

Our **Validatable Series** Automatic Ethylene Oxide Sterilizer are used by medical devices manufacturers manufacturing heat sensitive and heat labile medical devices which include long term invasive products like intra ocular lenses, cardiac pacemakers, vascular stents etc. They are floor standing, working in vacuum mode and use single use 100% E.O. cartridges for sterilization. The sterilization chamber is made from corrosion and gas resistant stainless steel. The inner surface of the chamber is smoothly finished to minimize any gas deposits and ensure a clean pleasing look. The chamber is electrically heated with our special ROTAHEAT arrangement and is insulated against heat emission.

The sterilizer door is hinged type, opening on the side and has a double latching arrangement with a quick release locking spring activated mechanism. To further ensure safety, a secondary locking arrangement gets activated once the CYCLE START button is activated which ensures that the door cannot be opened, once the CYCLE has started. A safety interlock is provided to ensure that the sterilization process does not start till the door is closed and latched.

To ensure smooth, silent and trouble free operation, the sterilizer is provided with an air motor vacuum pump which is used for vacuuming as well as degassing the sterilizer. As there are no moving or rotating parts in this pump, the maintenance is extremely low and it also ensures an almost silent and noiseless operation. It is a sturdy industrial model and the sterilization process can be validated as per EN ISO 11135 – 2014 standards for sterilization of medical devices. Already installed in many medical device manufacturing facilities who have been certified to USFDA, CE and other relevant medical compliance standards. Optionally we also offer 21 CFR Part - 11 Complaint Software and Recording.

Our Validatable Series sterilizers are especially custom designed for the application that they will be used for, with special software and hardware configurations and hence we offer different sterilizers for different industries. Our Validatable Series - Cardiac Stent Sterilizer is so very different from our Suture Industry Sterilizer.

DESCRIPTION

- Chamber: Made from stainless steel and provided with either a single or two doors as per requirement. Each door is provided with specially moulded “long life” silicon gasket.
- An efficient heating system which provides uniform heating to the material to be sterilized. The heating is electrical and completely dry.
- An air operated vacuum motor to efficiently draw vacuum and ensure faster cycle times and noiseless operation.
- a humidity system to humidify the load with an in built steam generator with microprocessor controlled heating.
- a control panel with “state of the art” automation controller and an auto manual feature which can be only be activated with a special key .
- a gas vaporizer to ensure that the EO going inside the chamber is in gaseous state.
- a microbiological air inlet filter- of 0.2 micron pore size - provides only filtered air inside the chamber during sterilization.
- a Colour Touch screen based programmable controller- provides multiple programs which can be tailored to a particular product range individually having independent temperature , humidity , vacuum , gas temperature etc. settings.

- A Colour Touch Screen Multi channel LCD multi color programmable online data recorder with a facility of storing upto five year batch records for easy recall and reference. It is provided with computer connectivity and the records can be uploaded from time to time as required.
- a sturdy dot matrix instrument printer which prints the data in real time as the events occur in the sterilizer.

Safety Features:

- All sensors linked to the automation, ensure reliability and failsafe operation.
- Before beginning each cycle, a Leak test is conducted; which checks the leakage and aborts the cycle if there is a leakage in the system.
- Locked door sensor does not allow the cycle to be started unless the door is closed.
- Double Door Safety – interlocks prevent both doors from being opened simultaneously.
- After cycle starts the doors are locked and cannot be opened.
- Unloading door cannot be opened unless the aeration is completed.
- Constant watch over entries and break diagnostic from automation, which warns the operator, by means of messages on indicator and buzzer.
- Cycle completion record is shown on the printout.
- Auto - Abort facility in case of abnormal conditions.
- “Tri-Aera” system involving degassing cycles, dynamic vacuuming and under vacuum aeration to enhance removal of residual EO.
- “Enviro –Pro” system to provide for operator safety on the unloading side.
- “Gas Diffusor “system provided to ensure diffusion of gas before it is let out of the exhaust.

Special Features

- Stainless steel chamber and fittings.
- Special easily operable flat doors with individual interlocks for added safety.
- Evacuation of chamber during washing cycle and aeration is programmable.
- Before the end of the cycle, to avoid the door to open safety interlock is provided.
- Auto – Manual Changeover possible in the unlikely case of failure of auto system.
- Password Protection for change of instructions.

Display & Printouts

Two continuous real time displays are provided with the sterilizer. The first Touch screen display shows the various cycle status and displays the current time, the date, the batch no. the temperature, the humidity, the time remaining in Gas exposure phase, the time remaining in the Aeration phase. Besides this the display also shows the various parameters, and the actual faults and also the fault code as and when applicable. The chamber is also represented in graphical form and the status of the sterilization cycle is depicted at actuals on it.

The second display is the **Programmable Touch Screen Graphical Data Recorder** which **records the data every 10 secs. And can display it in various forms like a graph, readings, bars graphs etc.** The multicoloured screen has six individual sensor heads which monitor the vacuum; humidity, the chamber temperature and the gas temperature also. It has a visual alarm facility which alerts the operator if a certain process parameter is not attained.

