



College of Physicians and Surgeons
of British Columbia

Reprocessing Requirements for Ultrasound Probes

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Reprocessing Requirements for Ultrasound Probes

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Reprocessing Requirements for Ultrasound Probes

Introduction

In 2016, the BC Ministry of Health directed that recommendations from the Provincial Infection Control network of BC (PICNet) for the reprocessing of ultrasound probes be implemented in all health-care settings. This directive was in response to published studies indicating that Human Papillomavirus (HPV) has become strongly resistant to the chemical disinfectants traditionally used for the reprocessing of ultrasound probes.

After seeking clarification from the ministry regarding implementation timelines and other medical devices potentially at risk, the College released *Reprocessing Requirements for Ultrasound Probes* in 2017.

Community-based physicians using ultrasound probes that come into contact with mucosal membranes and those used for needle guidance in an aseptic field are required to implement the Provincial Infection Control Network of BC's Recommendations for Cleaning and Disinfection in Medical Ultrasound to Prevent Human Papillomavirus (HPV) Transmission, which include using an oxidizing-based high-level disinfectant with label claims for non-enveloped viruses. The ministry has also confirmed that PICNet's recommendations do not include colonoscopes and other reusable medical devices at this time.

The ministry has directed that PICNet's recommendations should be implemented as soon as possible and no later than July 31, 2018.

Questions regarding the ministry's directive for the implementation of the PICNet recommendations can be directed to the following College programs/initiatives:

- Physician Office Medical Device Reprocessing Assessments (POMDRA)
- Diagnostic Accreditation Program (DAP)
- Non-Hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP)

More information on the PICNet's recommendation can be found [here](#).

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Highlights from the PICNet Recommendations

Infection prevention and control is critical to delivering safe, high-quality care to patients undergoing medical ultrasound procedures.

External Ultrasound Probes

External ultrasound probes that only come into contact with intact skin are considered non-critical devices and require cleaning using a low-level disinfectant after every use. Providers must follow the manufacturer's instruction for use (MIFU) for both the probe and low-level disinfectant to ensure compatibility and to avoid damage to the probe.

Internal Ultrasound Probes

Internal ultrasound probes are classified as semi-critical devices (e.g. vaginal, rectal and transesophageal probes). Internal probes require pre-cleaning at point of use, cleaning (using a detergent or enzymatic product), rinsing, drying and high-level disinfection between each patient use. Following high-level disinfection and prior to patient use, all internal probes must be covered with a single-use barrier; probe cover or a non-lubricated, non-medicated, 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 where there is a risk of blood or body fluid exposure, require the use of a sterile probe cover during the procedure and following the procedure require pre-cleaning at point of use, cleaning (using a detergent or enzymatic product), rinsing, drying and high-level disinfection.

HPV Transmission

Appropriate reprocessing of ultrasound probes between patients is critical to reduce the risk of HPV transmission.

Recently published studies have raised concerns regarding the efficacy of commonly used disinfectants against HPV.

Traditionally, high-level disinfection of internal ultrasound probes has been accomplished through immersion of the instruments in either glutaraldehyde or ortho-phthalaldehyde which are not virucidal for HPV.

Recommended High-level Disinfectant

The best recommendation is to employ an oxidizing-based high-level disinfectant (e.g. accelerated hydrogen peroxide) with label claims for non-enveloped viruses. Currently, health authorities employ the use of Revital-Ox (Resert) high-level disinfectant. PICNet has confirmed that Revital-Ox (Resert) or a high-level disinfectant with similar chemistry and label claims against non-enveloped viruses meets the recommendations.

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In addition to basic infection prevention and control measures, hand hygiene and environmental cleaning and disinfection are also essential to prevent the transmission of pathogens in medical ultrasound.

