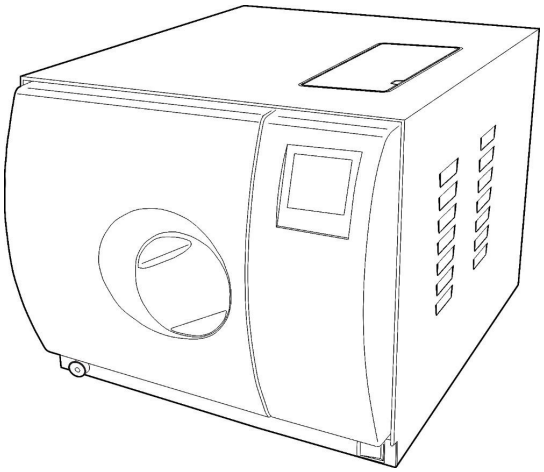
Kalstein®

Steam Sterilizer
YR0030-6-2
Instruction Manual



Thank you very much for purchasing Steam Sterilizer

YR0030-6-2.

Please read the “Operating Instructions” and “Warranty” before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the “Warranty” at a hand place for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

Thank you for choosing our steam sterilizers.

Prior to operating this instrument, please read the operations manual carefully and followall installation instructions.

IMPORTANT NOTICE:

If you can't open the door, please unlock the door according to the instruction “How to open the doorin the case of power outage” in the manual.

Need Maintenance

If E88 appears on the screen when power on or appears on the report, please call your dealer or localservice maintenance. Your steam sterilizer need a regular maintenance.

Table of Contents

1. General

1.1 Scope of Manual

This manual contains information concerning the installation, operation and maintenance of the steam sterilizers. To ensure proper performance of the autoclave, the instructions given in this manual should be thoroughly understood and followed.Keep the manual near to the sterilization in a readily accessible location for future reference.

1.2 Intended Use

The sterilizer described in this manual is intended for the sterilization for medical, dental, beauty, Vet and Tattoo fields.It is used for products non-sensitive to high temperature, water, or steam.

1.3 General Safety Instructions

-Read and understand this manual before attempting to install or operate the sterilizer.
-Make sure that all the installation conditions are fully complied with.
-Ensure that the supply voltage agrees with the supply voltage specified on the type plate of the sterilizer.
-This appliance must be grounded. Connect only to a properly grounded outlet.
-Do not cover or block any openings on this appliance.
-Use this appliance only for its intended use a described in this manual.
-Do not exceed the maximum weight limit of the loads specified in this manual.
-Do not operate this appliance if it has a damaged cord or plug, if it is not working properly, or if it has been damaged or dropped.
-Never must put into the sterilizer in flammables or explosives products.
-The sterilizer may not be operated in areas in which gas or any other explosive volatile substance is present.
-Installation and repair work should only be performed by authorized service technician. Work by unqualified persons could be dangerous and void warranty.

1.4 Standards and directives

The steam sterilizers were designed and has been produced in conformity with the following directives and standards: Directives:
2014/68/EC Pressure equipment.
93/42/EEC Medical devices (Class Ⅱ b).
Standards:
EN13060 Relative to small steam sterilizers.
EN61010-1 Safety regulations for laboratory devices-Part 1:General regulations.
EN61010-2-040 Safety regulations specific to sterilizers used in the processing of medical material.
EN61326-1 Electromagnetic compatibility regulations for laboratory devices.

1.5 Symbols

For safe operation, please pay close attention to the alert symbols below which can be found in the sterilizer or throughout this manual.

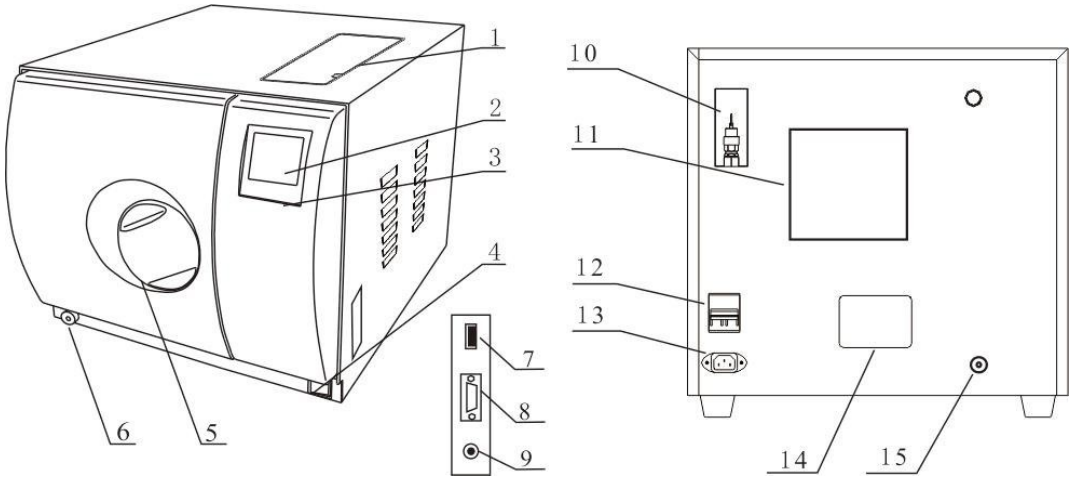
This symbol represents an electrical caution - ground protection.

Hot Surface
This symbol represents a warning of a potential hot surface.

Important safety information.

