

## **NHSScotland**

# **Endoscope Decontamination Documentation System (EDDS):**

Decontamination Policy  
for flexible thermolabile endoscopes  
PRO 179-1

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#### Disclaimer

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# 1. Introduction

Endoscopy is an important medical procedure carried out using thermolabile flexible endoscopes which enable clinicians observe the inside of the body. An endoscope is a flexible tube with a lens and connects to a video processor at the other end. Flexible thermolabile endoscopes have a varying number of internal channels or none at all (non lumen).

The endoscope can be used as a diagnostic tool or as a therapeutic tool. This treatment can be undertaken in numerous areas of the body. A large range of endoscopes are used across a range of specialities as shown in Figure 1. These are processed to a high level disinfected (HLD) state or a sterile state depending on use as shown in Figures 1 and 2. Decontamination of rigid endoscopes that can be processed in porous load sterilizers are not covered in this guidance.

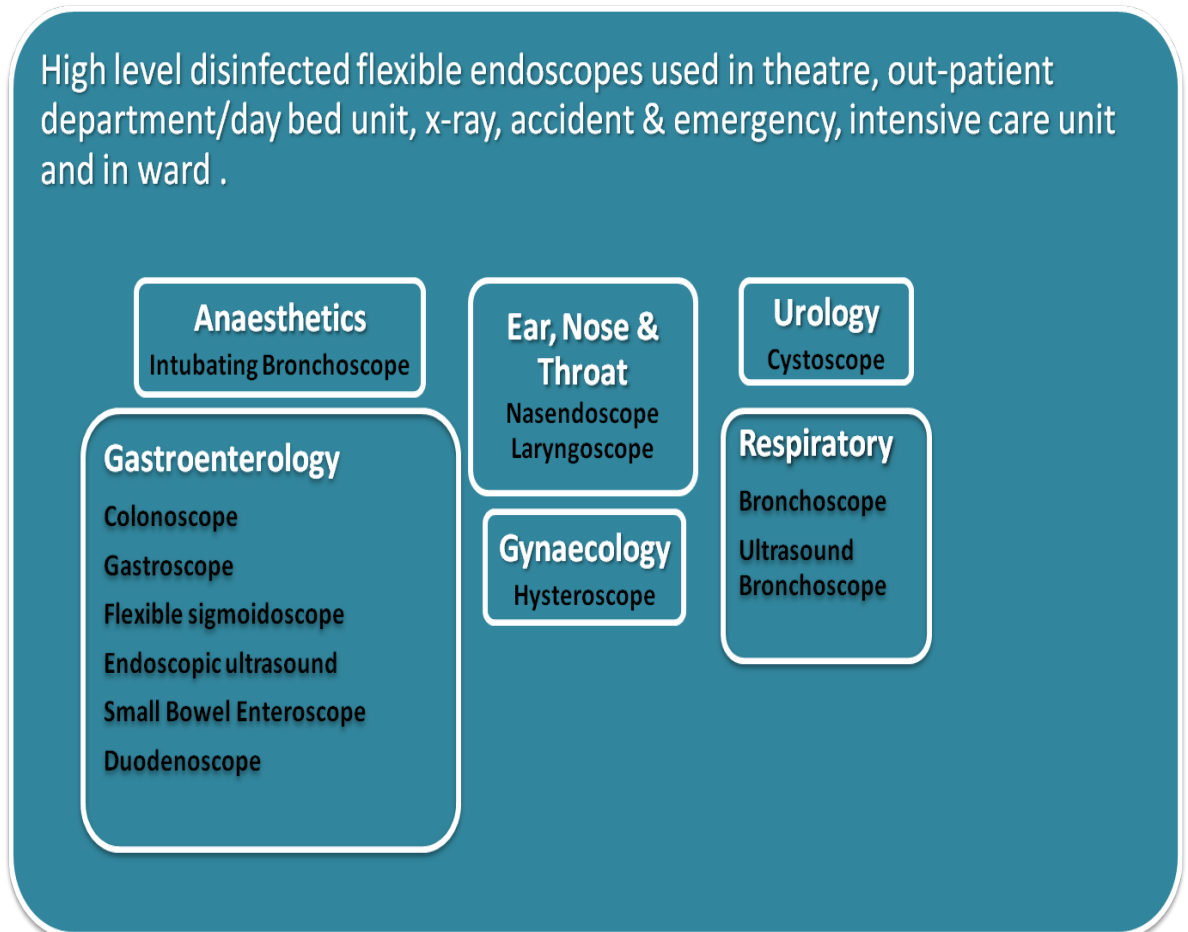


Figure 1: Flexible thermolabile endoscopes requiring high level disinfection

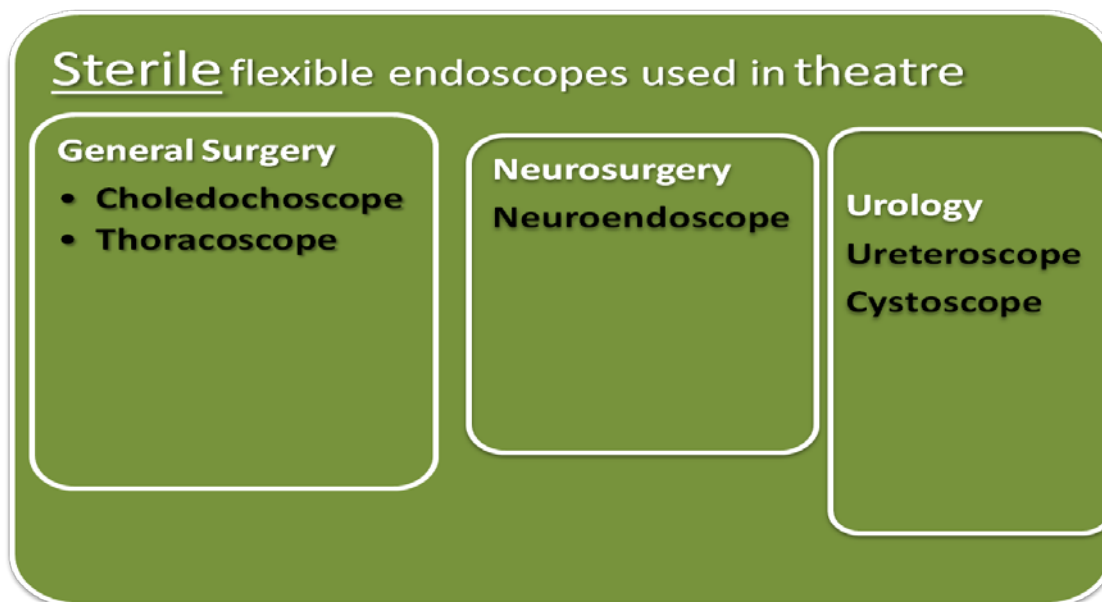


Figure 2: Flexible the rmolabile endoscopes requiring sterilization

Endoscopes are used in a variety of clinical settings and procedures within acute and community healthcare as shown in Figure 3. The initial endoscope cleaning process in any given clinical area will be the same for a given endoscope but the local facilities and staff will vary across the four areas comprising of theatre, day bed unit, X-Ray and patient in ward.

