Flexible Endoscope Reprocessing Procedure

Table of Contents

1. Purpose

The purpose of this procedure is to provide guidance on the cleaning, reprocessing, maintenance and storage of flexible endoscopes e.g. bronchoscopes, cystoscopes, colonoscopes and gastroscopes (hereafter collectively referred to as endoscopes). This includes guidance for the use of Automated Flexible Endoscope Reprocessors (AFERs) and Controlled Environment Storage Cabinets (CESCs) and requirements for microbiological testing.

This procedure applies to all WA Country Health Service (WACHS) healthcare workers that use or reprocess endoscopes.

2. Procedure

2.1 Key Principles

Endoscopes are reusable medical devices (RMDs) and guidance provided in the Reprocessing Reusable Medical Devices Policy should be followed in conjunction with this procedure.

The reprocessing of endoscopes requires specialised knowledge and skills, and the following key principles are to be adhered to:

- Only Endoscopy Nurses or Sterilisation Technicians who have completed the Gastroenterological Nurses College of Australia (GENCA) Fundamentals of Endoscope Reprocessing modules are permitted to reprocess endoscopes.
- All staff must adhere to appropriate work health and safety (WHS) guidelines, particularly when handling chemicals in the reprocessing area. Refer to the Managing Risks of Hazardous Chemicals and Dangerous Goods Procedure.
- Staff are to ensure that:
  - appropriate Personal Protective Equipment (PPE) is worn during endoscope reprocessing
  - the manufacturer's instructions for use (IFU) are adhered to when reprocessing endoscopes.
- Proof of process must be documented at each stage of the endoscope reprocessing process.

As outlined in the Infection Prevention and Control in Endoscopy 2021 guidelines:

- AFERs are mandated for the reprocessing of all endoscopes.
- Pass-through AFERs offer the optimal solution for compliance with the principle of separation of clean and dirty.
- The use of an automated cleaning process in a validated AFER is also preferred, as an automated process removes the human factors inherent in a manual cleaning process that may negatively affect consistency and compliance.
- Studies have shown and supported reduced rates of transmission of infection using AFERs compared with manual cleaning or reprocessing.
- Manual cleaning of an endoscope is required where the AFER manufacturer's validated cleaning instructions mandate manual cleaning (including brushing and flushing of channels and ports consistent with the manufacturer's IFU) of the device and as the step before reprocessing of an endoscope in an AFER if the system is not approved for a fully automated process.
- Manual cleaning may also be undertaken before automated cleaning.

- The most important step in the process of endoscope decontamination is scrupulous manual or mechanised cleaning before disinfection.
- Manual cleaning of accessories may be required as per the manufacturer's IFU as a prerequisite to high-level disinfection or sterilisation.

Staff must ensure that:

- accessories labelled "SINGLE USE ONLY" are not to be reused
- pre-cleaning of endoscopes at the bedside occurs immediately following use
- the timeline for commencing manual cleaning or automated cleaning in an AFER after immediate bedside instrument decontamination is < 60 minutes (preferably 15 minutes)
- after completion of high-level disinfection in an AFER, endoscopes should be immediately stored in the CESC unless being immediately used for another procedure
- endoscopes that are required to be sterilised should be transported to the Sterilisation Services Department (SSD) as per local procedures for further reprocessing
- the maximum time within which an endoscope may be used after removal from the CESC is 12 hours. After 12 hours, the endoscope should undergo a full reprocessing cycle
- unused endoscopes should undergo a full reprocessing cycle before being placed in a CESC.

Endoscopes require a full disinfection process to be performed at the end of the procedure and when stored in an approved CESC, once every seven (7) days OR as per the CESC manufacturer's IFU.

2.2 Use of Appropriate Personal Protective Equipment (PPE)

Appropriate PPE is to be worn during procedures, manual cleaning and reprocessing of endoscopes and accessories. This includes gloves, protective gown/apron and face/eye protection.

Refer to Appendix A for detailed guidance on specific PPE requirements.

Appropriate PPE must be worn:

- by staff when performing endoscopic procedures or reprocessing used endoscopes, associated accessories, instruments and equipment
- in any clinical situation where exposure to blood or body fluids is anticipated
- as relevant when aseptic technique is required
- and changed between patients, tasks or procedures or when visibly contaminated
- when handling, disposing of clinical waste and undertaking environmental cleaning.

For guidance on additional safety precautions for the storage and handling of peracetic acid (commonly used for the high-level disinfection of endoscopes), refer to Section 2.9: Safety considerations.

