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Learning Objectives:

1. ***Understand the theory of operation of Hydrogen Peroxide Gas Sterilizers***
2. ***Be able to identify the advantages and disadvantages of Hydrogen Peroxide Gas Sterilization***
3. ***Recognize the major differences in preparing reusable medical devices for sterilization in a Hydrogen Peroxide Gas Sterilizer versus a Steam Sterilizer***
4. ***Be able to explain the key steps required to assure a safe and effective Hydrogen Peroxide Gas Sterilization process***

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Using HPG sterilization for heat-sensitive devices

Nancy A. Robinson, Ph.D. and Randal W. Eveland, Ph.D.

Hydrogen peroxide gas: a low temperature reprocessing option

For over a century, steam sterilization has been the most commonly used method for sterilization of medical devices. However, as the number of devices requiring low temperature sterilization has grown, the selection and correct use of low temperature sterilization methods have become critically important for sterile processing departments. There are currently four methods of low temperature sterilization available in the United States:

- Ethylene oxide
- Ozone
- Liquid chemical sterilization
- Hydrogen peroxide gas sterilization

The choice of a low temperature sterilization method is based on a number of factors, such as financial implications, medical device requirements, safety and ease of use. AAMI ST58:2013[1] identifies the types of low temperature sterilization processes available (except for ethylene oxide sterilization, which is addressed in AAMI ST41:2008(R)2012[2]), and provides suggested questions that users should ask themselves when selecting a low temperature sterilization agent and/or equipment. Of the low temperature alternatives, ethylene oxide (EO) has fallen out of favor due to its long aeration period (10 – 15 hours total cycle time), the health hazards associated with the use of EO and government regulations. Ozone has not been widely adopted as a sterilization technology most likely due to the relatively long cycle times, 4-5 hours, and limited device validations. Liquid chemical sterilization is an immediate-use application in which the sterilized device must be immediately transported to the site of use. The last sterilization method, which is a popular choice for replacing ethylene oxide, is hydrogen peroxide gas (HPG) sterilization.

This self-study module will focus on the use of HPG as a sterilization process, emphasizing the importance of various steps in order to ensure a safe and effective process.

Theory of operation

In order to safely and effectively use a HPG sterilizer, a general understanding of the sterilization processes is required. Although there are a number of specific HPG sterilizers available, all HPG sterilization processes share common sterilization cycle features. The HPG sterilization process can be divided into three phases: conditioning, sterilization and aeration. These phases are described below and shown graphically in Figures 1 and 2 on the next page. Figures 1 and 2 are pressure graphs showing the pressure within the chamber over time for the two basic HPG processes: vaporized hydrogen peroxide, or VHP (Figure 1), and gas plasma (Figure 2). HPG sterilization phases:

1. Conditioning: The sterilization chamber is evacuated to remove air from the chamber and the load. The pressure achieved ranges from 1 to 0.15 Torr. Reducing the pressure to such a low level improves penetration into the load.
2. Sterilization: The load is exposed to hydrogen peroxide gas. Liquid 59 percent hydrogen peroxide passes over a heated element, which causes the liquid to form a gas. The HPG enters the sterilization chamber where it penetrates into the packaging to sterilize the enclosed medical devices. After a cycle-specific time, filtered air is introduced into the chamber increasing the chamber pressure to (or near to) normal atmospheric conditions. After a second, cycle-specific time, the chamber is evacuated in preparation for the next introduction of sterilant. Plasma, if used, is initiated between each sterilant introduction (Figure 2). Multiple sterilant exposure/removal steps (typically 2 or 4) are used. Please note that some gas plasma HPG sterilizers concentrate the sterilant as part of the process so that the hydrogen peroxide is increased from 59 percent up to approximately 94 percent.
3. Aeration: Toxic sterilant residuals are removed from the load.
   - For VHP HPG sterilization, a vacuum is applied to the chamber.
   - For gas plasma HPG sterilization, plasma is applied for a set time period after the chamber is evacuated.

