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LEARNING OBJECTIVES

1. *Discuss how vaporized hydrogen peroxide sterilization works*
2. *Review the keys to successful vaporized hydrogen peroxide sterilization cycles*
3. *Explain the recommended quality control plan for vaporized hydrogen peroxide sterilization processes*

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SELF-STUDY SERIES

Keys to success with vaporized hydrogen peroxide sterilization

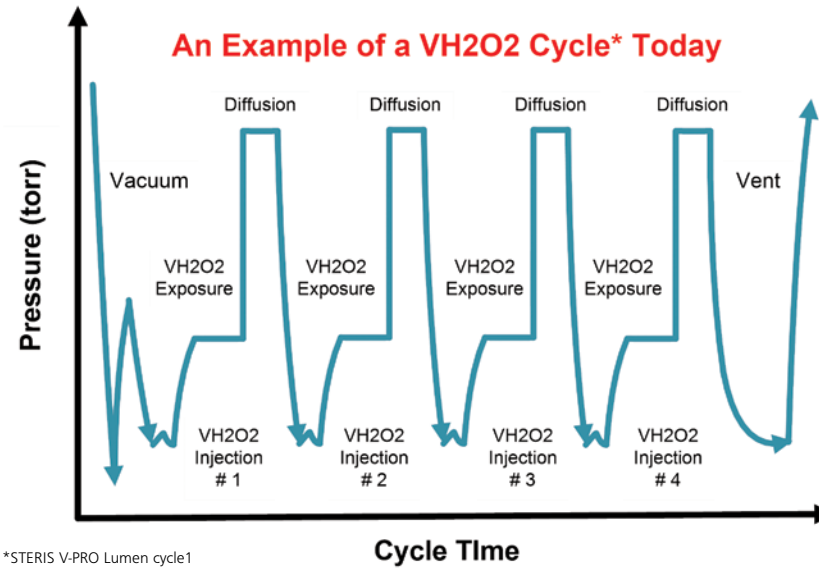
by Craig Wallace

Low temperature sterilization processes such as ethylene oxide and vaporized hydrogen peroxide play a critical role in sterile processing departments across the United States. More and more reusable medical devices are made of advanced materials and components that cannot withstand the high temperature and moisture present in steam sterilization processes. Vaporized hydrogen peroxide (VH2O2) is the most common low temperature sterilization process used today. While this technology is not new (the first VH2O2 sterilizers appeared in U.S. hospitals in 1993), it is very complex. Understanding this process and all the requirements for successful VH2O2 sterilization are critical for patient safety.

Hydrogen peroxide (H2O2) is a very effective biocidal agent, meaning that it kills all types of microorganisms when it comes into direct contact with them. Hydrogen peroxide is a strong oxidizing agent and kills microorganisms through this mechanism. The hydrogen peroxide molecule is by nature unstable, in that it will easily "fall apart" or dissociate into sub-components under ambient conditions. In addition, hydrogen peroxide sterilization processes use a vaporized form of hydrogen peroxide. A vapor is not the same as a true gas, in that a vapor will naturally condense on surfaces, like water vapor in the air condensing on the outside of a cold glass. Gasses, like ethylene oxide, do not condense. They are always in gas form in the temperatures and pressures found in sterilization processes. These points about hydrogen peroxide's oxidative properties, its molecular stability, and its vapor properties are extremely important attributes that have a significant impact on how VH2O2 sterilization processes work, and why certain procedures must be followed in the sterile processing department to assure the VH2O2 processes are safe and effective.

There are many different vaporized hydrogen peroxide sterilization processes used in the various commercial sterilizers available today, but all these processes follow a similar pattern. First, there is typically a very deep vacuum step to remove air and moisture from the chamber that

Figure 1 Example of a four-pulse vaporized hydrogen peroxide sterilization process



*STERIS V-PRO Lumen cycle1

could interfere with the process. Next, hydrogen peroxide vapor is injected into the chamber, where it will diffuse throughout a hold time. An air flush follows this hold time, then another deep vacuum is drawn to remove residual air and hydrogen peroxide. This process is considered one "pulse." These sterilization processes will use 2-4 pulses, depending on the sterilizer and the instruments to be processed in that cycle. At the end of the process the load is aerated (washed with air) to remove residual hydrogen peroxide, or, in some systems, the load is exposed to a gas plasma process to remove the residuals. An example of a four-pulse VH2O2 process is provided in Figure 1.

Factors that can affect the VH2O2 sterilization process

The chemical and physical properties of hydrogen peroxide discussed earlier (strong oxidizer, unstable molecule, vapor instead of gas) can lead to situations where a VH2O2 sterilization process is not as effective as expected. Let's take a closer look at how these properties could adversely affect a sterilization process.

1. VH2O2 sterilization processes inject a fixed amount of H2O2 vapor for each cycle type and for every load placed in the chamber. There are no make-ups or additions of sterilant during the sterilant exposure phase. Therefore, small loads and very large loads are exposed to the same amount of sterilant during the exposure phase. Load variation, plus the fact that the hydrogen peroxide molecule is relatively unstable and readily depletes during the exposure phase via several different chemical mechanisms [2,3,4] could lead to unexpected variation in the lethality of any given cycle.
2. Temperature is a critical process parameter for VH2O2 sterilization. This includes the temperature of the sterilizer chamber, the medical devices, packaging, and containers when they are placed into the chamber. If the load is too cool there can be excessive condensation of the fixed amount of hydrogen peroxide vapor.[5,6] This can have a negative impact on the process.
3. VH2O2 sterilizers are cleared by the U.S. FDA with a maximum weight limit for individual loads for each cycle type. The testing and validation supporting these clearances is completed with an understanding of the instability of the H2O2 molecule, and the H2O2 vapor behavior. Therefore, exceeding the weight limit for the load can result in cycles that are not effective.
4. "Materials compatibility" typically refers to the effects of a sterilant on the medical devices. This is important for VH2O2 sterilization, as hydrogen peroxide is an oxidizing chemical that can damage some materials. However, the phrase "materials compatibility" has an additional meaning when referring to VH2O2 processes. In this case, it can mean the materials' effect on the effectiveness of the process, because of interactions between the VH2O2 and the materials. We have noted that VH2O2 is an unstable molecule, which tends to break down into other compounds. Some materials can break down VH2O2 more quickly, resulting in a loss of process effectiveness. The user must be aware that some materials (e.g. some plastics and some metals) can have a dramatic effect on the available VH2O2 by absorbing, adsorbing or decomposing VH2O2 at a higher rate [2,3,4,7].
5. The use of extra (nonessential) materials in VH2O2 sterilization is another variable that is dependent on the user and can introduce significant variation to the VH2O2 sterilization process. 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 extraneous or nonessential materials in use in healthcare facilities. As described above, 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.

The Keys to Success

These factors - a fixed amount of sterilant, a relatively unstable molecule, temperature variations, materials compatibility and use of extra nonessential materials make VH2O2 processes "technique sensitive", that is, variability introduced by the sterile processing team regarding the composition, weight, and temperature of the load can dramatically affect the outcome of the VH2O2 sterilization process. In addition, there are many VH2O2 sterilizer cycles available in the U.S. that have different indications for use, different loading weight limits, different VH2O2 concentrations (mg/L), and different sterilant exposure times. Let's look at some key best practices that can help address this complicated situation by reducing variability and the potential for VH2O2 sterilization process failures.

Chamber Loading – Weight and Spacing

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 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)[8]. 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 1" space between). Items should not be stacked, should lay flat on shelves, and not contact the chamber walls or electrodes (if applicable). This type of loading allows the H2O2 vapor to easily access all the packages and devices; resist the practice of adding "just one more item".

Chamber Loading – Materials Compatibility

It is good practice to "know what you are loading, and only load what you know". It is imperative that all operators of VH2O2 sterilizers understand the composition of each load (devices and packaging) they place in the sterilization chamber. Some basic questions for this best practice include:

- Are the devices labeled for their specific VH2O2 sterilizer model and cycle type?
- Is the total load weight below the validated and FDA-cleared weight limit?
- Is the packaging type acceptable for use in VH2O2 and is the device weight under the limit for the packaging type?
- Could the device be labeled for another sterilization method like steam?
- Are there any nonessential extraneous packaging items that could be avoided?
- What is the total material composition of the load? Is the load overly weighted with items that have a higher propensity to deplete the fixed amount of VH2O2?

Understanding these basic variables for each VH2O2 load will help the sterile processing team discern the effects these factors have on the process and will ultimately help assure consistent and successful process outcomes.

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

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Rigid Containers, Plastic Trays and Lids

Rigid containers are a very important element of VH2O2 sterilization. These 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 materials 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 because subsequent processing in VH2O2 can cause corrosion. Containers that are not validated for VH2O2 or have worn surfaces can cause material compatibility issues with VH2O2 processes.

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 VH2O2 sterilization. Plastic trays and lids must have written instructions for use and the manufacturer should provide validation data on request for the labeled sterilization modality. The Instructions for Use (IFUs) should contain the recommended maximum weight and load distribution of the containment device and its contents.

