

PART 3: RECOMMENDED PRACTICES FOR CENTRAL DECONTAMINATION UNITS

Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices



Reader Information

Directorate:	Health Service Executive (HSE)
Title:	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
Document Purpose:	Standards & Recommended Practices—Part 3
Author:	Steering Committee for Decontamination of Reusable Invasive Medical Devices
Publication Date:	August 2007
Target Audience:	All relevant staff in the public health service who work in Central Decontamination Units (CDU), Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
Description:	The Code of Practice is a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
Superseded Docs:	NA
Review Date:	August 2008
Pictures:	All pictures in this document were taken with the kind assistance of the CDU staff in St. Vincent's Hospital, Dublin.
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Part 3

Part 3
Recommended Practices
For Central Decontamination Units

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Design of central decontamination unit facilities

1 Design of central decontamination unit facilities

1.1 Introduction

The decontamination of RIMD should take place in a designated and controlled area. This optimises the effect of the decontamination process, minimises contamination, provides a safe working environment and safeguards the products.

1.2 Scope

The objective of this procedure is to outline the principles of a safe working environment for decontamination of RIMD.

1.3 Contents

Section One: Unit design

Section Two: Lighting and electricity

Section Three: Ventilation and temperature

Section Four: Walls, floors and ceilings

Section Five: Workstations, furniture, shelving and equipment

Section Six: Restricted entry and movement between areas

Section Seven: Storage facilities

Section Eight: Environmental control

Section Nine: Cleaning

Section Ten: Other

Design of central decontamination unit facilities

1.4 Procedure

Section One: Unit design

- The department should be designed so that it is physically separated from all other work areas.
- The department should be designed to allow segregation of 'dirty' and 'clean' activities.
- The department should be designed to facilitate a unidirectional flow from the 'dirty' area to the 'clean' area.
- The department should not be used for any other purpose.
- The department should not be used as a thoroughfare.
- The department should not be part of any patient treatment area.
- There should be a changing area for donning work wear which includes shower, toilet facilities and lockers in proximity to the decontamination area.
- Access to the wash room and to the clean room should be through dedicated gowning rooms provided with hand hygiene facilities.
- The wash room, clean room and steriliser unloading area should be free from 'opening' windows, ledges, and uncleanable areas.
- The wash area and clean room should be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).

Section Two: Lighting and electricity

- There should be adequate lighting available to permit good working practices and visual examination of RIMD.
- Task lighting and magnification should also be in situ.
- There should be sufficient electricity supply points, computer terminal points and work stations in the department.

Design of central decontamination unit facilities

Section Three: Ventilation and temperature

- All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures should be controlled between 18-22°Celsius and relative humidity should be controlled within the range 35-60%).

Section Four: Walls, floors and ceilings

- The finishes on the walls and other surfaces should be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning.
- The junctions between the walls and floors should be coved and flush.
- The fitments (where possible) should be flush with wall surfaces.
- Floors should be covered in a washable non-slip material which is securely sealed.

Section Five: Workstations, furniture, shelving and equipment

- All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- The workstations should be equipped for the preparation of single or composite packs. They should be of adequate size to accommodate the wrapping material to be used and should be height adjustable.
- There should be adequate space between workstations for equipment and staff movement.
- The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- The shelving should be of sufficient depth for all the materials to be held and should not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.

Design of central decontamination unit facilities

Section Six: Restricted entry and movement between areas

- The area should be managed by trained staff whose sole or primary responsibility is management of the decontamination unit.
- Entry to the decontamination unit should be restricted to authorised personnel only.
- Staff movement between dirty and clean areas should not be possible without passing through a clothing change and wash-up area.

Section Seven: Storage facilities

- Safe storage facilities should be provided for process chemicals used in decontamination.
- Storage facilities for bulk items should be provided external to the clean room and the wash room.
- Required personal protective equipment should be easily accessible in each of the work areas.

Section Eight: Environmental control

- The clean area should be controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8.
- The environment in which clean non-sterile RIMD are inspected, assembled and packed should be micro-biologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003).

Section Nine: Cleaning

- The environment in which decontamination of RIMD takes place should be cleaned in accordance with methods, procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse).
- Dedicated cleaning provision (both equipment and storage) should be provided for the clean room and the wash room.

Design of central decontamination unit facilities

Section Ten: Other

- Further detailed guidance is given in Health Building Note 13 (Sterile Service Departments).

Environmental cleaning

2 Environmental cleaning

2.1 Introduction

Adequate regular cleaning of all work areas is essential for the decontamination lifecycle to be effective. Environmental cleaning procedures and schedules adopted must ensure that contamination from dirty areas does not contaminate the clean areas. The cleaning should be monitored by regular documented inspection of the cleanliness of the environment and the cleaning equipment. Written cleaning protocols should be prepared and passed by the appropriate committee, including methods and frequency of cleaning.

2.2 Scope

The objective of this procedure is to provide guidelines in relation to environmental cleaning in decontamination facilities.

2.3 Contents

Section One: Cleaning equipment

Section Two: Cleaning frequency and cleaning efficacy

Section Three: Floor cleaning equipment and method

Section Four: Floor cleaning agents

Section Five: Spillage kits

Section Six: Records

2.4 Procedure

Section One: Cleaning Equipment

- There should be a separate cleaner's utility room for the clean and dirty areas.
- Separate cleaning equipment should be used for the clean room and wash areas.
- Cleaning equipment should be regularly cleaned and maintained.

Environmental cleaning

Section Two: Cleaning frequency and cleaning efficacy

- Work surfaces should be cleaned at the start of the working day, periodically during the working day and whenever necessary.
- Entire rooms should be deep cleansed annually. Air vents and filters should be serviced regularly.
- There should be documented cleaning procedures for fixtures and fittings.
- There should be documented cleaning procedures for process equipment.
- There should be microbial count by passive sampling.
- Efficacy of cleaning should be monitored microbiologically.
- Warning/action limits should be set for microbial contamination in each area.

Section Three: Floor cleaning equipment and method

The following floor cleaning equipment and method should be used:

- Mop and bucket using 'two bucket' system and a free rinsing detergent.
- Vacuum fitted with HEPA filtered exhaust.
- Rotary scrubbers and polishers should not be used (unless all devices are first removed from the area, or covered, and all horizontal work surfaces are cleaned after the floors).
- Floors should be cleaned daily and also cleaned when visibly soiled.

Section Four: Floor cleaning agents

- Disinfectants should be used to ensure infection control and to ensure that cleaning equipment does not spread microbial load.
- If visible blood/body fluids are present, disinfectants should be used following thorough cleaning.
- Disinfectants should be made up according to the manufacturers' instructions/organisations policy.

Environmental cleaning

Section Five: Spillage kits

- The areas where used RIMD are received and handled should have a chlorine based disinfectant to decontaminate blood spills.
- The wash area should be equipped with spillage kits to contain, neutralise if necessary and remove spillages of process chemicals (guidance on the specific requirements should be found in the Material Safety Data Sheet (MSDS) supplied by the process chemical manufacturer).

Section Six: Records

Records should be kept of the following:

- Training of the personnel carrying out the cleaning.
- All cleaning carried out and by whom.
- Cleaning of the cleaning equipment.
- Periodic inspection of cleanliness.
- Any non-conformances found and the remedial action taken.

Decontamination equipment

3 Decontamination equipment

3.1 Introduction

All decontamination equipment that does not meet the requirements of current standards is identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment must be procured in conformance with extant harmonised standards.

All decontamination equipment must be validated, maintained, periodically tested and monitored to current standards.

3.2 Scope

The objective of this procedure is to provide guidelines in relation to decontamination equipment.

3.3 Contents

Section One: Specialist group

Section Two: Manual washing

Section Three: Ultrasonic cleaning

Section Four: Washer-disinfectors

Section Five: Steam sterilisers

Section Six: Low temperature sterilisers

Section Seven: Drying cabinets

Section Eight: Heat sealers

Decontamination equipment

3.4 Procedure

Section One: Specialist group

- Each organisation should have a specialist group in place to consider the decontamination equipment in the organisation with regard to the following:
 - i. Ability to meet current standards.
 - ii. Age and condition of equipment and availability of replacement parts.
 - iii. Cost of maintaining and repairing the equipment.
 - iv. Ability to interface with other equipment in the decontamination facility.
 - v. Ability to interface with user requirements.
 - vi. Ability to meet the requirements of current test methods.
 - vii. Ability to be validated and perform to intended purpose.
 - viii. Energy and water conservation.
 - ix. Ability for self-disinfection for washer-disinfectors and endoscope washer-disinfectors.
- Key representatives on the specialist group should include:
 - i. Decontamination Coordinator.
 - ii. Decontamination Unit Manager, e.g. Central Decontamination Unit Manager.
 - iii. Clinical Unit Manager, e.g. Theatre Manager.
 - iv. Infection Prevention and Control.
 - v. Bio-medical Engineering/Clinical Engineering/Medical Physics.
 - vi. Procurement.

The group may also include as required:

- i. Technical Services.
- ii. Materials Management.
- iii. Finance Manager/Budget Holder/Business Manager.
- iv. Other relevant experts (Authorised Person/Sterivigilance Nurse/Microbiologist).

Decontamination equipment

- The specialist group should identify all decontamination equipment which needs to be replaced.
- The specialist group should formulate a plan to replace or upgrade this equipment.
- The plan should be submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer).
- The specialist group should ensure that the decontamination equipment procured is compatible with the current stock of RIMD, trays, trolleys, etc.
- There should be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
- There should be clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment.
- The operational management of each item of decontamination equipment should be the defined responsibility of a named person (usually the decontamination unit manager).
- Validation and periodic testing should be carried out by qualified personnel.
- The validation and periodic testing data should be adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive.
- The department should have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

Section Two: Manual washing

- Manual washing should be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a washer-disinfector.
- Dedicated manual cleaning equipment and accessories should be available for specified RIMD that cannot be cleaned in an automated cleaning process.
- Separate sinks for washing and rinsing should be provided.
- The detergent used should be one specified by the manufacturer for the manual cleaning of RIMD.
- Means should be provided to control the concentration of detergent.
- A pass-through drying cabinet with inter-locking doors should be provided for hot-air drying of manually washed RIMD that cannot be processed through a washer-disinfector.

Decontamination equipment

Section Three: Ultrasonic cleaning

- A stand-alone ultrasonic cleaner should be provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers' instructions or as a pre-treatment for RIMD prior to processing through a washer-disinfector.
- The ultrasonic cleaner should be equipped with the facility for automatic filling and emptying directly to the drain.
- The ultrasonic cleaner should be fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- The detergent used should be one specified by the manufacturer for the ultrasonic cleaning of RIMD.
- Means should be provided to control the concentration of detergent.
- The ultrasonic cleaner should be used in accordance with the manufacturers' instructions.
- The ultrasonic cleaner should be validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006.

Section Four: Washer-disinfectors

- The specification of the washer-disinfector should comply with requirements of EN ISO 15883, parts 1 & 2.
- Washer-disinfectors should be double ended with the clean side discharging into the inspection area of the clean room.
- Each washer-disinfector should be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
- When lumened devices are being reprocessed, the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- Washer-disinfectors and accessories should be specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1, 2 & 5.
- The washer-disinfector should be subject to planned preventative maintenance.

Section Five: Steam sterilisers

- The specification of the steam steriliser should comply with requirements of EN 285 and the steriliser should be fitted with an air-detector.
- Each steam steriliser should be fitted with a process monitoring system independent of the automatic controller.

Decontamination equipment

- The sterilisation hold period should be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
- Steam sterilisers should be double ended with the loading side in the clean room.
- Sterilisers and accessories should be specified, installed, commissioned, tested and operated in accordance with the current standard EN 285 and EN ISO 17665, part 1.
- The steam sterilisers should be subject to planned preventative maintenance.

Section Six: Low temperature sterilisers

- Low temperature sterilisation methods should only be used where the manufacturers' instructions do not permit steam sterilisation.
- Low temperature sterilisation should be carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes.
- Low temperature sterilisation methods should be validated and subject to periodic testing in accordance with ISO 14937.
- Low temperature sterilisers should be subject to planned preventative maintenance.

Section Seven: Drying cabinets

- A pass-through drying cabinet between the wash-room and the clean room should be provided. The doors of the drying cabinet should be interlocked to prevent direct connection between the wash room and the clean room.
- The drying cabinet should be fitted with a temperature indicator and/or recorder independent of the controller.
- The drying temperature throughout the cabinet should be within $\pm 5^{\circ}$ Celsius of the set temperature.
- The drying cabinet should be fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than 10° Celsius the heating source is isolated.
- The air in the cabinet should be mechanically circulated and items placed throughout the cabinet should be dried uniformly.
- The drying cabinet should be subject to planned preventative maintenance.

Decontamination equipment

Section Eight: Heat sealers

- Where heat seal packaging is to be used, a rotary heat sealer should be provided.
- Heat-sealing equipment used as part of the terminal packaging process should be maintained and tested to manufacturer's performance criteria.
- The heat sealer should be validated and tested daily to verify the efficacy of the seal.
- The heat sealer should be subject to planned preventative maintenance.

Procurement of reusable invasive medical devices

4 Procurement of reusable invasive medical devices (RIMD)

4.1 Introduction

Procurement includes all activities from requisition, through payment to disposal and is the responsibility of all staff involved in the process. All staff engaged in procurement related activities are required to familiarise themselves with all relevant regulations. Any procurement undertaken must meet the terms of the Health Service Executive procurement policy.

4.2 Scope

The objective of this procedure is to provide guidelines on the procurement of RIMD and ancillary materials.

4.3 Contents

Section One: Specialist group

Section Two: Procurement policy

Section Three: Specification

Section Four: General principles

4.4 Procedure

Section One: Specialist group

- Each organisation should have a specialist group in place to consider the procurement of RIMD.
- Key representatives on the specialist group should include:
 - i. Decontamination Coordinator.
 - ii. Decontamination Unit Manager, e.g. Central Department Unit Manager.
 - iii. Clinical Unit Manager, e.g. Theatre Manager.
 - iv. Infection Prevention and Control.

Procurement of reusable invasive medical devices

The group should also include as required:

- i. Surgeon.
- ii. Technical Services.
- iii. Procurement.
- iv. Bio-medical Engineering/Clinical Engineering/Medical Physics.
- v. Materials Management.
- vi. Finance Manager/Budget Holder/Business Manager.
- vii. Other relevant experts (Authorised person/Sterivigilance Nurse/Microbiologist).
- viii. Health and Social Care Professional representative.

Section Two: Procurement policy

- Each organisation should have a documented procurement policy.
- The procurement policy should comply with the Irish Medicines Board (IMB) recommendations on the procurement of RIMD. SN2006(03)

Section Three: Specification

- The procurement of RIMD should be based on agreed specifications and should comply with the documented procurement policy.
- There should be a detailed specification for each RIMD which complies with current standards.

Section Four: General principles

- Sufficient RIMD and accessories should be purchased to allow adequate time for reprocessing in the decontamination unit(s) without adversely affecting throughput.
- A decontamination assessment should be undertaken prior to the purchase of RIMD to ensure that the organisation has the facilities to reprocess the RIMD in accordance with the manufacturers' instructions.

Procurement of reusable invasive medical devices

Note: The procurement group should carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the reprocessing procedure. Hence it is essential to consult the decontamination unit management before making a decision. This will require that the manufacturers' validated instructions for the reprocessing of RIMD are available prior to purchase and comply with local policies and procedures.

