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Foreword

This is an updated version of Part 2 of the manual on decontamination and contains the **Protocols** for decontamination using cleaning, disinfection and sterilization processes. The introduction provides general guidance on the need for systems of work for the decontamination of medical devices both prior to clinical use and prior to repair, service or investigation, followed by detailed protocols for cleaning, disinfection and sterilization.

This version should replace the previous version of part 2.

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Glossary of terms

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 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 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, 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 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 process used to render an object free from viable micro-organisms including viruses and bacterial spores (BS EN 556-1:2001)

Introduction

The protection of both patients and staff from the transmission of infection from medical devices and other equipment which come into contact with patients or their body fluids, requires the adoption of safe systems of work [1].

Here we describe the protocols for rendering medical devices safe for subsequent handling or use. It provides protocols for both:

- the reprocessing of devices intended for clinical reuse
- the decontamination of devices prior to inspection, service or repair and/or that are the subject of complaint or investigation

using the cleaning, disinfection and sterilization processes described in part 1 of this manual.

It also highlights legal requirements, gives guidance on systems of work, and provides examples of the documentation and records that are necessary to demonstrate that such systems are effective.

The common protocols in this part have been written to provide guidance to healthcare providers and cover the return of items to any area in which decontamination may be performed, such as sterile service departments (SSD) and electronic and biomedical engineering (EBME) departments.

The design and organisation of the SSD should be in accordance with the recommendations of Health Building Note 13 [2].

Written procedures should be available to ensure that all items are decontaminated to an acceptable standard. These procedures should be available to all appropriate personnel. Records should be retained to demonstrate that decontamination has been performed in accordance with the written procedures.

As a general guide, the method of decontamination that is selected should take account of the infection risk from the reprocessed device to the patient as defined in Table 1.

Table 1 Categorisation of infection risk to the patient from contact with an item

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
Low	• In contact with healthy skin	Cleaning may be acceptable in some agreed situations
	• Not in contact with patient	Cleaning

Reprocessing of devices intended for clinical reuse

The Consumer Protection Act [3] has implications for the reprocessing of devices used for patient care. In particular, it is essential to maintain adequate records demonstrating how a particular device was processed. The Medical Devices Regulations [13] will also affect the activities of some healthcare providers.

Devices intended for reprocessing

In supplying a device intended for reprocessing, the manufacturer should provide the user with adequate instructions. These user instructions should describe cleaning and subsequent disinfection and/or sterilization processes that are effective and do not affect the performance of the device adversely. The cleaning, disinfection and sterilization methods recommended by the manufacturer should have been fully validated by the manufacturer as suitable.

Validation of disinfection or sterilization is complicated by the situation where the level of microbiological contamination prior to sterilization or disinfection is unknown. It is likely to be extremely variable as a result of the uncertain efficacy of a cleaning process. If the device is capable of being mechanically cleaned followed by steam sterilization, a greater assurance of sterility will be provided than by other sterilization processes. Further information can be found in part 3 of this manual (Procedures).

You should seek guidance from the manufacturer if there is no reprocessing information provided with the product. Please notify MHRA if the manufacturer is unable to provide this information or if it is inadequate.

It is essential to maintain adequate records and demonstrate traceability. In addition adequate records should be maintained to show: i) the number of times an item has been decontaminated, and ii) the effectiveness of the process used.
The manufacturer should state in the product literature or on the packaging any restrictions on the number of reuses. Records should be retained so that items are discarded at the appropriate time. The absence of this information should disqualify an item for reuse.

Records should include the outcome of tests of function prior to use of an item of equipment. Under the Consumer Protection Act [3] litigation may commence up to ten years after a defective product was supplied by the manufacturer. This should be taken into account when establishing the period for which records are retained.

Devices designated for single-use only must never be re-processed.

There are a number of potential hazards associated with reprocessing and re-using medical devices intended for single use.

Further guidance on the reuse of medical devices supplied for single use only has been issued by the Medicines and Healthcare products Regulatory Agency in DB 2000(04) [4].

Decontamination of devices prior to inspection, service or repair

Health and safety legislation and guidance

Failure to comply with legislative requirements leaves a healthcare provider liable to prosecution.

A written safety policy is a requirement of the Health and Safety at Work Act [5]. This policy should contain, or reference, procedures to ensure that: healthcare professionals and other hospital staff; representatives of suppliers or service organisations; or recipients who are involved in the inspection, service, repair or transport of medical devices or other equipment are not placed at risk by being exposed to contaminated items. Individuals should be nominated by the organisation with responsibility for implementing a safe system of work.

An employer has a duty of care towards his employees (Health and Safety at Work Act [5]) and is required to ensure that they are not put at risk, for example from medical devices or other equipment

contaminated from or during use in healthcare establishments. Furthermore, employers must conduct their undertakings in such a way as to ensure that, as far as is reasonably practicable, persons not in their employment are not exposed to such risks.

The Management of Health and Safety at Work Regulations [6] place a statutory duty of co-operation between employers, e.g. the Health Service and its contractors, to provide each other with clear communication in health and safety matters. This includes any hazards associated with the transfer of material or equipment.

Whilst the advice contained in this document relates particularly to microbiological hazards, equipment may also become contaminated with chemicals which may be corrosive, irritant, toxic, cytotoxic or radioactive. The same requirements apply in such instances.

