

FACTORS RELATED TO QUALITY OF STEAM FOR STERILIZATION OF MEDICAL DEVICES

Fatores relacionados à qualidade do vapor para esterilização de produtos para saúde

Factores relacionados con la calidad del vapor para la esterilización de productos sanitarios

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ABSTRACT: Objectives: To identify and discuss the factors related to quality of steam and their relation to daily practices of the Central Sterile Supply Department (CSSD). **Method:** Documentary research based on the analysis of the normative theoretical framework about quality of steam for the sterilization of medical devices. **Results:** Factors that are directly related to quality of steam are: feedwater, steam contaminants, pipeline pressure fluctuations, non-condensable gases, steam dryness and superheating. **Conclusion:** Controlling factors that impact the success of steam sterilization is not an assignment for clinical engineering service only; it is a responsibility that should be shared with the manager of the CSSD. Safety in steam sterilization should not be reduced to monitoring of time, temperature or the result of physical, chemical and biological indicators, but include monitoring of the quality of steam, which is the sterilizing agent.

Keywords: Sterilization. Steam. Quality control. Quality management.

RESUMO: Objetivos: Identificar e discutir os fatores relacionados à qualidade do vapor e sua relação com as práticas do cotidiano do Centro de Material e Esterilização. **Método:** Pesquisa documental, construída com base na análise do referencial teórico normativo sobre a qualidade do vapor para esterilização de produtos para saúde. **Resultados:** Os fatores que estão diretamente relacionados à qualidade do vapor são: água de alimentação, contaminantes do vapor, flutuações de pressão na rede, gases não condensáveis, título e superaquecimento. **Conclusão:** O controle de fatores que impactam o sucesso de esterilização por vapor não é uma atribuição única da engenharia clínica, mas sim uma responsabilidade compartilhada com o gestor do centro de materiais. A segurança na esterilização pelo vapor não deve ser reduzida ao controle de tempo, à temperatura ou ao resultado de indicadores físicos, químicos e biológicos, mas incluir o controle da qualidade do vapor, que é o agente esterilizante.

Palavras-chave: Esterilização. Vapor. Controle de qualidade. Gestão da qualidade.

RESUMEN: Objetivos: Identificar y discutir los factores relacionados con la calidad del vapor y su relación con las prácticas cotidianas en el Centro de Material y Esterilización. **Método:** Investigación documental, construída a partir del análisis del marco teórico normativo sobre la calidad del vapor para esterilización de productos sanitarios. **Resultados:** Los factores que están directamente relacionados con la calidad del vapor son: agua de alimentación, contaminantes del vapor, fluctuaciones de presión en la red, gases no condensables, titulación y sobrecalentamiento. **Conclusión:** El control de los factores que impactan el éxito de la esterilización por vapor no es una tarea única de la ingeniería clínica, sino una responsabilidad compartida con el gerente del centro de materiales. La seguridad en la esterilización por vapor no debe reducirse al control del tiempo, la temperatura o el resultado de indicadores físicos, químicos y biológicos, sino que debe incluir el control de la calidad del vapor, que es el agente esterilizante.

Palabras clave: Esterilización. Vapor. Control de calidad. Gestión de la calidad.

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INTRODUCTION

Sterilization using saturated steam under pressure is the method that brings together the greatest advantages for patients and healthcare services, as it does not leave toxic residues, has fast cycles, is compatible with different packages and has an excellent penetration into lumens¹. During the cycle, the load is quickly heated by heat transfer promoted by the condensation of steam, when water changes from the gaseous to the liquid state, when it gets in contact with surfaces². The direct contact of the steam with all surfaces is thus essential for the transfer of thermal energy, which promotes microbial inactivation³.

The steam recommended for sterilization processes is saturated, in which there is a balance between condensation and evaporation⁴—that is, a maximum level of humidity—, but does not present the condensate, which is water in liquid state³. Therefore, not any steam is suitable for sterilization processes; for example, in the case of superheated steam, the temperature exceeds the boiling point at a certain pressure and the energy transfer by contact does not occur, since the steam is “dry” and the process becomes similar to sterilization in hot air sterilizers⁵.

