CONTROLLED DOCUMENT

University Hospitals Birmingham NHS Foundation Trust

Procedure for the Decontamination of Reusable Medical Devices Prior to Patient Use, Inspection, Servicing, Repair or Return to Departments or Organisations

CATEGORY:	Procedure
CLASSIFICATION:	Clinical
PURPOSE	This procedure is intended to provide guidance to enable staff to safely handle and decontaminate reusable medical devices including instruments, anaesthetic devices and equipment. This procedure does not include reusable medical devices used with cytotoxics or radiation. Further advice on decontamination can be obtained from Pharmacy for cytotoxics and the Regional Radiation Protection Physics Service for radiation.
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Distribution: • **Essential Reading for:** • **Information for:**	 All Directors, Senior Managers and Department Heads All Staff

Contents

1. Introduction

This procedure is intended to provide general guidance for the safe handling and decontamination of reusable medical devices to significantly reduce the risk of micro-organisms causing infections in either staff or patients. This includes instruments, anaesthetic devices and equipment.

Correctly applied, the procedure will enable staff to safely decontaminate reusable medical devices in accordance with manufacturer's guidelines, Health and Safety at Work Act; British Standards Institute; Medical Device Directive; Medicines and Healthcare Regulatory Agency (MHRA); Control of Substances Hazardous to Health (COSHH); Care Quality Commission (CQC) and National Decontamination Guidance, thus ensuring the safety of patients, staff and visitors within the Trust.

This procedure does not include reusable medical devices used with cytotoxics or radiation. Further advice on decontamination can be sought from Pharmacy for cytotoxics and the Regional Radiation Protection Physics Service for radiation.

Medical Device Definition:-

'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

- investigation, replacement or modification of the anatomy or of a physiological process;

- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

Medical Devices Directive 93/42/EEC 2007

This procedure has been prepared in response to documents issued by NHS England relating to decontamination of reusable medical devices. It proposes a safe system of work for all reusable medical devices that come into contact with patients, their body fluids or pathological specimens. (Please see Policy for Decontamination of Reusable Medical Devices and Shared Patient Equipment).

All reusable medical devices, to be used on a patient, inspected, serviced, repaired or returned to the lending organisation must undergo decontamination i.e. cleaning/disinfection / sterilisation. This is necessary to ensure that they are in a condition that makes them safe for reuse on patients and safe to handle by personnel who come into contact with the medical device. The reusable medical device should not expose the patient or handler to any biological or chemical risk.

This procedure applies to the following circumstances when reusable medical devices are:

- used on a new patient or reused on the same patient over a period of time
- attended on site by the manufacturer, medical engineering, renal technicians or Engie
- returned to the manufacturer, estates or medical engineering for service, repair or when no longer required
- returned to the Trust Equipment Store, B Braun Sterilog, Birmingham Equipment Loans Service - Community or an external organisation, if loaned.

2. General Guidance

When decontaminating reusable medical devices staff must wear appropriate Personal Protective Equipment (PPE) for example aprons, gloves, gowns, masks, visors and eye protection to protect themselves and their uniforms from contamination, foreign bodies, splashes or aerosols.

PPE may also be required to protect the user from the potential harmful effects associated with some chemical or pharmaceuticals, in line with COSHH and Pharmacy guidelines.

Clinical Risk Assessments for the Decontamination of Reusable Medical Devices should always be carried out in line with the manufacturer's instructions.

Single-Use Medical Devices must not be re-used, these are clearly identified by

- DO NOT REUSE

  Synonyms for this are:
  - Single-use
  - Use only once

- The choice of decontamination method should involve a clinical risk assessment of the infection risk associated with the intended use of the item.

- If contaminated with blood or blood stained body fluids, please refer to the manufacturer's instructions for guidance on compatible detergent and disinfectant for cleaning and disinfection

- If visibly chipped or damaged the medical device must be repaired or replaced.

