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LEARNING OBJECTIVES

1. Describe the conditioning phases of three steam sterilization cycles.
2. Explain the considerations for selecting steam sterilization cycles.
3. Identify a method to reconcile contradictory instructions for use.

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SELF-STUDY SERIES

It's time to rethink steam sterilization

by Heide Ames, BS, CCSVP

Doing laundry is a familiar and well understood household task. To safely and thoroughly clean clothes, we have always followed time-honored rules: colors must be separated from whites before washing; whites can be washed in hot water, while colors require cool water; delicate items must be washed in cold water in a gentle cycle, and sweaters should not be put in a dryer.

Over time, advances have been made in clothes washers, detergents and fabrics that offer new options to improve cleaning efficiency. For example, whites can now be washed in warm or cold water. New synthetic fabrics no longer need delicate cycles. Newer dryers have cycles and accessories that can be used for sweaters. Yet despite these advancements, many people still sort, wash and dry like they always have because it's familiar and comfortable. Unfortunately, doing laundry this old way can actually take longer and can cause faded colors and stretching or damage to fabrics.

Steam sterilization has parallels to this laundry example. New steam sterilizer cycle options offer efficiency benefits and are optimized for the challenges of today's medical instrumentation. Yet most facilities are still using the same preset sterilization cycles and load configurations they've been using for decades. It's time to rethink steam sterilization.

How steam sterilization works

Steam kills microorganisms by heating them and causing coagulation and denaturing of proteins within the cells. To be effective, steam must contact the microorganisms for a specific amount of time. The time required to coagulate the microbe's proteins is dependent on the steam's temperature. The higher the temperature, the less time is needed to accomplish microbial death.

Microorganisms also have natural defense systems to protect them against steam sterilization. Some microbes, like viruses, have very little defense and will die quickly. Others, like bacterial endospores, have many natural defenses and require much more steam exposure time before they die. In fact, bacterial endospores are considered the most difficult organisms to kill, which

is why they are used for testing sterilization cycle effectiveness.

To achieve microbial death, sterilizers must remove the air within and around the items to be sterilized and force steam to penetrate to all surfaces of the medical devices in each load. In recent years, the development of new steam sterilization cycles and advancements in medical device design have improved air removal, steam penetration and device heating to facilitate microbial destruction.

Cycle phases

Steam sterilization cycles have three distinct phases: *conditioning*, *exposure* and *exhaust*.

The conditioning phase removes air from the load and chamber and allows saturated steam to penetrate to the device surfaces. At the end of the conditioning phase, all air should be removed from the load and items should be heated to the necessary sterilization temperature for the cycle.

After conditioning, the sterilizer enters the exposure phase, which maintains the temperature and length of time required for a particular sterilization cycle. The amount of time required depends on the exposure temperature used for that cycle.

The last phase is the exhaust phase. During the final phase of the cycle, the sterilizer drain is opened, and steam is removed, depressurizing the vessel and allowing the items in the load to dry.

Conditioning cycle profiles

Sterilizers remove air in two ways. Gravity-type sterilizers use steam and gravity to displace the air in the load and chamber, while dynamic air removal steam sterilizers forcibly remove air using mechanical methods.

Gravity displacement relies on the natural properties of steam and air to create an opportunity for air removal. During the conditioning phase, steam is injected into the chamber so that it can flow through the chamber and out the floor drain. As the steam moves through the chamber, it pushes the air from chamber, displacing it (Figure 1).

The movement of steam through the chamber space creates a siphon effect.

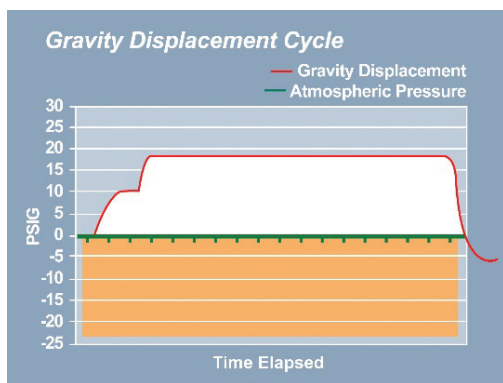


Figure 1: Gravity Cycle Profile

Air from within the packs is pulled into the stream and is replaced by steam. The siphon effect removes air from most areas, then the remaining air is removed by diffusion. Fluids such as gases will naturally move from an area of high concentration to an area of low concentration, until they are evenly dispersed. Any trapped gas (air) will move out of the pack, an area of high air concentration, to the sterilizer chamber, an area of low air concentration. Once in the chamber, the air, which is heavier than steam, sinks to the bottom of the chamber to exit through the chamber drain. As an imbalance develops between the pack and the chamber, additional air moves out of the pack. This cycle repeats until all the air has been removed and the steam has replaced it.

