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 B: General requirements for decontamination equipment and test equipment provision

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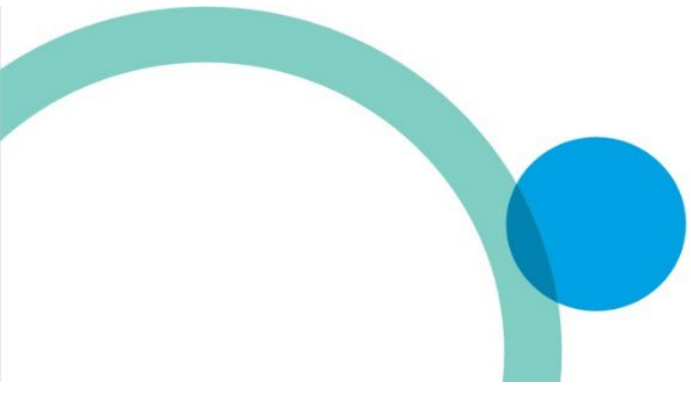

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1. Introduction

1.1 This part B of the SHTM 01-06 series includes guidance on the general requirements for decontamination equipment and provision of test equipment. The decontamination equipment includes the following:

- dry leak testers;
- wet leak testers;
- manual clean flushing units;
- endoscope washer disinfectors;
- storage cabinets;
- vacuum pack systems;
- pressure pack systems.

Decontamination equipment

1.2 Various decontamination equipment checks and tests should be confirmed as part of a Service Level Agreement (SLA). The SLA should include an agreed test schedule and the equipment manufacturer and User responsibilities for carrying out the specified tests and checks.

1.3 A programme of testing should also include the range of test parameters required to ensure decontamination equipment is functioning to the agreed specification and that routine maintenance is carried out under scheduled planned preventative maintenance.

1.4 The sequence of testing required to validate equipment includes:

- type testing and works tests at the manufacturers facilities;
- factory acceptance testing where requested by the User, carried out by the manufacturer at their facilities;
- testing of supporting equipment and or services at the Endoscope Decontamination Unit (EDU) prior to delivery of the equipment;
- the Installation Qualification (IQ);
- the Operational Qualification (OQ);
- the Performance Qualification (PQ).

In addition, periodic testing and maintenance of decontamination equipment should be carried out as per the manufacturer's instructions and may include daily, weekly, quarterly and annual work.

1.5 Detailed specifications and requirements for validation of specific types of decontamination equipment can be found in parts C, D and E of the SHTM01-06 series as follows:

- dry and wet leak testers and manual clean flushing units within part C;
- endoscope washer disinfectors within part D;
- storage cabinets, vacuum pack systems and pressure pack systems within part E.

Provision of test equipment

1.6 A large range of test equipment is required to measure the range of test variables (see table 4.1). A list of the test parameters for each item of decontamination equipment in use should be compiled. Parameters to be measured include:

- temperature;
- pressure;
- flow – liquids: water & process chemicals;
- flow – gas: air;
- volume;
- weight;
- air quality;
- particulate contamination in an airflow;
- oil content in supplied air;
- time;
- pH;
- conductivity;
- cleaning efficacy of an EWD;
- disinfection efficacy of an EWD;
- relative humidity (RH);
- drying efficacy;
- microbial quality of interior surface of storage cabinet;
- microbial quality of air in a storage cabinet;
- maintaining the quality of endoscopes (over maximum storage period in a cabinet or shelf life when vacuum packed/pressure packed).

1.7 Test equipment used to test the above may be provided by the manufacturer's CP(D) during routine maintenance, in house for periodic testing or, by CP(D)s appointed by the User to carry out periodic testing and annual validation/revalidation.

Note 1.1: For additional information on the management of the decontamination process, refer to SHTM 01-06 Part A.

Test equipment must be appropriate for the intended purpose, fully serviced and operational and calibrated to a recognised traceable national/international metrological standard.

2. General requirements for decontamination equipment

2.1 Where possible Health Boards (HB) should procure new EWDs under the terms of the NP143 framework for decontamination equipment, accessories and maintenance accessories, installation services, testing services and maintenance contracts.

2.2 It is essential that the purchase of decontamination equipment is planned, to ensure the User's pre-defined requirements are met. As part of this process, the equipment manufacturer should be provided with a detailed specification that includes any for the equipment being considered for purchase. In turn the manufacturer should provide a detailed specification of the available equipment including any services needed to operate the equipment. The two specifications should be considered as part of the pre-purchase assessments.

Safety checks and safe working

2.3 The Authorising Engineer (Decontamination (AE(D)) may advise on the documented programme of safety checks necessary for each equipment type in use. Safety checks are undertaken throughout the lifetime of the equipment including at the validation stage, prior to use and by periodic testing when the equipment is operational. Certain specific safety tests should also be carried out prior to or as part of the periodic test schedule. Where possible a test method provided by the manufacturer should be used. This will avoid invalidating warranties due to unauthorised changes to the operation or physical build of the equipment potentially causing an unsafe status to exist.

The safety requirements for electrical equipment for measurement, control, and laboratory use can be found in BS EN 61010-2-040: 2015 and should be part of the User specification. Manufacturers should provide assurance 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:

- electromagnetic compatibility directive (2014/30/EU);
- low voltage directive (2014/35/EU);
- machinery directive (2006/42/EC).

2.4 To ensure the safety of operational, technical and maintenance staff, the design and construction of EWDs, storage cabinets and packaging systems should also ensure that:

- loading systems are designed in compliance with the 'Manual Handling Operations Regulations: 1992' (as amended);
- interchangeable load carriers and baskets provided should be capable of being fitted and removed without the use of additional tools;
- the force required by the Operator, to unload the equipment should not exceed the limits set within local manual handling policy. This limit applies whether force is applied directly or indirectly.

2.5 Tests are also recommended before equipment is returned to service and after repairs that can effect one or more components, that could:

- influence the attainment of critical process control parameters;
- cause a change to cycle parameters;
- or where there is a change in process chemicals used.

2.6 The purchase of new decontamination equipment should comply with the requirements for testing of endoscope type test groups and product families. These are described in standards BS EN 15883 - 4: 2018 for Endoscope Washer Disinfectors (EWDs) and BS EN 16442:2015 'Controlled environment storage cabinets for processed thermolabile endoscopes'.

2.7 All decontamination equipment and associated test equipment is classed as work equipment and should comply with the Provision and Use of Work Equipment Regulations 1998 amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002 and the Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013.

Safety features

2.8 Safety features should be designed in accordance with the standard code of practice for safe use of machinery, PD 5304 (2019), and the standards for the safety of electrical equipment, BS EN 61010-1: 2010 + A1:2019 and BS EN 61010-2-040: 2015.

2.9 The equipment manufacturer should provide a list of all safety devices together with their settings and methods of adjustment and where needed methods of testing.

