# Contents

## Acknowledgements


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## Introduction

**Section 1** provides an overview of what the European Directives for medical devices mean for users. In particular, the implications of the Medical Devices Directive for those carrying out reprocessing activities will be reviewed, both in terms of self declaration of compliance with the Regulations and the information reprocessors may expect to be provided with by manufacturers of CE marked, reusable devices.

**Section 2** provides general procedures for the following groups of equipment:

- endoscopes and accessories
- dental equipment
- ophthalmic equipment
- surgical instruments
- ventilators
- miscellaneous items.

These procedures are a general guide that users may find particularly useful for older devices for which no re-processing instructions are available.

However, you are reminded to seek advice from device and equipment manufacturers on the suitability of agents and processes used for decontamination.

This section is not intended as a replacement for instructions provided by device and equipment manufacturers.

Reusable CE marked devices should be provided with re-processing instructions (see 5.0 below). If users have concerns over the suitability of the method recommended by the manufacturer for the decontamination of a medical device, they should initially approach the manufacturer for further information and then, if necessary, raise the issue with the Medicines and Healthcare products Regulatory Agency (MHRA). Users' attention is also drawn to the guidance contained in Health Service Circular HSC 1999/179, Controls assurance in infection control: decontamination of medical devices [1]. This circular emphasises the importance of implementing existing guidance on the decontamination of medical devices and equipment issued by the Department of Health in reducing the risk of transmission of infectious agents.

Users should be aware that all chemical solutions and the environment they are used in must be assessed with regard to Control of Substances Hazardous to Health (COSHH) Regulations concerning safe handling [2]. Further guidance can also be found in DB2002(5) [3].

# Section 1

## 1.0 Medical Devices Directives and UK Regulations

The Medical Devices Regulations 2002 [4] consolidates all the existing medical devices regulations into a single piece of legislation and came into force on 13 June 2002.

**1.1 The Active Implantable Medical Devices Directive (90/385/EEC)** [5]
This first Directive covers all powered implants that are left in the human body. Heart pacemakers are the most common example of powered implants.

**1.2 The Medical Devices Directive (93/42/EEC)** [6]
The second Directive covers most other medical devices, for example, first aid bandages, tongue depressors, hip prostheses, X-ray equipment, heart valves.

**1.3 The In Vitro Diagnostic Medical Devices Directive (98/79/EC)** [7]
The third Directive covers any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system intended for use in vitro for the examination of specimens, including blood and tissue donations, derived from the human body. Examples of in vitro diagnostic devices are: blood grouping reagents; pregnancy test kits; hepatitis B test kits.

Further information on these Directives can be found on the MHRA website: www.mhra.co.uk

## 2.0 CE marking

The CE marking that appears on a medical device and/or its packaging affirms that the manufacturer declares that their device satisfies those requirements of the Directive which make it fit for its intended purpose. In addition, it allows the device to be freely marketed throughout the European Community without any additional national controls.
All devices placed on the market must have a CE marking (with the exception of custom made devices and devices intended for clinical investigation and devices for performance evaluation).
The marking looks like this:

CE

The CE marking may appear on the device itself or on its packaging or both.

Users should be aware that a CE marking indicates that the manufacturer has declared that an item complies with the requirements of the Directive relevant to that device. A number of Directives may

apply to one single product, but there will only be one CE marking indicating that it complies with all of the relevant Directives.

The Medical Devices Directive [6] includes a classification system where the level of control applied to a device is related to the degree of risk associated with the device. This classification will in turn determine which route a manufacturer must use to demonstrate conformity with the relevant *essential requirements* and consequently be able to apply a CE marking to their product. Devices which present the highest risk are designated class III, medium risk devices are classified either as class IIa or IIb and the lowest risk group are class I.

A *notified body* is generally only involved in the assessment of high and medium risk devices. However, their involvement also extends to those class I devices that have a measuring function or are supplied sterile (see page 9 for further details on the implications of the Regulations for those healthcare facilities undertaking sterilization of medical devices).

If a *notified body* was involved in the assessment process of a device, the CE marking will be followed by a number designating the *notified body*, e.g. CE 097. If there is no number, this means that *notified body* involvement was not required and that the CE marking was applied to the device (for example, a class I, non-sterile, surgical instrument) solely on the basis of the manufacturer's self-declaration of conformity.

One of the roles of the Medicines and Healthcare products Regulatory Agency (the UK Competent Authority*)* is to ensure compliance with the regulations and to designate and control *notified bodies* in the UK.

## 3.0 Other regulations

There are other regulations, in force or under development, which may impact on the activities of those persons reprocessing reusable items. An example is the Pressure Systems Safety Regulations 2000 [8]. Bench top sterilizers must comply with these Regulations, which are intended to prevent risk of injury from stored energy as a result of a failure of a pressure system.
Compliance with the Regulations is primarily the responsibility of the owner of the sterilizer. Device Bulletin DB2002(06) [9] provides further details.

## 4.0 Information provided by manufacturers

The Medical Devices Directives define the information that manufacturers are required to provide to users. Some of this information may be presented as symbols, some of which users may not yet be familiar with. The symbols are intended to provide information in a concise form which may be understood by any user, irrespective of their native language. A number of the most commonly used symbols are reproduced in BS EN 980:2003 'Graphic symbols for use in the labelling of medical devices' [10].

Further information on the reuse of medical devices supplied for single-use only is contained in Device Bulletin DB2000(04) [11] and is discussed in Part 2 of this manual.

If there are any other restrictions on the number of reuses of a device, this must be conveyed in the instructions for use as defined in Annex 1, ER 13.6 (h) of Directive 93/42/EEC [6].

## 5.0 Reprocessing

Manufacturers of CE marked, reusable medical devices are required to provide 'information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized (Directive 93/42/EEC, Annex 1, ER 13.6 (h) [6]). Also for those devices which are supplied non-sterile and intended to be sterilized before use 'the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in section 1 [of Annex I of the Medical Devices Directive]' (Directive 93/42/EEC, Annex 1, ER 13.6 (h) [6]).

Whilst the level of detail provided for the reprocessing of medical devices will vary depending on the complexity of the device and the level of processing that is required, the following describes the type of information that users should be able to obtain from the manufacturer, as appropriate:

### 5.1 Cleaning instructions

Instructions on how to dismantle (and subsequently reassemble) the device, if necessary.

Cleaning agents, in generic or brand-named terms, known to be effective and compatible with the device.

Any accessories, where relevant, which may assist the cleaning process, such as automatic washers, ultrasonic cleaners or brushes.

**Note:** the mechanical cleaning of devices is preferred to manual cleaning.

### 5.2 Disinfection instructions

Generic or brand-named disinfectants known to be effective and compatible with the device.

**Note**: details of contact times may not necessarily be specified by the manufacturer of the device. Reference should then be made by the user to the disinfectant manufacturer's recommendations, together with current advice from recognised professional bodies, so that a local policy decision can be made.
Any equipment that may be used in conjunction with the disinfectant for the processing of the device, such as a washer/disinfector or adaptor.
Further information on liquid chemical disinfection can be found in Section 2 of Part 1 of this manual.

