Is the FDA validation process for sterilizers, as established in AAMI ST8, current with Today’s steam sterilization practices?

by Thomas K. "Chip" Moore

If you happened to manage a company that manufactures sterilizers for use in US healthcare, what steps would you take to sell a steam sterilizer in the United States? The first step is to recognize that sterilizers are used to process reusable medical devices for patient use, and sterilizers are considered as Class II medical devices. Therefore, they are regulated by the Food and Drug Administration (FDA). Before any Class II device can be placed into commercial distribution, the FDA must grant clearance of the labeling claims for the sterilizer. Many of those labeling claims are developed through a process called performance validation. Fortunately, a guidance document exists to help the sterilizer manufacturer develop performance data to base those labeling claims. Once the FDA clears the sterilizer for US commercial distribution, the product is considered safe and effective when the user follows the written instructions for use (IFU).

The guidance document for healthcare sterilizers is a nationally recognized standard, developed through the consensus method at the Association of the Advancement of Medical Instrumentation (AAMI). The document is ANSI/AAMI ST8, the Hospital Steam Sterilizer guidance document. The ST8 committee updates the document every five years. The current ST8 document was published in 2008. Yet, does the performance and validation testing contained in ST8 reflect current healthcare sterilization practices? This article will attempt to review those performance challenges and compare them to practices found today in US healthcare facilities, both large and small.

Preamble
Steam, when used as the sterilization agent, is robust. It penetrates easily and makes surface contact well, even with complex devices. Steam has excellent heat transfer capabilities. It’s considered inexpensive and generally a fast and efficient process. As long as the item is heat stable, the use of a steam process is recommended.

Additionally, where’s the science? Medical device manufacturers of complex, re-usable Class II devices must develop written sterilization IFUs. They do this through testing with biological challenges and internal temperature profiling to document efficacious cycle recommendations. The question is whether these device manufactures actually use healthcare steam sterilizer cycles that were cleared by the FDA when developing their instructions. On the other hand, healthcare sterilizers are tested to the generic performance standards in AAMI ST8. Annex A of ANSI/AAMI ST8 provides the history of generic sterilizer performance testing. Annex K of ANSI/AAMI ST79 provides the history of the 16 Towel Pack Biological Indicator challenge test. Both are suggested reading.

The Performance Challenges as defined in ANSI/AAMI ST8

There are a number of performance test defined in ST8. For the purposes of this article, only three will be examined. They are:

1. Paragraph 5.5.2, Biological performance with a fabric Processed Challenge Device (PCD).
2. Paragraph 5.5.4 and 5.5.5, Biological performance with wrapped/unwrapped instrument PCD.
3. Paragraph 5.6.1, mechanical air removal test

Biological performance with fabric PCD.
Prior to about 1980, the US Biological challenge pack had dimensions of 12”x12”x20”, was double wrapped in 50”x64” muslin and the contents consisted of three muslin gowns, 12 huck/surgical towels, 30 gauze sponges, 5 lap sponges, 1 muslin drape. About this time and at the request of AAMI, a
round robin testing was organized to develop a new biological user test, one that would provide users and sterilizer manufacturers with material more readily available than was found in the 12x12x20” configuration. The resulting testing documented comparable efficacious data and the new pack, called the 16 towel pack was accepted as the standard biological challenge pack. That was 30 years ago, back when processing items wrapped in textiles was common for both gravity cycles and vacuum. Today, most healthcare cycles have mostly metal, wrapped in either non woven material or devices placed inside containers. Many surgical devices are of complex design, many with lumens of various lengths and diameters. Healthcare facilities process less textiles (gowns/drapes) today and those that do use textiles, the material provides a more difficult steam penetration challenge than did the traditional 144 tread-count muslin. Further, ST8 has two test pack configuration, the 16 towel pack for a biological challenge and the other for the Bowie-Dick test. Both use the same surgical towels but folded differently. This will be discussed in more detail in the Bowie-Dick section.

Over the last 30 years, medical device companies developed disposable, self-contained Biological and challenge packs (PCD). These disposable tests are design to mimic the performance of the 16 towel pack design. Most healthcare facilities use self contained Biological instead of spore strips in envelopes that required local culturing. Similarly, sterilizer design and performance (the preconditioning phase) has improved with each new ST8 revision, thus impacting FDA clearance submissions (the 510k process).

