STEAM STERILIZATION: FUNDAMENTAL ASPECTS AND TECHNICAL RESOURCES TO REDUCE WATER CONSUMPTION

Esterilização pelo vapor: aspectos fundamentais e recursos técnicos para redução do consumo de água Esterilización por vapor: fundamentos y recursos técnicos para reduccion del consumo de água

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ABSTRACT: Objective: To discuss the fundamentals of steam sterilization and the technical resources that can be used for a reduction of water consumption in the sterilization process. Method: Review of literature and technical and international standards related to the principles of construction, operation, and use of sterilization equipment by saturated steam under pressure. Results: The reduction in water consumption can be obtained by preferential acquisition of equipment with free water pumps, shutdown of the source of steam-generating power when the equipment is not in use, use of equipment with built-in degassers, assembly of the load in a way to facilitate vapor penetration and reduction of drying time, re-adjustment of the depth of the vacuum to the low time of use of the vacuum pump, and the preventive maintenance of the steam line traps. In addition, a pretreatment system can reduce the waste from reverse osmosis water treatment systems for steam generation. Conclusion: Knowledge of the fundamentals of sterilization by saturated steam under pressure allows an implementation of measures for a reduction of water consumption in the sterilization process. Keywords: Steam. Water. Sterilization.

RESUMO: Objetivo: Discorrer sobre os aspectos fundamentais da esterilização pelo vapor e os recursos técnicos que podem ser utilizados para a redução do consumo de água no processo de esterilização. Método: Revisão da literatura e de normas técnicas nacionais e internacionais relacionadas aos aspectos construtivos, funcionais e de operação de equipamentos de esterilização pelo vapor saturado sob pressão. Resultados: A redução do consumo de água pode ser obtida pela aquisição preferencial de equipamentos com bombas water free, desligamento da fonte geradora de vapor quando o equipamento não estiver em uso, utilização de equipamentos com desgasificadores incorporados, montagem da carga de forma a facilitar a penetração do vapor e a diminuição do tempo de secagem, readequação da profundidade do vácuo para reduzir o tempo de uso da bomba de vácuo e manutenção preventiva dos purgadores da linha de vapor. Adicionalmente, a utilização de sistemas de pré-tratamento pode reduzir o rejeito de sistemas de tratamento de água por osmose reversa para geração de vapor. Conclusão: O conhecimento dos aspectos fundamentais da esterilização pelo vapor saturado sob pressão permite a implementação de medidas para a redução do consumo de água no processo de esterilização. Palavras-chave: Vapor. Água. Esterilização.

RESUMEN: Objetivo: Discurrir sobre los aspectos fundamentales de la esterilización por el vapor y los recursos técnicos que pueden ser utilizados para la reducción del consumo de agua en el proceso de esterilización. Método: Revisión de la literatura y de normas técnicas nacionales e internacionales relacionadas a los aspectos constructivos, funcionales y de operación de equipos de esterilización por el vapor saturado bajo presión. Resultados: La reducción del consumo de agua puede ser obtenida por la adquisición preferencial de equipos con bombas water free, desconexión de la fuente generadora de vapor cuando el equipo no estuviera en uso, utilización de equipos con desgasificadores incorporados, montaje de la carga de forma de facilitar la penetración

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del vapor y la disminución del tiempo de secado, readecuación de la profundidad del vacío para reducir el tiempo de uso de la bomba de vacío y manutención preventiva de los purgadores de la línea de vapor. Adicionalmente, la utilización de sistemas de pre-tratamiento pode reducir el rechazo de sistemas de tratamiento de agua por osmosis reversa para generación de vapor. **Conclusión:** El conocimiento de los aspectos fundamentales de la esterilización por el vapor saturado bajo presión permite la implementación de medidas para la reducción del consumo de agua en el proceso de esterilización. **Palabras clave:** Vapor. Agua. Esterilización.