**5.3 Method(s) of sterilization**
The name of the process (e.g. steam sterilization); the type of cycle (e.g. pre-vacuum/porous load); and any relevant cycle parameters (e.g. 134-137°C for a minimum holding time of 3 minutes).

***Warnings***
Any specific agent(s) or process likely to be in use in the healthcare environment that may prove detrimental to the device. Such warnings may relate, for example, to the incompatibility of a device with cleaning or disinfecting agents, (including prolonged contact times and any concentrations that may cause damage) or to damage associated with specific processes, e.g. sterilization. This may be caused by exposure to temperatures, pressures or vacuum. Handling precautions if the device and/or its components are of a particularly delicate nature.

## 6.0 Purchase of medical devices and equipment

The ability of any reusable medical device to be readily decontaminated should be considered prior to the purchase of that device. Once this information is available, the reprocessing instructions should be reviewed by those persons who will have responsibility for its routine cleaning, disinfection or sterilization. They should determine whether or not the healthcare facility has access to the specified agents and processes. The methods of decontamination that are most commonly available to those undertaking reprocessing in the UK are described in Part 1 of this manual.

Any concerns regarding reprocessing instructions should be raised before purchase and should influence purchasing decisions. Instructions may, for example, be contrary to advice offered by the MHRA and for steam sterilization may recommend cycle parameters which are not routinely available to UK users.

If users are aware that a manufacturer is not fulfilling his obligations under the Directive with respect to the provision of reprocessing instructions (or anything else), this should be brought to the attention of MHRA. If a decision is made by a user organisation to draw up their own instructions, these should be submitted to the manufacturer for approval. Procurement of medical devices and equipment is usually the responsibility of the supplies department and an activity which should also involve personnel in other departments. For items that are reusable, the participation of those who will have responsibility for its routine decontamination, such as the sterile services department (SSD) or theatre sterile service unit (TSSU) should be sought. A liaison should be established and maintained between the reprocessors and the supplies department to ensure this occurs. A number of hospitals have found it helpful to set up purchasing advisory groups, where such issues can be discussed. Such groups have been found to be effective in ensuring that the requirements of all personnel, including those reprocessing the devices, are met.

For those devices that were placed on the market prior to the requirement for CE marking, reprocessing instructions for reusable

devices should still be made available to those carrying out reprocessing. These instructions enable users to make an informed decision on how best to process the device in light of the information provided and the processes to which they have access. A number of manufacturers already provide adequate reprocessing instructions for their devices. However, the level of detail may not be sufficient. Section 2 of this part of the manual provides generic protocols which can be used in combination with the manufacturer's instructions. If there is any doubt, advice should always be sought from the manufacturer before reprocessing an item.

## 7.0 Standards

Standards are of relevance for three main reasons:

- purchasing
- implications of the Medical Devices Directive
- product liability.

### 7.1 Purchasing

The introduction of CE marking for medical devices has changed the significance of standards for those purchasing devices. For manufacturers they have become even more important, because they provide a means of demonstrating that the legal requirements have been met. Device purchasers, however, should no longer need to refer to standards in most purchase contracts, because the CE marking will constitute the manufacturer's declaration that the device meets the requirements of the Medical Devices Directive [6]. Even devices that are not CE marked (custom made or intended for clinical investigation) must still, by law, meet the requirements of the Directive in accordance with the manufacturer's stated intended purpose.

Purchasers should therefore still not need to call for conformity with standards. Device purchasers will, however, sometimes need to refer to standards in order to identify devices that are suitable for a particular use; for example where devices are supplied in various sizes or grades; where they need to be compatible with other devices or systems already in use which could comply with either an old national or a newer European standard; or items that are used in the healthcare environment but which are not classified as medical devices under the Medical Devices Directive (chemical or biological indicators used in sterilization processes, for example).

Further information on purchasing equipment can be obtained from the NHS Purchasing and Supply Agency (www.pasa.nhs.uk).

### 7.2 Implications of the Medical Devices Directive

The second interest relates to the implications of the Directive for those healthcare facilities placing devices on the market, in particular the activities of sterile services departments (SSDs) or others providing a similar service. Regulation 14 of the Medical Devices Regulations defines the procedure for systems and procedure packs, and devices to be sterilized before use.

The term ‘placing on the market’ refers to the ‘... first making available in return for payment or free of charge of a device . . . . with a view to distribution and/or use on the Community market....’ (Medical Devices Regulations [4]). In effect this means that a NHS SSD providing a sterile instrument service to a private hospital, or to any GP, clinic, health centre or other hospital under a different authority, e.g. another trust, where there is a transfer of ownership of the instruments, would be regarded as placing a device on the market. Such activity would fall within the scope of the Regulations. On the other hand if the devices were supplied by an SSD for use on patients in that same healthcare establishment, (that is, within the same legal entity) this would not be seen as ‘placing on the market’ and consequently the Regulations would not apply.

For procedure packs, a *notified body* is required to carry out an assessment of procedures relating to the ‘obtaining of sterility’. This will include the provision of those surgical instruments being supplied by a SSD or similar unit as sterile. The Essential Requirements of the Directive against which the *notified body* will perform its assessment include:

‘Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method’ (Directive 93/42/EEC, Annex 1, ER 8.4 [6]).

Compliance with a relevant harmonised European standard would meet this requirement, e.g. EN ISO 17665-1 – Requirements for the development, validation and routine control for medical devices – Moist Heat. The guidance described in HTM 2010 is intended to enable the requirements of EN ISO 17665-1 to be met.

‘Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.’ (Directive 93/42/EEC, Annex 1, ER 8.5 [6]).

The environment in which instruments are prepared for sterilization requires an appropriate level of particulate and microbiological control. The environment should be capable of consistently performing as intended to the extent that routinely recorded parameters may be correlated with known acceptable conditions. Monitoring of the environment only is not sufficient. The point at which control is necessary should be considered to be that at which the instrument is at its cleanest – the intention of the environmental control is to minimise the possibility of recontamination.

The harmonized European standard, which is relevant to this requirement is EN ISO 13485 [12]. This focuses on the requirements for medical devices manufacturers for CE marking.

Any SSD or unit undertaking reprocessing should also ensure that:

- all devices placed within a procedure tray or pack are compatible and can be processed together
- the instructions for reprocessing the device provided by the manufacturer have been followed (see ‘Reprocessing’ on page 7)
- relevant information, such as the user instructions, are made available to the user of the device
- there are relevant internal processing controls in place.

All SSDs or similar units should meet these same standards irrespective of whether they are providing a service within their own hospital or to another authority, i.e. ‘placing on the market’ as defined in the Directive [6].

### 7.3 Product liability

The third reason standards are important relates to liability. Those undertaking reprocessing activities should be able to demonstrate that they are carrying out best practice; following relevant standards is a means of doing this. The Medical Devices Directive encompasses these activities and meeting the standards laid down by the Regulations is considered the best practice. The lack of a legal requirement to comply with the Medical Devices Directive does not provide healthcare facilities undertaking reprocessing with an exemption from other legal obligations. For example, those undertaking reprocessing could be liable for damages for any injury caused to a patient by a device which was inadequately processed. If patients, or staff, are put at risk by a reusable device due to the way in which it was reprocessed, then a criminal offence may have been committed under the Health and Safety at Work etc. Act [13].