2.10 All safety devices should be designed to fail in a manner that does not cause a safety hazard to personnel.

2.11 Any error in the control or indication system should not cause a safety hazard.

Review of PPM programme

2.12 A programme of Planned Preventative Maintenance (PPM) is required to ensure the required standards of performance and safety are met and maintained. All parts of the equipment vital to correct functioning or safety should be subject to a PPM programme. The PPM programme recommended by the manufacturer should be supplied and used.

2.13 The manufacturer should also provide any limits to the lifetime of any tubing or piping that is part of the equipment and carries process fluids that contact endoscopes.

2.14 Although the supplier may carry out certain inspection and maintenance procedures under the terms of its guarantee, these may not constitute a full PPM programme. The User should ensure that the complete PPM programme is carried out.

2.15 The maintenance programme may be modified to take account of equipment usage level, equipment history and local conditions after a suitable period of operational

experience. It may be necessary to increase the frequency of the maintenance programmes for machines that are heavily used or for equipment supplied with water.

2.16 It is important that maintenance is planned to ensure the equipment is out of service for the shortest time possible. Maintenance should, where practicable, be scheduled to precede the periodic tests as specified in section 3, Validation.

2.17 The PPM programme should be reviewed at least annually to ensure the equipment is being fully maintained without unnecessary maintenance activity. The review should aim to identify:

- the adequacy of maintenance records and compliance with the PPM programme;
- any emerging defects;
- any changes required to the PPM programme;
- any changes required to any maintenance procedure;
- any additional training required by maintenance personnel.

2.18 Proposed changes to the PPM programme should be made in consultation with the AE(D) and manufacturer whenever possible.

Returning equipment to service

2.19 Whenever any work has been carried out on decontamination equipment which may affect its performance (e.g. major repairs, overhauls, etc.), the User and AP(D) with assistance from the AE(D), should draw up a schedule of checks and tests (requalification). These should be carried out before the equipment is returned to service. This may include some or all of the IQ, and OQ validation tests.

2.20 In line with the EDU's quality management system a set of maintenance procedures should be in place for each make and model of and type of equipment in use containing full instructions for the required maintenance tasks.

2.21 Systematic records should be kept of all maintenance work undertaken and log books and maintenance files should be maintained for each item of equipment. This should demonstrate that the work has been carried out and facilitate periodic review of the PPM programme. These records can be stored as electronic or paper records. Such records should be subject to periodic review.

Permit-to-work system

2.22 In order to prevent situations where equipment is taken out of use and returned into use without the mutual agreement of the technical staff and Users, the Endoscope Decontamination Unit (EDU) should operate a 'permit-to-work' system.

2.23 The permit-to-work system should be introduced for all decontamination equipment used in the EDU. This will ensure that equipment such as Endoscope Washer Disinfectors (EWDs) are declared safe and that any inherent hazards have been identified. Prior to undertaking repairs, it should be confirmed that maintenance and validation personnel working on any decontamination equipment have the required skills, qualifications and documented authority to do so. Whenever equipment is

taken out of service as part of the permit to work scheme it should be clearly identified with a temporary sign or label.

Note 2.1: Decontamination equipment may have inherent dangers including risks of burns, scalds, possible microbiological and/or chemical contamination and electrical hazards when handed over to the CP(D) for repair, fault-finding, or testing. These hazards will require the CP(D) to take appropriate precautions, for example, the use of Personal Protective Equipment (PPE). The hospital boards vaccination policy should also be considered.

2.24 The User is responsible for declaring the equipment safe (identifying hazards present) for the CP(D) to work on and, at the completion of work, safe for the equipment to return to service. They should state the precautions required to protect the CP(D) from biological or chemical contaminants. The User should also sign the permit to allow the equipment to be taken out of use prior to the commencement of work.

2.25 When the User is unavailable, for example during an evening shift or whilst on leave, a nominated deputy can be authorised to sign the permit in their absence. However, those deputising should be made aware of the responsibility they are undertaking.

2.26 When the work has been completed, the CP(D) should sign the permit to advise the User that the equipment is fit for use. In the event of work spanning a number of shifts or days, the signatures of all the CP(D)s involved should show continuity.

2.27 The AP(D) and the User should sign the permit to allow the equipment back into use after quarterly or annual validation tests.

2.28 The AE(D) under authorised delegation, should sign the initial permit to use the equipment after installation and validation testing (or revalidation testing for existing equipment that has been reinstalled).

2.29 When particular requirements dictate (for example, when testing involves using biological indicators), other personnel may also be required to sign the permit, for example the Microbiologist (Decontamination).

2.30 The AE(D) should formally audit the permit-to-work system records with the AP(D) at periodic intervals.

Warranty period

2.31 Where the installation and verification of decontamination equipment is delayed, ensure that any warranty period commences from when the equipment is handed over to the User.

2.32 The supply contract and subsequent warranty should clearly state what interventions the User, CP(D) and AP(D) can and cannot make with regard installation, validation, including safety checks requiring overriding safety devices, periodic testing and maintenance (according to PPM schedules). After the purchase of new equipment, the manufacturer may carry out certain inspection and maintenance procedures under the terms of the warranty. The User should comply with any reasonable

instructions from the manufacturer during the warranty period. Failure to do so could allow the manufacturer or supplier to pass liability on to the Health Board.

2.33 Where maintenance is carried out under a lump sum term contract, such failure may be a breach of contract and could give the manufacturer or supplier cause to terminate the contract.

General design considerations

Calibration of decontamination equipment instruments

2.34 The calibration of controls and instrumentation should be verified prior to testing. The equipment should be subjected to a suitable maintenance programme. Reference should be made to the manufacturer's maintenance schedules.

2.35 A method of adjusting each measurement system without the need to dismantle or remove it should be provided to the User for use during periodic testing. This will allow independent confirmation of cycle parameters and calibration. A key, code or a special tool should be required to gain access to the settings adjustment system to prevent accidental readjustment.

Note 2.2: Calibration adjustment or verification of calibration, should only be carried out by trained and authorised personnel, as removal of the connected sensor can be necessary during maintenance and testing. Careless adjustment can introduce errors into the measuring chains.

2.36 It should be possible to independently verify the calibration of instruments and process controls during an operating cycle during maintenance and servicing.

2.37 Occasionally, modifications to the equipment may be recommended by the manufacturer for reasons of efficacy and safety. The User should arrange for such modifications to be carried out within a reasonable period, normally coinciding with a scheduled maintenance/validation session.

2.38 The frequency with which each task is carried out will depend, in part, on the usage level for the equipment.

Instrumentation

2.39 Where an instrument can be adjusted the adjustment should require the use of a key code or tool that is not available to the Operator.

2.40 Where a fault is indicated as an error message shown on a visual display unit, it should be clearly distinguishable from normal messages, for example, by use of a different colour or larger size of text. The indication should remain displayed until acknowledged by the Operator, preferably by entry of a passcode which should be stored in the equipment event log.

