cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Reprocessing Ultrasound Transducers

IPAC program FAQ

Infection Prevention & Control (IPAC) Program
November 2025

Last updated November 2025

Purpose

CPSA's Infection Prevention & Control (IPAC) program has identified that physicians and clinic staff could benefit from additional information and considerations when reprocessing ultrasound transducers.

It is essential that reusable ultrasound transducers be properly reprocessed to prevent cross-contamination and ensure patient safety.

This FAQ document is intended to assist physicians and medical clinic staff in understanding:

- **Section 1:** Reprocessing requirements for ultrasound transducers
- **Section 2:** Reprocessing methods and frequency
- **Section 3:** Transporting of soiled or disinfected transducers
- **Section 4:** Using automated transducer reprocessors
- **Section 5:** Manual high-level disinfection requirements
- **Section 6:** Documentation, training and storage requirements

For assistance or more information, contact CPSA's IPAC program at ipac@cpsa.ab.ca or 780-969-5004.

1. Reprocessing requirements for ultrasound transducers

Why is proper reprocessing of ultrasound transducers important?

Proper reprocessing of ultrasound transducers is essential to prevent cross-contamination and ensure patient safety.

Follow the manufacturer's instructions for use (MIFU) and ensure self-compliance with CPSA's Reusable & Single-Use Medical Device Requirements for Medical Clinics (CPSA RMD Requirements).

Can sterile or clean barriers replace reprocessing?

No, sterile or clean barriers applied to probes are not a substitute for proper reprocessing. Barriers can reduce contamination risks, but do not eliminate them. Microscopic tears or improper application can compromise barrier effectiveness.

All ultrasound transducers must be reprocessed according to the MIFU, regardless of whether a barrier was applied.

2. Reprocessing methods and frequency

How should I determine the appropriate reprocessing method for an ultrasound transducer?

Reprocessing methods depend on the transducer's intended use and classification.

- **Non-critical classification:**
  - Used on intact skin only.
  - Requires low-level disinfection, at minimum.
- **Semi-critical classification:**
  - Contacts mucous membranes or non-intact skin.
  - Requires high-level disinfection, at minimum.
- **Critical classification:**
  - Enters sterile tissue or the vascular system.
  - Requires sterilization.

To identify the correct reprocessing method and classification for your transducer, refer to the MIFU (CPSA RMD Requirements, Section 7.1).

How often should ultrasound transducers be reprocessed?

Transducers must be reprocessed after each use and prior to reuse.

3. Transporting of soiled or disinfected transducers

How should transducers be transported?

Appropriate transportation of transducers prevents the potential for cross-contamination and device damage and ensures staff safety.

Transport soiled or ready-to-use transducers in a covered, fully enclosed, leak-proof and labelled container that can withstand frequent cleaning and disinfection.

Can disinfecting wipes be used for pre-cleaning if high-level disinfection is to follow?

No, disinfecting wipes should not be used as part of the pre-cleaning step when high-level disinfection (HLD) is to follow.

Use only transducer-compatible products as outlined in the MIFU for pre-cleaning. This may include a soft cloth with a mild detergent or a manufacturer-approved cleaning wipe to remove gel and debris immediately after use.

Disinfecting wipes may leave residues that can interfere with the effectiveness of high-level disinfectants and are not recommended unless explicitly stated in the MIFU.

4. Using automated transducer reprocessors

How do automated transducer reprocessors work?

Automated transducer reprocessors offer a standardized and efficient method for high-level disinfection of **semi-critical** ultrasound transducers.

Four key steps in using automated transducer reprocessors:

1. **Pre-cleaning:**
    - Immediately after use, remove gel and debris with a lint-free or low-lint disposable cloth using a manufacturer-approved detergent.
    - Do not use disinfecting wipes during pre-cleaning unless stated as compatible in the device MIFU (CPSA RMD Requirements, Section 5.3).

2. **Manual cleaning:**
    - Manual cleaning must occur prior to using the automated reprocessor. Perform a thorough cleaning using a detergent, solution or cleaning wipe specified in the MIFU to eliminate organic material, as residuals can interfere with the disinfection process.
3. **High-level disinfectant validation:**
    - Ensure the high-level disinfectant (HLD) and automated transducer reprocessor are validated for use with the specific transducer being reprocessed.
4. **Documentation**
    - Automated disinfection systems will provide a record that critical parameters (e.g., disinfectant temperature, concentration, contact time) have been met (CPSA RMD Requirements, Section 7.9).

5. Manual high-level disinfection requirements

What if we use manual high-level disinfection methods?

If you perform manual high-level disinfection (HLD):

- Use only high-level disinfectants listed as compatible in the transducers' MIFU and follow the high-level disinfectants' Safety Data Sheets (SDS) requirements.
    - For example:
        - Ortho-phthalaldehyde (OPA) requires a reprocessing room with 10 air exchanges per hour for adequate ventilation.
        - If your reprocessing area does not meet SDS ventilation requirements, OPA cannot be used.
- Ensure staff wear appropriate personal protective equipment (PPE), including gloves, gowns, eye protection and masks, as per SDS and CPSA requirements.

What are the documentation requirements for manual high-level disinfection?

At a minimum, the clinic shall document and maintain records on (CPSA RMD Requirements, Section 6.1):

- **HLD solution:**
    - Record the product name, drug identification number (DIN) or medical device licence (MDL) and batch/lot number.
- **HLD test strips:**
    - Record the product name, lot number and expiry date.
- **Results of MEC testing:**

  - Document the date, time and results of each test.
- **Contact time and temperature:**
  - Record the exact contact time and temperature during each disinfection cycle.
- **Cycle parameters (for automated transducer reprocessors):**
  - Document the cycle type, duration and any alerts or warnings.
- **Medical device name or type:**
  - Record the specific transducer, including model or serial number if applicable.
- **Personnel activity documentation**:
  - Document who performed the reprocessing activities for each individual transducer.

6. Documentation, training and storage requirements

What are the training and education requirements for reprocessing staff?

Training and education must include (CPSA RMD Requirements, Section 7.1):

- **Comprehensive in-house training:**
  - Staff must receive thorough training on the specific reprocessing methods used.
- **Vendor training:**
  - Attend training sessions provided by equipment and disinfectant manufacturers.
- **Training logs:**
  - Maintain accurate and up-to-date records of all training sessions.
- **Competency testing:**
  - Conduct regular competency assessments to verify that staff can correctly perform reprocessing tasks.

How do I track the transducer high-level disinfection?

The clinic must establish a system to track high-level disinfected transducers and link them to patients. This includes:

- **Recording transducer information:**
  - Document the transducer number or unique identifier in the patient's medical record for each use.

- **Tracking usage history:**
  - Maintain a log of which transducer was used on each patient, including the date and time of use.
- **Traceability:**
  - Ensure that all documentation allows for traceability.

All documentation must be retained, as per clinic policy. CPSA suggests a minimum of five years to ensure compliance and facilitate audits.

How do I store ready-to-use transducers?

The clinic must ensure transducers are stored in a manner that prevents potential contamination and damage as per the MIFU. Staff must store them in a protected and clean area, and ensure ready-to-use probes are only accessed from storage with clean hands.

Where can I find additional resources and guidelines?

- The device's manufacturer's instructions for use (MIFU)
- CPSA's Reusable & Single-Use Medical Device Requirements for Medical Clinics
- CSA Standards Z314.23: Canadian medical device reprocessing in all health care settings

For assistance or more information, contact CPSA's IPAC program at ipac@cpsa.ab.ca or 780-969-5004.