The Royal Infirmary of Edinburgh

Local Decontamination Policy for Flexible Endoscopes

<table>
<thead>
<tr>
<th>Date issued</th>
<th>1st May 2010</th>
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</thead>
<tbody>
<tr>
<td>Revised</td>
<td>July 11</td>
</tr>
<tr>
<td>Reviewed by</td>
<td>G Ellis-Pow</td>
</tr>
<tr>
<td></td>
<td>Decontamination Lead</td>
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<tr>
<td></td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Responsible</td>
<td>H Chisholm</td>
</tr>
</tbody>
</table>
The Royal Infirmary of Edinburgh Endoscopy Unit
Local Decontamination Policy

1. Introduction

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 fluids and other contaminants. Flexible endoscopes are heat labile and therefore cannot be autoclaved.

Historically, flexible endoscopes have been classified as semi-critical reusable instruments requiring a process of high level disinfection prior to use on patients. This was largely due to endoscopes been heat labile and therefore not appropriate for autoclaving. More recently, different methods of sterilisation are now available and are been used to sterilise small channel endoscopes. Studies are been carried to expand this practice to more commonly used gastrointestinal scopes and will lead to a change in decontamination practice for all endoscopes in the foreseeable future.

For the purpose of this document, high level disinfection as form of decontamination will be outlined.

The Joint Advisory Group (JAG) on Gastro Intestinal (GI) Endoscopy are responsible for accrediting endoscopy units in the UK. This accreditation includes a review of the decontamination service. There is a necessity to risk assess the decontamination process to establish the appropriate decontamination regimes for medical devices, one such assessment is the Spalding Classification.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Type of Procedure</th>
<th>Appropriate level of Decontamination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical (High Risk)</td>
<td>Invasive devices enter tissue that is usually sterile or enters a vascular system. This includes contact breaches in the skin and / or mucus membrane e.g. arthroscope, biopsy forceps, papilotomes etc</td>
<td>sterilisation</td>
</tr>
<tr>
<td>Semi-critical (Intermediate Risk)</td>
<td>Device contacts intact mucous membrane but does not penetrate sterile tissue e.g. gastroscope, colonoscope</td>
<td>High Level Disinfection Sterilisation preferred where practicable</td>
</tr>
<tr>
<td>Non-critical (Low Risk)</td>
<td>Devices only contacts intact skin e.g. stethoscope, sphygmomanometer cuff</td>
<td>Cleaning (and low level disinfection where necessary)</td>
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</tbody>
</table>

As can be seen for the classification endoscopes fall into the semi-critical/intermediate risk classification and the level of decontamination recommendation is High Level Disinfection.

This policy outlines the up to date operational procedures associated with the decontamination process including, personnel, cleaning, reprocessing, storage, tracking and validation.
2. Purpose

This document is to be used in conjunction with NHS Lothian’s Decontamination Policy and local Standard Operating Procedures (SOP) for endoscopy decontamination.

Endoscopy procedures have the potential for cross infection as the medical device used for diagnosis is reusable. It is difficult to estimate the real risk of endoscopy induced infection due to the nature of the service and the long incubation periods of diseases. However, there have been some significant reports of cross infection all of which were a result of poor practice within one or more parts of the decontamination cycle. The most important catalyst for change in the UK has been the possible iatrogenic transmission variant Creutzfeldt Jakob disease (vCJD). The prion protein, the causative agent of vCJD cannot be destroyed by current conventional decontamination practices. Hence, it is essential that the processes we have in place minimise the risk as much as possible and that analysis of data can be carried out retrospectively.

It is a requirement of the JAG for GI Endoscopy that all Boards can demonstrate the use of a local policy on the decontamination of flexible endoscopes to include risk assessment, risk management and quality control of all aspects of the decontamination process.

3. Scope

The unit provides a local decontamination service for all flexible endoscopes. This document therefore covers the reprocessing and storage of all GI endoscopes, bronchoscopes and TOE probes.

4. Background

The endoscopy unit provides and manages a local decontamination service for all flexible endoscopes within the endoscopy unit, and for TOE probe. Services utilising the area include:

- Endoscopy Unit
- Cardiac theatres

5. Operational Management

Key Personnel:

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
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<tbody>
<tr>
<td>Lead for Decontamination (NHS Lothian)</td>
<td>Gillian Ellis-Pow</td>
</tr>
<tr>
<td>Divisional Chair for Surgery and Decontamination</td>
<td>Gillian Ellis-Pow</td>
</tr>
<tr>
<td>Decontamination Manager / User</td>
<td>Helen Chisholm</td>
</tr>
<tr>
<td>Endoscopy Services Manager</td>
<td>Jenny Flemming</td>
</tr>
<tr>
<td>Microbiologist</td>
<td>Dr Elzbieta Czarniak.</td>
</tr>
<tr>
<td>Authorising Engineer (Decontamination)</td>
<td>Alan Heatlie</td>
</tr>
<tr>
<td>Test Person</td>
<td>Scott McKenzie, Colin Warmisham (Puricor)</td>
</tr>
<tr>
<td>Infection Control Nurse</td>
<td>Allison Hutchison</td>
</tr>
</tbody>
</table>

Quality Assurance:

The operational aspects of decontamination of flexible endoscopes including personnel, resources, tracking and compliance issues are discussed and reviewed at the following UHD meetings:

- NHS Lothian Decontamination Strategy Group
- UHD Decontamination Steering Group (still to be re-convened)
- Endoscopy Users Group meetings
- UHD Infection Control Committee

Adverse incidents relating to decontamination are reported by the UHD adverse incident pathway, presented at the UHD Decontamination Committee and investigated and reported by the Designated User.

