

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	2017.09.06	First Issue
Rev-B	2017.11.22	Update
Rev-C	2018.01.01	Update

Please verify that you are using the latest revision of this document. Information pertaining to this document is maintained within the manufactory. 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 accords with the requirements of European Class B:

93/42/CEE

97/23/CE

EN 61010-1:2010

EN 61010-2-040:2015

EN 13060:2015

EN 61326-1:2013

This product complies with the following regulatory requirements:

- 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

Manufactory has been certified with ISO 9001:2015 and ISO 13485:2016

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.

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Chapter 1. *Product Scope and Structure*

1.1 Warning

This operation manual contains necessary and enough information to operate the sterilizer safely, with optimal usage, safe and reliable operation, with regular and correct servicing requirements.

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

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 by doctors and professionals for dental clinics, laboratories, surgical rooms, emergency rooms, ophthalmology, gynecology, beauty salons and so on.

1.3 Contraindication

No available contraindication for this equipment.

Chapter 2. *Product Features*

2.1 Sign Explanation

Device Sign Description

	<p>“WARNING” - “Refer to this Operation Manual” is intended to alert the users to refer to the operation manual or other instructions when complete information cannot be provided on the label.</p>
	<p>“WARNING” - Pay attention to the high temperatures in the chamber, and to the sterilizer exterior when exhausting system is running.</p>
	<p>“Protective Earth” - Indicates the protective earth (grounding) terminal.</p>
	<p>“CAUTION” - “Dangerous Voltage” (the lightning flash with arrowhead) is intended to indicate electric shock hazards.</p>

Label 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>

Operation Prompt

Note	Indicates precautions or recommendations that should be used in the operations.
Caution	Indicates that a potential hazard may exist, which through inappropriate conditions or operation, will or can cause: <ul style="list-style-type: none"> • Minor injury; • Property damage; • Damage to machine.
Warning	Indicates that a specific hazard may exists, which through inappropriate conditions or operation, will or can cause: <ul style="list-style-type: none"> • Severe personal injury; • Substantial property damage; • Substantial damage to machine.

2.2 General Safety Recommendations

- ❖ The user is responsible for the proper operation and maintenance of the sterilizer in accordance with the instructions listed in this manual.
- ❖ The sterilizer should not be used for liquid.
- ❖ The sterilizer should not be used for gas.
- ❖ The trays and the load will still be hot at the end of each cycle. Use the removal tool 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 any label from the sterilizer.
- ❖ Do not pour water or any other liquid over the sterilizer.
- ❖ Do not fill the water tank with any caustic liquid.
- ❖ Do not fill the chamber with any caustic matter.
- ❖ Use only high quality distilled water.
- ❖ Unplug the power supply cable before inspecting or servicing the sterilizer.

- ❖ Only an approved technician using original spare parts can carry out repairs and maintenance.
- ❖ In case of transportation, drain both water tanks completely, wait for 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 is above 40°C.
- ❖ The special tools provided should be used when picking-up the sterilizing trays.
- ❖ During the transportation, the sterilizer should be carried by two people to avoid the turning over of the machine.
- ❖ Notice! This product cannot be connected in areas with frequent power cuts.
- ❖ Avoid covering the water tank at any time with any object.

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 function.

ElectroMechanical Protection

Part Name	Function
Security system	Ensure the door to be closed completely, avoiding safety risks.
Tray Removal Tool	Avoid being burnt when removing articles from the chamber.

Control Part

Part Name	Function
Temperature Sensor (Internal)	Measure temperature inside the chamber.
Temperature Sensor	Measure temperature of the heating ring.

(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 sterilization processes.

MANUFACTURER IS NOT HELD RESPONSIBLE FOR ANY ARBITRARY CAUTION DISASSEMBLY OR AMENDMENT BY UNAUTHORIZED PERSONNEL OR UNPROFESSIONAL TECHNICIAN.

2.4 Operation Risk

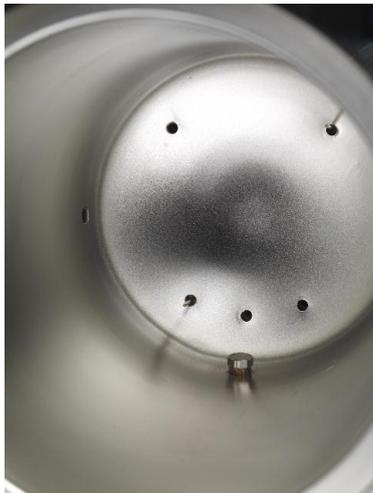
Please pay attention by avoiding risky operations.

Burn Risk

- ❖ When opening the door after the sterilization cycle, please keep an appropriate distance, as the chamber still contains high temperature steam.
- ❖ When opening the door after the sterilization cycle, please do not touch the main door or chamber, to avoid being burnt by the high temperatures.

Pollution Risk

Please clean the chamber after every usage to avoid any contamination left inside the chamber. *(Figure 2a)*



(Figure 2a)

2.5 Protection Device

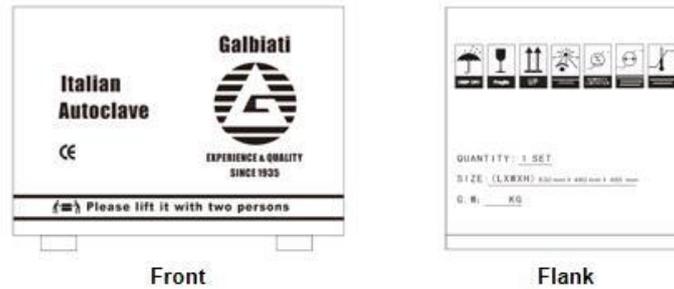
Device Name	Function
Plastic or Fabric Glove	Useful during load and remove articles, avoid being burnt.

Chapter 3. Receiving and Installation

3.1 Check the Package

Please check the package carefully when you receive the sterilizer. (Figure 3a & 3b)

Figure 3a



Item	18L Model	23L Model
Packing Size	670×550×560	770×550×560
Packing Weight	52kg	58kg

Figure 3b

3.2 Unpacking Process

Follow these steps to unpack the PRIMA Autoclave: (Figure 3c)

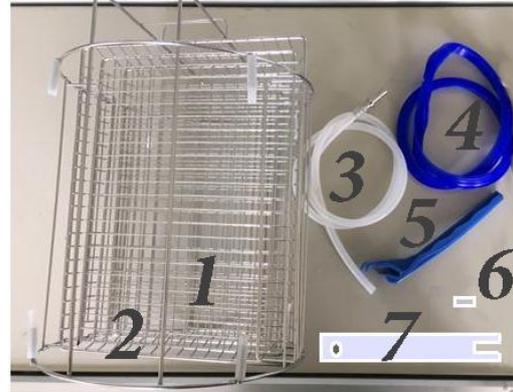


Figure 3c

Check that all the accessories listed below are present: (Figure 3d)

No.	Part Name	Quantity
1	Rack (For Trays)	1 piece
2	Tray	4 sets
3	Draining tube	2 pieces
4	Gasket	1 piece
5	Removal tool	1 piece
6	USB Key	1 piece
7	Door Key	1 piece
8	CE certificate	1 piece
9	Roll paper	1 piece
10	Spacers	2 pieces

Figure3d



3.3 Installation Environment

The sterilizer should be installed in an area with at least 10cm distance between each side (20cm of the top) as illustrated below: Figure 3e

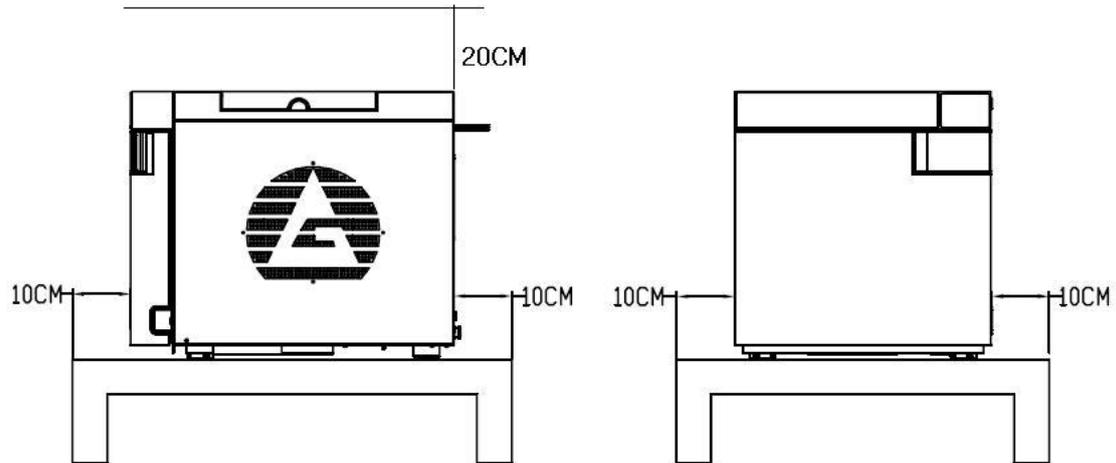


Figure 3e

- ❖ The sterilizer should be installed in an area with good ventilation.
- ❖ The temperature of the environment: 5-40°C.
- ❖ The humidity of the environment: ≤85%
- ❖ Atmospheric pressure: 860Hpa~1060Hpa
- ❖ A ground connection is necessary.

CAUTION DO NOT PUT ANY MATERIALS WHICH CAN EASILY MELT NEAR THE STERILIZER.

3.4 Set

- ❖ The sterilizer should be placed on a flat surface area; the front-end should be raised minimum 5° (or 3.5 cm) higher than the back-end. **(Figure 3f)**

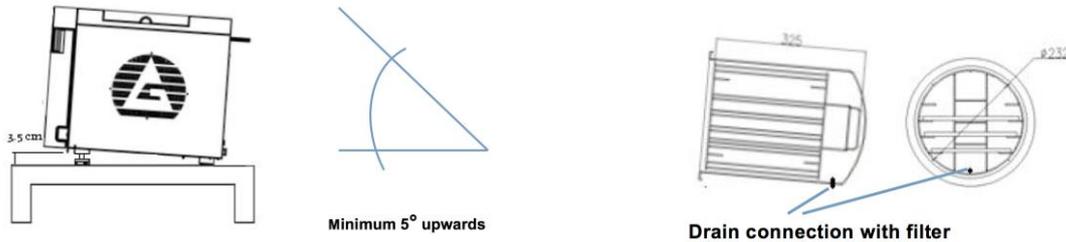


Figure 3f

- ❖ The sterilizer cooling and vent area should not be blocked.
- ❖ Do not place any objects on top of the sterilizer.
- ❖ Do not place any objects in front of the door, to avoid any accidents when opening the door.
- ❖ Do not place any corrosive materials near the sterilizer to avoid accidents or risks.

