Sterilization Cycle and Loading Optimization

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LEARNING OBJECTIVES

1. Describe the role of each saturated steam sterilization cycle phase to deliver medical devices that are both sterile and dry
2. Explain the impact different metallic and non-metallic materials used in medical devices and sterile barriers have on cycle performance
3. Identify available resources to optimize the sterilization cycle

Saturated steam sterilization is a common choice for sterilizing medical devices. The sterilant is obtained by vaporizing water; its use and control are generally perceived as simple.

There are only two general requirements to be met—inactivation of microorganisms and a dry load at the end of the cycle. The evolution of medical device manufacturing techniques has allowed the use of non-metallic materials in device construction, thereby expanding their applications in the healthcare area. These new products largely became available without additional research to determine how to correctly sterilize them using saturated steam sterilization. This lesson addresses how to optimize a cycle using current resources, until new evidence is produced to support updates in standards and guidelines to improve the cycle standardization and control.

Objective 1: Describe the role of each saturated steam sterilization cycle phase to deliver medical devices that are both sterile and dry

Sterilization Cycle Phases

Today, a saturated steam sterilization cycle is controlled by direct measurement of temperature and pressure during the cycle, over time. The temperature sensor is placed at the drain (see **Figure 1**) because it is the coldest temperature spot in the chamber. The technical justification is that steam will change from the gaseous phase to liquid as temperature cools, and the condensate will leave the chamber through the drain. The chamber pressure sensor can be placed anywhere in the chamber because pressure values will not be differentiated per steam state phase. This condition is supported by Dalton's law where the total pressure by a mixture of gases is equal to the sum of the partial pressures of each of the constituent gases.[1]

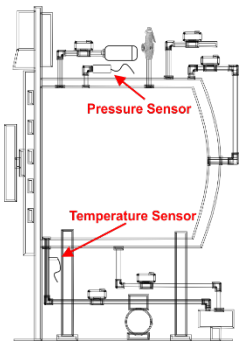

Figure 1. Saturated steam sterilizer temperature and pressure sensor locations

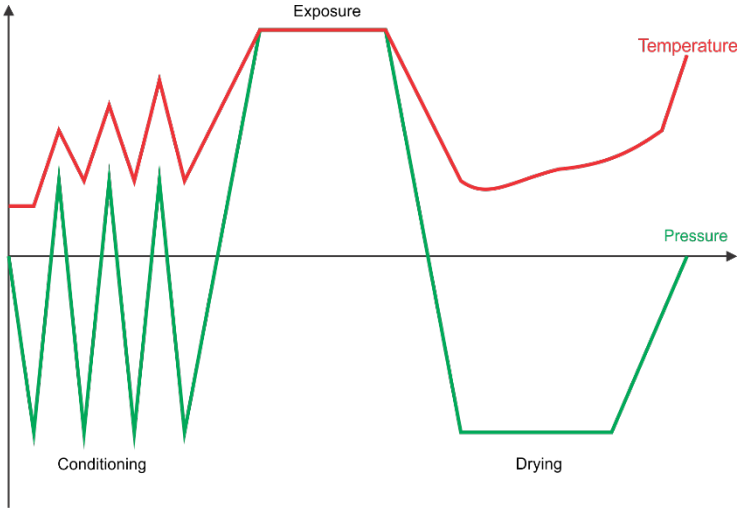

Figure 2. Sterilization cycle phases

A steam sterilization cycle is divided into three phases (see **Figure 2**):

Conditioning: Air removal and product warm-up;

Exposure: Inactivation of microorganisms; and

Drying: Evaporation of remaining condensate.

During the conditioning phase, the parameters are configured to thermally condition the load to be as close as possible to the sterilization temperature, thereby reducing condensate formation during the exposure phase, without residual non-condensable gases. This allows the equipment to reach the required steam saturation during the exposure phase, where the steam injects into the chamber and condensate is only being used to promote the inactivation of microorganisms, for the duration of the phase.[2]

Air removal, including for non-condensable gases, occurs when vacuum is pulled in the chamber. This occurs at the first vacuum pulse. The duration of this pulse varies based on the amount of air inside the chamber. It is common to see a longer duration in empty chambers than with loaded chambers because the load occupies volume or air space, reducing the total volume of air inside of the chamber.[3] This is why the Bowie-Dick test cycle must be run with empty chamber, thus the vacuum pump will be challenged with the largest amount of air.[4]

