Decontamination of Endoscopes

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Approved by:	TIPCC Trust Decontamination Committee
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Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All services involved in the use and decontamination of endoscopic equipment
Target staff categories	All staff groups involved in the use and decontamination of all endoscopes (including bronchoscopes, scopes used intra-operatively and non lumened flexible devices)

Policy Overview:

- The aim of this policy is to provide a framework for the safe decontamination of all flexible endoscopic equipment (this includes duodenoscopes, gastroscopes, colonoscopes, laryngoscopes, bronchoscopes, choledocoscopes, cystoscopes and hysteroscopes).
- Decontamination is a general term that is used for the destruction or removal of microbial contamination to render an item safe. This will include methods of cleaning, disinfection and sterilization, (Ayliffe 1993)

Key amendments to this Document:

Date	Amendment	By:
Nov 2010	**1.** Insertion of exclusions to this policy **B4.9.1** Insertion of instructions for reprocessing rigid nasendoscopes. **B4.13** Amendment to reduce frequency of final rinse water testing for mycobacterium from 6 months to every 12 months. Insertion of additional information on types of face mask usage information (Appendix 5)	H Gentry
Nov 2010	**B4.13** Insertion of HTM2030 guidance on maintenance testing to	S Steward

	the existing section on validation processes for Automatic washer disinfectors	
21/10/13	Document extended until the end of January 2014 whilst under review	TIPCC
21/07/14	Document extended for 3 months	Lindsey Webb
28/04/15	Document extended for 3 months	Lindsey Webb
11/08/15	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
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Nov 2017	Document extended for three months whilst under review	TLG
March 2018	Document extended for 3 months as approved by TLG	TLG
June 2018	Document extended for 3 months as approved by TLG	TLG
October 2018	Document extended until end of November	Heather Gentry
April 2019	Document extended for 6 months whilst review process takes place	TIPCC

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Medical and surgical devices may serve as a vehicle for the transmission of infectious disease to susceptible hosts, (Damani 1997)

1. Exclusions from this Policy

The use and processing of rigid re-usable and single use anoscopes, proctoscopes and sigmoidoscopes are excluded from this policy. For advice refer to the A to Z section of the General decontamination Protocol (WAHT-INF-009)

2. Cleaning and Disinfection (Decontamination) Of Endoscopes

Key Recommendations

Only suitably trained personnel who hold appropriate competencies for their role must carry out cleaning and disinfection of endoscopic equipment. Training should include an awareness of the channel configuration of all endoscopes and of the Automated Endoscope Reprocessor (AER) and available irrigation adaptors.

- If an emergency endoscopic procedure is performed out-of-hours, trained personnel must be available and be responsible for cleaning and disinfecting the equipment. This should include scopes that might be used in departments other than the endoscopy units e.g. ITU and operating theatres.
- MANUAL CLEANING of the instruments with a neutral or enzymatic DETERGENT is the most important aspect of the process. Manual cleaning is a pre-requisite (MDA July 2002) to further processing in an Automated Endoscope Reprocessor (AER) approved washer disinfector.
- When using or processing endoscopes, appropriate personal protective equipment should be worn (see **B4.11**).
- AIM OF CLEANING – To remove all blood, secretions and other organic material prior to the surfaces coming into contact with the disinfectant.

- All modern endoscopes are fully immersible but caps must be fitted when required (eg video endoscopes). Manufacturers' instructions must be followed.
- There must be systems in place for tracking endoscopes and re-usable accessories through decontamination processes, not only to assist with assuring their quality, but also to enable the identification of patients on whom the medical devices have been used.
- Scopes must not be used for anything other than manufacturer's intended use.

3. Practical Recommendations

The following recommendations are made for cleaning and disinfection of all endoscopes (including bronchoscopes) and are based on current best practice guidance published by the British Society Gastroenterologists (BSG 2008), Medicines and Healthcare Products Regulatory Agency (MHRA – formerly MDA) & NHS Estates HTM 2030.

4. Usage of Free-Standing Ultrasonic Cleaners

All free-standing ultrasonic cleaners MUST be on a planned preventative maintenance programme with the Estates Department as recommended in HTM 2030 Table 5g Validation and Verification Section. All ultrasonic cleaners must have lid / removable baskets.