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 be sure to verify that the connection power is aligned with the specifications in the nameplate at the back of the sterilizer. **(Figure 3g)**

DO NOT BEND THE POWER WIRE TO AVOID ANY DAMAGE.

DO NOT PUT ANY HEAVY OBJECTS ON THE POWER WIRE TO AVOID ANY DAMAGE.

CAUTION

DO NOT USE ANY OTHER POWER WIRES TO AVOID DAMAGE OF THE STERILIZER.

DO NOT PLUG THE WIRE TO SOCKETS CONTAINING MULTIPLE ATTACHMENTS.

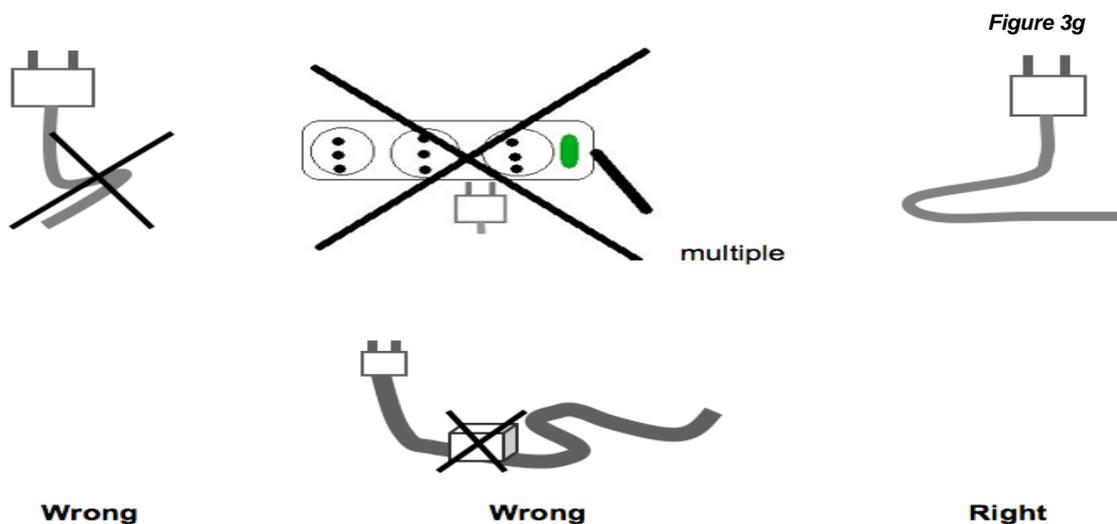


Figure 3g

Chapter 4. Description and Specifications

4.1 Front View

(Figure 4a)

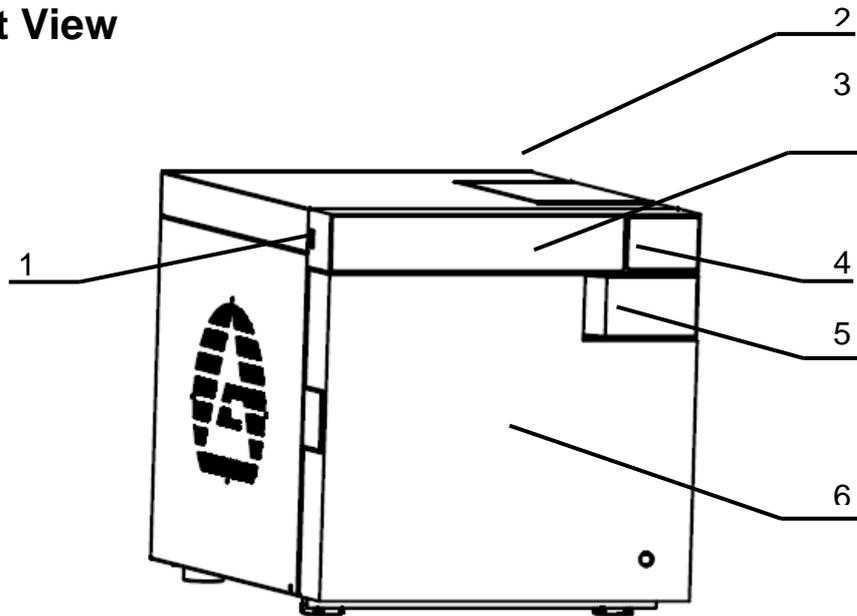


Figure 4a

Name	Description
1. USB Port	Access to the USB
2. Distilled Water Tank	Manually filling water
3. LED Screen	Shows menu, operation steps, contents, etc.
4. Printer	Built-in printer to print sterilization record
5. Door Handle	The Door Handle with pneumatic protection lock
6. Door body	Quick-to-open door body

4.2 Rear View

(Figure 4b)

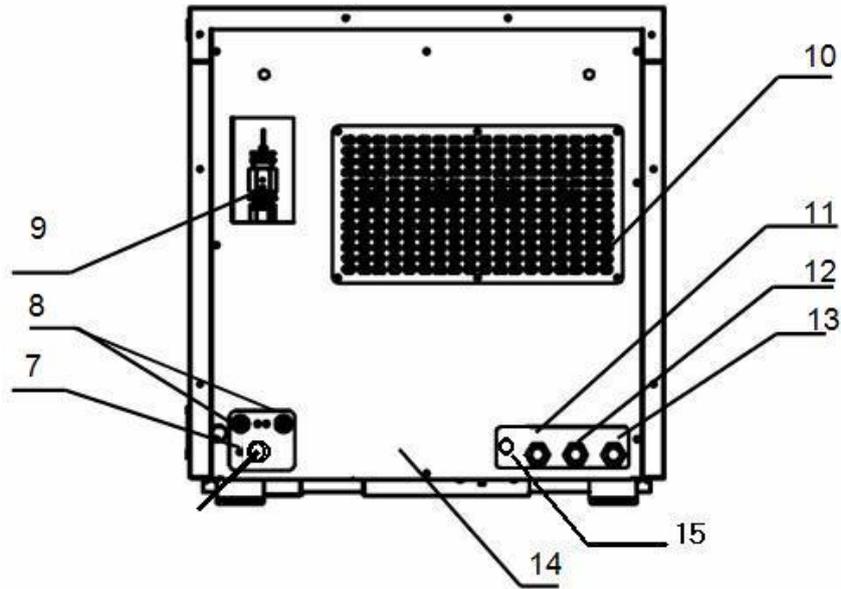


Figure 4b

Name	Description
7. Power socket	Connected to a power source
8. Fuses	Protects product when the power is not stable
9. Safety Valve	Automatically release pressure when over working range
10. Ventilation Grille	To cool the machine
11. Used Water Out	Connected to used water tank
12. Water Filling Port	Automatic water filling
13. Distilled Water Out	Connected to clean water tank
14. Identification plate	Basic manufacturers information
15. Pressure drain	Pressure release

4.3 Open View

(Figure 4c)

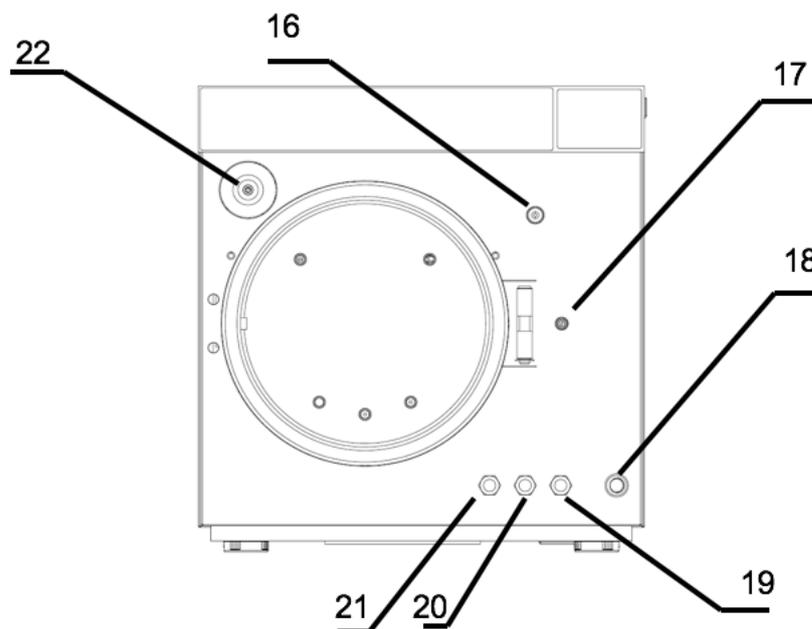


Figure 4c

Name	Description
16. Electric protection lock	Prevents the door from opening when the program is running
17. Door Micro-switch	Prevents the program from initiating when the door is not closed
18. Power Switch	Standard blue power switch
19. Distilled Water Out	Connected to clean water tank
20. Water Filling Port	Automatic water filling
21. Used Water Out	Connected to used water tank
22. Air Filter	Filter the air and ensure air within the chamber is clean

4.4 Exterior Size

(Figure 4d)

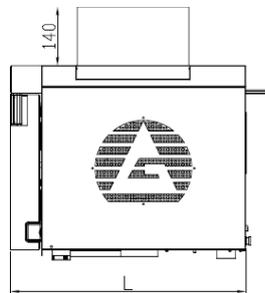
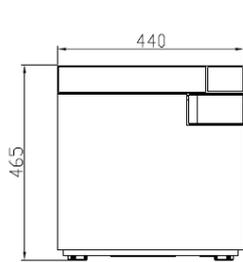
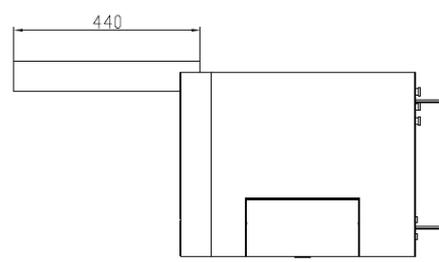


Figure 4d



Item	18L Model	23L Model
Size of Closed Door	L615x465x440	L715x465x440
Size of Open Door	L1005x605x440	L1105x605x440

4.5 Loading Size

The loading size of sterilizer is as follows: (Figure 4e)

