



Everyday practice using steam sterilizers

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History



Steam sterilization is the oldest method which is still used today to inactivate germs on goods (instruments, dressing material, linen, foods etc.)

As early as in the middle of the 19. century, Louis Pasteur found that germs could be inactivated by cooking.

This method was already used in food technology.



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Definitions



Sterilization...

- is the killing or irreversible inactivation of all viable microorganisms.

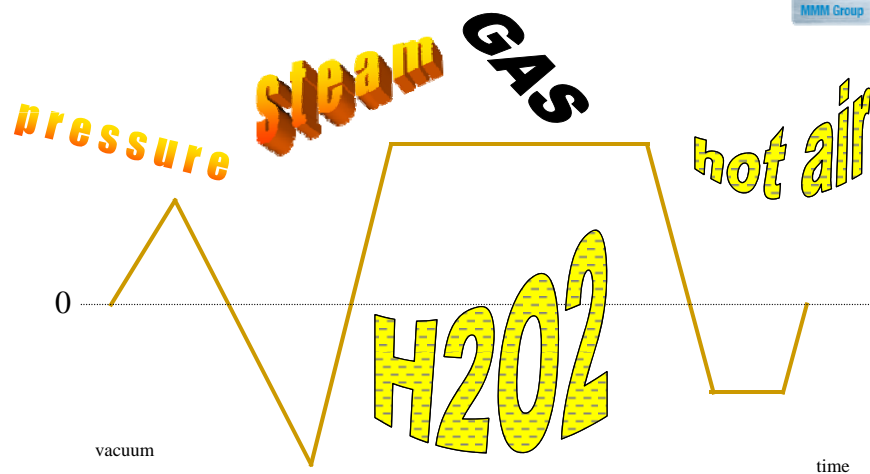
Sterile...

- A sterilization process must deliver a Sterility Assurance Level (SAL) of 1 in a million (10^{-6})
- It is not possible to measure "10⁻⁶"
- The required SAL can be achieved by applying a process that will reduce the number of organisms to zero and then apply a safety factor that will deliver an extra 6 log reduction



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Sterilisation process



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Let's talk about steam sterilization



Staff in CSSD need to know the main functions of a steam sterilizer

- Which kind of steam is used for steam sterilization
- How does the sterilizer work, what happens when the button "Start" is pushed
- Everyday practice using your Steam Sterilizer to sterilize equipment which needs to be sterile for treatment of patients
 - Daily testing of the sterilizer before first load is sterilized
 - Chemical indicators for sterilization
 - Biological indicators for sterilization
 - Further test methods



Steam Sterilization many years ago....



Medizinisches Waarenhaus, Berlin-Südwest, Berlin SW.

1700 Dampfsterilizer nach Schimmelbusch mit Vorrichtung zur Gewinnung destillierten und sterilen Wassers. Dieser Apparat, der ebenfalls in viele andere Ausföhrungen von Kupfer gefertigt, aus Eisen oder auch Blech aus Kupfer, ist ein sehr leicht zu handhabendes und die destillierte sterile Wasser erzeugendes Apparat. Er besteht aus einem Kessel, in dem sich ein kleinerer Kessel befindet, der durch ein Rohr mit dem Kessel verbunden ist. Die Destillation des Wassers erfolgt durch ein Rohr in dem sich ein kleinerer Kessel befindet, der durch ein Rohr mit dem Kessel verbunden ist. Die Destillation des Wassers erfolgt durch ein Rohr in dem sich ein kleinerer Kessel befindet, der durch ein Rohr mit dem Kessel verbunden ist.

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Steam Sterilizers today



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Sterilisation process



Steam sterilization uses humid heat to kill micro-organisms.

Lets see how this works in a steam sterilizer....

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What is vapour?



You know this: bring water to boil in a kettle. The steam will escape from the beak and if the lid is not tight, it will bounce up and down. What happened inside the kettle from the time of filling it with cold water up to the escaping of the steam from the beak? From the moment the kettle with the cold water has been placed on the fire, heat is penetrating the metal of the kettle and the water. The continuous supply of heat heats the water until it starts to boil.



