
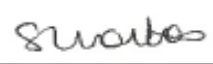



LEAK TEST AND MANUAL CLEANING OF FLEXIBLE BRONCHOSCOPE POST PROCEDURE	
Version Number	1
Date of Issue	January 2020
Reference Number	LTMCFBPP-01-2020-MS-NC-V1
Review Interval	3 yearly
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Document Review History
This SOP is replacing the SOP "Leak Test & Manual Cleaning of Wolf Bronchoscope Post Procedure

Document Change History	
Change to Document	Reason for Change
New HSE Standards	New HSE Standards
Updated the following sections: Purpose, Definition of Terms, Responsibility, Guideline, Procedure, Reference & Appendices	

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1.0 Purpose

To outline the procedure for leak testing and manually cleaning of Flexible Bronchoscope post procedure. Ensure all Reusable Invasive Medical Devices (RIMD) including flexible scopes are traced through the decontamination process to the service user and ensuring RIMD are checked and reprocessed in accordance with manufacturer's instructions.

2.0 Definition of Terms

Endoscopes: Flexible bronchoscopes.

Cleaning: A process using friction, detergent and water to remove soil, including organic debris.


High-level disinfection: A process that destroys all micro-organisms with the exception of high numbers of bacterial spores. High-level disinfectants have the capability of inactivating the hepatitis B virus, HIV and Mycobacterium tuberculosis.

3.0 Responsibility

It is the responsibility of each member of staff (Nursing, Endoscopy Healthcare Assistants) leak testing and manually cleaning the bronchoscope to follow the correct procedure.

4.0 Guidelines


- Endoscopes are leak tested and manually cleaned immediately after use.
- Endoscopes are checked as applicable; for defects, damage, functionality and cleanliness throughout the decontamination process, while in storage and before use on the patient.
- Failure to properly clean and perform high-level disinfection of endoscopic equipment after each examination can compromise patient safety.
- If the endoscope is not cleaned meticulously, effective disinfection may not be possible. The endoscope must be cleaned thoroughly before disinfection to remove microorganisms or organic material that could reduce the efficacy of disinfection.
- To minimise the risk of transmitting diseases from one patient to another after each examination, the endoscope must undergo thorough manual cleaning immediately after use followed by high-level disinfection.
- The endoscope must be rinsed internally and externally after manual cleaning and before being placed in the automated washer disinfectant. Rinse water must be visibly clean. If not, repeat manual wash.

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- It is estimated that a minimum time frame of 30 minutes is required to manually decontaminate and leak test a flexible multi-channeled endoscope safely, prior to automated disinfection. This time includes; key processors such as donning Person Protective Equipment (PPE), preparation of solution for cleaning, scope tracking, scope examination, connection of the endoscope to the Endoscope Washer Disinfector (EWD) etc (Appendix 1). It is estimated that the time taken to remove the endoscope EQD, visually inspect cycle parameters, perform scope tracking procedures and prepare the scope for transport, back to the user or storage or extended storage cabinet, requires a further 5 minutes.

5.0 Procedure

- Place patient addressograph into manual cleaning record book in decontamination room. Record scope barcode on addressograph and tick relevant boxes regarding bedside wipe, flush if applicable and Infection Control Alert.
- At bedside, **flush** Wassenburg Endohigh Detergent solution (1.25mls:250mls H₂O) for 30 seconds, remove from solution and flush air for 10 seconds. **Wipe** insertion tube with detergent soaked swab. Discard biopsy cap in clinical waste bag (if applicable).
- Personal protective equipment must be worn as outlined in policy "Attire to be Worn when Cleaning Endoscopes".
- Use disposable cleaning brushes ref. no. 1215A / J-cloth and 20mls syringes.
- Take endoscope to sink in the designated rigid scope container lined with a tray liner and covered with a **RED** plastic cover. Transport to washroom.
- Fill separate 1 litre bowls x 2 (if applicable); one with Wassenburg Endohigh detergent solution (check detergent concentrate document on cabinet door over sink), the other with clean water and leave beside sink (use this for rinsing purposes either manual rinse or using the Scope Buddy flushing aid).
- Perform dry leak test i.e. attach appropriate leak tester, inflate gauge indicator to green zone check for any leaks (continuous bubbles) observe instrument while angulating tip. Check scope for functionality and for any defects or damage.
- Fill sink with 15 litres of water, water temperature set at 25 degrees Celsius (press button on thermometer that is placed on the ledge over the sink), sink is marked at this level (don't immerse leak tester hand piece) observe instrument while angulating tip. A few bubbles may occur, this is normal but if there is a


