Reprinted from
PHARMACEUTICAL ENGINEERING
THE OFFICIAL TECHNICAL MAGAZINE OF ISPE
NOVEMBER/DECEMBER 2013, VOL 33, NO 6

www.PharmaceuticalEngineering.org

Steam Sterilization Principles

by Marcel Dion and Wayne Parker

This article presents how a good understanding of basic steam sterilization principles can help with avoiding most common mistakes made when using steam autoclaves.

Steam sterilization has been used for more than a century to sterilize items that can withstand moisture and high temperature. Steam is water in the vapor state; therefore, it is non-toxic, generally readily available, and relatively easy to control. A good understanding of basic steam sterilization principles and cycles is necessary to avoid mistakes that can lead to non-sterile load items, poor performance of the equipment, personnel injury, lower productivity, higher operation and maintenance costs, and damage to load items. Steam sterilizers are used for numerous applications in the pharmaceutical and medical device industries. The focus of this article is saturated steam applications, such as laboratory media sterilization, decontamination, and general component sterilization. Terminal sterilization of parenteral liquid products or devices containing liquids may require processes using steam-air mixtures or super-heated water-air mixtures. These processes, as well as in-situ sterilization of tanks, filters, etc., are not addressed in this article.

Steam Sterilization Principles

Six factors are particularly critical to assure successful steam sterilization:

1. Time
2. Temperature
3. Moisture
4. Direct steam contact
5. Air removal
6. Drying

1. Time

The exposure (sterilization) time is a critical factor simply because all the organisms do not die at the same time. A minimum amount of time at sterilization temperature is required to kill all the organisms. *Geobacillus stearothermophilus* (Bst) spores are generally used to test steam sterilizer cycles because they are extremely resistant to moist heat sterilization. They are also non-pathogenic and commercially readily available. The number of survivors is usually plotted on a logarithmic scale. A straight line survivor curve such as the one shown in Figure 1 is typical.

The D-value (time to reduce the microbial population by 90%) for Bst should be 1.5 to 3.0 minutes at 121.1°C (250°F) .[1] For the purpose of this discussion, a D_{121} value of 2.0 minutes and a sterilization temperature of 121°C (250°F) is used. A typical sterilization cycle will include an exposure phase

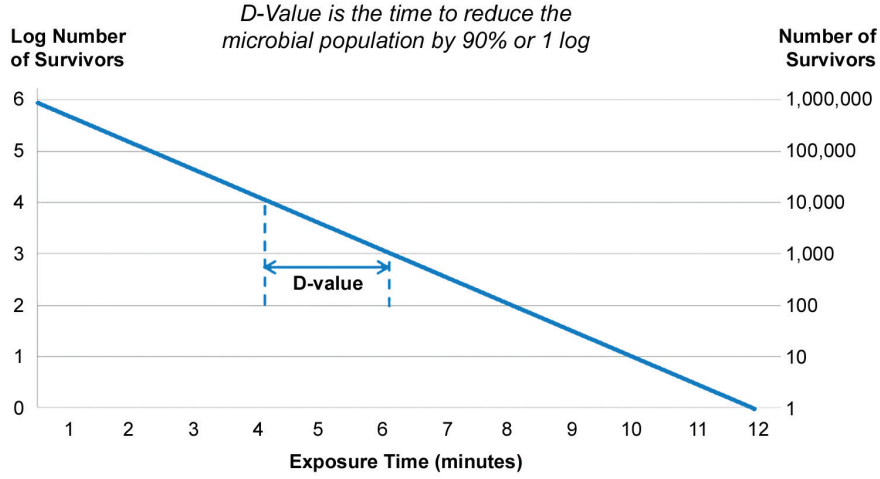

Figure 1. Typical survivor curve.

of at least 20 minutes at 121°C (250°F) for a Sterility Assurance Level (SAL) of 10^{-4}, assuming a starting population of one million (10^6) organisms. This means there is a one in ten thousand (10^{-4}) chance of a single viable Bst spore surviving the process. For each additional two minutes of exposure at 121°C (250°F), the SAL is decreased by a factor of ten. The required SAL varies with application. Care should be taken to assure the correct SAL is targeted prior to cycle development. The actual bioburden of the products being sterilized will logically be killed faster than Bst. The resultant "overkill" is an accepted method for sterilization of durable items and should be used when possible.[2]

