Standard Operating Procedure

Reprocessing of Flexible Endoscopes: General Requirements

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OBJECTIVES

- General requirements for endoscope cleaning outlines the basic aspects adhered to in reprocessing.

APPLICABILITY

This policy and procedure applies to all Alberta Health Services and Covenant Health facilities, staff, members of the medical staff, volunteers, students and any other persons acting on behalf of Alberta Health Services and/or Covenant Health.

ELEMENTS

Manufacturer's Instructions for Use (MIFU) of the endoscope shall be followed.

1. Point of use cleaning
   - Pre-cleaning shall occur at point of use. Pre-cleaning includes wiping the external components of the flexible endoscope, flushing and or suctioning detergent/enzymatic or water through the endoscope as per the device specific instructions for use.
   - Reprocessing of flexible endoscopes shall be initiated immediately post-procedure at the bedside and shall be completed in a timely manner.

2. Transport to Endoscope Reprocessing Room
   - Manual cleaning should be performed within 1 hour of the bedside cleaning; transportation should be planned to facilitate this window of time.
   - Endoscopes shall be transported in a closed or covered container to keep the device moist and prevent the contamination of surroundings.
   - Transport containers shall be labeled to identify the device is contaminated.
   - Staff transporting devices shall adhere to the use of proper PPE and hand hygiene.

3. Leak testing
   - Leak testing shall be performed to ensure integrity of the endoscope as per MIFU.
   - Leak testers should be routinely tested for functionality prior to use.

- If an endoscope fails the leak test, notify management team and follow MIFU prior to sending endoscopes out for repair.

  Note: In the event that a damaged endoscope cannot be reprocessed prior to transport for repair, or the MIFU requires the endoscope to be transported in a soiled state, the endoscope shall be secured in a leak proof, closed container marked with a biohazardous label and signed. Upon receipt of repaired endoscope reprocess as per MIFU before use.

4. Manual cleaning

- Endoscopes shall be cleaned according to the MIFU prior to automated high-level disinfection.
- Correct measured dosages of enzymatic and dilution of water volume shall be followed.
- Endoscope that cannot be completely immersed shall not be reprocessed by MDR.
- Endoscopes shall be disassembled for cleaning as per MIFU.
- Discard any disposable components (e.g., valves, suction buttons, etc.).
- Brushes, syringes, lint free cloths and other cleaning devices used for cleaning lumens will be of the correct size for the lumen, inspected prior to and during use, and discarded or reprocessed prior to re-use.
- Immerse all attachments in enzymatic/detergent solution and soak the endoscope with its components for the duration outlined in the MIFU (endoscope and/or detergent).
- The external endoscope shall be completely wiped and brushed clean of any visible debris while completely submersed. External cleaning will begin from the cleanest portion of the endoscope moving to the most soiled part. A clean, lint-free cloth shall be used to clean all exterior surfaces.
- Thoroughly brush all interior surfaces and openings beneath the surface of the water.
- Brush all channels as per MIFU.
- Flush the endoscope as per MIFU.

5. Rinsing

- Endoscopes, their channels, all removable parts, and accessories shall be immersed and thoroughly rinsed to remove residual detergent.
- If using a single sink system, thoroughly clean and disinfect sink before moving to the rinse phase of reprocessing.
- The endoscope, including all removable parts, channels, and accessories, shall be immersed and thoroughly rinsed with a recommended volume of clean, fresh tap water to remove residual debris and detergent according to the MIFUs.
- When flushing lumens, caution shall be used so that the flexible endoscope is not subjected to excessive pressure.
- Following rinsing, the excess water shall be removed from the exterior and lumens.

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- After each endoscope has been cleaned the sink shall be cleaned and disinfected.

Note: Endoscopes with elevator channels;

- Specific brushes outlined in the MIFU must be used.
- Endoscopes must have elevator channel brushed and flushed in accordance with MIFU.
- Pay particular attention to the air/water nozzle opening, objective lens and ensure all surfaces of the distal end are cleaned thoroughly.

6. Visual Inspection
   - Endoscopes shall be visually inspected for cleanliness, integrity and damage during reprocessing.

7. High-level disinfection
   - Connectors used to attach endoscopes to the automated endoscope reprocessor (AER) shall be approved for use by:
     a) Endoscope manufacturer;
     b) AER manufacturer;
     c) Connection ports for the endoscope and AER intended.
   - AER used to disinfect the endoscope shall be compatible with the high-level disinfectant (HLD) used.
   - AER used must be validated for reprocessing of the endoscope intended.
   - HLD used must be compatible and approved for use with the endoscope being reprocessed.
   - AER MIFU shall be followed.
   - Minimum effective concentration (MEC) testing shall be completed as per MIFU.
   - Staff will verify that the AER time and temperature settings are appropriate to the loads contents prior to starting the cycle.
   - Final rinsing in the AER shall be completed with bacteria-free submicron water, or reverse osmosis water.
   - Once cycle is complete confirm parameters have been met. Remove endoscope from AER, inspect for cleanliness, dry endoscope with a lint-free cloth.
   - All lumens shall be flushed with instrument air, followed by 70% isopropyl alcohol and flushing of the lumens shall be followed by a second purging of the channels with instrument air or filtered air to facilitate drying. The air pressure shall not exceed the endoscope MIFUs.

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Note: If the endoscope will be used for a patient procedure immediately, it is not necessary to flush the channels with alcohol for drying. Remove valves while drying the endoscope.

8. Endoscope storage
   - All endoscopes shall be stored in HEPA filtered dedicated storage cabinets. All endoscope cabinets shall remain closed when not in use.
   - All endoscope storage cabinets shall be made of cleanable, non-porous material. Endoscopes shall be hung in a manner that prevents kinking, scratching or damage to the device.
   - Endoscopes shall not be stored with channel valves or caps in place.

9. Shelf life
   - Unused flexible endoscopes shall be fully reprocessed after 7 days.

10. Bronchoscopes and cystoscopes
    - Cystoscopes are critical medical devices and shall be sterilized in accordance to the MIFUs.
    - If sterilization of a bronchoscope is not possible they shall be reprocessed before patient use.
    - If a bronchoscope is kept in inventory for emergency procedures, it shall be sterilized and stored in an appropriate sterilization container to be readily available.

11. Documentation and traceability
    - All records of endoscope reprocessing shall be documented and kept in accordance with the corporate policy regarding record retention.
    - Records shall include, but not be limited to the following:
      a) date of procedure;
      b) patient identification details;
      c) instrument identification details;
      d) AER identification number;
      e) documentation of (with staff identifier):
         - pre-cleaning at bedside
      f) manual cleaning, including:
         - leak testing
         - brushing; and
         - rinsing
      g) high-level disinfection;
      h) cycles performed;

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i) time and temperature for high-level disinfection;
j) endoscope identifier;
k) AER user identifier;
l) any associated alerts, errors, or other codes;
m) MEC testing results;
n) name of disinfectant;
o) expiry date of disinfectant, testing materials and test strips;
p) lot number and name of test strips used;
q) lot number and name of disinfectant used.

DEFINITIONS

None (as applicable)

REFERENCES

- Alberta Health Services governance documents
  - Records Retention Management Policy
- Non-Alberta Health Services Documents
  - Reusable & Single-Use Medical Device Standards. (Government of Alberta - Alberta Health) (September 2019).
  - Canadian Medical Device Reprocessing. (Canadian Standards Association) (CAN/CSA Z314-18).

VERSION HISTORY

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March 2021	Initial approval
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