INTRODUCTION

The basic principle of sterilization by saturated steam under pressure is to allow each product to be exposed to steam at a predetermined temperature, time, and pressure¹. This method of sterilization is widely used by health services for its many advantages for thermoresistant products: it does not form toxic waste, it is easy to control and monitor, it has fast cycles and excellent penetration power in lumens, and sterile barrier systems².

As the process requires water for the generation of steam and for the operation of the vacuum pump or Venturi system, professionals of the Clinical Engineering Service (CES) and the Central Sterile Supply Department (CSSD) need subsidies for the application of technical resources that reduce water consumption – a global trend, in addition to the current water crisis in the state of São Paulo.

Therefore, this review article aims at discussing the fundamental aspects of steam sterilization and the technical resources that can be used to reduce water consumption, in order to support CES and CSSD professionals with the necessary information for the revision of its processes, aiming at the safety and rational use of water, a natural and finite resource.

METHOD

This is a review of literature and national and international technical standards related to the constructive, functional, and operational aspects of sterilization equipment by saturated steam under pressure.

THE MECHANICS OF STEAM STERILIZATION

Saturated steam is considered as one of the best sterilization methods for thermoresistant products because of its ability to destroy bacterial spores in a short period of exposure by rapidly heating the products by heat transfer, which occurs by condensation of the vapor upon contact with the surfaces³.

Nowadays, saturated steam sterilization equipment is found in various shapes and sizes and is used in hospitals, clinics, laboratories, and pharmaceutical industries. Basically, an autoclave consists of a steel chamber, covered by another chamber, with a sealing port at one or both ends (barrier autoclave), with pressure, temperature, and time of exposure as critical process parameters (Figure 1).

The operating cycles of this system vary according to the process; however, they can be summarized in three steps: conditioning, exposure, and drying (Figure 1).

The sterilization process can be performed in vented saturated steam systems (similar to gravitational steam systems, indicated for surface sterilization, not efficient in removing air in density loads and lumens), with forced air removal (a mechanical device forces removal, indicated for the sterilization of density loads and lumens), air–water vapor mixture (air is allowed inside the inner chamber to preserve the integrity of the product, which may be affected by the elevation of temperature, indicated for liquid cycles), water spraying (water is used as a thermal conductor, raising the temperature



Figure 1. Stages of a sterilization cycle of a saturated steam system with forced air removal.

of the product, and is indicated for a cycle in which the sterile barrier can be damaged by steam) and water immersion (similar to the previous one, but the whole load is immersed in water, and is indicated for a cycle in which the product and the sterile barrier may be damaged by the steam)⁴.

In the conditioning phase, the air must be removed from the autoclave. The techniques used to remove air consist of gravitational displacement, mass flow dilution, pressure pulse dilution, high vacuum and gravitational displacement pressure pulses³. Regardless of the technique used, the air must be removed from the chamber for the vapor to be able to penetrate into the load, ensuring sterilization. Knowledge of the systems used to remove air from the chamber is essential, since its operation requires the use of water, both in the conditioning and in the drying phase. Thus, reducing the demand for these systems within the cycles is one of the main measures to reduce water consumption.

In order for the air to be removed from the chamber, a vacuum is required, which is obtained by means of a pump or Venturi system. There are several vacuum pump models and configurations, but they all use a mechanical means to create a centrifugal force to remove air, residual condensate, and steam from inside the inner chamber. The most common model is the water seal, in which the air enters the system composed of a rotor, whose movement of the vanes projects the water to the walls of the system, creating a vacuum zone and, consequently, a ring of water will be formed, which removes air and steam at the same time as it prevents reflux. In this process, the water used to form the ring is also disposed of with the air, condensate or steam, removed from the inner chamber⁵.

Other means of sealing, besides water, can be used, such as oil, which is available in pumps with latest technology, which are deemed water-free.

