PICNet
PROVINCIAL INFECTION CONTROL NETWORK OF BRITISH COLUMBIA
A program of the Provincial Health Services Authority

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Revised Ultrasound Cleaning and Disinfection Recommendations for All Health Care Settings

Introduction

Ultrasound is increasingly utilized as an imaging modality in a diversity of care settings. It is used at various points-of-care (POC) including Medical Imaging, Intensive Care Units (ICU), Emergency Departments, Nursing Units, Operating Rooms and Physician Offices. Often the probes are reprocessed at the POC rather than in a centralized Medical Device Reprocessing Department (MDRD). In June 2016, the Provincial Infection Control Network was tasked by the Ministry of Health to provide recommendations for the cleaning and disinfection of ultrasound probes for the prevention of transmission of Human Papilloma Virus. Since that time several questions and concerns have been raised regarding those recommendations and clarification was requested. The following revised recommendations were developed by a provincial working group including Infection Prevention and Control, MDRD, regulators and POC users.

Key to implementing these recommendations will be to ensure that all point of care health care providers that use ultrasound in their practice are educated as to the proper hand hygiene, environmental cleaning, and transducer probe reprocessing requirements. They are responsible for ensuring any probe they use is cleaned and disinfected after each patient use.

Spaulding's Classification System and Ultrasound Probe Reprocessing

The level of reprocessing required for a medical device is guided by the Spaulding's classification system.[1] Probes require cleaning and a level of disinfection based on their intended use. Ultrasound probes should be cleaned immediately following use to prevent gel residue and organic material from drying on the probe making them difficult to clean. Following cleaning, ultrasound probes are disinfected. Probe-specific manufacturer's instructions for use (IFU) should be followed at all times. Care and handling of each probe will vary with the type and manufacturer.

The use of a probe cover does not remove the requirement to clean and disinfect the ultrasound probe after each patient use.

Ultrasound probes

External probes used for surface imaging, e.g. abdominal, that only come into contact with intact skin are considered non-critical devices and require cleaning followed by low-level disinfection (LLD). If the external probe may come into contact with non-intact skin a sterile probe cover should be used as an added precaution.

External probes used for needle guidance, e.g. during biopsies, line placement, aspiration, drainage and interventional pain management (IPM) are considered non-critical devices as they are not intended to contact non-intact skin or mucous membranes. These probes

require the use of a sterile probe cover. Following the procedure the probe cover is removed and the probe requires cleaning followed by LLD. As these probes sometimes become soiled with blood and/or body fluids during the needle guidance procedure, cleaning to remove the soiling prior to disinfection is essential.

Internal probes used for endocavity imaging, e.g. vaginal, rectal and transesophageal, are considered semi-critical devices as they contact mucous membranes. These probes require the use of a sterile or non-sterile probe cover. Following the procedure the probe cover is removed and the probe requires cleaning followed by high-level disinfection (HLD). As there is some evidence that Human Papilloma Virus may not be completely inactivated by aldehyde-based HLD, it is recommended that endocavity probes be disinfected using an oxidizing HLD with a label claim for efficacy against non-enveloped viruses.[2,3] Before switching to a oxidizing HLD first check the probe manufacturer's IFU to ensure that the probe and HLD are compatible. If an oxidizing HLD is not validated for the endocavity probe, the healthcare provider and/or organization is responsible for ensuring that there is a process in place to contact the original equipment manufacturer (OEM) to request validation documentation. If the endocavity probe OEM is unable to provide validation documentation for an oxidizing HLD then the probe should to be disinfected using a validated HLD according to the manufacturer's IFU.

When purchasing new endocavity probes consideration should be given to acquiring probes that can be disinfected with an oxidizing HLD with label claims for efficacy against non-enveloped viruses. In addition, probes should be replaced over time (e.g. end-of-life, damaged) with probes that can be disinfected with an oxidizing HLD.

