

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.

## Technical Publications

# TANDA PRO Steam Sterilizer

**Operation Manual** 

ASS0007 REV-H **C**€<sub>0197</sub>

**Operation Documentation** 

### Regulatory Requirement

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.



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### **Revision History**

REV	ISSUE DATE	REASON FOR CHANGE
2024-A	2024.7.3	First Issue

Please verify that you are using the latest revision of this document. Information pertaining to this document is maintained on manufacturer. If you need to know the latest revision, please contact your distributor, sales representative, or our service dept.

### Regulatory Requirements

### **Conformance Standards**

The content of this instruction is fit for sterilizers.

Above sterilizer accord with the requirements of European Class B:

93/42/EEC

97/23/EC

EN 61010-1

EN 61010-2-040

EN 13060

EN 61326-1

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This product complies with the regulatory requirement of the following:

• Council Directive 93/42/EEC concerning medical devices:

The CE label affixed to the product testifies compliance to the Directive.

The location of the CE marking is shown in this manual.

#### Certifications

Manufacturer is EN ISO 9001 and EN ISO 13485 certified.

### **Original Documentation**

The original document was written in English.

### **Declaration of Conformity**

Council Directive 93/42/EEC concerning medical devices:

The CE label affixed to the product testifies compliance to the Directive.

The location of the CE marking is shown in this manual. In this manual there are present the CE certification and the Conformity. Check appendixes.

### **Table of Content**

Regulatory Requirement	1 -
Revision History	2 -
Regulatory Requirements	3 -
Table of Content	4 -
Chapter 1 Introduction	6 -
1.1 Attention	6 -
1.2 Usage Indications	
1.3 Contraindication	
Chapter 2 Safety	7 -
2.1 Explanation Symbol	7 -
Device Sign Description	
Label Description	
Operation Prompt	
2.2 General Safety Recommendations	8 -
2.3 Safety Parts	9 -
2.4 Operation Risk	
2.5 Protection Device	10 -
Chapter 3 Receiving and Installation	11 -
3.1 Check the Package	11 -
3.2 Unpacking the Accessories	11 -
3.3 Installation Environment	12 -
3.4 Installation	12 -
3.5 Power Connection	13 -
Chapter 4 Description and Specification	14 -
4.1 Front View	14 -
4.2 Rear View	15 -
4.3 Open View	16 -
4.4 External Dimension	16 -
4.5 Loading Size	17 -
4.6 Specification	17 -
4.7 Sterilization Cycle	19 -
Chapter 5 Panel and Functions	20 -
5.1 Function Panel	20 -
5.3 Sterilization Program	24 -
5.4 Interface of Sterilization Process	24 -
Chapter 6 Operation Process	27 -
6.1 Turning on Power	27 -

6.2 Adding Distilled Water	27 -
6.3 Alarming if Used Water Tank is Full	27 -
6.4 Selecting Program	28 -
6.5 Loading Articles	28 -
6.6 Closing the Door	29 -
6.7 Starting a Program	
6.8 End of Cycle	
6.9 W-Light Intelligent Lighting System	
6.10 Turning Off Power	
6.11 Abnormal Exit	33 -
Chapter 7 Essential Information	34 -
7.1 Please Ensure the Following	34 -
7.2 And Please Do Not	34 -
Chapter 8 Maintenance	36 -
8.1 Maintenance Schedule Chart	36 -
8.2 Daily Maintenance	36 -
8.3 Weekly Maintenance (More Often If Necessary)	37 -
8.4 Monthly Maintenance	38 -
8.5 Other Maintenance	39 -
8.6 Servicing by the Approved Technician	40 -
Chapter 9 Transportation and Storage	42 -
9.1 Preparation before Transportation and Storage	42 -
9.2 Draining	
9.3 Conditions for Transportation and Storage	42 -
9.4 Package	42 -
Appendix 1 Articles Preparation Procedure	43 -
Appendix 2 Error Code List	44 -
Appendix 3 Electric And Pipeline Diagrams	45 -
Pipeline Diagram	45 -
Electric Diagram	
Annendix 4 Inspection Checklist	- 17 -

### Chapter 1 Introduction

### 1.1 Attention

- This operation manual contains necessary and sufficient information to operate the sterilizer safely, like optimal usage, safe and reliable operation, regular and correct servicing requirements.
- Read and understand all instructions in this manual before attempting to use the product.
- Keep this manual with the sterilizer at all times. Periodically review the procedures for operation and safety precautions.

### 1.2 Usage Indications

Application to all wrapped or non-wrapped, solid, hollow load products type A and porous products or related articles.

This sterilizer can be used for dental clinic, laboratory, surgical room, emergency room, ophthalmology, gynecology and steam, cosmetic hospital and so on, by doctors and professionals.

### 1.3 Contraindication

There is no any contraindication of this equipment.

### **Chapter 2 Safety**

### 2.1 Explanation Symbol

### **Device Sign Description**



"ATTENTION" – Refer to this Operation Manual" is intended to alert the user to refer to the operation manual or other instructions when complete information cannot be provided on the label.



"ATTENTION" – Pay attention to the high temperatures in the chamber, and to the sterilizer exterior when exhausting system is running.



"Protective Earth" - Indicates the protective earth (grounding) terminal.



"CAUTION" - Dangerous voltage" (the lightning flash with arrowhead) is used to indicate electric shock hazards.

### **Label Description**

SN	Symbol for "SERIAL NUMBER"		Symbol for "MANUFACTURER"
REF	Symbol for "CATALOGUE NUMBER"	EC REP	Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Symbol for "DATE OF MANUFACTURE"	<u></u>	Symbol for "CAUTION"

### **Operation Prompt**

Note	Indicates that concerned information is easier or helpful in operation		
Caution	Indicates that a potential hazard may exist which, through inappropriate conditions or operation, will or can cause:  • Minor injury  • Property damage.  • Damage to machine		
Warning	Indicates that a specific hazard exists which, through inappropriate conditions or operation, may cause:  • Severe personal injury  • Substantial property damage  • Substantial damage to machine		

NOTE: Indicates precautions or recommendations that should be used in the operation.

