CRCST SELF-STUDY LESSON PLAN
Lesson No. CRCST 164 (Technical Continuing Education - TCE)

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3M Health Care

Vaporized Hydrogen Peroxide Sterilization

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LEARNING OBJECTIVES

1. Describe the change in complexity of vaporized hydrogen peroxide sterilization in healthcare facilities since its inaugural use in the early 1990s
2. Recognize significant variables that effect vaporized hydrogen peroxide sterilization in healthcare facilities
3. Identify clinical practices that can adversely affect the outcome of vaporized hydrogen peroxide sterilization in healthcare facilities.
4. Discuss best practices for the successful use of vaporized hydrogen peroxide sterilization in healthcare facilities

The inaugural use of vaporized hydrogen peroxide (VH2O2) sterilization in US healthcare facilities occurred in 1993; this sterilizer had one cycle, one injection of VH2O2 sterilant and a very limited number of compatible devices and packaging types, but this sterilizer launched a brand-new technology into the industry. Twenty-five years later, the inaugural sterilizer is obsolete and no longer supported by the manufacturer, and today there are multiple VH2O2 sterilizer manufacturers, multiple VH2O2 sterilizer models, and more than 20 different VH2O2 sterilization cycles in the US market. These sterilizers use different technologies, and the cycles have different sterilant injection numbers, sterilant exposure times, VH2O2 concentration levels, and cycle pressure profiles.

Table 1 summarizes some of the differences between VH2O2 sterilization today and those on the market 25 years ago.

Diagram 1 contains VH2O2 cycle pressure graphs and illustrates the dramatic change in the methods employed for VH2O2 sterilization over the last 25 years[2,16]. A cycle pressure graph helps illustrate the mechanism the sterilizer utilizes for sterilization. The left pressure graph in Diagram 1 is the mechanism of the first healthcare sterilizer utilizing VH2O2. As can be seen from the graph, the pressure profile is very similar to the stages in today's steam and ethylene oxide (EtO) sterilization cycles [e.g., air removal, sterilant injection, sterilant hold (exposure), and sterilant removal (plasma in this example)]. As our understanding of VH2O2 sterilization developed, the VH2O2 cycles of today have become much more complex, as depicted in the one example in the graph on the right side of Diagram 1.[16]

Furthermore, the device compatibility for VH2O2 sterilization has grown from simple devices like batteries and relatively

Table 1: VH2O2 Sterilizers and Sterilization Cycles in US Healthcare Facilities [1-9]

Year	Number of Manufactures	Number of Sterilizer Models	Number of Sterilizer Cycles	Number of Sterilant Injections per Cycle	Estimated VH2O2 Sterilant Concentration (mg/L)	Total Sterilant Exposure Time (min)	Estimated Total Cycle Time (min)
1993	1	1	1	1	6	50	>75
2018	3*	10+	20+	2-4	6-96.6*	6-32	16-60

*Includes VH2O2 plus ozone sterilizer[9]

