University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR DECONTAMINATION OF REUSABLE MEDICAL DEVICES

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Contact for Review	Trust Decontamination Lead's
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Introduction

Appropriate decontamination is the responsibility of all trust staff and is a complex process and by having safe systems in place will ensure the protection of patients, staff and others from the risk of cross infection from medical devices.

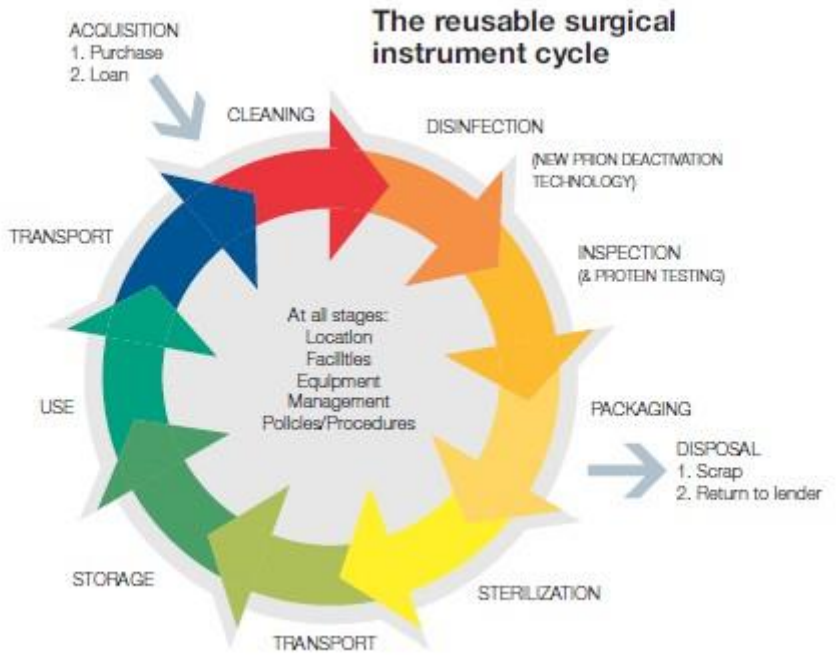
The purpose of this policy is to ensure effective decontamination processes are imbedded and related statutory requirements are met.

Purpose and Outcomes

The aim of this policy is to jointly engage all disciplines and departments at UHDB to ensure all reusable (whether owned, rented, on loan or acquired by any other means) medical devices are properly decontaminated and the risks associated are adequately managed, whilst aligning with national decontamination legislation (HTM01 suite).

Within the policy there is detailed guidance for cleaning, disinfection and sterilisation processes.

The decontamination process includes the cycle as shown below:



Whilst the above diagram encapsulates the life cycle of a reusable surgical instrument covers aspects of decontamination in general.

Additions to the above cycle would be:

- An inventory of reusable instruments/medical devices will be held and maintained.
- A process to identify maintenance of the above instruments/medical devices

- A monitoring process for reusable instruments/medical devices used to reduce the risks of transmission from person to person of prion-based disease
- A planned programme for replacement of decontamination equipment that does not meet the requirements of current standards and test methods.

Definitions Used

Cleaning	The removal of micro-organisms by cleaning with an approved detergent and hot water disposable Detergent wipes will sufficiently decontaminate most items of equipment. NB: Once items have been Cleaned, they should be rinsed, dried and stored dry to prevent recontamination. Damp dusting is carried out above floor level using a disposable cloth/wipe that is moistened with clean water (and Detergent). Dust will cling to it and thus avoid dispersal of micro-organisms.
Contamination	Is the soiling of inanimate objects or living material with harmful, potential infectious material, in the clinical situation this is most likely to be organic matter and micro-organisms but may also include inorganic substances such as dust. Such contamination may affect the function of the inanimate object and may also be transmitted to a susceptible host.
Decontamination	A combination of processes, that includes cleaning, disinfection and/or sterilisation used to render a re-useable medical device safe for further episodes of use. The level of decontamination depends on the situation involved. For e.g., instrumentation used in “sterile areas” of the body (e.g., internal organs), require sterilisation whereas rooms may only require cleaning/disinfection.
Disinfection	There are two methods: a) Heat method (thermal) This is the preferred method of disinfection and must always be chosen if available and tolerated by the device. Moist heat is used between 73º and 90º C. Automatic washer disinfectors are available in Sterile Services b) Chemical method This is the method of choice for devices that will not tolerate heat methods. All devices subject to chemical disinfection must be scrupulously clean to allow exposure to all surfaces to the chemical.
Drying cabinet	These are cabinets that are specifically designed to ensure safe and hygienic drying and storage of flexible endoscopes and allows for the decontamination status to be extended beyond the standard 3 hours post process.
EWD	These are endoscope washer disinfectors, manually cleaned flexible endoscopes are processed through these between patient use. The aim of the process is to render the reprocessed endoscope to be free of pathogenic microorganisms, protein, and chemical residue.
Maintenance	Includes both planned preventative and corrective maintenance: a) planned preventative maintenance (PPM)

	b) corrective maintenance: Servicing, repair, planned preventative maintenance, breakdown work, periodic maintenance
Medical Device	Any instrument, apparatus, appliance, material, or other health care article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of, diagnosis, prevention, monitoring, treatment or alleviation of disease. The focus is on medical devices deemed high or medium risk such as surgical instruments as they must be presented free from viable micro-organisms and therefore rendered "fit for use".
Microbiological Contamination	Equipment or accessory which has become soiled by one or more of the following: • bloody or body secretions or excretions • pathological specimens or samples
Sterile Service Department	Departments accredited to relevant standards which are specifically designed to reprocess re-usable medical devices. 'Burton Sterile Services' refers to all services operated by the Queen's Hospital Sterile Services Department, which includes endoscope decontamination at Sir Robert Peel. 'Derby Sterile Services' refers to all services performed by the Royal Derby Sterile Services Department – operated by Steris.
Sterilisation	The removal or destruction of all living microbes, bacteria, viruses, fungi, and parasites including bacterial spores. Sterilisation is achieved by the rapid and even penetration of steam into all parts of the load
Sterilisers/ Autoclaves	Sterilisation is part of the decontamination process. Sterilisers (sometimes referred to as autoclaves), are designed to process porous items using high temperature steam and medical devices processed through them are packaged/wrapped in materials such as paper, fabric or containers. Sterilisers undergo routine testing and validation following a planned programme
Vacuum storage, Hydrogen Peroxide (Sure Store)	This device is used for "conditioning" a flexible endoscope directly from an endoscope washer disinfector; the process includes displacing moisture with Hydrogen Peroxide and then sealing the package. The endoscope is then able to be stored and transported safely.

