

LTHT Infection Control Policies
Policy No. 5

Decontamination of Hospital Equipment
Including Medical Devices (Interim Policy)

All hospital equipment is either single-use or reusable. Single-use equipment should not be reused and should be discarded appropriately after use. All reusable equipment must be decontaminated between use and between patients. Infection can be spread via inadequately decontaminated items.

Scope

This policy applies to all staff and students working within LTHT.

Key Points

- Decontamination of equipment is the responsibility of the user.
- Equipment will need cleaning and/or disinfection or sterilisation. The choice of decontamination method will depend on the risk of infection associated with the equipment.
- Regardless of use, any equipment must, as a minimum, be cleaned between patients.
- Cleaning is an essential pre-requisite of any disinfection or sterilisation process.
- Moist heat with mechanical cleaning (using a washer-disinfector) is the preferred disinfection technique.
- The use of chemical disinfectants for medical and patient care equipment should be avoided wherever possible.
- Chemical disinfectants can fail if not selected and used properly.

- Autoclaving in HSDU is the preferred sterilisation technique.
- Items described as "single-use" or "not for reuse" should not be reused, or reprocessed, See Trust policy "Medical Devices supplied for Single Use Only"
- All equipment must be appropriately decontaminated before inspection, service or repair.
- DO NOT purchase new equipment without first checking that the Trust has suitable facilities for decontamination. If unsure contact the infection control team or the Trust's Decontamination Manager.
- DO NOT purchase new decontamination equipment, or chemical disinfectants without consulting Infection Control and the Department of Medical Physics and Engineering

INTRODUCTION

This policy covers the decontamination of hospital equipment, including items that do not come into direct contact with patients.

All hospital equipment from, bed frames to complex surgical equipment, can be associated with the transmission of infection to potentially vulnerable patients. All staff have a responsibility under the Health and Safety at Work Act etc. (1974) and the Control of Substances Hazardous to Health (COSHH) regulations (1994) to ensure that equipment in their area is correctly decontaminated between uses and between patients.

This policy DOES NOT cover - **Hand disinfection – (see LTHT Hand Hygiene policy).**

Transmissible Spongiform Encephalopathies (TSEs e.g. CJD) – (see LTHT policy).

The Decontamination, Storage and use of Flexible and Rigid Endoscopes – (see LTHT policy).

1. Decontamination of hospital equipment

Choice of decontamination method

- Equipment will need cleaning and/or disinfection or sterilisation. The choice of decontamination method will depend on the risk of infection associated with the equipment.
- Regardless of use any equipment must, as a minimum, be cleaned between patients.
- Decontamination methods must be chosen according to the risk of infection associated with the use of a particular piece of equipment as follows (Table 1)

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

Risk	Application of Item	Recommendation
High	<ul style="list-style-type: none"> • In close contact with a break in the skin or mucous membrane; or, • For introduction into sterile body areas 	Sterilisation
Intermediate	<ul style="list-style-type: none"> • In contact with mucous membranes or body fluids; or, • Contaminated with particularly virulent or readily transmissible organisms; or, • Prior to use on immunocompromised patients 	Sterilisation or high level disinfection required NB “high level” disinfection should remove microbes which may be harmful
Low	<ul style="list-style-type: none"> • In contact with healthy skin; or, • Not in contact with patients 	Cleaning may be acceptable in some agreed situations Cleaning

- Compatibility with the chosen method will be determined from information supplied by the equipment manufacturer. **If no reprocessing information is provided or is inadequate, please notify the Infection Control Team**

(ICT). Manufacturers of “medical devices” (which includes virtually all patient-care equipment) are required to provide decontamination guidance for reusable products.

- Wherever possible single use devices should be used provided they do not compromise clinical outcome.

Cleaning

- This procedure is **not** a disinfection process but is an essential component of any disinfection and sterilisation process.
- **Cleaning** is a process that physically removes contamination, but does not necessarily destroy micro-organisms. The reduction in microbial contamination is not quantified and will depend upon many factors including the efficiency of the cleaning process and the initial level of contamination.
- Cleaning can be effectively achieved using hot water, neutral detergent and single use cloths.
- Cleaning must be followed by effective drying, and storage in a clean environment, to prevent re contamination.
- Cleaning may be manual or mechanical (e.g. as part of the function of a washer-disinfector).
- When undertaking manual cleaning, a risk assessment should be performed and correct protective clothing should be worn E.g. apron gloves and eye protection to guard against potential splash injury.
- Protective clothing should be removed on completion of the cleaning procedure and hands thoroughly washed and dried.
- Cleaning may be aided by the use of an enzymatic cleaner (contact infection control for advice.)