## Further Reading

Institute of Decontamination Sciences (IDSc). Standards and Practice Document. www.idsc-uk.org

# Section 2

## Endoscopes and accessories

### Introduction

Endoscopes are used in many different areas of a hospital. The predominant types vary depending upon the area in which they are used: rigid endoscopes tend to be used in operating theatres whilst endoscopy suites tend to use flexible endoscopes. The use of video endoscopes is now well established.

Rigid endoscopes are generally made of stainless steel and have optical lenses fixed in place with epoxy cement. Recent improvements in the construction of rigid endoscopes have resulted in instruments which can be autoclaved, thus eliminating the need for liquid chemical disinfectants. Flexible endoscopes consist of a fibreoptic bundle with channels for air/water, suction and biopsy. Not all endoscopes have all these channels. Flexible endoscopes are unable to withstand normal autoclave temperatures (121°C-137°C) and therefore require immersion in disinfectants or sterilization using gaseous processes such as ethylene oxide.

The decontamination requirements for any endoscope depend upon the infection risk associated with use of the equipment. Bronchoscopes for example need a disinfection regimen that will be appropriate for contamination with mycobacteria. This is less important for GI endoscopes where hepatitis B virus, HIV and vCJD are of greater concern.

### 1.0 Cleaning

The presence of channels in flexible endoscopes makes cleaning particularly important as blood or body fluids within the channels could result in inadequate contact between the disinfectant and any adherent micro-organisms. Heat and aldehydes both fix protein, making subsequent removal of organic material difficult, and potentially create blockages of channels and the stiffening of moving parts.

**1.1 Cleaning of flexible endoscopes**

1) Machines are available for cleaning and disinfecting flexible endoscopes. All accessible channels and ports should be cleaned manually using appropriate brushes to ensure channels are not blocked. If the instrument was supplied with an air/water channel cleaning adaptor, replace the standard air/water valve with this adaptor and irrigate water through the air and water channels immediately upon removal from the patient.

2) If a waterproof cap is required to protect electrical connections on video endoscopes, ensure it is fitted according to the manufacturer's instructions prior to performing a leak test. Immerse the instrument in a warm neutral or enzymatic detergent solution not exceeding 35°C. Wash the outside thoroughly with non-woven swabs.

3) Brush the distal end with a disposable soft bristle brush, paying particular attention to the air/water outlet nozzle and bridge elevator (where fitted).

4) Using a suitable cleaning brush for the instrument and channel size, proceed as follows:
(a) Clean the biopsy channel opening and suction port;
(b) Introduce the cleaning brush from the biopsy port, through the insertion tube, until it emerges from the distal tip;
(c) Pass the cleaning brush through the suction valve port and down the insertion tube, until it emerges from the distal end;
(d) Pass the cleaning brush from the suction valve port, through the umbilical cord until it emerges from the suction port on the light guide connector.

Clean the cleaning brush itself in detergent with a soft bristle brush each time it emerges. Repeat until the brush emerges free of soil.

Flush each internal channel with a detergent solution. This should be done independently for each channel using irrigation or aspiration as appropriate. It is essential to expel all air from the channels in order to ensure that all internal surfaces are in contact with the detergent solution.

On endoscopes with a raiser bridge, attach the bridge channel adaptor and flush independently.
Some endoscopes also incorporate an auxiliary channel, which should also be flushed.

Endoscopes should then be reprocessed in a validated automated endoscope reprocessor (AER) compliant with HTM2030 [14]. All cleaning brushes should be disposable and discarded after use on a single endoscope.

### 1.2 Cleaning of rigid endoscopes

#### Automated cleaning

**Note:** This is the preferred method for cleaning rigid endoscopes.

Manufacturers' decontamination instructions increasingly indicate that rigid endoscopes, their associated accessories and instruments are compatible with automated decontamination processes.

Decontamination instructions should provide suitable and sufficient information, consistent with national requirements, to effect safe device decontamination, including the nature of the detergent to be used, for example neutral or enzymatic. Clarification should be sought from the manufacturer where this information is lacking or ambiguous.

Prior to procuring devices, it is advisable to determine that they are compatible with existing decontamination equipment, e.g. washer-disinfectors and sterilizers and the cycle parameters employed.

Optimum device surface exposure is critical to effective decontamination. Therefore, instruments and accessories must be fully disassembled and secured during the wash process. Attention should be paid to load configuration to ensure that surface exposure is not inhibited during the process. Ultrasonic cleaning may be indicated for instruments, components and accessories with the exception of telescopes and light leads due to the risk of damaging optic elements.

**Manual cleaning**

**Note:** This method should only be used if automated facilities are unavailable**.**

Cleaning is best achieved with a warm neutral or enzymatic detergent solution not exceeding 35°C. All valves must be dismantled prior to cleaning. Ultrasonic cleaning may be used for all instrument components and accessories with the exception of the telescope. Brush and irrigate with a detergent solution to remove all loosened organic soil and rinse with sterile distilled water (e.g. water for irrigation BP).

**Telescope**
Brush the distal end with a soft bristle brush and wipe the telescope outer tube and eyepiece with a non-woven gauze swab. Where present, the stopcock should be removed and brushed. If there is an operating channel this should be brushed and flushed through with a detergent solution followed by rinsing with sterile water.

**Trocar/cannula**
Remove the trocar from the cannula, wipe all external surfaces with a non-woven swab. Ensure lumens (including stopcock lumens) are brushed, pushing organic soil towards the main channel, and then flush with a detergent solution.

**Light guide cable**
Wipe down the length of the cable with a non-woven wipe and clean both ends with a soft bristle brush.

**Hand-held instruments**
Using an appropriate brush carefully clean all external surfaces taking care to remove all organic material from the jaw mechanisms and electrode surfaces.

**Sheath**
Brush the irrigation ports with an appropriate cleaning brush, pushing organic soil towards the main channel. Clean the cleaning brush in detergent solution with a soft bristle brush each time it emerges. Clean the locking ring with a soft bristle brush ensuring all crevices are accessed.

**Obturators (blunt or sharp)**
Wipe with a non-woven swab and detergent solution.

**Rinsing**
Rinse all surfaces and internal channels with water after cleaning to remove loosened soil and detergent residues. High pressure water jets or syringes may be used for the channels. Ensure there is an unimpeded flow of rinse water through each channel. If the rigid endoscope is to be autoclaved or gas sterilized, deionised or distilled water should be used.

**Drying**
All instrument components should be thoroughly dried, either by hand or in a drying cabinet. Care should be taken not to exceed the temperature tolerances advised by the manufacturer. Dry the equipment in a sloping position to facilitate drainage.

**Packaging**
Items should then be processed using a porous load steam or gas sterilizer. They should be suitably packaged after drying. Moulded or preformed tray inserts should be used to support and protect the instruments during processing. These give better protection than linen or paper packaging.

### 1.3 Cleaning of accessories

Many of the endoscopic accessories are invasive and therefore represent a risk of transmission of infective agents to subsequent patients. Single-use disposable accessories must be used whenever possible, as long as patient safety is not compromised. Where reusable accessories have to be used they must be processed in a porous load sterilizer. It is important that accessories are thoroughly cleaned, preferably using ultrasonication. They should then be dried, lubricated and packed before being heat sterilized.