Vacuum pack Plasma Typhoon	This is a device designed for fast drying of endoscope channels following the automated washing and disinfection procedure. Once dried, the endoscope is placed in a single-use “PlasmaBAG”, specifically designed for endoscope storage. Insufflating plasma, containing ozone molecules, into the bag for 5 seconds enables to maintain the endoscope in a disinfected state for up to 744 hours (31 days). The endoscope is then able to be stored and transported much easily, and safely.
Validation	Equipment used for decontamination purposes within the Trust, i.e., sterilisers, automatic endoscope washers and washer disinfector must be validated at installation and serviced and maintained in accordance with HTM01-01 guidance. Validation is the documented procedure required for obtaining, recording, and interpreting the results needed to show that a process will consistently yield a product complying with a pre-determined specification. Validation is a total process beginning with a review of the specification against which the equipment is purchased. This is to ensure that it will meet the User’s specified production needs including installation qualification, operational qualification, and performance qualification.
W/D	This is a washer disinfector which is used to clean and disinfect instruments intended for re-use. Washer disinfectors undergo routine testing and validation following a planned programme
Low temperature sterilisation technologies	Ethylene oxide (ETO) has been widely used as a low temperature sterilant since the 1950s. It has been the most used process for sterilising temperature- and moisture-sensitive medical devices and supplies. The microbicidal activity of ETO is the result of alkylation of protein, DNA, and RNA. Alkylation or the replacement of a hydrogen atom with an alkyl group, within cells prevents normal cellular metabolism and replication. The process is a long and potentially hazardous one (Direct ETO exposure) Hydrogen Peroxide Gas Plasma was patented in 1987 and marketed in the United States in 1993. Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. A free radical is an atom with an unpaired electron and is a highly reactive species. The proposed mechanism of action of this device is the production of free radicals within a plasma field that can interact with essential cell components (e.g., enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms. The by-products of the cycle (i.e., water vapour & oxygen) are nontoxic and eliminate the need for aeration. Thus, the sterilized materials can be handled safely, either for immediate use or storage.

4 Key Responsibilities/Duties

4.1 The Chief Executive

The Chief Executive has overall responsibility for the use and management of medical devices, including decontamination equipment within the trust.

4.2 Trust Board

The Trust Board will seek independent assurance that an appropriate and effective system of managing the decontamination of medical devices is in place and that the necessary levels of controls and monitoring are being implemented

4.3 Executive Medical Director

The Medical Director is the nominated Director for medical devices and has Board level responsibility for ensuring that there is clear and effective monitoring of all aspects of medical devices management, including decontamination, and that the Trust follows relevant legislation and Department of Health guidance with regards to decontamination. The Trust Executive Medical Director is the nominated Safety Alert Broadcast System (SABS) liaison officer for the Trust and is responsible for ensuring that safety information relating to medical devices is disseminated throughout the Trust, and acted upon; accordingly, this is delegated to the Risk and Clinical Governance Department and its Manager.

4.4 Executive Chief Nurse

The Executive Chief Nurse is the nominated Director for Risk Management and has Board level responsibility for ensuring that there is clear and effective monitoring of all aspects of Risk Management associated with the decontamination of medical devices.

4.5 Trust Decontamination Leads:

The nominated Decontamination Leads report directly to the Executive via the Executive Chief Nurse in exceptional circumstances, normally reporting through the Infection Prevention and Control Committee, and is expert on decontamination matters to provide advice at that level. In this trust the decontamination leads also take responsibility as the designated person as defined in HTM01-01

Decontamination Leads are organisationally responsible for:

- The technically compliant, provision of decontamination services
- The operational policy for decontamination, its implementation and monitoring.
- Working in co-ordination with the Infection Prevention and Control team to ensure all relevant legislative standards are met and maintained.

4.6 Infection Prevention and Control Team:

The Infection Prevention and Control Team will work in co-ordination with the Decontamination Lead to ensure that this process is a collaborative, cohesive and effective one. Supporting with Audit and knowledgeable advice, and deputising in absence.

4.7 Authorised Engineer (Decontamination) AE(D)

This role is undertaken by someone fully independent from the Trust and provides independent auditing and technical advice on decontamination procedures, for maintenance testing and the management of decontamination equipment, including washer disinfectors, sterilisers, and sterilisation and to review and witness documentation on validation.

This person is required to liaise closely with other professionals in various disciplines and, consequently, the appointment should be made known in writing to all interested parties.

The AE(D) will assist healthcare organisations in the appointments and interviews of the AP(D) and their subsequent annual assessments and has a reporting route to the Decontamination Lead and will provide professional and technical advice to the AP(D), CP(D) users and other key personnel involved in the control of decontamination processes.

4.8 Authorised Person (Decontamination) AP(D)

The role of AP(D) provides the Trust with day-to-day maintenance and testing of decontamination equipment. The individual must have adequate technical knowledge having had appropriate training; there appointment shall be approved by the AE(D).

The AP(D) has responsibility for the engineering management of decontamination equipment, including the safe and effective systems of work for all installed equipment within his/her areas of responsibility. This includes acceptance of decontamination equipment following repair, refurbishment or following quarterly or annual testing (permit to work).

4.9 Competent Person (Decontamination) CP(D)

The CP(D) is the person(s) who carry out maintenance, validation, and periodic testing of decontamination equipment.

The CP(D) reports directly to an appropriate member of the Estates department i.e., Estates Manager or the AP(D)

4.10 Risk and Clinical Governance Department:

The department receives reports of incidents involving the decontamination of medical devices within the Trust and works with specialist staff from other departments to investigate incidents and report findings. They Maintain a Risk Register that includes details of identified risks associated with the decontamination of medical devices and receive Safety Alert Broadcast System (SABS) information and alerts which are disseminated throughout the organisation.

The department acts as a focus; raising awareness amongst staff of the importance and procedures for reporting of all adverse incidents; in this case with special relevance to the decontamination of medical devices. Health and Safety procedures and the application of safe working practices for the decontamination of medical devices are advised upon by the Health and Safety Manager (now working from HR).

4.11 Senior Management Divisional Directors,

Divisional Medical Directors, Divisional Nursing Directors, Business Unit Leads and General Managers, Heads of Wards/Departments, and Clinical Governance Facilitators in conjunction with the Decontamination Links for each Directorate will ensure that there are adequate management controls in place throughout their clinical areas of responsibility, and that the principles contained within this policy are adhered to.

