Policy for Decontamination of Reusable Medical Devices

For use in (clinical areas): All areas of the Trust
For use by (staff groups): All Trust staff
For use for (patients/treatments): Decontamination of reusable medical devices
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1.0 Introduction

1.1 The decontamination of re-usable medical devices is a complex process that requires the use of appropriate equipment that is validated, monitored and audited by appropriately trained personnel. Effective decontamination is essential in reducing the potential risk of cross-contamination.

The purpose of this document is to outline the Trusts policy for the decontamination of re-usable medical devices the aims are to:

- maintain a compliant Sterile Services Department (SSD)
- ensure the management of decontamination is consistent with and supports the achievement of, the Trust’s strategic and corporate objectives
- provide a high quality service to patients
- minimise the human costs of risks i.e. to protect patients and staff from risks where reasonably practicable
- meet statutory and legal obligations
- improve compliance with the on-going requirements of Care Quality Commission registration
- maintain compliance with decontamination aspects of the Hygiene Code
- ensure key objectives set by independent monitoring bodies are met
- minimise the financial and other negative consequences of losses and claims, for example, poor publicity or loss of reputation
- centralise the decontamination process of high and moderate risk devices to the SSD where this is practical

1.2 The decontamination of re-usable medical devices is the combination of processes, which if not correctly undertaken, may increase the likelihood of microorganisms being transferred to patients or staff.

The re-usable medical device life cycle can comprise the following processes:
- Acquisition
- Cleaning
- Disinfection
- Inspection
- Packaging
- Sterilisation
- Transportation
- Storage before use

This cycle is used to render a reusable item safe for further use. The term reusable medical device applies to all such devices whether owned by the Trust, rented, on loan or acquired by any other means.

1.3 This policy should be read in conjunction with relevant Infection Prevention and Control Policies and standard operating procedures for the specific decontamination areas (identified in Scope below).

2.0 Scope

2.1 The Trust's approach for the decontamination of reusable medical devices is in accordance with national strategy. This means that the decontamination of such devices is only permitted at key locations, these are:
- Sterile Services Department - decontamination of all reusable medical devices with the exception of flexible endoscopes
- Endoscopy Unit (EU) - flexible endoscopes only.
2.2 Local decontamination is permitted for those items that are unable to withstand steam sterilisation, these are:

- Transoesophageal probes
- Transrectal probes
- Transvaginal probes
- Nasendoscopes - Ward F4

3.0 Exclusions

3.1 This policy does not cover laboratory sterilisers or any other non-clinical sterilisers used for waste.

4.0 Principles of decontamination

4.1 The general principles for the purpose of this policy are:

- Each item of equipment used on a patient must be appropriately decontaminated before and after use.
- The decontamination process used must be compatible with the equipment; this requires staff to follow the manufacturer’s instructions.
- The decontamination process must adequately deal with the risk of infection.
- Devices which have no manufacturer’s instructions or for which the manufacturer’s instructions are inadequate for managing the associated risk, must be considered for replacement by more suitable devices.
- The Infection Prevention Team will provide advice on this matter.

4.2 Definitions

- Decontamination - a general term used to describe the removal of microbial contamination, which can be achieved by cleaning, disinfection or sterilisation. The decontamination process is required to make medical devices safe for staff members to handle and / or for use on the patient.

- Cleaning - a physical process that removes large numbers of microorganisms and the organic matter on which they thrive. It also enables better contact with disinfectant and sterilisation agents. This is an essential part of the process prior to disinfection and / or sterilisation.

- Disinfection - reduces the number of microorganisms, using chemicals or heat, to a level that is not harmful to health. Disinfection does not usually remove or reduce bacterial spores.

- Sterilisation - a process used to render an object free from all living microorganisms including bacterial spores. This process is required for high-risk equipment.
4.3 Choice of decontamination method

<table>
<thead>
<tr>
<th>Risk</th>
<th>Function</th>
<th>Example</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>In close contact with break in the skin or mucous membrane</td>
<td>Surgical instruments</td>
<td>Sterilisation or</td>
</tr>
<tr>
<td></td>
<td>Introduced into sterile body cavity</td>
<td></td>
<td>Sterile single-use item</td>
</tr>
<tr>
<td>Medium</td>
<td>In contact with mucous membrane</td>
<td>Respiratory equipment</td>
<td>Sterilisation</td>
</tr>
<tr>
<td></td>
<td>For use on immunocompromised patients</td>
<td>Flexible endoscopes</td>
<td>High level disinfection</td>
</tr>
<tr>
<td></td>
<td>Contaminated with virulent or readily transmissible organisms</td>
<td></td>
<td>or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sterile single-use item</td>
</tr>
<tr>
<td>Low</td>
<td>In contact with intact skin</td>
<td>Stethoscopes</td>
<td>Manual cleaning and drying</td>
</tr>
</tbody>
</table>

4.4 Where items cannot be immersed in water manual cleaning may be necessary this should always be carried out to the departmental written procedure and in accordance with the manufacturer’s written instructions.

- Cleaning with neutral detergent and water will physically remove organic material and most microorganisms from a surface. When able to, items should be fully immersed in order to minimise splashing and the creation of aerosols. Items should not be cleaned under running water.

4.5 Cleaning should always be performed before disinfection and sterilisation.

4.6 Gloves and an apron should be worn during all cleaning procedures. Glasses/visor and mask should be worn if there is likely to be splashing or the creation of aerosols.

5.0 Legislation and standards

5.1 The Choice Framework for local Policy and Procedures (CFPP) covering decontamination have been archived; these are superseded by Health Technical Memoranda (HTM) – at the time of writing this document non-clinical sterilisers i.e. laboratory / pharmacy do not have an applicable HTM document.

5.2 HTM 01-01 - Parts A to E cover the decontamination of reusable medical devices and HTM 01-06 covers the decontamination of flexible endoscopes.

5.3 HTM, British and European standards should be referenced for all testing purposes.

5.4 Advice may be sought from the Authorising Engineer (Decontamination) where further guidance is required.

5.5 References for current standards are detailed in the reference section at the end of this document. The list is not intended to be exhaustive and other standards and guidance documents may also be applicable.
6.0 **Roles and responsibilities**

6.1 HTM Part A and B identify the roles and responsibilities required at the Trust to ensure that the decontamination process is managed effectively. At this Trust one or more roles may be covered by the same individual and in some cases the responsibilities may be covered by more than one individual.

The key roles and responsibilities are outlined below.

6.2 **Executive Manager**

- Chief Executive of the Trust who has overall responsibility for decontamination.

6.3 **Decontamination Lead**

- Maintain compliance with Directive 93/42/EEC.
- To advise the Trust in terms of decontamination in the delivery of Trust objective 1; to be the healthcare provider of first choice by providing high quality, safe and caring services.
- Accountability for decontamination service delivery at SSD.
- To co-ordinate reviews by external agencies.
- Working closely with the General Managers and senior Clinicians regarding decontamination compliance.
- At this Trust the Estate Development Manager is defined as the Decontamination Lead.

6.4 **Senior Operational Manager**

- Technically and managerially responsible for the implementation and effective management of the engineering aspects of decontamination.
- Oversee maintenance, validation and servicing of decontamination equipment/plant.
- Monitor SLA with external servicing and validation companies contracted to the Trust.
- At this Trust the Senior Operational Manager is defined as the Estates Specialist Service Manager supported by the Estates Competent Person for Decontamination Technician.