### 2.2 General Safety Recommendations

- The user is responsible for proper operation and maintenance of the sterilizer in accordance with the instructions listed in this manual.
- . The sterilizer could not be used for liquid.
- The sterilizer could not be used for gas.
- ❖ The trays and the load will still be hot at the end of each cycle. Use the tray holder to remove each tray from the chamber.
- Do not open the door of the chamber during the sterilization programs.
- ❖ Do not put your hands or face on the cover of the water tank when the sterilizer is running.
- Do not remove the instruction plate or any label from the sterilizer.
- Do not pour water or any other liquid over the sterilizer.
- Do not fill the caustic liquid into the water tank.
- Do not fill the caustic matter in the chamber.
- Use only high quality distilled water.
- Unplug the mains lead before inspecting or servicing the machine.

- Only an approved technician using original spare parts can carry out repairs and maintenance.
- In case of transportation, drain both water tanks completely, allow the sterilization chamber to cool down and preferably use the original packaging.
- ❖ The articles under sterilization should be removed by special tools when the temperature over 40°C.
- Picking-up the sterilizing trays should use the special tools provided.
- During the transportation, the sterilizer should be carried by two people in case of turning over.
- Notice! This product can't be put on the place that is not easy to cut off power supply.
- Prohibit covering the lid of water tank during usage.

### 2.3 Safety Parts

### **Temperature Protection**

Part Name	Function
Temperature Protector (Steam Generator)	Cut off current when the steam generator temperature is too high.
Temperature Protector (Heating Ring)	Cut off current when the heating ring temperature is too high.

### **Electricity Protection**

Part Name	Function
Double Fuse	Cut off current when the connected power is too high or unstable.
Electronic Filter	Filter the electromagnetic interference during working.

### **Mechanical Protection**

Part Name	Function
Jiggle Switch	Ensure the door closed completely, avoiding safety risk.
Tray Tong	Avoid scald when removing articles from the chamber

### **Control Part**

Part Name	Function
Temperature Sensor (Internal)	Measure temperature inside the chamber
Temperature Sensor (Heating Ring)	Measure temperature of the heating ring
Temperature Sensor (Steam Generator)	To measure temperature of the steam generator
Pressure Sensor	To measure pressure of the chamber
PCB Control	Control system for all the process of sterilization

CAUTION: Manufacturer is not held responsible for any arbitrary disassembly, amendment with the unit, by unauthorized person or unprofessional technician.

### 2.4 Operation Risk

Please take attention on avoid operation risk during operation.

#### Scald risk

- Every time opening the door after sterilization cycle, please keep an appropriate distance, because the chamber still has rudimental steam with high temperature.
- Every time open the door after sterilization cycle, please not touch the main door and chamber, because of high temperature, and avoid to be scalded.

#### **Pollution risk**

Please clean the chamber after every time use to avoid rudimental contamination left inside chamber.

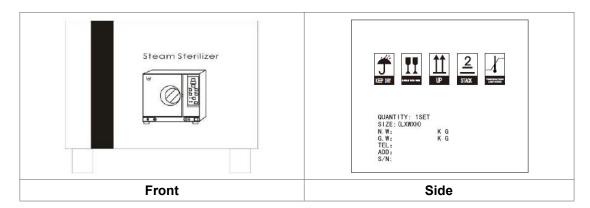
### 2.5 Protection Device

Device Name	Function
Plastic or fabric glove	Useful during load and remove articles, avoid scald.

### Chapter 3 Receiving and Installation

### 3.1 Check the Package

Please check package carefully when you receive the product.





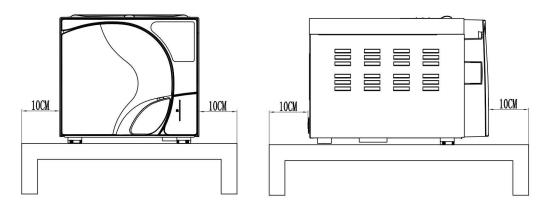
### 3.2 Unpacking the Accessories

Open the package and take the product out, remove the plastic bag then open the door to take all the accessories and check as following:

No.	Part Name	Qty	
1	Rack	1 piece	
2	Tray	3 sets	
3	Removal Tool	1 piece	
4	Draining Tube	1 piece	
5	Power Supply Cable	1 piece	
6	Door Gasket	1 piece	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$

### 3.3 Installation Environment

The sterilizer should be set in a place which at least has 10cm distance against each side (20cm to the top) as following:



- ❖ The sterilizer should be set in a place with good ventilation.
- **❖** The temperature of environment: 5-40 °C
- The humidity of environment: ≤85%
- ❖ Atmosphere pressure: 860Hpa~1060Hpa
- An earth connection is essential.

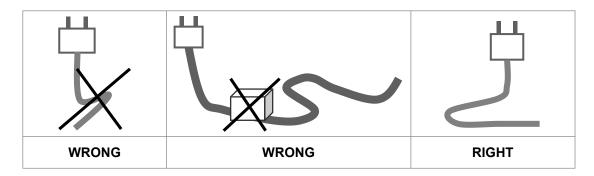
CAUTION: Do not place any stuff which easily melts near the sterilizer.

### 3.4 Installation

- The sterilizer should be set on level table or place; the front-end should be a little bit higher then back-end(via front pads).
- ❖ The sterilizer cooling and vent area should not be jammed or blocked.
- Do not put any stuff on the top of the sterilizer.
- ❖ Do not put any stuff in front of the door, to avoid accident when open the door.
- ❖ Do not put any corrosive stuff near the sterilizer to avoid accident or risk.

### 3.5 Power Connection

- ❖ The sterilizer should be connected with a stable and separated power source.
- Power socket is at the back of the sterilizer.
- Please confirm the connection power is complied with specification of nameplate at the back of sterilizer.



CAUTION: Do not bend the power wire to avoid damage of power wire.

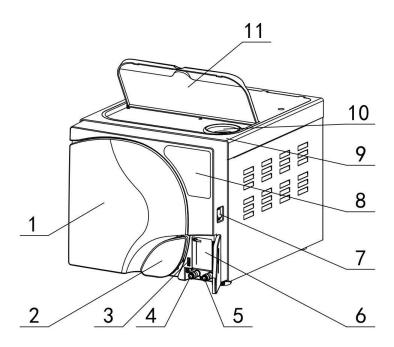
Do not put any heavy stuff on the power wire to avoid damage of power wire.