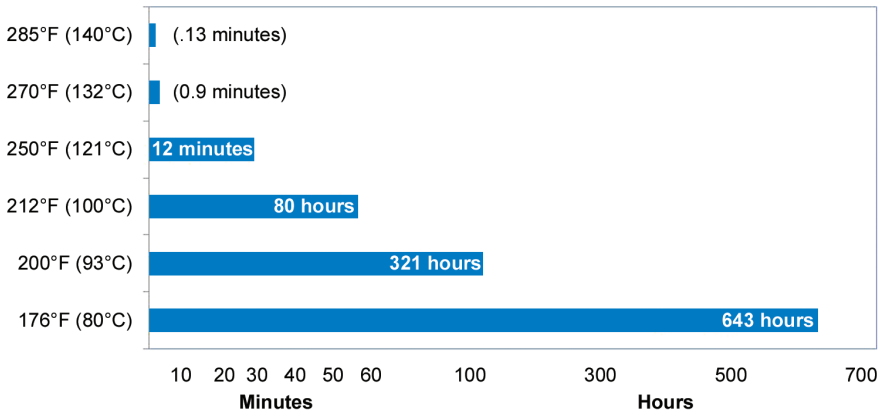

Figure 2. Sterilization time versus temperature.

2. Temperature

The second critical factor in steam sterilization is the temperature of the saturated steam controlled in the chamber of the sterilizer. Figure 2 clearly demonstrates how increasing the temperature dramatically reduces the time needed to achieve sterilization. Figure 2 illustrates approximately how much time is required to achieve equivalent microbial lethality (SAL 10^0 with a starting population of 10^6, D_{121} value 2.0 minutes) at different moist heat exposure temperatures.[3]
The temperature of saturated steam is directly related to the pressure at which it is controlled. The pressure-temperature relationship values are shown in saturated steam tables.[4]
A typical cycle at 121°C (250°F) will require 15 to 17 lbs of gauge pressure (103 to 117 kPa) in the chamber of the sterilizer. The gauge pressure required will be higher than the pressure shown in the saturated steam table due to air mixed with the steam and elevation above sea level. The maximum pressure in an autoclave is limited by the specifications (ASME pressure rating) of the pressure vessel (chamber and jacket).

3. Moisture

Moisture in the steam has a major impact on its ability to denature, or coagulate proteins; hence the importance of using saturated steam. Saturated steam is at equilibrium with heated water at the same pressure, which means it contains the maximum amount of moisture without liquid condensate present. Saturated steam is recommended for steam sterilization. Not all steam is acceptable for use in a sterilizer. A dedicated clean steam supply is recommended. Superheated steam, steam containing excessive liquid water, and steam containing excessive boiler additives or contaminates (such as rust) should be avoided. Superheated steam is defined as steam that is above its saturation temperature. Superheat occurs in steam distribution systems when the line pressure is dropped across a Pressure Reducing Valve (PRV). The larger the pressure drop, the more superheat is created. Superheated steam does not contain the required moisture necessary to assure sterilization. The excess energy in superheated steam is transient and is eventually dissipated by the items in the sterilizer chamber, but can cause difficulty when validating the sterilizer to the empty chamber temperature stabilization requirements of the European Standard EN285.[5] The ideal clean steam system for steam sterilizers is regulated at 30 to 35 psig (207 to 241 kPa) at the source. EN285 indicates the steam supply pressure should not be more than twice the chamber pressure at the desired temperature. Superheat is also created when saturated steam passes over a surface at a higher temperature. The sterilizer jacket temperature should always be set slightly below the chamber sterilization temperature to avoid superheating of the steam as it enters the chamber.

