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

Contents

Acknowledgements

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Foreword

This document was developed to provide guidance on disinfection and sterilization practices for application in the health service. It is not intended to replace the reprocessing instructions provided by manufacturers of CE marked, reusable medical devices. Part 3, (Section 1) of this manual has details of the information to be provided by manufacturers.

This document is not intended as a replacement for the detailed publications that it cites and from which it draws information.

The manual has been published in three parts:

- Part 1: describing the general **principles** of the processes that are available for decontamination. First published 1993; revised 2002.
- Part 2: containing **protocols** for decontamination using cleaning, disinfection and sterilization processes. First published 1996; revised 2005.
- Part 3: describing **procedures** for the decontamination of specific items of equipment, published in 2 Sections. First published 1999 (section 1) and 2000 (section 2); revised 2006.

The guidance in Part 1 of this document is particularly tailored to the needs of infection control doctors, infection control nurses and sterile services managers but it is hoped that it will be of assistance to other groups.

Misuse of terms is a particular problem that besets this subject and for that reason a glossary of terms is included.

All personnel advising on, or performing, decontamination procedures should be aware of the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations (2002) [1]. These Regulations require all employees to assess the risks from exposures to hazardous substances and the precautions needed to prevent or adequately control exposure. There are also requirements for providing information, instruction and training and, in some cases, for monitoring exposure and for health surveillance.

Introduction

The consequences of a failed sterilization process may not be immediately obvious; but, when healthcare associated infection due to spore forming organisms occurs, the sterilization process is often the first object of investigation. In the case of disinfection, however, the consequences of failure are well documented.

There have been many changes in decontamination methods during the last 20 to 30 years including the development of automatic high pressure autoclaves. While for most of the decontamination methods available the engineering and microbiological testing methods are well understood, practice in some hospitals and healthcare settings has not always been ideal. As early as 1958, the inefficient performance in 9 of 25 autoclaves was examined [2]. More recent work indicated that hospitals still experience problems with decontamination procedures [3].

The need for scrupulous attention to decontamination procedures has been highlighted for the medical and dental professions as well as the public due to incidents of transmission of viral infections including HIV and hepatitis B and C (Cowen 1991 [4], Cowen 2001 [5]).

Abnormal prion protein
Current Department of Health guidance advises that cleaning is of the utmost importance in minimising the risk of transmitting this agent between patients via surgical instruments. Further details are available in HSC 1999/178 [6] and HSC 2000/032 [3].

Problems may arise at all stages of the decontamination process, from the choice of the appropriate method for a piece of equipment, through plant maintenance, engineering and microbiological monitoring, to post-decontamination storage and handling. Individuals from a wide variety of disciplines may be responsible for different aspects of the decontamination processes (Figure 1).