6.5 **Authorised Person (Decontamination) AP(D) The AP(D) should be appointed by management in agreement with the AE(D); the individual should be suitably trained and have adequate technical knowledge of the equipment installed at the site.**

- At this Trust the Senior Operational Manager is defined as the Estates Specialist Service Manager supported by the Estates Competent Person for Decontamination Technician.

6.6 **Authorising Engineer (Decontamination) AE(D)**

- The AE(D) should be independent from the Trust and should be appointed in writing by the Trusts Decontamination Lead.
- The key responsibilities are outlined in HTM 01-01 Part A and include:
  - Provide impartial advice and guidance on any matters concerned with sterilisation and disinfection issues
  - Advise on validation programmes
  - To audit reports on validation, revalidation and yearly tests prepared by the test person
  - To advise on programmes of periodic tests and periodic maintenance
  - To advise on operational procedures for routine production
  - The AE(D) for this Trust is provided by AVM Services
6.7 Competent Person (Decontamination) CP(D)

- Responsible for the maintenance, periodic testing and validation of the decontamination equipment
- This role should be carried out by suitably trained and experienced individuals; at this Trust a combination of in-house personnel and contractors are responsible.
- To support the Authorised Person (Decontamination) in carrying out their duties to maintain compliance to the HTM.

6.8 User

- Designated by management to be responsible for the operation of the decontamination process
- The responsibilities for this role are outlined in HTM 01-01 Part A
- At this Trust the User is defined as the Sterile Services Manager and the Endoscopy Manager
- The SSD Manager has accountability for decontamination service delivery in line with ISO 13485:2016
- The SSD Manager is responsible for the management of SSD and applying all relevant standards so that resources are organised to effectively meet the needs of the wards and departments, with disinfected and sterilised medical and surgical equipment.

6.9 Instrument Co-ordinator

- The responsibilities for this role are outlined in HTM Part A.
- At this Trust no single person is designated for this role – the responsibilities are covered by the users of the medical devices e.g. theatre personnel, the SSD and endoscopy managers, infection control and the purchasing department.

6.10 Director of Infection Prevention and Control (DIPC)

- The DIPC is responsible for the infection control aspects of the decontamination process
- The DIPC reports directly to the Chief Executive.

6.11 Infection Control Officer

- Defined at this Trust as the Lead Nurse, Infection Control
- Responsible for advising on all infection control aspects of decontamination.

6.12 Microbiologist (Decontamination)

- Defined at this Trust as the Consultant Microbiologist who is also undertaking the Infection Control Doctor role
- Responsible for advising on all microbiological aspects of decontamination.

6.13 Operators

- Should be appropriately trained to use the decontamination equipment installed in their department of work
- They are responsible for recording instrument readings, using the traceability system and undertaking basic routine tests on the installed decontamination equipment.
6.14 Competent Person (Pressure Systems) CP(PS)

- Responsible for the written scheme of examination for all pressure vessels installed at the site
- The CP(PS) for this Trust is provided by the Trust’s contracted insurance inspector.

6.15 Manufacturer

- Responsible for ensuring that all decontamination equipment is designed, manufactured and tested in accordance with current standards

6.16 Contractor

- This could be the manufacturer in some instances; they are responsible for ensuring that all installation checks and tests specified in current standards are carried out prior to full validation of the decontamination equipment.

6.17 Decontamination Group

- To oversee the Trust’s development and implementation of decontamination strategies ensuring they are consistent with and support the achievement of the Trust’s strategic and corporate objectives
- The group meets on a quarterly basis and formally reports to the Infection Prevention and Control Committee.
- The terms of reference for the Decontamination Group can be seen in Appendix 3 and the accountability structure can be seen in Appendix 4.

- Additional roles and responsibilities for the cleaning of items in patient areas can be found in appendix 7.

7.0 Risk Management

7.1 Level of Risk

The choice of decontamination process for equipment depends on a number of factors:
- The type of equipment
- The organism involved
- The time required for processing
- The risk to patients and staff
- The manufacturer’s written instructions

NB
1. Items of equipment labeled by the manufacturer as single use must be discarded after use and must not be decontaminated in any form for use on another patient (see appendix 2 for single-use policy)
2. The Trust does not support the use of benchtop sterilisers

Refer to decontamination principles (section 4) for additional guidance.

See appendix 6 for suggested decontamination methods and appendix 7 for roles/responsibilities of cleaning furniture/equipment in patient areas.

7.2 Risk Assessment
7.3 Incident Reporting

- Any decontamination related incidents must be reported in accordance with the Trust policy for Incident reporting and management (PP105).

- A summary of decontamination related incidents will be reported to the Decontamination Committee and Infection Prevention and Control Committee by the Governance Department for monitoring purposes.

- Any incidents that are categorised above amber will be reported to the Decontamination Committee and Red incidents reported to the Infection Prevention and Control Committee for monitoring purposes and to ensure appropriate action has been taken.

8.0 Training

8.1 All staff who are involved in the use or management of any decontamination equipment or process must have successfully completed competence based training, which is documented and updated appropriately. The departmental line manager will audit training records on an annual basis.

8.2 Department Managers should ensure that that all users of equipment/decontamination solutions receive appropriate training, preferably by the manufacturer/supplier for the decontamination equipment that they will be required to operate. The instruction must take place before the equipment/decontamination solutions are put into use.

Provision should also be made for documentation of this training to be recorded.

8.3 There are various training courses available for all personnel involved with decontamination. These are provided at training establishments or can be run as in-house courses. Advice on the appropriate course can be sought from the AE(D).

8.4 The Infection Prevention Team can advise on the availability of in-house training sessions, and on the suitability of others available elsewhere.

8.5 Where staff have decontamination responsibilities, the appropriate level of training must be undertaken and recorded in their personal development plans and objectives.

- Staff undertaking the manual decontamination of endoscopes using the disinfectant wipe system must have specific training from the manufacturer and this must be documented on competency / training records.

8.6 Details of the appropriate qualifications, accreditation and experience for all levels of personnel
are identified in HTM 01-01 Parts A and B.

9.0 Tracking and Traceability

9.1 All items produced by the SSD will be tracked and traced in accordance with the requirements for accreditation purposes and with current standards.

9.2 It is the responsibility of SSD, wards and departments to ensure that all surgical instruments can be tracked through the decontamination processes; this should culminate in robust records that are retained for 11 years or, for people born after 1997, retained for 21 years. In addition, systems should be in place/local policy should be developed to enable the identification of patients on whom instruments have been used.

9.3 A suitable recording system (manual and/or electronic) should be maintained and these will be audited for compliance.

9.4 Tracking and traceability records must be maintained for all nasendoscopes processed manually using the disinfectant wipe system - the records must be maintained in accordance with the manufacturer’s written instructions.

10.0 Audit

10.1 The Trust Decontamination Lead will audit compliance of this policy on an annual basis and a report of findings will be tabled at the Decontamination Group (DG).

- Any audit identifying a non-conformity will require discussion and appropriate remedial action will need to be agreed – a follow up audit will be required to ensure that the remedial action taken had resolved the non-conformity
- SSD are audited by the Notified Body (SGS) on an annual basis and internal audits are also carried out – non-conformities noted by the Notified Body require remedial action to be taken and evidence supplied within a fixed timescale identified on the audit report
- Manual cleaning of nasendoscopes using the disinfectant wipe system will be audited on at least an annual basis – the results of these audits will be reviewed at the decontamination group and any remedial actions required determined and follow up audits agreed

10.2 It is the responsibility of SSD, EU, DSU, wards and departments to ensure that suitable local audit arrangements are in place to ensure that the Trust and local decontamination policy is being applied. A summary of the audit findings should be reported to the Decontamination Lead, relevant General Manager and DG on an annual basis.