4.12 Managers within Clinical Areas

Will ensure that:

- Medical devices are decontaminated appropriately, are free from defects and are used in accordance with approved instructions and Trust policies.
- Acceptance procedures are carried out on newly acquired clinical equipment, and local procedures are in place to manage maintenance and decontamination requirements.
- All professionals and end-users receive appropriate training before using decontamination equipment, and that they have access to approved instructions and guidance issued by the device manufacturer or the Trust.
- Local risk management and safety procedures are in place to manage the risks associated with the decontamination of medical devices.

4.13 Trust Clinical Staff

All Trust staff involved in decontamination of medical devices must ensure that:

- The principles contained within this Policy are adhered to within their area of work.
- They receive appropriate training before using decontamination equipment.
- Invasive devices designated for single use are not re-used under any circumstances.
- They follow local Risk Management and Safety procedures to manage the risks associated with the decontamination of medical devices.

5 Process for Managing Risks Associated with Medical Devices Processed through Sterile Services

Burton and Derby Sterile Services departments must have appropriate departmental procedures in place to ensure compliance with HTM and instruction of notified bodies. Decontamination must only be performed in designated decontamination areas which are properly designed, maintained and controlled using processes which have been validated for process effectiveness. Manufacturer guidelines on the reprocessing and maintenance of a device must be followed and not altered in any way. The reusable surgical instrument cycle outlined in section 2 ‘Purpose and Outcomes’ of this policy must be followed. Departmental written procedures must be in place for all stages of the decontamination process.

5.1 Validation, Testing and Maintenance of Automated Equipment used in the Decontamination Process

All decontamination equipment should be fully validated to the relevant HTM and relevant International Standards (ISO) prior to use. Whilst in use all equipment should be maintained in accordance with the manufacturer's instructions and should be fully tested to the periodic testing requirements identified in the HTM 01 Suite (HTM 01-01 through 01-06).

Periodic testing (indicated therein) will include tests to be performed as follows:

- Daily by user
- Weekly by User and Competent Person (Decontamination)
- Quarterly by Competent Person (Decontamination)
- Annually by Competent Person (Decontamination)

5.2 Acquisition – Purchase and Loan

5.2.1 Purchase

All re-usable medical devices and equipment used in the decontamination process must be evaluated prior to acquisition to ensure compatibility with Sterile Services processes. Under current Law ALL medical devices used must carry a relevant CE marking; the responsible manufacturer must also provide decontamination instructions and user information.

The purchaser/user must ensure that medical device decontamination instructions are compatible with the decontamination equipment available. It is essential that these are approved prior to acquisition.

Please see simplified flow chart for surgical instrumentation in Appendix 1

Further information regarding purchase of new medical devices is outlined in the Management of Medical Devices Policy section 8.1

Lack of consultation can result in devices being acquired which cannot be adequately decontaminated. For example, devices manufactured outside the UK may require processes that are not routinely available within the UK, such as those that require sterilisation temperatures other than the standard 134°C cycle. Advice on individual cases may be sought from the Trust's Decontamination Leads, who will in turn consult Infection Control and/or Consultant Microbiologist as required. The Decontamination Operational Group (DOG) will act as a resource/referral point for debate about these decontamination issues.

Decontamination equipment (this is not referring to surgical instruments) shall be purchased in compliance with current relevant British or European standards. Purchase of such equipment shall not proceed until the requirements of the organisation have been included in a specification document and advice has been sought from the AE(D), Decontamination Lead, Infection Prevention & Control Team and the AP(D) responsible for undertaking/organising monitoring, maintenance and testing of Sterile Services equipment in accordance with current international standards. All installations shall follow a formal documented programme of validation in accordance with HTM guidance,

validation reports must be accepted and signed off by an AP(D) and to ensure that all test procedures and results are acceptable to the AE(D).

5.2.2 "Loan in" of surgical instrumentation

Acceptance checking of this type of loan equipment prior to delivery to Sterile Services must be undertaken by theatre personnel in accordance with manufacturer's instructions. Decontamination of loan/trial equipment must be carried out prior to and after use.

Under no circumstances must contaminated loan items be returned to originating departments or companies.

Further information regarding procedure for loan equipment is in Appendix 2.

5.3 Cleaning/Disinfection

Cleaning and disinfection of surgical instruments is an essential pre-requisite to ensure effective decontamination of contaminated items. Automated (washer disinfector) methods of disinfection provide a robust, validated, and safe method for cleaning/disinfection. As such, automated cleaning/disinfection processes should be adopted. In some circumstances a manual pre-clean may also be required (for instance if the instrument is heavily soiled).

Manual (hand) cleaning of surgical instruments must only be employed when the device is incompatible with an automated washing process; this must be done in accordance with manufacturer's instructions.

When purchasing new devices, preference will be given to those that are compatible with automated cleaning processes.

Regardless of whether an automated or manual clean is used, complex devices must be dismantled before cleaning and care should be taken in loading instruments into a washer disinfector to prevent "shadowing", hinged instruments should be opened fully to allow adequate contact with the detergent solution; stacking of instruments in washers must be avoided; and instruments should be disassembled as much as possible during the washing process.

Under no circumstances should items be migrated between trays, as this will compromise traceability of each item – this applies at all stages of the decontamination/use process.

5.4 Inspection

Following automated cleaning/disinfection processes, Sterile Services staff must confirm that the equipment achieved adequate parameters. All items are visually inspected to ensure functionality and that a high standard of cleanliness was achieved in the cleaning/disinfection cycle. Departmental procedures must be in place to ensure non-conforming items/failed cycles are managed appropriately. To ensure traceability, items must not be migrated between trays at any point in the process. Inspection ensures the correct number/types of items are packed in accordance with specification.

5.5 Packaging

Items that are required to be presented in a sterile condition for use require packaging prior to sterilization, so that sterility can be maintained until point of use. The methods used permit aseptic opening without contaminating the product.

All items processed through Sterile Services must have packaging which displays the contents name/type, date of processing, expiry date and proof of sterility.

Different types of packaging are appropriate for different item types; packaging to be used in each instance must be agreed by Sterile Services and the user prior to the processing of the item upon acquisition. In all cases packaging must satisfy the relevant standards.

Appendix 5 illustrates the symbols used on medical devices and their packaging. Staff must be aware of the meaning of the symbols. (Include in here a sterilisation batch label and example of a label after sterilisation)

5.6 Sterilisation

All items processed through Sterile Services must be sterilized at a temperature of 134°c -137°c – all sterilization equipment must undergo daily checks to ensure function. Following automated sterilization processes, Sterile Services staff must confirm that the equipment reached adequate parameters. All items must be visually inspected to ensure adequate steam penetration was achieved. Departmental procedures must be in place to ensure non-conforming items/failed cycles are managed appropriately.