2. Description of the sterilizer

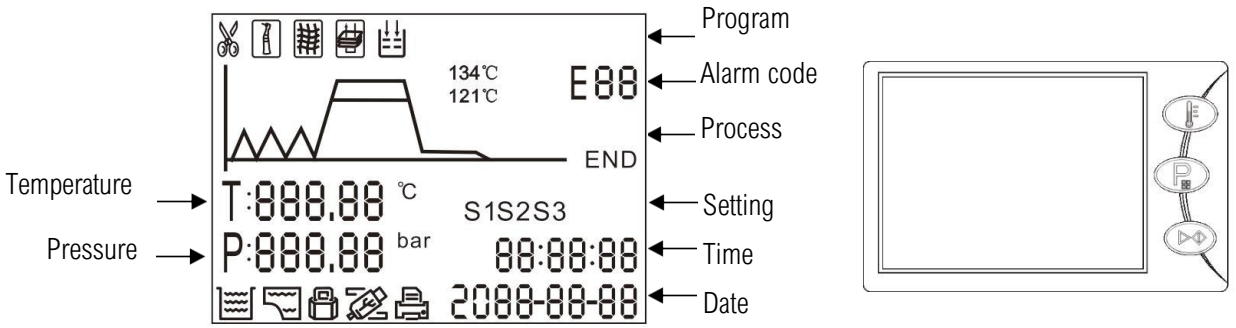
2.1 Sterilizer views



1. Distilled water tank
2. Screen
3. Control Panel
4. Main power switch
5. Door handle
6. Drain connector (Used water tank)
7. USB port
8. Printer (Optional)
9. Printer power
10. Safety valve
11. Condenser vent
12. Circuit breaker
13. Power socket
14. Rating plate
15. Drain connector (Distilled water tank)

	Date of manufacture
SN	Manufacture number
	Manufacturer Name
	Manufacturer Address
EC REP	EC-Representative Name
	EC-Representative Address

2.2 Control panel



	Distilled water tank is required water.		Door locked
	Distilled water tank is full		information output to USB port
	Used water tank is full.		Printer is connected
	Temperature button		Program button

Start/Stop button	

Notice: Button will be locked for the initial 10 seconds after powering up for system initialization.

2.3 Technical specifications

Item	Parameter
Chamber	φ230 x 360 mm
Rated Voltage	220-240 VAC; 50 Hz
Circuit breaker	F16A/400V
Nominal power	1600VA
Sterilization temperature	121°C /134°C
Capacity of the distilled water tank	Approx 2.5 L (Water at level Max)
	Approx 0.5 L (Water at level Min)
Operation temperature	5°C-40°C
Operation relative Humidity	Max. 80%, non condensing
Overall dimensions	440(W)x400(H)x620(D)
Net weight	39 kg
Max. Noise level	<70 dB
Atmospheric pressure	76 kPa - 106 kPa

2.4 Packing content

No.	Accessory	Quantity
1	Steam sterilizer	1
2	Instrument tray	2
3	Instrument tray rack	1
4	Instrument tray handle	1
5	Door adjustment tool	1
6	Draining hose	2
7	Instructions manual	1
8	Door seal	1

3. Installation

3.1 General conditions

Position the device on a plane surface with minimum capacity 60 kgs.The sterilizer should be placed on a level worktable.

Improper water level in the chamber could cause a sterilizer malfunction.

Leave at least 10cm between the device rear part and the wall. The clearance required to open the door is 40cm.

Position the autoclave at such a height as to make it possible for the operator to check the whole sterilization chamber and carry out the normal cleaning operations.

The room where the device is installed must be enough ventilated.

Do not install the device near washing basins, taps, etc. where it is likely to be splashed.Do not lean on the door when it is opened.

Do not place trays , papers, fluid containers, etc. on the sterilizer.

3.2 Power supply connection

Check the label on back panel o sterilizer to verify voltage rating for the unit. Failure to connect the autoclave to an appropriate power supply could result in damage to the unit, and electrical shock to personnel.

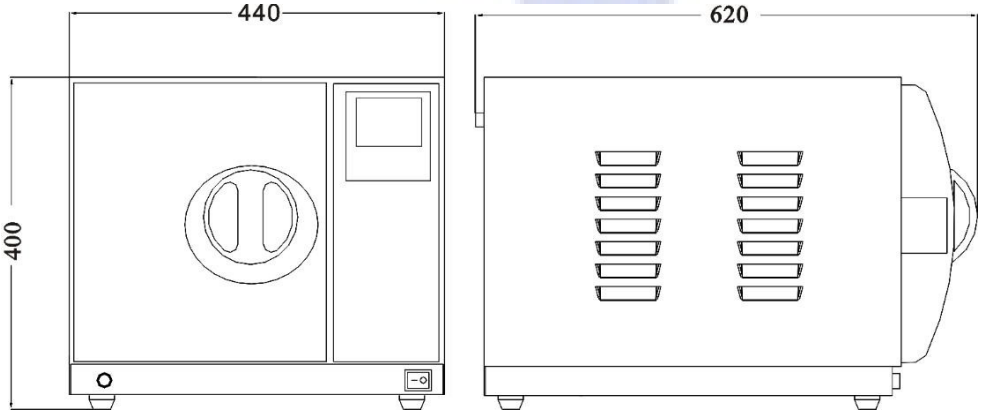
Plug power cord into a properly polarized and grounded receptacle rated. A dedicated circuit only used for the sterilizer is recommended.

Never connect the device pin to reductions of any type.

4 Setup

Open the door and remove all of the inner contents for unpacking.Connect the power cord to an outlet of the appropriate voltage.

Turn on the main power switch on the right side. After switching on, the machine turns on the LCD and shows the door position, water level, working program, date, time and etc.



Note: The control panel will be locked for the initial 10 seconds after powering up for system initialization.

