cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Reusable & Single-Use Medical Device Requirements for Medical Clinics

Self-Assessment Tool

Infection Prevention & Control (IPAC) Program

Effective January 2022
Last updated September 2021

Contents

Purpose

This resource is a companion to CPSA's Reusable and Single-Use Medical Device Requirements for Medical Clinics ("Requirements") and functions as a self-assessment tool. This tool can be used by medical clinic staff to ensure ongoing compliance and mirrors the tool utilized by CPSA Assessors during assessments of medical clinics.

Requirements are developed with input from experts in infection prevention & control, infectious disease, medical device reprocessing, environmental public health, the CPSA IPAC Advisory Committee, and community-based physicians and surgeons. Key references supporting the Requirements are the Alberta Health *Reusable & Single-Use Medical Devices Standards (2019)* and the Canadian Standards Association *CAN/CSA-Z314-18 Canadian medical device reprocessing (2018)*.

For assistance or more information on these requirements, contact the CPSA IPAC Program: ipac@cpsa.ab.ca or 780-969-5004.

Scope

The Requirements apply to independently operated (non-government) medical clinics in Alberta that provide services from CPSA regulated members and do not apply to prescribed health services requiring accreditation as outlined in CPSA Bylaws Part 5 Section A (48) Accreditation of Medical Facilities.

Assessment Measurement

Yes	In compliance with requirements
No	Not in compliance with requirements
CDA	Corrected during the assessment
N/A	Not applicable to this medical clinic

ASSESSMENT DETAILS

Performed by: _____ **Clinic Name:** _____

Self-Assessment Date: _____ **Results Reported to:** _____

REQUIREMENTS	YES	NO	CDA	N/A
PART A: SINGLE-USE MEDICAL DEVICES				
1 Single-use medical devices				
1.1. Single-use medical devices shall only be used on a single patient for a single procedure and then shall be discarded.				
1.2. A single-use medical device shall not be used beyond the expiry date specified by the manufacturer.				
1.3. A sterile critical single-use medical device shall be maintained as sterile until point of use.				
1.4. Opened but unused single-use medical devices shall be discarded, unless the manufacturer provides validated manufacturer's instructions for use (MIFU) for reprocessing.				
1.5. Prior to using a single-use medical device that was purchased in a non-sterile state, that single-use medical device shall be inspected and processed according to the validated MIFU.				
COMMENT				
PART B: REPROCESSING OF REUSABLE MEDICAL DEVICES				
2 Environmental & structural requirements for a medical device reprocessing area				
2.1. The medical device reprocessing (MDR) area shall be a designated area, separate from patient care, and activity in the area shall be restricted to the reprocessing of reusable medical devices.				
2.2. All MDR areas shall:				

REQUIREMENTS	YES	NO	CDA	N/A
2.2.1. Have physical separation of clean and dirty areas. In existing clinics and settings where physical separation (i.e., with walls or partitions) of reprocessing areas is not possible, spatial separation and a one-way work flow pattern shall be established to limit cross-contamination.				
2.2.2. Have at least two adjacent sinks, large enough to immerse the largest piece of equipment, to clean and rinse soiled items. In existing smaller clinics where two adjacent sinks dedicated for equipment cleaning and rinsing are not possible, a dedicated basin for rinsing equipment after cleaning in a dedicated sink is an acceptable alternative. The dedicated basin shall be large enough to fully submerse the item being rinsed.				
2.2.3. Have hand hygiene stations (either hand hygiene sinks or alcohol-based hand rub (ABHR) dispensers with products that have a Health Canada Drug Identification Number (DIN) or Natural Product Number (NPN), and contain 60% to 90% alcohol) at all entrances to, and exits from, the MDR area and readily available within the MDR area.				
2.2.3.1. Designated hand hygiene sinks shall have properly functioning soap dispensers and paper towel dispensers.				
2.2.3.2. Designated hand hygiene sinks shall be used for the purpose of hand hygiene only.				
2.2.4. Have surfaces that can be cleaned. All work surfaces and surrounding area shall be intact, cut-resistant, and seamless, and shall be composed of non-porous, non-shedding material capable of withstanding frequent cleaning.				
2.2.5. Restrict access to areas where reprocessing occurs. In existing smaller clinics, where MDR areas may also be used for other purposes, access shall be restricted during reprocessing activities and until the area has been appropriately cleaned.				
2.2.6. Be designed to facilitate one-way workflow.				
2.2.7. Have adequate lighting for the tasks being performed in all work locations.				
2.2.8. Use a water source which meets the equipment manufacturer's specifications for water and steam quality.				
COMMENT				

