eryiğit®
technologies for life

EXCELLENCE
IN R&D
PRODUCTION
SERVICE

ERYİĞİT Hydrogen Peroxide Gas Plasma Sterilizer and Cartridge

GOLDBERG GP40, GP80, GP120, GP135, GP 160, GP 200

OPERATION AND MAINTENANCE MANUAL

Low Temperature

Maximum

Sterilization

Thank you for choosing ERYİĞİT Hydrogen Peroxide Gas Plasma Sterilizer for your business.

CAUTION

YOUR DEVICE MAY MALFUNCTION IF IT IS NOT OPERATED IN ACCORDANCE WITH THIS USER MANUAL.

CAUTION

IF YOUR DEVICE MALFUNCTIONS, PLEASE FOLLOW THE TROUBLESHOOTING STEPS IN THIS DOCUMENT. IF THE FAULT CANNOT BE SOLVED BY THESE STEPS, CONTACT OUR TECHNICAL SERVICE.

Eryigit sets new standards in the cycle and efficiency of sterilization using low temperature Hydrogen Peroxide (H2O2) Plasma technology ideal for sensitive medical instruments.

Please read all precautions and keep this User Manual close to your device. Review the "Starting Sterilization" section of the manual and familiarize yourself with the ease of use of your device.

Information on materials and consumables compatible with the device is provided in the following chapters. Also, refer to the information on warranty conditions.

At Eryigit A.S., we care about customer satisfaction and the performance of our product. Your comments about the performance of the sterilizer are valuable for us. Please send your feedback to info@eryigit.com.tr
please send your feedback by e-mail to .

ERYİĞİT A.Ş.

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PRINT HISTORY

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The information contained in the booklet is subject to change without prior notice.

WARRANTY

ERYİĞİT provides a two-year warranty period starting from the date of delivery for the device you purchased.

LIFE OF USE

The lifetime of the Hydrogen Peroxide Gas Plasma Sterilizer given by the manufacturer is 10 years.

DECLARATION OF CONFORMITY

Manufacturer : Eryigit Industrial Machinery and Medical Devices Iml. Import. Ihr. Construction. Tic. A.Ş.
Manufacturer's Address : İvedik OSB, Öz Anadolu San. Sit 1453 Sokak No:3, Ostim Yenimahalle / Ankara
Product Name : HYDROGEN PEROXIDE GAS PLASMA STERILIZER
Model Name : GOLDBERG® GP

S/N	MODEL
	GOLDBERG
1	GOLDBERG GP40
2	GOLDBERG GP80
3	GOLDBERG GP120
4	GOLDBERG GP120D
5	GOLDBERG GP135
6	GOLDBERG GP135D
7	GOLDBERG GP160
8	GOLDBERG GP160D
9	GOLDBERG GP200
10	GOLDBERG GP200D

CARTRIDGE MODEL
GOLDBERG

Hydrogen Peroxide Gas Plasma Sterilizer is classified as II a according to the requirements of Annex VIII Rule 16 within the scope of EU 2017/745 Medical Device Regulation. This product is declared to comply with the following standards.

EMC **:** TS EN 60601-1-2
: TS EN 61326-1
LVD **:** TS EN 60601-1
TS EN 61010-1
: TS EN 61010-2-40
Validation **:** TS EN ISO 14937

We kindly ask you to read this entire manual, which covers information on the installation, use and service of your device, before using your product and to keep it as a reference source.

CAUTION!

In case of any malfunction, do not perform repair work with reference to this manual. Always request technical service from our company.

CONTACT INFORMATION

CENTER / FACTORY
Address : İvedik OSB, Öz Anadolu San. Sitesi 1453 Cad. No:3, Ostim, Yenimahalle, ANKARA
Tel : 0 312 395 57 95
Fax : 0 312 395 57 96
Web : http://www.eryigit.com.tr
E-mail : info@eryigit.com.tr

ISTANBUL BRANCH
Address : Ercüment Batanay Sok. No:14 A2 Bl. Kat.5 Apartment 44 Atasehir / Dumankaya, Istanbul
Tel : 0 312 395 5795
GSM : 0 530 764 0391
Fax : 0 312 395 5796

TECHNICAL SERVICE
Tel : 0 312 395 5795
GSM : 0 533 741 4258
E-mail : servis@eryigit.com.tr

OUR INTEGRATED MANAGEMENT SYSTEM POLICY

As Eryiğit Endüstriyel, our primary goal is to develop and continuously improve the services we provide in the medical device manufacturing field in accordance with scientific and technical standards. In line with this goal, we commit to the following principles with our expert, competent, and friendly team who take pleasure in working on the activities mentioned below:

Providing reliable and quality product services and continuously improving service quality in line with current scientific advancements,

Taking into consideration customer and staff requests, evaluating and conducting improvement activities, and aiming to ensure the satisfaction of stakeholders under all circumstances,

Establishing a quality service awareness in all units as management and staff, and ensuring employee participation in quality enhancement activities by creating training programs,

Being a modern company with well-trained personnel who know and apply quality management system documentation, and who continuously generate knowledge,

Adopting good professional and technical practices based on scientific foundations, maintaining independence, impartiality, and confidentiality in production and service delivery,

Closely following technological developments and conducting R&D activities within the framework of scientific ethics,

Fulfilling obligations arising from existing laws,

Ensuring efficient and effective use of resources,

Managing risks and opportunities effectively and continuously improving all processes,

Protecting the environment by preventing pollution at its source considering the environmental aspects of all our activities,

Taking measures to reduce our waste, using raw materials, energy, and natural resources efficiently,

Increasing recycling and reuse rates to prevent environmental pollution,

Continuously improving our environmental performance in line with economic and technological possibilities,

Creating a healthy and safe working environment by considering OHS (Occupational Health and Safety) hazards and managing risks,

Conducting necessary activities to raise awareness among our employees regarding quality, OHS, environmental, and information security consciousness,

Working with a zero-accident policy concerning occupational health and safety,

Encouraging the participation of employees and employee representatives in occupational health and safety efforts and ensuring an open communication environment,

Complying with national and international legislative requirements,

Continuously improving the performance of management systems,

Systematically and regularly ensuring environmental awareness in all areas of activity by adopting and fulfilling the requirements of the Environmental Management System, and improving the continuity of the system.

We aim to continuously improve our quality and management system in accordance with the requirements of the international EN ISO 13485:2016, EN ISO 9001:2015 Quality Management System Standards, the EN ISO 14000 Environmental Management System Standard, the 93/42 EEC Medical Devices Directive, and the (EU) 2017/745 Medical Devices Regulation, as well as innovations in science and technology.

Adem ERYİĞİT
Genel Manager

FOREWORD

Dear Customer

First of all, we would like to express our gratitude for your support for domestic production by purchasing this device.

Developed by expert scientists, /GOLDBERG series provides excellent results under the most difficult conditions with its scientific and technological innovations. Designed for maximum sterilization and speed at low temperatures, the GOLDBERG series operates fully automatically, you only need to touch only one button.

This device is manufactured with 20 years of medical device experience of ERYİĞİT END. MAK. AND MEDICAL DEVICE. İML. İTH. İHR. İNŞ. TİC. A.Ş., which exports to 50 countries around the world. The only thing you need to do is to read the user manual carefully and use the device by taking into account the warnings and conditions of use. Thanks to the feedback and suggestions of our valued users, our devices will get better day by day.

The device is designed to be used efficiently for many years as long as preventive maintenance is carried out on time. If you have any problems with the device, please contact our technical service. Our expert technical staff will put your device back into service as soon as possible.

Our device is user and environment friendly. The device does not emit any waste material harmful for users, only water and oxygen are released. All of the materials used in our device consist of environmentally friendly materials and are RoHS approved. In addition, the waste generated during the production of the device is sent to recycling centers.

Our company currently has ISO 9001, ISO 13485 and ISO 14001 quality management systems and our device complies with MDD 93/42/EEC (2007/47/EC) directive.

As Eryigit, we will continue to develop and produce new technologies for life.

Best regards,

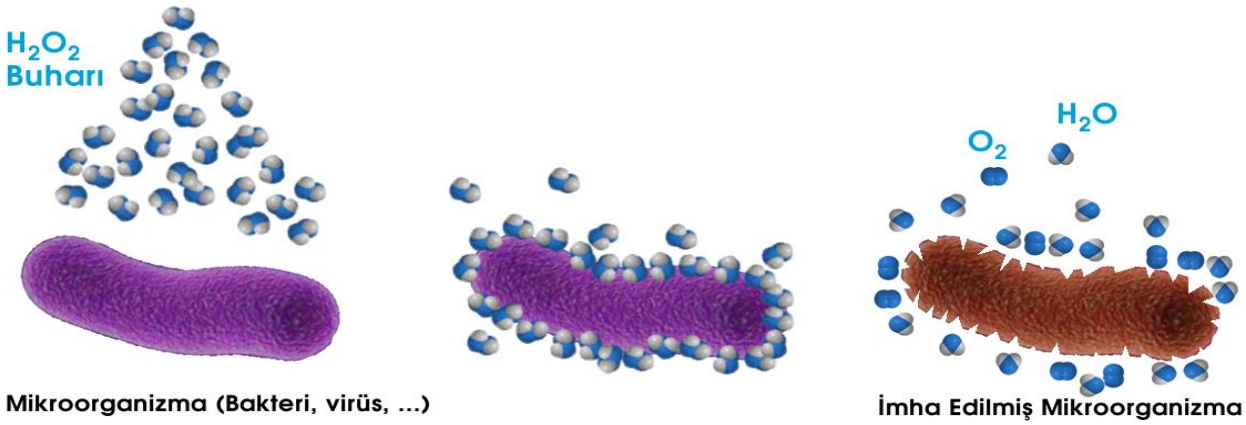
Halit ERYİĞİT

WHY HYDROGEN PEROXIDE STERILIZER?

- Hydrogen Peroxide breaks atomic bonds in the cell membrane and cell organelles of microorganisms with the free radicals it releases and kills the microorganism.
- It sterilizes heat and moisture sensitive instruments, prevents corrosion caused by moisture and allows the instruments to be used longer.
- Low temperature hydrogen peroxide plasma technology (40-55oC) provides sterilization without the use of high pressure water vapor, high temperature, ionizing radiation and highly toxic chemicals.
- It can sterilize devices with lumens.
- Does not release toxic substances, sterilized instruments can be used immediately.
- Completes sterilization in under 60 minutes and has a Sterility Assurance Level (SAL) of 10-6.
- There is no need for infrastructure other than electrical connection.
- It has low purchasing and operating costs.
- The loads to be sterilized can be sterilized in Tyvek packages.

- User and environment friendly, only water and oxygen are produced as waste.

- **Hydrogen peroxide vapor is an effective sterilization agent as it destroys microorganisms quickly.**



WHY GOLDBERG® SERIES?

- Developed by expert scientists, GOLDBERG® series provides effective sterilization at low temperatures in minimum time with its scientific and technological innovations.
- Since the process parameters are controlled in real time by the advanced microprocessor and all tests and preparation stages are done automatically by the system, the operator only needs to press a single button.
- In order for the device to be used with high performance for many years, the highest quality parts are used in its production.
- It is produced with more than 25 years of medical device experience of Eryiğit Endüstriyel A.Ş., which exports to 50 countries around the world.

Comprehensive ISO 14937 conformity verification tests for Goldberg devices were performed by an independent EN ISO/IEC 17025/20 accredited third European Laboratory.

OUR ADVANTAGES

Advanced technologies developed and patented by Turkish scientists
- Maximum Speed: Sterilization in 28 minutes with lumen-free program,
- Maximum Ease of Use: Ability to start a program very quickly with the One Button feature,
- Maximum Control: Fully automated system thanks to advanced microprocessor supervision and control,
- Maximum Performance: Effective sterilization at low temperatures, T < 55 oC (boiler)

- Maximum Quality: The /Goldberg range uses the world's highest quality vacuum pumps and vacuum gauges,
- Maximum Safety: The cartridge system ensures efficient and safe sterilization,
- Maximum Ease of Use: Logo coloring for remote monitoring of process status in central sterilization units,

- Maximum Sterilization: Precise results in tests with biological and chemical indicators,
- Maximum Safety: No toxic substances are released. User and environmentally friendly, producing only water and oxygen as waste.
- Maximum Safety: Its success has been confirmed by tests carried out by the Austrian accreditation company Hygcen,
- Maximum Cabin Volume: 20% increased boiler volume thanks to the plasma created outside the cabin,
- Catalytic converter for vacuum pump protection,
- Boiler volumes from 80 to 200 liters optimized for different applications,
- Thanks to its outer panels (body) made of 1.5 mm thick AISI 304 stainless steel, our device is resistant to impacts stronger than 5 J (IK08). For this reason, IK code is not given according to IEC 62262.
- There is no infrastructure requirement other than electrical connection,
- Aluminum boiler with rectangular cross-section for more efficient use volume,
- Door opening/closing function by foot,

- Timely and efficient technical service,
- Reduced maintenance, repair and consumables costs,
- RFID system that prevents the use of unauthorized and expired cartridges,
- 10 years of process parameters stored in external memory,
- Vacuum system that minimizes hydrogen peroxide residue when the process is complete,
- Many years of high performance use,
- Our devices are manufactured according to ISO 9001, ISO 13485 and ISO 14001 quality management systems standards.
- Shelves that can carry 30 kg load with minimized total surface area,
- Hydrogen Peroxide vapor injection from 6 different points to increase homogeneous spreading,
- Corrosion resistant evaporator,
- HEPA13 filter that prevents particles over 10 nanometers in size from entering the boiler,
- More effective sterilization process thanks to OH radicals resulting from the interaction of Hydrogen Peroxide and O3.

Note: Each system produced may not have all of the above features at once.

INTENDED USER OF THE DEVICE

The intended user of the Hydrogen Peroxide Gas Plasma Sterilizer and cartridge is a person with appropriate training, knowledge and experience and who has been certified as having been trained by the hospital receiving this system for the sterilization of medical equipment (authorized operator). They must have received the necessary training on how to use the device, correct cartridge insertion, sterilization procedures and maintenance of the device. The device must be operated in rooms in professional healthcare facilities that are suitable for the use of the Hydrogen Peroxide Gas Plasma Sterilizer.

CONTRAINDICATIONS OF THE DEVICE AND CARTRIDGE AND INFORMATION TO BE COMMUNICATED TO THE PATIENT

Our product has no direct contact with the patient. There are no known contraindications.

EXPECTED AND ANTICIPATED SIDE EFFECTS FOR THE DEVICE AND CARTRIDGE, ANY RESIDUAL RISK

The device has no side effects or contraindications, as its functions do not directly interact with living organisms undergoing diagnosis and treatment.

