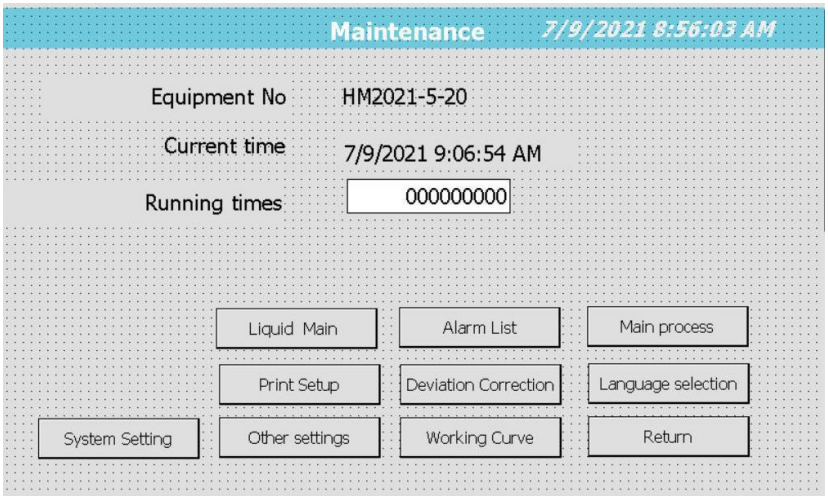
- Check the pressure in Chamber

Enter into the "Manual operation", press Chamber drain valve button and Air Valve F1 to check the pressure in Chamber

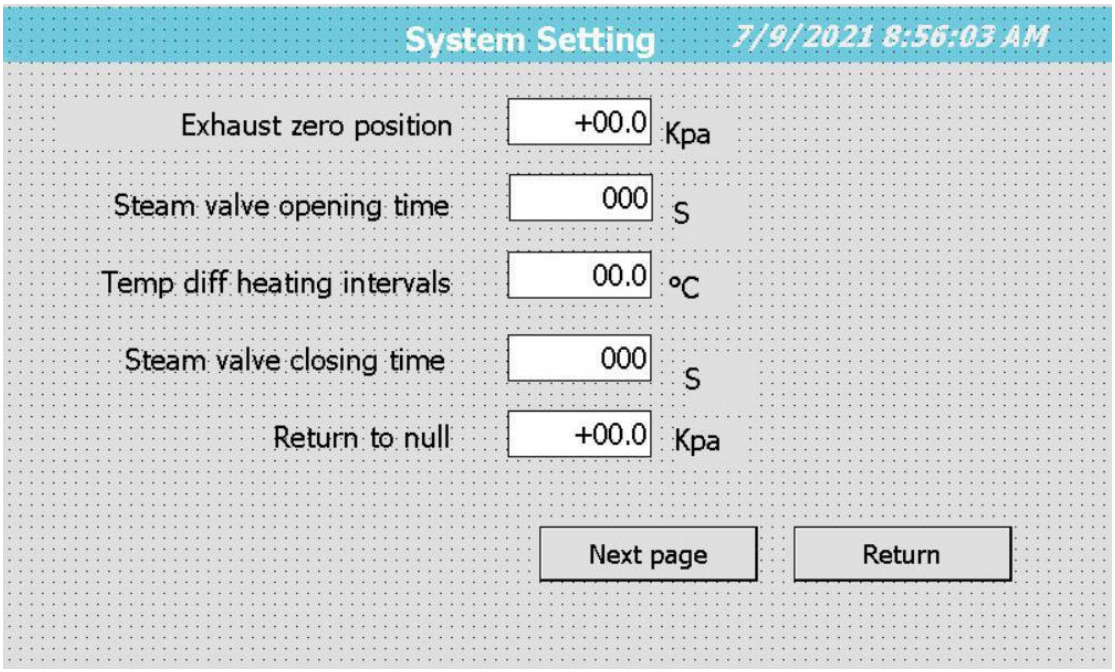


If the pressure value in chamber is between -2Kpa and 2Kpa, it is normal. Otherwise, we need to adjust the pressure value in chamber.

Enter into the Maintenance interface as the following picture.



Then select System setting button, enter into System setting interface.



If you find the pressure value in Chamber is P.

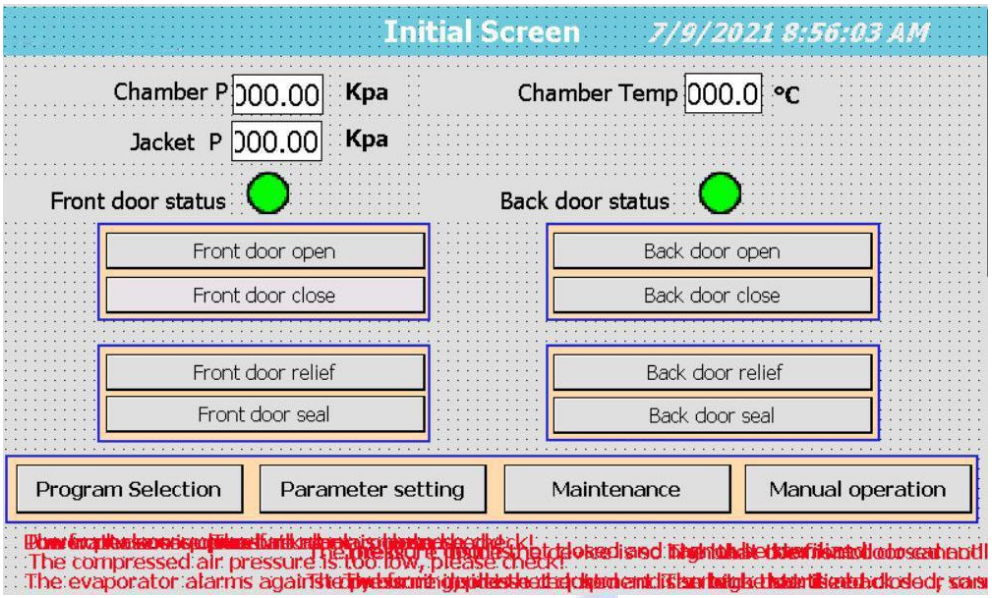
Set Exhaust zero position: **P+10KPa**

Set Return to null: **P-10KPa**

For example the **P is -24Kpa**, that means the local atmospheric pressure is **24KPa** lower than the standard atmospheric pressure. Set the exhaust zero position: **-14Kpa** and Return to null: **-34Kpa**

- Open and close door

Step 1: Enter into the Initial interface



Step 2: Open the front door

When the chamber pressure between the exhaust zero position and Return to null , the door can be opened.

Press the "Front door open" button to open the front door.

In the process of door opening, if the alarm of door motor overload occurs, it means that the door meets abnormal resistance, and the control system automatically cancels the opening operation.

Step3: Close the front door

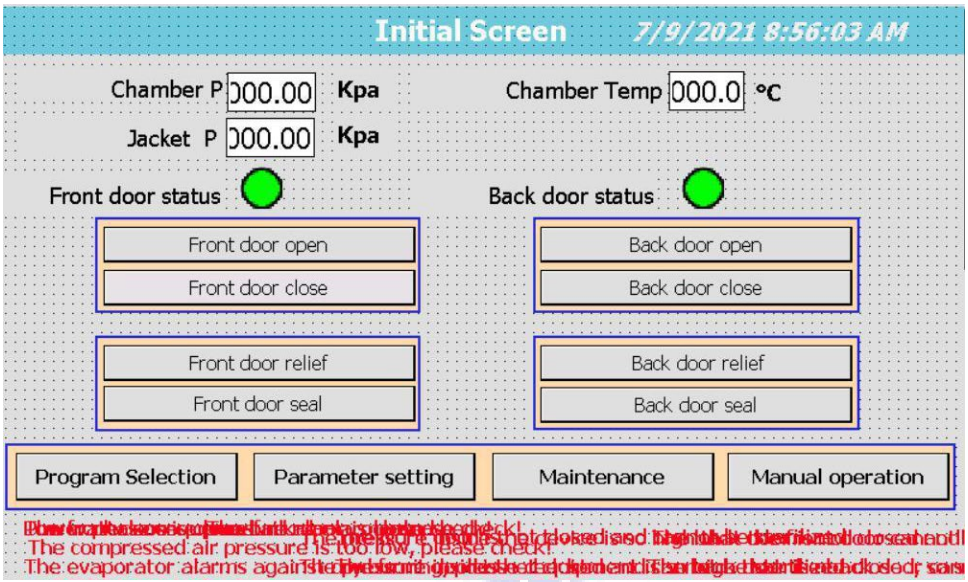
Click on the " Front door Close" button, and the front door rises vertically automatically. The

indicator lights is on, and the buzzer will ring for 5 seconds, indicating that the front door is closed completely.

If the door motor overloads, the program will automatically cancel the operation,

while corresponding alarm information display on the touch screen for 5 seconds and buzzer will ring for 5 seconds, then the screen will automatically close.

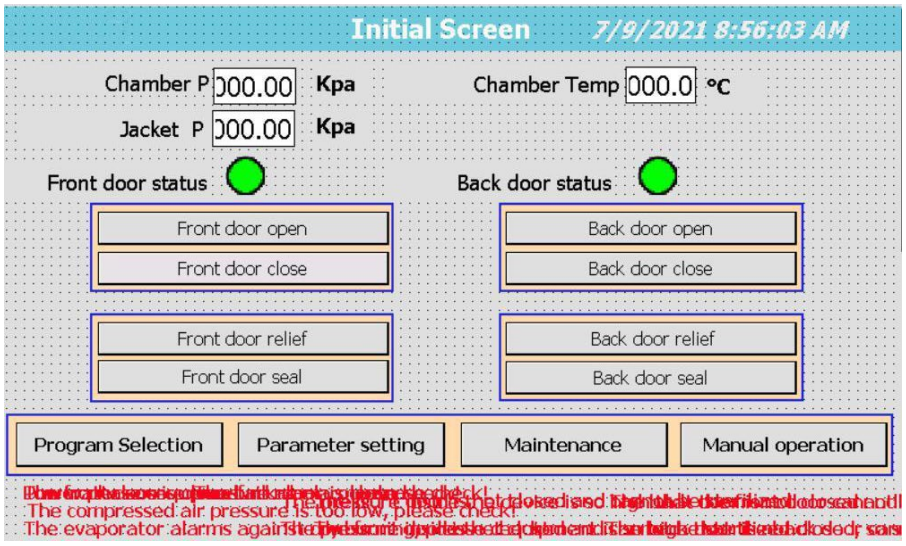
Step4: Close the back door



When the chamber pressure between the exhaust zero position and return to null, the door can be opened.

Press the "Back door open" button to open the front door.

Step5: Open the back door



Click the "Back door closed" button on the touch screen or the "Back door closed" button on the back cover, then the door will rise vertically automatically.

During the door closed, the indicator light of the front door will be on, and the buzzer will sound for 5 seconds, indicating that the back door has been closed completely.

If the door motor overloads, the program will automatically cancel the operation, while corresponding alarm information display on the touch screen for 5 seconds and buzzer will ring for 5 seconds, then the screen will automatically close.

