SELF-STUDY SERIES

Hydrogen peroxide sterilization in healthcare facilities today

by Larry Talapa

The most common low temperature sterilization methods used today in U.S. healthcare facilities are ethylene oxide (EO) and vaporized hydrogen peroxide (VH2O2). It is likely that low temperature sterilization will continue to grow because more and more critical and semi-critical reusable medical devices are made of materials and components that cannot withstand the high temperature and moisture in steam sterilization processes. Since the use of low temperature sterilization processes will continue to grow, let’s take a closer look at one of the methods: VH2O2 sterilization.

The use of hydrogen peroxide in preservation and disinfection is not new. Since 1913, hydrogen peroxide has been used for the “preservation of milk, water, as well as fruity juices.” In addition, hydrogen peroxide is used in pollution control, to bleach textiles and paper products, and to manufacture or process foods, minerals, petrochemicals, and consumer products. The concentration varies greatly depending on the application. The typical concentrations of hydrogen peroxide used in healthcare sterilizers and other applications is contained in Table 1.

### Standards and guidelines for VH2O2 sterilization

While hydrogen peroxide has a long history of use in varied applications, the focus of this article is to review the standards and real world challenges pertinent to its use as a sterilant in health care facilities. In 2013 AAMI published the ANSI/AAMI ST58:2013 – Chemical sterilization and high-level disinfection in health care facilities – which is the most recent end-user’s document to include a section on the safe and effective use of VH2O2 in health care facilities. Even though both steam and EO have well establish AAMI user standards (AAMI ST79 and AAMI ST41 respectively) over the past 25 years the industry has not provided end-users with a user’s guideline specific to VH2O2 sterilization. Currently the recommendations for this modality are limited and are combined with many other methods of sterilization and disinfection in ANSI/AAMI ST58:2013. For many years, AORN Guidelines for Perioperative Practice for Sterilization has provided information for end-users on the use of VH2O2 sterilizers. However, this article will focus on the more detailed guidance provided in AAMI ST58:2013.

### Table 1. Concentration of H2O2 for an array of products and applications

<table>
<thead>
<tr>
<th>H2O2 Concentration</th>
<th>Products and Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 8%</td>
<td>• Contact lens sterilant (2%)</td>
</tr>
<tr>
<td></td>
<td>• Over the counter pharmaceutical grade hydrogen peroxide (3%)</td>
</tr>
<tr>
<td></td>
<td>• Hair bleach (7.5%)</td>
</tr>
<tr>
<td>8 – 52%</td>
<td>• Pool shock (27%), Industrial strength – pulp and paper bleaching (20–52%)</td>
</tr>
<tr>
<td></td>
<td>• 125-280 Solution - STERIZONE VP4 (50% by weight)</td>
</tr>
<tr>
<td>52 – 91%</td>
<td>• STERRAD Cassette for STERRAD Sterilizers (58%)</td>
</tr>
<tr>
<td></td>
<td>• VAPROX HC Sterilant for STERIS AMSCO V-PRO Sterilizers (59%)</td>
</tr>
<tr>
<td></td>
<td>• Specialty applications and uses (52–91%)</td>
</tr>
<tr>
<td>&gt;91%</td>
<td>• Rocket propellant</td>
</tr>
</tbody>
</table>
f. Devices should be packaged in Tyvek-Mylar pouches, polypropylene wrap, or reusable rigid containers.

g. Use only trays and mats per IFU and cleared by the FDA.

h. Ensure adequate sterilant contact, follow all loading recommendations.

i. Chemical indicators and Geobacillus stearothermophilus biological indicators cleared by FDA to monitor VH2O2 sterilizers. VH2O2 sterilization requires close attention to proper procedures to ensure its effectiveness.

So let’s review some key aspects from ANSI/AAMI ST58:2013 regarding the effective use of VH2O2 sterilization as well as some real world case studies regarding the use of VH2O2 sterilization processes in healthcare facilities.

**VH2O2 sterilizer chamber loading practices – space and weight**

Good sterilizer chamber loading practices are critical for effective VH2O2 sterilization. Do not over load the chamber. Know the weight limit for your sterilizer and the weight limit for your sterilizer and the sterilization cycle(s) programmed on your sterilizer. VH2O2 sterilizers and cycles are cleared by the FDA with a weight limit per cycle (with exception of the STERRAD 100S where the load weight limit is not defined). Table 2 is an example of a chart you could create for your sterilizer operators. Always refer to the sterilizer manufacturer’s instructions for use for specific items allowed for each cycle type.