Standard Operating Procedures (SOPs) are reviewed and updated on a regular basis

**Out of hours decontamination**

The decontamination of endoscopes for out of hour’s service is carried out by the endoscopy on call nurse who has completed local decontamination competencies. The endoscopes a processed pre and post procedure, only when the patients condition is life threatening will an unprocessed endoscope be used.

**6. Decontamination environment**

The endoscopy unit opened in 2003 and currently does not meet the requirements of Scottish Health Planning Note (SHPN) 13 part 3, BS EN ISO 15883 parts 1 and 4, Health Technical Memorandum (HTM) 2030 part 3 and Health Protection Scotland (HPS) Guidance on endoscope reprocessing. This service is currently under review with consideration being given to a centralised decontamination unit on the RIE site. This will include the Endoscopy Unit, Theatres, RHSC and DCN.

The facility has 2 Sterilox QED and 1 Labcaire G4 endoscope washer disinfectors (EWD) none of which, due to age and design, comply with current guidance and legislation. All EWDs have a maintenance contract including a HTM 2030 testing schedule.

Sterilox generators are used to produce a high level disinfectant that is sporicidal within 5 minutes. Cidex-OPA is used for the Labcaire EWD.

**7. Safety**

There are no COSSH implications for the use of Sterilox.
Risk assessment has been undertaken for Cidex-OPA, and Gigasept both are held in health and safety folder
All staff have access to and must wear appropriate **Personal Protective Equipment (PPE)**.

- Aprons
- Single use gloves
- Full face visors
- Arm gauntlets

A spillage kit is stored outside the room together with a spillage policy, including respirator masks which relevant staff have been fitted for.
8. Personnel and Training

A safe and effective endoscope decontamination service requires competent staff to be responsible for each stage of the decontamination cycle; a robust validation and verification system; and maintenance of accurate records. The Health Act (2006) state that decontamination staff should be trained and hold appropriate competencies. Therefore, it is recommended that dedicated staff whose primary duties are decontamination are appointed to these roles. Technicians working in Operator roles and those with additional responsibilities related to testing and validation, require additional training. It is recommended that a senior technician have direct responsibility for decontamination and be accountable to the User and appropriate management teams.

The Royal Infirmary employs designated technicians within the decontamination area. Staff are required to undertake and complete a local decontamination training programme. Competency is assessed using the Lothian Decontamination Competencies.

Staff undertake SVQ level 2 modules and now also have access to SVQ Level 3 Clinical Healthcare Support (Endoscopy), Staff are trained in the use of equipment by the manufacturers.

9. CJD / vCJD Protocol

All patients referred to the endoscopy unit are risk assessed by the nursing staff for CJD/vCJD by using the questionnaire as detailed in Annex J - http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm

“Have you ever been notified that you are at risk of CJD or vCJD for public health purposes?”

At Risk Patients: appropriate action is taken to protect the internal channel of the endoscope from tissue contamination.

Known vCJD: the indications for the procedure will be assessed. If deemed necessary, steps will be taken to rebook the patient if possible in order to order an appropriate endoscope from the vCJD centre in Edinburgh. In the case of an emergency, the scope used will need to be quarantined.

For further guidance refer to Endoscopy Unit vCJD/CJD Protocol Appendix A.-

10. Testing and validation

All EWDs are under a service contract that is inclusive of HTM testing requirements. EWDs undergo quarterly testing and annual revalidation with extensive microbiological testing.

The technicians are responsible for undertaking the following tests: Appendix B:

Daily:
- Self disinfect cycle
- Automatic control test (limited)
- Filters/strainers checked and cleaned
- Door seals and locks checked
- LCD screen working
- Printer has ink and paper
- Chamber clean
- Visual check of flow through channels Appendix C
Weekly:
- Daily tests
- Automatic control test (full)
- Final rinse water – Total Viable Count (TVC)
- Water Hardness
- (Conductivity is only tested for on the G4 AER)
- Residual Protein Testing (Appendix D)
- Automatic Control Test (Appendix E)

Action on failed tests:
All test results are sent to the Lead for Decontamination and the users. Any non-compliance is documented on the testing documentation sheets and actions required will be notified to the Charge Nurse of the Endoscopy Unit by the Lead for Decontamination.

See Appendix F for Action on failed rinse water results.