2.3 Proof of Process

Proof of process must be documented throughout the process of endoscope reprocessing. This ensures that the appropriate process steps have been followed and that the process can be tracked/traced if required.

Staff are to:

- document the reprocessing steps undertaken, either electronically or manually as per local procedure
- monitor and document all cycle parameters for the reprocessing of endoscopes and accessories, specifically:
  - the patient and the procedure
  - the date of procedure
  - the serial number of the endoscope
  - name of the person who completed the manual cleaning phase of reprocessing as relevant
  - name of the person who connected the endoscope to the AFER
  - name of the person who removed the endoscope from the AFER and released the endoscope as ready for patient use.

Modern AFERs monitor the process parameters for the machine cycle and prevent continuation of cycle if the parameters are not met. They maintain an electronic record as well as a computer printout. If a manual record system is in use, the computer printout is to be attached to the unit record and a copy is to be attached to the patient's health care record.

2.4 Endoscope Reprocessing Steps

As noted, the most important step in the process of endoscope decontamination is scrupulous manual or mechanised cleaning prior to disinfection.

Manual cleaning refers to the physical task, performed by hand, of removing biological material from the endoscope with appropriate brushes, cloths, detergents and water. It should not be confused with mechanised cleaning, whereby a cleaning process is performed by a machine.

For manual cleaning to be effective, it must:

- be performed by a person with an accurate and complete knowledge of the structure of the endoscope and who is trained in cleaning techniques
- be undertaken immediately after the endoscope is used (starting with bedside pre-cleaning), so that biological material does not dry and harden
- follow a protocol that, using appropriate detergents and cleaning equipment, allows all surfaces of the endoscope (internal and external) to be cleaned
- be followed by thorough rinsing to ensure that all debris and detergents are removed before disinfection.

One person should complete the entire manual cleaning of the endoscope, to avoid omitting steps in the manual cleaning process. If a change in staff occurs during cleaning, the process should be recommenced from the manual cleaning step.

AFERs that perform mechanised cleaning are now common and provide an equivalent level of efficacy as optimal manual cleaning. They should ultimately replace manual cleaning to provide standardisation of the cleaning process and remove the human factors that can adversely affect the quality of manual cleaning.

Immediate Bedside Pre-cleaning and Decontamination in the Procedure Room

The process for immediate bedside pre-cleaning and decontamination in the Procedure Room is:

- Make up or open pack of fresh premixed enzymatic detergent cleaning solution for reprocessing each endoscope as per the manufacturer's IFU.
- **Immediately** after each procedure, with the endoscope still attached to the light source, the endoscopy nurse is to grasp the control head. Using a disposable cloth or sponge soaked in detergent solution, wipe the control head and insertion tube to the distal tip. Discard the cloth or sponge. Note: remove balloons from echoendoscopes and enteroscopes and any removable component from the distal tip of any endoscope.
- Place the distal tip in detergent solution and aspirate solution through suction channels by alternately suctioning cleaning fluid and air, raising and lowering the instrument tip into and out of the cleaning solution.
- Continue to aspirate until clean fluid is seen. Note that patient secretions from bronchoscopy are clear and may be difficult to identify when aspirating. The volume of fluid to be aspirated through the channel during bedside cleaning is 250 mL or as determined by the AFER manufacturer, if greater, as this is a prerequisite step to the automated cleaning process.
- Insert the air/water channel cleaning adaptor and depress the button to flush with water, then release for air flow to expel the water.
- Flush the auxiliary channel (when present) by depressing the foot flushing pump or with a syringe.
- Disconnect the water bottle connector from the endoscope. Take care not to contaminate the tip of the connector.
- Remove the endoscope from the light source.
- Attach the protective cap to the endoscope if applicable.
- Transport to cleaning area in designated covered container, taking care to avoid environmental contamination and ensure it is clearly identified as contaminated equipment.

Leak Testing

Leak testing detects damage to the external surfaces and internal channels of the endoscope that can lead to inadequate disinfection and further damage of the endoscope. Leak testing should be performed after each use prior to manual cleaning, or it may be performed by the AFER at the start of the reprocessing cycle/as per the manufacturer's IFU. Remove all valves and buttons before leak testing.

For suspected or confirmed COVID-19 patients: The risk of aerosol generation during wet leak testing is potentially significant and the Infection Prevention and Control in Endoscopy 2021 guidelines recommend for manual cleaning after a procedure performed on a patient with suspected or confirmed COVID-19, dry leak testing should be performed in the procedure room while staff are still in full airborne-precaution PPE. This carries a risk that a leak may go undetected, so to mitigate this risk, confirmation of the leak test process within the machine cycle is required.

The process for manual leak testing is:

- don appropriate PPE - refer to Section 2.2: Use of appropriate PPE
- remove all valves and buttons prior to leak testing
- attach the leak tester and pressurise the endoscope

- immerse the endoscope in a sink filled with water, ensuring all parts of the endoscope and control head/wheels are immersed
- carefully observe the insertion tube, distal bending section and the universal cord for a continuous stream of bubbles
- a leak is identified when there is a continuous stream of bubbles escaping from the exterior or interior channels of the endoscope
- if the endoscope fails the leak test, ensure that the leak tester remains connected while the endoscope is immersed and continue the manual cleaning process
- do not place the endoscope into the AFER for disinfection and as soon as possible:
  - notify Manager/Supervisor
  - notify technical services for repair
  - prepare the endoscope to be collected for repair
  - ensure the endoscope is clearly labelled “Not disinfected”.

Manual Cleaning, Rinsing and Visual Inspection

- gather required equipment:
  - appropriate enzymatic cleaning solution (to remove biofilm)
  - non-linting cloth and disposable cleaning brushes
  - transport receptacle for the endoscope
  - protective cap for endoscope (as applicable).
- follow the detailed steps outlined in IPC in Endoscopy 2021 guidelines:
  - Section 8.6.3 Manual or automated cleaning
  - Section 8.6.4 Rinsing after manual cleaning
- brush each channel at least three times, until all visible debris is removed. Note that:
  - the cleaning adaptors and brushes appropriate for the particular model must be used, as per the manufacturer’s IFU
  - some brushes are designed to be used with a pull-through method instead of withdrawing the brush
  - strict attention to current manufacturer’s IFU must be adhered to.
- connect to endoscope flusher and flush with enzymatic detergent solution, rinse and purge with air as required
- ensure all outer surfaces are wiped over with disposable cloth
- complete a visual inspection to confirm that the endoscope is intact and clean. If not, repeat the manual cleaning and rinsing process steps until the endoscope is clean.

High-level disinfection

- Place the endoscope into the AFER as per the manufacturer’s IFU.
- Wipe down the top and entry surface with disinfectant before closing the lid to minimise contamination when the endoscope is removed.
- Remove and discard gloves and perform hand hygiene.
- Scan the endoscope barcode (as required) or select the disinfection cycle on the AFER and press ‘start’ button.
- The AFER printer will generate a printout which provides a record of cycle completion. This printout remains with the endoscope until after use. For manual tracking processes, the Endoscopy Nurse is to attach the printout to the patient’s medical record.
- Confirm the disinfection/sterilisation cycle has been completed successfully on the AFER printout.
- Upon completion of the cycle, open the AFER then don a clean pair of gloves.

- Disconnect the cleaning tubes from the endoscope.
- Remove the endoscope from the AFER carefully to avoid kinking and damage. Place on clean surface.
- Remove and discard PPE and perform hand hygiene.
- Ensure cleaning and reprocessing details are entered into the Procedure Report (manual process) or electronic tracking system (as per local procedure), including:
  - endoscope number
  - person who completed the manual cleaning
  - AFER machine used
  - cleaning cycle.
- Refer to WACHS Automated Endoscope Reprocessor Local Work Instructions

Drying

At completion of reprocessing, endoscopes are wet, but those required to be used immediately will not require further channel drying. All others require forced-air drying of the channels either manually for 10 minutes with regulated, compressed air, or preferably within a Therapeutic Goods Association (TGA)-approved forced-air or channel-purge endoscope drying CESC.

The following principles apply to forced-air drying:

- The parameters for drying are specific to each cabinet and vary by type of endoscope, temperature, humidity and storage time.
- European Standard (EN) 16442 requires that the drying process is complete within three (3) hours.
- Although 70% alcohol has traditionally been used to assist with drying, increasing emphasis on forced air drying of channels has concurrently de-emphasised the value of alcohol flushes.
- The CESC will alarm if endoscope connectors are not correctly attached, or the drying parameters are breached.
- Endoscopes are to be placed into the CESC ensuring that all attachments are connected, in accordance with the manufacturer's IFU.

Further reprocessing

Flexible bronchoscopes and cystoscopes are to be transported to the SSD as per local procedure for sterilisation and then transported to their sterile storage location.

Storage

After reprocessing, all endoscopes are to be stored in a TGA-approved CESC. This delivers a continuous flow of clean air through the channels of the endoscope when connected to the forced-air drying connectors.

The process for storing endoscopes is:

- Endoscopes can be stored up to seven (7) days before needing to be reprocessed, or as per the manufacturer's IFU and validation of the CESC.
- Endoscopes should remain within the CESC until required for use.
- Staff loading and unloading endoscopes from the CESC are required to scan their individual staff ID along with the endoscope ID to track storage and endoscope movement.

- The CESC will print a receipt detailing the endoscope ID and time of removal which is to be attached to the patient procedure record along with the AFER printout for the endoscope.
- The CESC will alarm to alert staff when the recommended endoscope storage time has been exceeded. Endoscopes are to be removed from the CESC and reprocessed before being used or returned to storage as per manufacturer's IFU.

For guidance on the maintenance of CESCs, refer to Section 2.7: Monitoring and maintenance of equipment - CESCs.

2.5 Reprocessing of Reusable Endoscopic Accessories

Reusable endoscopic accessories may include:
- water bottles and tube sets
- forceps, valves and buttons
- hot biopsy cords
- dilators/bougies.

As with endoscopes, the cleaning of accessories as a prerequisite to sterilisation is mandatory. The process includes:
- immersing used equipment in enzymatic detergent immediately following use
- dismantling all endoscopic accessories as far as possible before cleaning
- manually brushing and cleaning valves and buttons, paying special attention to the internal surfaces, using brush size as per the manufacturer's IFU
- brush and flush each item to remove visible soiling
- items are to be transported to the SSD as per local procedure for further reprocessing.

2.6 Endoscope Transport (Internal and External to Hospital)

Vigilance is required when transporting endoscopes adhering to the following process:
- Endoscopes should remain in the CESC until immediately before use.
- After removal from the CESC, endoscopes should be placed in a dedicated endoscope container/tray with disposable or reusable plastic cover, before being transported to the endoscope storage trolley or procedure room for use.
- Following procedure and bedside pre-clean, the used endoscope is to be placed in the dedicated endoscope container with a disposable or reusable cover marked "contaminated endoscope" and transported directly to the endoscope cleaning room.

Principles for transporting items for external repair:
- Endoscopes should be transported in a manner that avoids environmental contamination.
- Transport cases must be lined with plastic to ensure they do not become contaminated.
- Endoscopes are not to be stored in transport cases as these may be contaminated and do not allow air flow to remove residual moisture from the endoscope.
- Staff are to advise the manufacturer of the most recent reprocessing that has been undertaken on the damaged endoscope and send documentation/confirmation of this with the endoscope.
- In most circumstances, the endoscope does not need to be placed in a biohazard bag; in exceptional circumstances, such as when the endoscope has not been cleaned or

as advised by IPC, place the endoscope in a biohazard bag and notify the courier of the biohazard status.

Principles for loan endoscopes:

- All endoscopes returning from servicing or received on loan are to be cleaned and reprocessed as per the manufacturer's IFU prior to initial use.
- The internal channel configuration diagram should be provided or available online for all endoscopes received on loan.
- A copy of the most recent microbiological test results may be requested from the supplier of loan instruments.
- Endoscopes can be used after cleaning and disinfection and do not need to be kept quarantined while awaiting microbiological surveillance test results.
- A microbiological surveillance culture for bacteria should be performed within 72 hours of receipt of the endoscope.
    - If the result of the culture is positive, refer to Section 2.8: Microbiological testing for guidance.
- Results of microbiological cultures from loan endoscopes should be provided to the manufacturer when the loan endoscope is returned.

2.7 Monitoring and maintenance of equipment

AFERs

AFERs require regular cleaning and preventive maintenance and:

- must comply with AS 5369:2023 and ISO 15883
- regular maintenance and servicing are to be performed by Technical Service personnel every 3 – 6 months, as per the manufacturer's IFU or as required
- all AFER maintenance should be documented.

AFERs are required to undergo:

- **Installation Qualification (IQ)** - IQ verifies that the AFER being qualified (as well as its subsystems and any ancillary systems) has been installed and configured according to the manufacturer's specifications or installation checklist. It is a process of establishing, by objective evidence, that all key aspects of the process equipment and ancillary system installation comply with the approved specification. It documents that the system has the necessary prerequisite conditions to function as expected.
- **Operational Qualification (OQ)** - OQ is performed after meeting each protocol of IQ. OQ's purpose is to obtain and document evidence that equipment performance is consistent with the user requirements and specifications when operating within the manufacturer-specified operating ranges. This includes identifying and inspecting individual components of the equipment that can affect final product quality. All testing is documented. Any non-conformance is documented and resolved, and later conformance is then demonstrated.
- **Performance Qualification (PQ)** - The final step of qualifying equipment is PQ, which is performed immediately after IQ and OQ. This phase is the process of establishing (by objective evidence) that the equipment, in simulated real-world conditions, consistently produces a product that meets all predetermined requirements.
    - PQ is an annual requirement, with assessments undertaken at defined intervals, or after any major maintenance, repairs or modifications to equipment, or if there is a change of endoscope type or manufacturer. Requalification should also be performed as part of routine quality assurance processes.

CESCs

CESCs require regular cleaning and preventive maintenance. The following principles apply:

- CESCs must comply with AS 5369:2023 and EN16442:2015 and must have IQ, OQ and PQ completed as per guidance above.
- Undertake monitoring and maintenance activities for CESCs on a daily, weekly and monthly basis as outlined in Table 1.

Daily	• check the correct endoscope connection sets are present • visually inspect the connection sets for damage • visually inspect support arms for damage • lubricate O rings on the connection sets as required • Check printer rolls and ensure replacement stock, sufficient chemicals are available • clean interior with alcohol or a non-abrasive disinfectant with a lint-free cloth.
Weekly	• clean the exterior with alcohol or a non- abrasive disinfectant with a lint-free cloth • check air-flow rate through the system menu.
Monthly	• remove all connectors and air filters • flush connectors with alcohol (70%) • flush connectors with air and allow to air dry before replacing in CESC.

Table 1: Regular monitoring and maintenance of CESCs.

2.8 Microbiological testing

Only Endoscopy Nurses or Sterilisation Technicians who have undertaken appropriate training can undertake the collection of samples for microbiological testing of endoscopes and AFERs.

Microbiological testing of AFERs

AFERs are to be tested **monthly** as follows:

- Early detection of machine contamination is best achieved by a concentration process.
- The exact method of sample collection for an AFER will vary depending on the design of the individual machine and the AFER manufacturer should provide detailed instructions of the sampling method.
- Sample collection should be undertaken a minimum of 12 hours after the last use of the AFER. Ensure waterline disinfection has not occurred during this time.
- For machines using a filter process, a sterile, sealed, bacteria-retentive 0.2 µm or 0.45 µm filter should be connected to the outlet of the machine where it normally attaches to the endoscope, and at least 200 mL of fluid cycled through the filter in the rinse cycle mode.
- When completed, the filter is to be placed into a specimen container and forwarded to the laboratory, where the disc can be removed and plated directly.
- Some machines have a cycle for collection of water samples that interrupts the flow of water into the bowl, allowing collection from the water outlet within the machine. Care should be taken not to contaminate the outlet when collecting the sample.

- If the machine does not provide either of these sampling processes, water remaining from a reprocessing cycle needs to be collected with a syringe and sterile cannula from the basin.

If culture results are positive, refer to the IPC in Endoscopy 2021 guidelines figure 8.

Microbiological testing of Endoscopes:

- Bronchoscopes and cystoscopes are to be tested monthly (unless sterilised and stored in a wrapped state).
- Endoscopes that have been reprocessed through a sterilisation cycle and stored in a wrapped state are to be tested every three months.
- Colonoscopes, gastroscopes and all other gastrointestinal endoscopes are to be tested every three months.

Loan endoscopes must be tested as outlined in Section 2.6: Endoscope transport (internal and external to hospital) - Loan endoscopes.

Positive microbiological testing results may be due to:

- contaminated AFERs
- delays in cleaning
- the use of inappropriate disinfectants
- inadequate/deficient reprocessing
- damaged endoscope.

If culture results are positive, refer to the IPC in Endoscopy 2021 guidelines figure 5 and 7.

The Endoscopy Nurse is to:

- remove the endoscope from use
- reprocess the endoscope as per the process steps outlined in Section 2.4: Endoscope reprocessing
- resample the endoscope
- ensure the endoscope is quarantined until resampling results are available
- document results and follow-up action/s taken in the logbook.

If the results remain positive following resampling:

- positive cultures require immediate assessment. Following consultation with the IPC representative/team and manufacturer, further action is to be taken to investigate the cause/s
- implement remedial action/s as agreed
- undertake repeat culture/s to assess effectiveness
- undertake a review of the post-incident monitoring plan to confirm its adequacy.

Microbiological testing of CESCs

CESCs are to be tested annually as part of PQ. It is recommended that the efficacy of cleaning and disinfection procedures be verified by determining the contamination level using contact agar plates placed in four zones in the CESC as per guidance provided in the IPC in Endoscopy 2021 guidelines.

If culture results are positive, refer to the IPC in Endoscopy 2021 guidelines figure 9.

2.9 Safety considerations

Ventilation

Reprocessing areas require appropriate ventilation to minimise staff inhalation of biological aerosols, with a minimum of 12 air exchanges per hour required.

Safety is an important aspect of reprocessing endoscopes and accessories. There are significant risks of acquiring an infectious disease from blood or other body fluid exposure or exposure to potentially hazardous substances. It is essential that staff use appropriate PPE to decrease the risk of exposure. Refer to Section 2.2: Use of appropriate Personal Protective Equipment (PPE).

Appropriate Safety Data Sheets (SDSs) and spill kits must be available.

Storage and handling precautions for peracetic acid

Peracetic acid is commonly used for high-level disinfection. It is flammable, corrosive and classified as hazardous to health. Exposure may cause:

- Eye irritation – lacrimation, burns, conjunctivitis, inflammation and permanent eye damage including blindness
- Respiratory irritation – coughing, sneezing, mucous production, nausea, headache and breathing difficulty
- Skin irritation – severe burns and contact dermatitis.

A manufacturer's SDS must be readily available, read and understood by all users of peracetic acid solutions. Staff must be trained in the use of peracetic acid.

Peracetic acid supplied for use in most AFERs is a two-part liquid dose system. The system uses two storage containers; one holds the peracetic acid concentrate and the other holds the buffer/anti-corrosive concentrate. The chemicals must be stored in separate chemical storage cabinets.

The process for working with peracetic acid is as follows:

- Don appropriate PPE:
  - chemical safety goggles or safety spectacles with side shields or face visors
  - gloves that cover any exposed skin and are not permeable to peracetic acid
  - impervious long-sleeved gown or apron.
- Handling and transporting of peracetic acid must be kept to a minimum. Do **not** decant peracetic acid back into bottles or transport open containers. Refer to the SDS.
- The containers must be stored upright and away from heat and light sources. Designated chemical storage cabinets are recommended.
- Areas where peracetic acid is in use are to be well ventilated, with a minimum of 12 air changes per hour. Alternatively, extractor fans are recommended.
- Empty peracetic acid containers are to be sealed and disposed by incineration. Dispose used containers and materials from spills clean-up in a sealed yellow plastic biohazard bag and put into incineration waste bin.
- Clean up spills immediately using a peracetic acid spill kit. The peracetic acid spill kit is kept at the point of use and contains:
  - half-face respirator with an organic vapour cartridge
  - skin and eye protection equipment
  - emergency eyewash solution

  - acid neutralising agent/absorbent pad
  - scoop scraper to pick up the spill
  - absorbent wipes
  - yellow biohazard waste bag
  - black waste bag.
- The Sterilisation Technician is responsible for checking the contents of the spill kit and its expiry dates and documenting in the chemical spill logbook.
- The SSD Manager/Supervisor must ensure the spill kit is checked monthly and recorded on the relevant checklist.

Process for cleaning peracetic acid spills

The process for cleaning peracetic acid spills is as follows:

- Collect spill kit.
- Don appropriate PPE plus:
  - half-face respirator with an organic vapour cartridge
  - nitrile rubber gloves
  - impervious material gown.
- Evacuate personnel from immediate area of spill. Place “Caution” sign on floor.
- Sprinkle acid neutralising agent over the spill and ensure it is completely covered. The acid neutralising agent will turn red on the spill and then yellow when neutralised.
- Pick up congealed matter with scoop and scraper and place into yellow clinical waste/ biohazard waste bag.
- Wipe any remaining residue from floor with dampened yellow cloth.
- Place contaminated wipes and all protective garments into the yellow biohazard waste bag. Dispose of used waste bag in clinical waste bin.
- Wash area and equipment with detergent and water, followed by a copious amount of water.
- Notify the Safety Representative and complete a Hazard Report. The report is to be sent to the Work Health and Safety representative to assess the incident and prevent an accident from reoccurring.
- Immediately inform the SSD Manager/Supervisor to replace the contents of the spill kit.

3. Roles and Responsibilities

Health Service Organisations are responsible for ensuring that adequate resources and support are provided to ensure a safe working environment for all staff.

The **SSD Manager/Supervisor** is to implement the requirements of this document to ensure the processing of RMDs is compliant with AS 5369:2023 and associated normative references and ensure the quality and safety of reprocessed endoscopes.

Sterilisation Technicians and/or endoscopy nursing staff must comply with the requirements of this document and report non-compliance to the SSD Manager/Supervisor or Perioperative Services Manager.

Engineering/Facilities Management staff are responsible for supporting the maintenance of reprocessing equipment in the SSD.
IPC staff are responsible for ensuring compliance with relevant IPC standards and providing advice/support in relation to microbiological testing results.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

4.1 Monitoring

Regular monitoring and auditing of reprocessing processes will facilitate compliance with relevant Standards, quality patient outcomes and improved staff satisfaction. Results of noncompliance are to be escalated to the local peri-operative/SSD meetings.

The SSD Manager/Supervisor or Perioperative Services Manager are responsible for ensuring that:

- monitoring of compliance with this document is carried out in line with AS 5369:2023 and IPC in Endoscopy 2021 guidelines
- risk assessments are completed, outcomes evaluated, and actions taken as required.

The results of microbiological testing must be reviewed monthly, three monthly, six monthly and annually by SSD/Perioperative Manager and an IPC team member. All identified issues must be escalated and reported to the local Perioperative Management Committee and Infection Prevention and Control Committee. They are also to be tabled at the Perioperative/Surgical Services Committee Meetings and Regional Infection Prevention and Control Committee meetings, with any issues escalated to the Regional Safety and Quality Committee.

4.2 Evaluation

Review of this document will be coordinated by the Surgical Services Program Team in collaboration with key stakeholders including relevant Advisory Forums. This will consider any trends in relation to clinical incidents and the results of ongoing quality monitoring activities that are undertaken at a site/regional level.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS 5369:2023.

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to Section 26 of the *Health Services Act 2016* (WA) 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 and procedures is mandatory.

6. References

AS/NZS 1336:2014. Eye and face protection – Guidelines. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

AS 5369:2023. Reprocessing of reusable medical devices and other devices in health and non-health related facilities. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

ISO 15883-1:2006. Washer-disinfectors – Part 1: General requirements, terms and definitions and tests. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

ISO 15883-4:2018. Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

EN 16442:2015. Controlled environment storage cabinet for processed thermolabile endoscopes. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

Australasian Health Infrastructure Alliance (AHIA). Australasian Health Facility Guidelines – Part B Health Facility Briefing and Planning. 0190 – Sterilizing Services and Endoscope Reprocessing Units. AHIA, 2022.

Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia (GESA), 2021.

Gastroenterological Nurses College of Australia (GENCA). Position Statement – Educational requirements for personnel reprocessing flexible endoscopic equipment. GENCA Board, 2010 (updated 2021).

7. Definitions

Term	Definition
Automated Flexible Endoscopic Reprocessor (AFER)	Machine designed to disinfect and rinse endoscopes, providing a reliable and effective high-level disinfection and chemical sterilisation.
Controlled Environment Storage Cabinet (CESC)	Designed for the storage of endoscopes, a cabinet that controls the storage environment, including temperature and humidity.
Endoscope	In the context of this procedure, this includes flexible endoscopes such as gastroscopes, colonoscopes, bronchoscopes, cystoscopes.
Gastroenterological Nurses College of Australia (GENCA)	Represents the interests of gastroenterology and endoscopy, promoting excellence in gastroenterology nursing practice.
Gastroenterological Society of Australia (GESA)	Represents Australian healthcare professionals and researchers working within gastroenterology and

	hepatology. GESA strives to set, promote and continuously improve standards and clinical practice.
Installation Qualification (IQ)	A process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.
Manual cleaning	Manual cleaning refers to the physical task, performed by hand, of removing secretions and contaminants from the endoscope with appropriate brushes, cloths, detergents and water.
Operational Qualification (OQ)	A process of obtaining and documenting evidence that installed equipment operates within pre-determined limits when used in accordance with its operational procedures.
Performance Qualification (PQ)	A process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with the operational procedures, consistently performs in accordance with pre-determined criteria and thereby yields product meeting its specification.
Personal Protective Equipment (PPE)	All equipment which is intended to be worn or held by a person to protect them from risk to health and safety while at work.
Reusable medical device (RMD)	A medical device designated or intended by the manufacturer as suitable for processing and reuse. Clarification notes: 1. An RMD is presented for use either as an individually packaged RMD or as more than one RMD assembled and packaged together as a group or set. For the purposes of this document, the term RMD includes a loan RMD and a trial RMD and applies to all reusable devices that require reprocessing.
Safety Data Sheet (SDS)	The SDS is specific to a particular chemical and includes information such as the properties of the chemical; the physical, health, and environmental hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical.
Sterilisation Services Department (SSD)	Also known as Central Sterilising Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service Organisation that performs cleaning, disinfection and sterilising actions on RMDs and manages storage of sterile stock and consumables.
Therapeutic Goods Association (TGA)	Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods.

8. Document Summary

Coverage	WACHS wide
Audience	All WACHS healthcare workers that use or reprocess endoscopes
Records Management	Non Clinical: Corporate Recordkeeping Compliance Policy Clinical: Health Record Management Policy
Related Legislation	• *Therapeutic Goods Act 1989* (Cwth) • *Health Services Act 2016* (WA)
Related Mandatory Policies / Frameworks	• Clinical Governance, Safety and Quality Policy Framework • National Safety and Quality Standards Accreditation Policy – MP 0134/20
Related WACHS Policy Documents	• Aseptic Technique Policy • Clinical Audit Policy • Environmental Cleaning Policy • Hand Hygiene Policy • Handling, Transport and Storage of Released Reprocessed Reusable Medical Devices Procedure • Infection Prevention and Control Policy • Managing Risks of Hazardous Chemicals and Dangerous Goods Procedure • Nonconforming Reusable Medical Devices Procedure • Packing, Wrapping and Sealing Reusable Medical Devices Procedure • Quality Management and Validation Procedure (under development) • Reprocessing Reusable Medical Devices Policy • Reusable Medical Devices on Loan and Instruments on Trial Procedure • Waste Management Policy • Work Health and Safety Policy
Other Related Documents	• GESA Infection Prevention and Control in Endoscopy 2021 guidelines • WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 2213
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.03, 3.05, 3.06, 3.07, 3.08, 3.09, 3.10, 3.11, 3.12, 3.13, 3.14, 3.17
Aged Care Quality Standards	Nil

Chief Psychiatrist's Standards for Clinical Care	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	23 January 2024	23 January 2024	New Procedure
1.01	24 May 2024	23 January 2024	Minor amendment to update broken link to GESA IPCE 2021 guidelines

10. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing - Perioperative
Business Unit	Nursing and Midwifery - Surgical Services
EDRMS #	ED-CO-23-318735

This document can be made available in alternative formats on request.

Appendix A: Personal Protective Equipment

Personal protective equipment (PPE) consistent with standard and transmission-based precautions in the endoscopy unit*

PPE consistent with standard precautions † – These practices apply to all patients and include the use of PPE as appropriate or when indicated, based on the risk of contact with, or splash and splatter by, blood and body fluids. This means PPE does not need to be used for all patients, but only when a risk is identified. The PPE chosen should be consistent with the risk:

- non-sterile single-use disposable gloves ± a gown for direct contact
- face and eye protection with face shield or goggles and mask for potential for splash.

PPE consistent with standard plus contact and droplet precautions:

- fluid-resistant surgical mask
- non-sterile single-use disposable gloves
- protective face wear (wrap around glasses or preferably single-use disposable/regularly cleaned reusable face shield)
- disposable impervious long-sleeved gown or apron.

PPE consistent with standard plus contact and airborne precautions:

- fluid-resistant particulate filter respirator (PFR) mask or powered air purifying respirator (PAPR)
- protective face wear (wraparound glasses or preferably single-use disposable/regularly cleaned reusable face shield)
- impervious long-sleeved disposable gown
- non-sterile single-use disposable gloves.

* Consideration may be given to also wearing surgical scrubs during endoscopic procedures.
† Note that a surgical mask is not required for standard precautions.
§ Before starting the procedure, PPE should be fit-checked for everyone who will be in the room during the procedure to confirm it is correctly fitted.

Eye protection

The selection and use of eye protection should be in accordance with AS/NZS 1336:2014. To assess what eye protection is required, consideration should be made of any risks associated with the task.

For example:

- When handling hazardous substances, where splashing of the concentrated solution may occur, chemical safety goggles should be used if indicated by the manufacturer.
- When handling small quantities of dilute solutions, chemical safety spectacles with side shields may suffice.
- When reprocessing endoscopes, face shields should be used to protect the wearer from exposure to biological and chemical hazards.