- Value for money issues should be considered when purchasing RIMD.
- Goods and services should be purchased from the suppliers in line with the HSE procurement policy.
- All RIMD and accessories should be CE marked as this will constitute the manufacturer's assurance that a device will be safe and will perform as intended.
- Suppliers should be selected based on their ability to supply RIMD in accordance with the specified requirements and ability to provide service support over the lifetime of the RIMD, where applicable.
- Where parts are single-use or have restricted use, this information should be provided prior to purchasing.

Manufacturers' instructions

5 Manufacturers' instructions

5.1 Introduction

Each RIMD must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the RIMD safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sale packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.

5.2 Scope

The objective of this procedure is to outline the information that must accompany each RIMD to ensure the safe use of the device.

5.3 Contents

Manufacturer

Section One: Requirements to be met by the RIMD manufacturer

Section Two: Label

Section Three: The instructions for use

Section Four: Precautions and contraindications

Section Five: Information supplied on request

Procedure for packs or sets in the central decontamination unit

Section Six: Label

Section Seven: Instructions for use

Manufacturers' instructions

5.4 Procedure

Manufacturer

Section One: Requirements to be met by the RIMD manufacturer

- If the RIMD is intended by the manufacturer to be reused, the following information should be provided:
 - i. Appropriate processes to allow reuse, including cleaning, disinfection, packaging and (if appropriate), the methods of sterilisation of the RIMD to be resterilised.
 - ii. The number of reuses.
 - iii. Any restriction to the reuse.
- If the RIMD is supplied with the intention that it can be sterilised before use, instructions for sterilisation methods should be provided.
- If the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas should be provided.
- Instructions for use should be included in the packaging of every RIMD. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to the harmonised European Standards. In areas for which no Standards exist, the symbols and colours should be described in the documentation supplied with the RIMD.
- The degree of accuracy claimed for RIMD with a measuring function should be provided.
- If the intended purpose of the RIMD is not obvious to the user, the manufacturer should clearly state the intended purpose on the label and in the instructions for use.
- Detachable components of the RIMD should be identified.
- Action to detect any potential risk posed by the RIMD and detachable components should be provided.
- Where parts are single use or have restricted use, this information should be provided.

Manufacturers' instructions

Section Two: Label

The label should contain the following details:

- The name or trade name and address of the manufacturer.
- The details strictly necessary for the user to identify the RIMD and the contents of the packaging.
- Where appropriate, the word 'STERILE'.
- Where appropriate, the batch code, preceded by the word 'LOT', or the serial number.
- Where appropriate, an indication of the date by which the RIMD should be used, in safety, stating the month and the year.
- Where appropriate, an indication that the RIMD is for single use.
- If the RIMD is custom-made, the words 'custom-made RIMD'.
- If the RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- Any special storage and/or handling conditions.
- Any special operating instructions.
- Any warnings and/or precautions to be taken.
- Year of manufacture.
- Batch or serial number.
- Where applicable, method of sterilisation.
- If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

Section Three: The instructions for use:

The instructions for use should contain the following particulars:

- If the RIMD must be installed with, or connected to, other medical RIMD or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct RIMD or equipment to use in order to obtain a safe combination should be provided.

Manufacturers' instructions

- All the information needed to verify whether the RIMD is properly installed and can be operated correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the RIMD operate properly and safely at all times should be provided.
- Where appropriate, information to avoid certain risks in connection with the implantation of the RIMD should be provided.
- Information regarding the risks of reciprocal interference posed by the presence of the RIMD during specific investigations or treatment.
- The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of resterilisation.
- If the RIMD is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the RIMD to be resterilised, and any restriction on the number of reuses.
- Details of any further treatment or handling needed before the RIMD can be used (for example, sterilisation, final assembly, etc).
- In the case of RIMDs emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

Section Four: Precautions and contraindications

The instructions for use should contain the following precautions and contraindications:

- Precautions to be taken in the event of changes in the performance of the RIMD.
- Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions; to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.
- Adequate information regarding the medicinal product or products which the RIMD in question is designed to administer, including any limitations in the choice of substances to be delivered.
- Precautions to be taken against any special, unusual risks related to the disposal of the RIMD.

Manufacturers' instructions

Section Five: Information supplied on request

- The identity or information on the test methods used.
- If the manufacturer differentiates between critical and less critical areas of the product, the rationale for this distinction.

Procedures for packs or sets in the central decontamination unit

Section Six: Label

The label should contain the following details:

- The name or trade name and address of the central decontamination unit.
- The details strictly necessary for the user to identify the contents of the packaging.
- Where appropriate, the word 'STERILE'.
- Where appropriate, the batch code, preceded by the word 'LOT', or the serial number.
- An indication of the date by which the RIMD should be used, in safety, stating the month and the year.
- Any special storage and/or handling conditions.
- Reference to any special operating instructions, warnings and/or precautions to be taken.
- Year of manufacture.
- Batch or serial number.
- Where applicable, method of sterilisation.

Section Seven: Instructions for use

In general, Class I and Class IIa devices (see part 1, page 17) which comprise most of the RIMD processed by a central decontamination unit, do not require specific instructions for use. Exceptionally where these are required, copies should be retained by the clinical user and the central decontamination unit and should be referenced on the label on the RIMD.

Personal protective equipment

6 Personal protective equipment

6.1 Introduction

Personal protective equipment (PPE) must be worn by personnel when decontaminating RIMD to reduce the risk of exposure to potentially infectious material. Managers must ensure that PPE is made available and all personnel are responsible for ensuring the correct use and disposal of same.

PPE involves use of protective barriers such as gloves, gowns, aprons, masks or protective eyewear. PPE also provides protection against other hazards in the healthcare facility such as chemicals and physical injury. Standard precautions and safe work practices are required to minimise the risk of infection to both patients and healthcare workers. They include, but are not limited to, good hygiene practices, particularly hand-washing, the use of PPE and the appropriate handling and disposal of waste. The provision of PPE is based on a risk assessment in accordance with Part V of the Safety, Health and Welfare at Work Act (General Application) Regulations, 1993.

6.2 Scope

The objective of this procedure is the outline the PPE that must be worn by staff to reduce risk of exposure to potentially infectious material.

6.3 Contents

Decontamination unit

Section One: Attire

Gowning for entry to the wash area

Section Two: Head/hair cover

Section Three: Protective eyewear and face-shields

Section Four: Masks

Section Five: Plastic aprons and gowns

Personal protective equipment

Section Six: Gloves

Section Seven: Footwear

6.4 Procedure

Decontamination unit

Section One: Attire

- All personnel working in the decontamination area should wear freshly laundered low linting attire.
- Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered attire should be changed daily or whenever it becomes visibly soiled or wet.
- Staff who are involved in the maintenance of decontamination equipment should be required to wear the same type of clothing.
- On leaving the decontamination area, staff should change into their normal day wear.
- After use, the attire should be discarded appropriately in a designated post use container/bag.
- Work attire should never be worn outside the decontamination unit.

Gowning for entry to the wash area

Section Two: Head/hair cover

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.
- After use, headgear should be discarded in the appropriate healthcare waste stream.

Personal protective equipment

- Stud earrings may be worn and should be totally confined within the head cover.
- **Note:** Make-up or jewellery (except wedding band) should not be worn in the decontamination unit.

Section Three: Protective eyewear and face-shields

- Healthcare workers (HCWs) should wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear or face shields should be single-use.
- Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- Face shields should cover the eyes, nose, mouth and chin.

Section Four: Masks

- HCWs should wear fluid repellent masks and/or face-shields to reduce the risk of pathogenic organisms being transferred to the nose or mouth.
- Fluid repellent masks and/or face-shields should be fitted and worn according to the manufacturers' instructions.
- Fluid repellent masks and/or face-shields should not be touched by the hand while being worn.
- Fluid repellent masks and/or face-shields should cover both mouth and nose while being worn.
- Fluid repellent masks and/or face-shields should be removed immediately if they become moist or visibly soiled and should be discarded in the appropriate healthcare waste stream.
- **Fluid repellent masks and/or face-shields should not be worn loosely around the neck.**

Personal protective equipment

Section Five: Plastic aprons and attire

- Healthcare Workers (HCWs) should wear impermeable attire with long cuffed sleeves and tuck-inside-gloves during procedures that are likely to generate splashes of blood or body fluids or during activities that may contaminate clothing, uniforms and/or personnel with microorganisms or infectious material.
- Fluid repellent attire and aprons should be changed whenever they become visibly soiled or wet.
- After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

Section Six: Gloves

- Gloves should be used for handling contaminated RIMD and waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- Avoid letting the gloves snap, as this may cause contaminants to splash into eyes or mouth or onto skin or other personnel in the area.
- **It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.**
- HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves should be discarded in the appropriate healthcare waste stream.

Personal protective equipment

Section Seven: Footwear

- Healthcare Workers (HCWs) should wear non-slip enclosed footwear that can protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally).
- Footwear should be regularly cleaned and disinfected.
- Footwear should be appropriate to the area in which HCWs are designated.

Figure 6-1: Personal Protective Equipment (Decontamination Unit)



Clean room attire and behaviour

7 Clean room attire and behaviour

7.1 Introduction

Protective clothing must be worn by personnel entering the clean room, to reduce the risk of adventitious contamination of the clean product. Managers must ensure that protective clothing is made available and all personnel are responsible for ensuring the correct use and disposal of same.

7.2 Scope

The objective of this procedure is the outline the personal protective equipment to be worn and the behaviour to be adopted by staff in the clean room to reduce the risk of contaminating clean devices.

7.3 Contents

Section One: Attire

Section Two: Head/hair cover

7.4 Procedure

Section One: Attire

- All personnel working in the clean room should wear a freshly laundered scrub suit.
- Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet.
- Appropriate clothing should be used by staff who are involved in the maintenance of reprocessing equipment.
- When working outside the decontamination area suitable cover attire should be worn.

Clean room attire and behaviour

Section Two: Head/hair cover

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.
- After use, headgear should be discarded in the appropriate healthcare waste stream.
- Stud earrings may be worn and should be totally confined within the head cover.

Figure 7-1: Personal Protective Equipment (Clean Room)



Process chemicals

8 Process chemicals

8.1 Introduction

Chemicals such as detergents and disinfectants may have hazardous properties associated with them (may be irritant, corrosive, flammable), e.g. bleach and ammonia if mixed will release lethal chlorine gas. Process chemicals are potentially hazardous as they may cause irritation to the skin, eye, respiratory tract and mucous membranes.

8.2 Scope

The objective of this procedure is to provide guidelines for staff in relation to the handling of chemicals.

8.3 Contents

Section One: Choice of process chemicals

Section Two: Control of process chemicals

Section Three: Material Safety Data Sheets and labels

Section Four: Training

Section Five: Spillage kit

8.4 Procedure

Section One: Choice of process chemicals

- Process chemicals should be chosen to be compatible with:
 - i. The RIMD to be processed.
 - ii. The decontamination equipment to be used and the intended use of the RIMD.
- The least hazardous chemical that will fulfil a process requirement should be chosen.

Process chemicals

Section Two: Control of process chemicals

- The methods to be used for handling and storage of process chemicals should be defined in written procedures.
- Chemicals that should not be stored together should be clearly identified.
- Chemicals should not be stored above shoulder height.

Section Three: Material Safety Data Sheets (MSDS) and labels

- Suppliers of chemical agents should provide MSDS for all chemical agents (including cleaning agents).
- Copies of all MSDS should be available to all employees in a designated area at all times, so that appropriate action can be taken in case of exposure to a hazardous substance.
- If information is incorporated into policies and procedures, the original wording should be used and the MSDS referred to.
- Personnel should read and follow the precautions and instructions given on the MSDS and on the label prior to handling and use.

Section Four: Training

All personnel who handle chemicals e.g. detergents, rinse aid, disinfectants, etc should be trained in following:

- Safe handling of chemicals.
- Method of cleaning process chemical spillages.
- First Aid required in the event of personal exposure.
- Correct disposal of material used.

Section Five: Spillage kit

Each area where chemicals are used, a spillage kit should be available.

Traceability

9 Traceability

9.1 Introduction

Systems should be in place to record the decontamination process used on RIMD (tracking) and link them with patients on which they have been used (tracing).

The tracking system should record the progress of sets of RIMD, or individual supplementary RIMD, through each stage of the decontamination process and allow retrospective demonstration that a particular set or supplementary RIMD has been correctly decontaminated.

The tracing system should permit retrospective tracing of the RIMD history including the patients on which it was used.

As a minimum, records should be kept that permit the tracking of RIMD to the cleaning process used and the steriliser cycle in which they were sterilised.

9.2 Scope

The objective of this procedure is to provide guidelines for the effective tracking and traceability of RIMD through the decontamination life-cycle.

9.3 Contents

Section One: Processing

Section Two: Tracing

9.4 Procedure

Section One: Processing

- Systems should be in place to allow the methods, operational cycles and personnel involved in the processing of a particular RIMD/RIMD set to be tracked through the decontamination processes in order to permit retrospective verification that the processes were carried out effectively.

Traceability

- Records should be maintained of:
 - i. The cleaning, disinfection and sterilisation process cycle used.
 - ii. The name of the person undertaking each stage of the decontamination process.
 - iii. The date, time and test result.
 - iv. Details of the RIMD being processed.
- As a minimum, sets of RIMD should be individually identified.
- Identification of individual RIMD may not be required. (The technology required for efficient and economical identification of individual RIMD is not sufficiently developed to recommend this as a requirement, although it is desirable).
- IT based systems are preferred. Manually based systems should only be used for small units with a very low turn-over or for back-up in the event of IT failure.
- Records relating to decontamination processes should be maintained for the lifetime of the RIMD/decontamination equipment plus eleven years.

Section Two: Tracing

- Systems should be implemented to enable the identification of patients on whom the RIMD/RIMD set have been used. This is important so that the relevant patients can be identified in the event of exposure to potential risk.

Choice of decontamination process

10 Choice of decontamination process

10.1 Introduction

To prevent infection, all RIMD that come into contact with the patient or surgical field should be systematically decontaminated after each surgical procedure and attention must be given to all potential sources of contamination. All decontamination processes must be validated.

10.2 Scope

The objective of this procedure is to provide guidelines on the choice of decontamination processes.

10.3 Contents

Section One: General principles

10.4 Procedure

Section One: General principles

- RIMD should be reprocessed to a level appropriate for their intended use. The appropriate level depends on the body sites where the RIMD will be used and the risk associated with a particular procedure.
- The minimum levels of processing and storage requirements for RIMD, based on three risk categories of use, are shown in the Spaulding Classification (See Table 7-1, Part 1). In brief, the minimum levels of reprocessing are as follows for different types of site:
 - i. **Critical site** – instruments should be sterile at the time of use. This means instruments should be single use, should be steam sterilised (for instruments that are capable of withstanding heat), or should have undergone low temperature sterilisation (for heat-sensitive equipment).
 - ii. **Semicritical site** – instruments should be single use or sterilised after each use. If this is not possible, high-level disinfection is the minimum level of reprocessing that is acceptable.

Choice of decontamination process

- iii. **Noncritical site** – cleaning alone is generally sufficient for all noncritical items after every individual use, although either intermediate or low-level disinfection may be appropriate in specific circumstances.
- Decontamination processes should be chosen to be compatible with the RIMD to be processed.
- Decontamination processes should be chosen to be capable of providing not less than the standard of decontamination required for the clinical procedures to be undertaken.
- Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- Decontamination processes should be chosen to be amenable to independent verification of the decontamination standards achieved.
- The decontamination methods selected should be economical and effective.
- The decontamination methods used should be compatible with recommended methods of validation.

