Operation Manual

(Pulsating Electrothermal Drying) Vertical Pressure Steam Sterilizer

(Please read the manual carefully before operating this machine)



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I Summary

(Pulsating Electrothermal Drying) Vertical Pressure Steam Sterilizer(hereinafter refers to as the sterilizer or equipment) is a capacious large-diameter sterilizer which utilizes saturated steam concentrated under high pressure to sterilize medical instruments.

This equipment is used by medical institutions to sterilize medical instruments which are able to withstand high-temperature steam under high pressure.

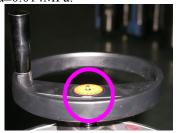
This equipment is manufactured in accordance with regulations of relevant technical specifications, such as GB 4793.1-2007 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements, GB 4793.4-2001 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Particular Requirements for Autoclaves Using Steam for the Treatment of Medical Materials and for Laboratory Process, YY1007-2005 Vertical Pressure Steam Sterilizer and Regulations on the Supervision of Safety Technology for Pressure Vessels (National Bureau of Quality and Technical Supervision(1999)).

II Technical Characteristics of this Equipment

- 1: The working temperature should range from 5° C to 40° C, the relative humidity should be no higher than 85%, and the atmosphere pressure should be between 70 Kpa and 106 Kpa.
- 2: This equipment is a fixed installation permanently connected to the power in the Lab and the external power should be of three-Phase, five-Wire.
- 3: The basic parameters for pattern and dimension of the sterilizer meet the requirements of Regulations on the Supervision of Safety technology for Pressure Vessels.
- 4: This fast-open sterilizer is equipped with safety interlocking device and caution light.
- 5: The pressure indicator of this equipment ranges from—100kPa to 300kPa and the reading of the atmospheric pressure is zero(see picture 29).
- 6: Controlled by the microcomputer, this equipment is capable of controlling the water level, time, and temperature with functions of water-break, over temperature alarming, automatic power failure and protection against low water level.
- 7: Warning tags are attached in appropriate positions of the sterilizer to alert the user. The user is supposed to read through the accompanying documents to master the operation of the equipment.
- 8: The maximum allowable working pressure of this equipment is 0.217MPa and there should be no noise if operated normally.
- 9: The equipment is equipped with reliable protective earthing connection with a clear grounding tag(see picture 2).
- 10: After sterilization, the vent valve at the bottom of the sterilizer, which needs manual operation, will make the sterilized items (except wares and solutions) drier as residual steam can be emitted from the valve(see structure chart of this equipment).
- 11: Protection Class: 1, Pollution Degree: 2, Overvoltage Category: II, Operating Conditions: Continuous Operation
- 12: Goods are sterilized in this equipment by utilizing the pressurized saturated steam generated from a solution with a boiling point of $100\,^{\circ}\text{C}_{\,\circ}$
- 13: The sterilizer can guarantee drier goods after sterilization, thanks to its additional function of pulsating electrothermal drying.

Ⅲ Technical Parameters

- 1: The power-line voltage of this equipment is AC 380V±38V, 50Hz and its power is 2kW×3 (five-wire).
- 2: The diameter of the sterilizer is Φ 500mm. The working volume can be classified into three types -100L, 150L and 200L and accordingly the net weight will be 170kg, 180kg and 190kg.
- 3: The working pressure of this sterilizer is 0.217MPa and the operating temperature is 134%.
- 4: The sterilizer is equipped with a safety valve whose allowable highest working pressure is 0.24MPa±0.014MPa.





Picture1

Picture2

- 5: The RT14 \sim RT18 fuse equipped on the sterilizer (ϕ 10×38 , 380V 16A×3) can effectively cut off the overrun short-circuit current.
- 6: There is an interlocking device equipped on the equipment. When the door(lid) is closed and the steam pressure is ≥ 0.028 Mpa, the lid will be locked; and the lid can only be reopened after the interlocking device is unlocked when the steam pressure is completely vented to the outside atmosphere and the pointer of the pressure gauge returns to zero.(see picture 1)
- 7: The service life of the quick actuating interlocking device on the sterilizer is 1000 sterilization cycles under normal working conditions.
- 8; The pulsating power for the pulsating electrothermal drying device can be adjusted within a range of $(2000W\times3)$ 1 \sim 15%.