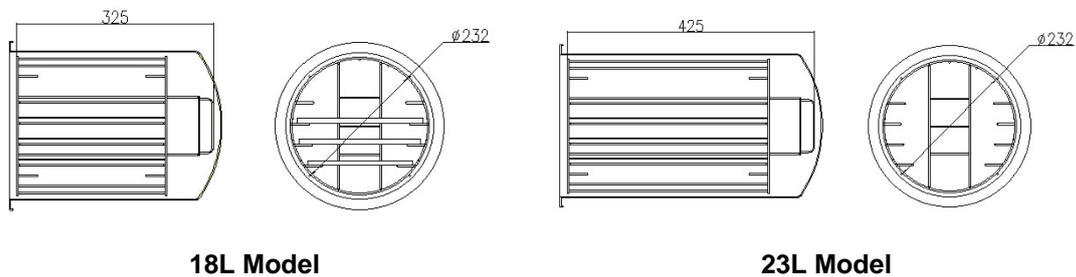


Figure 4e

4.6 Technical Specifications

Basic Specification

Rated voltage: a.c.220V-230V, 50Hz

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

Fuse: T10A

Operation temperature: 5~40℃

The board affording weight: 4000 N/m²

Noise: < 50db

The maximum capacity of a plate: 1000g

The frequency of water draining: once a day, drain the water once you find lack

of water "  light on 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: 2.5 bar

Min. work pressure: -0.9 bar

Max. temperature: 145 ℃

Chamber volume: 18L (Φ245×320mm) 23L (Φ245×450mm)

Loading size: 18L (198×204×285) 23 L(198×204×385)

Max. loading weight: 18L (3.07kg/cm²) 23L (3.21kg/cm²)

Working pressure/temperature: 1.10~1.30bar/121℃~122℃; 2.10~2.30bar/134℃~135℃

Water volume for one cycle: 0.16L (min) 0.18L (max)

Sterilizer Steam Safety Valve:

Safety release pressure: 2.45 bar

Max. Working temperature: 160 ℃

Clean Water Tank

Tank volume: 18L (3.5L) 23L (4L)

CAUTION **WATER ADDED INTO MAIN WATER TANK MUST BE DISTILLED WATER!**
WATER TEMPERATURE MUST BE UNDER 40℃.

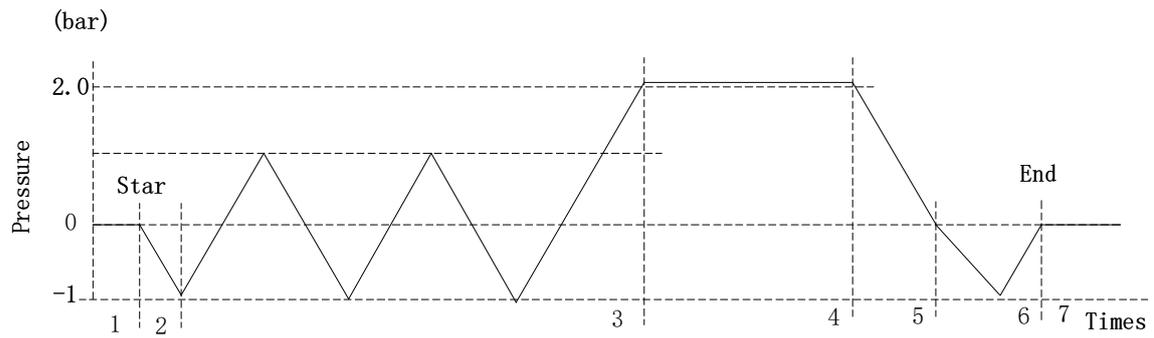
Test Method

Vacuum Test

B&D Test

Helix Test

4.7 Sterilization Cycle



- 1-2 pre-heating
- 2-3 pre-vacuum
- 3-4 sterilizing
- 4-5 air-discharging
- 5-6 drying
- 6-7 stabilizing
- 1-7 full cycle

Table—Types of Sterilization Cycles

Test type	Unwrapped	Wrapped	Soft	Prion
DIN EN 13060	S TYPE	B TYPE	B TYPE	B TYPE
Dynamic test pressure	✓	✓	✓	✓
leak air	✓	✓	✓	✓
chamber empty test	✓	✓	✓	✓
solid load	✓	✓	✓	✓
partial solid load	✗	✓	✓	✓
full solid load	✗	✓	✓	✓
hollow instrument B	✓	✓	✓	✓
hollow instrument A	✗	✓	✓	✓
single wrapping	✗	✓	✓	✓
multiple wrapping	✗	✓	✓	✓
dry solid load	✓	✓	✓	✓
dry hollow load	✗	✓	✓	✓
sterilization temp.	134 °c	134 °c	121 °c	134 °c
sterilization time	5 min	5 min	18 min	18 min
sterilization press.	2,1 bar	2,1 bar	1,2 bar	2,1 bar

✓ = Respects the DIN EN 13060 standard

✗ = Does not respect the DIN EN 13060 standard

Chapter 5. Panel and Functions

5.1 Function Panel

5.1.1 Digital Display



5.1.1.1 Integrated display windows

- ❖ Indicates chamber temperature during a cycle. Unit: degrees °c
- ❖ Indicates chamber pressure during a cycle. Unit: kPa
- ❖ Indicate the moment of the cycle, the time and the sterilizer alarms. A corresponding error code will be displayed here.

5.1.2 Program Choice: PROG. Button

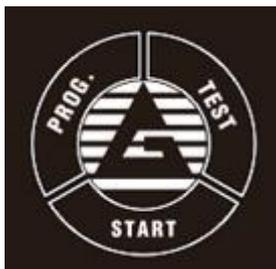
For the program selection function, press the button by choosing the sterilization program;

5.1.3 Test Choice: TEST Button

For the test program selection function, press the button to choosing the testing program;

5.1.4 START Button

This button is used for confirmation on the start or the end of the cycle, and for removing the malfunction of a selected program. After choosing a certain program, please press this button to confirm it. Press the button again will start a working cycle. Keep pressing it for 5 seconds during a program any time, the cycle will be terminated;



5.1.5 Sterilization program indicator light area

When choosing the sterilization program, the corresponding indicator light will be on. Press the start button to run;

5.1.6 Helix / B&D and Vacuum test indicator light area

When choosing the test program, the corresponding indicator light will be on. Press the start button to run test;

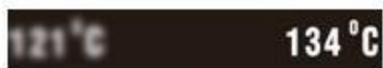
5.1.7 Pipeline cleaning and filling water automatic indicator light area

When choosing the different function program, the corresponding indicator light will be on. Press the start button to run;

5.1.8  When this light is on; the clean water level in the tank is low. Please fill the tank with high quality distilled water.

 When this light is on; the used water tank is full. Please drain it.

 When this light is on; the water quality is low. Please drain the low quality water and replace with higher quality distilled water.

5.1.9  Temperature indicator light area

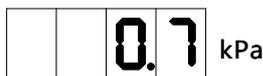
When choosing the different sterilization programs, the corresponding temperature indicator light will turn on.

5.2 Menu

5.2.1 Screen selection process

The last program selected before the prior shutdown, will always be the first program available during the next working session.

The boot screen, here on the right, displays the temperature and the pressure values. When the machine is not ready, (the water level is below the minimum, the door is not closed and so on) a flickering “LoAd” will be shown on the screen. When the machine is ready, a stable “LoAd” screen is displayed.

Temp.
 °C
 Press.
 kPa
 Time
 Min.

5.2.2 Sterilization Program

You can select different program by pressing “PROG.” button:



Display screen is unchanged when you select the program.

- ❖ **Unwrapped:** 134°C/4 min, for unwrapped instruments, 1-time vacuum, temperature: 134°C, pressure: 210kPa, sterilization time 4min, drying time 9min.
- ❖ **Wrapped:** 134°C/5min, for wrapped instruments or hand-pieces, 3-times vacuum, temperature: 134°C, pressure: 210kPa, sterilization time 5min, drying time 9min.

- ❖ **Prion:** 134°C/18min, for prion or virus, 3-times vacuum, temperature:134°C, pressure: 210kPa, sterilization time 18min, drying time 9min.
- ❖ **Porous:** 121°C/20min, for porous cotton. 3-times vacuum, temperature: 121°C, pressure: 110kPa, sterilization time 20min, drying time 18min.



- ❖ **User:** 121°C/134°C, when all four indicator lights are on:
 - 121°C: 1/3/5-times vacuum, sterilization time 20~60 min, drying time 00~60 min.
 - 134°C: 1/3/5-times vacuum, sterilization time 4~20 min, drying time 00~ 60min.

5.2.3 Test Program



Press the “TEST” button on the functional panel to select the test program. Press the “START” button to start the selected test.



- ❖ **Helix / B&D Test:** Spiral pipe and steam penetration test, 134°C/3.5min. 3-times vacuum, temperature: 134°C, pressure: 210kPa, sterilization time 3.5min, drying time 3min.



- ❖ **Vacuum Test:** is a test used for efficiency vacuum ; the process is:

Vacuum 5min → Steady pressure 5min → Testing 10min

<p>Temp. <div style="border: 1px solid black; padding: 2px; display: inline-block;"> -P °C </div></p> <p>Press. <div style="border: 1px solid black; padding: 2px; display: inline-block;"> -76.3 kPa </div> Real-time vacuum </p> <p>Time <div style="border: 1px solid black; padding: 2px; display: inline-block;"> 3.28 Min. </div> Countdown </p>	<p>Temp. <div style="border: 1px solid black; padding: 2px; display: inline-block;"> -85.5 °C </div></p> <p>Press. <div style="border: 1px solid black; padding: 2px; display: inline-block;"> -85.1 kPa </div> Real-time vacuum </p> <p>Time <div style="border: 1px solid black; padding: 2px; display: inline-block;"> 4.57 Min. </div> Countdown </p>	<p>Temp. <div style="border: 1px solid black; padding: 2px; display: inline-block;"> -85.5 °C </div></p> <p>Press. <div style="border: 1px solid black; padding: 2px; display: inline-block;"> -85.1 kPa </div> Real-time vacuum </p> <p>Time <div style="border: 1px solid black; padding: 2px; display: inline-block;"> 4.57 Min. </div> Countdown </p>
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Test passed

OR

Test failed

Temp.

85.5 °C

Press.

85.0 KPa

Time

PASS Min.

Temp.

85.5 °C

Press.

800 KPa

Time

FAIL Min.



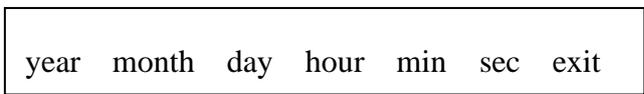
- ❖ Pipeline cleaning: start the pipeline cleaning function. This is a forced water circulation process that clean pipes, valves and steam generator. The time of the cycle is 1 minute. To start the cycle, press the “TEST” button, select the cleaning program and press “START”. At the end of the cycle, the machine will return in standby mode automatically.