Do not use other power wire to avoid damage of sterilizer.

Do not try to add the power wire to avoid accident and risk.

### **Chapter 4 Description and Specification**

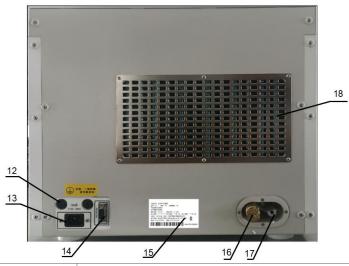
### **4.1 Front View**



No.	Name	Description	
1	Door	Door panel	
2	Door Handle	Door handle with air control protective lock	
3	USB Interface	USB3.0 interface used for data transmission	
4	Used Water Tank Drainage Port	Used to discharge waste water from waste water tank	
5	Distilled Water Tank Drainage Port	Used to empty the distilled water tank when the water tank is cleaned	
6	Built-in Printer	To output the cycle records	
7	Power Switch	To control the on/off of the machine	
8	Display Panel	To display the operation menu, operation steps, operation content, so that you can operate in the process of work	
9	Water Tank	Used to hold distilled water and used water	

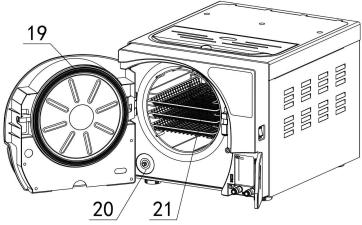
10	Adding Water Port	To add distilled water
11	Water Tank Rotatable Cover	To avoid foreign bodies to enter, ensure distilled water quality, when you want to manually add water or observe the inside, you can open the cover upward, please close it after adding water

### 4.2 Rear View



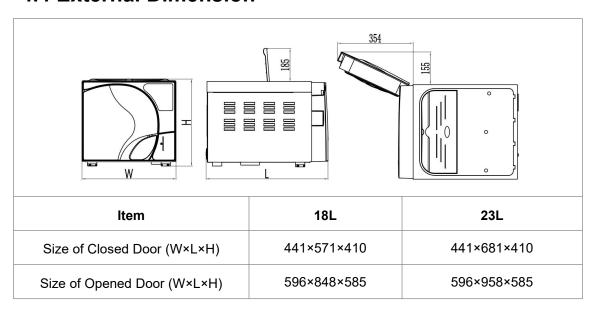
No.	Name	Description			
12	Fuse	Power fuse			
13	Power Socket	Connect the power			
14	Signal Interface	To output signal			
15	Nameplate	Basic information of the machine and manufacturer			
16	Safety Valve	Automatic pressure relief when the pressure inside the chamber exceeds the operating voltage			
17	Air Exhausting Port	Air outlet port			
18	Vent Area	Hot gas can be discharged from the vent area by the condenser			

### 4.3 Open View



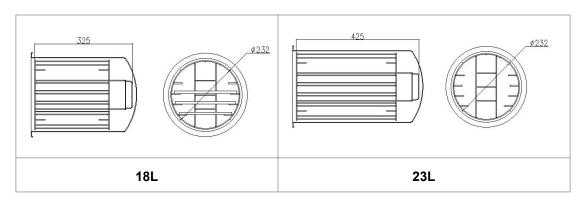
No.	Name	Description
19	Door Gasket	To seal the door
20	Air Filter	Filter the air and make sure that the air entering the pan is clean
21	Trays	To load the instruments to be sterilized

### **4.4 External Dimension**



### 4.5 Loading Size

The loading size of sterilizer as followed:



### 4.6 Specification

### **Basic Specification**

Rated voltage: AC220V~230V, 50HZ

AC110V~125V, 60HZ According to the product nameplate!

Rated power: 18L 1500VA, 23L 1700VA

Fuse: 220V:F12AL/110V:F25AL According to the product nameplate!

Operation temperature: 5~40°C

Atmospheric pressure range: 70kPa ~ 106kPa;

The board affording weight: 4000 N/m<sup>2</sup>

Noise: < 50db

Maximum capacity of one tray: 1000g

The frequency of water draining: once a day, drain the water once you find "waste water over"

during operation.

The maximum duration of using loading test: 90mins

The maximum thermal radiation energy under the condition of 20 ℃~26 ℃: <2000J

### Sterilizer Chamber

Material: stainless steel (for medical)

Max. work pressure: 2.5bar Min. work pressure: -0.9bar Max. temperature: 145 °C

Chamber volume: 18L(Φ245×352mm) 23L(Φ245×450mm) Loading size: 18L (198×204×285mm) 23L(198×204×385mm) 23L (3.21kg/cm<sup>2</sup>)

Max. loading weight: 18L (3.07kg/cm<sup>2</sup>)

Working pressure/temperature:  $1.10\sim1.30$ bar/ $121^{\circ}$ C $\sim122^{\circ}$ C;  $2.10\sim2.30$ bar/ $134^{\circ}$ C $\sim135^{\circ}$ C

Water volume for one cycle: 0.35L~ 0.4L

### **Sterilizer Steam Safety Valve**

Safety release pressure: 2.45bar Max. working temperature:  $160^{\circ}$ C

#### **Water Tank**

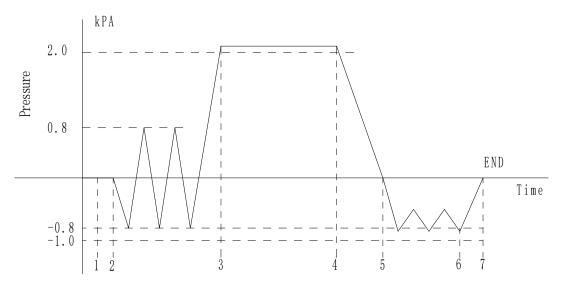
Main water tank volume: 18L (3.5L) 23L (4L)

CAUTION: Water added into main water tank must be distilled water! Water temperature must be under 40  $^{\circ}$ C.