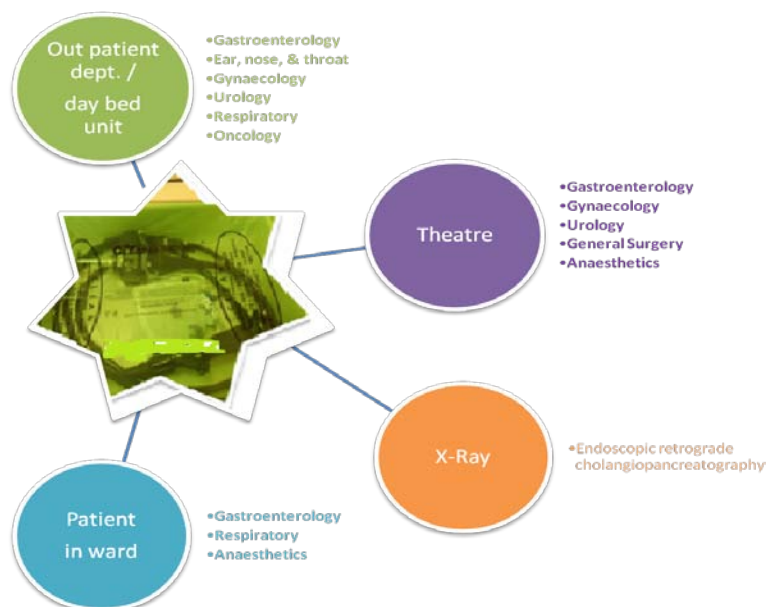


Figure 3: Clinical locations where endoscopes are used

## 2 Background

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- 2.1 In 2013 Healthcare Improvement Scotland published a national overview of Endoscopy Services. The report highlighted issues relating to the lack of standard operating procedures or local decontamination policies and staff training needs. It identified that some units did not have enough equipment to meet demand which meant that, in some cases, basic decontamination steps were omitted to ensure scopes were available for the next patient. It stated that systems for endoscope traceability seemed particularly variable and would require simplification and consistent implementation. The report further stated that it is essential that endoscopy units have safe and effective high level disinfection (HLD) in line with national standards and clear separation of clean and dirty equipment.
- 2.2 In May 2014 the HAI National Advisory Group approved the HFS publication: 'Requirements for Compliant Endoscope Decontamination Units 2014'. This established national compliance requirements for facilities, equipment, management and process in Endoscope Decontamination Units, in order that safe and effective decontamination practice is followed. One requirement identified in its management section, was the need for decontamination policy, procedures and records and that the Endoscope Decontamination Documentation System (EDDS), planned for development, would meet this need. Production of EDDS was government funded via the Scottish Antimicrobial Resistance and Healthcare Associated Infection (SARHAI) group.

### 3. Purpose and scope

- 3.1 This policy document establishes a document system for decontamination of endoscopes known as the Endoscope Decontamination Document System (EDDS). This is a set of generic documents that may be used in Endoscope Decontamination Units (EDUs) within NHSScotland. The set will comprise of a decontamination policy, a set of decontamination procedures and their associated record forms. These are intended to assist Health Boards to manage and operate compliant EDUs to provide a timely supply of safe, reliable and effectively decontaminated endoscopes.
- 3.2 The documentation system comprises of this decontamination policy document and a set of procedures covering the management of the flexible endoscope decontamination lifecycle including:
- decontamination facilities;
  - acquisition of endoscopes and decontamination equipment;
  - decontamination stages including leak testing, manual cleaning, automated cleaning & disinfection and storage of endoscopes;
  - decontamination equipment testing and maintenance;
  - endoscope repair;
  - endoscope traceability;
  - disposal of endoscopes.
- 3.3 Within the scope of EDDS: Flexible thermolabile endoscopes (both with and without lumens). Outwith the scope of EDDS: Decontamination of rigid endoscopes that can be processed through porous load sterilizers in Central Decontamination Units.
- 3.4 Figure 4 shows a flexible endoscope processing flowchart. The process (Figure 4) reveals the variable routes and presentations of the flexible endoscopes on return to the clinical setting for their next use. Depending on the clinical need the endoscope presentations include an endoscope within: a transport tray covered with a liner; a storage cabinet; a bag; a vacuum pack or within a sterile pack.
- 3.5 A large range of equipment may be employed when processing an endoscope to be ready for the next patient. Figure 5 gives an outline of the possible equipment. The endoscope type and its storage period requirements will influence the equipment required for satisfactory decontamination and its presentation fit for next use. Requirements for connection of individual circuits and items of equipment to uninterruptible power supply (UPS) and/or standby generation systems should be considered. Refer to SHPN 13 Part 3: 2010 section Emergency Electrical Supplies.