3. Classification of Infection Risk associated with the Decontamination of Reusable Medical Device

RISK	APPLICATION OF ITEM	EXAMPLES	RECOMMENDATION
High – Critical	• **In close contact with a break in the skin or mucous membranes** • **Introduced into sterile body areas or vascular systems**	**Surgical instruments; tray's and sets of implants**	**Cleaning followed by Sterilization – Complete destruction of all micro-organisms, including spores. (Prions destruction is not guaranteed)**
Medium – Semi-critical MHRA	• **In contact with mucous membranes** • **Contaminated with particularly virulent or readily transmissible organisms** • **Prior to use on**	**Glucometers; Vaginal probes; flexible endoscopes; Respiratory therapy equipment; Laryngoscopes**	**Cleaning followed by sterilization or disinfection – Reduces the number of micro-organisms to a level at which they are not harmful. Spores are not usually**

	immunocompromised patients		**destroyed.** **NB: Where sterilization will damage equipment, cleaning followed by high level disinfection may be used as an alternative.**
Low – Non-Critical	• **in contact with healthy skin** • **not in contact with patients**	**Bedpans; rails; crutches; ECG leads; stethoscopes; wheelchairs;**	**Cleaning – Physical removal of infectious agents and organic matter with detergent**

MHRA Managing Medical Devices April 2015

4. Responsibilities of Clinical Areas and Users

The manufacturer of a reusable medical device or accessory should supply information on how to clean and maintain the device. This information should include the types of decontamination agents that may be used to clean, disinfect or sterilise, and a warning of any compounds or processes which may be detrimental to the device. If the instructions are not available then the reusable medical device must not be purchased or used without first consulting the Infection Prevention and Control Team, Decontamination Advisor or Trust Sterile Service Manager.

Staff handling used, reusable medical devices, should assume that they are contaminated and take precautions to reduce the risk to themselves and others. The use of personal protective equipment is recommended when carrying out decontamination. All decontamination activities should be carried out in accordance with the medical device manufacturer's instructions. If manufacturer's instructions are not available, then advice should be sought from the Infection Prevention and Control Team (IPCT) or Decontamination Advisor.

The method used for cleaning / decontaminating must be one that is appropriate and is in adherence with the manufacturer's instructions:-

- the level of contamination of the medical device
- gives acceptable decontamination

- does not damage the device or any of its components within, subject to the requirements of the MHRA Managing Medical Devices, Guidance for healthcare and social services organisations April 2015

  https://www.gov.uk/government/publications/managing-medical-devices

Automated cleaning methods provide a number of advantages over manual methods. These include:

- the provision of efficient, reproducible processes which can be more easily controlled and validated than manual methods.

- provide protection for the user in reducing the exposure to chemicals and micro-organisms.

- automated cleaning provides simultaneous cleaning and disinfection of items.

- provides systems to track and trace surgical instrument sets/medical devices and trace them to the patients on whom they have been used.

The advice of NHS England is that all reprocessing of reusable surgical instruments / medical devices should be undertaken outside of the clinical environment where possible, and preferably in Sterile Services Departments or Endoscope Decontamination Units. However, irrespective of where decontamination takes place, patient safety must not be compromised.

The decontamination process must not be used on single use items. 

5. Manual Cleaning

Manual cleaning of reusable medical devices should only be carried out when the use of an automated washer-disinfector is unavailable or inappropriate to the medical device.

Some medical devices may have special decontamination requirements whereby they are single patient use, decontaminated between treatments and disposed of after a number of uses or days. Specific procedures are in place which gives instructions on their cleaning requirements.

5.1 Factors affecting manual cleaning

Staff must be trained in pre-cleaning and manual cleaning, to ensure that they understand the factors that may affect the efficiency of immersion and non-immersion manual cleaning methods, these include:

- staff training/competence
- water temperature
- detergent concentration
- mechanical action
- nature of soil
- method of soil removal
- accessibility of solutions to all surfaces of the item.

5.2 Decontamination Process

Pre-cleaning is a necessary pre-requisite for any reusable medical device, prior to manual cleaning, disinfection and / or sterilization. Please refer to departmental standing operational instruction if implemented. This is to ensure that organic material has been thoroughly removed from the item to make it safe for further handling. The presence of any organic material will inhibit the effectiveness of any disinfection or sterilization methods.
All medical devices which have been opened in a clinical area whether in direct contact with the patient or not must be manually cleaned and reprocessed.