At The Start of the Day
Fill with water and add recommended dose of cleaning solution, eg enzymatic detergent. See manufacturer's recommendations.

Daily User Test
Automatic Control Test (HTM 2030 sections 12.4 - 12.8)

At The End of the Day
Empty the chamber of solution, rinse or dry and if present leave drain valve open.

5. Preparation of the Automated Washer Disinfector

(Daily Inspection / Test)
Prior to first use of the day, the washer disinfector / Automated Endoscope Reprocessor (AER) must have undergone a self-disinfection cycle. (This is not necessary where Sterilox is used as the processor self disinfects automatically each cycle). This process may be automatic or pre-set to occur at a designated time dependant on the make of the processor.

The operator must then carry out the daily test according the manufacturer's instructions in order to comply with HTM 2030 Table 5e Validation & Verification Section.

6. At the Start Of The Day

1. All endoscopes to be used during the list should be checked for faults.

2. If endoscopes or valves have been thoroughly cleaned and disinfected at the end of the previous day, they should be put through an automated cleaning and disinfection process for a normal cycle. However if the endoscopes / valves have not been used for more than 24 hours it will be necessary to perform a manual clean prior to reprocessing

(this process is not be required if endoscopes have been stored after reprocessing in a HEPA filtered storage cabinet).

3. Test the instrument for leaks, faults or damage before immersing in a suitable neutral or enzymatic detergent (**NB:** enzymatic detergents are temperature dependant for optimum cleaning).

   The automated washer disinfector will perform steps 4 – 6 as outlined below.

4. All channels will be flushed with the disinfectant. It is essential that the endoscope is correctly connected to the connecting tubes including any auxiliary channels. If the scope has a bridge raiser this must be in the raised position when it is placed in the washer disinfector.

   Ensure disinfectant emerges from all ports on the light guide connector and distal end of the instrument by observing the machine's alarm mechanism or print out.

5. The instrument will remain fully immersed in the disinfectant / sterilant for the entire contact time.

6. After disinfection, endoscopes and valves will be rinsed in bacteria-free water, ensuring that all traces of disinfectant / sterilant are removed from the channels, control body and eyepiece.

7. Remove the endoscope and valves from the processor. Dry carefully and insert valves ready for use.

8. The instrument may then be plugged into the light source and connected to the suction pump.

   The instrument is then ready to use.

7. Between Cases – Lumened Endoscopes

1. Prior to detachment from the light source or video processor a preliminary cleaning routine should be undertaken followed by the dismantling of detachable parts of the endoscope.

   Flush the suction channel by immersing the distal tip of the endoscope in clean water and depressing the suction valve for at least 15 seconds. The air / water channel must then be flushed with water for at least 15 seconds to ensure that blood, mucus and other debris are expelled.

   NB: The air / water valve MUST be replaced with a high pressure-flushing valve to flush the air / water channel.

   The insertion tube must then be wiped down externally and checked for any bite marks or other surface damage. The endoscope may then be disconnected.

   Where an auxiliary channel is present the auxiliary washing pipe should be connected to the auxiliary channel port. Using a new syringe, flush the suction channel with clean water until it runs clear. The distal tip of the scope should remain immersed to reduce the risk of aerosol production.

If the scope has a raiser, lift the bridge, then clean and brush the cavity to remove any organic material trapped during the procedure. The outer surface of the insertion tube should be wiped to remove gross soiling using a solution of enzymatic detergent.

2. Test the instrument for leaks, faults or damage before immersing it in a suitable neutral or enzymatic detergent (**NB:** enzymatic detergents are temperature dependant for optimum cleaning).

3. The third stage of decontamination is manual cleaning and rinsing of all exposed internal and external surfaces. Clean the outer surface of the endoscope carefully, using either gauze or a clean cloth, paying particular attention to the control section and the angulation controls.

3a. Clean the distal end (especially the air / water nozzle) and the bridge mechanisms of duodenoscopes, with a disposable soft cleaning brush or small port channel brush.

