University Hospitals Birmingham NHS Foundation Trust

CONTROLLED DOCUMENT

Operational Procedure for the Decontamination of Flexible Endoscopes and Probes

CATEGORY:	Procedure
CLASSIFICATION:	Clinical
PURPOSE	This procedure is intended to outline the service which will be provided by the Central Endoscope Decontamination Unit and the roles and responsibilities of the individuals and departments involved.
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Contents

i. **Procedure Statement**

This procedure relates to the decontamination service provided by the Central Endoscope Decontamination Unit (CEDU) to on site user departments at the Queen Elizabeth Hospital Birmingham and the Heritage Building

ii. **Definitions**

CEDU- Centralised Endoscope Decontamination Unit

vCJD – variant Creutzfeldt-Jakob Disease

iii. **Service**

Provision of decontamination services by the CEDU to the following departments:

Outpatient endoscopy unit
Inpatient endoscopy unit
Urology East Block Day Unit
Theatres (2nd floor)
Ambulatory Care Theatres
Welcome Spinal Theatres
ENT Outpatients
ENT Inpatients
Critical Care Units
Cardiology
GI Physiology
Clinical Research Facility

These are the main users but scopes and probes will be provided to all areas of the QEHB and QE as required. Requirements need to be made clear to the coordinator in CEDU.

iv. **Core Elements**

The CEDU is to be operated in accordance with the standards reflecting in BS EN ISO 13485, HTM 01-06, ISO 15883 – 1 and 4.

v. **Audit**

The CEDU service will be subjected to internal audit which form an integral part of the Quality Management System. Third party certification from the Authorising Engineer as per BS EN ISO 13485 is carried out annually.

vi. **Review**

This Procedure will be reviewed every 3 years as per Trust guidelines.

vii. **References**

BS EN ISO 13485- Quality Management System. Requirements for regulatory purposes 2016

HTM 01 – 06 Endoscopy – Decontamination of Flexible Endoscopes June 2016

ISO 15883 – 1 Washer disinfectors: general requirements June 2014

ISO 15883 – 4 Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes May 2016

1. Purpose

To ensure all flexible endoscopes and probes are decontaminated in the CEDU to meet requirements of national standards and legislation for the decontamination, maintenance and use of flexible endoscopes, and to comply with Health and Safety requirements relating to endoscopes [1,2,3, 4, 5, 6].

This procedure outlines the service provided to departments from the CEDU.

2. Responsibilities

2.1 Managerial Responsibilities

2.1.1 *General*

Departments are to be responsible for:

- Appointing a lead person within their department who will be responsible for ensuring this procedure is effectively implemented and maintained in their area;
- Appoint a daily co-ordinator within the department who will be the initial point of contact for CEDU for matters relating to decontamination;
- Ensuring that service maintenance contracts are established through the Medical Engineering department for the endoscopes and probes. This is in accordance with the device manufacturers' recommendations and for ensuring that the endoscopes and probes are sent for servicing as appropriate;
- Arranging and funding the repair/replacement of endoscope and accessories and probes as necessary through the Divisional Structures;
- Complying with the Trust's trialling/loaning and procurement procedures for new equipment;
- Ensuring that prior to purchase/loan/trial of flexible endoscopes and probes, the CEDU manager is consulted in order to determine whether the endoscopes and probes will be compatible with the existing process equipment and chemicals used within the CEDU, that the endoscope and probe manufacturer's information for processing and use is obtained and that this forms part of the evaluation process;
- Ensuring that any new / loaned / trialled endoscope and probe are made available to the CEDU not less than three weeks prior to the need for commencement of processing,

together with all relevant equipment information and processing instructions;

- Ensuring that when new / loaned / trialled endoscopes and probes are to be obtained, training is available by the manufacturer where appropriate and that the CEDU Manager is consulted regarding training needs for CEDU personnel;

- Communicating any proposed changes or service/product developments to the CEDU, allowing sufficient time to permit resource planning and where necessary training and / or procurement of additional equipment;

- Ensure that endoscopy lists are available to CEDU staff by 4pm the previous working day. Any changes to these requests must be reported immediately to the CEDU;

- Ensuring that fast track requests are directed to the CEDU, extension 13850;

- Ensuring departmental staff are trained in the care and usage of scopes and that records of appropriate training are maintained;

- Ensuring there is a written procedure available within the Departments that describes out of hours arrangements for emergency endoscopy and probes. The procedure will require the departmental user of the endoscope to carry out the pre-cleaning procedure described in the Standard Operating Procedure;

- Ensuring the CEDU is informed if it becomes apparent that a endoscope has been used on a patient subsequently found to be infected by vCJD;

- Return the used post cleaned endoscope back to CEDU immediately following use so that the decontamination and reprocessing can take place in line with HTM 01-06 guidance;

- Ensuring that departmental staff complies with the traceability procedure for all patient use of medical devices; and

- Ensuring that departmental staff comply with the Trust CJD policy for screening of patients prior to an endoscopy procedure.