### **Test Method**

- Vacuum Test
- ❖ B&D Test
- Helix Test

### 4.7 Sterilization Cycle



1-7 Entire duration					
1-2 Pre-heating	2-3 Pre-vacuum				
3-4 Sterilizing	4-5 Air-discharging				
5-6 Drying	6-7 Stabilizing				

### Table—Types of sterilization cycles

Туре	Purpose description
В	The sterilization of all wrapped or non-wrapped, solid, hollow load products type A and porous products as represented by the test loads in this standard.
S	The sterilization of products as specified by the manufacturer of the sterilizer including non-wrapped solid products and at least one of the following: porous products, small porous items, hollow load products type A, hollow load products B, single wrapped products, multiple-layer wrapped products.
NOTE 1	The description identifies ranges of products and test loads.
NOTE 2	Non wrapped sterilized instruments are intended either for immediate use or for non sterile storage, transport and application (e.g. to prevent cross infection).

### **Chapter 5 Panel and Functions**

### 5.1 Function Panel

#### 5.1.1 Digital Display

Integrated display panel

- $\diamond$  Displays the temperature in the chamber in real time. Unit:  $^{\circ}\mathbb{C}$ .
- Displays the pressure in the chamber in real time. Unit: kPa.
- Displays cycle status/time.
- Displays the error code when the cycle fails.





### **Program Button**

To select sterilization programs.



To select test programs.



To start the program, force exit the program and remove the error code.

### 5.1.5 A M \* Sterilization Program Indicators

When the desired sterilization program is selected by pressing Program Button, the corresponding indicating light will be on. Programs from left to right are:

#### **UNWRAPPED**

Class-S sterilization program for non-encapsulated, non-cavity loaded instruments (cavity length to hole diameter ratio less than 1) that can withstand 134°C temperature.

1 time pre-vacuum; 4 minutes for sterilization of 134°C/210kPa; 9 minutes for drying.

#### **WRAPPED**

Class-B sterilization program for unwrapped or wrapped instruments that can withstand 134  $^{\circ}$ C temperature.

3 times pre-vacuum; 5 minutes for sterilization of 134 ℃/210kPa; 9 minutes for drying.

#### **PRION**

Class-B sterilization program for unwrapped or wrapped instruments with the presence or potential presence of haemophilic bacteria or viruses that can withstand 134°C temperature. 3 times pre-vacuum; 18 minutes for sterilization of 134°C/210kPa; 9 minutes for drying.

#### **POROUS**

Class-B sterilization program for unwrapped or wrapped instruments and hollow fabrics that cannot withstand 134  $^{\circ}$ C temperature and can withstand 121  $^{\circ}$ C temperature (fabrics are not allowed to be close to the chamber).

3 times pre-vacuum; 20 minutes for sterilization of 121°C/110kPa; 18 minutes for drying.



Test Program Indicators

When the desired test program is selected by pressing Test But indicating light will be on. Programs from left to right are:

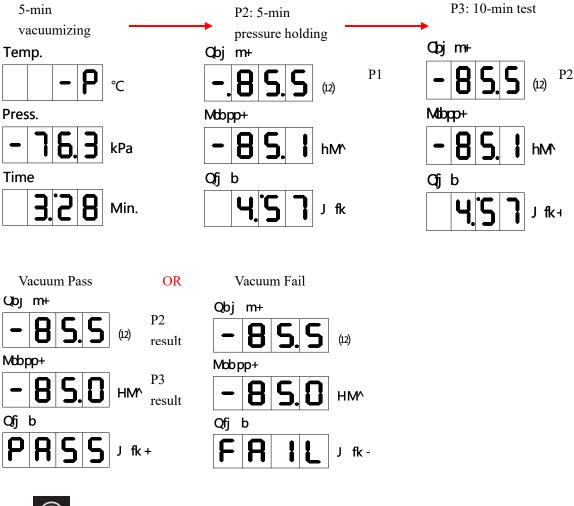
Test Button, the corresponding

#### **Helix&BD Test**

3 times pre-vacuum; 3.5 minutes for sterilization of 134°C/210kPa; 3 minutes for drying.

#### **Vacuum Test**

### Interface of vacuum test process





When the pipe rinse program is selected by pressing Test Button, this indicating light will be on.

The pipe rinse program is used for regular maintenance and automatic cleaning of pipelines.



When the drying program is selected by pressing Test Button, this indicating light will be on.

The program is used when there is high drying requirement for instruments and can be used for individual drying of instruments.



Distilled water shortage indicator, it will illuminate when the distilled water level is too low, to warn you that water should be added in (distilled water is still enough for this running cycle); Used water discharge indicator, it will illuminate when the used water tank is full, to warn you that water should be drained out.



Water quality alarm indicator, when the distilled water quality is substandard, the light goes on.



When a sterilization program is selected, the sterilization temperature indicator shows the sterilization temperature corresponding to this sterilization program.



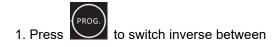
Please contact the local dealer or our service dept if there is any problem.

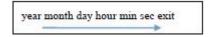
#### **5.2.2 CUSTOM PROGRAM**

Press to select program until all program indicators are illuminated, the machine will enter custom program interface, the user can set the sterilization time, vacuum time, sterilization temperature and dry time accordingly.

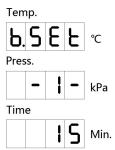
#### **5.2.3 TIME SETTING**

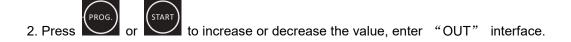
In standby mode, keep pressing + test for 8 seconds to enter the time setting interface

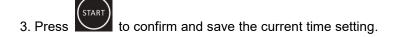




Term	year	month	day	hour	minute	second	Exit
	T. SET						
display	-0-	-1-	-2-	-3-	-4-	-5-	-6-
	14-	05-	24-	15-	45-	55-	out-







Attention: Keep the value of second item low than 60sec.

