

EtO –FCT
FLEXIBLE CHAMBER TECHNOLOGY

ETHYLENE OXIDE GAS
DIFFUSION SYSTEM STERILIZER

OPERATING MANUAL

CLASSICAL MODEL

ZEISS-80L

TABLE OF CONTENTS	PAGE NUMBERS
1. INTRODUCTION	3
1.1. Information About Manufacturer	3
1.2. Description of the Device and Intended Use	3
1.3. Products That Can Be Sterilized	4
1.4. Content of the Ethylene Oxide Sterilization Kit	4
1.5. Zeoss EO Gas Dosimeter Color Scale	4
1.6 Sterilization Cycle	5
2. SAFETY MEASURES	5
2.1. General Safety Warnings	5
2.2 Exposure to Gas	5
2.3 Qualified User	5
2.4 Basic Risk/Hazard Evaluation	6
2.5 Negative Pressure	6
2.6 Material Placement	6
3. CONSUMABLE MATERIAL UTILIZATION RECOMMENDATIONS	6
4. OPERATION OF THE EQUIPMENT	7
5. TROUBLESHOOTING/ERROR DEBUGGING	11
6. CLASSICAL MODEL ERROR MESSAGES	11

1. INTRODUCTION

1.1. Information about Manufacturer

NAME OF MANUFACTURER	: MED TIP MALZEMELERİ İTHALAT İHRACAT SANAYİ VE LİMİTED ŞİRKETİ
ADDRESS OF MANUFACTURER	: 10023 Sokak No: 7 A.O.S.B. Çiğli 35620 / İZMİR - TURKEY
TEL.	: +90 232 386 62 26 FAX: +90 232 386 62 44
E-Mail	: info@medtr.com Web: www.medtr.com
CERTIFICATES OF COMPANY	: ISO 13485: 2016, CE

1.2. Description of the Device and Intended Use

ZEISS STERILIZERS are next generation , high-tech ethylene oxide sterilizers , operated with a **gas diffusion system** that fulfills the sterilization process at low temperatures using smaller amounts of ethylene oxide (EtO) gas. The new technology has eliminated the requirement of substructures needed by the traditional gas sterilizers such as pressurized air, water, a vacuum line and drainage channels. Ampoules which include Ethylene Oxide gas are used for sterilization.

Gas diffusion eliminates "dead space" around loads by delivering Ethylene Oxide directly to the load. No harsh preconditioning is required, treating sensitive products gently and effectively. Conventional systems fill the entire chamber with EtO, possibly overdosing product to compensate for that dead space around loads. Forced preconditioning in a deep vacuum under high humidity may also damage sensitive products

Maximum sterilization safety is provided because of the special structure of the ampoules. The **ZEISS STERILIZER** consumes 1/10 less gas compared to equivalent systems. Environmental pollution is minimized due to the low amount of gas consumption. The Ethylene Oxide content of each gas ampoule is 20 grams. Aeration after sterilization is safely performed in the same chamber by discharging 100% of the ethylene oxide gas residues through a vacuum pump system.

The advantages of next generation Flexible Chamber Technology (FCT);:

- Practical Usage/Operation.
- Large Usage Capacity.
- Low gas consumption: Consumes 1/10 less gas compared to equivalent/similar systems.
- Eliminates "dead space" around loads
- Environmental pollution is reduced to lowest possible level due to limited gas consumption.
- Negative pressure.
- Microcomputer operation system.
- Aeration after sterilization is executed in the same chamber.
- 100 % discharging of ethylene oxide gas residues by means of a vacuum pump system.

SPECIFICATIONS FOR THE ZEISS-80L MODEL

TECHNICAL TABLE		
MODEL		ZEISS-80L
Internal Dimensions (mm)	WIDTH	370
	DEPTH	670
	HEIGHT	370
External Dimensions (mm)	WIDTH	450
	DEPTH	765
	HEIGHT	630
POWER		250W
CAPACITY		92 LT
VOLTAGE		110V - 220V
AMPERAGE		3A
EO GAS GR		11 gr, 15 gr
STERILIZATION BAG		50X50 cm

1.3. Products That Can Be Sterilized

Materials that can be sterilized between 37-54 °C by applying Ethylene Oxide (EtO) gas, an anti-bacteriologic agent, in ZEOSS series Ethylene Oxide Gas Sterilizers:

- All materials resistant or non-resistant to heat
- Plastics
- Rubbers
- Mechanical and Electromechanical parts
- Disposable/Single use Medical tools
- Disposable/Single use Laboratory tools
- Metallic products
- Endoscopic and Laparoscopic Equipment

1.4. CONTENT OF ETHYLENE OXIDE STERILIZATION KIT

- Ethylene Oxide Gas Ampoule
- Sterilization Bag
- Humidity Chip
- Dosimeter
- Zip Ties

