



Vacuum Sterilizer
Elite Premium B

Autoclave

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Dear Customer

We thank you for your selectivity and trust in purchasing domestically produced products, and we are pleased that after continuous efforts, we have been able to manufacture Autoclave device and put it at your disposal.

This product has been designed by our technical and engineering team of experienced and committed people in the fields of mechanical, electronics and computer engineering, and by utilizing updated technology and building upon 25 years of experience in manufacturing dental equipment, this product has reached production of export index quality.

In designing the product, three principles of accuracy, reliability and safety performance and also user friendly have been considered, so in order to correctly and completely utilize product features, we ask you to read the instruction manual carefully and if you have any questions or you need more information, contact the after-sales unit.

The instruction manual is a comprehensive reference for the efficient and safe use of the product. Following the instructions of this manual has a great role in reducing consumable costs, avoiding risks and ultimately increasing product life. The instruction manual should always be kept near the product and the user should periodically read it.

Please impart us with your constructive guidance, so that we can benefit from your comments, recommendations, and gain knowledge about your needs.

**We hope that you will find using Elite Premium to be an enjoyable and successful experience,
Polaris Engineering and Manufacturing**



Introduction

(1-1) How to use the manual

This manual presents the instructions about use, installation, and maintenance of Autoclave made by Polaris Co. It should be noted that:

- The product should be used according to the instructions of this manual. Thus, all parts of it should be read carefully before starting and installing the tool. Special attention should be paid to the highlighted parts. (refer to section 2-1).
- Observing the instructions of the manual assures the health and safe operation of the tool.
- Manual is an integral part of the product. Thus, it should always come with the product and should be used optimally as a reference for use during the operation of the product. It should be available even during the sale of the product, or even when it is not used.
- In case of losing or damaging the manual, get a replacement one from the after-sales service department of Polaris Co.

The following are explained in detail in this manual:

- Installation and start up of the product
- Operation details of the product and its parts
- Maintenance condition
- Primary safety and preventive details

(1-2) Terminology and signs

Knowledge of signs meanings is of great importance. A list of signs has been introduced in the following for initial recognition and reference to them if necessary.



Danger!

Indicates compulsory warnings.



Warning!

Indicates functional recommendations.



Forbidden!

Indicates forbidden activities.



Caution!

Refers to user instructions of the tool.



Type B device



Read the manual



General Information

(2-1) Company liabilities

Polaris Co. is not liable for any problem involving the following: Failure to follow the instructions of this manual (incorrect use of the product), repair by an unauthorized person and part replacement without coordination with the after-sales service department, failure due to power fluctuations.

(2-2) Guarantee

Guarantee of this product includes repairs, supply, and replacement. If used appropriately, Polaris Co, the guarantee covers all main parts of the device for 18 month.

Following cases and parts are not covered by guarantee:



- power fluctuations
- incorrect transportation of device
- inappropriate and frequent use of device despite having obvious flaws
- not observing the maintenance instructions
- power cable
- any repair or replacement by unauthorized persons.
- main and display keys



Commutation fees of company representatives to install or repair during guarantee period will be received from buyer at site.



The device can't be used before installation and insurance of correct operation of protective parts.



It is highly recommended that user has a general knowledge of this manual before using this device. The cases which appear to be operation flaws in the device should be registered by user and they should be sent to the after-sale service department.

General Information

- Authorized representatives of Polaris Co.
These persons are endorsed by the company to work on the device under any operational circumstances. They are also authorized to do any electrical and mechanical adjustment/repair, maintenance program and authorized parts replacement.



Product Introduction

(3-1) General Introduction of the Autoclave Device

What is an Autoclave?

Generally speaking, an autoclave is a device with a steam container used from sterilizing laboratory or hospital materials and equipment. Autoclave is used for medical, dental, medicinal, food industries, microbial environments culture and veterinary medicine purposes etc.

