Reusable Medical Device Reprocessing

1. Guiding Principles

Where RMDs are used and reprocessed, the health service must comply with current relevant legislation, national & international standards, and manufacturer's reprocessing instructions.

The purpose of reusable medical device (RMD) reprocessing is to provide reusable devices that are safe for patient care. This is achieved using current, evidence-based, best-practice in RMD reprocessing

This procedure applies to staff who use, transport or reprocesses reusable medical devices.

2. Definitions

RMD	Reusable Medical Device (instrument, scope, probe)
IFU	Information for use (reprocessing instructions)

3. Procedure

3.1 Role of the Central Sterilising Supply Department

CSSD provides a specialist RMD reprocessing service for critical and semi-critical devices as defined by Spaulding's Classification.

RMDs should be reprocessed to the highest possible level using Spaulding's Classification, while complying with relevant standards and company information for use (IFU).

The CSSD Manager/ Theatre Manager shall be involved prior to purchasing any new RMDs, to ensure CSSD has the facilities to reprocess the item.

The device manufacturer must provide an up-to-date, validated IFU with an RMD. It is the responsibility of the person purchasing the device to provide the IFU to the CSSD Manager, prior to purchase. In order to comply with current standards, these reprocessing instructions must be followed.

If there are no alternative to a specific RMD and the IFU cannot be followed, reprocessing should follow Spaulding's Classification and Table 5.1 (AS/NZS 4187:2014).

The RMD should be reflected on the facility's AS/NSZ 4187:2014 Compliance Gap Analysis and Action Plan, as per ACHS Advisory AS18/07.

The CSSD Manager/ Theatre Manager is responsible for implementing relevant policies and procedures for RMD reprocessing, in collaboration with Infection Control and other stakeholders.

3.2 RMD Reprocessing Education

Identifying the minimum training and education required for staff involved in the reprocessing of RMDs aims to ensure the provision of RMDs safe for patient use, while satisfying relevant legislation and standards.

WACHS is committed to providing a competent and properly trained workforce for reprocessing RMDs for the provision of safe patient care.

Inadequate training may lead to increased infection control risk to patients and potential workplace injury to staff

Minimum RMD Reprocessing Training Content

- Modes of transmission of infection
- Infection prevention control principles (including standard and transmission-based precautions)
- Hand hygiene (including the importance of removing nail polish, artificial nails and jewellery)
- Workplace health and safety, such as PPE, chemical handling, spill management, biohazard/blood exposure
- Reprocessing tasks
- Instrument tracking
- Documentation and record keeping

Principles for areas that conduct satellite reprocessing (ie Medical Imaging, facilities with no CSSD).

- AS/NZS 4187:2014 standards apply where RMD reprocessing takes place (not just in CSSD)
- Staff involved in processing RMDs must be trained in the reprocessing technique (ie using Tristel Wipes) and how to reprocesses the RMD (ie using the Tristel wipes on an ultrasound probe)
- Competency-based, refresher training should be undertaken annually for staff undertaking RMD reprocessing
- The CSSD Manager of an associated facility should be accessed as a resource for RMD reprocessing and training

Principles for facilities with a CSSD

- Senior staff in CSSD shall have relevant qualifications and experience
- It is expected that staff employed as a sterilisation technician will have completed, or be completing a Certificate III in Sterilisation Services (HLT31107)

- All staff involved in RMD reprocessing, in addition to completing the WACHS mandatory training requirements will:
  - undertake, at the commencement of employment, a CSSD specific mandatory induction/orientation program. The CSSD staff member will also complete a workplace, competency-based CSSD training program
  - undertake an annual competency-based skills refresher
  - complete retraining where necessary (ie change of standard, new RMD)
  - participate in ongoing competency-based training relevant to the role

Education Record Keeping

The CSSD Manager/ Theatre Manager is to:

- monitor and ensure compliance with staff RMD reprocessing competency-based training
- conduct annual assessment of staff skills to ensure they are competent to safely undertake reprocessing activities
- maintain records of RMD reprocessing staff training

3.3 RMD Quality Management

CSSD records keeping will comply with the WA State Records Act, with records kept a minimum 7 years.

The following outlines the requirements for the routine monitoring, validation, maintenance and calibration of CSSD equipment, and required corrective actions to be taken when issues are identified.

CSSD machinery (washers, high level disinfectors, low temp sterilisers, drying cabinets, heat sealers, steam sterilisers etc) must be validated at the following times:

- **Installation Qualification (IQ)** performed at installation, or when equipment is relocated, and provides objective evidence that the equipment processes conform to relevant standards and manufacturer's requirements
- **Operational Qualification (OQ)** performed at installation, or when equipment is relocated, service changed, existing equipment is modified, change to loading configurations is changed, a new RMDs is introduced, or after repair. Provides objective evidence that the equipment processes conform to relevant standards and manufacturer's requirements. An OQ is not considered a PQ.
- **Performance Qualification (PQ)** performed annually at a minimum, as well as after IQ, OQ, repair, change in process, new RMDs, change in load configurations.

Validation Report

The validation report summarises the data collected during the IQ and OQ for equipment, and PQ for specific processes. The CSSD Manager/ Theatre Manager shall review and approve the report. It is the CSSD/Theatre Manager's responsibility to identify the need for re-qualifications when it is required more often than the minimum specified by the Standards ie when there is a change in process.

PQ is to be performed on all equipment each year at a minimum. There should be a current PQ validation document in the department for all equipment.

The report, detailing the process that has been validated, should include the following (if applicable to the machine):

- Location and equipment identification (ie serial number)
- Equipment specifications
- Any modifications
- Pressure vessel certificates (if applicable)
- Compliance document
- Planned maintenance schedule (in collaboration with Tables 10.1 and 10.2 in AS/NZS 2014:2014)
- Load configurations for each product family and load
- Parameters for each cycle and specifications for each process
- Qualifications and name of person involved in validation
- Program for routine testing, periodic testing and requalification
- Details of any faults or corrective action
- Temperature, speed and pressure for heat sealers

Maintenance and training manuals should be provided by the manufacturer.

Monitoring

RMDs have validated reprocessing instructions submitted to the Therapeutic Goods Administration by the company. In order to ensure that process is being replicated each time CSSD reprocesses the device, it is essential to monitor all aspects of the process, take corrective action to fix any problems and record the result of corrective action

As a minimum, regular monitoring and control of reprocessing equipment in the department must adhere to the following tables in AS/NZS 4187:2014:

- Water quality used for reprocessing RMDs – Table 7.2
- Cleaning and disinfection equipment – Table 8.1
- Sterilising equipment – Table 8.2

As per Table 8.2, internal tray indicators are not mandatory.

Records of compliance with monitoring requirements should be kept, including documented evidence of non-compliance, action taken and result.

Monitoring and measuring equipment (ie equipment used for monthly water testing) should be National Association of Testing Assessors (NATA) calibrated and the person doing the testing, NATA accredited. This applies to hospital staff and contractors. Action will be taken with faulty equipment, and the outcome recorded. Current calibration reports must available for each piece of monitoring or measuring equipment.

Product Families

RMDs will be classified into product families to assist with setting reprocessing conditions during validation, in association with manufacturer's IFU. The product family classifications will include the following:

- RMD description
- RMD intended use
- RMD design (lumens, moving parts)
- RMD physical characteristics
- RMD packaging

Audits

The department will be audited against the AS/NZS4187:2014 standards quarterly, with results tabled to the Infection Control Committee. The results must be documented and an action plan developed to track corrective action and the result of that action. The action shall be reviewed to assess effectiveness.

3.4 Cleaning, Disinfection and Sterilisation of RMDs

Environmental Cleaning

Environmental cleaning of CSSD should occur as per the department's cleaning schedule. Cleaning of machinery should be done as per manufacturer's instructions. Environmental cleaning and equipment cleaning must be documented as per the schedule and records kept.

All work surfaces, fixtures and fittings must be made of robust, non-shedding material that is easy to clean.

Separate environmental cleaning equipment must be used for clean and dirty areas ie separate mop and bucket for Decon and Assembly areas.

Single-use devices

It is a breach of the Therapeutic Goods Act to reprocess single-use devices unless the facility is licenced by the TGA to do so. Hospital CSSDs are not licenced or equipped to reprocess single-use devices.

As such, all single-use devices must be disposed of by the clinician, at the point of use. Single-use devices that have been opened and not used, must be discarded.

The only exception to this is single-use devices supplied to CSSD in an intentional unsterile state, with a validated IFU on how they are to be processed.

Single-use sharps should be discarded at the point of use by the clinician.

Loan, trial and RMDs for repair

RMDs received on loan, trial or back from repair shall be reprocessed prior to use, according to their IFU. Reprocessing staff shall be educated on required reprocessing methods.

Loan, trial and RMDs for repair shall be decontaminated and/or disinfected prior to dispatch, so they are safe for others to handle. Documentation shall accompany the RMD, as evidence of this.

Pre-cleaning at the point of use

The reprocessing of a used RMD starts at the point of use, with clinical staff using a damp, lint-free cloth to remove gross soiling and debris immediately after use. Clean water should be used on the cloth, rather than saline, to reduce the risk of rust forming if there is a delay in reprocessing.

A device with multiple parts should be dismantled before pre-cleaning to reduce the risk of biohazard drying and biofilm forming in crevices.

Use of a pre-cleaning spray should be considered if recommended by the device manufacturer and there will be a delay of more than 1 hour before it is reprocessed in CSSD.

The used RMD should be placed in a designated transport box for transport to CSSD. Theatre may cover the soiled RMDs with a drape, rather than use a transport box

Personal Protective Equipment

Personal protective equipment (PPE) should be used as per the PPE Matrix. Any chemical spills should be managed following the instructions of a purpose designed spill kit.

Cleaning

Cleaning is the most important part of reprocessing as an RMD must be clean in order to be disinfected and/or sterilised.

Workflow occurs in one direction, from dirty to clean.

Sinks must be of a sufficient depth to allow an RMD to be fully submersed. There must dedicated sinks for pre-cleaning, manual cleaning, rinsing and handwashing, which are ergonomically designed.

There shall be facilities for air or water flushing of lumened RMDs at the sink.

Cleaning brushes and other accessories may be single use. It not, they will be thermally disinfected and/or sterilised daily with records kept. They should be in good condition and replaced regularly ie weekly.

Mechanical cleaning (ie in a washer) is preferred to manual cleaning, as the results are more reliable. Holding times for washer-disinfectors should follow Table 6.1 in AS/NZS4187:2014. However, the RMD's IFU must be followed when choosing a process. Manual cleaning is only used when required by the IFU, or as pre-treatment prior to mechanical cleaning.

With ultrasonic cleaning, ensure visible soiling is removed from the RMD before placing in the ultrasonic. The RMD must be further manually or mechanically cleaned after being removed from the ultrasonic. The ultrasonic cleaner shall be cleaned and emptied at least daily. Records of this shall be kept and action taken if there is a problem with the machine. Result of the action taken shall also recorded

To clean an RMD, follow the IFU to ensure mutli-part devices are dismantled. The RMDs should be divided into cleaning pathways, such as manual cleaning, mechanical cleaning, ultrasonic cleaning etc.

RMDs must be loaded into a mechanical cleaner (ie washer) in a way that all surfaces are cleaned, including lumened RMDs. RMD unloading is done in a way to limit cross-contamination of devices

Drying

Drying methods must not compromise the cleanliness of an RMD, and may include:

- Drying cycle in the washer
- Drying cabinet
- Airgun
- Disposable lint-free cloth

Disinfection

Disinfection is the process of killing microorganisms on a cleaned RMD. Refer to the RMD IFU for guidance on which items should be low, medium or high level disinfected.

Disinfection equipment must be monitored as per Table 8.1 to ensure it is functioning as required. The printout of each cycle must be checked at the end of the cycle to ensure the process was delivered as per the validated specifications. If not, action must be taken and documented. If the load does not pass the release criteria, the load must be failed and returned to Decontamination to be reprocessed.

A loan item or RMD sent for repair must be disinfected at a minimum, to ensure the RMD is safe for others to handle. Documentation should accompany the RMD as evidence of this.

Disinfection and /or sterilisation occurs on RMDs between patient use, even when using a single use sheath or sleeve (Refer: OD 0404/12: Reprocessing diagnostic ultrasound device).

Assembly

The Assembly area is where RMDs are inspected, tested and reassembled into trays after cleaning. Hand creams and alcohol-based hand rubs shall not be used by staff, as the products may leave residue on the instruments.

Visual inspection, assembly and testing of RMDs prior to packaging, are essential steps in ensuring the provision of a product safe for patient use. Task lighting, magnifying lamps and microscopes are used to identify possible contamination.

An RMD should not be cleaned in the Assembly area. A contaminated RMD should be returned to Decontamination for re-cleaning. If the RMD was part of a tray, then the whole tray must return to Decontamination for re-cleaning.

When assembling tray sets, instruments must not be packaged with tubing or textiles. RMDs with hinges and ratchets must be packed in the open position to ensure the sterilant makes contact with all surfaces.

Packaging

The selection of packaging materials should be based on the type of RMD, method of sterilising and the manufacturer's instructions. Accessories, such as tip protectors, must be intended for that purpose. Methods of sealing will maintain the integrity of the packaging.

The method of packaging will facilitate opening the RMD using aseptic technique.

The package will be labelled before being sterilised.

Each type of packaging used in the department must be validated for use as part of the annual PQ. If the annual PQ is not due, then a PQ of the process using the packaging will be performed.

Sterilising

Sterilising equipment must be monitored as per Table 8.2 to ensure it is functioning as required. The printout must be checked at the end of each cycle to check that the process was delivered as per the validated specifications. If not, action must be taken and documented. If the load does not pass the release criteria, the load must be failed and returned to Decontamination to be reprocessed.

Sterilising holding times should follow Table 6.2 in AS/NZS 4187:2014.

The RMD IFU will be followed when selecting a sterilising process. The RMDs shall be loaded in such as a way as to ensure all surfaces are exposed to the sterilant. This will be done with consideration with size, mass, orientation and configuration limits of the load as used during annual validation.

The sterilised load must be allowed to cool in a designated area where the environmental conditions will not compromise the sterility of the items. They must be cooled before handling.

3.5 Release Criteria

At each stage of reprocessing (cleaning, disinfection, assembly, packing, sterilising) the RMD must be assessed to ensure it satisfies the Release Criteria (Table 9.1, AS/NZS 4187:2014) in order to move onto the next phase of the process.

If an RMD fails to satisfy the Release Criteria at any stage of the process it must be returned to the Decontamination Area to re-start the process.

An RMD will not be released for use on a patient unless it satisfies all release criteria.

3.6 RMD Tracking

Tracking of RMDs will enable the facility to link the use of an RMD to a patient in the case of a re-call for non-conformance. In order to facilitate a recall of a non-conforming RMD, reprocessed items must have:

- Name of the RMD
- Date reprocessed
- Batch and load information on each pack/ tray
- Documented evidence of all RMDs that have been through reprocessing
- A process to facilitate the tracking of the item's reprocessing history
- A process to record the load contents
- A process to identify the patient that an RMD was used on
- Identification of the person who approved the process/ load

Electronic Tracking

Facilities with an electronic tracking system, such as Instacount/ Censitrac/ T Doc should ensure the following information is recorded:

- Details of patient
- RMD batch information (date, machine, cycle)
- Date of procedure
- Type of procedure
- Name of RMD used on patient
- Name, designation of staff involved in procedure
- Name of the person who approved the process

Manual Tracking

In areas or hospitals that do not have electronic tracking, when an RMD is used on a patient, record the following tracking information in the patient's progress notes, or on a dedicated tracking form:

- Details of patient (patient sticker)
- RMD batch label (taken off packaging)
- Date, location of procedure
- Type of procedure
- Name of RMD used on patient
- Name, signature, designation of staff involved in procedure

Auditing of compliance with the above shall be done annually. The result should be used to facilitate clinical staff education on compliance.

3.7 Recall of Non-conforming RMDs

A non-conforming RMD is one that does not meet acceptable criteria after reprocessing, and cannot be considered safe to use on a patient.

CSSD aims to prevent the need for a recall by:

- being aware of the grounds for recall ie failing release criteria
- monitoring for compliance with the standards during reprocessing
- ensuring accurate reprocessing recordkeeping
- using quality control measures to evaluate the effectiveness of the preventative actions (auditing)
- revising the preventative measures if indicated by the evaluation.

A RMD recall must be undertaken whenever there is evidence of reprocessing process failure.

Non-conforming RMDs must be removed from use and managed to ensure patient safety ie reprocessed.

Grounds for recall may include:

- release criteria not met
- user feedback
- biological indicator fail
- package came into contact with a wet surface after reprocessing
- placed or dropped on a dirty surface after reprocessing (ie floor)
- cannot be identified as having been reprocessed (ie indicator missing)
- exposed to incorrect storage parameters
- exposed to insects and/ or vermin during storage

Recall process

The person responsible for co-ordinating a RMD recall is the CSSD Manager/ Theatre Manager, or their delegate ie Team Leader.

The Nurse Manager of the affected area should be notified ie Theatre Nurse Manager of internal and/or external sites, Birth Suite Nurse Manager etc, or their delegate ie Shift Co-ordinator.

It is the responsibility of the person notified in the procedural area to ensure the affected RMD is removed from circulation and returned to CSSD for reprocessing. The task of retrieving the RMD may be delegated, however, the person notified is responsible for making sure it is done in a timely manner.

If the RMD was used on a patient, then a clinical incident should be lodged and escalated to senior nursing/ medical staff.

At a minimum, corrective action is to include:

- identification of the nature of the nonconformity (including user concerns or complaints)
- implementation of an action plan to correct the nonconformity
- documentation of action taken to address the nonconformity
- evaluation of corrective action.

It is the responsibility of the CSSD Manager of the site that reprocessed the RMD to report on the non-conformance and recall. The report will include:

- the circumstances that led to the recall
- identification of the root cause for the recall
- confirmation that all affected RMDs were recalled, when matched with the record of their distribution
- identification of any patients affected by the recall, and follow up of any action
- summary of corrective action taken regarding the recall
- outline of the consequences of the recall
- recommendations to prevent recurrence.

The report should be escalated to the CSSD Manager's line manager.

3.8 RMD Transport

Incorrect transport of RMDs may result in the item being inadvertently contaminated prior to use, presenting an infection control risk. Alternately, an incorrectly transported soiled item presents an OSH hazard.

Transport Box

A transport box protects reprocessed RMDs from contamination, which may result in an infection risk to patients. The box also contains soiled RMDs to prevent them from being an OSH hazard during transit.

- The transport box must be sealable, rigid, puncture proof, cleanable, with a lid.
- A designated transport box must be used to transport RMDs within a hospital, or between hospitals.
- There must be separate boxes for clean and dirty RMDs.
- The boxes must be cleaned between use.
- The transport box should be transferred flat on a trolley (depending on size).
- It should not be over filled (less than 7kg).
- The box must be sealed, or not left unattended, during transit (to a Ward, or another hospital) to prevent the contents from being tampered with.
- Soiled RMDs transported from theatre to CSSD may be covered.
- Clean and soiled RMDs should be transported in separate boxes.

Soiled RMDs transport

- Outlying areas (ie Ward) should have a designated transport box place in their dirty utility room
- Soiled RMDs must be placed neatly in the transport box
- The transport box should not be over-filled (less than 7kg)
- Each facility should have a local collection schedule to transport the box, flat on a trolley (depending on size), to CSSD for reprocessing
- A replacement box should be provided to the outlying area.

Clean RMD transport

- Plastic and paper bags are not suitable alternatives to a designated transport box, the requirements of which are specified previously
- The reprocessed RMD should be placed in a dust cover to protect the integrity of the packaging during transit and storage
- The RMD should be placed in a clean transport box (or transport cabinet) for transport to outlying areas
- The box should be sealable, or not left unattended, during transit to prevent tampering
- The RMD packaging integrity should be checked when taken out of the transport box, and returned for reprocessing if damaged
- The RMD should be stored with the dust cover on.
- The transport box should be cleaned between each use.

3.9 Storage and Handling of RMDs

Handling of reprocessed RMDs should be restricted to staff who have been trained in the correct principles:

- Reprocessed RMDs should be handled as little as possible to avoid contamination.
- Access to the storage areas should be restricted to control traffic, in order to minimise the movement of airborne contaminants.

Sterile storage areas must be air-conditioned and HEPA filtered with minimal air turbulence. They must comply with the following:

- Dedicated sterile stock storage area
- Free from dust, insects and vermin
- Temperature range between 18°C – 22°C
- Relative humidity range between 35% - 68%
- Follow company IFU for further storage requirements, if appropriate

Sterile stock must be stored on a wire rack shelf (compactus or fixed) for increased efficiency and space utilisation, with:

- shelving to be 250cm above the floor and 440mm below the ceiling
- protected from sunlight
- no inaccessible corners
- sealed seams and non-porous surfaces
- routinely cleaned/ shelving surfaces damp dusted.

A sterile stock rotation system should be maintained, with stock rotated regularly, based on the date of reprocessing, ensuring oldest stock is used first.

Return of sterile RMD to storage

- An RMD can be returned to sterile storage if the packaging is intact and has not been contaminated ie blood splatter, been in a procedure room with a patient on respiratory precautions
- An RMD that has been opened, but not used, must be returned to CSSD for full reprocessing and cannot be returned to sterile storage until reprocessed

4. Roles and responsibilities

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be, and contribute to the provision of safe patient care.

5. Compliance

This procedure is required by AS/NZS 4187:2014 Reusable Medical Device Reprocessing Standards.
Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Employment Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* (HSA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System.

Records Management Policy
Health Record Management Policy

7. Evaluation

Evaluation of this procedure is to be carried out by the CSSD Manager/ Theatre Manager. The following means or tools are to be used:

- Audit results as evidence of meeting the requirements of the standards

8. Standards

National Safety and Quality Health Service Standards (Second edition 2017) -
NSQHS Standard 3 – Preventing and controlling hospital acquired infections
Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)
ACORN Australian Perioperative Nursing Standards (2015)
AS/NZS 4187:2014 Reusable medical device reprocessing standards

9. Legislation

Therapeutic Goods Act (1989)

10. References

NSQHS Standard 3 – Preventing and controlling hospital acquired infections
AS/NZS 4187:2014 Reusable medical device reprocessing standards

11. Related WA Health System Policies

OD 0404/12: Reprocessing diagnostic ultrasound devices

OD 0369/12: Reprocessing infant feeding devices

OD 0456/12: CJD risk assessment and management

12. Policy Framework

Public Health

This document can be made available in alternative formats on request for a person with a disability

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