All instructions and operating steps in this User Manual must be followed completely and carefully. The system may only be operated by persons who have received the necessary training. This minimizes the risks that may arise from the use of the device.

Furthermore, all risks identified in the risk analysis have been reduced to acceptable risk levels and there is no longer any risk.

INTENDED USE OF THE H2O2 GAS PLASMA STERILIZER AND CARTRIDGE

The Hydrogen Peroxide Gas Plasma Sterilizer is a high-tech sterilization device designed and manufactured for the rapid, low-temperature sterilization of sensitive medical equipment.

Examples of these sterilization loads include medical instruments sensitive to heat and chemical corrosion, including diagnostic and surgical equipment containing optoelectronic components, or disposable precision medical instruments made of medically safe plastic.

The Hydrogen Peroxide Gas Plasma Sterilizer offers a safe sterilization technique where the sterilization load is not exposed to temperatures higher than 55 °C, high pressure water vapor, ionizing radiation, highly toxic and carcinogenic chemicals.

The short sterilization process time compared to all other sterilization methods is another feature targeted by the Hydrogen Peroxide Gas Plasma Sterilizer. Sterilization cycles are determined according to the sterilization requirements of the medical equipment to be sterilized. The sterilization program is intended to be completed in less than 60 minutes, depending on the selected program, the sterilization load and the characteristics of the material.

Hydrogen Peroxide Sterilization is a cost-effective sterilization method.

The H2O2 Gas Plasma Sterilizer Cartridge contains 59±0.5% by weight of hydrogen peroxide, a powerful oxidizing agent, which allows it to destroy a wide range of pathogens and is used to sterilize temperature-sensitive objects, such as rigid endoscopes. This property allows it to effectively destroy bacteria, viruses, spores and fungi within a short cycle time, even at low temperatures.

WARNING: It is strictly forbidden to use your device for purposes other than its production and intended use, and no responsibility will be accepted for damages and malfunctions that may occur to your device as a result of such use.

PROPERTIES OF HYDROGEN PEROXIDE

Properties of Hydrogen Peroxide solution in 59% water

Acidity	≤ 0.04 (% H_2SO_4)
Stability	≥ 97 (%m/m)
Odor	Odorless
Image	Clear, colorless liquid
Ignition Temperature	Non-flammable
Boiling Point	114 ^{O}C (%50)
Freezing Point	-52 ^{O}C (%50)
Flash Point	Non-flammable
Oxidation Properties	Strong oxidant
Volatile Gas Percentage	% 100
Active O2 Amount	% 23.5
Relative Density	1.19 (20 ^{O}C)
Water Solubility	100%
Total Vapor Pressure	18 torr (30 ^{O}C)
Partial Vapor Pressure	0.6 torr (30 ^{O}C)

HYDROGEN PEROXIDE

- It is a clear, colorless liquid with an irritating, faint odor.
- Non-flammable, but contact with flammable materials may cause fire or explosion.
- Dangerously reactive.
- Can cause temperature rise and severe corrosion.
- It can react violently with many chemicals or cause an explosion.
- Harmful to health at concentrations above 10% as it is a strong oxidant.
- Corrosive to steel, iron, nickel, copper and copper alloys.
- Contact with other materials may cause fire.

1. MATTERS TO BE CONSIDERED

1.1 WASTE INFORMATION

- Old devices are not worthless garbage! Through environmentally friendly recycling, valuable raw materials can be recycled for reuse.
- Waste management regulations must be observed.
- Disconnect old appliances from the mains. Disconnect the mains cable from the appliance under the supervision of authorized personnel.
- Do not give packaging and packaging parts to children to play with. Due to the collapsible cardboard boxes and foils, they may suffocate.
- Recycle the packaging properly. All used packaging materials are non-polluting and can be recycled. The wooden parts are not chemically treated.
- Ask your dealer or your local municipality for information about recycling centers for old appliances and garbage.
- Always wear latex gloves when collecting and disposing of Hydrogen Peroxide (Hydrogen Peroxide) waste cartridges and bottles.

1.2 SAFETY INFORMATION

- Read the information in the "Operation and Maintenance Manual" carefully before operating the device. This manual contains important information on the installation, positioning, operation and maintenance of the device.
- If you transfer your appliance to another organization or person, please also transfer this manual as a source of reference.
- The manufacturer is not liable for any consequences arising from failure to follow the written instructions in this manual.
- Do not operate damaged or defective equipment; if in doubt, contact your dealer or authorized technical service.
- Connect and install the appliance according to the installation instructions. Check that the electrical panel to which the device will be connected and the connection values indicated on the type plate are compatible with each other.
- The safety of the electrical connection of the device can only be ensured if the earth connection is made properly and in accordance with the regulations.
- In case of malfunction, disconnect the appliance from the mains during maintenance and cleaning activities.
- Repairs to electrical appliances must only be carried out by qualified specialists.
- Repairs that are not carried out by an authorized technical service may pose a danger to persons using the appliance.
- Do not allow unauthorized personnel to perform any operation related to the device.

1.3 WARRANTY TERMS

1.3.1 MATTERS COVERED BY THE WARRANTY

A. The product is warranted against defects in material, workmanship and manufacturing as of the invoiced delivery date for the period defined in the warranty certificate. The dates in the original Warranty Certificate are binding on the parties.

B. The warranty period for exported devices is 1 (one) year unless otherwise stated. This period can be extended by special contracts.

C. During the warranty period, maintenance, repair, part replacement, etc. cannot be performed by persons not officially authorized by ERYİĞİT END. MAK. TIBBİ DEV. İML. İTH. İHR. İNŞ. TİC. A.Ş. In case of intervention and/or detection, the device is excluded from the scope of warranty.

D. Damages and malfunctions that may occur due to interventions made outside the authorized service are not covered by the warranty. Labor services to be performed within the warranty period are free of charge.

E. Repair period starts after the day of written notification to our authorized dealer or our company. The elapsed time will be added to the warranty period.

F. If the failure notification is made for the devices sold in Turkey, the failure will be intervened within the following 48 hours and the device will be made operational within 10 business days.

G. In the event that the failure notification is made for devices sold abroad; If visa applications, climatic conditions, transportation conditions and foreign language difficulties are resolved, the device will be made operational regardless of time.

H. The determination of the malfunction and needs will be made by our company's technical staff.

I. Issues regarding the elimination of the malfunction on site or in authorized services are subject to the approval of the user or the administration.

J. No labor fee is charged for periodic maintenance defined in the contracts.

K. Consumers will be intervened if they notify ERYİĞİT END. MAK. MEDICAL DEVICE. İML. İTH. İHR. İNŞ. TİC. A.Ş. in writing about their disputes with Authorized Services that perform maintenance and repair services.

L. Following the end of the warranty period, the device has a Maintenance-Repair Warranty for 10 years for a fee.

M. At the end of the warranty period, a Maintenance-Repair Contract can be made in periods in line with the consumer's request.

N. Our company is not responsible for the possible risks arising from the administrations not using original spare parts after the end of the warranty period.

O. The issues not covered by the warranty include the issues written in the "User Manual" supplied with the device.

P. This warranty remains in force if the consumer or the consumer organization fulfills its responsibilities completely.

Q. The material invoice must be kept during the warranty period. Materials for which the invoice is not submitted shall be deemed to be out of warranty.

1.3.2 MATTERS NOT COVERED BY THE WARRANTY

A. The external factors listed below are issues that will affect the healthy operation of the device and the elimination of malfunctions within this scope is subject to a fee.

B.. Damages and malfunctions caused by not using the appropriate electrical connections and voltage defined by the manufacturer for the device.

C. Damages and malfunctions arising from improper connection, leveling, placement and proper installation of the electrical installation of the device.

D. Damages and malfunctions arising from improper installation of the ground line to the device.

E. Damages and malfunctions arising from not performing the necessary repairs in the electrical system of the devices by authorized services.

F. Damages and malfunctions arising from the operation of the sterilizer device by persons who have not received training on its use.G. Damages and malfunctions caused by blockage or blockage of the Hydrogen Peroxide vapor inlets and outlets of the device
H. After delivery; Damages and malfunctions caused by scratches and breakages of the outer body, plastic parts and PLC screen during loading, unloading and transportation and damages and malfunctions caused by errors in use are not covered by the warranty.
I. Fire and lightning strikes, low or excessive voltage, faulty electrical installation and incorrect connection, use of the product at a voltage different from the voltage range written on the label are not covered by the warranty.
İ. Damages and malfunctions caused during renovations and repairs in the area where the device is located.
J. Damages and malfunctions caused by the temperature and humidity of the environment where the device is used not being within the desired values.
K. Damages and malfunctions caused by cutting, piercing and scratching hardness of the materials loaded into the device.
L. Hepa filters should be replaced at minimum 3-month intervals, depending on the air pollution of the environment. It is out of warranty and subject to charge.
M. Consumables included in the maintenance kits are out of warranty and subject to charge.
N. Side covers covering the sterilizer are out of warranty and subject to charge.
O. Installing the software program on the device and upgrading its functions are subject to a fee.
P. Damages and malfunctions caused by fire and lightning strikes, floods and flooding, low or excessive voltage and force majeure specified in the law are not covered by the warranty and are subject to charge.
R. All damages and malfunctions during loading, unloading and transportation which are not under the control of our company in and out of Turkey after the completion of final acceptance procedures are not covered by the warranty and are subject to charge.
T. Operating Voltage of the device: 380 V AC ± 10 V and cannot be operated with any other electrical power. Repair of damages arising from this is subject to charge.
U. Operating ambient temperature must be between +10 °C - 40 °C. Malfunctions that may arise from the operation of the device outside these values are not covered by the warranty and are subject to charge.
V. Operating humidity must be between 20% - 75% and below condensation values. Failures that may occur in the electrical and electronic parts of the sterilizers due to condensation are not covered by the warranty and repair is subject to a charge.
Y. Out-of-warranty malfunctions shall be repaired for a fee. No rights and compensation can be claimed in cases outside the scope of warranty.

User,
device "within the warranty period", outside the authorized technical service,
gets repaired or serviced by any person or company,
the device is out of warranty!

1.4 WORKING ENVIRONMENT CONDITIONS

1. Designed for indoor use.
2. Operating Voltage of the device: 380 V AC ± 10 V and cannot be operated with any other electrical power.
3. Operating ambient temperature should be between +10 °C - 40 °C.

4. Operating humidity should be between 20% - 75% and below condensation values.
5. There should be a distance of at least 40 cm from the back and sides of the device and at least 100 cm from the top of the device to the ceiling.

1.5 STORAGE/TRANSPORTATION CONDITIONS

1. Store in a cool, dry, well-ventilated area away from sources of fire such as flames.
2. Store in a well-ventilated area away from sparks and static electricity, direct or indirect sunlight, heat, incompatible products, flammable materials.
3. Store in a container with a safety valve or ventilation hole.
4. Store in the original packaging, tightly closed.
5. Keep in an area surrounded by a set.
6. Check the condition and temperature of the containers regularly.
7. Information on special precautions required for bulk transportation is available upon request.
8. Rooms or storerooms should be made of non-flammable materials with impermeable floors.
9. Carry out regular checks to detect any abnormalities (body swelling, temperature rise, etc.).
10. When transporting the device; the device must always be on its own fixing feet, it must not be laid on any other surface, it must be securely fixed to the transport vehicle and the transport vehicle must be a closed box.

1.6 WHICH MATERIALS CAN BE STERILIZED WITH HYDROGEN PEROXIDE GAS PLASMA STERILIZER?

Medical equipment made of the following materials can be sterilized in GOLDBERG® Hydrogen Peroxide Gas Plasma Sterilizer:

CATEGORY A (very good material compatibility with H2O2 (no effect, no discoloration and no corrosion)
- Aluminum
- Glass
- Ceramic
- Polyvinyl Chloride (PVC)
- Polyethylene (LDPE)
- Polycarbonate
- Teflon (PTFE, PFA, FEP)
- Polyether Ether Ether Ketone (PEEK)
- Polystyrene
- Polypropylene
- Polyethylene terephthalate (Polyester)
- Styrene - ethylene - butadiene - styrene (Kraton)
- Latex

CATEGORY B (Good material compatibility with H2O2 (minor effects may occur with prolonged use).

- Stainless Steel
- Titanium
- Epoxy
- Acrylonitrile Butadiene Styrene (ABS)
- Silicones
- Polymethylmethacrylaye (Acrylic)

1.7 WHICH MATERIALS CANNOT BE STERILIZED WITH HYDROGEN PEROXIDE GAS PLASMA STERILIZER?

WARNING: Before sterilizing any material other than the A and B group materials listed above, check the compatibility of the material with Hydrogen Peroxide, if you are not sure, contact the manufacturer!

The following materials are not suitable for sterilization with Hydrogen Peroxide:
- Substances that have not been properly washed, disinfected and packaged before sterilization.
- Any material that is not completely dry.
- Substances or materials that contain Powder, Oil, Gel or Liquid, or have Liquid absorbent properties.
- Substances or materials containing cellulose or pulp such as cotton, paper or cardboard, linen fabric, towels, gauze.
- Equipment that cannot be immersed in and removed from liquid and will be difficult to clean, such as unsealed tampons with an inner side.
- Spreadsheet or date labels
- Single-use items for which a second sterilization is not recommended by the manufacturer.
- Dentures for which the manufacturer has not specifically recommended low temperature hydrogen peroxide steam sterilization.
- Instruments and equipment that are not vacuum tolerant and have a steam sterilization label in gravity conditions.
- Instruments and appliances with copper or brass components.

1.8 REASONABLY FORESEEABLE MISUSE

Reasonably foreseeable misuse is "the use of machines in a way not intended in the instructions for use, but which can be caused by easily foreseeable human behavior" and the following user behaviors fall into this area;

- Cooking Food: Using the sterilization device to cook food, e.g. chicken or other foods.

- Cleaning Personal Items: Placing personal items such as mobile phones, wallets or keys inside the device to sterilize them.

- Drying Clothes: Using the appliance to dry wet clothes or shoes.

- Sterilization of Chemicals: Attempting to sterilize chemicals inside the device without checking whether they are incompatible with the device

- Pet Cleaning: Attempting to clean small pets inside the appliance.

- Cosmetics Sterilization: Using the appliance to sterilize cosmetic products, makeup brushes or hair brushes.

- Diapers or Clothing: Attempting to sterilize baby diapers or clothing in the device.

Any such use that may jeopardize the performance and safety of the device is strictly prohibited and no responsibility will be accepted for any damage or malfunction that may occur to your device as a result of such use.

1.9 GENERAL SAFETY WARNINGS

Before operating the sterilizer, you must read and understand this User Manual, especially the safety information, warnings, cautions and notes in this section.

