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Step by step of the ETO sterilizer machine

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Step 1. Calculate the capacity of the sterilizer

① The actual capacity of the ethylene oxide sterilizer is about 70%.

Normally, a 10 cubic meter sterilizer can hold 7 cubic meters of product.

- Sterilization takes about 8~10 hours.
- The sterilizer can complete two sterilization cycles per day.
- The duration of sterilization depends on PQ.

② The size of the pallets.

The commonly used pallet sizes are: 800mm * 1200mm, 1000mm * 1200mm, 1100mm * 1100mm.

Once you have determined the pallet size and EO sterilizer capacity, you can proceed to the next step.

Step 2. Determine the function and configuration of the EtO sterilizer.

③ The voltage and frequency of your local industrial power supply.

380V50Hz, 380V60Hz, 415V50Hz, 440V60Hz?

You can request the use of a transformer or customized electrical equipment.

④ The percentage of ethylene oxide gas.

100%EO, 90%EO+10%CO2, 80%EO+20%CO2, 70%EO+30%CO2, 30%EO+70%CO2, 20%EO+80CO2, 10%EO+90%CO2?

Explanation: The lower the EO percentage concentration, the higher the required pressure, the higher the cost of the sterilizer, and the relatively shorter the required aeration time.

EO gas with a concentration of over 80% usually requires nitrogen gas for safety protection, and then it needs **nitrogen generator**.

- The EO sterilizers with concentrations ranging from 70% EO to 30% EO are standard configurations.
- The cost of an EO sterilizer with 20% EO is 10% higher than that of sterilizers with 30% EO.
- The cost of an EO sterilizer with 10% EO is 30% higher than that of sterilizers with 30% EO.

Note: In some countries, it is not easy to purchase ethylene oxide gas. You can consult the local EO supplier to determine the percentage of EO concentration that can be purchased.

⑤ **Humidity range**.

Default humidity: 30%RH-80%RH.

Determine whether to customize the humidity range.

Usually, absorbable and non absorbable sutures require a dry vacuum pump and nitrogen generator to ensure that the humidity is not too high.

⑥ Temperature range.

Default temperature range: 30 ℃ -55 ℃. Limit < 58 ℃.

Determine whether to customize the temperature range.

⑦ Types and quantities of EtO sterilizer doors.

Types of doors: sliding doors, revolving doors, and lifting doors.

Sliding Door

Lifting Door

- The sliding door has the lowest cost and occupies the largest area of the sterilization workshop.

Revolving Door

- The cost of revolving doors is relatively high. Many customers prefer revolving doors.
- The lifting doors save space, but have the highest cost. If the sterilization workshop has a tight area and a high internal height, a lifting door can be used.

Then determine the number of doors, whether it is one or two.

⑧. Material of sterilizer water jacket.

Material: Carbon steel, 201 stainless steel, 304 stainless steel.

stainless steel water jacket

- The price of 201SS is about 1.5 times that of carbon steel.
- Carbon steel water jacket Service life: more than 20 years.
- 201SS, 304SS jacket Service life: more than 30 years.
- 304SS is suitable for sterilizers with higher requirements, and its price is twice that of carbon steel.

⑨. Parameter release

Some customers use BI, while others require parameter release.

If parameter release is required, additional SEC sensor and humidity sensor isolation device needs to be installed inside the sterilizer, additional about $15,000.

⑩. The automatic conveyor device inside the sterilizer.

Some countries require worker safety regulations to prohibit workers from entering sterilizers. In this case, a automatic conveyor of sterilizer can be used.

The internal automatic conveyor of sterilizers can be done for safety and to save manpower.

⑪. Loading and unloading methods of sterilizer.

The commonly used loading and unloading methods include manual carts and electric forklifts.

You can choose your preferred loading method based on your budget and needs.

⑫. Special or customized items

To meet the 21 CFR Part 11 compliance standards, it is recommended to add the following configurations:

- Backup industrial computer (Auxiliary IPC)
- Online EO sensor
- Backup vacuum pump(option)

- Additionally, it is suggested to add EO monitor of the workshop environment. Sterilization workshop can set up 8 monitoring sampling points to improve workshop safety.

