

Technical Publications

Steam Sterilizer Operation Manual

**ASS090
REV-D**



Operation Documentation

Regulatory Requirement

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

Revision History

REV	ISSUE DATE	REASON FOR CHANGE
Rev-A	2013.05	First Issue
Rev-B	2015.11	Version Update
Rev-C	2018.03	Version Update
Rev-D	2019.07	Version Update

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

Regulatory Requirement

Conformance Standard

The content of this manual is fit for the sterilizers.

Above sterilizer accords with the requirements of European Class N:

93/ 42/ EEC

97/ 23/ EC

EN 61010 -1

EN 61010 -2 -040

EN 13060

EN 61326 -1

European Authorized Representative

DTF Technology s.r.l.

Address: Piazza velasca 6, 20122 Milano, Italy

Tel: 390284893641

Fax: 39 02 84718594

This equipment complies with the regulatory requirements 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.

Certification

Manufactory is certified with EN ISO 9001 and EN ISO 13485.

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 equipment 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

<i>Regulatory Requirement</i>	1
<i>Revision History</i>	1
<i>Regulatory Requirement</i>	2
<i>Chapter 1 Introduction</i>	4
1.1 Attention	4
1.2 Usage Indication.....	4
1.3 Contraindication.....	4
<i>Chapter 2 Safety</i>	5
2.1 Explanation Symbol	5
2.2 General Safety Recommendation	6
2.3 Operation Risk.....	7
2.4 Protection Device	7
<i>Chapter 3 Receiving and Installation</i>	8
3.1 Check the Package.....	8
3.2 Unpacking the Accessory	8
3.3 Installation Environment	9
<i>Chapter 4 Description and Specification</i>	10
4.1 Overview	10
4.2 Specification	11
<i>Chapter 5 Panel and Function</i>	12
<i>Chapter 6 Working Phase and Troubleshooting</i>	14
<i>Appendix Piping and Circuit Diagram</i>	16
Piping Diagram.....	16
Circuit Diagram.....	17

Chapter 1 Introduction

1.1 Attention

This manual contains necessary and sufficient information to operate equipment safely, such as optimal usage, secure and reliable operation, regular and correct servicing requirements.

Read and understand all instructions in this manual before attempting to operate equipment.

Keep this manual with the equipment at all times. Periodically review the procedures for operation and safety precautions.

1.2 Usage Indication

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 dentists and professionals.





1.3 Contraindication

There is no any contraindication of this equipment.




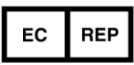


Chapter 2 Safety

2.1 Explanation Symbol

Device Icon Description

	<p>“ATTENTION” – Consult accompanying documents, alert the user to refer to the manual or other instructions when complete information cannot be provided on the label.</p>
	<p>“ATTENTION” – Pay attention to the high temperature in the chamber, and to the sterilizer exterior when exhausting system is running.</p>
	<p>“PROTRCTIVE EARTH” - Indicates the protective earth (grounding) terminal.</p>
	<p>“CAUTION” - Dangerous voltage (the lightning flash with arrowhead), indicates electric shock hazards.</p>

Label Icon Description

	<p>Symbol for "SERIAL NUMBER"</p>		<p>Symbol for "MANUFACTURER"</p>
	<p>Symbol for "CATALOGUE NUMBER"</p>		<p>Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"</p>
	<p>Symbol for "DATE OF MANUFACTURE"</p>		<p>Symbol for "CAUTION"</p>

Manual Prompt

Note	Indicates that concerning information which easier or helpful in the operation.
Caution	Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can cause: <ul style="list-style-type: none"> • Minor injury; • Property damage; • Damage to machine.
Warning	Indicates that a specific hazard may exist which through inappropriate conditions or actions will or can cause: <ul style="list-style-type: none"> • Severe personal injury; • Substantial property damage; • Substantial damage to equipment.

CAUTION INDICATES PRECAUTIONS OR RECOMMENDATIONS THAT SHOULD BE USED IN THE OPERATION.