All staff must have received training and their competency assessed before carrying out manual cleaning of medical devices. The training must be recorded and kept.

Depending on the construction of the medical device, manual cleaning can be either carried out by immersion (See appendix B) or non-immersion.

Cleaning must be carried out using water and an approved detergent at the correct concentration and temperature, as recommended by the manufacturer or Trust.

The changing of the water with detergent solution should be completed after every application of manually cleaning and soaking for long periods must be prohibited.

Manufacturer's instructions must be followed when cleaning medical devices in some instances detergent wipes can be used.

5.3 Training

Staff undertaking decontamination of reusable medical devices, must have specific instructions on decontamination of the item from the manufacturers of the medical device and/or the supplier of the decontamination equipment. B Braun Sterilog Decontamination parameters can be found in **Appendix D**. Manufacturer's instructions must be kept for each item in the clinical area. A Standard Operating Procedure is essential for all items.

Staff must be trained and assessed in the correct methods of disassembling and assembling of medical devices prior to and following decontamination. Records must be kept.

5.4 Personal Protective Equipment (PPE)

PPE must be worn at all times during the decontamination process e.g. gloves, gown, waterproof aprons, visors. A first aid kit and eye wash bath must be available nearby.

Decontamination must not be performed wearing surgical gowns, which have been worn during a procedure. Disposable apron, gown and gloves must be changed prior to or after decontamination.

Staff must wash their hands with soap and water, following the removal of PPE; Hands should then be dried using paper hand towels.

5.5 Facilities / Environment

The area used for manual cleaning, should be dedicated for the purpose, provide a workflow from dirty to clean and must not be shared with other activities. Surfaces must not be shared for dirty and clean items. If this is unavoidable, the surface must be cleaned before placing the clean item onto it.

There should be sufficient dedicated shelving or cupboard space for storage of decontamination materials, PPE, clinical waste bags, cloths, brushes etc. There should be adequate space for linen skips; foot controlled clinical waste bins and a foot controlled bin for paper hand towels. **No other equipment, sterile packs, disposables or cardboard boxes should be stored in this area.**

A sluice hopper for the disposal of contaminated material should be available.

There should be a dedicated sink for manual cleaning, that has water at a controlled temperature 35ºC (or a means to monitor the water temperature), measurement for the volume of water, a regulated dispenser for measuring detergent. A second dedicated sink is also required for rinsing items, if fitted. (A bowl may be used where there is no second sink). Provision must be made for a draining area or sink drainer.

A dedicated hand wash basin with elbow taps and a soap dispenser should be available. (alcohol hand rubs, where a wash basin is not available).

There should be available a supply of single use cleaning materials, recommended by the manufacturer i.e. brushes / cloths etc. Aggressive agents must not be used for manual cleaning i.e. green scourers.

Any reusable cleaning materials must be compatible with the medical device to be cleaned. These items must be cleaned and disinfected after each use, regularly checked and replaced. Single-use items should be discarded after each use.

There should be a supply of detergents, recommended by the medical device manufacturers or a documented local policy, which must be available. Up-to-date COSHH data sheets and risk assessments must also be available; these must be verified by the Trust's Occupational Health Department.

There must be clean, disposable, absorbent, non-shedding cloths for drying items following decontamination.

5.6 Inspection

Inspection, maintenance or testing of medical devices must be carried out by trained and competent staff, in accordance with the manufacturer's instructions or Trust policy and procedures. Inspection should be carried out away from the manual cleaning area.

The inspection, re-assembly and testing of medical devices should be carried out by a member of staff not responsible for the manual cleaning of the item. The member of staff inspecting the medical devices has the responsibility for ensuring that the item is fit for reuse. If not, the items are removed from the system and reported to the line manager.

Records should be written and kept within the department for audit purposes, this involves all work performed, including function testing.

5.7 Sterilization

Before purchasing a medical device the Line Manager must ensure it is compatibility with B Braun sterilog parameters. Where medical devices need to be sterilized, the Line Manager must contact the Decontamination Sterile Service Manager or Decontamination Advisor for advice on the transportation of the medical device to B Braun Sterilog for reprocessing.

