Safeguarding public health

MHRA

Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee (the MAC manual)

Part 1 Principles

3rd edition May 2010

Medicines and Healthcare products Regulatory Agency

3 Sterilization

3.1 Steam

<table>
<tr><td>Process</td><td>The process of steam sterilization requires direct contact between the material being sterilized and pure dry saturated steam at the required temperature for the required time in the absence of air. The recommended combinations of time and temperature given in HTM 2010, Part 3 are listed below (NB: This document will be superseded following the revision of the Hospital Technical Memorandum series of documents):
<table>
<tr><td>Sterilization temperature (°C)</td><td>115</td><td>121</td><td>126</td><td>134</td></tr>
<tr><td>Max allowable temperature (°C)</td><td>118</td><td>124</td><td>129</td><td>137</td></tr>
<tr><td>Minimum holding time (minutes)</td><td>30</td><td>15</td><td>10</td><td>3</td></tr>
</table>
The higher temperature of 134°C for 3 minutes is preferred for devices that will withstand this temperature and associated pressure.

In the simplest steam sterilization cycle, air is removed by displacement with steam (Type N). This limits the use of such machines to sterilization of unwrapped, nonporous clean items only. It is unsuitable for sterilizing the lumens of tubular devices.

Porous load sterilizers (Type B) have an operating cycle which incorporates a vacuum-assisted air removal stage prior to steam admission and they require a consistent supply of steam of suitable quality. For sterilization of wrapped goods the residual gas (the remaining air and gasses carried in the steam after the air removal stage) must not exceed 3.5ml per 100ml of condensed steam. An air detector is incorporated to monitor the adequacy of the air removal process.

Guidance on the purchase, operation and maintenance of benchtop steam sterilizers, DB 2002(06) published by the MHRA [7].

High vacuum porous load sterilizers are used in Sterile Service Departments. (SSDs). Where possible, the facilities of an SSD are preferable to local processing</td></tr>
<tr><td>Spectrum</td><td>Under optimal conditions, steam sterilization is effective with a significant safety factor, against all micro-organisms. Steam sterilization inactivates viruses, vegetative bacteria and their heat-resistant spore forms. There is some debate as to the reliability of this process for inactivating prion protein (see SN 2002(11) [8]).</td></tr>
<tr><td>Preferred uses</td><td>Steam sterilization is the established method of choice for sterilization in health services. It is commonly applied as a terminal sterilization process for previously cleaned items. It also has practical use as a decontamination process to enable safe handling or disposal of contaminated items. It may be applied to wrapped or unwrapped items, although care must be taken to use the type of sterilizer which has been designed and validated for the particular load. Appropriate care must be taken in loading the sterilizers to ensure optimal sterilizing conditions.</td></tr>
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Exclusions	• Devices comprising any material, e.g. thermolabile plastics and fibreoptic endoscopes, which will not withstand exposure to temperatures of 121– 138 °C for the appropriate period at pressure greater than atmospheric. • Gravity feed steam sterilizers (type N) for unwrapped instruments and utensils are not suitable for porous loads or wrapped goods. Devices with narrow lumens should not be processed in sterilizers of this type unless a pre-vacuum is drawn and the autoclave manufacturer's recommendations are followed (a type B machine should be used). Devices with narrow lumens should not be wrapped.
Advantages	Steam is a non-toxic, non-corrosive and highly effective sterilizing agent. The steam sterilization cycle is controlled by physical parameters and can therefore be used as a rapid and fully automatic process. In the event of a machine/process failure the cycle is stopped and an alarm sounded.
Disadvantages	• The quality of steam for sterilization is critical. For larger machines a limiting factor may be the requirement for mains steam and the performance of the steam boiler. Guidance is given in HTM2031. • For smaller benchtop machines, water of at least Water for Irrigation BP standard is required. The reservoir must be emptied at least daily and left dry overnight. • The operator must wear suitable protection to avoid direct contact with excessively hot loads. Pipes should be lagged.
Safety notes	• Steam at any pressure is hazardous. The design and use of steam sterilizers have to meet the Pressure Equipment Regulations (1999) and the Pressure Systems Safety Regulations (2000) (PSSR). The PSSR require the pressure system to be inspected periodically to ensure its safety. The Provision and Use of Equipment Regulations (1998) (PUWER) require the operator to be trained adequately. • Sterilizers intended for reprocessing reusable medical devices are regulated under the Medical Devices Regulations (MDR). Sterilizers placed on the market under the MDR have to meet the Essential Requirements of performance and safety. • For devices infected with dangerous pathogens in Hazard Group 4 (ACDP, 1990), additional precautions are needed in the design of the sterilizer's drainage and ventilation systems to protect users and the environment.