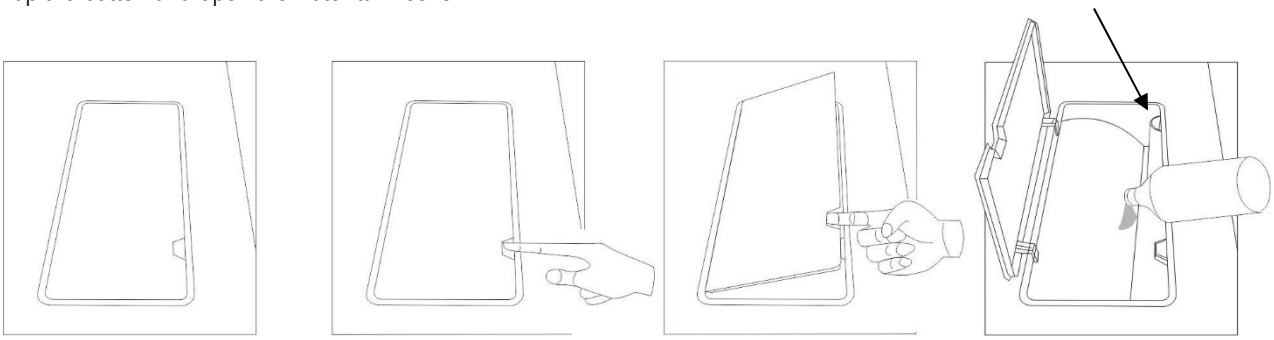
Notice: Before using the sterilizer or at any time the low water level icon blinks, fill the distilled water tank with distilled water.

4.1 Fill the distilled water tank

Ensure that the drain valve is closed.

Tap the button and open the water tank cover.

The water level should not exceed this port.



Use only high quality distilled water. (see Appendix 1)

4.2 Preparation of sterilization materials

For the most effective sterilization and to preserve the sample, please follow below:

*Clean instruments immediately after use.

*Treat the instruments by ultrasound cleaner.

*Residual chemicals left over after cleaning and disinfecting process may damage and corrode parts of the autoclave, always rinse off the instruments using distilled water.

*Follow instrument manufacturer's guidelines and recommendations for handing and cleaning instruments prior to sterilization.

*Check the manufacturer's instructions as to proper procedure for sterilizing of each item.

*Arrange the samples of different materials on different trays or with at least 3cm of space between them.

*Clean and dry instruments thoroughly before placing them into tray.

*Always insert a sterilization paper or cloth between the tray and sample to avoid direct contact.

*Arrange the containers (glasses, cups, test-tubes, etc) on one side or inverted position, avoiding possible water stagnation.

*Don't stack the trays one above the other or put them in direct contact with the walls of the sterilization chamber.

*Always use the instrument tray handle.

*Wrap the samples one by one or, if more tools have to be set in the same bag, verify that these are made of the same material.

*Don't use metallic clips, pins or other, as this jeopardizes the maintenance of the autoclave.

*Don't overload the trays over the stated limit (see appendix 2).

5. Operation

5.1 Select the program

Tap the button to select the program. And tap the button to select the temperature.

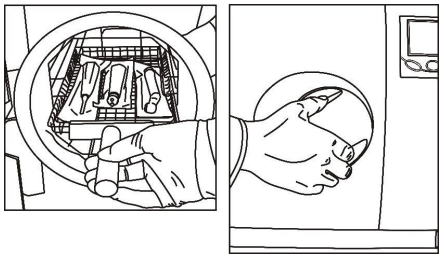
Solid	Wrapped	Textile	Prion	Liquid

5.2 Running the sterilization program.

After selecting program, the materials to be sterilized can now be placed on thetray, placed inside the chamber by the tray handle.

After the instruments are loaded, you may close the door.

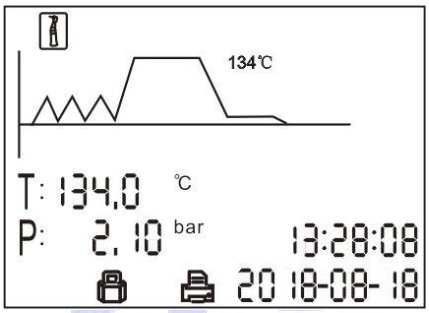
The icon will be lightened.



Caution: You must turn the door handle to the max. position, otherwise the machine will alarm and prevent starting the cycle.

5.3 Start the sterilization program.

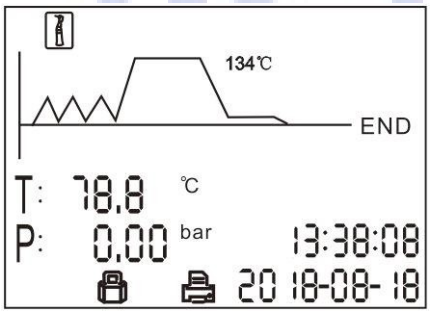
After the button is Taped, the stage and the status of the current cycle will appear on the display. The sterilizers will perform the program automatically. (see appendix 2).



Total time or count down until completion

5.4 End of cycle

After cycle is completed, the printer will be activated and print out a report of the cycle (if the optional printer has been connected) or save the report in the USB drive (optional).



Caution: Always use the tray handle to load or unload the tray into the autoclave. Failure to do so can result in burning.

5.5 Manual abort of the program

It is possible to interrupt a started cycle prematurely. If you need to interrupt a cycle and remove the items urgently, you may hold the button for 3 seconds during the drying time to skip the dry cycle.

If you interrupt a cycle before it reaches the “Drying” step, then the items inside the autoclave must be considered not sterile.

If you need to interrupt a cycle after the holding time of the sterilization cycle and during the drying step then the items inside the autoclave can be considered sterile.

Caution: Depending on the status of the Cycle, steam can escape from the sterilization chamber when you open the door.

