

XG1.U Steam Sterilizer

Product introduction

It can be widely used in department of stomatology and ophthalmology, operating room and other medical institutions. It is suitable for all wrapped or unwrapped solid instruments, A-class cavity instrument (dental hand-pieces and endoscopes), implantable instruments, dressing fabric and rubber tubes, etc.

Product features

- Equipped with professional and systematized sterilizing programs of fabric, instrument, rubber, liquid, cavity, testing and auxiliary programs of BD, PCD and leakage.
- Temperature, pressure, time, running status, failure warning liquid-crystal display.
- Intelligentized drying system to guarantee the residual humidity of instrument and dressing no more than 0.2% and 1% respectively.
- Build-in efficient steam generator, microcomputer temperature control, time and energy saving.
- Equipped with printer to print date, time and process parameters.
- Over-heat auto protection device, dual door safety lock device, overpressure relief valve, short-circuit protection, and overpressure protection.
- Perfect four-level authority management system to avoid misoperation.



Technical parameters

Design pressure: -0.1/0.25MPa Accuracy of temperature display: 0.1 C
 Maximum working pressure: 0.23MPa Accuracy of pressure display: 1KPa
 Vacuum limit: -0.080MPa Chamber material: 304 stainless steel
 Sterilization working temperature: 115~138 C

Configuration Selections Table

XG1.U Basic configuration

No.	Order code	Volume (L)	Chamber size (φ×L) mm	Overall size (L×W×H) mm	Net weight (kg)	Input power (kVA)
1	XG1.UCD-100D	100	400×850	1250×730×1660	260	10
2	XG1.UCD-100S	100	400×780	1264×730×1660	300	10
3	XG1.UCD-135D	135	500×710	1110×750×1742	400	11.5
4	XG1.UCD-135S	135	500×620	1140×750×1742	450	11.5
5	XG1.UCD-185D	185	500×950	1350×750×1742	460	11.5
6	XG1.UCD-185S	185	500×860	1365×750×1742	500	11.5
7	XG1.UCD-300D	300	632×1000	1415×890×1780	750	18
8	XG1.UCD-300S	300	632×890	1438×890×1780	800	18

- Number of Door(s)**
 - D-Single door
 - S-Double door
- Material of Chamber + Jacket**
 - SUS304+SUS304 ☆
 - SUS316L+SUS316L
- Material of Built-in steam generator**
 - SUS304 ☆
 - SUS316L
- Loading mode**
 - Shelf loading
- Voltage**
 - 380V, 3-Phases ☆
 - 220V, 3-Phases
 - 240V, 3-Phases
 - 400V, 3-Phases
 - 415V, 3-Phases
- Frequency**
 - 50Hz ☆
 - 60Hz
- Standard accessories**
 - Loading shelves×2

XG1.C Steam Sterilizer

Product introduction

It is applicable for the sterilization of unpacked solid instrument in department of stomatology, ophthalmology, operation room and CSSD.

Product features

- Touch screen display of temperature, pressure, time, running status and failure warning.
- Equipped with professional and systematized sterilizing programs of fabric, instrument, rubber and liquid.
- The positive pressure air-discharging system will effectively discharge the cold air from chamber to improve steam saturability.
- Build-in efficient steam generator, microcomputer temperature control, time and energy saving.
- Equipped with post-drying function which makes the residual humidity of sterilized articles less than 3%.
- Equipped with printer to print date, time and process parameters.
- Over-heat auto protection device, dual door safety lock device, overpressure relief valve, short-circuit protection and overpressure protection.
- Perfect four-level authority management system to avoid misoperation.



Technical parameters

Design pressure: 0 / 0.25MPa Chamber material: 304 stainless steel
 Maximum working pressure: 0.23MPa Accuracy of temperature display: 0.1 C
 Sterilization working temperature: 115~138 C Accuracy of pressure display: 1KPa

Configuration Selections Table

XG1.C Basic configuration

No.	Order code	Volume (L)	Chamber size (φ×L) mm	Overall size (L×W×H)mm	Net weight (kg)	Input power (kVA)
1	XG1.CD-100D	100	400×850	1250×730×1660	260	10
2	XG1.CD-100S	100	400×780	1264×730×1660	300	10
3	XG1.CD-135D	135	500×710	1110×750×1742	400	11
4	XG1.CD-135S	135	500×620	1140×750×1742	450	11
5	XG1.CD-185D	185	500×950	1350×750×1742	460	11
6	XG1.CD-185S	185	500×860	1365×750×1742	500	11
7	XG1.CD-300D	300	632×1000	1415×890×1780	750	17
8	XG1.CD-300S	300	632×890	1438×890×1780	800	17

- Number of Door(s)**
 - D-Single door
 - S-Double door
- Material of Chamber + Jacket**
 - SUS304+SUS304 ☆
 - SUS316L+SUS316L
- Material of Built-in steam generator**
 - SUS304 ☆
 - SUS316L
- Loading mode**
 - Shelf loading
- Voltage**
 - 380V, 3-Phases ☆
 - 220V, 3-Phases
 - 240V, 3-Phases
 - 400V, 3-Phases
 - 415V, 3-Phases
- Frequency**
 - 50Hz ☆
 - 60Hz
- Standard accessories**
 - Loading shelves×2

SHINVA 新华医疗

Pulse Vacuum Sterilizer
Operation Manual

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

Document No.: TD-XT-D004-001 V2.19

Revised Date: 2020-8-20

This Manual is applicable to the installation, operation and maintenance of Shinva XG1. U Pulse Vacuum Sterilizer.

The relevant standards and product information followed by the pulsating vacuum sterilizer produced by the Company are as follows:

Information of registrant and manufacturer:

- 1) Name of Registrant/Manufacturer: Shinva Medical Instrument Co., Ltd.
- 2) Medical Device Production License Number: Lu Food and Drug Administration Equipment Production License No.20100024
- 3) Hygiene License Number of Disinfection Product Manufacturing Enterprise: Lu Wei Xiao Zheng Zi [2014] No.0001
- 4) Domicile/Registered Address: Xinhua Medical Science Park, Zibo High-tech Industrial Development Zone
- 5) Production Address: No.2009 Xinhua Avenue, Zhoucun District, Zibo City
- 6) Tel: (86) 0533-3584911 (Sales) 3591216 (Customer Service)
- 7) Postal Code: 255300
- 8) After-sales service unit: Customer Service Center of Shinva Medical Instrument Co., Ltd.

Product Information:

- 1) Medical Device Registration Certificate No.: Lu Xie Zhu Zhun 20162110113
- 2) Product Technical Requirements No.: Luxie Zhuzhun 20162110113
- 3) Implementation standards: Product standard: Q/0303SXH083
- 4) Structure and composition:

This product consists of cabinet body, cabinet door, disinfection vehicle, handling vehicle, pipeline system and control system. Using saturated steam as medium, the effect of disinfection and sterilization can be achieved under high

temperature conditions, and the pulsation times can be set as required.

- 5) Product performance: For sterilizers with sterilization temperatures of 121 °C and 134 °C respectively, the maintenance time shall not be less than 15min and 3min respectively.
- 6) Scope of suitable (enabling) use of products: for medical units, pharmaceutical and other units to do sterilization of medical liquids, surgical instruments, dressings and fabrics.
- 7) Contraindications: None
- 8) Main bactericidal factors and intensity:
This equipment uses humid and hot steam as sterilization factor.
See Appendix D for the intensity data of sterilization factors.
- 9) Principle of sterilization:
The equipment uses a specific process to discharge the cold air in the sterilizer room, and uses saturated humid and hot steam as a sterilization factor to realize sterilization of articles that can be penetrated by steam under the combined action of high temperature, high pressure and high humidity environment and a certain temperature and time.
- 10) Killing Microorganisms Category: Killing or removing all microorganisms on medical devices, appliances and articles.
- 11) Special storage and transportation conditions and methods: None
- 12) Packing and transportation: in accordance with GB/T 191.
- 13) Production Date: See Equipment Nameplate.

Instructions







CAUTION

Keep the Manual completely within the service life of the equipment;

Ensure that all updates received can be saved in the Manual;

When the equipment using site or unit changes, the Manual must be transferred or handed over as a part of the whole equipment.

Please learn more about the symbols posted on the machine in the following list:

SN	Symbols	Content Explanation
1		High temperature near symbol surface, be careful of scalding
2		Note that please follow the detailed instructions
3		Grounding identification
4		There is a dangerous voltage here. Please cut off the power before operation or maintenance.

In the Manual, the following symbols are used to indicate the operation contents that should be paid attention to or highly valued:



CAUTION Great attention should be paid to it.



WARNING It should be observed or it will damage the equipment.



DANGER Strictly abide by it, otherwise his personal safety will be endangered.

Before carrying out any operation and maintenance on the equipment,

please carefully read and fully understand the contents in each chapter of this Manual, especially those with the above marks should be paid attention to.

If the equipment is not used according to the methods specified by the Company, the protection provided by the equipment may be damaged.

Instructions must be carefully kept to prevent loss or damage, even minor damage should be avoided.

Operators are obliged to carry out technical repairs and complete some contents, catalogues and relevant chapters lost, damaged or no longer applicable in the Manual.



CAUTION

No one can tear or take out anything from the Manual under any circumstances.

In the process of learning and using the equipment, if the user encounters any situation that does not conform to the instructions in the Manual or is not covered in the Manual, please contact our company in time, and we will answer for you in time. If necessary, the Manual will be upgraded or updated free of charge.

The storage place of this Manual shall be kept ventilated and dry to avoid humidity and high temperature.



WARNING This equipment is not suitable for sterilization of tightly sealed

bottled liquid. If you sterilize the above liquid, please contact our company and we will select a special sterilizer for you.



DANGER When sterilizing tightly sealed bottled liquid with this equipment, bottle explosion accidents are easy to occur due to negligence of operators or violation of operating procedures, seriously endangering the safety of people and equipment.




CAUTION Chloride ion is an important factor causing corrosion damage to stainless steel. If the sterilizer is used to sterilize articles containing chloride ions, the wall of the sterilization room must be washed with clear water every day to avoid the corrosion of the deposited chloride ions to the internal stainless steel and fully prolong the service life of the equipment.




WARNING If this sterilizer is used to sterilize articles containing chloride ions, but the equipment is not cleaned every day as required, the service life of the equipment will be seriously affected, and the additional damage and accelerated aging caused to the equipment will not be covered by our company!



CAUTION When symbols  are seen anywhere on the equipment, it is necessary to consult this manual and other relevant documents in order to understand the nature of the potential hazards and any countermeasures that must be taken.



CAUTION When a symbol  is seen anywhere on the equipment, it indicates that the surrounding temperature is relatively high. Please pay attention to avoid scalding.



DANGER

1. The user unit of this product shall carry out regular daily maintenance and regular self-inspection during use.

2. The user unit of the product shall conduct self-inspection of the products in use at least once a month and make records. If the user unit finds any abnormal situation during self-inspection and daily maintenance of the in-use products, it shall deal with it in a timely manner.

3. The user unit of the product shall regularly check and overhaul the safety accessories (safety valves, pressure gauges, etc.), safety protection devices, measurement and control devices and relevant ancillary instruments and meters of the products in use, and make records.

4. The operators of this product and their relevant management personnel shall, in accordance with the relevant provisions of the State, pass the examination by the special equipment safety supervision and management department and obtain the special operation personnel certificate in a unified national format before engaging in the corresponding operation or management work.

The user unit shall educate and train the operators on the safety and energy conservation of special equipment to ensure that the operators of special equipment have the necessary knowledge on the safety and energy conservation of special equipment. The operators of this product shall strictly implement the operation procedures of special equipment and relevant safety rules and regulations during the operation.



CAUTION

- 1. This equipment meets the emission and immunity requirements specified in GB/T 18268.**
- 2. This equipment is designed and tested according to Class A equipment in GB 4824. In the home environment, this equipment may cause radio interference, and protective measures need to be taken.**
- 3. It is recommended to evaluate the electromagnetic environment before the equipment is used.**
- 4. It is forbidden to use this equipment beside strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the equipment.**

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CHAPTER I BRIEF INTRODUCTION

Pulse Vacuum Sterilizer uses humid and hot steam as sterilization factor. The design life of the product is 8 years (or 16,000 sterilization cycles) (Note: This design life is the failure period estimated according to the standard use environment agreed by the equipment, and has nothing to do with the failure rate occurring during the actual use of the equipment. Improper use will also accelerate the damage of the equipment). In the design of the equipment, after the cold air in the inner chamber is removed according to the specified sterilization process, saturated humid and hot steam is used as the sterilization factor to realize sterilization of articles that can be penetrated by steam under the action of a certain time and pressure in a high temperature, high pressure and high humidity environment. All default process parameters of this equipment are determined under the load conditions described in this procedure, with thermophilic fatty liver bacteria spores under specific resistance or microorganisms with equivalent performance (see GB18281 and other relevant national standards for details) as representatives of sterilizable microorganisms, which can kill bacterial spores.

Note 1: When the resistance of microorganisms that may be infected by the load to be sterilized is greater than the resistance agreed in the standard (e.g. Microorganisms carried by mad cow disease pathogens), relevant process parameters such as sterilization pressure and sterilization time need to be adjusted according to the characteristics of specific microorganisms, and can only be used after confirmation by corresponding processes.

Note 2: The killing ability of the sterilization factor to the agreed microorganisms can effectively ensure the killing effect only when the equipment and related facilities are in normal working conditions. For example, the failure of the equipment, the failure of the external connection system, the loading and placement of the sterilized load, etc. may interfere with the killing effect of the sterilization factor.

Note 3: Due to the continuous updating and upgrading of the sterilized load, the operator shall verify that the sterilized load is suitable for

sterilization in this equipment before carrying out relevant operations, otherwise unpredictable damage may be caused to the equipment or load!

The standard equipment with the following order numbers is applicable to this manual:

Equipment Model	Volume	Size of lumen (mm)	Overall Dimensions	Net Weight	Power
XG1. U	100L	400×850 (Φ×L)	1250×730×1660	260kg	11kVA
XG1. U	135L	500×710 (Φ×L)	1110×750×1742	400kg	11.5 kVA
XG1. U	185L	500×950 (Φ×L)	1350×750×1742	460kg	11.5 kVA
XG1. U	300L	632×1000 (Φ×L)	1415×890×1780	750kg	18kVA

- Design pressure:-0.1/0.25 Mpa
- Temperature display accuracy: 0.1 °C
- Lower vacuum limit:-0.08 MPa
- Sterilization working temperature: 115 ~ 138 °C
- Pressure display accuracy: 1Kpa

According to the order number, the volume of the equipment will vary. The three types of equipment used in this manual are only different in volume and power, and other parameters are the same.



WARNING This sterilizer is only suitable for sterilizing high temperature and humidity resistant medical instruments and articles, and cannot be used for sterilizing oils and powders such as Vaseline.



DANGER It is strictly prohibited to use this equipment to sterilize the sealed liquid packaged in glass bottles or glassware, because the liquid bottles may

burst due to changes in operation or temperature and pressure, causing harm to people and equipment.

- Sterilizer cabinet door adopts radial door bolt locking mechanism. The sealing ring is made of silicone rubber with good temperature resistance and elasticity. The door center is equipped with a pressure safety interlock device-electromagnetic lock, which meets the requirements of the "Regulations for Safety and Technical Supervision of Pressure Vessels" issued by the State Bureau of Quality and Technical Supervision. Under any circumstances, the handwheel can only be rotated when the pressure in the inner chamber is within ± 10 KPa. The cabinet door is also equipped with a closing travel switch. Only when the cabinet door is tightened can the operation program be started. Therefore, the cabinet door has good overall sealing performance, safety and reliability, and convenient operation.
- The upper computer adopts a new type of liquid crystal display, which can display graphics, dynamic text, dynamic display of working flow and parameters such as time, temperature and pressure in the working process, and can carry out special configuration according to needs.
- The lower computer adopts a modern new control device-programmable controller (PC for short) for program control, which has the characteristics of strong function, high reliability and flexible use.
- The air removal mode of mechanical forced pulsating vacuum is adopted, and the cold point in the sterilization room is completely eliminated through multiple vacuum and multiple steam injection, so that the air removal amount reaches more than 99%, and the "dead angle" and "small loading effect" of temperature are completely eliminated, thus ensuring reliable sterilization effect.
- The sterilizer is divided into single door and double door (i.e. Single door and double door). The double door sterilizer can effectively isolate the

bacteria-bearing area from the sterile area and meet the specification requirements of the National Drug Production Management GMP.

- The main control parts and valve parts are all matched with world-famous brand high-quality parts, which greatly improves the stability and reliability of this kind of equipment.
- The service life of the equipment is 8 years (or 16,000 sterilization cycles).



CAUTION The correct installation of sterilization equipment plays a very important role in the normal performance of its equipment and must not be ignored.

Chapter II Technical Parameters

1. Rated working pressure: 0.205 MPa; Rated operating temperature: 132 °C;
2. Setting range of pulsation times: 0 ~ 99 times;
3. Sterilization time setting range: 0 ~ 7200 seconds (2 hours);
4. Setting range of drying time: 0-7200 seconds (2 hours);
5. Pulsation amplitude setting: positive value 0MPa ~ 0.1 MPa, negative value-0.1 MPa ~ 0MPa;

For other technical parameters, please refer to the equipment installation drawing. If there is any change in parameters, the equipment installation drawing shall prevail.

6. Pressure controller setting: upper switching value 0.24 MPa and lower switching value 0.22 MPa
7. Water source: demineralized water with pressure of 0.15 ~ 0.3 MPa;
8. Power supply: 380V ± 38 V/50Hz ± 1 Hz (the power shall be subject to the order number of the specific equipment);
9. Ambient temperature: 5 °C ~ 40 °C;
10. Relative humidity: no more than 85%;

For other technical parameters, please refer to the equipment installation drawing. If there is any change in parameters, the equipment installation drawing shall prevail.

Chapter III Installation and Commissioning



CAUTION The correct installation of sterilization equipment will play an important role in the normal performance of its equipment and must not be ignored.

