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LEARNING OBJECTIVES

1. *Recognize the change in culture regarding the use of vaporized hydrogen peroxide sterilization in healthcare facilities.*
2. *Identify clinical practices that can adversely affect the outcome of vaporized hydrogen peroxide sterilization in healthcare facilities.*

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SELF-STUDY SERIES

Collaborating a culture change

Relearning vaporized hydrogen peroxide sterilization

by Larry Talapa

Hydrogen peroxide (H_2O_2) may be regarded as nature's own disinfectant and preservative. It is naturally present in milk, and in honey which helps to prevent spoilage, and it is an ordinary resident of human tissues as a result of normal cell function. Furthermore, hydrogen peroxide protects us from infection by invading pathogenic microorganisms as a part of phagocytosis. In the mouth, where it is present in the mucous membranes, it acts as a powerful oxidant. Hydrogen peroxide is produced by both animal and plant cells.[1] The Bombardier Beetle uses a combination of hydrogen peroxide and other biochemicals as an explosive defense mechanism.[2]

From beetles to bees, to our saliva and our immune system, from water disinfection to the sterilization of reusable medical devices in healthcare facilities, hydrogen peroxide is used widely in nature and industry.

3M Technical Services and 3M Clinical Specialists have worked closely with hundreds of healthcare facilities regarding the successful use of vaporized hydrogen peroxide (VH2O2) sterilization. Based upon a mass of observational data, we have noticed a change in culture since the inaugural use of this sterilization modality in the 1990s in healthcare facilities. We discovered noteworthy best practices and found some common themes amongst VH2O2 users.

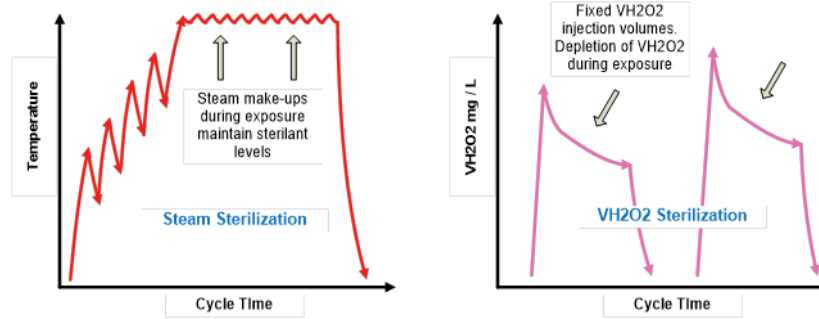
VH2O2 sterilization is technique sensitive

We have quickly come to realize that VH2O2 sterilization is technique sensitive. Technique sensitive is a term we have coined to describe that the variability introduced by the end-user or VH2O2 sterilizer operator can have a significant impact on the outcome of the VH2O2 sterilization process as compared to other sterilization processes. There are several reasons why. To expand further let us compare VH2O2 sterilization to steam sterilization. One of the most significant differences is that VH2O2 sterilization processes provide a set fixed amount of sterilant for each cycle type for every load placed in the chamber. In contrast, steam sterilization continuously provides the sterilant (steam) during the sterilant exposure phase to maintain the defined sterilization parameters. This difference is significant because if an operator places a small load in the VH2O2 sterilizer chamber or the complete opposite, a large load over the weight limit or a load with non-compatible materials, the VH2O2 sterilizer will still only provide the same fixed amount of sterilant. In contrast, a steam sterilization cycle may compensate with steam make-ups and use more sterilant (steam) for a heavier denser load. Each VH2O2 cycle could be compared to an oven that only has one temperature setting for every recipe.

VH2O2 is technique sensitive as well because the fixed amount of VH2O2 injected, by its nature, is relatively unstable and readily depletes during the exposure phase via several different chemical mechanisms.[1,3,4] Figure 1 illustrates the relative differences in sterilant levels maintained in steam sterilization vs the natural depletion that occurs during after the fixed injection amounts during VH2O2 sterilization.

To complicate the situation ever so slightly, the VH2O2 cycles available in the U.S. market are different in several design features: Different indications for use, different loading weight limits, different VH2O2 concentrations (mg /L), different sterilant exposure times and different cycle report acceptance criteria. The user must be knowledgeable about a lot of detail to assure their practices

Figure 1. Relative sterilant levels in steam and VH2O2 sterilization



and procedures meet all applicable IFUs for the VH2O2 sterilizers on the U.S. market. Figure 2 is a snapshot of the theoretical concentration of sterilant (mg/L of VH2O2) and the total sterilant exposure time in minutes for each sterilizer model and cycle type. The intent of Figure 2 is to illustrate the broad use of VH2O2 cycle types on the U.S. market today. Back in the early 1990s, we had one VH2O2 sterilizer and one cycle, today we have six different VH2O2 sterilizers and over 15 cycle types. VH2O2 cycles are not all created equal.