The vacuum obtained by Venturi systems is not the most efficient and generates greater consumption of water or compressed air. The operation of this system is relatively simple: water enters through a pipe with pressure and velocity, where the diameter is reduced to one-third of the inlet and then is raised again to a diameter larger than that of the inlet. At the point where the diameter is reduced, a small diameter inlet tube connected to the inner chamber (Figure 2) is connected. The difference in pressure generated in this region by the differences in the diameters of the pipes forms a vacuum in this inlet, allowing the removal of air, condensate, and steam from the inner chamber⁶. For equipment with a vacuum pump, the water consumption per sterilization cycle is 150–600 L, according to the model, brand, and size of the autoclave. Autoclaves that use the Venturi system to generate vacuum, whose internal chamber size does not exceed 250 L, can consume up to 700 L of water per cycle.

In the sterilization phase, also known as threshold or exposure stage, air has already been removed from the chamber, which is filled by saturated vapor, and the temperature prescribed for the cycle, generally 121 or 134°C, has been reached. Thus, the product is exposed to this temperature for the time necessary to achieve sterility³.

In the drying step, when the vapor of the inner chamber is exhausted through the vacuum system, drying begins. The residual condensate evaporates due to the reduction of the chamber's internal pressure and the high temperature at which the products and the walls of the chamber are at that moment. Upon reaching the maximum vacuum level, the evaporation rate is reduced due to the low thermal conductivity inside the inner chamber.

REDUCTION OF WATER CONSUMPTION IN STEAM STERILIZATION

During the steam sterilization process, water is used to generate steam and to operate the vacuum pump or Venturi system. Water consumption with the generator in the standby mode is of approximately 20% of the water consumption during the steam generation⁷. Therefore, there will be a reduction in water consumption with the shutdown of the steam-generating source when the equipment is not in use.

In the conditioning phase, one point to be observed is the quality of water for steam generation, which must be free of impurities and non-condensable gases, which will be drawn together with the vapor into the inner chamber, forming a barrier that will prevent the contact of the vapor with the load. This process increases the formation of condensate,



Figure 2. Venturi Vacuum System.

which will require a longer drying time, with a consequent increase in water consumption.

The detection of the presence of non-condensable gases requires the installation of an evaluation system, detailed in the European standard EN285:2009⁷ (Figure 3).

Some autoclave models have already incorporated systems that remove non-condensable gases, known as degassers, which are installed in the water supply line before the steam generator inlet.

As shown above, a critical factor in sterilization by saturated steam under pressure is the level of water contaminants to generate steam. As all technical and legal references indicate this responsibility to the manufacturer, it has become common sense to recommend the use of a reverse osmosis-type water treatment system, which is capable of removing from 90 to 99% of particles, organic matter, and microorganisms in only one processing8. However, the adoption of this system is based only on the final quality of the water, and the actual levels of contaminants in the inlet water and the negative impact that such a system generates on water consumption are not observed, as for each liter of high-quality water generated, 60-90% of the same volume is discarded as waste from the system. Theoretically, the purer the inlet water in the reverse osmosis system, the greater the water savings, which justifies the pretreatment of the water.



1: 50 mL Burette; 2: Temperature measurement system; 3: Funnet With parallel sides; 4: 2000 mL vial; 5: Steam supply inlet; 6: Needle valve; 7: 250 mL graduated cylinder; 8: For the sterilizer; 9: For the purge system. Source: Adapted and translated from the EN285:2009' technical standard.

Figure 3. System for evaluating the concentration of noncondensable gases in the steam.

REV.

Before adopting a water treatment system, it is important to analyze the quality of the water supplied to the autoclave and compare it with the water quality table required for the steam generator feed, contained in the ABNT NBR ISO 17665-2:2013 standard⁹. Based on the result of this analysis, a water treatment system should be scaled.

It should be noted that the water used to generate the steam is different from the water used in the seal of the vacuum pump or the Venturi system. The quality of the water that will generate the steam is controlled, as it directly impacts the quality of the sterilization. Thus, the use of purified water is required. However, the quality of the water used in the vacuum pump seal does not interfere with sterilization, which may only be potable or according to the manufacturer's guidelines.