Transportation—return of used items for reprocessing

11 Transportation – return of used items for reprocessing

11.1 Introduction

All RIMD are considered to be soiled and contaminated after each use and can be a potential source of infection. Contaminated RIMD should be handled, collected and transported in a manner that avoids dissemination of contamination. Transport of soiled RIMD to the decontamination area should be accomplished as soon **as possible after use**. If delay is unavoidable, the user must make sure that the item is safely contained and secured to await collection.

11.2 Scope

The objective of this procedure is to provide guidelines in relation to the transportation of contaminated RIMD.

11.3 Contents

Section One: Containers and trolleys

Section Two: Staff

11.4 Procedure

Section One: Containers and trolleys

- Contaminated RIMD should be placed in closed, sealed, secure containers and transported to the decontamination area as soon as possible after use. Transport containers should protect both the product during transit and the handler from inadvertent contamination.
- Bins with lids and closed sterilisation container systems are among the types of containers that may be used to transport contaminated items.
- Impermeable bags should be used also to contain RIMD within the container.

Transportation—return of used items for reprocessing

- Containers should be selected based on the characteristics of the items being transported; in particular they should be:
 - i. Leak-proof.
 - ii. Rigid, to contain RIMD, preventing them becoming a hazard to anyone handling the goods and to protect them against accidental damage.
 - iii. Capable of being closed securely.
 - iv. Lockable, where appropriate, to prevent tampering.
 - v. Clearly labelled to identify the user and the contents where applicable.
 - vi. Robust enough to prevent RIMD being damaged in transit.
 - vii. Have the ability to be easily cleaned, disinfected and dried, or discarded (as appropriate) using agreed methods.
 - viii. Designated containers should be used for the collection of RIMD, unless the central decontamination unit is equipped with a washer-disinfector for cleaning and thermal disinfection of containers after each use.
- RIMD/RIMD sets should be separated from healthcare risk waste at the point of use.
- Sharps should be removed and placed into approved containers conforming to BS 7320 (1990).
- Reusable textiles should be held in appropriate linen bags and returned to the laundry service.
- All fluids, e.g. blood, bodily fluids, cleaning and antiseptic solutions should be disposed of before placing RIMD in transport containers.
- All transportation equipment has to be cleaned in accordance with local policy.

Transportation—return of used items for reprocessing

Section Two: Staff

- Personnel should be trained to handle, collect and transport contaminated RIMD/RIMD sets and should wear PPE in accordance with local safety policies and procedures.
- Policies and procedures for transportation (return of used items for reprocessing) of contaminated RIMD/RIMD sets should be developed, reviewed periodically, and readily available within the practice setting.

Figure 11-1: Transportation—return of used items for reprocessing



Sorting and disassembly of contaminated reusable invasive medical devices

12 Sorting and disassembly of contaminated reusable invasive medical devices

12.1 Introduction

Effective and timely decontamination of RIMD should be performed where feasible. Sorting, disassembly and cleaning should be performed in a manner that minimises risk to those performing the task.

12.2 Scope

The objective of this procedure is to provide guidelines in relation to the sorting and disassembly of contaminated RIMD.

12.3 Contents

Section One: Sorting of items in the decontamination area prior to cleaning

Section Two: Disassembly of RIMD

12.4 Procedure

Section One: Sorting of items in the decontamination area prior to cleaning

- On receipt at the decontamination area, RIMD should be sorted according to the selected method of cleaning, e.g. manual cleaning process or automated cleaning process. The manufacturers' instructions for cleaning should be followed in order to ensure the RIMD is not damaged and is cleaned adequately.
- Policies and/or procedures should be developed for the handling, sorting and disassembly of RIMD.
- There should be written policies and/or procedures for handling specialised items.
- Care and handling of RIMD should be in accordance with manufacturers' instructions and organisation policies and procedures.

Sorting and disassembly of contaminated reusable invasive medical devices

Section Two: Disassembly of RIMD

To facilitate effective cleaning, the following activities should be completed:

- Open RIMD box locks.
- Place RIMD in mesh basket in a manner which ensures effective cleaning of RIMD. Do not place RIMD one on top of the other. **Overloaded baskets will result in ineffective cleaning.**
- Arrange RIMD in an orderly fashion in mesh trays so that all surfaces are exposed to the action of an automated cleaner, if used.
- Place each jointed RIMD in the open position in the mesh basket.
- If extra mesh baskets are required for cleaning purposes of an RIMD set, a marker should be placed in the extra baskets to identify the set name and number.
- Place heavy retractors and/or other heavy RIMD on the bottom or in a separate tray.
- Secure small and light items with a hold down screen or by other means, to ensure they are not free to move around during the cleaning process. Place scissors, light-weight RIMD, and microsurgical RIMD next.
- Receivers and gallipots should not be placed over RIMD, as they may interfere with the cleaning process.
- Separate all sharp RIMD from general RIMD. This is to ensure ease of identification for personnel assembling the RIMD after cleaning, in order to prevent sharps injury.
- For RIMD with one or more lumens, each lumen should be connected to the appropriate flushing system provided for that purpose.

Figure 12-1: Sorting and Disassembly of contaminated RIMD



Cleaning (including pre-cleaning)

13 Cleaning (including pre-cleaning)

13.1 Introduction

Cleaning is an essential prerequisite for all effective disinfection and sterilisation processes, as organic residue may prevent the disinfectant or sterilant from contacting the item being processed and may also bind and inactivate chemical disinfectants (Muscarella, 1998). **If the item cannot be cleaned, it cannot be disinfected or sterilised. The process must not be used for items intended for single-use only.**

13.2 Scope

The objective of this procedure is to provide guidelines in relation to cleaning of contaminated RIMD. Cleaning is the initial and most crucial step in breaking the chain of disease transmission.

13.3 Contents

Section One: Manufacturers' instructions

Section Two: Automated versus manual cleaning

Section Three: Initial cleaning

Section Four: Automated cleaning

Section Five: Manual cleaning

13.4 Procedure

Section One: Manufacturers' instructions

- The manufacturers' instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the RIMD will tolerate immersion.
- RIMD should be cleaned, handled and inspected according to manufacturers' instructions. Manufacturers' instructions provide direction for care, cleaning and handling of RIMD and powered equipment. The instructions for cleaning and sterilisation should be such that if correctly followed the device can be reused, without causing injury to the patient or personnel using the RIMD. (ISO, 17664).

Cleaning (including pre-cleaning)

Section Two: Automated versus manual cleaning

- The use of mechanical cleaners such as washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.
- The advantage of using automated cleaning equipment is that it provides an efficient, validated, reproducible process which can be more easily controlled than manual methods.
- Automated processes are generally more convenient and also provide protection for the user in reducing exposure to contaminated RIMD and chemicals.

Section Three: Initial cleaning

- Manual Cleaning (see section five) should be used where it is apparent that there is gross soiling on RIMD that it would be preferable to remove before automated cleaning takes place.

Section Four: Automated cleaning

1. *Washer-disinfectors*

a. Introduction

All washer-disinfectors used for decontamination of RIMD should conform to ISO/FDIS 15883 parts 1, 2 and 5, 2006. The water for the final rinse stage should be purified water (prepared by reverse osmosis or deionisation) as this gives the lowest levels of process residuals.

b. Factors to be considered when determining if the RIMD is compatible with the washer-disinfector

- Manufacturers' instructions.
- If the RIMD can be immersed in water.
- Maximum operating temperature.
- Mechanical damage which may occur from the impact of the water jets or other items in the load.
- The compatibility of the process chemicals.

Cleaning (including pre-cleaning)

c. Equipment

- See decontamination equipment section, page 20.

d. Procedure

- Ensure the washer-disinfector and all services are operational. The washer-disinfector should not start if any anomalies are present.
- Wearing protective clothing, load the rack/machine ensuring that the loading configuration does not impede the cleansing process and that the rotary spray arms can rotate.
- Only use load carrier and racks with the items for which they were intended.
- Keep a record of each RIMD/RIMD set processed in each washer-disinfector and each cycle in order to trace the RIMD/RIMD set through the decontamination process.
- Load the load carrier into the washer-disinfector.
- Secure the door (if fitted), select and start the cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the RIMD processed should be inspected.
- A typical cycle comprises the following phases:
 - i. Cold rinse.
 - ii. Warm wash.
 - iii. Rinse.
 - iv. Disinfection rinse.
 - v. Drying.
- Information should be recorded for each washer-disinfector cycle. Documentation is required for every washer-disinfector cycle and should contain the following:
 - i. Washer-disinfector identification number.
 - ii. Cycle number.
 - iii. Type of washer-disinfector.
 - iv. Type of cycle used.
 - v. Date and time of start of cycle.

Cleaning (including pre-cleaning)

- vi. Load content e.g. general instrument set, stitch set, mayo scissors.
 - vii. Critical parameters for the specific washer-disinfector cycle.
 - viii. Operator's name.
 - ix. Results of washer-disinfector process
 - x. Signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters
 - xi. Any notes or observation for the process cycle
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
 - Cycles which were aborted should be documented with the action taken in a log book.
 - Where single-ended washer-disinfectors are used adequate segregation of unprocessed goods from processed goods should take place.
- e. **Thermal disinfection**
- Thermal disinfection conditions are defined as A_0 values (see ISO 15883-1, Annex B).
 - For thermal disinfection of RIMD an A_0 of not less than 60 is required.
 - All washer-disinfectors complying with ISO 15883-2 are required to be capable of providing for disinfection times and temperatures to give an A_0 value up to a maximum value of not less than 3000.
 - Typical time-temperature relationships providing these values are shown in table 13-1 below.

Table 13-1: Automated washer-disinfector temperature bands (ref. EN ISO 15883-1)

A_0 value	Temperature	Holding Time (Seconds)	Holding Time (Minutes)
60	80	-	1
60	90	6	-
600	80	-	10
600	70	-	100
600	90	-	1
1200	93	-	1

Cleaning (including pre-cleaning)

f. Validation

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the washer-disinfector is functioning correctly and that it will produce cleaned and disinfected loads consistently.
- The effectiveness of the disinfection process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if correct conditions are created throughout the washer-disinfector chamber and the load during every cycle.
- Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is considered as a process which comprises:
 1. Commissioning (installation qualification and operational qualification).
 2. Performance qualification.
 3. Periodic testing.
 4. Annual and revalidation tests.

1. Commissioning

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier*, that it is safe to operate (installation qualification) and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions (operational qualification).

It consists of:

Installation qualification tests

- Verification of calibration of washer-disinfector instruments, automatic control test, water quality tests, water supply temperature and water supply pressure.

Operational qualification tests

- Weekly safety checks, automatic control test, verification of calibration of washer-disinfector instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, water vapour discharge test, aerosol discharge test, chemical additive dosing tests, load carriers, test for air quality, cleaning efficacy test, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric tests for thermal disinfection, load dryness test and sound pressure.

Cleaning (including pre-cleaning)

- These tests should be carried out when a new washer-disinfector is purchased or when a used washer-disinfector has been relocated to another premises.
- The tests should be carried out before the washer-disinfector is used for the first time. Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of washer-disinfector. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the washer-disinfector is functioning correctly.
- Even though the manufacturer should have tested a washer-disinfector before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is **working correctly**.

2. Performance qualification

Performance qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean/disinfect. Performance qualification is indicated for initial use of a new/relocated washer-disinfector or when the load profile changes (e.g. new RIMD). It should be carried out by a Test Person (or other suitably qualified person). These tests consist of:

- Thermometric tests for a full load of items not previously represented by the reference load, load dryness test (of RIMD requiring reprocessing), cleaning efficacy test and process residues.

3. Periodic testing

- After validation and when the washer-disinfector has been passed for use, it is subject to a schedule of periodic tests at daily, weekly quarterly and yearly intervals.
- The daily, weekly and quarterly tests supply evidence that the washer-disinfector is still operating within the limits established during commissioning.
- Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.
 - **Daily:** Spray arm rotation, spray nozzles, remove and clean strainers and filters.

Cleaning (including pre-cleaning)

- **Weekly:** Automatic control test, safety checks, daily tests, water hardness, water conductivity and cleaning efficacy test (residual soil detection).
- **Quarterly tests:** Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection and cleaning efficacy test.
- **Annual tests:** Yearly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, doors, door interlocks, fault interlocks, water vapour discharge, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, over-temperature cut-out, thermometric tests for thermal disinfection, load dryness test and process residues.

g. Monitoring and Control

- Cycle variables should be monitored to ensure that the specified parameters are obtained for each cycle. The critical cycle variables are temperature, time, detergent concentration and water pressure or flow rate.
- Validation, routine monitoring and control should be carried out in accordance with documented procedures in accordance with European standard EN ISO 15883, part 2, 2006.

h. Maintenance

- Preventative maintenance should be planned and performed in accordance with International Standards ISO 15883-1 and ISO 15883-2 and manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The washer-disinfector will not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.
- Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers' instructions and/or local policy, including:
 - i. Inspecting and cleaning all filters.
 - ii. Dismantling and cleaning spray arms and nozzles.
 - iii. Efficacy tests during operational conditions.

Cleaning (including pre-cleaning)

Figure 13-1: Washer-Disinfector



Figure 13-2: Loading the Washer-Disinfectors



Cleaning (including pre-cleaning)

2. Ultrasonic Cleaners

a. Introduction

Ultrasonic cleaners work by the use of high intensity, high frequency sound waves which cause soil to be dislodged from the RIMD, or to be sufficiently loosened to be removed during the rinsing process. Plastics and other similar materials cannot be successfully processed by this method. Cemented glass syringes and lenses will be damaged if repeatedly subjected to this process. The manufacturers' instructions should be considered in relation to the suitability of RIMD for ultrasonic cleaning.

b. Equipment Required

- See decontamination equipment, page 20.

c. Procedure

- Staff should wear personal protective equipment at all times while handling contaminated RIMD and working with the ultrasonic cleaner.
- Fill the tank with potable water (drinking quality) to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- Bring the solution up to the operating temperature.
- De-gas the water as recommended by the manufacturer.
- Place the opened/dismantled RIMD into the basket.
- Ensure all RIMD are fully immersed.
- If the RIMD is not for further cleaning, e.g. automated cleaning, record the following:
 - i. Method used.
 - ii. Solution dilution and temperature.
 - iii. Healthcare worker carrying out procedure.
 - iv. Date.
- Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.
- Close the lid and initiate the cleaning cycle.

Cleaning (including pre-cleaning)

- After the cycle has been completed, remove the basket from the tank and rinse the items with clean, potable water – unless the machine has an automatic rinse stage, or the load is to be transferred directly into a washer-disinfector for further processing.
- The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.
- Combine only RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.
- Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.
- It is recommended that the tank be emptied regularly. This should be at intervals not exceeding four hours, or when the water is visibly soiled.

d. Validation

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.
- Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is considered as a process which comprises:
 - i. Commissioning (installation qualification and operational qualification).
 - ii. Performance qualification.
 - iii. Periodic testing.
 - iv. Annual and revalidation tests.

1. Commissioning

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier*, that it is safe to operate (installation qualification) and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions (operational qualification).

Cleaning (including pre-cleaning)

It consists of:

Installation qualification tests

- Verification of calibration, automatic control test, water quality tests—hardness, and water supply temperature.

Operational qualification tests

- Weekly safety checks, verification of calibration, automatic control test, cleaning efficacy test, water system, drainage, doors and door interlocks, fault interlock, aerosol discharge, chemical additive dosing, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasound activity and sound pressure.
- These tests should be carried out when a new ultrasonic cleaner is purchased or when a used ultrasonic cleaner is has been relocated to another premises.
- Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of ultrasonic cleaner.
- Even though the manufacturer should have tested the ultrasonic cleaner before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is **working** correctly.