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Glossary of Terms

accelerated hydrogen peroxide	A patented synergistic blend of commonly used, safe ingredients that when combined with low levels of hydrogen peroxide dramatically increase its germicidal potency and cleaning performance. Product example is Revital-Ox (Resert) which is effective against most non-enveloped viruses.
cleaning	The physical removal of foreign material (e.g. dust, soil) and organic material (e.g. blood, secretions, excretions, microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action. Cleaning must be performed before low-level disinfection, high-level disinfection or sterilization.
critical medical devices	Medical devices that enter sterile tissues, including the vascular system (e.g. surgical instruments, biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical devices present a high risk of infection if the device is contaminated with any microorganisms, including bacterial spores. Reprocessing critical devices involves meticulous cleaning followed by sterilization.
decontamination	The process of cleaning, followed by the inactivation of microorganisms, in order to render an object safe for handling.
detergent	A synthetic cleansing agent that can emulsify oil and suspend soil. A detergent contains surfactants that do not precipitate in hard water and may also contain protease enzymes (see enzymatic cleaner) and whitening agents.
disinfectant	A chemical agent that kills most disease-producing microorganism, but not necessarily bacterial spores. Disinfectants are applied only to inanimate objects. Some products combine a cleaner with a disinfectant.
enzymatic cleaner	A cleaning agent that contains enzymes which breakdown proteins such as blood, body fluids, secretions and excretions from surfaces and equipment. Most enzymatic cleaners also contain a detergent. Enzymatic cleaners are used to loosen and dissolve organic substances.
gel (ultrasound)	A conductive medium that acts as a coupling agent and enables a bond between the skin and the ultrasound probe or transducer. Gels used for ultrasound procedures have been associated with cluster of infections.

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glutaraldehyde user station (GUS) Vapour control technology first introduced in 1995 and widely used for high-level disinfection of endocavity probes (transvaginal, trans-rectal, transesophageal). Initially, the station commonly uses glutaraldehyde but other high-level disinfectants such as OPA and the PICNet-recommended accelerated hydrogen peroxide can be used. When changing from one HLD to another, users are advised to check the MIFUs and/or contact the GUS, ultrasound probe, and high-level disinfectant manufacturers to ensure compatibility.

high-level disinfection (HLD) A process capable of killing vegetative bacteria, mycobacteria including *Mycobacterium tuberculosis*, fungi, and lipid and non-lipid viruses, as well as some, but not necessarily high numbers of, bacterial spores. High-level disinfection is considered to be the minimum level of disinfection required for semi-critical medical devices. Medical devices shall be thoroughly cleaned prior to high-level disinfection. The appropriate type of high-level disinfectant must be selected in accordance with the medical device and HLD MIFU. Disinfectant sprays and wipes are not considered high-level disinfectants.

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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 will contract the HPV virus at some point during their lifetime.
- HPV is not spread via bodily fluid; it is a skin-to-skin contact virus and can infect anyone who is or has ever been sexually active and many times, most infected individuals are asymptomatic, meaning they display no symptoms of the virus.
- HPV can be spread through oral, vaginal or anal sex.
- At times, HPV can be transmitted during birth to an infant causing genital or respiratory system infections.
- There is no cure for HPV but there are vaccines that can prevent infection with the most common types of HPV.
- Non-sexual transmission for the virus is often debated; however, it has been found that equipment and surfaces are contaminated by HPV despite routine cleaning. Although it is difficult to prove the viability and infectivity of the HPV virus on contaminated environmental surfaces, vigilant infection control measures and established cleaning protocols should be maintained.

Each HPV virus is given a number which is called its HPV type. There are more than 40 HPV types that can infect the genital areas of females and males.

Sexually transmitted HPV types fall into two categories:

1. Low-risk HPVs: Do not cause cancer but can cause skin warts (technically known as condylomata acuminata or papillomas) on or around the genitals, anus, mouth, or throat.
2. High-risk HPVs: Two of these, HPV types 16 and 18, are responsible for most HPV-caused cancers (e.g. cervical cancers, anogenital cancers and a significant portion of oropharyngeal cancers). They are spread during sexual intercourse and skin-to-skin contact of the genital areas. HPV is a highly resistant non-enveloped virus; more so than other non-enveloped viruses previously tested. Many commonly used disinfectants are ineffective against HPV. The unusually high resistance of HPV to disinfection supports other data suggesting the possibility of fomite or non-sexual transmission of HPV16.