Autoclave is an important device in treatment centers for sterilizing necessary equipment used in surgery. Performing a safe surgery, producing a medicine or culturing a microbial environment requires a proper autoclave.

(3-1-1) Classification of Autoclaves based on Steam Tank Availability

The autoclave works with water steam and the steam sterilizes the content inside the device such as pegs, gloves or other contaminated items at high temperature (121 – 134 °C) under pressure (2.3 – 3.2 Bar). Therefore the autoclave can be classified into two groups based on the steam factor:

A- Steam supplied from an exterior source (central steam)

B- Steam supplied from the steam generator of the autoclave, which can be provided using a series of electrical elements floating inside a water tank or through a gas-operated steam source generated through a gas torch put in front of the water tank.

Autoclave is manufactured in various types for laboratories, hospitals and dental clinics in cylindrical or cube shapes, vertically or horizontally, with one or two doors. They may be used based on the designated application.

(3-1-2) Classification of Autoclaves based on Geometry and Volume

Autoclave may be classified based on geometry and volume in the three following classes:

- 1- Vertical autoclave (laboratory autoclave)
- 2- Horizontal autoclave (gravity autoclave, pre-vacuum autoclave, pulsomatic autoclave) or hospital autoclave
- 3- Desktop autoclave (dentistry autoclave)

(3-1-3) Classification of Dental Autoclaves

Autoclaves can be classified in the field of dentistry regarding their application range (and method of sterilization) into three general classes:

N Type: for sterilizing unwrapped solid loads.

S Type: for sterilizing unwrapped solid loads and other loads recommended by the manufacturer. Please note that this type of autoclave is not capable of sterilizing every type of load (those special for B type autoclaves).

B Type: for sterilizing wrapped metal loads, unwrapped metal loads, wrapped hollow loads, unwrapped hollow loads, porous and cloth loads.

(3-1-4) General Components of an Autoclave Device

An autoclave (sterilizer) may be constructed with the following parts. Additional or less items may also be available based on the device's application.

Interior tank (chamber), exterior tank (jacket), autoclave door (sonar, pneumatic), steam generator source, elements, vacuum pump, valves (on-way, electrical and pneumatic), relief valve and connectors.

(3-2) Introduction of Elite Premium Dental Autoclave



Picture 1 – Elite Premium Dental Autoclave

Elite Premium is a B type dental autoclave and a new generation of sterilizers which provides an extensive range of application and assures a high performance authenticity by using the vacuum environment technology and steam pressure. Five functional programs according to global standards along with advanced hardware provides the capability of sterilizing all surgery equipment (metal or non-metal), clinical cloths and gowns, operating room equipment and items, injection systems etc. Considering the high importance and sensitivity of this product and in addition to national standard instructions 4860 and 4863 throughout all design and manufacture stages, all production stages are performed according to CE Europe, EN 13060 and ISO 13485 standards.

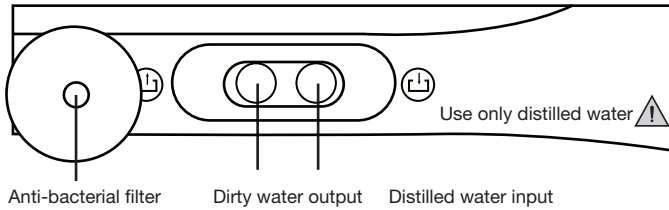
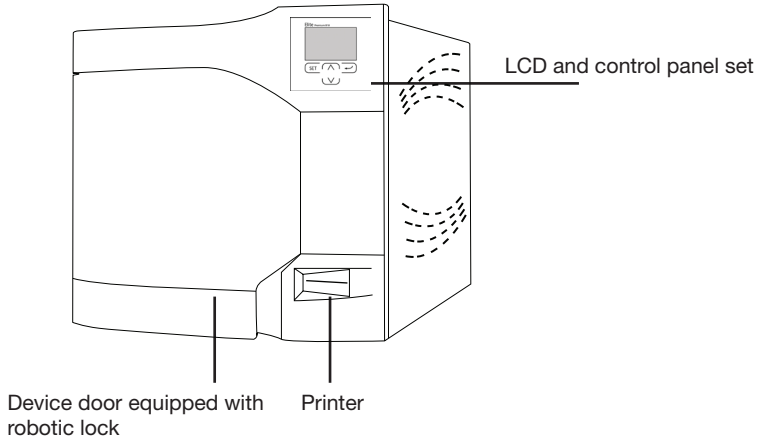
(3-2-1) Device Specifications