5.8 Record Keeping

The Medical Devices Regulations (1994), the Provision and Use of Workplace Equipment Regulations (1998) and the Consumer Protection Act (1987), in particular Product Liability has implications for the reprocessing of devices used for patient care.

It is essential to maintain adequate records that demonstrate how a particular medical device was cleaned and processed, along with a description of the method of decontamination and details of trained staff.

6. Patient Use

All reusable medical devices including surgical instruments, anaesthetic instruments and associated medical devices **must** be decontaminated between patient uses to achieve a level of cleaning, disinfection or sterilization that significantly reduces the risk of infection associated with its use. Further, to ensure that infection risks to staff are minimized within the Trust in accordance with manufacturers' guidelines.

However, where the decontamination of some anaesthetic instruments and associated medical devices may not be feasible within a sterile service department an alternative single-use device should be used. This procedure enables staff to undertake an informed clinical risk assessment. There are separate policies and guidelines for the decontamination of specialist medical devices

All disposable accessories must be discarded.

7. Medical Devices Requiring or Returning from Repair

- Reusable instruments etc. should be fully decontaminated via B Braun Sterilog and should be accompanied with a Declaration of decontamination note before sending to the repair agent or medical engineers.

- Medical devices requiring maintenance should follow the manufacturer's manually cleaning procedure.

Before returning a reusable medical device for decontamination all associated disposable single-use items **must** be discarded.

Sharp items, e.g. needles, scalpel blades, **must** be removed from trays / packs and disposed of in a sharps box.

All reservoirs / receptacles should be emptied into a sluice hopper.

Prior to collection; used, reusable instrument trays / anaesthetic devices / medical device must be placed in their original wraps or instrument bag and stored in a secure, designated B Braun transit trolley / container / cupboard for their area.

8. Returning Reusable Medical Devices for Maintenance, Repair or Disposal. (E.G. Pumps, Suction Machines, Beds, Mattresses Etc. (See Appendix C For Mattresses)

The manufacturer of a reusable medical device or accessory should supply information on how to clean and maintain the device. This information should include the types of decontamination agents that may be used to clean, disinfect or sterilise, and a warning of any compounds or processes which may be detrimental to the device.

The method used for cleaning / decontaminating must be one that is appropriate to:-

- the level of contamination of the medical device
- gives acceptable decontamination as defined by the manufacturer
- does not damage the article or any of its components within, subject to the requirements of MHRA – Managing Medical Devices – Guidance for Healthcare and Social Services Organisations (April, 2015)

For routine cleaning, detergent and water or a detergent impregnated wipe is usually sufficient. For blood or body fluid spillage, a disinfectant is required, e.g. chlorine releasing agent. For further information or advice on decontamination methods follow the Medical Device Cleaning Procedure Poster **(See Appendix C)**, Infection Control Procedure for Cleaning and Disinfection of Shared Patient Equipment or contact the Trust Decontamination Advisor or Infection Control and Prevention Team.

Any reusable medical device, where the possibility of internal contamination has occurred (such as internal contamination with blood/body fluids), may still be hazardous after external cleaning, e.g. suction machines. **The user must externally clean the medical device as per cleaning process, indicated in appendix C and complete the green "Returns Label" identifying the decontamination status of the medical device. (See Appendix D - UHFB Medical Device Decontamination Certificate).**

Where possible, the medical device must be place in a sealed clear plastic bag before being sent for service or **repair. Where medical devices are repaired or serviced at the point of care then a decontamination returns label must be completed.** The reusable medical device **must** not be used on another patient until it has been internally decontaminated and serviced by the Medical Engineering Department, Renal Technicians or Engie.

- Before returning reusable medical device for service or repair all associated disposable single-use items **must** be discarded.

- Sharp items, e.g. needles, blades, must be removed and disposed of in a sharps box.

- All reservoirs / receptacles should be emptied into a sluice hopper.

- All reusable medical devices that are **Electrical / battery operated equipment must never be submerged or soaked in water, manufacturer's instructions for cleaning and disinfection must be followed.**

Disinfectants, in accordance with the manufacturer's instructions, should be used where there is contamination with blood and body fluids, or if the reusable medical device has been used on patients with specific infections. If manufacturer's advice does not follow the recommended Trust Infection Control Procedure for Cleaning and Disinfection of Shared Patient Equipment, then advice should be sought from the Trust Decontamination Advisor or Infection Prevention and Control Team.

