

Cleaning, Decontamination & Validation of Flexible Endoscopes

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This is the most current document and should be used until a revised version is in place	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All Endoscopy Departments within Worcestershire Acute NHS Trust
Target staff categories	All staff groups involved in the use and decontamination of all flexible endoscopes in the Endoscopy Unit at Worcestershire Royal Hospital.

Policy Overview:
<ul style="list-style-type: none"> The aim of this policy is to provide a framework for the safe decontamination of all flexible endoscopic equipment (this includes duodenoscopes, gastroscopes, colonoscopes, bronchoscopes, cystoscopes, intubation scopes, ureteroscopes, Ultrasonic Endoscopes and Hysteroscopes). This version of the policy relates specifically to all Endoscopy Units within Worcestershire Acute Hospitals NHS Trust. For any other scopes used or processed outside the Trust endoscopy units please refer to WAHT-INF-026 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 2009).

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 the existing section on validation processes for Automatic washer disinfectors	S Steward

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
28/10/2014	Changes made to reflect current and up to date processes and equipment used in the Decontamination Room, Endoscopy, Worcestershire Royal Hospital.	
14/08/15	Document re-written and amended to reflect current decontamination processes within Endoscopy Units.	
28/04/17	Document checked no changes required.	Heather Gentry
26/07/2018	Policy reviewed amendments to reflect new EDW (Lance ED-Flow) and Traceability system T-Dot at Alexandra Hospital. Change in national guideline to HTM 0106. Also names added to contributors.	L Mahachi
February 2021	Document extended as per Trust agreement 11.02.2021	
9 th September 2021	Document extended for 6 months whilst under review	
18 th November 2021	Policy Reviewed and amended to adhere to current practice, equipment and personnel	K Brown
28 th January 2025	Policy Reviewed and amended to adhere to current practice, equipment and personnel	K Brown

INDEX PAGE

	Page No
1. Introduction	3
2. Scope of the Policy	3
3. Definitions of key words	4
4. Responsibilities & Duties	4
5. Policy Detail	4-12
5.1 Equipment	
5.2 Key principles of Decontamination	
5.3 Stage 1	
5.4 Stage 2	
5.5 Stage 3	
5.6 Stage 4	
5.7 Stage 5	
5.8 Cleaning and Disinfecting Accessories	
5.9 Maintenance Testing & Validation	
5.10 Breakdown of Machines / Spillages	
5.11 Special precautions in Endoscopy for patients with or at risk of CJD or vCJD	
6. Audit Mechanisms	12
7. Implications of Non-Adherence	13
8. Implementation of the Policy	13
9. Monitoring and Compliance	14
10. Policy Review	15
11. References	15
12. Background	15-16
12.1 Equality Requirements	
12.2 Risks and Mitigations	
12.3 Consultation Process	
12.4 Approval Process	
13. Contribution List	16

1. Introduction

To provide clear guidance for all Endoscopy staff taking part in the decontamination process:

- To act as reference material to inform members of staff to achieve the same standards, follow relevant guidelines and maintain a high quality decontamination service.
- To ensure patient and staff safety is paramount.

2. Scope of the policy

2.1 This policy applies to all staff involved in the decontamination process within the Endoscopy Units in the following hospitals: Alexandra Hospital, Redditch (ALX), Evesham Community Hospital (ECH), Kidderminster Treatment Centre (KTC), Malvern Community Hospital (MCH) and Worcester Royal Hospital (WRH).

2.2 This document relates to all flexible endoscopes used within the Endoscopy Department.

2.3 This policy supports standards set out by the BSG, JAG, MHRA (Appendix i) and HTM 01-06 guidance, aiming to continuously achieve high standards.

