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5
6
STERIS
V-PRO maX 2
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MAX 2
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Select Cycle
DOOR CLOSED
EMERGENCY POWER
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DOOR
Turn left to power off.
Turn right to power on.

Vaporized Hydrogen Peroxide Sterilization in Healthcare Facilities Today

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LEARNING OBJECTIVES

1. Review guidance on vaporized hydrogen peroxide (VH2O2) sterilization provided in ANSI/AAMI ST58:2013/(R)2018
2. Identify VH2O2 sterilizer chamber loading practices
3. Discuss containment systems for VH2O2 sterilization
4. Review biological indicators for monitoring VH2O2 sterilization

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 advance because an increasing number of 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 increase, let's take a closer look at one of the methods: VH2O2 sterilization.

The use of hydrogen peroxide (H2O2) in preservation and disinfection is not new. Since 1913, H2O2 has been used for the "preservation of milk, water, as well as fruity juices."[1] In addition, H2O2 is used in pollution control, to bleach textiles and paper products, and to manufacture or process foods, minerals, petrochemicals and consumer products. As shown in **Table 1**, the concentration varies greatly depending on the application.

Objective 1: Review guidance on VH2O2 sterilization provided in ANSI/AAMI ST58:2013/(R)2018

While H2O2 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 healthcare facilities. In 2013, the Association for the Advancement of Medical Instrumentation (AAMI) published ANSI/AAMI ST58:2013 *Chemical sterilization and high-level disinfection in health care facilities.* Revised most recently in 2018, the document includes a section on the safe and effective use of VH2O2 in healthcare facilities. Even though both steam and EO have

H2O2 Concentration	Products and Applications
< 8%	· Contact lens sterilant (2%) · Over-the-counter pharmaceutical grade H2O2 (3%) · Hair bleach (7.5%)
8–52%	· Pool shock (27%) · Industrial strength – pulp and paper bleaching (20–52%) · 125–280 Solution – STERIZONE VP4 (50% by weight)
52–91%	· STERRAD Cassettes for STERRAD Sterilizers (58%) · VAPROX HC Sterilant for STERIS AMSCO V-PRO Sterilizers (59%) · Specialty applications and uses (52–91%)
> 91%	· Rocket propellant

Table 1: Concentration of H2O2 for an array of products and applications

	Model	Cycle	Weight (lbs.) Limit
Advanced Sterilization Products (ASP)	STERRAD 100S	Standard (default)2	Not defined
	STERRAD NX	Standard3	10.7
		Advanced3	10.7
	STERRAD 100NX	Standard4	21.4
		FLEX4	21.4
		EXPRESS4	10.7
		DUO4	13.2
STERIS	V-PRO maX	Non Lumen5	50.0
		Flexible5	24.0
		Lumen5	19.6
Stryker	Sterizone VP4	Cycle 16	75.0

Table 2: Chamber weight limits per sterilizer model and cycle

well-established AAMI user standards (AAMI ST79:2017/(R)2022 and AAMI ST41:2008/(R)2018, respectively), over the past 30 years the industry has not provided end users with a guideline specific to VH2O2 sterilization. Currently, the recommendations for this modality are limited and combined with many other methods of sterilization and disinfection in ST58. *Note: For many years, the Association of periOperative Registered Nurses (AORN)* Guidelines for Perioperative Practice for Sterilization *has provided information for end users on the use of VH2O2 sterilizers. This article, however, will focus on the more detailed guidance provided in ST58.*

ST58 Annex H.3 includes the following considerations for the effective use of VH2O2 sterilizers:

- Follow the device and sterilizer manufacturers' written instructions for use (IFU).
- Do not use absorptive cellulose-based products (towels, gauze or paper).
- Confirm that lumen sizes are cleared by the U.S. Food and Drug Administration (FDA) based on the sterilizer model and cycle.
- Thoroughly clean and dry devices before sterilization.
- Open hinged instruments.
- Package devices in Tyvek-Mylar pouches, polypropylene wrap or reusable rigid containers cleared for the sterilizer model and cycle.
- Use only trays and mats per the IFU and cleared by the FDA.
- Follow all loading recommendations to ensure adequate sterilant contact.
- Use chemical indicators (CIs) and *Geobacillus stearothermophilis* biological indicators (BIs) cleared by the FDA to monitor the sterilization cycle.

VH2O2 sterilization requires close attention to proper procedures to ensure its effectiveness. Given this, the following objectives review key aspects from ST58 regarding the use of VH2O2 sterilization as well as some real-world case studies regarding the use of VH2O2 sterilization processes in healthcare facilities.

Half-Size Containers	Depth (inches)	STERRAD 100S Weight (lbs.) excluding container, unless otherwise noted
CareFusion V. Mueller Genesis Containers7	4.0	3.4
	5.0	4.4
	6.0	5.2
B. Braun Aesculap SterilContainer System	4.5	7.0
	5.5	7.0
	6.0	7.0
Case Medical SteriTite9 container and contents	4.0	31.95*
	6.0	
	8.0	

*Caution: Do not use nylon coated brackets or silicone mats.

Table 3: Weight limits for different rigid containers when used in the same VH2O2 sterilizer model and cycle

Objective 2: Identify VH2O2 sterilizer chamber loading practices

Good sterilizer chamber loading practices are critical for effective VH2O2 sterilization. Do not overload the chamber. Know the weight limit for your sterilizer and the programmed sterilization cycle(s). VH2O2 sterilizers and cycles are cleared by the FDA with a weight limit per cycle; the exception is the STERRAD 100S where the load weight limit is not defined.[2] **Table 2** provides a sample chart for sterilizer operators.

