Most people working in the sterilization field would consider steam sterilization to be fairly straightforward; it has a long history of use and the mechanisms of kill are well understood. The parameters needed to achieve sterilization for wrapped instrumentation at various temperatures are well described, with examples including:

- 250°F (121°C), 15 minutes exposure
- 270°F (132°C), 4 minutes exposure
- 275°F (134°C), 3 minutes exposure

These conditions are based on achieving a known level of antimicrobial activity, referred to as a sterility assurance level (SAL) of 10^-6 (McDonnell & Sheard, 2012). The sterility assurance level is the probability of a viable microorganism surviving on an item after sterilization and an SAL of 10^-6 is equivalent to a 12 log reduction of bacterial spores (specifically Geobacillus stearothermophilus spores, which are considered the most resistant to steam sterilization processes). However, achieving these parameters can be more complicated than it seems. It is important to note that these conditions need to be achieved in the sterilizer and in the various devices and loads within the sterilizer chamber. This is why steam sterilization cycles consist of at least three phases: conditioning (to ensure the conditions are reached for steam sterilization, particularly to include air removal and heating), sterilization (at the defined temperature and time to provide the SAL) and drying/cooling (to render the load safe for removal and transport/storage). A typical vacuum assisted steam sterilization cycle is depicted in Figure 1 (below).

This prevacuum steam sterilization cycle includes conditioning (1-2), sterilization (3) and drying/cooling (4-6).

Although defined sterilization cycles can be validated by the sterilizer manufacturers to various standards and guidelines (e.g., ANSI/AAMI ST8:2013), this should be verified at each facility given the range of load configurations that can be specified and variation in steam delivery to the chamber (ANSI/AAMI ST79:2012). Many factors can therefore influence the probability that a particular steam sterilization cycle actually produces a sterile product. Some factors include:

- Cycle conditioning
- Steam penetration
- Steam quality

Figure 1. A Typical Steam Sterilization Cycle.
Steam sterilization conditioning

The conditioning phase in steam sterilization is used to remove air from the chamber and the load. Since air and steam do not mix, it is necessary to remove all air from the sterilization chamber. Any air remaining in the chamber during the exposure phase of the sterilization cycle might prevent steam from contacting all surfaces of the device being sterilized. Air is removed from the chamber either through the use of gravity or the use of dynamic air removal processes.

In gravity processes, steam is injected into the top of the sterilization chamber. The steam builds up in the chamber and forces the air down and out through the drain in the bottom of the chamber. This passive process of air removal cannot remove air from certain types of device configurations, where air can become trapped. Examples include problems with removing air from any concave surfaces that have not been loaded properly in the sterilizer chamber. Unlike the passive gravity air removal process, dynamic air removal processes employ either a series of negative or positive pressure pulses to actively remove air from the sterilizer contents. Two main types of dynamic air removal processes are used: prevacuum and steam-flush pressure-pulse.

In prevacuum steam sterilizers, a series of negative pressure (vacuum) pulses may be combined with a series of positive pressure pulses of steam into the chamber. The number and type of pulses can vary with each sterilizer design, typically with repeated pulses three to four times, depending on the sterilizer programming.

A steam flush pressure pulse (SFPP) steam sterilizer uses positive steam pressure followed by a rapid decrease in chamber pressure to remove air from the chamber. This sequence is typically repeated two to three times, depending on the sterilizer programming.

Both of the dynamic air removal processes actively remove air from the devices in the chamber. The number and types of negative or positive pulses can affect the overall air removal efficacy in the sterilizer. For example, fewer pulses can result in less efficient air removal and conversely, more pulses can often result in more efficient air removal, but this will vary depending on the design of the sterilizer conditioning cycle. In the USA, standardized tests to confirm adequate air removal and steam penetration are required (in compliance to AAMI/ANSI ST8: 2013).