In practice, the quality of steam is essential to ensure the safety of sterilization processes. As an example, in situations where steam is superheated, *Bacillus subtilis* spores can be 2.5x more resistant than they would be in saturated steam conditions. However, only a 1.3x increase was observed in the resistance of *Geobacillus stearothermophilus* in superheated steam^{6,7}.

This shows the need for steam quality control in healthcare services, since cycles are monitored with biological indicators that use the *Geobacillus stearothermophilus* spore, which may not identify all changes in steam quality and provide a false sense of safety.

OBJECTIVE

To identify and discuss factors related to the quality of steam and its relation to daily practice in the Central Sterile Supply Department (CSSD), supporting risk management.

METHODS

This is a documentary research based on the analysis of normative theoretical references about the sterilization of medical devices, aimed to identify factors related to steam quality:

- Association for the Advancement of Medical Instrumentation, *ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*⁸;
- Department of Health, United Kingdom. *Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care. Part C: Steam sterilization*⁹;
- European Committee for Standardization. *EN 285: Sterilization. Steam sterilizers. Large sterilizers*⁴;
- Brazilian Association of Technical Standards (ABNT). *NBR ISO 17665-2: sterilization of health care devices – steam – Part 2: ABNT NBR ISO 17665-1 Application Guide*¹⁰.

The documents were sent to selective reading to identify factors of interest for the objective of the study, to analytical reading to summarize the information needed by CSSD professionals, and, finally, to interpretive reading, when authors sought relationships between the scientific literature and daily practice¹¹.

RESULTS

All information found is shown in Chart 1.

Chart 1. Factors related to the quality of steam, according to the documents analyzed.

Document	Factors related
Association for the Advancement of Medical Instrumentation ⁸	<ul style="list-style-type: none"> • Steam dryness*; • Non-condensable gases; • Superheating; • Water contaminants; • Various problems (e.g. obstructions and pressure variations in the pipeline).
Department of Health, United Kingdom ⁹	<ul style="list-style-type: none"> • Steam dryness*; • superheating; • Non-condensable gases; • Contaminants.
European Committee for Standardization ⁴	<ul style="list-style-type: none"> • Non-condensable gases; • Dryness value*; • Superheating; • Contaminants; • Pressure fluctuations; • Water for steam generation.
Brazilian Association of Technical Standards ¹⁰	<ul style="list-style-type: none"> • Non-condensable gases; • Dryness value; • Superheating; • Contaminants; • Variations in steam pressure.

*Variants of the term *dryness*. In this study, we chose to use the term “steam titration”, commonly used in our field.

For discussion purposes, the factors identified were classified into five categories: feedwater and steam contaminants, pressure fluctuations, non-condensable gases (NcG), steam dryness and superheating.

DISCUSSION

Feedwater and Steam Contaminants

Contaminants can originate from water or steam contact with supply lines and materials, or during steam generation and transport¹⁰. These substances not only are related to changes in the steam dryness, but can also be toxic, corrosive and create a barrier between microorganisms and the sterilizing agent¹⁰. In practice, there are autoclaves that present with incrustations in the pipeline, in the steam generator and various stains and corrosion both in the chamber and instruments. The risks related to contaminated steam increase according to the length of the path that the steam must travel to reach the autoclave.

Since the level of contaminants in steam can be influenced by the quality of the feedwater^{4,10}, there are specific control recommendations, for example, the technical report n° 34 by the Association for the Advancement of Medical Instrumentation¹² and the standard EN285⁴.

Steam contaminants and their reference values, such as silicates, iron, cadmium, phosphate and conductivity, can be found in NBR ISO 17665-2¹⁰ and EN285⁴ standards, which also describe the test and the sampling method of the condensate for analysis.

