



## **Steam sterilization: are we applying recent advances in control and validation process?**

### **ABSTRACT**

Currently, sterilization processing is at the dawn of a new era of quality improvement. There are many new technologies demonstrated to be effective that will contribute to improved patient care. The efficiency, reliability, and performance monitoring of modern equipment is continually improving; however, the fundamental process remains essentially the same in most health care settings. This article emphasizes the steam sterilization process commonly available in countries with limited resources because it is a simple, efficient, reliable, fast and inexpensive way to sterilize reusable medical devices. Universally accepted approaches to validation or process approval have been introduced as a suitable standard to measure conformity for which an international standard (ISO) has been published that identifies requirements for sterilization processes. The ISO should provide a format for establishing a common standard for the acceptance or rejection of sterilizing processes. A national guideline defines all the correct processes of sterilization to insure all medical devices are properly processed and safe for reuse on patients by implementing the following: correct cleaning; packaging; loading; proper use of sterilization equipment; monitoring; and storage. Therefore, all health care settings in Libya, should adopt central sterile service department system and all relevant factors must be taken into consideration, including instrument characteristics, design of the load carrier, process controls, water qualities and the computability of washer-disinfector and detergent, as it is the key solution that will increase safety for patients and staff.

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### **INTRODUCTION**

Sterilization, as a specific discipline, has been

with us for over a century, since the invention of the steam autoclave. Since that time, there has been progressive refinement of steam sterilizers. Sterilization processes have been altered by new organisms and resistances, different products to be sterilized and new techniques and methods of practice. Sterilization processes that employ physical agents are preferred because of their

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relative simplicity. In addition, the conditions required to achieve sterility can be closely defined and measured directly (1). Although many sterilization methods have been developed during last century such as ethylene oxide, and hydrogen peroxide gas plasma, each of these technologies has a combination of desirable and undesirable characteristics that can affect materials, assembly methods, adhesives, packaging and shelf life (2). In contrast steam is still the preferred and most cost-effective medium for the sterilization of re-usable medical devices worldwide and especially in limited resources countries. In such countries there is no other process that is more efficient, flexibly employed, easy to monitor and control, non-poisonous and economical. Despite these positive aspects, it would be wrong to think that steam sterilization can be used without a minimum knowledge of how it works and the need for compliance with certain regulations. Guidelines for steam sterilization are laid down in the European standards. This trend has been promoted by the current harmonization of European standards (CEN) and international standards, International Standardization Organization (ISO) (3).

### Microorganisms and sterilization

Most cycles are performed at 134°C, but some cycles are still run at 121°C for materials that cannot withstand the higher temperature. Sterilization has not been modified to cope with new pathologies (for example, AIDS, hepatitis, etc.), new microorganisms (*Legionella*) or new resistances such as methicillin resistant *Staphylococcus aureus* (MRSA) and vancomycin resistant enterococci (VRE). The prion (infectious protein) or non-conventional transmissible agent (NCTA) challenges laws of nature concerning its resistance, duplication and transmission. Extra measures must be applied to inactivate infectious proteins because they are not readily inactivated by conventional

equipment reprocessing methods. According to the EU, items are allowed to be called 'sterile' if the probability of contamination is less than, or equal to,  $10^{-6}$  (EN 556) (4).

### Preparation of instruments to be sterilized

The general aspects of disinfection and sterilization in healthcare facilities have been reviewed recently in detail (5). The decontamination of medical devices is a complex task. Chemical decontamination (pre-disinfection) by soaking in a detergent and disinfectant liquid is now a well-established practice. There are two types of packaging, reusable (containers) and disposable (pouches and sheets). The composition of containers has evolved considerably (composite materials with patterns that facilitate the elimination of condensates). Trays wrapped with sterilization sheets, preferably non-woven, are now preferred because they provide very good steam diffusion.

The development of telesurgery and/or computer-assisted surgery creates real difficulties for the sterilization teams. The equipment required is becoming more complicated and fragile, whereas, in sterilization, robust and dismantable equipment is preferred.