2. *Performance qualification*

Performance Qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean. Performance qualification is indicated for initial use of a new/relocated ultrasonic cleaner or when there is a requirement to process a new type of product. It should be carried out by a Test Person (or other suitably qualified person). These tests consist of:

- Cleaning efficacy test, load dryness test and process residues test.

3. *Periodic testing*

- After validation and when the ultrasonic cleaner has been passed for use, it is subject to a schedule of periodic tests and daily, weekly quarterly and yearly intervals.
- The daily, weekly and quarterly tests supply evidence that the ultrasonic cleaner is still operating within the limits established during commissioning.

Cleaning (including pre-cleaning)

- Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.
 - *Daily:* Remove and clean strainers and filters.
 - *Weekly:* Daily tests, automatic control test (if using an automated ultrasonic cleaner) safety checks, and cleaning efficacy test (residual soil detection).
 - *Quarterly tests:* Weekly safety checks, automatic control test, verification of calibration of instruments, test for ultrasonic activity and cleaning efficacy test.
 - *Annual tests:* Weekly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, doors and door interlocks, fault interlock, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, chamber wall and load carrier temperature test, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasonic activity and sound pressure test.

e. Monitoring and control

Validation, routine monitoring and control should be carried out in accordance with documented procedures as recommended by the manufacturers' instructions. It is recommended that a soil test and a residual protein test should be performed as part of the weekly tests to establish the efficacy of the washers' cleaning process. The following simple test may be undertaken to establish that there is ultrasonic action in the tank.

f. Maintenance

- Preventative maintenance should be planned and performed in accordance with documented procedures as recommended by the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The ultrasonic cleaner should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan, main procedures and maintenance records periodically.

Cleaning (including pre-cleaning)

g. Test for Ultrasonic Activity (reference HTM 2030)

The activity of an ultrasonic cleaner may be tested by the erosion pattern which is created on aluminium foil exposed in a bath for a short period. Note: the activity will not be uniform throughout the bath. The exposure time will depend on the thickness of the foil, the hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.

Equipment

- Aluminium foil (sold as aluminium foil wrap for cooking).
- Steriliser indicator tape.
- Stopwatch.
- Ruler/tape measure graduated in mm.

Method

- Measure the depth of the bath from the level of the lid to the bottom of the bath.
- Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.
- Carry out the manufacturer's recommended start-up procedure.
- Ensure that the water in the tank is at the required level, that the amount of chemical additive specified by the manufacturer has been added and that the water in the tank is at the specified operating temperature.
- Using strips of steriliser indicator tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3 x 3 grid.
- The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should not be more than 10mm above, but not touching the bottom of the bath.
- Operate the bath for the predetermined exposure time.
- Remove the strips from the bath, blot dry and examine.
- The zones of maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent (on visual inspection).
- On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

Cleaning (including pre-cleaning)

Section Five: Manual cleaning

1. Immersion

a. Introduction

The use of automated cleaning methods may be contra-indicated for washing certain delicate or complex RIMD. These RIMD should be carefully hand-washed and rinsed according to the manufacturers' instructions.

b. Equipment required

- A sink (not a hand hygiene sink), or a receptacle which will hold sufficient volume of water/detergent so that the item of equipment to be cleaned can be fully immersed.
- Dirty put-down area adjacent to the wash sink adjacent to a washed RIMD put-down area, adjacent to the rinse sink adjacent to the rinsed RIMD out-down area (See figure 13-3 below).

Figure 13-3: Sink required for manual cleaning



- A validated method of dispensing a measured quantity of detergent.
- A method of controlling temperature of the water in the wash and rinse sinks: thermostatic mixer taps are preferred.
- A warm detergent solution. (Follow manufacturers' instructions for dilution and temperature).

Cleaning (including pre-cleaning)

- A selection of brushes in a range of diameters and lengths for cleaning both the external surfaces and the internal surfaces of RIMD.
- After cleaning, manually washed RIMD that are not to be further processed through the washer-disinfector should be dried.
- RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free, absorbent wipe should be used.

c. Procedure

- Healthcare workers should wear personal protective equipment at all times while handling contaminated RIMD.
- The sink should be filled with potable water to a predetermined level, at the specified temperature and with the appropriate amount of detergent (as per manufacturers' instructions). The sink should be solely dedicated for the cleaning of instruments and not for any other purpose.
- Detergents used should be specifically designed to clean RIMD: **washing up liquid must not be used**. A mild detergent is preferred for manual cleaning of RIMD (pH range 8.0–11.5).
- Detergent dilution and water temperature should be in accordance with the manufacturers' instructions and local policies and procedures.
- Consideration should be given to the use of an enzymatic detergent to facilitate the cleaning of RIMD with channels or complex parts.
- Carefully immerse the item in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reaches all surfaces including those of lumened RIMD.
- Remove all visible soiling from the RIMD, including lumens and valves. Remove stubborn staining by using a non-abrasive scouring pad or soaking in an approved stain-removing solution.
- Flush all lumened RIMD with a jet-gun (discharge under water).
- Rinse the item finally in warm-to-hot water (unless contra-indicated).
- Dry mechanically in a drying cabinet or hand dry with a clean, lint-free cloth.
Note: items should not be left to dry in ambient air.
- Inspect RIMD and equipment to establish that they are clean before further processing or storage.
- Thoroughly wash and dry receptacles before storing and re-use.

Cleaning (including pre-cleaning)

- Cleaning brushes should be identified for cleaning only and should be washed, thermally disinfected, and stored dry.
- A record should be kept of each RIMD/RIMD set that has been manually cleaned.
- The records should contain:
 - i. Name of RIMD/RIMD set.
 - ii. Name of processor.
 - iii. Date.
 - iv. Type of cleaning.
 - v. Type of detergent and detergent dilution used.

d. Monitoring and control

Validated process control requires that the process can be replicated precisely; this is only possible with an automated process. Where a non-automated process is used, every effort should be made to control all the variables that affect the process. For manual washing, these include:

- i. Staff training/competence.
- ii. Water temperature.
- iii. Detergent concentration.
- iv. Nature of soil.
- v. Method of soil removal.
- vi. Accessibility of fluid to item.

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

e. Maintenance

Regularly inspect all receptacles, sinks, surfaces including water supply and drains, for damage. Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.

Cleaning (including pre-cleaning)

2. *Non-Immersion*

a. Introduction

Non-immersion manual cleaning methods are appropriate for certain RIMD as some RIMD may become compromised by soaking in aqueous solutions, e.g. electrical, powered RIMD. Cleaning information about the methods to be used for specific devices should be sought from individual RIMD manufacturers.

b. Equipment required

- A warm detergent solution. Follow manufacturers' instructions for dilution and temperature.
- RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free, absorbent wipe should be used.

c. Procedure

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- Wearing protective clothing immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Commencing with the upper surface of the RIMD, wipe thoroughly ensuring that the detergent solution does not enter electrical components.
- Periodically rinse the cloth in clean water and repeat the previous two steps.
- Remove detergent solution using clean, damp, non-linting cloth.
- RIMD should be placed in a drying cabinet. Where a drying cabinet is not available, a clean disposable lint free absorbent wipe should be used.

Cleaning (including pre-cleaning)

d. Monitoring and control

Validated process control requires that the process can be replicated precisely; this is only possible with an automated process. Where a non-automated process is used, every effort should be made to control all the variables that affect the process. For manual washing, these include:

- Staff training/competence.
- Water temperature.
- Detergent concentration.
- Nature of soil.
- Method of soil removal.
- Accessibility of fluid to item.

Disinfection

14 Disinfection

14.1 Introduction

Disinfection is a process that inactivates infectious agents, using either thermal (moist or dry heat) or chemical means. The level of disinfection achieved depends on the temperature, exposure time and/or type of chemical disinfectant used.

14.2 Scope

The objective of this procedure is to provide guidelines in relation to disinfection of RIMD.

14.3 Contents

Section One: Level of disinfection

Section Two: Disinfection process

14.4 Procedure

Section One: Level of disinfection

- **High-level disinfection** – this is the minimum treatment recommended for reprocessing RIMD that cannot be sterilised, for use in semi-critical sites or when there are specific concerns regarding contamination of surfaces with species of mycobacteria, for example, mycobacterium tuberculosis.
- **Low-level disinfection** – this is the minimum treatment recommended for reprocessing RIMD for use in noncritical sites.

Section Two: Disinfection process

- **Thermal disinfection** can be achieved in a thermal washer–disinfector by choosing the appropriate cycle.
- **Chemical disinfection** can be achieved with a compatible RIMD-grade disinfectant of the required level, used alone or in conjunction with a chemical washer–disinfector.

Disinfection

- Disinfection should be carried out using a thermal disinfection process whenever practicable. Chemical disinfection should be employed only when required by the RIMD manufacturers' instructions.

1. *Thermal Disinfection*

a. Introduction

If items can withstand heat and moisture and do not require sterilisation, then thermal disinfection using moist heat at temperatures and times that destroy pathogenic agents, is the simplest, most efficient and cost-effective method of disinfection.

b. Equipment required

- Automated equipment, such as washer-disinfectors are recommended for use in thermal disinfection processes.
- The level of disinfection depends on the water temperature and the exposure time. Thermal washer-disinfectors can be programmed to deliver a range of disinfection levels, depending on the cycle selected (i.e. set temperature and exposure times).
- The manufacturers' instructions should be followed to achieve the required level of disinfection.

c. Monitoring and control

- Whenever practicable disinfection should be carried out using a validated disinfection process using automated equipment (e.g. washer-disinfector).
- Thermal disinfection equipment should be provided with means to independently monitor and/or record the time for which the load was exposed to the required temperature.
- The thermal disinfection process should provide adequate assurance of the required microbial lethality.

Disinfection

2. Chemical Disinfection

a. Introduction

- The ability of chemical disinfectants to effectively inactivate contaminating infectious agents depends on a number of factors, including the initial number of agents present, temperature, pH and concentration (Chiba 1994). Only RIMD disinfectants or sterilants are suitable for use with RIMD. Hospital or household/commercial-grade disinfectants should not be used on RIMD; they are suitable only for use on environmental surfaces (e.g. walls, floors, cupboards).

b. Equipment required

- RIMD disinfectant or sterilant.
- Automated equipment.

c. Monitoring and control

- Chemical disinfection processes should provide adequate assurance of the required microbial lethality.
- Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.
- Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- All surfaces should be immersed and channels flushed whether manually or automatically to ensure the solution is present within the channels during ensuring the decontamination process.
- Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.
- After chemical disinfection RIMD should be free from toxic residues and should be rinsed free from disinfectant with purified water free from microbial contamination. The quality of water used should be appropriate to the clinical procedures being undertaken.
- When rinsing, channels should be flushed thoroughly if rinsing is performed manually.

Drying

15 Drying

15.1 Introduction

Drying minimises rusting, staining and reduces the risk of recontamination during inspection and assembly of RIMD. Residual moisture interferes with the sterilisation process, and can damage RIMD.

15.2 Scope

The objective of this procedure is to provide guidelines in relation to the drying of RIMD.

15.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Monitoring and control

Section Four: Maintenance

15.4 Procedure

Section One: Equipment

- See decontamination equipment, page 20.

Section Two: Procedure

- RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free, absorbent wipe should be used.
- Care should be taken not to exceed the temperature tolerances advised by the manufacturer.
- Dry the RIMD in a sloping position to facilitate drainage.

Drying

Section Three: Monitoring and control

- Manual drying should be avoided unless a single-use lint free cloth is used.
- Items should not be left to dry in ambient air.
- Alcohol or other flammable liquids should not be used as drying agents, other than in automated equipment designed for this purpose, e.g. some endoscopes washer-disinfectors.

Section Four: Maintenance

- Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- Drying cabinet maintenance and repair log book should be maintained for each dryer.
- The dryer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485: 2003(E).

Post cleaning inspection and function testing

16 Post cleaning inspection and function testing

16.1 Introduction

Inspection, maintenance and testing of RIMD should be carried out by trained persons in accordance with the manufacturers' instructions. All RIMD should be inspected to ensure that they are intact and that there are no chips, worn spots, flaking or other damage. The functionality of all RIMD should be tested or checked before being packaged for further processing or storage. The area where inspection takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the RIMD/RIMD sets.

16.2 Scope

The objective of this procedure is to provide guidelines in relation to the post cleaning inspection and function testing of RIMD.

16.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Documentation post automated cleaning

Section Four: Inspection and function testing

Section Five: Monitoring and control

Section Six: Maintenance

Post cleaning inspection and function testing

16.4 Procedure

Section One: Equipment

- Work bench.
- Magnifying glass and oblique of stereo-microscope.
- Light source.
- Diathermy pin hole detector

Section Two: Procedure

When the automated cleaning process is complete, the following should be carried out:

- Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted.
- Check that the operating cycle is in accordance with the specification for the load used, (e.g. laryngeal masks do not require rinse aid).
- Check that arms rotate. If arms do not rotate, loads should be rejected as the load has not been exposed to the water spray effectively.
- Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the RIMD or RIMD may not be compatible with automated washing.
- If staining and/or residue are present, this may be due to the configuration of the load, overloaded cart or malfunction in the washing cycle.
- Make a visual inspection of the load for dryness.
- Where a load may not be properly cleaned the load is rejected and returned for re-cleaning.
- Unless there is clear indication why a small percentage of RIMD in a load were not cleaned and/or dried effectively, the entire load should be returned for re-processing.
- Where a small percentage of the load is suspect the items are rejected and returned for re-cleaning.

Post cleaning inspection and function testing

- Any load or items rejected should be documented as a non conformance; this non conformance should also be documented into the washer-disinfector log book for further investigation.

Section Three: Documentation post automated cleaning

- All documentation for automated cleaning should contain the following information:
 - i. Washer-disinfector identification number.
 - ii. Cycle number.
 - iii. Type of washer-disinfector.
 - iv. Type of cycle used.
 - v. Date and time of start of cycle.
 - vi. Load content, e.g. general RIMD, stitch set, mayo scissors.
 - vii. Critical parameters for the specific washer disinfector cycle.
 - viii. Operators name.
 - ix. Results of washer-disinfector process.
 - x. Signature of an authorised qualified person confirming whether or not the process cycle was within recommended parameters.
 - xi. Any notes or observation for the process cycle.
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- Before commencing inspection the person carrying out inspection should ensure that:
 - i. RIMD/RIMD set has been recorded as being through the specific cleaning process.
 - ii. If there is no record of cleaning the RIMD/RIMD set is rejected and returned for re-cleaning. Items which have been manually cleaned should also be recorded as being cleaned through the manual cleaning process.
 - iii. The signature of identified responsible person confirming that the cycle has passed.

Post cleaning inspection and function testing

Section Four: Inspection and function testing

- Each RIMD set should be inspected separately.
- Box joints, serrations and crevices, should be critically inspected for cleanliness.
- Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.
- Jaws and teeth should be checked for alignment.
- Ratchets should be checked for security.
- Ratchets should close easily and hold firmly.
- Any damaged, incomplete or malfunctioning RIMD should be reported immediately to the supervisor.
- Cannulated RIMD should be checked to ensure channel is patent.
- Telescopes and light cables should be function checked as per manufacturers' instructions.
- Each RIMD set should be checked for completeness and defects.
- Cutting edges (on RIMD such as scissors, rongeurs, chisels, curettes) should be checked for sharpness.
- Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.
- RIMD that have an outer insulation coating, for example diathermy forceps etc., require close inspection to ensure that the insulation remains intact. Insulated RIMD should be checked using a diathermy pin point tester. Damaged surfaces not only will allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and patients.
- Each RIMD should be checked that there is free movement of all parts and that joints do not stick. A water based lubricant may be used if required.
- Each RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.
- Each RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.
- The diathermy pin hole detector should be used in accordance with the manufacturers' instructions to ensure safe use of equipment.