The positive pressure pulses (steam injection) are used to warm up the medical devices. The vacuum pulses (air removal or negative pulse) after each positive pulse are responsible for evaporating the condensation created by the temperature difference between the medical device and steam. A larger amount of condensate will be present in the first steam positive pulse due to the medical device temperature being close to ambient temperature as it was placed inside the chamber. This condensate will be reduced to a minimum during the last positive pulse, as the medical devices' temperature rises. The vacuum pulses will help evaporate the condensate faster because the temperature required for water to boil is lower at vacuum levels (lower pressure). The parameters of the conditioning phase are programmed to assure that the temperature of the medical devices in their sterile barriers is as close as possible to the sterilization temperature, preventing large amounts of condensate during the exposure phase and without any air inside the chamber.[2]

When the cycle switches to the exposure phase, it is expected to have the chamber temperature equal to or above the setup value—with minimal variations—oscillating between a temperate band of 5° F (see **Figure 3**). Only in this phase is it assumed that the saturated steam conditions are present and the inactivation of microorganisms will occur by the presence of latent heat.[5]

The small temperature drop during this phase will create steam condensate, and 80% of the energy used to boil water into steam will be transferred to the surface of the medical device where the condensation occurred (known as latent heat), thus inactivating microorganisms. During this phase, steam will be admitted into the chamber to compensate for the condensation and temperature drop. This sequence will be repeated during the entire exposure phase.[6]

Once the exposure phase has reached the end of the programmed duration, the sterilization cycle moves to the drying phase. This phase will evaporate all condensate created during exposure using a deep vacuum pulse, thereby evaporating the condensate as the pressure level drops into the lowest possible vacuum point. The vacuum

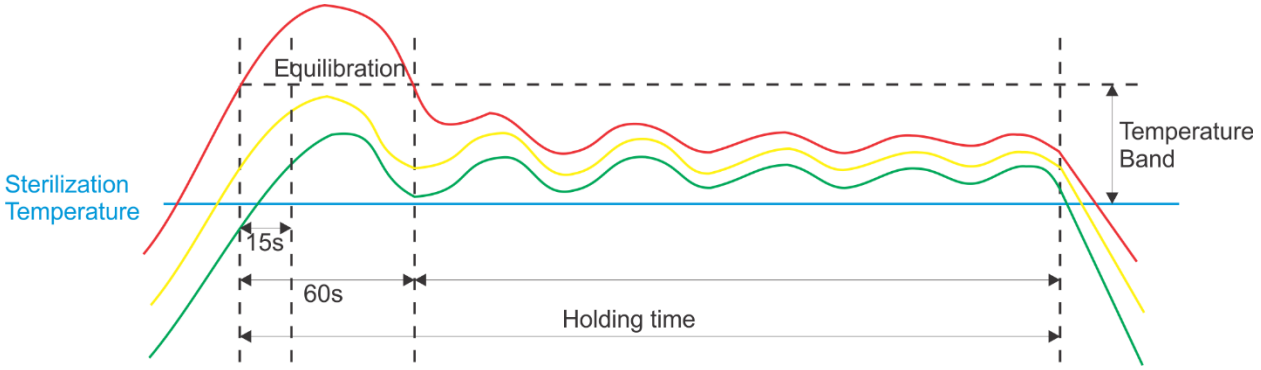

Figure 3: Temperature band during exposure after equilibration

point will be maintained for a period of time to help the remaining condensate to evaporate as heat is transferred from the medical device to the condensate near it; this helps it reach its boiling point. Only the condensate near a heated medical device or sterile barrier will evaporate because in vacuum there is a very low temperature conductivity. Without a heat source very near the condensate, it won't evaporate immediately and will require extended exposure to temperature. That is why the sterilizer jacket is kept pressurized during this phase, at a temperature 3% to 5% above the sterilization temperature setting.

At the end of the drying phase, the internal pressure will be brought up to ambient, the sterilizer door can be opened, and the load cart can be removed from inside the chamber. It is important to wait to remove the packages until they reach a safe handling temperature. This will protect technicians from hazardous working conditions and prevent sterile barriers from being handled at higher temperatures, which could compromise their integrity.[6]

Objective 2: Explain the impact different metallic and non-metallic materials used in medical devices and sterile barriers can have on cycle performance

Hospital sterilization loads typically consist of medical devices and surgical drapes that are wrapped by or placed into a sterile barrier. The sterile barrier is used to maintain the sterile condition of the medical device after it has been processed and must be designed to not interfere with any sterilization phases, or cause minimal impact.[7]