5.6 Record of the cycle

USB Flash memory (Optional)

A USB drive can be used as a method of storing a report of the cycle. To do so, insert the USB drive into the slot located on the service door of the sterilizer.

The information will automatically output directly to the USB drive after the cycle has completed. The name of the file is determined by the serial number of the machine and the cycle number.

For example:

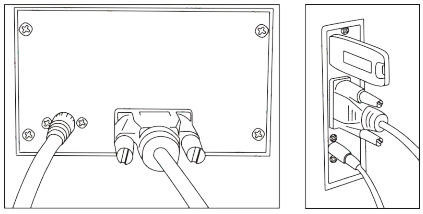
The serial number is E00001. The cycle number is 0012.

The file name in the USB stick is 01001200.txt.

The first two numbers represent machine number. The middle four numbers represent cycle number. The last two numbers represent error code.

E.g. 00:no error;01: error E01

5.7 Printer (Optional)

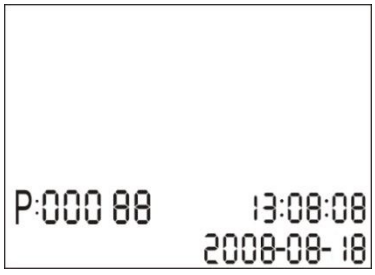


5.7.1 Connect the printer cable.

5.7.2 Connect the printer power.

The printer (Optional) will produce a report of the cycle that just ended. At the end of each cycle the printer will print out a report of the cycle.

5.8 Report

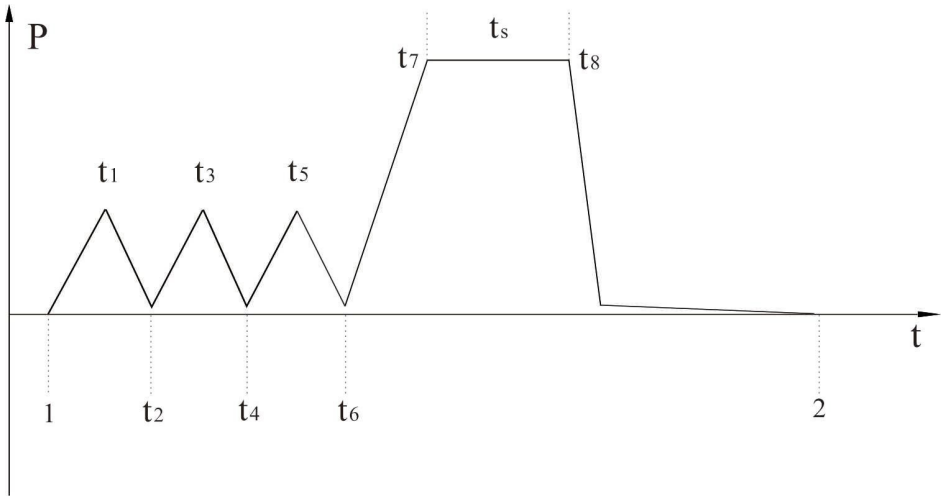


Internal Memory

In this menu you can read the latest information of the last 20 cycles stored in the internal memory of the sterilizer.

Holding the button when switch on until you enter to the prior program storage screen. This will show the cycle No. Tap the button to toggle between different cycles. To print or send the report to the USB drive, tap the button. The most recent 20 records are stored.

When vising printed data records, refer to the diagram below:



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Program: WRAPPED

Temperature: 134C

Pressure: 206.0 kPa

Dry Time: 02Min

Ster Time: 4.0Min

	time	temp.	pressure
Start	15:24:20	042.0C	
T1:	15:32:11	070.0C	053.2kPa
T2:	15:36:08	075.3C	009.7kPa
T3:	15:39:21	090.3C	050.4kPa
T4:	15:44:32	094.3C	009.6kPa
T5:	15:47:12	119.0C	102.4kPa
T6:	16:00:11	110.2C	009.3kPa
TS:		134.8C	221.6kPa

MAX.Temperature:135.1C

MIN.Temperature:134.5C

MAX.Pressure:230.4kPa

MIN.Pressure:212.9kPa

T7: 16:04:02 135.0C 223.5kPa

T8: 16:06:32 134.8C 214.1kPa

End 16:14:12 78.2C

Cycle No: 0005

Ster Value: Success

Date: 2018-01-18

SN:E00001

Operator:

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6. Advance setting

6.1 Enter the setting

6.1.1 Power on the machine while holding the button for 5 seconds. This will enterinto the advanced setting mode.

6.1.2 Select the state (state 1 to state 3) by taping the program button. Tap the button toenter the setting.

6.2 S1 State

If you select the S1. You may change the unit of the temperature and pressure, and adjusttime

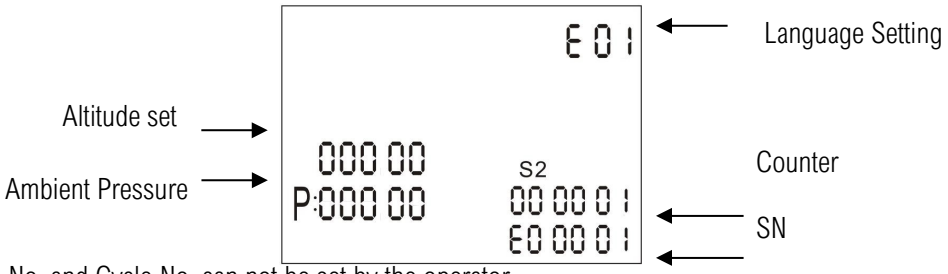
and date.

6.2.1 The first option is to select the unit of temperature. Tap button to select the unit.The unit you selected will be lighted. Tap the button to the next item.