Emerging pathogens are of growing concern to the general public and infection prevention and control professionals. A recent study showed that a considerable number of ultrasound probes are contaminated with HPV (28 percent pre-examination).

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hydrogen peroxide	Disinfectant with broad-spectrum efficacy against viruses, bacteria, yeasts and bacterial spores.
low-level disinfection (LLD)	A process capable of eliminating vegetative (“live”) bacteria, some fungi and enveloped viruses. Low-level disinfection is used for non-critical medical equipment/devices and some environmental surfaces. Common LLD products include, sprays, wipes or solution. Low-level disinfectants are appropriate for non-critical items that come in contact with intact skin such as stethoscopes, blood pressure and tourniquet cuffs, ECG leads, bedside equipment, and environmental surfaces. External ultrasound transducers such as abdominal or pelvic that come in contact with intact skin are considered non-critical devices and low-level disinfection is appropriate.
manufacturer’s instructions for use (MIFU)	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. For information regarding reprocessing steps always follow the MIFU for the medical device, cleaning agents and disinfectants (low-level and high-level) to ensure compatibility. Individual medical device manufacturers should provide detailed information on which disinfectants are compatible, and should be prepared to provide further product testing upon request.
medical device	Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap; investigation, replacement, or modification of the anatomy or of a physiological process; or control of conception.
minimum effective concentration (MEC)	The minimum concentration of a liquid chemical disinfectant that achieves the claimed microbial activity.
non-critical medical device	Devices that either touches only intact skin (but not mucous membranes) or do not directly touch the client/patient/resident. Reprocessing of non-critical devices 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.

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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 a lint-free cloth. Following HLD the ultrasound probe shall be rinsed and dried prior to storage.
semi-critical medical device	Medical device that comes in contact with non-intact skin or mucous membranes but ordinarily does not penetrate them (e.g. respiratory therapy equipment, trans-rectal probes, specula). Reprocessing semi-critical devices involves 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).

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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.

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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 [Best Practices Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices](#) (2011), CSA standards and manufacturer's instructions for use (MIFU).

Manual High-level Disinfection

Prior to switching from ortho-phthalaldehyde or glutaraldehyde 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.

GUS High-level Disinfection Soak Stations

GUS stations are compatible with ortho-phthalaldehyde (Cidex OPA, Metricide OPA), glutaraldehyde (GTA) and accelerated hydrogen peroxide (APH).

Prior to switching from ortho-phthalaldehyde or glutaraldehyde high-level disinfectant to the recommended oxidizing-based high-level disinfectant (e.g. accelerated hydrogen peroxide (APH)), contact the manufacturer of the GUS station to confirm it is validated and compatible for high-level disinfection using an oxidizing-based high-level disinfectant and contact the manufacturer of the endocavity probe(s) to ensure it is validated and compatible for high-level disinfection using an oxidizing-based high-level disinfectant.

Trophon High-level Disinfection System

Trophon systems are intended to use a hydrogen peroxide-based high-level disinfectant, therefore if using a trophon system with a hydrogen peroxide-based high-level disinfectant with label claims for non-enveloped viruses, it is compliant with the PICNet recommendations.

Antigermix AS1 Quick Protocol System

This system is currently used in some health authorities.

Contact the manufacturer of the system to confirm it is validated and compatible for high-level disinfection using an oxidizing-based high-level disinfectant and contact the manufacturer of the endocavity probe(s) to ensure it is validated and compatible for high-level disinfection using an oxidizing-based high-level disinfectant.

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Use of Ultrasound Gel

Non-critical items can potentially contribute to secondary transmission of infectious agents by contaminated hands of health-care personnel or by contact with medical devices that will subsequently come in contact with patients. Gels used for ultrasound procedures can become contaminated and have been associated with outbreaks of infection.