What is vapour?



As soon as the water starts boiling, it has reached a state where it cannot absorb more heat without changing its state. But because the kettle is still on the fire or oven, heat continues to penetrate the water. What happens? The water has to change its state. The excess heat reaching the water is changing part of the water into vapour. The escaping water vapour discharges the excess heat. Such water vapour is meant when we talk of „**steam**“ here.



What is vapour?



Let's have a look at the kettle again:

First of all let's check the temperature of the steam. If we put a thermometer in the boiling water and another thermometer in the steam escaping from the beak, we will see, that both thermometers show the same temperature, i.e. the steam is as hot as the boiling water (approx. 100°C).



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Steam pressure



Now: the steam boiler is a closed vessel. The more steam is generated inside this vessel, the higher the pressure within the vessel, because the steam requires more volume than water, from which is made.

If we measure the temperature within the vessel, we'll see that temperature is higher than 100°C

The higher the pressure, the higher the boiling temperature of water



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Heat and temperature



The terms „heat“ and „temperature“ must be clearly defined.

Heat is the energy that makes things warmer.

A change in **temperature** shows that a heat transfer has taken place.

The actual temperature of the material depends on the **heat capacity** of the material.



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Heat and temperature



At first, a hot-water bottle loses a lot of heat and at the same time heats the bed. The cooling becomes slower because of the less heat difference. Next morning, both the bottle and the bed have the same temperature.



The heating up of a container with a steam coil is quite fast at first, but then slows down. The heat loss per hour of a steam pipe is bigger the hotter the steam pipe.



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Steam quality and term definition



Depending on its use there are three different kinds of steam qualities used, in order to meet the various requirements, e.g. for heating, disinfecting, and sterilization.

The steam qualities are defined as follows:

- Heat steam
- Clean steam and
- Pure steam



Heat steam



Steam used for heat supply and energy transmission. Generated in steam boilers that are operated with boiler water, prepared according to the VdTÜV – guidelines for feed and boiler water condition for steam generators.

Heat steam can be saturated steam or overheated steam.



Clean steam and pure Steam



Clean steam and pure steam are made of demineralized water in steam generators from austenitic, stainless steel.

The steam quality for sterilization must at least correspond to the category **clean steam** as the goods to be sterilized must always meet the high requirements that are valid for surgery, for example.

At present most sterilizers use **pure steam** for sterilization. International standard provide a guide for water quality used for steam generation



Steam for sterilization



Steam for sterilization must be **saturated steam** – it must not be **superheated steam** or **wet steam**.

Reasons:

- saturated steam has the best heat transfer coefficient
- Wet steam causes a heavy humidification on the goods
- superheated has a lower sterilizing effect

Saturated steam is generated in closed vessels with an even state between pressure and temperature.



Superheated steam



If all water contained in a closed vessel is transformed into steam and more heat is added, the steam becomes superheated.

The same effect can be achieved by a reduction of the pipe pressure, where the steam pressure is changed after the reduction station, but keeps its high temperature for some time.

Such overheated steam can absorb water or cool down without condensation. That is why it is also called non-saturated steam.

It only condensates, after the best relation between pressure and temperature is reached again.



Overheated steam is bad



It is not possible to sterilize or disinfect with overheated steam, because the steam must at first give up its overheating energy to become saturated.

The escaping energy is too low to kill any germs, this can be done only with **condensated saturated steam**.

That is why pressure reduction stations must be carefully planned to avoid any overheating of steam.