Post cleaning inspection and function testing

Section Five: Monitoring and control

The user should be aware of the factors that may alter the efficacy of the method:

- Staff training/competence.
- Age of the RIMD.

Section Six: Maintenance

- Preventative maintenance is to be planned and performed for all equipment, (e.g. light source and pin hole detector) in accordance with documented procedures as recommended by the manufacturers' instructions.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485:2003(E).

Figure 16-1: Post cleaning inspection



Assembly

17 Assembly

17.1 Introduction

The purpose of assembly and checking is to ensure that:

- All RIMD are present in accordance with RIMD list.
- All RIMD are assembled correctly in accordance with manufacturers' instructions.
- All RIMD are placed in the correct tray in a manner that ensures ease of use by the user.

The area where assembly and checking takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the RIMD/RIMD sets.

17.2 Scope

The objective of this procedure is to provide guidelines in relation to the assembly of RIMD.

17.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: RIMD set weight

17.4 Procedure

Section One: Equipment

- RIMD list.
- Accessories, e.g. tray liner.
- RIMD protectors.

Assembly

Section Two: Procedure

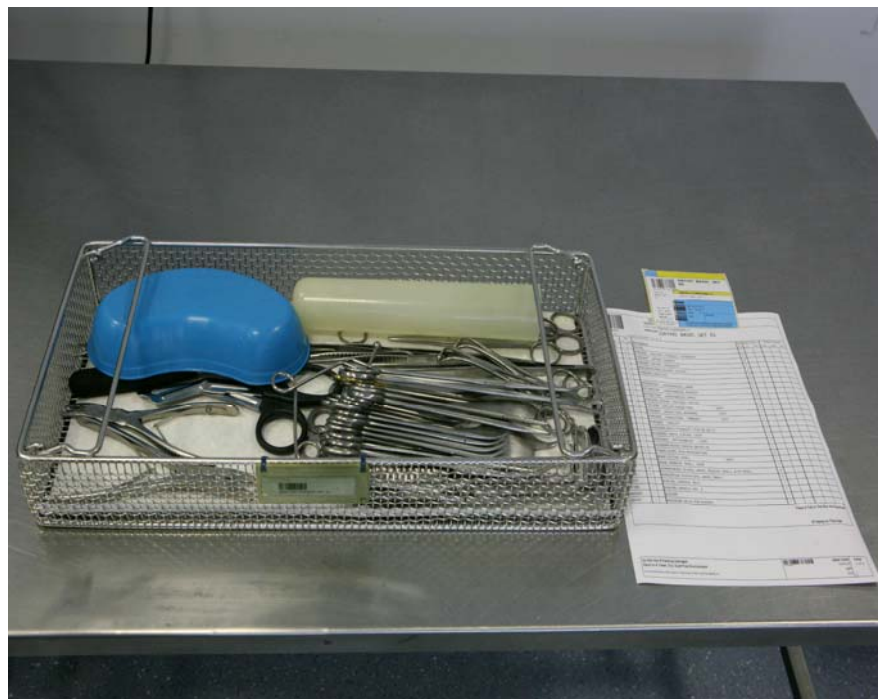
- RIMD should be assembled in accordance with the manufacturers' instructions, prior to packaging and/or further reprocessing.
- In preparing RIMD for wrapping and sterilisation, it is essential that all surfaces are presented to the sterilisation media (i.e. steam). Where the manufacturers' instructions indicate that RIMD to be sterilised are disassembled, it is essential that they are presented in this state.
- For RIMD with ratchets, they should be closed on the first ratchet only, to ensure steam can penetrate to all surfaces.
- Similar RIMD should be kept together when placing in tray, e.g. artery forceps can be placed on an RIMD pin together.
- The RIMD tray should be selected so that the RIMD can preferably be placed in one single layer.
- Tray liners should be placed in the base of the RIMD tray.
- RIMD should be spread evenly by weight over the tray surface, this helps prevent condensate flowing together.
- Each RIMD should be checked against the RIMD list specific to the tray being assembled.
- Plastic items should be evenly placed in the tray; avoid collecting them in one area.
- Ensure sharp RIMD are assembled correctly to avoid penetration of the outer packaging.
- Protectors to be placed on sharp RIMD should be validated for steam penetration.
- Ensure delicate RIMD are placed in tray in a manner which will not cause damage to the RIMD.
- Any RIMD which is missing from a tray should be reported to supervisor for further action and non conformance documented.
- Any extra RIMD found while assembling tray should be reported to supervisor for further action and non conformance documented.

Assembly

Section Three: RIMD set weight

- The ability of a given sterilisation cycle to produce a dry load is largely dependant on the configuration and thermal mass of the load.
- The condensate is produced as the steam heats the load, the heat from the load is used to boil-off the condensate during the vacuum drying stage. The mass specific heat and thermal conductivity determine the efficacy of this process for any particular set of RIMD
- The configuration of sets of RIMD required to permit dry loads should be established during performance qualification testing of the steam steriliser.
- The validated configurations should be documented as specifications for use during packaging.

Figure 17-1: Assembly



Packaging

18 Packaging

18.1 Introduction

RIMD require packaging prior to sterilisation. The packaging material and packaging techniques are designed to hold and protect the RIMD in order to facilitate sterilisation and to maintain sterility. The material selected depends on which particular method of sterilisation is recommended and must comply with EN 868, parts 1-10.

18.2 Scope

The objective of this procedure is to provide guidelines in relation to the packaging of RIMD.

18.3 Contents

Section One: General principles
Section Two: Packaging systems
Section Three: Packaging materials
Section Four: Single use packaging
Section Five: Types of packaging
Section Six: Packaging techniques
Section Seven: Sealing of packs and bags
Section Eight: Labelling
Section Nine: Monitoring and control
Section Ten: Maintenance

Packaging

18.4 Procedure

Section One: General principles

- The choice and type of wrapping material will depend on the type of sterilisation process used.
- Materials used should comply with EN ISO 11607-1 and EN ISO 11607-2, 2006 and EN 868 parts 2-10, inclusive. RIMD may be packaged in any of the following products: papers/non-wovens, polypropylene, containers, and plastic/paper pouches.
- When selecting packaging system each specific products capability to meet predetermined requirements and criteria should be evaluated.
- The appropriate size wrapping material should be chosen to attain adequate coverage of the item being packaged.
- Hollowware, RIMD or dressings should not be placed in textile (linen) packs as difficulty may be experienced in drying the combined pack materials and sterilisation may be compromised as the temperature increases in these materials at different rates.
- Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.
- RIMD packs should be packed in a manner that prevents damage to delicate items.
- Trays used for packaging RIMD should be perforated to allow for penetration of the sterilant.
- Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.
- Hollowware should be packaged so that all openings face the same direction.
- Only the minimum of raw materials commensurate with daily production should be held within the clean room.
- Compatibility of the packaging material with the sterilisation process should be established.
- If chemical indicators are used inside the pack, they should conform to European Standard EN ISO 11140-1 and should be compatible with the pack.
- Sequential wrapping using two barrier-type wrappers is recommended as it provides a torturous pathway to impede microbial migration.

Packaging

Section Two: Packaging systems

Packaging systems should:

1. *Be appropriate to the items being sterilised, i.e.*
 - Permit identification of contents.
 - Permit complete and secured enclosure of items.
 - Protect package contents from physical damage.
 - Permit delivery of contents without contamination.
 - Maintain sterility of package contents until opened.
 - Should facilitate aseptic technique at all times including opening of package.
2. *Be appropriate to the method of sterilisation, i.e.*
 - Provide adequate seal integrity.
 - Provide an adequate barrier to particulate matter and fluids.
 - Be compatible with and able to withstand physical conditions of the sterilisation process.
 - Allow penetration and removal of sterilant.
 - Maintain integrity of the pack.
 - Permit use of material compatible (i.e. non-degradable) with the sterilisation process.
3. *Be used according to the manufacturers' instructions*
4. *Be of the following*
 - Resistant to punctures, tears and other damage which may break the barrier and cause contamination.
 - Resistant to penetration by micro-organisms from the surrounding environment.
 - Free of holes.
 - Be free of toxic ingredients.
 - Low-linting.

Packaging

- Tamper proof and able to seal only once.
- Provide an adequate barrier to particulate matter and fluids.

Section Three: Packaging materials

Packaging materials should:

- Be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity equilibrium of packaging material is important to maintain the integrity of the product.
- Not be stored adjacent to external walls or other surfaces which may be at a lower temperature or a higher temperature than the ambient temperature of the store room.
- Be stored on shelves and clear of the floor.
- Be rotated to ensure it does not exceed its shelf life.

Section Four: Single use packaging

The medical device regulations include a requirement that sterile RIMD should be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile. There is thus a clearly stated preference for single-use packaging as the primary packaging for sterile RIMD.

Section Five: Types of packaging

1. *Papers and non-wovens*

- Both papers, which are made from cellulose fibres, and non-wovens made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilisation and most gas processes because they are permeable to air, steam and other gases.
- Plain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gusseted to accommodate bulky items.
- Non-wovens are generally less effective as a microbial barrier and may need to be used in, or as one of, two layers; they are however generally softer with better handling and drape characteristics.

Packaging

2. Containers

Rigid reusable containers:

- Should be easily disassembled for cleaning, drying and storage.
- Should be suitable for the method of sterilisation being used.
- Should be compatible to the cleaning method and cleaning agent being used
- Should be suitable to the storage configuration.
- Should have locking devices which are tamperproof and non resealable.
- Should be packed in a manner which allows for penetration of the sterilising agent.
- Lid and contents should be removable without the risk of contamination of the contents.
- Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.
- The filter plate should be examined for integrity both before installation and after the sterilisation process.
- If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system should be used in the practice setting.
- The integrity of the rigid container system is essential to permit sterilisation of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination.
- Loosened rivets, improperly maintained valves, worn gaskets or dents compromises to the integrity of the container system, will compromise the sterilisation process and may not permit the contents to remain sterile or be delivered aseptically.
- When re-usable containers are being evaluated it is important that the sterilisation, cleaning, inspection, maintenance and storage procedures and methods are also evaluated for their ability to be consistently re-used and for their compatibility with the process being used.
- Containers should be cleaned between each use; automated cleaning is the preferred method of cleaning.

Packaging

Section Six: Packaging techniques

- RIMD may be packaged in any combination of **flat wrapping material** (sheets, bags, pouches, or reels) or **containers** to maintain the integrity of the product. Devices wrapped with sheet material using either the **envelope** or **parcel fold** technique.
- RIMD should be wrapped in a manner which minimises the risk of contamination during opening and removal of contents.

1. *Flat wrapping material*

a. **Equipment required**

- Packaging material.
- Sterilisation chemical indicator tape.
- Marking pen.
- Label (where applicable).
- Tray liners.

b. **Procedure (parcel-fold wrapping method)**

- Select appropriate packaging material and place on work top.
- The RIMD set is placed on the wrap, approximately in the centre of the packaging material.
- Verify the accuracy of the RIMD identification label with the RIMD/RIMD set, (i.e. corresponds to RIMD list, internal tray label, etc).
- The long edge of the tray should be aligned parallel to the long edge of the wrap.
- One of the long edges of the wrap is folded over the pack contents to the base of the tray, and the edge of the wrap is turned back on itself.
- The opposite side of the wrap is then folded over the pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself.
- The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- The same procedure may then be repeated for an outer wrap(s).

Packaging

- The wrap is secured in position using sterilisation indicator tape.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- RIMD identification label is placed on outside wrap.

Figure 18-1: Parcel-fold wrapping method



Step 1



Step 2



Step 3



Step 4



Step 5



Step 6



Step 7

Packaging

c. Procedure (envelope wrapping method)

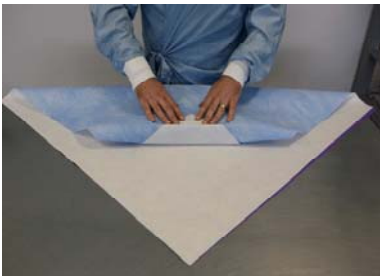
- Select appropriate packaging material and place on work top.
- The RIMD set is placed on the wrap diagonally and slightly off the centre line.
- Verify the accuracy of the RIMD identification label with the RIMD/RIMD set (i.e. corresponds to the RIMD list, tray internal label, etc).
- The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.
- This is repeated with the corners to the right and left of the first folded corner.
- In each case the corner is turned back to provide a flap for opening.
- Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.
- The same procedure may then be repeated for an outer wrap(s).
- The wrap is secured in position using sterilisation chemical indicator tape.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- RIMD identification label is placed on the outside wrap.

Packaging

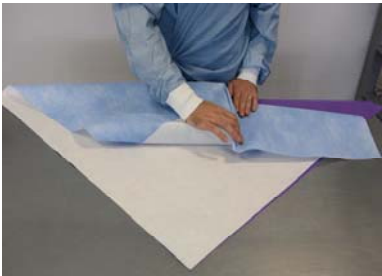
Figure 18-2: Envelope wrapping method



Step 1



Step 2



Step 3



Step 4



Step 5



Step 6



Step 7



Step 8



Step 9



Step 10

Packaging

2. *Pouches and bags (requiring folding)*

Folding is the simplest method to obtain a satisfactory closure for both pouches and bags, although it may not be a convenient method for high volume production.

a. Equipment required

- Pouches and/or bags.
- Sterilisation chemical indicator tape.
- Marking pen.
- Label (where applicable).

b. Procedure

- The corners at the open end of the pouch are folded diagonally to give mitred corners.
- The top of the pouch is then folded over three times in succession.
- The same procedure may then be repeated for an outer wrap(s).
- The pouch is secured in place with sterilisation chemical indicator tape. It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the RIMD to be viewed.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- RIMD identification label is placed on the outside wrap.

Packaging

3. *Self-seal Pouches*

When closing self seal bags follow manufacturers' instructions for sealing.

4. *Paper and paper/plastic pouches using heat seal*

a. General Principles

- The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above or below those specified by the packaging manufacturer.
- Packaging intended for heat sealing may be film coated, grid lacquered, or have an adhesive band.
- Heat seal pouches should be sealed using suitable heat sealing equipment.
- Heat seal pouches should be hermetically sealed.
- Heat seal pouches should provide a seal of proven integrity and not allow resealing.
- Before commencing wrapping procedure ensure that work area and packaging equipment are clean.
- Check size of edges for easy aseptic opening by user.

b. Equipment required

- Heat-seal Pouches.
- Heat sealer.
- Marking pen.
- Label (where applicable).

c. Procedure

- Select appropriate size heat seal pouch.
- Place RIMD into pouch.
- Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.

Packaging

- As much air as possible should be removed from the pouches before sealing. Air acts as a barrier to heat and moisture. Expansion of air during the sterilisation process may cause the bag to rupture during the sterilisation process.
- Place open end of pouch in heat sealer.
- Apply heat and pressure to the surface of the open end of the heat seal pouch.
- Checks should be made that the seal is complete, especially over the gusset folds of the pouches.
- A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.
- The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- When double wrapping using heat seal pouches the packages should be used in such a way as to avoid folding the inner package to fit into the outer package.
- Edges of inner heat seal pouches should not be folded as air maybe entrapped in the folds and inhibit sterilisation.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. this also enables the RIMD to be viewed.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the sterilant into and out of the package.
- If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.
- It is important to wrap the RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- Use adhesive RIMD identification label, do not write on the paper side of the pouch.
- RIMD identification label is placed on the outside packaging.

