Tek-bal
Tıbbi Cihazlar

STR Series Desktop Steam Sterilizer User Manual

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1. WARRANTY

1.1 WARRANTY

If Tek-Bal Medical Devices Company is used in accordance with the instructions contained in this manual, it guarantees the quality of its equipment according to the conditions pecified in the Warranty Certificate (see section 1.2).

CAUTION: CUSTOMER must fill in all parts on the Warranty Certificate and send it to Tek-Bal Medical Devices.

The warranty period starts on the date of delivery of the device to the customer. This date is confirmed by the sending of the duly filled and signed warranty certificate to the company. In case of dispute, the purchase invoice showing the serial number of the device will be considered valid.

1.2 WARRANTY CERTIFICATE (Copy)

WARRANTY CERTIFICATE Model: Serial Number: Purchase Date: Agency Name: Address: Phone: Fax: **USER INFORMATION** Clinic Name: Address: Professional Operator: Tel / Fax / E-mail: Suggestion:	**EXAMPLE**	**WARRANTY** Tek-Bal Tıbbi Cihazlar San. Tic. Ltd. Şti. offers a one-year warranty provided that the operator uses the device in accordance with the instructions for use. However, Tek-Bal Tıbbi Cihazlar San. Tic. Ltd. Şti. assumes no responsibility for any accident, damage or damage to the device caused by failure to read the manual. These after-sales services will be provided for a fee. Tek-Bal Tıbbi Cihazlar San. Tic. Ltd. Şti. Address: M.Dokumacılar Sitesi No:36 Maltepe-Zeytinburnu-Istanbul-Turkey Tel: +90 212 482 27 34 / 482 27 34 Pbx. Fax: +90 212 482 33 86 E-mail: info@tek-bal.com www.tek-bal.com

2. INTRODUCTION

2.1 REFERENCE STANDARDS

STR Series Steam Sterilizers
The saturated steam sterilizer complies with the basic requirements of the Council Directives:
14/06/93 Medical Devices 93/42/EEC, class IIB - CE – 2195.
It complies with national standards in its harmonized versions:
EN 13060, EN 61010-1, EN 61010-2-040, EN 61326, EN ISO 14971.

Steam Generator
It complies with the basic requirements of the Council Directives:
29/05/1997 basınçlı kaplar 2014/68/EU - Kategori II-D1- C E 2413.
The steam generator is also suitable for the following standards: **EN 13445:2002.**

2.2 STAFF REQUIREMENTS

Authorized person using the equipment must comply with the following requirements:
- A general culture sufficient to understand the contents of this user guide,
- Sufficient information about the machine and installation location,
- Information on health, accident prevention and technical regulations.

The main people who will use the device are listed below:
OPERATOR, is the person who physically uses the device for the purposes for which it was designed.

AUTHORIZED PERSON, is the person or group responsible for the use, regular maintenance and operator training of the device. Authorized person is legally responsible for.

2.3 USE AND STORAGE OF USER GUIDE

This user guide is an integral part of the product and shuold be kept close to the device for quick and easy consultation. This manual contains instructions on the following:

- Correct usage
- Safe and efficient use of the device
- Continuous and regular maintenance

The device must be used according to the procedures contained in this user guide and only for the purpose for which it was designed.
The occupational health and safety regulations in force in the country of use must be observed.
The user guide must be kept in a safe place and easily accessible to personnel. Modifying, removing or rewriting the contents of this manual is prohibited.
Drawings and other documents that come with the device should not be given to third parties. Tek-Bal Medical Devices is the sole owner of these documents and has all rights.
It is strictly prohibited to reproduce, in whole or in part, the photocopy of the texts and illustrations contained in the operating instructions.
Tek-Bal Medical Devices reserves the right to make changes to the user manual and equipment without having to update the previous product and user manuals. The information contained in this document relates to the characteristics of the device described in the section entitled "5.3.1 Rating Plate".
If the device is sold again, it must be delivered with the instruction manual. In such a case, the manufacturer must be informed of the new owner of the device (see section 11.2 “Reselling”).

2.4 READING THE MANUAL: SYMBOLS AND RULES

This user guide contains various symbols and warnings. These symbols are used to draw the attention of readers. Meanings of the symbols are described below:

SYMBOL	DESCRIPTION
	**ABSOLUTELY PROHIBITED** This symbol indicates that the operation is strictly prohibited. Failure to comply with the rules, the operator may be injured or the equipment may be damaged.
	**INFORMATION AND PRECAUTIONS** This symbol represents general instructions and recommendations.
	**IMPORTANT SAFETY INFORMATION** This symbol is used to draw the reader's attention to important issues of operator's safety.

This guide is divided into sections and subsections. The pictures are numbered according to the section number to which they refer. For example: Figure 3.4-1 (Figure 1 of section 3.4).

2.5 OBTAINING A NEW COPY OF THE USER'S GUIDE

In case of loss or damage to the user guide, ask for a new copy from Tek-Bal Medical Devices. When requesting a new copy, the following information must be provided:

- Name and model of the device
- Person and address to which the instruction manual will be sent.

Request new copies to the address below:

Tek-Bal Tıbbi Cihazlar San. Tic. Ltd. Şti.

Adr: M.Dokumacılar Sitesi No:36 Maltepe-Zeytinburnu-Istanbul-Turkey

Tel: +90 212 482 27 34 / 482 27 34 Pbx.

Faks: +90 212 482 33 86

E-mail: info@tek-bal.com

Web: www.tek-bal.com

3. SAFETY

3.1 GENERAL SAFETY WARNINGS

Be sure to read the safety instructions carefully before using the equipment. Failure to follow the instructions may cause accidents or damage the machine.

- Before using the device, operator should be thoroughly understand all the control functions.
- The operator must know how to apply the safety instructions for use of the device.
- The operator should know the meaning of all signs in this user guide and interpret correctly.
- The operator must not operate the device on his own initiative or in applications that are not part of his work.
- Responsible authority is responsible for the vocational training of operators.
- In malfunctions or potentially dangerous situations, operators MUST notify the responsible authority.
- It is strictly forbidden to use or neutralize safety devices.
- Make sure the device is connected to the correct voltage
- Ensure that the device is connected to ground and meets the applicable standards in the country of use.
- Do not remove parts from the device.
- Do not remove the external security protection. If the power supply is connected, the cooling fan will continue to operate even if the device is not in operation. There is a risk of injury for hands. (see section **3.4 "Residual Risks**").
- High voltage inside the device is dangerous.

- If it is not possible to disconnect the power supply, disconnect the power supply from the device. If it is out of sight or away from the person performing the maintenance work, "work in progress" is hanged on the mains breaker after turning the device OFF.
- Keep the area around the device clean and dry.
- Do not use solvents on the label.
- Do not remove the label on the unit. If necessary, request a new label.
- Clean the device with a damp cloth after checking that it is not connected to the power source. Dry the appliance before using it again.
- Do not spill water or any liquid on the device that may cause a short circuit or corrosion of the device.
- Never touch the device with wet hands. If your hands are wet, always follow the necessary precautions for the use of electrical tools.
- The device is not intended for operation in environments where explosive gases or vapors.
- Do not subject the device to excessive mechanical stress, such as impacts or strong vibrations.
- Do not lean towards the front of device or stand in front of the device when the door is open. There is a risk of burns (see section **3.4 Residual Risks**").
- Used water in the drain chamber may contain contaminated residues if not properly sterilized: wear latex gloves when contacting with draining water (see section **6.6 "Reservoirs: Filling and Draining"** and section **"3.4 Residual Risks"**).
- Empty both water tanks before moving the device to another location. Use the drain pipe provided for the drain and follow the instructions (see section **6.6 "Reservoirs: Filling and Draining").**

3.2 INTENDED USE

STR Series Steam Sterilizers: The device is designed and developed for sterilization of equipment that can be steam sterilized at 121 ° C and 134 ° C for medical, dental, veterinary or pediatric operations.

This device is designed for professional use only and should be used only by qualified persons. The device must only be used for its intended purpose.

The manufacturer cannot be held liable for any deterioration, damage or malfunction in case the device is not used properly and the necessary maintenance is not done!

3.3 SECURITY TOOLS

Electrical Safety

DEFINITION	IMPACT
Dual pole thermal safety switch to protect the device against short circuits	Disconnects the main electrical power supply.
Electronic card protection against short circuits: The transformer and all low voltage circuits are self-protected.	It interrupts one or more low voltage circuits.

Thermal Protection

DEFINITION	IMPACT
The electronic board, vacuum pump and vibration pump are protected by a thermostat.	Temporarily interrupts the circuit for cooling.
Thermal protection of the unit: If the device is operated in conditions not within the ambient temperature range, it is blocked.	Due to unsuitable environmental parameters, alarm message and machine operation are prevented.
Mechanical pressure switch in accordance with PED 2014/68 / EU standards, protecting the steam generator against excessive pressure	Deactivation of steam generator heaters.
Resettable safety thermostat to protect the heating resistance of the chamber	Disconnecting the resistors from the power supply.
Safety valve in accordance with PED 2014/68/EU standards, protecting the device against excessive pressures.	Pressure rebalancing and vapor discharge according to safety values.

Mechanical Safety Tools

DEFINITION	IMPACT
Door safety micro switch: the door closes properly.	The message indicating incorrect door position
Door lock micro switch: shows the correct position of the locking system.	The sign indicating that the door is not locked
Door lock: Electromechanical device to prevent accidental opening of the door.	Prevents opening of the door while the device is operating.
Basket extraction tool: It is used to avoid touching the internal parts of the device.	It prevents hands from burning when removing the tray containing the sterilized elements.

Control Tools

DEFINITION	IMPACT
Setting the pressure level: It returns the system to normal pressure during the cycle in the event of manual stop or alarm and / or warning situations.	Automatic pressure balancing in the sterilization chamber.
Fully microprocessor-driven system that evaluates process parameters	If an error occurs during the cycle, the program in progress is stopped immediately and the alarm sounds.
Continuous monitoring of the device: The autoclave components are continuously monitored during the process.	In case of an error, alarm and warning messages are given.

It is forbidden to remove, modify, tamper with, or disable security tools.
Tek-Bal Medical Devices is not liable for accidents, damage or deterioration due to failure to observe the above warning.

Periodically check the safety system (see section 10 "Maintenance").

3.4 RESIDUE RISKS

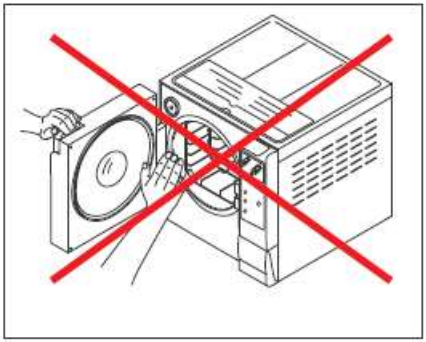
The operator is exposed to certain risks during normal operation that cannot be completely eliminated due to the structure of the device.

-- Burn Hazard

1. When the sterilizer completes the sterilization process and the door is opened to remove the sterilized elements, the interior of the water heater tank and the door are still very hot. Do not touch these parts to avoid burning your hands (Figure 3.4-1). Use the appropriate basket removal tool for this process (see section 3.3 "Security Tools").

2. When the door is opened, do not lean or stand in front of it. There is danger of burning due to hot steam. (Figure 3.4-2).

Resim 3.4-1



Resim 3.4-2

-- Contamination Hazard
Used water in the drain chamber may contain contaminated residues if not properly sterilized: wear latex gloves when contacting with draining water (see section 3.5).

-- Danger of Injury to Hands
If the power supply is connected, the cooling fan will continue to operate even if the device is not in operation (see section 3.5). **Do not remove the external security protection without interrupting the power supply.**

3.5 SAFETY SIGNS ON THE DEVICE

	**CAUTION: If the pressure inside chamber exceeds 3 bar, the safety valve will be activated to discharge the high temperature steam.**
	**CAUTION: Hot surface.**

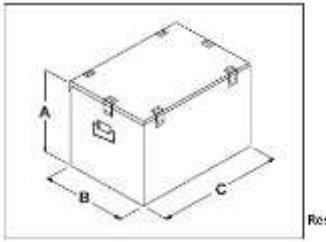
These marks must never be removed, covered or damaged.

3.6 PERSONAL PROTECTIVE EQUIPMENTS (PPE)

Latex safety gloves.

4. MOVING THE MACHINE

4.1 PACKAGE WEIGHT AND SIZE



Resim 4.1-1

Overall dimensions of the package	
A = 560 mm B = 550 mm C = 660 mm	
Total weight of the package	
STR-18	STR-23
50 KG	52 KG

4.2 MOVING THE PACKAGE

When you receive the device, check whether the package is intact (Keep the box for future shipments). Please open the package and check the following:
- The product complies with the technical specifications given (see section 4.3 "Content Description").
- There is no damage on the product.

