TEKNOMAR®

ETO C 1445
INDUSTRIAL ETHYLENE OXIDE HIGH TECHNOLOGY STERILIZATION DEVICE

Wherever you need sterilization

1-5-10-15-20-34-62,5...100 m³

Biggest In The World!
With 62,5 m³

Preconditioning, Gassing, Aeration In One Chamber

Since 1993, TEKNOMAR GROUP has been producing high-tech devices with the TEKNOMAR Brand in 8 different product groups and many sectors. It produces; broke new ground in the world with its R&D studies on Surgical Instrument Sterilization Devices (Industrial Ethylene Oxide, Hospital Type Ethylene Oxide, Hydrogen Peroxide Plasma, Heavy Molecule Sterilization Devices) and Air Cleaning and Conditioning Systems. In addition, it has become a pioneer to the world in technology by developing the HdrOzone Hydronium Heavy Molecule new generation sterilization technique.

Best solution partner for medical equipment manufacturers since 1993

Teknomar has produced world's largest Industrial Type Of Ethylene Oxide Sterilization Device which is 62.5 m^3.

Ethylene Oxide Sterilization Devices that

Working Under Vacuum

For All kinds of Medical Equipment, Absorbable and Non-Absorbable Sutures, Medical Textile Products etc.

TEKNOMAR ETHYLENE OXIDE DEVICE PRODUCTION AREA

Teknomar is a strong market player that has become a global brand in the production of low temperature (37- 55°C) Ethylene Oxide, Hydrogen Peroxide, hdrOzone Heavy Molecule sterilization devices.

Since 1993, serial and special Industrial Ethylene Oxide Sterilization Devices have been produced in Teknomar Group's high-tech, modern **4000 m²** production facilities.

Teknomar offers economical solutions in the field of EO sterilization devices by employing the best engineers, software developers and technicians in the production of ETO C 1445 Industrial Ethylene Oxide Sterilization Device, without sacrificing quality and safety, in accordance with customer needs.

In addition to providing the highest level of sterilization safety and accuracy in the ETO C 1445 Device, the sterilization cycle and operating costs are also lower than other EO Sterilization Devices in the market.

Active, Fast, Dry System

High-Tech Industrial Ethylene Oxide Low Temperature Sterilizer

ETO C 1445 Ethylene Oxide Sterilization Device; it is a device that can sterilize all kinds of disposable and re-sterilisable medical instruments, lumen materials (without diameter and length limit), plastic, inorganic, electro-mechanical, temperature and humidity sensitive equipment and material with ethylene oxide gas at low temperature (37-55°C).

The device sterilizes all kinds of heat-resistant or non-heat-resistant plastic, latex and made of metal, electro-mechanical, medical and surgical materials (absorbable and non-absorbable sutures, catheters, laparoscopic surgical instruments, implants, precision flexible medical products, endoscopes, rigid and semi-rigid lumen-shaped instruments) and disposable laboratory equipment, textile products, nonwoven materials, syringes etc. using ethylene oxide gas. Provides absolute safe sterilization on microorganisms, spores and insects.

The most important advantage of the Industrial Ethylene Oxide sterilization method is that the packaged material can be completely sterilized with parcels and pallets. The product is stored for a long time on the shelf without losing its sterilization effect. The sterilizer consists of a complete chamber, and sterilization and air washing are carried out in the same chamber under vacuum. The products sterilized in the device are purified from ethylene oxide gas by air washing process automatically in the same chamber.

Ethylene oxide gas expelled by the water neutralization system is dissolved and converted into ethyl glycol, degassed air is given to nature.

The device automatically detects the pressure, gas, humidity, air washing values and completes the sterilization stages without any intervention.

In the device, for sterilization of different products in different parameters, software and hardware infrastructure for different sterilization studies and multiple validation applications are made with SCADA. The ETO C 1445 reduces all possible costs to give you optimized economies of scale.

Preconditioning, Sterilization with EO Gas and Aeration are done in the same chamber at Industrial ETO C 1445.

This reduces the workload of employees, sterilization time and sterilization cost. (Nowadays in low-tech devices, users have to use separate devices for preconditioning and aeration of products.) (In Old Technologies with Bags and Bulbs, Under Pressure, the prolongation of the time, the workload and the need for large space increase the costs.)

World's Largest ETO manufacturer with 62.5 m^3 + 62.5 m^3

ETO C 1445
INDUSTRIAL ETHYLENE OXIDE STERILIZER
MAIN SPECIFICATIONS & ADVANTAGES

- *** Preconditioning, Sterilization, Aeration in One Chamber**
- Negative Pressure, Under Vacuum Sterilization Method (10^{-1} Torr)
- Operation at Desired Temperature Between 37 - 55 °C
- Reliable Sterilization of Humidity and Temperature Sensitive Long Lumen Products
- One Cycle Sterilization Cycle Time Including All Stages 6-8 hours
- **IQ (Installation Qualification), OQ (Operational Qualification), PQ (Performance Qualification) Validation**
- Halogen Free Electrical and Electronic Hardware
- **SCADA Software and Process Control**

ETO C 1445®

Easy Loading with Pallet and Unloading Roller Systems

Loading and Sterilization Feature of the Materials to be Sterilized with Parcels /Pallet

Complete Dissolution of EO Gas by Enhanced Neutralization Technique – Water Scrubber Method

Compatibility to Connect to Acidic and Catalytic Neutralization System (Optional)

High-Tech Sensor Systems Suitable for MDD and MDR

PLC Industrial Electronics and Process Control

Compliance with EN 1422 - EN ISO 11135 Standards

Compliance with EN ISO 14937 Validation Standards

Validation and Calibration for Different Products

EN ISO 14937 Reporting and Graphical Output Conforming to EO Validation

Detailed Reporting Function

Low, O&M Cost, Operation and Energy Efficiency

Single or Double Door Option

All Stainless Steel Sterilization Chamber (316 ℓ)

Easy Use with HMI Colours, Large Touch Screen Panel

Kiosk Control Unit

Safe, Accurate and Durable Sterilization Solution

Ability to Operate with Different EO Gas Mixtures

Enhanced User Safety and Alert Features

* ETO C 1445 offers a new technique where preconditioning, sterilization and aeration are done by only one device. When the sterilization processes are over, the sterilized products can be shipped immediately without the need for extra ventilation, as there is no EO gas residue on the products.

SUTURE EO STERILIZATION AND DRYING DEVICE

SUTURE EO sterilization and drying device system is a special production and includes standard EO device features. Unlike the EO process, it is used for suture sterilization. In addition, moisture drying is done between 0-10 ppm under N_2, CO_2 or inert gases for suture sterilization. Suture process, packaging and sealing are done with trays in small batches.

Main Specifications;

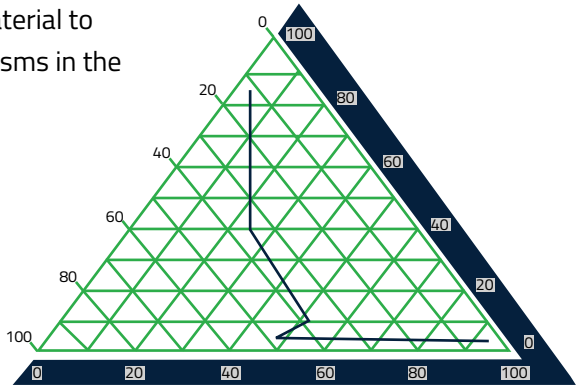
- Operating under nitrogen
- 0 -10 ppm Drying
- Moisture-Free Operating Sterilization Feature
- Shelf System / Tray System
- Deep Vacuum Operating Value 950 mbar
- Operating with Oil Vacuum Pump
- Different Capacity Production for Suture EO (500 ℓ – 5 m^3)

Correct and Complete Necessary Conditions for EO Sterilization

TEMPERATURE: Ethylene Oxide Device should be operated between 37°C and 55°C for full efficiency in sterilization.