European Directives on protection against biological agents [7,8] and the management of health and safety were implemented in legislation within the UK under the Control of Substances Hazardous to Health (COSHH) Regulations [9] which are applicable to both chemical and biological hazards.

Guidance on the need for decontamination of equipment prior to inspection, service or repair has been issued by the Medicines and Healthcare Regulatory Agency in DB 2003(05) [10].

Suppliers have a responsibility to provide information on the compatibility of their particular medical device or item of equipment with methods and agents for decontamination.

Purchasers also have a responsibility to select equipment for which a suitable method of decontamination is available, in accordance with local policy. Requests for product information on a pre-purchase questionnaire (PPQ) provide the opportunity to obtain such information in advance of placing a purchase order. Further advice on purchasing can be found in MDA DB9801 and part 3 of this manual (Procedures).

Contamination status

All medical devices and equipment used in either a hospital or community environment may become contaminated with biological, chemical or radioactive material and thus present a risk to those subsequently handling or using them.

All reusable medical devices and equipment to be inspected, serviced, repaired, returned to the lending organisation or disposed of should undergo decontamination. This is necessary to ensure that they are in a condition that makes them safe to be handled by all personnel who may come into contact with them during transit and subsequent handling [10].

The MHRA continues to receive reports that medical devices and other items of equipment are being presented for inspection, service or repair without documentation to indicate their contamination status.

Anyone who inspects, services, repairs or transports medical devices and equipment, either on hospital premises or elsewhere, has a right to expect it to have been appropriately treated so as to remove or minimise the risk of infection or other hazards; appropriate documentation is required to indicate the contamination status of the item.

If items are dispatched to suppliers, or presented for service or inspection on hospital premises, without a declaration of contamination status and without prior agreement, suppliers may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.

In particular situations, for example when the condition of an item which is the subject of complaint or investigation and may be altered or influenced by a decontamination process, the investigator may wish the item not to be decontaminated. In such situations, the advice of the investigating body should be sought and prior warning given to the intended recipient.

Advice on reporting incidents involving medical devices to the Medical Devices Agency has been issued in Device Alert MDA/2005/01 [11].

Packaging and dispatch of contaminated items

Where decontamination of the equipment could remove evidence of a fault or hinder any subsequent investigation, advice on transportation arrangements should be sought from the manufacturer, repair organisation or investigating body as it may require the use of a specialist courier. In this case:

- double package the device in appropriate packaging
- give prior warning to the intended recipient
- clearly label equipment to indicate that it is contaminated

In addition:

- the packaging should be sufficiently robust to withstand transport
- the inner packaging should be suitable to ensure that the outer packaging does not become contaminated or breached during transit.

Inactivation of unconventional agents

This document is not intended to provide specific protocols for the handling of items suspected of being contaminated with the agents of transmissible spongiform encephalopathies (TSE) such as that

responsible for Creutzfeldt-Jakob Disease (CJD). Guidance on the handling and subsequent processing of such contaminated items has been published by the Department of Health in December 2003 [12].

References

1. Spaulding EH. Chemical disinfection and antisepsis in the Hospital. Journal of Hospital Research 1972: 9; 5-31

2. Health Building Note 13, Sterile Services Department. NHS Estates; (2004).

3. Great Britain. Consumer Protection Act 1987. London: HMSO, 1987. ISBN 0105443875

4. Device Bulletin DB 2000(04) Single-use medical devices: implications and consequences of reuse. Medical Devices Agency; 2000

5. Great Britain. Health and Safety at Work Act 1974. London: HMSO, 1974.

6. Statutory Instrument 1999 No. 3242 The Management of Health and Safety at Work Regulations. The Stationery Office; 1999.

7. 90/679/EEC Council Directive of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work. Official Journal L374; 31.12.1990.

8. 93/88/EEC Council Directive of 12 October 1993 amending Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work. Official Journal L268; 29.10.1993.

9. Statutory Instrument 2002 No 2677 The Control of Substances Hazardous to Health Regulations. The Stationery Office; 2002.

10. Device Bulletin DB 2003(05) Management of Medical Devices Prior to Repair, Service or Investigation. Medicines and Healthcare products Regulatory Agency; 2003.

11., Medical Device Alert (action) MDA/2005/001. Reporting adverse incidents and disseminating medical device alerts. Medicines and Healthcare products Regulatory Agency; 2005.

12. Department of Health. Transmissible Spongiform Encephalopathy Agents : Safe working and prevention of infection. December 2003. Website: www.dh.gov.uk/publications [last checked March 2005]

13. Statutory Instrument 2002 No. 618 The Medical Devices Regulations. HMSO; 2002. ISBN 0110423178.

Common protocols for use in decontamination areas

Introduction

This section describes an overall system for the decontamination of medical devices and equipment for reuse or prior to inspection, repair or investigation. Subsequent sections will describe general protocols for the cleaning, disinfection and sterilization of devices.

This system of work should control all stages of handling of devices to be decontaminated, from notification of the need for decontamination to the return to the user of the decontaminated item.

Work flow charts

Figure 1 provides a work flow chart for use in decontamination areas [from NHS Estates Decontamination Guidance CD ROM]. The decontamination life cycle model highlights the extent to which decontamination affects the whole of an organisation and not just those areas processing equipment. Traditionally, decontamination has been the responsibility of the departmental heads of specialist units, for example sterile services, endoscopy units, theatre suites etc. Management arrangements within organisations often divided these functions and made it difficult for a totally co-ordinated approach to the application of decontamination standards and practices to be achieved. However, regardless of the location, the same standards should be applied to decontamination practices throughout an organisation.