IV Installation Requirements

- 1: Before using the equipment, the operator should refer to the accompanying documents for the operation and safety items of the machine
- 2: The equipment should be placed in a dry spacious room with good lighting and ventilation conditions as well as smooth floor.
- 3: The protective grounding wire should be reliably connected to the outside grounding.
- 4: The power for the sterilizer is three- phrase, five-wire.
 From the moment of leaving the factory, the five wires are respectively marked with L1, L2, L3, N and G. Among them, L1 with a color of brown, L2 with a color of blue and L3 with a color of green are all live wires; N with a color of grey is zero line; while G with a color of yellow-green is protective grounding wire. Th can not be connected as one.
- Picture 3
- 5: The sterilizer is permanently connected to the network power. The bread is NDMI-63D40A/4P, should be installed on the inner wall of the building with a distance of at least 50 centimeter away from the sterilizer itself and at a height of 1.5 meters above the ground. Before connected to the breaker, the power wires should be firmly fixed to the building in case it falls off.
- 6: To emit waste water for cleaning the equipment, there should be a sewer beneath the position where the equipment is located.

7: Caster wheels are equipped at the bottom of the sterilizer to facilitate handling. When the equipment is moved to a specific location, it should be stopped with caster breakers or fixed with a space block to avoid further slipping.

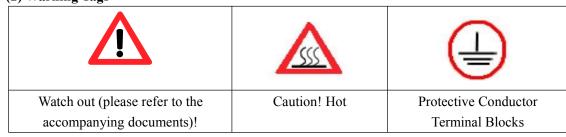
V Operation of the Equipment

1: Identification Instruction

(1): Control Panel

- 1. pressure gauge light
- 2. light for sterilization temperature setting
- 3. light for sterilization time setting
- 4. light for drying time setting
- 5. key for "increase"
- 6. key for "confirmation"
- 7. key for "decrease"
- 8. low water level indicator light
- 9. high water level indicator light
- 10.sterilization status light
- 11. heating status light
- 12. power switch
- 13. indicator light for interlocking device
- 14. digital display window (upper)-red: working conditions
- 15. digital display window (lower) green: temperature ar
- 16. shift key
- 17. water-shortage indicator light
- 18. light indicating the status of automatic exhaust or drainage
- 19. light indicating exit status
- 20. light indicating the status of drying(not appropriate for sterilizers without drying function)
- 21. light indicating the option of automatic exhaust and drainage
- 22.light indicating the option of drying(not appropriate for sterilizers without drying function)
- 23. function key for automatic exhaust and drainage
- 24.function key for drying

(2) Warning Tags

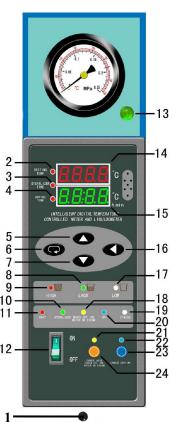


Picture 5

2: Instructions on the Placement of the Equipment

- (1) The equipment must be put alone in an independent spacious room with good ventilation and lighting conditions as well as smooth floor. No other equipment or caustic goods shall be put in the same space with the equipment.
- (2) The equipment must be put in the position where it can be conveniently operated and switched off.

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(3)The fuse, heating tube, solid state relay, pressure gauge, safety valve and sealing ring on the equipment are all consumables that the equipment should be placed in a position where these parts and components can be easily disassembled and installed. No other objects should be placed in the 50cm- diameter circle with the sterilizer as the center.

(4)Incrustation and deposits will emerge after the equipment has been repeatedly used, so that the equipment should be placed in a position where it can be conveniently cleaned.

3: Operation of the Equipment

Prior to use, the accompanying documents of the pressure vessel must be registered in the local auditing agency for filing. The operator must be well trained to familiarize with the operation of the pressure vessel. Each operation must be performed in accordance with the requirements of instruction book to prevent any misoperation or accidents. When the equipment is working, someone professional must be available to avoid any accident.

The safety valve should be verified at least once a year as per Regulations on the Supervision of Safety Technology for Pressure Vessels.

1) Open the lid

Note: Before opening the lid, it must be checked that the pointer of the pressure gauge has returned to zero and there is no pressure in the autoclave.

Rotate anticlockwise the hand wheel (see picture 6) several turns until it can't be moved any more and the lid then gets completely separated from the hold down groove(see picture 7). Heave up the handle (see picture 8) and the lid can be opened.