MOISTURE: Humidity is needed in the sterilization process with ethylene oxide gas. Sterilization cannot be completed without sufficient moisture content. Humidity is required to open the pores of the packaging roll papers (Tyvek etc.) used in sterilization and to allow the diffusion of EO gas to the material to be sterilized. In addition, moisture is needed to revive microorganisms in the materials to be sterilized.

GAS: The gas to be used in the device is ethylene oxide gas. Eto Sterilization system (Ethylene Oxide) operates with gas. Gas ratios to be used for EO Sterilization can be between at least 30% ethylene oxide and 70% carbon dioxide or 100% ethylene oxide gas ratio values.



SAFETY: Ethylene Oxide gas consists of the molecular formula C_2H_4O. It is a colourless, toxic and flammable gas at room temperature and pressure. Flammability and explosive properties, as shown in the graphic, for a mixture of 25% + 75% EO + CO_2, poses danger in case there is more than 50% pollution in the air. All kinds of safety must be taken against dangers in ETO C 1445.

EO GAS MIXES and CONSUMPTION

Gas option program infrastructure and hardware are available for ETO C 1445 Industrial Sterilizer, according to the EO gas mixture (EO %, CO_2 %) supplied and used.
Different EO gas mixtures can be used in ETO C-1445 Industrial Sterilizer. EO gas supply rates vary in user countries.

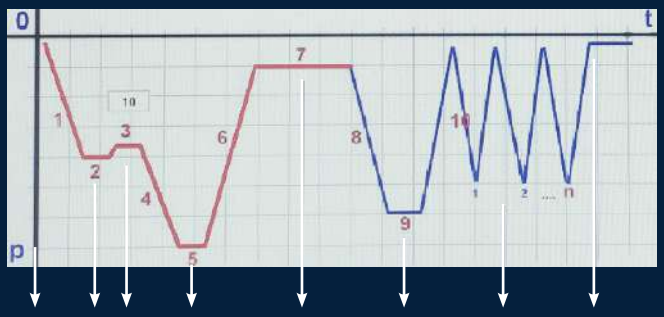
		Approximate Amount of EO Gas Consumed for Sterilization According to Gas Ratios in 1 m³ (g)	
EO Gas Ratio	**CO_2 Ratio**	**For 480 ppm (g EO)**	**For 560 ppm (g EO)**
% 30 EO	% 70 CO_2	890	1000
% 40 EO	% 60 CO_2	820	940
% 50 EO	% 50 CO_2	760	870
% 60 EO	% 40 CO_2	700	800
% 70 EO	% 30 CO_2	645	750
% 80 EO	% 20 CO_2	590	690
% 90 EO	% 10 CO_2	540	630
% 100 EO	% 0 CO_2	480	560

WATER CONSUMPTION

In each sterilization process, 1.5-2 ℓ of clean water is consumed per m³ for steam. In the neutralization process, 3-6 ℓ of water is consumed per m³ according to the flow rate in each cycle. (Depends on the time required by the customer.) For 34 m³ ETO device; In 100 sterilization cycles, approximately 5 tons of water is consumed for steam and approximately 20 tons of water is consumed for neutralization. Consumption may vary according to different ppm studies and gas ratios used. Water consumption in the scrubber is adjusted according to the most efficient situation.

ETO C 1445 INDUSTRIAL ETHYLENE OXIDE STERILIZATION DEVICE UNDER VACUUM OPERATING PROCESS

Sterilization Process



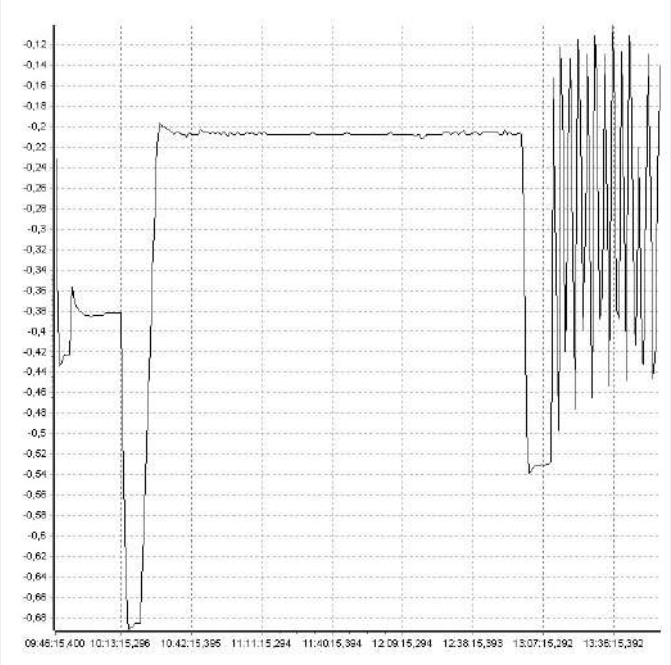
Teknomar Industrial Ethylene Oxide Sterilizer Operation Diagram

▪ **Vacuum 1:** Before the device starts the sterilization process, the 1st and 2nd leak tests are performed under vacuum for safety control.

▪ **Leakage 1 Period:** Leakage 1 Period: After the first vacuum operation, there is a leak test waiting period. At the end of this period, the vacuum level in the chamber is measured and checked whether there is a change in the pressure/vacuum value, leak. In case of leakage, the device does not start the sterilization process. Gives a leak warning. If the leak test is successful, the EO sterilization process starts.

▪ **Moisture / Preconditioning:** After the leak test is successfully completed, the device is preconditioned with moisture intake.

▪ **Vacuum 2 Period:** The device performs the deep vacuum process after the preconditioning is completed. Secondary sub vacuum conditioning continues.



Industrial ETO Device Under Vacuum Operation Graph (-mbar)

▪ **Leakage Test 2:** After the deep vacuum and conditioning process, the device performs a second leak test again for high safety without giving gas. During this period, it waits without any operation, and at the end of this period, the sterilization process begins with gas intake.

▪ **Gas Intake:** The sterilization phase starts with the inlet of EO gas. EO gas is taken until this process reaches the safe vacuum value in the device. The sterilization process begins. In the sterilization stage, the products are exposed to Ethylene Oxide (EO) gas to eliminate the microorganism at a certain time and under vacuum.

▪ **Sterilization Period:** Sterilization time is the most important and longest part of the system. The products in the device are exposed to gas during this period. In this process, the sterilization process is carried out.

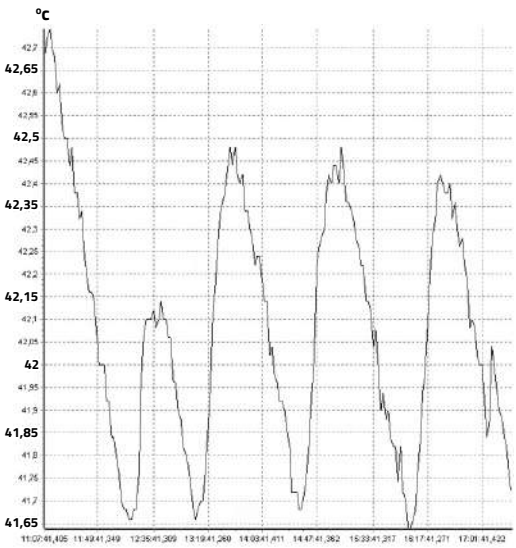
▪ **Exhaust Vacuum:** After the sterilization period is completed, the EO gas in the device is evacuated by vacuuming. With the water neutralization system, the gas is neutralized and exhaust is made. When the deep vacuum value of the sterilization chamber is reached, the dilution period starts.

