100% EtO processing: Another alternative

by Dan Mayworm

ABSTRACT

An ongoing challenge to hospital CS departments is finding less costly alternatives to 12/88 EtO gas sterilization for the countless items that require low-temperature sterilization. There are drop-in replacements using HCFCs, new plasma systems, new technology in 100% EtO chamber systems, hydrogen peroxide, and perhaps coming soon, ozone systems. They all have their pluses and their minuses.

This article examines one solution to the problem, a 100% EtO system that uses proprietary gas cartridges placed in a plastic bag that becomes essentially the sterilization chamber. This process is the result of attention to the clinical and safety issues involved and has validation data and usage history to support its claim of efficacy.

Something old.
Something new.
Something borrowed.
Something blue.

This old folklore, ensuring a bride's happiness, came to mind while thinking about a recent visit to H.W. Andersen Products, Inc. (Haw River, NC). It started with my article on current sterilization technologies (ICST, September 1995) that mentioned Andersen's 100% EtO system. Most of the information on this process came from talking to the sales manager and reviewing company literature, since I hadn't seen the product in use for a while. Knowing how interested our readers...
are in anything new dealing with low-temperature sterilization, I accepted an invitation to visit the facilities when Andersen Products wanted to show me their “new” version of the “old” technology. I also found something borrowed and something blue.

The “old” technology consisted of breaking open an ampoule containing 100% EtO liquid and putting it into a container that was loaded with packaged products for sterilization. The liquid EtO vaporized into a gas, which then permeated the packages. The

to overload the bags. The containers are co-extruded polyethylene/Surlyn® bags that come in three sizes; #6 has a volume of 50 liters (2.12 ft³), the #5 is 25 liters (.88 ft³) and #4 is 15 liters (0.53 ft³). The packaged products to be sterilized are loaded into the proper size bag. Matched to each size bag is the appropriate size EtO cartridge, a Humidichip®, a Dosimeter®, and a biological indicator (Figure 1). These are all placed into the bag, which is then heat sealed and the cartridge activated.

The Humidichip is a moistened blotter that evaporates enough moisture vapor at the chamber temperature to maintain 60% relative humidity within the bag. Humidity is an important factor in EtO sterilization, therefore, care should be taken to precondition the load prior to sterilization. Highly desiccated or absorbent loads might cause a sterilization problem.

The Dosimeter is a proprietary chemical integrator providing visual assurance that conditions for sterilization have been met. Any biological indicator appropriate for EtO sterilization (B. subtilis) can be used, either self-contained BIs or spore strips.

The system “borrows” the name sterilizer for a modular chamber that has controls bolted to it for temperature, exhaust, and timing mechanisms. The chamber is available in 6, 10, 24 and 33 ft³ models as standard but can also be custom-designed to fit the user’s load capacity and equipment requirements. After activating the cartridge, the bag is placed into the chamber where it remains in a 50°C controlled temperature environment. The gas slowly elutes through the bag and is then exhausted from the chamber. Sterilization and aeration is accomplished in 16 hours. If at any time the temperature deviates from 50°C, the operator is notified both visually with a flashing light and aurally with a warning bell.

That’s all there is to it. The secret is in the controls that are bolted to the chamber and the safety features incorporated into its design. For example, operators must input their discrete code numbers. Then a fast five-minute purge cycle evacuates any residual gas in the chamber before the door will open. The door can only be left open for three minutes, ample time to remove a completed load and/or place a new one into the sterilizer. Close adherence to this protocol ensures op-
operator exposures remain well within OSHA guidelines.

Continuous processing
Depending on the size of the chamber and the size of the bags being loaded, sterilization can take place as a continuous process. In other words, unlike a batch process, you do not have to wait for one load to be finished before starting another. Bags can be loaded and unloaded as a continuous process, each one identified with a preprinted label. You don't have to think about starting or stopping at any particular time. While there is no cut-off time typical of batch processing, you do have to be careful to only remove bags that have undergone the full cycle.

To help you do this is a multi-load tracking system. A microprocessor tracks the progress of each load. The status of any load can be checked or printed out as many times, either automatically or manually, as you require. The microprocessor prints when each load went in and the time remaining. These printouts are the necessary documentation that each load was in the chamber for the required time and temperature. In addition, of course, you have chemical and biological indicators for each load.