4. Direct Steam Contact

Direct steam contact with the surface of the object to be sterilized is required for the steam to transfer its stored energy to the object. Without direct steam contact to all surfaces, the item will not be sterilized. The amount of energy stored in steam is much higher than dry air or water at the same temperature. From the saturated steam table mentioned above, one can see that it takes 419 kJ/kg (180 Btu/lb) to heat water from 0°C to 100°C (32°F to 212°F). This is the enthalpy of water (hl). It takes an additional 2,257 kJ/kg (970 Btu/lb) to create steam at atmospheric pressure (100°C or 212°F). This additional energy stored in the steam is the enthalpy of vaporization (he), and is the key to steam sterilization. In order for the steam to transfer its stored energy, it must condense on the surface of the object being sterilized.

5. Air Removal

Air is the biggest deterrent to steam sterilization. Air must be removed from the chamber and the load before direct steam contact and sterilization can occur. This is accom-

plished in a steam sterilizer by a series of vacuum pulses prior to sterilization (pre-conditioning phase). A small amount of air will always be present in the autoclave chamber, but must be minimized. Insufficient air removal, sterilizer chamber vacuum leaks and poor steam quality (excess non-condensable gases) are the most common causes of sterilization failures.

6. Drying

Wrapped items must be dry before they can be aseptically removed from the sterilizer. Condensation is the natural result of steam contact with the cooler surfaces of the load during the heating and exposure phases. The presence of condensation (wet packs or pouches) can cause re-contamination of the load when removed from the sterilizer. A steam sterilizer dries the load after sterilization by drawing a deep vacuum in the chamber (post- conditioning phase). A vacuum level of 1.0 to 2.0 psia (6.9 to 13.8 kPa) is recommended for efficient drying. At 1.0 psia (6.9 kPa) chamber pressure, water boils at 38.7°C (101.7°F). Therefore, the condensate will boil and be removed as steam through the sterilizer's vacuum system. The energy required to boil the condensate comes from the load itself. As the temperature of the load cools due to evaporation of the condensate, evaporation (drying) decreases. When the load temperature cools to the boiling point of water at the drying vacuum level, drying is negligible. Adding further drying time past this point will not provide any further drying. Optimal load drying times depend primarily on load density and packaging. Due to their low density, plastic and rubber items may require additional drying, as they cool rapidly (pulsed air or heated pulsed air drying post-conditioning processes). The amount of residual moisture in a package can be determined by weighing the package before and after the sterilization process. Typically, verification of the absence of visible water droplets on or in the package is sufficient.

Steam Sterilization Basic Cycles

Steam sterilization cycles typically consist of three phases:

1. Pre-Conditioning: during this phase, air is removed from the chamber and the load is humidified by means of alternating vacuum and pressure pulses.
2. Exposure: during this phase, the chamber temperature is raised to and held at the programmed sterilizing temperature for the programmed exposure time (both are user selectable). The exposure also may be controlled by accumulated F_o for liquids if a load probe and appropriate sterilizer controls are used. Refer to point #7 in common mistakes section below for more information on F_o.
3. Post-Conditioning: during this phase, dry goods loads are cooled and dried or a liquids load is cooled. The chamber pressure is brought to atmospheric.

Over the years, various cycles have been developed for different applications. It is critical that the proper cycles be used.

- A basic **gravity cycle** (cycle without pre-vacuum) can be used for items such as unwrapped metal components, glassware, or non-porous items that do not entrap air.
- **Liquids** require modified gravity cycles to prevent liquid loss from boiling over. Liquids in open or vented containers or in bottles with loose caps can be processed in a "basic" liquid cycle (with slow exhaust). The cooling (exhaust) phase of this cycle allows for the chamber to **slowly** return to atmospheric pressure to prevent boil-over as seen in Figure 3. Nominal liquid loss due to evaporation during the slow exhaust phase is typically 10 to 15%. The time required for the slow exhaust phase can vary considerably depending on the volume of liquid per container and per load. Larger volumes require slower exhaust rates. Use of a load probe and Fo exposure control is recommended. **Vented containers only are to be used with this process.**

Liquids are at or near boiling temperature at the end of a slow exhaust cycle and must be allowed to cool before the load can be safely removed from the sterilizer. Liquids in sealed containers require an air overpressure cooling cycle to prevent explosion of the container(s) during the cooling

