Pulse Vacuum Sterilizer

Operation and Service Manual

(BKQ-Z100H/150H/200H/300H)

Introduction

This manual is suitable for the installation, operation and maintenance of BKQ-Z series normal pressure steam sterilizer.

Welcome to use BIOBASE Normal Pressure Steam Sterilizer. To bring the maximum performance into full play and ensure that the product operate safely, please read the manual carefully first and strictly comply with the requirements of installation, operation and maintenance mentioned in this manual.

The following symbols in the manual are used to get highly attention and caution:

Caution: Highly attention should be paid.

Warning: The cases possibly cause equipment damage.

Danger: The cases possibly endanger personal safety.

Please read each chapter carefully and fully understand it before any operation, maintenance on the product especially the contents with the above symbols.

Please properly keep this manual away from loss and damage.
The operator has responsibility to renovate the manual and complete the lost, damaged or unsuitable contents.

Caution

Anyone in any situation cannot tear off any page from the manual. During the usage of the product, please do not hesitate to contact us if there is any inconsistent explanation or unmentioned cases. We will timely solve the problems and update or renew the manual for free.
This manual booklet should be stored in dry and ventilated place without high temperature.

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Chapter 1 General

1.1 The Sterilization Factor and Characteristics

The product adopts damp and hot steam as sterilization factor.
According to the specified sterilization process, the product, in the environment of high temperature, high pressure and high humidity with certain pressure and time, adopts saturated damp and hot steam as factor to sterilize the items which can be penetrated by steam.

1.2 Detailed Applied Scope of the Manual

This manual is applicable for the following products:

Design pressure:	**-0.1/0.28mpa**
Design temperature:	**150℃**
Max. working pressure:	**0.23mpa**
Vacuum limit:	**-0.08mpa**
Temperature range:	**105~136℃**
Temperature display accuracy:	**0.1℃**
Pressure display accuracy:	**1kpa**

The volume of the products will be different according to the models. All the parameters of the models mentioned above are same except the volume.

1.3 Special Messages of the Product

Warning:

The product is not applicable for bottled liquid with tight seal. Please contact us to order special liquid sterilizer.

Danger:

The bottle explosion that could endanger the personal and product safety may happen, if bottled liquid with tight seal is sterilized by this product.

Model	Volume (L)	Chamber Dim (mm)	Overall Dim (mm)	Net weight	Power (kw)
BKQ-Z150H	150	500×710（Φ×L）	1110×750×1742	400kg	10
BKQ-Z200H	200	500×950（Φ×L）	1350×750×1742	460kg	10
BKQ-Z300H	300	632×1000（Φ×L）	1400×890×1780	750kg	16

 **Caution:**

Since the chloridion is the important factor of corroding stainless steel, if the items that contain chloridion are sterilized by this product please wash the chamber everyday by clean water to increase the product service life. Otherwise, the chloridion may corrode the chamber.

 **Warning:**

The improper operation (i.e. sterilize the items that contain chloridion without washing the chamber everyday) that decreases the product service life is not included into our warranty.

 **Caution:**

In order to adopt proper measures when you see the  **sign in any place please consult the manual or other relevant document to clarify the potential danger.**

 **Caution:**

 **indicates high temperature, please protect yourself from scald when you see this sign.**

Chapter 2 Brief introduction

The hand-operated door sterilizer is applicable for medical liquid, instrument and dressing fabric in medical institution and pharmaceutical factory.

Warning: The product is only applicable for high temperature and humidity tolerance items not for oil or powder sterilization such as Vaseline.

Danger: Sterilization of bottled liquid with tight seal is forbidden since the bottle explosion that could endanger the personal and product safety may happen.

- **The door of the product is equipped by radial door bolt mechanism. The sealing ring adopts silicon rubber with good temperature endurance and flexibility. The electromagnetic lock which installed in the middle of the door is qualified by National Bureau of Quality Technical Supervision. The door cannot be opened in any case only if the chamber pressure is below 10Kpa.**
- **The upper device of the product adopts new type LCD to display graph, dynamic text and workflow, time, temperature, pressure and other parameters.**
- **The lower device adopts new type process control equipment.**
- **Pulse vacuum method is adopted to infuse the steam into chamber while discharge the air. The amount of discharged air from the chamber is above 99%.**
- **The models of single-door and double-door are available and the double-door product can be used to achieve segregation of contaminated and sterile area.**
- **The main control elements and valves are worldwide band that increase the stability and reliability.**
- **The design service life of the equipment is 8 years.**

Caution: The items will probably be affected by the hot steam (134℃).

Chapter 3 Technical parameters

1 Rated working pressure: **0.205mpa**
Rated working temperature: **132℃**
2 Pulse frequency setting range: **0~99 times**
3 Sterilization time setting range: **0~7200s**
4 Drying hour setting range: **0~7200s**
5 Pulse range setting: **positive 0~0.1mpa negative -0.08~0mpa**
Please refer to product installation diagram for other parameters.
6 Pulse range setting: **positive 0~0.09mpa negative -0.065~0.08mpa**
7 Pressure controller setting: **upper switching value: 0.23mpa**
lower switching value: 0.21mpa
8 Water: **softened water (0.15~0.3mpa)**
Please refer to product installation diagram for other parameters.

Chapter 4 Installation and Debugging

Caution: Proper installation is very important for product operation. Please do not neglect.

4.1 Product Unloading

Please pay attention to the following matters:

· Do not stand under the crane;
· Sufficient wide berth should be given around the lifting product;
· Use qualified crane;
· Keep the lifting product balanced;
· Pay attention to protect the packing plate.

4.2 Unpacking and Inspection

- **After unpacking please check the consistency between the model number (written on the nameplate) and purchase order;**
- **Please check each part of the machine and make a record. Contact us if there is any problem.**
- **Please carefully check the links and fastening parts whether they are loosing after a long distance transportation. If any, make the fastening for them.**
- **Please check and record the spear parts.**

4.3 Installation

For the product you ordered, please feel free to request the installation diagram from us.

Installation should be done under the instruction of specialist by qualified workers.

Warning: We are not responsible for any danger or product disfunction caused by improper installation

1 Preparations and requirements before installation

- **Space required: Considering the operation and maintenance of the equipment, the height of the space should be no less than 2.9m. The distance between the wall and the sides of the autoclave should be no less than 0.5m. For conveniently carrying the product, the depth of loading and unloading direction should be no less than 1.5 times of the product.**
- **Groundsill: If installed on the ground, the ground surface must be tamped and planished. If on the second floor or above, please consider whether to strengthen the floor.**

- **Airiness and heat dissipation: In order to assure the equipment work normally in comfortable working condition , please fix a suited airiness system that controlled the temperature in the range of 15 ~35℃ and humidity below 85% around the autoclave.**
- **Dewatering: The diameter of the drain pipe should be wider than the product water outlet. Please make sure the drain pipe fixed in the sewer and not connected with other pipe in the building. Otherwise the drain water from the product may affect other rooms.**

Caution: The drain pipe should be installed downward from the product water outlet; otherwise the sterilizing and drying results will be affected by undischarged condensate water. In the case that a drain pipe is connected with more than one product, please notice that the water flow of this drain pipe should be larger than the total of each product water flow. The material of the drain pipe should be thermostable, corrosion-resistant and aging-resistant. Please adjust the foundation bolt to ensure that the water outlet is the lowest point.

- **Water supply: The water is used for vacuum pump and steam generator. The size of the joint is 1/2 inner thread. Pressure requirement: 0.15~0.3map. For the flow requirement please refer to the installation drawing. A valve and a 0~0.6mpa pressure gauge should be installed in the water inlet pipeline.**

Warning: The vacuum program cannot be started if the pressure of water supply is less than 0.1map.

Warning: Only the softened water is allowed for the product build-in steam generator.

- **Electrical source: The standard product is AC 380v and three phases with five wires. Three of the wires are active line, one is zero line (light blue) and another is ground line (yellow and green). Also, a power box is required on the right or back wall of the equipment, in which a 3 phase breaker and a one phase breaker are needed.**

To ensure person and equipment safety, please join a wire with the ground and reliably join the wire marked "ground "in the control cable with ground.

Danger: The hull of product and steam generator must be safely

grounded.

All the pipe lines should be well fixed.

Cautions:

1) Installation is not allowed in a place of conductive particles, corrosive gas, and inflammable gas.

2) Installation should avoid any places with possible electrical shock and vibration.

3) Places of high temperature, high humidity or accessible to rain are not suitable for installation.

4) Places of high magnetic intensity are not allowed, either.

2 Product positioning

- **Move the product to certain position. Do not injure the trim cover during moving.**
- **Take the documents out from the packing bag and carefully store them.**

3 Balance adjusting

Please adjust the balance after positioning the product.

4 The connection of water, power and steam

Please connect the water and power with the product accordingly. To avoid leaking, filling material should be used in the layup of the pipe. Keep the product away for any leaking pipe.

Warning: The earth wire must be grounded!

Warning: Please install the leakage protection to avoid safety problem during installation.

4.4 Debugging

According to the relevant standard, the program of the product is partly set before sale and the program parameters could always be modified if necessary. Please refer to Chapter 5 for detailed parameter setting.

- **Before debugging, please check whether the wires are well fixed and the water inlet/outlet are correctly connected.**
- **Turn on the water-in valve and air compressor. Check whether the pressure has met the requirement. Otherwise, do not carry out the following debugging.**

1) Vacuum pump direction of rotation

Switch on the power and login to the manual operation as an administrator or higher authority. Click B (vacuum pump) to turn it on. Make sure its direction of rotation is clockwise, otherwise, swop any two of the wires on the

three-phase load switch.

2) Check whether the valves work well

In manual operation state, click the corresponding mark to turn on the valve (F2 air-in valve; F3 vacuum valve; F4 vacuum breaking valve; F5 slow discharge valve; F6 water injection valve; F7 pump water valve).

3) No-load test

- **Before starting the program, please carry out the leakage test according to Chapter 5. If there is any leaking point please repair it and retest.**
- **Parameter setting: Please refer to Chapter 5.**
- **After setting the parameters, users could run the program according to Chapter 5. During the operation please check the tightness of the pipeline and door.**

4) Load test

Load test should be carried out after the no-load test. For the load test, the loading capacity of the non-liquid items should not exceed 80% of the chamber volume. All articles should be put on the rack and leave 10mm gap between packs.

Caution: Parameter modification is allowed during debugging.

Chapter 5 Mechanical Features and Operating Principles

The product is made of chamber body, door, frame, pipe line system and control system. The sterilizing effect is achieved by steam (medium), high temperature and pressure.

5.1 The Main Body

- **The main body adopts double jacket structure to keep certain temperature inside the chamber that decreases the condensate water.**
- **The chamber adopts imported anti-corrosion stainless steel, which welded and polished by professional welding and polishing machine, to keep the chamber surface smooth and corrosion-resistant.**
- **The outer board adopts good thermal insulating material which could decrease the thermal radiation effectively.**

5.2 The Door

The door is made of door board plate, bolt and lock, gasket rubber, hinge plate, door cover, hand wheel, pressure safety lock and control elements.

