Control and Validation of the Steam Sterilization Process

Validation & Monitoring Solutions

Ellab White Paper - 07/19

Steam sterilization has been used for decades and is by now a highly common method used for sterilizing items or goods that can withstand the moisture and the relatively high temperature and pressure. The main purpose of steam sterilization is to deactivate microorganism through total elimination of germs providing a sterile product for later use.

Exposing microorganisms to saturated steam under pressure in an autoclave ensures that they are destroyed by the irreversible denaturation process of enzymes and structural proteins. The temperature at which denaturation occurs depends on the amount of water present – sterilizing with saturated steam therefore requires highly accurate control of time, temperature and pressure. As saturated steam is much more powerful than an air/steam mixture, due to the heat released during condensation, exchanging the air by steam is mandatory. This is why the ambient air inside the autoclave chamber is evacuated and diluted by steam during the several vacuum pulses before the remaining steam is introduced.

This paper is focused on Steam Sterilization but besides steam sterilization you will find other commonly used Sterilization Methods.

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Where is Steam Sterilization Used?

Moist heat sterilization (or autoclaving) is typically used in hospitals for sterilizing the surfaces of wrapped goods or hollow items. The process is conducted by supplying dry, saturated steam under pressure into an autoclave. The heat from the condensation of steam envelops the items in the sterilizer and kills the microorganisms in an easy and fast manner. It does so by irreversibly damaging the cells by coagulation. Moist heat sterilization takes a minimum of 15 minutes at 121 °C and a pressure of 2 ABS – or a minimum of 3 minutes at 134 °C and a pressure of 3 ABS. Objects that are sterilized with moist heat are often non heat-sensitive items, e.g. simple surgical instruments, dental instruments, reusable medical equipment, textiles or surgical equipment with cavities.

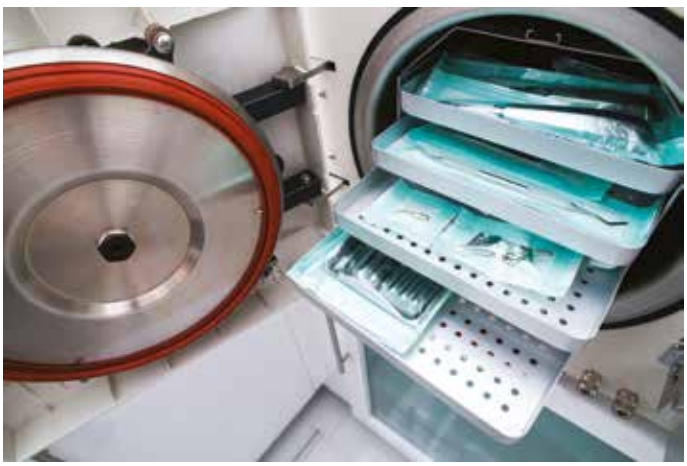
The use of saturated steam to sterilize pharmaceutical products, equipment and reagents is also a fairly common sterilization method. The latent heat released when steam condenses on the items makes this process highly energy efficient. This can be advantageous, particularly for pharmaceutical products. Creating the vital vacuum, however, can be difficult, but insufficient level results in a limited capability for the steam to penetrate cavities in instruments etc. The use of testing equipment is therefore recommended for frequent routine monitoring in order to allow the conditions at various points in the process to be assessed.

Description of a Steam Sterilizer

A steam sterilizer (or autoclave) is a high-pressure vessel with a sealed lid/door and gasket (the sterilizing chamber), an air removal system and a control system consisting of a timer, pressure control valve and safety valve. It makes use of pressurized steam at around 115-134 °C to heat the load and achieve sterilization. Moist heat sterilizers are typically used within the medical and pharmaceutical industries and designed in two different ways:

1. The traditional design uses gravity to replace the air with steam. As steam fills the chamber, air is forced out through a drain vent. This process is generally used for unwrapped goods, glassware or non-porous items.

2. A more advanced design can be used when removing air from the chamber or load proves to be a challenge, e.g. wrapped goods or hollow loads, by incorporating a vacuum system that removes the air prior to operation. It does this by using several steam injections and vacuum pulses that ensures saturated steam conditions. Saturated steam is the most humid steam and presents the highest killing effect and penetration ability.



Sterilizers come in many sizes, from small bench-top portable laboratory autoclaves to large production autoclaves. The larger autoclaves are usually built into the walls, from which “contaminated” products enter one side and the sterilized product exits on the other clean side. They are typically used for sterilizing large volume utensils and are rather advanced in design and control. They tend to be cylindrical as this design has proven to be very strong when it comes to high and low amounts of pressure.

The product is located on shelves within various trays or in cages in order to optimize the distribution of the load and steam. Uniform and full loads are highly recommended as it is important for validation purposes that the load is standardized.