### 5.3 Sterilization Program

When sterilizer's power is switched on, you can select following programs by different items:

Program	Temp.	emp. Pres. Vacuun		Sterilization Time	Drying Time
UNWRAPPED	<b>134</b> ℃	210kPa	1	4 min	9 min
WRAPPED	134℃	210kPa	3	5 min	9 min
PRION	134℃	210kPa	3	18 min	9 min
POROUS	<b>121</b> ℃	110kPa	3	20 min	18 min

### 5.4 Interface of Sterilization Process

3 times pre-vacuum program example: PACKED 134  $^{\circ}\mathrm{C}$ 

	21.3			21.3			116.7	
	0.7			-80.4			80.8	
	HE			UA.1			Pr.1	
1st F	Preheating		U/	A.1: 1st vacuu	m	Pr.1: 1st pressurize		ize
	21.3			116.7			21.3	
-	-60.4			60.8			-60.0	
	UA.2			Pr.2			UA.3	
UA.: 2	UA.: 2nd vacuum		Pr.2: 2nd pressurize			UA.3: 3rd vacuum		
	116.7			134.8			21.3	
	50.8			218.3			0.7	
	Pr.3			St			rE	
Pr.3: 3rd pressurize		ize	ST: Sterilization			rE: Exhaust		
	21.3			90.2				
-	-80.4			0.11				
	dr			PASS				
	dr: Dry			End				

	21.3			21.3			116.7	
	0.7			-80.4			80.8	
	HE			UA.1			Pr.1	
	Pre-vacuum		U	A.1: 1st vacuu	m	Pr.	.1: 1st pressuri	ze
	134.8			21.3			21.3	
	218.3			0.7			-80.4	
	St			rE			dr	
;	ST: Sterilizatior	1		rE: Exhaust			dr: Dry	
	90.2							
	0.11							
	PASS							
	End							

### **Chapter 6 Operation Process**

### 6.1 Turning on Power

Before starting the operation, please connect the power supply. The power switch controls the on/off of the machine, which is located in the lower right corner of the sterilizer. When you turn on the power supply, the display will enter the full light interface, wait 1 second, enter the version number display interface, wait 1 second, automatically jump into the previous sterilization procedure interface.

### 6.2 Adding Distilled Water

Switching on sterilizer, if the "Water" indicator illuminated, it means the distilled water in the water tank is of its lowest level and you have to add water in. And even press "START" button, it will not work either, so you need to add distilled water until the indicator light off.

Fill in distilled water from the top of sterilizer.



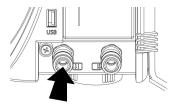
CAUTION: Use distilled water only to extend the life time of sterilizer.

Do not tilt the sterilizer when the reservoir is full of water.

### 6.3 Alarming if Used Water Tank is Full

The "Drain" indicator light illuminates during the cycle, which means that the used water tank reach the alarm line and needs to be drained.

Connect the drainage tube to used water outlet, and used water will be drained automatically.



Generally, the maximum temperature of drained water should be under 70 °C. If it is higher, you need to check whether the fan work normally, or contact the local distributor immediately.

### 6.4 Selecting Program

Select the required sterilization program which you need. When you choose, the corresponding indicator light will be illuminated.

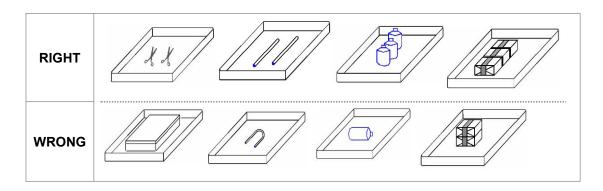
### 6.5 Loading Articles

Articles should be put on the trays with some gap between each articles so that the steam can be ventilated freely. Please use the attached removal tool to load trays into chamber to avoid scalding.



### Tray arrangement note:

- Read the following instructions for proper placing of articles and material.
- Make sure that the articles of different materials are separated and placed on different trays.
- In case of carbon steel articles, place a towel or paper-wrap between the tray and the articles in order to avoid a direct contact.
- ❖ All the articles must be sterilized in an open position.
- ❖ Make sure that the articles remain apart during the sterilization cycle.
- Do not overload the trays.



CAUTION: Recommended to clean the articles before loading.

ATTENTION: It is helpful to turn on power for warming 5 ~ 10mins before running cycles, if the environment temperature under 10℃.

### 6.6 Closing the Door

After the instruments to be sterilized is loaded, please close the door, "LoAd" will stop blinking, and then proceed to the next step. If the door is not completely closed, "LoAd" will continue to blink.



CAUTION: The door should be shut tightly before running program to avoid the danger.

ATTENTION: The "Load" code will twinkle if the door not closed. The sterilizer will not run unless the door has been closed completely.

If the door has been opened during the cycle, the sterilizer will display error code"Er06". Press "START" to cancel alarm, and then close the door to restart.

### 6.7 Starting a Program

Close the door completely, and press "Start/Stop" button to start a working cycle.

The sterilizer will heat, sterilize and drying articles automatically. The whole process will take 20-50mins. It depends on the articles being sterilized, the initial temperature, and the program you selected.

#### The Process of Sterilization

### Pre-heating: Display HE

Chamber will start to be pre-heating when turning on the power switch, and keeping the chamber warm.

21.3

0.7

HE

### Pre-vacuum: Display UA

Outputted the airs in the chamber, and inputted steam in the chamber, run 3 cycle times.

21.3

-80.4

UA.1

21.3

-60.4

UA.2

21.3

-50.4

UA.3

### Pressurize: Display Pr

Keep heating until getting the time of sterilization.

116.7

8.00

Pr.1

116.7

60.8

Pr.2

116.7

8.00

Pr.3

### Sterilization: Display ST

Display sterilizing time and temperature. The sterilizer keeps the temperature of sterilization with time is counted down.

134.8 218.3 St

#### Vacuum drying: Display rE and dr

Display dry-vacuum time and the temperature. Draining used water and steam. Sterilizer will automatically switch to vacuum drying process after the steam pressure drop and chamber temperature down.

21.3	21.3
0.7	-80.4
rE	dr

### **End: Display PASS**

The buzzer make a sound means the total sterilization processes have been finished, then wait for the pressure down to "0" bar at the steam manometer on command front panel.

90.2 0.11 PASS

CAUTION: Releasing pressure until the pressure down to under 10 kPa.

Do not put or cover any stuff on the machine to keep heat venting well.

When using the sterilizer at an altitude of more than 500 meters, make the necessary settings. Please contact the dealer or the company's after-sales service department.

### 6.8 End of Cycle

When working cycle has been finished, the display window will show alternatively "PASS" and Full cycle time, and give you a sound notice. You can open the door and take out articles.

WARNING: Do not try to open the door when the pressure value is higher than 10kPa.