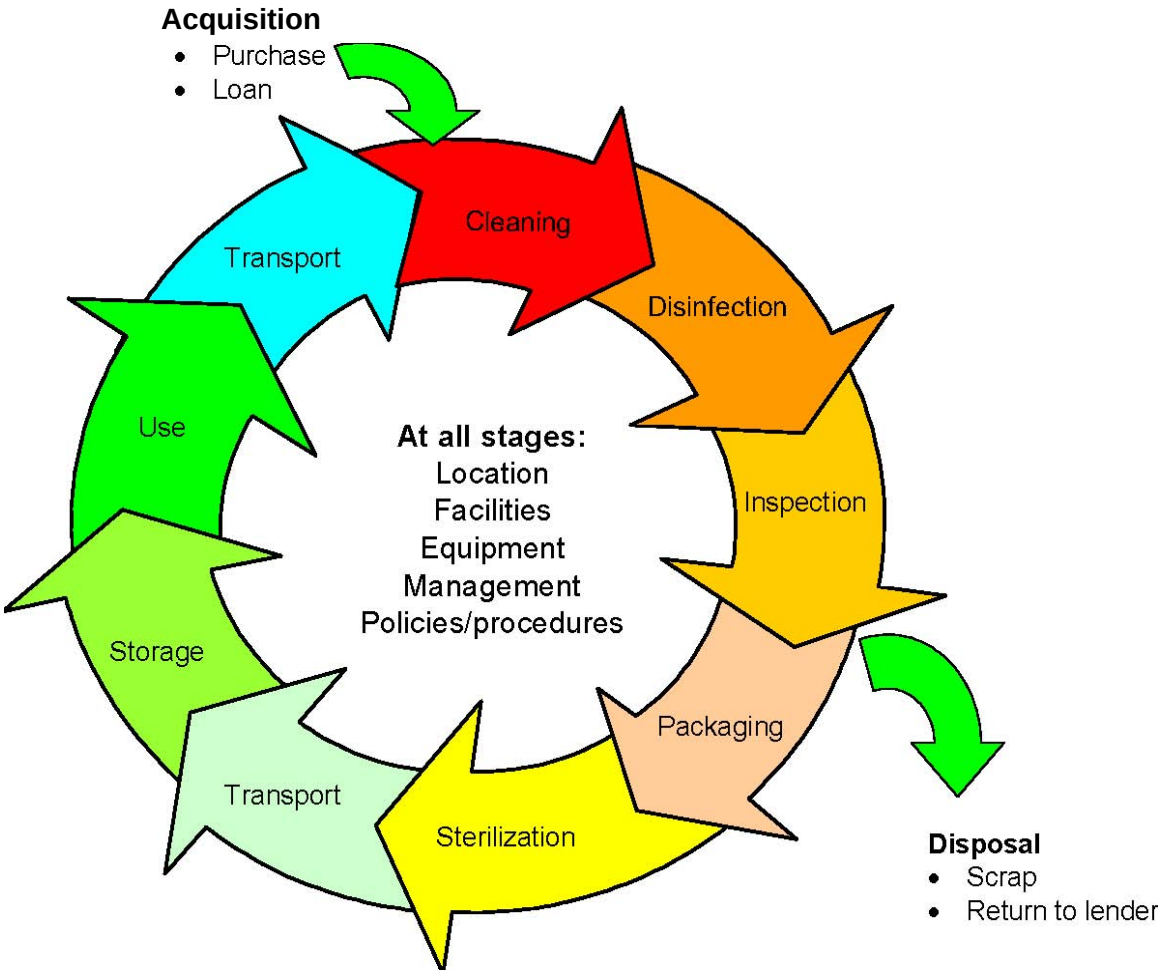

Figure 1 Work flow chart – decontamination life cycle

Since the previous edition of this guidance a major and ongoing revision of the Hospital Technical Memorandum series of documents (HTMs) has taken place.

The HTM 01 series will be published by the Department of Health (DH) and provide technical guidance on aspects of decontamination and the health care environment.

HTM 01 Decontamination is subdivided into the following volumes:
HTM01-01 Decontamination of reusable medical devices
HTM01-02 Decontamination of laboratory equipment
HTM01-03 Decontamination in pharmacy
HTM01-04 Laundry
HTM01-05 Dentistry
HTM01-06 Flexible endoscopes
HTM01-07 Primary care.

The choice of decontamination method may be related to the infection risk associated with the intended use of the equipment (Table 1).

Table 1: Classification of infection risk associated with the decontamination of medical devices

Risk	Application of item	Recommendation
High	• in close contact with a break in the skin or mucous membrane • introduced into sterile body areas.	Sterilization.
Intermediate	• in contact with mucous membranes • contaminated with particularly virulent or readily transmissible organisms • prior to use on immunocompromised patients.	Sterilization or disinfection required. Cleaning may be acceptable in some agreed evidence based situations.
Low	• in contact with healthy skin • not in contact with patient.	Cleaning.

Advice on decontamination is already available in a number of documents. The aim of this publication is to bring this advice together in a format that can be updated and in a way which will provide easily accessible information to healthcare workers. They can then provide the high standards of decontamination required by modern medical and surgical practice.