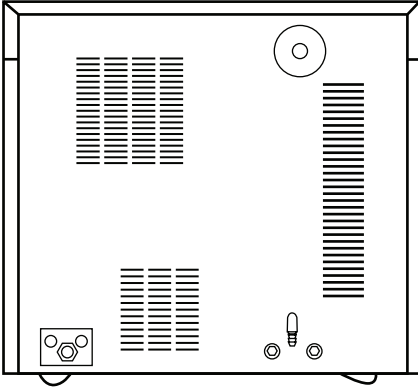
- Equipped with procedure performance authenticity assessment system
- Equipped with mechanical controllers (relief valve) and electronic controllers for the pressure (with feedback from the pressure sensor) to assure maximum performance safety
- Equipped with water level controller and warning system
- Equipped with five fixed programs and two user-adjusted programs

- Equipped with heat and pressure calibration system
- Equipped with a robotic lock system with a uniform appearance
- Equipped with an integrated tank made out of stainless steel
- Equipped with two water outlet and inlet valves on the front and back of the device
- Equipped with a printer installed on the device for printing the sterilization process details
- Equipped with a timer and time recorder for extracting time-based information and details from the total sterilization process
- Equipped with an LCD monitor
- Equipped with a relief valve to assure maximum safety
- Easy application
- Equipped with an active drain system for the dirty water tank in both manual and automatic modes
- Can be manufactured in 18 to 24 liter capacities (made to order capacity)
- Resistant against explosion
- Having temperature adjustment, pressure, hydrostatic test and sterilization process quality control certificates with biologic standard indicators (ISO 11138 standard) and chemical and Bowie & Dick test certificates (ISO 11140 standard)
- Equipped with air micro filters for putting clean air into the chamber
- Equipped with an automatic electrical pump for water supply

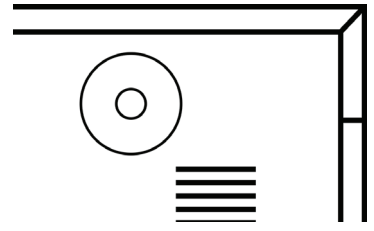
into the clean water tank
•Manual water supply option

(3-2-2) Description of the Main Components of the Device

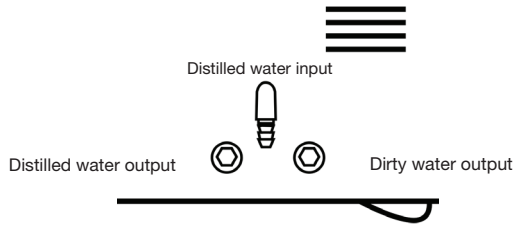
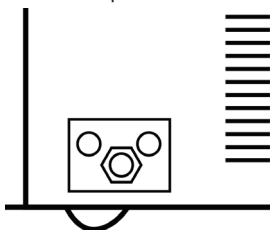




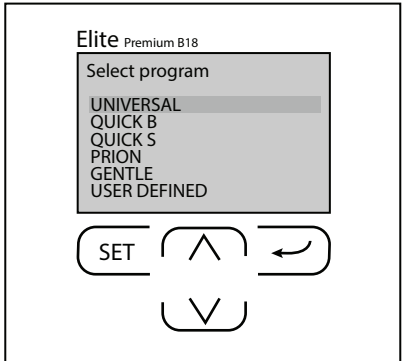
Output current guiding canal from relief valve



Fuses and power cables



(3-2-3) Description of Device Panel



FF: FRESH FULL
 FE: FRESH EMPTY
 WF: WASTE FULL

Enter
 Setting
 Down
 Up

(3-2-4) Technical Specifications

All our products at Polaris Co. are manufactured according to the latest global technology at the highest quality. We use the latest design and production methods to increase the lifespan of our products and to improve our quality.