Packaging

Figure 18-3: Using the heat seal



Figure 18-4: Heat seal pouch



Packaging

Section Seven: Sealing of packs and bags

a. Introduction

The purpose of sealing is to maintain pack integrity, this can be achieved by the use of heat sealers, sterilising chemical indicator tape and seal secures. The indicator tape should meet European standard EN 867-1.

b. Accessories used to close or secure packages should be able to perform the following:

- Allow sterilisation.
- Avoid constriction of the package.
- Maintain package integrity.

The accessories should also be recommended by the manufacturer.

c. The following accessories should not be used:

- Tape (other than sterilisation chemical indicator tape).
- Safety pins.
- Paper clips.
- Staples.

d. Sterilising indicator tape

Sterilising indicator should be:

- Specific to the method of sterilisation being used and which will change colour when exposed to the relevant sterilisation agent.
- Pressure sensitive.
- Non toxic, adhere to clean surfaces and leave no adhesive residue on removal.
- Compatible with the wrapping material used.
- Heat stable.
- Moisture-stable and permeable to the sterilising agent.

Packaging

Section Eight: Labelling

- Packages to be sterilised should be labelled before sterilisation.
- The information of the label should include the following:
 - i. Name of product.
 - ii. Name of wrapper.
 - iii. Lot control number.
 - iv. Use by date or/and sterilisation date.
 - v. Where appropriate the word sterile.
- Label information should be documented on sterilisation chemical indicator tape or label and not on the packaging material. Plastic/paper pouches can be labelled on the plastic portion.
- Marking pen used to label the pack should be indelible, nonbleeding, and non-toxic. Sharp tipped water based or ball type pens should not be used as these may compromise the integrity of the pack.
- Label fixed to the surface of the packaging should be able to withstand exposure to the sterilisation process.
- Policies and/or procedures for wrapping and labelling and sealing of RIMD to be sterilised should be developed, reviewed periodically, and readily available within the practice setting.

Section Nine: Monitoring and control

The following should be monitored during labelling:

- General appearance of the packaging material.
- Whether packages are complete.
- Whether the correct products and packaging material are used.
- Whether the labelling is correct on the product.
- Whether the sealing is correct.
- Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.
- Material should be checked for tears, flaws and holes.
- Containers seals and filters should be checked.
- Containers should be checked for dints which may interfere with maintaining sterility.

Packaging

Section Ten: Maintenance

- Reusable containers should be subject to thermometric performance tests.
- Containers should be validated periodically for reuse according to manufacturers' instructions.
- Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policy.
- Heat seal efficiency, integrity and strength test should be performed on each heat sealer daily.
- Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.
- Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.
- Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The heat sealer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all maintenance, validation and servicing should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

Sterilisation

19 Sterilisation

19.1 Introduction

Sterilisation is a process including the use of a physical or chemical procedure to destroy all microbial life including high resistant bacterial spores. The function of sterilisation is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones. To be effective, cleaning must precede sterilisation.

19.2 Scope

The objective of this procedure is to provide guidelines in relation to the sterilisation of RIMD.

19.3 Contents

Section One: Types of sterilisers

Section Two: Choice of sterilisation process

Section Three: Steam sterilisation

Section Four: Loading the loading trolley prior to sterilisation

Section Five: Loading the steriliser

Section Six: Steam sterilisation of RIMD

Section Seven: Criteria for release of processed RIMD

Section Eight: Sterilisation records

Section Nine: Validation

Section Ten: Monitoring and control

Section Eleven: Maintenance

Sterilisation

19.4 Procedure

Section One: Types of sterilisers

- Sterilisers can be divided into those based on exposure to elevated temperature (thermal processes) and those based on exposure to microbicidal chemical agents. (low temperature processes).
- Thermal processes include dry heat (not covered in this document) and high temperature steam sterilisation. The steam sterilisers intended to be used for sterilisation of wrapped RIMD are referred to as porous load sterilisers.
- Low temperature processes include ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), and Hydrogen Peroxide Plasma.
- The preferred method of low temperature sterilisation is Hydrogen Peroxide Plasma.

Section Two: Choice of sterilisation process

- Whenever possible the preferred method of sterilisation for RIMD is high temperature steam at 134-137°C for three minutes in a porous load steriliser. A lower temperature steam sterilisation process may sometimes be required. (See table 19-1).

Figure 19-1: Steriliser



Sterilisation

Table 19-1: Sterilisation temperatures, steam pressures and hold times

Minimum Sterilisation	Corresponding Steam Pressure	Maximum Permissible	Minimum Sterilisation
121°C	1.03 bar gauge	124°C	15 minutes
134°C	2.30 bar gauge	137°C	3 minutes

- For RIMD that cannot tolerate the temperature for steam sterilisation a low temperature process may be used.
- Whenever possible, RIMD that will withstand steam sterilisation should be chosen.
- **Note:** The manufacturers instructions for RIMD purchased from the United States will often specify steam sterilisation cycles that are different from the standard cycle given above, e.g. 132°C for ten minutes. In most cases these RIMD can be processed through the standard cycle but confirmation should be obtained from the RIMD manufacturer.
- Hydrogen Peroxide Plasma is the preferred low temperature sterilisation method because, compared with EO and LTSF, the installation and health and safety requirements are greatly reduced.

Section Three: Steam sterilisation

- Effective steam sterilisation requires the removal of air from all parts of the chamber and load so that steam can reach all of the surfaces to be sterilised.
- For simple solid unwrapped devices, this may be achieved by the natural displacement of air by steam. For hollow devices, tubing, fabrics and wrapped goods, natural displacement cannot be relied upon to remove the air effectively and a forced air removal system is required.
- Flash sterilisers rely on natural air displacement and should not be used for wrapped goods, hollow devices or tubing.
- Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.

Sterilisation

- The operating cycle of a porous load steriliser generally has five stages:
 - i. Air removal.
 - ii. Steam admission.
 - iii. Sterilisation holding time.
 - iv. Vacuum drying.
 - v. Filtered air admission.

Section Four: Loading the loading trolley prior to sterilisation

a. Equipment

- See decontamination equipment, page 20.
- Loading trolley.
- IT based/Manual tracking system and accessories, i.e. paper, pen, scanner.
- Batch control labeller.
- Personal protective equipment—(heat resistant gloves).

b. Procedure

- Healthcare workers (HCWs) should wear personal protective equipment.
- HCWs should ensure that all items within the load are compatible with the process to which they are to be exposed.
- Loading should allow for free circulation of steam around each pack and each item.
- RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
- Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.
- Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.
- Hollowware should be placed upside-down or tilted, to prevent collection of condensate.

Sterilisation

- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the air and steam into and out of the package.
- Containers should be loaded onto the trolley such that an air space is formed between each container layer.
- When using the basket system Healthcare Workers (HCWs) should ensure that the appropriate size basket is used. Select the height of the basket so that there will always be a few centimetre air gap between the pack and the basket above.
- When loading HCWs should ensure that each RIMD is labelled.
- When loading is complete each item on the loading trolley should be recorded using the IT (or manual) tracking system.

Section Five: Loading the steriliser

- HCWs should load the steriliser using the loading trolley.
- HCWs should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.
- Doors should be open only when loading and unloading. An open door will cause the chamber to cool down and may cause condensation during the subsequent process.
- Manufacturers' instructions and protocols agreed during validation should be followed for loading.
- Overloading of sterilisers may compromise the process.

Figure 19-2: Loading the Steriliser



Sterilisation

Section Six: Steam sterilisation of RIMD

- HCWs should wear personal protective equipment.
- HCWs should ensure that all necessary tests and maintenance have been carried out satisfactorily before using the steriliser. HCWs should ensure that the cycle recorder(s) has sufficient paper and ink to record the cycle.
- HCWs should ensure that the correct operating cycle has been selected (**Note:** test cycles such as a Bowie and Dick test and leak rate test cannot be used for sterilising product).
- Healthcare workers (HCWs) should initiate the cycle in accordance with the steriliser manufacturers' instructions.
- Where single door steriliser is in use a system should be in place to ensure segregation of and sterile RIMD.
- When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.
- The fail cycle will require a special key to open the steriliser door.
- On a pass cycle, the load should be removed and held in quarantine in the cooling area until the sterile produce release procedure has been completed.

Section Seven: Criteria for release of processed RIMD

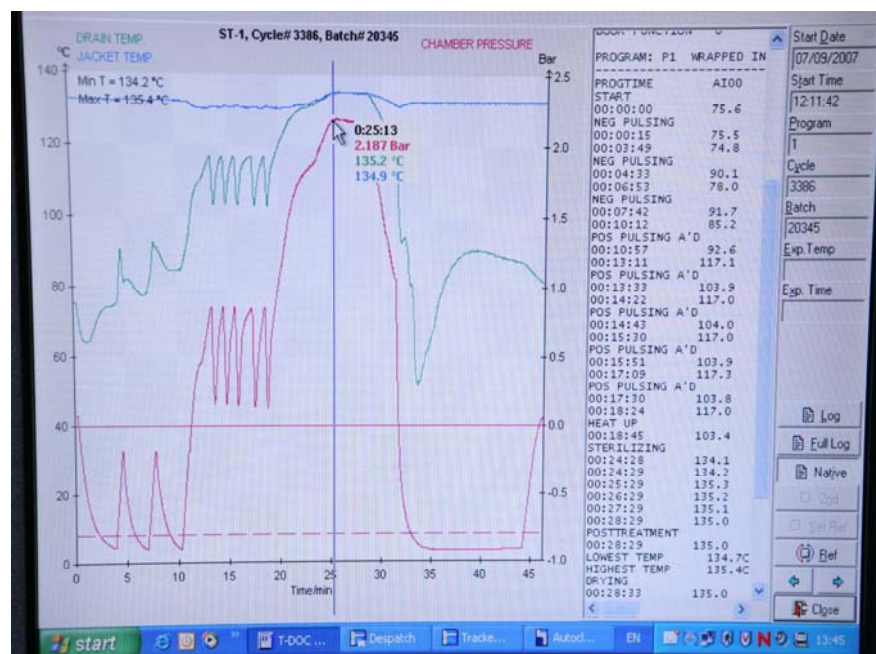
In order to release processed RIMD evidence is required that the sterilisation cycle was satisfactory, i.e. within the limits established during validation, and that the load items are undamaged and fit for use. There is a documented procedure specifying the actions to be taken and the criteria to be met in accepting the sterilisation cycle and releasing product as sterile. The sterilisation release procedure is only carried out by staff who have been trained to undertake this task and have been authorised to do so by the decontamination unit manager.

Sterilisation

a. Sterilisation cycle verification

- The cycle records should be examined to confirm that the cycle variables were within the limits established as satisfactory during validation. This should include:
 - i. The number and extent of air removal pulses.
 - ii. The temperature and duration of the sterilisation plateau period.
 - iii. The depth and duration of the drying vacuum.
 - iv. The data should be read from the independent recorder not from the automatic controller record.
- Any cycle not meeting the criteria, although indicated as a pass by the automatic controller, should be rejected. The load should be repacked and sterilised and the steriliser removed from service until the cause of the fault has been established and remedied.
- A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

Figure 19-3: Cycle Records



Sterilisation

b. Inspection of sterilised load

- Each item sterilised should be inspected to ensure that:
 - i. Chemical process indicators have changed colour as described in the indicator manufacturers' instructions. (Chemical process indicators do not indicate sterilisation, they are evidence only that the load has been exposed to the sterilising process).
 - ii. The packaging is in place and undamaged (i.e. seals, taped joints have not come undone, packs are not torn).
 - iii. The packaging is dry and free from visible dampness.
 - iv. All labels are intact and legible.
- Any load RIMD not meeting these criteria should be rejected and quarantined, non conformance must be recorded and the RIMD returned to the clean room for repackaging and sterilisation.

Section Eight: Sterilisation records

Sterilisation cycle records should contain the following information for each sterilisation cycle:

- i. Steriliser identification.
- ii. The cycle number and batch number if applicable.
- iii. Name of the loading operator and unloading operator.
- iv. Type of cycle used.
- v. Date and time of start of cycle.
- vi. Contents of the load.
- vii. Chart record and/or print-out from steriliser cycle.
- viii. Signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.
- ix. Any notes or observation for the process cycle.
- x. Read out results of physical, chemical or biological indicators that are used.
- xi. All records should be retained for the lifetime of the steriliser plus eleven years.

Sterilisation

Section Nine: Validation of steam sterilisers

Sterilisation cannot be confirmed by inspection and testing of the product. Thus the sterilisation processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained.

Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that a steam steriliser is functioning correctly and that it will produce sterilised loads consistently. The purpose of routine monitoring and control is to demonstrate that a validated and specified sterilisation process has been completed successfully during every cycle.

Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is comprised of:

- Commissioning (installation qualification and operational qualification).
- Performance qualification.
- Periodic testing.
- Revalidation.

Confirmation that the steriliser continues to function correctly is provided by periodic testing and revalidation.

i. Commissioning

Installation qualification is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier* and that it is safe to operate.

Installation checks and tests

- Preliminary checks.
- Electrical checks.
- Functional checks.
- Response to faults.

Sterilisation

Operational qualification is the process of obtaining and documenting evidence that the equipment functions within predetermined limits when operated in accordance with the manufacturer's operating instructions. It consists of:

- i. Air leakage test.
 - ii. Thermometric test.
 - iii. Calibration.
 - iv. Steam Penetration test.
- These tests should be carried out when a new steriliser is purchased or when a used steriliser has been relocated to another premises.
 - The tests should be carried out before the steriliser is used for the first time
 - Installation and operational checks and tests should be performed by a person with specialist technical training in testing of sterilisers.
 - Data from the installation and operational tests provide evidence that the steriliser is functioning correctly.

ii. Performance Qualification

Performance qualification is required to show that sterilising conditions are attained for loads and test loads that are assessed by the user to be difficult to sterilise.

Performance qualification is required for initial use of a new/relocated steriliser or when the load profile changes (e.g. new instruments). It should be carried out by a Test Person (or other suitably qualified person).

These tests consist of:

- Air leakage tests (automatic).
- Thermometric tests of all RIMD to be processed.
- Steam penetration and complete sterilant contact of all test loads.
- Load dryness test (of RIMD requiring reprocessing).
- Microbiological tests.

The decontamination unit manager should identify all the types of load to be sterilised agree worst case loads to be tested. The performance qualification test protocol and data should be audited by the qualified person (decontamination).

Sterilisation

iii. Periodic testing

Periodic testing consists of a programme of tests that are intended to demonstrate that the sterilisers' performance is satisfactory.

The appropriate tests should be carried out at daily, weekly, quarterly and annual intervals. A Test Person (or other suitably qualified person) should draw up a schedule for periodic testing. It is the responsibility of the Test Person (or other suitably qualified person) and the decontamination unit manager to ensure that these tests are performed.

I. Daily Test—Steam Penetration Test /Bowie and Dick (EN ISO 11140)

a. Introduction

The steam penetration test is intended to show that steam will penetrate rapidly and evenly into a test device that is at least as difficult to sterilise as the intended load. The test device contains an indicator that responds only when steam penetration is adequate (usually it changes colour – and should do so completely) . If a cycle is provided specifically to test the effectiveness of steam penetration, it should have the same air removal stage as used during routine sterilisation cycles.

b. Test procedure

- A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.
- At the end of the process the test device is removed from the chamber.
- The test device is checked for a pass or fail in accordance with the manufacturers instructions. The test results should be recorded.
- If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results.
- The sterilisation temperature for the operating cycle to be tested should be selected – this should be the highest temperature compatible with the load. The cycle should be commenced.
- A batch (cycle) process record should be made in the steriliser log book.