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continuous stream of bubbles from the same spot, this indicates a leak. Remove immediately from water, release pressure from tester and remove tester from endoscope. Dry brush biopsy channel if present and externally wipe down endoscope with detergent soaked cloth. Inform Clinical Engineering & CNM II to send for repair as per SOP "Sending Olympus, Pentax or ENT for Repair"

- If there is no leak, release pressure on leak tester gauge, **N.B.** detach it from scope out of the water to prevent water leakage into scope.
- Proceed to cleaning by adding Wassenburg Endohigh Detergent 75mls i.e. press detergent pump once to 15litres of water already in sink.
- Use 20ml syringe, to **flush** detergent solution (minimum 90mls) through biopsy channel (if applicable).
- Use detergent soaked J-cloth to **wipe** all external parts of the endoscope starting from the least contaminated part the (camera insert section) and ending at distal end of the endoscope. Repeat wipe on insertion tube and wipe across lens (distal tip). Then large cleaning brush is used to clean external channel and angulating knob on the endoscope
- Using small disposable cleaning brush; **brush** biopsy channel (if applicable), cleaning brush at distal end before retracting it back up the endoscope (minimum 3 times brushing). Use the large cleaning brush to clean the internal channel. Change water and detergent solution if necessary. (Do not use excessive force. Do not squeeze or bend endoscope). Never insert brush in distal end. Please ensure that the brush is intact after completing the brushing stage.

5.1 Steps for Manual Rising of scopes – **Sink is still full of detergent**

- For all ENT channeled scopes; flush biopsy channel with 90mls of detergent
- Leave soaking for 5 minutes.
- Empty sink, fill with clean water, flush biopsy channel with 90mls of clean water
- **Wipe** externally the non-channel endoscope with clean water
- Empty the sink and flush 90mls of air down the biopsy channel

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SCOPE BUDDY

Scope Buddy Endoscope Flushing Aid is designed to facilitate the flushing of rinse water, cleaning solutions and approved room temperature high-level disinfectants, through the channels of flexible, immersible endoscopes. This device is to be used during the manual pre-cleaning, high-level disinfection and rinsing phases of endoscope reprocessing. Scope Buddy Endoscope Flushing Aid does not replace an automated endoscope re-processor (AER).

The Scope Buddy Flushing Aid is designed to be used as a flushing aid only and assists in the circulation of cleaning or high-level disinfectant solutions through endoscope channels. All endoscopes must undergo cleaning and high-level disinfection prior to use on a patient.

Safety: Intended Use

The Scope Buddy Endoscopy Flushing Aid is an electro-mechanical device intended to flush fluids through channels of flexible, immersible endoscopes. The device is designed to assist in the circulation of fluids by replacing manual syringing of endoscope channels. Endoscopes must be meticulously cleaned and high-level disinfected by an approved endoscope re-processor or manual HLD soaking prior to use on a patient. This device is not an endoscope disinfectant and does not take the place of an Automated Endoscope Re-processor (AER).

Steps for Using Scope Buddy Rinsing Aid:

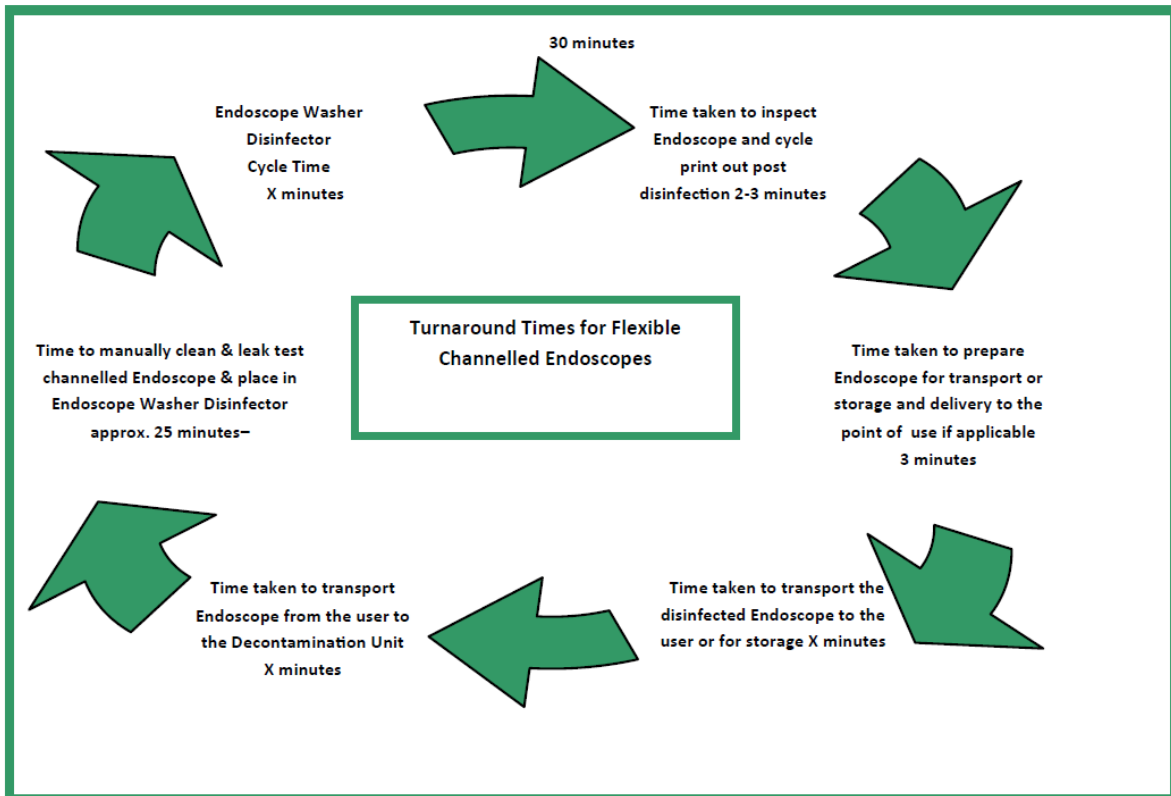
- To ensure correct Scope Buddy operation, the Quality Assurance Flow Validation Test **must be** performed prior to the first use of the day (see Appendix 2).
 - Use the Scope Buddy flushing aid to rinse the biopsy channel (see Appendix 3)
 - If Scope Buddy is used, you **must** decontaminate the machine (see Appendix 2).
- Load into washer / disinfectant as per policy "Loading Endoscope into Wassenburg Washer / Disinfectant".
 - Sign the manual wash record.
 - The transport container is then cleaned. This cleaning process involves manually washing the designated rigid scope container with water and Brial detergent. Then dried and wiped with Azowipe and placed in the decontaminated transport trolley on the clean side. Sink and surrounding area is washed with Brial solution and / or actichlor if infected scope used.


5.0 References

HSE Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities June 2019 V.1 (QPSD-D-082-1)

6.0 Appendices

Appendix 1



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Appendix 2

QUALITY ASSURANCE PROCEDURE – SCOPE BUDDY

To ensure correct Scope Buddy operation, the Quality Assurance Flow Validation Test must be performed prior to the first use of the day. The Scope Buddy Decontamination Procedure must be performed DAILY if recirculating solutions from sink; or MONTHLY if drawing solutions from clean and dedicated supply container. Record all results using the Quality Assurance Log. Contact Medivators Customer Support at 1-800-444-4729 or your local distributor (if located outside the U.S.) for further assistance.