Following cleaning and prior to the reusable medical device being moved to another department within UHB, the medical device must be thoroughly dried and placed, in a sealed clear plastic bag, where ever possible. The **'Ready for Use**' section of the Returns Label should then be completed and attached to the medical device prior to being collected or sent to, Medical Engineering, Equipment store, Renal Technicians or Engie.

Following cleaning and drying all cloths, wipes, aprons and gloves that have been used to clean equipment must be safely disposal of.

Clinical areas should ensure that equipment going back to the Community Equipment Store is clean, separately stored from Trust equipment and that Community returns are identified. The Trusts returns form will also need to be completed for community equipment.

Following the transfer to another clinical department, the reusable medical device may be removed from the clear plastic bag and the green label removed immediately prior to use.

All mattress replacement systems receive an annual deep clean from an external agency. Any pressure relieving equipment requiring a deep clean due to internal contamination / contamination with virulent organisms or due to malodour should be externally cleaned and the green label completed identifying the decontamination status of the system, Mattresses are transported to the Equipment store where they are inspected and arrangements made for them to be sent for cleaning.

9. Responsibilities of Medical Engineers Trust Equipment Store, Renal Technicians and Engie

If reusable medical devices are received into the department and are suspected or found to be visually contaminated, and this has not been identified on the returns label, a Trust Incident Form must be completed. The manager for the ward / department must be contacted and informed and the reusable medical device should be returned to the manager of the ward / department for external cleaning.

If working on reusable medical device reveals that it is contaminated, then a safe system of work should be adopted (decontamination advice may be sought from the manufacturer of the reusable medical device and the Trust Decontamination Advisor or Infection Prevention and Control Team).

Medical Engineering, Renal Technicians and Engie must ensure that before reusable medical devices are sent to a third party for service or repair that an appropriate decontamination certificate **(See Appendix E – Declaration of Contamination Status)** has been completed and all appropriate health and safety measures have been taken.

10. Medical Device Incidents

If a reusable medical device is found to be involved in an incident and is to be subjected to a defects / infection control / incident investigation it must not be decontaminated prior to the investigation.

The reusable medical device must be stored safely at departmental level in a clear plastic bag. A **datix online incident report** should be completed. During working hours the Infection Control Team / Decontamination Advisor / Medical Engineering must then be informed, who will advise on further action, if required. For return to the manufacturer a Declaration of Contamination Status (see Appendix D) must be completed.

11. Bibliography

Classification, Packaging and Labelling of Dangerous Substances Regulations 1984

Consumer Protection Act 1987, Health and Safety Executive

Control of Substances Hazardous to Health (COSHH) Regulations 1994

HEI 98 Management of Medical Equipment and Devices (revised January 1991), Appendix 5. Preparation of Equipment and Materials to be returned to, or Handled Locally by, Service Departments, Manufacturers, or their Representatives: Infection Hazard. Health and Safety at Work Act 1974

HSC 1999/178 Variant Creutzfeldt Jakob Disease (vCJD): Minimizing the risk of Transmission

HSC 1999/179 Controls Assurance in Infection Control: Decontamination of Medical Devices

Health Technical Memorandum, Decontamination HTM 01-01
https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

MHRA Managing Medical Devices April 2015
https://www.gov.uk/government/publications/managing-medical-devices

Medical Devices Act 1994, Health and Safety Executive

NHS Executive HCS 2000/032 Decontamination of Reusable medical device October 2002
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4002990

Protocol for the Local Decontamination of Surgical Instruments: NHS Estates, Department of Health, March 2001

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_4005492

Provision and Use of Workplace Equipment Regulations 1998, Health and Safety Executive

