
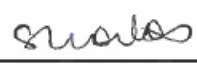



LEAK TEST AND MANUAL CLEANING OF PENTAX GASTROSCOPE AND COLONOSCOPE POST PROCEDURE	
<b>Version Number</b>	V6
<b>Date of Issue</b>	January 2020
<b>Reference Number</b>	LTCPGCPP-01-2020-MS-NC-V6
<b>Review Interval</b>	3 yearly
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Document Review History		
<i>Review Date</i>	<i>Reviewed By</i>	<i>Signature</i>
August 2019	Mary Scully Niamh Clohessy	

Document Change History	
<i>Change to Document</i>	<i>Reason for Change</i>
New HSE Standards	To bring in line with new standards
Updated the following sections: Responsibility, Guideline, Procedure, Reference & Appendices	

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## 1.0 Purpose

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

## 2.0 Definition of Terms

*Endoscopes:* Flexible, gastroscopes, colonoscopes

*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 theatre staff (Nursing, Endoscopy Healthcare Assistants) to leak test and manually clean the endoscope according to this SOP.

## 4.0 Guidelines

### Bedside:

- The Pentax endoscope accessory buttons, uniquely colour coded to each Pentax endoscope are returned to HSSD for autoclave sterilisation. Dispose of single use **RED** biopsy button.
- Endoscope is **wiped down** and **flushed and suctioned** with detergent and water 1.25mls in 250mls of water. If auxiliary channel is present – Flush with 30mls of detergent / solution by the user.
- Endoscopes are checked as applicable for defects, damage, functionality and cleanliness throughout the decontamination process before use on the patient.
- Failure to properly leak test, manually clean and perform high-level disinfection of endoscopic equipment after each procedure can compromise patient safety.
- To minimise the risk of transmitting diseases from one patient to another after each examination; the endoscope must undergo thorough manual cleaning immediately after


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use followed by high-level disinfection. The endoscope must be cleaned thoroughly before disinfection to remove micro-organisms or organic material that could reduce the efficacy of disinfection. The endoscope must be rinsed internally and externally after manual cleaning and before being placed in the automated washer disinfector. Rinse water must be visibly clean. If not, repeat manual wash.


- If the endoscope is not cleaned meticulously; effective disinfection will not be possible.
- It is estimated that a minimum time frame of 30 minutes is required to manually decontaminate and leak test a flexible multi-channelled endoscope safely, prior to automated disinfection. This time include; key processes 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). EWD (Pentax) takes approximately 25 minutes. It is estimated that the time taken to remove the endoscope from the EQD, visually inspect cycle parameters, perform scope tracking procedures and prepare the scope for transport (back to the user or storage) requires a further 5 minutes.

## 5.0 Procedure

- Place patient addressograph into manual cleaning record book in decontamination room. Record scope barcode on the addressograph and tick relevant boxes regarding bedside wipe, flush and Infection Control alert.
- At bedside post procedure performed by user:
  - Wipe entire insertion from central to distal end (Lint free cloth dipped in detergent + H<sub>2</sub>O, discard cloth).
  - Remove biopsy cap and discard; attach irrigation tubing MM-856 to biopsy port.
  - Place distal end of endoscope into diluted Wassenburg Endohigh cleaner solution (1.25mls : 250mls H<sub>2</sub>O)
  - Suction, depressing red button x 30 seconds
  - Remove both out of detergent solution and suction air x 10 seconds
  - Remove air water button (blue) and attach “channel cleaning adaptor MM948”
  - Place distal end scope only into detergent
  - Press “channel cleaning adaptor MM948” button + hold x 3 seconds, release button x 10 seconds (scope is still under water)
  - Auxiliary channel – if attached to endogator, depress x 10 seconds, if not attach 20ml syringe + flush 30mls H<sub>2</sub>O through.

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- Ensure protective cap is attached if applicable (on older model i.e. loan endoscope). Take endoscope to sink in the designated rigid scope container lined with tray liner and covered with the **RED** plastic cover. Bring the Olympus bowl and cleaning accessories set to decontamination room as the Octopus is required.
- Personal protective equipment must be worn as outlined in *“SOP Attire to be Worn when Cleaning Endoscopes”*.
- Fill separate 1 litre bowls x 2; one with Wassenburg Endohigh detergent solution, the other with clean water and leave beside sink. See concentration document on door of cabinet above sink (use this for rinsing purposes either manual rinse or using the Scope Buddy flushing aid). SEE reference on **Scope Buddy** below.
- Use single use cleaning brushes ref. no. BW-412T / J-cloth / 20 ml syringes.
- Perform dry leak test i.e. follow (Step 1) attach Olympus leak tester to scope (Step 2 & 3) turn on switch 2, and switch 3 on leak tester box, then (step 4) push leak tester prong into leak tester box, check for any leaks (continuous bubbles), observe endoscope while angulating tip in all 4 directions.
- Fill sink with 15 litres water (sink is marked at this level), water temperature set at 25 degrees Celsius (press button on thermometer that is placed on the ledge over the sink), observe endoscope while angulating tip. If no leak observed, reverse steps 4,3,2,1 and release out of water.
- A few bubbles may occur, this is normal but if there is a **continuous stream of bubbles** from same spot, this **indicates a leak**, remove immediately from water. **Never disconnect leak tester under water** as this can cause water leakage into endoscope. Externally wipe down endoscope with detergent solution and dry brush internal channels. Inform CNM II or Endoscopic HCA and they will send to Keymed Ireland for repair as per SOP “Sending Olympus, Pentax, Wolf Endoscope for Repair”.
- Proceed to cleaning by adding 75mls (press detergent pump once) to 15 litres of water already in sink. Keep scope submerged under water to prevent splashing during cleaning.
- Change water and detergent solution if necessary and repeat wash.
- Use 20ml syringe to **flush** 90mls of detergent solution through auxiliary water channel (if present).
- Use detergent soaked j-cloth to **wipe** all external parts of endoscope starting from least contaminated part (camera insert section) and ending at distal tip of endoscope. Repeat wipe on insertion tube and wipe across lens (distal tip). Using the larger brush, brush around the external opening of all channels including the angulating control knobs, gently

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brush across the distal tip of the endoscope from metal to camera lens once.