▪ **Resting:** After the gas is evacuated in the device, the sterilized products are diluted. The sterile air washing process starts after the waiting period, subject to dilution, expires.

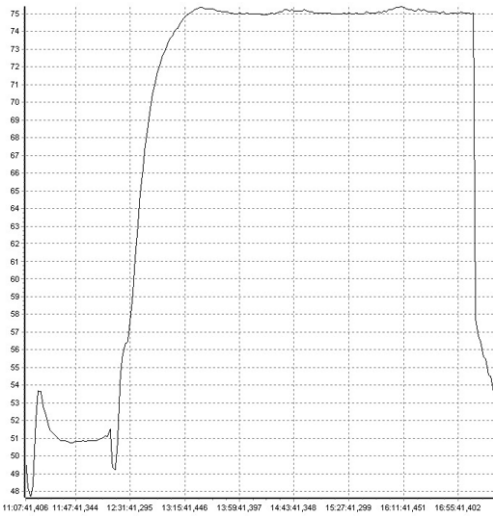
▪ **Washing with Fresh Air:** After the waiting period for purifying the EO gas in the device, air washing is performed to ensure that there is no residue on the sterilized material. At the end of the air washing process, atmospheric pressure is reached and the doors are allowed to be opened.

▪ **Number of Washings, Entering the Number of Washings:** For the air washing process, a minimum of 3 air washing programs are available as fixed values in the sterilization operating program. Apart from this, the user is given the opportunity to enter a value between 1-99 for the number of air washes.

▪ **Temperature:** The device can be adjusted at the desired temperature between 37 - 55^{0}C degrees. The device keeps the temperature at the set value constant during operation and sterilization.



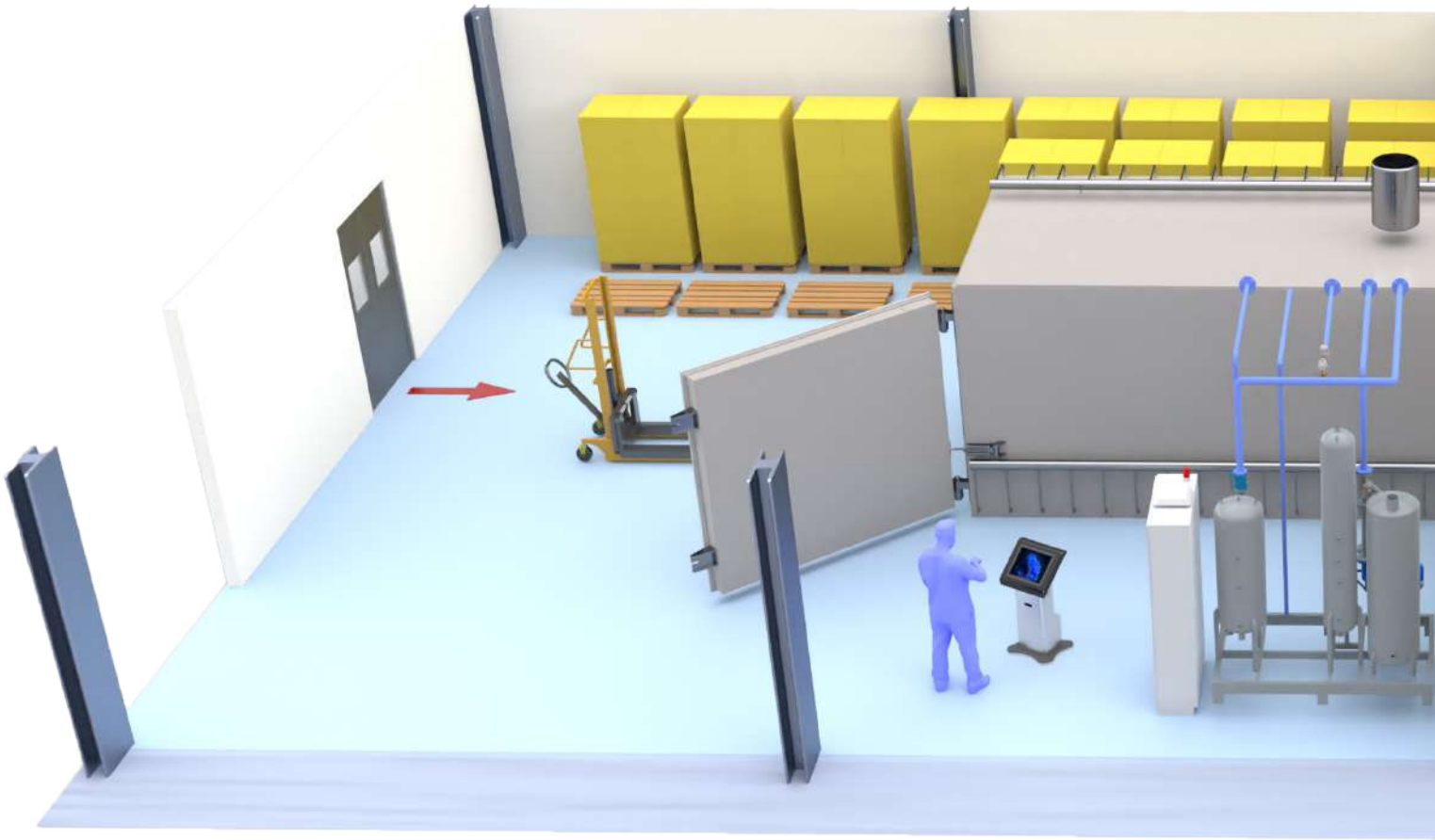
END ETO Device Temperature Operating Graph (°C)



END ETO Device Moisture Operating Graph (Rh)