2.2 General Safety Recommendation

- ❖ The user is responsible for operation and servicing the sterilizer in accordance with the instructions listed in this manual.
- ❖ The sterilizer could not be used for liquid.
- ❖ The sterilizer has not been designed to operate in the presence of gas or explosive vapors.
- ❖ The trays and the load will still be hot at the end of each cycle. Use the tray holder provided to remove each tray from the chamber.
- ❖ Do not open the door of the chamber during the sterilization programs. Do not open the door until the pressure inside chamber is getting to 0bar.
- ❖ Do not put your hands or face on the cover of the sterilizer during the sterilization programs.
- ❖ 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 matter in the chamber.
- ❖ Use only high quality distilled water.
- ❖ Unplug the main lead before inspecting or servicing the machine.
- ❖ Only an approved technician using original spare parts can carry out repairs and maintenance.
- ❖ During the transportation, the sterilizer should be carried by two people in case of turning over.
- ❖ Do not use the equipment for cooking.

2.3 Operation Risk

Please take attention on avoid operation risk during operation.

Scald risk

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

Pollution risk

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

2.4 Protection Device

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

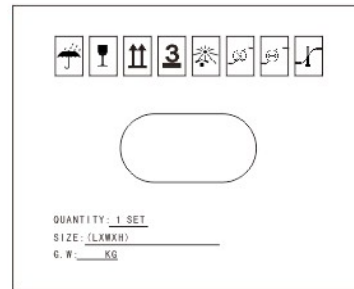
Chapter 3 Receiving and Installation

3.1 Check the Package

Please check package carefully when you receive the equipment.



Front



Flank

Item	16 L
Packing Size	640x495x475mm
N./G. Weight	25/28 KGs

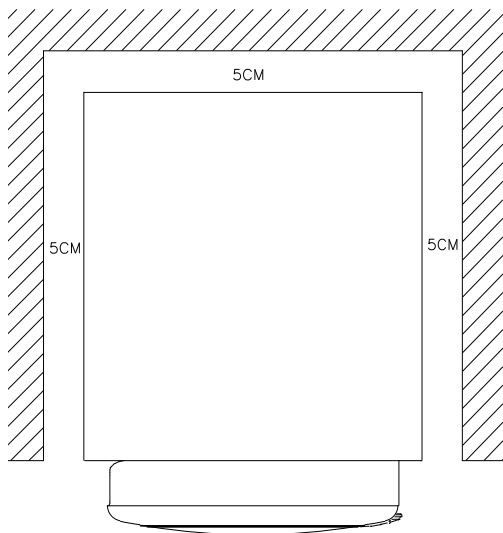
3.2 Unpacking the Accessory

Open the door and take out all the accessories, item listed below:

No.	Part Name	Qty
1	Tray rack	1 piece
2	Tray	3 pieces
3	Removal tool	1 piece
4	Draining tube	1 piece
5	Power supply cable	1 piece
6	Door gasket	1 piece
7	Operation manual	1 piece

3.3 Installation Environment

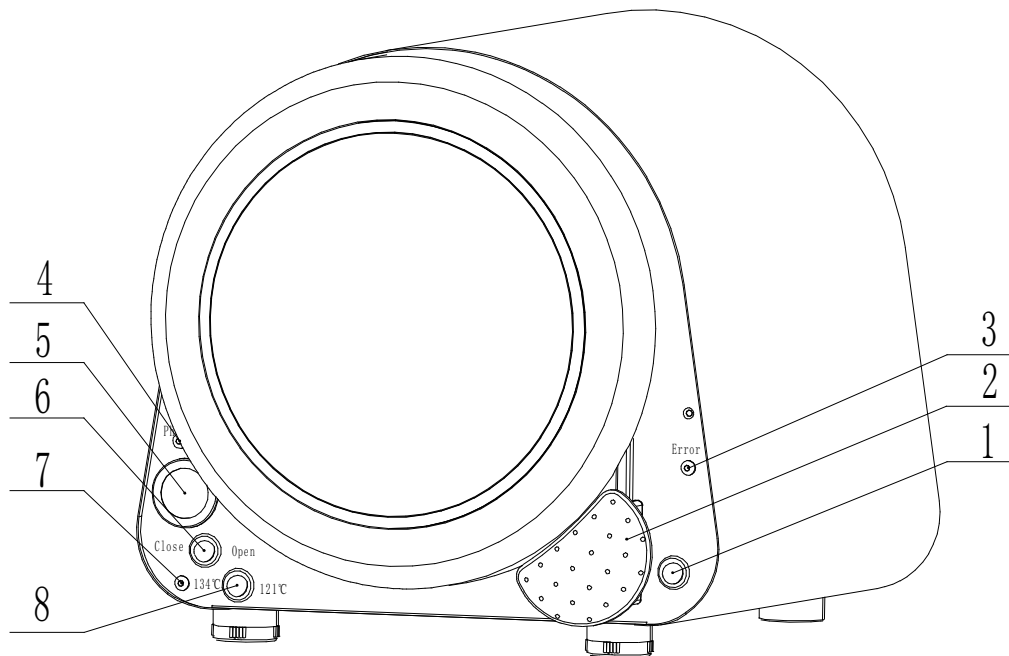
After remove the package, the sterilizer should be set in a level place which at least has 5 cm distance with each side (20cm of the top) as followed:



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

Chapter 4 Description and Specification

4.1 Overview



NO.	Item	Description
1	Power Switch	Turn on and off power
2	Door Handle	Push to close the door
3	Alarm Lamp	Turn Red to report error
4	Working Lamp	Green lamp on during cycle
5	Pressure Gauge	Show chamber pressure
6	Exhausting Valve	Control valve to exhaust Chamber air
7	Yellow Lamp	Yellow lamp on under 134C, turns off under 121C
8	Temperature Selector	Select Sterilization under 121°C/ 20mins or 134°C/ 5mins

4.2 Specification

Basic specification

Rated Voltage: AC 220V/ 50~60Hz/ 4A, or AC 110V/ 50~60Hz/ 8A if request.

Rated Power: 1400VA (8A); 1200VA (4A);

Fuse: F12AL AC220V /F25AL AC110V

Operation Temperature: 5~40°C

The Board Affording Weight: 4000 N/m²

Noise :< 50db

The Max. Capacity of a plate: 1000g

The Max. Duration of using loading test: 90mins.

The Max. thermal radiation energy under the condition of 20°C~26°C: <2000J.

Sterilizer Chamber

Material: stainless steel 304 (for medical)

Work Pressure: -0.9 bar~2.5 bar

Max. Temperature: 145 °C

Chamber Volume: 16L (Φ230×350mm)

Loading Size: 16L (180×180×280)

Max. Loading Weight: 16L (3.07kg/cm²)