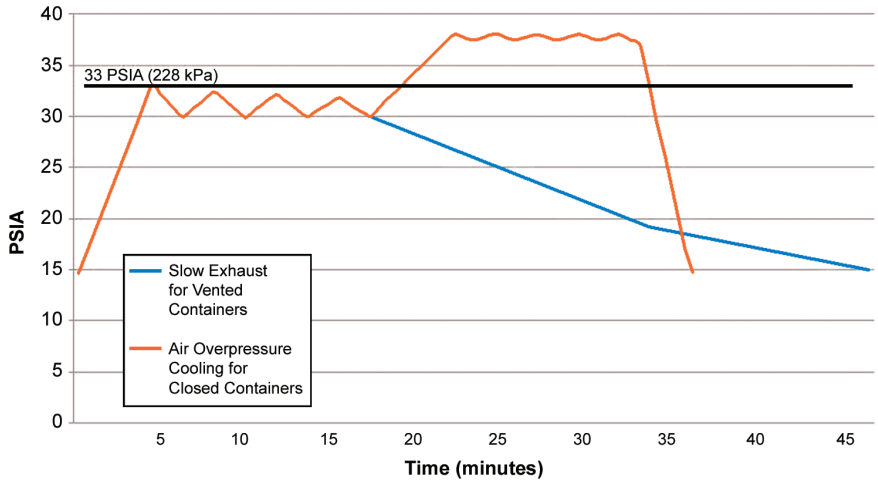

Figure 3. Typical liquid cycle chamber pressure at 121°C (250°F).

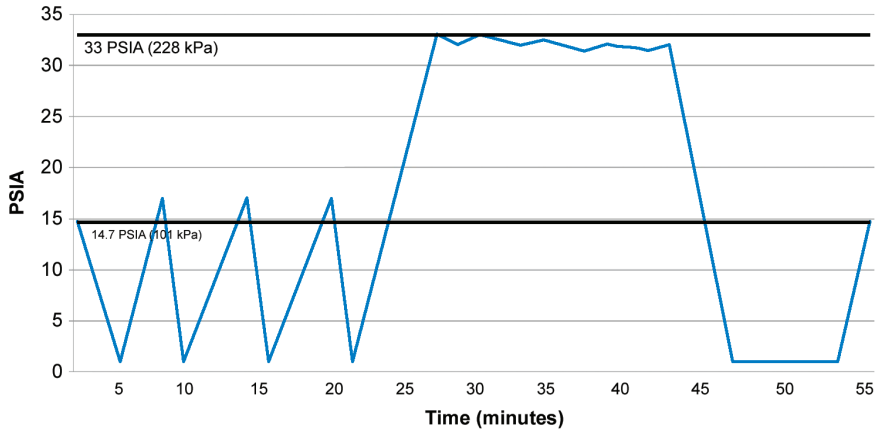

Figure 4. Typical prevacuum cycle chamber pressure at 121°C (250°F).

phase or unloading process as seen in Figure 3. Clean, dry compressed air (process air) is admitted to the sterilizer chamber at the end of the exposure phase and controlled at a pressure higher than the pressure of saturated steam at the temperature of the load probe. As the air flows over the load, the load is cooled and the chamber pressure starts to drop due to condensation of steam in the chamber. The supplied compressed air flow rate must be sufficient to maintain overpressure during the entire cooling phase. This "Air Cooling" process is highly recommended for sterilization of liquids in sealed OR vented containers because it eliminates evaporation and boil-over during the cooling phase. In addition, liquids can be cooled to a temperature safe for handling (60°C to 80°C (140°F to 176°F)) during the process by flowing water through the sterilizer jacket during the cooling phase. The load can be safely removed immediately upon cycle completion. The American Society of Mechanical Engineers (ASME) pressure rating of the sterilizer limits the amount of overpressure than can be utilized. Fill volume has a significant effect on the internal pressure of the sealed container. The lower the fill volume, the lower the internal pressure will be due to compression of the air in the head space of the container. The approximate internal pressure of a sealed container can be calculated using Robert Beck's equation.[6]

- Since air is generally a deterrent to sterilization, a "**Prevacuum**" cycle (alternating vacuum and pressure preconditioning pulses) is recommended for all loads other than liquids (Figure 4).

Measuring Performance

Several methods can be used to verify the efficacy of the sterilization process. Typical methods use Biological Indicators (BIs) and Chemical Indicators (CIs) that are placed in worst case positions in the load and/or in test packs.