All brushes used to clean endoscopes and accessories should be disposable and discarded after use.

## 2.0 Disinfection and sterilization

### 2.1 Heat

If the endoscope is heat tolerant (and most new rigid endoscopes now are) autoclaving in a validated porous load sterilizer is the method of choice. Rigid endoscopes sterilized in an autoclave should not be rapidly cooled as this stresses components and shortens the life of the instrument. Unfortunately flexible endoscopes cannot tolerate processes in excess of 65°C. It is therefore essential that the heat, chemical, pressure and moisture tolerance of the instrument be established from the manufacturer before selecting the method of decontamination, to ensure that the process will not damage the endoscope.

### 2.2 Chemical

Although aldehydes (particularly 2% activated alkaline glutaraldehyde) have previously been widely used for disinfection of flexible endoscopes, they are extremely irritating and sensitising. Health and

safety concerns have resulted in the use of alternative agents. Suitable alternatives to 2% activated alkaline glutaraldehyde may include:

- peracetic acid
- chlorine dioxide
- orthophthalaldehyde (OPA)
- electrolysed water/saline
- hydrogen peroxide gas plasma ($H_2O_2$ gas plasma).

None of these agents are without problems and user safety, endoscope compatibility and cost all need to be considered when making a choice.

Further information may be found in DB2002(05) Decontamination of endoscopes [15].

**2.3 Disinfection and sterilization of flexible endoscopes**
E.g. gastroscope, colonoscope, bronchoscope.

All endoscopes should be totally submersible. Before processing perform a leak test in accordance with the manufacturer instructions. Ensure that the disinfectant is compatible with the endoscope or accessory.

**Manual disinfection**
Manual disinfection is a process which cannot be sufficiently validated for routine reprocessing of endoscopes. An automated endoscope reprocessor (AER) should be used.

**Automated disinfection**
Several AERs are available which can be programmed to clean, disinfect and rinse the internal and external surfaces of flexible endoscopes and accessories. These machines offer a more reliable, reproducible and safer process than manual processing. The AER should comply with, and be maintained and validated in accordance with HTM2030 [14].

Endoscopes should always be cleaned manually prior to automated processing to ensure channels are not blocked. This cleaning must include brushing of all channels (see section 1) with single-use, disposable brushes. It is important that the person brushing the channels is familiar with the design of the endoscope so that channels are not missed.

The rinse water must be of a suitable microbiological quality for the instruments being processed. Bacteria, including Gram negative bacilli, may be introduced if the water reservoirs or any other parts of the machine are not disinfected on a sessional basis. The disinfectant should not become over-diluted or neutralised by organic matter; the maximum number of cycles or other means should be used to determine this point. The raiser bridge channel (where fitted) may be overlooked, therefore it is important that such channels are identified and cleaned and disinfected appropriately.

On completion of disinfection, the endoscope should be purged with compressed air to facilitate thorough drying. Alternatively, 70% alcohol may be used to dry internal surfaces and channels.

**2.4 Storage of disinfected endoscopes**
Flexible endoscopes must be stored in a vertical position in ventilated storage cabinets, to allow circulation of air and to facilitate drainage of rinse water otherwise there is a risk of growth of micro-organisms in the channels overnight. Because this risk cannot be eliminated (even with vertical storage), it is recommended that endoscopes that have been stored for more than 3 hours are reprocessed in an AER before use on the next patient.

To avoid the extra workload created by the requirement to reprocess endoscopes at the beginning of the list, some manufacturers have developed drying cabinets which claim to keep endoscopes free of significant contamination for an extended period of time.

These cabinets use a combination of filtered air and UV light. However, they do not all use the same technology and not all have been rigorously evaluated. If such a cabinet is to be utilised it is important that the user satisfies themselves that the manufacturer has undertaken appropriate validation studies to ensure that microbial growth is prevented for the time period claimed.

**2.5 Disinfection and sterilization of rigid endoscopes**
E.g. arthroscope, laparoscope, cystoscope

In accordance with the manufacturer's instructions, completely dismantle the instrument into all its component parts.

a) Sterilization

Sterilization should be used in preference to disinfection wherever possible. Always check with the instrument manufacturer’s instructions to ensure that processing will not damage the instrument. Autoclavable instruments are normally marked to indicate their tolerance.

Validated porous load sterilizers must be used for devices with lumens. Traditional bench top sterilizers or gravity displacement sterilizers should be used only for devices with no lumens.
Heat sensitive rigid endoscopes that need to be sterile can be processed using hydrogen peroxide, gas plasma or ethylene oxide.

b) Disinfection

Some rigid endoscopes which are not heat compatible (e.g. cystoscopes) are still in use. Simple rigid endoscopes without channels can be disinfected using a compatible disinfectant as recommended by the manufacturer. However, consideration must be given to replacing these older, heat sensitive endoscopes with autoclavable ones.

## 3.0 Traceability

All medical devices used for invasive procedures can potentially transmit infections. It is important, therefore, to record which patients have been investigated or treated with a particular device. This allows look-back exercises to be performed where a patient is known to have an infection so that subsequent patients can be appropriately investigated and advice and treatment can be given if required.

The requirements for traceability can be reduced by using disposable, single-use devices where appropriate. All accessories including biopsy ports should be single-use and disposable. Occasionally, disposable accessories are unacceptable clinically (e.g. biopsy forceps) in which case reusable accessories may be used. However, this course should only be adopted after an adequate risk assessment. Furthermore, if reusable accessories are used, these accessories must be traceable either by marking them with a unique identifier, or by placing in a bag which must stay with the endoscope throughout the reprocessing. This latter approach is particularly useful for ensuring traceability of the removable valves.

# Dental equipment

## Introduction

There is a wide range of methods that can be used to decontaminate dental materials and equipment. It can therefore be difficult for the dental practitioner to choose the most appropriate process. General guidelines on the decontamination of dental premises and equipment will be found in the British Dental Association Advice sheet A12 – Infection Control in Dentistry [16]. This provides guidance on good dental infection control practice. There are a number of items in frequent use that are almost impossible to decontaminate reliably. Examples include 3-in-1 syringe tips, endodontal files and burs [17]. These items should be single-use and discarded (see below).

Decontamination methods can be categorised as follows:

## 1.0 Cleaning

Instruments must be thoroughly cleaned before any disinfection or sterilization procedures. Many dental instruments are sharp and difficult to clean manually and therefore detergent washing in an ultrasonicator is to be preferred. It is important to ensure that instruments are compatible with ultrasonic cleaning.
The instrument manufacturer should be able to provide this information. The increasing use of washer/disinfectors is to be encouraged as these machines provide a reliable, repeatable process that can be validated.

After cleaning, instruments should be rinsed, to remove detergent residues, before sterilization or disinfection.
Many smooth impermeable surfaces do not require formal disinfection. A good detergent wash of the whole surface, using a smooth unidirectional cleaning action, followed by drying with a single-use cloth should be adequate.