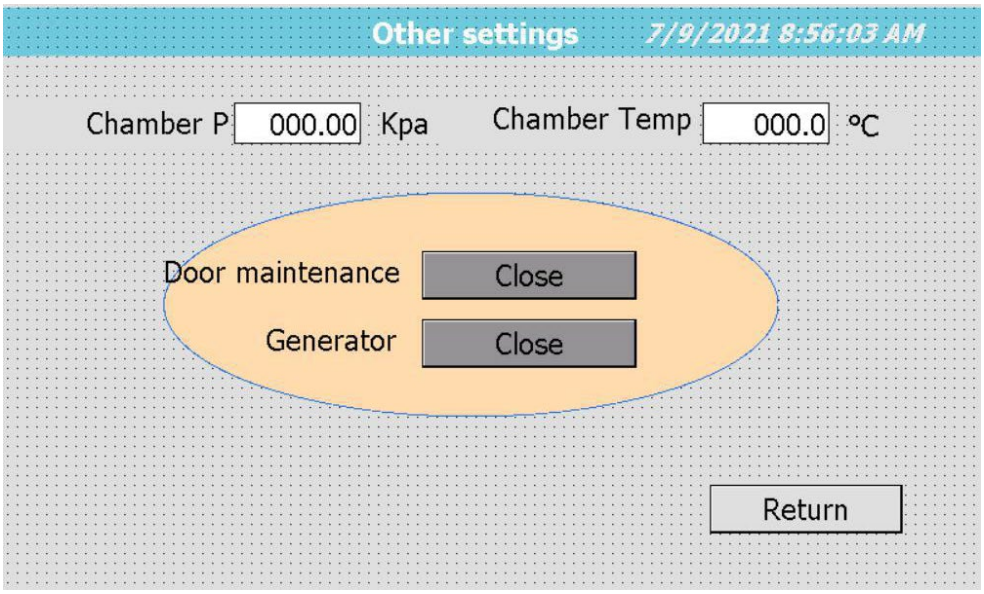
- Door motor overload alarm troubleshooting

First of all, when the door is open, press the "Seal" button, observe whether the sealing gasket is pumped into the sealing groove, if not, the sealing gasket should be cleaned.

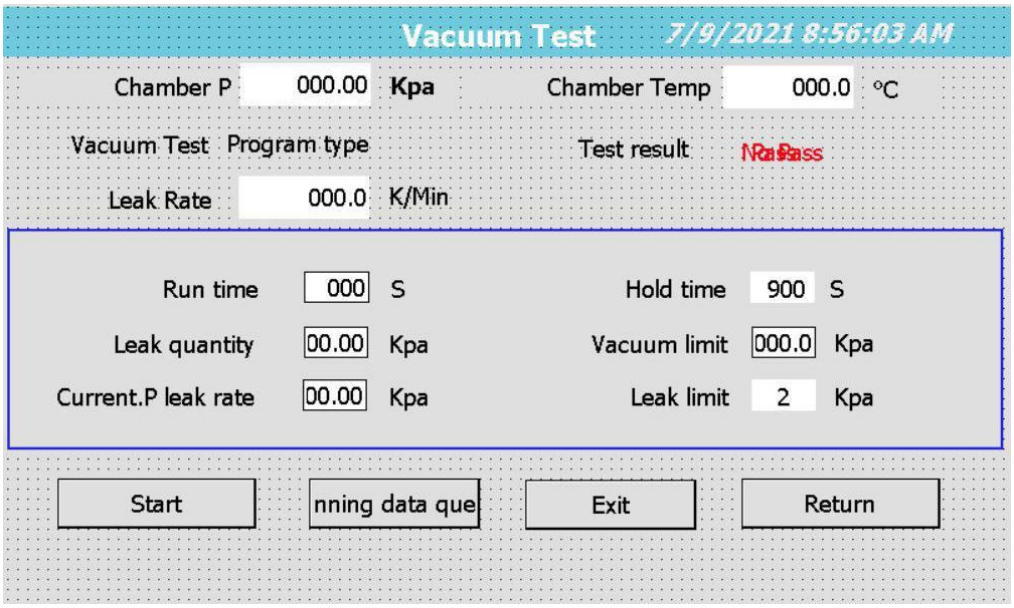
When the door is open, compressed air filled into the sealing groove by pressing "Seal " button, the sealing gasket is ejected, it can be cleaned with clean water (or add a certain detergent), and the sealing groove can be wiped clean. Re-manually press the door sealing gasket into the sealing groove, press "Press Relief", the vacuum pump starts to work in order to pull the sealing gasket back into the groove.

- Vacuum testing

Attention: Open the steam generator firstly.



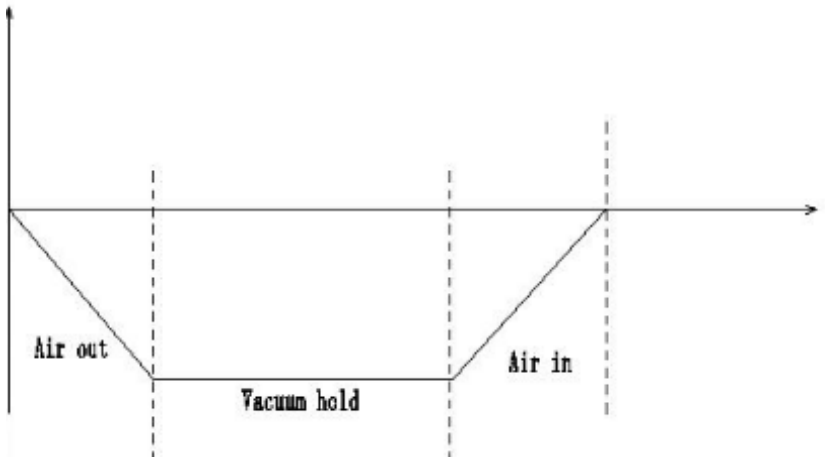
Enter into the Vacuum test interface



It is used for the debugging or routine testing, especially after long-distance transportation, loosening of pipeline may occur (or B-D test is not qualified).

Vacuum testing program can be used to test the vacuum leakage of sterilization equipment in order to detect the sealing condition of pipeline. This test is carried out on the condition that the chamber is empty, the jacket and the chamber are not heated.

The work-flow of the vacuum test shown in the figure.



In the pumping stage, the evacuation valve and vacuum pump are opened and the pressure drops to - 85Kpa (can be set), then it will turn to the pressure holding stage.

The time of pressure holding stage is 15 minutes. After it, the leakage rate is displayed.

If the leakage rate is greater than 0.13Kpa/min, that means the seal is unqualified, the prompting information will show on the screen, and the air valve is opened for vacuum return.

If the leakage rate is less than 0.13Kpa/min, that means the seal is qualified with prompting information shown the screen, and open the air valve to return to vacuum.

- B-D testing

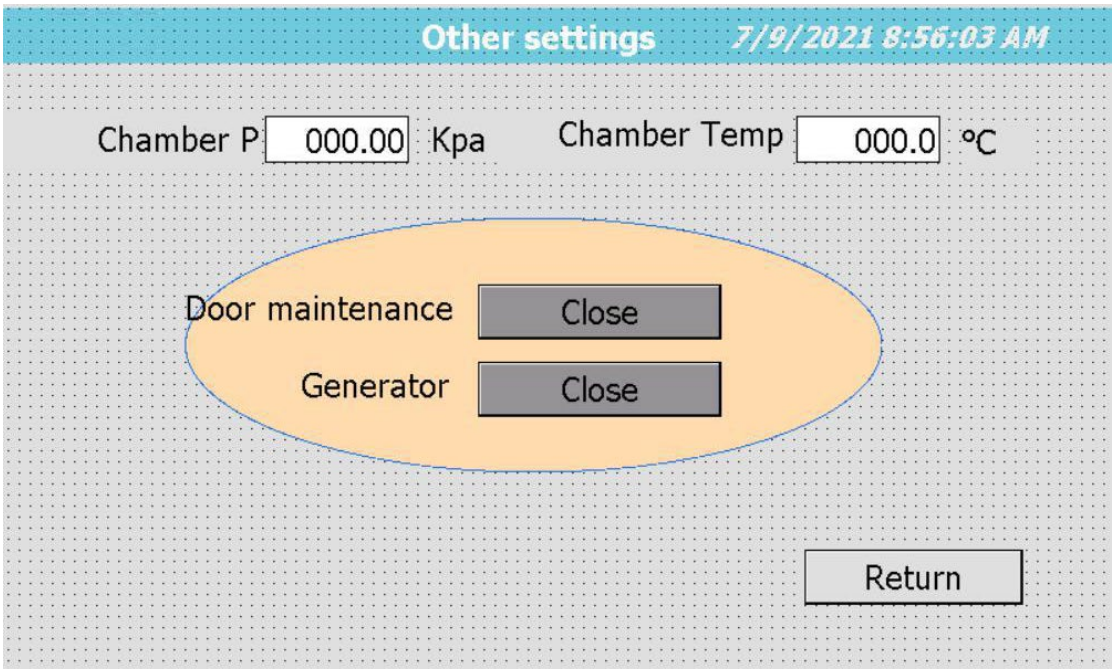
It is specially used to test the air removal effect of vacuum pulsating vacuum sterilizer.

The test should be carried out before the first sterilization every day.

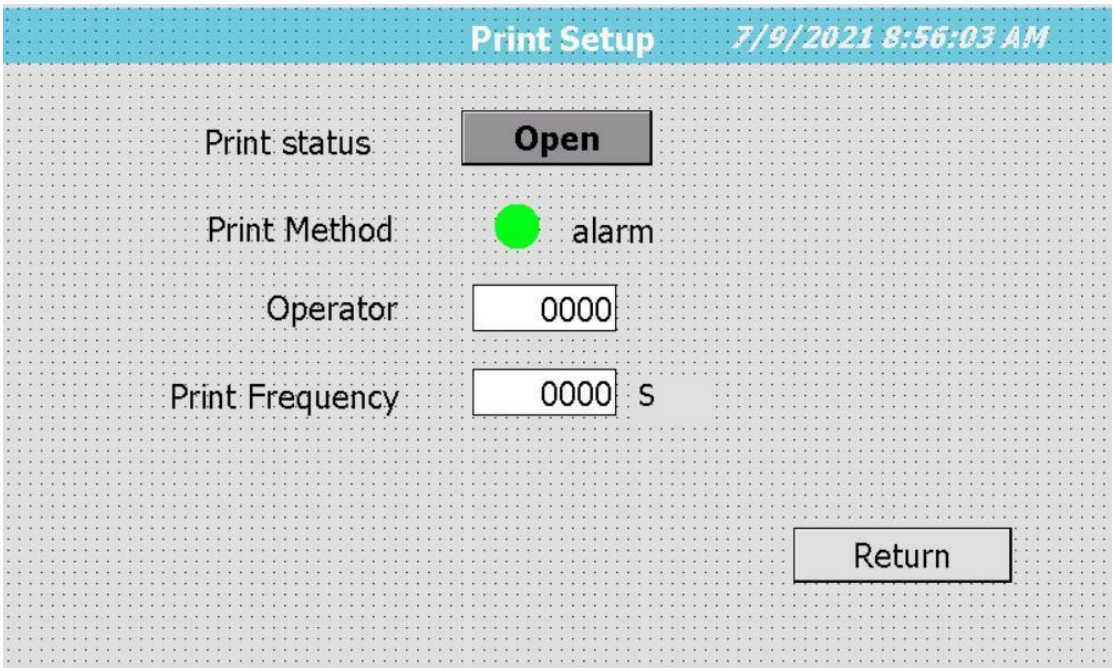
Place disposable B-D test kit in the middle, then put it at the outlet of the chamber, close the sealing door, and run a program according to the B-D test procedure. Once the process is over, open the door, unlock the test kit, take out the disposable B-D test kit to observe the test results.

- Program running

Attention: After the equipment is in normal operation, please set the door maintenance status to **OFF** to ensure that the double doors are interlocked. The Generator is set to **ON**.