Picture 6



Picture 7



Picture 8

2) Power on the equipment

Power on the electricity required by this equipment and press "ON" of the power switch on the control panel, and the water-shortage indicator light and low water level indicator light are on (see picture 9). The low water level indicator light-LOW red light, indicates water-break in the evaporation boiler, while the water-shortage indicator light- LACK yellow light, indicates that power has been successfully input into the equipment.



Picture 9

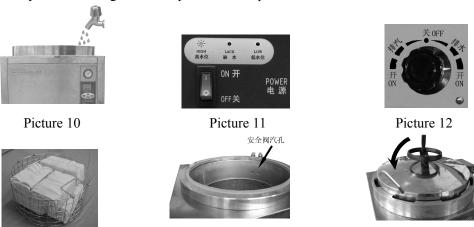
3) Add water

Open the lid, add 12L pure water or the water for daily life directly into the evaporating pan (see picture 10). While doing so, the operator should watch the water level indicator light on the control panel (see picture 11): the LOW red light and LACK yellow light will be off one after another when the water level exceeds the low water level and water- shortage level in succession. The operator is supposed to continue to add more water until the high water level indicator light (HIGH green light) is on (every time, the water must be added to this high level before using the equipment). If water is over added, there will be some water left in the inner container, and in this case the vent valve should be opened to discharge the redundant water in the inner container (see picture 12).

4) Pile up items

The packed items (preferably with a volume of not more than 200×200×100mm) are piled up in the sterilization basket (picture 13) in turn. There should be some space between each two packs so that the

steam can penetrate thoroughly to achieve better sterilization results. Remember that the packed items should not block the release holes of safety valve (picture 14), or else the steam pressure can not be released easily that there might be an explosion in the pan.



Picture 14

5) Seal up the lid

Picture 13

Lay down the lid (as shown in picture 15), rotate clockwise the hand wheel for several turns until it can not be moved any more (see picture 16), and the airproof switch is switched on till this moment to end up with the sealing-up of the lid. The sterilizer is equipped with the safe interlocking device, and when the pressure within the pan is around 0.028MPa, the self-locking device will push the hand wheel to the neutral position (see picture 17) where it can not drive the interlocking device but idle, ensuring that the lid can not be lifted even when pressure exists in the pan.



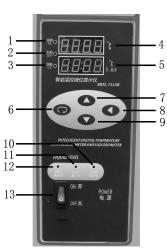
6) Temperature and Time Setting

Please check the name of each part on the control panel before operating the equipment (see picture 18).

- high temperature indicator light
 heating light
 low temperature indicator light
 digital display window for working conditions(red)
- 5. digital display window for setting temperature and time (green)
- 6. key for confirmation 7.key for "increase" 8. shift key
- 9.key for "decrease"10. low water level indicator light11.water-shortage indicator light12. high water level indicator light

13.power switch

Once powered on, the lights of digital display window on the control panel (picture 18) will be on. The upper red digital display window shows the temperature and the work in progress, and the lower green digital display window shows the set value of the temperature and time. The temperature can be adjusted within the range of $50^{\circ}\text{C} \sim 134^{\circ}\text{C}$, and the safety valve will release pressure if the temperature goes beyond



Picture 15

Picture 18

that range. The time can be set in a range from 0 to 99 hours (with the actual effective time determined by the water level of the evaporation boiler). The time displayed on the control panel goes in the form of the countdown and the timer will not start counting down time until the temperature within the autoclave has reached to the set value.

Operating Steps for Setting Temperature

① Press the key for confirmation (picture 19) to enter the setting procedure of the digital display; if the green digital display (picture 20) is flickering, it indicates that setting can be started now.



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Picture 19

Picture 20

② Press the key for increase to increase the temperature and key for decrease to reduce the temperature (see picture 21). Having set the temperature, the operator needs to press the key of confirmation again (picture 19) to confirm the newly set data. The procedure of setting temperature ends when the newly set data are confirmed.



Picture 21



Picture 22

Operating Steps for Setting Time

①Having finished setting the temperature, the operator needs to press the key for confirmation (picture 23) once more to switch over to the procedure of setting time. When finding the green setting window (picture 24) flickering, it indicates that time setting can be started. The first two digits indicate the hour while the last two digits indicate the minute.