In addition to this passive cycle, there are two dynamic air removal sterilization cycles. *Vacuum-assisted (prevacuum or prevac)* sterilization cycles create a vacuum in the chamber that pulls air from the pack and removes it through the drain. After a prescribed time at vacuum, steam is injected into the chamber. The steam is forced into the packs and heats the instruments. Several vacuum/steam injection pulses are required to remove all air from the load and heat all pack contents (Figure 2).

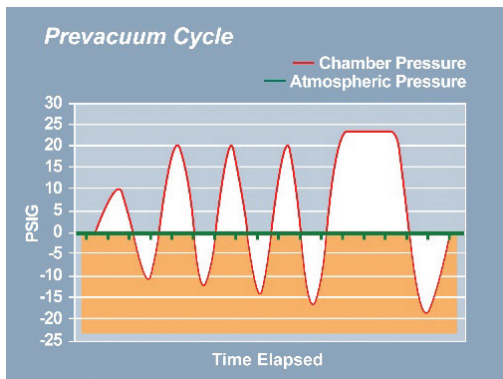


Figure 2: Prevacuum Cycle Profile

Prevac sterilization cycles are more efficient than gravity cycles at removing air

from challenging instrument packs and complex and lumened medical devices. For this reason, it is the most common sterilization cycle used in central processing departments. However, prevac cycles are sensitive to air leaks. When air leaks into the chamber, it may prevent full air removal from the packs in the load. Because of this sensitivity, additional quality assurance tests (leak tests and Bowie Dick air removal tests) are required when using this type of sterilizer.

The second dynamic air removal method is the *steam-flush pressure-pulse (SFPP)* cycle. It uses a series of steam injections followed by steam flushes, which create a strong siphon -- similar to a vacuum -- to pull air from the pack while staying above atmospheric pressure. Once a specific pressure point is achieved during steam injection, the chamber is evacuated. The rapid change from high pressurization to atmospheric pressure creates a strong siphon that actively pulls the air and steam mixture from the packs. This is followed by pressurizing the chamber with more steam. The steam is forced deep into the packs. Several steam injection/evacuation pulses are completed to remove all the air and heat all surfaces within the pack.

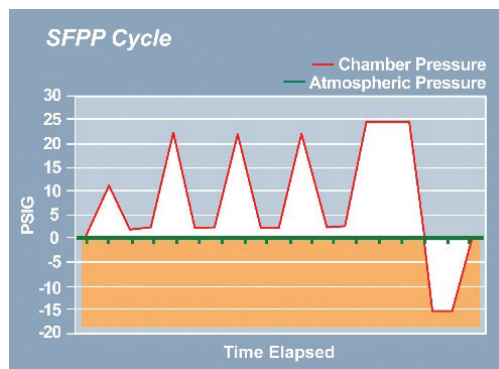


Figure 3: Steam Flush Pressure Pulse

Because this unique dynamic air removal process stays above atmospheric pressure, air leaks have no effect on the cycle's effectiveness. Bowie Dick test packs are not required for this type of cycle.

There is no single steam cycle that works for all instruments and devices. Each cycle type has advantages and disadvantages. Gravity and SFPP cycles are gentle on devices that may be compromised by exposure to a vacuum. On the other hand, prevacuum and SFPP high air-removal efficiency makes them the preferred option for sterilizing lumened

devices and complex multilayered original equipment manufacturer trays.

Selecting the right sterilization cycle

The air removal process is one important consideration, but there are other factors to consider when selecting the optimal sterilization cycles for your various instruments, including:

1. Urgent need for a device or set
2. Medical device manufacturers' reprocessing instructions
3. Sterilizer instructions for use (IFU)
4. Available sterilization accessories and assurance tools

Most healthcare procedures are scheduled ahead, and the necessary instruments and supplies are sterilized in advance of their use. However, situations may arise that cause an unforeseen need for a medical device. These urgent situations may require sterilization to be completed in a very short time, which may affect the type of sterilization cycle chosen.