6.2.2 You may select the unit of pressure in the same manner.

6.2.3 Then tap button to the next item to adjust the time and date. After the last letter of the date or time is set, then the data is permitted to be saved. If you want to finish the setting you shall tap . It will return to the screen of selecting stages.

6.3 S2 State.



Note: The Serial No. and Cycle No. can not be set by the operator.

6.3.1 You may check the count of sterilization cycle. It can not be changed by operator.

6.3.2 Set the parameter for high altitude (above 2.0 km or atmospheric pressure is below 80 kPa) you may need toadjust this parameter.

6.3.3 The value of pressure is not zero if in a high altitude place. We can set the ambient pressure manually. Open thedoor, select this item, press START button. The pressure will change to zero after set the pressure.

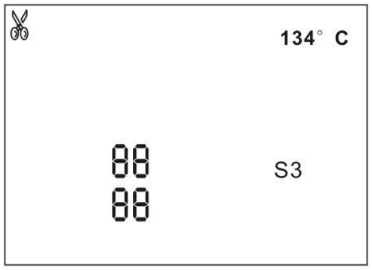
6.3.4 Language set.

00	English	01	German	02	Spanish	03	Polish
04	French	05	Hungary	06	Romanian	07	Dutch
08	Lithuanian	09	Latvian	10	Czech	11	Italian

6.4 S3 State

6.4.1 Adjust the length of the sterilization and drying time. Tap program button to select the program.

Tap temperature button to select the temperature of program. Then tap button to adjust the drying time and holding time.



6.4.2 First to adjust the holding time.

Press button to adjust the data.

Press the button to select the items.

6.4.3 Press to save.

6.4.4 Drying time is 0-60.

Holding time of 121 °C is 1-60.

Holding time of 134 °C is 1-20.

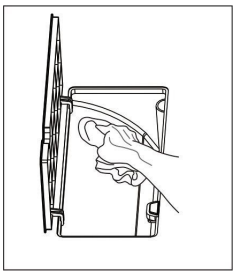
Notice: The default sterilization parameters have been chosen to provide optimal sterilization result. We do not suggestadjusting these parameters unless it is necessary.

7. Maintenance

To assure proper operation and maximum autoclave life, carefully follow all recommendations for periodic maintenance. One of the MOST important steps you can take to prevent problems with your sterilizer is to use ONLY distilled water.

Frequency	Number of cycles	Maintenance operation
Monthly	50	Clean the door seal
		Clean the filter inside the chamber and in the cleanwater tank
		Clean the chamber the trays and the rack
		Clean the external surface
Every 3 months	200	Clean the distilled water tank
Every year	800	Replace the door seal

7.1 Clean the distilled water tank



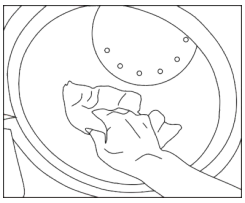
Disconnect the main cable.

Drain the tank completely using the drain tube and leave it connected into the connector in aopen position.

Clean the internal surface with a soft sponge and a small soft brush for the areas that are difficult to reach using and a mild soap.

Remove the filter and clean it with a small soft brush and mild soap, rinse it with distilled water and put it back in to the position.

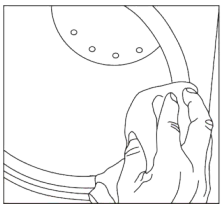
7.2 Clean Chamber, door seal, trays and tray Rack.

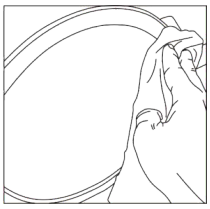


Remove the trays and tray rack from the chamber. Clean trays, rack and inside of chamber with mild soap.

Rinse the trays, rack and inside of chamber with a smooth cloth and distilled water. Examine door seal for possible damage.

Clean door seal and mating surfaces with a damp cloth.

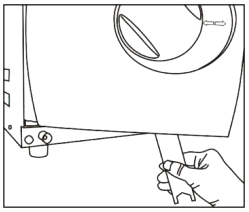




Note: Do not use bleaching agents or any abrasive materials / substances in chamber. Failure to comply may result in damage to the chamber and/or other components.

Caution: To prevent burns, let unit to cool before cleaning gaskets andtouch the surface.

7.3 Door adjustment

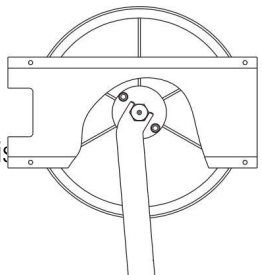


Under normal circumstances the chamber door does not require adjustments. However, you mayuse the spanner tool to tighten the door seal if the seal fails (resulting in steam leaking from the front of the chamber).

Open the door.

Insert the spanner tool in the gap beneath the plastic cover; use the spanner to grip the adjustingnut.

Turn the nut counter clockwise as the figure below. This will tighten the sealing plate.



Turn the nut until the sealing plate is tight. If the door knob is too tight, you may also turn the nutclockwis

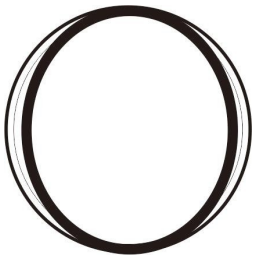
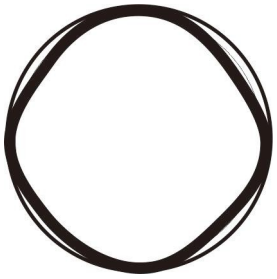
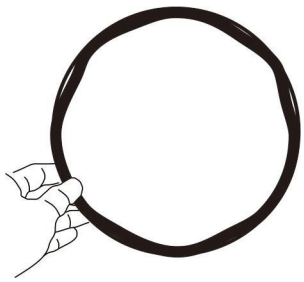
loosen it.