In addition to sterilizing pharmaceutical product, sterilizers are also used for sterilizing equipment and reagents. Most pharmaceutical companies and hospitals will have microbiological laboratories that include sterilizers for preparing media and equipment.

How Does the Steam Sterilization Process Work?

The steam sterilization process has the distinct advantages of being non-toxic and relatively easy to control.

The main parameters are:

- Time
- Temperature
- Pressure
- Moisture
- Steam contact
- Air removal
- Drying

Temperature and pressure measurements are the most critical factors. Their measurements must have an accuracy of +/- 0.5 °C or better at the used sterilization temperature and +/- 1.6 % or better for the pressure over the scale range of 0 to 4 Bar (according to EN285).

Time

The first parameter, Time, is a critical factor as bacteria does not die instantly, which is why a minimum time is required to eliminate them all. The parameter is closely linked to temperature as the killing effect (death value/lethality value) depends on both. The correlation is logarithmic, which is why the same killing effect can be obtained simply by adjusting the temperature and exposure time accordingly. The killing effect is expressed as the lethality value, which should reach the same value by sterilizing at 121 °C for 15 minutes as one would by sterilizing at 134 °C for 3 minutes. This means that if a product can withstand the higher temperatures, quite a substantial amount of time can be saved by choosing 134 °C. When deciding on the required lethality value for a specific application, the Sterility Assurance Level (SAL) must be considered. The required SAL varies based on the application, but it is usually defined as sterile around 1/1,000,000, meaning that only one out of a million bacteria will have survived the sterilization process.

Temperature and Pressure

As Temperature is directly linked to the lethality value, this parameter can also be used to check how well the autoclave performs. Additionally, when using Moist Heat Sterilizers, pressure can be converted into theoretical temperature which can then be compared to the actual temperature in order to evaluate if the steam is saturated. This eliminates the risk of air pockets, which could otherwise jeopardize the process.

Moisture

Steam moisture has a very high impact on destroying proteins by denaturation (coagulation), which is why it is very important to use saturated steam. The steam should be clean and superheated steam (above its saturation temperature) should be avoided as it will not contain enough moisture to ensure proper sterilization if this occurs.

Steam Contact

The direct steam contact to the potentially contaminated surface is important in order to ensure that enough of its stored energy is transferred to the object by the means of condensing. For comparison, the amount of energy stored in steam is much higher than in dry air or water at the same temperature, which is why operating with saturated steam is the preferred solution.

Air Removal

To secure saturated steam conditions, air must be removed from the sterilizer chamber and load prior to operation. This is done by using a vacuum system that provides a series of vacuum pulses. Removing all of the air is technically impossible, but the level should be kept at an absolute minimum (high dilution factor). Insufficient air removal, leaks in vacuum or a bad steam quality (presence of too many non-condensable gasses), is typically the main reason for sterilization failures.

Drying

Ensuring that the load is dry enough when leaving the sterilizer is critical, as it could otherwise be re-contaminated. Appropriate drying is usually ensured by applying vacuum to the chamber at the end of the cycle, which boils all condensates and transports them away through the vacuum system.

Documentation Requirements

Daily Routine Control:

In the hospital Central Sterilization Service Departments (CSSD), chemical and biological indicators are used to control the sterilization process as a daily routine control of air removal autoclaves that make use of vacuum.

These indicators, however, can only provide highly subjective results, and the purchase and running costs can be a significant strain on a budget. Alternative electronic devices have therefore been developed and available on the market for some time now, allowing for the validation of autoclaves or washers/disinfectors, but also for daily routine controls. These devices measure and evaluate critical physical parameters of the process and allow for parametric release of the loads based on the findings. The Sterilization Guidelines developed by experts that passed in 2017 for the first time, officially admitted this as a possibility.

Parametric release is based on the measurements of critical physical parameters by an independent electronic device. The method is not only more accurate, but also offers a much faster releases than biological tests. The test result is available virtually immediately after the process has finished and data is read, while biological tests require long-term incubation. This provides a sizable advantage, for instance in the case of urgent orders involving the sterilization of surgical sets.

Regular Qualification & Validation:

In addition to the daily routine control of sterilizers every morning and the batch control of every load, all sterilizers require regular qualifications and their processes regular validations as a regulatory requirement. The requirements for testing or qualifying steam sterilizers depend on the use and the country. In Europe, standardized cycles are recommended with sterilization temperatures of 121 °C for 15 minutes or 134 °C for 3 minutes. In addition to achieving minimum and maximum temperatures for set time periods, there are a number of other measurements which could be considered critical. These include the equilibration time, which is the difference between the first sensor achieving the set temperature and the last sensor to do so – as well as the spread of temperatures during the sterilization period and the deviation of individual temperature sensors over the sterilization period.