- ❖ Automatic water filling: The sterilizer has the function of an automatic filling of distilled water.

5.2.4. Setting the time

In standby mode, keep pressing the two buttons “PROG.” + “TEST” for 8 seconds to enter the time settings. Press “PROG.” button to select a specific setting.

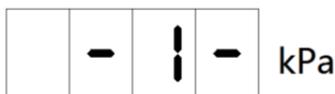


Term	year	month	day	hour	minute	second	exit
	T. SET						
display	-1-	-2-	-3-	-4-	-5-	-6-	-7-
	--14-	--05-	--24-	--15-	--45-	--55-	--OUT -

Temp.



Press.



Time

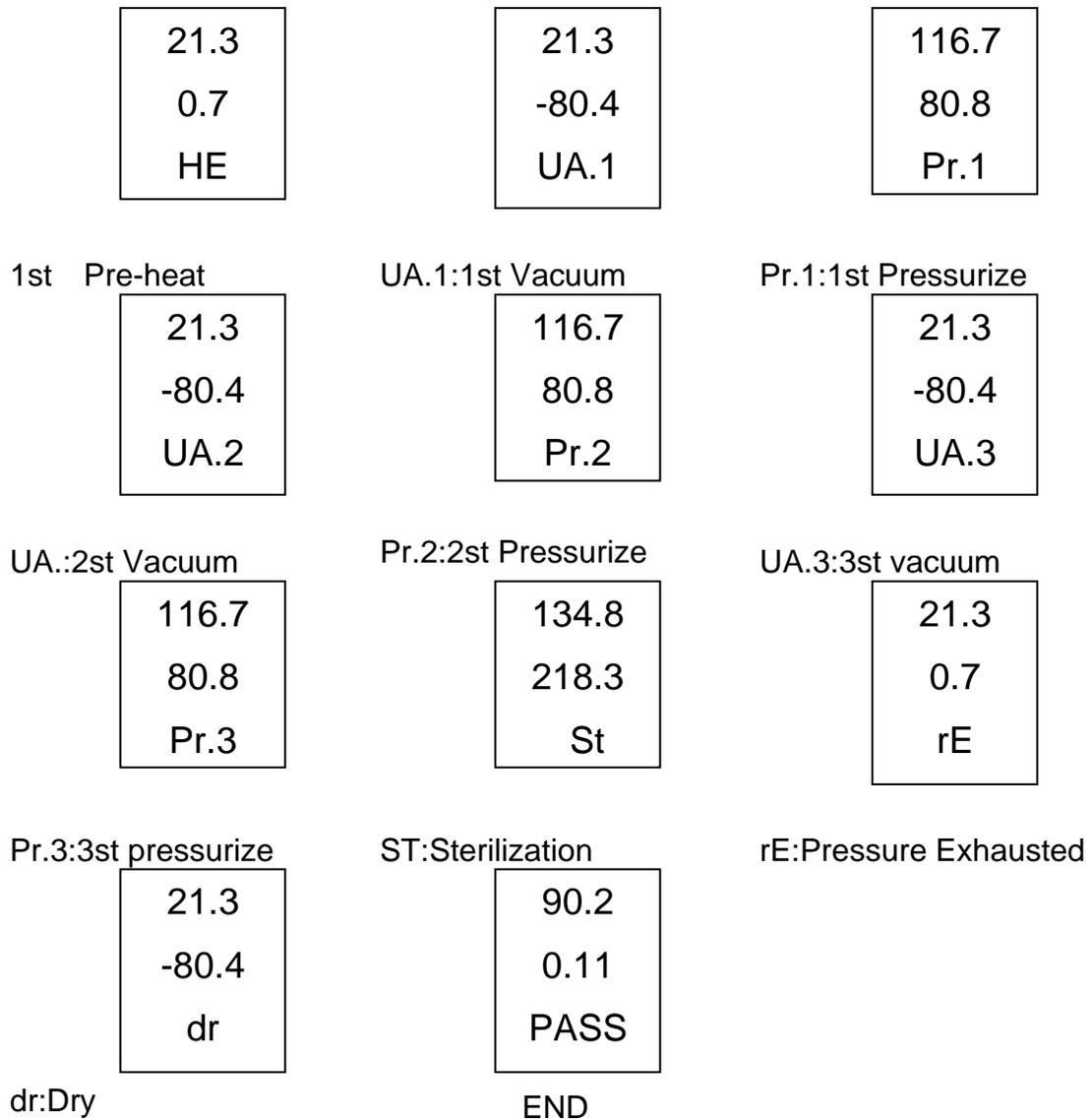


Press “TEST” to increase and “START” to decrease the values. Once finished, to exit, keep pressing “PROG.” until “OUT” will appear on the interface; press “START” to confirm and save the current time and to return to the standby screen.

Note: seconds needed to be adjusted to less than 60 seconds!

5.3 Window of Sterilization Process

3-times pre-vacuum program example: Wrapped 134°C



The total time of the sterilization and results are displayed alternately at the end of the cycle

1-time pre-vacuum program example: Unwrapped 134°C

21.3
0.7
HE

Pre-heat

21.3
-80.4
UA.1

UA.1:1st vacuum

116.7
80.8
Pr.1

Pr.1:1st pressurize

134.8
218.3
St

ST: Sterilization

21.3
0.7
rE

rE: Pressure exhaust

21.3
-80.4
dr

dr: Dry

90.2
0.11
PASS

The total time of the sterilization and results are displayed alternately at the end of the cycle

Chapter 6. *Operation Process*

6.1 Switch On

Please connect the power supply cable before you start the operation. The power switch is located on the bottom right corner of the front side of the sterilizer. When you turn the power on, the display will show a “Loading” sign. Wait 10 seconds and the sterilizer will automatically be directed into the last sterilization procedure interface.

6.2 Add Distilled Water

After you connect the machine to the power, the system will enter into self-inspection mode.

If the water in the storage tank is below the warning line, a light showing the lack of water will turn on “”. The device will not work until enough distilled water is added to the tank.

You can fill in water automatically or manually into the water tank on the top of the machine.

Automatically: Connect the water tube to the machine in “Distilled water in” inlet connector, and press “TEST” button to choose the add water program “”. Press “START” button to run.

Manually: Open up the top cover, to fill the water tank, stop filling in water when you hear a “beep” sound.

If the water shortage alarms during the sterilizing process, you should not worry about it as the water need will not influence this process. The water that had been left in the tank is enough for the operating cycle, however you need to add water before starting the next cycle.

CAUTION **USE DISTILLED WATER ONLY TO EXTEND THE LIFE TIME OF THE MACHINE.**
DO NOT TURN OVER THE STERILIZER WHEN THE RESERVOIR IS FULL OF WATER TO AVOID LEAKAGE.

6.3 Alarming if Used Water Reservoir is full

If the “” indicator light illuminates during the cycle, this means that the used water reservoir is full and needs to be drained out.

To drain out the water, connect the water tube to the inlet connector on the left as marked in the following picture. **(Figure 6a)**



Figure 6a

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

6.4 Selecting Sterilizing Program

Select the required sterilization program which you need. When you choose a program, the corresponding indicator light will illuminate. After the sterilization program has been selected, the temperature will be automatically set as default mode.

6.5 Loading Articles

Articles should be placed on the trays with some spaces among them, so the steam can circulate easily. Please use the removal tool to load the trays avoiding any possible burns.

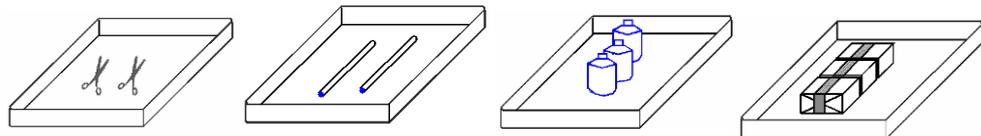
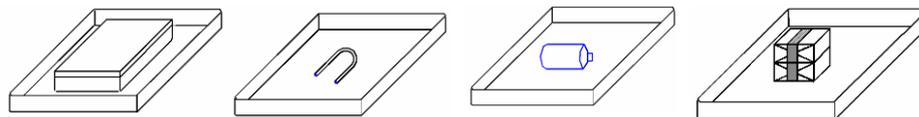
(Figure 6b)



(Figure 6b)

Arrangement on Trays before Sterilization: (Figure 6c)

- ❖ Read the following instructions for proper usage and maintenance 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 spread apart during the sterilization cycle.
- ❖ Do not overload the trays.

RIGHT**WRONG**

(Figure 6c)

CAUTION IT IS RECOMMENDED TO CLEAN THE ARTICLES BEFORE LOADING.

IT IS HELPFUL TO TURN ON THE POWER FOR 5 TO 10MINS BEFORE RUNNING PROGRAM, TO WARM THE MACHINE IF THE ENVIROMENT TEMPERATURE IS UNDER 10°C.

6.6 Closing the Door

After loading articles please close the door. When the “LoAd” sign is shown normally, you can move to the next step. If the door is not completely closed, the “LoAd” sign will be flickering.

6.7 Starting a Program

Close the door completely, and press the “Start/Stop” button to start a working cycle. The sterilizer will heat up; sterilize and dry the instruments automatically. The whole process will take 20-50 minutes. It depends on the object being sterilized, the initial temperature, and the program you selected.

CAUTION DO NOT PLACE ANY OBJECT ON THE MACHINE TO ALLOW HEAT VENTILATION.

6.8 End of the Sterilization Working Cycle

When the working cycle is finished, a writing "ED" will illuminate and give out an alerting sound. You can now open the door and take the sterilized instruments out.

WARNING DO NOT TRY TO OPEN THE DOOR IF THE PRESSURE DOES NOT SHOW "0 kPa".

When the door of the sterilizer is opened, the program will return to the initial state, waiting for the next sterilizing cycle. The machine will be kept in a heat-preserving condition for some time before the start of a new program.

CAUTION AFTER THE STERILIZATION IS FINISHED, PLEASE USE THE MATCHED REMOVAL TOOL TO TAKE THE TRAYS OUT FROM THE STERILIZING CHAMBER. IT WOULD BE BETTER TO STORE THE STERILIZED INSTRUMENTS AFTER THEY HAVE BEEN COOLED DOWN COMPLETELY.

6.9 Power Off

Once the sterilization process is over, please turn off the power switch. Make sure the door is left partially open and not locked (to make sure of this, do not use the door handle)

If the machine will not be used for a long time, please unplug the power supply cable.

ATTENTION WHEN USING THE MACHINE, WE SUGGEST THAT YOU USE THE STERILIZING INDICATOR TAPE TO ENSURE THAT THE STERILIZATION PROCESS IS RELIABLE.