Caution: Never adjust the chamber door while the door is closed.

7.4 Replacement of the door seal

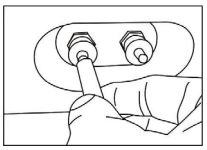
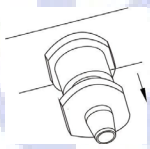
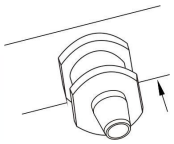
Open the chamber door. Remove the door seal ring carefully by hand. Clean the door seal ring carefully with a smooth cloth with distilled water.Moisten the new seal with distilled water.

Insert the new seal and Tap in sequence as follows:

		
1) Press in the top and bottom of the door seal.	2) Press in the left and right sides of the door seal.	3) Press the remaining sections of the seal.

Caution: Please ensure the chamber and the door are cooled prior to replacing the seal ring.

7.5 The drain valve

		
1.Press the included hose on to the drain valve firmly.	2.Pull the drain valve outward to drain the tank.	3. Push the drain valve back after draining the tank.

8. Error codes

Code	Description	Proposed solution
E1	Steam generator temperature sensor error	Power off & run a new cycle Contact your supplier if error persists.
E2	Inner temperature sensor error	Power off & run a new cycle Contact your supplier if error persists.
E3	Temperature sensor of the chamber wall error	Carefully ensure that the chamber wall is heated and contact your supplier
E5	Fail to release the pressure	Power off & run a new cycle Contact your supplier if error persists.
E6	Door lock problem during the cycle	Make sure you had closed the door properly. check the door switch
E9	Failure to hold temperature	Ensure the distilled tank isn't empty. Check the inner temperature sensor. Check somewhere for leaking.
E11	Failure to preheat the steam generator	Power off & run a new cycle Contact your supplier if error persists.
E12	Failure to preheat the chamber	Power off & run a new cycle Contact your supplier if error persists.
E20	Program manually interrupted	Shut off the power and restart the power.
E21	Failure to reach the holding time. (sterilization time)	Check somewhere leaking inside the autoclave. Contact your supplier if error persist
E24	It takes too long time to enter the next status.	Check somewhere leaking. Or contact your supplier if error persists.
E28	The pressure is overload.	Power off and contact your supplier if error persists.
E34	The pressure is higher than 30kPa during drying.	The solenoid valves are blocked.

9. Transportation and storage

9.1 Switch off the sterilizer before transportation or storage.

9.2 Pull out the plug. Let the machine cool down.

9.3 Drain the distilled water tank and the used water tank.

Condition for transport and storage

Temperature: -20°C ~ +50°C

Relative humidity: ≤ 85%

Atmospheric pressure: 50kPa~ 106kPa.

10. Safety devices

1. Main fuses: Protection the instrument against possible failures of the heating resistor.

Action: Interruption of the electric power supply.

2. Thermal cutouts on the main transformer winding: protection against possible short circuit and main transformer primary winding overheating

Action: Temporary interruption of winding.

3. Safety valve: Protection against possible sterilization chamber over-pressure.

Action: Release of the steam and restoration of the safety pressure.

4. Safety micro-switch for the door status: Comparison for the correct closing position of the door.

Action: Signal of the wrong position of the door

5. Thermostat on chamber heating resistors: Protection for possible over heating of the chamber heating resistors.

Action: Interruption of the power supply of the chamber resistors.

6. Thermostat on steam generator heating resistors: Protection for possible overheating of the steam generator heating resistors.

Action: Interruption of the power supply of the steam generator resistors.

7. Door safety lock: Protection against accidental opening of the door.

Action: Impediment of the accidental opening if the door during the program.

8. Self-leveling hydraulic system: Hydraulic system for the natural pressure leveling in case of manual cycle interruption, alarm or black-out.

Action: Automatic restoration of the atmospheric pressure inside chamber.

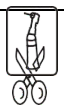
Appendix 1

Water properties / Characteristics

Description	Feed water	Condensate
Evaporate residue	≤ 10mg/ l	≤ 1.0mg/kg
Silicium oxide sio2	≤ 1mg/ l	≤ 1.0mg/kg
Iron	≤ 0.2mg/ l	≤ 0.1mg/kg
Cadmiun	≤ 0.005mg/ l	≤ 0.05mg/kg
Lead	≤ 0.05mg/ l	≤ 0.1mg/kg
Rest of heavy metals	≤ 0.1mg/ l	≤ 0.1mg/kg
Chloride	≤ 2mg/ l	≤ 0.1mg/kg
Phosphates	≤ 0.5 mg/ l	≤ 0.1mg/kg
Conductivity	≤ 15µs /cm	≤ 3 µs /cm
PH Value	5 – 7.5	5-7
Appearance	Colorless, clean	Colorless, clean
Hardness	0.02 mmol/ l	0.02 mmol/ l