① Door opening direction

- **For the double-door sterilizer, the front door is installed on operating end and the back door is on the other end of the sterilizer.**
  Double-door sterilizer opening direction:
  Front door: open to right hand side
  Back door: open to left hand side
  Single-door sterilizer opening direction: open to left hand side

② Door cover removing

Firstly, remove the lid in the middle of the hand wheel, and then twist down the screw in the middle of the decoration cover plate to remove the hand wheel base. Remove the screws on top left and bottom right of the door cover. Now hold the cover and lift it to take it off.

③ Bolt and lock

Turn the hand wheel manually to lock the door. The door equipped with 9 bolts to support door locking. The bolt gaskets are well adjusted before sale, please do not readjust it.

- **Door closing**

Shut the door and turn the hand wheel clockwise. The bolts will be plugged into the front cover plate. Keep turning the hand wheel until "click" is heard then continue turning it a circle or half to fully close the door.

It is forbidden to turn the hand wheel when the door is open!

- **Door opening**

Turn the hand wheel anti-clockwise to open the door.

Caution: The door can be open only if the chamber pressure is same as atmosphere pressure!

- **The door switch**

The switch, which acted by bolts oppressing, is installed in the door cover. For the double-door sterilizer, there is one such switch on each door. Before start the system, please make sure both doors are well closed. Otherwise the system will not be started.

④ Pressure safety lock

The door equipped with double-proofed connection. There is a travel switch on the bottom left of the door plate to control the door opening and closing. The electromagnetic lock will acted by starting the system. In this case the door cannot be opened until the sterilization is finished (chamber pressure ±10kpa).

⑤ Bolt permanent seat (back)

The bolt permanent seat (manual door), which has been used for two years and above, will probably be damaged. This mostly due to improperly open or close the door. Please avoid any improper operation on the door.

⑥ Gasket rubber

- **Structure**

It is an annular rubber processed by specific technique. Its composition, design, proper installation and maintenance are fairly important for its service life. We adopt high quality rubber material, which has better stability and reliability, to ensure the gasket works effectively in high temperature condition.

- **Working principle**

The gasket rubber, which is fixed on the sealing ring seat, is pushed to the front sealing plate when the door is closed.

- **Maintenance**

Although the material and design of the gasket rubber has been fully considered, the following factors still can affect the rubber service life. Please carefully read these factors and avoid during the operation.

a. To protect the gasket rubbers from high temperature please shut the master pressure valve timely and open the door after each working shift.

b. Take the gasket rubber off and clean it with alcohol once or twice a year. Put it back when it gets dry.

c. During the usage, please protect the rubber from any tough item to avoid sealing invalidation.

d. Regular cleaning will well affect the gasket rubber.

- **Invalidation**

a. The rubber becomes tough and has no flexibility. Reticular lines are found.

b. There is fissure on the rubber or it has already been damaged.

Caution: Please carefully judge whether the gasket rubber is invalidation. The judgment mostly depends on the experience of the operator.

- **Un/installation**

When it is necessary to take out the gasket rubber, please make sure all the programs are terminated.
Simply plug the rubber into the sealing groove to install it.
Since the perimeter of the rubber is larger than of the groove, it is required to fix the rubber evenly.

Tip: Two people will be better to fix the gasket rubber.

⑦ **Faults and elimination**

Phenomena	**Reasons**	**Correct Operation**
1. The door cannot be opened.	**1. Residual pressure in the chamber.** **2. The program is running.** **3. The chamber temperature is higher than the allowable limit.** **4. Electromagnetic lock faults.**	**1. Wait till the chamber pressure back to zero then open the door.** **2. Terminate the program.** **3. Wait till the temperature decrease to allowable limit then open the door.** **4. Check the electromagnetic lock and the wiring.**
2. The door cannot be closed.	**1. The door is displaced and prolapsed.** **2. The bolts are not in position.** **3. Drive system damage.** **4. One of the bolts is blocked.**	**1. Adjust the position of front sealing plate.** **2. Turn the hand wheel to have the bolts back in right position.** **3. Check the drive system.** **4. Adjust the position of bolts holder and the height of the gasket.**
3. Steam leaking.	**1. Sealing gasket damage.** **2. The door is not fully closed.**	**1. Change the sealing gasket.** **2. Adjust the door position after chamber exhausting.**

5.3 The Pipeline System

1. Jacket air admission pipeline

For those products with build-in steam generator, the steam is generated by heating the softened water in the generator. The steam enters into the jacket through the outlet (on the top of the steam generator) and the connector (on the bottom of the chamber). The steam in the jacket protects the chamber from cold air and maintains the chamber temperature at a certain level, so that the steam condensation is decreased effectively.

- **The following configurations are adopted to fully develop the function of the steam generator:**

a. The main body of the generator adopts high quality seamless steel tube and welded by professional welding technique.

b. The electrical-heated tube is made of stainless steel tube which has small volume and long service life.

c. The water pump is high quality heat resisting pressure pump which has small volume and good reliability.

d. The water level is controlled by three probes ("high" "medium" and "low"). The glass water level indicator is installed on the outer decoration cover to show the water lever of each working stage.

- **The steam generator is equipped with the following auto-control functions:**

a. Automatic water adding. The water pump will work automatically when the water level has been under "high level" for three minutes. It also automatically stops adding water as soon as the water reaches "high level".

b. Automatic pressure control. The power will be shut automatically if the pressure of the steam generator rises up to the upper limit. The power will not be switched on until the pressure decreased to the lower limit.

c. Automatic switch off. In any case of that the water level decrease to "low level", the pump is switched off automatically to protect the electrical-heated tube.

d. Automatic overpressure self-protection. In any case of that the pressure exceeds the upper limit, the safety valve will release the pressure automatically to protect the operator and product.

2. Chamber air admission pipeline

The steam enters into chamber from the jacket through valve F2.

3. Vacuum pipeline

It is used for discharge the air, steam and condensate water from chamber.

- **Vacuum valve F3: it is controlled by executive program.**
- **Vacuum pump: it is water-ring pump. Please keep adding water into it to make sure it can work normally.**

  Note: The temperature of pump water supply should be no more than 25℃.

4. Drain pipeline

The condensation water released out from the outlet, which is on front bottom of

the chamber, through the electromagnetic valve, ball valve and one-way valve.

5. Air exhaust pipeline
The steam from the chamber is exhausted through the outlet (on front bottom of the chamber), filter, electromagnetic valve and one-way valve.
Both the air exhaust and admission pipeline use the same electromagnetic valve.
6. Air-in pipeline
The air enters into chamber via the filter and valve F4 to eliminate negative pressure.
7. Water supply pipeline
The purified water flows into the steam generator through the filter, water-adding electromagnetic valve and water pump. The normal water enters into vacuum pump through pump valve for water circulation.
8. Pressure control pipeline
The product equipped with pressure controller, pressure transmitter, platinum thermistor (PT100) and jacket and chamber pressure gage.

- **Pressure controller**

It is applicable for controlling the working pressure within certain range. The controller is adjustable.

Caution: The pressure controller is well adjusted before sale. If necessary, only licensed operator can readjust it.

- **Pressure transmitter**

Please refer to the relevant information 5.4.

- **Platinum thermistor (PT100)**

Please refer to the relevant information 5.4.

- **Safety valve**

It is applied for safety protection when the pressure is above the upper limit.

- **Pressure gage**

It is the indicator of the chamber and jacket pressure.

5.4 The Structure Principles of the Control System
The control system consists of the master controller, monitor, micro thermal printer, electromagnetic valve, pressure controller, pressure transmitter, indicating light and gages.
1. Front control panel
It is installed on the front cover. The monitor, printer and key switch are included.

- **Monitor**

-displays diagrams and dynamic text
-convenient touching-screen
-good communication function

- **Pinter**

-high quality printing
-low consumption
-small volume
-records start time, operating frequency, operator number, program type, and all program parameters.

2. Back control panel

It is only available for double-door sterilizer. It is equipped with five indicating lights and a chamber pressure gage.

- **Indicating lights**

-operating (green)
-door closed (yellow)
-door locked (yellow)
-alarm (red)
-terminal (green)

3. Master control cabinet

- **Master controller**

-powerful function
-the main element adopts American large scale integration chip
-high reliability
-superior to traditional PLC
-higher cost performance and easy to use
-it is widely used in controlling industry
-power: 24VDC; working environment: 0~55℃

The equivalent circuit of this controller consists of the following four parts:

a. Input
-accepts operational order
-accepts all types of information of controlled object
-controls the operation and exchanging of program

b. Control
-it is customer-editing program
-the controlling program is stored in ROM

c. Output
-drive load by program execution directly or through intermediate relay

d. Analog quantity exchanging
-five-way analog quantity input
-twelve-digit exchanging accuracy
-exchange the standard current signal into digital quantity (i.e. temperature and pressure)

Caution: The earth wire must be reliable grounding to avoid temperature and pressure fluctuation.

- **Buzzer**

  The buzzer alarms if any improper operation happens, or the termination of the sterilization.
- **Indicating lights**

  -operating (green)
  -door closed (yellow)
  -door locked (yellow)
  -alarm (red)
  -terminal (green)
- **Fuse base**

  -The base equipped with fuse which is used for protecting the control system from excessive current.
- **Vacuum pump contactor: supply three-phase 380V AC power for the pump.**
- **Pipeline pump relay: supply 220V power for the pump.**
- **Heating tube contactor: supply three-phase 380V AC power to heat up.**

4. Electromagnetic valve

The control system outputs the signal to control the electromagnetic valve.

5. Pressure controller

-The contactor will be shut off if the pressure of steam generator reaches upper limit.

-The contactor will be turned on if the pressure of steam generator decreased lower limit.

6. Pressure transmitter

The chamber pressure signal will be exchanged into 4~20mA current signal firstly, then into digital signals (i.e. chamber pressure value).

7. Platinum thermistor (PT100)

- **Working principles**

  There is linear relation between PT100 and the temperature within certain range. At normal temperature (20℃)，the resistance value of PT100 is 107.79Ω. The resistance value is transferred from PT100 to temperature transmitter. The analog quantity accepts the value and transferred to the touching-screen after exchanging the value signal.

8. Pressure gage

Please refer to the relevant information in 5.3.

5.5 The Operating Principles of the Control System

The master control chip of the control system adopts high-integrated chip and touching-screen monitor as human-computer interface. The collection of temperature and pressure signal achieved by analog standard module:

-The controller exchanges the resistance value signal, which is transferred from PT100, into acceptable digital quantity;

-The pressure transmitter exchanges the pressure value signal into 4~20mA current signal.

The advantage of analog quantity control is that the continues changing of temperature and pressure could be simply inspected and clearly displayed on the screen.

Please careful adjust and set gage parameters according to specific requirements before operation. Please refer to Chapter 6 for parameter setting.

1. Power supply

Turn the key switch to "1" position to get 220VAC power supply.

