Health Facilities Scotland

NHS National Services Scotland

Scottish Health Technical Memorandum 01-06

Decontamination of flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units Part C: Dry and wet leak testers, and manual clean flushing unit equipment

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Contents

1. Introduction

1.1 This part of the guidance series covers the use, validation, testing and maintenance of the following items of decontamination equipment that may be used in the Endoscope Decontamination Unit (EDU):

- Dry leak tester;
- Wet leak tester;
- Manual clean flushing unit.

At the time of publication there were no national or international standards on the technical requirements for these items. This guidance establishes requirements. Manufacturer's instructions for use should be followed.

Note 1.1: Wet and dry leak testers and manual clean flushing units are not used in the decontamination of TOE ultrasound probes.

1.2 Decontamination equipment should be subjected to a defined test/maintenance programme with associated records as per GUID 5013 - Requirements for compliant Endoscope Decontamination Units v2, 2014.

Note 1.2: Where the manual clean flushing unit is used, this must be followed by processing the endoscope through a validated endoscope washer disinfector (refer to SHTM 01-06 Part D).

1.3 The NHSScotland Endoscope Decontamination Documentation System (EDDS) was published by National Services Scotland in 2017. EDDS includes a Decontamination Policy for flexible thermolabile endoscopes and Standard Operational Procedures (SOPs) for the endoscope decontamination process. EDDS also includes specific SOPs on the wet leak tester (SOP reference in EDDS PRO 179-30), the dry leak tester (EDDS SOP reference PRO 179-35), and manual clean flushing unit (EDDS SOP reference PRO 179-240).

Note 1.3: A process should be in place to inform EDU staff when any damage or reduced functionality is identified by clinical staff during use, or when carrying out the initial cleaning of the endoscope. This will help prevent additional damage to the endoscope and allow investigation of the issue by EDU staff.

1.4 On arrival at the EDU the endoscope should be inspected for damage, including undertaking a leak test (using either a dry or wet leak tester as instructed by the endoscope manufacturer). This should determine if the endoscope has sustained damage that could allow liquid to access the inner working parts of the endoscope during later stages of the decontamination process posing an infection risk and loss of functionality.

1.5 During the manual cleaning stages of the decontamination process, single use cleaning brushes as recommended by the endoscope manufacturer must still be used prior to rinsing internal channels of the endoscope. Because of a recognised risk of staff developing injury due to repetitive tasks, manual clean flushing units have

been introduced to manual rinsing prior to processing in an Endoscope Washer Disinfector.

1.6 Planning note guidance SHPN 13 Part 3: 2010 specifies that wet leak testing is carried out at a dedicated test sink in the Wash Room of the Endoscope Decontamination Unit. Where required, a manual clean flushing unit to assist in the manual clean should be located between the wash and rinsing sinks.

1.7 Consult SHTM 01-06 Part A for guidance on Standard Infection Control Precautions in the National Infection Prevention and Control manual: 2022, repair, refurbishment and quarantine and disposal of endoscopes. Information on the ‘Permit-to-work’ system is included in SHTM 01-06 Part B.

2. Specification of the equipment

2.1 Several types of dry and wet leak testers and manual clean flushing units are available on the market. These may be single function or in other cases multifunction, e.g., the ability to carry out a wet leak test and manual clean flushing. Some manual clean flushing units may have additional capabilities. Therefore, it is essential that the purchase of an item of decontamination equipment is planned correctly in order that the Users' pre-defined requirements are met.

2.2 Some manual clean flushing units may have variable flushing times, programmable according to the challenge presented by different types of endoscopes, e.g., a narrow elevator guide channel in duodenoscopes. Where the manual clean flushing unit has a range of programmable functions the ‘User’ or manager should have access to amend the programme selection and the stages of the process where it is used.

2.3 A detailed specification should be compiled prior to purchase and include all essential requirements as discussed in the general requirements section of SHTM 01-06-part B and the equipment specific requirements below. Further guidance on acquisition is provided in SHTM 01-06 Part A and in the SHTN 00-04 Management of medical devices and equipment in Scotland’s Health and Social Care Services 2021.