The choice of decontamination method will also depend on many other factors including the nature of the contamination, the time required for processing, the heat, pressure, moisture and chemical tolerance of the object, the availability of the processing equipment and the quality and risks associated with the decontamination method. Details of these limitations are given in Sections 2, 3 and 4. Table 2 summarises the microbicidal activity of current, readily available decontamination methods. Cleaning is not included in the table as it physically removes infectious agents without necessarily destroying them.

Table 2: Microbicidal activity of decontamination methods

	Spores	Mycobacteria	Bacteria	Viruses
Thermal washer-disinfector	X	✓✓✓	✓✓✓	✓✓
Low temperature steam	X	✓✓✓	✓✓✓	✓✓
Chemical disinfectant	See Section 2.3, Table 3			
Steam	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Dry heat	✓	✓	✓	✓
Gas plasma/activated hydrogen peroxide	✓✓✓	✓✓✓	✓✓✓	✓✓✓

Key: X None ✓ Poor ✓✓ Moderate ✓✓✓ Good

Glossary

Abnormal prion protein
A form of protein thought to be the causative agent of transmissible spongiform encephalopathies (TSEs) e.g. Creutzfeldt-Jakob disease (CJD). The protein is remarkably resistant to conventional methods of disinfection and sterilization.

Automated endoscope reprocessor (AER)
An AER is a machine intended for the decontamination of endoscopes. The AER will have a disinfection phase and may also include a washing phase prior to the disinfection cycle. Many AERs have integrated fume extraction systems.

Bioburden
The population of viable infectious agents contaminating a medical device.

Cleaning
A process which physically removes infectious agents and the organic matter on which they thrive but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite to ensure effective disinfection or sterilization.

Contamination
The soiling or pollution of inanimate objects or living material with harmful, potentially infectious or other unwanted material. In the clinical situation, this is most likely to be organic matter and infectious agents but may also include other undesirable substances e.g. chemical residues, radioactive material, degradation products, packaging materials etc. Such contamination may have an adverse effect on the function of a medical device and may be transferred to a person during use or subsequent processing and storage.

Decontamination
A process which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are used depending on the device and the procedure involved. The levels of decontamination are:

- cleaning
- cleaning followed by disinfection
- cleaning followed by sterilization.

Disinfectant
A chemical agent which under defined conditions is capable of disinfection.

Disinfection
A process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilization.

High level disinfectant
A liquid chemical agent that can kill bacteria, viruses and spores. It is only sporicidal under certain conditions.

Infectious agents
The term includes micro-organisms and other transmissible agents e.g. abnormal prion proteins.

Single-use device
A medical device which is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be re-processed and used on another patient. The labelling identifies the device as disposable and not intended to be re-processed and used again..

Sporicide
A chemical agent which under defined conditions is capable of killing bacterial spores.

Sterilant
A liquid chemical agent which can kill bacteria, viruses and spores. However this term is not precise and should not be used. The term high level disinfectant is preferred.

Sterile
Free from viable microorganisms.

Sterile Service Department (SSD)
A centralised department specifically designed to reprocess re-usable medical devices and equipment and to distribute pre-sterilized, commercially prepared packages for clinical use.

Sterilization
A validated process used to render a product free from viable microorganisms (BS EN ISO 14937:2009)

Note: In a sterilization process, the nature of microbial inactivation is exponential, and the survival of a microorganism on an individual item can thus be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

Washer-disinfector
An automated machine intended to clean and disinfect medical devices

1 Cleaning

Cleaning is an essential prerequisite of equipment decontamination to ensure effective disinfection or sterilization. The process may be combined with chemical disinfection. The process must not be used for items intended for single-use only.