2. Door control

-turn on the power switch

-turn the hand wheel to close the door

-the travel switch works to transfer signal

-the front door screen displays that the door is closed

-the back door indicator light is on

Note: the back door indicator is only equipped in double-door sterilizer.

① Steam generator controlling

② Chamber air admission controlling

③ Pulse heating controlling

④ Chamber air exhausting

⑤ Drying stage

⑥ Program termination

3. Steam generator control

Check whether the water reaches the certain level. The steam generator will start working only if the water reaches the certain level. The pressure of steam generator will be kept in certain range.

4. Chamber steam-in control

Once the power is switched on, all signals will be processed by PLC according to the processing requirements to control the steam-in valve.

5. Chamber vacuum

In the programs of 'fabric', 'instrument' and 'BD', the equipment needs to pulse 3 times to vacuum the chamber so that improve the steam penetrability. In vacuum stage, the air comes out from chamber via vacuum valve and pump. The vacuum valve F3 will close when the chamber pressure reaches the lower pulse limit. When the chamber pressure reaches the upper pulse limit, the equipment starts to vacuum again. After 3 times of pulse the discharge rate of air will be 99.2%.

6. Chamber exhausting

- **The exhausting control of non-liquid program**

  The program turns into exhausting stage after sterilizing stage. The chamber exhausting valve F0 will be opened firstly. The pump water valve F7 and vacuum valve F3 will be opened when the chamber pressure decreases to certain value. The vacuum pump starts working to boost exhausting speed.

- **The exhausting control of liquid program**

  In liquid program, steam will be discharged from chamber via valve F5. The chamber pressure decreases slowly to avoid liquid spill caused by over boiling.

7. Drying stage

The program turns into drying stage when the chamber pressure decreases to certain value. The pump water valve and vacuum valve will be opened in this stage. When the drying time is up the pump water valve, vacuum valve and vacuum pump stop working.

8. End of program

After drying stage the air valve F4 will be opened to recover the chamber pressure.

5.6 The Outer Plate

The entire outer decoration plate adopts carbon steel with spraying plastics (stainless steel is also available to order). During the usage, the plate could always be removed if required.

Chapter 6 Operation

After installation and debugging according to chapter 4, please turn on the power and water supply. Switch the key to "1" to initiate the product self-checking. The process of self-checking will be displayed on the screen.
Suggestion:
If the control system works abnormally please restart the system to check whether it is under interference.

P1

P2

 unlock  lock

In the initial display, the two pictures above show the status of unlock and lock. In the initial display, the chamber pressure (kpa) and temperature (℃) are showed on the top of the screen. The second line of information shows the current time. The display screen and PLC program number are showed on the bottom left corner. The "Log on" button is on the bottom right corner.

 **Warning: After sterilization for bottled liquid, do not open the door until the chamber temperature is below 80℃ (in the area that below 1000m altitude) and the pressure is back to 0. Then slightly open the door (keep 10mm gap) and wait for 10 minutes. Now open the door widely and take out the bottled liquid. Please follow this regulation during the liquid sterilization!**

6.1 Operating Instructions

- **Key parameters instruction:**

  Sterilization temperature and time are the key parameters. During the sterilization the control system is applied to keep the temperature between upper limit (+3℃) and lower limit (set by operator).

Notice:
In the case of that the load, packing, temperature are same, the result of long time sterilization is better than the short time one. The test can only be used for the short time sterilization.

No.	Program	134℃ pulse vacuum program	121℃pulse vacuum program
1	Sterilizing Temperature	134℃	121℃
2	Sterilizing Time	5mins	20min
3	Scope of application	The items that are vacuum/heat resisting (i.e. instrument and dressing).	The items that are not vacuum/heat resisting (i.e. rubber).

The parameters setting could be modified according to specific conditions but biological testing is required after any modification. The results of the test should be qualified.

The following table indicates the 13 programs set in the sterilizer. Please choose according to your requirements.

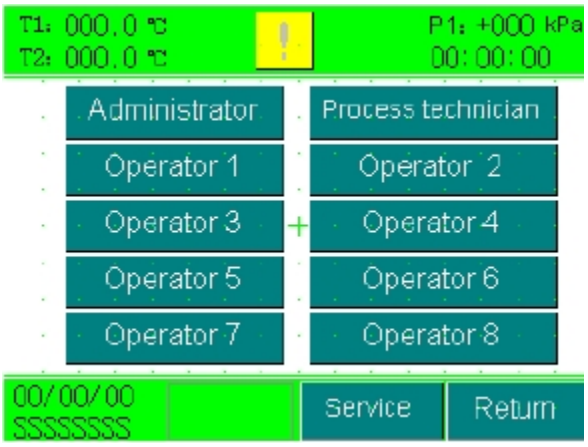
Code	Type	Temp. of Ster.	Time of Ster.	Time of drying	Pulse
1#	Fabric	132	600	480	3
2#	Instrument	132	600	480	3
3#	Rubber	121	1200	480	3
4#	Rapid	134	210	210	1
5#	Liquid	121	1200	----	0
6#	Preheating	121	210	210	1
7#	User-defined1	132	600	480	3
8#	User-defined2	132	600	480	3
9#	Lumen	132	600	480	3
10#	BD	134	210	480	3
11#	PCD	134	210	480	3
12#	Leakage	Vacuum test: maintain stage 300s, test stage 900s			

13#	Drying	----	0	900	0

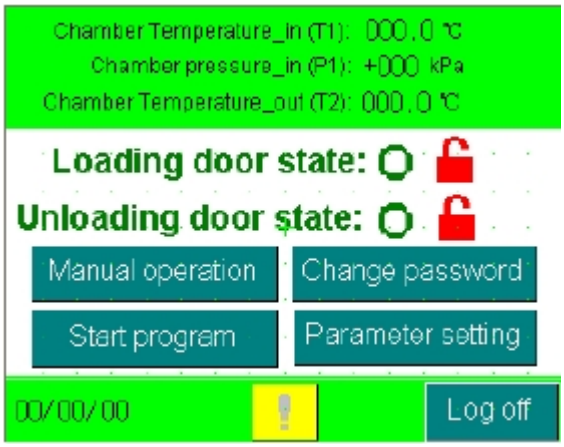
Note: If the case of heating failure arises (especially in rapid program), user could modify the upper limit of chamber pressure in P8 (normally increase 10 kpa and 1℃).

1. Operation

Enter into starting up menu and click landing.

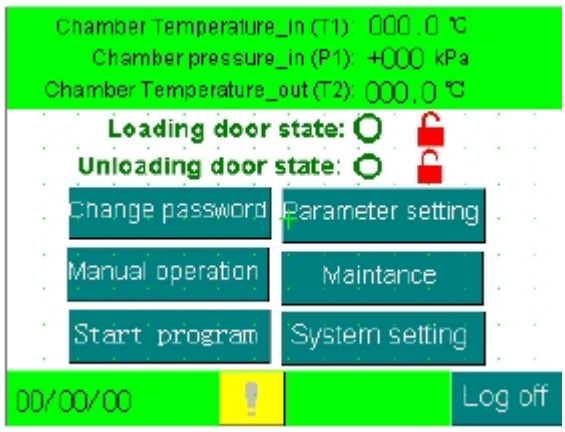


P3

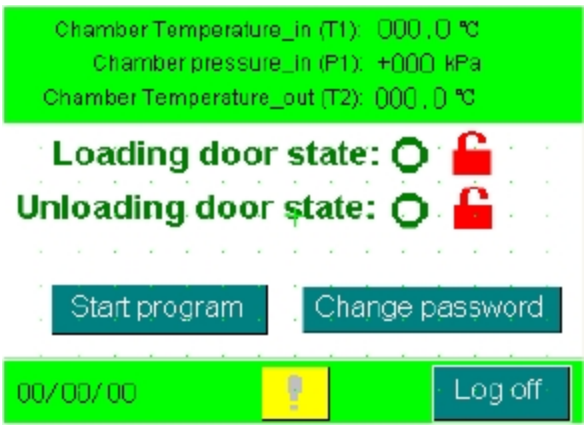


P4

The system has set administrator, process technician and 8 operators, the password of administrator and process operator is 149, and the administrator's holds the highest operating authority.



P5



P6

P4~P6 display the interfaces operated by operator, process technician and administrator.

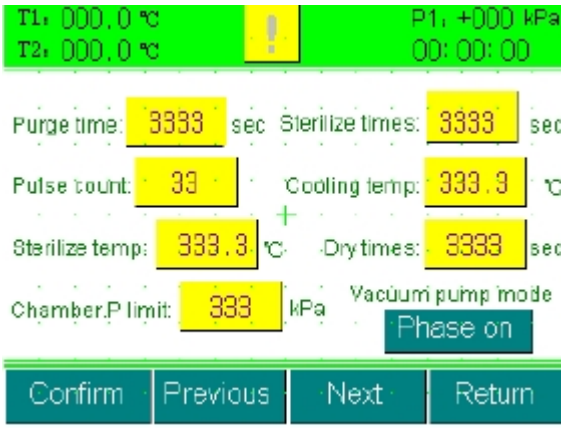
2. Parameter setting for different authorities

- **Operator: Operators can log on without password. The password could always be set or change by operators. Operators are only given the authority to choose and start the program.**
- **Process technician: Process technicians can change their password. P10 is the program choosing interface after log on. Choose a program and press "Edit" to enter P7. Some of the parameters could be changed. See P7 and P8. Also, the sterilization time, pulse frequency, temperature, chamber pressure**

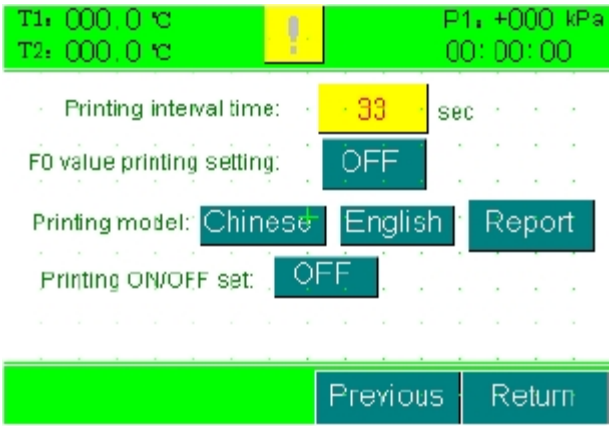
upper limit, cooling temperature and drying time could always be changed.

- Administrator: Administrators hold the highest operating authority. They can modify and print the parameters (as picture 9). The following printing parameters can be set: print interval, F0 print, language, report printing. Administrator can also modify the password both of process operator and operators.