2.4 Ensure that the manual clean flushing unit manufacturer can provide a validated method for the decontamination of any accessories e.g., reusable tubing and connectors supplied with the equipment (BS EN ISO 17664-1: 2021 Processing of health care products).

2.5 Reusable tubing and connectors that connect endoscope channels should be protected from blockages by filters. The filter size to be used should be specified and agreed by both the manual clean flushing unit and endoscope manufacturers.

2.6 Manufacturers should provide certification to the purchaser that the equipment is designed and manufactured in conformity with all relevant standards, national guidance and regulations including but not restricted to:

- BS EN IEC 61010-1: 2010+A1: 2019;
- BS EN IEC 61326-1: 2021;
- BS EN 62304: 2006+A1: 2015;
- BS EN IEC 62366-1: 2015+A1: 2020;

Health and safety requirements

2.7 A risk assessment should be carried out (Health and Safety at Work Act 1974) to identify equipment and activities that could pose a hazard to staff and ensure suitable precautions are considered, including:

- engineering service provision;
- maximum and minimum operational temperatures;
- process chemical type and concentration;

- required pump pressure;
- water flow volume rate and pressure;
- water quality (chemical and microbial);
- ensure that electrically powered equipment located close to the sink is suitably installed to prevent it from falling into the sink;
- suitable eye protection for staff using pressurised systems;
- further guidance for health and safety risk assessments can be found in Parts A and B of this SHTM (01-06).

3. Dry leak testers and wet leak testers

Leak testing

3.1 There are two methods of leak testing. These make use of either a dry leak tester or a wet leak tester as specified by the endoscope manufacturer. Leak testers should be operated by staff trained and competent in the appropriate method of leak testing for the model of endoscope in use.

Note 3.1: Some endoscope manufacturers require that a dry leak test is carried out prior to a wet leak test. Where this is the case, the use of the dry leak tester should confirm a satisfactory test result before making use of the wet leak tester.

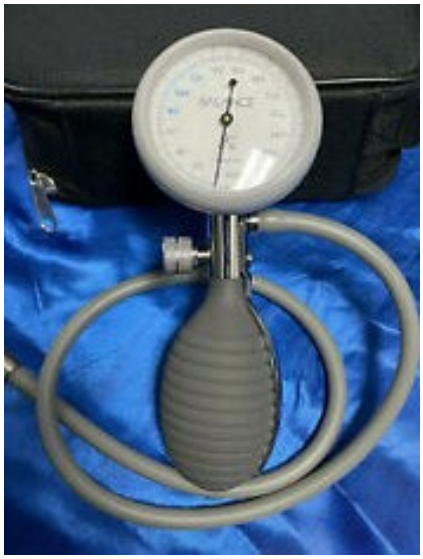
3.2 Prior to use of a leak tester ensure that:

- the unit has been validated for use with endoscope make and models decontaminated by EDU staff;
- the leak tester manufacturer has confirmation from the endoscope manufacturer it is suitable for use;
- that the range and duration of pressurisation of the endoscope does not exceed the pressures advised by the endoscope manufacturer;
- connectors provided for leak testing have been designed specifically for connection to the endoscope venting connector.

Dry leak testers

3.3 Where the endoscope manufacturer recommends the use of dry leak testers, these should be used prior to immersion of the endoscope in any cleaning fluid. An example of a manually operated dry leak tester is shown in image 3.1. Automated dry leak testers may also be available.

Image 3.1: Example of a manually operated dry leak tester



Dry leak tester operation

3.4 Follow the dry leak tester manufacturer's instructions for use. A typical example of its use would be:

- using the inflation bulb squeeze until the needle reaches the recommended level;
- If the needle stays in the advised position for the required time the test is satisfactory and it is safe to progress on to the next stage of the decontamination process;
- if the needle falls below the recommended level, a leak has been detected;
- if there is a leak:
  - open the valve on the dry leak tester;
  - wait to allow deflation of air from the endoscope;
  - disconnect the leak testing equipment;
  - repeat for confirmation of failure, if required;
  - undertake a non-immersion manual wash on the endoscope;
  - place the endoscope into a clean tray with lid;
  - label as not for use/for repair;
  - quarantine the endoscope to prevent it being used;
  - follow local policy for management of damaged endoscopes;
  - inform the manager if further action is required.