11. Maintenance

All endoscopes have a service contract and are sent for repair according to local policy and recorded on the electronic tracking system. Loan scopes are recorded in Unisoft and EWD,s a label is produced and attached to the scope during the duration of the loan.

All Olympus scopes need to be protected including loan scopes with the SPS wiping system according to the Olympus protocol.

The control wires within the control head should be checked quarterly for any stretching and if identified, scopes should be sent for a routine service.

12. Stages of the Decontamination Cycle

The standards for each stage are in accordance with HPS (2007) Guidance on the Reprocessing of Endoscopes
a. Preliminary cleaning
The nurse in the procedure room is responsible for flushing all channels of the endoscopes following the procedure and for wiping external surfaces to remove gross bioburden. This includes exchanging the air/water button for the flushing valve, attaching the biopsy cleaning adaptor and if necessary attaching a bridge channel cleaning adaptor:
- Using a pre-filled container of detergent and water, suction 200-250mls of fluid down the biopsy and suction channels, followed by flushing with water to remove detergent residue
- Simultaneously, depress the air/water cleaning valve to flush clean water down both the air and water channels.
- Wipe the insertion tube with a detergent wipe
- Turn off the air button to prevent excessive drying of channels
- Cover endoscope tray with red contaminated liner and transfer to the decontamination room

b. Manual cleaning
The aim of the manual cleaning process is to inspect the scopes, carry out a function test and to clean all channels using detergent and water. The detergent should be used according to the manufacturer’s guidelines relating to temperature and the correct ratio of water to detergent. The detergent should be dispensed close to the water line of a filled sink. Appendix G

- Wear appropriate PPE (red apron, full face visor and gloves and sleeve gauntlets)
- Fill sink with clean water to fill line
- Inspect external surfaces for abnormalities
- Dispose of biopsy cap
- Remove valves from the scopes
- Attach Olympus/Fujinon leak tester and turn on to pressurise the scope
- Fully submerse into water and angulate the bending section. (Olympus scopes only)
- Assess for leakages (continuous stream of bubbles)
- If leak identified, remove scope from water, deflate tip, turn off and detach leak tester. Document location of leak and send for repair
- If no leak identified, deflate tip, turn off and remove leak tester.
- Dispense correct amount of detergent into sink using the automatic dispenser
- Using an underwater cleaning technique, brush all accessible channels until visually clean
- Clean external surfaces including the distal tip and the control wheels
- Attach ‘Octopus’ to GI scopes and irrigate all channels with detergent followed by water. Attach a bridge channel cleaning adaptor if necessary and use appropriate flushing connectors for non GI scopes. Rinse external surfaces with clean water
- Manually clean all valves and rinse with clean water
- Record manual cleaning process appropriately on the QED print out
- Drain sink, change PPE and wash hands before handling the next scopes

c. Reprocessing scopes
EWDS are used at all times for reprocessing endoscopes. Manual disinfection of scopes is not carried out at any time.
In:
- Wear appropriate PPE (White apron and gloves)
- Transfer socially cleaned scope to EWD in the endoscope tray
- Reprocess scopes within the EWDbut do not reprocess invasive and non-invasive scopes simultaneously i.e. colonoscope and cystoscope
- Connect all channels according to manufacturers guidelines
- Add in measured amount of detergent
- Close lid, programme correct cycle and start cycle
- Decontaminate endoscopes tray with disinfectant wipes and insert clean liner
- Record process in the electronic tracking system

Out:
- Wear appropriate PPE (white apron and gloves)
- Position clean endoscope tray and liner next to the EWD
- Check the print out to confirm that it has passed the cycle
- Disconnect scope from EWD
- Hang vertically until excess water has drained and dry external surfaces (Non-invasive: clean disposable towel) –
- Place in endoscope tray with unique valve set and cleaning connectors
- Record process on the electronic tracking system and attach tracking print out to the tray
- Cover with green liner and transfer to appropriate location

d. Transportation
Endoscopes within the endoscopy unit should be transferred in a purpose built endoscope tray with protective liners. Endoscopes transferred outside the unit should have a hard lid to prevent possible recontamination to the endoscope or contamination to the environment.
- Green liners are used to transfer clean scopes
- Red liners are used to transfer dirty scopes

e. Storage
Endoscopes stored in High Efficiency Particulate Air (HEPA) filtered storage cabinets can be used up to 31 days post reprocessing providing there has been no electrical or mechanical interruption to the cabinet during this period. If there is an interruption to power supply then all endoscopes will be reprocessed. All endoscopes once processed and if not for immediate use must be placed in the cabinets within half an hour of processing. All endoscopes following removal from HEPA cabinets are used within 3 hours unless in an emergency situation

f. Tracking and traceability
A paper system is in place to track scopes. Every time a scope is decontaminated and used two printouts are produced, one is attached to the patients care pathway, the other is placed in a folder in the procedure room, the patients details and scopes used are also recorded in the procedure room operations book and on the Unisoft patient report. If the scope has been removed from the HEPA cabinet then the cabinet printout is also attached. Regular audit of scope tracking system is undertaken.

g. Accessories
Single use accessories are used for all procedures. Reusable water bottles are used, however these have been labelled and can be tracked appropriately. These bottles are changed after each session, cleaned and sent to HSDU for reprocessing. All accessories including cleaning and AER consumables are incinerated if exposed to patients at risk of or with known vCJD
Endoscopy Unit vCJD/CJD Protocol

The British Society of Gastroenterology requires that policies relating to the decontamination of endoscopic equipment must include assessment criteria for identifying high risk procedures with relation to Prion contamination.