### Steam sterilization

The basic sterilizing cycle has changed little over many years, and the reliability of autoclaves is constantly improving. All have to comply with EN 285 and all the processes are now validated according to EN 554 (6,7). Where change has occurred, it was in response to legislative, regulatory and performance requirements introduced in recent years.

Assessment of sterilization is now performed systematically with the Bowie and Dick test, the analysis of the cycle record and class six

indicators. Data loggers used in each cycle now represent a more frequent alternative, associated or not with an electronic global traceability. The logbook contains all the elements leading to the load release, including the traceability of the steps of pre-disinfection and cleaning.

The high temperatures associated with steam can cause damage and lead to safety concerns. Most plastics cannot withstand high temperatures. Steam can corrode surgical alloys and cutting edges. Chrome stainless-steel surgical blades and other related devices have developed pitting and dulling of the cutting edges after multiple steam sterilization cycles. Low-temperature gas plasma is generally compatible with most materials used in medical devices (8). In Libyan healthcare settings, the use of steam continues to be the preferred and cost-effective medium for the sterilization of reusable medical devices.

### Implementation

The hospitals in Libya should designate well trained qualified personnel responsible for supplying, preparing, distributing and managing the sterile medical devices. The authorization of any activity in sterilization, from cleaning to storage, is required. A guide to good sterilization practices, defining how to perform sterilization from beginning to end, should be available for implementing quality assurance: procedures from the use of the instrument to its storage; the necessity of validation of every sterilization process; staff education; core training and regular updating.

The development of more complex instruments for use in minimally invasive surgery has resulted in more cleaning and disinfection challenges, therefore cleaning plays an immensely important role in this process. The majority of our hospitals adopted manual cleaning, using low quality detergents/cleaning agents and brushes. Above all water quality is essential and has a great influence on the

result of the cleaning process. Quality control in cleaning is currently a topic that is heavily under review and various test methods are being developed in order to verify the adequate cleaning. According to the new standard for automatic washer/disinfectors (ISO 15883) the cleaning performance has to be validated for each type of load. This resulted in the development of standard test soils and process challenge devices for cleaning process.

ISO 17665 describes the requirements for ensuring that the activities associated with the process of moist heat sterilization are performed properly (9). These activities are described in documented work programmes designed to demonstrate that the moist heat sterilization process consistently yields sterile products on treatment with process variables falling within the predetermined limits. Compliance with the requirements ensures this process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after sterilization. Specification of this probability is a matter to be handled by regulatory authorities and can vary from country to country.

The effectiveness of steam sterilization is monitored with a biological indicator containing spores of *Bacillus stearothermophilus*. Positive spore test results are a relatively rare event (10) and can be attributed to operator error, inadequate steam delivery (11), or equipment malfunction. Biological indicators are now defined in ISO 14937 as organisms possessing a greater resistance to the sterilizing agent than the intrinsic bioburden of the product to be sterilized, irrespective of species or form (3,12). Currently, no Libyan hospital is using a biological indicator, wireless loggers nor Boie and Dick test for routine monitoring and to validate the performance of the steam sterilizer according to ISO 17665. Libyan hospitals rely on traditional process indicators such as tapes. In addition, none of the hospitals is using chemical

integrated indicators to verify sterilization conditions at the point of placement in order to achieve sufficient exposure to the three critical components namely, steam, time, and temperature.

## CONCLUSION

Hospitals are increasingly pressured to carry out sterilization procedures on complex materials such as cameras, fiber optic cables, and rigid endoscopes. Sterilization process becomes more challenging. There is a need for safer methods of sterilization that are suitable for these heat-sensitive items. When properly used, steam sterilization can ensure the safe use of invasive and non-invasive medical devices, provided that there is strict adherence to the guidelines for the process.

A national guide line for sterilization practices should be introduced to all Libyan healthcare sectors: defining performance and monitoring of the process of sterilization; implementation of quality assurance; and validation of every sterilization process, from the use of the instrument to its storage. Adopting central sterile service department system is the key solution that will increase safety for patients and staff, and producing sterilization standards for use in all hospitals will take time; therefore, we should try to apply the international standards and guidelines to the currently used procedures and equipment as initial steps to improve the quality of patient care.

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