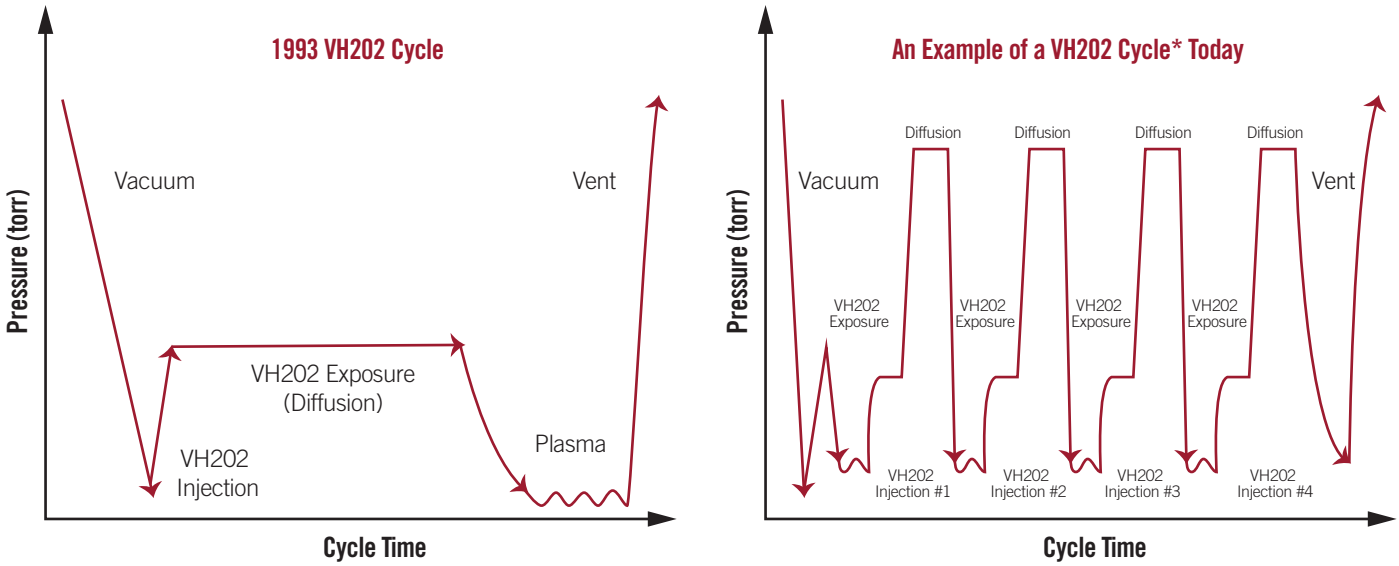

Diagram 1: Pressure Graphs Illustrating the Change in VH2O2 Sterilizer Cycle Complexity *STERIS V-PRO™ Lumen cycle[16]

wide channeled devices to laparoscopic devices with narrow metal channels (0.7 mm inner diameter), long single-channel flexible endoscopes (1050 mm in length), large endoscopes for the most advanced robotic instrumentation (8.9 pounds in weight, endoscope plus sterilization tray) and multi-channel flexible endoscopes (3500 mm in length, indicated for the hydrogen peroxide plus ozone sterilizer only)[4-9].

In 2016, the US Food and Drug Administration (FDA) cleared the first rapid readout biological indicator (BI) for VH2O2 sterilization. This new BI was developed with the same rapid readout technology used in BIs to monitor steam and EtO sterilization processes for the last 20 years. A year or more later, two more rapid readout BIs for VH2O2 were FDA-cleared.

All three of these new VH2O2 BIs use the same principal rapid readout technology and provide a final result in just a few minutes. Most notably, all of these new BIs present an increased challenge to the VH2O2 sterilization process as compared to the historical conventional readout BIs used for the last 20 years.

The combination of a decreased BI readout time and the increased challenge these new BIs present to the VH2O2 process – combined with the increased complexity of the VH2O2 sterilizers, cycles and load items – has led our profession to an increased awareness of the technique sensitivity of VH2O2. "Technique sensitive" is a term that