REQUIREMENTS	YES	NO	CDA	N/A
3 Procurement of reusable medical devices & reprocessing equipment and supplies				
2.3. The decision to purchase or trial reusable medical devices, reprocessing equipment and supplies, or reusable surgical textiles shall involve representatives from the personnel in the clinic that will use, reprocess, and maintain the items.				
2.4. Prior to purchasing or trialing a medical device, including medical device reprocessing equipment, the clinic shall confirm that the device has a valid medical device license issued under the Government of Canada's Medical Devices Regulations. The clinic shall not purchase or trial a reusable medical device that does not have a valid medical device license.				
2.5. Prior to purchasing or trialing a reusable critical or semi-critical medical device, personnel accountable for medical device reprocessing (MDR) shall review the written, validated MIFU to determine that the recommended reprocessing procedures can be achieved, given the clinic's reprocessing resources.				
COMMENT				
4 General reprocessing requirements				
4.1. Reusable medical devices that have been used shall be reprocessed. Contaminated reusable medical devices that have not undergone reprocessing shall be clearly identified.				
4.2. Reusable medical devices that come from an opened or compromised package shall be reprocessed prior to use.				
4.3. Newly purchased reusable critical and semi-critical medical devices shall be reprocessed before initial use unless they are packaged and sterilized by the manufacturer.				
Cleaning accessories				
4.4. Cleaning accessories shall be inspected before use to ensure they are not damaged. Damaged cleaning accessories shall not be used.				
4.5. Reusable cleaning accessories shall be reprocessed after use in accordance with the manufacturer's instructions for use (MIFU), inspected for damage, and stored in a clean, dry place.				

REQUIREMENTS	YES	NO	CDA	N/A
4.6. Single-use cleaning accessories shall be discarded following use.				
COMMENT				
5. Pre-cleaning & transportation of contaminated reusable medical devices				
5.1. Personnel shall pre-clean used reusable medical devices immediately after use and prior to transportation and further manual or automated cleaning.				
5.2. At the point of use, single-use sharps shall be removed from reusable medical devices and disposed of in a puncture-resistant sharps container.				
5.3. Organic matter shall not be allowed to dry on reusable medical devices. Reusable medical devices shall be kept moist by using foam, spray, or gel specifically intended for this use, or by using a towel moistened with water, and in accordance with the manufacturer's instructions for use (MIFU).				
5.4. Contaminated items shall be transported in covered, fully-enclosed, leak-proof containers or closed carts that are designed to prevent the spill of liquids, protect reusable medical devices from damage, and allow for effective decontamination after each use.				
5.5. Sterile or clean reusable medical devices and soiled reusable medical devices shall be transported in a manner that prevents cross-contamination (i.e., in separate containers and carts).				
5.6. All containers and carts containing contaminated medical devices shall be so identified.				
5.7. Contaminated reusable medical devices shall be transported to the medical device reprocessing (MDR) area in such a way so as not to contaminate the surrounding environment.				
COMMENT				
6. Preparation & Cleaning of Reusable Medical Devices				
Sorting & disassembly				