3.1 Unloading of Equipment

When the equipment arrives at the customer's place, attention should be paid to:

- Do not stand under the hoisting equipment.
- Ensure that there is a sufficient safe distance around the hoisting equipment.
- Qualified hoisting equipment shall be used.
- Adjust the hoisting equipment to find out the center of gravity so that the equipment can be hoisted horizontally.
- During hoisting, attention should be paid to protecting the outer packaging board.

3.2 Unpacking and Inspection

- After unpacking the equipment, first check whether the model and name on the product nameplate are consistent with the order form. (The product nameplate is on the side of the equipment)
- According to the details of the equipment packing list, carefully check whether all parts of the equipment are in good condition, damaged or lost. If so, make records and contact our company in time.
- Carefully check whether all connections or fixing parts are loose due to long-distance transportation, and tighten if any.

- Check and record the accessories randomly carried by the equipment.

3.3 Equipment Installation

Before the equipment is installed, if necessary, we can provide our company with the purchased equipment model so as to ask for the installation drawing. During the installation process, professional construction personnel shall be responsible under the guidance of professional personnel.



WARNING Non-standard installation will bring harm to human life and property and hinder the normal and reliable operation of equipment.

Our company does not bear the consequences of non-standard installation.

1. Preparation and requirements before installation

- Installation space: considering the operation and maintenance of the equipment, the space height for installing the sterilizer should not be less than 2.9 meters; The distance between the left and right sides of the sterilizer and the wall shall not be less than 0.5 m; The depth of the loading/unloading direction of the sterilizer shall not be less than 1.5 times of the length of the sterilizer, so as to facilitate the transportation of sterilized articles. When installing a single-leaf sterilizer, the distance between the non-operating end and the wall should also not be less than 0.5 meters.
- Foundation: The surface shall be firm and flat, and the load-bearing capacity shall meet the corresponding equipment requirements. If it is installed above the second floor, the user should consider whether the corresponding parts of the floor need to be reinforced according to the specific situation.
- Ventilation and heat dissipation: In order to better ensure the normal

operation of the equipment and a comfortable working environment, it is suggested that a suitable ventilation system should be installed in the working room to control the ambient temperature and humidity around the sterilizer.

- Drainage: A drainage pipe with a size at least one specification larger than that of the drainage pipe outlet configured by the sterilizer shall be selected, and the drainage pipe shall be led to the trench separately for discharge outside, and shall not be communicated with other drainage pipes in the building (such as cleaning, floor drain, etc.), otherwise some gas discharged by the equipment during operation will affect other rooms.



CAUTION

The drainage pipe shall be installed from high to low at the drainage outlet of the equipment without back pressure, otherwise the sterilization or drying effect will be affected due to poor discharge of condensed water. When multiple devices share a total drain pipe, the flow rate of the total drain pipe shall be greater than the sum of the drain pipe flows required by each device. Drainage pipe materials shall be high temperature resistant (140 °C), corrosion resistant and aging resistant materials. When installing the equipment, the anchor bolts should be adjusted to ensure that the drain outlet of the main body is the lowest point.

- Water source: used for water ring vacuum pump and steam generator. The interface size is 1/2 inch internal thread, the pressure requirement is 0.15 ~ 0.3 MPa, and the flow requirement is shown in the installation drawing. During installation, a valve and a pressure gauge of 0 ~ 0.6 MPa shall be connected in the middle of the water inlet pipe. (Note: If the

water source pressure is higher than 0.4 MPa, the measuring range of the pressure gauge shall be correspondingly increased to ensure that the pressure gauge works at 2/3 of the full measuring range.)



WARNING If the water source pressure is lower than 0.1 MPa, the vacuum procedure cannot be started.



WARNING The steam generator carried by the equipment itself must use demineralized water to generate steam.

- Power supply: Conventional equipment power supply AC380V shall be three-phase five-wire system, three-phase live wire, one zero wire and one ground wire. Among them, the zero line is blue, the ground wire is yellow-green, and the three live wires are red, yellow and green. The load capacity of the user's power supply and power cord should be greater than the load of the equipment. It is required to install a power switch box on the right or right rear wall of the sterilizer to ensure that the switch box is located close to the equipment and easily accessible by operators. The switch box shall be marked as special for the sterilizer. A three-phase knife switch (or circuit breaker) and an overcurrent protection device must be installed in the switch box to realize the functions of on-off and overcurrent protection of the equipment power supply. Special equipment shall be wired according to the actual contract requirements.

In order to ensure the safety of people and equipment, a ground wire must be laid, and the ground wire in the equipment enclosure and control cable must be reliably connected with the external ground wire.



DANGER Equipment and steam turbine enclosure must be strictly grounded!

The pipelines and lines shall be horizontally, horizontally, vertically and effectively fixed.

Notes:

- Avoid installation in the environment of heavy dust, oil mist containing conductive particles, corrosive gas and combustible gas.
 - Avoid installation in situations prone to electric shock or vibration.
 - Avoid installation in places with high temperature, high humidity or easy to get wet by rain.
 - Avoid installation in strong magnetic field environment.
2. Equipment in place
- Move the machine to the selected location. During the movement, care should be taken not to damage or scratch the decorative covers. In case of special circumstances, make records and marks, remove the pipeline and outer cover, and restore the equipment as it is after it is in place.
 - Take out the packaging bag, take out the random documents and keep them properly.
- Attention should be paid not to scratch the original ground during handling.

3. Adjustment Level

The equipment can be directly placed on the horizontal ground. If it is slightly uneven, it can be properly adjusted with thin iron sheets.

4. Connection of water, electricity and gas sources

According to the specific installation position and installation requirements of the equipment, connect water, electricity and sterilizer with each other. Sealing filler shall be used at the pipe joint to prevent leakage, and

no condensable liquid such as water source shall drip above the electrical appliance box.



CAUTION The power supply ground wire must be reliably grounded!



WARNING When installing equipment, please install leakage protection device to prevent safety problems caused by component damage.

3.4 Equipment Commissioning

Some procedures have been preset according to relevant standards when the equipment leaves the factory. During debugging, users can modify program parameters according to usage requirements. Please read Chapter 5 "Usage and Operation" for specific parameter settings.

- Before commissioning, check whether the wiring and socket of electrical appliances fall off or loose, and tighten if there is one. Whether the water inlet, drainage and connection are correct, otherwise adjust and tighten.
- Open the inlet valve to ensure that the water source pressure meets the requirements.

1) Vacuum pump rotation direction

Turn on the power switch, log in with administrator or above authority, enter the manual operation state, click the automatic/manual switch button, and click B (vacuum pump) to start the vacuum pump at this time. Observe whether the rotation direction of the vacuum pump motor fan is clockwise, otherwise any two load lines on the three-phase load switch should be switched.

Note: When performing this operation, if two people cooperate with each

other, the reversal time of the vacuum pump will be reduced.

2) Check each valve part

In the manual state, click the corresponding label of the solenoid valve (F2 intake valve F3 evacuation valve F4 return valve F5 slow discharge valve F6 water injection valve F7 pump valve), open the solenoid valve, and gently approach the top of the solenoid valve with a screwdriver to feel strong magnetic attraction.

3) No-load test

- Before running the program, the leak test shall be carried out according to the instructions in Chapter 5 "Use and Operation". If the test fails, there is leakage in the pipeline communicating with the inner chamber. At this time, check carefully to eliminate leakage points and retest until the test is qualified, otherwise the sterilization effect of the equipment will be affected.
- Parameter Setting: refer to the working parameters of the program in Chapter 5 "Usage and Operation" for setting.
- After the parameters are set, the routine operation of fabric, equipment and BD experimental procedures can be carried out. Please read Chapter 5 "Use and Operation" for the specific procedure process. During the operation of the program, the tightness of the pipeline and the door shall be checked, and any steam leakage found in the pipeline shall be handled in time.

4) Load Test

The above procedures are all carried out under no-load, and the load test shall be carried out after the no-load test is completed. In the load test, the load of non-liquid sterilized articles such as instruments and fabrics shall not exceed 80% of the volume of the inner chamber, and shall be placed on shelves, and each dressing bag and instrument bag shall maintain a gap of 10mm. The load test must test the sterilization effect of the inner

center point of the package. According to the introduction of Chapter 9, B-D test procedure, chemical test and biological test are carried out on the sterilizer to observe whether the test effect meets the requirements.



CAUTION Allow the sterilizer to modify the program during commissioning according to the actual situation.

Chapter IV Structural Features and Working Principle

This product consists of cabinet body, cabinet door, shelf, pipeline system and control system. Using saturated steam as medium, the effect of disinfection and sterilization can be achieved under the condition of high temperature, and the pulsation times can be set as required. See Appendix 3: General Assembly Drawing.

4.1 Cabinet

- The exterior of XG1.UCD-100M cabinet adopts electric heating film to ensure that the inner cabinet keeps a certain temperature to reduce condensation of condensed water during internal sterilization.
- XG1.UCD-135M/185M/300M cabinet adopts double-layer jacket structure to ensure that the inner cabinet keeps a certain temperature to reduce condensation of condensed water during internal sterilization.
- The cabinet is made of imported stainless steel plates with excellent corrosion resistance and is automatically welded by a special welder. The surface is treated by mechanical polishing and electrochemical polishing. It is bright, smooth and clean, corrosion resistant and durable.
- The cabinet body adopts high-quality thermal insulation materials on the surface of the outer cabinet board, which is not only beautiful and durable, but also can reduce the heat radiation of the equipment to a minimum and effectively ensure the working environment of the equipment.

4.2 Cabinet Doors

The cabinet door of this series of sterilizers is mainly composed of door panel, door bolt and locking mechanism, sealing ring, hinge plate, door cover, handwheel, pressure safety interlocking system and control elements.

1) Door-open Direction:

- The operating end is called the front door and the non-operating end is called the rear door (only for double-door sterilizers). General configuration is that the single door is left open, the double door is right open for the front door and left open for the back door.

- If it is a device that needs to change the direction of opening the door according to the user's requirements, some of its functions need to be operated in reverse according to the following introduction.

2) Removal of door cover:

- First remove the logo in the middle of the handwheel, then unscrew the screw in the center of the decorative cover with a cruciform screwdriver before removing the handwheel seat. Then remove the screws on the upper left and lower right of the door cover. At this time, hold the two sides of the door cover with your hands, break it slightly outward and lift it upward. At this time, the door cover can be removed.

3) Door bolt and locking mechanism:

The locking of the door is completed by manually driving the screw to rotate through the revolving door handwheel so that the nine door bolts extend outward.

When leaving the factory, each door bolt gasket has been adjusted. If air leakage is found, users should not adjust it indiscriminately. The adjustment must be carried out by professional personnel, otherwise the adjustment will get worse.

- Close the door

Before closing the door, each door bolt is in the fully contracted position, i.e. The door handwheel turns counterclockwise to the limit position. Close the door, make the handwheel rotate clockwise, the door bolt automatically extends out and inserts into the front sealing plate, and then continue to rotate the handwheel. When the operator hears the "click" sound of the door switch in the door cover being pressed, continue to rotate for half a circle to one circle to completely press the handwheel.

It is strictly prohibited to rotate the handwheel clockwise when opening the door to prevent the door bolt from extending outward. Closing the door in this state will cause damage to the equipment cover and cabinet door!

- Open the door

The door can be opened by turning the left hand wheel to the limit position.

Note: The door will only open when the inner chamber pressure is equal to the atmospheric pressure!

- Door switch

The door switch is installed in the door cover and acts by the pressure of the door bolt. The front and rear doors of the double-leaf cabinet each have a door switch. The program can only be started after the current rear door is tightly closed. If the door is not tightly closed, the program cannot be started, thus avoiding the phenomenon of starting the machine without the cabinet door being tightly closed. In case of special circumstances, the pressure plate on the door bolt can be adjusted to adjust the sequence of door opening and closing actions.

4) Pressure safety interlock:

- The cabinet door is equipped with double safety. A travel switch is installed at the lower left of the door panel. The switch is pressed down before the door is locked to turn on the program control circuit of the equipment. That is to say, the cabinet door is not locked and the program cannot be started. When the program is started, the electromagnetic lock pops up (both the front and rear doors of the double-leaf series pop up). At this time, the handwheel cannot rotate and the door cannot be opened. When the sterilization procedure is completed and the inner chamber pressure drops to less than ± 10 KPa, the electromagnetic lock is retracted and the door can be opened.

5) Post-Haff

For manual doors that are used for two years or more, some of them will have

serious consequences of long-term abrasion of the rear Haff two positioning pins and cam spiral grooves, especially at the rear Haff two positioning pins, which will cause them to break from the root in serious cases and the doors cannot be used normally. Most of the above phenomena are related to the operator: if the cabinet door is not in a good position and is forced to close the door, the part will be severely worn if the force is too large, and serious wear will lead to the cabinet door being completely unusable. Therefore, the opening and closing force should be moderate to prevent damage to transmission components.

6) Sealing ring

- Structure: Sealing ring is a specially processed annular silicone rubber ring. Its material composition, shape design, correct installation and maintenance are crucial to its normal work and service life. The sealing ring used by our company adopts a special formula of silicone rubber material, which effectively ensures its stability and reliability in high temperature working environment.
- Principle: The sealing ring is fixed on the sealing ring seat of the main body. When the cabinet door is closed, the sealing ring is tightly attached to the sealing plate in front of the end of the cabinet body under the action of external force. Due to the ladder shape of its sealing surface, certain deformation will occur in the sealing process to realize the sealing of the door.
- Maintenance: Although the long-term use of the sealing ring has been fully considered in the design and material selection, the following factors may affect the service life of the sealing ring. These factors should be avoided as much as possible to ensure the longer service life of the sealing ring.
 - a. At the end of one shift, the main steam control valve entering the sterilizer shall be closed in time to keep the cabinet door in the open position, otherwise the sealing ring will gradually age due to high temperature and pressure for a long time.
 - b. After half a year to one year of use, the sealing ring should be removed,

gently scrubbed with alcohol, dried and installed back to the end surface of the cabinet door panel together with the sealing bead.

- c. During operation, attention should be paid to prevent hard objects from colliding with the sealing ring, otherwise it is easy to cause permanent damage to the sealing ring, thus reliable sealing cannot be realized.
 - d. In the process of use, regular scrubbing of the surface of the sealing ring and door panel will prolong the service life of the sealing ring.
- Failure: It can basically be determined that the sealing ring has failed when the following reasons occur.
 - a. The surface of the sealing ring is obviously hardened, and when pulled, it feels that it has lost its elasticity and has mesh lines.
 - b. The sealing ring is cracked or has broken.

Note: The judgment of whether the sealing ring fails or not should be considered comprehensively, which has a great relationship with the long-term accumulation of operators' experience.

- Remove and install:

When taking out the sealing ring, stop all programs to open the door and take out the rubber strip from the sealing groove of the ring seat.

During installation, the sealing bead can be squeezed into the sealing groove again. Note: Because the perimeter of the general sealant strip is a little more than the perimeter of the sealing groove, the excess length should be evenly distributed in the sealing groove during installation.

Note: When installing the sealing ring, it can be easier to install it with the help of another person!

7) Troubleshooting: (See Table 1)

Table 1: Troubleshooting Table of Cabinet Door 1

Fault phenomenon	Cause Analysis	Solutions
1. The cabinet door cannot open.	<ol style="list-style-type: none"> 1. There is pressure in the inner chamber 2. The program is running 3. The temperature of the inner chamber is higher than the set temperature for opening the door. 4. Electromagnetic lock failure 	<ol style="list-style-type: none"> 1. After the indoor pressure returns to zero, open the door again. Step 2 Exit the sterilization procedure 3. Wait for cooling to within the temperature range before opening the door. 4. Check the electromagnetic lock and its connection
2. The cabinet door cannot close completely.	<ol style="list-style-type: none"> 1. The position of the cabinet door changes and the door sags. 2. Door bolts are not fully retracted 3. Damage to the drive system inside the door 4. A certain door bolt cannot protrude against the front sealing plate. 	<ol style="list-style-type: none"> 1. Adjust the position of the cabinet door relative to the front sealing plate 2. Turn the handwheel so that the door bolt is fully retracted. 3. Check the drive system inside the door 4. It is necessary to adjust the position of the door bolt frame or the height of the gasket.
3. Steam leaks around the door during operation.	<ol style="list-style-type: none"> 1. Wear or aging of door sealing ring 2. There is dirt in the pressing place of the rubber strip on the door panel. 3. The cabinet door is not closed tightly. 4. Uneven stress on door bolt 	<ol style="list-style-type: none"> 1. Replace the door sealing ring 2. Clean the pressing position of the rubber strip on the door panel 3. Adjust the cabinet door position again after the chamber is deflated 4. Adjust the height of the door bolt frame gasket

4.3 Pipeline System

1) Jacket steam inlet pipeline

Equipment that produces steam by its own steam generator, Steam is generated by

heating demineralized water in the steam generator. The outlet of the upper part of the steam generator is connected with the interface of the lower part of the sterilizer cabinet body, and the generated steam enters the jacket through the interface. The jacket steam can effectively isolate the influence of external cold air on the inner chamber, and can also maintain the temperature of the inner chamber to reduce condensation of the steam in the inner chamber.

- The steam generator is designed to give full play to its best performance and has chosen the following optimal configuration:
 - a. The body of the device is made of high-quality seamless steel pipes and carbon steel plates for pressure vessels, which are welded under the protection of carbon dioxide flux-cored wire. The weld quality is good and the overall strength is high.
 - b. The electric heating pipe is made of stainless steel pipe, which has the characteristics of small volume and long service life.
 - c. The high-quality temperature-resistant high-pressure pump is selected for the water adding pump, which has the characteristics of small volume, high outlet pressure and reliable operation.
 - d. The liquid level is controlled by the upper, middle and lower probes, and the liquid level of each working stage is displayed through the glass tube water level gauge on the outer decorative cover.
- The steam generator can realize the following automatic control functions:
 - a. Automatic water adding function: During the working process, the water level in the steam generator body drops due to the continuous output of steam. When it is lower than the high water level for three minutes, the water adding pump will automatically start to replenish water to the normal working water level (upper water level); When the water level rises to the normal working water level, the water addition

pump is closed to stop water inflow so that it can continuously supply steam to the equipment. In the sterilization stage, when the water level reaches the low water level, water replenishment is started.