Medical devices are initially developed to deliver a result that will improve patient procedures, safety and/or recovery. If the device is not single use, it will require reprocessing testing and development. The manufacturers of these devices will prepare instructions for use (IFU) to describe how to clean, inspect, prepare and sterilize their product (relying on testing done at their facilities). These tests may be conducted in cycles with only the manufacturer's medical device. They might also test different types of sterile barriers. As such, the results will be different from a single unit sterilized in the chamber, which does not represent Sterile Processing department (SPD) routine.[8]

It is common today to see medical devices, trays and containers being built with non-metallic materials. Some materials are known to be used as insulation in other areas because they do not conduct heat. This characteristic is the main cause of excessive condensation formation in saturated steam sterilization, as it challenges the dryness that is required at the end of the sterilization cycle. To better observe the temperature profile between metallic and non-metallic materials, **Figure 4** shows the temperature values measured with thermocouples (a type of temperature sensor) with their measurement tip fixed with temperature insulation tape on the surface of each type of medical device. Sensor 12 (black) was placed at the drain and the other four sensors on medical devices as follows: sensor 3 (yellow) on a heavyweight non-metallic, sensor 4 (red) on a heavyweight metallic, sensor 8 (green) on a lightweight metallic, and sensor 11 (blue) on a lightweight non-metallic.

The conditioning phase of the sterilization cycle in Figure 4 was configured as a trans-atmospheric cycle, with initial pulses below atmospheric pressure and end pulses above atmospheric pressure. The initial phase of the conditioning shows the difference between metallic and non-

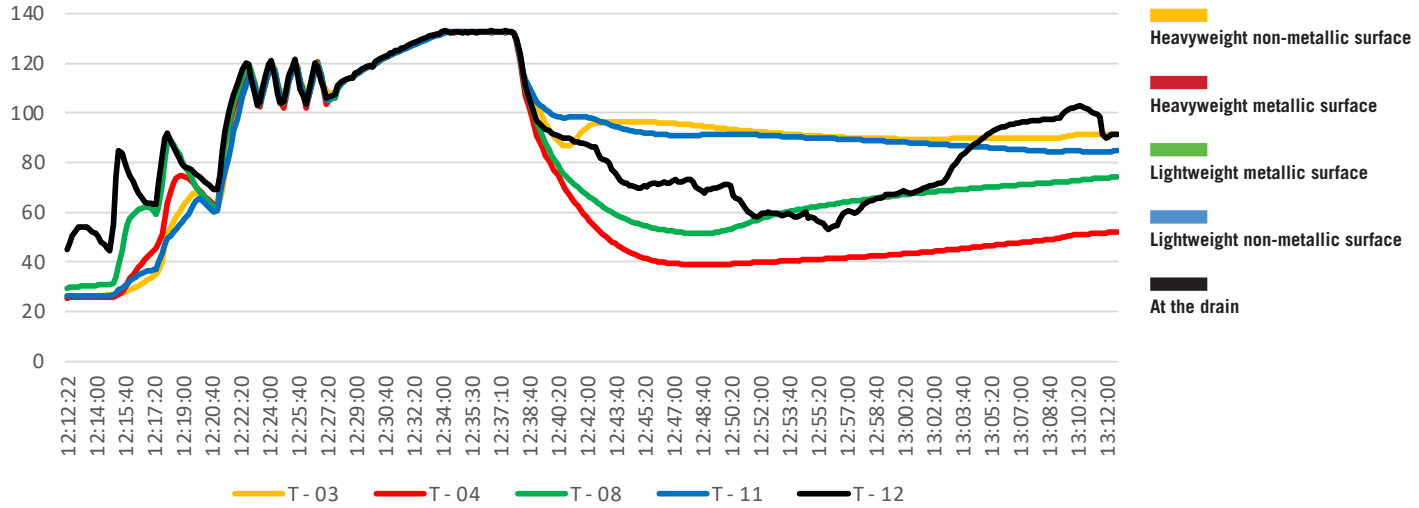

Figure 4: Temperature profile of different medical devices

metallic medical devices, where non-metallic devices demonstrated more resistance to warm up than non-metallic devices. Only at the last vacuum pulse did all medical devices start to have the same temperature behavior, reaching the exposure phase with minimum temperature difference between them. The graph in Figure 4 also shows that heavier products will take longer to warm up as compared to the same material of a lighter weight.

Objective 3: Identify available resources to optimize the sterilization cycle

All saturated steam sterilizers will have the same cycle temperature profile as indicated in the theorical cycle curve (**Figure 2**) when the cycle is run with an empty chamber; therefore, initial cycle parameter adjustments must be done and validated *without any load* to ensure the equipment can perform according to standard requirements.