Size	B18: 475 × 475 × 465 mm B24: 475 × 705 × 465 mm
Sterile tank volume	B18: 18 liters B24: 24 liters
Functional temperature	121 and 134 `C
Net weight	B18: 53 kg B24: 57 kg
Power source	210-240 V AC – 50.60 Hertz
Maximum power consumption	1800 Watts
Vacuum pump	Compatible with urban electricity 210-240 V AC – 50.60 Hertz
200 Watts power	0.5 mg /l
Vacuum pump	Compatible with urban electricity 240-210 V AC – 50.60 Hertz 200 Watts power Capable of creating vacuum at 850- millibar
Fuse	15 ampere

Table 1 Technical Specifications of the Autoclave

(3-2-5) Auxiliary Equipment

Part	Units
Water flask	1
Hose (attached to flask)	1
Tray	3
Manual	1
Fuse	2
Automatic water connection hose	1
Dirty water connection hose	1
Tray handle	1
O-ring	2
Printer paper	1
Hose head	1
Tray holder handle	1
Tray holder	1

Table 2 List of Auxiliary Equipment of the Device



**Transportation and
installation**

In order to avoid accidents, it is really important to follow the following instructions during the installation and fixing of equipment. All steps are explained in detail:

(4-1) Unboxing

Having received the device, make sure that the main box is sealed and intact. Otherwise, inform the after-sales service department of Polaris Co, or its authorized representatives.

(4-2) How to move the device

The device should be moved as follows:

- 1 Unplug it from the power source
- 2 The device should remain in a vertical position during movement. For more safety and prevention of any injury due to neglecting the technical details, refer to section 4-1.



Failure to follow the aforementioned instructions results in device being damaged, and Polaris Co, won't be held liable.

(4-3) environmental circumstances

It is important to choose an appropriate environment during installation and operation for personal safety, correct operation and long lifetime.

Workplace temperature: 0-28°C

Maximum humidity: 50%

the distance between the device and the wall is supposed to be at least 20cm from each side.



The device should not be used in a place where there is danger of explosion or firing

The light of the place should be high enough so that all parts of the device can be seen clearly.



The device should never be exposed directly to sunlight or humidity of rain, etc.



The grid single-phase electricity should match the power supply specifications of device.

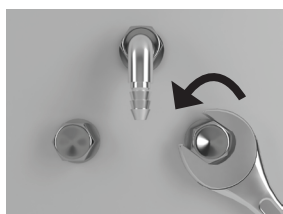
(4-4) device installation

1. Make sure that the device is put on a flat and level surface.
2. Water loading and device draining:

Automatic mode:

When clean and dirty water connectors are connected on the back of the device, the device will automatically perform the water loading and draining duties using the onboard electrical pumps (picture 6).

In order to permanently connect the device to the distilled water tank, put the device in a place close to the tank. Connect the distilled water tank with a hose to the clean water input on the back of the device and then push the down button. The pump will work for 3 minutes and in case distilled water is required to remove the FE alarm, push the down button again.



Manual mode:

In case you do not wish to connect the device permanently to the distilled water and drainage tanks, you can use a flask and connection hose for manual water loading and draining. Please note that you will need to use the water input on the front of the device.

For loading the device, fill the flask with distilled water. After connecting the flask hose to the clean water input on the front of the device, place the flask on the top of the device. For draining dirty water after connecting the empty flask hose to the drainage on the front of the device, place the flask on a surface lower than the device.



The minimum water required for a full cycle is 600 cc.



The quality of the distilled water used should be according to table 3.