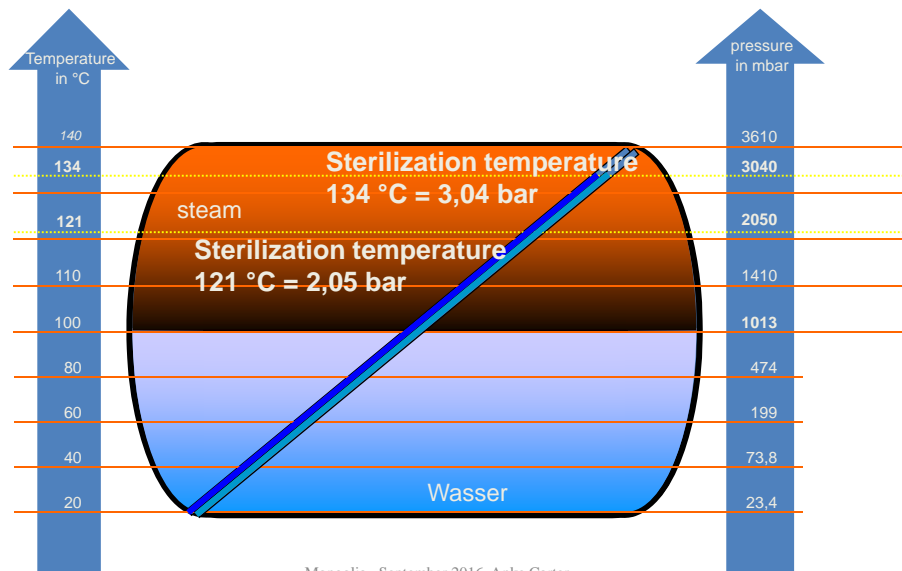
Wet steam



Wet steam is saturated steam that has just undershot its point of saturation and started to condense. Wet steam can be a problem of long steam pipes that are poorly insulated. The emerging condensate will deposit in the pipes and is carried along with the steam. It may then wet the goods to be sterilized and it may result in so called "Wet loads". When you take out your sterilized items the packages are wet.



Correlation between temperature and pressure



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Sterilization programmes

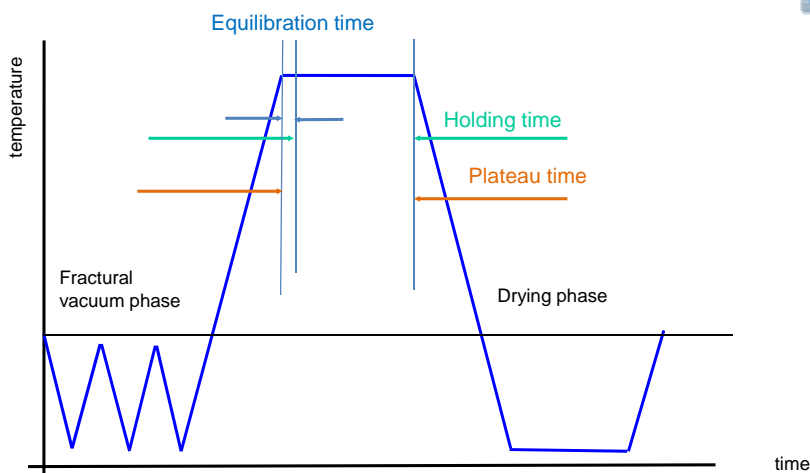


- Mostly used cycle for instruments: **134°C over 5 minutes**
- Some rubber and other materials require a lower temperature and the so called “rubber cycle is used: **121°C over 20 minutes**

Note: Different countries use different sterilization temperatures and times

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Steam sterilization process



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Vacuum



- Vacuum is a most important prerequisite for proper sterilization
- Existing air or inert gases prevent the steam getting to all goods inside the sterilizer
- The aim is the optimal evacuation of all air from the chamber and the removal of air from the goods inside

Note: Remaining air prevents steam to get to the goods and sterilization does not work in those spots



Fractural vacuum phase and heating phase



- By repeatedly evacuating the chamber (vacuum pump) and inject steam air in the chamber is replaced by steam
- In each evacuation about 90% of air to be removed
- After 3 times the proportion of air in the chamber is reduced to about 0.1%
- During this process step the goods in the sterilizer are already heated.
- In the heating phase the temperature inside the chamber is rising to 134°C