If you notice any damaged or missing parts, please immediately inform the shipping company, wholesaler or Tek-Bal Medical Devices in details. Place the package as described in section 6.1 "Operating Environment: Positioning". (Picture 6.1-1).

4.3 CONTENT DESCRIPTION

Definition	Details	Piece
STR Series Steam Sterilizer	18 / 23 liters Autoclave	1
Trays	Stainless steel trays	3
Tray Rack	Three-section stainless steel tray rack	1
Tray Holder	Tray removal holder	1
Water Drain Pipe	Transparent PVC pipe with connector	1
Power Cable	1.5 m long power cable with VDE socket	1
User Guide	User Guide	1

4.3.1 OPTIONAL DEVICES

Definition	Details	Piece
Mini Printer	External printer device	1
External Memory	USB disk (at desired capacity)	1

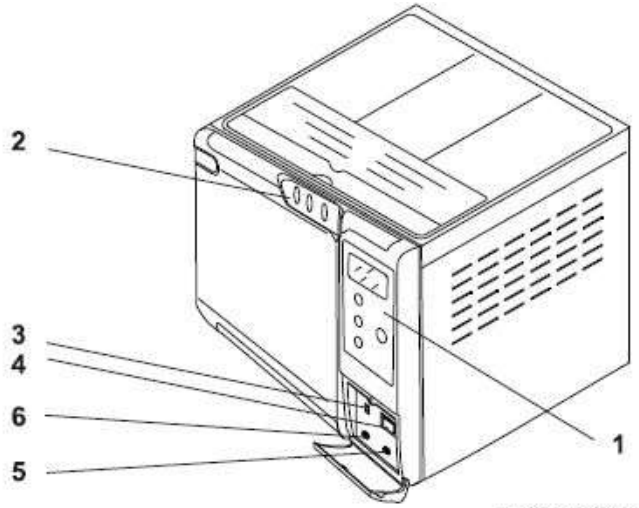
5. DEVICE DESCRIPTION

5.1 DEVICE DESCRIPTION

STR Series Steam Sterilizer: Fully automatic steam sterilizer used to sterilize the materials in sterilization paper.

5.1.1 FRONT ELEMENTS

1. Control Panel: The control panel is used to set and control all functions of the device. "5.1.4 Description of Control Panel" and "6.5 Using of Control Panel" sections describe the functions of the various buttons.
2. Door opening handle. The safety lock is located inside the handle.
3. Port for USB Disk.
4. ON-OFF button
5. Connector for used water drain.
6. Connector for clean water drain.

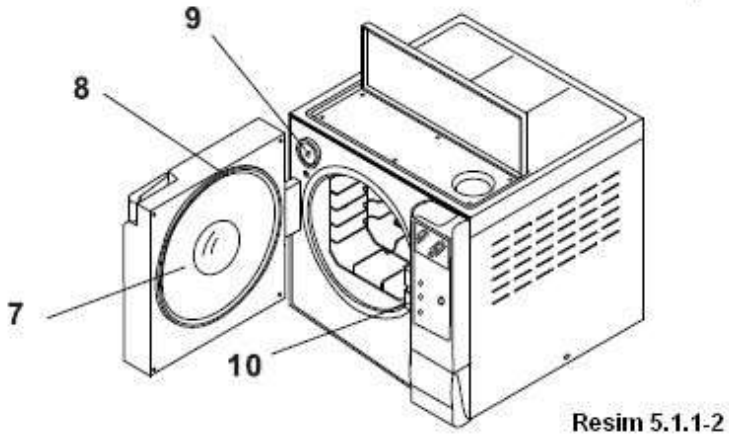


Resim 5.1.1-1

Vehicles in front of the unit with the door open:

7.Door Cover 8. Door seal

9. Bacteriological filter 10.Electromagnetic pin and internal safety micro-switch closing system.



Resim 5.1.1-2

5.1.2 REAR ELEMENTS

1. Main power electric cable socket
2. Fuse connection
3. Mini-printer connection
4. Drain connector
5. Safety valve
6. Radiator

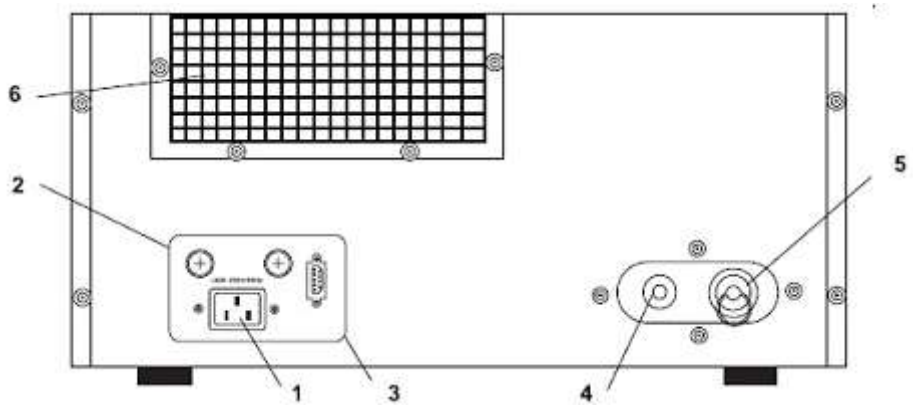
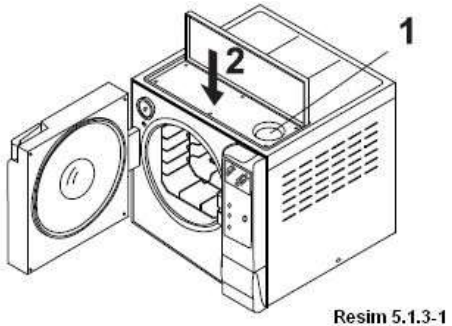


Figure 5.1.2-1

5.1.3 TOP ELEMENTS

1. Manual filling inlet for distilled water
2. Tank inside the unit which located under the object storage compartment



Resim 5.1.3-1

5.1.4 DEFINITION of CONTROL PANEL

1. LCD Touch Screen (240x160 pixel). Below the screen is a control panel that leads to the 3-button button panel.

2. SELECT button 3. UP button 4. DOWN button 5. START-STOP button

To use the control panel correctly, read 6.5 "Using of the Control Panel".

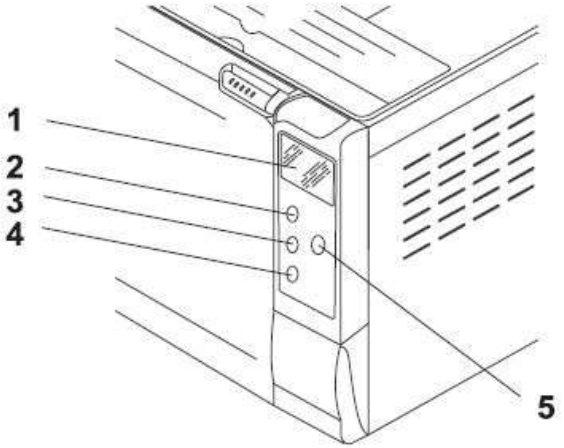
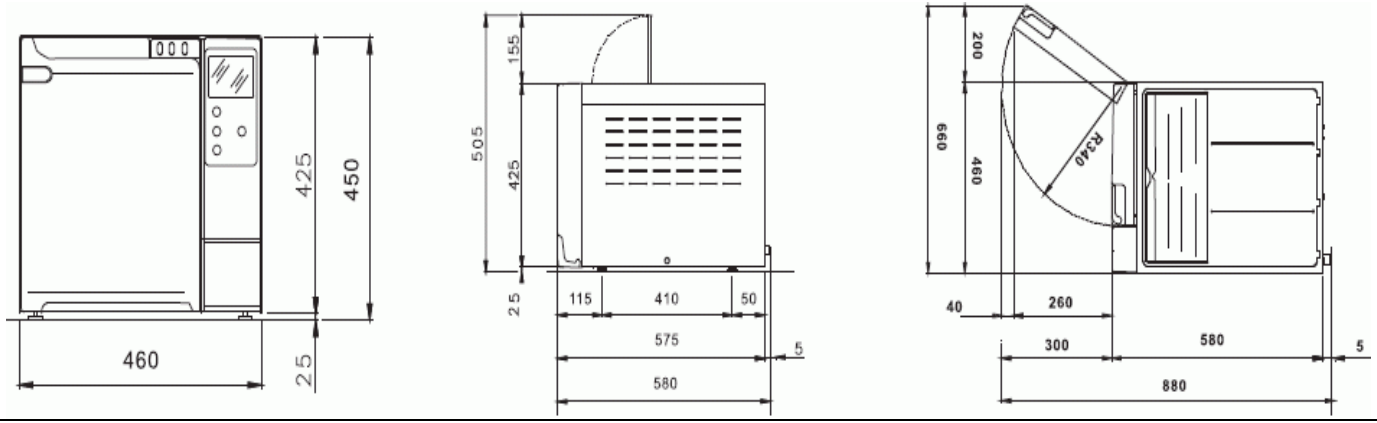


Figure 5.1.4-1

5.2 REQUIRED GAP AROUND THE DEVICE



General dimensions of the device when the door is closed	
STR-18	**STR-23**
U = 460 mm Y = 450 mm G = 580 mm	
General dimensions of the device when the door is opened	
STR-18	**STR-23**
U = 660 mm Y = 450 mm G = 880 mm	
Weight of the device	
STR-18	**STR-23**
Empty: 48 Kg. Maximum weight with full reservoir and load: 57 K.	Empty: 50 Kg. Maximum weight with full reservoir and load: 62 Kg.

5.3 TECHNICAL DATAS AND NOISE RATIO

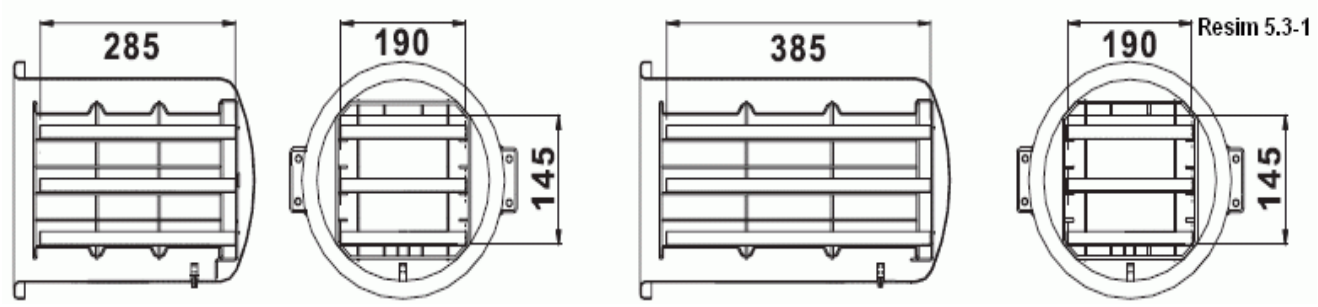
CHARACTERISTIC	STR-18	STR-23	CHARACTERISTIC	STR-18	STR-23
Power supply voltage	220 V ± %10		Chamber Volume	18 liter	23 liter
Feeding Frequency	50 – 60 Hz		Usable area of the chamber	190x145x285 mm	190x145x385 mm
Power output	1500 W		Process control	Microprocessor	Microprocessor
Current drawn	10 A		Clean water tank capacity	4 L	4 L
Sterilization cycles	8 sterilization cycles		Water tank capacity used	3.5 L	3.5 L
Test Programs	Vacuum test B&D test Helix test		Dimensions of chamber	Diameter: 250mm Depth: 350mm	Diameter: 250mm Depth: 450mm
Environmental conditions suitable for operation of the device	- Indoor use - Altitude up to 2000 m - Temperature: +5 ~ +40 °C - Max. moisture: %85		Weight of support parts (Maximum weight with full chamber)	3.07 Kg/cm^3	3.21 Kg/cm^3

*** ! The word "pressure" as used in this guide is always used to mean "relative pressure".**
**** Usable space**

Internal capacity of the sterilization chamber where the material to be sterilized can be placed (Figure 5.3-1)

Usable area for 18 liters = 7.85 liters

Usable area for 23 liters = 10.60 liters



Resim 5.3-1

5.3.1 NOMINAL VALUE PLATE

The nominal value (Figure 5.3.1-1) lists the main information and characteristics of the device. This information is used to identify the device when receiving information or when ordering spare parts.