Protocol 0673 – Creutzfeldt–Jakob disease or any other Transmissible Spongiform Encephalopathy identifies which patients should be considered high risk. All patients are risk assessed at admission prior to endoscopic procedures by asking the question:

‘Have you ever been notified that you are at risk of CJD/vCJD for public health purposes?’

If the answer ‘yes’ the appropriate precautions in Annex F and the consensus document should be taken. Downloadable document available on website http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm

The admitting healthcare professional should also briefly search the notes for any undiagnosed neurological illness and document any evidence of obvious unexplained neurological disturbance on assessment. Advice may need to be sought from a physician and/or neurologist prior to an elective endoscopic procedure to assess whether an alternative would be more appropriate, or rescheduling to allow for special precautions as stated below such as sheathed biopsy forceps.

Due to high levels of lymphoid tissue along the gastro-intestinal tract all GI endoscopy procedures carry some risk of contamination of the endoscope, in particular the biopsy working channel where Prions cannot be decontaminated.

Procedures can be categorised according to risk by applying the following table for patients known to be at risk of vCJD/CJD

<table>
<thead>
<tr>
<th>Procedure type</th>
<th>Risk/Intervention</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic Gastroscopy</td>
<td>No risk of tissue contamination</td>
<td>No precautions Required</td>
</tr>
<tr>
<td>Gastroscopy with biopsy</td>
<td>Possible contamination of biopsy channel</td>
<td>Use of identified scope Quarantined</td>
</tr>
<tr>
<td>Gastroscopy with brush cytology</td>
<td>Instrument sheathed, no risk of contamination</td>
<td>No precautions required</td>
</tr>
</tbody>
</table>

No Risk (patients known to be at risk for vCJD/CJD)

- Any purely diagnostic procedure without biopsy or accessories does not carry risk of contamination of the biopsy working channel.
- Procedures utilising accessories which are re-sheathable prior to being withdrawn through the instrument carry minimal risk and require no precautions eg: cytology brushes, sheathed biopsy forceps.
- Accessories inserted through a outer sheath i.e. pushing catheter or internal sheaths from Olympus protects the channel and therefore carries minimal risk.

Contamination which requires quarantine of scope (for at risk patients)

Contamination occurs if tissue samples are taken and withdrawn via the working channel of the endoscope using unsheathed accessories (unsheathed biopsy forceps, snares, injection needles etc.). Follow the guidelines for at risk patients be
Decontamination Protocol For Endoscopes
used on at risk or known vCJD patients

AT RISK Patients

1. Potential risk is identified via referral or patient admission (ideally non-endoscopic investigation is performed eg: radiologically inserted gastrosomy (RIG) is inserted instead of a PEG insertion).

2. If no other alternative is appropriate perform a non-invasive procedure where possible (see table above)

3. If an invasive procedure is required follow the guidelines for a protected invasive procedure and inform:
   - Nurse-in Charge of shift
   - any other healthcare professionals in direct contact with the patient
   - Decontamination staff

4. Decontaminate scope separately

5. Run an extra cycle before the next scope is reprocessed

6. Discard and incinerate any accessories or consumables within the EWD: filters, port adaptors

7. Discard liquid waste by normal direct discharge form the EWD

8. If a non-protective invasive procedure is carried out quarantine scope and follow guidelines below as per known vCJD/CJD diagnosis

KNOWN vCJD/CJD diagnosis post procedure - Guidelines for notification when a previous patient has been diagnosed with CJD/vCJD

1. Identify scope and take out of service and quarantine immediately

2. Commence electronic traceability procedure to identify every patient subsequently linked to the endoscope

3. Inform relevant bodies regarding possible contamination once patients have been identified to ensure appropriate testing and follow up:
   - Contact GP’s of affected patients
   - Health Protection Unit
   - National Unit for CJD – Edinburgh (for further advice and collection of contaminated scope)
## Appendix B