Pressure Fluctuations

Some devices are fed with steam through an external source, for example, sterilizers that receives steam from a boiler. The recommendation in such cases is that the autoclave be designed to operate with pressure fluctuations of $\pm 10\%$ of the pressure measured from the inlet to the final pressure reduction valve, at most⁴.

In practice, when the steam supply line also supplies other sectors, such as Nutrition and Diet Service and Laundry, the line pressure may fluctuate, affecting this requirement.

Non-condensable Gases

Non-condensable gases (NcG) are those that “occupy space in the autoclave’s inner chamber”, competing with steam.

Therefore, their presence is a potential failure, as they act as a thermal insulator, compromising the thermocoagulation of proteins and the inactivation of microorganisms^{13,14}. The volume of NcG should not exceed 3.5% or 3.5 mL for every 100 mL of water⁴.

Biological and chemical indicators do not specify the presence of less than 10% of NcG¹⁴. If small amounts (about 1% or more) are present in the chamber, the conditions required for the sterilization process can occur on directly exposed surfaces, but steam penetration into porous materials or narrow channels can be seriously reduced¹⁵.

NcG can also lead to wet loads after the sterilization, which is considered inadmissible⁸. Several factors can contribute to the increase of NcG in the process:

- Presence of NCG in the steam-generation water—NcG dissolved in the water itself, such as CO₂ and O₂, and other water contaminants that can become NcG when heated—and interruption in water supply. In case of NcG from water, a degasser can be installed before the water enters the autoclave steam generator, so that the feedwater reaches specified tolerances⁴;
- Inefficiency at the air removal stage: failure of the pressure measurement system, inadequate programming of the conditioning phase, e.g. inadequately reduced number of vacuum pulses to reduce total cycle time, performance variables in the vacuum pump due to wear or variation in the temperature of the water supply required for the pump to operate;
- NcG coming from the load itself: families of porous products or lumens (details of this variable can be consulted in ABNT NBR ISO 17665-3)¹⁶; indiscriminate use of the sterile barrier system, such as adding spunbond-meltblown-spunbond (SMS) sheets to packages, which results in a more challenging condition than used in performance qualification; presence of volatile chemical agents from the fabric washing process⁴;
- Leakage failure in the steam generator or piping: when the steam is cooled, the volume decreases in such a way that a vacuum forms in the generator and the piping. Thus, if there are leaks or design flaws, there will be unwanted entry of air into the system;
- Chamber tightness failure: perforations caused by corrosion or loose connections, which can commonly occur after trepidation resulting from the operation of the autoclave. Both situations will allow air to enter when the autoclave is in vacuum;

- Failure to seal doors: failure in preventive maintenance, use of gaskets with mountings other than the specified by the manufacturer, mechanical failure in the gasket channel, failure in the autoclave gasket pressure adjustment with pressurized air.

The Bowie and Dick Test (BD) is one of the mostly used to verify the removal of air and NcG. The effectiveness of the BD built by the CSSD staff depends on the correct assembly and conditioning of the package, in accordance with specifications in technical standards^{4,8}.

The commercially available packages have different sensitivities, according to chemical indicators used¹⁷. In the last decade, electronic devices have been introduced to replace the BD penetration test. These devices are equivalent in performance to the original BD test and are currently available in compliance with the requirements of EN ISO 11140-4¹⁸.

A study about the monitoring of steam penetration with the aid of an electronic device was carried out for a year and a half in three sterilizers. The conclusion was that the monitoring of steam penetration should be carried out every cycle and not just in the first cycle of the day¹⁹—which rationally is pertinent due to the randomness of a moment where failures can occur.

The differences between the temperature measured by the sensor positioned at the theoretically coldest point of the chamber (usually, the drain) and the temperature calculated based on chamber pressure may not be adequate to detect small volumes of air concentrated in lumens and internal spaces. Under such circumstances, air removal and steam penetration should be predicted by data obtained from a steam penetration test^{10,20} such as the BD test.