After completion of aeration, the chamber is returned to atmospheric pressure. The load is removed and either stored or used immediately.With that basic understanding of the HPG sterilization process, we next consider the advantages and disadvantages of HPG sterilization.

Advantages and disadvantages of HPG sterilization

Listed below are advantages of HPG sterilization:

- Relatively short cycle times: 24-60 minutes as compared to 10-15 hours for EO and 4-5 hours for ozone sterilization
- Compatibility with heat and/or moisture-sensitive medical devices
- Sterile storage of the sterilized devices within containers, wrapped trays or Tyvek pouches
- No cool-down after sterilization
- Environmentally-safe sterilant: hydrogen peroxide decomposes into water and oxygen
- Easy to install and operate
  - The only utility required is an electrical source
  - The HPG cycles are pre-programmed and selectable from a user-friendly touch screen

As with all sterilization methods, there are also disadvantages to HPG sterilization. These disadvantages are:

- Limited penetration of the HPG. HPG sterilization cycles have limitations on the internal diameter and length of the lumens that can be processed.
- Limitation on load weight. Load weights are much less than can be processed in steam: 9-24 pounds total versus 25 pounds per tray.
- Devices **must be** thoroughly dried
  - If the load is not properly dried, effective sterilization may not be achieved. As the chamber pressure is reduced, residual water evaporates causing localized cold spots. The cold spots cause HPG to condense (turn into a liquid), making the HPG unavailable for the sterilization process. Usually, the cycle will abort due to low pressure. The condensed HPG may remain at the end of the aborted cycle and pose a hazard to the user. For this reason, any liquid seen in or on a load at the end of a HPG cycle is assumed to be liquid hydrogen peroxide, and personal protective equipment, such as gloves, must be worn to protect the user from a chemical burn (AAMI ST58[1] part H.4.1.4.2).
- Use of special packaging materials
  - HPG sterilizers cannot use paper peel pouches, towels or paper products to package devices. Instead, Tyvek peel pouches and polypropylene wrap are used. Paper products (composed of cellulose) absorb hydrogen peroxide and can, under certain circumstances, lead to spontaneous combustion of the paper. The first two HPG disadvantages, limited penetration and load weight, are a source of complexity, as these criteria vary between sterilizer models and cycles within a model. Table 1 (next page) presents a comparison between the indications-for-use for two HPG sterilizers (V-PRO maX Sterilizer, VHP methodology, and STERRAD 100NX Sterilizer, Gas Plasma technology), illustrating the complexity of the penetration and load-weight limitations. This important information is found within the sterilizer's operator manual. After consideration of the advantages and disadvantages of HPG sterilization, many sterile processing departments elect to use HPG sterilization to process heat- and moisture-sensitive devices. The next section presents the steps to prepare devices for HPG sterilization.

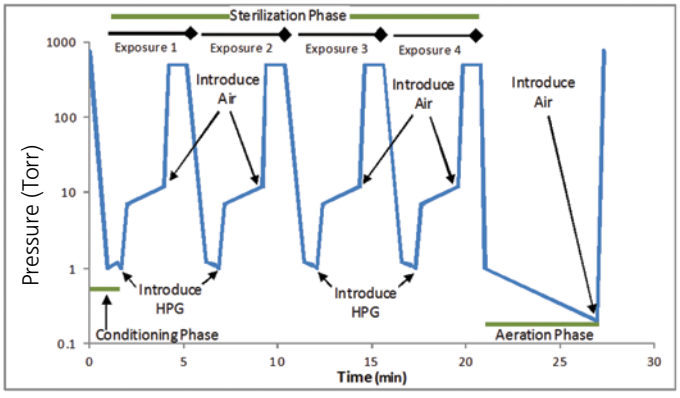

Figure 1. Chamber pressure versus time for a hydrogen peroxide gas VHP sterilization cycle.