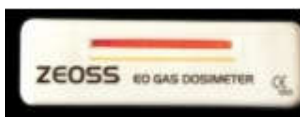
Materials to be sterilized are placed into the sterilization bag (after being wrapped with medical packing material) along with the gas ampoule, humidity chip and dosimeter. Seal the mouth of sterilization bag firmly with ties or tape. The sterilization bag is made from a special gas diffusion membrane . Ampoules of 20 grams are used in ZEOSS Sterilizers. The gas is released into the sterilization bag during the cycle for 4 hours. Sterilization bags constitute a secondary safe field in the equipment chamber . Dosimeter test results indicate humidity homogenization and concentration sufficiency in the sealed sterilization bags during the ideal cycle and sterilization period.

The humidity chip containing 4 % pure water provides required humidity for the sterilization process. The dosimeter controls main parameters like temperature, time period, gas saturation and humidity sufficiency. If one of these parameters does not meet specified parameters, the dosimeter will not reach the reference color.

GAS AMPOULE INGREDIENTS

Active Agent (EO)	Inactive Agent (Others)	Net Weight
%97	%3	20gr

1.5 ZEOSS EtO GAS DOSIMETER COLOR SCALE



BEFORE

EtO GAS DOSIMETER COLOR VIEW BEFORE STERILIZATION



AFTER

EtO GAS DOSIMETER VALID COLOR VIEW AFTER STERILIZATION

1.6 Sterilization Cycle

8 HOURS OPERATION PROGRAM

- Sterilization Temperature : 37-54 °C
- Sterilization Period : 4 hours
- Aeration (Vacuum) Period : 4 hour

2. SAFETY MEASURES

- *An emergency stop button is available on the device when needed.*
- *A secondary safety thermostat is installed in the device to prevent the temperature from exceeding its limit and damaging the materials.*
- A 30-mA residual current circuit breaker has to be mounted where the device will be placed to prevent electrical risks.
- The device must be installed by a trained professional in accordance with the installation instructions to maintain the safety of the equipment.

2.1. GENERAL SAFETY WARNINGS

PRODUCTS, FORBIDDEN TO BE STERILIZED

- Pressurized equipment and devices
- Equipment and devices containing flammable gas
- [Flammable and flashing products when contacted with electricity](#)

PRODUCTS, FORBIDDEN TO BE USED

- [Solid surface cleaners](#)
- [Solvents and detergents for cleaning equipment](#)

WARNING:

- Use mask, filter, glove and protective clothing to ensure personal safety.
- In case of power outage, do not open the sterilizer until it has finished the cycle and terminated the sterilization process.

2.2 EXPOSURE TO GAS

- Ethylene Oxide gas may be harmful for human beings and the environment when handled incorrectly.
- Required protective measures must be taken.
- If accidentally exposed to gas, the exposed area should be flushed with water immediately.
- Wear gloves that are resistant to ethylene oxide gas during cycle preparation.
- In case of inhalation, nausea and headache may occur.

2.3 QUALIFIED USER

- Sterilizer should be operated by an authorized and trained employee.
- Unauthorized personnel should not be allowed to operate this equipment.
- Damages incurred due to an unauthorized employee operating the equipment may nullify the warranty.

2.4 BASIC RISK EVALUATION

The MSDS (Material Safety Data Sheet) includes all technical data and protective measures related to the safety of gases like ethylene oxide.

The toxicity evaluation according to the MSDS, obtained from Supplier Company is exactly as follows:

- EtO vapor has a narcotic and sometimes neurotoxic effect.
 - Approximately 0.01 % concentration may cause sicknesses.
 - The toxic effect of EtO gas is not cumulative and there is no known chronic intoxication.
 - However, if exposed to the gas for a long period of time it may cause pulmonary edema and serious eye irritations.
- Health specialists have confirmed the maximum concentration as 50 ppm, which are 50 g/m³.

2.5 NEGATIVE PRESSURE

- Diffusion of gas from inside to outside the device is physically prevented due to negative pressure.
- ZEOSS sterilizers have been manufactured by taking this principle into consideration.
- The internal chamber is always under negative pressure compared to the external environment.
- Control systems execute all of the related tests during each cycle.
- All gas molecules released from the sterilization bag are discharged rapidly into the discharging pipe insuring no toxicity inside.

2.6 MATERIAL PLACEMENT

- There is no limitation for the placement of packed materials into the sterilization bag.
- Fan, resistance and vacuum pump can be monitored visually and during each cycle.
- Do not tear or perforate sterilization bags.
- Unplug equipment from electricity when maintenance-repair is required.
- Avoid touching the interior surface of the chamber due to heat generated during the cycle.