In practice, each steam sterilization cycle should be considered a unique event. Therefore, European standards specify an automated control to detect failures at each cycle, thus reducing human errors⁴. Air detectors can be specified to control each cycle, as they are capable of detecting NcG and cancel cycles in which inadequate removal could compromise safety^{4,17}.

Steam dryness

The steam dryness corresponds to the mass of the gas fraction in the saturated steam mass⁴. It is also referred to as “dryness factor”^{1,8} and “dryness value”¹⁰, being expressed, in general, as a percentage. For example, 95% means there is 5% of moisture in the steam.

Sterilization requires a continuous supply of steam, free from condensate and with a minimum dryness of 97⁸, 95⁴ or 95% to sterilize loads containing metal products and a minimum of 90% to sterilize loads containing textiles¹⁰. Therefore, there is no consensus on the aforementioned standards.

Excessive steam humidity can result in sterilization failure and wet loads, while low humidity can result in sterilization failures due to superheating⁴. Although necessary, accurate measurements of this variable are still difficult nowadays. The EN285 standard describes a test for this purpose, but it should not be considered the actual measurement of the steam moisture content, but a method to demonstrate that the quality of the steam is acceptable⁴. In practice, possible reasons for excessively wet steam can be: inadequate drainage and slope of drains and pipes, steam supply through pipes with stagnant flow and piping without proper insulation between the generator and the autoclave, which causes excessive condensation⁹.

In autoclaves where wet steam becomes a persistent problem, two interrelated phenomena can be the cause. The first is called priming and occurs when the water level in the generator rises due to foam formation, resulting in water droplets and other impurities carried along with steam^{21,22}. The second is foaming, which consists of the formation of bubbles (foam), due to the presence of contaminants in the generator²². Both priming and foaming can be caused by: inadequate treatment of the steam generator feedwater; exceeding water level in the steam generator; generator in need of internal cleaning; violent boiling of water inside the pipes due to small volumes and high amount of total dissolved solids (generally 2,000 ppm)^{8,9}.

Superheated Steam

The microbicidal activity of steam is based on the temperature and duration of contact between water molecules and microorganisms¹⁰. In order for the steam to have a lethal action on microorganisms at the times and temperatures used in the CSSD, the ideal saturation condition must be present, but there is another physical condition of the water when it reaches the gaseous state that also does not allow the heat exchange to promote microbicidal action: superheated steam.

In this condition, steam has a lower density than saturated steam, reaching higher temperatures at the same pressure of the saturation condition. Then, the less efficient heat exchange between the superheated steam and the load is

called sensible heat, the same as in another sterilization technique: dry heat used in ovens. Compared to saturated steam, dry heat requires higher temperatures and contact time, in some cases ranging from 160 and 170°C for periods of 2 to 4 hours²³, or 170°C for 30 minutes^{24,25}—predominantly used in industrial processes.

These conditions contradict the common sense that “the higher the temperature, the shorter the sterilization time”, because the energy exchange in sensible heat has low efficiency compared to the latent heat of saturated steam. Therefore, if saturated steam turns into superheated steam, there will be no condensation in contact with the load, so the effectiveness of heat exchange is reduced.

In practice, superheated steam results in failures in the sterilization process, can damage materials such as rubbers, reduce the useful life of surgical instruments, cause burns, and damage the wrapping used as a sterile barrier⁹, especially pouches, favoring the contamination of the load. As for the factors that can contribute to the steam becoming superheated, the following stand out:

- Storage of natural fiber fabrics, such as cotton, in places with relative humidity below 40%¹⁰. Recommendations are that fabrics that will be submitted to sterilization must be washed shortly before so that the fibers are rehydrated and, consequently, avoid steam superheating⁸. Additionally, manufacturers should be consulted regarding package sizes, dimensions and validated densities for sterilization with saturated steam⁸. In the case of boxes lined with cotton fields or other absorbent products, performance qualification is essential. Services that sterilize cotton fabrics can show dark stains on the fabric, which are similar to burns, especially on the package that is next to the steam inlet of the equipment’s internal chamber. This event is potentially associated with superheating;
- Steam supply lines with excessive pressure reduction, by a valve or other devices restricting the flow of steam in the piping. When this factor is associated with high dryness values prior to pressure reduction, superheating can be significant⁹. This factor can be controlled through engineering devices such as pressure reduction stages along the steam supply line or at the autoclave steam inlet, in addition to controlling the steam transport speed in the supply lines so that it does not exceed 25 m/s¹⁰, the latter being more difficult to scale and control.