END ETO C 1445®

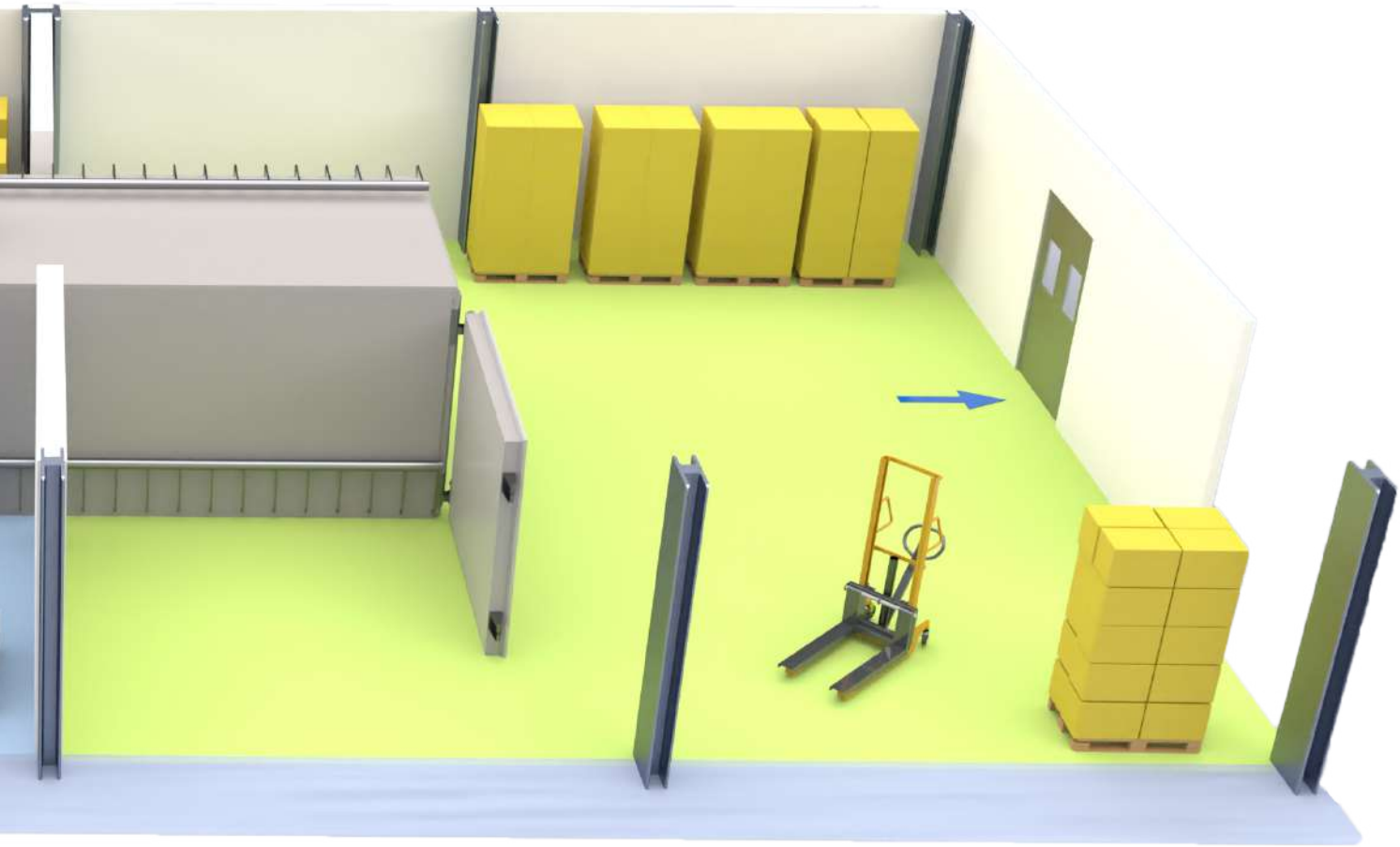
Industrial Ethylene Oxide Sterilization Device
Sterilization Unit Layout Plan



NON STERILE PRODUCT AREA

Preconditioning, Gassing,

Sterilization should be considered as the first and most important stage of production.