10.3 Internal Audit will undertake an external audit of compliance of this policy on a 24-month basis. A report of findings will be tabled at the DG.

11.0 Single use medical devices

11.1 All items supplied as ‘single-use’ will not be re-processed - please see appendix 2 for single-use policy.

12.0 Suspected prion contamination

12.1 Please refer to Clinical Guideline CG10031 “Creutzfeldt-Jacob Disease (CJD and variant CJD)” in the Infection Control Manual.

This guideline outlines the Department of Health recommendations which are regularly updated.
13.0 Acquisition of equipment

13.1 All clinical sterilisers and washer-disinfectors for SSD should be purchased in accordance with the specifications detailed in HTM Parts C & D respectively. Endoscope washer-disinfectors should be purchased in accordance with the specification in HTM 01-06. In all instances advice should be sought from the AE(D) as to the additional information required.

13.2 The selection of medical equipment/devices, whether it be replacement of existing equipment or the introduction of new, is managed by the Medical Equipment Group, who has responsibility for the evaluation, introduction and development of all equipment and associated consumables, training and maintenance, Reference Policy (PP024), Policy and Procedure for the Management of Medical Equipment appendix A.

Advice must be sought from key individuals and groups (see list in 13.3) before any of the following take place: -
- Purchase of new equipment
- Loan of equipment
- Changes in decontamination processes for existing equipment
- Methods of decontamination i.e. chemical disinfection/ sterilisation

All reusable equipment must be easily decontaminated after each patient use avoiding or minimising any exposure to hazards, i.e. body fluids/chemicals.

13.3 The purchasing decision should be made after a full option appraisal has been made, and in conjunction with all relevant parties:

a) General Manager
b) Budget holder
c) Medical Devices Management Group Lead
d) Decontamination Lead
e) Infection Prevention Team
f) Purchasing Department
g) Estates and EBME departments
h) An Authorised Person
i) Potential users of the equipment.

The ability/ease of decontamination of equipment is a factor that must be considered when contemplating the purchase of equipment. Specific consideration must be given to:

- Always purchasing disposable single use items whenever possible.
- Never re-use or plan to re-use single use equipment.
- Always using equipment in accordance with the manufacturer's instructions and the graphic symbols for use in the labeling of medical devices (BSEN980) displayed in all wards/departments.
- Ensuring facilities are available to adequately and safely decontaminate medical devices prior to purchasing.

Efficient and effective service support is vital and should be an important factor in the purchasing decision. Reference should be made to the purchasing procedures outlined in policy (PP024) Procedure for the Management of Medical Devices and the pre-purchase questionnaire at appendix C and D.

13.4 To ensure that all high and moderate risk medical devices are processed through the SSD plans to purchase devices should include for a sufficient quantity for this to happen.
14.0 Permit to work system

14.1 A permit to work system is operated to ensure that accurate records are maintained and all work is recorded.

14.2 Any persons working on decontamination equipment will be required to sign a permit to work on arrival and departure from the department.

14.3 A sample permit to work form can be seen in Appendix 8, which will follow in principle the format indicated in HTM 01-01 and 01-06.

15.0 Maintenance and testing of decontamination equipment

15.1 The washer-disinfectors and porous load sterilisers installed at the SSD and the endoscope re-processors in the endoscopy unit will be tested in accordance with current standards and guidelines. Further guidance can be sought from the AE(D).

15.2 The User is responsible for ensuring that decontamination equipment is made available for maintenance and testing.

15.3 Records of daily, weekly, quarterly and annual testing will be retained in the department for 21 years as liability for the provision of unsafe goods or materials continues for a period of 10 years under the Consumer Protection Act 1987.

15.4 Daily tests

- Operators / users are responsible for carrying out the daily tests – these are defined in the relevant CFPP, British and European standards.
- All test packs used will comply with current standards.
- All test results will be recorded in the equipment logbook.
- Any test failure must be noted and appropriate action taken to remedy any faults.

15.5 Weekly tests

- CP(D)s are responsible for carrying out the weekly tests on decontamination equipment; these are defined in the relevant HTM, British and European standards.
- All test results will be recorded in the equipment logbook; these records will be countersigned by the User to certify that the equipment is fit for use.
- Any unacceptable results should be repeated. Further guidance can be sought from the AE(D) if necessary.
- Endoscope Washer Disinfectors (EWD) should have a weekly monitoring to check the quality of the rinse water (refer to decontamination guideline: water quality monitoring and results).

15.6 Quarterly tests

- CP(D)s are responsible for carrying out the quarterly tests on the decontamination equipment.
- The tests are defined in the relevant HTM, British and European standards.
15.7 Annual, revalidation and performance qualification tests

- CP(D)s are responsible for carrying out these tests on the decontamination equipment.
- The tests are defined in the relevant HTM, British and European standards.
- All test results should be recorded in the equipment logbook or provided as a separate report.
- Logbooks / reports will be countersigned by the User to certify that the equipment is fit for use.
- Unacceptable test results should be repeated. Further guidance can be sought from the AE(D) where necessary.
- The annual test for surgical instrument washer-disinfectors should include a chemical analysis of the water as defined in HTM, British and European standards.
- The annual test for the endoscope washer-disinfectors should include a chemical analysis of the final rinse water and microbiological testing in accordance with HTM, British and European standards.
- The annual test for the porous load sterilisers should include steam quality and a sample of the steam condensate taken for analysis of the purity; in accordance with HTM, British and European standards.

15.8 Where applicable all pressure vessels will be tested by the CP(PS) and certificates made available to the User, AP(D) and AE(D) where appropriate.

16.0 Storage

16.1 Sterile products are stored at point of use. All wards and departments storing sterile products should have a dedicated storage area, which is appropriately designed to prevent damage to packs and allow for the rotation of stock.

16.2 Any sterile equipment must be stored:

- Away from public
- In a dedicated area
- In a clean dry area, (i.e. where risk of contamination with dust and /or body fluids is minimal)
- Shelving should be easily cleaned and allow the free movement of air around the stored product
- Above floor level
- Away from direct sunlight and water

16.3 Flexible endoscopes should be stored by hanging in a dedicated cupboard where they can be protected against damage and recontamination.