2.1.2 *Use of endoscopes*

Departments are responsible for:

- Ensuring endoscopes and probes are used for their intended purpose (as stated by the device manufacturer);

- Scanning the endoscopes and probes into the Information Management System (IMS) and attaching tracker labels to patient care plan/patient notes on receipt from the CEDU and prior to returning used or time expired endoscopes to the CEDU;

- Ensuring all sections of the tracking and tracing forms (Appendix A and B) are completed with all details;

- Ensuring all endoscope channels are flushed immediately following the procedure and the endoscope wiped;

- Ensuring an air/water flushing valve is used in endoscopes with combined air/water channels. Channels are to be checked for patency during this process;

- Ensuring all parts of the endoscope are present when sending used endoscopes back to CEDU;

- Ensuring all single use items including the biopsy port cap are discarded after use within the clinical department;

- Placing used endoscopes and accessories on their dedicated trays and ensuring that the trays are covered with an appropriate red plastic contaminated cover prior to transportation to the CEDU, placing trays on the designated collection trolley. See Sections.1.4 and 3.2;

- Ensuring trolleys are kept away from patients and are not tampered with; and
- Delivering used endoscopes and accessories to CEDU for reprocessing within an hour of being used in a timely fashion. See Sections 4.5 and 4.6

2.1.3 *Storage*

- Ensuring that processed endoscopes and probes are stored in the dedicated drying cabinets provided in user areas;

- Using the drying/storage cabinet in accordance with manufacturer's guidance and the Standard Operating Procedure;

- Ensuring that the storage cabinets are locked and that the access key is stored in a secure place or with nurse in charge;

- Ensuring only designated, named and trained personnel have access to the storage cabinets and that records of training are kept;

- Storing endoscopes with their detachable parts having been dismantled, in a manner that ensures security of the items and keeps components together;

- Ensuring that endoscopes and probes are handled and stored in a manner preventing contamination prior to use;

- Checking the expiry date and time of endoscopes and probes prior to use and for arranging the reprocessing of any endoscopes that have exceeded the 31 day (744 hours) storage time;

- Conducting daily / weekly checks on the storage cabinet and completing the log book;

- Reporting faults to the helpdesk on ext.777 and the CEDU Team-leader on ext 13850;

- Ensuring that the Cardiac and Liver tracheoesophageal (TOE) probes are only handled by staff from the Cardiac and Liver Theatres. Ensure that the expiry dates on the outside of the vac packed endoscopes cases are in date. If expired return to the CEDU for reprocessing; and

- Ensuring only designated, named and trained personnel have access to the vac packed endoscopes and that printouts are placed in the patient notes.

2.2 <u>CEDU Responsibilities</u>

2.2.1 *Operational management*

All flexible endoscopes will be decontaminated in CEDU

The CEDU will be operational between the following hours:-

Monday and Friday 07.00 am to 19:00 pm
Tuesday to Thursday 07:00 am to 20:00pm
Saturday 08.00 am to 16.00 pm
Bank Holiday Monday 08.00 am to 12.00 pm

These hours may be revised at the discretion of the CEDU Manager in order to take account of user activity and requirements. Departments will be kept informed regarding any proposed changes.

- Routine turnaround times for endoscopes will be 4 hours. Where endoscopes need to be fast-tracked, the CEDU will

aim to process the endoscope within 2 hours. This assumes that the endoscope reaches CEDU in a timely fashion, that there are no process failures and that there are no other fast-track requests being dealt with at the same time.

The CEDU will:

- Implement and maintain a Quality Management System based on ISO 13485;

- Develop, implement and maintain operational procedures for all aspects of its activities in relation to endoscope reprocessing and collection and distribution of endoscopes. These procedures will also address the management responsibilities of the CEDU including microbiological monitoring;

- The endoscope washer-disinfectors are to be validated quarterly by an external company and annually by a body (Authorised Engineer);

- Ensure that any non-conformity are investigated and that effective corrective action is taken. Maintain a customer complaints procedure and customers will be provided with feedback following investigation. This information will advise regarding the action taken to prevent a re-occurrence of the problem;

- Ensure decontamination matters are raised and discussed at the Decontamination Group meeting;

- Ensure involvement from the infection prevention and control department and named microbiologist in managing and maintaining the service;

