Document Details	
Title	Decontamination and Storage of Flexible Endoscopes Policy
Trust Ref No	1572-72316
Local Ref (optional)	Bridgnorth Community Hospital
Main points the document covers	This policy details the decontamination and storage of flexible endoscopes
Who is the document aimed at?	All staff who work within day surgery units
Author	Sister Lesley Warren, Day Surgery Unit, Bridgnorth Hospital
Approval Process	
Approved by (Committee/Director)	Infection Prevention and Control Governance Meeting
Approval Date	9 February 2022
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Full Equality Impact Assessment	Not required
Lead Director	Director of Nursing & Allied Health Professionals, DIPC
Category	Clinical
Subcategory	Community Hospitals
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Who the policy will be distributed to	Distributed to senior staff as defined by directors
Method	Electronically to senior staff and available to all staff via the Trust website
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Required by CQC	Yes
Key Words	Flexible; Endoscopes; Decontamination; Storage

Amendments History		
No	Date	Amendment
1	27 March 2012	New Policy
2	February 2016	General Update and Review
		Storage cabinet information included
		New title to reflect addition of the storage of endoscopes
3	January 2019	General Update and Review
4		

Contents

1 Introduction

The aim of this policy is to prevent adverse consequences arising from contamination of flexible endoscopes.

Flexible endoscopes are complex reusable instruments that require unique consideration with respect to decontamination. In addition to the external surfaces of endoscopes, their internal channels for air, water, aspiration and accessories are exposed to body fluid and other contaminants. Flexible endoscopes are heat labile and therefore cannot be autoclaved.

Endoscopic procedures carry a risk of causing infection. Contamination of endoscopes can occur from previous patients, from failure of the decontamination process (e.g. if the final rinse water is contaminated) or during endoscope storage.

Decontamination of endoscopes begins with thorough manual cleaning, with a suitable detergent, which should be performed as soon as possible after the endoscope has been used. Following manual cleaning the endoscope must be thoroughly rinsed. The endoscope is then disinfected, using an Automated Endoscope Reprocessor (AER)

2 Purpose

The policy is intended to provide guidance on the manual and mechanical decontamination of flexible endoscopes including safe storage.

3 Definitions

Term/Abbreviation	Explanation/Definition
ACC	Aerobic Colony Count
AE (d)	Authorising Engineer (Decontamination)
AER	Automated Endoscope Reprocessor
CJD	Creutzfeldt-Jacob Disease
CSSD	Central Sterile Services Department
HTM	Health Technical Memorandum
IPC	Infection Prevention & Control
IPCT	Infection Prevention & Control Team
PPE	Personal Protective Equipment
RO	Reverse Osmosis
SCHT	Shropshire Community Health NHS Trust
SSSFT	South Staffordshire and Shropshire Foundation Trust
TSE	Transmissible Spongiform Encephalopathy
TVC	Total Viable Count
vCJD	Variant Creutzfeldt-Jacob Disease

3.1 Registered Authorising Engineer (Decontamination) (AE (d))

A person designated by Shropshire Community Health NHS Trust (SCHT) to provide independent auditing and advice on sterilisers and sterilisation and to review and witness validation and periodic test documentation. A list of suitably qualified AE (d)

is maintained by the institute of Healthcare Engineering and Estates Management (IHEEM).

(Spencer Nixon contact number 07867780555)

3.2 Test Person

Undertake maintenance and testing work at quarterly intervals. Retain a maintenance 'hotline' for urgent requests. Together with manufacturers, ensure commissioning tests are undertaken (Cantell Medical Engineer).

3.3 User

The person designated by management to be responsible for the decontamination of flexible endoscopes. The users are the Nursing staff and Health Care Assistants who work in the Diagnostic and Day Surgery Unit. An important function of the User is to ensure the Operator operating and testing decontamination equipment is suitably trained and competent.

3.4 Operator

Any person with the authority to operate the AER. The person designated as the User or by delegation the operator has the ultimate responsibility for certifying that decontamination equipment is fit for use (day Surgery Staff).