2.41 Where required within the specification, the contractor should carry out adjustments to the instruments on site. This ensures the accuracies specified for chemical dosing, disinfection and self-disinfect temperatures can be met with the plant running and under the conditions normally prevailing on site. Values should be recorded before and after adjustment.

Programmable electronic systems

2.42 Decontamination equipment frequently uses programmable electronic systems (PES) for control and data recording. Where such systems are used, they should be designed in accordance with the principles set out in the BS EN 61508: 2010 series "Functional safety of electrical/electronic/ programmable electronic safety-related systems" in safety related applications.

2.43 Where a PES is used for control or monitoring of the process, the values of cycle variables critical to process performance determined during validation, should be documented in the validation report even if they are held in the PES memory. The version number of the software should be available for display when required.

2.44 Combined control and instrumentation systems that are wholly operated by means of PES should incorporate into at least two timing systems, independent of each other, such that the timer used to control the holding time is verified by the other timer. Any future changes to software should be advised and agreed with the User prior to an upgrade, in order that any revalidation requirements are addressed.

3. Validation

Overview of qualification stages and periodic testing

3.1 Validation is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification. In the Endoscope Decontamination Unit the qualification stages for the decontamination equipment comprise of the Installation Qualification (IQ), the Operational Qualification (OQ) and the Performance Qualification (PQ).

3.2 Validation consists of tests performed by the manufacturer/supplier/manufacturer's agent or another Competent Person (Decontamination) defined as qualification exercises comprising of an installation, operational and performance qualification.

3.3 The User is responsible for ensuring that the decontamination equipment has a target date for annual validation. This date is determined by the User and should be communicated to the CP(D), AP(D) and AE(D).

3.4 Records of the results, conclusion of validation and any necessary actions from the validation should be maintained. When data is in the form of electronic data files, the report should contain the data in a format compatible with local systems and storage policies.

3.5 The AP(D) or User should ask the AE(D) to certify that annual and commissioning test reports have been carried out in accordance with standards and guidance and that the results were satisfactory. The AE(D) should issue a report of findings to the User and any other persons nominated by the Health Board to perform the actions recommended by the AE(D).

3.6 Any report of microbiological test results should be signed by the Microbiologist or an accredited test facility.

3.7 The validation report should be retained by the User for 13 years. Copies may be retained as necessary by the CP(D), the AE(D), the AP(D), the Microbiologist and the Quality Manager.

3.8 Validation requirements for specific types of equipment are given in Scottish Health Technical Memorandum (SHTM) 01-06 Parts C, D and E.

3.9 The organisation should document procedures for validation of decontamination equipment and processes including:

- setting defined criteria for review and approval of processes;
- use of specific methods, procedures and acceptance criteria;
- equipment validation testing and qualification to the relevant standards;
- documented training and competencies of personnel;
- requirements for records;

- a set criterion for periodic testing, maintenance and revalidation carried out annually;
- an annual schedule for testing of all equipment;
- a policy and procedure for contingency planning where a failure of equipment or facility occurs;
- approval of changes including process chemical, cycles, spare parts, software etc through a change management process.

3.10 Documented procedures should be in place for validation of computer software used in production and service provision, including equipment software for monitoring and measurement.

3.11 Such software applications should be validated prior to initial use and, after changes to the software or its application. The specific approach and activities associated with software validation and revalidation should be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

3.12 Where the sterilization of endoscopes is required and carried out in house, the validation processes and procedures should be documented prior to implementation. The sterile barrier systems should also be validated prior to implementation, following any changes to process or, the type of device being sterilized. SHTM 01-01: 2018 part E provides guidance on low temperature sterilization.

Type tests, works tests and factory acceptance tests (user defined works tests)

3.13 The manufacturer will carry out type tests on representative samples of EWDs and storage cabinets in serial production to demonstrate compliance with their design specification and the requirements of published relevant standards BS EN ISO 15883-2009 A+: 2014, BS EN ISO15883-4:2018 clause 6.11, Annex B and H and, BS EN 16442: 2015.

Note 3.1: At the time of publication, there was no specific standard that defined validation of performance for the dry leak tester, wet leak tester, manual clean flushing units, vacuum pack systems and pressure pack systems. The manufacturer's instructions should provide the information needed to use their equipment safely and properly, taking account of the training and knowledge of the potential users. Requirements for validation of this equipment are included in the relevant parts of the SHTM 01-06 series (parts C, D or E).

3.14 Where equipment is a new make or model not previously seen by the AE(D) or where the customer has specified additional requirements the AE(D) and purchaser representative(s) should, on User request, witness 'factory acceptance tests' to ensure it meets the required specification. These tests should include all tests specified in the relevant standards and include any additional tests required by the User, AP(D) and AE(D).

3.15 The results of any type tests, works tests and factory acceptance tests (User defined) can be requested by the purchaser as part of the specification for tender or purchase.

It may be necessary for the purchaser, or their representative, to visit the manufacturer's premises to witness testing. The advice of an AE(D) may be sought.

Installation qualification

3.16 Installation Qualification (IQ) is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its agreed specification.

3.17 The equipment supplier and contractor responsible for the installation of services such as ventilation systems, drainage and electrical connections should confirm and document that the equipment services provided are satisfactory as part of IQ checks.

3.18 The supplier or agreed contractors Competent Person (CP) should carry out the required installation checks after delivery and installation of the decontamination equipment to ensure that the machine has been supplied and installed correctly and is safe to operate.

3.19 When the above checks have been completed and found satisfactory, the contractor should carry out IQ tests necessary to demonstrate that the decontamination equipment is working satisfactorily. Any assistance required from the purchaser should be agreed as part of the purchase contract. A roles and responsibilities matrix should be prepared as part of the specification and contracting process.

Operational qualification

3.20 Operational Qualification (OQ) is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits established during type testing when used in accordance with its operational procedures.

3.21 When the decontamination equipment has been installed and initial IQ tests completed, the Competent Person (Decontamination) should carry out a sequence of operational performance tests (as applicable in Parts C, D or E of SHTM 01-06) to evaluate the cycle parameters and safety of the decontamination equipment.

3.22 The contractor responsible for installing the decontamination equipment also should carry out any additional checks specified by the manufacturer.

Performance qualification

3.23 Performance Qualification (PQ) is defined as the process of obtaining and documenting evidence that the equipment when installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and yields a product meeting the agreed specification. Test data obtained from the PQ tests should be recorded in a written PQ report.

3.24 The PQ should not be undertaken on any piece of equipment until the requirements of the installation and operational qualification tests have been met.

3.25 PQ tests should be performed as part of the initial validation procedure, as part of any repeat validation procedure, and whenever the User judges that a new test is

required. The performance qualification should consider the worst-case scenarios of time, temperature etc.

3.26 Circumstances that may require new PQ tests include changes to:

- the quality of the water supply;
- the process chemicals used in the cleaning and/or disinfection process;
- the loading system;
- the requirement to process a new type of endoscope or TOE ultrasound probe;
- the packing systems in use.