- b Automatic pressure control function: when the steam pressure in the evaporator reaches the upper limit set by the pressure controller, the heating power supply can be automatically cut off; When the steam pressure in the evaporator decreases to the set lower limit, the heating power supply can be automatically turned on to ensure that the steam is output at a basically constant pressure.
- c Automatic protection function for water shortage: When the water level in the device body drops to the lower water level due to unexpected reasons, the heating power supply can be automatically cut off to ensure that the electric heating pipe will not be damaged due to dry burning due to water shortage.
- d Overpressure automatic protection function: When the pressure in the body exceeds the upper pressure limit set by the safety valve due to unexpected reasons, the safety valve can be effectively and timely released to protect the safety of equipment and operators.

2) Chamber steam inlet pipeline

The jacket steam enters the inner chamber through the inner chamber intake valve F2 to disinfect and sterilize the articles.

3) Vacuum pumping line

The pipeline passes the air, steam and condensed water in the inner chamber through the steam outlet at the lower part of the inner chamber, passes through the vacuum valve F3, enters the vacuum pump, and is discharged through the pump outlet.

- Vacuum valve F3: This valve is controlled by the execution program to open or close.

- Vacuum pump: This pump is a water ring vacuum pump and is the main equipment for vacuum. It uses clean water as working fluid. During the working process of the pump, the working fluid will form a water ring around the blades. The water ring plays a role of sealing and heat conversion, so it should be continuously supplemented during the working process.

Note: The limit vacuum degree of the water ring vacuum pump is directly related to the temperature of the water ring and the compression capacity of the pump. The lower the water temperature, the higher the limit vacuum degree. Therefore, the lower the water supply temperature of the pump, the better, with a maximum of not more than 25 °C.

4) Drain Pipeline

In the drain pipeline of the inner chamber, the condensed water generated by the steam of the inner chamber passes through the steam outlet at the front and lower part of the inner chamber, passes through the filter, 1/4 solenoid valve, 1/4 ball valve and single valve to the drain outlet, and automatically discharges the condensed water in the inner chamber.

One-way valve: It is a valve that only allows one-way flow of medium. One is installed on the door evacuation pipeline and one on the inner chamber drain pipeline respectively. The common faults are spring failure, sealing rubber pad rupture or nut loosening and falling off, which is manifested as water inflow from the sealing groove or steam return from the inner chamber. The valve is a straight-through check valve to prevent external steam or water from returning to the inner chamber and affect the working performance of the equipment.

5) Upper drain line

The upper air discharge pipeline of the inner chamber, and the steam generated in the inner chamber passes through the steam discharge water port at the front and lower part of the inner chamber to the water discharge port through the filter, 1/2 solenoid valve and single valve to remove the steam from the inner chamber. Only when the pressure of the inner chamber drops below 30KPa can the

vacuum operation be carried out.

The upper drain pipeline and the drain pipeline share the same solenoid valve.

6) Air inlet line

After the impurities and bacteria are filtered out by the sterilization filter, the air enters the inner chamber through the air return solenoid valve F4, so as to eliminate the negative pressure formed at the later stage of work, the air is dry and sterile, and the secondary pollution of the sterilized articles is prevented.

- Air filter: The air filter is cylindrical and uses high-precision medical filter paper with a filtering accuracy of 0.22 μm , which can filter out bacteria and impurities in the air.

7) Water supply pipeline

- Water supply pipeline: purified water enters the evaporator through the filter, the inlet solenoid valve and the water injection pump F6, and tap water enters the vacuum pump through the F7 pump valve for circulation. Filter: The filter can effectively prevent and precipitate solid sundries carried by the water delivery pipeline into the barrel-shaped filter screen to prevent them from entering the equipment.

8) Pressure control line

This series of equipment is equipped with pressure controller, pressure transmitter, platinum thermal resistor, interlayer and inner chamber pressure gauge and other accessories.

- Pressure controller: The pressure controller controls the working pressure of the evaporator within a certain range. The adjusting nut at the upper part of the controller can adjust the size of the set pressure value, which can be adjusted clockwise and counterclockwise. The right side adjusting nut of the controller can adjust the difference between the upper and lower limits of the set pressure value, which can be increased clockwise and decreased counterclockwise.



CAUTION The pressure controller has been adjusted when the product leaves the factory. If adjustment is needed, it should be carried out by personnel with work license.

- Pressure Transmitter: Please refer to the Structural Principle Section of the Control System.
- Platinum thermal resistance: also known as PT100, please refer to the structural principle section of the control system.
- Safety valve: The evaporator and the inner chamber are equipped with safety valves respectively, which play the final role of safety protection when improper operation or abnormal pressure of equipment occurs. When the pressure is higher than its upper limit set value, it will automatically open and reduce the pressure. When it is lower than the lower limit setting value, it will automatically close.
- Pressure gauge: For single-leaf sterilizer, two pressure gauges are installed at the front door control end, one showing evaporator pressure and the other showing inner chamber pressure. In the case of a double-leaf sterilizer, the rear end is also equipped with the same pressure gauge indicating the pressure of the inner chamber as the front end.

4.4 Structure and Principle of Control System

The control system consists of a main controller, a display, a micro thermal printer, an electromagnetic valve, a pressure controller, a pressure transmitter, an indicator lamp and a display instrument.

1) Front panel

The front panel is installed at the upper end of the front cover of the equipment and contains a display, a printer and a key switch.

- Display: UCD-T57 display with the following features

- a) Display graphics, dynamic text
 - b) Full touch operation, simple and convenient
 - c) Excellent communication function
- Printer: Micro power consumption, micro volume, panel installation and high quality printing are the primary characteristics of this printer. Function: This printer can record the working start time, operation times, operator number, program nature, program setting parameters and pressure and temperature values at the same time during program operation. The printing interval can be set by the user himself.
- 2) Rear panel
- The rear control is only applicable to the double-leaf sterilizer. It is equipped with five indicator lights and one inner chamber pressure gauge. The indicator lights run (green), the door is closed (yellow), the door lock (yellow), the alarm (red) and the end (green).
- 3) Main control box
- Main controller: Powerful function, the main control part of the controller is a highly integrated chip produced in the United States, with reliable performance; Logic judgment, floating-point number operation, data storage, communication networking and other performances are better than traditional PLC control. It is a general industrial device integrating microcomputer technology, automation technology and communication technology. It is cost-effective and convenient to use, and has been widely used in various neighborhoods of industrial control. It works according to pre-input programs, receives and processes various input and output signals, and controls the process of sterilization programs. The allowable range of power supply voltage is 24VDC; Its working environment is 0 °C ~ 55 °C.

The equivalent circuit of the controller consists of four parts:

A. Input part: receiving operation instructions or receiving various state information of the controlled object; Control the process and conversion of

program flow.

B. Control part: This part is the control program compiled by the user, and the control program is placed in the ROM of the controller. When the system is running, the controller reads the program storage area in turn, interprets and executes their contents, and sends the instructions that need to be output to the output terminal of the controller to control the external load.

C Output part: drive the load directly or through the intermediate relay according to the execution of the program.

D. Analog conversion part: 5 analog inputs with 12-bit conversion accuracy; The input standard current signal is converted into a digital signal, which is converted into different quantities according to the definition of the program. In this control, it is converted into temperature and pressure.



CAUTION The inner wire of the control box must be reliably grounded, otherwise there will be temperature and pressure jump! !

- Buzzer: When misoperation occurs or the sterilization program is abnormal, the buzzer will sound an alarm sound to prompt. When sterilization is completed, the buzzer will also prompt.
- Indicator light: (double-door equipment) There are five indicator lights, from top to bottom are door closing light, door locking light, running light, alarm light and end light. When the loading door and the unloading door are closed at the same time, the door closing lamp is on, and when the electromagnetic locks of the loading door and the unloading door are locked at the same time, the door locking lamp is on.
- Safety seat: The safety seat is equipped with a fuse, which is the protective umbrella of the control system to prevent excessive current from damaging electrical components. Equipped with cylindrical cap fuse.
- Vacuum pump contactor: PLC outputs signals to the vacuum pump contactor

coil. The contactor coil is electrically closed, providing three-phase 380V AC power supply to the pump, and the pump starts to operate.

- Pipeline pump relay: PLC outputs signals to the relay coil of the pipeline pump. The relay coil is powered on and closed to provide 220V power supply to the pump. The pump starts to operate and starts to enter water (if it is used for the first time and the water source is not under pressure or the pressure is low, water diversion shall be added in advance).
- Heating tube contactor: PLC outputs signals to the contactor coil of the heating tube. The contactor coil is electrically closed, providing a three-phase 380V AC power supply to the heating tube. The heating tube is electrically powered and starts heating.
- Heating film contactor (only applicable to equipment of 100L and below): PLC outputs signals to the heating film contactor coil, the contactor coil is electrically closed, AV 220V AC power supply is provided to the heating pipe, the heating film is electrically supplied, and heating starts.

4) Solenoid valve: The control system outputs a signal to the solenoid valve, so that the coil of the solenoid valve is electrically sucked on and the pipelines at both ends of the solenoid valve are connected. After the coil is powered off, the valve is closed.

5) pressure control:

- When the evaporator pressure reaches the upper limit of its set value, close the contactor for heating.
- When the evaporator pressure is lower than the lower limit of its set value, open the contactor for heating.

6) Pressure transmitter: The inner chamber pressure signal is converted into a current signal of 4 ~ 20mA, and then converted into a digital signal through the module, which is reflected in the touch screen to be the actual inner chamber pressure value.

7) Platinum thermal resistance:

- Working principle: Within a certain range, the resistance of PT100 is linearly proportional to temperature. As the temperature rises, the resistance value increases. The temperature decreases and the resistance value decreases. At normal temperature (20 degrees Celsius), the resistance value of PT100 platinum resistor is 107.79 ohms. The thermoelectric resistance value of PT100 is sent to the temperature transmitter, which is then transmitted to the analog module by the temperature transmitter. After conversion, the PT100 is sent to the touch screen to display its actual temperature value.
- Installation and use: Platinum thermal resistor is installed at the lower exhaust port of the chamber and cannot contact with pipe wall and accumulated water. The connection shall be firmly fixed to the terminal.

8) Pressure gauge: Refer to the Piping System section.

4.5 Working Principle of Control System

The control system uses a high-integration chip as the main control chip and a touch screen display as the man-machine interface. In the control, the analog quantity standard module is used for collecting temperature and pressure signals: the temperature measuring probe PT100 sends the resistance value signal to the controller and converts it into an acceptable digital quantity; The pressure transmitter for pressure measurement converts the pressure signal into a standard 4-20mA current signal, which is processed into a unit of quantities. The advantage of analog control is that the programmable controller can timely detect the continuous change of temperature and pressure during sterilization and display it on the man-machine interface.

Before work, all instrument parameters must be adjusted and preset according to the sterilization requirements of the sterilized articles, and the corresponding sterilization procedures and working methods must be selected. Please refer to Chapter 5 "Usage and Operation" for specific parameter settings.

1) Start up

Open the three-phase knife switch (or circuit breaker) in the power switch box, then open the switch (key switch) on the front panel of the equipment, turn the switch to the "On" position, and the switch is closed. The 220VAC power supply supplies power to the controller and the standard power supply (for + 5V/24VDC) in the control box through fuses, and the standard power supply supplies power to the touch screen and printer. When the power supply is turned on, the indicator light of PLC in the control box is on, the indicator light of standard switching power supply is on, the initial picture is displayed after the touch screen is self-checked, and the indicator light of the printer is on, all of which are in standby state.

2) Door control

First, turn on the power switch. For XG1. UCD pulse vacuum sterilizer, turn the door handwheel after closing the door, and rotate it for 1-1.5 turns after the door bolt is in place. After the door travel switch is closed, the input signal returned to the PC will enter the standby state when the front door display screen shows the door closing state and the rear door indicator light shows that the door state input has signals.

The front and rear door switches of the sterilizer are controlled by whether the sterilization program is running, the temperature of the inner chamber and whether there is pressure in the inner chamber, so as to ensure the safety of equipment and operators. For the double-door sterilizer, the isolation between the contaminated area and the sterile area can be effectively ensured. In standby state or at the end of the process, when the front door (back door) is opened, the electromagnetic lock of the back door (front door) pops open to lock the door to achieve the effect of isolation.

Note: If it is a single door (single door) sterilizer, there is no rear door indication.

3) Evaporator control

The system is powered on. After self-checking, the main controller is in

working state. If the low water level is not reached for water injection, the water level is heated after reaching and then the pressure of the evaporator is automatically maintained within a certain range.

If there is an jacket, the equipment jacket and the evaporator are connected. When the pressure reaches the upper limit of the evaporator pressure, the main heating stops heating, and when the evaporator pressure drops to the lower limit of the pressure controller for a period of time, the main heating starts heating again, thus circulating.

During the operation of the program (non-sterilization phase), if the water level is lower than the high water level for 3 minutes, the water injection pump (valve) will be opened for water injection, thus keeping the water level in the evaporator at the upper water level.

4) Steam inlet control in the chamber

After the key switch is powered on, each signal is processed by PLC, and the intake valve is switched and controlled according to the flow requirements.

5) Evacuation of the chamber

In the programs of "fabric", "instrument" and "BD", the chamber should be evacuated three times during pulsation to make the chamber close to vacuum so as to enhance the penetration ability of steam. After running the program, the pulsation stage is entered first after the preparation is completed, and the air in the chamber is pumped out by the vacuum pump through the evacuation valve. When the chamber pressure reaches the lower limit of pulsation, the evacuation valve F3 is closed to stop evacuation. When the chamber pressure reaches the upper limit of pulsation, the exhaust valve F0 opens, and when the chamber pressure drops to the evacuation turning pressure (default 30kPa), vacuum starts again. This cycle is repeated until the set number of pulsations is reached. After the pulsation is over, the evacuation valve F3 is closed and the vacuum pump stops running.

Causes of pulsation for three times: in general, the upper limit of pulsation is 80kPa, the lower limit of pulsation is 80kPa, evacuation is once, and the discharge

is 80%; When evacuated twice, the discharge rate is 96%; When evacuated three times, the theoretical value of discharge can reach 99.2%, so multiple pulsation vacuum effect is better, and the system pulsation setting can reach 99 times at most.

6) Steam exhaust from the chamber

- Exhaust Control in Non-Liquid Programs

After the sterilization phase is completed, the program is transferred to the exhaust phase. First, open the chamber exhaust valve F0 and start exhaust. When the pressure in the chamber drops to the evacuation turning pressure, the pump water valve F7 is opened, the evacuation valve F3 is opened, the vacuum pump starts to operate, and the exhaust speed is accelerated.

- Liquid program exhaust

In the liquid program, after the sterilization process is completed, the slow drain trap F5 is intermittently opened, and the steam in the chamber is slowly discharged through the slow drain trap, forcing the pressure in the chamber to slowly drop, thus preventing the liquid from overflowing through excessive boiling.

7) Dry stage

Due to the different properties of articles, when the drying stage is needed in vacuum programs such as instruments, fabrics and BD, when the pressure in the inner chamber drops to the exhaust zero position, the program shifts to the drying stage. The pump water valve and evacuation valve are opened, and the vacuum pump is operated to evacuate and dry. When the drying time arrives, the evacuation valve, pump water valve and vacuum pump stop running and the drying process ends.

8) Program End

In the programs of fabrics, instruments, BD, etc., when the drying time is up, the air valve F4 is opened, the air inlet pipeline of the chamber is unblocked, air inlet is started, and the pressure of the chamber is restored. When the pressure of the chamber reaches the zero position of empty return, the program is delayed and

turned to an end.

4.6 Exterior Decorative Panel

All exterior decorative plates of this equipment are routinely sprayed with carbon steel (stainless steel can be customized), with beautiful appearance and convenient disassembly and assembly. During the use of the equipment, if necessary, the two buckles in the middle of the exterior decorative panel on the left and right can be lifted, and the outer trim side cover can be removed by lifting up.

Chapter V Usage and Operation

After the sterilizer can be used normally according to Chapter 3 "Installation and Commissioning", turn on the total control power supply and water source of the equipment, turn the key switch of the operation end to the "ON" side, and the system starts self-inspection when powered on. The initial picture will appear on the text display during the self-inspection process.

* Special Tip: When the control system is abnormal, you can judge whether the control system is really abnormal or disturbed by power failure and restart.

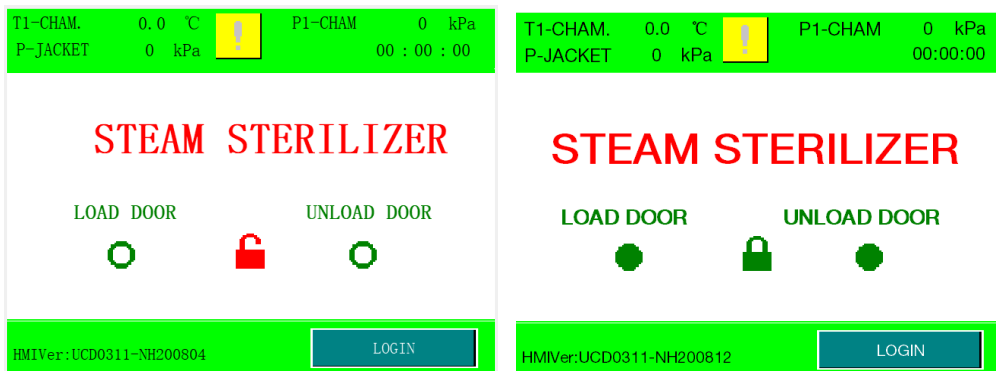


Fig. 1

Fig. 2

In the initial screen, the above picture shows the two indicating states of door closing and door lock respectively.