3. CONSUMABLE MATERIAL UTILIZATION RECCOMENDATIONS

- Wrap the products to be sterilized in medical packing material.
- Place those packs directly into the sterilization bags.
- Use the Zeoss brand ampoules and sterilization bags with the Zeoss sterilizer system.
- We are not responsible for ineffective sterilization results due to the use of different brands of gas ampoules or sterilization bags.

4. OPERATION OF THE EQUIPMENT

Working guide for the Zeoss Sterilizer System is on the following pages:

ZEOSS-80L STERILIZER WORKING GUIDE

To open and close the door:



1



2

FOLLOW INSTRUCTIONS TO STERILIZE EQUIPMENT

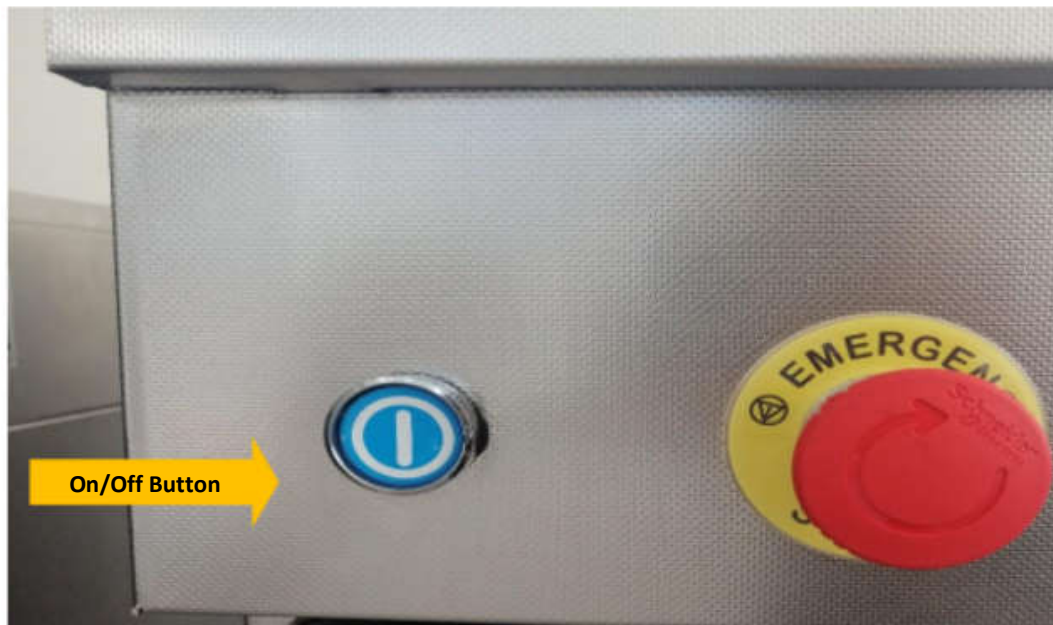
1- Place the wrapped materials to be sterilized inside the sterilization bag



2-Place the ampoule, dosimeter and humidity chip inside the sterilization bag and seal using the zip tie included with the sterilization kit.



3-Press the On/Off button to turn on the sterilizer and begin the heating process. Allow the temperature to rise to 37 degrees before moving on to step 4.



4-Place the sealed sterilization bag inside of the chamber



5- Once the sterilization bag is inside the chamber, break the ampoule to activate then close sterilizer door. The ampoule is easily broken where the tube narrows at the top.



6- Touch the down arrow button to select 8 hours. The temperature will begin to climb up to 54 degrees and the clock will begin to count down from 8 hours.



7-At the end of the cycle, the alarm will sound and the screen will display the word "End"

8-If necessary to stop the sterilizer in mid-cycle--Press the emergency button. To restart, turn emergency button to the right where it will pop back out and restart the 8 hour cycle.



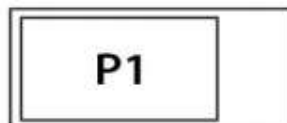
5. TROUBLESHOOTING/ERROR DEBUGGING

If the door of the equipment is not shut and an audible warning is heard...	An object prevents the door to be shut.	<p>a. Check the doorway with visual inspection and try to find any objects that prevent the door to be shut.</p> <p>b. Apply pressure on the door switch and check whether the audible warning is stopped or not.</p> <p>c. If the trouble is not found after all controls, call to ZEOSS service</p>
If the temperature value on display rises...	Thermocouple failure	If the temperature continues to rise, unplug the equipment and call to ZEOSS service.

6. CLASSICAL MODEL ERROR MESSAGES



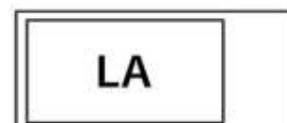
→ Door is left open more than 30 seconds.



→ Thermocouple failure



→ High temperature alarm



→ Low temperature alarm unreached to negative pressure. Temperature should be under 40 °C for longer time.