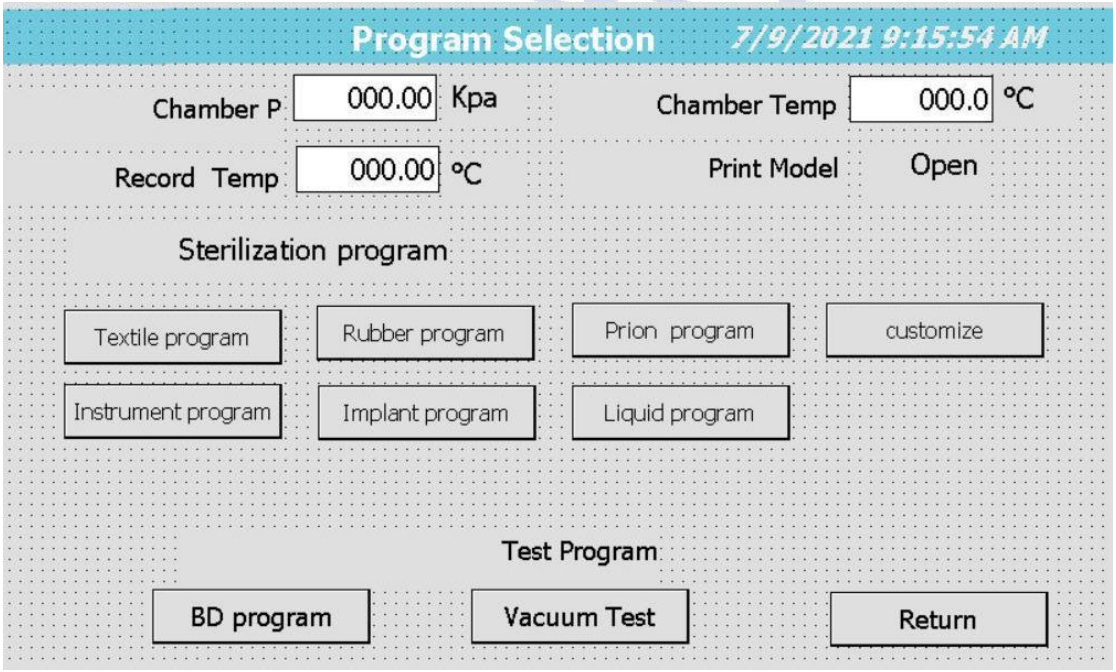


When the Generator is set to "ON", the equipment will automatically enter the jacket preheating status, and inject water to low liquid level automatically. And then automatically start heating, and inject water to high liquid level. The preheating will be completed 5 minutes after the jacket pressure reaches the control pressure range.



The printer is set to ON to let the printer work.

In the initial screen, click the "Program Selection" button to enter the program selection interface, and select the appropriate program according to the sterilization items. The program runs automatically.



If the jacket is not preheated, it will prompt "jacket is being preheated", and it will run automatically after preheating.

Emergency stop switch

The device is equipped with an emergency stop switch on each of the front and rear end panels. Press or rotate the switch to cut off the power of the device when any operation needs to be stopped while the device is running.

EQUIPMENT INSTRUCTIONS

Warning： Non-operating person do not touch the control panel, to ensure the clarity of the screen!

- **Door Operation and Safety Testing System**

Turn on the control power, steam source (non-electric type), water source and compressed air source of the equipment, and turn on all the power of the equipment.

After a period of self-test, the touch screen display will enter into the initial screen shown in Figure 1. This screen can display the chamber pressure, the chamber temperature and the current time.

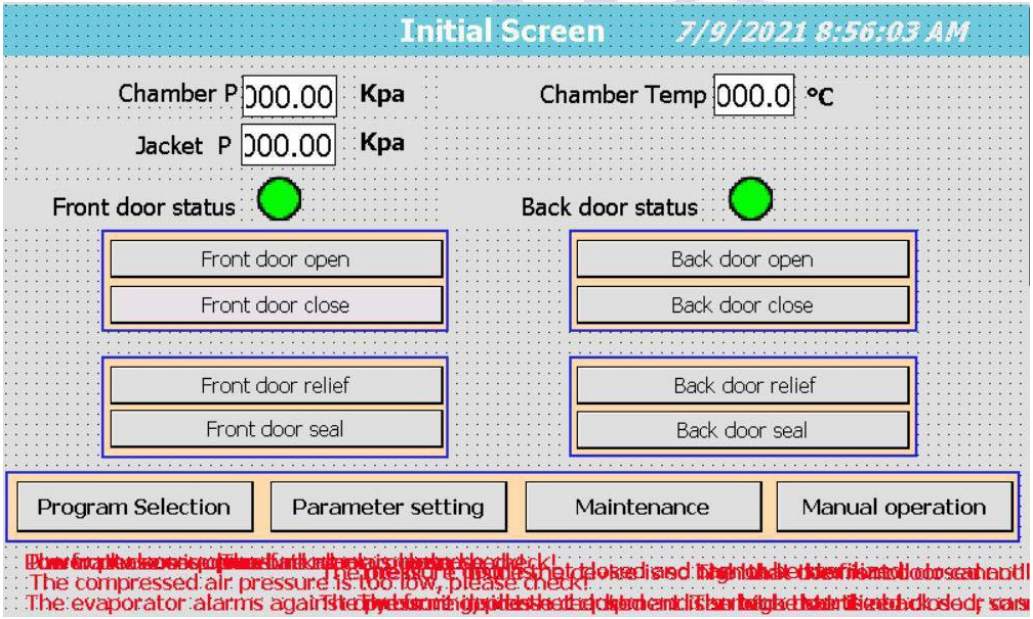


Figure 1

1. **Open the front door**

Press the "open the front door" button on the touch screen to open the front door.

The same action as the back door opened.

2. Close the front door

Press the "close the front door" button on the touch screen to close the front door. The same action as the back door closed.

3. Door safety interlock

In the process of running the program, the door safety interlock will be started. Through the pressure sensing mechanism and the micro switch, the action of the front door of the sterilizer is fully met.

4. Pressure control device of compressed air pipe

When the pressure of compressed air source is less than 0.4MPa, this device will cut off the operation of the program to make the system back to the original state, meanwhile, the screen will display as Figure 2 shown and alarm sounds.

Figure 2

5. Matters attention

- If emergency things happened such as equipment failure or power outage, firstly, you need to check if the chamber pressure is between Exhaust zero position and return to null before opening the door. If it is, please rotate the manual lever with the equipment accessory ratchet wrench, raise the door, and then open the door.

- When the touch screen prompt "communication timeout!" it means that PLC and touch screen have no communication, please check the communication line.

- **Parameter Settings Of Program And System**

The common parameters of system control the operation of all programs. Please check and set up before sterilization work.

1. **Deviation correction**

From the initial screen to enter the system maintenance screen, click the "deviation correction" button.

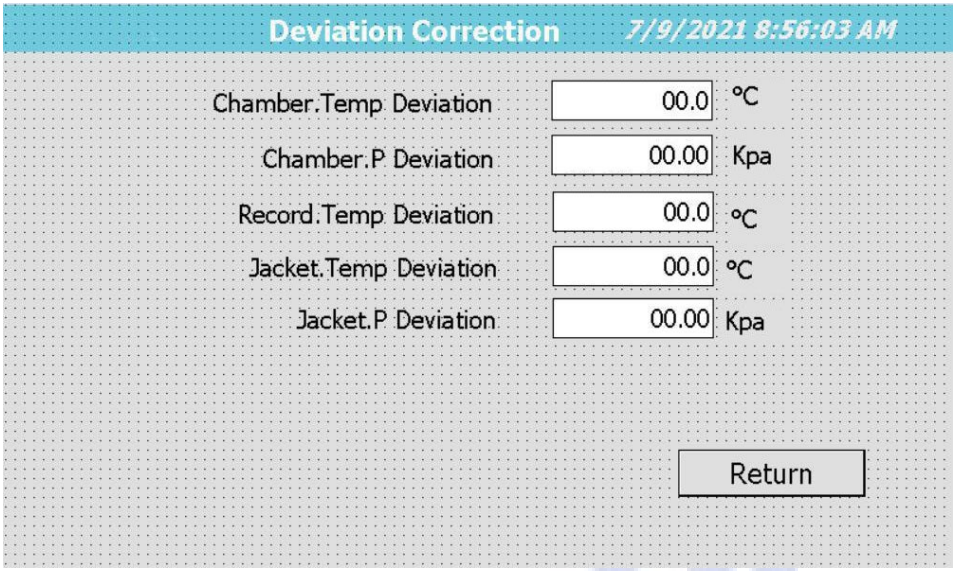


Figure 3

The parameters of this screen are used to correct the deviation between the displayed and actual values.

The actual values are tested through professional tool by experienced staff.

2. **Work trends**

Click the "working curve" button in the system maintenance interface.

The trend of graph shows the curve of chamber pressure, chamber temperature within 1 hour.

The sliding cursor can read the value corresponding to the intersection of cursor and curve.

Red curve: chamber pressure

Blue curve: chamber temperature

The sliding cursor can read the corresponding time value at the intersection of the cursor and the curve.

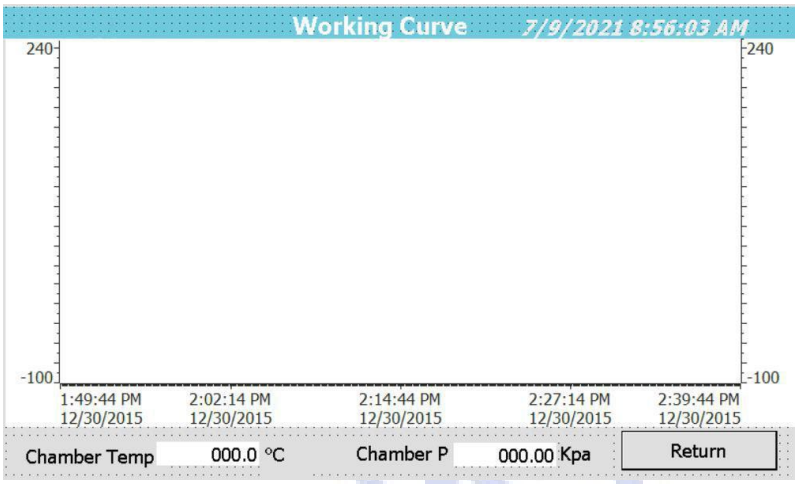


Figure 4

3. Print settings

Click the "Print Setting" button on the system maintenance screen as Figure 5 shown.

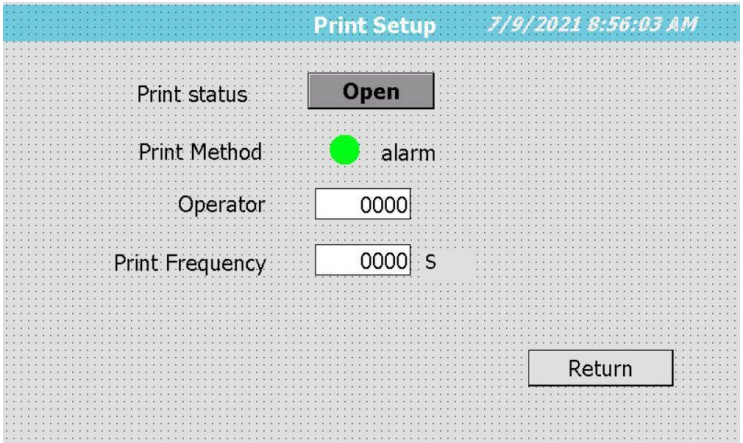
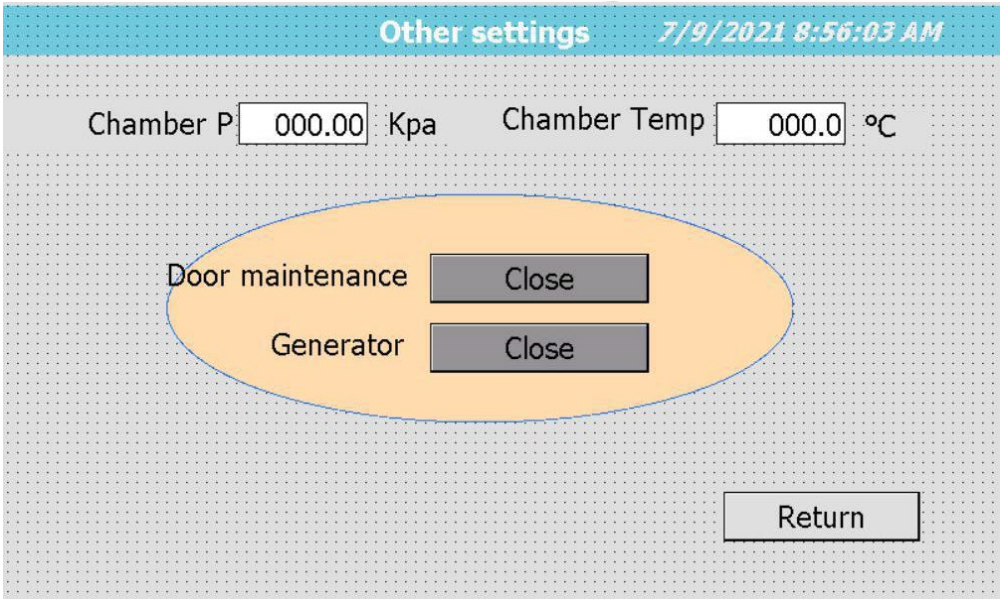


Figure 5

- Print Status Settings: Touch the dot in front of On or Off to turn the printer on and off.
- Operator: Operator Number
- Print frequency setting: print frequency is to print a real-time data every few seconds, slide the slider to change the print frequency.