In the starting screen, the upper end of the display screen displays the pressure and temperature of the inner chamber, and the temperature of the pan wall will also be displayed if the heating film is used for heat preservation. The units are kPa and °C respectively; The second line of information shows the current time; The lower left corner displays the display screen program model and PLC program model, and the lower right corner is the login button.



WARNING After the sterilization of the liquid bottle is completed, when the temperature of the inner cabinet drops below 80 °C (in areas below 1000 meters above sea level) and the pressure of the inner chamber drops to zero, open the cabinet door to a gap of about 10mm and wait for about 10 minutes, then open the large cabinet door and take out the liquid bottle. When using liquid sterilization, the operating procedures must be observed!

5.1 Operation Instructions

- Description of key parameters of sterilization program:

Sterilization temperature and sterilization time are the key parameters that affect the sterilization process. During the sterilization process, the control system controls the lower limit of the sterilization temperature range in the sterilization room to be the set sterilization temperature and the upper limit to be the set sterilization temperature +3 °C . The combination of default sterilization temperature and time for this control system is shown in the following table. When non-recommended loads, non-recommended packages, or other combinations of sterilization temperatures and times are selected, relevant sterilization process verification is required before use.

Note: When the load, packaging and sterilization temperature are the same, it is considered that the sterilization effect with longer sterilization time is better than that with shorter sterilization time, and only the shortest sterilization time required can be verified.

SN	Program	134 °C pulse vacuum program	121 °C pulse vacuum program
1	Sterilize Temp.	134 °C	121 °C
2	Sterilize time	5 minutes	20 minutes

3	Overview of the scope of application of articles	Withstand high vacuum and high temperature tolerance, such as instruments and dressings.	Withstand high vacuum and low temperature tolerance, such as rubber.
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Note: The setting of each program parameter shall be corrected according to the specific situation or its own sterilization process during use. After the correction is completed, it shall be verified to be qualified, and finally the biological test shall be fully qualified before use.

This control system has compiled 13 sets of programs as shown in the following table. You can choose the application as needed. The following is an introduction to the operation flow of each program and the setting of working parameters.

SN	Program Type	Sterilization Temp.(°C)	Sterilization time (S)	Drying time (S)	Pulse count
1 #	Fabric	132	600	480	3
2 #	Instrument	132	600	480	3
3 #	Rubber	121	1200	480	3
4 #	Fast	134	210	210	1
5 #	Liquid	121	1200	---	0
6 #	Preheating	121	210	210	1
7 #	Custom 1	132	600	480	3
8 #	Custom 2	132	600	480	3
9 #	Lumen	132	600	480	3
10 #	BD	134	210	480	3
11 #	PCD	134	210	480	3
12 #	Leak	Vacuum test procedure: hold phase 300s, test phase 900s			
13 #	Dry	None	0	900	0

Table 1

Note: In the program (especially the fast program), if the temperature cannot rise (less than 2 °C lower than the sterilize temperature), the upper limit of the chamber pressure can be modified in Fig. 8 to increase the pressure (generally 10KPa, about 1 °C higher)

(1) Screen operation:

If the equipment uses jacket insulation mode, the boiler wall temperature will no longer be displayed in the operation screen.

After entering the startup screen, click Login to enter the login selection screen:

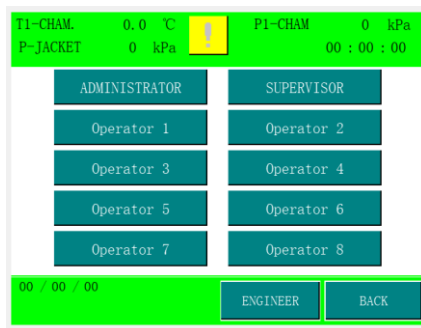


Fig. 3

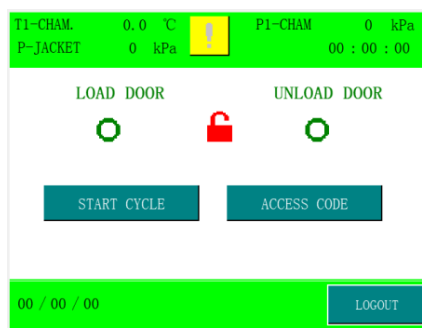


Fig. 4

There are administrators, craftsmen and eight operators. The administrator password and craftsman password are 149. The operator has no initial password. The operator or administrator and craftsman can set the operator password. The authority of technician is higher than that of operator, and that of administrator is higher than that of technician. The service personnel shall be logged in by the manufacturer's service personnel.

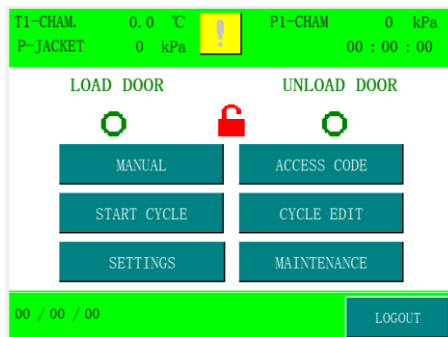


Fig. 5

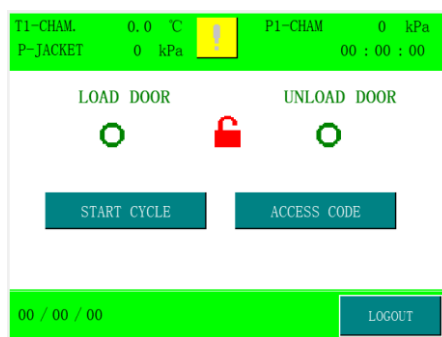


Fig. 6

Figures 4-6 show the login images of operator, supervisor and administrator respectively.

(2) Parameter settings after logging in with different permissions:

- Operator: The operator has no password by default and can log in directly. The operator can change the operator's password, for example, logging in to Operator 1, then the password changed under the logging in of Operator 1 is the new logging in password of Operator 1, and the operator can only select and start the program.
- Supervisor: The supervisor can change the password of the supervisor. After logging in, the supervisor enters the program selection screen Fig.10. After selecting the program, click Edit to enter the Fig 7. The process can modify some parameters of the sterilization process as shown in Fig 7 and 8. The sterilization temperature, pulse count, sterilize temperature, chamber pressure limit (upper limit), cooling temperature and drying time can be changed. The stage configuration in Fig.7 belongs to the standard configuration of the device and does not need to be set up.

Fig. 7

Fig. 8

- Administrator: On top of the supervisor's authority, some parameters of the program can be set. The system parameter settings are shown in Fig. 9 below. Parameters can be set for printing: printing time interval, whether F0 is printed, whether Chinese and English are printed, whether to print, and whether to print reports. Print trends are not standard for devices. Administrator permissions can change administrator, supervisor, and operator passwords (trend chart printing is not currently supported).

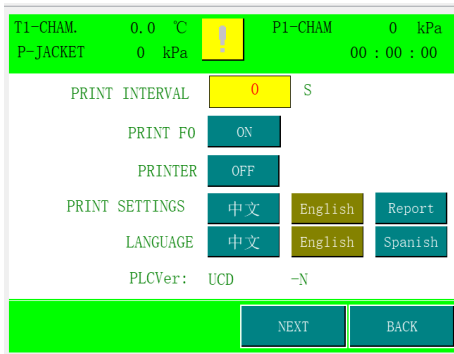


Fig. 9

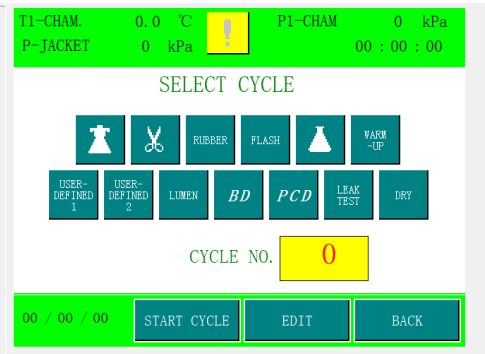


Fig.10

(3) Program selection and startup

Select program startup or program setting to enter the startup screen, as shown in Figure 11. When logging in as an administrator or technician, you can click the Edit button to set some sterilization parameters, as shown in Parameter Setting. Click the start program to enter the start parameter screen, as shown in Fig. 11. Click the start button to start the program.

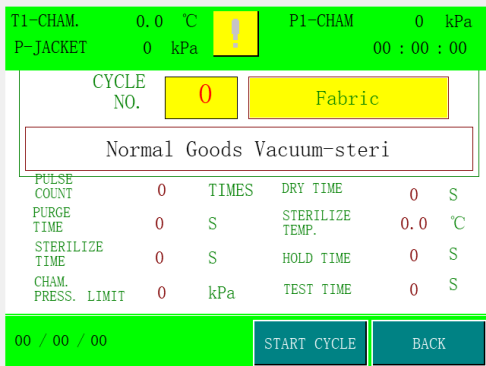


Fig. 11



Fig.12

(6) If the atmospheric pressure in the area where the user is located is not a standard atmospheric pressure, please contact the service personnel to set the relevant parameters and adjust the exhaust zero position and the return zero position.

(4) System Maintenance: After logging in with administrator rights, click the System Maintenance button to enter Figure 12 of the Time Setting screen. After modifying the time, click Time Save to return. MAC and IP do not need to be set up. When the equipment is monitored by the microcomputer, MAC and IP need to be set up, which is not the standard configuration of the equipment.

5.2 Parameter Setting:

1) Program parameter settings:

When entering Fig. 7 and 8 above the supervisor's authority, the sterilization parameters of the program can be modified:

The setting range is as follows:

Replacement time: set range [0 7200], default liquid program has replacement phase 300s

Pulse times: set range [0 99], defaults to 3 times

Sterilization temperature: set range [0 150], default 132 °C/134 °C

Sterilization time: setting range [0 7200], which varies according to different loads

Cooling temperature: set range [50 130], default 105 °C (except liquid)

Drying time: setting range [0 7200], which varies according to different loads

Chamber pressure limit: set the range [0 300] and set the corresponding value according to different sterilization temperatures.

Vacuum pump mode: In the pulsating phase, whether the vacuum pump will continue to work (the evacuation valve is closed) after the vacuum is finished and the air intake is started can be intermittent or normally open. Default break. This item is set to protect the vacuum pump.

Replacement time: the heating stage in the liquid program, when the steam enters into chamber from the jacket and discharges steam from the exhaust port, the purpose is to gradually replace the cold air in the inner chamber.

Pulse count: The function of pulsation is to forcibly empty the cold air in the sterilization room and sterilized articles by vacuum pump before sterilization. The amount of cold air removed determines the sterilization effect, and the number of pulsation times and the amplitude of pulsation determine whether the air is completely removed.

Sterilization Temperature: This temperature should be set according to

different sterilization articles and production processes. Different temperatures will have different effects on sterilized articles. High temperatures will require shorter sterilization time, otherwise longer sterilization time will be required.

Sterilization Time: The sterilization time should be set differently according to different sterilization articles and production processes, with a maximum of 9999 seconds (166.65 minutes). Sterilization time includes heat penetration time, heat death time and safe death time. Penetration time refers to the time required after the sterilization chamber reaches the set sterilization temperature and starts recording, and when the inside of the sterilized article also reaches the set sterilization temperature. Thermal death time refers to the killing time of microorganisms at the specified sterilization temperature, generally 121 °C (12 minutes), 126 °C (10 minutes) and 132 °C (3 minutes). The safe time is to ensure the effectiveness of sterilization. Generally, 1/2 ~ 1/3 of the thermal death time of microorganisms is taken.

Note: Too long sterilization time will affect sterilized articles!

Drying Time-This time should be set according to different sterilized articles and production processes, with a maximum of 9999 seconds (166.65 minutes). Drying depends on the high temperature of the jacket to maintain baking and the vacuum pump to maintain the vacuum degree of the chamber. After a certain period of time, the moisture in the sterilized articles is gradually volatilized and kept dry and clean.

Chamber pressure limit: refers to the highest set value of internal chamber pressure during operation. This pressure will be affected by the jacket pressure. In the process of heating and sterilization, when the temperature is low or high, this value can be slightly increased or decreased (generally, the increase or decrease of 10kPa corresponds to the increase or decrease of 1 °C). This value is set according to the relationship between the pressure and temperature of saturated water vapor. When the steam is supersaturated (overheated) or not saturated enough (the steam

contains too much water), the relationship between temperature and pressure does not correspond, and both overheated and unsaturated steam cannot achieve effective sterilization effect.

2) System parameter setting:

- Vent limit and exhaust limit: If the local atmospheric pressure of the user is non-standard atmospheric pressure, the return zero position and exhaust zero position shall be set accordingly, which requires the service personnel of our factory to set at the beginning of debugging.
- Upper and lower limits of pulsation: If users need to change, please consult after-sales service personnel.
- Time Setting: Change the time in the system maintenance options, and click Save to modify the current time of the equipment.

3) Special program description: liquid program

The liquid program sterilization load is non-sealed liquid articles, and the sealed liquid cannot be sterilized during sterilization. The sterilization time defaults to 20 minutes.

Replacement time-Before the liquid temperature is programmed, the inner chamber enters steam from the jacket and discharges steam from the exhaust port at the same time. Its purpose is to gradually replace the cold air in the inner chamber.

Sterilization Time: For liquid articles, it should be set according to the amount of liquid contained by referring to the table on the right. The sterilization time listed in this table is the minimum time required at the sterilization temperature of 121 °C. Appropriate correction should be made according to the specific situation during use. If a lower sterilization

Bottle Volume (ml)	Sterilization time (minutes)
75	20
250	25
500	30
1000	35
1500	45
2000	45

temperature is required, the sterilization time should be prolonged accordingly.

Discharge Pressure Difference-The liquid program adopts a slow discharge valve during the exhaust process to prevent the pressure in the sterilization chamber from dropping too fast and causing the liquid to boil excessively or the vessel in which the liquid is placed to explode. In order to further reasonably control the exhaust speed, the parameter exhaust pressure difference is introduced into the program, i.e. The value of the pressure in the inner chamber when the slow exhaust valve is opened each time. If the set exhaust pressure difference is 10kPa, the slow exhaust valve will be closed after the inner chamber pressure drops by 10kPa after opening, and the next opening time will be determined by the parameter exhaust interval.

Exhaust Interval: The time interval between each slow exhaust valve closing and the next slow exhaust valve opening during liquid exhaust. Setting this parameter can control the exhaust speed of the inner chamber by controlling the opening frequency of the slow exhaust valve.

5.3 Manual Operation

Users can manually operate the equipment after logging in with the rights of technicians and administrators, as shown in Fig. 13. Clicking the automatic button will switch to the manual operation state, and clicking on each component can switch it on and off. Among them, F0 inner chamber exhaust valve, F2 inner chamber intake valve, F3 vacuum extraction valve, F4 empty return valve, F5 slow discharge valve, F6 water injection valve (water injection pump), F7 circulating water valve, F8 evaporator pressure relief valve (manual ball valve), DR1 evaporator heating pipe, DR2 heating membrane (no heating membrane for jacket equipment). Two small triangles respectively represent the high and low water levels of the evaporator. Then click the Manual button to exit the manual operation. In the figure B is a vacuum pump. If XG1. C type equipment has no vacuum pump, evacuation valve F3, circulating water valve F7 and return valve F4.

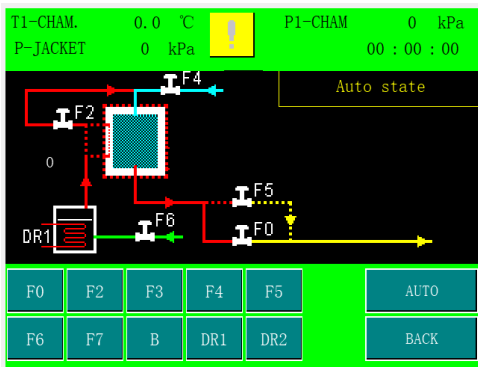


Fig. 13

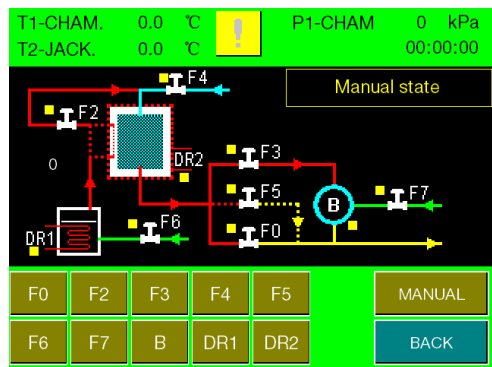


Fig. 14

Note: The heating pipe DR1, the heating film DR2 and the vacuum pump B cannot be manually opened for a long time, and the evaporator water level must be ensured to be higher than the low water level when opening the heating pipe. The pump should not work for too long without water.

5.4 Program Operation

After logging in with different permissions, select the startup program, enter the program selection screen as shown in Fig. 10, and select the corresponding program. If you need to modify the parameters, click Edit to modify the parameters. If you do not need to modify, click Start directly, enter the startup parameter screen as shown in Fig. 11, and click the startup program again to enter the main process screen as shown in Fig. 15.

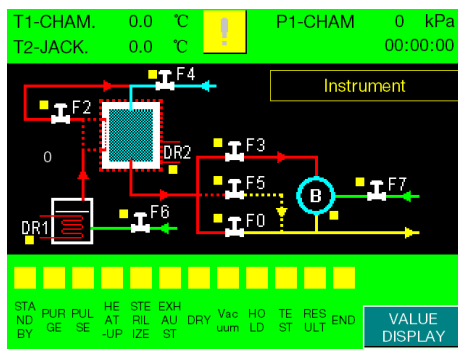


Fig. 15

1) First, the meter head is printed, and the preparation stage is carried out after the meter head is printed. The non-liquid program includes the following

stages, namely, "Preparation", "Pulsation", "Heating", "Sterilization", "Exhaust", "Drying" and "End" stages. Liquid procedures include: "Preparation", "Purge", "Heating", "Sterilization", "Exhaust" and "End" stages.