6.10 Abnormal Exiting

Any interruption in the cycle caused by a technical problem, or by keeping pressed the "START" button. This "Er99" writing will appear on the state window as shown below: *(Figure 6d)*

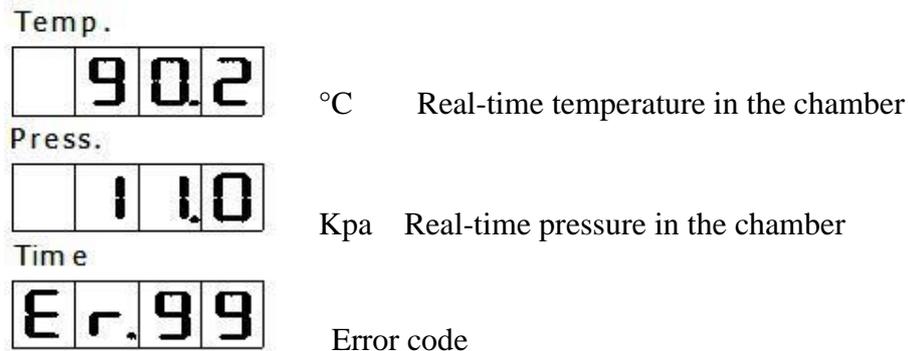


Figure 6d

Press "START" button to relieve the error alarm and the machine will start automatically the five-minute-long drying process. After drying, the machine will return to the standby interface automatically. *(Figure 6e)*

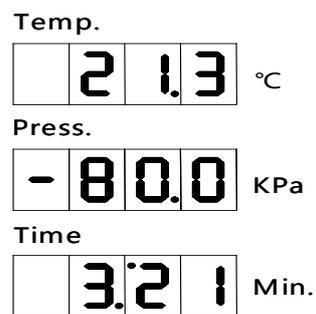


Figure 6e

If you don't need to dry, press "START" button to return to the standby interface directly. Once the problem is solved, open the door, open and close the door once again, and if needed restart the sterilization program.

WARNING DO NOT TRY TO OPEN THE DOOR IF THE PRESSURE DOES NOT SHOW "0 kPa".

6.11 Sudden Power Outages

In case of a sudden power outage, while the program is running, the machine will turn off. Once the power outage is restored, the interface will display the error code along with the real-time temperature and pressure in the chamber.

WARNING THIS MODEL USES ELECTRONIC PROTECTION LOCK, RESTORE THE POWER TO OPEN THE DOOR.

Chapter 7. *Essential Information*

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

7.1 Please Ensure the Following....

- ❖ You have read and followed these operating instructions.
- ❖ The load is suitable for the cycle selected.
- ❖ The load can be sterilized at the selected temperature.
- ❖ The load has been rinsed thoroughly before sterilization to avoid any contamination from chemical residues.
- ❖ 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 surface above.
- ❖ Only distilled, deionized or sterile water can be used.
- ❖ The sterilizer should be placed 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 can perform service on the sterilizer.
- ❖ Keep and stock the package for transportation.

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 harm the sterilizer.
- ❖ ...use in areas of risk associated with flammable materials or gases.

Chapter 8. Maintenance

Service is essential for an effective sterilization and proper performance of the machine.

We suggest general servicing by an approved technician every 2-years, or every 2500 cycles. Every 3 months replace the bacteriological filter, every year replace the gasket of the door .

8.1 Maintenance Schedule Chart

MAINTAINANCE REQUIRED	PERSONNEL REQUIRED
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

8.2.1 Cleaning Door Gasket

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

Use warm soapy water for removing persistent marks from the sterilizer. Ensure that all soap residues are completely removed by wiping both the gasket and the chamber with a lint free damp cloth.

WARNING REFER TO QUALIFIED PERSONNEL FOR SERVICING: NEVER USE A WIRE BRUSH, STEEL WOOL, ABRASIVE MATERIAL, OR PRODUCTS CONTAINING CHLORIDE TO CLEAN BOTH DOOR AND CHAMBER. BEFORE COMING INTO CONTACT WITH THE MACHINE, ENSURE THAT THE STERILIZER IS COOLED DOWN TO AVOID BURNS.

8.2.2 Cleaning after Liquid Loads

Biological liquid tends to boil at a higher rate than other liquids (water). In this condition, dirty saturated steam is produced inside the chamber. Therefore, the chamber must be cleaned daily when you are sterilizing material containing this type of liquid. Clean as follows:

- ❖ Wait for the unit to cool down.
- ❖ Wipe out chamber and door with a clean, damp cloth.

WARNING MINERAL DEPOSITS AND DEBRIS WITHIN THE STAINLESS STEEL CHAMBER CAN DAMAGE THE MACHINE.

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 antibiological cleaners. Wipe all residues from the surfaces with a dampened, lint-free cloth.

WARNING TO PREVENT THE COLLECTION OF MINERAL DEPOSITS AND CORROSION OF CHAMBER COMPONENTS, USE DISTILLED WATER ONLY AS SPECIFIED. CLEAN CHAMBER AFTER EACH USE BY NON-SALINE SOLUTIONS.

Cleaning water draining filter (Figure 8a)

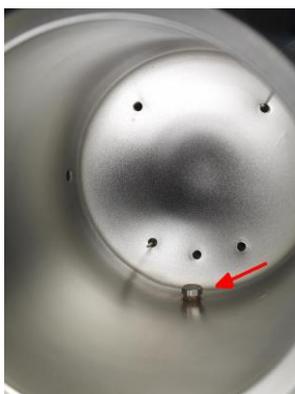


Figure 8a

The water draining filter might have been jammed by some dust due to long-term use, so the vacuum and the drying processes could be influenced. Some tiny impurities might be deposited on the filter after a long-term use, blocking the filter, influencing the vacuuming and water discharging. These kind of impurity come from smeary dust on the instruments being sterilized or some calcification from the water.

Keep cleaning inside the chamber in order to increase life-time of filter; please consider the following advices:

- ❖ Use distilled water;
- ❖ The instruments should be cleaned before being placed; it is good to use specified packing for the instruments with oil or other impurity, don't forget to seal them.
- ❖ Rotate the water filter which is composed by filter net tube(A) and filter holder(B) inside the chamber. Cleaning parts A and B, ensure that there is no dirt on it. (We suggest using an ultrasonic machine to clean these parts). Then place the filter back and rotate to secure at the bottom of the chamber. *(Figure 8b)*



Figure 8b

8.4 Monthly Maintenance

Cleaning Reservoir

There may be some impurities in the reservoir due to the distilled water being stored for a long time; regular drainage and regular cleaning is needed. Open the cover to clean inside the reservoir.

For the cleaning of the used water tank please use the cleaning program by pressing the



“ ” button and keep the automatic used water drain tube attached to the machine.

Use the front or rear connection. *(Figure 8c)*



Figure 8c

8.5 Other Maintenance

Changing Door Gasket

Switch off the machine, and ensure that it is cool and depressurized. *(Figure 8d)*

- 1) Hold the verge of the gasket and slowly pull it out of its groove.
- 2) Once you pulled out one part of the gasket, you can draw it out slowly. After taking out the gasket, please check and clean both the groove and the gasket. Please replace it if there are any damages.
- 3) Fix the clean gasket back in the door groove. At first, equally insert the 4 spots into the groove.
- 4) Press the gasket using your thumb to make sure that it is completely placed into the groove.

WARNING: THE GASKET SHOULD BE CAREFULLY EMBEDDED IN THE GROOVE.

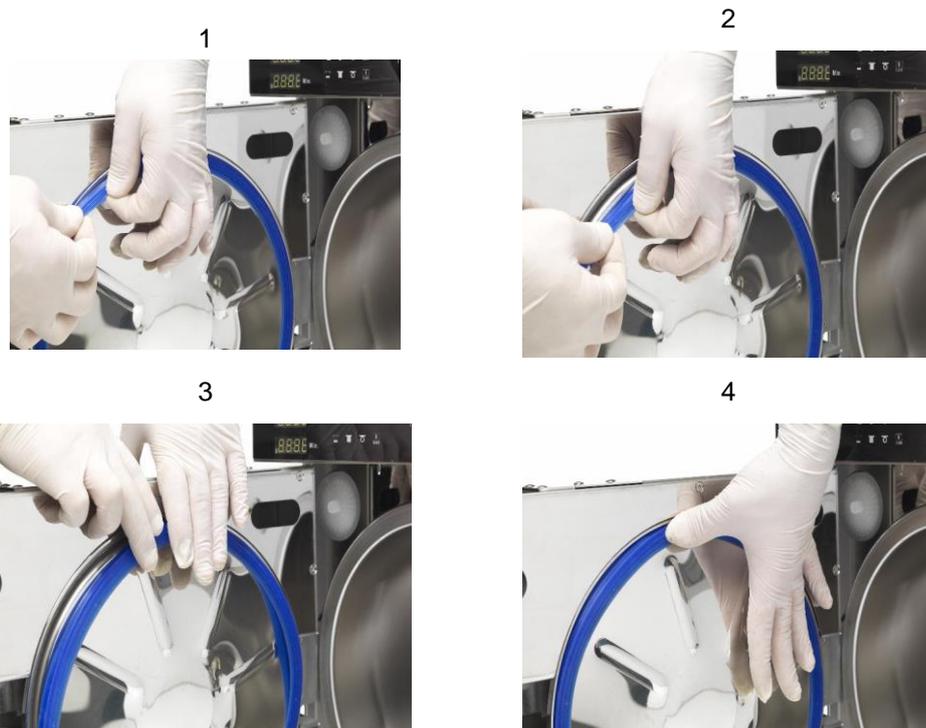


Figure 8d

Use the soft area of a clean sponge to wipe the external part of the gasket as shown below:

(Figure 8e)

Figure 8e



8.6 Servicing by the Approved Technician

Service is essential for an effective sterilization and a long-term run.

We suggest general servicing by an approved technician every 2-years, or 2500 cycles. Every 3 months replacing the bacteriological filter, every year replacing the door seal.

Check-list based on general servicing:

1. Check the solenoid valves
2. Check the water pump
3. Check the vacuum pump
4. Check the distilled water drain valve and the used water drain valve
5. Check the safety valve
6. Check the door-locking system
7. Check the sensor of pressure and temperature
8. Check the water level sensor
9. Check the electrical connections
10. Check the hydraulic connections
11. Check the safety thermostat
12. Clean the sterilization chamber
13. Clean the trays and the tray holder
14. Clean the reservoirs
15. Replace the water filter
16. Replace the air filter
17. Replace the door gasket

Statement: Calibration is not required when recommended operating conditions are followed.