3.27 Within one month of the completion of the validation process, the CP(D) should prepare a full validation report which should include:

- a certificate providing the version of software installed and verified;
- all the data supplied by the contractor, collected during the installation checks and tests with written confirmation that they meet the manufacturer's specification;
- written confirmation that the calibration of all measuring instruments fitted to the machine have been verified;
- all the data collected during the commissioning (validation) tests, with written confirmation from the CP(D) that they meet the specified requirements;
- data showing the correlation between the performance of the measuring instruments fitted to the machine and the test instruments used during commissioning and PQ;
- reports containing all the data collected during the PQ tests, with written confirmation from the CP(D) and the User;
- data from the instruments fitted to the machine, independent monitoring system data and validation instrument data, along with comments on any changes or adjustments made.

Periodic testing of decontamination equipment

3.28 After validation the equipment should be subject to a schedule of periodic tests which may be completed at daily, weekly, quarterly and yearly intervals. This provides evidence that the machine continues to operate within the limits established during commissioning. See the relevant parts of SHTM 01-06 Part C, D or E for the periodic test frequencies of decontamination equipment.

3.29 The yearly test schedule provides a more comprehensive test programme than the other periodic tests; it serves to demonstrate that data collected during commissioning and the PQ remain valid.

Revalidation (requalification)

3.30 Where there is a delay in the completion of an annual validation beyond the target date, it is User's responsibility to undertake a documented risk assessment. Refer to

BS EN ISO 14971: 2019 “Medical devices. Application of risk management to medical devices” with support from an AE(D) and AP(D). The risk assessment should consider the maintenance programme, the outcomes of other periodic testing and other risks/issues emerging since the last annual validation. Elements of the annual revalidation test schedule may also need to be carried out if certain changes are made to the machine components, the control system, or the variables. Some examples of when this may be applicable are when:

- the equipment is to be returned to service after repair or replacement of a part that affects satisfactory attainment of the pre-set variables of the operating cycle;
- the pre-set values of the cycle variables have been modified;
- there is a change to the process chemicals in use;
- the software in a programmable electronic system (PES), used for control of the process, has been modified;
- the User/AE(D)/AP(D) advises that revalidation is necessary;
- the equipment fails a periodic test;
- the results of any protein testing of live endoscope or surrogate devices are unsatisfactory;
- the equipment is modified to such an extent that it may be considered that the original data is no longer valid;
- the equipment has been moved and installed at a new site;
- the machine has been dismantled or extensively overhauled;
- revalidation fails to confirm compliance with the original data and no cause for the discrepancy can be found;
- there are changes to the pre-set values of the cycle variables or parameter;
- a new packaging system (e.g. a vacuum pack or pressure pack system has been introduced that may require alteration of the configuration of the machine (e.g. an extended drying stage) to ensure attainment of storage system requirements.

3.31 There are occasions when it might be necessary to repeat the full set of tests carried out during the initial validation in order to obtain a new set of data.

3.32 It may not always be necessary to carry out a full revalidation, and the advice of AE(D) may be sought on which tests are required following any particular event.

3.33 Failure of a test generally indicates that the equipment is not working to specification; it should be withdrawn from service and the failure investigated in line with the quality management system.

3.34 The AE(D)/AP(D), User and IPC team may agree the course of action to be taken.

3.35 The User has the ultimate responsibility to ensure that decontamination equipment is fit for use.

4. Test parameters and test equipment general requirements

General considerations

4.1 This section reviews the key items of test equipment required to carry out the testing of decontamination equipment as procedures described in parts C, D and E of SHTM 01-06.

4.2 The aim of this section is to define the essential requirements that apply to all test equipment while supporting both new and traditional test methods. Specifications for instruments fitted permanently to decontamination equipment are given in the relevant European and International standards.

4.3 Some items of test equipment previously comprising separate instruments (a data recorder and sensors) are now available as combined units with sensors integrated into self-contained computer-controlled data recorders (data-loggers). Data-loggers with integrated sensors and software enable the system to verify the required conditions were attained and produce a detailed written report, containing tabulated or graphed data. These systems offer advantages in clarity of presentation and reduced operator time. The requirements for accuracy and calibration to a known metrological standard remain. If dataloggers are used the effect of exposure to the process (e.g., temperature changes) on measurement accuracy should be known. The use of traditional instruments, such as chart recorders, remains acceptable where they meet the accuracy requirements.

Note 4.1: Retention of data for long-term use is important. Modern data-recording equipment should have storage facilities that ensure data is accessible, stored securely and easily retrieved at a later date. Consideration to IT backup protocols must be made to ensure data security and longevity.

4.4 When measurement and/or recording techniques not covered in this guidance are proposed, the Authorising Engineer (Decontamination) (AE (D)) may be consulted throughout the assessment.

Test parameters

4.5 Specifications and calibration methods for test equipment, used on decontamination process equipment and the wide range of parameters required to verify that decontamination equipment is operating within specification are shown in table 4.1.

Table 4.1: Parameters to be measured by test equipment

Parameter tested	Test equipment	Application examples
Temperature	Technologies with platinum resistance sensors or thermocouples	Thermometric test for thermal disinfection. Temperature measurement in a storage cabinet.

Parameter tested	Test equipment	Application examples
Pressure and pressure differential	Pressure sensors/ meters/gauges with required scale and resolution for the application. Differential monitoring requires inputs from two locations.	Water supply pressure, differential pressure across water filters, differential pressure across doors of storage cabinets and leakage pressure checks. Note, double ended storage cabinets require two pressure differentials to be measured.
Flow – liquids: water & process chemicals	Liquid flow meter. Surrogate device defined according to Annex H (BS EN 15883-4: 2018) for blockage and disconnection tests.	Recording of liquid flows (for both chemical dosages and endoscope channel flow) at each stage of the Endoscope washer disinfector (EWD) cycle. Note**,** where used the flow through a manual clean flushing unit should be checked during installation after maintenance and servicing.
Flow – gas: air	Thermal anemometer (Air Flow).	To ensure the air flow to the endoscope channels and the storage cabinet environment is delivered at the required rate.
Volume	Graduated vessel (BS EN 384: 2015.)	Recording of process chemicals in the EWD cycle.
Weight	Laboratory balance/analytical balance.	Calibration of flow meters. Total Dissolved Solids (TDS) determination in feedwater. Weighing of surrogate devices.
Air filter integrity Airflow particulate contamination	Aerosol generator & particle counting photometer.	Measure the air particulate levels to confirm air quality for purging endoscopes in the EWD and that filter performance is satisfactory for use in EWDs or storage cabinet if applicable.
Air quality –oil content	Detector tube or oil impactor.	Measure the oil content in air supplying the storage cabinet.
Time	Calibrated time piece.	Measurement of stage times for automatic control tests, verification of the chart recorder time-base.
pH and Conductivity	Calibrated pH and conductivity meter.	Water quality testing of pH and conductivity in EWDs.
Relative Humidity(RH)	RH meter or Sword Hygrometer.	To ensure a moisture controlled environment in the storage cabinet.
Cleaning efficacy of an EWD		
Protein level µg/cm^2	Test soil and/or operational endoscopes as described in BS EN ISO 15883-5:2021.	Confirmation that EWDs cleaning stage is effective and removes test loads from the EWD basin and inoculated test pieces. Visual inspection of the EWD basin and soiled endoscope/surrogate device.