2) While the program is running, Click the numerical display button to monitor the running times and running time of each stage in real time from the screen, display the pressure and temperature in the sterilization chamber on the main process screen and display the current stage of the equipment, as shown in Fig. 15 (when the program is running or has been running, there is a light on the top of the stage, such as).

5.5 Precautions for Sterilization Operation

- During the operation of the program, the operator should not stay away from the equipment and pay attention to the operation of the equipment.
- Manual operation procedures can only be performed by operators who are familiar with the characteristics of sterilization equipment and articles to be sterilized.
- If the display does not respond, you can choose the mode of power failure and restart to check whether there is any problem with the control system.



CAUTION When using the sterilizer to sterilize below 132 °C, it is necessary to manually adjust the upper limit of the evaporator pressure controller to about +40 of the inner chamber pressure limit. For example, when sterilizing at 121 °C, it is necessary to manually adjust the evaporator pressure controller to 130-150kPa, otherwise the inner chamber temperature in the sterilization stage will exceed the sterilization temperature by 121 °C.

Precautions for liquid sterilization:

*** Please use liquid sterilization carefully to avoid accidents such as explosion and scalding, and strictly abide by the following operations;**

- Liquids can only be non-closed liquids
- Only the liquid can be sterilized by the liquid program. It is strictly prohibited to start the pump to evacuate after exhaust, otherwise bottle explosion and liquid boiling will occur.
- After sterilization is completed, when the temperature of the chamber drops below 80 °C (settable), open the cabinet door to a gap of about 10mm and wait for about 10 minutes, then open the large cabinet door and take out the liquid bottle.
- When loading or taking out the liquid bottle, you should handle it with care as much as possible to avoid turbulence, vibration and collision.

Chapter VI Troubleshooting



CAUTION In the process of use, we should be alert to every abnormal thing, such as pipeline leakage, compressed gas leakage, programs different from usual, etc.

6.1 Analysis and troubleshooting of common faults:

A. Equipment Alarm Information Table:

SN	Alarm information	Analysis
Alarm Code 1	The chamber temperature detection error, please check the wiring.	Check wiring, PT100, etc.
Alarm Code 3	Record temperature detection error, please check wiring.	Check wiring, PT100, etc.
Alarm Code 4	The boiler wall temperature detection error, please check wiring.	Check wiring, PT100, etc.
Alarm Code 7	The chamber pressure test error, please check wiring.	Check wiring, pressure transmitter, etc.
Alarm Code 12	Evaporator water level detection error.	Check wiring, water level relay, water level probe, etc.
Alarm Code 13	The evaporator is short of water.	Check the water source pressure to see if the inlet solenoid valve is damaged.
Alarm code 15	Vacuum pump protection.	Vacuum pump thermal protector overload protection, please reset the thermal relay, and check the thermal relay protection current, water supply, three-phase power supply, and whether there is foreign matter blocking the vacuum pump, etc.
Alarm Code 17	The door is not closed and the program cannot be started.	Programs cannot be initiated until the front (rear) door is closed
Alarm code 20	There is negative pressure in the chamber and the door cannot open.	Please wait until the pressure in the chamber is higher than the limit before opening the door.
Alarm	There is positive pressure in the	Please wait until the pressure in

code 21	chamber and the door cannot open.	the chamber is lower than the vent limit before opening the door.
Alarm code 23	The program is not configured and cannot be started.	Please ask the customer service personnel to configure the program parameters before starting the program.
Alarm code 25	Non-pulse vacuum equipment cannot run vacuum programs	Equipment without vacuum pump cannot run vacuum programs, such as lumen program, BD program, PCD program, leakage program and drying program.
Alarm code 30	Please configure the hardware parameters of the equipment for the factory-level service personnel.	The equipment configuration code has not been set, so after-sales personnel should be found to configure it.
Alarm code 32	Parameter has been initialized, please reset.	Sterilization parameters are restored to their default values and need to be set again as needed.
Alarm code 35	Evaporator water injection timeout.	Check the water source pressure to see if the inlet solenoid valve is damaged.
Alarm code 37	The temperature and pressure of the inner chamber correspond abnormally.	Check whether the steam quality is qualified and calibrate the temperature and pressure.
Alarm code 38	The chamber over-temperature alarm.	Check the steam quality and whether the chamber pressure limit is too high.
Alarm Code 44	Chamber over-pressure, please check.	Check the steam quality and whether the chamber pressure limit is too high.

B. Analysis and troubleshooting of common faults:

Any parts and electrical components have their own inherent service life, and faults are difficult to avoid. In order to help the operation and maintenance personnel find out the cause of the failure as soon as possible, the following lists some possible failures, possible causes of the failure, and treatment and elimination methods for reference.

Troubleshooting Table of Sterilizer

Failure	Possible causes	Solutions
1. After turning on the power, the display screen cannot work.	<ol style="list-style-type: none"> 1. The power supply of the display screen is not connected; 2. The fuse is blown out; 3. No 24V power supply 	<ol style="list-style-type: none"> 1. Check the text power supply; 2. Replace the fuse 3. Check the 24V power supply
2. The program does not start	<ol style="list-style-type: none"> 1. The cabinet door is not closed properly. 2. Alarm not eliminated 	<ol style="list-style-type: none"> 1. Please close the cabinet door 2. Check and eliminate alarms
3. Display Communication Failure	<ol style="list-style-type: none"> 1. The communication interface is burnt out due to live plug unplugging; 2. Poor contact; 	<ol style="list-style-type: none"> 1. Replace the communication line to check whether the interface is burnt out; 2. After shutdown, reconnect;
4. No display on the screen	<ol style="list-style-type: none"> 1. Poor communication line contact 2. No 24V power supply 	<ol style="list-style-type: none"> 1. Check communication and restart 2. Check the 24V power supply

<p>5. The pump evacuates too slowly and the negative pressure is not up to the standard.</p>	<ol style="list-style-type: none"> 1. There is leakage in the evacuation pipeline; 2. Improper adjustment of flow ball valve; 3. No water or the water pressure is low; 4. Pressure transmitter failure; 5. The one-way valve of the chamber drain pipeline is damaged; 6. Condensate exists in the pipeline system; 7. The evacuation valve or pump is not opened; 8. Too much fouling in the pipeline 9. Plateau issues 	<ol style="list-style-type: none"> 1. Check all connecting parts of the pipeline and carry out pressure keeping test; 2. Adjust that opening of the ball valve; 3. Check whether there is water supply; 4. Check or replace the pressure transmitter; 5. Repair or replace the check valve; 6. Check valves and pipelines and make necessary cleaning; 7. Check the solenoid valve or pump; 8. Carry out chemical descaling on condenser, pump and other pipeline systems 9. Absolute and relative pressures at high altitude are not consistent. Please refer to Table 3: Pressure Calibration Table
<p>6. The vacuum pump is noisy</p>	<ol style="list-style-type: none"> 1. The water source is not connected; 2. The angle of the pump inlet ball valve is too large. 3. Vacuum pump scaling is serious 4. The circulating water pressure is too high 	<ol style="list-style-type: none"> 1. Check the water source; 2. Adjust that opening angle of the ball valve; 3. Descaling pump and pipeline 4. Adjust ball valve angle
<p>7. Vacuum pump does not start</p>	<ol style="list-style-type: none"> 1. No power supply; 2. The vacuum pump is damaged; 	<ol style="list-style-type: none"> 1. Check the vacuum pump power supply; 2. Replace that vacuum pump;

10. Solenoid valve does not run	1. Coil failure; 2. Loose wiring;	1. Check the solenoid valve coil; 2. Check the solenoid valve wiring;
12. The jacket pressure is high but the inner chamber pressure cannot be increased or F2 cannot be opened.	1. The jacket trap is opened too large; 2. There is leakage in the pipeline 3. The pressure limit in the chamber is set too low. 4. Solenoid valve damaged 5. Loose wiring	1. Adjust the trap 2. Check steam leakage 3. Set the chamber pressure limit 4. Check the solenoid valve 5. Check solenoid valve wiring
13. Heating too slowly	1. Main heating is slow 2. That number of pulsation is less or the replacement time is short	1. Check the main heating 2. Increase that number of pulsations or prolong the purge time
14. The pressure is reached, but the temperature cannot rise.	1. The opening of the drain valve is too small, resulting in accumulated water in the drain pipeline; 2. The number of pulsations is too small. 3. The pressure in the chamber is slightly lower.	1. Adjust the opening frequency of the trap 2. Increase the number of pulsations (default three) 3. Increase that pressure limit of the chamber according to the actual temperature
15. That temperature is shown to be 0 or 200	1. The platinum thermal resistor is not connected properly.	1. Check platinum thermal resistance and reconnect
16. Pressure is not shown as-100	1. The pressure transmitter is not connected properly	1. Rewire

17. Temperature and pressure jump	<ol style="list-style-type: none"> 1. The ground wire is not connected properly; 2. There is a strong magnetic field around the equipment; 	<ol style="list-style-type: none"> 1. Re-grounding the ground wire; 2. Check the source of the surrounding magnetic field;
18. Temperature does not match pressure	<ol style="list-style-type: none"> 1. Correct temperature 	<ol style="list-style-type: none"> 1. Correct chamber temperature
19. Evaporator water level detection error	<ol style="list-style-type: none"> 1. Wiring error of water level float (probe) 2. Water level float (probe) damaged 	<ol style="list-style-type: none"> 1. The electrician rechecks the wiring 2. Check and replace float (probe)
20. Low Temperature Alarm	<ol style="list-style-type: none"> 1. The intake valve is blocked or the exhaust valve leaks 2. The cold air is not discharged cleanly. 	<ol style="list-style-type: none"> 1. Clean and check the solenoid valve 2. Raise the upper limit of inner chamber pressure Or increase the number of pulsations or replacement time.
21. Evaporator water injection timeout	<ol style="list-style-type: none"> 1. Insufficient water in the water storage tank 2. Blockage of the inlet filter 3. Evaporator Water Level Sensor Failure 4. Check the water injection pump (if any) 	<ol style="list-style-type: none"> 1. Fill up the water storage tank and try again 2. Please check the filter element of evaporator inlet filter 3. Replace the water level sensor 4. Add water diversion or overhaul and replace the water injection pump
22. Chamber over-pressure	<ol style="list-style-type: none"> 1. Intracavity pressure sensor failure 2. The temperature of PT100 in the cavity is low 3. The solenoid valve cannot be sealed 	<ol style="list-style-type: none"> 1. Please ask the electrician to check the circuit and replace the pressure sensor. 2. Contact the supplier to correct the deviation Step 3: Clean filters and solenoid valves

23. Chamber sensor failure	<ol style="list-style-type: none"> 1. Intracavity PT100 sensor disconnected 2. Intracavity PT100 temperature fault 	<ol style="list-style-type: none"> 1. Please check the circuit by the electrician and re-press the sensor connection in the cavity. 2. Examine that intracavity PT100
24. Over-temperature in sterilizer chamber	<ol style="list-style-type: none"> 1. The air intake solenoid valve cannot be sealed 2. Intracavity PT100 temperature fault 	<ol style="list-style-type: none"> 1. Clean the solenoid valve 2. Examine that intracavity PT100
25. The indicator light on the rear door panel is not on.	<ol style="list-style-type: none"> 1. Loose wiring; 2. The bulb is burnt out or the fuse is broken; 	<ol style="list-style-type: none"> 1. Loose wiring; 2. Replace bulbs or fuses;
26. The front and rear doors show pressure discrepancy.	<ol style="list-style-type: none"> The pressure gauge is not displayed correctly. 2. Pressure gauge damaged 	<ol style="list-style-type: none"> 1. Check the pressure gauge Step 2 Replace the pressure gauge
27. Possible faults of steam generator: (only applicable when the equipment has its own evaporator)		
No electricity	<ol style="list-style-type: none"> 1. The power cord is not connected properly. 2. Damaged control switch 	<ol style="list-style-type: none"> 1. Fix the power cord 2. Replace control switch
No water inflow	<ol style="list-style-type: none"> 1. Water level electrode fault 2. The inlet solenoid valve does not work when electrified. 3. Damage to water pump 4. Water level relay is broken 	<ol style="list-style-type: none"> 1. Maintenance 2. Maintenance 3. Replace 4. Replace

Water inflow does not stop.	<ol style="list-style-type: none"> 1. Upper water level detection fault 2. The inlet solenoid valve is not closed tightly. 3. Water level relay is broken 4. Manual opening of evaporator water injection 	<ol style="list-style-type: none"> 1. Maintenance 2. Maintenance 3. Replace 4. Turn the manual switch to the automatic state
No heating	<ol style="list-style-type: none"> 1. Water level electrode open circuit 2. Pressure controller contact damaged 3. Damage of electric heating pipe 4. AC contactor coil shall not be electrified. 5. Water level relay is broken 	<ol style="list-style-type: none"> 1. Maintenance 2. Replace 3. Replace 4. Check control loop 5. Replace
The pressure is out of control and the safety valve is open.	<ol style="list-style-type: none"> 1. The pressure control switch is not adjusted correctly. 2. Damaged pressure control switch 3. Pressure gauge failure 	<ol style="list-style-type: none"> 1. Readjustment 2. Replace 3. Replace

In a word, faults are often of various kinds, but no matter what kind of faults occur, the possible causes of the faults and the pipelines and circuits involved should be analyzed first according to the fault phenomena, then eliminated one by one, and finally the real fault points should be found for maintenance. Of course, if you don't know the working principle of the equipment and the purpose and installation location of various parts, you can't start. Maintenance should also know the structural principle of various parts and electrical components.

6.2 Analysis and Troubleshooting of Wet Package:



CAUTION The weight of dressing bag after sterilization is 3% higher than that before sterilization. This phenomenon is called wet package phenomenon.

- Loading problem: Is the loading capacity too large so that some packages come into contact with the wall of the sterilization chamber and condensed water seeps into the packages. Check whether there are any accumulated water vessels in the bag, so that condensed water cannot be drained during sterilization.
- Poor drainage pipes: Check whether there are too many corners in the drainage pipes, which are discharged from low to high, and whether there are impurities blocking the pipes.
- Damage to the one-way valve of the drain pipe in the chamber: This is manifested as wet outside and dry inside, and the water in the drain pipe flows back to the chamber during drying.
- The drying time is too short: increase the drying time appropriately to observe whether the drying effect is improved.
- Negative pressure does not meet the standard: check according to "Sterilizer Failure and Troubleshooting Table".
- Local wet package should be analyzed according to the specific wet package position and comprehensively investigated.

6.3 Analysis and elimination of unqualified sterilization:



CAUTION The three major elements of sterilization: saturated steam, sterilization temperature and time.

- Washing of articles: Check whether each washing process is strictly operated according to the working flow of the supply room to ensure the cleaning quality.
- Packaging of articles: whether the packaging is too large and tight, whether the packaging materials are breathable and other factors will affect the removal of cold air and the penetration of steam.
- Loading principle: whether the loading is placed according to regulations, whether the loading is too tight and the quantity is too large to affect the smooth circulation of steam.
- Residue of cold air: The amount of cold air removed determines the effect of disinfection and sterilization, so it is important to check whether the performance of sterilization equipment is normal. First, use B-D test paper for detection. If there is any problem, carry out pressure maintenance test or use manual operation to pass the inner chamber into steam to check whether there is leakage in pipelines and other places.
- Sterilization temperature: check whether the actual temperature in the package reaches the sterilization temperature and is consistent with the displayed temperature by using a point thermometer, check whether the inner chamber pressure and temperature correspond to each other, and appropriately increase the inner chamber pressure to see if the observation results have improved.
- Sterilization time: whether the setting of sterilization time is reasonable, whether the steam intake in the inner chamber is too fast, whether the penetration time is not enough, and whether the observation results are improved by appropriately prolonging the time.
- Faults of sterilization equipment: refer to the "Sterilizer Faults and Troubleshooting Table" for systematic investigation of the equipment.
- Improper detection method, repeated detection or other batch number reagents.

6.4 Problems that cannot be resolved:

After careful analysis and investigation, you may encounter some problems that cannot be solved through analysis. At this time, you need to make preparations in the following order:

- Record the model of the defective equipment and the cabinet number below the front end of the chamber.

For example: XG1.UCD-135M 20106447

- Recall any abnormalities in the operation of the equipment before the failure, the specific performance after the failure, and what inspections and adjustments you have made. Try to analyze the possible causes and parts that may be damaged, and record them.
- Contact the regional office or the company's after-sales service department to tell us what you know. We will give you technical guidance or arrange personnel to repair according to the situation you reflect.

Chapter VII Maintenance

7.1 How to check and replace the safety valve

In order to prevent the safety valve from being blocked, the steam pressure is released through it once a month during normal use.

1. According to the manual, carry out sterilization operation.
2. A pressure of 0.21 MPa was generated in the sterilization container.
3. Push the safety valve pull ring with a screwdriver so that it is open for approx. 2 seconds.
4. Turn off the main switch and terminate the operation. At that same time, the water vapor in the sterilization contain is discharged.
5. Wait until the pressure drops to 0MPa before opening the door.

Replace safety valve:

This operation is limited to professionals only.

1. Remove safety valve.
2. Replace it with a qualified safety valve. (Qualification criteria: ensure that the safety valve is opened when the pressure is between 0.24 MPa and 0.25 MPa).
3. Test a sterilization process.
4. Check the opening pressure and closing pressure of the safety valve once a year.