Chapter 9. *Transportation and Storage*

9.1 Preparation before Transportation and Storage

Turn off the machine using the power switch, unplug the power supply cable, and make sure the sterilizer has been cooled down completely.

9.2 Draining

Drain the water from the reservoir and the waste-water collector completely. Insert one end of the tube to the drain connection. (The quick-connector on the left is used to drain the “used-water”, the quick-connector on the right is used to drain the “clean-water”) (*Figure 9a*)



Figure 9a

Used-Water out

Clean-Water out

9.3 Conditions for Transportation and Storage

Temperature: -5 °C ~ +55 °C

Relative Humidity: ≤85%

Atmospheric pressure: 500HPa~1060HPa

9.4 Package

The package is used to offer the proper protection to the product during the transportation process (delivery, sales, or any movement of the machine).

The sterilizer package requirement should be the following:

- 1) The volume of the product should not exceed $\frac{3}{4}$ of the package.
- 2) Product should be fixed inside the package.
- 3) Package should be 6mm higher than the product.

Appendix 1. *Articles Preparation Procedure*

The articles should be treated as following:

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

CAUTION THE STERILIZED INSTRUMENTS SHOULD BE CHECKED TO MAKE SURE THEY ARE NOT DAMAGED. WHEN THE TEMPERATURE OF THE STERILIZED INSTRUMENT IS STILL HIGH AVOID STORING TO ACCELERATE COOLING.

CAUTION MAKE SURE THE PACKED INSTRUMENTS ARE IN GOOD CONDITION. THE STERILIZED INSTRUMENTS CAN STILL BE HOT.

Appendix 2. *List of message code*

Message on the display	Description
LOAD	Wait for the correct temperature to start command
PASS	The test or cycle is correct
FAIL	The test or cycle is incorrect
HE	Heating the steam generator and chamber
UA	Vacuum process
PR	Pressure process
ST	Sterilization process
RE	Release pressure
DR	Drying process

Appendix 3. Printer



The printer is located on the top right of the front of the machine.
(Figure AP3a)

Figure AP3a

The paper should be installed correctly. Open the front cover of the printer, raise the lever with a finger and pull it open. (Figure AP3b)



Figure AP3b

Remove the roll of the paper, and insert a new one if needed. Please pay attention to how the paper is positioned: the shiny side of the paper should be on top.

If the green light is flashing the internal sensor is not able to see the paper inside the printer. Please check that the paper is positioned correctly and clean the sensor if needed. (Figure AP3c)



Figure AP3c

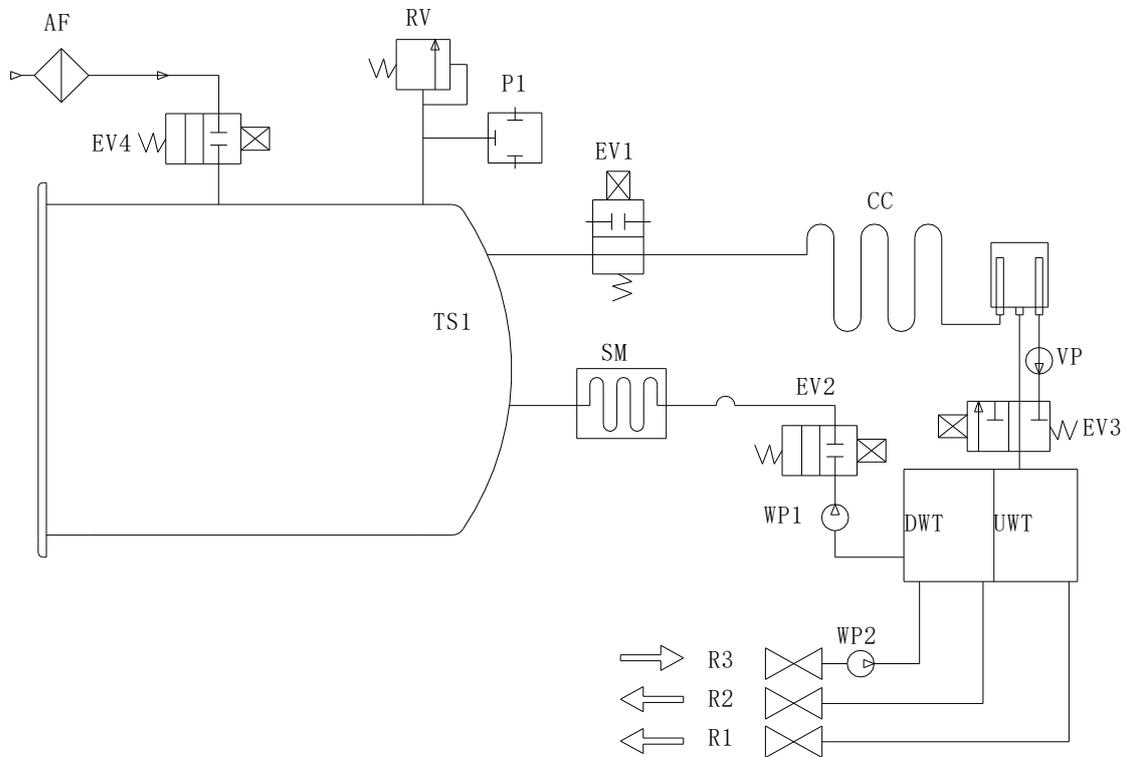
Appendix 4. *Alarm Code List*

The sterilizer will show Error information as following when it fails.

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 required temperature and pressure
5	Er05	Pressure cannot be released
6	Er06	Door is open during cycle
7	Er07	Working overtime
8	Er08	Over pressure
9	Er09	In-chamber sensors temperature too high or too low (dual sensors)
10	Er10	Temperature cannot match with pressure parameters
11	Er11	Protection lock
12	Er12	Vacuum Test is failed
13	Er14	Difference is too big between dual inner sensors
14	Er98	Sudden Power Off
15	Er99	Abnormal Exiting

Appendix 5. Piping and Circuit Diagram

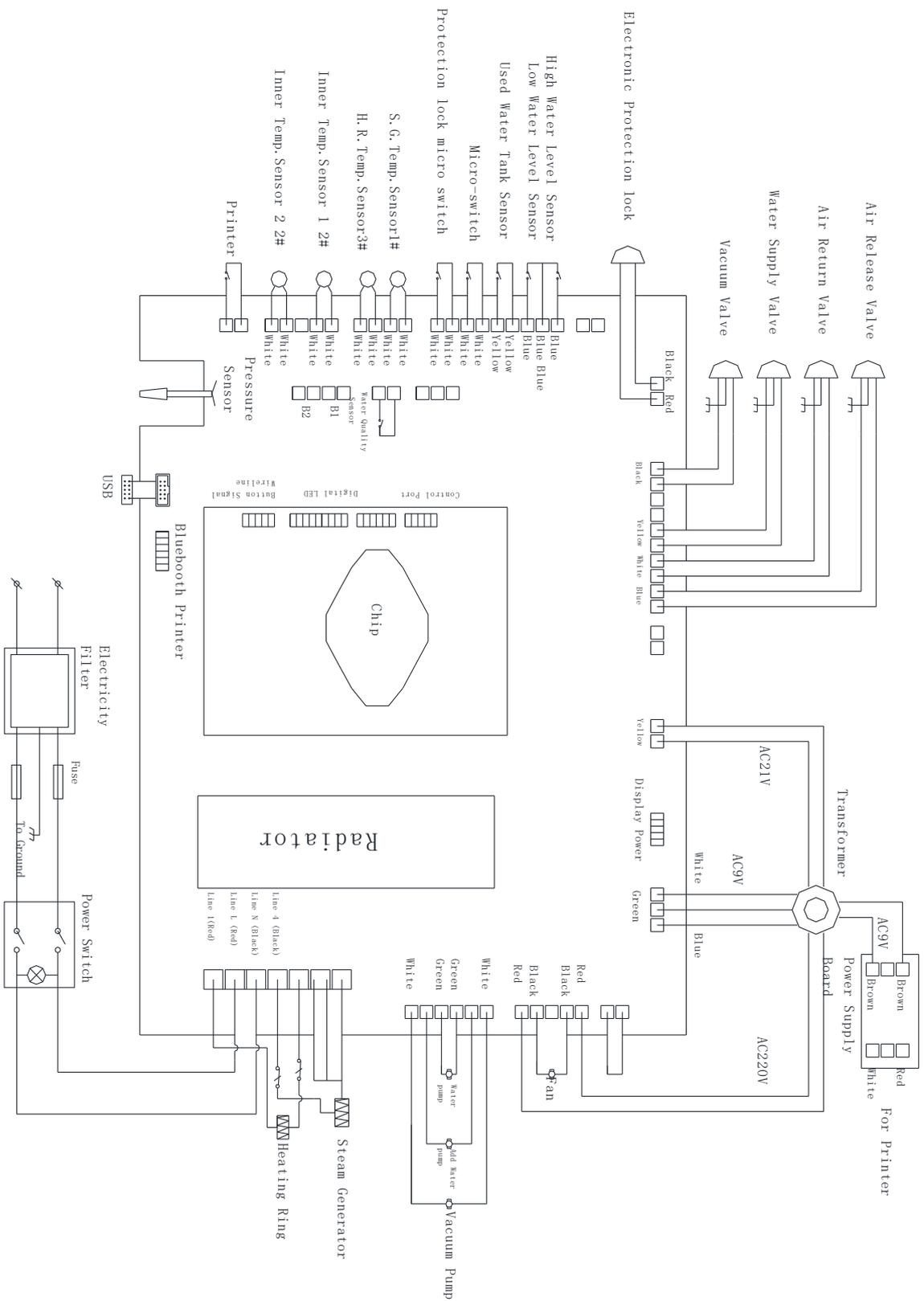
Piping Diagram



AF	Air Filter
UMT	Used Water Tank
DWT	Distilled Water Tank
EV1	Air Release Valve
EV2	Water Supply Valve
EV3	Vacuum Valve
EV4	Air Return Valve
P1	Pressure sensor
CC	Condensate Collector

WP1	Main Water Pump
WP2	Add Water Pump
SM	Steam Maker
VP	Vacuum Pump
RV	Relief Valve
R1	Distilled Water Drain Port
R2	Used Water Drain Port
R3	Water Adding Port
TS1	Temperature Sensor