3. Definitions of key words

HTM	Health Technical Memorandum
BSG	British Society of Gastroenterology
JAG	Joint Advisory Group
Flexible Endoscopes	Umbrella term for instruments used within Endoscopy that can move in various directions.
EWD's	Endoscopic Washer Disinfector
MHRA	Medical & Healthcare products Regulatory Agency
TSSU	Trust Sterile Services Unit
Unisoft	Electronic Endoscopy Reporting and Scheduling Tool
SOP	Standard Operating Procedure

4. Responsibilities & Duties

4.1 Endoscopy Staff

All Endoscopy staff are responsible for adhering to this policy.

4.2 Decontamination Team

Decontamination teams are responsible for compliance with BSG, HTM 01-06 and JAG standards. The team is responsible for adhering to the policy.

4.3 Trust Decontamination Lead

Responsible for implementing the policy and ensuring it is adhered to.

4.4 Unit Manager

Responsible for monitoring adherence to the policy and ensuring staff competencies are achieved and signed off.

4.5 Unit Manager & Decontamination Lead

Responsible for updating and ensuring the policy is valid and up to date.

5. Policy Detail

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 of Gastroenterologists (BSG 2020), Medicines and Healthcare Products Regulatory Agency (MHRA – formerly MDA) & NHS Estates HTM01- 06.

5.1 Equipment

Details of key equipment:

- Washer Disinfectors(EWD)
- Drying Cabinets
- Endoscopes
- Single use cleaning brushes
- Valves & Biopsy Bungs
- Adjustable Endoscopy specific sinks
- Irrigation pumps
- Cleaning station
- Leak Tester

5.2 Key principles of Decontamination

- Decontamination of flexible endoscopes is undertaken in each of the Endoscopy Units.
- A specific area has been allocated and designed for this purpose.
- The dirty and clean areas are separated where possible.
- Endoscopes are decontaminated using an automated process.
- The tracking and traceability form for each contaminated scope must be completed throughout the decontamination process, not only to assist with assuring their quality, but also to enable the identification of patients on whom the medical devices have been used. The tracking and traceability form identifies the member of staff handling the endoscope at each part of the decontamination process. The tracking and traceability form is placed in the patient notes and scanned in with all other endoscopy documentation (Appendix ii).
- Decontamination is undertaken using manufactures guidelines and the latest standards set out by affiliated governing bodies in order to protect both patients and staff.
- Decontamination equipment must be operated and maintained according to approved guidelines, HTM01-06 and manufacturer's instructions
- Only suitably trained personnel who hold appropriate competencies for their role can carry out cleaning and disinfection of endoscopic equipment. The Training will be regulated by the endoscopy lead and departmental lead, appropriate to the staff requirements and unit equipment.
- 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.
- When using or processing endoscopes, appropriate personal protective equipment must be worn (Appendix iii).
- Rules for entry and exit from both clean and dirty decontamination rooms must be followed.
- If an emergency endoscopic procedure is performed out-of-hours, trained personnel must be available and be responsible for cleaning and disinfecting the equipment (Staff must follow the out of hour's decontamination flowchart –Appendix iv). This should include scopes that might be used in departments other than the endoscopy units e.g. ITU and operating theatres.
- Records associated with decontamination processing of reusable medical devices or endoscopes to be retained for a minimum of 11 years.
- Reusable medical devices identification details are to be retained in individual patient case records for the life of those documents.
- A permanent record must be kept, detailing decontamination process information so as to allow identification and recall of reusable medical devices if required.

- All decontamination equipment maintenance records must be kept by the user.

5.2.1 Decontamination Staff.

Staffing Levels and Skill Mix

- All rostered endoscopy decontamination staff are trained to decontaminate endoscopes and operate all decontamination equipment within the endoscopy unit.
- Staffing levels varies from site to site, depending on list numbers and variants of duties. Each site will have a local SOP for appropriate staffing levels due to work type and department layout.

5.2.2 Orientation and Training

- Please refer to section 6.3, page 9 of the Endoscopy Operational Policy for Orientation and general Induction training and Annual Appraisal of all staff. Specific decontamination training is taught both within the Endoscopy Unit and externally.
- Training within the endoscopy unit by:
 - Designated mentor.
 - The Regional Endoscopy Decontamination Lead
 - Decontamination staff that hold a valid decontamination T.N.T. (Train the Nurse Trainer) certificate.
 - External training resources inside the unit.
- Externally:
Manufacturer study daysheld either offsite or over virtual seminars. .