REQUIREMENTS	YES	NO	CDA	N/A
6.1. All contaminated medical devices shall be inspected and sorted before reprocessing to ensure that the appropriate cleaning agents and procedures are applied to the correct devices.				
6.2. All medical devices consisting of multiple components (e.g., minimally invasive surgical medical devices) shall be disassembled in accordance with the manufacturer's instructions for use (MIFU).				
Cleaning				
6.3. Each medical device shall be thoroughly cleaned prior to disinfection or sterilization.				
6.4. Cleaning methods shall be consistent with the medical device's manufacturer's instructions for use (MIFU) and appropriate for the type of medical device and the amount of soil to be removed.				
Manual cleaning				
6.5. If manual cleaning is required, the medical device's manufacturer's instructions for use (MIFU) for reprocessing shall be followed, including any specifications for detergent type, water type, or water temperature and cleaning methods.				
6.6. Immersible medical devices shall be completely submerged during cleaning to prevent the generation of aerosols and non-immersible medical devices shall be cleaned according to the manufacturer's instructions for use (MIFU).				
Automated cleaning				
6.7. Automated washers and ultrasonic cleaners used for cleaning shall be used in accordance with the manufacturer's instructions for use (MIFU).				
6.7.1. The performance of the automated cleaning system (e.g., automated washers) shall be tested each day that it is in use, using commercially available indicators or test kits.				
6.7.2. Ultrasonic cleaners shall be tested for sonication performance (e.g., commercial methods or the foil test) at least weekly.				
6.7.3. The ultrasonic detergent solution shall be changed at least daily or more frequently when visibly soiled or if the ultrasonic cleaner or solution MIFU specifies more frequent changes (e.g., with every cycle).				

REQUIREMENTS	YES	NO	CDA	N/A
6.8. The medical device's MIFU shall be followed to ensure medical devices are compatible with the automated washer's process conditions (e.g., moisture, temperature, chemicals, water quality, and pressure).				
Rinsing & drying				
6.9. Chemical residues and loosened soil shall be completely rinsed from the medical device prior to disinfection or sterilization. Rinsing may be included as a final step in an automated cleaning process. If not, the medical device shall be rinsed manually.				
6.10. Reusable medical devices shall be dried prior to disinfection or sterilization, as directed by the manufacturer's instructions for use (MIFU). Unless dried using an automated process, the exterior surfaces of medical devices shall be manually dried with a clean, lint-free or low-lint soft-absorbent towel.				
Reassembly				
6.11. Decontaminated medical devices shall be reassembled according to the manufacturer's instructions for use (MIFU). Reassembly shall take place in a clean and dry area.				
Inspection				
6.12. Medical devices shall be visually inspected for cleanliness, damage, integrity, and functionality prior to disinfection, sterilization, or subsequent use.				
6.12.1. Cleaned medical devices that are visibly soiled shall be cleaned again.				
6.12.2. Medical devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable medical devices. Such medical devices shall either be repaired or disposed of in accordance with the documented procedures.				
COMMENT				
7. Disinfection of reusable medical devices				

REQUIREMENTS	YES	NO	CDA	N/A
7.1. Disinfection of reusable medical devices shall take place in accordance with the manufacturer's instructions for use (MIFU) of the device and shall also follow the MIFU for the disinfection process, equipment, and products.				
7.2. Only chemical disinfectants that have a Health Canada drug identification number (DIN) or a medical device licence (MDL) issued by Health Canada, shall be used in clinics and settings for the disinfection of reusable medical devices.				
7.3. A liquid chemical disinfectant shall not be used beyond its expiry date and in-use life.				
7.4. Reusable liquid chemical disinfectant solutions shall be:				
7.4.1. Clearly identified and include the expiry date.				
7.4.2. Stored in containers that are cleaned, disinfected, and dried prior to changing the solution.				
7.4.3. Kept covered with a tight-fitting lid, except when introducing or removing a medical device to or from the solution.				
Non-critical devices				
7.5. Non-critical reusable medical devices shall be disinfected between patient uses using an intermediate-level disinfectant (ILD) or low-level disinfectant (LLD).				
7.5.1. ILD or LLD wipes shall be moist enough to thoroughly wet the surface for the indicated contact time and a new wipe shall be used if the area to be disinfected cannot be completely wetted with a single wipe.				
Semi-critical medical devices				
7.6. If a reusable semi-critical device cannot be sterilized, then it shall, at a minimum, be high level disinfected between patient uses.				
Liquid chemical high level disinfection (HLD)				
7.7. The minimum effective concentration (MEC) of a reusable HLD shall be tested and recorded, according to the manufacturer's instructions for use (MIFU) of the disinfectant.				

