



# IPAC CANADA PRACTICE RECOMMENDATIONS

## Reprocessing Ultrasonic Transducer Probes Used in All Healthcare Settings

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### **Background:**

Ultrasound transducer probes are being used for a wide range of external, interventional and endocavitary procedures throughout health care. There is a lack of knowledge and consistency regarding how to manage these devices to prevent cross-transmission between patients.<sup>1,2</sup> Contaminated transducer probes, handles and medical gels have been implicated in transmitting organisms from patient to patient.<sup>3-24</sup> The goal of this document is to provide reprocessing and IPAC recommendations for the safe management of ultrasound devices between patients. This will include ultrasound transducer probe point-of-use pre-cleaning, cleaning, disinfection, sterilization, safe transportation, storage, and use of medical gels.<sup>25-29</sup>

**Scope:** Ultrasound transducer probes used on intact or non-intact skin, mucous membranes, sterile body cavities, or vascular systems.

Refer to the Endoscopy section of the current Canadian Standards Association (CSA) Z314 for guidance for Endoscopic Ultrasound (EUS) or Endobronchial Ultrasound (EBUS).<sup>27</sup> Endoscopic ultrasounds are not in scope for these practice recommendations.

### **Introduction:**

Patients expect and require safe care regardless of the procedure or where the procedure using an ultrasound transducer probe is performed in any healthcare setting.

The Spaulding classification (see Appendix) of any medical device is based on the intended or potential use of that device (see definitions). This will determine the cleaning, disinfection, and safe reprocessing of the ultrasound transducer probe, hand piece<sup>29,30</sup> and cable. Decide the correct level of reprocessing according to the Spaulding classification before use.

Portable handheld wireless transducers must meet the same level of reprocessing in the Spaulding Classification as outlined in the Appendix.

If non-critical transducer probes and handles will potentially be used on broken skin, or for interventional procedures such as biopsy or aspiration, the transducer must be high level disinfected, at a minimum, before and after the procedure, to meet the requirements for semi-critical or critical transducer probes. Low level disinfection does not kill microorganisms to the level needed for semi-critical and critical procedures.

As a minimum, “high level disinfection must be performed for all semi-critical and critical ultrasound procedures as persistent contamination following low level disinfections (LLD) has been demonstrated even with transducer cover use.”<sup>28</sup> Carrico<sup>2</sup>, Rutala<sup>3</sup> and LeRoy et al<sup>31</sup> support the use of high level disinfection for these procedures even with the use of a sterile probe cover. Zali et al<sup>18</sup> found that disinfecting transvaginal probes with low level disinfectant wipes and covering with a disposable cover increased the risk of cross contamination of organisms such as Human papillomavirus (HPV), *Chlamydia trachomatis*, mycoplasmas and other organisms, and created a potential risk to patients.

## **I. Practice Requirements and Recommendations pertaining to all procedures.**

**The current Canadian Standards Association (CSA) Z314<sup>27</sup>, *Medical Device Reprocessing* and national/provincial/territorial IPAC best practices shall be followed.**

***If there is discrepancy between the MIFU and national standards, the higher standard shall be used***<sup>32</sup>

### **A. All health care settings:**

1. Shall have sufficient numbers of ultrasound transducer probes to perform reprocessing according to standards.
2. Shall have manufacturer’s instructions for use (MIFU) (cleaning, disinfection and or sterilization). Ultrasound transducer probes shall not be purchased, used, or reprocessed if there is no MIFU.
3. Shall follow the MIFU, current national guidelines including current CSA Z314, the Public Health Agency of Canada (PHAC/Health Canada), and provincial/territorial standards.
4. Shall have a process for soiled/used medical devices to be handled and transported in a manner which reduces the risk of exposure and/or injury to personnel and patients, or contamination of environmental surfaces.

**Note:** Pre-cleaning (or point of care cleaning) is performed at the bedside immediately post procedure and cleaning is performed in a physically separate designated reprocessing area.

### **B. All healthcare providers shall:**

1. Perform hand hygiene before and after cleaning any medical device.
2. Consistently follow Routine Practices and Additional Precautions (including risk assessment, hand hygiene, and use of personal protective equipment (PPE)); and the applicable provincial/territorial Occupational Health and Safety Standards.
3. Follow occupational health and safety regulations and manufacturer’s instructions for safe use of all detergents and chemicals.
4. Ensure that all ultrasound transducer probes are reprocessed to the required level according to the planned procedure (e.g., Spaulding’s Classification - refer to Table 1).