Thoughts about the future for the fabric PCD

The question today, does the 16 towel pack BI configuration still represents a valid challenge for sterilizer design? Does it represent a sufficient challenge for steam penetration and process lethality for the varied packaged items routinely processed in healthcare facilities today? “Over kill” cycles should be a familiar term. Through biological testing during cycle development, it is documented that biological kill (no growth) is achieved at ½ the recommended time at temperature. ANSI/AAMI ST8 does not specifically dictate the exposure temperature in the standard. Some US manufactures use 270° F (132.2° C) while others use 275° F (135° C). All steam cycles are controlled at above the selected temperature throughout the exposure phase, using a temperature sensor in the chamber drain. In Europe, they have standardized on one temperature, 134° C (273.2° F) and the standard temperature for the Bowie-Dick test is also 134° C (273.2° F). Why not have one standard US steam sterilizer exposure temperatures at 134° C (273.2° F) for all healthcare Dynamic Air Removal cycles and for the Bowie-Dick test?

Included in the ST8 performance testing is defined test loads for wrapped gravity cycles at selected time and temperatures. Are Gravity cycles still a valid user requirement or can the wrapped gravity cycles be deleted from ST8? Deleting the requirement would save cycle validation time for the sterilizer manufacture and eliminate labeled use. Do users like you really use wrapped gravity cycles at either 250° F (121° C) or 270° F (132.2° C)?

Biological performance with wrapped and unwrapped instrument PCD.

There are two testing elements for this category but the load challenge is the same, at least 25 lbs (11.3 kg) of metal weight. In both challenges, lumen items are suggested but not required. Both test use a wire mesh surgical instrument tray with the metal items spread evenly. For the wrapped challenge, two layers of 140 tread count muslin is used, each 54” square. Both challenges have biological indicators in envelope placed inside with the metal instruments to measure process lethality at ½ the recommended exposure time at the selected temperature. A cotton surgical towel is placed under the metal items and is used to measure moisture gain immediately after the cycle that includes a dry time.

Thoughts about the future for the wrapped/unwrapped PCD

In the summer and the fall of 2009, The Joint Commission (TJC) and the Centers of Medicare and Medicaid Services (CMS) respectively issued guidelines for Immediate Use Steam Sterilization (IUSS), formally known as “Flash” sterilization. At the end of 2010, AAMI, in cooperation with a number of agencies and societies, issued a joint statement entitled Immediate Use Steam Sterilization (IUSS). The key practice change contained in each of these IUSS advisories recommends the use a containment device to deliver items aseptically from the sterilizer to the point of immediate use. This recommendation makes the unwrapped cycle as part of ST8 validation testing and labeling, obsolete. This could
impact users who should be following sterilizer manufacturers written instructions for use, namely, the labeling for the “Flash” cycles, especially if TJC inspectors look for users to follow manufactures instructions (i.e sterilizer manufacture). Using unwrapped trays to sterilize items for immediate use is simply not recommended today.

A lumen challenge
There is no US recognized challenge for lumens. There should be. Unfortunately, there is controversy surrounding a lumen test, based primarily on commercial interest. Hopefully, some day in the near future, there will be a lumen test challenge and it will be incorporated into ST8 during a revision process. Until then, we can hope that the US steam cycles cleared for healthcare use are robust enough to insure steam contact to all surfaces, even inside lumen devices. There is strong indication in Europe that the initial start of the cycle should be a negative vacuum pulse for air removal from inside the lumen, whereas all US cycles have a positive pulse. Until we have the science to support a lumen test for healthcare validation, we rely on the 16 towel biological PCD as the sole challenge for steam cycle development for healthcare use.