4. Other settings

Click the "Other Settings" button in the system maintenance screen to enter the other settings screen.



Door maintenance should be OFF to ensure the door interlock function work.

When the door maintenance is On status, the front door and back door can be opened meanwhile.

When the generator is on, the steam generator will automatically add water, automatically heated to the set evaporator pressure (non-electric type do not have this setting).

5. Language select

In the system maintenance screen, click the "language selection" button to enter the language selection screen.

Figure 7

6. Program Parameter

This control system includes seven sterilization procedures: Textile program, Instrument program, Liquid program, Rubber program, Implant program, Prions program, User-defined.

Two test procedures: the BD program, vacuum test.

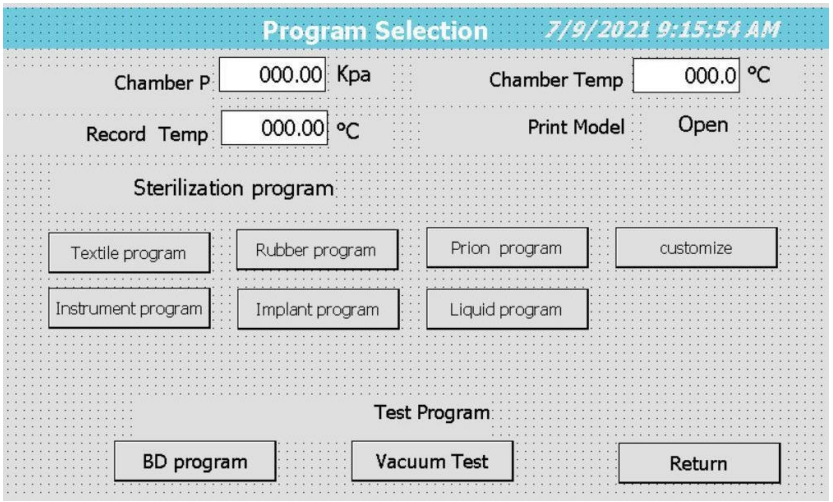


Figure 8

Items	Negative pressure pulsation times	Cross pressure pulsation times	Positive pressure pulsation times	Sterilization Temperature	Sterilization Time	Drying Time
	-80Ka~0KPa	-80KPa~80KPa	134℃: 180~130KPa 121℃: 100~50KPa	134	Min	Min
Textile	4	1	3	134	7	15
Instrument	3	1	3	134	5	10
Implant	4	1	3	134	12	8
Prions	3	1	3	121	18	15
Rubber	3	1	3	121	20	15
Liquid	Gravity displace	0	0	134	25	0
BD	4	1	3	134	3.5	5
User-Defined	1~9	0~1	0~3	134	5~15	10~15

- Program parameters

Table 1

The work flow of Textile, Instrument, Implant, Prions, Rubber, BD, User-Defined in table 1 is shown in Figure.

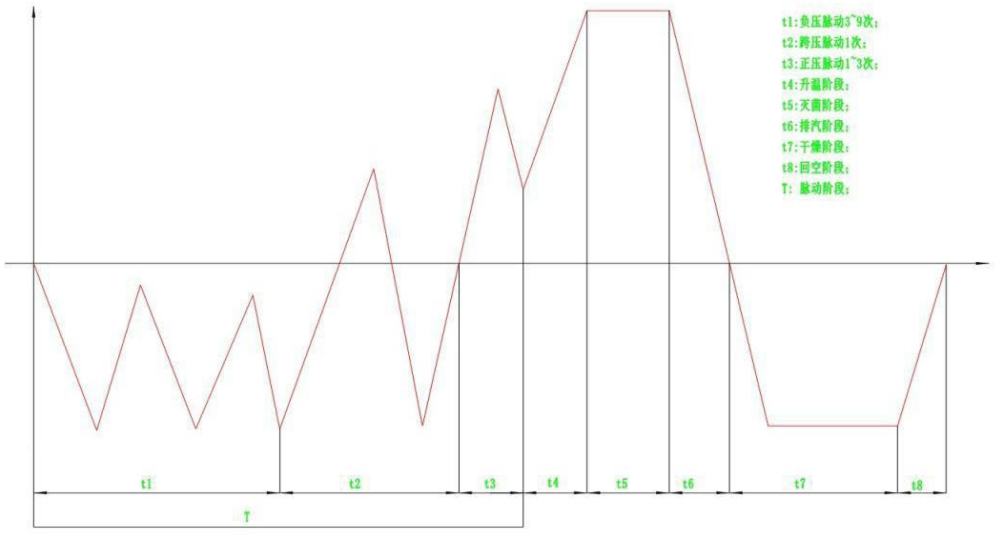


Figure 9

01 stage: Negative pressure pulsation times

02 stage: Cross pressure pulsation times

03 stage: Positive pressure pulsation times

04 stage: Heating up

05 stage: Sterilization

06 stage: Exhaust

07 stage: Drying

08 stage: Empty

The parameters have been set as table 1 shown before leaving factory.

If operator needs to modify it, he can enter to the initial screen, and click on the "parameter setting" button to input user name and password, then it goes into parameter settings screen, to change the program parameters you want.

Note: The user name and password only be known by the authorized professional staff who is allowed to change.

The parameters of pulse amplitude, pulse times, sterilization temperature, sterilization time and drying time affect the sterilization effect and drying effect.

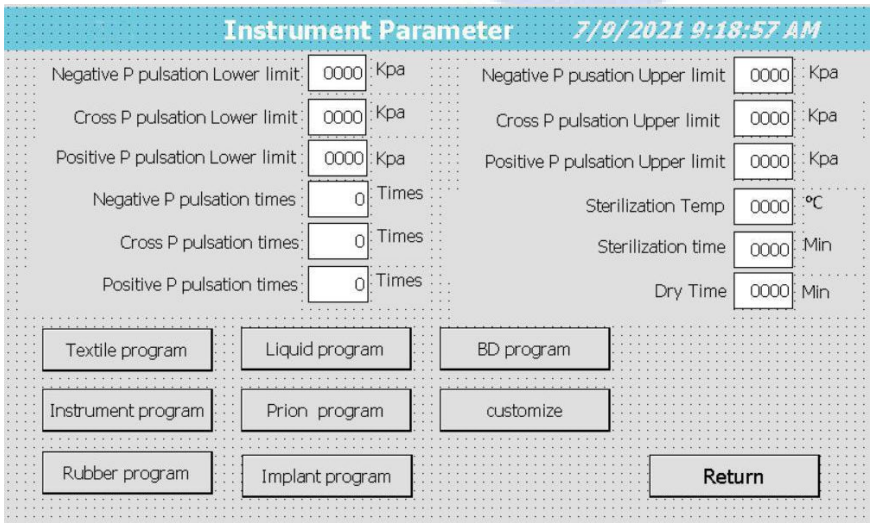


Figure 10

- Program running for solid items

This program is for Textile, Instrument, Rubber, Implant, Prion and user-defined.

Select a program according to the kind of items to be sterilized.

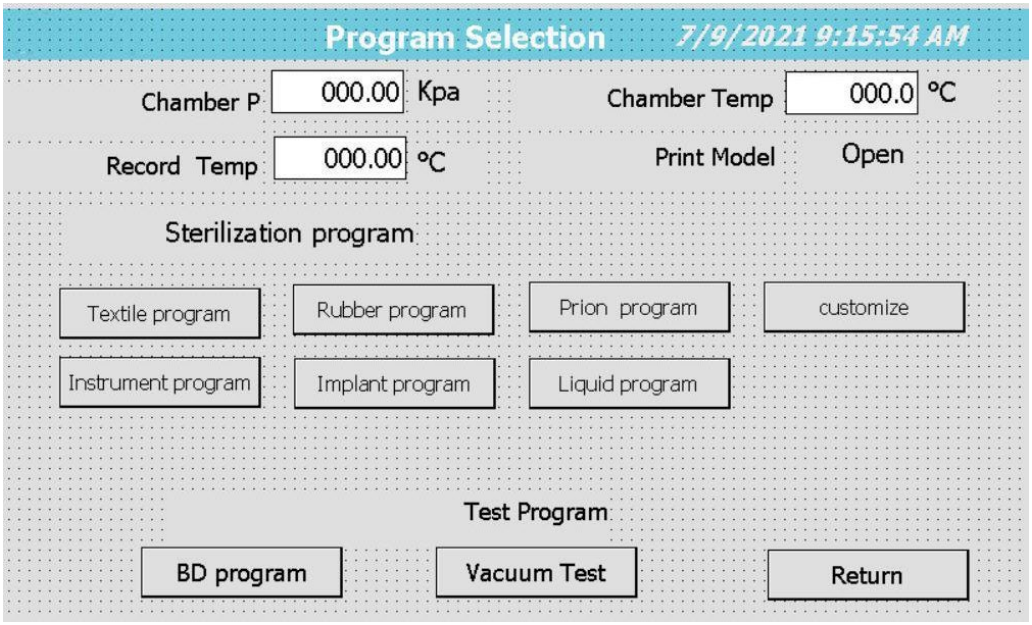


Figure 11

The main process interface as below:

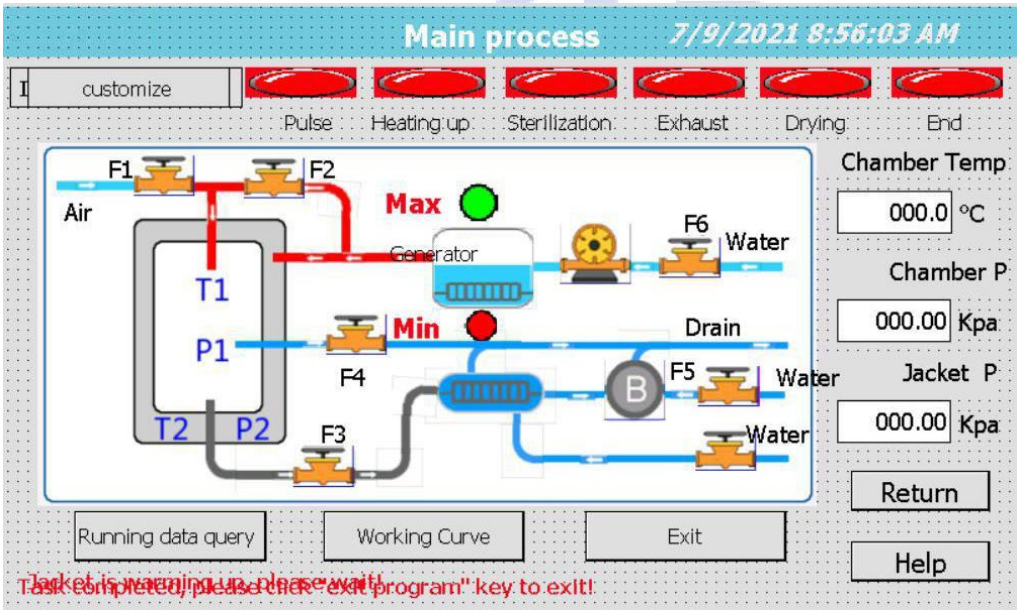


Figure 12

Press the Working curve button to see the curve of the chamber pressure and chamber temperature.