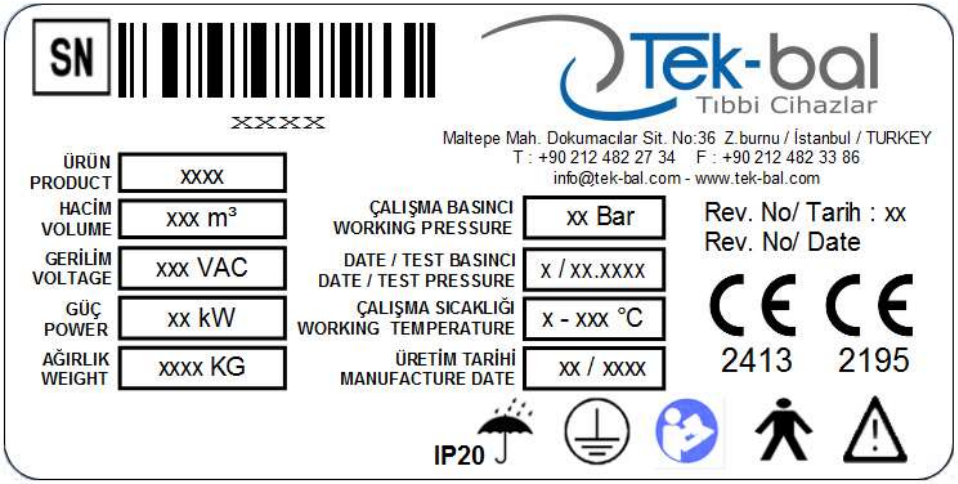


Figure 5.3.1-1

The device has various symbols on the label. The meanings of these symbols are given below.

SYMBOL	DEFINITION
	**"SERIAL NUMBER"**
	**"DATE OF MANUFACTURE"**
	**"MANUFACTURER"**
	**"CAUTION! FOLLOW THE INSTRUCTIONS"**
	**"REFER TO USER GUIDE"**
IP20	**"IP DECLARATION"**
	**"KEEP DRY"**
	**"TYPE B APPLIED PART"**
	**"PROTECTIVE EARTH GROUND"**

5.3.2 NOISE LEVEL

The device is designed and manufactured with a noise ratio of less than 50 dB (A).

5.4 EXTERNAL PRINTER

The device provides copies of the data for the ongoing sterilization cycle as well as information such as the selected cycle type, cycle phase, temperature and pressure values, split and total running times via printer.

During each cycle, the printer provides a summary report with all the information, regardless of whether the cycle was successful and whether the cycle was stopped by alarm or manually, regardless of the cycle result and total time. This function can be deactivated in the settings if desired. (see section 7.5.3 "Printer Settings")
-- The printer only works when paper is loaded.
-- If the paper roll is not loaded, the printer will not work.
-- The red POW LED is always on when the printer is operating.
-- The green LED flashes to indicate that there is a problem. (out of paper, cover not closed, etc.).
-- Press the OPEN button to open the cover and load the paper.
-- Press the LF button to automatically remove the paper. Press again the STOP button.
Use thermal printer paper with the following specifications:
Width: 55-56 mm Maximum diameter: 40 mm

External printer:

Do not expose thermal printer paper to direct sunlight, temperature or moisture before and after use.
Also avoid direct contact with polyvinyl-containing materials, solvents, and similar materials (PVC envelopes, acrylic and paper treated with ammonia vapors).

Paper rolls should be stored in a dry place with humidity not exceeding 70% and direct temperature not exceeding 35 °C.

6. INSTALLATION AND FIRST RUN

6.1 OPERATING ENVIRONMENT: POSITIONING

The device is packaged as follows: covered with bubbly polyethylene sheet, protected by fully recycled polyethylene foam mold, placed on a wooden pallet approved for sea, air transportation.

Carefully lift the unit and do not turn it upside down.

The package and equipment are very sensitive, so be very careful when transporting process. Please ship with delicate shipping

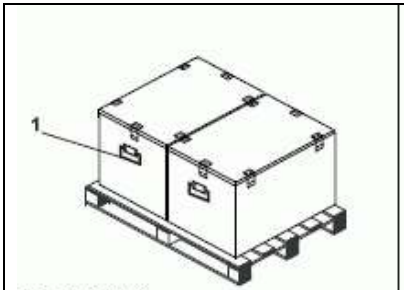
THE PACKAGE (Nr. 1 of Figure 6.1-1) MUST BE USED FOR VERTICAL LIFTING ONLY.
Keep in a dry and safe place. The package of the product must be kept for the entire warranty period.

NOTE: Keep the original packaging and use for shipping the device. Use of a different package during shipment may damage the product.

Holding the unit by the carrying straps, remove the unit from the box: this must be done by two people at the same time (Figure 6.1-2).

-- Remove the upper guard. Then two people lift the unit out of the box. The unit must be horizontal.
-- Place the unit in the work area and remove the straps by lifting them slightly.

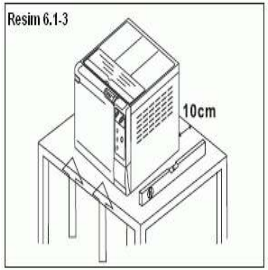
CAUTION: Follow the instructions shown in Figure 6.1-2.



Resim 6.1-1


Resim 6.1-2

-- The device should be placed in a laboratory accessible only to authorized persons.
-- Place the device on a smooth and horizontal surface.
-- Install the spacer screws as shown in the pictures to ensure the correct distance to the rear wall. (Figure 6.1-3)
-- Do not place the device near a source of steam or where water may splash. Water splashing will damage internal electronic circuits.
-- Do not place the device in a place that is not adequately ventilated.(Figure 6.1-4).
-- Do not place the device near a heat source. (Figure 6.1-4).
-- The place where the device is located should be illuminated in accordance with UNI 12464-1 standards.
-- Acceptable environmental conditions: temperature from 5 to 40 ° C, maximum 85% moisture without condensation, maximum height 2000m.



6.2 DEVICE SETUP

Installation is an important process for proper operation and efficient use of the device.

CAUTION: **The device must be installed by qualified technicians. After installing the unit, always complete the installation form and update the service manuel. Fill in the date and signature parts in the installation section.**

This device is intended for use under normal environmental conditions (see section 5.3 "Technical Datas"). However, the instructions given below are mandatory.

-- Place the device in a position where it can be easily plugged in socket that the power cord is not entangled or crushed.

-- Place the unit in a position where it can easily reach the outlet.

-- Place the device in a position so that the user can easily observe and clean the sterilization room.

-- Do not place items such as trays, newspapers or containers filled with liquid on the device. The ventilation grid must never be blocked.

-- Do not lean over the device when the door is open.

-- When draining water from the drain tank directly into the waste water pipe, hold the device at a higher position than the pipe.

ATTENTION: After the unit is installed and connected to the electrical supply it is ready for use.

6.3 ELECTRICAL CONNECTIONS

CAUTION: Electrical connections must be made by qualified technicians.

-- Check whether that the power supply voltage indicated on the rear label corresponds to the socket voltage (Figure 5.3.1-1).
-- The device must be connected to a grounding line in accordance with the standards of the country of use with the overcurrent cut-off switch.
-- The system must be connected according to current standards.
-- Maximum mains voltage variability: +/- 10%.
-- A differential switch with the following characteristics must be located in the direction of the power socket of the unit. Differential sensitivity: 0.03 A, rated current: 10 A.
-- Connect the supplied cable to the back of the unit.
-- Place the unit in a position where it can easily reach the outlet.

Do not allow to bend the cable or place any objects on it. Do not use an extension cable.

Use only original cable. USE ONLY ORIGINAL SPARE PARTS.

If the device is not operating properly, refer to the "Appendix 9: Troubleshooting" section of this guide for possible reasons. For more information or repair service, contact your supplier or technical service of Tek-Bal Medical Devices.

WARNING: The unit complies with the electrical safety requirements of the Standards Institute and comes with a dual pole plug that provides grounding.
Certainly check the capacity of the electrical system, whether the electrical system is sufficiently grounded and whether the sockets correspond to the values indicated on label of the device. (see section 5.3.1 "Nominal Value Plate"). The system must be checked by qualified personnel.
Tek-Bal Medical Devices,
DO NOT ACCEPT ANY LIABILITY IF THE ABOVE INSTRUCTIONS ARE NOT FOLLOWED.

6.4 FIRST RUN

The device is packaged with the door closed.
-- Take the equipment out of the sterilization chamber and unpack it.
-- Connect the device to the power supply according to the instructions in Section 6.3 "Electrical Connections".
-- Switch the unit on using the ON-OFF button. (Figure 5.1.1-1 in 4)
-- After the welcome message, the text "Please add distilled water" will appear and disappear after a few seconds. To fill water, first read the instructions in section "6.6 Containers: filling and emptying".

6.5 USING OF CONTROL PANEL

The STR series steam sterilizer is a complete system consisting of a 4-button panel (2-3-4-5 in Figure 6.51) and an LCD graphical user interface (1st in Figure 6.5-1).
The 4 buttons on the button panel (2-3-4-5 in Figure 6.5-1) are used to perform all programming, operation and maintenance of the unit.

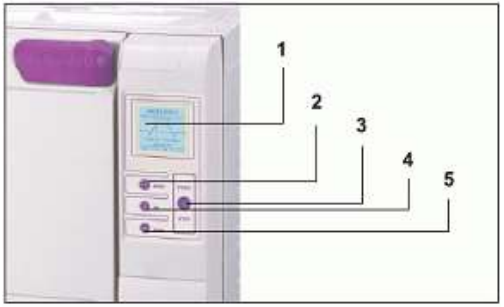


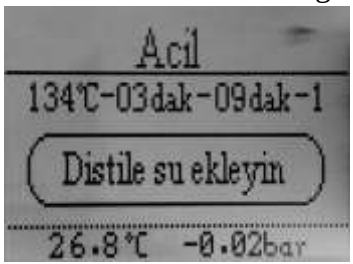
Figure 6.5-1

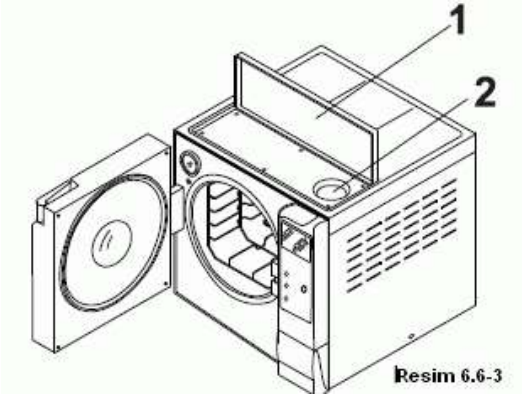
6.6 RESERVOIRS: FILLING AND DRAINING

The device has two separate reservoirs: the first is for purified water, which is necessary for cycles; the second is for used water collected at the end of the cycle. Both chambers are connected to the drain valve.

First time distilled water filling:

1. Switch the unit on with the ON-OFF button. The message shown below will appear on the display.





Resim 6.6-3

2. Lift the top cover (1 in Figure 6.6-3) and fill the inlet with the amount of distilled water specified in "5.3 Technical Data" (2 in Figure 6.6-3).

WARNING: Only use distilled water (Appendix 8: “Quality of Processed Water”).

3. When the filling is complete, it can also be checked by the level indicator next to the input (2nd in Figure 6.6-3). The following display appears: "Add distilled water" disappears.
Then, when the unit is used, "add distilled water" will reappear each time the water drops to the minimum level. In this case, no cycles or tests can be performed until the reservoir is refilled.

Adding Distilled Water

1. When the clean water tank is full, the display shows "Please stop adding distilled water!" appears (Figure 6.6-2) and "di" sounds three times.
2. Fill the clean water tank with distilled water using the corresponding port (Figure 6.6-3 2).

WARNING: Only use distilled water (Appendix 8: "Quality of Processed Water").

WARNING: Before using the unit, **empty both reservoirs**. Use the supplied pipe for this operation. To drain the clean water tank, connect one end of the pipe with the connector to the connector which is located under the dashboard (Figure 5.1.1-1 5-6), and connect the other end of the pipe to an empty container. To drain the used water tank, follow the instructions given below.

Discharging of Used Water

If the used water tank is full, the screen shown on the right is displayed and the control panel's screen flashes. (Figure 6.6-4).

1. To drain the used water tank:

CAUTION: CONTAMINATION HAZARD: Used water in the reservoir contains contaminated residues, if not sufficiently sterilized; use latex gloves during draining (section 3.4 "Residual Risks").

NEVER REUSE USED WATER.

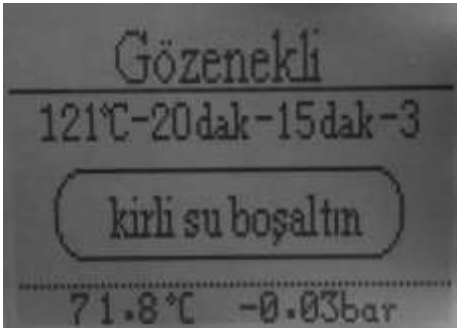


Figure 6.6.4

2. Take an empty container, connect the transparent tube to the connector under the front panel (Figure 5.1.1-1 5). At the end of the drain, press the clip to disconnect the pipe from the connector.