### Daily QED Start up Procedure

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Frequency</th>
<th>Housekeeping tasks (P for pass or F for Fail)</th>
<th>HTM Schedule</th>
<th>Mon</th>
<th>Tues</th>
<th>Wed</th>
<th>Thurs</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
</tr>
</thead>
<tbody>
<tr>
<td>User</td>
<td>Daily</td>
<td>Services turned on</td>
<td>Manual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User</td>
<td>Daily</td>
<td>Adequate chemical in machine</td>
<td>Manual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User</td>
<td>Daily</td>
<td>No broken female bulkheads are present</td>
<td>Manual</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>User</td>
<td>Daily</td>
<td>O’rings on male bulkheads are intact</td>
<td>Manual</td>
<td></td>
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<td></td>
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<tr>
<td>User</td>
<td>Daily</td>
<td>All tubing/connectors are intact</td>
<td>Manual</td>
<td></td>
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<tr>
<td>User</td>
<td>Daily</td>
<td>Monitor/display operating correctly</td>
<td>Manual</td>
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<tr>
<td>User</td>
<td>Daily</td>
<td>Check printer</td>
<td>Manual</td>
<td></td>
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<tr>
<td>User</td>
<td>Daily</td>
<td>Verify flow through water channels</td>
<td>Manual</td>
<td></td>
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<tr>
<td>User</td>
<td>Daily</td>
<td>Cycle complete</td>
<td>Manual</td>
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# Appendix C

## Weekly Scope and QED test

### Residual Protein

<table>
<thead>
<tr>
<th>Date:</th>
<th>Batch no:</th>
<th>Scope number and Q,E,D</th>
<th>Ex Date:</th>
<th>Pass/Fail</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
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<tr>
<td>PROCESS STAGE</td>
<td>NOMINAL DURATION</td>
<td>MEASURED DURATION</td>
<td>% VARIATION WITHIN 10%</td>
<td></td>
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<tr>
<td>---------------------------------------------------</td>
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<tr>
<td>START</td>
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<tr>
<td>DETERGENT WASH FILL TO MAX LEVEL</td>
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<tr>
<td>ULTRASONIC WASH WITH ENDO SOAP</td>
<td>3MIN</td>
<td></td>
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<tr>
<td>DETERGENT WASH DRAIN FULLY</td>
<td>*</td>
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<tr>
<td>FIRST RINSE FILL TO MAX LEVEL</td>
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<tr>
<td>FIRST RINSE</td>
<td>1MIN 30SEC</td>
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<tr>
<td>FIRST RINSE DRAIN FULLY</td>
<td>*</td>
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<tr>
<td>STERILOX FILL TO MAX LEVEL</td>
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<td></td>
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<tr>
<td>EXPOSED TO STERILOX</td>
<td>5MIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STERILOX DRAIN FULLY</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAST RINSE FILL TO MAX LEVEL</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAST RINSE</td>
<td>1MIN 30SEC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAST RINSE DRAIN FULLY</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYCLE COMPLETE</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* OBSERVE AND THICK “✓” IF YES OR “x” IF NOT

<table>
<thead>
<tr>
<th>CYCLE COMPLETE</th>
<th>DOOR LOCKED</th>
<th>ANY MECHANICAL ANOMALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES/NO</td>
<td>YES/NO</td>
<td>YES/NO</td>
</tr>
</tbody>
</table>

The cycle printout containing the operating parameters for this cycle should be printed out and attached to this document.

.................................................................

/signature/

ATTACH PRINTOUT HERE

13
Guidelines for Actions following identification failed endoscopy water tests at RIE

Location: Decontamination Area
Endoscopy Unit
Ground floor, RIE

Equipment: 2 x QED Endoscope Washer Disinfectors
1 x Guardian Endoscope Washer Disinfectors

Testing Schedule: Samples of rinse water are collected from all machines weekly and submitted to the Scottish National Blood Transfusion Service Product Testing Unit

Resource: BS EN ISO 15883 parts 1 and 4, HTM 2030 part 3, HPS Guidance on the Reprocessing of Endoscopes

Final rinse water must comply with the specification as outlined in the above noted standard and guidance. There is an opportunity of residual water from a processed endoscope to be transferred to the patient if the endoscope is not dry at the end of the automated process. Therefore any residual water must not harm the patient. For practical purposes the levels of contaminants described for potable water are sufficient, unless an endoscope is to be used in a normally sterile area. Therefore the final rinse water must not contain any harmful chemicals or organisms. Details are given below for acceptable levels of micro-organisms suitable for final rinse water.

Table 1 Microbiological Standards for specific organisms

<table>
<thead>
<tr>
<th>Total viable count (tested weekly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>There should be no more than 10 cfu/100ml of Gram-positive organisms</td>
</tr>
<tr>
<td>There should be no <em>Pseudomonas aeruginosa</em> detected</td>
</tr>
<tr>
<td>There should be no coliforms detected</td>
</tr>
</tbody>
</table>

**Other micro-organisms**

*Mycobacterium* sp. not detected in 100 ml water (tested every quarter)

*Legionella* sp. not detected in 100 ml water (not routinely tested)

**Microbiology Results**

Final rinse waters are processed for Total Viable Counts (TVC) in the Scottish National Blood Transfusion Service Product Testing Unit. Samples are cultured from each machine every week. Samples of the final rinse water from a cycle is taken on a weekly basis as per BS EN ISO 15883 part 4 and HTM 2030 part 3.