4 Duties

4.1 Manager

Managers and Service Leads have the responsibility to ensure that their staff including bank and locum staff etc. are aware of this policy, always adhere to it and have access to the appropriate resources in order to carry out the necessary procedures.

It is the responsibility of the manager to ensure that staff are aware of this policy, have suitable adequate supply of cleaning and decontamination products/equipment, and know how to use appropriately, effectively, safely and compatible with manufacturer's decontamination guidance.

Managers and Service Leads will ensure compliance with this policy is monitored locally and ensure their staff fulfil their Infection Prevention and Control (IPC) mandatory training requirements in accordance with the Trust Training Needs Analysis.

4.2 Staff

All staff have a personal and corporate responsibility for ensuring their practice and that of staff they manage or supervise comply with this policy. Appropriate staff must access training on decontamination from the manufacturer before use of flexible endoscopes.

Mandatory IPC training must be up to date.

4.3 Committees and Groups

4.3.1 Board

The Board has collective responsibility for ensuring assurance that appropriate and effective policies are in place to minimise the risks of healthcare associated infections.

4.3.2 Quality and Safety Committee

Is responsible for:

- Reviewing individual serious incidents/near misses and trends/patterns of all incidents, claims and complaints and share outcomes and lessons learnt
- Agreeing and escalating key risks/items of concern to the appropriate Directors and/or the Trust Board

5 Assessing the Risk from Endoscopy

Factors which influence the risk of infection from endoscopy include:

- **The type of endoscopic procedure undertaken.** Procedures which penetrate the mucosal barriers carry a greater risk
- The infectious agents present in the previous patient's secretions.
- Organisms which pose a recognised risk include gram-negative bacteria include *Pseudomonas aeruginosa*, Klebsiella species, *Enterobacter spp*, *Serratia marcescens*, and Salmonella species.
- *Mycobacterium tuberculosis*,
- Viruses (including hepatitis B),
- *Giardia*, and *Cryptosporidium,*
- New variant Creutzfeldt-Jacob (vCJD) also has a theoretical risk of transmission
- **The effectiveness of the procedure used to decontaminate the endoscope.** Thorough cleaning is essential prior to disinfection in the AER. If a disinfectant is used at too low a concentration of or for too short a contact time, then there is an increased risk of subsequent infection
- **The duration and conditions of storage after endoscope decontamination.** The quality of the rinse water used for rinsing the endoscope is extremely important in preventing contamination (e.g. with Mycobacterium chelonae and Pseudomonas aerations)
- Prolonged Storage after decontamination is a risk factor for recontamination of the instrument
- **The individual susceptibility of the patient to infection.** Patients who are immunocompromised are at an increased risk of developing infections by organism which are of low pathogenicity, such as environmental Mycobacteria

Two adverse consequences may arise from contamination of endoscopes. Firstly, an infection may be transmitted to the patients. Secondly a patient may be incorrectly diagnosed with an infection because of a contaminated sample. Incorrect diagnosis may lead to the patient receiving inappropriate and potentially harmful drugs.

Transmissible Spongiform Encephalopathy (TSE) and Endoscopy

All patients admitted for endoscopy will be risk assessed for TSE using the endoscopy documentation which is filed in the patient's notes. Patients will be asked if they have ever been notified that they are at risk of CJD/vCJD for public health reasons. (This is the official terminology for someone who is potentially at risk e.g. a dura mater graft recipient, or recipient of factor V111 who is potentially at risk of

developing CJD. These patients will have had an official letter from the CJD incident panel informing them that they are ‘’at risk for public health purposes’’).