This information is necessary for your own safety and for the safe operation of the Goldberg Hydrogen Peroxide Gas Plasma Sterilizer.

WARNING: Indicates events or conditions that could result in injury, death or other serious adverse reactions to the user in connection with the use or misuse of the device.

CAUTION: Used for assembly and material hazards.

OPINION: Used for general explanations about the operation of the device.

PERSONAL SAFETY AND FIRST AID

WARNING! HYDROGEN PEROXIDE IS CORROSIVE

Hydrogen peroxide is corrosive to the skin, eyes, nose, throat, lungs and digestive system. Hydrogen Peroxide Sterilant may remain in the load or hopper after a cycle has been canceled or stopped. Chemical resistant latex, PVC (vinyl) or nitrile gloves should always be worn when handling the load after a cycle has been canceled or stopped.

WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER

Hydrogen peroxide is a highly corrosive and reactive substance; avoid contact with organic materials such as paper, cotton, wood, or greases. Concentrated hydrogen peroxide is a strong oxidizer and can ignite organic materials. Do not use or store near sources of heat or open flames. Any clothing or other flammable materials that come into contact with hydrogen peroxide should be thoroughly flushed with water immediately to prevent a potential fire hazard. In the event of a fire, only water should be used to extinguish.

WARNING! RISK OF SKIN IRRITATION

Direct contact of hydrogen peroxide with the skin can cause burns or severe irritation. Seek medical attention immediately. Remove contaminated clothing and shoes and wash the affected skin thoroughly with plenty of soap and water for at least 15 minutes. If irritation persists or worsens, seek medical attention.

WARNING! MOVING PARTS

Various parts of the body can get caught in moving parts (e.g., sterilization lids and sterilant loading units). Keep hands and other body parts away from these parts and ensure that the protective panels surrounding them are always locked.

WARNING: ELECTRIC SHOCK HAZARD

High Voltage is present in subcomponents, wiring, and circuitry.

WARNING! RISK OF EYE DAMAGE

Eye contact with Hydrogen Peroxide may cause permanent eye damage. In case of eye contact, immediately flush eyes with plenty of water for at least 15-20 minutes, occasionally lifting upper and lower eyelids. Remove your contact lenses, if any, and continue to rinse your eyes with water. Seek

medical attention immediately. DO NOT allow the person exposed to the substance to rub or cover the eyes.

WARNING! RISK OF RESPIRATORY IRRITATION

Harmful if inhaled. May cause respiratory irritation with burning pain in the nose and throat, coughing, wheezing, shortness of breath and pulmonary edema. Immediately take the person breathing the substance into the open air. If the person is not breathing, give artificial respiration. Give oxygen if the person has difficulty breathing. Get medical help immediately. DO NOT perform mouth-to-mouth artificial respiration.

WARNING! HOT SURFACE
The sterilization lid(s), the inside of the chamber and the shelves heat up during operation. Do not touch the inside of the chamber, the shelves or the lid(s) with gloves or bare hands. Turn off the sterilizer and allow it to cool before touching the lid(s) or interior surfaces.

WARNING! HYDROGEN PEROXIDE MAY LEAVE RESIDUE

Hydrogen Peroxide Sterilant stabilizers may leave a white residue. Chemical resistant latex, PVC (vinyl) or nitrile gloves should be worn if white residue is visible on the load. Regular maintenance through authorized services can reduce the white residue of Hydrogen Peroxide Sterilant stabilizer. Please follow the maintenance guidelines outlined in the "Preventive Maintenance" section of this manual in a timely manner.

Hydrogen Peroxide Sterilant may remain in the load or chamber after a cycle has been canceled or stopped. Hydrogen Peroxide is used as a Sterilant consumable in the sterilizer. Chemical resistant safety goggles and latex, PVC (vinyl) or nitrile gloves should always be worn when inserting/removing/ handling Hydrogen Peroxide Sterilant cartridges.

Indicates that the front of the body should be protected with an apron

Indicates the need to use eye protection

Indicates the need to wear a face mask

DEVICE SECURITY
CAUTION: MATERIAL COMPATIBILITY (What can be sterilized?)

Familiarize yourself with the compatibility guidelines and process limitations contained in this manual and how sterilization processes will affect them. Read, understand and follow the medical device manufacturers' instructions for their products. This guide shows specific types of items and materials that can be safely processed in specific cycle selections. Make sure you understand the parameters of each cycle type before processing your items. This guide is not intended to replace any instructions from medical device manufacturers. The device is not suitable for sterilization of fabric, materials containing water and cellulose, liquids, powders, copper, gels and materials containing or made of oil. If you have questions or are in doubt about the materials in your devices, contact the medical device manufacturer or Manufacturer/Representative for more information.

WARNING! RISK OF INJURY OR STERILIZER DAMAGE

The sterilizer must not be used in stacks with other equipment.

CAUTION: RISK OF BREACH OF WARRANTY
Improper treatment may limit our liability for damage to treated devices. Improper treatment may also void the warranty of your sterilizer. Improper service by unauthorized technicians will void the warranty**.**

CAUTION: RISK OF LOAD DAMAGE

Make sure that the load is correctly packaged and placed in the sterilization racks.

Do not use this device to sterilize your pressurized devices and equipment and materials that may become explosive or ignitable when in contact with an electrical load.

GOLDBERG® Series Hydrogen Peroxide Gas Plasma Sterilizers must be used by trained persons and this user must be the only person responsible for the device.

If the program is canceled during the operation of the device, the material loaded into the device to be sterilized must be re-prepared for sterilization and sterilization must be performed again. Pay attention to the shelf life of sterilized materials. Re-sterilize materials whose shelf life has expired.

Always use biological and chemical indicators in each cycle. Pay attention to the shelf life and storage conditions of the biological indicators you use. Do not use expired biological indicators. Always use packaging material suitable for Hydrogen Peroxide.

GOLDBERG® Hydrogen Peroxide Gas Plasma Sterilizer is an environmentally friendly and chemically safe device. It does not utilize flammable, explosive and toxic chemicals and does not emit ionizing radiation. GOLDBERG® Hydrogen Peroxide Gas Plasma Sterilizer does not contain pressurized parts.

Thanks to the Faraday cage provided by the device cabinet, there is no electromagnetic interference between the components inside the device and other nearby devices. Only the display is excluded from this protection. For this reason, devices that can generate strong EM waves, such as cell phones, should not be held closer than 4 cm to the screen.

It is recommended not to operate the device for more than 12 (twelve) hours in a day, and it is recommended to turn off the device if it will not be used for more than 8 hours.

If any liquid is spilled into the boiler, clean it immediately.

When the device is not in use, nothing should be left and stored inside.

Have the device serviced by our company or technical services authorized by our company on time.

SYMBOLS


Hot surfaces. It may cause injury. Do not touch without protective equipment.


Harmful chemicals.
Use protective equipment.


Corrosive chemicall.
Use personel protective equipment.


Oxidizing chemical. Avoid exposure, contact or ingestion. Use personel protective equipment.


WEEE Symbol


Use chemical resistant gloves.


Refer to user manual.


Wear mask


Vertical transport warning label


RF energy.
There is strong RF inside. Do not open theperimeter panels


Toxic chemical.
Avoid exposure contact or ingestion.


High voltage hazard


Alternative current


Warning label


Waste disposal warning sign! Do not throw away


In case of contact rinse with water


Wear goggles


Wear aprons.

STERILANT MATERIAL SAFETY
LABELING ACCORDING TO EC DIRECTIVES
Hazard Statements
: H272; It can strengthen the fire; oxidizer.
: H302; Harmful if swallowed.
: H314; Causes severe skin burns and eye damage.
: H332; Harmful if inhaled.
: H335; May cause respiratory irritation.
Precautionary Statements General
: P101; if medical advice is needed, have the container or label available.
P200 Precautionary statements
: P210; Keep away from heat / sparks / open flames / hot surfaces. No smoking.
: P220; Keep / store away from clothing / cotton, wool, leather etc./ combustible materials.
: P221; Take any precaution to prevent mixing with flammable / wood, grain, paper, etc. / organic materials that can be burned.
: P280; Wear protective gloves / protective clothing / eye protection / face protection.
: P260; Do not breathe its dust / smoke / gas / mist / vapor / spray.
: P261; Avoid breathing its dust / fumes / gas / mist / vapor spray.
: P271; Use only outside or in a well-ventilated area.
: P264; Wash skin thoroughly with water after handling.
: P270; Do not eat, drink or smoke anything while using this product.
HYDROGEN PEROXIDE GAS PLASMA STERILIZER
13
P300 Precautionary statements for intervention
: P312; if you feel unwell, contact the doctor / physician.
: P363; Wash contaminated clothing before reuse.

: P310; Call the POISON CENTER or doctor / physician immediately.
: P321; Special intervention required (see label)
: P330; Rinse your mouth.
: P304+P340; when inhaled - If breathing is difficult, remove the victim to fresh air and keep them in a comfortable position for easy breathing.
: P370+P378; In case of fire - Use water spray or water fog for extinguishing, (suitable material is specified by the manufacturer).
: P301+P312; if swallowed - If you feel unwell, call a POISON CENTER or doctor / physician.
: P301+P330+P331; when swallowed - Rinse your mouth. Do not induce vomiting.
: P303+P361+P353; In contact with skin or hair - Remove / take off immediately all contaminated clothing. Rinse your skin with water / shower.
: P305+P351+P338; In case of contact with eyes - Rinse carefully with water for a few minutes. Remove
contact lenses, if present and easy to do. Continue rinsing.
P400 Precautionary statements regarding storage
: P403+P233; Store in a well-ventilated area. Keep container tightly closed.
: P405; Store locked up.
P500 Precautionary statements for disposal
: P501; Dispose of contents / container in accordance with the Waste Management Regulation (29314).

EFFECTS ON HEALTH (H2O2)

Eye Contact:

Causes eye burns. It causes a burning sensation, redness, watery eyes, inflammation and possible damage
to the cornea.

Skin Contact:

Causes superficial burns on the skin.

If Swallowed:

It can cause major and permanent damage to the digestive system. Causes burns in the digestive tract. It
can cause perforation of the digestive system. It can cause severe damage to the digestive system with
symptoms of abdominal pain, nausea, vomiting and diarrhea.

In case of inhalation:

Harmful if inhaled. It may cause respiratory tract damage and pulmonary edema, manifested by burning
sensation in the nose and throat, coughing, wheezing, and shortness of breath. Causes chemical burns in
the respiratory tract. It can cause ulceration of the nasal tissue, insomnia, numbness and tremors in hands
and feet, chemical pneumonia, loss of consciousness and even death.

Chronic Injuries:

Prolonged repeated skin contact may cause inflammation.

1.10 FIRST AID AND MEASURES

- ✓ Eye contact: Rinse eyes immediately with plenty of water for at least 15-20 minutes. During the procedure, lift your eyelids at intervals. Get medical help immediately. Do not allow the person to rub or keep their eyes closed.
- ✓ Skin Contact: After removing your hydrogen peroxide contaminated clothes and shoes, wash the skin with plenty of water and soap. If irritation develops and persists, seek medical attention. Wash your clothes before wearing them again. Dispose of contaminated shoes.

- ✓ Swallowed: Get medical help immediately. Do not induce vomiting. If the victim is conscious and awake, give 2-4 cups of water or milk. Never try to give anything by mouth to an unconscious person. Call the National Poison Information Center.
- ✓ Inhalation: Get medical help immediately. Take the person outdoors. If there is no breathing, give artificial respiration. If breathing is slow, give oxygen.
- ✓ Notes for Medical Doctors: Use symptomatic and supportive therapy.

2. DEVICE CONTROL SYSTEM AND SPECIFICATIONS

2.1 DEVICE CONTROL SYSTEM AND SPECIFICATIONS

- Monitoring and management of control and sterilization phases from the screen with the help of PLC (Programmable Logistic Controller)
- Full control with electromagnetic compatibility tested control unit
- Microprocessor controlled main control system
- Programs that have undergone Conformity Tests according to TS EN ISO 14937 validation standard

PROGRAM CHART

PROGRAM	DURATION (MIN.)*	NUMBER OF CAPSULES USED	DESCRIPTION
Non Lumen	28-32	2	Non Lumen equipment, Devices with simple geometry (Load < 5 kg)
Standard	45-49	2	All non-lumen program tools and devices Endoscopes and other lumen instruments (Lumen diameter > 1.5 mm)
Intensive	55-58	2	All standard program tools and devices Endoscopes and instruments with narrow channels and long lumens (Lumen diameter > 0.7 mm)

* The variation in sterilization time is related to different sized device cabinets. In addition, there may be an increase in process times depending on the load not being dry enough and the type of load. Hollow containers and non-woven synthetic textile products increase the duration of the program as they prolong the vacuuming time.

2.2 STERILIZATION CONTROL SYSTEM

- Network connection via Ethernet connection (TCP/IP) (optional)
- Possibility to connect to the central computer system and other computers via RS 232 output socket and remote access.
- Access to error information in writing by the user
- Ability to monitor, change and save the values selected for programming from the graphical display
- Possibility to measure pressure with a pressure transmitter,
- Continuous control of device safety elements with PLC system
- Ability to Monitor Parameters During Sterilization from the Screen
- Which program is used
- Cell pressure and temperature value
- The time of the sterilization phase and, in case of any error, the name of the error.

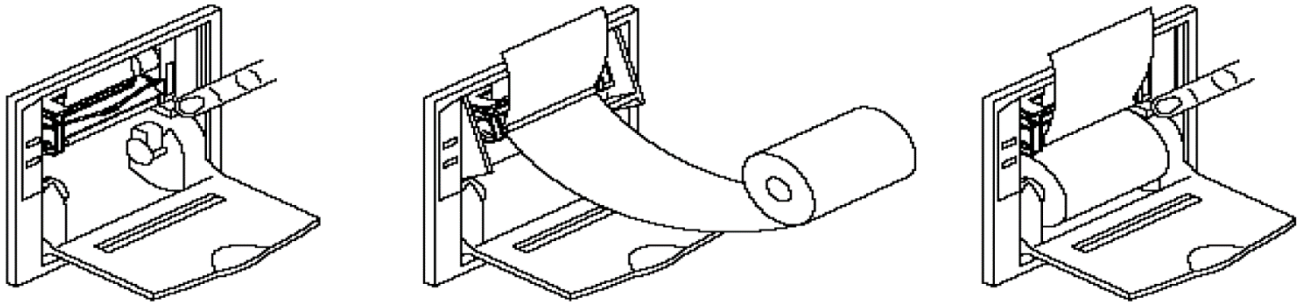
2.3 PRINTER

The basic device output used to store sterilization records is provided via printer.

2.3.1 CHANGING PRINTER PAPER

1- Pull the cover handle until the printer cover is released from the locked position.