16.4 Before use sterile products should be checked to ensure that:

- Packaging is intact
- Sterilisation indicator indicates that the pack has been subject to an appropriate sterilisation process
- Product is still within the expiry date
17.0 **Loaned equipment**

17.1 **Loan to the Trust**

Service managers/Heads of Departments should take the following actions as part of the procurement process of loaned medical devices and surgical instruments:

- Advice must be sought from key groups (see list in 10.1) when the acquisition of loaned equipment is anticipated including the signing of indemnity agreements (NHS Form of Indemnity) and definition of the Trust's liability in the event of loss or damage to the device.
- Advise EBME/SSD of details of the loaned equipment for entry onto a register, including ownership, service history, current location, service responsibility and instructions for use.
- Ensure the initial acceptance checking of loaned equipment prior to putting into service, in accordance with manufacturers’ instructions is undertaken by EBME or via the appropriate service contractor.
- Ensure users are provided with instructions for use (and updates).
- Ensure periodic checking of loaned equipment for functionality and safety and repair in accordance with manufacturers’ instructions, is undertaken by EBME or via the appropriate service contractor.
- Define responsibilities for the maintenance, repair and regular safety checks of loaned equipment (including identifying the person(s) responsible for initiating the testing of the equipment and those responsible for performing the testing).
- Ensure unwanted or obsolete loaned equipment is returned as soon as it is no longer needed.
- Ensure that loaned equipment is accompanied by relevant decontamination/sterilisation instructions and a comprehensive list of contents. If these are missing or if you do not have the facilities to follow them (e.g. inappropriate sterilisation time/temperature relationships are quoted) the instruments should not be used.
- Ensure medical devices borrowed from a manufacturer or other Trust will arrive in time to ensure decontamination prior to use and will be accompanied with a certificate of decontamination from the previous user and a copy of the manufacturer’s instructions. Failure to do so will result in a delay in getting the equipment processed.
- Ensure all loan equipment that arrives in containers unsuitable for the decontamination process will be transferred into instrument baskets. After use, the SSD will decontaminate the loan equipment and provide a certificate of decontamination for its release.
- Do not send contaminated items through the post.
- Establish that organisations loaning equipment to the Trust have a robust tracking system in place and that the Trust has immediate access to information in respect of patients where loaned equipment has been used in their care/treatment.
- Ensure that records are maintained of any loan equipment for a period of 11 years, and children born after 1997 21 years.
- Theatres will maintain a list of approved suppliers and review it on an annual basis to ensure it is current.
- Transport of loan equipment from and to the supplier will be the responsibility of the relevant departmental manager.

17.2 **Loan by the Trust**

- Loaned equipment must not be used for the care/treatment of high-risk patients. Sterile Services Department has adopted ‘Universal Precautions’ for handling all returned items; therefore there is no requirement to notify the department about instruments used on known infected cases. The only exceptions to this are:
  - Creutzfeldt Jacob Disease (CJD) and variant Creutzfeldt Jakob Disease (vCJD)
  - Gerstmann-Stäussler-Scheinker Syndrome (GSS)
- In the event of items being used on patients with definite, probable or possible CJD, vCJD or GSS, contact the Sterile Service Department on 01284 713000.

- Before returning the equipment to the Trust it must be cleaned/decontaminated in accordance with the guidelines. The decontamination certificate must be completed, signed and attached to the equipment.

- All loaned equipment returned to Sterile Services must be placed in a dry state in the instrument return boxes and secured by the security tags provided.

- All sharps/clinical waste items should be removed from sets prior to transportation to Sterile Services for decontamination.

- Those borrowing equipment must demonstrate evidence of robust tracking records and ensure that the Trust has immediate access to information in respect of patients where loaned equipment has been used in their care/treatment.

- All equipment loaned by the Trust remains the property of the Trust and as such they must:
  ▪ not be used for functions other than those for which they are intended
  ▪ be maintained in a satisfactory condition at all times
  ▪ be returned to the West Suffolk Hospital NHS Trust at the end of the loan period.

18.0 **Decontamination of equipment for investigation, inspection, service or repair**

18.1 All medical devices being sent for inspection, service or repair to other departments must be rendered safe to handle. A decontamination certificate must be completed and sent with the equipment so that any biological risks can be assessed and safely managed. See example certificate at Appendix 5. Reference Policy (PP024), Policy and Procedure for the Management of Medical Equipment, section 3.0. Recipients of equipment for inspection, service or repair which does not have a decontamination certificate attached must not handle the equipment until the ward/department manager has been contacted to clarify whether the equipment has been contaminated.

18.2 The person preparing the equipment for inspection, service or repair must complete certificates at ward or department level. If equipment is sent to SSD for sterilisation prior to inspection etc then SSD staff should complete the decontamination certificate.

18.3 Equipment that is sent to the manufacturer for service/repair must be packed according to current Post Office regulations. A certificate must be enclosed in a prominent position so as to be visible before opening the internal wrapper, stating what decontamination procedure has been done, or if none, that protective clothing should be worn when handling the equipment. If a full decontamination procedure has not been carried out, this must be clearly stated on the outer wrapper.

18.4 Collection/delivery of equipment for repair will be the responsibility of the Trust in accordance with The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.

19.0 **Transportation**

19.1 All used surgical instruments represent a risk of infection. To minimise this risk the instruments must be placed in closed, secure containers and transported to the decontamination area as soon as possible following use. A decontamination certificate must be completed, signed and attached to the equipment.
19.2 To protect the equipment and handler transport containers must be:
- Leak proof
- Easy to clean
- Rigid
- Capable of being securely closed
- Lockable
- Labeled to identify the user and contents
- Robust enough to protect equipment in transit

19.3 Transport containers must be cleaned, disinfected and dried before reuse.

19.4 Staff handling contaminated equipment must wear PPE in accordance with local policy and be vaccinated against hepatitis B.

19.5 Transportation of medical devices must be in accordance with The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.

19.6 Methods of external transport considered appropriate are:
- Suffolk Mental Health NHS Trust Transport Department fleet
- EBME fleet
- SSD fleet

19.7 Members of staff are not permitted to transport medical devices in their own vehicles.

19.8 Collection/delivery of equipment loaned by the Trust will be the responsibility of the loaner in accordance with The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.

19.9 It is essential that a method of transportation be used to ensure segregation of contaminated equipment from sterile products.
Policy for Decontamination of Reusable Medical Devices

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| Approved Person |
| Approvals and endorsements: | Decontamination Group (02/03/17)  
| Estates and Facilities Directorate Governance Steering Group (28/03/17) |
| Consultation: | Decontamination Group  
| Infection Prevention Team  
| Clinical Governance  
| Matron’s  
| EBME  
| Estates Manager  
| Authorised Engineer (Decontamination) |
| Issue no: | Version 2 |
| File name: | Charlie Facilities/J Grimwood/decontamination/policy/PP (17) 204 |
| Supersedes: | PP (06) 204, PP (06) 204, PP (11) 204, PP(14)204 |
| Equality assessed: | Yes |

Monitoring:
The Decontamination Group according to the agreed frequency of the policy review will monitor implementation, compliance and effectiveness of the policy. This will be achieved through reporting against defined key performance indicators (see below) as part of the policy review process.

The Trust’s Decontamination Lead will review this policy on an annual basis. The policy may be revised before the review date if there are changes in legislation, changes to the organisation or if a significant risk is identified that requires a change in policy.

Relevant department managers on an annual basis will undertake internal audit of compliance to the policy their findings will be reported to the relevant general manager and the DG, with an overall return of 75% expected to be achieved. Suffolk Audit Services will undertake external audit of compliance to the policy on a 24-month basis.

Action plans will be developed for areas of non-compliance identified during internal and external audits. The DG will monitor progress against these on a quarterly basis.

The DG will also monitor decontamination performance against key performance indicators on a quarterly basis, these include:
- Number of decontamination incidents
- Level of needle stick injuries below 1%
- Maintain post sterilisation failures to below 5%

The DG will report progress against the policy to the Infection Prevention and Control Committee twice a year. The report will
identify areas of non-compliance and areas of best practice/improvements made.

Deviation from the policy will be reported to the Decontamination Lead and Committee for appropriate discussion/action.