REQUIREMENTS	YES	NO	CDA	N/A
7.7.1. MEC testing shall be performed at the beginning of each day that the solution is used for manual HLD (or more frequently if specified in the MIFU of the disinfectant) and in each cycle for automated HLD.				
7.7.2. Quality assurance testing of test strips used to test MEC shall be followed in accordance with test strip MIFU.				
7.7.3. Test strips used to test MEC shall not be used beyond the test strip's expiry date or the manufacturer's in-use shelf life.				
7.7.4. An HLD shall not be used beyond a failed MEC test.				
7.8. When performing manual disinfection of a semi-critical medical device:				
7.8.1. All parts of the medical device shall be in complete contact with the HLD, and all air bubbles shall be removed.				
7.8.2. The contact time and temperature shall be measured from the point at which the semi-critical medical device achieves complete contact with the HLD and there are no trapped air bubbles.				
7.9. If an automated disinfection system is used, the contact time and temperature shall be monitored as specified in the MIFU and the disinfectant maintained within the manufacturer's recommended ranges for temperature and concentration throughout the contact time.				
7.10. Automated disinfection systems shall provide a record that critical cycle parameters (e.g., disinfectant temperature, concentration, contact time) have been met.				
7.11. Following chemical HLD, each semi-critical medical device shall be thoroughly rinsed.				
7.11.1. If rinsing is done manually, it shall include at least three separate rinses in water of acceptable quality unless otherwise specified by the disinfectant manufacturer.				
7.12. After HLD and rinsing, the semi-critical medical device shall be dried in accordance with the MIFU.				
7.13. At a minimum, the clinic shall document and maintain records on:				
7.13.1. HLD solution.				

REQUIREMENTS	YES	NO	CDA	N/A
7.13.2. HLD test strips.				
7.13.3. Results of MEC testing.				
7.13.4. Contact time and temperature during HLD.				
7.13.5. Cycle parameters.				
7.13.6. Medical device name or type documentation.				
Thermal disinfection/pasteurization				
7.14. If a washer-disinfector or washer-pasteurizer is intended to provide thermal high level disinfection (HLD), the clinic shall obtain documentation from the washer-disinfector or washer-pasteurizer manufacturer or a third party to confirm that it has been validated for thermal HLD.				
7.15. If a washer-disinfector or pasteurizer is used for thermal disinfection, it shall be equipped with sensors and a recording device for time and temperature and/or equivalent A0 value.				
7.15.1. The accuracy of the recording device shall be periodically confirmed with an independent calibration device, and the frequency and method of testing shall be in accordance with the manufacturer's instructions for use (MIFU).				
7.15.2. When a washer-disinfector is used for the thermal HLD of semi-critical medical devices (e.g., respiratory devices), the washer-disinfector shall provide a record of attaining A0 600 through either printed or electronic means.				
7.16. The clinic shall ensure the washer-disinfector or pasteurizer and the selected cycle are appropriate to the medical device being reprocessed and its intended use.				
7.17. The washer-disinfector or pasteurizer MIFUs for loading configurations and cleaning agents shall be followed.				
7.18. Validated manifolds and attachments shall be used to facilitate optimal circulation of water through the reusable medical devices being reprocessed.				