6 Causes of Inadequate Decontamination

The major causes of inadequate decontamination are as follows;

- Failure to immediately flush channel post procedure
- Insufficient or inadequate training
- Inadequate manual cleaning prior to putting the endoscope in the AER
- Hard deposits of organic material on the endoscope surfaces
- Damaged and deformed surfaces on the endoscopes
- Perforated instrument channels
- Parts of the instrument not being exposed to the cleaning process due to being closed off by valves or seals
- Failure to clean hinge joints, recessed surfaces, endoscopic lumens and other intricate areas
- Ineffective rinsing and final drying procedure
- Contamination of wash bottles and tubes connected to the endoscope
- Inappropriate and incomplete decontamination methods (e.g. the wrong choice of disinfection or the wrong contact times)
- Use of disinfectant which is diluted below its effective concentration or which is beyond its recommended shelf life
- Design faults in the AER which allow persistent growth of micro organisms on the AER or on the endoscope
- Use of water (or other fluids) which is of poor microbiological quality
- Lack of water filters in the system

7 Stages of Decontamination

7.1 Decontamination before the procedure and prior to the session

- The endoscopes will have been cleaned and disinfected prior to storage, therefore repeat brushing is not required
- The endoscope must be disinfected using an appropriate time cycle in the AER. The cycle should include a rinse phase to remove chemical residues
- After this the endoscope will be safe for use on a patient
- The angulations of the endoscope will be checked, and the condition of the fibre bundles will be inspected before use. Any defects noted will be reported to the nurse in the department immediately and the scope taken out of use.

7.2 Preliminary Cleaning

Effective cleaning is paramount for the removal of debris. This removes organic matter and ensures better contact between the disinfectant and any remaining micro-organisms during disinfection. This is to ensure endoscope lumens do not become blocked by disinfectants which can act as tissue fixative

- The detergent used for initial cleaning must be approved by the endoscope manufacturer (Olympus Keymed) and the AER manufacturer (*Cantel*)
- In the procedure room the endoscope channels must be flushed immediately following the procedure with cool tap water mixed with a *non*-enzymatic detergent, diluted as per manufacturer's instructions
- The endoscope is then transported in a designated covered scope tray through the 'dirty hatch' to the decontamination room and placed in the dirty area next to the sink

7.3 Manual Cleaning

- Endoscope valves and detachable distal tips must be removed from the endoscope prior to manual cleaning.
- Endoscopes must be leak tested to check the integrity of all channels and inspected for damage prior to manual cleaning. Connect leakage tester (MB-155) turn on pump and check airflow. Connect leakage tester to water resistant cap and confirm bending section has expanded. Immerse entire endoscope in clean water, if a leak is present small bubbles will be seen in the water. The leak tester must be switched off and the scope depressurised before removal of the leak tester. **If a leak is detected the endoscope must be taken out of service immediately and returned to the manufacturer for repair via Electrical and Biomedical Engineering (EBME) at Princess Royal Hospital.**

Manual cleaning is carried out in a dedicated sink filled with water mixed with a *non*-enzymatic detergent (*Intercept plus* used at present) to a dilution of 0.5 -1% as recommended by the manufacturer. The sink has been marked at a level of 12 litres and requires 75mls of *Intercept **plus*** clean.

- Water temperature should be below 32 degrees Celsius.
- Detergent and water should be discarded after each use down the sink
- Wherever possible keep the endoscope under water during the cleaning process to prevent aerosol contamination.
- Instructions for the manual cleaning of endoscopes are displayed on the wall in the decontamination room.
- All accessible channels and ports are brushed with a purpose made single use cleaning brush at least three times each; using the correct size brush and ensuring that the brush is visibly clean at the end of the process.
- Biopsy caps should be discarded if a biopsy has been performed.
- Channels are cleaned as recommended by the manufacturer of the scope (Olympus Keymed).
- The external surfaces of the endoscope are cleaned according to the manufacturer's instructions using a disposable wipe and solution of *Intercept plus*
- The endoscope is rinsed to remove residual detergent by immersing in clean warm water after manual cleaning.
- The endoscope is transported to the AER.

- The surfaces and lumens of reusable valves and detachable parts are cleaned in accordance with the manufacturer's instructions.
- Visual checks are made to ensure valves are visually clean and undamaged prior to processing in the AER.

