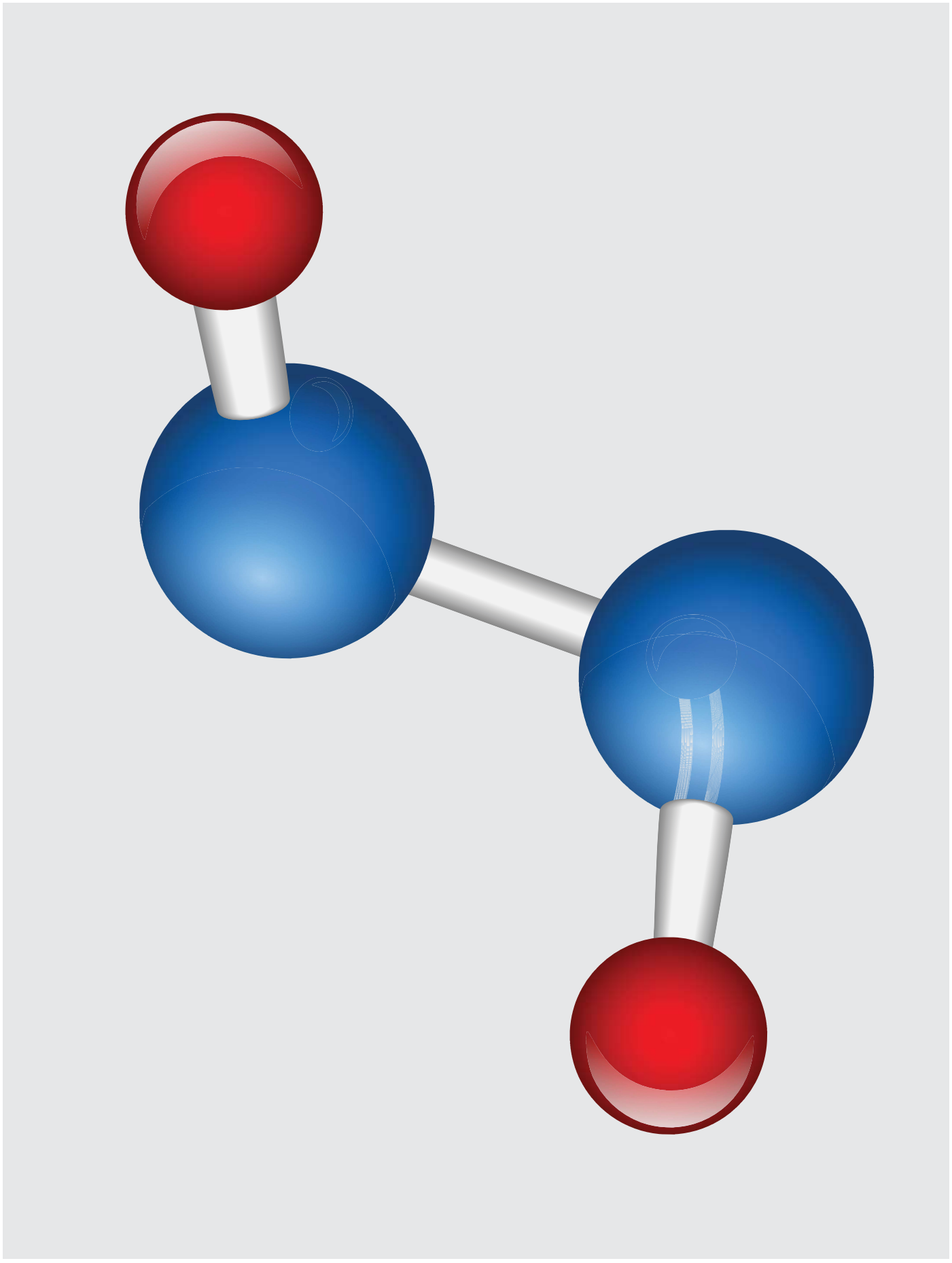

Vaporized Hydrogen Peroxide Sterilization

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LEARNING OBJECTIVES

1. Describe the change in complexity of vaporized hydrogen peroxide sterilization in healthcare facilities since its initial use in the early 1990s
2. Recognize significant variables and practices that affect vaporized hydrogen peroxide sterilization in healthcare facilities
3. Discuss best practices for the successful use of vaporized hydrogen peroxide sterilization in healthcare facilities

The first use of vaporized hydrogen peroxide (VH2O2) sterilization in U.S. healthcare facilities was in 1993. At that time, the sterilizer had one cycle, one injection of VH2O2 sterilant, and a very limited number of compatible devices and packaging types; however, this sterilizer was a brand-new technology for the industry.