Figure 1 highlights each stage of the decontamination process through which surgical instruments pass before every use. Effective decontamination requires the attainment of acceptable standards at all stages of the life cycle. Failure to address issues in any of these stages will result in inadequate decontamination. At all stages of reprocessing, the following issues need to be taken into account:

- the location and activities where decontamination takes place
- facilities and equipment at each location
- ensuring that equipment used is validated, maintained and tested in accordance with manufacturer's guidelines and legislation
- the existence of effective management arrangements
- the existence of policies and procedures for all aspects of decontamination work.

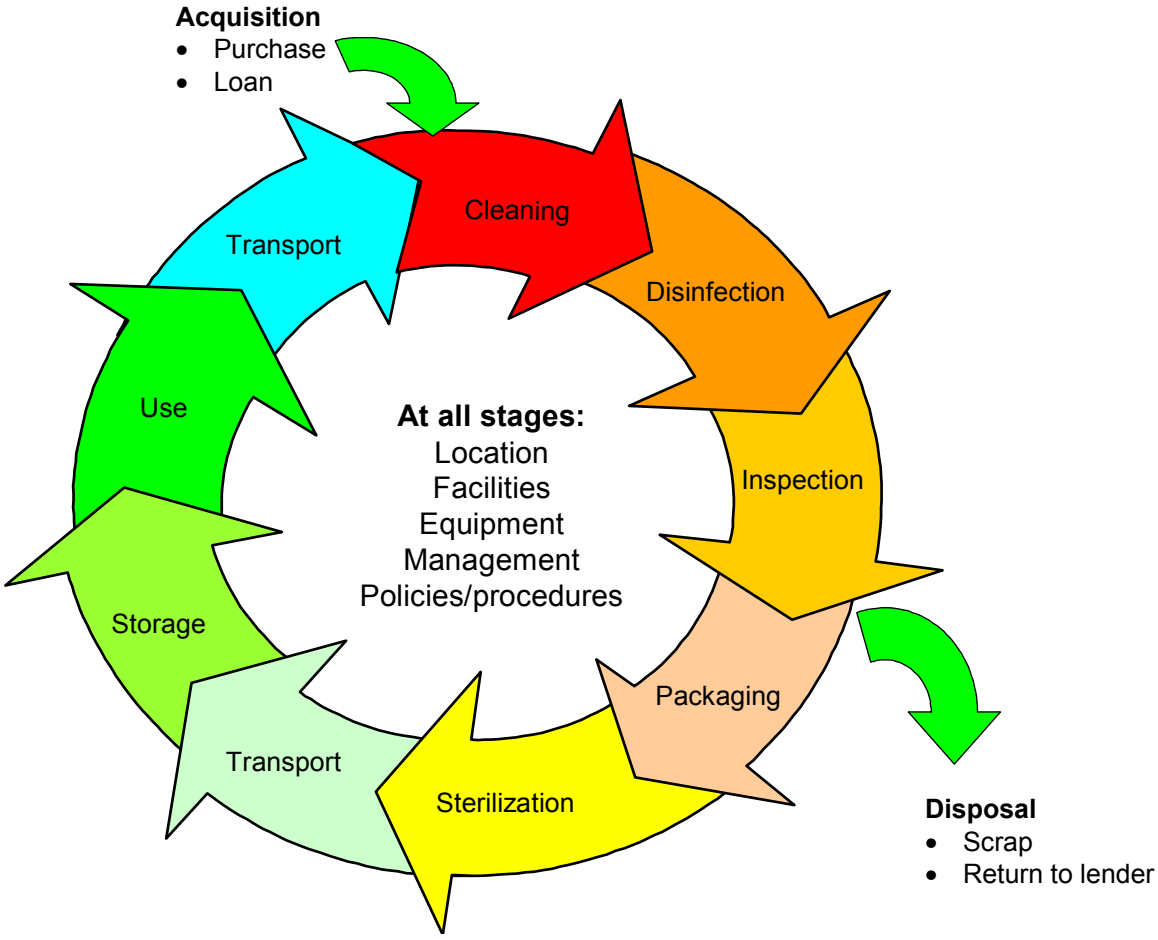

Figure 1 Work flow chart – decontamination life cycle

Notification to decontamination area

The user of the device is responsible for notifying that an item requires reprocessing. They should include details of the contamination status (see appendix 1).

Arrangements are made between the user and the reprocessor for collection and transport of contaminated devices.

Collection and transport of contaminated devices

All items in direct contact with patients or their body fluids, respired gases or pathological samples should be considered to be contaminated and should be safely and securely contained. The item should be isolated in a robust, leak-proof box or plastic bag.

Items should be transferred to the decontamination area as soon as possible after use. If delay is unavoidable, the user must make sure that the item is safely contained and secured to await collection.

Transport

The transport system used for the collection and delivery of items may be for the exclusive use of the decontamination area or shared with other departments. Containers and trolleys/carts should be easy to clean and disinfect, properly maintained, provide protection for the load and be designed so that items can be securely and safely held during transit.