5.2.3 Assessment of decontamination clinical skills and knowledge.

- All endoscopy staff are registered with JETSWORK Force.
- Clinical skills and knowledge are assessed within the endoscopy unit by:
- Mentors
-
- Senior Staff.
- Competency level of clinical skills/ knowledge and all training is documented using the following methods:
- JETSWORCE FORCE eportfolio assigned competencies – Self, Formative and Summative assessments and GIN DOPS (direct observation of practical skill) Form.
- Written evidence for JETSWORKFORCEeportfolio competency – Reflective, Case Study and Witness Statement.
- Professional Portfolio folder – Record of all training and certificates.
- Up to date records of staff kept on Training Matrix

5.2.4 Medical Device Log and Training.

- All staff are given a Trust medical device log on induction this outlines all medical equipment and level of competency required for job description

It is the responsibility of the staff to complete a self-assessment and arrange with their mentor training required, record all medical device training and keep up to date during their time employed by the Trust.

5.2.5 Decontamination Room Layout

- The decontamination room is divided into clean and dirty working areas and the transfer of all endoscopes follow a one way system. Ventilation is controlled via an air conditioning unit and existing windows remain closed.

5.2.5.1 Dirty Working Area

Area which accommodates the height adjustable decontamination sinks which comply with HTM 04-01 and the health and safety at work act, machine endoscopy flushing aids and Leak Tester. This area is designated for the manual cleaning and checks of all contaminated endoscopes.

5.2.5.2 Clean Working Area

This area accommodates the drying cabinets, endoscopes storage trolley's, receptacle trays and storage area for clean endoscopes. This area is designated for the assembly of clean endoscopes for transportation.

At ALX, Malvern and WRH, pass through EWD available therefore there is a separate a clean dirty and clean room.

At ECH and KTC, the decontamination team have to follow the one way system below.

5.2.5.3 One Way System

Controlling the transfer of all endoscopes into and out of the decontamination room is important to prevent transfer of infection from dirty to clean areas. All contaminated or post 3 hours of decontamination endoscopes are transferred into the decontamination room via the dirty area entry and clean endoscopes are collected from the clean area and transferred out of the decontamination room via the clean entry door by the patient preparation area.

5.3 Stage 1 (refer to Appendix v)

- At the beginning of each Endoscopy case, a trained member of staff checks the Endoscope for faults
- Prior to first use of the day, the washer disinfectant / EWD must have undergone a self-disinfection cycle. This process may be automatic or pre-set to occur at a designated time dependent 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 HTM01-06.
- Any Endoscopes in an endoscope storage cabinet that have breached the manufactures recommended storage time must be re-processed before use. Once Endoscopes have been re-processed they must be used within three hours or placed back in the storage cabinet, if they are not they must be re-processed again before use. (Appendix vi).
- Following removal from the endoscopy storage cabinets or EWD and after checks to confirm the endoscope and valves are fit for purpose, the scope is placed in a tray with the traceability form and covered by a green tray liner in order to identify clean scopes or a red tray liner to identify a contaminated endoscope. If a traceability form is not present with the scope, the scope must not be used on a patient under any circumstances, until it has been re-processed.
- Endoscopes required for the endoscopy session are stored in a clean scope trolley for dispatch to the appropriate Endoscopy procedure room.

- Prior to use of the scope, the scope number is documented on the tracking & traceability form, the Endoscopy Procedure Report using the electronic GI Reporting Tool and the Nursing Admission Assessment Form.