WARNING: This process is crucial for the correct operation of the unit.

CAUTION: When the autoclave is operating, if the distilled water in the clean water tank is insufficient or the used water tank is full, the unit can continue to run until the cycle time is over. But before the next cycle, the operator must solve all problems.

Maximum Load

Never exceed the maximum load limit specified in Appendix 5 “Definition of Programs”.

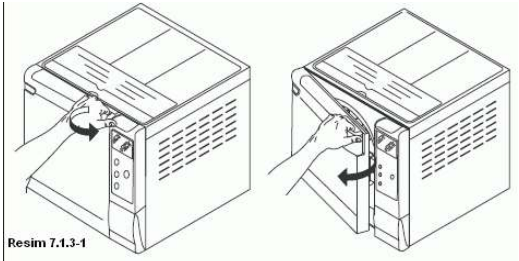
-- Always check each solid material to be sterilized for maximum load limit specified by Tek-Bal Medical Devices.
-- The maximum load that can be loaded into the device is shown in Appendix 5.
-- If the internal load does not exceed the specified maximum values, the device provides the specified levels of performance.

7. OPERATING

7.1 PRE-OPERATION PREPARATION

Before operating the device, carefully read all warnings in this manual, in particular Section "3. Safety".

During the sterilization cycle, never lift the top cover that covers the object storage area and the water inlet.



Resim 7.1.3-1

7.1.1 Switch the unit on by pressing the ON-OFF button and fill it with distilled water as described in Section 6.6.

7.1.2 Set the time and date. According to Section 7.5.1, enter “Year-month-day” and “Hour-minute-second”. Enter “user information” in accordance with Section 7.5.2.

7.1.3 Place the material

Before starting the cycle of the selected program, place the material to be sterilized into the device:

-- Open the door (Figure 7.1.3-1).

-- Place the material to be sterilized on the loading platform, and place it in the device.

⚠	Carefully read the instructions in “Appendix 1: Preparing Elements for The Sterilization”, “Appendix 2: Packaging” and “Appendix 3: Load Positioning” to load the material to be sterilized correctly.

-- Close the door: push the door in, pull the handle towards you, and then rotate the door handle back into the unit.

-- Select the program cycle according to the instructions given in Section 7.2.

7.2 STERILIZATION CYCLE SELECTION

Press the “Select” button on the control panel for 3 seconds. The screen in Figure 7.2-1 will appear and the light cursor will appear on the program list. Press the “Up” icon, the screen in Figure 7.2-2 will appear. Select the suitable program for the material by pressing the “Up” or “Down” icons. Press the “Start and Stop” icon to confirm and exit. The screen in Figure 7.2-1 will appear again, but the light cursor will appear above the "exit". Press the button. The screen in Figure 7.2-3 will appear.

Figure 2.7.1

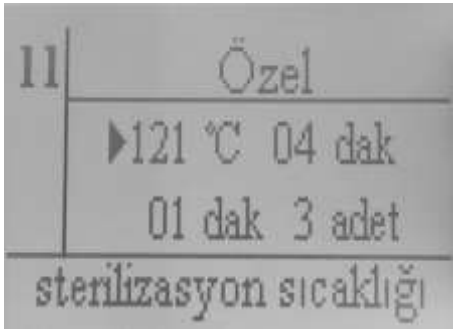
Press the "Start and Stop ◈" button and the machine will start.

Figure 7.2.3

ATTENTION

1. The name of the program selected by the user will appear on the screen. Likewise, it will vary according to the changes the user has made.
2. Each time the user presses the ON-OFF button and starts the unit, the program name displayed on the autoclave screen will be the last used program name.

7.3 USER DEFINED SETTINGS



Press the "Select ☞" button on the control panel. The screen in Figure 7.2-1 will appear. The light cursor will appear on the program list. Press the "Up △" or "Down ▽" buttons to move the light cursor to "Custom" and press the "Start and Stop ◈"button. The screen in Figure 7.3-1 will appear. Select 4 items using the "Select ☞" button: "Temperature", "Sterilization", "Drying Time", "number of pre-vacuum". By pressing the "Up △" or "Down ▽" buttons, the parameters for each item can be increased or decreased.

CAUTION:

1. Temperature: two types of temperature can be selected: 134 ° C or 121 ° C.

2. Sterilization time: minimum time is 4 minutes.

3. Drying time: minimum time: 4 minutes. maximum time: 60 minutes.

4. Pre-Vacuum number: without pre-vacuum, single pre-vacuum and three pre-vacuum.

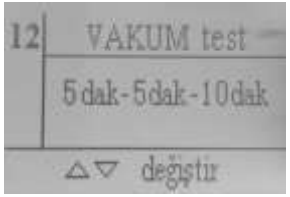
7.4 TESTING PROGRAM

Press the "Select" button on the control panel for 3 seconds. The light cursor will appear on the program list. Press the "Up" or "Down" buttons to select "B&D Test" or "Helix Test". Select one of the test programs. Press the "Start and Stop" icon to confirm and exit. Then press the "Start and Stop" button twice, one of the "B&D Test" or "Helix Test" programs will start.

7.4.1 VACUUM TEST

Press the "Select" button on the control panel for 3 seconds. The screen in Figure 7.2-1 will appear. The light cursor will appear on the program list. Select the "Vacuum Test" program by pressing the "UP" or "DOWN" buttons. Press the "START and STOP" button.

Vacuum time: 5 minutes. After 5 minutes, the machine will record the "P1" pressure. It will go to the second step. This step takes 5 minutes.
After 5 minutes, the machine will record the "P2" pressure. It passes to the third step after the second. This step takes 10 minutes.
After 10 minutes, the machine will record the "P3" pressure. Figure 7.4-1-5 indicates that the entire vacuum test is over. The autoclave value system will evaluate whether the vacuum test yields positive or negative results.



The vacuum test can only be activated when the machine is cold, that is, within the first 3 minutes after starting the unit.

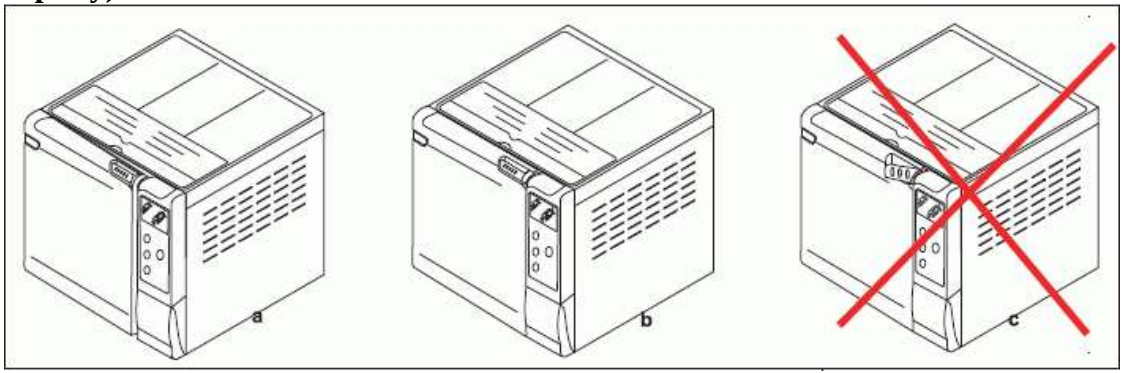
7.5 EMERGENCY DOOR OPENING AND CLOSING

If user wants to stop while the unit is running, user should press the“START and STOP button for three seconds. The machine will stop suddenly. “Emergency door opening” will be displayed on the screen. Connecting with the air, the solenoid valve will open automatically and balance the pressure inside and outside the chamber, press “START and STOP ” again. After vacuuming for 4 minutes, you will hear the “door lock” sound. This sound indicates that the lock is unlocked. You can open the door after the cell pressure reaches 0 bar.

CAUTION: Please do not press the “START and STOP ” button again and wait 4 minutes. Wait for the vacuum pump to absorb the water vapor inside the room. If the operator presses the “START and STOP ” button without stopping the vacuum pump, water vapor can harm people when the door is opened.

CAUTION: If the autoclave has not been operating for more than 40 seconds and no button has been pressed, the screen's light will turn on again. The purpose of this is to protect the LCD screen and save electricity.

WARNING: When the autoclave is closed, make sure the door is open (a) or completely closed (b). Avoiding the situation shown in (c) is important (the door handle is not seated properly).



CAUTION: DANGER OF BURNS: When the device completes the sterilization process and the door is opened to remove the sterilized elements, the door and the interior of the device is still very hot. Avoid touching these parts to prevent burning your hands (see Section **3.4 Residual Risks**"). Use the appropriate extraction tool.

CAUTION: DANGER OF BURNS: Do not lean towards the front of device or stand in front of the device when the door is open. There is a risk of burns (see Section **3.4 Residual Risks**"). Use the appropriate extraction tool.

If the sterilization process is not successful, an error message will appear on the screen indicating the cause of the problem (**Appendix 9 "Troubleshooting"**).

CAUTION: When the cycle starts, a safety pin automatically locks the door. This pin will open only at the end of the cycle. Trying to open the door with the pin closed may damage the locking system. Always wait for the message on the LCD screen that the cycle is complete before opening the door. If the alarm sounds, the door can only be opened by pressing the corresponding button (see 7.6).

8. MAINTENANCE

8.1 SAFETY ALERTS

Before performing and maintenance on the device, check the safety instruction, (especially chapter 3 "Safety").
WARNING: Changing parts of the device is important for the safety. Use only **ORIGINAL REPLACMENT PARTS**.

DANGER: HIGH VOLTAGE
WARNING: SWITCH OFF THE POWER SUPPLY. Failure to follow the instructions may cause injury or damage to the device.

ALL MAINTENANCE OPERATIONS MUST BE PERFORMED ONLY BY AUTHORIZED PERSONNELS OR BY TECHNICIAN BY TEK-BAL MEDICAL DEVICES.

-- Observe the intervals specified in the manual. Enable notification messages to assist the user in case of general or exceptional maintenance.
-- It is forbidden to disable the safety devices installed on the autoclave. (See Chapter 3.3 "Security Tools").
-- Check at regularly schedule.
-- If a dangerous situation occurs, immadiately press the ON-OFF button (Number 4 in Figure 5.1.1-1).
-- Unauthorized persons should stay away from the machine during maintenance process.

After maintenance and before starting the device, the authorized person must ensure that the operation is worked correctly. Safety devices must be activated.

8.2 ROUTINE MAINTENANCE

As with all other electronic items, this unit should be used and checked regularly. These measures make the unit run smoother and safer. In order to prevent damage to the operator, the unit should be checked regularly by authorized technical personnel.
-- Clean the device regularly with a damp cloth to keep it in good condition. Do not use strong detergents and disinfectants.
-- Do not use abrasive cloths or metal brushes.
-- Before each cycle starting, clean the door seal with a damp cloth.
-- White stains on the floor of the sterilization chamber indicate that the distilled water used is of poor quality.

Maintenance Program

There is a cycle counter on the main screen of the device. It gives automatic warning in maintenance cycles.

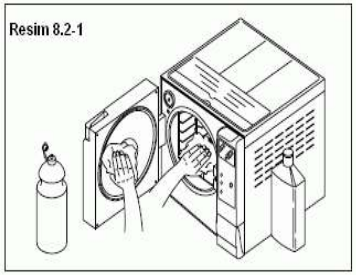
FREQUENCY	PROCESS
DAILY	Cleaning the door seal Cleaning the autoclave external surface Cleaning the autoclave internal surface
WEEKLY	Cleaning the sterilization chamber Cleaning of tray and tray holders
YEARLY	Maintenance the safety valve
EVERY 500th CYCLE	CYCLES. Bacteriological filter replacement
EVERY 500th CYCLE	CYCLES. Gasket replacement
AFTER 10 YEARS	Request a room check
IN CASE OF NEED	Adjustment of the closing mechanism

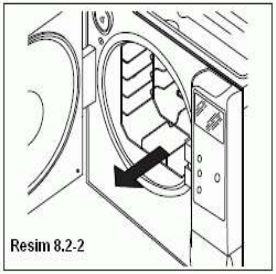
Cleaning of sterilization chamber, accessories, door and seal.

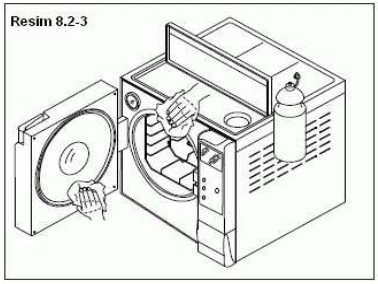
WARNING: SWITCH OFF THE POWER SUPPLY BEFORE CLEANING THE DEVICE.
Failure to follow the instructions may cause injury or damage to the device.