**C. Education and Training:**

1. Staff in the clinical setting shall be trained in Routine Practices, point of use pre-cleaning and safe transportation of contaminated devices.
2. Staff who perform reprocessing shall be trained and have current competency in the cleaning, disinfection/sterilization, safe transport and storage of medical devices.
3. Standard Operating Practices (SOPs) for all aspects of reprocessing shall be available for staff.<sup>25</sup>
4. There shall be a process for auditing of reprocessing practices.

CI. **Cleaning Agents:** All probes (non-immersible and immersible) shall be cleaned according to the MIFUs. Detergents and enzymatic detergents used for cleaning ultrasound transducer probes shall be validated for use with the make/model of the ultrasound transducer probe. Personnel shall ensure that the manual cleaning being performed is compatible for the specific model of ultrasound transducer probes.<sup>27</sup> (CSA Z314)

CII. **Low level disinfectants** shall be approved by Health Canada for use in health care settings and have a Drug Information Number (DIN) and be validated for use by the ultrasound transducer probe manufacturer.

CIII. **High level disinfectants** shall be approved by Health Canada, have a Class II Medical Device License and be validated for use by the manufacturer of the transducer probe. Refer to: [Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices](#)

**\*Product Guidance for High level disinfectants (HLD) and HPV:**

It is recommended that the HLD used is effective against non-enveloped viruses (e.g., Human Papilloma Virus (HPV).

CIV. Items labeled **single use** shall not be reused (e.g., needles, transducer probe sheath/covers).<sup>27</sup>

CV. Medical **gels** used for ultrasound shall be used according to the IPAC Position Statement.<sup>33</sup>

**CVI. Transducer probe sheath/cover:**

- a. Single-use disposable sheaths/covers shall be applied to the transducer probe just before use on the patient. Sheaths/covers do not remove the requirement to reprocess reusable transducer probes.<sup>27,28</sup> (CSA Z314)

**Note:** For external non-invasive examinations, where there is no potential to come into contact with blood, body fluids or non-intact skin, sheaths/covers are not required.

- b. Ultrasound transducer sheaths/covers shall be validated for use on transducer probes.
- c. Condoms, gloves, plastic wrap and sterile transparent dressings are not acceptable for use as a transducer probe cover.<sup>28</sup> Latex sheaths/covers are not to be used for patients identified with latex allergies.<sup>29</sup>
- d. The use of sterile transducer sheaths/covers is required for all endocavitary ultrasound transducer probes, including trans-vaginal, trans-rectal and trans-esophageal ultrasound procedures.<sup>28</sup>
- e. Sterile transducer covers shall be used for all high-level disinfected transducer probes used for major and minor interventional procedures and whenever transducers may be in contact with body fluids such as blood, secretions, or purulent discharge. "This includes all invasive

interventions as well as injections, fine needle aspirations and transducer contact with infected or broken skin, eczema and wounds”.<sup>28</sup>

- f. Follow all manufacturer’s recommendations for the use of sterile sheath/covers on sterilized transducer probes.
  - g. It is recommended to only stock sterile covers to eliminate the risk of accidental use of non-sterile covers.<sup>28</sup>
  - h. **Keyboards** shall be cleaned, and low level disinfected between patients as per the MIFU.
  - i. The **transducer handle and cable** shall be cleaned and disinfected according to intended use, between each patient and as per the MIFU.<sup>29</sup>
- J. Pre cleaning is to occur at point of care. Then transport each used probe in a covered transport container labelled as contaminated to a designated decontamination area as soon as possible.
- K. **Audits and documentation:**
- a. There shall be an ongoing auditing and documentation process to ensure that clean ultrasound transducer probes are clearly differentiated from contaminated ultrasound transducers; so that soiled medical devices are not inadvertently used for patient procedures.
  - b. Documentation and tracking of ultrasound transducer probes must follow CSA standards.<sup>27</sup>

## II. Practice recommendation for transducer probes according to intended Spaulding classification (noncritical, semi-critical, and critical). Refer to Appendix: Table 1.

Refer to Practice requirements and recommendations ‘A-K’ above for basic reprocessing requirements. In addition, the following recommendations are for non-critical procedures:

### A. Non-Critical procedures:

CSA Z314<sup>27</sup> states, “An ultrasound transducer probe that is used on intact skin shall be cleaned and undergo low-level disinfection between patient uses, according to the manufacturer’s validated instructions.”