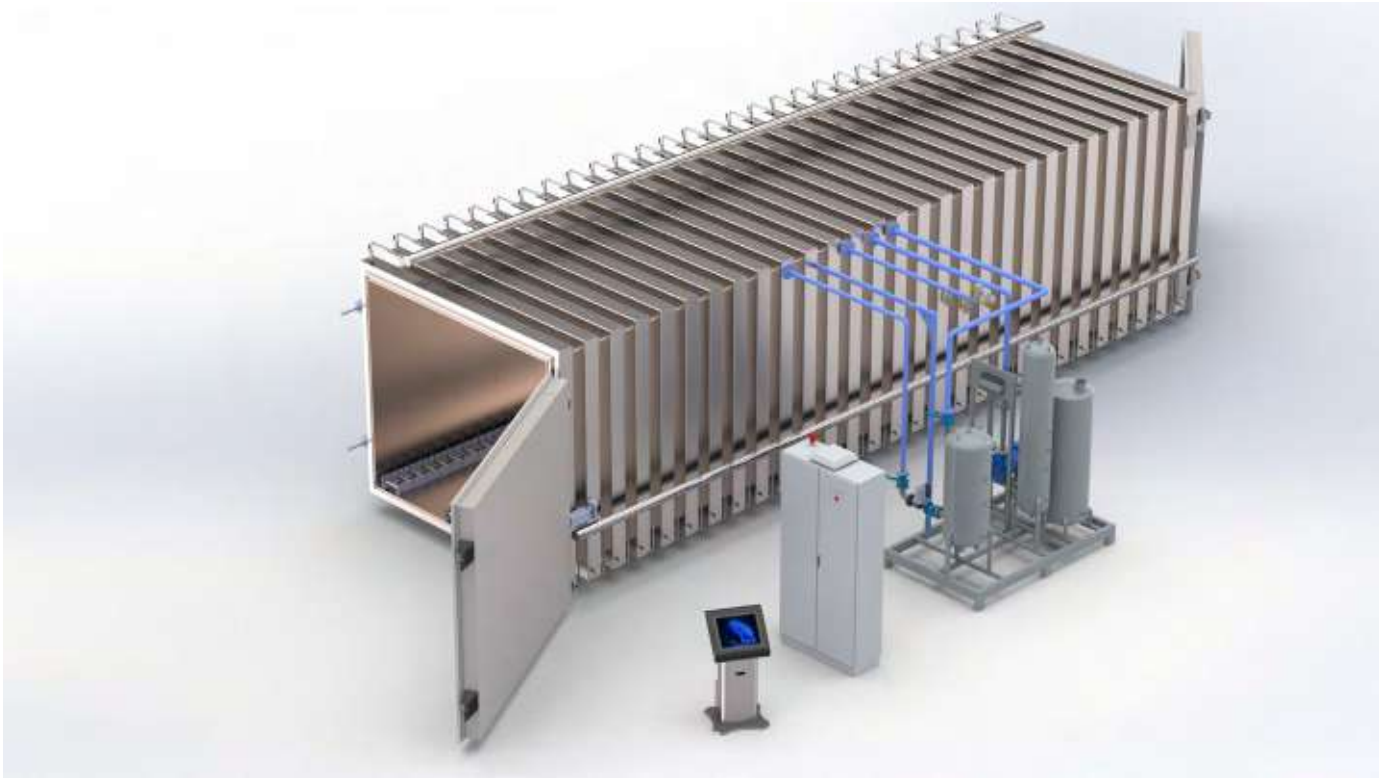


STERILE PRODUCT AREA

Aeration In One Chamber

ETO C 1445 STERILIZATION CHAMBER SIZES

Product option in standard sizes



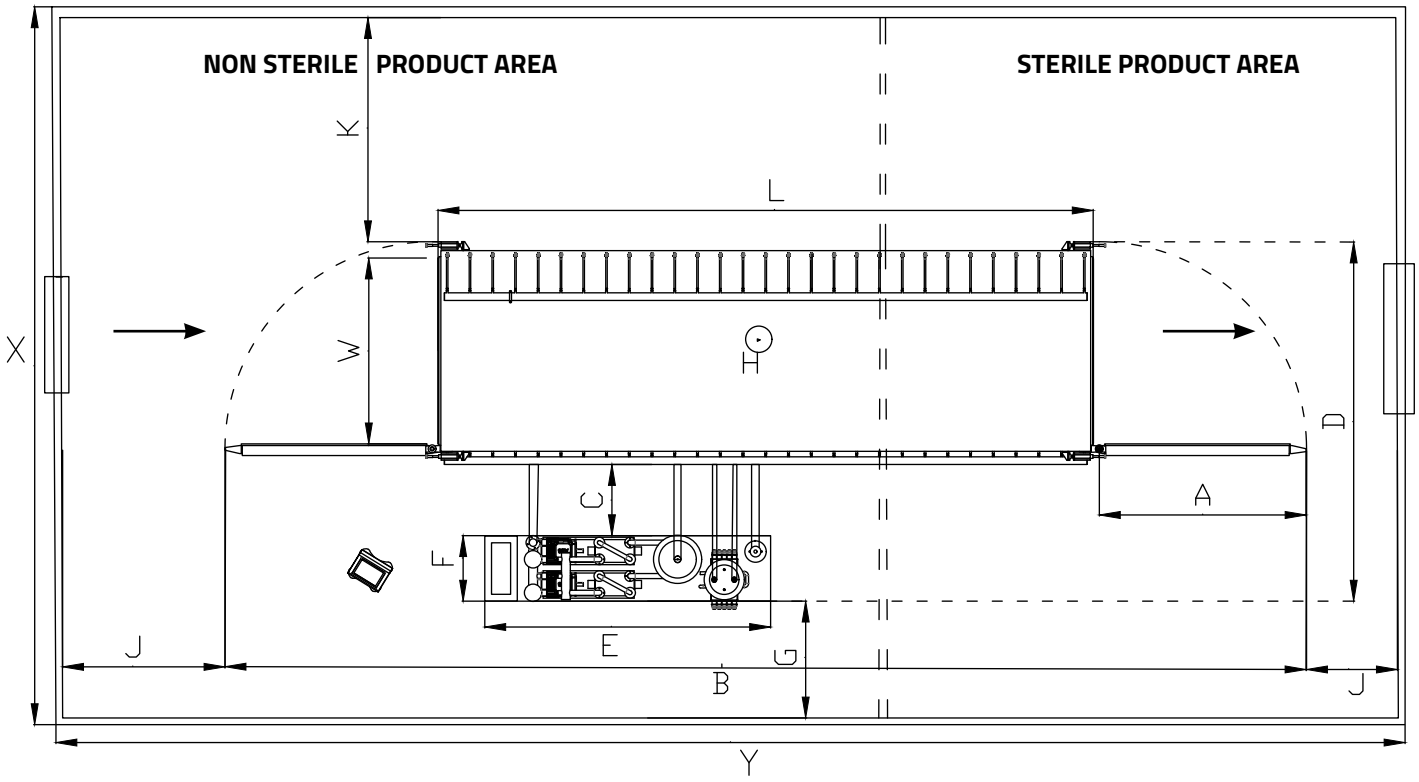
European Pallet Size (80x120cm) US Pallet Size (100x120cm)

Industrial Type EO Sterilization Device END ETO C 1445			Ethylene Oxide Sterilization Device Chamber Inner Dimensions			Weight (~kg)	Power (kW)
Chamber Volume (~m³)	Loading Pallet Number*	Door	Width (W) cm	Depth (L) cm	Height (H) cm		
0,5 Suture	-	Single	82,5	74	82,5	960	10 kW
1	-	Single	90	110	100	1450	21 kW
1,6 Suture	-	Single / Double	90	158	113	2000	25 kW
2,1 Suture	-	Single / Double	90	160	140	2500	30 kW
2	-	Single	120	120	140	1900	25 KW
5	-	Single	135	275	135	2800	50 kW
6	2	Single / Double	135	190	235/240	3500	50 kW
10	4	Single / Double	180	260	220	5800	60 kW
15	6	Single / Double	180	390	220	6600	70 kW
20	8	Double	180	520	220	8500	70 kW
27	10	Double	180	640	235/240	10000	75 kW
34	12	Double	180	780	240	12000	80 kW
40	14	Double	260	640	240	14500	100 kW
44	16	Double	260	705	240	15500	110 kW
50	18	Double	260	800	240	17000	120 kW
62,5	24	Double	260	1010	240	21000	140 kW

And more...

* The dimensions above show standard production. Production in special sizes is available. Please contact your representative for more information.

For Industrial Ethylene Oxide Sterilizer Minimum Layout Area Requirement



	Definition	
A	Door Length	Min. 220 cm
B	Device Layout Area Length (When Doors Are Opened)	A+L+A
C	Distance between Machine Unit and Device	Min.150 cm
D	Device and Machine Unit Layout Area Width	W+C+F
E	Machine Park Length	Min. 240 cm
F	Machine Park Unit Width	Max.130 cm
G	Machine Park Wall Distance	Min. 60 cm
H	Device Height	Max. 310 cm
J	Loading Warehouse Distance Between Device - Door	Min. 3 m
K	Device Chamber – Sidewall Distance	Min. 2 m
W	Device Width	W+40 cm
L	Device Length / Depth	L
X	Minimum Device Layout Area Width	G+F+C+W+K
Y	Minimum Device Layout Area Length	J+A+L+A+J

Minimum (XxY) Layout Area Calculation = (G+F+C+W+K) x (J+A+L+A+J)

Sampling for a Double Door 34 m³ EO Device = (60+130+150+40+W+ 200) x (300+220+L+220+300)

= (580+W) x (1040+L)

= (580+180) x (1040+780)

∑ = Width (760 cm) x Length (1820 cm) = Area (138.2 m²)

NOTE: For single door device layout area calculation, distance A is deducted.
These area calculations are recommended for minimum ETO C 1445 Device placement. The user can arrange larger sterilization areas according to her / his own needs. Dimensions may vary in niche productions.

ETO-C 1445

INDUSTRIAL ETHYLENE OXIDE STERILIZATION DEVICE COMPONENTS

▪ Sterilization chamber, water heating and recirculation system, EO gas system, vacuum pump, vacuum system, steam chamber and pipeline systems, neutralization system with water.

Water Heating Tank and Hot Water Recirculation System

Water Scrubber Neutralization Tank

2 Bar 134^{0}C Fully Automatic Steam Chamber

Pipe and EO Gas Connection System

Vacuum System and Vacuum Pump

▪Machine park, pneumatic control system, pipes and connections, activators, connectors, EO Exhaust system, HEPA Filter fresh air system,

HEPA Filter Sterile Aeration System

Pneumatic Control System

EO Device Water Distribution System and Water Consumption, Electronic Counter Control

▪ Door and gasket system, loading and unloading roller system

EO Device Gasket

Loading and Unloading Roller System

Pneumatic Door System

▪ Electrical panel, PLC, sensor system (heat, humidity, pressure, etc. safety sensors), SCADA software, electronic hardware, HMI display kiosk, electronic scales

EO Device Kiosk Control

HMI Display, SCADA Software

Halogen-Free Connection Connectors

EO Tube and Electronic Balance

Electrical Panel, PLC, Sensor System (Temperature, Humidity, Pressure, etc. Safety Sensors), Electronic Equipment

▪ Internal parts of ETO-C 1445 are made of AISI 316 ℓ, other parts are made of AISI 304 stainless steel. All welding in the device is made of AISI 316 ℓ food-grade stainless steel. The exterior of the sterilization chamber is insulated with nanotechnology insulation paint and insulation material that protects the temperature and is covered with steel plates.

▪ All components in the machine park such as; pipeline system and connections, activators, connectors, EO exhaust system, sterilization chamber and all parts related to it are made of stainless steel.

▪ Materials resistant to ethylene oxide gas are used for parts that require vibration and flexing.