Maintenance of the dry leak tester

3.5 Wipe down the dry leak tester surface after each use with an approved detergent solution as described by the manufacturer's instructions. Periodically inspect for signs of damage or deterioration, including the bulb, connectors or the external tubing used with the connectors.

Note 3.2: If the endoscope requires repair by a service department or contractor a certified validated decontamination process will be required before the unit can be shipped.

Wet leak testers

3.6 Where the endoscope manufacturer's instructions for use requires the use of a wet leak tester, a visual inspection of the endoscope for damage should be carried out first. This will prevent any additional damage due to fluid entering the endoscope.

Wet leak testing method

3.7 The wet leak tester manufacturer's instructions for use should be followed. An example of a standard operating procedure is included below:

- remove the biopsy, suction and air/water valves from the endoscope and dispose of any single use items. If reusable valves are used place them in the wash sink;
- ensure the waterproof cap is secure and correctly located, as per manufacturer's instructions;
- fill the sink with water to the level indicator on the up-stand overflow tube or sink;
- connect the wet leak tester to the venting connector on the endoscopes waterproof cap;
- switch on the wet leak tester;
- place the distal end of the endoscope into the sink, move the hand controls to bend the distal end in all directions and observe for any bubbles in the water;
- gradually lower the endoscope into the water and continue to watch for leaks until the endoscope is fully immersed. If any continuous bubbling is detected, stop immersing the endoscope immediately. Bubbles emerging continuously at any section of the endoscope can indicate a leak;
- if no leak is observed;
  - switch off the leak tester, open the pin;
  - lift the endoscope connector and tubing out of the water;
  - wait 30 seconds to allow the endoscope to deflate;
  - disconnect the wet leak tester tubing from the venting connector of the endoscope and dry;
  - ensure the water proof cap is secure before placing the endoscope into the wash sink.
- if there is a leak;
  - remove the endoscope from test sink, re-test the endoscope if confirmation is necessary;
  - switch off the wet leak tester, open the pin;
  - wait 30 seconds to allow the endoscope to deflate;
  - disconnect the wet leak tester tubing from the endoscope venting connector and dry;
  - undertake a non-immersion manual wash of the endoscope;
  - place the endoscope into a cleaned endoscope tray with lid;
  - quarantine the endoscope to prevent it being used;
  - follow local process for management of damaged endoscopes;
  - complete the associated non-conformance record form (PRO-179-520R).

Maintenance of the wet leak tester

3.8 Maintenance of the wet leak tester should follow the manufacturer's instructions. This may include:

- a daily test for airflow and valve function;

- wiping down the unit surface with a detergent solution approved by the manufacturer at the start of the day and at the end of each endoscopy list;
- after each use clean and dry the unit cable and connector (do not allow the inside of the connector valve to become wet);
- periodically inspect for signs of damage or deterioration, including the connectors or the external tubing used with its connectors.

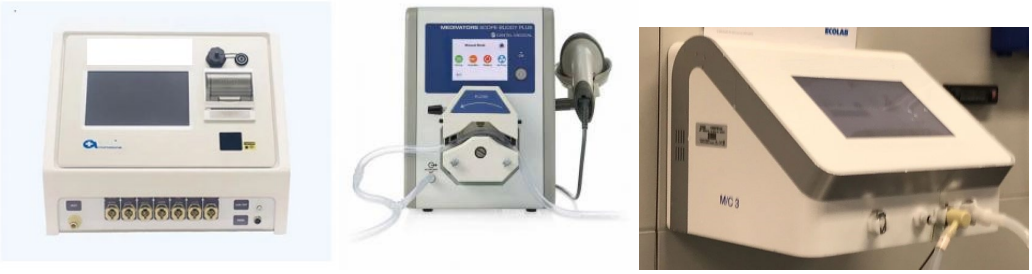
Note 3.3: If the endoscope requires repair by a service department or contractor a certified validated decontamination process will be required before the unit can be shipped.