REQUIREMENTS	YES	NO	CDA	N/A
7.19. Pasteurizers shall reach a minimum temperature of 71° Celsius for a minimum contact time of 30 minutes, unless a higher temperature is specified in the MIFU for the medical device.				
7.20. Air pockets shall be displaced from the load before pasteurization via manipulation of the load by the washer-pasteurizer in accordance with the equipment MIFU and all devices shall be completely submerged in a water bath during the pasteurization cycle.				
7.21. Following thermal disinfection in a washer-disinfector or pasteurizer, reusable medical devices shall be handled in a manner that minimizes contamination.				
7.22. Following the disinfection cycle, respiratory devices shall be dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used only for the drying of disinfected medical devices.				
COMMENT				
8. Sterilization of reusable medical devices				
8.1. A reusable critical medical device shall be sterilized between patient uses.				
8.2. Sterilization of reusable medical devices shall take place in accordance with:				
8.2.1. The manufacturer's instructions for use (MIFU) of the device.				
8.2.2. The MIFU for the sterilization process, equipment, and products.				
8.3. Installation qualification of sterilization equipment (including large chamber and table top steam sterilizers and chemical sterilizers) shall be performed and documented according to the manufacturer's specifications.				
8.4. Operational qualification and requalification shall take place at least annually and following a major sterilizer repair, sterilizer relocation, an unexplained sterility failure, and, for steam sterilizers, following any disruption to steam supply or change to steam pressures.				
8.4.1. Operational qualification and requalification testing shall include a verification of each cycle used by the clinic, according to the MIFU for testing.				

REQUIREMENTS	YES	NO	CDA	N/A
8.4.2. Operational qualification and requalification testing shall be conducted by:				
8.4.2.1. Running three consecutive cycles in an empty chamber using process challenge devices (PCDs) with biological indicators. For table-top steam sterilizers, testing will take place in a fully loaded chamber.				
8.4.2.2. Additionally, in dynamic air removal sterilizers that use pre-vacuum cycles, ensuring that the sterilizer meets the requirements of an air removal test and leak-rate test and is tested with three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer.				
Packages & labels				
8.5. Packaging of reusable medical devices for sterilization shall take place in accordance with the MIFU of the device, the sterilization equipment, and the sterilization packaging manufacturer, and when packaging is required, it shall be done using a validated sterile barrier system (e.g., pouches, wrappers, or rigid sterilization container systems).				
8.6. Packages shall be labelled with sterilizer load identification information, including the sterilizer number, the load number in that sterilizer, and the sterilization date.				
8.6.1. Labelling systems shall be validated for the sterilization process.				
8.6.2. For pouches, a label shall be placed on the transparent portion of the packaging.				
8.6.3. For wrapped packages, writing shall be on the closure tape, not directly on the wrappers.				
Loading & unloading				
8.7. Packages shall be placed in the sterilizer chamber in a manner that facilitates air removal, sterilizing agent penetration, sterilant evacuation, and, in the case of steam sterilization, drying.				
8.7.1. Wrapped items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper.				
8.7.2. Pouches and wrapped packages shall not be stacked or compressed.				

REQUIREMENTS	YES	NO	CDA	N/A
8.7.3. Between packages there shall be adequate space to ensure effective sterilizing agent penetration, evacuation, and drying.				
8.8. Sterile packages shall be cooled to room temperature before handling.				
8.9. During unloading, packages shall be inspected for package integrity, dryness, presence of a label, the correct change in an external chemical indicator, an intact seal if used, and evidence of potential contamination. If a package does not meet the inspection criteria, the contents shall not be used.				
Sterility assurance				
8.10. Sterilization indicators shall be used only for the sterilizer type and sterilization cycle for which they were designed and validated and shall be used according to the sterilizer and indicator manufacturer's instructions for use (MIFU).				
8.10.1. Sterilization indicators shall not be used beyond their expiry date and shall be stored according to the MIFU.				
Chemical indicators				
8.10.2. Both internal and external chemical indicators shall be included with each package prepared for sterilization.				
8.10.2.1. The internal chemical indicator shall be placed in the area of the package that is least susceptible to sterilizing agent penetration. If a multi-layer container is being used, chemical indicators shall be placed at each level.				
Air removal testing				
8.10.3. For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test shall be performed every day the sterilizer is used.				
Biological indicators				