4. All valves should be removed and cleaned individually with a small brush designed for this purpose.

5. The bridge raiser or auxiliary channel in some endoscopes will require manual flushing using a 2 ml syringe and a channel adaptor prior to reprocessing. A new syringe should be used for each endoscope.

6. Prior to the channels being cleaned and brushed the suction and air / water ports must be cleaned with a valve brush.

7. The suction / biopsy channel must be cleaned with a flexible brush of the correct length to pass through the full length of the endoscope. The flexible brush is passed in a single direction from the proximal to the distal tip of the endoscope using several short pushing actions in one direction.

Ensure:

- That the flexible cleaning brush is passed through the suction port at each entry point – the insertion tube and umbilicus.
- When the flexible cleaning brush appears at the distal end, the distal tip of the scope and the flexible cleaning brush is cleaned using the soft cleaning brush before the flexible cleaning brush is pulled through and out of the scope.
- This is repeated a minimum of 3 times and until the flexible cleaning brush appears visually clean.
- Manual cleaning must be carried out under water to prevent the risk of splashing or aerosol production. Brush the distal tip of the endoscope with a soft cleaning brush to remove any remaining debris following the brushing of channels.

8. Use the all channel irrigator and a 20 ml syringe to flush all channels with a solution of enzymatic detergent.

9. The fourth stage of decontamination is high level disinfection. Place the scope in the wash chamber as per instruction manual. Connect to the appropriate ports on the machine. The endoscope must be fully immersed in the disinfectant for the correct time, ensuring that all channels are filled with the solution in order to achieve high level disinfection.

10. Wipe down the top of the endoscopy trolley with detergent wipe between patients.

11. Once the endoscope is disinfected, rinsed and dried, fresh valves can be inserted and the instrument placed on the clean surface ready for immediate use or hung for storage.

    NB: Scopes must be used within 3 hours of processing as beyond this time the bio-burden will have reached significant levels.

8. Between Cases – Non-Lumened Endoscopes

1. Wipe the outer surface of the insertion tube with gauze or a clean cloth to remove gross soiling. Detach from the light source or video processor if used.

2. Test the instrument for leaks, faults or damage before being immersed in a suitable neutral or enzymatic detergent (**NB:** enzymatic detergents are temperature dependant for optimum cleaning).

3. Clean the outer surface of the endoscope carefully using either gauze or clean cloth.

4. Place the scope in the wash chamber. As the scope has no channels there will be no need to connect the scope to any ports. The endoscope must be fully immersed in the disinfectant for the correct time, ensuring that all surfaces are in contact with the solution in order to achieve high level disinfection.

5. Wipe down top of endoscopy trolley with detergent wipe between patients.

   Once the endoscope is disinfected, rinsed and dried, fresh valves can be inserted and the instrument placed on the clean surface ready for immediate use, or hung for storage.

9. After The Last Case – Lumened Endoscopes

1. Endoscopes used during the list should be tested for leaks, cleaned and disinfected after each use.

2. Endoscopes should be dried before storage.

   The AER will partially dry channels by blowing filtered air through the system after the disinfection cycle is completed.

3. Endoscopes should be stored hanging vertically and without valves or caps in a designated ventilated cupboard, not in their transit cases. Where possible the

ventilated cupboard should be HEPA filtered as this will increase the hang time without need for re-processing considerably, e.g. from hours to days.

4. Each endoscope should have an individual set of valves that are processed along with the scope and remain with it at all times.

   All valves used during the list should be washed, brushed and placed in the AER with the relevant scope. Where the AER in use does not have integral ultrasonic cleaning facilities, place the washed and brushed valves in an ultrasonic machine for at least 20 minutes then rinse in clean water. Dependant upon type, the valves will either be autoclavable or require chemical disinfection in the washer disinfector.

   After processing and prior to storage valves should be dried.

   They must not be placed in the scope case for storage.

   All ultrasonic cleaning is currently integral to AER processors used in the Trust.

10. After The Last Case – Non-Lumened Endoscopes

1. Endoscopes used during the list should be tested for leaks, cleaned and disinfected after each use.

2. Endoscopes should be dried before storage.

3. Endoscopes should be stored hanging vertically in a designated ventilated cupboard, not in their transit cases.

10.1 Non-Lumened Flexible Nasendoscopes In The Outpatient Setting

It is recommended that all endoscopic equipment is processed through an Automated Endoscope Reprocessor (AER). Where no AER is available non lumened flexible scopes such as nasendoscopes may be processed using a purpose designed manual process e.g. Tristel sporicidal wipe system.