- At **Brush stage** use **small** end of disposable cleaning brush; (1) the brush is inserted at 45 degree angle through the proximal air channel port and exits at the suction port of the endoscope, (2) the same brush is inserted via the same outlet as before at a 90 degree angle exiting at the distal end, (3) the brush is inserted down through the biopsy channel and exit at the distal end of the endoscope. Brush a minimum of 3 x times for each channel. Clean the brush each time it exits the endoscope before drawing it back up through the channel. Using the larger brush, brush **all of the internal** channels. Change water and detergent solution if necessary. Never insert brush in opposite (distal) end. **Do not use excessive force. Do not squeeze or bend endoscope and ensure cleaning brushes are intact.**
- **Do not empty detergent filled sink.**
- Steps for Manual Rinsing of Olympus Endoscopes (Appendix 2)

### 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 a EWD.

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 EWD.

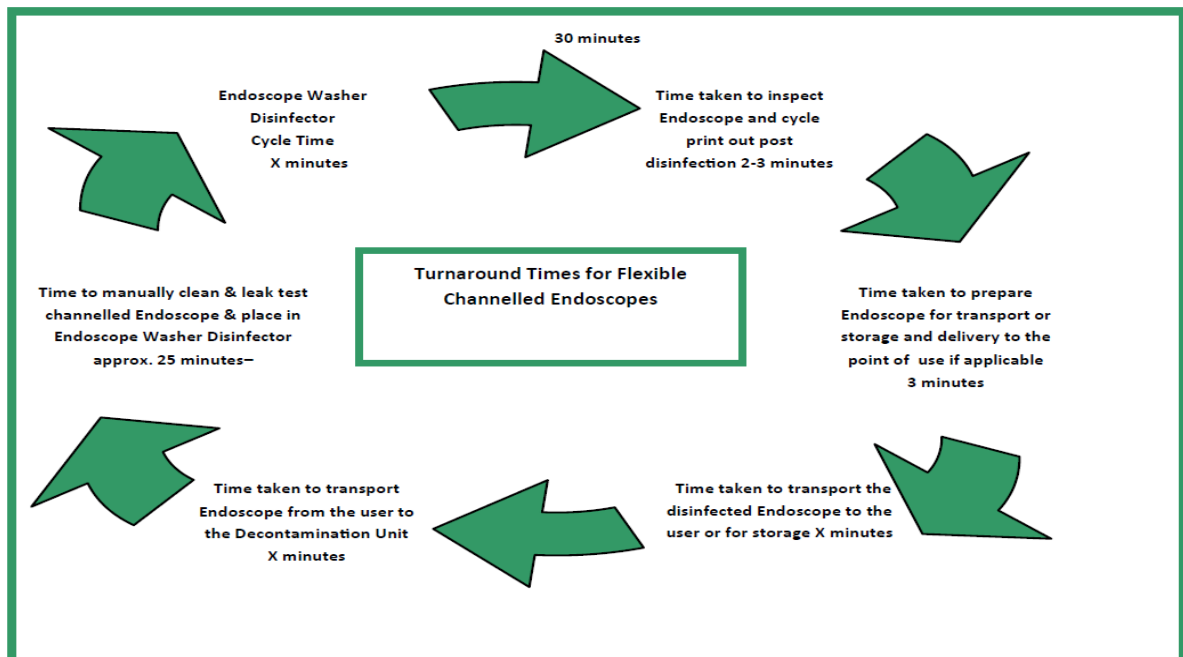
- Steps for using Scope Buddy rinsing aid:
  - To ensure correct Scope Buddy operation, the Quality Assurance Flow Validation Test must be performed prior to the first use of the day (see Appendix 3).
  - Use the Scope Buddy flushing aid to rinse the Olympus endoscope (Appendix 4).


- Decontaminate Scope Buddy and see decontamination frequency on Appendix 3
- Place Olympus bowl and cleaning accessories with signed checklist into HSSD collection box in disposal room.
- Load endoscope into Wassenburg processor as per SOP “Loading Endoscope into Wassenburg Washer / Disinfector”.
- 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.

## 6.0 References

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

## 7.0 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](http://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**

<b>1</b>		<p><b>IN Connection</b></p> <p>Perform Scope buddy Flow Validation Test, prior to first use of the day ( Procedure on Ot6 door ) &amp; <b>Sign</b></p> <p>Connect Fluid intake Line to 'IN' port and place filter screen in diluted detergent solution.</p>
<b>2</b>		<p><b>OUT Connection</b></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>
<b>3</b>		<p><b>ATTACH Endoscope</b></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>
<b>4</b>		<p><b>FLUSH Endoscope</b></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 soukage time.</p> <p>Upon completion tone sounds and display flashes 000.</p>
<b>5</b>		<p><b>RINSE Endoscope</b></p> <p>Empty Sink / fill clean water &amp; 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>
<b>6</b>		<p><b>PURGE Endoscope AIR</b></p> <p><b>Empty Sink.</b> 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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