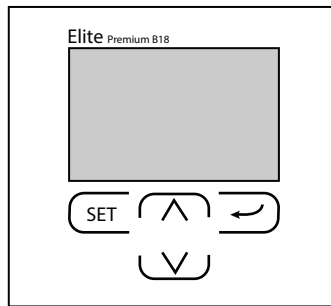
Engineering Parameter	Maximum Possible Level for Water Loaded into the Device
Silicon dioxide	1 mg /l
Iron	0.2 mg /l
Cadmium	0.005 mg /l
Lead	0.05 mg /l
Heavy metals	0.1 mg /l
Chlorine	2 mg /l
Phosphate	0.5 mg /l
Transfer coefficient at 20 °C	15µS
Evaporation residue	10 mg /l
PH	5/7-5
Appearance	Colorless, clean, without Sodium
Hardness	0.02 mmol/l

Table 3 Quality of Distilled Water Used



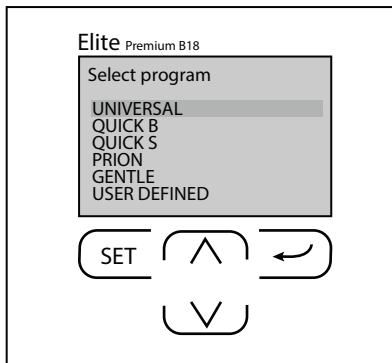
Production application

Press Power to turn the device on. The following will be displayed on the monitor. The device is now ready to use and you may open the door and insert the items.



Picture 8 – Device Monitor

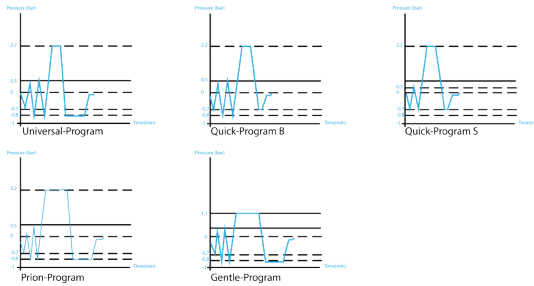
You can enter the program selection menu or settings by pressing Set. Programs can be chosen by using the up and down buttons. The program title will change color when selected and you can enter into the program by pressing Enter.



Picture 9 – Device Monitor

(5-1) Application Programs

Five functional programs according to national standards 4860 and 4863 and EN 13060 are capable of sterilizing all loads with complex or porous shapes (made out of metal, polymers which are capable of sterilization and medical cloths). Please fully read the following instructions before using the device and select the proper program according to load type:



Program Title	Sterilization Temperature (°C)	Holding Time (Minutes)	Sterilization Pressure (Absolute, BAR)	Load Type	Drying Time (Minutes)	Authorized Weight
Universal	134	5.5	3.2	Only wrapped items (single or multi layered)	20	5 kg
Quick B	134	5.5	3.2	Only unwrapped or single layered wrapped items	10	5 kg unwrapped or 1.5 kg wrapped
Quick S	134	5.5	3.2	Only unwrapped items	5	5 kg
Gentle	121	20.5	2.2	Only fabrics and wrapped plastics (single or multi layered)	22.5	1.8 kg paper and fabrics or 5 kg heat-sensible items

Production application

Prion	134	20.5	3.2	Only singled layered or multi layered tools, suspected of contamination with dangerous diseases such as Hepatitis, Bovine Spongiform Encephalopathy and AIDS, porous surgery tools with protein-based contamination is already removed.	20	5 kg
Bowie & Dick	-	-	-	Indicator	-	-
Vacuum Test	-	-	-	Without tool	-	-

Bowie & Dick Program:

This program is for assessing steam penetration level. It is strongly recommended to run this program every day before using the device and check the integrity of the device's performance by studying the related indicator.