4. Manual clean flushing units

Performance requirements

4.1 Manual clean flushing units may be used to assist in the manual cleaning of endoscopes, provided their use is in line with the endoscope manufacturer's instructions. They should only be used after initial manual cleaning of the endoscope (including brushing of any internal channels) and as an alternative to manual flushing using syringes. Examples of manual clean flushing units are shown in image 4.1.

Image 4.1: Examples of manual clean flushing units



4.2 The performance of a manual clean flushing unit depends on a number of external factors. Therefore, the manufacturer should specify any requirements for the operational variables the equipment could encounter during use, including:

- water quality;
- water flow rate and pressure;
- process chemicals pH, concentration etc. and flushing time;
- operational temperature for each stage;
- required run time for the manual clean process.

4.3 Process chemicals for use in the manual clean flushing unit should be:

- approved by the endoscope manufacturer intended purpose;
- compatible with the quality of water and other process chemical used;
- compatible with tubing and other components that contact solutions;
- non-abrasive;
- low foaming;
- effective;
- biocompatibility studies should be provided by the process chemical manufacturer;
- Control of Substances Hazardous to Health (COSHH) 2002 risk assessed for staff safety;
- removable (that is leaves no chemical residue).

Note 4.1: The use of open containers of chemical disinfectants is not advised as they can be toxic and irritant.

4.4 Connectors used to flush the detergent solution and rinse water 'Liquid in hose' should be fitted with a filter to prevent any particulates dislodged during flushing from re-entering the endoscope lumens.

4.5 Manual clean flushing units should be designed and constructed to allow all pipework to be drained and dried when not in use.

4.6 A method of decontaminating the manual clean flushing unit should be provided by the manufacturer. This should include a method of disinfecting each day, after maintenance, repairs, or testing.

4.7 Detergent residue can reduce the efficacy of chemical disinfectants. Effective rinsing of the manual clean flushing unit and its accessories is required before a self-disinfect cycle (whether chemical or thermal self-disinfection is employed).

4.8 Tubing used to flush detergent solutions into endoscope lumens cycle should have a validated method for self-disinfection. This should be carried out at the manufacturers' specified intervals. Thermal disinfection is the preferred method of disinfection.

Note 4.2: Detailed evidence of the effectiveness of this process should be provided for review prior to purchase and the lifetime of any required accessories stated.

Operation

The manual clean flushing unit manufacturers' instructions for use should be followed. A method of use below has been included as an example.

Method of use

4.9 Flush the endoscope using the manual clean flushing unit as follows:

- fill the wash sink with water to the level indicator on the up-stand overflow tube or sink;
- place the 'Liquid in hose' in potable water or detergent solution as required at each stage of the process. (A dedicated container of detergent solution should be used);
- connect the flushing unit liquid and or air out hose to the endoscope;
- operate the manual clean flushing unit as per the manufacturer's instructions;
- confirm that all accessible lumens (as specified by the endoscope manufacturer's instructions) have been flushed, paying special attention to any razor bridge components if present;
- drain excess liquid before transferring the endoscope to the next workstation, some manual clean flushing units may have a purge cycle for this purpose;
- rinse the endoscope and accessories with potable water;
- drain or purge the endoscope then place on the clean set down area;

- acknowledge each stage in the process and that all actions have been completed satisfactorily;
- complete the manual clean record and sign;
- enter operator ID and scope details into the tracking system;
- clean all sinks before reuse.

Note 4.3: Ensure that during all stages of the endoscope manual cleaning, process fluids flow freely though endoscope lumen(s).

Maintenance

4.10 The manual clean flushing units' manufacturers' instructions for use (IFU) concerning maintenance should be followed. A schedule for maintenance should be included in the IFU. A programme of Planned Preventative Maintenance (PPM) should be in place. Additional requirements for PPM can be found in part B of this SHTM (01-06). An example of a method is included below.