In some circumstances, the autoclave detects this type of failure, and one may assess them by means of pressure and temperature values on the cycle tape printout, during the sterilization cycle or at the end of it. According to NBR ISO 17665-2, at a temperature of 134°C the absolute pressure must be 3,042 mBar¹⁰, indicating a probable satisfactory quality of steam. In cases where the temperature displayed by the autoclave control is higher than the corresponding pressure indicated, the steam will potentially be superheated. For example: at 135°C, the corresponding pressure is 3,132 mBar (absolute); however, when there is superheating, the records show 3,132 mBar with incompatible temperatures, such as 133 or 136°C, even considering the uncertainties in the calibration of instruments. The autoclave will not always detect these failures, due to its dynamics of temperature monitoring in the drain, since this is a theoretically “cold” location that could lead to an underestimation of temperatures.

Steam superheating must not reach values above 25°C when compared to the value of boiling water at atmospheric pressure. An apparatus coupled to the steam supply pipeline is used for this measurement, promoting the compression of the steam extracted from the supply line and its expansion at atmospheric pressure to allow the temperature to be measured at that time.

As an example, the temperature of boiling water at sea level is 100°C. The steam will be considered superheated when its temperature is above 100°C, but it cannot exceed 125°C, which is the maximum value tolerated, according to the EN285 standard, under the conditions of the example shown⁴. It is important to emphasize that the temperatures used to exemplify are a parameter for evaluating the quality of steam and not the temperature used to promote microbial inactivation during sterilization. The method, construction and use of the measuring apparatus are described in detail in standard EN285⁴.

FINAL REMARKS

The analysis of the documents helped us to identify that the factors related to steam quality are: feedwater, steam contaminants, network pressure fluctuations, NcG, steam dryness and superheating. Assessing these factors led us to conclude that the safety of steam sterilization should not be reduced to time and temperature control due to the complexity and specificity of factors related to steam quality. Thus, it is recommended that CSSD managers, along with the clinical engineering service, aim to:

- ensure the acquisition of adequate and safe equipment for the CSSD, supported by regulations and technologies based on evidence that demonstrate the impact, effectiveness and safety of processes;
- ensure preventive and predictive maintenance, installation, operation and performance qualifications, as well as establish change control to guide requalification;
- undertake a water quality monitoring program for different uses at the CSSD, with a view to controlling adverse events, preserving equipment, and ensuring optimal operating conditions and steam quality;
- train and supervise CSSD personnel in the proper use of packaging systems and procedures for loading autoclaves;
- invest in staff training, especially for the decision-maker regarding load release, since potential failures can be identified in the printed physical indicator and in load-release devices, which constitute an important verification instrument;
- consider, in risk management, that not all failures in the sterilization process will be merely detected by chemical and biological indicators; therefore, the safety of the process must not be reduced to the results of these devices;
- establish criteria to support the choice of companies for the thermal qualification of autoclaves, considering

the factors presented in this study, since there is no institution responsible for certifying the competence of these companies to date.

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None.

CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

RQO: Conceptualization, Investigation, Writing — original draft, Writing — Review & editing. **SBR:** Conceptualization, Investigation, Writing — original draft, Writing — review & editing. **EAM:** Conceptualization, Investigation, Writing — original draft, Writing — Review & editing. **KUG:** Conceptualization, Investigation, Writing — original draft, Writing — Review & editing.

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