Always refer to the sterilizer manufacturer's IFU for specific items allowed for each cycle type. Furthermore, per 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 (estimate about an inch) between packages and items in the chamber. Ensure items are lying flat on shelves and not stacked or in contact with 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 review a fundamental statement found in ST58: "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 on the sterilizer to alert an end user of every unacceptable practice and failed sterilization processes. Even though "the sterilizer never indicated there was a problem," it is possible that procedural errors influenced the effectiveness of the sterilization process.

Objective 3: Discuss containment systems for VH2O2 sterilization

Among the most common containment systems for VH2O2 sterilization systems are rigid containers and plastic trays and lids. Self-contained reusable rigid sterilization containers do not require a barrier system. Plastic trays and lids require a sterilization wrap or pouch to maintain sterile integrity once the containment device and its contents are sterilized. Both are discussed in detail below.

Rigid containers

Rigid containers are validated to a weight limit for VH2O2, and these limits can get a little complex. To find the validated weight limit for a specific rigid container, the user must consider the size and depth of the container, the sterilizer model and the sterilization cycle. This data is available in the IFU, but are your procedures and loads compliant? Are you weighing each of your container sets and loads to verify that the filled weight is acceptable for use in the VH2O2 sterilization process? **Table 3** presents validated weight limits from three rigid container manufacturers for a specific cycle on one sterilizer model.

When used in VH2O2 sterilizers, rigid containers 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

	FDA Cleared	Indicator Organism	H2O2 Concentration Test Level	Typical Kill Time	Typical Survival Time
BI A	Yes	*Geobacillus stearothermophilus*	2.5 mg/L	60 seconds	4 to 6 seconds
BI B	Yes	*Geobacillus stearothermophilus*	2.7 mg/L	16 minutes	4 seconds
BI C	Yes	*Geobacillus stearothermophilus*	10 mg/L	7 minutes	5 seconds

Table 4: Typical performance values for three BIs cleared for VH2O2 sterilization

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 corrosion.

Rigid container variables add complexity to the technique sensitivity of VH2O2 processes. Staff at one 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 CI results and rejection of packages and loads. After a collaborative effort, led by the facility with a team including the rigid container manufacturer, sterilizer manufacturer and sterilization indicator manufacturer, the final resolution was the purchase of new rigid containers. Although the root cause was never definitively ascertained, brand-new containers from the container manufacturer resolved the issue of failed sterilization indicators.

Plastic trays and lids

Plastic trays and lids for use in healthcare facilities are regulated by the FDA as medical devices. The FDA has identified ANSI/AAMI ST77:2013/(R)2018 *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.

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 must have written IFU, and the manufacturer should provide validation data on request for the labeled sterilization modality. Per ST77, IFU should contain the recommended maximum weight and load distribution of the containment device and its contents. As an example, under the Precautions section, the ASP APTIMAX Tray IFU recommends APTIMAX Trays not be stacked 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.[10]

In an interesting case study, a Sterile Processing department (SPD) was experiencing automatic sterilizer cancellations with their VH2O2 sterilizer as well as intermittent failing of VH2O2 sterilization cycles as indicated by positive biological indicators (BIs). Collaborative investigative teamwork with the SPD, sterilizer manufacturer and indicator manufacturer revealed that the trays and lids used to contain their devices were incompatible and adversely affecting the amount of H2O2 available for sterilization during the sterilization cycle. The SPD changed the material composition of their trays and lids, which significantly increased the robustness of the VH2O2 sterilization process in use. This minor change eliminated marginal cycles and automatic sterilizer cancellations, resulted in passing (negative) BIs, and provided the option to increase output by sterilizing more instruments per cycle with the new, smaller containment devices.

Objective 4: Review biological indicators for monitoring VH2O2 sterilization

As a final topic, let's review information on BIs for monitoring VH2O2 sterilization processes in healthcare facilities. There is no international standard that provides performance requirements for BIs for VH2O2 sterilization processes, so the global healthcare industry has no standardization on performance requirements for BIs used in VH2O2. Because of this, VH2O2 BIs from different manufacturers may be designed and tested differently, and there may be variation in the performance of these BIs.

In the U.S., the FDA regulates BIs used in healthcare facilities and has a set of testing requirements for the 510(k) clearance of VH2O2 BIs in the

U.S. market. The FDA is the highest authority in the U.S. (not the sterilizer manufacturer) and holds the final decision on which BIs are cleared as compatible (safe and effective) for use in VH2O2 sterilizers for healthcare facilities. Furthermore ST58, section 9.5.4.2 states, "Health care personnel should use the BIs and PCDs [process challenge devices] 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 illustrates the similarities and differences between three available self-contained BIs for VH2O2. 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. Yet, these BIs differ significantly in the H2O2 concentration used to test their performance. Estimated VH2O2 sterilizer chamber levels across all cleared sterilizer models are ~6–26 mg/L. The typical kill time is the maximum time required to inactivate all the bacterial spores and helps define the resistance of the BI. A higher test concentration of H2O2 corresponds to an increased challenge that may be a closer representation of sterilization cycle exposure concentrations. The typical survival time is the time where the bacterial spores survive, or the BI shows a positive result at the test concentration of H2O2.

Table 4 presents values gathered from multiple performance certificates from each manufacturer. It is a clear example that BIs for VH2O2 sterilization are not designed and tested in the same way. This information can be found in the quality assurance certificate that accompanies the BI or requested from the manufacturer. Being aware of these differences will help an end user understand how their BIs work.

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 teamwork between SPDs and the manufacturers of sterilizers, containment devices, packaging and disposable wraps, and 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 parties is common practice for troubleshooting steam sterilization process failures, and in the interest of patient safety, this practice should continue for vaporized hydrogen peroxide sterilization. P

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