2- Remove the remaining paper.
3- Unroll a few centimeters from the new paper roll
4- Since you will be inserting a new roll of paper into the hopper, keep about 5 cm of the paper outside the device.
5- Close the lid by applying even pressure on all sides of the lid until the lid is in the locked position



2.4 HYDROGEN PEROXIDE CARTRIDGE INSERTION

GOLDBERG® Hydrogen Peroxide Sterilizer uses 59% sterilization agent (H2O2) with cartridge system. Each cartridge contains 12 H2O2 capsules. The device obtains the required amount of H2O2 from these capsules according to the selected program. The operator using the device must wear heat and H2O2 resistant gloves. The insertion direction of the cartridge is indicated by the arrows on it. When inserting the cartridge into the device, care must be taken to ensure that this arrow direction is correct. If the cartridge is inserted incorrectly, the sensor activates and warns the user visually and the device does not work. In this case, the cartridge must be removed and placed back into the device in the correct direction.

2.5 SERVICE DOOR

The service doors of the device provide access to the internal modules. The service door is not for end user use and special equipment is required to open this passage.

2.6 USB INPUT

The USB port is for the user and serves different purposes. This port can be diversified with different types of adapters if required. The use of the USB port can be, but is not limited to, the following;

External Printers: In order to comply with the organization's documentation standards and policies, the end user may wish to use a variety of external printers. In order to connect external printers to the device, their software must be installed on GOLDBERG®'s operating system. The installation of such software requires GOLDBERG® service support. This service is available as an option.

Data Backup: The end user can obtain a copy of the validation information stored in the device.

Tracking Devices: The end user may wish to utilize different types of tracking devices such as barcode readers, printers or RFID products to comply with the institution's sterilization load monitoring standards and policy. In order to connect such external devices, the software for these devices must be installed in /GOLDBERG®'s operating system. Installation of such software requires service support from /GOLDBERG®. This service is offered as an option.

External Storage Devices: In order to comply with the institution's sterilization validation policy, the end user may wish to utilize various external storage devices to make periodic backups of the device's validation information. The connection of such external devices requires the installation of their software in /GOLDBERG®'s operating system. Installation of such software requires service support from /GOLDBERG®. This service is available as an option.

2.7 ETHERNET PORT

The Ethernet port of the GOLDBERG® device is used for external data transfer. The Ethernet port can be connected to a distribution device, router or a suitable entry point. The device then obtains a virtual IP address from the subnet of the end user's network system or a real IP address over the internet. The end user can utilize the Ethernet port for, but not limited to, the following applications. This feature is optional.

Data backup and utilization over a network or the internet: The end user can connect to the device over a network and use stored validation data and device information for backup or evaluation. The network connection of the device requires GOLDBERG® service and in some cases plug-in software. In some cases, when the end user is using monitoring or validation software from a different provider (server), cooperation with this provider may become mandatory. This feature is optional.

Remote firmware update: The end user may require a remote firmware update. The device can only be accessed for remote system control from GOLDBERG® on a temporary or permanent basis with the express written consent of the end user. This feature is optional.

2.8 DOUBLE DOORS SYSTEM

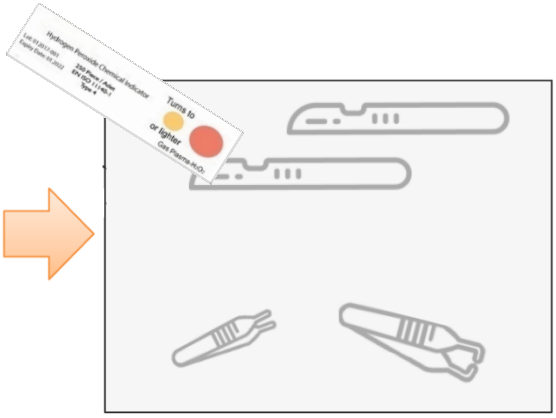
The double-door pass-through option of the device is designed to meet the clean and dirty area separation requirements of modern central sterilization units. In case of unsuccessful termination of the sterilization cycle, the sterilization load is returned to the contaminated handling area. If a situation such as stopping or stopping is encountered in the device, if the door of the device is double-door, it is opened from the dirty side and either the loads are taken back or the program is restarted without opening the door at all.

2.9 PROCESS CONTROL

WEEKLY ROUTINE CONTROL

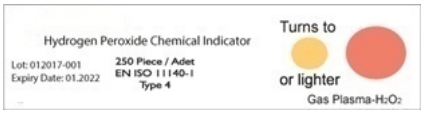
All maintenance operations of the device are carried out by technical personnel trained and authorized by the company. However, the responsibility for routine process control of the sterilizer rests with the healthcare facility operating the device.

One H2O2 Chemical Indicator should be placed in each sterilization package.



Each day, the first sterilization program of its kind should be placed in the Tyvek pack with a Biological Indicator load. Recommended use is one Biological Indicator in Tyvek pack per treatment.

Chemical Indicators, s use sensitive chemicals to evaluate physical conditions such as temperature during the sterilization process. Chemical indicators such as heat sensitive tape rapidly change color when a certain parameter is reached. An internal chemical indicator should be placed in each sterilization package to ensure that the sterilizer has penetrated the packaging material and reaches the instruments inside..



(Pictures show a strip not exposed to the sterilizing agent) Success = the color transition indicated on the chemical indicator used after exposure has occurred.

Biological Indicators, sare the most accepted tools for monitoring the sterilization process, as they donot only determine whether the physical and chemical conditions required for sterilization are met, they directly determine whether the most resistant microorganisms (e.g. Geobacillus or Bacillus species) are present.

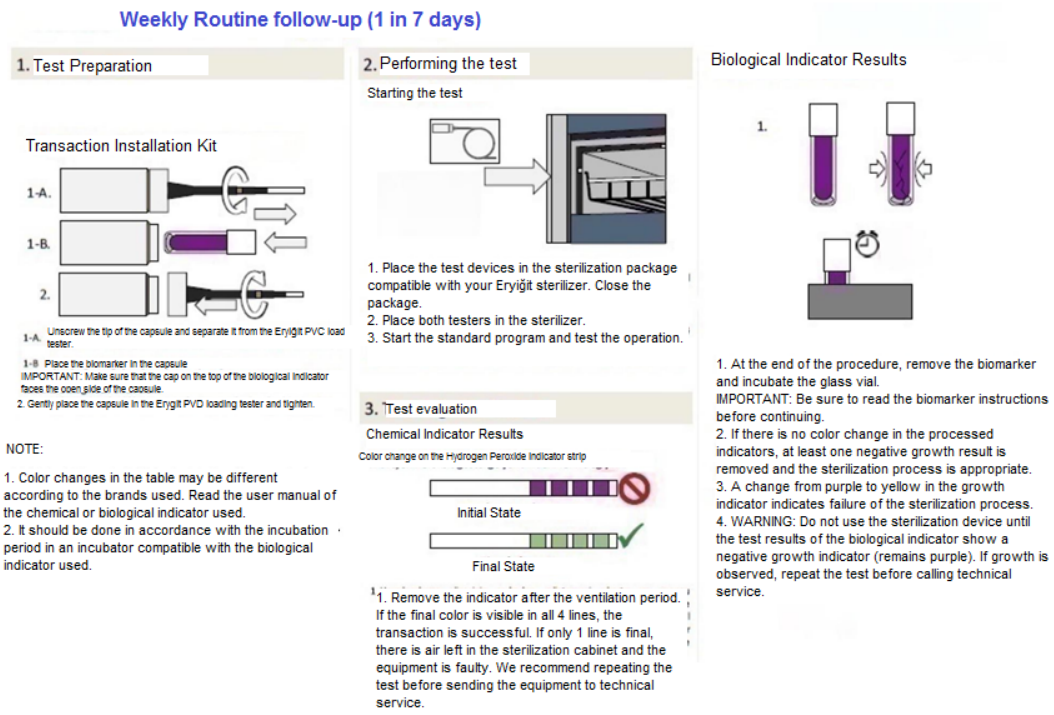
Because the spores used in Biological Indicators are more resistant and present in greater numbers than common microbial contaminants detected in patient care equipment, an inactivated Biological Indicator indicates that other potential pathogens in the burden have also been killed.

Eryiğit A.Ş. proposes to use a biological indicator placed in a teflon box behind 2mmx1200mm PTFE lumen for regular process control. This PTFE kit, also called Eryiğit process validation kit (device), can be obtained from Eryiğit A.Ş.

After the biological indicator has been placed in the kit, the kit should be placed in the most inaccessible part of the empty vessel for the sterilant in accordance with ISO 14937. In Goldberg Hydrogen Peroxide Gas Plasma Sterilizers, the most difficult part of the sterilant to access is the front (near the door) of the lower shelf. After the kit is placed here, the door should be closed and the Standard Program should be started.

At the end of the process, the biological indicator should be removed from the lumen, placed in the reading device and the result should be checked. If the result is positive, Eryiğit A.Ş. must be notified immediately.

This procedure allows the operator to detect any noticeable deviation in the performance of the sterilizer or Sterilant and thus stop the use of the equipment until the defects are corrected.



3. TECHNICAL INFORMATION

3.1 BOILER (CELL) AND DEVICE DIMENSIONS OF THE MODELS

S/N	MODEL	Door Type	Boiler Dimension			Device Dimension			
			Width (mm)	Height (mm)	Depth (mm)	Width (mm)	Height (mm)	Depth (mm)	Weight (kg)
1	TEKSTERİL TSP80	Single Sliding Door	450	400	560	740	1850	1000	330
2	TEKSTERİL TSP120	Single Sliding Door	450	400	700	740	1850	1000	350
3	TEKSTERİL TSP135	Single Sliding Door	450	400	800	740	1850	1000	380

4	TEKSTERİL TSP160	Single Sliding Door	450	400	930	830	1850	1350	400
5	TEKSTERİL TSP200	Single Sliding Door	450	400	1150	830	1850	1350	440

S/N	MODEL	Door Type	Boiler Dimension			Device Dimension			
			Width (mm)	Height (mm)	Depth (mm)	Width (mm)	Height (mm)	Depth (mm)	Weight (kg)
1	GOLDBERG GP40*	Single Sliding Door	295	295	425	554	900	481	123
2	GOLDBERG GP80	Single Sliding Door	450	400	560	740	1850	1000	330
3	GOLDBERG GP120	Single Sliding Door	450	400	700	740	1850	1000	350
4	GOLDBERG GP120D	Double Sliding Door	450	400	700	740	1850	935	350
5	GOLDBERG GP135	Single Sliding Door	450	400	800	740	1850	1000	380
6	GOLDBERG GP135D	Double Sliding Door	450	400	800	740	1850	1035	380
7	GOLDBERG GP160	Single Sliding Door	450	400	930	830	1850	1350	400
8	GOLDBERG GP160D	Double Sliding Door	450	400	930	830	1850	1165	400
9	GOLDBERG GP200	Single Sliding Door	450	400	1150	830	1850	1350	440
10	GOLDBERG GP200D	Double Sliding Door	450	400	1150	830	1850	1385	440

*This model is an R&D project. Size and other information about this model may be revised.

3.2 VOLUME AND POWER TABLE BY STERILIZER MODELS

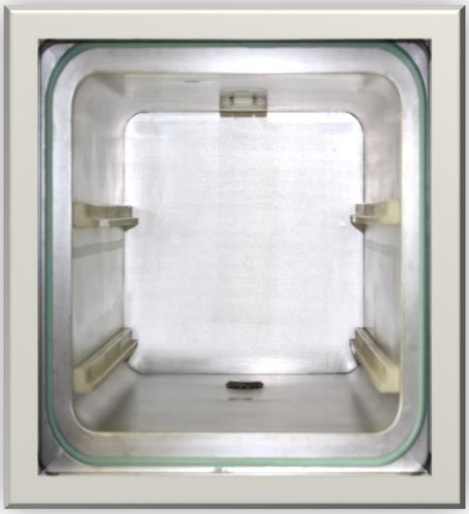
MODEL	TSP 80/ GP 80	TSP 120/ GP 120	TSP 135/ GP 135	TSP 160/ GP 160	TSP 200/ GP 200
Volume (L)	80	120	135	160	200
Power Consumption (kW)	2.8	4.1	4.1	5.5	5.5

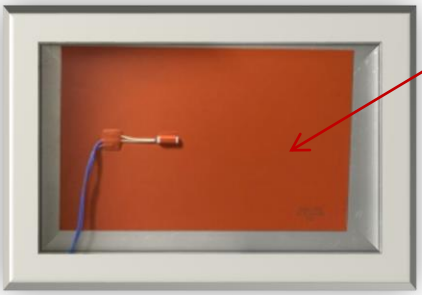
3.3 TECHNICAL SPECIFICATIONS

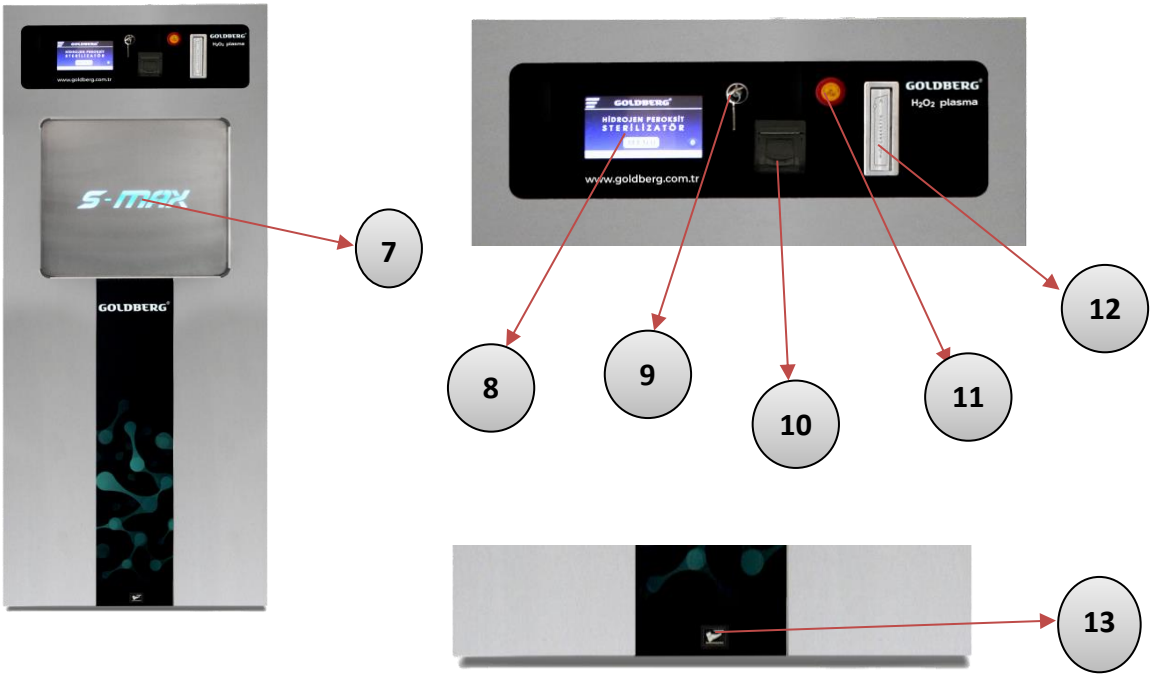
TECHNICAL SPECIFICATIONS	
Chamber Shape	Rectangular Prism
Chamber Material	Aluminum
Number of Trays	2 units (each with 30 kg. carrying capacity)
Door	Automatic Sliding Door with Jam Sensor
Thermal Printer	Yes
Foot Petal	Yes
H_2O_2 Concentration	%59
H_2O_2 Steam Injection	6 different points / Homogeneous Diffusion
Touchable Screen	7" (10" Optional)
Electrical Connection	3 Phase, 380 V, 50/60 Hz, Cable 5x4 mm2
Device Ready Time	15 - 30 min
Sterilization Temperature	40 - 55 oC
Sterilization Duration	Lumen-free: 30 ± 2 min, Standard: 45 ± 2 min, Dense: 57± 2 min
Number of Cycles/ Cartridge	Lumen-free:6, Standard:6, Dense:6
Number of Cartridge	12 independent
Ventilation	HEPA filter (0.01 µm)
Plasma Location	Boiler top
Plasma Power Supply	120 W HF (High frequency)
Electronic Control	PLC
Remote Access to the Device	Yes
User Access Level	Operator / Supervisor/Service
Logo Colouring	Yes (Blue, Red, Green) / Remote Process Status Monitoring
Waste Product	Water and Oxygen
Protection Against Liquid and Solid Ingress	IP00