Internal probes that enter tissue, the vascular system or sterile body cavities, e.g. intraoperative, sentinel node, are considered critical devices. These probes require the use of a sterile probe cover. Following the procedure the probe cover is removed and the probe requires cleaning followed cleaning by sterilization. If, according to the manufacturer's IFU the internal probe cannot withstand sterilization, then the probe requires cleaning followed by HLD as a minimum. When purchasing new internal probes that enter tissue, the vascular system or sterile body cavities, consideration should be given to acquiring probes that can withstand sterilization. In addition, probes that cannot withstand sterilization should be replaced over time (e.g. end-of-life, damaged) with probes that can withstand sterilization.

Ultrasound Handle, Cable and Connector Housing

The probe handle, cable and connector housing should be cleaned and LLD between patient uses according to manufacturer's IFU.[4,5]

Use of Probe Covers

Probe covers may be non-sterile or sterile. All probe covers are considered single-use, applied just prior to use and discarded following the procedure and prior to cleaning the probe.

Reference Table for Probe Cover Selection			
Probe Type	Probe Use	Probe Cover	Guidance
External	Intact skin	Non-sterile/optional	The use of a probe cover is at the discretion of the person performing the procedure
	Non-intact skin	Sterile	
	Needle guidance	Sterile	
Internal	Endocavity	Non-sterile or Sterile	A condom may be used as a non-sterile probe cover. The condom may be latex or non-latex, lubricated or non-lubricated and must be non-medicated. Before using a latex condom, the patient should be consulted regarding latex sensitivity and allergies.
	Intraoperative	Sterile	

Ultrasound Gel

Ultrasound gels are available in both sterile and non-sterile preparations. Gels that are defined as sterile are unopened packets or sachets that are specifically labelled as 'sterile.'

Gel bottles should never be 'topped up' and should be discarded when empty. The use of bulk gel dispensers and refillable gel bottles is discouraged due to the risk of contamination. If reusable gel bottles are used, they must be emptied, cleaned, low-level disinfected, rinsed and dried prior to refilling. When opening a new gel bottle or a newly refilled bottle, the bottle should be marked with the date opened and any remaining gel discarded after one month.[6]

Reference Table for Gel Selection		
Probe Type	Probe Use	Gel Selection
External	Intact skin	Non-sterile
	Non-intact skin	Sterile*
	Needle guidance	Sterile*
Internal	Endocavity	Sterile*
	Intraoperative	Sterile*
* Sterile gel should be used for all invasive procedures (e.g. needle aspiration, needle localization, biopsy), procedures involving a sterile environment or non-intact skin and on neonates. Sterile gels should also be used for procedures performed on intact mucous membranes (e.g. esophageal, gastric, rectal, vaginal) and for patients with immunodeficiencies or on immunosuppressive therapy.		

Environmental Cleaning and Disinfection

Between each examination, infection prevention and control measures should include:

- Hand hygiene
- Disinfection of high touch surfaces such as:
  - keyboards
  - exam tables and rails
  - external surfaces of multiuse gel bottles
  - probe holders

Ultrasound machines should be cleaned and disinfected daily.

1. Spaulding E. The role of chemical disinfection in the prevention of nosocomial infections. In: Proceedings of the International Conference on Nosocomial Infections, 1970. Chicago, IL: American Hospital Association; 1971. p. 247-54.
2. Leroy et al. Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis. Journal of Hospital Infection: 83 (2013) 99e106.
3. MZali et al. Persistence of Microbial Contamination on Transvaginal Ultrasound Probes despite Low-Level Disinfection Procedure. PLoS ONE 2014: 9(4): e93368.
4. Ngu et al. Intracavity ultrasound transducer handles are not routinely immersed in liquid high-level disinfectants. Infect Control and Hospital Epidemiology 2015; 36(5):581–584.
5. Westerway et al. Potential Infection Control Risks Associated with Ultrasound Equipment – a Bacterial Perspective. Ultrasound in Med. & Biol., Vol. 43, No. 2, pp. 421–426, 2017
6. IPAC Canada position statement on medical gels. Available at: https://ipac-canada.org/photos/custom/Members/pdf/17Dec_Medical%20Gel_Final.pdf.