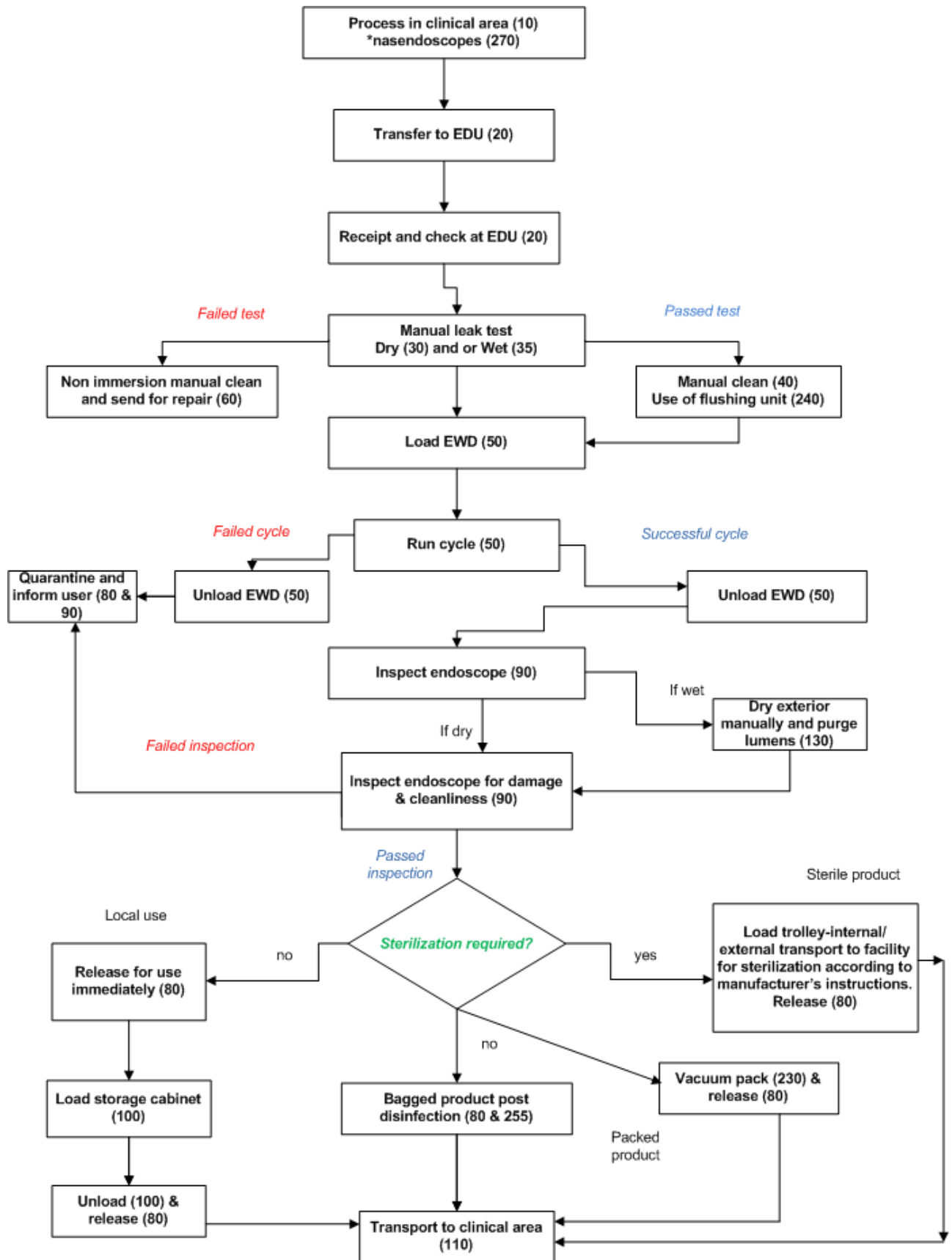


Figure 4: flexible endoscope decontamination process flow - \*(interim solution for nasendoscopes) – Note the numbers in brackets in the flow chart are the SOP reference numbers.

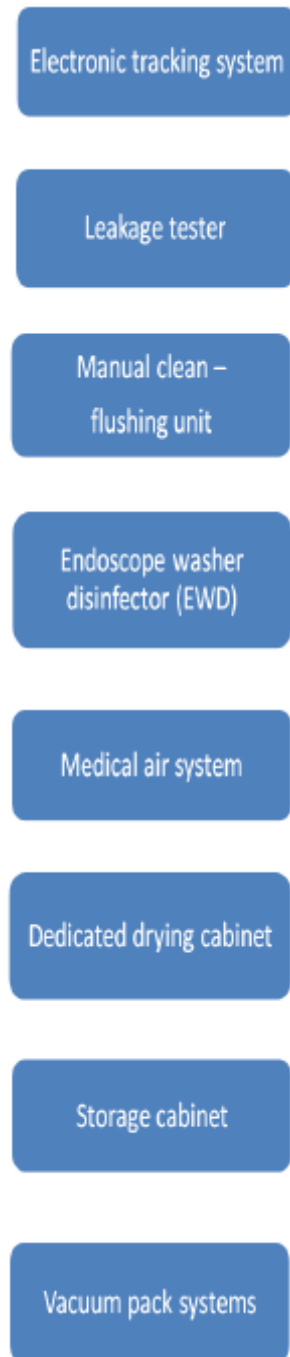


Figure 5: Range of equipment that may be employed in processing flexible endoscopes for next patient use (refer to section 3.5)



## 4. Operational Policies

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### Decontamination process for the flexible endoscope and its accessories