Sterilization Chamber

Remove the sterilization chamber with a damp cloth that is not abrasive by removing the tray holder (Figure 8.2-1). Use only distilled or demineralized water to moisten the cloth. Follow the same procedures to clean the trays and support. Cleaning the sterilization chamber is important for removing debris and for efficient machine operation. To disassemble the tray holder: remove the holder from the room (Figure 8.2-2). Be careful not to damage the shaft at the bottom of the room. After cleaning, perform the same in reverse order.







⊖ **DO NOT** use disinfectants to clean the sterilization chamber.

Conta ve Kapı

Clean the door seal and the outer edge of the chamber with a non-abrasive cloth moistened with water or vinegar to remove lime deposits. The purpose of this process is to prevent the dirt formed from causing pressure problems in the chamber and the formation of the cuts on the seal.

WARNING: Do not allow the accumulation dirt or lime residues on the seal.
These residues may cause the device to malfunction over time.

Periodically clean the exterior with a soft and damp cloth to ensure that the device always works well. Do not use abrasive and strong detergents.

⊖ **DO NOT WASH the device with direct jets of water, either under high-pressure or sprinkled. If water enters the electrical parts, it affects the operation of the device and the safety system.**

Reservoirs Draining and Cleaning

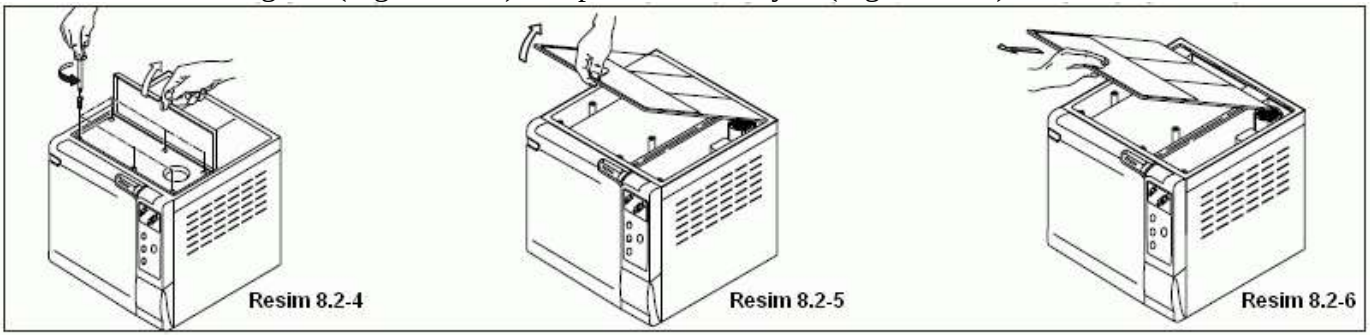
WARNING: SWITCH OFF THE POWER SUPPLY BEFORE CLEANING THE DEVICE. Failure to follow the instructions may cause injury or damage to the device.

WARNING: If the unit will not be used for more than 3 days, both reservoirs must be emptied to prevent residue buildup.

1. Drain the clean water tank: Connect one end of the pipe with the connector to the connector under the front panel (Figure 5.1.1-1 6) and connect the other end to an empty container.
2. To empty the used water tank: Connect one end of the transparent tube with the connector to the connector under the front panel (Figure 5.1.1-1 5) and connect the other end to an empty container.
3. At the end of draining, press the clip to remove the pipe from the connector.
4. Remove the cover to access the reservoir:

-- Unscrew the 6 screws (Figure 8.2-4);

-- Lift the cover 45 degrees (Figure 8.2-5) and pull it towards you (Figure 8.2-6).



Resim 8.2-4 Resim 8.2-5 Resim 8.2-6

5. Clean the chambers with sponge and water. Use the soft part of the sponge, not the abrasive part. Carefully clean it, taking care not to leave any dirt on the edges.
6. Rinse well and drain the water used for cleaning.
7. Perform a sterilization cycle without loading the unit.

WARNING: During cleaning, be careful not to damage the swimmer sensor located in the chamber.

8.2.1 PERIODICALLY MAINTENANCE

WARNING: SWITCH OFF THE POWER SUPPLY BEFORE CLEANING THE DEVICE.
Failure to follow the instructions may cause injury or damage to the device.

Safety Valve Maintenance

WARNING: HIGH TEMPERATURE or HOT SURFACES! Ensure that the device is cold.
WARNING: SWITCH OFF THE POWER SUPPLY BEFORE CLEANING THE DEVICE.
Failure to follow the instructions may cause injury or damage to the device.

1. Access the safety valve mounted on the back of the machine.
2. The lever at the top of the valve is counterclockwise, turn it until it loosens and comes out of its position.
3. Replace the valve and tighten it by turning. Repeat the process at least several times.

WARNING: This maintenance ensures the smooth operation of the safety valve for a long time. Make sure the lever is properly back in original position.

Setting the Closing Mechanism

WARNING: HIGH TEMPERATURE. Perform this operation only when the unit is cold.
The closing mechanism of the unit needs to be adjusted occasionally. This depends on the normal structure of the mechanical parts and the aging of the seals. This process is very important; because a damaged seal causes the desired pressure level to not be reached, thereby negatively affecting the outcome of the cycle. Perform the following actions:

1. Open the door. **Always perform this operation when the machine is cold**.
2. Holding the disassembly and adjustment arm by its widest part, place it between the door seal and its guard. Then insert the end into the nut located in the middle of the door seal.
3. Turn the adjusting pin counterclockwise, facing the door seal (1/8).
4. Make sure that the door is closed properly.
If the handle is too hard, turn it a littlein the opposite direction (clockwise).
5. Perform a test cycle to make sure it is properly adjusted.

Resetting the Safety Thermostat

WARNING: The safety thermostat can only be adjusted by authorized personnel.
WARNING: DISCONNECT THE POWER SUPPLY BEFORE CLEANING THE UNIT.
Failure to follow the instructions may cause injury or damage to the device.
WARNING: HIGH TEMPERATURE. Perform this operation only when the unit is cold.
Perform the following steps to readjust the safety thermostat:
1. Wait 10 minutes for the machine to cool.
2. Unscrew the black protruding plug (on the back of the machine, bottom right).
3. Press the red button inside the hole using a pointed object (screwdriver etc.).

4. Turn the black plug back into place. Now the machine has been adjusted again.
After resetting the safety thermostat, reconnect the power supply. Restart the cycle and make sure that the problem is fixed.

WARNING: If the problem persists, turn off the machine and call technical service. Do not try to install the thermostat again.
PERFORM THIS ACTION ONLY ONCE.

8.3 EXCEPTIONAL MAINTENANCE

Any application other than those mentioned above is considered exceptional maintenance. In such cases, contact the authorized personnel of Tek-Bal Medical Devices Company.

The air filter and seals are not covered by the warranty.

Service Maintenance

After 500 cycles, or 1 year after installation, it must be performed by authorized personnel of the Tek-Bal Medical Devices Company.

WARNING: Exceptional maintenance must be only performed by authorized personnel of the Tek-Bal Medical Devices Company.

Replacing the Air Filter

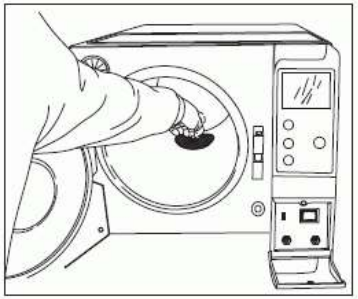
-- Remove the air filter by turning it counterclockwise. (Figure 5.1.1-2).
-- Replace the new air filter and tighten it by turning clockwise.

Replacing the Door Seal

-- With two fingers, grasp the seal by the end and pull it out;
-- Carefully clean the seal seat with a moistened cloth with alcohol;
-- Insert the new door seal into the place and press it evenly with your fingers. Make sure the door seal is properly back in original position;
-- Run the autoclave, close the door and make sure it is properly closed. If necessary, adjust the closing force with the relevant adjusting tool.

Cleaning the Drain Water Filter

If necessary, clean the drain water filter. As shown in the picture, twist the filter out and wash it with water. Be careful not to allow objects such as screws, etc. to fall into the solenoid valve. (Figure 8.3-1).



Resim 8.3-1

Power Fuse

Type of fuse on the internal card: 5x20A and 10A

8.3.1 RUST

The device is designed so as not to allow rusting of the elements to be sterilized.
Corrosion that may occur on the device or the elements to be sterilized is due to the fact that, although it is made of stainless steel, some of the rusted elements or normal steel elements causing galvanization are put into the device.
Even placing a single rusted element into the device is enough to cause the device and other elements to rust.

WARNING: SWITCH OFF THE POWER SUPPLY BEFORE CLEANING THE DEVICE.
Failure to follow the instructions may cause injury or damage to the device.

If rust occurs on the device, clean the walls and tray handles of the sterilization chamber thoroughly using special cleaning products for stainless steel, as described in the paragraph entitled “Cleaning the sterilization chamber, accessories, door and gasket”.

WARNING: Do not use a metal sponge or metal brush. Use a damp cloth to remove dirt.

9. SCRAPPING

9.1 INSTRUCTIONS OF SCRAPPING

STR series devices are made of stainless steel, electrical and plastic materials. To scrap of the device, separate the parts according to the material they are made of. This facilitates the reuse or disposal of the device. After scrapping, no special process is required.
Do not attempt to dispose of the device yourself and hand it to the waste disposal company.
Always dispose of in accordance with the waste disposal laws of the country of use.

9.2 RE-SELLING

If you are going to sell the product, give all the technical documentation with the device. The person who purchases the device is informed about the repairs and maintenance and the conditions under which it is used. In addition, inform Tek-Bal Medical Devices about sales and the new owner of the device.

Electromagnetic Compatibility Test Table

- This device producing, using, and radiating the energy with radio frequencies (RF). When this equipment shall not be used as specified in the user guide, that situation could cause the interference.
- This equipment was tested properly to EN 60601-1-2:2015 Standard for Medical Devices and its conformity to compliance limits has been identified. That limits, in case of the device is used as specified in the user guide, this device provides protection towards electromagnetic-interference (EMI) on acceptable levels.
- This device is designed and produced in conformity with requirements of EN 60601-1-2 Standard.
- This device could be influenced by portable, and mobile RF communication devices. This device should not be kept with another equipment.
- To receiving further information about this device, and EMC/EMI **see also:** (Table-1, Table-2, Table-3)

Guide and Declaration of Manufacturer – Electromagnetic Emissions		
This device designed for the purpose of get used electromagnetic environment specified below. User or a customer of this device shall be ensured/guaranteed that using this device in such a way.		
Emission Test	**Compatibility**	**Elektromagnetic Environment – Guide**
RF emissions CISPR 11	Group 1	This device is using only RF energy for its internal functions. Therefore, its RF emissions are ultra low, and it is a slightly possibble this device cause interference to equipment nearby it.
RF emissions CISPR 11	Class B	This device is appropriate for usage in all setups including with local setups, and feeding buildings are used for local that directly connected with low-voltalge (LV) power supply disturbition network.
Harmonized emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Coherent (Please confirm / check!)	

Table-1

Guide and Declaration of Manufacturer – Electromagnetic Immunity			
This device designed for the purpose of get used electromagnetic environment specified below. User or a customer of this device shall be ensured/guaranteed that using this device in such a way.			
Immunity Test	**Immunity Test**	**Immunity Test**	**Immunity Test**
Electrostatic Discharge (ED) IEC 61000-4-2	Electrostatic Discharge (ED) IEC 61000-4-2	Electrostatic Discharge (ED) IEC 61000-4-2	Electrostatic Discharge (ED) IEC 61000-4-2
Electrical rapid temporary regime/explosion IEC 61000-4-4	Electrical rapid temporary regime/explosion IEC 61000-4-4	Electrical rapid temporary regime/explosion IEC 61000-4-4	Electrical rapid temporary regime/explosion IEC 61000-4-4
Shock wave IEC 61000-4-5	Shock wave IEC 61000-4-5	Shock wave IEC 61000-4-5	Shock wave IEC 61000-4-5
On the input lines of power plant; voltage dips, short interruptions and voltage variations IEC 61000-4-11	On the input lines of power plant; voltage dips, short interruptions and voltage variations IEC 61000-4-11	On the input lines of power plant; voltage dips, short interruptions and voltage variations IEC 61000-4-11	On the input lines of power plant; voltage dips, short interruptions and voltage variations IEC 61000-4-11
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	Power frequency (50/60Hz) magnetic field IEC 61000-4-8	Power frequency (50/60Hz) magnetic field IEC 61000-4-8	Power frequency (50/60Hz) magnetic field IEC 61000-4-8
NOTE: Ut value is the mains voltage a.a before the test level is applied.			