5.7 Transport

Prior to despatch to end user all items must be checked as additional confirmation that items have been packed and sterilised correctly. All items must be issued to the appropriate end-user.

Items must be transported in a leak-proof, lockable, and easy to clean container in a manner that prevents damage or tampering of any item.

Containment should be achieved through the use of some type of container that has been identified to prevent health care staff and patients/public from contact with the contaminated instruments and prevention of airborne microorganisms during transport.

5.8 Storage & Handling of Sterilised Equipment

The end-user of the item is responsible for checking all items upon receipt to ensure integrity and sterility of the item has not been compromised. Following acceptance of the item the end-user must ensure that these are stored in an appropriately designed location to prevent damage during storage. Shelving should be easily cleaned and allow free movement of air around the stored product. Products must be stored above floor level away from direct sunlight and water in a secure, dry and cool environment. Heavy items must not be placed on top of other medical devices, as this may cause damage to the item and/or compromise packaging integrity. End-users must ensure that stock-rotation is carried out to prevent items exceeding their use-by date (12 months from date of sterilisation).

Care must be taken when handling sterilised products by the Sterile Services operatives and Theatre staff alike to ensure damage to wrapping material (sterile barrier) is not

compromised; lifting sets rather than dragging will help to eliminate damage to the wrapping material.

5.9 Use

The end-user must check items prior to use, following removal from storage, to ensure sterility has not been compromised. Where more than one tray/item is used during a procedure the user must ensure that items are not migrated onto other sets, and that operating procedures pertaining to preventing retained instruments are followed.

Dropping of instruments (Perioperative or otherwise) compromises sterility, such items must be replaced with sterile alternatives. Where frequently used sets are used there should always be an additional set readily available. On occasions, for example if loan sets are being used, provisions may not allow for an additional set to remain available and a local risk assessment must be completed by the operating team to assess the relative risk of the options available, for example:

- Continuation of the procedure without the item,
- Abandonment of surgery,
- Return of the item to Sterile Services for full decontamination.

5.10 Return to Sterile Services

All contaminated reusable medical devices must be handled, collected and transported to the Sterile Services decontamination area in a manner that avoids the risk of contamination to patients, staff and any area of the health care facility.

The end-user must ensure that items are secured in original packaging and placed at the collection point for return to Sterile Services as soon as possible after use, to prevent soiling (bioburden) from drying/baking onto the instruments, as the removal process becomes more difficult.

Upon receipt of used items Sterile Services must ensure that a full set of items have been returned by the end-user. Departmental procedures must be in place to ensure non-conforming/missing items are managed appropriately.

5.11 Disposal

All reusable medical devices at the end of their working life must be disposed of in line with waste management procedure and must be logged as disposed of and removal from the inventory/traceability system.

5.12 Inventory and Traceability

The Trust will ensure that systems are in place, which facilitates the tracing of surgical instrument sets and endoscopes through the decontamination process and to the individual patients on which they have been used.

Sterile Services departments maintain a database, within a traceability system, of all reusable instrument sets and supplementary instruments reprocessed within their

facility. The traceability system enables all instrument sets and supplementary instruments to be traced throughout the decontamination process, therefore providing an auditable trail of processes items have been subject to. The traceability system also extends to include decontamination of endoscopes processed by Burton Sterile Services, the Trust endeavours to compile and maintain an inventory which also incorporates flexible endoscopes processed by Derby Endoscopy staff.

All instrument trays and supplementary items are allocated a unique barcode to enable identification and traceability of the tray and corresponding instruments throughout working life.

In order to comply with GS1 legislation each individual instrument processed should be marked with a unique GS1 code. Some items processed by Sterile Service will carry a unique identifier (PIN/etching) in addition to a barcode; the Trust will work towards full compliance with GS1.

Each Sterile Services operative is assigned a unique identifier which enables traceability of medical devices throughout the decontamination process and provides assurance that devices can be linked to a responsible operator for each stage of reprocessing.

5.13 Decontamination Prior to Inspection, Service, Repair or Investigation

Equipment must wherever possible be decontaminated by following the manufacturer's guidelines, prior to being inspected, serviced or repaired. A "Declaration of Contamination Status" form must accompany any medical device that may have been contaminated by contact with blood or other body fluids, pathological specimens, or exposed to infection. This form must be completed and signed by the person in charge of the ward/department or a nominated staff member. Equipment will not be accepted if visibly soiled or is presented without a completed "Declaration of Contamination Status" form, or label (in the case of return to the medical equipment library or Medical/Clinical Engineering for repair)

If the device is the subject of an investigation or complaint it may be inappropriate for it to undergo decontamination. The procedure to be followed in such instances is detailed in the Trust Policy and Procedures for Incident Reporting, Analysing, Investigating and Learning located in the Risk Management and Health and Safety Manual.

Further advice on decontamination issues may be sought from the Decontamination Lead or Infection Control Team.

6 Process for Managing Risks Associated with Endoscopes

6.1 Flexible Endoscopes

As flexible endoscopes are heat-labile (i.e., cannot be high temperature sterilised) the decontamination method of choice for these devices is automated cleaning and chemical disinfection. Emphasis must be given to the manual cleaning of an endoscope prior to processing through the endoscope washer disinfector. This is the most important means of removing potential pathogens and will remove most microorganisms and organic matter. All removable devices i.e. (buttons) associated with a scope must remain with the scope through-out the decontamination process and re-use, for tracking purpose. Decontaminated endoscopes must be transferred to the end-user in a secure trolley for storage in a fit-for-purpose drying cabinet which enables safe storage for 31 days. Care must be taken not to allow the distal tip to rest on the cabinet floor, or for the endoscope to become twisted (stressed) as this could affect the endoscopes performance.

Whilst in routine operation, the clinical application for which an endoscope has been used will not alter. Where endoscopes will be used for clinical examinations outside of routine operation clinical teams must advise Sterile Services of any altered risk.

6.2 Decontamination of Nasendoscopes

Decontamination of Nasendoscopes requires the same standard of cleanliness and disinfection as other flexible endoscopes. To that end, Nasendoscopes used within the trust should be those without lumens to enable manual decontamination using wipes and procedures validated for the specific purpose of decontaminating such items. The use of single use sheaths does not negate the need to clean and disinfect these endoscopes between patients and after use. Written departmental procedures must be in place for the decontamination, storage and traceability of Nasendoscopes endoscopes.

It should be noted that currently not all Nasendoscopes are decontaminated using automated cleaning processes; this is something the Trust must work towards

6.3 Trans-oesophageal echocardiography (TOE) trans-vaginal (TVUS) and trans-rectal ultrasound probes (TRUS)

These probes do not have lumens, only the patient insertion tube can be immersed in liquid.