A suitable vehicle which allows for the segregation of clean and dirty items should be used for the transportation of equipment. The inside of the vehicle should be able to be cleaned and disinfected on a regular basis e.g. weekly and when visibly soiled.

Receipt of contaminated items in decontamination area

Items will be received into the designated dirty items section of the decontamination area.

The item should be checked and the user notified if any part of the equipment is missing upon receipt.

Choice of decontamination method

The choice as to which method of decontamination is the most suitable will depend upon many factors including:

- the manufacturer's instructions
- the nature of the contamination
- the ultimate use of the item
- the heat, pressure, moisture or chemical tolerance of the item or of individual components
- availability of processing equipment
- the risks associated with the decontamination process
- the physical nature of the equipment, e.g. size.

Disassembly of contaminated items

Where necessary devices should be disassembled by trained staff in line with the instructions provided by the manufacturer.

A designated, trained member of staff is responsible for ensuring that the decontamination process is undertaken.

Care must be taken for the safe handling and disposal of sharp items.

Application of decontamination method

After dismantling, the device should be cleaned and disinfected thoroughly. Methods of cleaning, disinfection and sterilization are described in the following pages.

The devices should be dry on completion of the decontamination process.

A certificate of decontamination or other means of identifying the status of the equipment should be completed (see Appendix 1).

Re-assembly of decontaminated devices

Re-assembly of items has to be performed to the manufacturer's instructions and/or local policy.

Devices must be in a condition that will allow maintenance or inspection to be carried out safely.

Inspection, maintenance or testing of items

Inspection, maintenance or testing of items should be carried out by trained persons in accordance with the manufacturer's instructions.

Records of all work performed, including test results should be maintained.

Packaging
If the device is to be sterilized after the inspection process, it should be wrapped in a medical grade packaging material (wrapper, bag or pouch). In circumstances where items are processed at the point of immediate use, then packaging may not be necessary and may not be suitable for use with the sterilization process.

(Note: There are a number of European Standards specifying requirements for sterilization paper for medical use).

Storage
All processed items should be stored on clean impermeable off-floor shelving in well ventilated and secure stores to avoid damage or tampering. A record of items in store and available for use should be retained within the storage administrative area. The despatch of any item from this area should be documented and consideration given to the rotation of stock.

Transportation to user
The processed item should be returned to the user in a clean, secure transit container which protects the item from damage, in accordance with local policy.

Before use of the equipment, the user has a responsibility for ensuring that the item is fit for reuse.

Further reading

British Standards Institution, Packaging Materials and Systems for Medical Devices which are to be Sterilized – Part 2 – Sterilization Wrap – Requirements and Test Methods BS EN 868-2 (1999).

BS 6256:1989 Paper for steam sterilization paper bags, pouches and reels for medical use. BSI; 1989.

BS EN 868-4:1999 Packaging materials and systems for medical devices which are to be sterilized – paper bags – requirements and test methods. BSI; 1999.

BS EN 868-5:1999 Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – requirements and test methods. BSI; 1999.

Cleaning

Process

Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization of equipment. It is a method of decontamination for non-invasive (low risk) items but should not be used as the only process for high or intermediate risk equipment, where sterilization or disinfection is required.

Wherever available, the use of mechanical cleaners such as washer-disinfectors and ultrasonic washers is preferred to the manual cleaning of items. The cleaning method should be assessed to ensure the effectiveness of the cleaning process without damage to equipment.

The advantage of using automated cleaning equipment is that it provides an efficient, reproducible process that can be more easily controlled than manual methods.

Automated processes are generally more convenient and also provide protection for the user in reducing the exposure to aerosols, chemicals and vapours.

The use of an automated mechanical washer-disinfector can also provide disinfection using moist heat. Some automated endoscope reprocessors also perform a cleaning process prior to the chemical disinfection process.

Further detail on the cleaning processes used for medical devices can be found in part 1 of this manual (Principles).

Cleaning (manual) – immersion

Hand washing of items should only be undertaken when other mechanical methods are inappropriate or unavailable. Refer to the manufacturer's instructions.

Scope of action

This procedure is not a disinfection process and therefore some items may require subsequent disinfection or sterilization.

Equipment required

- A sink (not a designated hand wash basin), or a receptacle which will hold sufficient volume of water/detergent such that the item of equipment to be cleaned can be fully immersed.
- A warm, compatible water/detergent solution at correct dilution and temperature, i.e. not greater than 35°C.
- Brush(es) and jet washer/handspray.
- A receptacle to contain rinse water e.g. a second sink; a drainage surface.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility e.g. drying cabinet or industrial hot air dryer.
- A chemical neutraliser, first aid kit and eye wash bottle in case of splashing with detergent.

Procedure

- Ensure that the cleaning receptacle is clean and dry.
- Wearing protective clothing (see safety precautions) fill the sink or receptacle with sufficient warm water/ detergent solution to ensure complete immersion of the item.
- Equipment should be dismantled where necessary in line with the manufacturer's instructions before cleaning.
- Carefully immerse the item in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reaches all surfaces including internal surfaces of lumened or cannulated devices.