<table>
<thead>
<tr>
<th>Other relevant policies/documents &amp; references:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust Policy - (PP024) Policy and Procedure for the Management of Medical Equipment</td>
<td></td>
</tr>
<tr>
<td>CG10022 Cleaning and Disinfection Clinical Equipment and Environment</td>
<td></td>
</tr>
<tr>
<td>(PP132) Risk Assessment Policy and Procedure</td>
<td></td>
</tr>
<tr>
<td>(PP105) Incident reporting and management</td>
<td></td>
</tr>
<tr>
<td>The Medical Devices Regulations (MDR) 2002 (as amended 2003) – incorporating EU legislation</td>
<td></td>
</tr>
<tr>
<td>The Control of Substances Hazardous to Health regulations 2002 (as amended 2003)</td>
<td></td>
</tr>
<tr>
<td>The Personal Protective Equipment at Work regulations 1999 (as amended 2002)</td>
<td></td>
</tr>
<tr>
<td>Code of Practice for the Prevention and Control of Health Care Associated Infections 2006</td>
<td></td>
</tr>
<tr>
<td>HTM 01-01 Parts A to E</td>
<td></td>
</tr>
<tr>
<td>HTM 01-06 supersedes Health Technical Memoranda</td>
<td></td>
</tr>
<tr>
<td>BS EN 13060. Small steam sterilisers.</td>
<td></td>
</tr>
<tr>
<td>BS EN 61010-2-040. Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilisers and washer-disinfectors used to treat medical materials.</td>
<td></td>
</tr>
<tr>
<td>BS EN 556-1 &amp; 2.</td>
<td>Sterilisation of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for terminally sterilised medical devices.</td>
</tr>
<tr>
<td>BS EN 1041.</td>
<td>Information supplied by the manufacturer of medical devices.</td>
</tr>
<tr>
<td>BS EN ISO 17664.</td>
<td>Sterilisation of medical devices. Information to be provided by the manufacturer for the processing of resterilisable medical devices.</td>
</tr>
<tr>
<td>BS EN ISO 14971.</td>
<td>Application of risk management to medical devices.</td>
</tr>
<tr>
<td>The Health and Social Care Act 2008 Regulations 2010</td>
<td></td>
</tr>
<tr>
<td>Care Quality Commission: Essential Standards of Quality and Safety (2010 update)</td>
<td></td>
</tr>
<tr>
<td>BS EN ISO 15883-1, 2, 3 &amp; 4.</td>
<td>Washer-disinfectors.</td>
</tr>
<tr>
<td>MDA SN2002(17).</td>
<td>Management of loaned medical devices, equipment or accessories from manufacturer’s or other hospitals.</td>
</tr>
<tr>
<td>MDA SN2002(18).</td>
<td>Handling of surgical instruments on loan from another organisation.</td>
</tr>
<tr>
<td>The Carriage of Dangerous Goods and use of Transportable Pressure Equipment regulations (CDG) 2009</td>
<td></td>
</tr>
</tbody>
</table>

**Additional information**

NA
### Appendix 1

#### DATEX Risk Form

| Risk Assessment | 
|-----------------|---|
| Name of person completing the form | Jacqui Grinwood |
| Your e-mail address | |
| Name of additional assessor (if applicable) | 
| Date of inspection | 2018 |
| Reference number - Local Department / Work identifier | WR 150 |
| Title of Risk | Ensuring all reusable medical devices are properly decontaminated |
| Original Assessment date (MM/YYYY) | 03/03/2018 |
| Please circle the area specific to the Risk | Test tube |
| Trust | West Suffolk NHS Foundation Trust |
| Site | 
| Directorate | Estates and Facilities |
| Specialty | Sterile Services Department |
| Risk Type | Corporate Risk |
| Which board committee monitors this risk? | CSEC |
| CSEC requires input from: | 
| Risk Category | Environment / Facilities / Library |
| Risk Subtype | Decontamination |
| Description of Task / Activity / Issue | To ensure that all reusable medical devices are properly decontaminated prior to use and that the risks associated with the service are reduced. The risks are minimised by ensuring that the equipment is properly decontaminated. The responsibilities of the decontamination team are to ensure that all equipment is properly decontaminated. |
| Frequency of task / activity | Daily |
| Category of people affected | Staff / Patients |
| Staff / Patients / Visitors / Contractors / Others (Indicate all that apply) | 
| Estimate of number of people affected | 2006 |
| Hazards identified | 
| For Generic Risk Assessments follow link to template and copy and paste relevant hazards into this field. | 
| Significant consequences | 
| For Generic Risk Assessments follow link to template and copy and paste relevant hazards into this field. | 
| Initial Risk rating (without controls in place) | 
| Consequence (initial): | Catastrophic |
| Likelihood (initial): | Expected to occur weekly |
| Risk level (initial): | High |
| Current Risk rating (with existing controls in place) | 
| Consequence (current): | Catastrophic |
| Likelihood (current): | Expected to occur once every 5 years |
| Risk level (current): | High |
| Are further controls (Actions) required? | Yes |
| Describe the "Key" risks to be addressed and the action plan to be implemented | Manual decontamination taking place to individual instrument maximisation and high risk procedures - breach of NICE guidelines |
| Status of the Action Plan | 
| Action Plan must be completed | 

---

Appendix 1
### Policy for Decontamination of Reusable Medical Devices

**Source:** Decontamination Lead  
**Status:** Approved Decontamination Group  
**Issue date:** March 2017  
**Valid until date:** January 2020  
**Document reference:** PP(17) 204

<table>
<thead>
<tr>
<th>Recipients</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Message</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Message history</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date/Time</strong></td>
<td><strong>Sender</strong></td>
</tr>
<tr>
<td><strong>No-messages</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Progress notes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No progress notes.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Notifications</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Recipient Name</strong></td>
<td><strong>Recipient E-mail</strong></td>
</tr>
<tr>
<td><strong>No notification e-mails sent</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Final Approval
- Has recent staff been made aware of risk? Yes  
- As "Final Approval" do you agree with the current risk grading? Yes  
- Does the action plan adequately address any relevant risks? Yes  

**Risk Source:** Activity based assessment (pro-active)  
**Strategic Objectives:** 1) Quality and effectiveness  
**Area specific risk:** "GREEN" - Engagement, Risk Managers  
**AMBASSADOR Service Managers, etc.**  
**"RED" - General Manager, or equivalent,  
Trust wide risk, based on the subject area grading of the risk.

---

**Please print a final copy of this Risk Assessment and file where it is accessible for all Staff.**

**Date KBM Administrator only**  
In correct holding area  
Action Plan completed correctly  
Final Approver allocated  
Finaly approved  
Status current  

**RED Risk**  
- Date Risk assessment entered  
- Date finally approved  
- Has the Risk been finally approved within 7 days  
- Date Risk reported to TEG  
- Risk assessment grade approved at TEG  
- Risk assessment grade downgraded at TEG  
- Date reported to Board (from TEG)
Appendix 2

Policy Document for Single use Medical Devices

1. Introduction

2. Devices covered
This document applies to all single use medical devices, there are no exceptions.

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

Some single-use devices are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.

The expression ‘Single Use’ on the packaging of medical devices means that the manufacturer:

- intends the device to be used once and then discarded;
- considers the device is not suitable for use on more than one occasion;
- has evidence to confirm that reuse would be unsafe.

The above symbol is used on medical device packaging indicating ‘Do Not Reuse’ and may replace any wording.

4. Usage
Once a single use medical device’s package has been opened its sterile integrity has been compromised. It must not be reprocessed.