The use of an Endoscope Washer Disinfector (EWD) to decontaminate the immersible parts of these types of probes is to be preferred but not always practical.

A controlled gross clean followed by both detergent clean and disinfectant wipe is an Essential Quality Requirement. A local risk assessment could indicate that manual cleaning immersion of the insertion tube in an EWD whilst manually cleaning and disinfecting the non-immersible parts would represent progress towards Best Practice.

The area where decontamination is carried out should have a sink of adequate size for cleaning the probe and a separate clinical wash-hand basin. The area used, be it in a separate room or incorporated in a clinical procedures room, should have a clearly defined flow from used (dirty) through cleaning and disinfection process to clean and available for storage and use. Separating dirty and clean areas is a major step in eliminating probe recontamination or mistakenly using a probe that has not been fully decontaminated.

There should be satisfactory record keeping so that the patient's identity can be clearly established against the equipment and chemistry used to decontaminate the equipment.

Written departmental procedures must be in place for the decontamination, storage and traceability of TOE, TBUS and TRUS devices.

7 Process for Managing Risks Associated with Medical Devices NOT Processed through Sterile Services

Departments using medical/patient care devices which are not decontaminated via Sterile Services are responsible for ensuring that these are cleaned in an appropriate manner, on an adequate schedule. The Trust Policy for Cleaning provides further information regarding cleaning of commonly used items, any devices not included in either the Decontamination Policy or Trust Policy for Cleaning must be subject to individual departmental cleaning procedure.

All reusable medical devices and equipment to be inspected, serviced, repaired, disposed of or transferred to another part of the organisation must undergo contamination/cleaning and should be labelled (Appendix 3) in line with the Trust Policy for Cleaning.

TOE probes are currently decontaminated locally and not through a Sterile Services department

7.1 Single Use Items

Items supplied as “single use” are commercially sterilized and supplied in packaging labelled for single use.

Single use devices/equipment is identified by two categories:

- Single use **MUST NEVER** be used more than once, reference to this can be found in the Medical Devices Bulletin DB 2000(04) for single use devices
- Single patient use is adopted when a medical device can be used multiple times through a patients care pathway and is reprocessed in accordance with manufacturer’s guidance between each use on the same patient. The device is destroyed when the use of the device is no longer required for the patient.

The expression “single patient use” written on the manufacturers packaging means that the manufacturer intends for the device to be used multiple times on the same patient.

For further information on single use devices refer to the Trust Policy for Single use Devices.

8 CJD and vCJD Creutzfeldt – Jacob disease (CJD/vCJD, (a Transmissible Spongiform Encephalopathy (TSE))

All instruments returned to Sterile Services for processing are classified as contaminated regardless of the instrument/surgery type; therefore, all instruments apart from those known or suspect CJD are handled in the same way. Appropriate PPE is worn by all personnel whenever contaminated instruments are being handled. Devices used on patients with known or high-risk of CJD/vCJD should be managed in line with Trust Policy for Transmissible Spongiform Encephalopathy (Creutzfeldt - Jakob disease).

Sterile Services management must be notified of any planned procedure involving a patient with possible CJD to ensure internal quarantine procedures can be followed. In instances of emergency procedures Sterile Services management must be notified as soon as practically possible. To ensure products are not held in quarantine without review the Sterile Services Manager/Decontamination Lead will liaise with the IPC team if items remain in quarantine for a period of three months without a definitive diagnosis/action plan. This will be repeated at three monthly intervals for a period of no more than 9 months until a definitive diagnosis is obtained and the instruments either incinerated or returned to use.

For further information about CJD and vCJD refer to the Transmittable Spongiform Encephalopathy (TSE/CJD) - Trust Policy and Procedure

9 Monitoring, Compliance and Effectiveness

Monitoring Requirement:	Review the monitoring and reporting mechanisms in place throughout the Trust to ensure that all reusable medical devices are properly maintained and repaired to the required standard.
Monitoring Method:	Review of Decontamination audits Review of minutes of Decontamination Groups Exception reports from Subgroups
Report Prepared by:	Decontamination Leads
Monitoring Report presented to:	Infection Prevention and Control Committee
Frequency of Report	Six Monthly

10 Subgroups

10.1 In house Sterile Services Provision (Burton campus)

The in-house facility has a Quality Management System (QMS) which meets the requirements of BS EN ISO 13485:2016 and the Medical Devices Directive, using Article 12 as the route to compliance. This ensures that any medical devices (surgical instruments in this instance) that are used in a surgical procedure are fit for purpose and sterilised to the highest standards.

Monthly quality management review meetings in accordance with the QMS are held, this is the forum in which the organisation's QMS is reviewed to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement including the quality policy and quality objectives, inputs and outputs.

Monthly meetings between sterile service management and theatre managers are scheduled and this provides a decision making/problem solving opportunity which responds to service development and innovation.

Items raised from both meetings are reported through either the decontamination user group (DUG) or decontamination operation group (DOG) and may result in being escalated through the infection control committee.

10.2 Steris/Synergy Contract/ Sterile Service Provision (Derby campus):

This process is managed through the Performance Management and Monitoring (PMM). Whilst a Theatre User Group aims to improve the patient's experience of support services through cross-cutting communication and work streams. It provides a decision making/problem solving forum that responds to service development/innovation and reflects relevant strategies, this reports by exception to DOG.

10.3 Decontamination Groups

These groups are separated into user (DUG) and an operational group (DOG) which provides specialist advice and managerial guidance on decontamination/single use issues and the purchase of decontamination equipment.

These groups will also:

- Ensure that systems are in place throughout the Trust, so that all reusable medical devices are decontaminated appropriately and in a timely manner prior to use, and that the risks associated with decontamination facilities are adequately managed.
- Provide advice on the procurement of surgical instruments to ensure they can be processed appropriately in accordance with manufacturer's instructions
- Review and monitor the use of decontamination equipment in accordance with current guidance.
- Act as an advice point for the decontamination of reusable medical devices including those suspected as coming into contact with CJD.
- Ensure risk Management are kept informed of any problems or issues in relation to risk and decontamination/single use issues.
- Provide 3 monthly reports to the Infection Prevention & Control Committee on decontamination issues.

10.4 Medical Devices Group

Will authorise and advise on the purchase of appropriate decontamination equipment and ensure that these are maintained and managed in accordance with current international standards.

10.5 Medical Devices and Product User Group

This Group will provide the Trust an operational and consumables governance forum, to allow a financial focus to be at the Medical Devices Group. This group receives regular reports on training and service compliance, and monitors the Device and consumable based National alerts, including the Decontamination Leads by exception.