Electric Drawing



Appendix 6. *Inspection Checklist*

NO.	Testing item	Request of standards
1	Exterior	The exterior of the sterilizer should be tidy and have no disfigurements, such as deflection, hollowness, collision, scratches, or sharp edges.
2	Cover Plate	Ensure that disassembling is easy to facilitate the repairs of the equipment.
3	Cover Plate	The digit and letter in the screen must be legible.
4	Electroplate Components	The Electroplate should agree with YYOO76-1992 Class 2, for the request of characteristics.
5	Printer Components	The Electroplate should accord with YYOO76-1992 Class 2, for the request of characteristics.
6	Door Safe Lock	Under normal conditions, if the sterilizer door is not locked tightly, the program cannot start.
7	Chamber Pressure	Ensure that the door can't be opened when the chamber pressure is over 0.027Mpa.
8	Safety Valve	The sterilizer must be installed with a safety valve. Safety valve opening pressure is $0.27\text{Mpa} \pm 0.01\text{Mpa}$, and automatically opens when reaching the set value.
9	Sterilizing Program	Sterilizer should have the pre-established programs at 121°C and 135°C .
10	Controlling System	The control system in the sterilizer should limit the steam which enters in the chamber, controlling at a highest average temperature of $\pm 3^{\circ}\text{C}$ on a pre-establish station. Ensure the temperature value accords with the pressure controlling value.
11	Timing Control	Able to control the timing of the sterilization and drying processes. The error should not be greater than 10% of the preset value.
12	Button and Switch	Be flexible and reliable on the sterilizer.
13	Indicator and Display	The indicators and displays of the sterilizer should show the exact states of every sterilizing procedure. Under the normal situation, the sterilizer should indicate: <ul style="list-style-type: none"> a). Chamber temperature b). Chamber pressure c). Sterilizer working state d). Water level state e). State of the door
14	Leakage Forbidden	In the condition of the vacuum - 0.07Mpa, the sterilizer should not leak 0.0013Mpa within 10min.

15	Leakage Forbidden	The sterilizer cannot leak under the work pressure.
16	Protective grounding Impedance	The impedance between protective grounding point of the power input faucet and any metallic parts of the structure. Do not exceed 0.1Ω.
17	Successional Leakage Current under the Work Temperature	a) Earth leakage current on the normal condition: ≤0.5mA the single state: ≤1 mA.
		b) Crust leakage current on the normal condition: ≤0.1 mA the single state: ≤0.5mA.
18	Dielectric Strength with Working Temperature	a) A-a1: It should bear the peak wave test alternative voltage, 50Hz, 1500v, which between the web power input port and protective grounding can be touched all metallic parts. It lasts 1min, and hasn't the phenomenon of breakage and flash over.
		b) A-a2: It should bear the peak wave test alternative voltage, 50Hz, 1500v, which between the web power input port and the enclosure of which should not be pretended grounding. It lasts 1min, and does not have the breakage phenomenon of and flash over.
19	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 are: (<i>Warning: the theory of steam temperature is accounted by measuring pressure, which can be considered the test temperature</i>).
		Not lower than the sterilization temperature.
		Not more than 4°C above the sterilization temperature.
		Does not differ from each other by more than 2°C.
		The usable place temperature during the no-load cannot exceed the scope of the highest temperature.
20	Hollow Load	For hollow load A and B, in order to confirm the presence or absence of saturated steam, the indication system changes in accordance with the system manufacturer predetermined color.
21	Wet instruments: Solid and Wrapped Load	For wrapped load, any remaining moisture should not lead to wet packages and should 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 in the chamber before beginning the cycle should not exceed 0.2%.

Appendix 7. Classic Printed Report

```

GALBIATI REPORT — Name
Ver: 4.0 ————— Version of the memory report
SN:SW1707ZA0001 — Serial number of the autoclave
USER: _____ Space for the user name
Cycle no: 00091 — Number of the cycle
-----
Program: 02 — Program selected
      134.0C-210kpa
Pre vacuum: 3 — Information about the program
Sterili. 05 min
Drying: 09 min
-----
Process:
-----
Pre-vacuum:
min   C   kpa
00:00 037.4 000
01:48 039.7 -082
04:43 113.1 090
06:36 080.4 -060 — Value of the vacuum moment (in this case 3-time Vacuum
07:58 110.5 050 process)
09:56 081.3 -060
-----
Pressurize:
min   C   kpa
09:56 081.3 -060
14:49 134.8 208 — Pressure process and values
-----
Sterilization:
min   C   kpa
14:50 134.8 210
      134.2
15:20 134.9 209
      134.4
15:50 135.0 209
      134.5
16:20 135.0 209 — Sterilization process and time, pressure and temperature
      134.5 values
16:50 135.0 209
      134.5
17:20 135.0 208
      134.5
17:50 135.1 208
      134.6
19:50 135.0 208
      134.5
MAX   134.6 ————— Min and max temperature during the cycle
MIN   134.2
-----
Exhaust:
min   C   kpa
19:50 135.0 208 — Exhaust process
20:46 110.6 019
-----
Drying:
min   C   kpa
20:48 109.9 016
21:48 089.8 -052
22:48 078.5 -066 — Drying process and values
23:48 082.5 -045
29:48 092.5 000
-----
RESULT: OK — Final result (positive or negative)
TIME TOTAL: — Total time of the cycle
029min
Operator: _____ Space for the user signature
Date: 02/10/2017 — Date and time of the sterilization
Time: 19:09:34

```

Appendix 8. *Digital Report USB*

This sterilizer is able to save the report for any cycle by an internal printer and a USB key in digital format (.txt format). **(Figure AP8a)**



Figure AP8a

Please insert the USB key that you find in the accessories in the special port that is on the upper left side of the autoclave like in the picture.

Do not insert or remove the key when the autoclave is on! There is the risk of losing all data files.

Digital format: the program and the files

To view the report on the USB key, you need to install the program contained on the USB key that you will find in the accessories supplied with the machine.

On the USB Key you will find a directory “Record reader_setup”.

Open the directory with a double click of the mouse and you will see the file “Record reader _setup.exe”

Start the installation with a double click of the mouse and the following window will appear: **(Figure AP8b)**

Now click the “NEXT” button.

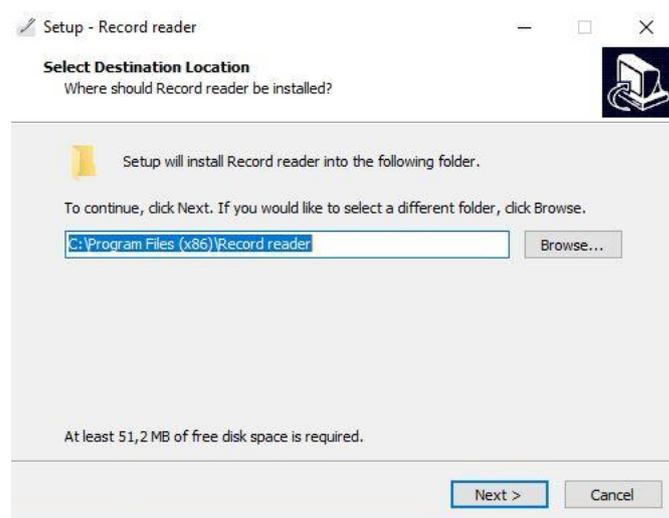


Figure AP8b

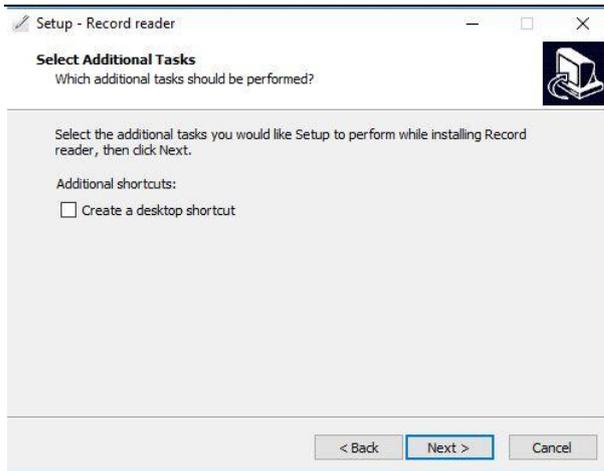


Figure AP8c

Choose your directory for the installation and click “NEXT”: (Figure AP8c)

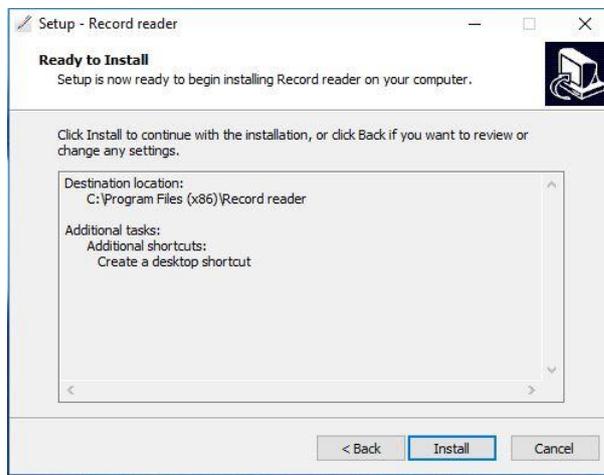


Figure AP8d

If you want an icon of the program on your desktop mark the selection and then click NEXT. (Figure AP8d)



Figure AP8e

The next window is the final information of the setup. Please make sure that the directory and the selection are correct. Click “INSTALL” to complete the installation. (Figure AP8e)

Click "FINISH" to complete.

If the installation was done correctly, the program window should appear on the desktop.