▪ All electrical, electronic cables connections and hardware used in the device are Halogen Free. (Fireproof)

REQUIREMENTS FOR EO DEVICE INSTALLATION

- Layout: Required area for device placement
- Electric: 380-440 V, 50-60 Hz (Volts and frequency vary according to countries. Production is made according to all kinds of volts and frequencies.)
- Power (Watt): Given in the table according to device sizes.
- Pressure air: 6-8 Bar, Minimum 100 ℓ / min.
- Clean water: Water with minimum 4 bar, 1/2" pipe
- Drainage Connection: Goes with a minimum Ø 5 cm pipe.
- EO gas: EO Tube according to preferred gas concentration
- Exhaust connection: Ø 10-12 cm external environment flue connection

Spare Parts and Service Supply

All over the world;

- Spare parts and service supply
- Program upgrade with remote access
- Gasket, activator, vacuum motor etc. supply of spare parts
- Use and maintenance training for device user technicians

Some Well-Known Machinery Manufacturers We Collaborate With In The Production Of **TEKNOMAR®** Industrial Ethylene Oxide Sterilizer

FESTO SIEMENS ABB

ADVANTECH oKSitem Yeni kromsan

Reliance Industrial SCADA/HMI system Schneider Electric PHOENIX CONTACT INSPIRING INNOVATIONS

LOADING TO EO STERILIZER WITH PALLET

Easy Loading and Unloading Roller Systems with Pallet

LOGISTICS

Area Upload and Download

It is Transported With Open Top Containers.

1 - 10- 20 -34 -50- 62,5-100 m^3

Industrial Ethylene Oxide Sterilizers suitable for sterilization with parcels and pallets

NEUTRALIZATION

What is neutralization?

At the end of EO sterilization, the most important and critical stage is the Neutralization process, which starts with the gas evacuation process. It is the process of giving ETHYLENE OXIDE GAS, after the ethylene oxide sterilization process, to the atmosphere by eliminating its toxic and poisonous properties. Three types of Neutralization techniques can be applied for ETO sterilization.

- Washing with Water
- Washing with Acid
- Catalytic Oxidizer and Catalytic

Why Teknomar Scrubber?

Teknomar's design water and acidic Scrubber can be used as internal or external environment. Scrubbers are designed and placed depending on the volume of the sterilizers. Multiple sterilizers can be integrated into one scrubber for cost-effectiveness.

The scrubber is integrated with SCADA software and controlled by the SIEMENS PLC unit. There is an ETO Detector in the exhaust (PPM) to monitor the residue left from the exhaust. The system is preferred for GMP, CE, FDA registered factories.

Teknomar Ethylene Oxide Gas Neutralization System with Water

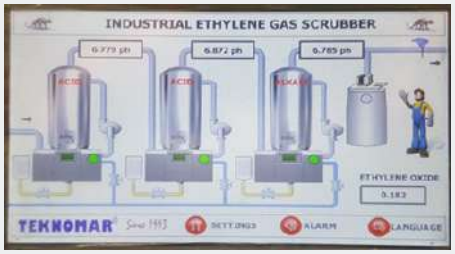
Neutralization System with Water : It is available as standard in all our devices. In the ETO C1445 Device, while the vacuum is being made, the gas is neutralized by 95-97% with the effect of water in the 1st stage with the water pump feature. In the 2nd stage, 99.9% of the gas is neutralized in the aqueous neutralization tank.

Diluted ethyl glycol is obtained as a result of the water neutralization process. Ethyl glycol is a fertilizer raw material. It is not harmful to nature. The diluted aqueous ethyl glycol from the device is not a highly usable industrial waste. It is given to the drainage. It is environmentalist. Does not need to be stored.

TEKNOMAR EO GAS ACIDIC NEUTRALIZATION SCRUBBER DEVICE (OPTIONAL)

What's, Working Principle ?

The Acidic Scrubber is the unit that additionally neutralizes the ETO Gas after the sterilization phase. Uses Sulphuric Acid (H_2SO_4) and Sodium Hydroxide (NaOH) to inactivate Ethylene Oxide Gas as 99.99%.



The Acidic Scrubber consists of 3 towers . ETO gas is taken in the first tower, a turbulent effect is created inside the tower for continuous acidic washing and homogeneous washing. The majority of EO gas neutralization is done at this stage.

The second tower is used to neutralize the residual EO gas from the first tower. EO gas dissolves 99.99% at a rate of 0-10 ppm.

The third and last tower eliminates the acidic steam with sodium hydroxide. From here occurs the alkali-based salt and diluted ethyl glycol. This waste is stored in an external tank. Filled chemical waste tanks are delivered to the relevant institutions for disposal. In order not to pollute the environment and nature, the waste should not be given to the drainage.

The rate of gas ejected from the Acidic Scrubber with the exhaust varies between 0 – 10 ppm, depending on the flow rate/time, the percentage value of the acid used, and the pH value. The ppm value can be adjusted according to the operating cost-effectiveness and customer request.

Each of the scrubber towers is made of acid-resistant material. Equipped with high-quality sensor groups and PLC to detect EO ppm, PH, Solution, Water Level and Temperature.

Industrial ETO C1445 Ethylene Oxide Sterilizer SCADA Software and Process Control

HMI Display

Software - SCADA SYSTEM SOFTWARE – RELIANCE

- Real Time Operating Process Graph
- Temperature, Humidity, Vacuum, Device Operation Functions Process Control
- Remote Access
- Database
  - ✓ Access to records in a user-readable format
  - ✓ Ability to print copies of records
  - ✓ The system detects invalid or altered results
  - ✓ The integrity of the entire record is maintained throughout the retention period.
  - ✓ Recordings are backed up
  - ✓ Access by unauthorized persons is not allov
  - ✓ User authorization
  - ✓ Trusted user encryption technique
  - ✓ Automatic sensor calibration database

- Detailed Reporting
- Industrial Software Security
- 1-10ms data recording
- Up to 10 years of retroactive, nonerasable data, report, graphic record
- Entering and reporting sterilization record with LOT, Serial

Due to high security, the SCADA Process of the EO device does not start the device for sterilization when ideal operating conditions cannot be provided or in case of adverse operating conditions (power failure, water outage, lowering in air and water pressure, etc.) Waits until ideal operating conditions are met.

While the device is in operation or if the infrastructure conditions (electric, water, air etc.) are disrupted during sterilization, the system automatically switches to safety mode. Stays in standby and sleep mode.Does not open the sterilizer doors until the user intervention.

Kurulum Kalifikasyonu

IQ - OQ - PQ

Sterilization Validation consists of 3 stages:**IQ, OQ, PQ**

OBJECTIVE: EO DEVICE INSTALLATION QUALIFICATION

Teknomar® brand ETO-C 1445 Ethylene Oxide Sterilization Device's; Performing the Installation, Operational and Performance Qualification and verifying the sterilization process against the Sterility Assurance Level (SAL) 10^{-6}

ISO 11135 Sterilization of Medical Device- Requirement for the Development; Validation &Routine Control of a Sterilization Process for Medical Devices – Ethylene Oxide

In addition, the device production is based on the EN 1422 standard.

PQ: It is a validation process for sterilization of the product.The manufacturer performs performance qualification validation for the products it produces.

INSTALLATION QUALIFICATION - IQ

The purpose of this installation qualification is to provide control with FAT (Factory Area Test) during the production phase of Teknomar® brand ETO-C 1445 Ethylene Oxide Sterilization Device and with SAT(Site Acceptance Test) during installation and is to verify the device technical values.

Teknomar® brand ETO-C 1445 Ethylene Oxide Sterilization Device is verified during Installation Qualification-IQ.

- Equipment Identification and Control
- Resource Requirement (Location, electricity, water, gas, exhaust, expense etc.)
- Main Components Specifications
- Verification of Main Parts Specifications
- Safety Precautions
- Calibration (for sensors)
- Software – SCADA SYSTEM SOFTWARE- RELIANCE

Also;

- The suitability of the place where the device will be installed
- Ventilation of the area where the device will be installed, expenses, exhaust, electricity
- Suitability of the working area
- Safety precautions taken
- Installation area suitability for occupational health

Finally;

- All pressure gauges, temperature controllers, calibrations are checked.
- The operation of all supporting utilities is checked.
- All equipment is installed and made ready for operation.