Table-2

Guide and Declaration of Manufacturer – Electromagnetic Immunity			
This device designed for the purpose of get used electromagnetic environment specified below. User or a customer of this device shall be ensured/guaranteed that using this device in such a way.			
Immunity Test	**IEC 60601 Experiment Level**	**IEC 60601 Experiment Level**	**IEC 60601 Deney Seviyesi**
Transmitted RF IEC 61000-4-6	150kHz-80MHz, 3V rms, 80% AM (1kHz) (6Vrms for ISM bands)	1 Vetkin 1 Vetkin	Portable and mobile RF communication equipment, including the cables, any part of the Model 005 should not be used closer than separation distance which is proper for transmitter frequency and calculated equationally. **Recommended separation distance:** $d = 1.16\sqrt{P}$ $d = 1.2\sqrt{P}$ 0,15 MHz and 80 MHz
Radiant RF IEC 61000-4-3	80MHz - 2700MHz, 3V/m, 80% AM (1kHz)	3 V/m	$d = 2.3\sqrt{P}$ 80 MHz and 2.7 GHz

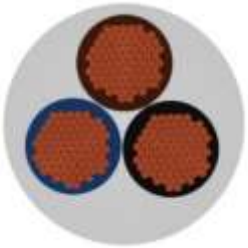
			Where P is the maximum rated output power of the transmitter specified by the transmitter manufacturer in watts (W), and d is the recommended separation distance in meters (m).[b] Area power emitted from constant RF transmitters that detecting with an electromagnetic region discovery, should be lower than each frequency levels compability level. [d] Interference could happen due to proximity to hardware marked with symbol below. 
NOTE-1: On the 80 MHz and 800 MHz frequency levels, superior frequency range is used. NOTE-2: This guides may not be appropriate to all conditions. Electromagnetic emission is affected by absorptions and reverberations from buildings, objects, and humans.			
[a] Between the 150 KHz and 80 MHz ISM (industrial, scientific and medical) bands; their ranges 6,765 to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27,283 MHz, and 40,66 MHz and 40,70 MHz. [b] In the 150 KHz and 80 MHz frequency range, on the ISM frequency band EBT 80 MHz ilâ 2,5 GHz compliance levels in the frequency range are intended to reduce the likelihood of interference caused by unintentional transport of mobile / portable communications equipment to patients. Therefore, in these frequency ranges, an additional factor 10/3 is taken into account in the formula used to calculate the recommended separation distance for transmitters. C The strength of the area emitted by fixed transmitters such as base stations and mobile ground radios, amateur radio, AM and FM radio broadcast and TV broadcast of cordless telephones (cellular / wireless) cannot be predicted theoretically accurately. For the evaluation of the electromagnetic environment due to fixed RF transmitters, the discovery of the electromagnetic site should be considered. If the measured field strength where Model 005 is used exceeds the applicable RF compliance level mentioned above, [ET Equipment or ET System] should be observed to operate normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the Model 005. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 1 V / m.			

Table-3

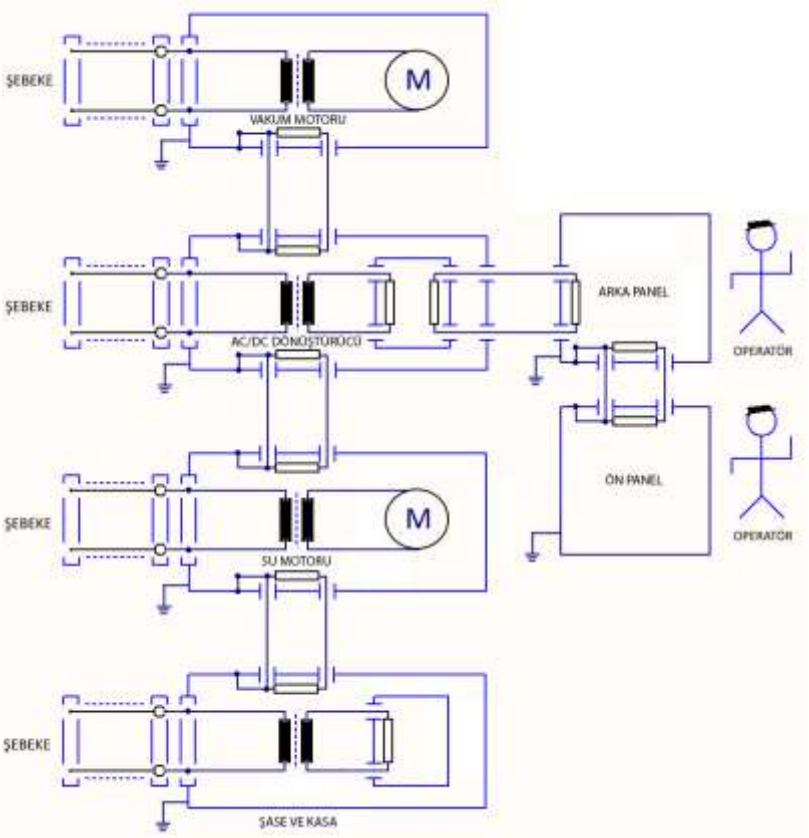
Fuse and Surge Disconnectors

High Current Circuit Breaker (Fuse)	➢
Varistor (High Voltage Protection)	➢
Filter Capacitors (Voltage Fluctuations)	➢
Line Filter (Voltage Fluctuations)	➢

Power Supply Cable

Power Supply Cable	3x1,5 H 05 VV-F (TTR)
	

Isolation Diagram



Contraindications:

Powders, oils, PMMA-based materials, ABS, acrylic, styrene, low-density polyethylene (PE) and polyvinyl chloride (PVC) can be damaged at high vapor temperatures, and polyurethane is hydrolytically toxic when exposed to steam.) as contraindications.

Complications:

There are no known complications of our device.

Side effects :

Our device has no known side effects.

Lifetime :

The service life of the device also depends on the time wear of the device chamber, which is the pressure vessel. For this reason, pre-production calculations and hydrostatic tests are carried out by us. Due to these reasons, the service life of our device has been determined as 10 years and it is foreseen that it can be continued with hydrostatic tests to be performed every year after 10 years.

ANNEX 1 PREPARING ELEMENTS FOR THE STERILIZATION

The proper operation of a sterilization process depends on the correct implementation of the following procedures.

Each of these procedures is equally important:
1. Preparing the elements to be sterilized
2. Packing
3. Installation
4. Sterilization
5. Storage of sterilized elements
6. Routine maintenance of the unit

All objects must be decontaminated and carefully cleaned before sterilization process. For objects with interconnected parts, disassemble as much as you can. In the case of reusable fabrics, these fabrics should be washed and dried before sterilization process. In this way, organic materials are destroyed and the life of the fabric is extended. The natural water content is balanced (ie the degree of moisture).
The purposes of the initial decontamination procedure are as follows:
a) to inactivate the proliferation of bacteria,
b) to prevent mutual contamination during transport of elements,
c) to prevent drying of any product on the elements,
d) To protect personnel.
Decontamination is carried out using effective detergents and solutions or by washing in thermo-disinfector at 93 ° C for ten minutes against HIV, HBV and HCV. Follow the instructions in the technical data sheets for the product being used.

The purpose of cleaning the elements is to destroy blood, saliva, dentin and organic substances that may damage the materials to be sterilized or the sterilizer. The use of ultrasound bath offers many advantages over conventional cleaning methods such as efficiency, speed and thinness on the object being cleaned. Therefore, it is recommended. Always follow the recommendations of the respective manufacturers. It is generally recommended to rinse the elements after ultrasound cleaning with detergent or disinfectant is applied. Because disinfectants may show corrosive properties due to heat.
Always clean the solutions on the materials to avoid residues. Materials to be sterilized should be properly packaged when they are dry.
It is important to check the elements to be used.
Ensure that materials with the following properties are not sterilized:

- Broken,
- Stained,
- Rusty,
- Disposable products

ANNEX 2 PACKAGING

Correct packaging of materials is important for the protection of sterile materials. Materials must be packaged properly in order to remain sterile until they are used. How sterilized materials are packaged and stored determines the status of the sterilization protection.

The following can be used as the containers: metal containers with lids, perforated paper containers, polypropylene or paper bags, sterilization paper or trays (perforated or grid).
Polypropylene-paper bags are the best packaging products for steam sterilized small medical materials.

Use materials complying with EN868-1 for packaging of sterilized materials.

Do not resterilize polypropylene-paper bags and medical grade paper.
Because their structural characters are subject to change. Therefore, they lose their protective properties.

For packaging, follow the recommendations below (for polypropylene-paper bags):

1. The content should not exceed 3/4 of the bag volume.
2. The materials should be placed in such a way that they can be removed from the handles.
3. The sealing width on the bag must be at least 6 mm high and continuous (EN 868-3).

! For successful packaging, use sealing devices according to EN ISO 11607.

All prepared packages must indicate the sterilization date, the type of cycle applied and the end date of sterilization.
Sterilization life is determined by factors such as the time specified by the package manufacturer, the internal procedure used and the storage conditions of the sterilized materials.
Shelf life is determined as 30 days if the products sterilized in separate bags for sterilization have more sterilization life than each other. Those packed in double bags have a 60-day life if stored in closed cabinet. These periods are for informational purposes.
Protection of sterilization may vary according to factors such as where the packages are kept, environment, moisture of the environment, microbe level, granulometry of environmental dust, temperature and pressure. You can get help from the specialists of Tek-Bal Medical Devices for the correct detection.

ANNEX 3 LOAD POSITIONING

One of the important points in the sterilization process is that how the load to be sterilized is arranged in the chamber. Always observe the maximum load limits specified in this guide. This maximum value is tested by the manufacturer.

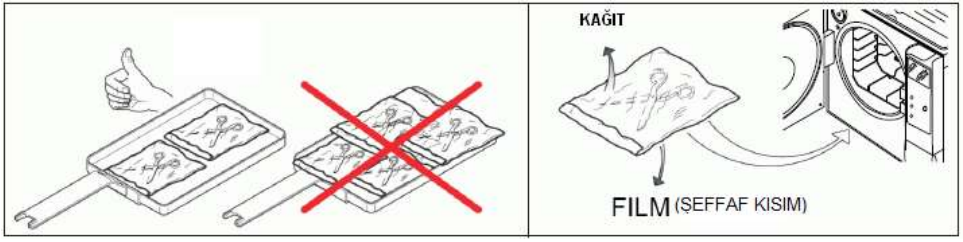
- Always use the tray holders to facilitate the circulation of steam.
- Do not load unused trays.
- Place unused trays upside down to prevent water from accumulating in them.
- When loose materials are to be sterilized, cover the tray with paper and avoid direct contact of the materials with the tray.
- Separate the materials according to their materials and place them on different trays.
- For better sterilization, place the surgical materials by disassembling or opening them, if possible.
- When placing materials, keep a sufficient distance between them.
- Do not overload the tray. This prevents the success of sterilization in some places within the chamber.
- The mirrors must be placed with the glass sides on the floor.
- Do not stack trays on top of each other. Use the tray holders. It is very important to keep sufficient distance between the trays to allow circulation of steam.
- Place the chemical or biological indicator into each package in the middle position.
- To measure the success of sterilization of the following "Hollow Tools", use Helix PCD test systems with chemical and / or biological indicators. For more information, please consult Tek-Bal Medical Devices Specialists.
- "Hollow Tools" **(Lumen, catheters, hollow products, etc ..)**

  Always clean the inside of hollow instruments such as lumens, catheters, etc. with special brushes, disinfect them, rinse with pyrogen-free water and dry them. Then place it on the tray so that it cannot be folded.

Sterilization of hollow materials is much more difficult than in other solid materials. Therefore, you should sterilize your loads containing these materials in cycles containing with at least 3 (three) pre-vacuum cycles.
To check the success of sterilization, use Helix-PCD systems according to EN 867-4 and 5.

- Packages
Place the packages side by side and upwards. Do not allow them to touch the walls of the sterilization chamber.

- Materials in bags
When sterilizing materials in the bag, do not stack the bags on top of each other. (Picture A3-1). Place the bags with the transparent side on the floor. The paper should be face up. (Picture A3-2). Materials should be placed in separate bags.



After following the instructions given above, place the tray holder and trays in the sterilization chamber.

WARNING: When placing the tray holders and trays, be careful not to damage the door seal.