P7



P8

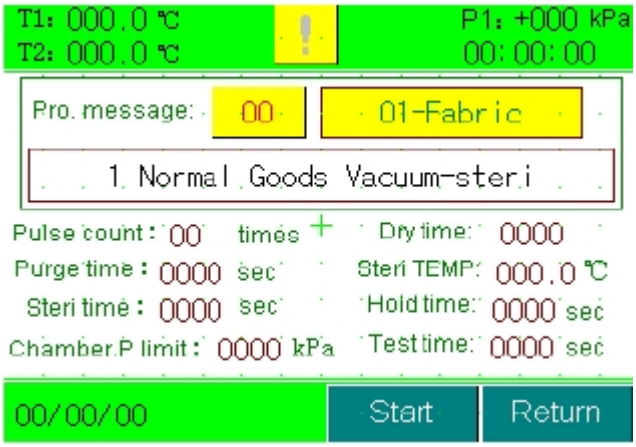


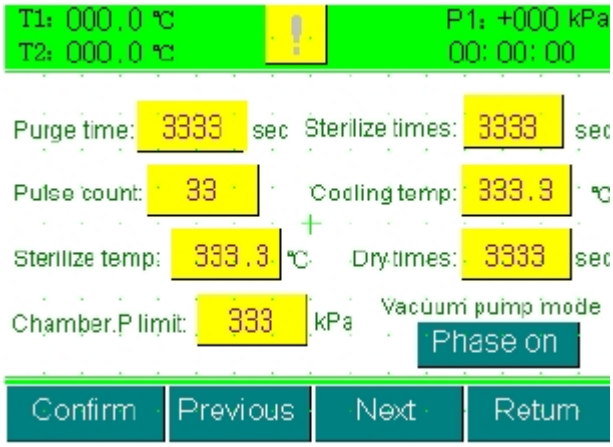
P 9

P 10

3. Choose and start program

Choose program start or setting to enter into startup interface (see P11). Under this status, administrator and process technician can set some of the parameters by pressing “Edit” button. Click start to initiate the program.





P 11 **P 12**

4. Please contact us to adjust the parameters if the atmosphere pressure at your area is not standard.

5. System maintenance

After log on as administrator, click "maintenance" button to enter into time setting (see P12). Please click "save" then "back" after modification. MAC and IP setting is necessary only if the product monitored by computer.

6.2 Parameter Setting

1. Program parameter setting

Process technician could change the parameters under the status of P7 and P8. Please refer to the following setting range:

Displacement time:	**0~7200s.**	**System default 300s**
Pulse frequency:	**0~99.**	**System default 3 times**
Sterilization temperature:	**0~150℃**	**System default 132/134℃**
Sterilization time:	**0~7200s**	
Cooling temperature:	**50~130s**	**System default 105℃ (not for liquid)**
Drying time:	**0~7200s**	

Chamber pressure limit:0~300

- **Displacement time**
  It is a temperature rise period during liquid program. The steam enters into the chamber to displace the cold air.
- **Pulse frequency**
  The purpose of pulse is that vacuum the chamber before sterilizing the items. The sterilization result depends on the vacuum degree, while the vacuum degree depends on the pulse frequency and amplitude.
- **Sterilization temperature**
  The setting of this temperature should according to specific items and manufacture technique. Different temperature has different effect on items. Increase the temperature to shorten the sterilization, while decrease the temperature to extend it.
- **Sterilization time**
  The setting of this time should according to specific items and manufacture technique.

  Caution: Over time sterilization has negative effects on items!
- **Drying time**
  The setting of this time should according to specific items and manufacture technique. To dry the items, high temperature from the chamber and vacuum pump work together to support heat and maintain the vacuum degree in the chamber.
- **Chamber pressure limit**
  It is the maximum value of chamber pressure. It is affected by jacket pressure. The setting of this pressure is according to the relation between

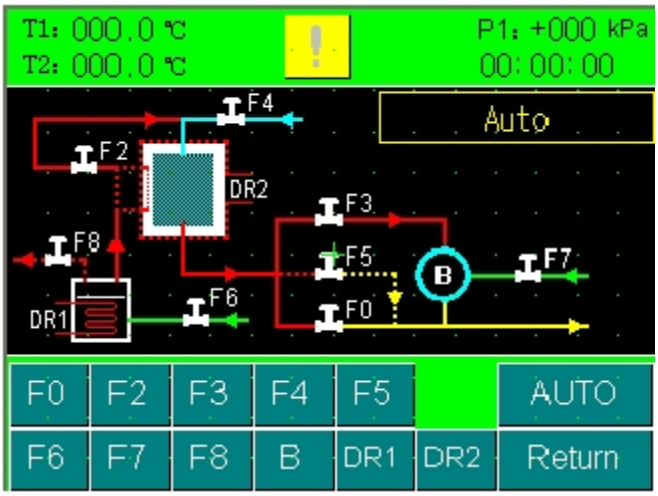
saturated steam pressure and temperature. The sterilizing effect cannot be reached if one of the following happens: steam over saturated or unsaturated, inconsistency between temperature and pressure.

2. System parameter setting

- **Vacuum breaking and exhausting limit**
  The service staff will adjust the parameters if the local atmosphere pressure is not standard.
- **Pulse upper/lower limit**
  This parameter is applied for U series product. Please contact the service staff if necessary.
- **Time setting**
  Set the time under System Maintenance options finish by pressing Save.

6.3 Hand Operation

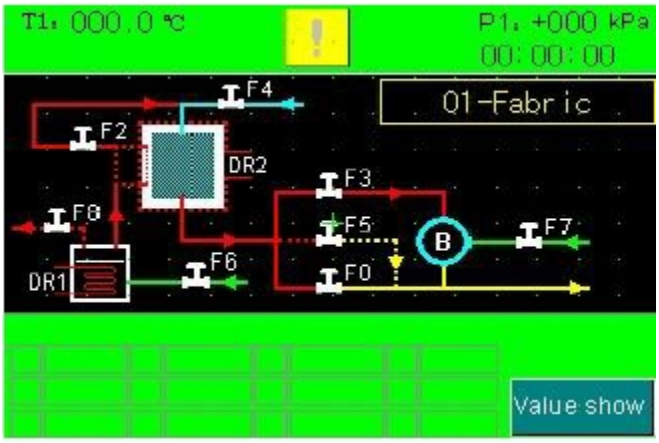
Hand operation only can be used by process technician and administrator (see P 13). Click the button "auto" to switch to manual operation; click each part to modify the status. "B" indicates vacuum pump as the picture shows. TMQ.C series has no vacuum pump valve, recycling water valve and Circular valve.
Caution: It is forbidden to keep heating pipe DR1 and heating film DR2 stay in manual status for long time. The pump cannot work long without water.



P 13

6.4 Program Running

Log on and choose a program then click Start. Click Edit to change the parameters if necessary.



P 14

1. Firstly, print the title of the report then enter into the preparation stage. The program (except liquid program) includes the following procedures: Preparation, Pulse, Heating, Sterilization, Exhausting, Drying and Terminate. The liquid program includes Preparation, Displacement, Heating, Sterilization, Exhausting and Terminate.

2. During the operation, the parameters of each procedure can be monitored by clicking "value show"

6.5 Attention matters in Sterilization

- **Please keep supervising the product during the operation.**
- **Manual operation should be done by full skilled and qualified operator only.**
- **Turn off and restart the product to check the system if the display screen does not work.**

Caution: When operate the sterilization which below 132℃, please manually decrease 40kpa on the pressure controller upper limit of the steam generator. For example, when you operate the sterilization which is 121℃, it is required to manually adjust the steam generator pressure controller to 130-150kpa, otherwise the chamber temperature may exceeds 121℃ during the sterilizing stage.

Attention matters for liquid sterilization:

*** To avoid explosion or scald accident, please strictly comply with the following rules:**

- **The liquid should not be sealed.**
- **Liquid can only be sterilized by liquid program. To avoid explosion or liquid ebullition, it is forbidden to vacuum the chamber after air exhausting.**
- **After sterilization for bottled liquid, do not open the door until the chamber temperature is below 80℃ (in the area that below 1000m altitude) and the pressure is back to 0. Then slightly open the door (keep 10mm gap) and wait for 10 minutes. Now open the door widely and take out the bottled liquid.**
- **Avoid bump, shake and crash when handle the bottled liquid.**

Chapter 7 Fault Analysis and Elimination

 **Caution: Please always be aware of the leaking in any part of the product.**

7.1 Analysis and Elimination of Common Fault

Phenomena	Possible reasons	Correct operation
1. The screen doesn't work when power is turned on.	1 The screen power is not on. 2 The fuse is broken. 3 No 24v power.	1 Check the text power. 2 Change the fuse. 3 check the 24v power.
2. The program does not initiate.	1The door is not closed. 2 Alarm is not eliminated.	1 Close the door. 2 Check and eliminate the alarm.
3.Screen communication failure.	1 The communication port is broken. 2 Poor connection.	1 Check the port and change the communication line. 2 Restart the product.
4. Pump disfunction.	1 Vacuum pipe leaking. 2 The flow control valve is not well adjusted. 3 Water pressure is low or no water. 4 Pressure transmitter fault. 5 The one-way valve of the chamber dewatering pipe is damaged. 6 Condensate in the pipe line. 7 Pump-out valve or pump is not on. 8 Pipe dirt. 9 Altitude problem.	1 Check the connection of all pipe and do a pressure test. 2 Adjust the flow control valve. 3 Check the water supply. 4 Check or change the pressure transmitter. 5 Repair or change the one-way valve. 6 Check and clean all the pipes and valves. 7 Check the electromagnetic valve or pump. 8 Clean up the dirt. 9 Adjust the pressure prameters.
5.Over loud pump noise	1 No water supply. 2 The water inlet ball valve is not well adjusted. 3 Pump dirt. 4 High circulating water pressure	1 Check the water supply. 2 Turn down the ball valve slightly. 3 Clean up the pump dirt. 4 Adjust the ball valve.
6. Pump does not work.	1 No power. 2 Pump damage.	1 Check the pump power. 2 Change the pump.

Phenomena	Possible reasons	Correct operation
7. Electromagnetic valve does not work.	1 Coil fault. 2 Loose wiring.	1 Check the valve coil. 2 Check valve wiring.
8. High jacket pressure but low chamber pressure or F2 cannot be opened.	1 The chamber dewatering valve is not adjusted. 2 Pipe leaking. 3 The chamber pressure limit is too low. 4 Electromagnetic valve damage. 5 Loose wiring.	1 Adjust the dewatering valve. 2 Check the leaking. 3 Reset the chamber pressure limit. 4 Check the electromagnetic valve. 5 Check the wiring.
9. Low heating rate.	1 The primary heater works slowly. 2 Less pulse or displace time.	1 Check the primary heater. 2 Increase the pulse or displace time.
10. The temperature is low when the pressure is ready.	1 Hydrops in the dewatering pipe. 2 Less pulse time. 3 Low chamber pressure.	1 Adjust the working frequency of the dewatering valve. 2 Increase the pulse time (defaulting set is 3 times). 3 Increase the chamber pressure limit according to the actual temp.
11 Temperature indicates 0 or 200.	1 Platinum thermometer is unconnected.	1 Connect the platinum thermometer.
12. Pressure indicates -100	1 Pressure transmitter is unconnected.	1 Connect the pressure transmitter.
13 Temperature and pressure fluctuate.	1 The earth line is not well grounded. 2 Strong magnetic filed around the product.	1 Ground the earth line. 2 Check the source of the magnetic filed.
14. The inconsistency between temperature and pressure.	1 The temperature is not adjusted	1 Adjust the temperature.
15 Water level detecting errors of the steam generator.	1 Wrong wiring of the water probe. 2 Water probe damage.	1 Check the wiring. 2 Change the water probe..
16 Low temperature alarm.	1 Air inlet valve blocked or air outlet valve leaking. 2 Air is not fully discharged.	1 Check and clean the valve. 2 Increase the chamber pressure upper limit or pulse and displace time.