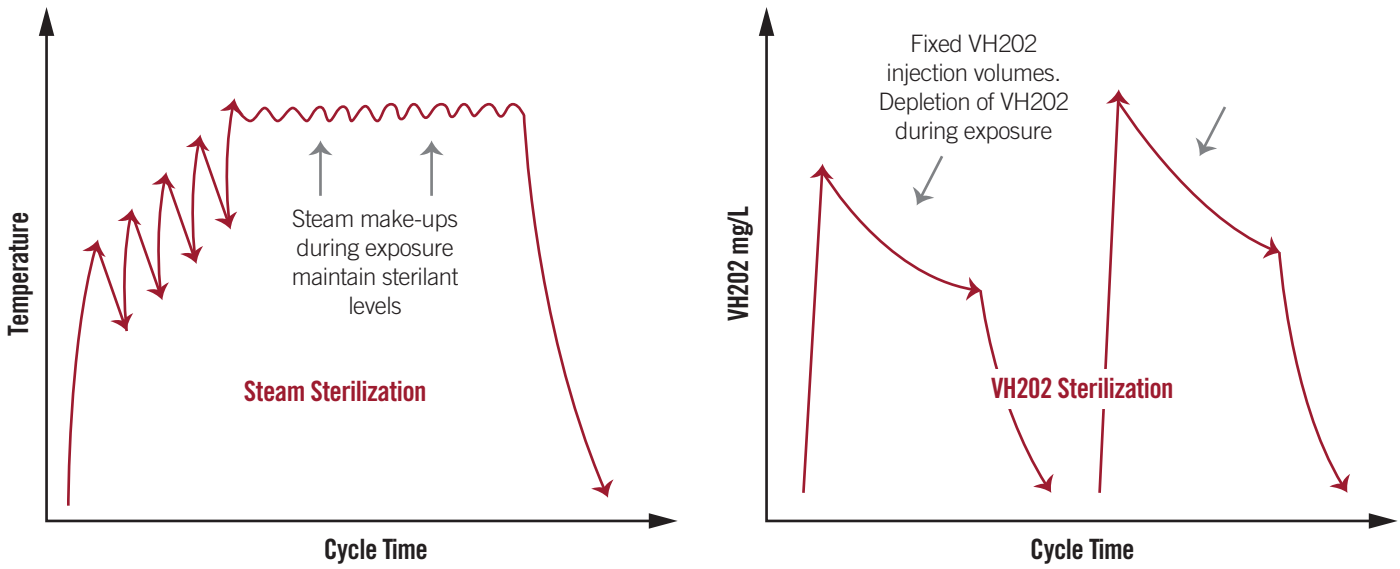

Figure 1: Relative Sterilant Levels in Steam and VH2O2 Sterilization

describe the variability introduced by the end-user, or VH2O2 sterilizer operator, which can have a significant impact on the outcome of the VH2O2 sterilization process as compared to other sterilization processes. This awareness of technique sensitivity became the spark for a culture change in the US to correct and then stay the course of VH2O2 sterilization.

VH2O2 Sterilization is Technique Sensitive

Our industry has quickly come to realize that VH2O2 sterilization is technique sensitive. There are several reasons why, including:

1. VH2O2 sterilization processes provide a set fixed amount of sterilant for each cycle type and for every load placed in the chamber. There are no make-ups of sterilant during the sterilant exposure phase; therefore, a small load (or a very large load) is exposed to the same amount of sterilant during the exposure phase. Each VH2O2 cycle could be compared to an oven that only has one temperature setting for every recipe.
2. The fixed amount of VH2O2 injected, by its nature, is relatively unstable and readily depletes during the exposure phase via several different chemical mechanisms[1,10,11]. Figure 1 illustrates the relative differences in sterilant levels maintained in steam sterilization versus the natural depletion that occurs during exposure after VH2O2 injection.
3. Today, VH2O2 sterilizers are validated and cleared by the FDA, with a maximum weight limit for individual loads for each cycle type. Table 2 is a chart of weight limits for each VH2O2 sterilizer model and cycle[4-9]. *Note: Exceeding the weight limit for the load can result in an automatic cycle cancellation and/or failure of quality monitoring tools. Always refer to the sterilizer manufacturer's instructions for use (IFU) for specific restrictions on devices allowed for each cycle type.*
4. VH2O2 sterilization processes are not compatible with excessive moisture in and around devices and packaging. Excessive moisture can cause automatic cycle cancellations and failure of quality monitoring tools, resulting in rejected sterilization cycles[13].
5. Temperature is a critical process parameter for VH2O2 sterilization; this includes the temperature of the devices, packaging and the environment of the Central Service/ Sterile Processing (CS/SP) department. The temperature of the load and department where the VH2O2 sterilizer is installed can have a negative impact on the process. If the temperature is too cool, excessive condensation of the fixed amount of VH2O2 sterilant can occur[6,7].
6. Materials compatibility is very important to understand for successful VH2O2 sterilization. The use of incorrect materials could result in a dramatic failure of the process. All materials that undergo a VH2O2 sterilization process will affect the relatively unstable VH2O2 molecule in

Table 2: Chamber weight limits per common sterilizer model and cycle types

	Model	Cycle	Weight (lb) Limit
Advanced Sterilization Products (ASP)®	STERRAD® 100S	Standard (default) [5]	Not defined
	3*	STANDARD [14]	10.7
		ADVANCED [14]	10.7
		STANDARD [15]	21.4
		FLEX [15]	21.4
		EXPRESS [15]	10.7
		DUO [15]	13.2
STERIS®		Non-Lumen [8]	50.0
		Lumen [8]	19.6
		Flexible [8]	24.0
		Fast Non-Lumen [8]	11.0
TS03	STERIZONE® VP4* (VH2O2 plus ozone sterilizer)	Cycle [19]	75.0

some form, but the user must be aware that some materials (e.g., some plastics versus some metals) can have a much more dramatic effect on the available VH2O2 by absorbing, adsorbing or decomposing VH2O2 at a higher rate[1,10-12].