## 2.0 Surface disinfection

Impressions should be rinsed under running water until visibly free of all biological debris. They should then be disinfected following the impression material manufacturer's instructions. Equipment surfaces should also be cleaned and disinfected after use according to the equipment manufacturer's instructions. Disinfection is best done with an alcohol wipe. Spray-on products should be avoided because of the generation of unnecessary aerosols. Further information on choice of disinfectants can be found in Part 2 of this manual.

## 3.0 High level disinfection

Reusable devices that cannot withstand steam sterilization may be cleaned and fully immersed in an appropriate liquid chemical, recommended by the device manufacturer for the recommended time. Devices should then be removed, rinsed in sterile water and dried. If they are to be used in a sterile environment, they will need to be re-sterilized immediately before use. Devices should not be stored immersed in liquid chemicals. Liquid chemicals are not reliable as sterilizing agents. The spectrum of antimicrobial activity differs between

classes of disinfectant, as does the effect of materials and biological products on them. They should only be used as a substitute for sterilization as a last resort, when there is no alternative method available or when single-use items are not available. A wide variety of chemicals are available; it is important to ensure that the disinfectant manufacturer's recommendations with regard to their use are followed. General guidelines on the use of liquid chemical disinfectants are to be found in Part 1 of this manual

## 4.0 Sterilization

All reusable instruments that have become contaminated with saliva, blood or other biological fluids should be cleaned and sterilized after use. Hand pieces should also be cleaned and sterilized after each patient treatment. In order to prolong the life of hand pieces, they should be processed in accordance with the manufacturer's instructions.

Steam sterilization is the method of choice for most dental instruments. It is recommended that validated, pre-vacuum autoclaves are used for sterilizing wrapped instruments (Type B). Autoclaves drawing only a post-sterilization vacuum for drying purposes are not suitable for processing wrapped instruments. Validated, pre-vacuum autoclaving is generally carried out in hospital sterile service departments (SSD), and this should be the process of choice in hospital-associated dental departments.

In general practice, traditional (non-vacuum assisted gravity feed, type N) bench top autoclaves are suitable, but instruments must not be wrapped prior to placing in the autoclave chamber.

Guidance on the purchase and maintenance of the various types of autoclaves available can be found in Device Bulletin DB2002(06) Bench top steam sterilizers – guidance on purchase, operation and maintenance' [18].

The autoclave manufacturer should specify the types of instruments for which the sterilizer is suitable (Type S). If it is claimed to be suitable for wrapped loads, the manufacturer should specify the types and nature of wrapping material and the maximum number of layers that may be used. Device Bulletin DB9804 'The validation and periodic testing of bench top vacuum steam sterilizers' [19] gives guidance on the validation and periodic testing of this type of bench top autoclave in addition to the guidance in Device Bulletin DB2002(06) [18]. The daily and weekly maintenance of bench top autoclaves is the responsibility of the user, and includes a number of tests detailed in the above Bulletins.

Maintenance of the reservoir and chamber and changing the water frequently, using water of an appropriate quality (water for Irrigation BP or approved equivalent standard), will help to reduce contamination of the water, for example with oil from dental handpieces. Further information on clean steam, and more general guidance, is available in Health Technical Memorandum 2031 'Clean steam for Sterilization' (paragraphs 4.50 to 4.66) [20] provide information that is particularly relevant to users of bench top steam sterilizers).

Instruments should be cleaned, sterilized and used within the session, on the same day. If they are not used immediately they should be stored and covered in clean, dry conditions until used. They should not be stored beyond the working day end of session without being re-sterilized. If there is a need to wrap or use instruments with lumens, then a pre-vacuum drawing autoclave must be used (Type B). Gaseous processes have little place in dental practice.

Concern has been expressed over the use of non-vacuum assisted autoclaves for processing dental handpieces. These items contain a lumen. Pre-sterilization cleaning is the key to adequate decontamination and the use of a mechanical handpiece irrigator is strongly recommended. This will ensure that handpieces are adequately decontaminated prior to lubricating and processing in a standard autoclave.

## 5.0 Single-use devices

It is recommended that, where possible, consideration should be given to using single-use devices. Because three-in-one tips are difficult to clean, single-use tips should be used. Similarly, burrs, endodental files and reamers, scalpel blades, aspirator tips, saliva ejectors, matrix bands and impression trays should also be single-use. Needles and anaesthetic cartridges must be disposed of after a single patient use.

## Further reading

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Gurevich I, Dubin R and Cunha BA. Dental instrument and device sterilization and disinfection practices. J Hosp Infect 1996; 32:295-304.

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# Ophthalmic equipment

## Introduction

Ophthalmic surgery employs a wide range of delicate and precise instrumentation, which must be handled carefully during decontamination. Wherever possible, these instruments should be reprocessed in a hospital sterile services department. Any limitations on the number of reuses, specified by the manufacturer, must be observed.

## 1.0 Cleaning

All reusable instruments require thorough cleaning before sterilization and must be cleaned as soon as possible after use to avoid drug solutions, tissue, blood or other residues drying on them. This should be done in a hospital sterile service department (SSD). If items are to be initially cleaned by theatre staff, then they should be adequately trained in the procedures to be employed.

Whilst mechanical cleaning is the preferred method of decontaminating instruments, manual cleaning may be the only option for certain ophthalmic instruments. Instruments should be disassembled where possible and cleaned with a recommended detergent solution at a temperature no greater than 35°C. Temperatures above this may cause coagulation of proteinaceous substances and should be avoided. Lumened devices should be flushed with detergent solution to remove organic material. Following cleaning, instruments should be carefully examined for organic material or damage (under magnification, where appropriate).

### 1.1 Manual cleaning

For example, diamond knives, phacoemulsification handpieces. Using a soft brush pay particular attention to joints, locks serrations or any area where debris may collect. Metal brushes, steel wool or abrasive powders must not be used. Some devices, such as diamond knives may need to be cleaned using special techniques to prevent damage to the cutting edge – the instructions provided by the manufacturer must be followed.

Cleaning brushes should be cleaned after use and disinfected, ideally in a washer-disinfector. They should be stored dry. Cannulated instruments should be flushed using sterile distilled water (e.g. water for irrigation BP) via a jet gun or syringe.

### 1.2 Mechanical cleaning

For example, scissors, fixation forceps, retractors, lens holders, specula, metal cannulae. The ultrasonic cleaning process is very efficient at loosening debris trapped in joints, locks and along serrations, and will significantly aid the removal of obstructions in cannulae and needles. All instruments should be thoroughly immersed in appropriate detergent solutions. This should be made up and used in accordance with the detergent manufacturer instructions and be compatible with the ultrasonicator and device being decontaminated. Cleaning solutions should be replaced frequently. In general, a 5 minute ultrasound cycle should be sufficient. To protect ophthalmic instruments from accidental contact with the surfaces of the ultrasonicator or other instruments,

silicone ‘stipple’ mats or securing blocks are recommended as device supports.

Ophthalmic instruments that can withstand processing in a washer-disinfector should be decontaminated in the same manner as surgical instruments (see Section on surgical instruments). For other devices, e.g. cryoprobes, fibre optic cables, horizontal sub retinal forceps and endogripping forceps, follow manufacturer’s instructions.