REQUIREMENTS	YES	NO	CDA	N/A
8.10.4. A biological indicator contained within a process challenge device (PCD) shall be used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity) and at the shortest exposure time, within a full load. This test shall be done at least daily when the sterilizer is in use.				
8.10.4.1. If a steam sterilizer will be used for multiple types of cycles, each type of cycle used shall be tested daily.				
8.11. At the conclusion of a sterilization cycle and before the load is removed, the operator shall confirm that the required parameters and all phases of the sterilization cycle including aeration (if required) have been met.				
8.12. If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.				
8.13. All sterilizers used in Alberta clinics and settings shall come equipped with a printer or electronic record that records cycle parameters effective January 1, 2023.				
In the period before the transition required by 8.13 is completed, if a clinic is using a sterilizer that does not come equipped with a printer, personnel shall check the sterilizer's displays and manually record the sterilization time and temperature at intervals during each cycle and use a Type 5 chemical indicator in each package.				
8.14. Documentation of sterility assurance shall include a printout or electronic cycle parameter record, a load control label, a load contents record, and associated chemical or biological indicator test results for each cycle.				
COMMENT				
9. Storage				
9.1. Reprocessed critical and semi-critical medical devices shall be protected from contamination by:				
9.1.1. Rotating stock via first-in, first-out.				
9.1.2. Keeping items clean, dry, and protected.				

REQUIREMENTS	YES	NO	CDA	N/A
9.1.3. Keeping items well-separated from soiled items and soiled areas via barriers and/or distance.				
9.1.4. Ensuring they are not stored on the floor or a window sill, under sinks or near water sources, in open corridors or patient rooms, or in the same area as hazardous materials.				
COMMENT				
10. Education & training				
10.1. The clinic shall ensure all personnel involved in the reprocessing of critical and semi-critical medical devices are appropriately educated and trained for the reprocessing duties/tasks that they perform.				
10.1.1. Personnel who reprocess critical and semi-critical medical devices, but are not employed as medical device reprocessing technicians, shall receive training in a formal medical device reprocessing training program recognized by the clinic, or comprehensive in-house training, and shall successfully complete competency testing.				
10.2. The clinic shall document and maintain records of education, training, orientation, and competency assessments of personnel who reprocess critical and semi-critical medical devices.				
COMMENT				
PART C: QUALITY MANAGEMENT SYSTEMS				
11. Quality management systems				
11.1. The clinic shall have clear accountability and lines of responsibility for all aspects of medical device reprocessing (MDR), wherever MDR takes place in the clinic, and the appropriate use of single-use medical devices.				
11.2. The clinic shall have written policies and procedures in place that meet or exceed appropriate provincial and national standards and guide the clinic through all aspects of MDR. The clinic's medical device reprocessing policies and/or procedures shall include (but not be limited to):				

REQUIREMENTS	YES	NO	CDA	N/A
11.2.1. All steps in the reprocessing of reusable medical devices, based on MIFU.				
• Pre-cleaning and transportation				
• Sorting, disassembly, and soaking				
• Manual and/or automated cleaning				
• Rinsing				
• Drying				
• Inspection				
• Chemical high level disinfection (HLD) if applicable				
• Thermal disinfection / pasteurization (if applicable)				
• Packaging and labelling				
• Sterilization				
• Sterility assurance, including physical, chemical, and biological				
• Storage				
11.2.2. Education and training.				
11.2.3. Recall procedures.				
11.2.4. Specific, detailed procedures for medical devices that present unique and complex challenges for reprocessing, such as flexible endoscopes, based on manufacturer's instructions for use (MIFU).				
11.2.5. The required occupational health and safety activities, including use of appropriate personal protective equipment (PPE) when performing MDR and when using single-use medical devices.				