7.4 Disinfectants

The disinfectants used in the AER must be approved by the AER manufacturer and the endoscope manufacturer. The disinfectant should be replaced in accordance with the protocol by the disinfectant manufacturer. Advice on minimum effective concentration and minimum contact time of the disinfectant should be sought from the disinfectant manufacturer. This enables the AER to be programmed to run for the correct time.

7.5 Automated Endoscope Reprocessor (AER)

AERs are used for all endoscopic decontamination following manual cleaning. Either process alone is not acceptable.

- The AER must be *self*-disinfected *daily* as recommended by the manufacturer using the thermal disinfectant method.
- AERs must have service contracts in place and preventative maintenance schedules and records should be kept and retained, otherwise the AER can become a potential source of infectious agents.
- Connectors must be inspected prior to removal of the endoscope on completion of the cycle to confirm all channels have been irrigated.
- Verification that the cycle was successful and complete is obtained from the printout and via electronic means prior to removal from the AER.*Staff who carry out the manual clean should sign the back of the printout*
- The AER should be used in accordance with the manufacturer's instructions –*Cantel* manuals must be available in the decontamination room.
- Mineral free water (filtered by the reverse osmosis unit (RO Unit) and the AER) is used for the final rinse of the decontamination cycle which is crucial for removing micro-organisms.
- External surfaces of the endoscope are dried and the scope is stored immediately in a dedicated cabinet to prevent recontamination or damage.
- When the endoscopes are removed from the AER and are due to be used again within three hours, they are transported into the clean procedure room via the 'clean hatch' on a designated tray covered with a sterile drape.

8 Endoscope Storage (Cystoscopes)

- Endoscopes are stored suspended vertically in a designated endoscope storage cabinet to allow circulation of air. They should not be in contact with other endoscopes or with flat surfaces.
- Endoscopes should be stored hanging up so that any residual fluid does not remain in the channels. Each endoscope should be stored with its detachable parts having been dismantled in a manner which ensures security and keeps components together as a unique set.

8.1 Cantel Endoscope Cabinet

Flexible endoscopes can be stored following decontamination in the cantel storage cabinet. The cabinet is designed to store five scopes up to thirty-one days prior to their use.

Should the power fail for more than thirty minutes, all endoscopes stored in the cabinet must be reprocessed in the AER prior to their use. A printout from the machine will indicate power failure.

When an endoscope is removed from the cabinet it must be used within three hours and cannot under any circumstances be returned to the cabinet without being processed in the AER.

9 Patient Traceability

Flexible endoscopes have unique serial number. This must be recorded in the patient's notes and the unit register when a procedure is performed. This will facilitate tracing of patients in the unlikely event of them being exposed to a contaminated device.

- Tracking of the decontamination cycle, personnel and patient association of each endoscope is undertaken using manual or electronic methods.
- Each step of the decontamination cycle is recorded including the name of the person undertaking each step and is directly associated to individual patient use.
- A record of the decontamination process is recorded in the patient's notes.
- The printout from the AER should be attached to the patient's nursing sheet and this must be used in conjunction with the logbook.
- All records should be kept securely for the time specified in the SCHT Records Management Policy.
- Valves and removable parts are kept with the endoscope to form a unique set of equipment.

10 Accessories

- Single use cleaning devices must be used for manual cleaning.
- Single use accessories should be used for all procedures.

11 Maintenance

- There must be documented evidence of planned and unplanned maintenance of endoscopes and the AER. Regular servicing is carried out quarterly.
- The AER is covered by a service contract, this is provided by Cantell Medical and contract renewal is the responsibility of the South Staffordshire and Shropshire Foundation Trust (SSSFT) estates department.
- Maintenance and disinfection of the water purification (RO unit) system is undertaken as per manufacturer's guidelines, this is provided by Environmental Water.
- Salt container must be filled as required and should not become less than 25% full. This is checked by SSSFT estates department on a weekly basis.

- The RO unit is covered by a service contract with Environmental Water. It is the SSSFT Estates Department's responsibility to arrange servicing.