1. Staff shall have access to SOPs for cleaning and disinfecting ultrasound transducer probes. These shall be based on the MIFU and meet the current standards. There shall be SOPs for the use of cleaning and chemical agents.<sup>28, 37</sup>
2. SOPs shall include instructions for pre-cleaning at the bedside, safe transportation to reprocessing area, cleaning, and disinfection, drying and storage as per the MIFU.
3. Cables, cords, handles, keyboards, machines etc. used during the ultrasound procedure shall be cleaned and low level disinfected between each patient according to MIFU<sup>28-30</sup>
4. All disinfected equipment shall be clearly labelled as clean and separated from soiled items.

### B. Semi-critical procedures<sup>2,3,26-28,32,35,37-40</sup>

Refer to Practice requirements and recommendations ‘A-K’ for basic reprocessing requirements. In addition, the following recommendations are to be followed for semi-critical procedures:

1. Transducer probes used on mucous membrane or non-intact skin are considered a semi-critical medical device and require cleaning followed by high-level disinfection between each patient procedure. Semi-critical procedures are endocavitary such as transvaginal, transrectal, transesophageal (TEE) or those that contact non-intact skin (e.g., abrasions, dermatitis, rash, psoriasis, cuts, and chapped skin).

At a minimum, “high level disinfection must be performed for all semi-critical and critical ultrasound procedures as persistent contamination following low level disinfections (LLD) has been demonstrated even with transducer cover use.”<sup>28</sup>

2. Reprocessing of semi-critical transducers/probes shall be performed in a separate medical device reprocessing area. (Reprocessing shall not be performed in the patient treatment room or clean storage area; and there must be separation between clean and soiled areas). (CSA Z314)<sup>27</sup>
3. Staff shall have access to SOPs for cleaning and disinfecting ultrasound transducer probes. These shall be based on the MIFU and meet the current standards. There shall also be SOPs for use of the cleaning and disinfection chemical agents.<sup>27,37</sup>
4. SOPs shall include instructions for pre-cleaning at the bedside, safe transportation to reprocessing area, cleaning, and disinfection, drying, storage, and traceability including documentation as per the MIFU.
5. Cables, cords, handles, keyboards, machines etc. used during the ultrasound procedure shall be cleaned and disinfected between each patient according to MIFU.<sup>28-30</sup>
6. Immediately after the procedure at point of use, discard the transducer probe cover, remove the medical gel using a low lint cloth and immediately perform pre-cleaning with an approved cleaning agent according to MIFU.<sup>27</sup>
7. Transportation to reprocessing area
  - a) Place in a covered transport container clearly labelled as contaminated and safely transport to designated decontamination area as soon as possible.<sup>27</sup>
  - b) Limit to one transducer probe per covered transport container.
8. For Transesophageal probes (TEE), perform electrical leak test as per MIFU.
9. Perform cleaning as per the validated MIFU; this should be completed within one hour after use.
10. Inspect transducer probe for cracks and defects.
11. Disinfection: Automated reprocessing of semi critical transducer probes is preferred because of standardized processes.
  - a) Perform manual or automated high-level disinfection of transducer probes as validated by MIFU.
  - b) Perform LLD on cord as per MIFU.
  - c) Conduct quality monitoring for the disinfectant MIFU process to verify correct preparation; contact time, temperature, concentration; monitoring; rinsing
  - d) Following HLD, perform a final rinse with bacteria-free water (achieved by submicron filtration) or sterile water.
  - e) Dry the transducer probe with a clean lint free wipe prior to storage. Discard the wipe after each use.
12. Storage:
  - a) Transducer probes shall be hung in a dedicated, closed, ventilated cabinet outside of the decontamination area, procedure room, waiting room or hallway.<sup>27</sup> (HEPA filtered cabinets are preferred as they provide positive air pressure and facilitate drying). Cabinets shall be nonporous material and cleaned weekly at a minimum. Do NOT store in enclosed drawers or cases.
  - b) Reprocessed transducer probes shall be labelled clearly that they are reprocessed by HLD.

- c) Quality assurance records shall be kept for all reprocessing processes and allow traceability of transducer probes to patient.<sup>27</sup>

**C. Critical Procedures** <sup>2,3,26-28,32,35,37-40</sup>

**Refer to Practice requirements and recommendations 'A-K'** for basic reprocessing requirements. In addition, the following recommendations are to be followed for critical procedures:

1. Transducer probes that enter a sterile body cavity, vascular system, tissue or where a biopsy is being performed are considered a critical medical device and require cleaning followed by sterilization between each patient procedure.
2. Transducer probes, used during interventional procedures including percutaneous shall be cleaned between patients followed by sterilization if validated by the manufacturer.
3. Staff shall have access to SOPs for cleaning, disinfection or sterilization of ultrasound transducer probes. These shall be based on the MIFU and meet the current standards. There shall also be SOPs for use of the cleaning and disinfection chemical agents.<sup>27,28</sup>
4. SOPs shall include instructions for pre-cleaning at the bedside, safe transportation to reprocessing area, cleaning, and disinfection/sterilization, drying, storage, and traceability including documentation as per the MIFU.
5. Cables, cords, handles, keyboards, machines etc. used during the ultrasound procedure shall be cleaned and disinfected between each patient according to MIFU.<sup>28-30</sup>
6. Immediately after the procedure at point of use, discard the transducer probe cover, remove the medical gel using a low linting cloth and immediately perform pre-cleaning with an approved cleaning agent according to MIFU.<sup>27</sup>
7. If sterilization of the transducer probe is not validated by the manufacturer, then they shall be reprocessed by HLD at a minimum.<sup>27</sup>
8. If purchasing new intraoperative transducers probes, future purchases should be transducer probes that have been validated for sterilization.
9. Sterile transducer covers and sterile gel shall be used for all high-level disinfected transducer probes used for critical procedures. The handles and cables used within the sterile field shall also be covered by a sterile sheath.
10. Follow all manufacturer's recommendations for the use of sterile sheath/covers on sterilized transducer probes. Sterilized transducer probes must be maintained as sterile until point of use as outlined in CSA Z314.
11. Reprocessing of critical transducer probes shall be performed in a separate designated medical device reprocessing area (MDR). (Reprocessing shall not be performed in the patient treatment room or clean storage area and must have separation between clean and soiled areas).<sup>27</sup>

**Examples of Procedures requiring a sterile transducer (not all inclusive):**

- Pericardiocentesis
- lumbar puncture
- ultrasound-guided regional/local anesthesia
- trans-rectal ultrasound guided biopsies
- Diagnostic and therapeutic injections
- fine needle aspiration
- vascular access
- Thoracentesis
- Arthrocentesis
- Fluid aspiration
- Ultrasound-guided perineural and spinal pain procedures
- Core biopsies
- Deep organ biopsies

12. Point of Use Pre cleaning:

Immediately after the procedure discard the transducer probe cover, remove the medical gel using a low lint cloth and perform pre-cleaning with an approved cleaning agent according to MIFU.

13. Transportation to reprocessing area:

- a) Place in a covered transport container labelled as contaminated and safely transport to designated decontamination area as soon as possible<sup>27</sup>.
- b) Limit one transducer probe per covered container

14. Perform cleaning as per the validated MIFU; this should be completed within one hour after use.

15. Inspect transducer probe for cracks and defects

16. Disinfection and Sterilization:

- a) Most transducers probes are heat sensitive and therefore high temperature sterilization may damage the probe. Newer models may be validated for sterilization for low temperature sterilization. If MIFU indicates the probe can be sterilized, then the probe shall be sterilized following the MIFU.
- b) If the transducer probe cannot be sterilized, then automated reprocessing is preferred because of standardized processes.
- c) If sterilization is not validated, perform manual or automated high-level disinfection of transducer probe and handle as validated by MIFU.
- d) Perform LLD disinfection on cord according to the MIFU.
- e) Perform quality monitoring processes for the disinfectant MIFU to verify correct preparation; contact time, temperature, concentration monitoring; and rinsing. Document results.
- f) A final rinse following HLD shall be performed with bacteria-free water or sterile water.
- g) The transducer probe shall be dried with a clean lint free cloth prior to storage.

## 17. Storage:

- a) High level disinfected Transducer probes shall be hung in a dedicated, closed, ventilated cabinet outside of the decontamination area, procedure room, waiting room or hallway.<sup>27</sup> (HEPA filtered cabinets are preferred as they provide positive air pressure and facilitate drying). Do NOT store in enclosed drawers or cases.
- b) Sterilized transducer probes must be maintained as sterile in the wrap/container until point of use as outlined in CSA standards.
- c) Reprocessed transducer probes shall be labelled clearly that it is reprocessed.

18. Quality assurance records shall be kept for all reprocessing processes and traceability of transducer probes to patient.<sup>27</sup>

## Definitions

### As per the Canadian Standard Association (CSA) the definitions of Shall, Should and May:<sup>27</sup>

“SHALL” is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard

“SHOULD” is used to express a recommendation or that which is advised but not required and

“MAY” is used to express an option or that which is permissible within the limits of the Standard, an advisory or optional statement.