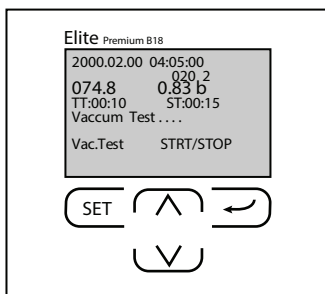
If the indicator color change is not proper, you may not use the device. You should immediately contact the after sale services department of the company under this circumstance.



If you wish to test the steam penetration indicator with other cycles, please remember that this test is only for cycles that are designed for porous or multi-layered wrapped items which include Universal, Prion and Gentle programs. You may only include unwrapped or thin single layered wrapped items in Quick B and Quick S programs. Such loads do not require a high level of steam penetration. Therefore do not include the steam penetration indicator for these programs.

Vacuum Test:

You can perform a vacuum test by selecting it from the menu. The result will be shown at the end on the screen and a report will be printed. If Vacuum OK! is shown, the vacuum creation inside the chamber works properly.



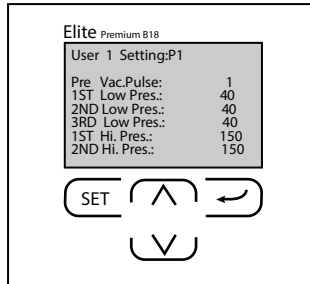
Picture 11



The Vacuum Test program is for testing the performance of the device when creating the required vacuum level. When Vacuum Error is shown on the monitor, first empty the container from any loads and then run the Vacuum Test program. If there are any problems with the vacuum level the device will show an error and you should stop using the device immediately and contact the after sale services department of the company.

(5-2) Defining New Programs

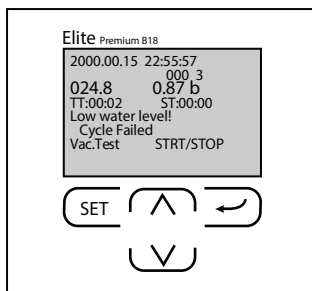
Adjusting desired programs: First enter the program menu by placing Set and then put the indicator on either User 1 or User 2 and press Set again. You can choose your desired parameter by pressing up or down and enter your desired value by pressing Set again, using the up and down buttons. You can enter the value by pressing Set and then choose another parameter by pressing up or down. To save your program press Enter.



Picture 12

Notes on Selecting and Running a Program:

1. If the door of the device is open and you choose and select a program (by pressing Enter), Door is Open! Will be shown on the monitor and the program will not run until the door is closed.



Picture 13

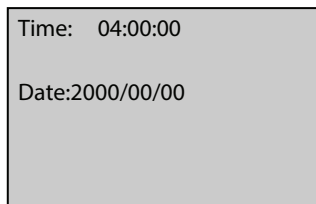
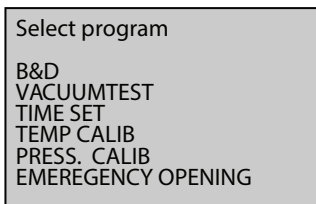
2. If the water inside the tank is low and you choose and select a program (by pressing Enter), Water Level Low will be shown on the monitor and unless at least liters of water is not added to the tank the program will not run.

To stop a running program use the Enter key on the main page of the program.

Note: If you press Set when a program is running the device will go back to the program selection menu and if another program is selected using the Enter button then the title of the new program will be shown on the screen but the program will not run and the program that is already running will not stop. In other words the same previous program will keep on running unless it is stopped manually using the Enter key as described before.

(5-3) Time and Date Adjustment

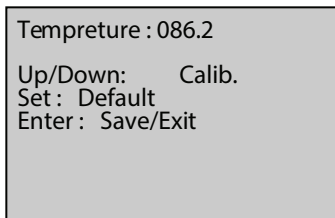
First press Set to enter the program selection screen and then put the indicator on TIME SET and press Set. You can change the location of the marker in the time menu using the up and down keys and change the value by pressing Set and highlighting the parameter and enter the new value using Set. Pressing Enter will save the adjustments.