Another important factor when qualifying steam sterilizers is the calibration of temperature sensors. It is essential that it can be demonstrated that the sensors being used are within an acceptable accuracy (at least 0.5 °C). This means calibrating prior to the validation run, a process known as Pre Calibration. The accuracy is then checked after the validation process to ensure that the sensors are still within the predefined tolerances, this process is known as Post Calibration or Verification. If the post calibration reveals that the accuracy was outside of the required limits, the validation study is considered failed and must be repeated after possible correction of the cause.

Finally, it is important to check the pre-vacuum sterilizer for possible leaks. The insurance of having saturated steam available is completely lost if air can penetrate and enter the chamber during operation, which is why a leak test is mandatory. When working with wired systems, multiple leak tests are required before and after mounting the feed through system on the autoclave.

Using the Appropriate Equipment

Using extremely versatile and reliable equipment is critical for patient safety, as it provides smooth and compliant processes. The differences between various methods and equipment can be detrimental and should therefore not be taken lightly. There are several pieces of equipment that are deemed acceptable for routine control and/or validation of steam sterilization processes, but they each come with a certain set of pros and cons that are worth considering.

Daily Routine Control:

Electronic devices are highly recommended for Bowie Dick testing, due to the aforementioned objective result and effective process. Some devices are able to perform both routine- and batch control, thereby eliminating the need for both kind of indicators (chemical and biological).

In addition to this, selecting a device that can generate and print auditable reports is rather essential, as they provide a clear-cut view of the process and result.

Finally, choosing an electronic Bowie Dick test device that can run several cycles in a sequence can be highly beneficial. As most simple models must cool down for 90 minutes before use, which subsequently results in downtime or expensive backup devices.

Regular Qualification & Validation:

According to the European norm, a minimum of 12 measuring points is required for a single sterilizer validation run with a volume of less than 2 m^3.

It is a known fact that wireless loggers, due to the RTD sensor design, are more accurate, stable and repeatable. They also drift far less over time. The most important factor may be the price, while wired cable systems may initially be cheaper from an investment point of view, they require far more resources to operate. A wireless data logging system on the other hand, is a larger investment initially, but saves users considerable resources in the long run as they are far faster to operate. In other words, time is money and working with a wireless system generally saves operators a noteworthy amount of time. It should also be noted that cables require a feed through system for the thermocouples to access the chamber – a setup the requires additional costs/resources and introduces the risk of leakage.

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Conclusion

Validation and Qualification Solutions:
Ellab provides suitable solutions for qualifying autoclaves and validating steam sterilization processes that focuses on safety and ease of operation. Using TrackSense® or E-Val™ Pro bundled with the ValSuite® software, executes the sterilization process in full compliance with norms and regulations in a quick manner, providing full documentation for instant evaluation or later use.

The highly user-friendly and FDA 21 CFR Part 11 compliant ValSuite software is at the core of a smooth and problem-free validation process. It analyzes and evaluates data and features an extensive amount of specific reports based on various customizable templates. ValSuite also helps ensure the accuracy of sensors and probes with the imbedded and fully automatic calibration features.

Routine Control Solution:
SteriSense® is Ellab's brand new and innovative solution for electronic Bowie Dick testing. The game-changing Process Challenge Device (PCD), is designed to perfectly reflect the reference method originally developed by Bowie and Dick in the 1960's. The PCD concept is used to challenge (or simulate) the steam penetration capability of a steam sterilizer that makes use of vacuum. The PCD has the unique feature of being interchangeable, allowing for several test cycles to be run in a sequence without having to cool it or purchase backup devices.

The device is EN ISO 11140-4 compliant and unrivaled in terms of accuracy, performance, size and reliability. The SteriSense software automatically reads and analyzes the data from the testing device and generates printable PDF reports for appropriate documentation.

Other methods of Sterilization - and some we provide solutions for

Chemical Sterilization Methods

- Liquid Methods
  - Alcohols
  - Surface Active Agents
- Gaseous Methods
  - Ozone
  - Formaldehyde
  - EtO Sterilization
  - H2O2 (Plasma Sterilization)
  - Peracetic Acid

Physical Sterilization Methods

- Thermal (Heat) Methods
  - Dry Heat Sterilization
    - Infra-Red (IR)
    - Flaming
    - Hot Air Oven
    - Microwave
  - Moist Heat Sterilization
    - Dry Saturated Steam (autoclaving)
    - Boiling Water – Steam at elevated pressure (retorting)
    - Boiling Water – Steam at atmospheric pressure (cooking)
- Radiation Methods
  - Gamma Radiation
  - Particulate Radiation (accelerated electrons)
  - UV light
- Filtration Methods
  - Depth Filtering (HEPA Filtering)
  - Membrane Filtering