Phenomena	Possible reasons	Correct operation
17 Steam generator injection over time.	1 Water shortage in the water tank 2 Inlet water filter blocked. 3 Steam generator water level sensor fault.	1 Fully inject the water into the tank 2 Check the filter element. 3 Change the water level sensor.
18 Chamber over pressure.	1 Chamber pressure transmitter fault. 2 Poor PT100 temperature collections. 3 The valve does not work well.	1 Check the electric circuit and change the transmitter. 2 Contact the supplier to modify the deviation. 3 Clean the valve and filter.
19 Chamber transmitter fault.	1 The PT100 is not wired. 2 PT100 temperature fault.	1 Check the electric circuit and rewiring the PT100. 2 Check the PT100.
20 Chamber over heat.	1 The valve does not work well. 2 PT100 temperature fault.	1 Clean the valve. 2 Check the PT100.
21 Back door panel indicator light does not work	1 Loose wiring. 2 The lamp or fuse damage.	1 Rewiring. 2 Change the lamp or fuse.
22 The inconsistency between front and back door pressure indicator.	1 Pressure indicator inaccurate. 2 Pressure indicator damage.	1 Revise the pressure indicator. 2 Change the pressure indicator.
23 Possible disfunction for the build-in steam generator:		
● No power in	●The wire is not connected. ●Control switch damage.	●Fix the wire. ●Change the control switch.
● No water in	●Water level electrode fault. ●Water inlet valve fault. ●Water pump damage. ●Water level relay damage.	●Repair. ●Repair. ●Change. ●Change.

7.2 Analysis and Elimination about "Wet Package"

Caution: "Wet Package" means the weight of the dressing package becomes 3% larger after sterilization.

- **Loading problem**
  Condensate water seeps into the dressing package caused by chamber overload. Check the package and take out the wet ware if any.
- **Poor water flow in dewatering pipe line**

Check the pipeline whether there are too many bends or dirt blocked in pipe.

- **Chamber dewatering pipe one-way valve damage**
  The water may flow back into the chamber during the drying procedure that makes the package wet.
- **Insufficient drying time**
  Increase the drying time and observe the drying results.
- **Negative pressure does not reach the standard**
  Check according to the table mentioned in 7.1.

7.3 Analysis and Elimination of Unqualified Sterilization

Caution: Three important factors of sterilization: saturated steam, sterilization temperature and time.

- **Item cleaning**
  Check the cleaning procedure whether it accords with CSSD working process strictly to ensure the cleaning quality.
- **Item packing**
  Do not pack the item too tight. The air permeability of packing material will affect the cold air discharge and steam penetration.
- **Loading rules**
  The items should be rightly placed to keep the steam flow well.
- **Air residual**
  The sterilization result depends on the amount of air discharged. Please check whether the sterilizer works normally.
- **Sterilization temperature**
  Check the consistency between the temperature of the package and the temperature displayed. Check the correspondence between the chamber pressure and temperature. Slightly increase the chamber pressure and observe the result.
- **Sterilization time**
  Check the rationality of the sterilization time. If necessary, please extend the sterilization time.
- **Sterilizer fault**
  Check according to the table mentioned in 7.1.
- **Improper testing method**
  Retesting or change another batch of reagent.

7.4 Unsolvable Problems

After sufficient analysis and troubleshooting, you may possibly have some unsolvable problems. Now you need the following preparation work:

- **Record the product series model number (e.g 20106447 BKQ-Z-135M).**
- **Make a record for all the operation faults and inspection or adjustment history.**
- **Contact our after-sale service center.**

Chapter 8 Maintenance

8.1 Inspection and Changing of Safety Valve

In order to prevent the safety valve from blockage, it is necessary to release the steam through it once a month.

1. Operate a sterilization cycle according to the manual

2. Allow a pressure of approximately 0.21Mpa to build up in the chamber.

3. Pull the ring of the safety valve using a screwdriver, and lift the safety valve for 2 seconds.

4. Switch off the power supply to interrupt the operation, and exhaust steam from the chamber.

5. Wait until the pressure goes down to zero, then open the door

Change the safety valve

This operation should be done only by professionals

1. Remove the fixing screws and take down the safety valve from the base.

2. Replace it with a new one (be sure the valve opens at a pressure between 0.25 MPa-0.26Mpa).

3. Testing all the work process.

4. Please verify the opening and closing pressure of the safety valve yearly.

8.2 The Procedures of Changing Electric Heating Tube

This should be done only by professionals

1. Take down the back cover of autoclave

2. Take down the wires on the heater of steam generator.

3. Remove the heater

4. Replace the damaged one with a new heating element.

5. Reconnect the wires.

6. Install the back cover of autoclave.

7. Testing all the work process.

8.3 The Cleaning of Electromagnetic Valve

1. Remove the outer cover of the autoclave

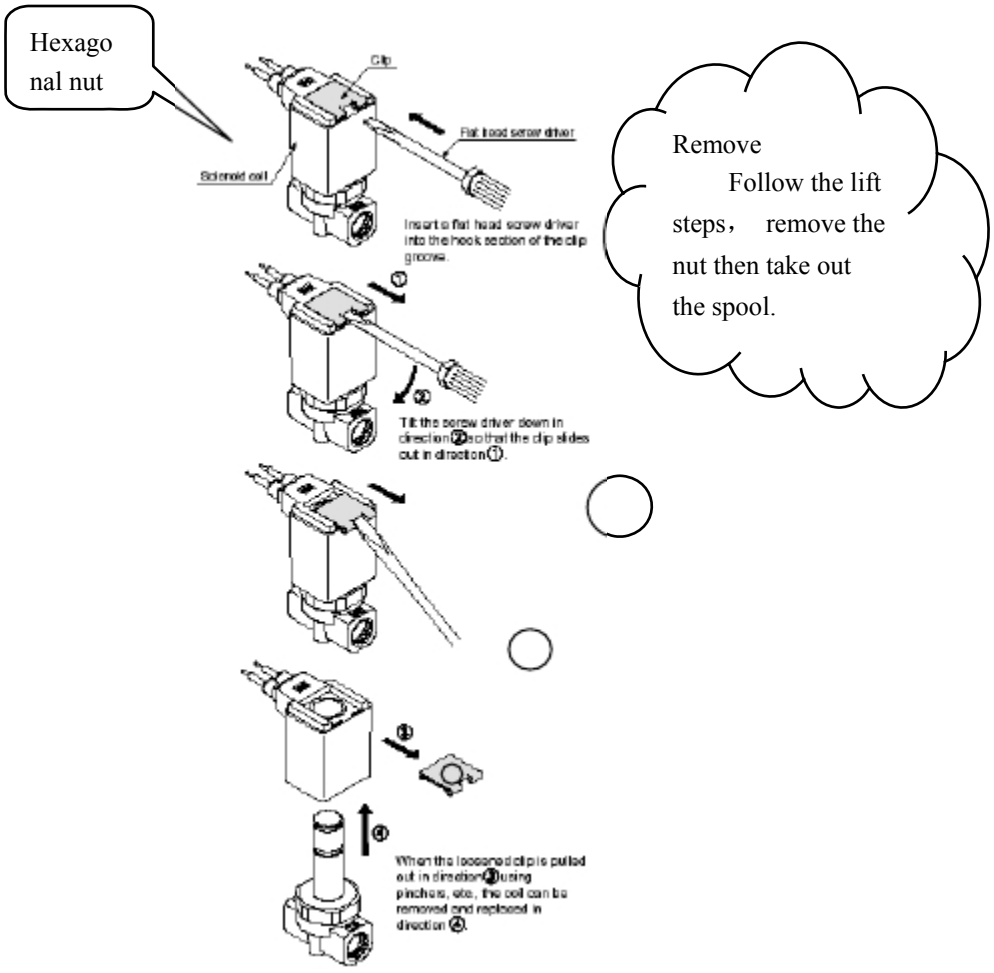
2. Pull out the stainless press slip on top of the electrical magnetic valve with a screwdriver.

3. Pull up the ring coil of electrical magnetic valve.

4. Open the valve body with the spanner.

5. Clean the sundries on the valve center with clean water.

6. Restore the electrical magnetic valve.



8.4 The Cleaning of Water Filter and Drainage Filter

1. The water feeding filter is used for preventing dirt enter into the steam generator.

2. The drainage filter is used for preventing enter into the inside pipeline and the magnetic valve

3. Remove the net and gland of filter with wrench

4. Clean the net of filter with pure water

5. Re-install the filter

8.5 The Changing of Water Level Monitoring Device

Caution: Be sure power is cut off

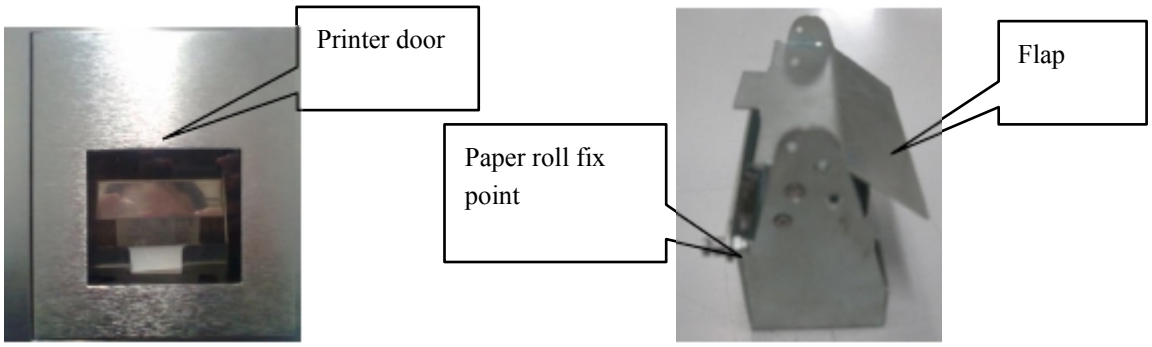
1. Remove the back cover of Autoclave.