Working Pressure/Temperature: 1.1~1.3bar/ 121~122°C; 2.1~2.3bar/ 134~135°C

Water Volume for One Cycle: 0.3L~0.4L

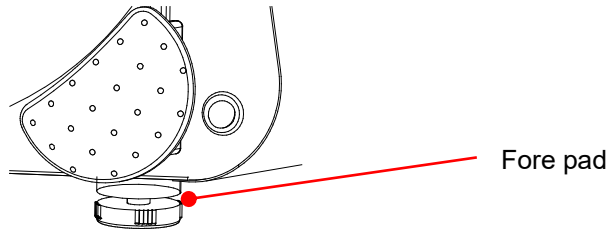
Sterilizer Steam Safety Valve

Safety Release Pressure: 2.45 bar

Max. Working Temperature: 160 °C

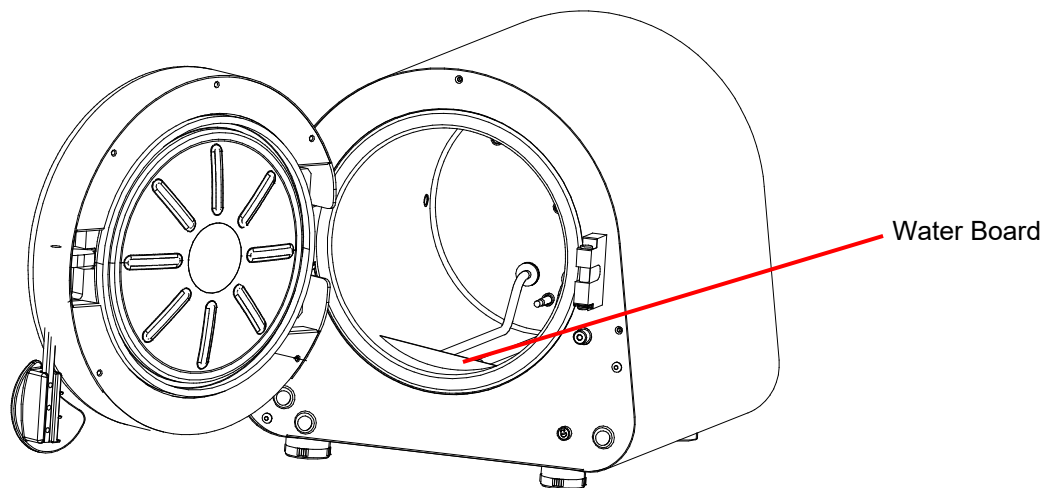
Chapter 5 Panel and Function

5.1. Adjust the both fore pads to ensure that the front part of Autoclave is higher than rear.

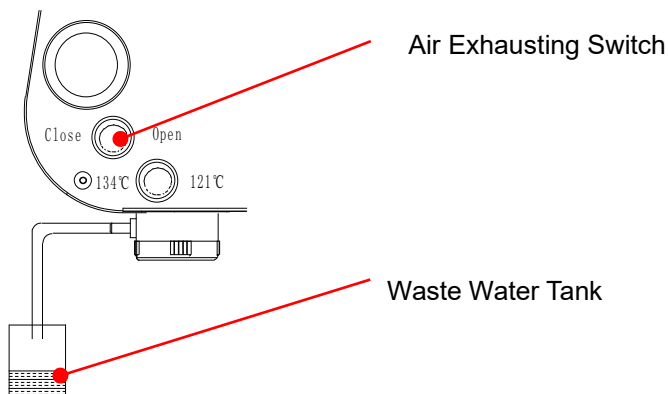


5.2. Open the door and make sure that there is no dust or impurity left inside chamber, fill 600-800ml distilled water into the chamber.

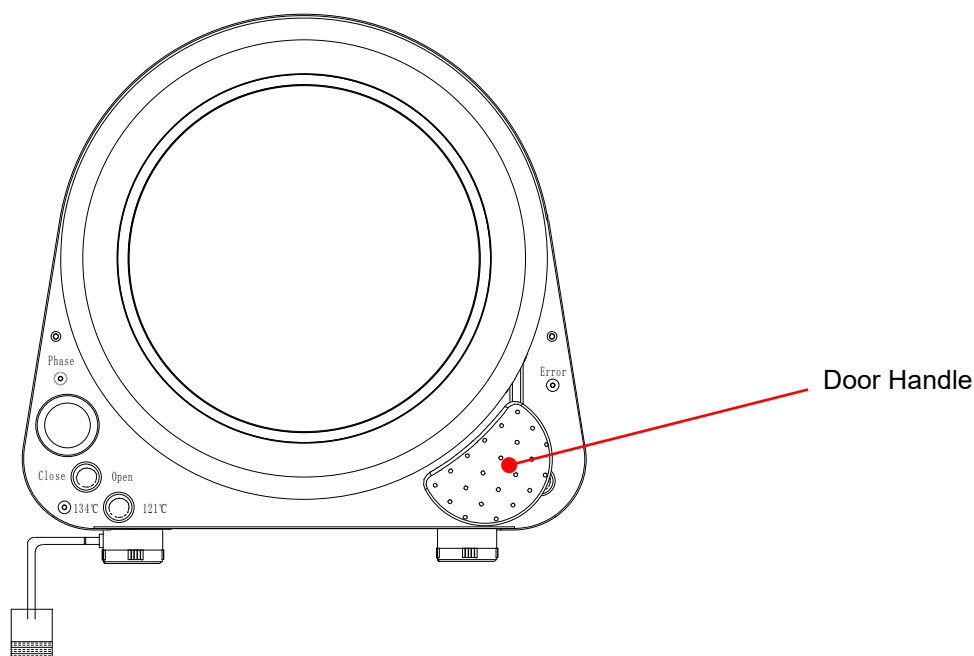
MAKE SURE THAT THE WATER SURFACE IS NOT HIGHER THAN THE CAUTION WATER BOARD OF THE CHAMBER. IT IS NOT ALLOWED TO START THE CYCLE WITHOUT WATER.



5.3. Connect one end of the draining tube to the equipment and put the other end into the waste water tank, then to turn off the air exhausting switch.



- 5.4. Load the trays into the chamber with tray removal tool, and put the instruments which need to be sterilized on the trays.
- 5.5. Turn on the power switch, then set the sterilization temperature, temperature select switch ON: 134°C / 0.22Mpa/ 6mins, temperature selection OFF: 121°C / 0.12Mpa/ 25mins.