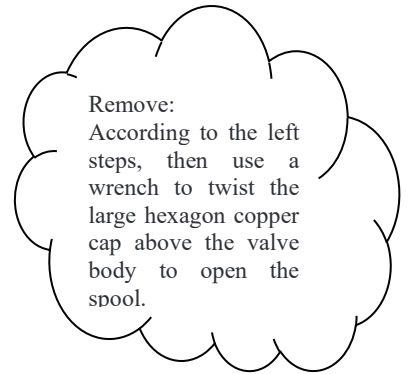
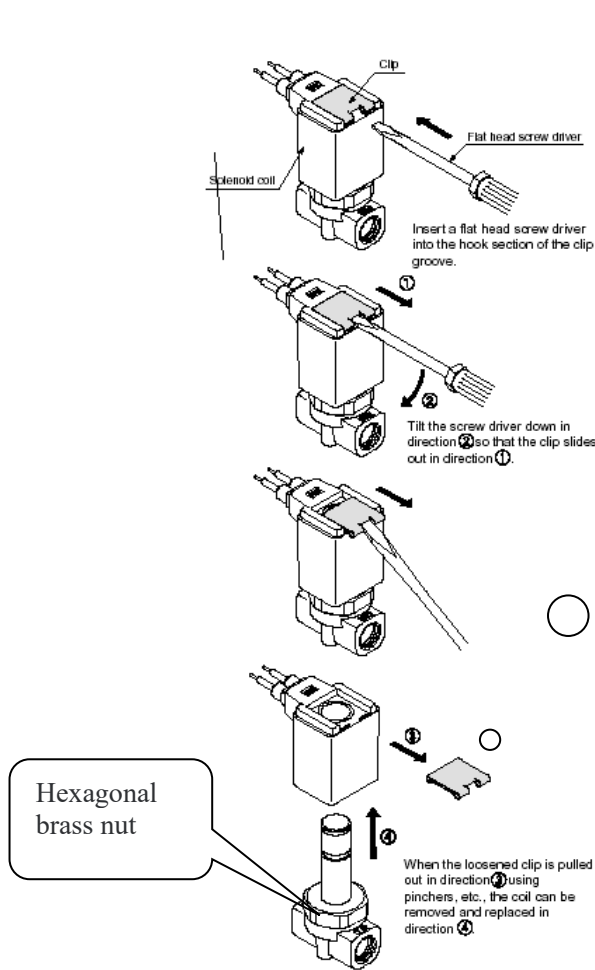
7.2 Procedures for Replacing Electric Heating Pipe

This operation is limited to professionals only.

1. Remove the rear cover of the sterilizer.
2. Remove the wiring on the steam generator heating pipe.
3. Remove the heating pipe.
4. Replace the damaged electric heating pipe with a new one.
5. Rewire.
6. Install sterilizer rear cover.
7. Test a sterilization process.

7.3 Cleaning of solenoid valve

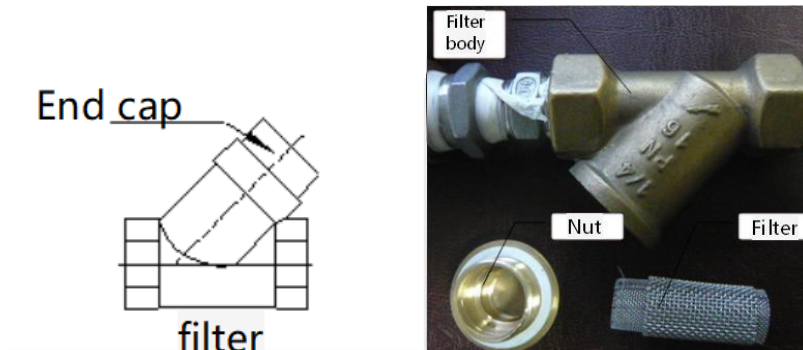
1. Remove the sterilizer housing.
2. Use a screwdriver to remove the stainless steel tablettes on the top of the solenoid valve to be cleaned or use a wrench to remove the nuts on the coil.
3. Lift solenoid coil.
4. Open the valve body with a wrench.
5. Rinse the solenoid spool with clean water.
6. Re-install the solenoid valve.



7.4 Cleaning of water inlet filter and drainage filter

1. The inlet filter is used to prevent foreign matters from entering the evaporator.
2. Drainage filters are used to prevent foreign matters from entering internal pipelines and solenoid valves.
3. Remove the filter gland with a wrench and take out the filter screen.
4. Clean up the sundries on the filter net with clean water.

5. Re-install the filter.



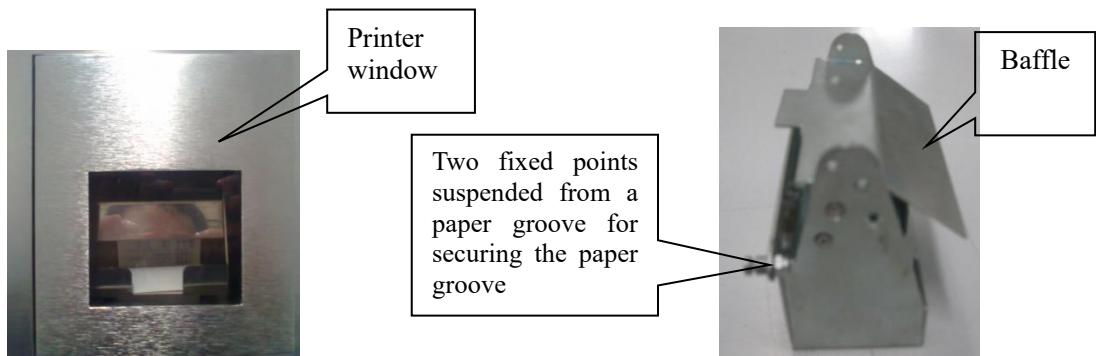
7.5 Replace the water level detection device



Warning: Make sure the machine is powered off.

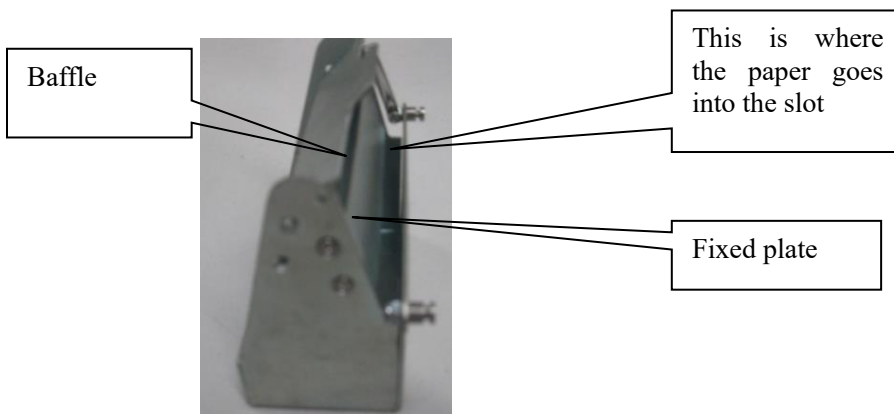
1. Remove the rear cover of the sterilizer.
2. Remove the wiring of high, medium and low water level probes.
3. Remove the high, medium and low water level probe.
4. Replace the damaged water level probe with a new one.
5. Re-install the water level detection device and connect it.
6. Install the sterilizer rear cover.
7. Re-test all working processes to prevent water leakage, wiring errors, installation jamming and other problems

7.6 Use and Maintenance of Origami Printer



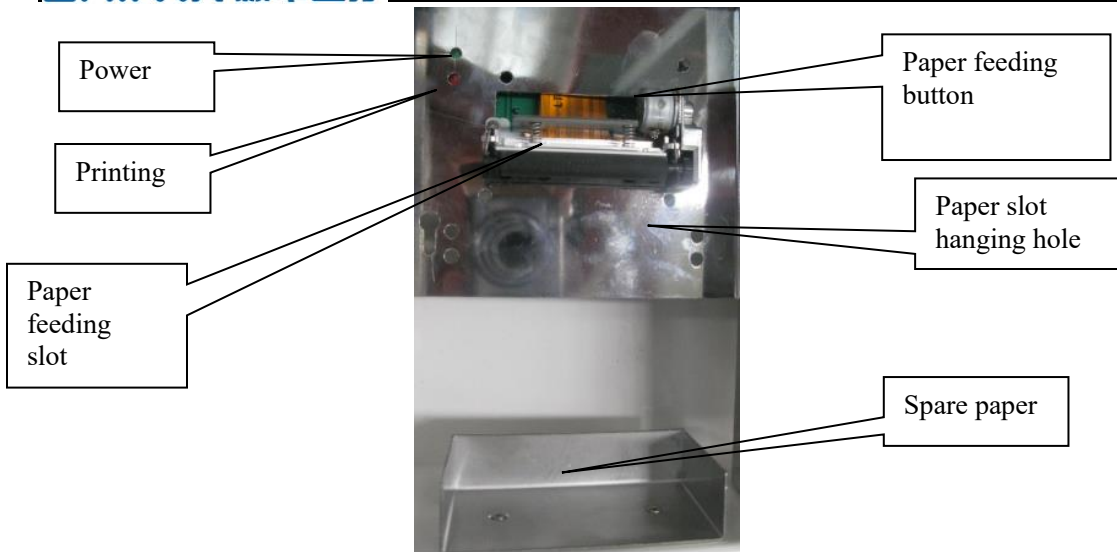
Press the lower right corner of the window door lightly, and the window door pops open. If you want to take out the origami hanging slot, you need to first press and hold the origami baffle with your hand, then lift the hanging slot upward and take it out.

The appearance of the printer is stored and printed. After holding down the baffle, the origami paper slot is shown in the following figure.



Note: Paper should enter the slot between the baffle plate and the fixed plate.

Press the lower right corner or upper right corner of the printer window door, and when you hear the faint closing sound of the switch, the window door can pop open. The printer uses origami to print, and the printed paper is automatically folded and stored in the paper slot.



Open the printer window and the appearance of the paper slot.

After opening the printer window door, as shown in the figure, the green light in the upper left corner is the power indicator light, the red print indicator light in the lower corner, and a paper feeding button in the upper right corner (when pressed, the printing paper will quickly feed); When the printer is working, the red indicator light is on. When replacing the printing paper, first remove the hanging paper slot, then insert the printing paper horizontally into the paper feed slot, press and hold the paper feed button in the upper right corner (power on), paper will automatically enter, and hang the paper slot for storing the recording paper.

7.7 Components that are only allowed to be maintained and replaced by professionals



CAUTION When replacing and maintaining the following accessories, please contact professional personnel for operation. Users are not allowed to

replace and maintain them without permission.

The following is a list of spare parts that are only allowed to be maintained and replaced by professionals:

Order No.: XG1.UCD-100M

SNr	P&ID	Name	Origin	Size/Range	Qty
1	F2	Solenoid valve	Japan	Rc3/8	1
2	F4, F5, F6, F7	Solenoid valve	Japan	Rc1/4	4
3	F0, F3	Solenoid valve	Japan	Rc1/2	2
4	B	Vacuum pump	Germany	Rc1	1
5	GB	Add pump	Italy	Rc 1/4	1
6	T1	Temperature probe	China	0 ~ 180 °C	1
7	NA	Air filter	China	R1/4	1
8	NA	Sealant strip	China	NA	2
9	NA	Travel switch	Japan	NA	2
10	NA	Pressure switch	Japan	NA	4
11	NA	Pressure transmitter	Switzerland	NA	2
12	NA	Control system	China	NA	1

Order No.: XG1.UCD-135M, XG1.UCD-185L

SN	P&ID	Name	Origin	Size/Range	Qty
1	F2	Solenoid valve	Japan	Rc3/8	1
2	F4, F5, F6, F7	Solenoid valve	Japan	Rc1/4	4
3	F0, F3	Solenoid	Japan	Rc1/2	2

		valve			
4	B	Vacuum pump	Germany	Rc1	1
5	GB	Add pump	Italy	Rc 1/4	1
6	T1	Temperature probe	China	0 ~ 180 °C	1
7	NA	Air filter	China	R1/4	1
8	NA	Sealant strip	China	NA	2
9	NA	Travel switch	Japan	NA	2
10	NA	Pressure switch	Japan	NA	4
11	NA	Pressure transmitter	Switzerland	NA	2
12	NA	Control system	China	NA	1

Order No.: XG1.UCD-300M

SN	P&ID	Name	Origin	Size/Range	Qty
1	F2	Solenoid valve	Japan	Rc3/8	1
2	F5, F6, F7	Solenoid valve	Japan	Rc1/4	3
3	F0, F4, F3	Solenoid valve	Japan	Rc1/2	3
4	B	Vacuum pump	Germany	Rc 1	1
5	GB	Add pump	Italy	Rc 1/4	1
6	T1	Temperature probe	China	0 ~ 180 °C	1
7	NA	Air filter	China	R1/2	1
8	NA	Sealant strip	China	NA	2
9	NA	Travel switch	Japan	NA	2
10	NA	Pressure switch	Japan	NA	4

11	NA	Pressure transmitter	Switzerland	NA	2
12	NA	Control system	China	NA	1

Chapter VIII Others

Any kind of disinfection and sterilization equipment, Whether in the form of lower exhaust or programmed automatic control, To achieve a reliable sterilization effect, In addition to the design, manufacturing quality and perfect maintenance of the equipment itself, the human factors for the success of sterilization are to correctly grasp the basic knowledge of sterilization and sterilization, to be familiar with the working principle of the equipment, to strictly follow the operation specifications of sterilization and sterilization, and to seriously treat each regulation related to sterilization.

8.1 Self-protection

During disinfection, the staff must have the awareness of self-protection and take self-protection measures to prevent injuries to personnel caused by disinfection accidents and improper operation methods.



CAUTION Sterilization equipment works at high temperature, special attention should be paid to burns.

8.2 Guarantee of Sterilization Quality

1) Ensure the cleanliness of sterilized articles

Cleaning is the key to successful sterilization, especially for some medical supplies that are difficult to clean. Studies abroad have found that

thorough cleaning can reduce the number of bacteria by 3-4 logarithms and greatly reduce the content of organic matter. If pollutants such as organic matter cannot be effectively removed, it will greatly reduce the activity of the sterilization agent, and bacteria hidden in the organic matter are not easy to be killed by the sterilization agent; Therefore, if the cleaning is not complete, the whole sterilization process will fail. It must be noted that the cleaning requirements cannot be reduced by prolonging the sterilization time and increasing the temperature of the sterilization agent. In order to facilitate and effectively remove organic matter, it is best to use enzyme-containing detergent to enhance the cleaning effect. Cleaning includes manual cleaning and machine cleaning. Manual cleaning is time-consuming and laborious, and cannot guarantee the consistency of each cleaning. In addition, medical personnel must wear waterproof masks, blindfolds, gloves, sleeves, hats, waterproof shoes and aprons during manual cleaning. Machine cleaning costs a lot, but it can ensure the consistency of cleaning. However, it must be noted that machine cleaning cannot completely replace manual cleaning. For some pipelines, fine instruments and parts that are difficult to clean, manual cleaning must be carried out. In addition, cleaning equipment must be cleaned and maintained frequently to avoid machine cleaning failure.



CAUTION Without proper washing, a high level of disinfection or sterilization

cannot be guaranteed.

2) Water quality control

The hardness of water is divided into two types: first, temporary hardness is mainly formed by bicarbonate of calcium and magnesium; Second, the hardness mainly formed by sulfate, nitrate and chloride of calcium and magnesium cannot be removed by boiling, so it is also called permanent hardness.

Because disinfection and sterilization equipment works under humid and hot conditions for a long time, impurities in water, such as dissolved oxygen, carbon dioxide, hydrogen sulfide, chloride, etc., whether gaseous or particulate, all produce intergranular corrosion to stainless steel and metal. Therefore, the PH value of water supply and steam supply for disinfection and sterilization equipment is required to be between 7 and 7.8, and boiler water and disinfection equipment water must be treated.

3) Environment of sterilization chamber

- The ground of the disinfection and sterilization room must be flat and smooth, with cement ground as the appropriate, with a slight inclination to the waste water discharge port to keep the operation area clean and dry. The roof should be equipped with a ceiling to prevent dust from accumulating. The walls should be flat and clean, and isolated from the washing, preparation and other studios.
- The discharge ports of waste steam and waste water must go through walls or be buried in trenches, or be discharged into the atmosphere; Do not allow

residual water and steam to return and invade the room.

- Install ventilation devices at appropriate positions on the top end face of the wall or ceiling.

4) Preparation and placement of articles

- Dressing fabric should be moderately tight when folding and wrapping to facilitate steam penetration.
- When the package is discharged on the shelf, a gap of 10mm shall be kept between them, and the loading capacity shall not exceed 90% of the volume of the chamber, so as to facilitate the smooth circulation of steam.
- Commercial aluminum lunch boxes and enamel boxes shall not be used to contain articles to be sterilized, and shall be packed with utensils with vent holes.

6) Requirements for sterilized articles

- A batch of similar articles should be sterilized as far as possible, and direct contact between the equipment bag and the cotton bag should be avoided.
- The volume of articles used for sterilization shall not exceed 30cm×30cm×50cm.
- The bundle of articles should not be too tight, and the chemical indication card should be placed in each bag for sterilization protection.

7) Clean sterilization chamber.

When the temperature of the sterilization chamber and shelf drops to close to room temperature, scrub with neutral detergent, then rinse with tap water, and

finally dry with a cloth that does not fluff.

Clean up the fiber chips and deposits attached to the filter screen at the front of the chamber to ensure that the vacuum rate, the smooth flow of condensed water and the temperature indication are consistent with the pressure.

8.3 Detection of Sterilization Effect

Detection of sterilization effect is a necessary means to evaluate whether the sterilization method is reasonable and whether the sterilization effect is reliable.

Detection methods are divided into three categories: physical, chemical and biological:

1) Physical mode:

① Instrument detection: The equipment is equipped with a pressure gauge to show the pressure of the jacket (if any) and the chamber. And the temperature and pressure values of the chamber are displayed on the touch screen, The equipment is also equipped with a micro printer, which can record the pressure, temperature and corresponding time values of each sterilization state in the sterilization process, as well as the properties of the use program, pulsation times, sterilization time, drying time, sterilization temperature and other parameters. The sterilization effect can be preliminarily judged by observing whether these values are consistent with the requirements.

② Point thermometer detection: The structure of the point thermometer is the same as that of the thermometer, but its maximum temperature can reach

180 °C, which needs to be thrown below 50 °C when in use. When in use, it is placed in the center of the sterilization bag, and the temperature of each point is tested by using a plurality of retention point thermometers. After sterilization, it is observed whether the displayed temperature value reaches the required temperature. The disadvantage of this method is that only the temperature can be displayed, and the duration of the point at this temperature cannot be expressed.