4. DEVICE PARTS AND THEIR DESCRIPTIONS

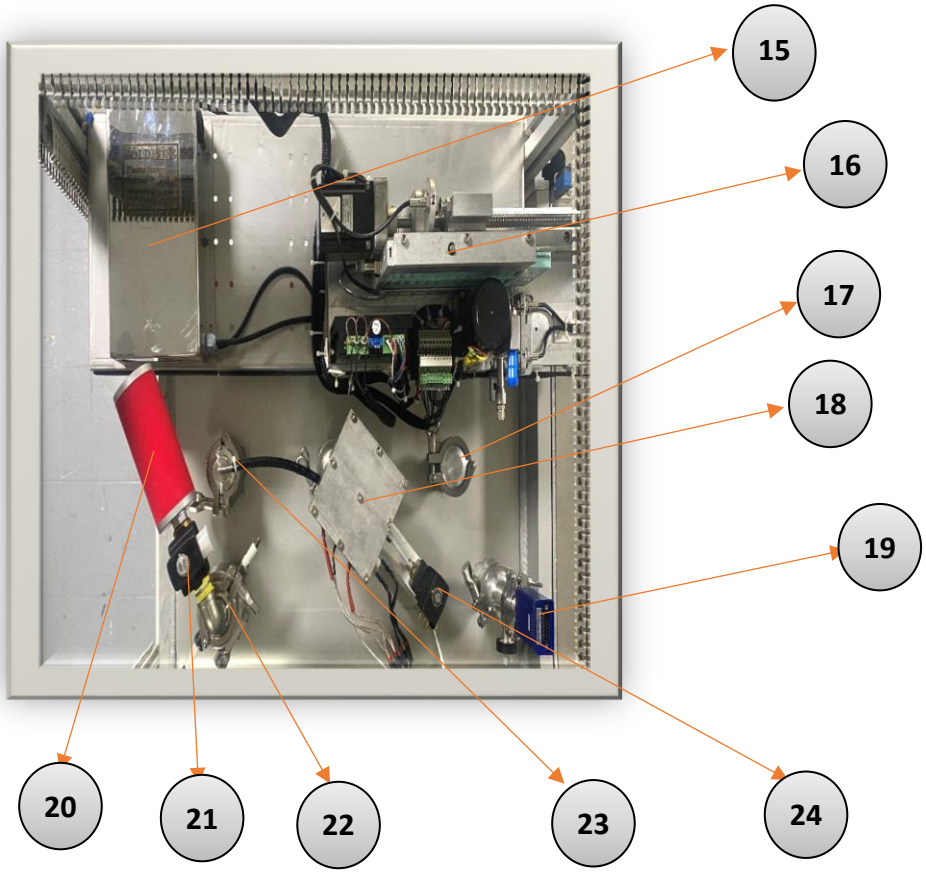
SN	Component Foto	Component Name	Component Description
1		Chassis	It is the carcass that collects all the elements of the sterilizer on it. The side covers on the chassis can be easily removed and installed. This facilitates technical intervention to the device. The device can move easily thanks to the wheels connected to the chassis.

SN	Component Foto	Component Name	Component Description
2		Sterilization Room Cell	It is manufactured in the form of a rectangular prism or cylinder. It is the volume where sterilization takes place. It is completely made of aluminum.
3		Gasket	It is used for sealing the cover system of the device. 100% vulcanized silicone based.

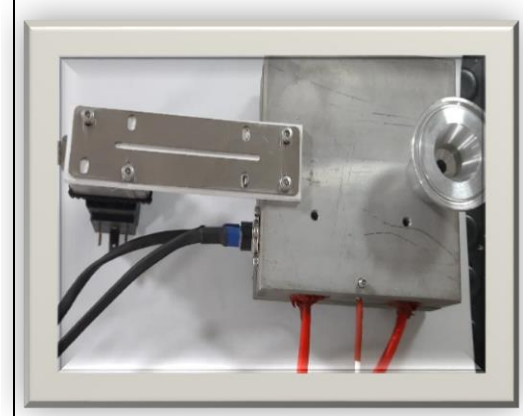
SN	Component Foto	Component Name	Component Description
4		Sterilization racks	Sterilization racks are for keeping the materials in the boiler in an orderly manner.
5		Leaf Resistance	It is used to keep the boiler temperature at the desired level.
6		Isolation	Glass wool is used as insulation material in the sterilizer boiler and heat areas. Thanks to the insulation, heat transfer from the device to the outside and from the outside to the device is isolated.

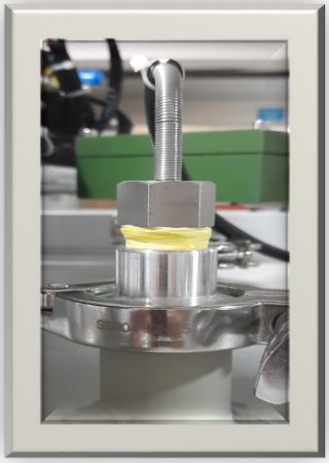
SN	Component Foto	Component Name	Component Description
			
7	**LOGO COLORING**		
	S-MAX (Flashing)	Indicates that the device is being prepared for use.	
	S-MAX	Indicates that the device is ready for use.	
	S-MAX	Indicates that the process has been stopped for any reason before completion.	
	S-MAX (Yanıp-sönen/Flashing)	Indicates that the operator needs to perform an operation on the device. For example, changing a cartridge during the cycle.	
	S-MAX	Indicates that the sterilization process has started and the device is in the sterilization process.	
	S-MAX (Flashing)	Indicates that the sterilization process has been successfully completed.	
8	Monitoring Screen	The monitoring screen is an LCD touch screen. It allows the sterilization process to start, stop and monitor the process. It allows temperature, time, pressure and program phases to be monitored and controlled on the screen.	

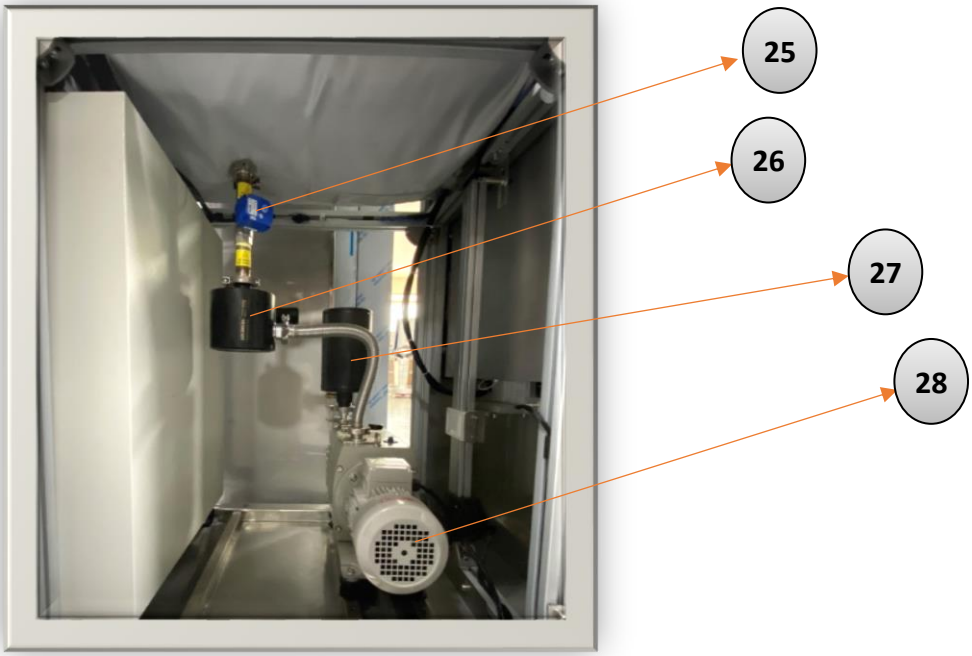
SN	Component Foto	Component Name	Component Description
9	On/Off Switch	It is the switch that turns the device on and off.	
10	Printer	It is used to print out the operations performed by the device. There is a thermal or cartridge ribbon printer on the device.	
11	Emergency Stop Button	In any adverse situation, it ensures that the device stops when pressed.	
12	Cartridge Entry	The place where the hydrogen peroxide cartridge is installed.	
13	Foot Pedal	Allows the front door to be opened by foot.	
14		Electric Panel	It is the main location for electrical power and control equipment.

SN	Component Foto	Component Name	Component Description
			
15		Plasma Power Supply	It is the power supply that provides high voltage to the plasma unit to obtain the plasma phase.

SN	Component Foto	Component Name	Component Description
16		Cartridge Driver	The cartridge driver is used to move the cartridge to the desired position.
16a		Hydrogen Peroxide Cartridge	Contains 59% hydrogen peroxide sterilization agent. There are 12 tubes in the cartridge and each tube contains 4.5ml ±0.5 ml of H2O2 sterilization agent.
17		Validation Port	It is the port for device validation. Different measurements such as temperature and pressure can be made from this port.

SN	Component Foto	Component Name	Component Description
18		EVAP	It allows the hydrogen peroxide solution to evaporate and turn into gas.
19		Precision Pressure Sensor	With this sensor, the pressure inside the cell can be measured precisely.
20		Ventilation (air) Filter	It filters and cleans the air entering the device with the help of Hepa Filters with 0.2 or 0.3 micron pores and 99.99% bacteria filtration.

SN	Component Foto	Component Name	Component Description
21		Air Valve	It allows the device to take air from outside during pressure equalization.
22		Plasma Unit	It is the unit that ensures the breakdown of H2O2 molecules by creating the plasma phase while the boiler is under vacuum.
23		Temperature Sensor (PT 100)	Measures the temperature inside the device.

SN	Component Foto	Component Name	Component Description
24		Gas Valve	It is used to pass H2O2 liquid from the cartridge to the EVAP.
			

SN	Component Foto	Component Name	Component Description
25		Vacuum Valve	The vacuum valve is the valve for opening and closing the connection between the cell and the vacuum motor.
26		Pre-filter	This filter prevents harmful particles from entering the vacuum motor through the boiler.

SN	Component Foto	Component Name	Component Description
27		Exhaust Filter	The exhaust filter is used to prevent the release of harmful gases from the vacuum motor.
28		Vacuum Motor	Provides vacuuming of air or H2O2 gas inside the cell.
29		Wheel and Rubber Feet	The device has 4 wheels for easy movement and adjustable rubber feet to ensure the stability of the device.
30		Up Down Buttons	Buttons that allow the device back cover to move up or down.

5. INSTRUCTIONS

5.1 STERİLİZATÖR MONTAJ TALİMATI

TEKSTERİL/GOLDBERG® Hidrojen Peroksit Sterilizatörünün kurulumunun, Eryiğit A.Ş. teknik servisinden bir personel tarafından yapılması gerekmektedir. Söz konusu teknik personel, açma/kapama düğmesini kullanarak cihazı çalıştırır. Başarılı bir şekilde kurulduktan sonra, cihazın kurulumu sonlandırılmak istenmiyorsa, bu düğme kapatma durumuna getirilmemelidir.
Cihaza elektrik sağlanmasını takiben 20 saniye içerisinde ana menü kullanıcı panelinde görünür.
Kurulum prosedüründe, teknisyenin bir test programı çalıştırması ve bu test raporunun çıktısını kurulum dokümanlarına iliştirilmesi gerekmektedir.

NOT: Cihazı forklift yardımı ile dik şekilde taşıyınız. İndirdiğiniz yerden kurulacağı yere kadar da cihazın tekerleklerini kullanarak götürünüz. Cihazı kesinlikle yan yatırmayınız ve 30°'den fazla eğmeyiniz.

5.1.1 PRE-ASSEMBLY PREPARATIONS

5.1.1.1 Electric Line and Panel

a. The INSTALLED POWER at the place where the device will be installed must be known.
b. The electrical line coming to the panel must be made of a single piece of cable, no additional cables should be used. The cable should be 5x4 mm^2.
c. The ground line coming to the panel must be made by qualified persons in accordance with the standards.
d. All switches and fuses used in the panel must comply with the standards.
e. The place where the panel is located should not be close to the water system or line.
f. The electricity coming to the panel should provide a 3-phase 380 V AC ±10 Volt voltage. There is a phase protection relay in the device in case the phase sequence is not correct. In such a case, when the device is turned on, "Phase Error" warning will be seen on its screen. The problem is solved by changing the phase order.
g. A fuse should be used depending on the electrical power consumed by the device in the panel.
h. Since our devices are designed and manufactured according to the principles of EN 61010-2-40, they do not produce critical interference with other devices produced with the same standards.

5.1.1.2 General Area Requirements:

a. The floor and walls where the device will be used must be suitable for removing accumulated dust and preventing microbial contamination.
b. Ceilings should be constructed to minimize condensation, dust accumulation and potential sources of pollution. It should not allow sticking and holding.

c. Ventilation should be ensured that the air present in the space is filtered from the clean area to the dirty area, with at least 10 air changes per hour.