Once used a single use medical device must be disposed of in accordance to the Trust’s Waste Disposal Policy.
5. **Key points**

1. Devices designated for ‘single-use’ must not be reused under any circumstances.

2. The re-use of ‘single-use’ devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

3. The re-use of ‘single-use’ devices has legal implications.

4. Anyone, who reprocesses or re-uses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.

5. Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
Appendix 3

DECONTAMINATION GROUP
TERMS OF REFERENCE

1. Purpose
The purpose of the Decontamination Group is to provide guidance to the Infection Prevention and Control Committee and Clinical Safety and Effectiveness Committee in matters relating to decontamination. As well as providing direction to the Trust’s clinical divisions on how to implement and enforce decontamination policy.

2. Membership
Executive Director Chief Nurse (Chair)
Decontamination Lead
Governance/Risk Manager
Consultant Microbiologist/IC Doctor
Infection Prevention Nurse
Theatre/DSU Manager
EU Sister
Estates Specialist Services Manager
SSD Manager
ETC Sister
OPD Sister

2.1 A representative is required from each department suitable alternative should be substituted if a member cannot attend.

2.2 Internal or external persons may be invited to attend meetings at the request of the Chairperson to provide advice and assistance considered necessary.

3. Duration of meetings
The committee will meet on a quarterly basis.

4. Standard agenda items
At each meeting there will be a standard agenda consisting of:
- Apologies
- Minutes of the last meeting
- Matters Arising
- Decontamination report
- Emerging issues
- Items for escalation
- Any other business

5. Forum administration (Nursing Directorate)
5.1 Prepare agendas and issue notices for meetings, ensuring all documentation for comment is attached to the agenda.

5.2 Distribute the Agenda one week prior to the meeting.

5.3 Take notes of proceedings and preparation of the minutes of meetings for circulation to members and the project team.
6. Quorum
6.1 If unable to attend members may nominate another representative from their organisation to attend.

6.2 A quorum of 4 is required for the meeting to proceed.

7. Reporting arrangements:
7.1 Trust Board via the Clinical Safety and Effectiveness Committee through the Infection Prevention and Control Committee, see structure below.

---

8. Areas of responsibility:
8.1 To keep an accurate record of all areas of Trust decontamination and those responsible for the decontamination process within those areas.

8.2 To be responsible to, and make recommendations on operational and financial implications of decontamination to the Infection Prevention Control Committee and the Trust Board through the Clinical Safety and Effectiveness Committee.

8.3 To oversee the development and implementation of decontamination arrangements ensuring they are consistent with and support the achievement of the Trust’s strategic and corporate objectives.

8.4 To be responsible for planning and evaluating the Trust’s decontamination strategy and policy arrangements through the review of audit standards and outcomes.
8.5 To evaluate the impact of implementing new guidance and directives in relation to decontamination.

8.6 To make an annual decontamination report to the Clinical Safety and Effectiveness Committee via the Infection Prevention Control Committee.

8.7 To monitor decontamination related incidents.

8.8 To provide guidance to the Trust on purchases of decontamination equipment.

9. **Terms of reference**
9.1 To be ratified at the meeting on 02/03/17 and reviewed by September 2020, or before, if required.
Appendix 4

Healthcare Governance accountability structure

Trust Board
- Charitable Funds Committee
- Scrutiny Committee
- Quality & Risk Committee
- Clinical Safety & Effectiveness Committee
- Patient Experience Committee
- Corporate Risk Committee

Audit Committee
- Executive Directors Meeting
- Trust Executive Group

Patient Safety Implementation Group
- Pressure Ulcer Group
- Falls Group
- Deteriorating Patient Group

Blood Transfusion Committee
- Cancer Network Group
- Children & Young Persons Group
- CPR Committee
- Clinical Guideline Editorial Group
- Dementia Group
- Drugs and Therapeutics Committee
- Infection Control Committee (inc. Water and Decon.)
- Morbidity Surveillance Group
- Near Patient Testing Group
- Nutrition Committee
- Radiology Protection Committee
- Research Governance Committee
- Safeguarding Children Committee
- Safeguarding Adults Committee
- Safer Surgery Group
- Thrombosis Committee

End of Life Steering Group
- Engagement Committee of the Council of Governors
- Equality and Diversity Group
- Frail Elderly Steering Group
- Family Carers Group
- Nutrition Steering Group
- Patient Environment Action Group
- Patient & Carer Experience Group

Divisional Executive Performance Meetings
- Divisional Governance Steering Groups
- Ward/Dept Governance Groups

Clinical Directors Group
- Transformation Steering Group
- e-Care Programme Board
- Sustainability Committee
- Trust Negotiating Committee
- Trust Council

Responsibilities:
- Incident reporting
- NICE & national best practice reports and inspections
- Clinical outcome measures
- Clinical audit programme

Responsibilities:
- PALS, Complaints & Claims
- Patient and staff feedback, including local and national surveys and patient forums
- “Back to the floor” visits by Board members
- Feedback from Trust members and Governors
- PLACE
- “In your shoes”
- Community Conversations
- Staff Pride
- Staff Intelligence

Responsibilities:
- Health & Safety
- NHS Litigation Authority
- Central Alerts System (CAS)
- Risk Register
- Workforce risk management
- Counter Fraud
- Information Governance (IG)
- Mandatory training

Responsibilities:
- Quality
- Income/costs
- Performance (national/local targets)
- Human Resources

Source: Decontamination Lead
Status: Approved Decontamination Group
Issue date: March 2017
Valid until date: January 2020
Document reference: PP(17) 204
Appendix 5

Decontamination Certificate

Declaration of Contamination Status

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Is the item/s contaminated?**

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Has the item/s been decontaminated?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

What method of decontamination has been used? Please provide details

- **AER:**
  - ☐
  - +Cycle No:………

- **Hand Wash:**
  - ☐

- **Sterilisation:**
  - 121° ☐
  - 134° ☐

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:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>………………………………………</td>
<td>………………………………………</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>………………………………………</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Tel</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>………………………………………</td>
<td>……………</td>
<td>…………..</td>
</tr>
</tbody>
</table>
## Appendix 6