Sterilisation

Figure 19-4: Bowie-Dick Test



II. Weekly tests

The user should perform safety checks before starting the sequence of weekly tests.
The schedule of weekly tests is summarised in Table 19-2 below.

Table 19-2: Summary of Weekly Tests for Steam Sterilisers (Note: All tests can be combined into one test)

Weekly Checks/Tests
Safety Checks
Vacuum Leak Test (automatic)
Air Detector Function Test
Automatic Control Test
Bowie-Dick Test for Steam Penetration

Sterilisation

1. Safety checks

These tests are intended to ensure the steriliser is both safe to use and to test. They consist of:

- Examining the door seal for signs of deterioration or leaks.
- Checking the security and performance of door safety devices.

No attempt should be made to open the door while the chamber is pressurised.

Any defects should be corrected before attempting to perform the weekly tests or before using the steriliser.

2. Vacuum leak test

- The air leakage test is intended to check that air does not leak into the steriliser during periods of vacuum, at a rate that is greater than that specified by the steriliser manufacturer.
- Air leaking into the chamber can impair steam penetration into the load and prevent sterilisation and/or recontaminate the damp load during the drying phase.
- Air is first removed from the chamber until the pressure is the lowest achieved in all of the cycles available on the steriliser and then the vacuum source is isolated and all valves connected to the chamber are closed.
- The absolute pressure is measured at the end of the vacuum stage. Any subsequent rise in the chamber pressure will be caused by air leaking into it - and the rate of pressure rise in the chamber is measured.
- Ideally the steriliser/autoclave should be equipped with an automated test cycle so that the user can do the test. If there is not an automatic test facility, a Test Person (or other suitably qualified person) should do the test using special, calibrated instruments.

The pass/fail criteria are:

- The absolute pressure at the end of the air removal stage should be within the limits specified by the manufacturer. After an initial 5 minute equilibration period the rate of pressure rise should not be greater than 1.3 mbar per minute over a 10 minute period.
- A machine that fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.

Sterilisation

3. Air detector function test

The air detection system should be tested weekly to demonstrate that it is functioning correctly. There is such a wide variety of steam sterilisers that there is not a standard air detection system and each steriliser manufacturer should therefore specify the test method to demonstrate that the automatic air detection system is functioning correctly.

4. Automatic control test

- The purpose of this test is to verify that all the operational components of the steam steriliser are satisfactory and that no anomalies are observed.
- The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the steriliser was validated to be working correctly, e.g. immediately after the Test Person (or other suitably qualified person) had tested it using calibrated instruments.
- The test should be performed using the sterilising cycle with the highest temperature compatible with the load. The following parameters should be noted during the sterilising (holding) stage of the cycle:
 - i. Chamber temperatures and pressures, their maximum values and duration in minutes and seconds.
 - ii. The values on the cycle record should be compared with those on the master process record.
 - iii. The test can be considered satisfactory if at the end of the cycle if:
 - a. The chamber temperature and pressure is within the limits of the appropriate band, for the duration of the holding time, as specified in table 19-2.
 - b. A visual display of 'cycle complete' is indicated.
 - c. No mechanical or other anomaly is observed.

5. Test procedure for automatic control test of a steriliser with a cycle recorder

- The recorder should make a batch process printout. The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be noted.
- All the parameters recorded should be compared with the parameter results obtained during validation.

Sterilisation

III. Quarterly tests

These require specialised test equipment and only a person (e.g. a Test Person or other suitably qualified person) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate.

Quarterly tests for steam sterilisers are summarised in table 19-3.

Table 19-3: Summary of Quarterly Tests for Steam Sterilisers

Test Description
Safety Checks
Vacuum Leak Test
Vacuum Leak Test (temperature and pressure sensors connected)
Automatic Control Test
Verification of Calibration of Steriliser Instruments
Thermometric Test for a Small Load
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration

Sterilisation

III. Annual Tests

These require specialised test equipment and only a person (e.g. a Test Person or other suitably qualified person) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during validation remain consistent and accurate. Annual tests for steam sterilisers are summarised in table 19-4.

Table 19-4: Summary of Annual Tests for Steam Sterilisers (EN285)

Test Description
Safety Checks
Vacuum Leak Test (automatic)
Vacuum Leak Test (temperature and pressure sensors connected)
Automatic Control Test
Verification of Calibration of Steriliser Instruments
Steam Non-condensable Gas Test
Steam Super-heat Test
Air Detector Performance Test for a Small Load
Air Detector Performance Test for a Full Load
Steam Dryness Test
Thermometric Test for a Small Load
Thermometric Test for a Full Load
Tests for Performance Requalification (as required)
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration

Sterilisation

Section Ten: Monitoring and control

- 134°C is the preferred sterilisation temperature. For RIMD, which may be damaged at 134°C, any of the other lower temperature bands may be used.
- There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
- Routine monitoring and testing should be carried out in accordance with documented procedures in line with I.S. EN ISO 17665 part 1.

Section Eleven: Maintenance

- Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' instructions and European Standards.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The steriliser should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665, 2006.
- A nominated **qualified** person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- A record of mechanical testing, repairs and preventative maintenance should be recorded in a logbook for each steriliser. Records should be maintained in a designated storage area for the lifetime of the steriliser plus eleven years.

Revalidation may be required after steriliser relocation, engineering work, repair work, software control function modifications and when required by the decontamination unit manager. Some examples of requirement for revalidation are:

- Adjustment to steam controls.
- Adjustment to microprocessor controls.
- Adjustment to control parts.

Low temperature sterilisation

20 Low temperature sterilisation

20.1 Introduction

Low temperature sterilisation methods may be required for heat-sensitive RIMD.

20.2 Scope

The objective of this procedure is to provide guidance on the choice and use of low temperature sterilisation methods.

20.3 Contents

Section One: General principles

Section Two: Validation

Section Three: Periodic testing

Section Four: Chemical and Biological Indicators

Section Five: Sterilisation of RIMD

Section Six: Sterile product release

Section Seven: Storage and use

20.4 Procedure

Section One: General principles

- The microbial lethality provided by low temperature methods is less than that provided by high temperature steam (134 – 137°C for 3 minutes). Steam sterilisation should be used for all RIMD that will withstand the process.
- Four different methods of low temperature sterilisation are available for use in healthcare premises; ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), vapour phase hydrogen peroxide (VHP) and hydrogen peroxide plasma.
- The hydrogen peroxide based methods are preferred. (The residuals from EO and LTSF are toxic and must be degassed from RIMD after sterilisation whereas the residuals from hydrogen peroxide are innocuous (water and oxygen); also, EO and LTSF are alkylating processes which are believed to stabilise prion proteins).

Low temperature sterilisation

- Low temperature sterilisation methods should only be used for:
 - i. RIMD specifically identified by the RIMD manufacturer or steriliser manufacturer as suitable for processing in the steriliser, or
 - ii. RIMD made of materials of a size and configuration (e.g. length and diameter of lumen) within the criteria specified by the steriliser manufacturer.
 - iii. **Note:** Documentation of items that can and cannot be processed should be obtained from the RIMD and steriliser manufacturers.
- RIMD to be processed in a low temperature steriliser must be scrupulously clean and thoroughly dried prior to sterilisation. (The presence of residual soiling or droplets of water may seriously impair the sterilisation process.)
- The packaging used to contain RIMD to be sterilised must be compatible with the process. Only products designed for use with the particular process should be used.

Section Two: Validation

- The effectiveness of the sterilisation process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if sterilising conditions are created throughout the steriliser chamber and the load during every cycle.
- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the steriliser is functioning correctly and that it will produce sterilised loads consistently.
- Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is comprised of:
 - i. Commissioning (installation qualification and operational qualification).
 - ii. Performance qualification.
 - iii. Periodic testing.
 - iv. Revalidation.

Confirmation that the steriliser continues to function correctly is provided by periodic testing and revalidation.

- Revalidation is required annually and whenever any major change is made to the steriliser, sterilisation cycle or nature of the loads to be sterilised.

Low temperature sterilisation

- Validation and re-validation should be carried out in accordance with the requirements of EN ISO 14937.
- A qualified person (decontamination) with specific training on the process to be validated should advise on the validation programme and audit the data obtained.

Section Three: Periodic Testing

- Periodic testing consists of a programme of tests that are intended to demonstrate that the performance of the steriliser remains within the limits established during validation.
- The tests and checks specified by the steriliser manufacturer should be carried out at the intervals specified by the steriliser manufacturer. (This will normally require detailed functional and calibration tests and checks at intervals of 3 , 4 or 6 months).
- A qualified person (decontamination) should review and approve the schedule for periodic testing.
- It is the responsibility of the operational manager to ensure that these tests are performed and that the results were satisfactory before allowing the continued use of the steriliser.

Section Four: Chemical and Biological Indicators

Chemical indicators

- Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).
- The type used should be in accordance with the steriliser manufacturers' recommendations.
- The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- The use of an inappropriate indicator may give dangerously misleading results; indicator performance can be adversely affected by the storage conditions and methods of use.
- Indicators should not be used beyond their expiry date.

Low temperature sterilisation

- Two types of chemical indicator are commonly used:
 - i. **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
 - ii. **Integrating indicators and/or emulating indicators:** These indicators are intended to monitor the attainment of two or more critical variables in the sterilisation process, either by a graduated response or a defined end point reaction. These types of indicators are not currently available for hydrogen peroxide processes.

Biological indicators

- Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained.
- Biological indicators must meet the requirements of BS EN ISO 11138-1:2006.
- They are of limited value in routine process control (because of the delay before the results are available) and are restricted to a few special applications e.g. in process validation.
- When used for validation studies they should always be regarded as additional to the physical measurement of the critical control variables (e.g. temperature, pressure, sterilant concentration and time).

Section Five: Sterilisation of RIMD

- Wear personal protective equipment (PPE).
- Ensure that any checks and test that are to be carried out prior to sterilisation have been complete and were satisfactory
- Where single door steriliser is in use a system must be in place to ensure segregation of non-sterile and sterile RIMD.
- The steriliser door/s should be kept closed when the steriliser is not in use.
- Select the validated cycle programme suitable for the load being processed.
- Ensure the load is suitable for the process to which it will be exposed.
- Manufacturers written instructions for operating the steriliser should be followed.

Low temperature sterilisation

Section Six: Sterile product release

In order to release processed RIMD as sterile evidence is required to ensure that the sterilisation cycle was completed satisfactorily.

a. Parametric release

- When cycle is complete post sterilisation inspection is carried out to verify that the sterilisation cycle has completed with defined, validated critical parameters (VCP).
- Parameter release should show evidence that the RIMD were subjected to a process and have met all-processing variables achieved during performance qualification.

b. Non-parametric release

When it is not possible to measure the value of all the critical variables throughout the sterilisation cycle a non-parametric release method must be used. Non-parametric release involves verifying that the required values were met during the sterilisation cycle for those variables that can be measured and, in addition, using biological indicators. The load cannot be released until biological indicators that were placed in the load before sterilisation have been removed from the load at the end of the steriliser cycle and incubated under the conditions, and for the time, specified by the manufacturer of the biological indicator.

In both parametric and non-parametric release post-sterilisation inspection is carried out to ensure that:

- The values of the recorded cycle variables (e.g. temperature, pressure, time) are checked to ensure that they are within the limits determined as satisfactory during validation.
 - i. Failure of one or more of the cycle variables to meet the specified value (s) must lead to the steriliser load being transferred to the clean room to be repacked and sterilised.
 - ii. The cause of failure should be investigated and documented.
 - iii. A steriliser cycle in which there is no record from the automatic controller or from the independent recorder should be regarded as a sterilisation failure.

Low temperature sterilisation

- The chemical process indicator has undergone the expected colour change.
- The integrity of the outer wrap and its seals has not been compromised, e.g. torn wrap, sealing tape undone).
- The packed RIMD are sensibly dry.
- The labelling remains in place and legible.
- If the integrity of the packaging or labelling is compromised the sterilised load is regarded as non-sterile. The RIMD must be reprocessed and the cause of the failure investigated and documented.
- A record of mechanical testing, repairs and preventative maintenance should be recorded in a logbook for each steriliser. Records should be maintained in a designated storage area for the lifetime of the steriliser plus eleven years.

Section Seven: Storage and use

- Sterile RIMD should be stored in a clean, dry area, which is secure, dust free and above floor level.
- Packs should be labelled with the contents, the word 'Sterile' , the date of sterilisation and a unique identifier from which all stages of the decontamination process to which it was subjected may be traced.
- Packs should be stored so that they are used in sequential order, i.e. the oldest first.
- Packs should be inspected for damage before they are opened. If there is any sign of damage to the packaging, the contents should be returned to the decontamination unit to be re-sterilised before they are used.

Storage

21 Storage

21.1 Introduction

All decontaminated RIMD must be stored in such a way that their integrity and microbial state is maintained (e.g. sterile, high-level disinfected). RIMD packs should be stored in a clean, dry environment and protected from sharp objects that may damage the packaging.

21.2 Scope

The objective of this procedure is to provide guidelines in relation to the storage of RIMD.

21.3 Contents

Section One: Storage areas

Section Two: Storage equipment

Section Three: Shelf life/rotation of stock

Section Four: Non-conforming stock

21.4 Procedure

Section One: Storage areas

The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stocks. The design should be conducive to good inventory management. All materials and processed goods should be stored in designated purpose built storage areas enabling different classifications of stored goods to be segregated and maintained in appropriate environmental conditions. There are two types of storage area:

1. The processed goods store.
2. The raw materials store.

Storage

1. *Processed goods store*

The processed goods store should be located adjacent to the cooling bay in the sterilisation area and with access to the despatch area. This store is for RIMD produced by the department and RIMD which have been commercially manufactured and sterilised.

- The outer packaging (shipper carton) should be removed from RIMD which have been commercially manufactured and sterilised – if stored in the same store as those RIMD which have been produced by the department.
- Raw materials should not be stored in the processed goods store.
- Loose, processed RIMD should be stored separately from those packed in cases.
- Storage areas should be kept secure and access should be restricted to authorised personnel.
- Sterile materials should be stored at least 20 to 80 centimetres from the floor, at least 18 inches from the ceiling, and at least 5 centimetres from outside walls.
- The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.
- Medical and surgical process goods should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.
- Processed goods should be stored on appropriate designated shelving.

2. *Raw materials store*

The storage area is for the reception, storage and supply of all non-sterile materials including textiles and where appropriate, bulk cased supplies of commercially sterilised RIMD. The raw materials store should be located between the goods reception and the clean room area.

- Materials should be segregated and stored separately according to their specific requirements.
- Sterile RIMD should not be stored in this area (unless supplies are bulk cased).
- Single items should be stored separately from those in cases.
- Storage areas should be kept secure and access restricted.

Storage

- Accommodation should be designed in accordance with guidance in PD CEN ISO/TR 14969:2005.

Section Two: Storage equipment

a. General principles

- Sterile items should not be stored anywhere but on, or in, designated shelving, counters, or containers, because other areas may not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside.
- Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that may form on the interior surfaces of outside walls.
- Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it micro organisms from the air and surfaces.
- RIMD made of polymeric materials (especially latex) should not be stored adjacent to electric switch gear, laser printers, photocopiers or other sources of ozone. (Ozone can cause rapid degradation of these materials).

b. Shelving and racking

- Shelves and racking should afford adequate space to store the required stock in line with local supply policy and production demands.
- Shelving and racking should be purpose built, easily cleaned and maintained.
- There should be enough space between shelves and racking to allow an adequate passageway between fixtures.
- Shelving or racking should enable items to be clearly labelled.

c. Closed or covered cabinets

- Closed or covered cabinets are recommended for the storage of seldom-used sterile supplies.
- Closed cabinets limit dust accumulation, discourage handling, and minimise inadvertent contact with sterile items.