Follow the manual cleaning routine as outlined in sections **B4.7** and **B4.9**. High level disinfection may then be achieved using the chlorine dioxide (Tristel sporicidal) wipe system. All staff involved in this process must be suitably trained personnel who hold appropriate competencies for their role.

It is imperative the procedure is adhered to fully to ensure a quality and re-producable process.

Rigid nasendoscopes must be returned to sterile services department for processing between uses.

11. Cleaning and Disinfection of Accessories

- Use of single use accessories should be encouraged where access for cleaning is difficult or the item is heat sensitive, e.g. biopsy forceps.
- Many re-usable accessories are autoclavable, and if used must be processed using this method (ie water bottles, dilators and guide wires).

- During ERCP disposable accessories must be used.
- Disposable flexible cleaning brush and soft cleaning brush should be used for manual cleaning procedures.

Accessory	Recommended process
Biopsy forceps / hot biopsy forceps	Single use
Snares	Single use
Graspers	HSDU if re-usable / single use
Mouth guards	Disinfection / single use
All ERCP accessories MUST be single use	Single use
Flexible cleaning brushes	Single use
Soft cleaning brushes	Single use
Biopsy valve	Single use (BSG Guidelines)
Suction valve for bronchoscope	Single use
Suction valve for laryngoscope	Disinfection

12. Protection of Personnel in Endoscopy

- Wear disposable waterproof aprons. Change between patients. Discard if soiled with disinfectant or body fluids.
- Goggles, gloves, arm protectors and visors prevent conjunctival irritation and protect the wearer from splashes of body fluids or chemicals.

Single use particulate respirator face shields (e.g. SSP2B from Safety Plus or FFP2 Duckbill mask) should be worn during bronchoscopy procedures to protect against the exposure to Tuberculosis.

WHERE	WHAT	WHEN
Endoscopy Units	All of above except masks	Bronchoscopy All other procedures
Theatres	All of above	
Hysteroscopy	All of above except masks	
OPD/ENT	All of above	

NB: Face protection must be worn where there is a risk of aerosol production or splashing from body fluids / chemicals.

13. Recommended contact times for chemical disinfection of all endoscopes

	Sterilox	0.35% Peracetic Acid (Nu-Cidex)	Chlorine Dioxide (Tristel)
Before a session	5 mins	5 mins	5 mins
Between cases	5 mins	5 mins	5 mins

End of session	5 mins	5 mins *	5 mins *
High level disinfection,eg BEFORE ERCP BETWEEN ERCP patients BEFORE / AFTER use in immunocompromised patients (HIV) AFTER patients with Pulmonary Tuberculosis	 5 mins 5 mins 5 mins 5 mins	 5 mins * 5 mins 5 mins 5 mins	 5 mins * 5 mins 5 mins 5 mins
AFTER a patient with known infection with Mycobacterium avium intracellulare or other highly resistant mycobacteria	5 mins	5 mins	5 mins

* Sporicidal activity is achieved in 10 mins.

PROCEDURE	TYPE OF ENDOSCOPE	DECONTAMINATION PROCESS
INVASIVE Enters normally sterile body cavity	**Rigid**	Autoclave via Sterile Services
	Arthroscope	Autoclave
	Bronchoscope	Autoclave
	Laparoscope	Autoclave
	Hysteroscope	Autoclave
	Choledocoscope	Autoclave
	Flexible	
	Angioscope	Autoclave
	Bronchoscope	Chemical
	Cystoscope	Chemical
	Foetoscope	Autoclave
	Hysteroscope	Chemical
	Ureterorenoscope	Chemical
NON-INVASIVE	**Rigid**	
	Nasendoscope	Autoclave
	Flexible	
	Gl endoscope	Chemical
	Colposcope	Chemical
	Non-lumened nasendoscope	Chemical
	Digital camera	Chemical
	Scope camera	Manufacturer's Instructions
	Fibreoptic laryngoscope	Chemical