**Suggested Methods for Decontamination:**
Always refer to the manufacturer’s instructions

<table>
<thead>
<tr>
<th>Equipment or site</th>
<th>Preferred method</th>
<th>Risk</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture needles</td>
<td>Disposable</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Air ways</td>
<td>Disposable</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Aurosopes</td>
<td>Disposable</td>
<td>Moderate</td>
<td>SSD Reusable</td>
</tr>
<tr>
<td>Ampoules</td>
<td>No need to disinfect</td>
<td>Minimal</td>
<td></td>
</tr>
<tr>
<td>Bath hoists</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Baths/baby baths</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Bed frames, cradles etc.</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>For outbreaks enhanced cleans disinfection required.</td>
</tr>
<tr>
<td>Bed pans, urinals</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>Clean carriers after each use using Chlorclean</td>
</tr>
<tr>
<td>Beds/cots/ examination couches</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>For outbreaks enhance cleans disinfection required.</td>
</tr>
<tr>
<td>Bidets</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>For outbreaks, disinfection required.</td>
</tr>
<tr>
<td>Blood pressure cuffs</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>See isolation procedures disposable cuffs are available Clean with detergent wipes between use</td>
</tr>
<tr>
<td>Forceps-biopsy/ magills</td>
<td>Return to SSD or use disposable</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Clinical thermometers</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Single patient use. Temporal thermometers cleaned with 70% alcohol wipe – others probe covers</td>
</tr>
<tr>
<td>Equipment or site</td>
<td>Preferred method</td>
<td>Risk</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>--------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Commode</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>For outbreaks, disinfection required.</td>
</tr>
<tr>
<td>Crockery and cutlery</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Return all crockery and cutlery to catering department for washing</td>
</tr>
<tr>
<td>Drain bottles</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Add gelling agent before disposal into clinical waste</td>
</tr>
<tr>
<td>Dressing trays and trolleys</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>Clean with detergent wipe if required</td>
</tr>
<tr>
<td>Ear phones</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>Disposable single patient use disposed of after patient discharge.</td>
</tr>
<tr>
<td>Electrical equipment</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>See decontamination Procedure before servicing. (8)</td>
</tr>
<tr>
<td>Endoscopes</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>High or Moderate</td>
<td>See departmental endoscopy procedures</td>
</tr>
<tr>
<td>Feeding bottles</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Moderate</td>
<td>Steam steriliser may be used or use disposable</td>
</tr>
<tr>
<td>Foam appliances</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Replace plastic cover if damaged. If foam is blood stained, destroy</td>
</tr>
<tr>
<td>Floors</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>Mop heads to be laundered daily. Or use disposable mop heads. (see procedure 5.) See also Enhanced Cleaning Guidelines.</td>
</tr>
<tr>
<td>Flower containers</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td></td>
</tr>
<tr>
<td>Equipment or site</td>
<td>Preferred method</td>
<td>Risk</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Furniture and fittings</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>See Enhanced Deep Cleaning Guidelines.</td>
</tr>
<tr>
<td>Hoists</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Infected cases see isolation nursing procedure</td>
</tr>
<tr>
<td>Incubators</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Infected cases - see isolation procedure. Single patient use and disposed of</td>
</tr>
<tr>
<td>Laryngoscope blades</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Disposables are available</td>
</tr>
<tr>
<td>Lenses (non-disposable)</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Moderate</td>
<td>Check manufacturer recommended cleaning solution</td>
</tr>
<tr>
<td>Masks</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Mattresses</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Enhanced/deep cleaning guidelines.</td>
</tr>
<tr>
<td>Medical equipment eg. ECG machines,</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>Follow decontamination procedure before servicing/repair. Refer to Decontamination Policy</td>
</tr>
<tr>
<td>Nebuliser boxes, syringe drivers, scales.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc. Medicine pots clean with detergent and water allow to dry or use disposables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouth pieces for inhalation (lung function tests, inhalers etc)</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>Store dry</td>
</tr>
<tr>
<td>Nail brushes</td>
<td>Single patient use</td>
<td>Minimal</td>
<td>For use on wounds or surgical scrub consider as high risk</td>
</tr>
<tr>
<td>Equipment or site</td>
<td>Preferred method</td>
<td>Risk</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>--------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Nipple shields</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Moderate</td>
<td>May be steam sterilised</td>
</tr>
<tr>
<td>Oxygen tubing</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Moderate</td>
<td>See theatre policy for ventilator tubing</td>
</tr>
<tr>
<td>Phones</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td></td>
</tr>
<tr>
<td>Pillows / Charnley wedges</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>Check that cover is not damaged</td>
</tr>
<tr>
<td>Probes</td>
<td>Send to SSD</td>
<td>High</td>
<td>Do not clean prior to sending to CSSD. Disposables are available</td>
</tr>
<tr>
<td>Razors electric</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>High</td>
<td>Use patients own razor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient facial shave only</td>
</tr>
<tr>
<td>Razor safety</td>
<td>Single patient use</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Disposable Sigmoidoscopes</td>
<td>Discard after use</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Reusable Sigmoidoscopes</td>
<td>Clean with detergent and water send SSD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinks</td>
<td>Clean with detergent and water</td>
<td>Minimal</td>
<td></td>
</tr>
<tr>
<td>Sheep skins</td>
<td>Clean with detergent and water</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Skin preparation for injection</td>
<td>Clean with detergent and water</td>
<td>Low</td>
<td>Clean skin if dirty</td>
</tr>
<tr>
<td>Skin preparation for insertion of lines etc.</td>
<td>Clean with detergent and water</td>
<td>Moderate</td>
<td>Allow to dry prior to procedure</td>
</tr>
<tr>
<td>Slings /sliding sheets</td>
<td>Use disposable</td>
<td>Low</td>
<td>If non-disposable, launder after each patient use.</td>
</tr>
<tr>
<td>Equipment or site</td>
<td>Preferred method</td>
<td>Risk</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>------------------------------------------------------------</td>
<td>--------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Stands/ holders</td>
<td>Clean with detergent and water</td>
<td>Minimal</td>
<td></td>
</tr>
<tr>
<td>Specula</td>
<td>CSSD or use disposable.</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Stethoscopes</td>
<td>Clean with detergent and water</td>
<td>Low</td>
<td>An detergent wipe may be used, following cleaning.</td>
</tr>
<tr>
<td>Suction bottles</td>
<td>Clean with detergent and water or use disposable liner.</td>
<td>Low</td>
<td>Add gelling agent before disposal</td>
</tr>
<tr>
<td>Anti-embolism Stockings</td>
<td>Single patient use</td>
<td>Low</td>
<td>Single patient use</td>
</tr>
<tr>
<td>Tonometer heads</td>
<td>Single patient use</td>
<td>Low</td>
<td>Single patient use</td>
</tr>
<tr>
<td>Toilets</td>
<td>Clean with detergent and water</td>
<td>Low</td>
<td>Chlorclean x 3 a day</td>
</tr>
<tr>
<td>Toys</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td>No communal soft toys. Child’s own may be brought in.</td>
</tr>
<tr>
<td>Ventilator circuits / breathing tubes</td>
<td>Send to SSD or use disposable</td>
<td>High</td>
<td>Store dry. See departmental policy</td>
</tr>
<tr>
<td>Ventilators</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Minimal</td>
<td>See decontamination procedure</td>
</tr>
<tr>
<td>Washing bowls</td>
<td>Clean with detergent and water</td>
<td>Minimal</td>
<td>Single patient use and disposed of – or disposable</td>
</tr>
<tr>
<td>X ray cassettes</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>X ray machine</td>
<td>Please refer to Manufacturers Cleaning instructions within the User manual</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

**NB**  If low risk items become contaminated with blood/body fluid, disinfect after cleaning.

**NB**  Cutan detergent wipes can be used as an alternative to hot water and detergent solution.
## Appendix 7

### Methods of decontamination

**Clean** = hot, soapy water and disposable cloths.

**Damp dust** = excess moisture removed disposable cloths moistened with water.

**Disinfect** = If items are soiled with blood / body fluid then clean with hot, soapy water and decontaminate with hypochlorite or chlorclean as Spillage Policy.