2. Remove the connection wires from the detection device.

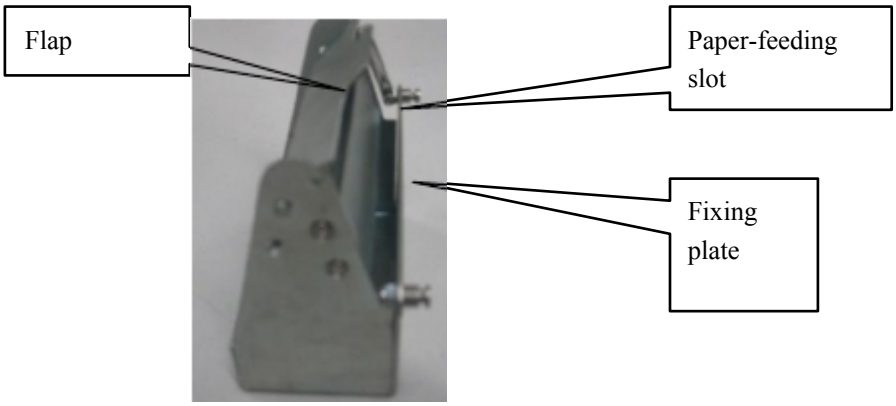
3. Take off the detector.

4. Replace the damage one with a new water level detector.
5. Re-install the detector and connect the wires.
6. Restore the back cover.
7. Test all the cycle procedures.

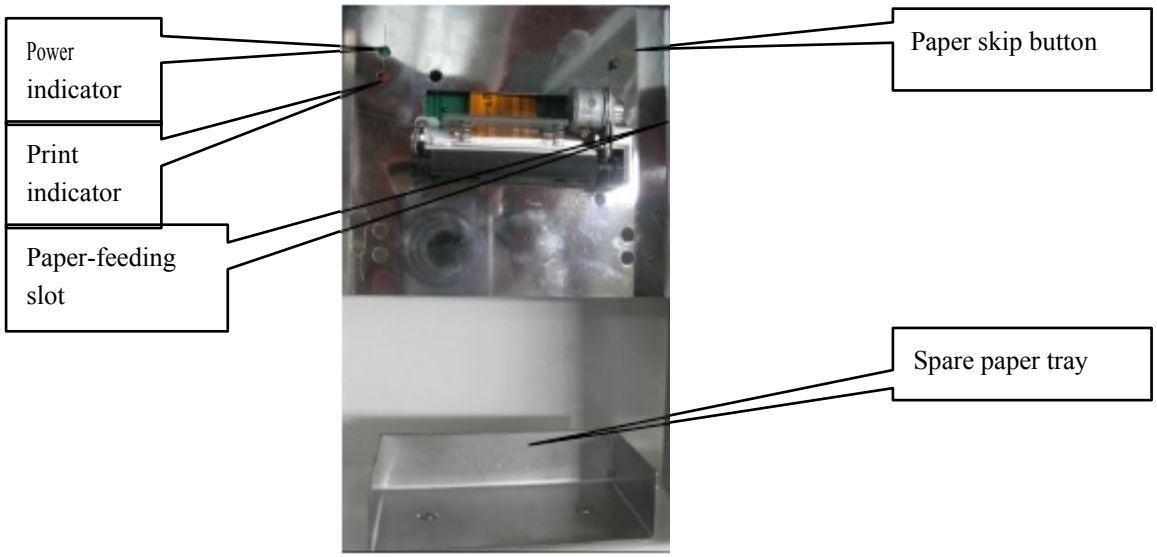
Printer operation and maintenance.



Press the bottom right corner of the printer door to open it. To take out the paper slot please press the flap and simply lift the paper slot.



Please feed the paper between the flap and fixing plate



Chapter 9 Other Terms

9.1 Self-Protection

During the sterilization, the staff should have self-protection awareness and measures to avoid accident and personal injury.

 **Caution: Since the product works in the high temperature condition, please protect yourself from scald.**

9.2 The Quality Guarantee of Sterilization

1. Guarantee the cleanliness of the items to be sterilized.

 **Caution: The sterilization effect cannot be achieved without cleaning.**

2. **Control the quality of water used in the sterilizer.**
3. **The environment of sterilization room**
   - **the ground of the room must be even and smooth**
   - **keep the operation area clean and dry all the time**
   - **the wall of the room must be clean and even**
   - **ventilating device must be installed**
4. **Item preparation**
   - **the dressing fabric should not be packed tightly**
   - **10mm gap should be left between packages**
   - **the total volume of the packages should not exceed 90% of the chamber volume**
   - **please use special sterilization container**
   - **the volume of the sterilizing package should not exceed 30cm*30cm*50cm**
   - **the package should be taped on by chemical indicating tape with indicating card inside**
5. **Clean the chamber**
   - **wipe the chamber with neutral detergent before cleaning it by water, and then wipe the chamber by dry cloth**
   - **clean up the chamber filter mesh**

9.3 The Inspection of Sterilization Results

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

1. Physical inspection

- **Gage inspection**

  The build-in printer could record the parameters that displayed on the

screen for result inspection use.

- **Stationary point thermometer inspection**
- **Thermocouple inspection**

2. **Chemical inspection**

- **Chemical indicator**

  There are three types of indicators (115℃, 121℃, 132℃) are available for result inspection. Take the indicator out of the package after sterilization and compare it with standard color. The sterilization is qualified if the color is darker than the standard color.

- **Chemical indicating tape**

  The tape will turn into black if the package has been sterilized.

Note: "Black tape" does not indicate that the package is sterilizing qualified.

Caution: Chemical indicator/tape must be qualified by hygiene institution. Must use before expiration date!

3. **Biological inspection**

9.4 Energy Saving and Environment Protecting

The design of the product has already considered the energy saving and environment protecting before sale. However, for customer special requirement, it is necessary to adjust the program. For better energy-saving effects, you are welcome to contact us for program adjustment technical support.

Appendix 1 Operation specification

1. Preparation before Operation:

- ✓ Add softened water or pure water into clean water tank and circulating water tank in accordance with the requirements, and connect the power supply for this equipment.
- ✓ Connect the control-purpose power supply, turn the power switch of sterilizer to "1" side, and make proper preparation for operation of the program.
- ✓ Mark the B-D testing paper with the name or code of operator and date, place it into the sterilizer, start the B-D testing program, and monitor whether this equipment leaks and whether this equipment works normally.
- ✓ Set in order the parcel to be sterilized, make sure that it is not bound too tightly, paste the chemical indicator tape on it, and place the chemical indicator card in the chamber.

2. Operation of Sterilization:

- ✓ After the B-D testing is successfully carried out, open the front door, place the article to be sterilized into the sterilizing chamber, and make sure that there is clearance between every two parcels and no parcel contacts with inner wall or door plate.
- ✓ Close the front door, select the appropriate sterilization program in light of the article to be sterilized, inspect whether the sterilization parameters are correct, and 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 rear door and take out the article.
- ✓ After taking out the sterilized article from the sterilizer, put it in an appropriate place, so as to prevent the secondary contamination.

3. Works after Operation:

- ✓ Open the door, turn the power switch to "○" side, and cut off the control-purpose power supply and main power supply.
- ✓ Discharge the residual water in water tank, or discharge the water in accordance with the required interval.
- ✓ Discharge the residual water in steam generator (or fully discharge the water accumulated in evaporator in accordance with the required interval).
- ✓ After the works are completed every day, please keep the inside and outside

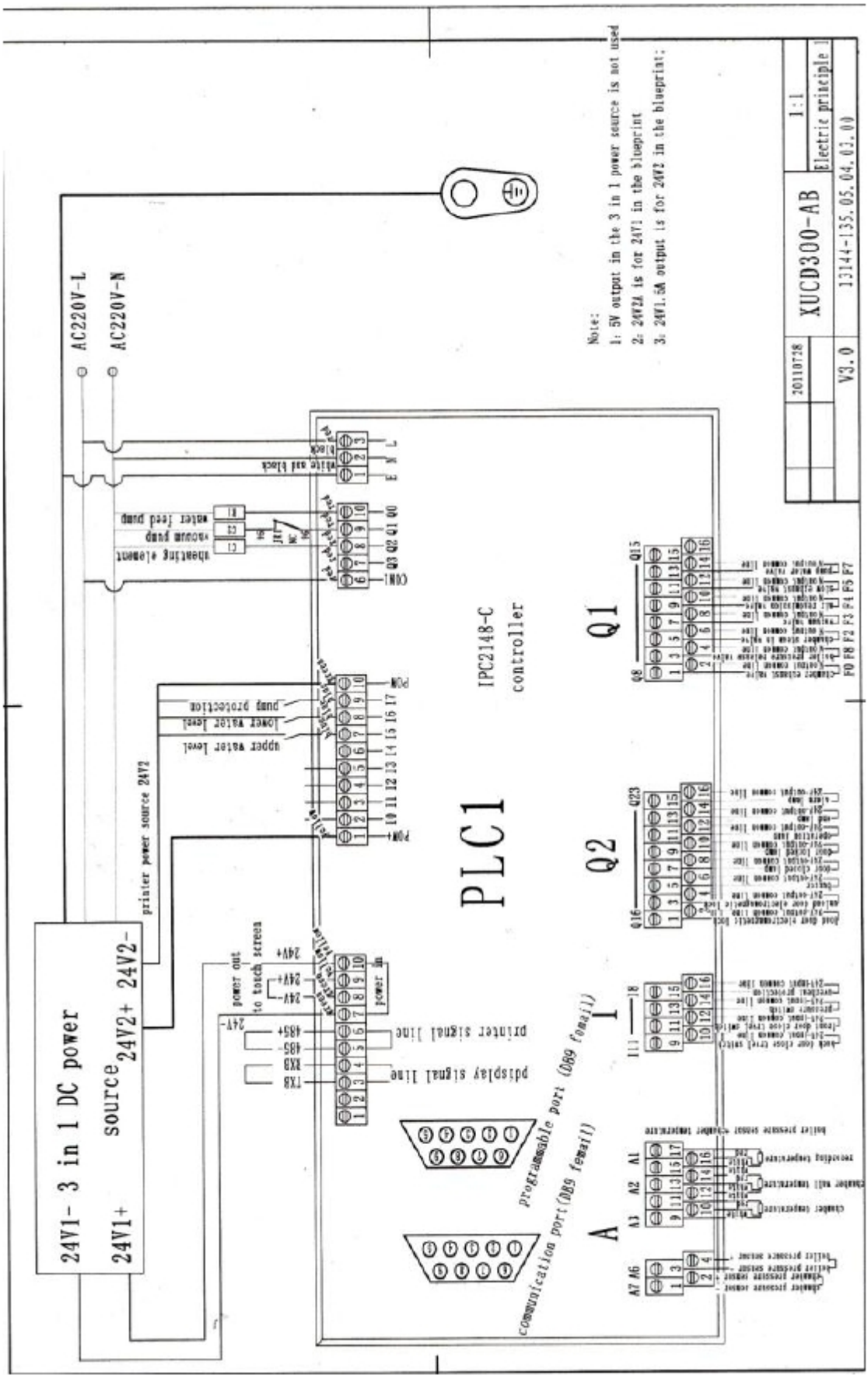
of sterilizer clean, clear away all dirt from the chamber, carry out simply maintenance once a week, and carried out thorough maintenance once a month.