Picture 14

(5-4) Temperature and Pressure Calibration

You can press Set and use Temp Calib or Press Calib options from the program menu for temperature and pressure calibration adjustments.



Picture 15

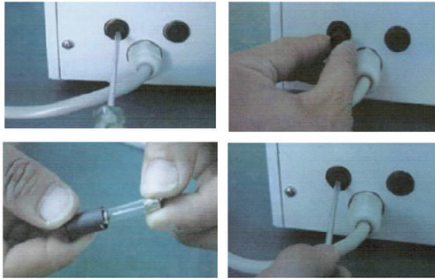
Never change or adjust menu 4-5. This is only for experts. If changed, please contact company experts.

(5-5) Emergency Door Opening Key

For opening the door under emergency circumstances when the door will not open for any reason or in case of mistake by operator.

(5-5) Fuse Replacement

Proceed as shown in Picture 16:



Picture 16



Safety

(6-1) general safety

The user should fully read the recommendations and warnings in this section and must follow them at all times. Following these instructions guarantee the fault-free performance of the device in long-term.

Never use a faulty or defective device.

- Only users that have fully read the manual may use the device.
- The working environment should be clean, free of any obstructions and fully lighted.
- In case any defects are observed in the performance of the device please immediately stop using it and unplug the device from power and contact the after sale services department of the company and report the issue.
- Do not open the electrical and pneumatic parts of the device.
- Never replace the power supply or other parts directly connected to the plug.
- The device should never be used for purposes other than those defined for it.
- Never use gasoline or flammable solvents as cleaning agent. Always use non-flammable, non-corrosion and non-toxic agents.

(6-2) Safety Measures of the device

To improve safety, Polaris Co. always uses raw materials with guaranteed long-term quality through advanced production procedures.

The quality control process and carried out in three stages for entering items, middle control and final control through multiple checkpoints to minimize the chance of error or defect of the device.

Please remember that items such as the protective door on the device and the arm and also the automatic door lock along with multiple electronic controllers are all parts of the safety modules of the device.

In order to assure maximum safety, steam pressure is checked electronically in real time. Also there is a standard and calibrated relief valve to control the pressure mechanically.



Maintenance

(7-1) Clean-Up

Clean the body of the device with a dry cloth. If needed, you may dampen the cloth with a small dose of water or a non-fat solvent (only for the body).

The user should always keep the device clean and free from dirt, water or other unnoticed solvents.

If the device is not being used, make sure to drain the distilled and dirty water inside the device.

Never use flammable, corrosive, alkali or toxic solvents for cleaning the device.

(7-2) periodic maintenance

Periodical inspection and cleaning of the device should be performed based on the device's usage. It is recommended for the user to state the amount of application and usage of the device after installation to the company experts and ask for the proper time for periodical inspection and cleaning of the device. If during periodical inspections some parts of the device are found to be worn out or damaged, the user should be able to recognize them and contact the after sale services department of the company for obligatory maintenance and service.

Periodical services are performed by the company at the discretion of the user. A maximum time interval of 12 months is recommended for periodical maintenance and repair.

If the user finds any defects or issues with the device, the user should install a warning sign on the device to indicate it being under repair and maintenance and that the device should not be used (EC warning signs may be purchased through related shops).

Cleaning, periodical maintenance and proper use of the device are some of factors and affect and guarantee the life and safety of the device.

In case of defect, the device should never be put to use

before the defect is resolved.

Do not present the device to unauthorized repairers without the approval of the company.

Reminder

Dear user, please remember to put the device to rest for 15 to 30 minutes after each working cycle and then start using the device again. If the device will not be used for more than 72 hours for any reason, it is recommended to drain the clean and dirty water tanks of the device.

Important Recommendation:

Always use the indicators for observing the quality of the sterilization and also the steam penetration test devices as indicators for determining the quality of the sterilization. Otherwise the sterilization quality determination shall be the responsibility of the buyer.