Furthermore, per AAMI ST58 to ensure adequate sterilant contact, personnel should load the sterilizer as recommended in the sterilizer manufacturer’s written IFU. A good rule of thumb is to ensure there is a minimum of a hand’s width space between packages and items in the chamber (estimate about a one-inch space between). Ensure items are not stacked and are lying flat on shelves and no items are contacting the chamber walls or electrodes (if applicable). Provide room for the sterilant to penetrate. Resist the practice of adding “just one more item.”

Before we leave good loading practices for VH2O2 sterilization let’s look at a fundamental statement found in AAMI ST58:2013: “Physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.” In other words, we should not rely solely on the sterilizer to alert an end-user of every unacceptable practice and failed sterilization processes. It is possible that even though “the sterilizer never indicated there was a problem” there still could have been procedural errors that could affect the effectiveness of the sterilization process.

**Rigid containers – weight and use in VH2O2**

Let’s review the use of rigid containers in VH2O2 sterilization (self-contained reusable rigid sterilization containers that do not require a barrier system). Weight limits also apply to rigid containers. Rigid containers are validated to a weight limit for VH2O2. The weight limits for rigid containers can get a little complex. To find the validated weight limit for a specific rigid container, the user must consider the size of the container, the depth of the container, the sterilizer model and the sterilization cycle. We have found all of this data in the instructions for use but are your procedures and loads compliant? Are you weighing each of your container sets and loads to verify the filled weight is acceptable for use in the VH2O2 sterilization process? Table 3 is an example table representing three rigid container manufacturer’s validated weight limits for a specific cycle on one sterilizer model.

Rigid containers are a very important consideration when used in VH2O2 sterilizers. They have advantages and limitations. Their use can increase standardization of procedures and reduce waste but they can also introduce unexpected variation over time in a VH2O2 process. Some facilities have found that rigid container surfaces and material composition are designed differently (e.g., some are anodized some are not anodized and some are expected to change in appearance over time when used in VH2O2). One manufacturer also warns against the use of soft water for the final rinse as subsequent processing in VH2O2 can cause corruption.

Rigid container variables add to the complexity of the technique sensitivity of VH2O2 processes. Recently staff at a healthcare facility noticed that over time surface damage and wear and tear of rigid containers adversely affected the container compatibility in their VH2O2 sterilization processes resulting in failed chemical indicator results and rejection of packages and loads. After a collaborative effort, led by the facility with a team including the rigid container manufacturer, the sterilizer manufacturer and the sterilization indicator manufacturer, the final resolution was the purchase of new rigid containers. Although the exact root
cause was never definitively ascertained, brand new containers from the container manufacturer resolved the issue of failed sterilization indicators.

### Plastic trays and lids for VH2O2 sterilization

Plastic trays and lids are containment devices that require a sterilization wrap or pouch to maintain sterile integrity once the containment device and its contents are sterilized. Manufacturers of containment devices (including plastic trays and lids) and packaging/disposable wraps are responsible for validating that their products are compatible with a specified sterilization method. Plastic trays and lids are regulated by the FDA as medical devices. The FDA has identified ANSI/AAMI ST77:2013 Containment devices for reusable medical device sterilization as a consensus standard for the testing required to demonstrate plastic trays and lids are safe and effective and compatible in a specific sterilization process. Plastic trays and lids must have written instructions for use and the manufacturer should provide validation data on request for the labeled sterilization modality. Per ANSI/AAMI ST77:2013, IFUs should contain the recommended maximum weight and load distribution of the containment device and its content. As an example, under PRECAUTIONS section, the ASP APTIMAX Trays IFU recommends not to stack APTIMAX Trays in any sterilizer and not to exceed a total weight of 9.7 lbs. per tray. The instructions go on to recommend discontinuing the use of APTIMAX Trays when they become cracked or damaged in any way.

In another interesting case study, a Sterile Processing Department (SPD) was experiencing automatic sterilizer cancellations with their VH2O2 sterilizer. The SPD also was experiencing intermittent failing VH2O2 sterilization cycles as indicated by positive BIs. Collaborative investigative team work with SPD, sterilizer manufacturer, and the indicator manufacturer revealed that the trays and lids used to contain their devices were incompatible with one another, and were adversely affecting the amount of hydrogen peroxide available for sterilization during the sterilization cycle. The SPD then made a change in the material composition of the trays and lids used to contain their devices, which significantly increased the robustness of the VH2O2 sterilization process in-use. This minor change eliminated marginal cycles, automatic sterilizer cancellations, resulted in passing (negative) biological indicators and, in addition, provided the option to increase output by sterilizing more devices per cycle with the new smaller containment devices.