When a load is added to the chamber, the equipment performance will vary according to the total mass of the load and construction material (metallic and non-metallic), sterile barrier type and load configuration.

In addition to referencing the manufacturer's IFU, there are many loading configuration recommendations in the literature that can be referenced. Every healthcare facility has its own unique considerations, with significant differences in materials, saturated steam source, equipment, location, etc. It is virtually impossible, therefore, to create a standard for everyone.

A common detail that applies to all steam sterilizers is that 25 pounds of metallic load will generate 7.7 ounces of condensate, and non-metallic loads will create much more condensate. The recommendation of limiting the weight of a single package or tray to 25 pounds is focused on the equipment performance and has the additional benefit of protecting the user from lifting heavy loads. Also, it is important to limit the total amount of 25-pound packages to no more than 30% of the load.[6]

These measures support optimal sterilization cycles, helping to reduce failed cycles due to wet packs as well as reducing the water consumption of water-sealed vacuum pumps. Another critical point to consider relates to drying phases that have a duration of more than 15 minutes. The addition of dry times beyond 15 minutes is a common practice used to mitigate wet packs. The extended drying time might show a satisfactory result of minimizing the occurrence of wet packs; however, it comes at a cost of an average of 2.6 gallons of water per additional minute (for water-sealed vacuum pumps only). Other vacuum systems might have higher or lower water consumption.

There are many IFU available to end users from steam sterilizer, sterile barrier and medical device manufacturers. According to ISO 17664[8], these IFU are required to be validated, and the manufacturing testing process may be different than what is actually done in healthcare facilities, which might lead to a processing failure.

Hospital-certified sterilizers have very few options for users to adjust their cycle parameters. This is done to prevent end users from selecting the wrong sterilization cycle for a specific medical device processing category. As such, medical device and sterilization equipment manufacturers are encouraged to use standardized cycles to validate their IFU.

Because exposure time and temperature and drying time are the only parameters that can be changed by the end user, other actions have to be taken to optimize the sterilization cycle. A series of cycle comparisons need to

be run to determine the optimal loading configuration for the best sterilizer performance.

The cycle performance can be measured by the duration of the conditioning and drying phases, and the exposure phase is expected to be identical on every cycle configuration. The peak performance of a sterilizer occurs during a cycle without any load (an empty chamber). An average sterilizer will have a 28-minute conditioning phase and an 18-minute drying phase for a 15-minute drying time. Considering a four-minute exposure, the total cycle time will be about 50 minutes.

When a load is added and the drying time is maintained at 15 minutes, the total cycle time will range from 60 to 80 minutes. Most of the additional time comes from the conditioning phase, where the condensation volume will impact these times and take longer to reach temperatures and evaporate condensate.

If a cycle has a duration longer than 80 minutes or if wet packs are present at the end of the cycle, the loading configuration needs to be addressed, even if the weight limits per package are met. This assessment should include a review of sterile barrier types, positioning on the cart, and the construction materials of the medical devices, trays and containers.

The extension of total cycle time is related to the amount of condensate formation during the cycle. This is caused not only because of the weight of the items but also the construction materials used on the medical devices and their sterile barriers.

To reduce the cycle duration, the weight limit per package will need to be reviewed if non-metallic materials are present, and lighter-weight loading will need to be adopted. It is better to run two successful 60-minute cycles than a 90-minute cycle that might fail.

If wet packs are present, the last solution to be adopted is to increase the drying time. As previously explained, the effectiveness of the drying phase in vacuum is very low and a lot of time will have to be added to avoid having wet packs at the end of the cycle. A loading configuration assessment will yield a better result.

The use of temperature sensors (i.e., thermocouples coupled to a data acquisition system) will improve the sterilization cycle analysis, helping to identify critical loads and components that need a more critical assessment on how to place them in the loading configuration.

Longer cycles increase the consumption of water and power and typically are the cycles that have frequent failed results. Shorter and lighter-weight cycles will significantly reduce the reprocessing of failed cycles, with the added benefit of reducing the consumption of natural resources.

Conclusion

Sterilization of medical devices in a healthcare facility requires an alignment of all products' IFU sterilization specifications. Continuous assessment of the sterilization process is needed to address loading configuration changes that were not predicted when the IFU were initially validated. This includes the addition of new medical devices to the practice to ensure that these devices are safely released after sterilization.

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