Another relevant aspect in the conditioning phase is the removal of air from the chamber. The first vacuum pulse is the most time consuming due to the large amount of air in the inner chamber. If the load is too thick or compressed, more time will be required to force the air out of the load, with increased demand for the vacuum system.

Immediately after the first vacuum pulse, steam enters the inner chamber, which will condense on contact with the products, thus heating them. If the medical device is too thick, the condensate volume will be larger, and the second vacuum pulse will be more time consuming due to vaporization of the excess condensate.

That said, measures aimed at reducing the formation of condensate should be implemented, since, by reducing the formation of condensate, there will be less use of the system, with consequent reduction of water consumption.

In the drying phase, all remaining condensates need to be vaporized. The vacuum pump plays a key role in this phase because by reducing the pressure in the inner chamber, a part of the condensate is vaporized as the pressure decreases to the minimum limit established by the manufacturer. Then the process is a bit more time consuming due to the need for other energy sources, such as the residual heat of the sterilized product, thermal radiation from the walls of the inner chamber. These processes are relatively slow due to the inefficiency of thermal transfer under vacuum⁹. The fraction of the mass of condensate remaining after the rapid vaporization afforded by the initial vacuum curve in the initial drying phase is given by the Equation 1¹⁰:

$$=\frac{u_{ini}-h_g}{u_{final}-h_g}$$

(1)

x

In which

x = fraction of the mass of liquid remaining after reaching the vacuum level;

 u_{ini} = internal energy of the saturated liquid at the end of the sterilization phase;

 u_{final} = internal energy of the saturated liquid at the maximum vacuum level;

 h_g = mean enthalpy of saturated steam during the drying phase (mean enthalpy at the end of the sterilization phase and at the maximum vacuum level).

Currently, in identifying wet packs, the solution commonly adopted by professionals is to increase the drying time. This solution is not the most suitable, as one must first observe whether the vacuum plateau is correctly configured per the minimum limit established by the manufacturer. Otherwise, the drying time should be longer to achieve the expected result, which implies higher water consumption. For every minute with the vacuum pump or Venturi system working, the water consumption will be between 10 and 20 L per minute, depending on the equipment and the model.

The adjustments in equipment for product drying need to be reviewed based on the operating mechanics, since the drying efficiency is not tied to the time, but to the depth of the vacuum, in which the technical argument must be to increase the depth of the vacuum instead of increasing the time. The efficiency of the vacuum system is also increased by reducing the temperature of the water passing through the vacuum pump. In countries that adopt EN285:2009⁷, the maximum water temperature should be 15°C, because the viscosity of the water interferes with the performance of vacuum pumps. Following the recommendations presented, users who work with a drying time of more than 15 minutes will have a significant reduction in water consumption. In addition to the depth of the vacuum, there are other measures to avoid wet packs and consequent increase in drying time, such as the placement of concave– convex conformation products in vertical or inclined position¹¹, which prevents condensation from forming in the concavity and facilitates drying, reducing the use of the vacuum pump; use of boxes that do not exceed 11.5 kg, since the excess weight makes drying difficult¹²; and use of sterile barrier systems, perforated boxes and vapor-permeable instrument holders¹², which will consequently facilitate drying. It should be noted that the drying process of products made from polymers will be longer because they do not have the same heat conduction properties as metallic ones such as stainless steel and anodized aluminum.

For the reduction of the use of the vacuum system, the equipment must be kept in optimum operating conditions. Thus, it is necessary to investigate the possible clogging of the drainage channel¹² and proper dimensioning of the steam trap¹³.

CONCLUSION

The reduction of water consumption can be achieved by measures such as preferential acquisition of equipment with water-free pumps, shut-off of the steam generator when equipment is not in use, use of equipment with built-in degassers, assembly of the load in order to facilitate vapor penetration and reduce drying time, vacuum depth adjustment to reduce the use time of the vacuum pump, and preventive maintenance of steam traps. In addition, the use of pretreatment systems can reduce waste in reverse osmosis water treatment systems for steam generation.

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