12 Testing and Validation

12.1 Monitoring the Quality of the Final Rinse Waters

Refer to Appendix 1 - procedure for monitoring final rinse water.

The final rinse water should not be contaminated. Mains water is not sterile and therefore a water treatment system is required to provide water which is free from bacterial contamination. A final filter of bacteria-retentive grade is crucial for removing micro-organisms. It is therefore important to monitor the final rinse water to ensure it is of adequate quality. Samples should be taken following the manufacturer's instructions. The site which should be tested is the rinse water which has circulated through the AER to identify any build up of bio film.

Water testing is carried out in accordance with National Guidance HTM 01-06 (2013). At present an average of 24 Cystoscopy sessions are performed monthly. Water sampling is undertaken every Wednesday, (by a member of staff who has received appropriate training) and sent via a courier to 20/30 laboratory. A copy of the results is sent to the department & to the Infection Prevention and Control Team (IPCT)via email. Water quality test results that fall below the acceptable standards must be reported to the IPCT and appropriate action must be taken (see appendix 2).

12.2 Cleaning Efficacy

Tests should be performed alongside water testing to comply with HTM 01-06

(refer to table 5e HTM 01-0610.37-10/48 - Cleaning Efficiency by Residual Soil Test Detection).

12.3 Maintaining Records

- AER records are available as evidence that the AER has been validated on installation in accordance with the recommendations described in HTM 01-06 (Management and decontamination of flexible endoscopes Department of Health 2013)
- Endoscope Drying Cabinet Records are available as evidence the endoscopes have been stored correctly.
- An appropriately trained person is responsible for organising daily, weekly and quarterly testing of the AER in accordance with HTM 01-06. All records are kept in the AER file logs which are kept in the decontamination room.
- All records must be kept securely for the time specified in the SCHT Records Management Policy.

13 Safety

- Endoscopy decontamination areas are designed to ensure an effective and efficient service that does not harm staff, patients or the public.
- All staff involved in decontamination must have access to and wear appropriate personal protective equipment (PPE) including full face visors, single use gloves and aprons.
- Staff must wear PPE as instructed by the manufacturers when loading chemicals into the AER.
- Health and safety information and equipment available for spillages including, chemicals, detergents and body fluids.

- In the event of the inability to provide an automated decontamination system, the endoscopy activity must cease until the automated process is regained.

Manual disinfection and rinsing are not acceptable.

13.1 Spillage

- Spillage of chemical disinfectants may pose a risk to staff and patients.
- If spillage is suspected, immediate action must be taken to evacuate the area.
- The spillage must then be cleared away in accordance with local department and COSHH guidance.

DATIX incident form must be completed for each incident.

14 Consultation

This policy has been developed by the Day Surgery Unit at Bridgnorth Hospital in consultation with Endoscopy Unit, Royal Shrewsbury Hospital, clinical services managers, IPC team and IPC Meeting members.

A total of three weeks consultation period was allowed, and comments incorporated as appropriate.

14.1 Approval Process

The IPC Meeting members will approve this policy and its approval will be notified to the Quality and Safety Committee.

15 Dissemination and Implementation

This policy will be disseminated by the following methods:

- Managers informed via Datix who then confirm they have disseminated to staff as appropriate
- Staff - via Team Brief and Inform
- Awareness raising by the IPC team
- Published to the Staff Zone of the Trust website

The web version of this policy is the only version that is maintained. Any printed copies should therefore be viewed as 'uncontrolled' and as such, may not necessarily contain the latest updates and amendments. When superseded by another version, it will be archived for evidence in the electronic document library.

16 Staff Training

Evidence of staff training in decontamination is available and is kept in the department.