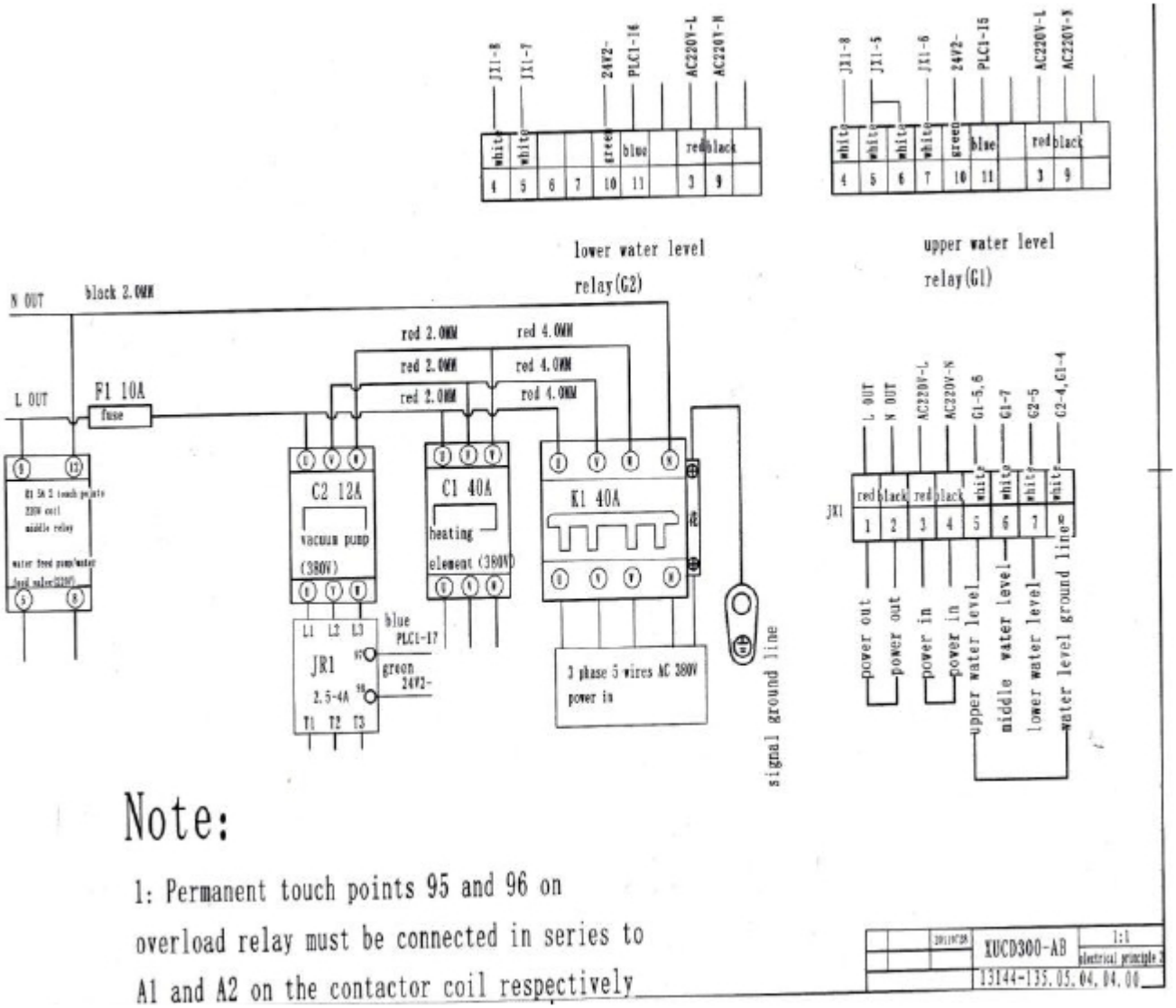
4. Notices:

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

Name of User: Date:

Appendix 2 Drawings

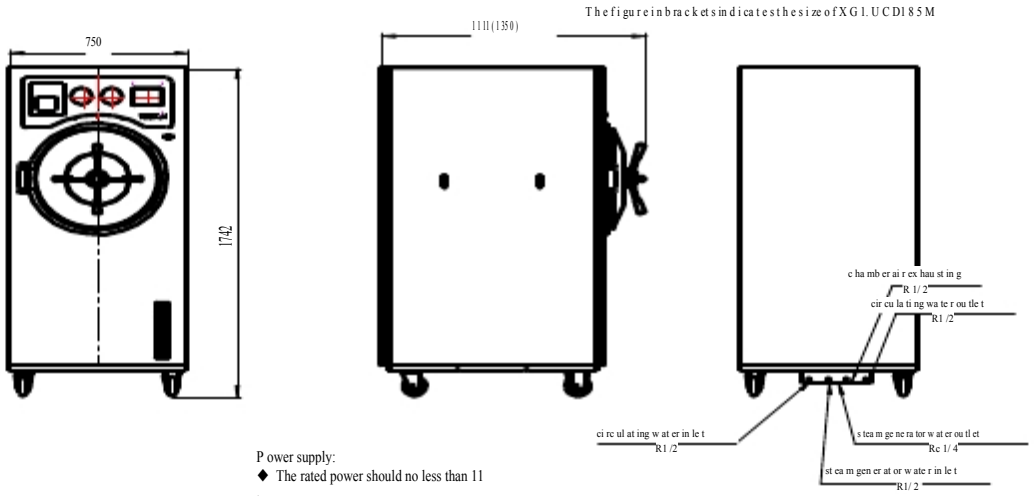




Note:

1: Permanent touch points 95 and 96 on overload relay must be connected in series to A1 and A2 on the contactor coil respectively

BKQ-Z 150H/200H



P ower supply:

◆ The rated power should no less than 11 k w.

◆ 380V/50Hz AC wi th reliable earth wi re.

Technical requirements:

Dewatering: To av oid the residual wa ter affects other r ooms, the dewaterin g p ipe should be fixed in the sewer separa tely to let the wat er drain out of b uilding. The thermo s tability of the dewa tering pipe and sew er is 150 ℃ . In the c ase of that there ar e more than one wat er outlets, the dew atering pipes shoul d b e fixed separately.

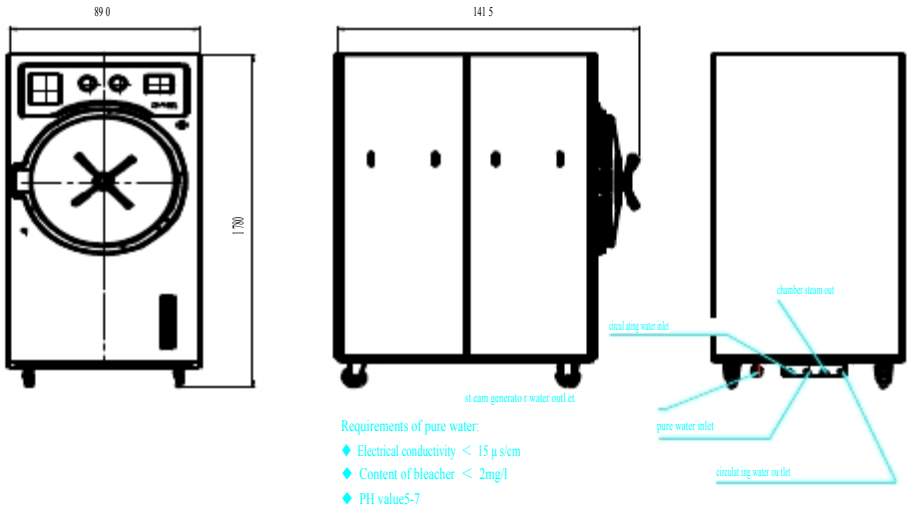
Water supply: The circulating water that connected to v acuum pump can be u sed as water supply (≤ 2 5 ℃ , pressure: 0. 05-0.10Mpa). If the c irculating water p ressure is out of th e certain range ple ase adjust it befor e start the equipme nt.

In order to obser ve and control the water pressure conv eniently, a 0-0.4Mp a p ressure gage and val ve should be fixed in the water-in pip eline.

! Caution: Do not use high hardness water since the pum p and condenser wil l b e affected.

Power line: The p ower supply of AC38 0V equipment should be three-phase fiv e l ittle system that in cludes three-phase fire wire, a zero w ire (light blue), a nd a n earth wire (kelly) . The load capacity o f user power supply and power line s hould be greater tha n the equipment loa d capacity. Please in stall a power switc h box in the right sid e of the equipment or back right wall. T here must be a thre e - phase chopper switch (or a breaker) and single-phase chopp er switch (or a b reaker) installed in the switch box.

BKQ-Z300H



Requirements of pure water:

- ♦ Electrical conductivity ＜ 15 μ s/cm
- ♦ Content of bleacher ＜ 2mg/l
- ♦ PH value5-7
- ♦ Hardness ＜ 0.02mmol/l
- ♦ Temperature ≤ 45 ℃ ; pressure ≤ 0.05Mpa

Note: The steam must be generator from pure/distilled water.

Power supply

- ♦ The rated power should no less than 17 kw.
- ♦ 380V/50Hz AC with reliable earth wire.

Technical requirements:

Dewatering: To avoid the residual water affects other rooms, the dewatering pipe should be fixed in the sewer separately to let the water drain out of building. The thermo stability of the dewatering pipe and sewer is 150 ℃. In the case of that there are more than one water outlets, the dewatering pipes should be fixed separately.

Water supply: The circulating water that connected to vacuum pump can be used as water supply (≤ 25 ℃ , pressure: 0.05-0.10Mpa). If the circulating water pressure is out of the certain range please adjust it before start the equipment.

In order to observe and control the water pressure conveniently, a 0-0.4 Mpa pressure gage and valve should be fixed in the water-in pipeline.

! Caution: Do not use high hardness water since the pump and condenser will be affected.

Power line: The power supply of AC380V equipment should be three-phase five little system that includes three-phase fire wire, a zero wire (light blue), and an earth wire (kelly). The load capacity of user power supply and power line should be greater than the equipment load capacity. Please install a power switch box in the right side of the equipment or back right wall. There must be a three-phase chopper switch (or a breaker) and single-phase chopper switch (or a breaker) installed in the switch box.

BIOBASE

ADD: No.51 South Gongye Road, Jinan, China250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

Medical Devices Directive 93/42/EEC has been taken as reference for these processes

Company Name:	**Biobase Biodustry (Shandong) Co., Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Examination Intent:	Examination the completeness of the Technical Documentation according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC
Product(s):	**Sterilizer**
Type(s)/Model(s):	BKM-Series, BKQ-Series
Classification:	IIb
Harmonized Standards Applied:	All requirements of the appropriate EU directive(s) should be met.
Examination Period:	December 24, 2017
Date of Expiry:	December 23, 2022
Review Result:	During the examination of the provided Technical Documentation, no Non-compliance according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC has been detected.

Year of DOC marking: **2017**

Signed for and on behalf of Company: **Biobase Biodustry (Shandong) Co., Ltd.**

General Manager: Robert Wang

Document No: MDD-17081110

BIODUSTRY (SHANDONG) CO., LTD 山东博科生物产业有限公司

CE

Certificate of Registration

This is to certify that the Quality Management System of

Biobase Biodustry (Shandong) Co., Ltd.