ANNEX 4 UNLOADING AND PROTECTION OF STERILIZED ELEMENTS

The material is at great risk of contamination while still hot. Because, the barrier capability of the package is greatly reduced by the effect of moisture, compared to the normal ambient temperature. Therefore, when materials are removed, they should never be placed on top of each other to cool down more quickly.
Before storage, allow their temperature to drop to room temperature. Before storage, check the robustness of the packages and the success of sterilization by looking at the indicators. If the sterilization fails or the package is torn, replace the packaging of all materials and repeat the sterilization process. And never use these packages.
Protection of sterilization may vary according to factors such as where the packages are kept, environment, moisture, microbe level, granulometry of environmental dust, temperature and pressure. Therefore, the duration of the packages to remain sterile may be different in each institution. You can get help from Tek-Bal Medical Devices Specialists for the correct detection. The following periods are given as examples, but these periods are valid if the materials are kept in compliance with the standards of storage conditions.

Material Type	Estimated Time (in days)
Paper-polypropylene combination	30 (single) – 60 (double)
Standard filtered metal container	28/30
Double Orthogonal Layered Medical Grade	28/30

Material should be stored in sealed cabinets at a distance of 30 centimeters from the floor and 5 centimeters from the ceiling. If this is not possible, store the material in nylon bags.

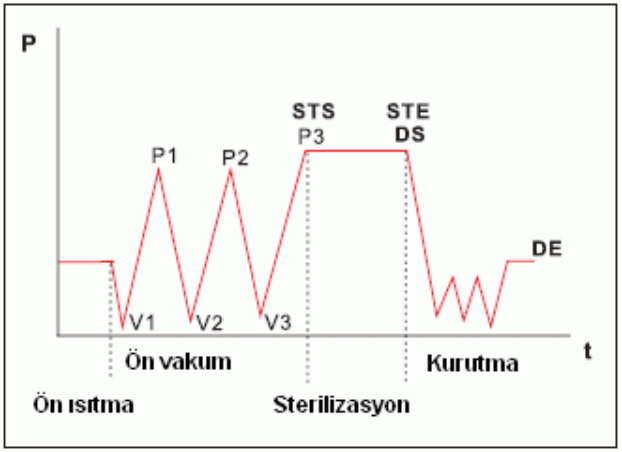
The periods given in the table above are for information purposes. Protection of sterilization can be influenced by factors such as environmental microbial level, size of dust particles, environmental temperature, pressure and moisture.

ANNEX 5 DEFINITION OF PROGRAMS

134 °C - Sterilization Temperature
04 m - Sterilization Time
06 m - Drying Time
3 - Pre-Vacuum

	STR-18	STR-23
Katı	4.5kg	6.0kg
Gözenekli	1.5kg	2.0kg

Pre-Vacuum	**V1**	1. Vacuum
	P1	1. Pressure increase
	V2	2. Vacuum
	P2	2. Pressure increase
	V3	3. Vacuum
	P3	3. Pressure increase
Sterilization	**STS**	Start of sterilization
	STE	End of sterilization
Drying	**DS**	Start of Drying
	DE	End of Drying



Individual sterilization cycles are shown above. Since they are all Class B devices, they can sterilize porous, solid or hollow loads. In any case, the manufacturer's recommendations regarding sterilization methods and timing should be followed.

ANNEX 6 DEFINITION OF TESTS

It is very important to perform tests periodically to check the performance of the device. The STR series can perform three different tests:

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

The frequency of these tests is given below: The parameters of the respective cycles are indicated below:

Vacuum Test	**Weekly**
B&D Test	**Daily**
Helix Test	**Daily**

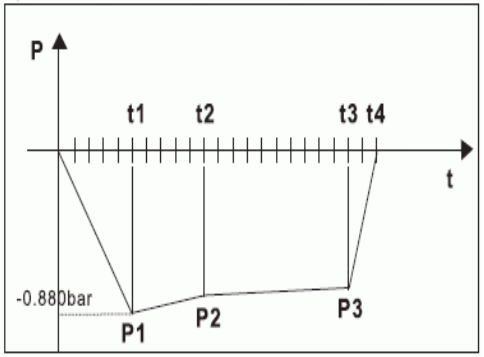
Parameters	**Vacuum Leak Test**	**B&D Test**	**Helix Testi**
Temperature	**------**	**135.5 °C**	**135.5 °C**
Pressure	**-0.840 bar**	**2.16 bar**	**2.16 bar**
Sterilization	**------**	**3'30"**	**3'30"**
Dry	**------**	**9'**	**9'**

Vacuum Test

This test is performed to measure the sterilizer performance of the device.
Especially:
- Efficiency of the vacuum pump,
- Tightness of the pneumatic circuit.

The test is carried out as follows;
1. A vacuum of -0.880bar should be created.
2.This pressure is kept constant for 5 minutes and then measured.
3. This pressure is kept constant for 10 minutes and then measured.
4. The pressure in the room is balanced by air pressure, for 2 min.

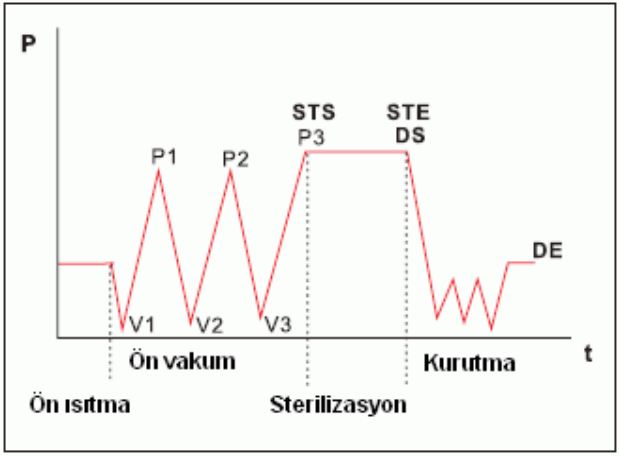
In accordance with the EN13060 standard, a tightness equal to or less than 1.mbar / minute should be obtained within a test period of 10 minutes. If the leak is greater than this value, the test result will be negative. This means that the pneumatic circuit seal of the device must be checked.



	**To get the right results, tests should be performed when the device is cold. (ie. within 3 minutes after running the device)**

Bowie & Dick Test

This test, performed with test systems (Helix or paper package) simulating the original Bowie-Dick-Textile Package described in EN 285, tests the Physico-Chemical status of the device.
The B&D test aims to measure the performance of the device's sufficient air purge and steam penetration.



Especially:
- Pre-vacuum efficiency and thus steam penetration,
- Temperature and pressure parameters of the saturated steam during the holding time.

The B&D test should be placed on the bottom tray, near the door.
After performing the cycle, remove the test system (be careful, it will still be hot) and evaluate the indicator according to the instructions.

Helix Test

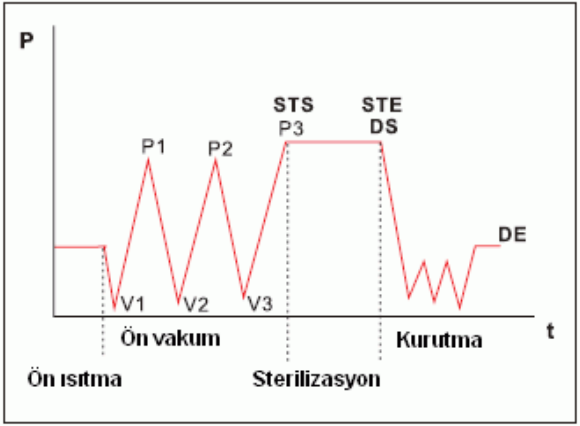
Helix test is performed for hollow loads (Type A) according to EN 867-5. (loads with the most critical characteristics)
The test consists of a tube with an internal diameter of 2 mm and a length of 1500 mm.
The Helix test is used to measure device performance for hollow loads.

Especially:
- Pre-vacuum efficiency and thus steam penetration,
- Temperature and pressure parameters of the saturated steam during the holding time.

WARNING: Perform the Helix test only after one sterilization cycle.

After placing the indicator in the test device and test device should be placed on the bottom tray, near the door.

After performing the cycle, remove the test system (be careful, it will still be hot) and evaluate the indicator according to the instructions.



ANNEX 7 APPROVAL OF CYCLES

According to EN 13060, the following cycles are approved:

	134C-04m-3 Pre-Vacuum	134C-18m-3 Pre-Vacuum	121C-20m-3 Pre-Vacuum
Dynamic pressure test of the chamber	●	●	●
Air leak	●	●	●
Empty chamber	●	●	●
Solid load	●	●	●
Small porous product	●	●	●
Few porous product	●	●	●
Full porous item	●	●	●
Hollow Load B	●	●	●
Hollow Load A	●	●	●
multiple package	●	●	●
Dryness →solid load	●	●	●
Dryness → porous load	●	●	●

For a better understanding of the table above, some definitions are given below:
-- Solid load: Non-prous material. They are loads where the steam input is not difficult. Easily sterile than hollow instruments.
-- Porous Load: These are the loads that steam can pass through, classified below:
A. If the load covers 95 ± 5% of the available space, full porous load
B. If the load covers 20-25% of the available space, few porous load
C. If the load covers 0,5-5% of the available space, small porous load

-- **Hollow Load A**: Loads with 1<L/D<750, L<1500mm clearance at one end (D: hollow body diameter, L: hollow body length); or loads with 2<L/D<1500, L<3000mm clearance at both end.
-- **Hollow Load B**: Loads with 1<L/D<5, D>5mm clearance at one end (D: hollow body diameter, L: hollow body length); or loads with 2<L/D<10, D>5mm clearance at both end.

ANNEX 8 QUALITY OF PROCESSED WATER

Tek-Bal Medical Devices sterilizers use distilled or demineralized water to generate steam for the sterilization process according to referance standards EN 13060. The table below lists the maximum content of minerals and the specifications for the water used for steam sterilization. The table also specifies the chemical-physical characteristics of condensate and inlet water. Condensation is generated by steam in the empty sterilizer chamber.

The manufacturer's warranty is void if the sterilizer is used water containing contaminant or chemical levels exceeding those listed in the table above.

	Feed Water	Condensate Value
Evaporate residue	<10 mg/l	<1 mg/l
Silicon oxide, SiO2	<1 mg/l	<0.1 mg/l
Iron	<0.2 mg/l	<0.1 mg/l
Cadmium	<0.005 mg/l	<0.005 mg/l
Lead	<0.005 mg/l	<0.05 mg/l
Heavy metals	<0.1 mg/l	<0.1 mg/l
Chloride	<2 mg/l	<0.1 mg/l
Phosphate	<0.5 mg/l	<0.1 mg/l
Conductivity (at 20°C)	<15 µS/cm	<3 µS/cm
PH value	5-7	5-7
Appearance	colorless, clean, free from sediment	
Hardness	0.02 mmol/l	

ANNEX 9 TROUBLESHOOTING

The following table lists all alarm messages and their possible causes. If one of these messages appears on the screen, perform the specified operation before calling technical service.

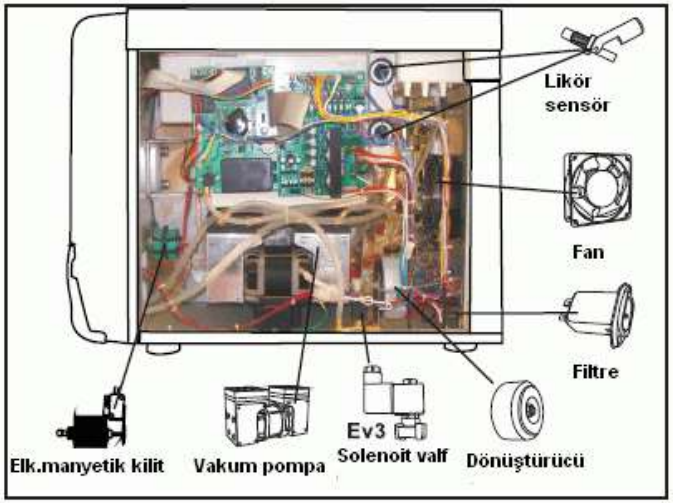
Alarm Code	Alarm Cause	Solution
E00	Emergency Door Opening!	Press the “START / STOP” button, the vacuum discharge program will start automatically. After one minute, press the “START / STOP” button again. You will hear “CLICK”. This sound indicates that the lock is unlocked. Now you can open the door.

