Non-Hospital Medical and Surgical Facilities Accreditation Program

MANUAL

Reprocessing Requirements for Ultrasound Probes

# Table of contents

Introduction	3
Highlights from the PICNet Recommendations	3
External Ultrasound	

## Introduction

In 2016, the BC Ministry of

latex-free condom to prevent gross contamination. Single-use barriers are not a substitute for high-level disinfection. Providers must follow the MIFU for the probe, and low-level and high-level disinfectants to ensure compatibility and to avoid damage to the probe.

#### Critical/sterile Procedures Ultrasound Probes

Critical/sterile procedure ultrasound probes used for needle guidance during biopsies, aspirations, drainages, etc. and

human papillomavirus (HPV)	Human papillomavirus (HPV) is a small, non-enveloped deoxyribonucleic acid
	(DNA) virus that infects skin or mucosal cells. HPV represents a group of more than 150 viruses that affect the skin and mucous membranes of the body, examples include the cervix, anus, mouth and throat. HPV is estimated to be among the most common sexually transmitted diseases. Genital HPV infections are common and highly contagious:
	Around 80% of sexually active men and women

	involves cleaning and may also require low-level disinfection (e.g. blood pressure cuffs, stethoscopes).
oxidizing agents	Types of chemicals classified by their primary mechanism for killing microorganisms. Examples include chlorine, iodine, peracetic acid, hydrogen peroxide, chlorine dioxide, ozone. Oxidizing agents include a broad range of compounds that can be broken down into three general categories one of which is hydrogen peroxide-based.
pre-cleaning at point of use	Prevents soil from drying on devices. Immediately after use, the user shall
	clean medical devices of gross soil by rinsing with water or a water-moistened lint-free cloth. If using a cleaning or detergent product for pre-cleaning soaking they must be approved by the device manufacturer and the MIFU followed (e.g. mixed to the correct in-use dilution). Some low-level disinfectants manufacturers claim dual action for cleaning and disinfection provided the MIFU is followed for cleaning and disinfection contact times. Note: Do not use saline as a soaking solution as it damages some medical devices.
probe cover/sheath	A single-use disposable cover applied just before use on the patient to form a barrier for the prevention of infection. Internal probes must be covered with a single-use, non-lubricated, non- medicated, latex-free barrier (probe cover/sheath). For sterile procedures a sterile probe cover must be used. For probes used during non-invasive procedures, a clean probe cover is recommended as applicable to the procedure.
	Single-use barriers do not remove the requirement to reprocess ultrasound probes between patient use.
reprocessing	The steps performed to prepare used medical devices for reuse (e.g. pre- cleaning, cleaning, disinfection, and sterilization).
reusable	A term given by the manufacturer of medical devices that allows it, through the selection of materials and/or components, to be re-used.
rinsing	A required step following cleaning and disinfection. The ultrasound transducer probe shall be immersed and thoroughly rinsed with clean, tap water to remove debris and detergent. Before immersion in the HLD, the ultrasound probe shall be dried with

	meticulous cleaning followed by, at a minimum, high-level disinfection.
single-use/disposable	A device designated by the manufacturer for single-use only. Device must be discarded following single use.
sterilization	A validated process used to render a product free from viable microorganisms. This is the level of reprocessing required for critical medical devices. Devices must be cleaned thoroughly before sterilization can take place. Sterilization is used on critical medical devices and, whenever possible, semi-critical medical devices. The preferred method for sterilization of heat- resistant critical devices is steam sterilization (pre-vacuum sterilization is preferred).
tracking	A procedure should be in place to track the use of ultrasound probes. Note: The use of unique identifiers will facilitate tracking of medical devices in the event of a failure in the reprocessing system.
trophon® EPR	An automated high-level disinfectant reprocessing machine specific to validated ultrasound probes. Uses concentrated hydrogen peroxide (Sonex- HL). Trophon EPR Validated.
ultrasound probes	Complex, fragile, highly specialized medical devices that required particular care in their cleaning and handling. They may be used on, but not limited to, intact or non-intact skin, mucous membrane, sterile body cavities or vascular systems. They are used in various clinical settings including, but not limited to, operating rooms, diagnostic imaging, emergency department, ambulatory clinics and physician offices.

## Methods for High-level Disinfection of Semi-critical Endocavity Ultrasound Probes

Prior to any method used for high-level disinfection (HLD) all pre-cleaning, cleaning, rinsing and drying steps must be performed in accordance with BC Ministry of Health <u>Best Practices</u> <u>Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical</u> <u>Devices</u> (2011), CSA standards and manufacturer's instructions for use (MIFU).

#### Manual High-level Disinfection

Prior to switching from ortho-phthalaldehyde or glutarladehyde high-level disinfectant to the recommended oxidizing-based high-level disinfectant, contact the manufacturer of the ultrasound probe to ensure it is validated and compatible for high-level disinfection using an oxidizing-based high- level disinfectant.

Currently, health authorities employ the use of Revital-Ox (Resert), an oxidizing-based accelerated hydrogen peroxide high-level disinfectant with label claims against non-enveloped viruses.

- o prior to refilling, emptied and cleaned (using a medical grade detergent, rinsed and dried) followed by low-level disinfection
- o refilled using a dispensing device

When opening a new gel bottle or newly refilled bottle it is marked with the date and any unused gel is discarded after 28 days

Unused gel is discarded if at any time the bottle or contents is questioned or compromised or the bottle is not marked with the original entry date

After each patient use the outside of the gel bottle is low-level disinfected and the lid closed

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Can all types of ultrasound probes be high-level disinfected using an accelerated hydrogen peroxide high-

# References

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