Steam penetration

Rapid steam penetration to all parts of the load is important to steam sterilization. In healthcare, steam sterilization cycles and sterilizers are programmed to allow for the sterilization of devices within specific criteria. Devices and loads that impede the ability of steam to penetrate to all surfaces in the allotted time frames, and with the specified parameters, will be difficult, if not impossible to sterilize.

Steam penetration tests

Because steam penetration and steam contact with all surfaces of a device is so important to steam sterilization, there are a number of tests available to ensure that steam penetration will occur in a steam sterilizer. Steam penetration tests check the amount of non-condensable gas (NCG, such as air) in the sterilizer chamber to ensure that the NCG present will not prevent steam contact with all surfaces being sterilized.

Steam penetration tests can include temperature monitoring, biological indicator (BI) results or chemical indicator (CI) results or a combination of these. These tests should provide a challenge representative of the items and loads being sterilized within the sterilizer. ANSI/AAMI ST79:2012 provides specific guidance on the types and frequency of such tests, to include monitoring every pack/load, routine sterilizer testing, quality testing after installation or major repair, and periodic product/load quality assurance testing.

Included in these tests are the two most common steam penetration tests used in the USA: the Chamber Leak Test and the Daily Air Removal (Bowie Dick) Test.

Chamber leak test

A sterilizer chamber leak test is used to measure air leakage into the sterilization chamber. The leak test is required for all types of sterilizer conditioning cycles. The maximum leak rate allowed is 1.0 mmHg/minute (ANSI/AAMI/ISO 17665-2:2009). According to ANSI/AAMI/ISO 17665-2:2009, the leak test should be run at least quarterly. Some authorities recommend this test be run weekly, or even daily, depending on the volume of sterilization being performed.

Bowie-Dick/Daily air removal test

A Bowie-Dick or other daily air removal test is used to test the ability of a prevacuum steam sterilizer to remove air from the sterilizer chamber. This test is used daily, before beginning to run normal sterilization loads for the day. There is a chemical indicator inside a test pack. Typically, the color on the test CI must show a uniform color change. If the color change is not uniform, then the test has failed.

Extended exposure times and steam penetration

Exposure time can also be an indication of a steam penetration issue associated with a particular instrument or containment device. Today, there are many devices available where the manufacturer’s instructions for use require an extended exposure time for steam sterilization.

The amount of time needed for steam sterilization has not changed at the point where steam contact must occur. The problem has to do with the length of time required for the steam to penetrate to all areas of the device or load. Complex devices or device sets may require more time for steam to penetrate and therefore a longer exposure time is needed to ensure the minimum exposure time has been achieved at the point of contact.

Wet packs

Good steam penetration is essential to sterilization. In the process water condensate is formed. Failure to remove the moisture can provide bacteria a pathway for recontamination of the sterile instruments during transport and storage. Failure to effectively remove moisture from packs is referred to as ‘wet packs’.

The occurrence of wet packs can be understood with some basic physics. The energy needed to transform 1 gram of water to steam is the same amount of energy given off when steam transforms into water. If energy is not available, then re-evaporation cannot occur. This means that condensate must stay in contact with the material it condensed on, or it must be drained away. Many factors can contribute to the formation of wet packs. Some factors include:

- Steam quality
- Sterilizer function
- Device challenges
- Sterilization load practices

Steam quality

Steam quality, in particular its saturation, can have a direct impact on the occurrence of wet packs. Steam quality should be between 97 – 100% saturation (ANSI/AAMI ST79:2012). If steam is too ‘wet’ this will transfer directly to the load and this additional moisture will need to be removed by drying after the sterilization process.

Condensate from poor steam quality can occur in the steam pipes leading to the steam sterilizer. This condensate can be carried over into the chamber. Since this condensate did not occur in the sterilizer chamber there is no
energy to use for re-evaporation; thus causing a wet pack or packs to occur.

During peak steam capacity requirements, the demand for steam might be higher than the steam generator can deliver. When this happens, pressure drops and condensed water from the pipes can be carried along in the generated steam. Again, there is no energy available to re-evaporate this condensate.