Steam sterilization cycles are categorized as either terminal or immediate use processes. Terminal sterilization processes result in a sterilized medical device or set of devices that can be placed in storage for use later. The devices are packaged to prevent environmental contamination and are dried

following the sterilization process. Terminal sterilization is the preferred steam sterilization method.

When an emergency or unplanned procedure occurs that requires a particular medical device or set, it may need to be processed in an immediate use steam sterilization (IUSS) cycle. IUSS processes result in sterilized medical devices that cannot be stored. The device is often wet after the sterilization process and must be used immediately.

Both terminal and IUSS cycles employ the same conditioning phases, but their cycle profiles can be significantly different. Often, IUSS cycles are terminal cycles with abbreviated dry times, exposure times or conditioning requirements. This allows a faster sterilization time for a limited number of instruments. Table 1 compares commonly used IUSS cycles to their terminal cycle counterparts.

When choosing an IUSS cycle, it is important to consider the item(s) needing to be sterilized and how soon they are needed. The fastest IUSS cycle is the 3-minute 270°F gravity IUSS cycle, but it's restricted to a single device with no lumens. Few IUSS cycles processed today contain a single non-lumened device.

Table 1: Comparison of common IUSS cycles to corresponding terminal sterilization cycles

IUSS Cycle (1-min dry time)	Example of Terminal Cycle	Abbreviated component
3-minute 270°F gravity	15-minute 270 °F Gravity, 30-minute dry time	Exposure time reduced to 3 minutes Dry time reduced to 1 minute
10-minute 270°F gravity	15-minute 270 °F Gravity, 30-minute dry time	Exposure time reduce to 10 minutes Dry time reduced to 1 minute
3-minute 275°F gravity	10-minute 275 °F Gravity, 20-minute dry time	Exposure time reduced to 3 minutes Dry time reduced to 1 minute
10-minute 270°F gravity	10-minute 275 °F Gravity, 20-minute dry time	Dry time reduced to 1 minute
4-minute 270°F prevac	4-minute 270 °F prevacuum, 30-minute dry time	Dry time reduced to 1 minute
3-minute 275°F prevac	4-minute 270 °F prevacuum, 30-minute dry time	Dry time reduced to 1 minute

Of the remaining IUSS cycles, the 4&1 270°F prevac takes the longest time. But in comparison with the second shortest cycle, the total processing time difference is 10 minutes or less. Ten minutes is not much time to wait to achieve an IUSS cycle that sterilizes complete sets with the same lethality as comparable terminal sterilization cycles.

The second consideration for cycle selection is the medical device manufacturer's reprocessing instructions. The manufacturer must confirm through testing that their device can be safely sterilized within available cycles. The validated sterilization cycles are listed in the medical device's instructions for use (IFU). Each medical device's IFU must list at least one validated sterilization cycle. Some IFU have very detailed instructions (including the number of vacuum pulses required for a prevacuum cycle, for example). Others are very general, providing only a temperature and exposure time. Even similar devices made by different manufacturers can have different instructions for sterilization. *Each device must be evaluated separately to ensure that the right cycle is selected.*

In addition, device IFU are always evolving. A reprocessing instruction written 10 years ago for a device may be different today. For example, many instructions now differentiate between US sterilization and outside-US sterilization. US sterilization instructions are based on validations performed for the US FDA. These cycles will be available on US FDA cleared steam sterilizers. A sterilization cycle identified as "outside the US" may not be able to match the specific parameters of a US FDA cleared sterilizer cycle. *When reviewing newer sterilization instructions, always look for US instructions.*

The third factor when selecting a sterilization cycle is the sterilizer IFU. Sterilizer instructions provide guidance on the type of items that can be processed within a specific sterilization cycle. They also identify

maximum set and chamber weights. When using a sterilization cycle from the medical device's IFU, the cycle must also meet the requirements of the sterilizer.

The final factor to consider is the accessories that will be used to contain, protect, confirm sterilization parameters provided to, and identify the processed devices. Each container, tray, sterilization wrap, and sterilization pouch have IFU with sterilization instructions. These may differ from the medical device and sterilizer's IFU. For example, a sterilization pouch might limit the content weight to 4 lbs. and the sterilizer cycle may indicate up to 40 lbs. per pack. This would be acceptable, but a tray with a content weight of 50 lbs. would not be acceptable for that sterilization cycle.

In addition, the containment device restrictions, chemical indicators, biological indicators, corner protectors, record cards and other accessories processed in the same sterilization cycle with the medical device must all be acceptable for that medical device's sterilization IFU.