③ Thermocouple detection: The method is to put the electrode of the thermocouple into the part of the sterilizer to be tested, close the cabinet door and lead out the wire, analyze the data by the verifier, and display the temperature values of the tested points in time by the computer. The method can detect the uniformity of temperature and the stability of sterilization temperature at each point in the inner chamber of the sterilizer.

2) Chemical detection method:

① Chemical indication cards: This type of indication cards can be divided into chemical indication cards that can be used for pressure steam sterilization effect detection at 115 °C, 121 °C and 132 °C. When in use, a chemical indicator card that can indicate both temperature and temperature duration is put into the middle of the dressing bag to be sterilized. After one sterilization cycle, the indicator card is taken out and compared with the standard color for judgment. If the indicator color is darker than the standard color, the sterilization is qualified, otherwise, the sterilization is required again.

② Chemical indicator tape: The tape is coated with adhesive on one side

and chemical indicator on the other. It can be used as an indication to distinguish "sterilized" from "unsterilized" and can also be pasted on the surface of the dressing bag as a package seal. After the sterilization is completed, the uniform blackening of the indicator color can indicate whether the sterilization treatment has been carried out, thus further proving the possibility of successful sterilization.



CAUTION The chemical indicator used for testing must be approved by the Health Department and used within its validity period!

3) biological detection method:

Biological detection refers to the final detection method that uses living microorganisms to detect sterilized articles to identify whether all microorganisms in sterilized articles are dead and to evaluate whether sterilization equipment is qualified.

- Calibration indicator bacteria: The spores of "thermophilic adipose bacillus", which are the most difficult to be killed and have the strongest heat resistance in the world, are used as sterilization indicators.
- Medium: The medium used in the experiment is bromocresol violet peptone water medium.
- Detection method: Two thermophilic adipose bacillus spore tablets were put into sterilized small paper bags respectively and placed in the middle of the standard test package (package size 25cm× 30cm×30cm). The test package

was placed above the exhaust port in the sterilization room. After sterilization, the standard test package was taken out and put into bromocresol purple peptone water medium under aseptic conditions. The medium was cultured at 56 °C for 7 days to observe the color change of the medium. Negative control and positive control were set up during detection.

- Results: The color of all media did not change, which was determined to be qualified for sterilization. If it changes from purple to yellow, it is considered that sterilization has failed.
- Treatment: If the sterilization is not qualified, the batch of articles can be temporarily sealed to find out the possible causes of sterilization failure, and then the sterilization treatment can be resumed. The sterilization effect of the sterilizer can also be re-detected with the same biological indicator from multiple or multiple manufacturers of the same manufacturer. Carefully check the production date, effective date, damage and contamination of the biological indicator during cultivation.
- Other testing methods approved by the Ministry of Health are allowed to be used for biological testing of sterilization effect according to their instructions.
- The equipment shall be commissioned before normal use or after overhaul, and shall not be put into use until it has passed the biological tests for three consecutive times.

Physical detection, chemical detection and biological detection have

different purposes and meanings, so they cannot be replaced by each other and should be used in combination with each other.

Physical detection-can explain the operation status of sterilization equipment itself, and can intuitively display relevant parameters such as time, temperature, pressure, etc. in the working process.

Chemical detection-can detect whether the sterilization process has been completed, can understand the penetration of steam to the package, and can provide the first visual inspection at the moment after the sterilization is completed to assist in judging the sterilization effect.

Biological testing-mainly used for the final judgment of sterilization effect, but its cost is high and time is long, so it cannot be used per package or per pot.

4) Bauer-Dick test (abbreviated as B-D test)

The B-D test was designed by two Scottish microbiologists J.H. Bowie and J.Dick in 1963 to test the air exhaust effect of vacuum pressure steam sterilizer.

- Vacuum test chart: Indicator ink is made from a mixture of various chemicals through a certain carrier. Indicator ink is printed on paper of special size with certain air permeability through a specific printing method to form a certain pattern, thus becoming a B-D test vacuum test chart. The chemical indicator on the test chart is sensitive to residual air and can detect whether residual air exists in the test package.
- B-D test: This test should be carried out before the first sterilization every day. In the experiment, the vacuum test chart is placed in the middle of the

test package (disposable B-D test package can also be used), then the test package is placed at the exhaust port of the sterilization room, the cabinet door is closed, and the sterilization test is carried out according to the set sterilization parameters (134 °C 4min). After sterilization, the cabinet door is opened, the test package is untied, the test chart is taken out, and the test results are observed.

- Preparation of the test package: The test package consists of 46 ~ 50 cm × 80 ~ 90cm pure cotton cloth towels. The cloth towels are folded horizontally into three layers and then vertically into six layers. Stack the folded cloth towels one by one to a height of 25cm. When stacking, each layer of cloth towel is alternately arranged left and right according to the folding side so that the thickness on both sides is equal. After the cloth towels are arranged, the vacuum test chart is sandwiched between the cloth towels in the central layer, then wrapped with the cloth towel, and the outside is fixed with chemical indicator adhesive tape to form a test bag. The size of the whole test package is about 27-30cm in length, 23-25cm in width, 25-28cm in height and 4-5kg in weight.
- Results Judgment: The test chart turned black and uniform, i.e. The colors of the central part and the edge part were the same, indicating that the air was completely discharged and the sterilizer vacuum system was good, indicating that it could be used. If the color change of the test chart is uneven, the color of the central part is usually lighter than that of the edge part, indicating that

the air is not completely discharged and the sterilizer has poor performance.

Only after repair can it be used.

- Note: The cloth towel should be washed at least once before use, but should not be scalded, because excessive drying will affect the test results; For reused test bags, the cloth towel must be washed. During continuous tests, the bag should be opened every time, the cloth towel should be dried for 1 hour, and then repacked. Too wet the cloth towel can also affect the test results. The package should be loose, not too tight or too small.
- Necessary Conditions: Name of Sterilization Package; Sterilization date or expiration date; The name or code of the equipment checker and packer; There is a sterilization mark on the seal.
- The results only show the vacuum state of the equipment and the residual amount of cold air, and do not show whether the sterilized articles are qualified for sterilization.

8.4 Energy Saving and Environmental Protection

Although the protection of the environment and energy saving in the operation of the equipment have been fully considered in the design process, However, you may use this equipment for disinfection and sterilization of special articles, so you should contact our company in time so that we can make appropriate adjustments to the procedures you use to reduce consumption to a greater extent and save energy.

Appendix

Appendix A Operating Procedures

Appendix B Electrical Drawing

Appendix C Installation Drawing

Appendix D Intensity of Sterilization Factors

Appendix A Operating Procedures

Applicable to XG1.UCD

- ✓ Open the water source supply.
- ✓ Turn the power switch of sterilizer to “ON” side, make proper preparation for operation of the program.
- ✓ Open the door, loading the packages into the chamber, and make sure that there is clearance between every two packages and no packages contacts with inner wall or door plate.
- ✓ Log on and close the front door, select the appropriate sterilization program, start the program.
- ✓ In the course of sterilization, the operator may not get far away from this equipment, but shall closely observe the operation of equipment. If any abnormal situation is found, please handle it in time, so as to prevent the occurrence of any accident.
- ✓ Monitor the sterilization effect and properly make and retain the record, so as to ensure the traceability.
- ✓ After the sterilization is completed and the pressure in sterilizing chamber returns to zero, open the door and unloading the packages.
- ✓ After taking out the sterilized packages from the sterilizer, put it in an appropriate place, so as to prevent the secondary contamination.

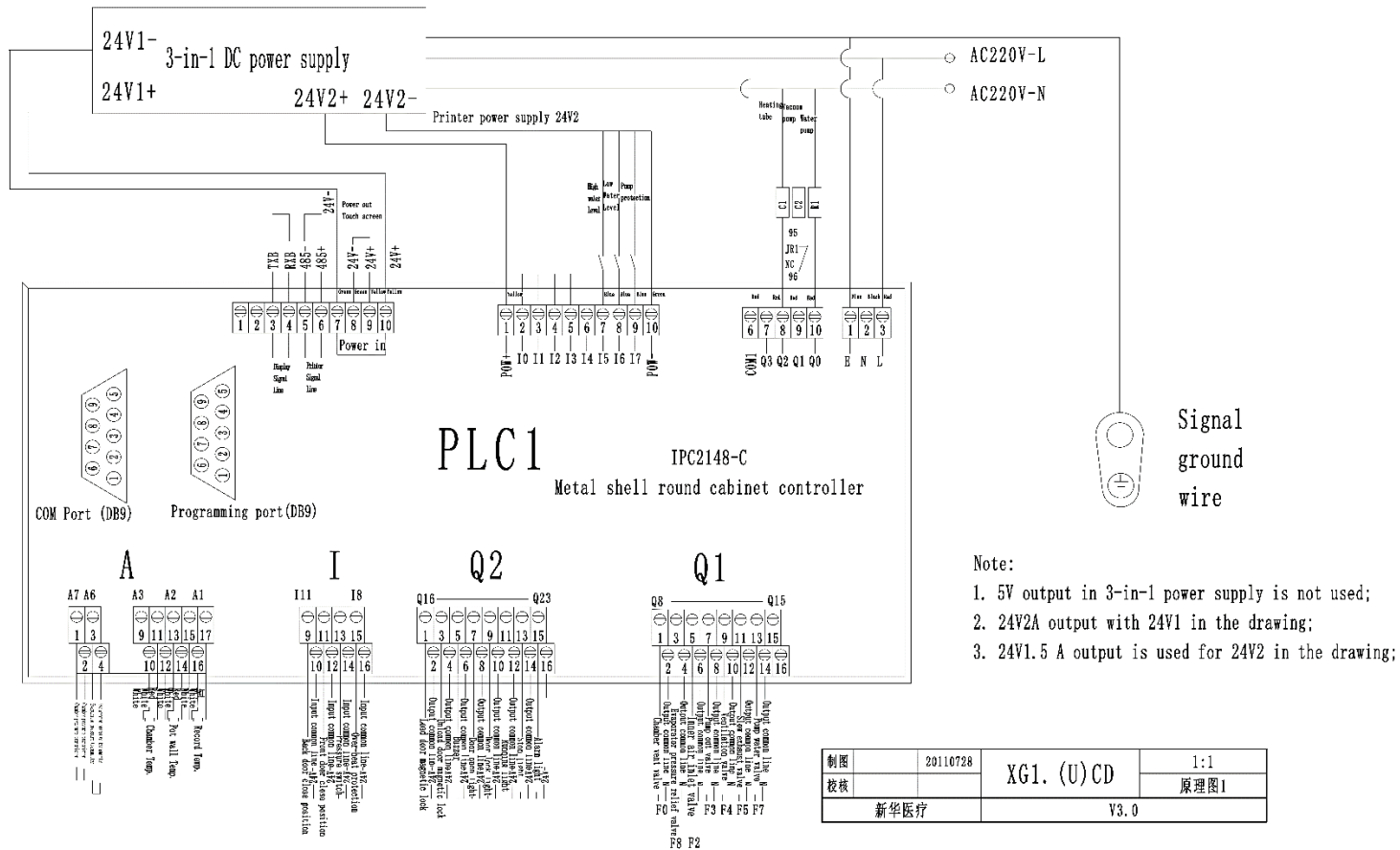
Works after Operation:

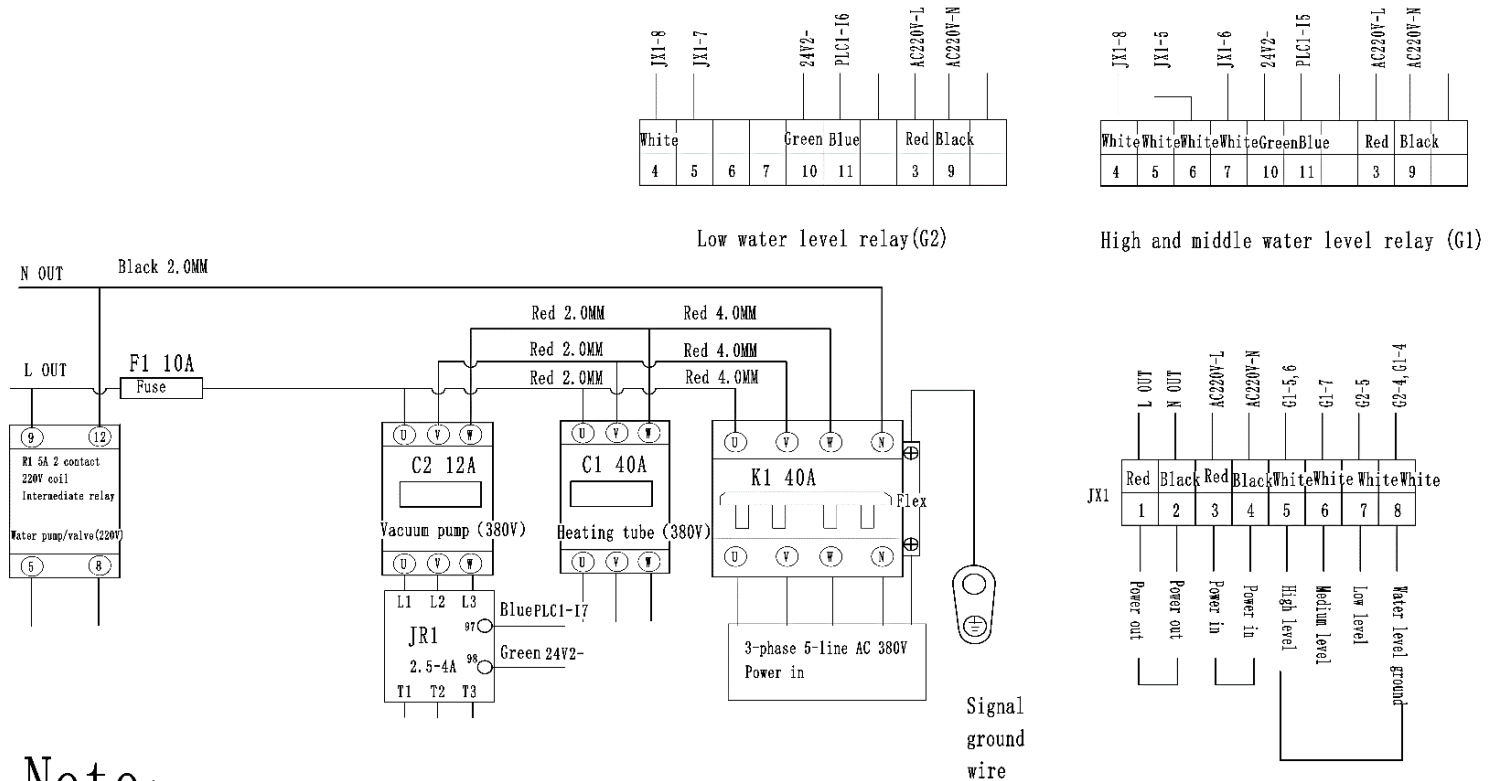
- ✓ Open the door, turn the power switch to “OFF” side, and cut off the power supply.
- ✓ Discharge the residual water in boiler (or fully discharge the water accumulated in boiler in accordance with the required interval).
- ✓ After the works are completed every day, please keep the inside and outside of sterilizer clean, clear away all dirt from the chamber, carry out simply maintenance once a week, and carried out thorough maintenance once a month.

Notices:

- ✓ No packages which has been sterilized may be placed together with unsterilized packages.
- ✓ The packages which have been successfully sterilized shall be marked with sterilization date and qualified sign.

Appendix B Schematic 1





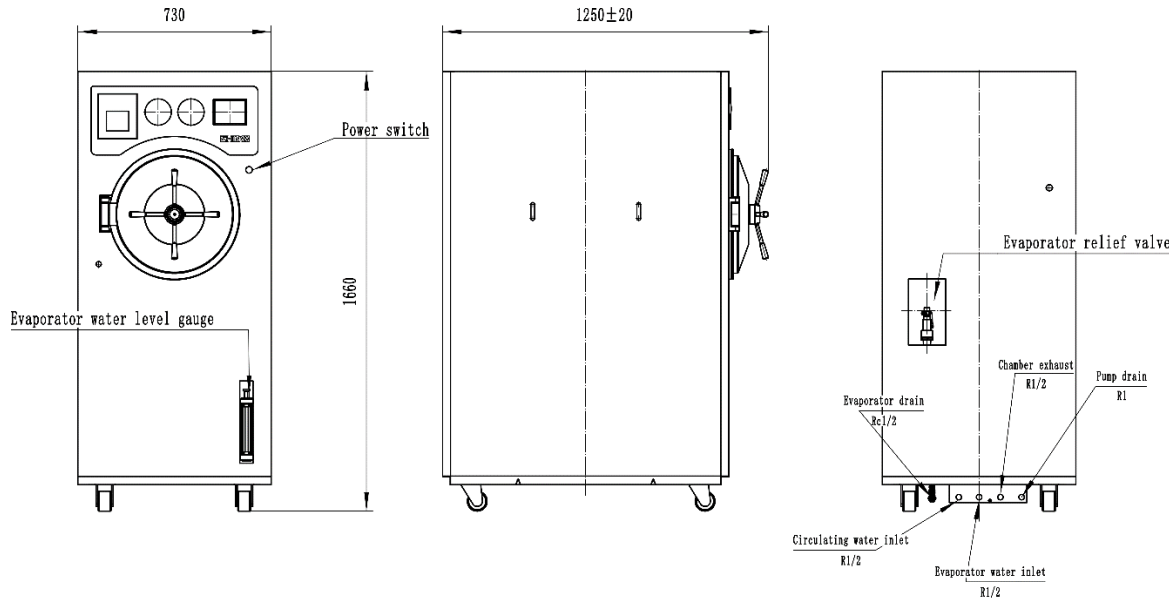
Note:

1: The normally closed contacts 95, 96 of the overload relay must be connected in series to the coils A1, A2 of the corresponding contactors.

