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LEARNING OBJECTIVES

1. *Understand the general processing capabilities of HPG sterilizers.*
2. *Explain the use of HPG sterilizers for fast-turn devices and stainless-steel loads.*
3. *Identify flexible endoscopes suitable and not suitable for HPG processing.*

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SELF-STUDY SERIES

A fast-turn solution

Hydrogen peroxide gas sterilization

by Randal Eveland, PhD

Surgical department directors and sterile processing department (SPD) managers have new options for using hydrogen peroxide gas (HPG) sterilizers, thanks to recent advances in HPG technology and greater availability of these newer systems for hospital use. HPG sterilizers (with hydrogen peroxide as the sterilizing agent) are well known for their short total process time and their suitability for temperature-sensitive devices and materials.[1] The sterilizers are also easy to use, with unalterable sterilization cycles and specific guidelines for the types of devices to be processed in their cycles. Device manufacturers provide instructions for use (IFU), and some HPG sterilizer manufacturers offer internet tools that help users identify compatible devices for specific sterilizer cycles to ensure that a device is compatible with the selected HPG sterilization process. Before loads are processed in HPG sterilizers, they must be cleaned, rinsed and thoroughly dried. Then they are packaged to provide a sterile barrier, whether the load is used immediately or stored for future use.

Improving performance and efficiency

SPD managers who are working to maximize department performance and minimize total device reprocessing time should give serious consideration to the processing capabilities of HPG sterilizers. While typically identified as low-temperature sterilization systems, there is no restriction on using HPG sterilizers to process devices that are compatible with steam sterilization processes. In fact, there are distinct advantages to using HPG systems for processing some heat-stable items, including improving battery life and reducing repair time for items such as telescopes (these items exhibit reduced performance over time due to the thermal cycling of steam sterilization processes).

In addition to offering improved device compatibility, HPG sterilizers can significantly reduce reprocessing time. For example, when devices are urgently needed in the surgical suite, steam has been the predominant sterilization option. However, the fast sterilization cycles of newer HPG systems can also effectively support unplanned operating room needs. HPG sterilizers in the U.S. market now have sterilization cycles as fast as 16 to 28 minutes (Table 1). And, as a distinct advantage to processing in steam or ethylene oxide, the packaged devices from a HPG sterilizer are ready for use immediately after processing, with no cooling or additional aeration required.

Healthcare providers have the potential to significantly improve sterile processing and surgical suite efficiency by taking advantage of HPG sterilizing capabilities. In particular, SPD managers should consider using their HPG sterilizers for the following applications:

- As a replacement/alternative to immediate use steam sterilization (IUSS)
- For stainless steel loads
- For flexible endoscope sterilization

Replacing IUSS with HPG sterilization

IUSS has earned a bad reputation because overuse and inappropriate use have raised concerns about patient safety. IUSS is defined in AAMI ST79-2017 as:

Sterilization method that involves the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team.[2]

The reality is, time constraints continue to push hospitals towards IUSS. There are no indications that these pressures will go away.

Consider this alternative: devices are processed in a fast HPG sterilizer cycle rather than an "immediate use" or "flash" steam sterilization cycle. There are no reporting requirements because the re-

processed devices are packaged before being processed in the HPG sterilizer. This solution would also address another key concern of the IUSS process: whether the devices were aseptically transported and cooled prior to use. If HPG sterilization is used, aseptic transport and temperature post-process are not an issue because cooling and/or aeration are not required, so the packaged devices are immediately ready for use at the completion of the sterilization cycle.

A pre-vacuum 132°C/270°F steam cycle with a 4-minute sterilization phase and a 1-minute drying time takes approximately 18 minutes to complete, and this does not include cooling time. Using an HPG sterilizer with sterilization cycles from 16 to 28 minutes (and doesn't require additional time for cooling with sterile water or aseptic transfer) will result in a faster overall process. And, as already mentioned, HPG sterilizer cycles are validated to process packaged devices, which is another distinct advantage for immediate-use events.

Like other sterilization methods, HPG sterilization requires an initial decontamination step (cleaning, rinsing and thorough drying of all devices), then packaging with appropriate sterility assurance products for the sterilization cycle. Hospitals may choose to locate HPG sterilizers close to the surgical suite, or they may require sterilization to be performed in the SPD. Typically, SPD professionals have direct access to device manufacturers' published IFU, so they may be better suited to clean and disinfect the instruments in accordance with those instructions.

HPG sterilization also requires that all appropriate department and hospital infection control and quality policies and procedures be followed, including those requiring full compliance with all manufacturer's indications and IFU. This means that, although steam processes may have a general indication for implants, HPG sterilizers can only process implants specifically identified by the implant manufacturer, and only in the specific cycle identified by the manufacturer. Likewise, any loaner sets must have HPG sterilization indicated in the IFU.