- **Biological indicators** provide the best test for sterilization and are used to establish the efficacy of the cycle. In this category, we can find:
  - Inoculated spore test strips. The strips must be aseptically transferred to an incubated growth media soon after the sterilization process is complete.
  - Self-Contained Biological Indicators (SCBI) (Figure 5). Because they are self-contained, SCBI's reduce chances for false positives due to poor aseptic transfer technique. They are typically used to monitor the effectiveness of steam sterilizing process.
  - Glass ampoules are also used when the indicators must be placed in a liquid product to be sterilized (culture media as an example).
- **Chemical indicators** provide immediate proof of steam penetration (not necessarily of sterilization). In this category, we can find:
  - Autoclave tapes that show the process has occurred with no correlation to time/temperature.
  - Chemical integrators that are correlated to time and temperature. These particular indicators can help reduce cycle development time by providing immediate indication of sterilization efficacy.
  - **Steam penetration studies:** temperature sensors can be placed in hard to reach locations to provide indication of steam penetration.

Prevacuum sterilizers should be tested routinely for air leaks and air removal capability. Automatic chamber leak tests (vacuum hold tests) are typically provided in the software of modern prevacuum sterilizers, and should be run daily after

Figure 5. Self-Contained Biological Indicators (SCBI).

a warm-up cycle. The sterilizer chamber is evacuated to the limit of the vacuum system (<1.0 psia or 6.9 kPa) and the chamber and associated piping are isolated (valves closed) for a hold period. The difference between the absolute pressure at the beginning and end of the hold period is the total leak rate. The leak rate should be < 1.0 mm (0.039 inches) Hg/minute[2]. Hold time varies per procedures, from 10 to 30 minutes. It should be noted that a pressure rise during the hold phase is not always indicative of a chamber vacuum leak. Wet steam can cause condensate to be introduced into the chamber during the test preconditioning pressure pulses. Any condensate in the chamber will evaporate at the test vacuum level, causing a rise in chamber pressure. One practical way to determine the source of the pressure rise is to observe the leak rate during the vacuum hold phase with an absolute pressure gauge connected to the sterilizer chamber. An air leak rate will be fairly constant over the vacuum hold period. A pressure rise from evaporation of condensate will result in a high rate at first, and then will diminish as the condensate is evaporated.

In addition to the vacuum hold test, a challenge test such as the Bowie-Dick test should be run periodically as seen in Figure 6. The challenge test is different from a vacuum hold test in that it challenges the sterilizer to remove the air from within a dense package and displace the air with steam. It is fairly uncommon for a sterilizer to pass a vacuum hold test and fail a challenge test, but it has been observed. Insufficient air removal during the prevacuum phases and/or poor steam quality (excess entrained non-condensable gases, superheated steam or wet steam) can cause this anomaly. Challenge tests are temperature specific, and tests designed for 132°C (270°F) will not function properly in a 121°C (250°F) test cycle.

The Ten Most Common Mistakes in Steam Sterilization

Most mistakes regarding the programming and operation of typical steam sterilizers are related to the basic principles of steam sterilization.

1. ***Containers with closed valves, empty glass bottles with tightened screw caps or secured aluminum foil are placed in the sterilizer.***

As a result, steam cannot directly contact the inside surfaces and sterilization does not occur. This problem can be resolved by assuring that all items in the sterilizer have a way for the steam to get in and the air to get out. If there is uncertainty about whether an item's configuration, set-up, packaging, or orientation will allow adequate steam penetration, a thermocouple, chemical and/or biological indicator can be placed inside the item to be certain.

Figure 6. Bowie-Dick test pack.

2. **Pouched and/or heavily wrapped items are tightly packed in the chamber.**

As a result, air may remain trapped in the items after the preconditioning phase and prevent sterilization. Items should not be overwrapped, and sufficient space should be maintained between load items. The preconditioning vacuum and pressure pulses must be set correctly to attain complete air removal from the load. Typically, four (or more) preconditioning vacuum pulses should be programmed to reach at least 28 in (711 mm) Hg vacuum ((1.0 psia or 6.9 kPa (absolute)) to assure sufficient air removal for worst case loads. Some very dense loads may require a short (2 to 5 min) hold phase at peak preconditioning vacuum to allow time for trapped air to be removed. Preconditioning pressure pulses should be programmed for 3 to 5 psig ((21 to 34.5 kPa (gauge)). Higher pressures set for prevacuum pressure pulses can result in an excessive amount of superheat and difficulties with temperature stabilization during the first few minutes of the exposure phase.