The samples are taken by members of the team trained in the process using an aseptic technique. A staff member performs the sampling by following the manufacturer instruction...
for water sampling contained within the AER manual. The purpose of the sample is to ensure that the final rinse water does not contain any harmful organisms or chemicals.

The sample taken is:

- Total Viable Count (TVC) plastic red lid bottle

The samples are labelled and placed into a central fridge within day bed reception area where they are collected by the testing laboratory.

The samples are reported on 5 days after receipt. The results come via the e-mail system to Endoscopy Charge nurse and Deputy Charge Nurse. This information is also sent to Decontamination lead, Microbiologist and Infection Control Nurse. The report highlights any concern and any required action will be confirmed via a second e-mail or telephone call from the Decontamination lead.

The inoculated plates are incubated for 48 hours in the laboratory. The majority of results will be therefore available 48 hours after sample collection. Some results may take longer if identification of bacterial colonies is required.

**Interpretation of results and actions**

Actions are based on the interpretation in table 1 above and table 2 below

**Table 2 Interpretation of results and actions**

<table>
<thead>
<tr>
<th>Aerobic colony count in 100 ml</th>
<th>Interpretation/ action</th>
<th>Colour grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>Satisfactory</td>
<td>Green</td>
</tr>
<tr>
<td>1-9 on a regular basis</td>
<td>Acceptable</td>
<td>Yellow</td>
</tr>
<tr>
<td></td>
<td>- indicates that bacterial numbers are under a reasonable level of control</td>
<td></td>
</tr>
<tr>
<td>10-100</td>
<td>Unsatisfactory</td>
<td>Orange</td>
</tr>
<tr>
<td></td>
<td>- investigate potential problems and super-chlorinate or repeat AER self-disinfect</td>
<td></td>
</tr>
<tr>
<td>Over 100</td>
<td>Unacceptable</td>
<td>Red</td>
</tr>
<tr>
<td></td>
<td>- take AER out of service until water quality improved</td>
<td></td>
</tr>
</tbody>
</table>

1. If the sample indicates a pass i.e. are in accordance with the standards in tables 1 and 2, no further action is required.

2. If the sample has a count >10 cfu/100 ml of Gram-positive organism, but less than 100 cfu/100 ml arrange for repeat testing.
   a. If the repeat sample is <10 cfu/ml, no further actions are needed.
   b. If the repeat sample has a count >10 cfu/100ml
      i. Do not use the machine
      ii. Arrange for disinfection of the machine
      iii. Contact Infection Control to discuss actions for patients
iv. Only use the machine again when counts are satisfactory

3. If the sample has a count of >100 cfu/ml
   a. Do not use the machine
   b. Arrange for disinfection of the machine
   c. Contact Infection Control to discuss actions for patients
   d. Only use the machine again when counts are satisfactory

4. If the sample has any growth of coliforms or pseudomonas
   a. Do not use the machine
   b. Arrange for disinfection of the machine
   c. Contact Infection Control to discuss actions for patients
   d. Only use the machine again when counts are satisfactory

**Infection Control Actions**

Several factors will need to be considered by the Lead for Decontamination and these will include:

- **Quantity and identity of bacteria in failed sample**
  - e.g. Low levels of environmental type organisms or commensals such as Gram positive cocci may be less significant than coliforms or pseudomonas

- **Type of endoscope potentially contaminated**
  - Endoscope used in sterile sites will e.g. cystoscope are more likely to required action than an endoscope used at a site with a normal bacterial flora e.g. colonoscope

- **Patient factors**
  - Immunocompromised patient may be more at risk

For guidance see the matrix below:

<table>
<thead>
<tr>
<th>Sampling result</th>
<th>Immunocompetent patient, endoscope used in non-sterile site e.g. colonoscope</th>
<th>Immunocompetent patient, endoscope used in sterile site e.g. cystoscope</th>
<th>Immunocompromised patient, endoscope used in non-sterile site e.g. colonoscope</th>
<th>Immunocompromised patient, endoscope used in sterile site e.g. cystoscope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low count (&lt;100 cfu/100ml) environmental or commensal bacterium e.g. GPC</td>
<td>Negligible risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>High risk</td>
</tr>
<tr>
<td>Low count (&lt;100 cfu/ml) potential pathogen e.g. coliform and pseudomonas</td>
<td>Low risk</td>
<td>High risk</td>
<td>High risk</td>
<td>High risk</td>
</tr>
<tr>
<td>High count (&gt;100 cfu 100ml) environmental or commensal organism e.g. GPC</td>
<td>Low risk</td>
<td>High risk</td>
<td>High risk</td>
<td>High risk</td>
</tr>
<tr>
<td>High count (&gt;100 cfu/ml) potential pathogen e.g. coliform or pseudomonas</td>
<td>Low risk</td>
<td>High risk</td>
<td>High risk</td>
<td>High risk</td>
</tr>
</tbody>
</table>

Possible actions are:

Negligible risk: No action
Low risk: Notify patient’s consultant and be aware of possible development of infection

High risk: Notify patient’s consultant and consider use of prophylactic antibiotics

The above is only guidance and different actions may be considered depending on circumstances.