Or other items that customers want to customize.

After determining the functional configuration of the sterilizer, the third step can be carried out as follows:

Sep 3. Precondition room.

Regarding the Precondition room, determine if a separate one is needed.

Precondition room can shorten the entire sterilization cycle.

The function of the Precondition room is to humidify and heat the products to be sterilized, This way, the product can be quickly sterilized in the sterilizer, thereby shortening the sterilizer cycle.

If no precondition room, the product will undergo heating and humidification processes in the sterilizer.

If you require a shorter sterilization cycle, you can choose a precondition room.

Step 4. Aeration room.

Regarding the aeration room, determine if a separate one is needed.

Aeration room can quickly remove some EO residues from the product.

There are usually three ways of aeration:

- **Option A**: Aeration in the separate Aeration room for 1-2 days.

  Generally, Syringes, long catheters, gloves require separate Degassing/Aeration room.

- **Option B**: Aeration in the same sterilization chamber. At this point, due to the products to be sterilized being in the sterilizer for 24 hours or longer, it is necessary to expand the capacity of the sterilizer to load more products.

- **Option C**: If option A or B is not selected, sterilized products can be placed in a well ventilated warehouse and naturally aerated for 14-20 days. In this case, there is a risk of EO residue not meeting the standard.

Additionally, what is the requirement for EO residue of sterilized products in ppm? 10ppm? or other?

Generally, standard requires the EO residue of products after EO sterilization shall not exceed 10ppm (10μg/g) when leaving the factory.

It is usually recommended to use **option A** or **option B** to allow for the removal of gaseous residues down to a legally acceptable level.

As mentioned in steps 3 and 4 above, the three stages of heating, sterilization, and aeration can be carried out in the same sterilizer chamber or in three separate chambers/rooms.

Step 5. Nitrogen generator.

Regarding the Nitrogen generator, determine if it is needed.

The function of nitrogen is to ensure dryness and protect safety.

Items sensitive to humidity require nitrogen to ensure dryness.

When the percentage of EO gas exceeds 80%, nitrogen is required to improve safety. Nitrogen can improve safety at all times.

Step 6. EO waste gas treatment equipment/Apparatus.

EtO scrubber for EO sterilizer.

Hydrolysis method: Ethylene oxide has a good affinity for water and can form ethylene glycol with water. Ethylene oxide is more prone to form ethylene glycol with water under acidic conditions. We add sulfuric acid to catalyze the production of ethylene glycol during the hydrolysis process of ethylene oxide waste gas, and then neutralize it with alkali, with a pH value close to 7.

Ethylene oxide can hydrate with water: $C_2H_4O + H_2O$ — $CH_2OH\text{-}CH_2OH$.

Regular disposal of waste liquid is required.

Material of Scrubber: PPH, FRP, 304SS.

Choose one of the three materials according to your budget.

Emission standard of Eto Scrubber: 80mg/Nm³ (44ppm), 40mg/Nm³ (22ppm), 5mg/Nm³ (3ppm), 1mg/Nm³ (½ppm).

Note: Please consult the local regulatory agency for emission standards.

Step 7. Layout and preparation of workshop conditions for sterilization.