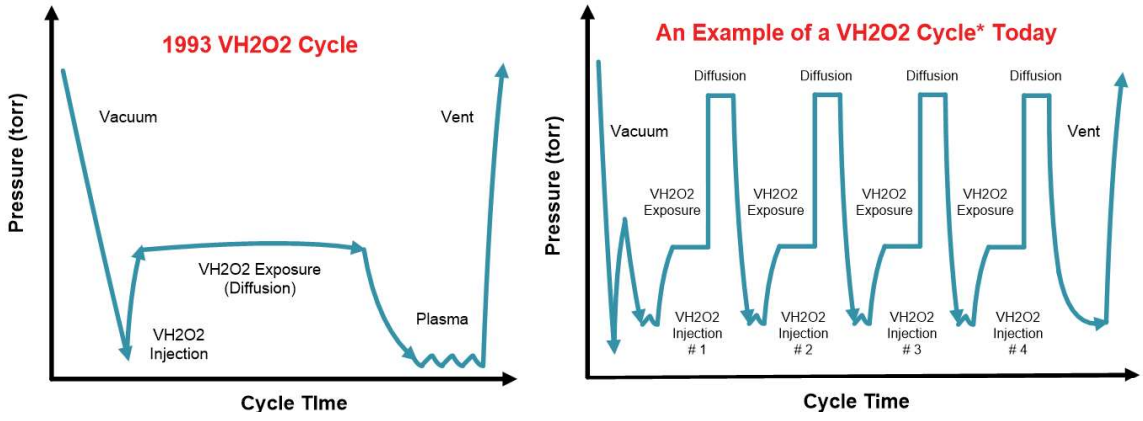
Objective 1: Describe the change in complexity of vaporized hydrogen peroxide sterilization in healthcare facilities since it was introduced in the early 1990s

Twenty-five years after its introduction, the inaugural sterilizer became obsolete and is no longer supported by the manufacturer. Today, there are multiple VH2O2 sterilizer manufacturers and sterilizer models, and over 20 different VH2O2 sterilization cycles in the U.S. market. These sterilizers use different technologies, 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 used today versus 30 years ago.

Table 1 features VH2O2 cycle pressure graphs and illustrates the dramatic change in the methods employed for VH2O2 sterilization over the last 30 years.[2,16] A cycle pressure graph helps to 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.[2] As you can see from the graph, the pressure profile is very similar to the stages in today's steam and ethylene oxide (EO) 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]

	VH2O2 Sterilizers and Sterilization Cycles in the U.S. Healthcare Facilities [1-9]						
Year	Number of Manufacturers	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
2023	4*	10+	20+	2-4	6-96.6*	6-32	16-60

*Includes VH2O2 plus ozone sterilizer[9]
Table 1



*STERIS V-PRO™ lumen cycle[16]
Diagram 1: Pressure graphs illustrating the change in VH2O2 sterilizer cycle complexity

Device compatibility for VH2O2 sterilization has grown from simple devices, like batteries and relatively wide-channeled devices, to laparoscopic instruments with narrow metal channels (0.7mm inner diameter), long, single-channel flexible endoscopes (1050 mm in length), large endoscopes for the most advanced robotic instrumentation (8.9 pounds in weight for the endoscope and 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 U.S. 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 ethylene oxide (EO) sterilization processes for the last 20 years. A year or more later, two more rapid readout BIs for VH2O2 received FDA clearance.

All three of these new VH2O2 BIs use the same principal rapid readout technology, provide a final result in just a few minutes, and most notably, present an increased challenge to the VH2O2 sterilization process compared to the conventional readout BIs used over the last 20 years. The decreased BI readout time and increased challenge the new BIs present to the VH2O2 process, combined with the increased complexity of the VH2O2 sterilizers, cycles and load items, has led to the profession's increased awareness of the technique sensitivity for VH2O2. This awareness sparked a culture change in the U.S. to correct and stay the course for VH2O2 sterilization.