3. ***Heavier items are placed on top shelves.***

Water droplets and/or stains are observed on the outside of wrappers of items placed on the mid to lower shelves after the sterilization cycle is complete. Because the items are not dry, they cannot be aseptically removed from the sterilizer. Condensation is the natural result of steam contact with the cooler surfaces of the load. The condensate will fall from shelf to shelf. The denser the load item, the more condensate is created. Therefore, place heavier items on the bottom shelf. In addition, consider placing a cotton sheet or lint free towels on each sterilizer loading cart shelf prior to loading to allow the condensate to be absorbed. This also aids in drying. As the condensate wicks into the sheet or lint free towels, the condensate surface area is greatly increased and evaporates much more rapidly during the drying phase than the same amount of condensate in a droplet or a puddle.

4. ***Load is too dense or items are positioned incorrectly in the load.***

As a result, wet or damp items are observed at the end of the cycle. Wrapped items positioned so that condensate is allowed to collect will not be dried. Items should be positioned so that the condensate is allowed to flow downward. Items (wrappers, pouches, filters, or other porous biological barriers) that remain wet at the end of cycle cannot prevent con-

tamination of the load when removed from the sterilizer. As the load cools outside the sterilizer, the water in the wrapper will be drawn into the wrapped item. Any contamination that is present in the environment can be drawn through the sterile barrier along with the water. There are numerous other possible causes for wet loads. The most common are:

a. Insufficient drying vacuum level or time programmed
b. Rubber or plastic items in pouches (i.e., rubber stoppers, plastic tubing) may require additional drying (a pulsed-air or heated pulsed-air drying process is recommended for these items)
c. Wet steam

While there is no single solution to eliminating wet loads, it's likely that experimenting with drying time, repositioning items, reducing load density, modifying cycle settings, and investigating steam quality will resolve the problem.

5. Pouches are placed flat on the sterilizer shelves or stacked on top of one another.

As a result, pouches may have water droplets inside and cannot be aseptically removed from the sterilizer. Typical cause is when the condensate naturally created when steam penetrates the pouch and contacts the surface of the item within is not removed during the post-conditioning drying phase. Pouches should be spaced properly and placed in rack that holds the pouch on its edge (Figure 7) to prevent pooling of the condensate inside the pouch. Pouches should not be placed flat on the sterilizer shelf. Pouches should not be overloaded. Remember that more mass means more condensate.

Sufficient drying vacuum level and time should be programmed to allow for complete evaporation of the condensate. Wet steam should be corrected. Double pouching may require additional prevacuum pulses with dwell time at maximum vacuum and increased drying time. Doubled pouches should never be assembled so that the items inside cannot be seen. Pouch flaps should not be folded over.

6. Liquids in vented containers are placed in a deep pan to catch boil-over (slow exhaust cycle).

The pan will hold water and it will hold air. The steam cannot contact the surfaces within the pan because of the trapped air, and they will not be sterilized. The solution is to eliminate the pan and adjust the sterilizer slow exhaust rate to prevent boil-over. A shallow pan, less than 1" (25 mm) deep, can be used in the event that a small amount of boil-over cannot be eliminated by adjusting the slow exhaust rate.