Process	• Cleaning removes soil and a high proportion of infectious agents by washing with a solvent (usually water and detergent) which may be heated. Cleaning can be achieved by either manual or automated methods. • Manual cleaning of items should only be undertaken when automated methods are inappropriate or unavailable. Automated cleaning is a controlled process that will provide more consistent results. Further details of automated cleaning and, in particular, the thermal disinfection aspects are given in section 2. • The use of ultrasonic baths and enzyme detergent solutions for cleaning devices is recommended where the process is compatible with the device. It should be noted that all lumens should be irrigated during ultrasonic cleaning to remove dislodged organic matter. Irrigation pumps are available for flushing instrument lumens and components. • Effective cleaning is an essential prerequisite to all subsequent methods of decontamination. • Where possible the process should be validated to ensure consistency.
Spectrum	The process is broad-spectrum in action and will reduce the bioburden. The effectiveness of the cleaning process is limited by the nature of the soil, its accessibility and the vulnerability of the infectious agents to the process.
Preferred uses	Cleaning has a wide application for the decontamination of environmental (walls, floors, furniture and fittings) and equipment surfaces including devices and other items in contact with healthy skin.
Exclusions	• Cleaning is not acceptable as the sole or terminal process for invasive equipment for which disinfection or sterilization is required. • **The process must not be used for items intended for single use only.**
Advantages	The process is relatively cheap and safe for the operator. It does not require expensive processing equipment.
Disadvantages	• Manual processes require a high level of training and are time consuming. There are risks associated with the handling of contaminated items. • Manual processes are almost impossible to validate adequately. This means that the method is inherently unreliable
Safety notes	• Care should be taken in the direct handling of intricate or sharp-edged devices to avoid injury to the handler or damage to the device. A waterproof protective apron or gown and robust waterproof gloves should be worn. Eye protection may be required if splashing is likely to occur. A risk assessment, under the Control of Substances Hazardous to Health (COSHH) Regulations, will have to be undertaken before a procedure can be used. • The production of aerosols during the cleaning process and the provision of adequate protective equipment should be considered as part of the risk assessment.

2 Disinfection

2.1 Thermal washer-disinfectors

Process	Thermal washer-disinfectors use a combination of physical cleaning and thermal microbicidal action to achieve disinfection of contaminated reusable items. This can either be as a process prior to reuse or to make items safe to handle before further reprocessing.
Spectrum	• Disinfection with thermal washer-disinfectors will inactivate all microorganisms except bacterial spores, some heat-resistant viruses and cryptosporidium. • Abnormal prion proteins are not inactivated by this process unless a suitable detergent is involved
Preferred uses	This process can be used only for devices that will withstand repeated exposure to wet heat at temperatures of about 80°C. The devices must be sufficiently robust to withstand powerful water jets and be compatible with the detergents.
Exclusions	• **This process must not be used for items intended for single use only.** • Also excluded are hollow or porous items where the hot water will not adequately penetrate any internal lumen unless special adaptors to allow access to lumens are available. • This process does not sterilize but items may be sterilized subsequently by an appropriate process.
Advantages	The process is safe for the operator. In addition, there is good disinfection of items by cleaning and heat and involves minimal handling of contaminated instruments by staff. The process that may combine cleaning and disinfection can be validated and should produce consistent results.
Disadvantages	The equipment has a high initial cost and requires adequately trained staff to operate and load the machine correctly. Planned preventative maintenance costs may be high and will include routine thermometric monitoring. The process may need water of a specified quality both to disinfect and then to rinse disinfected devices.
Safety notes	Detergents may be an irritant when allowed to come into contact with the skin or mucous membranes. A risk assessment, under the Control of Substances Hazards to Health (COSHH) Regulations, will have to be undertaken before a procedure can be used (see also Part 2 – Protocols, appendix 2 ‘Instrument disinfectants: properties at room temperature’)