### 1.3 Rinsing and drying

After cleaning, instruments should be rinsed several times in water for irrigation BP or equivalent. Lumened devices should be rinsed to remove detergent residue. Thorough drying is essential immediately after rinsing and before reassembly. A lint free gauze or hot air may be used. Compressed air of an appropriate medical grade may be employed for devices such as cannulae or phacoemulsification instruments.

### 1.4 Lubrication

When necessary, instruments should be lubricated on all moving parts after cleaning, as recommended by the instrument manufacturer. An appropriate lubricant should be used in order to withstand the high temperatures of autoclaving. Lubricating baths are not normally recommended.

## 2.0 Sterilization

Moist heat (steam) is the preferred method for sterilizing surgical instruments. A validated pre-vacuum autoclave should be used for wrapped instruments. Traditional bench top autoclaves may be suitable for unwrapped instruments. Hot air sterilizers may be used for devices that can withstand high temperatures (>160°C) (see Part 1 of this manual for further information on sterilization by hot air). In the case of heat-sensitive (thermo-labile) devices, the use of gaseous processes (e.g. ethylene oxide, low temperature steam and formaldehyde) may be considered. Such facilities are available in some hospital SSDs, but generally not in peripheral decontamination units.

Using these methods, additional time for sterilizing must be allowed due to the control and monitoring methods required in gaseous processes. Health Technical Memorandum 2010 [21] provides guidance on the validation and routine control of sterilization of medical devices, based on the requirements of the European standards for sterilization by ethylene oxide and moist heat. Alternative methods for terminal sterilization may be used, for example, hydrogen peroxide gas plasma. The sterilization process should be validated and controlled and documentary evidence should be retained to demonstrate this.

During processing, instruments must be protected and secured against possible movement using stippled silicone mats. Incompatible materials should not be processed together.

## 3.0 Disinfection

Where sterilization using any of the methods described above is not possible, high level chemical disinfection may be achieved using chemical disinfectant solutions (see Part 1 of this manual). These should only be used when devices cannot be safely sterilized and where the device is not used for invasive procedures. Disinfection processes need to be validated, compatible with the instrument and effective. The disinfection agent requires appropriate evaluation before final selection. Note that sodium hypochlorite solution is the disinfectant of choice where prion contamination is a possibility (20,000ppm available chlorine for 1 hour and rinse).

## 4.0 Single patient use of ophthalmic medical devices: implications for clinical practice

Components of ophthalmic devices that touch the surface of the eye e.g. tonometers should be restricted to single patient use wherever practicable, and where this does not compromise clinical outcome. Where this is not practicable, e.g. for gonioscopy lenses, fundus lenses, 3 mirror lenses and A scan probes, devices should be thoroughly cleaned and disinfected between uses.

## 5.0 Single patient use of contact lenses: implications for clinical practice

Do not use contact lenses, including trial contact lens fitting sets (diagnostic lens fitting sets), on more than one patient.

## Further reading

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# Surgical instruments

## Introduction

For the purpose of this section surgical instruments are a family of medical devices used in surgery which are designed to be re-processed using widely used decontamination methods.

As part of any instrument procurement exercise it is advisable, prior to purchase or borrowing, to determine compatibility with existing decontamination equipment and process parameters.

## 1.0 Containment of used devices

All used surgical instruments should be regarded as contaminated. Their handling, collection and transportation should be strictly controlled to minimise any possible risks to patients, personnel and any area of the healthcare facility. All contaminated surgical instruments should be separated from clinical waste at the point of use. ‘Sharps’ should be removed and disposed of in appropriately designated containers. Contaminated liquids should be placed into leak-proof containers for disposal unless facilities exist within the user area for emptying into a clinical sluice.
Further details on the containment of contaminated surgical instruments can be found in Part 2 of this manual.

## 2.0 Preparation of devices for reprocessing

If the instrument is to be disassembled, or any particular maintenance actions are required during reprocessing, the manufacturer’s instructions for doing so should be followed.

Any instructions on the limitations and restrictions of reprocessing should be adhered to.

Wherever possible all parts of disassembled devices should be kept together, in one container.

## 3.0 Decontamination

The preferred method of decontaminating surgical instruments is by mechanical cleaning with a detergent solution, followed by thermal disinfection and then drying using an automated washer-disinfector. Where an automated washer-disinfector is not available, manual cleaning using the processes described in Part 2 of this manual may be used, followed by disinfection using chemical solutions.
For lumened devices, ultrasonic cleaning should be used (unless contraindicated by the manufacturer) either as part of the washer-disinfector cycle or prior to mechanical cleaning. See Health Technical Memorandum 2030 [14] for guidance on the use of washer-disinfectors and ultrasonic cleaners. Manual methods of cleaning are required for devices which cannot be immersed in water or other solutions, for example power tools. It should be noted that where manual cleaning takes place, it might not be possible to disinfect the device prior to further handling.

## 4.0 Water quality

Water for irrigation BP or equivalent should be used for each stage of the decontamination process to ensure it is effective. Advice should be sought from both the manufacturer of the washer-disinfector and the detergent on the quality of water to be used in combination with their products

## 5.0 Detergents

Detergents should be used at the correct concentration and temperature and be compatible with both the device to be decontaminated and the washer-disinfector if used. Enzymatic detergents are preferred as they will remove the majority of soils.

## 6.0 Preparation of devices for mechanical cleaning/disinfection

Surgical instruments should be handled carefully to avoid damage. Damage, such as misalignment, may not be readily apparent and may adversely affect the performance of the instrument.
All instruments should be placed in a suitable container, in such a way that all surfaces are exposed to the detergent solution. For example:

- heavy instruments should be placed in the bottom of containers;
- any instruments with concave surfaces, such as curettes, should be placed with the cup down to prevent pooling of water;
- all hinged instruments must be fully opened;
- multi-part instruments, skin hooks, scissors etc., should be segregated within the container to prevent damage.

## 7.0 Inspection and function testing

All instruments should be visually inspected for cleanliness and any signs of deterioration that may cause failure in use (such as cracks or crossed joints) and wherever possible, function tested before being packaged for further processing or storage.
Particular attention should be given to:

- box joints, serrations and crevices, which should be critically inspected for cleanliness;
- cutting edges (on instruments such as scissors, rongeurs, chisels, curettes) which should be checked for sharpness;
- hinges (on instruments such as artery forceps and clamps) which should be checked for ease of movement;
- jaws and teeth which should be checked for alignment;
- ratchets, which should close easily and hold firmly.

All instruments should be inspected to make sure they are intact and that there are no chips, worn spots, flaking or sharp edges.
Electrosurgical equipment e.g. diathermy instruments and cables, should be checked for insulation integrity and circuit continuity.
Any damaged, incomplete or malfunctioning instrument should be set aside and a decision should then be made on how to deal with them.

## 8.0 Assembly

Surgical instruments should be assembled in accordance with the manufacturer's instructions, prior to packaging and/or further processing.

## 9.0 Packaging

Instruments should be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use. An appropriate packaging material should be used, of which there is a wide range available to suit a variety of needs. (A European standard has been published which specifies requirements for packaging materials and systems for medical devices which are to be sterilized [22]).
The following should be considered in the selection of a packaging material for each type of instrument:

- does the material adequately protect the instrument from contamination and physical damage?
- can the package be adequately sealed?
- is the material compatible with the instrument and the sterilization process intended to be used?
- if necessary, can the instrument be presented in an aseptic manner?
- is the packaging 'tamperproof'?
- can the packaging be readily labelled?