Just as is true of any sterilization system, operator training is necessary. Can you fool the system and remove a load before its time? Yes, but it isn't easy. By following a few rules, operator error can be eliminated. In an emergency, there is a supervisor-only discrete code that will allow the supervisor to interrupt a cycle and remove a bag before its full time. This is strictly for emergencies, when the product in the load is needed and there is no alternative. Even then, the supervisor must wait for the five-minute purge cycle before the door will open.

Is this Andersen EO Gas Sterilization System a viable alternative to low temperature sterilization problems? Yes. On the plus side, it uses EtO, which has a proven record of reliability. The unit-dose cartridges can be handled and stored safely. Cartridges contain only enough EtO to sterilize the contents of the bag for which they are designed. Typically, they will use less gas than a chamber system because there is no chamber dead air space to fill. Figure 2 shows gas concentration over the entire cycle in a #6 bag containing items that do not absorb the EtO gas. A load containing PVC or rubber products would peak later and degas over a longer period of time.

The load tracking system is effective and the modular design is flexible. It appears easy to install and maintain. There are no compressed air or water lines. It only requires tying in to an existing dedicated exhaust system. There is a back-up battery system in the event of power interruptions. Maintenance requirements are low, mainly regular temperature calibration, lubrication of fans, and changing air filters.

Besides being a primary sterilization system, it could also find a market as an EtO system for anyone with a low-temperature sterilization system that cannot sterilize everything the hospital uses. Total annual processing costs for 300 cycles in the large #6 bag size would be about $5,000.

In states that have emission controls, a gas disposal system can be acquired and operated very economically. Because the sterilizer uses less gas and releases it very slowly, a low-cost passive catalyst-bed system can be employed. With the small 6 ft³ unit running every day, emissions can be below the four-pound thresholds at which state EPAs, like California, require gas disposal equipment.

On the minus side, you have the cost of acquiring the sterilizer, approximately $30,000 for the 6 ft³ chamber, $40,000 for the 10 ft³, $50,000 for the 24 ft³ unit, and $60,000 for 33 ft³. These costs should be compared to upgrading or acquiring another system. Training is required, as it would be with any new system. You are limited to one supplier for
your gas and other components, and currently you are required to use the entire 16-hour cycle.

![Figure 3: EOGas Sterilizer Fractional Cycles](image)

**User experience**
We checked with some users to find out how satisfied they were. Fitzroy Jennings, CS Supervisor at Lincoln Hospital (Bronx, NY) does low-temperature sterilization primarily for cystology and surgery. His department is open from 5 a.m. to 10 p.m. He has three Andersen EOGas™ System sterilizers and does 15 to 20 bags a day, seven days per week, enough to meet all the hospital’s needs. He has had the system for a few years and feels that it is safer than the old 12/88 system they had with leaking tanks. His sterilizer operators were certified after five days of intensive training by the company.

Others have found the modular concept of this system useful. The ability to choose the bag size to match their needs is cost effective compared with running a full load regardless of the number of items requiring sterilization. Users advise to be careful not to overload the bag. With support from Andersen, they have been able to validate their procedures for determining how much of a load each bag can sterilize.

**Conclusion**
We found no serious negatives with the process and end users seem to be content with what they are doing. As with any low-temperature sterilization process, meticulous cleaning and drying of items prior to sterilization is essential. Validate carefully the ability to sterilize complex, difficult-to-clean products with lots of places for air to be trapped and long, closed-ended tubes. Fractional cycles run on their Model 310 in a #6 bag showed a six log reduction (half-cycle) in 45 minutes with the BI in a glassine envelope, just under two hours when placed in the barrel of a disassembled syringe and a little over three hours in an AAMI routine test pack (Figure 3).

Remove batteries or any other potential source of electrical discharge from items that are to be sterilized. They can be safely sterilized once all connections are removed and accidental discharge prevented.

Economically, and systemically this is another viable alternative to low temperature sterilization.

Oh yes, the sterilizer and its storage cabinet base are “blue.”

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