14. Maintenance Testing And Validation

In order to ensure that any washer disinfector is fit for purpose it is necessary to have a control protocol in accordance with HTM 2030. This is based on four key aspects to ensure that the required standards of performance and safety are met and sustained:

a). all WDs are subjected to a planned programme of tests to validate their performance, that is, to provide experimental evidence that, when operated under the specified conditions, the WD will reliably produce
cleaned and disinfected items to the standard required;

b). all WDs are subjected to a planned programme of tests to monitor their performance;

c). all WDs are operated in accordance with an agreed procedure by staff trained in the use of the WD;

d). all WDs are subjected to a planned programme of preventive maintenance irrespective of whether a preventive maintenance scheme is operated on the premises.

- **Weekly:**

  - **Endoscope Check for Residual Soil**

  1. Pass a sterile brush through internal channel of a randomly chosen endoscope following disinfection. The person sampling should use an aseptic technique and wear sterile gloves and a plastic apron.

  2. Roll the brush gently onto a nutrient agar plate.

  3. Seal, date, label and send to Microbiology Laboratory for culture.

  4. Wash sampling brush and return to Sterile Services for autoclaving.

     Results
     A copy should be sent to the source Department and the Infection Control Team

     Interpretation of Results
     There should be no recovery of micro-organisms

     Action to be taken in the event of recovery of micro-organisms:
     Discuss with Infection Control Team (ICT)

  - **Final Rinse Water Check for Total Viable Count Weekly plus Mycobacterium 12 monthly**

  1. Fill two sterile 250 ml containers with rinse water from the washer disinfector

     Person sampling should use an aseptic technique and wear sterile gloves and a plastic apron

Any connectors used to collect the rinse water must be sterile

2. Send both containers to Microbiology at Worcestershire Royal Hospital for Total Viable Count (TVC). Every 12 months the samples will also be tested for mycobacterial culture by prior arrangement with the Microbiology laboratory at WRH.

3. Return sampling tubing to Sterile Services for autoclaving after use

Interpretation
For endoscopy washer disinfectors in which the product is rinsed after the disinfection stage, there should be no recovery of micro-organisms, including mycobacteria from the rinse water.

All other water services supplied to washer disinfectors should contain less than 100 cfu / 100 ml of water.

To achieve the standards set by the Medicines and Healthcare products Regulatory Agency (MHRA), staff must be trained and competent to use medical devices. A comprehensive training log must be maintained for all staff using this type of equipment.

15. Traceability of Endoscopes and Accessories

A system must be in place that enables the use of each scope and its accessories to be traced, to include patient identity, whether or not the equipment was decontaminated prior to use, procedure performed, whether or not the decontamination process was effective / complete.

The Trust AER has an integral barcode traceability system which identifies the serial number of each endoscope used and the operator loading and unloading the machine.

Records must be kept for a minimum of 11 years.

16. Special Precautions In Endoscopy For Patients With Or At Risk Of CJD Or vCJD

Patients who fall into a risk category for CJD or vCJD should have been identified by screening questions pre-procedure. The additional precautions required for decontamination of endoscopes, are included in British Society of Gastroenterology (BSG) Guidance issued in February 2008 advises:

- To avoid the use of aldehyde disinfectants which are known to fix proteinous matter to surfaces
- Those involved in endoscopy ensure procedures are in place to minimise contamination and maximise cleaning
- Brushes and other purpose built catheters used to clean the channels of the endoscope should be single use to ensure maximum efficiency of cleaning and reduce the risk of inoculating other endoscopes

17. Single Use Items

Single use items should always be used where available.

18. Audit Mechanism

Annual audit by Infection Control Nurse Link Staff within the departments using the DOH ICNA or HCC Audit Tool

Weekly microbiological check as per sampling programme

Weekly microbiological check of final rinse water

Infection Control Department to co-ordinate testing and monitor results

21. References

- Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee (2008) BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy
- Medicines and Healthcare products Regulatory Agency. Decontamination of Endoscopes July 2002 DB2002(05)
- NHS Estates (1995) Health Technical Memorandum 2030 Washer Disinfectors: Management policy, design considerations, validation and verification and operational management NHS Estates.

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