Appendix 2

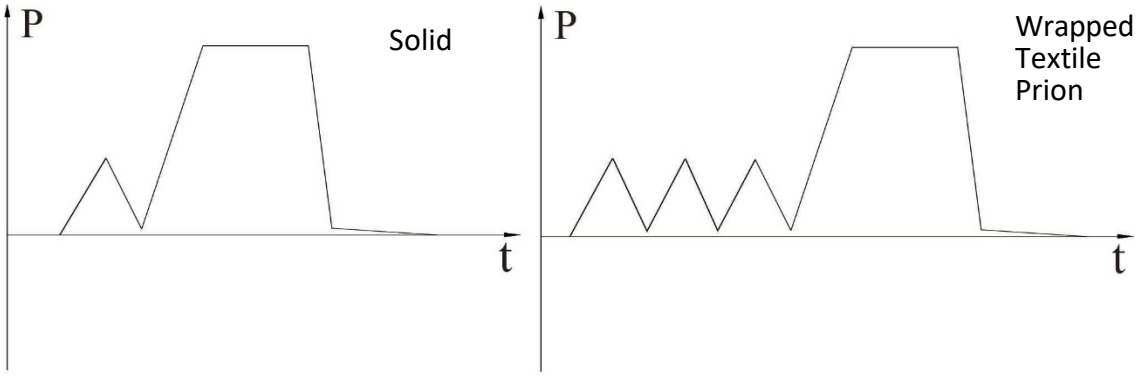
Diagrams of the sterilization programs

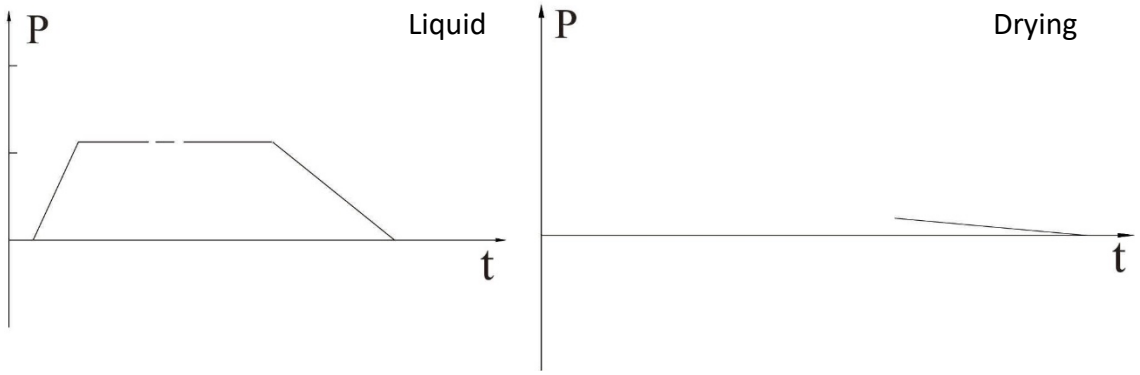
Programs	Temperature (°C)	Pressure (kPa)	Holding time (min)	Total time (min)	Type	Max load (kg)	Max load per tray (kg)
 SOLID	134	210	4	15-25	Unwrapped solid material	4.00	1.20
	121	110	20	25-35			
WRAPPED 	134	210	4	20-30	Unwrapped solid material	3.50	1.10
	121	110	20	30-40	Single-wrapped solid or hollow material	3.50	1.10
TEXTILE	134	210	8	24-34	Unwrapped porous material	1.00	0.30
					Single-wrapped porous material	0.75	0.20
	121	110	30	40-50	Dual-wrapped porous material	0.50	0.15
					Single-wrapped hollow material	3.50	1.00
					Dual-wrapped solid and hollow material	1.50	0.50
 PRION	134	210	18	34-44	Unwrapped porous material	1.00	0.30
					Single-wrapped porous material	0.75	0.20
					Dual-wrapped porous material	0.50	0.15
					Single-wrapped hollow material	3.50	1.00
					Dual-wrapped solid and hollow material	1.50	0.50
 LIQUID (Optional)	134	210	10	30-40	Liquid	1.00	0.30
	121	110	30	45-55			
Drying (Optional)	—	—	—	1-20	—	—	—

The time required for sterilizer to be ready for routine use after the power is switched is less than 5minutes.

The max. Temperature of the 134°C sterilization cycle is 137°CThe max.

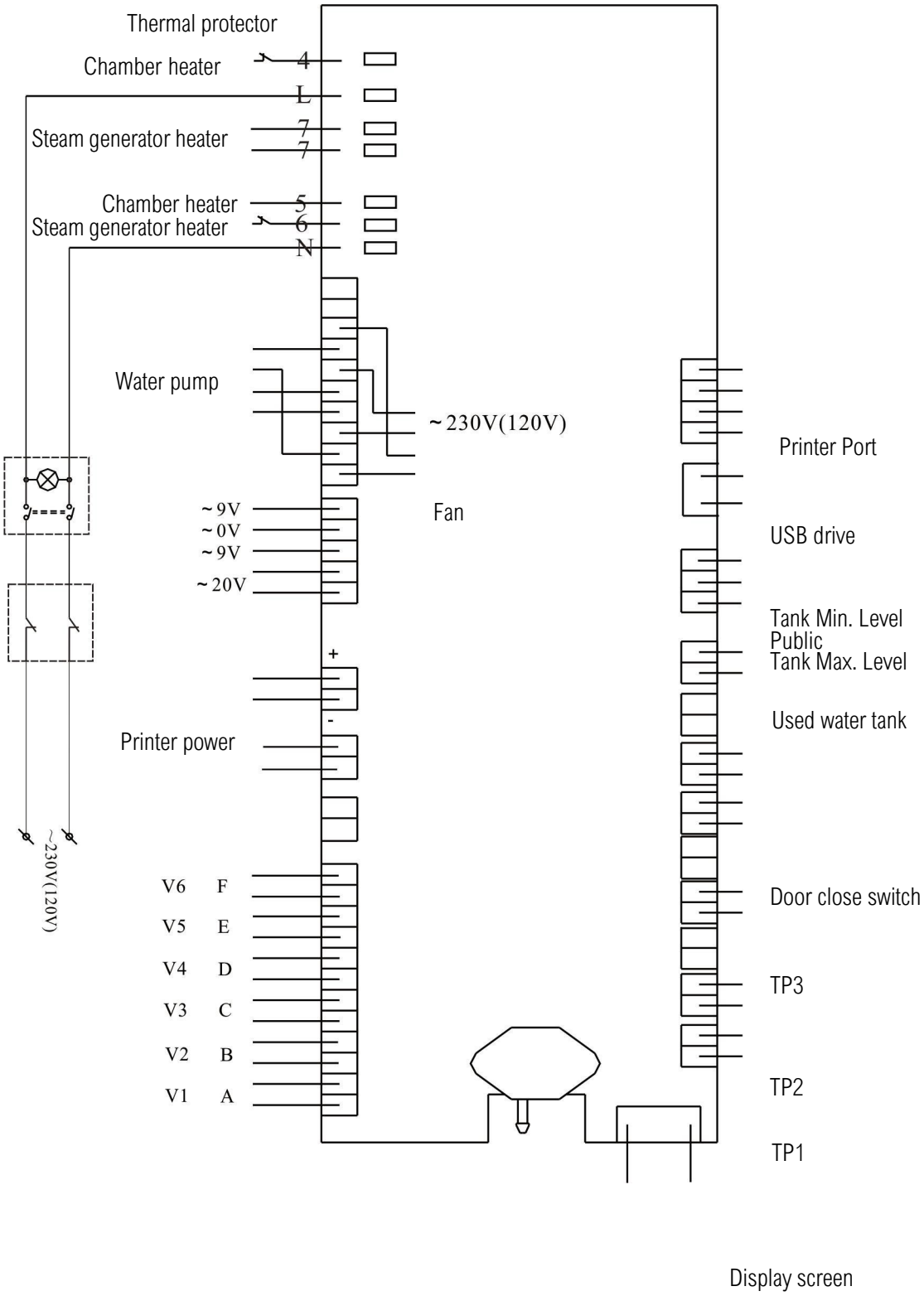
Temperature of the 121°C sterilization cycle is 124°C