11 References

- DOH (2001) A review of the decontamination of surgical instruments in the NHS in England, Department of Health.
- Decontamination Standards for Flexible Endoscopy (2007). National Endoscopy Programme.
- Sterilisation, Disinfection & Cleaning of Medical Equipment: Guidance on Decontamination from Microbiology Advisory Committee to Department of Health, Medical Devices Agency.
- HSC 2000/032 Decontamination of Medical Devices
- Medical Devices Directive 93/42/EEC Annex 1 ER 13.6,h
- MDA Safety Notice SN 9619 Compatibility of Medical Devices and their Accessories and Reprocessing Units with Cleaning, Disinfecting and Sterilising Agents.
- Consumer Protection Act 1987(6)
- HTM 01-01 through 01-06 (2016)
- Trust Policy and procedure for the Competency and Training Requirements Connected with Medical Devices
- NHSLA (April 2008) Risk Management Standards for Acute Trusts
- Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance
- Scan4Safety; IT systems and coding (including GS1)

Standards relevant to decontamination management

- BS EN ISO 13485. Medical devices. Quality managements systems. Requirements for regulatory purposes.

Standards relevant to safety requirements for decontamination equipment

- BS EN 61010-2-040. Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.

- BS EN ISO 13849-2. Safety machinery. Safety-related parts of control systems. Validation.

Standards relevant to medical devices

- BS EN 556-1. Sterilization of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for terminally sterilized medical devices.

- BS EN 556-2. Sterilization of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for aseptically processed medical devices.

- BS EN 1041. Information supplied by the manufacturer of medical devices.

- BS EN ISO 17664. Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re-sterilisable medical devices.

- BS EN ISO 14971. Application of risk management to medical devices

Standards relevant to decontamination processes and equipment:

- BS EN ISO 11737-1. Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products.

- BS EN ISO 11737-2. Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation, and maintenance of a sterilization process.

- BS EN ISO 14937. Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.

- BS EN ISO 17665-1. Sterilization of health care products. Moist heat. Requirements for the development, validation, and routine control of a sterilization process for medical devices. (This includes porous load and fluid sterilizers (except when used for medicinal products), and sterilizers or unwrapped instruments and utensils.)

- BS EN 285:2006+A2. Sterilization. Steam sterilizers. Large sterilizers.

- BS EN 13060. Small steam sterilizers.

- BS EN 1422:1997+A1. Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.

- BS EN 14180:2003+A2. Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers.

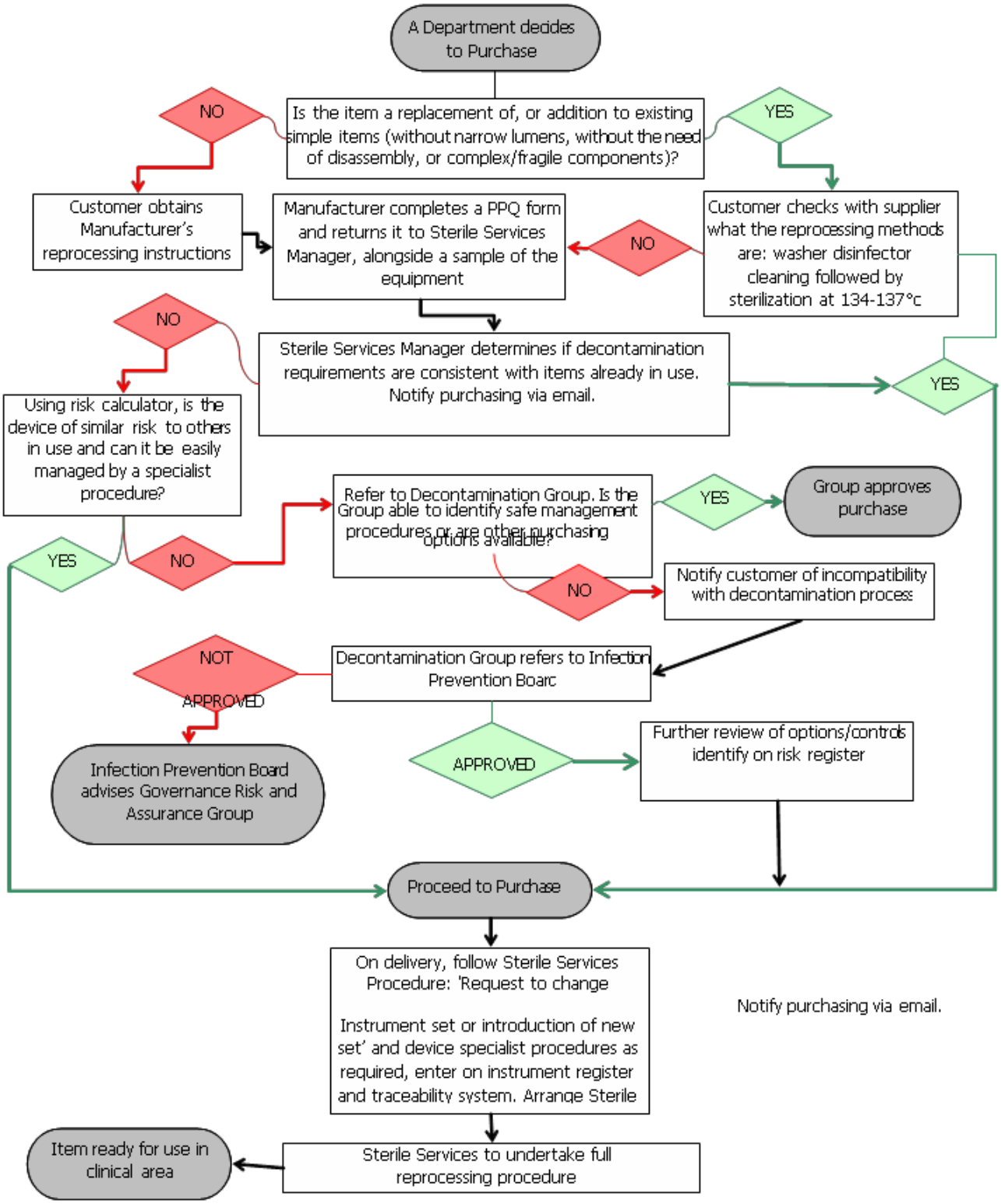
Requirements and testing.

- BS EN ISO 15883-1. Washer-disinfectors. General requirements, terms and definitions and tests.

- BS EN ISO 15883-2. Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

- BS EN ISO 15883-3. Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers.