Staff using endoscopes will receive competency-based training on the following:

- Identification of individual endoscopes and all associated channels
- Design and function of endoscopes
- Theory on decontamination, microbiology, detergents, disinfectants and AERs
- Health and safety and infection prevention and control

- Knowledge and skills assessment on assembly and dismantling of scopes, pre-cleaning, manual cleaning, reprocessing accessories and ancillary equipment, disinfection and the use of the AER, drying, transportation, storage, tracking and traceability and maintenance, testing and validation
- Training is carried out both in and off site by equipment manufacturers. Infection control issues are updated at mandatory training sessions
- Staff can go to larger Endoscopy units (Princess Royal Hospital and New Cross hospitals) annually to update competences
- A nominated member of staff who is competent in the decontamination process will act as trainer for other members of staff. This person will assess the competencies of other staff members involved in the decontamination process.
- Instructions for decontamination process should be visually displayed
- Up to date manufacturer (endoscope, AER and chemical) instructions and relevant trust policies are easily accessible

17 Monitoring Compliance

Compliance with this policy will be monitored locally by managers. All managers and service leads must therefore ensure that all relevant staff are aware of this policy and appropriate action is taken where breaches occur.

18 References

BSG Guidance For decontamination Of Equipment for Gastrointestinal Endoscopy. November 2017

Management and decontamination of flexible endoscopes Department of Health 2013 (HTM01-06)

NATIONAL Endoscopy Programme (2007) Decontamination Standards for Flexible Endoscopy. British Society of Gastroenterology, NHS, Industry, London

Department of Health (2007) Health Technical Memorandum 01-05, Decontamination. DOH, London

NHS National Endoscopy Programme (2008) Decontamination Standards for Flexible Endoscopes. National Endoscopy Team, Leicester

Hospital Infection Society and Public Health Laboratory Service (2002). Rinse Water for Endoscopy Equipment. Journal of Hospital Infection 51: 7-16

Health Protection Agency (2010) Examining Food, Water & Environmental Sample from Healthcare Environment: Microbiological Guidelines. HPA

NHS Estates (1997) Washer-Disinfectors. Health Technical Memorandum HTM2030.London: The Stationary Office

Quality of Final Rinse Water Used in Washer-Disinfectors for Endoscopes, Journal of Hospital Infection (2002):51 151-153

19 Associated Documents

This policy should be read in conjunction with the following SCHT policies;

- Hand Hygiene
- Cleaning and Disinfection
- Standard Precautions including surgical hand scrub, gowning and gloving

- Transmissible Spongiform Encephalopathy (TSE)
- Records Management Policy

20 Appendices

Appendix 1 – Procedure for Taking Water Sample

- Programme the AER for water sample taking, the machine will then pause the cycle during the final rinse stage to allow for the water sample to be taken
- The operator should wear an apron and sterile gloves during the procedure
- Water sample (500mls) is extracted through the thermocouple entry port on the front of the AER into a sample bottle supplied by 20/30 Labs The sample bottle must be specific for chlorinated water collection
- The sample bottle label must be competed with the date and source details.
- The sample must be placed in cool box with cooling pad and sent via courier to 20/30 Labs
- Conformation of receipt of samples will be sent via email from 20/30/Labs

Results

Results should show an aerobic colony count (ACC) of nil, demonstrating the presence of bacteria is not detected. Water should be tested quarterly for Mycobacterium.

The ACC may be reported at counts of up to 100 colony forming units (cfu). This will be reported as exact number, and state that bacteria have been detected. A figure above 100 is simply reported as being over 100. Occasionally the comments section may state that *Pseudomonas* has been detected. Presence of any bacteria or *mycobacterium* in rinse water constitutes a rinse water test failure.

Appendix 2 – Actions in the Event of Rinse Water Test Failure

TVC Count < 10	• No further action – repeat water test at next scheduled time
TVC Count from 10 to 100	• Restricted use of machine – do not process Cystoscopes through the AER • Repeat water sample • If no improvement, follow guidelines for procedure with TVC count over 100
TVC Count > 100	• Machine is immediately taken out of use • Document in logbook • Run self-disinfect programme twice • Following this action, a repeat rinse water sample will be sent to the laboratory for testing • If repeat water sampling demonstrates an on-going problem, the situation should be discussed urgently with the manufacturer, estates and the infection prevention and control team and on-call consultant Microbiologist at SaTH on 01743 261000