In the high risk situation an incident management meeting should be arranged by infection control team to include the following: Infection Control Doctor or deputy, Infection control nurse, Endoscopy manager, Lead Consultant for Endoscopy Unit, Lead for Decontamination (NHS Lothian), service manager for endoscopy. The following may also need to attend: Health Facilities Scotland and Communications.
This procedure must only be undertaken by staff who have completed the NHS Lothian Endoscopy Decontamination Competency Framework. All training must be documented and annually assessed.

**Equipment Required:**
- Non-sterile, latex free gauntlet style gloves
- Disposable Plastic Aprons - white and red
- Full Eye and Face Protection
- Disposable channel and port cleaning brushes
- Non-linting disposable cloths
- Leak tester (Hand pump)
- Detergent wipes (i.e. Tuffie wipes)
- Neutral Detergent
- Water thermometer (If built into sinks)
- Protective arm sleeves
- 10ml syringe
- Channel Flushing Valve

**General Points:**

All needles, biopsy forceps, injection needles and other sharps items should be disposed of into a sharps bin at the point of use.

All reusable items should be returned to HSDU for reprocessing following agreed protocols.

All solutions used for cleaning flexible endoscopes should be used once and then discarded.

Prior to reuse, the flexible endoscope must be visually inspected to ensure it is fit for use.

Ensure that all equipment used for the reprocessing of flexible endoscopes is washed thoroughly with warm water and neutral detergent (or Tuffie wipes) and dried thoroughly at the end of each session.

**Step 1 - Pre-Clean**

Carried out in consulting room by nursing staff

Put on clean apron, gloves and eye protection (PPE).

1. Wipe Endoscope insertion tube top to bottom with detergent wipe.
2. If air/water (blue) valve is attached, remove and replace with channel flushing valve. Immerse distal tip of the endoscope in detergent solution. Depress valve
for 30 seconds and allow to bubble freely.
3. Attach biopsy channel suction attachment.
4. Immerse distal tip of the endoscope in detergent solution and depress valve for 30 seconds.
5. If suction (red) valve is attached, depress for at least 30 seconds until suction tubing is clear.
6. Switch off video converter before disconnecting endoscope. Replace waterproof cap (where applicable)
7. Switch off and disconnect suction.
8. If water bottle used, disconnect and send to HSDU at the end of list.
9. Dispose of biopsy cap
10. Transfer endoscope to decontamination area within tray system (if in use)

Step 2 - Leak testing

Wearing red apron, appropriate gauntlet gloves, protective arm sleeves and full face protection

1. Fill sink with warm water to preset level (25 litres). Check water temperature no greater than 35° C.
2. Remove all valves from endoscope prior to leak testing (ensure taps are fully dismantled)
3. Attach appropriate leak tester to endoscope,
4. Pump to 150mmHg or to 12 o clock position.
5. Rotate handle curving end tip in all directions. Observe for 30 seconds.
6. Release air from scope if no leaks are found.
7. Put scope into water.
8. If leak is detected Follow agreed arrangement for repair.

Step 3 – Manual Washing

1. Add correct amount of detergent, 25mls Hospec (as per manufacturers instruction) to the water.
2. Immerse entire endoscope and all buttons/valves. Keep endoscope immersed at all times during cleaning.
3. Wipe entire length of endoscope with a disposable cleaning cloth.
4. Clean valves, ensuring cuffs are pulled back. Use appropriate sized brush – each hole should be brushed a minimum of 3 times. Place valves in correct net bag. (BAG SHOULD BE LABELED FOR SCOPE)
5. Clean biopsy, suction and water channel entrances – minimum of 3 times until brush appears clean.
6. Clean channels in this order:
   i. Biopsy – with small brush only
   ii. Suction
   iii. Umbilical
Using the appropriate sized brush, clean each channel a minimum of 3 times. Clean the brush head each time it emerges from distal end of the endoscope.
7. Ensure that any mechanism at the distal tip of the endoscope is visibly clean and
free from debris.
8. Irrigate auxiliary channels if present with detergent solution using 10 ml syringe
9. Flush air water channel with flushing valve
10. Fill rinsing sink if available with fresh clean water no greater than 35 °C. Or empty
    sink, rinse, clean and refill with clean water.
12. Remove gloves and decontaminate hands.

Step 4 – Disinfection

Wearing clean white apron and gloves

1. Place endoscope into AER and ensure all necessary channels and appropriate
   accessories are connected.
2. Place accessories in wash bag tray ensuring this corresponds to endoscope being
   processed.
3. Add appropriate detergent if required (full plunge of Endosoap for QED). Start AER.
4. Wipe the front of the AER (and any other part in direct contact with potentially
   contaminated uniform, PPE or equipment) with a Tuffie wipe and dry.
5. Remove remaining PPE and decontaminate hands.
6. On completion of the washer / disinfector cycle affix pass certificate. No.1 in the
   clients case notes. No.2 affix to endoscopy / theatre suite records.