The market introduction of fast-reading biological indicators for HPG sterilizers (with read times of 20 to 30 minutes) has further enhanced departments' fast-turn capabilities. Just as for steam sterilizers, the biological indicator selected must be

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Table 1. HPG Sterilizer Limitations

Type & Sterilizer Model[4]	Cycles	Load Config. Limitations	Limits of Types of Devices that Can be Reprocessed	Approx. Cycle Time
Vaporized Hydrogen Peroxide V-PRO® MAX[2]	Fast Non Lumen	11 lbs. No Lumens	Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.	16
	Non Lumen	50 lbs. No Lumens	Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.	28
	Flexible	2 Flexible endoscopes (no weight requirement)	Single or dual lumen surgical flexible endoscopes and bronchoscopes with the following configurations Single Lumen ID ≥ 1 mm and ≤ 1050 mm in length Dual Lumen ID ≥ 1 mm and ≤ 990 mm in length, and ≥ 1 mm and ≤ 850 mm in length	35
		1 Flexible endoscope and additional non-lumen up to a total load weight of 24 lbs.	One flexible endoscope same as above and non-lumened devices and instruments with diffusion restricted spaces.	35
	Lumen	19.65 lbs. 20 lumens	Instruments with diffusion restricted spaces Devices with single, dual and triple stainless-steel lumens Single lumen ID ≥ 0.77 mm and ≤ 500 mm in length Dual Lumen ID ≥ 0.77 mm and ≤ 527 mm in length Triple Lumen Instruments with diffusion restricted spaces, ID ≥ 1.2 mm and ≤ 275 mm in length, ID ≥ 1.8 mm and ≤ 310 mm in length or ID ≥ 2.8 mm and ≤ 317 mm in length	52
Gas Plasma STERRAD® 100NX	Express	10.7 lbs. on the bottom shelf No Lumens	Instrument surfaces and instruments with diffusions-restricted spaces*	24
	Standard	21.4 lbs. 10 lumens	Single channel stainless steel lumens with an ID ≥ 0.7 mm and ≤ 500 mm in Length	47
	Flex Scope	2 Flexible endoscopes (no weight requirement)	Single channel flexible endoscopes with ID ≥ 1 mm and ≤ 850 mm Length	24
	Duo	13.2 lbs. 2 Flexible endoscopes	Single channel flexible endoscopes with ID ≥ 1 mm and ≤ 875 mm Length Accessories normally connected to a flexible endoscope during use	60

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

identified for use in the specific HPG sterilizer cycle being performed.

Processing stainless steel loads

Even though steam sterilization has historically been the method of choice for stainless steel instruments, HPG sterilizers are validated to process stainless steel items. They are not limited to processing temperature-sensitive devices. Steam and HPG modalities are not mutually exclusive, so SPDs have more options than they may realize. Managers should select the optimal sterilization method to account for available time, load size, device utilization and department workflow.

Although the enhanced device compatibility of HPG processes may not be an issue for stainless steel devices, reprocessing time is. Consider that a pre-vacuum 132°C/270°F steam cycle with a 4-minute sterilization phase and a 30-minute dry time will take approximately 45 minutes to complete. Then it will be followed by a 60-minute cool-down period, for a total cycle time of just under two hours. With cycles that range from 16 to 60 minutes (see Table 1), and no cool-down period, processing a device in an HPG sterilizer can reduce the time to return a device to the surgical suite by 30 to 90 minutes. Devices processed in HPG sterilizers will always be cooler than those processed in steam, so they are ready for use immediately after processing. Removing cooling time from the standard work process allows much faster turns of device inventory. And for specialty or surgeon-specific sets, this quicker turn time also helps optimize their utilization.

There are some limitations to the use of HPG sterilizers for device sets that are currently being steam-sterilized. One is load configuration. A simple set of stainless-steel instruments placed flat in a tray allows for HPG diffusion to all instrument surfaces, but there are some device configurations that may not be validated for HPG sterilization. Examples include stringers of medical instruments that may not allow hydrogen peroxide gas diffusion to all surfaces, and multi-layer trays or containers that may not be indicated by their manufacturers for HPG sterilization. It's always important to review loaner set sterilization instructions to determine if HPG sterilization is suitable for that particular set.

Device set and total sterilizer load weights may also determine the reprocessing methodology. While steam sterilizers can process total load weights in the hundreds of pounds, HPG sterilizer cycles are limited by the indications for use for each cycle, which currently list load weights of between 11 and 50 pounds, depending on the load properties and sterilization cycle selected (see Table 1).

Processing flexible endoscopes

HPG sterilizers have indications for reprocessing flexible endoscopes. Typically, the indications call for a specific sterilization cycle, specified lumen internal diameter and length, and load limitations. These cycles provide a terminally sterilized packaged scope and may also be used to sterilize the endoscope's accessories or other devices in the same sterilization cycle (depending on the specific HPG sterilizer and cycle).