- Ensure that detergents, disinfectants, endoscopes, probes, washer-disinfectors, cabinets, Antigermix and vac pack heat sealer are used in accordance with manufacturer's guidelines;

- Ensure compatibility of the endoscopes and probes with the process equipment and chemicals used within the CEDU, prior to processing;

- Ensure scopes and probes are tagged and identified at all stages of processing;

- Ensure washer-disinfector, Antigermix, vac pack heat sealer and storage cabinets (including those located in the clinical units) are maintained, tested and validated according to manufacturer's guidance and the quality

system standards applied by the CEDU. Maintenance, testing and validation records will be kept at CEDU for the purpose of audit;

- Take responsibility for supplying endoscope covers for the transport trays. See section 3.1.2;

- Ensure spare endoscope buttons and bungs are decontaminated, individually packed and sent to users; and

- Ensure there is a procedure in place for endoscopes used on vCJD patients.

2.2.2 *Safety*

The CEDU will ensure:

- COSHH risk assessment is carried out;

- There is a policy for spillages; chemicals, detergents, body fluids; and

- A spillage kit and eye wash station is available within the department and staff fully aware of the safety procedures in place.

2.2.3 *Staff Training*

The CEDU will ensure all staff undertake competency based training in relation to the following:

- Decontamination of different types of endoscopes and probes;

- identification of individual endoscopes and all associated channels;

- design and function of endoscopes and probes;

- decontamination process (assembly and dismantling of endoscopes, manual cleaning, accessories, disinfection, washer/disinfector, drying, storage, transportation, tracking/traceability);

- basic microbiology and infection control;

- detergents, disinfectants;

- washer/disinfector-testing and validation;

- storage cabinet-testing and validation;
- operation of the vac pack vacuum/heat sealer;
- health and safety;
- COSHH training;
- Tracking and tracing systems;
- Training from manufactures on using the washer/disinfectors, storage cabinets, vacuum pack system and tracking system; and
- Current standards and legislations, including Top-Ten Tips from MHRA.

2.3 Microbiological Responsibilities

2.3.1 The CEDU Manager will be responsible for ensuring that the final rinse water quality is routinely tested in accordance with currently HTM 01-06 and ISO EN 15883 and they will appoint the services of an appropriate third party test laboratory to undertake this work.

2.3.2 The Consultant Microbiologists will be consulted in matters relating to microbiology as appropriate.

2.4 Transportation of scopes between Clinical Departments and the CEDU

2.4.1 Each department will return used endoscopes and probes for reprocessing. A schedule will be agreed with each department. CEDU staff will deliver endoscopes on a daily basis according to the users demand. Some departments will deliver used endoscopes and probes and collect throughout the day.

2.4.2 Collection times 8.00am - 6.00pm. After 6.00pm scopes will be decontaminated the following morning. However, the endoscope must be subjected to the pre-clean procedure immediately after use in accordance with the manufacturers' instructions.

2.4.3 All endoscopes and probes are to be returned to the relevant departments by the end of each working day – unless the scope has been quarantined as non-conforming, in which case the department manager will be advised as soon as the matter is identified.

2.4.4 If departments require scopes at other times they will be responsible for delivery and collection.

2.5 Contract Facilities Services

2.5.1 Ensuring the manufacturers and estates provide service and maintenance, of equipment according to HTM 0101 and HTM 01-06.

2.5.2 Respond within 1 hour to breakdown of estates or decontamination equipment in CEDU.

2.5.3 Contact the manufacturer of the equipment if repairs cannot be completed within 24 hours.

2.5.4 Provide 24 hours on call maintenance service.

3. Summary of Decontamination Process

3.1 Post-Cleaning by Users

- Departments are responsible for wiping external surfaces and flushing of channels immediately after use following the manufacturer's recommendations.
- Ensuring the probe / endoscope and its accessories are placed on the dedicated tray, together with all relevant data to permit traceability.
- Returning the used endoscope / probe to CEDU immediately following use to be reprocessed in accordance with HTM 01-06.
- Using the IMS to record patient use.

3.2 Collection

- Each area will transport the used endoscopes / probe back to CEDU for reprocessing.
- Returning the used endoscope / probe to CEDU immediately following use to be reprocessed in accordance with HTM 01-06.
- Trolleys need to be left in the designated areas for used endoscopes/probe to be stored ready for transfer to the CEDU.
- If departments require endoscopes / probes at other times they will be responsible for delivery and collection.

3.3 Using Vac-Packed Endoscopes

- Before use each user should check the reprocessing label on the front of the case to see that the vac-packed scope is in date.