Picture 23



Picture 24

- ② Press the key of increase (picture 25) to increase time, and key for decrease (see picture 25)) to reduce time.
- ③Having set the holding time, the operator needs to press the key of confirmation again (picture 26) to confirm the newly set time data. The procedure of setting time ends when the newly set data are confirmed.



Picture 25



Picture 26



Picture 27

Warning:If setting fails or there is wrong operation, the data should be reset. The operator just needs to press the key for confirmation (picture 27) to choose temperature or time. When the green setting window is flickering, resetting can be started.

The shift key (see picture 28) used for fast data adjustment can only be pressed to shift the flickering data when setting the digital display window.



Picture 28



Picture 29

7) Sterilization

① When the temperature and time have been set, the equipment will perform the procedure of automatic sterilization. With the heating light (green light) on the control panel is on (see picture 29), the equipment is proceeding with heating, and the temperature and pressure are going up at the same time. Once the pressure within the sterilizer reaches 0.028MPa(when the temperature will be 100 °C), the pressure indicator light will be on (see picture 30). With the temperature of the sterilizer increases to the set value, the heating light will be off, indicating temperature preservation, and the automatic control system begins to undergo countdown to sterilization while the setting window(see picture 31) on the control panel is displaying the time to be consumed for sterilization.

Warning: This moment, the operator should put up the welt of the steam release valve and rotate the knob of the lower exhaust valve anticlockwise until the pointer points to the maximum exhaust position, keep in this state for some time until the pressure temperature within the pan rises up to about $105\,^{\circ}$ C. Once the pressure temperature reaches about $105\,^{\circ}$ C and the steam runs very fast in both the steam release valve and the lower exhaust valve, the operator is supposed to lay down the welt and rotate the knob anticlockwise until the pointer points to 1/3 position of the maximum exhaust value until a little steam has come out(in this process, the cold air is discharged from the pan). Then the sterilization starts.



Picture 30



Picture 31

(2) For different items to be sterilized, the value of time, temperature and pressure can be determined with a reference to the Reference Table for Items to Be Sterilized as follows. However these values are subject to *Technical Standards for Disinfection* published by Ministry of Health.

Reference Table for Items to Be Sterilized

table 1

Items	Holding Time(minute)	Relative Steam Temperature(°C)	Relative Steam Pressure(MPa)
rubber	15	~121	0.125~
dressing	30-45	121~126	0.125~0.155
ware	15	121~126	0.125~0.155
instrument	10	121~126	0.125~0.155
solution	20-40	121~126	0.125~0.155
dishware	20	121~126	0.125~0.155
others	5	126~134	0.155~0.21

8) Drying

1: Manual exhaust and drying

Rotate the master vent and drain valve clockwise to the position of "open" (see picture 34) to let out water

and steam in the sterilizer and dry the residual water vapor on the materials in a fast way. This method of drying is not appropriate for any solution sterilized by this equipment.

2: Automatic drying

(1)Press the drying key and the key for exhaust and drain, the indicator lights will be on. When sterilization ends and it does not need to preserve heat for sterilization any more, the temperature will decrease to about $102\,^{\circ}$ C and the equipment will switch to the state of pulsating drying. During pulsating drying, the heating light flickers discontinuously until the set time for drying has been used up.

(2) Drying temperature setting;

Press the key for confirmation for more than five seconds, then the word "dry" will emerge on the digital display window. Press "up" "down" "left" and "right" to set the temperature. The temperature can be set in a range of $50 \sim 90^{\circ}$ C and the default setting is 60° C.

(3) Drying time setting;

Set the time for drying in the procedure as described in 6) Temperature and Time Setting.

(4)Set the drying power in percentage term;

Press the key for confirmation \bigcirc for more than five seconds, then the word "RATE" will emerge on the digital display window. Press "up" "down" "left" and "right" to set drying power in percentage term. The drying power can be set in a range of $1\sim15\%$ and the default setting is 10%.

Note: The key for confirmation has to be pressed for five seconds before making any setting.

(5) When heat preservation for sterilization ends, the master vent and drain valve should be rotated clockwise to the largest extent (picture 34) to discharge water and steam and dry the articles that just finished sterilization.

Warning: It indicates that the whole process of sterilization ends when the word "End" appears on the digital display window and the buzzer beeps several times. By this time, the pointer of the pressure gauge should return to zero (see picture33), and the operator is supposed to press "OFF" on power switch (see picture 32) to power off the equipment.