Unified Social Credit Code： 9137018179889855X7

Operation Address : Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China(Production);No.51, South Gongye Road, Jinan City, Shandong Province, China(Sale)

Registered Address : Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China

applicable to

R & D, production and sales of in vitro diagnostic kit(see attachment for details), biosafety cabinet, medical aerosol absorber, pressure steam sterilizer, blood bank refrigerator, microbial incubator and automated ELISA processor(within the scope of license qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **45014**

Date: 09 July 2018

Valid Until: 09 July 2021

EAC Code: 19

UKAS MANAGEMENT SYSTEMS 015

Certificate of Registration

Biobase Biodustry (Shandong) Co., Ltd.

Annex I

1. Triglyceride detection kit (enzyme colorimetric method)
2. Low density lipoprotein cholesterol test kit (direct method)
3. High-density lipoprotein cholesterol test kit (direct method)
4. Total cholesterol test kit (enzyme colorimetric method)
5. Creatine kinase isoenzyme detection kit (IFCC recommended method)
6. Total bilirubin test kit (diazo-2,4-dichloroaniline colorimetric method)
7. Alanine aminotransferase detection kit (IFCC recommendation method)
8. Cholinesterase detection kit (butyryl thiocholine method)
9. Glucose detection kit (oxidase method)
10. Chlorine detection kit (mercury thiocyanate colorimetric method)
11. Magnesium detection kit (colorimetric method)
12. Carbon dioxide detection kit (enzymatic method)
13. Inorganic phosphorus detection kit (colorimetric method)
14. Apolipoprotein A1 detection kit (immunotransparency turbidity method)
15. Glucose detection kit (hexose kinase method)
16. Creatinine test kit (enzymatic method)
17. Calcium detection kit (arsenazo III method)
18. Glycosylated serum protein detection kit (two points method)
19. Lipoprotein (a) detection kit (immunotransparency turbidity method)
20. Total protein detection kit (biuret method)
21. Aspartate aminotransferase detection kit (IFCC recommended method)
22. Alkaline phosphatase test kit (IFCC recommended method)
23. Albumin detection kit (bromocresol green method)
24. Apolipoprotein B detection kit (immunotransparency turbidity method)
25. Urea detection kit (urease-glutamate dehydrogenase method)

Managing Director

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Date: 09 July 2018
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Certificate of Registration

Biobase Biodustry (Shandong) Co., Ltd.

Annex II

26. α-amylase detection kit (EPS-G7 method)
27. α-hydroxybutyrate dehydrogenase detection kit (DGKC recommended method)
28. Rheumatoid factor detection kit (immunotransparency turbidity method)
29. Total bile acid detection kit (circulating enzyme method)
30. γ-glutamyl transferase detection kit (SZASZ method)
31. Lactate dehydrogenase detection kit (DGKC recommended method)
32. Direct bilirubin test kit (diazo-2,4-dichloroaniline colorimetric method)
33. Adenosine deaminase detection kit (enzymatic method)
34. Creatine kinase test kit (IFCC recommended method)
35. Creatinine test kit (bitter acid method)
36. Urine microalbumin detection kit (immunotransparency turbidity method)
37. Uric acid detection kit (TBHBA method)
38. Total cholesterol test kit (oxidase method)
39. Sodium detection kit (enzymatic method)
40. Potassium detection kit (enzymatic method)
41. Serum iron detection kit (pyrazine method)
42. Zinc test kit (colorimetric method)
43. Copper detection kit (colorimetric method)
44. 5'-ribonucleotide hydrolase detection kit (colorimetric method)
45. Monoamine oxidase detection kit (colorimetric method)
46. Alpha-fetoprotein detection kit (immunoturbidimetry)
47. Ammonia detection kit (glutamate dehydrogenase two-point method)
48. Leucine aminopeptidase detection kit (colorimetric method)
49. Cystatin C detection kit (immunoturbidimetry)
50. β2-microglobulin detection kit (latex enhanced immunoturbidimetry)

Managing Director

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Biobase Biodustry (Shandong) Co., Ltd.

Annex III

51. N-acetyl-β-D-glucosaminidase detection kit (colorimetric method)
52. Triglyceride detection kit (oxidase method)
53. Homocysteine detection kit (enzymatic method)
54. Apolipoprotein E test kit (immunoturbidimetry)
55. Phospholipid test kit (oxidase method)
56. Glucose detection kit (glucose oxidase method)
57. Glycosylated hemoglobin detection kit (enzymatic method)
58. D3 hydroxybutyric acid detection kit (enzymatic method)
59. Lactic acid test kit (enzyme color method)
60. Myoglobin detection kit (immunoturbidimetry)
61. Angiotensin converting enzyme detection kit (colorimetric method)
62. Lactate dehydrogenase isoenzyme 1 detection kit (lactic acid matrix rate method)
63. Lipase detection kit (enzyme coloring method)
64. Pepsinogen I detection kit (immunoturbidimetry)
65. Pepsinogen II detection kit (immunoturbidimetry)
66. Anti-streptococcus O detection kit (immunoturbidimetry)
67. High-sensitivity C-reactive protein detection kit (immunoturbidimetry)
68. Pre-albumin detection kit (immunoturbidimetry)
69. Transferrin detection kit (immunoturbidimetry)
70. Glucose-6-phosphate dehydrogenase detection kit (UV rate method)
71. D-dimer detection kit (immunoturbidimetry)
72. Complement C3 detection kit (immunoturbidimetry)
73. Complement C4 detection kit (immunoturbidimetry)
74. Immunoglobulin IgA detection kit (immunoturbidimetry)
75. Immunoglobulin IgG detection kit (immunoturbidimetry)

Managing Director

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Biobase Biodustry (Shandong) Co., Ltd.

Annex Ⅳ

76. Immunoglobulin IgM detection kit (immunoturbidimetry)
77. α1-acid glycoprotein detection kit (immunoturbidimetry)
78. α1-antitrypsin detection kit (immunoturbidimetry)
79. Ethanol detection kit (enzymatic method)
80. Apolipoprotein A2 detection kit (immunoturbidimetry)
81. Apolipoprotein C2 detection kit (immunoturbidimetry)
82. Apolipoprotein C3 detection kit (immunoturbidimetry)
83. Anti-thrombin III detection kit (immunoturbidimetry)
84. B factor detection kit (immunoturbidimetry)
85. C-reactive protein detection kit (immunoturbidimetry)
86. Direct bilirubin detection kit (vanadate oxidation method)
87. Direct bilirubin detection kit (oxidase method)
88. Fibrinogen detection kit (immunoturbidimetry)
89. Ferritin detection kit (latex enhanced immunoturbidimetry)
90. Fiber binding protein detection kit (immunoturbidimetry)
91. Glutamate dehydrogenase detection kit (enzymatic method)
92. Glycyl valine dipeptidyl aminopeptidase detection kit (enzymatic method)
93. Glycosylated hemoglobin detection kit (latex enhanced immunoturbidimetry)
94. Homocysteine detection kit (enzymatic method)
95. Immunoglobulin E detection kit (immunoturbidimetry)
96. Ischemic modified albumin detection kit (colorimetric method)
97. Aspartate aminotransferase mitochondrial isoenzyme detection kit (enzyme inhibition method)
98. Plasminogen detection kit (immunoturbidimetry)
99. Retinol binding protein detection kit (immunoturbidimetry)
100. Total bilirubin test kit (vanadate oxidation method)

Managing Director

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Biobase Biodustry (Shandong) Co., Ltd.

Annex V

101. Total bilirubin test kit (oxidase method)
102. Troponin I test kit (latex enhanced immunoturbidimetry)
103. Unsaturated iron binding force detection kit (Ferene method)
104. Urine total protein detection kit (colorimetric method)
105. α1-microglobulin test kit (latex enhanced immunoturbidimetry)
106. Fibrin and fibrinogen decomposition product determination kit (latex immunoturbidimetry)
107. Haptoglobin assay kit (immunoturbidimetry)
108. Procalcitonin assay kit (latex immunoturbidimetry)
109. Glycocholic acid assay kit (latex immunoturbidimetry)
110. Free fatty acid determination kit (ACS-PAP method)
111. Glycated albumin assay kit (peroxidase method)
112. α2 macroglobulin determination kit (immunoturbidimetry)
113. Heart-shaped fatty acid binding protein assay kit (latex immunoturbidimetry)
114. Anti-cyclic citrullinated peptide antibody assay kit (latex immunoturbidimetry)
115. Neutrophil gelatinase-related lipocalin assay kit (latex immunoturbidimetry)
116. Sialic acid assay kit (neuraminidase method)

Managing Director

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EUROPEI TECNOLOGICI

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Cod. Fisc. e P.IVA 02 332 750 369
Reg. Imprese 02 332 750 369
REA MN 0221098

CERTIFICATE OF COMPLIANCE

Certificado de Conformidade - Сертификат соответствия - Konformitätserklärung

1) APPLICANT:
Biobase Biodustry (Shandong) Co., Ltd.
Mingshui Economic Development Zone, Zhangqiu,Jinan City, Shandong,China (Biobase Biodustry Park,Crossing of Jingshi East Road and Mingbu Road)

2) CERTIFICATE NO.:
IT021717BB150820S

TCF(S) NO.:
TCF(14)-056-LVD

3) WITH REFERENCE TO EC DIRECTIVE APPLIED:
Low Voltage Directive 2006/95/EC

HARMONIZED STANDARDS APPLIED:
EN 61010-1:2010,
EN 61010-2-040:2005

4) CERTIFICATION ISET MARK:

ISTITUTO SERVIZI
EUROPEI TECNOLOGICI

5) PRODUCT CHARACTERISTICS: BK Series Pressure Steam Sterilizer(Autoclave)

MODEL(S): BKM-Z12, BKM-Z16, BKM-Z18, BKM-Z24, BKM-Z50, BKQ-B30, BKQ-B50, BKQ-B75, BKQ-B100, BKQ-B120, BKQ-B150, BKQ-B200, BKQ-B300, BKQ-B400, BKQ-B 500, BKQ-Z30, BKQ-Z50, BKQ-Z75, BKQ-Z100, BKQ-Z120, BKQ-Z150, BKQ-Z200, BKQ-Z300, BKQ-Z400, BKQ-Z500

REMARK: ***The verification has been carried out on voluntary application of the manufacturer based only on the documents prepared and provided by the manufacturer itself. The product(s) satisfies the requirements of the Certification Mark of ISET according to the ISET regulations. The manufacturer is responsible to maintain the internal production control to ensure the compliance of the product. ISET declines any liability with reference to any other noncompliance of documents, product or test report that have been submitted to evaluation. However marking and EC declaration are duties of the manufacturer before putting into service of its product(s) on market. The manufacturer is liable to take all the necessary actions required by the applicable directives&procedures.***

6) DATE OF ISSUE: 08/20/2015 *DATE OF EXPIRE:* 02/12/2019

CERTIFICATION MANAGER:

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