A water separator installed in the steam lines providing steam to the sterilizer can be used to control carry-over of condensate. The water separator must be at the lowest point of the pipes, and close to a sterilizer with good drainage, to prevent carry-over from occurring.

Sterilizer function
Wet packs are rarely caused by the sterilizer design. However, there are some sterilizer design features that can cause wet packs to be more prevalent. Design features combined with bad practices may result in an uneven distribution of temperature on chamber surfaces providing another area of concern during the sterilization cycle.

Poor chamber design
The chamber walls must maintain a consistent temperature that will prevent significant condensation of steam during the processing cycle. To do this, some sterilizers line the outer chamber wall with a series of “ribs” supplied with steam. Others use a second “jacket” that surrounds the chamber. The jacket is filled with steam to provide heat to the chamber wall.

Sterilizers designed with only partial jackets or ribs around a single walled chamber are also supposed to heat the chamber walls. Depending on the number of ribs or length of the partial jacket, this may be very inefficient. The more distance between the ribs, the harder it will be to evenly heat the chamber wall, for example.

Sterilization chambers tend to cool down between cycles; even if the door is closed. When the sterilization cycle is started, the walls may be cool enough for condensation to occur on them. This condensate can then “rain” on the load, causing wet packs to occur. Sterilizers with chamber heating designs that are inefficient increases the amount of condensate produced and may result in wet packs.

Open door
Leaving the sterilizer door open between cycles allows the door and chamber walls to cool off. When the door is closed, and the cycle started, the steam in the chamber heats the door. Since the door has cooled down, there will be condensate.

Depending on the temperature of the door, this can cause large amounts of condensate to occur. The turbulence in the chamber during sterilization can cause this condensate to be removed from the door and deposited on the load contents; again causing wet packs to occur. This condensate cannot be re-evaporated because it is no longer in contact with the energy source.

Device challenges
Condensation formation is a natural part of steam sterilization. Devices to be sterilized are at room temperature. When steam contacts the load items condensation occurs. For re-evaporation to occur energy needs to be provided to the condensate or the condensate must be drained away.

Large temperature difference within the load will cause large amounts of condensate to form. This can happen with the presence of large amounts of solid devices, such as in the case of heavier orthopedic device sets. This condensate drips off the solid devices and onto other devices below. If the condensate is then absorbed, as will happen with porous materials, by the item below there will be a wet pack. Proper loading configuration can minimize this problem.

Preheating the load by leaving it in the empty chamber for a period of time prior to starting the cycle might seem like a good idea. But this can cause other issues such as poor steam penetration, super heating of the steam and damage to wrapping materials and other porous items.

Sterilization load practices
The types of devices and loads will create various degrees of condensation. Proper processing of the devices through the sterilization process can assist in removing and preventing the formation of excess condensation.

If wet items are placed in the sterilizer, a high probability of wet packs can be expected. There is no energy available for the sterilizer to evaporate this excess water. If items are not dry after the end of the cleaning process, they need to be dried (such as with a lint free cloth) prior to placing them in the sterilizer.

It may seem that draining all of the condensate away is the best thing to do. This however, can cause other problems. Condensate is needed to remove the energy created during the sterilization process. If this energy is not removed, the load will remain too hot to handle for several hours. To ensure the best draining of the condensate, it is critical that the condensate remains in contact with its energy source. Applying basic loading principles will go far in preventing wet packs.

When possible, use single layer trays. Recognize that multiple layered trays will cause top layers to “rain” on lower layers. The use of wicking materials and tray liners will help to minimize this and keep the energy produced in close contact with the condensate. Trays should never be stacked, as the same problem can occur as in trays with multiple layers.

Use of support devices that separate the wrap and the base of the tray, or the container and the base of the tray, can contribute to wet pack problems. Dented or deformed trays can also contribute to wet packs. Overloading the sterilizer increases condensate and might make it difficult to re-evaporate the condensate.