5.4 Stage 2

After each use, a bedside clean must be undertaken by firstly wiping down the insertion tube from boot to distal tip. Then Flush the suction channel by immersing the distal tip of the endoscope in clean water and depressing the suction valve for 30 seconds. The air / water channel must then be flushed with water for at least 30 seconds to ensure that blood, mucus and other debris are expelled. The endoscope would then be suctioned through with detergent, using the appropriate cleaning apparatus, before being detached from the Endoscopy Stack

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

The waterproof cap must be replaced and the scope coiled appropriately into a tray. The tray is covered with a red tray liner, highlighting contamination.

(For certain scopes) 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.

The tracking and traceability form is completed by the nurse carrying out the bed side endoscope clean. Electronic tracking varies from site to site and controlled by local SOPs.

5.5 Stage 3

AIM OF CLEANING – After flushing the scopes with water below 32 Celcius after every case, scopes are cleaned to ensure removal of all blood, secretions and other organic material prior to the surfaces coming into contact with the disinfectant.

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 EWD approved washer disinfectant.

All Endoscopes are tested for leaks, faults or damage before immersing it in a suitable neutral or enzymatic detergent.

(NB: enzymatic detergents are temperature dependent on the water, for activation and optimum cleaning).

If the leak test fails, the scope is packaged for repair as per departmental instructions (Appendix vii).

If the leak test is passed, continue with full manual cleaning before placing the scope in the EWD, as per guidelines.

ALL 3 channels of the scope must be brushed i.e. biopsy, suction channel out at suction connector (Christmas tree) and suction channel out to distal tip.

Use the scope channel irrigator or a 20 ml syringe to flush all channels with water or a solution of neutral detergent.

5.6 Stage 4

The fourth stage of decontamination is high level disinfection via a suitable EWD. Place the scope in the wash chamber as per manufacturer's instructions. Connect to the appropriate ports on the EWD to achieve high level disinfection.

Poorly maintained or inadequate decontamination equipment can result in inadvertent exposure to harmful micro-organisms or biological agents – which could be hazardous to health. Staff are

encouraged to report any faults immediately. The Endoscopy Unit makes contact with relevant personnel to arrange repair and/or temporary replacement.

All Endoscopy staff are aware that any incidents are reported using the Trust's Incident Reporting Policy.

On completion of high level disinfection, endoscopes and valves are stored in a storage cabinet until required where available, or if for immediate patient use, stored in a hard based tray, with a green liner to identify ready for use, with the traceability document completed.

All stages of the disinfection process are recorded on the tracking and traceability form. All staff involved in the process are identified on this form, to enable traceability, should it be necessary.

5.7 Stage 5

All decontaminated Endoscopes should be stored using the manufactures' users recommendations where available, and not in their transit cases. Hangers are used in the drying cabinets to ensure scopes do not hang on the bottom of the cabinet where possible and are connected to the adapters continuously. The ventilated cupboard should comply with BS EN ISO 15883-4, and EN 1822-1:2019. Be HEPA filtered as this will considerably increase the hang time without need for re-processing, e.g. from hours to days. The Endoscopy Units use approved storage cabinets with a tracking system where available.

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

All non-disposable valves used during the list should be washed, brushed and placed in the EWD with the relevant scope to form a unique equipment set. They must not be placed in the scope case for storage.

All ultrasonic cleaning is currently integral to EWD processors used at KTC and ALX only.

5.8 Cleaning and Disinfection of Accessories

- Single use accessories are used where access for cleaning is difficult or the item is heat sensitive, e.g. biopsy forceps.
- Any accessories that are re-usable are manually cleaned and sent directly to TSSU (not endoscope valves refer to 5.7).
- Disposable flexible cleaning brush and soft cleaning brush should be used for manual cleaning procedures.

5.9 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 HTM01-06. This is based on four key aspects to ensure that the required standards of performance and safety are met and sustained:

- a). All EWD's 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 EWD will reliably produce cleaned and disinfected items to the standard required.
- b). All EWD's are subjected to a planned programme of tests to monitor their performance.
- c). All EWD's are operated in accordance with an agreed procedure by staff trained in the use of the EWD's.

d). All EWD's have a quarterly and annual maintenance and testing regime check as part of the service package.