Because of these differences, the techniques and variability introduced by the operator play a significant role in assuring the load does not overwhelm the fixed amount of the unstable VH2O2 sterilant and result in a failed sterilization cycle.

We also observed two additional factors that play a significant role in the successful use of the VH2O2 sterilization process that also depend on the experience and expertise of the operator: Residual moisture and the use of extra (nonessential) materials. You likely already know that residual moisture can directly impact VH2O2 sterilization, but are you aware of the effects of using extra materials in the load?

These factors — different cycle types, a fixed amount of sterilant, a relatively unstable molecule, residual moisture and use of extra nonessential materials — make a technique sensitive setting where the variability introduced by the user regarding the composition and weight of the load can dramatically affect the outcome of the VH2O2 sterilization process.

Let's explore some of these items in more detail and review some common themes amongst users that demonstrate how a change in culture can help assure a successful outcome by preventing these factors from dramatically affecting the VH2O2 sterilization processes.

Double check the sterilizer, packaging, and device IFUs. Is that item actually labeled for VH2O2 sterilization?

We have observed all too often plastic trays, rigid containers, and yes, entire device sets processed in VH2O2 sterilizers that were never tested, validated, nor labeled to be processed in VH2O2 sterilization. Upon discovery we heard a multitude of explanations for these procedural stumbles:

- That is how we always processed these devices.
- That is how we did it in my old department.
- We have never had any problems processing the devices this way.
- We want a quicker turnaround time for these devices, we don't want to wait for a large steam load to cool.
- We were told it was OK.

It is not OK to process items that are not labeled for use in the process in a VH2O2 sterilizer. If there are devices or sets or loads that seem to have a higher frequency of failure in your VH2O2 sterilization process, double check your IFU for each item in the load. You might be surprised at what you find. Our observations in facilities across the world have included many items sterilized in VH2O2 that were never validated nor labeled for sterilization in the process.

To begin, review your VH2O2 sterilizer operator's manuals once again. We have found some noteworthy restrictions and helpful hints in these manuals. Here are some quotes from common VH2O2 sterilizer operator manuals:

- Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results. - STERRAD100S Operator's Manual v01/2009
- Do not stack instruments inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within the trays. - STERRAD 100NX v03/2011 and 100S Operator's Manual v11/2009
- Configure loads with a combination of metal and nonmetal items - STERRAD 100S Operator's Manual v11/2009
- Do NOT stack pouches on top of each other. – V-PRO maX Operator's Manual v02/2011
- Do NOT stack trays within trays. Do NOT wrap instruments within a wrapped tray. –sV-PRO maX Operator's Manual v02/2011

Know and follow the sterilizer cycle's validated weight limits

Until recently, it was very rare to encounter a sterile processing department that is intimately familiar with the validated weight limits for their VH2O2 cycles. Even rarer was the use of a scale to weigh individual loads prior to processing. Good sterilizer loading practices are critical for effective VH2O2 sterilization! Table 1 (next page) is a chart of weight limits for each VH2O2 sterilizer model and cycle. Always refer to the sterilizer manufacturer's instructions for use for specific restrictions on devices allowed for each cycle type.

Completely dry devices according to manufacturer's instructions for use

Moisture is not a friend of VH2O2 sterilization. The STERIS Corporation specifically calls out the incompatibility of moisture with hydrogen peroxide: "*Materials NOT Compatible With Hydrogen Peroxide - Items that are NOT completely dry* (V-PRO maX Operator's Manual v02/2011). Excessive moisture in and around devices and packaging can cause automatic cycle cancellations and failure of our quality monitoring tools resulting in rejected sterilization cycles. Let's review both scenarios and discuss why each can occur.

Common VH2O2 sterilization processes begin with a very deep vacuum as compared to common steam sterilization cycles. As a comparison, if we were to equate these

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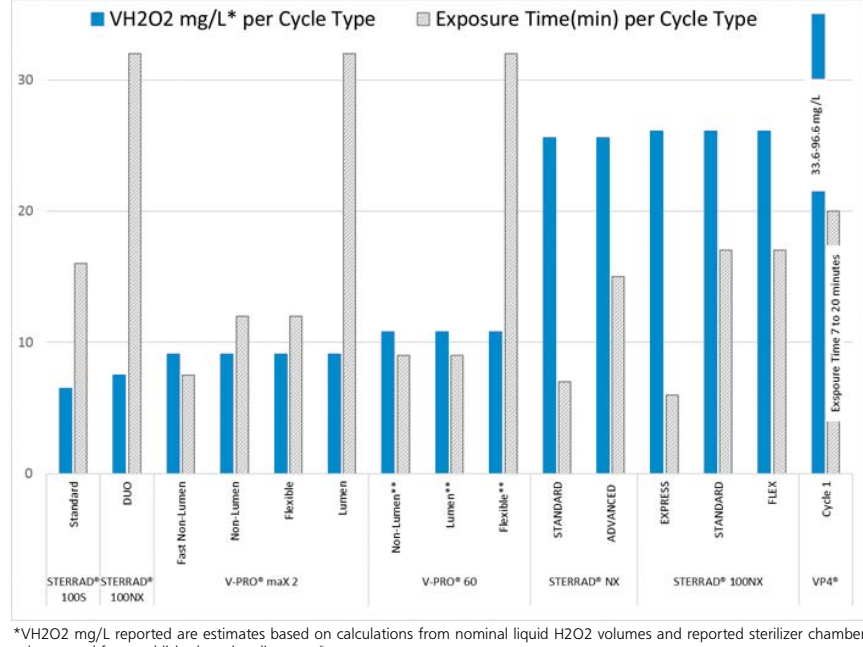
Figure 2. Theoretical concentration of sterilant (mg/L of VH2O2) and total sterilant exposure times



*VH2O2 mg/L reported are estimates based on calculations from nominal liquid H2O2 volumes and reported sterilizer chamber volumes and from published product literature[5].

**Reference exposure time details in STERIS Document# M3644EN2012-10, Rev. B.

Self-Study Test Answers: 1. A, 2. A, 3. B, 4. B, 5. A, 6. B, 7. A, 8. A, 9. A, 10. A

Table 1. Chamber weight limits per common sterilizer model and cycle types

Brand	Model	Cycle	Weight (lb) Limit
Advanced Sterilization Products (ASP)	STERRAD 100S	Standard (default)[6]	Not defined
	STERRAD NX	STANDARD[7]	10.7
		ADVANCED[7]	10.7
	STERRAD 100NX	STANDARD[8]	21.4
		FLEX[8]	21.4
		EXPRESS[8]	10.7
		DUO[8]	13.2
STERIS	V-PRO maX 2	Non-Lumen[9]	50.0
		Lumen[9]	19.6
		Flexible[9]	24.0
		Fast Non-Lumen[9]	11.0
TS03	STERIZONE VP4	Cycle 1[10]	75.0

vacuum level differences to scuba diving in the ocean (vacuum parameter of torrs to miles), VH2O2 sterilization would require an estimated 100 miles deeper dive than common steam sterilization processes. That's a long way down and a big difference. The deep vacuum is required to remove residual air and moisture from the load and to help maintain the VH2O2 in a gaseous state (remember VH2O2 is a relatively unstable molecule).

As we all are probably aware, residual moisture can be the root cause of a cancelled VH2O2 cycle during its initial deep vacuum phase. As the sterilizer pulls a deep vacuum, residual moisture will evaporate from devices and packaging. The residual moisture actually boils off the surface to form water vapor, but this vapor is cool, not hot. This newly formed water vapor slows down the deep vacuum process. The vacuum now must remove the newly formed water vapor as well as the remaining air in the load and chamber. If the deep vacuum cannot reach the specified vacuum level within a specific time frame, the cycle will automatically cancel.

I would like to bust the myth that many of us believe that residual moisture always cancels the VH2O2 cycle. Residual moisture or water in the load does not always cancel the cycle. In some cases, the deep vacuum can remove residual moisture before the cycle cancels, but if this occurs we could develop the second problem with residual moisture, cold spots.

When residual moisture is evaporated from the load and packaging during the deep vacuum phase, the evaporation of the moisture will significantly cool the spot where the evaporation occurred. The principle is the same as sweating on a hot day, evaporating sweat cools us down. Evaporation of residual moisture can cool down spots on devices and packaging. This cold spot can result in condensation of the fixed amount of VH2O2 in that spot, making the VH2O2 unavailable for sterilization and subsequently resulting in an automatic cycle cancellation and/or failure of our quality monitoring tools and a rejected sterilization cycle.[11] Again, moisture is not a friend of VH2O2 sterilization.

Stop the use of extra (nonessential) materials in VH2O2 sterilization

Another important observation we have made was the use of extra materials in VH2O2 sterilization. For example, foam tray liners, polyethylene sheet tray liners, underneath guard liners, bubble wrap tray liners and tray protectors, rubber corner protectors, foam pocketed instrument protectors, CI indicator holders, transport trays, oversized disposable sterilization wrap, 600 and 650 weight disposable sterilization wrap, and preformed disposable wraps are all examples of what we call extraneous or nonessential materials in use in healthcare facilities with failed VH2O2 sterilization cycles. As we have described because VH2O2 cycles use a fixed amount of sterilant, best practices would be to limit or eliminate the use of any extra materials that could absorb the fixed amount of available VH2O2 sterilant.

Furthermore, we found that many of the IFUs for these items do not call out any of the 15-plus individual VH2O2 cycles available. As we noted above, all of these cycles have many different design features and limitations. Which leads us to question, are each of these items validated for use in loads containing the maximum weight limit for each of the many different cycle types available? We have observed that these details can be important in VH2O2 sterilization and these details are not readily described in the IFUs for these nonessential items.

As a best practice in line with our changing culture, we supplicate every Sterile Processing Department to review their use of these extra nonessential materials in VH2O2. A Sterile Processing Department could assemble a cross functional team and conduct a risk assessment on why these materials are currently used in their VH2O2 process. Is the need to use these items still real and is the need still current? Could the department save time by removing the use of these materials? Could the department save money by removing the use of these materials? Is there a better practice or procedure? Eliminating the use of these extra nonessential materials could increase the robustness of the VH2O2 process while saving time and money. A review of your sterilizer's operator's manual will help develop your case. Here are some examples:

- Select the proper size wrap for the items to be sterilized. —V-PRO maX Operator's Manual v02/2011
- Do not use foam pads in instrument trays. They may absorb the hydrogen peroxide. —STERRAD 100S Operator's Manual v11/2009
- Do NOT use tray mats that have not been cleared by FDA for use in the V-PRO Sterilization Trays. Do NOT use other padding with V-PRO Sterilization Trays. —V-PRO maX Operator's Manual v02/2011

Every load monitoring (ELM) and quarantining all loads from VH2O2 sterilizers

Another observation we have seen across the globe is an increased frequency of BI monitoring to every load monitoring combined with quarantining the load until the BI result is known. AAMI ST58 states: "A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle." (Section 9.5.4.3)[12] AORN's Guideline for Sterilization is slightly more specific and states, "Routine sterilizer efficacy monitoring should be performed at least daily on each cycle type, preferably with each load." (Recommendations XX.h.4 and XX.h.5)[13] We have observed in hospitals, end-users typically place a BI and an internal CI in a peel-pouch indicated for use in VH2O2 sterilizers and then position the pouched BI in the sterilizer chamber as recommended by the sterilizer manufacturer. We have observed, when users switch to a BI that provides a result in minutes vs. days, they quickly move to every load monitoring (ELM) to provide a consistent level of patient care. In addition, the same users now quarantine every VH2O2 load until the BI result is known to mitigate the risk of large recalls should the sterilization cycle fail. The culture is changing.

FDA cleared BIs are acceptable to use!

Unfortunately, misinformation has propagated through our industry regarding the use of BIs for VH2O2 sterilization, so we must address it here. 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 VH2O2 biological indicators cleared for use in the U.S. 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. Many users were unaware that there is NO requirement for a sterilizer manufacturer to validate nor endorse indicators designed to monitor their sterilizers. The decision regarding the safety and efficacy of sterilization monitors is addressed by the U.S. FDA's review and clearance procedures. There are many examples of monitoring products from multiple manufacturers being used to monitor steam, EO, and VH2O2 sterilizers.

Conclusions

Recently we have observed a change in culture, a wide-reaching shift in our practices and procedures, and discovered some noteworthy best practices, and found some common themes amongst VH2O2 users that have helped improve their VH2O2 processing practices and procedures. The observed culture change has required some relearning of a few VH2O2 practices and procedures but will ultimately help us collaboratively meet our common goal of striving for the highest level of patient safety. HPN

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Collaborating a culture change

Relearning vaporized hydrogen peroxide sterilization

Circle the one correct answer:

1. **H_2O_2 is found naturally in animals and plants.**
   A. True B. False
2. **Technique sensitive is a term to describe variability introduced by the VH2O2 sterilizer operator that can have a significant impact on the outcome of the VH2O2 sterilization process.**
   A. True B. False
3. **VH2O2 sterilant concentration during exposure is unchanging.**
   A. True B. False
4. **There are 8 different VH2O2 sterilization cycles on the U.S. Market.**
   A. True B. False
5. **VH2O2 sterilization cycles have loading weight limits.**
   A. True B. False
6. **Residual moisture on devices have no effect on the VH2O2 sterilization process.**
   A. True B. False
7. **Best practice is to limit the use of extra or nonessential materials in VH2O2 sterilization .**
   A. True B. False
8. **AAMI ST58 states: "A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle" .**
   A. True B. False
9. **Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results.**
   A. True B. False
10. **There is no requirement for a sterilizer manufacturer to validate nor endorse indicators designed to monitor their sterilizers.**
    A. True B. False

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