PRIOR TO FIRST USE OF THE DAY

Perform Scope Buddy Flow Validation as follows:

1. Connect Fluid Intake Line to 'IN' port and place filter screen in clean water;
2. Connect Universal Cleaning Adapter Extension Line to 'OUT' port and Flow Verification Tube to remaining luer lock end;
3. Using the front panel arrow keys; set the time display to one (1) minute;
4. Prime the tubing by pressing the "START / STOP" which initiates water flow;
5. When a steady column of water exits the Flow Verification Tube; press "START / STOP" to halt flow;
6. Place open end of pre-primed Flow Verification Tube into empty graduated cylinder;
7. Using the front panel arrow keys; set the time display to ten (10) seconds;
8. Press "START / STOP" button to begin fluid flow into graduated cylinder;
9. Upon time-out; the display flashes zeros and an audible tone is heard;
10. Remove Flow Verification Tube from graduated cylinder and read dispensed volume:
 - If volume is \geq 100mls, record a "Pass" result on the "Scope Buddy Quality Assurance Log";
 - If volume is $<$ 100mls, record a "Fail" result on the "Scope Buddy Quality Assurance Log".

DECONTAMINATION FREQUENCY

Perform DAILY if recirculating solution from sink; MONTHLY if drawing solutions from clean and dedicated supply container. Perform Scope Buddy Decontamination Procedure by:

1. Locate Fluid Intake Line and place filter screen in decontamination solution;
2. Locate open end of outflow tubing and place in decontamination solution;
3. Using the front panel arrow keys, set the timer for:
 - Two (2) minutes if Scope Buddy is to soak for the minimum contact time specified by the decontamination solution labelling.
4. Press "START / STOP" button to begin fluid flow and verify decontamination fluid delivery through Scope Buddy and tubing:
 - If timer set to 5 minutes, the press "START / STOP" to halt fluid flow and allow solution to soak for full contact time specified by manufacturer's decontamination solution labelling;
 - If timer set to contact time specified by manufacturer's decontamination solution labelling, then allow cycle time to complete.
5. Document decontamination procedure on Scope Buddy Quality Assurance Log;
6. If Scope Buddy is to be unused for an extended period of time such as overnight or over the weekend, **it should be left full of decontamination fluid or clean water.** This maintains pump-head decontamination, lubrication and facilitates priming. Once the tubing is decontaminated, it can be detached during this time.

www.minntech.com/medivators







1-800-444-4729

Endoscope reprocessing the way it should be MEDIVATORS

Appendix 3

SCOPE BUDDY

Endoscope Flushing Aid USE POST CLEANING

1		<p>IN Connection</p> <p>Perform Scope buddy Flow Validation Test, prior to first use of the day (Procedure on Ot6 door) & Sign</p> <p>Connect Fluid intake Line to 'IN' port and place filter screen in diluted detergent solution.</p>
2		<p>OUT Connection</p> <p>Using Universal Extension Line, connect to "OUT" port and to Universal 2 or 3 way adapter.</p> <p>Use 3 way adapter for endoscopes with 3 channel and 2 way adapter for endoscopes with 2 channel.</p>
3		<p>ATTACH Endoscope</p> <p>Connect endoscope to Scope buddy universal extension line and appropriate adapter. Use vygon green adaptor + 3 way stopcock for Pentax suction port. Ensure endoscope is fully immersed in clean Detergent filled sink.</p>
4		<p>FLUSH Endoscope</p> <p>Use ▲ or ▼ arrows to set flush time. 30 seconds for 2 channel and 45 seconds for 3 channel scopes.</p> <p>Press "START/STOP" to begin cycle. Verify fluid exits all channels, wait 5 minutes detergent soakage time.</p> <p>Upon completion tone sounds and display flashes 000.</p>
5		<p>RINSE Endoscope</p> <p>Empty Sink / fill clean water & wipe endoscope. Place fluid intake Line in clean water. Set flush time. 30 seconds for 2 channel and 45 seconds for 3 channel scopes. Press "START/STOP" to begin cycle. Verify fluid exits all channels.</p>
6		<p>PURGE Endoscope AIR</p> <p>Empty Sink. Remove Fluid intake line from fluid. Set flush time as before. Press "START/STOP" to begin cycle.</p> <p>Press "START/STOP" when fluid no longer exits.</p>

Decontaminate Scope Buddy Tubing and Adaptors and sign.
 (See procedure for decontamination of scope buddy)

Our Lady's Children's Hospital Crumlin, Operating Theatre Department Endoscopy Theatre

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