- Before use each user should check that that the vac-packed endoscope has a green clean tag secured around the handles.
- Once opened the endoscope should be sealed inside a clear heavy duty plastic bag with accessories.

- Inside the case should be a patient tracking form, red contaminated returns bag, red cable tie and tag to be secured around handles once used.

3.4 Manual cleaning

- Single use cleaning devices will be used for manual cleaning.

- Scopes will be visually checked for obvious damage.

- Valves and detachable distal tips to be removed.

- Endoscope to be leak-tested.

  - If the endoscope passes the leak test it will be manually cleaned.

  - If the endoscope fails the leak test it will be manually cleaned using a non-immersion method (i.e. wiped with a damp cleaning cloth using a solution of detergent and water, subsequently wiped with a damp cloth soaked in clean rinse water and manually dried) and returned to Medical Engineering who will send to the appropriate manufacturer for service/repair.

  - All accessories will be kept together with the endoscope.

  - All channels will be brushed and flushed according to endoscopes manufacturer instructions.

3.5 Automated wash/disinfection

- Endoscope and accessories will be placed in endoscope washer/disinfector (EWD).

- All channels will be connected for irrigation to the (EWD).

- If cycle is successful endoscope and probes will either be returned to the departments in appropriate packaging (green clean plastic cover and tray) in the trolley, vac packed in a blue case or placed in a storage cabinet.

- If the cycle fails the problem will be identified and the endoscope or probe either reprocessed or the machine checked by an engineer – whichever is appropriate. If the endoscope or probe is required for immediate use, the user will be informed.

- A traceability label will be issued with all processed endoscopes.

3.6 Storage

- Endoscopes to be protected from external contamination.
- Endoscopes are transferred from the CEDU in designated trolleys with hard trays and covered with sterile green clean plastic covers.
- Endoscopes are transferred from CEDU in vac packed hard cases.
- Traceability labels to be attached with endoscope and probe.
- Any non-conformity in testing will be communicated to the departments and agreed actions will be taken.
- Departments are responsible for daily check of storage cabinets and keeping the log book up to date.
- CEDU is responsible for maintenance, testing and validation (quarterly, annual).

3.7 Delivery

- Communication to the CEDU regarding daily endoscope requirements need to be sent on the previous day to ensure appropriate endoscopes are available for use.
- Storage cabinets in departments will be topped-up at the end of every day by CEDU staff according to the agreed stock levels of each endoscope or probe.

3.8 Tracking of endoscopes

3.8.1 All endoscopes and probes are to be tagged with a unique identifier in order to permit traceability to product history (i.e. to processes and patients). All valves and accessories will be retained with the endoscope.

3.8.2 Endoscopes and probes will be scanned on receipt into the CEDU and after processing.

3.8.3 Each endoscope and probe will be labelled with the date and time of processing in order to identify whether the scope is within the stated shelf-life and suitable for immediate use.

3.8.4 A record will be placed in the patient notes of the endoscope/probe used and confirmation of successful decontamination.

4. Communication

4.1 To ensure that departments have lines of communication with the Central Endoscope Decontamination Unit through direct phone contact and meetings where necessary to discuss any concerns.

4.2 To ensure service issues/incidents are raised and investigated/managed in a professional manner.

5. Contingency Arrangements

5.1 Cabinets

All cabinets should have UPS.

In the event that a cabinet is out of use, the endoscopes will be stored in a cabinet within another clinical unit or CEDU.

5.2 Washer/disinfectors

The CEDU has allowed sufficient throughput capacity to deal with the impact of one of its WD not being available for use i.e. due to repair/ maintenance. In the event that two WD not being available for use, the CEDU could extend its working hours.

5.3 Service Failure

In the event that the CEDU cannot run its machines due to a service failure e.g. water, the CEDU Manager would immediately inform all relevant Clinical Departments in order that plans can be put in place to re-schedule patient procedures and seek off-site processing.

6. Service, repairs and replacement programme for endoscopes- Department's responsibilities

6.1 Ensuring agreement is in place with Medical Engineering for service, maintenance and repairs of all endoscopes.

6.2 Ensuring replacement programme is in place to plan for replacement endoscopes.

6.3 Ensuring bid for capital investment in case of growth and expansion of services.

Appendix A

Tracking & Tracing Form for Endoscopes / Probes Without Channels

Date.....

Time.....

Department. .....

Patient ID Label

Please print and circle details clearly and include contact details

***Is this patient known to have any significant infections? e.g. blood borne / resp / gastro etc. YES/NO**

***Is this patient on the "at risk" for public health purposes list for vCJD? YES/NO**

Person Using the Endoscope/ TOE Probe**:** ……..……..Contact No……..