Disinfection

- Moist heat with mechanical cleaning (using a washer-disinfector) is the preferred disinfection technique.
- The use of chemical disinfectants for medical and patient care equipment should be avoided wherever possible.
- Chemical disinfectants can fail if not selected and used properly.

- **Disinfection** is a process used to reduce the numbers of micro-organisms but which may not destroy bacterial spores or some viruses. Disinfection is considered to reduce the numbers of micro-organisms to a level that is safe for the purpose for which the piece of equipment is intended.
- The two main methods of disinfection are the use of an automated washer-disinfector (e.g. “bed pan washer”) or the use of chemical disinfectants

Automatic washer-disinfectors

- Washer-disinfectors combine mechanical cleaning and heat disinfection and are used to process items for reuse (e.g. bedpans), or to render items clean and safe prior to sterilisation.
- Items that are compatible with washer-disinfectors should be processed in this way in preference to the use of chemical disinfectants.
- Items may be disinfected using a washer-disinfector either in the clinical area or in the HSDU.
- Washer disinfectors must be serviced regularly and comply with HTM2030
- Users of washer-disinfectors should report any fault immediately. This includes failure to clean items. Reports of failure to clean should be specific, rather than simply stating “broken” or similar.

Chemical disinfection

- A chemical disinfectant is a compound or mixture, which under defined conditions is capable of disinfection.
- The use of chemical disinfectants for medical and patient care equipment should be avoided wherever possible.
- Chemical disinfectants can fail if not selected and used properly.

Chemical disinfectants can be used for:

- Blood and body fluid spillage (see Standard Infection Control Precautions).
- Hard surface/equipment decontamination between patients.
- Disinfection of equipment that is damaged by heat. If a disinfectant is used all residue should be removed prior to the device being used. (E.g. flexible endoscopes).

- Hand (see hand hygiene) and skin disinfection (prior to invasive procedures).
- Environmental disinfection (e.g. during and after outbreaks of infection).
- For list of approved chemical disinfectants and examples of usage see Appendix A.

Use of chemical disinfectants:

- Only use disinfectants on clean objects/surfaces, remove any physical dust or dirt by cleaning before disinfection.
- When diluting always measure the amounts, never estimate.
- Use the correct dilution – too low is ineffective, too high is wasteful and may cause damage.
- Do not mix disinfectants with detergents or other disinfectants.
- Use the correct contact time, too short will be ineffective, too long may cause damage or the solution could become contaminated.
- Always use freshly prepared solutions; discard any unused solutions after a maximum of 24 hours. Unused solutions can become contaminated by certain microbes if stored as opposed to discarded. Subsequent use of such solutions may actually result in worsening microbial contamination of apparently disinfected items.
- For equipment disinfection always seek and follow the advice of the equipment manufacturer regarding compatibility with chemical disinfectants.
- Some chemical disinfectants are hazardous; always ensure that the COSHH regulations are followed when using chemicals.

Sterilisation

- Autoclaving in HSDU is the preferred sterilisation technique
- **Sterilisation** is the complete removal or destruction of all viable micro-organisms including viruses and bacterial spores.

Methods of sterilisation for medical equipment:

- Steam under pressure (autoclaving) in; HSDU (Hospital Sterilisation and Disinfection Unit), Hydrogen peroxide gas plasma (“Sterrad”)
- Liquid chemical sterilant (e.g. “Steris system 1”)
- Ethylene oxide gas.

Choice of method:

- Any item (requiring sterilisation) that can be autoclaved in HSDU should be.
- Following the decontamination advisory group guidelines (DAG), no area within the trust should be using a BTSS. These must be maintained and used in accordance with Medical Devices Agency guideline MDA DB 2002 (06). This in practice is very difficult to achieve full compliance and sending items to HSDU is preferable.
- Items that cannot be autoclaved may be suitable for “Sterrad” or a liquid chemical sterilant – contact Infection Control for advice.
- Ethylene oxide gas is not available on-site and has a two-week turnaround time, making it very impractical for most uses.


Use of sterilised items:

- Always check sterilised items before use. Packaging must be dry and intact. Inspect any sterilisation indicators (e.g. autoclave tape) and check expiry date.