- **Cleaning:** The removal of all visible soil. Commonly performed using detergent and water to rinse.
- **Critical:** A classification for medical devices, which contact normally sterile tissue.
- **Health Care Setting:** Any location where health care is provided, including settings where emergency care is provided, hospitals, complex continuing care, rehabilitation hospitals, long-term care homes, mental health facilities, outpatient clinics, community health centres, and clinics, physician offices, dental offices, offices of allied health professionals and home health care.<sup>32</sup>
- **Healthcare Worker:** a person who works in a healthcare setting.
- **HEPA:** High efficiency particulate air
- **High-level disinfection (HLD):** A disinfection process, which inactivates all microorganisms except bacterial endospores. This process is appropriate for semi-critical medical devices which contact non-intact skin or mucous membranes.
- **Low level disinfection (LLD):** A disinfection process which inactivates vegetative bacteria, enveloped viruses, some non-enveloped viruses and some fungi. This process is appropriate for non-critical medical devices only.
- **Manufacturer’s instructions for use (MIFUs):** The written directions provided by the manufacturer or distributor of a product that contain the necessary information for the safe and effective use of the product.) Care should be taken to ensure that the MIFUs are correct for the product. Any questions or discrepancies regarding the appropriateness of the instructions should be resolved before the product is used.<sup>27</sup>
- **Non-intact skin:** Areas of the skin that have been opened by cuts, abrasions, dermatitis chapped skin, etc.
- **Non-critical:** A classification for medical devices which only contact intact skin, and which do not contact mucous membranes or penetrate skin.
- **Patient:** Refers to client/patient/resident which is any person receiving care within a health care setting.



- **Pre-cleaning/Point of Use Cleaning:** Performed at point of use and prevents drying of soils (e.g., faeces, sputum, blood). Pre-cleaning makes the cleaning process easier. To keep devices moist until received in the decontamination area, commercially prepared pre-cleaning agents as a gel or foam or a lint free cloth, moistened with water can be used that will prevent any soil from drying prior to cleaning.
- **Semi-critical:** A classification for medical devices, which contact non-intact skin and mucous membranes.
- **Spaulding's Classification:** An instrument classification system used for reprocessing matching disinfection and sterilization of surfaces particularly, the surfaces of reusable medical/surgical devices. Instruments are classified according to infection risk into; critical, semi-critical and non-critical categories.
- **Transducer probe:** A device that converts electrical signals into ultrasound waves and ultrasound waves back into electrical impulses". All ultrasound devices also referred to, as "probes" are ultrasound transducers.<sup>27</sup> The probe includes the head and handle.

**Appendix:**

**Spaulding Classification for disinfection of ultrasound transducer probes and equipment (Adapted from CDC)<sup>26</sup>**

Category	Level of disinfection	Examples <i>(not all inclusive)</i>
<p><b>Non-Critical</b> Device only touches on intact skin.</p>	<p>Cleaning followed by Low level disinfection <b>after each use.</b></p>	<ul style="list-style-type: none"> <li>• Ultrasound transducer probe, cable and machine.</li> <li>• Surface ultrasound (e.g., gallbladder [external], echocardiogram)</li> <li>• Transabdominal</li> <li>• Doppler (blood flow)</li> </ul>
<p><b>Semi-Critical</b> Device contacts non-intact skin and/or mucous membrane</p>	<p>Cleaning followed by high level disinfection <b>after each use.</b> Use sterile gel and sterile cover.</p>	<ul style="list-style-type: none"> <li>• Transducer probes used outside sterile fields for needle or aspiration guidance.</li> <li>• Endocavitary probes for transvaginal scanning, transrectal ultrasound, transesophageal procedures.</li> </ul>
<p><b>Critical</b> Device/probe contacts sterile tissues, body fluids, blood or enters the sterile field.</p>	<p>Cleaning followed by sterilization <b>after each use.</b> Use sterile gel and sterile cover.  If the manufacturer has not provided a validated sterilization process for the probe; then reprocess by high-level disinfection (HLD) according to the manufacturer’s instructions for use (MIFU), and a sterile transducer sheath/cover.</p>	<ul style="list-style-type: none"> <li>• Ultrasound guided procedures performed within a sterile field.</li> <li>• Intravascular, (e.g., central line placement, vascular access) <sup>1-3</sup></li> <li>• Guided local anesthesia, spinal pain procedures</li> <li>• Intraoperative probe procedures</li> <li>• Intracardiac</li> <li>• Fluid aspiration (e.g., arthrocentesis)</li> <li>• Lumber puncture</li> <li>• Fine needle aspiration</li> <li>• Laparoscopic</li> <li>• Vascular ablation</li> <li>• Biopsies</li> </ul>

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**Stakeholders:** Infection Prevention and Control Professionals and all Healthcare Workers who use and/or reprocess ultrasonic probes.

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