User Post Cleaning immediately following Use:

Person Post Cleaning the Endoscope/ TOE Probe: Print name: .....

Type of Endoscope / Probe..........**Serial Number**.....

- Insertion tube wiped **YES/NO**
- Control head / Eye piece wiped **YES/NO**

Endoscope Damage

Endoscope Decontamination Unit Manual Cleaning Checks

Date …… Time …… Serial No. ……..

- Patient tracking form completed **YES/NO**
- Cleaning post procedure carried out **YES/NO**
- Leak Test carried out for 30 seconds **YES/NO**

EWD 1 2 3 4 5 6 JetAER Fail Time …….

EWD 1 2 3 4 5 6 JetAER Pass Time …….

Decontamination Technicians Signature ……

IMPORTANT If this form is not returned with the correct information completed and the scope / probe has not been pre cleaned, the Decontamination staff will not accept the scope and return to the user

Tracking & Tracing Form For Endoscope's With Channels

Date.....

Time.....

Department. .....

Patient ID Label

Please print and circle details clearly and include contact details

***Is this patient known to have any significant infections? e.g. blood borne / resp / gastro etc. YES/NO**

***Is this patient on the "at risk" for public health purposes list for vCJD? YES/NO**

Person Using the Endoscope**:** ……..Contact No…….....

User Post Cleaning Immediately Following Use (Post cleaning method on reverse)

Person Post Cleaning the Endoscope: ……..... Print Name…….....

Type of Endoscope..... **Serial Number**.....

- Insertion tube wiped **YES/NO**
- Channels flushed with 500ml bedside detergent kit **YES/NO**
- Time Channels flushed with detergent

……

Endoscope Damage

Endoscope Decontamination Unit Manual Cleaning Checks

Date …… Time …… Serial No. ……

- Patient tracking form completed by user **YES/NO**
- Pre cleaning post procedure carried out by user **YES/NO**
- Leak Test carried out for 30 seconds **YES/NO**

EWD 1 2 3 4 5 6 JetAER Fail Time …….

EWD 1 2 3 4 5 6 JetAER Pass Time …….

Decontamination Technicians Signature ……

IMPORTANT If this form is not returned with the correct information completed and the scope / probe has not been pre cleaned, the Decontamination staff will not accept the scope and return to the user

OLYMPUS ENDOSCOPE PRE CLEANING PROCEDURE

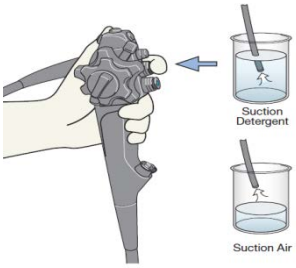
Introduction

The pre cleaning procedure is an essential stage in the decontamination process. During this stage the readily detachable proteinaceous material is removed before it has chance to dry and/or adhere to the internal and external surfaces of the endoscope.

2 Method

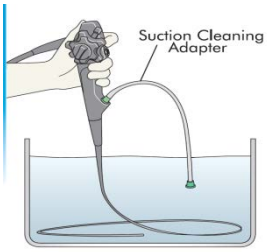
1. With the endoscope still attached to the light source, water bottle and suction pump, wipe down the insertion tube with a detergent soaked lint free cloth (single use).

2.



Depress the suction valve and aspirate freshly prepared detergent solution through the suction channel for 30 seconds followed by air for 10 seconds.

3.



Attach the suction cleaning adaptor to the biopsy port and aspirate freshly prepared detergent into the suction channel for 30 seconds followed by air for 10 seconds.

4.

Replace the air/water valve with the air water cleaning adaptor. Depress the valve to flush water through the air water channel for 30 seconds

5. If the endoscope has an elevator wire or auxiliary channel attach the appropriate adaptor and syringe detergent down these channels.

6. Remove the biopsy port cap and discard.

7. Attach the water resistant cap.

8. Place the endoscope and reusable valves into a lined tray with a red cover

9. **Endoscopy Unit** Place the endoscope tray into the hatch to the dirty side of CEDU. Notify the CEDU staff that an endoscope is in the hatch using the bell system.

10 **Theatres and In-patient Endoscopy** If the endoscope is required again during a patient list, staff from the area where the endoscope is used should take the endoscope to the receiving area of CEDU. Alternatively, place in the "dirty" endoscope trolley which will be collected by CEDU staff at designated times of the day.

11. **Vac Packed Endoscopes - Theatres and Critical Care Units** Place the endoscope on the tray with all accessories in the red bag. Place the red bag inside the vac-a-scope case and close. Secure the case with the red tie and label identifying that the endoscope has been used and return to the CEDU for reprocessing.