2. The reuse of medical devices labelled “single use”

- Items described as “single-use” or “not for reuse” should not be reused, See Trust policy “Medical Devices Supplied for Single Use Only”

Medical devices (which include virtually all patient care equipment) are classified as;

- Reusable (may be used more than once for different patients subject to proper decontamination)
 - Single patient use (may be used more than once for the same patient – may or may not need decontamination between uses).
 - Single-use (must be used once only and discarded).
- Items labelled “single-use” or “not for reuse” or with the international single-use sign - “ “must not be reused or reprocessed in any way (including decontaminating, refilling or reloading).

The problems associated with reuse and reprocessing of single use devices are:

- Inability to guarantee effective cleaning
- Lack of knowledge of the compatibility of a device with the cleaning, disinfection or sterilisation process chosen.
- Absorption of the processing agents, or the sterilisation agents by the device, which may be transferred to the patient during use, or may react with administered medicinal products.
- Absence of quality assurance procedures to confirm that reprocessed devices have not deteriorated during reprocessing e.g. plastic materials may become brittle, lose flexibility or crack. An example of

the consequences of such deterioration would be the loss of electrical insulation properties in diathermy leads.

Such problems could lead to patient harm due to:

- Infection – because of decontamination failure
- Injury – because of structural damage to the device
- Exposure to harmful substances – due to absorption of reprocessing agents.

The consequences to the user and the Trust of reuse may be:

- Exposure to civil liability to pay damages for any injury caused to another person by the device, either on the basis of negligence or under the strict product liability provisions of part 1 of the Consumer Protection Act 1987, if the product is found to be defective.
- Prosecution for a criminal offence under the Health and Safety at Work Act 1974 by contravening the provisions relating to “general duties” by carrying out activities that expose patients or staff to risk.
- Further guidance on the reuse of medical devices supplied for single use only has been issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) In DB2000(04) [4]

The Infection Control Team will not support any proposal for reuse of single-use items.

3. Decontamination of equipment prior to inspection, service or repair.

- All equipment must be appropriately decontaminated before inspection, service or repair.
- Equipment may be inspected serviced or repaired both on site and elsewhere, by both hospital staff and staff employed by suppliers.
- In any situation such staff must not be placed at risk by being exposed to contaminated items.
- Equipment that is to be dealt with by non-trust staff must have been appropriately decontaminated (see Table 1), and a decontamination certificate completed (Contact Medical Physics for advice).
- Complete decontamination may not be possible in certain circumstances i.e. the equipment is the subject of an investigation, and decontamination may affect the investigation, **or**;

- The user is unable to safely decontaminate internal parts of the equipment e.g. where body fluids have accidentally leaked.
- Under these circumstances the user must indicate the nature of the remaining risk(s), for external repairers this includes completing a declaration of contamination status.
- If these measures have not been taken then service and repair staff may refuse to handle the item(s).
- NB. For blood and body fluid contamination see Standard Infection Control Precautions.
- Further information can be obtained from;
 - Infection Control
 - Medical Physics
 - Estates
 - MHRA in DB 2003(05)[10]

Consultation Group

Infection Control Steering Group

Documentation Control

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Appendix 1.

Approved chemical disinfectants

Chemical	Brand name(s)	Concentration	Applications	Comments
Sodium dichloroisocyanate (NaDCC)	Chlor Clean	1,000 ppm	Environmental/ surface disinfection	As Above
Sodium dichloroisocyanate (NaDCC)	"HazTabs" "Sanichlor"	10,000 ppm	Blood spillage	As above
As above	As above	1,000 ppm	Environmental / surface disinfection	As above
As above	As above but in granules	Use neat	Blood spillage	As above
Peracetic acid	"Perasafe"	0.26%	Heat sensitive equipment	Check compatibility with equipment. May sterilise
Alcohol (ethyl or isopropyl) ^{note 1}	Various	60 – 70 %	Hard surface or equipment disinfection	Not suitable for use with <i>Clostridium difficile</i>

Notes

1. Also used for skin disinfection (hands or sites of invasive procedures), may be combined with other skin disinfectants e.g. chlorhexidine.
2. Other chemicals may be in use in some specialist areas e.g. in laboratories, or for unusual circumstances e.g. gross spillage of sewage.
3. Milton is no longer available for use except in certain areas by arrangement with Infection Control.

References and Further Reading

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