5.9.1 Weekly:

Endoscope Protein Test

A weekly test for protein is performed by the endoscopy staff according to the manufacturer's equipment specifications and recorded, in unit log book. In the case of a failed protein test additional scopes to be tested and failed scopes reprocessed and not used until successful protein test.

Action to be taken in the event of recovery of micro-organisms:

Remove scope from use, re-process and re-test. Discuss findings with Infection Control Team. Carry out immediate sampling of further selection of endoscopes.

5.9.2 Weekly/Quarterly

- Final Rinse Water Check for Total Viable Count Weekly plus Mycobacterium 12 monthly (see Appendix viii).

5.9.3 Annual

Environmental checklist (appendix xii) and IHEEM (appendix xiii)

5.9.4 Water quality, water hygiene and microbiology

All EWD rinse water is analysed, monitored and managed weekly as per International Standard – BS EN ISO 15883 Guidelines, HTM01-01 Part A and Part C. Water sampling management is controlled by local SOPs.. In event of failure, Decontamination team is to follow the algorithm in management of scopes depended on water result.

Decontamination Lead and Unit manager are responsible to ensure results are checked and inputted into Countywide Water results database.

5.10 Breakdown of Machines / Spillages

In the event of breakdown or failure of the EWD's, the decontamination team report immediately to the appropriate service contract provider for their site. In loss of service on site, refer to business continuity plan and report to EPRR.

Any EWD not functioning correctly must be taken out of use immediately and the Unit Manager and Directorate Manager notified at the earliest opportunity, to sort endoscopy lists accordingly. If all EWD's are out of use, Endoscopy procedures must cease.

SOP's are in place to help deal with spillages and two emergency spillage kits are located within the Endoscopy sluice and one within the dirty decontamination area (Appendix ix/x/xi).

5.11 CJD or vCJD Special Precautions in Endoscopy for patients

Patients who fall into a risk category for CJD or vCJD should have been identified by screening questions pre-procedure refer to trust CREUTZFELDT–JAKOB DISEASE (CJD) AND VARIANT CJD policy. The additional precautions required for decontamination of endoscopes, are included in British Society of Gastroenterology (BSG) Guidance issued in 2020. This advises:

- Those involved in endoscopy ensure procedures are in place to minimise contamination and maximise cleaning

Cleaning, Decontamination & Validation of Flexible Endoscopes		
WAHT-INF-039	Page 10 of 24	Version 3

- Brushes and other purpose built catheters used to clean the channels of the endoscope are single use to ensure maximum efficiency of cleaning and reduce the risk of inoculating other endoscopes
- All accessories used during the endoscopic procedure are discarded and never re-used.

Type and Status of vCJD diagnosis	Management of the Endoscope
1. vCJD diagnosis confirmed	Destroy or decontaminate and store in quarantine for use on the same patient
2. Symptoms of CJD but awaiting diagnosis	Decontaminate and store in quarantine. If vCJD confirmed manage as above.
3. Asymptomatic patients at increased risk through receipt of labile blood components (whole blood, red blood cells, white cells or platelets) from a donor who later developed vCJD	Destroy or decontaminate and store in quarantine for use on the same patient.
4. At increased risk (e.g plasma product recipients) For details about the different types of at increased risk classification see the ACDP TSE guidance Part 4 (table 4a) http://www.dh.gov.uk/health/files/2012/11/Part-4-Infection-Control-Jan13.pdf.pdf	Decontaminate and reuse.