Method

4.11 Maintenance schedule activities should include:

- before each use visually inspect the manual clean flushing unit for signs of damage or deterioration including the connectors and the external tubing used with those connectors;
- after each use, wipe down the manual clean flushing unit surface and screen with the approved solution;
- carry out self-purging of the manual clean flushing unit daily;
- where required carry out self-disinfection of the manual clean flushing unit periodically using the chemical and self-disinfection cycle as defined by the manufacturer's instructions;
- carry out weekly self-testing of the manual clean flushing unit including any printer, air pump and liquid pump.

5. Validation/periodic testing of equipment

General principles

5.1 Dry and wet leak testers and manual clean flushing units should perform consistently and demonstrate that the equipment meets the original specifications. An overview of the requirements for qualification stages and periodic testing of all decontamination equipment is given in Part B of this SHTM (01-06).

5.2 Dry and wet leak testers and manual clean flushing units should perform consistently and demonstrate that the equipment meets the original specifications. The manufacturer should provide documented evidence that the equipment performs in accordance with criteria agreed by the User.

5.3 As some of the decontamination equipment may be electrically powered and located close to water, a Competent Person should carry out safety checks to confirm the equipment is safe for use. These checks should include:

- confirmation that the equipment location is satisfactory;
- that the equipment has been provided with the necessary services e.g. the correct waterproof electrical sockets are provided in line with the requirements of SHPN 13 part 3:2010.

5.4 When these checks have been completed and found satisfactory, carry out the validation qualification stages to demonstrate that the decontamination equipment is working satisfactorily. Any assistance required from the purchaser should be agreed as part of the purchase contract.

5.5 Documented procedures should be in place for validation of the decontamination equipment and process. This should include records of the results, for the predetermined test criteria and include:

- pressure;
- flow rate;
- chemical dosing (if applicable);
- traceability system where available (I.D. scanners and printers or IT connections).

Testing should have considered the worst-case scenarios in terms of challenge to the equipment/system being tested, e.g. where a blockage occurs in the endoscope lumen.

5.6 Test data results should be recorded in a written report that includes:

- confirmation that the calibration of all measuring instruments fitted to the machine have been verified;

- data showing the correlation between the performance of any measuring instruments fitted to the equipment and the test instruments used during testing;
- all data collected during the testing, with written confirmation from the CP(D) and the User that they meet the specified requirements;
- any independent monitoring system and validation instrument data, along with comments on any changes or adjustments made;
- conclusion of validation and necessary actions from the validation should be maintained.

Dry leak tester qualification

5.7 **Installation Qualification** – confirm that the equipment delivered is that ordered and that the components (aspirator bulb, tubing and pressure gauge) are visually intact and the pressure gauge has an associated valid calibration certificate. Assemble the dry leak tester following the manufacturer's instructions.

5.8 **Operational Qualification** – follow the manufacturers' instructions for operation of the dry leak tester. Acceptance criteria: Confirm the dry leak tester will hold pressure.

5.9 **Performance Qualification** – run the dry leak test with an endoscope attached. Repeat a further two tests. As a control, repeat a test with an endoscope or surrogate device known to leak. Acceptance criteria: verify that the dry leak tester detects a leak. There should be no pressure drop over the time recommended by the manufacturer for each test. Record the test results and confirm these to be satisfactory prior to putting the dry leak tester into service.

Wet leak tester qualification

5.10 **Installation Qualification** –the checks carried out by a competent person should confirm that the wet leak tester has been installed in a safe location and is safe for use.

5.11 **Operational Qualification** – follow the manufacturers' instructions for operation of the wet leak tester. Acceptance criteria: after connecting to the electrical supply the wet leak tester is switched on and the endoscope release valve tested to confirm air is flowing through the pump and tubing by depressing the central pin. The competent person should then connect a test piece to the leak tester.

5.12 **Performance Qualification** – operate the wet leak tester with an endoscope connected. Confirm the wet leak tester operates to the manufacturer's specification. Repeat a further two tests. The test piece should be observed to ensure the inflatable portion becomes pressurised within acceptable limits. As a control, repeat a test with a surrogate device known to leak. Acceptance criteria: verify this by the sight of bubbles escaping into the water. Record the test results and confirm these to be satisfactory prior to putting the wet leak tester into service.