Mechanical air removal test
The construction of the Bowie-Dick test pack is similar to that of the 16 towel biological pack in that both require the use of the same surgical towels. However, that is about the only similarity. The towels for 16 towel BI challenge pack are folded to achieve dimensions of 9x9x6", not wrapped, but secured with string or tape and has a density of 11.3 lbs per CF. The Bowie-Dick test pack uses the same towels folded to achieve dimensions in a range: 9.8" (+/- 0.8") by 11.8" (+/- 0.8") and between 9.8" to 11" high. The overall weight of the Bowie-Dick test pack is very specific, 8.8 lbs (4 kg) with +/- 5% variance allowed. The density of the Bowie-Dick pack is not specified, although it could be calculated for minimal and maximum dimensions. A Bowie-Dick indicator test sheet is placed in the geometric center of the pack with temperature sensing thermocouples positioned to document actual temperatures within the pack and to report temperatures under or overshoot at the beginning of the exposure phase.

Users of healthcare sterilizers, cleared by the FDA, should want a robust steam cycle. The question then is whether either the current challenge methods described in ST8 (BI and Air Removal) does that. The answer is no. The European Bowie-Dick test packs do offer a greater degree of air removal and steam penetration benefit. If the US were to adopt the European Bowie-Dick test pack, designed to EN867, Part 4 or ISO 11140, Part 3 or 4, US steam sterilizers would have improved steam penetration performance. Obviously, any ANSI/AAMI ST8 revision begins with the AAMI ST8 Working Group and a New Work Item proposal.

You might ask whether the US healthcare sterilizers are currently designed to past the European design Bowie-Dick test. To find out, six US hospitals volunteered in the summer of 2010 to run test at their facility. Two hospitals were located in New England area, two in the Midwest and two in the West, all were good size, short term, acute care facilities. The vacuum steam sterilizers were the typical Central Service sizes, manufactured and supplied by Steris, Getinge USA and
Belimed. Steritec Products Mfg. Co. of Englwood CO furnished the disposable European designed Bowie-Dick test pack. Each facility received 4 disposable test packs and ran the test in an otherwise empty chamber after their normal morning Bowie-Dick run. All 24 test documented Pass results. Steri8Tec stated the European Bowie-Dick test was a tougher air removal challenge and would show failed results before the US designed Bowie-Dick test did, but that a well-maintained sterilizer should provide routine Pass results. Isn’t that what every Sterile Processing Manager wants and desires, the assurance that their healthcare sterilizer is working efficiently, as designed, each and every day?

Finally, a number of Infection Control companies in Europe market electronic test devices, designed to be processed inside the sterilizer, report cycle performance and Bowie-Dick results. Of course, there is capital investment expense, but once purchased, it eliminates the cost of daily disposable test. Why shouldn’t US healthcare facilities have the same opportunities to purchase computer operated test devices? Running a daily Bowie-Dick test is the single, most important quality assurance test available today.

Summary
The intent of this article is to awaken users and device manufactures alike. AAMI ST8 has either dated test requirements and/or the tests are not as robust as they could be. Thirty years is a long time to have the same test requirements, especially when there are other, proven performance test available that could improve sterility assurance. You can help drive the change. Ask your sterilizer manufacturer if their vacuum cycles provides the optimum air removal and steam penetration cycles compare to sterilizer designed to European standards. The truth is in the outcome. The patients will be the beneficiaries. HPN

Where’s the science?

About the author:

Thomas K. "Chip" Moore retired from Getinge in November 2007 after a 39 year career. During his employment at Getinge (fka Castle Company and MDT Corporation), he was a sales rep, Product Manager, Market Manager, Manager - Marketing Services, and Sales Manager for Getinge Sourcing LLC. During 2011, he was under contract as the Marketing Director and Business Development Consultant for Sterilucent, a Minneapolis MN technology based company. Most of his career dealt with sterilizers and sterilization, new product introduction, training and organizing educational seminars. He has 20 plus years experience working on AAMI Committees and is still active on selected Working Groups, was a member of the AAMI Sterilization Standards Committee, is a member of IAHCSMM and the AORN Specialty Assembly for Sterile Processing. He served as an Ex-Officio Board member for NYSACSP for three years. He was a recipient of the 2003 IAHCSMM Award of Honor and was selected by HPN as one of the 30 most influential industry people. Moore is a graduate of Coe College in Cedar Rapids, Iowa and served in the USAF as a Medical Supply Officer.

References:
3. ANSI/AAMI ST8:2008