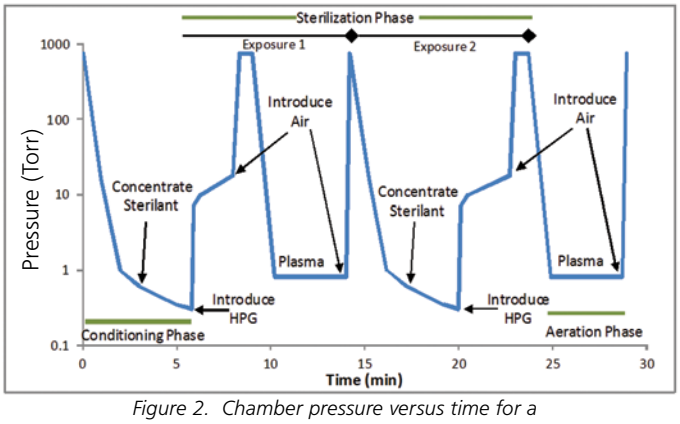

Figure 2. Chamber pressure versus time for a hydrogen peroxide gas plasma sterilization cycle.

Preparation of reusable medical devices for HPG sterilization

The following steps are required to prepare devices for HPG sterilization. Although many steps are the same as for other sterilization processes, there are important differences. These differences are emphasized in the steps.

1. **Cleaning:** One of the critical steps in preparing a device for reprocessing is cleaning per the manufacturer's instructions for use. If the devices are not clean or if they are not functional, there is no assurance that the device has been sterilized even though all of the process monitors indicate a successful sterilization cycle.
2. **Rinsing:** The devices must be rinsed to remove cleaner residue in accordance with the cleaner manufacturer's recommendations. Residual cleaning chemistries may appear after processing as light-colored residue on devices. If such residues are observed, the device should be re-cleaned, thoroughly rinsed and re-sterilized.
3. **Drying:** It is extremely important to thoroughly dry the medical devices prior to packaging for HPG sterilization. Drying device lumens is particularly difficult for flexible endoscopes. Refer to the device manufacturer's drying instructions or contact the manufacturer for specific guidance and instructions.
4. **Inspection and preparation:** After cleaning, devices are inspected to ensure that they are cleaned and dried. Any required functionality checks are conducted (e.g., the flexible endoscope leak test) and the devices are prepared for sterilization following the device manufacturer's instructions. For example, flexible endoscopes must have the gas cap in place (if provided). If the gas cap is not placed properly onto the device, the flexible endoscope will be damaged due to the low pressure of the sterilization cycle.
5. **Packaging:** After inspected and prepared for sterilization, the devices are packaged using various packaging options: Tyvek pouches, containers or trays wrapped with polypropylene sterilization. Whatever packaging option is used, be sure it has been validated for use in the HPG process. Chemical indicators validated for use in the specific HGP sterilizer are included in each package.

*See **SELF-STUDY SERIES** on page 32*

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

Summary: HPG sterilizer device preparation is very similar to that for steam sterilization with the following exceptions:
- All devices must be **thoroughly dried**, including crevices and lumens.
- Heat-sensitive surgical flexible endoscopes and bronchoscopes can be sterilized in HPG. If a gas cap is provided, it must be used.
- Packaging accessories, such as paper peel pouches, towels, tray liners and paper count sheets are not compatible with HPG sterilization. Instead, use Tyvek peel pouches and polypropylene wraps.

Effective sterilization of reusable medical devices in a hydrogen peroxide gas sterilizer

The following steps are performed to safely and effectively sterilize instruments in a HPG sterilizer:

1. **Preparation of the devices** (discussed in detail above).
2. **Loading**: HPG sterilization systems have a limitation on the total load weight that can be sterilized in each cycle. Never exceed these limitations. Place the packaged items in a single layer on the shelves; never stack on top of another. For gas plasma HPG processes, the load should not touch the radio frequency coil or block the UV sensor, as the cycle may abort.
3. **Routine monitoring with BIs:** AAMI ST58[1] (9.5.4.3) recommends that an appropriate biological indicator (BI) be used at least daily, but preferably in every sterilization cycle. Follow BI instructions for proper placement in the sterilizer.
4. **Cycle selection:** Depending upon the HPG sterilizer model, there may be a choice of cycles. Cycle selection is based upon load contents. If a medical device exceeds the cycle limitations, there is no assurance that the device has been sterilized.
5. **Unloading:** First, check the cycle tape to confirm successful cycle completion. If the process was aborted, the contents have not been sterilized and the load must be re-packaged and re-sterilized. While removing the load, evaluate external process indicators, including indicators within Tyvek pouches, to verify a passing color change.When items have been properly prepared (thoroughly cleaned, rinsed and dried) and the cycle successfully completes, the risk of hydrogen peroxide contact when removing the load is negligible. However, as a precaution, it is recommended in AAMI ST58[1] (H.4.1.4.2) that personnel should wear appropriate personal protective equipment (PPE) when using hydrogen peroxide gas sterilizers. Polyvinylchloride or nitrile gloves should be worn when removing items after a cycle cancels, or any time that items have any visible moisture or liquid, as hydrogen peroxide could be present.
6. **Storage:** The sterilized packages may be immediately used or placed into storage until needed. There is no cool down period prior to use.
7. **Staff training and competency:** Consistent, correct use by trained and competent staff is essential in achieving a sterile device every time. To help ensure a successful outcome for every cycle, sterilizer manufacturers provide aids for staff training and competency demonstration. These training tools can supplement the department programs and ensure the specific steps essential for a successful outcome are understood and followed.

Summary: The key factors to ensure a safe and effective HPG sterilization process are:

- Correct preparation of devices
  - Cleaning, rinsing, **thoroughly drying** and packaging in compatible materials
- Proper loading of the sterilizer
  - Never exceeding the HPG sterilizer cycle weight or device lumen limits
  - Arranging wrapped trays/containers or Tyvek peel pouches in a single layer on the sterilizer shelves
- Selection of the correct cycle
- Cycle tape confirmation that the cycle successfully completed
- Wearing gloves to unload the sterilizer if the cycle did not complete successfully or if any moisture is noted

Conclusion

HPG sterilization use is increasing as the need for a safe and rapid method for sterilization of heat-sensitive devices increases. As with all sterilization methods, it is important to understand the physical process by which sterilization is achieved, as well as the key steps for preparation and loading of the sterilizer to ensure an effective process. HPN

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Dr. Randal Eveland is a Senior Manager in STERIS Corporation's research and development department. He holds a B.S., M.S. and a Ph.D. in

Table 1. Examples of hydrogen peroxide gas sterilizers limitations: load weights and types of devices.

Type & Sterilizer Model	Cycles	Load Limitations	Limits of Types of Devices that Can be Reprocessed	Approx.Cycle Time
Vaporized Hydrogen Peroxide (VHP) V-PRO maX*	Lumen	19.65 lbs 20 lumens	Instruments with diffusion restricted spaces Devices with single, dual and triple stainless steel lumens with the following configurations: Single lumen ID ≥ 0.77 mm and ≤ 500 mm in length (L) Dual Lumen ID ≥ 0.77 mm and ≤ 527 mm L Triple Lumen ID ≥ 1.2 mm and ≤ 275 mm L ID ≥ 1.8 mm and ≤ 310 mm L or ID ≥ 2.8 mm and ≤ 317 mm L	55
	Non Lumen	19.65 lbs No Lumens	Non-lumened instruments and instruments with stainless steel diffusion restricted spaces	28
	Flexible	2 Flexible endoscopes (and light cords if not integral to the endoscope)	Single or dual lumen surgical flexible endoscopes and bronchoscopes with the following configurations: Single Lumen ID ≥ 1 mm and ≤ 1050 mm L Dual Lumen ID ≥ 1 mm and ≤ 998 mm L, and ID ≥ 1 mm and ≤ 850 mm L	35
		1 Flexible endoscope and additional non-lumen instruments up to a total load weight of 24lbs	One flexible endoscope (same as above) and non-lumened devices and instruments with diffusion restricted spaces	35
Gas Plasma STERRAD 100NX**	Express	10.7 lbs on the bottom shelf No Lumens	Instrument surfaces and instruments with diffusions-restricted stainless steel and titanium spaces	24
	Standard	21.4 lbs 10 lumens	Instruments with diffusions-restricted spaces Single channel stainless steel lumens with an ID ≥ 0.7 mm and ≤ 500 mm L	47
	Flex Scope	2 Flexible endoscopes (no additional load)	Single channel flexible endoscopes with ID ≥ 1 mm and ≤ 850 mm L	42
	Duo	13.2 lbs 2 Flexible endoscopes	Single channel flexible endoscopes with ID ≥ 1 mm and ≤ 875 mm L Accessories normally connected to a flexible endoscope during use	60

