Policy

IWK Health

Policy Title:	Reprocessing Requirements for Flexible Endoscopes	
Applies To:	Medical Device Reprocessing Department (MDRD) and Pediatric Operating Room (OR) team members	
Location Applicability:	MDR Department and Pediatric OR, IWK Health	
Approved:	**Effective:**	**Next Review:**
November 27, 2023	November 30, 2023	November, 2027
Sponsor:	Director, Quality, Patient Safety and Patient Experience	
Approval Authority:	Policy and Practice Committee	
Number: #1445	**Manual:** Medical Device Reprocessing	

Contents

PURPOSE

Flexible endoscopes are complex, fragile, highly specialized medical devices that require particular care in their cleaning, disinfection, and handling.
Contaminated flexible endoscopes and reusable accessory items are considered potential sources of transmission of infection for both IWK Health patients and team members. The purpose of this policy is to outline expectations aligned with Infection Prevention and Control (IPAC) standards and practices that MDRD and Pediatric OR team members must adhere to when reprocessing endoscope equipment.

POLICY STATEMENTS

1. The Medical Device Reprocessing Department (MDRD) and Pediatric OR Managers must be responsible for MDRD and Pediatric OR team members performing endoscopy reprocessing, and must:

    1.1. Ensure MDRD and Pediatric OR team members are competent to reprocess Flexible Endoscopes and related equipment (See 4.0 Competency Requirements).

    1.2. Identify a Qualified Assessor to perform competency assessments annually or more frequently if required.

    1.3. Maintain records of competencies including initial training, annual recertification in educational file for each MDRD and Pediatric OR team member reprocessing flexible endoscopes for a minimum of 10years.

    1.4. Ensure accurate and comprehensive documentation of the Flexible Endoscope Reprocessing (Appendix B) is completed by MDRD and Pediatric OR team members after each scope is used.

        1.4.1. Maintain documentation records by the departments for a minimum of ten years.

    1.5. Ensure the permanent record of the reprocessing steps that will facilitate the ability to retrospectively link the scope used for every patient procedure, are stored by the departments for a minimum of ten years.

2. The Medical Device Reprocessing Department (MDRD) and Pediatric OR Manager ensure all scopes must be reprocessed in accordance to the Manufacturer's Instructions for Use and CSA Standard Z314.23.

3. OR team members must maintain a complete, accurate and up-to-date inventory of flexible endoscopes and loaners in the department.

    3.1. OR team members must inform the MDR Liaison of any new or loaned flexible endoscopes and provide appropriate documentation.

    3.2. MDR technicians must send endoscope repairs to MDR liaison to send to the appropriate OR.

Competency Requirements

4. Medical Device Reprocessing (MDR) and Pediatric OR team members must obtain appropriate education and hands on training for all stages of flexible endoscope reprocessing, which must include:

4.1. Review of this policy.

4.2. Review of relevant standard operating procedures (SOPs) for each Flexible Endoscope which includes but not limited to:

4.2.1. Manual cleaning
4.2.2. High level disinfection/sterilizing
4.2.3. Drying
4.2.4. Storage

4.3. Be certified as competent by manufacturer's representative prior to completing the task independently.

4.4. Participate in ongoing training and complete annual recertification requirements for flexible endoscope reprocessing.

RESPONSIBILITIES

MDR and Pediatric OR Manager must:

5. Ensure the Automated Endoscope Reprocessor (AER)/sterilizer is compatible with all scope models in the inventory and the required hook-ups are available.

5.1. Obtain AER/sterilizer compatibility information from the AER Manufacturer in written form.

5.2. Complete preventative and scheduled maintenance, including repairs and maintain documentation for each AER/sterilizer.

6. Ensure full Personal Protective Equipment (PPE) is worn for all steps of cleaning and disinfection of flexible endoscopes and accessories. PPE must include, but is not limited to hair covering, full face protection, long-sleeve fluid resistant gown and chemical resistant gloves.

7. Ensure all required quality assurance activities are completed and documented for the following equipment: Automatic Endoscope Reprocessor (AER), Scope Buddy, and Cleaning Verification Test.

8. Ensure Cleaning Verification Tests in performed in accordance with the Manufacturer Instruction for Use (MIFU's) recommendations.

9. Ensure flexible endoscopes with lumens that are stored **without** air purge capability for more that seven days are fully reprocessed before use.

10. Ensure flexible endoscopes stored in a validated HEPA-filtered channel purge cabinet follow the device Manufacturer Instruction for Use (MIFU) for shelf life.