Parameter tested	Test equipment	Application examples
	A protein detection test systems listed in the NP 143 contract for decontamination consumables should be used.	Measuring the level of residual protein on inoculated test loads compliant with the requirements of BS EN ISO 15883-4: 2018 annex H (where justified) or representative endoscopes (annex I) during (PQ testing). PQ test 4.1.5 b) of BS EN ISO 15883-5: 2021 with surrogate product. Swabbing or rinsing of endoscope using 1% SDS sample area of 10cm^2 minimum. Note: Rinsing allows better access to internal lumens.
Analyte level for •Total organic carbon (TOC) •Carbohydrate •Haemoglobin •ATP •Endotoxin	Suitable field test kits.	Type test only for an EWD - One of a range of analytes listed should be measured as BS EN ISO 15883-4: 2018.
Disinfectant concentration	Chemical test strips (as advised by the disinfectant manufacturer).	Used to measure disinfectant strength.
Chemical residue		Measure of residual chemical in final rinse water in an EWD. Process residuals as section 4.4.4 of BS EN ISO 15883-5: 2021.
*Disinfection efficacy of an EWD	Surrogate Devices inoculated with known high numbers of specified test organisms. Operational endoscopes.	To ensure the disinfectant used results in the correct level of microbial reduction. For specified bacteria and mycobacterium the inoculum should contain not less than 10^8 CFU/ml (BS EN ISO 15883-4: 2018). During Performance Qualification, confirm using endoscopes that flow conditions yield cleaned and disinfected endoscopes (BS EN ISO 15883-4: 2018 Annex C, Table C.)
Drying efficacy of a storage cabinet	In-situ testing of surrogate devices.	To confirm a storage cabinet with a drying function can dry an endoscope within the specified time as BS EN 16442:2015.
*Microbial quality of interior surface of storage cabinet	Microbiological contact plates.	Microbiological test of the storage cabinet interior.
*Microbial quality of air in a storage cabinet	Active air microbial sampler or passive air microbial sampling using settle plates.	Microbiological test of the air in a storage cabinet.

Parameter tested	Test equipment	Application examples
*Maintaining the quality of the endoscope	Disinfected endoscopes - Sample distal end and membrane filtration samples on TSA and SAB DEX media.	Microbiological (PQ) test of endoscopes as: stored for maximum defined storage time of storage cabinets as BS EN 16442: 2015; maximum defined shelf life of packed endoscopes by vacuum pack systems or pressure pack systems.
*Microbiological samples should be tested in a laboratory with accreditation to ISO/IEC 17025 must be used for testing of all microbiological samples. A Microbiologist responsible for decontamination may also be required.		

Measurement errors

4.6 Errors of measurement occur for several reasons. These include intrinsic errors related to the instrument's best capability and cannot be improved without modification. Sources of error can include:

- the design of the measuring instrument;
- damaged or poorly maintained equipment;
- variations in the sensors;
- the method of introducing the sensors into the machine.

4.7 Positioning of measuring equipment also needs to be taken into account to minimise the effect of environmental variations. For example, temperature fluctuations within pressure-sensing elements can contribute to errors.

4.8 Significant errors can also arise through improper use of test equipment and calibration instruments; therefore, it is important that staff are trained and competent. The integrity of the measuring system is essential to obtain meaningful results. Attention to detail including the location of test equipment, effective maintenance, and careful handling of the test equipment during use, can eliminate or minimise errors.

Test equipment calibration

4.9 Careful calibration is essential to reduce systematic errors; therefore, test equipment should be subject to a planned maintenance and calibration programme following the manufacturer's recommendations, at least annually.

4.10 Calibration of the test equipment should be carried out using a validated method and following the equipment manufacturer's instructions. A written procedure describing the calibration method should be prepared. This may be made available for the AE(D) to review prior to putting in place.

4.11 A reference standard of suitable accuracy, certified within the previous twelve months by an BS EN ISO/IEC 17025: 2017 accredited test laboratory should be used. The calibration laboratory should be instructed to adjust the equipment under test to read

true values and to report before and after calibration results so that instrument drift can be monitored.

4.12 The drift status of test equipment should be monitored to ensure they remain within their intrinsic specification. The stability of the equipment should also be reviewed to ensure the maximum calibration interval is satisfactory. Each instrument or piece of test equipment should be labelled with a unique identifier, the calibration date and a reference from which its current calibration status may be traced.

4.13 A full equipment test history, including all maintenance and calibration details, should be recorded and kept for each test instrument. The test equipment should have a valid calibration test certificate.

Note 4.2: Be aware of the difference between a calibration check prior to use and recalibration where an accredited laboratory, or the manufacturer confirms that the equipment is within the manufacturer's original specification.

4.14 Calibration data should cover the range of measurement required for the parameter being tested and include at least one measurement within the process operating band. Examples include:

- a temperature within the disinfection temperature band;
- a pressure within the operating range of the water or air pump during the EWD wash and drying stages;
- a temperature within the cleaning stage temperature band;
- where an EWD has a thermal self-disinfect cycle, a temperature within the disinfection range.

4.15 Extra care should be taken when measuring parameters that can be affected by temperature variations; such test equipment should be located in a position protected from draughts and not subjected to rapid temperature variations. Where applicable test equipment should be allowed to stabilise within the environment of the test site prior to use. The manufacturer's instructions should be followed.

Portable self-contained measurement and recording systems

4.16 Several designs of small self-contained single or multi-channel data-loggers for measurement of temperature and pressure are commercially available. They are powered independently and can be programmed to take readings at the required rate and duration. Recorded data can be transmitted in real time or downloaded after completion of the test.

4.17 Units capable of withstanding the environment found in endoscope washer-disinfectors are needed. Those housed in protective cases rated at IP68 (as defined in BS EN 60529:1992+A2:2013) are suitable for use in endoscope washer-disinfectors.

Some dataloggers will have inbuilt temperature compensation to allow good accuracy across a wide range of measurement values. The requirements remain the same for

accuracy and reproducibility. In selecting a datalogger the effect of exposure to the process on measurement accuracy and reproducibility should be considered.

Data-logger requirements

4.18 The accuracy, resolution and sampling rate requirements should be detailed in the test equipment specification. Self-contained measurement and recording systems should comply with the requirements of BS EN ISO 15883-1: 2009+A1:2014 and BS EN ISO 15883-4:2018.