P
Solid
t
P
Wrapped
Textile
Prion
t


P
Liquid
t
P
Drying
t

Appendix 3

Wiring diagram



TP1: Steam generator temperature sensor

TP2: Inner temperature sensor 1

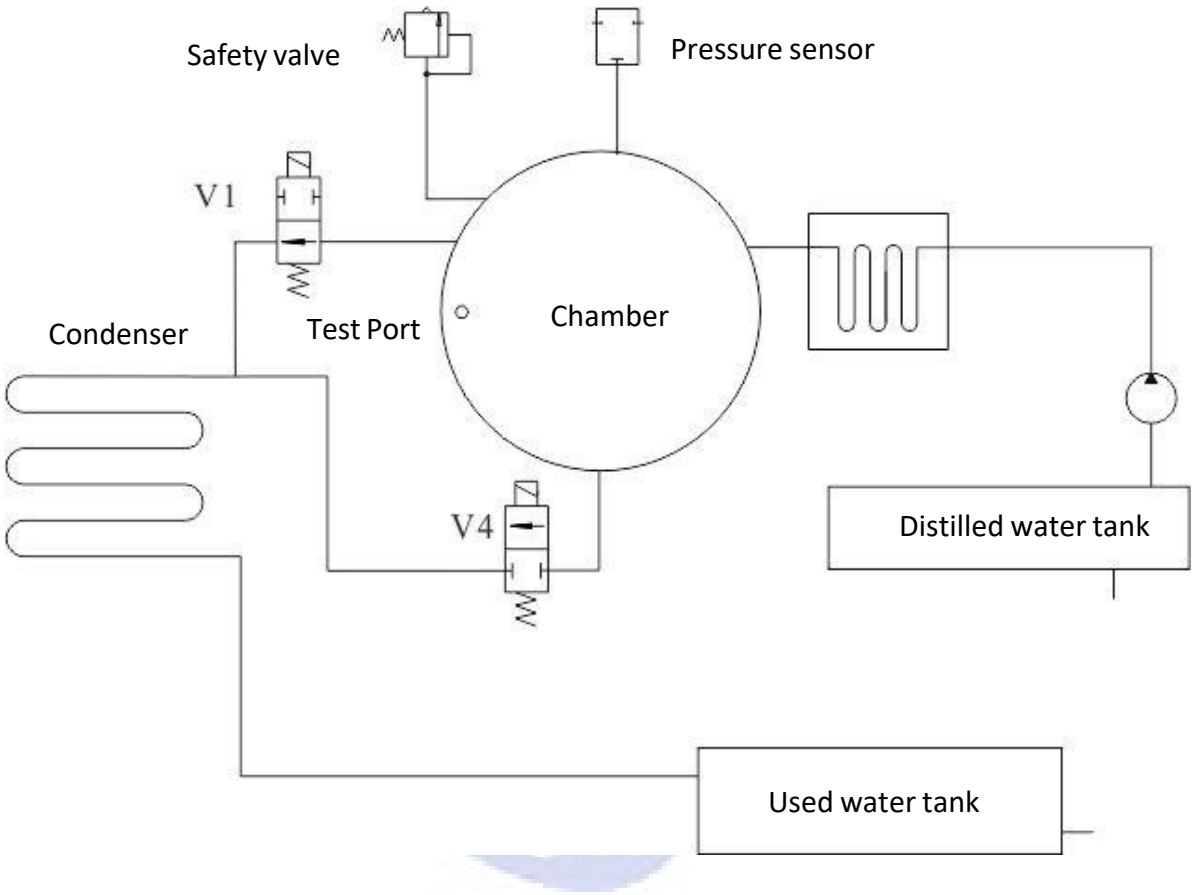
TP3: Temperature sensor of chamber wallV1:

Air release valve

V4: Water release valve

Appendix 4

Hydraulic diagram



V1: Air release valve V4:
Water release valve