Appendix 1 Surgical Instrument Procurement Flowchart



Appendix 2 – Loan Equipment:

<table>
<tr><td>Reference Number
xxxxxxxx</td><td colspan="2">Version:
V2</td><td colspan="2">Status
Draft</td><td>Authors: Wendy Kirk & Mark Cannell
Job Title: Decontamination Leads</td></tr>
<tr><td rowspan="2">Version/ Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td colspan="2">Reason</td></tr>
<tr><td>V2</td><td>June 2020</td><td>Wendy Kirk & Mark Cannell</td><td colspan="2">Joint UHDB policy</td></tr>
<tr><td colspan="6">Intended Recipients: All relevant clinical and medical staff, Divisional Directors, Relevant Business Unit Managers and Quality and Governance Leads.</td></tr>
<tr><td colspan="6">Training and Dissemination: All clinical staff identified by the training Needs Analysis and other identified users will be trained by local trainers and assessors. Relevant changes to be updated in Training Packages.</td></tr>
<tr><td colspan="6">To be read in conjunction with: Trust Policy and Procedures for Infection Control, Trust Policy for the Assessment and Management of Risk, Staff Training and Development Policy, Trust Policy and Procedures for the Management of Medical Devices, Trust Policy and Procedure for the Competency and Training Requirements Connected with Medical Devices, Disinfection and Sterilisation in the Infection Control Manual, Trust Policy for Cleaning.</td></tr>
<tr><td colspan="6">In consultation with and Date: Decontamination Groups, Infection Prevention and Control Committee</td></tr>
<tr><td colspan="6">EIRA stage One Completed: Yes
stage Two Completed: NA</td></tr>
<tr><td colspan="3">Approving Body and Date Approved</td><td colspan="3">Infection and Prevention Control Committee</td></tr>
<tr><td colspan="3">Date of Issue</td><td colspan="3">June 2020</td></tr>
<tr><td colspan="3">Review Date and Frequency</td><td colspan="3">June 2022 (then 3 yearly)</td></tr>
<tr><td colspan="3">Contact for Review</td><td colspan="3">Trust Decontamination Lead’s</td></tr>
<tr><td colspan="3">Executive Lead Signature</td><td colspan="3">Chief Nurse</td></tr>
</table>

1. Introduction

The Trust is committed to developing safe systems and processes that seek to provide rigorous controls over equipment that is loaned to the Trust and is loaned out to other organisations. There are many issues to be considered in this process including responsibility, transportation, traceability of equipment, liability for damage or loss, costings and decontamination.

The aim of this policy is to ensure compliance on the process required for completion when loaning in and out of any department or operating theatre at the Derby Hospitals. This policy will stipulate the situations that may require the loan of theatre equipment in and out of the Trust.

The policy will provide procedures that should be followed when a requirement is identified for loan equipment that is being maintained by the Trust or borrowed into the Trust.

It is the responsibility of all Trust employees to follow the requirements of this procedure. Any member of staff who takes equipment from the Trust without proper authorisation, as described below may be considered to be operating outside of Trust policy and could be subject to disciplinary procedures.

2. Aims of the Policy

- To identify situations where the loaning of equipment is acceptable (see trust contract with other organisations)
- To establish a set of procedures for loan of theatre equipment into and out of the Trust
- To identify clear areas of responsibility
- To identify a consistent approach
- To ensure adequate tracking and record keeping of equipment loaned into and out of the Trust
- To identify liability for damage or loss of equipment
- To promote a consistent approach to financial recompense

3. Area of the Policy

This policy will include all departments and operating theatres in the Trust that may receive requests to loan equipment outside of the Trust.

4. Objectives

To inform all relevant staff of the procedure to be followed, for the loan of sterilised theatre equipment, into and out of this Trust.

5. Scope of the Policy

The policy covers:

- Identification and authorisation of loaned theatre equipment
- Procedure for loaning equipment into and out of the Trust's Theatres
- Responsibilities for loaned theatre equipment
- Traceability of equipment
- Guidelines for return of equipment and safety checks required
- Adequate remuneration for equipment loaned out of the organisation

- Actions when equipment returned in an unacceptable condition

6. PROCEDURE

The Trust (theatres and related departments) will only loan equipment out of the organisation in an emergency.

This is defined as when:

- Equipment is required when a patient is anaesthetised
- An unforeseen situation has arisen i.e., a dropped instrument, damage to instrumentation
- When a trauma case is being undertaken
- When deemed necessary by the respective Theatre Managers to avoid an emergency occurring.

The loan of all theatre equipment into and out of the Trust must be authorised by the relevant Theatre Co-ordinator / Theatre Manager.

Please see attached flow charts for loans into and out of the operating theatre (appendices A and B). The procedure for the return of loaned theatre equipment is outlined in appendices C and D.

7. Responsibilities

The current liability arrangements for loaned equipment to the Trust will be maintained (appendix E).

Liability for loans out of the Trust to other Organisations will be discussed on request in accordance with Trust Policy for Loan Equipment.

The responsibility for the transportation of the equipment lies with the organisation who is borrowing the equipment. They should ensure that the equipment is transported in a safe and legal manner.

8. Traceability

For traceability purposes patient information must be supplied and kept by the organisation who is loaning out the equipment.

This information must consist of the patient's name, Date of Birth and Hospital Number. This will be stored in the relevant file at the Theatre Reception in the Operating Theatres.

9. Guidelines for the Return of Equipment

On receipt of the theatre equipment back into the organisation ["Synergy Reception RDH"] the equipment must be checked by the ["Synergy Decontamination"] staff and a decontamination certificate, and patient details included with the equipment.

The decontamination sheet and data must be forwarded to the Loaning area for them to record loan return on will be informed and the patient information recorded.

The loan equipment will be compared to the contents sheet held by, any defects and losses will be reported to the "administrator/instrument co-ordinator" for billing purposes.

10. Payment for Loan Equipment

When equipment is loaned from Theatres the “administrator/instrument co-ordinator” for theatres must be informed. The required information will be entered onto the H-Track Database. The relevant information will be forwarded onto the Finance Department, who will in turn raise an invoice. A handling charge will be made of 20% and included in the raised invoice.

11. Actions to be taken when equipment returned in an unacceptable condition

The receiving agency, on checking returned equipment, is required to identify if there is a fault or loss found at this point, the “administrator/instrument co-ordinator” and [relevant] Theatre Co-ordinator must be informed of fault or concern regarding the equipment, as may impact this area’s business activity.