chemistry. He has more than 10 years of experience in the design and development of liquid chemical sterilization/high level disinfections systems, hydrogen peroxide gas sterilizers and system accessories.

References

1. ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in healthcare facilities.

2. ANSI/AAMI ST41:2008(R)2012 Ethylene oxide sterilization in health care facilities: Safety and effectivenessHPN Self-study #58 – Hydrogen Peroxide Gas Sterilization *http://www.accessdata.fda.gov/cdrh_docs/pdf13/K131120.pdf.

**http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111377.pdf.

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Using HPG sterilization for heat-sensitive devices

Circle the one correct answer:

1. **Which of the following are the three phases of a hydrogen peroxide gas (HPG) sterilization cycle?**
   A. Conditioning, Sterilization and Aeration
   B. Washing, Rinsing and Drying
   C. Sterilization, Pressurization and Aeration
   D. None of the above

2. **Which of the following is (are) advantages of HPG sterilization?**
   A. Relatively short cycle times
   B. Compatibility with heat- and moisture-sensitive medical devices
   C. Storage of the sterilized devices
   D. No cool-down period required
   E. All of the above

3. **Which of the following is not considered a disadvantage of HPG sterilization?**
   A. Limitation on load weight
   B. Devices must be thoroughly dry prior to sterilization
   C. Wet pack is a common problem
   D. There are limitations on the ability of the HPG to penetrate lumens

4. **It is not important to understand the specific indications for use for a particular HPG sterilizer model and cycle because all HPG sterilization systems are the same.**
   A. True B. False

5. **Which of the following device preparation steps is more critical for an effective HPG sterilization process as compared to a steam sterilization process?**
   A. Cleaning
   B. Rinsing
   C. Drying
   D. Inspection

6. **The device packaging used for HPG sterilization is identical to that used for a steam sterilizer.**
   A. True B. False

7. **To prepare a flexible endoscope for sterilization in a HPG sterilizer,**
   A. simply place the cleaned device in the sterilizer; no need to dry the lumens.
   B. clean, dry and package the device prior to placing in the HPG sterilizer.
   C. leak test (if applicable), clean and rinse following the manufacturer's instructions, dry the device (paying attention to the lumens), engage the gas cap (if applicable), package and place in the HPG sterilizer.
   D. None of the above; HPG cannot be used to sterilize flexible endoscopes.

8. **Trays, containers and peel pouches must not be stacked on top of another when loading a HPG sterilizer.**
   A. True B. False

9. **Which of the following describe the correct method to determine what HPG sterilization cycle is selected if the sterilizer has multiple cycles?**
   A. It does not matter; most people select the shortest cycle available for all loads.
   B. The safest method is to choose the longest cycle, to make sure everything is sterilized.
   C. The cycle is selected based upon the load contents.
   D. HPG sterilizers only offer one cycle option, so there is no selection required.

10. **Which of the following steps are important for a successful HPG sterilization cycle?**
    A. Correct preparation of the devices (cleaning, rinsing, drying and packaging)
    B. Loading the packages in a single layer on the provided shelves
    C. Not exceeding the load weight limitation
    D. Selecting the appropriate cycle for the load being sterilized
    E. All of the above

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