Assessing risk when sterilization parameters don't align

There are times when the IFU of the medical device and that of the sterilizer do not match. When this happens, a risk assessment is needed to ensure that the best choice is made. A risk assessment evaluates the possible negative outcomes, determines the probability of the event occurring that will lead to those outcomes, and then weighs the relative risk against the harm that may be caused if that choice is not made.

Some risks are low to nonexistent. For example, if a medical device instructs the use of a 270°F 4-minute prevacuum steam sterilization cycle, but the sterile processing department uses a 270°F 4-minute SFPP sterilization cycle. Is there a risk in this case? By performing an assessment, the following is determined:

1. Both prevacuum and SFPP cycles are dynamic air removal cycles. They both forcibly remove air during conditioning. There is no risk of poor air removal.
2. Both cycles require a temperature of 270°F, an exposure time of 4 minutes, and a dry time of 30 minutes
3. No new additional tests or special packaging is required to sterilize the item in SFPP cycles.

Conclusion: The SFPP sterilization cycle operating at 270°F for 4 minutes may be used.

Some risks are not as easily reconciled. Consider the use of extended sterilization cycles, which are steam sterilization cycles that increase the exposure time, dry time or both beyond the sterilizer's validated parameters. Though many medical device manufacturers have revalidated their devices for standard sterilization cycle parameters, some IFU still require extended cycles. Check with your device manufacturer to ensure that the extended cycle is needed.

In this case, risks that would need to be assessed and addressed include:

- The sterilizer's ability to maintain the sterilization parameters for an extended time
- The ability of the containment device to withstand the condition
- Quality assurance tools needed to ensure proper sterilization
- The possibility of picking the wrong sterilization cycle in practice
- If the risk is too high, an alternative medical device or sterilization method may need to be used.

Choose the right cycle for the right purpose

Steam sterilization is a familiar process that sterile processing teams have been comfortable using for decades. But the advancements in cycle functions and medical device designs offer options to make steam reprocessing more efficient and just as effective. The selection of a steam sterilization cycle should be a thoughtful decision based on when the medical device(s) are needed, what the IFU state for all equipment used in the process, and the availability of suitable accessories and quality assurance tools for each specific cycle. By making selections carefully, a department can streamline workflow without compromising sterilization quality. **HPN**

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CONTINUING EDUCATION TEST • MAY 2019

Rethink your steam sterilization cycle options

Circle the one correct answer:

1. How does steam sterilization kill microorganisms?

- A. Oxidation of sulfhydryl bonds in microbial proteins
- B. Coagulation and denaturing of microbial proteins
- C. Fixation of microbial proteins
- D. None of the above

2. In which phase of the sterilization cycle is air removed from the load?

- A. Conditioning Phase
- B. Exposure Phase
- C. Dry Time Phase
- D. Exhaust Phase

3. How is air removed from a load during a gravity sterilization cycle?

- A. Vacuum
- B. A siphon is created when the pressurized chamber is exhausted
- C. Gravity displacement and diffusion
- D. Irradiation

4. Which sterilization cycles are included in dynamic air removal?

- A. Gravity and prevacuum
- B. Vacuum-assisted and displacement
- C. Prevacuum and steam flush pressure pulse
- D. Steam pulse pressure pulse and gravity

5. Steam flush pressure pulse (SFPP) sterilization cycles use a vacuum to remove air from the load.

- A. True
- B. False

6. Which item(s) are true of immediate use steam sterilization cycles?

- A. Items may be stored for later use
- B. Cycles have abbreviated 1 minute dry times
- C. Some cycles have abbreviated exposure times
- D. B and C only

7. Which item is true of terminal sterilization?

- A. Items are for planned healthcare procedures
- B. Cycles have an abbreviated 1 minute dry time
- C. Exposure time is shortened to process items faster
- D. Medical devices are wet after sterilization

8. Which is not considered when selecting a sterilization cycle?

- A. Device's instruction for use
- B. Container's instruction for use
- C. Sterilizer's operator manual
- D. Sterilizer's maintenance manual

9. Identical devices made by different manufacturers can always be sterilized using the same cycle.

- A. True
- B. False

10. When is a risk assessment required when selecting sterilization cycles?

- A. When the device IFU uses an extended cycle
- B. When the lot of sterilization wrap changes
- C. When the same model of sterilizer is installed
- D. None of the above

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