Picture 32



Picture 33



Picture 34

9) Open the Lid

Rotate anticlockwise the hand wheel (see picture 36) until it can not be moved any more when the lid comes apart from the hold down groove (see picture 37). Lift up the hand wheel and the lid (see picture 38) can be opened now.



Picture 36



Picture 37



Picture 38

VI Care and Maintenance

If any parts or components need to be replaced, the operation must be performed by the qualified person that has received professional trainings or the one from the manufacturer. Prior to the replacement,

the professional must first disconnect the breaker to let go the residual steam and wait until the pointer of the pressure gauge returns to zero.

Fault Analysis and Troubleshooting

Table 2

No.	Fault Phenomenon	Cause Analysis	Troubleshooting
1	The actual temperature of the pressure gauge doesn't agree with the digit displayed.	There is cold air in autoclave.	Open the master vent and drain valve appropriately.
2	The water level exceeds the high water level, but the indicator light (green light) is off.	The inner bore of water level regulator gets blocked.	The professional dredges the pipe.
3	The high water level indicator light (green light) is on without having the temperature displayed increased.	a. Holding time has not been set.b. The solid state relay is broken.c. The tubular electric heating element is broken.	Set holding time. The professional replaces the broken solid state relay or/and the broken tubular electric heating element.
4	The red digital display window shows	a. The temperature transmitter is broken.b. The control panel is broken.	The professional replaces the broken parts.
5	The digital display window shows- O O O	The computer control panel is broken.	The professional replaces the broken part.
6	There is no water in autoclave and the heating light (green) is on.	The water-level needle gauge is in contact with the copper shell.	a. Cut off the electricity immediately.b. Revise the water-level needle gauge.
7	There is water vapor in the pressure gauge.	Vapor leaking is found at the joints.	The professional tightens up the joints.
8	When pressing the shift key, there is no flicker.	The control panel is broken.	The professional replaces the control panel.
9	The interlocking light is off or there is no beep.	a. The lid is not tightly closed;the interlocking pin is not in place.b. The interlocking light is broken.c. The water level is lower than the low water level sensor.	a. Open the lid and reclose it tightly.b. The professional replaces the interlocking light.c. Open the lid and refill water to the level higher than the low water level sensor.
10	Water leakage is found on the seal ring.	The seal ring is broken.	The professional replaces the broken seal ring.

No.	Name	Specification	Quantity
1	pressure and temperature switch	high/low voltage	one for each type
2	solid state relay	440V 40A	3
3	rocker switch	250V 15A	1
4	fuse	380V 16A	3
5	tubular electric heating element	2000W	3
6	spring-loaded safety valve	0.217-0.24Mpa	1
7	steam relieve valve	0.25Mpa	1
8	pressure gauge	1.6"	1
9	silica gel seal ring		1

Packing List

Table 4

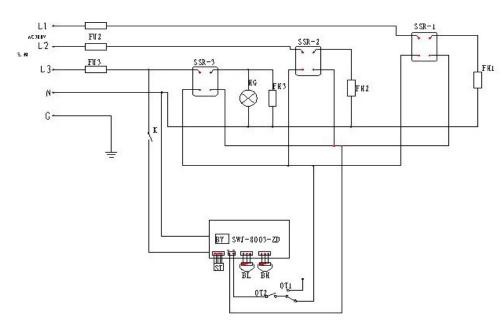
No.	Items	Quantity	Remarks
1	Vertical Pressure Steam Sterilizer with large	1	
1	volume	1	
2	Instruction for Use	1	
3	Product Certification and Warranty Card	1	
4	Quality Tracking Card	1	
5	Inspection Certificate for Pressure Vessels	1	
6	sterilization baskets	3	

- 1. This equipment has functions of over temperature alarm and automatic power off. In case the temperature can not reach to the set value, the heat responsive elements shall be replaced.
- 2. The equipment is equipped with overpressure safety device- the safety valve. Under normal conditions, the welt of the safety valve should be pulled upwards with a clamp several times to ensure the flexibility of the valve. And if the safety valve fails to perform, it should be replaced timely.
- 3. The interlocking device coated with lubricant is equipped on the door (lid) of the equipment. The operator should examine the interlocking device every half year and coat it with the medical level petroleum jelly which is essential for the lubrication of the device. If any parts of the interlocking device are found to be heavily worn, the operator should contact the manufacturer for the replacement. A professional with proper training is also qualified for the replacement. Replacement should be carried out by a professional who is experienced and has received appropriate training.
- 4. After 1000 sterilization cycles, the personnel responsible should contact the manufacturer to replace the interlocking device.
- 5. The normal service life of this equipment is 10,000 hours (about 5 years).
- 6. Fault analysis and troubleshooting (see table 2).
- 7. List of major components (see table 3).
- 8. Packing list (see table 4).