Proper loading techniques will help to minimize these issues. Textile packs and peel packs should be placed on shelves above trays. Wrapped trays should be placed above sterilization containers. Adequate space must be provided between packs and trays. Trays, containers and packages should never be stacked unless they have been designed to compensate for condensation distribution.

Compensation through dry time
One would think that wet packs may be solved by increasing the dry time. This is not always the case. Sterilizer loads are often dried under vacuum. The vacuum will provide insulation if there is no energy available for re-evaporating to occur. As a result, increasing the dry time may have little effect under such vacuum conditions. This will depend on the specific design of the sterilizer and sterilization process. Remember, if periodic wet packs are identified, these are most often due to problems with steam supply and improper loading of the sterilizer.

Conclusion
Many factors affect the ability of a steam sterilizer to produce sterile product. These factors include cycle conditioning, steam quality, dry time, device configuration, tray configuration and loading cart configuration. Each of these factors must be considered when preparing devices for sterilization. Failure to do so can cause problems that may affect the ability of the sterilizer to perform as expected and to produce sterile products.

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Donna Swenson has over 30 years of experience in the sterilization of medical devices. She has worked with both healthcare providers and the medical device industry. For the past few years she has been implementing industrial sterilization standards in the hospital setting. For several years Swenson has been the lead USA delegate to the ISO committee on Most Heat Sterilization of Medical Devices. In this position she actively participated in the development of ANSI/AAMI/ISO 17665-1 and -2; Sterilization of health care products - Moist heat - Part 1 Requirements and Part 2 Guidance. She is currently working with ISO/TC 198 WG3 on ISO/TS 17665-3, Guidance on the description of a medical device by product family. Swenson
1. Sterility assurance level (SAL) is:
   A. The probability of a single viable microorganism occurring on an item after sterilization.
   B. The log of the initial number of spores minus the log of the spores surviving the sterilization treatment.
   C. The time required to achieve inactivation of 90% of a population of test microorganisms under stated conditions.
   D. The particular value of a sterilization parameter that is needed to move one log on the spore log reduction curve.

2. Which of the following steam sterilization conditions have been cleared in the US to achieve a 10^4 sterility assurance level as part of a validated cycle?
   A. 275°F (134°C), 1 minute exposure
   B. 270°F (132°C), 2 minutes exposure
   C. 270°F (132°C), 4 minutes exposure
   D. 275°F (134°C), 3 minutes exposure
   E. C & D

3. A typical steam sterilization cycle profile includes:
   A. Conditioning
   B. Sterilization phase
   C. Drying/cooling
   D. All of the above

4. The chamber leak test measures:
   A. The presence of excess moisture in the sterilizer chamber.
   B. Air leakage into the sterilizer chamber.
   C. The presence of air in the sterilizer chamber.
   D. Leakage of condensate from the sterilizer chamber.

5. True or false. The energy needed to transform 1 gram of water to steam is less than the amount of energy given off when steam transforms into water.
   A. True
   B. False

6. Steam quality for steam sterilization should be:
   A. Over 50%
   B. 100%
   C. Less than 90%
   D. 97-100%

7. Common causes of wet loads include:
   A. Steam supply.
   B. Device or load configuration.
   C. Loading of the sterilizer chamber.
   D. All of the above.

8. Large amounts of solid instrumentation in a steam sterilizer can create:
   A. Problems with chamber evacuation.
   B. Superheated steam.
   C. Excessive amounts of condensate.
   D. Damage to wrapping materials.

9. Methods of air removal and steam penetration in steam sterilization cycles include:
   A. Gravity displacement.
   B. Prevacuum.
   C. Steam-flush pressure-pulse.
   D. Dynamic air removal processes.
   E. All of the above.

10. True or false. Increasing the dry time in a steam sterilizer under vacuum conditions may have little effect in drying a load.
    A. True
    B. False