Devices that are wrapped (including pouches) should only be processed in a bench top sterilizer if it has an effective forced air removal system and it is validated for the intended load.

## 10.0 Sterilization

Moist heat (steam) is the preferred method for sterilizing surgical instruments. A validated pre-vacuum autoclave should be used for wrapped instruments. Traditional bench top autoclaves may be suitable for unwrapped instruments, other than cannulated.
Dry heat sterilizers may be used for devices that can withstand high temperatures (>160°C). See Part 1 of this manual for further information on sterilization by hot air.
In the case of heat-sensitive (thermo-labile) devices, the use of gaseous processes (e.g. ethylene oxide, low temperature steam and formaldehyde) may be considered. Such facilities are generally only available in hospital sterile services departments (SSD). Additional time for sterilizing using these methods must be allowed due to the control and monitoring methods used in gaseous processes.
Health Technical Memorandum 2010 [21] provides guidance on the validation and routine control of sterilization of medical devices, based on the requirements of the European standards for sterilization by ethylene oxide [23] and moist heat [24]. Alternative methods for terminal sterilization may be used, for example, hydrogen peroxide gas plasma. The sterilization process should be validated and controlled and documentary evidence should be retained to demonstrate this.

## 11.0 Disinfection

Where sterilization using any of the methods described above is not possible, high level chemical disinfection may be achieved using chemical disinfectant solutions (see Part 1 of this manual).
These should only be used when devices cannot be safely sterilized using moist or dry heat, or gaseous processes.
Disinfectant solutions should only be used in accordance with the manufacturer's instructions and should take into account any relevant health and safety legislation, for example COSHH.
Devices processed using disinfectant solutions cannot be wrapped and must be thoroughly rinsed with sterile distilled water after immersion in a high level disinfectant.

## 12.0 Storage of sterilized (processed) medical devices

The storage of processed instruments should be designed and managed to ensure optimum quality conditions are maintained. Sterile instruments should be stored to ensure that their sterility or physical properties are not compromised. They should be stored:

- away from the floor, ceiling and any outside walls
- so that packaging is not crushed
- in a dry, clean, well ventilated environment
- segregated from non-sterile items.

Closed or covered cabinets are recommended for the storage of seldom used supplies. Sterile instruments should be sufficiently labelled so that stock can be rotated. The shelf-life of a packaged sterile instrument is event-related. However, provided the integrity of the packaging remains intact, that the packaging is not subject to any restrictions on use life and it stays clean and dry, the instruments will remain sterile indefinitely. Users of the instruments should be made aware that the item cannot be guaranteed sterile if the packaging is open, damaged or wet. A label on the packaging should therefore instruct users to check the packaging before using the instrument. Further information on the storage of sterile medical devices can be found in SN1999(32) [25].

# Ventilators

## Introduction

Mechanical ventilation plays an important part in the treatment of patients in the intensive therapy unit (ITU) and is an essential component in the anaesthetic support of patients undergoing surgery. Exogenous infection (which accounts for less than 10% of ventilated associated pneumonia) can occur via equipment used for respiratory therapy such as ventilator tubing and humidifiers.
Ventilators may also be the source of infection unless they are designed in such a way that this is prevented or minimised.

## 1.0 Ventilator design

There are now many types of ventilators available and further detailed description here is not appropriate. The three main types are:

- ventilators with permanent circuits – the patient breathing circuits are always attached to the ventilator but may be isolated from the main body
- ventilators with detachable circuits (detachable exhalation blocks) – the patient's breathing circuits are totally detachable and can be dismantled, cleaned and decontaminated
- ventilators with single limb circuits – the patient's breathing circuit is a single inspiratory circuit with a distant exhaust valve. Circuits can readily be removed, cleaned, decontaminated and reused.

## 2.0 Ventilator maintenance

Only purchase ventilators if the manufacturer's instructions include information on the decontamination of the machine. Under the Medical Devices Regulations [4] manufacturers must provide written advice on appropriate methods of decontamination that can be used and in addition provide advice on how the ventilator can be protected from subsequent contamination from microorganisms.
All ventilators should be maintained and serviced regularly as part of a planned preventative maintenance scheme in accordance with the relevant manufacturer's instructions and local infection control policies. The maintenance scheme should include regular cleaning or replacement of all internal parts as identified by the manufacturer (e.g. rubber diaphragms acting as an interface between the machine and respiratory circuit and air filters).

Where possible, ventilators, reusable circuits and other accessories should be sent for decontamination in a sterile services department.

## 3.0 Breathing circuits and filters

Increasingly, single-use breathing circuits are used. In accordance with current Department of Health guidance (HSC 1999/178) [26] single-use devices should be used wherever possible provided they do not compromise the clinical outcome. Single-use anaesthetic breathing circuits and filters should only be used once and then discarded. These devices should never be reused. The term 'single-use' does not apply to devices that:

- have multiple uses for one patient ('single patient use')

- can be reused a limited number of times
- can be reused on a limited number of patients.

Reuse of single-use devices could result in transfer of liability from the device manufacturer to the user in the event of any injury or damage associated with a failure of the device.

**3.1 Frequency of change intervals**

Current guidance from the Department of Health [26] and the Association of Anaesthetists of Great Britain and Ireland [27] recommends the following:

- single-use devices should be replaced after each patient;
- reusable devices with a limit on the number of times they can be used, or the number of patients they can be used with, should be changed in accordance with the manufacturer's instructions.

If the circuit is known to be, or is suspected of being, contaminated, then it should be changed. Further guidance from the Association of Anaesthetists of Great Britain and Ireland [27] recommends that breathing circuits should be replaced at the end of the day as part of the routine maintenance and cleaning programme for the ventilator. The frequency of ventilator circuit changes does not influence the incidences of ventilator associated pneumonia (Dodek et al 2004) [28]

**3.2 Breathing circuits**

All detachable, reusable circuits should be:

- dismantled at the frequency recommended by the manufacturer and in accordance with the local infection control policy
- reprocessed in accordance with the manufacturer's instructions.

The manufacturer of the breathing circuit should be contacted if reprocessing instructions are unclear or unavailable. All equipment should be examined and tested carefully prior to use. Damaged items should be replaced. Single-use items should be disposed of safely as clinical waste in accordance with local clinical waste disposal policies.

**3.3 Filters**

With improved ventilator design, only one additional filter is needed to protect the ventilator from contamination and the patient from infection. The internal filter is placed at the patient end of the system. Use of internal filters has become commonplace during ventilation of patients undergoing surgery. Filters with a high microbial and viral retention property are available at reasonably low cost. However, their permeability and airflow resistance may increase if they become wet. Filter types include heat and moisture exchange filters (HMEF) and pleated hydrophobic breathing system filters; the latter are more expensive. Users should carry out a risk assessment and option appraisal to determine the most appropriate filter. For known cases of tuberculosis, or patients with multi-drug resistant organisms in their sputum, it is recommended that a protective filter is used and that the breathing circuit and filter are changed after use on the specific patient and before reuse of the ventilator.