5.1.1.3 Ambient Temperature and Humidity

a. The ambient temperature in which the device will be installed should not exceed +10 °C to +40 °C.
b. The humidity of the environment should be between 20% and 75% and definitely below the condensation values.

NOTE: There must be a distance of at least 40 cm from the back and sides of the device, and at least 100 cm from the top of the device to the ceiling.

5.2 STERILIZER OPERATING INSTRUCTIONS

PRE-PREPARATION

Before sterilization, a cleaning process is required to remove all organic and inorganic residues from the sterilization load. According to EN ISO 17664, all blood, tissue and other residues in the sterilization load should be cleaned with hot water and detergent containing enzymes in accordance with the manufacturer's instructions for the instruments or devices in question. To ensure effective sterilization, cleaning, rinsing and drying must be carried out as specified in the approved methods.

After cleaning, the sterilization load must be dried. The material must not remain damp in any way. Only dry materials should be placed in the sterilization chamber.

If the sterilization load is damp, the sterilization process will take longer or even fail!

- Preparation of the sterilization load continues with the packaging. Do not use bags containing paper for packaging!
- Do not sterilize instruments containing sponges.
- AVOID using materials or materials containing cellulose or pulp, such as cotton, paper or cardboard, linen fabric, towels, gauze in packaging. If needed, use polypropylene wrap (Wrap).

LOADING THE STERILIZATION CHAMBER

The sterilization chamber should be loaded in such a way that the gas can circulate freely and penetrate each package. For this:

- Use polypropylene wrap and Tyvek® bags compatible with hydrogen peroxide steam sterilization for packaging.
- The transparent surfaces of Tyvek® bags are not gas permeable; only opaque, white surfaces are gas permeable. Therefore, do not stack Tyvek bags; Place them side by side and vertically. The best way to do this is to place the packages upright and side by side in a stainless steel basket. Packages that you place directly on the shelf, not in a basket, may lie on their side and partially cover each other during vacuuming, even if you put them upright at the beginning.
- Packages should not touch any wall of the chamber; There should be a gap of 2 cm between the packages and the side walls, and at least 3 cm between the top wall. Otherwise, it will block the gas

circulation, and sufficient sterilant contact may not occur in overheated instrument.

- Large tools that cannot fit in the basket can be placed horizontally. However, in this case, there should be no other packages above or below them.
- Materials to be sterilized should be placed on device shelves or baskets without being compressed and forcefully applied.
- Rubber gloves and lumens should be laid flat and not folded.
- Always prefer the upper compartment for long and narrow lumens when loading. Lumen instruments refer to perforated/hollow pipes and hoses.
- Keeping the lid of the device open for a long time when it is not working may prolong the vacuuming time in the next sterilization process.

6. DEVICE OPERATION AND SCREEN APPLICATION

To turn the sterilizer ON, insert the switch into the slot and turn it clockwise from OFF to ON.
When the device is switched on, the following screen appears. Press the "MENU" button on the touch screen to access the programs screen. Press the "SETTINGS" button to access the service screen.

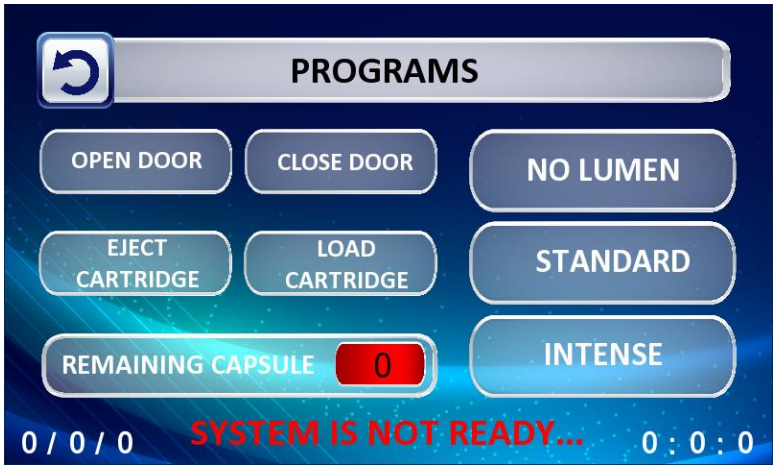
LOADING THE CARTRIDGE

If the remaining number of capsules is "0", a new cartridge is loaded. First of all the empty cartridge must be removed. Then Press the "Eject Cartridge" button on the touch screen and wait. When the cartridge comes out, it is taken out of its slot by holding it by hand and pulling it outwards. The full cartridge is pushed into the slot and the "Load Cartridge" button is pressed. The cartridge is automatically replaced.

After opening the door of the device from the programs screen and placing the loads in the chamber properly, the door is closed. The sterilization process is started by selecting a suitable program according to the amount and characteristics of the load placed in the cabinet. When the number of "Remaining Capsules" is "0" or the device cover is open, program cannot be selected and therefore the device cannot be operated. If the remaining number of capsules is not sufficient for the selected program, the program can be started, but the cartridge must be loaded during the cycle. When it's time to load cartridges in the process, the S-MAX logo will flash red.

Program Selection

The device has 3 different programs. Since the device works automatically, the main task of the user is to select the appropriate program for the load to be sterilized.



Program (Non Lumen, Standard or Intensive) should be selected according to the type of material to be sterilized and the loading amount. The user must select one of these three programs based on the size of the remaining free space, the lumen characteristics, and the critical mating surfaces of the sterilization load. You can use the guide below when making this choice:

The Two Golden Rules of Program Choice:

1. In a sterilization load containing different instruments, the program of the device that requires the longest program is selected. Even if there is only one of these tools…
2. If you are undecided between the two programs, choose the longer one.

Non Lumen Program:

The Non Lumen Program can be selected for:

1. General medical devices requiring only surface sterilization;
2. Tools such as scissors and forceps made of stainless steel and titanium with a partially covered surface
3. Non lumen Rigid, semi-rigid and flexible scopes.

Examples of instruments that can be sterilized in the Non Lumen Program are:

- Non Lumen scopes such as rhinoscope, otoscope
- Non lumen general surgery instruments
- Paddle type defibrillator electrodes
- Non Lumen scopes such as rhinoscope, otoscope
- Ophthalmology instruments
- Cables and cords
- Laryngoscope blades
- Batteries, control instruments

- Cameras

Standard Program:

Standard Program is primarily used to sterilize flexible endoscopes and bronchoscopes (such as those used in ENT, urology, and surgical care). Devices with stainless steel lumen can only be sterilized in the Intensive program. Anything that can be sterilized in the Non Lumen Programs can also be sterilized in the Standard Program.

Examples of instruments that can be sterilized in the Standard Programs are:

- Non-illuminated rigid endoscopes (telescopes)
- Surgical endoscopes
- Single-channel flexible endoscopes with an internal diameter of 1.5 mm or greater and a length of 100 cm or less
- Dual-channel flexible endoscopes up to 85 cm long with the same diameter
- Endoscopes
- Bronchoscopes
- Small diameter flexible scopes such as hysteroscopes, cystoscopes, ureteroscopes and choledoscopes
- All Lumen-Free Program tools and devices

The following should be considered in sterilization with the Standard Program:

1. Up to 2 flexible endoscopes with light cables can be sterilized per load or
2. In each load, 1 flexible endoscope as above and non-lumen instruments weighing up to 5 kg can be sterilized.
3. Instruments such as scissors and forceps made of materials other than stainless steel and titanium with a partially covered surface

Intensive Program:

The Intensive Program is available for:

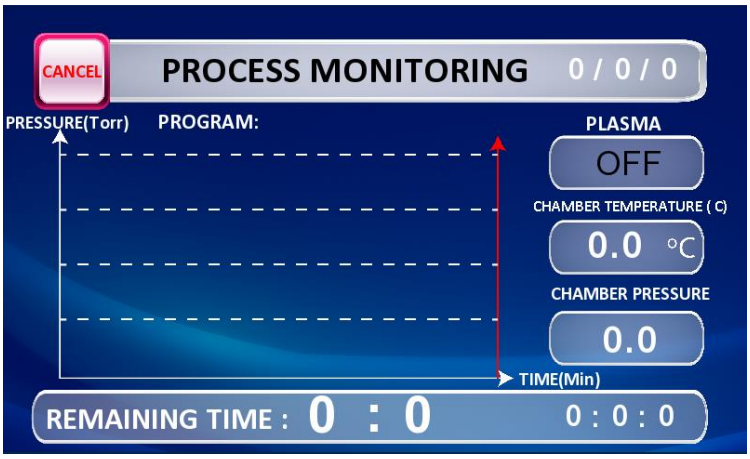
Dual-channel flexible endoscopes up to 85 cm long with an inner diameter of less than 1.5 mm and a lumen of more than 100 cm, the same diameter as flexible endoscopes

1. Among the lumen, stainless steel devices, those with a length of 30 cm or more are recommended to be sterilized on the intensive program.
2. All instruments and devices that can be sterilized in the Short and Standard Program, except cameras. Cameras and electronics should not be sterilized in the Intensive Program as they may contain copper parts that may be affected by hydrogen peroxide.

Examples of instruments that can be sterilized in the Intensive Program are:

- Rigid and semi-rigid endoscopes and laparoscopic instrument sets (arthroscopes, cystoscopes, ureteroscopes)
- Instruments such as trocars, resectoscopes, cannulas made of stainless steel
- Handpieces of energy-based devices such as laser or ultrasonic
- Non Lumen and Standard Program instruments and devices

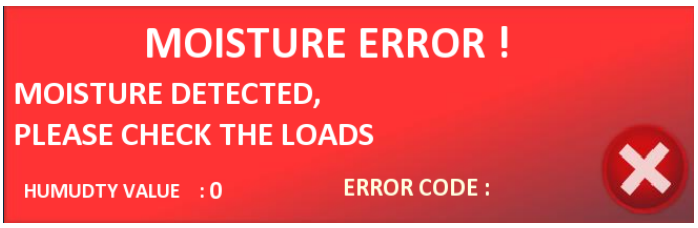
STERILIZATION PROCESS



After deciding on the program to be used, when the program is selected and sterilization is started, you will see the screen above. The sterilization process can be followed from the beginning to the end from this screen. On the left side of the screen, there is a graph with time on the horizontal axis. In this graph, it is possible to monitor the pressure and temperature inside the chamber continuously.

On the right side, you can see whether the plasma module is active or not as "ON-OFF" and the cabin temperature and pressure can be seen with their instantaneous numerical values. At the bottom, the time remaining until the end of the sterilization program and the time of the device are displayed.

The sterilization process starts by pre-vacuuming the cabinet. After the pre-vacuum is completed, the device vacuums again. During vacuuming, the device automatically detects moisture. If the humidity of the load is higher than the maximum permitted value, the program is automatically canceled and the following screen appears:



Humidity Failure Error

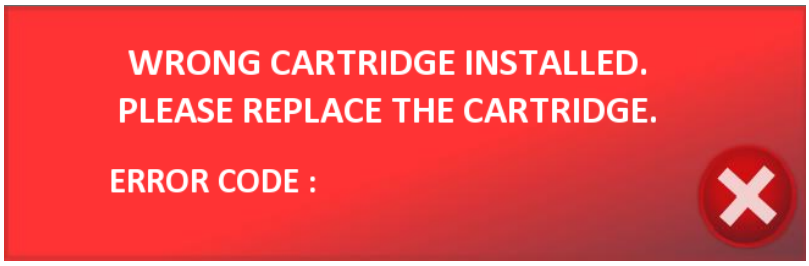
In these cases, the operator should open the device door and check whether there is any moisture left in the sterilization load. Once it is sure that the sterilization load is dry, the sterilization process can start again.

After the moisture test, the inside of the vessel starts to be vacuumed again. When the in-vessel pressure drops to 10 Torr, the vacuum valve closes and the device performs a vacuum leak test. In this test, the internal pressure can go down to the range of 8-9 Torr as the vacuum pump will also operate while stopped. For 20 seconds the vacuum increase is checked. If the increase is less than allowed, the program continues to run. If it is more, it gives "Vacuum Leakage Error" and stops the program and ventilates the boiler.

When the vacuum reaches sufficient level, Hydrogen Peroxide vapor is given to the cabin. Hydrogen Peroxide vapor reaches the inner and outer surfaces of all loads within a certain period of time. After each diffusion process, the cabin is ventilated for a certain period of time. At the end of the cycle, the cabin is vacuumed and ventilated several times to remove any residual Hydrogen Peroxide.

Other errors that may be encountered during the sterilization process and their explanations are as follows:

This error occurs when the chamber cannot be lowered to the appropriate vacuum (1 Torr). It may be due to the presence of cloths containing paper or cellulose in the sterilization load. Therefore, in this error case, the sterilization load needs to be checked. If the load is properly placed, it could mean a



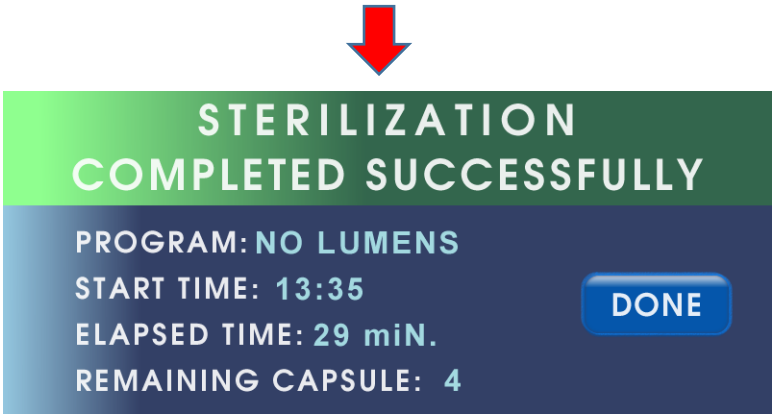
vacuum leak in the sliding door. Therefore, it is necessary to contact the technical service.

This error occurs when a cartridge not approved by the manufacturer is inserted into the device or a depleted cartridge is inserted. The user needs to check the cartridge.

Gas Failure error occurs when hydrogen peroxide vapor cannot be introduced into the chamber. In such a case, the user should check the cartridge, if there is no problem with it, the technical service should be contacted.

Sterilization Pressure Error is a very rare error. It has been set in case the gas valve does not close after gas intake and therefore too much air enters. If this occurs, technical service should be contacted.

When the sterilization process is successfully completed, the following screen appears. When service time is approaching, a warning appears on the same screen indicating the service time.



Pressure, temperature, plasma and other parameters of critical times of the sterilization process are output from the thermal printer. Optionally, real-time sterilization parameters can be stored on USB.