The following icon of the Galbiati USB Reader should now be visible on your desktop:



To start the program, double click on the icon, the following window will appear:
(Figure AP8f)

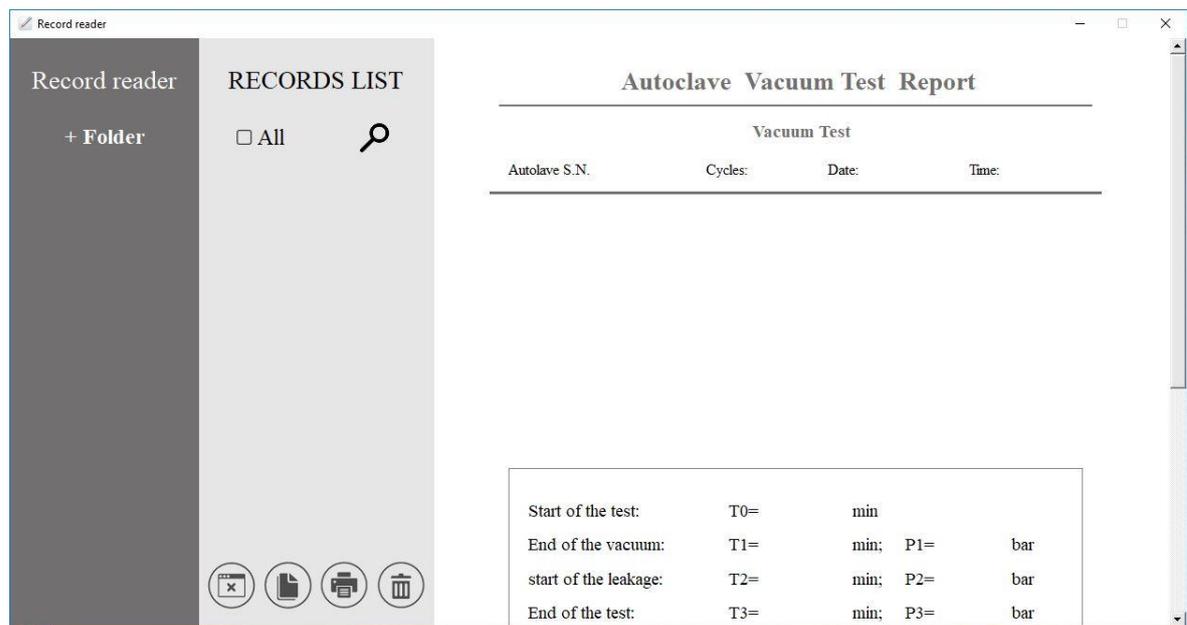


Figure AP8f

On the left side of the window there are the commands used to check, open, view and print the diagram of the cycles.

Insert the USB key in the USB port on the left side of the machine. Wait for the operative system to recognize the key. Click onto the "+FOLDER" icon as shown above: (Figure AP8g)

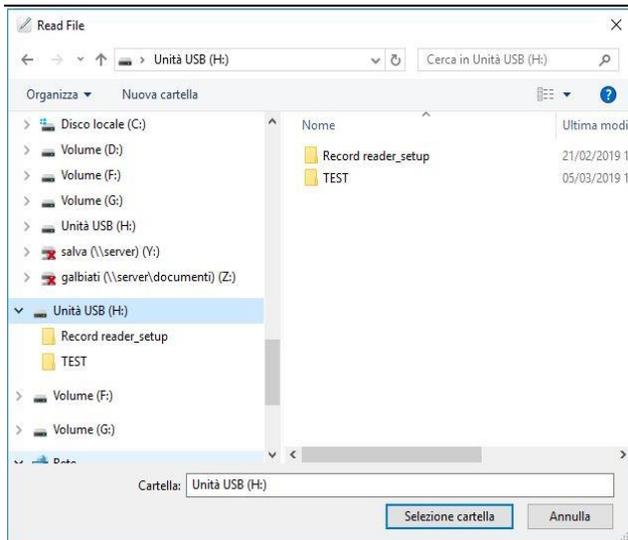


Figure AP8g

Select the wanted DRIVE (in the example is mobile disk H:) and click SELECTION FOLDER button. (Figure AP8h)

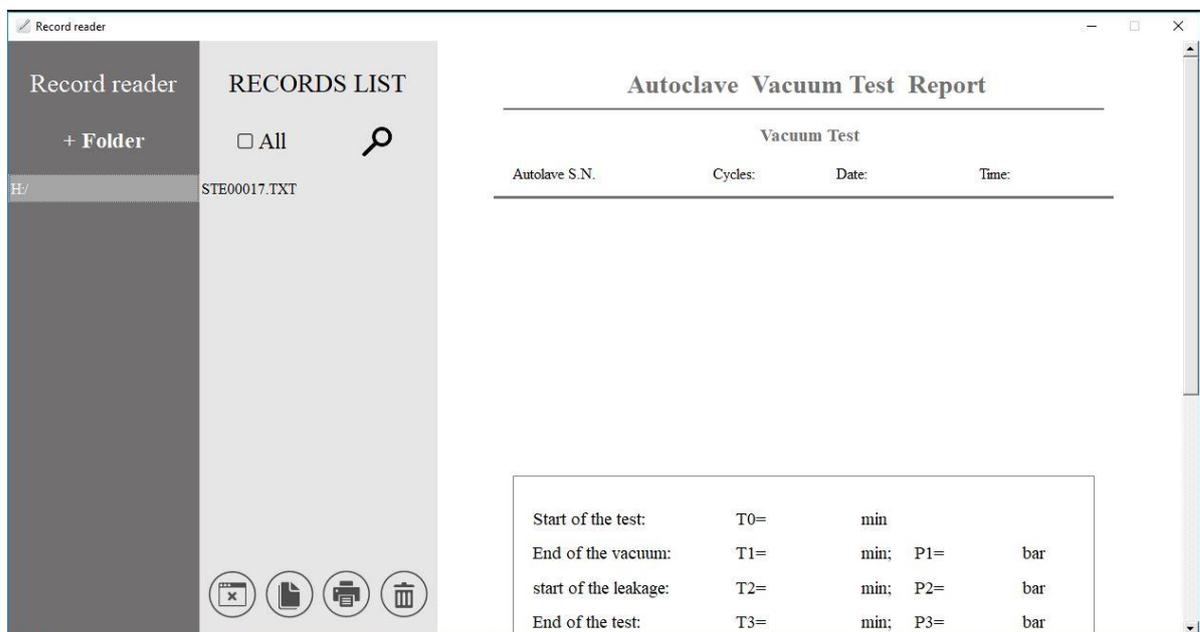


Figure AP8h

In the white window the list of the report of the cycles will appear;
The format is:

STE (sterilization file)

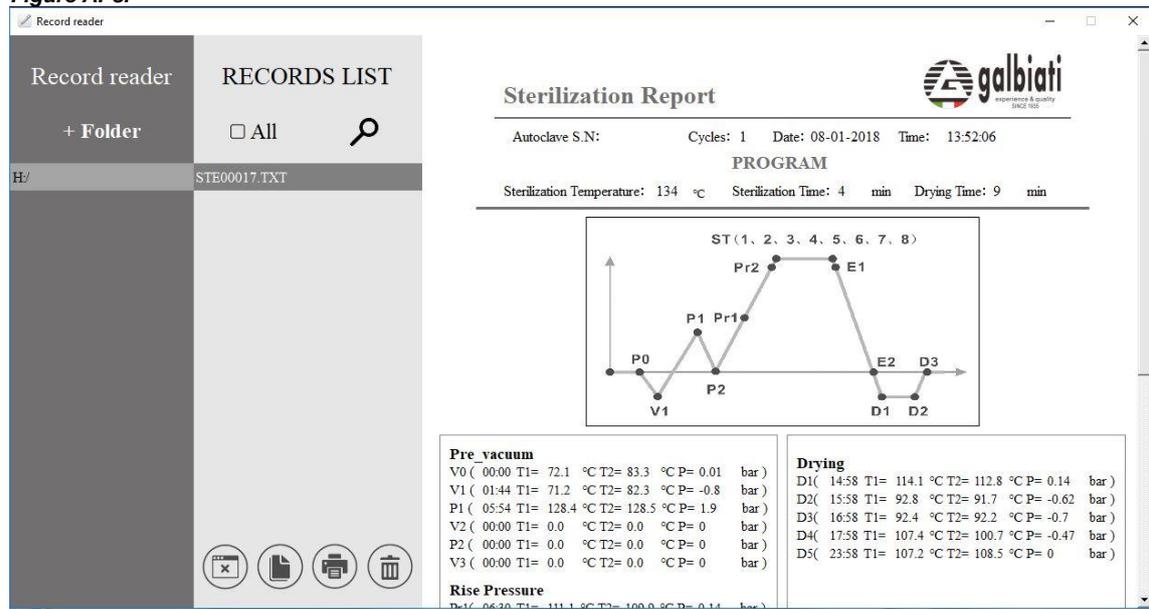
00001 (number of the cycle)

TXT (the format of the file)

The autoclave saves the cycle by sequential number 00001,00002,00003 etc.

To view a cycle, select a file report by clicking on it. (Figure AP8i)

Figure AP8i



Now you can see the report and any needed information on the cycle (diagram and values). Click on "PRINTER" icon to print.

Appendix 9. *Drain pressure tube for the used water tank.*

On the lower rear side of the autoclave there is a quick connector for a tube.

This tube is the drain pressure tube; during the cycle the chamber releases pressure four times (three times at 1.2 bar and one times at 2.1 bar).

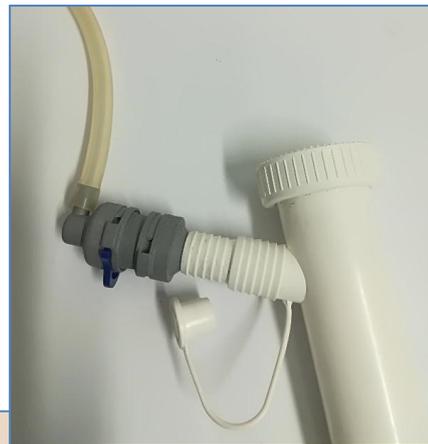
To drain the pressurized air from the used water tank, use the drain tube and insert it in the fitted drain of the clinic.

The staff working in the sterilization area must not breathe this steam. For this reason, it is sent through a tube directly into the nearest outlet (drain to the wall or floor, or a sink drain).

Here are three connection examples: *(Figures AP9a)*



Figures AP9a



Appendix 10. *Setting User Program*

In standby mode keep pressing the “PROG” button for 5 seconds until “bLUE-Prt-[00]” will be appeared on the display. For entering the User program, please press the “PROG” button one time and “USER- OUT---” will be displayed. For setting the parameters, please press “TEST” button. The parameters are:

tE= Temperature

St= Sterilization time

dr=Drying time

VA=Times vacuum

Setting temperature

By pressing “TEST” you can see the temperature parameter and by pressing “START” button you can select the degrees: 121°C or 134°C.

Setting sterilization time

By pressing “TEST” you can see the sterilization time parameter and by pressing “PROG.” button you can increase the value of the sterilization time and by pressing the “START” button you can decrease the value of the sterilization time.

N.B. If you select 121°C temperature value, the range of the sterilization time is: 20~60min. If you select 134°C temperature value, the range of the sterilization time is: 4~20 min.

Setting drying time

By pressing “TEST” you can see the drying time parameter and by pressing “PROG.” button you can increase the value of drying time and by pressing the “START” button you can decrease the value of drying time.

The range of drying time is: from 00min to 60min with an interval of 5 min.

Setting times vacuum

By pressing “TEST” you can see the times vacuum parameter and by pressing “PROG.” button you can increase the numbers of times vacuum and by pressing “START” button you can decrease the numbers of times vacuum. The numbers of vacuum are:1 or 3 or 5.

For the end of the setting please press the “TEST” button one more time. For save and exit press the “START” button.