- Brush, wipe, agitate, irrigate, jet wash or hand spray the item to dislodge and remove all visible soiling, taking care that the action is undertaken beneath the surface of the solution.
- Remove the item from the solution and drain over the detergent solution before transferring to a clean-rinse receptacle or sink.
- Rinse item thoroughly with clean water or with a water jet gun, ensuring that the item being rinsed is fully immersed.
- Remove item from rinse water and drain.
- Carefully hand-dry using absorbent, non-shedding cloth or industrial hot air dryer, or place into drying cabinet.
- Thoroughly wash and dry receptacles before storing and reuse.
- Used brushes should be decontaminated after use and discarded if there are signs of wear.
- Complete necessary documentation.

Monitoring and control

- Owing to the lack of acknowledged methods of control available to the user to test the efficiency of immersion cleaning, the user should be aware of the factors that may alter the efficiency of the method:
    - > staff training / competence
    - > water temperature
    - > detergent concentration
    - > nature of soil
    - > method of soil removal
    - > accessibility of fluid to item
- If either the cleaning solution or rinse water becomes obviously soiled or contaminated, it should be changed and the process repeated.

Maintenance

- Regularly inspect all receptacles, sinks, surfaces including water supply and drains, for damage.
- Plan preventative maintenance for all equipment and utilities.
- Check eye wash bottle.

Safety precautions

- Always wear protective waterproof clothing, robust gloves and eye protection.
- Avoid splashing.
- Eye protection should be worn when hand operated water jet washers are used.
- Protective clothing should be removed on completion of procedure and hands thoroughly washed and dried.

Cleaning (manual) – non-immersion

Scope of action

- Non-immersion manual cleaning methods are appropriate for certain equipment where items will become compromised by soaking in aqueous solutions, e.g. electrical and electronic equipment.
- Alcohol wipes should be used to clean electrical contacts on equipment.

Equipment required

- A warm water/detergent solution at correct dilution.
- A clean, disposable, absorbent, non-shedding cloth for application of detergent solution.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (e.g. drying cabinet or industrial hot air dryer).
- An appropriate chemical neutraliser, first aid kit and eyewash bottle, in case of splashing with detergent.

Procedure

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- Wearing protective clothing, immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Commencing with the upper surface of the item, wipe thoroughly ensuring that detergent solution does not enter electrical components.
- Periodically rinse the cloth in clean water and repeat the above steps.
- Surfaces should be carefully hand-dried using a cloth or industrial hot air dryer or placed into a drying cabinet.

Note: Non-immersion, manual cleaning is not a disinfection process, but where an alcohol wipe is used to dry surfaces, this may have a disinfecting effect.

- Safely dispose of cleaning materials and alcohol wipes, if used.

Monitoring and control

Owing to the lack of control methods available to the user to test the efficiency of non-immersion cleaning, the user should be aware of the factors that may alter the efficiency of the method:

- staff training
- physical application
- nature of soil
- accessibility of cleaner to item/part of equipment
- detergent concentration

Safety precautions

- Always wear protective waterproof clothing, robust gloves and eye protection if splashing is likely to occur.

- After removing protective clothing on completion of task, thoroughly wash and dry hands.

- Avoid splashing.

- Precautions should be taken when using alcohol, as it is flammable.

- The ‘pooling’ of alcohol on equipment should be avoided and alcohol evaporation ensured, if necessary by forced air drying. Care should also be taken to ensure that alcohol does not enter the item e.g. via ventilation slots.

Cleaning (mechanical) – thermal washer-disinfectors

Scope of action

- Cleaning is achieved by the continual spraying or deluging of items with water and detergent during several stages of a timed cycle. The initial clean should be at or below 35°C to avoid fixation of biological material on the surface of the devices. This is followed by a hot water disinfection rinse where the surface temperature of the item processed should reach a minimum temperature of 71°C for a minimum of 3 minutes, 80°C for 1 minute or 90°C for one second (HTM2030). Equipment should emerge dry at the end of the process.

- A typical cycle comprises the following phases:
  - > cold rinse
  - > warm wash
  - > disinfection rinse
  - > drying

Equipment required

- A washer-disinfector validated in accordance with HTM2030.

- A compatible detergent and rinse aid if designated.

- Storage racks for dirty devices; personal protective equipment (PPE), chemical neutraliser and first aid.

- An appropriate chemical neutraliser, first-aid kit and eyewash bottle, in case of leakage or splashing with detergent or rinse aid.

Procedure

- Load devices appropriately to ensure maximum exposure and optimum circulation of water/chemical throughout load.

- Start process.

- Check the cycle has been successful.

Monitoring and control

- Machines should be regularly tested.

- Relevant tests are given in BS EN ISO 15883 and HTM2030.

Maintenance

- Regular planned preventative maintenance should be undertaken in accordance with the manufacturer's recommendations, local policy and HTM 2030.
- Inspect and clean all filters.
- Dismantle and clean spray arms and nozzles.
- A log book should be maintained for each washer-disinfector.

Safety precautions

- Always wear protective waterproof clothing, robust gloves and eye protection if splashing is likely to occur.
- After removing protective clothing on completion of task, thoroughly wash and dry hands.

References

BS 15883 Washer-disinfectors
Part 1: General requirements, definitions and tests.
Part 2: Requirements and tests for washer disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware etc.
Part 3: Requirements and tests for washer disinfectors employing thermal disinfection for human waste containers.
Part 4: Requirements and tests for washer disinfectors employing chemical disinfection for thermo-labile endoscopes.

HTM 2030: Washer-disinfectors, management policy. NHS Estates;1995.