7. "Overcooked" Media

Over sterilization of media will caramelize the sugars and

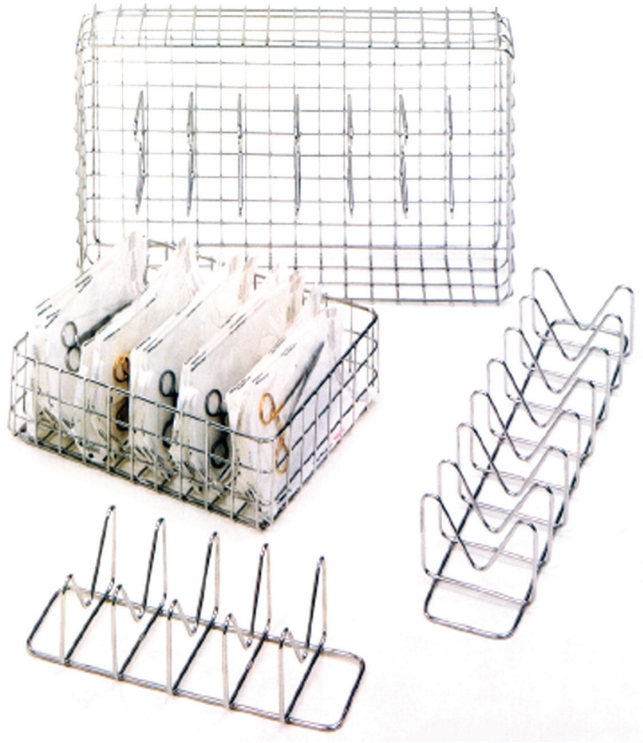

Figure 7. Proper position for pouches.

render the media useless. The typical overkill approach is not recommended for sterilization of media. The exposure phase should be programmed to achieve the desired SAL and no longer. Use of a load probe and Fo exposure control is recommended for sterilization of media in containers larger than 100 ml (3.4 oz). As illustrated in Figure 8, Fo is a calculation of the equivalent exposure at temperatures other than 121.1°C (250°F). As the liquid is heated, the calculated Fo (from the load probe temperature) is accumulated until the selected Fo exposure value (minutes) is achieved, at which point the cycle proceeds to the exhaust/cooling phase. For example, on the graph, the kill rate on the same population of organisms is half as effective at 118°C (245°F) as at 121°C (250°F). Therefore, at 118°C (245°F), it will require twice the exposure time to kill the same number organisms.

A common formula for calculating the F_o value is:

$$Fo = \int_0^t L\,dt \quad \text{where} \quad L = 10^{\frac{(T - 121.1)}{z}}$$

where:

- L is lethal rate of bacterial spores
- t is exposure time, [s]
- T is exposure temperature, [°C]
- z is a constant, [°C]

The constant z describes the slope of the thermal death

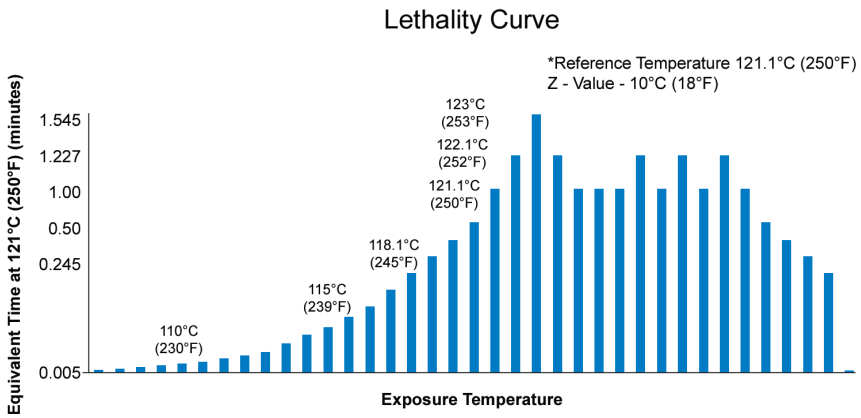

Figure 8. F_0 as a function of temperature.

curve. The widely accepted value for z is 10°C (18°F) in steam sterilization.