Gel products that are labelled as non-sterile or containers that are not labelled with respect to sterility are considered not sterile. Gels that are sterile are available as single-use packets that are specifically labelled as “sterile.” The use of non-sterile multi-use gel bottles should be limited to low-risk general examinations on intact skin. Sterile gel must be used during all sterile procedures and it is recommended by Health Canada for use during semi-critical procedures (e.g. mucous membrane or non-intact skin). For patients on transmission-based precautions a single-use sterile or non-sterile gel packet must be used and discarded after use.

To minimize the transmission risk of contaminated ultrasound gel the following is required:

- Single-use sterile packets must be used for all critical/sterile procedures and are recommended for semi-critical procedures
- Single-use containers are recommended for non-sterile gels
- If reusable non-sterile gel containers are used, they must be:
 - dispensed from the original gel manufacturer’s container
 - never “topped-up”
 - prior to refilling, emptied and cleaned (using a medical grade detergent, rinsed and dried) followed by low-level disinfection
 - 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
- For procedures that require the use of sterile gel, ensure that only unopened packets labelled “sterile” are used
- Any unused portion of single-use sterile gel packets must be discarded and not reused for another examination or patient
- Due to the risk of bacterial contamination and growth within a warm environment, heating of gel is not recommended
- Prior to cleaning and disinfection/sterilization of ultrasound probes the ultrasound gel must be manually removed from transducer using a moistened lint free cloth.

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Frequently Asked Questions

I currently high-level disinfect (HLD) my internal ultrasound probe using glutaraldehyde (GTA). The PICNet recommends disinfectants that use oxidizing chemistries to prevent transmission of HPV should be used. I want to know if I can continue to use glutaraldehyde and if not, what type of high-level disinfectant should I purchase to meet the PICNet recommendations.

1. Glutaraldehyde (GTA) and ortho-phthalaldehyde (OPA) have been found not to be effective against HPV.
2. The best choice to prevent transmission of HPV is to use an oxidizing agent which includes a broad range of compounds that can be broken down into three general categories one of which is hydrogen peroxide-based. For high-level disinfection of internal ultrasound probes PICNet supports the health authorities' choice of Revital-Ox (Resert), an accelerated hydrogen peroxide high-level disinfectant (HLD), or another brand of accelerated hydrogen peroxide high-level disinfection that has equal label claim as Revital-Ox (Resert) against non-enveloped viruses.

What exactly do I need to see on the Revital-Ox (Resert) or other accelerated hydrogen peroxide HLD product label to make sure it is effective against HPV.

It is extremely important to read the HLD product label carefully. HPV is a small, non-enveloped virus. All HLD label claims must state that the product is effective against non-enveloped viruses. Not all accelerated hydrogen peroxide high-level disinfectants are effective against non-enveloped viruses; therefore, it is always required that you read the fine print on the label to know exactly what it is effective against.

Can all types of ultrasound probes be high-level disinfected using an accelerated hydrogen peroxide high-level disinfectant (HLD)?

First check the individual manufacturer's instructions for use (MIFU) to ensure compatibility with the ultrasound probe, cleaning agents, low- and high-level disinfectants, automated HLD reprocessors and sterilization methods. Manufacturers can provide detailed information on which disinfectants are compatible, and should be prepared to provide further product testing upon request. In addition to following MIFU practitioners should follow the Ministry of Health [Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices](#) (2011) and CSA standards.