Cleaning (mechanical) – ultrasonics

Scope of action

- This is not a disinfection process.
- Ultrasonic cleaning is dependent upon cavitation (rapid formation and collapse of minute bubbles in a liquid) which is produced by introducing high frequency (ultrasonic), high intensity, sound waves into a liquid. The consequent agitation creates a highly penetrative cleaning system. As this is not a disinfection process, subsequent disinfection may be required.
- Ultrasonics may form part of an automated process or be stand-alone.

Equipment required

- An ultrasonic washer with lid which will hold enough liquid to immerse items fully.
- Connectors for lumened or cannulated items.
- Supporting racks or trays to suit a range of instruments processed.
- A timing device as appropriate.
- A warm, compatible water-detergent solution (ultrasonic cleaner) at correct dilution and temperature, i.e. not greater than 35°C.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility e.g. drying cabinet or industrial hot air dryer.
- An appropriate chemical neutraliser, first aid kit and eye wash bottle, in case of leakage or splashing with detergent.

Procedure

- Refer to device manufacturer's instructions for compatibility with ultrasonic process.
- Ensure that the ultrasonic washer is clean and dry prior to use.
- Wearing protective clothing, fill the fluid reservoir with sufficient water/detergent to ensure complete immersion of the item. Replace lid.
- Switch on and leave for required time to de-gas the water where necessary following manufacturer's instructions.

- Switch off.
- Remove lid and carefully immerse the item in the fluid ensuring that any air contained within the item is displaced. Irrigate lumened/cannulated devices or connect to accessory port.
- Replace the lid, switch on and leave for the recommended time.
- Switch off, lift lid, remove the item and drain before transferring to a clean-rinse receptacle.
- Rinse thoroughly with clean water, ensuring irrigation of lumened/cannulated devices, and drain.
- Carefully hand-dry using absorbent, non-shedding cloth, industrial hot air dryer or place into drying cabinet.
- Complete the documentation.
- Dry the equipment before storing until required for reuse.

Monitoring and control

- Electronic devices are available to measure the effectiveness of the ultrasound process. However, advice should be sought from an Authorised Person (AP) on the use of these devices.
- A simple test can be carried out using aluminium foil strips as detailed in HTM2030.
- The user should be aware of the following factors that may alter the efficiency of the system:

  > detergent concentration
  > ultrasound frequency
  > water temperature
  > exposure time
  > the type of soiling
  > quantity and configuration of the load.

- Devices with lumens require irrigation before and after processing.

Maintenance

- Change solution when it becomes visibly soiled or every 4hrs, whichever is the sooner as described in HTM2030.
- The tank should be inspected regularly to ensure that surfaces are undamaged and inlets and drains are free from obstructions.
- Regularly inspect the ultrasonic cleaner for electrical safety following HTM2030 guidance.
- A logbook should be maintained of the results.

Safety precautions

- Always wear protective waterproof clothing, robust gloves and eye protection if splashing is likely to occur.
- Frequency of the ultrasonic waves should be checked to ensure that the operator's hearing is not compromised.
- Further information on ultrasound exposure limits may be obtained from the Health and Safety Executive.

Disinfection – chemical washer-disinfector

For heat-sensitive endoscopes and accessories.

Scope of action
Cleaning is achieved by soaking, spraying and irrigating channels or deluging with water and compatible detergent or exposure to ultrasonics during a timed cycle. The temperature of the cleansing stage should be at or below 35°C. Disinfection is achieved by exposure to an approved disinfectant at a defined temperature for a predetermined period. This is followed by one or more rinses in water to remove disinfectant residues. The final stage of the cycle includes fluid expulsion from the lumens by air pressure and an optional warm air dry or alcohol rinse.

A typical cycle comprises the following stages:

- cold wash
- chemical disinfection at less than 60°C
- water rinse
- drying

Equipment required

- The washer-disinfector chosen should:
    - > have a thermal cut-out particularly if the chemical disinfectant is used at elevated temperature
    - > have a validated cycle
    - > have channel connectors and supporting racks and trays to suit the range of instruments processed
    - > clean, chemically disinfect and rinse (to remove toxic residues of disinfectant) all external surfaces and lumens of the endoscopes and accessories
    - > be programmable to suit the contact times for the disinfectant chosen
    - > have a draining or drying facility
    - > have facilities to contain or extract irritant vapours
    - > be able to supply rinse water of a suitable quality
    - > self disinfect
    - > indicate disinfectant exchange frequency due to a reduction of potency, expiry of shelf life period etc.

> safely discharge detergent, disinfectant and rinse water (machines that do not reuse detergent and rinse water are preferred)

> preferably have calibrated automated dosing systems.

- A compatible detergent (neutral/enzymatic).
- An appropriate disinfectant i.e. effective, safe and compatible with the washer-disinfector and endoscopes processed.

Procedure

- Ensure washer-disinfector and all services are operational.
- Wearing protective clothing, manually clean external surfaces and lumens with a clean, disposable, non-shedding cloth, test for leaks, check instrument function, ensure that all valves and taps are in the 'open' position.
- Load washer-disinfector ensuring the loading configuration does not impede the cleansing process and attach channel connectors to ensure irrigation of all lumens.
- Secure lid (if fitted), select and start cycle.
- On completion of cycle, ensure all stages and parameters have been achieved; remove load, inspect for signs of soiling or damage, drain off excess water, dry if necessary and check function of instrument.
- At the end of each session, drain tanks of washer-disinfector and thoroughly clean accessible surfaces and strainers.
- Before commencing a further session, disinfect all fluid pathways, tanks and immersion trays.
- If a water treatment system is fitted, disinfect or sterilize the connecting pathway between the system and washer-disinfector in accordance with manufacturer's instructions.
- Complete the documentation.