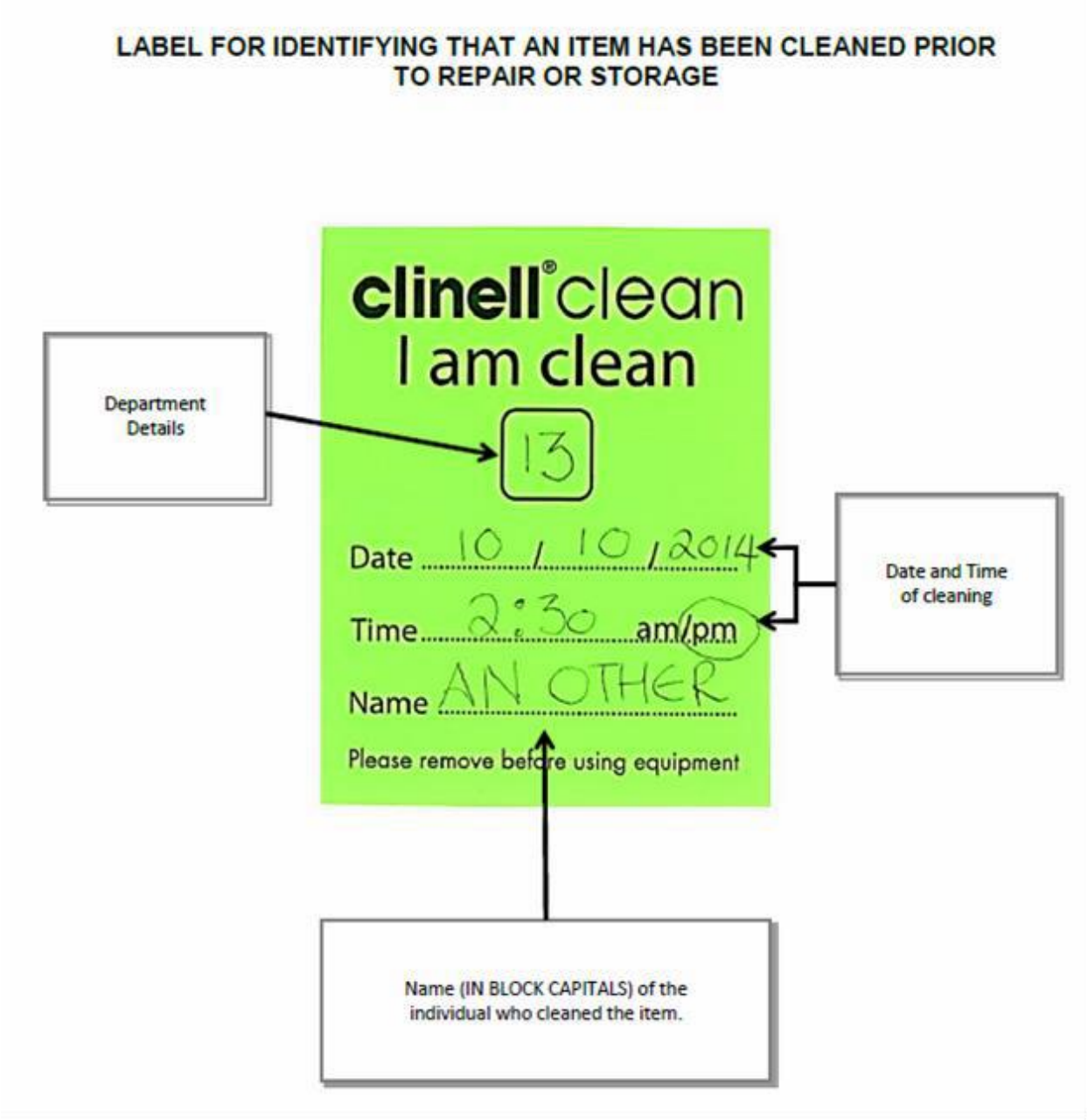
A record of the damage, the corrective costs, and business impact costs this damage is required to be completed [Appendix F] by the loaning areas, this will then need to feed to the DFM for recompense and planning.

An Invoice will be raised by finance and the borrowing organisation informed.


(E) Indemnity - Form A - Delivery Note.xls


(E) Indemnity - Form A (Loan-Trial).doc

Appendix 3 – Decontamination Label:



Appendix 4 – Decontamination Certificate

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Certification of Decontamination

Instructions
Where equipment is to be taken off Trust premises for inspection, service or repair a **COPY** of this certification must accompany the item, the other retained by the relevant Budget holder/Department lead.

To be completed by the department the device/equipment is leaving	
Date and time	
Department and site	
Department Lead Name	
Name and designation of who is completing this form	

Device details	
Description/Name of device	
Equipment Number/Serial Number/s	

Chose one of the following three options			
Option 1 This device does NOT require decontamination			
Tick here for this option	The Equipment **HAS NOT** been exposed to Biological, Chemical, Radiological or other known Hazards The equipment **HAS** been cleaned according to the cleaning procedures detailed below		
Option 2 This device has been decontaminated			
Tick here for this option	This device has possibly been exposed to potential Hazards		
	Please identify (tick the box) any or all hazards this device could have been exposed to,		Biological
			Chemical
			Radiological
			Other (please identify)
	Decontamination Processes		
	Method of decontamination, with detail of names of products used to make this product safe.		
Option 3 This device has NOT been decontaminated			
Tick here for this option	This equipment HAS been used in a potentially contaminated environment. The nature of the hazard has been assessed and the details are given below. **ESSENTIAL** Details of handling precautions to be written below, together with an explanation as to why the decontamination process has not been completed.		
	Continue on rear of sheet if necessary		

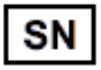
UHDB Decontamination Certificate, 2020.V1

Appendix 5 - Symbols on Packaging and their Meaning

CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. The CE marking does not in itself indicate that the product is fit for purpose – only that it meets a specific EEA standard.

The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA.

The UKCA (UK Conformity Assessed) marking is a new UK product marking that will be used for certain goods being placed on the UK market if there's a no-deal Brexit. However, a product bearing the CE marking would still be valid for sale in the UK so long as it was also UKCA marked and complied with the relevant UK rules.

Symbol	Used for	Symbol	Used for
	Do not reuse		Use by YYYY-MM-DD or YYYY-MM
	Batch code		Serial number
	Date of manufacture		Sterile
	Sterilized using ethylene oxide		Sterilized using irradiation
	Sterilized using steam or dry heat		Catalog number
	Caution, consult accompanying documents		Sterilized using aseptic processing technique
	Manufacturer		Authorized representative in the European community
	Contains sufficient for < n > tests		For in vitro diagnostic performance evaluation only
	In vitro diagnostic medical device		Upper limit of temperature
	Lower limit of temperature		Temperature limitation
	Consult instructions for use		Biological risks