When the door opened, the sterilizer will return to the initial state, heat-preserving and waiting for next sterilizing cycle. Before starting a new cycle, it will be kept in a heat-preserving condition all the while.

CAUTION: After sterilizing has been finished, please use the removal tool to take the trays out from sterilizing chamber. It will be better to store sterilized articles after cooled down totally.

### 6.9 W-Light Intelligent Lighting System

The RGB LOGO light on the front of the door will change in different colors according to the working state of the machine: ① Open the door: white light flashes; ② Door closed: steady purple light; ③ During program: purple breathing light; ④ Error alarm: steady red light; ⑤ End of cycle: steady green light. ⑥ Force exit or suddenly power cut: steady yellow light.



### 6.10 Turning Off Power

If you finished the sterilization, please turn off the power switch. The power switch light will be off, and close the door but do not lock it.

If do not use it for a long time or for storage, please unplug the power cord.

ATTENTION: During the sterilizing, we suggest that you use the indicator tape. Put them in the chamber in order to ensure reliability of sterilization.

### 6.11 Abnormal Exit

In the cycle, if the program is interrupted by the error or press "start/stop" button 2times continuously, it will enter "abnormal exiting program", issue a long alarm sound and exhaust air directly to 0 kPA.

In this state the air release solenoid valve will be opened and exhaust air. You need to cancel this alarm by pressing "Start/Stop" button, and back to normal display.

WARNING: Do not try to open the door when the pressure value is higher than 10kPa.

### **Chapter 7 Essential Information**

Please ensure the sterilizer operated correctly. It is very important to follow below points and carry out the necessary maintenance procedures as specified.

### 7.1 Please Ensure the Following....

- You have read and follow these operating instructions.
- ❖ The load is suitable for sterilizing in the selected program.
- The load can be sterilized at the selected temperature.
- The load has been rinsed thoroughly in clean water before sterilization to avoid any chemical residues left after cleaning contaminating the sterilizer.
- When placing instruments on trays, ensure that they are placed on the ribs of the tray (to help drainage), they must not touch each other and must not interfere with other trays or the chamber above.
- Only distilled water can be used.
- The sterilizer should be set in a ventilated area.
- ❖ The sterilizer is not installed in an enclosed cupboard space.
- Keep the door ajar if not in use.
- Only qualified personnel could do the service of sterilizer.
- Keep and reserve the package for transportation.
- If the place which you use the machine is over 500m height, it should be set before use.
  You can contact with local dealer for the detail.

### 7.2 And Please Do Not....

- ...lose this manual.
- ...add any chemicals or whatsoever analogous water to the sterilizer.
- ...attempt to sterilize volatile substances, toxic materials or other unsuitable loads. Refer to your "Authorized Person" for advice.
- ...place the sterilizer in direct sunlight.

- ...place the sterilizer on heat sensitive surfaces.
- ...use inappropriate cleaning materials.
- ...drop or abuse the sterilizer.
- ...use in areas of risk associated with flammable materials or gases.

## **Chapter 8 Maintenance**

### 8.1 Maintenance Schedule Chart

Maintenance Required	Person Responsible	
Daily		
Clean Door Gasket	User	
Clean Chamber	User	
Weekly		
Clean Chamber, Trays and Rack	User	
Clean Water Draining Filter	User	
Monthly		
Clean Reservoir	User	
Yearly		
Performance verification and maintenance	Qualified service personnel	
As Required		
Change Door Gasket	User	
Cleaning function	User	

## 8.2 Daily Maintenance

#### **Cleaning Door Gasket**

The door gasket and the mating surface should be wiped off clean each day with a clean, damp cloth. Do not use abrasive cleaners on the gasket or mating surface.

Use warm soapy water for keeping marks of sterilizer persistent, but ensure any soap residues are completely removed by wiping both the gasket and the vessel again with water using a lint free damp cloth.

WARNING: Refer to qualified personnel for servicing.

Never use a wire brush, steel wool, abrasive material, or chloride-containing products to clean door and chamber assembly.

"Caution hot surface. Avoid contact." ensure that the sterilizer is cooled down fully before cleaning to avoid burns.

#### **Cleaning after Liquid Loads**

Biological media tends to boil at a higher rate than other liquids during venting. This causes media to be spattered inside the chamber. Therefore, the chamber must be cleaned daily when you are sterilizing media. Cleaning as follows:

- Allow unit to be cooled down.
- ❖ Wipe out chamber and door with a clean, damp cloth.

WARNING: Failure to keep the interior of the stainless steel chamber free of mineral deposits and debris can cause premature failure of the sterilizer.

## 8.3 Weekly Maintenance (More Often If Necessary)

#### **Cleaning Chamber, Trays and Rack**

At least once a week, the trays and tray rack should be removed from the sterilizer chamber. The trays, tray rack and chamber should be thoroughly cleaned to remove any deposits from the surfaces.

Clean the trays, rack and chamber (especially the bottom of the chamber) with appropriate anti biological cleaners. Wipe all residues from the surfaces with a dampened, lint-free cloth.

WARNING: To prevent from collection of mineral deposits and corrosion of chamber components, use distilled water only as specified. Clean chamber after each use if sterilizing saline solutions.

#### Cleaning water draining filter

Water draining filter (pic 8-1) might has been jammed by some dust because of use for a long-term, so effect of vacuum and drying would be influenced. Some tiny impurity might be deposited on the filter after a long-term use, blocking the filter, so as to influence the effect of

the vacuuming and water discharging. The kinds of impurity come from smeary dust on the instruments being sterilized or some calcification in the water.



Keep cleaning of the inside chamber in order to make life-time of filter much longer. Please take the following advice for consideration:

- Use eligible distilled water.
- The articles should be cleaned before placing in. It is good to use specified packing for the articles with oil or other impurity, don't forget to seal up.
- Rotate the filter which composed by filter net tube (A) and filter holder (B) inside the chamber.



pic 8-2

Cleaning both parts, ensure that there is no any dirty thing on it ( suggest to clean by ultrasonic cleaning machine). Then set it back to the bottom of the chamber.

## 8.4 Monthly Maintenance

#### **Cleaning Reservoir**

There are some impurities and some toxins had been left behind in the reservoir because distilled water stored for a long time. Need to drain and clean regularly. As pic 8-3 shows, loose the screw by screw-driver, and open the cover to clean inside.