Monitoring and control

- It is important that the machine is operated and controlled in accordance with the manufacturer's instructions. In addition, further testing should be carried out regularly in accordance with HTM2030 and when commissioning new equipment.

- Regular microbiological monitoring of the rinse water should also be performed as detailed in HTM2030:

    > when commissioning new equipment and on a regular basis thereafter

    > following a change in the disinfection procedure, e.g. type of disinfectant, concentration, contact time

    > following an episode of infection which may be attributable to the machine or disinfection procedure

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Maintenance

- Regular planned preventative maintenance should be undertaken in accordance with the manufacturer's recommendations and/or local policy, including:

    > inspecting and cleaning all filters and strainers
    > dismantling and cleaning spray arms and nozzles

- A log book of maintenance carried out should be completed for each washer-disinfector.

Safety precautions

- Always wear protective waterproof clothing, robust gloves and eye protection if splashing is likely to occur.

- After removing protective clothing on completion of task, thoroughly wash and dry hands.

- A chemical neutraliser, first aid kit and eye wash bottle in case of leakage or splashing with detergent or disinfectant.

References and further reading

HTM 2030: Washer-disinfectors, management policy. NHS Estates;1995.

Bradley CR and Babb JR. Endoscope decontamination: automated vs manual. Journal of Hospital Infection (1995); 30: 537-542 Supplement

Reichert M. Automatic washers/disinfectors for flexible endoscopes. Infection Control and Hospital Epidemiology (1991); 12: 497-499

Medical Devices Agency. Decontamination of endoscopes. Device Bulletin July 2002 MDA DB2002(05). (www.mhra.gov.uk)

Anon (1991). Nosocomial infection and pseudoinfection from contaminated endoscopes and bronchoscopes. MMWR (1991); 40/No.39: 675-678.

British Society of Gastroenterology. Guidelines for decontamination of equipment for gastrointestinal endoscopy (2003). (www.bsg.org.uk)

British Thoracic Society guidelines on diagnostic flexible bronchoscopy. Thorax 2001;56(Suppl 1):i1-i21 (February).

Dr Judith Richards, PHLS. Rinse Water for heat labile endoscopy equipment. A report from a Joint Working Group of the Hospital Infection Society and the Public Health Laboratory Service; 2001 (available on HIS website www.his.org.uk).

Disinfection – liquid chemical immersion

As the effectiveness of a disinfectant relies on good contact between the disinfectant and the item to be disinfected, items of equipment require thorough cleaning before disinfection.

A risk assessment should be undertaken in accordance with the Control of Substances Hazardous to Health (COSHH) Regulations, before using hazardous chemicals such as disinfectants.

Disinfectants can cause irritation to the skin, eyes, mucous membranes and respiratory tract and can also be flammable, volatile, and corrosive.

The decision as to which disinfectant to use for a particular situation is ultimately made at a local level. However, this should be after consulting with a member of the infection control team.

All irritant disinfectant residues should be removed before the item is reused and care should be taken when rinsing to ensure that items are not re-contaminated during this procedure.

Note: For chemical disinfectant solutions formulated for repeated or prolonged use, record the date of preparation/activation of the solution and check that the solution is free from debris and discoloration before each use.

Scope of action

- **Should be a last resort process only.**
  A risk assessment should be carried out including COSSH infection control.

- The establishment of a disinfection policy must involve infection control personnel as such a decision is based on a number of different factors, including the information supplied by the manufacturer of the device or accessory. Once a policy has been agreed and implemented, deviations should not be permitted unless there has been prior consultation with local infection control personnel.

- Appendix 2 provides a summary of the main groups of disinfectants, their range of activity, stability, compatibility and toxicity.

Equipment required

- A receptacle (with a lid) which can be sterilized or disinfected and with sufficient capacity to immerse the item fully.
- A means to contain or extract any irritant vapours.
- A timing device with audible signal, e.g. electronic stopwatch.
- A solution of freshly prepared chemical disinfectant, at use concentration.
- A receptacle which can be sterilized or disinfected to contain rinse water.
- Clean water to rinse items after chemical disinfection.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer).

Procedure

- Liquid chemical disinfectants can be supplied ready to use or may require mixing with an activator. Alternatively it may need accurate dilution to an in-use strength.
- Ensure that the disinfectant receptacle is clean and dry.
- Wearing protective clothing, robust gloves and eye protection, fill the receptacle with sufficient prepared disinfectant solution so as to ensure complete immersion of the item to be processed.
- Carefully immerse the item in the solution in such a way as to displace any trapped air within the item; it is important to ensure that the solution reaches all surfaces including lumens. An irrigation device may be required.
- Place the lid on the receptacle and leave for the recommended time.
- Remove the item from the solution, drain into receptacle before transferring to clean rinse receptacle.
- Rinse thoroughly with water of suitable microbiological quality.
- Remove item from rinse solution and drain.
- Carefully hand-dry using clean, absorbent, non-shedding cloth or industrial hot air dryer or place into drying cabinet.
- Complete the documentation.