7. The use of extra (nonessential) materials in VH2O2 sterilization is another variable that is dependent upon 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, chemical indicator (CI) holders, transport trays, oversized disposable sterilization wrap, 600- and 650-weight disposable sterilization wrap, and pre-formed disposable wraps are all examples of extraneous or nonessential materials in use in healthcare facilities. As previously stated, 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.

VH2O2 Sterilization Best Practices

ANSI/AAMI ST58:2013, *Chemical sterilization and high-level disinfection in health care facilities*[17] and the Association of periOperative Registered Nurses (AORN) *Guidelines for Perioperative Practice*[18] are standard references in the US for the use of VH2O2 sterilization in healthcare facilities. Both references point to some of the items previously addressed in this lesson, but are not explicit on many items that help assure a successful VH2O2 sterilization cycle. ANSI/AAMI ST58:2013 is currently under revision by AAMI Working Group 61.

What follows are some best practices to reduce the risk of variation introduced to the process.

Follow the Device Manufacturer's Instructions for Use

Following device manufacturer's IFU seems straightforward; however, CS/SP professionals might be very surprised at what they uncover if they verify each detail in the IFU for every device their facility sterilizes in VH2O2. Let's look at a very common scenario that triggers many inquiries regarding failed cycles.

The subject device is Intuitive Surgical's da Vinci Xi® endoscope processed for one type of sterilization cycle. The length of the da Vinci Xi endoscope is approximately 600mm and the diameter of the shaft is 8.8mm. The maximum weight of the tray and endoscope is 8.9 pounds; this is one of the largest devices in the US labeled for VH2O2 sterilization. If the cycle is validated for a load with a maximum weight limit of 10.7 pounds, loaded only on the sterilizer chamber's bottom shelf, this cycle has the shortest total VH2O2 exposure time (six minutes) for any VH2O2 sterilization cycle currently on the US market. When one of the largest devices is combined with the shortest total VH2O2 sterilant exposure times, it now becomes very important to understand the intricate details in Intuitive Surgical's IFU for processing the da Vinci Xi in this cycle. The details in the IFU for the da Vinci Xi endoscope processed specify the following[19]:

- Confirm endoscope is properly loaded into tray (PN 400490);
- Do not stack trays during sterilization;

- Do not process more than one tray at a time;
- Only process one tray on the bottom shelf;
- Only use the Express Cycle (on the STERRAD® 100NX);
- Always use sterilization wrap rated for 9- to 13-pound medium-weight or lighter, or 400-weight thickness or lighter for the plastic tray (PN 400490) with the STERRAD 100NX (Express Cycle). Use of a thicker wrap may result in incomplete sterilization of the Xi endoscope.

Furthermore, excessive moisture is not compatible with VH2O2 sterilization. Ensuring the da Vinci Xi endoscope is dry and verifying there is no water trapped in the device (button flush ports, input discs, housing and plastic tray) is crucial to ensure successful VH2O2 sterilization. Merely verifying all the recommended drying steps are completed per the IFU can solve failed VH2O2 sterilization cycles in the aforementioned scenario.

Know What You Are Loading; Load Only What You Know

The following saying rings true for a best practice for VH2O2 sterilization: know what you're loading; load only what you know. It is imperative that all operators of VH2O2 sterilizers understand the composition of each load 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 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 user understand the effect these factors have on the process and will ultimately help ensure consistently successful process outcomes.

Training and Competencies for the Facility's New Technicians

Many CS/SP technicians have worked in several facilities in the same city or even in several facilities across the country. This trend can bring both good and bad outcomes. Providing thorough training and competency evaluations of every new employee based upon one's own facility policy and procedures helps ensure this practice results in the best possible outcomes. There have been correlations to failed VH2O2 sterilization cycles, based upon practices brought from one facility to another facility by a new CS/SP technician. This is relatively simple to explain and even simpler to remedy with training.