- 4.1 Flexible endoscope decontamination should be a controlled process (see Figure.4), carried out after each clinical procedure using a validated method in accordance with the endoscope manufacturer's instructions. The process should be inclusive of national guidance and ACDP guidance on CJD/vCJD for patients at risk.
- 4.2 Flexible endoscopes should be handled with care at all times throughout the decontamination process (as detailed in Figure 4).
- 4.3 The endoscope and the decontamination equipment manufacturer's instructions for processing are to be followed and consulted to ensure they are compatible with these operational policies.
- 4.4 A master list of flexible endoscopes and their accessories detailing their specific decontamination requirements should be generated, maintained and followed. This should consider both lumen and non-lumen endoscopes. (Refer to PRO 179-210). The requirement for high level disinfection or sterilization of the endoscope should be defined in the master list. Ensure that endoscopes with elevator wire channels such as duodenoscopes used in ERCP procedures are manually cleaned appropriately (Refer to PRO 179-240). It is noted that some endoscopes such as cystoscopes may be require to be high level disinfected in some clinical procedures and sterile when introduced through skin. Those endoscopes to be high level disinfected should be processed through an endoscope washer disinfectant. It is recognised that in the case of nasendoscopes requiring high level disinfection this may be carried out on an interim basis through the use of a validated manual multi wipe system. (Refer to PRO 179-270) A plan should be in place to move these nasendoscopes to processing through an endoscope washer disinfectant.
- 4.5 Endoscopes exposed to the clinical environment (i.e. connected to the stacking unit) should be returned to the EDU for processing if the patient procedure is stopped prior to using the endoscope.
- 4.6 Standard Infection Control Precautions (SICPs) should be followed throughout the endoscope decontamination process. (Refer to National Infection Prevention and Control Manual with regard to hand hygiene and PPE)
- 4.7 In line with the endoscope manufacturers' instructions an initial clean of the endoscope should be carried out immediately after use, in the clinical area, prior to transfer to the Endoscope Decontamination Unit (EDU). (Refer to PRO 179-10) This activity should address the removal of gross contamination from the external surface and flushing of all channels as applicable.

- 4.8 All used endoscopes and their associated valves must be transported safely and together as a set as soon as practicably possible from the clinical area to the EDU (refer to PRO 179-20). Container labels should indicate that the contents are contaminated. For circumstances where there is a delay in returning a used endoscope to the EDU a procedure should be in place.
- 4.9 Contaminated endoscopes should not be stored and or transported in the same trolley as clean processed endoscopes.
- 4.10 A manufacturer specified leak test of the endoscope (refer to PRO 179-30 for Wet leakage test and PRO 179-35 for Dry leakage test) should be carried out prior to manual wash. A visual inspection for damage of the endoscope should be carried out in conjunction with the leak tests.
- 4.11 Manual cleaning of the endoscope (refer to PRO 179-40) should be carried out prior to processing in an endoscope washer disinfector (EWD). Flushing units, as an alternative to the use of syringes, may be used to assist in the manual cleaning of endoscopes (refer to PRO 179-240) provided their use is in line with the endoscope manufacturer's instructions.
- 4.12 Automated cleaning and disinfection should be carried out in a validated EWD (refer to PRO 179-50) in line with the requirements of SHTM 2030 and EN ISO 15883-1, 4 (see reference section).
- 4.13 Endoscopes should be inspected (Refer to PRO 179-90) and dried (Refer to PRO 179-130) if required after completion of a satisfactory EWD cycle.
- 4.14 The release criteria (refer to PRO 179-80) for an endoscope should be met before it is released for immediate use on the next patient or stored.
- 4.15 Verification of endoscope functionality and confirmation of fitness for purpose is determined by clinical staff when the endoscope is connected to a video processor before use on the patient.
- 4.16 The endoscope storage time for any given make of storage cabinet should be validated. Cleaned and disinfected endoscopes removed from storage cabinets (refer to PRO 179-100) should be inspected before use on the patient.
- 4.17 Vacuum packed (refer to PRO 179-230) or bagged disinfected endoscopes (refer to PRO 179-255) should have the integrity of the packaging checked before leaving the EDU and when checked into and removed from clinical stores prior to use on the patient. The product label details should be confirmed as satisfactory prior to release from the EDU.
- 4.18 Cleaned and disinfected endoscopes must be transported safely from the EDU to the clinical area (refer to PRO 179-110) in a manner which protects them from damage or contamination. Container labels should indicate that the contents are clean and disinfected.
- 4.19 Clean processed endoscopes should not be stored and or transported in the same trolley as contaminated endoscopes.