EMPTYING THE STERILIZATION CABINET

When the entire sterilization process is completed and the chamber reaches atmospheric pressure, the door of the device can be opened and the chamber can be emptied. Sterilized loads can be used immediately.

CLOSING THE DEVICE

After the entire sterilization process is completed, the device remains in stand-by, ready for the next sterilization process. In this state, the evaporator and cabinet temperature is maintained. Therefore, a new sterilization load can be loaded into the device immediately.

If no new sterilization will be performed for a long period of time, the device can be switched off to save energy. To switch off the device, the "start switch" must be set to OFF.

EMERGENCY STOP

In an emergency or dangerous situation, use the emergency stop button to turn off the sterilizer. The emergency stop button immediately cuts off the power to the unit.
The Emergency Button does not automatically return to its original position after being pressed. Therefore, in order to restart the unit, you must pull the button outward to return it to its original position.
In non-emergency or non-hazardous situations, the on-off switch must be used to switch off the machine. The emergency stop must not be used to switch off the machine in non-emergency or non-dangerous situations.

7.RESIDUAL RISKS

All risks identified in the risk analysis study have been reduced to acceptable risk levels and there is no longer any risk.

8. NOTIFICATION TO THE COMPETENT AUTHORITY

In case of adverse events, notify the manufacturer and the competent authority.

9.INFORMATION SECURITY INFORMATION

For devices containing electronic programmable systems, including software, or software that is itself a device, the minimum requirements necessary for the software to function as intended are met with respect to IT security measures, including hardware, IT network features and intrusion protection.

To prevent unauthorized access to the device, only the technical service and production personnel responsible for the device can log in with a password, which is updated daily. The PLC software used in the device is also encrypted and can only be accessed by authorized technical service personnel.

MAINTENANCE& REPAIR

WITHOUT MAINTENANCE AND REPAIR

WORK SAFETY FIRST

SECTION 1. SERVICE RELATED ISSUES

1. Cleanliness

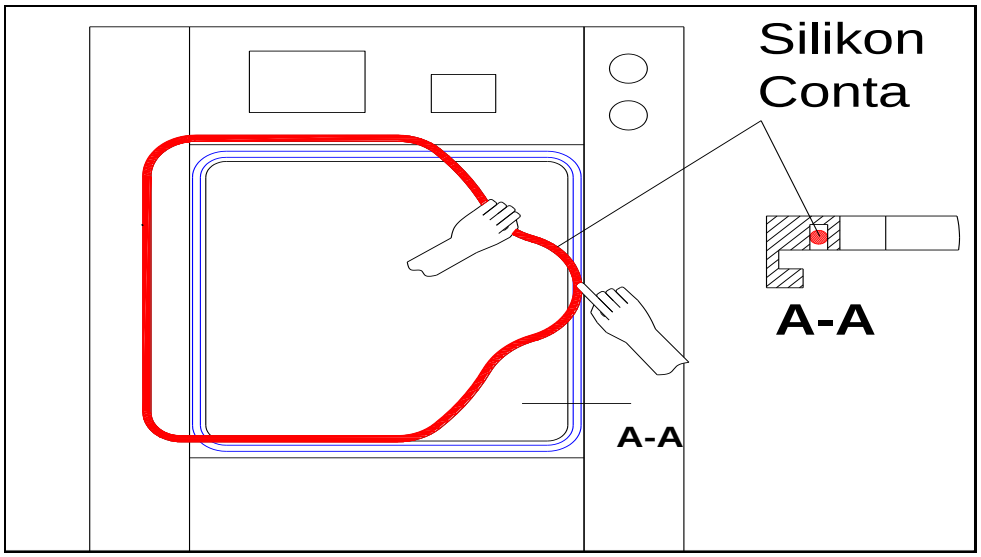
- Hydrogen Peroxide Gas Plasma Sterilizer devices are cleaned according to the manufacturer's recommendations.
- The inside of the boiler, shelf and door are wiped with a soft cloth dipped in warm water with detergent and dried.
- The plastic part of the control panel is cleaned with a damp cloth without rubbing.
- The outer surface of the device is polished by rubbing with the recommended stainless polisher.

2. Sterilizer User Care Instructions

- Do not disturb or disturb the stabilization - balance position made by the company during maintenance. Do not change the installation location.
- Check whether there are any material particles that may remain in the cell.
- Clean the cover gaskets once a week with the recommended spray.
- Never tamper with the electrical, electronic and mechanical parts of the device without the knowledge of the authorized service.
- Do not allow the devices to be moved during fine and rough cleaning of the sterilization center.
- Do not use very hard materials with cutting and scraping properties during maintenance.
- Disconnect the electricity and water connection of the device that will not be used for a long time.
- Do not allow unauthorized personnel who are not trained to perform maintenance on the device.
- Do not put anything other than sterile materials inside the device.
- Never wipe the inside of the cell with chemical compound material.
- Do not use petroleum-based, flammable, oily, flammable liquids during maintenance in line with environmental factors or misguidance.

3. Gasket Change

After gasket replacement in sterilizers, it is RECOMMENDED to spray gasket spray on the gasket surfaces at least once a month for maintenance purposes.



- Empty the chambers and wipe the surfaces between uses. Any foreign matter or liquid residue (dust, pieces of cloth, etc.) may affect the quality of sterilization and the lifetime of the device.
- Do not, under any circumstances, open the device for maintenance or repair. Call the customer support hotline instead.
- In case of a problem with the power supply cable of the device, the cable should only be replaced by Eryigit technical service personnel.

4. Cleaning the Outside of the Sterilizer

The outside of the sterilizer can be cleaned with a soft cloth and, if necessary, a mild, non-abrasive detergent solution. Follow these guidelines when cleaning the outside of the sterilizer:

1. Turn off the power to the sterilizer before cleaning the exterior.

2. Never allow cleaning solution or water to enter the interior or room. Wet a cloth with a non-abrasive detergent solution and use the wet cloth to clean surfaces.

3.Take care to prevent any cleaning solution or water from entering the interior of the appliance (or chamber).

4. Do not spray the cleaning solution directly onto the touch screen. Use a dampened cloth to clean the screen.

BÖLÜM 2. MALFUNCTIONS AND SOLUTIONS

Steps Before Calling the Service

It may not be necessary to call technical service for every fault symptom. Before calling the technical service, check whether you can intervene in the malfunction with the help of the following solutions. Do not intervene and do not intervene in the software program related malfunction. Even within the warranty period, you will have to pay the full cost of the service in such cases. If the fault cannot be eliminated despite the solutions we have suggested, call our Authorized Technical Service. In this case, do not attempt any further operation yourself, especially do not touch the electrical part. In the following malfunctions, if part replacement or part control is to be performed, it must be done with the knowledge of the authorized technical service;

ERROR CODE/ DESCRIPTION	CAUSE OF FAULT	CORRECTION OF ERROR
Phase Error	Any issue with the device's electrical connection	• Check the electrical connection of the device. • If the problem persists, unplug the device and contact Eryiğit technical service.
No Cartridge	No cartridge installed in the Cartridge Driver or insufficient capsules inside	Insert a cartridge into the cartridge driver and press the Load Cartridge button on the Menu screen.
Cartridge Driver Not Working	If the Cartridge Driver does not reach the forward/backward sensor within the specified time after the Load/Unload command is given	Contact Eryiğit technical service.

ERROR CODE/ DESCRIPTION	CAUSE OF FAULT	CORRECTION OF ERROR
Gas Error	If the amount of vapor delivered to the chamber is below the critical value for any reason, the following warning appears and the cycle is canceled.	Check the cartridge inserted in the device. If there is no visible problem with the cartridge, contact Eryiğit technical service.
Humidity Error	When the pressure drops below 10 Torr but not below 1 Torr	Contact Eryiğit technical service.
Power Failure	Occurs when the power to the device is cut and then restored	Check the mains voltage If this error recurs despite no issue with the mains, contact Eryiğit technical service.
Door Not Working	This error message appears if the Door Open/Close command is given but the door does not reach the Open/Closed sensor within the specified time.	Contact Eryiğit technical service.
Undefined Cartridge	The RFID reader did not recognize the cartridge or a used cartridge was inserted.	Check that the cartridge inserted in the device is not used and that it has an RF-ID label. If there is no issue with these, contact Eryiğit technical service.
Vacuum Leak Error	The cabin internal pressure increases more than allowed when at 10 Torr.	Contact Eryiğit technical service.
Sterilization Pressure Error	The pressure exceeds the allowed limits during the diffusion process.	Contact Eryiğit technical service.
Communication Error	This error occurs if there is a connection error between the RFID module and the PLC.	Contact Eryiğit technical service.
System in Vacuum Door Cannot Open	This message appears if the door is attempted to be opened before the cycle is complete. The door cannot be opened while the device is under vacuum.	Do not force the door in this situation. After the cycle is complete and the chamber is ventilated, the internal pressure will reach atmospheric pressure, and the door can be opened.
Cartridge Driver Not in Place	If the Cartridge Driver does not see the Rear Sensor	The Cartridge Back Sensor must be active. If not, the programme cannot be started on the device.
Needle is not in place	If the Needle Does Not See Back Sensor	Contact Eryiğit technical service.

ERROR CODE/ DESCRIPTION	CAUSE OF FAULT	CORRECTION OF ERROR
/ Door Not Closed	If Door Does Not See Closed Sensor	Close the door by pressing the Close Door button on the menu screen. Contact Eryiğit technical service.
Leybold/Ulvac Sensor Faulty	If the Sensitive Pressure Sensor Reads Values Other Than the Required Values	Contact Eryiğit technical service.
Keller Sensor Failure	If the Keller Sensor Reads Values Other Than the Required Values	Contact Eryiğit technical service.
Cabin External PT100	If the PT100 Sensor Reads Values Other Than the Required Values	Contact Eryiğit technical service.
Door PT100	If the PT100 Sensor Reads Values Other Than the Required Values	Contact Eryiğit technical service.
Evap PT100 Cabinet Interior PT100	If the PT100 Sensor Reads Values Other Than the Required Values	Contact Eryiğit technical service.
Cabinet Interior PT100	If the PT100 Sensor Reads Values Other Than the Required Values	Contact Eryiğit technical service.
Vacuum Pump Failure	It occurs when the cabin internal pressure does not fall below 1 Torr within the specified time.	Contact Eryiğit technical service.
Air Valve Failure	If the cabin internal pressure does not reach the specified atmospheric value within the specified time after the air valve is opened	Contact Eryiğit technical service.
/ Needle Failure	This error message is displayed when the needle carriage does not reach the relevant sensor within 15 s after receiving the forward/reverse command	Contact Eryiğit technical service.
Out-of-Cabin Late Warming	If there is no temperature change in the specified time and degrees in the cabin exterior PT100	Contact Eryiğit technical service.
Cover Late Warm-up	If there is no temperature change in the cover PT100 within the specified time and degrees	Contact Eryiğit technical service.
Evaporator Late Warming up	Evaporator temperature does not reach the desired level in the specified time	Contact Eryiğit technical service.
Late warm-up in the	If there is no temperature	Contact Eryiğit technical

ERROR CODE/ DESCRIPTION	CAUSE OF FAULT	CORRECTION OF ERROR
cabin	change at the specified time and degrees in the cabin interior PT 100	service.
System General Late Warm Up	If the system does not reach the hibernation temperature within the specified time	Contact Eryiğit technical service.

Software Errors Solutions		
"PLC No Response" Error on Display PLC communication error	PLC communication error	Restart the device. If the problem persists, please contact Eryiğit technical service.
Printer Fault	When there is a problem with the communication protocol and cables	Check the communication protocol and cables.
Printer Not Printing	When there is a problem with printer feeds	Check printer feeds.
Note: In case of software errors, the device must be restarted after the checks are made.		

SECTION 3. PERIODIC/PREVENTIVE MAINTENANCE

Periodic maintenance of the device includes the following operations:

Periyod	Prosedür	Yedek parçalar
3 Months / 300 cycles	Vacuum pump oil change	OIL-X
3 Months / 300 cycles	Vacuum pump exhaust filter replacement	VEF-X
6 Months / 450 cycles	Ventilation filter replacement	AVF-X
6 Months / 450 cycles	Vacuum pump pre-filter replacement	FLF-X
6 Months / 450 cycles	Inspection and maintenance of Hydrogen Peroxide needles1	
6 Months / 450 cycles	Plasma system maintenance[2]	
6 Months / 450 cycles	Evaporator maintenance[3]	

/Goldberg Hydrogen Peroxide Gas Plasma sterilizers use 10 A, 16 A and 25 A electrical fuses, all of which are type C fuses in accordance with IEC/EN 60898-1 standard.

1.Visually check the needles for blockage. If there is a blockage, the needle is replaced.
2. Check the electrodes of the plasma unit for wear. If there is visible wear, the electrodes are replaced.
3. The evaporator is removed and opened. Visually check the channels for clogging. If there is a blockage, remove it with a clean brush and reinstall the evaporator.

PREVENTIVE MAINTENANCE AND SPARE PARTS

- Every 6 months or after 900 capsules (450 cycles on average), perform a general maintenance (whichever comes earlier).
- When the device is due for maintenance, a reminder message will appear on the display. Call customer service immediately and schedule maintenance at the earliest possible time.
- The device must be serviced by authorized persons.
- The service procedure and spare parts are listed below.

MAINTENANCE KIT

The contents of the Annual Preventive Maintenance Kit may vary according to the manufacturer's recommendation for the devices in use (daily operations).

3-month Maintenance Kit
Vacuum Pump Exhaust Filter
Vacuum Pump Oil

6-month Maintenance Kit
Vacuum Pump Exhaust Filter
Vacuum Pump Oil
Ventilation Filter (HEPA)
O ring Gasket set

Annual Maintenance Kit
Vacuum Pump Exhaust Filter
Vacuum Pump Oil
Ventilation Filter (HEPA)
O ring Gasket set
Vacuum Pump Pre-Vacuum Filter

CHAPTER 4. DEVICE CONSUMABLES AND ACCESSORIES

Consumables	Product Code	Description
Hydrogen Peroxide Cartridge	CRT-B-X	Contains 59% hydrogen peroxide sterilization agent.

Process Validation Device	PVD	Process validation device
Vacuum Pump Oil	OIL-X	
Ventilation Filter (HEPA)	AVF-X	
Vacuum Pump Exhaust Filter	VEF-X	
Vacuum Pump Pre-Vacuum Filter	FLF-X	
O ring Gasket Set	O-ring	
Thermal Printer Paper	TYK 56*16	56 MM X 16 MT
Sterilization Rack		Contact Manufacturer for compatible list with models

For 80 L devices X=1, >=120 L devices X=2; >=160 L devices X=3.