Objective 2: Recognize significant variables and practices that effect vaporized hydrogen peroxide sterilization in health care facilities

VH2O2 sterilization is technique sensitive, which describes the variability introduced by the end user or VH2O2 sterilizer operator that can have a significant impact on the outcome of the VH2O2 sterilization process. The majority of VH2O2 sterilization processes provide a set/fixed amount of sterilant for each cycle type and load placed in the chamber. There are no make-ups of sterilant during the

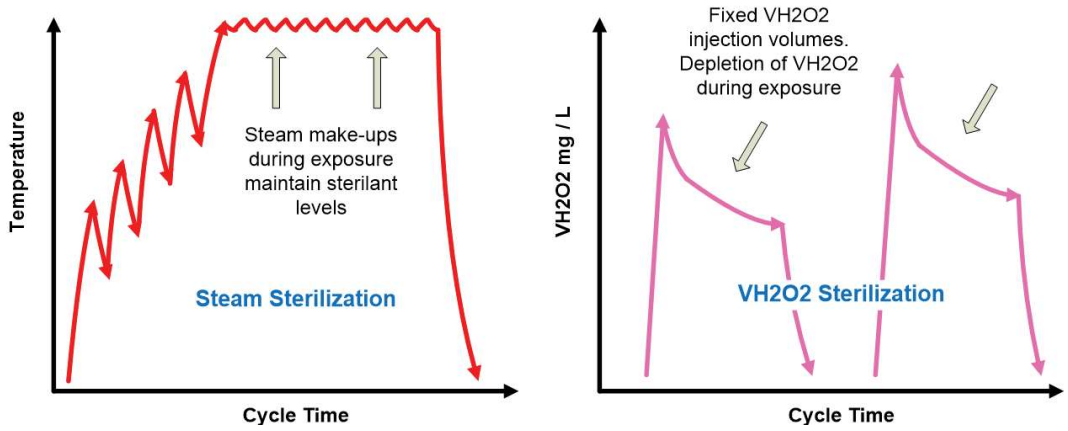


Figure 1: Relative sterilant levels in steam and VH2O2 sterilization

sterilant exposure phase; therefore, a very small or large load is exposed to the same amount of sterilant during the exposure phase. Each VH2O2 cycle can be compared to an oven that only has one temperature setting for every recipe.

The fixed amount of VH2O2 injected 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. Today, VH2O2 sterilizers are validated and cleared by the FDA, with a maximum weight limit for individual loads and each cycle type. **Table 2** shows 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 for specific restrictions on devices allowed for each cycle type.*

VH2O2 sterilization processes are not compatible with excessive moisture in and around devices and packaging. Excess moisture can cause automatic cycle cancellations and failure of quality monitoring tools, resulting in rejected sterilization cycles.[13] Temperature is a critical process parameter for VH2O2 sterilization.[20] This includes the temperature of the devices, packaging, and the environment of the Sterile Processing 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]

Materials compatibility is also essential for successful VH2O2 sterilization. Use of the wrong materials could result in a dramatic failure of the process. All materials placed in a VH2O2 sterilization process will affect the relatively unstable VH2O2 molecule in some way, 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]

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 used in healthcare facilities. Again, because VH2O2 cycles use a fixed amount of sterilant, best practice would be to limit or eliminate the use of any extra materials that could absorb the fixed amount of available VH2O2 sterilant.

ANSI/AAMI ST58:2013 (R2018) *Chemical sterilization and high-level disinfection in health care facilities*[17] and AORN Guidelines for Perioperative Practice[18] are our standard references in the U.S. for the use of VH2O2 sterilization in healthcare facilities. Both refences point to some of the items discussed previously in this lesson but are not explicit on many items that help ensure a successful VH2O2 sterilization cycle. ANSI/AAMI ST58:2013 is currently under revision by AAMI Working Group 61.