The ETO Sterilizer is installed according to the manufacturer's recommendations.

OPERATIONAL QUALIFICATION – OQ

ETO C 1445 Ethylene Oxide Sterilizer is to prove the correct operation of the equipment for Operational Qualification (OQ). OQ is a system simulation study only and will be performed without a product. Involves the actual physical parameter controls required for the equipment.

The following information is verified during the Operational Qualification (OQ) of the ETO C 1445 Ethylene Oxide Sterilizer.

- The function of installation temperature, pressure, vacuum, humidity sensors.
- The function of door safety sensor, door lock and on/off system
- Function of alarm indicators on the sterilization process flow screen.
- The function of the vacuum pump for vacuum and pressure leakage inside the chamber.
- Software and hardware control, software validation
- Accuracy of sensors
- Control of operational functioning, etc. testing and stages are checked.

The operating criteria are checked from the graph below.

			STANDARD CRITERIAS		
EO STERILIZATION CYCLE TECHNICAL DATA	**UNIT**	**Full Cycle 1**	**Min.**	**Max.**	**Tolerance**
1. PRECONDITIONING IN THE CHAMBER					
PRECONDITIONING TIME	minute		10	120	±%5
PRECONDITIONING CHAMBER TEMPERATURE	C°		37	55	±2
PRECONDITIONING CHAMBER MOISTURE	rh		30	80	±%5
2. GAS LEAK TEST VACUUM VALUE					
FIRST VACUUM PRESSURE (LEAK TEST)	-mBar		300	600	±%2
FIRST LEAK TEST TIME	minute		3	30	±%2
2nd VACUUM PRESSURE (2nd LEAK TEST)	-mBar		500	800	±%5
2nd LEAK TEST TIME	minute		1	20	±%5
3. CONDITIONING					
CONDITIONING TIME (MOISTURIZING TIME)	minute		10	90	±%10
RELATIVE HUMIDITY IN THE CHAMBER AT THE END OF CONDITIONING	rh		30	80	±%5
CONDITIONING TEMPERATURE	C°		37	55	±2
4. EO GAS INTAKE					
EO GAS TEMPERATURE (At the time of Gas Intake)	C°		37	45	±2
EO GAS INTAKE VACUUM VALUE	-mBar		450	800	±%2
EO GAS INTAKE MOISTURE VALUE	rh		30	80	±%5
5. EXPOSURE TO EO GAS (STERILIZATION)					
VACUUM VALUE AFTER EO GAS INTAKE	-mBar		125	250	±%5
STERILIZATION TEMPERATURE	C°		37	55	±2
IN-CHAMBER MOISTURE DURING STERILIZATION	rh		30	80	±%5
EO GAS EXPOSURE TIME (STERILIZATION)	minute		200	600	±%2
EO GAS INTAKE PPM VALUE	ppm		400	760	±%2
EO GAS INTAKE KG VALUE	kg		4	6	±%2
EO /CO_2 GAS CONCENTRATION	%		40/60	100	_
6. IN-CHAMBER AERATION					
IN - CHAMBER WAITING TIME END OF STERILIZATION	minute		0	90	-
AIR WASHING PRESSURE	-mBar		400	800	±%2
NUMBER OF AIR WASHING	pcs		3	99	-
7. RELEASE					
RELEASE TIME (AERATION)	time		37	55	-
BIOLOGICAL INDICATOR TEST TIME	time		24	48	-
8. VALIDATION / VALUES SELECTED FOR STERILIZATION					
STERILIZATION TEMPERATURE	C°		37	55	±2
MOISTURE	rh		30	80	±%5
STERILIZATION VACUUM VALUE	-mBar		400	800	-
RESIDENCE TIME IN- CHAMBER	minute		-	-	-
STERILIZATION TIME	minute		200	600	±%2
WAITING TIME AFTER IN-CHAMBER STERILIZATION	minute		5	60	-
VALIDATION VALUES					
TEMPERATURE					
MOISTURE					
PRESSURE					
MINIMUM RESIDENCE TIME IN- CHAMBER 5:55 ±%5 (35')					

PQ Performans Kalifikasyonu

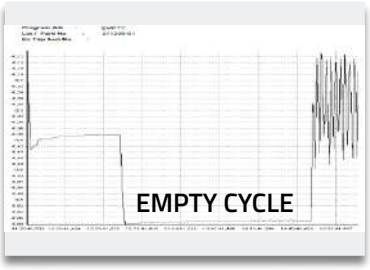
IQ - OQ - PQ

PQ (performance qualification) validation is done for the product(s) to be sterilized. Validation conditions are determined by the cycles of the empty, quarter, half1, half2, half3, full, full+full, and validation monitoring is provided by biological and chemical indicators.

PRODUCT VALIDATION - PQ

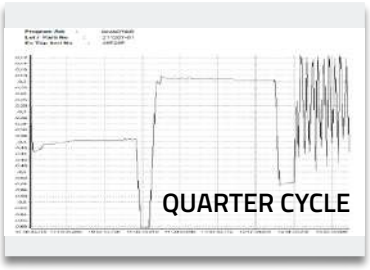
EMPTY CYCLE:

While products to be sterilized with EO in their original package, before exposure to EO gas, the basic values to be used for sterilization are examined, such as whether the sterilization packages and the products in the package are deformed and physically damaged under heat, humidity and vacuum. It is a preliminary study to determine the temperature, humidity, vacuum and pressure values for the sterilization to be carried out with EO gas. In addition, the functional parameters of the EO device are also tested in the Empty Cycle, without EO gas being injected.



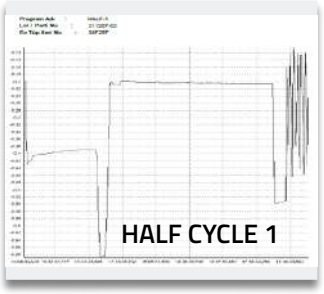
QUARTER CYCLE:

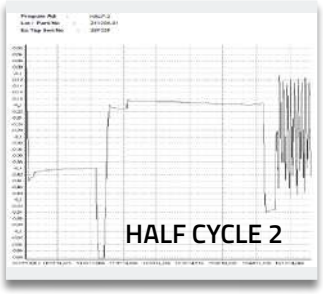
The minimum target sterilization time for EO exposure is determined. The sterilization process is applied to the load in a minimum of ¼ of the target standard sterilization time determined in a Quarter Cycle. During the quarter sterilization cycle, proportional sterility analyses are performed with the biological indicators placed in the device with the products.

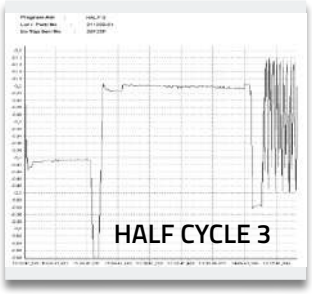


HALF CYCLE:

In Half Cycle, EO gas is used, the amount and value of which is fixed in a Quarter Cycle, valid for the products to be validated without damaging the load. The time given for the sterilization of the products in Half Cycle is 2 times the time value used in the quarter cycle.In Half Cycle, sterilization conditions and sterilization efficiency are aimed to be correct. It is at least half of the standard time.