4.19 These should be capable of measuring the temperature of the test load items described in BS EN ISO 15883-1:2009+A1: 2014 and EN ISO 15883-4:2018 and not only the temperature of the data logger (e.g. within the lumen of an instrument or the surface of a chamber). This may necessitate the use of loggers with flying leads.

4.20 The temperature sensors contained within these devices are usually platinum resistance thermometers, which are less likely to display short-term calibration drift. Where short-term drift of the device can be demonstrated as negligible between annual calibration intervals, the requirements of the test equipment verification section need not apply. Where this cannot be demonstrated to the satisfaction of the AE(D) with calibration data, it is not acceptable to use self-contained data loggers without undertaking verification of calibration. Dataloggers having flying probes can have calibration verified in the same way as normal measurement systems.

4.21 Where two or more data-loggers are used together on the same process, the time bases of the instruments should be synchronised and the results of all the loggers used during a specific test should be shown as a graphical representation on the same chart.

4.22 Sufficient data loggers to meet the testing requirements of the SHTM 01-06 Parts D and E, BS EN ISO 15883-1:2009+A1: 2014 and BS EN ISO 15883-4:2018 and BS EN 6442:2015 as applicable are required.

Data recorders with separate sensors

4.23 Data recorders are required to measure temperature and pressure in all types of decontamination equipment and may be required for the measurement of flow rates and other critical parameters. They should be designed for use with the appropriate sensors and be independent of those fitted to the machine. Data logging equipment, with flying leads for temperature measurement that can be immersed in an independent temperature reference source, should be used.

4.24 Sufficient input channels and connections to meet the testing requirements of the SHTM 01-06 Parts D and E should be provided.

4.25 The accuracy, resolution and sampling rate requirements should be as detailed in the test equipment specification section. Data recorders should comply with the requirements of BS EN ISO 15883-1:2009+A1:2014 and BS EN ISO 15883-4:2018 and BS EN 16442:2015 as applicable.

Test equipment verification

4.26 Before and after each series of tests on any item of decontamination equipment, the temperature and pressure test equipment should be verified. This verification should be by comparison with an independent reference source within the process temperature and pressure ranges. Where possible self-contained measurement and recording systems (data-loggers) discussed earlier should be subjected to similar verification studies. However, if this is not possible an understanding of the long term drift in relation to incorrect measurement of process conditions is needed. The AE(D) may be consulted.

4.27 Heat sources should be designed to meet the recommendations of EURAMET cg-13 Version 4: 2017 'Calibration of temperature block calibrators'. The procedures used when applying comparison calibrations should be in accordance with these guidelines. Precautions regarding temperature block calibrators should be adhered to. The comparison reference sources used (digital thermometer and digital or analogue pressure gauge) should be traceable to BS EN ISO/IEC 17025: 2017 calibration standards.

4.28 No adjustment should be made to the test instrumentation in an uncontrolled environment unless the test contractor or organisation holds a site calibration procedure and BS EN ISO/IEC 17025: 2017 certification. Records of adjustments should be available for inspection or audit. Any adjustments made to test instrumentation should be recorded and included within the test report. Confirmation that the need for adjustment was not due to an instrument fault should be made.

4.29 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ±0.1°C and within the process temperature band should not differ by more than 0.5 °C between sensors. The combined error of the whole measuring chain should be considered.

4.30 Pressure measurement data-loggers will need to allow a connection to a pressure calibrator for the same reason. The pressure measured by all pressure sensors, when compared to a pressure reference standard and within the process pressure band, should not differ by more than 50 mBar.

Note 4.3: The accuracies quoted by data recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. The whole measuring chain should be calibrated prior to use.

5. Test equipment specification

5.1 Test equipment should have the facility to record data to a central computer, external hard drive or another validated method that can be removed for secure storage. Data storage should be subject to appropriate backup procedures to ensure integrity and security.

5.2 Software developed and validated under a recognised quality system (e.g. BS EN ISO 9000 series or BS EN ISO 13485: 2021 where applicable) for use with digital test equipment is required.

5.3 At all stages of the endoscope washer-disinfector operating cycle, the measured values of cycle variables (temperature, pressure, etc.) are critical. Other decontamination equipment will also have critical variables. Test equipment should be accurate, confirm that the process conditions have been attained and have a range that can accommodate any deviations resulting from a malfunction in the decontamination equipment. The specification will depend upon the range of equipment tested.

5.4 Complete measurement systems able to measure cycle variables to the accuracy of the instruments fitted to the decontamination equipment should be used.

Recording systems

5.5 Attention should be given to the accuracy of the time base of any recording system, particularly on longer cycles, where any error will become more obvious. This can be checked using a calibrated timepiece against a calibrated time signal.

5.6 The scale range for each variable measured should cover all values occurring during the decontamination process and have calibration certificates for each item of the measuring chain. The complete system should be verified in the working environment (for example, the EDU).

5.7 Digital test equipment details to consider include:

- the sampling interval should not exceed one second per channel and be short enough for the holding time to contain at least five independent measurements in each recording channel;
- the response time (integration time) of the measurement chain should be short enough to enable the output to follow significant fluctuations in the cycle variables and ensure that successive measurements are independent of each other. The response time of the measurement chain will relate to a number of factors such as the time a sensor takes to reach a steady state when subjected to a change, the sampling rate and processing time of the recording system. Similarly, the hysteresis of the system should be known when exposed to rapidly rising and falling process parameters;
- the response time should be no longer than the sampling interval;
- it should register and record in increments of no more than 0.1°C for temperature;

- it should be accurate enough to show if the measured temperatures are within the required temperature band;
- the uncertainty of any pressure measurement should be no more than 1% of the full absolute pressure during the plateau period.

Analogue instruments details to consider include:

- pen recorders chart speed should be fast enough to allow rapid fluctuations in process parameters to be clearly resolved;
- the holding time should be measurable to within 1%;
- the minor mark interval for temperature and the resolution should not exceed 0.5°C;
- the chart speed should be not less than 10 mm per minute/600 mm per hour.

Temperature measurement

Temperature sensors

5.8 Where temperature sensors are used to measure the operational temperature in EDU equipment, the sensors should be platinum resistance elements compliant with class A (of BS EN 60751:2008 Table 1) or thermocouples with Tolerance Class 1 (of BS EN 60584-1:2013 Table 1). Other sensors of demonstrated equivalence can be used.

5.9 A single strand thermocouple wire, not exceeding 0.7 mm diameter over the covering of one core of a twin cable where the width of the cable does not exceed 2 mm, is required. The cross-sectional area of any part of the test probe and its connecting wires should not exceed 3.1 mm^2.

5.10 Thermocouples can be argon arc-welded or micro-welded and should not be fitted with a heat sink which will affect response time. Alternatively, cleaned wires can be twisted together to form the hot junction but it should be noted that such junctions can corrode which will then introduce measurement errors. Brazing, silver brazing and welding with filler rods is discouraged as it is no more reliable than the above method.