### Biological indicators for VH2O2 sterilization

As a final topic for this article, let’s review information on biological indicators for monitoring VH2O2 sterilization processes in healthcare facilities. Because there is no international standard that provides performance requirements for biological indicators for VH2O2 sterilization processes, VH2O2 biological indicators from different manufacturers may be designed and tested differently, and there may be variation in the performance of these biological indicators. Because an international standard does not yet exist, the global health care industry has no standardization on performance requirements for BIs used in VH2O2. In the U.S., the FDA regulates biological indicators used in healthcare facilities and has a set of testing requirements for the clearance of VH2O2 biological indicators in the U.S market. The FDA is the highest authority in the U.S. (not the sterilizer manufacturer) on the final decision on which biological indicators are cleared as compatible (safe and effective) for use in vaporized hydrogen peroxide sterilizers for healthcare facilities.

Furthermore ANSI/AAMI ST58:2013 section 9.5.4.2 states that “Health care personnel should use the BIs and PCDs recommended by the manufacturer of the selected gaseous chemical sterilization system and cleared by the FDA for use with that sterilization system or BIs and PCDs cleared by the FDA as substantially equivalent.”

Table 4 provides a clear example that BIs for VH2O2 sterilization may not be designed and tested in the same way. Understanding this information will help an end-user understand how their biological indicators work. The information in Table 4 is typically found in the BI quality assurance certificate that accompanies the biological indicators, or it can be requested from the manufacturer. Table 4 contains a few examples of similarities and differences between three available self-contained BIs for VH2O2 in healthcare. All three indicators are cleared by the FDA for use in healthcare facility sterilizers. All three manufacturers use the bacterial spore species Geobacillus stearothermophilus as the indicator organism. These BIs differ significantly in the H2O2 Concentration used to test the performance of the biological indicators, as well as the Typical Kill time (a test time at which the biological indicators should be killed. This test helps define the resistance of the biological indicator). A higher test concentration of H2O2 corresponds to an increased challenge that may be a closer representation of sterilization cycle exposure concentrations. Estimated VH2O2 sterilizer chamber levels across all cleared sterilizer models is ~ 6 - 26 mg / L. The Typical Kill Time is the maximum time required to inactivate all the BIs. A longer time tested at a higher H2O2 concentration corresponds to a stronger biological indicator challenge and is a closer representation of sterilization cycle exposure times. The Typical Survival Time is the time where all biological indicators survive or show a positive result at the test concentration of H2O2. Data in Table 4 are typical values and were gathered from multiple performance certificates from each manufacturer.

### Conclusion

It is important to follow correct procedures when using VH2O2 sterilization. Variability introduced by the end-user, or drifts from appropriate practices, can result in failed monitoring devices indicating failed sterilization processes. Collaborative team work between sterile processing departments, sterilizer manufacturers and manufacturers of sterilization monitoring products can result in successful outcomes when all parties agree to the common goal of striving for the highest level of patient safety. Collaboration of these three parties

<table>
<thead>
<tr>
<th>Biological indicator A</th>
<th>Yes</th>
<th>Geobacillus stearothermophilus</th>
<th>2.5 mg / L</th>
<th>60 seconds</th>
<th>4 – 6 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological indicator B</td>
<td>Yes</td>
<td>Geobacillus stearothermophilus</td>
<td>2.7 mg / L</td>
<td>16 minutes</td>
<td>4 seconds</td>
</tr>
<tr>
<td>Biological indicator C</td>
<td>Yes</td>
<td>Geobacillus stearothermophilus</td>
<td>10 mg / L</td>
<td>7 minutes</td>
<td>5 seconds</td>
</tr>
</tbody>
</table>

Table 4. Typical performance values for BIs cleared for VH2O2 sterilization
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Circle the one correct answer:

1. FDA regulates rigid containers used in VH2O2 sterilization.
   A. True  B. False

2. Sterilizer manufacturers determine which biological indicators can be used to monitor their sterilizers.
   A. True  B. False

3. AAMI ST58 provides recommended practices for VH2O2 sterilization.
   A. True  B. False

4. All rigid containers have been validated to contain the same weight of instrumentation.
   A. True  B. False

5. Hydrogen peroxide is used in an array of products and applications.
   A. True  B. False

6. The FDA clears all indicators for use in monitoring VH2O2 sterilization processes.
   A. True  B. False

7. VH2O2 sterilizers should be packed as tightly as possible.
   A. True  B. False

8. Inappropriate loading may not be detected by the physical monitors of the sterilizer (cycle printout).
   A. True  B. False

9. Performance requirements for biological indicators for VH2O2 sterilizers are defined in national and international standards.
   A. True  B. False

10. All FDA cleared VH2O2 sterilization processes have the same chamber loading weight limit.
    A. True  B. False

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References

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