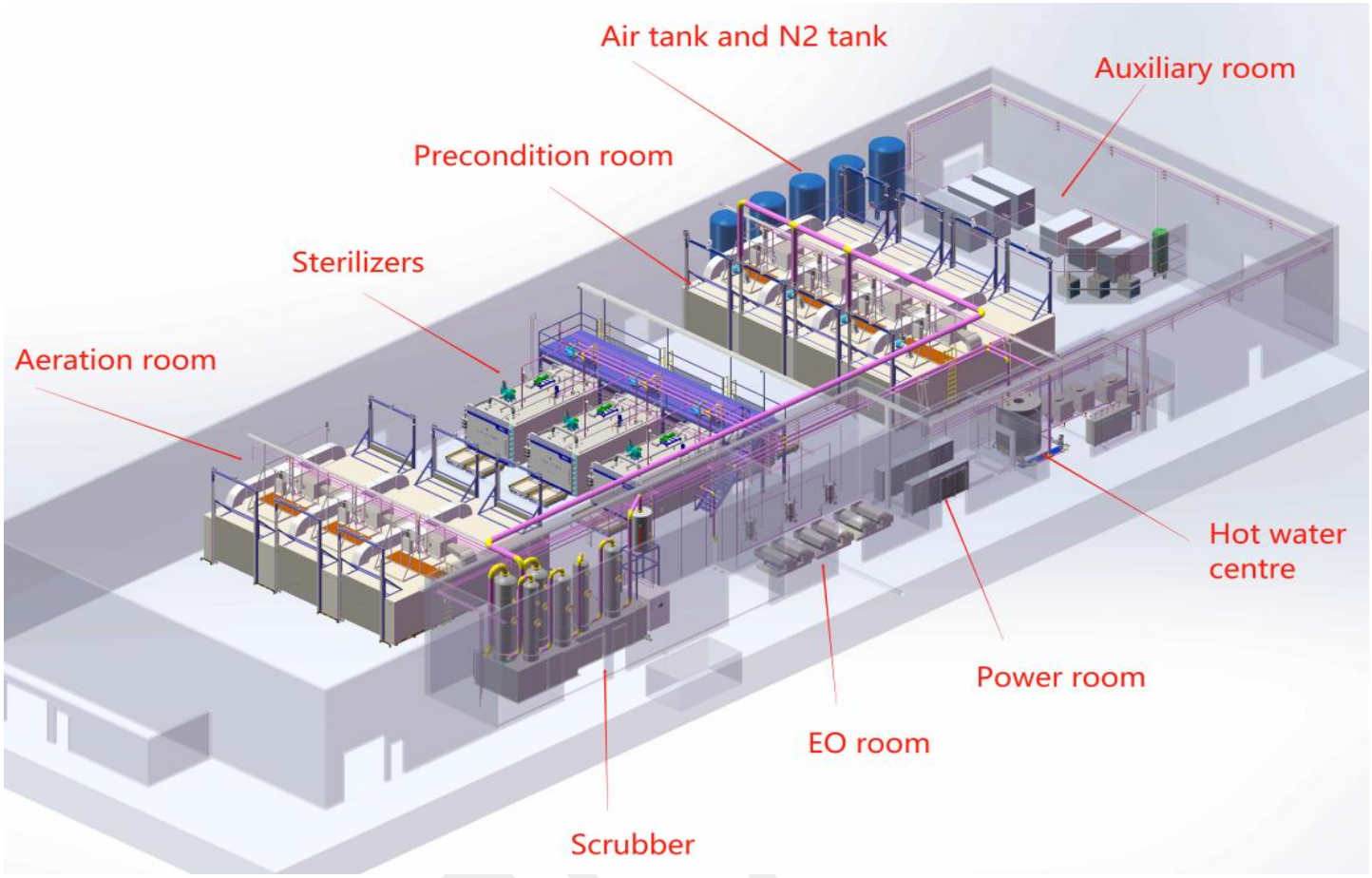
Generally, EO sterilizer needs EO Room, Auxiliary Room and Control Room.

Standard requires that the door of EO room cannot lead to sterilization workshop.

- The whole sterilization workshop it is forbidden to open fire, away from the fire. Solid ground level.
- Sterilization workshop shall ensure the temperature over 10 degrees Celsius (heating in winter).
- The sterilizer room should guarantee the well ventilated, use explosion-proof lamps and lanterns and switch.
- The sterilizer room, explosion-proof axial flow fan, installed in 300-500 mm off the ground.
- EO room should be well ventilated, avoid direct sunlight, use explosion-proof lamps and lanterns and switch.
- EO room /control room /Auxiliary room height 3000mm(min).

From the analysis made above, we can understand the configuration of sterilizer machines and quickly carry out the progress of sterilizer projects step by step.

We(Bocon) will quickly provide free sterilizer workshop proposal and layout design based on your needs.



Layout of Ethylene Oxide Sterilizer Workshop