- 4.20 The shelf life specified for endoscopes in a packaging system should be defined and validated. A procedure should be available in the clinical area to inspect the expiry date of packaged endoscopes to ensure they are not used after their validated storage time.
- 4.21 A system allowing the tracking and tracing of each endoscope passing through all stages of the decontamination process (inclusive of decontamination equipment, staff and service users) should be in place. Tracking of endoscopes to the patients on whom they are used is a requirement (NHS MEL (1999)65).
- 4.22 A procedure should be in place for managing endoscopes being sent for repair or servicing and return of the endoscope back into service (refer to PRO 179-60).

### Quality Management System

- 4.23 EDU Management should ensure that the operation and control of the decontamination procedures are effective. The necessary resources and information should be available to support the decontamination process and meet current and future demand. Records should be maintained to demonstrate the decontamination process is in control and effective. Effective staff communications should be in place.
- 4.24 An annual management review should be conducted. This should ensure that the decontamination procedures, equipment, facilities and staff in place are adequate and effective. Future service needs should also be addressed (refer to PRO 179-180).
- 4.25 Ensure procedures for handling complaints from services users, (PRO 179-190) managing non conformances, (PRO 179-200) and undertaking an internal audit program are in place. (PRO 179-220).
- 4.26 Where processed endoscopes are supplied by the EDU to other legal entities the quality management system in use should be accredited to the standard EN 13485: 2016 by a notified body.
- 4.27 Consideration must be given to the security of endoscopes throughout the decontamination process and during transport and storage.

### Acquisition

- 4.28 Acquisition of endoscopes (including loan endoscopes), endoscope decontamination equipment, accessories and consumables should be carried out in line with national procurement requirements (PRO 179-120). Ensure any new endoscope is compatible with the existing EDU decontamination process and equipment.

### Health and Safety

- 4.29 Health & Safety legislation should be followed (See References section “Acts and Regulations”).

## Staff protection

- 4.30 The type and nature of the personal protective equipment (PPE) for the ‘dirty’ processes of the EDU should be specified based on a COSHH and Infection control risk assessment for the area (see 4.6).

## Education and training

- 4.31 All staff working within the EDU require initial and regular ongoing training and an approved competency assessment. The documented training scheme requires training records for each individual are kept, identifying that staff have the required competency to carry out their assigned duties, and to support cross-site working, if required. A skills register should be maintained. All staff processing endoscopes should have their roles and responsibilities clearly defined. Consult the 2016 NES publication titled “Framework to support staff development in decontamination of reusable medical devices”.

## Decontamination Equipment

- 4.32 All decontamination equipment in use should be operated, tested and maintained as per the manufacturer’s instructions and should be subjected to a defined test/maintenance programme with associated records. National guidance “Requirements for compliant Endoscope Decontamination Units” published by HFS 2014 specifies requirements for decontamination equipment and should be considered. Decontamination equipment (see 3.5) may include as applicable:

- endoscope wet leak tester (PRO 179-30);
- endoscope dry leak tester (PRO 179-35);
- manual clean flushing unit (PRO 179-240);
- Endoscope Washer Disinfector (EWD), Storage cabinet and tracking system. (refer to PRO 179-70, PRO 179-140 & PRO 179-150);
- Medical air system (PRO 179-130);
- Vacuum pack systems (PRO 179-230).

HFS has published an EWD logbook containing a range of record forms. The logbook is available on the HFS website.

<http://www.hfs.scot.nhs.uk/publications-/reports-and-information/>

## Facilities and workflow

- 4.33 The Endoscope Decontamination Unit (EDU) should be built or upgraded in line with the planning note SHPN13 Part 3. The EDU layout should have organisational workflow with dirty and disinfected product segregation (linear flow). There should be secure and restricted access to the EDU and its associated equipment for authorised staff. Site visitors should be supervised at all times.

- 4.34 There should be suitable facilities for cleaning all surfaces of the transit containers and trolleys between each use. A procedure for cleaning the EDU should be in place and records of cleaning maintained.
- 4.35 High standards of cleanliness are required throughout the EDU. Dedicated and appropriate cleaning equipment and materials should be available for the EDU. The NHSScotland National Cleaning Services Specification should be followed and cleanliness of the EDU audited.

#### Waste disposal

- 4.36 The arrangements for handling and storage of waste should be in line with SHTN3. Follow the ACDP guidance on disposal of endoscope used on patients with CJD/vCJD.