Standards and IFUs

Vaporized hydrogen peroxide sterilization processes are complex and technique-sensitive. Consequently, understanding and carefully following all IFUs from the sterilizer manufacturer, medical device manufacturer, and packaging manufacturer are critical to success. In addition, the Association for the Advancement of Medical Instrumentation (AAMI) provides additional guidance on VH2O2 processes in AAMI ST58, "*Chemical sterilization and high-level disinfection in health care facilities*".[9] This standard provides the following points to consider for the effective use of VH2O2 sterilization:

a. Follow device and sterilizer manufacturers' written IFUs
b. No cellulose-based products (towels, gauze, or paper)
c. Lumen sizes cleared by the FDA (based on model + cycle)
d. Devices should be thoroughly cleaned and dried
e. Hinged instruments should be opened
f. Use only trays and mats per IFU and cleared by the FDA
g. Ensure adequate sterilant contact, follow all loading recommendations
h. Chemical indicators and *Geobacillus stearothermophilis* biological indicators cleared by the FDA to monitor VH2O2 sterilizers

Quality Control

A robust quality control program is essential for VH2O2 processes. AAMI ST58[9] recommends the use of physical monitoring (cycle printout), chemical indicators, and biological indicators inside of Process Challenge Devices (PCDs), with the information from all three monitors combined to make a decision on the quality of the process and whether or not the devices are safe and ready for patient use. The standard provides the following guidance on the use of chemical indicators, and biological indicators in PCDs:

"A CI should be used on the outside of each package unless the internal indicator is visible"[9].

"An internal CI should be used inside each package, tray, containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) to be sterilized"[9].

"A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle (see 9.5.4.5). Each load containing implantable devices should be monitored and, whenever possible, quarantined until the results of the BI testing are available"[9]

The standard acknowledges that achieving the highest level of assurance for VH2O2 sterilization processes will require both consistent adherence to IFUs as well as use of a rigorous QC program:

"Most temperature sensors indicate temperature in the chamber, not at the center of packs. Improper load configuration or package composition can interfere with air evacuation and sterilant penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures."[9]

Final notes regarding biological indicators for VH2O2

Currently, 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. Since an international standard does not yet exist, the global healthcare 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.

In addition, the evolution of biological indicator technology has reduced incubation times on biological indicators used to monitor VH2O2 process to 30 minutes or less. These fast readout times can enable more frequent monitoring of VH202 processes without interfering with the timing of the flow of instruments through the sterile processing department.

Conclusion

Vaporized hydrogen peroxide sterilization is a complex and technique-sensitive process that requires strict adherence to IFUs from the sterilizer manufacturer, the instrument manufacturer, and the manufacturer of the packaging used in the load. In addition, a rigorous quality control program based on the use of physical sensors, chemical indicators, and biological indicators inside of PCDs is required. HPN

3M Health Care sponsored this article.

Craig Wallace, President of Wallace Sterilization Consulting, LLC, has over 26 years of experience in the field of medical device disinfection and sterilization. Craig is the Convenor of the ISO Biological Indicator Working Group (TC 198, Working Group 4), the ISO committee responsible for international biological indicator performance standards, as well as a U.S. Technical Expert for Chemical Indicators (ISO WG 6) and Moist Heat Sterilization (WG 3). He is also the Co-Chair of the United States (AAMI) Biological Indicator Working Group, and an active member of several other AAMI working groups including chemical indicators, vaporized hydrogen peroxide sterilization, and ethylene oxide sterilization.

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CONTINUING EDUCATION TEST • APRIL 2020

Keys to success with vaporized hydrogen peroxide sterilization

Circle the one correct answer:

1. **"Technique sensitive" is a term to describe potential variability introduced by the sterile processing department personnel that can have a significant impact on the outcome of the VH2O2 sterilization process?**
   A. True B. False
2. **VH2O2 sterilization cycles and containers have loading weight limits?**
   A. True B. False
3. **Best practice is to limit the use of extra or nonessential materials in VH2O2 sterilization?**
   A. True B. False
4. **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
5. **There is no requirement for a sterilizer manufacturer to validate nor endorse indicators designed to monitor their sterilizers?**
   A. True B. False
6. **Sterilizer manufacturers determine which biological indicators can be used to monitor their sterilizers.**
   A. True B. False
7. **AAMI ST58 provides recommended practices for VH2O2 sterilization.**
   A. True B. False
8. **All rigid containers have been validated to contain the same weight of instrumentation.**
   A. True B. False
9. **The FDA clears all indicators for use in monitoring VH2O2 sterilization processes.**
   A. True B. False
10. **Inappropriate loading may not be detected by the physical monitors of the sterilizer (cycle printout).**
    A. True B. False

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