PARTS REPLACEMENT INSTRUCTIONS:

The following parts must be replaced only by Eryiğit A.Ş. technical service personnel. Circuit diagrams, component part lists, recipes, instructions or other information to assist technical service personnel can be obtained from Eryiğit A.Ş.

Occupational health and safety rules must be complied with during the replacement of the parts for which replacement instructions are given. When replacing the vacuum pump pre-filter (FLF-X), protective glasses must be worn.

1. The device must not be in operation.

2. Since there is no risk of electric shock during filter changes, it is not necessary to disconnect the power of the device.

3. The boiler must not be in vacuum. Otherwise, when the clamps are removed, the metal hoses may fly uncontrollably and cause injury. For this reason, if the boiler is in vacuum, the vacuum should be broken by opening the air valve and filter change operations should be started afterwards. To open the air valve, press the Settings button from the Main Menu on the touch screen and press the Open Air Valve button on the screen that appears.

Ventilation (Air) Filter Replacement Instructions:

1. Remove the left cover from the front of the device upwards by holding the handles.
2. Remove the air filter shown in Figure from its housing by turning it counterclockwise.
3. Insert the new filter into the same socket by turning it clockwise.

Ventilation (air) Filter

Vacuum Pump Pre-filter Replacement:

1. Remove the cover, which is on the left side of the device, by holding the handles in the upward direction.

2. Loosen and remove the vacuum pump pre-filter box, which is seen below, by holding the handles of the 2 buckets located at the bottom and the top, first by turning the lower clamp then the upper clamp counter clockwise..

3. Remove the filter box from the device and place it on a flat surface. Insert the filter key into the holes on the filter and turn the key clockwise to unscrew the filter cap.

4. Lift the cover of the filter box and remove the filter. Insert the new filter into the filter box.

Vacuum pump pre-filter

5. Ensure that the gasket on the filter cap is properly seated and that there are no tears or deformations. Once confirmed, place the cap back in its position.

6. Use the same filter key to turn the cap clockwise to close it, completing the replacement process.

7. Lastly, reattach the filter to the vacuum line at the top and bottom using the clamps removed at the beginning. Ensure that the gaskets are properly seated. Complete the process.

Changing the Vacuum Pump Exhaust Filter:

1. Remove the right-side cover by holding the handles and lifting it upward from the front of the device.

2. The vacuum pump exhaust filter is clamped to the vacuum pump on the right (Figure). Detach the filter housing connected to the vacuum motor's exhaust line by removing the clamp.

3. Place the removed filter on a flat surface and open the cap by turning it counterclockwise with the filter key.

4. Remove the cover, the inner filter is

located under the cover.
5. After removing the cover and filter, drain the oil accumulated in the filter chamber, if any. Remove any oil residue with alcohol and a cloth.

6. Place the new filter into the filter chamber and attach the filter cap to the filter chamber first by turning it by hand (clockwise), then tighten it with the filter wrench by turning it clockwise again and complete the filter change process by making sure that the cap is fully tightened.

Things to do after changing the filter:

Vacuum leakage test should be performed after changing the filters other than the activated carbon exhaust filter. For this, start any sterilization program from the Menu screen and wait for the device to perform the automatic vacuum test. If the vacuum test is passed successfully, the pressure drop is monitored for a while. If the final pressure drops below 1 Torr, the device is ready for use. If these two conditions are not met, the installed filters are removed one by one, and defects that may cause vacuum leakage such as poorly fitting gaskets at the connection points, dust on the gasket are searched and eliminated. Vacuum leakage test is performed again.

CHAPTER 5 EMC COMPATIBILITY TECHNICAL DATA

EMISSION TEST	IEC 60601-1-2 TEST LEVEL	COMPATIBILITY LEVEL	ELECTROMAGNETIC CONDITIONS - RECOMMENDATIONS
Emission Distortion test CISPR 11 IEC 5011:2016/A1:2017	Group 1	Group 1 (30MHz- 1GHz)	It uses the RF energy of the device only for its internal function. Therefore, its RF emissions are very low and unlikely to cause any interference in nearby electronic equipment.
Connection End Emission Test CISPR 11 (Conducted Emission) IEC 5011:2016/A1:2017	Class B	Class B (150 kHz - 30 MHz)	/Goldberg Hydrogen Peroxide Gas Plasma Sterilizer Devices are suitable for use in all workplaces, including local Uses. It can also be used in networks used for household appliances, which are directly connected to the general low voltage power supply network.
Harmonic Emission Test IEC 61000-3-2:2014	Class A	Class A	
Voltage Fluctuations and Flicker test IEC 61000-3-3:2013	Pst 1, dc 3,3% dmax 4%	Compatible	

Recommended separation distances between the /Goldberg Hydrogen Peroxide Gas Plasma Sterilizer and portable and mobile RF communications equipment

The /Goldberg Device is intended for use in an electromagnetic environment in which radiant RF disturbances are controlled. The customer or the user of the /Goldberg Device, by ensuring the minimum distance between portable and mobile RF communications equipment (transmitters) and /Goldberg as recommended below, in accordance with the highest output power of the communications equipment, they can help prevent electromagnetic interference.

Separation distance according to the frequency of the transmitter

Highest transmitter side output power W	150 KHz - 80 MHz d=(3.5/V1) * √ (P)	80 MHz - 800 MHz d=(3.5/V1) * √ (P)	800 MHz - 2.5 GHz d=(7/V1) * √ (P)
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

The recommended separation distance d in meters (m) for transmitters with the highest rated output power not listed above can be determined using an equation that matches the frequency of the transmitter. The P value in this equation is the highest transmitter rated output power in watts (W) specified by the transmitter manufacturer.

Note 1 - The separation distance in the high frequency range of 80 MHz and 800 MHz is applied.

Note 2 - These guides may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

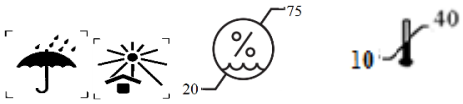
The Goldberg Hydrogen Peroxide Gas Plasma Sterilizer Device is intended for use in the electromagnetic environment as specified below. The user or customer of the Goldberg Hydrogen Peroxide Gas Plasma Sterilizer Device must assure use in such an electromagnetic environment.

IMMUNITY TEST	IEC 60601-1-2 TEST LEVEL	COMPATIBILITY LEVEL	ELECTROMAGNETIC CONDITIONS - RECOMMENDATIONS

Electrical Fast Transient / Burst Immunity Test IEC 61000-4-4: 2012	± 2 kV (LEVEL 3) Burst Frequency 100kHz Application Time>=60s	±2 kV (LEVEL 3)	Mains power supply quality can be such that it supports a typical commercial or hospital environment.
Immune Test Against Sudden Elevations IEC 6100-4-5: 2014	± 1 kV Differential ± 2 kV Earth	± 1 Kv Differential ± 2 kV Earth Output Impedance: 2Ω (L-L) Output Impedance: 12Ω (L PE)	
Electrostatic Discharge Immunity Test 61000-4-2:2009	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors can be wood, concrete or ceramic tiles. Floors If the material is covered with synthetic, the relative humidity should be at least 30%.
Voltage Pits, Short Interruptions and Voltage Variations Immunity Test IEC 61000-4-11	< 5% UT (> 95% Voltage Trough) ½ during the period <5% UT (> 95% Voltage Trough) during 1 period 70% UT (30% Voltage Trough) for 25 periods	Voltage Pits Test Voltage: 0% Time 0.5 Period 10ms Angle: 0-45-90-135-180- 225-270-315 Test Voltage: 0% Duration: 1 period 20ms Angle: 0 Test Voltage: 70% Duration: 25 periods 500ms Angle: 0	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device wants to continue in case of power outages, it must be fed with an uninterrupted power supply.
Immunity Test Against Conducted Distortion Induced by RF Fields IEC 61000-4-6:2014	Field Strength: 6 V Frequency Range: 150 kHz 80MHz Modulation: AM, 80% Amplitude, 1kHz, Sinusoidal (2 seconds cooldown in 1% steps)	Field Strength: 6 V Frequency Range: 150 kHz 80MHz Modulation: AM, 80% Amplitude, 1kHz, Sinusoidal (2 seconds cooldown in 1% steps)	Portable and mobile RF communications equipment should be used no closer to any part of the Goldberg Sterilizer Device, including cables, than the distance calculated by an equation suitable for the frequency of the transmitter. Recommended distance distance: d = 1.2√P 80MHz-800Mhz d = 2.3√ P 80MHz - 2.5 Ghz In these equations, the P value is the highest transmitter rated output power from the Watt (W) value specified by the transmitter manufacturer, and the d value is the recommended separation distance in meters (m). The strength of the radiated field from fixed RF transmitters, as determined by an electromagnetic zone discovery (*), should be less than the compliance level in each frequency range (b). Interference may occur near equipment marked with the symbol below. 
Radiant, Radio Frequency, Electromagnetic Field Immunity Experiment IEC 61000-4-3:2006	3 V/m (80 MHz 2,7 GHz)	Field Strength: 3 V / m (80 MHz 2.7 GHz) Antenna Distance 3m Modulation 1 kHz Sine	
NOTE 1 These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 2 It is necessary to verify that the actual shielding efficiency of the armored zone and the filter attenuation provide the lowest property.			

CHAPTER 6 PRODUCT LABELING

Endüstriyel Makina ve Tıbbi Cihazlar İml. İth. İhr. İnş. Tic A.Ş.	**Adres /** *Address*	İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453 Sok. No:3 Ostim, Yenimahalle, Ankara, Türkiye	
	Tel / *Phone*	+90.312.395 57 95	
	Faks / *Fax*	+90.312.395 57 96	
	E-posta /*E-mail*	info@eryigit.com.tr	
	Web	www.eryigit.com.tr	

HİDROJEN PEROKSİT GAZ PLAZMA STERİLİZATÖRÜ **HYDOGEN PEOXIDE GAS PLASMA STERILIZER**			
MODEL *Model*	TEKSTERİL/GOLDBERG	SN **SERİ NO** *Serial No*	20__/03-__
HACMİ *Volume*	__ L	**GÜCÜ** *Power*	3x 220/380 V AC, E+Z, 50 Hz, _ A, _ kW
Toplam Ağırlık *Total Weight*		__ kg	
	__/20__		
UDI	(01)0 XXXXXXXXXXXX (11) YYAAGG (21) 20YY/BB-CCC		

Kullanma Kitabını Okumadan Cihazı Çalıştırmayınız!
Do not switch on the device before you read the instructions

MD

3N ~

CE 1984

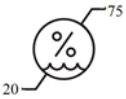
Medikal Cihaz Regulasyonu
Medical Device Regulation
EU 2017/745

ISO 9001 & ISO 13485& ISO 14001

TD.03.02.04

PRODUCT LABEL DESCRIPTIONS

	Manufacturing date	**3N~**	**Three-phase alternating current with neutral conductors**
SN	**Serial Number**		**Radio Frequency Emission Warning**

	**Electronic waste**		**Protective earthing**
	**Follow the instructions for use**		**Do not use the product with damaged packaging.**
	**Manufacturer**		**Warning**
	**Medical Device**		**Keep dry**
	**Keep away from sunlight**		**Humidity Limit**
	**Temperature Limit**		**Refers to the Number of the Notified Body**

Warranty Certificate
WARRANTY CONDITIONS

1. The product is guaranteed for a period of (1-2) years between the dates written in the document (according to the terms of the contract) against material, workmanship and production defects from the invoiced delivery date.
2. During the warranty period, ERYİĞİT END. MAK. AND MEDICAL DEVICE. İML. İTH. İHR. İNŞ. TİC. A.Ş. In case of intervention and / or detection of intervention for maintenance, repair, part replacement, etc. by persons not officially authorized by ERYİĞİT END.
3. Damages and malfunctions that may occur due to interventions made outside the authorized service are not covered by the warranty. Labor services to be performed within the warranty period are free of charge.
4. Repair period starts after the day of written notification to our authorized dealer or our company. The elapsed time will be added to the warranty period.
5. After delivery; Damages and malfunctions caused during loading, unloading and transportation and / or external body, plastic parts and PLC screen scratches and breakages, damages and malfunctions caused by usage errors are not covered by the warranty.
6. Fire and lightning strikes, low or excessive voltage, faulty electrical installation and incorrect connection, use of the product at a voltage different from the voltage written on the label are not covered by the warranty.
7. Elimination of out-of-warranty faults is done for a fee. No rights and compensation can be claimed in cases outside the scope of warranty.
8. The malfunction will be intervened within 48 hours following the failure notification and the device will be made operational within 10 working days.
9. The determination of the malfunction and needs will be made by our company's technical staff.
10. Issues regarding the elimination of the malfunction on site or in authorized services are subject to the approval of the user and / or the administration.
11. No labor fee is charged for periodic maintenance defined in the contracts.
12. If consumers notify ERYİĞİT END. MAK. AND MEDICAL DEVICE. İML. İTH. İHR. İNŞ. TİC. A.Ş. in writing about their disputes with Authorized Services that perform maintenance and repair services, they will be intervened.
13. Following the end of the warranty period of the device, there is a Maintenance-Repair and Spare Parts Supply Warranty for 10 (ten) years for a fee.
14. At the end of the warranty period, a Maintenance-Repair Contract can be made in periods in line with the consumer's request.
15. Administrations; Our company is not responsible for possible risks arising from not using original spare parts in our production devices after the end of the warranty period.
16. The issues not covered by the warranty include the issues written in the "User Manual" supplied with the device.
17. This warranty remains in force in the event that the consumer and / or the consumer organization fulfills the responsibilities of the customer completely.
18. The warranty certificate shall be issued in two originals, the documents and the serial numbered label of the device cannot be falsified.
19. The material invoice must be kept during the warranty period. Materials for which the invoice is not submitted shall be deemed to be out of warranty.
20. The use of this Warranty Certificate is authorized by the Ministry of Industry and Trade, General Directorate for the Protection of Consumers and Competition in accordance with the Law No. 4077 and the Communiqué No. TRKGM-95/116-117 issued on the basis of this Law.

GOODS TYPE : HYDROGEN PEROXIDE GAS PLASMA STERILIZER
BRAND : ERYİĞİT
MODEL : /GOLDBERG
SERIAL NO :
PLACE OF DELIVERY :

SELLER COMPANY : ERYİĞİT END. MAK. AND MEDICAL DEVICES.İML.İTH.İTR.İNŞ.TİC.A.Ş.
ADDRESS : IVEDİK OSB ÖZANADOLU SAN.SİT.1453.SOK.NO:3 OSTİM,YENİMAHALLE/ANKARA
TEL : 0 312 395 5795
FAX : 0 312 395 5796
Web : www.eryigit.com.tr
E-mail : info@eryigit.com.tr

INVOICE DATE
INVOICE NO :