#### Materials procurement and storage

- 4.37 Only materials used in the EDU and those items that are to be processed should be stored or passed through the EDU. Materials and items should be stored in a way that allows appropriate cleaning of the area, and does not compromise the decontamination process in the EDU.

#### Adverse incident reporting

- 4.38 All NHS Boards are required to have suitable arrangements in place for the safe provision and use of RMDs as CEL 43 (2009) and its addendum. Report adverse incidents by completing the forms which can be found on the Incident Reporting and Investigation Centre (IRIC) website: <http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/how-to-report-an-adverse-incident/>

## References

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These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current versions of any references.

### Acts and Regulations

**Consumer Protection Act 1987**, HMSO.

**Control of Substances Hazardous to Health Regulations 2002**, SI 1999 No 2677, HMSO.

**Electrical Equipment (Safety) Regulations 1994**. SI 1994 No 3260, HMSO,

**(The) Fire Precautions (workplace) Regulations 1999**, HMSO

**Health & Safety at Work etc Act 1974**, HMSO.

**(The) Management of Health and Safety at Work Regulations 1999**, SI 1999 No. 2051, HMSO.

**(The) Medical Devices Regulations 2002**, SI 2002 No 3017, HMSO.

**Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR 95)**. SI 1995 No 3163, HMSO.

**(The) Workplace (Health, Safety and Welfare) Regulations 1992**, SI 1992 No 3004, HMSO.

### European/ International Standards

**EN ISO 15883-1:2014** Washer-disinfectors. General requirements, terms and definitions and tests. CEN

**EN ISO 15883-4:2009** Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes. CEN

**CEN ISO / TS 15883-5:2005** Washer-disinfectors. Part 5 Test soils and methods for demonstrating cleaning efficacy. CEN

**EN ISO 16442:2015** Controlled environment storage cabinet for processed thermolabile endoscopes. CEN

**EN 61010-1:2001, IEC 61010-1:2001** Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements.

## Consultation European/ International Standards

**EN 15883-4: 2016 consultation expired July 2016** Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

**EN 17664: 2016 consultation expired June 2016** Processing of health care products – information to be provided by the medical device manufacturer for the processing of medical devices.

## Health Facilities Scotland publications

**Requirements for Compliant Endoscope Decontamination Units.** Health Facilities Scotland 2014.

**SHTM 2010:** Sterilization, Health Facilities Scotland, 2001.

**SHTM 2030:** Washer Disinfectors, Health Facilities Scotland, 2001.

**SHPN 13 Part 3** Decontamination Facilities: Endoscope Decontamination Units. Health Facilities Scotland, 2010.

**SHPN 52** Accommodation for day care – Part 2 - Endoscopy unit. Health Facilities Scotland (formerly NHS Scotland, Property & Environment Forum), 2002.

**SHFN 30:** Infection Control in the Built Environment, Health Facilities Scotland, 2007.

**SHTN 3** Management and disposal of clinical waste, Health Facilities Scotland, 2002.

**Endoscope Washer Disinfector Logbook** HFS 2012

**National Cleaning Services Specification.** Health Facilities Scotland 2014.

**Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices, 2013.** Health Facilities Scotland. [www.hfs.scot.nhs.uk/](http://www.hfs.scot.nhs.uk/)