**Enhanced clean** = Hot, soapy water followed by hypochlorite, or “Chlorclean”

<table>
<thead>
<tr>
<th>Item</th>
<th>Agreed responsibility</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard hospital bed - mattress</td>
<td>Nursing</td>
<td>Clean after each patient use.</td>
</tr>
<tr>
<td>Standard hospital bed - frame below</td>
<td>Housekeeping</td>
<td>Damp dust weekly. (Risk assessment to be carried out and procedure to be drawn up)</td>
</tr>
<tr>
<td>mattress base</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard hospital bed - frame, the mattress base and above</td>
<td>Nursing</td>
<td>After patient use/discharge.</td>
</tr>
<tr>
<td>Bed frames - traction</td>
<td>Nursing</td>
<td>After patient use/discharge.</td>
</tr>
<tr>
<td>Specialist mattress and motor</td>
<td>Nursing</td>
<td>Clean after each patient use / damp dust motor daily.</td>
</tr>
<tr>
<td>Locker - inside</td>
<td>Nursing</td>
<td>Nurses to clean inside and outside in its entirety on discharge.</td>
</tr>
<tr>
<td>Locker - outside</td>
<td>Housekeeping</td>
<td>Thoroughly damp dust tops of lockers daily.</td>
</tr>
<tr>
<td>Bed table</td>
<td>Housekeeping</td>
<td>Clean daily and on discharge.</td>
</tr>
<tr>
<td></td>
<td>Nursing on discharge</td>
<td></td>
</tr>
<tr>
<td>Bedside chair</td>
<td>Housekeeping / Nursing</td>
<td>Clean daily and on discharge.</td>
</tr>
<tr>
<td>Bedside stools</td>
<td>Housekeeping / Nursing</td>
<td>Damp dust daily and on discharge.</td>
</tr>
<tr>
<td>Suction and oxygen</td>
<td>Nursing</td>
<td>Check clean and after use / discharge.</td>
</tr>
<tr>
<td>Kardex holders on beds</td>
<td>Nursing</td>
<td>Clean on discharge.</td>
</tr>
<tr>
<td>Alcohol hand rub holders on beds in</td>
<td>Housekeeping</td>
<td>Damp dust daily. Clean holder on discharge. Replenish.</td>
</tr>
<tr>
<td>corridors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drip stands</td>
<td>Nursing (after use)</td>
<td>Full clean after each use including legs/wheels. Clean / disinfect if soiled in use.</td>
</tr>
<tr>
<td></td>
<td>Housekeeping (weekly)</td>
<td></td>
</tr>
<tr>
<td>Infusion pumps</td>
<td>Nursing (after use)</td>
<td>Full clean after each use including legs. And before returning to medical equipment library Clean / disinfect if soiled in use.</td>
</tr>
<tr>
<td></td>
<td>Housekeeping (weekly)</td>
<td></td>
</tr>
<tr>
<td>Blood pressure machines</td>
<td>Nursing</td>
<td>Cuff should be wiped after each patient use. Check clean.</td>
</tr>
<tr>
<td>Bed cradle</td>
<td>Nursing</td>
<td>Clean on discharge. Check and clean during use (do not store / place on floor).</td>
</tr>
<tr>
<td>Zimmer frames</td>
<td>Nursing</td>
<td>Clean on discharge. Check and clean during use.</td>
</tr>
<tr>
<td>Commodes etc</td>
<td>Housekeeping (weekly)</td>
<td>After each patient use clean arm rests, top and underneath seat. Check and clean rest of commode – minimum enhanced clean at least weekly.</td>
</tr>
<tr>
<td></td>
<td>Nursing (after use)</td>
<td></td>
</tr>
<tr>
<td>Raised toilet seats</td>
<td>Housekeeping - daily</td>
<td>Domestics to clean in line with toilet regime. Nurses to check / clean as required.</td>
</tr>
</tbody>
</table>
### Roles / Responsibilities of Cleaning Furniture / Equipment in Patient Areas

<table>
<thead>
<tr>
<th>Item</th>
<th>Agreed responsibility</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ice machines / water coolers / vending machines</td>
<td>Housekeeping</td>
<td>Clean daily</td>
</tr>
<tr>
<td>Drug fridges</td>
<td>Nursing</td>
<td>Minimum weekly.</td>
</tr>
<tr>
<td>Staff fridges</td>
<td>Nursing</td>
<td>Minimum weekly.</td>
</tr>
<tr>
<td>Patient fridges</td>
<td>Housekeeping</td>
<td>Daily clean and keep only “in date” products. Refer to Food Hygiene policy</td>
</tr>
<tr>
<td>Staff microwaves</td>
<td>Nursing</td>
<td>Minimum weekly.</td>
</tr>
<tr>
<td>Visitors chairs</td>
<td>Housekeeping</td>
<td>Weekly clean.</td>
</tr>
<tr>
<td>Notes trolleys</td>
<td>Ward Clerk</td>
<td>Weekly damp dust / clean.</td>
</tr>
<tr>
<td>Desk equipment (computer)</td>
<td>Ward Clerk (Housekeeping will wipe desks if they are clear)</td>
<td>Weekly damp dust / clean.</td>
</tr>
<tr>
<td>Bed pan masher</td>
<td>Housekeeping (Lid and Handle)</td>
<td>Daily clean.</td>
</tr>
<tr>
<td></td>
<td>Nursing (inside lid and if any spillages)</td>
<td>As per Spillage Policy. (requires process flowchart and training)</td>
</tr>
<tr>
<td>Washing machine</td>
<td>Housekeeping</td>
<td>Clean outside daily.</td>
</tr>
<tr>
<td>Tumble dryer</td>
<td>Nursing - to clean filter and condenser following each use</td>
<td>Clean outside daily.</td>
</tr>
<tr>
<td></td>
<td>Housekeeping - clean outside</td>
<td></td>
</tr>
<tr>
<td>Linen skip</td>
<td>Nursing</td>
<td>Damp dust / clean weekly.</td>
</tr>
<tr>
<td>Fans</td>
<td>Housekeeping</td>
<td>6 monthly. Between patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Base &amp; lead damp dust daily</td>
</tr>
<tr>
<td>Patient call system</td>
<td>Housekeeping (daily)</td>
<td>Damp dust / clean on discharge.</td>
</tr>
<tr>
<td></td>
<td>Nursing – between patients</td>
<td></td>
</tr>
<tr>
<td>Baths</td>
<td>Housekeeping - daily</td>
<td>Clean.</td>
</tr>
<tr>
<td></td>
<td>Nursing - between patients</td>
<td></td>
</tr>
<tr>
<td>Hoists &amp; slings</td>
<td>Nursing</td>
<td>Check clean after each patient use.</td>
</tr>
<tr>
<td>Radiators</td>
<td>Housekeeping</td>
<td>Weekly on outside / exposed radiators. 6 monthly on concealed radiators</td>
</tr>
<tr>
<td>Resus. trolley</td>
<td>Nursing</td>
<td>Clean daily</td>
</tr>
<tr>
<td>Patient entertainment</td>
<td>Premier bedside</td>
<td>Between patients</td>
</tr>
<tr>
<td>Window frames</td>
<td>Housekeeping</td>
<td>Weekly on plastic frames and window ledges. 6 monthly on aluminium frames</td>
</tr>
</tbody>
</table>
Appendix 8 - Decontamination permit to work

Location of decontamination equipment:
SSD / Endoscopy / Pathology / Theatres: delete as appropriate

Manufacturer:

Serial No

Model

I confirm that the above decontamination equipment will be taken out of service for:
Please delete as appropriate
A. Weekly maintenance and testing
B. Quarterly maintenance and testing
C. Annual maintenance and testing
D. Breakdown

User Name: ____________________ Signature _________________ Date _____Time____

RECEIPT
I accept responsibility for carrying out the work on the above decontamination equipment
I have received the guidance on safe working practices

Name CP (D) ____________________ Signature _________________ Date _____Time____

HAND BACK (Delete as Appropriate)
The work on the above decontamination equipment has been completed/ not completed & requires further work

CP (D) Taking over permit:

Name CP (D) ____________________ Signature _________________ Date _____Time____

The decontamination equipment may be returned / not be returned to service

Name CP (D) ____________________ Signature _________________ Date _____Time____

Name AP (D) ____________________ Signature _________________ Date _____Time____

I accept that the above equipment is available for service

User Name ____________________ Signature _________________ Date _____Time____