The alphanumeric printer prints the various parameters like the Start time , End time , Date , the batch no. and the operator's ID mark, Faults and Fault codes ,the various parameters , Gas exposure time , Aeration Time as and when applicable.

USP FOR OUR PRODUCTS

1. Our **Validatable Series** sterilizer has a digital printout and a graphical data recorder output. This helps the Quality controller to view each segment and parameter of the cycle and ensure that each process control limit as specified, has been met or not. The graphical format is multi-colour representing the different sensors. The built in memory card has the capability to store up to five years of data which can be used as an immediate reckoner in case of product recall. The recorder has the facility of computer connectivity with a USB port and also the reliability of the standalone data recorder which is useful if the cycle were to be taken in manual mode.
2. Our **Validatable Series** sterilizer has **six side heating** with and has a separate steam generator to generate humidity in the sterilizer as well as a vaporizer for evaporating the gas; as mentioned in the EN ISO 11135 - 2014 document. In our sterilizer, the steam supplied is of sterile grade and not high temperature water sprays.
3. Our **Validatable Series** sterilizer's sterilization process is validatable as per EN ISO 11135 - 2014.
4. Our **Validatable Series** sterilizer is made for medical device manufacturers and not for the hospital industry and is much sturdier. Our sterilizers have been used by medical device manufacturers for long term invasive product sterilization successfully.
5. Requirement of temperature profile and humidity profile as stipulated in EN ISO 11135 - 2014 are met in our sterilizer.
6. Determination of leak test, rate of vacuuming, rate of injection of gas available in our sterilizer.
7. Our Validatable sterilizer has a Performance Qualification Control program button which is used to automatically carry out the PQ by Half Cycle Method as described in EN ISO 11135- 2014.
8. During the gas puncturing stage the exact vacuuming process control limit is correctly defined in our sterilizer.
9. The sterilizer has a Large Colour Touch screen to select and view parameters, and insert alpha numeric Batch Codes, Name of material and Material Quantity.
10. We provide local support as and when required and can help out medical device industries in validating their sterilization process and make the proper documentation.

FEATURES AND BENEFITS OF OUR STERILIZER

Our Validatable **Series** sterilizer is compact stand-alone sterilizer chamber. Our sterilizer is floor mounting type suitable for indoor use only. The following points make our sterilizer more advantageous:

STERILIZER

1. One Touch operation makes operator expertise & dependence unessential.
2. Repeatability of cycle parameters and time assured.
3. **Chamber made of stainless steel with trays for easy material handling.**
4. A unit dose cartridge of 100% pure Ethylene Oxide is punctured automatically inside the chamber with a unique puncturing mechanism.
5. A printer is installed in the panel of the sterilizer to permanently record time, batch no. , cycle parameters , cycle status, gas exposure time and aeration time and fault messages.
6. Colour Touch screen display shows the time, cycle parameters, cycle status and exposure time. It also indicates the time remaining for gas exposure and aeration and fault messages and has a virtual keyboard for data entry.
7. Flexibility of setting multiple sterilization cycles with possibility to set all the parameters independently.
8. **Computer interfacing port provided.**

SAFETY

1. The cycle operates in vacuum and hence is safer to operate as there is minimum chance of leakage.
2. The time tested electronic design provides accuracy of operation, dependability and repeatability.
3. **In the Single as well as in Double door models, the doors are provided with an interlock, unless both the doors are closed, the cycle cannot be initiated.**
4. Once a cycle is started, the doors gets locked automatically and do not open till cycle is complete.
5. Double Door Safety – interlocks prevent both doors from being opened simultaneously.
6. The sterilizer aerates the load after sterilization and this operation is continuous in one chamber and it thereby eliminates gas exposure to operators during load transfers of improperly aerated load..
7. **Cycle Completion record is shown on the printout and display and only after successful completion of batch.**
8. **Auto – Abort facility in case of any abnormal conditions.**

UNIQUE FEATURES

1. Special Time Tested Software where cycle parameters can be programmed as per actual requirement of the load.
2. **“ENVIRO-PRO”** system which acts as an additional area safety feature by sucking air away from operator.
3. Unique **“TRI_AERA”** system, to enhance removal of residual EO from the products.
4. Unique **“LEAKALERT”** sequence which performs a leak test automatically at the beginning of each cycle, and if leakage is found, it alerts the operator and aborts the cycle.
5. Fault and time out **messages** are displayed for easy diagnosis by operator and not only as Fault numbers.

6. Unique “ROTA-HEAT” system which enhances all round heating and lower electric charges.
7. Unique “AUTO-MAN” feature which allows Manual operation in case of emergency break down of Auto system.
8. Price economical with more features to price ratio.
9. Designed to work in tropical conditions and does not go in fault if the humidity or temperature is high.

WHY US

1. Sterilizer manufactured in INDIA and using all locally available quality components, hence spare and services easily available at low cost independent of foreign currency fluctuations.
2. We offer 100 % Ethylene Oxide Gas cartridges manufactured in INDIA and hence easily available at economical price and not dependent on foreign currency fluctuations.
3. More than 4000 sterilizers sold since the last 23 years in India and abroad.
4. **PROUDLY DESIGNED AND MADE IN INDIA.**