To ensure successful sterilization of endoscopic devices in an HPG system, it's critical to follow each scope manufacturer's instructions. Users typically are instructed to leak-test flexible endoscopes before cleaning them. Then flexible endoscopes must be cleaned, rinsed and dried per the IFU (paying particular attention to the lumens). Once the cleaning process is complete, the flexible endoscope is prepared for sterilization. Since HPG sterilization is a low-pressure process, technicians should always install any gas cap that was supplied with the endoscope. The scope is then packaged and placed into the sterilizer.

It's important for reprocessing personnel to understand that there are significant design differences among flexible endoscopes that dictate reprocessing methodology. For example, processing a GI endoscope (e.g., a colonoscope, duodenoscope or sigmoidoscope) in an HPG sterilizer without a specific indication for HPG use by the endoscope manufacturer may lead to device damage and potential patient injury. GI endoscopes that are not indicated for HPG sterilization may contain a chemical within the endoscope that will react with the HPG sterilant (hydrogen peroxide) to form an acid. The acid will damage the scope from the inside out, and if the acid leaks from the scope during a procedure, it can potentially injure a patient.[3]

Staff Training and Competency

The variety and complexity of medical devices continues to increase and so the appropriate use of low-temperature sterilization processes must keep pace. 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, some sterilizer manufacturers provide tools for staff training and for demonstrating competency. These training aids can supplement the facility's programs and ensure that the specific steps that are essential for a successful HPG sterilization outcome are understood and followed.

Not your mother's sterilizer

HPG sterilizers are useful for an increasing variety of loads and devices in hospitals and clinics, and users are beginning to realize the full capabilities of this type of system. The advent of fast-acting biological indicators and advances in cycle technology allow HPG sterilizers to provide extremely fast device turnaround times, which helps optimize device inventory and logistics and specialty instrument use. HPG sterilizers also enable compliance to the hospital's infection control and quality policies and procedures, and they can help address compliance issues by providing an alternative sterilization method for items that typically undergo only steam sterilization. In short, HPG sterilizers are not just for low-temperature devices anymore! HPN

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References

1. ANSI/AAMI ST58:2015. *Chemical sterilants and high-level disinfection in healthcare facilities*.

2. ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.

3. Patent US 5716322, Medical Instrument and Method for Lubrication Therof, H Hui, L Feldman, HP Nguyen, D Timm, R Albers. Johnson and Johnson Medical, Inc.

4. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm is the web address for the FDA 510(k) Premarket Notification database. To access the cleared indications for use for a specific HPG sterilizer 1) enter either the manufacturer's name (into the "Applicant Name" field) or the Sterilizer model (into the "Device" field) and press search, 2) select the Device by clicking on the Device name, and 3) click on the Summary link. The 510(k) Summary will be displayed. The cleared indications for use are located at the end of the Summary packet.

CONTINUING EDUCATION TEST • JANUARY 2019

A fast-turn solution: Hydrogen peroxide gas sterilization

Circle the one correct answer:

1. HPG sterilizers can be used to sterilize
- A. Non-lumened devices
- B. Lumened devices within sterilization cycle claims
- C. Heat sensitive and heat stable devices
- D. All of the above

2. How much time do devices processed in HPG sterilizers require for cooling or aeration post-sterilization?
- A. 15 minutes
- B. 30 minutes
- C. 60 minutes
- D. They do not require any cooling or aeration and are ready for use immediately

3. Which of the following is not required for a device processed in a HPG sterilizer?
- A. Follow hospital infection control and quality procedures
- B. Confirm that an IUSS cycle was performed
- C. Package device for sterilization
- D. Ensure device meets any cycle-specific requirements for lumen dimensions or load weight

4. Which of the following is false?
- A. Users should review manufacturer instructions for use and/or the HPG sterilizer manufacturer website for a device's compatibility with HPG systems
- B. Any device that can be processed in steam should never be processed in HPG sterilizers
- C. Appropriate sterilizer cycles are specified by a medical device's manufacturer
- D. Hydrogen peroxide is the sterilizing agent in HPG sterilizers

5. Devices must be thoroughly dried before processing in a HPG sterilizer
- A. True B. False

6. Training for reprocessing personnel should include information about flexible endoscope design differences and the potential consequences of using a non-indicated reprocessing method.
- A. True B False

7. Which of the following are potential limitations when considering replacing current steam loads with HPG cycles?
- A. HPG sterilizer load weights may not be as high as allowable load weights for a steam sterilizer
- B. Implants are typically indicated for steam sterilization and may not have HPG sterilization identified
- C. Multiple level sterilization containers identify steam sterilization in their instructions for use, but not HPG sterilization
- D. All of the above

8. 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 the device and place in the HPG sterilizer
- D. None of the above; HPG cannot be used to sterilize flexible endoscopes

9. All GI endoscopes can be processed in any HPG sterilizer.
- A. True B. False

10. Which of the following are risks when processing a GI endoscope in a HPG sterilizer?
- A. Manufacturer does not identify HPG as a sterilization method
- B. Acid can be formed that will damage the device and may injure a patient
- C. Device was not designed for hydrogen peroxide sterilization
- D. All of the above

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