- Thoroughly wash, dry and disinfect or sterilize receptacles before storing in clean area until required for use.

Monitoring and control

Due to the lack of control methods available to the user to test the efficiency of a solution being used, the user should be aware of the factors that may alter the efficacy of the disinfectant:

- staff training
- contact time
- temperature
- stability and age
- presence of organic material and other inactivating substances
- water quality
- concentration
- nature of the contaminating organism(s)

Staff must be adequately trained in the safe handling and processing of equipment to be disinfected.

Maintenance

- To ensure process integrity, regularly inspect receptacles and irrigation devices for damage or deterioration.

Safety precautions

- All disinfectants must be assessed under COSHH in respect of irritancy to skin, eyes and respiratory tract (see also appendix 2).
- A chemical neutraliser, first aid kit and eye wash bottle, in case of splashing with disinfectant.
- Always wear protective waterproof clothing, robust, chemical resistant gloves e.g. nitrile, and eye protection if splashing is likely to occur.
- After removing protective clothing on completion of task, thoroughly wash and dry hands.
- In case of spillage, respirators and/or protective masks and other appropriate materials should be made available in accordance with local policy.

References and further reading

Health and Safety Executive (2002) Control of Substances Hazardous to Health Regulations: general COSHH ACOP and carcinogens ACOP and biological agents ACOP (Approved Codes of Practice), HSE Books.

Great Britain. Health and Safety at Work Act 1974. London: HMSO, 1974.

Ayliffe G A J, et al, Chemical Disinfection in Hospitals. PHLS; 1993.

Health and Safety Executive. Guidance Note EH40/2004, Occupational Exposure Limits (revised annually).

CRONER'S substances hazardous to health - Emergency Spillage Guide, CD ROM and looseleaf (published every three months) Croner Publications Ltd.

Russell, Hugo & Aycliffe's Principles and Practice of Disinfection, Preservation and Sterilization (Fourth edition Edited by A P Fraise, P A Lambert and J-Y Maillard). Blackwell Publishing Ltd; 2003. ISBN 1405101997.

Sterilization

Scope of action

- Sterilization can be achieved by moist heat at raised pressure, by dry heat at normal pressure, by gas plasma at ambient temperature or by ethylene oxide at sub-atmospheric or high pressure. Sterilization can also be achieved using low temperature steam and formaldehyde vapour.

- Moist heat sterilization using steam under pressure should always be used in preference to other methods since it is more reliable and can be more effectively monitored and the process validated. This is not suitable for items that are damaged by heat or moisture.

Procedure

Methods of sterilization are described in full in part 1of this manual.

Further reading

HTM 2010: Sterilization. NHS Estates; 1997.

Device Bulletin DB 9804 The validation and periodic testing of benchtop vacuum steam sterilizers. Medical Devices Agency; 1998.

Device Bulletin DB 2002(06) Benchtop Steam Sterilizers – Guidance on Purchase, Operation and Maintenance. Medical Devices Agency; 2002.

Appendix 1 Declaration of contamination status

From (consignor): _____

Address

Reference _____

Emergency tel _____

To (consignee): _____

Address

Reference _____

Type of equipment _____ Manufacturer _____

Description of equipment _____

Other identifying marks _____

Model No _____ Serial No _____

Fault _____

Is the item contaminated? **Yes*** **No** **Don't know**

* State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard: _____

Has the item been decontaminated? **Yes†** **No‡** **Don't know**

† What method of decontamination has been used? Please provide details

Cleaning _____

Disinfection _____

Sterilization _____

‡ Please explain why the item has **not** been decontaminated:

_____

Contaminated items should not be returned without prior agreement of the recipient

This item has been prepared to ensure safe handling and transportation:

Name Position

Signature

Date Tel

Appendix 2 Instrument disinfectants: properties at room temperature

Disinfectant	Microbicidal activity					Stable	Inactivation by organic matter	Corrosive/ damaging	Irritant (I) Sensitising (S)
	Spores+	Mycobacteira#	Bacteria#	Viruses#					
				Env.	Non env.				
Glutaraldehyde 2%	3 hours	20 mins	< 5 mins	< 5 mins	< 5 mins	Moderate e.g. 14-28 days	No (fixative)	No	I/S
Ortho-phthalaldehyde 0.55%	> 6 hours	< 5 mins	< 5 mins	< 5 mins	< 5 mins	Moderate 30 days	No (fixative)	No (staining)	I
Peracetic acid 0.2-0.35%*	10-20 mins	5-20 mins	< 5 mins	< 5 mins	< 5 mins	No 1-3 days	No	Slight	I
Alcohol (usually 70%)	None	< 5 mins	< 5 mins	< 5 mins	5-10 mins	Yes	Yes (fixative)	Slight (lens cements)	No (flammable)
Chlorine dioxide	< 5 mins	< 5 mins	< 5 mins	< 5 mins	< 5 mins	No 1-5 days	Yes	Yes	I
Superoxidised water (electrolysed saline)	< 5 mins	< 5 mins	< 5 mins	< 5 mins	< 5 mins	No < 1 day	Yes	Yes	No

* activity varies with concentration of product

+ time required to achieve 6 log 10 reduction

time required to achieve 5 log 10 reduction