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Appendix C Installation Drawing

XG1.UCD-100M



Power:

- ◆ Power not less than 11KW
- ◆ 380V/50Hz AC. Reliable grounding

Drainage: Lead the drainage pipe to the trench separately and drain it out of the room. Try not to communicate with other drainage pipes in the room, otherwise some vapor removed by the equipment during operation will affect other rooms. If there are multiple drainage outlets, they shall be led out separately.

Water source: reliable inflow ($\leq 25\text{ }^{\circ}\text{C}$, pressure 0.05-0.10 MPa). If the water source pressure is not within the required range, please adjust the pressure before starting the equipment. The water source should be soft water.

In order to observe the pressure of the water source in time and conveniently, a pressure gauge and valve with a measuring range of 0 ~ 0.4 MPa should be connected to the water pipeline entering the sterilizer so as to observe and control the water inflow.

! Note: Do not use water with too high hardness, otherwise it will affect the working performance of the pump and condenser.

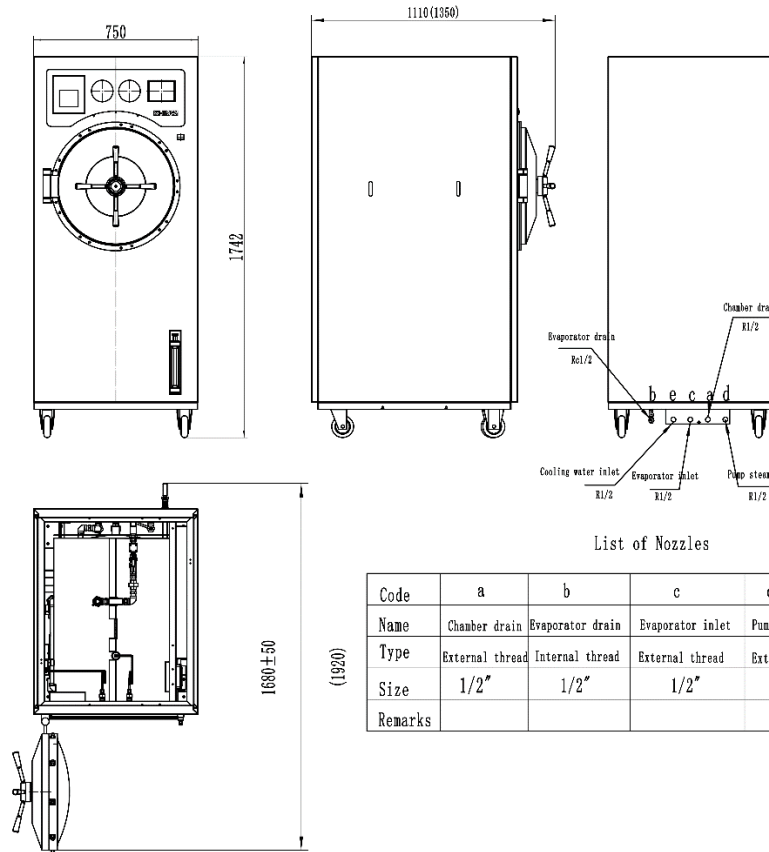
Power cord: The power supply of AC380V equipment shall be three-phase five-wire system, three-phase live wire, one zero wire and one ground wire. The zero line is light blue and the ground line is yellow-green. The load capacity of the user's power supply and power cord shall be greater than the load of the equipment. It is required to install a power switch box on the right or right rear wall of the sterilizer. A three-phase knife switch (or circuit breaker) and a single-phase knife switch (or circuit breaker) must be installed in the switch box.

Appendix C Installation Drawing

XG1.UCD-135M/185M

Technical Requirements

The size in parentheses is XG1.UCD-185M



1) Equipment Parameters

- a) Weight: 135L:350kg, 185L:430kg
- b) Overall dimensions (L*W*H): 135L:1110X750X1742mm, 185L:1350X750X1742mm

2) User supporting facilities

a) Power supply
380V\ three-phase five-wire\ 50Hz, with a power of not less than 11.5 kVA.
Circuit breakers of corresponding specifications shall be equipped according to the power of the equipment. The equipment shell must be strictly grounded, and the grounding device and connection shall meet the requirements of relevant standards and specifications.

b) Water
Cooling water:
Pressure: 0.15~0.3 MPa, clean water, hardness < 2mmol/L,
water temperature ≤ 20 ℃, peak dosage 1m³/h;
Evaporator water:
Pressure: 0.15 ~ 0.3 MPa, pure water, conductivity ≤ 15 μs/cm,
peak dosage 50kg/h

c) Drainage
Embedded pipe diameter ≥ DN100, high temperature resistant metal material, equipment without pressure drainage, cannot be mixed with other indoor drainage pipelines, it is strictly prohibited to connect steam source to equipment drainage pipelines.

D) Ambient temperature
When working, the temperature of the equipment installation area shall not be higher than 35 ℃.

E) Lighting
Explosion-proof lighting lamps are set in the installation area to facilitate equipment maintenance.

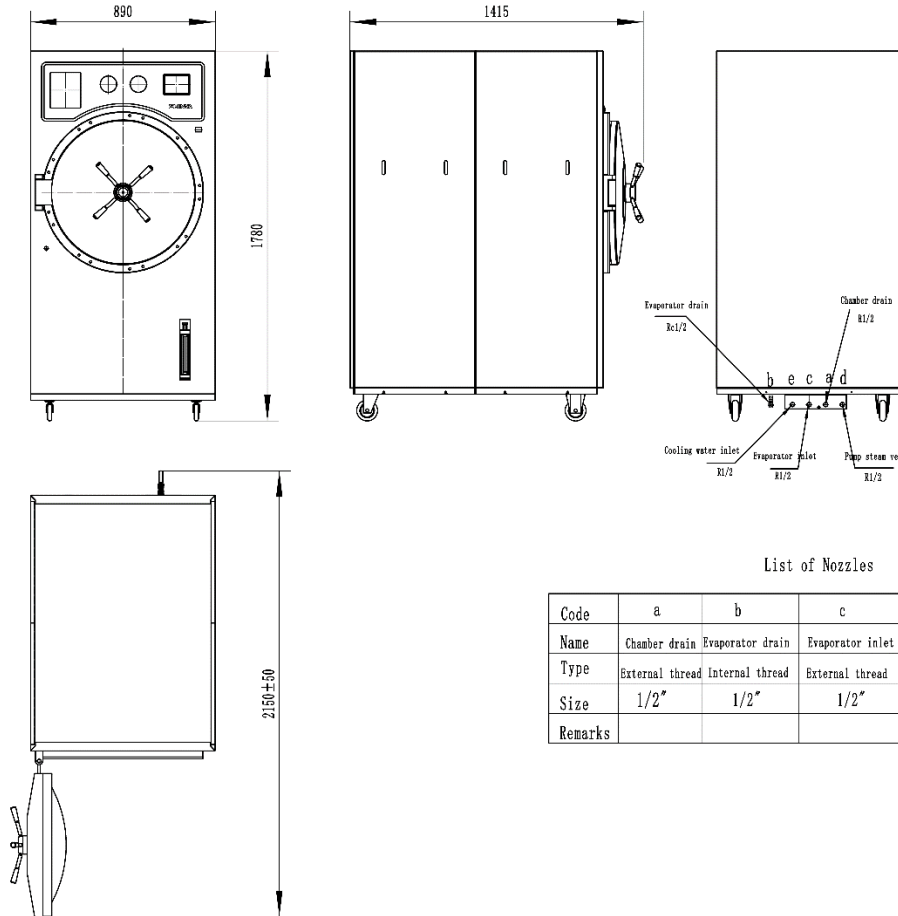
F) Ground flatness
Every 2 m² flatness ≤ 3 mm.

List of Nozzles

Code	a	b	c	d	e
Name	Chamber drain	Evaporator drain	Evaporator inlet	Pump steam vent	Cooling water inlet
Type	External thread	Internal thread	External thread	External thread	External thread
Size	1/2"	1/2"	1/2"	1/2"	1/2"
Remarks					

Appendix C Installation Drawing

XG1.UCD-300M



- 1) Equipment Parameters
- a) Weight: 610kg
 - b) Overall dimensions (L*W*H): 1462X890X1780mm
- 2) User supporting facilities
- a) Power supply
 - 380V three-phase five-wire\ 50Hz, with a power of not less than 18 kW.
 - Circuit breakers of corresponding specifications shall be equipped according to the power of the equipment. The equipment shell must be strictly grounded, and the grounding device and connection shall meet the requirements of relevant standards and specifications.
 - b) Water
 - Cooling water:
 - Pressure: 0.15~0.3 MPa, clean water, hardness< 2mmol/L,
 - water temperature ≤ 20 ℃, peak dosage 1m³/h;
 - Evaporator water:
 - Pressure: 0.15 ~ 0.3 MPa, pure water, conductivity ≤15 μs/cm,
 - peak dosage 50kg/h
 - c) Drainage
 - Embedded pipe diameter ≥ DN100, high temperature resistant metal material, equipment without pressure drainage, cannot be mixed with other indoor drainage pipelines, it is strictly prohibited to connect steam source to equipment drainage pipelines.
 - D) Ambient temperature
 - When working, the temperature of the equipment installation area shall not be higher than 35 ℃.
 - E) Lighting
 - Explosion-proof lighting lamps are set in the installation area to facilitate equipment maintenance.
 - F) Ground flatness
 - Every 2 m² flatness ≤ 3 mm.

List of Nozzles

Code	a	b	c	d	e
Name	Chamber drain	Evaporator drain	Evaporator inlet	Pump steam vent	Cooling water inlet
Type	External thread	Internal thread	External thread	External thread	External thread
Size	1/2"	1/2"	1/2"	1/2"	1/2"
Remarks					

Appendix D Intensity of Sterilization Factors

The temperature of XG1. U pulsating vacuum sterilizer of Xinhua brand was tested in the sterilization stage,

At 121 °C, the minimum temperature of small load temperature test in exhaust program is 121.14 °C, and the maximum temperature is 122.72 °C. The difference between each point at the same time is not more than 2 °C, and the maintenance time is 20min.

At 121 °C, the lowest temperature of full load temperature test of exhaust program is 121.27 °C, and the highest temperature is 122.62 °C. The difference between each point at the same time is not more than 2 °C, and the maintenance time is 20min.

The minimum temperature of 121 °C pulsating program small load temperature test is 121.02 °C, the highest temperature is 122.95 °C, the difference between each point at the same time is not more than 2 °C, and the maintenance time is 20min;

The minimum temperature of 121 °C pulsating program full load temperature test is 121.04 °C, the highest temperature is 122.64 °C, the difference between each point at the same time is not more than 2 °C, and the maintenance time is 20min;

The lowest temperature is 134.03 °C and the highest temperature is 135.78 °C in the small load temperature test with 134 °C pulsating program. The difference between each point at the same time is not more than 2 °C, and the maintenance time is 20min.

The lowest temperature is 134.01 °C and the highest temperature is 135.97 °C in the full load temperature test of 134 °C pulsating program. The difference between each point at the same time is not more than 2 °C, and the maintenance time is 20min.

The lowest temperature is 132.04 °C and the highest temperature is 134.54 °C in the small load temperature test with 132 °C pulsating program. The difference between each point at the same time is not more than 2 °C, and the maintenance

time is 8min.

The lowest temperature is 132.05 °C and the highest temperature is 134.64 °C in the full load temperature test of 132 °C pulsating program. The difference between each point at the same time is not more than 2 °C, and the maintenance time is 8min.

Note: The intensity data of sterilization factor comes from the prototype of sterilization factor intensity determination and detection.



Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declarație de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
<input type="text"/>	<input type="text"/>	<input type="text"/>	Xg1.U	<input type="text"/>	<input type="text"/>	shinva	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
DM000397637	AUTOCLAV	SHINVA	XG1.U		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.	Rg04- 000307	27-12-2022	

[Содержит\(\[Producatorul\], 'shinva'\) И Содержит\(\[Model\], 'Xg1.U'\)](#) [Очистить](#)



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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003076 0003 Rev. 02

Manufacturer:

Shinva Medical Instrument Co., Ltd.

Xinhua Medical Scientific Zone
Zibo New & Hi-Tech Industrial Development Zone
255086 Zibo
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer, Radiotherapy Simulator, Medical Electron Linear Accelerator, Dental Unit.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ19501033

Valid from: 2019-12-09

Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003076 0003 Rev. 02

Facility(ies):

Shinva Medical Instrument Co., Ltd.
Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial
Development Zone, 255086 Zibo, PEOPLE'S REPUBLIC OF
CHINA

Shinva Medical Instrument Co., Ltd.
No. 99 Beixin Road, Zibo New & Hi-Tech Zone, 255086 Zibo,
PEOPLE'S REPUBLIC OF CHINA

Shinva Medical Instrument Co., Ltd.
No. 2009 Xinhua Ave, Zhoucun, 255300 Zibo, PEOPLE'S
REPUBLIC OF CHINA



Certificate

No. Q5 003076 0004 Rev. 02

Holder of Certificate: **Shinva Medical Instrument Co., Ltd.**
Xinhua Medical Scientific Zone
Zibo New & Hi-Tech Industrial Development Zone
255086 Zibo, Shandong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Dental Unit, Dental Zirconia Ceramic, Medical High-energy Equipment (Medical Electron Linear Accelerator, Multi-leaf Collimator), Blood Irradiator, Remote Control After Loading Machine with Gamma Rays, Medical Laser Instrument Equipment (CTSim), Software (Radiotherapy Information System), Digital Medical X-ray Radiography System, Mobile Digit X-ray Unit, Digital X-ray Fluoroscope Radiography System, Digital Medical X-ray Photography System, Vehiclemounted Digital Medical X-ray Radiography System, Radiotherapy Simulator, Co-60 Therapy Unit, X-ray Equipment for Computed Tomography, Digital Mammography X-ray Equipment, X-ray Blood Irradiator, Digital Operation Room Equipment (Electric Operating Table, Operation Surgical Lamp, LED Surgical Lamp, Patient Transport Vehicle, Orthopedic Extension Device, Electric Multi-Purpose Obstetric Table, Electro-hydraulic Operating Table), Medical Ceiling Pendant, Moist Heat Disinfection and Sterilization Equipment, Dry Heat Disinfection and Sterilization Equipment, Chemical Sterilization Equipment, Washer and Disinfection Equipment, Autoclave, Rapid Automatic Washer-Disinfector, H2O2 Low Temperature Plasma Sterilizer, Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 003076 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_003076_0004_Rev._02)

Report No.: BJ20050106
Valid from: 2021-05-19
Valid until: 2024-03-18



Date, 2021-05-19

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 003076 0004 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Shinva Medical Instrument Co., Ltd.
No. 2009 Xinhua Ave, Zhoucun, 255300 Zibo, Shandong,
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Moist Heat Disinfection and Sterilization Equipment, Dry Heat Disinfection and Sterilization Equipment, Chemical Sterilization Equipment, Washer and Disinfection Equipment, Autoclave, Rapid Automatic Washer-Disinfector, H₂O₂ Low Temperature Plasma Sterilizer, Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer.





Shinva Medical Instrument Co., Ltd.
No. 99 Beixin Road, Zibo New & Hi-Tech Zone, 255086 Zibo, Shandong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical High-energy Equipment (Medical Electron Linear Accelerator, Multi-leaf Collimator), Blood Irradiator, Remote Control After Loading Machine with Gamma Rays, Medical Laser Instrument Equipment (CTSim), Software (Radiotherapy Information System), Digital Medical X-ray Radiography System, Mobile Digit X-ray Unit, Digital X-ray Fluoroscope Radiography System, Digital Medical X-ray Photography System, Vehiclemounted Digital Medical X-ray Radiography System, Radiotherapy Simulator, Co-60 Therapy Unit, X-ray Equipment for Computed Tomography, Digital Mammography X-ray Equipment, X-ray Blood Irradiator, Digital Operation Room Equipment (Electric Operating Table, Operation Surgical Lamp, LED Surgical Lamp, Patient Transport Vehicle, Orthopedic Extension Device, Electric Multi-Purpose Obstetric Table, Electro-hydraulic Operating Table) , Medical Ceiling Pendant, Dental Zirconia Ceramic.

Shinva Medical Instrument Co., Ltd.
Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial Development Zone, 255086 Zibo, Shandong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Autoclave, Dental Unit, Dental Zirconia Ceramic.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

	Shinva Medical Instrument Co.,Ltd. Xinhua Medical Scientific Zone Zibo New & Hi-Tech Industrial Development Zone 255086 Zibo PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Pulse Vacuum Sterilizer
MODELS:	XG1.DM,XG1.DW,XG1.H,XG1.U,MAST-A,MAST-H,MAST-C,MAST-V
CLASSIFICATION	IIb
GMDN CODE:	38671
CONFORMITY ASSESSMENT ROUTE:	ANNEX II EXCL. SECTION 4 OF MDD 93/42/EEC
WE, <u>Shinva Medical Instrument Co., Ltd.</u> HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/ EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE. WE IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.	
STANDARDS APPLIED: (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. EN 285:2015; EN 12347:1998; ISO 17665-1:2006; IEC 61010-1:2010+AMD1:2016; IEC 61010-2-40:2015; EN 61326-1:2013;EN ISO 15223-1:2012;EN 1041:2008;ISO 13485:2003; EN ISO 14971:2012;IEC 60204-1:2009;EN 10204:2004;EN ISO 9606:2017;EN ISO 9712:2012; EN ISO 15614-1:2017;ISO 14732:2013;MDD/93/42EEC; 2007/47/EC;2006/42/EC ; EN 62304:2006+AC:2008;EN 62366:2008	
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER:	 0123
(EC) CERTIFICATE(S):	<u>G1 003076 0003 Rev.02</u>
	MEDNET GMBH BORKSTRASSE 10, 48163 MÜNSTER, GERMANY
START OF CE-MARKING:	<u>09TH December, 2019</u> (Date or Lot or serial number)
PLACE, DATE OF DECLARATION:	ZIBO, 09 TH December, 2019
SIGNATURE:	 President