Equilibration time and holding time



- equilibration time is the time period between reaching the sterilization temperature (134°C) in the chamber and reaching the sterilization temperature at all points of the load
- Holding time is the time span in which the temperature is maintained at all points inside the sterilizer and the load within the sterilization temperature band
- Equilibration time + holding time are called “Plateau time”



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Plateau time, Drying time, Ventilation



- Throughout the plateau time an active steam flow through the load must be guaranteed to have even steam flow and to remove any residual air from the load
- The heat transferred into the load during sterilization allows the drying. By lowering the chamber pressure, the boiling point of water is lowered and at the same time the vacuum pump evacuates the steam
- At the end of the cycle the pressure inside the chamber is brought to room pressure level by bringing in clean air and the door can be opened to remove the load



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Routine testing of sterilizer and Process



Requirements of routine tests are stated in international and national standards and guidelines and in manufacturers instructions

- Daily tests: visual inspection, feed water quality, air removal/steam penetration, vacuum test (manufacturers instruction)
- Load tests: according to national requirements
- Monthly tests: vacuum test (manufacturers instruction)
- Periodic tests: Validation, chemical or biological tests according to national requirements, regular maintenance of the sterilizer



Daily tests



- Visual inspection of the sterilizer before daily production is started. Check inside chamber for cleanliness
- Vacuum test according to manufacturers instructions to check the integrity of chamber and door seals. The sterilizer has to keep the vacuum over 10 Minutes at a certain level.
The limit according to EN 285 is 1.3 mbar per minute, no more than 13 mbar pressure rise in 10 minutes



Daily tests (continued)



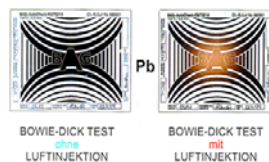
- Is used to check the air removal and steam penetration
- Detection of non-condensable gases in the steam
- Daily before start of production in a warm sterilizer
- If not passed, the test must be repeated once and if the test fails a second time, the sterilizer can't be used until it is checked and repaired
- Continuous operation of a sterilizer requires one Bowie and Dick test within 24 hours
- Test packs which fulfill requirements of international standards can be used

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Examples of Bowie and Dick Tests



BAG-AutoCheck-Kit



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Batch control systems



Batch control systems are used to check every batch produced. Usually chemical indicators are used.

Examples of batch checks



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Biological indicators



Biological indicators are used in some countries for batch control and/or for periodic checks of the function of a sterilizer. In Europe they have been mostly replaced by "Process Validation". Examples for biological tests are:



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Validation



Validation is a documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

(EN ISO 14937:2009-Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices)



Process Validation



Process validation is required within the European Union since about 1998. Validation of the steam sterilization process consists of:

- Installation qualification
- Operation qualification
- Performance qualification

First time validation is a very extensive tasks. After first validation, performance qualification is repeated annually



Further tasks of staff



- Staff in CSSD have to check every item of a load before and after the sterilization process.
- Before loading the sterilizer all parts of the load have to be correctly packed and labelled with required information
- During loading the sterilizer all parts of the load have to be placed on the sterilization trolley following a certain pattern (heavy good on lower shelves, light goods on the top)



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Further tasks of staff



- After Sterilization the load has to be released for use by checking the following
 - All packages are dry
 - All packages are undamaged
 - All packages are correctly labelled
 - The process indicator has changed color
- After sterilization the process record has to be checked
 - Correct procedure (temperature, pressure and time)

Note: Only if all requirements are fulfilled the load can be released for use



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Conclusion



- Steam sterilization is complex and precisely regulated
- A review of the products of successful sterilization is not possible without destroying sterility
- Therefore, correct working prior to sterilization and while using a steam sterilizer, monitoring and checking the sterilization process are of critical importance.
- Special knowledge of staff working in CSSD is necessary to use a sterilizer properly

Education of staff in CSSD is of utmost importance!



Thank you



very much for your attention during this presentation!

I am looking forward to hear your questions!