REQUIREMENTS	YES	NO	CDA	N/A
• Facial protection (eye protection with mask or full face shield)				
• Disposable, moisture impervious gown				
• Tear and chemical resistant gloves				
• Cleaning and disinfection of reusable PPE				
11.3. The clinic shall have a written policy regarding single-use medical devices that is consistent with Part A of the Requirements.				
11.4. The clinic shall conduct a regularly scheduled review of all written policies and procedures.				
Documentation				
11.5. The clinic shall retain records of reprocessing according to the clinic's policy and applicable legislation. These records shall include, but not be limited to, the following:				
11.5.1. Preventative maintenance of reusable medical devices and equipment.				
11.5.2. Results of installation, operational qualification and requalification, and routine testing of reprocessing equipment and products.				
11.6. The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.				
11.7. If reprocessing of reusable medical devices is being performed by an external or internal subcontractor, the subcontractor shall comply with the Requirements.				
COMMENT				
PART D: FLEXIBLE ENDOSCOPE REPROCESSING				
Note: Where appropriate, requirements in Parts A, B, and C are applicable.				

REQUIREMENTS	YES	NO	CDA	N/A
12. General requirements				
12.1. Endoscopes and reusable accessories that come into contact with mucous membranes shall be cleaned and receive at least high level disinfection (HLD) after each patient use.				
12.2. Reusable accessories (e.g., biopsy forceps, other cutting instruments) that break the mucosal barrier (enter sterile tissues or sterile body cavities) shall be cleaned and sterilized in accordance with manufacturer's instructions for use (MIFU) and Part B of the Requirements after each patient use.				
12.3. The water bottle used to provide sterile intra procedural flush solution and its connecting tube, shall be sterilized or receive HLD at least daily.				
12.4. Processes for endoscope reprocessing shall be in accordance with endoscope, equipment, and supplies validated MIFU.				
COMMENT				
13. Cleaning, flushing, rinsing, and drying				
13.1. Pre-cleaning of the endoscope shall be performed at the point-of-use immediately following the clinical procedure.				
13.2. A leak test shall be performed prior to and/or during immersion of the endoscope in accordance with manufacturer's instructions for use (MIFU).				
13.3. Meticulous cleaning shall be performed prior to high level disinfection (HLD) or sterilization.				
13.4. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be immersed in detergent or enzymatic cleaning solution unless otherwise specified in MIFU. Non-immersible components shall be cleaned in accordance with MIFU.				
13.5. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be soaked in detergent or enzymatic cleaning solution in accordance with MIFU to ensure proper contact time.				

REQUIREMENTS	YES	NO	CDA	N/A
13.6. Accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be disconnected and disassembled as far as possible and completely immersed in detergent or enzymatic cleaning solutions.				
13.7. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be completely immersed during the entire cleaning process to prevent splashing or aerosolization unless otherwise specified in MIFU.				
13.8. The bending section shall be kept straight so brushing does not damage the endoscope.				
13.9. The exterior of the endoscope shall be cleaned with a soft brush or lint-free or low-lint soft absorbent towel.				
13.10. Brushing and flushing channels (e.g., brush biopsy/suction channel in the insertion channel) until returns are clear (all visible debris removed), including brushing and flushing endoscopes with an elevator in both the up and down positions shall be done. The brush shall be cleaned in detergent or enzymatic cleaning solution each time it is passed through the channel.				
13.11. The suction valve housing and instrument channel port shall be cleaned with a channel-opening brush until all debris is removed.				
13.12. Brushing and flushing channels shall be done using only brushes, cloths, syringes, and other cleaning devices of a correct size, and inspected for cleanliness and good repair before use.				
13.13. A 30 mL syringe shall be attached to the adapter and detergent or enzymatic cleaning solution injected into all channels at least three times, or an approved automated system provides equivalent cleaning.				
13.14. Detergent or enzymatic cleaning solutions shall be discarded after each use.				
13.15. The endoscope, channels, and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly rinsed by immersing in tap water and brushing/flushing to remove all traces of detergent or enzymatic cleaning solution and debris.				
13.16. Final rinses prior to disinfection shall be performed in clear tap water followed by air purges using 30 mL syringes, or an approved automated system provides equivalent rinsing and drying.				