Manual clean flushing unit checks

5.13 Manual clean flushing units are typically automated and controlled via Information Management Systems. Follow the manufacturer's instructions for use.

5.14 **Installation Qualification** – verify that the manual clean flushing unit has been installed safely. Acceptance criteria: the IQ checks carried out by a competent person confirm that the manual clean flushing unit has been installed in a safe location and is safe for use.

> **Note 5.1:** Where the manual clean flushing unit has additional functionality such as a leak test capability, this should be tested in line with the tests specified for the wet leak tester.
>
> Where a manual clean flushing unit has been procured to provide more than a manual clean flush, the instructions for testing the additional capability should be defined in the manufacturer's instruction for use – this should be checked at the IQ stage.

5.15 **Operational Qualification** – operate by flushing water through sample tubing. Where several cycles are available, check that each cycle performs to the required specification for example, dedicated blockage detection cycles are tested using surrogate devices with a simulated blockage. Acceptance criteria: confirm the manual clean flushing unit tester operates to the manufacturer's specification. The test piece should be observed to ensure that fluid flows freely during the cleaning and rinsing cycle for the required time. Where a blockage has been introduced that the flushing unit alerts the operator to the blockage.

5.16 **Performance Qualification** – connect the manual clean flushing unit to an endoscope. Acceptance criteria: confirm that any parameters specified by the manual clean flushing unit manufacturer e.g. quantity of water flushed through the endoscope is confirmed. Repeat this test on a further two occasions and verify that each test meets the acceptance criteria defined by the manufacturer. Record the test results and confirm these to be satisfactory prior to putting the manual clean flushing unit into service.

Periodic testing

5.17 There should be daily checks and annual performance qualification tests, or when the equipment is returned to service after repair or replacement of a part that affects the pre-set variables of the operating cycle.

Daily checks should include:

- the function of valves, aspirator bulbs, tubing;
- ensuring pressure gauges or displays are intact and legible;
- that any fluids or air required during use is flowing freely;
- that any defined calibration checks are performed;
- that any visual or audible alerts and alarms are working as intended.

Appendix 1: References

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.

Standards

BS EN IEC 61010-1: 20010+A1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. BSI.

BS EN IEC 61326-1: 2021 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements. BSI.

BS EN 62304: 2006+A1:2015 Medical device software. Software life-cycle processes. BSI.

BS EN IEC 62366-1: 2015+A1: 2020 Medical devices. Application of usability engineering to medical devices. BSI.

BS EN ISO 13485: 2021 Medical devices. Quality management systems. Requirements for regulatory purposes. BSI.

BS EN ISO 14971: 2019 medical devices — Application of risk management to medical devices. BSI.

BS EN ISO 15223-1: 2021. Symbols to be used with labels, labelling and information to be supplied by the manufacturer - Part 1: General requirements. BSI.

BS EN ISO 17664-1: 2021 Processing of health care products – information to be provided by the medical device manufacturer for the processing of medical devices. Part 1 Critical and semi-critical medical devices. BSI.

BS EN ISO 20417:2021 Medical devices. Information to be supplied by the manufacturer.

Health Facilities Scotland publications

Scottish Health Technical Memorandum (SHTM) 01-06 v1 series 2022.

GUID 5013 - Requirements for compliant Endoscope Decontamination Units v2, 2014.

Scottish Health Planning Note Part 3: Decontamination Facilities: Endoscope Decontamination Units, 2010.

Endoscope Decontamination Document System (EDDS) 2017.

PRO 179-30-Wet leakage test.

PRO 179-35-Dry leakage test.

PRO 179-70-Periodic testing and maintenance of decontamination equipmen.t

PRO 179-90-Inspection of endoscopes.

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

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

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

Health Protection Scotland publications

National Infection Prevention and Control Manual 2021 Health Protection Scotland.

Other publications

Control of Substances Hazardous to Health 2002 (COSHH) Published by the Health and Safety Executive.