2.2 Low temperature steam

Process	• Devices to be treated are placed in the chamber of an automatically controlled disinfector under conditions that ensure the removal of air and subsequent exposure to steam on every surface and part of the device concerned. • Typical conditions are exposure to saturated steam below atmospheric pressure at 73°C for a period of not less than 10 minutes.
Spectrum	The process kills vegetative micro-organisms and some heat-sensitive viruses. It disinfects but does not sterilize. Abnormal prion proteins are not inactivated by this process unless a suitable detergent is involved
Preferred uses	Items and materials not damaged by the conditions of the process are suitable, provided that air removal and subsequent steam penetration are assured.
Exclusions	• Sealed, oily or greasy items, or those with retained air are unsuitable, as are those liable to damage by the conditions of heat, moisture and pressure variation involved. • This process is unsuitable for items requiring sterilization and objects likely to be contaminated by bacterial spores or other agents of similar resistance to heat.
Advantages	This is a physical process under automatic control capable of reproducible and recordable performance to specified parameters. Machine and processing faults are automatically detected and signalled and the process is stopped. The process has a broad-spectrum of disinfection action, is non-toxic and non-corrosive.
Disadvantages	It must be carried out by a trained operator, and there is a range of exclusions. The capital cost of the equipment is considerable, and it needs regular and skilled maintenance. The equipment is fixed and requires considerable amounts of steam power and water as well as insulation to contain noise and heat.
Safety notes	Low temperature steam disinfectors and components such as chambers, electrical fittings, pipework and instruments are covered by current standards. Operators must be given appropriate courses of instruction and training. Declared machine faults and recorded deviations require immediate investigation and correction by skilled engineers including the manufacturer, if necessary. Manufacturer‘s instructions must be followed.

2.3 Chemical disinfectants

A chemical disinfectant is a compound or mixture which, under defined conditions, is capable of destroying micro-organisms by chemical or physico-chemical means. It is usually in the form of a liquid, and occasionally a gas. Disinfectants can be supplied ready for use or may need accurate dilution to an appropriate in-use strength. Disinfectants vary in their properties, making the correct choice of a disinfectant for a specific task in a particular set of circumstances important.

Physical cleaning of the device prior to chemical disinfection should always be carried out as this:

- lowers the microbial challenge (bioburden) to the disinfectant
- removes barriers to disinfectant penetration
- removes substances that may inactivate the disinfectant e.g. protein residues.

Care must be taken that cleaning solutions and materials do not themselves inactivate the disinfectant or react dangerously.

Chemical disinfectants can be used in combination with other methods of killing or removing micro-organisms such as heat and cleaning. These can be sufficiently complementary to achieve sterilization or may just increase the degree of microbial elimination given in Table 3.

Process	• The process of disinfection is the use of a chosen disinfectant, at the specified concentration with good contact between the disinfectant and the device for the specified minimum time, to disinfect the device being processed. • Some disinfectants contain surfactants and may be used for combined cleaning and disinfecting but devices should be cleaned thoroughly before immersion in a disinfectant. • If a disinfectant is used all residues should be removed before the device is • Reused. Care should be taken when rinsing to ensure that devices are not recontaminated.
Spectrum	Most disinfectants are capable of eliminating Gram-positive and Gram-negative vegetative bacteria and enveloped viruses (sometimes referred to as lipophilic or hydrophobic viruses). Sequentially less easily eliminated targets are: • non-enveloped viruses (sometimes called hydrophilic viruses); • mycobacteria (particularly the slower growing atypical mycobacteria); • protozoan cysts and bacterial endospores. A summary of the microbicidal activity of selected chemical disinfectants is given in Table 3. Specified disinfectants may have activity against abnormal prion proteins
Preferred uses	• Chemical disinfection must always be considered with a particular aim in mind and not as a routine housekeeping procedure. • It is not a substitute for sterilization and is not as effective as heat • disinfection. • The selection of the disinfectant used is governed by the type and amount of soiling, the compatibility of the disinfectant with the device and the required spectrum of activity.