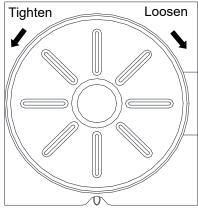


ATTENTION: Make sure that use distilled water properly in order to extend the sterilizer life-time.

Do not rave about the sterilizer when the tank has been filled.

### 8.5 Other Maintenance

#### **Door Sealing Cover Adjustment**



Pull down the pull ring

After long-term use, the aging of the door gasket may cause the sealing cover to be loose and cause steam leakage or vacuum fail, so it is necessary to adjust the sealing cover:

- 1. Pull down the pull ring at the bottom of the door.
- 2. Keep the pull ring down and rotate the sealing cover at the same time.
- 3. Release the pull ring and slightly turn the sealing cover until the pull ring returns.

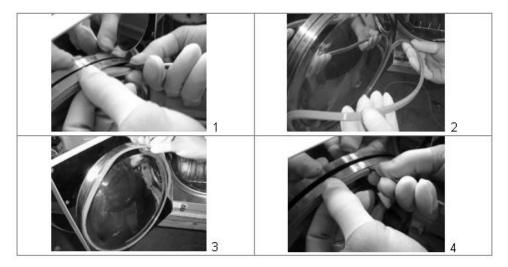
#### Attention:

- 1. The adjustment should be carried out in the cold machine state.
- 2. Do not adjust the sealing cover too loose;
- 3. After adjustment, please carry out vacuum test to verify the sealing of the chamber.

#### **Door Gasket Replacement**

Tool: A plain screw driver without sharp head is needed.

Cut off the power supply, ensure that the sterilizer is cool and depressurized.



- 1. Hold verge of the seal by one hand softly, and another hand should be inserted the screwdriver into the gap between gasket and door, take out the seal slowly.
- 2. Once you take out one part of the seal, you can draw out the whole seal slowly. After taking out the seal, please check and clean the groove of gasket, so does the gasket, please replace it if there is some damage.
- Fix the clean gasket in initial door groove. At first, embed 4 spots equably into groove when fix the gasket, then embed the other parts. Next, embed it equably by hands.
- 4. The inner edge of gasket may be ectropion during embedding it in the door groove. You'd better to tight it back to the groove by using screwdriver carefully.

## 8.6 Servicing by the Approved Technician

Service is essential for consistently effective sterilization.

We recommend servicing by an approved technician every 2 years.

#### **Check-list:**

- 1 Checking the solenoid valves.
- 2 Checking the water pump.
- 3 Checking the vacuum pump.
- 4 Checking the distilled water drain valve and the used water drain valve.
- 5 Checking the relief valve.
- 6 Checking the door locking system.

- 7 Checking the probe of the pressure and temperature.
- 8 Checking the probe of the water in the sterilization chamber.
- 9 Checking the electrical connections.
- 10 Checking the hydraulic connections.
- 11 Checking the safety thermostat.
- 12 Cleaning the sterilization chamber.
- 13 Cleaning the trays and the tray rack.
- 14 Cleaning the reservoirs.
- 15 Replacing the water filter.
- 16 Replacing the air filter.
- 17 Replacing the door gasket.

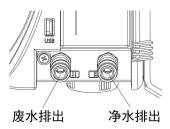
## **Chapter 9 Transportation and Storage**

### 9.1 Preparation before Transportation and Storage

Shut off the power switch, unplug the cord, and make the sterilizer been cooled down completely.

## 9.2 Draining

Drain water from reservoir and the condensate collector completely: insert the joint end of the attached tube to drain connection. The spout on the left is the water spout used for the "used water out", the one on the right is used for the "distilled water out".



### 9.3 Conditions for Transportation and Storage

◆ Temperature: -5 °C ~ +55°C

Relative Humidity: ≤85%

❖ Atmospheric Pressure: 500HPa~1060HPa

## 9.4 Package

Package is used in transportation for protecting product, conveniently delivery and sales.

The sterilizer package requirement should as followed:

- 1. Product can not over 3/4 volume of package.
- 2. Product should be fix inside the package.
- 3. Package bag should be higher than product 6mm.

## **Appendix 1 Articles Preparation Procedure**

The articles should be treated as following:

- 1. Clean articles completely before sterilization, keep dry.
- 2. Pack articles into sterilization roll (if need).
- 3. Place articles onto trays.
- 4. Run selected sterilization programs.
- 5. Take out and store.

**CAUTION:** Make sure the packing of articles in good condition.

The sterilized articles still exist lots of warmth. Do not fold in order to exhaust the residual steam.

# Appendix 2 Error Code List

The sterilizer will show Error information when malfunctions happen.

#### Example

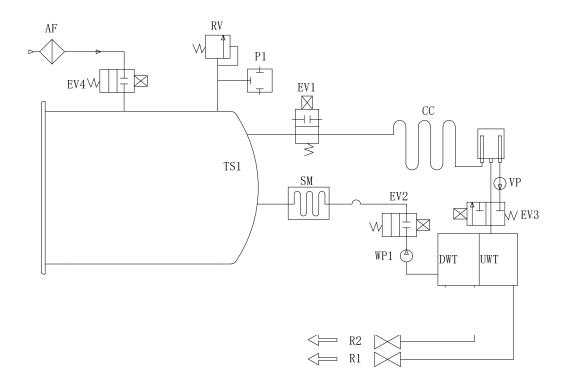
1.0 112 Er01

#### **Error Code List**

No.	Error Code	Description
1	Er01	Steam Generator over temperature
2	Er02	Heating Ring over temperature
3	Er03	Chamber over temperature
4	Er04	Fail to maintain temperature and pressure
5	Er05	Pressure not exhausted
6	Er06	Door open during cycle
7	Er07	Working overtime
8	Er08	Over pressure
9	Er09	Temperature of inner temperature sensors is too high or too low (dual sensors only)
10	Er10	Temperature and pressure do not match
11	Er12	Vacuum fail
12	Er14	The temperature difference of the inner temperature sensors is too large (dual sensors only)
13	Er16	Heating ring does not heat or heats slowly
14	Er17	Steam generator does not heat or heats slowly
15	M98	Out of power during cycle
16	M99	Forced exit