Standard and Practice 2000 edition: Institute of Sterile Service Management

Appendix A Cleaning Responsibility not covered by Domestic Services

AU – After Use D – Daily W – Weekly M – Monthly

Please refer to cleaning schedule for items not listed here

Item	Frequency e.g. daily / weekly	Method (see associated procedures)	Staff group responsible ("ward staff" means any healthcare or clinical staff as appropriate)	Standard
Audiometer Headphones	AU	Detergent Wipes	Ward staff	All parts, including underneath, should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Bedpan holders/ storage racks	AU	Universal wipe	Ward staff	All parts, including underneath, should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Blood gas analyser	W and if visibly contaminated	Universal wipe followed by chlorclean if visibly soiled with body fluids	Ward staff	Cleaned by Point of Care Team after repair. All parts, including underneath and wheels, should be visibly clean with no, blood and body substances, dust, dirt, debris or spillages.
Blood Glucose Monitors	AU	Universal wipe	Ward staff	All parts, including underneath and wheels, should be visibly clean with no blood and body substances, dust, dirt, debris or spillages.
Blood pressure cuffs BP Testing Equipment	AU	Universal wipe	Ward staff	Cleaned by Medical Engineering after repair.
Cardiac Monitors	D and AU	Universal wipe	Ward staff	Cleaned by Medical Engineering after repair. All parts, including underneath and wheels, should be visibly clean with no blood and body substances, dust, dirt, debris or spillages.
Catheter stands	W and AU	Universal wipe	Ward staff	All parts should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Dressing trolleys	AU	Universal wipe	Ward staff	Including wheels. All parts, including underneath, should be visibly clean with no blood and body substances, dust, dirt, debris or spillages.

Item	Frequency e.g. daily / weekly	Method (see associated procedures)	Staff group responsible ("ward staff" means any healthcare or clinical staff as appropriate)	Standard
Examination couches	AU	Universal wipe	Ward staff	All parts, including underneath should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Handling belts	AU	Universal wipe	Ward staff	Laundry for the cloth belts when patient discharged
Portable nebulisers	AU	Universal wipe	Ward staff	Cleaned by Medical Engineering after repair, clean prior to sending
Oxygen / suction equipment (portable)	W and AU	Detergent wipes	Ward staff	Cleaned by Medical Engineering after repair
Pillows	AU	Detergent / Water / Bowl / Disposable Cloths or Universal wipe	Ward staff	To be wiped after use removing any blood or body substances. In the event, that the pillow is very badly soiled it is to be replaced. Once clean the pillow is to be recovered with a clean pillow case.
Pressure relieving mattresses and pillows	AU	Detergent / Water / Bowl / Disposable Cloths or Universal wipe Use chloclean if visibly contaminated with body fluids or used on an infected patient	Ward staff	Before returning to the equipment store. All parts, including underneath should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Screens (ITU, X Ray)	AU and W	Universal wipe	Ward staff	All parts, should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Thomas splints	Au and D	Universal wipe	Ward staff	All parts, including underneath should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Ventilator equipment)	Au and W	Universal wipe	Ward staff	Cleaned by Medical Engineering after repair

Item	Frequency e.g. daily / weekly	Method (see associated procedures)	Staff group responsible ("ward staff" means any healthcare or clinical staff as appropriate)	Standard
Weights	AU	Universal wipe	Ward staff	All parts should be visibly clean with no blood and body substances, dust, dirt, debris or spillages
Wheelchairs	AU	Universal wipe	Ward staff	All parts, including underneath should be visibly clean with no blood and body substances, dust, dirt, debris or spillages

APPENDIX B

Manual Cleaning Methods

Immersion Method

To minimize the risk to staff, splashing and the creation of aerosols must be avoided at all times. **Mask, eye protection, gloves and disposable apron must be worn at all times.**

All sinks must be clean and dry, before commencing the decontamination process.

HAND WASH BASINS MUST NOT BE USED FOR CLEANING OF EQUIPMENT

Single-use cleaning brushes and cloths should be used for cleaning.

1. ***Clean PPE*** must be worn each time, (not those worn during a procedure), fill the cleaning sink with the correct amount of water and detergent (follow manufacturers instructions or documented local procedure). This solution should completely cover the device that is to be manually cleaned. The water temperature should be no greater then 35^{o}C and not less then 30^{o}C.