Exclusions	Chemical disinfection must not be used where sterilization or heat disinfection methods, or the use of single-use items, would be more appropriate.
Advantages	• Chemical disinfection is used mainly to reduce the infection risk from equipment that would be damaged by the temperatures used in the more readily available sterilization processes or by more effective methods of heat disinfection. It allows relatively convenient and rapid decontamination without high financial outlay on equipment. It is usually an inherently mobile decontamination method and can readily be used outside as well as within hospitals. • Mechanical processes that can be properly validated should always be preferred.
Disadvantages	Disinfection, by definition, does not guarantee a sterile product; as such it cannot be used for surgically invasive devices which are required to be free of all microbial contamination and abnormal prion proteins. Chemical disinfectants can be toxic, flammable, corrosive or have other material incompatibilities. Various factors can result in the failure of chemical disinfection. These include: • innate microbial resistance • inactivation of the disinfectant by dilution • inappropriate storage of the disinfectant resulting in loss of efficacy, particularly at elevated temperature; • inactivation by a wide variety of substances (e.g. blood and other body fluids, wood, cork, plastics, rubbers and some inorganic chemicals) • physical protection of the micro-organisms as some disinfectants act as a tissue fixative. Under certain circumstances chemical disinfectants may also support microbial growth. The use of chemical disinfectants may also present problems in relation to their disposal and potential pollution. Incompatibility between the disinfectant and the device, or parts of it, may result in damage. The manufacturer's guidelines must be followed. Chemical disinfectants e.g. alcohols and aldehydes may fix prion protein onto surfaces
Safety notes	Chemical disinfectants are often toxic to skin, mucous membrane and/or by vapour inhalation. They may also be corrosive and flammable. The Control of Substances Hazardous to Health (COSHH) Regulations require a risk assessment to be undertaken before a disinfectant can be used.

Table 3: Microbicidal activity of chemical disinfectants

Disinfectant	Spores	Mycobacteria	Bacteria	Viruses
Alcohol	X	✓✓	✓✓✓	✓✓
ortho-phthalaldehyde [1]	✓*	✓✓✓	✓✓✓	✓✓✓
Other aldehydes**, [1]	✓*	✓✓✓	✓✓✓	✓✓✓
Chlorine dioxide	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Peracetic acid**	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Other peroxygen compounds**	X	✓	✓✓✓	✓✓
QACs**	X	✓✓	✓✓	✓✓
Superoxidized saline	✓✓✓	✓✓✓	✓✓✓	✓✓✓

Key: X None ✓ Poor ✓✓ Moderate ✓✓✓ Good

1. Aldehydes are potent fixatives of protein, including prion protein

* The sporicidal activity of aldehydes is increased with extended contact times e.g. greater than 3 hours.
** The activity of other aldehydes e.g. succine dialdehyde, peroxygen compounds and QACs (Quaternary Ammonium Compounds) varies with concentration.

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>
</table>

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.

3.2 Dry heat (hot air)

Note: Dry heat (hot air) is not recommended for use in a hospital environment as it is difficult to control the process (see SN 2002(02) [9]).

Process	Dry heat sterilizers offer a satisfactory method of sterilization, provided that the load is exposed to one of the following time temperature relationships, (HTM 2010 Part 3, NHS Estates): • 160 to 170 °C for 120 minutes • 170 to 180 °C for 60 minutes • 180 to 190 °C for 30 minutes The sterilizer should have an automatic controller to ensure that: • the appropriate temperatures are achieved throughout the load and are maintained for the duration of the sterilizing time • appropriate safeguards operate to prevent normal access to a load in the event of the cycle failing, to reduce the possibility of non-sterile product being used • the holding time starts only when every item in the load (not the air in the sterilizer) has reached the sterilizing temperature. It is also important for the user to understand that the holding time is not the total cycle time. The total cycle time includes: • the time required for every item of the load to reach the sterilizing temperature, which can vary considerably and depends on the composition of the load • the holding time, which is the time for which the load must be held at the sterilizing temperature the cooling time, which is the time taken by the load to cool to a temperature at which the operator can remove items from the sterilizer safely.
Spectrum	• The efficacy of dry heat sterilization depends on the initial moisture of the microbial cells. • Compared with moist heat sterilization, dry heat sterilization is inefficient.
Preferred uses	The main advantage of dry heat sterilization is its ability to treat: • solids • non-aqueous liquids, grease/ointments • closed containers • items which could be damaged by steam or moist heat.
Exclusions	This process is not to be used for aqueous fluids or materials that are denatured or damaged at 160°C (e.g. intravenous fluids, glycerol/water mixtures, rubber, plastics).
Advantages	• Dry heat is a useful method for sterilizing heat stable powders, waxes and non-aqueous liquids. Non-aqueous liquids include white soft paraffin, paraffin gauze dressings, eye ointment bases, oily injections, silicone lubricant and pure glycerol. • Dry heat is a suitable method of sterilization for non-stainless metals and all glass syringes.
Disadvantages	• The heat-up time varies widely with load volume and the type of material and is slow. Powders and oils have very long penetration times because they are poor conductors of heat. This means that loads must contain similar types and quantities of materials with the particular process validated. • The sterilization time is long and additional time is required for the items to cool to room temperature prior to use. Items must be able to withstand at least 160°C for periods of 2 hours or more.
Safety notes	Items should not be removed from the oven unless heat protective gloves are worn. The contents may be very hot. Items must be allowed to cool before use.