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
	STERRAD® NX	STANDARD[14]	10.7
		ADVANCED[14]	10.7
	STERRAD® 100NX	STANDARD[15]	21.4
		FLEX[15]	21.4
		EXPRESS[15]	10.7
		DUO[15]	13.2
STERIS®	V-PRO maX 2	Non-Lumen[8]	50.0
		Lumen[8]	19.6
		Flexible[8]	24.0
		Fast Non-Lumen[8]	11.0
STYRKER®	STERIZONE® VP4* (VH2O2 plus ozone sterilizer)	Cycle[19]	75.0

Table 2

Objective 3: Discuss best practices for the successful use of vaporized hydrogen peroxide sterilization in healthcare facilities

Following the device manufacturer's instructions for use (IFU) seems straight forward and unassuming, but one may be surprised by what can be uncovered verifying each detail in the IFU for each device the facility sterilizes using VH2O2. Let's explore a common scenario regarding failed cycles.

For the subject device, Intuitive Surgical's da Vinci Xi® endoscope processed in the ASP® STERRAD® 100NX EXPRESS cycle, the length of the endoscope is approximately 600 mm, and the diameter of the shaft is 8.8 mm. The maximum weight of the tray and endoscope is 8.9 pounds. This represents of the largest devices in the U.S. labeled for VH2O2 sterilization. The ASP® STERRAD® 100NX EXPRESS 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 (estimated six minutes) for any VH2O2 sterilization cycle currently on the U.S. market. When combining of the largest devices with the shortest total VH2O2 sterilant exposure time, it is imperative to diligently follow the IFU for the da Vinci Xi endoscope and ASP® STERRAD® 100NX EXPRESS cycle to ensure consistent, successful cycles. The IFU for the da Vinci Xi endoscope processed in the STERRAD® 100NX EXPRESS cycle notes 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:
  - » 9-13 pounds (medium weight or lighter) or
  - » 400-weight thickness or lighter
- for the plastic tray (PN 400490) with the STERRAD 100NX (Express Cycle)
- Using a thicker wrap may result in incomplete sterilization of the Xi Endoscope

Again, 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 ensuring successful VH2O2 sterilization. Verifying all recommended drying steps are completed per the IFU can solve and prevent failed VH2O2 sterilization cycles in the previously described scenario.

This saying rings true for a best-practice 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 placed 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 (such as steam)?
- Are there any non-essential 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 of depleting the fixed amount of VH2O2?

Understanding these basic variables for each VH2O2 load will help the user better understand the effect these factors have on the process and will help ensure consistent, successful process outcomes.

Many SP technicians have worked in more than one facility in the same city or even in several facilities across the country, which means they have experienced different processes and practices. There are correlations to failed VH2O2 sterilization cycles based on practices brought from one facility to another facility by a new SP technician. Providing thorough training and competency evaluations for every new employee, based on the hiring facility's policies and procedures, helps promote process and practice consistency and better outcomes. Each facility has common sets of devices routinely sterilized using VH2O2 as well as procedures and methods for drying devices, packaging devices, loading devices. Further, they may use non-essential (extraneous) packaging items and different sterilizer models and cycle types. Because of the technique sensitivity of VH2O2 sterilization, a small shift in procedures by a new SP technician may result in a sporadic failed VH2O2 sterilization cycle.

Another commonly observed occurrence is the increased frequency of BI monitoring for every load, combined with quarantining the load until the BI result is known. ANSI/AAMI ST58, Section 9.5.4.3, states that " …[a] BI should also be used at least daily, but preferably in every sterilization cycle."[17] The Association of periOperative Registered Nurses Guideline for Sterilization, Section 10.10.2) is slightly more specific: "Perform routine sterilizer efficacy monitoring every day the sterilizer is used for each cycle type … preferably with each load."[18] In hospitals, end users typically place a BI and internal CI in a peel pouch designed for use in VH2O2 sterilizers and position the pouched BI in the sterilizer chamber as recommended by the sterilizer manufacturer. When users switch to a new BI that provides a result in minutes versus days, they can quickly move to every load monitoring 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 of a cycle failure.

Unfortunately, misinformation exists regarding the use of BIs for VH2O2 sterilization. Because 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., BIs are medical devices; the FDA regulates BIs used in healthcare facilities and has a set of testing requirements for VH2O2 BIs 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 BIs are cleared as compatible (safe and effective) for use in healthcare facilities' VH202 sterilizers. 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 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.

Conclusion

Many factors contribute to safe, effective and efficient VH2O2 sterilization, including user knowledge about their facility's policies, procedures and practices and consistent adherence to the manufacturers' IFU. Ensuring safe, effective VH202 outcomes also requires thorough training for SP technicians and strict adherence to industry standards, guidelines and best practices.

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