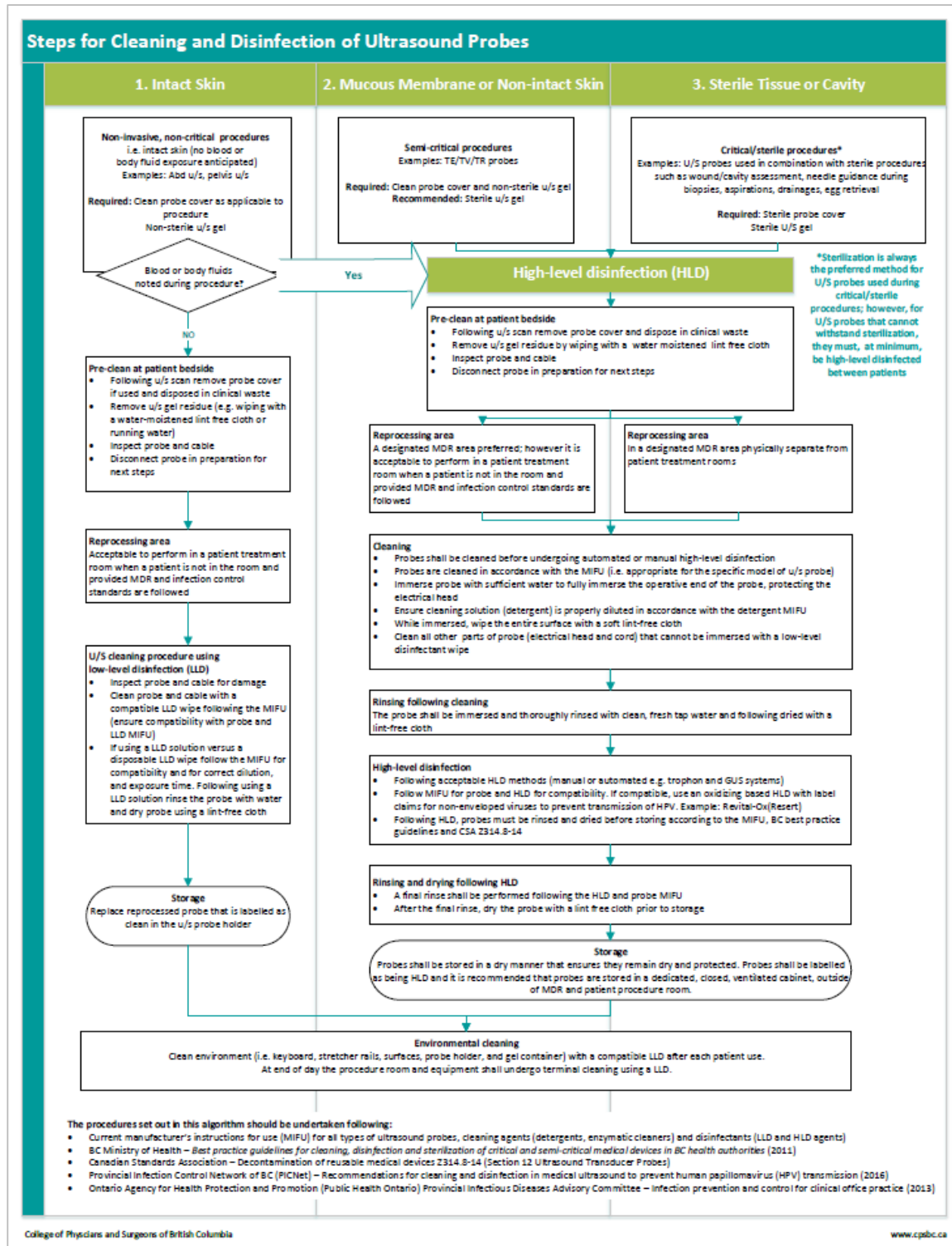
I am an otolaryngologist and although I don't use medical ultrasound in my office I am concerned about the transmission of HPV for other medical devices I currently use and high-level disinfect between patient use (e.g. flexible endoscopes). Can I switch from the current high-level disinfectant I am using to an accelerated hydrogen peroxide high-level disinfectant?

Contact the endoscope manufacturer and ask if they will validate in writing the use of the high-level disinfectant product you intend to switch to. You must always ensure that both the medical device (e.g. flexible endoscope) and HLD are compatible with one another to ensure that switching to different high-level disinfectant will not damage the medical device.

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Steps for Cleaning and Disinfecting Ultrasound Probes

The full flow chart can be downloaded from the College [website](#) for use in facilities.



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