VII Structure Chart and Electrical Diagram



- 1.hand wheel
- 2.lid
- 3. pan
- 4.safety valve, steam release valve
- 5. master vent and drain valve(manually operated)
- 7. control panel
- 8. castor wheel
- 6. pressure gauge
- 9.water and steam discharge outlet(caution, hot!)



Picture 40

- 1: FU1-3 fuse;
- 2: SSR1-3 solid state relay;
- 3: HG indicator light for heating pipe (it looks green

- when the pipe is working)
- 4: FH1-3 heating pipe;
- 5: K power switch; 6: ST touch control panel;

- 7: BL water level sensor;
- 8: BH temperature sensor;
- 9: SWJ-8003 -ZD computer-controlled

- circuit board;
- 10: QT1 thermal loads control switch;
- 11: QT1 thermal loads control switch;

- 12: QT2 micro-interlock switch;
- 13: LI-3 N G electrical wire

VII Precautions

- 1. When loading articles to be sterilized, exhaust holes of the safety valve and vent valve can not be blocked and enough space must be saved for a free flow of air or else the safety valve and vent valve will not be able to work normally, in which case accidents may happen.
- 2. When sterilizing a solution, the solution should be filled in a heat-resistant glass bottle. The volume of the solution should be no more than 3/4 of the total cubage of the glass bottle, and the bottle neck should be stopped with cotton fabric rather than hole-free rubber or cork.

Be cautious: When finishing sterilizing a solution, the steam can not be released immediately. You have to wait until the pointer of the pressure gauge returns to zero before you emit the residual steam.

- 3. Articles of different types or different sterilization requirements, like dressing and solution, can never be put together for sterilization to avoid any damage.
- 4. If the pointer of the pressure gauge has returned to zero after sterilization, but the lid can not be easily unveiled, the operator needs to adjust the vent valve to let outside air get into the sterilizer, in which case the vacuum will be eliminated and the lid can be opened then.
- 5. If the pointer of the pressure gauge points to wrong figures or can not return to zero after being repeatedly used, the pressure gauge should be examined and repaired or replaced. It should be calibrated with the standard pressure gauge regularly, and if it fails to work, it should be replaced with the new one.
- 6. The equipment shall be kept clean and dry for longer service term. The rubber seal is aging as it is used day and day that it should be replaced regularly.
- 7.Instructions on the replacement of the fuse and other components: when plugged into a power supply, but the power source indicator light is off, the operator should check if the fuse has been damaged. If found broken, the fuse should be replaced immediately to rework the equipment.
- 8. The safety valve should be validated for its reliability every year, or else it might fail to work, in which case the redundant pressure within the pan can not be released and an explosion may take place.
- 9. The manufacturer shall replace or repair a broken product for free on condition that the user operates strictly in accordance with rules in Instructions for Use and he or she has altered no internal structure of the product within 12 months from the date of purchase.
- 10. Protective Conductor Terminal; Caution! Hot; Caution! Danger (please refer to the accompanying documents).
- 11. For the external electricity of this equipment, there should be an earth-leakage protection switch capable of cutting an electric current of more than 16A.
- 12. Power supply voltage for this equipment:380V; the fuse: RT14~RT18, 380V 16A ×3, φ10 ×38.
- 13. The electric parts of the equipment can be bought from us or replaced with identical ones with safety certification in the market.
- 14. It's best to use pure water to reduce incrustant.
- 15. The equipment should be cleaned once a week. When cleaning, brush off the incrustant attached to the inner wall with a hairbrush, and then scrub it clean with a piece of clean cloth.
- 16. If any component listed in table 3 is found damaged and needs replacing, the personnel responsible shall contact the manufacturer for a plan of replacement.