2. Dismantle and / or open all devices that are to be cleaned. Fully submerge the items, ensuring displacement of air and organic material from complex parts. The solution must cover and reach all surfaces of the medical device.

3. Brush, wipe and agitate the item to dislodge and remove all visible soil, take care to ensure that the item remains under the surface of the water to prevent the creation of aerosols.

4. If the cleaning solution or the rinse water becomes obviously soiled or contaminated, it should be changed and the process repeated.

5. Prior to removing the items from the cleaning sink, fill the rinsing sink (bowl) with clean hot water. Remove the items from the cleaning solution and drain the excess solution, prior to transferring to the rinsing sink or bowl, as available.

6. Under the surface of the clean water rinse the item thoroughly.

7. Remove and drain the item on a clean surface. All surfaces and parts must be carefully hand dried, using a clean non-shedding cloth.

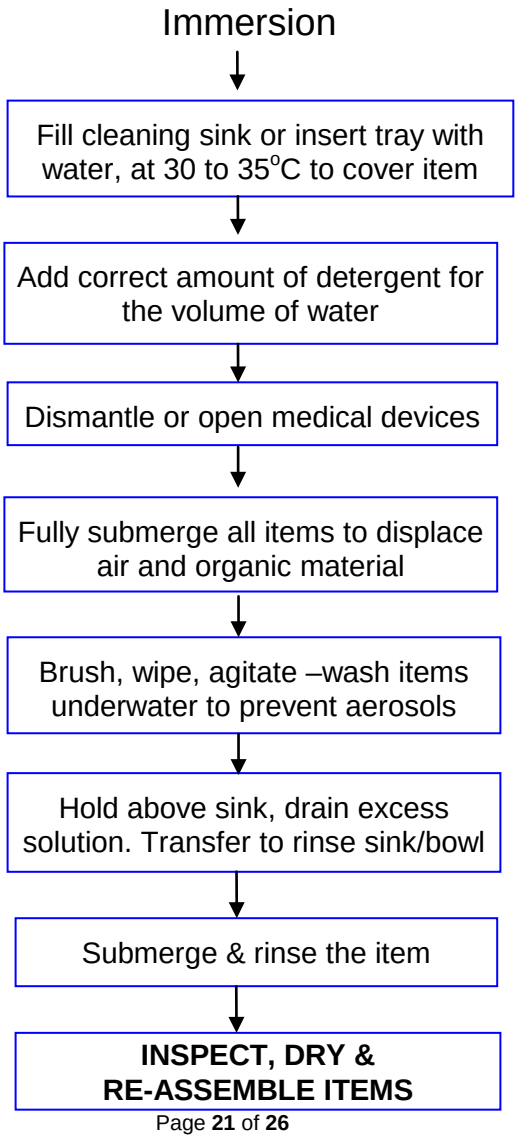
8. Complete all necessary documentation on an approved form, recording the items being processed, the method and detergent used and also the person carrying out the procedure.

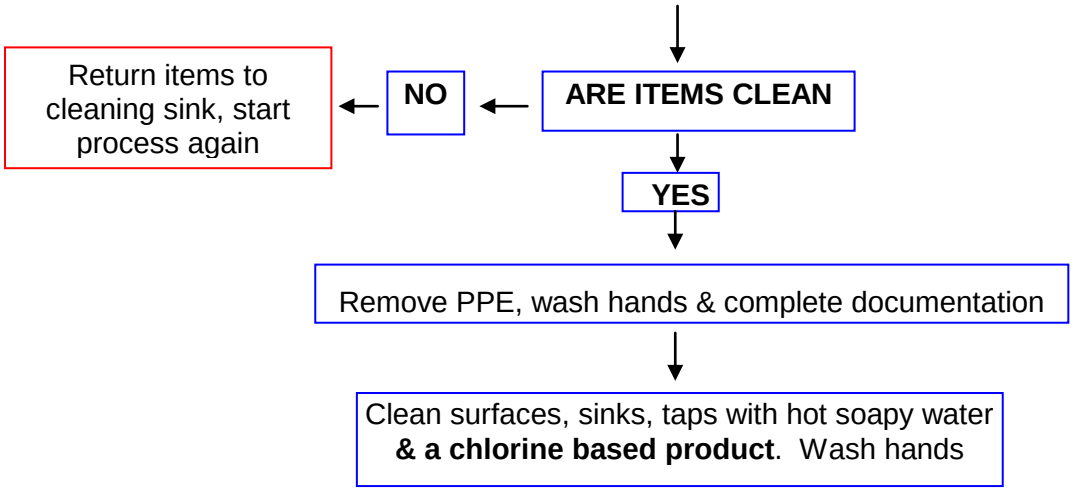
During draining and drying, if the items cleaned have visible traces of soil or soiled water marks, the decontamination process must be repeated.