5.12. Traceability

On completion of a EDW. cycle the electronic tracking system will produce a tracking label this label is affixed to the receptacle carrying the endoscope. On using the endoscope the following processes are followed:

- The endoscopist/assisting nurse is responsible to ensure the tracking label details match the assigned endoscope with another member of staff and the tracking label is affixed to the patient endoscopy nursing pathway.
- Patient details, endoscopy and endoscope serial and identification numbers are manually entered into the procedure room register.
- Endoscope serial and identification number is entered by the endoscopist to the patients endoscopy report using the electronic Gastro Intestinal endoscopic reporting tool
- If used outside the Endoscopy Unit the tracking label is affixed inside the patient's medical notes.
- A patient hospital identification label is checked and affixed to the endoscope receptacle.
- The patients name and hospital number and endoscope serial and identification numbers are entered into the decontamination electronic tracking system on commencement of the EDW cycle if available.
- At ALX hospital scanning is required in addition to traceability form

5.12.1 Identification of purchased and Loan endoscopes

All endoscopes serial and identification numbers are entered by the decontamination staff into the electronic tracking system and are manually displayed within the decontamination room.

Loan endoscopes are allocated an identification number by the decontamination staff.

6. Audit Mechanism

The following Audits will be carried out on all sites using the BSG 2020 guidance

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
- Link nurse for infection control attends annual updates
- Annual water testing completed by the manufacturer
- Tracking & Traceability form audit – biannual.
- **VENTS** Decontamination audits must include the function and efficiency and effectiveness of the room ventilation.
- **SCOPE TRACKING** The detachable components should be kept with their corresponding endoscope, forming a unique set. A record of the decontamination process should be retained. There must also be a means of tracking for each patient use of any reusable endoscopy accessories. The tracking system operating in each unit should be subject to regular audit. There is a move towards using single use endoscope valves to enable full traceability and prevent cross infection caused by inadequate reprocessing
- **IHEEM** Institute of Healthcare Engineering and Estate Management (37)
- **IPC** Infection Prevention Society (38).
- **WEEKLY WATER** Weekly total viable counts of bacteria in end rinse water from EWDs
- **QUARTERLY 3RD PARTY** Quarterly testing for a typical mycobacteria and *Pseudomonasaeruginosa*, -
More frequent testing for a typical mycobacteria and *Ps.aeruginosa* may be prudent in centre carrying out procedures in augmented care.
- **Annual** testing for endotoxin
- **WEEKLY PROTEIN**

7. Implications of Non-Adherence

Non adherence to this policy may result in:

- Patients being put at risk
- Staff being put at risk
- Failure to comply with appropriate standards
- Damage to equipment / impact on the service leading to financial consequences
- Poor service
- Loss of accreditation
- Financial loss

8. Implementation of the Policy

Plan:

- All appropriate staff to be trained according to relevant competencies. Records must be kept within the department.
- Policy to be disseminated to all Endoscopy staff.

Dissemination

- The policy will be placed on the Trust's Endoscopy Intranet page and a signature page will be in each department for when the staff have read the policy.

9 Monitoring and compliance

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: (Responsible for also ensuring actions are developed to address any areas of non- compliance)	Frequency of reporting:
	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
	<ul style="list-style-type: none"> Ensure all equipment is checked and in good working order prior to each list. Identify any issues/problems and report through correct channels. Ensure all Decontamination staff follow the correct training process and competencies. 	<ul style="list-style-type: none"> Completion of Daily/weekly Decontamination checklist. Monitor breakdown of EWD's. Monitor Datix submissions. Training pack and PDR for all endoscopy Decontamination staff. 	<ul style="list-style-type: none"> 4 times per year Continuous Continuous Yearly 	<ul style="list-style-type: none"> Decontamination leads on individual endoscopy sites. Endoscopy unit manager. Endoscopy unit managers/Matron/Directorate manager. Decontamination unit lead /endoscopy manager/sister. 	<ul style="list-style-type: none"> Endoscopy directorate meetings. Individual unit staff. Decontamination leads on individual Sites. 	4 times per year.

10. Policy Review

This policy is due for review in one year, unless practice or equipment changes before.