Storage

Section Three: Shelf life/rotation of stock

- General factors which influence shelf life are event related and include the following:
 - i. Packaging materials.
 - ii. Storage and handling conditions.
 - iii. Likelihood of product material deterioration.
 - iv. Package design.
- Each central decontamination unit should develop a system of stock rotation based on the date of sterilisation. Good management practices demand that stock be maintained at adequate levels.
- As a “rule of thumb”, product which has remained unused for more than six months should be deemed to be a product of over-stocking and an assessment undertaken as to its future need.
- There are occasions where devices must form part of emergency stocks and as a result may not be used within this time frame. Procedures should be put in place to ensure that these products are subject to a reprocessing regime over time.

Section Four: Nonconforming Stock

- A package should be considered nonconforming, i.e. non sterile and not suitable for use when:
 - i. It is incorrectly wrapped.
 - ii. It is damaged or opened.
 - iii. The product is outside the expiry date.
- The sterilisation process indicator does not confirm that the pack has been subject to an appropriate sterilisation process.

Storage

Figure 21-1: Storage



Transportation—of sterile items

22 Transportation – of sterile items

22.1 Introduction

Sterile RIMD should be transported in a manner that will not compromise their status. Loss of sterility is event related and depends on the extent and nature of handling, environmental conditions during transportation and storage, and the quality of the packaging material.

22.2 Scope

The objective of this procedure is to provide guidelines in relation to the transportation of sterile RIMD.

22.3 Contents

Section One: General principles

Section Two: External transportation

22.4 Procedure

Section One: General principles

- Sterile RIMD should be transported in clean dry conditions in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage to devices and flexible packaging.
- Sterile RIMD should be cooled before they can be transported.
- Sterile RIMD should be transported in closed solid walled containers, or in covered or enclosed carts with solid-bottom shelves to protect them from exposure to environmental contaminants along the transportation route.

Transportation—of sterile items

Section Two: External transportation

- Where sterile RIMD are transported in vehicles the vehicles should be dedicated to the purpose, should provide appropriate segregation for the transport of sterile and used RIMD and the loading area should be constructed so that it is easily cleanable.
- Where small quantities of sterile RIMD are to be transferred or where it is only occasionally required, they may be transported in a socially clean general purpose vehicle provided they are contained within a closed solid walled container.

Figure 22-1: Transportation of sterile items



Water supply for washer-disinfectors

23 Water supply for washer-disinfectors

23.1 Introduction

The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process.

23.2 Scope

The objective of this procedure is to provide guidelines in relation to provision of water of optimum quality for each stage of the cleaning process.

23.3 Contents

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

23.4 Procedure

Section One: General requirements

- At each stage in the cleaning process the water quality should be compatible with:
 - i. The materials of construction of the washer-disinfector.
 - ii. The RIMD to be processed.
 - iii. The process chemical to be used.
 - iv. The process requirements of that particular stage.

Water supply for washer-disinfectors

- The key quality elements to be considered are:
 - i. Hardness.
 - ii. Temperature.
 - iii. Ionic contaminants (e.g. heavy metals, halides, phosphates and silicates).
 - iv. Microbial population.
 - v. Bacterial endotoxins.
- The water supply should be controlled to ensure that it is of the required quality.

Section Two: Water Quality

i. Hardness

- Water hardness is caused by the presence of dissolved salts of the alkaline earths (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (lime-scale) when water is heated or evaporated.
- The deposition of lime-scale on electrical heating elements or heat exchange components, within pipes and around the edges of spray nozzles will seriously impair the performance of a washer-disinfector (WD).
- Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- Using hard water in the thermal disinfection and final rinse stages of the WD cycle is one of the major causes of white powdery deposits on load items. These are unsightly and act as a focus for soiling and recontamination of the item in use. In some applications (e.g. with optical systems) such deposits may seriously impair the utility of the item.

ii. Temperature

- The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.
- Water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to “fix” proteinaceous soil to the surface of the load items. EN ISO 15883 recommends that the initial temperature should not exceed 45°C. The initial flushing stage should be supplied with water from a cold supply.

Water supply for washer-disinfectors

- When enzymatic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.
- The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

iii. Ionic contaminants

- Ionic contaminants in the water may react with materials such as stainless steel.
- Water used for stainless steel instruments should have a chloride concentration less than 120 mg/l Cl⁻ to minimise the risk of corrosion.
- Tarnishing of stainless steel instruments, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discoloration.

iv. Microbial population

- The microbial population in the water used in the washer-disinfector (WD), particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.
- For items which are intended to be used without further processing (e.g. flexible endoscopes processed in an endoscope washer-disinfector) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the patient, either through infection or by leading to a erroneous diagnosis.

v. Bacterial endotoxins

- Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse. They are not readily inactivated at the temperatures used for disinfection or sterilisation.
- Water used for the final stages of processing in a WD, where there is a significant risk of residual water remaining on the load items, should not contain more than 0.25EU/ml when the WD is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.

Water supply for washer-disinfectors

Section Two: Water treatment

There are three methods of water treatment generally used on water supplies for washer-disinfectors (WDs):

- i. “Base-exchange” softeners.
- ii. De-ionisers.
- iii. Reverse osmosis.

i. “Base-exchange” softeners

- Base-exchange softeners, consist of an ion exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride).
- The concentration of total dissolved solids in the water is not reduced by this process. The sodium salts which remain do not readily form hard deposits to foul heat exchangers or spray nozzles but if used as the final rinse will leave white deposits on the load items as they dry.
- After regeneration high levels of chloride ions may be present in the initial output from the softener which should be configured to automatically run an initial volume to waste.

ii. Deionisers

- De-ionisation (demineralization) systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in separate columns.
- Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers.
- De-ionised (DI) water may be heavily contaminated with micro-organisms and DI water stored at ambient temperatures will be colonised rapidly (The chloride ions normally present in drinking water to control microbial growth have been removed).
- DI water should not be used for the final rinse of products intended for invasive use without further decontamination processing .

Water supply for washer-disinfectors

iii. Reverse osmosis

- Reverse osmosis (RO) treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.
- When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.
- Appropriate measures include:
 1. A continuous recirculation system water.
 2. Filtration, e.g. through a 0.22 µm filter to remove microbial contaminants.
 3. Treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J. m⁻²)).
- The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Stainless steel pipes are preferred for all qualities of purified water.
- All pipe work should be run with a continuous fall to the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.

Water supply for washer-disinfectors

Table 23-1: Water quality for washer-disinfectors

Washer-disinfector process stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Flush	Cold soft/mains	Cold mains
Wash	Reverse osmosis	Hot soft/mains
Rinse	Reverse osmosis	Reverse osmosis
Thermal disinfection	Reverse osmosis	Reverse osmosis
Chemical disinfection*	Reverse osmosis	Soft/mains
Post chemical disinfection	Reverse osmosis 0.22 mm filtered	De-ionised 0.22 mm

*Endoscope washer-disinfector only

Table 23-2: Water quality for cleaning RIMD

Washer-disinfector process stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Manual wash	Reverse osmosis @ 35-45°C	Soft/mains @ 35-45°C
Manual rinse	Reverse osmosis	Soft/mains ¹
Ultrasonic wash	Reverse osmosis @ 35-55°C	Soft/mains @ 35-55°C
Ultrasonic rinse	Reverse osmosis	Soft/mains ¹

¹ When the manually/ultrasonically cleaned RIMD are to be further processed through an automated washer-disinfector

Textiles and non-wovens

24 Textiles and non-wovens

24.1 Introduction

Textiles (re-usable) and non-wovens (single-use) may be used as drapes, gowns and wrapping materials. Drapes should provide a safe effective means of protecting patients and healthcare workers. (Reference EN 13795).

24.2 Scope

The objective of this procedure is to provide guidelines in relation to the use and processing of textiles and non-wovens in a central decontamination unit.

24.3 Contents

Section One: General principles

24.4 Procedure

Section One: General principles

- Re-usable textile drapes and gowns should not be inspected, folded and packed in the same area as clean RIMD.
- If it is intended to process re-usable textiles through a central decontamination unit a separate clean room must be provided to deal with the re-usable textiles because of their high particulate generation rate.
- Single-use (disposable) drapes and gowns are preferred.
- Single-use (disposable) drapes and gowns may be provided within an RIMD set if this is convenient to the end-user.
- If it is intended to sterilise water repellent single-use (disposable) drapes in a steam steriliser it will be necessary to specify the folding method and to carry out performance qualification tests during validation in order to establish that there is steam penetration to all surfaces of the drape.
- Re-usable textiles should not be used as wrapping materials for RIMD sets.
- Single-use (disposable) drapes and gowns should be disposed of within the healthcare risk waste in the clinical unit.

Textiles and non-wovens

- Single-use (non-woven) wrapping materials may be retained on used RIMD being returned to the central decontamination unit to provide added protection. Any single-use (non-woven) wrapping materials returned with used RIMD should be discarded as healthcare risk waste.

Single use invasive medical devices

25 Single use invasive medical devices

25.1 Introduction

A single use invasive medical device (SIMD) is defined as a device intended by the manufacturer to be used on one patient during one procedure. The device is **not intended for reprocessing** and/or use on another patient or on the same patient at another time.

25.2 Scope

The objective of this procedure is to provide guidelines in relation to SIMD.

25.3 Contents

Section One: General principles

25.4 Procedure

Section One: General principles

- To avoid cross-contamination between patients, SIMD should be used wherever this is practical.
- Single-use items should be used for a single patient and not reused on subsequent patients. Patient care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- Devices intended for single-use and labelled 'single-use' by the manufacturer should be immediately disposed of after use.
- Decontamination unit managers who disregard this information and prepare single use products for further use, are transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them and have become the manufacturer of the device.
- The symbol for single use instruments is as given in ISO EN 980:2003.
- Synonyms for "do not reuse" are "single use", use only once".
- See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).
- Organisations should have well established criteria for their choice of SIMD or RIMD where both are available.

Transfer of used reusable invasive medical devices to third parties

26 Transfer of used reusable invasive medical devices to third parties

26.1 Introduction

Anyone who inspects, services, repairs or transports RIMD, either on hospital premises or elsewhere, has a right to expect that the RIMD have been appropriately treated so as to remove or minimise the risk of infection or other hazards.

26.2 Scope

The objective of this procedure is to provide guidelines in relation to the transfer of RIMD to third parties for the inspection, service, repair, or disposal of RIMD.

26.3 Contents

Section One: General principles

26.4 Procedure

Section One: General principles

- All RIMD intended for inspection, service, repair, or disposal must be decontaminated before despatch and must be accompanied by a certificate stating the method by which they were decontaminated.
- All RIMD must be decontaminated in accordance with the manufacturers' instructions.
- If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, the recipient may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.
- RIMD that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.
- When RIMD are returned after being repaired, the RIMD must be decontaminated and, where relevant, replaced in the original RIMD set.
- Each RIMD set should be checked for completeness as per hospital policy.

Loan reusable invasive medical devices

27 Loan reusable invasive medical devices

27.1 Introduction

RIMD may be loaned to an organisation so that a particular procedure can be performed. The RIMD may be borrowed either from manufacturers or other hospitals and are returned after use. This practice increases the risks associated with the decontamination and reprocessing of such devices because the organisation may not be familiar with the RIMD or the required decontamination process.

27.2 Scope

The objective of this procedure is to provide guidelines in relation to the transfer of RIMD to third parties for the repair, loan and disposal of RIMD.

27.3 Contents

Section One: General principles

Section Two: Procedure for loaning and borrowing RIMD

27.4 Procedure

Section One: General principles

- Borrowed RIMD must be accompanied by relevant reprocessing instructions (including disassemble and reassemble instructions where relevant) and a list of contents.
- All borrowed RIMD must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly.
- RIMD on loan must be registered, including ownership, service history, current location, service responsibility and instructions for use.

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Section Two: Procedure for loaning and borrowing RIMD

a. Requests

- All requests for the loan of RIMD must be made directly by clinical manager of the unit intending to use the RIMD.
- When agreement has been reached that the RIMD may be borrowed, the manager of the central decontamination unit that will be responsible for decontamination must be informed.

b. Documentation

- The owner of the RIMD being loaned is responsible for ensuring that the loaned RIMD are accompanied by the following documentation:
 - i. Contents list.
 - ii. Decontamination certificate.
 - iii. Reprocessing instructions, including disassembly and reassembly, where relevant.

c. Log book

- Details of all RIMD which are loaned to/borrowed from other institutions should be entered into a log book detailing:
 - i. Name and description of the RIMD.
 - ii. RIMD identification number(s).
 - iii. Name of the person to whom the RIMD is being loaned to/borrowed from.
 - iv. Identity of the institution providing/receiving the RIMD.
 - v. Identity of the person who is making the loan.
 - vi. Date of loan.
 - vii. Expected date of return.
 - viii. The unique identifier permitting traceability of the decontamination cycle(s) for the RIMD prior to use.
 - ix. The unique identifier for the patients on which the RIMD was used.
 - x. The unique identifier permitting traceability of the decontamination cycle(s) for the RIMD after use.

Loan reusable invasive medical devices

d. Arrangements for return of RIMD

- Arrangements for the return of RIMD must be made directly by the person who borrowed the RIMD within the defined time period agreed.
- Responsibility for logging the safe and complete return of the RIMD rest with the designated person to whom the RIMD are returned.
- The return date, the name of the institution and the person returning the RIMD should be recorded.

Action on non-conforming product

28 Action on non-conforming product

28.1 Introduction

To ensure patient safety and compliance with the Safety, Health and Welfare at Work Act, 2005 and S.I. 252 of 1994, the organisation must establish procedures to expedite the retrieval of reprocessed items that are suspected to be non-sterile, contaminated or otherwise defective and to ensure appropriate follow-up actions. Follow-up actions may include quarantine of the RIMD, notification of clinicians and surveillance of patients as well as remedial action to prevent any recurrence.

28.2 Scope

The objective of this procedure is to provide guidelines in relation to action on non-conforming product.

28.3 Contents

Section One: Policies and procedures

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

28.4 Procedure

Section One: Policies and procedures

- Written policies and procedures for the recall of non-conforming product should be developed, available and implemented in the organisation.
- Where any occurrence gives cause for concern that the required assurance of sterility, functionality and freedom from contamination has not been met, the infection control nurse and risk manager should be notified so that follow-up surveillance of patients can be conducted.
- The nature and seriousness of the fault and the risk category of the product will determine whether it will be necessary to issue an advisory notice or to institute a recall. These factors will also determine the speed and extent of the action. Ref: EN 724:1994.

Action on non-conforming product

Section Two: Recall procedure

A recall procedure should:

- Be written.
- Outline the circumstances for issuing a recall order.
- Designate the person(s) authorised to issue a recall order.
- Designate the person(s) responsible for reporting on the execution of a recall order.

Section Three: Recall order

A recall order should:

- Be written.
- Identify by sterilisation lot number the products to be recalled.
- Identify the persons or departments to whom the order is addressed.
- Require the recording in terms of kind and quantity of the products obtained in the recall.
- Specify the action to be taken by the person or persons receiving the order (e.g. destruction or return of product).

Section Four: Recall report

A report of a recall order should:

- Identify the circumstances that prompted the recall or order.
- Specify the corrective action(s) taken to prevent a recurrence.
- State, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall.