

Reprocessing guidelines

Frequently asked questions (FAQ)

Updated RACGP Infection prevention and control guidelines – Reprocessing of reusable medical devices

Implementation notice

This FAQ reflects the updated RACGP IPC Guidelines for reprocessing reusable medical devices aligned with Australian Standard AS 5369. These requirements are subject to a transition period and are not mandatory for accreditation purposes until 1 January 2028.

The responses provided outline the future requirements and are intended to support practices in understanding, preparing for, and progressively implementing the changes ahead of the accreditation deadline.

Why have the guidelines been updated?

Accepted best practice has changed. The updates were necessary to ensure RACGP IPC Guidelines align with the new Australian Standard AS 5369: *Reprocessing of reusable medical devices in health and related services*. The changes to the RACGP's IPC Guidelines ensure that general practice reprocessing meets the latest and current national standard for patient safety, infection prevention, and quality care.

The Australian Standard AS 5369 sets a consistent national benchmark for reprocessing across healthcare settings. The RACGP has contextualised AS 5369 for general practice, and changes to our IPC Guidelines are intended to strengthen infection prevention and control while remaining practical and implementable for general practice.

Changes made to reprocessing guidelines in the RACGP IPC Guidelines reflect:

- patient safety and quality – reprocessing is a high-risk activity, and consistent best practice reduces the risk to patients of healthcare-associated infections
- national consistency – aligning with the Australian Standard AS 5369 to ensure general practice is in step with current best practice and national standards
- accreditation clarity – the updates provide practices and surveyors with clearer guidance.
- future-proofing – embedding a risk-based approach allows flexibility and scalability across diverse general practice contexts.

Key updates for reprocessing reusable medical devices

What are the key changes I need to know about?

Table 1 outlines the key changes are to reprocessing in the IPC Guidelines.

Table 1 Overview of key changes for reprocessing in general practice in the IPC Guidelines

| Area | Prior practice/guideline | New/clarified guideline (aligned to AS 5369) |
|------------------------------|---|--|
| National standard referenced | AS/NZS 4187:2014 and AS/NZS 4815:2006 | AS 5369 – Reprocessing of reusable medical devices and other devices in health and non-health related facilities |
| | Informally guided | These guidelines are explicitly aligned to Australian Standard AS 5369 |
| Framework | General instructions only | Risk-based approach where each practice needs to document a structured risk assessment for reprocessing Risk assessment is now a documented, auditable requirement under the <i>Standards for general practices</i> (6th edition) criterion CG9.E |
| Cleaning equipment | Manual cleaning was acceptable | Washer-disinfector is required for pre-cleaning (manual cleaning alone no longer sufficient, except when the manufacturer advises) |
| Ultrasonic cleaning | Optional | Remains an optional step before washer-disinfector |
| Dedicated area | Separation between clean/dirty zones required | Dedicated or clearly segregated area required; layout and workflow must prevent contamination and be documented |
| Initial treatment timing | “Promptly after use” (undefined) | Ideally within 1 hour, no later than 4 hours after use |
| Training | Staff must be competent | Structured, documented training and competency assessment required; formal qualifications are not mandatory. Practices need to ensure that training, supervision, and competency assessment are delivered and overseen by a competent person. |
| Traceability | Strongly encouraged | Explicit requirement to record device tracking, batch/cycle numbers, and patient linkage |
| Validation | Annual validation of steriliser only | Annual validation applies to all reprocessing equipment, including washer-disinfector, with defined monitoring intervals |
| Outsourcing | Allowed to any external provider | Must be a hospital or an accredited facility (including accredited general practice), or co-located site that surveyors can review. |
| Environmental impact | Mentioned briefly | Emphasis on sustainability and considering environmental impact of resources and processes |

What does a risk-based approach to reprocessing reusable medical devices involve?

A risk-based approach is a structured method used to ensure the safe and effective reprocessing of reusable medical devices. It involves identifying potential risks at each stage of the reprocessing cycle and applying appropriate controls to minimise those risks.

This approach helps practices:

- protect patients, staff, equipment, and the environment
- make informed decisions based on the likelihood and consequences of risks
- comply with national safety and accreditation standards.

The IPC Guidelines provide practices with a framework for risk-based approach – a structured, stepwise risk management process aligned with best-practice standards. This incorporates the following steps:

- Appointing a team: Forming a reprocessing team including an IPC lead.
- Process mapping: Defining clear workflow for evaluating and managing device risks.
- Risk identification: Recognising hazards, potential misuse, and device-specific concerns.
- Risk evaluation: Assessing likelihood, consequence, and overall acceptability of risks.
- Risk control: Applying measures to reduce risk (e.g., training, improved instructions, redesign).
- Residual risk assessment: Understanding any remaining risks after controls are applied.
- Review and monitoring: Continuously monitoring and updating risk controls for ongoing safety.
- Implementation: Collecting, reviewing, and acting on information to maintain safe reprocessing practices.

By following a risk-based approach, practices can tailor their infection prevention strategies to their specific context and complexity, ensuring consistent and compliant reprocessing.

Is a dedicated reprocessing area required?

Practices need to have a designated area for processing reusable medical devices and need to establish a workflow pattern that prevents the packaging, sterilisation and storage areas becoming contaminated. This involves systematically moving from 'dirty' to 'clean' within the designated area.

The reprocessing area needs to be segregated from treatment and administration areas.

Ideally, there is a dedicated room for reprocessing. In shared spaces, a practice needs to be able to demonstrate what physical methods or barriers are used to segregate reprocessing activities. If reprocessing is conducted in a shared space, the practice needs to use physical methods or barriers to segregate reprocessing activities, for example, by locating the patient bed away from the sterilising area, not processing equipment when there are patient/s in the treatment room. The methods used need to be identified in the risk register and the mitigants identified

Is a washer-disinfector required for reprocessing reusable medical devices?

Yes – it is now required and considered best practice. Key benefits and requirements include:

- Improved safety and compliance:
 - Delivers consistent, validated cleaning and thermal disinfection.
 - Reduces variability and error compared to manual cleaning.
 - Supports alignment with AS 5369 and national standards.
- Operational efficiency:
 - Minimises staff exposure to contaminated instruments.
 - Reduces manual workload and improves workflow.
 - Frees up time for clinical care.

- Installation flexibility:
 - Different units are available that can be placed under the bench, on the bench, or as a tall unit.
 - Needs to support ergonomic loading/unloading and maintain unidirectional workflow.

Is manual cleaning acceptable?

Manual cleaning alone is not acceptable unless the device's instructions for use specifically prohibit automated cleaning.

Is an ultrasonic cleaner required for reprocessing reusable medical devices?

No. Ultrasonic cleaners are an optional pre-cleaning step that use high-frequency sound waves to create microscopic bubbles in water.

Ultrasonic cleaning is not a complete cleaning process – it does not remove all debris and does not provide thermal disinfection. Therefore, items must be promptly transferred to a washer-disinfector immediately after the ultrasonic cycle for thorough cleaning and thermal disinfection.

Are two sinks required in the reprocessing area, given a washer-disinfector is needed for pre-cleaning?

Not necessarily. If a washer-disinfector is used for pre-cleaning reusable medical devices, manual cleaning is not routinely required. In this case, a second sink is not mandatory provided the practice can demonstrate, through a documented risk assessment, that:

- all devices are compatible with the washer-disinfector, and
- contingency procedures are in place for times when the washer-disinfector is unavailable.

The number and purpose of sinks in the reprocessing area must be recorded in the practice's risk register and reviewed regularly to ensure ongoing compliance and safety.

What training or qualifications are required for staff involved in reprocessing activities?

There is no formal and certified qualification requirement, but staff involved in reprocessing must receive adequate education, training, and competency assessments. These need to be documented and reviewed regularly.

Training needs to ensure that staff:

- understand each step of the reprocessing process and can perform it correctly
- have access to clear, up-to-date instructions
- are assessed as competent in tasks such as cleaning, sterilisation, record keeping, and equipment maintenance.

Training can be delivered in-house by a knowledgeable and experienced staff member, provided it is based on current standards and guidelines. Additional training is required when new equipment or procedures are introduced.

What is the required timeframe for reprocessing reusable medical devices after use?

Reusable medical devices must undergo initial treatment immediately after use at the point of care. This typically involves wiping with a low-lint disposable cloth or applying a TGA-registered instrument pre-cleaning product to remove visible soiling.

Devices should then be transported to the reprocessing area in a dedicated, sealable, leak- and puncture-resistant container.

The time between use and full reprocessing is:

- ideally within one hour, and
- no more than four hours.

If cleaning is unavoidably delayed, devices that have undergone initial treatment may be held in a suitable, labelled container with a compatible pre-cleaning product, used according to the manufacturer's instructions and maximum holding time.

Can a general practice use offsite sterilisation services for reusable medical devices?

Yes, a general practice may use offsite sterilisation services if in-house reprocessing is not feasible. The service needs to meet current reprocessing standards and be:

- provided by an accredited facility (eg another accredited general practice, hospital sterilisation service), or
- in a co-located reprocessing facility – such as those within a shared or multi-site setting – that can be accessed and assessed by a surveyor during on-site accreditation.

The practice must have a documented agreement that outlines:

- the accreditation standard the provider meets
- scope of services and responsibilities for each reprocessing stage
- safe transport procedures (if applicable)
- tracking and traceability systems
- evidence of equipment calibration and validation

Managing implementation costs

Are there any financial considerations or supports to help with implementation?

Yes. Practices should consider available financial and planning options to support the transition to the updated reprocessing requirements.

Asset write-offs and tax considerations¹

Eligible small businesses may be able to claim an immediate deduction or accelerated depreciation for certain capital purchases (such as washer-disinfectors and related equipment), subject to current Australian Taxation Office (ATO) rules and thresholds. As tax rulings change over time, it is recommended that practices seek advice from their accountant or tax adviser to understand what concessions apply at the time of purchase.

¹ This information is general in nature and reflects typical arrangements as at the time of publication. As tax settings may change, practices should seek advice from their accountant or tax adviser to understand what concessions apply to their specific circumstances.

RACGP advocacy

The RACGP recognises the cost implications of these changes and will continue to advocate for appropriate support mechanisms, including potential Primary Health Network (PHN) funding or other government assistance, to help practices implement the updated requirements.

Practical strategies to manage costs

- **Plan early during the transition period:** Use the implementation timeframe to stage purchases and spread costs across financial years.
- **Prioritise high-risk gaps first:** Focus initial investment on areas with the greatest patient safety or compliance risk.
- **Explore different equipment options:** Bench-top and under-bench washer-disinfectors may offer more affordable or space-efficient alternatives.
- **Consider shared or outsourced models:** Where appropriate, using accredited external reprocessing services or shared facilities may reduce upfront capital costs.
- **Integrate upgrades with broader improvements:** Align reprocessing changes with planned refurbishments or equipment replacement cycles.
- **Engage suppliers early:** Suppliers may offer leasing, payment plans, or bundled servicing arrangements.

Record progress for accreditation

During the transition period, keeping evidence of financial planning, procurement steps, and staged implementation can support demonstration that the practice is actively working towards compliance.

Additional changes to the IPC Guidelines

Have any additional updates been made to the IPC Guidelines outside of the reprocessing section?

Yes. In addition to updates across the reprocessing section of the IPC Guidelines, the following updates have been made elsewhere:

Role of the Infection prevention and control coordinator

The IPC Coordinator's responsibilities now include chemical safety management.

Practices need to ensure the IPC coordinator maintains a hazardous chemicals register with current safety data sheets.

The coordinator also needs to inform staff and emergency services personnel about safe chemical handling and storage, or ensure this information is easily accessible.

Work health and safety – Environmental cleaning

Work health and safety requirements now explicitly apply to both employed and contract cleaners.

Practices need to:

- have contractors follow work health and safety protocols
- retain contractor documentation
- establish formal agreements outlining responsibilities for chemical safety and documentation.

Chemical safety procedures

Practices need to have documented procedures for the safe use, storage, transfer, and disposal of all chemicals used on-site.

This includes chemicals used in reprocessing and by contractors.

Procedures need to cover:

- secure storage and correct labelling
- use of PPE and first aid measures
- spill kit contents and emergency protocols.

Implementation of updated guidelines

Is there an implementation period?

Yes – To support a smooth transition, practices will have **until 1 January 2028** to implement the updated requirements. During this period:

- accreditation assessments will not require full compliance with the updated reprocessing guidelines; however, surveyors may look for evidence that practices are aware of the changes and are actively preparing for implementation
- practices are strongly encouraged to begin reviewing current processes, identifying gaps, and planning for necessary changes – including equipment, workflows, and staff training
- the transition period is designed to allow time for thoughtful implementation, not to delay action.

From 1 January 2028, adherence to the updated reprocessing guidelines will be assessed as part of accreditation.

Do we need to buy new equipment right away?

If your practice does not currently have a washer-disinfector, you will need to plan for one. You may continue using current processes during the implementation period, provided you can demonstrate steps towards meeting the requirement (for example, budget approval, supplier engagement, workflow planning).

How do the changes affect accreditation?

During the implementation period, surveyors will:

- expect practices to be aware of the new requirements
- look for evidence that the practice is working towards implementation
- review records of training, servicing, validation, and monitoring of equipment.

What should we do now?

- Read the updated IPC Guidelines.
- Assess your current processes and equipment against the new requirements.
- Develop an implementation plan (eg equipment upgrade, staff training, workflow adjustments).
- Keep records of your progress during the transition period.