Reminder:

In case of sudden power outage when the device is running a program, the door of the device will open only when the interior pressure is the same as the environmental pressure and the temperature of the device falls below 100` C.

(7-3) Technical Maintenance Issues (Device Troubleshooting)

The device software is designed in a way that shows an error message in case there are defects in the performance of the device. The error is shown as a description (rather than a code) which facilitates its understanding by the user without referring back to the manual.

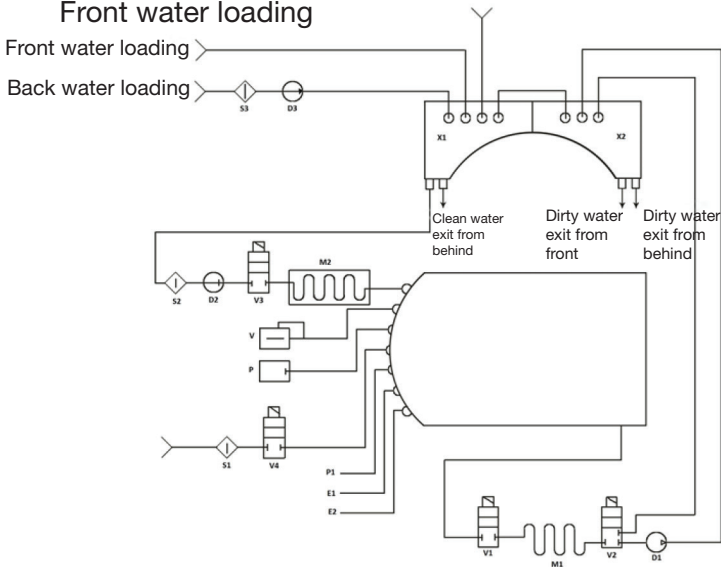
Row	Message (Error)	Status	Solution
1	Door is open!	Door is open.	Close the door.
2	Door lock error!	Door is not locked.	Open the door and close it again.
3	Low water level!	Distilled water tank is near empty.	Run water loading operation.
4	High waste water!	Dirty water tank is full.	Run water draining operation.
5	Check steam sensor	Steam sensor is defected.	Call the after sale services department of the company.
6	Check inside sensor!	Steam temperature sensor inside the chamber is defected.	Call the after sale services department of the company.
7	Check wall sensor!	Body temperature sensor inside the chamber is defected.	Call the after sale services department of the company.
8	Vacuum error!	Device is not successful with creating ideal vacuum level.	Run the Vacuum test cycle. If it is not completed successfully, call the after sale services department of the company.
9	Temperature error!	Temperature is not increasing.	Call the after sale services department of the company.
10	Steam Pressure Error!	Pressure is not rising in proportion to the temperature.	Call the after sale services department of the company.

11	Power Failure Error!	Power was lost during the previous cycle.	Run the cycle again after power is supplied.
12	END CYCLE	Work is complete or the device is not ready for work yet.	Open the door for 3 seconds and close it.
13	LOW PRESS	Device did not calculate the environmental pressure.	Open the door.
14	X	Selected program is not running.	Press Enter.
15	Thermocouple fail		
16	Chamber fail		
17	steam generator fail		

Attachments

Piping and Connections Blueprint :1 Attachment

Front water loading



Code	Description	Code	Description
V1	Vacuum valve (pre radiator)	P	Pressure sensor
V2	Vacuum valve after radiator	P1	Pressure switch
V3	Steam generator valve (in steam current path)	S1	Air antibacterial filter
V4	Air valve (for completing vacuum in container)	S2	Water filter
D1	Vacuum pump	S3	Water filter
D2	Water pump (from water tank to steam generator)	S4	Lattice filter
D3	Water pump (from exterior distilled water tank to interior water tank)	E1	Test sensors connection port
M1	Radiator (distilling hot steam before entering into the drain tank)	E2	Temperature sensor connection port (PT1000)
M2	Steam generator	X1	Water tank
V	Relief valve connection port	X2	Drainage tank

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