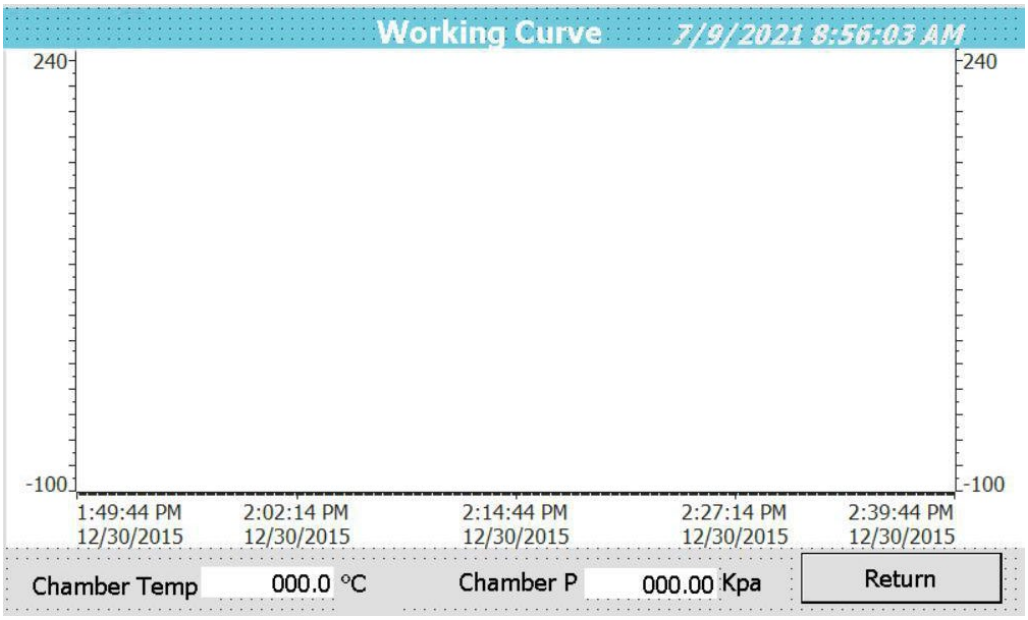


Figure 13

Press the Running data button to the following interface.

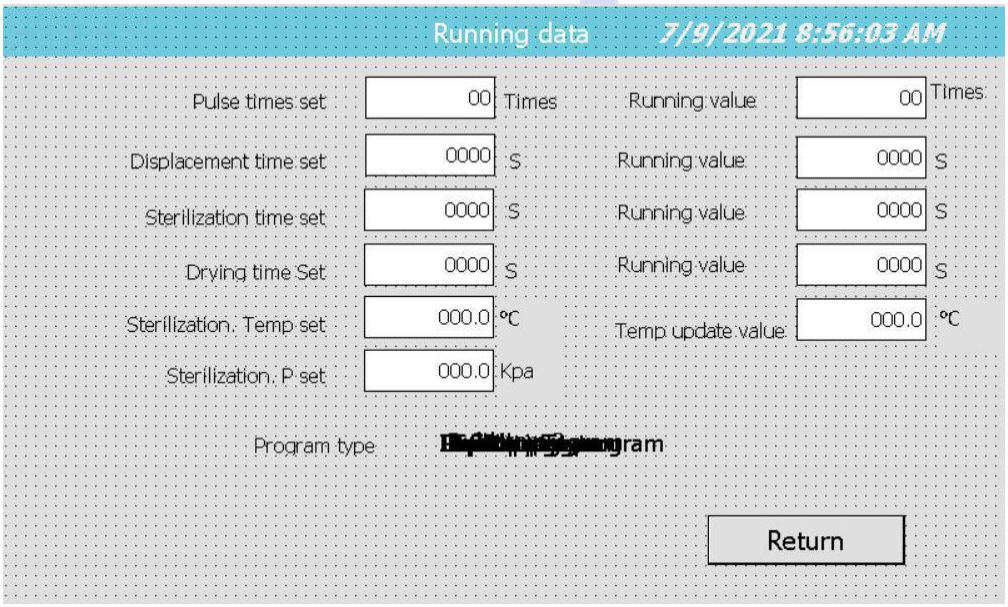


Figure 14

The value on the left side is default, and the value on the right side is current running data.

If you want to cancel the cycle, please press the Exit in the Main process interface.

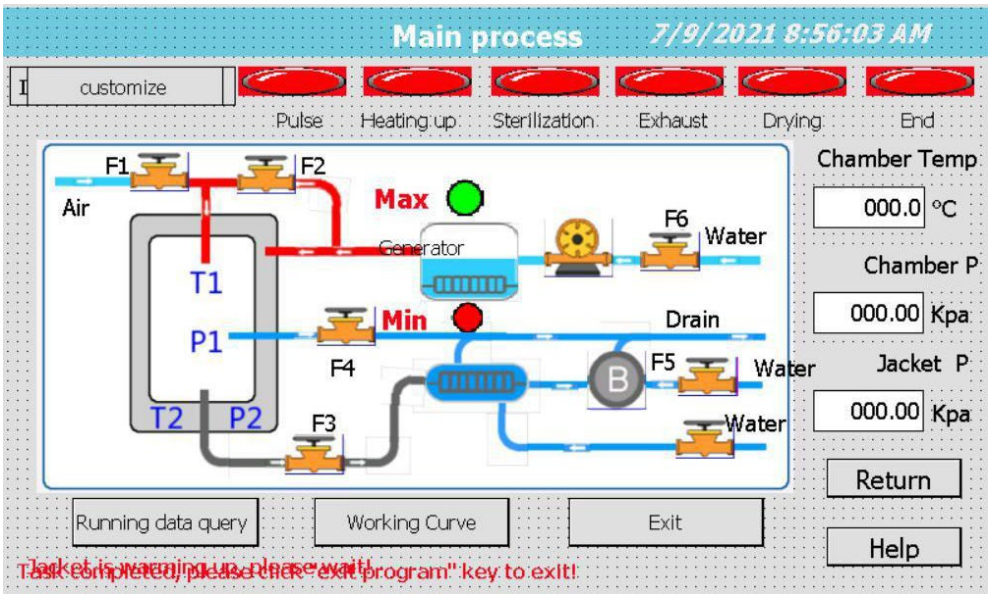


Figure 15

After pressing the Exit button, the following interface will show.

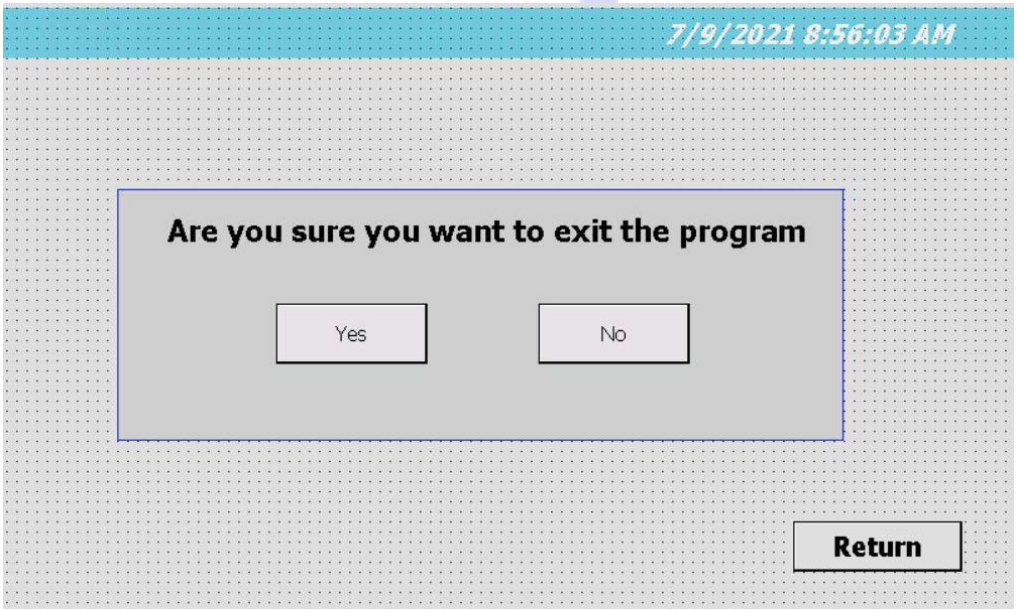


Figure 16

"Sterilization finished, please open the back door" will appear on the touch screen after cycle end.

Meanwhile, the light on the back is on and buzzer sounds.

- Program running for Liquid items

Select the Liquid program for Liquid items.

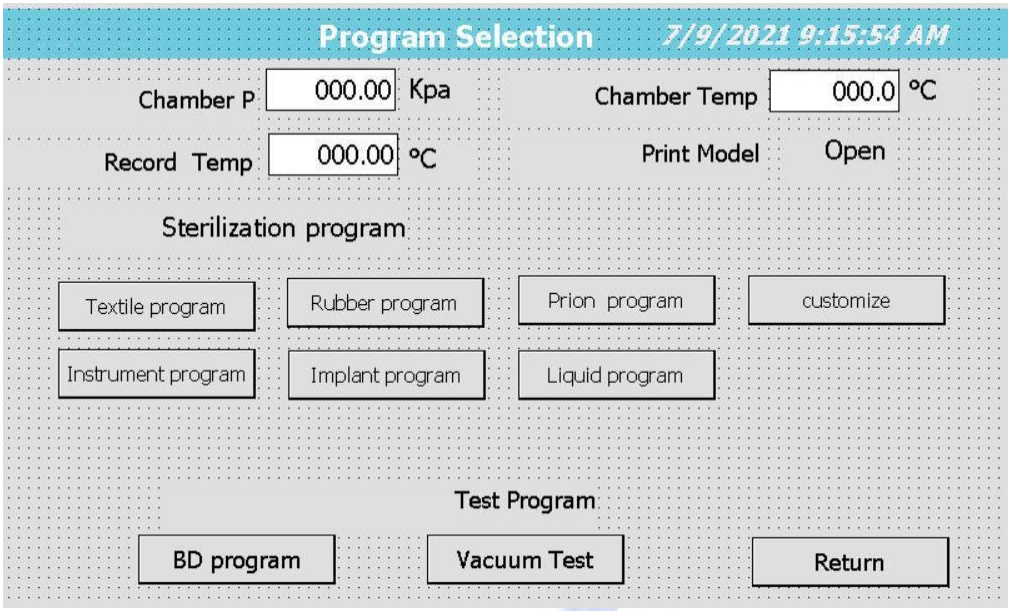


Figure 17

The Main process for Liquid program as below:

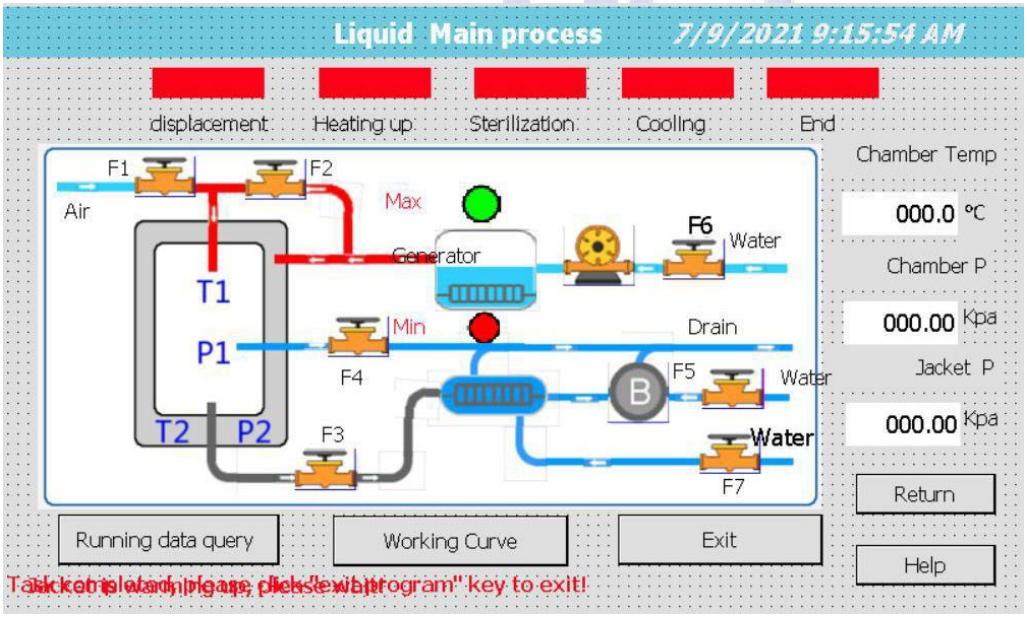
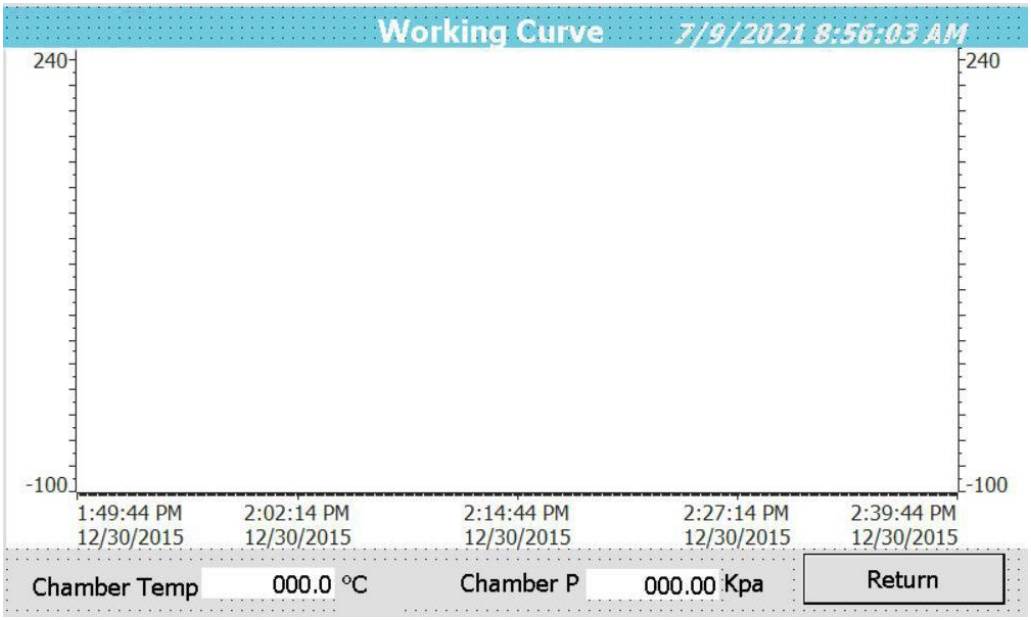
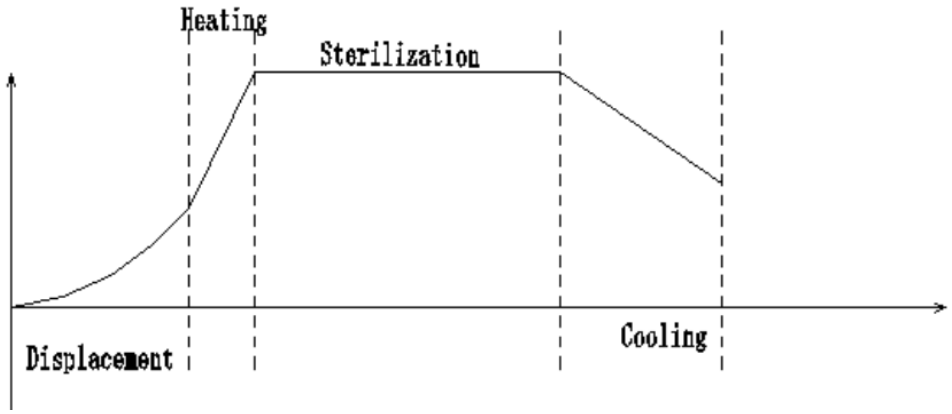


Figure 18

Press the Working curve button to see the curve of the chamber pressure and chamber temperature.



The work flow of Liquid program as below:



Sterilization time: the sterilization temperature for liquid is 121 ℃, the minimum sterilization time is 20 minutes. The larger the load is, the longer the sterilization time is.

Press the Running data button to the following interface.

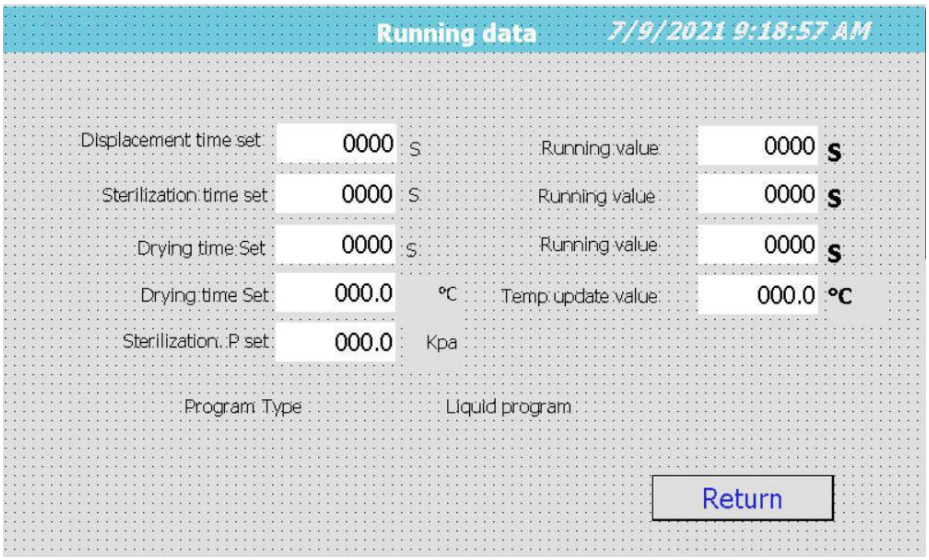


Figure 20

If you want to cancel the cycle, please press the Exit in the Main process interface of Liquid as below:

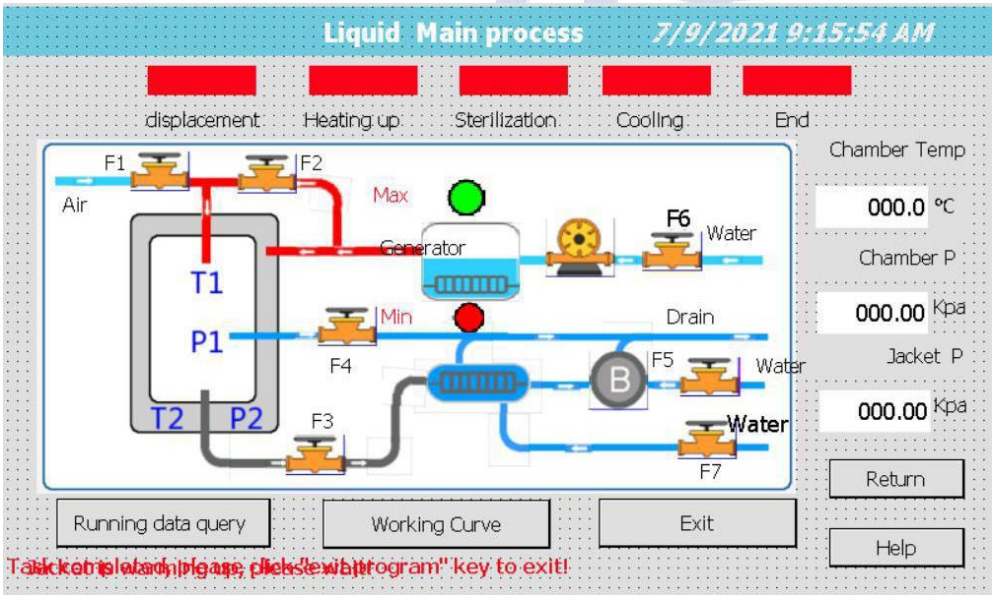


Figure 21

After pressing the Exit button, the following interface will show.

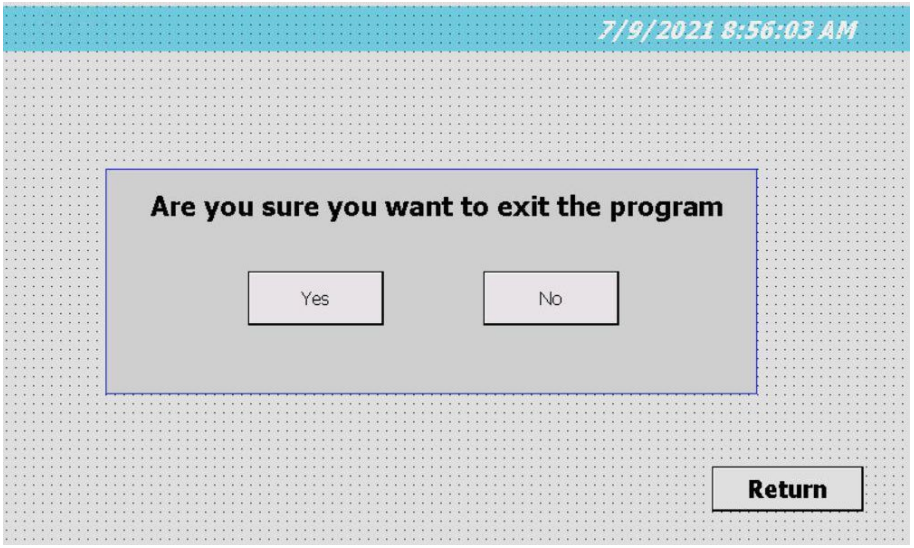


Figure 22

"Sterilization finished, please open the back door" will appear on the touch screen after cycle end.

Meanwhile, the light on the back is on and buzzer sounds.

Attention

- During the operation of the program, please do not touch the indicator button of the printer to prevent communication interruption and printing stop.
- Manual operation procedure can only be done by experienced staff who are familiar with the characteristics of equipment and articles to be sterilized.
- If the touch screen does not respond, do not press the selection button frequently.

EQUIPMENT ROUTINE MAINTENANCE, REPAIR AND OPERATING

The equipment is operating normally without any malfunction, but it should also be overhaul after a certain period of operation. Failure is not only related to the service life and intrinsic quality of the equipment components, but also to the operator's knowledge of how the equipment is being used and whether it is routinely maintained. Many failures are caused by improper use, incorrect operation and neglect of routine maintenance and regular maintenance toward equipment.

The correct use and routine maintenance of sterilizing equipment is necessary for the extension of equipment service life and the decrease of failure. This chapter provides a brief overview of precautions and maintenance in service.

- Equipment Routine Maintenance

1. The flowing works need to be done before getting off work

- Turn off all control and power supplies.

- Close the steam source valve. Close the steam valve in the inter-layer, the steam in the interlayer

will naturally be condensed and discharged from the inter-layer steam trap.

- Shut off the compressed air valve or cut off the air compressor power supply.

- Close the water supply valve.

- Clean the inside of the door of sterilization room (inner room) and the sterilization trolley.