Each facility has its common set of devices routinely sterilized in VH2O2. Each facility also has its procedure and methods for drying, packaging and loading devices; its own use of nonessential extraneous packaging items; and, possibly, even different sterilizer models and cycle types. Because of the technique sensitivity of VH2O2 sterilization, a small shift in procedures by a new CS/SP technician may swing the variation of the process to sporadically result in failed VH2O2 sterilization cycles. Again, this is easily remedied with thorough training and competency evaluations, based upon the facility's own policy and procedures.

Every Load Monitoring and Quarantining All Loads from VH2O2 Sterilizers

Another observation seen across the globe is an increased frequency of biological indicator (BI) monitoring to every load monitoring, combined with quarantining the load until the BI result is known. ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities*, states that "A process challenge device (PCD) with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle" (Section 9.5.4.3)[17]. 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)[18]. 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. It has been observed that when users switch to a new BI that provides a result in minutes versus 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 in the event that the sterilization cycle fails.

FDA-Cleared BIs Are Acceptable to Use

Unfortunately, misinformation has propagated through our industry regarding the use of BIs for VH2O2 sterilization. Because an international standard does not yet exist, the global healthcare industry has no

There is a significant amount of detail for the operator to understand in order to use VH2O2 sterilization technology safely, efficiently and effectively. Over the years, VH202 sterilization has earned its rightful place in our industry; however, it must be approached with a great deal of discipline.

standardization on performance requirements for BIs used in VH2O2. In the US, the FDA regulates BIs used in healthcare facilities and has a set of testing requirements for VH2O2 BIs cleared for use in the US. The FDA is the highest authority in the US (not the sterilizer manufacturer) on the final decision on which BIs are cleared as compatible (safe and effective) for use in healthcare VH202 sterilizers. Many users have been unaware that there is currently no requirement for a sterilizer manufacturer to validate or endorse indicators designed to monitor their sterilizers. The decision regarding the safety and efficacy of sterilization monitors is addressed by the FDA's review and clearance procedures. There are many examples of monitoring products from multiple manufacturers being used to monitor steam, EtO and VH2O2 sterilizers.

Conclusion

There is a significant amount of detail for the operator to understand in order to use VH2O2 sterilization technology safely, efficiently and effectively. Over the years, VH202 sterilization has earned its rightful place in our industry; however, it must be approached with a great deal of discipline. The user must be knowledgeable regarding his or her facility's own practices and procedures, and all the applicable IFU to ensure consistent and successful sterilization outcomes. The task is not insurmountable; it requires adherence and devotion to recommended/best practices, standards and IFU – all of which will help meet the common goal of delivering the highest level of patient safety. C

Resources

1. Block, S. Peroxygen Compounds. *Disinfection, Sterilization, and Preservation*, Seymour Block, Fifth Edition. Chapter 9. 2001.
2. Russell, Hugo and Ayliffe's. *Principles and Practice of Disinfection, Preservation and Sterilization*, Fourth Edition. Chapter 12. 2004.
3. STERIS® Document# M3644EN2012-10, Rev. B
4. FDA 510(k) K991999 _ STERRAD® 100S STERILIZER
5. FDA 510(k) K111377 _ STERRAD® 100NX STERILIZER DUO CYCLE
6. FDA 510(k) K042116 _ STERRAD® NX Sterilizer
7. FDA 510(k) K071385_ STERRAD® 100NX Sterilizer
8. FDA 510(k) K172754_V-PRO® maX 2 Low Temperature Sterilization System
9. STERIZONE® VP4® Low Temperature Sterilizer Brochure, April 2018
10. US Patent 6,528,016 B1 March 4, 2003. Kohler, et al.
11. US Patent 6,875,399 B2 April 5, 2005. McVey
12. US Patent 5,830,409 November 3, 1998, Childers, et al.
13. Robinson, Nancy and Eveland, Randall. *Using HPG sterilization for heat-sensitive devices* HPN January 2015
14. FDA 510(k) K160818 _ STERRAD® NX Sterilizer with ALLClear™ Technology
15. FDA 510(k) K160903_ STERRAD® 100NX Sterilizer with ALLClear™ Technology
16. Technical Data Monograph STERIS V-PRO maX Document #10037127 Rev. C (M3635EN)
17. ANSI/AAMI ST58:2013, *Chemical sterilization and high-level disinfection in health care facilities.*
18. AORN *Guidelines for Perioperative Practice. 2018.*
19. Reprocessing Manual for the da Vinci Xi Endoscope. PN 552793-01 Rev. G