5.11 As EWD environments can be corrosive, and to ensure the performance characteristics of selected sensors will not be adversely affected by the environmental conditions, thermocouple junctions should be inspected for corrosion, remade and recalibrated at specified intervals.

5.12 Guidance on test apparatus designed to introduce thermometric measuring equipment into the endoscope washer-disinfector chamber is provided in BS EN ISO 15883-1:2009+A1:2014 and BS EN ISO 15883-4:2018. Other methods of introducing temperature sensors into a chamber which guarantee a watertight seal are acceptable.

Thermometric recording instrument(s)

5.13 Thermometric recording instruments, with the temperature sensors used to take measurements in specified locations BS EN ISO 15883-1:2009+A1:2014, should

have a scale range from 0°C to 100°C. The recording error for the instrument, (excluding temperature sensors), should not exceed ±0.1°C when tested in an ambient temperature of (20 ± 3°C).

5.14 The additional error due to changes in environmental temperature should not exceed 0.04°C. Accuracy of the system should be ± 2% of the value to be measured unless another value is specified for a specific measuring system.

5.15 All reporting software should be validated, backed-up and kept in a secure location off-site to ensure no unauthorised access.

Pressure measurement

Pressure sensors and gauges

5.16 Pressure gauges should be temperature compensated and should meet accuracy class 0.25 (that is, the error should not exceed 0.25% of full-scale deflection). Electronic pressure measurement systems should be used where possible, as they will be far more accurate, reproducible and reliable than Bourdon-tube gauges. When measuring a pressure differential two inputs from different locations are required.

Measurement ranges

5.17 Water supply pressure measurement ranges for EWDs should be up to 1000 kPa [10 bar], while the working water pressure measurement during a cycle may vary from 3 to 10 kPa [30-100 mbar].

5.18 Differential pressure measurements of air pressure of 0.1 - 10 kPa [1-100 mbar] may be required for the determination of the pressure drop across filters. When measuring pressure differential as overpressure between the inside of a storage cabinet to outside ambient the test equipment requires to measure low pressure differences of a few pascals and have a resolution of 1Pa.

The scale range requirements for gauges used for testing decontamination equipment vary depending on the application (see table 5.1).

Table 5.1: Scale range requirements for pressure measurements

Scale range	Mark Interval	Medium to be measured	Application
0 to 1000 kPa [0 to 10 bar]	5 kPa [50 mbar]	Liquid	-Water supply pressure. -Recirculating pump pressure
3 to 10 kPa [30-100 mbar].	1 kPa [10 mbar]	Liquid	Channel flow
0 to 100 kPa [0 to 1 bar]	1 kPa [10 mbar]	Liquid	Differential pressure across water filters
0-50 Pa	1 Pa	Air	Overpressure of storage cabinet to ambient (overpressures in the case of a double-ended storage cabinet)

Scale range	Mark Interval	Medium to be measured	Application
0.1 - 10 kPa [1-100 mbar]	0.1 kPa [1 mbar]	Air	Differential pressure across air filter
As per EWD manufacturers' instructions	± 0.1 kPa [± 1 mbar]	Air	Leak test-surrogate device

Flow measurement

Water flow

5.19 The volume of water used for each stage of the operating cycle may be measured using a water meter complying with BS EN ISO 4064-1: 2017 Class A. The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 1000 kPa [10 bar].

5.20 The meter should have a minimum scale division of 0.1 L or less and be designed to measure flow rates over the range 1 L/min to 25 L/min.

5.21 A single jet turbine system is sufficiently accurate for the purpose. Other systems, such as multi-jet turbine or semi-positive displacement systems complying with BS EN ISO 4064-1: 2017 Class B or Class C, may also be used.

5.22 The calibration of the flowmeter should be verified by comparing the indicated flow rate with a measured volume collected over a measured time period. The collected volume of liquid may be determined by either gravimetric or volumetric measurement. The gravimetric method is generally more accurate as the temperature of the liquid increases.

Process chemicals flow measurement

5.23 The volume of process chemicals used for each stage of the operating cycle may be measured using a flowmeter. A number of commercially available flow sensors designed to monitor flows in the range 0 to 2 L/min are suitable for interfacing to a recorder or data logger.

5.24 The sensor should be suitable for use with fluids having a viscosity in the range 0.8 to 20 centistokes and should be calibrated for the viscosity of the fluid to be measured.

5.25 The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 1000 kPa [10 bar].

5.26 The meter/recorder should have a minimum scale division of 10 ml or less and be designed to measure flow rates over the range of 50 ml/min to 1500 ml/min. The system should have an accuracy of ± 2.5% of full scale or better.

5.27 The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing this with the collected volume.

Note 5 1: When the flowmeter is connected in the pipe, there will be a noticeable pressure drop across the meter. Although this should be less than 1 bar it may interfere with the normal operation of the EWD and therefore should not be used during tests for other characteristics than the volume of water used.

Note 5 2: A meter of the rotating vane type calibrated using water at 20°C as the flowing medium and then subsequently used to measure the flow of a detergent solution with a viscosity of 30 centistokes would have an error of 15–20% if no correction was applied.

Volume measurement

5.28 The volume of process chemicals and the volume of water used in each stage are critical variables in the control of the washing-disinfecting process.

5.29 The volume used may be measured directly by collection in a graduated vessel of appropriate size.

5.30 Alternatively, for liquids of known density, the volume may be determined by collection in an appropriate size vessel of known mass (empty), determination of the mass of the vessel and contents, calculation of the mass of the liquid and hence (by dividing this volume by the density) calculating the volume of liquid.

5.31 Whichever method is used the accuracy should have an error of less than ± 2%. Volumetric measuring containers complying with BS EN ISO 384: 2015 are suitable.

Airflow metering device

5.32 A diagram of the circulation pathway of the air for all channels of each endoscope that the storage cabinet is intended to store should be provided by the manufacturer.

5.33 The minimum and maximum air pressure that the storage cabinet is designed to deliver to each channel or channel system of the endoscope connected to the storage cabinet should be specified.

5.34 A metering device (such as a needle valve) is required to admit air into EWD chambers for the pressure leak tests. The device should be capable of controlling the flow of air into the chamber. It should be adjustable and have a range that includes a flow of 0–5 ml/min per litre volume of the chamber. The error in repeatability between 10% and 90% of the setting range should not exceed - 5%. The device is connected to the chamber by a valved port provided by the manufacturer.

Balance for measuring weight

5.35 A laboratory balance is required for calibration of flowmeters (for measuring the flow of water and/or process chemicals). It should be capable of measuring the mass of loads up to 4 kg to an accuracy of 0.1g and up to 400g to an accuracy of 0.01g.

Note 5.3: All balances should be placed on a flat level surface free of vibration and allowed to equilibrate to ambient conditions prior to measurement.

5.36 An analytical balance is required for determination of the Total Dissolve Solids (TDS) (evaporative residue) in feed water. It should be capable of measuring a mass of up

to 100g with an accuracy of 0.1mg. These tests are best carried out by or in an analytical laboratory.