When the sterilization chamber and sterilization trolley temperature dropped to near room temperature, scrub with a neutral detergent, and then rinse with tap water,

and finally wipe with lint free cloth.

- Clean up the lint and sediment attached to the filter net of the front lower part of the inner chamber to ensure that the evacuation rate and the cooling water flow and the temperature indication is consistent with the pressure.

 **Caution:** Cleaning person should first turn off the emergency stop switch (power switch) when entering the inner chamber, carry the key of the switch with you, and then enter the inner chamber to work.

- When the sterilizer in not in use, open the front door in case of the affection toward the tightness and service life of the door due to the chronic compression and deformation of the door seal.

- Inspect the door seal for damage and clean it with a clean, soft cloth.

2. The routine maintenance of the main components

- Pneumatic angle seat valve: The pneumatic valves are powerful on-off valves and imported high-quality valves with high reliability. Please pay attention to the influence of the foreign matter in the pipe toward the valves in use.

- Liquid-ring vacuum pump: the vacuum pump is vacuuming by using water ring seal. The water ring seal play the role of seal and energy transformation. Due to the discharge of steam mixed with a lot of water during the exhaust, the work process should continue to add water, continue to add water in the work process. However, the amount of water should not be too much, which increases the pump power loss and adversely affecting the working environment of the pump.

- The amount of water automatically sucked through the water tank according to the actual situation. The amount of water and water temperature directly affect the vacuum rate and pump service life. The lower the water temperature, the higher the ultimate vacuum, the general requirement is no more than 25 ℃.

- For longtime machine halt, you can open the pump plug, drain the water from the pump, and then block the drain hole and fill the equipment with saponated liquid. Otherwise, the pump body will rust and frost crack which will affect the efficiency and service life of pump.

- Traps (pneumatic angle seat valve, solenoid valve): Inside the exhaust pipe of the inner chamber there is a small angle seat valve to drain the water from the inner chamber, inside the intercalated exhaust pipe there is a small solenoid valve to do jacketed drain. The drain work will directly affect the sterilization effect. If water can't be properly discharged, the trap should be opened for cleaning.

A small amount of vapor discharge is normal during the work.

- Safety valve: Safety valve is respectively installed on the jacket and inner chamber. The safety valve plays a role of protecting the equipment and operator. The opening pressure and re-seating pressure of the jacket safety valve which is installed on the top of cabinet top and the inner chamber safety valve which is installed on the side of cabinet are previously and properly adjusted in the factory, so the user does not arbitrarily adjust the equipment in case of accidents caused by improper adjustment.

The user need to pull its handle for several times in half a year and scour it with steam in case of corrosion which caused by longtime non-use and will lead to malfunction of over-pressure safety valve caused by any reason at work.

Caution: Remember not to directly touch the safety valve handle, pull it with a screwdriver or a strip of cloth in hand to avoid the harm toward operator caused by steam!

- Pressure regulating valve (optional): The steam pressure regulating valve had been previously and properly adjusted before left the factory. Readjustment of the equipment could be achieved according to the customer needs. The two sylphons of the pressure regulating valve are easy to corrode and snap duo to the longtime stretch or compression, so the sylphon need to be replaced in time when air leak happens.

- Sterilizing air filter: The filter play a role in the vacuum break stage with high filtration accuracy, energy saving, safety, reliability and so on. Gas filtration accuracy can effectively avoid recontamination caused by incoming air of inner chamber toward items after sterilization and the filter element can be used for one to two years in general.

- Filter: The filters which are respectively installed on steam inlet pipe and water inlet pipe play the role of filtering out impurities and guaranteeing the smooth of pipe and reliability of valves.

Therefore, regular cleaning is required to prevent clogging. When cleaning, twist off the bottom of the screw, clean the filter net, and then tighten the screw plug. In

addition, respectively install a filter on jacket drain valve and inner chamber drain valve. These filters play a crucial part in the normal drain of jacket and inner chamber, therefore, the filter net should be regularly removed and cleaned.

- One-way valve (check valve): There is a one-way valve on the evacuation pipe of the door, which should be inspected periodically to prevent any foreign matter from affecting the one-way sealing performance. The easiest way is to use the nozzle test after cleaning, no feeling of air leaks is normal.

- Solenoid valve: In order to make the solenoid valve work normally, the solenoid valve core and valve seat must be scrubbed once a quarter to prevent impurities in the pipeline from affecting the open and close of valve.

Note: In order to check whether the solenoid valve is energized, use a screwdriver to test the nut on the valve head with or without magnetism.

- **Condenser:** Pay attention to the quality of water, excellent water quality will condense a large scales inside the condenser, which will affect the condensing effect. As a result, the condenser should be chemically descaled according to the situation. For long time machine halt, screw down the lower plug of the condenser, drain the internal storage water, and then block the drain hole.

3. Maintenance of electrical components

- Electrical components and connections are strictly prohibited from contacting with water, if accidentally stained with water, they should be properly dealt with, and then the power can be switched on.

- Dustproof is required and dust extraction must be done quarterly.

- The connector assembly of the connection, the plug-in components should be always checked, they need to be tightened if they become loose.

4. Scale deposit removal

Due to the water quality in some areas is too hard, the long-term operation of the equipment will deposit a lot of scale in the pump and pipeline, and the accumulation of scale will affect the normal operation of the equipment. It is recommended to use a water source that meets the standard of boiler water or deionized water to periodically (it is recommended to use semi-annually) do full descaling with various types of chemical descaling agents.

Descaling process:

Firstly, drain the water from the vacuum pump and the condenser.

There is a flange connection in the outfall of the vacuum pump, discharge the flange screws and pour the chemical descaling agent into the vacuum pump from here.

Fill the vacuum pump, condenser and the pipeline connected with the inner chamber with the chemical descaling agent, and then waiting for about 4 hours (If you use other types of cleaning agents, you should follow the instructions in the cleaning agent specification for handling).

Taking the JT-100 water system safe cleaning agent as an example: mix the cleaning agent with water at a ratio of 1:10 (if you use of other types of cleaning

agents, the ratio should be in accordance with the proportion required in the specification), and then turn on the vacuum pump to drain the water into the sewer. Finally, repeatedly rinse the pump with water and wash out the remanent cleaning agent.

Note: During the descaling operation, please avoid making the cleaning agent contact with the body, so as not to burn the skin!

- **Equipment Routine Operation Specification**

1. Preparation before using equipment

1. First, completely discharging the condensate water from steam pipeline; second, opening steam source which connects with sterilizer and water switch; third, checking whether the pressure of the steam source is up to 0.3-0.5MPa or not, and whether the water pressure is up to the 0.15-0.30MPa specified value or not.

2. Please turn on the air compressor power supply. Opening compressed air valve until pressure reaches the specified value.

3. Closing the power supply and control source of the equipment and turning the sterilizer power switch to the "-" side. Please preheat the equipment and prepare for the running of the program.

4. Marking the operator's name, date, etc. on the B-D test paper and putting it into the sterilizer to run the B-D test program, which to check the leaks of equipment and condition of equipment.

5. Tidying the packages to be sterilized and strapping should not be too tight. Outside the chemical instructions tape and make chemical instructions card inside.

6. Checking seals, front cover and door with or without debris and damages and cleaning them with clean cotton cloth.

- Operation of Sterilizer

1. After passing the B-D test, opening the sealed door and pushing the sterilizing vehicle with the sterilization articles into sterilizing chamber. (There should be gaps between the packages. The packages are not contact with the wall and door panels).

2. Please close the front door. Choosing sterilizing programmer according to the sterilization articles and checking the right of sterilization parameters. Then you can run the program.

3. The operator shall not stay away from equipment in sterilization process, closely observed the operation status, dispose timely and prevent accidents if in unusual condition.

4. Testing the effect of sterilization and recording it, which is easy to doing trace investigation.

5. After the sterilization completed, you can opening back door to take items until the indoor pressure back to zero.

6. Taking the sterilization articles out from sterilizer and putting it on shelf, which in case of the possibility of secondary pollution.

- Work After Use Of Equipment

Step1: You shall open the front door, press the power emergency switch and cut off equipment

control source, power supply and air compressor power supply.

Step2: Closing steam source, water supply valve and compressed air valve.

Step 3: After daily work, you should keep clean of the sterilizer and its operation room and clean up the dirt of sterilization room. The sterilization room should have minor maintenance weekly and major maintenance monthly. Drain valve should be cleaned once in three month. Filter of steam inlet pipe and water inlet should be clean once in 6 months to prevent the impurities from blocking.

QUALITY ASSURANCE MEASURES FOR STERILE PRODUCTS

Any kinds of disinfection and sterilization equipment which no matter downward facility or pulse vacuum facility want to have reliable effect need many conditions. The design of the device itself, manufacturing quality and improvement and maintenance are all important factors. And the important human factors are the staff quality, which he can correctly master the basic knowledge about sterilization and disinfection and, familiar with the equipment working principles, hew to the standard of sterilization and sterilization and take relevant regulations on sterilization seriously.

1. The Sterilized Items Must Be Cleaned Before Sterilization

The cleaning of sterilized articles before sterilize is the key to successful sterilization, especially for some medical supplies which difficult to clean. The studies have found that thoroughly cleaning can reduce the 3-4 logarithm germs and can reduce the content of organic matter, if it can't effectively remove organic pollutants, it will greatly reduce the activity of sterilizing agent, the bacteria in the organic matter is not easy to kill by sterilizing agent.

So if cleaning is not complete, the entire sterilization process may fail. It must be noted that the cleaning requirements cannot be reduced by extending the sterilization time and increasing the temperature of the sterilizing agent. In order to effectively remove organic matter, it is better to use an enzyme cleaner to enhance the cleaning effect.

Cleaning is divided into manual cleaning and machine cleaning.

Manual cleaning takes time and effort and cannot guarantee the consistency of each cleaning. In addition, medical personnel must wear waterproof face mask, eye mask, gloves, sleeve, hat, waterproof shoes, apron, etc.

Machine cleaning is a big investment, but it can guarantee the consistency of cleaning. However, it is important to note that machine cleaning is not completely replaced by manual cleaning, and manual cleaning is necessary for certain pipes, fine instruments and difficult cleaning parts. In addition, cleaning equipment must be cleaned and maintained frequently to avoid machine cleaning failure.

Caution: High level disinfection and sterilization effect cannot be achieved without correct cleaning.

2. The Quality Of The Steam Source

*** Saturated steam:** it refers to the steam rising from the vaporized water to the liquid phase line.

*** Steam Dryness:** it is another requirement of steam properties that, as far as is practiced, the saturated steam content should not be less than 97%. In other words, the water vapor source should contain less than 3% water particles or impurities. Otherwise, it is easy to cause wet package phenomenon.

3. Water Quality Control

The hardness of water is divided into two kinds: first, temporary hardness, mainly formed by calcium and magnesium bicarbonate; Second, it is mainly composed of

calcium and magnesium sulfate, nitrate and chloride, which can't be removed by boiling method, so it is also known as permanent hardness. Because disinfection and sterilization equipment is working under conditions of damp heat for a long time, impurities in water such as dissolved oxygen, carbon dioxide, hydrogen sulfide, chloride, etc., whether in gaseous state or particulates, can cause inter-crystalline corrosion of stainless steel and metal.

Therefore, the water supply for sterilization equipment and the PH value of the supply of steam are between 7 and 7.8, and the water of boiler water and sterilization equipment must be softened.

4. The Environment Of Sterilization Room

* The ground of sterilizing chamber must be even and smooth, with cement floor as appropriate, with a slight tilt to the effluent discharge port, keeping the operation area clean and dry. The roof should be equipped with a ceiling to prevent dust accumulation. The walls should be clean and even and isolated from the washroom, preparation and other workrooms.

* Exhaust steam and waste water must be put through the wall or in the trench, or be exhaust to the atmosphere. Don't make the residual water, steam return and invade the interior.

* Install ventilators at the right place on the top or ceiling of the wall.