- 5.6. Close the door. It will start sterilization cycle automatically.
- 5.7. When the cycle is finished, the green lamp will be kept on. Then please turn on the air exhausting switch to release the pressure inside the chamber to 0 bar, which takes about 6 to 8mins. Then you can open the door.

CAUTION PLEASE DO NOT OPEN THE DOOR UNTIL THE PRESSURE INSIDE CHAMBER FALLS TO 0 BAR.

- 5.8. Please turn off the power switch and take the instruments out.

Chapter 6 Working Phase and Troubleshooting

Phase Description	LED Description	Buzzer	Solution
Self-test when power-on	Red, green and yellow lights blink in turn 10s	Rings 1 time	Turn off the power, then restart the equipment
Self-test turns off normally	Green light blinks 3 times and off	-	-
Self-test turns off unexpected power outage last time	Red light blinks every 0.5s	Stops 1s between every 0.2s ring	Turn off the power, then restart the equipment
Self-test turns off that air exhausting valve is open	Red light blinks	Stops 1s between every 2 rings	Turn off the air exhausting valve switch, and restart the equipment
Over temperature inside chamber	Red light blinks	Stops 1s between every 3 rings	Stop heating and turn off the power
Sterilization temperature is too low	Red and yellow lights blink in turn	Stops 1s between every 4 rings	Turn off the power and restart the equipment after cooling
Temperature sensor fails	Red light always on	Stops 1s between every 5 rings	Turn off the power and restart the equipment after cooling
Close the door improperly	Red light blinks	Stops 1s between every 1 s ring	Close the door properly
Fail to get sterilization temperature in 30mins	Yellow light blinks	Stops 1s between every 6 rings	Turn off power to check if the following situations exist: the heating ring is broken, low voltage, water inside chamber is not enough or loaded too many instruments
In process of heating or air exhausting	Green light blinks	Rings 1 time at the beginning of working, steam discharging and sterilizing	-

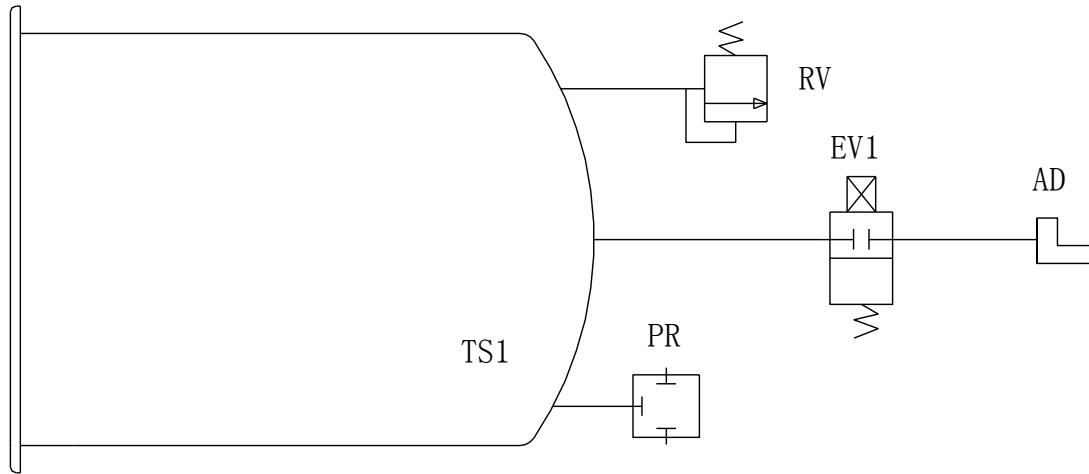
In state of constant temperature and pressure	Green light blinks	Rings at the beginning and ending of constant temperature	-
Sterilization complete successfully	Green light always on	Stops 1s between every 3 rings	-

The yellow light is always on at the temperature of 134 °C. But it blinks under the situation of alarming.

Attention: the program can't start when the door is not closed properly.

Appendix Piping and Circuit Diagram

Piping Diagram



Code	Name
RV	Relief Valve
AD	Air Exhausting Port
EV1	Solenoid Valve (Normal-Close)
PR	Manometer
TS1	Temperature Sensor

Circuit Diagram