Gas-monitoring equipment

5.37 A gas monitoring instrument is required for tests on equipment using process chemicals with a significant vapour pressure that may pose a potential risk to human health (e.g. are toxic) or the safety of the environment in which the equipment is installed (e.g. is flammable). This equipment is not suitable for monitoring residual chemical levels for product quality or as an indication of the success of the process.

5.38 The type of the monitoring instrument is dependent on the substance being monitored. In case of doubt, advice may be sought from the manufacturer of the process chemical or the AE(D).

5.39 The scale range of the measuring instrument should include the appropriate short-term or occupational exposure limit and extend to at least ten times that exposure limit.

Aerosol generator for use when testing air filters

5.40 An aerosol generator is required for tests on machines incorporating air filters intended to deliver air free from most microorganisms.

5.41 The device should be capable of generating a polydisperse aerosol with particles having the size distribution as Table 2 of BS EN ISO 14644-3: 2019.

Particle-counting photometer – testing filter media effectiveness

5.42 A particle counter is required for tests on machines incorporating air filters intended to deliver air free from most microorganisms. The particle counter should be suitable for estimation or comparison of the mass concentration of airborne particles (see table 5.2).

5.43 It should have an accuracy of better than ± 5% over the range of a five expandable, six-decade resolution (that is 0.01% to 100% of the test cloud) as specified in BS EN ISO 14644-3: 2019.

5.44 The photometer should have a minimum threshold sensitivity of 0.0001 µg/L and should be capable of measuring aerosol concentration in the range 80 to 120 µg/L.

5.45 The sampling flow rate should be 0.40 ± 0.05 L/s and sampling should be via a suitable probe.

Table 5.2: Mass concentration airborne particles at varying particle sizes

Particle size [µm]	Fraction% by mass
<0.5	>20
<0.7	>50
<1.0	>75

Timepiece for measuring time

5.46 A calibrated time piece is required for measurements of time. Examples of applications included; measurement of stage times for automatic control tests and verification of the chart recorder time-base.

Relative humidity measurement

5.47 Measurement of relative humidity using a calibrated probe is required. Applications include calibrated temperature/humidity meter ('sword hygrometer').

Conductivity measurement

5.48 Measuring conductivity using a calibrated probe is a requirement. This may be used as part of a series of water quality tests. Be aware that the ambient temperature variation can affect the conductivity measurement.

Process chemical residuals

5.49 A sampling method for extraction of process residuals from the load and the analytical method for detection of process residuals in the samples should be specified by the chemical manufacturer. The method should be capable of determining the presence of process chemical(s) at concentrations below the level considered potentially harmful, (see BS EN ISO 15883-1:2009+A1:2014).

5.50 The number and type of devices required to constitute a test load should be contaminated with one or more of the appropriate test soils by the method given in BS EN ISO 15883-5: 2021.

Protein detection

5.51 A protein detection test systems listed in the NP 143 contract for decontamination consumables should be used. All equipment, systems and or chemicals used, should be maintained, calibrated (if applicable), stored and used in according to manufacturers' instructions.

5.52 A relevant test standard operating procedure (SOP), should be in place and adhered to for each test system on the NP 143 contract. The SOP should take account of the manufacturer's instructions, and include:

- sample incubation time;
- amount of reagent required;
- sampling method;
- areas to be sampled;
- recovery method (where required).

5.53 The results should be interpreted in accordance with the manufacturers' instructions and comply with the requirements of BS EN ISO 15883 Part 1:2006 as amended 2014 Appendix C, BS EN ISO 15883 Part 4: 2018 and BS EN ISO 15883 Part 5: 2021.

Note 5.4: Interpretation of the results should take account of the possibility of false negative and false-positive results.

5.54 When testing EWDs, at least one other validated quantitative analytical test method should be used to measure another analyte in addition to protein. Acceptance criteria for any analyte should be specified in terms of both an alert and action level.

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.

Regulations

Provision and Use of Work Equipment Regulations 1998 amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002 and the Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013.Health and Safety Executive.

Manual Handling Operations Regulations: 1992' (as amended) Health and Safety Executive.

European directives

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) Text with EEA relevance Commission Communication published in OJ C.

Consolidated text: Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (Text with EEA relevance)Text with EEA relevance THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (2014/35/EU) Commission Communication published in OJ C.

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (Text with EEA relevance) Commission Communication published in OJ C.

Standards

PD 5304:2019 - Guidance on safe use of machinery 2019. BSI.

BS EN 837-1: 1998 - Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing. BSI.

BS EN 837-2: 1998 - Pressure gauges. Selection and installation recommendations for pressure gauges. BSI.

BS EN ISO 384: 2015 Laboratory glass and plastics ware. Principles of design and construction of volumetric instruments. BSI.

BS EN ISO 4064-1:2017 Water meters for cold potable water and hot water. Metrological and technical requirements (ISO 4064-1:2014).

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 14644-3: 2019 - Cleanrooms and associated controlled environments. Test methods. BSI.

BS EN ISO 15883-1: 2009+A1: 2014 - Washer-disinfectors. General requirements, terms and definitions and tests. BSI.

BS EN ISO 15883-4: 2018 - Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for Endoscopes. BSI.

BS EN ISO 15883-5: 2021 - Washer-disinfectors. Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy. BSI.

BS EN 16442: 2015 - Controlled environment storage cabinet for processed thermolabile endoscopes. BSI.

BS EN 60584-1: 2013 Thermocouples. EMF specifications and tolerances. BSI.

BS EN 60751: 2008 - Industrial platinum resistance thermometers and platinum temperature sensors. BSI.

BS EN IEC 61000-6-1: 2019 - Electromagnetic compatibility (EMC). Generic standards. Immunity for residential, commercial and light-industrial environments. BSI.

BS EN 61508-1: 2010 - Functional safety of electrical/electronic/ programmable electronic safety-related systems – General. BSI.

BS EN 61672-1: 2013 - Electroacoustics. Sound level meters. Specifications. BSI.

BS EN ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories. BSI.

BS EN 60529: 1992+A2: 2013 Incorporating corrigendum February 2019: Degrees of protection provided by enclosures (IP code). BSI.

BS EN 61508: 2010 series - Functional safety of electrical/electronic/ programmable electronic safety-related systems. BSI

HFS Publications

Scottish Health Planning Note 13 Part 3 – Decontamination Facilities: Endoscope Decontamination Units, 2010.

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

Scottish Health Technical Memorandum (SHTM) 01-06 series (Parts A to E) - Decontamination of Flexible Thermolabile Endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units 2022.

National Framework NP143/21 - Decontamination Equipment (2021). NSS.

Scottish Health Technical Memorandum 01-01 - Decontamination of Medical Devices in a Central Decontamination Unit Part E: Sterilization by Hydrogen Peroxide or Ethylene Oxide: 2018.

Other publications

EURAMET cg-13 Version 4: 2017.