Optimizing The Sterilization Cycle: A Case Study

PATRICK SMITH

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By precisely monitoring operating parameters, a contract-sterilization company has cut manufacture-to-market time from two weeks to two days for its medical product customers. Making sure every sterilization cycle is exactly the same means the company can meet stringent FDA requirements without the usual week-long germ-kill verification tests.

Instead, the company runs a test batch of the medical product plus a glassine envelope filled with bacterial spores highly resistant to ethylene glycol (EtO), the sterilization gas. Then the spores are incubated for a week. If the kill rate meets FDA requirements, the medical product can be sterilized on a production basis by precisely replicating the test cycle time/temperature/humidity/pressure/EtO parameters. And this eliminates the quarantine period, shortening product delivery time by a week.

Until recently, maintaining precise EtO levels inside the sterilization chamber was a big problem. For while time, temperature, humidity, and pressure can be closely controlled, EtO could not. The reason is that EtO levels can vary wildly during the sterilization cycle. One factor is the product itself: cloth, for example, absorbs EtO far more readily then plastic or paper. Another problem is during the initial rush of EtO into the chamber, the product soaks up the gas, dropping EtO levels.

Product packaging is another factor. Plastic wrap, for examples, resists EtO. So adding the H_2O (steam) forms a molecular "conduit" that conducts the EtO through the wrap to the product. But while this moisture helps the plastic inhale the EtO, it also distorts EtO levels in the chamber. Worse, too much moisture can condense on the product, the plastic wrap and chamber walls.

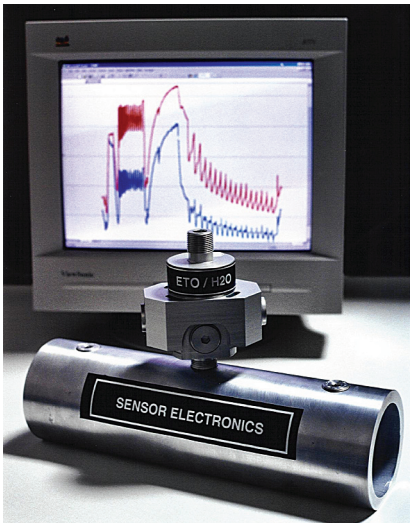
A crude way for measuring EtO levels has been checking for pressure (vacuum) changes. As the EtO/H_2O mixture feeds into the chamber the ambient pressure rises, giving a coarse indication of EtO strength. But such guesstimates are rough at best, since pressure variations can also be caused by the product absorption, leaking chamber seals, worn gaskets, varying nitrogen levels, and even air movement in the chamber.

Unfortunately, conventional EtO sensors are not at all satisfactory, being costly, cumbersome and, even worse, not particularly accurate. Instead of checking chamber atmospheres directly, these detectors simply funnel a sample of chamber air through a bypass pipe. And compounding these inaccuracies is the significant time lag between these readings and what is actually happening inside the chamber at any given moment.

To overcome these haphazard measurements and results, operators had to boost EtO levels and sterilization times, boosting costs as well. Even so, all the sterilization variable could not be replicated exactly, meaning those subsequent week-long incubation periods.

The solution for the sterilization company was a compact dual-gas analyzer developed by Sensor Electronics. Because it simultaneously measures and monitors both EtO and H_2O over the entire sterilization cycle (even during the initial EtO inrush) the sterilization company can meet applicable FDA requirements while eliminating the weeklong manufacture–to–market delay.

In operation, the analyzer has twin IR sensors continually measuring EtO and H_2O levels through the entire sterilization cycle, ignoring fluctuations in chamber temperatures, pressures, humidities, air movement and particularly product absorption rates. Those IR sensors focus on any changes in the molecular "signatures' of EtO and H_2O, twice every second



comparing the two against standard reference signals for each gas. The result is a constant and continuous readout of real-time values of both gases inside the chamber, regardless of variations, in the other operating parameters, effectively maintaining EtO levels to meet rigorous FDA requirements, with second–by–second chart printouts for verification.

For direct gas measurements the analyzer plugs directly into the chamber wall. It maintains its accuracy for hundreds of cycles without requiring recalibration or fine-tuning. The analyzer even keeps a watchful eye on itself: If anything goes wrong anywhere in the system it flashes an alarm, then spells out what's wrong where.

For this contract-sterilization company the analyzer ensures repetitive sterilization cycles that meet strict FDA requirements without requiring week-long kill-rate verification; for its medical-product customers it means moving product from manufacture to market in hours instead of weeks.

PATRICK SMITH *IS VICE PRESIDENT AND DIRECTOR OF RESEARCH AND DEVELOPMENT AT SENSOR ELECTRONICS. HE CAN BE REACHED AT 952-938-9486 OR PSMITH@SENSORELECTRONICS.COM.*