Updated for Endoscopy RIE by K Smith

Reviewed
July 2010
Review
Date July
2011
Decontamination of Flexible Olympus Endoscopes
Manual Washing SOP JANUARY 2011

This procedure must only be undertaken by staff that have completed the NHS Lothian Endoscopy Decontamination Competency Framework. All training must be documented and annually assessed.

Equipment Required:

- Non-sterile, latex free gauntlet style gloves
- Disposable Plastic Aprons- white and red
- Full Eye and Face Protection
- Disposable channel and port cleaning brushes
- Non-linting disposable cloths
- Leak tester (electrical pump)
- Detergent wipes (i.e. Tuffie wipes)
- Neutral Detergent
- Water thermometer (If built into sinks)
- Protective arm sleeves
- 5ml luer lok syringe
- Octopus
- 30ml luer lok syringe
- Measuring cup

General Points:

All needles, biopsy forceps, injection needles and other sharps items should be disposed of into a sharps bin at the point of use.

All reusable items should be returned to HSDU for reprocessing following agreed protocols.

All solutions used for cleaning flexible endoscopes should be used once and then discarded.

Prior to reuse, the flexible endoscope must be visually inspected to ensure it is fit for use.

Ensure that all equipment used for the reprocessing of flexible endoscopes is washed thoroughly with warm water and neutral detergent (or Tuffie wipes) and dried thoroughly at the end of each session.

Step 1 -Pre-Clean

Carried out in consulting room by nursing staff
Put on clean apron, gloves and eye protection (PPE).

1. Wipe Endoscope insertion tube top to bottom with detergent wipe.
2. If air/water (blue) valve is attached, remove and replace with channel flushing
valve. Immerse distal tip of the endoscope in detergent solution. Depress valve for 30 seconds and allow to bubble freely.

3. Attach biopsy channel suction attachment.

4. Immerse distal tip of the endoscope in detergent solution and depress valve for 30 seconds.

5. If suction (red) valve is attached, depress for at least 30 seconds until suction tubing is clear.


7. Switch off and disconnect suction.

8. If water bottle used, disconnect and send to HSDU at the end of list.


10. Transfer endoscope to decontamination area within tray with red cover.

**Step 2 - Leak testing**

Wearing red apron, appropriate gauntlet gloves, protective arm sleeves and Full face protection.

9. Fill sink with warm water to preset level (25 litres). Check water temperature no greater than 35° C.

10. Remove all valves from endoscope prior to leak testing (ensure taps are fully dismantled).

11. Switch on air pump, depress needle valve of leak tester and listen for audible hiss.

12. Attach appropriate leak tester to the endoscope cap.

13. Immerse distal tip of endoscope.


15. Remove endoscope from water immediately if continuous bubbling is detected. Follow agreed arrangement for repair.

16. Switch off leak tester.

17. Detach MU prong from box. Wait 30 seconds.

18. Ensure leak tester attachment is removed from water prior to disconnection from endoscope.

**Step 3 – Manual Washing**

13. Add correct amount of detergent (as per manufacturers instruction) to the water.

14. Immerse entire endoscope and all buttons/valves. **Keep endoscope immersed at all times during cleaning.**

15. Wipe entire length of endoscope with a disposable cleaning cloth.

16. Clean valves, ensuring cuffs are pulled back. Use appropriate sized brush – each hole should be brushed a minimum of 3 times. Place valves in correct net bag. **(BAG SHOULD BE LABELED FOR SCOPE)**

17. Clean biopsy, suction and water channel entrances – minimum of 3 times until brush appears clean.

18. Clean channels in this order:
   i. Biopsy – with small brush only
   ii. Suction
   iii. Umbilical

Using the appropriate sized brush, clean each channel a minimum of 3 times. Clean the
brush head each time it emerges from distal end of the endoscope.

19. Ensure that any mechanism at the distal tip of the endoscope is visibly clean and free from debris.
20. Irrigate auxiliary channels if present with detergent solution using 5 ml syringe
21. Flush all channels with octopus with 30 ml luer lok syringe
22. Flush air water channel with flushing valve
23. Fill rinsing sink if available with fresh clean water no greater than 35 °C. Or empty sink, rinse, clean and refill with clean water.
25. Remove gloves and decontaminate hands.

Step 4 — Disinfection

Wearing clean white apron and gloves

7. Place endoscope into AER and ensure all necessary channels and appropriate accessories are connected.
8. Place accessories in wash bag tray ensuring this corresponds to endoscope being processed.
9. Add appropriate detergent if required (full plunge of Endosoap for QED). Start AER.
10. Wipe the front of the AER (and any other part in direct contact with potentially contaminated uniform, PPE or equipment) with a Tuffie wipe and dry.
11. Remove remaining PPE and decontaminate hands.
12. On completion of the washer / disinfector cycle affix pass certificate. No. 1 in the clients case notes. No. 2 affix to endoscopy / theatre suite records.