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CRCST Self-Study Lesson Plan Quiz - Vaporized Hydrogen Peroxide Sterilization

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1. Vaporized hydrogen peroxide sterilization was first introduced to healthcare facilities:
   a. With limited cycles and packaging selections
   b. With multiple cycles and packaging selections
   c. With multiple injections of hydrogen peroxide
   d. In the early 2000s

2. A cycle pressure graph illustrates:
   a. The process flow for all sterilization methods
   b. Device compatibility for vaporized hydrogen peroxide
   c. The mechanism the sterilizer uses for sterilization
   d. When the sterilizer is due for maintenance

3. The pressure profile of vaporized hydrogen peroxide sterilizers is:
   a. Similar to the first hydrogen peroxide sterilizers
   b. Similar to ethylene oxide and steam sterilizer cycles
   c. Representative of the total chamber weight
   d. None of the above

4. Today's vaporized hydrogen peroxide sterilizers can sterilize:
   a. All items requiring low-temperature sterilization
   b. Some multi-channeled flexible endoscopes, laparoscopic devices and robotic devices
   c. Only wide-channeled devices
   d. None of the above

5. Vaporized hydrogen peroxide is technique sensitive because of the:
   a. Variability introduced by the sterilizer operator
   b. Varying temperatures during the cycle
   c. Lack of instructions for use
   d. All the above

6. When using vaporized hydrogen peroxide, it is important to monitor:
   a. Moisture on the instruments
   b. The materials being processed in the sterilizer
   c. Temperature of the devices and the environment
   d. All the above

7. As long as the chamber is loaded properly, exceeding the validated load maximum weight limit has no effect on the sterilization process.
   a. True
   b. False

8. Which of the following materials can affect the vaporized hydrogen peroxide sterilization process?
   a. Rubber corner protectors
   b. Oversized sterilization wrappers
   c. Foam instrument protectors
   d. All the above

9. It is considered best practice for vaporized hydrogen peroxide sterilization to follow:
   a. The Centers for Disease Control and Prevention's low-temperature document
   b. ANSI/AAMI ST58 and Association of periOperative Registered Nurses *Guidelines for Perioperative Practice*
   c. The US Food and Drug Administration's Good Manufacturing Practice document
   d. Safety protocols set forth by the Occupational Safety and Health Administration

10. Best practice for loading vaporized hydrogen peroxide sterilizers includes:
   a. Knowing what to load
   b. Not exceeding the weight load for the sterilizer
   c. Using the correct packaging
   d. All the above

11. Central Service/Sterile Processing technicians who have successful experience with vaporized hydrogen peroxide sterilization at another facility still need competency assessments performed at the new facility.
   a. True
   b. False

12. Vaporized hydrogen peroxide cycles should be monitored with a biological indicator:
   a. Monthly or, preferably, weekly
   b. Weekly or, preferably, daily
   c. At least daily
   d. None of the above

13. Many facilities are increasing the frequency of:
   a. Monitoring hydrogen peroxide concentrations
   b. Competency evaluations for all staff members
   c. Running a biological indicator in every vaporized hydrogen peroxide sterilization cycle
   d. Vaporized hydrogen peroxide chamber cleaning

14. Which of the following is considered the highest authority for the clearance of biological indicators in the US?
   a. The Occupational Safety and Health Administration
   b. The US Food and Drug Administration
   c. The sterilizer manufacturer
   d. The biological indicator manufacturer

15. The user must approach the use of vaporized hydrogen peroxide with:
   a. Great discipline
   b. Knowledge of the US Food and Drug Administration's labeling document
   c. Knowledge of the sterilizer's manufacturing process
   d. None of the above

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