* Conditions can be cut off the equipment, the use of high-temperature steam sterilization equipment sterilization medium, the use of vacuum pump, air

compressor door seal and pneumatic valve to provide compressed air, it will have some impact on the surrounding environment， recommendation apparatus with color plates in position after the operating end or other material - and a non-operating end front - back door partition (Single door sterilizer can cut off the front door), which will effectively prevent the heat around and working noise environmental impact, greatly improve the working conditions of sterilization.

5. The Environment Of Sterilization Room

* The ground of sterilizing chamber must be even and smooth, with cement floor as appropriate, with a slight tilt to the effluent discharge port, keeping the operation area clean and dry. The roof should be equipped with a ceiling to prevent dust accumulation. The walls should be clean and even and isolated from the washroom, preparation and other workrooms.

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* Install ventilators at the right place on the top or ceiling of the wall.

* Conditions can be cut off the equipment, the use of high-temperature steam sterilization equipment sterilization medium, the use of vacuum pump, air compressor door seal and pneumatic valve to provide compressed air, it will have some impact on the surrounding environment， recommendation apparatus with color plates in position after the operating end or other material - and a non-operating end front - back door partition (Single door sterilizer can cut off the

front door), which will effectively prevent the heat around and working noise environmental impact, greatly improve the working conditions of sterilization.

6. Sterilized Items Are Packed And Placed In A Sterile Cart

* Dressing fabric should be loosely wrapped in order to facilitate steam penetration.

* When the package is placed on the sterilizing vehicle, the space between the adjacent parcels should be kept 10 mm, and the loading volume should not exceed 80% of the volume of the inner chamber, which so as to facilitate the smooth circulation of steam.

* Aluminum lunch boxes and enamel boxes shall not be used to hold sterilizing articles or to install utensils with standard sterilizing boxes or ventilation holes.

* Sterilization of similar items should be done and the direct contact of the equipment bag with the cotton bag should be avoided. If different types of articles must be put together, the temperature and time required for the most difficult to reach sterilized articles shall prevail.

* Article bundles should not be too tight, the package should be taped on by chemical indicating tape with indicating card inside.

* In the process of placement, the plates, basins, bowls and other metalware should be placed vertically. The fiber material should be folded in a vertical state; Glass bottles, glass tubes and other utensils should be opened to the lower or side to facilitate the entry of steam and air exclusion.

* When the cloth and metal products are sterilized at the same time, the metal articles should be put under the dressing bag to make the two heating basically the

same, and prevent the condensation water produced by the sterilization of metal products from getting wet cloth.

* Large bags that are difficult to sterilize should be placed in the upper layer, easily sterilized packets in the lower layer.

Containers and conveyors should be cleaned and disinfected daily.

THE INSPECTION OF STERILIZATION RESULTS

Sterilization detection is to evaluate the sterilized sterilization methods used is reasonable, the sterilization effect is reliable means.

The method of inspection consists of three types: physical, chemical and biological.

- Physical Inspection

Monitoring instrument (process): the series equipment is equipped with display sandwich and chamber pressure gauge, and displayed on the touch screen has a chamber temperature and pressure values, equipment configuration has the micro printer.

(Microcomputer monitoring system is not equipped with microprinter).

The printer can print out as shown in table 4 sterilization data sheet on file for future reference.

Recording paper can record the sterilization process of each sterilization process pressure, temperature, and the corresponding time value, can also be recording equipment operation, the operator code, using the program, pulse frequency, the properties of the liquid in the replacement time, sterilization, drying, sterilization parameters such as temperature, time by looking at these values are in conformity with requirements whether can preliminary judge of sterilization effect.

Table 4 shows the sample of sterilization program data printing paper. In order to facilitate users' use, we added a record item of whether the chemical indicator card and the chemical indication tape were qualified in the sterilization process on

the sterilization data record paper. After sterilization, the operator shall put the square root in the box for archiving according to the actual results.

Table 4: Sterilization process data printing paper

DateTime 2018 07 05 16:20:24
Product : Autoclave 01
Program : Fabric
User NO.: 0
Print Freq 30S
Indicator strip: √ or ×
Indicator tape: √ or ×

Time	Promed Pre. KPa	Tem.℃
Pulse		
16:21:08	-80.19	93.02
16:22:02	80.12	99.08
16:22:28	-80.32	98.30
16:23:22	80.03	101.03
16:23:48	-80.17	99.54
16:24:15	80.78	100.08
Heat		
16:24:44	61.10	100.83
16:25:14	87.25	101.24
16:25:44	126.07	110.43
16:26:14	146.41	117.10
16:26:44	158.44	121.61
16:27:14	166.55	124.69
16:27:44	175.45	126.91
16:28:14	186.92	128.73
16:28:44	197.75	130.34
Ster		
16:29:14	208.41	132.81
16:29:44	202.95	132.86
16:30:15	199.26	133.18
16:30:45	199.48	133.38
16:31:15	197.72	133.42
16:31:45	191.33	133.34
16:32:15	192.66	133.21
16:32:45	191.66	133.13
16:33:15	191.73	133.04
16:33:45	187.84	133.02
16:34:15	189.17	132.93
16:34:45	190.19	132.88
Exha		
16:35:15	189.73	132.79
16:35:45	41.61	128.34
16:36:00	8.85	124.08
Dry		
16:36:50	65.14	105.20

Thermocouple detection: this method is to thermal galvanic electrode into the sterilizer to test parts, then close and will wire leads, the verification instrument for data analysis, testing each point temperature by computer will in due course, according to the method can be used to detect sterilizer chamber of each point temperature uniformity and stability of sterilization temperature, or directly use wireless electrode test directly on the sterilizer.

In order to increase the reliability of physical monitoring, it is necessary to

strengthen the debugging and verification of testing equipment, and combine chemical detection and biological monitoring to comprehensively analyze the quality of sterilization.

- Chemical Indicator

The chemical indicator is used to determine whether to meet the required parameters of sterilization under certain temperature and time conditions.

Chemical indicator card： This kind of indicator card is used for the detection of the sterilization effect of pulsation vacuum sterilizer. The indicating color block on the indicator card will change from light yellow to black during sterilization, and the result of sterilization can be judged from the depth of color change Claim. Such instructions cards have 115 ℃, 121 ℃ and 132 ℃ three kinds of temperature steam sterilization test results of chemical indicators.

When used, a chemical indicator indicating both the temperature and the duration of the temperature is put in the package to be sterilized. After one sterilization cycle, the indicator card is taken out and compared with the standard color.

If the indicator color is darker than Standard sterilization time, on the contrary, that the role of temperature and duration of time did not meet the requirements, need to re-sterilize. Indicator cards subject to water wet can affect the accuracy of discoloration, so try to avoid sterilization and metal, glass and other surfaces prone to condensation of water contact articles.

Chemical indicating tape: The tape is coated with adhesive on one side and a chemical indicator on the other side. Can be used as a distinction between

"sterilized" and "non-sterile" instructions, but also as a package seal attached to the appearance of the dressing package. After the sterilization is finished, the packet sterilization can be initially judged through the uniform darkening of the indicator color.

- Biological Inspection

Biological inspection refers to the use of live microbes to detect the sterilized items to identify all the microorganisms in the sterilized articles are dead, to assess whether the sterilization equipment is the ultimate test means.

- **Calibration indicator bacteria:** internationally recognized as the most difficult to kill, the strongest heat-resistant "thermophilic Bacillus stearothermophilus" as a sterilization indicator.

- **Medium:** The test medium is bromocresol peptone water medium

- **Detection method:** 3M produced 132 ℃ (121 ℃) biological indicators, placed in the standard test package (package size 220mm × 300mm × 250mm) in the middle. Put the test pack over the steam outlet in the sterilizing chamber, and under the aseptic condition after the sterilization process is completed, remove the standard test pack and put it into a 3M-producing petri dish for 48 hours to observe the change of the color of the medium. Test set negative control and positive control.

In addition, other testing equipment and articles approved by the Ministry of Health can also be used according to the manufacturer's instructions.

- **Results:** The color of all media did not change, judged as sterile. Such as from

purple to yellow, the sterilization fails.

- **Disposal**: If sterilization fails, this batch of items can be temporarily sealed to find out the possible causes of sterilization failure, and then sterilized; also available from the same manufacturer's or multiple manufacturers of the same kind of biological indicator Re-test the sterilization effect of sterilizer; carefully check the biological indicator of the production date, expiration date, with or without damage and culture process is contaminated.

- If the equipment is adjusted before normal use or after overhaul, the equipment should be qualified for three consecutive times before it can be put into use.

- **The test results should be recorded, including:** test date, sterilizer number, sterilization temperature, sterilization time, indicator source, lot number and expiration date, incubation.

incubation time, observations and testers.

Caution: After the sterilization of bacteria should be promptly removed according to the manufacturer's instructions for bacterial culture.

Physical inspection, Chemical indicator, Biological inspection of these three methods have their own different purposes and significance, it can not be replaced by each other, should be combined with each other.

Physical inspection——Can explain the operation of sterilization equipment itself, can directly display the work process time, temperature, pressure and other related sterilization parameters are normal, to determine whether the initial sterilization of sterile items is successful.

Chemical indicator——May detect presence or absence of the sterilization process is completed, steam penetration can learn how to package, may be provided in an instant a first visual inspection after the completion of sterilization, the sterilization effect of the auxiliary determination.

Biological inspection——Can explain the operation condition of sterilization equipment itself, can directly show whether the relevant sterilization parameters such as time, temperature and pressure in the working process are normal, so as to preliminarily determine whether the sterilized articles are successfully sterilized.

- B-D Test

The b-d test was designed by two Scottish microbiologists, bowe and dick, in 1963 to test the effect of air removal in a vacuum pressure steam sterilizer.

-**BD test chart:** is a mixture of a variety of chemicals through a certain carrier made of indicator ink, through a specific printing method of the indicator ink is printed on a certain air permeability of special size paper, to form a certain pattern Become a BD test vacuum test chart. The chemical indicator on the test chart is sensitive to residual air and can detect the presence of residual air in the test pack.

-**B-D test:** This test should be carried out daily before the first sterilization. Test is to place the BD test chart in the middle of the test pack (disposable BD test pack is also available), place the test pack in the vent of the sterilization chamber, close the sealed door, and press the manufacturer of the BD test pack The instructions set the parameters, run a sterilization

program, the sterilization program is finished, open the door, unpack the test package, remove the test chart and observe the test results.

- **The preparation of the test package:** the test package consists of a pure cotton cloth of 46-50cm * 80-90cm, which is folded into three layers and then folded into six layers. Fold the folded cloth to a height of 25cm.

When stacked, each layer of cloth will be arranged alternately on the folded side, so that the thickness of the two sides is equal. After the cloth is arranged, place the b-d test folder between the central cloth, then wrap it in a cloth towel, and then use the chemical indicator to fix it and become a test bag.

The whole test package is about 27-30cm long, 23-25cm wide, 25-28cm high, and weighs about 4-5kg.

- **Result Judgment:** The test chart is black and uniform, that is, the color of the central part and the edge part are the same, indicating that the air is completely discharged. The vacuum system of the sterilizer is good and the seals of all the departments are in good condition, indicating that they can be used. If the test chart discoloration uneven, usually the central part of the color than the edge of the light, air exclusion is not complete, the sterilizer performance is poor, can be used after repair.

- **Note:** the cloth should be washed before use, but not hot, because excessive drying will affect the test results. For repeated test kits, cloth towels must be washed and continuously tested. Each time, the cloth should be opened. The cloth towel

should be dried for 1 hour, then repackaged, and the cloth is too wet, which can affect the test results. Package should be loose, not too tight or too small.

- **Necessary conditions: name of sterilization bag;** Date of sterilization or expiry date; The name or code name of the device and the packer; The seal is marked with sterilization. The result only indicates the vacuum state of the equipment and the residual amount of cold air, which does not indicate whether the sterilization product is qualified.

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