# Miscellaneous items of equipment

## Introduction

This section considers all other devices and items that have not been covered by the previous sections. You are reminded to seek advice from device and equipment manufacturers on the suitability of agents and processes used for decontamination. These methods are not intended as a replacement for instructions provided by device and equipment manufacturers.

## General aspects of decontamination

In general, it is possible to categorise the risk of infection to the patient from contact with an item of equipment into three groups (see introduction to Part 2 of this manual):

1. High risk. These items penetrate skin or mucous membrane, enter the vascular system or sterile spaces. These items need to be sterilized.
2. Intermediate risk. These items come into contact with intact mucous membranes or maybe contaminated with particularly virulent or readily transmittable organisms.
3. Low risk. These items come into contact with intact skin or do not contact the patient. They require cleaning.

For all categories, following patient use, and routine, regular decontamination should be the cornerstone of infection control. Routine microbiological monitoring is not necessary for most devices.
Wherever possible, contaminated items of equipment should be dismantled and parts categorised as described above and processed as appropriate. Electrical equipment must be disconnected from electrical supply prior to decontamination.

Manufacturers of reusable medical devices are required by the Medical Devices Directive [6] to supply clear written decontamination instructions, which should include appropriate cleaning, disinfection or sterilisation methods.
Certain fabrics or materials can be difficult to decontaminate. Prior to purchasing equipment, it is advisable to carefully assess the relevant decontamination methods to ensure that they are practical, safe and reliable.

## List of items

Listed below are some common patient equipment and suggested decontamination methods. This must not replace manufacturers' guidance or local infection control policy. For example, patients with certain infections or if items are contaminated with blood/other body fluids, may also require disinfection.

**Arm splint**
Wash with detergent, rinse and dry.

**Apnoea and enuresis monitors**
Clean and dry regularly as part of a routine. If contaminated, disinfect and then rinse and dry.

**Auroscope tip**
Use single-use tips and discard after a single use. For reusable tips, wash and autoclave between patient use.

**Bed frames**
For normal cleaning, use detergent and hot water. Perform after discharge of each patient and regularly in the case of long-stay patients.

**Bedpans and urinals**
Dispose of single-use. If reusable, then heat disinfection in bedpan washer-disinfector (e.g. 80°C for 1 min, see HTM 2030 [14]). Store dry.

**Birthing pools**
Use disposable pool liner where possible. Clean and disinfect, paying particular attention to the outlet.

**Breast pumps**
For single patient use only; wash with detergent and rinse.

**Cardiac monitors, defibrillators and ECG equipment**
If patient contact, then surface clean unless disposal is necessary (if single-use item).

**Commodes**
Wash with detergent and rinse. Follow with disinfection if visibly contaminated.

**Drip stands**
Clean after each use.

**Hoist (patient)**
Sling to be laundered, examine material and clips for wear or damage before each use. Surface clean the hoist frame.

**Hydrotherapy pools**
Filter, drain and clean regularly as part of a routine. Maintain disinfectant levels within water. Microbiological monitoring is recommended. See further reading below.

**Haemodialysis machines**
Clean and disinfect, paying particular attention to the microbial quality of water and the fluid pathway. Regular microbiological monitoring is essential to validate effective disinfection

**Infant incubator**
Clean and dry regularly as part of a routine. If contaminated, disinfect and then rinse and dry.

**Mattresses and covers**
Clean cover regularly as part of a routine and following patient use. Rinse thoroughly and dry. Mattresses should be enclosed in a waterproof cover and routinely inspected for damage.

**Nebulisers**
Clean all parts, empty in hot wash with detergent between single patient use. Ensure all parts are thoroughly dried. Re-fill with sterile water only. Dispose of when patient is discharged.

**Neurological test pins**
Single-use only.

**Patient bowls**
Clean after each use.

**Patient tables and lockers**
Clean as part of daily routine and between patient use.

**Scissors**
Clean after each use.

**Specula**
Single-use or clean and steam sterilize.

**Splints and walking frames**
Wash and clean with detergent.

**Stethoscope**
Clean after each use.

**Thermometers (electronic, oral and rectal)**
Use a single-use sleeve on each use. Clean as a routine.

**Trolley (dressing, patient), theatre tables**
Clean and surface disinfect.

**Wheelchairs**
Clean, rinse and dry.

## Further reading

Hygiene for hydrotherapy pools. London: Health Protection Agency; 1990. ISBN 0 901144266

# Glossary

For the purpose of this document the following definitions apply:

**Notified body** – An independent certification organisation whose assessors check that the appropriate *conformity assessment* procedure has been followed for relevant medical devices.

**Conformity assessment** – The method by which a manufacturer demonstrates that a medical device complies with the relevant *essential requirements* of the Medical Devices Directive [6].

**Essential requirements** – Those requirements listed in Annex I of the Directive, with which a device has to comply.

**Competent authority** – A body which is authorised to act on behalf of the government of a Member State to ensure that the requirements of the Directive are carried out. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Secretary of State for Health as the *Competent Authority.*

**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.

**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 on many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential pre-requisite 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 or 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 that, 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 which 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 prions.

**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 that, under defined conditions, is capable of killing bacterial spores.

**Sterilant** – A liquid chemical agent that 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 service department (SSD)** – A centralised department specifically designed to reprocess reusable medical devices and equipment and to distribute pre-sterilized, commercially prepared packages for clinical use.

**Sterilization** – A process used to render an object free from viable micro-organisms including viruses and bacterial spores.

# References


**1** Department of Health. Health Service Circular HSC 1999/179, 'Controls assurance in infection control: decontamination of medical devices'. www.dh.gov.uk

**2** Statutory Instrument 2002 No. 2677 The Control of Substances Hazardous to Health Regulations 2002. The Stationery Office; 2002. ISBN 0 11 042919 2

**3** Device Bulletin DB2002(05) Decontamination of Endoscopes. Medical Devices Agency; 2002.

**4** The Medical Devices Regulations 2002. SI 2002 No. 618. London: HMSO; 2002. ISBN 0110423178.

**5** Council of the European Communities. Active Implantable Medical Devices (AIMDD) - Directive 90/385/EEC. OJ 1990; L189: 17-36.

**6** Council of the European Communities. Medical Devices Directive (MDD) - Directive 93/42/EEC. OJ 1993; 169:1-43.

**7** Council of the European Communities. In Vitro Diagnostic Directive (IVDD) - Directive 98/79/EC. OJ 1998; 331: 1-37.

**8** Statutory Instrument 2000 No. 128 The Pressure Systems Safety Regulations 2000. ISBN 0 11 085836 0.

**9** Device Bulletin DB2002(06) Bench top steam sterilizers – guidance on purchase, operation and maintenance. Medical Devices Agency; 2002.

**10** BS EN 980:2003 Graphic symbols for use in the labelling of medical devices. British Standards Institution; 2003. www.bsi-uk.com

**11** Device Bulletin DB2000(04) Single-use medical devices: implications and consequences of reuse. Medical Devices Agency; 2000. (under review).

**12** BS EN ISO 13485:2003. Medical devices. Quality management systems. Requirements for regulatory purposes. British Standards Institution; 2003.

**13** Health and Safety at Work Act 1974. London HMSO; 1974.

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