8. Using cold water for vacuum pump that is too hot.

As a result, the vacuum pump may not be able to reach 1.0 psia (6.9 kPa). The heart of the prevacuum sterilizer is the water-ring vacuum pump. The efficiency and maximum vacuum capability of a water-ring vacuum pump are adversely affected by higher water temperatures typically encountered during the summer months. During operation, the water within the pump is heated by mechanical friction and heat energy from the sterilizer chamber. If the temperature of the water inside the pump reaches 39°C (102°F) during the preconditioning or post conditioning vacuum peak, the water inside the pump will boil at ≤ 1.0 psia (6.9 kPa) and cause cavitation. In this case, the recommended preconditioning vacuum level of 1.0 psia (6.9 kPa) cannot be achieved in the sterilizer chamber. A common "work-around" for this situation is to change the set point of the prevacuum pulses to a level that can be achieved. Insufficient air removal can be the result unless the number of vacuum pulses is increased, causing longer cycle times and less effective air removal. Internal pump temperatures higher than 39°C (102°F) are often observed during the summer months if the water supplied to the pump is not cooled. Chilled water is ideal, but typically too expensive to use in a sterilizer vacuum pump arrangement in which the water flows from the vacuum pump to drain. The recommended solution is a recirculation/cooling system for the vacuum pump water that uses chilled water in a closed loop heat exchanger. This configuration is eco-friendly as it saves a significant amount of water. In addition, the vacuum pump efficiency is not subject to seasonal water temperature fluctuations.

9. Load probe is available, but not used.

Most modern sterilizers include (optional) an RTD load probe and F_0 exposure control for use in liquids sterilization, but many times the probe is not used. If equipped with a load probe, the exposure can be controlled by the temperature of the liquid rather than the temperature in the drain line. Without the load probe, the temperature of the liquid is not known and can only be estimated, resulting in inadequate (non-sterile) or excessive F_0 (overcooked). The load probe should be placed in a container of water approximating the volume of the largest volume of liquid being sterilized. Load probe control/F_0 must then be selected in the sterilizer control settings.

10. Pressure/vacuum rate control is available, but not used.

Most modern sterilizers include (optional) rate control for the vacuum and pressure ramps, but many times the rate control is not used. When no pressure rate control is applied steam will enter the chamber at maximum velocity during the preconditioning pressure pulses, which creates a superheat problem and EN285 compliance problems as discussed earlier. Slowing the pressure rate allows time for superheat to dissipate during the ramp up.

When no vacuum rate control is applied the chamber will depressurize at the maximum rate of the vacuum pump. The typical problem associated with this is burst pouches. Slowing the vacuum rate allows time for the pouch internal pressure to equilibrate and prevents bursting during the preconditioning and post conditioning vacuum phases.

Conclusion

Steam sterilization is a process that is dependent on basic principles that are sometimes unknown or disregarded by the sterilizer user. A large percentage of steam sterilizer failures can be solved by logical and practical application of these basic principles. It should be noted that proper training for sterilizer users should include this education. Proper wrapping and loading techniques are critical for safe and successful sterilization. As with any critical process equipment, proper maintenance and calibration is essential.

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About the Authors

Marcel Dion is Director of Marketing for Washing and Steam Sterilization Systems in the Life Sciences Division of Steris Corporation. Dion holds a diploma in instrumentation and control from Levis-Lauzon CEGEP in Quebec, Canada. He was involved in designing and manufacturing washing systems for the life sciences industry during the first 20 years of his career. For the past 13 years, he has been responsible for developing and bringing to the market innovative and efficient cleaning and steam sterilization systems for critical parts/components that are involved in the drug manufacturing process. Dion has been a member of ISPE, PDA, LAMA and AALAS organizations for several years. He can be contacted by tel: +1-418-664-7512.

Steris, 490 Armand-Paris, Quebec G1C8A3, Canada.

Wayne Parker is an independent consultant for moist heat sterilization to the pharmaceutical, biotech, and research industries. Parker graduated from Hillsborough High School in Tampa, FL in 1965 as a member of the National Honor Society. He attended the University of South Florida in Tampa from 1965 to 1968. Parker served in the U.S. Air Force from 1968 to 1972 as a Radar Maintenance NCO and continued his education through the U.S. Air Force Extension University. He was employed by the American Sterilizer Co. (now Steris Corporation) from 1972 to 2012, when he "retired." During his career, Parker held numerous positions, including; field service technician, field service cGMP specialist, area sales manager and key pharmaceutical accounts manager. He has provided training and consulting services to numerous companies, and continues as a guest lecturer several times per year at the University of Tennessee, Memphis, College of Pharmacy post-graduate course in aseptic processing. He has been a member of ISPE, PDA, and AALAS organizations for many years. He can be contacted by email: autoclaveman2007@yahoo.com.