11. Follow-up on adverse incidents and complete the following:

    11.1. Notify Infection Prevention and Control.

    11.2. Complete a safety improvement management report.

GUIDING PRINCIPLES AND VALUES

People Centered Care & Safety: Cleaning and disinfecting the health care environment including health care tools used is necessary to ensure the safety of patients, and IWK Health team members. It reduces physical environmental hazards, the amount and number of infectious pathogens that may be present and reduces the risk of infection by minimizing the transfer of microorganisms from one person/object to another.

Evidence-Informed Practices: IWK Health promotes the delivery of safe, high-quality care and holds all team members accountable for maintaining clean and safe facilities. Through attention and adherence to cleaning and disinfecting best practices, we strive to increase the confidence and trust amongst our patients and IWK Health team members.

REFERENCES

ANSI/AAMI *ST91: Endoscope processing in healthcare facilities*. Default. (n.d.). https://www.aami.org/ST91.

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Public Health Ontario, Provincial Infectious Diseases Advisory Committee. (2013). *Best practices for cleaning, disinfection, and sterilization of medical equipment/devices in all health care settings, 3rd edition*. https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?la=en

Public Health Agency of Canada. (2010). *Infection prevention and control guideline for flexible gastrointestinal endoscopy and flexible bronchoscopy*. https://www.canada.ca/en/public-health/services/infectious-diseases/nosocomial-occupational-infections/infection-prevention-control-guideline-flexible-gastrointestinal-endoscopy-flexible-bronchoscopy.html.

RELATED DOCUMENTS

Appendices

Appendix A: Definitions
Appendix B: Required Documentation for Flexible Endoscope Reprocessing

Appendix A: Definitions

Automated Endoscope Reprocessor (AER)	A machine designed to assist in the reprocessing of endoscopes and endoscope accessories.
Biological Indicator (BI)	A test system containing viable micro-organisms providing a defined resistance to a specific sterilization process.
Flexible Endoscope	Flexible fiberoptic or video endoscope used in the examination of hollow viscera (bronchoscope, colonoscope, duodenoscope, gastroscope, sigmoidoscope, etc.).
Cleaning Verification Test:	A visual inspection combined with other verification methods that allows the assessment of both external surfaces and internal housing and channels.
Lumen	The inner spaces in tubes that transport liquids, gases, or surgical devices during a surgical procedure.
MDR Liaison	An MDR team member identified by the MDR Manager to who acts as a link to assist communication or cooperation between Pediatric OR and MDR Departments.
MDR Team Member	All employees working in Medical Device Reprocessing Department.
Minimal Effective Concentration (MEC)	The lowest concentration of a chemical or product, used in a specific process, that achieves a claimed activity.
Qualified Assessor	Team Member deemed competent to perform competency assessments or Manufacturer's Qualified Competency Assessor.
Scope Buddy	A device designed to be used as a flushing aid only during the manual cleaning process of a flexible endoscope. This device is not an endoscope disinfector.
Sterilizer	A machine designed for rendering a product free from viable micro-organisms.
Team Member	Refers to employees and contractors within IWK Health.

Appendix B- Required Documentation for Flexible Endoscope Reprocessing

Records must include, but are not limited to the following:

1. Date and time of procedure
2. Patient identification details
3. Instrument identification details
4. AER identification number
5. Unique identifier (signature, initials) of the person who is responsible for:
   a) point of use cleaning at the bedside, (also time point of use cleaning was performed),
   b) manual cleaning (including leak testing, brushing, rinsing),
   c) High Level Disinfection procedures including correct connection to the AER, time/temperature, and contact time for the HLD
6. For disinfectants:
   a) Minimal Effective Concentration (MEC) testing of reusable disinfectants shall be completed prior to each use following MIFUs (note: some AER perform post cycle MEC and some are single dose disinfectants that do not require MEC testing, however some AER will document that the disinfectant was present in the chamber),
   b) signature of the person conducting the testing,
   c) record of the cycle count of AER if it pertains to the expiry of the HLD,
   d) quality assurance of strip testing in accordance to the MIFU,
   e) lot number and expiry date of disinfectant,
   f) date new disinfectant was installed or activated.
7. Cleaning of the flexible endoscope storage cabinet at a minimum every seven days.
8. Documentation records must be stored by the department for a minimum of ten years**.**

IWK/NSH Policy Documents Being Replaced

(Please List)

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)