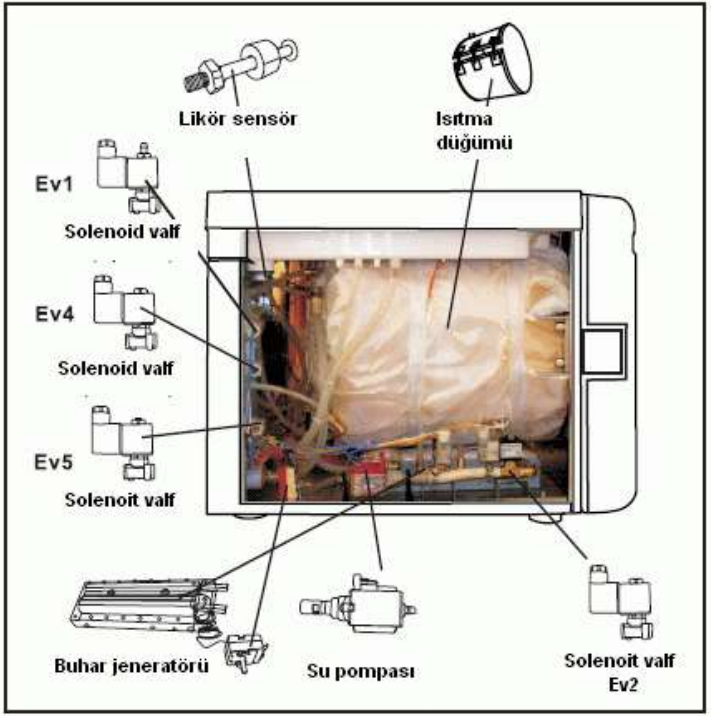
E01	Temperature sensor (steam generator) broken!	Check these: Defective on the temperature sensor of the steam generator may be! - The silicon on the power board may be on fire! - The circuit connection between the temperature sensor and the control panel may be loose!
E02	Temperature sensor (out-cell) broken!	Check these: The temperature sensor (intracellular) may be corrupted! - The silicon on the power board may be on fire! - The circuit connection between the temperature sensor and the control panel may be loose!
E03	Temperature sensor (in-cell) broken!	Check these: The temperature sensor (intracellular) may be corrupted! - The circuit connection between the temperature sensor and the control panel may be loose!
E04	Sterilization failed!	Check these: Opened - Malfaction of solenoid valve (Ev1)! Drained water - Soleonid valve (Ev5) and vacuum pump - Solenoid valve (Ev3) may be leaking! - Leakage in pipe connections!
E05	Unable to relieve pressure!	Check these: Opened - Malfunction of the solenoid valve (Ev1) and the drained water-solenoid valve (Ev5)! - The connection between the solenoid valve and the control panel may be loose! - There may be a malfunction in the pipe between the four connections and the used water tank!

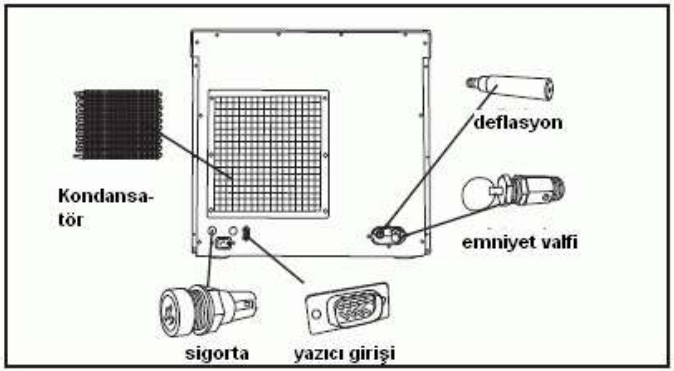
E06	The door was opened during operation!	Check these: Is the signal switch on the right door side connected to the door hook properly?!
E07	Processing time exceeded!	Check these: Leakage in the steam generator! - Opened - Malfaction of solenoid valve (Ev1)! - Drained water - Soleonid valve (Ev5) and vacuum pump - Solenoid valve (Ev3) may be leaking! - Damaged heating bar!- Vacuum pump motor and start capacitor may be faulty! - The door cover may be leaking! - The heating ring may be defective! - The temperature regulator 160℃ in the heating chamber may be defective!
E08	High pressure	Check these: Opened - Malfaction of solenoid valve (Ev1)! (especially in gas port)
E09	High temperature	Check these: The temperature sensor (intracellular) may be corrupted! Opened - Malfaction of solenoid valve (Ev1)!
E10	Pressure and temperature do not match!	Check these: The temperature sensor (intracellular) may be corrupted! - The connection between the power panel and the control panel may be loose! - Check each selonoid valves for leaks.

E11	Electric door lock does not move!	Check these: The two signal wires (red) on the electronic lock microswitch may be disconnected! - The stretch of the tensioning head on the electronic lock – Properly connected contact point and contact bar on the micro switch of the electronic lock! - DC 24V voltage supply the circuit normally!
E12	Vacuum process failed!	Check these: Malfunction on water intake filters! (in the cell) - Leakaging between the water pump-solenoid valve (Ev2) and the steam generator-room section! - Fault in the open-solenoid valve (Ev1), water drain-solenoid valve (Ev5) and air filter-solenoid valve (Ev4) may cause leakage! - Leaking on the door cover. - Faulty on vacuum pump motor and start capacitor. - The vacuum function of the vacuum pump may not be working properly! - Leaking on the copper insert between the vacuum and the pipe!

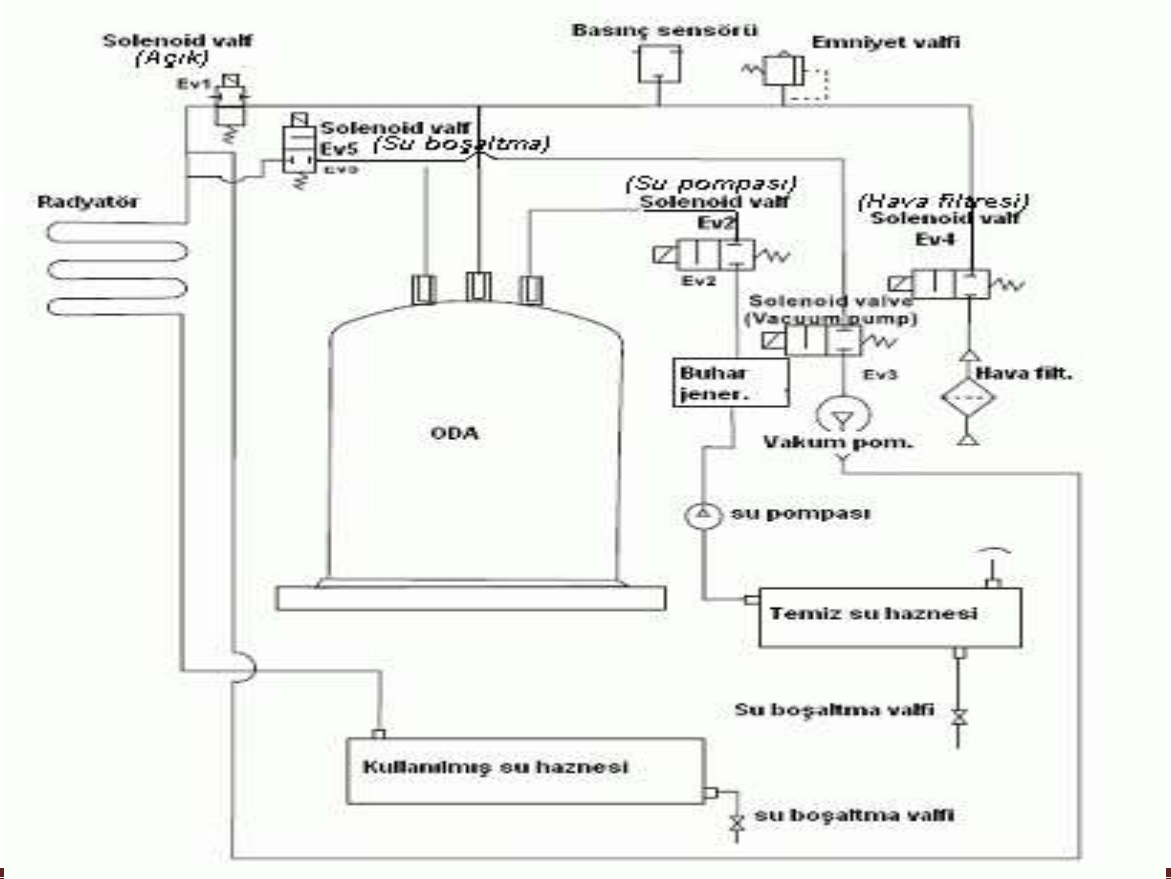
ANNEX 10 ALL COMPONENTS OF THE MACHINE



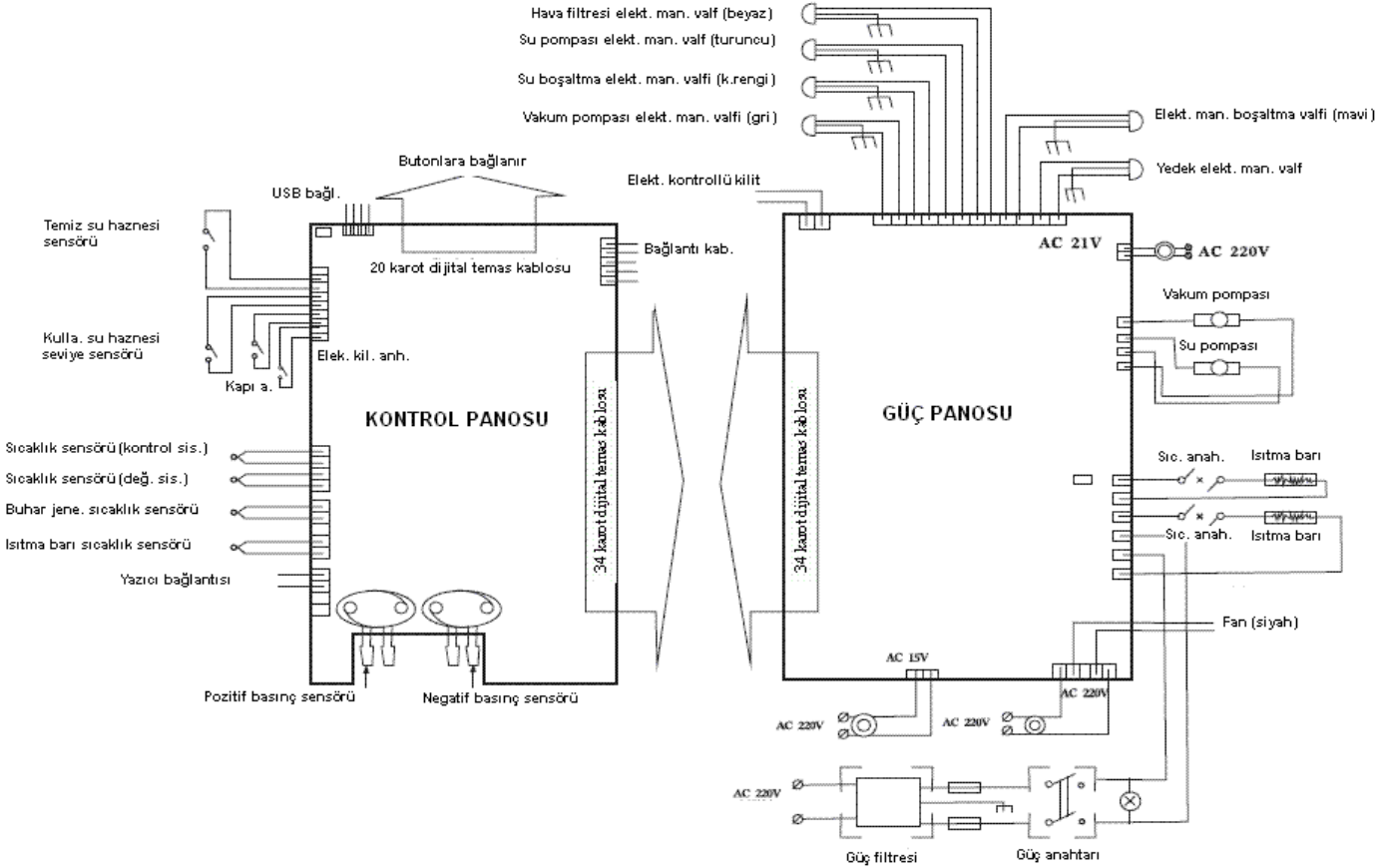




ANNEX 11 PNEUMATIC CIRCUIT



ANNEX 12 STR SERIES STERILIZER CIRCUIT DIAGRAM



SUMMARY NOTES:

1. The sterilizer should be placed at the table level.
2. Be sure to use purified water to extend the lifetime of the sterilizer.
3. Do not cover or block the sterilizer radiator.
4. Place the elements to be sterilized in the trays and keep a distance between them.
5. The used water tank must always be drained after each use.
6. Tightly close the door during the sterilization process.
7. Never open the door until the pressure drops to “0” bar.
8. Do not stand in front of the door, there is a risk of burns.
9. Always disconnect the power supply before repairing or cleaning the door seal.
10. When transporting the sterilizer, do not drag it on the floor.
11. Electrical voltage must be grounded.
12. It should not be installed in places where electricity cannot be easily cut off.

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