REQUIREMENTS	YES	NO	CDA	N/A
13.17. The exterior of the endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly dried using a clean, lint-free or low-lint soft absorbent towel.				
COMMENT				
14. High level disinfection (HLD), final rinsing, and drying				
Manual disinfection				
14.1. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be immersed in a basin of high level disinfectant unless otherwise specified in manufacturer's instructions for use (MIFU). Non-immersible components shall be intermediate or low-level disinfected in accordance with MIFU.				
14.2. Immediately following cleaning, rinsing, and drying, the endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be completely immersed in HLD solution for the recommended time and temperature.				
14.3. The HLD solution shall be flushed through all channels using a 30 mL syringe to purge air from the channels and to ensure that all channels are perfused.				
14.4. Air shall be flushed through the endoscope channels using adapters (suction cleaning adapters).				
14.5. The endoscope, channels, and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be immersed in fresh water.				
14.6. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be rinsed/flushed, and all channels flushed (water volume at least 3 times the volume of the channel) using three separate rinses in water of acceptable quality unless otherwise specified by MIFU.				
14.7. A channel air flush, followed by 70% alcohol, and a second forced-air purge shall be performed.				
14.8. The exterior of the endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly dried using a clean, lint-free or low-lint soft absorbent towel.				

REQUIREMENTS	YES	NO	CDA	N/A
Automated endoscope reprocessor (AER)				
14.9. There shall be documentation from manufacturers confirming the AER and connectors can effectively reprocess the specific brand and model of endoscopes.				
14.10. High level disinfectant concentration is checked daily, at a minimum, with an appropriate chemical test strip and discarded/changed if the concentration is less than the minimum effective concentration (MEC).				
14.11. Immediately following manual cleaning, the dried endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be placed in the AER and loading shall be in accordance with manufacturer's instructions for use (MIFU).				
14.12. The AER channel attachments shall be appropriate to the endoscope being reprocessed.				
14.13. The endoscope connectors/adapters shall be attached to the AER.				
14.14. The AER shall be run so that the endoscope is completely immersed in high level disinfectant solution for the recommended time and temperature.				
14.15. The AER or an external system shall provide final rinse water of acceptable water quality.				
14.16. The endoscope shall be removed promptly after the final cycle has been completed.				
14.17. A channel air flush, followed by 70% alcohol, and a second forced-air purge shall be performed.				
14.18. Endoscopes and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly dried before being stored.				
COMMENT				
15. Storage				
15.1. Endoscopes shall be stored in a well-ventilated, protected, clean area to facilitate drying, with channeled endoscopes hung in a vertical position.				

REQUIREMENTS	YES	NO	CDA	N/A
15.2. Endoscopes shall be stored in a manner that protects them from contamination (e.g., do not touch the floor of the cabinet).				
15.3. Caps, valves, and other detachable components shall be removed during storage and reassembled before use.				
15.4. Endoscopes shall not be coiled or stored in their cases.				
15.5. Endoscope storage cabinets shall be cleaned and disinfected at least weekly.				
15.6. Channeled endoscopes shall be reprocessed if in storage for more than 7 days.				
COMMENT				
16. Documentation				
16.1. There shall be a permanent record of endoscope use and reprocessing.				
16.2. There shall be a system to track endoscopes and patients that includes recording the endoscope number in the patient record.				
16.3. For each procedure, the patient's name and record number, the date and time of procedure, type of procedure, endoscopist, and serial number or other identifier of both the endoscope and the automated endoscope repressor (if used) shall be documented.				
COMMENT				

PART E: REFERENCES

1. Alberta Health, Government of Alberta. 2019. Reusable & Single-Use Medical Devices Standards: Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings.
2. Canadian Standards Association. 2018. CAN/CSA-Z314-18 National Standard of Canada – Canadian medical device reprocessing.

3. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. 2013. Best practices for cleaning, disinfection, and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario.

Assessor Name: _____

FINAL ASSESSMENT COMMENTS