3.3 Gas plasma/hydrogen peroxide

Process	• Gas plasma is a highly active gas containing ions and molecules and free radicals that are capable of inactivating micro-organisms. It is a complicated process that has been developed and adapted for the sterilization of medical devices. • The most well known of these systems uses a low temperature (<50°C) hydrogen peroxide gas plasma.
Spectrum	There is a broad-spectrum of activity against vegetative bacteria, bacterial spores, fungi and viruses.
Preferred uses	Instruments such as flexible and rigid endoscopes may be processed using this method but it is important to note that special adaptors are required for use with lumened devices due to the inability of the sterilant to readily access these areas (see Exclusions below).
Exclusions	Compatibility of the process with specific devices should be checked with the manufacturer of the device and the manufacturer's instructions must be followed. Devices with very long lumens should not be processed with this method.
Advantages	Typically, the entire cycle takes 75 minutes.
Disadvantages	Instruments need to be dry and can only be packaged in specially designed packaging.
Safety notes	No toxic emissions or residues are said to result from the process.

4 Use of chemical and biological indicators

If the sterilizer's controller indicates a failed operating cycle, the cycle must be regarded as unsatisfactory, regardless of the results obtained from any chemical or biological indicators.

Chemical indicators and biological indicators do not indicate that the load is sterile.

4.1 Chemical indicators

Chemical indicators should meet the requirements of relevant European and international standards and they should be used only for the process specified by the manufacturer.

Chemical indicators are designed to show a defined colour change when specified conditions have been attained and should only be used to supplement definitive thermometric results.

The selected indicator should be the correct one for the process and the manufacturer’s recommended instructions, both for use and storage, should be followed. The use of an inappropriate indicator may give dangerously misleading results; indicator performance can be adversely affected by the storage conditions before use, the methods of use, and storage conditions after use.

Indicators should not be used beyond the expiry date stated by the manufacturer. Three types of chemical indicator are commonly used in steam sterilizers:

- **process indicators** e.g. autoclave tape and indicators printed onto bags and pouches. These indicators serve only to distinguish processed items from unprocessed items, and should not be used for any other purpose;
- **performance indicators** for specific tests e.g. the indicators used to check the effectiveness of steam penetration into a test pack or a process challenge device;
- **integrating indicators** (emulating integrators) are available for monitoring steam sterilizers. They are designed to monitor the attainment of two, or more, critical variables in the sterilization process, either by a graduated response or a defined end point reaction.

Integrating indicators do not indicate sterility of the product.

4.2 Biological indicators

Biological indicators must meet the requirements of EN 866. They are of limited value in steam sterilization and are restricted to a few special applications in process validation. In those applications they should always be regarded as additional to the measurement of temperature, pressure and time.

Biological indicators should not be used for periodic testing of steam sterilizers or for the routine monitoring of the process.

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