# Appendix 3 Electric And Pipeline Diagrams

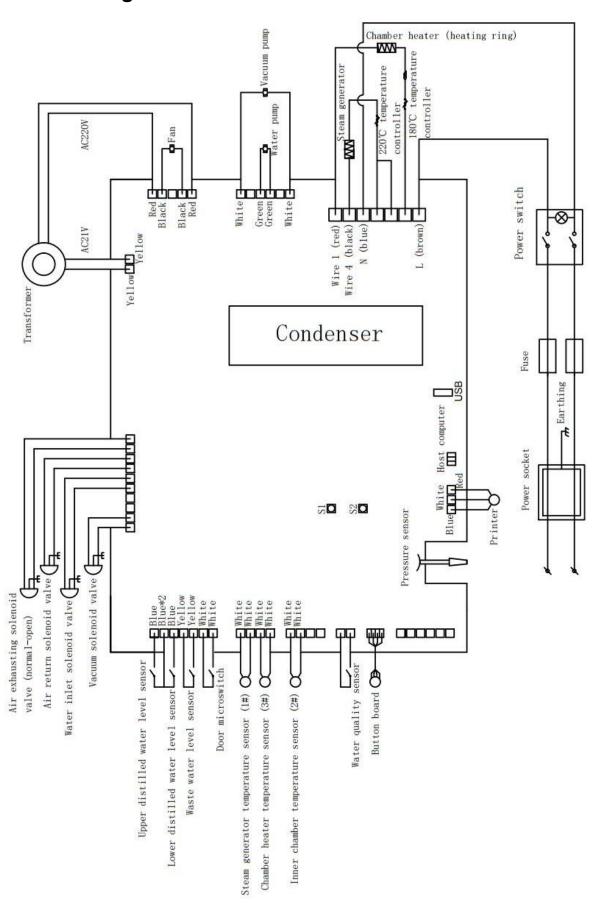
## **Pipeline Diagram**



AF	Air Filter
UMT	The Used Water Tank
DWT	The Distilled Water Tank
EV1	Air Release Valve
EV2	Water Supply Valve
EV3	Vacuum Valve
EV4	Air Return Valve
P1	Pressure Sensor

SM	Steam Maker
WP1	Main Water Pump
VP	Vacuum Pump
СС	Condensate Collector
RV	Relief Valve
R1	Distilled Water Drain Valve
R2	Used Water Drain Valve
TS1	Temperature Sensor

## **Electric Diagram**



# Appendix 4 Inspection Checklist

NO.	Testing item	Request of standards
1	Exterior	The exterior of sterilizer should be tidy and mustn't have disfigurements, e.g.deflection, hollowness, collision, nick, sharp edge.
2	Cover plate	The cover plate should be assured to disassemble easily in order to repair the equipment.
3	Digit and letter	The digit and letter in screen should be legible.
4	Electroplate Component	The electroplate should accord with YYOO76-1992 class 2, which for the request of aspect.
5	Printer Component	The printer components should accord with YY1055-1999 the class II which for the request of aspect.
6	Door Safe Lock	On the normal condition, if the sterilizer door hasn't been locked tightly, the program can not start.
7	Chamber Pressure	The sterilizer should ensure that the door can't be opened when chamber pressure is greater than 0.27MPa.
8	Safety Valve	The sterilizer must install a safety valve, safety valve opening pressure 270kPa±10kPa, and automatically open when reaching the set value.
9	Sterilizing Program	Sterilizer should have the pre-established program about 121°C and 134°C, dressing and instruments.
10	Controlling System	The control system in sterilizer should limit the steam which in the chamber be controlled at the highest average temperature in ±3°C of pre-establish station. And ensure the temperature value accords with the pressure controlling value.
11	Timing Control	Able to timing control of the sterilization and drying, and the error should not be greater than 10% of the preset value.
12	Button and Switch	Buttons and switches should be flexible and reliable on the sterilizer.
		The indicators and displays of sterilizer should show the states of every sterilizing procedure exactly. Under the normal situation, sterilizer should indicate:
		a) Chamber temperature
13	Indicator and Display	b) Chamber pressure
		c) Sterilizer working state
		d) Water level state
		e) State of door
14	Quantum of Leakage	In the condition of the vacuum - 0.07Mpa, the sterilizer shouldn't leak 0.13kPa/min.
15	Leakage Forbidden	The sterilizer can't leak under the work pressure
	I .	

16	Protective Earthing Impedance	The impedance between protective earthing point of the power input faucet and protective earthing can be touched all metallic parts, doesn't over than $0.1\Omega$ .
17	Successional Current Leakage under Work Temperature	a) Earth leakage current on the normal condition: ≤0.5mA, the single blooey state: ≤1 mA
		b) Crust leakage current on the normal condition: ≤0.1 mA, the single blooey state: ≤0.5mA
18	Dielectric strength with Working Temperature	a) A-al: It should bear the sine wave test alternative voltage, 50Hz, 1500v, which between the web power input port and protective earthing can be touched all metallic parts. It lasts 1min, and hasn't the phenomenon of breakage and flashover.
		b) A-a2:It should bear the sine wave test alternative voltage, 50Hz, 1500v, which between the web power input port and the enclosure of which isn't be pretended earthing. It lasts 1min, and hasn't the phenomenon of breakage and flashover.
	Empty Load	For all loads except hollow load A, the presence of saturated steam in the usable space and the load is deemed to have been achieved when, throughout the holding time, all temperatures measured in the usable space and the load.
		Attention: the theory of steam temperature is accounted by measuring pressure, which can be considered the test temperature.
19		are not lower than the sterilization temperature.
		are not more than 4 K above the sterilization temperature.
		do not differ from each other by more than 2 K.
		The usable place temperature during the no-load can not over than the scope of highest temperature.
20	Hollow Load	For hollow load A and B, in order to confirm the presence or absence of saturated steam, discriminate whether the indication system change in accordance with the system manufacturer predetermined color.
21	Dryness, Solid and Wrapped Load	For wrapped load, any remaining moisture should not lead to wet packages and shall not result in detrimental effects on the sterilizer load. Any remaining water droplets on the inner side of pouch should evaporate within 5 min.
		For solid load the moisture content should not exceed 0.2%.