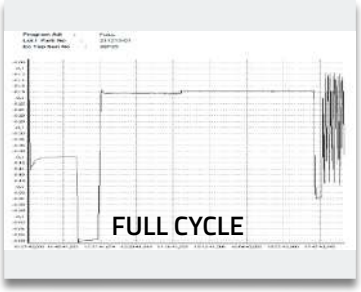


HALF + HALF CYCLES (1-2-3):

The most common verification method for EO is at least one fractional cycle (applied when changes are seen in the sterilized time parameters) and 3 half-cycles. The values determined for Half Cycle are the preliminary work done for safety purposes before the full sterilization is started, and sterilization control can be provided by interrupting. After half-cycles, sterility analysis is performed for sterilization safety on products that represent difficult conditions, and parametric values to be applied in Full Cycle are determined as a result of Half + Half Cycle (Half 1, Half 2, Half 3). The time value in the full cycle is 2 times of Half + Half Cycle.

FULL CYCLE:

It is the cycle in which the final sterilization parameters of the product to be sterilized in ETO C 1445 with a full load are clarified and sterilization is verified. In Full Cycle, validation of program operating values accepted for final sterilization is performed. Second Full Cycle sterilization is done for difficult products, again for safety.



All Operations and Certification System in ETO C 1445 Industrial Ethylene Oxide Device COMPLIED with 93/42, ISO 13485 MDD Directives and (EU) 2017/745 European Parliament and Council Regulation MDR.

PROFESSIONAL REPORTING

TEKNOMAR® Since 1993 Group

EO STERILIZATION REPORT

Cycle Number : 2
Sterilization Date : 18.08.2021
Program Name : FULL
Lot / Batch No : 18.08.21-01
Tube Serial No : 6411D5

EO Gas ppm: 711,0008 ppm

STERILIZATION PARAMETERS

First Vacuum Pressure	:	-0,449	**bar**	**Sterilization Time**	:	300	**m**
First Leakage Time	:	10	**m**	**Gas Vacuum Pressure**	:	-0,550	**bar**
Conditioning Time	:	120	**m**	**Waiting Time**	:	10	**m**
Second Vacuum Pressure	:	-0,649	**bar**	**Air Washing Pressure**	:	-0,449	**bar**
Second Leakage Time		1	**m**	**Air Washing Cycle**	:	21	**cycle**
EO Gas Fill Pressure	:	-0,280	**bar**	**Sterilization Temperature**		52	**degC**

STERILIZATION RESULT TABLE

EO Gas ppm : 711,0008 **ppm** **EO Gas kg :** 7,90000 **kg** **Used Water :** 118 **liter**

		Start Time	End Time	Pressure (bar)	Temp (degC)	Humidity (%)
	Sterilization Start	14:27:08		-0,001	53,26	23,80
1	**First Vacuum Process**	14:27:08	14:28:50	-0,450	53,22	19,68
2	**First Leakage Test**	14:28:50	14:38:48	-0,444	53,36	26,11
3	**Conditioning Process**	14:38:48	16:39:18	-0,417	51,63	62,16
4	**Second Vacuum Process**	16:39:18	16:40:54	-0,650	51,61	45,34
5	**Second Leakage Test**	16:40:54	16:41:53	-0,647	51,61	51,31
6	**EO Gas Fill Process**	16:41:53	16:49:20	-0,279	51,75	71,82
7	**Sterilization Process**	16:49:20	21:49:21	-0,361	51,61	72,16
8	**EO Gas Vacuum Process**	21:49:21	21:50:23	-0,550	51,58	67,86
9	**Waiting Process**	21:50:23	22:00:23	-0,536	51,68	68,97
10	**Air Washing Process**	22:00:23	22:55:41	-0,014	51,71	29,61
	Sterilization Finish		22:55:41			

Opearator Signature

QC Signature

ETO C 1445

Industrial Type Ethylene Oxide Sterilizer

134 L

800 L Suture

1.6 m³ Suture

4.4 m³

5 m³

10 m³

10 m³

15 m³

ETO C 1445

Industrial Type Ethylene Oxide Sterilizer

20 m^3

20 m^3

20 m^3

27 m^3

27 m^3

34 m^3

34 m^3

34 m^3

ETO C 1445

Industrial Type Ethylene Oxide Sterilizer

34 m^3

34 m^3 + 34 m^3

40 m^3

50 m^3

50 m^3

16 m^3 (+) Pressurised

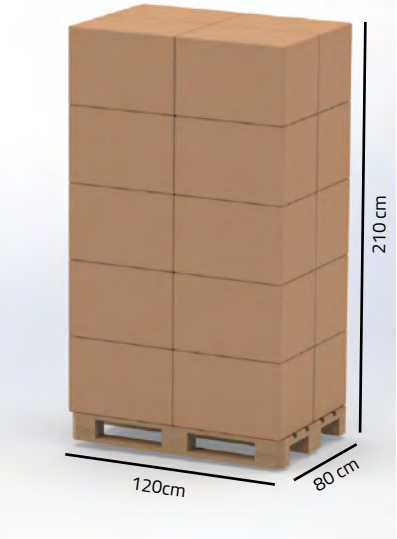
62,5 m^3 + 62,5 m^3

EO DEVICE CAPACITY SELECTION

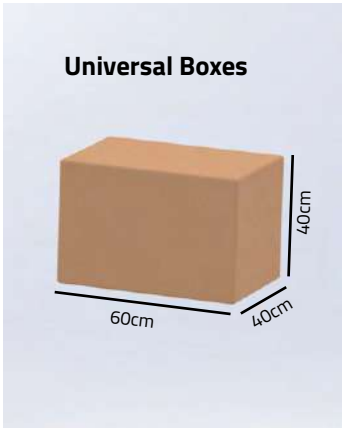
While choosing the capacity of the device you need before determining the device capacity selection that your company needs, we recommend that you consider your annual production capacity and your capacity increase in the coming years.

Dimensioning of the devices that we produce is in m^3 or Euro pallet (80x120cm). E.g.; It is designed and produced in line with your needs, starting from $1m^3$ to $120m^3$ as $10m^3$=4 Euro Pallets, $20m^3$ = 8 Euro pallets.

EU Pallet (80x120)



Universal Boxes



EU Pallet (80x120) takes an average of 20 universal boxes (40x60x40 box size). Let's assume that your daily product sterilization requirement is 240 units per box. $10m^3$ device (4 EU Pallet) sterilizes 80 boxes in one cycle. This cycle varies between 6-7 hours depending on the validation. Also offers you the opportunity to sterilize 3 times in 24 hours. 3 sterilization cycles mean 240 boxes. According to this calculation, you can find your daily sterilization need in as m^3 or Euro Pallet. You can refer to the device capacity table for the m^3 and Euro Pallet table.

Sample sterilization capacity calculation,

E.g.; If you are producing a catheter, the 1-year production capacity is determined.
Your annual capacity is 2,000,000 catheters
The amount of catheters placed in 1 box is 100 pieces.
1 pallet is 20 boxes
20 boxes x 100 pcs = 2000 pcs (amount of product on a pallet)
In 1 sterilization cycle for 10 m^3 device 8,000 pcs (4 Pallet x 2000) products are sterilized.
If 300 sterilization cycles are to be made annually, you will have a sterilization capacity of 300 x 8,000=2,400,000 pcs.
The ETO C 1445 device you need = 10 m^3, 4 Pallet

NOTES

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ISO 13485:2016 ISO 9001:2015 CE 1984

Wherever you need sterilization...

Teknomar provides services to its customers in the fields of design, manufacturing, assembly, training, technical service and validation. ETO C 1445 maintenance is simple and easy and does not require professionalism. Daily and routine maintenance can be done easily by the user.