11. References

- Ayliffe (2009) Ayliffe's Control of Healthcare-Associated Infection A practical handbook 5th edition, Published Edward Arnold Ltd, London
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- MHRA Medicines and Healthcare products Regulatory Agency.(2013) Top 10 Tips on Endoscope Decontamination . Available at: <https://www.gov.uk/government/publications/top-10-tips-on-endoscope-decontamination> [Accessed 27/04/2016]
- Health & Safety at Work Act 1974.
- Joint Advisory Group
- DATIX Incident Reporting Policy.

12. Background

12.1 Equality

The assessment conducted for this policy reveals no equality issues.

12.2 Risks and mitigation

There are a number of background risks stated below which failure to adhere to this document can occur and what steps have been taken in the creation and review of this document.

a. Fiscal Risk

Failure of JAG standards will lead to a 10% reduction Best Practice Tariff.

b. Health Risk

Failure to comply could result in Health Risk to both staff and patients.

c. Consultation

A broad selection of Endoscopy staff has been sought, along with review by the Infection Control Team.

d. Approval

This policy will be approved by the Endoscopy Directorate Meeting Group and Infection Control Team.

CONTRIBUTION LIST

Key individuals involved in developing the document

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Kirsty Hinton	Directorate Support Manager Endoscopy- left organisation











Circulated to the following individuals for comments




Name	Designation
Dr Thekli Gee	Consultant Medical Microbiologist
Endoscopy Directorate Group	
TIPCC Group	

Circulated to the chair of the following committees / groups for comments

Name	Committee / Group
Janice Stevens	Trust Infection Prevention & Control Committee and Director Infection Prevention and Control
Ray Cochrane	Trust Water Quality Committee and Head of Estates
Martin Long	Trust Decontamination Committee

Appendix 1: Attached documents

i	 MHRA Top Ten Tips.pdf
ii	 Tracking & Traceability Form.pdf
iii	 PPE.docx
iv	 Protocol for Procedures performe
v	 Decontamination Process.docx
vi	 Three Hour Rule.docx
vii	 Scope Repair Instructions.docx
viii	 Weekly & Quarterly Mycobacterium Testin
ix	 SOP - Spillage Procedure.doc
x	 SOP - Spillage Procedure External to

xi	 SOP - Procedure for Safe Disposal of Resi
xii	 JAG_IHEEM_AED_audit_checklist_-_Sampl
xiii	 9.1 JAG_Environment_Ch
xiv	https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06/

Appendix 2 Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form

Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	✓	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	Karen Bishop
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Details of individuals completing this assessment	Name	Job title	e-mail contact
	Karen Bishop	JAG/Governance Lead	karen.bishop12@nhs.net
Date assessment completed	25/06/2025		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	Title: Policy			
What is the aim, purpose and/or intended outcomes of this Activity?	A guideline for staff to adhere to when cleaning, decontaminating and validating flexible endoscopes.			
Who will be affected by the development & implementation of this activity?	✓ ✓ <input type="checkbox"/> <input type="checkbox"/>	Service User Patient Carers Visitors	✓ <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Staff Communities Other _____

Is this:	<input checked="" type="checkbox"/> Review of an existing activity <input type="checkbox"/> New activity <input type="checkbox"/> Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.)	Latest HTM01 standards and guidance.
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Circulated to directorate, decontamination staff and unit managers for comment. Also discussed at decontamination committee.
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale.** Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		✓		
Disability		✓		
Gender Reassignment		✓		
Marriage & Civil Partnerships		✓		
Pregnancy & Maternity		✓		
Race including Traveling Communities		✓		
Religion & Belief		✓		
Sex		✓		

Equality Group	Potential <u>positive</u> impact	Potential <u>neutral</u> impact	Potential <u>negative</u> impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		✓		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		✓		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		✓		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
None				
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	At policy review date			


Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	25/06/2025
Comments:	
Signature of person the Leader Person for this activity	
Date signed	25/06/2025
Comments:	

Appendix 3 Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	NO
2.	Does the implementation of this document require additional revenue	NO
3.	Does the implementation of this document require additional manpower	NO
4.	Does the implementation of this document release any manpower costs through a change in practice	NO
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	NO
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.