All decontamination sinks, bowls, taps, jet guns and drainers must be cleaned with a chlorine-based product and dried. Single use items discarded after the decontamination process.

Staff must remove and dispose of PPE and wash their hands on completion of the decontamination process.

Manual Cleaning Flow Chart for Medical Devices




ARE ITEMS CLEAN
NO
Return items to cleaning sink, start process again
YES
Remove PPE, wash hands & complete documentation
Clean surfaces, sinks, taps with hot soapy water **& a chlorine based product**. Wash hands

APPENDIX C Equipment (Medical Devices) Cleaning Procedure Poster

Wear gloves and aprons when carrying out all cleaning procedures

If equipment is between patient use or visibly soiled -

Clean with hot water and detergent or detergent impregnated wipes. Dry.

OR

If equipment is contaminated with a known infection or visibly soiled with blood and/or body fluids - Clean with hot water and detergent or detergent impregnated wipe then with chlorine releasing agent solution. Dry.

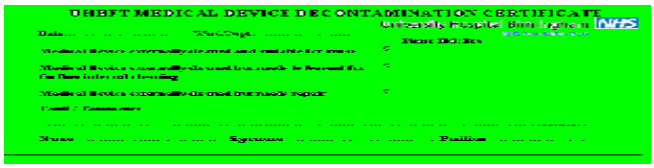
Foam Mattress/cushions

Air mattress/ cushions

All other equipment
E.g. pumps, monitors, bed bases)

Commodes, drip stands, trolleys.

Remove gloves and aprons.
Complete and attach decontamination certificate stating whether equipment can be reused/needs repair/ further internal cleaning.



Sign and apply Verna-care clean indicator tape.

Store in a suitable area for collection/ Re-use

Deflate and roll up, place in bag (if available) and notify equipment store when ready for collection

Place small items in a plastic bag. Store in a suitable area for collection

Remove tape prior to use of equipment

Wash your hands after each procedure

For Further Information refer to the Decontamination & Infection Control Procedures
Advice can be sought from the Infection Prevention and Control Team, or from the Equipment Store Ext 12395

Green returns label - order code UHB130, Cost £25 per 500, order from Print room ext no 18309

APPENDIX D

Braun Sterilog Decontamination Parameters

	Washer Disinfector	Sterilisation Autoclave	Ultrasonic	Manual process
Machine	Bellimed washer disinfectors W390	Belimed 42 cubic feet	No provision at this time	Double sinks (Cleaning & Rinse)
Total Cycle time	45 minutes	65 minutes		Rinse with RO water
Critical cycle temperature	90°C for 60 seconds	134°C to 137°C 3 to 3.5 mins		Piped irrigation guns
Accessories	Lumen racking and Flushing port connections Racking 10 din size			Assorted brush sizes
				Filtered air gun
Detergent	Alkaline (for now)			Alkaline Enzymatic

EXAMPLE APPENDIX E – Declaration of Contamination Status

From (consignor): ……..... **To** (consignee): ……..... ……. ……. Address …….. Address …….. ……. ……. ……. ……. Reference …….. Reference …….. Emergency Tel ……..

Type of equipment …….. Manufacturer……..

Description of equipment ……

Other identifying marks ……

Model No. ……..... Serial No. ……

Fault ……

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

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

……..…… ….

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

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

Cleaning ……

Disinfection……..…… ..

Sterilization……..
..

‡ Please explain why the item has **not** been decontaminated?.....

……
….

……..
…

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

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

Name…… Position……..

Signature……

Date …….. Tel……..

MHRA Managing medical Devices April 2014