## EDDS Documents – National Services Scotland 2016

**PRO 179-10-Initial clean in clinical area**

**PRO 179-20-Return to EDU from clinical area**

**PRO 179-30-Wet leakage test**

**PRO 179-35-Dry leakage test**

**PRO 179-40-Manual clean of endoscope & accessories**

**PRO 179-50- Load/operate/unload EWD**

**PRO 179-60-Endoscopes for repair and servicing**

**PRO 179-70-Periodic testing and maintenance of decontamination equipment**

**PRO 179-80-Endoscope product release**

**PRO 179-90-Inspection of endoscopes**

**PRO 179-100-Storage of endoscopes in an endoscope storage cabinet**

**PRO 179-110-Transport of endoscopes to clinical area**

**PRO 179-120- Acquisition of endoscopes, endoscope decontamination equipment and accessories**

**PRO 179-130- Manual drying of endoscopes**

**PRO 179-140-Daily EWD tests**

**PRO 179-150-Daily & weekly tests of an endoscope storage cabinet**

**PRO 179-180 Annual management review**

**PRO 179-190 Management of internal and external complaints**

**PRO 179-200 Management of non conformances in the decontamination process**

**PRO 179-210 Identifying methods/conditions for processing endoscopes**

**PRO 179-220 Internal audit**

**PRO-179-230 Vacuum packing of processed endoscopes**

**PRO-179-240 Use of flushing units to assist in manual cleaning**

**PRO-179-255 Preparation of processed endoscopes packed in a sterile bag or pouch**

**PRO-179-270 Decontamination of nasendoscopes: using a manual (chlorine dioxide) multi-wipe system.**

## **Health Protection Scotland publications**

**Health Protection Scotland. Endoscope Reprocessing:** Guidance on the Requirements for Decontamination Equipment, Facilities and Management, Dec 2004. [www.hps.scot.nhs.uk/](http://www.hps.scot.nhs.uk/)

**National Infection Prevention and Control Manual 2016.** Health Protection Scotland. [www.nipcm.hps.scot.nhs.uk/](http://www.nipcm.hps.scot.nhs.uk/)



## Other publications

**A look inside Scotland's Endoscopy Services – National Overview** March 2013 published by Healthcare Improvement Scotland

**Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex F** by Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup 2015.

[www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/470292/ACDP\\_TSE\\_Annex\\_F\\_Oct\\_2015.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470292/ACDP_TSE_Annex_F_Oct_2015.pdf)

# Endoscope Decontamination Documentation System (EDDS)

Document title	Doc reference no.
<b>Policy</b>	
Decontamination policy for flexible thermolabile endoscopes (attached)	PRO 179-1
<b>Standard Operating procedures (SOPs)</b>	
Initial endoscope cleaning process in the clinical area	<a href="#">PRO 179-10</a>
Return of contaminated endoscopes to the Endoscope Decontamination Unit	<a href="#">PRO 179-20</a>
Endoscope wet leak test & maintenance of the leak tester	<a href="#">PRO 179-30</a>
Endoscope dry leak test and maintenance of the leak tester	<a href="#">PRO 179-35</a>
Manual cleaning of the endoscopes	<a href="#">PRO 179-40</a>
Automated processing in an Endoscope Washer Disinfector	<a href="#">PRO 179-50</a>
Endoscopes for repair and service	<a href="#">PRO 179-60</a>
Periodic testing and maintenance of decontamination equipment	<a href="#">PRO 179-70</a>
Endoscope product release	<a href="#">PRO 179-80</a>
Inspection of endoscopes	<a href="#">PRO 179-90</a>
Storage of endoscopes in Endoscope Storage Cabinets	<a href="#">PRO 179-100</a>
Transport of processed endoscopes to the clinical area	<a href="#">PRO 179-110</a>
Acquisition of endoscopes, decontamination equipment and accessories	<a href="#">PRO 179-120</a>
Manual drying of endoscopes	<a href="#">PRO 179-130</a>
Daily Endoscope Washer Disinfector tests	<a href="#">PRO 179-140</a>
Daily and weekly tests of an Endoscope Storage Cabinet	<a href="#">PRO 179-150</a>
Annual management review	<a href="#">PRO 179-180</a>
Management of internal and external complaints	<a href="#">PRO 179-190</a>
Management of non-conformances in the decontamination process	<a href="#">PRO 179-200</a>
Identifying the method/conditions for processing of endoscopes	<a href="#">PRO 179-210</a>
Internal audit	<a href="#">PRO 179-220</a>
Vacuum packing of processed endoscopes	<a href="#">PRO 179-230</a>
Use of flushing units to assist in manual cleaning	<a href="#">PRO 179-240</a>
Preparation of processed endoscopes for storage in a sterile bag or pouch	<a href="#">PRO 179-255</a>
Decontamination of nasendoscopes: using a (chlorine dioxide) multi-wipe system	<a href="#">PRO 179-270</a>
<b>Record Forms</b>	
Master list of endoscope decontamination method/conditions	<a href="#">PRO 179-500R</a>
Complaints record	<a href="#">PRO 179-510R</a>
Endoscope repair log	<a href="#">PRO 179-515R</a>
Non conformance record	<a href="#">PRO 179-520R</a>
Master list of equipment - testing and maintenance programme	<a href="#">PRO 179-530R</a>
Tracking log sheet	<a href="#">PRO 179-550R</a>
Endoscope Storage Cabinet daily and weekly tests	<a href="#">PRO 179-590R</a>